EUROPEAN COMMISSION
Directorate-General for Communications Networks, Content and Technology

Digital Society, Trust and Cybersecurity
eHealth, Well-Being and Ageing

GRANT AGREEMENT

NUMBER 951938 — X-eHealth

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Union** ('the EU'), represented by the European Commission ('the Commission'), represented for the purposes of signature of this Agreement by Head of Unit, Directorate-General for Communications Networks, Content and Technology, Data, Administration and Finance, Mikaela FARR-DAVID,

and

on the other part,

1. 'the coordinator':

SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE (SPMS), established in AVENIDA DA REPUBLICA, 61, LISBOA 1050 189, Portugal, VAT number: PT509540716, represented for the purposes of signing the Agreement by Member of the Board of Directors, Domingos Pereira

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. **BUNDESMINISTERIUM FUER ARBEIT, SOZIALES, GESUNDHEIT UND KONSUMENTENSCHUTZ (ATNA)**, established in Radetzkystrasse 2, WIEN 1030, Austria,

3. **GESUNDHEIT OSTERREICH GMBH (GÖG)**, established in STUBENRING 6, WIEN 1010, Austria, VAT number: ATU62777178,

4. **SERVICE PUBLIC FEDERAL SANTE PUBLIQUE, SECURITE DE LA CHAINE ALIMENTAIRE ET ENVIRONNEMENT (FPS Health Be)**, established in SQUARE VICTOR HORTA 40 BUR 1D 1G, BRUSSELS 1060, Belgium, VAT number: N/A,

5. **INTEGRATING THE HEALTHCARE ENTERPRISE-EUROPE AISBL (IHE-EUR)**, established in BOULEVARD AUGUSTE REYERS 80, BRUXELLES 1030, Belgium,

6. **HL7 INTERNATIONAL FONDATION (HL7 Europe)**, established in SQUARE DE MEEUS 38-40, BRUSSELS 1000, Belgium,

7. **STICHTING KONINKLIJK NEDERLANDS NORMALISATIE INSTITUUT (NEN)**, established in VLINDERWEG 6, DELFT 2623 AX, Netherlands, VAT number: NL002814237B01,

8. **HRVATSKI ZAVOD ZA ZDRAVSTVENO OSIGURANJE (HZZO)**, established in MARGARETSKA 3, ZAGREB 10000, Croatia, VAT number: HR3580261,

9. **UNIVERSITY OF CYPRUS (UCY)**, established in KALLIPOLEOS STREET 75, NICOSIA 1678, Cyprus, VAT number: CY90001673W,

10. **MINISTERSTVO ZDRAVOTNICTVI CESKE REPUBLIKY (MZCR)**, established in PALACKEHO NAMESTI 375/4, PRAHA 12801, Czech Republic,

11. **VYSOCINA KRAJ (Kraj Vysočina)**, established in ZIZKOVA 57, JIHLAVA 587 33, Czech Republic, VAT number: CZ70890749,

12. **SOTSIAALMINISTEERIUM (MSAE)**, established in Suur-Ameerika 1, TALLINN 10122, Estonia,

13. **AGENCE DU NUMÉRIQUE EN SANTÉ (ANS)**, established in RUE GEORGES PITARD 9, PARIS 75015, France,

14. **MINISTERE DES AFFAIRES SOCIALES ET DE LA SANTE (MoH-FR)**, established in AVENUE DUQUESNE 14, PARIS CEDEX 75350, France, VAT number: N/A,

15. **DEUTSCHES INSTITUT FUR MEDIZINISCHE DOKUMENTATION UND INFORMATION (DIMDI) (DIMDI)**, established in WAISENHAUSGASSE 36-38A, KOLN 50676, Germany, VAT number: DE123052538,

16. **GEMATIK GMBH (GEMATIK)**, established in FRIEDRICHSTRASSE 136, BERLIN 10117, Germany, VAT number: DE241843684,

17. **TMF - TECHNOLOGIE UND METHODENPLATTFORM FUR DIE VERNETZTE MEDIZINISCHE FORSCHUNG EV (TMF)**, established in CHARLOTTENSTRASSE 42 ECKE DOROTHEENSTRASSE, BERLIN 10117, Germany, VAT number: DE244871253,

18. **MINISTRY OF HEALTH (MoHGR)**, established in ARISTOTELOUS STREET 17, ATHINA, Greece,

19. **ALLAMI EGESZSEGUGYI ELLATO KOZPONT (AEEK)**, established in DIOS AROK 3, BUDAPEST 1125, Hungary, VAT number: HU15324683,

20. **SEMMELWEIS EGYETEM (SE)**, established in ULLOI UTCA 26, BUDAPEST 1085, Hungary, VAT number: HU15329808,

21. **DEPARTMENT OF HEALTH (DoH)**, established in Block 1, Miesian Plaza, 50 – 58 Lower Baggot Street, Dublin D02 XW14, Ireland,

22. **AGENZIA PER L'ITALIA DIGITALE (AGID)**, established in VIA LISZT 21, ROMA 00144, Italy,

23. **AZIENDA REGIONALE PER L'INNOVAZIONEE GLI ACQUISTI S.P.A. (ARIA)**, established in VIA TORQUATO TARAMELLI 26, MILANO 20124, Italy, VAT number: IT05017630152,

24. **MINISTERO DELLA SALUTE (MIN SAL)**, established in Via Giorgio Ribotta 5, ROMA 00144, Italy, VAT number: N/A,

25. **REGIONE LOMBARDIA (REGLOMB)**, established in PIAZZA CITTA DI LOMBARDIA 1, MILANO 20124, Italy, VAT number: IT12874720159,

26. **NACIONALAIS VESELIBAS DIENESTS (NVD)**, established in 31 Cēsu str., k-3, 6.entrance, Riga LV-1012, Latvia, VAT number: 90009649337,

27. **LIETUVOS RESPUBLIKOS SVEIKATOS APSAUGOS MINISTERIJA (SAM)**, established in VILNIAUS G 33, VILNIUS LT 01506, Lithuania,

28. **STICHTING NATIONAAL ICT INSTITUUT IN DE ZORG (NICTIZ)**, established in Oude Middenweg 55, Den Haag 2491AC, Netherlands,

29. **NARODNE CENTRUM ZDRAVOTNICKYCH INFORMACII (NCZI)**, established in LAZARETSKA 26, BRATISLAVA 811 09, Slovakia, VAT number: SK2020830119,

30. **NACIONALNI INSTITUT ZA JAVNO ZDRAVJE (NIJZ)**, established in TRUBARJEVA CESTA 2, LJUBLJANA 1000, Slovenia, VAT number: SI44724535,

31. **FUNDACIO TICSALUT (TICSALUT)**, established in C ERNEST LLUCH 32 Planta 6 Porta 4 TECNOCAMPUS MATARO MARESME TORRE TCM 3, MATARO BARCELONA 08302, Spain, VAT number: ESG64350374,

32. **EQUALIS AB (Equalis AB)**, established in KUNGSGATAN 113, UPPSALA 751 09, Sweden, VAT number: SE556515280701,

33. **E-HALSOMYNDIGHETEN (SEHA)**, established in SANK ERIKSGATAN 117, STOCKHOLM 118 60, Sweden, VAT number: SE202100655201,

34. **INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM)**, established in RUE DE TOLBIAC 101, PARIS 75654, France, VAT number: FR31180036048,

Unless otherwise specified, references to ‘beneficiary’ or ‘beneficiaries’ include the coordinator.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

2a Additional information on the estimated budget

Annex 3 Accession Forms

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

TERMS AND CONDITIONS

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CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the action entitled '**X-eHealth: eXchanging electronic Health Records in a commom framework**' — '**X-eHealth**' **('action')**, as described in Annex 1.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be **24 months** as of 1 September 2020 ('**starting date of the action**').

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary (and linked third party) and budget category (see Articles 5, 6, and 14).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted — without an amendment (see Article 55) — by transfers of amounts between beneficiaries, budget categories and/or forms of costs set out in Annex 2, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR 2 999 980.00** (two million nine hundred and ninety nine thousand nine hundred and eighty EURO).

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **100% of the action's eligible costs** (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **2 999 980.00** (two million nine hundred and ninety nine thousand nine hundred and eighty EURO).

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (**unit costs**);

(b) for **direct costs for subcontracting**: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**:

- for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**');
- for all other costs: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

(f) **specific cost category(ies):** not applicable.

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Commission — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 — Application of the reimbursement rates to the eligible costs

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) declared by the beneficiaries and linked third parties (see Article 20) and approved by the Commission (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the Commission.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary or to a linked third party specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Commission will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors,

irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Commission rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the Commission on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Commission for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) for **actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) for **unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2a or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A and Article 6.2.D.5)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) for **flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

A. Direct personnel costs

<u>Types of eligible personnel costs</u>

A.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[1] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

'Additional remuneration' means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agreed otherwise), and

[1] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs, if the conditions in Article 11.1 are met.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**') who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

the number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

{number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person in that year, for other EU or Euratom grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs** (i.e. budget categories A.1, A.2, A.3): the hourly rate is calculated *per full financial year*, as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the

reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate *per month*, as follows:

{actual monthly personnel cost (excluding additional remuneration) for the person

divided by

{number of annual productive hours / 12}}

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or
- standard annual productive hours.

Time spent on **parental leave** may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespective of the amount actually paid for that month).

Each beneficiary must use only one option (per full financial year or per month) for each full financial year;

(b) for personnel costs declared on the basis of **unit costs** (i.e. budget categories A.1, A.2, A.4, A.5): the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

  The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B. Direct costs of subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

C. Direct costs of providing financial support to third parties

Not applicable

D. Other direct costs

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

D.2 The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with

Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.

The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or

(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

D.4 **Capitalised and operating costs of 'large research infrastructure'**[2] directly used for the action are eligible, if:

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[3]);

(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the conditions as further detailed in the annotations to the H2020 grant agreements.

[2] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[3] For the definition, see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

D.5 **Costs of internally invoiced goods and services** directly used for the action are eligible, if:

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary's usual cost accounting practices;

(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

'Internally invoiced goods and services' means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

E. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting and

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises;

(c) not applicable;

(d) not applicable.

Beneficiaries receiving an operating grant[4] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.

F. Specific cost category(ies)

Not applicable

6.3 Conditions for costs of linked third parties to be eligible

[4] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('**Financial Regulation No 966/2012**')(OJ L 218, 26.10.2012, p.1): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

Costs incurred by linked third parties are eligible if they fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 14.1.1.

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary or linked third party), if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the Commission;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Commission for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14);
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the Commission and the other beneficiaries for implementing the action.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

Not applicable

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

The beneficiaries must ensure that the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[5] (or 2014/24/EU[6]) or 'contracting entities' within the meaning of Directive 2004/17/EC[7] (or 2014/25/EU[8]) must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

The beneficiaries may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties' costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The third parties and their contributions must be set out in Annex 1. The Commission may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Commission, the European Court of Auditors (ECA) and the

[5] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[6] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC. (OJ L 94, 28.03.2014, p. 65).

[7] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1)

[8] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.03.2014, p. 243).

European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties free of charge.

The beneficiaries may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The Commission may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The Commission may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC (or 2014/24/EU) or 'contracting entities' within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

14.1 Rules for calling upon linked third parties to implement part of the action

14.1.1 The following **affiliated entities**[10] and **third parties with a legal link to a beneficiary**[11] ('**linked third parties**') may implement the action tasks attributed to them in Annex 1:

[10] For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However the following relationships between legal entities shall not in themselves be deemed to constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

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The linked third parties may declare as eligible the costs they incur for implementing the action tasks in accordance with Article 6.3.

The beneficiaries must ensure that the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their linked third parties.

14.1.2 The beneficiaries must ensure that their obligations under Articles 18, 20, 35, 36 and 38 also apply to their linked third parties.

14.2 Consequences of non-compliance

If any obligation under Article 14.1.1 is breached, the costs of the linked third party will be ineligible (see Article 6) and will be rejected (see Article 42).

If any obligation under Article 14.1.2 is breached, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14a — IMPLEMENTATION OF ACTION TASKS BY INTERNATIONAL PARTNERS

Not applicable

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

Not applicable

15.2 Financial support in the form of prizes

Not applicable

15.3 Consequences of non-compliance

Not applicable

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

Not applicable

[11] '**Third party with a legal link to a beneficiary**' is any legal entity which has a legal link to the beneficiary implying collaboration that is not limited to the action.

16.2 Rules for providing virtual access to research infrastructure

Not applicable

16.3 Consequences of non-compliance

Not applicable

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any information requested in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the Commission and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:

  (i) changes in its legal, financial, technical, organisational or ownership situation or those of its linked third parties and

  (ii) changes in the name, address, legal form, organisation type of its linked third parties;

(b) **circumstances** affecting:

  (i) the decision to award the grant or

  (ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of five years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Commission may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2.

The beneficiaries and linked third parties may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs

covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, for **personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Commission may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

For costs declared by linked third parties (see Article 14), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the linked third parties.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the Commission may apply any of the measures described in Chapter 6.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the Commission (see Article 52) the technical and financial reports set out in this Article. These reports include requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 12
- RP2: from month 13 to month 24

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'.

The report must indicate the communication activities;

(iii) a **summary** for publication by the Commission;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary and from each linked third party, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries and linked third parties must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Commission.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary and each linked third party must **certify** that:

- the information provided is full, reliable and true;

- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary and from each linked third party, for the reporting period concerned;

(iii) not applicable;

(iv) a '**periodic summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary and for each linked third party, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries and linked third parties with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries and linked third parties with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance

If the reports submitted do not comply with this Article, the Commission may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the Commission may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment**;
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR **2 399 984.00** (two million three hundred and ninety nine thousand nine hundred and eighty four EURO).

The Commission will — except if Article 48 applies — make the pre-financing payment to the

coordinator within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR **149 999.00** (one hundred and forty nine thousand nine hundred and ninety nine EURO), corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the Commission from the pre-financing payment and transferred into the '**Guarantee Fund**'.

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The Commission will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the Commission in the following steps:

Step 1 — Application of the reimbursement rates

Step 2 — Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) declared by the beneficiaries and the linked third parties (see Article 20) and approved by the Commission (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Commission will

pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Commission by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
    - is positive, it will be paid to the coordinator
    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the Commission or an executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the Commission will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The Commission will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the Commission from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: AGENCIA GESTAO DA TESOURARIA E DIV. PUBLICA, IGCP EPE
Full name of the account holder: SERVICOS PARTILHADOS DO MINISTERIODA SAUDE EPE
IBAN code: PT50078101120112001528863

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the Commission bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the Commission are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the Commission does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Commission

22.1.1 Right to carry out checks

The Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the Commission may be assisted by external persons or bodies.

The Commission may also request additional information in accordance with Article 17. The Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information

on the use of resources). The Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The Commission may request beneficiaries to provide such information to it directly.

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013[16] and No 2185/96[17] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[18], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

22.4 Checks, reviews, audits and investigations for international organisations

Not applicable

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

[16] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[17] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

[18] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The Commission may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the **correction rate for extrapolation** established by the Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the Commission in justified cases.

The Commission may then start a rejection procedure in accordance with Article 42, on the basis of:

- the revised financial statements, if approved;

- the proposed alternative correction method, if accepted

or

- the initially notified correction rate for extrapolation, if it does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements.

22.5.3.2 If the findings concern **substantial errors**, **irregularities or fraud** or **serious breach of obligations**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

The Commission may then start a reduction procedure in accordance with Article 43, on the basis of:

- the proposed alternative flat-rate, if accepted

or

- the initially notified flat-rate, if it does not receive any observations or does not accept the observations or the proposed alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the EU programme.

Evaluations may be started during implementation of the action and up to five years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the Commission may apply the measures described in Chapter 6.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[19].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Commission may apply any of the measures described in Chapter 6.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

[19] Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) —

to affiliated entities[20] established in an EU Member State or '**associated country**'[21], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

Not applicable

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

[20] For the definition, see 'affiliated entity' footnote (Article 14.1).

[21] For the definition, see Article 2.1(3) of the Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 EU ownership, to protect results

26.4.1 The EU may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the Commission and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the Commission decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the Commission takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 The EU may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the Commission at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the Commission decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 EU ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, the EU may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the Commission requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 951938".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

If results could reasonably be expected to contribute to European or international standards, the beneficiary concerned must — up to four years after the period set out in Article 3 — inform the Commission.

If results are incorporated in a standard, the beneficiary concerned must — unless the Commission requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

> "Results incorporated in this standard received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 951938".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible —

'**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the Commission before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms "European Union (EU)" and "Horizon 2020";
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

Not applicable;

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the Commission requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

> "This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 951938".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Commission.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding Commission responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the Commission is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification

must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licenses

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) not applicable.

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 Commission right to object to transfers or licensing

Not applicable

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.

Such access rights are limited to non-commercial and non-competitive use.

This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).

31.6 Access rights for third parties

Not applicable

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[23], in particular regarding:

[23] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

- working conditions;
- transparent recruitment processes based on merit, and
- career development.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Commission may apply any of the measures described in Chapter 6.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Commission may apply any of the measures described in Chapter 6.

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

34.1 Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity)

and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells).

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

In addition, the beneficiaries must respect the fundamental principle of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[24].

This implies compliance with the following fundamental principles:

- **reliability** in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources;
- **honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way;
- **respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment;
- **accountability** for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts

and means that beneficiaries must ensure that persons carrying out research tasks follow the good research practices and refrain from the research integrity violations described in this Code.

This does not change the other obligations under this Agreement or obligations under applicable international, EU or national law, all of which still apply.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law

needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the coordinator to the Commission (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out, in addition to Article 34.1, only if:

[24] European Code of Conduct for Research Integrity of ALLEA (All European Academies) http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval (in writing) from the Commission (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest (‘**conflict of interests**’).

They must formally notify to the Commission without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The Commission may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed (‘**confidential information**’).

If a beneficiary requests, the Commission may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The Commission may disclose confidential information to its staff, other EU institutions and bodies. It may disclose confidential information to third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[25], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

Not applicable

37.2 Classified information

Not applicable

[25] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013 p.81).

37.3 Activities involving dual-use goods or dangerous materials and substances

Not applicable

37.4 Consequences of non-compliance

Not applicable

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the Commission (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Commission requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities:

"This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 951938".

For infrastructure, equipment and major results:

"This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 951938".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Commission.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding Commission responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the Commission is not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the Commission

38.2.1 Right to use beneficiaries' materials, documents or information

The Commission may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material received from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

If the Commission's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the Commission not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) translation;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[27], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the Commission.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the

[27] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the Commission will insert the following information:

> "© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the European Union (EU) under conditions."

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the Commission

Any personal data under the Agreement will be processed by the Commission under Regulation No 45/2001[28] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the Commission (publicly accessible in the DPO register).

Such data will be processed by the '**data controller**' of the Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the privacy statement(s) that are published on the Commission websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the Commission. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the Commission.

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[28] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the Commission may apply any of the measures described in Chapter 6.

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE COMMISSION

The beneficiaries may not assign any of their claims for payment against the Commission to any third party, except if approved by the Commission on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the Commission has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the Commission.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES — RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES — RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibility towards the Commission

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Commission expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Article 44.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself and its linked third parties and, if required, certificates on the financial statements (see Article 20);
- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Commission (in particular, providing the Commission with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Commission and verify their completeness and correctness before passing them on to the Commission;

(iv) submit the deliverables and reports to the Commission (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Commission of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Commission.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

41.3 Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must have internal arrangements regarding their operation and co-ordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the beneficiaries, which may cover:

- internal organisation of the consortium;
- management of access to the electronic exchange system;
- distribution of EU funding;
- additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);

- settlement of internal disputes;
- liability, indemnification and confidentiality arrangements between the beneficiaries.

The consortium agreement must not contain any provision contrary to the Agreement.

41.4 Relationship with complementary beneficiaries — Collaboration agreement

Not applicable

41.5 Relationship with partners of a joint action — Coordination agreement

Not applicable

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The Commission will — after **termination of the participation of a beneficiary**, at the time of an **interim payment**, **at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the **extension of findings from other grants to this grant** (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full.

If the rejection of costs does not lead to a recovery (see Article 44), the Commission will formally notify the coordinator or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the Commission of its disagreement and the reasons why.

If the rejection of costs leads to a recovery, the Commission will follow the contradictory procedure with pre-information letter set out in Article 44.

42.3 Effects

If the Commission rejects costs at the time of an **interim payment** or **the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary

financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the Commission rejects costs **after termination of the participation of a beneficiary**, it will deduct them from the costs declared by the beneficiary in the termination report and include the rejection in the calculation after termination (see Article 50.2 and 50.3).

If the Commission — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the Commission rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

The Commission may — **after termination of the participation of a beneficiary**, **at the payment of the balance** or **afterwards** — reduce the grant amount (see Article 5.1), if :

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the Commission will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Commission does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the Commission reduces the grant **after termination of the participation of a beneficiary**, it will calculate the reduced grant amount for that beneficiary and then determine the amount due to that beneficiary (see Article 50.2 and 50.3).

If the Commission reduces the grant **at the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the Commission reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the Commission will recover the difference (see Article 44).

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The Commission will — after **termination of the participation of a beneficiary, at the payment of the balance** or **afterwards** — claim back any amount that was paid, but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt (including undue amounts paid by the Commission for costs declared by its linked third parties), except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the Commission will claim back the undue amount from the beneficiary concerned, by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Commission will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Commission may offset before the payment date specified in the debit note;

(b) not applicable;

(c) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under

Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[29] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Commission will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the Commission decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the Commission by the date in the debit note and has not submitted the report on the distribution of payments: the Commission will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the Commission by the date in the debit note, but has submitted the report on the distribution of payments: the Commission will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

[29] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

{{{{beneficiary's costs declared in the final summary financial statement and approved by the Commission multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

plus

its linked third parties' costs declared in the final summary financial statement and approved by the Commission multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing and interim payments received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund**. The Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the

payment date in the debit note, up to and including the date the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the Commission.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the Commission multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned

plus

its linked third parties' costs declared in the final summary financial statement and approved by the Commission multiplied by the reimbursement rate set out in Article 5.2 for each linked third party concerned}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the Commission will also recover these amounts.

The Commission will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Commission decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Commission will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund**. The Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

ARTICLE 45 — ADMINISTRATIVE SANCTIONS

In addition to contractual measures, the Commission may also adopt administrative sanctions under Articles 106 and 131(4) of the Financial Regulation No 966/2012 (i.e. exclusion from future procurement contracts, grants, prizes and expert contracts and/or financial penalties).

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the Commission

The Commission cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The Commission cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

46.2 Liability of the beneficiaries

Except in case of force majeure (see Article 51), the beneficiaries must compensate the Commission for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The Commission may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The Commission will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the Commission (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the Commission if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the Commission may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The Commission may — at any moment — suspend payments, in whole or in part and interim payments or the payment of the balance for one or more beneficiaries, if:

(a) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed or is suspected of having committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

If payments are suspended for one or more beneficiaries, the Commission will make partial payment(s) for the part(s) not suspended. If suspension concerns the payment of the balance, — once suspension

is lifted — the payment or the recovery of the amount(s) concerned will be considered the payment of the balance that closes the action.

48.2 Procedure

Before suspending payments, the Commission will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Commission does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the Commission.

If the conditions for resuming payments are met, the suspension will be **lifted**. The Commission will formally notify the coordinator or beneficiary concerned.

During the suspension, the periodic report(s) for all reporting periods except the last one (see Article 20.3), must not contain any individual financial statements from the beneficiary concerned and its linked third parties. The coordinator must include them in the next periodic report after the suspension is lifted or — if suspension is not lifted before the end of the action — in the last periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the Commission the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Commission.

Once circumstances allow for implementation to resume, the coordinator must immediately formally

notify the Commission and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.2 Suspension of the action implementation, by the Commission

49.2.1 Conditions

The Commission may suspend implementation of the action or any part of it, if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the Commission will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Commission does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action

and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the Commission (see Article 46).

Suspension of the action implementation does not affect the Commission's right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the Commission (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Commission considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the Commission does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The Commission will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the Commission (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the Commission considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Articles 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the Commission (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Commission, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The Commission will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary and its linked third parties in the termination report and approved by the Commission.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the Commission will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The Commission will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the Commission will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases, in particular if termination takes effect after the period set out in Article 3, the Commission will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Commission the amount due and the Commission will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator according to the procedure above, unless:

    - termination takes effect after an interim payment and

    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

In this case, the Commission will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Commission the amount due. The Commission will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the Commission does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the Commission does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that
- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the Commission

50.3.1 Conditions

The Commission may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation (or those of its linked third parties) is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

  (i) resumption is impossible, or

  (ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2);

(n) despite a specific request by the Commission, a beneficiary does not request — through the coordinator — an amendment to the Agreement to end the participation of one of its linked third parties or international partners that is in one of the situations under points (e), (f), (g), (k), (l) or (m) and to reallocate its tasks.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Commission will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the Commission of the measures to ensure compliance with the obligations under the Agreement.

If the Commission does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or beneficiary concerned **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the Commission does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The Commission will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the Commission's right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the Commission (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources,

the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the Commission (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Commission, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The Commission will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary and its linked third parties in the termination report and approved by the Commission.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the Commission will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The Commission will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the Commission will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases, in particular if termination takes effect after the period set out in Article 3, the Commission will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund

will pay to the Commission the amount due and the Commission will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator according to the procedure above, unless:

  - termination takes effect after an interim payment and

  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

  In this case, the Commission will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Commission the amount due. The Commission will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the Commission does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the Commission does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,

- was unforeseeable, exceptional situation and beyond the parties' control,

- was not due to error or negligence on their part (or on the part of third parties involved in the action), and

- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,

- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

All communication must be made through the Participant Portal **electronic** exchange system and using the forms and templates provided there.

If — after the payment of the balance — the Commission finds that a formal notification was not accessed, a second formal notification will be made by registered post with proof of delivery ('formal notification on **paper**'). Deadlines will be calculated from the moment of the second notification.

Communications in the electronic exchange system must be made by persons authorised according to the Participant Portal Terms & Conditions. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'legal entity appointed representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Participant Portal Terms & Conditions).

If the electronic exchange system is temporarily unavailable, instructions will be given on the Commission website.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/myarea/projects

The Commission will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the Commission** must be sent to the official mailing address indicated on the Commission's website.

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Participant Portal Beneficiary Register.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

Not applicable

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[30], periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which

[30] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8.6.1971, p. 1).

would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The Commission may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the Commission has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58).

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Commission's right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium.

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU.

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the Commission or the coordinator, depending on which is later.

SIGNATURES

For the coordinator

Domingos Pereira with ECAS id n003a89o signed in the Participant Portal on 04/06/2020 at 07:34:17 (transaction id SigId-71983-oUsQqRiqcYsShmT1EX7qwJpvNzp3zmQKUgd4YPxgAzb17Dfye3yZk5MAGAwUxCbnGe3yCgKvA2dbJdgpI84xHWm-jpJZscgsw0K73X2i3UbBsu-U318XkCu0G0vrUzbpuzqwW0FB1rdwMXbupnTMhOjGZrG85JrWbTb9YdY4tWzyr8a6tzwQHdnclBrmrc4DCvSqPa). Timestamp by third party at
Thu Jun 04 08:34:23 CEST 2020

For the Commission

Signed by Mikaela FARR-DAVID with ECAS id farrdmi as an authorised representative on 04-06-2020 09:03:58 (transaction id SigId-72264-dJ5KAeeoXdHtOwLioeu8wTUzQT5wOSzm8xENUcffwDlyHLcQlDtJQAM1bcZQSxndzU5ChDa0zo4A97SBztF3VMU-jpJZscgsw0K73X2i3UbBsu-8RCqAYY6FvYtcNPUcVwHqVujzi8uQ2Z62SrctAkEGHtx0ogwvy6EbxlZRUCUZRjVa5GS66XowzgN4QneG73x2u)
Thu Jun 04 09:04:02 CEST 2020

EUROPEAN COMMISSION
Directorate-General for Communications Networks, Content and Technology

CNECT.H – Digital Society, Trust and Cybersecurity
H.3 – eHealth, Well-Being and Ageing

ANNEX 1 (part A)

Coordination and support action

NUMBER — 951938 — X-eHealth

Table of Contents

1.1. The project summary

Project Number [1]	951938	Project Acronym [2]	X-eHealth

One form per project

General information	
Project title [3]	X-eHealth: eXchanging electronic Health Records in a commom framework
Starting date [4]	01/09/2020
Duration in months [5]	24
Call (part) identifier [6]	H2020-SC1-DTH-2019-2
Topic	SC1-HCC-07-2020 Support for European eHealth Interoperability roadmap for deployment
Fixed EC Keywords	
Free keywords	EHRxF; laboratory results; hospital discharge reports; medical imaging and reports; rare diseases

Abstract [7]

X-eHealth's project stands herein for a project of strategic relevance for tomorrow's European eHealth Union. Assembling at the time of this proposal submission a shared commitment of 47 health actors, the underlying idea of this project is to develop the basis for a workable, interoperable, secure and cross border Electronic Health Record exchange Format in order to lay the foundation for the advance of eHealth sector while using the 3 pillars put forward by the EC as reference.
Aimed at promoting a faster and sustainable EU digital transformation, this Cooperative and Support Action is made up of 8 Work Package in which 4 exclusively focus on technical-functional activities (WP4 to WP7). From Generic Aspects to System Architecture and Integration, passing by Functional and Technical Specifications, X-eHealth objective is to move towards a uniform interoperable data-sharing format framework. In addition, to enhance EU's public health state of play, WP1 and WP8 are responsible for implementation studies, practicality and continuity of eHealth interoperability development.
On this basis and building upon the already in place Patient Summary, X-eHealth purpose is to develop the foundations for a common framework for medical imaging, discharge letters, laboratory results and rare diseases to flow both alongside citizens care pathway and across health entities between EU Member States and Neighbour Countries.
Focus on cross-border services, this consortium aims to advance an interoperable Common European Health Data Space for citizens and health providers engagement in accordance with privacy and cybersecurity regulations.
To achieve this end, X-eHealth gathers 36 consortium partners plus 5 collaborative partners and 6 eHealth skilled experts, eager to develop the abovementioned 4 domains, and distinguished by policy and political actors mixed with national competent authorities to indeed concretely plan, implement and maintain national eHealth infrastructures.

1.2. List of Beneficiaries

Project Number [1]	951938	Project Acronym [2]	X-eHealth

List of Beneficiaries

No	Name	Short name	Country	Project entry month[8]	Project exit month
1	SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE	SPMS	Portugal	1	24
2	BUNDESMINISTERIUM FUER ARBEIT, SOZIALES, GESUNDHEIT UND KONSUMENTENSCHUTZ	ATNA	Austria	1	24
3	GESUNDHEIT OSTERREICH GMBH	GÖG	Austria	1	24
4	SERVICE PUBLIC FEDERAL SANTE PUBLIQUE, SECURITE DE LA CHAINE ALIMENTAIRE ET ENVIRONNEMENT	FPS Health Be	Belgium	1	24
5	INTEGRATING THE HEALTHCARE ENTERPRISE-EUROPE AISBL	IHE-EUR	Belgium	1	24
6	HL7 INTERNATIONAL FONDATION	HL7 Europe	Belgium	1	24
7	STICHTING KONINKLIJK NEDERLANDS NORMALISATIE INSTITUUT	NEN	Netherlands	1	24
8	HRVATSKI ZAVOD ZA ZDRAVSTVENO OSIGURANJE	HZZO	Croatia	1	24
9	UNIVERSITY OF CYPRUS	UCY	Cyprus	1	24
10	MINISTERSTVO ZDRAVOTNICTVI CESKE REPUBLIKY	MZCR	Czech Republic	1	24
11	VYSOCINA KRAJ	Kraj Vysočina	Czech Republic	1	24
12	SOTSIAALMINISTEERIUM	MSAE	Estonia	1	24
13	AGENCE DU NUMÉRIQUE EN SANTÉ	ANS	France	1	24
14	MINISTERE DES AFFAIRES SOCIALES ET DE LA SANTE	MoH-FR	France	1	24
15	DEUTSCHES INSTITUT FUR MEDIZINISCHE DOKUMENTATION UND INFORMATION (DIMDI)	DIMDI	Germany	1	24
16	GEMATIK GMBH	GEMATIK	Germany	1	24
17	TMF - TECHNOLOGIE UND METHODENPLATTFORM FUR DIE VERNETZTE MEDIZINISCHE FORSCHUNG EV	TMF	Germany	1	24
18	MINISTRY OF HEALTH	MoHGR	Greece	1	24
19	ALLAMI EGESZSEGUGYI ELLATO KOZPONT	AEEK	Hungary	1	24
20	SEMMELWEIS EGYETEM	SE	Hungary	1	24
21	DEPARTMENT OF HEALTH	DoH	Ireland	1	24
22	AGENZIA PER L'ITALIA DIGITALE	AGID	Italy	1	24

1.2. List of Beneficiaries

No	Name	Short name	Country	Project entry month[8]	Project exit month
23	AZIENDA REGIONALE PER L'INNOVAZIONEE GLI ACQUISTI S.P.A.	ARIA	Italy	1	24
24	MINISTERO DELLA SALUTE	MIN SAL	Italy	1	24
25	REGIONE LOMBARDIA	REGLOMB	Italy	1	24
26	NACIONALAIS VESELIBAS DIENESTS	NVD	Latvia	1	24
27	LIETUVOS RESPUBLIKOS SVEIKATOS APSAUGOS MINISTERIJA	SAM	Lithuania	1	24
28	STICHTING NATIONAAL ICT INSTITUUT IN DE ZORG	NICTIZ	Netherlands	1	24
29	NARODNE CENTRUM ZDRAVOTNICKYCH INFORMACII	NCZI	Slovakia	1	24
30	NACIONALNI INSTITUT ZA JAVNO ZDRAVJE	NIJZ	Slovenia	1	24
31	FUNDACIO TICSALUT	TICSALUT	Spain	1	24
32	EQUALIS AB	Equalis AB	Sweden	1	24
33	E-HALSOMYNDIGHETEN	SEHA	Sweden	1	24
34	INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE	INSERM	France	1	24

1.3. Workplan Tables - Detailed implementation

1.3.1. WT1 List of work packages

WP Number[9]	WP Title	Lead beneficiary[10]	Person-months[11]	Start month[12]	End month[13]
WP1	Project coordination	1 - SPMS	45.50	1	24
WP2	Dissemination, communication & Stakeholders	1 - SPMS	12.00	1	24
WP3	Evaluation	3 - GÖG	7.00	1	24
WP4	Generic Aspects of EEHRxF recommendation	23 - ARIA	29.67	1	24
WP5	Definition of EEHRxF functional specifications	28 - NICTIZ	56.34	1	24
WP6	Definition of EEHRxF implementable specifications	6 - HL7 Europe	41.75	1	24
WP7	Architecture integration and System specifications	23 - ARIA	42.00	7	24
WP8	EEHRxF Communities of Practice: from Proof of Concept to large scale adoption and Infrastructure for Innovation	18 - MoHGR	28.50	1	24
WP9	Ethics requirements	1 - SPMS	N/A	1	24
		Total	262.76		

1.3.2. WT2 list of deliverables

Deliverable Number[14]	Deliverable Title	WP number[9]	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D1.1	D1.1 - Interim report I	WP1	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D1.2	D1.2 Final Report	WP1	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D1.3	D1.3 - Roadmap for new domains	WP1	28 - NICTIZ	Report	Public	24
D1.4	D1.4 Proposal of a sustainable governance model for eHDSI beyond CEF	WP1	28 - NICTIZ	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D1.5	D1.5 - Readiness assessment report	WP1	28 - NICTIZ	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D1.6	D1.6 - Ethics Requirements	WP1	1 - SPMS	Other	Confidential, only for members of the consortium (including the Commission Services)	3
D1.7	D1.7 Progress towards internal deliverables	WP1	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D2.1	D2.1 - X-eHealth official website	WP2	1 - SPMS	Websites, patents filling, etc.	Public	3
D2.2	D2.2 X-eHealth leaflet	WP2	1 - SPMS	Other	Public	3
D2.3	D2.3 - Communication, Dissemination and Engagement Plan	WP2	1 - SPMS	Report	Confidential, only for members of the consortium (including the	3

Deliverable Number[14]	Deliverable Title	WP number[9]	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
					Commission Services)	
D2.4	D2.4 X-eHealth promotional video	WP2	1 - SPMS	Websites, patents filling, etc.	Public	6
D2.5	D2.5 - X-eHealth Dissemination Activities Report I	WP2	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D2.6	D2.6 X-eHealth Stakeholders leaflet	WP2	1 - SPMS	Other	Public	18
D2.7	D2.7 - X-eHealth Dissemination Activities Report II	WP2	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D3.1	D3.1 Project evaluation plan and impact matrix	WP3	3 - GÖG	Report	Confidential, only for members of the consortium (including the Commission Services)	5
D3.2	D3.2 - Overall Evaluation report	WP3	3 - GÖG	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D4.1	D4.1.1 eID in eHealth: survey of national solutions	WP4	23 - ARIA	Other	Public	6
D4.2	D4.1.2 eID in eHealth: from national solutions to eIDAS	WP4	23 - ARIA	Report	Public	18
D4.3	D4.2.1 Information paper on the current challenges in legal aspects of cross-border exchange of personal data	WP4	11 - Kraj Vysočina	Report	Public	9
D4.4	D4.2.2 Recommendation paper on legislative enablers for cross-	WP4	11 - Kraj Vysočina	Report	Public	14

Deliverable Number[14]	Deliverable Title	WP number[9]	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
	border personal data interoperability					
D4.5	D4.3.1 European trust space background	WP4	20 - SE	Report	Confidential, only for members of the consortium (including the Commission Services)	5
D4.6	D4.3.2 Policy recommendation for EU level actions to achieve digital health data trust in the cyber space	WP4	20 - SE	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D5.1	D5.1 X-eHealth use cases driven methodology	WP5	16 - GEMATIK	Report	Public	23
D5.2	D5.2 EEHRxF and its relationship with clinical guidelines	WP5	23 - ARIA	Report	Public	23
D5.3	D5.3 Laboratory Requests and Reports guideline and functional specifications	WP5	10 - MZCR	Report	Public	23
D5.4	D5.4 Medical Imaging and Reports guideline and functional specifications	WP5	28 - NICTIZ	Report	Public	23
D5.5	D5.5 Hospital Discharge Reports guideline and functional specifications	WP5	11 - Kraj Vysočina	Report	Public	23
D5.6	D5.6 Refine PS functional specifications to account for eHN Guidelines and rare diseases	WP5	25 - REGLOMB	Report	Public	23
D5.7	D5.7a Final Conclusions and Recommendations	WP5	28 - NICTIZ	Report	Public	24
D6.1	D6.1 X-eHealth Services Specifications	WP6	5 - IHE-EUR	Report	Public	24
D6.2	D6.2 X-eHealth Testing Tools	WP6	5 - IHE-EUR	Report	Public	24
D6.3	D6.3 X-eHealth Implementation Guide	WP6	6 - HL7 Europe	Report	Public	24

Deliverable Number[14]	Deliverable Title	WP number[9]	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D7.1	D7.1 EEHRxF architecture specifications	WP7	23 - ARIA	Report	Public	15
D7.2	D7.2 EEHRxF Testability strategies	WP7	5 - IHE-EUR	Report	Public	22
D7.3	D7.3 Possible upgrades of eHDSI core and generic services	WP7	33 - SEHA	Report	Public	24
D7.4	D7.4 Proposal guidelines to implement EEHRxF in National Services	WP7	33 - SEHA	Report	Public	24
D8.1	D8.1 EEHRxF Community of Practice	WP8	6 - HL7 Europe	Report	Public	6
D8.2	D8.2 Report on EEHRxF proof of concept demonstrators for-rare diseases	WP8	23 - ARIA	Report	Public	19
D8.3	D8.3 Report on EEHRxF proof of concept demonstrators for chronic disease management and prevention	WP8	18 - MoHGR	Report	Public	20
D8.4	D8.4 Exploratory study for decision aids and citizen driven health-science	WP8	6 - HL7 Europe	Report	Public	21
D8.5	D8.5 EEHRxF as infrastructure for innovation	WP8	7 - NEN	Report	Public	23
D8.6	D8.6 Evaluation of EEHRxF proof of Concept	WP8	9 - UCY	Report	Public	22
D9.1	POPD - Requirement No. 1	WP9	1 - SPMS	Ethics	Confidential, only for members of the consortium (including the Commission Services)	1
D9.2	POPD - Requirement No. 2	WP9	1 - SPMS	Ethics	Confidential, only for members of the consortium (including the Commission Services)	1

1.3.3. WT3 Work package descriptions

Work package number [9]	WP1	**Lead beneficiary** [10]	1 - SPMS
Work package title	Project coordination		
Start month	1	**End month**	24

Objectives

Feature by WP1, the Project Coordinator's objectives are to ensure:
Smooth development and successful execution of X-eHealth purposes;
Productive guidance, efficient communication and proper coordination of X-eHealth bodies, partners, and associates;
Optimization of the allocated necessary inputs so processes may be reformed and updated toward enhancing the project sustainability;
Deliverables are promptly produced and thoroughly reviewed for delivery to the EC;
Communication between Member States and the EC for close cooperation aimed at further developing the exchange of health data across borders in Europe;
Compliance with the "ethics requirements" set out in this work package;

Description of work and role of partners

WP1 - Project coordination [Months: 1-24]
SPMS, MoHGR, NICTIZ, TICSALUT
T1.1: Project management, quality control and risk management (Lead: SPMS; QM, RM) M1-M24
Being vertically accountable to the EC by virtue of the Grant Agreement, the Project Coordinator stands as the official interface connecting the Consortium and the EC. Aimed to succeed in carrying out the abovementioned objectives, this task consists of organizing, controlling and coordinating the whole project with the outmost quality standards.
It is the responsibility of this task to: ensure communication practices between WPs occur regularly to better monitor the variations that are to arise against the relevant schedule line, thus ensuring milestones are carried out smoothly and conflicts are settled with consensus.
To further support project management capabilities, both the Quality and Risk Managements stand as integral fractions of the PC (WP1). The appointed Quality and Risk managers shall ensure that the Quality Assurance of Deliverables and the Risk Assessment procedures are both thoroughly e observed and nforced as outlined in section 3.2.
T1.2: Project administrative and financial management (Lead: SPMS) M1-M24
Aimed at strengthening X-eHealth's administration and financial management, this task focuses exclusively on complying with the time limits, fostering a reporting mechanism and improving budgetary governance.
Its objective is to continuously compile partners' financial activities to enhance budget management and, whenever required, accountability reports to the EC. Amendments to the Grant Agreement shall be executed within this task.
This task functionalities comprise all administrative issues, from legal to financial and from technical to organizational, and shall ultimately ensure X-eHealth develops smoothly towards a successful impact.
This task deals with the ongoing financial reporting, budget management as well as the establishment of the work procedures and operational rules. It aims to establish the project’s reporting mechanism and set the general rules of operations for all involved bodies and partners.
T1.3: Roadmap of new domains and sustainability plan (Lead: NICTIZ; Participant: SPMS, MoH-GR, TIC-Salut) M1-M24
This proposal addresses the development of four use cases: medical images, lab results, hospital discharge letters and patient summary supporting patients with rare disease. The EEHRxF should enable the subsequent expansion of cross border exchange of health data. To this end, this task will develop a roadmap for the identification of new domains and use cases to be included in the EEHRxF. The national challenges as identified in Task 1.4 as well as specified enablers and barriers will be taken into consideration in the development of the roadmap. Active involvement and close cooperation between MS's and EC are essential for viable future developments.
Additionally, this task will develop a sustainability model for the structural management, maintenance and further development of the eHealth Digital Service Infrastructure, in line with the EEHRxF roadmap.
The development of the roadmap and the sustainability plan will be aligned with the ongoing developments of the Joint Coordination Process.
The work in this task will be aligned with the results of activities in programs with similar or related objectives, such as eHAction (D6.1), IPS and the gap analysis produced by the EC on the adoption of IPS guidelines.

T1.4: Mapping national challenges for EEHRxF adoption (Lead: NICTIZ; Participant: SPMS, MoH-GR, TIC-Salut) M1-M24
The objective of this task is to assess the readiness of MS's to deploy the use cases developed in this proposal. A framework, based on the ReEIF model, will be developed to perform a general mapping of MS' readiness. The assessments will be executed in workshops organized at the beginning, mid-term and end of the project. The mapping at the start of the project is a preliminary gap-analysis intended to offer useful information to WP 5, 6 and 7. At mid-term, the assessment is used to formulate a set of recommendations, barriers and enablers intended for use in the guidelines for the developed use cases. The iterative approach is aimed at the development of solutions that are suitable for rapid deployment and adoption by MS's.
The work in this task will be aligned with the work of relevant EU working groups/projects, such as eHMSEG, JCP, eHN Subgroup on Semantics, etc.
Task 1.5: Ethics Requirements (Lead: SPMS; Participant: ARIA and Vysocina) M1-M24
Task 1.5 objectives are: to ensure compliance with the ethics requirements established by the General Data Protection Regulation (i), to set out the ethics requirements that the project must comply with (ii), and to produce a deliverable clearly stating that the personal data from workshop and survey participants will be handled in a GDPR compliant manner, therefore in accordance with the 'data minimisation' principle (iii). In addition, this sub-task will specify in its associated deliverable D1.6 that all the deliverables produced by X-eHealth must contain a section specifically designed to address the ethics requirement that the same deliverable content may rise.

Participation per Partner

Partner number and short name	WP1 effort
1 - SPMS	36.00
18 - MoHGR	1.00
28 - NICTIZ	7.50
31 - TICSALUT	1.00
Total	45.50

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D1.1	D1.1 - Interim report I	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D1.2	D1.2 Final Report	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D1.3	D1.3 - Roadmap for new domains	28 - NICTIZ	Report	Public	24
D1.4	D1.4 Proposal of a sustainable governance model for eHDSI beyond CEF	28 - NICTIZ	Report	Confidential, only for members of the consortium (including the Commission Services)	24

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D1.5	D1.5 - Readiness assessment report	28 - NICTIZ	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D1.6	D1.6 - Ethics Requirements	1 - SPMS	Other	Confidential, only for members of the consortium (including the Commission Services)	3
D1.7	D1.7 Progress towards internal deliverables	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	12

Description of deliverables

D1.1 - Interim report I (M12)
X-eHealth 12 months report on performed activities, deliverables and milestones.
D1.2 - Final report (M24)
This report describes the CSA implementation and the results achieved.
D1.3 - Roadmap for new domains (M24)
A plan for the identification of new domains and use cases to be included in the EEHRxF.
D1.4 - Proposal of a sustainable governance model for eHDSI beyond CEF (M24)
A model for the structural management, maintenance and further development of eHDSI
D1.5 - Readiness assessment report (M24)
This report contains a mapping of national characteristics and challenges per MS for each of the developed use cases.
D1.6 - Ethics Requirements (M03)
This deliverable states how the personal data collected from workshop and survey participants will be limited to the purposes of the research project (in accordance with the 'data minimisation' principle) and handled in a GDPR compliant manner. This deliverable also describes the technical and organisational measures that will be implemented to safeguard the rights and freedoms of data subjects.
D1.7 - Progress towards internal deliverables (M12)
To be submitted during the first reporting period, this deliverable objective is to ensure that the progress of all internal deliverables pops up formally into an official deliverable of the project. This way, allowing the EC to check the internal work of the project while fostering a mechanism for keeping tracked the progress of X-eHealth internal deliverables.

ID1.5.1 - Readiness assessment report (M04)
ID1.5.2 - Readiness assessment report (M12)

D1.1 : D1.1 - Interim report I [12]

X-eHealth 12 months report on performed activities, deliverables and milestones.

D1.2 : D1.2 Final Report [24]

This report describes the CSA implementation and the results achieved.

D1.3 : D1.3 - Roadmap for new domains [24]

A plan for the identification of new domains and use cases to be included in the EEHRxF

D1.4 : D1.4 Proposal of a sustainable governance model for eHDSI beyond CEF [24]

A model for the structural management, maintenance and further development of eHDSI

D1.5 : D1.5 - Readiness assessment report [24]

This report contains a mapping of national characteristics and challenges per MS for each of the developed use cases.

D1.6 : D1.6 - Ethics Requirements [3]

This deliverable states how the personal data collected from workshop and survey participants will be limited to the purposes of the research project (in accordance with the 'data minimisation' principle) and handled in a GDPR compliant manner. This deliverable also describes the technical and organisational measures that will be implemented to safeguard the rights and freedoms of data subjects.

D1.7 : D1.7 Progress towards internal deliverables [12]

To be submitted during the first reporting period (M12), this deliverable objective is to ensure that the progress of all internal deliverables pops up formally into an official deliverable of the project. This way, allowing the EC to check the internal work of the project while fostering a mechanism for keeping tracked the progress of X-eHealth internal deliverables.

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS1	MS1.1	1 - SPMS	1	Consortium agreement
MS2	MS1.2	1 - SPMS	12	Report template for partners

Work package number [9]	WP2	Lead beneficiary [10]	1 - SPMS
Work package title	Dissemination, communication & Stakeholders		
Start month	1	End month	24

Objectives

Being liable for the project Communication and Dissemination strategy, WP2 objectives are:
• Development and implementation of X-eHealth Communication, Dissemination and Engagement Plan to maximize impact
• To ensure effective communication among partners so that results can be published in a timely fashion and generated knowledge disseminate accordingly
• Management, development and updating of X-eHealth's media to enhance the project visibility among external stakeholders, in accordance with the provisions for cross-border eHealth services
• To support the organization of X-eHealth face-to-face and virtual events to advance the assimilation of knowledge and experience among Member States' entities
• To produce suitable, sophisticated and tailored content materials for digital dissemination

Description of work and role of partners

WP2 - Dissemination, communication & Stakeholders [Months: 1-24]
SPMS, GÖG, IHE-EUR, HL7 Europe
T2.1: Communication, Dissemination and Engagement Plan (Lead: SPMS; Participant: IHE, HL7) M1-M24
This task comprises the development of the project's strategic communication plan to ensure it reaches national decision-makers as well as business, scientific and societal stakeholders. The plan builds upon a set of activities (different diffusion channels, content types and actions) aimed at supporting the dissemination of the project outcomes.
T2.2: Healthcare providers, Health professionals and Citizens motivation (Lead: SPMS; Participant: GoeG, HL7) M3-M24
This task consists of furthering communication activities through target capacity-building training sessions earmarked to instruct and qualify health professionals concerning the usage of cross-border services while raising knowledge of the different MS legislative environment. Health care providers, in turn, should act as direct means of communication, addressing citizens with information on how to use digital services.
As regards citizens' engagement, specific communication actions will be designed and implemented in order to raise awareness of European citizenship rights in relation to cross-border care services, as well as its accessibility and interoperability with national health systems. For this purpose a glossary with common terms shall be developed together with WP 3. HL7 will support from the perspective of the CoP (WP8.4).
T2.3: MS and National Authorities involvement (Lead: SPMS; Participant: GOeG, HL7) M1-M24
The purpose of this task is to convey MS and National Health Authorities the development progress of X-eHealth activities. Decision-makers will be approached to enhance the achievement of eHealth cross-border services. Overall strategies and the action roadmap should be agreed upon engaged Member States and implemented according to national specificities. HL7 will support from the perspective of the CoP (WP8.4).
T2.4 Industries, researchers and developers' liaison (Lead: SPMS, Participants: HL7) M3-M24
This task goal is to promote liaison with major players of the health sector in order to promote knowledge sharing and exchange of relevant experiences among X-eHealth partners. Representatives from leading health industries, researchers and developers will be actively involved at different stages of the project, thus contributing to enhancing its development and outcomes. HL7 will support from the perspective of the CoP (WP8.4) linking to collaborative partners.
T2.5 "X-Hospitals" - Hospital Network for the exploration of the EEHRxF (Lead: SPMS; Participant: HL7) M1-M24
In this task it will be promoted network methodologies, such as, teleconference, between nationals' hospitals across Europe, with the objective of promote a dialogue and sharing of experiences and vision of how to contribute to develop EEHRxF specifications in hospital relevant domains, such as the ones under the current call, but more importantly to share awareness about the EEHRxF, and to foster cross-fertilization of methods of adoption, usage and overcoming implementation challenges.
The EEHRxF can serve to create useful and needed interhospital digital connections, not just cross-border but even more relevant, intraborders. It is by engaging concrete organizations providing care, that we are sure to guarantee usefulness and pertinence to the all project. Such can build on existing networks of HP such as hospitals in the ERNs and other networks, like research networks including hospitals.

So synergies with those initiatives will be pursued actively. Sub tasks: satellite workshops or meetings in events where many hospital representative may be, regular podcasts, regular TCONs of networks of hospitals, creation of collateral and clustered (into domains) sub-networks of practical experience facing common interoperability challenges. Ensuring national and EU level hospital or hospital managers associations include/incorporate into their dynamics debates and follow-up on the development and later the deployment of the EEHRxF. HL7 will support connecting to the CoP (WP8.4).

Participation per Partner

Partner number and short name	WP2 effort
1 - SPMS	10.00
3 - GÖG	1.00
5 - IHE-EUR	0.50
6 - HL7 Europe	0.50
Total	12.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D2.1	D2.1 - X-eHealth official website	1 - SPMS	Websites, patents filling, etc.	Public	3
D2.2	D2.2 X-eHealth leaflet	1 - SPMS	Other	Public	3
D2.3	D2.3 - Communication, Dissemination and Engagement Plan	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	3
D2.4	D2.4 X-eHealth promotional video	1 - SPMS	Websites, patents filling, etc.	Public	6
D2.5	D2.5 - X-eHealth Dissemination Activities Report I	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D2.6	D2.6 X-eHealth Stakeholders leaflet	1 - SPMS	Other	Public	18
D2.7	D2.7 - X-eHealth Dissemination Activities Report II	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	24

Description of deliverables

D2.1 - X-eHealth official website (M03)

Development of an official website to communicate the project ongoing activities and disseminate outcomes-Deliverables
D2.1 - X-eHealth official website (M03)
Development of an official website to communicate the project ongoing activities and disseminate outcomes.
D2.2 - X-eHealth leaflet (M03)
Development of a leaflet at the beginning of the project to promote the main objectives of X-eHealth to external stakeholders.
D2.3 - Communication, Dissemination and Engagement Plan (M03)
This deliverable consists of the development of X-eHealth's Plan for Communication, Dissemination and Engagement. The plan shall outline the underlying strategy for effective communication to foster target stakeholders' engagement.
D2.4 - X-eHealth promotional video (M06)
Promotional video highlighting X-eHealth activities and expected impacts.
D2.5 - X-eHealth Dissemination Activities Report I (M12)
Report on communication activities (dissemination, Deliverables, Milestones and outcomes) carried out in the first 12 months of X-eHealth.
D2.6 - X-eHealth Stakeholders leaflet (M18)
Development of a leaflet to disseminate expected benefits for X-eHealth stakeholders accordingly.
D2.7 - X-eHealth Dissemination Activities Report II (M24)
Report on communication activities (dissemination, Deliverables, Milestones and outcomes) carried out in the second 12 months of X-eHealth.

D2.1 : D2.1 - X-eHealth official website [3]

Development of an official website to communicate the project ongoing activities and disseminate outcomes

D2.2 : D2.2 X-eHealth leaflet [3]

Development of a leaflet at the beginning of the project to promote the main objectives of X-eHealth to external stakeholders.

D2.3 : D2.3 - Communication, Dissemination and Engagement Plan [3]

This deliverable consists of the development of X-eHealth's Plan for Communication, Dissemination and Engagement. The plan shall outline the underlying strategy for effective communication to foster target stakeholders' engagement

D2.4 : D2.4 X-eHealth promotional video [6]

Promotional video highlighting X-eHealth activities and expected impacts.

D2.5 : D2.5 - X-eHealth Dissemination Activities Report I [12]

Report on communication activities (dissemination, Deliverables, Milestones and outcomes) carried out in the first 12 months of X-eHealth.

D2.6 : D2.6 X-eHealth Stakeholders leaflet [18]

Development of a leaflet to disseminate expected benefits for X-eHealth stakeholders accordingly.

D2.7 : D2.7 - X-eHealth Dissemination Activities Report II [24]

Report on communication activities (dissemination, Deliverables, Milestones and outcomes) carried out in the second 12 months of X-eHealth.

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS3	MS2.1	1 - SPMS	12	1st X-eHealth Innovation Day
MS4	MS2.2	1 - SPMS	22	Professional Training Sessions

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS5	MS2.3	1 - SPMS	24	2nd X-eHealth Innovation Day
MS6	MS2.4	1 - SPMS	24	X-eHealth interoperability award 2022

Work package number [9]	WP3	Lead beneficiary [10]	3 - GÖG
Work package title	Evaluation		
Start month	1	End month	24

Objectives

The success of this undertaking depends on the effectiveness and productiveness to achieve the defined outcomes and goal. To do so, both the project management and the vertical Work Packages (WPs) need to come up with comprehensive deliverables of high-quality bringing value to the overarching goal of well implemented interoperable eHealth services for European health professionals and citizens.
The main objective of the "WP3 Evaluation" is to verify if the Action is being implemented as planned and whether it reaches its foreseen objectives.

Description of work and role of partners

WP3 - Evaluation [Months: 1-24]
GÖG, IHE-EUR, UCY, MoHGR, REGLOMB
The evaluator will take stock on the achievements of the project, e.g. assessing if the necessary pillars and building blocks for a Common European eHealth space were produced or at least prepared for the next steps.
The evaluator will use a Logic Framework Approach as a starting point, as it is considered as an appropriate point of reference for evaluating EC funded projects since published in 2004. It allows to look at the rationale of the various planned undertakings, their interdependencies and is an import building block to ascertain the quality of results.
T3.1: Evaluation Plan and Impact Matrix (Lead: GOeG; Participant: MoH-GR, Reg. Lombard., IHE, UCY) M1-M6
As first milestone we would generate as part of the evaluation plan an impact matrix with perhaps the following headings (draft for display only).
We aim to measure the impact on the following potential user of results
• Decision makers in e-Health (Competent Authorities, EU services)
• eHealth Agencies
• eHealth Stakeholders (e.g., service providers)
• General population
The evaluation plan will include a set of measurable indicators for the three pillars (Citizens' secure access to their health data, also across borders; Personalised medicine through shared European data infrastructure and Citizen empowerment with digital tools for user feedback and person-centred care).
Per pillar each two to three "process", "output" and "outcome" indicators will be defined that will allow for a monitoring. Examples could be, e.g.
• how many Member States EHR solutions were assessed by the end of the project and in which way or
• regarding deployment, the number of specifications based the European Commission recommendation on the European EHR exchange format 2 or
• whether the targeted number of citizens (overall number and perhaps targets per participating country) using the considered eHealth platforms (compliant with EC recommendations)
Also, a sort of glossary of common terms used in the undertaking will be prepared at the beginning to ensure that the same things are meant throughout the collaboration and in the different work packages.
T3.2: Continuous Evaluation and Monitoring (Lead: GOeG; Participant: IHE, MoH-GR, Reg. Lombard., UCY) M6-M24
For evaluation we suggest using a "triangulated" approach, meaning that different evaluation instruments, ranging from on-the-spot surveys in meetings, via observation and document analysis to individual phone/e-mail mini-surveys with WP-leads and co-leads will be used. The necessary tools to support information collection (e.g., Mentimeter®) or WebEx© are available to the Evaluator.
The evaluation will include internal evaluation, i.e. if the working structure and project team communication is working accordingly. Questions could be for instance:
• Are there cross-WP-interactions to avoid "silo-thinking"?
• Are WP leaders and co-leaders taking actively part in (online) meetings etc.
Based on the proceedings the evaluator will also try to up-date the glossary, that should be put on the project website in a constant manner.
The progress of the project will be assessed based on indicators, deliverables and milestones achievement. Any discrepancies in accomplishing the specific steps should be reported to the project lead SPMS who will act as supervisor

of the evaluation. We also foresee an internal milestone in M14, a mid-term evaluation report in form of a presentation at one of the planned partner meetings to show-case the state of play and giving the participants room to re-adjust activities if necessary.
Both the evaluation plan, and the evaluation report (D 3.2) will be prepared by the Evaluator and assessed by other WP leads and co-leads, namely WP 8, as WP3 is clearly complementary to the proof of technical concept and upscaling to practice. It will summarise the achievements made towards the project objectives. The report will contain graphical displays of achievements (infographics).

Participation per Partner

Partner number and short name	WP3 effort
3 - GÖG	4.50
5 - IHE-EUR	0.50
9 - UCY	0.50
18 - MoHGR	0.50
25 - REGLOMB	1.00
Total	7.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D3.1	D3.1 Project evaluation plan and impact matrix	3 - GÖG	Report	Confidential, only for members of the consortium (including the Commission Services)	5
D3.2	D3.2 - Overall Evaluation report	3 - GÖG	Report	Confidential, only for members of the consortium (including the Commission Services)	24

Description of deliverables

D3.1 - Project evaluation plan and impact matrix (M5)
D3.2 - Overall Evaluation report (M24)

D3.1 : D3.1 Project evaluation plan and impact matrix [5]

n/a

D3.2 : D3.2 - Overall Evaluation report [24]

n/a

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS7	MS3.1	3 - GÖG	5	Project Evaluation Strategy
MS8	IM3.1	3 - GÖG	14	Half-time evaluation report in form of a presentation at a partner meeting

Work package number [9]	WP4	**Lead beneficiary** [10]	23 - ARIA
Work package title	Generic Aspects of EEHRxF recommendation		
Start month	1	**End month**	24

Objectives

The EEHRxF Recommendation sets out a framework for the development of a European electronic health record exchange format in order to achieve secure, interoperable, cross-border access to, and exchange of, electronic health data in the Union.
This framework is intended for cross-border exchange of electronic health records which lists principles for access to and cross-border exchange of electronic health records, namely that a) Member States should ensure that citizens are able to access and securely share their electronic health data across borders, b) Member States are encouraged to give citizens the ability to choose to whom they provide access to their electronic health data, and which health information details are shared, and c) Member States should ensure that these principles are observed when developing solutions enabling access to, and exchange of electronic health data in the Union.
To objective of this work package is to help define in more concrete terms what are the practical implications of principles listed in the Recommendation, focusing on its link to ongoing eHealth initiatives, especially in regard to 1) roadmapping of eID usage in health, 2) ethics of using personal data and analysing legal aspects and enablers needed for interoperability, and 3) identifying common cybersecurity efforts directly related to electronic health record exchange.
The above listed three aspects are not the main goals of the project, but important to be permanently investigated to ensure the continuous compliance of the project to achieve the best intended outcome. The below detailed three tasks are highly interrelated – i.e. CyberSecurity by design can only be established if the background legal framework is robust and transparent for all participants; eID implementation also build on legal blocks, and the trust of the services is mostly dependent on its security levels.
The work of the tasks will be continuously aligned, as well as directly coordinate with the implementation WPs.

Description of work and role of partners

WP4 - Generic Aspects of EEHRxF recommendation [Months: 1-24]
ARIA, SPMS, ATNA, GÖG, HZZO, MZCR, Kraj Vysočina, MSAE, MoH-FR, AEEK, SE, AGID, NVD, NIJZ, TICSALUT
T4.1: Electronic Identification implementation (Lead: ARIA; Participants: SPMS, ATNA, MZCR, SE, AgID, NIJZ, TIC Salut) M1-M18
Task 4.1 will first take into consideration the outcomes achieved and the lessons learned from previous national projects focused on the usage of eID instruments for the eHealth domain; a comprehensive view of national-specific implementations among the core Member States of the proposal will be provided, highlighting how and where improvements are needed (subtask 4.1.1).
Then, we will focus on a possible adaptation path which can lead MS to surpass national, specific solutions - often expensive and difficult to integrate outside the country – in principle implementing a full eIDAS-based approach, fulfilling the rights that patients have to use their national eID across European countries, taking into account usability (subtask 4.1.2); an appropriate focus will be given on how an eIDAS cross-border authentication can improve the patient journey, with a high level of security, which is a key concern in eHealth.
The alignment with the modern electronic identification standards must be matched with possible concrete use cases; this goal will be covered by subtask 4.1.3, which will present, study and select different scenarios in order to deliver a comprehensive patient empowerment and patient-centric solutions. Should the eIDAS approach raise usability aspects, they will be taken into account and, where possible, different authentication solutions will be provided. The project aims to establish a solid foundation for many years, so we will describe how the new eIDAS technical specifications v1.2.00 – released by the EU in mid October 2019 - could be adopted, replacing during the project timeframe the current implementation based on the 1.1 standard (subtask 4.1.4).
In order to be interoperable even with the Member States not yet ready with their eIDAS infrastructure, we will describe an approach and an adaptation path to fulfill this need (subtask 4.1.5).
Considering the number of EU-funded projects that have already studied, or even implemented, solutions for the eID in the eHealth domain, the subtask 4.1.6 - and the project as a whole - will leverage previous experience gathered from different projects, e.g. Health-eID (https://www.spms.min-saude.pt/healtheid/) and Konfido (https://konfido-project.eu/).

T4.2: Legal aspects & enablers (Lead: Vysocina; Participants: SPMS, MZCR, MSAE, MoH-FR, SE, NIJZ, TIC Salut, ARIA, AEEK) M1-M14
Task 4.2 will include two subtasks, namely 4.2.1 (Legal and ethical aspects of cross-border exchange of data) and 4.2.2 (Legal and ethical enablers for cross-border interoperability of personal data).
Task 4.2 will provide an analysis of the identified legislative aspects, challenges and enablers for cross-border personal data interoperability, regarding the current cross-border exchange scenarios, and the planned new domains. The Deliverables of this task shall serve as a guide for the other Work Packages.
Subtask 4.2.1 will be focused on the following topics. Cross-border exchange of personal health data is governed by several legal documents, on EU as well as national level. While the cross-border exchange of some personal/patient data is already taking place, it is necessary to re-think it in the light of the new domains, whether there are currently limitations to further development of cross-border services or if the status-quo on the EU level is sufficient. The identification of legal topics and the relevant EU legislation, with special focus on the protection of personal data, electronic identification, and cybersecurity, needs to be performed in order to identify possible limitations and suggestions for future improvements of interoperability of health data from a legal point of view. Considering the legislative differences in Member States in combination with EU legislation, legal enablers for health data interoperability need be identified, which form the foundation of free flow of personal/patient data in a cross-border setting. These enablers pertain to the data use, protection and security, data privacy, data transparency, and ethics of using personal data. The main goal of 4.2.2 will be to analyze legal obstacles for data use, data protection and security in a cross-border setting, as well as to identify legal enablers in order to improve the cross-border exchange of personal data, data privacy, and data transparency on the EU level which is a crucial step towards ensuring that data subject rights' are respected in cross-border healthcare. The cross-border exchange of patient data naturally raises further issues, which are not only the subject-matter of legislation but cross the legal boundary into the ethical domain. This is the case particularly in the question of secondary use of personal/patient data. Such issue should not be omitted in a discussion regarding the flow of data of patients among healthcare providers of European countries, as national legislations regarding secondary use of such sensitive data may differ. The legal and ethical limitations of secondary use of personal/patient data in the current setting, as well as with regards to the new domains, will be explored to the extent of their association with obstacles to cross-border data exchange.
T4.3: Cybersecurity (Lead: SE; Participants: SPMS, ATNA, GOeG, HZZO, MZCR, ARIA, AgID, NVD, Vysocina, AgID) M1-M24
The first subtask needs to ensure, that project partners know from the very beginning which building blocks can be used, thus we have to take an inventory of common criteria certification, common policies (e.g. ENISA), ICT scenarios, the current and forming standards (e.g. NATO) and EU level regulations as well as the current environment.
The aim is to paint a quick landscape extracting information from the relevant stakeholders (4.3.1: European trust space background). The second step is to create a recommendation for suitable cyber security methodology along the lines of data source inventory, data protection, F.A.I.R. principles, sensitivity and risk management. The work of this subtask should be closely coordinated with subtask 4.2.2. (4.3.2: Methodology framework recommendation).
The aim of the 3rd subtask is to compile a decision support document policy actions to obtain the highly necessary trust factor for health data exchange through cyber security efforts. This document is the main product of the work within the task, combining the cyber actions with certification, standardisation needs and legal framing of the actions.
The high level proposals should be based on findings from stakeholder conversation, collecting case studies and analysing them internally (ensuring MS differentiation, user level outcome, experience and benefit) as well as on stakeholder workshops to enable wide support for the recommendations (4.3.3: Policy recommendation for EU level actions to achieve digital health data trust in the cyber space).
The first technical subtask is formulating the minimum technological expectations, directly relating to and aligning with the work of T4.1. The minimum criteria should consider the independent transaction log, privileged user security control level and rules of enforcing multi-channel data access (4.3.4: Confidential document for standardised security control).
The second technical subtask is working out the methodology of the implementation process of the cyber solutions. The proposed methodology manual should be based on a certification process, which is unique to health cybersecurity standards. The proposal should elaborate recommendations for a standardised validation process with minimum cybersecurity controls, cyber range testing and validated test data collection. The nature of this product is sensitive, its dissemination should be limited and carefully orchestrated (4.3.5: System modelling).

Participation per Partner

Partner number and short name	WP4 effort
1 - SPMS	1.50

Partner number and short name	WP4 effort
2 - ATNA	1.50
3 - GÖG	1.50
8 - HZZO	0.50
10 - MZCR	1.00
11 - Kraj Vysočina	6.17
12 - MSAE	3.00
14 - MoH-FR	0.50
19 - AEEK	0.50
20 - SE	4.00
22 - AGID	1.00
23 - ARIA	5.00
26 - NVD	0.50
30 - NIJZ	1.50
31 - TICSALUT	1.50
Total	29.67

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D4.1	D4.1.1 eID in eHealth: survey of national solutions	23 - ARIA	Other	Public	6
D4.2	D4.1.2 eID in eHealth: from national solutions to eIDAS	23 - ARIA	Report	Public	18
D4.3	D4.2.1 Information paper on the current challenges in legal aspects of cross-border exchange of personal data	11 - Kraj Vysočina	Report	Public	9
D4.4	D4.2.2 Recommendation paper on legislative enablers for cross-border personal data interoperability	11 - Kraj Vysočina	Report	Public	14
D4.5	D4.3.1 European trust space background	20 - SE	Report	Confidential, only for members of the consortium (including the Commission Services)	5

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D4.6	D4.3.2 Policy recommendation for EU level actions to achieve digital health data trust in the cyber space	20 - SE	Report	Confidential, only for members of the consortium (including the Commission Services)	24

Description of deliverables

D4.1.1 – eID in eHealth: survey of national solutions (M06)
This deliverable will describe the state of play of eID in the eHealth domain
D4.1.2 - eID in eHealth: from national solutions to eIDAS (M18)
This deliverable will propose an adaptation path towards a comprehensive eIDAS-ready approach
D4.2.1 – Information paper on the current challenges in legal aspects of cross-border exchange of personal data (M09)
The deliverable to identify and analyse current legislative obstacles to cross-border data exchange (so, unlike eHAction T6.2 which "only" lists and briefly elaborates on the current legislative documents and uses a simple language in order to inform non-experts; D4.2.1. would be an expert analysis of legal issues that cross-border exchange of personal data is facing, aimed at a more expert level). The analysis will list all current and foreseen challenges in cross-border exchange of personal data
D4.2.2 – Recommendation paper on legislative enablers for cross-border personal data interoperability (M14)
The aim of which is to provide legislative and technical recommendations for tackling challenges identified in D4.2.1, most notably those pertaining to: a) Data Use, b) Data Protection & Security, c) Data Privacy, d) Data Transparency, e) Data Ethics in the context of cross-border exchange of personal data, and others identified in D4.2.1, in order to improve the current state of personal data exchange in the EU and enable the deployment of future eHealth services.
D4.3.1 – European trust space background (M05)
This deliverable will present a state of play of the cybersecurity technology landscape
D4.3.2 – Policy recommendation for EU level actions to achieve digital health data trust in the cyberspace (M24)
Decision support document for policy actions

ID4.3.1 – Methodology framework recommendation (M08)
Standard template
ID4.3.2 – Confidential document for standardised security control (M18)
Minimum technological expectations
ID4.3.3 – Recommendation for cyber implementation process methodology (M24)
Confidential methodology manual of the implementation process.

D4.1 : D4.1.1 eID in eHealth: survey of national solutions [6]

This deliverable will describe the state of play of eID in the eHealth domain

D4.2 : D4.1.2 eID in eHealth: from national solutions to eIDAS [18]

This deliverable will propose an adaptation path towards a comprehensive eIDAS-ready approach

D4.3 : D4.2.1 Information paper on the current challenges in legal aspects of cross-border exchange of personal data [9]

The deliverable to identify and analyse current legislative obstacles to cross-border data exchange (so, unlike eHAction T6.2 which "only" lists and briefly elaborates on the current legislative documents and uses a simple language in order to inform non-experts; D4.2.1. would be an expert analysis of legal issues that cross-border exchange of personal data is facing, aimed at a more expert level). The analysis will list all current and foreseen challenges in cross-border exchange of personal data

D4.4 : D4.2.2 Recommendation paper on legislative enablers for cross-border personal data interoperability [14]

The aim of which is to provide legislative and technical recommendations for tackling challenges identified in D4.2.2, most notably those pertaining to: a) Data Use, b) Data Protection & Security, c) Data Privacy, d) Data Transparency,

e) Data Ethics in the context of cross-border exchange of personal data, and others identified in D4.2.1, in order to improve the current state of personal data exchange in the EU and enable the deployment of future eHealth services

D4.5 : D4.3.1 European trust space background [5]

This deliverable will present a state of play of the cybersecurity technology landscape

D4.6 : D4.3.2 Policy recommendation for EU level actions to achieve digital health data trust in the cyber space [24]

Decision support document for policy actions

Schedule of relevant Milestones

Milestone number[18]	**Milestone title**	**Lead beneficiary**	**Due Date (in months)**	**Means of verification**
MS9	MS4.1	26 - NVD	9	Generic aspects of EEHRxF – Part 1
MS10	MS4.2	26 - NVD	24	Generic aspects of EEHRxF – Part 2

Work package number [9]	WP5	**Lead beneficiary** [10]	28 - NICTIZ
Work package title	Definition of EEHRxF functional specifications		
Start month	1	**End month**	24

Objectives

1. Define a common methodology for WP5, 6 and 7 based on a Use Cases driven methodology;
2. Identify business (functional) requirements.
3. Establish a common definition of the medical information set to be used;
4. Examine the clinical terminologies and information structures currently used by EHR systems for exchange in the given domains;
5. Determine a mechanism for managing terminology and concept mapping within the scope of this project;
6. Specify the context and meaning of the exchanged content, using a common clinical data structure;
7. Identify information structures with essential/recommended or optional elements;
8. Define functional specifications for new services.

Description of work and role of partners

WP5 - Definition of EEHRxF functional specifications [Months: 1-24]
NICTIZ, SPMS, FPS Health Be, IHE-EUR, HL7 Europe, UCY, MZCR, Kraj Vysočina, MSAE, ANS, DIMDI, GEMATIK, TMF, MoHGR, AEEK, DoH, ARIA, MIN SAL, REGLOMB, SAM, NCZI, NIJZ, TICSALUT, Equalis AB, INSERM
Interoperability as a practical necessity.
Sharing health information is vital in healthcare nowadays. Over the last decades, the relation between healthcare providers and patients has shifted from a one-to-one, often one-way relationship to networked care, where the patient also has become a valuable member of the healthcare team.
For the healthcare process to work efficiently, information needs to be shared, combined and reused.
Shareable information also means reusable information, for scientific research, discharge letters, decision support, financial-, management- and quality reporting et cetera.
Scope
Work Package 5 focuses on functional requirements for a common set of shared information building blocks and assets on all levels of interoperability that can be used by European Member States (MS) as a means of achieving true interoperability in exchange of EHR content across borders and within MS. It proposes principles and methods to achieve this goal, as well as a basic framework for the further development and maintenance of these building blocks.
Work Package Tasks
T5.1 provides the principles, architecture and tools for the definition of the subsequent Tasks. It aims at the definition of a collaborative process to reach agreement between member states on the architecture of this growing EEHRxF information standardisation framework. It provides a methodology for the description of use cases, the process steps and the information needed to assist these process steps. It will also provide guidance on the concept of clinical models that can be used as reusable information building blocks throughout the EU.
T5.2 complements these activities by proposing and developing methods to establish consensus between stakeholders on clinical content, where cross-border exchange and reusability is the goal. T5.3 (laboratory), T5.4 (images), T5.5 (hospital discharge reports) and T5.6 (extending PS for rare diseases) aim at extending the pool of internationally usable clinical content “modules”. These also require alignment of already existing initiatives. T5.7 compiles and summarizes the WP results, outlining a way forward to a growing set of sustainable and consensus-based “European core building blocks”.
This Work Package will create a model to establish a coordinated process to connect MS partners using collaborative tools, where results are made publicly available for sharing knowledge and experiences. Wherever possible, partners will build on and connect to current strategic and networking activities within and between their countries, establishing of National Digital Health Networks, as foreseen in the EEHRxF recommendation.
WP5 provides the basis for the subsequent technical specifications of WP6 and WP7. Note: As WP 5, 6 and 7 are closely related, networking between these WPs is an important aspect to achieve the goals of the project.
T5.1: X-eHealth use cases driven methodology (Lead: GEMATIK; Participants: SPMS, MZCR, MoH-GR, ARIA, NICTIZ, TIC Salut) M1-M24
Task 5.1 delivers a general introduction to definition of EEHRxF functional specifications. It provides principles, guidelines and frameworks for the collaborative definition and sustainable maintenance and governance in a multi-

national environment. A tight cooperation with WP6 is envisioned to support the co-creation of the functional specifications. This Task will identify and provide access to tools that capture reusable elements, to support a use case-based approach within the domain-specific tasks. Both WPs jointly strive for maximum reuse of interoperability assets such as clinical building blocks and models, document exchange patterns, users and their roles, value sets etc.

T5.2: EEHRxF and its relationship with clinical guidelines (Lead: ARIA; Participants: MZCR, DoH-IR, INT, NICTIZ, equalis) M1-M24

This Task represents the link with the national and international organisations who already have developed clinical guidelines that specify the relevant information for different use cases. As an example, in the CSA H2020 PHC-34 "VALUeHEALTH", the Guidelines from the European Association of Diabetologist were used to quickly identify the key elements to be considered in the PS for Unplanned and Planned Care of diabetic patients, Task 5.2 will define a methodology for retrieving and mapping the clinical requirements in the collaborative framework for clinical requirements and data structures to be provided by T5.1.

T5.3: Laboratory Requests and Reports guideline and functional specifications (Lead: MZCR; Participants: SPMS, IHE, ANS, TMF, DoH-IR, MIN SAL, SAM, NICTIZ, NIJZ, TIC Salut, equalis) M1-M24

This Task will follow the work of the ongoing activities of the CEF eHDSI eHealth Member State Expert Group (eHMSEG) Semantic Task Force. CEF eHDSI eP/eD and PS functional specifications will be revised to the adaptation of EEHRxF to the new Laboratory domain.

Its main objective is to formulate a set of clinical and functional requirements and definitions for the Laboratory domain, based on the identified use cases. The scope of this Task includes logical definition of the necessary data elements and data structures and specification of links to the terminologies needed for Laboratory orders and reports in the selected subdomains that are considered essential for cross-border EHR exchange. Existing national conventions for coding laboratory results (LOINC, NPU, SNOMED) will be reflected as viable starting points towards European laboratory data harmonization. Additional guidelines will be provided for subdomains that are out of the scope of this Task.

T5.4: Medical Imaging and Reports guideline and functional specifications (Lead: NICTIZ; Participants: SPMS, FPS, IHE, UCY, MIN SAL, MZCR, TIC Salut) M1-M24

Based on the identified use cases, Task 5.4 focuses on the requirements for interoperable and safe exchange of medical images and imaging reports. It provides guidance, principles, definitions and examples on different levels of interoperability (of the ReEIF model). It will take into account the international standardization activities in this field. T5.4 provides recommendations on standardization of the classification of medical images and imaging reports. It will also look into the structured reporting of radiological studies. As an example, a functional specification of a radiological report (e.g. for colon cancer imaging reports) will be added. Infrastructural topologies for the sharing of medical images and imaging reports will be proposed to enable the fair, secure and timely availability of medical images and imaging reports across Europe.

T5.5: Hospital Discharge Reports guideline and functional specifications (Leader: Vysocina; Participants: SPMS, FPS, HL7, MZCR, MSAE, AEEK, SAM, NICTIZ, NCZI, TIC Salut) M1-M24

This Task will provide the requirements for the structured definition of different Hospital Discharge Reports. It will build upon the already existing functional definition of the PS, extending its use to planned care where specialists report on episodes of care.

Extra sections that are foreseen at this point in time are: Laboratory test results, Imaging results report, Reason for Referral, Procedures performed, Conclusions, Discharge Medication, Advance Directives and other typical sections that are common in Hospital Discharge Letters.

A methodology will be presented to organise the growing number of structured information elements, and an example will be provided as an illustration of this methodology. It is assumed that the existing MVC can be reused, to enable alignment of future development.

T5.6: Refine PS functional specifications to account for eHN Guidelines and rare diseases (Lead: INT; Participants: SPMS, MZCR, MSAE, ANS, DIMDI, NICTIZ, INSERM) M1-M24

Task 5.6 will also build upon the already existing data definitions of the current PS. The activity will be two-folded: align with the Version 3 of the eHN European Guidelines on PS/eP, including the adoption of the CEN International Patient Summary (CEN IPS) and the extensions to make the PS suitable for patients with Rare Diseases, in line with the European Reference Network (ERN) requirements and the results of the RD-Action.

This Task provides an extension of the Problems list with the identified rare diseases (aligned with current scope of concepts, such as Orphacode, in accordance with the ongoing EU project RD-Code); a review on existing rare-disease-related exchange specifications (from relevant regional or national initiatives) suitable as PS extensions; the addition of the healthcare organisation that is currently assigned to the rare disease patient; and the possibility to link the PS to relevant scientific information on these rare diseases. A functional definition of these rare disease related data items will be provided in the relevant development tools. Examples of these will also be provided.

T5.7: Final Conclusions and Recommendations (Lead: NICTIZ; Participants: MZCR, MoH-GR) M20-M24

Task 5.7 captures conclusions and recommendations that were gathered during the creation of this Work Package, from the collaboration with the other WPs, from connections with representatives of the knowledge fields, and from ideas and suggestions for further development on the topic of structured data definition. Recommendations on further development of the functional elements of EEHRxF and the ReEIF, and on the basic structures for Enhancing National Digital Health Networks will be presented by this Task.

Participation per Partner

Partner number and short name	WP5 effort
1 - SPMS	6.50
4 - FPS Health Be	1.00
5 - IHE-EUR	2.00
6 - HL7 Europe	1.00
9 - UCY	1.00
10 - MZCR	7.00
11 - Kraj Vysočina	4.34
12 - MSAE	2.00
13 - ANS	2.00
15 - DIMDI	1.00
16 - GEMATIK	2.00
17 - TMF	1.00
18 - MoHGR	2.00
19 - AEEK	1.00
21 - DoH	1.50
23 - ARIA	2.50
24 - MIN SAL	1.00
25 - REGLOMB	0.00
INT	2.50
27 - SAM	1.00
28 - NICTIZ	7.00
29 - NCZI	1.00
30 - NIJZ	1.00
31 - TICSALUT	2.00
32 - Equalis AB	1.50
34 - INSERM	1.50
Total	56.34

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D5.1	D5.1 X-eHealth use cases driven methodology	16 - GEMATIK	Report	Public	23
D5.2	D5.2 EEHRxF and its relationship with clinical guidelines	23 - ARIA	Report	Public	23
D5.3	D5.3 Laboratory Requests and Reports guideline and functional specifications	10 - MZCR	Report	Public	23
D5.4	D5.4 Medical Imaging and Reports guideline and functional specifications	28 - NICTIZ	Report	Public	23
D5.5	D5.5 Hospital Discharge Reports guideline and functional specifications	11 - Kraj Vysočina	Report	Public	23
D5.6	D5.6 Refine PS functional specifications to account for eHN Guidelines and rare diseases	25 - REGLOMB	Report	Public	23
D5.7	D5.7a Final Conclusions and Recommendations	28 - NICTIZ	Report	Public	24

Description of deliverables

Deliverables
The produced principles, guidelines and tools that are the result of this WP, including the functional artefacts will be made available in an appropriate repository for enabling the discovery, the reuse and the sustainable hand-over of the produced artefacts.

ID5.1 - X-eHealth use cases driven methodology (M3)
Use case driven approach. Generic principles, methodologies and tools that support the objectives of this Work Package and Tasks 5.3 to 5.6.
ID5.2 - EEHRxF and its relationship with clinical guidelines (M3)
Definition of the methodology to exploit Clinical Guidelines, clinical data structure for EEHRxF enriched by Clinical Guidelines.
ID5.3 - Laboratory Requests and Reports guideline and functional specifications (M4)
Definition of functional requirements – Laboratory requests and reports.
ID5.4 -Medical Imaging and Reports guideline and functional specifications (M4)
Definition of functional requirements – Medical Imaging and Reports
ID5.5 - Hospital Discharge Reports guideline and functional specifications (M4)
Hospital Discharge Reports guideline and functional specifications
ID5.6 -Refine PS functional specifications to account for eHN Guidelines and rare diseases (M4)
Detailed refinement of PS for ERN functional requirements.

D5.1 - X-eHealth use cases driven methodology (M23)
Use case driven approach. Generic principles, methodologies and tools that support the objectives of this Work Package and Tasks 5.3 to 5.6.
D5.2 - EEHRxF and its relationship with clinical guidelines (M23)

Definition of the methodology to exploit Clinical Guidelines, clinical data structure for EEHRxF enriched by Clinical Guidelines.
D5.3 - Laboratory Requests and Reports guideline and functional specifications (M23)
Definition of functional requirements – Laboratory requests and reports.
D5.4 - Medical Imaging and Reports guideline and functional specifications (M23)
Definition of functional requirements – Medical Imaging and Reports
D5.5 - Hospital Discharge Reports guideline and functional specifications (M23)
Hospital Discharge Reports guideline and functional specifications
D5.6 - Refine PS functional specifications to account for eHN Guidelines and rare diseases (M23)
Detailed refinement of PS for ERN functional requirements.
D5.7 -Final Conclusions and Recommendations (M24)
Conclusions from the entire WP, and recommendations for Enhancing National Digital Health Networks.

D5.1 : D5.1 X-eHealth use cases driven methodology [23]

Use case driven approach. Generic principles, methodologies and tools that support the objectives of this Work Package and Tasks 5.3 to 5.6.

D5.2 : D5.2 EEHRxF and its relationship with clinical guidelines [23]

Definition of the methodology to exploit Clinical Guidelines, clinical data structure for EEHRxF enriched by Clinical Guidelines.

D5.3 : D5.3 Laboratory Requests and Reports guideline and functional specifications [23]

Definition of functional requirements – Laboratory requests and reports.

D5.4 : D5.4 Medical Imaging and Reports guideline and functional specifications [23]

Definition of functional requirements – Medical Imaging and Reports

D5.5 : D5.5 Hospital Discharge Reports guideline and functional specifications [23]

Hospital Discharge Reports guideline and functional specifications

D5.6 : D5.6 Refine PS functional specifications to account for eHN Guidelines and rare diseases [23]

Detailed refinement of PS for ERN functional requirements

D5.7 : D5.7a Final Conclusions and Recommendations [24]

Conclusions from the entire WP, and recommendations for Enhancing National Digital Health Networks.

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS11	IMS5.1	28 - NICTIZ	3	Preliminary (internal) release of the overall principles and guidelines (D5.1 and D5.2)
MS12	IMS5.2	28 - NICTIZ	4	Preliminary (internal) release of the Functional Specifications (D5.3, 5.4, 5.5 and 5.6).
MS13	MS5.1	28 - NICTIZ	23	Definiton of EEHRxF technical specifications – Part 1
MS14	MS5.2	28 - NICTIZ	24	Definiton of EEHRxF technical specifications – Part 2

Work package number [9]	WP6	**Lead beneficiary** [10]	6 - HL7 Europe
Work package title	Definition of EEHRxF implementable specifications		
Start month	1	**End month**	24

Objectives

• Specify how to technically implement the use cases selected by WP5 by using existing standards and profiles. This will be done by
o Providing an implementable standard representation of the clinical content defined by WP5, hopefully provided as clinical models. This includes also the specification of the Value Set and Value Set Bindings, taking in account terminologies requirements identified by WP5. [Content specifications]
o Specifying the transport mechanisms for this content relying on security requirements and other infrastructural services developed by WP4 and implemented in WP7. [Service specifications]
• Facilitate the discovery, the reuse and the testing of the content and service specifications, and of the related assets for example used in eHDSI.
• Generate the testing tools (e.g. test scripts, validation tools)

Description of work and role of partners

WP6 - Definition of EEHRxF implementable specifications [Months: 1-24]
HL7 Europe, SPMS, IHE-EUR, HZZO, UCY, MZCR, MSAE, ANS, MoH-FR, GEMATIK, MoHGR, DoH, AGID, ARIA, MIN SAL, REGLOMB, NVD, SAM, NCZI, TICSALUT, Equalis AB, INSERM
This WP concurs with WP5 to the achievement of these project goals for a set of selected domains and use cases (e.g. Laboratory Results, Imaging Reports, Discharge Letter, Rare Diseases Patient Summary): support cross-border and inter-institutional interoperability; contribute to requirements, specifications and guidelines at national and cross-border level; support integration under the eHDSI; provide open, extensible and harmonisation-based citizen health records solution for service and app developers.
While WP5 collects and formalizes the clinical and functional requirements for the content and the processes; WP6 is responsible to convert these requirements into implementable specifications and associated validation tools. A tight cooperation with WP5 is envisioned to support the co-creation of the functional specifications. This WP will also explore the use of appropriate repository/ies for enabling the discovery, the reuse and the hand-over of the produced artefacts and specifications (e.g. CDA templates, any other relevant specifications, value sets). It is envisioned that WP5 will consider and provide guidelines and models for several use cases within the identified domains (e.g. Laboratory request and reporting; Laboratory Results); a set of relevant cases (e.g. Laboratory Results), at least one per domain, will be then converted by WP6 into technical content and services specifications.
To take properly in account the complexity of the different dimensions involved, a matrix approach has been applied: domain focused tasks have been chosen, while their results (and deliverables) have been grouped per type (e.g. content specifications, validation tools and so on), this will also facilitate their mapping with the ReEIF and assure the separation of concerns. It will also permit their generalization into common cross-domain building blocks (the actual E-EEHRxF) and enable their reuse in different contexts or environments.
T6.1: Definition of technical specification for the Laboratory Domain (Lead: IHE; Participants: SPMS, HL7, MZCR, ANS, MoH-FR, MoH-GR, AgID, MIN SAL, NVD, SAM, TIC Salut, equalis) M1-M12
This task has as the main objective to publish a set of implementable specifications for the Laboratory domain. This task will be performed starting from the requirements (e.g. use cases, terminologies) collected by WP5 and taking in account the constraints from each country involved in the action as collected by WP5, the CEF eHDSI technical specifications and the most recent international standardization activities (e.g. IHE XD-Lab, HL7 IPS).
An implementable representation of the Laboratory results (e.g. CDA Template) expressed by using standardized computable formats will be at least produced (D6.1) and published in a human readable form. The produced artefacts (e.g. Value Set; CDA Templates) will be then made available in an appropriate repository for enabling the discovery, the reuse and the hand-over of the produced artefacts. This task will also concur to the definition of the technical specifications (D6.6) used for the exchange of the identified content.
T6.2: Definition of technical specification for the Medical Imaging Domain (Lead: IHE; Participants: SPMS, HL7, UCY, AgiD, ARIA, MIN SAL, TIC Salut, equalis) M1-M15
This task has as main objective to publish a set of implementable specifications for the Medical Imaging Reports. This task will be performed starting from the requirements collected by WP5 and taking in account the constraints from each

country involved in the action as collected by WP5 and the most recent international standardization activities (e.g. DICOM SR; DICOMWeb; XDS-I, HL7 IPS).
An implementable representation of the Medical Imaging Results (e.g. CDA Template) expressed by using standardized computable formats will be at least produced (D6.2) and published in a human readable form. The produced artefacts (e.g. Value Set; CDA Templates or other relevant specifications) will be then made available in an appropriate repository for enabling the discovery, the reuse and the hand-over of the produced artefacts. To take in account the specificity of the imaging part, a dedicated deliverable for imaging evidences will be also produced (D6.8) by using the most appropriate formalism (e.g. DICOM Conformance Statement). This task will also concur to the definition of the services specifications (D6.5) used for the exchange of the medical results and reports and, depending on the solution chosen (e.g. XDS-I), for the imaging evidences.
T6.3: Definition for the technical specifications Hospital Discharge Reports (Lead: HL7; Participants: SPMS, IHE, HZZO, MZCR, ANS, GEMATIK, TMF, DoH-IR, AgiD, ARIA, MIN SAL, SAM, NCZI, TIC Salut) M3-M15
This task has as main objective that of publishing a set of implementable specifications for Hospital Discharge Reports. This task will be performed starting from the requirements collected by WP5 and taking in account the constraints from each country involved in the action as collected by WP5, the CEF eHDSI technical specifications and the most recent international standardization activities.
An implementable representation of the Hospital Discharge Reports (e.g. CDA Template) expressed by using standardized computable formats will be produced (D6.3) and published in a human readable form. The produced artefacts (e.g. Value Set; CDA Templates) will be then made available in an appropriate repository for enabling the discovery, the reuse and the hand-over of the produced artefacts. This task will also concur to the definition of the services specifications (D6.5) used for the exchange of the identified content.
T6.4: Refinement of Patient Summary (PS) technical specifications for supporting rare diseases (Lead: HL7; Participants: IHE, HZZO, ANS, DoH-IR, ARIA, INT, NVD, TIC Salut, INSERM) M1-M12
This task has as main objective that of refining the PS specifications to extend the use of the PS to rare diseases. This task will be performed starting from the requirements collected by WP5 and taking in account the constraints from each country involved in the action as collected by WP5, the CEF eHDSI technical specifications and the most recent international standardization activities (International Patient Summary).
An implementable representation of the patient summary for rare diseases (e.g. CDA Template), based on the cases identified by WP5, expressed by using standardized computable formats, will be produced (D6.4) and published in a human readable form. The produced artefacts (e.g. Value Set; CDA Templates) will be then made available in an appropriate repository for enabling the discovery, the reuse and the hand-over of the produced artefacts. This task will also concur to the definition of the services specifications (D6.5) used for the exchange of the identified content.
T6.5: Publication and maintenance of the services specifications and testing tools (Lead: IHE; Participants: HL7, MZCR, MoH-FR, MIN SAL, SEHA) M10-M24
This task aims to assure the cross-domain harmonization of the service specifications and of the testing tools; and their maintenance during the project. All main contributors of the other WP6 tasks will be engaged.
Service technical specifications, defining how the specified contents should be exchanged, will be created and maintained during the whole project life, in order to continuously improve them based on the lessons learned during the project. [D6.5]. A set of testing tools for content and technical specifications that include test scripts will be also selected and specified from the defined specifications [D6.7].
Finally, for the service part, suggestions for CEF eHDSI change proposals will be produced and shared with WP7. The possibility to maintain backward compatibility with the current solutions of PS and eP/eD will be carefully analysed.
T6.6: Publication and maintenance of the X-eHealth Implementation Guide (content) (Lead: HL7; Participants: IHE, MZCR, GEMATIK, MoH-GR, AgiD, MIN SAL, TIC Salut, equalis, SEHA) M10-M24
This task aims to assure the cross-domain harmonization of the content specifications (X-eHealth implementation guide); and their maintenance during the project. All main contributors of the other WP6 tasks will be engaged.
An Implementation Guide collecting the content specifications and associated artefacts specified by the T6.1-T6.4 will be created and maintained during the whole project life, in order to continuously improve this guide based on the lessons learned during the project. [D6.6].
Finally, for the content part, suggestions CEF eHDSI change proposals will be produced and shared with WP7. The possibility to maintain backward compatibility with the current solutions of PS and eP/eD will be carefully analysed.

Participation per Partner

Partner number and short name	WP6 effort
1 - SPMS	1.50

Partner number and short name	WP6 effort
5 - IHE-EUR	5.00
6 - HL7 Europe	6.50
8 - HZZO	1.00
9 - UCY	1.00
10 - MZCR	1.75
12 - MSAE	2.50
13 - ANS	1.00
14 - MoH-FR	1.00
16 - GEMATIK	1.75
18 - MoHGR	2.00
21 - DoH	1.75
22 - AGID	2.00
23 - ARIA	1.50
24 - MIN SAL	1.00
25 - REGLOMB	0.00
INT	1.00
26 - NVD	1.50
27 - SAM	1.50
29 - NCZI	1.50
31 - TICSALUT	2.00
32 - Equalis AB	1.50
34 - INSERM	1.50
Total	41.75

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D6.1	D6.1 X-eHealth Services Specifications	5 - IHE-EUR	Report	Public	24
D6.2	D6.2 X-eHealth Testing Tools	5 - IHE-EUR	Report	Public	24
D6.3	D6.3 X-eHealth Implementation Guide	6 - HL7 Europe	Report	Public	24

Description of deliverables

ID6.1 - X-eHealth Implementation Guide: Laboratory Domain [M12].
First release of the content technical specifications (e.g. CDA Template) for the Laboratory domain, expressed by using standardized computable formats and published in a human readable format. Internal deliverable (IHE).

ID6.2.1 - X-eHealth Implementation Guide: Medical Imaging Domain [M12].
First release of the content technical specifications (e.g. CDA Template) for the Medical Imaging domain, expressed by using standardized computable formats and published in a human readable format. Internal deliverable (IHE).
ID6.2.2 - Technical Specifications for Images [M15].
First release of the content technical specifications for the imaging evidences. Internal Deliverable (IHE).
ID6.3 - X-eHealth Implementation Guide: Hospital Discharge Report [M15].
First release of the content technical specifications (e.g. CDA Template) for the Hospital Discharge Report, expressed by using standardized computable formats and published in a human readable format. Internal deliverable (HL7).
ID6.4 - X-eHealth Implementation Guide: Patient Summary for Rare Diseases [M12].
First release of the content technical specifications (e.g. CDA Template) for the Patient Summary for Rare Diseases, expressed by using standardized computable formats and published in a human readable format. Internal deliverable (HL7).
ID6.5.1 - X-eHealth Services Specifications [M15].
Service (e.g. transport services) technical specifications for the domain and use cases selected. Interim release. (IHE)
ID6.5.2 - X-eHealth Testing Tools [M16].
A set of testing tools for content and technical specifications that include test scripts. Interim release. (IHE)

D6.1 - X-eHealth Services Specifications [M24].
Service (e.g. transport services) technical specifications for the domain and use cases selected. (IHE)
D6.2 - X-eHealth Testing Tools [M16 (interim) – M24 (final)].
A set of testing tools for content and technical specifications that include test scripts. (IHE)
D6.3 - X-eHealth Implementation Guide [M24].
Implementation Guide collecting harmonized and updated content technical specifications and associated artefacts initially specified by the Tasks 6.1-6.4. (HL7)

D6.1 : D6.1 X-eHealth Services Specifications [24]

Service (e.g. transport services) technical specifications for the domain and use cases selected

D6.2 : D6.2 X-eHealth Testing Tools [24]

A set of testing tools for content and technical specifications that include test scripts

D6.3 : D6.3 X-eHealth Implementation Guide [24]

Implementation Guide collecting harmonized and updated content technical specifications and associated artefacts initially specified by the Tasks 6.1-6.4

Schedule of relevant Milestones

Milestone number[18]	**Milestone title**	**Lead beneficiary**	**Due Date (in months)**	**Means of verification**
MS15	IMS6.1	6 - HL7 Europe	12	First Content Specifications (ID6.1, ID6.2.1, ID6.4)
MS16	IMS6.2	6 - HL7 Europe	16	First Release of Technical Specifications and Testing Tools (ID6.2.2, ID6.3, ID6.5.1, ID6.5.2).
MS17	MS6.1	6 - HL7 Europe	24	Final Release of Technical Specifications and Testing Tools

Work package number [9]	WP7	Lead beneficiary [10]	23 - ARIA
Work package title	Architecture integration and System specifications		
Start month	7	End month	24

Objectives

The objective of WP 7 is to define the X-eHealth architecture for the new use cases EEHRxF domain and for dealing with all issues impacting on the sustainability of X-eHealth services beyond the proof of concept stage. The X-eHealth architecture shall take as a starting point the current eHDSI architecture.
WP7 will be responsible for:
• Make a coherence check of the specifications produced within the other work packages to be able to create a coherent architecture.
• Define the appropriate changes needed in the current eHDSI architecture for both core and generic service.
• Create guidelines on how to adopt the new EEHRxF domain within the member states
• Create testing strategies for the new use-cases in the EEHRxF domain

Description of work and role of partners

WP7 - Architecture integration and System specifications [Months: 7-24]
ARIA, SPMS, FPS Health Be, IHE-EUR, HL7 Europe, HZZO, UCY, MZCR, Kraj Vysočina, ANS, MoH-FR, GEMATIK, TMF, MoHGR, SE, DoH, AGID, REGLOMB, NIJZ, TICSALUT, Equalis AB, SEHA
In order to exchange health information between the member states the epSOS project created a common architecture to do so. The resulting infrastructure has been put into production through CEF eHDSI and the integration by member states of the National Infrastructures. The architecture was created for two specific use-cases, ePrescription and Patient Summary. With the advent of the new use-cases form of the EEHRxF domain this architecture may need to be revised in order to make it fit for purpose. That is the main purpose of this work package. But it is not limited to that. The work package will also create guidelines for easier adoption of the new use-cases by the member states within the Country and cross-border, as well as creating testing strategies for the new use-cases.
T7.1: Global architecture for EEHRxF Domains use (Lead: ARIA; Participants: SPMS, FPS, IHE, HL7, HZZO, UCY, MZCR, GEMATIK, TMF, MoH-GR, SE, DoH-IR, AgiD, Reg Lomb, NIJZ, TIC Salut, equalis, SEHA) M7-M24
To make a coherent and sustainable architecture and infrastructure it is necessary to go through the documents created by WP4, WP5, WP6 and analyse, find and correct the inconsistencies. This will ensure that all documents are aligned to create a solid and sustainable architecture and infrastructure.
In order to make the uptake of the new use-cases of the EEHRxF domain, defined in WP5 and addressed in WP6, as easy as possible it is necessary to explore the member states national prerequisites, cooperating with Task 1.4. What are the commonalities and differences facing the member states regarding architecture and infrastructure? Armed with this information it is possible to describe different architecture options that face the member states in order to adopt the new use-cases of the EEHRxF domain at a national level. Suggestions of a few alternative architecture solutions for the integration of EEHRxF components in the services will be provided.
The scenarios will cover different options of implementation of EEHRxF on national level and the architectural solutions will promote support for the cross-border eHealth services (eHDSI).
These will include possible new ways of providing data (e.g. FHIR resources) and performing transactions (e.g. foresee document push-mode, in addition to the current pull-mode).
As for the ERN, the possibility of going beyond the eHDSI architecture will be considered, by assessing the needs and the possibility of feeding clinical documents to the ERN collaborative platform, mainly for second opinion services.
This task will organize in a structured manner lessons learned. In the second part of the CSA, this task will perform the verification of coherence between requirements and the specifications develop by WP7.
T7.2: Testing strategies (Lead: IHE; Participants: SPMS, GEMATIK, DoH-IR, AgiD, ARIA, Reg Lomb) M13-M22
This task will define the process, rules, test plan and criteria for testing the conformity of products and solutions implementing the X-eHealth specifications developed in WP7 at the cross border and national levels by extending the existing eHDSI test framework already available. The Testing strategy will be based on the adoption of the Testing Tools developed in WP6.
In the other hand provide guidance based on the EURO-CAS guideline for implementing the national/regional scheme (EURO-CAS D4.4) to national programme for implementing the testing strategy for their own needs. In the case of the eHDSI extension, a Change proposal will be the main input of the task when a specific framework will be specified in the case of the national context. These draft change proposals will be gathered by Task T7.4.

The outcomes from T7.2 will be transferred to WP8, for implementing the demonstrators.
T7.3: Needs for upgrade of CEF eHDSI core and generic services (Lead: SEHA; Participants: HL7, MZCR, Vysocina, ANS, TMF, SE, AgiD, ARIA, INT, TIC Salut) M15-M24
Task 7.3 will analyse the new use-cases in the EEHRxF domain and their impact on both the eHDSI core and generic services. It will highlight, describe and quantify where there is a need to make changes in order to make the core and generic services fit for purpose for the new use-cases. The task will describe the difference between the as-is state and the to-be state of the eHDSI core and generic services.
The draft change proposals, originated by this and other Tasks, will be gathered and transferred to theEEHRxF Joint Coordination Group, for further assessment and handing over to CEF eHDSI Solution Provider and to the relevant eHN Subgroups.
T7.4: Guidance for the new EEHRxF domains (Lead: SEHA; Participants: IHE, HL7, HZZO, MZCR, Vysocina, MoH-FR, GEMATIK, MoH-GR, AgiD, ARIA, Reg Lomb, equalis) M13-M24
With materials from mainly task 7.2 and task 7.4, this task is responsible for giving guidance on how to establish national and cross-border services for the new EEHRxF domain. It will emphasize cross-border compliance, made evident by the adoption of the testing strategies defined in T7.3.
Additionally, sharing of lessons learned, organized in a structured manner by Task T7.2, will be part of the training materials, which will emphasize cross-border compliance and possibilities for the establishment of stable national and cross-border services.
Task T7.4 will provide inputs to WP1 task 1.3, as a contribution to define the Roadmaps and inputs to WP8 as support material for the Community of Practice and for the evaluation processes.

Participation per Partner

Partner number and short name	WP7 effort
1 - SPMS	2.00
4 - FPS Health Be	1.00
5 - IHE-EUR	3.50
6 - HL7 Europe	2.00
8 - HZZO	1.00
9 - UCY	1.00
10 - MZCR	1.50
11 - Kraj Vysočina	1.00
13 - ANS	1.00
14 - MoH-FR	1.00
16 - GEMATIK	1.50
17 - TMF	1.00
18 - MoHGR	1.50
20 - SE	1.50
21 - DoH	1.00
22 - AGID	2.00
23 - ARIA	8.50
25 - REGLOMB	2.00
INT	0.50
30 - NIJZ	1.00
31 - TICSALUT	1.50

Partner number and short name	WP7 effort
32 - Equalis AB	1.00
33 - SEHA	4.00
Total	42.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D7.1	D7.1 EEHRxF architecture specifications	23 - ARIA	Report	Public	15
D7.2	D7.2 EEHRxF Testability strategies	5 - IHE-EUR	Report	Public	22
D7.3	D7.3 Possible upgrades of eHDSI core and generic services	33 - SEHA	Report	Public	24
D7.4	D7.4 Proposal guidelines to implement EEHRxF in National Services	33 - SEHA	Report	Public	24

Description of deliverables

ID7.1 - EEHRxF architecture specifications (M12)
It will define the architecture to implement and deploy EEHRxF services.
ID7.2 - Proposal guidelines to implement EEHRxF in National Services (M20)
It provides guidelines proposals for the implementation of EEHRxF at National level, to allow cross-border deployment.

D7.1 - EEHRxF architecture specifications (M15)
It will define the architecture to implement and deploy EEHRxF services.
D7.2 -EEHRxF Testability strategies (M22)
Based in WP6 Testing Tools, it will extend the current CEF eHDSI Testng Strategy to EEHRxF domains.
D7.3 - Possible upgrades of eHDSI core and generic services (M24)
It will include the draft Change Proposals to extend CEF eHDSI attest to EEHRxF.
D7.4 - Proposal guidelines to implement EEHRxF in National Services (Internal deliverable on M20, Official final deliverable M24)
It provides guidelines proposals for the implementation of EEHRxF at National level, to allow cross-border deployment.

D7.1 : D7.1 EEHRxF architecture specifications [15]

It will define the architecture to implement and deploy EEHRxF services.

D7.2 : D7.2 EEHRxF Testability strategies [22]

Based in WP6 Testing Tools, it will extend the current CEF eHDSI Testng Strategy to EEHRxF domains

D7.3 : D7.3 Possible upgrades of eHDSI core and generic services [24]

It will include the draft Change Proposals to extend CEF eHDSI attest to EEHRxF

D7.4 : D7.4 Proposal guidelines to implement EEHRxF in National Services [24]

It provides guidelines proposals for the implementation of EEHRxF at National level, to allow cross-border deployment.

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS18	MS7.1	23 - ARIA	16	Definition of Architecture specifications
MS19	MS7.2	23 - ARIA	22	EEHRxF Testing Strategy definition
MS20	MS7.3	23 - ARIA	24	Provision of the CEF eHDSI Change Proposals and guidelines to implement EEHRxF at National Level

Work package number [9]	WP8	Lead beneficiary [10]	18 - MoHGR
Work package title	EEHRxF Communities of Practice: from Proof of Concept to large scale adoption and Infrastructure for Innovation		
Start month	1	End month	24

Objectives

• Deliver, demonstrate, and evaluate proof-of-concept demonstrators for selected EEHRxF use cases for rare diseases patients and patients with chronic disease and comorbidities, and decision aids delivering value for citizens.
• Build capacity in an EEHRxF Community of Practice (CoP) engaging stakeholders including patients, implementers, developers, clinicians, researchers, business analysts, and policy makers.
• Support implementers and developers of EEHRxF in member states and across the world.
• Engage collaborative partners and other interested projects in implementing EEHRxF identifying a priority list of scenarios, tools and resources needed for future use cases in eHDSI bringing together government, healthcare organisations, industry and research in the transformation of health and care and enabling innovative paradigms that actively empower the patient.
• Collaborative partners such as Digital Europe, MedTech, EFMI, ECPC, COCIR, ECHALLIANCE, EHTEL: trade, patient advocacy, and professional associations will be engaged in the activities of this WP. At the same time, outreach for synergies, in coordination with WP2, will involve other sectors (e.g. transport), innovation hubs, large scale public private partnerships such as programs in life sciences e.g. ELIXIR, IMI and BDVA, EU projects, as well as regional, national and international interoperability initiatives. Karolinska institute will contribute to T8.3 under subcontract with HL7

Description of work and role of partners

WP8 - EEHRxF Communities of Practice: from Proof of Concept to large scale adoption and Infrastructure for Innovation [Months: 1-24]
MoHGR, ATNA, HL7 Europe, NEN, HZZO, UCY, MoH-FR, GEMATIK, ARIA, REGLOMB, NVD, SAM, INSERM
In this work package, participants will connect within and beyond x-eHealth and will liaise with digital health stakeholders, including large scale programs and initiatives to deliver and evaluate proof of concept demonstrators of EEHRxF in selected use cases that cover local, regional, national and cross-border/international aspects, to also deliver value for European citizens.
This WP, respectively T8.1, T8.2, and T8.3 will cooperate closely with WP1 (T1.3/T1.4 sustainability), WP2 (Dissemination), WP5, WP6, and WP7. TP8.4 will establish the CoP in the first 6 months of the project, building and extending of the concept of the Global IPS Community of Practice.
The EEHRxF CoP will be established and linked to any recognised entity in the domain, for example eHDSI, application providers, innovation hubs, standards affiliates (HL7), CEN national member bodies, national deployment committees, PCHA, IHE, HIMSS affiliated entities, and ecosystems and will be clustered to relevant ongoing H2020 and future Digital Europe projects related to the exchange or sharing of health data. The aim of the EEHRxF CoP is twofold:
• to accelerate EEHRxF adoption by considering different representations (HL7 CDA, HL7 FHIR) and in collaboration with other standard bodies.
• to build capacity through training, tools, and a mentorship program.
Driven by community interest and formalized collaborations with large scale initiatives, this WP will allow to check and validate the feasibility of scaling up, adoption, and implementation of extensions to EEHRxF for e.g. clinical and outcomes-based research, use of genomics information, AI, patient decision aids, and citizen driven health science, etc, all in the context of the prospective EEHRxF roadmap.
In cooperation with WP2 (Dissemination), partnerships with connectathons, transferathons, datathons, hackathons, ideathons or other similar innovation events, will allow to further prove fitness for purpose of EEHRxF, raising awareness and building capacity and knowledge in Europe. The output will inform governments, trade associations, patients, health professionals, and informal care giver associations as well as new use cases of the eHN multiannual work programme.
The specific tasks are as follows:
Task 8.1: Proof of concept: EEHRxF in rare diseases (lead: ARIA, Participants: UCY, MoH-GR, INT, NVD, INSERM): M9-M19.

This task uses the EEHRxF domains to construct the patient case of a rare disease and interface rare disease registries. The project would seek to collaborate with a rare disease network for this proof of concept concentrating on meaningful data. The actual use case will be selected from the output of T1.4 (Mapping national challenges of EEHRxF adoption) according to the use cases of T5.1 (X-eHealth use cases driven methodology) and T5.2 (EEHRxF and its relationship with clinical guidelines) and elaborated in T5.6 (Refine PS functional specifications to account for eHN guidelines and rare diseases) and T6.4 (Refinement of Patient Summary (PS) technical specifications for supporting rare diseases).
Taking a patient-centric approach, this work will contribute towards addressing local, national, cross-border/ international aspects along with professional collaboration with patients, multi-lingualism, differences in terminology, and other well-known organizational barriers. This task will provide feedback to WP5 and WP6 to refine patient summaries, discharge summaries, lab results, images studies and reports for rare disease patients. Output D8.2.
Task 8.2: Proof of concept: EEHRxF in chronic diseases management and prevention (Lead: MoH-GR, Participants: HZZO, UCY): M9-M20.
This task will provide at least one proof of concept EEHRxF demonstrator for chronic disease patients or patients suffering from comorbidity. The actual use case(s) will be selected earlier in the project, according to the use cases of T5.1 and T5.2 and carried out in collaboration with other projects, e.g. in cancer, diabetes, chronic pain, hypertension, cardiovascular/stroke, or other chronic conditions. The work will contribute towards addressing local, national, cross-border/international aspects along with professional collaboration with patients, multi-lingualism, differences in terminologies, and other existing barriers.
This task will provide feedback to WP5 and WP6 to refine patient summaries, discharge summaries, lab results, images studies and reports for chronic disease patients or patients suffering from comorbidity. Output D8.3.
Task 8.3: Exploratory Proof of concept study: from EEHRxF to decision aids and citizen driven health-science (Lead: HL7; Participants: UCY, MoH-FR, MoH-GR, SAM) M9-M21.
This exploratory task links EEHRxF to parallel initiatives that are in the process of assessing and integrating new concepts and tools such as for example AI, outcomes-based research, clinical research, clinical trial integration, business analytics, decision aids for patients, and citizen-driven health-science, etc.
The study would result into clear recommendations for incorporating the EEHRxF in these areas taking into account technical, legal, procedural, and other barriers. Collaborative partners, projects or initiatives that wish to explore the implications of using EEHRxF in their area of work, will do so by engaging in the CoP. Output D8.4.
Task 8.4: EEHRxF community of practice: building capacity and scaling up (Lead: HL7; Participant: UCY, GEMATIK, MoH-GR, ARIA, SAM, SEHA, INSERM): M1-M24
This task will build capacity and a European community that understands EEHRxF and use it in their daily work as developers, designers, health professionals, policy makers, etc., or as needed.
This task can be connected to several KPIs: number of people aware of EEHRxF, number of people able to implement it, procurers that refer to it, projects that support its development or adoption, etc.
In the first 6 months of the project, the community of practice will be set up delivering in output: D1, terms of reference, and online presence.
For the rest of the project, the task will be nurturing the community; for example with training, sample data, reference implementations, tools, meetups and events, broadly supporting T8.1, T8.2, T8.3, with participation of all x-eHealth partners. Regular updates in KPIs will be consolidated in periodic reports. Output D8.1
Task 8.5: Exploitation: EEHRxF as infrastructure for innovation (Lead: MoH GR; Participants: ATNA, HL7, UCY, MoH-FR, GEMATIK, MoH-GR, ARIA, NSH, SAM, NEN, SEHA, INSERM) M19-M23
This task is exploring the role of EEHRxF in other domains, broadly noted registries, etc. The task will deliver a priority list for use cases, tools, and resources for the future, aligned with the policy agenda of the European eHealth Network. MoH GR will also ensure and provide input to the sustainability task of the project (T1.3-Roadmap of new domains and sustainability plan).
The task will strongly involve the CoP with standardization stakeholders at the national, European, and international level, including CEN/ISO national member bodies and HL7 affiliates and will provide input to the rolling plan for ICT standardization and similar activities. Output D8.5.
Task 8.6: Evaluation of EEHRxF proof of concept demonstrators (Lead: UCY; Participants: HZZO, MoG-GR, NVD, SAM, NEN, SEHA, INSERM): M18-M22
This task will evaluate the proof of concept outcomes of T8.1 and T8.2 with a formal methodology and will provide input to the sustainability task of the project (T1.4) avoiding duplications with WP3 on overall evaluation.
The following domains will be evaluated across the proof of concept practices to infer optimised EEHRxF adoption and implementation framework/s: readiness for implementation, organisation capacity to implement changes, integration into existing workflows and the adoption of new ones, workforce training and education needs. Best practise guidelines will be prescribed to drive efficiencies and accelerate the interoperability in EEHRxF implementation. Output: D8.6

Participation per Partner

Partner number and short name	WP8 effort
2 - ATNA	1.00
6 - HL7 Europe	5.00
7 - NEN	1.00
8 - HZZO	1.00
9 - UCY	3.00
14 - MoH-FR	0.50
16 - GEMATIK	2.00
18 - MoHGR	7.00
23 - ARIA	2.50
25 - REGLOMB	0.00
INT	0.50
26 - NVD	2.00
27 - SAM	2.00
34 - INSERM	1.00
Total	28.50

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D8.1	D8.1 EEHRxF Community of Practice	6 - HL7 Europe	Report	Public	6
D8.2	D8.2 Report on EEHRxF proof of concept demonstrators for-rare diseases	23 - ARIA	Report	Public	19
D8.3	D8.3 Report on EEHRxF proof of concept demonstrators for chronic disease management and prevention	18 - MoHGR	Report	Public	20
D8.4	D8.4 Exploratory study for decision aids and citizen driven health-science	6 - HL7 Europe	Report	Public	21
D8.5	D8.5 EEHRxF as infrastructure for innovation	7 - NEN	Report	Public	23

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D8.6	D8.6 Evaluation of EEHRxF proof of Concept	9 - UCY	Report	Public	22

Description of deliverables

D8.1 - EEHRxF Community of Practice: terms of reference [HL7, M6]
This deliverable will provide the terms of reference as well as governance and operations manual for the community of practice.
D8.2 - Report on EEHRxF proof of concept demonstrators for rare diseases [ARIA, M19]
This deliverable describes the proof of concept demonstrator (s) for rare diseases noting links to projects and collaborative partners.
D8.3 - Report on EEHRxF proof of concept demonstrators for chronic disease management and prevention [MoH GR M20]
This deliverable describes the proof of concept demonstrator (s) for chronic disease patients and multimorbidity noting links to projects and collaborative partners.
D8.4 - Exploratory study for decision aids and citizen driven health-science [HL7, M21]
This study describes the process of assessing and integrating new concepts and tools such as for example AI, outcomes-based research, clinical research, clinical trial integration, business analytics, decision aids for patients, and citizen-driven health-science.
D8.5 - EEHRxF as infrastructure for innovation [NEN, M23]
This deliverable will compile lessons learned and identify areas where further funding, coordination and standardisation work is needed, in order to successfully position the EEHRxF in the context of the projected development of digital health and care in Europe. D8.5 is overseen and validated by MoH GR.
D8.6 - Evaluation of EEHRxF proof of Concept [UoCyprus, M22]
A methodology is defined and applied to evaluate this proof of concept.

D8.1 : D8.1 EEHRxF Community of Practice [6]

This deliverable will provide the terms of reference as well as governance and operations manual for the community of practice.

D8.2 : D8.2 Report on EEHRxF proof of concept demonstrators for-rare diseases [19]

This deliverable describes the proof of concept demonstrator (s) for rare diseases noting links to projects and collaborative partners.

D8.3 : D8.3 Report on EEHRxF proof of concept demonstrators for chronic disease management and prevention [20]

This deliverable describes the proof of concept demonstrator (s) for chronic disease patients and multimorbidity noting links to projects and collaborative partners.

D8.4 : D8.4 Exploratory study for decision aids and citizen driven health-science [21]

This study describes the process of assessing and integrating new concepts and tools such as for example AI, outcomes-based research, clinical research, clinical trial integration, business analytics, decision aids for patients, and citizen-driven health-science.

D8.5 : D8.5 EEHRxF as infrastructure for innovation [23]

This deliverable will compile lessons learned and identify areas where further funding, coordination and standardisation work is needed, in order to successfully position the EEHRxF in the context of the projected development of digital health and care in Europe. D8.5 is overseen and validated by MoH GR.

D8.6 : D8.6 Evaluation of EEHRxF proof of Concept [22]

A methodology is defined and applied to evaluate this proof of concept

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS21	MS8.1	18 - MoHGR	6	Establishment of the European EEHRxF CoP
MS22	MS8.2	18 - MoHGR	21	Proof of concept demonstrators completed
MS23	MS8.3	18 - MoHGR	22	Evaluation of the EEHRxF proof of Concept

Work package number [9]	WP9	**Lead beneficiary** [10]	1 - SPMS
Work package title	Ethics requirements		
Start month	1	**End month**	24

Objectives

The objective is to ensure compliance with the 'ethics requirements' set out in this work package.

Description of work and role of partners

WP9 - Ethics requirements [Months: 1-24]
SPMS
This work package sets out the 'ethics requirements' that the project must comply with.

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D9.1	POPD - Requirement No. 1	1 - SPMS	Ethics	Confidential, only for members of the consortium (including the Commission Services)	1
D9.2	POPD - Requirement No. 2	1 - SPMS	Ethics	Confidential, only for members of the consortium (including the Commission Services)	1

Description of deliverables

The 'ethics requirements' that the project must comply with are included as deliverables in this work package.

D9.1 : POPD - Requirement No. 1 [1]

The beneficiary must explain how all of the personal data they collect from stakeholder workshop participants will be limited to the purposes of the research project (in accordance with the ‘data minimisation ‘principle) and handled in a GDPR compliant manner.

D9.2 : POPD - Requirement No. 2 [1]

A description of the technical and organisational measures that will be implemented to safeguard the rights and freedoms of the data subjects/research participants in compliance with GDPR must be submitted. This must be done for the processing of patients' personal data (if applicable).

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification

1.3.4. WT4 List of milestones

Milestone number[18]	Milestone title	WP number[9]	Lead beneficiary	Due Date (in months)[17]	Means of verification
MS1	MS1.1	WP1	1 - SPMS	1	Consortium agreement
MS2	MS1.2	WP1	1 - SPMS	12	Report template for partners
MS3	MS2.1	WP2	1 - SPMS	12	1st X-eHealth Innovation Day
MS4	MS2.2	WP2	1 - SPMS	22	Professional Training Sessions
MS5	MS2.3	WP2	1 - SPMS	24	2nd X-eHealth Innovation Day
MS6	MS2.4	WP2	1 - SPMS	24	X-eHealth interoperability award 2022
MS7	MS3.1	WP3	3 - GÖG	5	Project Evaluation Strategy
MS8	IM3.1	WP3	3 - GÖG	14	Half-time evaluation report in form of a presentation at a partner meeting
MS9	MS4.1	WP4	26 - NVD	9	Generic aspects of EEHRxF – Part 1
MS10	MS4.2	WP4	26 - NVD	24	Generic aspects of EEHRxF – Part 2
MS11	IMS5.1	WP5	28 - NICTIZ	3	Preliminary (internal) release of the overall principles and guidelines (D5.1 and D5.2)
MS12	IMS5.2	WP5	28 - NICTIZ	4	Preliminary (internal) release of the Functional Specifications (D5.3, 5.4, 5.5 and 5.6).
MS13	MS5.1	WP5	28 - NICTIZ	23	Definiton of EEHRxF technical specifications – Part 1
MS14	MS5.2	WP5	28 - NICTIZ	24	Definiton of EEHRxF technical specifications – Part 2
MS15	IMS6.1	WP6	6 - HL7 Europe	12	First Content Specifications (ID6.1, ID6.2.1, ID6.4)
MS16	IMS6.2	WP6	6 - HL7 Europe	16	First Release of Technical Specifications and Testing Tools (ID6.2.2, ID6.3, ID6.5.1, ID6.5.2).
MS17	MS6.1	WP6	6 - HL7 Europe	24	Final Release of Technical Specifications and Testing Tools
MS18	MS7.1	WP7	23 - ARIA	16	Definition of Architecture specifications

Milestone number[18]	Milestone title	WP number[9]	Lead beneficiary	Due Date (in months)[17]	Means of verification
MS19	MS7.2	WP7	23 - ARIA	22	EEHRxF Testing Strategy definition
MS20	MS7.3	WP7	23 - ARIA	24	Provision of the CEF eHDSI Change Proposals and guidelines to implement EEHRxF at National Level
MS21	MS8.1	WP8	18 - MoHGR	6	Establishment of the European EEHRxF CoP
MS22	MS8.2	WP8	18 - MoHGR	21	Proof of concept demonstrators completed
MS23	MS8.3	WP8	18 - MoHGR	22	Evaluation of the EEHRxF proof of Concept

1.3.5. WT5 Critical Implementation risks and mitigation actions

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
1	Key partner or person leaves the project (Medium)	WP1, WP2, WP3, WP4, WP5, WP6, WP7, WP8	Set a single shared platform containing all X-eHealth essential information in order to ensure continuity and smoothness in the event of a permanent or temporal replacement.
2	Lack of budgetary resources (High)	WP1, WP2, WP3, WP4, WP5, WP6, WP7, WP8	X-eHealth partners are well aware of this situation and if it turns unsustainable and jeopardizes X-eHealth purposes, the PC may address the EC for issue solving.
3	Delay in submission of key Deliverables and Milestones due to disagreement on scope and purpose (Low)	WP1, WP2, WP3, WP4, WP5, WP6, WP7, WP8	The RM should have predicted the delay and reported to the PC. The Conflict Resolution process shall be applied if needed.
4	Low quality recommendations (Low)	WP4, WP5, WP6, WP7, WP8	Further deepening AB and CPs involvement to address internal gaps
5	Meaningful National differences for EEHRxF usage (Medium)	WP4, WP5, WP6, WP7, WP8	Differences categorization by type and degree. Align MS with similar levels to assess, brainstorm and overcome identical challenges
6	Disagreements on how to exploit outcomes (Low)	WP8	Organize an internal series of teleconferences and face to face meeting to reach a consensus
7	Lack of time to develop useful deliverables (Medium)	WP1, WP2, WP3, WP4, WP5, WP6, WP7, WP8	Keep WP's closely aligned and determine in early stage the required level of detail for deliverables
8	A MS/C adapts an inconsistent standard in a national flavor, undermining interoperability (Low)	WP1, WP4, WP5, WP6, WP7	Include as many partners as possible in WP5 and 6; assess readiness multiple times during the project to recognize this possibility as early as possible
9	Different work packages or tasks that are dependent of each other operate at different speed or fail to align (Low)	WP4, WP5, WP6, WP7, WP8	Increase alignment efforts between work packages and tasks
10	Gaps in specifications become apparent in CoP's (Low)	WP4, WP5, WP6, WP7, WP8	Early alignment during development of specifications with partners involved in CoP's, to enable timely discovery and addition of incomplete specifications
11	No consensus on clinical guidelines due to irreconcilable differences between medical experts (Low)	WP5	The objections will be clearly documented and efforts to overcome those in practice will be documented.
12	Low risk of participation into the Community Of Practice - COP (Low)	WP8	Perform additional awareness activities, increase the number of invited entities, review the governance documentation of the COP
13	Difficulty to allocate proof of concepts (Medium)	WP8	Collaborate with WP1, WP5, WP6 and WP7 to review technical documentations and apply minor relaxations or use cases simplifications, perform additional dissemination and awareness activities.

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
14	Large scale initiatives not engaged in WP8 (Low)	WP8	Additional dissemination support

1.3.6. WT6 Summary of project effort in person-months

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	Total Person/Months per Participant
1 - SPMS	36	10	0	1.50	6.50	1.50	2	0	✓	57.50
2 - ATNA	0	0	0	1.50	0	0	0	1		2.50
3 - GÖG	0	1	4.50	1.50	0	0	0	0		7
4 - FPS Health Be	0	0	0	0	1	0	1	0		2
5 - IHE-EUR	0	0.50	0.50	0	2	5	3.50	0		11.50
6 - HL7 Europe	0	0.50	0	0	1	6.50	2	5		15
7 - NEN	0	0	0	0	0	0	0	1		1
8 - HZZO	0	0	0	0.50	0	1	1	1		3.50
9 - UCY	0	0	0.50	0	1	1	1	3		6.50
10 - MZCR	0	0	0	1	7	1.75	1.50	0		11.25
11 - Kraj Vysočina	0	0	0	6.17	4.34	0	1	0		11.51
12 - MSAE	0	0	0	3	2	2.50	0	0		7.50
13 - ANS	0	0	0	0	2	1	1	0		4
14 - MoH-FR	0	0	0	0.50	0	1	1	0.50		3
15 - DIMDI	0	0	0	0	1	0	0	0		1
16 - GEMATIK	0	0	0	0	2	1.75	1.50	2		7.25
17 - TMF	0	0	0	0	1	0	1	0		2
18 - MoHGR	1	0	0.50	0	2	2	1.50	7		14
19 - AEEK	0	0	0	0.50	1	0	0	0		1.50
20 - SE	0	0	0	4	0	0	1.50	0		5.50
21 - DoH	0	0	0	0	1.50	1.75	1	0		4.25
22 - AGID	0	0	0	1	0	2	2	0		5
23 - ARIA	0	0	0	5	2.50	1.50	8.50	2.50		20

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	Total Person/Months per Participant
24 - MIN SAL	0	0	0	0	1	1	0	0		2
25 - REGLOMB	0	0	1	0	0	0	2	0		3
· INT	0	0	0	0	2.50	1	0.50	0.50		4.50
26 - NVD	0	0	0	0.50	0	1.50	0	2		4
27 - SAM	0	0	0	0	1	1.50	0	2		4.50
28 - NICTIZ	7.50	0	0	0	7	0	0	0		14.50
29 - NCZI	0	0	0	0	1	1.50	0	0		2.50
30 - NIJZ	0	0	0	1.50	1	0	1	0		3.50
31 - TICSALUT	1	0	0	1.50	2	2	1.50	0		8
32 - Equalis AB	0	0	0	0	1.50	1.50	1	0		4
33 - SEHA	0	0	0	0	0	0	4	0		4
34 - INSERM	0	0	0	0	1.50	1.50	0	1		4
Total Person/Months	45.50	12	7	29.67	56.34	41.75	42	28.50		262.76

1.3.7. WT7 Tentative schedule of project reviews

Review number [19]	Tentative timing	Planned venue of review	Comments, if any
RV1	12	Luxembourg	Linked to payment
RV2	24	Luxembourg	Linked to payment

1. Project number

The project number has been assigned by the Commission as the unique identifier for your project. It cannot be changed. The project number **should appear on each page of the grant agreement preparation documents (part A and part B)** to prevent errors during its handling.

2. Project acronym

Use the project acronym as given in the submitted proposal. It can generally not be changed. The same acronym **should appear on each page of the grant agreement preparation documents (part A and part B)** to prevent errors during its handling.

3. Project title

Use the title (preferably no longer than 200 characters) as indicated in the submitted proposal. Minor corrections are possible if agreed during the preparation of the grant agreement.

4. Starting date

Unless a specific (fixed) starting date is duly justified and agreed upon during the preparation of the Grant Agreement, the project will start on the first day of the month following the entry into force of the Grant Agreement (NB : entry into force = signature by the Commission). Please note that if a fixed starting date is used, you will be required to provide a written justification.

5. Duration

Insert the duration of the project in full months.

6. Call (part) identifier

The Call (part) identifier is the reference number given in the call or part of the call you were addressing, as indicated in the publication of the call in the Official Journal of the European Union. You have to use the identifier given by the Commission in the letter inviting to prepare the grant agreement.

7. Abstract

8. Project Entry Month

The month at which the participant joined the consortium, month 1 marking the start date of the project, and all other start dates being relative to this start date.

9. Work Package number

Work package number: WP1, WP2, WP3, ..., WPn

10. Lead beneficiary

This must be one of the beneficiaries in the grant (not a third party) - Number of the beneficiary leading the work in this work package

11. Person-months per work package

The total number of person-months allocated to each work package.

12. Start month

Relative start date for the work in the specific work packages, month 1 marking the start date of the project, and all other start dates being relative to this start date.

13. End month

Relative end date, month 1 marking the start date of the project, and all end dates being relative to this start date.

14. Deliverable number

Deliverable numbers: D1 - Dn

15. Type

Please indicate the type of the deliverable using one of the following codes:

R	Document, report
DEM	Demonstrator, pilot, prototype
DEC	Websites, patent fillings, videos, etc.
OTHER	
ETHICS	Ethics requirement
ORDP	Open Research Data Pilot
DATA	data sets, microdata, etc.

16. Dissemination level

Please indicate the dissemination level using one of the following codes:

PU	Public
CO	Confidential, only for members of the consortium (including the Commission Services)
EU-RES	Classified Information: RESTREINT UE (Commission Decision 2005/444/EC)
EU-CON	Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC)
EU-SEC	Classified Information: SECRET UE (Commission Decision 2005/444/EC)

17. Delivery date for Deliverable

Month in which the deliverables will be available, month 1 marking the start date of the project, and all delivery dates being relative to this start date.

18. Milestone number

Milestone number:MS1, MS2, ..., MSn

19. Review number

Review number: RV1, RV2, ..., RVn

20. Installation Number

Number progressively the installations of a same infrastructure. An installation is a part of an infrastructure that could be used independently from the rest.

21. Installation country

Code of the country where the installation is located or IO if the access provider (the beneficiary or linked third party) is an international organization, an ERIC or a similar legal entity.

22. Type of access

VA	if virtual access,
TA-uc	if trans-national access with access costs declared on the basis of unit cost,
TA-ac	if trans-national access with access costs declared as actual costs, and
TA-cb	if trans-national access with access costs declared as a combination of actual costs and costs on the basis of unit cost.

23. Access costs

Cost of the access provided under the project. For virtual access fill only the second column. For trans-national access fill one of the two columns or both according to the way access costs are declared. Trans-national access costs on the basis of unit cost will result from the unit cost by the quantity of access to be provided.

History of Changes (HoC)

Date	Change Description	Change Justification	Part/ Section / Page
13/04/2020	**Restructuring of Annex 1 – Part B** according to the Grant Agreement instructions	Incorporation of the instructions put forward by the Annex 1 – Description of the Action (part B). • Remove cover page & list of participants • Add a table with HoC and a table of contents • Remove tables 3.1a, 3.1b, 3.1c, 3.2a, 3.2b and 3.4a. • Include proposal number and acronym as footer • **Include section 5 – ethics and security**	B / entire document
13/04/2020	**Ethics Requirements** **Task and deliverable adjustment** T1.5 – Ethics Requirements	Following the EC's Ethics Apprisal Report, task T1.5 *Ethics Requirements* was added to the project coordination workpackage (WP1). The objectives of WP1 were complemented accordingly.	A / 1.3.3 / 11-12
		Together with T1.5, a deliverable named *D1.6: Ethics Requirements* was also created. Both the task and deliverable are described in detail in Part A.	A / 1.3.3 / 13
13/04/2020	**Gantt Chart update**	Update of the project gant chart in accordance with the ethics requirements' task and deliverable mentioned above.	B / 3.1 / 15
13/04/2020	Section 4.2 **Sub-contracting** • **5 – IHE** • **11 – Vysocina**	Although some partners initially planned to subcontract, as described in section 4.2 of part B of Annex 1, this situation is no longer true. Thus, the respective section 4.2 of these same partners has been changed to: **it does not plan to subcontract.**	B / 4.2 / 158; 162
13/04/2020	**Linked Third Party** • **10 – MZCZ**	Although MZCZ and DoH initially envisioned that part of their work were to	B / 4.2 / 161; 167-68

	• **23 – DoH**	be performed by linked third parties, as described in section 4.2 of part B of Annex 1, this situation is no longer true. Thus, the respective section 4.2 of these same partners have been changed to: **it does not envision to have part of its work performed by a linked third party.**	
27/04/2020	**Withdraw from Consortium** **13 – THL**	Due to capacity-related matters, THL informed their intention to withdraw from the X-eHealth Consortium. This withdrawal affects the following project features: • List of beneficiaries • WP4 – T4.2 participant and effort (1.00) • WP5 – T5.5 participant and effort (2.00) • WT6 Summary of project effort in person-months	A / 1.2 / 4 A / 1.3.3 / 22-23 A /1.3.3 / 27-29 A / 1.3.6 / 50
27/04/2020	**Filling the gap opened by THL's withdrawal** **11 - Vysocina**	**Vysocina** T4.2 – Vysocina assumes the role and effort of THL in WP4. This way, Vysocina increases their effort in WP4 from 4 to 6.17 PMs.	A / 1.3.3 ; 1.3.6 / 24 ; 50
		Vysocina T5.5 Lead – Vysocina takes over the role and effort of THL in WP5. This way, Vysocina becomes a participant in WP5 with 4.34 PMs	A / 1.3.3 ; 1.3.6 / 28-29 ; 50
27/04/2020	Filling the gap opened by THL's withdrawal **Beneficiary Number Reajustment**	As a result of THL departure, the beneficiaries whose number identification is after 13, go down 1 number to readjust the order. That is to say: • ANS (former 14) becomes 13 • Beneficiary (X>13) becomes X-1 • INSERM (former 36) becomes 35	A & B / entire document
27/04/2020	Section 4.2 **Sub-contracting** **1 – SPMS** **7 – NEN** **13 – ANS**	Adding and update of further information in section 4.2 of the following beneficiaries: • SPMS – explanation added • NEN – update • ANS – update	B / 4.2 / 156; 159-160; 163-164

27/04/2020	**Table 3.4b:** Other Direct Costs **Update**	Update of Table 4.3b by adding missing partners information and readjusting the correct amount requested for other direct costs.	B / 3.4 / 22-26
28/04/2020	**Withdraw from Consortium** **(temporally)** **14 – CNAM**	Due to the current context and since CNAM's "LEAR" is not reachable for the time being, CNAM will be removed from the Consortium in order to X-eHealth meet the EC's deadline and therefore, be able to sign the Grant Agreement. Once CNAM's "LEAR" is available, an amendment to the GA shall take place to undeal this same change. Concerning CNAM' budget, SPMS (coordinator) will hold its resources until this situation is solved. This situation also impacts in the beneficiaries whose number is after 14. The same logic applied for THL's withdrawal is herein applied as well.	A & B / entire document
28/04/2020	**Internal Deliverables Report** D1.7 - Progress towards interim deliverables	In order to ensure that progress towards all internal deliverables are also described in the formal deliverables of the project, a deliverable named D1.7 "Progress towards interim deliverables" was added to WP1.	A / 1.3.2; 1.3.3 / 7; 13-14

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1. Excellence

1.1 Objectives

The lack of interoperability is the most persistent barrier to the deployment of the digital health services and one major factor holding back investments in digital health infrastructures. Well implemented and interoperable eHealth services used by health professionals and citizens can be a major societal contribution to improve healthcare in Europe with a high socio-economic return.

Support the Digital Transformation of Health and Care (DTHC) and its priorities

The digital transformation of health and care is among the top priorities on the EU'a agenda. Recognizing that digital health and care has the potential to innovate and increase the overall efficiency of the healthcare sector, X-eHealth intends to contribute to the Digital Single Market Strategy of the European Commission. The underlying idea of realising a connected Digital Single Market in Europe is based on three pillars:

1. Pillar 1: Citizens' secure access to their health data, also across borders

In order to position the citizen as active and determinant actor in the process of sharing health data, each person needs to be electronically identified and authenticated. The General Data Protection Regulation GDPR and eIDAS Regulation1 are major enablers for citizen' access to and management of their personal health data, by providing a European legal framework for cross-border sharing of health data. Adding to efforts and contributions undertaken by the eHealth Network (eHN), the eHealth Digital Service Infrastructure (eHDSI) and the wide number of projects e.g. under H2020 Conneting Europe Facility (CEF) and Innovative Medicines Initiative (IMI), the X-eHealth is aiming to foster the uptake of European Eletronic Health Record Exchange Formant (EEHRxF) on regional, national and European level. This is done by defining on functional and technical level the requirements for the newly added use cases Laboratory Results, Medical Imaging and Reports and Hospital Discharge Reports, by specifying them and by demonstrating and measuring their technical feasibility for cross-border data sharing as well as on local, regional or national level within Member States. The already introduced use case patient summary will be reassessed in the light of possible reuse of technical and semantical components and also applied to rare and undiagnosed diseases. The proposal brings together key European policy leaders to drive forward collaboration on this 1st priority of DTHC. The X-eHealth proposal will bring recommendations to secure data access and sharing with compliance of the EU regulations, as GDPR (Regulation (EU) 2016/679), eIDAS (Regulation (EU) N°910/2014) and PSI.

In order to guarantee this compliance, our proposal will be contributing to: better articulation of eHealth services with the progressive and common use of Digital identification in health (in alignment with strategies currently being discussed in the ehealth); digital ID analysing legal aspects and enablers needed for interoperability; identifying common cybersecurity efforts directly related to electronic health record exchange. This project intends to contribute to better access for consumers and businesses to digital services across Europe.

2. Pillar 2: Personalised medicine through shared European data infrastructure

The eHealth digital service infrastructure needs to evolve towards a more European citizen centred approach and usage. This will facilitate once implemented, tailored diagnosis and treatment of citizen in need of acute emergency care or suffering from chronic diseases and help through dedicated health services to be better prepared to respond to cross-border health threats.

X-eHealth aims to contribute to sharing health data for research, faster diagnosis and improved health by introducing and defining reusable semantic and technical components, which can be used on local, regional, national and European level. X-eHealth intends to streamline existing efforts on EU-level and align them with e.g. established initiatives for national genomic databanks. The proposed project will among also refine the patient summary's functional and technical specifications to support rare diseases and connect with dedicated registries.

3. Pillar 3: Citizen empowerment with digital tools for user feedback and person-centred care

Citizen participation, prevention and care integration have been recognised as key aspects to successfully address current health system challenges.[2]

Due to an ageing population, more and more people in the EU are suffering from multiple chronic diseases. This increases the demand for healthcare. At the same time, there is a shortage of medical professionals[3]. Digital health,

[1] https://www.eid.as/home/

[2] State of the Health in the EU Companion Report 2017. https://ec.europa.eu/health/sites/health/files/state/docs/2017_companion_en.pdf

[3] European Public Health Alliance. "Digital Solutions for Health and Disease Management; Digital Health Discussion Paper". May, 2017

starting with the standardisation of health information, can increase both the quality and the efficiency of healthcare, by streamlining the effective exchange of information, reducing the administrative burden and clears the way to secondary use of information, such as scientific research, management information, benchmarking, decision support and deep learning techniques. Structured information also allows solutions where medical information can made more understandable to citizens using laymen's term for clinical information.

In this sense, X-eHealth strengthens citizen' empowerment by supporting individualized care through national and cross-border available digital services. The digital eHealth services can improve the prevention and management of chronic conditions and allow patients to provide feedback to healthcare providers and act as an important partner in shared decision making. Health systems will also benefit from innovative care models that use telehealth and mHealth to address the rising demand for healthcare. Rural geographic areas can profit significantly, if patients can receive care in their home environment.

Digital patient-centred health solutions need to be deployed more widely and in a more innovative way. X-eHealth aims to provide principles, guidelines, models and specifications of functional and technical level for the above-mentioned use cases Laboratory, Imaging, Hospital Discharge letters and rare diseases, thus widening the scope of interoperability to better support European citizens. It will also deliver proof-of-concept demonstrators for selected EEHRxF use cases in rare diseases, chronic disease patients and patients with comorbidity, delivering value for citizens. Additionally, the project aims to build capacity in an EEHRxF Community of Practice engaging stakeholders including patients, healthcare professionals, developers, business analysts, and policy makers and also to explore infrastructures for innovation, including mobile solutions for the citizens' use.

Align efforts of ongoing initiatives supporting the DTHC priorities

The strategic initiatives put forward by the European Commission to advance towards a borderless eHealth Union are emphasised by two priority measures: start the application of a common and uniform Electronic Health Record exchange Format (EEHRxF) to ensure interoperability in the use of ICT and to incite a rapid and sustainable digital transformation of national healthcare systems in the light of the *EU eGovernment Action Plan 2016-2020*[4].

Focusing on the practical application of cross-border initiatives, the operationalisation of this projects is supported by the Joint Action supporting the eHN (eHAction) and conducted in accordance with the *Multiannual Work Program 2018-2021*[5] of the eHealth Network. Thus, under the Commission's Digital Single Market umbrella, this intergovernmental eHealth cooperation action established eight working groups, five of which focus exclusively on delivering technical-scientific expertise for the advancement of the eHealth sector. Building on that, X-eHealth is aimed at improving both the quality and well-being of citizen's health within Member States and on European level.

During the 13th eHN meeting held on 15th May 2018, eHealth interoperability and policy actions to improve semantic interoperability in the EU were discussed.[6] This was intended to initiate a constructive discussion among members of the eHN with the objective to further improve semantic interoperability in the EU. As a result of this discussion, it was noted by the participants that a Common Semantic Strategy (CSS) in the EU was needed. As such, a provisional working group was raised under the eHAction activities, to discuss the principles, scope and ambition of such a strategy. This group is composed by the MS representatives and wrote the CSS document with a 5-year semantic strategy for semantics on EU. It considers the 5 information domains from the EEHRxF EC recommendation 7 (Patient Summary; ePrescription/eDispensation; Laboratory Results; Medical Imaging and Reports and Hospital Discharge Reports) to describe the semantic strategy. The group got mandate from eHN to integrate their scope under the name "eHN Subgroup on Semantics" to develop and elaborate guidelines and recommendations regarding this strategy.

Currently, the information domains Patient Summary and ePrescription/eDispensation are managed by the eHMSEG STF. The other 3 domains (Laboratory Results; Medical Imaging and Reports and Hospital Discharge Reports), however, still need to be integrated to their scope. The CSS document propose the integration of these three domains to the eHMSEG in order to extend their mandate and provide support to all 5 information domains described in the EEHRxF recommendation.

This way, this consortium recognizes the importance of health data interoperability as a key enabler for digital transformation in health and care, for which a common semantic language, as well as a common data exchange format, needs to be available.

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4 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016DC0179&from=EN
5 https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20171128_co01_en.pdf
6 Cover Note by eHealth Network Secretariat: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20180515_co02_en.pdf
7 https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format

On this basis, X-eHealth project aims to lay the foundations to advance the integration process of the abovementioned eHealth services features into the already in place European cross border Patient Summary.

The overall vision of X-eHealth is to contribute to a Europe with integrated health processes in which the health record of every European citizen can be immediately accessed in any Member State. Regardless of where in Europe the patient receives health care, every health professional will fully understand the patient data with **the European Electronic Health Record exchange Format (EEHRxF).**

An important goal of X-eHealth is to contribute to a *Common European Health Data Space*, that addresses the challenge of healthcare integration through interoperable and implementable data models, exchange formats and standardized solutions, at cross-border, but also at national, regional and local levels, between providers themselves and between providers and citizens and taking into account privacy and cybersecurity regulations.

Thus, the proposed work is to **highlight, contribute and support the European eHealth interoperability and the implementation of the EEHRxF** through standardisation and harmonisation of health data, providing with quality and safety and empowering the patients, professionals and health institutions.

The overarching goal of the project is the contribute to a future adoption of a eHealth governance framework and an Information & Communication Technology (ICT) infrastructure that will enable secure across borders access for the citizens and health professionals to the patient health information, particularly with respect to laboratory results, medical imaging and reports and hospital discharge letters and add rare diseases to the patient summary service.

The project will focus also on verifying the feasibility on re-using eHealth assets created by both European and national initiatives and projects, as well as the potential of accelerated deployment of these services across borders.

For this purpose, the consortium intends to support the presently running eHDSI infrastructure (Patient Summary and ePrescription/ eDispensation services) for the different referred services of EEHRxF. The project aims to define the appropriate changes needed in the current eHDSI architecture for both core and generic services. This way the project intends to enhance the interoperability and security of national digital health systems and support the secure exchange of health data across borders, the I services mentioned in the previous paragraph.

It is the objective of the X-eHealth consortium to proceed to a national analysis/mapping of the challenges for EEHRxF adoption (electronic identification implementation, legal aspects & enablers and cybersecurity) in order to define the EEHRxF specifications, functional and implementable, related to the laboratory results, medical imaging and hospital discharge reports and rare diseases. Thus, the work plan of the project is organised to guarantee that the following clear, measurable and realistic objectives will indeed be achieved within the duration of the propose two-year project:

The key goals are to:

- Improve the healthcare quality and safety for citizens by allowing them to access and manage their electronic health record from any place in the EU
- Contribute to standardisation and harmonisation of eHealth services in the EU by setting European agreements on diverse levels of interoperability
- Contribute to defragmentation of European services
- Facilitat interaction between patients and healthcare providers, to support prevention and citizen empowerment

X-eHealth specific objectives are:

1. To reach a common understanding in the EU on the efforts needed to adopt the commonly defined EEHRxF specifications at different levels and within their nationIEHR solutions
2. To define, specify and demonstrate the EEHRxF use cases laboratory results, medical imaging and reports, hospital discharge reports and patient summary for those suffering from rare disease and/or comorbidities.
3. To elaborate the roadmap for the above-mentioned use cases for future uptake on the eHDSI as well as for the additional usage within MS on national, regional or local level
4. To submit the outcomes and recommendations of X-eHealth regarding EEHRxF deployment to the relevant bodies on policy, strategic and operational level (e.g. eHealth Network, National Competence Centres for eHealth, eHDSI operators)

5. To propose a governance framework for the sustainable maintenance, evolution and distribution of standardisation and interoperability

1.2 Relation to the work programme

X-eHealth recognizes the importance of the future usage of Electronic Health Record exchange Format within the EU. The project is fully aligned with the Horizon 2020 Programme's Call theme of "Digital transformation in Health and Care" and addresses the topic "Support for European eHealth Interoperability roadmap for deployment" (SC1-HCC-07-2020).

It focuses on defining and agreeing on the exchange formats for the EEHRxF[8] use cases laboratory results, medical imaging and reports, hospital discharge reports and rare diseases as part of the patient summary. Health data acquired at the point of care will be recorded in a standard way, according to the agreed standards and formats. This allows for an easy and understandable exchange of information among healthcare systems in EU. X-eHealth will set the scene for the definition, deployment, maintenance and monitoring of interoperable eHealth services within the EU, which can be used both across and within national borders.

X-eHealth will build on past and current efforts and activities in cross-border eHealth, which have been very valuable contributions to standardisation and harmonisation on structured health information and on privacy and security. Crucial milestones towards eHealth interoperability in the EU have been reached by projects and initiatives such as: epSOS I and II, EXPAND, national CEF eHealth projects to connect to the eHDSI, VALUEeHEALTH, openMedicine and eSENS. The X-eHealth project will carry on these important efforts.

The X-eHealth roadmap will envisage steps to create an open and interoperable digital health ecosystem where health data and information flow securely between and across platforms from different vendors and across borders.

It's also important to refer that the Directive on open data and the re-use of public sector information, also known as the 'Open Data Directive' (Directive (EU) 2019/1024) replaces the Public Sector Information (PSI) Directive, also known as the 'PSI Directive' (Directive 2003/98/EC). All the work of X-eHealth project will follow these EU regulations to develop its work and ensure compliance to any kind of updates during the two-years of project.Directive 2003/98/EC). The Directive on open data and the re-use of public sector information, also known as the 'Open Data Directive' (Directive (EU) 2019/1024) replaces the Public Sector Information (PSI) Directive, also known as the 'PSI Directive' (Directive 2003/98/EC). All the work of X-eHealth project will follow these EU regulations to develop their work and ensure compliance to any kind of updates during the two-years of project.

The work proposed by X-eHealth will completely follow the scope of the H2020 topic: We are considering the Health Records at national context (WP 1 – T1.4), the empowerment of the European Citizens (WP 2 and WP 8), compliance with GDPR (WP 4 – T4.2 and T4.3), as well as the ethics and legal issues for all relevant data (WP 4 – T4.2, that will closely work with eHMSEG group). The X-eHealth goals will be pursued successfully and commonly by its consortium, its collaborative partners and its advisory board.

Call specific challenges/scope vs How they are addressed in WPs, tasks and outputs
The Call supports the deployment and monitoring of eHealth interoperability resulting in real life interoperable solutions for use by citizens, researchers, health services and the workforce across borders in the EU Digital Single Market
Tasks & Outputs
X-eHealth's WP1, T1.4, will analyse and map national challenges for EEHRxF adoption, by assessing the current state of the play. This knowledge will allow us to understand better the current digital platforms and solutions available for usage by citizens, researchers and health services and to develop a support methodology and monitoring of eHealth interoperability across borders of those solutions. The focus will be in 4 domains: laboratory results, medical imaging and reports, hospital discharge reports and explore rare diseases into the patient summary.

[8] Commission Recommendation on European Electronic Health Record exchange format. European Commission. 02.02.2019. https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format

The project will, especially through WP8, connect eHealth experts within and beyond of the x-eHealth project and will liaise with digital health stakeholders, including large scale programs to deliver and evaluate proof of concept applications of EEHRxF for selected use cases. The use cases will be dedicated to rare diseases, chronic diseases and related with the decision aids and citizen driven health-science (T8.1, T8.2 and T.8.3) and cover local, regional, national and cross-border interoperability aspects. **The work will contribute towards addressing local, national, cross-border/international interoperability challenges in a collaborating and multilingual manner, which also takes into account semantic and terminology issues.**

The deployment should build on the Commission Recommendation on the European EEHRxF format and be guided by strong and systemic contributions for better data and better computational approaches to advance disease prevention and personalised medicine.

Tasks & Outputs

The EC Recommendation of EEHRxF suggests a framework for cross-border exchange of electronic health records which lists principles for access to and cross-border exchange of electronic health records, namely that a) Member States should ensure that citizens are able to access and securely share their electronic health data across borders, b) Member States are encouraged to give citizens the ability to choose to whom they provide access to their electronic health data, and which health information details are shared, and c) Member States should ensure that these principles are observed when developing solutions enabling access to, and exchange of electronic health data in the Union.

The WP4 will be dedicat“d to "Generic Aspects of EEHRxF recommen”ation" and will be define, in more concrete terms, what are the practical implications of the aforementioned principles. This will be done by keeping in mind relevant ongoing eHealth initiatives, especially regarding 1) road mapping of eID usage in health, 2) analysing legal aspects and enablers needed for interoperability, and 3) identifying common cybersecurity efforts directly related to electronic health record exchange.

The outcomes of WP4 will be used by the WP5, WP6 and WP7 for the definition of functional and technical specifications and for the global architecture of the four concrete use cases: **laboratory results, medical imaging, hospital discharge letters and rare diseases into the patient summary service.**

The deployment should consider interoperability of electronic Health Records across national borders, the empowered European citizen, compliance with the General Data Protection Regulation, the Network and Information Systems Directive and the operation in a European digital single market.

Tasks & Outputs

The X-eHealth project and its outcomes **strives to** significantly **support the initiative of a Common European Health space,** that through interoperable and standardized platforms and solutions, which are compliant with the data protection, privacy and cybersecurity laws will foster cross-border exchange of patient data through future eHealth services such as but not limited to: **laboratory results, medical imaging, hospital discharge letters and rare diseases into the patient summary service**. Especially WP1 T1.3 “Roadmap of new domains and sustainability plan” will develop a sustainability model for the management, maintenance and further development of the eHealth DSI, in line with the EEHRxF Roadmap and other relevant ongoing and upcoming strategic activities.

1.3 Concept and methodology; quality of the measures

X-eHealth will support the vision of the European roadmap for building innovative communities of knowledge in digital health by promoting and demonstrating the joint work on the definition and practical usage of EEHRxF.

As a Coordination and Support Action X-eHealth will on one hand coordinate almost all Member States to work jointly on the definition and adoption of EEHRxF and on the other hand support the uptake of EEHRxF by 1) fostering decisions making on policy level about the implementation of EEHRxF and 2) initiate communities of practice for support to early implementers and users, and capacity building.

The main approach is a broad collaboration and networking mechanism with relevant EU projects, bodies and organisations to support the standardization and uptake of EEHRxF through open innovation strengthening European

participation. This joint work will be done in an innovative and incremental approach, keeping an open eye on new and approaching technologies without losing track off established technical standards. For instance, X-eHealth will take actions to facilitate the adoption of EEHRxF in the mobile health market by providing also appropriate technical specification using FHIR resources for EEHRxF use cases: laboratory results, medical imaging, hospital discharge letters and considering rare diseases into the patient summary service.

X-eHealth will develop and undertake in collaboration with large scale projects and initiatives Proof of Concept demonstrators on EEHRxF in rare diseases and one on EEHRxF in chronic diseases management and prevention. Additionally, an explanatory proof of concept study on EEHRxF to support decision aids and citizen driven health-science will be done as well as an exploitation of the possible the role of EEHRxF in other domains, broadly noted registries, etc. The evaluation of the proof of concepts and their demonstrators will be used to capture and share best practices and guidelines for EEHRxF implementation.

X-eHealth reveals a balanced scale between coordination and support activities. The consortium with partners across Europe collaborates in developing, reviewing and validating interoperability EEHRxF assets, receiving strategic advices from relevant experts and leaders from all MS and European level organisations and stakeholders.

In order to achieve its objectives, X-eHealth will rely on and make use of relevant network of European networks (e.g. eHN, eHMSEG and their working groups) and other projects and initiatives through bilateral cooperation, which brings added value to both sides. Furthermore, X-eHealth will remain open for other organizations, which may join forces non-funded as collaborative partners and advisory board members during the project lifetime. Already, collaborative partners, EHTEL, COCIR, and ECHAlliance, representing the industry and local ecosystems have expressed interest to act as multipliers of impact for EEHRxF activities in X-eHealth.

It is also important to mention that in order to ensure the success of the tasks, within the stipulated time, in addition to the Deliverables that will be submit to the EC (D), they will be also produced Internal Deliverables (ID)10nalysenalyze the current situation of each WP. In the same way, there will be Milestones (M) and Internal Milestones (IM).

2. Impact

2.1 Expected impacts

X-e'ealth's commitment is to add societal and scientific value by preparing, validating the EEHRxF for deployment. Aimed at expanding the already in place Patient Summary services to support rare disease patients as well as patients with comorbidities, this CSA intends to systematically harmonize the exchange of images, laboratory results and discharge letters so that local, regional, national and European health entities can effectively interoperate with each other, thus enhancing the positive impact of technology and in particular of digital transformation on society.

The opportunity that large amounts of health data exploration offer for public health management, empower health providers with the availability of real-time data to improve clinical decision making, whether for more reliable prevention, accuracy or even innovation in health and care. Nevertheless, as far as information exchange is concerned, interoperability standards are still poorly tailored to users' needs. With this in mind, Figure 1 outlines what has ultimately to be achieved by this CSA:

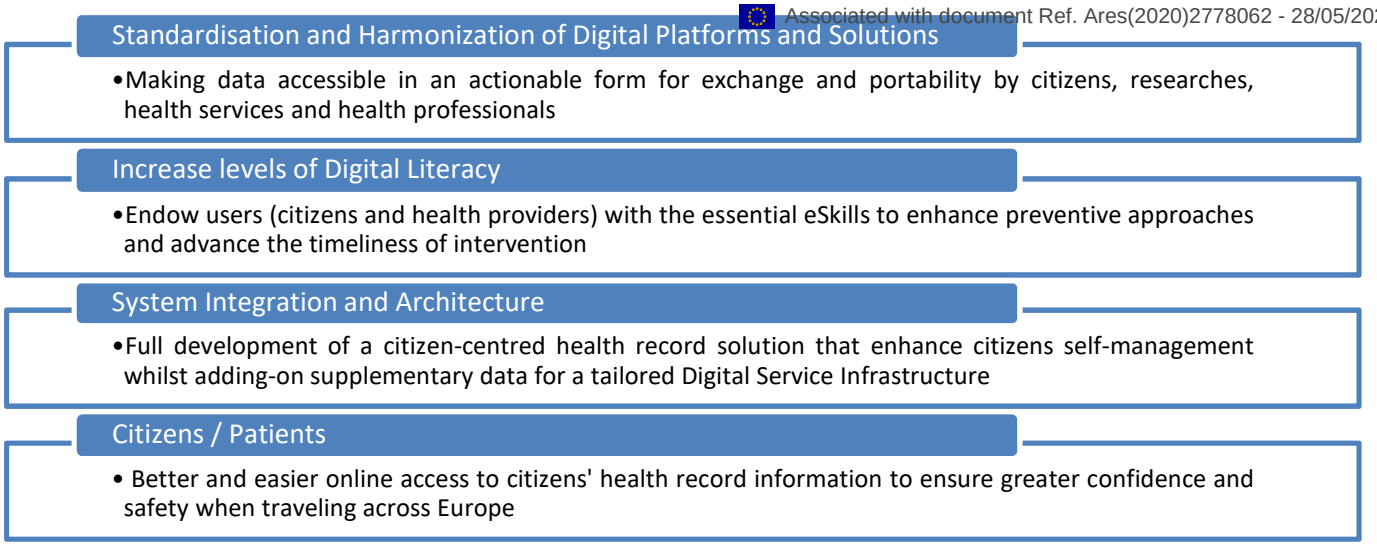

Figure 1 – X-Health targets for expected impact.

Working on the basis of a European-wide electronic health reId (EHR) exchange format supported by the Connecting European Facility, this Consortium, comprising 36 entities from 22 Member States/Countries, embraces this specific challenge with the aim of putting the C'mmission's EEHRxF Recommendation into action in the form of a flexible and sustainable solution, broad enough to address most barriers to cross-border interoperability.

By relying on the outcomes in open specifications and software delivered by previous projects (epSOS 1 and 2, EXPAND, eHDSI, VALUEeHEALTH and eSENS), X-eHealth expected impact builds upon this framework to ensure safer freedom of movement for EU citizens on the basis of an integrate and interoperable EU healthcare system, in which'citizens' health information flows alongside their care pathway with minimal loss of meaning (or no loss at all), thereby facilitating the provision of health care whenever needed.

For this purpose, the roadmap put forward by this project thrives on a meaning-oriented strategy that whilst aggregating health data records within a shared integrated system, strive for capitalizing the different strands of information sharing to ensure that it has the intended impact. From easier access and portability of EHRs for the citizen to more effective and personalized care for eHealth professionals, the X-eHealth roadmap envisions to advance thorough research by supporting a faster pace for innovation in the sector.

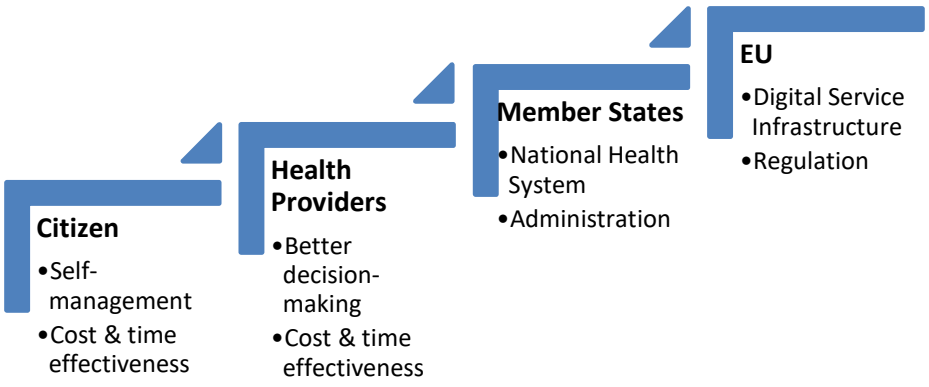

Figure 2 – Actors' roles for developing eHealth interoperability in EU.

Looking ahead to an interoperable eHealth Europe, these 22 Member States/Countries, acting on the basis of the recommended EEHRxF guidelines, supported by Standards Developing Organizations (HL7, IHE, NEN) commit themselves to further develop coordination mechanisms for assessing the long-term sustainability of the EEHRxF.

Through a joint cooperative approach, the impact that X-eHealth aspires to is: **to move forward into the Digital Single Market by ensuring that developed health services based on the EEHRxF specifically contribute to improving the health conditions of citizens and health providers, thereby improving the state of health in the EU as a consequence of alignment to the EEHRxF specifications.**

Two types of obstacles stand to obstruct achieving in full the expected impacts of X-eHealth. These are obstacles that might prevent or constrain the development of cross-border care services and can be procedural and / or structural.

While procedural obstacles may result from meaningful differences at the time of developing functional and technical specifications for the interoperability of eHealth services, structural obstacles emphasize underlying issues between national legislations, therefore making the advancement of cross-border e-care services inconsistent, competitive and overlapping

In order to jointly overcome the above obstacles, the methodology proposed by this consortium as well as the established problem-solving mechanism will cooperate to get over this induced lack of interoperability by bridging Memb'r States' legal diversity towards the common purpose of a better and healthier tomorrow.

2.2 Measures to maximise impact

a) Dissemination and exploitation of results

To maximise project impact, a special focus is given to the development of X-eHealth's Plan for Communication, Dissemination and Engagement (see also WP2 DoW). On the basis of effective application of measures tailored to stakeholder conditions, this Plan purpose is to ensure the intended information reaches out and touches the target audience – citizens, academia, business, health professionals, health providers and decision-makers – to the maximum extent possible, for cross-border health care services awareness-raising. Towards this end, this plan objective is to inform target stakeholders with X-eHealth's results in order to engage them in the process of its development and improvement whilst fostering wider dissemination.

Besides releasing project results, the dissemination strategy aims at bringing together the European eHealth actors to share information on best practices and interoperability assets to serve the needs of the community. Likewise, X-eHealth is citizen-centred, thus meant to raise people's consciousness of their own rights and benefits concerning the eHealth domain, particularly at cross-border healthcare level.

The first steps taken toward establishing a plan for the dissemination and exploitation of the project results were identifying the target audience, the most suitable approaches and measures to maximise its reach.

The identified target audience comprises the following stakeholder groups:

- Citizens;
- Health Professionals and healthcare providers;
- Industries, researchers and developers;
- Member States and National Health Authorities.

The approaches and measures pointed out to reach the target audience are:

- create X-eHealth official – identity - logotype;
- create X-eHealth Website, Facebook and Twitter;
- provide timely information keeping stakeholders up to date;
- customize the approach for each stakeholder group to ensure greater receptiveness;
- promote interactive initiatives to attract and engage stakeholders;
- boost stakeholder's engagement and keep them interested.

All the project's actions and results will be given large and appropriate visibility to have an impact on the public in general. Before proceeding with the communication approach, the model illustrated in Figure 3 shows what is aimed to accomplish, as outlined below:

- **Attention or A-wareness:** attract the attention of the stakeholders and keep raising awareness through the partners' websites updates/briefings/notes of events. Awareness does not come from website updates though, it must come from the public outreach, via potential multipliers.
- **Interest:** raise user's interest by focusing on and demonstrating advantages and benefits of using EEHRxF nationally and across-borders; raise stakeholders' interest on the H2020 programme, in order to become engaged on the EU health policies and programmes.
- **Desire:** convince stakeholders that using EEHRxF best practices will enhance a Common Europe culture and increase EU competitiveness.
- Action: lead stakeholders towards taking action by promoting joint events and activities.

Figure 3 - AIDA methodology

We propose to add an additional point to this methodology:

- **S**ustain: the interest of people on the project must be sustained, so they boost the use of EEHRxF and contribute to the growth of Europe health ecosystem. Sustainability and scalability are key aspects that must be kept in mind from the beginning onward as a fundamental pillar of all work.

Reaching the audiences will be achieved by a set of tools among which we have identified the following essentials:

⇒ e-publications that have the power to rapidly disseminate on the web while keeping the essence of solid publications;
⇒ posters, roll-ups and physical display materials to be placed in as many relevant events connected to public health as possible;
⇒ videos with a viral edge that allow the image of an evolved health system, ✓ presentation in wide international public events and initiatives.
⇒ and most importantly, shareable content that can be created from scratch or curated from other sources and published on official channels of the awareness-raising campaign, such as the applicants' websites and the applicants' Twitter and LinkedIn accounts.

The targeted dissemination strategy of X-eHealth aims to share the early results of the project among the eHealth stakeholders and bring together the eHealth community in Europe sharing information on best practices of interoperability. The plan for dissemination and exploitation of project results will be driven by Work Package 2 from the beginning of the project to promote X-eHealth among the community. In the Communication activities section further information will be given on the specific dissemination channels to be used and actions to be implemented before, during and after the project.

The dissemination activities of X-eHealth will be multiplied by the contribution of collaborative partners and through the community of practice (WP8), which will serve both in developing the European culture of interoperability but also in building capacity among developers and implementers.

b) Communication activities

Communication plays a crucial role both internal and externally. Thus, to maximise the project impact among its stakeholders, different dissemination channels, content types and actions will be managed in order to achieve this goal.

The selected dissemination channels will be used accordingly:

- X-eHealth Website (to be launched and updated as often as needed);
- X-eHealth social networks (to be launched and updated as often as needed);
- news agencies and media outlets (to reach a wider audience whenever applicable);
- mailing list (to share any kind of information internally or externally).

The following content will be produced and provided in accordance:

- news articles (reporting project activities on time);
- social media posts (including infographics and videos);
- periodic newsletters (to be set as monthly or quarterly);
- press releases and papers (to reach a wider audience whenever applicable);
- X-eHealth booklets and flyers (online and print versions);
- project video (for online and event dissemination);
- customised –aterial - pens and notebooks with X-eHealth logo (events).

The following initiatives will be promoted face to face and/or online:

- Consortium meetings;
- X-eHealth Work Packages' Workshops;
- X-eHealth Innovation Days, in partnership with HL7 (other entities to be confirmed):
    - 1st X-eHealth Innovation Day - at the end of the 1st year,
    - 2nd X-eHealth Innovation Day - at the end of the 2nd year;
- X-eHealth interoperability award 2022;
- Portugal eHealth Summit 2020;
- Other conferences or events to be confirmed.

In this context, the overall dissemination objectives are: raise a–areness - ensuring the key initiatives are spread and understood among stakeholders, through tailored methods and channels to increase awareness and eventual feedback; sustain stakeholders' engagement; influence decision makers concerning person-centred integrated care and digital innovations and ensure sustainability of the effective and structured vision after the end of project.

3. Implementation

3.1 Work plan – Work packages and deliverables

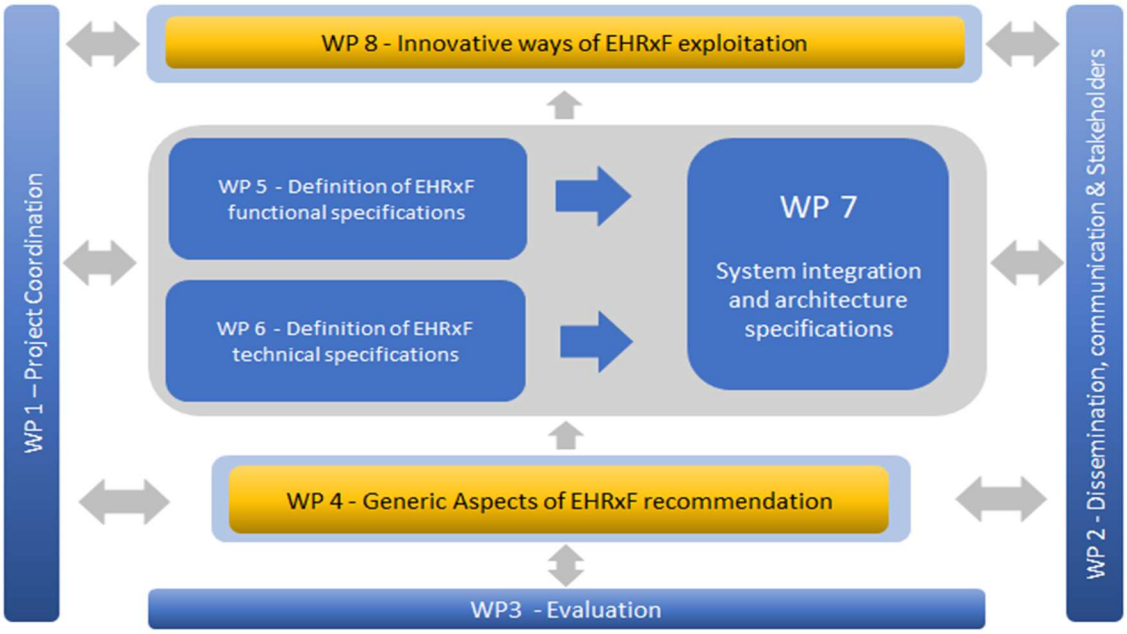

Figure 4 – X-eHealth's Work Packages relationship

Work Package / Task	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
WP1 Project coordination																								
1.1 Project management, quality control and risk management																								
1.2 Project administrative and financial management																								
1.3 Roadmap of new domains and sustainability plan																								D1.3 D1.4
1.4 Mapping national challenges for EHRxF adoption				ID1.5.1								ID1.5.2												D1.5
1.5 Ethics Requirements			D1.6																					
WP2 Dissemination, Communication & Stakeholders																								
2.1 Communication, Dissemination and engagement plan			D2.1 D2.2 D2.3			D2.4						D2.5												D2.6
2.2 Health professional and citizens education																								
2.3 MS and stakeholder involvement																		D2.6						
2.4 Industries, researchers and developers' liaison																								
2.5 Hospital digital network																								
WP3 Evaluation																								
3.1 Establish evaluation strategy				D3.1																				
3.2 Evaluation of results for the new services																								D3.2
WP4 Generic Aspects of EHRxF recommendation																								
4.1 Electronic Identification implementation					D4.1.1													D4.1.2						
4.2 Legal aspects & enablers								D4.2.1					D4.2.2											
4.3 Cybersecurity					D4.3.1			ID4.3.1										ID4.3.2						D4.3.2 ID4.3.3
WP5 Definition of EHRxF functional specifications																								
5.1 X-eHealth use cases driven methodology			ID5.1																					D5.1
5.2 EHRxF and its relationship with clinical guidelines			ID5.2																					D5.2
5.3 Laboratory Results guideline and functional specifications					ID5.3																			D5.3
5.4 Medical Imaging and Reports guideline and functional specs					ID5.4																			D5.4
5.5 Hospital Discharge Reports guideline and functional specs					ID5.5																			D5.5
5.6 Refine PS guideline and functional specifications to account for rare diseases					ID5.6																			D5.6
5.7 Final conclusion and recommendations																								D5.7
WP6 Definition of EHRxF implementable specifications																								
6.1 Definition of technical specification for the Laboratory Domain												ID6.1												
6.2 Definition of technical specification for the Medical Imaging Domain												ID6.2.1			ID6.2.2									
6.3 Definition for the technical specifications Hospital Discharge Reports															ID6.3									
6.4 Refinement of Patient Summary (PS) technical specifications for supporting rare diseases												ID6.4												
6.5 Publication and maintenance of the services specifications and testing tools															ID6.5.1	ID6.5.2								D6.1 D6.2
6.6 Publication and maintenance of the X-eHealth Implementation Guide																								D6.3
WP7 Architecture integration and System specifications																								
7.1 Global architecture for EHRxF Domains use												ID7.1				D7.1								
7.2 Testing strategies																						D7.2		
7.3 Needs for upgrade of CEF eHDSI core and generic services																								D7.3
7.4 Guidance for the new EHRxF domains																				ID7.2				D7.4
WP8 EHRxF Communities of Practice: from Proof of Concept to large scale adoption and Infrastructure for Innovation																								
8.1 Proof of concept: EHRxF in rare diseases																			D8.2					
8.2 Proof of concept: EHRxF in chronic diseases management and prevention																				D8.3				
8.3 Exploratory Proof of concept study: from EHRxF to decision aids and citizen driven health-science																					D8.4			
8.4 EHRxF community of practice: building capacity and scaling up						D8.1																		
8.5 Exploitation: EHRxF as infrastructure for innovation																							D8.5	
8.6 Evaluation of EHRxF proof of concept demonstrators																						D8.6		

Figure 5 – Gantt Chart

3.2 Management structure and procedures

Organized into two segments, this section outlines the project organizational structure and describes the frames procedural practices with a special focus on their roles and accountabilities.

By acknowledging the managerial complexity of this large-scale project, X-eHealth consortium partners firmly believe that the best way to operationalize the exchange of electronic health records within a common framework is best accomplished by Project Management Pro'essional's best practice approach (PMP) developed by the internationally distinguished Project Management Institute (PMI).

Aiming at jointly working for the effective deployment of the objectives, the agreed management methodology is specifically designed for projects in controlled environments and is commonly used by X-eHealth consortium partners as a managerial tool in their activities for such kind of projects.

Modelled on the flexible concept of preventive maintenance, the chosen arrangement is designed to promptly adjust to change and unexpected events so that the project may keep on delivering the right results on time and within budget, towards causing the desired impact.

Making the best of existing opportunities while mitigating the threats arising throughout the project, this organizational structure is conceived to strengthen risk management, to enhance operational quality and efficiency, and to meet regulatory requirements.

Furthermore, to assure the smooth and effective development of X-eHealth purposes, we outline herein the behavioural principles that will conduct these consortium cooperation procedures for the next two years:

Figure 6 displays X-eHealth's governance structure, which consists of the following bodies, functions and roles:

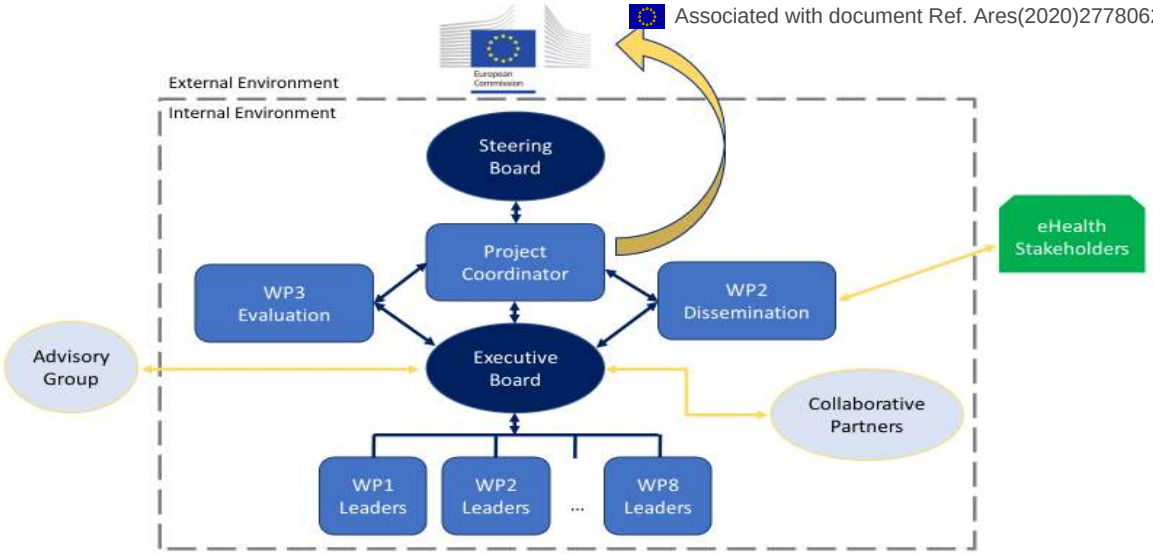

Figure 6 – X-eHealth's governance structure

1. Steering Board (SB)

Designed to be the highest decision-making body in the project, the Steering Board assembles all X-eHealth consortium partners to jointly leading the project on the strategic level.

Its responsibilities range from decision-making to monitoring as all issues with possible significant effects on the project have to be decided within this body. These include financial/administrative decisions such as amendments to the Grant Agreement, project procedural rules, resources reallocation and deliberating recommendations.

The SB shall assemble at least once every three months to present the progress of the project to its associates and to disseminate outcomes. In-person meeting shall occur twice a year. Extraordinary meetings are to be arranged if circumstances demand so. Herein, voting rights are exclusively held by consortium partners (one per partner). The PC shall chair these body meetings.

Concerning decision-making procedures, a consensus is the preferred practice, however, the Steering Board decides by a two-thirds majority when the quorum is reached (half of the partners with voting rights are present).

2. Project Coordinator (PC)

The PC takes on the responsibility of organizing, controlling and coordinating the entire project. The project coordinator shall guarantee by appropriate management tools that the project develops smoothly and effective communication is ensured between bodies, partners and associates.

To optimize its coordination responsibilities, the PC role (feature by WP1) shall be aligned with the WPs for dissemination and evaluation, WP2 and WP3 respectively. The PC chairs and shall act as a link between the Steering and the Executive Boards assemblies. PC team shall carry out all the project administrative issues, from legal to financial and from technical to organizational.

WP1 is responsible for monitoring project activities (including risk and quality management) while maintaining an up-to-date view of progress, serving at the same time as the official interface between the consortium and the EC.

3. Executive Board (EB)

The Executive Board is responsible for aligning, coordinating and monitoring the course of the project across all WPs. These liabilities shall factor to address the PC with recommendations for its overall coordination and are to be reported to the SB semi-annually.

Although the SB stands as the highest decision-making in X-eHealth, it is the EB's competence to undertake executive decision that does not require the SC approval. Executive decisions that go beyond its competence shall be prepared by this body and proposed as recommendations for deliberation in the SB.

The EB is chaired by the PC and comprises the representatives of each WP: Leaders, Co-Leaders and Task Leaders. (The risk and quality managers are herein represented by WP1 Leaders). The EB shall assemble via monthly telephone conferences and might have face to face meetings each half a year.

The EB decides by a simple majority, still, a consensus is the preferred practice. Each WP and Task Leader holds one vote only, despite of leading more than one WP or Task within the project.

The quorum is reached if half of the partners with voting rights are present.

4. Advisory Group (AG)

Designed as an external body with counselling functions, the Advisory Group for digital health innovation and practice was instituted to assist the EB with the technical-scientific expertise in the following domains: interoperability assets, use cases, and future pilots.

Jointly composed of senior experts and representatives of international organizations, this body gathers a set of high-level strategic advisors eager in the abovementioned domains with a special focus on the EEHRxF component. Their role in X-eHealth is to contribute with high-quality advice to the project strategic direction, to provide operational guidance and to assess programme effectiveness when the group needs.

The AB shall meet twice a year by using remote communication means. The AG does not have voting rights neither budget allocation. However, travel costs to attend X-eHealth conferences may be provided by the project funds.

More names will be added to the Advisory Group, for now are mention:

Daniel Karlsson, ♂, MSc, PhD. Daniel has a master of computer science and received PhD in medical informatics in 2001 from Linköping University. He has worked as a research assistant and later a senior lecturer at Linköping University and as a health terminologist at Östergötland County Council. Daniel has been active in national and international standardisation, e.g. as a secretary of CEN/TC 251 terminology and knowledge representation working group, chair of the corresponding Swedish working group, a member of the NPU Terminology steering committee, and in several advisory roles in SNOMED International. Daniel has participated in European research projects from GALEN-IN-USE in the 1990ies to ASSESS CT in 2015-16, and is the Swedish representative of the eHealth Network subgroup on semantics. He is currently employed at the Swedish National Board of Health and Welfare.

Jeremy Thorp, ♂, was Business Architecture Director in the Health and Social Care Information Centre. Previously, he was the Director for the NHS Information Reporting Services (NIRS) Programme, run jointly by NHS Connecting for Health and the NHS Information Centre. Prior, Jeremy Thorp was Director of Business Requirements in NHS Connecting for Health with responsibility for the Business Architecture of the National Programme for IT in England, liaising closely with the Department of Health on policy and strategy issues. Jeremy Thorp worked at national, regional and local levels in the NHS: nationally in the Department of Health Information Policy Unit and in the NHS Information Authority, regionally in the South and West, and locally in the Bristol area.

Larry Garber, ♂, is the Medical Director of Informatics at Reliant Medical Group, in USA. a 525-provider multispecialty group practice. He is a board-certified Clinical Informaticist and has had decades of experience and success in Medical Informatics. He is Chair of the Massachusetts eHealth Collaborative's Executive Committee, a member of the Massachusetts State Health Information Technology Council, and has been a member of ONC Policy Committee's Interoperability Workgroup, Jason Task Force, Privacy & Security Tiger Team, and Interoperability Experience Task Force.

Jaime Ferguson, ♂, is a Fellow at the Institute for Health Policy and Vice President of Health Information Technology Strategy and Policy for Kaiser Permanente, responsible for health IT informatics standards, health IT policies and priorities, as well as government relations and industry relations for IT. Prior to these assignments Jamie was Executive Director of Information Management at Kaiser Permanente. He is also active in national and international organizations for health IT and informatics. Before joining Kaiser Permanente Jamie worked as a research investigator in the Department of Molecular Biophysics and Biochemistry at Yale University School of Medicine, specializing in renal and hepatic protein structures and pathways. He also was employed as an economist in the Federal Reserve System and at Bank of America, and as an independent consultant.

Kai Rannenberg, ♂, is a Full Professor, Department Director at Goethe University Frankfurt. He has been at Goethe University since 2002, before which he was with the System Security Group at Microsoft Research Cambridge, focussing on "Personal Security Devices and Privacy Technologies ", such as within the CamWebSIM project. For six years from 1993, Kai worked at Freiburg University and coordinated the interdisciplinary "Kolleg Security in Communication Technology," sponsored by the Gottlieb Daimler and Karl Benz Foundation, that worked on multilateral security, especially protection for users and subscribers. Since 1991, Kai has been active in the international (ISO/IEC) standardization of IT Security and Criteria (JTC 1/SC 27/WG 3 "Security Evaluation Criteria"). Since 2007, he has served as Convenor of the SC 27 Working Group 5 on "Identity management and privacy technologies" after having led the SC 27 Study Periods on Privacy and Identity Management.

Liora Alschuler, ♀, is a developer of XML-based standards for the exchange of electronic healthcare information, and a consultant in their application to providers and system vendors. In 1997, she led the project that produced the design of the first XML-based exchange specification for healthcare—the Health Level Seven (HL7) Clinical Document Architecture (CDA). As CEO the Lantana Consulting Group, Liora oversees the company's implementation of standards-based solutions for the nation's largest healthcare providers and public health agencies. She provides leadership on projects with clients such as the Centers for Medicare & Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), the American Society of Clinical Oncology (ASCO), and commercial clients, including Vanderbilt University Medical Center, Dartmouth Hitchcock Medical Center, McKesson, and GE. Liora is an active volunteer promoting healthcare interoperability. She co-founded and served on the executive committee for the Healthcare Information and Management Systems Society (HIMSS) Health Story Project, which develops and promotes the adoption of information technology standards. Liora served on the HL7 International Board of Directors 2005-2008, and as co-chair of the HL7 Structured Documents Work Group. She is a frequent guest speaker at industry events.

5. Collaborative Partners (CPs)

CPs bring together a set of international organizations with the interest and expertise to be a significant asset for X-eHealth areas of focus.

On the table below it is the list of the collaborative partners, al'hough it's important to mention that new names will be add to this list.

Table 3.2: Collaborative partners

Entity	Name	Contact
MedTech Europe	Michael Stubin	m.strubin@medtecheurope.org
COCIR	Nicole Denjoy	denjoy@cocir.org
EFMI	Lacramoira Stoicu-Tivadar	Lacramoira.stoicu-tivadar@aut.upt.ro
EHTEL	Marc Lange	Marc.lange@ehtel.eu
ECHAlliance	Brian O'Connor	brian@echaliance.com

Established as an external resource aimed at supporting the project development, engaged collaborative partners are free to integrate the WPs of their area of interest. Still, the EB shall encourage CPs involvement to match the project needs. MedTech Europe, EHTEL, COCIR, EFMI, and ECHALLIANCE have already agreed to participate as collaborative members.

CPs shall be part of EB meetings whenever X-eHealth consortium considers their expertise needed and appropriated. CPs do not hold voting rights neither budget allocation. Still, travel costs to attend X-eHealth F2F meetings may be granted if consortium partners deem it appropriate.

6. Quality Management (QM)

Since knowledge generated by the project arises from the elaboration of deliverables, X-eHealth could not but have a fraction focuses exclusively on the Quality Assurance of Deliverables.

The Quality Manager is liable to ensure that the process of deliverables production follows a structural approach, to meet the required standards in order to be considered final and therefore, delivered thoroughly to the European Commission (see figure 7).

The Quality Manager shall be nominated by the PC. The QM stands as an integral part of WP1.

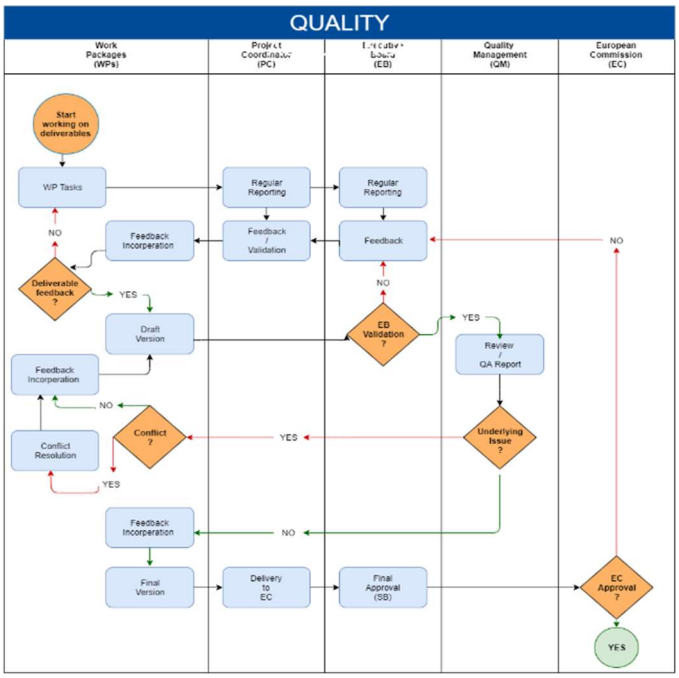

Figure 7 – Quality Management Process

7. Risk Management (RM)

RM is accountable for the process of Risk Assessment and its management of all the risks which may arise throughout the project lifetime. Divided into three stages, the RM shall systematically: (1) identify and assess potential risks, while in parallel, (2) plan and perform mitigation measures and (3) control outcomes and track the project's response and progress.

To perform these tasks, a risk manager shall be nominated by the PC and is an integral part of WP1.

8. Work Package Leaders (WPL)

By acknowledging the operational challenge of some of WPs, this consortium agreed that the number of managerial agents should be enlarged in the working packages where technical-scientific tasks require greater coordination and engagement.

This way, each WP is jointly represented by a designated Leader and Co-Leader, and depending on the degree of specificity of each WP's content, Task Leaders are designated to reinforce the same WP managerial features.

This Leaders shall be co-responsible for leading their designated WP and its respective Tasks, according to the objectives put forward in that same WP description of work.

These three agents shall coordinate, monitor and assess the progress of the working group in close cooperation, supporting each other, making decisions and being able to substitute each other, if needed, in meetings and communication activities.

9. Innovation Management (IM)

With the view of setting up X-eHealth in pursuit of Digital Health Innovation Practices, this consortium recognised the need to establish an IM fraction.

Aimed at capitalizing the innovative potential that are to arise from the multiple tasks, this fraction brings together the collaborative partners and the working group Leaders for innovative ways for EEHRxF exploitation (WP8). These responsibilities shall be herein aligned to enhance the deployment of EEHRxF.

To perform this task, the IM is responsible for nominating a spokesperson who shall factor as a direct link to effective communication between IM insights and the overall governance of X-eHealth.

The operationalization of this responsibility should be done through teleconferences on a regular basis. IM ideas shall be presented in the form of recommendations to the PC and the EB.

The IM is overseen and shall report to the SB.

10. Conflict Resolution

In order to strengthen ’-eHealth's internal management, this consortium presents herein the conflict resolution process to be used in case of disagreement on the conduct and purpose of the project activities.

In accordance with figure 8, the process of conflict settlement shall first be addressed, informally, by the WP Leaders at issue. If the issue persists, the EB shall be formally informed to settle the conflict. At the last resort, the SB shall assemble to take the final decision.

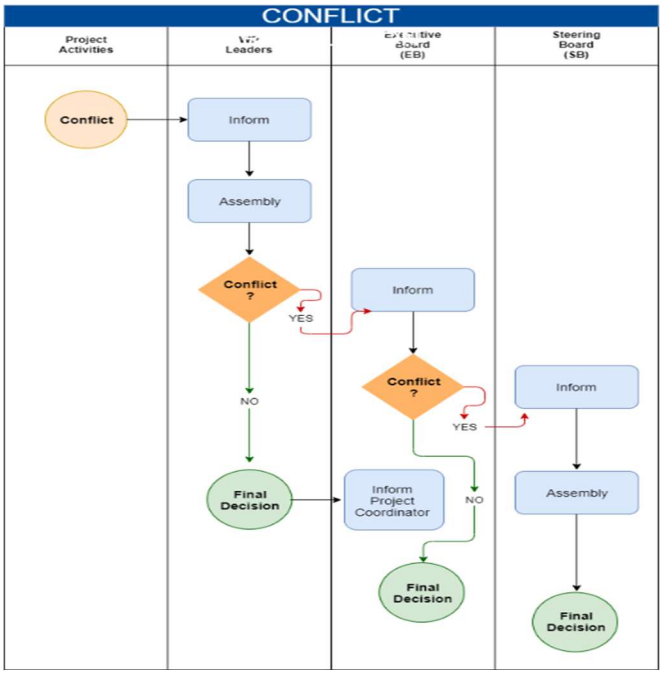

Figure 8 – Conflict resolution process

11. Risk Mangement

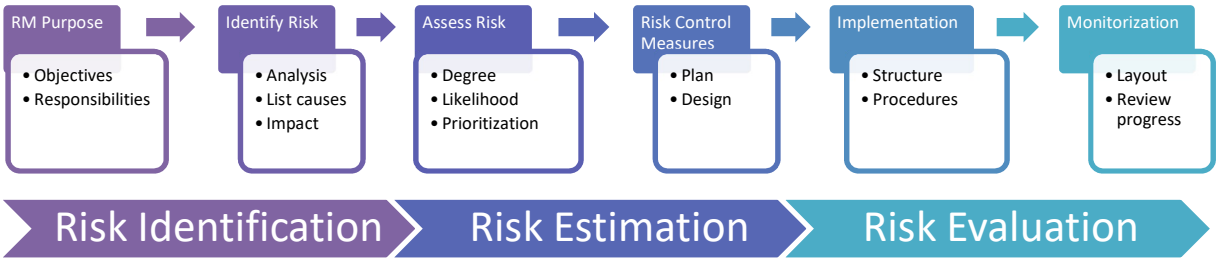

Figure 9 – Risk assessment framework

Conceived as an integral element ’f the PC's body therewith its own designated manager and responsibilities, the risk assessment procedure established by X-eHealth is divided into three main stages consisting of six steps. This procedure’s underlying idea is to identify and overcome internal and external issues that might jeopardise the purpose of X-eHealth workflows.

As displayed in figure 9, the risk assessment framework sets a stepwise and consecutive approach to ultimately transform arising risks into opportunities through continuous processes of risk identification, risk estimation and risk evaluation.

To ensure X-eHealth delivers the proposed outcomes, it is the responsibility of the RM, headed by its representative, to identify risks, categorize them, design appropriate safety measures, implement control actions and monitor the project reaction to them, as illustrated above.

The risk manager shall maintain regular contact with WP Leaders and, as the need arises, single X-eHealth associates to better perceive the project milieu, thus optimizing RM issue awareness and effectiveness. Potential risks shall be communicated to the PC and EB and reported to the SB.

The main risks identified at this stage as well as their respective risk-mitigation measures are listed hereinbelow.

3.3 Consortium as a whole

X-eHealth's project stands herein for a project of strategic relevance for tomorrow's European eHealth Union. Assembling at the time of this proposal submission a shared commitment of 47 health actors, the underlying idea of this project is to **develop the basis for a workable, interoperable, secure and cross border Electronic Health Record exchange Format** in order to lay the foundation for the advance of eHealth sector while using the 3 pillars put forward by the EC as reference.

Aimed at promoting a faster and sustainable EU digital transformation, this Cooperative and Support Action is made up of 8 Work Package in which 4 exclusively focus on technical-functional activities (WP4 to WP7). **From Generic Aspects to System Architecture and Integration passing by Functional and Technical Specifications towards a uniform interoperable data-sharing format framework**. In addition, to enhance EU's public health state of play, WP1 and WP8 are responsible for implementation studies, practicality and continuity of eHealth interoperability development.

On this basis and building upon the already in place Patient Summary**, X-eHealth purpose is to develop the foundations for a common framework for medical imaging, discharge letters, laboratory results and rare diseases** to flow both alongside citizens care pathway and across health entities between EU Member States and Neighbour Countries.

Aimed at promoting the flourish of health care cross border services at the European level, X-eHealth gives a special focus to the legal and security issues arising from national legislations diversity. By acknowledging this context, WP4 for Generic Aspects of EEHRxF was conceived to address most of these issues and reckons on the established methodology which combines strong theoretical foundations with practical and political considerations.

Hence, this consortium makes efficient use of project resources through eliminating overlap, the smart selection and prioritisation of the sector and the regions covered at this stage and the maximisation of synergies among all partners. As such this consortium ensures:

- WPs are correctly aligned and effectively communicate occurs regularly for keeping on delivering what has been agreed upon the list of Deliverables and Milestones and displayed in the Gantt Chart
- Detailed risk management plan identifying potential project risks along with appropriate risk management/mitigation actions
- Cybersecurity and legal issues are not a hindrance to the X-eHealth purposes
- Functional and technical specifications are developed in tune to build up the basis for a common framework for the proposed domains
- Emerging knowledge of Deliverables is made public and dissemination events and activities are strategically arranged for raising community awareness.

This consortium represents a smart combination of best-in-class expertise across the health sector. From Public to Private and from Non-for-profit to Standards to Profile Developing Organisations and Academia research, X-eHealth covers the value chain through a combination of 36 entities:

- 11 Government and Public Administration Organizations
- 18 Public Health Entities
- 4 Solutions Providers / Universities
- 3 Standards and Profile Developing Organisations on European level

In total, X-eHealth gathers 36 consortium partners plus 5 collaborative partners and 6 eHealth skilled experts. A total number of 47 health actors are involved in the project. 22 Member States / Countries are constituent parts of X-eHealth consortium. The consortium also very well represents policy and political actors mixed with national competent authorities to indeed concretely plan, implement and maintain national eHealth infrastructures.

Additionally, consortium members will make use of their wide variety of contacts and formal and informal exchanges with actors in their own country or beyond, e.g. other member states, which are not a beneficiary of this consortium. Together with the project-specific dissemination activities of WP2 each member of the X-eHealth consortium plays their facilitating role in sharing experience and the transfer lessons learned of the X-eHealth project to other Union member states and regions and foster the project's impact to the broadest extend possible.

3.4 Resources to be committed

Table 3.4 b 'Other direct cost' items (travel, equipment, infrastructure, goods and services, large research infrastructure)

1/SPMS	Cost (€)	Justification
Travel	56 200	It is planned 3 types of events (Steering Board – 2/year, Executive Board – 2/year and Workshops – 5/year). SPMS, as Coordinator should be present in all meetings (18 in total). 2 people will be attending each event. This value includes also the cost with the external experts' travels. It was considered an average price per trip of 700€. For the external experts' travels it was considered an overall value of 31 000€
Other goods and services	52 199	In total it's planned 18 events, this value should cover expenses with catering, room rental, etc.
Total	108 399	

2/ATNA	Cost (€)	Justification
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

3/GOeG	Cost (€)	Justification
Travel	18 200	The partners WP leader/co-leader will be present in 4 Steering Board, 4 Executive Board and 5 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	18 200	

4/FPS	Cost (€)	Justification
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

5/IHE	Cost (€)	Justification
Travel	18 200	The partners WP leader/co-leader will be present in 4 Steering Board, 4 Executive Board and 5 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	18 200	

6/HL7	Cost (€)	Justification

Travel	18 200	The partners WP leader/co-leader will be present in 4 Steering Board, 4 Executive Board and 5 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	18 200	

7/NEN	**Cost (€)**	**Justification**
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

8/HZZO	**Cost (€)**	**Justification**
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

9/UCY	**Cost (€)**	**Justification**
Travel	18 200	The partners WP leader/co-leader will be present in 4 Steering Board, 4 Executive Board and 5 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	18 200	

10/MZCR	**Cost (€)**	**Justification**
Travel	18 200	The partners WP leader/co-leader will be present in 4 Steering Board, 4 Executive Board and 5 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	18 200	

11/Vysocina	**Cost (€)**	**Justification**
Travel	27 300	The partners WP leader/co-leader will be present in 4 Steering Board, 4 Executive Board and 5 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	27 300	

12/ MSAE	**Cost (€)**	**Justification**
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

13/ANS	**Cost (€)**	**Justification**
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

14/MoH-FR	Cost (€)	Justification
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

15/DIMDI	Cost (€)	Justification
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

16/GEMATIK	Cost (€)	Justification
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

17/TMF	Cost (€)	Justification
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

18/MoH-GR	Cost (€)	Justification
Travel	18 200	The partners WP leader/co-leader will be present in 4 Steering Board, 4 Executive Board and 5 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	18 200	

19/AEEK	Cost (€)	Justification
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

20/SU	Cost (€)	Justification
Travel	18 200	The partners WP leader/co-leader will be present in 4 Steering Board, 4 Executive Board and 5 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	18 200	

21/DoH-IR	Cost (€)	Justification
Travel	9 100	The partners (that aren't WP leadea/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

22/AgiD	Cost (€)	Justification
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

23/ARIA	Cost (€)	Justification
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

24/MIN SAL	Cost (€)	Justification
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

25/Reg. Lomb.	Cost (€)	Justification
Travel	13 100	The partners WP leader/co-leader will be present in 4 Steering Board, 4 Executive Board and 5 Workshops. 2 people will be attending each event (partner chose to lower travel costs). It was considered an average price per trip of 700€. This value includes the cost with the travels of link 3ª parties.
Total	13 100	

26/ NVD	Cost (€)	Justification
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

27/SAM	Cost (€)	Justification
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 675€.
Total	9 100	

28/NICTIZ	Cost (€)	Justification
Travel	18 200	The partners WP leader/co-leader will be present in 4 Steering Board, 4 Executive Board and 5 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	18 200	

29/NCZI	Cost (€)	Justification
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.

Total	9 100

30/NIJZ	**Cost (€)**	**Justification**
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

31/TIC Salut	**Cost (€)**	**Justification**
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

32/equalis	**Cost (€)**	**Justification**
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

33/SEHA	**Cost (€)**	**Justification**
Travel	18 200	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 5 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	18 200	

34/INSERM	**Cost (€)**	**Justification**
Travel	9 100	The partners (that aren't WP leader/co-leader) will be present in 4 Steering Board and 3 Workshops. 2 people will be attending each event. It was considered an average price per trip of 700€.
Total	9 100	

4. Members of the consortium

4.1. Participants (applicants)

Partner Full N–me	SPMS - Serviços Partilhados do Ministério do Saúde, E.P.E		
Short Name	**SPMS**	**Partner No.**	1
Country	Portugal	**Website**	www.spms.pt
Type of organisation	Public organisation/ eHealth Agency	**Logo**	

Brief Partner Profile

SPMS stands for Shared Services of the Ministry of Health and is the Health Ministry Central Purchasing and the national IT authority.

Conceived in 2010 as a State-Owned Enterprise (SOE) by the Ministries of Health and Finance, SPMS purpose is to provide shared services – in the areas of purchasing and logistics, financial services, human resources and ICT – to entities who operate specifically in the area of health and health care, in order to "centralise, optimise and rationalise" the procurement of goods and services within the Portuguese National Health System (NHS).

Focus on the development of shared services for information systems and technologies, SPMS, SOE objective is to cooperate on the basis of knowledge and information sharing while developing projects and activities for the advance health care services in the areas of health information and communications systems and technologies. Aimed at ensuring that all information is available in the best way for all citizens, SPMS plays a central role in disseminating health services state of play, thus promoting digital literacy for better prevention and selfcare in Portugal and European Union. In addiction, SPMS also promotes the definition and use of standards, methodologies and requirements that guarantee interoperability and interconnection of health information systems with each other and with cross-sectional information systems of the Public Administration.

Main tasks in Project

SPMS main tasks in X-eHealth are the following:

WP1 – Project Coordinator (Leader)

- T1.1: Project management, quality control and risk management (Leader)
- T1.2: Project administrative and financial management (Leader)
- T1.3: Roadmap of new domains and sustainability plan
- T1.4: Mapping national challenges for EHRxF adoption

WP2 – Dissemination, Communication & Stakeholders (Leader)

- T2.1: Communication, Dissemination and Engagement Plan (Leader)
- T2.2: Healthcare providers, Health professionals and Citizens motivation (Leader)
- T2.3: MS and National Authorities involvement (Leader)
- T2.4 Industries, researchers and developers' liaison (Leader)
- T2.5 Hospital Digital Network (Leader)

WP4 – Generic aspects of EHRxF recommendation

- T4.1: Electronic Identification implementation
- T4.2: Legal aspects & enablers
- T4.3: Cybersecurity

WP5 – Definition of EHRxF functional specification

- T5.1: X-eHealth use cases driven methodology
- T5.5: Hospital Discharge Reports guideline and functional specifications
- T5.6: Refine PS functional specifications to account for eHN Guidelines and rare diseases

WP6 – Definition of EHRxF technical specifications

- T6.3: Definition for the technical specifications Hospital Discharge Reports
- T6.4: Refinement of Patient Summary (PS) technical specifications for supporting rare diseases

WP7 – Architecture integration and System specification

- T7.1: Global architecture for EHRxF Domains use
- T7.2: Testing strategies

Relevant expertise and experience of the institution

As the Portuguese national authority for cross-border matters in the field of eHealth, SPMS represents Portugal in the **eHealth Network** (eHN), the voluntary network of national authorities of Member States responsible for eHealth, with a view to enhance cooperation, knowledge sharing and good practices between Member States.

SPMS active participation and involvement in the eHN is emphasised by the nomination of its President, Prof. Henrique Martins, to jointly **Co-Chair the eHN** (on behalf of Member States) with the European Commission. This involvement builds upon insightful contributions at the time of dratfting the **eHN Multi-Annual Work Plan (MWP 2018-2021),** acting as rapporteur.

Furthermore, SPMS played an active role in **JAseHN,** participating in four Work packages of this project. JAseHN objectives were to ensure the regular production of instruments and recommendations to be presented to the eHN, as well as to ensure the smooth functioning of the Work Packages.

SPMS background also reckons on an active membership on the **eHealth Member States Expert Group (eHMSEG)**, having coordinated the application process of 20 countries to the

2015 EC call for proposals on Patient Summary & ePrescription/eDispensation, CEF TELECOM CA–LS 2015 - CEF-TC-2015-2: eHealth.

On the basis of its active and leading role in definition and implementation of eHealth Strategy at European level, in May 2017, SPMS was nominated by EU Member States to assume the coordination of the ongoing Joint Action on e^{He}alth (3rd JA – **eHealth Action**). Currently, eHealth Action just complete its first of three years of action and so far, the project has been developing smoothly.

Further to the above, SPMS has a solid track record of successful implementation of international collaborative projects, and is currently involved in several Horizon 2020 funded projects, of which we highlight: **CEF eHDSI Cross-Border** services deployment (on **Cross-Border Patient Summary & ePrescription/eDispensation**), eStandards (a coordination and support action to strengthen the standards & interoperability pillar of Digital Agenda for Europe 2020), **VALUeHEALTH** (on how interoperability of health information can consistently create, deliver, and capture value for all stakeholders), **EURO-CAS** (aiming at maintaining and developing the adoption and take-up of testing the interoperability of ICT solutions against identified eHealth standards and profiles defined in the eHealth European Interoperability Framework), **ProEmpower** (a PCP aiming at tackling the incidence of type 2 diabetes among populations through patient empowerment), **Trillium II** (on further advancing the agenda of the EU/US roadmap on eHealth/HIT collaboration), **ESPDint** (aiming at implementing a "customised" European Single Procurement Document, service into the existing software solutions of tendering/pre-qualifications platforms in 6 MS, including Portugal)

Among the concluded projects we highlight the participation in projects such as **epSOS, Antilope, e-Sens, TrilliumBridge or Expand** (for which it was coordinator).

Key Personnel's CVs (incl. gender)

Arlete Monteiro – Chief Information Office, ♀, PMP® graduated in Mathematics (Computing and Operations Research) and Mathematics (Teaching) with post-graduations in Project Management and Evaluation from Universidade Católica Portuguesa and in Advanced Management for Healthcare Organizations from AESE Business School. Since 2011 she works in SPMS, and at the present is an IT director, responsible for several areas, including Mobile and Citizens Services, Hospital Systems and ePrescription.

Diogo Martins – SPMS' Coordinator for International Relations and Projects, ♂, MD, Graduated in Health Equipment and Technology, academic background consists on Electronics, ICT & Medical Devices. Holds a MD in Healthcare Information Systems Management obtained in partnership between the Polytechnic Institute of Leiria (IPL) and Faculty of Medicine of Oporto (FMUP) with thesis in eHealth field: "Impact of using mobile handheld technology in health care delivery: a Systematic review". He has worked as Medical devices consultant, key account manager and most recently as ICT Project Manager in SPMS working on Healthcare data sharing – Radiology and DICOM Imaging; Infrastructure for Healthcare data–sharing - XDS, IHE and Telemedicine Platform. He has been able to make a "bridge" from ICT field experience how important is to engage Healthcare professionals and citizens to healthcare improvements. Currently he works at SPMS and is responsible for the International Projects as well as and International Cooperation.

Lília Marques – SPMS'executive secretary for International Relations and Projects, ♀, has a degree in Systems Engineering from University of Minho. She has more than 20 years of experience in Information systems in the health domain. Currently works at the International Relations and Projects Unit of SPMS. She has been involved in several eHealth European projects, namely: EXPAND as project manager and quality manager, epSOS as project coordinator deputy and also in e-SENS, Trillium Bridge, CARDLINK 2 as technical responsible and SHINE as project manager and technical responsible. She supported the eHMSEG chair directly, collaborating actively with the eHMSEG chairs in the coordination activities of eHMSEG with the goal to promote and achieve a harmonized and shared collaboration among countries on cross-border services deployment under CEF funding.

Cristiano Marques – SPMS' Coordinator for Services Integration Platforms for Citizen Care, ♂, MD, is the current Head of Integration Platforms and Citezen Services at Ministry of Health in Portugal. He started his career in banking sector with financial projects. About six years ago, he went to health where he went through several eHealth projects, namely: death certificate system, patient portal, national registry of professionals, etc. He has a degree in Computer Engineering and h's master's degree in Artificial Intelligence and Software Engineering.

Relevant publications, products, services, or other achievements (max. 5)

SPMS is involved and committed to generate scientific material and knowledge, and to present them in international conferences. In accordance with X-eHealth pruposes, we outline hereinbelow SPMS' relevant achievements:

- Santos, A., Sá, P., Romão, R., D'Arrábida, C., Coelho, A., Alexandre Diniz, J., Martins, H., The Rare Disea'e Person's Card Implementation Strategy in Portugal, Procedia Computer Science, Volume 64, 2015, Pages 1149–1156 Conference on ENTERprise Information Systems/International Conference on Project MANagement/Conference on Health and Social Care Information Systems and Technologies, CENTERIS/ProjMAN / HCist 2015 October 7-9, 2015

  Moen, A., Bruun-Rasmussen, M., Mendes, R., Hurlen, P., Chronaki, C., eHealth Consumers at the age of hyper-personalization, 2016, STC 2016
- – Paris

  Gomes, R., Soares, B., Cybersecurity Match Supply And Demand in Portuguese HealthCare Sector – Industry Collaboration, 2016, HC–st 2016 - International Conference on Health and Social Care Information Systems and Technologies On the Paperless Prescription project not only was developed a reference implementation but all the technical specifications were provided to the market to develop e-Prescription and e-Dispensation
- systems

  Marques, C., Monteiro, A., Rebuge, A., Martins, H., Mob–le SICO - Mobile E-Death Certification, Procedia Computer Science, Volume 64, 2015, Pages 1149–1156 Conference on ENTERprise Information Systems/International Conference on Project MANagement/Conference on Health and Social Care Information Systems and Technologies, CENTERIS/ProjMAN / HCist 2015 October 7

- -9, 2015

SPMS is both a software development and an eHealth regulation entity. There are several projects with high visibility that were developed internally as well as several mHealth initiatives under the umbrella of the **My SNS** branding. To name a few: Portuguese Health Data Platform (PDS), Paperless Eletronic Medication Prescription (RSP) and Digital Heath Certificates (SICO) are some of the available features in **My SNS family apps** (for more information see https://comunity.mysns.pt).

Within **My SNS family apps**, these are our latest products:

1. **My SNS** – a National Health Service informational app;
2. **My SNS Tempos** – this app shows the average waiting times of the national health service emergency departments;
3. **My SNS Carteira** – provide all the health and administrative information of the patient on a modular way, like a wallet, where every bit of information is a card;

My SNS was developed to provide alerts and display the news of the NHS, feed by the NHS portal; provides information related to the health services provided by the NHS; provides geographical information of the Hospitals, Primary Care Facilites and Pharmacies, and a way to evaluate them. An international, initially in English, version is planned, and the introduction of general public health alert is also planned.

My SNS Tempos provides a way for patients to choose which hospital emergencies are closer geographically and where the waiting times are lower, right now two languages are available Portuguese and English. All hospitals are listed but currently only about 84% of institution share waiting times. There is a new version planned that will include the display of average waiting times for specialty medical appointments and surgeries.

My SNS Carteira objective is to help patients managing their health information. The app is based on four principles: security, safety, portability and tailoring. Regarding security features, several technical mechanisms provide a truly secure information exchange and storage.

In order to foster organizational synergy and knowledge sharing, and in view of the need to protect’citizens' information, MySNS Community seeks to be a collaborative platform for all citizens, health professionals and programmers, promoting the sharing of related information with the technologies used in the development as well as the dissemination of the built code, ensuring transparency and a thorough knowledge of their operation.

Through an online platform, any citizen can have access to the open source code, as well as guidelines and other information, and can contribute adequately and safely to the technological advance31nalyse31 european panorama, the implementation of this project would “eet the "Open source software strategy ”014-2017" published by European Commission, which aims to strengthen the role of open source software for many of its key services and ICT software

solutions. The renewed strategy puts a special emphasis on procurement, contribution to open source software projects and providing more of the software developed within the Commission as open source.

The existen32nalyse32 european online community, would facilitate access to information and a wider dissemination and contributions to existing projects in each country, giving a special emphasis on procurement, contribution to open source software projects and providing more of the software developed within the Commission as open source. Also, highlights the cooperation between countries, bringing citizens and health professionals closer to technological development and innovation.

Previous projects or activities related to the project subject (max. 5)

eHAction – SPMS features as Project Coordinator. eHAction is the 3rd Joint Action supporting the eHealth Network, which, in its Multiannual Work Programme 2018-2021, sets targets for deepening further the eHealth sector with the goal to facilitate the management of chronic diseases and multi-morbidity, by increasing sustainability and efficiency of health systems, and by facilitating personalized care and empowering the citizen.

Specifically, it is working to find ways to empower people (WP4) by giving them an active role in managing their health care data and processes, to use health data in an innovative way and to enhance continuity of care through the use of interoperable and cross-border solutions. eHAction is in line with the Third EU Health Programme. Together, the JA and the Programme, aim to advance European public health status by promoting the use of eHealth in a structured policy framework.

eHAction also functions as a platform for organizational, strategic and technical cooperation between MS/C, including close collaboration with EC, DG SANTE, DG CONNECT and DG DIGIT and other EU stakeholders.

The commitment undertaken by eHAction shall lead to quality results for the continuity, safety and efficiency of ICT, supporting healthcare. Therefore, this will result, as much as possible, in practical results for the users (citizens, healthcare providers, health professionals, decision makers, etc.).

“Exames sem papel” – Paperless exams

It is an important national initiative from the Portuguese Ministry of Health developed by SPMS that aims to dematerialize the processes of request, realization and invoicing of Complementary Diagnostic and Therapeutic Means (MCDT), as well as ensure that all the data related with the execution of the exams follows the patient in digital support. The project is from SPMS responsibility and start**ed** at 19th July of 2019 on the primary care units and later on Hospital Care services. At October 2019, SPMS already have registration of 2.598.501 paper-less exams.

EXPAND was a project coordinated by SPMS that aimed to preserve the actives of the infrastructure of European scope that were developed by European projects, namely epSOS, SemanticHealthNet, HER.Q or eH4CR until the launch of CEF. The project faced the challenge of skip from set of pilot solutions to the large-scale implementation of cross-border eHealth services. EXPAND ensured the sustainability and the expansion of epSOS services, including the suitable deliver until the launch of CEF (eHDSI) and promoted the reuse of the eHealth actives created at national and European level.

RSE – Electronic Health Record

This national project started in 2019 and its implementation organized into 3 phases. RSE aims to gather essential information of each Citizen for the improvement of the provision of health care. The 1st phase consisted only on a small samp**le**, the 2nd phase is target to family physicians identified to the pilot together with the PEM team (Electronic Prescription of medicines) and the 3rd and final phase will the national scale. The project objective is to develop a Electronic Health Record plataform that compiles patients basic health data to be provided to health professionals, always that it is needed an urgent service or a scheduled service in a national health entity or foreigI. The EHR includes the patient identification, unit healthcare and family physician identification, allergies, chronic medication, vaccines, medical diagnosis, medical procedures and medical devices) accessible to healthcare professionals and the patients themselves.

eHDSI

The eHealth Digital Service Infrastructure (eHDSI or eHealth DSI) is the initial deployment and operation of services for cross-border health data exchange under the Connecting Europe Facility (CEF). eHDSI sets up and starts deploying the core and generic services, as defined in the CEF, for Patient Summary and ePrescription. The generic services are the necessary implementation of data exchange at country level, the core services at EU level. These together enable the provision of Cross Border eHealth Information Services (CBeHIS).

The eHDSI is financed by the Member States and the European Union through the CEF programme. The core services are set-up and deployed by the European Commission using its own resources and through calls for tender financed by CEF. The generic services are funded from the national sources and supported by grants from the CEF through a call for proposals.

Following SPMS' (the national authority for eHealth) active participation in the epSOS, EXPAND and e-SENS projects, Portugal is fully committed to converging and pursuing EU-wide interoperability for cross-border healthcare. With that specific context as blueprint, Portugal is preparing, testing, deploying (Patient Summary in 2018 and the ePrescription in 2019) and operate the National Contact Point for eHealth (NCPeH), according best practices and sound experience, properly connected with the already available national infrastructure.

Partner Full Name	Bundesministerium für Arbeit, Soziales, Gesundheit und Konsumentenschutz		
Short Name	**ATNA**	**Partner No.**	2
Country	Austria	**Website**	www.sozialministerium.at
Type of organisation	Ministry	**Logo**	Bundesministerium Arbeit, Soziales, Gesundheit und Konsumentenschutz

Brief Partner Profile

The Federal Ministry of Labour, Social Affairs, Health and Consumer Protection (ATNA) is the national authority in health-related policy areas in Austria. Amongst others, the Ministry is responsible for health system legislation and financing, health insurance, consumer health, eHealth, communicable and non-communicable diseases, health promotion, vaccination, medicinal products and medical devices, genetics, public health but also for animal health and food safety. ATNA is in the lead of the Austrian e-health initiative and is engaged in several national and international eHealth projects. The most important national eHealth project in Austria is the Electronic Health Record system (ELGA), which is implemented nationwide and which introduces a unique communication platform for Austrian in- and outpatient health care providers with a view to increasing quality of services and patient safety. Over the past 15 years ATNA had taken over several leading roles in European projects, committees and initiatives, such as the role of the Members States co-chair in the eHealth network, project coordinator and work package leader for instance.

Main tasks in Project

ATNA will participate in this CSA project as contributor:

WP4 – Generic aspects of EHRxF recommendation

- T4.1: Electronic Identification implementation
- T4.3: Cybersecurity

WP8 – EHRxF Communities of Practice: from Proof of Concept to large scale adoption and Infrastructure for Innovation

- T8.5: Exploitation: EHRxF as infrastructure for innovation

Relevant expertise and experience of the institution

In its role as a Ministry and thus a public national authority, ATNA is responsible for the public health system in Austria, with a high priority on eHealth governance deployment. ATNA has been acting as the **eHealth Network** Member States co-chair between 2013 and 2018 and has also contributed to the transformation process of the informal high-level eHealth

governance group to the eHealth Network, which is since its establishment acting on a legal base according to Directive 2011/24/EU. Since 2013, ATNA had also been chairing several sub-groups of the eHealth Network: One among those dealing with the implementation of the Communication on the Digital Transformation of Health and Care, has delivered the "Guideline on an interoperable eco-system for digital health and investment programmes for a new/updated generation of digital infrastructure in Europe", which is closely linked to the "Commission Recommendation on the Iopean EHR exchange format". This can be considered as a result from the informal Council meeting in fall 2018 (under the Austrian EU Presidency), where the topic "Investment in Digital Health" was considered a priority. ATNA is still leading the ongoing work of this sub-group which is currently still in progress aiming to further define the governance process related to it.

From 2015 until 2018 ATNA was the project coordinator of the **Joint Action to support the eHealth Network** (JAseHN), that acted as the sole preparatory body for the eHealth Network and delivered several policy documents, frameworks and guidelines serving as the main basis for the establishment of the eHealth Digital Service Infrastructure, under which eHealth Information Services (based on real patient data) are being exchanged across European countries.

ATNA chaired both, the joint action and the thematic network of the **eHealth Governance Initiative** as project coordinator from 2011 until 2014. This initiative successfully established a governance structure for eHealth within Europe in order to ensure continuity of healthcare on the national level and across borders, while seeking a strong coordinated political leadership and the integration of eHealth into national health policies.

ATNA was leading WP2 Dissemination of epSOS project and was engaged in project eSENS. In project STORK I, ATNA was co-leading the eHealth field test and in project STORK II in charge of the eHealth pilot.

ATNA is further involved in epidemic surveillance dealing with a complete infrastructure and corresponding workflows from LABS to the Ministry and furthermore to ECDC via online communication.

ATNA is also managing surveillance including workflows to EMA, UNODC, etc.

Key Personnel's CVs (incl. gender)

Robert Scharinger ♂ , Chief Information Officer. Studied computer science and IT in healthcare in Austria and United Kingdom. Delegate to e.g. the European Medicines Agency (EMA), to the European Centre of Communicable Diseases (ECDC), and to the eHealth Member States Expert Group (eHMSEG) of the European Commission; member of the national ICT coordination platform; experience in eHealth coordination; experience in project management, system planning, implementation and operation as well as in quality assurance, especially in eHealth projects on a national and on an international level.

Christopher Ozvald ♂ , IT Security Officer and Cyber Security Coordination for eHealth. He studied information and communication systems in the'bachelor's programme with a focus on IT-security and is currently continuing his studies in t'e master's programme on IT-security. He supports the work of the Ministry, respectively the department for health telematics, since 2011 in several areas, such as digitalization, cybersecurity, IT-security, national coordination of ICT activities. In those areas he has been working as project, process and application manager, IT-security architect, database administrator and national coordinator. He currently also acts as the national delegate in CISO AG in the course of cyber security governance in eHealth.

Relevant publications, products, services, or other achievements (max. 5)

In particular, all passed laws (or published draft laws) in the health sector are to be considered as publications. Most relevant is the Health Telematics Law for securing the transmission of sensitive patient data. The law elaborates security measures already stipulated in the Data Protection law 2000 and aims at preventing malpractice and assure confidentiality of sensitive individual data travelling through networks. It further aims to harmonize data safety measures Austrian-wide and raise the standards of those measures. Moreover it shall provide broad baseline information for decision makers.

ATNA has published information in the form of national drug reports, national epidemic reports and bulletin and national public health bulletin. In addition, information on current topics is published on an ongoing basis and the population is informed accordingly via various channels.

Previous projects or activities related to the project subject (max. 5)

On the national level, the Electronic Health Record system ELGA is the most important success achieved so far when it comes to a nationwide implementation of a Iional EHR system. ELGA is an information system that simplifies the process of accessing patients health records for patients and their doctors, as well as other healthcare professionals at hospitals, care facilities and pharmacies. Health data such as a patient's test results are generated by a variety of health institutions. ELGA networks all of them and makes them available digitally by means of a link.

ATNA is also focusing on epidemic surveillance, web-services for ECDC and complete online workflow processes for the healthcare sector.

Partner Full Name	Austrian National Public Health Institute in German; Gesundheit Österreich GmbH (GÖG)		
Short Name	**GOeG**	**Partner No.**	3
Country	Austria	**Website**	http://www.goeg.at/
Type of organisation	Public Health Institute	**Logo**	Gesundheit Österreich GmbH

Brief Partner Profile

The Austrian National Public Health Institute (Gesundheit Österreich GmbH, GÖG) is the institution responsible for researching and planning public healthcare in Austria, and also acts as the national competence and funding centre for the promotion of health. It is organised in three business units. Set up by federal law on 1 August 2006, GÖG has the federal government as its sole shareholder, represented by the Ministry of Health.

The staff of the Austrian National Institute for Health Services Research (in German: Österreichisches Bundesinstitut für Gesundheit, OeBIG) founded in 1973 analyses data, provides comprehensive information in the field of public health policy, and facilitate reform and innovation processes. For a few years GÖG is working in the field of e-Health and Digital Health, being the partner already in the three Joint Actions to support the e-Health Network.

Main tasks in Project

GOeG will participate in this CSA project as partner in:

WP 2 Dissemination, Communication & Stakeholders

- T2.2: Healthcare providers, Health professionals and Citizens motivation
- T2.3: MS and National Authorities involvement

WP 3 Evaluation (Leader)

WP 4 Generic Aspects of EHRxF recommendation

- T4.3: Cybersecurity

Relevant expertise and experience of the institut37nalysehe approx. 220 persons working for us are multi-disciplinary, with backgrounds in health economics, epidemiology, sociology, planning, ICT, psychology, statistics, medicine, communication, prevention, gender health, etc.).

Current research focuses on supporting the ongoing national healthcare reform (e.g. in the field of digital health and web-based health information) and in reaching the national health targets. Besides working for national stakeholders (e.g., ministries, provinces, social insurance institutions) we perform a number of projects and consultancies for the European Commission, WHO and countries like the Ukraine. We are also involved in a number of Joint Actions, among them the previous and current JAs on eHealth. We also have performed a number of

evaluations using a variety of tools for national and lately international undertakings. A full list of references can be provided in German language.

The Executive Department ‚Digital Health and Innovation' has been created in 2019 to support evidence-based health policy-making around the issues of digitalisation and innovation. The department has an in-house role as a knowledge and network hub around digital health supporting units across the entire organisation. Externally, department experts support national and international digital health-related research projects and policy-making.

Also we run the Austrian national electronic health information platform **www.gesundheit.gv.at**.

Key Personnel's CVs (incl. gender)

Mag. Claudia A. Habl, ♀. Head of International Affairs and Consultancy Department and lEAR of GOeG. After completing her studies in Business Administration and her post-graduate in hospital management, Claudia Habl is working in the field of health care for almost 25 years. After working in hospital administration, she joined the Austrian National Public Health Institute GOeG in 1998, where she worked on a number of topics in the field of health and social care. She is (co-)author of a number of publications in the field, for instance the recently published EU Study on Big Data in Public Health, Telemedicine and Healthcare and has more than a decade of experience in managing and leading large-scale EU project. She has more than 20 years of experience in working on cross-country projects, also involving monitoring activities and dissemination on conferences of public interest.

Dr. Alexander Degelsegger-Márquez,♂, heads the executive department "Digital Health and Innovation" at GOeG. In this role, he advises national stakeholders in digital health-related policy-making. He also carries out research and policy advisory work in a number of national and international projects. Before joining GÖG at the beginning of 2019, Alexander was Head of Department for "Research Policy and Development" at the Centre for Social Innovation in Vienna/Austria and coordinator of a number of evaluation studies as well as a Horizon 2020 research project on science diplomacy.

Alexander has a background in political science, international development and the sociology of science and innovation. He holds a PhD from the University of Vienna's Science and Technology Studies department and currently lectures on big data in health at the University's political science department.

PhDr. Isabella Weber, M.A., ♀, employed by GOeG but works for ATNA since 2010. She studied European Economics and entrepreneurship and holds a PhDr for health administration. She was responsible operational project coordinator in the eHealth Governance Initiative. She was project coordinator of the Joint Action to support the eHealth Network (JAseHN and is leading WP 3 Evaluation in the current eHAction Joint Action to support the e-Health Network.

Dipl.-Ing. (FH) Kathrin Trunner, MSc, ♀, obtained two academic degrees from the University of Applies Sciences Technikum Wien in Vienna and is currently responsible for the management of national and EU-funded projects in the field of health telematics / eHealth at the public health institute Gesundheit Österreich GmbH. From 2010 until 2019 she has worked for the Federal Ministry of Health in Austria where she was the national contact point and a Work Package Leader in the biggest EU large scale eHealth pilot. She also wrote the feasibility study on behalf of the Minister of Health on the implementation of an electronic vaccination data system in Austria, which is currently being realized as a project.

Thomas Fleischmann, ♂ is employed by GOeG but works for ATNA since 2008. He works as IT-architect and IT-expert, especiIy for EHR systems. He is responsible for the technical management of the ministry's big data and knowledge management platform. Furthermore, he is engaged in the European projects the Ministry is involved in as IT-coordinator and deals with a smooth exchange of knowledge between the many actors involved in technical and organisational processes.

Relevant publications, products, services, or other achievements (max. 5)

Together with Sogeti from Luxembourg, GÖG investigated the potential of Big Data in the health sector and developed recommendations for exploiting its potential in the EU Member States. The results can be found in the recently published Study on Big Data in Public Health, Telemedicine and Healthcare.

GOeG is involved and committed to generate scientific material and to present it in international conferences, such as:

- Habl, C., Laschkolnig, A.: How Big Data could improve the performance of health care systems in Europe. European Health Management Association 2018 Annual Conference, 22nd of June 2018, Budapest.
- Habl, C., Are EU healthcare systems ready for medical innovation? Biogen Workshop "A new era for Alzheimer's". European Health Forum Gastein, 3rd of October 2018, Gastein.

Services:

- Among others, GOeG runs the Austrian national electronic health information platform www.gesundheit.gv.at and the health professional register.

Previous projects or activities related to the project subject (max. 5)

Related projects with GOeG participation:

- eHAction, **http://ehaction.eu/**: Taking over the work from JAse^{HN}, the 3rd Joint Action called eHAction continues the operational, strategic and technical support of the eHealth–Network - a group of representatives from all EU Member States getting together twice a year.

- TO.REACH, **https://to-reach.eu/**: TO-REACH is a coordination and support action (CSA) to prepare a joint European research programme aimed at producing research evidence supporting health care services and systems to become more resilient, effective, equitable, accessible, sustainable and comprehensive (in Europe, and abroad).
- Among the concluded projects we highlight the participation in projects such as JAseHN, InfAct and Euripid.

Partner Full Name	FPS Health Belgium		
Short Name	**FPS Health Belgium**	**Partner No.**	4
Country	Belgium	**Website**	https://www.health.belgium.be/en?fodnlang=fr
Type of organisation	Public organisation/ Public Health	**Logo**	federale overheidsdienst VOLKSGEZONDHEID, VEILIGHEID VAN DE VOEDSELKETEN EN LEEFMILIEU

Brief Partner Profile

The SPF Public Health is responsible for the protection of human health, in particular the provision of well-organized and high-quality health care services that are affordable, accessible and integrated and meet the needs of the population, nutrition policy, the provision of medical expertise in the context of the exercise of professional activities and alcohol, tobacco and cosmetics policies;

In the field of human health, health care, with the exception of medicines, is largely a matter of national competence, which is widely shared and interconnected between the federal level and the communities. The latter, after all, exercise many powers with regard to the organization of health care institutions, preventive health care and health care professions. Other policies (eg related to consumer and trade products, environment) have a direct or indirect impact on health and are set at international level. The Interministerial Public Health Conference is the coordinating body for both inter-federal consultations and the international representation of Belgium. The FPS is responsible for its secretariat, as well as for the antimicrobial resistance (AMR) working group.

The federal level coordinates and interprets, for th“ domain "hum”n health", the Belgian position in the international forums. The FPS is also in charge of the secretariat of the international inter-cabinet working group of the IMC Public Health, which has a mandate that has been extended to all international bodies competent in the field of health. The FPS also organizes coordination with the other partners at the federal level, i.e., among others, the

FAMHP and the RIZIV. In this context, the basic principle implies that the FPS in its cap“city as "Ministry ”f Health" is the first point of contact for international organizations and the other Member “tates. ("National Fo”al Point").

Main tasks in Project

SPF Health Belgium will be a partner in 2 workpackages:

WP5 Definition of EHRxF functional specifications

- T5.3. Laboratory Results guideline and functional specifications
- T5.4. Medical Imaging and Reports guideline and functional specs
- T5.5. Hospital Discharge Reports guideline and functional specs

WP6 Definition of EHRxF technical specifications

- T6.1. Coherence check for system integration

WP7 Architecture integration and System specifications

- T7.1: Global architecture for EHRxF Domains use

Relevant expertise and experience of the institution

An integrated actionplan on eHealth, called the roadmap eHealth 2013-2018, has terminated at the end of 2018 and was followed by a new actionplan eHealth 2019-2021, with new and updated principles and accents.

This actionplan eHealth 2019-2021 has been signed by all responsible ministers, both on federal as on regional level.

Among the accents are continuation of on-going projects (like e-prescription), extension of existing systems to other target audiences of healthcare domains, focus on ‘Operational Excellence’ (meaning the support during the use of the systems), connection with Europe and international initiatives and programs.

This actionplan eHealth 2019-2021 contains 44 projects, bundled in 7 clusters. All of the projects aim to contribute to the program goals, being a better quality of healthcare and a more effective healthcare.

A number of the projects are so-called concept-projects where the goal is to define a clear description of the implementation solution of a given problem, allowing to achieve the necessary support by all stakeholders before actually building the system.
Other projects build new, extend or optimize existing systems.

The Interministerial Conference on Public Health decided in 2018 to prepare a new Action Plan. A number of principles and points of attention were used as a basis for the preparation of this new plan:

Continuing inter-federal cooperation on eHealth strategy and further optimization of the cooperation model continue where appropriate, adjust if necessary, and systematically finalize ongoing projects and / or extend them to new target groups or fields of application

reinforce and monitor the focus on operational excellence to continuously improve the availability and performance of the systems and tools used by the patient and the healthcare provider pay more attention to European and international eHealth initiatives

Based on these principles, 7 clusters of 44 interdependent projects have been identified and clear ambition and objectives were agreed for each of them.

The 7 clusters are:

- **The foundation of the eHealth landscape**: for example, the management and evolution of the principles and systems of computerized patient consent, the service access matrix and eHealth information for patients. providers, management and use of basic services, terminology and technical standaI used ... This means that the same rules and agreements apply to patients, healthcare providers and software providers.
- **Cross-cutting aspects of the eHealth plan**: for example, ensuring proper communication, as well as ensuring good project management and monitoring by closely monitoring their coherence.
- **Support for implementation**: this includes, for example, the policy on incentives for health care providers to use eHealth services.
- **Operational excellence**: Over the 2013-2018 period, we have moved from many eHealth projects from the ideation phase to their development and actual application in the field. A number of issues and concerns have also been identified, for example with regard to the stability of the systems and the quality levels to be achieved. As noted above, the CIM believes that improving operational excellence is an important work area; that is why the Action Plan also includes concrete projects aimed at ensuring the smooth implementation of new tools and systems, with both a solid / reliable technical infrastructure and support and support initiatives for all stakeholders. actors: citizens, healthcare providers, software pIiders ...
- **Healthcare providers and care institutions**: This cluster includes a series of projects aimed at delivering value-added services to healthcare providers, such as multidisciplinary and transmural data exchange tools, further development of prescriptions the development of DPI in hospitals, the implementation of the BelRai inIument ... As can be seen, these are to a large extent projects that had already been launched in the previous Action Plan. and which are now realized and extended.
- **The patient as co-pilot**: This cluster includes eHealth projects that directly target the patient. This is for example the further development of the Personal Health Viewer (MaSanté) personal health portal, with the ambition that a citizen, through a single portal of entry, access all electronic information existing health records, regardles“ of th” "source". Citizens will also have the opportunity to directly manage their donation return.

- **Mutualities**: a specific cluster of the eHealth plan tar43nalyse mutuals with which a series of projects are underway in the field of digital transformation of administrative processes with health care providers, patients and public authorities, such as eAttest, eFacturation , the digitization of agreements and authorizations such as the drugs of ChIer IV ...

The eHealth Action Plan 2019-2021 describes, for each of the 7 clusters and 44 projects, the current situation, the desired situation and the main challenges to achieve this desired situation. A program director has been appointed, along with project leaders for each of the 44 projects, to translate the ambitions of the eHealth plan into concrete work plans. Mechanisms for consultation with patients, healthcare providers, industry, mutual societies and other stakeholders exist and will be supported by program management. The Inter-Ministerial Conference will periodically monitor the implementation of the eHealth plan.

Key Personnel's CVs (incl. gender)

Erik Vertommen ♂ Program Manager–eHealth - Federal Public Service Health Belgium

Supported by a long and rich experience and a history of successful projects and programs in many areas of IT. His main goals are to anchor the results in the organization by highlighting the right structures, communication, and the centrality of people.

And to strive for a transparent, predictable and efficient IT organization that has added value to its business customers.

Core competencies are

- IT Service Management
- IT Strategy
- Infrastructure
- Program Management
- Data Center
- Integration

For further details

https://www.linkedin.com/in/erik-vertommen-5b6b165/?originalSubdomain=be

Andries Nelissen - ♂ Project Manager–eHealth - Federal Public Service Health Belgium

Responsible for the project management of the Iject 'EHR in care institutions' one of the projects of the actionplan eHealth 2019-2021 which contains 44 projects, bundled in 7 clusters. All of the projects aim to contribute to the program goals, being a better quality of healthcare and a more effective healthcare. Main goal is to establish contacts, develop networks, encourage consultation between different partners to achieve shared results.

Core activities:

- Project Management
- Management Support of Intercabinet Working Group on eHealth.
- Participation in Benelux Task Force on cross-border eHealth initiatives.
- Participation in Task Force to improve security and resilience of hospitals information systems.

For further details

https://www.linkedin.com/in/andries-nelissen-424b742/

Relevant publications, products, services, or other achievements (max. 5)

The program management of this integrated eHealth actionplan is organised by the FPS Public Health.

An limited excerpt of all 44 projects :

- **Project 0.5 'Information standards'** : define and implement the standards for data exchange that will be used for new projects. These standards will be based on international standards, like FHIR.
  The techno-informatic basis of the projects of the e-health action plan has largely contributed to the growth and the extension of e-health.
  The development of e-health in Belgium is largely based on international information standards interoperability and information security (XMISOAP, ...). In some areas, however, others standards are emerging now (REST, JSON, OAuth, etc.).
  Based on the current situation, in Belgium, e-Health is built on the Belgian KmeHR standard for structuring of messages. There are now also international standards in this area, such as HL7-CDA, HIFHIR, ...
  It is desirable that the future development of eHealth is based, as far as possible, on open and advanced international organizations offering reasonable guarantees of backward compatibility. It will be very certainly the case for new projects.
  In this context, it is desirable that the Belgian KmeHR standard evolve towards international standards. This will be a necessity at the international level, but it is also a demand from software vendors. In this good practices developed in other countries, such as the Netherlands with Nictiz, or can serve as examples.

- **Project 0.6 'Terminology'** : provide validated codifications and thesaurus (like SnoMed CT) in Dutch and French
  A well-thought-out terminology policy should contribute to better communication between different actors of care and the improvement of the quality of care, among others, by decision and alerts. Reducing the administrative burden associated with the responsible extraction of information from secondary purposes (such as billing, quality control, scientific research and information policy) also contributes to the achievement of this goal.
  This project related to the following high-level objectives continues in the framework of the 2019-2021 action plan
  - The development of an operational coordination center and expertise at the level of the FPS Health terminology (including the designation of SNOMED CT as a standard central terminology).

- Support for other projects in the use of structured health data storage encoded.

The mission of the terminology center is to define, coordinate, facilitate and stimulate the use of terminology standards in Belgian health care. Through a phased approach, the long-term objective term is to achieve full implementation of the SNOMED CT terminology standard in the system of Belgian health.
Phasing consists of focusing first on the second and third lines and then, but only in a later stage, on the first line.

- **Project 4.1 'Multidisciplinary data exchange'** : define and implement data exchange flows between different care professionals, based on international standards
  This project starts from the availability of a Computerized Patient Record (IPR) for all professional groups concerned (so-called AR78 care providers). A number of occupational groups (doctors, pharmacists, nurses, dentists, physiothelists, ...) have already set up this system, but some others still have to do it. This definition will describe the different blocks of information that must be included in a CIO so that you can share the data with other care providers.
  The next step is to design and implement an exchange system: whatever the type of data exchanged between different providers, there is a model and fixed activities (between others, data filling, data publication, data storage in a data structure, secure storage, data retrieval, data adaptation, access rules). An inventory of roles and responsibilities (including software developers) is built for each generic step specific project objectives. Then, the information blocks are elaborated, these blocks of information are called Care-Sets.
  The way in which information blocks are structured in terms of information technology depends on the choices project 0.5 Information standards and the possibility of using existing structures to abroad (for example, Nictiz Clinical Building Blocks, HL7 FHIR or IHE7 CDA / XDS).

- **ProjI 4.9** 'EHR in care institutions' : stimulating the implementation of an inIrated EHR in care institutions by providing financial incentives in a structured and well-defined way. The important goal is to share patient information among all concerned means of highly integrated applications and a single portal.
  Another important goal is the establishment of what is known as Clinical Decision Support, which implies that the systematic structuring and codification of data is taken into account from departure.
  Creating an added clinical value is also a mI. The EHR must also be connected to the eHealth platform and support extramural collaboration. Because, in fact, the inIrated EHR is in a context that allows a system-wide and secure exchange of health information. An inIrated EHR is, moreover, a base and a facilitator for effective resource planning (machinery, equipment and people) within a health facility.

For the hospitals the **Belgian Meaningful Use Criteria** were defined, a set of ambitious, but realistic criteria. A significant amount of financial support is provided by the federal government to the hospitals to implement these criteria.

- The B.M.U. criteria are not only focusing on automation of internal workflows but also on connecting the hospitals to the first line care providers so to advance away from a disease-centered model of care toward patient-centered approaches.

Previous projects or activities related to the project subject (max. 5)

The previous e-Hea–th 2015 - 2018 action plan was finalised at the end of 2018

Some of the achievements were

1. **Personal Health“Viewer**

"m”santé.be" gives people access to all their health data that is digitally available, so they are better informed and can play a more active role in their care.

From the portal you can click through to all platforms that offer health data (medical, administrative, advance directive, etc.). You only have to register once and you can go anywhere.

The new portal site is a work in progress. At this moment you can request information about the summary of your file from your doctor; hospital reports and results; electronic medication prescriptions and vaccinations; information about implants; the permission for healthcare providers to share medical data electronically; registration as an organ donor and directives.

The FPS Public Health is already working on the next version of the personal health viewer, which is scheduled to be launched in end of 2019. Some mutual societies will have made the link with Masanté, which will allow citizens to have direct access to their personal health insurance file since portal. It will also be possible to report side effects of medications through the personal health viewer and patients will be able to access their home nursing record in just a few clicks.

In addition to these innovations, the various actors in the field are striving to improve and expand the existing range of products and services. For example, many hospitals are making an increasing amount of digital information available to their patients.

2. **CoBRHA (Common Base Registry for HealthCare Actor)**

CoBRHA is the common, consolidated authentic source of the various public institutions that are competent for the recognition of healthcare actors in Belgium (RIZIV, FPS Public HealthIAMHP, ...).

Via this database 3 questions can be answered regarding a healthcare actor:

- Who is he? This actor can be a healthcare professional (doctorIurse, ...) or a healthcare institution (hospital, retiremeIhome, ...)
- What can he do? For a healthcare institution it is about the recognized activities of this institution (general hospital, intensive care, SMUI MUG, ...). For a professional it is about the professional recognition and recognized specializations of this person (diploma, RII-nr., ...).
- What are his responsibilities? This corresponds to the roles of the actors in health care, possibly with regard to another actor in health care (head doctor in a hIital, ...).

CoBRHA +: Phase 1 of the unique counter has been completed. The unique counter went into production on 1 May 2016, which means that individual care providers can consult their personal and professional data in the unique counter. Phase 2 was completed on October 23, 2016, which means that individual healthcare providers can also change their data.

A working group has been set up to elaborate a proposal for the creation and allocation of a unique identification number of care providers and care institutions in CoBRHA (+). This number must be unique over authentic sources, healthcare actors and healthcare institutions. It must be meaningless and stable over time.

The next important milestone for the unique counter is the granting of access to healthcare institutions (phase 3).

Recip-e–Recip-e - Electronic regulations in the ambulatory sector

Recip-e is a system for the temporary storage of encrypted, electronic outpatient care regulations. The care provider who creates the electronic prescription encrypts it and sends it to the Recip-e server. The care provider chosen by the patient to perform the care prescription collects it from the Recip-e server and decrypts it. Recip-e therefore only stores the care prescriptions (both prescriptions for medicines and physiotherapy prescriptions or nursing prescriptions) temporarily and encrypted until the care provider chosen by the patient comes to collect the prescription to perform it. Every electronic data exchange takes place via the eHealth platform.

Advantages: making fraud impossible, integration into medical and pharmaceutical files, additional functions such as “feedback to the prescriber”, integration with MyCareNet query for insurability, possibility of withdrawing a prescription if justified and, in the long term, making paper unnecessary.

3. **Mobile Health**

From the end of October 2018, producers can register their mobile health applications (hardware and software) at Mobile Health Belgium, an initiative of Minister De Block supported by the Riziv, the FPS Public Health, the FAMHP, the eHealth platform and sector

federations Agoria and beMedTech. A validation pyramid will be used to assess whether the applications meet the necessary conditions in terms of quality, safety and effectiveness.

The validation pyramid consists of three levels:

Level 1 defines the basic criteria for all registered applications. The application must have a CE marking and must comply with the regulations for medical devices. The Federal Agency for Medicines and Health Products monitors this. The application must also comply with the European regulation on data protection.

Level 2 determines the conditions for interoperability with other mobile applications and with other digital applications within the healthcare sector, such as the basic services of the eHealth platform. The eHealth platform defines these conditions, the effective testing of interoperability will be done by independent testing centers. In addition, all basic criteria (level 1) apply.

Level 3 is reserved for applications with proven health-economic added value. An adapted financing model is being developed for these applications. The Riziv checks whether they have a place within a broader treatment plan. All Level 3 applications must also meet all Level 1 and 2 criteria.

On www.mhealthbelgium.be the applications are published per level that meet the required criteria. In the first instance it will be about level 1 apps. The other two levels are currently being finalized.

Partner Full Name	IHE-Europe		
Short Name	IHE	**Partner No.**	5
Country	Belgium	**Website**	www.ihe-europe.net
Type of organisation	AISBL	**Logo**	IHE EUROPE Integrating the Healthcare Enterprise
Brief Partner Profile			

IHE-Europe is a non-profit association dedicated to interoperability in Health IT. IHE-Europe gathers a broad range of stakeholders to advance the shared exchange of patient information. It begins with an open process of developing integration profiles to assure IT systems can talk to each other. Then it requires testing these systems to verify that complex system delivers the data. Finally, IHE-Europe actively promotes wider awareness and use of these methods for assuring continued conformance and compatibility. As the mission of IHE is to improve interoperability (1) IHE develops Technical Framework Documents for IHE Integration Profiles, (2) organizes the IHE Connectathon to provide a possibility to test interoperability, (3) organizes IHE demonstrations in order to promote the use of interoperable products, (4) and ensures the credibility of interoperability claims by individual vendors. IHE-Europe has two operational committees: IHE-Services offers services of testing developed by IHE testing hosted at Kereval, which is an ISO/IEC 17025 accredited company dedicated to IHE profiles assessment scheme. IHE-Europe was the technical coordinator of the Antilope project, which developed the refined ehealth Interoperability Framework and the definition of the quality label and certification processes in Europe. The main recommendations on Labelling processus were introduced in the European project EURO-CAS that defines the conformity assessment scheme for Europe (www.EURO-CAS.eu).
IHE-Europe is developing the Gazelle management tools (a GITB c49nalyset testBed platform) used for the epSOS Projectathon, EXPANDATHON , eHDSI and any other epSOS tests, including the tests of the Patient Summary, ePrescription, and eDispensation. IHE-Europe is developing a high level of quality on testing methodology. www.ihe-europe.net.

Main tasks in Project

IHE-Europe will actively contribute on:

WP2 Dissemination, Communication & Stakeholders

- T2.1: Communication, Dissemination and engagement plan

WP3 Evaluation (Co-Leader)

WP5 Definition of EHRxF functional specifications

- T5.3: Laboratory Requests and Reports guideline and functional specifications
- T5.4: Medical Imaging and Reports guideline and functional specifications

WP6 Definition of EHRxF technical specifications (Co-Leader)

- T6.1: Definition of technical specification for the Laboratory Domain (Leader)
- T6.2 : Definition of technical specification for the Medical Imaging Domain (Leader)
- T6.3: Definition for the technical specifications Hospital Discharge Reports
- T6.4: Refinement of Patient Summary (PS) technical specifications for supporting rare diseases

- T6.5: Publication and maintenance of the services specifications and testing tools (Leader)
- T6.6: Publication and maintenance of the X-eHealth Implementation Guide

WP7 Architecture integration and System specification

- T7.1: Global architecture for EHRxF Domains use
- T7.2: Testing strategies
- T7.4: Guidance for the new EHRxF domains

Relevant expertise and experience of the institution

IHE-Europe has been implementing for many years the use case driven approach (see also papers below) and has developed a broad expertise on

- **Integrating profiles and more specifically the 27 profiles that were identified by the European Commission in 2015**. All the profiles are based on basic standards such as HL7 CDA and FHIR, DICOM, OASIS, CEN IPS, internet standards; IEEC, etc;
- **The testing**: IHE is developing the Gazelle test platform that is used in mamy projects in Europe and beyond, such as eHDSI project, Suisse EPD project, Sequoaia project etc. The main objectif is to reduce costs and to mutualize efforts on testing in order to improve the data quality in eHealth;
- **The organisation of testing event** such as the IHE connectathon and projectathons and contribute to several testing strategy. IHE developed the testing strategy of eHDSI. A projectathon is a testing event dedicated to assess the project specifications in a control environment using Gazelle platform.
- **The Conformity assessment Scheme** specifications (EURO-CAS, Suisse certification).

In conclusion IHE team has a deep expertise on

- Implementing methofdology (use case driven approach);
- Implementing all types of standards;
- Developingtesting strategy and testing tools and methods;

Organising connectathon and projectathons.

Key Personnel's CVs (incl. gender)

Dr Karima Bourquard, PhD (female) is IHE-Europe Director of Interoperability, and Senior Consultant and founder of IN-SYSTEM. She assists several regional/national projects on teleradiology and telemedicine or cooperation between Healthcare Professionals. She has a solid background on Healthcare IT as eHealth project director and on eHealth interoperability.
During the last 15 years, she contributed to the creation and development of IHE (Integrating the Healthcare Enterprise) in France and in Europe. She is user co-chair of IHE-France and was IHE-Europe user co-chair (www.ihe-europe.net). She is member of IHE International. She is currently Director of Interoperability of IHE-Europe and board member of InteropSanté in France, working on EU Affairs. She was involved in several European projects such as epSOS, Antilope (she was

the technical coordinator),eStandards, EXPAND, etc.. She is currently scientific coordinator of EURO-CAS project (www.euro-cas.net)
With the expertise of ISO/IEC 17025, she contributed as IHE International team member to the design and development of the Conformity Assessment Scheme (CAS), and the certification scheme in Switzerland
She also contributes to several European national programs in Europe or worldwide by providing her expertise.

Charles Parisot (Male) chair of IHE-Services Committee of IHE-Europe, InteropeHealth,, is working in the interoperability technologies. He was in charge of standardisation and IT architecture coordinating overall GE Healthcare products implementation of health information exchange standards. Through his extensive experience in contributing to a user driven harmonisation and implementation of interoperability standards, Charles has earned the trust of many healthcare user communities in Europe and in the USA to effectively achieve the rapid adoption of interoperability standards using a collaborative approach.

Charles was one of the key contributors in the European eHealth Standards Mandate that delivered a recommendation to the European Commission on how to organise effectively the European-wide agreement on eHealth interoperability specifications across the 27 European countries. He is also contributing to epSOS, a European large scale project, where he has been elected to the Steering Committee of the Industry Team representing more than 30 vendors. He has contributed to the epSOS decision to base its interoperability specification on IHE profiles, to leverage the use of IHE test tools, and to organise the epSOS Projectathon, based on the model of IHE Connectathon. Charles is also engaged in the eHealth Governance Initiative (eHGI).

He brings an extensive and practical understanding of the entire healthcare interoperability standards value chain, from standards development (HL7, DICOM, ISO TC215), to use case profiling (IHE and Continua), to product implementation, testing and market adoption.

Charles has been a member of the IHE-Europe Steering Committee since the inception of IHE-Europe in the early 2000. He is currently member of the IHE International Board, as a past co-chair of the Radiology and the IT Infrastructure Technical Committees.

Active in the national healthcare field for the past 20 years, Charles has focused on bridging the clinical and business domains with the complex technical domain of health IT interoperability standards. In doing so, he has gained the respect of several physician societies, regional and international health information exchange projects, the European Commission and leading government health officials around the world.

Hilary Rabé (Kereval sub-contracting), female, is working for Kereval. She is an expert for Art décor and validate the CDA templates used in several IHE profiles. She also adds some CDA definitions that were missing in ART-Décor IHE instance. She also worked for Ireland Cross Border project and she created a sample to validate the Art Décor Irish instance (2019).

Relevant publications, products, services, or other achievements (max. 5)

1. Bourquard K, Orlova A, Parisot C. Understanding User Needs for Interoperability: Collaborative Approach. JAHIMA. 2017. 88(10): 58-61: URL: **http://bok.ahima.org/doc?oid=302323**
2. Bourquard,Karima and Berler, Alexander. Use case driven approach for a pragmatic implementation of interoperability in eHealth. IGI Global Journal
3. Abderrerrazk Boufahja, Eric Poiseau, Guillaume Thomason, Anne-Gaelle Bergé. Model-Based analysis of HL7 CDA R2. Conformance and requirements coverage. IHIC 2015.
4. Ib Johansen, Morten Bruun-Rasmussen, Karima Bourquard, Eric Poseau, Milan Zoric, Charles Parisot, Michael Onken. Quality Management System for Interoperability Testing. MIE- Publication 2011.
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Previous projects or activities related to the project subject (max. 5)

1. epSOS and eHDSI: the project demonstrated the cross border exchange of medical data (Patient Summary, ePrescription and dispensation) among European countries. 25 European countries were involved in the project during 6 years (2008-2014). www.epsos.eu.
2. ANTILOPE (2013- 2015) supported the dissemination and adoption of the eEIF and built a Refined eEIF (ReEIF) with use cases and a selection of a set of 27 profiles. Quality management on interoperability testing, test methods were considered as well as a framework for supporting the development of a Conformity Assessment Scheme regarding HITCH recommendations. www.antilope-project.eu
3. Trillium Bridge (2014-2015) supported the extension of the cross border European medical exchanges (epSOS) to the US. The testing strategy that was developed was aligned to the epSOS strategy. www.trilliumbridge.eu
4. eHDSI (eHealth Digital Service Infrastructure) (2016-) is the initial deployment of services cross border health data exchanges under CEF. eHDSI is built upon epSOS and EXPAND projects https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHDSI+Mission
5. EURO-CAS (2016-2018) – European eHealth Interoperability Conformity Assessment Scheme aims at maintaining and developing the adoption and take-up of testing the interoperability of ICT solutions against identified eHealth stand52nalyse5252rotocoles defined in the ReEIF

HL7

Partner Full Name	HL7 International Foundation Europe

Short Name	HL7 Europe	**Partner No.**	6
Country	Belgium	**Website**	http://www.hl7.org/
Type of organisation	Non-profit	**Logo**	HL7 Europe

Brief Partner Profile

The vision of HL7 is a world in which everyone can securely access and use the right health data when and where they need it. Its mission is to provide standards that empower global health data interoperability.

The HL7 Foundation established in Brussels in 2010, addresses European standardization needs in the area of digital health, 23 years after the establishment of Health Level Seven International in 1987. It works in close cooperation with 21 European Affiliates and umbrella organizations in Europe and supports the creation of health information technology standards that are widely and easily used enabling interoperability in healthcare. Specifically, the objectives of HL7 in collaboration with its Affiliates currently established in European Countries are: (a) to promote and encourage the use of HL7 frameworks and protocol specifications that serve the needs of the European community by health systems and service providers; (b) to provide education services, promote tools and facilitate testing and certification (c) to enable high quality, cost-effective use of information systems in health and healthcare related environments.

The HL7 International Foundation has been actively involved or coordinated a range of currently active EU funded projects in the area of interoperability such as UNICOM, Gatekeeper, FAIR4Health, mHealth Hub, as well as previously the Trillium Bridge, open Medicine, Antilope, Expand, eHDSI, and currently Trillium II scaling up adoption of patient summaries (HL7 FHIR IPS).

HL7 International provides a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. Notable and broadly adopted HL7 standards are the HL7 Clinical Document Architecture (CDA) used by the European Digital Health Infrastructure (eHDSI) to record patient summaries and ePrescriptions. HL7 is also the home of Fast Healthcare Interoperability Resources (FHIR) and profiles, which facilitate access to health data to unlock their innovation potential and improve quality and safety of care.

Main tasks in Project

HL7 Foundation will be:

Leading **WP6 Definition of EHRxF implementable specifications**

Co-leading **WP8 EHRxF Communities of Practice: from Proof of Concept to large scale adoption and Infrastructure for Innovation**,

and contributing to:

WP2 Dissemination, communication & Stakeholders

WP5 Definition of EHRxF functional specifications

WP6 Definition of EHRxF implementable specifications

WP7 Architecture integration and System specifications

The contribution of HL7 center in standardization aspects, in the implementation of HL7 Standards for the EHRxF, as well as issues related to the adoption of proof of concept demonstrators, and path-finding exploratory studies. Moreover, HL7 will contribute in education, community building and adoption aspects in WP8. It will provide educational resources, extend and adapt FHIR profiles as needed and facilitate further adoption of the HL7 FHIR IPS and EHRxF liaising with standardization stakeholders beyond the consortium.

Relevant expertise and experience of the institution

HL7 Europe has been part o54nalyse5454ab**ntiatives supporting** standardization in **cross-border health care, starting with the CALLIOPE** action**, the eHealth Governance Initiat**ive, antilope, expand, assessCT, and open Medicine. **and** successfully coordinated **Trillium Bridge and Trillium II, and estandards** projects. HL7 has been instrumental in the development, promotion and alignment of the International Patient Summary (IPS) standards collaborating closely with CEN and other standards developing organizations under the Joint Initiative Council. Through Trillium Bridge and Trillium II, HL7 has been also instrumental in engaging stakeholders across the Atlantic. This experience will be used in x-eHealth to develop and refine the EHRxF, and prove its being fit for use in the selected use cases, while also exploring AI and outcomes based research. HL7 Europe is particularly fit for this role engaging the 22 national HL7 affiliates in Europe, and also engaging collaborative partners.

Key Personnel's CVs (incl. gender)

Catherine Chronaki (female) (Dipl Eng1988, MSc 90, 91); Secretary General HL7 Foundation. Catherine has engaged in eHealth projects since the early 90's. She has played a key role within National and European eHealth projects, addressing the wider scope of eHealth: health Information Infrastructures employing interoperability standards for integrated Electronic Health Records (EHRs) and digital health services. Catherine has served on the HL7 International Board (as Affiliate Director 2008-2012). She is member of the Board of HL7 Hellas, the Council of the European Federation of Medical Informatics and current Vice President (EFMI), and the eHealth Stakeholders group of the European Commission. She has served on the Nucleus of the eCardiology WG of the European Society of Cardiology. She recently concluded the Trillium II and Trillium Bridge project operational arm of the EU/US MoU Roadmap, and the eStandards support action which collects evidence to deliver a standardization roadmap for large scale eHealth deployment in Europe.

Giorgio Cangioli (male) Senior Consultant of ICT in Health and Social Care, Degree in Physics, PhD in Energy Engineering, Master in ICT for Radiology. Giorgio worked for several years for private ICT companies in different roles (Production Manager, QMS Responsible, R&D Responsible) and has been a consultant since 1999. He has more than 15 years of experience in ICT, standards and business process reengineering applied to health and social care. Giorgio is involved in several European, National and Regional projects of telemedicine; teleradiology, social care, primary care, Regional/National/Cross-Country HIE (Health Information Exchange), eGov projects. It was also involved in eHealth Regional projects assessments on behalf of an Italian governmental agency. He provides coaching and learning servic54nalyse5454 modeling, methodologies, and standards applied to the Health and Social Care. Giorgio has been responsible of the Clinical and Semantic Experts Group in epSOS and WP lead in several eHealth EU Project. Involved in the past in IHE and DICOM WG 5 (author of the DICOM Supp 88), he is the main

author of the International Patient Summary Implementation Guides and author of the CEN IPS standards (currently Chair of HL7 Italy and he has been elected as International Affiliate Representative to the HL7 Technical Steering Committee (2012; 2014-2015).
Relevant publications, products, services, or other achievements (max. 5)
Schulz S., Stegwee R., Chronaki C. (2019) Standards in Healthcare Data. In: Kubben P., Dumontier M., Dekker A. (eds) Fundamentals of Clinical Data Science. Springer, Cham https://link.springer.com/chapter/10.1007/978-3-319-99713-1_3 Chronaki C, Stegwee R, Moen A (2017) In search of a digital health compass to navigate the health system, Medinfo2017,China Heitmann K, et al. Interoperability Assets for Patient Summary Components: a Gap Analysis, MIE2018, Gothenburg, Sweden CE Chronaki, F Ploeg: Towards mHealth Assessment Guidelines, in Proc. pHealth2016 Heraklion, May 29-31 2016
Previous projects or activities related to the project subject (max. 5)
• FAIR4Health (2018-2021): GA 824666 • Trillium II (2017-2019): Scaling adoption of the International Patient Summary and advancing interoperability of EHRs (coordinator) • eStandards (2015-2017): Create a Roadmap for the large-scale adoption of eHealth interoperability standards (coordinator) • openMedicine (2015-2016): Advance equivocal identification of medicines in Europe • AssessCT- Assessing SNOMED CT for Large Scale eHealth Deployments (2015-2016)

Partner Full Name	Stichting Nederlands Normalisatie Instituut		
Short Name	NEN	**Partner No.**	7
Country	Netherlands	**Website**	www.nen.nl
Type of organisation	Non-profit	**Logo**	cen Health Informatics TC251
Brief Partner Profile			
NEN is a not for profit organ55nalysen (approx. 300 employees) that stimulates and supports the development of standards. NEN is the Dutch national member body of CEN and ISO, respectively the European Committee for Standardization and the International Standardization Organization. In this project, NEN represents CEN/TC 251 Health Informatics, for which NEN holds the secretariat. NEN will align the project's efforts with its partnership in the Joint Initiative Council (JIC) in whic' the SDO's ISO/TC 215, CEN/TC 251, HL7, SNOMED International, GS1, CDISC, IHE, DICOM and PCHA cooperate to enable common, timely health informatics standards by addressing and resolving issues of gaps, overlaps, and counterproductive standardization efforts.			

NEN is well experienced in managing European, international and national projects; NEN was responsible for the standardization projects, facilitated by the European Commission, for the eHealth Mandate 403 Phase 1 and the development of 5 European and international standards in the domain of 'Identification of Medicinal products'(IDMP) (EN ISO 11238, EN ISO 11239, EN ISO 11240, EN ISO 11615 and EN ISO 11616 and the accompanied technical specifications as implementation guides) and 'Pharmacovigilance' (EN ISO 27953-1 and -2). NEN, representing CEN/TC251, has also participated in the successful projects Antilope, Trillium Bridge, OpenMedicine, eStandards and Trillium II.

Over the last 2 years, CEN/TC 251 developed with the support by European Commission (ref. SA/CEN/2015-16) the European standard 'N 17269 'The International Patien' Summary' and CEN/'S 17288 'The International Patient–Summary - Guideline for European Imple'entation'. The European standard EN 17269 has bee adopted by ISO/TC 215 to be further developed as ISO standard as well.

Main tasks in Project

NEN is a member of the Project consortium, with main input–to

WP8 - EHRxF Communities of Practice: from Proof of Concept to large scale adoption and Infrastructure for Innovation,

and will also contribute–to:

WP2 - Dissemination, communication & Stakehol–ers

WP4 - Generic Aspects of EHRxF recommendation

WP5 – Definition of EHRxF functional specificat–ons

WP6 - Definition of EHRxF implementable specifications

It will align the project's efforts with its core business related to standardization where it acts on the behalf of CEN/TC 251 and through its partnership in the Joint Initiative Council (JIC).

Relevant expertise and experience of the institution

CEN/TC 251 delivers and maintains health informatics standards for Europe, preferably by producing them in co-operation with other SDOs at a global level and by adopting standards from other SDOs. Over the last years, experts have participated in EU projects to engage and interact with other experts to deliver univocal guidance for the EC and other relevant stakeholders. In parallel, the projects results flow back into related standardisation activities.

The International Patient Summary activity is integral to taking the eHN guidelines to the next stage in terms of providing a workable and productive level of standardization for Europe.

Key Personnel's CVs (incl. gender)

Robert A. Stegwee (M) - Robert A. Stegwee, PhD is Principal Consultant for IT in Healthcare. He has been involved in healthcare IT in different capacities since 1993, starting in a hospital

environment and consulting in different sectors of healthcare, including at national and international level. Robert has participated in the development of the HL7 standards and has served as chairman of the board of HL7 the Netherlands. He has served as co-chair of the HL7 International Council and HL7 Affiliate Representative to the Joint Initiative Council on SDO Global Health Informatics Standardization (JIC). As of March 2011, Robert serves as chair of the European standards organization CE‘/TC 251 'Health In’ormatics' and represents CEN in the JIC. Robert has been WP Co-lead in eStandards and Trillium II projects.

Shirin Golyardi (F) - Shirin Golyardi, LLM, is senior consultant and has broad experience as a project manager of standardization processes in the healthcare sector in topics such as information security and interoperability. Shirin is the secretary of the European standards committee CE‘/TC 251 'Health in’ormatics' and the ISO Working Group Iso/TC‘215/WG6 'Pharmacy and m’dication'. Shirin has law degree in European and international law and Dutch law. Currently, the European standard ‘N 17269 'International Patien’ Summary' and its accompanying implementation guide (CEN/TS 17288) are being finalized.

Stephen–Kay (M) - Stephen Kay, Ph.D FBCS FACMI, has been involved in Health Informatics since 1976. He was elected international fellow of the American College of Medical Informatics. He has been the British Computer Society (BCS) Health representative on BSI since the early 90’s. He is on the senior management teams of BSI IST/35, CEN/TC 251, ISO/TC 215 and the Joint Initiative Council. He is the current Vice Chair of CEN/TC 251. He was team leader for the EHRCOM Architecture (Part 1 of 13606) between 1996-2000 and gained the first BCS funded project on System Accreditation tools for Primary Care in the UK. As well as authoring over 80 papers, he has been editor of an international journal and led numerous research projects in health Informatics. He was CEN’s expert on the SHN, Antilope, Trillium Bridge, eEIF, VALUeHEALTH, ASSESS CT and part of the NEN/CEN team in eStandards and Trillium II projects. Over the last 2 years, Steve was the Project Lead for the development of EN 17269 and CEN/TS 17288, the European standard and implementation guide for the International Patient Summary.

Matthias Pocs (M) - is the convenor of CEN/TC 251/WG I and has been actively working in health ICT innovation projects with leadership experience in research and innovation in several EU projects related to eHealth and active and healthy aging in relation to privacy and data protection. Matthias is also ANEC head of delegation at CEN-CENELEC/JTC 13/WG 5, executing EC Standardization Request M/530, and involved in international standardization activities in ISO/TC 215 as well as in the national mirror committee as a representative of DIN-Verbraucherrat. His work is related to the demand side of health informatics products and services, in particular, society and citizens. His network includes representatives of data protection authorities, e.g., in the technology subgroup of European Data Protection Board (ARTICLE 29 Working Party) and EC policy units.

Relevant publications, products, services, or other achievements (max. 5)

- R Stegwee, CE Chronaki: The case for formal standardization in large scale eHealth deployment, White Paper, Oct 2015.
- S Kay: The Concurrent Use reports, Workshops organized by CEN/TC 251 during 2012-2015.
- S Kay: Final CEN IPS workshop report, March 2019
- Communication with all CEN/European member bodies and JIC via meetings and website

Previous projects or activities related to the project subject (max. 5)

- E-Health Mandate M/403 – Phase 1 (SA/CEN/ENTR/000/2007-20)
- Participation in eHealth Interoperability Framework Study (eHealth EIF) (Framework contract N° DI/06691-00)
- eStandards (H2020 PHC34-GA643889): A roadmap for the coexistence and gradual alignment of standards in large scale eHealth deployment
- Trillium II (H2020-727745-2)
- CEN IPS (SA/CEN/2015-16)

Partner Full Name	**Hrvatski zavod za zdravstveno osiguranje**		
Short Name	**HZZO**	**Partner No.**	**8**
Country	Croatia	**Website**	www.hzzo.hr
Type of organisation	national health insurance fund	**Logo**	

Brief Partner Profile

Hrvatski zavod za zdravstveno osiguranje HZZO (Croatian Health Insurance Fund) is a key stakeholder in the national health care system. HZZO is the single purchaser of health care services provided within the MHI (mandatory health insurance) scheme. It may also offer supplemental VHI (voluntary health insurance) to persons insured under the MHI scheme. Under the supervision of HZZO, large scale health care projects have been implemented using national and foreign resources. HZZO also operates the central information system with the registry of patients, health resources registry including portal of messaging system for communication between health providers and HZZO.

Main tasks in Project

HZZO will participate as partner in X-eHealth in the following tasks:

- **Task 4.3** - Cybersecurity
- **Task 5.1** - X-eHealth use cases driven met–odology - relative effort
- **Task 5.5** - Hospital Discharge Reports guideline and function–l specs - relative effort
- **Task 5.6** - Refine PS guideline and functional specifications to account for rare – iseases - relative effort
- **Task 6.3** - Definition for the technical specifications Hospital Discharge Reports
- **Task 6.4** - Refinement of Patient Summary (PS) technical specifications for supporting rare diseases
- **Task 7.1** - Global architecture for EHRxF Domains use
- **Task 7.4** - Guidance for the new EHRxF domains
- **Task 8.2** - Exploratory Proof of concept study: from EHRxF to decision aids and citizen driven health-science
- **Task 8.6** - Evaluation of EHRxF proof of concept demonstrators

Relevant expertise and experience of the institution

HZZO was involved in few cross-european projects such as the epSOS, EXPAND, ENJECT, INCA, AdriHealthMob, JAseHN, EESSI, eHAction and project for the upcoming period within HORIZON 2020-ASSESS CT. HZZO has a main role in implementation and deployment of eHealth in Croatia and together with Ministry of Health a significant role as policy maker concerning health in general.

Key Personnel's CVs (incl. gender)

Hrvoje Jezidžić ♂, Bsc EE graduated from the University of Zagreb, Faculty of Electrical Engineering and Computing. Within 25+ years of his career in HZZO, he was working as System Admin, IT manager, Head of Technical Department, Head of Informatics Department. He was working as project manager and consultant for the Ministry of Health. Hrvoje was evaluator in The World Bank project „ Drafting the procurement documents (proposed specification for consulting services) for public bidding procedure for the integration of national health registers (databases) in Croatian health system." Hrvoje is supervisor of system CEZIH (Central health information system in Republic of Croatia) and he is internal auditor in implementation ISO 9001:2008 Quality Management System in Croatian Health Insurance Fund and Internal auditor and EOQ ISMS MANAGER (ISO 27001:2013) in implementation ISO 27001:2013 Information security management in Croatian Health Insurance Fund. From April 2017 he is assistant director for ICT in HZZO. He is member of eHealth Member States Expert Group and he is participating eHAction project.

Jelena Curać ♀ Bsc in Physics, graduated from the University of Zagreb, Faculty of Science, Department of Physics. She has 20+ years of working experience in software maintenance for

health insurance information system and software development of new applications in HZZO. She was Project leader in implementing electronic data exchange between HZZO and other government institution in Croatia. Since 2011, she is Department Manager responsible for Decision Support and Business Reporting. She is participating eHAction and EESSI project

Sanja Gusić ♀ graduated in Faculty of Electrical Engineering and Computing (University of Zagreb). She works in IT section. She has a background in software and information strategy development and implementation. She has been involved in national projects such as CEZIH, ePrescriptions, etc. She is participating eHAction and EESSI project.

Vesna Kronstein Kufrin ♀, Bsc Math graduated from the University of Zagreb, Faculty of Science, Department of Mathematics. She has 30 years experience in Information technologies and project management. She was a project manager for the BI project financed by the World Bank and some other projects of Software development and implementation in CHIF. She has successfully finished internal workshop on project lifecycle. She was the Project Manager on the‘project 'Development and implementation of the new information solution for national screening’programs'. Project activities included coordination among several institution and their–experts - Ministry of Health, HZZO, Croatian Institute of Public Health, ho60nalyse6060abilicologists and GPs. All users of the newly developed solution uses ePrescription and eRefferal on a daily basis. She was responsible for monitoring the implementation in all healthcare institution involved in providing national screening programs.

Tomislav König ♂, prof. spec. ing. logist. graduated at the University of Applied Sciences Velika Gorica, professional study of Management of Logistic Systems and Processes. He has 60nalyse6060aexperince in IT sector in Croatian health insurance fund and actively planed and worked at several National eHealth projects such as the ePrescriptions, eRefferal and eResult , eOrdering and eWaiting lists. He is participating eHAction project

Relevant publications, products, services, or other achievements (max. 5)

JAseHN

- **D6.1.1** Report on the implementation of Patient Summary Guidelines
- **D6.1.3** Report on the The Implementation of Patient Registries Guidelines in Member States

Previous projects or activities related to the project subject (max. 5)– JAseHN - HZZO was responsible for preparing the Legal Agreement for future CEF eHealth project. It becamed the legal basis for cross-border exchange of ePrescription and Patient Summary in MS.–

D6.1.1 - Report on the implementation of Patient Summary Guideline–

D6.1.3 - Report on the The Implementation of Patient Registries Guidelines in Member States

HZZO has participate in several cross-european projects such as the **epSOS, JAseHN, EESSI, eHAction** and project within HORIZON 2020-ASSESS CT. HZZO has a main role in implementation and deployment of eHealth in Croatia and together with Ministry of Health a significant role as policy maker concerning health in general.

Partner Full Name	University of Cyprus		
Short Name	UCY	Partner No.	9
Country	Cyprus	Website	www.ucy.ac.cy
Type of organisation	No profit organization, University	Logo	

Brief Partner Profile

The University of Cyprus (UCY) is a young university, established in 1989 as the first university in Cyprus with the aim to become a leading educational and research institution, distinguishing itself internationally through the promotion of scholarship and being recognised as an institution of excellence in the Mediterranean region. The most recently founded schools of UCY are the School of Engineering (founded in 2003) and the School of Medicine (founded in 2013). While a relatively young university with 7,000 students and nearly 1,000 employees (academic and administrative), UCY has many accomplishments to show over a very short period of time. Apart from being the leading university and the most active research institution in Cyprus (according to the most recent European Research Rankings), UCY is the youngest institution to be ranked in the top 550 Higher Education Institutions in the world (placed in the 351-400 group for 2015-2016 in the Times Higher Education World University Rankings). Furthermore, UCY has been recently ranked 55th worldwide in the "150 Under 50 Rankings" of the top 150 universities under 50 years old (The World University Rankings). Furthermore, it currently delivers up to 350 externally funded research projects, including several FP7 and H2020 projects, and 10 ERC Grants, as well as national and regional research programmes funded by the National Research Promotion Foundation and the European Structural Funds.

The Department of Computer Science has 22 faculty members, and more than 130 postdoctoral Research Fellows and PhD students. The Department is highly research oriented with an overall rate of ~ 5 journal publications per faculty per year. Since Cyprus joined the EU in 2004, it has participated in over 250 projects funded by various frameworks of the European Union as well as other local and international sources with a total funding in the level of about 35M EUROs. Currently the active department projects are over 22 with a total funding that exceeds the 5 MEUROs.

Main tasks in Project

UCY will participate in the following tasks:

- **WP3 Evaluation**

- **WP5 Definition of EHRxF functional specifications**
  T5.4: Medical Imaging and Reports guideline and functional specifications

- **WP6 Definition of EHRxF technical specifications**
  T6.2: Definition of technical specification for the Medical Imaging Domain

- **WP7 Architecture integration and System specification**
  T7.1: Global architecture for EHRxF Domains use

- **WP 8 EHRxF Communities of Practice: from Proof of Concept to large scale adoption and Infrastructure for Innovation (Co-Lead: UCY)**
  T8.1: Proof of concept: EHRxF in rare diseases

  T8.2: Proof of concept: EHRxF in chronic diseases management and prevention

  T8.3: Exploratory Proof of concept study: from EHRxF to decision aids and citizen driven health-science

  T8.4: EHRxF community of practice: building capacity and scaling up

  T8.5: Exploitation: EHRxF as infrastructure for innovation

  T8.6: Evaluation of EHRxF proof of concept demonstrators (Leader)

Relevant expertise and experience of the institution

eHealth Lab (www.medinfo.cs.ucy.ac.cy) – Department of Computer Science – The lab has more than 20 years' experience with funded eHealth research projects. It hosts a multidisciplinary team of experts with a strong background on eHealth, mHealth, intelligent diagnostic systems, medical imaging, and life sciences informatics and has a long list of completed and on-going projects in the above areas in Europe and internationally with a total funding managed in excess of 7 MEuro. The Lab has a long-standing experience in eHealth projects and is strongly collaborating with the Ministry of Health of Cyprus (including the Nicosia and Pafos General Hospitals, and numerous rural centres), major private hospitals (Areteion, Ippokratio), "Paedi" Center for Specialized Pediatrics and the Cyprus Institute of Neurology and Genetics. Moreover, the lab is collaborating with numerous eHealth informatics and sensor informatics SMEs (3AHealth, Unilogic, Infotex, Signal Generix, Stremble, Istognosis, and other).

The eHealth Lab of the Department of Computer Science of the University of Cyprus, and the Ministry of Health of the Republic of Cyprus have a long-standing collaboration on eHealth projects, consulting and services spanning in the last 25 years. Selected activities are

highlighted simply to demonstrate the strength of collaboration in support of the CEF proposal. The eHealth Lab team in collaboration with the Accident & Emergency Department of the Nicosia General Hospital participated in one of the first EU eHealth projects carried out in Cyprus (when Cyprus was eligible for inclusion in EU projects). The AMBULANCE project was funded by FP4 in 1996-1998 and targeted in the development of a mobile unit for health care provision via telematics support. This project was followed by Emergency-112 (1998-2000). Both projects were a great success and the mobile units developed that facilitated the collection of vital signs (ECG, blood pressure, SPO2, and other) and the wireless transmission from the mobile unit to the base station in Nicosia were installed in 2 ambulance units and 1 remote medical centre. The systems developed in emergency telematics were further advanced via the funding of 2 Interreg IIIB projects (2004-2008) that enabled the connection of 2 more remote medical centres to the Pafos General Hospital. Moreover, several projects were awarded by the 2 collaborators related to higher and continuing medical education and the establishment of a Mediterranean network (Leonardo Da Vinci Programmes (1997-2001) and Interreg IIIB & IIIC projects (2004-2008).

More recently, as it has been mentioned above, the 2 organisations are collaborating for the **Deployment of Generic Cross Border eHealth Services in Cyprus** funded by the EU CEF INEA Agency. Cyprus will be a Wave 3 Country with respect to the eHDSI Go-Live plan. Moreover, the 2 organisations also are collaborating in the development of the project entitled **Integrated National eHealth Ecosystem (eHealth4U)** funded by the Research Promotion Foundation of Cyprus. These 2 projects are also carried out in collaboration with the newly **established eHealth Authority of Cyprus**.

Key Personnel's CVs (incl. gender)

Constantinos S. Pattichis (male) is *Professor* with the Department of Computer Science and *Co-Director* of the eHealth Lab of the University of Cyprus, as well as *Co-Leader* of MRG 7 Smart, Ubiquitous, and Participatory Technologies for Healthcare Innovation in the Research Centre on Interactive Media, Smart Systems and Emerging Technologies (RISE). He has 30 years of experience in Digital Health, Connected Health, eHealth, mHealth, Medical Imaging and Video, Biosignal Analysis and AI, Machine Learning and Intelligent Systems. He has been involved in numerous projects in these areas funded by EU and other bodies, with a total funding managed in excess of 11 million Euro. He is also leading the "Deployment of Generic Cross Border eHealth Services in Cyprus", an EU Innovation and Networks Executive Agency (INEA) Connecting Europe Facility (CEF) funded project where 23 member states participate. He was Co-PI of the EU H2020-WIDESPREAD-04-2017-Teaming Phase 1 project "Integrated Precision Medicine Technologies Research Centre of Excellence (IPMT)". More recently, he was awarded as Co-PI the development and implementation of a highly competitive national integrated project entitled "Integrated National eHealth Ecosystem (eHealth4U)", that targets to develop the national eHealth infrastructure based on strict adherence to interoperability protocols for the offering of advanced big-data eHealth services. He has published more than 100 journal publications, 220 conference papers, and 30 chapters in books in these areas (no. of citations

more than 8000, h-score 47). He is Co-Editor of *M-Health: Emerging Mobile Health Systems* (considered to be the first published book on mHealth), and *Ultrasound and Carotid Bifurcation Atherosclerosis*, published in 2006 and 2012 by Springer, and more recently of the *Handbook of Speckle Filtering and Tracking in Cardiovascular Ultrasound Imaging and Video*, published by IET, UK, 2018. He is Guest Co-Editor of the Special Issues of the IEEE Journal of Biomedical and Health Informatics (J-BHI) on *Integrated Precision Medicine Informatics (2019)* and on *Computational Solutions to Large-Scale Data Management and Analysis in Translational and Personalized Medicine (2014)*. He was also Guest Co-Editor of the Special Issues of the IEEe Trans. on Information Technology in Biomedicine on *Emerging Technologies in Biomedicine (2009), Computational Intelligence in Medical Systems (2009)*, *Citizen Centered eHealth Systems in a Global Health-care Environment (2011)*, and *Atherosclerotic Cardiovascular Health Informatics (2012).* Moreover, he served as Distinguished Lecturer (2013-2014), and currently serves as member of the Technical Committee on Biomedical and Health Informatics of the IEEE EMBS, and an Associate Editor and Member of the Steering Committee of the IEEE J-BHI. He was Program Co-chair of the IEEE International Conference on Biomedical and Health Informatics (BHI 2019 and 2018), IEEE Computer-Based Medical Systems (CBMS2017), General Co-chair of t**he** IEEE 4th Middle East Conference on Biomedical Engineering (MECBME 2018), IEEE International Conferences on Information Technology Applications in Biomedicine (ITAB 2009), Bioinformatics and Bioengineering (BIBE 2012), and 13th Medical and Biological Engineering and Computing (Medicon 2016). He is a **Fellow of IEEE**, IET, International Academy of Medical and Biomedical Engineering (IAMBE) and European Alliance for Medical & Biological Engineering & Science (EAMBES).

Prof. Christos N. Schizas (male) is Professor with the Department of Computer Science and Co-Director of the eHealth Lab, and Director of the Computational Intelligence Lab (CIL). http://www.ehealthlab.cs.ucy.ac.cy/index.php/faculty. He has 35 years of experience in information systems development with more emphasis on eHealth, computational intelligence, medical diagnosis, medical informatics, biosignal analysis, intelligent, and more recently in brain activity modelling with emphasis on attention. He was born in Cyprus and studied at QMC, University of London, UK, B.Sc. (Eng). Graduate studies at the University of Indianapolis, USA, MBA, and at QMC, University of London, UK, PhD in 1981. He received the William Lincoln Shelley award from the University of London for excellence in research, and a Fulbright fellowship for collaborative research in the USA. He served as Postdoctoral Fellow at the University of London, and Professor of Computer Information Systems at the University of Indianapolis. Since 1991 he has been with the Department of Computer Science at the University of Cyprus and he served as Vice Rector of the University during 2002-2006. He published more than 150 research papers in International Scientific Journals, International Conferences, and Edited Book volumes. He is the Section Editor (eHealth) of the journal Technology and Health Care, served as area editor of the journal IEEE Transactions on Information Technology in Biomedicine, and member of the editorial board of the journal of Intelligent Systems. His research interests include eHealth, computational intelligence, and

system modeling & identification of brain activity. He is the founder of the Computational Intelligence lab and co-director of the eHealth lab of the University of Cyprus. He is one of the founders–of **RISE - Research Centre on Interactive Media Smart Systems and Emerging Technologies** and member of the Board of Directors of RISE Ltd. He has taken part in European Commission initiatives for promoting the Information Society, especially the Euro-Mediterranean partnership and the eHealth initiatives. He attends regularly as invited speaker the annual EU Ministerial Forum meeting on eHealth. **He is since 2016 the national representative to EU for the SC1 (Health) HORIZON 2020 Program Committee Expert.** In August 2015 he has been appointed as personal advisor to the Cyprus Minister of Health on all eHealth matters, especially in proposing the road map for implementing the National Health System and monitoring its steps. Chair of the Ad hoc eHealth Committee, appointed by the Minister of Health. **In April 2016 he has been appointed by the President of the Republic of Cyprus as Presidential Counselor for eHealth and matters related to the National Health System (ΓεΣΥ) reform.** Participated in the eHealth Week, Ministerial meeting – Dublin 2013 as National Representative and invited speaker at the eHealth Forum, Ministerial meetings in Athens, Riga, and Amsterdam. He lectures two courses on eHealth in the School of Medicine (UCY) and at master's level in the CS Department.

Dr Marios Neofytou (♂) is a *Senior Research Scientist* of the eHealth Lab of the Department of Computer Science of the University of Cyprus. He received his diploma degree in Electrical & Computer Engineering from the National Technical University of Athens (NTUA) and his Ph.D. degree in Biomedical Engineering from the department of Electrical & Computer Engineering of the National Technical University of Athens, Greece. He is working in research projects (IPPOKRATHS, CATIA, InteMEDnet, LLM, Meducator etc.) dealing with e-learning, medical imaging, telemedicine, and image processing.

Dr. Andreas. S. Panayides (♂) is a *Senior Research Scientist* of the eHealth Lab of the Department of Computer Science of the University of Cyprus and a *Visiting Assistant Professor* at the Image and Video Processing and Communications Lab of the University of New Mexico, and the R&D Project Manager of Integrated Precision Medicine Technologies (IPMT) phase 1 project, a competitive EU funded project. Dr. Andreas S. Panayides (EMBS Member, Senior IEEE Member) is a Visiting Assistant Professor and Assistant Director at the Image and Video Processing and Communications Lab of the University of New Mexico and a Senior Research Fellow with the Electronic Health (eHealth) Laboratory of the University of Cyprus. He is also the R&D project manager of the Integrated Precision Medicine Technologies (IPMT) – Teaming Phase 1 project. Formerly, he was a Marie Curie Fellow with the Communications and Signal Processing group at Imperial College. His research interests are in adaptive video delivery for real time applications, computer vision for healthcare applications, interactive and distributed analytics of large video databases, and mHealth and eHealth systems. He has published more than 55 peer-reviewed journal and conference papers, and book chapters, in these areas. He was the lead Guest Editor of IET Healthcare Technology

Letters; Special Issue on mHealth-Emerging Mobile Health Systems and Services, published in September 2016 and the lead organizer of the special session entitled The Potential of Big Data Medical Video Analytics in Healthcare in the IEEE Biomedical and Health Informatics International Conference, BHI 2017, USA. Dr. Panayides is actively involved in national and international research projects, funded by the European Commission, the Research Promotion Foundation of Cyprus, and the National Science Foundation, USA. In 2016, he cofounded 3AHealth (3ahealth.com), a start-up company based in Cyprus, that provides integrated solutions for electronic health Iords (EHR) storage, sharing, and analysis based on IHE interoperability profiles, where he holds the position of R&D Director. At the same time, Dr. Panayides has cofounded and is the Head of Engineering at ClearStream Technologies LLC (2017), a start-up company based in Albuquerque, New Mexico, USA, that optimizes video encoding for adaptive video delivery applications (including telemedicine). CleaStream licensed rights to a pending patent in adaptive video coding and delivery that Dr. Panayides co-invented at UNM. ClearStream was a National finalist to the 2017 Creative Business Cup, USA.

Relevant publications, products, services, or other achievements (max. 5)

1. Schiza, E. C., Kyprianou, T. C., Petkov, N., & Schizas, C. N. (2018). **Proposal for an ehealth based ecosystem serving national healthcare.** *IEEE Journal of Biomedical and Health Informatics*, *23*(3), 1346-1357.
2. A.S. Panayides, M. S. Pattichis, S. Leandrou, C. Pitris, A. Constantinidou, and C.S. Pattichis, **Radiogenomics for Precision Medicine with A Big Data Analytics Perspective,** *IEEE Journal of Biomedical and Health Informatics*, pp. 1-17, 2018. DOI: 10.1109/JBHI.2018.2879381.
3. Schiza, E., Matsangidou, M., Neokleous, K. and Pattichis, C.S., 2019. **Virtual Reality Applications for Neurological Disease: A Review.** *Frontiers in Robotics and AI*, vol. 6, pp. 1-14. doi: 10.3389/frobt.2019.00100
4. Pattichis, C.S. and Panayides, **Connected Health**, A.S, *Frontiers in Digital Health*, vol. 1, pp. 1, 2019, Frontiers.
5. Christoforou, E.G., Panayides, A.S., Avgousti, S., Masouras, P., Pattichis, C.S., **An Overview of Assistive Robotics and Technologies for Elderly Care**, *Mediterranean Conference on Medical and Biological Engineering and Computing*, pp. 971-976, 2019, Springer.

Previous projects or activities related to the project subject (max. 5)

- **Integrated National eHealth Ecosystem (eHealth4U):** Co-PI, Research Promotion Foundation, Cyprus, Restart 2016-2020 – Integrated Projects, Oct. 2018 – Apr. 2021, Funding: 1,000,000 Euro
- **Integrated Precision Medicine Technologies Research Centre of Excellence (IPMT)**: EU H2020-WIDESPREAD-04-2017-Teaming Phase 1. Sept. 2017 – Aug. 2018, Funding: 399,999 Euro (UCY 140,287 Euro)
- **Deployment of Generic Cross Border eHealth Services in Cyprus:** EU Innovation and Networks Executive Agency (INEA). Depa–tment C - Connecting Europe Facility (CEF).Unit C4 Energy & ICT [2015-CY-IA-0095]: Jan. 2017 – Dec. 2020, Funding: 593,356 Euro
- **Future Internet Social and Technological Alignment Research (FI-STAR):** Electronic Health Record Application Support Service EIlers (EHR-EN): EU FP7 THEME Future Internet ICT: 604691 [FI.ICT-2011.1.8]: April 2014 – September 2015, Funding: 121,120 Euro
- **A Next-Generation, Secure Linked Data Medical Information Space for Semantically-Interconnecting Electronic Health Records and Clinical Trials Systems Advancing Patients Safety in Clinical Research (Linked2Safety):** FP7-ICT-2011-7, Oct. 2011-Sept. 2014, Funding: 560,600 Euro

Partner Full Name	National eHealth Centre, Ministry of Health of the Czech Republic		
Short Name	**MZCR**	**Partner No.**	10
Country	Czech Republic	**Website**	http://www.mzcr.cz
Type of organisation	Ministry of Health,	**Logo**	MINISTERSTVO ZDRAVOTNICTVÍ ČESKÉ REPUBLIKY

Brief Partner Profile

MZCR is a department (directorate) of the Ministry of Health of the Czech Republic. MZCR is responsible for strategic development and national architecture of the digital health services in the Czech Republic and being part of the ministry bears responsibility for preparation of legislative environment and national standardization in the field of digital healthcare. National eHealth Centre was created in January 2019 by ministerial decision.

Main tasks in Project

MZCR will participate in all key project activities, especially in the activities –f:

WP 4 - Generic Aspects of EHRxF recommenda–ion

WP5 - Definition of EHRxF functional specificat–ons

WP6 - Definition of EHRxF implementable specificat–ons

WP7 - Architecture integration and System specifications

MZCR will be a co-leader of the WP 5, task leader of the task T5.3, active participant in WP4 – with focus on Legal aspects & Enablers and Cyber security, WP6 – with main focus on lab and discharge letter and WP7.

Relevant expertise and experience of the institution

MZCR team, before its formal establishment, developed national e-Health strategy under the umbrella of the MoH. The work was conducted by several workgroups with broad presentation of all relevant stakeholder organizations during period of 2014 – 2016. Strategy document was formally adopted by the Czech government at the end of 2016.

MZCR committed several national projects since its establishment: Strategic management of development of digital health in the Czech Republic, Development of basic digital health infrastructure, Strengthening of the capacity of the Ministry of health in the Czech Republic in its effort to set up a National eHealth Centre, Development of the communication strategy of the Digital Health and Care in the Czech Republic. MZCR team also participated in several EU wide and eHealth network (eHN) projects. As the Czech national authority for cooperation matters in the field of eHealth, MZCR represents Czech Republic to the eHealth network (eHN), the voluntary network of national authorities of Member States responsible for eHealth, and is currently involved as partner in the CEF eHDSI Cross-Border services deployment (on Cross-Border Patient Summary & ePrescription/eDispensation). MZCR is a partner of the eHAction, co-leading one of its Work packages (Cyber security, Data Protection). Furthermore, MZCR actively contributed to several eHAction workgroups: CSS – Common Semantic Strategy WG andIRxF – EHR exchange format workgroup. Recently, MZCR participates in the development of the eHN Guidelines to the MS and EC on an interoperable eco-system for digital health and investment programmes for a new/updated generation of digital infrastructure in Europe.

Key Personnel's CVs (incl. gender)

Martin Zeman – Chief Executive Officer of MZCR ♂, Studied Cybernetics.

He obtained his master's degree in technical cyb–rnetics - medical biocybernetics at the Czech Technical University in Prague and postgraduate Diploma in Management Studies, specialization for management of health service organizations at The Nottingham Trent University. He has several publications in the area of management and informatics in healthcare. He currently works at MZCR as director. MZCR is the national e-Health authority under the Ministry of Health. He was formerly the Chief Information Officer (CIO) of the North Bohemia Regional Hospital Trust. He is aChairman of the Czech Society of Medical Informatics and Scientific Information. Martin is responsible for nationwide strategy and implementation of the digital health services in the Czech Republic.

Jiri Borej – leading eHealth architect, ♂, Studied Electrical Engineering.

Jiří Borej holds a master's degree in the Electrical Engineering at the Czech Technical University in Prague. He works 12 years in ICT management positions in top management of international TELCO companies, over 12 years as business consultant. He has been awarded the highest ISACA certification –f CGEIT - ISACA (Certified in the Governance of Enterprise IT). He is currently working for the Ministry of the Czech Republic in several roles: Major Enterprise Architect of eHealth, Head of Department, and member working group of Government Council for Information Society.

Tomas –ezouska - Cyber Security manager,♂, Studied Information sciences and economics.

Tomáš Bezouška graduated with a'bachelor's degree (Bc.) in information sciences and economics at the Faculty of Economics of Technical University of Liberec. He was certified as a Certified Information Systems Auditor (CISA) by Information Systems Audit and Control Association (ISACA). In 2010 has Tomáš Bezouška cofounded the Czech Republic Group of the Information and Records Management Society (IRMS CRG) and was elected its President. In 2016 IRMS CRG was transformed to non-profit organisation (IPSD) closely cooperating with both central and local government institutions in areas of records management, personal data protection and digitisation of public administration and Tomáš Bezouška was confirmed as a President of IPSD. Mr. Bezouška is a member of the Cyber Security Council of the Office of the Government of the Czech Republic and a Cyber Security Architect of the Ministry of Health of the Czech Republic. He regularly lectures and publishes in areas of Records Management, Data Protection, Cyber Security and Personal Data Protection.

Hynek Kruzik – Senior Consultant, ♂, Studied Cybernetics.

Hynek graduated in technical cyb–rnetics - medical biocybernetics at the Czech Technical University of Prague. He works in healthcare sector since his graduation. Since 2006 he started his freelance healthcare IT consultancy carrier and he conducted many international healthcare ICT and consultancy projects in Europe, Asia and Central America where he utilized his long-term experience from development of healthcare information systems, regional and national digital health solutions. Hynek also worked with Hewlett-Packard (HP) as a member of the CEE Business Development Group. Hynek works as external consultant of the Czech Ministry of Health since 2013. He is one of the key contributors to the Czech National eHealth strategy 2016-2020 and Digital Health Semantic strategy of the Czech Republic. Hynek is currently a national representative of the Czech Republic in the European Union eHealth Digital Service Infrastructure semantic woIroup, EHR exchange format (EHRxF) workgroup and EU Common strategy workgroup (CSS). He is responsible for semantic interoperability in cross border services project and for preparation of new projects in the area of digital health and standardization. Hynek is a leader of the semantic WG of the Czech MoH. He is a member of

the Czech HL7 affiliate office, Czech Society of Medical Informatics and Scientific Information and Czech National e-Health standards WG.

Milan Cabrnoch, M–D., MBA - Senior Consultant, ♂, Studied Medicine

Milan Cabrn70nalyse7070abiliatrician. He graduated from the Faculty of Pediatrics of Charles University in Prague. He has two attestations in paediatrics. He worked at the'children's ward of the hospital. Later he worked at the Ministry of Health as a deputy minister responsible for public health insurance and legislation and was a member of the Parliament of the Czech Republic and the European Parliament.
Now Milan Cabrnoch works as an independent consultant in health and social care. He teaches at the CEVRO Institute in Prague. Milan is currently working as s head of the eHealth education centre at the Institute of Postgraduate Education in HealthCare. In 2007 Milan established the NGO Czech National eHealth Forum and still is a chairman of it. He has been involved in eHealth issues for many years, specifically in areas such as PHR and health pro'essional's education.

Petr Tu–a, M.D. - Clinical terminology specialist, ♂, Studied Medicine

Petr Tůma has M.D. diploma from the Charles University in Prague. He worked as an endoscopist and later as a manager of healthcare facility. He is expert in clinical terminology and clinical coding systems and medical data analyst. Petr is a member of the Czech national semantic WG and participates in the work of the eHMSEG semantic workgroup.

Eliska Urbancova – Project management specialist ♀, Studied Project management

Eliška Urbancová is a project manager. She graduated with a'bachelor's degree (Bc.) in management and economics at the Faculty of Economics and Management of the Czech University of Life Sciences in Prague. She obtained her master´s degree (Ing.) from project management at the same faculty. Eliska has Prince2 Foundation certificate in project management. Currently she works as a project manager in Department of the National eHealth Centre for the Ministry of Health.

Irena Rubeso–a, M.D. - Clinical terminology specialist, ♀, Studied Medicine and Mathematical and Computer Sciences

Irena Rubesova has M.D. diploma from the Charles University in Prague (1999) and graduated with a'bachelor's degree in Mathematical and Computer Sciences at the University of Nimes in France (2014). She worked as an internist and later as DRG hospital manager. Currently she works as terminologist in Department of Clinical Classifications in the Institute of Health Information and Statistics of the Czech Republic.

Relevant publications, products, services, or other achievements (max. 5)
List of relevant publications: MZCR team prepared a national e-Health strategy for 2016-2020 of the Czech Republic and e-Health Action Plan. Both documents were adopted by the Czech government. MZCR established a catalog of national e-Health standards, standards development processes, and basic e-Health Dictionary system. MZCR prepared several legislative norms: regulation on national Patient Summary and new e-health law that will be sent to the parliament in 2020.
Previous projects or activities related to the project subject (max. 5)
• eHAction • eHDSI (CEF) • EPSOS • ANTILOPE • PROREC

Partner Full Name	Vysočina Region		
Short Name	**Vysocina**	**Partner No.**	11
Country	Czech Republic	**Website**	www.kr-vysocina.cz
Type of organisation	Regional Governing Authority	**Logo**	Vysočina Region

Brief Partner Profile

Vysočina Region Regional Authority is the governing body of the Vysočina Region, which is located in central part of the Czech Republic. In the past few years, Vysočina has profiled itself as one of the leading public authorities in using advanced solutions in information and communication technologies. The region has built its own backbone optical“network”"ROWANet", which allows for fast and reliable data transfer in public administration, among emergency rescue services and non-commercial data connections for wide public. The IT Department of the regional authority has been involved in a number of European projects.

Vysočina Region has been playing a major role in the implementation of eGovernment and the electronization of health care (eHealth), particularly the eMeDocs project (the Exchange of Medical Documentation System among medical facilities of the region).

In the implementation of eHealth projects, Vysočina Region relies on good cooperation with the Ministry of Health of the Czech Republic, Institute of Health Information and Statistics of

the Czech Republic, Office for Personal Data Protection of the Czech Republic as well as its own legal department.

Main tasks in Project

Vysočina Region will take part as the co-leader of **WP 4 – Generic Aspects of EHRxF recommendation. –ask 4.2** - Legal Aspects and Enablers.

And as a partner in **WP7 – Architecture integration and System Specification** – **Tasks 7.3** (Needs for upgrade of eHDSI core and generic services) and **7.4** (Guidance for the new EHRxF domains).

Relevant expertise and experience of the institution

Vysočina Region currently maintains and operates the NCPeH for Czech Republic, on the basis of authorization by the Ministry of Health, for 2 services – patient summary (country A and B) and ePrescription/eDispensation (country A and B). PS service is in operation, eP/eD service is foreseen to enter operation in 2020/21.

Key Personnel's CVs (incl. gender)

Mr. Petr –avlinec - head of the Vysočina Region IT Department, operational manager and main architect of NCPeH for Czech Republic.

Mr. Jarosla– Krotký - head of the regional Applications and Database Maintenance Unit, technical manager of NCPeH, responsible for OpenNCP implementation.

Mr. Milan Lysa – senior programmer, technical worker of NCPeH, responsible for OpenNCP implementation.

Ms. Klára –iráková - lawyer and coordinator of national and international projects carried out by the IT department, NCPeH CZ system coordinator, project manager of the CEF eHealth project, and co-chair of the eHealth Member State Expert Group, eHDSI Legal Work Group co-lead, Patient Summary Cluster WG co-lead.

Mr. Dominik Marek – IT security lead of NCPeH Czech Republic, cybersecurity manager of Vysočina Region Regional Authority.

Relevant publications, products, services, or other achievements (max. 5)

- Successful implementation of the eHDSI National Contact Point of Czech Republic, cross-border exchange of patient summary (A and B). Currently working on the implementation of cross-border exchange of ePrescription/eDispensation.

- Operator of the regional medical exchange platform eMeDocS.
- Co-author of the national Ordinance on Medical Documentation – Patient Summary.
- Working on national methodology for Patient Summary.

Previous projects or activities related to the project subject (max. 5)

- Co-ordinator of the Czech Inter-regional eHealth Work Group
- Project partner in the CEF HEALTHeID project.

Partner Full Name	Ministry of Social Affairs/Health and Welfare Information Systems' Centre		
Short Name	MSAE /HWISC	**Partner No.**	12
Country	Estonia	**Website**	www.sm.ee
Type of organisation	Public organization/eHealth Agency	**Logo**	SOTSIAALMINISTEERIUM TERVISE JA HEAOLU INFOSÜSTEEMIDE KESKUS

Brief Partner Profile

The Ministry of Social Affairs of Estonia operates under the vision that Estonia should be a sustainable and innovative country, which is socially and economically balanced, where viable family relationships, common social cohesion, and high-quality living environment would be the basis for the social sense of security, well-being, and a high standard of living.

The role of the Ministry of Social Affairs is to plan health and social care policy and to organise its implementation. We operate in the field of social security, where we have set for ourselves five strategic objectives:

- to ensuse people's economic prosperity and their good work;
- to ensuse people's social coping and development;
- to support the well-being of children and families;
- to promo'e people's mutual care, equal opportunities, and gender equality;
- to ensu'e people's long and high-quality life.

MSAE achieves this through a variety of actions:

- Compiles solution plans for 'he state's social issues and manages their implementation.
- Designs and implements the policy in the field of social security, ensures timely and targeted granting and payment of social insurance benefits.

- Manages social insurance and welfare services.
- Develops and implements the working life and labour market policy, in order to ensure prevailing of people with long-term working capacity and employment.
- Organises the protection of public health, as well as medical care.
- Promotes the equal treatment'of women'' and men's equality, in order to incorporate different social groups into the life of the society.
- Deals with social welfare and social security issues of disabled people.
- Coordinates the formulation of policies on'children's rights and child protection, and organises international adoptions.
- Shapes the family policy, which sets a priority of collocation of working life and private life, as well as parental education.
-

Further, the eHealth Strategy of the Ministry outlines five key priorities

- High-quality health information and an infrastructure of health data.
- Focus on persons and personal medicine.
- Comprehensive case management and cooperation of organisations.
- Effectiveness of health services and capacity for analysis.
- Development of remote services.

The Health and Welfare Information Systems' Centre is the state's e-services agency that operates under the Ministry by providing technical expertise and services to achieve the goals of the Estonian social security system. Among their areas of expertise are e-health interoperability & semantics and cybersecurity.

Main tasks in Project

MSAE /HWISC shall be contributing–to:

WP4 - Generic Aspects of EHRxF recommendat–on

WP5 - Definition of EHRxF functional specificat–ons

WP6 - Definition of EHRxF implementable specifications

Relevant expertise and experience of the institution

The Ministry has overseen the development of the Estonian e-health system alongside HWISC and its predecessor the Estonian e-Health Foundation. Estonia has implemented numerous digital services within healthcare including a state-wide interoperable electronic health record. MSAE /HWISC is the official representative of Estonia in the eHealth Network and has actively contributed to discussions around eHealth interoperability in generalId the EHR Exchange Format in particular. We are also permamently represented in the eHMSEG,

the subgroup on the implementation of the Commission Communication on the Digital Transformation of Health and Care and the working group on the Common Semantic Strategy. MSAE /HWISC was the co-chair of the mHealth subgroup of the eHealth Network and is the current leader of the eHAction Work Package on Empowering People, with particular regard to mHealth and Telehealth. MSAE /HWISC have also contributed to eHAction work packages on enhancing continuity of care, overcoming implementation challenges (data protection & interoperability guidelines) and integration into national policies. MSAE /HWISC is also a member of the Global Digital Health Partnership, the International Consortium for Personalized Medicine, SNOMED, HL7 and the 1 Million Genomes Initiative. MSAE /HWISC were responsible for implementing the CEF cross-border digital prescription in Estonia with HWISC as the NCC.

Key Personnel's CVs (incl. gender)

Dr Priit Tohver, MD, male, is the Advisor for E-Services Innovation at the Ministry of Social Affairs in Estonia, overseeing the digital transformation and innovation of health and welfare systems in Estonia. Priit's core function is to direct global cooperation in e-health between Estonia and a variety of stakeholders. He is the official representative of Estonia in the eHealth Network and the Global Digital Health Partnership. He thus works closely on cross-border interoperability issues both for the primary and secondary use of health data. He is the project manager on behalf of Estonia in the 3rd Joint Action to support the eHealth Network and is leading the effort to reform the secondary use of health and social data within Estonia. He is also a member of the board at the Digital Health Society, an ecosystem of activists within digital health founded under the Estonian presidency of the Council of the EU. He is a doctor by training and has previously served as an advisor to the Estonian Mission in Geneva on diplomatic matters related to health, development and trade, covering organizations such as WHO, UNCTAD and WTO. Priit also has six years of experience as a civil society and global health activist, having also served as the Regional Director for Europe at the International Federation of Medical Students' Associations (IFMSA).

Kristel Niidas, female, MA (law). Kristel is working as a legal adviser at the Ministry of Social Affairs. She is responsible for the legal aspects in digital development including Estonia´s Health Information System and provides legal support for cross border data exchange issues.

Nele Nisu, female, MA (Law). Nele is working as a Legal Adviser at the Ministry of Social Affairs and deals with various topics concerning legislative drafting and among other issues provides legal support in all aspects of privacy and data protection.

Katre Pruul, female, MSc. Katre is a semantics expert, who was formerly the Estonian representative in eHMSEG as well as the project lead for the implementation of the cross-

border patient summary. She has previously contributed to the eHAction consortium for future eHDSI use cases and the development of a Common Semantic Strategy.
Relevant publications, products, services, or other achievements (max. 5) - Successful implementation of CEF cross-border digital prescription exchange (both Country A and Country B) and continued work in implementing cross-border Patient Summary. - Contributor to Common Semantic Strategy, Roadmap for future eHDSI use cases and interoperability guidelines for hospital CIOs, lead author of framework for people empowerment under 3rd Joint Action to support the eHealth Network. - Responsible entity for SNOMED CT Estonian extension to be released in autumn of 2019. - Implemented numerous digital solutions in the Estonian healthcare system e.g. patient portal, sIewide EHR, e-consultation, e-ambulance, e-booking etc. Responsible for e-health standards and publishing centre. - Responsible for drafting EU council conclusions on health in the digital society, covering also data interoperability issues.
Previous projects or activities related to the project subject (max. 5)
The drafting of the Estonian E-Health Strategic Development Plan 2015-2020 was a multistakeholder process focusing on, among other things, high quality health data infrastructure, laying down a 5-year strategic plan for the reinvention of our national health information system. This plan has been further developed into the New Generation Health Information System roadmap by MSAE /HWISC.

Partner Full Name	Agence des Systèmes d'Information Partagés de Santé (ANS)		
Short Name	**ANS**	**Partner No.**	13
Country	France	**Website**	https://esante.gouv.fr/
Type of organisation	Public organisation/ eHealth Agency	**Logo**	asipsanté L'AGENCE FRANÇAISE DE LA SANTÉ NUMÉRIQUE
Brief Partner Profile			

ANS, the French Agency for eHealth, was created in 2009 and works under the auspices of the Ministry of Health. The agency is in charge of the implementation of the digital transformation of the health system.

The main mission of ANS is to build an environment of trust to allow secure share and exchange of personal health data in compliance with the new legal framework (2016/01 health Modernisation Law). The Agency is also mandated to implement strategic national eHealth programs, maintain the (French) Health Terminologies Management Center (HTMC, Centre de Gestion des Terminologies de santé, CGTS, in French) and works on different projects such as the secure health emailing system (MSSanté) or the modernization of the hospital emergency departments information and telecommunication systems (SI-Samu).

ANS fosters the development of the eHealth ecosystem in order to create value, and participates in the construction of cross-border eHealth information services. ANS has been present since 2008 at European level, both on strategical and operational levels, by actively participating in European projects such as epSOS, JAseHN, CEF eHealth, EURO-CAS, eHAction…

Main tasks in Project

ANS will be a partner in 3 work packages:

- **WP5 – Definition of EHRxF functional specifications**
- **WP6 – Definition of EHRxF workflow and technical specifications**
- **WP7 – Architecture integration and System specifications**

ANS intends to provide its expertise and experience on some of the new uses cases introduced by t77nalyse7777abilimandation especially laboratory results and hospital discharge reports that have, with patient summary, already successfully been defined and deployed in France at national level.

Moreover, ANS will also make available its knowledge of the eHDSI Patient Summary both as coleader of the Patient Summary cluster and French National Contact Point for eHealth (NCPeH) to help assess impacts on the current Patient Summary specificiations as well as on the eHDSI core and generic services.

Relevant expertise and experience of the institution

European expertise and experience

As part of the CEF eHealth project, ANS is mandated by the Ministry of Health as the National Contact Point for eHealth (NCPeH). Very involved in the achievement of this European project, the agency is co-leader of the Patient Summary Cluster and also an active participant of the different eHDSI working groups (semantics, legal, technical, etc.).

With regards to the eHAction joint action, ANS acts with two roles: it is the risk manager and also active partner of different work packages, particularly on empowerment people, future us77nalyse7777abilityerability guidelines, legaIspects... Moreover, the agency has a coordinating role in the work package on Integration in national policies and sustainability.

ANS has also active members in the European IHE's consortium.

National expertise and experience

ANS has developed and is responsible for maintaining the Health Information Systems Interoperability Framework (HIS-IF) based on international standards and norms. It is built on a strong structure of 3 layers (content, service and transport) including functional and technical specifications as well as end-user systems integration requirements:

- Content layer: Specification of exchanged or shared content in terms of structure and vocabularies;
- Service layer : Specification of content sharing or exchange services, their rules and usage parameters;
- Transport layer: Specification of exchange protocols used by services.

This interoperability framework has been fully implemented when ANS was building the Iional EHR, the DMP (Dossier Medical Partagé) in 2009. As of today, DMP platform has more than 7 millions users all over the country and aims to reach 40 millions in 2023, demonstrating the usability and efficiency of the adopted standards.

This framework is public and used by all the eHealth ecosystem in France including local or regional health institutions, private vendors, health professionals assIations...

The content layer defines more than 20 different types of medical document, the most relevant for this project being laboratory results and hospital discharge reports.

On top of the classic layers of interoperability, ANS has also worked on a conceptual interoperability layer that allows to manipulate health objects (MOS: “Modèle des objets de Santé”). The main advantage of this approach is to be able to share the same understanding of various sources of data standards. These objects are compliant with international standards such as the FHIR (Fast Healthcare Interoperability Resources) Specification.

Key Personnel’s CVs (incl. gender)

Pascale Sauvage, ♀**,** is the Deputy Director at ANS since July 2019. Previously, she was Director of strategy at ANS from 2014 to 2018, before becoming Interim Director of ANS between 2018 and 2019. Pascale is an expert in leading large public organizations and information systems projects. Graduated in political public bodies before joining ministry of finance in 2002 to implement a new financial system. Since she joined the public health sector in 2006, Pascale has been participating in strategic projects and also managed a wide range of international activities, specifically with Europe and Quebec.

Angelica Cavalcante Galvão, ♀**,** is Project Manager at ANS since 2012. Previously working in the eHealth projects department, she joined the direction of strategy in 2017. She was then appointed to coordinate the European eHealth projects in which ANS is involved, in particular CEF eHealth and the joint actions JASeHN and eHAction. As part of the eHAction project, Angélica Cavalcante Galvão is in charge of the risk management and leads the operational team working on the work package Integration in National policies and sustainability. Formerly, Angélica Cavalcante Galvão was responsible for the accreditation of information systems for the Iional EHR, DMP (Dossier Médical Partagé), and also in charge of the project of certification of information systems for MDPH (Institutes for Disabled People)

in France. Computer Engineer for Health Information Systems, she has also a Masters Degree in Innovation from Paris-Saclay University.

Florence Eon, ♀, is Legal expert specialized in health, new technologies and data protection Law, Florence Eon has started in healthcare facility, then in law practice and since 2012 she is working in the legal department of ANS. She takes on the role of IT and freedom correspondent at ANS. Since October 2014, she was appointed director of the legal department. She contributes to define the legal framework of eHealth major projects, as the secure health emailing system. She was actively involved in legal tasks of JAseHN and she took part in the elaboration of D6.2 AGREEMENT between National Authorities or National Organisations responsible for National Contact Points for eHealth on the Criteria required for the participation in Cross-Border eHealth Information Services. Currently, Florence Eon is a member of the the Legal Work Group of the CEF eHealth project.

Thierry Dart, ♂, is Assistant-Director of the medical affairs department at ANS since 2017. Beforehand he worked in the agency for more than 5 years as research manager. Medical doctor with a Master Degree in Computer Science, specialized in healthcare software applications, Thierry Dart is a semantic expert and an HL7 CDA spe79nalyse79actively involved in the IHE community. He was also a committed leader for the implementation of the Health Record Systems (HRS) at –he HEGP - European Hospital Georges Pompidou (one of the most computerized hospital in France).

Alain Périé, ♂, is a Program Manager for semantic interoperability at ANS. Very committed in the eHealth policies area since 2006, he has participated in several French projects: Iional EHR (DMP), the secure health emailing system (MSSanté), Cancer Services. He is now member of the medical affairs department defining guidelines for semantic interoperability at the national level. At the European level, he has been in charge of managing the epSOS project at ANS. He has participated in several work packages and took part in the deployment of the national pilots of the epSOS project performed in several French Universities, in coordination with the ERASMUS program. He was also in charge of the risk management of the epSOS project and the JAseHN project.

Emmanuel Clout, ♂, is Interoperability Project Manager in the medical affairs department at ANS, since 2016. Since 2018, he worke79nalyshe french specification of laboratory report according to Sharing Laboratory Reports Integration Profil (XD-LAB) and the maintenance of LOINC for France. Before, he was Projet Directo79nalyshe french Electronic HealthIrd, konwn as “DMP”.

Manuel Metz, ♂, is a security and interoperability senior engineer at ANS since 2007, Manuel Metz is in charge of defining French security and interoperability frameworks for Health Information Systems. As such, he is co-author of all transport and service layer documents in the Health Information Systems Interoperability Framework and many documents of the General Security Policy for Health Information Systems on various topics including non-repudiation, identification and authentication. Actively involved in the IT Infrastructure domain of IHE since 2007, he has been co-chair of the ITI technical committee from 2008 to 2010 and is participating to North American and European connectathons where he is a reference monitor on XD profiles as well as a trainer for new monitors. At the European level, Manuel Metz contributes to the EURO-CAS project (H2020 program). This project aims at maintaining and developing the adoption and take-up of testing the interoperability of ICT solutions against identified eHealth standards and profiles defined in the eHealth European Interoperability Framework (eEIF).

Relevant publications, products, services, or other achievements (max. 5)

The most relevant national achievements of ANS for this project are :

- French Health Information Systems Interoperability Framework (HIS-IF) including patient summaries, laboratory results and discharge reports
- MOS : “Modèle des Objets de Santé » describing from a functional perspective and use-case agnostic way how to deal with health data
- French Health Terminologies Management Center (HTMC, Centre de Gestion des Terminologies de santé, CGTS, in French)
- National eHealth services : Secure health emailing system (MSSanté) used in the whole country to securely exchange patient health data between health professionals; Iional EHR, DMP (Dossier Medical Partagé)
- Global security policy (PGSSI): This policy refers to the best health practices in terms of information systems security. It contains organizational, legal, technical best practices than can be used by different kind of stakeholders (software vendor, health professionals, patients, CIO…)

Previous projects or activities related to the project subject (max. 5)

ANS has already been involved in several European eHealth projects, mainly :

- **epSOS** project piloting cross border Patient Summary (country A and country B) and gaining first experience in deploying operational solutions (real patient data) for cross border services
- **JASeHN, as risk manager and active partner** especially on work packag–s **:**
  - WP5 - Interoperability & Standardizatio– :
    - T5.1 - Trusted eHealth National Contact Poin–s,
    - T5.2 - Electronic Identification for eHeal–h,
    - T5.4 - Alignment of standardization activities in eHeal–h,
    - T5.5 - Semantic Interoperabili–y,
    - T5.6 - CEF operational suppo–t ;
  - WP6 - Monitoring & Assessment of Implementatio– :
    - T6.1 - Implementation of eHealth guideline–,
    - T6.2 - Legal challIes of EHR systems in the MS in the cross-border context and recommendations on how to fill the gaps (with special emphasis on the implementation of the new Data Protection Regulation);
  - WP7- Exchange of Knowledg– :
    - T7.1 - Sharing of national eHealth strategies and action plans,
    - T7.3 - Research on added value eHealth too–s,
    - T7.5 - Patient access to electronic health records.
- **CEF eHealth,** as national contact point for eHealth (NCPeH) and also as an active member of the following working groups :
  - Patient Summary Cluster, as co-leader
  - Business requirement WG
  - Semantic Task Force
  - OpenNCP Community Working Groups
  - OpenNCP Steering Working Group
  - Technical Working Group
  - Legal Work Group
- **eHAction**, as risk manager and especially active on work packages **:**

- WP1 – Coordination (Risk Manager)
- WP4 – T4.1 mHealth and health apps reliability
- WP6 – T6.2 Support of legal eHDSI matters
- WP7 – T7.1 Implementing interoperability guidelines to cross-border health services
- WP8 – T8.1 (Co-leader) National and international eHealth strategies
- WP8 – T8.3 Post 2021 scenarios for eHealth policy cooperation

Partner Full Name	Ministry of Solidarity and health		
Short –ame	**MoH - FR**	**Partner No.**	14
Country	France	**Website**	www.sante.gouv.fr
Type of organisation	Public organisation	**Logo**	Ministère des Solidarités et de la Santé

Brief Partner Profile

The Ministry of Solidarities and Health is responsible for laws, regulations and national policies within the fields of health, public health, medical and social care, patient safety & security and social services. The ministry is coordinating eHealth policies as well as proposing and following -up of the National Strategy for eHealth through a dedicated permanent structure. This permanent structure is also coordinating the French eHealth Agency (ANS). The French electronic health patient record DMP (Dossier Medical Partagé) was created by law then designed and launched by ANS in 2011. In 2016, a new legal framework had delegated the DMP to the National health insurance fund (CNAM see below) which will progressively be in charge of running the system. In France, DMP is the vehicle to share French Patient Summaries (Volet de synthèse médicale). Both ANS and CNAM, under the coordination of the French Ministry of health have built a solid relationship of confidence that will be a strong asset in the conduct of national programmes and projects.

Main tasks in Project

WP4 - generic aspects of the EHRxF recommendation

- T4.2: Legal aspects & enab–ers

WP5 - definition of EHRxF functional specifications

- T6.1: Definition of technical specification for the Laboratory Domain

- T6.5: Publication and maintenance of the services specifications and testing t–ols

WP7 - architecture integration and system specifications

- T7.4: Guidance for the new EHRxF domains

Relevant expertise and experience of the institution

The ministry is coordinating eHealth policies as well as proposing and following-up of the National Strategy for eHealth through a dedicated permanent structure. This permanent structure is also coordinating the French eHealth Agency (ANS).

MoH-FR was/is involved in many European programmes and projects on Health and eHealth such as CALLIOPE, ePSOS, SemanticHealth, eHGI, Trillium, JAseHN, ASSESS-CT, ValueHealth, eHAction as well as in studies, conferences and strategic plans at international level (OECD, WHO, ITU…).

Acting as the French eHealth authority, MoH-FR has coordinated the French participation in all the projects mentioned above, led the interoperability roadmap in Calliope, led the international cooperation with WHO and oECD in JAseHN as well as proposed a semantic interoperability roadmap and under the umbrella of eHAct–on (WP8 - Leader) for the the post 2021 sustainability plan preparation on the health data exchanges between Member States in the EU.

Key Personnel's CVs (incl. gender)

Dr **Michèle Thonnet**, (female) neuropharmacologist, PhD, Michèle Thonnet is also graduate in applied mathematics and medical informatics, political sciences and public law and from the industrial strategies institute. She is a health, information systems and security specialist, with more than 30 years of experience and over 190 publications. Michèle was assistant professor in Paris University, researcher at INRIA (National research institute in computer sciences and automatic). She used to hold different positions in the pharmaceutical industry as well as the IT one (international standardization) and works many years in AP-HP hospitals. In the ministry of health after several years in the IT directorate, she organised and works six years for the transversal department on information system integration in policies at IGAS (General inspection of the MoH). Under the umbrella of the general secretariat of the ministry, she actively participated to the discussions and negotiation for the French government on several European texts (eIDAS, GDPR,…). She is the official representative of the French ministry of Health, member of the eHealth Network set up under the art 14 of the DIR 2011/24/EU.

Michèle was/is involved in many European programmes and projects on Health and eHealth such as CALLIOPE, ePSOS, SemanticHealth, eHGI, Trillium, JAseHN, ASSESS-CT, ValueHealth, eHAction as well as in studies, conferences and strategic plans at international level (OECD, WHO, ITU…). For example she has coordinated the French participation in all the projects mentioned above, led the interoperability roadmap in Calliope, led the international cooperation with WHO and oECD in JAseHN as well as proposed a semantic interoperability roadmap and under the umbrella of the eHAction she presently leads the post 2021sustainability plan preparation on the health data exchanges between Member States in the EU.

Thomas David, (male)**,** is policy officer at DSSIS. He's in charge of monitoring the work programme of ANS and improving processes between ANS and its stakeholders. Thomas is a high ranking public servant specialized in IT technologies. Before joining in the Ministry of

Health, he was leading a software development team (30+ developers) for the IT team of a French ministry and has as strong experience in complex IT projects. Since his arrival at MoH, he participated in the CEF project like the Boot Camp in February.

Relevant publications, products, services, or other achievements (max. 5)

Not applicable.

Previous projects or activities related to the project subject (max. 5)

- eHealth Action
- CALLIOPE
- ePSOS
- SemanticHealth
- JAseHN

Partner Full Name	German Institute of Medical Documentation and Information		
Short Name	**DIMDI**	**Partner No.**	15
Country	Germany	**Website**	www.dimdi.de
Type of organisation	Public organisation	**Logo**	DIMDI medicalknowledge German Institute of Medical Documentation and Information

Brief Partner Profile

The German Institute of Medical Documentation and Information (DIMDI), an authority within the German Federal Ministry of Health, provides high-quality information for all areas of the health system via Internet. It publishes official medical classifications and maintains medical terminologies, thesauri, nomenclatures and catalogues.

In addition, DIMDI develops and operates database-supported information systems for drugs, medical devices, clinical studies, health technology assessment (HTA) and health care data. DIMDI designs and maintains modern software applications for online access to its information systems and operates its own computer centre.

Main tasks in Project

DIMDI main contribution will be in **WP 5 – Definition of EHRxF functional specifications,** T5.6 Refine PS functional specifications to account for eHN Guidelines and rare diseases.

Relevant expertise and experience of the institution

DIMDI (German Institute of Medical Documentation and Information) publishes official medical classifications and provides additional terminologies and standards for the health care system on behalf of the German Federal Ministry of Health (BMG).

DIMDI contributed with its expertise on standardisation, coding and semantics in a number of European eHealth projects.

There is a close collaboration between DIMDI and the World Health Organization on the maintenance of ICD-10 and ICD-O-3 and for further development of new terminologies in healthcare (diagnoses, procedures, functioning and disability covering also medical Devices and active substances) . To institutionalize this collaboration, DIMDI was designated WHO Collaborating Center for the Family of International Health Classifications. DIMDI is participating in the work of several committees of the WHO Collaborating Centers since several years and is active in the Joint Task Force on ICD-11.

DIMDI is in close cooperation with Regenstrief Institute for LOINC and maintains the LOINC translation into German for Germany.

In Health Telematics and eHealth, in particular, only a consistent use of standards can ensure interoperability. For that reason, the DIMDI is member of a range of standardisation committees in an advisory role.

Key Personnel's CVs (incl. gender)

The DIMDI classification team comprises of medical doctors and pharmacists with expertise in medical informatics as well as classifications and terminologies, computer scientists specialized in medicine, health information managers and team assistants. The classification team is part of the medical information departm84nalyseth approx. 50 employees from all fields of biosciences. This project can therefore rely on a widespread knowledge if need arises. In particular the following persons will be involved:

Stefanie Weber, ♀, MD, is the lead of the medical vocabularies unit at DIMDI.. She is head of the German WHO Collaboration Centre for the Family of International Classifications and active in several WHO committees. She oversees and coordinates a number of projects in healthcare in Germany with semantic context, for example on electronic death certification or on rare diseases. She is involved in European activities as RD Action, RD-Code and Common Semantic Strategy.

Christine Haas, ♀, studied pharmacy with specialization in drug information. She has a working experience in hospital pharmacy and regulatory clinical product development. At DIMDI, she gained experience as Project Manager for development and implementation of registries and information systems. As a Member of DIN and ISO, she is involved in standardization activities. On behalf of the German Ministry of Health and the German Regulatory Agencies she was and is involved in interoperability and standardization projects in healthcare and advisor in telematics projects. Currently she is also member of the eHDSI Semantic Task Force.

Relevant publications, products, services, or other achievements (max. 5)

- Marx MM, Dulas, FM, Schumacher, KM: Improving the visibility of rare diseases in health care systems by specific routine coding (Verbesserung der Sichtbarkeit seltener Erkrankungen in Gesundheitssystemen durch spezifische Routinekodierung). Federal Health –ulletin - Health –esearch - Health Protection, May 2017.
- Dulas FM, Marx MM, Hebestreit H, Himstedt C, Mohnike K, Mücke M, Ripke A, Stieber C, Tunc S, Weber S: How to improve the codification of RD with ICD-10 and Orphacodes. ECRD 2018
- Faccin P, Mazzucato M, Dulas FM, Marx MM, Weber S, Angin C, KRamdi F, Salamanca E, Messiaen C, Orly A, Rath A: Orphacodes' use for the codification of rare diseases: results of the testing activity carried out within the RD-Action framework. ECRD 2018
- Dulas FM, Marx MM, Kirch K, Angin C, Kramdi F, Messiaen C, Salamanca E, Mazzucato M, Facchin P, Weber s: Recommendation and Guidelines for the Coding with Orphacodes. GMDS 2018
- Dulas FM, Marx MM, Angin C, Choquet R, Facchin P, Weber S: How to make rare diseases visible in European healthcare systems. ECRD 2016

Previous projects or activities related to the project subject (max. 5)

The following EU-projects include involvement of DIMDI:

- epSOS project
- RD-action (DIMDI was WP5 lead) (www.rd-action.eu)
- RD-Code (ongoing) (www.rd-code.eu)
- eHMSEG Semantic Task Force

National projects (relevant for this proposal):

- "Coding of rare diseases 1+2" (https://www.dimdi.de/dynamic/en/classifications/icd/alpha-id/)

Partner Full Name	gematik – Gesellschaft für Telematikanwendungen der Gesundheitskarte mbH		
Short Name	**GEMATIK**	**Partner No.**	16
Country	Germany	**Website**	https://www.gematik.de/
Type of organisation	Competence Center	**Logo**	gematik

Brief Partner Profile

gematik was founded in 2005 by the 15 top organizations of the German Health System. gematik is the non-governmental body responsible for telematic applications of the eHealth card and the health telematics infrastructure in Germany and acts as the national competence centre for EHealth. gematik is mandated to introduce, maintain and develop further the eHealth card and its corresponding telematics infrastructure. This infrastructure is the platform for various healthcare applications thus connecting all parties within the healthcare

system and facilitating secure data exchange. The eHealth card forms the key for this data exchange.

gematik issues the specifications based on which the national telematics infrastructure is implemented and operated.

gematik closely works with the Federal Ministry of Health, the Federal Office for Information Security (BSI) and the Federal Commissioner for Data Protection and Freedom of Information (BfDI).

Main tasks in Project

Gematik will be the task leader of **T5.1: X-eHealth use cases driven methodology** and takes part in most of the content-related work packages and tasks. Gematik will contribute to the CSA mainly with its technical, semantical and strategic experience in diverse eHealth areas.

Relevant expertise and experience of the institution

- gematik is responsible for the health telematics infrastructure in Germany and is also the national competence centre for eHealth.
- gematik introduces, maintains and develops further the eHealth card and its corresponding telematics infrastructure.
- gematik issues the specifications based on which the national telematics infrastructure is implemented and operated.
- gematik commands all necessary competencies and is the key player in all eHealth activities under the auspices of the German health system.
- gematik was part of the epSOS, EXPaND and JAseHN consortia and is part of HEALTHeID and eHealthAction consortia.
- gematik coordinates the German consortium under CEF eHealth.

Key Personnel's CVs (incl. gender)

Andreas Grode (Male), Head of Section "Innovation" at gematik, Expert in the working group "Interoperability", "Cards" and "Security" and Vice-Chair of section "Medical Informatics" at DIN, Member of the technical committee of HL7 Germany, former Rapporteur (Chairman) of the last AdHoc Group "eEHIC" of CA.SS.TM (EU DG EMPL); former Project Manager in epSOS Technical Project Management. He is chairman of the EHTEL/ELO-Group and member of the Board of Directors of EHTEL (European Health Telematik Association).

Beatrice Kluge (Female) holds a master's degree in medical information technology. At gematik she works in the section "Innovation" on a number of future applications related to the electronic health card and the national infrastructure. In that capacity she is frequently involved with the stakeholders of the German health system and the reconciliation of diverse interests in the various bodies and project groups of gematik. Within JAseHN she was in charge of eID, of health professional registries and of Stakeholder Liaison with EC's eHealth Stakeholder Group. She is work package and task leader as well as member of the Leadership and Steering Council of eHealthAction.

Christof Gessner (Male), Dr. rer. nat. (PhD), graduated in Physics, PhD, post-graduate study in Medical Physics. 20 years professional experience in Medical Informatics and healthcare IT, including experience as product manager, and as an independent consultant. Working at gematik since 2012 in the department of Innovation, he is responsible for healthcare IT standards and standardization in the context of establishing the national healthcare IT infrastructure in Germany. Currently, he is also chairman of HL7 Germany, the national Affiliate of Health Level Seven International (HL7). He actively contributes to European projects, acting as a task leader in eHealthAction, and as a leader of the Architecture Work Group of the eHMSEG Semantic Task Force.

Anna Wolfe (Female), PhD, in the telecommunications sector Anna worked as a senior project manager in technical development bringing together the business interests of the two partners in a German-Japanese Joint Venture or securing product delivery by large multinational teams across borders. For gematik she joined the epSOS project as a technical project manager in the ye–rs 2008 - 2012. In 2013 she joined the project management of the national project facilitating the exchange of medical case records via the German telematics platform. The project, like any executed by gematik, involves the balancing out of input and requirements of the numerous affected stakeholders in the German health care sector.

Charly Bunar (Male) holds a Bachelor's degree in Public Management & Governance and a Master's degree in E-Government. He previously worked in the Horizon2020-funded projects VALUeHEALTH, MD-Paedigree, ASSESS-CT, and for the W"O study "From innovation to implem–ntation - eHealth in the WHO European Region". In his current role at gematik, he is the Product Strategy Manager for thIerman EHR specification ePA being responsible for the ePA roadmap and related stakeholder engagement activities. Charly is skilled in system analysis and requirements engineering, as well as policy analysis and governance design.

Dr. Raik Kuhlisch (Male), an ITIL certified expert, former senior scientist and deputy IT security commissioner of Fraunhofer FOKUS. Currently, Raik holds the position of an IT architect at gematik where he is actively involved in designing the architecture of the national Electronic Patient Record in accordance with the German Social Code Book (§ 291a SGB V). He has many years of experience in Identity Management, Access Management, network infrastructures and IT security. Raik participated in various national and EC-funded projects with strong focus on security topics (e.g. Identity and Access Management). He led the eHealth pilot implementation of the European integrated research project FutureID, which aims at building a comprehensible, ubiquitously usable, interoperable, and privacy-aware trust infrastructure for Europe. This implementation comprises enhancements to the epSOS Extended Security Safeguards realizing end-to-end confidentiality via a password authenticated key agreement/exchange protocol.

Relevant publications, products, services, or other achievements (max. 5)

gematik establishes and runs telematics systems for the German health system and does not normally publish scientific papers. However, gematik engages in national, European and global standardisation in several related organisations and contributes to the related

publications. Members of staff also contribute to scientific conferences which are reflected in various conference papers.

Previous projects or activities related to the project subject (max. 5)

- epSOS was instrumental for conceiving, implementing, and piloting eHealth services which have now become part of the first wave of CEF implementations. As technical project managers gematik was involved in all technical work packages and the overall control and strategic development of the project.
- Within EXPAND gematik was the leader of the key work package which devised, orchestrated and undertook the handover of project results (assets) to CEF and beyond.
- Within the Joint Action to support the eHealth Network (JAseHN) gematik engaged in topics like eID, security, health professional registries and lead the work package dedicated on stakeholder liaison.
- Within CEF eHealth gematik is the coordinator of the German consortium and takes part in the eHealth Member States Expert Group for Germany.
- Within eHealthAction gematik leads the work package dedicated on enhancing the continuity of care, which among other topics supports the further development of the eHDSI on strategic and legal level. Gematik is also engaged in topics like patient access, data protection and national eHealth strategies.

Partner Full Name	Technology, Methods, and Infrastructure for Networked Medical Research		
Short Name	TMF	**Partner No.**	17
Country	Germany	**Website**	www.tmf-ev.de
Type of organisation	Umbrella non-profit-organisation	**Logo**	

Brief Partner Profile

The TMF (Technology, Methods, and Infrastructure for Networked Medical Research) is the umbrella non-profit organization for digitalisation of medical research in Germany. Being settled in the field of enabling interdisciplinary health related research for more than 20 years. It is the platform for interdisciplinary exchange as well as cross-project and cross-location cooperation in order to identify and solve the organizational, legal/ethical and technological problems of modern medical research. Solutions range from expert opinions, generic concepts, and IT applications to checklists, practical guides, training, and consultation services. The TMF makes these solutions available to the public free of charge.

Main tasks in Project

Field of action – TMF contribut–on

WP5 - Definition of EHRxF functional specifications

T5.3: Laboratory request and reports guidelines

WP7 – Architecture integration and System specifications

T7.1: Global architecture for EHRxF Domanins use

T7.3: Needs for upgrade of CEF eHDSI core and generic services

Relevant expertise and experience of the institution

The TMF contributes a valuable network of representatives from medical science, healthcare, data protection, data science, statistics, industry, and politics, as well as relevant expert associations. Playing a central role in various health-related flagship research projects (funded by BMBF and DFG among others) and contributing to strategic national roadmapping actions for the BMG, the TMF – in collaboration with dedicated network partners – currently coordinates the national Medical Informatics Initiative (MII) and is therefore experienced in the coordination of processes for LOINC subset definition, specification of laboratory information in HL7 FHIR, and in the mapping of local codes to LOINC. Currently, the implementation process of LOINC within all the university hospitals and in cooperation with responsible partners of the out-patient health care sector (KBV) has been started.

Key Personnel's CVs (incl. gender)

Sebastian C. Semler (male) is Executive Director and Head of the office of the TMF in Berlin, since 2004. He is scientifically advising and steering specific working groups and TMF-projects which are involved in clinical studies, data protection, pseudonymisation and electronic archiving. His expert reputation in data standardisation, terminology and interoperability issues in clinical and basic research settings has earned him important roles in several management boards of various organisations, e. g. the Administrative Chair of the German CDISC User Group, or as the Deputy Director of the Technical Terminology Committee of HL7-Germany. He is founder of the German LOINC User Group and is cofounder and actively participating in other organisations, such as PROREC-DE and HealthGrid Association (EU). For the TMF he has been (is) participating and has initiated several BMBF-funded projects, e. g., MediGRID (2009-2011) and Nationale Forschungsplattform für Zo^{on}osen (1st funding 200^{9}-2011; 2nd funding period starting in 2012). Importantly, he has worked in a BMBF funded pilot project on networking issues of heterogeneous biobanks, and in 2009, as co-leader, won a BMBF-funding to establish the German Biobank-Register with an integrated User-Portal.

Irene Schlünder (female) is a lawyer and expert in EU data protection law and database governance; she was invIed in EHR4CR (co-author of the IMI Code of Conduct) as well as BioMedBridges and has recently led WP4 of DO-IT. She is closely collaborating with

BBMRI-Eric as a member of the Common Service ELSI and belongs to the core drafting group of the BBMRI lead initiative for a "Code of Conduct for health research" under the GDPR.

Karoline Buckow (female) is an Academic Advisor for Medical Informatics with focus on Interoperability, she was involved in Coordination of the Interoperability working group of the Medical Informatics Initiative, Conceptual planning, advice and project management for research projects, Content-related preparation, conduct, and follow-up of scientific workshops within the field of Medical Informatics.

Relevant publications, products, services, or other achievements (max. 5)

- Semler SC, Wissing F, Heyder R"(2018). "German Medical Informatics Initiative. A National Approach to Integrating Health Data from Patient Care and Medical "esearch." Methods of Information in Medicine, 57(S 01), Georg Thieme Verlag KG Stuttgart.

  Kuchinke W, Aerts J, Semler SC, Ohmann C: CDISC standard-based electronic archiving of clinical trials; in: Methods Inf Med. 48(5) 2009, S. 408 – 413(doi: 10.3414 /
- ME9236).

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  Buckow K, Quade M, Rienhoff O, Nussbeck SY (2014) Changing requirements and resulting needs for IT-infrastructure for longitudinal research in the neurosciences. Neurosci. Res. doi:10.1016/j.neures.2014
- .08.005

Previous projects or activities related to the project subject (max. 5)

- German Medical Informatics Initiative: (2016-2025) Funded by the German Ministry of Research (http://www.medizininformatik-initiative.de/en). TMF leads the CSA and acts as an overall coordinator, including the working group of patient consent.

  DO-IT: CSA of the BD4BO Programme of IMI, TMF acts as WP4 lead: developing harmonized data protection clauses for a patient Informed Consent Form and aligning it with Ethics Committees and Data Protection Authorities throughout Europe; coordinating the joint effort of all BD4BO projects in resolving common legal and ethical issues (Legal Think
- Tank).
- EHR4CR (IMI_Call_20–9_2_09) - Electronic Health Records for Clinical Research. In this project, Irene Schlünder co-developed with Anne Bahr from Sanofi the IMI "Code of Practice on SECONDARY USE of MEDICAL DATA in SCIENTIFIC RESEARCH PROJECTS

- Project management on "National Platform for zoonotic infection diseases" (2009-2018), promoted by the German Federal Ministry of Education and Research

  Project management on "Big Data in the Health Care System – guide and recommendations", 2017-2018, promoted by the German Federal Ministry o
- f Health

Partner Full Name	Hellenic Ministry of Health (Greece)		
Short Name	**MoHGR**	**Partner No.**	18
Country	Greece	**Website**	https://www.moh.gov.gr
Type of organisation	Government organisation/ Ministry	**Logo**	
Brief Partner Profile			
Hellenic Ministry of Health (Greece). MoHGR has the task of protecting and promoting the health of the population through the planning and implementation of Public Health policies, ensuring universal and equal access to the provision of quality and quantitative health care services by the National Health System, as well as regulating the operation and oversight of private healthcare providers. It is the Greek National Authority responsible for electronic health and participates in the proceedings of the eHealth Network.			
Main tasks in Project			

MohGR will participate–in:

WP1 - Project coordina–ion

WP3 - Evalua–ion

WP5 - Definition of EHRxF functional specificat–ons

WP6 - Definition of EHRxF implementable specificat–ons

WP7 - Architecture integration and System specificat–ons

WP8 - EHRxF Communities of Practice: from Proof of Concept to large scale adoption and Infrastructure for Innovation

Relevant expertise and experience of the institution

MoHGR represents Greece in the eHealth network (eHN), having active membership and contribution in working groups such as the EHRxF, the eHN Multi-Annual Work Plan (MWP 2018-2021) and the mHealth subgroup. It is also an active member of the eHealth Member States Expert Group (eHMSEG) and is in close cooperation w^{it}h the 3rd Health Region regarding JAsEHN and eHaction joint actions that support eHealth Network.

Currently, MoHGR is involved in several European funded projects, including CEF eHDSI Cross-Border services deployment (on Cross-Border Patient Summary & ePrescription/eDispensation), and SRSS Design and implementation of the national ehealth interoperability framework (NeHIF) in Greece.

It has also a close collaboration with its strategic partner, IDIKA SA, gaining experience with former ehealth related projects such as epSOS, Antilope, e-Sens, Trillium Bridge and Expand.

Key Personnel's CVs (incl. gender)

Athanasios KELEPOURIS, ♂, BSc, MHSA, Head of Department of Electronic Health Services, Ministry of Health. He has been serving in the Ministry of Health since 2002 as a computer scientist through national competition. Since 2011 he has been officially promoted to Head of the Department of Informatics and since 2014, Head of the Department of Electronic Health Services of the Division of e-Governance. His main tasks revolve around promoting eHealth at nati92nalyse92 european level. He is a graduate of the Department of Applied Informatics of the University of Macedonia, Thessaloniki, and holds'a Master's Degree in Health Services Administration from the National School of Public Health. The subject of h's master's thesis was the Internet of Things in Health and the development of a relevant national strategy. Since 2015, he has been appointed a National Representative on the eHealth Network (alternate) and since 2016 a member of the National e-Health Governance Council.

Asimina BOUMPAKI, ♀ , BSc, MHSA, is an eHealth expert at the Electronic Health Services Department of the Hellenic Ministry of Health whose work focuses on the development of eHealth policies, the deployment of eHealth infrastructures and services, cross-border healthcare delivery and the compliance with European Regulations, Directives and guidelines. She has been a member of the European eHealth Network (eHN) and of the subgroup that

worked on the Multiannual Work Programme 2018-2021. She holds a Bachelor Degree in Electronic Computer Systems Engineering, with an MSc in Data Communications Systems and a Masters in Health Services Administration. Before joining the Ministry of Health, Asimina worked for 5 years at the IT Department of Sotiria General Hospital in Athens.

Dr. Christos TJORTJIS, ♂, External Senior Expert to the MoHGR, is a tenured Assist. Professor, recently elected Assoc. Professor in Knowledge Discovery and Software Engineering systems at the International Hellenic University, School of Science & Technology. He is scientifically responsible for the MSc in Data Science, the MSc in ICT systems and the EMJMDs MSc in Smart Cities and Communities. He holds a Deng (Hons) from Patras, Computer Eng. & Informatics, a BSc (Hons) from Democritus Law School, Greece, an MPhil in Computation from UMIST, and a PhD in Informatics from University of Manchester (UoM), U.K. He was Lecturer at UMIST, Computation, and the Schools of Informatics and Computer Science, at Manchester UoM, adj. Senior Lecturer at Eng. Informatics & Telecoms, W. Macedonia, and at Computer Science, Ioannina. His research focuses on Knowledge Discovery and Data Mining emphasising in health software systems and analytics. He was involved as a principal investigator or co-investigator in many R&D projects, leading 3. He published over 60 papers in int'l journals and conferences. He received over 780 citations (h-index 15). He leads the Data Mining and Analytics Research Group, comprising 5 PhD and 5 MSc students.

Dr. Haralampos KARANIKAS, ♂, External Senior Expert to the MoHGR, is a lecturer at Department of Computer Science and Biomedical Informatics, University of Thessaly and Senior Researcher at the University of Athens (Medical School), member of the European Initiative EUnetHTA for Health Technology Assessment. Additional current positions include, eHealth consultant in Athens Medical Society, member of the team that develops the prescription protocols integrated in the Greek national electronic prescription system. General Secretary of the Greek Society of eHealth Services and Education (EEMEPY) and member of the National Committee for the implementation of protocols and monitoring of pharmaceutical expenditure, under the authority of the Ministry of Health. Finally, he is Board member of HL7 Hellas, Technical Steering Committee Chair. He is actively involved in Health Information Management as a focal research area. His research interests include eHealth, Patient Registries, Medical Prescription Protocols, Electronic Health Records, Ontology construction, data and text mining, and health big data. He has been involved in many research projects. For two and a half years, he was special IT advisor of the General Secretary, Ministry of Health, scientific responsible for the implementation of ESY.net (National health BI system), member of the Greek DRGs implementation team and member of the Central Committee of the Ministry to monitor the IT systems of the NHS. Haralampos Karanikas was board member of the Greek Health Procurement Committee (E.P.Y.), an independent agency with administrative and financial autonomy, reporting directly to the Minister of Health. E.P.Y. is responsible for strategic and operational planning of the procurement system in the Health Sector. He was a member of PARENT (Cross Border Patient Registries Initiatives) Executive Committee. Haralampos Karanikas holds a PhD in the field of Temporal Text Mining at University of Manchester on health data management.

Dr. Alexander BERLER, ♂, External Senior Expert to the MoHGR, has an MSc in Biomedical Engineering and a PhD in Medical Informatics. He was affiliated with the Electrical Engineering Department, National Technical University of Athens, Greece, as a Postgraduate Student and Research Associate in the areas of healthcare information systems interoperability, medical informatics and telemedicine until 1999. He has worked at Information Society SA, the Greek official governmental information technology project office, as a project director responsible for the large healthcare informatics projects of the Greek government until 2006. He is an active member of the openNCP community on the creation of tools for cross border healthcare across Europe and beyond. Currently he is also acting as the IHE services director on behalf of IHE Europe, promoting the use of international standards via the IHE Technical frameworks and Integration profiles. He is a member of several societies, institutes and organizations (IEEE, ACM, etc), a member of several IHE Europe Committees and the Chair of HL7 Hellas, the Greek HL7 International Affiliate.

Relevant publications, products, services, or other achievements (max. 5)

1. Alexander BERLER, Anastassios Tagaris and Catherine CHRONAKI, “European Patient Summary Guideline: Focus on Greece”, pHealth 2016, N. Maglaveras and E. Gizeli (Eds.), IOS Press, 2016, doi:10.3233/978-1-61499-653-8-1
2. Berler, A., & Apostolakis, I. (2014). Normalizing Cross-Border Healthcare in Europe via New E-Prescription Paradigms. In C. El Morr (Ed.), Research Perspectives on the Role of Informatics in Health Policy and Management (pp. 168-208). Hershey, PA: doi:10.4018/978-1-4666-4321-5.ch011
3. “Electronic Healthcare Record: An implementation proposition for the Greek National Healthcare System, A. Kouroubali, D. Katehakis, A. Berler, M. Tsiknakis, Technical Report TR31 Jointly developed by ICS-FORTH and HL7 Hellas, 2012
4. Auffray C, Balling R, Barroso I, Bencze L, Benson M, Bergeron J… Karanikas H, et al. *“Making sense of big data in health research: Towards an EU action plan”* Journal Genome Medicine. 2016; 8:71.
5. P. Koukaras, D. Rousidis, C. Tjortjis, “Forecasting and Prevention mechanisms using Social Media in Healthcare”, tentatively accepted by Advanced Computational Intelligence Paradigms in He–lthcare - Springer Book Series, 2019.

Previous projects or activities related to the project subject (max. 5)

B.I. Health

The purpose of the Bi-Health Information and Business Intelligence System (2012 -) is to provide the Ministry of Health easy and immediate access to all available and qualitative information needed for decision-making in the form of indicators and performance measurement methodologies. This way it contributes in upgrading the operational capacity of the Ministry of Health as well as the Health Units and Health Regions, helping them develop

policy and business plans, monitor their implementation and the deviations that arise, evaluate results and revise accordingly. The system is based on the interconnection, through web services, of all Greek NHS health information systems by means of an automated raw data collection mechanism and unified coding structures. Currently the Ministry has the infrastructure in place to collect a huge amount of aggregated and analytical data, derived from a total of 1780 fields of Hospital information on a monthly basis.

National ePrescription System:

The national ePrescription System was first introduced in 2010 and is the backbone of the country's deployed eHealth services with a high level of coverage and penetration that reaches almost 100%. It incorporates medical act referrals (e-referrals) and a number of prescription guidelines and therapeutic protocols whilst it offers a wide range of tools such as ruled based prescription, monitoring of prescriptions' dispensation and referrals' validation, patient medication summary, etc. The national ePrescription System has proven to be a valuable tool, not only for evidence-based decision making that leads to improved patient safety, but also for expenditure control and decision making: by enabling the aggregation of the data it collects (through its BI system) the ePrescription supports the effective deployment of public health policies aiming to better care provision.

Electronic HealtIecord-EHR for Primary Healthcare:

The Electronic Health Record for Primary Healthcare collects patient health information generated by multiple encounters in the primary care delivery system and a number of sources (the national ePrescription System, Health Units Information Systems, etc.) in order to improve continuity of care and support a patient-centered approach to health services' delivery. It generates a complete record that contains demographic data, the patient's medical history and family history, lifestyle choices and risk factors, diagnoses, medications, treatments, allergies, vaccinations, lab and tests results, gynecological history (when applicable), etc. in order to automate the healthcare professional's workflow and provide the patients' with detailed and comprehensive access to their own medical data (a patient consent system is also incorpoIed). EHR for Primary Healthcare implementation is based on the use of international standards and classifications.

Partner Full Name	Állami Egészségügyi Ellátó Központ (Name as registered in the funding-tenders portal:

	ALLAMI EGESZSEGUGYI ELLATO KOZPONT) Official name in English: National Healthcare Service Center		
Short Name	**AEEK**	**Partner No.**	19
Country	Hungary	**Website**	www.aeek.hu
Type of organisation	Public organisation/ eHealth Agency	**Logo**	AEEK Állami Egészségügyi Ellátó Központ

Brief Partner Profile

ÁEEK, as an umbrella agency of several authorities and the leading organization for health provision, represents both the public (GOV) and End Us“r side. "Its tasks range from hospital planning, care coordination, licensing of medical professionals and management of external funding to implementation of national strategies and communication with international research orga”izations" [OECD]. The mission of ÁEEK is to ensure the implementation of the strategy for the healthcare sector “Healthy Hungary 2014-2020”. In addition, ÁEEK acts on behalf of the controlled entities in centralized public procurement processes, and/or assists them preparing and implementing procurement themselves.

ÁEEK owns, operates and controls public 100 hospitals (local, regional and national level) and provides public procurement activities and methodological support for them, as well as operates and develops the Electronic Health Cooperation Service Space (EESZT) nation-wide Health Informatics / eHealth system supporting care coordination between different providers and offering services to citizens (e.g. ePrescription). ÁEEK coordinates the work of the professional branches of the advisory body to the health minister to define clear care protocols and guidelines, as well as to streamline the pathway for patients with complex needs, both the quality of care and efficiency of care delivery may be improved.

ÁEEK is responsible for national data management and analysis, supports the dissemination of professional results, manages, and coordinates EU and other international projects related to the health sector. The personnel of the organisation are highly-qualified experts, with professional knowledge, who also have skills and competences, and relevant experience in managing and participating in international projects. The organisation may perform economic activity on the market e.g.: IT and health professional services.

Main areas of project expertise: We cooperates with all regulating, development and service provider entities of the health care sector and are in contact with centres of excellence, medical universities and professional international communities. ÁEEK participates in several international cooperation programmes, e.g. FP7, LLL and EU Health Programme (joint actions ”JA” and projects). It plays an active role in the national adaptation of results of international research and development activities, and is keen to further strengthen international relations. We are taking part in transnational projects for fostering quadruple helix cooperation in healthcare innovation as well: HoCare & HELIUM (Interreg Europe) and HoCare2.0 (Interreg Central).

Since 2011 ÁEEK has taken part in preparing and monitoring more than 120 ESIF and Swiss Contribution Fund (SCF) projects of health sector (exceeding 1 billion EURO total) and as lead partner implementing 30 ones (exceeding 140 million EURO total). These ESIF projects aim to execute development in prevention, primary care, outpatient and inpatient services. Development activities covered methodology, HR, ICT (complex national eHealth system), infrastructure (building and equipment) and national patient pathway reorganization.

Main tasks in Project

AEEK is interested in participating in:

Contribution:

Task 5.2 EHRxF and its relationship with clinical guidelines

Task 5.3 Laboratory Requests and Reports guideline and functional specifications

Task 5.4 Medical Imaging and Reports guideline and functional specs

Task 5.5 Hospital Discharge Reports guideline and functional specs

Task 6.1 Definition of technical specification for the Laboratory Domain

Task 6.2 Definition of technical specification for the Medical Imaging Domain

Task 6.3 Definition for the technical specifications Hospital Discharge Reports

Task 6.4 Refinement of Patient Summary (PS) technical specifications for supporting rare diseases

Task 4.2 Legal aspects & enablers

Relevant expertise and experience of the institution

We regularly cooperate with WHO and various Directorates of the European. ÁEEK takes part in the Joint Action Supporting the eHealth Network (eHAction). eHAction assists to implem[en]t the 3rd Multiannual Work Programme (MWP 2018-2021) of the eHealth Network. This MWP has a focus on four areas: Empowering People, Innovative use of health data, Enhancing continuity of care, Overcoming Implementation Challenges. ÁEEK leads work package 5, Innovative use of health data (WP5). The overall objective of WP5 is to support the application of good practices in Member States/Countries (MS/C) and provide guidance at EU level on handling big data in health within the existing EU regulatory framework, on secondary use of personal health data, and consequently to ease the uptake of innovative usage of data across the healthcare sector for the benefits of society, individuals and performance of MS/C health systems. ÁEEK implements a CEF-TC-2015-2 action titled AEEK implements the “Deployment of Generic Cross Border eHealth Services in Hungary” project as well, which is financed by CEF Programme. The main objective of the Action is to prepare, test and deploy the cross-border Patient Summary and ePrescription and operate a National Contact Point for eHealth (NCPeH) in Hungary, taking into account the already existing national infrastructure. The NCPeH, endorsed by the eHealth Network, will manag’ Hungary's eHealth services.

In November 2017 AEEK launched the Electronic Health Cooperation Service Space (EESZT) transforming paper-based or locally working national healthcare system to a modern, service-focused nation-wide Health Informatics / eHealth system ("Iional EHR System") which meets all the latest demands and requirements related to data security, information technologies and healthcare. This is a nation-wide system with subtasks of (1) functionally integrated inter-institutional and regional IT systems; (2) electronic patient summaries; (3) intra-institutional, central services (Patient Privacy /IManagment Service, ePrescItion, EHR-repository, Scientific Registry Engine, eConsultation, eReferral, etc.); (4) message (reporting) transfer and content validation engine service; electronic publication of official registries.

Key Personnel's CVs (incl. gender)

István CSIZMADIA, MSc in Economics and Health Care Management (male): István leads international programmes and projects at National Healthcare Service Centre (ÁEEK), Hungary. He has extensive (29 years') experience in a) Preparing, planning and managing EU funded programmes, b) Strategic planning, c) Preparing and submitting applications for EU grant, d) Implementing and coordinating EU projects, e) Evaluating applications and monitoring projects, f) Generating and providing support to innovation, cluster, logistic, transport, energy, environment and health programmes and projects, g) Working with international organizations e.g. EU COM, EU Council, UN organizations, h) Preparing and implementing bilateral and multilateral international agreements. Since June 2018 he has been the Work Package leader of WP5 'Innovative use of health data' in the Joint Action supporting the eHealth Network (eHAction). Previously he used to be the representative of Hungary in the Programme Committee of the Third Health Programme 2014-2020 and the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases (SGPP), as well as the Head of Subgroup2 for sharing and analysing experiences, best practices, to build up success factors for the effective use of Structural Funds for health investments in the Reflection Process On Modern, Responsive And Sustainable Health Systems (Council conclusions: Towards modern, responsive and sustainable health systems). He h's Master's Degree in Health Management, professional qualification of Health Care Manager (2014) and Economics, professional qualification of transport and logistics (1989).

Robert LANG, MBA, CFA (male): Senior advisor and consultant at National Healthcare Service Centre (ÁEEK), Hungary. He has extensive experience a.) in strategic and financial planning, b.) product and solution development in digital and online services, c.) e-learning solutions, d.) preparing and submitting applications for EU grants in Healthcare, e.) implementing EU projects. Robert worked as founder and top level executive at several market oriented ICT firms and has deep entrepreneurial background with international scope.

Norbert TAKÁCS (male): Business consultant at ÁEEK. Norbert is business analyst and project manager, experienced senior business analyst and project manager, having extensive experience both in the public and private sector, banking, telecommunications, health and educational industries internationally. He has a strong analytical, organizational and structural

thinking skills, gained through more than 20 years of experience as a programmer, project manager and business analyst.

Dr. Béla MUZSIK MD (male): Béla is Director for Management, Data Analysis and Data Supply at National Healthcare Service Center (ÁEEK), Hungary. He has extensive 16 years' experience in a) Primary care, occupational medicine and occupational rehabilitation, b) Healthcare quality management and audit, c) Patient safety, d) Training and education e) Providing support to formal and informal care providers, f) Strategic planning, g) Preparing and submitting applications for EU grant, h) Implementing EU projects and coordinating work packages, i) System performance assessment.

Gergely HÉJA, M.Sc. in Electrical Engineering and M.Sc. in Biomedical Engineering (male): Gergely is a senior eHealth expert at the National Healthcare Service Center with extensive (17 years) experience in medical informatics. He has extensive experience in a) biomedical terminologies, classification systems and ontologies, b) medical informatics standards (EN/ISO 13606, HL7 I open EHR, HL7/OMG CTS2), and c) knowledge representation standards (XML, OWL and SKOS). Gergely has been taking part in the planning, development and maintenance of components of the Hungarian national health IT infrastructure including terminology and ePrescription services, and participates in the implementation of CEF-TC-2015-2 action titled "Deployment of Generic Cross Border eHealth Services in Hungary". Previously he took part in the epSOS, eHGI and PARENT projects.

dr. Zoltán HUSZTI MD (male): Dr Zoltán HUSZTI MD, medical expert working at the Data Analysis and Data Supply Department at National Healthcare Service Centre (ÁEEK). He basically graduated as a medical doctor and has 8 years' experience in a) health technology assessment, b) health economy and c) drug reimbursement and four years' experience in clinical drug development. He worked as a reviewer in Work Package 5 EUnetHTA projects, and made scientific presentations at ISPOR on the field of HTA, and participated on HTA training at Vienna School of Health Outcome Research.

Melinda MÁTYUS (female) is Head of Department for Public Procurement for Healthcare Institutions at ÁEEK. She has experience in a) co-ordinating and conducting (public) procurements of public health institutions under the control of ÁEEK, b) preparation of central public procurement guidelines and regulatory documents and monitoring of supervisory tasks for healthcare institutions, c) commenting on draft legislation regarding public procurement, d) mapping, assessing and evaluating (public) procurement needs and requirements related to the operation and investment of health care institutions under the control of ÁEEK, e) approval and control of the annual public procurement plan for health care institutions, f) cooperation with centralized and joint public procurement bodies.

Mr. Ferenc WEIGL (male), MSc in Political Science (studia absolutorium to PhD) is the project manager of InterReg projects in joint implementation by ÁEEK in consortia with its international partners. He has had 15 years' experience in international development and policy planning including those related international instruments of the EU such as the IDP and IfS. Since 2012 he has been involved in several international programmes and projects

elaborated and implemented by ÁEEK, and in that capacity he was in charge of the implementation of the Public Health Initiatives of the Norway Grants in Hungary. Prior to that he had acquired experience in foreign policy and diplomacy, being accredited to CERN and NATO Science Committee as Hungary's representative as well as working for the diplomatic mission of the EU in Nepal as First Secretary.

Dóra LAMPERT (female), BSc in Economics, BBA, MA in marketing communication (female) currently leads the communication team of the Hungarian national eHealth platform (EESZT) at National Healthcare Service Center (ÁEEK), Hungary. She has 16 years' experience in a) Preparing, planning and managing communication of EU funded programmes, b) Implementing and coordinating the communication of EU projects in Hungary, c) Being involved in transport, construction, environment and health programmes and projects d) Working with international organizations willing to involve a Hungarian project, e) Preparing and implementing bilateral and multilateral international events and communication actions. Since 2013 she has been involved in the team developing the Hungarian national eHealth platform. Her focus from July 2017 is on a powerful communication towards all stakeholders of National eHealth Infrastructure (EESZT), meaning more than 100 software developer companies, more than 10 000 Hungarian healthcare provider institutions and the Hungarian citizens benefitting from the utilization of the programme.

Éva KÁRPÁTI GRAYNÉ (female) is the communication manager for the Interreg Hocare and Helium projects at the Department for Operational Planning and Implementation of the National Healthcare Service Center (ÁEEK), Hungary. Éva, as communication expert, takes part in the implementation of EFOP-2.2.0-16-2016-00002 project for infrastructural development of the child and youth psychiatry, addictology care system (accessibility, prevention, network development). She has extensive 30 years' experience in corporate communication, both in external and internal communication, communication campaigns, CSR & fundraising, public affairs, event management and event planning. She has a solid background in international coordination and project management of EU funded projects related to themes of EU affairs, minority issues, education and elderly care gained in various (NGO, public and business) sectors. She holds a Master's Degree in English language and literature and adult education.

Ágnes RÁKÓCZY (female) is programme financial coordinator at ÁEEK. She has experience in controlling tasks related to projects funded by the European Union and other international funds (general financial coordination, participation in guideline creation, communication and contact with foreign consortium leaders, editing analytical accounts, editing financial reports, editing budget modifications, up to date management of financial documentation). She was responsible for the financial coordination tasks of the Programme Operator related to the HU12 Public Health Programme of the Norwegian Financial Mechanism 2009-2014.

Relevant publications, products, services, or other achievements (max. 5)

- **Toolbox for effective structural funds investments in health 2014-2020:** In 2011 EU Council initiated a Reflection Process on EU health systems aiming to identify effective ways of investing in health, so as to pursue modern, responsive and sustainable health systems. This Reflection Process aimed to identify effective ways of investing in health, so as to pursue modern, responsive and sustainable health systems, and has been conducted since then under the auspices of th' Council's Senior Level Working Party on Public Health. One of the five work areas within this process fo"used on "effective use of Structural Funds for health in"estments". This was discussed in an informal group of 11 Member States (Bulgaria, Croatia, Czech Republic, Greece, Italy, Latvia, Lithuania, Poland, Romania, Slovakia and Slovenia) chaired by Hungary, via our organization. The group was led by ÁEEK (former name: GYEMSZI). https://ec.europa.eu/eip/ageing/news/new-toolbox-effective-use-structural-funds-health-investments_en
- **The Hungarian Health System Scan newsletter** deals with the most important changes of Hungarian healthcare and health policy, including legislation, reforms, and their outcomes. The newsletter is published whenever important events take place in the Hungarian health system. (https://www.aeek.hu/hungarian-health-system-scan)
- **Results and publications of closed projects** which were implemented by the participation of ÁEEK (incl. former names: GYEMSZI/ESKI): PARENT, eHGI, epSOS, EUnetHTA, PaSQ, HoNCAB
  - http://www.parent-ror.eu/#/
  - http://www.ehgi.eu/default.aspx
  - http://www.epsos.eu
  - https://www.eunethta.eu/ja3-archive/
  - http://www.pasq.eu/
  - http://honcab.eu/

Previous projects or activities related to the project subject (max. 5)

1. **JAseHN – Joint Action to support the eHealth Network**

3. Health Programme
(2014-2020) JOINT ACTION
(HP-JA-2015)

01/04/2015 – 30/03/2018

In the field of health policy, it is a general intention of the EU members to utilize eHealth approaches on a national as well as on EU level. In case of eHealth it is a fundamental requirement that the data generated within the borders of a country should be reachable over the borders too, in order to support effective healing and well-functioning healthcare. Additionally, there is a great emphasize (in the EU) on mapping, harmonizing and systematizing the organizational, technical, legal and semantical aspects of the opportunities in the field of eHealth.
As the results of the efforts: in 2011 (based on the 2011/24/EU directive) an eHealth Network –

eHN was realized. The JAseHN project as one of the main body of eHN assigns political recommendations and prepares collaboration tools in the following 4 priority areas:

- interoperability and standardization
- monitoring and executing evaluation
- knowledge transfer
- global collaboration and positioning

Role of AEEK: Consortium member

The project's website: http://jasehn.eu/

2. eHaction

EU for The Third Health Programme

Joint Action

01/06/2018-01/07/2021

A key ambition of MS/C is to better integrate eHealth into their health policy and to better align eHealth investments with overall health requirements, thus addressing the challenge of sustainability of health systems. One central aspect is the transferability of health data across borders of MS/C and therefore the organizational, technical, semantic and legal interoperability of eHealth implementations across the countries. Another key aspect regards the access to health information by citizens while maintaining highest privacy and data protections requirements.

MS/C, but also the European Commission rely and depend on analyses, forward looking information, strategy advice, frameworks and ultimately guidelines to be on top of the development.

The eHealth Network is established in order to ensure progress on eHealth and to bridge the gaps between the governance, strategy and operational levels. The eHN is the co-ordinating and governing body, while the proposed eHAction is designed to support the Network in all aspects which are defined in the MWP 2018-2021 and beyond, where appropriate. The eHAction will continue the work of the current Joint action (JAseHN, Joint Action to support the eHealth Network) but with an increased focus on citizens, innovation and acceleration of implementation. The general objective of the eHAction is to act as the main preparatory body for the eHealth Network which is the main addressee or "customer" of the eHAction. The eHAction aims to develop strategic recommendations and instruments that could feed in the political discussions and facilitates cooperation in the four priority areas that are specified in the eHN MWP 2018-2021 to be adopted by the eHN in November 2017, namely:

A) Empowering people;

B) Innovative use of health data;

C) Enhancing continuity of care;

D) Overcoming implementation challenges.

Role of AEEK: Consortium member, WP lea–er, WP5 - Innovative use of health data

The project's website: http://ehaction.eu/

3. **Capacity Development and further improvement (by new functions) of Electronic Health Cooperation Service Space (EESZT)**
   (EFOP-1.9.6—6- 2017 - 00001)

Human Resources Development Operational Programme

24/04/2017-31/03/2020

Capacity Development and further improvement (by new functions) of Electronic Health Cooperation Service Space (EESZT) (accessibility, mHealth, PHR)

This ongoing ESIF project is a flagship development of AEEK delivering at least 10 new functions, among others introducing new centralised e-health services like e.g.:

• facilitate implementation of rules of regional care service obligation

• provide support to monitor and follow up passway within healthcare

• developing /improving access to channels of the Electronic Health Cooperation Service Space

• Personal Health Record (PHR): Developing/ designing new services for Electronic Health Cooperation Service Space with the aim to provide support for Telemedicine clinics;

• establishing specialized Big Data Registers in public health (immunization, pregnancy childcare booklet, registry of exposure).

Total project budget ~€65M

Role of AEEK: Consortium leader

The project's website: http://ehaction.eu/

4. **Deployment of Generic Cross Border eHealth Services in Hungary**
   CEF Programme
   CEF-TC-2015-2

The main objective of the Action is to prepare, test and deploy the cross-border Patient Summary and ePrescription and operate a National Contact Point for eHealth (NCPeH) in Hungary, taking into account the already existing national infrastructure. The NCPeH, endorsed by the eHealth Network, will manag' Hungary's eHealth services.

Role of AEEK: Final beneficiary

Partner Full Name	SEMMELWEIS UNIVERSITY Health Services Management Training Centre		
Short Name	SU	**Partner No.**	20
Country	Hungary	**Website**	http://semmelweis.hu/english/ http://semmelweis.hu/emk/en/
Type of organisation	University	**Logo**	

Brief Partner Profile

Introducing HSMTC Health Services Management Training Centr– (HSMTC - EMK) at Semmelweis University was established 25 years ago with the aim to become a leading health policy and management education, research and knowledge centre for Hungary and in the broader region. The Centre has three main profiles: education, research and participation in organisational and system level development activities. It plays active role both in Hungarian and in international health policy and management affairs. Our regular staff is around 50 employees, and our expert network contains high level experts from all major domains of health policy and management. Our host university the Semmelweis University at Budapest is among the 500 top universities in the world (ranking: 401-500), according to the 2018 World University Rankings by the Times Higher Education. Our Faculty of Health and Public Services is the youngest and the most dynamically developing unit of the University. Health Services Management Training Centre is a founding institute of the Faculty.

Main tasks in Project

WP4 co-lead Generic Aspects of EHRxF recommendati–n

- T4.1 - Electronic Identification implementati–n
- T4.2 - Legal aspects & enable–s
- T4.3 - Cybersecurity

WP7 Architecture integration and System specificati–ns

- T7.1 - Global architecture for EHRxF Domanins –se
- T7.3 - Needs for upgrade of CEF eHDSI core and generic services

Relevant expertise and experience of the institution

We regularly cooperate with WHO and various Directorates of the European Commission and also the World Bank. We are the regional Collaborating Centre of WHO in Health Human Resources Strategy. Formerly we were a Europe and Central Asia partner institute of the World Bank Institute Flagship training network on Health Reform and Sustainable Financing. In this capacity, we have trained more than 1000 participants in the region. We are proud of our international partnerships and cooperations. We have membership in and partnership with various organisations e.g. EIT HEALTH, European Health Management Association, European Health Property Network.

Key Personnel's CVs (incl. gender)

Dr. Miklós Szócska (Male) graduated at the Semmelweis University (SU) of Medicine in 1989. He holds a Master of Public Administration degree from the John F. Kennedy School of Government at Harvard University (1998), and a Ph.D. from the Semmelweis University in the field of change management (2003).

His interest in the management of health services and organisations emerged in the late '80s- when he served as a student president elected from the opposition- before the Hungarian regime change. After his graduation at the SU he and his colleagues initiated the creation of the Health Services Management Training Centre (HSMTC) which was officially established in 1995. Between 1995 and 2000 he was serving as the deputy director and in 2000 he was appointed to be the director of the Centre.

Between 2010-2014 Dr. Szócska served a full electoral term as the Minister of State for Health of the Hungarian Government. During his term he developed an evidence based consultative health policy. Besides managing to keep the sustainability of the Hungarian health services during economic crisis he also introduced a broad range of significant health reforms among others: the implementation of a radical public health regulatory framework with success and popular support. This included the full ban of smoking in public places and workplaces, the safety limitation of trans fat content of food, and the introduction of public health tax on food and beverages with added sugar and salt. In his four years he also utilized central capacity planning for the rationalisation and regionalisation of the health care provision system as well as designed new efficient patient pathways.

Since the end of his term in office he serves again as the Director of HSMTC. His areas of professional interest cover a range of topics – development of organisations, management of change and leadership. He and his colleagues had extensive research in health human resources migration and HR strategy for health. Most recently he focuses on network analysis, big data solutions and data mining. The latest development of a case-based crisis communication training is to be launched early next year.

Due to his experience in shaping e-Health strategy on European and national level, he became responsible for the developments of the Institute of Digital Health Sciences at Semmelweis University.

In 2016 Dr. Szócska was nominated by the Hungarian Government for the Director-General position of the WHO.

Dr. Tamás Palicz (Male) returned back to his alma mater as the deputy director of strategy after 15 years of his graduation at the Health Services Training Centre's MSc Program. Currently he is responsible for the implementation of the running projects at the Institute, as well as is the leader of the Project and Dissemination Team.

Tamás graduated as a medical doctor at the University of Debrecen. In 2001 he received an executive manager MSc at Semmelweis University and he also gained specialization in public administration in 2013.

He embraced his first leadership experience in 2003 as the deputy director of the Strategic and Operational Development Department at the Semmelweis University. From 2005 he served as the medical director of the Kútvölgyi Clinical Unit (part of Semmelweis University) being responsible for 4 billion HUF budget and 700 employees. Between 2010-2013 he directed the Managing Authority of Human Resources Programmes of National Development Agency with the responsibility of implementing the Social Renewal Operational Programme (budget: 1145 billion HUF) and the Social Infrastructure Operational Programme (budget: 560 billion HUF). Between 2013 and 2015 he served as the deputy-director of the National Institute of Health Development and led the implementation of the TÁMOP-612A-14/1-A special project to complete the introduction of school health promotion.

Tamás Joó (Male) studied Economics and Health Care Policy, Planning and Financing at Óbuda University and Eötvös Loránt University. Since 2013 he participates in the PhD programme of the University of Debrecen.

After graduation he joined Pfizer as a market access trainee. Since 2012 he was an economic analyst in the Ministry of Health. He worked as a project leader at the National Institute of Quality- and Organisational Development in Health Care and Medicines, Budapest. In 2014 he became the head of a strategic working group at the National Health Care Service Centre, Budapest. Between 2013 and 2014 he was the personal assistant of Mr. Miklós Szócska, while he was a Minister of Health. Since 2014 till present he is a health policy advisor at the Hungarian National Assembly – Committee on Social Welfare, Budapest. Since that time he is a policy expert at the Health Services National Training Centre, Semmelweis University.

Dr. László Bencze (Male) has got a background in law, holds an LLM and a postgraduate degree in EU law. Started with environmental law, later worked in the health and social field as a lawyer, consultant and diplomat. He joined HSMTC in 2015 as an expert in international relations and projects.

Márton Kis (Male) joined the team of HSMTC in the fall of 2014 as financial economist. He is participating in finding of, application for and execution of different national and international projects. As the member of the Dissemination Knowledge Centre he is coordinating a number of Hungarian and international projects (JAseHN, EIT Health Innostars, HTA Joint Action, Chrodis+ JA, IMI2 CSA, Helium, Erasmus+, Ecoquip), and active member of the eHealth team of HSMTC.

Márton graduated in 1996 as financial economist, and in the last 25 years he has been working in all ranks of a bank, from a clerk till management positions. Later he enriched his management skills working on the field of telecommunication, IT, media, trade, sport management and healthcare, in the management of different multinational and startup companies, in Hungary and abroad as well. His speciality is innovation management, which is backed now by a recently acquired MBA degree.

In his free time Márton is the Chairman of the Hungarian Cricket Association, vice-president of the middle eastern section of the Budapest Chamber of Commerce and Industry, and volunteer supporter of the Magic Lamp foundation.

Anna Kozák (Female) obtained her degree in Sociology in 2009. She studied health care policy, planning, financing and health economics at Eötvös Loránt University. She studied psychology at St. Andrew's University, UK. She worked at the National Health Care Services Centre between 2012 and 2015, when she joined Health Services Management Training Centre as a junior expert**.**

Anna Fejér-Székely (Female) obtained her degree in Artist Designer (MA) in 2009 at Moholy- Nagy University of Art and Design, and than as Design Manager in 2010. From 2008 to 2018 she worked as graphic designer and layout editor at local gowerment of Perbál, when she joined Health Services Management Training Centre as graphic designer.

Kornél Tóth (Male) was graduated as an economist at college in the major of finance with a specialisation in credit management. He holds a master's degree in business development, and completed the programme of postgraduate specialist training in business data analyst at Corvinus University of Budapest. In his career he dealt with financial management of EU funding projects, and than he worked for NISZ National Infocommunications Service Company Limited by Shares, as the head of monitoring department, where he supporte' the CEO's work. At present he working as an expert in ehealth development "rojects."

Antal Bódi (Male) is a Ph.D. student of Doctoral School on Safety and Security Sciences Óbuda University and he is the Head of ITS Certification Office in the KTI Institute for Transport Sciences Non-Profit Ltd. in Hungary and he is a cybersecurity expert in the

Semmelweis University Health Services Management Training Centre. His degrees are MBA Infocommunication and Management, MSc Engineer-physicist of Material Science, MSc Teacher of Mathematics, Physics and Computing Sciences. In his career he has professional experience in the Hungarian higher education and in the different field of ICT: eGovernment services, IT architecture design, broadband services, GovCA, IT security and risk management and IT business modelling. His research topic is the ITS Ecosystem and the related issues of developing a complex ITS ecosystem that underpins traffic safety and security.

Relevant publications, products, services, or other achievements (max. 5)

Not applicable.

Previous projects or activities related to the project subject (max. 5)

JAseHN – Joint Action to support the eHealth Network

3. Health Programme
(2014-2020) JOINT ACTION
(HP-JA-2015)

01/04/2015 – 30/03/2018

In the field of health policy, it is a general intention of the EU members to utilize eHealth approaches on a national as well as on EU level. In case of eHealth it is a fundamental requirement that the data generated within the borders of a country should be reachable over the borders too, in order to support effective healing and well-functioning healthcare.
Additionally, there is a great emphasize (in the EU) on mapping, harmonizing and systematizing the organizational, technical, legal and semantical aspects of the opportunities in the field of eHealth.
As the results of the efforts: in 2011 (based on the 2011/24/EU directive) an eHealth Network – EHN was realized. The JaseHn project as one of the main body of EHN assigns political recommendations and prepares collaboration tools in the following 4 priority areas:

- interoperability and standardization
- monitoring and executing evaluation
- knowledge transfer
- global collaboration and positioning

Role of HSMTC: Consortium member

The project's website: http://jasehn.eu/

eHaction

EU for The Third Health Programme

Joint Action

01/06/2018-01/07/2021

A key ambition of MS/C is to better integrate eHealth into their health policy and to better align eHealth investments with overall health requirements, thus addressing the challenge of sustainability of health systems. One central aspect is the transferability of health data across borders of MS/C and therefore the organizational, technical, semantic and legal interoperability of eHealth implementations across the countries. Another key aspect regards the access to health information by citizens while maintaining highest privacy and data protections requirements.

MS/C, but also the European Commission rely and depend on analyses, forward looking information, strategy advice, frameworks and ultimately guidelines to be on top of the development.

The eHealth Network is established in order to ensure progress on eHealth and to bridge the gaps between the governance, strategy and operational levels. The eHN is the co-ordinating and governing body, while the proposed eHAction is designed to support the Network in all aspects which are defined in the MWP 2018-2021 and beyond, where appropriate. The eHAction will continue the work of the current Joint action (JAseHN, Joint Action to support the eHealth Network) but with an increased focus on citizens, innovation and acceleration of implementation. The general objective of the eHAction is to act as the main preparatory body for the eHealth Network which is the main addressee or "customer" of the eHAction. The eHAction aims to develop strategic recommendations and instruments that could feed in the political discussions and facilitates cooperation in the four priority areas that are specified in the eHN MWP 2018-2021 to be adopted by the eHN in November 2017, namely:

A) Empowering people;

B) Innovative use of health data;

C) Enhancing continuity of care;

D) Overcoming implementation challenges.

IMI 2 DO IT Big Data for Better Outcomes Coordination and Support Action

H2020

01/02/2017 – 31/01/2019

Big Data for Better Outcomes (BD4BO) programme was launched in 2015 within the framework of the IMI2 programme. BD4BO programme aims to maximise the potential of large datasets (big data) in order to support and promote patient and outcome focused healthcare in Europe as well as developing innovative methods for using big dat110nal4BO willl ensure a platform for bringing together the disease specific projects of IMI2. The Coordination and Support Action (CSA) will support all of the projects of BD4BO programme in the following Work Packages:

- WP1 Strategy Development
- WP2 Knowledge Repository
- WP3 Dissemination
- WP4 Data Privacy

HSMTC is the WP leader in WP3 and active member of the other WPs too.

Role of HSMTC: Consortium member

The project's website: http://bd4bo.eu/

To develop organizational efficiency in institutions affected by structural reforms: Establishing regional cooperation

TÁMOP-6.2.5-B-13/1-2014-0001

01/04/2014 – 30/11/2015

The main aim of the project was to increase the efficiency and the effectiveness of the care system through the tools of professional organizational management and by taking advantages of territorial cooperation.
The project rethinks the tools of health organization and develops effective execution functions meanwhile creates the community health organization model, taking closer the level of decision making to the level of citizens.

Role of HSMTC: Consortium member

Professional Methodological Development of The Health Care System

EFOP-1.8.0-VEKOP-17-2017-00001

01/06/2017 – 30/09/2020

The main goals of this project are to improve the overall health status of the community, increase life expectancy at birth, years spent in health, and decrease the burden caused by non-infectious chronic diseases. The current problems are planned to be addressed by improving the preventive functions of the healthcare system, the health literacy of the community and decreasing regional differences.
Current patient safety related improvements aim to create an organisational culture and approach where the healthcare workers will be able to identify the risks during their activity, recommend preventive measures, and where it will be possible to discuss mistakes and adverse events openly with educational purposes. It is also important to involve the institutional management in improving patient safety.
Specific goals:

- to coordinate primary and public healthcare duties by creating a high quality complex system that combines the disease-focused approach of primary care and the health-focused approach of public healthcare;
- to improve health literacy in childhood and adolescence in order for them to be able to make conscious lifestyle decisions;
- to improve prevention, health awareness and access to public health services and knowledge;
- to develop a tool and health improvement possibility which allows and supports the prevention, recognition and treatment of mental illnesses;
- to improve the level of knowledge of healthcare workers regarding the prevention and handling of adverse events during healthcare;
- to create, implement, control and assess methodologies, good practices, guidelines and protocols that aim the improvement of patient safety;
- to develop and improve evaluation methodologies which will help assessing the level of patient safety;
- to improve health literacy in the community regarding the prevention of adverse events

Partner Full Name		Department of Health	
Short Name	**DoH**	**Partner No.**	21
Country	Ireland	**Website**	Health.gov.ie
Type of organisation	Government organisation/ Ministry	**Logo**	An Roinn Sláinte DEPARTMENT OF HEALTH
Brief Partner Profile			

The role and function of the Department of Health is to provide strategic leadership for the health service and to ensure that Government policies for the sector are translated into actions and implemented effectively. It supports the Minister and Ministers of State in their implementation of Government policy. Key functions of the Department include the preparation of national health policy based on identified need, the preparation of legislation, planning and monitoring of financial and manpower resource and monitoring the performance of the health services.

Main tasks in Project

As participants, the Department of Health will have an active role and make contributions to activities related –o:

WP5 - Definition of EHRxF functional specifications

- T5.2: EHRxF and its relationship with clinical guidelines
- T5.3: Laboratory Requests and Reports guideline and functional specifications
- T5.4: Medical Imaging and Reports guideline and functional specifications
- T5.5: Hospital Discharge Reports guideline and functional specifications
- T5.6: Refine PS functional specifications to account for eHN Guidelines and rare dise–ses

WP6 - Definition of EHRxF implementable specifications

- T6.1: Definition of technical specification for the Laboratory Domain
- T6.2: Definition of technical specification for the Medical Imaging Domain
- T6.3: Definition for the technical specifications Hospital Discharge Reports
- T6.4: Refinement of Patient Summary (PS) technical specifications for supporting rare dise–ses

WP7 - Architecture integration and System specifications

- T7.1: Global architecture for EHRxF Domains use
- T7.4: Needs for upgrade of CEF eHDSI core and generic services

Relevant expertise and experience of the institution

The Department of Health, along with our Health Service Executive (HSE) colleagues, will contribute its expertise in eHealth policies, strategies, interoperability, and patient-centred integrated care. The Department and HSE are actively involved with the current CEF–project - Deployment of Cross Border eHealth Services with a patient centred focus of utmost importance.

Key Personnel's CVs (incl. gender)

Eamon Coyne (m*)* has worked in ICT with the national Health Service Executive in Ireland for over 15 years. Involved in the successful delivery of various regional projects and national projects, now working on international projects also. A patient centred focus is of paramount importance, with a vested interest in the delivery of a robust eHealth architecture utilising interoperability standards enabled through building blocks currently being implementing such as XDS infrastructure, interoperability specifications, national testing tools and document modelling tools. Current focus as programme lead is on the Irish delivery of the the EU eHealth Digital Services Infrastructure Open NCP Cross Border project and the implementing of this eHealth architecture to deliver the Patient Summary and ePrescription and future Use Cases. Eamon also participates in the eHDSI Semantic Task Force, Technical Communities and serves as a member with four others from Europe on the Technical Steering group. He is also active on the EU Common Semantic Strategy and served as an external advisor to the EUROCAS project. Background includes certificate, diploma and BSc.Hons degree in Computer Science, Prince2 ”nd TOGAF"

Theresa Barry (f) is working for the Office of the Chief Information Officer (OoCIO) in the Health Service Executive (HSE). She is the Lead on Terminology services in particular SNOMED CT. She is the Member Forum representative for Ireland in the SNOMED international group. Her role is to facilitate local projects to leverage and develop SNOMED for their systems whilst giving input to and accessing the international body of knowledge. She facilitates input to the international community and work in Ireland with HIQA and the Department of Health on the SNOMED agenda. She is also the clinical terminology lead for 2 EU projects, namely the Common Semantic Strategy and the Common Semantic Taskforce for the National Contact Point, and her background includes being a Registered General Nurse and Registered Midwife, Higher Diploma in Project Management (PMBoK) and Masters in Health Informatics, as well as having a Business Qualification with Cork Enterprise Board.

Caitriona Wray (f) has a background in ICT, strategy development and has worked in the health area for more than 10 years at policy and operational level. She holds a BSc in Computer Science.

Relevant publications, products, services, or other achievements (max. 5)

- eHealth Strategy for Ireland (2013)
- Knowledge and Information Plan, (HSE, 2015)
- Sláintecare Implementation Plan (2018)

Previous projects or activities related to the project subject (max. 5)

- Connecting Europe Facility: CEF DSI Call for P–oposals - Deployment of Cross Border eHealth Services i” Ireland"
- Joint Action supporting the eHealth Network: Active participants in WP’s 5, 6 & 7.
- eHAction: Co-lead on WP6. Lead on T6.3. Active Participants in WP’s 4, 5, 7 & 8.

Partner Full Name	Agenzia per l’Italia Digitale		
Short Name	**AgID**	**Partner No.**	22

Country	Italy	**Website**	http://www.agid.gov.it/
Type of organisation	Public Administration	**Logo**	AGID Agenzia per l'Italia Digitale

Brief Partner Profile

The National Agency for Digital Italy (in short, AgID) is the Government agency responsible for the implementation of the Italian Digital Agenda. The Agency is the Italian representative at EU level, in the subjects of its competence. Furthermore, AGID promotes the definition and development of large strategic projects of research and innovation related to the implementation of the Italian Digital Agenda and in conformity to the European program Horizon 2020.

The Agency supports public administrations in their effective adoption and use of ICT, improving quality of services and reducing costs, with broad competences in e-Government, information society and technology innovation, including such areas as new generation networks, security, open standards, e-health, digital literacy, open data, online education, digital inclusion, and smart communities.

It identifies and promotes the main principles and rules on interoperability, usability, accessibility, etc. to be carried out by PAs in order to implement and sustain in the long-term concrete and shared objectives and actions.

It is also in charge of the design and management of IT national strategic projects, such as the development of the national civil registry, the electronic health record (HER), the electronic invoicing to Italian PA.

In the health sector, the Italian law confirms AgID the competence of implementing and evolving the national infrastructure for the interoperability of the national EHRs, in accordance with the Ministry of Health. In fact, is responsible to design the national architecturIf the EHR and to define interoperability standards and technical specifications and is responsible to define the technical structure and the guidelines of the documents a data that are going to compose the national HER.

https://www.fascicolosanitario.gov.it/

Main tasks in Project

AgID can contribute to analyse, define and improve the general X-eHealth architecture (**Work package 7 "Architecture integration and System specifications"**), to define guidelines of EHRxF domains (**work package 6 "Definition of EHRxF implementable specifications"**) and to analyse and to give advice on generic aspects of EHRxF recommendation (**work package 4 "Generic Aspects of EHRxF recommendation"**) as partner.

Relevant expertise and experience of the institution

AgID represents Italy in the several eHealth Strategy, contributing actively to policy definition and implementation.

The main experience of the institution is provided in:

- Publishing guidelines on the Iional EHR;
- Defining the national architecture;
- Defining standards for the eHealth sector;
- Defining technical specifications;
- Participating in national working group;
- Participating in several eHealth projects.

Key Personnel's CVs (incl. gender)

Enrica Massella (female) is head of Digital Ecosystems Unit. She is involved as project manager on several EU projects about the implementation of e-government processes and digital ecosystems. She is member of several boards about digital transformation for Italian Digital Agenda in the fields: e-invoicing, e-payments, ANPR (register of the resident population), documents dematerialization, electronic health records and workflows management systems.

Ing. Stefano van der Byl (male). Graduated in Management Engineering Senior in 2006 at the University of Rome "Tor Vergata"; Master degree in ICT, Logistics and Transport at the University of Salerno. In 2008 he joined the Presidency of the Council of Ministers, where he worked as Project Manager, implementing and supervising many ICT project, both national and international, and coordinating e-Government program. He worked for the "Innovation and Technology Department" on various national and European projects focused on the e-Government deployment and on the innovation support until 2012. He has been member of several groups of the European Commission. From 2013 he works for AgID as responsible of the eHealth sector and for implementing the Electronic Health Record by the national side.

Ing. Chiara Basile (female). Graduated in Biomedical Engineer Senior in 2006 at the University of Rome "Tor Vergata"; Master degree in "Management of Clinical Engineering" at the University of Trieste. She joined the San Camillo Forlanini Hospital from 2010, where she worked as Biomedical Engineer. The main activities in hospital were focused in Telemedicine, Teleradiology, Management of Electronic Clinical Records, LIS-RIS-PACS systems. She also involved in Planning and management of technical and administrative procedures for the testing activities of medical equipment. She is author of over 40 publications (including articles in international journals, national, conference proceedings, technical reports and contributions in volumes) in the field of e-health and Telemedicine. From 2017 she works for AgID in the eHealth sector and for implementing the Electronic Health Record by the national side.

Relevant publications, products, services, or other achievements (max. 5)

- National guidelines for implementing the Iional EHR;
- Architecture of the National Infrastructure for the Interoperability of Electronic Health Records;

- Technical specifications for interoperability between the regional systems;
- Technical specification and procedure to access Iional EHR form a single point. **https://www.fascicolosanitario.gov.it/linee-guida-manuali-documenti-tecnici**

Previous projects or activities related to the project subject (max. 5)

- Set up the national electronic health record infrastructure;
- eSENS;
- EpSOS;
- Dematerialisation of the electronic prescription;
- NCPeH;

Partner Full Name	**ARI– S.p.A. - Azienda Regionale per l'Innovazione e gli Acquisti**		
Short Name	***ARIA***	**Partner No.**	23
Country	Italy	**Website**	www.ariaspa.it
Type of organisation	Private	**Logo**	

Brief Partner Profile

ARI– S.p.A. - Azienda Regionale per l'Innovazione e gli Acquisti is a Company totally participated by Regione Lombardia within the Regional System (SiReg), created by the Regional Law 30/2006, modified by the Regional Law 12/2010, in order to contribute to the implementation of the regional programming objectives. ARIA S.p.A. operates with the Region according to the Framework Convention and the annual planning, approved by the Regional Government.

ARIA mission is to innovate services and increase the Regional System's productivity through Information Technology. As Regione Lombardia's IT partner, ARIA designs and implements ICT Systems for the Regional Government. The company's main projects are development and the provision of the eHealth / Electronic Health Record and e-Gov services within Regione Lombardia.

ARIA operates the Regional Electronic Health Record (SISS: Sistema Informativo Socio Santario) which gathers the clinical documents of 10 million Lombardy citizens. 95% of the GPs, all public hospitals and Labs, and most of the private ones are integrated in SISS. The Lombardy Iional EHR is connected to the Lombardy citizens' PHR, where trusted clinical data are stored through qualified Apps or formally published documents. These services will be extended by including patients' provided information.

The Data Warehouse connecteIo the EHR is the Big Data historical source for analytical analysis for Public Health statistics. Artificial Intelligence based predictive tools are in use to forecast healthcare needs.

Since epSOS LISPA (the previous company name of ARIA) operated the Italian National Contact Point for eHealth. In CEF eHDSI, where new regions are included, the Italian NCPeH has been transferred to the Italian Ministry of Economy and Finance. The Ibardy EHR is connected to the other Iional EHR system through the NationalIntral EHR Interoperability System (INI). INI is connected to the NCPeH to allow the provision of Cross-Border eHealth Services.

Main tasks in Project

ARIA will be the **WP4 leader Generic Aspects**. In addition, ARIA will be **Task Leader of T4.1 Electronic Identification implementation,**

ARIA will contribute **to WP5 – "Definition of EHRxF functional specifications",** as **T5.2 "EHRxF and its relationship with clinical guidelines" leader.**

ARIA will be the **WP7 Leader – "Architecture integration and System specifications", Task T7.1 Leader. and WP9 – "Proof of concept to the adoption of EHRxF by eHealth service" as Co-leader** and **T7.1 Leader**, to demonstrate the **application and generalisation of the guidelines to Rare Diseases**.

ARIA will also contribute to **WP3 and WP6**.

Relevant expertise and experience of the institution

ARIA will bring the experience and the use of the Lombardy highlyIcured EHR (FSR Fascicolo Sanitario Elettronico, operated over the Infrastructure "Sistema Informativo Socio Sanitario" (SISS)) for 10 million citizens, which integrates all GPs, Public and Private Hospitals and labs. The SISS is connected to theIalian EHR Interoperability System (INI) and to the Italian NCPeH to interoperate PS and eP as Country of Affiliation and Country of Service.

Key Personnel's CVs (incl. gender)

Dr. **Marcello Melgara** (male) Degree in Electronic Engineer (1980), 36 years' experience in ICT based EU projects (18 years in healthcare sector). Previous experience in Telecom Italia (1979-2001), ATOS Origin (2001-2008). Since 2008 Senior consultant at ARIA. Reviewer of several EC projects on eHealth and Semantic Interoperability. epSOS skills: WP manager for Implementation and Testing, semantic interoperability, sustainability, testing and piloting, system architecture. epSOS responsible for Implementation, testing, Semantic Services and National Pilot. Italian e-SENS eHealth pilot responsible. Trillium Bridge: WP Specification leader. EXPAND responsible for epSOS asset maintenance and relation with Institutions. H2020 PHC 34 eStandards, openMedicine, ASSESS-CT, VALUeHEALTH WP leader and contributor. He is the appointed Italian member of the eHMSEG – Semantic Task Force and WP Organisation Leader within that Task Force. He is leading tasks in the CEF eHealth Italy

Preparation and Implementation. H2020 Trillium II: responsible for Pilot implementation and Validation. CEF HEALTHeID: responsible for validation and handing over to CEF eHDSI.

Dr. **Livio De Nardi** (male) Degree in management Engineer (2008), Executive Course in Digital Innovation Management (2015), 8 years' experience in healthcare sector (which 1 year in healthcare EU projects). Since 2015 Program Manager and Demand Manager at ARIA in the role of International R&D and Prevention Service Manager. Principal eHealth Skills: Strategy management, Program management, Business Analysis, contracts procurement.

Dr. **Alberto Zanini** (male), Degree in Electronic Engineering (1997), PMP® certified (2011), 20 years' experience in ICT with a strong background on security, identity management, e-payments, e-health, and innovative technologies. Dr. Zanini is a Senior Project Manager in ARIA since 2003, and also covers the role of independent expert and reviewer for the European Commission since 2017. He was involved in several EU-funded projects on behalf of ARIA, like CREDENTIAL (H2020, Grant Agreement no. 653454), with the responsibility of the lead architect and project manager of the eGovernment pilot, and HEALTHeID (CEF, Grant Agreement no. 1444644), with the role of interoperability and cross-border identity expert.

Dr. **Francesca Fecchio** (female): management engineer (2002), 11-years working experience in health informatics at regional and national level as Demand Manager at ARIA. She has been involved in the e-Prescription implementation, in Pharmaceutical process controls management, Iional EHR system interoperability, clinical documents standardization and regional chronic-care model implementation.

Dr. **Luca Augello**: (male): Biomedical engineer (2001), post-graduate master degree in Health Technology Assessment (2005), 17-years working experience in health informatics both at hospital, regional, national & international level. Has been Involved in Iional EHR system development, chronic-care models implementation, clinical documents standardization, semantic interoperability at national & European level (CEF ehealth DSI), open data & data governance.

Dr. **Francesca Sapio** (female) has a Master's Degree in Natural Science and has attended the Post-Graduate Course in Remote Sensing and Natural Resources Evaluation starting her experience in GIS and Remote sensing applied to environmental and natural resource management in Europe and in developing countries (the final project has been development in Eritrea). Her educational and training experience has been completed with a Master in Environmental Management organized by EAME (European Association Environment Management Education), financed by EU and developed in Athens. She worked at the European Institute of Research and Development at JRC Ispra Environmental Department where she carried out technical activities for RSDE companies within European projects funded by V and VI Framework Programme (ALPMON, AWARE) and other large-scale projects as LACOAST, Corine land cover, MURBANDY managed in collaboration with national and European working groups. Since 2008, in GeneGIS GI she acts as a technical manager in the working groups for activities related to the management of gas transportation network of leading Italian operator. From 2012 the work in GeneGIS GI has been focused and specialized

in the proposal preparation and management of research and development projects (at national, European and international level), related to the management of networks, transport and critical infrastructure based on geospatial information.

Relevant publications, products, services, or other achievements (max. 5)

- M. Melgara: eHealth Interoperability – What is the future? Keynotes at Lisbon eHealth Summit 2019
- M. Melgara: The Challenges of Managing Healthcare Systems, Lisbon eHealth Summit 2019
- M. Melgara et al: Converging Patient Summaries: finding the common denominator between the European Patient Summary and the US-based Continuity of Care Document, European Journal for Biomedical Informatics. Special issue 15th International HL7 Interoperability Conference (IHIC 2015)
- M. Melgara: Are there business opportunities in the transatlantic exchange of electronic records by providers and patients? 5th EU-US eHealth Marketplace. Boston, MA, 21-22 October 2014
- A. Zanini et al: Secure and Privacy-Friendly Storage and Data Processing in the Cloud, publication, 2017

Previous projects or activities related to the project subject (max. 5)

- CEF eHDSI Italy: Implement the ePrescription and Patient Summary Cross-Border services for Euripean Citizens, CEF 2017-2020
- CEF HEALTHeID: connecting eIDAS and eHDSI to authenticate citizens seeking for eHealth Services while abroad. CEF 2018-2019.
- UNICOM: Up-scaling the global univocal identification of medicines, H2020 SC1-DTH-09-20–9, 2020 - 2023
- epSOS: Smart Open Services for European –atients - Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription CIP PSP 2008 – 2014
- CREDENTIAL: Innovative cloud-based services for Digital Identity, secure authentication and cyber-security, 2015-2017

Partner Full Name		MINISTERO DELLA SALUTE	
Short Name	**MIN SAL**	**Partner No.**	24
Country	Italy	**Website**	http://www.salute.gov.it/portale/home.html
Type of organisation	Public organisation	**Logo**	

Brief Partner Profile

The Italian Ministry of Health is the central body of the National Health Services; it is on charge of health care policies definition, health planning and provision to all citizens across the country to ensure fundamental levels of assistance, in terms of universal access and high quality of health services. Within the scope and purpose of protection and integrated management of health and social services and the protection of constitutional rights to human dignity and health, the Ministry of Health performs the functions due to the State in the following subjects: Protection of human health, coordination of the national health system, veterinary health, protection of health in the workplace and hygiene and food safety. Furthermore, the Ministry of Health is the Italian representative at EU level, in the subjects of its competence. The Italian Ministry of Health is the official government authority in Italy for health and the link with international and European institutions on all health-related topics. The Ministry of Health guarantees the respect of the national socio-economic planning in consideration of health protection objectives, identified at international level and in accordance with funding entities reserved for the National Health System.

It prepares the National Health Plan that outlines the strategic actions of healthcare for Italy that have to be implemented by regions.

- priority areas of intervention

- Essential levels of healthcare assistance (minimum threshold of health services paid by the NHS guaranteed to citizens)

- per capita amount of financing secured to the Regions for each year of validity of the plan

- needs and guidelines for staff training

- guidelines for diagnostic-therapeutic pathways

- criteria and indicators for verifying effective levels of assistance compared to what was expected

The Ministry of Health monitors the use of resources, promotes research and training

Main tasks in Project

MIN SAL will participate as a partner in the following WP and ta–ks:

WP1 - Project coordination

- T1.4: Mapping national challenges for EHRxF adoption

WP5– Definition of EHRxF functional specifications

- T5.3: Laboratory Results guideline and functional specifications
- T5.4: Medical Imaging and Reports guideline and functional specs
- T5.5: Hospital Discharge Reports guideline and functional specs

WP6 – Definition of EHRxF implementable specifications

- T6.1: Laboratory Results technical specifications
- T6.2: Medical Imaging and Reports technical specifications
- T6.3: Hospital Discharge Reports technical specifications
- T6.6 Publication and maintenance of the X-eHealth Implementation Guide (content)

Relevant expertise and experience of the institution

MIN SAL represents Italy in the several eHealth Strategy, contributing actively to policy definition and implementation. It represents Italy in the eHealth network (eHN), the voluntary network of national authorities of Member States responsible for eHealth, with a view to enhance cooperation, knowledge sharing and good practices between member States.

MIN SAL is also engaged in the 3rd Joint Action, the eHAction supporting the eHealth Network (June 2018 – June 2021) and is involved i– WP 6.1 - Roadmap on future eHDSI use cases and features and i– WP 8.1 - National eHealth strategies.

MIN SAL is also fully engaged with the OpenNCP Community for development (see https://openncp.atlassian.net/wiki/display/ncp/OpenNCP+Community+Home). Through the representative of Regione Lombardia and its affiliated entities LISPA, Italy was among the founders of the OpenNCP Community, has adopted Open NCP Solution in the framework 121nalyseOS poject (see section “previous projects” for more details).

The Ministry of Health has been financed by the Connecting Europe Facility (CEF) to implement the Italian National Contact Point for eHealth (NCPeH). The project is aimed to prepare, test and deploy the cross-border Patient Summary and the ePrescription taking into account the already existing national infrastructure. Italy intends to implement cross-border Patient Summary and ePrescription during the third quarter of 2021. The consortium involved in NCPeH project implementation is composed of the Italian Ministry of Health as Coordinator, Digital Italy Agency (AgID), Emilia Romagna, Lombardy and Veneto; an amendment request was recently submitted to introduce the Ministry of Economics and Finance as new partner.

At national level, MIN SAL is a National eHealth System owner and contribute to design eHealth regulation and strategy. Indeed, it has identified eHealth as one of the strategic goals to be reached since 2008. Furthermore, eHealth is one of the areas for the digital growth listed by the Italian Government in its “ocument "Strategy for digital growth ”014-2020". On 2019,

MIN SAL has approved The Digital Healthcare Pact that represents the strategic plan aimed to achieve efficiency, transparency and sustainability of the NHS, through digital innovation in healthcare.

The pact proposes to implement actions aimed at:

- use of new technologies that allow information to be networked and ensure transparency

- collection of performance data in order to guarantee investments

- control and validation of the protocols to be tested and / or inserted into the system in terms of economy, validity, efficiency and measurability of the effects for the purpose of replicability

- complete and certified collection of NHS information for

a) the construction of databases with strong governance (addresses, standardization, interoperability)

b) guarantee a continuous comparison of activity and economic data between the various actors and levels of the NHS

Since 2008, the Ministry of Health has been implementing many different eHealth initiatives nation-wide in collaboration with Regions.

MIN SAL create the New Health Information System (NSIS) that is the reference tool for the quality, efficiency and appropriateness of the National Health Service (SSN), through the availability of information, which, for completeness, consistency and timeliness, supports the Regions and the Ministry in the exercise of their duties. NSIS was born, therefore, with the aim of making available, nationally and regionally, a wealth of data, rules and methodologies for quality, efficiency, appropriateness and cost measures to support the NHS government, monitoring and control of health expenditure, shared among the various institutional levels and centred on the citizen.

The objectives of NSIS objectives are:

• monitoring the health status of the population;

• monitoring the effectiveness / efficiency of the health system;

• monitoring the appropriateness of the provision of benefits in relation to the demand for health;

• monitoring of health expenditure;

• availability at national level of an integrated system of individual health information;

• facilitating user access to facilities and services through IT tools;

• promotion of the globalization of service ”fferings"

MIN SAL is responsible of the Electronic Health Record in Italy, a set of digital data and documents, related to health and social aspects of the patient and generated from present and past clinical events.

The data collIed in EHR can be used for purposes of care, research and governance.

Key Personnel's CVs (incl. gender)

Serena Battilomo (female), Graduated in Statistical and Economic Sciences with 110/110 cum laude, she earned an Executive Master in Public Administration Management at SDA Bocconi. In March 2019, she was appointed as Director of Office 3 of the Directorate General for the Digitalization, of the Health Information System and Statistics. In particular, it deals with the identification of the information needs of the NHS (National Health System) in conjunction with the other general directorates. The Directorate is in charge of the coordination of the NHS computerization through the planning, design, development and management of the systems and information flows. She handles the proposals on the national e-health strategy and its implementation as well as the integration of technological innovation in healthcare processes. It provides support to the functions of the control room of the New Health Information System and coordinates, with MEF and AGID, the implementation process of the Electronic HealthIcord (EHR) and the digitization of health documentation. She participate in European projects for e-health, as representative of Italy. Previously, within the competences of the Office for the health of migrants, she was the Italian focal point of the Equi-health project coordinated by the International Organization for Migration (IOM). She collaborates with the Ministry of the Interior as part of initiatives inter-institutional financed with FAMI funds. She coordinated the work for the drafting of national guidelines for assistance to refugees who are victims of torture, rape and intentional violence. In July 2013, she has the role of office manager at the General Directorate of Health Prevention in the context of the protection'of women's health, developmental age and all vulnerable subjects, including migrants, disabled, elderly and LGBTI. In 2008, she was awarded the "onor of "Knight of Merit of the Italian"Republic".

Valeria Proietti (female) Graduated in Physics, she works in the National Healthcare Information System (SISN) Unit of the Directorate General of Digitization, Health Information System and Statistic of the Ministry of Health. Work experience: implementation of e-health solutions; project manager for design and development of healthcare information systems; expert in exchange data relating patients international mobility, referent for the establishment of the National Contact Point. Previously she was in charge of planning, designing, monitoring development and managing the systems of the Ministry of Health and the Italian Drug Agency for medical devices, human and veterinary drugs. From 1994 to 1999 she works as contractor at the European Space Agency, taking care of the testing and validatio123nalyse123 european environmental satellites data processing systems. She was a scholarship holder and scientific consultant for Thales Alenia Space Italia Spa, dealing with the development of decision support systems for environmental risk management and land protection.

Sergio Tedeschi (male), graduated in Information Technology Engineering at University of Naples Federico II, with post-graduation in Information Systems Government at Roma Tre University. He worked as IT specialist at National Institute of Statistics of Italy (Istat) in an

environmental project. He has been working at Ministry of Health of Italy since 2005, holding positions in the statistics office and in the IT infrastructure office. Recently he had a two-years job experience at European Commission (DG ESTAT), working on the validation of social protection and health data. Now he is working in the National Health Information System office, following several eHealth projects funded by European Commission, specifically at the Cross Border project of the National Contact Point of ePrescription and eDispensation at the level of the Connecting Europe Facility.

Relevant publications, products, services, or other achievements (max. 5)

MIN SAL is involved and committed to generate scientific material and to publish it in dedicated magazines as for example:

Article on Integrated use of healthcare utilization databases: the Italian Legislative Decree on the interconnection of information flows Epidemiol Prev 2019; 43 (1): 106-108

Several projects with high visibility were developed internally as the **New National Health Information System** that manage several flux of dates such as:

- Information system for home care monitoring
- Information system for emergency assistance monitoring
- Information system for Hospices assistance monitoring
- Residential and semi-residential assistance
- Addictions Information System
- Errors in healthcare monitoring
- Service network monitoring
- Public investment in healthcare observatory
- Information System for the monitoring and protection of Mental Health

Se Parto Per Guide

MIN SAL develop an interactive guide, called “Se parto per” that allows all assisted (all those who are registered and are dependent by the National Health–Service - SSN) and all health workers to have information on the health care system during their permanence in any country in the world. In particular they can have information on:

- how to get healthcare in any country in the world
- who are the healthcare contact
- how to request any refunds

To use the guide you will need to answer three questions:

Where are you going? For what reason? What category do you belong to?

All your choices will be guided and you will have the list of all the countries of the world available; the list of all the possible reasons for the trip and the list of all the types of users envisaged (worker, student, etc.).

Previous projects or activities related to the project subject (max. 5)

The MIN SAL participate in different projects relative to eHealt–:

EPSOS - European Patients Smart Open Services (J–ly 2008 - June 2014)

The Ministry of Health, through delegation to the Lombardia region, participated in the Smart Open Services project for European Patients (epSOS).

Scope: a European large-scale pilot testing the cross-border sharing of certain health data: a summary of ’ patient's most important health data in case of unplanned care (the patient summary) and the electronic prescription (ePrescription).

At the end of the epSOS, within the eHN, a sub-group has been set up to preserve the functionality of the developed services and to pursue the implementation of the same large-scale services within“the CEF "Connecting Europe”Facility"–

PARENT - Cross-Border pAtient REgistries iNiTiative. (J–ly 2008 - June 2014)

Scope: Support member states in developing comparable and coherent patient registries in fields of identified importance with the aim to rationalize and harmonize the development and governance of patient registries

Products: Guidelines on Patient Registries (November 2015)–

ProMIS - International Health Brick Program (national project – 2011 onwards)

The Italian Ministry of Health supports the 21 Italian Autonomous Regions in their internationalization processes connected with the health and social dimensions through participation in ProMIS.

ProMIS stands for Programma Mattone Internazional– Salute - International Health Brick Program: the building blocks of the New National Health System are called Mattoni (bricks), they define the contents and the methodology on which the serv“ces a”e "built".

Since its establishment in 2011, ProMIS has been promoting opportunities of cooperation among the Italian regions about themes identified as main topics for a common approach; they are jointly developed and implemented by the central, regional and local administrations.

eHGI – eHealth Governance Initiative, (Feb 2011 – Jan 2014)

Products:

Guidelines on Patient summary (Nov 2013)

Guidelines on ePrescription (Nov 2014)

JAseHN – Joint Action to support the eHealth Network (May 2015; May 2018)

MIN SAL was partner to the JAseHN, ensuring participation in this project; JAseHN has as objectives to ensure the regular production of instruments and recommendations to be presented to the eHN.

Products:

Guideline on the electronic exchange of health data under Directive 2011/24/EU (Nov 2016)

Partner Full Name	**Regione Lombardia**		
Short Name	**REGLOMB**	**Partner No.**	25
Country	Italy	**Website**	www.regione.lombardia.it
Type of organisation	Public	**Logo**	RegioneLombardia

Brief Partner Profile

Regione Lombardia General Directorate for Welfare is responsible for healthcare policy design, implementation and delivery to its 10 million citizens. The General Directorate for Health holds the regulatory and administrative competencies in the healthcare domain, including planning and supplying, quality monitoring and control, appropriateness and efficiency of services. As regional governing authority Lombardy plans its own programming and strategies in prevention area based on efficacy, effectiveness and sustainability criteria and multi-stakeholders'approach**.**

Main tasks in Project

Since epSOS Large Scale Pilot, Regione Lombardia acted as National Contact Point for eHealth

The Lombardy Department participating to X-eHealth is in charge of managing the policies and the guidelines Hospitals in Lombardy, and related clinical data exchange. It is also managing the European Projects for DG Welfare.

In X-eHealth, Regione Lombardia will **co-operate in:**

WP3 – Evaluation

- T3.1: Establish evaluation strategy
- T3.2: Evaluation of results for the new services

WP7 – Architecture integration and System specification.

- T7.4: Guidance for the new EHRxF domains

and provide support to Istituto Nazionale Tumori (INT), its Linked Third Party.

Relevant expertise and experience of the institution

Regione Lombardia will bring its experience in defining, governing and managing the healthcare services for the Lombardy citizen, together with the clinical knowledge from the 19 Research Hospitals, also members of the ERN, the Public/Private network of Primary and Secondary Healthcare Providers. All these entities are connected through the Iional EHR (SISS: Sistema Informativo Socio-Sanitario), also accessible to citizens, and connected to the Iional EHR and, through it in future, to the CEF eHealth Digital Service Infrastructure for Cross-border Services.

ePrescriptions/eDispensations, Hospital Discharge Letters, Laboratory Test Reports, Encounter Reports, Rare Disease Patient Records and Repository, Continuity of Care Plans for chronic patients are the most relevant among the clinical documents managed by the Iional EHR. The Personal Health Record (called Taccuino) is connected to the Iional EHR. A new September 2019 Regional Law has established the creation of a centralised repository for Clinical Images and reports, included in the Iional EHR.

Lombardy Region started collecting structured data on healthcare events, resources & costs (leveraging on Lombardia Informatica (currently ARIA) technological expertise) around year 2000, mainly to support health care system governance & evaluation, within a regional data ware-house (DWH) ecosystem that has progressively grown up in features offered.

With 10 million inhabitants & about 3,2 million chronic population, progressively ageing and developing comorbidities, it was earlier recognized that data governance could strongly support the required changes in chronic care management.

In 2012 it was launched an experimental chronic care model reform targeted at more than 100.000 citizens, that ended in 2017 and was overcome by a new larger implementation targeted at all chronic conditions (up to 3.2 million people), started in January 2018.

Key Personnel's CVs (incl. gender)

Dr. **Alessandra Piatti** (female). Medical Doctor and PhD, specialised in Hygiene and Prevention Medicine (University of Milan and London School of Hygiene). Manager, Head of the Unit "Planning and Projects", under the General Directorate "Welfare", Regione Lombardia, with mandate on the definition and assessment Health & Social Support Plans, the promotion of the creation of Network of Pathologies (chronicity, frailty, rare diseases, transplant networks), to guarantee homogeneity over the territory and the compliance with National / International Guidelines in particular for high complexity pathologies, the management of International projects on Health. She covered several relevant roles in different Lombardy healthcare institutions (Preventive Medicine, Italian Cancer Registry, Disaster Management Unit).

Dr. **Annalisa Bodina** (female). Medical Doctor and PhD, specialised in Hygiene and Prevention Medicine (University of Milan) and doctor on Public Administration (University Bocconi), Manager of Network of Pathologies and Rare Diseases, Unit Clinical Research and Organisation, under the General Directorate "Welfare", Regione Lombardia. She was responsible for the ISO 9001-2015 Quality Certification of Lombardy Territorial Healthcare

Institutions. Responsible for appropriateness KPI monitoring of the Discharge Letters for the DG Welfare.

Relevant publications, products, services, or other achievements (max. 5)

For Lombardy Region:

- L Moja, A Piatti, V Pecoraro, C Ricci, G Virgili, G Salanti, L Germagnoli et al.: Timing matters in hip fracture surgery: patients operated within 48 hours have better outcomes. A meta-analysis and meta-regression of over 190,000 patients. PloS one 7 (10), e46175
- Benedetti G, Radice C, Schieppati S, Bodina A, et al. : Telemedicine System for the management of patient affected by Acute Stroke. Tecnica Ospedaliera, novembre 2017: 44-46.
- Tagliabue L, Banzi R, Bertizzolo L, Bodina A, Piatti A, et al.: Horizon for Public Health within the Cochrane Collaboration. Ann Ig 2013; 25 (Suppl. 1): 401-410.
- Carlotta Franchi, Ida Fortino, Angela Bortolotti, Luca Merlino, Alessandro Nobili: Rapid response: How to move to a palliative approach to care for people with multimorbidity. 8 January 2013 – BMJ N.1840
- Gianni M, Terao M, Fortino I, LiCalzi M, Viggiano V, Barbui T, Rambaldi A, Garattini E.: Stat1 is induced and activated by all-trans retinoic acid in acute promyelocytic leukemia cells. Blood. 1997 Feb 1;89(3):1001-12.

For Istituto Nazionale Tumori (INT), Linked Third Party of Lombardy Region:

- Casali PG. Rare cancers: from centralized referral to networking. Ann Oncol. 2019 Jul 1;30(7):1037-1038. doi: 10.1093/annonc/mdz146. No abstract available.
- Frezza AM, Trama A, Blay JY, Casali PG. Networking in rare cancers: What was d'ne, what's next. Eur J Surg Oncol. 2019 Jan;45(1):16-18. doi: 10.1016/j.ejso.2018.03.030. Epub 2018 Apr 12.
- Pasquali S, Bonvalot S, Tzanis D, Casali PG, Trama A, Gronchi A; RARECARENet Working Group. Treatment challenges in and outside a network setting: Soft tissue sarcomas. Eur J Surg Oncol. 2019 Jan;45(1):31-39. doi: 10.1016/j.ejso.2017.09.015. Epub 2017 Sep 19.
- Casali PG, Bruzzi P, Bogaerts J, Blay JY; Rare Cancers Europe (RCE) Consensus Panel.Rare Cancers Europe (RCE) methodological recommendations for clinical studies in rare cancers: a European consensus position paper. Ann Oncol. 2015 Feb;26(2):300-6. doi: 10.1093/annonc/mdu459. Epub 2014 Oct 1.
- Casali PG. Rare cancers: work in progress in Europe. Ann Oncol. 2014 Apr;25(4):914. doi: 10.1093/annonc/mdu033. No abstract available.

Previous projects or activities related to the project subject (max. 5)

- **CEF eHDSI Italy:** Implement the ePrescription and Patient Summary Cross-Border services for Euripean Citizens, CEF 2017-2020
- **VALUeHEALTH**: Establishing the value and business model for sustainable eHealth services in Europe, H2020 CSA, 2015-2017
- **ALIAS:** Alpine Hospitals Networking for Improved Access to Telemedicine Services, Alpine Space 2009 – 2012
- **NATHCARE**: Networking Alpine Health for Continuity of Care, Alpine Space 2012 – 2015
- **epSOS**: Smart Open Services for European –atients - Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription CIP PSP 2008 – 2014

Partner Full Name	National Health Service of the Republic of Latvia		
Short Name	**NVD**	**Partner No.**	26
Country	Latvia	**Website**	http://www.vmnvd.gov.lv/en
Type of organisation	Public organisation	**Logo**	Ministry of Health Republic of Latvia

Brief Partner Profile

NVD is a subordinate institution of the Ministry of Health. It is a public enterprise created in 2011. Its aim is to implement State policy for availability of health care services,

administrate the State budgetary funds prescribed for health care, implement State policy in the planning of health care services, ensure rational and the most effective use of State budget, implement the e-Health program according to the policy decided by the State.

Main tasks in Project

NVD will participate in this CSA project and will share expertise and will work on the development of deliverables in **WP4 in cybersecurity task T4.3**, as well as in **WP6 working on laboratory results domain's technical specification and rare diseases adding to**

patient summary, and in **WP8 tasks** on deliverables in rare disease as well as in tasks 8.4 till 8.6.
Relevant expertise and experience of the institution
Being Latvian National authority for cooperation matters in the field of eHealth, NVD together with the Ministry of Health represents Latvia in the eHealth Network (eHN). Currently NVD is participating in Electronic Exchange of Social Security Information project and is planning to apply for Connecting Europe Facility eHealth project (Call CEF-TC-2019-2) in order to join ePrescription and Patient Summary exchange platform.
Key Personnel's CVs (incl. gender)
Edg–rs Goba - Deputy Director of National Health Service, responsible for information and communication technology field, ♂, graduated in Information Technology. He obtained his Master degree in Riga Technical University. Currently he is responsible for implementation the e-Health program in the State, participation in international projects in the field of eHealth, for planning and organization of IT resources in National Health Service. In total, he possesses 20 years' experience in the field of IT management in public sector. **Vera Gubernatorova** – Project Manager in Information Technology Projects Development Unit, National Health Service, ♀, graduated in Analytical Economics. Since the beginning of 2019 she is responsible for such areas in eHealth 's People's Recovery Empowerment Development Assistance IS, eReferral&eBooking system, eResults (including Hospital Discharge, Visual Diagnostics, outpatient eResults), system of classifiers (including ORPHA code classification), as well as exchange process with external systems.
Relevant publications, products, services, or other achievements (max. 5)
NVD has more than 10 years' experience in implementation of IT solutions in Health Industry at both local and European level. As organization responsible for eHealth management in Latvia, NVD has developed and already introduced in production Visual Diagnostics result and image, as well as Hospital Discharge. Laboratory results are to be implemented by the end of 2021.
Previous projects or activities related to the project subject (max. 5)
Within EU funding (**ERDF)** NVD by the end of 2014 has developed eHealth Integration platform. Based on the platform several major projects have been carried out: for the purpose of centralized gathering of patients' data Electronic Health Record was implemented; furthermore NVD developed Patient Summary for representation of main health information; the most popular systems introduced by NVD since the beginning of eHealth in Latvia have been ePrescription IS and system of eSick Leave Certificates.

Partner Full Name	Ministry of Health of The Republic of Lithuania

Short Name	**SAM**	**Partner No.**	27
Country	Lithuania	**Website**	http://sam.lrv.lt/en/
Type of organisation	Ministry of Health	**Logo**	MINISTRY OF HEALTH OF THE REPUBLIC OF LITHUANIA

Brief Partner Profile

The Ministry of Health of the Republic of Lithuania (Sveikatos apsaugos ministerija – SAM) is an institution that exercises executive powers, carries out State administration functions established by the laws and other legal acts in the health care sector, and implements State policy in the health care sector. Mission of Ministry of Health is to form and implement health policy that ensures public health, high quality health promotion activities, and rational use of resources.

Main tasks in Project

SAM will participate in this X-eHealth project and will share expertise in **WP4, WP5, WP6 and WP8** at the required extent.

Relevant expertise and experience of the institution

Ministry of Health leads digital health strategy in Lithuania and represents Lithuania various European and Global eHealth events and networks, for instance European eHealth network (eHN), the voluntary network of national authorities of Member States responsible for eHealth, with a view to enhance cooperation, knowledge sharing and good practices between member States.

Currently, Ministry of Health is involved in CEF project and is planning to test cross border exchange of ePrescription/eDispensation.

In addition, Ministry of Health is actively involved in the Joint Action of the third Health Programme (eHAction – Joint Action supporting the eHealth Network).

Key Personnel's CVs (incl. gender)

Linas Kavolius - ♂, Advisor for eHealth information technology coordination and implementation in the Ministry of Health of the Republic of Lithuania. Holds a master's degree in informatics and a bachelor's degree in international business from Vilnius university. Linas has 20-year experience in information technology project analysis, specification, development and project management. Worked in these areas: state registers and information systems, insurance, leasing, risk management, customer relationship management, finance.

Lukas Galkus - ♂, Chief Specialist at Electronic Health System and Informational Resources Division. Lukas has graduated Lithuanian University of Health Sciences in 2018 and holds a degree of medical doctor. He has experience in other European projects in the public health field. His current responsibilities include surveillance of central eHealth System (ESPBI IS),

consulting health care providers on eHealth topics and implementing development plan of eHealth.

Justas Trinkunas - ♂, Information systems project manager in Informatics and Development Centre at Vilnius University Hospital Santariskiu Klinikos (VULSK). He is responsible for the development of the Hospital Information Systems. He has more than 10 years' experience working with e-health information systems. He participated in Joint action to support the eHealth network (JAseHN) project in 2015-2019. In 2010 he become Doctor of Science (Sciences of technology, informatics engineering, Vilnius Gediminas University). He has experience as a lecturer and researcher in Vilnius Gediminas University from 2006. He wrote more than 20 scientific papers on information systems development and lectured in universities in Europe, Africa and Asia.

Simona Cirtautaite-Kaminskiene – ♀ Chief Specialist at Electronic Health System and Informational Resources Division. Simona has graduated Vilnius University Faculty of Law in 2004 and holds a master 's degree in Laws. She has experience as lecturer in Vilnius University since 2004 and is a member of Science Centre of Labour Law at Vilnius University Faculty of Law. His current responsibilities include surveillance of central eHealth System (ESPBI IS), consulting health care providers on eHealth legislative topics and implementing development plan of eHealth

Relevant publications, products, services, or other achievements (max. 5)

- SAM is an active participant in present EC projects (eHAction, engaged in topics as empowering people, enhancing continuity of care and innovative use of health data);
- SAM has more than 10 years' experience in development and implementation of IT solutions in healthcare sector. As governor of eHealth system, SAM has implemented an excIge of EHR, medical images, ePrescriptions, etc.
- Successful deployment of Iional EHR platform, comprising of documentaIn and EHR records (> 1,3 million records monthly);
- Successful deployment of ePrescription. A fully deployed system (>95% of all reimbursed drugs prescriptions, > 99 % HC providers, > 95% of the population);
- Successful implementation of patient portal.

Previous projects or activities related to the project subject (max. 5)

Ministry of Health is the main manager of ESPBI IS (central eHealth system) after its launch in 2015.

The Lithuanian e-health system consists of:

- The central IS (ESPBI IS), which contains the storage of electronic medical history, as well as its sub-systems: e-recipe and Medical Images;
- The main IS / registers of the health sector: IS of medical terms (SNOMED CT), Register of medical licenses of healthcare and pharmaceutical professionals, IS of medicinal products, IS of institution licensing;

- 23 HIS.

ESPBI IS ensures a unified access to e-health services for both citizens, and healthcare professionals. The patient health data (history, analyses, diagnoses, recipes, referrals, x-rays, certificates, etc.) is submitted to said system by the healthcare institutions who participated in eHealth projects via the e-health portal www.esveikata.lt. PHIs that do not have electronic systems can also submit data to the central IS via said portal. 150 PHIs took part in the e-health system's development programme.

Partner Full Name	Nationaal ICT Instituut in de Zorg		
Short Name	**Nictiz**	**Partner No.**	28
Country	Netherlands	**Website**	https://www.nictiz.nl/
Type of organisation	National Competence Centre	**Logo**	Nictiz Betere gezondheid door betere informatie

Brief Partner Profile

Nictiz (National IT institute for Healthcare) is the national Dutch competence centre for eHealth, interoperability and standardization. It is an independent, not for profit, organization and has an intermediary position between healthcare, industry, and government. Nictiz is an adviser for the Ministry of Health of the Netherlands on national and international affairs, such as the eHealth Network. Nictiz supports the development of national interoperability standards and profiles. To this end Nictiz maintains close cooperation with the international Standardization Organizations: IHE, HL7, SNOMED International, PCH Alliance, CEN/NEN. Nictiz is the National Release Center for SNOMED CT. Nictiz is a member of EHTEL and participates in the network for European competence centers (EHTEL/ELO).

Main tasks in Project

WP1: Nictiz will be co-lead for WP1 and task lead for tasks 1.3 and 1.4
WP5: Nictiz will be work package leader for WP5 together with MZCR (Czech Republic). In this WP Nictiz will be task lead for tasks 5.4 and 5.7.

Relevant expertise and experience of the institution

- Nictiz is the national competence centre for eHealth
- Nictiz is an independent liaison between healthcare, industry and government
- Nictiz works on the development of interoperability standards and profiles
- Nictiz is involved in several national programs working on information exchange
- Nictiz was part of epSOS, Antilope, JAseHN and is part of eHAction and eHDSI
- Nictiz is member of IHE and HL7, SNOMED, PCH Alliance and CEN/NEN

Key Personnel's CVs (incl. gender)

Elise Peters (female) works at Nictiz since 2016 as eHealth adviser international. She did her masters in business communication & digital media and public information management. Before Nictiz she did a traineeship in information management and worked at the Erasmus Medical Centre in Rotterdam. As eHealth adviser at Nictiz she was involved in JAseHN and currently she is involved in eHDSI (use case PS-B) and eHAction (WP4 lead).

Maayke Klinkenberg (female) has worked since 1981 in informatics in different sectors . Since 2007 she has worked as an information analyst and IT consultant in several hospitals, most recently at an Academic Medical Centre (Amsterdam UMC). She has a PDEng in Clinical Informatics. She joined Nictiz in 2019 as senior advisor and is currently involved in various international interoperability projects.

Vincent van Pelt (male) is a senior advisor at Nictiz, the Dutch healthcare ICT competence centre. He is a physician with a drive to improve information exchange and cooperation between all relevant parties concerning the health issues of citizens. He has worked in many fields of healthcare ICT and has a broad knowledge of healthcare ICT related topics. He is a member of IHE Netherlands, IHE international and HL7 Netherlands. He is or has been involved in a number of European projects, such as Antilope, eStandards and CEN IPS (International Patient Summary). In the Netherlands, he is one of the architects of a standards-based set of rules defining the national Personal Health Environment (MedMij). In the context of an Implementation Guide to interoperability between XDS Affinity Domains he is currently part of a taskforce that focuses on a multi-country harmonization of national definitions for an interoperable cross-community exchange of XDS metadata.

Pim Volkert (male) joined Nictiz in 2012 and is the coordinator of the Terminology Centre and the SNOMED National Release Centre. Pim is also one of the managers of the Clinical Informatics study at the Technical University Eindhoven. Before that he worked 3 years for an interIional EHR vendor and 11 years in a hospital. Pim started his career as an Agricultural Economist and worked for the Netherlands Ministry of Foreign Affairs and the United Nations World Food Program in several African Countries.

Relevant publications, products, services, or other achievements (max. 5)

Nictiz does not publish scientific papers. However, with the involvement in European and national standardisation, Nictiz publishes many communication materials and papers. Nictiz is involved in the national program and the development of the framework MedMij (https://www.medmij.nl/en/personal-health-environment/). In addition, Nictiz has a national release center in zibs (health and care information models) (https://zibs.nl/wiki/HCIM_Mainpage), a Terminology Centre and the SNOMED National Release Centre. Nictiz was involved in introducing the ReEIF to the eHN

(https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf). A program running in the Netherlands currently is Twiin with one of the objective to share images between health professionals (information on website only in Dutch).

Previous projects or activities related to the project subject (max. 5)

Nictiz is an active participant in present and past EC projects (eHAction, ASSESS CT, eStandards, JAseHN, Antilope, epSOS and CEN IPS).

- Within CEN IPS Nictiz worked on creating the international patient summary.
- Within JAseHn and eHAction Nictiz was and is WP leader and engaged in topics as interoperbality and empowering people
- Within eHDSI Nictiz works on use case PS-B; retrieving PS from other EU countries and is involved in eHMSEG, PS WG and Semantic Task Force

Partner Full N–me	NCZI - National Health Information Centre		
Short Name	**NCZI**	**Partner No.**	29
Country	Slovak Republic	**Website**	www.nczisk.sk
Type of organisation	Public sector undertaking	**Logo**	

Brief Partner Profile

The mission and the subject of the activities of NCZI in the Slovak Republic is to promote the use of IT systems in healthcare, to support and ensure the operation of implemented eHealth solutions, and to ensure a flexible information base for authorized persons. Because of that, NCZI also supports the introduction of ITC standards into the healthcare arena.

NCZI is a state-funded organization founded by the Ministry of Health of the Slovak Republic.

NCZI performs tasks in the following areas:

- informatization of health services, administration of the National Health Information System
- standardization of health informatics
- health statistics
- administration of National Health Administrative Registries and National Health Registries

- provision of library and information services in the field of medical sciences and healthcare services

NCZI collaborates with institutions such as the Statistical Office of the Slovak Republic, the Healthcare Surveillance Authority, the Public Health Authority of the Slovak Republic, the State Institute for Drug Control, institutes of the Slovak Academy of Sciences, healthcare providers, chambers and health professional organisations, health insurance companies and medical faculties.

At international level, NCZI collaborates with WHO, EOCD, EUROSTAT and EMCDDA.

Main tasks in Project

NCZI will participate in **WPs 5 and 6** and in both packages hande t–e topic - **Hospital Discharge Reports.**

Relevant expertise and experience of the institution

NCZI has experience in operating national eHealth services.
Since the 1.1.2018 medical documentation exchange in the Slovak Republic occurs on a central level and the Information System of NCZI is the unique central system for medical documentation storage and exchange. Since than more than 83 million ePrescriptions and about 27 million medical records have been saved into the Slovak National eHealth System.
At the same time, as member of the eHMSEG, NCZI follows the implementation, deployment and operations processes of other Members States which have already undergone this process.

Key Personnel's CVs (incl. gender)

Pavol Rieger, ♂, Ing., currently in NCZI responsible for International Projects and International Cooperation. He is a deputy representative of the Slovak Republic in eHN, member of eHMSEG, member of general assembly of Snomed CT.

In the past, he participated in epSOS project and ANTILOPE project.

Eva Sabajova, ♀, Mag., studied Economics and Linguistics at Comenius University of Bratislava (Slovakia) and University of Bremen (Germany). Since 2017, she works at NCZI, where she established Call Centre for the purpose of performing the support for health professionals regarding eHealth services. Nowadays, she performs analytical functions in the area of cross-border health data exchange, primary at the semantic level.

She actively collaborates on actual and planned European projects, specifically at the cross-border health data exchange project of the National Contact Point of ePatient Summary.

Relevant publications, products, services, or other achievements (max. 5)

- NCZI is a national correspondent for OECD in field of healthcare since 2001. NCZI contributes annually to upload and update OECD databases according to established methods
- NCZI provides statistical health data to WHO database named HFA – European Health for All

Previous projects or activities related to the project subject (max. 5)

In past, NCZI participated in the **epSOS project**, piloted cross border Patient Summary (country A and country B) and ePrescription (country A and country B), and gained experience in deploying operational solutions (real patient data) for cross border Patient Summary (country A and country B) and ePrescription (country A and country B). Later on, NCZI took part in the **EXPAND** project and contributed to maintain and sustain key cross-border eHealth Interoperability assets. NCZI also participated in the **e-SENS** eHealth pilot where technological assets were refined and upgraded to adopt CEF Building Blocks and elevated to Technology Readiness–Level 9 - Actual system proven in operational environment.

Partner Full Name	SI: Nacionalni inštitut za javno zdravje, NIJZ EN: National Institute of Public Health, NIPH		
Short Name	NIJZ	**Partner No.**	30
Country	Slovenia	**Website**	www.nijz.si
Type of organisation	Public institution/ Publich health, eHealth	**Logo**	NIJZ Nacionalni inštitut za javno zdravje

Brief Partner Profile

The National Institute of Public Health (NIJZ) is the central Slovenian institution for public health practice, research and education. Its academic staff work on various tasks covering the areas of epidemiology of communicable and non-communicable diseases, health promotion, health protection, health system research and national coordination of preventive programmes in primary health care Although public health practice is not in the exclusive domain of a single type of organisation or profession, the majority of important public health functions and services in Slovenia are provided by NIJZ. Furthermore, NIJZ functions as the central statistical authority in health sector and is responsible for the governance of the national eHealth system. The main function of NIJZ is to provide research in the field of health, protect and increase the level of health of the population by raising the awareness of population and carrying out other preventive measu'es. NIJZ's activities include national health statistics and research in the field of public health, health care systems; identification and control of health threats; designing and providing health promotion programmes and preparing a scientific background for health-friendly policies, programmes and measures for disease prevention. As of 2015 NIJZ is appointed for governance of national eHealth services.

Main tasks in Project

NIJZ will be a contributing participant in the work packages/ta–ks:

WP4 - Generic Aspects of EHRxF recommendation

- T4.1: Electronic Identification implementation
- T 4.2. Legal aspects & enable–s;

WP 5 - Definition of EHRxF functional specifications

- T5.3 Laboratory Requests and Reports guideline and functional specification–;

WP 7 - Architecture integration and System specifications

- T7.1 Global architecture for EHRxF Domains us;

Relevant expertise and experience of the institution

NIJZ is engaged in numerous activities covering the areas of epidemiology, health promotion, statistics, and national coordination of preventive health programmes.

In accordance with Healthcare Databases Act, NIJZ is controller of various healthcare databases and is an authority for terminologies, coding standards and classifications in the Slovenian healthcare sector. Furthermore, NIJZ is lawfully authorised entity for national eHealth governance, responsible for design, development, implementation, deployment and maintenance of eHealth services. Slovenia has a mature and widely deployed eHealth system, providing valuable services such as ePrescription, eAppointment, eReferral, Central Registry of Patients Data (Iional EHR platform) and Patient Portal.

NIJZ has successfully coordinated and participated in many international collaborative projects. Being competent on all aspects of the public health, NIJZ presents a capable partner in any health-related projects.

Key Personnel's CVs (incl. gender)

The following persons are envisaged for carrying out the proposed activities:

Dalibor Stanimirović, PhD, is a researcher and Head of Centre for health care informatics at the National Institute of Public Health of the Republic of Slovenia (NIJZ). He is an Assistant Professor of informatics at the University of Ljubljana. His research work has been published in high-ranked scientific journals and presented at leading conferences and seminars. His general research interests include ICT policies and projects in health care, evaluation metrics and models, government enterprise architectures, and health information systems. In the last years, he has been actively involved in several research projects: Development of Pan-European information society services in Slovenia (EuPAN), Development of an integrated model of indicators for monitoring and evaluation of e-government policies (KRONOS), Deploying sustainable cross-border eHealth services in the EU (EXPAND), e-Certification of Causes of Deaths (e-DC), Analysis and development in the field of rare diseases in Slovenia, Cro–dHEALTH - Collective wisdom driving public health policies, etc.

Vedrana Matetić is an IT professional with extensive experience in analysis, development and management of various IT projects. She is currently a member of eHealth team at Centre

for health care informatics at the National Institute of Public Health of the Republic of Slovenia (NIJZ), where she is in charge of the national ePrescription solution. She has been actively involved in several research and development projects, including EU funded Assistance for the blind and visually impaired (ALICE), Humane technology for enhanced user experience (Emphatic Products), etc.

Nina Zenkovič, graduated in Computer and Information Science from the University of Ljubljana. She has worked as a member of Centre for Healthcare Informatics at the National Institute of Public Health of the Republic of Slovenia (NIJZ) since 2017 and joined their eHealth team in 2018. She has been involved in the eAppointment segment of the national eHealth platform, as well as research and development projects regarding telehealth. The focus of her previous work experience was complex data analysis in the field of spatial informatics.

Alen Vrečko, MSc, is currently employed as a health care informatician and researcher at the National Institute of Public Health of the Republic of Slovenia (NIJZ). In 2014-2015, he was actively involved in EU funded cross-border projects PARENT (Cross-border patient registries initiative) and EXPAND (Expanding health data interoperability services). His past research interests include cognitive systems, robotics, computer vision and artificial intelligence. As a member of the Visual Cognitive Systems Laboratory at the University of Ljubljana, he participated in EU FP6 and FP7 proje–ts Cosy - Cognitive systems for cognitive assistants (2007-2008) –nd CogX - Cognitive systems that Self-Understand and Self-Extend (2008-2012). He authored and contributed to several scientific publications from the fields of artificial intelligence, cognitive systems and ”obotics."

Lucija Tepej Jočić, graduated in physics at the University of Mathematics and Physics in Ljubljana. She is a member of Centre for healthcare informatics team at the National Institute of Public Health of the Republic of Slovenia (NIJZ). She is currently working as business analyst and project coordinator in the field of national eHealth solutions. She is actively involved in different activities on many viewpoints of the Electronic Health Record in Slovenia. Her previous work experience includes management of complex ICT projects in the field of telecommunication.

Relevant publications, products, services, or other achievements (max. 5)

Publications:

- Stanimirović, Dalibor, Murko, Eva, Battelino, Tadej, Grošelj, Urh. Development of a pilot rare disease registry : a focus group study of initial steps towards the establishment of a rare disease ecosystem in Slovenia. Orphanet journal of rare diseases, ISSN 1750-1172, 9 Jul. 2019, vol. 14, no. 172, str. 1-13, ilustr. https://ojrd.biomedcentral.com/track/pdf/10.1186/s13023-019-1146-x, doi: 10.1186/s13023-019-1146-x.
- Beštek, Mate, Stanimirović, Dalibor. Special topic interoperabiIy and EHR : combining openEHR, SNOMED, IHE, and continua as approaches to interoperability on national eHealth. Applied clinical informatics, 2017, vol. 8, iss. 3, ilustr. https://aci.schattauer.de/en/contents/archive/issue/2503/issue/special/manuscript/27811/show.html , doi: 10.4338/ACI-2017-01-RA-0011.

Other achievements:

- Successful deployment of Cental Registry of Patients Data – Iional EHR platform, including OpenEHR based Patient summary Records. > 2,5 mio records monthly, > 90 % of the population has a record;
- Successful deployment of ePrescription. A fully deployed system;
- Successful implementation of patient portal accessing Iional EHR

Previous projects or activities related to the project subject (max. 5)

- NIJZ has taken on the role of lead partner in PARENT – Cross-border Patients' Registries Initiative.
- NIJZ participated in epSOS project, implementing Patient Summary and piloting its cross border exchange (country A and country B).
- NIJZ has recently implemented "Slovenian eIDAS Node and Integrated –ervices " SI-PASS", action number 2017-SI-IA-0037
- NIJZ is an active partner in eHAction project, participating in WP4, WP5, WP6, WP7 and WP8.

Partner Full Name	FUNDACIÓ TICSALUT		
Short Name	FTSS	**Partner No.**	31
Country	Spain	**Website**	www.ticsalutsocial.cat
Type of organisation	Public organisation	**Logo**	TIC Salut Social

Brief Partner Profile

Fundació TIC Salut Social is a public agency within the Catalan Ministry of Health founded in 2006 whose aim is to facilitate and promote the development and transformation of health and social care models fostering innovation in the use of ICT. The agency acts as an observatory for trends, innovations and emerging initiatives in the health and social care and provides services for the standardization and accreditation of products.

FTSS's strategy is focused on e-Health and m-Health to improve healthcare processes, in order to ensure conformity with current standards to guarantee interoperability and standardization in IT systems. The Foundation has also the role of "Observatory for e-Health" for the Catalan region, exploring and disseminating e-Health-related projects and use of ICT in the health and social care sectors at both national and international level. TIC Salut Social team has international expertise in semantics and syntactic medical information standards. Thus, the Foundation is involved in several national, European and international initiatives that define standards that ensure interoperability and that allow integration with the existing IT systems.

The TIC Salut Social's Foundation's Standards and Interoperability Office works on behalf of the Catalan Ministry of Health and the Ministry of Work, Social Affairs and Families to identify and define interoperability standards between information systems. Interoperability is the capacity of components, such as systems and devices, to exchange information coherently, without altering its meaning. It has different layers or dimensions: technical, syntactic, legal, and organizational. The Standards and Interoperability Office analyses SISCAT's needs. It identifies and changes the various standards as a result; it also helps to the implementation of standards in the social sector, managing pioneering projects at the international level. The Standards and Interoperability Office also heads integrations and standardization in the mHealth and mSocial fields, defining controlled vocabularies and communication interfaces. The goal of interoperability is to ensure that all relevant, necessary information is made available for decision making.

Main tasks in Project

FTSS will bring in expertise in the area of interoperability frameworks definition and implementation and the public health system in Catalonia region. As a participant of EPSOS project and CEF Telecom project coordinator for Catalonia, FTSS will also ensure that all future planning and activities foreseen in the project are in line with the current CEF wave implementation plan. Besides, FTSS will bring its expertise in Laboratories (LOINC), medical imaging (DICOM) and FHIR.

FTSS will take part in the following WP/Tasks:

WP1 – Task 1.4

WP5 – Task 5.1, 5.3, 5.4, 5.5 and 5.6: As the entity in charge of ensure the interoperability in the Public Health System in Catalonia, FTSS will provide its expertise in system definition and architecture: TIC Salut Social team has international expertise in semantics and syntactic medical information standards like HL7, DICOM, LOINC, IHE, FHIR and cross-border exchange of health Data (patient summary and ePrescription).

WP6 – Task 6.1, 6.2, 6.3, 6.4 and 6.6. FTSS will provide its expertise in Lab (LOINC) , medical imaging (DICOM), Patient Summary and ePrescription.

WP7 – Tasks 7.1, 7.2 and 7.3. As CEF Catalonia project coordinator, FTSS will contribute in the whole integration strategy definition.

Relevant expertise and experience of the institution

Promotion in the use of ICT standards in the healthcare sector, as the key element to ensure a coherent exchange of information at an international level.

Definition and implementation of the interoperability framework for the public health system of the Catalonian Government.

TIC Salut Social acts as an observatory for trends innovations and emerging initiatives in the health and social care and provides services for the standardization and accreditation of products.

Josuè Sallent Ribes (M), PhD, is the director of Fundació TIC Salut Social (FTSS). He studied Physics at the University of Barcelona and studied Business at the UOC in Barcelona. Josuè has a strong background in development and strategic implementation of technological solutions such as IoT, 5G in the context of Smart Cities and Industry. Before becoming director of FTSS, he was strategic director of the Centre for Telecommunications and Technology (CTTI) that delivers all digital services for the Catalan central government. He has also been the CEO of the Societat de la Informacio at the Generalitat and Director at the Fundació Observatori per a la Societat de la informacio de Catalunya (FOBSIC). As a director his main focus is to boost the ICT innovation and its adoption in the Health and social services providers

Ariadna Rius (F) is the Manager of the Office of Standards and Interoperability (OFSTI) at Fundació TIC Salut Social. She holds a degree in Computing Engineering, a master's degree in Computing Engineering and is currently doing a master in Advanced Artificial Intelligence. She worked as a web developer in insurances and marketing sectors. Since 2010, she has been working on semantic interoperability and standards issues. She is specialized in the clinical terminology SNOMED CT and in the definition of terminology services. Ariadna participates in the managing and the execution of the "Clinical Dictionary for e-Health", and also provides support to healthcare providers, private companies and public agencies, as well as in different European projects and national initiatives.

David Rodríguez (M) is Project manager at the Office of Standards and Interoperability (OFSTI) of Fundació TIC Salut Social. He holds a degree in a Technical Engineering in Computer Management. He has advanced knowledge of medical information standards like DICOM, HL7 FHIR, HL7 messaging (V2.7 certified in 2013) and HL7 CDA R2 (certified in 2011), as well as IHE interoperability frameworks and Continua guidelines. He works since 2010 in integration projects to facilitate interoperability between information systems, applications and medical devices, applying medical standards using integration engines like Mirth Connect as well as teaching training courses (DICOM, HL7, IHE, etc) in the field of ICT health.

Juan Antonio De los Cobos (M) is a technical computer engineer and graduated computer engineering at UOC. Juan Antonio has more than 20 years of experience working as a program analyst of clinical data in healthcare research projects. He worked as a functional consultant in the Health information system obtaining functional requirements, test data and system validation. Later on he worked to optimize service delivery processes in insurance and healthcare companies. Currently Juan Antonio is coordinating technical tasks using different interoperability standards like FHIR or HL7 or terminologies like SNOMED related to analysis and design of standards and terminology in projects such as the European Patient summary sharing and interregional Databases. He is currently an associate teacher at the faculty of social sciences and wellbeing at the UVIC for e-health.

Joan Solans Puig (M) is a technical computer engineer at Tecnocampus (UPF). He is working on different projects using different interoperability standards like FHIR or HL7 or terminologies like SNOMED. He has developed a mobile application for a project called IPS (International Patient Summary). This app has been tested in a real simulation exercise of a tsunami (EUMODEX) in Estonia. Joan is providing support to others healthcare projects to facilitate interoperability between information systems.

Relevant publications, products, services, or other achievements (max. 5)

Digital Medical Image Observatory. FTSS, in collaboration with the Ministry of Health in Catalonia, created the Digital Medical Image Observatory; a new body that aims to become a search space and a meeting point in the sector to share knowledge and experiences, and at the same time, developed a 143nalyseo analyze the viability of the innovative services proposed to be incorporated into the SIMDCAT project.

Clinical Dictionary for iHealth – Ministry of Health (Generalitat de Catalunya): This project aims to standardize the controlled vocabulary used in the Catalan Health System to exchange information between IT systems. It includes different vocabularies like LOINC, ICD-10, ATC, ICPC-2, etc. but uses SNOMED CT as reference terminology and ontology of representation. This project includes the management of the Catalan Extension of SNOMED CT that was created in 2011 by the OFSTI. In the project we also use a standard methodology developed by the OFSTI to create refsets of SNOMED CT.

Publication of laboratory results in HC3. The Health Shared Folder in Catalonia (HC3) is the Electronic Health record model that allows all public healthcare centers to share millions of clinical documents to facilitate the work of healthcare professionals and improve care for citizens. FTSS has given and is currently supporting the definition and standardization of various types of documents currently available in the HER, as for example, the laboratory results.

Relevant publications:

1. Sanz, X. et al. Definition of a SNOMED CT pathology subset and microglossary, based on 1.17 million biological samples from the Catalan Pathology Registry. J. Biomed. Inform. 78, 167-176 (2018)
2. Lamine, E. et al. An inventory of interoperability in healthcare ecosystems: Characterization and challenges in Enterprise Interoperability: INTEROP-PGSO Vision 167-198 (2017).

Previous projects or activities related to the project subject (max. 5)

TRILLIUM BRIDGE II, H2020, 2 years, **https://trillium2.eu/**: International patient summary (IPS) standards consistently adapted and localized to serve the needs of specific use cases are essential to attaining of vision of the patient summary as a social good and human right. The Trillium Bridge project (2013-2015) compared patient summary standards and specification in Europe and the United States and demonstrated the technical feasibility of

exchanging electronic health record summaries across the Atlantic in the context of emergency or unplanned care abroad. Reflecting on its results, the Trillium Bridge consortium reached a broadly endorsed recommendation: "Advance an International Patient Summary standard to enable people to access and share their health information for emergency or unplanned care anywhere and as needed starting with immunizations, allergies, medications, clinical problems, past operations and implants."

Trillium II builds on the recommendations of Trillium Bridge and places IPS standards at the core of a global community for digital health innovation with the aim to advance patient safety & trust by bridging the gap between strategic intent and capability to deliver interoperability at a global scale.

IS3 WiFIS – Ministry of Health (Generalitat de Catalunya): IS3 WiFIS is the project to coordinate and integrate different assistance levels like primary care and specialized care. It covers the workflows for referrals, appointments, laboratory, notifications and patient data queries. In the project, HL7 2.x messaging is used as the protocol of communication. The project IS3 aims to include the process management layer to the ICT strategy of Catalonia. It includes an interoperability platform that implements the messaging protocols of the WiFIS project, with the encoded content using the semantic standards of the Clinical Dictionary. IS3 includes the development of a Terminology Server and the OFSTI is collaborating in its design and development.

Deployment of Generic Cross Border eHealth Services in Spain (Project Coordinator in the Catalan Region), CEF TELECOM, Spain: The main objective of this Connecting Europe Facility project (2017-ES-IA-0068) is to support Spain's effort to be part of a secure peer-to-peer network allowing the exchange of Patient Summaries and ePrescriptions, which will pave the way to enable seamless cross-border care and secure access to patient health information between European

EpSOS (I and II, ICT PSP, 6 years, www.epsos.eu) (Project Coordinator in the Catalan region): epSOS is focused on improving medical treatment of citizens while abroad by providing health professionals with the necessary patient data in a secure electronic format, epSOS aimed to offer seamless healthcare to European citizens by building and evaluating a service infrastructure. epSOS was a six years project with 25 different countries involved with the common goal to design, build and a service infrastructure to demonstrate cross-border interoperability between electronic health record systems in Europe.

Partner Full Name	Equalis AB		
Short Name	Equalis	**Partner No.**	32
Country	Sweden	**Website**	www.equalis.se

Type of organisation	Not for profit private company	**Logo**	EQUALIS

Brief Partner Profile

Equalis is not-for-property private company owned by the Swedish Association of Local Authorities and Regions (SKL), the Swedish Medical Association and the Swedish Institute of Biomedical Laboratory Science. The core activity is External Quality Assurance (EQA) for laboratory medicine with focus on the Swedish health care system. The EQA activities cover a broad range of activities within clinical microbiology, immunology, clinical chemistry, haematology, haemostasis, morphological pathology, clinical physiology, nuclear medicine and radiology.

Equalis also act as the national release centre for the NPU-terminology (http://www.npu-terminology.org/). NPU is the terminology recommended for the unique coding and identification of laboratory results used in electronic communication in Denmark, Norway and Sweden.

Equalis is an active expert partner in the national "Laboratory medicine project" coordinated by Inera (managing joint digital solutions in Sweden). The aim of the project is to extend the current information model for laboratory medicine results to enable exchange of more complex data with the national service platform. To this end, the general public and authorised health care staff will be able to see laboratory results from additional areas e.g., microbiology and immunology.

Main tasks in Project

Equalis is an active partner in the following WPs:

WP5 (Tasks 5.2 and 5.3)

WP6 (Task 6.1, 6.2 and 6.6)

WP7 (Tasks. 7.1 and 7.4)

Relevant expertise and experience of the institution

Broad competence of quality assessment and interpretation of results of laboratory investigations of different types.

Responsible for the NPU-terminology used by the Swedish laboratories for the identification of laboratory results.

Active involvement in IUPAC, IFCC and JCGM working groups on topics related standardization and laboratory medicine.

Engaged in the work for an extended information model for exchange of laboratory results on a national level in Sweden.

Available network of expert groups for the relevant fields of laboratory medicine.

Key Personnel's CVs (incl. gender)

Gunnar Nordin, senior advisor, ♂, MD. Specialist in clinical chemistry. 10-year experience (5 as head of department) from hospital laboratory with clinical chemistry, clinical microbiology and transfusion medicine services). 17 years' experience as CEO for Equalis.

General interest in informatics, especially for laboratory test results. Member of the IFCC and IUPAC committee on nomenclature, and in the JCGM WG2 for the revision of VIM.

Rebecca Ceder,♀, health informatician at Equalis. Holds a MSc in Biomedicine (2006) and PhD in Medical Science (2011) from Karolinska Institutet, Stockholm. Doctoral and post-doctoral work included application of computational biology approaches for biomarker discovery and toxicological endpoints, with several publications in the area. She has also worked in the Data Science team at the pharmaceutical company Roche in Basel, Switzerland, supporting scientist with literature and business information in early drug discovery. In 2016, she joined Equalis with responsibility for the terminology work and serving as a project member in national e-health projects for laboratory medicine. Current engagements also include IFCC and IUPAC projects on nomenclature for laboratory medicine, in particular, genomics and molecular biology.

Relevant publications, products, services, or other achievements (max. 5)

- Helmersson-Karlqvist, J., Ridefelt, P., Boija, E.E, Nordin, G.“(2019). "Lower creatinine concentration values and lower inter-laboratory variation among Swedish hospital laboratories in 2014 compared to 1996: results from the Equalis external quality assessment”program." Clin Chem Lab Med. 57(6): 838-844.
- Nordin, G., R. Dybkaer, U. Forsum, X. Fuentes-Arderiu“(2018). "Vocabulary on nominal property, examination, and related concepts for clinical laboratory sciences (IFCC-IUPAC Recommendatio”s 2017)." Pure Appl. Chem. 90(5): 913-935.
- Nordin, G.“(2018). "Accuracy of HbA1c as Monitored by External Quality Assessment and Compared with Patient Mea” Values." Journal of Diabetes Science and Technology 12(4): 771-779.
- Kohonen, P., Parkkinen, J.A., Willighagen, E.L., Ceder, R., Wennerberg, K., Kaski, S., Grafström, R.C. (2017). ”A transcriptomics data-driven gene space accurately predicts liver cytopathology and drug-induced liver injury.” Nat Commun. (8):15932.
- Nordin, G.“(2017). "Cystatin C-Incremental Improvement in Measurement and Understanding of”Results." Clin Chem 63(4): 802-803.

Previous projects or activities related to the project subject (max. 5)

- The laboratory terminology expert in the national “Laboratory medicine” project. Application of terminologies is central in this project.
- Works actively with the clinical laboratories in Sweden to increase the implementation of coding and structured reporting.
- Was a partner in the national project DigiPat3 (2014-2017, Vinnova 2014-04257) with the aim to implement digital pathology in Sweden. Within the project a hub was developed, providing forms for synoptic reporting and for quality assessment of pathology using digital images.

Partner Full Name	**Swedish eHealth Agency (E-hälsomyndigheten)**		
Short Name	SEHA	Partner No.	33
Country	Sweden	Website	https://www.ehalsomyndigheten.se
Type of organisation	Governmental body	Logo	eHälsomyndigheten

Brief Partner Profile

The Swedish eHealth Agency (E-hälsomyndigheten) is a governmental authority responsible for coordinating the G'vernment's initiatives and efforts in eHealth and for overall monitoring the development of eHealth.

The Agency is also responsible for registries and IT functions which outpatient pharmacies and healthcare providers need access to, for a patient-safe and cost-effective drug management. The Agency is responsible for the Swedish e-prescription infrastructure and is designated as National Contact Point for eHealth (NCPeH) in accordance with the directive on patients' rights in cross-border healthcare. The Agency also gathers and supplies statistics about pharmaceutical sales from pharmacies, retailers and wholesalers.

The Agency provides several services such as:
- The medicine check
- My issued prescriptions
- Keep track of medicines via electronic expert support (EES)

In an agreement between the Swedish Government and the Swedish Association of Local Authorities and Regions (Sveriges Kommuner och Landsting) a goal was stated that in the year 2025 Sweden shall be world-leading in eHealth – this agreement is called Vision eHealth 2025. The Swedish eHealth Agency coordinates the office for this national multi-party work and contributes to the Vision by leading, driving and working in partnership, as well as creating structures and monitoring quality. A crucial part of this work involves international collaboration and global outlook.

The Swedish eHealth Agency is based in Kalmar with an office in Stockholm.

Main tasks in Project

WP7 Co-Leader: ***Architecture integration and System specification*** and active participation in **WP5:** ***Definition of EHRxF functional specifications***

T5.3 Active participant: Laboratory Results guideline and functional specifications
T5.4 Active participant: Medical Imaging and Reports guideline and functional specs
T5.5 Active participant: Hospital Discharge Reports guideline and functional specs

T5.7 Active participant: Final conclusion and recommendations

T7.1 Active participant: Global architecture for EHRxF Domains use
T7.3 Leader: Needs for upgrade of CEF eHDSI core and generic services
T7.4 Leader: Guidance for the new EHRxF domains

Relevant expertise and experience of the institution

The Swedish eHealth Agency is a government agency in the specific field of eHealth, with extensive experience of working with interoperability issues, on a national as well as international basis.

Key Personnel's CVs (incl. gender)

Michel Silvestri, ♂, PhD, Reg. Biomedical Scientist. PhD from Karolinska Institutet with a position for 15 years as Senior lecturer, and for 6 years as Programme Director of Biomedical Laboratory Science. 2001-2007 President of the Swedish Institute of Biomedical Laboratory Science and member of the Equalis Board of Directors. 2014-2017 elected Member of Stockholm County Council with positions such as member of the Board of Healthcare for the Stockholm Region. 2016-2019 head of the Medical Laboratory Centre of Gotland at Visby hospital. Experience from procurement of e.g. Laboratory Information Management Systems (LIMS). From April 2019 Head of Unit, Dept. of Coordination, at the Swedish eHealth Agency.

Emanuel Andersson, ♂, MSc Computer Science and Electrical Engineering, holds a position as a senior advisor and enterprise architect. Between 2015 and 2018 he had a position as a work package leader for interoperability and standardisation in the project JAseHN (Joint Action to Support the eHealth Network,

https://webgate.ec.europa.eu/chafea_pdb/health/projects/677102/summary).

He has in 2018, as a member of a core team consisting of architects from different authorities, created the national interoperability framework out of the European interoperability framework, EIF. Recently, in an assignment from the Swedish government, he investigated what building blocks needs to be created on a national level to be able to create a secure and efficient information exchange with and within the Swedish public sector, e.g. eId framework, API-management, different national services.

Emanuel has also been responsible for setting up the architecture for national e-prescription infrastructure in Sweden and is currently involved in collaboration with various national governmental and other organizations, including standards development organizations with respect to digitalisation, standardisation and interoperability in health and social care.

Relevant publications, products, services, or other achievements (max. 5)

Silvestri M. Initiative and project owner of regional e-health service for patients with anticoagulation treatment, Region of Gotland, Sweden.

Previous projects or activities related to the project subject (max. 5)
Andersson, E. **Actively** involved in JAseHN, primarily interoperability and standardisation. Member of core team developing the national interoperability framework out of EIF. building blocks needs to be created on a national level to be able to create a secure and efficient information exchange with and within the Swedish public sector, e.g. eId framework, API-management, different national services. Emanuel has also been responsible for setting up the architecture for national e-prescription infrastructure in Sweden and is currently involved in collaboration with various national governmental and other organizations, including standards development organizations with respect to digitalisation, standardisation and interoperability in health and social care.

Partner Full Name	**French National Institute of Health and Medical Research**		
Short Name	INSERM	**Partner No.**	34
Country	France	**Website**	www.orpha.net
Type of organisation	Public organisation	**Logo**	orphanet Inserm

Brief Partner Profile
The French National Institute of Health and Medical Research (INSERM), founded in 1964 is a public scientific and technological institute which operates under the joint authority of the Prime Minister and French Ministry of Research. INSERM has been acting as coordinator of the Orphanet network since the beginning of the European projects in 2001. The INSERM also acted as co-ordinator of the Rare Diseases Task Force (2004-2009) and the European Union Committee of Experts on Rare Diseases (EUCERD)(2010-2013) and of RD-ACTION (2015-2018).

Main tasks in Project
Orphanet will play an active role in X-eHealth in the following ta–ks: **WP5 - Definition of EHRxF functional specifications** • **T5.6**: Refine PS functional specifications to account for eHN Guidelines and rare dise–ses **WP6 - Definition of EHRxF implementable specifications** • **T6.4:** Refinement of Patient Summary (PS) technical specifications for supporting rare dise–ses **WP8 -** EHRxF Communities of Practice: from Proof of Concept to large scale adoption and Infrastructure for Innovation

- **T8.1:** Proof of concept: EHRxF in rare diseases

Relevant expertise and experience of the institution

Promotion in the use of ICT standards in the healthcare sector, as the key element to ensure a coherent exchange of information at an international level.

Definition and implementation of the interoperability framework for the public health system of the Catalonian Government.

TIC Salut Social acts as an observatory for trends innovations and emerging initiatives in the health and social care and provides services for the standardization and accreditation of products.

Key Personnel's CVs (incl. gender)

Orphanet Director **Dr. Ana Rath** (female) is a medical doctor and has a Master degree in Philosophy. She oriented her career to medical information in 1997 (working in medical information and terminologies) and joined Orphanet (www.orpha.net) in 2005. In Orphanet she has been in charge successively of the Orphanet encyclopaedia, the rare diseases database, and of the Scientific Direction. She became Deputy Director in 2011and is currently acting as Director of Orphanet since May 2014. She was Rd-ACTION Project coordinator (www.rd-action.eu), HIPBI-RD project coordinator (www.hipbi-rd.net) and is currently the coordinator of the RD-CODE **project (www.r**d-code.eu) **Marc Hanauer** (male) the Chief Technology officer and Deputy Director has a master's degree in Sciences Information & communication. From 2000 to 2009 he worked for different Internet Start-ups. He is Engineer at INSERM and CTO of Orphanet since 2009. He is Orphanet deputy director since 2017. The Scientific Operating Director

The Director of production and Nomenclature Resposible **Annie Olry** (female) has a PhD in cellular biology. She has worked for Orphanet since 2007. First in charge of the literature survey, she has been in charge of the diseases inventory and classification system for 4 years. She now manages the scientific team and ensures overall scientific validity of the diseases inventory and classification system, genes inventory, epidemiological and disability data. She is involved in most of the scientific partnerships, notably handling the Orphanet rare diseases ontology collaboration.

Relevant publications, products, services, or other achievements (max. 5)

Standard nomenclature and classification of rare diseases: the ORPHAcodes. ORPHAcodesare at the center of a normalized, manually curated and quality control semantic system allowing for interoperability between health information systems (i.e. electronic health records in hospitals at the national level) and other resources (i.e. registries, cohorts, databases, biobanks) at the transnational level.

The Orphanet Rare Disease ontology (ORDO) was jointly developed by Orphanet and the European Bioinformatics Institute (EBI) and provides a structured vocabulary for RD, capturing relationships between diseases, genes and other relevant features, providing a useful resource for the computational analysis of RD.

Orphanet provides phenotypic annotations of the rare diseases in the Orphanet nomenclature using the Human Phenotype Ontology (HPO). **HOOM** is a module that qualifies the annotation between a clinical entity and phenotypic abnormalities according to a frequency and by integrating the notion of diagnostic criterion.

Relevant publications:

1. **Estimating cumulative point prevalence of rare diseases: analysis of the Orphanet database.** Nguengang Wakap S, Lambert DM, Olry A, Rodwell C, Gueydan C, Lanneau V, Murphy D, Le Cam Y, Rath A. **Eur J Hum Genet**. 2019 Sep 16.

2. **Plain-language medical vocabulary for precision diagnosis.** Vasilevsky NA, Foster ED, Engelstad ME, Carmody L, Might M, Chambers C, Dawkins HJS, Lewis J, Della Rocca MG, Snyder M, Boerkoel CF, Rath A, Terry SF, Kent A, Searle B, Baynam G, Jones E, Gavin P, Bamshad M, Chong J, Groza T, Adams D, Resnick AC, Heath AP, Mungall C, Holm IA, Rageth K, Brownstein CA, Shefchek K, McMurry JA, Robinson PN, Köhler S, Haendel MA. **Nat Genet**. 2018 Apr;50(4):474-476.

Previous projects or activities related to the project subject (max. 5)

RD-CODE (www.rd-code.eu): The project, co-funded by the European Union's Third Health Programme, started on January 2019 and it will end in June 2021. The objective of this project is to support Member States in improving gathering information on rare diseases by implementation of Orphacodes (rare diseases specific codification system). The implementation process will be guided by the « Standard procedure and guide for the coding with Orphacodes » and the « Specification and implementation manual of the Master file » both developed in the frame of the previous Joint Action on rare Diseases RD-ACTION (2015-2018). The aim of the RD-CODE project is to promote the use of the Orphanet nomenclature for implementation into routine coding systems. This enables a standardised and consistent level of information to be shared at European level. Starting with countries that have no systematic implementation of the Orpha codification yet, but that are actively committed already in doing so, this project will provide a sufficient real-world implementation experience to be captured by other countries in the future.

HIPBI-RD(www.hipbi-rd.net) : This project has built on three resources largely adopted by the RD community: Orphanet, and its ontology ORDO, HPO and PhenoTips. It is aimed to provide the community with an integrated, RD-specific informatics ecosystem that will harmonize the way phenomics information is stored in databases and in patient files worldwide, and thereby contribute to interoperability. This ecosystem will consist of a suit of tools and ontologies, optimized to work together, and available to clinicians and scientists through commonly used software repositories. Additionally, the ecosystem will improve and streamline the interpretation of variants identified through exome and full genome sequencing by harmonizing the way phenotypic information is collected.

4.2. Third parties involved in the project (including use of third party resources)

SPMS

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**Y**
Acting in two domains - coordinator and participant - SPMS requires € 85 000 in subcontracting to promote the smooth development of the project and support the working capacity of its internal teams. In this sense, the breakdown of the required amount for subcontracting attends the following reasoning: 1.1) at the level of project coordination and aiming at tackling the barriers that are to arise to develop the specifications for a common framework for an EHRxF, € 28 000 are directed to function as an operational fund for addressing the insufficiencies that X-eHealth Consortium may have throughout the project. This amount is specifically directed for approaching relevant experts and stakeholders of the sector towards solving the puzzle at issue. 1.2) Since quality management stands as a fundamental element for the quality of the project's outputs, and since this consortium does not have native English speakers for content review and Copywrite functions, 12 000 € are foreseen for this aspect. 2) As for the level of effective participation of SPMS' teams in the development of the project objectives, € 45 000 are designed to subcontract the external expertise necessary for supporting the advance of the project. Since the participation of SPMS focuses on work packages WP1, WP2, WP4, WP5, WP6 and WP7, there is a need to resort to subcontracting to deal with certain technical-functional domains that the project demands and SPMS lacks. Namely, specific knowledge about medical specifications such as images and laboratory results.	
Does the participant envisage that part of its work is performed by linked third parties[9]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model	**N**
Does the participant envisage that part of the work is performed by International Partners[10] (Article 14a of the General Model Grant Agreement)?	**N**

[9] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[10] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

ATNA

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**Y**
ATNA plans to subcontract certain activities to third parties such as ELGA GmbH, AGES or other national organisations in order to ensure involvement of national expertise, in particular when it comes to contributions to WP5, WP6, WP7. The national expertise for architecture, functional specifications and definitions of workflows is concentrated in the national competent authorities that are linked with ATNA. Therefore, ATNA plans to involve relevant experts on certain topics and key questions the CSA is working on. To ensure the involvement of this know-how the amount of minimum 20.000 EUR needs to be allocated for subcontracting.	
Does the participant envisage that part of its work is performed by linked third parties[11]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[12] (Article 14a of the General Model Grant Agreement)?	**N**

GOeG

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[13]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**

[11] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[12] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[13] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

Does the participant envisage that part of the work is performed by International Partners[14] (Article 14a of the General Model Grant Agreement)?	**N**

FPS Health

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[15]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[16] (Article 14a of the General Model Grant Agreement)?	**N**

IHE

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[17]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[18] (Article 14a of the General Model Grant Agreement)?	**N**

[14] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[15] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[16] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[17] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[18] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

HL7

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**Y**
Part of task 8.3 delivering D8.4 will be subcontracted to Karolinska Institute to contribute to an exploratory proof of concept study on how to integrate EHRxF into research studies and specifically citizen-driven health science. This exploratory task links EHRxF to initiatives assessing and integrating new concepts and tools such as AI, outcomes-based research, clinical research, clinical trial integration, business analytics, decision aids for patients, and citizen-driven health-science. The study would result into clear recommendations for incorporating the EHRxF in these areas taking into account technical, legal, procedural, and other barriers, engaging also collaborative partners and the community of practice. The Health Informatics Centre (HIC) at the department of Learning, Informatics, Management and Ethics (LIME) performs research in the areas of clinical decision making, integrated patient-centred information systems for collaborative care and patient e-services with special focus on usability. Our aim is to perform needs driven research and to enhance clinical practice through informatics, delivering new evidence-based knowledge into patient care, prevention and self-management. We systematically use knowledge about care processes, information flows in health and social care, patients' information and communication needs, usability and health informatics standards to develop new methods and tools. These are evaluated to create new knowledge about how to best design and implement eHealth to create benefits for both patients and healthcare professionals. We apply a sociotechnical approach, combining technical and methodological research with research on how implementation and use of eHealth affects roles, relationships and tasks for patients and healthcare professionals.	
Does the participant envisage that part of its work is performed by linked third parties[19]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[20] (Article 14a of the General Model Grant Agreement)?	**N**

[19] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[20] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

NEN

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**Y**
As one of the 34 formal members of CEN (the European Committee for Standardization), NEN holds the secretariat of CEN/TC 251 'Health informatics' for which this H2020 project proposal is of interest for the CEN/TC 251 work programme. CEN as legal entity does not participate in EU projects and defer to its members (such as NEN) to participate in relevant projects. Participation in NEN and CEN standardization activities is carried out by nominated experts that are not employed by NEN. The three nominated experts for this project are the chairman, vice-chairman and WG-convenor in CEN/TC 251. NEN plans to subcontract the 3 experts to provide the technical expertise from a CEN/ISO standardisation point of view. The three experts will contribute to T8.6 and their technical expertise will be employed to evaluate the proof of concept outcomes of T8.1 and T8.2, as well as, to provide input to the sustainability task of the project (T1.4). They will also contribute to T8.6 linked deliverable.	
Does the participant envisage that part of its work is performed by linked third parties[21]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[22] (Article 14a of the General Model Grant Agreement)?	**N**

HZZO

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[23]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**

[21] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[22] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[23] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

Does the participant envisage that part of the work is performed by International Partners[24] (Article 14a of the General Model Grant Agreement)?	**N**

UCY

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[25]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[26] (Article 14a of the General Model Grant Agreement)?	**N**

MZCR

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**Y**
Participation of the Czech Medical Association of J. E. Purkyně (CMA) is envisaged in area of the clinical aspects of the project. Czech Medical association is a professional association of medical, biomedical and healthcare IT experts and valuable partner of the Czech MoH. CMA, under the lead of its presidency and e-Health workgroup, will bring clinical and healthcare IT experience and expertise of its leading Czech specialists. CMA will be involved as contributor and consultative partner in the task T5.1: X-eHealth use cases driven methodology, T5.2: EHRxF and its relationship with clinical guidelines, T5.3: Laboratory Requests and Reports functional specifications, T5.4: Imaging and Reports functional specifications and T5.5: Hospital Discharge Reports functional specifications.	

[24] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[25] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[26] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

Does the participant envisage that part of its work is performed by linked third parties[27]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[28] (Article 14a of the General Model Grant Agreement)?	**N**

Vysocina

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[29]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[30] (Article 14a of the General Model Grant Agreement)?	**N**

MSAE

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[31]	**N**

[27] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[28] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[29] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[30] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[31] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[32] (Article 14a of the General Model Grant Agreement)?	**N**

ANS

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**Y**

ANS needs to subcontract external expertise because, as a national public organization, the law imposes a cap on the number of employees and subcontracting is the usual way to mobilize resources. ANS's internal experts will be in charge of the clinical, functional and technical activities of the project. Namely, T5.3 (Laboratory functional specifications), T6.1 (laboratory technical specifications), T6.3 (Discharge letters technical specifications) and T7.3 (Needs for upgrade of CEF eHDSI core and generic services). The internal experts will also focus on strategic tasks, in particular those related to governance issues. The amount requested is allocated proporcionally among the tasks.
In this context, subcontractors – under the auspices of ANS – will provide support, contributing to the creation of content for the deliverables, as well as participate in meetings and phone calls, in close collaboration with internal experts.

Does the participant envisage that part of its work is performed by linked third parties[33]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[34] (Article 14a of the General Model Grant Agreement)?	**N**

[32] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[33] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[34] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

MoH France

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[35]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[36] (Article 14a of the General Model Grant Agreement)?	**N**

DIMDI

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[37]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[38] (Article 14a of the General Model Grant Agreement)?	**N**

Gematik

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**

[35] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[36] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[37] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[38] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

Does the participant envisage that part of its work is performed by linked third parties[39]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[40] (Article 14a of the General Model Grant Agreement)?	**N**

TMF

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[41]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[42] (Article 14a of the General Model Grant Agreement)?	**N**

MoH Greece

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**Y**

[39] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[40] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[41] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[42] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

MOHGR plans to subcontract specific tasks to HL7 Hellas, the Greek affiliate of HL7 International.

Tasks proposed to be subcontracted will be part of WP 5, 6, 7, and 8.

HL7 Hellas will perform the following tasks for MoHGR

1. organise consensus building local stakeholders' meetings
2. organise national technical committees and provide technical support on the specifications and deliverables in WP 5-6-7
3. Review deliverables and provide expert comments on recommendations especially concerning the proper use of HL7 standards within EHRxF and integration profiles and implementation guide
4. Localise final technical documents to the Greek environment and support the ministry to create national standards in Greece for EHRxF
5. Assist MOHGR in performing proof of concept demonstration in Greece (WP8).
6. Provide recommendations to MOHGR on the WP8 community of practice

Does the participant envisage that part of its work is performed by linked third parties[43]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[44] (Article 14a of the General Model Grant Agreement)?	**N**

AEEK

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[45]	**N**

[43] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[44] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[45] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[46] (Article 14a of the General Model Grant Agreement)?	**N**

SE

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[47]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[48] (Article 14a of the General Model Grant Agreement)?	**N**

DoH

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[49]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**

[46] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[47] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[48] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[49] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

Does the participant envisage that part of the work is performed by International Partners[50] (Article 14a of the General Model Grant Agreement)?	**N**

AGiD

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[51]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[52] (Article 14a of the General Model Grant Agreement)?	**N**

ARIA

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[53]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**

[50] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[51] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[52] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[53] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

Does the participant envisage that part of the work is performed by International Partners[54] (Article 14a of the General Model Grant Agreement)?	**N**

MIN SAL

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[55]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[56] (Article 14a of the General Model Grant Agreement)?	**N**

RegLomb

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[57]	**Y**
Fondazione IRCCS Istituto Nazionale Tumori, Milano, Italy (INT) is the largest comprehensive cancer centre in Italy. Since its establishment (1928), it has aimed to provide the highest standards of cancer care and to pursue pre-clinical and clinical research in such a way as to swiftly translate innovation into better prevention, diagnosis, therapy and rehabilitation for Italian cancer patients. INT has a long-standing record on rare cancers, serving as one of the Italian reference centres for several rare cancers, including childhood	

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[56] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[57] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

cancers, sarcomas, head & neck cancers, peritoneal and pleural mesothelioma and thymoma, neuroendocrine tumours, male genital tumours, rare female genital cancers, lymphomas and myeloma.

Three units of INT will contribute to this project: Medical Oncology Unit 2, Medical Oncology Unit 3 and Evaluative Epidemiology Unit. Medical Oncology Units 2 and 3 are medical oncology facilities exclusively devoted to families of rare adult cancers, i.e., sarcomas and head and neck cancers, respectively. Medical Oncology Units 2 coordinates the Italian Rare Cancer Network. The Evaluative Epidemiology Unit coordinated the RARECARE and RARECAREnet projects, in addition to national project dedicated to rare cancers. This Unit is also involved in the evaluation of public health activities related to cancer in Italy, Europe and extra-European countries. The unit is involved in several national and international projects estimating cancers indicators and comparing them across EU and extra EU countries. The Medical Oncology Units 2 and the Evaluative Epidemiology Unit coordinated the Joint Action on Rare Cancers (JARC). Finally, INT hosts and coordinates the project "State-of-the-art oncology in Europe" (START). START is intended as a state-of-the-art knowledge base to support oncologists in their clinical decisions and is currently devoting its efforts completely to rare cancers.

Two medical oncologists will also contribute. Prof. **Paolo Casali** (male) is chairing INT's Medical Oncology Unit 2, on mesenchymal tumours; coordinating the Italian Rare Cancer Network; chairing the steering committee of Rare Cancers Europe (a multi-stakeholder European effort on rare cancers); serving as the secretary of the Italian Sarcoma Group (the Italian collaborative research group on sarcomas); chairing the EU Policy Committee of the European Society for Medical Oncology (ESMO), coordinating the EURACAN domain on sarcomas and involved in the knowledge generation WG of the ERN.

Dr. Lisa Licitra (female) is a senior medical oncologist chairing INT's Medical Oncology Unit 3, exclusively devoted to head & neck cancers; serving as the coordinator of Clinical Practice Guidelines on head & neck cancers of the European Society for Medical Oncology (ESMO); serving as co-opted Board member of the Organisation of European Cancer Institutes (OECI); serving as Board member of the European Organisation for Research and Treatment of Cancer (EORTC) and, coordinating START. She is the domain leader of the EURACAN domain on rare head and neck cancers. Annalisa Trama, epidemiologist, with a Master's in health services/system research and a PhD in Public Health. She has important experience in cancer and rare cancer registration. She has experience in pattern of care study, evaluation of health care system and, use of different data sources. She has experience also on rare diseases since she worked at the National centre for rare diseases (ISS, Italy) and was a member of the EU task force on rare diseases (Monitoring & Evaluation) WG. Knowing rare diseases and rare cancers community, she is well placed to support collaboration with cancer and rare diseases dedicated ERNs.

Within X-eHealth, the Istituto Nazionale Tumori will bring its relevant clinical knowledge both on Rare Diseases, as member and responsible for ERN and on International Clinical Guidelines driven Clinical Model definition.

IST will support Regione Lombardia in Task T5.2: "EHRxF and its relationship with clinical guidelines" and T5.6: "Refine PS guideline and functional specifications to account for rare diseases". It will also participate to WP8.	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[58] (Article 14a of the General Model Grant Agreement)?	**N**

NVD

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[59]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[60] (Article 14a of the General Model Grant Agreement)?	**N**

SAM

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**

[58] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[59] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[60] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

Does the participant envisage that part of its work is performed by linked third parties[61]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[62] (Article 14a of the General Model Grant Agreement)?	**N**

NICTIZ

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[63]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[64] (Article 14a of the General Model Grant Agreement)?	**N**

NCZI

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[65]	**N**

[61] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[62] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

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[64] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[65] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[66] (Article 14a of the General Model Grant Agreement)?	**N**

NIJZ

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[67]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[68] (Article 14a of the General Model Grant Agreement)?	**N**

TIC Salut

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties69	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**

66 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

67 A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

68 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

69 A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

Does the participant envisage that part of the work is performed by International Partners70 (Article 14a of the General Model Grant Agreement)?	**N**

Equalis

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[71]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[72] (Article 14a of the General Model Grant Agreement)?	**N**

SEHA

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[73]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**

[70] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[71] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[72] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[73] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

Does the participant envisage that part of the work is performed by International Partners[74] (Article 14a of the General Model Grant Agreement)?	**N**

Inserm

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	**N**
Does the participant envisage that part of its work is performed by linked third parties[75]	**N**
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	**N**
Does the participant envisage that part of the work is performed by International Partners[76] (Article 14a of the General Model Grant Agreement)?	**N**

[74] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

[75] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

[76] 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.

4.3. Financial support to third parties

SPMS

N/A

ATnA

N/A

GOeG

N/A

FPS Health

N/A

IHE

N/A

HL7

N/A

NEN

N/A

HZZO

N/A

UCY

N/A

NCEZ

N/A

Vysocina

N/A

MSAE

N/A

ANS

N/A

MoH France

N/A

DIMDI

N/A

Gematik

N/A

TMF

N/A

MoH GR

N/A

AEEK

N/A

SE

N/A

DoH

N/A

AGiD

N/A

ARIA

N/A

MIN SAL

N/A

REgLomb

N/A

NVD

N/A

SAM

N/A

NICTIZ

N/A

NCZI

N/A

NIJZ

N/A

TIC Salut

N/A

Equalis

N/A

SEHA

N/A

Inserm

N/A

5. Ethics and Security

5.1 Ethics

Being the protection of personal data a crucial element that must be safeguarded, X-eHealth sets out in this section how does the project intend to safeguard the rights and freedoms of the data subjects / research participants.

Following a self-assessment of the ethical assumptions that the project must comply with, the subsequent main issues shall be considered:

- Will X-eHealth have workshops?
  - Yes
- Does this research involve personal data collection and/or processing?
  - Yes, limited to the workshops' attendance
- Will the project collect information about the registered participants?
  - Yes, yet, they will be acting on behalf of their institution and role
- Does it involve the collection and/or processing of sensitive personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?
  - No, no real sensitive personal data will be collected or processed in X-eHealth
- Will X-eHealth ask participants about their health status?
  - No
- Will X-eHealth ask their "consent" to openly include their names in the Deliverable?
  - Yes

Since the project intends to carry out several workshops and surveys, the participation of stakeholders stands as a meaningful element for these activities' productiveness. This way, even though collection and/or processing of personal data does not act as relevant for X-eHealth goals, in order to safeguard data protection for any purpose other than the ones stipulated by the project, a task named *T1.5 Ethics requirements* was created to address the way personal data will be handled within the confines of the project itself, i.e. how personal data of project members, workshop participants, et cetera, will be used by the project coordinator and the respective working packages during the project timeline.

On this basis, feature by the project coordination work package (WP1), task T1.5 was specifically designed to cover the project-related aspects for safeguarding participants and stakeholders' personal data towards ensuring its ethical compliance. To do so, T1.5 objectives are: to ensure compliance with the ethics requirements established by the General Data Protection Regulation (i), to set out the ethics requirements that the project must comply with (ii), and to produce a deliverable clearly stating that the personal data from stakeholder and survey participants will be handled in a GDPR compliant manner, therefore in accordance with the ‘data minimisation' principle (iii).

In order to operationalize these abovementioned objectives, two measures have been established: 1) The first, already referenced, is a deliverable named *D1.6 - Ethics Requirements (due month 3)* stating how the personal data collected from stakeholders will be dealt with in a GDPR compliant way; 2) The second measure is that every single deliverable submitted by X-eHealth will include an ethics section in order to particularly address the issue at stake within a specific context and from an ethical perspective.

In parallel, a content-related task essential for structural cooperation was also designed to address the fundamental legal and ethical provisions for the exchange of cross-border data. Namely, the sub-tasks T4.2.1 (*Legal and ethical aspects of cross-border exchange of data*) and T4.2.2 (*Legal and ethical enablers for cross-border interoperability of personal data*), will strive to develop the ethical guidelines to safeguard EU citizens on how their data will be treated.

Concerning the proof of concept tasks (T8.1 and T8.2) to be carried out by WP8, it should be noted that these activities will be tested with dummy data. In other words, all data to be used during these tests will always be fictitious, therefore, focusing specifically on the operationalization of the concept, without using or endangering real-life data.

Since the data to be used to test the interoperability of the concepts is fictitious and formulated specifically for that purpose, the project will not process any data, thus it will not consider a data management plan.

5.2 Security

- Activities or results raising security issues: NO
- 'EU-classified information' as background or results: NO

ESTIMATED BUDGET FOR THE ACTION

Associated with document Ref. Ares(2020)2778062 - 28/05/2020

	Estimated eligible[1] costs (per budget category)										EU contribution			Additional information		
	A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs		E. Indirect costs[2]	Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]	Information for indirect costs	Information for auditors	Other information:
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary				D.1 Travel D.2 Equipment D.3 Other goods and services *[D.4 Costs of large research infrastructure]*	D.5 Costs of internally invoiced goods and services						Estimated costs of in-kind contributions not used on premises	Declaration of costs under Point D.4	Estimated costs of beneficiaries/ linked third parties not receiving funding/ international partners
Form of costs[6]	Actual	Unit[7]	Unit[8]		Actual	Actual	Actual	Unit[9]	Flat-rate[10] 25%							
	a	Total b	No hours	Total c	d	*[e]*	f	Total g	h = 0,25 x (a +b+c+f+g +*[i1]*[13]+*[i2]*[13]-n)	j = a+b+c+d +*[e]*+f+g+h +*[i1]*+*[i2]*	k	l	m	n	Yes/No	
1. SPMS	276 000.00	0.00	0.00	0.00	85 000.00	0.00	117 499.00	0.00	98 374.75	576 873.75	100.00	576 873.75	576 873.75	0.00	No	n/a
2. ATNA	21 250.00	0.00	0.00	0.00	20 000.00	0.00	9 100.00	0.00	7 587.50	57 937.50	100.00	57 937.50	57 937.50	0.00	No	n/a
3. GÖG	57 400.00	0.00	0.00	0.00	0.00	0.00	18 200.00	0.00	18 900.00	94 500.00	100.00	94 500.00	94 500.00	0.00	No	n/a
4. FPS Health Be	17 400.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	6 625.00	33 125.00	100.00	33 125.00	33 125.00	0.00	No	n/a
5. IHE-EUR	149 500.00	0.00	0.00	0.00	0.00	0.00	18 200.00	0.00	41 925.00	209 625.00	100.00	209 625.00	209 625.00	0.00	No	n/a
6. HL7 Europe	142 500.00	0.00	0.00	0.00	25 000.00	0.00	18 200.00	0.00	40 175.00	225 875.00	100.00	225 875.00	225 875.00	0.00	No	n/a
7. NEN	8 100.00	0.00	0.00	0.00	50 000.00	0.00	9 100.00	0.00	4 300.00	71 500.00	100.00	71 500.00	71 500.00	0.00	No	n/a
8. HZZO	8 925.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	4 506.25	22 531.25	100.00	22 531.25	22 531.25	0.00	No	n/a
9. UCY	32 500.00	0.00	0.00	0.00	0.00	0.00	18 200.00	0.00	12 675.00	63 375.00	100.00	63 375.00	63 375.00	0.00	No	n/a
10. MZCR	45 000.00	0.00	0.00	0.00	15 000.00	0.00	18 200.00	0.00	15 800.00	94 000.00	100.00	94 000.00	94 000.00	0.00	No	n/a
11. Kraj Vysočina	40 285.00	0.00	0.00	0.00	0.00	0.00	27 300.00	0.00	16 896.25	84 481.25	100.00	84 481.25	84 481.25	0.00	No	n/a
12. MSAE	26 250.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	8 837.50	44 187.50	100.00	44 187.50	44 187.50	0.00	No	n/a
13. ANS	36 000.00	0.00	0.00	0.00	10 000.00	0.00	9 100.00	0.00	11 275.00	66 375.00	100.00	66 375.00	66 375.00	0.00	No	n/a
14. MoH-FR	36 000.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	11 275.00	56 375.00	100.00	56 375.00	56 375.00	0.00	No	n/a
15. DIMDI	6 500.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	3 900.00	19 500.00	100.00	19 500.00	19 500.00	0.00	No	n/a
16. GEMATIK	43 500.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	13 150.00	65 750.00	100.00	65 750.00	65 750.00	0.00	No	n/a
17. TMF	16 000.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	6 275.00	31 375.00	100.00	31 375.00	31 375.00	0.00	No	n/a
18. MoHGR	63 000.00	0.00	0.00	0.00	45 000.00	0.00	18 200.00	0.00	20 300.00	146 500.00	100.00	146 500.00	146 500.00	0.00	No	n/a
19. AEEK	4 950.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	3 512.50	17 562.50	100.00	17 562.50	17 562.50	0.00	No	n/a
20. SE	23 100.00	0.00	0.00	0.00	0.00	0.00	18 200.00	0.00	10 325.00	51 625.00	100.00	51 625.00	51 625.00	0.00	No	n/a
21. DoH	28 050.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	9 287.50	46 437.50	100.00	46 437.50	46 437.50	0.00	No	n/a
22. AGID	30 000.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	9 775.00	48 875.00	100.00	48 875.00	48 875.00	0.00	No	n/a
23. ARIA	134 000.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	35 775.00	178 875.00	100.00	178 875.00	178 875.00	0.00	No	n/a
24. MIN SAL	14 000.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	5 775.00	28 875.00	100.00	28 875.00	28 875.00	0.00	No	n/a
25. REGLOMB	20 100.00	0.00	0.00	0.00	0.00	0.00	4 000.00	0.00	6 025.00	30 125.00	100.00	30 125.00	30 125.00	0.00	No	n/a
- INT	30 150.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	9 812.50	49 062.50	100.00	49 062.50	49 062.50	0.00	No	n/a
Total beneficiary	50 250.00	0.00			0.00	0.00	13 100.00	0.00	15 837.50	79 187.50		79 187.50	79 187.50	n/a	n/a	0.00
26. NVD	20 000.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	7 275.00	36 375.00	100.00	36 375.00	36 375.00	0.00	No	n/a
27. SAM	18 000.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	6 775.00	33 875.00	100.00	33 875.00	33 875.00	0.00	No	n/a
28. NICTIZ	193 575.00	0.00	0.00	0.00	0.00	0.00	18 200.00	0.00	52 943.75	264 718.75	100.00	264 718.75	264 718.75	0.00	No	n/a
29. NCZI	13 750.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	5 712.50	28 562.50	100.00	28 562.50	28 562.50	0.00	No	n/a
30. NIJZ	17 500.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	6 650.00	33 250.00	100.00	33 250.00	33 250.00	0.00	No	n/a
31. TICSALUT	40 800.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	12 475.00	62 375.00	100.00	62 375.00	62 375.00	0.00	No	n/a

ESTIMATED BUDGET FOR THE ACTION

Associated with document Ref. Ares(2020)2778062 - 28/05/2020

	Estimated eligible[1] costs (per budget category)										EU contribution			Additional information		
	A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs		E. Indirect costs[2]	Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]	Information for indirect costs	Information for auditors	Other information:
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary				D.1 Travel D.2 Equipment D.3 Other goods and services *[D.4 Costs of large research infrastructure]*	D.5 Costs of internally invoiced goods and services						Estimated costs of in-kind contributions not used on premises	Declaration of costs under Point D.4	Estimated costs of beneficiaries/ linked third parties not receiving funding/ international partners
Form of costs[6]	Actual	Unit[7]	Unit[8]		Actual	Actual	Actual	Unit[9]	Flat-rate[10] 25%							
	a	Total b	No hours	Total c	d	*[e]*	f	Total g	h = 0,25 x (a +b+c+f+g +*[i1]*[13]+*[i2]*[13]-n)	j = a+b+c+d +*[e]*+f+g+h +*[i1]*+*[i2]*	k	l	m	n	Yes/No	
32. Equalis AB	40 000.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	12 275.00	61 375.00	100.00	61 375.00	61 375.00	0.00	No	n/a
33. SEHA	0.00	0.00	0.00	0.00	0.00	0.00	18 200.00	0.00	4 550.00	22 750.00	100.00	22 750.00	22 750.00	0.00	No	n/a
34. INSERM	24 000.00	0.00	0.00	0.00	0.00	0.00	9 100.00	0.00	8 275.00	41 375.00	100.00	41 375.00	41 375.00	0.00	No	n/a
Total consortium	1 678 085.00	0.00			250 000.00	0.00	521 899.00	0.00	549 996.00	2 999 980.00		2 999 980.00	2 999 980.00			0.00

[1] See Article 6 for the eligibility conditions.
[2] Indirect costs already covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.5.(b)) are ineligible under the GA. Therefore, a beneficiary/linked third party that receives an operating grant during the action's duration cannot declare indirect costs for the year(s)/reporting period(s) covered by the operating grant, unless it can demonstrate that the operating grant does not cover any costs of the action (see Article 6.2.E).
[3] This is the theoretical amount of EU contribution that the system calculates automatically (by multiplying all the budgeted costs by the reimbursement rate). This theoretical amount is capped by the 'maximum grant amount' (that the Commission decided to grant for the action) (see Article 5.1).
[4] The 'maximum grant amount' is the maximum grant amount decided by the Commission. It normally corresponds to the requested grant, but may be lower.
[5] Depending on its type, this specific cost category will or will not cover indirect costs. Specific unit costs that include indirect costs are: costs for energy efficiency measures in buildings, access costs for providing trans-national access to research infrastructure and costs for clinical studies.
[6] See Article 5 for the forms of costs.
[7] Unit : hours worked on the action; costs per unit (hourly rate) : calculated according to the beneficiary's usual accounting practice.
[8] See Annex 2a 'Additional information on the estimated budget' for the details (costs per hour (hourly rate)).
[9] Unit and costs per unit : calculated according to the beneficiary's usual accounting practices.
[10] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs (see Article 6.2.E).
[11] See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit).
[12] See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit, estimated number of units, etc).
[13] Only specific unit costs that do not include indirect costs.
[14] See Article 9 for beneficiaries not receiving funding.
[15] Only for linked third parties that receive funding.

ANNEX 2a

ADDITIONAL INFORMATION ON THE ESTIMATED BUDGET

- **Instructions and footnotes in blue will not appear in the text generated by the IT system (since they are internal instructions only).**
- **For options *[*in square brackets*]*: the applicable option will be chosen by the IT system. Options not chosen will automatically not appear.**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): IT system will enter the appropriate data.**

⚠ **Transitory period: Until SyGMa fully supports Annex 2a, you must prepare it manually (using this template by choosing and deleting the options/entering the appropriate data).**
For the 'unit cost tables': either fill them out manually or use currently existing tables from Annex 1 or the proposal.
The document can then be uploaded in SyGMa and attached to the grant agreement.

Unit cost for SME owners/natural beneficiaries without salary

1. Costs for a *[*SME owner*][*beneficiary that is a natural person*]* not receiving a salary

Units: hours worked on the action

Amount per unit ('hourly rate'): calculated according to the following formula:

{the monthly living allowance for researchers in MSCA-IF actions / 143 hours}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}

The monthly living allowance and the country-specific correction coefficients are set out in the Work Programme (section 3 MSCA) in force at the time of the call:

- for calls *before* Work Programme 2018-2020:
  - for the monthly living allowance: **EUR 4 650**
  - for the country-specific correction coefficients: see Work Programme 2014-2015 and Work Programme 2016-2017 (available on the Participant Portal Reference Documents page)
- for calls *under* Work Programme 2018-2020:
  - for the monthly living allowance: **EUR 4 880**
  - for the country-specific correction coefficients: see Work Programme 2018-2020 (available on the Participant Portal Reference Documents page)

[additional OPTION for beneficiaries/linked third parties that have opted to use the unit cost (in the proposal/with an amendment): For the following beneficiaries/linked third parties, the amounts per unit (hourly rate) are fixed as follows:

- beneficiary/linked third party [short name]: EUR [insert amount]
- beneficiary/linked third party [short name]: EUR [insert amount]

[same for other beneficiaries/linked third parties, if necessary] *]*

Estimated number of units: see Annex 2

Energy efficiency measures unit cost

2. Costs for energy efficiency measures in buildings

Unit: m^2 of eligible 'conditioned' (i.e. built or refurbished) floor area

Amount per unit*: see (for each beneficiary/linked third party and BEST table) the 'unit cost table' attached

* Amount calculated as follows:
{EUR 0.1 x estimated total kWh saved per m^2 per year x 10}

Estimated number of units: see (for each beneficiary/linked third party and BEST table) the 'unit cost table' attached

Unit cost table (energy efficiency measures unit cost)[1]

Short name beneficiary/linked third party	BEST No	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)

[1] Data from the 'building energy specification table (BEST)' that is part of the proposal and Annex 1.

Research infrastructure unit cost

3. Access costs for providing trans-national access to research infrastructure

Units[2]: see (for each access provider and installation) the 'unit cost table' attached

Amount per unit*: see (for each access provider and installation) the 'unit cost table' attached

* Amount calculated as follows:

$$\frac{\text{average annual total access cost to the installation (over past two years[3])}}{\text{average annual total quantity of access to the installation (over past two years[4])}}$$

Estimated number of units: see (for each access provider and installation) the 'unit cost table' attached

Unit cost table (access to research infrastructure unit cost)[5]

Short name access provider	Short name infrastructure	Installation		Unit of access	Amount per unit	Estimated No of units	Total unit cost (cost per unit x estimated no of units)
		No	Short name				

Clinical studies unit cost

4. Costs for clinical studies

Units: patients/subjects that participate in the clinical study

Amount per unit*: see (for each sequence (if any), clinical study and beneficiary/linked third party) the 'unit cost table' attached

* Amount calculated, for the cost components of each task, as follows:

For **personnel costs**:

For personnel costs of doctors: 'average hourly cost for doctors', i.e.:

{certified or auditable total personnel costs for doctors for year N-1

{1720 * number of full-time-equivalent for doctors for year N-1}

multiplied by

estimated number of hours to be worked by doctors for the task (per participant)**}**

For personnel costs of other medical personnel: 'average hourly cost for other medical personnel', i.e.:

{certified or auditable total personnel costs for other medical personnel for year N-1

{1720 * number of full-time-equivalent for other medical personnel for year N-1}

---

2 Unit of access (e.g. beam hours, weeks of access, sample analysis) fixed by the access provider in proposal.

3 In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.

4 In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.

5 Data from the 'table on estimated costs/quantity of access to be provided' that is part of the proposal and Annex 1.

multiplied by
estimated number of hours to be worked by other medical personnel for the task (per participant)**}**

For personnel costs of technical personnel: **'**average hourly cost for technical personnel', i.e.:

{certified or auditable total personnel costs for technical personnel for year N-1
_____
{1720 * number of full-time-equivalent for technical personnel for year N-1}
multiplied by
estimated number of hours to be worked by technical personnel for the task (per participant)**}**

'total personnel costs' means actual salaries + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract/equivalent appointing act

For **consumables**:

For each cost item: 'average price of the consumable', i.e.:

{{certified or auditable total costs of purchase of the consumable in year N-1
_____
total number of items purchased in year N-1}
multiplied by
estimated number of items to be used for the task (per participant)**}**

'total costs of purchase of the consumable' means total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for the consumable delivered in year N-1, provided the contracts were awarded according to the principle of best value- for-money and without any conflict of interests

For **medical equipment**:

For each cost item: 'average cost of depreciation and directly related services per unit of use', i.e.:

{{ certified or auditable total depreciation costs in year N-1 + certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned}
_____
total capacity in year N-1
multiplied by
estimated number of units of use of the equipment for the task (per participant)**}**

'total depreciation costs' means total depreciation allowances as recorded in the beneficiary's accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value for money and without any conflict of interests + total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees

For **services**:

For each cost item: 'average cost of the service per study participant', i.e.:

{certified or auditable total costs of purchase of the service in year N-1
_____
total number of patients or subjects included in the clinical studies for which the service was delivered in year N-1**}**

'total costs of purchase of the service' means total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests

For **indirect costs**:

{{{cost component 'personnel costs' + cost component 'consumables' + cost component 'medical equipment'}

minus

{costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises + costs of providing financial support to third parties (if any)}**}**

multiplied by

25%**}**

The estimation of the resources to be used must be done on the basis of the study protocol and must be the same for all beneficiaries/linked third parties/third parties involved.

The year N-1 to be used is the last closed financial year at the time of submission of the grant application.

Estimated number of units: see (for each clinical study and beneficiary/linked third party) the 'unit cost table' attached

Unit cost table: clinical studies unit cost[6]

Task, Direct cost categories	**Resource per patient**	**Costs year N-1 Beneficiary 1 [short name]**	**Costs year N-1 Linked third party 1a [short name]**	**Costs year N-1 Beneficiary 2 [short name]**	**Costs year N-1 Linked third party 2a [short name]**	**Costs year N-1 Third party giving in-kind contributions 1 [short name]**
Sequence No. 1						
Task No. 1 Blood sample						
(a) **Personnel costs:** - Doctors	n/a					
- Other Medical Personnel	Phlebotomy (nurse), 10 minutes	8,33 EUR	11,59 EUR	10,30 EUR	11,00 EUR	9,49 EUR
- Technical Personnel	Sample Processing (lab technician), 15 minutes	9,51 EUR	15,68 EUR	14,60 EUR	15,23 EUR	10,78 EUR
(b) **Costs of consumables**:	Syringe	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Cannula	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Blood container	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(c) **Costs of medical equipment**:	Use of -80° deep freezer, 60 days	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	Use of centrifuge, 15 minutes	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(d) **Costs of services**	Cleaning of XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(e) **Indirect costs** (25% flat-rate)		XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
Task No. 2						
…						
Amount per unit (unit cost sequence 1):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**
Sequence No. 2						
Task No. 1						

[6] Same table as in proposal and Annex 1.

XXX						
(a) **Personnel costs:** - Doctors	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
- Other Medical Personnel	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
- Technical Personnel	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(b) **Costs of consumables**:	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(c) **Costs of medical equipment**:	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(d) **Costs of services**	XXX	XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
(e) **Indirect costs** (25% flat-rate)		XX EUR	XX EUR	XX EUR	XX EUR	XX EUR
Task No. 2						
…						
Amount per unit (unit cost sequence 2):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**
…						
Amount per unit (unit cost entire study):		**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**	**XX EUR**

1

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

BUNDESMINISTERIUM FUER ARBEIT, SOZIALES, GESUNDHEIT UND KONSUMENTENSCHUTZ (ATNA), established in Radetzkystrasse 2, WIEN 1030, Austria, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('2')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Robert SCHARINGER with ECAS id nshariro signed in the Participant Portal on 08/06/2020 at 08:16:42 (transaction id SigId-6367-PRC0cExzGoriAWfwE7kvEBP9Z6JuEAy9Zp2cTvQDULCu7lUYNEc0BSKK6IDMTFpc1O3STfsRApXyv8MDZtsOla-rS0vSrmBGYCubIhZmPp76e-jgHat66bjgpAfFrnYT43PAEbGvDNzv8CcyTkNAj3hE7t6K3a88At7jR3WIA3zcSm4BXv2WwOOaZgYc4uBTvU9x). Timestamp by third party at Mon Jun 08 09:16:52 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

GESUNDHEIT OSTERREICH GMBH (GÖG), established in STUBENRING 6, WIEN 1010, Austria, VAT number: ATU62777178, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('3')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Claudia HABL with ECAS id nhablhcl signed in the Participant Portal on 04/06/2020 at 19:34:30 (transaction id SigId-346-NnvMGssww9PGF8GC9b1k2yvp4bPQiU4ZHKyqjq0AkyuiPUC3wLCuoIdfXvGAhfdVwlTV6QGAzVroKi1UzVYQKc-rS0vSrmBGYCdSIzzSbUCdZm-SAIlcFZwqBkyr4K5a0cuYazHU5gA4bec1wi5evxFZFIbzhsBMS38UzwG4V9wyxhHR1xbD2040NurIwzOpJRdhRO). Timestamp by third party at Thu Jun 04 20:34:41 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

SERVICE PUBLIC FEDERAL SANTE PUBLIQUE, SECURITE DE LA CHAINE ALIMENTAIRE ET ENVIRONNEMENT (FPS Health Be), established in SQUARE VICTOR HORTA 40 BUR 1D 1G, BRUSSELS 1060, Belgium, VAT number: N/A, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('4')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Els EEMAN with ECAS id neemanel signed in the Participant Portal on 04/06/2020 at 09:08:16 (transaction id SigId-73192-MQOR7O8dueywpeaZYcyGLIOVvfio0qXO4HRE0BuqQMCqRPbtigYqfzut0MBmOcHKp0TN9WKzxiBeQsPlweibqZ-jpJZscgsw0K73X2i3UbBsu-tvGrfIW92sd9guQqj4uqeRxBUUcohukuRmZK6K1q38QBpshIXNwSWe1memrVzGbhtZiFHrjlwyzgnuRaP6Lxgd).
Timestamp by third party at
Thu Jun 04 10:08:22 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

INTEGRATING THE HEALTHCARE ENTERPRISE-EUROPE AISBL (IHE-EUR), established in BOULEVARD AUGUSTE REYERS 80, BRUXELLES 1030, Belgium, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('5')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Els Kooij with ECAS id n001yyfq signed in the Participant Portal on 09/06/2020 at 10:39:05 (transaction id SigId-9991-HbFxYEcL8SoTjr2puzKyKJ96BstckuuUls1W2tvwM4SzU7N BcNzHnuELYXmZzVsyyqijx9uvZLtA9gOsUFOM4oi-rS0vSrmBGYC6zI2UmTgCaa-eJulANaerzM5YwQKqYTpUxzypHIEkAw2slDkBaHcAhMdY NQlygb7CvShjgwJhiczrBjSfVbY9mGZChqPlB7f5BW). Timestamp by third party at Tue Jun 09 11:39:12 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

HL7 INTERNATIONAL FONDATION (HL7 Europe), established in SQUARE DE MEEUS 38-40, BRUSSELS 1000, Belgium, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('6')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Catherine CHRONAKI with ECAS id nchroncn signed in the Participant Portal on 04/06/2020 at 08:14:08 (transaction id SigId-72400-sczU6T1an8YrEK3qQDVTzZWKdZrX110iuzPEG2HG1Zo4nY0doODrG3HDrJcigMF0B6vP8nYVY5NLbzMm206thoS-jpJZscgsw0K73X2i3UbBsu-i9x63pMUizZuJLaTyooQ9LtgXFw7HCukTCc1gcnV20MeL1FBnn0XffriBtq8lEzhYgp85BtZ9YQgSTWZHX2BzQm). Timestamp by third party at Thu Jun 04 09:14:13 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

STICHTING KONINKLIJK NEDERLANDS NORMALISATIE INSTITUUT (NEN), established in VLINDERWEG 6, DELFT 2623 AX, Netherlands, VAT number: NL002814237B01, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('7')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Rik van Terwisga with ECAS id n00219i0 signed in the Participant Portal on 10/06/2020 at 10:44:26 (transaction id SigId-20716-0LuVcLj9D9gRdGWx8h9IRmVaVckmp4kZyjpZ9MeniARzsAwszKLkmX2liqCJS3oL32pSet7h2lsF3N7zqvgO2mm-rS0vSrmBGYC6zl2UmTgCaa-QsLIbCHUFHgAQbNyioKsCFMF2Yait3KIIqe9JCF64agRzZcm75RFhVMemncYzmGDxwOzeB2PI8jrjLd1Whg0ONm). Timestamp by third party at Wed Jun 10 11:44:33 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

HRVATSKI ZAVOD ZA ZDRAVSTVENO OSIGURANJE (HZZO), established in MARGARETSKA 3, ZAGREB 10000, Croatia, VAT number: HR3580261, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('8')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Lucian Vukelić with ECAS id n00292h5 signed in the Participant Portal on 05/06/2020 at 12:18:46 (transaction id SigId-82607-xzUzyisTKYm6Ky57RnDclf6nqvR25XmD88zsDcq1ha16xhPSS QzxYRabADXWpzRH17gKL5LykQlCZFco5MMMK8P-jpJZscgsw0K73X2i3UbBsu-SN8zPRDoszxZKCNQbiGGKlMW5zY3zdzdPhDVPy1gQCDozTj 4H60L52k8200Sq3lKx6xdpHwBZ2NiDXCMUMzviOpG). Timestamp by third party at Fri Jun 05 13:18:56 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNIVERSITY OF CYPRUS (UCY), established in KALLIPOLEOS STREET 75, NICOSIA 1678, Cyprus, VAT number: CY90001673W, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('9')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Marios DEMETRIADES with ECAS id ndmemari signed in the Participant Portal on 04/06/2020 at 08:22:50 (transaction id SigId-72528-IYZFnLqLjbIolYzYLhJ8O0lioR9loesL0l4evD5H1aJgbE2lM6Yc4bPIc03ZDJkNX1NIR7N4QuJG4fQ60sInzR-jpJZscgsw0K73X2i3UbBsu-MNuFPytDfJj2JSTAAcmA3gzI1owv6WtD5WIafXrugnhIzITk601ZFMBQKi9rKKcJhN9dQdUPLIWxp4SYDGiB0U). Timestamp by third party at
Thu Jun 04 09:22:58 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

MINISTERSTVO ZDRAVOTNICTVI CESKE REPUBLIKY (MZCR), established in PALACKEHO NAMESTI 375/4, PRAHA 12801, Czech Republic, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('10')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Adam Vojtěch with ECAS id n003f2zf signed in the Participant Portal on 30/06/2020 at 09:46:05 (transaction id SigId-8574-bdozmBfDDezexbbWcCzvvqa2l6Vfmx5kt28gsrRzsA3oFWFDgfzMYvQHzU2tOkDiZWSSzYtD5p3zizNzarvouRtuS-rS0vSrmBGYCccyzjTUxfs7-ILSgAxMErl3PDI3mKFP9w4yxJZluxZumo0Gkps2m4D7CJNfL6wBEGpsTls43zn2ADGjkTB6yYiK7sYrCNWUgHa). Timestamp by third party at Tue Jun 30 10:46:14 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

VYSOCINA KRAJ (Kraj Vysočina), established in ZIZKOVA 57, JIHLAVA 587 33, Czech Republic, VAT number: CZ70890749, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('11')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Jiri Behounek with ECAS id n003ad0q signed in the Participant Portal on 22/06/2020 at 13:08:04 (transaction id SigId-105828-5kvgR17Afqafwf86Knr6CXGxZ3FuDPzuF0ANMUMS0tbd04zqmZLk4Axu6jbajjrtxkVA1wchJQIHAo8XvvszIKW-rS0vSrmBGYC6zI2UmTgCaa-88JiatddJUBzpsTTSPqXcbkt3zNNGkZD0KcpI0fg8y6SqFQAzfRv1uHUjjP2fRo8zotsHp1TUzzs2ybVJKBo7xTm). Timestamp by third party at Mon Jun 22 14:08:14 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

SOTSIAALMINISTEERIUM (MSAE), established in Suur-Ameerika 1, TALLINN 10122, Estonia, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('12')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Marika PRISKE with ECAS id nprmaika signed in the Participant Portal on 22/06/2020 at 05:52:52 (transaction id SigId-101361-fzNSuUO3Qn25Mb7bPewjAChMat72DocVG6jsRNE9ATbSNnOG8uTlTqigTaQrzrNEme6Ot5enzdg92lhLXGbyNs0-rS0vSrmBGYC6zl2UmTgCaa-lMAdGiByOHQk9ihNAfIYzhpgQqHKVzZVS5zPmVmapNhYDXC0aVsqkF3pZ7FXyGKPp0ND5CyG2YzdoFc6VUl1Rn4).
Timestamp by third party at
Mon Jun 22 06:53:05 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

AGENCE DU NUMÉRIQUE EN SANTÉ (ANS), established in RUE GEORGES PITARD 9, PARIS 75015, France, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('13')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Pascale SAUVAGE with ECAS id nsauvpas signed in the Participant Portal on 12/06/2020 at 08:56:53 (transaction id SigId-39459-fxmMwPwyJs3JXKO3NIJIXe5FjNqqEHzMjCMhDkL6zL8Iepg5cKRN1zzjEn07cK0G1toKGUtolRXIPiK3walICQi-rS0vSrmBGYC6zl2UmTgCaa-zpPd8GzcVemZfloiMX3620NZzs779CfiKJ4MGzzkIcYsx5TG5zeOIALxOWt1T9rWTziWb0UyjNzpPOXNkozuWmT6m). Timestamp by third party at Fri Jun 12 09:57:02 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

MINISTERE DES AFFAIRES SOCIALES ET DE LA SANTE (MoH-FR), established in AVENUE DUQUESNE 14, PARIS CEDEX 75350, France, VAT number: N/A, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('14')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Laura Létourneau with ECAS id n003aews signed in the Participant Portal on 23/06/2020 at 18:12:50 (transaction id SigId-119974-QxzoKB1XQoqqCymD5vPuYt8FfSb0i4SeaAG4YOQIPIXmjDPAQzJHdzZmcIXdYn0gOlu24flQiwk2w18Phw6ddBW-rS0vSrmBGYC6zl2UmTgCaa-1K16mzqoog9dMHrs8sM9sAff8KQc6otqSOTxespkzuyPG4LcBogeWwFdKc1zzzdmftcf625HzRGOzmzuhI8cfWg6). Timestamp by third party at Tue Jun 23 20:13:05 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

DEUTSCHES INSTITUT FUR MEDIZINISCHE DOKUMENTATION UND INFORMATION (DIMDI) (DIMDI), established in WAISENHAUSGASSE 36-38A, KOLN 50676, Germany, VAT number: DE123052538, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('15')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Weber STEFANIE with ECAS id nstefweb signed in the Participant Portal on 30/06/2020 at 08:55:21 (transaction id SigId-7569-TuBOzRvw5g52y9VQsFD4R3VDSbfHKXenBzGHicL6IZafcVTzgUqMiqr5JFUdQubqhRgizJwNaPwB4YgpREJzpLf-rS0vSrmBGYCccyzjTUxfs7-rwhwlgk0MET6ZXzjXtHdq6157HdCDsHNoO8TcnAGjirfHBkF0l2u89Nv8I5gzqnvBT0gudAQUouhNXq6xpN0bzm). Timestamp by third party at
Tue Jun 30 09:55:30 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

GEMATIK GMBH (GEMATIK), established in FRIEDRICHSTRASSE 136, BERLIN 10117, Germany, VAT number: DE241843684, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('16')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Stefan Höcherl with ECAS id n003eubh signed in the Participant Portal on 25/06/2020 at 16:13:39 (transaction id SigId-19701-yPV0zbliDhUOSi1W5e1OzrzJ9QZqL19Hl2VIJ6FGdcsXI1zrzfZV3jN50f0xBxVnSGJIMCqFyLWLV5Aql4oI7R5-jpJZscgsw0KNihoCvhiTby-4cFpejPWRJ8ZoYVPR8WfZjA1I3JsH7HR5f6rkbkgfTjcRlp7wTu3qjUGNGDesxWqo56pCUTXEZv3vek9PF8DMW). Timestamp by third party at Thu Jun 25 17:13:46 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

TMF - TECHNOLOGIE UND METHODENPLATTFORM FUR DIE VERNETZTE MEDIZINISCHE FORSCHUNG EV (TMF), established in CHARLOTTENSTRASSE 42 ECKE DOROTHEENSTRASSE, BERLIN 10117, Germany, VAT number: DE244871253, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('17')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Karoline Buckow with ECAS id n002zuwf signed in the Participant Portal on 30/06/2020 at 11:37:17 (transaction id SigId-10805-5szwCDPL7yvGLLqBzkHANY6fzLqW4zhoRI4FbEjJlzPmJZ3tWhN9zR5IVAip66IVyv07qgCNdwJRnx8JxHJXnvZm-rS0vSrmBGYCccyzjTUxfs7-t53ID7Fb5CyDpFctmIuzfHvzHU5JrA4i3p7i4ghIib3uztlCK6KMzQm43k3aZOcyfzkwQtYTuA1A9HpcRr3be3H). Timestamp by third party at
Tue Jun 30 12:37:24 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

MINISTRY OF HEALTH (MoHGR), established in ARISTOTELOUS STREET 17, ATHINA, Greece, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('18')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Konstantinos Gogosis with ECAS id n0027t8y signed in the Participant Portal on 09/06/2020 at 17:31:58 (transaction id SigId-16107-owROZLQzUgp55UnoqKoRjX8EObYusLNrHpSEdB651azZBKNbGlRtUCtWh9kzblJqSi17zPNDYJr0DacP3zq7YVf-rS0vSrmBGYC6zl2UmTgCaa-zaL7GkvIGA0tSAzkc4lUyh7K2wPC2fb6SshmALIVIBUzNRzG4Y8BVvMS9SBrYLUxrGogmMUXfuNX5UB2tqKa1GO). Timestamp by third party at Tue Jun 09 18:32:07 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

ALLAMI EGESZSEGUGYI ELLATO KOZPONT (AEEK), established in DIOS AROK 3, BUDAPEST 1125, Hungary, VAT number: HU15324683, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('19')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Miklós GONDOS DR. with ECAS id n00298lv signed in the Participant Portal on 29/06/2020 at 15:09:04 (transaction id SigId-2518-gFvqhIXCUeZiBzOdQ0uADaRE2IzIU1GtkIRimARTJFBj1HY2mDfgGh6heczKQw47zUNHw7vVJejhY6aURVu9yH4-rS0vSrmBGYCccyzjTUxfs7-ImSVaBrLLKY4v79sQzHOlWzSvAtO3HdgtPltxT1p5FMErrwD2zMVSzG6bW46hdA62YWJOvv9kofzOX0g6O8a11R). Timestamp by third party at Mon Jun 29 16:09:15 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

SEMMELWEIS EGYETEM (SE), established in ULLOI UTCA 26, BUDAPEST 1085, Hungary, VAT number: HU15329808, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('20')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Béla Dr. Merkely with ECAS id n002coer signed in the Participant Portal on 17/06/2020 at 14:17:22 (transaction id SigId-76552-uM86fWVZB06HfgXdHjouERCBDFblDnSjhaMdp4FzPyL2lbPtjnbP6sLkel3QS51TeDsN55ipSbrh8qU7bC3Fi0-rS0vSrmBGYC6zl2UmTgCaa-XpYCJXj0XY6zxB6n9eALhLm7WLWK80k48IHB6AcazaS4F1Q2p1Z1WE5XxfTCqgibgdaPJlbZ6G3YuRYd8mNzxp0). Timestamp by third party at Wed Jun 17 15:17:32 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

DEPARTMENT OF HEALTH (DoH), established in Block 1, Miesian Plaza, 50 – 58 Lower Baggot Street, Dublin D02 XW14, Ireland, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('21')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Sarah Murphy with ECAS id n0028css signed in the Participant Portal on 04/06/2020 at 10:27:56 (transaction id SigId-74711-db0V9DLP3zzOtDStkbTjt2uMRtHDKlXxipN10RQlovPnKK0fCs0nnud5fJwOebZoWIJV59jT0fpBmPQFx46I8Q-jpJZscgsw0K73X2i3UbBsu-iD2Ch8SKU4kCxwTmmKt2RGiUUyXDDT5lxJm32Sx97yvNn321uRpYo4DhoziSXmZqApvO4zm3zzIkJqxgknU5OXW). Timestamp by third party at Thu Jun 04 11:28:11 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

AGENZIA PER L'ITALIA DIGITALE (AGID), established in VIA LISZT 21, ROMA 00144, Italy, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('22')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Francesco Paorici with ECAS id n0038zfv signed in the Participant Portal on 30/06/2020 at 17:36:13 (transaction id SigId-15990-XNBKfy4MIXy3TpPZJBT39wDVCuzUrlysSXhEjGKhPzk7Rj31zUcCsbuSl9NsN6ATl1TQ0UgpdYUePAbRaG2r7e0-rS0vSrmBGYCccyzjTUxfs7-wuO3iQD93bfA8TX6NJHIeR9DLnKZP10esg6RzJ5WVHKcj1PbSXEt8L1TRAg3cdBW2rQ1MwIqsyeLqgMCAzU6Nv). Timestamp by third party at Tue Jun 30 18:36:28 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

AZIENDA REGIONALE PER L'INNOVAZIONEE GLI ACQUISTI S.P.A. (ARIA), established in VIA TORQUATO TARAMELLI 26, MILANO 20124, Italy, VAT number: IT05017630152, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('23')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Francesco Ferri with ECAS id n0030re3 signed in the Participant Portal on 04/06/2020 at 08:11:45 (transaction id SigId-72359-pCaacVKdvBgGhgbUBQPRGpK5RiU3H192obcqiD10r0dA30W3sSgCDihUN0yylLK20zo97wAQTYgbUW1EvtaOu0-jpJZscgsw0K73X2i3UbBsu-rcfUgczoTPituUHkC5IOcLw9Grzcaoixpfh6CNMCwvS2WT7fVVrgYaDaqTK1DM2aY6JG2uBaEM9ZLYH3qENtpn). Timestamp by third party at Thu Jun 04 09:11:51 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

MINISTERO DELLA SALUTE (MIN SAL), established in Via Giorgio Ribotta 5, ROMA 00144, Italy, VAT number: N/A, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('24')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Giuseppe Viggiano with ECAS id n001zb0n signed in the Participant Portal on 10/06/2020 at 10:56:08 (transaction id SigId-20911-3yaEk3bl3PpCJusainSAE7S80PPQUR1eMijUJ5JO0zTwhx4l56D2P6JnERGhefziMn4e88AfMFUUKgSzt7XAunG-rS0vSrmBGYC6zl2UmTgCaa-PRwZD9kiN4w9ms0uLZaiSQXR3zIzzh58kuxD9kbdnqotKBnWzWI4BgLje4uB0dL3Hy7QJ75dPvsXJWFzQTLKjIo). Timestamp by third party at Wed Jun 10 11:56:14 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

REGIONE LOMBARDIA (REGLOMB), established in PIAZZA CITTA DI LOMBARDIA 1, MILANO 20124, Italy, VAT number: IT12874720159, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('25')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Marco Trivelli with ECAS id n003enuf signed in the Participant Portal on 10/07/2020 at 14:14:11 (transaction id SigId-69417-N42bDlnV2GaPRzQ85OiWZ2tXMiTyo3L00cIa70kPsgLs39Vw0KwBcs0zifi9zQg5kNPcPWSVu2kVkCTdJBlDFzq-jpJZscgsw0KmE9g55QdRE4-ThIzq7ni6f0jMjoGEaS91gt6ScdiiIQr49ZszhhzjuXLfrSZ4rVDPUzXot9Nya0jRUOg93s86sRwIpIrze5TUfp). Timestamp by third party at Fri Jul 10 15:14:18 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

NACIONALAIS VESELIBAS DIENESTS (NVD), established in 31 Cēsu str., k-3, 6.entrance, Riga LV-1012, Latvia, VAT number: 90009649337, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('26')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Inga MILAŠEVIČA with ECAS id nmilasin signed in the Participant Portal on 04/06/2020 at 11:48:31 (transaction id SigId-76100-Zplyn0B0F34xoHxOLmbwBc1kIQfRdTZNVwrRv7TrmRszazMQs48o8Yq6HTzbc5PHaPhbP434nozRQu97u97eQ2S-jpJZscgsw0K73X2i3UbBsu-hYDJcUnOWkT4gP9MIyMzOKaziCNEhVYtF4MK2PX44zIyE4k0eMGbANcs7ZSOKfMmHfx8EzSf9rjOazzZ9ow415cG). Timestamp by third party at Thu Jun 04 12:48:41 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

LIETUVOS RESPUBLIKOS SVEIKATOS APSAUGOS MINISTERIJA (SAM), established in VILNIAUS G 33, VILNIUS LT 01506, Lithuania, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('27')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Audrone ASTRAUSKIENE with ECAS id nastraau signed in the Participant Portal on 08/06/2020 at 15:14:06 (transaction id SigId-2776-egHZD1GwDDOwRAtsZOszppSF4BVFTshoU8zKjZEXXIOuzWzLQCAgLAZzyFdXXJv10iyDiDKziSIEt26zUgYjCx4S-rS0vSrmBGYC6zl2UmTgCaa-xxnklHbrPrBG7iQwfkaShzkjeBWIwktaTEjzLaSUuzdhcPVmwzlFe0CVrn1cvteUea01Qdzyn0GU4ZdTfhqLNO6). Timestamp by third party at Mon Jun 08 16:14:13 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

STICHTING NATIONAAL ICT INSTITUUT IN DE ZORG (NICTIZ), established in Oude Middenweg 55, Den Haag 2491AC, Netherlands, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('28')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Leonique Niessen with ECAS id n002yny8 signed in the Participant Portal on 22/06/2020 at 11:34:52 (transaction id SigId-104727-jwLIWBqdI1FnU3ThahVdeY6dPp6zrKVzfzzRkUwaojzjBJ7Qoi6SKLEuzrbmaJ159QrxE773JrRRNUEKgcamzc5i-rS0vSrmBGYC6zl2UmTgCaa-q7etizi8A2LMsnQN7rsSzqctRe6RuMT6vLd8eJUgkYdD7XlRrEPUM6oQ0Y3NXSUdCJFoitLNmS2cBRpUGMMd2H). Timestamp by third party at Mon Jun 22 12:35:02 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

NARODNE CENTRUM ZDRAVOTNICKYCH INFORMACII (NCZI), established in LAZARETSKA 26, BRATISLAVA 811 09, Slovakia, VAT number: SK2020830119, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('29')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Peter Bielik with ECAS id n003dmkt signed in the Participant Portal on 18/06/2020 at 11:55:01 (transaction id SigId-85440-Kgx25IFqzKodHXYyOeOOM2bVwGLDrtSx5BLElpeIRPfbzIbn4iunzkrFzzHWGej9ycUqczmswttHYhVasbWmHNl0-rS0vSrmBGYC6zl2UmTgCaa-emOobHezfg7zY3cSEd5BDbw7PlwG8hYVRE6WT4yiAhYPvUSGXjbzPU7n1VKUv9XkiXESY7nSgeK9RisnmtaksRm). Timestamp by third party at Thu Jun 18 12:55:12 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

NACIONALNI INSTITUT ZA JAVNO ZDRAVJE (NIJZ), established in TRUBARJEVA CESTA 2, LJUBLJANA 1000, Slovenia, VAT number: SI44724535, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('30')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Milan Krek with ECAS id n003bif0 signed in the Participant Portal on 04/06/2020 at 09:48:48 (transaction id SigId-73913-DavwADNc0MfWeay5laDdbCasHqyov4l4HjIR1qdMLtzaiPR OiF5suGX3j3zfleFRUPeVbGtxkktMymX56mq9dF-jpJZscgsw0K73X2i3UbBsu-csb2GQsFprQ0alM2hqcKUK2eJSqV1J3zp2iLClAaUIlRYqRz pcuodUjCqJQ6ypFw1nwdNoLCT8Ks7txr6vzd6i0). Timestamp by third party at Thu Jun 04 10:48:54 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

FUNDACIO TICSALUT (TICSALUT), established in C ERNEST LLUCH 32 Planta 6 Porta 4 TECNOCAMPUS MATARO MARESME TORRE TCM 3, MATARO BARCELONA 08302, Spain, VAT number: ESG64350374, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('31')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

JOSUE SALLENT RIBES with ECAS id n002am4g signed in the Participant Portal on 04/06/2020 at 09:24:22 (transaction id SigId-73515-3j1OqSjTdmUYX8NmwmQLSTMPPavOoulIgC4wzJZ1f7yuq1Mt1ArUWoKYip4zhgXLWa9jZ9p9N5DWRZRUTbq4EN-jpJZscgsw0K73X2i3UbBsu-uy3u9yyVQMiAImmpxSN1KYzQwjnZfOmnpLmCgdrJ03UoUZxpgM7hvwnvSZ6B4xNOK37GQX3djbqLxWDlziGzzsC). Timestamp by third party at Thu Jun 04 10:24:28 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

EQUALIS AB (Equalis AB), established in KUNGSGATAN 113, UPPSALA 751 09, Sweden, VAT number: SE556515280701, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('32')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Gunnar Nordin with ECAS id n002wchh signed in the Participant Portal on 04/06/2020 at 18:44:20 (transaction id SigId-159-zNqpLQtvtJmQqsq6yoKiTlkFDQxejt8B8De3mmzNWAQx4BmdSkUA8sszhsZt58XlIOXo0nBeQzzzt4NdvPU6wwyW-rS0vSrmBGYCdSIzzSbUCdZm-1bv15yB4pcMyOsk1bjzH6TvdtavznyaDozzfdCEW7XiKryzG5jzsQAnyxBajDhR96UUi827Z9UAq1l9ezHRzg7RT). Timestamp by third party at Thu Jun 04 19:44:27 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

E-HALSOMYNDIGHETEN (SEHA), established in SANK ERIKSGATAN 117, STOCKHOLM 118 60, Sweden, VAT number: SE202100655201, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('33')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Michele Silvestri with ECAS id n002v8z3 signed in the Participant Portal on 13/06/2020 at 09:01:42 (transaction id SigId-47606-AYwzWpr3zduOa4uhBNGKBCWp3JMyVlviRNzM0ZhXzfrVxSOrDJNDFSRVQczSVGnrHI1nVIhSzka6KBnO9gVGznjW-rS0vSrmBGYC6zl2UmTgCaa-ezha5Q8eXQrAygcMU1zzkTBd35NJkIYGM45euSMqp1cQM8OVDLhtcmBLdyjJLaaNc7758kIzhOHjALzV4hqF2cg). Timestamp by third party at Sat Jun 13 10:01:53 CEST 2020

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM), established in RUE DE TOLBIAC 101, PARIS 75654, France, VAT number: FR31180036048, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('34')

in Grant Agreement No 951938 ('the Agreement')

between SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled 'X-eHealth: eXchanging electronic Health Records in a commom framework (X-eHealth)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Camille CHAUDONNERET with ECAS id nchaucmi signed in the Participant Portal on 04/06/2020 at 13:58:41 (transaction id SigId-78181-eINtNY4jtIOPJdLIyG78DQdq744ehcWQXUiXeMk32jB7RxhdKW3s6S1k04BK9umWEuPH4BgxTG30fzLTyIlENm-jpJZscgsw0K73X2i3UbBsu-zhDCdp2q00qqD04lKvBLzxTInGoObX8UV1PSMy0FTyXGzHNyuBfJA0ZjrE4XBKQfOp4zLzJwjarmdmGYI1dFjFj). Timestamp by third party at Thu Jun 04 14:58:48 CEST 2020

ⓘ print format A4 landscape

MODEL ANNEX 4 FOR H2020 GENERAL MGA — MULTI

Associated with document Ref. Ares(2020)2778062 - 28/05/2020

FINANCIAL STATEMENT FOR *[BENEFICIARY [name]/ LINKED THIRD PARTY [name]]* FOR REPORTING PERIOD [reporting period]

	Eligible[1] costs (per budget category)													Receipts	EU contribution			Additional information
	A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs			E. Indirect costs[2]	*[F. Costs of …]*		Total costs	Receipts	Reimbursement rate %	Maximum EU contribution[3]	Requested EU contribution	Information for indirect costs :
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary			*[C.1 Financial support]* *[C.2 Prizes]*	D.1 Travel D.2 Equipment D.3 Other goods and services	*[D.4 Costs of large research infrastructure]*	D.5 Costs of internally invoiced goods and services		*[F.1 Costs of …]*	*[F.2 Costs of …]*		Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
Form of costs[4]	Actual	Unit	Unit		Actual	Actual	Actual	Actual	Unit	Flat-rate[5] 25%	Unit		*[Unit][Lump sum]*					
	a	Total b	No hours	Total c	d	*[e]*	f	*[g]*	Total h	i=0,25 x (a+b+ c+f+*[g]* + h+ *[j 1]*[6] +*[j2]*[6] -p)	No units	Total *[j1]*	Total *[j2]*	k = a+b+c+d+*[e]* +*f* + *[g]* +h+ i + *[j1]* +*[j2]*	l	m	n	o	p
[short name beneficiary/linked third party]																		

The beneficiary/linked third party hereby confirms that:
The information provided is complete, reliable and true.
The costs declared are eligible (see Article 6).
The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).
For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘ Please declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace other costs that are found to be ineligible.

[1] See Article 6 for the eligibility conditions

[2] The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.2.E). If you have received an operating grant during this reporting period, you cannot claim indirect costs unless you can demonstrate that the operating grant does not cover any costs of the action.

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying the reimbursement rate by the total costs declared). The amount you request (in the column 'requested EU contribution') may be less,

[4] See Article 5 for the forms of costs

[5] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs (see Article 6.2.E)

[6] Only specific unit costs that do not include indirect costs

ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data**

TABLE OF CONTENTS

Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the Financial Statement(s)[1] drawn up by the *[Beneficiary] [Linked Third Party]* for the Horizon 2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a Certificate on the Financial Statements' ('CFS') referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement has been concluded under the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union][Euratom][Agency]* is not a party to this engagement.

1.1 Subject of the engagement

The coordinator must submit to the *[Commission][Agency]* the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the coordinator the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement.

The CFS is composed of two separate documents:

- The Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

[1] By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

- The Auditor's Independent Report of Factual Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures ('the Procedures') to be performed by the Auditor, and the standard factual findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the Commission *[Agency,]* the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

1.2 Responsibilities

The *[Beneficiary] [Linked Third Party]:*

- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the *[Beneficiary's] [Linked Third Party's]* accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- accepts that the Auditor cannot carry out the Procedures unless it is given full access to the *[Beneficiary's] [Linked Third Party's]* staff and accounting as well as any other relevant records and documentation.

The Auditor:

- *[Option 1 by default:* is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations*]*.
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer:* is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary*]*.
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation:* is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation*]*.

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[2]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the *[Commission][Agency]* requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]*, and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the Commission*[, the Agency],* the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [*the European Union*] [*Euratom*] budget. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the Commission *[, the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by *[*dd Month yyyy*]*.

1.6 Other terms

[*The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.*]

[legal name of the Auditor]	[legal name of the *[Beneficiary][Linked Third Party]*]
[name & function of authorised representative]	[name & function of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary][Linked Third Party]*

[2] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent Report of Factual Findings on costs declared under Horizon 2020 Research and Innovation Framework Programme

(To be printed on the Auditor's letterhead)

To
[name of contact person(s)], [Position]
[[*Beneficiary's*] [*Linked Third Party's*] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')],*

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)[3] of the *[Beneficiary] [Linked Third Party]* concerning the grant agreement [insert grant agreement reference: number, title of the action and acronym] ('the Agreement'),

with a total cost declared of
[total amount] EUR,

and a total of actual costs and unit costs calculated in accordance with the [*Beneficiary's*] [*Linked Third Party's*] usual cost accounting practices' declared of

[sum of total actual costs and total direct personnel costs declared as unit costs calculated in accordance with the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practices] EUR

and **hereby provide our Independent Report of Factual Findings ('the Report')** using the compulsory report format agreed with you.

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') examined.

[3] By which the Beneficiary declares costs under the Agreement (see template 'Model Financial Statement' in Annex 4 to the Agreement).

The Procedures were carried out solely to assist the *[Commission] [Agency]* in evaluating whether the *[Beneficiary's] [Linked Third Party's]* costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The *[Commission] [Agency]* draws its own conclusions from the Report and any additional information it may require.

The scope of the Procedures was defined by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the *[Beneficiary's] [Linked Third Party's]* Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

Not applicable Findings

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

Explanation (to be removed from the Report):

*If a Finding was not applicable, it must be marked as '**N.A.**' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related Procedure(s) did not have to be carried out.*

The reasons of the non-application of a certain Finding must be obvious i.e.

i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable;

ii) if the condition set to apply certain Procedure(s) are not met the related Finding(s) and those Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the Procedure and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.

….

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

Explanation (to be removed from the Report):

- *If the Auditor was not able to successfully complete a procedure requested, it must be marked as '**E**' ('Exception') in the corresponding row on the right-hand column of the table. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the Procedure must be indicated below.*
- *If the Auditor cannot corroborate a standard finding after having carried out the corresponding procedure, it must also be marked as '**E**' ('Exception') and, where possible, the reasons why the Finding was not fulfilled and its possible impact must be explained here below.*

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.

….

Example (to be removed from the Report):

1. *The Beneficiary was unable to substantiate the Finding number 1 on … because ….*
2. *Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: …*
3. *After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____ EUR. The difference can be explained by …*

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. *Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because …*
2. *In order to be able to confirm the Finding number 15 we carried out the following additional procedures: ….*

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the *[Beneficiary] [Linked Third Party]* and the [*Commission*] [*Agency*], and only to be submitted to the *[Commission] [Agency]* in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the *[Beneficiary] [Linked Third Party]* or by the *[Commission] [Agency]* for any other purpose, nor may it be distributed to any other parties. The *[Commission] [Agency]* may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the *[Commission] [Agency]* by the *[Beneficiary] [Linked Third Party]* for the Agreement. Therefore, it does not extend to any other of the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s).

There was no conflict of interest[4] between the Auditor and the Beneficiary *[and Linked Third Party]* in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR _____ (including EUR_____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]
[name and function of an authorised representative]
[dd Month yyyy]
Signature of the Auditor

[4] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The European Commission reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

The 'result' column has three different options: 'C', 'E' and 'N.A.':

- 'C' stands for 'confirmed' and means that the auditor can confirm the 'standard factual finding' and, therefore, there is no exception to be reported.
- 'E' stands for 'exception' and means that the Auditor carried out the procedures but cannot confirm the 'standard factual finding', or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- 'N.A.' stands for 'not applicable' and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than the euro' the Procedure related to 'beneficiaries with accounts established in euro' is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A	**ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE**		
	The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A. (*The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)* The Auditor sampled _____ people out of the total of _____ people.		

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.1	**PERSONNEL COSTS** For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs) To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract; o the payslips of the employees included in the sample; o reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system; o information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent; o the Beneficiary's usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); o applicable national law on taxes, labour and social security and o any other document that supports the personnel costs declared. The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA) and recalculated the personnel costs for employees included in the sample.	1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary's sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary's usual practices.	
		2) Personnel costs were recorded in the Beneficiary's accounts/payroll system.	
		3) Costs were adequately supported and reconciled with the accounts and payroll records.	
		4) Personnel costs did not contain any ineligible elements.	
		5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.	
	Further procedures if 'additional remuneration' is paid To confirm standard factual findings 6-9 listed in the next column, the Auditor: o reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory	6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	obligations, the Beneficiary's usual policy on additional remuneration, criteria used for its calculation, the Beneficiary's usual remuneration practice for projects funded under national funding schemes…); o recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, usual remuneration paid for projects funded by national schemes) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 'Productive hours' and A.4 'Time recording system'). *'ADDITIONAL REMUNERATION' MEANS ANY PART OF THE REMUNERATION WHICH EXCEEDS WHAT THE PERSON WOULD BE PAID FOR TIME WORKED IN PROJECTS FUNDED BY NATIONAL SCHEMES.* *IF ANY PART OF THE REMUNERATION PAID TO THE EMPLOYEE QUALIFIES AS "ADDITIONAL REMUNERATION" AND IS ELIGIBLE UNDER THE PROVISIONS OF ARTICLE 6.2.A.1, THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION UP TO THE FOLLOWING AMOUNT:* *(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR;* *(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR* *(C) IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.*	7) The amount of additional remuneration paid corresponded to the Beneficiary's usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required.	
		8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used.	
		9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000 per FTE/year (up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).	
	Additional procedures in case "unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices" is applied: Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5 and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard	10) The personnel costs included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. This methodology was consistently	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	factual findings 10-13 listed in the next column: o obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs;. o reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; o verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records; o verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts; o verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents.	used in all H2020 actions.	
		11) The employees were charged under the correct category.	
		12) Total personnel costs used in calculating the unit costs were consistent with the expenses recorded in the statutory accounts.	
		13) Any estimated or budgeted element used by the Beneficiary in its unit-cost calculation were relevant for calculating personnel costs and corresponded to objective and verifiable information.	
	<u>For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no subcontractors).</u> To confirm standard factual findings 14-17 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary: o the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary; o the employment conditions of staff in the same category to compare costs and; o any other document that supports the costs declared and its registration (e.g. invoices, accounting records, etc.).	14) The natural persons worked under conditions similar to those of an employee, in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed.	
		15) The results of work carried out belong to the Beneficiary, or, if not, the Beneficiary has obtained all necessary rights to fulfil its obligations as if those	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
		results were generated by itself.	
		16) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		17) The costs were supported by audit evidence and registered in the accounts.	
	<u>For personnel seconded by a third party and included in the sample (not subcontractors)</u> To confirm standard factual findings 18-21 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o their secondment contract(s) notably regarding costs, duration, work description, place of work and ownership of the results; o if there is reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the amount invoiced by the third party did not include any profit; o if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll;	18) Seconded personnel reported to the Beneficiary and worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		19) The results of work carried out belong to the Beneficiary, or, if not, the Beneficiary has obtained all necessary rights to fulfil its obligations as if those results were generated by itself..	
		If personnel is seconded against payment: 20) The costs declared were supported with documentation and recorded in the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ any other document that supports the costs declared (e.g. invoices, etc.).	Beneficiary's accounts. The third party did not include any profit.	
		If personnel is seconded free of charge: 21) The costs declared did not exceed the third party's cost as recorded in the accounts of the third party and were supported with documentation.	
A.2	**PRODUCTIVE HOURS** To confirm standard factual findings 22-27 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that: ○ the annual productive hours applied were calculated in accordance with one of the methods described below, ○ the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated. If the Beneficiary applied method B, the auditor verified that the correctness in which the total number of hours worked was calculated and that the contracts specified the annual workable hours. If the Beneficiary applied method C, the auditor verified that the 'annual productive hours' applied when calculating the hourly rate were equivalent to at least 90 % of the 'standard annual workable hours'. The Auditor can only do this if the calculation of the standard annual workable	22) The Beneficiary applied method [*choose one option and delete the others*] [**A**: 1720 hours] [**B**: the 'total number of hours worked'] [**C**: 'standard annual productive hours' used correspond to usual accounting practices]	
		23) Productive hours were calculated annually.	
		24) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	hours can be supported by records, such as national legislation, labour agreements, and contracts. *BENEFICIARY'S PRODUCTIVE HOURS' FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS:* ***A**. 1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)* ***B**. THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL NUMBER OF HOURS WORKED' IN THE NEXT COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE).* ***C**. THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS 'STANDARD ANNUAL PRODUCTIVE HOURS' IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS.* *'ANNUAL WORKABLE HOURS' MEANS THE PERIOD DURING WHICH THE PERSONNEL MUST BE WORKING, AT THE EMPLOYER'S DISPOSAL AND CARRYING OUT HIS/HER ACTIVITY OR DUTIES UNDER THE EMPLOYMENT CONTRACT, APPLICABLE COLLECTIVE LABOUR AGREEMENT OR NATIONAL WORKING TIME LEGISLATION.*	*If the Beneficiary applied method B.* 25) The calculation of the number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary. 25.1) The Beneficiary calculates the hourly rates per full financial year following procedure A.3 (method B is not allowed for beneficiaries calculating hourly rates per month). *If the Beneficiary applied method C.* 26) The calculation of the number of 'standard annual workable hours' was verifiable based on the documents provided by the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
		27) The 'annual productive hours' used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the 'annual workable hours'.	
A.3	**HOURLY PERSONNEL RATES** I) For unit costs calculated in accordance to the Beneficiary's usual cost accounting practice (unit costs): If the Beneficiary has a "Certificate on Methodology to calculate unit costs " (CoMUC) approved by the Commission, the Beneficiary provides the Auditor with a description of the approved methodology and the Commission's letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary. If the Beneficiary does not have a "Certificate on Methodology" (CoMUC) approved by the Commission, or if the methodology approved was not applied, then the Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the unit costs (hourly rates) of staff included in the sample following the results of the procedures carried out in A.1 and A.2. II) For individual hourly rates: The Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates;	28) The Beneficiary applied [*choose one option and delete the other*]: [Option I: "Unit costs (hourly rates) were calculated in accordance with the Beneficiary's usual cost accounting practices"] [Option II: Individual hourly rates were applied] *For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC):* 29) The Beneficiary used the Commission-approved methodology to calculate hourly rates. It corresponded to the organisation's usual cost accounting practices and was applied consistently for all	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ recalculated the hourly rates of staff included in the sample (recalculation of all hourly rates if the Beneficiary uses annual rates, recalculation of three months selected randomly for every year and person if the Beneficiary uses monthly rates) following the results of the procedures carried out in A.1 and A.2; ○ (only in case of monthly rates) confirmed that the time spent on parental leave is not deducted, and that, if parts of the basic remuneration are generated over a period longer than a month, the Beneficiary has included only the share which is generated in the month. *"UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES":* *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2.* *HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS:* *IT IS CALCULATED FOLLOWING ONE OF THE TWO OPTIONS BELOW:* *A) [OPTION BY DEFAULT] BY DIVIDING THE ACTUAL ANNUAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2 (FULL FINANCIAL YEAR HOURLY RATE);* *B) BY DIVIDING THE ACTUAL MONTHLY AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY 1/12 OF THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2.(MONTHLY HOURLY RATE).*	activities irrespective of the source of funding.	
		For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission: 30) The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	
		For option II concerning individual hourly rates: 31) The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary. 31.1) The Beneficiary used only one option (per full financial year or per month) throughout each financial year examined. 31.2) The hourly rates do not include additional remuneration.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.4	**TIME RECORDING SYSTEM** To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records: o description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system); o its actual implementation; o time records were signed at least monthly by the employees (on paper or electronically) and authorised by the project manager or another manager; o the hours declared were worked within the project period; o there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below) ; o the hours charged to the action matched those in the time recording system. *ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).*	32) All persons recorded their time dedicated to the action on a **daily/ weekly/ monthly** basis using a **paper/computer-based** system. (*delete the answers that are not applicable)*	
		33) Their time-records were authorised at least monthly by the project manager or other superior.	
		34) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.	
		35) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.	
	<u>If the persons are working exclusively for the action and without time records</u> For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.	36) The exclusive dedication is supported by a declaration signed by the Beneficiary and by any other evidence gathered.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
B	**COSTS OF SUBCONTRACTING**		
B.1	**The Auditor obtained the detail/breakdown of subcontracting costs and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 37-41 listed in the next column, the Auditor reviewed the following for the items included in the sample: o the use of subcontractors was foreseen in Annex 1; o subcontracting costs were declared in the subcontracting category of the Financial Statement; o supporting documents on the selection and award procedure were followed; o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment). In particular, i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC (or 2014/24/EU) or of Directive 2004/17/EC (or 2014/25/EU), the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement. ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement..	37) The use of claimed subcontracting costs was foreseen in Annex 1 and costs were declared in the Financial Statements under the subcontracting category.	
		38) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
		39) The subcontracts were not awarded to other Beneficiaries	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	For the items included in the sample the Auditor also verified that: o the subcontracts were not awarded to other Beneficiaries in the consortium; o there were signed agreements between the Beneficiary and the subcontractor; o there was evidence that the services were provided by subcontractor;	of the consortium.	
		40) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.	
		41) There was evidence that the services were provided by the subcontractors.	
C	**COSTS OF PROVIDING FINANCIAL SUPPORT TO THIRD PARTIES**		
C.1	**The Auditor obtained the detail/breakdown of the costs of providing financial support to third parties and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). The Auditor verified that the following minimum conditions were met: a) the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex 1; b) the financial support to third parties was agreed in Annex 1 of the Agreement and the other provisions on financial support to third parties included in Annex 1 were respected.	42) All minimum conditions were met	

D	OTHER ACTUAL DIRECT COSTS		
D.1	**COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). The Auditor inspected the sample and verified that: o travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy; o travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference; o no ineligible costs or excessive or reckless expenditure was declared (see Article 6.5 MGA).	43) Costs were incurred, approved and reimbursed in line with the Beneficiary's usual policy for travels.	
		44) There was a link between the trip and the action.	
		45) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.	
		46) No ineligible costs or excessive or reckless expenditure was declared.	
D.2	**DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). For "equipment, infrastructure or other assets" [from now on called "asset(s)"] selected in the sample the Auditor verified that: o the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures;	47) Procurement rules, principles and guides were followed.	
		48) There was a link between the grant agreement and the asset charged to the action.	
		49) The asset charged to the action was traceable to the accounting records and the underlying documents.	

	○ they were correctly allocated to the action (with supporting documents such as delivery note invoice or any other proof demonstrating the link to the action) ○ they were entered in the accounting system; ○ the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table); The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary's country and with the Beneficiary's usual accounting policy (e.g. depreciation calculated on the acquisition value). The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).	50) The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy. 51) The amount charged corresponded to the actual usage for the action. 52) No ineligible costs or excessive or reckless expenditure were declared.	
D.3	**COSTS OF OTHER GOODS AND SERVICES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). For the purchase of goods, works or services included in the sample the Auditor verified that: ○ the contracts did not cover tasks described in Annex 1; ○ they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting); ○ the goods were not placed in the inventory of durable equipment; ○ the costs charged to the action were accounted in line with the Beneficiary's usual accounting practices; ○ no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA). In addition, the Auditor verified that these goods and services were acquired in conformity with	53) Contracts for works or services did not cover tasks described in Annex 1. 54) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment. 55) The costs were charged in line with the Beneficiary's accounting policy and were adequately supported. 56) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups.	

	the Beneficiary's internal guidelines and procedures, in particular: o if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC (or 2014/24/EU) or of Directive 2004/17/EC (or 2014/25/EU), the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement. o if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement. For the items included in the sample the Auditor also verified that: o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment); *SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.*	57) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were made in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
D.4	**AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE** The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020.	58) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology described in the positive ex-ante assessment report.	

	In the cases that a positive ex-ante assessment has been issued *(see the standard factual findings 58-59 on the next column)***,** The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment; ***In the cases that a positive ex-ante assessment has NOT been issued*** *(see the standard factual findings 60 on the next column),* The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category; ***In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes*** *(see the standard factual findings 60 on the next column),* • The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large Research Infrastructures or issued recommendations.	59) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly. 60) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure.	
D.5	**Costs of internally invoiced goods and services** **The Auditor sampled cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 61-65 listed in the next column, the Auditor: ○ obtained a description of the Beneficiary's usual cost accounting practice to calculate costs of internally invoiced goods and services (unit costs); ○ reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; ○ ensured that the methodology to calculate unit costs is being used in a consistent manner, based on objective criteria, regardless of the source of funding; ○ verified that any ineligible items or any costs claimed under other budget categories, in particular indirect costs, have not been taken into account when calculating the costs of	61) The costs of internally invoiced goods and services included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. 62) The cost accounting practices used to calculate the costs of internally invoiced goods and services were applied by the Beneficiary in a consistent manner based on objective criteria regardless of the source of funding. 63) The unit cost is calculated using the actual costs for the good or service recorded in the Beneficiary's accounts, excluding any ineligible cost or costs included in other	

	internally invoiced goods and services (see Article 6 GA); ○ verified whether actual costs of internally invoiced goods and services were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, and correspond to objective and verifiable information. ○ verified that any costs of items which are not directly linked to the production of the invoiced goods or service (e.g. supporting services like cleaning, general accountancy, administrative support, etc. not directly used for production of the good or service) have not been taken into account when calculating the costs of internally invoiced goods and services. ○ verified that any costs of items used for calculating the costs internally invoiced goods and services are supported by audit evidence and registered in the accounts.	budget categories. 64) The unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service. 65) The costs items used for calculating the actual costs of internally invoiced goods and services were relevant, reasonable and correspond to objective and verifiable information.	
E	**USE OF EXCHANGE RATES**		
E.1	a) For Beneficiaries with accounts established in a currency other than euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS RECORDED IN THE ACCOUNTS IN A CURRENCY OTHER THAN EURO SHALL BE CONVERTED INTO EURO AT THE AVERAGE OF THE DAILY EXCHANGE RATES PUBLISHED IN THE C SERIES OF OFFICIAL JOURNAL OF THE EUROPEAN UNION (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.* *IF NO DAILY EURO EXCHANGE RATE IS PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION FOR THE CURRENCY IN QUESTION, CONVERSION SHALL BE MADE AT THE AVERAGE OF THE MONTHLY ACCOUNTING RATES ESTABLISHED BY THE COMMISSION AND PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm),*	66) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final figures.	

	DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.		
	b) For Beneficiaries with accounts established in euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY'S USUAL ACCOUNTING PRACTICES.*	67) The Beneficiary applied its usual accounting practices.	

[legal name of the audit firm]
[name and function of an authorised representative]
[dd Month yyyy]
<Signature of the Auditor>

ANNEX 6

MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data.**

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Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and claiming direct personnel costs declared as unit costs ('the Methodology') in connection with grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] ('the Agreement(s)')

The Agreement(s) has(have) been concluded between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*.

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union] [Euratom] [Agency]* is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, beneficiaries *[and linked third parties]* that declare direct personnel costs as unit costs calculated in accordance with their usual cost accounting practices may submit to the *[Commission] [Agency]*, for approval, a certificate on the methodology ('CoMUC') stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which is composed of two separate documents:

- the Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

- the Auditor's Independent Report of Factual Findings ('the Report') issued on the Auditor's letterhead, dated, stamped and signed by the Auditor which includes; the standard statements ('the Statements') evaluated and signed by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') performed by the Auditor and the standard factual findings

('the Findings') assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.

The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the *[Beneficiary] [Linked Third Party]* and the Auditor.

The *[Beneficiary] [Linked Third Party]:*

- is responsible for preparing financial statements for the Agreement(s) ('the Financial Statements') in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the *[Beneficiary's] [Linked Third Party's]* accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading 'Statements to be made by the Beneficiary/ Linked Third Party' in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the *[Beneficiary] [Linked Third Party]* providing full and free access to the *[Beneficiary's] [Linked Third Party's]* staff and to its accounting and other relevant records.

The Auditor:

- *[Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations].*
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].*
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].*

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the Beneficiary's *[and Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with these ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out and the Findings to be endorsed by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[1]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there was no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report, and must specify – if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the Commission, *[the Agency]*, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from *[the European Union] [Euratom]* budget. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the Commission*[, the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by [dd Month yyyy].

1.6 Other Terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]	[legal name of the [Beneficiary] [Linked Third Party]]
[name & title of authorised representative]	[name & title of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary] [Linked Third Party]*

[1] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Independent report of factual findings on the methodology concerning grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

(To be printed on letterhead paper of the auditor)

To
[name of contact person(s)], [Position]
[[Beneficiary's] [Linked Third Party's] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]*,

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the agreed-upon procedures ('the Procedures') and provide hereby our Independent Report of Factual Findings ('the Report'), concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and declaring direct personnel costs declared as unit costs ('the Methodology').

You requested certain procedures to be carried out in connection with the grant(s)

[title and number of the grant agreement(s)] ('the Agreement(s)').

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes: the standard statements ('the Statements') made by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the *[Beneficiary] [Linked Third Party]*.

The Report covers the methodology used from [dd Month yyyy]. In the event that the *[Beneficiary] [Linked Third Party]* changes this methodology, the Report will not be applicable to any Financial Statement[1] submitted thereafter.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not give a statement of assurance on the costs declared on the basis of the *[Beneficiary's] [Linked Third Party's]* Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

…..

Explanation of possible exceptions in the form of examples (to be removed from the Report):

i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number … because…;

ii. the Auditor could not carry out the procedure … established because …. (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);

iii. the Auditor could not confirm or corroborate the standard Finding number … because ….

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates …

Regarding standard Finding 15 it has to be noted that …

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner: …

Annexes

Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the Commission:

[1] Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;
2. Brief description of the time recording system in place;
3. An example of the time records used by the [*Beneficiary] [Linked Third Party*];
4. Description of any budgeted or estimated elements applied, together with an explanation as to why they are relevant for calculating the personnel costs and how they are based on objective and verifiable information;
5. A summary sheet with the hourly rate for direct personnel declared by the [*Beneficiary*] [*Linked Third Party*] and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the [*Beneficiary*] [*Linked Third Party*] in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:

- is confidential and is intended to be submitted to the Commission by the [*Beneficiary*] [*Linked Third Party*] in connection with Article 18.1.2 of the Agreement;
- may not be used by the [*Beneficiary*] [*Linked Third Party*] or by the Commission for any other purpose, nor distributed to any other parties;
- may be disclosed by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the [*Beneficiary*] [*Linked Third Party*].

No conflict of interest[2] exists between the Auditor and the Beneficiary *[and the Linked Third Party*] that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR _____ (including EUR _____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]
[name and title of the authorised representative]
[dd Month yyyy]
Signature of the Auditor

[2] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Statements to be made by the Beneficiary/Linked Third Party ('the Statements') and Procedures to be carried out by the Auditor ('the Procedures') and standard factual findings ('the Findings') to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party's usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
A. Use of the Methodology I. The cost accounting practice described below has been in use since *[*dd Month yyyy*]*. II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy*]*.	**Procedure:** ✓ The Auditor checked these dates against the documentation the Beneficiary has provided. **Factual finding:** 1. The dates provided by the Beneficiary were consistent with the documentation.
B. Description of the Methodology III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures. *[Please describe the methodology your entity uses to calculate personnel costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]* *[If the statement of section "B. Description of the methodology" cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* - *…]*	**Procedure:** ✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology. **Factual finding:** 2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed. 3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
C. **Personnel costs** General IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act; V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility; VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means that personnel costs are charged in line with the Beneficiary's usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to the European Union or Euratom, unless explicitly provided for in the grant agreement(s); VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice; VIII. Personnel costs are based on the payroll system and accounting system. IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements and were based on objective and verifiable information. *[Please describe the 'budgeted or estimated elements' and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate].* X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary's bank for transfers from the Commission/Agency; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action. XI. Personnel costs were not declared under another EU or Euratom grant	**Procedure:** *The Auditor draws a sample of employees to carry out the procedures indicated in this section C and the following sections D to F.* *[The Auditor has drawn a random sample of 10 employees assigned to Horizon 2020 action(s). If fewer than 10 employees are assigned to the Horizon 2020 action(s), the Auditor has selected all employees assigned to the Horizon 2020 action(s) complemented by other employees irrespective of their assignments until he has reached 10 employees.].* For this sample: ✓ the Auditor reviewed all documents relating to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax , labour and social security law and any other documents corroborating the personnel costs claimed; ✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that: i. they were employed directly by the Beneficiary in accordance with applicable national legislation; ii. they were working under the sole technical supervision and responsibility of the latter; iii. they were remunerated in accordance with the Beneficiary's usual practices; iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary's usual cost accounting practices; ✓ the Auditor verified that any ineligible items or any costs claimed under other costs categories or costs covered by other types of grant or by other grants financed from the European Union budget have not been taken into account when calculating the personnel costs; ✓ the Auditor numerically reconciled the total amount of personnel costs used to calculate the unit cost with the total amount of personnel costs recorded in the statutory accounts and the payroll system.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
(including grants awarded by a Member State and financed by the EU budget and grants awarded by bodies other than the Commission/Agency for the purpose of implementing the EU or Euratom budget in the same period, unless the Beneficiary can demonstrate that the operating grant does not cover any costs of the action). <u>If additional remuneration as referred to in the grant agreement(s) is paid</u> XII. The Beneficiary is a non-profit legal entity; XIII. The additional remuneration is part of the beneficiary's usual remuneration practices and paid consistently whenever the relevant work or expertise is required; XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding; XV. The additional remuneration included in the personnel costs used to calculate the hourly rates for the grant agreement(s) is capped at EUR 8 000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action). *[If certain statement(s) of section "C. Personnel costs" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* *- …]*	✓ to the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, the Auditor carefully examined those elements and checked the information source to confirm that they correspond to objective and verifiable information; ✓ if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8 000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s). ✓ the Auditor recalculated the personnel costs for the employees in the sample. **Factual finding:** 4. All the components of the remuneration that have been claimed as personnel costs are supported by underlying documentation. 5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility. 6. Their employment contracts were in line with the Beneficiary's usual policy; 7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month's pay, etc.); 8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records; 9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were relevant for calculating the personnel costs and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values). 10. Personnel costs contained no ineligible elements; 11. Specific conditions for eligibility were fulfilled when additional

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	remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to objective criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8 000 per full-time equivalent (or up to up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).
D. Productive hours XVI. The number of productive hours per full-time employee applied is *[delete as appropriate]*: A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time). B. the total number of hours worked in the year by a person for the Beneficiary C. the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours. <u>If method B is applied</u> XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave). XVIII. 'Annual workable hours' are hours during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation. XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the annual workable hours.	**Procedure (same sample basis as for Section C: Personnel costs):** ✓ The Auditor verified that the number of productive hours applied is in accordance with method A, B or C. ✓ The Auditor checked that the number of productive hours per full-time employee is correct. ✓ If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts. ✓ If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90 % of the standard number of working hours per year. **Factual finding:** <u>General</u> 12. The Beneficiary applied a number of productive hours consistent with method A, B or C detailed in the left-hand column. 13. The number of productive hours per year per full-time employee was accurate. <u>If method B is applied</u> 14. The number of 'annual workable hours', overtime and absences was

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Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
If method C is applied XX. The standard number of productive hours per year is that of a full-time equivalent. XXI. The number of productive hours per year on which the hourly rate is based i) corresponds to the Beneficiary's usual accounting practices; ii) is at least 90% of the standard number of workable (working) hours per year. XXII. Standard workable (working) hours are hours during which personnel are at the Beneficiary's disposal preforming the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence. *[If certain statement(s) of section "D. Productive hours" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *…]*	verifiable based on the documents provided by the Beneficiary and the calculation of the total number of hours worked was accurate. 15. The contract specified the working time enabling to calculate the annual workable hours. If method C is applied 16. The calculation of the number of productive hours per year corresponded to the usual costs accounting practice of the Beneficiary. 17. The calculation of the standard number of workable (working) hours per year was corroborated by the documents presented by the Beneficiary. 18. The number of productive hours per year used for the calculation of the hourly rate was at least 90% of the number of workable (working) hours per year.
E. Hourly rates The hourly rates are correct because: XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above. *[If the statement of section 'E. Hourly rates' cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *…]*	**Procedure** ✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used. ✓ The Auditor has obtained a list of all the relevant employees, based on which the personnel rate(s) are calculated. For 10 employees selected at random (same sample basis as Section C: Personnel costs): ✓ The Auditor recalculated the hourly rates. ✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding. **Factual finding:**

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	19. No differences arose from the recalculation of the hourly rate for the employees included in the sample.
F. Time recording XXIV. Time recording is in place for all persons with no exclusive dedication to one Horizon 2020 action. At least all hours worked in connection with the grant agreement(s) are registered on a **daily/weekly/monthly** basis *[delete as appropriate]* using a **paper/computer-based system** *[delete as appropriate]*; XXV. For persons exclusively assigned to one Horizon 2020 activity the Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time; XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly; XXVII. Measures are in place to prevent staff from: i. recording the same hours twice, ii. recording working hours during absence periods (e.g. holidays, sick leave), iii. recording more than the number of productive hours per year used to calculate the hourly rates, and iv. recording hours worked outside the action period. XXVIII. No working time was recorded outside the action period; XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates. *[Please provide a brief description of the time recording system in place together with the measures applied to ensure its reliability to the Auditor and annex it to the*	**Procedure** ✓ The Auditor reviewed the brief description, all relevant manuals and/or internal guidance describing the methodology used to record time. The Auditor reviewed the time records of the random sample of 10 employees referred to under Section C: Personnel costs, and verified in particular: ✓ that time records were available for all persons with not exclusive assignment to the action; ✓ that time records were available for persons working exclusively for a Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a Horizon 2020 action; ✓ that time records were signed and approved in due time and that all minimum requirements were fulfilled; ✓ that the persons worked for the action in the periods claimed; ✓ that no more hours were claimed than the productive hours used to calculate the hourly personnel rates; ✓ that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period; ✓ the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been effective. In addition, the Auditor has verified that no more hours were charged to Horizon 2020 actions per person per year than the number of productive hours per year used to calculate the hourly rates, and verified that

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present certificate[1]]. *[If certain statement(s) of section "F. Time recording" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *…]*	no time worked outside the action period was charged to the action. **Factual finding:** 20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements. 21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available; 22. For the random sample the time records were signed by the employee and the action manager/line manager, at least monthly. 23. Working time claimed for the action occurred in the periods claimed; 24. No more hours were claimed than the number productive hours used to calculate the hourly personnel rates; 25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the action period. 26. Working time claimed is consistent with that on record at the human-resources department.

[1] The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as it information flow up to its use for the preparation of the Financial Statements.

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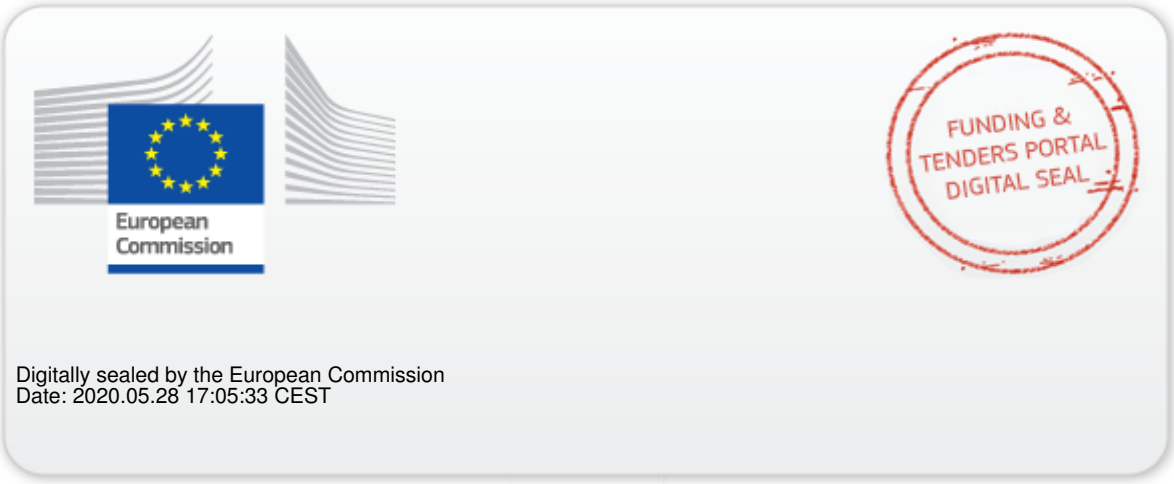
[official name of the *[Beneficiary] [Linked Third Party]**]* ***[name and title of authorised representative]*** ***[dd Month yyyy]*** ***<Signature of the*** *[Beneficiary] [Linked Third Party]>*	***[official name of the Auditor]*** ***[name and title of authorised representative]*** ***[dd Month yyyy]*** ***<Signature*** *of the Auditor>*



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