

#### **EUROPEAN COMMISSION**

Consumers, Health, Agriculture and Food Executive Agency





#### **GRANT AGREEMENT**

NUMBER — 801558 — eHAction

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

#### on the one part,

the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'), represented for the purposes of signature of this Agreement by Veronique WASBAUER, Director, or his/her duly authorised representative,

#### 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 President of the Board, Henrique MARTINS

and the following other beneficiaries if they have signed their 'Accession Form' (see Annex 3 and Article 40):

- 2. BUNDESMINISTERIUM FUER ARBEIT, SOZIALES, GESUNDHEIT UND KONSUMENTENSCHUTZ (ATNA), established in Radetzkystrasse 2, WIEN 1030, Austria,
- 3. **Ministry of Health of the Republic of Cyprus (MoH-CY)**, established in 1 Prodromou Street & 17 Chilonos Street 1 & 17, Nicosia 1448, Cyprus,
- 4. **MINISTERSTVO ZDRAVOTNICTVI CESKE REPUBLIKY (MZCR)**, established in PALACKEHO NAMESTI 375/4, PRAHA 12801, Czech Republic,
- 5. **GEMATIK GESELLSCHAFT FUR TELEMATIKANWENDUNGEN DER GESUNDHEITSKARTE MBH (GEMATIK)**, established in FRIEDRICHSTRASSE 136, BERLIN 10117, Germany, VAT number: DE241843684,
- 6. **SOTSIAALMINISTEERIUM (MoSA)**, established in Suur-Ameerika 1, TALLINN 10122, Estonia,
- 7. **DIOIKISI 3IS YGEIONOMIKIS PERIFEREIAS MAKEDONIAS (3rd RHA)**, established in ARISTOTELOUS 16, THESSALONIKI 54623, Greece, VAT number: EL999122114,

- 8. MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD (MSSSI), established in PASEO DEL PRADO 18-20, MADRID 28014, Spain,
- 9. **TERVEYDEN JA HYVINVOINNIN LAITOS (THL)**, established in MANNERHEIMINTIE 166, HELSINKI 00271, Finland, VAT number: FI22295006,
- 10. **MINISTERE DES AFFAIRES SOCIALES ET DE LA SANTE (MoH-FR)**, established in AVENUE DUQUESNE 14, PARIS CEDEX 75350, France, VAT number: N/A,
- 11. **HRVATSKI ZAVOD ZA ZDRAVSTVENO OSIGURANJE (HZZO)**, established in MARGARETSKA 3, ZAGREB 10000, Croatia, VAT number: HR3580261,
- 12. **ALLAMI EGESZSEGUGYI ELLATO KOZPONT (NHSC)**, established in DIOS AROK 3, BUDAPEST 1125, Hungary, VAT number: HU15324683,
- 13. **DEPARTMENT OF HEALTH (DoH)**, established in poolbeg St, Hawkins House, Dublin dn 6, Ireland,
- 14. **MINISTERO DELLA SALUTE (MINSAL)**, established in Via Giorgio Ribotta 5, ROMA 00144, Italy, VAT number: N/A,
- 15. LIETUVOS RESPUBLIKOS SVEIKATOS APSAUGOS MINISTERIJA (SAM), established in VILNIAUS G 33, VILNIUS LT 01506, Lithuania,
- 16. **AGENCE ESANTE (AeS)**, established in ALLEE MARCONI VILLA LOUVIGNY, LUXEMBOURG 2120, Luxembourg, VAT number: LU25854803,
- 17. **NACIONALAIS VESELIBAS DIENESTS (NHS)**, established in 31 Cēsu str., k-3, 6.entrance, Riga LV-1012, Latvia, VAT number: 90009649337,
- 18. **Ministry for Health Government of Malta (MFH)**, established in Palazzo Castellania, Merchants Street 15, Valletta VLT 200, Malta, VAT number: MT12979127,
- 19. **STICHTING NATIONAAL ICT INSTITUUT IN DE ZORG (NICTIZ)**, established in Oude Middenweg 55, Den Haag 2491AC, Netherlands,
- 20. **DIREKTORAT FOR E-HELSE (NDE)**, established in VERKSTEDVEIEN 1, OSLO 0277, Norway,
- 21. INSTITUT ZA ZASTITU ZDRAVLJA SRBIJEDR MILAN JOVANOVIC BATUT (IPHS), established in DR SUBOTICA STREET 5, BEOGRAD 11000, Serbia, VAT number: RS102000930,
- 22. **NACIONALNI INSTITUT ZA JAVNO ZDRAVJE (NIJZ)**, established in TRUBARJEVA CESTA 2, LJUBLJANA 1000, Slovenia, VAT number: SI44724535,

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 the action under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

# The Grant Agreement is composed of:

# Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 2a Not applicable

Annex 3 Accession Forms

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

# 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 'Joint Action supporting the eHealth Network — eHAction' ('action'), as described in Annex 1.

#### ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be **36 months** as of the first day of the month following the date the Agreement enters into force (see Article 42) ('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 affiliated entity) and budget category (see Articles 5, 6 and 11).

#### 4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted — without an amendment (see Article 39) — 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 10.

#### **CHAPTER 3 GRANT**

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

#### 5.1 Maximum grant amount

The 'maximum grant amount' is EUR 2,699,989.67 (two million six hundred and ninety nine thousand nine hundred and eighty nine EURO and sixty seven eurocents).

#### 5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses 60% 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 **4,499,982.78** (four million four hundred and ninety nine thousand nine hundred and eighty two EURO and seventy eight eurocents).

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

- (a) for direct personnel costs: as actually incurred costs (actual costs);
- (b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);
- (c) for other direct costs: as actually incurred costs (actual costs);
- (d) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2.D ('flat-rate costs');

#### 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 Agency — when the payment of the balance is made — in the following steps:

- Step 1 Application of the reimbursement rate 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 rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (actual costs and flat-rate costs; see Article 6) declared by the beneficiaries and affiliated entities (see Article 15) and approved by the Agency (see Article 16).

#### 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 Agency.

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;
- (b) financial contributions given by third parties to the beneficiary or to an affiliated entity specifically to be used for costs that are eligible under the action.

The following are however **not** considered receipts:

- (a) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);
- (b) 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 in proportion to the final rate of reimbursement of the eligible actual costs approved by the Agency (as compared to the amount calculated following Steps 1 and 2).

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

If the grant is reduced (see Article 27), the Agency 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 27.2) 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 17) — the Agency rejects costs (see Article 26) or reduces the grant (see Article 27), it will calculate the 'revised final grant amount' for the action or for the beneficiary concerned.

This amount is calculated by the Agency 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 Agency for the beneficiary concerned;
- in case of **reduction of the grant**: 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 27.2) from the maximum grant amount set out in Article 5.1 or from the maximum EU contribution indicated for the beneficiary in the estimated budget (see Annex 2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount 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 15);
- (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**: not applicable;

### (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) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.
- (d) for **lump sum costs**: not applicable;

#### 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. other direct costs;
- D. indirect costs;

'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 D 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

#### Types of eligible personnel costs

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, 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).

They may also include **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.
- A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract or **seconded by a third party against payment** are eligible personnel costs, if:
  - (a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;
  - (b) the result of the work carried out belongs to the beneficiary, and
  - (c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

#### Calculation

Personnel costs must be calculated by the beneficiaries as follows:

for persons working exclusively on the action:

```
{monthly rate for the person
multiplied by
number of actual months worked on the action}.
```

The months declared for these persons may not be declared for any other EU or Euratom grant.

The 'monthly rate' is calculated as follows:

{annual personnel costs for the person

```
divided by 12}
```

using the personnel costs 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 monthly rate of the last closed financial year available.

#### - for all **other** persons:

```
{daily rate for the person
multiplied by
number of actual days worked on the action (rounded up or down to the nearest half-day)}.
```

The number of actual days declared for a person must be identifiable and verifiable (see Article 13).

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

```
{number of annual productive days for the year (see below)
minus
total number of days declared by the beneficiary, for that person for that year, for other EU or Euratom
grants}.
```

#### The 'daily rate' is calculated as follows:

```
{annual personnel costs for the person divided by number of individual annual productive days}
```

using the personnel costs and the number of annual productive days 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 daily rate of the last closed financial year available.

The 'number of individual annual productive days' is the total actual days worked by the person in the year. It may not include holidays and other absences (such as sick leave, maternity leave, special leave, etc). However, it may include overtime and time spent in meetings, trainings and other similar activities.

**B. Direct costs of subcontracting** (including related duties, taxes and charges, such as non-deductible value added tax (VAT) paid by beneficiaries that are not public bodies acting as public authority) are eligible if the conditions in Article 10.1.1 are met.

#### C. Other direct costs

C.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges, such as non-deductible value added tax (VAT) paid by beneficiaries that are not public bodies

acting as public authority) are eligible if they are in line with the beneficiary's usual practices on travel.

C.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 9.1.1 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 beneficiaries that are not public bodies acting as public authority) 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 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.

C.3 Costs of other goods and services (including related duties, taxes and charges, such as non-deductible value added tax (VAT) paid by beneficiaries that are not public bodies acting as public authority) are eligible, if they are purchased specifically for the action and in accordance with Article 9.1.1.

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

#### **D.** Indirect costs

**Indirect costs** are eligible if they are declared on the basis of the flat-rate of 7% of the eligible direct costs (see Article 5.2 and Points A to C above).

Beneficiaries receiving an operating grant<sup>1</sup> financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

#### 6.3 Conditions for costs of affiliated entities to be eligible

Costs incurred by affiliated entities 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 11.1.1.

### 6.4 Ineligible costs

#### 'Ineligible costs' are:

- (a) costs that do not comply with the conditions set out above (Article 6.1 to 6.3), in particular:
  - (i) costs related to return on capital;

<sup>&</sup>lt;sup>1</sup> 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 (OJ L 218, 26.10.2012, p.1) ('Financial Regulation No 966/2012'): '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.

- (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 Agency;
- (viii) excessive or reckless expenditure;
- (ix) deductible VAT;
- (x) costs incurred during suspension of the implementation of the action (see Article 33);
- (xi) in-kind contributions provided by third parties;
- (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 Agency 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;
- (c) costs for staff of a national (or local) administration, for activities that are part of the administration's normal activities (i.e. not undertaken only because of the grant);
- (d) costs (especially travel and subsistence costs) for staff or representatives of EU institutions, bodies or agencies.

#### 6.5 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 26).

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 27).

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 9);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 10);
- call upon affiliated entities to implement action tasks described in Annex 1 (see Article 11).

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

# ARTICLE 8A — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

Not applicable

# ARTICLE 9 — PURCHASE OF GOODS, WORKS OR SERVICES

#### 9.1 Rules for purchasing goods, works or services

9.1.1 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 20).

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 17 and 18 also towards their contractors.

9.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC<sup>2</sup> (or 2014/24/EU<sup>3</sup>) or 'contracting entities' within the meaning of Directive 2004/17/EC<sup>4</sup> (or 2014/25/EU<sup>5</sup>) must comply with the applicable national law on public procurement.

<sup>&</sup>lt;sup>2</sup> 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).

<sup>&</sup>lt;sup>3</sup> 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, 28.3.2014, p. 65).

<sup>&</sup>lt;sup>4</sup> 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).

#### 9.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 9.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 26).

If a beneficiary breaches any of its obligations under Article 9.1.2, the grant may be reduced (see Article 27).

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

#### ARTICLE 10 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

#### 10.1 Rules for subcontracting action tasks

10.1.1 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 20).

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 Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 39), 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 Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 17 and 18 also towards their subcontractors.

10.1.2 The beneficiaries must ensure that their obligations under Articles 20, 21, 22 and 30 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.

#### 10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 26).

<sup>&</sup>lt;sup>5</sup> 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, 28.3.2014, p. 243).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 27).

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

#### ARTICLE 11 — IMPLEMENTATION OF ACTION TASKS BY AFFILIATED ENTITIES

#### 11.1 Rules for calling upon affiliated entities to implement part of the action

11.1.1 The following 'affiliated entities' <sup>6</sup> may implement the action tasks attributed to them in Annex 1:

- GESUNDHEIT ÖSTERREICH GMBH (GOeG), affiliated or linked to ATNA
- ELGA GmbH (ELGA), affiliated or linked to ATNA
- UNIVERSITY OF CYPRUS (UCY), affiliated or linked to MoH-CY
- GENIKO NOSOKOMEIO THESSALONIKIS G.PAPANIKOLAOU (HGP), affiliated or linked to 3rd RHA
- GENIKO NOSOKOMEIO PAPAGEORGIOU (Hpapa), affiliated or linked to 3rd RHA
- AGENCE NATIONALE DES SYSTEMES D INFORMATION PARTAGES DE SANTE (ASIP), affiliated or linked to MoH-FR
- Caisse nationale assurance maladie (CNAM), affiliated or linked to MoH-FR
- SEMMELWEIS EGYETEM (SU), affiliated or linked to NHSC

The affiliated entities 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 Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 17 and 18 also towards their affiliated entities.

11.1.2 The beneficiaries must ensure that their obligations under Articles 13, 15, 20, 21 and 22 also apply to their affiliated entities.

#### 11.2 Consequences of non-compliance

If any obligation under Article 11.1.1 is breached, the costs of the affiliated entity will be ineligible (see Article 6) and will be rejected (see Article 26).

<sup>&</sup>lt;sup>6</sup> For the definition, see Article 122 of the Financial Regulation (EU, Euratom) No 966/2012: **entities** affiliated **to the beneficiary** are:

<sup>(</sup>a) entities that form a 'sole beneficiary' (i.e. where an entity is formed of several entities that satisfy the criteria for being awarded a grant, including where the entity is specifically established for the purpose of implementing an action to be financed by a grant);

<sup>(</sup>b) entities that satisfy the eligibility criteria and that do not fall within one of the situations referred to in Article 131(4) and that have a link with the beneficiary, in particular a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

If any obligation under Article 11.1.2 is breached, the grant may be reduced (see Article 27).

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

#### ARTICLE 11A — FINANCIAL SUPPORT TO THIRD PARTIES

Not applicable

# SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

### ARTICLE 12 — GENERAL OBLIGATION TO INFORM

#### 12.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 25.2 — 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.

# 12.2 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 36) 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 Agency 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 affiliated entities and
  - (ii) changes in the name, address, legal form, organisation type of its affiliated entities;

### (b) circumstances affecting:

- (i) the decision to award the grant or
- (ii) compliance with requirements under the Agreement.

## 12.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27).

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

#### ARTICLE 13 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

#### 13.1 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 12) or in the context of checks, reviews, audits or investigations (see Article 17).

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 17), 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 Agency may accept non-original documents if it considers that they offer a comparable level of assurance.

# 13.1.1 Records and other supporting documentation on the technical implementation

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

#### 13.1.2 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**: not applicable;
- (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;
- (d) for **lump sum costs**: not applicable;

In addition, for **personnel costs** (declared as actual costs), the beneficiaries must keep **time records** for the number of days 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 days worked on the action, the Agency may accept alternative evidence supporting the number of days 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 affiliated entities (see Article 11), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of its affiliated entities.

### 13.2 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 26), and the grant may be reduced (see Article 27).

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

#### ARTICLE 14 — SUBMISSION OF DELIVERABLES

#### 14.1 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.

#### 14.2 Consequences of non-compliance

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

#### ARTICLE 15 — REPORTING — PAYMENT REQUESTS

#### 15.1 Obligation to submit reports

The coordinator must submit to the Agency (see Article 36) the technical and financial report(s) set out in this Article. These reports include request(s) for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 36).

#### 15.2 Reporting periods

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

- RP1: from month 1 to month 18

- RP2: from month 19 to month 36

#### 15.2a Request(s) for further pre-financing payment(s)

Not applicable

#### 15.3 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;

- (iii) a **summary** for publication by the Agency;
- (iv) the answers to the 'questionnaire': covering issues related to the action implementation and its impact;

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

(i) an 'individual financial statement' (see Annex 4) from each beneficiary and from each affiliated entity, for the reporting period concerned.

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

The beneficiaries and affiliated entities must declare all eligible costs, even if — for actual 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 Agency.

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 affiliated entity 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 13) that will be produced upon request (see Article 12) or in the context of checks, reviews, audits and investigations (see Article 17), 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 10) from each beneficiary and from each affiliated entity, 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;
- (v) a 'certificate on the financial statements' (drawn up in accordance with Annex 5) for each beneficiary and for each affiliated entity, if:
  - the (cumulative) amount of EU contribution it requests as reimbursement of actual costs (and for which no certificate has yet been submitted) is EUR 325 000 or more and
  - the maximum EU contribution indicated, for that beneficiary or affiliated entity, in the estimated budget (see Annex 2) as reimbursement of actual costs is EUR 750 000 or more.

#### 15.4 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 dissemination;
  - (ii) the conclusions on the action and
  - (iii) the impact of the action;
- (b) a 'final financial report' containing 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.

#### 15.5 Information on cumulative expenditure incurred

Not applicable

#### 15.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

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

#### 15.7 Language of reports

All report(s) (including financial statements) must be submitted in the language of the Agreement.

#### 15.8 Consequences of non-compliance

If the report(s) submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 31) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the report(s) and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 34) or apply any of the other measures described in Chapter 6.

#### ARTICLE 16 — PAYMENTS AND PAYMENT ARRANGEMENTS

#### 16.1 Payments to be made

The following payments will be made to the coordinator:

- a pre-financing payment;
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 15), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 15).

#### 16.2 Pre-financing payment — Amount

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 **809,996.90** (eight hundred and nine thousand nine hundred and ninety six EURO and ninety eurocents).

The Agency will — except if Article 32 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 42) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

#### 16.3 Interim payments — Amount — Calculation

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

The Agency will pay to the coordinator the amount due as interim payment within 60 days from receiving the periodic report (see Article 15.3), except if Articles 31 or 32 apply.

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

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

```
Step 1 – Application of the reimbursement rate
```

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

#### 16.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to the eligible costs (actual costs and flat-rate costs; see Article 6) declared by the beneficiaries and the affiliated entities (see Article 15) and approved by the Agency (see above) for the concerned reporting period.

### 16.3.2 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}}.
```

#### 16.4 Payment of the balance — Amount — Calculation

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 28).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 60 days from receiving the final report (see Article 15.4), except if Articles 31 or 32 apply.

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

The **amount due as the balance** is calculated by the Agency by deducting the total amount of prefinancing 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}}.
```

If the balance is positive, it will be paid to the coordinator.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the Agency, the Commission or another 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).

If the balance is negative, it will be recovered from the coordinator (see Article 28).

#### 16.5 Notification of amounts due

When making payments, the Agency will formally notify to the coordinator the amount due, specifying that 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 27 and 28.

#### 16.6 Currency for payments

The Agency will make all payments in euro.

### 16.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the Agency 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 90% of the beneficiaries have acceded to the Agreement (see Article 40) and
- (b) to beneficiaries that have acceded to the Agreement (see Article 40).

#### 16.8 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: SPMS -SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE

Full account number (including bank codes): IBAN code: PT50078101120112001513343

# 16.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the Agency 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.

#### 16.10 Date of payment

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

#### 16.11 Consequences of non-compliance

16.11.1 If the Agency 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 31 and 32) 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.

16.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 27) and the Agreement or the participation of the coordinator may be terminated (see Article 34).

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

# ARTICLE 17 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

### 17.1 Checks, reviews and audits by the Agency and the Commission

### 17.1.1 Right to carry out checks

The Agency or 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 Agency or the Commission may be assisted by external persons or bodies.

The Agency or the Commission may also request additional information in accordance with Article 12. The Agency or 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.

#### 17.1.2 Right to carry out reviews

The Agency or 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) and compliance with the obligations under the Agreement.

Reviews may be started **up to five 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 9 to 11a), the beneficiary concerned must inform the third party.

The Agency or 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 Agency or 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 Agency or 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.

#### 17.1.3 Right to carry out audits

The Agency or 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 five 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 9 to 11a), the beneficiary concerned must inform the third party.

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

#### 17.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013<sup>7</sup> and No 2185/96<sup>8</sup> (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.

### 17.3 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<sup>9</sup>, the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

<sup>&</sup>lt;sup>7</sup> 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 232, 18.09.2013, p. 1).

<sup>8</sup> 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).

<sup>&</sup>lt;sup>9</sup> 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).

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

#### 17.4 Checks, reviews, audits and investigations for international organisations

Not applicable

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

#### 17.5.1 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 26), reduction of the grant (see Article 27), recovery of undue amounts (see Article 28) 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 39).

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.

## 17.5.2 Findings in other grants

The Agency or 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 five years after the payment of the balance** of this grant.

The extension of findings may lead to the rejection of costs (see Article 26), reduction of the grant (see Article 27), recovery of undue amounts (see Article 28), suspension of payments (see Article 32), suspension of the action implementation (see Article 33) or termination (see Article 34).

#### 17.5.3 Procedure

The Agency or 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.

- 17.5.3.1 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 Agency or 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 Agency or the Commission in justified cases.

The Agency or the Commission may then start a **rejection procedure** in accordance with Article 26, either on the basis of the revised financial statements, the alternative method or the correction rate announced

17.5.3.2 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 Agency or 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 Agency or the Commission may then start a **reduction procedure** in accordance with Article 27, either on the basis of the alternative flat-rate or the flat-rate announced.

### 17.6 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 26).

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

# ARTICLE 18 — EVALUATION OF THE IMPACT OF THE ACTION

# 18.1 Right to evaluate the impact of the action

The Agency or 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 Agency or 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.

### 18.2 Consequences of non-compliance

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

#### **SECTION 3 OTHER RIGHTS AND OBLIGATIONS**

# ARTICLE 19 — PRE-EXISTING RIGHTS AND OWNERSHIP OF THE RESULTS (INCLUDING INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS)

#### 19.1 Pre-existing rights and access rights to pre-existing rights

Where industrial and intellectual property rights (including rights of third parties) exist prior to the Agreement, the beneficiaries must establish a list of these pre-existing industrial and intellectual property rights, specifying the owner and any persons that have a right of use.

The coordinator must — before starting the action — submit this list to the Agency.

Each beneficiary must give the other beneficiaries and their affiliated entities access to any pre-existing industrial and intellectual property rights needed for the implementation of the action and compliance with the obligations under the Agreement.

### 19.2 Ownership of results and rights of use

The results of the action (including the reports and other documents relating to it) are owned by the beneficiaries.

The beneficiaries must give the Agency and the Commission the right to use the results for their communication activities under Article 22.

#### 19.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27).

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

#### **ARTICLE 20 — CONFLICT OF INTERESTS**

#### 20.1 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 Agency 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 Agency may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

#### 20.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27) and the Agreement or participation of the beneficiary may be terminated (see Article 34).

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

#### ARTICLE 21 — CONFIDENTIALITY

#### 21.1 General obligation to maintain confidentiality

During implementation of the action and for **five years after the payment of the balance**, 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'**).

They may use confidential information to implement the Agreement.

The confidentiality obligations no longer apply if:

- (a) the disclosing party agrees to release the other party;
- (b) the information becomes generally and publicly available, without breaching any confidentiality obligation;
- (c) the disclosure of the confidential information is required by EU or national law.

#### 21.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27).

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

### ARTICLE 22 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

#### 22.1 Communication activities by the beneficiaries

#### 22.1.1 General obligation to promote the action and its results

The beneficiaries must promote the action and its results.

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

Unless the Agency requests or agrees otherwise, any communication activity related to the action (including at conferences, seminars, in information material, such as brochures, leaflets, posters, presentations, etc., in electronic form, via social media, etc.) and any infrastructure, equipment or major results funded by the grant must:

- display the EU emblem and
- include the following text:

"This [insert appropriate description, e.g. report, publication, conference, infrastructure, equipment, insert type of result, etc.] was funded by the European Union's Health Programme (2014-2020)."

When displayed in association 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 Agency.

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.

#### 22.1.3 Disclaimer excluding Agency and Commission responsibility

Any communication activity related to the action must indicate the following disclaimer:

"The content of this [insert appropriate description, e.g. report, publication, conference, etc.] represents the views of the author only and is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains."

#### 22.2 Communication activities by the Agency and the Commission

#### 22.2.1 Right to use the beneficiaries' materials, documents or information

The Agency and the Commission may use 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 21, which still apply.

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

- (a) **use for its own purposes** (in particular, making them available to persons working for the Agency, 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<sup>10</sup>, 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 Agency or the Commission.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the 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 Agency or the Commission will insert the following information:

"© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) and the European Union (EU) under conditions."

#### 22.3 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27).

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

#### ARTICLE 23 — PROCESSING OF PERSONAL DATA

#### 23.1 Processing of personal data by the Agency and the Commission

Any personal data under the Agreement will be processed by the Agency or the Commission under Regulation No 23/2001<sup>11</sup> and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the Agency or the Commission (publicly accessible in the DPO register).

Such data will be processed by the 'data controller' of the Agency or 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 17).

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.

<sup>&</sup>lt;sup>11</sup> 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).

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) on the Agency and Commission websites.

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

#### 23.2 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 Agency or the Commission. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the Agency or the Commission.

#### 23.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 23.2, the Agency may apply any of the measures described in Chapter 6.

#### ARTICLE 24 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE AGENCY

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

If the Agency 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 Agency.

#### CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES

#### ARTICLE 25 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES

#### 25.1 Roles and responsibilities towards the Agency

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 Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 28, 29 and 30.

#### 25.2 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 12);
- (ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 12);
- (iii) submit to the coordinator in good time:
  - individual financial statements for itself and its affiliated entities and, if required, certificates on the financial statements (see Article 15);
  - the data needed to draw up the technical reports (see Article 15);
  - any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly.

#### (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 Agency (in particular, providing the Agency with the information described in Article 12), unless the Agreement specifies otherwise;
- (iii) provide a pre-financing guarantee if requested by the Agency (see Article 16.2);
- (iv) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;
- (v) submit the deliverables and reports to the Agency (see Articles 14 and 15);
- (vi) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 16).

The coordinator may not subcontract the above-mentioned tasks.

#### 25.3 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 pre-existing rights and results (see Article 19);
- settlement of internal disputes;
- liability, indemnification and confidentiality arrangements between the beneficiaries.

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

# <u>CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE</u>

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

#### ARTICLE 26 — REJECTION OF INELIGIBLE COSTS

#### 26.1 Conditions

The Agency will — 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 17).

The rejection may also be based on the **extension of findings from other grants to this grant** (see Article 17.5.2).

#### 26.2 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 28), the Agency 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 16.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the rejection of costs leads to a recovery, the Agency will follow the contradictory procedure with pre-information letter set out in Article 28.

#### 26.3 Effects

If the Agency 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 Article 15.3 and 15.4). It will then calculate the interim payment or payment of the balance as set out in Article 16.3 or 16.4.

If the Agency — 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 costs declared in the next periodic summary financial statement or final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Article 16.3 or 16.4.

If the Agency 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. If the revised final grant amount is lower than the final grant amount, the Agency will recover the difference (see Article 28).

#### **ARTICLE 27 — REDUCTION OF THE GRANT**

#### 27.1 Conditions

The Agency may — at the payment of the balance or afterwards — reduce the grant, 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 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 17.5.2).

#### 27.2 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 Agency 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 Agency 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 16).

#### 27.3 Effects

If the Agency reduces the grant at the time of 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 Article 5.3.4 and 16.4).

If the Agency reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the action or for the beneficiary concerned (see Article 5.4). If the revised final grant amount is lower than the final grant amount, the Agency will recover the difference (see Article 28).

#### ARTICLE 28 — RECOVERY OF UNDUE AMOUNTS

#### 28.1 Amount to be recovered — Calculation — Procedure

The Agency will — at the payment of the balance or afterwards — claim back any amount that was paid but is not due under the Agreement.

The coordinator is fully liable for repaying debts of the consortium (under the Agreement) even if it has not been the final recipient of those amounts.

The other beneficiaries' financial responsibility in case of recovery is limited, for each beneficiary, to its own debts.

Undue amounts paid by the Agency for costs declared by an affiliated entity will be considered as amounts unduly paid to the beneficiary.

#### 28.1.1 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 16.4), the Agency 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 and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note** with the terms and the date for payment (together with the notification of amounts due; see Article 16.5).

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

(a) by 'offsetting' it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, Commission or another executive agency (from the EU or Euratom budget).

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

- (b) not applicable;
- (c) not applicable;
- (d) by taking legal action (see Article 41) 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 16.11, from the day following the payment date in the debit note, up to and including the date the Agency or 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.

#### 28.1.2 Recovery of amounts after payment of the balance

If — after the payment of the balance — the Agency revised the final grant amount for the action or for the beneficiary concerned (see Article 5.4), due to a rejection of costs or reduction of the grant, and the revised final grant amount is lower than the final grant amount (see Article 5.3), the Agency will:

- if the rejection or reduction does *not* concern a specific beneficiary or its affiliated entities: claim back the difference from the coordinator (even if it has not been the final recipient of the amount in question)

or

- otherwise: claim back the difference from the beneficiary concerned.

The Agency will formally notify a **pre-information letter** to the coordinator or beneficiary concerned:

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

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator or 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 Agency or the Commission will **recover** the amount:

- (a) by 'offsetting' it without the coordinator's or beneficiary's consent against any amounts owed to the coordinator or beneficiary by the Agency, Commission or another executive agency (from the EU or Euratom budget).
  - In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;
- (b) not applicable;
- (c) by taking legal action (see Article 41) 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 16.11, from the day following the date for payment in the debit note, up to and including the date the Agency or 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 29 — ADMINISTRATIVE SANCTIONS**

In addition to contractual measures, the Agency or 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 and expert contracts and/or financial penalties).

#### **SECTION 2 LIABILITY FOR DAMAGES**

#### **ARTICLE 30 — LIABILITY FOR DAMAGES**

#### 30.1 Liability of the Agency

The Agency 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 Agency 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.

#### 30.2 Liability of the beneficiaries

Except in case of force majeure (see Article 35), the beneficiaries must compensate the Agency 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 31 — SUSPENSION OF PAYMENT DEADLINE

#### 31.1 Conditions

The Agency may — at any moment — suspend the payment deadline (see Article 16.2 to 16.4) if a request for payment (see Article 15) cannot be approved because:

- (a) it does not comply with the provisions of the Agreement (see Article 15);
- (b) the technical or financial report(s) 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.

#### 31.2 Procedure

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

The suspension will take effect the day notification is sent by the Agency (see Article 36).

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 Agency if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial report(s) (see Article 15) and the revised report or statement is not submitted or was submitted but is also rejected, the Agency may also terminate the Agreement or the participation of the beneficiary (see Article 34.3.1(i)).

#### **ARTICLE 32 — SUSPENSION OF PAYMENTS**

#### **32.1 Conditions**

The Agency may — at any moment — suspend payments, in whole or in part 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 this 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 17.5.2).

If payments are suspended for one or more beneficiaries, the Agency will make partial payment(s) for the part(s) not suspended. If suspension concerns the payment of the balance, the payment (or recovery) of the amount(s) concerned after suspension is lifted will be considered to be the payment that closes the action.

#### 32.2 Procedure

Before suspending payments, the Agency 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 Agency 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 Agency.

If the conditions for resuming payments are met, the suspension will be lifted. The Agency 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 15.3) must not contain any individual financial statement(s) from the beneficiary concerned and its affiliated entities. 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 33.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 34.1 and 34.2).

#### ARTICLE 33 — SUSPENSION OF THE ACTION IMPLEMENTATION

#### 33.1 Suspension of the action implementation, by the beneficiaries

#### 33.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 35) — make implementation impossible or excessively difficult.

#### 33.1.2 Procedure

The coordinator must immediately formally notify to the Agency the suspension (see Article 36), stating:

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

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

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the Agency 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 39) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 34).

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).

#### 33.2 Suspension of the action implementation, by the Agency

#### 33.2.1 Conditions

The Agency 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 this Agreement or during the award procedure (including improper implementation of the action, submission of false declaration, 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 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 17.5.2).

#### 33.2.2 Procedure

Before suspending implementation of the action, the Agency 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 Agency 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 39) — unless the Agreement has already been terminated (see Article 34).

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 Agency (see Article 30).

Suspension of the action implementation does not affect the Agency's right to terminate the Agreement

or participation of a beneficiary (see Article 34), reduce the grant or recover amounts unduly paid (see Articles 27 and 28).

## ARTICLE 34 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

#### 34.1 Termination of the Agreement, by the beneficiaries

#### 34.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the Agency (see Article 36), 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 Agency 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.

#### **34.1.2** Effects

The coordinator must — within 60 days from when termination takes effect — submit a periodic report (for the open reporting period until termination; see Article 15.3) and the final report (see Article 15.4).

If the Agency does not receive the report(s) within the deadline (see above), only costs which are included in an approved periodic report will be taken into account

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 16.4) on the basis of the report(s) 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 27).

After termination, the beneficiaries' obligations (in particular, Articles 15, 17, 18, 19, 20, 21, 22, 24, 26, 27 and 28) continue to apply.

#### 34.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

#### 34.2.1 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 Agency (see Article 36) 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 39), 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 40). 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 Agency 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.

#### **34.2.2 Effects**

The beneficiary concerned must submit to the coordinator:

- (i) a technical report and
- (ii) a financial statement covering the period from the end of the last reporting period to the date when termination takes effect.

This information must be included by the coordinator in the periodic report for the next reporting period (see Article 15.3)

If the request for amendment is rejected by the Agency (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 34.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 39).

Improper termination may lead to a reduction of the grant (see Article 27) or termination of the Agreement (see Article 34).

After termination, the concerned beneficiary's obligations (in particular Articles 15, 17, 18, 19, 21, 22, 24, 26, 27 and 28) continue to apply.

## 34.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

#### 34.3.1 Conditions

The Agency 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 40);
- (b) a change to their legal, financial, technical, organisational or ownership situation (or those of its affiliated entities) 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 39);
- (d) implementation of the action is prevented by force majeure (see Article 35) or suspended by the coordinator (see Article 33.1) 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) 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;
- (i) 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);
- 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 17.5.2);
- (k) despite a specific request by the Agency, a beneficiary does not request through the coordinator an amendment to the Agreement to end the participation of one of its affiliated entities that is in one of the situations under points (e), (f), (g), (h), (i) or (j) and to reallocate its tasks

#### 34.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency 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 (i.ii) above to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency 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), (i.ii) and (k) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (h), (i.i) and (j) above: on the day after the notification of the confirmation is received.

#### **34.3.3 Effects**

#### (a) for termination of the Agreement:

The coordinator must — within 60 days from when termination takes effect — submit a periodic report (for the last open reporting period until termination; see Article 15.3) and a final report (see Article 15.4).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 15.8 and 34.3.1(i)), the coordinator may not submit any reports after termination.

If the Agency does not receive the report(s) within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 16.4) on the basis of the report(s) 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 Agency's right to reduce the grant (see Article 27) or to impose administrative sanctions (Article 29).

The beneficiaries may not claim damages due to termination by the Agency (see Article 30).

After termination, the beneficiaries' obligations (in particular Articles 15, 17, 18, 19, 21, 22, 24, 26, 27 and 28) 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 a request for amendment (see Article 39), 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 40). 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.

The beneficiary concerned must submit to the coordinator:

- (i) a technical report and
- (ii) a financial statement covering the period from the end of the last reporting period to the date when termination takes effect.

This information must be included by the coordinator in periodic report for the next reporting period (see Article 15.3).

If the request for amendment is rejected by the Agency (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 34.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 39).

After termination, the concerned beneficiary's obligations (in particular Articles 15, 17, 18, 19, 20, 21, 22, 24, 26, 27 and 28) continue to apply.

#### **SECTION 4 FORCE MAJEURE**

#### ARTICLE 35 — 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 36 — COMMUNICATION BETWEEN THE PARTIES

#### 36.1 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.

**Until the payment of the balance**: all communication must be made through the electronic exchange system and using the forms and templates provided there.

**After the payment of the balance**: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

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 Agency and Commission websites.

#### 36.2 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.

#### 36.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

https://ec.europa.eu/research/participants/portal/desktop/en/projects/

The Agency 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 Agency must be sent to the following address:

Consumers, Health, Agriculture and Food Executive Agency (CHAFEA)
Health and Food Safety Unit Health and Food Safety Unit
Drosbach Building
L-2920 Luxembourg

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 37 — INTERPRETATION OF THE AGREEMENT

#### 37.1 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.

#### 37.2 Privileges and immunities

Not applicable

#### ARTICLE 38 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71<sup>12</sup>, 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 39 — AMENDMENTS TO THE AGREEMENT

#### **39.1 Conditions**

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

<sup>&</sup>lt;sup>12</sup> 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).

Amendments may be requested by any of the parties.

#### 39.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 36).

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 Agency 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 Agency 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 40 — ACCESSION TO THE AGREEMENT

#### 40.1 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 36) within 30 days after its entry into force (see Article 42).

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 42).

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 Agency's right to terminate the Agreement (see Article 34).

#### 40.2 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 39. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 36).

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 41 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

#### 41.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium.

#### **41.2** 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).

As an exception, if such a dispute is between the Agency and 'DIREKTORAT FOR E-HELSE', 'INSTITUT ZA ZASTITU ZDRAVLJA SRBIJEDR MILAN JOVANOVIC BATUT', the competent Belgian courts have sole jurisdiction.

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 79(2) of the Financial Regulation No 966/2012 and Article 299 TFEU (see Articles 28, 29 and 30), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. Actions against enforceable decisions must be brought against the Commission (not against the Agency).

#### ARTICLE 42 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the Agency or the coordinator, depending on which is later.

**SIGNATURES** 

For the coordinator

For the Agency



#### **EUROPEAN COMMISSION**

Consumers, Health, Agriculture and Food Executive Agency

Health and Food Safety Unit

ANNEX 1 (part A)

**Project** 

NUMBER — 801558 — eHAction

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### 1.1. The project summary

Project Number <sup>1</sup>	801558	Project Acronym <sup>2</sup>	eHAction
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One form per project				
	General information			
Project title <sup>3</sup>	Joint Action supporting the eHealth Network			
Starting date <sup>4</sup>	The first day of the month after the signature by the Commission			
Duration in months 5	36			
Call (part) identifier <sup>6</sup>	HP-JA-2017			
Торіс	HP-JA-05-2017 Joint Action supporting the eHealth Network			
Fixed EC Keywords				
Free keywords	eHealth, Action			
Abstract 7				

Abstract '

Ageing population and increased prevalence of chronic conditions combined with limited human and financial resources are putting health systems under increasing strain. Digital tools, however, bring an opportunity to improve health care sector. Integrating eHealth into health policy and aligning eHealth investments with health requirements is of high importance, especially when recommendations and practices can be transferred across countries. Targeting Members Sates and Countries of the EU and eHealth stakeholders, as well as the general public, this project aims to improve health care with the use of ICT. eHAction is the Joint Action supporting the eHealth Network, which, in its Multiannual Work Programme 2018-2021, sets targets for exploring eHealth 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 will work to find ways to empower people 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. The eHAction is in line with the Third Programme of EU actions in the field of health contributing to foster health in Europe by promoting the use of eHealth in a structured policy framework.

### 1.2. List of Beneficiaries

Project Number <sup>1</sup>	801558	Project Acronym <sup>2</sup>	eHAction
-			

#### List of Beneficiaries

No	Name	Short name Country		Project entry month <sup>8</sup>	Project exit month
1	SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE	SPMS Portugal		1	36
2	BUNDESMINISTERIUM FUER ARBEIT, SOZIALES, GESUNDHEIT UND KONSUMENTENSCHUTZ	ATNA	Austria	1	36
3	Ministry of Health of the Republic of Cyprus	МоН-СҮ	Cyprus	1	36
4	MINISTERSTVO ZDRAVOTNICTVI CESKE REPUBLIKY	MZCR	Czech Republic	1	36
5	GEMATIK GESELLSCHAFT FUR TELEMATIKANWENDUNGEN DER GESUNDHEITSKARTE MBH	GEMATIK	Germany	1	36
6	SOTSIAALMINISTEERIUM	MoSA	Estonia	1	36
7	DIOIKISI 3IS YGEIONOMIKIS PERIFEREIAS MAKEDONIAS	3rd RHA	Greece	1	36
8	MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD	MSSSI Spain		1	36
9	TERVEYDEN JA HYVINVOINNIN LAITOS	THL Finland		1	36
10	MINISTERE DES AFFAIRES SOCIALES ET DE LA SANTE	MoH-FR	France	1	36
11	HRVATSKI ZAVOD ZA ZDRAVSTVENO OSIGURANJE	HZZO	Croatia	1	36
12	ALLAMI EGESZSEGUGYI ELLATO KOZPONT	NHSC	Hungary	1	36
13	DEPARTMENT OF HEALTH	DoH	Ireland	1	36
14	MINISTERO DELLA SALUTE	MINSAL	Italy	1	36
15	LIETUVOS RESPUBLIKOS SVEIKATOS APSAUGOS MINISTERIJA	SAM	Lithuania	1	36
16	AGENCE ESANTE	AeS	Luxembourg	1	36
17	NACIONALAIS VESELIBAS DIENESTS	NHS	Latvia	1	36
18	Ministry for Health - Government of Malta	MFH	Malta	1	36
19	STICHTING NATIONAAL ICT INSTITUUT IN DE ZORG	NICTIZ	Netherlands	1	36
20	DIREKTORAT FOR E-HELSE	NDE	Norway	1	36
21	INSTITUT ZA ZASTITU ZDRAVLJA SRBIJEDR MILAN JOVANOVIC BATUT	IPHS	Serbia	1	36
22	NACIONALNI INSTITUT ZA JAVNO ZDRAVJE	NIJZ	Slovenia	1	36

## 1.3. Workplan Tables - Detailed implementation (2018)3532486 - 03/07/2018

### 1.3.1. WT1 List of work packages

WP Number <sup>9</sup>	WP Title	Lead beneficiary <sup>10</sup>	Person- months <sup>11</sup>	Start month <sup>12</sup>	End month <sup>13</sup>
WP1	Coordination	1 - SPMS	108.00	1	36
WP2	Dissemination	1 - SPMS	34.10	1	36
WP3	Evaluation	2 - ATNA	9.00	1	36
WP4	Empowering People	19 - NICTIZ	97.04	1	36
WP5	Innovative use of health data	12 - NHSC	77.50	1	36
WP6	Enhancing continuity of care	5 - GEMATIK	115.70	1	36
WP7	Overcoming implementation challenges	7 - 3rd RHA	154.50	1	36
WP8	Integration in national policies and sustainability	10 - MoH-FR	61.78	1	36
		Total	657.62		

#### 1.3.2. WT2 list of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	WP number <sup>9</sup>	Lead beneficiary	Type <sup>15</sup>	Dissemination level <sup>16</sup>	Due Date (in months) <sup>17</sup>
D1.1	Interim report 1	WP1	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D1.2	Interim report 2	WP1	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D1.3	Final report	WP1	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D2.1	Dissemination and stakeholders engagement strategy	WP2	1 - SPMS	Report	Public	8
D2.2	Internal dissemination report	WP2	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D2.3	External dissemination report	WP2	1 - SPMS	Report	Public	36
D2.4	Leaflet	WP2	1 - SPMS	Websites, patents filling, etc.	Public	3
D2.5	Layman version of the final report	WP2	1 - SPMS	Report	Public	36
D2.6	Web-site	WP2	1 - SPMS	Websites, patents filling, etc.	Public	3
D4.1	Policy framework on Patient Empowerment	WP4	19 - NICTIZ	Report	Public	22
D4.2	Policy proposal	WP4	19 - NICTIZ	Report	Public	30
D5.1	Report on policy level actions	WP5	12 - NHSC	Report	Public	24
D5.2	Report on cross-border use cases	WP5	12 - NHSC	Report	Public	18

Deliverable Number <sup>14</sup>	Deliverable Title	WP number <sup>9</sup>	Lead beneficiary	Type <sup>15</sup>	Dissemination level <sup>16</sup>	Due Date (in months) <sup>17</sup>
D5.3	Paper on common principles for big data governance	WP5	12 - NHSC	Report	Public	36
D6.1	Roadmap on future eHDSI use cases and features	WP6	5 - GEMATIK	Report	Public	12
D6.2	eHDSI legal report	WP6	5 - GEMATIK	Report	Public	18
D6.3	Report on eSkills for Professional	WP6	13 - DoH	Report	Public	24
D7.1	Guidelines for IT interoperability	WP7	7 - 3rd RHA	Report	Public	30
D7.2	Best practices report	WP7	7 - 3rd RHA	Report	Public	14
D7.3	Common security framework for eHealth	WP7	7 - 3rd RHA	Report	Public	21
D8.1	Sustainability plan and recommendation	WP8	10 - MoH-FR	Report	Public	18
D8.2	Technology & policy final report	WP8	10 - MoH-FR	Report	Public	30
D8.3	Report on integration in national policies and sustainability	WP8	10 - MoH-FR	Report	Public	36

#### 1.3.3. WT3 Work package descriptions

Work package number 9	WP1	Lead beneficiary 10	1 - SPMS
Work package title	Coordination		
Start month	1	End month	36

#### Objectives

The objective of this WP is to coordinate the different parts of the work from both, administrative and content perspective as laid out in the general description of objectives of this JA. Another major objective is to ensure timely submission of the project's deliverables intended for submission to the eHN prior to their bi-annual meetings in order to support the work progress of the eHN members.

Also, the monitoring of the project's overall strategy as well as the active support of the general work progress of the other WPs is to be carried out by WP1. In case administrative, financial or management issues will arise, WP1 shall effectively deal with their resolving in a way that the project will be implemented successfully and on schedule. For this task, WP1 is supported by the Risk Management. Financial management, reporting and monitoring of the budget shall be carried out by this WP as well. The Coordinator also acts as the interface between representatives from the EC (DG SANTE and CHAFEA) and the project participants.

In the inception phase of the project WP1 shall focus on the elaboration of concrete operations procedures for work delivery (incl. a production approach for deliverables) and financial reporting templates.

#### Description of work and role of partners

#### **WP1 - Coordination** [Months: 1-36]

SPMS, MoH-FR

Task 1.1 – Project Management

Perform the planning and monitoring of the overall project execution, prepare and submit the interim progress and final reports. In close interaction with WP3, an internal assessment of the project on an annual basis will also be performed to identify and correct any possible deviations. It could include proposals for change management or activities needed to the benefit the overall project execution.

Task 1.2 – Organisation of meetings, workshops, TCons, etc.

This task covers the organisation of all committee meetings (SC and LC) and their related TCons, video conferences, etc. as well as project internal coordination meetings and any other meetings of the Coordinator with other parties, e.g. the EC or external parties.

#### Task 1.3 - Project public presence and project representation

Participation in several conferences, events, meetings and workshops of other projects/institutions/etc. on demand and upon needs.

#### Task 1.4 - Organisation of steering meetings and support with workshop meetings

This task includes the organisation of meetings of the strategic and operational PSC as well as of the Coordination Group. Furthermore, WP1 will provide support to other WP leaders with broader workshop meetings, where needed.

#### Task 1.5 - Project Administration and Reporting

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.

#### Participation per Partner

Partner number and short name	WP1 effort
1 - SPMS	105.00
10 - MoH-FR	3.00
Total	108.00

#### List of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type <sup>15</sup>	Dissemination level <sup>16</sup>	Due Date (in months) <sup>17</sup>
D1.1	Interim report 1	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D1.2	Interim report 2	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D1.3	Final report	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	36

#### Description of deliverables

#### D1.1x Interim reports CO M12, M24

The interim reports describe the activities carried out, deliverables, milestones and results achieved after each 12 months of the JA as well as the general work progress.

#### D1.2 Final report PU M36

This report describes the JA overall implementation and the results achieved.

#### D1.1: Interim report 1 [12]

The interim report 1 describes the activities carried out, milestones and results achieved after 12 months of the JA. Deliverables produced by other WPs within the covered time period can be attached as annexes

#### D1.2: Interim report 2 [24]

The interim report 2 describes the activities carried out, milestones and results achieved after 24 months of the JA. Deliverables produced by other WPs within the covered time period can be attached as annexes

#### D1.3: Final report [36]

This report describes the JA implementation and the results achieved

#### Schedule of relevant Milestones

Milestone number <sup>18</sup>	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS1	Consortium Agreement	1 - SPMS	1	Consortium agreement among MS
MS2	Rules of Operations	1 - SPMS	2	Operational governance models and rules of operations
MS3	Reporting Templates for partners	1 - SPMS	2	Report templates for financial reports, management reports, etc.

Work package number 9	WP2	Lead beneficiary 10	1 - SPMS
Work package title	Dissemination	l	
Start month	1	End month	36

#### Objectives

The objective of this WP is to develop an effective, macro and common dissemination strategy as laid out in the general description of objectives of this JA.

The main goal of dissemination activities is to inform the MS/C community about the JA, its orientation and available outputs for further exploitation. Dissemination activities will be oriented both externally (Health professionals; Hospitals; Stakeholders; Citizens; European Patient's Forum and the European Cancer Patient's Coalition) and internally (eHN and therefore the MS/C of the EU).

In order to produce a sustainable communication model for eHealth Network, this dissemination plan will be performed and managed by a communication team which will set up new ways of engaging participants and the interaction among them. By creating dissemination for awareness of the JA vision and goals, an identity and profile will be created within the community of MS. The forms of public dissemination aim at the engagement of JA participants' leaders, their presentation and institutional results, as well as the development of instruments for empowering citizens. Moreover, it will be important that the targeted groups/ audiences have a deeper understanding of JA's work. Thus, JA leaders will be encouraged to, frequently, use common digital tools to inform and support discussion and decisions making. Project workshops will be frequent and the outcomes projects and initiatives will be exposed to transparent and reliable information via liaison activities.

#### Description of work and role of partners

**WP2 - Dissemination** [Months: 1-36]

**SPMS**, MoH-CY, MoSA, AeS, MFH Task 2.1. Public dissemination

Dissemination and Communication of information about the JA and coordination with relevant networks, will be a continuous activity over the project lifetime. As part of this dissemination and communication, newsletters will be produced for electronic distribution and inclusion on the website and social media. Information posted on the website will additionally be subject to monthly review and update in conjunction with periodic project reporting in cooperation with others WP.

This task has as major public awareness/communication activities:

- eHealth Action website at: http://jointaction3.spms.min-saude.pt/ (already online);
- eHealth Action branding (logo) and key visual (already set up);
- eHealth Action project social media presence and Social Network's presence;
- Communication supporting materials:
- o Advertising brochure of the eHealth Network Action and its review during the project to keep it updated;
- o Short videos to present to a wide public the project aims, results achieved and final reports (subtitled in the official languages of the countries involved);
- Quarterly newsletter;
- Press releases (promoting and summarizing the main activities of the project).
- Press Kit.

#### Task 2.2. Specific dissemination

The specific dissemination strategy of JA aims to share the results of the project among eHealth stakeholders, to engage them in the process of their incremental elaboration & endorsement, and eventually their even wider dissemination. A specific dissemination channels and communication modes will be used to ensure that vision of the JA reaches its stakeholders. It comprises multitude activities and adopts a holistic approach to communication and dissemination.

This task has as Major scientific/technical dissemination activities:

- Pool of Representatives: comprised of eHealth Action Ambassadors
- Conferences
- Symposia
- Meetings
- Other events: Summits; Expert Talks; Conferences

#### Task 2.3. Internal project dissemination

Internal communication aims for information exchange among project partners and for generally ensuring the successful implementation of overall project objectives. It creates an optimal common understanding of the project partners about the on-going activities within different working packages as well as fosters the involvement and identification of all project partners because they all are important multipliers of the project and its results.

This task will include Digital Tools and Training/ Education Initiatives:

- Chat
- Skype
- Email
- Web Conferences
- Internet Forums
- Workshops

#### Task 2.4. Stakeholders engagement & involvement

The stakeholders engagement & involvement strategy will provide the means for stakeholders to interact with one another and discuss the JA findings and recommendations.

To this end, it will suggest and explore a variety of means to improve JA deliverables.

Identify and engage stakeholders throughout the course of the project in order to ensure that the results of the project are applicable and appropriate to stakeholders.

The JA dissemination strategy provides the basis for engaging with stakeholders through a stakeholder identification, analysis and interaction process.

The intent here is to create an impact that will last beyond the end of the JA by making the results of the projects to those who could benefit from them (i.e., our identification of the issues, opportunities and challenges surrounding the eHealth Network at the Member States, across different disciplines, and what this means for EU policy and the framework to be used in the future for supporting the eHealth Network.

This objective implies identification of a wide stakeholder audience, compilation of a contact list to whom we can send information about JA and its findings, and development of differentiated and targeted communication approaches for different categories of stakeholders.

This task will deal with Communication and dissemination while Promote innovative project partnerships between stakeholders through:

- Technical visits at enterprises and innovation eHealth industries
- Workshop with the project leads for the current H2020 INNOSUP 1 innovation action projects
- Innovation Technical Staff Talks
- Expertise & high-level research meetings
- · Network meetings
- Best practices & knowledge sharing between stakeholders Semester Reports/Newsletter
- Creation of White Papers or policy and technology reports

Partner number and short name	WP2 effort
1 - SPMS	27.00
3 - MoH-CY	1.10
6 - MoSA	2.00
16 - AeS	1.00
18 - MFH	3.00
Total	34.10

#### List of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type <sup>15</sup>	Dissemination level <sup>16</sup>	Due Date (in months) <sup>17</sup>
D2.1	Dissemination and stakeholders engagement strategy	1 - SPMS	Report	Public	8
D2.2	Internal dissemination report	1 - SPMS	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D2.3	External dissemination report	1 - SPMS	Report	Public	36
D2.4	Leaflet	1 - SPMS	Websites, patents filling, etc.	Public	3
D2.5	Layman version of the final report	1 - SPMS	Report	Public	36
D2.6	Web-site	1 - SPMS	Websites, patents filling, etc.	Public	3

#### Description of deliverables

- D2.1 Dissemination and stakeholder engagement strategy PU M6
- D2.2 Internal dissemination report CO M36
- D2.2.1 Internal dissemination Report I (M12)
- D2.2.2 Internal dissemination Report II (due in M24)
- D2.2.3 Internal dissemination Report III (due in M36)
- D2.3. External dissemination PU M36
- D2.3.1 External dissemination Report I (due in M12)
- D2.3.2 External dissemination Report II (due in M24)
- D2.3.3 External dissemination Report III (due in M36)
- MD.1 Leaflet PU M3
- MD.2 Layman version of the final report PU M36
- MD.3 Web-site PU/CO M3
- D2.1 : Dissemination and stakeholders engagement strategy [8]

This report describes the 3rd JA dissemination for stakeholders engagement strategy and the results to be achieved

D2.2 : Internal dissemination report [36]

The internal reports describe the activities carried out, milestones and results achieved

D2.3: External dissemination report [36]

The external reports describe the activities carried out for outside actors and results achieved.

D2.4 : Leaflet [3]

A leaflet to promote the project must be produced at the beginning

D2.5: Layman version of the final report [36]

This is a short (e.g. 10 pages) version of the final report, written for the interested public as a target group.

D2.6: Web-site [3]

Each project must have a dedicated web-site / web-pages. This can have a public part and another one accessible only to the applicants.

#### Schedule of relevant Milestones

Milestone number <sup>18</sup>	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS4	Draft dissemination and stakeholders engagement strategy 1	1 - SPMS	6	Information about dissemination strategy and stakeholders involvement
MS5	Draft dissemination and stakeholders engagement strategy 2	1 - SPMS	7	Document about dissemination strategy and stakeholders involvement to be approved by MS
MS6	Final dissemination and stakeholders engagement strategy for adoption	1 - SPMS	8	Document about dissemination strategy and stakeholders involvement
MS7	Internal dissemination report	1 - SPMS	6	Report about dissemination internal activities each semester
MS8	Internal dissemination report 2	1 - SPMS	12	Report about dissemination internal activities each semester
MS9	Internal dissemination report 3	1 - SPMS	18	Report about dissemination internal activities each semester
MS10	Internal dissemination report 4	1 - SPMS	24	Report about dissemination internal activities each semester
MS11	Internal dissemination report 5	1 - SPMS	30	Report about dissemination internal activities each semester
MS12	Internal dissemination report 6	1 - SPMS	36	Report about dissemination internal activities each semester
MS13	External dissemination report	1 - SPMS	6	Report about dissemination external activities each semester
MS14	External dissemination report 2	1 - SPMS	12	Report about dissemination external activities each semester
MS15	External dissemination report 3	1 - SPMS	18	Report about dissemination external activities each semester
MS16	External dissemination report 4	1 - SPMS	24	Report about dissemination external activities each semester

#### Schedule of relevant Milestones

Milestone number <sup>18</sup>	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS17	External dissemination report 5	1 - SPMS	30	Report about dissemination external activities each semester
MS18	External dissemination report 6	1 - SPMS	36	Report about dissemination external activities each semester

Work package number 9	WP3	Lead beneficiary 10	2 - ATNA
Work package title	Evaluation		
Start month	1	End month	36

#### Objectives

The success of the Action depends on the effectiveness and productiveness to achieve the defined goals. For this, it is essential that the WPs elaborate high quality products (i.e. Deliverables) delivering certain value to the eHealth Network at the policy level. Therefore, the main objective of WP3 is to verify if the action is being implemented as planned and reaches its objectives. The evaluation tasks and activities shall focus on the eHealth Network as the main target group but also on the performance of the WPs delivering input to the eHealth Network. WP3 shall further verify and assess how the delivered inputs (i.e. Deliverables) of the Action have satisfied the needs and expectations of the eHealth Network and how the Action has dealt with requests from the eHealth Network.

At the beginning of the project, WP3 focuses on the establishment of the Action's methodology for evaluation and an internal evaluation plan which are to be reflected in the evaluation strategy. After the 14th eHealth Network meeting, evaluation activities shall be performed on regular basis and in accordance with the evaluation strategy. Key indicators could be included in the evaluation strategy laying out how the Action contributed to the eHealth Network's Multiannual Work Programme 2018-2021.

An external evaluator shall be considered for carrying out WP3 tasks and activities and for consultancy.

#### Description of work and role of partners

#### WP3 - Evaluation [Months: 1-36]

#### ATNA

Task 3.1: Establish Evaluation Strategy (Lead: ATNA)

Focuses on the establishment of the Action's evaluation strategy that shall define the internal operational evaluation processes, methodologies for the ongoing evaluation and an evaluation plan. This task works closely with the Coordinator and the other WP Leaders. If needed, an external evaluator shall be consulted for the verification of the established evaluation strategy.

This task operates from M1 until M6.

Task 3.2 Evaluation of ongoing work (Lead: ATNA)

Aims to carry out the evaluation activities that are defined in the evaluation strategy. Evaluation activities shall start after the 14th eHealth Network meeting and are to be continued on a regular basis and in a proactive way. The conclusions/recommendations shall be reported to the Steering Council. T3.2 is expected to support with guiding the deliverable elaboration processes in a way as they will match policy needs (by the eHealth Network). Thus, contributing in delivering the right content in the right format and thereby fulfilling its main objective, namely to support the work of the eHealth Network. An external evaluator shall support this task to ensure integration of external expertise as well.

This task operates from M7 until M36.

#### Participation per Partner

Partner number and short name	WP3 effort
2 - ATNA	9.00
Total	9.00

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Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type <sup>15</sup>	Dissemination level <sup>16</sup>	Due Date (in months) <sup>17</sup>
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#### Description of deliverables

N/A

#### Schedule of relevant Milestones

Milestone number <sup>18</sup>	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS19	Draft evaluation strategy produced	2 - ATNA	3	The first version of the evaluation strategy to be used is produced
MS20	Final evaluation strategy produced	2 - ATNA	4	The final version of the evaluation strategy to be used is produced
MS21	Draft of final evaluation report produced	2 - ATNA	32	The first version of the final evaluation report deliverable is produced
MS22	Final Evaluation Report	2 - ATNA	36	Report on strategy, outcomes and evaluation results of the project activities

Work package number 9	WP4	Lead beneficiary 10	19 - NICTIZ		
Work package title	Empowering I	Empowering People			
Start month	1	End month	36		

#### Objectives

WHO defines patient empowerment as "a process in which patients understand their role, are given the knowledge and skills by their health-care provider to perform a task in an environment that recognizes community and cultural differences and encourages patient participation.".

In this process it's important for patients/citizens being more informed about (their own) health, to allow them to be more active partners to healthcare professionals. The tasks digital health literacy and patient access and use of data will include this aspect. Secondly, the number of (new) digital tools for patients/citizens are increasing. This leads to self-management where reliability for instance is very important. The mHealth and health apps reliability and TeleHealth tasks will include this aspect.

The overall objective of this WP is to empower people to take active part in their health and care process by building their capacity to use, understand and control their medical data, to provide them the opportunity to really participate and to motivate them to do so. Not only in (shared) decision situations with their medical professionals on their medical status, but also in active situations such as self-monitoring (e.g. mHealth) and/or in making use of e.g. TeleHealth services for prevention and/or health care reasons.

In order to achieve this, the secondary objectives of this WP are;

- To create a policy framework with regard to Patient Empowerment keeping in mind the subjects mHealth, patient access and use of data, digital health literacy and TeleHealth which will be input for the policy proposal (deliverable 1).
- To build and create a policy proposal for Patient Empowerment for the eHealth Network based on the ReEIF model in the context of the cross-border directive keeping in mind the subjects mHealth, patient access and use of data, digital health literacy and TeleHealth (deliverable 2). This proposal should also include concrete actions/next steps to implement on MS/C level.
- Create awareness and put emphasis on the motivation aspect for patients and health care professionals besides the capacity and opportunity aspects. People will not change behaviour only by improving the capacity (e.g. increasing digital health literacy) or providing them the opportunity (e.g. by health apps) to access their data. Therefore, motivation is a third important aspect to include in this WP.

To have a wider perspective in the creation of an effective policy framework with real impact, it is important to have various stakeholders included in the process. For that, cooperation with the Digital Health Society will be established. Input from task forces dealing with

- 1. legal framework
- 2. barriers of implementation of digital health services,
- 3. as well as change management in digital health, will be collected.

#### Description of work and role of partners

#### WP4 - Empowering People [Months: 1-36]

NICTIZ, SPMS, ATNA, MoH-CY, GEMATIK, MoSA, THL, MoH-FR, HZZO, NHSC, DoH, SAM, AeS, NHS, NIJZ

All MS/C are working on eHealth and the majority describes Patient Empowerment in their national health policies. The objective within and across MS/C is to increase the empowerment of citizens in general and patients in particular. To achieve this objective, this WP is divided in four tasks, namely mHealth and health apps reliability, patient access and use of data, digital health literacy of patients and TeleHealth;

Task 4.1: mHealth and health apps reliability (Lead: MoSA)

The sharing of best practices, existing guidelines and other information regarding mHealth and health apps reliability is needed in order to achieve a common understanding on eHN. Input from the mHealth subgroup will be used with coordination and awareness-raising and capacity building activities. This task will focus on:

• Perform desk research including input from a consultation round with external stakeholders and input from JAseHN, and other projects. In addition, investigate ways to motivate or create incentives for patients to participate in their health care process by adopting and using mHealth services.

- Analyse the findings and define a common understanding on the subject
- Develop a state of play/positioning report (common framework for the assessment/endorsement of health apps) with regard to mHealth and health apps reliability in relation to Patient Empowerment.
- Participate in workshops as task 4.1 member to deliver deliverable 1 and 2 of this WP.

#### Task 4.2: Patient access and use of data (Lead: NICTIZ)

This task will focus on the sharing of best practices, existing guidelines and other information regarding patient access and use of data. Examples are the project "MyHealthMyData". JAseHN 7.5, SUSTAINS and PALANTE. This is needed in order to achieve a common understanding on this subject between MS/C on EU level. There is overlap with T5.1, T5.3 and T7.2.

- Perform desk research; input from the consultation round with external stakeholders, JAseHN (e.g. task 7.5) and other projects. In addition, investigate ways to motivate or create incentives for patients to participate in their health care process by accessing and using their health data.
- Analyse the findings and define common understanding on the subject
- Develop a state of play/positioning report with regard to patient access and use of data in relation to Patient Empowerment.
- Participate in workshops as task 4.2 member with the objective to deliver deliverable 1 and 2 of this WP.

#### Task 4.3: Digital health literacy of patients (Lead: NICTIZ)

The sharing of best practices, existing guidelines and other information regarding digital health literacy is needed in order to achieve a common understanding between MS. There is overlap with T6.3.

- Starting with desk research including input from the consultation round with external stakeholders and input from JAseHN (e.g. task 7.5) and other projects. In addition, investigate ways to motivate or create incentives for patients to participate in their health care process by increasing their digital health literacy.
- Analyse the findings and define common understanding on the subject
- Consult existing coalitions, such as https://ec.europa.eu/digital-single-market/en/national-local-coalitions
- Develop a state of play/positioning report with regard to digital health literacy in relation to patient empowerment.
- Participate in workshops as task 4.3 member with the objective to deliver deliverable 1 and 2 of this WP.

### Task 4.4: TeleHealth (Lead: MoSA)

The sharing of best practices, existing guidelines, a catalogue of TeleHealth services and other information regarding TeleHealth is needed in order to achieve a common understanding between MS. The work of this task will take into consideration results and recommendations from the study on telemedicine commissioned by DG SANTE (final report end of 2018).

- Perform desk research including input from the consultation round with external stakeholders and input from JAseHN and other projects. In addition, investigate ways to motivate or create incentives for patients to participate in their health care process by adopting and using TeleHealth services.
- Analyse the findings and define a common understanding on the subject
- Develop a state of play positioning report with regard to TeleHealth in relation to patient empowerment
- Participate in workshops as task 4.4 member with the objective to deliver deliverable 1 and 2 of this WP.

#### Participation per Partner

Partner number and short name	WP4 effort
1 - SPMS	4.50
2 - ATNA	10.00
3 - MoH-CY	8.80
5 - GEMATIK	3.00
6 - MoSA	12.00
9 - THL	3.00
10 - MoH-FR	4.75
11 - HZZO	7.00
12 - NHSC	8.00

Partner number and short name	WP4 effort
13 - DoH	6.99
15 - SAM	6.00
16 - AeS	1.00
17 - NHS	7.00
19 - NICTIZ	12.00
22 - NIJZ	3.00
Total	97.04

#### List of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type <sup>15</sup>	Dissemination level <sup>16</sup>	Due Date (in months) <sup>17</sup>
D4.1	Policy framework on Patient Empowerment	19 - NICTIZ	Report	Public	22
D4.2	Policy proposal	19 - NICTIZ	Report	Public	30

#### Description of deliverables

#### D4.1 - Policy framework on Patient Empowerment PU M22

A policy framework on Patient Empowerment in the current Cross border context in which the input of the four separate tasks and relations between these tasks is included and the objective to empower patients is expressed in capacity, opportunity and motivation. With this we aim to create a policy framework within the eHN based on which we can create deliverable 4.2.

#### D4.2 – Policy proposal PU M30

A policy proposal with first/next concrete actions for the separate tasks with regard to Patient Empowerment in the EU which can be implemented on MS/C level based on D4.1.

#### D4.1 : Policy framework on Patient Empowerment [22]

A policy framework on Patient Empowerment in the current Cross border context in which the input of the four separate tasks and relations between these tasks is included and the objective to empower patients is expressed in capacity, opportunity and motivation. With this we aim to create a policy framework within the eHN based on which we can base deliverable 4.2

#### D4.2 : Policy proposal [30]

A policy proposal with first/next concrete actions for the separate tasks with regard to Patient Empowerment in the EU which can be implemented on MS/C level based on D4.1.

Milestone number <sup>18</sup>	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS23	Positioning report task 4.1 finished	19 - NICTIZ	10	Positioning report with status about T4.1
MS24	Positioning report task 4.2 finished	19 - NICTIZ	10	Positioning report with status about T4.2

Milestone number <sup>18</sup>	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS25	Positioning report task 4.3 finished	19 - NICTIZ	10	Positioning report with status about T4.3
MS26	Positioning report task 4.4 finished	19 - NICTIZ	10	Positioning report with status about T4.4
MS27	Draft for discussion D1 finished	19 - NICTIZ	16	The first version of the D4.1 – Policy framework on Patient Empowerment
MS28	Draft for discussion D2 finished	19 - NICTIZ	28	The first version of the D4.2 – Policy proposal
MS29	Final for adoption D2 finished	19 - NICTIZ	34	Final document on Policy proposal
MS47	Final for adoption D1 finished	19 - NICTIZ	22	Final document about Policy framework on Patient Empowerment

Work package number 9	WP5	Lead beneficiary 10	12 - NHSC		
Work package title	Innovative use	Innovative use of health data			
Start month	1	End month	36		

#### Objectives

The overall objective of WP 5 is to support the application of good practices in MS/C and provide guidance at EU level on handling big data in health (large routinely or automatically collected datasets, which are electronically captured and stored) within the existing EU regulatory framework, 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. The aim of the WP is:

- To enable the communication of the value of big data to different stakeholder groups and to provide a way for public health promotion, preventive measures and care from the analysis of big data across healthcare sector and MyData following FAIR data principle (i.e. Findable, Accessible, Interoperable, Reusable)
- To collect and to compile experiences of MS/C for developing knowledge base and a framework for continuous exchange of best practices on EU level
- To build practical guidance on practical governance of big data and knowledge to MS/C based on the big data efforts and practices of MS improving recognition of the practical conditions for rational governance of big data in eHN and MS (in order to ensure patient-centered health systems, evidence-based health policy and decision-making, as well as data-driven innovation).

#### Description of work and role of partners

#### WP5 - Innovative use of health data [Months: 1-36]

NHSC, SPMS, ATNA, 3rd RHA, THL, MoH-FR, HZZO, DoH, SAM, NHS, NIJZ

- T5.1 Mapping, awareness raising and policy relevant actions on innovative use of big data in health (Lead: NHSC)
- Compile policy relevant documentation including the EU Study and the effects of GDPR and review MS/C policy level efforts on governing big data in health.
- Also assess the implications of FAIR data principle.
- Identify obstacles preventing MS/C policies from being replicable either in other MS/C or on EU level, and investigate how to overcome these.
- Provide an initial set of enabling actions for the information of the eHN by translating recommendations of the EU Study into operationalized solutions that can be communicated for increased awareness.
- T5.2 Sharing and learning best practices on European level (Lead: THL)
- Define and use methods to identify underlying needs and barriers experienced by stakeholders (pros & cons) affecting efficient and effective sharing of best practices in order to reach the objectives of the WP and the JA.
- Investigate already formalized cross-border use cases such as European Reference Networks for rare diseases as well as practical solutions in R&D including analytics in order to identify new possibilities for innovative use of big data on the European scale, to assess feasibility of network optimization to cross-border IT infrastructure and data flow management and to enhance interdisciplinary and openness, the most potential usage and stakeholders that could benefit.
- T5.3 Towards an attempt to define common principles for practical governance (Lead: NHSC)
- Make available guidance on practical governance for eHN and MS.
- Provide a framework for the implementation of common principles for practical governance of big data including privacy protection and security aiming at improving health data transferability across borders with a special focus on data to be used in public health, research and quality assurance in healthcare on a European scale.
- The guidance will include guidance on implementation of data access and focus on helping Member States to utilize the potential of harnessing new opportunities arising from big data and improved data analytics capabilities, as well as from personalized medicine, use of clinical decision support systems by health professionals and use of mobile health tools for individuals to manage their own health and chronic conditions, in order to:
- facilitate preparation of actions to improve the comparability, accuracy and reliability of health data and to encourage the use of health data to enable more transparent and patient-centered health systems focusing on health outcomes and evidence-based health policy and decision-making, as well as to promote data-driven innovation;
- to enable the use of health data for research and innovation, in full compliance with data protection requirements and FAIR data principle;
- apply network optimization to cross-border IT infrastructure and data flow management;

77.50

- foster patient-centered interoperability;
- improve service effectiveness for the individual patient in which benefits are experienced locally;
- enhance interdisciplinary and openness that removes barriers between data sources and infrastructure to provide 'fit for purpose' data platforms.

Participation per Partner				
WP5 effort				
3.50				
7.50				
8.00				
14.00				
1.50				
4.00				
26.50				
2.00				
4.50				
3.00				
3.00				

#### List of deliverables

**Total** 

Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type <sup>15</sup>	Dissemination level <sup>16</sup>	Due Date (in months) <sup>17</sup>
D5.1	Report on policy level actions	12 - NHSC	Report	Public	24
D5.2	Report on cross-border use cases	12 - NHSC	Report	Public	18
D5.3	Paper on common principles for big data governance	12 - NHSC	Report	Public	36

#### Description of deliverables

- D5.1 Report for the information of the eHN on policy level actions PU M24
- D5.2 Report on identified cross-border use cases, including assessment of pros & cons of stakeholders, and practical solutions with potential for European scale benefits PU M18
- D5.3 Proposal for the eHN on the guidance for the implementation of common principles for practical governance of big data with a special focus on data to be used (and the implementation of data access and use) in public health, research and quality assurance in healthcare on a European scale PU M36
- D5.1: Report on policy level actions [24]

Report for the information of the eHN on policy level actions

D5.2: Report on cross-border use cases [18]

Report on identified cross-border use cases, including assessment of pros & cons of stakeholders, and practical solutions with potential for European scale benefits

D5.3 : Paper on common principles for big data governance [36]

Discussion Paper for the eHN on the implementation of common principles for practical governance of big data with a special focus on data to be used in public health, research and quality assurance in healthcare on a European scale with guidance on implementation of data access and use.

Milestone number <sup>18</sup>	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS30	Document on compiled policy relevant documentation finished	12 - NHSC	6	Document on compiled policy relevant documentation including the EU Study and the effects of GDPR and review on MS/C policy level efforts on governing big data in health
MS31	Document on identified obstacles finished	12 - NHSC	12	Document on identified obstacles preventing MS/C policies from being replicable either in other MS/C or on EU level, and proposal on how to overcome these
MS32	Document outlining the added value of big data finished	12 - NHSC	18	Document outlining the added value of big data on eHN/ governance level with the EU Study recommendations operationalized
MS33	Report for the information on policy level actions finished	12 - NHSC	24	Report for the information of the eHN on policy level actions including an initial set of enabling actions based on the recommendations of the EU Study to support awareness raising and communication of the added value of big data to different stakeholder groups, especially on the Governance level in MS/C via the eHN. (Deliverable D5.1)
MS34	Preparation for task 5.2 finished	12 - NHSC	18	Preparation for task 5.2 by analysing and structuring delivered information of D5.1
MS35	Report on identified cross- border use cases finished	12 - NHSC	18	Report on identified cross- border use cases, practical solutions with potential for European scale usage and benefits, including assessment of pros & cons

Milestone number <sup>18</sup>	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
				of stakeholders. (Deliverable D5.2)
MS36	Preparation for task 5.3 finished	12 - NHSC	32	Preparation for task 5.3 by analysing and structuring delivered information of D5.1 and D5.2
MS37	Paper on the implementation of common principles finished	12 - NHSC	36	Discussion Paper for the eHN on the implementation of common principles for practical governance of big data with a special focus on data to be used in public health, research and quality assurance in healthcare on a European scale with guidance on implementation of data access and use. (Deliverable D5.3)

Work package number 9	WP6	Lead beneficiary 10	5 - GEMATIK		
Work package title	Enhancing con	Enhancing continuity of care			
Start month	1	End month	36		

#### Objectives

Addressing countries' and their health fitness for the eHDSI uptake.

#### Description of work and role of partners

#### **WP6 - Enhancing continuity of care** [Months: 1-36]

**GEMATIK**, SPMS, ATNA, MoH-CY, MZCR, MoSA, MSSSI, THL, MoH-FR, HZZO, NHSC, DoH, MINSAL, SAM, AeS, NHS, IPHS, NIJZ

Task 6.1: Support of eHDSI uptake (Lead: gematik)

Support countries through eHMSEG for long term policy development in eHDSI by facilitating the uptake of current use cases PS and eP/eD and especially the new ERN use case and by shaping an overall roadmap for eHDSI use cases and additional features for a sustainable and continued usage of the NCPeH. This task will be carried out in close cooperation with the Task T7.1 Implementing interoperability guidelines to cross-border health services and Task T8.1 Post 2021 scenarios for eHealth policy cooperation. After the provision of D6.1 Roadmap on future eHDSI use cases and features task T6.1 will continue on facilitating the eHDSI uptake by providing implementation guidance for countries through eHMSEG in close cooperation with EC.

#### Task 6.2: Support of legal eHDSI matters (Lead: gematik)

Support countries through eHMSEG by facilitating the national implementation of the eHDSI legal environment (including but not limited to the eIDAS regulation, GDP regulation, NIS directive and the 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) by providing a forum for sharing expertise, problems and solutions and by synthesising shared elements into an eHDSI legal report for an non-lawyer audience. This task will be carried out in close cooperation with Task T7.2 Data protection and data security.

#### Task 6.3: eSkills for Professionals (Lead: DoH)

Support countries through eHMSEG by developing a process to ensure that the eSkills necessary to gain full advantage from the implementation of European eHealth Strategies and cross-border healthcare services, identifying current challenges and appropriate actions that can be taken to build the necessary eSkills framework for healthcare professionals.

#### Participation per Partner

Partner number and short name	WP6 effort
1 - SPMS	7.50
2 - ATNA	8.00
3 - MoH-CY	9.90
4 - MZCR	4.00
5 - GEMATIK	23.00
6 - MoSA	4.00
8 - MSSSI	1.30
9 - THL	3.00
10 - MoH-FR	5.50
11 - HZZO	5.00

Partner number and short name	WP6 effort
12 - NHSC	5.00
13 - DoH	21.00
14 - MINSAL	1.50
15 - SAM	3.00
16 - AeS	3.00
17 - NHS	3.00
21 - IPHS	5.00
22 - NIJZ	3.00
Total	115.70

#### List of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type <sup>15</sup>	Dissemination level <sup>16</sup>	Due Date (in months) <sup>17</sup>
D6.1	Roadmap on future eHDSI use cases and features	5 - GEMATIK	Report	Public	12
D6.2	eHDSI legal report	5 - GEMATIK	Report	Public	18
D6.3	Report on eSkills for Professional	13 - DoH	Report	Public	24

#### Description of deliverables

#### D6.1 Roadmap on future eHDSI use cases and features PU M12

An eHDSI Roadmap on future use cases and features of the NCPeH including a proposal for a timeline. The roadmap is based on the current use cases and its timing.

#### D6.2 eHDSI legal report PU M18

A synthesised eHDSI legal report which describes the common elements of the legal environment of eHDSI for a non-lawyer audience.

#### D6.3 Report on eSkills for Professionals PU M24

An evidenced based report with a supportive roadmap outlining a how a targeted education programme capable of supporting a matrix of progressive eSkills for the identified professional roles and allowing up skilling and re-skilling as appropriate to support eHealth strategies and roll outs amongst the MS.

#### D6.1 : Roadmap on future eHDSI use cases and features [12]

An eHDSI Roadmap on future use cases and features of the NCPeH including a proposal for a timeline

#### D6.2 : eHDSI legal report [18]

A synthesised eHDSI legal report, which describes the common elements of the legal environment of eHDSI.

#### D6.3 : Report on eSkills for Professional [24]

An evidenced based report with a supportive roadmap outlining a how a targeted education programme capable of supporting a matrix of progressive eSkills for the identified professional roles and allowing up skilling and re-skilling as appropriate to support eHealth strategies and roll outs amongst the MS.

Milestone number <sup>18</sup>	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS38	Adoption of the Roadmap reached	5 - GEMATIK	12	Adoption of the Roadmap on future eHDSI use cases and features by eHealth Network reached
MS39	Adoption of the eHDSI legal report reached	5 - GEMATIK	18	Adoption of the eHDSI legal report by eHealth Network reached
MS40	Adoption of the Report on eSkills reached	5 - GEMATIK	24	Adoption of the Report on eSkills for Professionals by the eHealth Network reached

Work package number 9	WP7	Lead beneficiary 10	7 - 3rd RHA
Work package title	Overcoming in	mplementation challenges	
Start month	1	End month	36

#### Objectives

Addressing transversal enabler issues that cross all previous categories.

#### Description of work and role of partners

#### **WP7 - Overcoming implementation challenges** [Months: 1-36]

**3rd RHA**, SPMS, ATNA, MoH-CY, MZCR, GEMATIK, MoSA, THL, MoH-FR, HZZO, NHSC, DoH, SAM, AeS, NHS, NICTIZ, IPHS, NIJZ

Task 7.1: Recommendations on how to implement interoperability guidelines in large health-care organisations (Lead: 3rd RHA)

Interoperability has long been identified as the fundamental facilitator of communication, exchange and use of patient information between healthcare providers, hospitals, government, insurers etc., especially in the context of cross-border health services.

During the past decades various standards have been developed regarding messaging (HL7, DICOM, ASC-X12, IEEE 1073 etc.), terminology (ICD-10, ICD-11 which is due by 2018, LOINC, SNOMED CT etc.), documents, conceptual frameworks, application and architectures, both for syntactic interoperability, and for semantic interoperability.

Nevertheless, and despite the efforts, interoperability is still considered as an "open field" in the healthcare ecosystem, especially when striving to provide cross-border health services.

The aim of this task is to exploit any previous work in the field of interoperability as described in the Digital Agenda, the eHealth Action Plan, the "Refined European eHealth Interoperability Framework" (reEIF), the epSOS project, SemanticHealthNet, JAseHN and more, in order to facilitate patients' rights in cross-border healthcare.

All previous work will be combined to produce recommendations for IT Management on how to implement interoperability guidelines in large healthcare organizations (e.g. hospitals). The main purpose is to align all work done about various EU regulations/common frameworks and provide it to IT Management of hospitals for implementation. The deliverables of this task will provide recommendations, guidelines to facilitate implementation of the interoperability framework by hospital IT management staff taking into consideration the recommendations included in the new European Interoperability Framework (EIF). Hospital experts will contribute to this task with F2F Workshops. The task will be implemented in the following steps:

- Review of previous work, interoperability frameworks and standards that can be implemented from the IT departments in healthcare organizations
- IT challenges in implementing interoperability in/ between large healthcare organizations
- Recommendations, guidelines and priorities for IT Management on implementing interoperability actions in healthcare organizations.
- Interoperability guidelines for hospital IT management staff in the following cases:
- o Software supply
- o Software building
- o Software deployment

#### Task 7.2: Data protection (Lead: MZCR)

This task will focus on the GDPR implementation and its implications in cross border healthcare.

The aim of this task will be to share best practices and approaches on data protection at national level. Situation regarding data protection and the new requirements GDPR brings in eHealth.

It is proposed to implement the topic in 5 steps:

- 1. Review of the GDPR topic in general and view of its impact on the health care stakeholders.
- 2. Characteristics of main points and requirements of GDPR adoption in the health care sector
- 3. Proposal of the set of relevant recommendations/policies for successful completion of GDPR adoption in the health care sector
- 4. Sketches of collaborative instruments for related information and education in current and future dealing with GDPR topic in the health care settings.
- 5. Foresight vision and mission of the future fulfilment and development of the GDPR

The task is motivated by both urgent needs for correct GDPR adoption in the health care sector and the utilization of GDPR potential for comprehensive respecting human rights for the health care provision practice in long-term run. In topics No. 2, 3 and 5 the cooperation with public interest groups (patient and health care professionals' organizations) will be actively sought and utilized.

#### Task 7.3: Data and systems security (Lead: 3RD RHA)

The aim of this task is to create a common Framework for cyber security for eHealth systems and services:

- 1. Common security framework for eHealth systems and services at a national and at a cross border level.
- 2. Use cases: Cyber security in eHealth services and architectures, cyber security requirements for Patient Summary
- 3. Security of eHealth systems e.g. medical devices: how can the healthcare organisations be ready to accommodate threats deriving from eHealth systems deployments e.g. medical devices. How can interoperability and portability be assured in a secure way.
- 4. Deliverable: the framework including guidelines for all stakeholders in the eHealth ecosystem.

This task is in accordance with the activities ENISA is running to support healthcare organisations building more secure infrastructures and resilient systems (see WannaCry incident).

artic	cipation	n per	Partner

Partner number and short name	WP7 effort
1 - SPMS	7.50
2 - ATNA	2.50
3 - MoH-CY	12.10
4 - MZCR	23.00
5 - GEMATIK	5.00
6 - MoSA	8.00
7 - 3rd RHA	23.77
9 - THL	1.00
10 - MoH-FR	7.63
11 - HZZO	6.00
12 - NHSC	10.50
13 - DoH	2.00
15 - SAM	11.50
16 - AeS	3.00
17 - NHS	8.00
19 - NICTIZ	4.00
21 - IPHS	11.00
22 - NIJZ	8.00
Total	154.50

#### List of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type <sup>15</sup>	Dissemination level <sup>16</sup>	Due Date (in months) <sup>17</sup>
D7.1	Guidelines for IT interoperability	7 - 3rd RHA	Report	Public	30
D7.2	Best practices report	7 - 3rd RHA	Report	Public	14
D7.3	Common security framework for eHealth	7 - 3rd RHA	Report	Public	21

#### Description of deliverables

- D7.1 Recommendations and guidelines for IT Management on implementing interoperability actions in healthcare organizations PU M30
- D7.2 Report on best practices and approaches on data protection at national level. PU M14
- D7.3 Common security framework for eHealth systems and services at a national and at a cross border level
- D7.1 : Guidelines for IT interoperability [30]

Recommendations and guidelines for IT Management on implementing interoperability actions in healthcare organizations

D7.2 : Best practices report [14]

Report on best practices and approaches on data protection at national level

D7.3 : Common security framework for eHealth [21]

Common security framework for eHealth systems and services at a national and at a cross border level

Milestone number <sup>18</sup>	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS41	Draft of D7.1 finished	7 - 3rd RHA	30	First draft of deliverable D7.1 finished and sent to partners for validation
MS42	Draft of D7.2 finished	7 - 3rd RHA	14	First draft of deliverable D7.2 finished and sent to partners for validation
MS43	Draft of D7.3 finished	7 - 3rd RHA	21	First draft of deliverable D7.3 finished and sent to partners for validation

Work package number 9	WP8	Lead beneficiary 10	10 - МоН-FR		
Work package title	Integration in	ntegration in national policies and sustainability			
Start month	1	End month	36		

#### Objectives

To propose elements for preparing the continuity post 2021of the cross border policy cooperation, and integration of its results in national policies.

WP8 is a CHAFEA mandatory task, and requires wide participation from MS/C to prepare consensus and commitment.

#### Description of work and role of partners

#### WP8 - Integration in national policies and sustainability [Months: 1-36]

MoH-FR, SPMS, ATNA, MoH-CY, MZCR, GEMATIK, MoSA, 3rd RHA, MSSSI, THL, HZZO, NHSC, DoH, MINSAL, SAM, AeS, NHS, MFH, NICTIZ, NDE, IPHS, NIJZ

All tasks will engage and be extended to the willingness of the stakeholders to participate, based on existing EU practices of stakeholder involvement., STH existing bodies and building upon the cooperation with JAseHN.

#### Task 8.1: National and international eHealth strategies (Lead: MoH-FR)

The objective of this task is to support present and future eHealth strategy alignment, and present mechanisms on how to maintain the existing strategy knowledge base for this purpose.

- The task will build upon the analysis done by JAseHN (WP7/Greece D7.1.1) based on a dedicated survey
- The task will propose to structure the information already gathered in order to create a toolset for task 8.3.
- The task take into account not only the EU stategies, but will also try to learn from other countries best practices
- The task will describe how to maintain the strategy database proposed by JAseHN WP8 in order to better align strategies and projects in the future and ease the information and knowledge exchanges among the countries

#### Task 8.2: Policy document about technology report (Lead: NDE)

The objective of this task is to activate stakeholder groups in producing relevant technology reports identifying technology trends and developments with impact on health and social care. The policy document following technology reports intend to contextualize technology trends and development in health and care to support MS/C in adopting the technologies in question.

- The task will suggest for Leadership Council (LC), and receive suggestions from LC, on what topics technology reports should cover and which stakeholder groups should be engaged. The number of reports per year will be based upon an evaluation of need and relevance. The expectation is between 1 and 3 technology reports per year.
- · LC decides on topics, stakeholder group involvement and frequency of technology reports
- The task participants execute by engaging the stakeholder groups
- The task participants produce a policy document corresponding to each technology report. The policy document contextualises the content of the technology report in health and care / eHealth.
- The task organizes two stakeholder meetings every year to coordinate the described activities, and to keep the stakeholders involved in the overall process and production of the eHealth Action.

#### Task 8.3: Post 2021 scenarios for eHealth policy cooperation (Lead: NDE/MoH-FR)

The objective of this task is to describe post 2021 scenarios for cross border eHealth policy cooperation and present these for helping the eHN to develop discussion on this matter

- The task will define a number of policy cooperation scenarios post 2021 that illustrate potential implications, requirements, risks and opportunities, and how to support the implementation of a policy recommendation or the adoption of an identified best practice at an adequate level in different EU MS.
- An early production in the task will be to deliver a sustainability plan that will visualize a projection of the future following reasonable probabilities, describing which elements/deliverables/results will be further developed, consolidated or run and by which entity/organisation this will/should be done.
- The task participants will work with the possibility of recommending a scenario for eHN adoption, and present this for discussion in LC. The objective is to identify if there is sufficient consensus within the MS/C to recommend a specific scenario for future policy cooperation or what are the main barriers to overcome
- Depending upon this outcome, the continued work of the task will be to either specify further how the recommended scenario is to be implemented, or develop a decision base for eHN.

Participation per Partner				
Partner number and short name	WP8 effort			
1 - SPMS	1.50			
2 - ATNA	1.50			
3 - MoH-CY	4.05			
4 - MZCR	1.00			
5 - GEMATIK	6.00			
6 - MoSA	1.00			
7 - 3rd RHA	8.75			
8 - MSSSI	1.00			
9 - THL	1.00			
10 - MoH-FR	7.23			
11 - HZZO	2.00			
12 - NHSC	0.75			
13 - DoH	2.00			
14 - MINSAL	2.50			
15 - SAM	1.00			
16 - AeS	2.00			
17 - NHS	0.50			
18 - MFH	1.00			
19 - NICTIZ	1.00			
20 - NDE	10.00			
21 - IPHS	3.50			
22 - NIJZ	2.50			
Total	61.78			

## List of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type <sup>15</sup>	Dissemination level <sup>16</sup>	Due Date (in months) <sup>17</sup>
D8.1	Sustainability plan and recommendation	10 - MoH-FR	Report	Public	18
D8.2	Technology & policy final report	10 - MoH-FR	Report	Public	30
D8.3	Report on integration in national policies and sustainability	10 - MoH-FR	Report	Public	36

Description of deliverables

Two main deliverables are planned. WP8 will produce two deliverables, one halfway in the project and one by the end of it. Production from task 8.1 and 8.3 will be combined into these two deliverables.

D8.1 Sustainability plan and recommendation PU M18

D8.2 Final report PU M30

MD.4 Report on integration in national policies and sustainability PU M36

Production from task 8.2 will be technology reports and policy documents with a frequency and on topics decided upon by LC. Technology reports will be produced by external parties to leverage their capacity and expertise. The corresponding policy document will be produced by the participants in the task. This production will be presented to LC continuously, and will not be part of the WP deliverable as such, but a synthesis will be annexed to support the scenario proposed.

D8.1 : Sustainability plan and recommendation [18]

Report on national and international eHealth Strategies and describe post 2021 scenarios

D8.2 : Technology & policy final report [30]

Technology & policy report in order to support the scenarios proposed for sustainability

D8.3: Report on integration in national policies and sustainability [36]

Report on national and international eHealth strategies and describe post 2021 scenarios

Milestone number <sup>18</sup>	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS44	Draft of D8.1 finished	10 - MoH-FR	12	First draft of deliverable D8.1 finished and sent to partners for validation
MS45	Early draft of D8.2 finished	10 - MoH-FR	18	Very early draft of deliverable D8.2 finished and sent to partners for filling
MS46	Draft of D8.2 finished	10 - MoH-FR	36	Second draft of deliverable D8.2 finished and sent to partners for validation

## 1.3.4. WT4 List of milestones

Milestone number <sup>18</sup>	Milestone title	WP number <sup>9</sup>	Lead beneficiary	Due Date (in months) <sup>17</sup>	Means of verification
MS1	Consortium Agreement	WP1	1 - SPMS	1	Consortium agreement among MS
MS2	Rules of Operations	WP1	1 - SPMS	2	Operational governance models and rules of operations
MS3	Reporting Templates for partners	WP1	1 - SPMS	2	Report templates for financial reports, management reports, etc.
MS4	Draft dissemination and stakeholders engagement strategy 1	WP2	1 - SPMS	6	Information about dissemination strategy and stakeholders involvement
MS5	Draft dissemination and stakeholders engagement strategy 2	WP2	1 - SPMS	7	Document about dissemination strategy and stakeholders involvement to be approved by MS
MS6	Final dissemination and stakeholders engagement strategy for adoption	WP2	1 - SPMS	8	Document about dissemination strategy and stakeholders involvement
MS7	Internal dissemination report 1	WP2	1 - SPMS	6	Report about dissemination internal activities each semester
MS8	Internal dissemination report 2	WP2	1 - SPMS	12	Report about dissemination internal activities each semester
MS9	Internal dissemination report 3	WP2	1 - SPMS	18	Report about dissemination internal activities each semester
MS10	Internal dissemination report 4	WP2	1 - SPMS	24	Report about dissemination internal activities each semester
MS11	Internal dissemination report 5	WP2	1 - SPMS	30	Report about dissemination internal activities each semester
MS12	Internal dissemination report 6	WP2	1 - SPMS	36	Report about dissemination internal activities each semester
MS13	External dissemination report 1	WP2	1 - SPMS	6	Report about dissemination external activities each semester
MS14	External dissemination report 2	WP2	1 - SPMS	12	Report about dissemination external activities each semester

Milestone number <sup>18</sup>	Milestone title	WP number <sup>9</sup>	Lead beneficiary	Due Date (in months) <sup>17</sup>	Means of verification
MS15	External dissemination report 3	WP2	1 - SPMS	18	Report about dissemination external activities each semester
MS16	External dissemination report 4	WP2	1 - SPMS	24	Report about dissemination external activities each semester
MS17	External dissemination report 5	WP2	1 - SPMS	30	Report about dissemination external activities each semester
MS18	External dissemination report 6	WP2	1 - SPMS	36	Report about dissemination external activities each semester
MS19	Draft evaluation strategy produced	WP3	2 - ATNA	3	The first version of the evaluation strategy to be used is produced
MS20	Final evaluation strategy produced	WP3	2 - ATNA	4	The final version of the evaluation strategy to be used is produced
MS21	Draft of final evaluation report produced	WP3	2 - ATNA	32	The first version of the final evaluation report deliverable is produced
MS22	Final Evaluation Report	WP3	2 - ATNA	36	Report on strategy, outcomes and evaluation results of the project activities
MS23	Positioning report task 4.1 finished	WP4	19 - NICTIZ	10	Positioning report with status about T4.1
MS24	Positioning report task 4.2 finished	WP4	19 - NICTIZ	10	Positioning report with status about T4.2
MS25	Positioning report task 4.3 finished	WP4	19 - NICTIZ	10	Positioning report with status about T4.3
MS26	Positioning report task 4.4 finished	WP4	19 - NICTIZ	10	Positioning report with status about T4.4
MS27	Draft for discussion D1 finished	WP4	19 - NICTIZ	16	The first version of the D4.1 – Policy framework on Patient Empowerment
MS28	Draft for discussion D2 finished	WP4	19 - NICTIZ	28	The first version of the D4.2 – Policy proposal
MS29	Final for adoption D2 finished	WP4	19 - NICTIZ	34	Final document on Policy proposal
MS30	Document on compiled policy relevant documentation finished	WP5	12 - NHSC	6	Document on compiled policy relevant documentation including the EU Study and the effects of GDPR and review on MS/C policy level

Milestone number <sup>18</sup>	Milestone title	WP number <sup>9</sup>	Lead beneficiary	Due Date (in months) <sup>17</sup>	Means of verification
					efforts on governing big data in health
MS31	Document on identified obstacles finished	WP5	12 - NHSC	12	Document on identified obstacles preventing MS/C policies from being replicable either in other MS/C or on EU level, and proposal on how to overcome these
MS32	Document outlining the added value of big data finished	WP5	12 - NHSC	18	Document outlining the added value of big data on eHN/governance level with the EU Study recommendations operationalized
MS33	Report for the information on policy level actions finished	WP5	12 - NHSC	24	Report for the information of the eHN on policy level actions including an initial set of enabling actions based on the recommendations of the EU Study to support awareness raising and communication of the added value of big data to different stakeholder groups, especially on the Governance level in MS/C via the eHN. (Deliverable D5.1)
MS34	Preparation for task 5.2 finished	WP5	12 - NHSC	18	Preparation for task 5.2 by analysing and structuring delivered information of D5.1
MS35	Report on identified cross-border use cases finished	WP5	12 - NHSC	18	Report on identified cross- border use cases, practical solutions with potential for European scale usage and benefits, including assessment of pros & cons of stakeholders. (Deliverable D5.2)
MS36	Preparation for task 5.3 finished	WP5	12 - NHSC	32	Preparation for task 5.3 by analysing and structuring delivered information of D5.1 and D5.2
MS37	Paper on the implementation of common principles finished	WP5	12 - NHSC	36	Discussion Paper for the eHN on the implementation of common principles for practical governance of big data with a special focus on data to be used in public health, research and quality assurance in healthcare on a European scale with guidance

Milestone number <sup>18</sup>	Milestone title	WP number <sup>9</sup>	Lead beneficiary	Due Date (in months) <sup>17</sup>	Means of verification
					on implementation of data access and use. (Deliverable D5.3)
MS38	Adoption of the Roadmap reached	WP6	5 - GEMATIK	12	Adoption of the Roadmap on future eHDSI use cases and features by eHealth Network reached
MS39	Adoption of the eHDSI legal report reached	WP6	5 - GEMATIK	18	Adoption of the eHDSI legal report by eHealth Network reached
MS40	Adoption of the Report on eSkills reached	WP6	5 - GEMATIK	24	Adoption of the Report on eSkills for Professionals by the eHealth Network reached
MS41	Draft of D7.1 finished	WP7	7 - 3rd RHA	30	First draft of deliverable D7.1 finished and sent to partners for validation
MS42	Draft of D7.2 finished	WP7	7 - 3rd RHA	14	First draft of deliverable D7.2 finished and sent to partners for validation
MS43	Draft of D7.3 finished	WP7	7 - 3rd RHA	21	First draft of deliverable D7.3 finished and sent to partners for validation
MS44	Draft of D8.1 finished	WP8	10 - MoH-FR	12	First draft of deliverable D8.1 finished and sent to partners for validation
MS45	Early draft of D8.2 finished	WP8	10 - MoH-FR	18	Very early draft of deliverable D8.2 finished and sent to partners for filling
MS46	Draft of D8.2 finished	WP8	10 - MoH-FR	36	Second draft of deliverable D8.2 finished and sent to partners for validation
MS47	Final for adoption D1 finished	WP4	19 - NICTIZ	22	Final document about Policy framework on Patient Empowerment

# 1.3.5. WT5 Critical Implementation risks and mitigation actions

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
1	Delays in providing deliverables by WPs	WP1, WP2, WP3, WP4, WP5, WP6, WP7, WP8	Preliminary reporting; detailed responsibilities; clear process, output and outcome indicators; link reimbursement to delivery
2	Changes in JA key personnel	WP1, WP2, WP3, WP4, WP5, WP6, WP7, WP8	Existence of Standard Operating Procedures (SOPs); procedure in case of withdrawal of a partner prior to the start of the JA (in the consortium agreement)
3	MS/C and stakeholders not sufficiently engaged	WP1, WP2, WP3, WP4, WP5, WP6, WP7, WP8	Nomination of in-country knowledge brokers; establishment of a Stakeholder Forum
4	Low response rate for evaluation surveys	WP1, WP2, WP4, WP5, WP6, WP7, WP8	Establishing a steering committee/Core Working Group, to facilitate communication
5	Deliverables not used by MSs (not attractive nor appropriate)	WP4, WP5, WP6, WP7, WP8	Content provided by core WPs formatted and edited centrally by WP2 taking into account stakeholder analysis and input from in-country knowledge brokers
6	Unclear authoring or intellectual property rights	WP1, WP4, WP5, WP6, WP7, WP8	Clear decision on those rights before the start of the JA (in the consortium agreement)

# 1.3.6. WT6 Summary of project effort in person-months

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	Total Person/Months per Participant
1 - SPMS	105	27	0	4.50	3.50	7.50	7.50	1.50	156.50
2 - ATNA	0	0	9	10	7.50	8	2.50	1.50	38.50
· GOeG	0	0		0 0	0	0	0	0	0
· ELGA	0	0		0 0	0	0	0	0	0
3 - MoH-CY	0	1.10	0	8.80	0	9.90	12.10	4.05	35.95
· UCY	0	0		0 0	0	0	0	0	0
4 - MZCR	0	0	0	0	0	4	23	1	28
5 - GEMATIK	0	0	0	3	0	23	5	6	37
6 - MoSA	0	2	0	12	0	4	8	1	27
7 - 3rd RHA	0	0	0	0	8	0	23.77	8.75	40.52
· HGP	0	0		0 0	0	0	0	0	0
• Нрара	0	0		0 0	0	0	0	0	0
8 - MSSSI	0	0	0	0	0	1.30	0	1	2.30
9 - THL	0	0	0	3	14	3	1	1	22
10 - MoH-FR	3	0	0	4.75	1.50	5.50	7.63	7.23	29.61
· ASIP	0	0		0 0	0	0	0	0	0
· CNAM	0	0		0 0	0	0	0	0	0
11 - HZZO	0	0	0	7	4	5	6	2	24
12 - NHSC	0	0	0	8	26.50	5	10.50	0.75	50.75
· SU	0	0		0 0	0	0	0	0	0
13 - DoH	0	0	0	6.99	2	21	2	2	33.99
14 - MINSAL	0	0	0	0	0	1.50	0	2.50	4
15 - SAM	0	0	0	6	4.50	3	11.50	1	26

Associated with document Ref. Ares(2018)3532486 - 03/07/2018

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	Total Person/Months per Participant
16 - AeS	0	1	0	1	0	3	3	2	10
17 - NHS	0	0	0	7	3	3	8	0.50	21.50
18 - MFH	0	3	0	0	0	0	0	1	4
19 - NICTIZ	0	0	0	12	0	0	4	1	17
20 - NDE	0	0	0	0	0	0	0	10	10
21 - IPHS	0	0	0	0	0	5	11	3.50	19.50
22 - NIJZ	0	0	0	3	3	3	8	2.50	19.50
Total Person/Months	108	34.10	9	97.04	77.50	115.70	154.50	61.78	657.62

# 1.3.7. WT7 Tentative schedule of project reviews

No project reviews indicated

#### 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

#### 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.



# EUROPEAN COMMISSION CONSUMERS, HEALTH AND FOOD EXECUTIVE AGENCY

Health Unit

# **eHAction**

# Joint Action supporting the eHealth Network

Applicant No	Applicant organisation name	Applicant Acronym	Country
1 (Coordinator)	SPMS - Serviços Partilhados do Ministério da Saúde, E.P.E.	SPMS	Portugal
2	Bundesministerium für Arbeit, Soziales, Gesundheit und Konsumentenschutz	ATNA	Austria
3	MINISTRY OF HEALTH	МоН-СҮ	Cyprus
4	The Ministry of Health of the Czech Republic	MZCR	Czech Republic
5	gematik - Gesellschaft für Telematikanwendungen der Gesundheitskarte mbH	Gematik	Germany
6	Ministry of Social Affairs Republic of Estonia	MoSA	Estonia
7	3η ΥΓΕΙΟΝΟΜΙΚΗ ΠΕΡΙΦΕΡΕΙΑ ΜΑΚΕΔΟΝΙΑΣ – 3rd Regional Health Authority of Macedonia	3rd-RHA	Greece
8	Ministerio de Sanidad, Servicios Sociales e Igualdad	MSSSI	Spain
9	National Institute for Health and Welfare	THL	Finland
10	Ministry of Health	MoH-FR	France
11	Croatian Health Insurance Fund	HZZO	Croatia
12	National Healthcare Service Center	NHSC	Hungary
13	Department of Health (eHealth Unit)	DoH	Ireland
14	Ministero della Salute	MINSAL	Italy
15	Ministry of Health of the Republic of Lithuania	SAM	Lithuania
16	Agence eSanté	AeS	Luxembourg
17	the National Health Service	NHS	Latvia
18	Ministry for Health	MFH	Malta
19	Stichting Nationaal ICT Instituut in de Zorg	NICTIZ	Netherlands
20	Norwegian Directorate of eHealth	NDE	Norway
21	Institut za javno zdravlje Srbije "Dr Milan Jovanović Batut"	IPHS	Serbia
22	National Institute of Public Health of the Republic of Slovenia	NIJZ	Slovenia

		R	EVISION HIST	ORY
Revision	Date	Author	Organization	Description
1	28-09-2017	Consortium	all	Proposal submitted
2	07-02-2018	Lília Marques	SPMS	Update based on the review by the WPL/Co- Leaders after evaluators validation Workshop; 7.2 Workpackages description; 8. Milestones and Deliverables; 10.1.3 Subcontract costs
3	08-02-2018	Lília Marques Diogo Martins	SPMS	Update based on the review of WPL/Co-L; 7.1.1 Overview on workpackages; 8. Milestones and Deliverables; 9.2.2 ATNA organization profile & key staff 10.3 Detailed budget
4	09-02-2018	Lília Marques Diogo Martins Diogo Gomes	SPMS	Update based on the review of WPL/Co-L; 7.2 Workpackages description – WP2; 10.1.3 Subcontract costs
5	14-02-2018	Lília Marques Diogo Martins	SPMS	Consolidation after consortium feedback
5a	15-02-2018	Lília Marques	SPMS	Submitted to CHAFEA
6	23-03-2018	Lília Marques	SPMS	Update after preparatory meeting with inputs from WPL/Co-L 6. Expected Outcomes; 7.2 Workpackages description;
7	26-04-2018	Lília Marques	SPMS	Update and review after partners feedback 7.3 update Timetable and Gantt 9.2.6 update EE partner key staff 10: Budget
8	14-05-2018	Lília Marques	SPMS	Update 8. Milestones and Deliverables accordingly to what was registered at the EC Participant Portal
9	15-05-2018	Lília Marques Diogo Martins	SPMS	General final review
10	18-05-2018	Lília Marques	SPMS	Updated with "Revision History"; Released for submission
11	24-05-2018	Lília Marques	SPMS	Include consortium answers to evaluators' comments
12	25-05-2018	Jürgen Wehnert Lília Marques	SPMS	Final review; Released for submission
13	06-06-2018	Jürgen Wehnert Lília Marques	SPMS	English review of "Answers to evaluators' comments" table and small update on 9.1 Quality of the partnership (number of affiliated entities and collaborating stakeholders); Updated header with the Project ID Serbian partner name changed from "English" to "Serbian" as requested by the partner; Released for submission

#### How the comments from evaluators were addressed:

The comments made by the evaluators were analysed primarily by the Workpackage Leaders and Co-Leaders and further reviewed by the consortium. As the History of changes was not created since the beginning (we were not aware of this requirement), but only at the end, and as there were several revisions of the proposal, it is now difficult to match exactly the answer to evaluators' comment to a specific version. So, the answers on how these comments were addressed are shown on the table below, as they were collected and as they are reflected in the final version presented.

comment	answer	WP
clarify how the general public will get to know about this JA	WP2 description was revised; Dissemination material to be provided in	WP2
better network with key stakeholder networks at EU level that will intern enable the JA3 consortium to "reach out" to patients and industry at national and sub national levels.	the first months of the project will take this into account. The concept of having three types of dissemination (public, specific, project internal) has been strengthened. Stakeholders are directly linked to the WP2 which in turn is led by the project coordinator SPMS, ensuring a good listenand-act setting.	WP2
For patients - might include the European Patient's Forum and the European Cancer Patient's Coalition	will be involved as stakeholders	WP2
For industry this might include a workshop with the project leads for the current H2020 INNOSUP 1 innovation action projects	this must be aligned at Leadership Council level to see its feasibility	WP2
more obvious connection should be made with the eHealth stakeholder panel.	foreseen to happen through Dissemination and stakeholders' engagement activities, see above "better network"	WP2
No external evaluation is foreseen and the internal one focuses on the network & main target group.  JA3 will benefit from an independent external evaluation & this should be factored into WP3	External evaluation is considered in the budget as subcontracting and is now reflected accordingly in the WP3 description.	WP3
WP description is too succinct: stating the elaboration of an evaluation strategy & evaluating ongoing work.	The WP3 description was revised and described on a more detailed level.	WP3
a proactive evaluation strategy could help identify and use a set of key indicators to facilitate comparative benchmarking & analysis of subsequent actions at national and subnational levels – and contribute to the body of knowledge on how the difficult implementation of Digital Transformation can be assessed.	T3.2 is expected to work in a proactive way. This is reflected in the T3.2 description accordingly. The formulation of key indicators is considered that may help to figure out how the Action contributed to the eHealth Network's Multiannual Work Plan 2018-2021. The work package is led by ATNA, the co-ordinator of the previous Joint Action, with its host of experience in guiding the production and quality assessment of documents and activities with a particular view to the guiding requirements of the eHN policy level. The assessment of the Digital Transformation would go beyond the aim of this Action and is thus out of scope of WP3. See, however, WP4 for digital Transformation aspects:	WP3

comment	answer	WP
	To have a wider perspective in the creation of an effective policy framework with real impact, it is important to have various stakeholders included in the process. For that, cooperation with the Digital Health Society will be established. Input from task forces dealing with  1. legal framework  2. barriers of implementation of digital health services,  3. as well as change management in digital health,	
	will be collected.	
Overall evaluation strategy should be finalized by M3	Draft evaluation strategy will be finalized	WP3
by M3 more explicitly involve patients/advocates through a foresight process to enable co- creation.	by M3.  WP4 description was revised considering this comment. See also WP2 for the involvement of stakeholders, including patients/advocates.	WP4
how to contribute to smoothing paths to uptake for validated new mHealth products.	WP4 description was revised considering this comment. The highly dynamic scientific and market development can be monitored, modulated and guided by the Joint Action. The Action's influence on the uptake is expected to be indirect, though, as a Joint Action by definition does not command the tools and means to directly influence uptake. Tasks 4.2 and 4.3 in particular have been scrutinized to contain all possible means and ends to liaise with parties which are more directly related to the practical uptake.	WP4
WP5 - innovation in the use of health data should have one or more of the following characteristics:  (1) network optimization applied to crossborder IT infrastructure and data flow management;  (2) patient-centered interoperability;  (3) service effectiveness for the individual patient in which benefits are experienced locally;  (4) enhanced interdisciplinarity and openness that removes barriers between data sources and infrastructure to provide 'fit for purpose' data platforms  The JA shows that 2 and 3 are present but not the other 2	WP5 description was revised and described on a more detailed level to show the 1st and the 4th characteristics as well.  The 2nd paragraph of T5.2 was complemented by an according description: "to assess feasibility of network optimization to cross-border IT infrastructure and data flow management and to enhance interdisciplinarity and openness"  T5.3 was complemented by a 2nd paragraph listing relevant objectives, e.g. "enhanced interdisciplinarity and openness"	WP5

comment	answer	WP
Added value – at the EU policy expose how this JA links to and builds on the existing initiatives, particularly on patient empowerment. With regard to this – and the data protection directive, an explicit upfront commitment to the FAIR data principle in its work (i.e. Findable, Accessible, Interoperable, Reusable) should be indicated, together with a description of the implications for WP4 and WP5.	We took this comment in consideration by making modifications in the text about WP5 objectives (1st aim), complemented by "following <i>FAIR</i> data principle (i.e. Findable, Accessible, Interoperable, Reusable)" and such as in the description of T.5.1 – added 2 <sup>nd</sup> bullet "Also assess the implications of <i>FAIR</i> data principle" and T5.3 – improved 2 <sup>nd</sup> bullet, namely with "to enable the use of health data for research and innovation, in full compliance with data protection requirements and FAIR data principle".	WP5
Clear guidance on the activities, mapping of clear entities to be involved like INEA	there was a typo - the entity to be involved is ENISA for cybersecurity issues through GR partner	WP7
Consortium - What is missing are patient advocates	They will be involved at Workshops and through the communication and stakeholders engagement. See also comments to WP2	general
Task distribution between the partners remains unclear. A summary matrix of the expertise provided by individual consortium members could be stated after the logic framework in 2.2. This would give an early indication of what each partner will do and how all will work together.	after project start it is a responsibility of the coordinator to do this mapping of individual expertise in alignment with the partners. At that point in time deliverables of the project will be defined on a more detailed level; then the required qualifications and expertise will be identified and mapped to partners and members of staff.	general
Better explanation of what expertise the sub- contractors will bring into the JA that the consortium members don't already provide.	Done for those partners where additional information appeared necessary in chapter 10.1.3: ATNA, MSSSI, MoH-FR	general
This proposal seems a bit "lite" on practical resources for policy implementation in the MS/Cs.	The proposal was revised namely on Deliverables and Outcomes (eg. WP4) - it should be sufficient to generate engagement at MS/C policy level through the eHN recommendations. The efforts made available for national implementation are not considered a core duty of a Joint Action. While this is true for financial resources and certainly for national and regional activities significant effort is put into the dissemination channels (see WP2 for internal dissemination activities).	general
Some partners have a very low budget/very low person months. A better distribution will assure genuine involvement and commitment by all partners	Each partner identified its way to participate; for several reasons some are more involved than others but this was the way they could commit; besides that there was adjustments between partners; Coordination and Dissemination will work in order to ensure that everyone will do its job adequately	general

comment	answer	WP
With Partners 8 and 10 the sub-contracting budget is higher than for the partners themselves. This should be better justified, or	8 - ES – done 10 - FR - done	general
changed		
Reduce # of Deliv	It was concluded not to reduce the number of Deliverables in a big scale (WP3 changed 2 Deliverables to Milestones); Deliverables are distributed according to eHN MWP and meeting plans; the Joint Action is thus bound by the requirements of the eHN	general
Outcomes (section 6) - to everyone	this section was revised with small changes; thus considered ok by the consortium	general
clearer lay out how the sub-national / regional levels are taken into account, also regarding the use of structural funds, and the support, JA partners will give to the national and sub-national stakeholders.	it is responsibility of each MS/C to ensure the dissemination of information internally; Dissemination activities will work to promote this; see also task 2.3.	general
relevant docs and studies to be considered	There are several references to other past and present projects, standards, standardisation initiatives, legislation and studies in the GA text. We have scrutinized the GA text though and did not find any severe omission. It will also be the task of the WP leaders and co-leaders (also as task leaders) and the deliverable authors to check for sources and references at the time of production. Also in the highly dynamic eHealth world new material which should be considered will occur during the lifecycle of the project, completeness can thus not be achieved in the GA.	general

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#### 1. PROBLEM ANALYSIS INCLUDING EVIDENCE BASE

Member States/Countries (MS/C) are facing common challenges in ensuring the sustainability of their health systems. Ageing population and increased prevalence of chronic conditions combined with limited human and financial resources are putting health systems under increasing strain in many MS/C. The need to move towards more preventive and participatory health systems has been widely acknowledged in Member States/Countries' health policies.

At the same time, the digital society brings new challenges but also opportunities for the health sector. Our society is becoming more and more information driven and people are increasingly using digital tools in their everyday lives. This also extends to citizens using digital tools for health purposes, both proactively and as patients. In other words: Citizens and businesses in the EU have the means to easily access various parts and systems of the Digital Single Market (DSM), and it is in the interest of the health sector to take full advantage of this.

In Europe, responsibility for health lies with each Member State/Country, and not with the European Union (EU), unlike most other domains. The European Commission (hereinafter also referred as the EC or Commission), has oversight of two areas – public health and cross-border care – but otherwise only acts as co-ordinator or funder of specific actions and projects. For several years, the Commission has run R&D programmes to stimulate particular areas of interest, and Framework Programmes (FP) have funded a number of projects. Many benefits have been derived from sound pieces of work. One of the persisting challenges is to continue work once the funding runs out. Also parallel activities on related topics are not always sufficiently co-ordinated. To address this and to foster the move from research to deployment, the Commission started a small number of large-scale pilots (LSPs). The eHealth LSP was epSOS (European Patient Smart Open Services); its scope was the cross-border use cases of Patient Summary (PS) and ePrescription (eP). epSOS started in 2008 and ended in 2014 having demonstrated the successful exchange of data, but also provided sustainable output which was sanctioned by the eHealth Network (eHN), namely the PS and eP Guidelines.

In 2011, the European Commission issued the directive on cross-border care (2011/24/EU). The directive led to the establishment of the eHealth Network, initially co-chaired by the Commission and the Member State Austria, comprising all Member States, plus Norway and Switzerland and the relevant directorates of the Commission.

The Commission wanted to build on this success, and hence established four sets of activities:

- A Multiannual Work Programme (MWP) 2018-2021 through the eHealth Network (eHN), which is a Member States' strategic plan on eHealth. The document will be adopted during the 12<sup>th</sup> eHN meeting in November 2017;
- R&D through the Horizon 2020 programme, covering all domains, but including a number of eHealth projects (see below);
- The work of the LSPs has been brought together in e-SENS, a pilot of pilots, which demonstrated the potential for cross-sectoral working and the re-use of common building blocks (such as eID and eSignature);
- the Connecting Europe Facility, which is about funding mass-deployments of generic services in domains such as eHealth (and transport and telecommunications, etc.). The first eHealth CEF call in 2015 has led to 17 countries preparing for waves of implementation of Patient Summary and e-Prescription in 2018, 2019 and 2020: Austria, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, Malta, Portugal, Sweden and Switzerland. The second CEF eHealth call was launched in May and closed in September 2017; the Commission expect a further five MS/C will submit their application.

With the introduction of the Connecting Europe Facility (CEF) the Commission has established the concept of reusable building blocks to be used across different application domains. The eHealth domain is represented by the eP and PS use cases but faces major challenges because of its specific security and application requirements. The Joint Action to support the eHealth Network (JAseHN) is playing an important

role in supporting the CEF implementation. There is strong evidence that further use cases and the application of the eIDAS Regulation and the General Data Protection Regulation (GDPR) require continuous efforts to foster eHealth uptake. While the 3rd Joint Action (JA) on eHealth (HP 2017), so called "eHAction", is building upon JAseHN, it is neither repeating its work nor is it a simple continuation.

The Commission signed a Memorandum of Understanding (MoU) with the USA, focussing on workforce competencies and the Trillium Bridge project which was examining the feasibility of a transatlantic shared patient summary.

### Joint Actions for eHealth

There have been two Joint Actions, co-funded by the European Commission addressing key topics for the eHealth Network. Under the coordination of Austria, the second Joint Action, called JAseHN, was initiated in May 2015, and runs for three years until May 2018, involving 27 (out of 28) Member States.

Also, four projects under the Horizon 2020 banner have recently completed:

- ASSESS CT, appraising the feasibility of SNOMED CT as a standard clinical terminology for Europe;
- OpenMedicine, considering options for the identification of medicinal products;
- ValueHealth, aiming to produce a sustainable business model for eHealth;
- eStandards, looking at what other standards are needed to enable eHealth implementation.

In parallel, the Commission have commissioned study on mHealth, and launched the "Digital Single Market" strategy to help a vibrant Europe-wide industry to compete on a global scale.

A third Join Action needs to be created in the way to continue the support to the eHealth Network. The activities of the third Joint Action are built on the four priority areas identified in the eHealth Network's MWP 2018-2021:

- Empowering people
- Innovative use of health data
- Enhancing continuity of care
- Overcoming implementation challenges

Furthermore, the work of the third Joint Action is aligned with the three pillars mentioned in the Digital Single Market's mid-term review of the European Commission:

- To ensure the citizen's secure access to electronic health records and their sharing cross-border, including use of e-prescriptions;
- To support data infrastructure, to advance research, disease prevention and personalized health and care in key areas: rare diseases, infections and complex diseases;
- To facilitate feedback and interaction between patients and healthcare providers, to support prevention and citizen empowerment as well as quality and patient centred care, focusing on chronic diseases and on a better understanding of the outcomes of health systems.

## 2. AIMS AND OBJECTIVES OF THE PROJECT

## 2.1 General objective of the project

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.

With a stronger focus on patients and beyond that on citizens caring about their health a second target group has been identified. The eHAction does, however, respect the prevalence of MS/C to address their citizens while the Action will suggest methods and provide to a limited extent means of addressing them.

Overcoming implementation challenges is a complex task. It comprises all four elements of interoperability framework and has to consider MS/C aspects but also needs to navigate in the evolving CEF schemes and to eventually consider continuity beyond CEF.

The eHAction relies on the output of projects and actions mentioned in Chapter 1 and in particular on the policy papers, frameworks and guidelines produced by JAseHN. With a number of senior participants being active in eHMSEG, JAseHN and now the eHAction, continuity will be assured while avoiding double work and friction.

Work on MWP 2018-2021 started in March 2017 and has been refined by MS and the European Commission in close cooperation with the Coordinator of this JA. As such, the content-related work packages (WP) of this JA are articulated in a way that they can address the topics of the four priority areas of the MWP; the description of work of this JA is in line with the MWP 2018-2021 in its current draft version. This MWP is expected to be adopted by the eHN in Nov 2017. If the eHN should change the MWP 2018-2021 after the submission of the eHAction proposal, the Description of Work (DoW) will need to be aligned in the course of the final review process of this proposal.

Thereby, the eHAction shall serve also as a platform for operational, strategic (at eHN level) and technical cooperation between MS/C on eHealth including engagement with the main stakeholders and EU umbrella organisations such as the members of the eHealth Stakeholder Group (facilitated by DG CONNECT and DG SANTE).

Within this framework, the eHN, the European Commission and the MS/C will discuss and agree on political and strategic issues related to eHealth, in accordance with Art. 14, Directive 2011/24/EU, including political prioritization. To ensure coordination, coherence and consistency between the political level (the eHN) and

the operational level (experts working in the WP of the eHAction), the eHN needs to provide guidance as well as feedback on the work of the JA as appropriate.

The overall work that will be performed by the eHAction shall lead to quality results for the continuity, safety and efficiency of healthcare provided support by ICT, taking as much as possible practical results to be used by the target groups (citizens, healthcare providers, health professionals, decision makers, etc.).

The eHAction will also identify synergies with other ongoing and/or planned JAs which work on the topic of eHealth, such as CHRODIS PLUS, Health Information, etc., in order to avoid the duplication of the efforts by complementing the work or joining the work toward reaching the common objectives.

## 2.2 Specific objective(s) of the project

Specific Objective Number	1	
Specific Objective	Preparation of eHealth Network meetings	
Process Indicator(s)		Target
• Structured involvement of stra	tegic experts	SC
• Coordination of overlapping tasks between the JA and the eHN secretariat WP1, e		WP1, eHN secretariat
Output Indicator(s)		Target
Preparation of relevant meetings		WP1
Collaboration between the MS's co-chair and the EC's co-chair of the eHN		WP1, EC
Outcome/Impact Indicator(s)		Target
• Increased awareness of content to be presented at the eHN meetings and contribution of strategic experts in meetings		SC
Documents adopted by the eHN		eHN

Specific Objective Number 2		
Specific Objective	Dissemination of content produced within MS/C and Stakeholder Groups and dialogue with relevant EU eHealth stakeholder groups	
Process Indicator(s)		Target
<ul> <li>Planning of actions related to a dissemination strategy at EU level</li> <li>Selection and involvement of relevant EU eHealth stakeholder groups</li> </ul>		WP2 WP1, WP2, SC
Output Indicator(s)		Target
<ul> <li>Establishment of specific dissemination communication tools within 4 months after the beginning of the JA</li> <li>Contribution of relevant eHealth stakeholder groups to each defined priority area</li> </ul>		WP2 Consortium, eHealth stakeholder groups
Outcome/Impact Indicator(s)		Target
<ul> <li>Increased awareness of the JA and related eHN activities through dissemination actions</li> <li>Awareness and contribution of relevant EU eHealth stakeholder groups to the JA</li> </ul>		Broad eHealth community, MS/C eHealth stakeholder groups involved

Specific Objective Number	3	
Shecific Uniective	Verification and validation of the project's workplan im progress towards objectives, and quality of results	plementation,
Process Indicator(s)		Target

<ul><li>Continuous monitoring of the project's workplan implementation</li><li>Where necessary implementation of corrective action</li></ul>	WP1 all WPs
Output Indicators	Target
<ul> <li>Establishment of the action's evaluation strategy</li> <li>Provision of the final evaluation report</li> </ul>	WP1, all content WPs eHN
Outcome/Impact Indicator(s)	Target
<ul> <li>Successful support of eHN and eHN meetings</li> <li>Quality assured output meeting the defined evaluation standards</li> </ul>	eHN all content WPs

Specific Objective Number	4	
Specific Objective	Translation of defined priority area A (Empowering people) of the MWP 2018-2021 into actions (incl. related specific requests made by the eHN)	
Process Indicator(s)		Target
<ul> <li>Alignment with other priority areas</li> <li>Synchronization of all WP task aspects in order to achieve successful consideration of all aspects of priority area A</li> </ul>		all content WP WP4
Output Indicators		Target
1		eHN, MoH and agencies of MS/C
<ul> <li>Provision of D4.2 - Policy proposal with first/next concrete actions for</li> </ul>		MoH and agencies of MS/C
Outcome/Impact Indicator(s)		Target
<ul><li>Adoption of framework</li><li>Dissemination of policy and</li></ul>	concrete actions	eHN WP2, MS/C

Specific Objective Number 5		
Specific Objective	Translation of defined priority area B (Innovative use of health data) of the MWP 2018-2021 into actions (incl. related specific requests made by the eHN)	
Process Indicator(s)		Target
• Planning of actions related t	o the defined priority area B	WP5
Output Indicators		Target
		eHN, MS/C, eHMSEG
Outcome/Impact Indicator(s)		Target
• Increased awareness and understanding of added value of big data, and guidance on practical governance of big data		eHN, eHMSEG, MS/C, MoH, authorities and agencies of MS/C,

specialist and research communities, pati communities
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pecific Objective Number   6		
Specific Objective	Translation of defined priority area C (Enhancing continuity of care) of the MWP 2018-2021 into actions (incl. related specific requests made by the eHN)	
Process Indicator(s)		Target
<ul><li>Planning of actions related t</li><li>Practical and ongoing support</li></ul>	<u>*</u>	• WP6
Output Indicators		Target
<ul> <li>Roadmap, framework and recommendations in the field of enhancing continuity of care</li> <li>Provision of D6.1 - Roadmap on future eHDSI use cases and features</li> <li>Provision of D6.2 - eHDSI legal report</li> </ul>		eHN, eHMSEG, MS/C eHN WP7, DSI Owner, eHN, MoH and agencies of MS/C WP6, eHN
Outcome/Impact Indicator(s)		Target
• Introduction of practical measures as promoted by T6.3 at least on a small scale		eHN, eHMSEG, MS/C specialist communities MS/C

Specific Objective Number	7	
Specific Objective	Translation of defined priority area D (Overcoming implementation challenges) of the MWP 2018-2021 into actions (incl. related specific requests made by the eHN)	
Process Indicator(s)		Target
Planning of actions related to the defined priority area D on implementation challenges and impact		WP7
Output Indicators		Target
<ul> <li>Provision of D7.1 - Recommendations and guidelines for IT Management</li> <li>Provision of D7.2 - Report on best practices and approaches on data protection at</li> </ul>		MoH and agencies of MS/C eHN WP6, eHN, DSI Owner, MoH and agencies of MS/C
Outcome/Impact Indicator(s)		Target
<ul> <li>Improved awareness and disseminated knowledge in the field of eHealth as basis for action in the defined priority (D)</li> <li>Improved uptake and usage of both national and cross-border eHealth services</li> </ul>		MS/C, DSI Owner

Specific Objective Number	8	
Specific Objective	Integration in national policies and sustainability	
Process Indicator(s)		Target
<ul> <li>Progress action plan</li> <li>Sustainability plan</li> <li>Stakeholder engagement plan</li> </ul>		WP8
<b>Output Indicators</b>		Target
<ul> <li>Execution of task and stakeholder meetings</li> <li>Production according to plan for LC (Leadership Council) and eHN.</li> <li>Feedback/input from stakeholders</li> <li>Provision of D8.1 Sustainability plan and recommendation</li> <li>Provision of MD.4 Report on integration in national policies and sustainability</li> <li>Provision of D8.2 Final report</li> <li>Production of technology reports and corresponding policy document</li> </ul>		MoH and agencies of MS/C eHN  WP6, eHN, DSI Owner, MoH and agencies of MS/C
Outcome/Impact Indicator(s)		Target
<ul> <li>Process in place for continued alignment of national strategies on priority areas</li> <li>eHealth policy cooperation between MS post 2021 is supported by an established structure.</li> </ul>		MS/C, DSI Owner

### 3. TARGET GROUPS

The eHAction will address the following main target groups which are expected to be positively affected by the JA:

- The primary target is the eHN and therefore the MS/C of the EU. This group of high level national representatives, policy-makers and decision-makers of the competent authorities responsible for eHealth will use deliverables elaborated by the eHAction in their formulation of EU wide policies and decisions. The majority of activities of the JA arises from the premise that its output will be used to inform and support discussion and decision making. Also other European countries will benefit from this work.
- eHealth stakeholder groups and Standards Developing Organisations (SDO). These groups and organisations will be incorporated via the governance process allowing a varying level of activity. Projects and initiatives and their experts and representatives will be addressed with transparent, reliable information and liaison activities.
- Another important target group is the general public caring about their health and being interested in eHealth. Citizens will be directly informed e.g. via the eHAction website and conferences and via health-themed topics in social networks. Primarily, though, the Action will provide support material and concepts while leaving it to the MS/C to address their citizens.

## 4. POLITICAL RELEVANCE

# 4.1 Contribution to meeting the objectives and priorities defined in the annual work programme

The third Programme of EU actions in the field of health (2014-2020) is about fostering health in Europe by encouraging cooperation between MS/C to improve the health policies that benefit their citizens. The programme builds on the two previous health programmes (2003-2007 and 2008-2013) with the objective of complementing the health policies of EU MS/C to promote health, reduce health inequalities, protect people

from serious cross-border health threats, encourage innovation in health and increase the sustainability of their health systems. The programme aims to support and complement MS' efforts to achieve four objectives:

- Objective 1: Promote health, prevent diseases, and foster supportive environments for healthy lifestyles. In practice: identify, disseminate and promote the uptake of evidence-based and good practices for cost-effective disease prevention and health promotion measures by addressing in particular the key lifestyle related risk factors with a focus on the Union added value.
- Objective 2: Protect citizens from serious cross-border health threats by identifying and developing coherent approaches and promoting their implementation for better preparedness and coordination in health emergencies.
- Objective 3: Support public health capacity building and contribute to innovative, efficient and sustainable health systems. In practice: identify and develop tools and mechanisms at Union level to address shortages of resources, both human and financial, and facilitate the voluntary uptake of innovation in public health intervention and prevention strategies.
- Objective 4: Facilitate access to better and safer healthcare for Union citizens. This would be achieved through increasing access to medical expertise and information for specific conditions, also beyond national borders. It would also entail helping to apply research results and developing tools for the improvement of healthcare quality and patient safety through, inter alia, actions contributing to improve health literacy

The vision of eHealth Action Plan 2012-2020 is to utilise and develop eHealth to address several of the most pressing health and health system challenges of the first half of the 21th century:

- to improve chronic diseases and multi-morbidity (multiple concurrent disease) management and to strengthen effective prevention and health promotion practices;
- to increase sustainability and efficiency of health systems by unlocking innovation, enhancing patient/citizen-centric care and citizen empowerment and encouraging organizational changes;
- to foster cross-border healthcare, health security, solidarity, universality and equity and improve legal and market conditions for the development of eHealth products and services.

The Action Plan addresses the barriers and the following operational objectives:

- Interoperability and standardisation;
- Exchange of knowledge;
- Monitoring and assessment of implementation;
- Global cooperation and positioning.

Directive 2011/24/EU provides rules for facilitating access to safe and high-quality cross-border healthcare and promotes co-operation on healthcare between MS, in full respect of national competencies in organising and delivering healthcare. In particular, Article 14 of Directive 2011/24/EU states:

- "1. The Union shall support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States.
- 2. The objectives of the eHealth network shall be to:
- (a) work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare;

*(b)* [...]

(c) support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare. [...]"

The main reasons for accelerating the introduction of interoperable eHealth solutions in a collaborative and coordinated way in Europe are increasing mobility of European citizens, expectations and needs, improving

patient safety and addressing common challenges. More specifically, interoperability of electronic health record systems is claimed to be an appropriate means to:

- bring about better quality of treatment because of better information about the patient;
- improve cost efficiency of medical treatments and thus prevent further rapid growth of health care deficits;
- furnish the necessary data for quality control, statistics and planning in the public health care sector which should also have a positive effect on public health care budgets.

Thus, the work of the eHN is vital in enabling and supporting the health objectives above.

## 4.2 Added value at EU level in the field of public health

The eHealth Network sub-group working on the MWP 2018-2021 identified four priority areas:

- A) Empowering people addressing citizens as individuals who should take an active role in their health care process;
- B) <u>Innovative use of health data</u> addressing the society to benefit from the analysis of large volumes of data generated across the healthcare sector and others;
- C) Enhancing continuity of care addressing healthcare systems and providers to adopt and implement interoperable cross-border solutions;
- D) Overcoming implementation challenges addressing transversal enabler issues across all previous categories.

The diagram below illustrates the four agreed priority areas, while it is not necessarily exhaustive or exclusive of subtopics under each of the four areas. It should be noted that all topics put forward by the MWP are being addressed while they are not reflected one-to-one in work packages and tasks. All four priority areas will impact the three identified core target groups. The Action is designed to produce tangible output providing measurable and sustainable output for all the target groups in all priority areas.

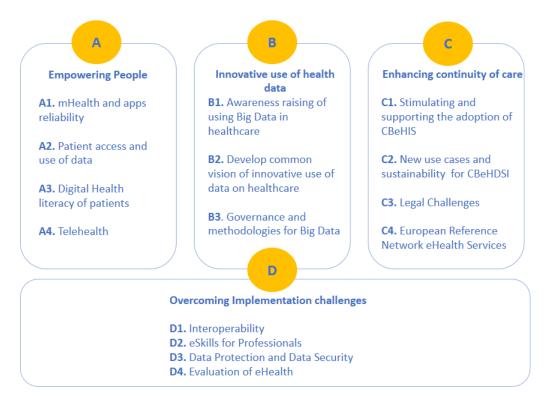


Figure 1: Focus areas of the eHealth Network MWP 2018-2021 (from draft version of 21st Sep 2017)

## 4.3 Pertinence of geographical coverage

Participating authorities represent 28 MS plus Norway, Serbia, Moldova and Switzerland, and hence the consortium represents nearly all of Europe.

The eHN has representatives from all 28 MS with participation also from Norway and Switzerland. The Deliverables of the eHAction depending of the needs will be submitted to the eHealth Network for information, discussion or formal adoption, thus ensuring comprehensive ownership of the resulting documents.

## 4.4 Consideration of the social, cultural and political context

The JA reflects both the diversity of the European health systems and the aim to overcome existing hurdles of interoperable cross-border eHealth systems. It thus fully works in the context of the social, cultural and political contexts of the European Union as pursued by the eHN for which the JA is a support activity. To that end the JA addresses legal, ethical and regulatory issues when formulating proposals for the eHN, which in turn provides guidelines and legislative and regulatory interventions that should be taken up by MS/Countries and the European Union as deemed necessary by the MWP 2018-2021. The work does not include studies involving human beings.

## 5. METHODS AND MEANS

The JA is not a classical technical IT project, but it intends to continually support a politically driven mechanism primarily established by the eHealth Governance Initiative JA and Thematic Network on governance development to coordinate ongoing and future activities in eHealth in the European space. In order to inform and support discussion and decision-making of the eHN it is foreseen to follow up the eHealth Governance Initiative Model based on MS/C cooperation with the organisation and management suited to attain its objectives. The following JA, JAseHN, continued the support and decision making with a similar, yet optimized design.

The conceptual and operational components already established are organized at three levels and will be maintained as such by the eHAction:

- 1. Decision makers' and political governance level;
- 2. Strategy level and
- 3. Operational level.

The governance level should be understood as high level national representatives with the responsibility to design and implement health and eHealth policies. This refers to the eHN according to Art. 14, Directive 2011/24/EU only.

The strategy level should be understood as advisors and/or senior officials who have a key role in developing national strategies for eHealth. National representatives of the strategy level shall be directly appointed by the governance level. The following specific objects of the JA refer to this level as a support for the Governance level:

- Specific Objective #1: Preparation of eHealth Network meetings (WP1) and
- Specific Objective #2: Dissemination of content produced within MS/C and Stakeholder Groups and dialogue with relevant EU eHealth stakeholder groups

The operational level should be understood as experts and representatives of national, regional and/or EU wide projects and/or pilots which are deploying eHealth services. The following specific objectives of the JA refer to this level as a support for the Strategy and Governance level:

- Specific Objective #3: Verification and validation of the project's workplan implementation, progress towards objectives, and quality of results (WP3)
- Specific Objective #4: Translation of defined priority area A of the MWP 2018-2021 into actions (incl. related specific requests made by the eHN) (WP4)

- Specific Objective #5: Translation of defined priority area B of the MWP 2018-2021 into actions (incl. related specific requests made by the eHN) (WP5)
- Specific Objective #6: Translation of defined priority area C of the MWP 2018-2021 into actions (incl. related specific requests made by the eHN) (WP6)
- Specific Objective #7: Translation of defined priority area D of the MWP 2018-2021 into actions (incl. related specific requests made by the eHN) (WP7)
- Specific Objective #8: Post 2021 sustainability (WP8)

While the governance and the strategy levels are often linked, the gap between the operational and the governance level remains a common challenge both at national as well as European level. Often the outcome of the work done at the operational level is not adequately communicated and therefore not fully reflected in the strategy and/or policy decisions.

The ambition of the JA is to bridge these gaps and enable evidence based eHealth. This would provide further added value by enabling healthcare systems to fully benefit from the opportunities offered by ICT and thus contribute to fulfilling their political goals. When shifting focus to deployment of eHealth services, there is also a strong need for including all relevant stakeholders, both users (e.g. patient, healthcare staff) and industry, in the governance process.

The following methods are applied across all objectives:

- The governance model of the eHAction implements a sophisticated review process for all documents produced by the work packages. It ensures that all documents meet the requirements of all target groups;
- Whenever decision documents for the eHN are being produced, such as policy papers or guidelines or guidance, the eHAction will endeavour to bridge the gap between the different levels by ensuring both sufficient detail for operations and adequate governance coverage. To that end, the interaction between the coordinator, the CG and the SG are instrumental;
- The project management structure enables the WP leaders to oversee and influence the shaping and structure of deliverables and to align the aims of them with the coordinator;
- A stringent quality control also covers the "bridging the gap" aspects as described above;
- The eHAction will produce a limited number of deliverables, several of them in a number of increments. That way a continuous improvement process can be established;
- A number of work items involve more than one work package. This ensures that different points of view from different perspectives are considered; more coherent and comprehensive results can be expected which will also support to better serve the three levels alike.

## **6.** EXPECTED OUTCOMES

Topic	Intended Outcomes
mHealth and health apps reliability	Safe and informed patients' and professionals' usage of mHealth/health apps
Patient access and use of data	Ensure that the individual countries' approach to patient access and re-use of data are synergistic, non-conflicting, and support cross-border needs
Digital health literacy of patients	A clear understanding of the importance of digital and health literacy in all MS and an improvement of digital and health literacy for citizens/patients.
TeleHealth	Safe and informed patients' and professinals' usage of Telehealth solutions.
Mapping, awareness raising and policy	Increased awareness and understanding on the added value of

Торіс	Intended Outcomes
relevant actions on innovative use of big data in health	big data focused on in eHN/ governance level
Sharing and learning best practices on big data in health on European level	Increased applicability of big data by mobilizing knowledge across borders
Towards an attempt to define common principles for practical governance of big data	Guidance on practical governance made available for eHN and MS
Support of the eHDSI uptake	Commitment on sustainable usage of NCPeH among MS/Cs and between MSs and EC
Support of legal eHDSI matters	Increased legal awareness and legal certainty for eHDSI among MS/Cs and between MSs and EC
eSkills for Professionals	A clear understanding of the eSkills requirements necessary to support eHealth in MS/C amongst designated professional groupings in healthcare with a defined action plan based on evidenced based assessment on how to bridge the identified skills gap underpinned by innovative approaches like Massive Open Online Courses (MOOCs) along with newly designed and developed curricula and programmes where necessary.
Implementing interoperability guidelines in large health-care organisations	Recommendations and guidelines for IT Management on implementing interoperability actions in healthcare organizations
Data protection	Share best practices and approaches on data protection at national level.
Data and systems security	A common framework for cyber security for eHealth systems and services
Post 2021 scenarios for eHealth policy cooperation	Guidance on ICT enabling continuing deliverable eH cross- border services
Stakeholders involvement post 2021	Common framework of approaches by stakeholders in eHealth
National and international eHealth strategies	Define national strategies of Member States alignment with EC on ICT and health
Policy document about technology report	Practical guide on policy and technology

## 7. WORK PACKAGES

## 7.1 Overview on work packages

There are two types of WPs: horizontal and core (content-related). The horizontal WPs are mandatory. These are: Coordination (WP1), Dissemination (WP2), Evaluation (WP3) and Integration in national policies and sustainability (WP8) and they are linked to deliverables. Each core or content-related WP is linked with one or several specific objectives of the action and produces one or several deliverables. Core WP are: Empowering people (WP4), Innovative use of health data (WP5), Enhancing continuity of care (WP6) and Overcoming implementation challenges (WP7).

## 7.1.1 Work Packages

WP number	Title	Description
1	Coordination	Actions undertaken to manage the action and to make sure that it is implemented as planned
2	Dissemination	Actions undertaken to ensure that the results and deliverables of the action will be made available to the target groups
3	Evaluation	Actions undertaken to verify if the project is being implemented as planned and reaches the objectives
4	Empowering people	Addressing citizens as individuals who should take an active role in their health care process
5	Innovative use of health data	Support the application of good practices in MS/C and provide Guidance on practical governance of big data at EU level on handling big data in health
6	Enhancing continuity of care	Addressing MS's and their health fitness for the eHDSI uptake
7	Overcoming implementation challenges	Addressing transversal enabler issues that cross all previous categories
8	Integration in National policies and sustainability	To ensure the long-term sustainability of the developed body of work by ensuring stakeholder involvement, and integration of its results in national policies

## 7.1.2 Deliverables' elaboration

The process of producing Deliverables will be detailed and agreed at consortium level, but will include writing content, quality assurance review and formal approval by Steering Council, before submission to eHN and EC.

The elaboration of Deliverables' content, especially the ones related to the priority areas of the Multi-annual Work Plan (MWP 2018-2021) – *Empowering people, Innovative use of health data, Enhancing continuity of care, Overcoming implementation challenges and Integration in National policies and sustainability* – will be done mainly through active contributions at F2F workshops with consortium members. Stakeholders and experts considered to provide added value to achieve the defined target may also be involved.

There will be four Workshops per year, 12 in total during the three-year life-cycle of the Joint Action. Each Workshop will tackle two themes and each theme can combine more than one single work package (WP) matter. Identified matters that are correlated between different WP will be worked at during the same workshop (WS) and at the end of the WS, one or more chapters of Deliverables will have been prepared.

In case a deliverable requires contributions from more than one WP it is assigned to the more relevant WP for management and reporting purposes. Following a request from the EC the consortium agreed to produce a smaller number of deliverables than previous Joint Actions. To meet this requirement the eHAction had to package more than one topic in some deliverables and also there can be no strict assignment of a deliverable

to a work package. The creation of deliverables will be an evolutive process that might include publicization of briefs (300 words) or some pages during the time of its elaboration for online criticism by stakeholders.

## 7.2 Work package description

Work package number	1							
Work package title	Coordinat	Coordination						
Starting month	1			Endi	ing Month	l	36	
Leading participant	<i>SPMS</i>							
Participant number	1	10						
Participant short name	SPMS	MoH-FR (ASIP)						
Person-months per participant	105	3						
Participant number								
Participant short name								
Person-months per participant								

## **Objectives**

The objective of this WP is to coordinate the different parts of the work from both, administrative and content perspective as laid out in the general description of objectives of this JA. Another major objective is to ensure timely submission of the project's deliverables intended for submission to the eHN prior to their bi-annual meetings in order to support the work progress of the eHN members.

Also, the monitoring of the project's overall strategy as well as the active support of the general work progress of the other WPs is to be carried out by WP1. In case administrative, financial or management issues will arise, WP1 shall effectively deal with their resolving in a way that the project will be implemented successfully and on schedule. For this task, WP1 is supported by the Risk Management. Financial management, reporting and monitoring of the budget shall be carried out by this WP as well. The Coordinator also acts as the interface between representatives from the EC (DG SANTE and CHAFEA) and the project participants.

In the inception phase of the project WP1 shall focus on the elaboration of concrete operations procedures for work delivery (incl. a production approach for deliverables) and financial reporting templates.

## **Description of work**

## Task 1.1 – Project Management

Perform the planning and monitoring of the overall project execution, prepare and submit the interim progress and final reports. In close interaction with WP3, an internal assessment of the project on an annual basis will also be performed to identify and correct any possible deviations. It could include proposals for change management or activities needed to the benefit the overall project execution.

## Task 1.2 – Organisation of meetings, workshops, TCons, etc.

This task covers the organisation of all committee meetings (SC and LC) and their related TCons, video conferences, etc. as well as project internal coordination meetings and any other meetings of the Coordinator with other parties, e.g. the EC or external parties.

## Task 1.3 - Project public presence and project representation

Participation in several conferences, events, meetings and workshops of other projects/institutions/etc. on demand and upon needs.

## Task 1.4 - Organisation of steering meetings and support with workshop meetings

This task includes the organisation of meetings of the strategic and operational PSC as well as of the Coordination Group. Furthermore, WP1 will provide support to other WP leaders with broader workshop meetings, where needed.

## Task 1.5 - Project Administration and Reporting

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.

### **Deliverables**

## D1.1 Interim report 1

CO M12

The interim reports describe the activities carried out, deliverables, milestones and results achieved after each 12 months of the JA as well as the general work progress.

## D1.2 Interim report 2

CO M24

The interim reports describe the activities carried out, deliverables, milestones and results achieved after each 12 months of the JA as well as the general work progress.

D1.3 Final report CO M36

This report describes the JA overall implementation and the results achieved.

## Milestones to be reached by this WP

M1 (M1.1) Consortium Agreement, M1

M2 (M1.2) Rules of Operations, M2

M3 (M1.3) Reporting Templates for partners, M2

Work package number	2								
Work package title	Dissemina	Dissemination							
Starting month	1	Ending Month 36							
Leading participant	SPMS		·						
Participant number	1	3	6		16	18			
Participant short name	SPMS	МоН-СҮ	MoSA	A	AeS	MFH			
Person-months per participant	27	1.1	2		1	3			
Participant number									
Participant short name									
Person-months per participant									

## **Objectives**

The objective of this WP is to develop an effective, macro and common dissemination strategy as laid out in the general description of objectives of this JA.

The main goal of dissemination activities is to inform the MS/C community about the JA, its orientation and available outputs for further exploitation. Dissemination activities will be oriented both externally (Health professionals; Hospitals; Stakeholders; Citizens; European Patient's Forum and the European Cancer Patient's Coalition) and internally (eHN and therefore the MS/C of the EU).

In order to produce a sustainable communication model for eHealth Network, this dissemination plan will be performed and managed by a communication team which will set up new ways of engaging participants and the interaction among them. By creating dissemination for awareness of the JA vision and goals, an identity and profile will be created within the community of MS. The forms of public dissemination aim at the engagement of JA participants' leaders, their presentation and institutional results, as well as the development of instruments for empowering citizens. Moreover, it will be important that the targeted groups/ audiences have a deeper understanding of JA's work. Thus, JA leaders will be encouraged to, frequently, use common digital tools to inform and support discussion and decisions making. Project workshops will be frequent and the outcomes projects and initiatives will be exposed to transparent and reliable information via liaison activities.

## **Description of work**

#### Task 2.1. Public dissemination

Dissemination and Communication of information about the JA and coordination with relevant networks, will be a continuous activity over the project lifetime. As part of this dissemination and communication, newsletters will be produced for electronic distribution and inclusion on the website and social media. Information posted on the website will additionally be subject to monthly review and update in conjunction with periodic project reporting in cooperation with others WP.

This task has as major public awareness/communication activities:

- eHealth Action website at: <a href="http://jointaction3.spms.min-saude.pt/">http://jointaction3.spms.min-saude.pt/</a> (already online);
- eHealth Action branding (logo) and key visual (already set up);
- eHealth Action project social media presence and Social Network's presence;
- Communication supporting materials:
  - Advertising brochure of the eHealth Network Action and its review during the project to keep it updated;
  - o Short videos to present to a wide public the project aims, results achieved and final reports (subtitled in the official languages of the countries involved);
- Quarterly newsletter;
- Press releases (promoting and summarizing the main activities of the project).
- Press Kit.

## Task 2.2. Specific dissemination

The specific dissemination strategy of JA aims to share the results of the project among eHealth stakeholders, to engage them in the process of their incremental elaboration & endorsement, and eventually their even wider dissemination. A specific dissemination channels and communication modes will be used to ensure that vision of the JA reaches its stakeholders. It comprises multitude activities and adopts a holistic approach to communication and dissemination.

This task has as Major scientific/technical dissemination activities:

- Pool of Representatives: comprised of eHealth Action Ambassadors
- Conferences
- Symposia
- Meetings
- Other events: Summits; Expert Talks; Conferences

## Task 2.3. Internal project dissemination

Internal communication aims for information exchange among project partners and for generally ensuring the successful implementation of overall project objectives. It creates an optimal common understanding of the project partners about the on-going activities within different working packages as well as fosters the involvement and identification of all project partners because they all are important multipliers of the project and its results.

This task will include Digital Tools and Training/ Education Initiatives:

- Chat
- Skype
- Email
- Web Conferences
- Internet Forums
- Workshops

## Task 2.4. Stakeholders engagement & involvement

The stakeholders engagement & involvement strategy will provide the means for stakeholders to interact with one another and discuss the JA findings and recommendations.

To this end, it will suggest and explore a variety of means to improve JA deliverables.

Identify and engage stakeholders throughout the course of the project in order to ensure that the results of the project are applicable and appropriate to stakeholders.

The JA dissemination strategy provides the basis for engaging with stakeholders through a stakeholder identification, analysis and interaction process.

The intent here is to create an impact that will last beyond the end of the JA by making the results of the projects to those who could benefit from them (i.e., our identification of the issues, opportunities and challenges surrounding the eHealth Network at the Member States, across different disciplines, and what this means for EU policy and the framework to be used in the future for supporting the eHealth Network. This objective implies identification of a wide stakeholder audience, compilation of a contact list to whom we can send information about JA and its findings, and development of differentiated and targeted communication approaches for different categories of stakeholders.

This task will deal with Communication and dissemination while Promote innovative project partnerships between stakeholders through:

- Technical visits at enterprises and innovation eHealth industries
- Workshop with the project leads for the current H2020 INNOSUP 1innovation action projects
- Innovation Technical Staff Talks
- Expertise & high-level research meetings
- Network meetings
- Best practices & knowledge sharing between stakeholders Semester Reports/Newsletter
- Creation of White Papers or policy and technology reports

Deliverables		
D2.1 Dissemination and stakeholder engagement strategy	PU	M6
D2.2 Internal dissemination report  D2.2.1 Internal dissemination Report I (M12)  D2.2.2 Internal dissemination Report II (due in M24)  D2.2.3 Internal dissemination Report III (due in M36)	СО	M36
D2.3. External dissemination D2.3.1 External dissemination Report I (due in M12) D2.3.2 External dissemination Report II (due in M24) D2.3.3 External dissemination Report III (due in M36)	PU	M36
D2.4 (MD.1) Leaflet	PU	M3
D2.5 (MD.2) Layman version of the final report	$\mathbf{PU}$	M36
D2.6 (MD.3) Web-site	PU/CO	M3

## Milestones to be reached by this WP

M4 (M2.1.1) Draft Dissemination and stakeholder engagement strategy (due in M06)

- M2.1.1.1 Positioning report task 2.1 eHealth Action website (M01)
- M2.1.1.2 Positioning report task 2.1 eHealth Action branding (M03)
- M2.1.1.3 Positioning report task 2.1 eHealth Action project social media presence (M06)
- M2.1.1.4 Positioning report task 2.1 Communication supporting materials (M12)
- M5 (M2.1.2) Dissemination and stakeholder engagement strategy for approval (due in M07)
- M6 (M2.1.3) Final for adoption D2.1.4 (M08)

M7 & M8 (M2.2.1) Internal dissemination Report I (M6|12)

M9 & M10 (M2.2.2) Internal dissemination Report II (M18|24)

M11 & M12 (M2.2.3) Internal dissemination Report III (M30|36)

M13 & M14 (M2.3.1) External dissemination Report I (M6|12)

M15 & M16 (M2.3.2) External dissemination Report II (M18|24)

M17 & M18 (M2.3.3) External dissemination Report III (M30|36)

Work package number	3							
Work package title	Evaluation							
Starting month	1	1 Ending Month 36						
Leading participant	ATNA	ATNA						
Participant number	2							
Participant short name	ATNA							
Person-months per participant:	9,0							
Participant number								
Participant short name								
Person-months per participant:								

## **Objectives:**

The success of the Action depends on the effectiveness and productiveness to achieve the defined goals. For this, it is essential that the WPs elaborate high quality products (i.e. Deliverables) delivering certain value to the eHealth Network at the policy level. Therefore, the main objective of WP3 is to verify if the action is being implemented as planned and reaches its objectives. The evaluation tasks and activities shall focus on the eHealth Network as the main target group but also on the performance of the WPs delivering input to the eHealth Network. WP3 shall further verify and assess how the delivered inputs (i.e. Deliverables) of the Action have satisfied the needs and expectations of the eHealth Network and how the Action has dealt with requests from the eHealth Network.

At the beginning of the project, WP3 focuses on the establishment of the Action's methodology for evaluation and an internal evaluation plan which are to be reflected in the evaluation strategy. After the 14th eHealth Network meeting, evaluation activities shall be performed on regular basis and in accordance with the evaluation strategy. Key indicators could be included in the evaluation strategy laying out how the Action contributed to the eHealth Network's Multiannual Work Programme 2018-2021.

An external evaluator shall be considered for carrying out WP3 tasks and activities and for consultancy.

## **Description of work**

## Task 3.1: Establish Evaluation Strategy (Lead: ATNA)

Focuses on the establishment of the Action's evaluation strategy that shall define the internal operational evaluation processes, methodologies for the ongoing evaluation and an evaluation plan. This task works closely with the Coordinator and the other WP Leaders. If needed, an external evaluator shall be consulted for the verification of the established evaluation strategy.

This task operates from M1 until M6.

## Task 3.2 Evaluation of ongoing work (Lead: ATNA)

Aims to carry out the evaluation activities that are defined in the evaluation strategy. Evaluation activities shall start after the 14th eHealth Network meeting and are to be continued on a regular basis and in a

proactive way. The conclusions/recommendations shall be reported to the Steering Council. T3.2 is expected to support with guiding the deliverable elaboration processes in a way as they will match policy needs (by the eHealth Network). Thus, contributing in delivering the right content in the right format and thereby fulfilling its main objective, namely to support the work of the eHealth Network. An external evaluator shall support this task to ensure integration of external expertise as well.

This task operates from M7 until M36.

### **Deliverables**

### Milestones to be reached by this WP

- M19 (M3.1) Draft Evaluation Strategy (M3)
- M20 (M3.2) Final Evaluation Strategy (M4)
- M21 (M3.3) Draft of Final Evaluation Report (M32)
- M22 (M3.4) Final Evaluation Report (M36)

Work package number	4							
Work package title	Empoweri	Empowering People						
Starting month	1	1 Ending Month 36						
Leading participant	NICTIZ (leader); MoSA (Co-leader)							
Participant number	1	2	3	5	6	9	10	
Participant short name	SPMS	ATNA	МоН-СҮ	Gematik	MoSA	THL	MoH-FR	
Person-months per participant:	4.5	10	8.8	3	12	3	4.75	
Participant number	11	12	13	15	16	17	19	
Participant short name	HZZO	NHSC	DoH	SAM	AeS	NHS	NICTIZ	
Person-months per participant:	7	8	6.99	6	1	7	12	
Participant number	22							
Participant short name	NIJZ							
Person-months per participant:	3							

## **Objectives**

WHO defines patient empowerment as "a process in which patients understand their role, are given the knowledge and skills by their health-care provider to perform a task in an environment that recognizes community and cultural differences and encourages patient participation."<sup>1</sup>.

In this process it's important for patients/citizens being more informed about (their own) health, to allow them to be more active partners to healthcare professionals. The tasks digital health literacy and patient access and use of data will include this aspect. Secondly, the number of (new) digital tools for patients/citizens are increasing. This leads to self-management where reliability for instance is very important. The mHealth and health apps reliability and TeleHealth tasks will include this aspect.

The overall objective of this WP is to empower people to take active part in their health and care process by building their capacity to use, understand and control their medical data, to provide them the opportunity to really participate and to motivate them to do so. Not only in (shared) decision situations with their medical professionals on their medical status, but also in active situations such as self-monitoring (e.g. mHealth) and/or in making use of e.g. TeleHealth services for prevention and/or health care reasons.

<sup>&</sup>lt;sup>1</sup> Health promotion glossary. Geneva: World Health Organization; 1998.

In order to achieve this, the secondary objectives of this WP are;

- To create a policy framework with regard to Patient Empowerment keeping in mind the subjects mHealth, patient access and use of data, digital health literacy and TeleHealth which will be input for the policy proposal (deliverable 1).
- To build and create a policy proposal for Patient Empowerment for the eHealth Network based on the ReEIF model in the context of the cross-border directive keeping in mind the subjects mHealth, patient access and use of data, digital health literacy and TeleHealth (deliverable 2). This proposal should also include concrete actions/next steps to implement on MS/C level.
- Create awareness and put emphasis on the motivation aspect for patients and health care professionals besides the capacity and opportunity aspects. People will not change behaviour only by improving the capacity (e.g. increasing digital health literacy) or providing them the opportunity (e.g. by health apps) to access their data. Therefore, motivation is a third important aspect to include in this WP.

To have a wider perspective in the creation of an effective policy framework with real impact, it is important to have various stakeholders included in the process. For that, cooperation with the Digital Health Society will be established. Input from task forces dealing with

- 1. legal framework
- 2. barriers of implementation of digital health services,
- 3. as well as change management in digital health,

will be collected.

## **Description of work**

All MS/C are working on eHealth and the majority describes Patient Empowerment in their national health policies. The objective within and across MS/C is to increase the empowerment of citizens in general and patients in particular. To achieve this objective, this WP is divided in four tasks, namely mHealth and health apps reliability, patient access and use of data, digital health literacy of patients and TeleHealth;

## Task 4.1: mHealth and health apps reliability (Lead: MoSA)

The sharing of best practices, existing guidelines and other information regarding mHealth and health apps reliability is needed in order to achieve a common understanding on eHN. Input from the mHealth subgroup will be used with coordination and awareness-raising and capacity building activities. This task will focus on:

- Perform desk research including input from a consultation round with external stakeholders and input from JAseHN, and other projects. In addition, investigate ways to motivate or create incentives for patients to participate in their health care process by adopting and using mHealth services.
- Analyse the findings and define a common understanding on the subject
- Develop a state of play/positioning report (common framework for the assessment/endorsement of health apps) with regard to mHealth and health apps reliability in relation to Patient Empowerment.
- Participate in workshops as task 4.1 member to deliver deliverable 1 and 2 of this WP.

## Task 4.2: Patient access and use of data (Lead: NICTIZ)

This task will focus on the sharing of best practices, existing guidelines and other information regarding patient access and use of data. Examples are the project "MyHealthMyData".JAseHN 7.5, SUSTAINS and PALANTE. This is needed in order to achieve a common understanding on this subject between MS/C on EU level. There is overlap with T5.1, T5.3 and T7.2.

- Perform desk research; input from the consultation round with external stakeholders, JAseHN (e.g. task 7.5) and other projects. In addition, investigate ways to motivate or create incentives for patients to participate in their health care process by accessing and using their health data.
- Analyse the findings and define common understanding on the subject
- Develop a state of play/positioning report with regard to patient access and use of data in relation to

Patient Empowerment.

• Participate in workshops as task 4.2 member with the objective to deliver deliverable 1 and 2 of this WP.

## Task 4.3: Digital health literacy of patients (Lead: NICTIZ)

The sharing of best practices, existing guidelines and other information regarding digital health literacy is needed in order to achieve a common understanding between MS. There is overlap with T6.3.

- Starting with desk research including input from the consultation round with external stakeholders and input from JAseHN (e.g. task 7.5) and other projects. In addition, investigate ways to motivate or create incentives for patients to participate in their health care process by increasing their digital health literacy.
- Analyse the findings and define common understanding on the subject
- Consult existing coalitions, such as https://ec.europa.eu/digital-single-market/en/national-local-coalitions
- Develop a state of play/positioning report with regard to digital health literacy in relation to patient empowerment.
- Participate in workshops as task 4.3 member with the objective to deliver deliverable 1 and 2 of this WP.

## Task 4.4: TeleHealth (Lead: MoSA)

The sharing of best practices, existing guidelines, a catalogue of TeleHealth services and other information regarding TeleHealth is needed in order to achieve a common understanding between MS. The work of this task will take into consideration results and recommendations from the study on telemedicine commissioned by DG SANTE (final report end of 2018).

- Perform desk research including input from the consultation round with external stakeholders and input from JAseHN and other projects. In addition, investigate ways to motivate or create incentives for patients to participate in their health care process by adopting and using TeleHealth services.
- Analyse the findings and define a common understanding on the subject
- Develop a state of play positioning report with regard to TeleHealth in relation to patient empowerment
- Participate in workshops as task 4.4 member with the objective to deliver deliverable 1 and 2 of this WP.

### **Deliverables**

### **D4.1** - Policy framework on Patient Empowerment

PU M22

A policy framework on Patient Empowerment in the current Cross border context in which the input of the four separate tasks and relations between these tasks is included and the objective to empower patients is expressed in capacity, opportunity and motivation. With this we aim to create a policy framework within the eHN based on which we can create deliverable 4.2.

## D4.2 – Policy proposal

PU M30

A policy proposal with first/next concrete actions for the separate tasks with regard to Patient Empowerment in the EU which can be implemented on MS/C level based on D4.1.

## Milestones to be reached by this WP

- M23 (M4.1.1) Positioning report task 4.1 (M10)
- M24 (M4.1.2) Positioning report task 4.2 (M10)
- M25 (M4.1.3) Positioning report task 4.3 (M10)
- M26 (M4.1.4) Positioning report task 4.4 (M10)
- M27 (M4.2.1) Draft for discussion D1 (M16)
- M47 (M4.2.2) Final for adoption D1 (M22)
- M28 (M4.3.1) Draft for discussion D2 (M28)
- M29 (M4.3.2) Final for adoption D2 (M34)

<b>TT</b> 7 1		-
Work	package	number

Work package title	Innovative	Innovative use of health data						
Starting month	1	1 <b>Ending Month</b> 36						
Leading participant	NHSC (lea	NHSC (leader); THL (co-leader)						
Participant number	1	2	8	10	11	12	13	
Participant short name	SPMS	ATNA	3rd-RHA	THL	MoH-FR	HZZO	NHSC	
Person-months per participant:	3.50	7.5	8.0	14.0	1.5	4.0	26.5	
Participant number	14	16	17	26				
Participant short name	DoH	SAM	NHS	NIJZ				
Person-months per participant:	2.0	4.5	3.0	3.0				

## **Objectives**

The overall objective of WP 5 is to support the application of good practices in MS/C and provide guidance at EU level on handling big data in health (large routinely or automatically collected datasets, which are electronically captured and stored) within the existing EU regulatory framework, 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. The aim of the WP is:

- To enable the communication of the value of big data to different stakeholder groups and to provide a way for public health promotion, preventive measures and care from the analysis of big data across healthcare sector and MyData following *FAIR* data principle (i.e. Findable, Accessible, Interoperable, Reusable)
- To collect and to compile experiences of MS/C for developing knowledge base and a framework for continuous exchange of best practices on EU level
- To build practical guidance on practical governance of big data and knowledge to MS/C based on the big data efforts and practices of MS improving recognition of the practical conditions for rational governance of big data in eHN and MS (in order to ensure patient-centered health systems, evidence-based health policy and decision-making, as well as data-driven innovation).

## **Description of work**

## T5.1 Mapping, awareness raising and policy relevant actions on innovative use of big data in health (Lead: NHSC)

- Compile policy relevant documentation including the EU Study and the effects of GDPR and review MS/C policy level efforts on governing big data in health.
- Also assess the implications of *FAIR* data principle.
- Identify obstacles preventing MS/C policies from being replicable either in other MS/C or on EU level, and investigate how to overcome these.
- Provide an initial set of enabling actions for the information of the eHN by translating recommendations of the EU Study into operationalized solutions that can be communicated for increased awareness.

## **T5.2 Sharing and learning best practices on European level** (Lead: THL)

- Define and use methods to identify underlying needs and barriers experienced by stakeholders (pros & cons) affecting efficient and effective sharing of best practices in order to reach the objectives of the WP and the JA.
- Investigate already formalized cross-border use cases such as European Reference Networks for rare
  diseases as well as practical solutions in R&D including analytics in order to identify new
  possibilities for innovative use of big data on the European scale, to assess feasibility of network
  optimization to cross-border IT infrastructure and data flow management and to enhance
  interdisciplinary and openness, the most potential usage and stakeholders that could benefit.

## T5.3 Towards an attempt to define common principles for practical governance (Lead: NHSC)

- Make available guidance on practical governance for eHN and MS.
   Provide a framework for the implementation of common principles for practical governance of big data including privacy protection and security aiming at improving health data transferability across borders with a special focus on data to be used in public health, research and quality assurance in healthcare on a European scale.
- The guidance will include guidance on implementation of data access and focus on helping Member States to utilize the potential of harnessing new opportunities arising from big data and improved data analytics capabilities, as well as from personalized medicine, use of clinical decision support systems by health professionals and use of mobile health tools for individuals to manage their own health and chronic conditions, in order to:
  - facilitate preparation of actions to improve the comparability, accuracy and reliability of health data and to encourage the use of health data to enable more transparent and patient-centered health systems focusing on health outcomes and evidence-based health policy and decisionmaking, as well as to promote data-driven innovation;
  - to enable the use of health data for research and innovation, in full compliance with data protection requirements and FAIR data principle;
  - apply network optimization to cross-border IT infrastructure and data flow management;
  - foster patient-centered interoperability;
  - improve service effectiveness for the individual patient in which benefits are experienced locally;
  - enhance interdisciplinary and openness that removes barriers between data sources and infrastructure to provide 'fit for purpose' data platforms.

#### **Deliverables**

(Focusing on translation of the EU Study recommendations to assist MS/C and EU/EC in implementing them)

D5.1 Report for the information of the eHN on policy level actions

PU M24

D5.2 Report on identified cross-border use cases, including assessment of pros & cons of stakeholders, and practical solutions with potential for European scale benefits

PU

M18

D5.3 Proposal for the eHN on the guidance for the implementation of common principles for practical governance of big data with a special focus on data to be used (and the implementation of data access and use) in public health, research and quality assurance in healthcare on a European scale PU M36

## Milestones to be reached by this WP

#### T5.1

- M30 (M5.1) Oct 2018 (M 01-06): Document on compiled policy relevant documentation including the EU Study and the effects of GDPR and review on MS/C policy level efforts on governing big data in health.
- M31 (M5.2) Apr 2019 (M 07-12): Document on identified obstacles preventing MS/C policies from being replicable either in other MS/C or on EU level, and proposal on how to overcome these.
- M32 (M5.3) Oct 2019 (M 13-18): Document outlining the added value of big data on eHN/ governance level with the EU Study recommendations operationalized
- M33 (M5.4) Apr 2020 (M 24): Report for the information of the eHN on policy level actions including an initial set of enabling actions based on the recommendations of the EU Study to support awareness raising and communication of the added value of big data to different stakeholder groups, especially on the Governance level in MS/C via the eHN. (Deliverable D5.1)

## T5.2

- M34 (M5.5) Apr 2020 (M01-18): Preparation for task 5.2 by analysing and structuring delivered information of D5.1
- M35 (M5.6) Oct 2020 (M 18): Report on identified cross-border use cases, practical solutions with

potential for European scale usage and benefits, including assessment of pros & cons of stakeholders. (Deliverable D5.2)

## T5.3

- M36 (M5.7) Oct 2020 (M 25-32): Preparation for task 5.3 by analysing and structuring delivered information of D5.1 and D5.2
- M37 (M5.8) Apr 2021 (M 31-36): Discussion Paper for the eHN on the implementation of common principles for practical governance of big data with a special focus on data to be used in public health, research and quality assurance in healthcare on a European scale with guidance on implementation of data access and use. (Deliverable D5.3)

Work package number	6						
Work package title	Enhancing	continuity	of care				
Starting month	1		Endi	ing Month	36	5	
Leading participant	gematik (l	gematik (leader);DoH (Co-leader)					
Participant number	1	2	3	4	5	6	8
Participant short name	SPMS	ATNA	МоН-СҮ	MZCR	gematik	MoSA	MSSSI
Person-months per participant:	7.5	8.0	9.9	4.0	23.0	4.0	1.3
Participant number	9	10	11	12	13	14	15
Participant short name	THL	MoH-FR	HZZO	NHSC	DoH	MINSAL	SAM
Person-months per participant:	3.0	5.5	5.0	5.0	21.0	1.50	3.0
Participant number	16	17	21	22			
Participant short name	AeS	NHS	IPHS	NIJZ			
Person-months per participant:	3.0	3.0	5.0	3.0			

## **Objectives**

Addressing countries' and their health fitness for the eHDSI uptake.

## **Description of work**

## **Task 6.1: Support of eHDSI uptake** (Lead: gematik)

Support countries through eHMSEG for long term policy development in eHDSI by facilitating the uptake of current use cases PS and eP/eD and especially the new ERN use case and by shaping an overall roadmap for eHDSI use cases and additional features for a sustainable and continued usage of the NCPeH. This task will be carried out in close cooperation with the Task T7.1 Implementing interoperability guidelines to cross-border health services and Task T8.1 Post 2021 scenarios for eHealth policy cooperation. After the provision of D6.1 Roadmap on future eHDSI use cases and features task T6.1 will continue on facilitating the eHDSI uptake by providing implementation guidance for countries through eHMSEG in close cooperation with EC.

## Task 6.2: Support of legal eHDSI matters (Lead: gematik)

Support countries through eHMSEG by facilitating the national implementation of the eHDSI legal environment (including but not limited to the eIDAS regulation, GDP regulation, NIS directive and the 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) by providing a forum for sharing expertise, problems and solutions and by synthesising shared elements into an eHDSI legal report for an non-lawyer audience. This task will be carried out in close cooperation with Task T7.2 Data protection and data security.

## Task 6.3: eSkills for Professionals (Lead: DoH)

Support countries through eHMSEG by developing a process to ensure that the eSkills necessary to gain full advantage from the implementation of European eHealth Strategies and cross-border healthcare services,

identifying current challenges and appropriate actions that can be taken to build the necessary eSkills framework for healthcare professionals.

#### **Deliverables**

## D6.1 Roadmap on future eHDSI use cases and features

PU M12

An eHDSI Roadmap on future use cases and features of the NCPeH including a proposal for a timeline. The roadmap is based on the current use cases and its timing.

## D6.2 eHDSI legal report

U M18

A synthesised eHDSI legal report which describes the common elements of the legal environment of eHDSI for a non-lawyer audience.

### **D6.3 Report on eSkills for Professionals**

PU M24

An evidenced based report with a supportive roadmap outlining a how a targeted education programme capable of supporting a matrix of progressive eSkills for the identified professional roles and allowing up skilling and re-skilling as appropriate to support eHealth strategies and roll outs amongst the MS.

## Milestones to be reached by this WP

- M38 (M6.1) Adoption of the Roadmap on future eHDSI use cases and features by eHealth Network reached (M12)
- M39 (M6.2) Adoption of the eHDSI legal report by eHealth Network reached (M18)
- M40 (M6.3) Adoption of the Report on eSkills for Professionals by the eHealth Network reached (M24)

Work package number	7							
Work package title	Overcomi	Overcoming implementation challenges						
Starting month	1		Endi	ing Month	36	5		
Leading participant	3 <sup>rd</sup> RHA (	3 <sup>rd</sup> RHA (leader); MZCR (Co-leader)						
Participant number	1	2	3	4	5	6	7	
Participant short name	SPMS	ATNA	МоН-СҮ	MZCR	gematik	MoSA	3rd RHA	
Person-months per participant:	7.5	2.5	12.1	23.0	5.0	8.0	23.77	
Participant number	9	10	11	12	13	15	16	
Participant short name	THL	MoH-FR	HZZO	NHSC	DoH	SAM	AeS	
Person-months per participant:	1.0	7.63	6.0	10.50	2.0	11.50	3.0	
Participant number	17	19	21	22				
Participant short name	NHS	NICTIZ	IPHS	NIJZ				
Person-months per participant:	8.0	4.0	11.0	8.0				

#### **Objectives**

Addressing transversal enabler issues that cross all previous categories.

## **Description of work**

## Task 7.1: Recommendations on how to implement interoperability guidelines in large health-care organisations (Lead: 3<sup>rd</sup> RHA)

Interoperability has long been identified as the fundamental facilitator of communication, exchange and use of patient information between healthcare providers, hospitals, government, insurers etc., especially in the context of cross-border health services.

During the past decades various standards have been developed regarding messaging (HL7, DICOM, ASC-X12, IEEE 1073 etc.), terminology (ICD-10, ICD-11 which is due by 2018, LOINC, SNOMED CT etc.),

documents, conceptual frameworks, application and architectures, both for syntactic interoperability, and for semantic interoperability.

Nevertheless, and despite the efforts, interoperability is still considered as an "open field" in the healthcare ecosystem, especially when striving to provide cross-border health services.

The aim of this task is to exploit any previous work in the field of interoperability as described in the Digital Agenda, the eHealth Action Plan, the "Refined European eHealth Interoperability Framework" (reEIF), the epSOS project, SemanticHealthNet, JAseHN and more, in order to facilitate patients' rights in cross-border healthcare.

All previous work will be combined to produce recommendations for IT Management on how to implement interoperability guidelines in large healthcare organizations (e.g. hospitals). The main purpose is to align all work done about various EU regulations/common frameworks and provide it to IT Management of hospitals for implementation. The deliverables of this task will provide recommendations, guidelines to facilitate implementation of the interoperability framework by hospital IT management staff taking into consideration the recommendations included in the new European Interoperability Framework (EIF). Hospital experts will contribute to this task with F2F Workshops.

The task will be implemented in the following steps:

- Review of previous work, interoperability frameworks and standards that can be implemented from the IT departments in healthcare organizations
- IT challenges in implementing interoperability in/ between large healthcare organizations
- Recommendations, guidelines and priorities for IT Management on implementing interoperability actions in healthcare organizations.
- Interoperability guidelines for hospital IT management staff in the following cases:
  - Software supply
  - Software building
  - Software deployment

## **Task 7.2: Data protection** (Lead: MZCR)

This task will focus on the GDPR implementation and its implications in cross border healthcare. The aim of this task will be to share best practices and approaches on data protection at national level. Situation regarding data protection and the new requirements GDPR brings in eHealth. It is proposed to implement the topic in 5 steps:

- 1. Review of the GDPR topic in general and view of its impact on the health care stakeholders.
- 2. Characteristics of main points and requirements of GDPR adoption in the health care sector
- 3. Proposal of the set of relevant recommendations/policies for successful completion of GDPR adoption in the health care sector
- 4. Sketches of collaborative instruments for related information and education in current and future dealing with GDPR topic in the health care settings.
- 5. Foresight vision and mission of the future fulfilment and development of the GDPR

The task is motivated by both urgent needs for correct GDPR adoption in the health care sector and the utilization of GDPR potential for comprehensive respecting human rights for the health care provision practice in long-term run.

In topics No. 2, 3 and 5 the cooperation with public interest groups (patient and health care professionals' organizations) will be actively sought and utilized

## **Task 7.3: Data and systems security** (Lead: 3<sup>RD</sup> RHA)

The aim of this task is to create a common Framework for cyber security for eHealth systems and services:

- 1. Common security framework for eHealth systems and services at a national and at a cross border level
- 2. Use cases: Cyber security in eHealth services and architectures, cyber security requirements for Patient Summary
- 3. Security of eHealth systems e.g. medical devices: how can the healthcare organisations be ready to

accommodate threats deriving from eHealth systems deployments e.g. medical devices. How can interoperability and portability be assured in a secure way.

4. Deliverable: the framework including guidelines for all stakeholders in the eHealth ecosystem.

This task is in accordance with the activities ENISA is running to support healthcare organisations building more secure infrastructures and resilient systems (see WannaCry incident).

### **Deliverables**

- D7.1 Recommendations and guidelines for IT Management on implementing interoperability actions in healthcare organizations

  PU M30
- D7.2 Report on best practices and approaches on data protection at national level. PU M14
- D7.3 Common security framework for eHealth systems and services at a national and at a cross border level PU M21

## Milestones to be reached by this WP

- M41 (M7.1) draft of D7.1 (M33)
- M42 (M7.2) draft of D7.2 (M14)
- M43 (M7.3) draft of D7.3 (M21)

Work package number	8							
Work package title	Integration	Integration in national policies and sustainability						
Starting month	1		End	ing Month	a 36	5		
Leading participant	MoH-FR (	MoH-FR (leader); NDE (Co-leader)						
Participant number	1	2	3	4	5	6	7	
Participant short name	SPMS	ATNA	МоН-СҮ	MZCR	gematik	MoSA	3 <sup>rd</sup> RHA	
Person-months per participant:	1.5	1.5	4.05	1.0	6.0	1.0	8.75	
Participant number	8	9	10	11	12	13	14	
Participant short name	MSSSI	THL	MoH-FR	HZZO	NHSC	DoH	MINSAL	
Person-months per participant:	1.0	1.0	7.23	2.0	0.75	2.0	2.5	
Participant number	15	16	17	18	19	20	21	
Participant short name	SAM	AeS	NHS	MFH	NICTIZ	NDE	IPHS	
Person-months per participant:	1.0	2.0	0.5	1.0	1.0	10.0	3.50	
Participant number	22							
Participant short name	NIJZ							
Person-months per participant:	2.50							

### **Objectives**

To propose elements for preparing the continuity post 2021of the cross border policy cooperation, and integration of its results in national policies.

WP8 is a CHAFEA mandatory task, and requires wide participation from MS/C to prepare consensus and commitment.

## **Description of work**

All tasks will engage and be extended to the willingness of the stakeholders to participate, based on existing EU practices of stakeholder involvement., STH existing bodies and building upon the cooperation with JAseHN.

## Task 8.1: National and international eHealth strategies (Lead: MoH-FR)

The objective of this task is to support present and future eHealth strategy alignment, and present mechanisms on how to maintain the existing strategy knowledge base for this purpose.

- The task will build upon the analysis done by JAseHN (WP7/Greece D7.1.1) based on a dedicated survey
- The task will propose to structure the information already gathered in order to create a toolset for task 8 3
- The task take into account not only the EU stategies, but will also try to learn from other countries best practices
- The task will describe how to maintain the strategy database proposed by JAseHN WP8 in order to better align strategies and projects in the future and ease the information and knowledge exchanges among the countries

## Task 8.2: Policy document about technology report (Lead: NDE)

The objective of this task is to activate stakeholder groups in producing relevant technology reports identifying technology trends and developments with impact on health and social care. The policy document following technology reports intend to contextualize technology trends and development in health and care to support MS/C in adopting the technologies in question.

- The task will suggest for Leadership Council (LC), and receive suggestions from LC, on what topics technology reports should cover and which stakeholder groups should be engaged. The number of reports per year will be based upon an evaluation of need and relevance. The expectation is between 1 and 3 technology reports per year.
- LC decides on topics, stakeholder group involvement and frequency of technology reports
- The task participants execute by engaging the stakeholder groups
- The task participants produce a policy document corresponding to each technology report. The policy document contextualises the content of the technology report in health and care / eHealth.
- The task organizes two stakeholder meetings every year to coordinate the described activities, and to keep the stakeholders involved in the overall process and production of the eHealth Action.

## Task 8.3: Post 2021 scenarios for eHealth policy cooperation (Lead: NDE/MoH-FR)

The objective of this task is to describe post 2021 scenarios for cross border eHealth policy cooperation and present these for helping the eHN to develop discussion on this matter

- The task will define a number of policy cooperation scenarios post 2021 that illustrate potential implications, requirements, risks and opportunities, and how to support the implementation of a policy recommendation or the adoption of an identified best practice at an adequate level in different EU MS.
- An early production in the task will be to deliver a sustainability plan that will visualize a projection of the future following reasonable probabilities, describing which elements/deliverables/results will be further developed, consolidated or run and by which entity/organisation this will/should be done.
- The task participants will work with the possibility of recommending a scenario for eHN adoption, and present this for discussion in LC. The objective is to identify if there is sufficient consensus within the MS/C to recommend a specific scenario for future policy cooperation or what are the main barriers to overcome
- Depending upon this outcome, the continued work of the task will be to either specify further how the recommended scenario is to be implemented, or develop a decision base for eHN.

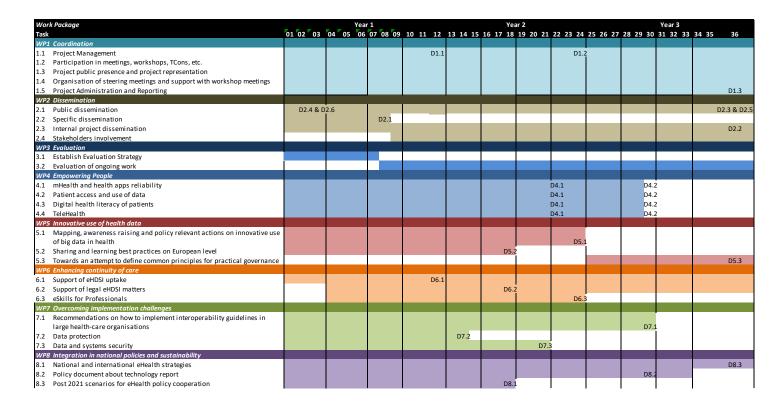
### **Deliverables**

Two main deliverables are planned. WP8 will produce two deliverables, one halfway in the project and one by the end of it. Production from task 8.1 and 8.3 will be combined into these two deliverables.

D8.1 Sustainability plan and recommendation	$\mathbf{PU}$	M18
D8.2 Technology & policy final report	PU	M30

D8.3 (MD.4) Report on integration in national policies and sustainability	$\mathbf{PU}$	M36
Production from task 8.2 will be technology reports and policy documents with a free decided upon by LC. Technology reports will be produced by external parties to leve expertise. The corresponding policy document will be produced by the participants in production will be presented to LC continuously, and will not be part of the WP delives synthesis will be annexed to support the scenario proposed.	rage their can the task. T	apacity and his
Milestones to be reached by this WP		
• M44 (M8.1) Draft of D8.1		M12
• M45 (M8.2) Early draft of D8.2		M18
• M46 (M8.3) Draft of D2		M36

## 7.3 Timetable or Gantt Chart



## 8. MILESTONES AND DELIVERABLES

## 8.1 Deliverables

Deliver. Number	Deliverable name	WP	Lead Applicant	Content Specification	Diss. Level	Delivery Month
D1.1	Interim report 1	1	SPMS	The interim reports describe the activities carried out, milestones and results achieved after each 12 months of the JA. Deliverables produced by other WPs within the covered time period can be attached as annexes	СО	M12
D1.2	Interim report 2	1	SPMS	The interim reports describe the activities carried out, milestones and results achieved after each 12 months of the JA. Deliverables produced by other WPs within the covered time period can be attached as annexes	СО	M24
D1.3	Final report	1	SPMS	This report describes the JA implementation and the results achieved	СО	M36
D2.1	Dissemination and stakeholders engagement strategy	2	SPMS	This report describes the 3 <sup>rd</sup> JA dissemination for stakeholders engagement strategy and the results to be achieved	PU	M08
D2.2	Internal dissemination report	2	SPMS	The internal reports describe the activities carried out, milestones and results achieved.	СО	M36
D2.3	External dissemination report	2	SPMS	The external reports describe the activities carried out for outside actors and results achieved.	PU	M36
D4.1	Policy framework on Patient Empowerment	4	NICTIZ	A policy framework on Patient Empowerment in the current Cross border context in which the input of the four separate tasks and relations between these tasks is included and the objective to empower patients is expressed in capacity, opportunity and motivation. With this we aim to create a policy framework within the eHN based on which we can base deliverable 4.2	PU	M22
D4.2	Policy proposal	4	NICTIZ	A policy proposal with first/next concrete actions for the separate tasks with regard to Patient Empowerment in the EU which can be implemented on MS/C level based on D4.1.	PU	M30
D5.1	Report on policy level actions	5	NHSC	Report for the information of the eHN on policy level actions	PU	M24
D5.2	Report on cross- border use cases	5	NHSC	Report on identified cross-border use cases, including assessment of pros & cons of stakeholders, and practical	PU	M18

Deliver. Number	Deliverable name	WP	Lead Applicant	Content Specification	Diss. Level	Delivery Month
				solutions with potential for European scale benefits		
D5.3	Paper on common principles for big data governance	5	NHSC	Discussion Paper for the eHN on the implementation of common principles for practical governance of big data with a special focus on data to be used in public health, research and quality assurance in healthcare on a European scale with guidance on implementation of data access and use.	PU	M36
D6.1	Roadmap on future eHDSI use cases and features	6	gematik	An eHDSI Roadmap on future use cases and features of the NCPeH including a proposal for a timeline.	PU	M12
D6.2	eHDSI legal report	6	gematik	A synthesised eHDSI legal report, which describes the common elements of the legal environment of eHDSI.	PU	M18
D6.3	Report on eSkills for Professional	6	DoH	An evidenced based report with a supportive roadmap outlining a how a targeted education programme capable of supporting a matrix of progressive eSkills for the identified professional roles and allowing up skilling and re-skilling as appropriate to support eHealth strategies and roll outs amongst the MS.	PU	M24
D7.1	Guidelines for IT interoperability	7	3 <sup>rd</sup> RHA	Recommendations and guidelines for IT Management on implementing interoperability actions in healthcare organizations	PU	M30
D7.2	Best practices report	7	3 <sup>rd</sup> RHA	Report on best practices and approaches on data protection at national level	PU	M14
D7.3	Common security framework for eHealth	7	3 <sup>rd</sup> RHA	Common security framework for eHealth systems and services at a national and at a cross border level	PU	M21
D8.1	Sustainability plan and recommendation	8	MoH-FR	Report on national and international eHealth Strategies and describe post 2021 scenarios	PU	M18
D8.2	Technology & policy final report	8	MoH-FR	Technology & policy report in order to support the scenarios proposed for sustainability	PU	M30

Mandatory Deliverables (MD)								
Deliver. Number	Deliverable name	WP	Lead Applicant	Content Specification	Diss. Level	Delivery Month		
D2.4 (MD.1)	Leaflet	2	SPMS	A leaflet to promote the project must be produced at the beginning	PU	M3		

D2.5 (MD.2)	Layman version of the final report	2	SPMS	This is a short (e.g. 10 pages) version of the final report, written for the interested public as a target group.	PU	M36
D2.6 (MD.3)	Web-site	2	SPMS	Each project must have a dedicated web-site / web-pages. This can have a public part and another one accessible only to the applicants.	PU (and CO)	М3
D8.3 (MD.4)	Report on integration in national policies and sustainability	8	MoH-FR	Report on national and international eHealth strategies and describe post 2021 scenarios	PU	M36

## 8.2 Milestones

Milestone Number	Milestone name	WP	Lead Applicant	Content Description	Diss. Level	Delivery Month
M1 (M1.2)	Consortium Agreement	1	SPMS	Consortium agreement among MS	СО	M1
M2 (M1.2)	Rules of Operations	1	SPMS	Operational governance models and rules of operations	СО	M2
M3 (M1.2)	Reporting Templates for partners	1	SPMS	Report templates for financial reports, management reports, etc.	СО	M2
M4 (M2.1.1)	Draft dissemination and stakeholders engagement strategy	2	SPMS	Information about dissemination strategy and stakeholders involvement	СО	M06
M5 (M2.1.2)	Draft dissemination and stakeholders engagement strategy	2	SPMS	Document about dissemination strategy and stakeholders involvement to be approved by MS	СО	M07
M6 (M2.1.3)	Final dissemination and stakeholders engagement strategy for adoption	2	SPMS	Document about dissemination strategy and stakeholders involvement	PU	M08
M7, M8, M9, M10, M11 & M12 (M2.2.x)	Interim dissemination report	2	SPMS	Report about dissemination internal activities each semester	PU	M6, M12, M18, M24, M30, M36
M13, M14, M15, M16, M17 & M18 (M2.3.x)	External dissemination report	2	SPMS	Report about dissemination external activities each semester	PU	M6, M12, M18, M24, M30, M36
M19 (M3.1)	Draft evaluation strategy produced	3	ATNA	The first version of the evaluation strategy to be used is produced	СО	M3
M20	Final evaluation	3	ATNA	The final version of the evaluation	PU	M4

Milestone Number	Milestone name	WP	Lead Applicant	Content Description	Diss. Level	Delivery Month
(M3.2)	strategy produced			strategy to be used is produced		
M21 (M3.3)	Draft of final evaluation report produced	3	ATNA	The first version of the final evaluation report deliverable is produced	СО	M32
M22 (M3.4)	Final Evaluation Report	3	ATNA	Report on strategy, outcomes and evaluation results of the project activities	PU	M36
M23 (M4.1.1)	Positioning report task 4.1 finished	4	NICTIZ	Positioning report with status about T4.1	PU	M10
M24 (M4.1.2)	Positioning report task 4.2 finished	4	NICTIZ	Positioning report with status about T4.2	PU	M10
M25 (M4.1.3)	Positioning report task 4.3 finished	4	NICTIZ	Positioning report with status about T4.3	PU	M10
M26 (M4.1.4)	Positioning report task 4.4 finished	4	NICTIZ	Positioning report with status about T4.4	PU	M10
M27 (M4.2.1)	Draft for discussion D1 finished	4	NICTIZ	The first version of the D4.1 – Policy framework on Patient Empowerment	PU	M16
M47 (M4.2.2)	Final for adoption D1 finished	4	NICTIZ	Final document about Policy framework on Patient Empowerment	PU	M22
M28 (M4.3.1)	Draft for discussion D2 finished	4	NICTIZ	The first version of the D4.2 – Policy proposal	PU	M28
M29 (M4.3.2)	Final for adoption D2 finished	4	NICTIZ	Final document on Policy proposal	PU	M34
M30 (M5.1)	Document on compiled policy relevant documentation finished	5	NHSC	Document on compiled policy relevant documentation including the EU Study and the effects of GDPR and review on MS/C policy level efforts on governing big data in health	PU	M6
M31 (M5.2)	Document on identified obstacles finished	5	NHSC	Document on identified obstacles preventing MS/C policies from being replicable either in other MS/C or on EU level, and proposal on how to overcome these	PU	M12
M32 (M5.3)	Document outlining the added value of big data finished	5	NHSC	Document outlining the added value of big data on eHN/ governance level with the EU Study recommendations operationalized	PU	M18
M33 (M5.4)	Report for the information on policy level actions finished	5	NHSC	Report for the information of the eHN on policy level actions including an initial set of enabling actions based on the recommendations of the EU Study to support awareness raising and communication of the added value of	PU	M24

Milestone Number	Milestone name	WP	Lead Applicant	Content Description	Diss. Level	Delivery Month
				big data to different stakeholder groups, especially on the Governance level in MS/C via the eHN. (Deliverable D5.1)		
M34 (M5.5)	Preaparation for task 5.2 finished	5	NHSC	Preparation for task 5.2 by analysing and structuring delivered information of D5.1	СО	M18
M35 (M5.6)	Report on identified cross-border use cases finished	5	NHSC	Report on identified cross-border use cases, practical solutions with potential for European scale usage and benefits, including assessment of pros & cons of stakeholders. (Deliverable D5.2)	PU	M18
M36 (M5.7)	Preparation for task 5.3 finished	5	NHSC	Preparation for task 5.3 by analysing and structuring delivered information of D5.1 and D5.2	СО	M32
M37 (M5.8)	Paper on the implementation of common principles finished	5	NHSC	Discussion Paper for the eHN on the implementation of common principles for practical governance of big data with a special focus on data to be used in public health, research and quality assurance in healthcare on a European scale with guidance on implementation of data access and use. (Deliverable D5.3)	PU	M36
M38 (M6.1)	Adoption of the Roadmap reached	6	gematik	Adoption of the Roadmap on future eHDSI use cases and features by eHealth Network reached	PU	M12
M39 (M6.2)	Adoption of the eHDSI legal report reached	6	gematik	Adoption of the eHDSI legal report by eHealth Network reached	PU	M18
M40 (M6.3)	Adoption of the Report on eSkills reached	6	gematik	Adoption of the Report on eSkills for Professionals by the eHealth Network reached	PU	M24
M41 (M7.1)	Draft of D7.1 finished	7	3 <sup>rd</sup> RHA	First draft of deliverable D7.1 finished and sent to partners for validation	PU	M30
M42 (M7.2)	Draft of D7.2 finished	7	3 <sup>rd</sup> RHA	First draft of deliverable D7.2 finished and sent to partners for validation	PU	M14
M43 (M7.3)	Draft of D7.3 finished	7	3 <sup>rd</sup> RHA	First draft of deliverable D7.3 finished and sent to partners for validation	PU	M21
M44 (M8.1)	Draft of D8.1 finished	8	MoH-FR	First draft of deliverable D8.1 finished and sent to partners for validation	PU	M12
M45 (M8.2)	Early draft of D8.2 finished	8	MoH-FR	Very early draft of deliverable D8.2 finished and sent to partners for filling	СО	M18

Milestone Number	Milestone name	WP	Lead Applicant	Content Description	Diss. Level	Delivery Month
M46 (M8.3)	Draft of D8.2 finished	8	MoH-FR	Second draft of deliverable D8.2 finished and sent to partners for validation	PU	M36

## 9. PROJECT MANAGEMENT STRUCTURE

## 9.1 Quality of the partnership

The JA consortium is composed of organizations competent in the field of eHealth nominated by the participating EU Member States and third countries as required by the procedure for JA under the Third Programme for the Union's action in the field of health (2014-2020). It includes ministries, national competent authorities or national executive agencies, universities, healthcare providers and health insurance funds. In total, the JA consortium has 22 associated partners, 8 affiliated entities and 10 collaborating stakeholders. Hence, a total number of 40 partners from 28 EU countries plus Moldova, Norway, Serbia and Switzerland are involved in this JA. The consortium contains broad and diverse expertise relevant to carry out this JA as the partners are all key actors in the European and national field for the development and deployment of eHealth. To ensure the success and efficiency of the JA, close collaboration with high-level policy makers will be maintained through the direct communication with the eHN co-chairs.

The governance structure of the JA consists of the following bodies:

- eHealth Network (eHN)
- Steering Council (SC)
- Leadership Council (LC)
- Action Coordinator (AC)
- Coordination Office (CO)
- Quality Management (QM)
- Risk Management (RM)
- Work Package Leader and Co-Leader (WPL)

The overall governance structure is depicted below:

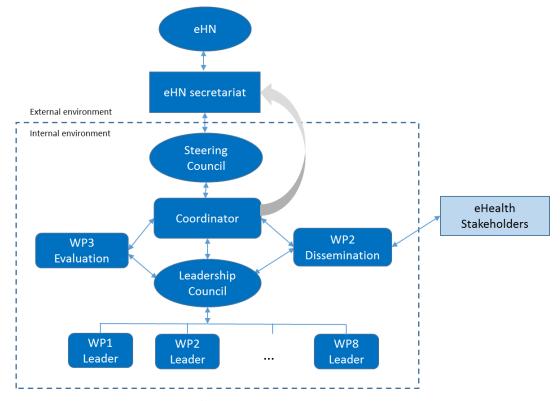


Figure 2: Governance structure

#### eHealth Network

The eHealth Network (eHN) was formally established in 2011 through the Commission's Implementing Decision 2011/890/EU based on Art. 14.3 Directive 2011/24/EU and represents the highest decision-making body at EU political level. The eHN is substantially influencing the work on both levels of the JA, the strategic and operational level. Deliverables elaborated by WP4 – WP8 are expected to be submitted to the eHN as discussion or decision basis. Its content follows closely the structure of the eHN's MWP 2018-2021. The eHN is composed of the secretaries of states, director generals or CEOs of the competent authorities of the MS/C and is co-chaired by EC and a MS/C representative, elected by its members on a regular basis and according to the eHN's Rules of Procedures. The eHN meets twice per year. These bi-annual meetings are prepared by the eHN secretariat provided by DG SANTE. For the success of this JA, a close strategic and organisational cooperation between the eHN and this JA is absolutely vital.

## **Steering Council**

The Steering Council (SC) deals with the strategic implementation of the eHAction and focuses on the final preparations of eHN meetings with regards to contents. The SC is chaired by the Action Coordinator and is composed of all nominated entities and their affiliated entities. The SC will be supported by the **Coordination Secretariat (CS)**.

The SC meets on a quarterly basis (every 3 months) – twice F2F plus twice by tcon. In addition, informal meetings (twice per year) are to be arranged in order to debrief project partners on eHN meeting outcomes. These activities are important for proper preparation and follow-up of eHN meetings and to move forward quickly and in accordance with the needs of the eHN.

## **Leadership Council**

The Leadership Council (LC) is responsible for aligning and coordinating the ongoing work across all WPs through a continuous assessment of inputs and emerging results. It is composed of all WP leaders and coleaders and is chaired by the Coordinator. LC is also responsible for preparing proposals for SC as well as carrying out executive decisions, i.e., actions that do not require SC approval. LC works closely with the Risk Management and Quality Management. The WPLs itself are responsible for leading (or co-leading) their WP and the respective Tasks in accordance with the objectives in this proposal.

The LC will meet F2F twice a year, on the following day of eHN meeting and regularly once a month by Tcon. Additional communication is to be done by email or Tcon.

#### **Action Coordinator**

The Action Coordinator (AC) ensures close strategic alignment between the two eHN co-chairs, particularly when it comes to the preparation of the eHN's meeting agendas. The AC ensures appropriate and endorsed contact between the consortium and the European Commission (EC) services and will oversee liaison with the eHN particularly through the eHN secretariat. The AC represents the partners in all formal relationships with the EC and the eHDSI Governance bodies. The AC chairs meetings of the SC and the LC. The AC is supported by a Project Management Team in charge of daily management of the Action incl. organisational and financial issues. The Project Management Team, together with the LC, supports the AC with a proper steering of the project and its technical and organisational implementation.

### **Coordination Secretariat**

The administrative support of the Action will be carried out by the Coordination Secretariat (CS) established at the premises of the Coordinator. The CS team is in charge of carrying out secretarial support with financial and administrative matters as well as dealing with communication and legal matters.

The CS also liaises with the EC services on all project administrative issues and deals with all relevant reports towards the EC. The CS is also in close contact with the eHN secretariat. Technical execution of the project is followed and monitored by the CS based on reporting sheets delivered regularly by relevant partners. Furthermore, the CS is in charge of secretariat's activities, organization and logistics of meetings, workshops and other corresponding events. The CS thereby assists WP1 and also WP2 with all kinds of

communication activities as well as the organisation and maintenance of the project's collaborating platform(s) availability for the project participants.

For this JA it is of utmost importance that all aspects of dissemination and communication are very well articulated. To have strong marketing, WP1 and WP2 will be very connected, through the CS team. The CS ensures a strong interconnection among all relevant groups of eHealth stakeholders guaranteeing their access to information and promoting their active role on direct and reliable dialogue with different tasks of the project. The SC further deals with a proper steering of the communication to all partners and eHealth stakeholders involved.

## Work Package Leader/Co-Leader

All core Work Packages have a Leader and a Co-Leader. Both are co-responsible for leading the WP and the respective Tasks accordingly to the objective and description of work in this proposal. For e.g., if a WP has 4 Tasks, each WPL will be responsible also for 2 Tasks. Both coordinate the work in close cooperation, supporting each other, taking decisions and being able to substitute each other if needed in meetings.

## **Quality Management**

The Quality Manager (QM) is responsible to establish and follow a proper process of Quality Assurance of Deliverables. This process aims to ensure a structured mechanism for the elaboration of the project's deliverables and its professional review before the documents will reach the main target group, i.e. the eHN. The QM is delivered by the AC.

## Risk Management

The Risk Manager (RM) is responsible for guarantee the process of Risk Assessment. Through a defined process, risks need to be systematically identified, assessed, planned and mitigation measures implemented. Threats and planned responses will be communicated inside and outside the Action. Risks are monitored and managed at all levels throughout the project.

The risk manager is not responsible for issue management.

## eHealth Stakeholders

eHealth stakeholders can engage any time by their own decision, preferably through the eHealth Stakeholder Group<sup>2</sup>, provided that its mandate will be get extended. The main communication channel of the eHAction towards the eHealth Stakeholders is WP2 (in close cooperation with WP1). Furthermore, the LC can propose to the SC concrete suggestions about eHealth Stakeholder involvement in certain activities.

The potential participation of eHealth Stakeholder representatives in meetings or workshops of the eHAction is to be aligned between the respective WP Leader(s) and WP2 and communicated towards the SC. The concrete operational process on how to involve eHealth Stakeholders is to be defined at the beginning of the project and agreed by the SC. Recommendations from JAseHN WP4 Stakeholder Liaison are to be considered when setting up this process.

Further details and rules about the above listed bodies and how these are interacting with each other are to be defined in the project's Rules of Operation.

## 9.2 Capacity of the staff

## 9.2.1 PT – SPMS – Serviços Partilhados do Ministério da Saúde, E.P.E. (SPMS) – Coordinator

Organization profile

<sup>&</sup>lt;sup>2</sup> https://ec.europa.eu/digital-single-market/en/news/new-members-ehealth-stakeholder-group-have-been-selected

SPMS is the Shared Services for Ministry of Health. It is the Health Ministry Central Purchasing and IT authority. It is a public enterprise created in 2010 functioning under the guardianship of the Ministries of Health and Finance. Its aim is to provide shared services – in the areas of purchasing and logistics, financial services, human resources and ICT – to organizations operating specifically in the area of health, in order to "centralise, optimise and rationalise" the procurement of goods and services within the NHS.

As part of the shared services of information systems and technologies, SPMS, E.P.E. aims to cooperate, to share knowledge, information but also to develop activities for providing services in the areas of health information and communications systems and technologies ensuring that all information is available in the best way for all citizens, taking a central role in their dissemination and thus in promoting digital literacy in health in Portugal.

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.

SPMS will be the **coordinator** of the Joint Action and WP2 Dissemination leader.

## CV of key persons

Henrique Martins, of, MD, PhD. Studied Medicine and is an Internal Medicine Specialist. He obtained his PhD degree in Management from the Judge Business School, University of Cambridge. He has several publications in the area of management and informatics in healthcare. He currently works at SPMS as Chairman of the Board. SPMS is the Health Ministry Central Purchasing and IT authority. He was formerly the Chief Medical Information Officer (CMIO) of the Hospital Prof Dr Fernando Fonseca and later Adjunct for Health IT to the Health Secretary of State. He is responsible for nationwide efforts on complete electronic prescription and new Health Information Platform Sharing for Electronic Health Records.

Diogo Martins, of, 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 d in the field eHealth: "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 citizen's in order to healthcare improvements. Currently he works at SPMS and is responsible for the International Projects as well as and International Cooperation

Lília Marques,  $\$ , 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 Projects Office 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 is supporting 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.

Micaela Seemann Monteiro, ♀, is a physician, senior specialist in Internal Medicine. She was conferred the Competence in Emergency Medicine by the Portuguese Medical Board. She graduated at the Heinrich-Heine-Universität in Düsseldorf, Germany and trained in Germany, Great Britain and Portugal. She was director of emergency departments for over 10 years. In this context, Micaela and her team won the Quality Award of Maria Amélia de Mello. She is Board Member of the Portuguese Resuscitation Council. Micaela investigated and published in the field of serious games for medical education. She is member of the Special Interest Group Technology and Process of Care da European Society of Emergency Medicine. She attended the Health Sector Senior Management Programme of AESE Business School and is postgraduate in information management and business intelligence in healthcare by NOVA Information Management School. Since September 2016 she works at the Shared Services of the Portuguese Ministry of Health − first as Planning and Organizational Development Director with the major task of setting up the new National

Center of Telehealth – and more recently as Director of the National Center of Telehealth with responsibility of the Contact Center of the National Health Service. Micaela has participated in several European projects in the health IT area.

**Diogo Gomes**, , MD, has a bachelor degree in Industrial Management Engineering, holds a Master Degree in Public Management with thesis in the field of Information Systems in Public Administration, European University, postgraduate in Organization of Events, Image and Protocol, Lisbon University, Postgraduate in digital strategic communication. He currently works at SPMS as Coordinator of public relations, external affairs, protocol and strategic digital communication. He was councillor adjunct at Municipality of Santarém and Engineer at Lusiprojecto – Engineering Solutions.

Vanessa Viana, ♀, graduated in Civil Engineering and in a course in Graphic Design. She has worked in the private health sector, in the area of Neurodevelopmental disorders, creating multi neurocognitive stimulation apps for children. Vanessa Viana has also worked in branding and digital communication for the pharmaceutical sector. She currently works at SPMS as a graphic designer in the communication and public relations department, being responsible for websites, apps and digital communication.

*Kelly Santos*, ♀, has a degree in Law from Universidade Portucalense Infante D. Henrique, Porto, holds a MD in Administrative-Law Science. She obtained his PhD in Politics Science from ISCTE-UL. She was formerly Jurist in "Julgado de Paz" and Nacional Ministry of Defence. She currently works at SPMS as Jurist in specific for International Projects and Legal affairs.

João Pedro Martins, of, has BSc and MSc in Biophysics and Biomedical Engineering with specialization on Clinic Engineering and Medical Instrumentation from University of Lisbon. He is also postgraduate in information management and business intelligence in healthcare by NOVA Information Management School. In 2014-2015 he worked on developing Business Intelligence solutions in the health sector (SPMS - Shared Services of the Portuguese Ministry of Health) and telecommunication sector. Since 2015 he works on SPMS as a project manager of Business Intelligence projects, namely, the Economic and Financial Managements Information System, the Contratualization and Monitoring Information System and the health open data initiative (Transparency Area). More recently, he is coordinator of Advanced Analytics and Intelligence unity with the responsibility of managing all the Business Intelligence products of SPMS providing and sharing data to NHS professionals and Portuguese citizens.

*Rui Galhardo*, ♂, MD, Graduated in Management in ISEG – UTL. Holds a post-graduated in Auditing, Public Finance and Budget Management and more recently a Mater degree in Economics and Public Policies. He was formerly consultant, auditor and inspector at several private companies and public entities. He currently works at SPMS as Coordinator of Internal Financial Services.

João Nascimento, of, graduated in Financial Enterprises Degree by ISCAL with expertise and certification in Official Accountant. He has several experience in account and Finance Controller. Currently he works at SPMS as Finance Controller with the following responsibilities: ensuring the compliance of program controlling procedures, such as public budget; Definition of financial processes and reporting; International Report Period analysis;

Ana Almeida, postgraduate in Public Accounting, Public Finance and Budget Management by ISEG and a degree in Organization and Management of Companies by UML with several specialized courses: Specialization in Procurement and Public Procurement, Training Program in Public Management. She has worked as a trainer in the Management and Administration area in several training entities. She was director of Cultural Strategy, Planning and Evaluation in the Office of Strategy, Cultural Planning and Evaluation - GEPAC; Director of the Ministerial Unit for Cultural Purchases, at the General Secretariat of the Ministry of Health; She was head of the division of assets and facilities of the General Secretariat of the Ministry of Finance and Public Administration. Since 2014, she has been the Director of Human Resources at SPMS. She is also responsible for the SPMS Training Academy, supporting all qualification and innovation activities directed to the National Health Service and entities under the Ministry of Health.

# 9.2.2 AT – Bundesministerium für Arbeit, Soziales, Gesundheit und Konsumentenschutz (ATNA)

Organization profile

The Federal Ministry of Labour, Social Affairs, Health and Consumer Protection 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, eHealth, communicable and non-communicable diseases, medicinal products and medical devices, public health but also for animal health and food safety. The Ministry of Labour, Social Affairs, Health and Consumer Protection has taken over 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 current nationwide implementation of an Electronic Health Record system (ELGA), 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.

## CV of key persons

*Dr. Clemens-Martin Auer* is the Director General. He is responsible for financing and planning issues of the Austrian Health System, for hospitals, eHealth, ministry infrastructure and European as well as international relations

*Manfred Pregartbauer* is head of department 'Information Management' and CIO, member of the national ICT coordination platform for the public administration sector, in this context responsible for aligning eGovernment and eHealth applications; experience in eHealth coordination nationwide and at EU level.

**Robert Scharinger**, Deputy 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.

**Dr. Peter Brosch** studied Science of Communication, is Head of the Unit "Hospital Financing, DRG, Semantics". He worked in several information projects, Austria's EU-integration and several working groups at the European level, among others on eHealth. Main areas of work are the Austrian DRG-system and the improvement of medical documentation primarily in the ambulatory care sector, aiming at a better integration of inpatient and outpatient care services. By now work on European level focuses on Semantic Interoperability.

**Leonhard Kamper, LLM** studied law in Austria and France with a focus on Austrian Public law as well as European Union law, and has been working as a legal advisor since 2011. He is involved in various national activities related to eHealth and has been following the work of the eHealth Network and its preparatory projects since 2012. In 2016/2017 he was leading the JAseHN legal task which delivered the Legal Agreement now serving as the legal basis for cross-border exchange of health data in scope of eHDSI.

#### GOeG – Affiliated entity profile

Gesundheit Österreich GmbH (Acronym: GOeG), www.goeg.at is Austria's national non-profit Public Health Institute, owned by the Federal Ministry of Health and Women's Affairs (MoH). It was established in August 2006 with 3 business units.

- OeBIG (Austrian Health Institute): Established in 1973 to govern and promote the Austrian health care system. It is providing scientific services in the form of research, consultancy, policy advice, evaluation, education and training.
- BIQG (Austrian Institute for Quality Assurance in Health Care): Established in 2007 to evaluate, ensure and further develop the quality of health care services.
- FGOe (Austrian Health Promotion Foundation): Since 1992 FGOe has the goal of strengthening the role of health promotion and prevention in Austria.

Our 200 employees 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 health care reform (e.g. in the field of primary health care 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 JAs on e-Health.

In 2016, GOeG was present at a number of international meetings and conferences, such as the EPH Conference "All for Health - Health for All" in Vienna where we organised a session. GOeG contributes for instance also to the Expert Group on health systems performance assessment.

e-Health, electronic health information, telemedicine and big data is of growing importance for public health of European citizens, which is why this topic is high on our agenda. We have also plenty of experience with managing health data, with hosting one of Austria's most comprehensive data warehouse systems in health. Also we run the Austrian national electronic health information platform www.gesundheit.gv.at

## CV of key persons

**Prof. Dr. Herwig Ostermann** is Executive director of the Austrian Public Health Institute GOeG and associate professor (part-time) at the Department for Public Health and Health Technology Assessment at the University for Health Sciences, Medical Informatics and Technology in Hall/Tyrol, Austria (UMIT). He studied international economics in Innsbruck and Dublin and holds a master's and doctoral degree in Health Sciences from UMIT. Herwig has an in-depth knowledge of national and international health systems serving as an advisor to the Austrian Ministry of Health with regard to structural and economic impacts of the health reform. His research interests encompass various aspects of economic forecasting, impact assessment and economic evaluation based on routine data. He is member of various international committees and expert groups (e.g. Austrian Country Focal Point for Austria for the Coordinated/Integrated Health Services Delivery (CIHSD) of WHO/Europe; Member of the EU Expert Group on Health System Performance Assessment, Country Focal Point for the European Observatory on Health Systems and Policies) and has served as an international expert in various policy dialogues organised by the European Observatory. Herwig Ostermann hosted the session on "Big Date for Public Health – Public Data for Big Health" at the 2017 eHealth Summit.

Mag. Claudia A. Habl 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 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 Study on Big Data in Public Health, Telemedicine and Healthcare, https://ec.europa.eu/digital-single-market/en/news/study-big-data-public-health-telemedicine-and-healthcare and has more than a decade of experience in managing and leading large-scale EU project.

She is currently General Secretary of the EURIPID Collaboration and Austrian Member of the TO.Reach project towards an ERA-NET. She is consultant to EU and WHO for a number of topics, including Big Data in Health care, medicines policy, and HTA – just to mention the current ones.

*PhDr. Isabella Weber, M.A.*, is employed by the Gesundheit Österreich GmbH but works for the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection 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. Since 2015 she is project coordinator of the Joint Action to support the eHealth Network (JAseHN).

*Mag. Barbara Schmeissl* is employed by the Gesundheit Österreich GmbH but works for the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection since 2014. After she finished her studies in law, she was working for the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection as a legal trainee for medical law, especially in the fields pharmaceutical law and patient rights. Since 2015 she is responsible for the operational project management of the Joint Action to support the eHealth Network (JAseHN).

## ELGA – Affiliated entity profile

ELGA GmbH is the joint institutional body set up by the Austrian health authorities on national and regional level and the social insurance. Tasks are the conception, implementation and ongoing servicing of a national EHR-system. Co-operations encompass all national eHealth and eGovernment activities (e.g. person identification, registers, electronic signature). ELGA GmbH was the active beneficiary and participant in the

EC large scale pilot epSOS and supported the development of national interoperability standards and implementation guides.

## CV of key persons

Norbert Répás studied Radio Electronics and Medical Electronics at the Technical University in Pressburg, Faculty of Electrical Engineering and Information Technology. He followed a study at the Slovak Academy of Sciences at the Institute of Measurement, focusing on tomographic methods. Has many years of experience in programming of technological, industrial and pharmacy processes. Participated in the epSOS (service infrastructure that demonstrates cross-border interoperability between electronic health record systems in Europe) project and was involved mainly in the NCP (National Contact Point) testing automation. He works on different requirements documents and solution descriptions at the Architecture and Standards Department at ELGA GmbH.

**Stefan Sabutsch**, he is senior project manager and director of division usability and standards. He is founder and chairman of HL7 Austria and primarily responsible for the specification of HL7 CDA Implementation Guides and accompanied usability guidelines in Austria. He is contributing and coordinating several activities on standardization in context of eHealth with national and international SDOs.

Oliver Kuttin, holds degrees in computer science and public health informatics (MSc.), medical university of Vienna, center for medical statistics, informatics and artificial intelligence. He is solution architect for ELGA at the division for standards and architecture. He has contributed to the epSOS large scale pilot as task leader for requirements management and member of the technical project management team. His work focuses primarily on methods of semantic interoperability utilizing classification systems, taxonomies & ontologies (e.g. ICD, SNOMED-CT), on standard-based approaches for integrating medical data from distributed health information systems, as well as security concepts facilitating user identification /authentication/authorization in federated usage scenarios

## 9.2.3 **CY – Ministry of Health (MoH-CY)**

## Organization profile

The Cyprus team consists of the Ministry of Health and the University of Cyprus. This team was awarded the CEF proposal entitled "Deployment of Generic Cross Border eHealth Services in Cyprus". eHealth is one of the priority initiatives of the Ministry for achieving high-quality and sustainable health care and envisions that the award of this proposal will facilitate the Ministry in achieving its mission

The University of Cyprus (UCY) is the largest University and main research organisation in Cyprus. UCY has a student population of 7000 (2000 graduate). The Dep. of Computer Science has 21 faculty members, and 100 postdoctoral researchers and PhD students. Its research activities cover Intelligent and Distributed Systems, Software Engineering, Internet and Mobile Technologies, eHealth, and eGovernment. The Dep. publishes more than 100 journal papers per year and attracted a total funding of more than 30 MEuro in the last decade.

## CV of key persons

**Monica Kalakouti** (female) is Senior Information Technology Officer. She has been working at the Information Technology Services of the Public Service of Cyprus, in various positions since 1989. Currently she is in charge of the IT Unit of the Ministry of Health which consists of 28 IT officers. Current responsibilities include: apply the Ministry's strategy in terms of ICT Systems, managing of all the IT Computerized Systems in the Ministry, managing all projects and Tenders in progress (new IHCIS system for all hospitals, National Contact Point for Cross Border (NCPeH) under CEF, Digitization of Health Records, etc.).

Minas I. Kyriakides (male) is ICT Coordinator. Graduated from Athens University in 1988. Master in Public Sector Management (2000). M.A in Health management (2013). Registered as Dental Surgeon in the Cyprus Dental Association (1988). Appointed in the public service as a Dental Officer (1991-2001). ICT coordinator of the Ministry 2001 - today with active involvement in various co-funded projects, participation in EU committees, working groups and steering groups and current involvement as expert in eHealth.

Constantinos S. Pattichis (male) is Professor with the Dep. of Computer Science and Director of the eHealth Lab. He has 25 years of experience in eHealth systems, medical imaging, biosignal analysis, intelligent systems, and more recently in life sciences informatics. He has been involved in numerous projects in these areas funded by EU and other bodies, with a total funding managed close to 7 million Euro. He has published 100 journal publications, 210 conference papers, and 27 chapters in books in these areas (no. of citations more than 6300, h-score 40). He is Co-Editor of the books M-Health: Emerging Mobile Health Systems, and Ultrasound and Carotid Bifurcation Atherosclerosis, published in 2006 and 2012 by Springer, and was 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 others.

Christos N. Schizas (male) is Professor with the Dep. of Computer Science and Co-Director of the eHealth Lab, and Director of the Computational Intelligence Lab (CIL). 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. Received the B.Sc. degree in electronic engineering from the University of London, UK, in 1978, the M.B.A degree from the University of Indianapolis, Indiana, in 1988, and the Ph.D. degree in systems theory from the University of London in 1981. He received the 1979 William Lincoln Shelley award from the University of London for excellence in research, and a Fulbright fellowship for collaborative research in the USA in 1993. He was a Fellow of the IEE, Fellow of the British Computer Society and Senior Member of the IEEE. He edited conference proceedings and served as associate editor of the journal Technology and Health Care, area editor of the journal IEEE Trans. on Information Technology in Biomedicine, and member of the editorial board of the journal of Intelligent Systems.

*Dr Kleanthis Neokleous* received his PhD from the Computer Science Department of the University of Cyprus in June 2011. He has previously obtained a BA and MSc in Mechanical Engineering from the National Technical University of Athens (NTUA) as well as a double MSc in Space Science and Technology from the Lulea University of Technology in Sweden and an MSc in Space Systems and Automation from the Czech Technical University in the Czech Republic. His research interests are mostly concentrated around the scientific areas of computational intelligence (CI) and eHealth. Dr. Neokleous has been a Research Associate at the Department of Computer Science of the University of Cyprus since 2008, where he is a member of the Computational Intelligence Laboratory.

## University of Cyprus – Affiliated entity

#### Organization profile

The University of Cyprus (UCY) is the largest University and main research organisation in Cyprus. UCY has a student population of 7000 (2000 graduate). The Dep. of Computer Science has 21 faculty members, and 100 postdoctoral researchers and PhD students. Its research activities cover Intelligent and Distributed Systems, Software Engineering, Internet and Mobile Technologies, eHealth, and eGovernment. The Dep. publishes more than 100 journal papers per year and attracted a total funding of more than 30 MEuro in the last decade.

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 (Unilogic, Infotex, Signal Generix, Stremble, Istognosis, and other).

The eHealth lab based on previous project experience is working towards deploying in real operation in the clinical setting the following three platforms: (i) EHR, (ii) Patient, and (iii) Multi-centre data analytics and knowledge extraction. To cover the needs of the first two platforms the eHealth lab exploits the knowhow and open source software tools of the electronic health record and PACS that were developed under the fi-

star project by our team (see P.1 below - Fi-star is an EU FP7 Future Internet ICT project, www.fi-star.eu). Moreover, the needs of the EHR and PACS were clearly identified and shaped in the EHR national project carried out by our team in collaboration with the Ministry of Health of Cyprus, the eHealth unit (see P.3). Additionally, for the patient platform, the group capitalizes on its expertise and tools in the development of serious games and home monitoring for the elderly via the partnership with the Long Lasting Memories – project (see P.5, <a href="https://www.longlastingmemories.eu">www.longlastingmemories.eu</a>).

## CV of key persons

**Prof. Constantinos S. Pattichis** (male) is Professor with the Dep. of Computer Science and Director of the eHealth Lab. He has 25 years of experience in eHealth systems, medical imaging, biosignal analysis, intelligent systems, and more recently in life sciences informatics. He has been involved in numerous projects in these areas funded by EU and other bodies, with a total funding managed close to 7 million Euro. He has published 100 journal publications, 210 conference papers, and 27 chapters in books in these areas (no. of citations more than 6300, h-score 40). He is Co-Editor of the books M-Health: Emerging Mobile Health Systems, and Ultrasound and Carotid Bifurcation Atherosclerosis, published in 2006 and 2012 by Springer, and was 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), and of the IEEE Journal of Biomedical and Health Informatics (J-BHI) on Computational Solutions to Large-Scale Data Management and Analysis in Translational and Personalized Medicine (2014). Moreover, he serves as Distinguished Lecturer and member of the Technical Committee on Biomedical and Health Informatics of the IEEE EMBS, and an Associate Editor of the IEEE J-BHI. He was general chair of IEEE International Conferences on Information Technology Applications in Biomedicine (ITAB 2009), and Bioinformatics and Bioengineering (BIBE 2012), and he is the general chair of the 13th Medical and Biological Engineering and Computing (Medicon 2016). He is a Fellow of IET, and Senior Member of IEEE.

**Prof. Christos N. Schizas** (male) is Professor with the Dep. of Computer Science and Co-Director of the eHealth Lab, and Director of the Computational Intelligence Lab (CIL). 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. Received the B.Sc. degree in electronic engineering from the University of London, UK, in 1978, the M.B.A degree from the University of Indianapolis, Indiana, in 1988, and the Ph.D. degree in systems theory from the University of London in 1981. He received the 1979 William Lincoln Shelley award from the University of London for excellence in research, and a Fulbright fellowship for collaborative research in the USA in 1993. He was a Fellow of the IEE, Fellow of the British Computer Society and Senior Member of the IEEE. He edited conference proceedings and served as associate editor of the journal Technology and Health Care, area editor of the journal IEEE Trans. on Information Technology in Biomedicine, and member of the editorial board of the journal of Intelligent Systems. He was 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 Dep. of Computer Science, University of Cyprus, where he served as Interim Chair, Member of the Senate, and Vice Rector. He has taken part in European Commission initiatives for promoting the Information Society, especially the Euro-Mediterranean partnership. He has been a member of the Committee, formed by the Minister of Communications and Works in 1996 for establishing the Information Society in Cyprus, and member of the advisory committee of the Ministry of Commerce and Industry for promoting High Technology in Cyprus. Advisor to the Cyprus Ministry of Health; coordinator of a team of experts that prepared the tender document and evaluated the proposals for the Health Information System in Cyprus. Participated in the eHealth Week, Ministerial meeting – Dublin 2013 as National Representative and invited speaker at the eHealth Forum, Ministerial meeting - Athens 2014, Riga 2015, Amsterdam 2016 and Malta 2017. He lectures the course on eHealth at a master's level, and at the Schools of Medicine (UCY).

*Dr Marios Neofytou*, 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. From 2008-today, is a Visiting Lecturer in the several public and private Universities. Also, he is the administrator of the eHealth Lab of the Computer Science Department, at the University of Cyprus. He has published several journals and conference papers in the fields of telemedicine, e-learning, medical imaging and medical informatics. Dr Neofytou is a member of IEEE EMB Society, IEEE Computer Society and the Hellenic society of Biomedical Engineering.

*Dr Kleanthis Neokleous* received his PhD from the Computer Science Department of the University of Cyprus in June 2011. He has previously obtained a BA and MSc in Mechanical Engineering from the National Technical University of Athens (NTUA) as well as a double MSc in Space Science and Technology from the Lulea University of Technology in Sweden and an MSc in Space Systems and Automation from the Czech Technical University in the Czech Republic. His research interests are mostly concentrated around the scientific areas of computational intelligence (CI) and eHealth. Dr. Neokleous has been a Research Associate at the Department of Computer Science of the University of Cyprus since 2008, where he is a member of the Computational Intelligence Laboratory.

Dr Andreas. S. Panayides (EMBS Member, Senior IEEE Member) is with the Electronic Health (eHealth) Laboratory of the University of Cyprus. He is also a Visiting Research Assistant Professor at the University of New Mexico (Image and Video Processing and Communications group). Formerly, he was a Marie Curie Fellow with the Communications and Signal Processing group at Imperial College. His research interests lie in adaptive video delivery for real time applications, mHealth and eHealth systems, pervasive computing for healthcare applications, and interactive and distributed analytics of large video databases. He has published more than 50 peer-reviewed journal and conference papers, and book chapters, in these areas. He is the Guest Editor of IET Healthcare Technology Letters, Special Issue on mHealth-Emerging Mobile Health Systems and Services, and the holder of a pending patent on adaptive video processing and delivery. Dr. Panayides is actively involved in national and international research projects, funded by the European Commission, the Research Promotion Foundation of Cyprus, and recently the National Science Foundation (USA).

**Zinonas C. Antoniou** was born in Nicosia, Cyprus. He received his 5-year Engineering Diploma (Dipl.-Ing.) from the School of Electrical and Computer Engineering, of the National Technical University of Athens, in 2010. His major area was Computer Science. He is currently a Ph.D. student in the Department of Computer Science of the University of Cyprus, under the guidance of Prof. Constantinos Pattichis. He is also a member of the eHealth Laboratory. His major research interests include video processing and communications and mobile telecommunication networks. Zinonas has work experience as an IT programmer and administrator both in a University environment and in a non-governmental organization, giving him varied skills and the ability to work with many different types of people. He a conscientious person who works hard and pays attention to detail. Also, he is flexible, quick to pick up new skills and eager to learn from others.

*Ioannis Constantinou*, is a PhD candidate with the Dep. of Computer Science of the University of Cyprus. He graduated from the Department of Electrical and Computer Engineering from the National Technical University of Athens, and he has 8 years' experience in the development and implementation of eHealth web-based systems including medical imaging and mobile health systems.

## 9.2.4 CZ – The Ministry of Health of the Czech Republic (MZCR)

## Organization profile

The Ministry of Health is the central body of state administration for health services, public health, medical research activities, a provider of health services in the scope of direct control, the use of addictive substances, preparations and precursors and auxiliaries, search, protection and use of natural healing, natural healing spas and natural mineral water sources, pharmaceuticals and medical devices for the prevention, diagnosis and treatment of people, health insurance and health information system for use of biocidal products and the placing of biocidal products and active substances on the market.

## CV of key persons

Tomáš Bezouška graduated with a bachelor 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 nonprofit 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.

*Jiří Borej* holds a degree from the Faculty of Electrical Engineering, Czech Technical University in Prague (Master - Ing.). 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 of 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.

*Karel Neuwirt* graduated with a doctoral degree (RNDr) in informatics at the Faculty of Natural Sciences of Palacký University. In 2000, Václav Havel, President of the Czech Republic, appoints Dr. Karel Neuwirt President of the Office for Personal Data Protection. In 2006-2007 he worked as the team leader of the EU CARDS project on personal data protection in Macedonia. In 2009 he leaded the Council of Europe project for data protection in Albania. He has published a number of works and lectures on data protection in IT. Since 1995 he has been the Czech representative in the Council of Europe's data protection expert group (CJ-PD). By the end of 2003 he was elected first vice-chairman of the T-PD, the highest body of the Council of Europe for personal data protection. In March 2007 he was elected CoE Data Protection Commissioner. At its 26th meeting on 1-4 June 2010, the Consultative Committee of the Convention for the protection of individuals with regard to automatic processing of personal data (T-PD) re-elected Mr Karel Neuwirt.

**Petr Struk**, M.D., M.A. is a physician, psychologist, researcher, senior consultant, experienced project author and coordinator. Education: MD graduated 1977 – Medical School, MA graduated 1984 – Philosophy Faculty, Charles University, Prague. Former ministerial official and senior consultant. Retired since 2016. Since 2016 – temporary adviser to the Czech Ministry of Health, head of the eHealth committee of the Czech Medical Society, head of board - Czech Institute for Health Literacy.

*Martin Zeman*, holds a degree by The Faculty of Electrical Engineering, the Czech Technical University in Prague, course of technical cybernetics - medical biocybernetics (Master - Ing.), and a Postgraduate Diploma in Management Studies (DMS), specialization for management of health service organizations (The Nottingham Trent University, B.I.B.S, a.s.). He is a Chairman of the Czech Society of Medical Informatics and Scientific Information (part of Czech Medical Association of J.E. Purkyně) and a Director of Dept. of Informatics at Ministry of Health of the Czech Republic, that department has a function of a National eHealth Centre.

## 9.2.5 DE – Gesellschaft für Telematikanwendungen der Gesundheitskarte mBH (gematik)

## Organization profile

gematik was founded in 2005 by the 15 top organizations of the German Health System, gematik is the non-governmental body responsible for telematics 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).

- 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 and EXPAND consortium and is part of JAseHN consortium and coordinator of the German CEF eHealth consortium.
- 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 gematik engages in topics like eID, security, health professional registries.
- Within CEF eHealth gematik is the coordinator of the German Consortium and takes part in the eHealth Member States Expert Group for Germany.

## CV of key persons

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 Streit** (Female) holds a master's degree in medical information technology. At gematik she works in the section "Innovation" on a number of future applications including electronic Identification 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. She is work package and task leader as well as member of the strategic Project Steering Committee of JAseHN. Within JAseHN she is in charge of eID and of Stakeholder Liaison with EC's eHealth Stakeholder Group.

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 years 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.

**Rita Willecke** (Female) holds a degree in law and has been working as a test manager and project manager in several sectors, like banking, automotive and health care. She joined gematik in 2013 and worked as an expert for the admission board before joining the section "Innovation". She is now a member of the project management team CEFeH Germany and there she is responsible for all legal and organisational matters.

## 9.2.6 EE – Ministry of Social Affairs Republic of Estonia (MoSA)

## Organization profile

Objectives of the Ministry of Social Affairs emerge through compiling development plans for the fields being under our control, as well as organization-based development plans. We operate in the field of social security, where we have set for ourselves five strategic objectives:

- to ensure people's economic prosperity and their good work;
- to ensure people's social coping and development;
- to support the well-being of children and families;

- to promote people's mutual care, equal opportunities, and gender equality;
- to ensure people's long and high-quality life.

The role of the Ministry of Social Affairs is to plan the health care policy and organise its implementation.

The health care system and its developments are affected by changes in the society. The population is ageing, shrinking, and moving. As a result of increased health awareness and improvement in diagnostics and the overall standard of living, the number of appeals made to health service providers is increasing, as are the expectations of the people. Higher demands are placed on the availability, quality, and safety of health services as well as on the staff, whereas financial resources are always limited.

The objective of the Ministry of Social Affairs, together with relevant institutions, is to ensure the following through health policy:

- the availability, quality, and safety of health care;
- the awareness of and satisfaction with health services among residents.

## CV of key persons

Priit Tohver is currently the Advisor for E-services and Innovation at the Ministry of Social Affairs in Estonia supporting the digital transformation and innovation of the social security field in Estonia, including health, labor and social matters. Mr. Tohver is responsible for international affairs and is also the representative of Estonia to the eHealth Network. He is acting as a liaison officer for international organizations and networks coordinating and facilitating cross-border healthcare-service activities. Mr Tohver is a junior doctor by training. He 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 during the Estonian presidency of the Council of the EU. He has several years of experience representing Estonia to high level health meetings such as the World Health Assembly, the WHO Executive Board and the European Regional Committee. Priit 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' Association

## 9.2.7 EL – $3\eta$ YFEIONOMIKH HEPI $\Phi$ EPEIA MAKE $\Delta$ ONIA $\Sigma$ - 3rd Regional Health Authority of Macedonia - (3rd-RHA)

#### Organization profile

The 3rd Hellenic Health Region/ Regional Health Authority belongs to a network of seven (7) Regional Health Authorities established by the Greek state in the year of 2001, in order to meet the healthcare needs of the country, to advance primary and secondary healthcare, to ensure the effectiveness and proper organization of healthcare Institutions, to coordinate actions and promote policies concerning health services at regional level. The 3rd HHR is committed to meet the healthcare needs of its region and to implement health care policies designed by the Ministry of Health for Public Hospitals and a wide primary care network of health centres and units (e.g. 15 hospitals, 34 primary health centres, etc). It is important to notice that it is responsible to monitor the implementation of regional health policies set by the Ministry of Health. Moreover, is responsible to submit to the Minister of Health recommendations, proposals and plans aimed at comprehensive and effective delivery of health services to the Region.

## CV of key persons

Chondropoulos Konstantinos: Electronic Engineer (BEng), Electrical and Computer Science Engineer (BEng), MEng Electrical Sector, MSc Digital Systems. Holds PMP certification from PMI. Worked in big Technical Companies of Greece, in Petroleum industry, Cement Industry and in Hellenic Institute of Metrology. Worked at General Hospital of Thessaloniki "G. Papanikolaou", initially at the Biomedical Department and later as Head of the IT Department. Project Manager in various Biomedical and IT projects in Hospitals. Has teaching experience since 2000 in technical universities, in the National Centre of Public Administration (Regional Teaching Institute of public servants) and other training institutes. Currently he is Deputy Manager at General Hospital of Thessaloniki "O Agios Dimitrios". Member of JAseHN Greek work team since 2015. Coordinator of the Greek team of the 3rd JA on Ehealth.

**Dr. Mrs Stergiani** (Stella) Spyrou: Head of Directorate of Information Technology of 3d Hellenic Health Region. She has many years of experience in IT departments and more specifically in designing and implementing Hospital Information Systems. She has much experience in policy issues regarding information systems in health care and especially in eHealth in regional systems. She has participating in many r&d programs, in conferences and also she is a writer of several papers within the area of eHealth. She has also worked as a lecturer, teacher, tutor in educational departments (universities etc) in the thematic area of eHealth.

*Lambros Dermentzoglou*: Electrical and Computer Engineer. He received his M.Sc. on Signal Processing and Computer Networks from National and Kapodistrian University of Athens (Department of Informatics and Telecommunications) in 2002 and his Ph.D. on Microelectronics also from the same department in 2010. In 2011 he completed his M.Sc degree in Construction Management from Hellenic Open University. He has worked as an R&D engineer in Greece and abroad. Currently he is a member of the IT Department in Papageorgiou General Hospital of Thessaloniki.

Christina Dalatsi: B.Sc Computer Science, M.Sc Information Systems, M.Sc Quality Assurance. Head of IT Department at General Hospital of Thessaloniki "O Agios Dimitrios" since 2010. Member of JAseHN Greek work team. In master degrees' theses has dealt with eGovernment in health sector and implementing statistical analysis of quality data relating to the greek e-prescribing information system. Has teaching experience since 2011 in the field of eGovernment in the National Centre of Public Administration (Regional Teaching Institute of public servants). Excellent knowledge of English, French.

*Georgios Moysidis*, B.Eng. Systems Engineer. Head of Software Department of Directorate of IT of General Hospital of Thessaloniki "G. Papanikolaou", since 2006. Has worked as a Programmer at Singular-Logic in Thessaloniki and at Financial Company Profit House in Moscow) Excellent knowledge of English, Russian

## General Hospital Papageorgiou – Affiliated entity

## Organization profile

Papageorgiou General Hospital is a pioneer in the Greek Public Health sector for many years. The commencement of its operation in August 1999 and the establishment of the Teaching Clinics in 2004, has completed in the best possible way the staffing of the Hospital (1800 staff & approximately 500 students) which is currently engaged in a standing cooperation with the School of Medicine of the Aristotle University of Thessaloniki. The hospital includes: 30 clinics, 9 collaborative departments and 10 laboratory centers. The cornerstone of the hospital's philosophy behind its operation is the provision of high quality & patientcentric healthcare services. Over 71.500 patients per year are being treated at the hospital on an impatient basis. Approximately 20.000 surgeries are performed each year and 317.700 exams per year are done on an outpatient basis. The organization is dedicated in providing top quality care and has already certified the quality management systems which have been implemented in five different departments so far - the Nephrology Department, the Pathological Oncology University Clinic, the Radiodiagnostics Laboratory, the Emergency Rooms, the Department of Medical Physics & the Obstetrical and Gynecological clinic. The inspections performed by the TÜV Hellas certification body confirm the compliance of the departments with the requirements of ISO 9001:2008 in the administrative-organizational and nursing area. The G.N. Papageorgiou has recently established a Project Management Office, directed by PMP-certified project manager, in order to coordinate the several national and international projects and to ensure projects are meeting strategic objectives, staying on budget and sticking to their original goals. The hospital is active, among others, in the European Territorial Cooperation Programme CP INTERREG V-A Greece-Bulgaria 2014-2020, titled "Health Care Centre- Improving quality and accessibility of social health care services in cross-border regions" and in the Third Health Programme 2014-2020 - Joint Action-05-2016 -"Authorization of preparation processes in blood and tissues and cells".

## CV of key persons

*Lambros Dermentzoglou*: Electrical and Computer Engineer. He received his M.Sc. on Signal Processing and Computer Networks from National and Kapodistrian University of Athens (Department of Informatics and Telecommunications) in 2002 and his Ph.D. on Microelectronics also from the same department in 2010.

In 2011 he completed his M.Sc degree in Construction Management from Hellenic Open University. He has worked as an R&D engineer in Greece and abroad. Currently he is a member of the IT Department in Papageorgiou General Hospital of Thessaloniki.

## General Hospital of Thessaloniki George Papanikolaou – Affiliated entity

## Organization profile

The origins of the General Hospital of Thessaloniki "G. Papanikolaou" date back in 1920, when the Greek State founded a Sanatorium for patients with tuberculosis. Over the years, the General Hospital has evolved into a major institution for advanced medical care while at the same time providing a strong foundation for clinical and scientific research. Its clinical reputation was built on the treatment of medical conditions notably of the heart and lungs as well as of the hematopoietic system. The GHTH has 650 beds. It employs over 1200 medical doctors, biomedical scientists, nurses and other qualified personnel. It is organized in 24 departments, 6 intensive care units (2 general, 1 cardiology, 1 cardiac surgery, 1 respiratory, 1 burn), 17 Laboratories It is a reference centre for pulmonary diseases (specific infections and Cystic Fibrosis), Bone Marrow Transplant Centre in adults and children, and has a gene and cell therapy unit in experimental animals. It has a stem cell bank. It is also a Centre for Transcatheter Aortic Valve Implantation (TAVI) and other specialized units, Centre of spinal cord diseases and injury centre. It has a cochlear implant unit and a corneal transplant unit. It is a centre of plastic surgery and burn recovery for northern Greece. It has the unique maxillo-facial surgery department in northern Greece and is a centre for the rehabilitation of deficits in patients with oral cancer. It is a training centre for medical students from Aristotle University of Thessaloniki because it has 6 university departments. It trains doctors in 16 specialties. It also provides training to other health professionals such as psychologists, medical lab technicians, rescuers etc. It is also an official training centre for courses of urgent medicine such as BLS an ALS. Finally, it has its own nursing school. www.gpapanikolaou.gr/

## CV of key persons

*Georgios Moysidis*, B.Eng. Systems Engineer. Head of Software Department of Directorate of IT of General Hospital of Thessaloniki George Papanikolaou, since 2016. He has worked as a Programmer at the software firm Singular-Logic in Thessaloniki and at Financial Company Profit House in Moscow. He has excellent knowledge of English and Russian.

## 9.2.8 ES – Ministerio de Sanidad, Servicios Sociales e Igualdad (MSSSI)

#### Organization profile

The Ministry of Health, Social Services and Equality (MSSSI) is part of the General State Administration. It is responsible for implementing the Government's policy on health, strategic planning and health care, as well as the execution of the General State Administration powers to ensure citizens with the right to health protection. It is also responsible for the proposal and implementation of the Government's policy on social cohesion and inclusion, family, protection of children and care for dependent or disabled persons and equality, as well as against all kinds of Discrimination and against gender-based violence. Within the competences, the MSSSI is on charge of the coordination of the Regional Health Information systems within the National Health System, enhancing the interoperability among them as well as towards the EU. On this regard, since 2006 the MSSSI has participated previously in several European projects which main objective was the implementation of cross border services among Member States in order to allow the exchange of clinical information

## CV of key persons

Mercedes Alfaro Latorre, MD, graduated in Medicine and Surgery from the University of Zaragoza and Specialist in Clinical Analysis, Master in Health Administration, Specialist in Information and Communication and University Expert in Management of Innovation of the TICs. She has developed all her professional activity in the field of public health, initially in the Council of Social Welfare of the Junta de Castilla y León and later in the General Directorate of INSALUD for 15 years. Since 2002, she has been

working in the development of the Health Information System of the NHS in the Ministry of Health, Social Services and Equality, where she currently manages the General Subdirection of Health Information and Evaluation.

Juan Fernando Muñoz Montalvo, graduated in Computer Science and a Master's Degree in Knowledge Engineering from the Polytechnic University of Madrid. He has passed the Higher Management Program in Public Policies of INAP and has several international certifications in the area of Computer Security and Technology Management in Organizations Such as CISA, CISM, CGEIT of the North American Association of Audit and Control of Information Systems (ISACA). He currently works as Deputy Director General of Information Technologies of the Ministry of Health, Social Services and Equality where he has developed his career from 2002, after having gone through other public and private organizations such as: Ministry of Defense, Spanish Agency of Protection of Personal Data, Ministry of Public Administration, European Commission and various consulting firms. He is the director of National Project of Electronic Healthcare Record and ePrescription/eDispensation National project, and has participated in the EPSOS steering board and other cross-border clinical information projects, JAseHN and is a member of eHN.

Arturo Romero-Gutiérrez, MD, PhD, graduated in Medicine and Surgery from the Complutense University of Madrid and Master in Hospital Management, EADA Business School, Barcelona. He was the Medical Director, Clinical Information Systems (CMIO) in Hospital de Toledo Coordinator, Admissions and Medical Documentation in the same Hospital, where he also worked as a Surgeon. Actually he is 1) Technical Advisor for Clinical Information Systems in the General Vice-Direction of Healthcare Information and Evaluation - Ministry of Health, Social Services and Equality, 2) project Leader of the National Project of Electronic Healthcare Record, 3) representative for Spain in the SNOMED CT International General Assembly, and 4) advisor in the Technical Committee, ISO-AENOR CTN 139. Arturo has also participated in several European projects as representative of the Spanish Ministry of Health, especially in epSOS, eHGI, EXPAND and JAseHN, being also deputy in the eHMSEG.

Celia Varela Núñez, graduated in Physics and has a PhD in Physics in the field of Computer-Aided Diagnosis of Breast Cancer. She has developed most of her professional activity in the field of public health, initially at the IT Department of the Regional Healthcare Service of Castilla-La Mancha in Spain during more than 6 years. She was responsible of the Computer-Aided Detection Systems in the Regional Healthcare Service of Castilla-La Mancha, Coordinator of the epSOS project from 2008-2012, participating in the Spanish PS large scale Pilot. She was responsible of the National Healthcare Electronic Record at regional level and responsible and analyst of different Healthcare Information Systems (Radiology, Nuclear Imaging, Screening program,...). At the Ministry of Health, Social Service and Equality since July 2012 she has been working in epSOS, eSens, JAsehn and she is the technical responsible of some national Interoperability projects, among them, National System of Healthcare card, and National Project of Electronic Healthcare Record, supervising deployment, support and evolution of the project at a National level and managing the connection of the regions to the system. She participates as deputy in the eHMSEG.

Ana Delgado Roy, lawyer specialized in health care management, eHealth and data protection & privacy. She has developed most of her professional activity in the field of the public health, at the General Subdirection of Health Information and Evaluation within the Spanish Ministry of Health, as well as in other regional departments as the Healthcare Service of Castilla-La Mancha and the Health Institute of Aragón, in Spain. She has eight years of experience in providing professional services particularly in relation to digital Health Care. She has participated in the Electronic Health Records and ePrescription national project as well as in several European projects (epSOS, eSENS, JAseHN, eHGI) providing legal support. She has also participated in the drafting of the Agreement among National Authorities for the exchange of health information under the mandate of the Cross Border directive 2011/24/EU and the eHealth Network. Ana has also performed services in the following areas: Health law and data protection advisory, health business/project assessment and monitoring, strategic planning and partnership, institutional relations and stakeholder management, creating alignment across multiple disciplines areas and teams.

## 9.2.9 FI – National Institute for Health and Welfare (THL)

Organization profile

The Terveyden ja hyvinvoinnin laitos THL (National Institute for Health and Welfare) is a research and development institute under the Finnish Ministry of Social Affairs and Health. THL is the national authority responsible for the planning, management and monitoring of the electronic processing of client data in health care and social welfare as well as for the management of related information structures and terminologies. As a statistical authority THL maintains and develops statistical and register resources in its domain being the focal point for international health statistics for EU, OECD and WHO. THL has been or is actively involved in many of the recent European joint endeavors in eHealth (epSOS, EXPAND, PARENT, ASSESS CT, JAseHN, Trillium II). THL is the national coordinator of the Finnish eHDSI Action under CEF. In addition, THL provides expertise support to the eHealth Network. Consequently, the Institute commands a broad range of competencies and experience in the areas of the MWP that can benefit the 3<sup>rd</sup> Joint Action.

## CV of key persons

**Juha Mykkänen**, (PhD) is Development Manager for certification, interoperability and standards at the Department of Information Services, THL. He has lead several national standardization groups and projects, and participated in various international health information systems standardization committees. He has published more than 150 papers, reports or specifications in relation to interoperability, standards and architecture of health information systems. His main interests include the evaluation of interoperability standards, management and support of standard portfolios and governance of large-scale eHealth initiatives using enterprise architecture frameworks.

Adjunct Professor Sangita Kulathinal is a Senior Data Scientist at THL and has earlier worked as a senior expert at THL in projects on genomics. She has almost two decades of experience of teaching and supervision as well as consultation in various fields. Her expertise lies in designing epidemiological studies, developing statistical methods needed for analysing data collected under special design. Her current work focuses on data integration from various registers and surveys, and on developing machine learning techniques to carry out predictive analysis. She obtained her PhD in Statistics from University of Pune, India in 1996.

Adjunct professor *Tarja Heponiemi* is working as a Research Manager at THL. She has long experience on health services research. Her areas of interest are employees' well-being, e-skills, competence, and stress related to information systems. She also actively participates in dissemination of research results and has a long experience on interactional projects with different stakeholders.

**Joni Komulainen**, Master of Laws, joined THL in 2015 to work as Legal Adviser at the Department of Information Services. Komulainen is a highly experienced lawyer with a long history of service in various positions in municipal Social and Health Care administration. Currently he is a co-writer of the Acts on the Electronic Processing of Client Data in Social and Health Care Services and on Electronic Prescriptions, and is actively involved in the eHMSEG Legal Taskforce, JAseHN and the Finnish eHDSI Action under CEF. Possesses a deep understanding of domain relevant EU regulations such as the GDPR.

*Viveca Bergman*, M.Sc.Pol., Development Manager at the Department of Information Services at THL since 2010. She has a broad working experience from a variety of public health projects both on the national and international scene, and has been working in both research and expert organizations in health care. Programme management expert. She was the coordinator of the Finnish epSOS project, and has participated in EXPAND, PARENT, ASSESS CT, eHGi, JAseHN, and is currently the national coordinator of Finnish eHDSI Action under CEF.

## 9.2.10 FR – Ministry of Health (MoH-FR)

## Organization 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 (ASIP santé). The French electronic health patient record DMP (Dossier Medical Partagé) was created by law then designed and launched by ASIP Santé 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 ASIP santé 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.

## CV of key persons

Michèle Thonnet, 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 25 years of experience and over 190 publications. She used to hold different positions in the pharmaceutical industry as well as the IT one (international standardization). As 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, as well as in studies, conferences and strategic plans at international level (OECD, WHO, ITU...)

**Thomas David** is policy officer at DSSIS. He's in charge of monitoring the work programme of ASIP Santé and improving processes between ASIP Santé 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.

## ASIP Santé-Affiliated entity profile

ASIP Santé, 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 ASIP Santé 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 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). ASIP Santé fosters the development of the eHealth ecosystem in order to create value, and participates in the construction of cross-border eHealth information services. ASIP Santé has been present since 2008 at a European level, both on strategical and operational levels, by actively participating in European projects such as epSOS, JAseHN, CEF eHealth, EURO-CAS... ASIP Santé is mandated by Ministry of Health as the National Contact Point for eHealth.

## CV of key persons

**Pascale Sauvage** is director of strategy at ASIP Santé since 2014, and member of the board. She is in charge of program management office, quality management and communication. 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 such as Dossier Médical Partagé (DMP). She also managed a wide range of international activities, specifically with Europe and Quebec.

Angelica Cavalcante is a Project Manager in the eHealth projects department at ASIP Santé since 2012, Angélica Cavalcante Galvão is in charge of the European eHealth projects in which ASIP Santé is involved, in particular CEF eHealth. She is also in charge of the project aiming at certifying information systems for MDPH (Institutes for Disabled People) in France. Previously, Angélica Cavalcante Galvão was responsible for the accreditation of information systems for the national patient record project, DMP (Dossier Médical Personnel).

*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 ASIP Santé. She takes on the role of IT and freedom correspondent at ASIP Santé. Since October 2014, she was appointed director of the legal department. She contributes to define the legal framework of eHealth major projects, the secure health emailing system, SI. 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.

Manuel Metz is a security and interoperability senior engineer at ASIP Santé 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).

Alain Périé is Project Manager at ASIP Santé since 2006. Very committed in the eHealth policies area, he has participated in several French projects: National EHR (DMP), the secure health emailing system (MSSanté), Cancer Services. He is now member of the medical affairs department. At the European level, he has been in charge of managing the epSOS project at ASIP Santé. 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. In the JAseHN project, Alain was also in charge of the risk management.

Adrien Picard is project manager at ASIP Santé since 2016. Adrien Picard is in charge of national project of convergence of healthcare information system for public group hospitals. From 891 public hospitals in France, 135 groups of public hospitals have been created. The main goal is that each group converges on a unique healthcare information system. He is dealing directly with CIO to follow this convergence and promotes national e-health frameworks health. Previously, Adrien Picard has been working in an academic public hospital, CHRU Tours, for more than four years, as integration architect in charge of the patient chart. He was involved on functional and technical projects, from improving nursing and physician workflow to changing the HIS on remote hosted mode. Prior from this experience in a hospital, Adrien has spent five years implementing Cerner millennium clinical solutions in France but also in Spain mostly on academic hospitals.

#### CNAM – Affiliated entity profile

CNAM (Caisse Nationale d'Assurance Maladie) is the French national Health Insurance Fund for Salaried Workers. It can rely on its own existing network of more than 100 regional funds in the whole territory with dedicated resources for the dissemination and the training of Healthcare Professionals. CNAM is also in charge of the issuance of European healthcare cards to French citizens traveling abroad. For this reason, this population can easily be targeted in the dissemination program with a specific incitation to ask for a DMP and a Patient Summary.

## CV of key persons

**Stéphanie Naux** is currently a Mission Director in the Directorate of Strategy, Studies and Statistics of Cnam. As a specialist in health law and data protection law, she deals in particular with the legal issues related to access to health insurance data (SNIIRAM). She participates in the work on the definition of the new legal framework for access to health data in France. Previously, she held various positions with CNAM on public health projects, relations with liberal health professionals and was advisor to the CEO of Cnam.

*Helene Caillol* is currently Head of the information system management department in the Strategy, Research and Statistics Directorate of the CNAM. Her skills include information technology, data analysis,

health data, open data and big data. She has held several positions within the CNAM Strategy, Studies and Stats Directorate: information systems management, analysis of health data, forecasts of health insurance expenses. She holds a PhD of mathematics of the university Paris 6- Pierre and Marie Curie.

Sandrine Lorne since 2010, Sandrine Lorne is headed a strategic program of the French National Health Insurance - the "Program 1"- to develop digital personalized services and multi-channel tools of customer relationship management (CRM). This innovation program gathers experts in digital and CRM services, and IT and digital developers, web designers. It main digital project i: the "compte Ameli" = health insurance online, on Web site, smartphone and tablet applications (26 million personal accounts, 20 million connections / month). The Program 1 works with the French administration in the national project "France Connect": "Say it once to the administration", no more paper but data sharing between administrations, using the digital ID of the "Ameli account" to access other administrations sites. Previously, Sandrine Lorne managed financial and accountant department, and health department in local agencies of the Health Insurance. And before she joined the public health sector, she worked in marketing, finance, and oenology in the private sector. Sandrine Lorne is graduated from the high business school "EDHEC", from Sciences Po Paris (master's degree in financial strategy), the East Paris University (master's degree in health organization), and graduated from the High Social Security School "EN3S".

Ursula Descamps MD, has been involved for many years in health projects related to European and International affairs. She currently heads the European department of the French National Health Insurance (Cnam). As such, she represents its interests in stakeholders' meetings and actively participates in European-fund projects in the health field like the CEF health. Her field of expertise includes medical affairs as well as institutional and European affairs. Before joining CNAM, Ursula worked as a general practitioner in the North-East of France.

Ms Morgane PIERRE is currently health economist in the French public health insurance CNAM, working on the eHealth project for the next report of the insurance which proposes a progress for its own charges and products to the French social security minister and the parliament. This project aims to determine how the health insurance may grow in this field, what it has already done and is doing, and how it wishes to contribute in the French healthcare system. In order to manage this project she is working with every department of the health insurance that is involved in any eHealth action. Because of this, she have the skills required to be part of the eHaction project as an expert in eHealth. Indeed, she is also graduated from Dauphine University in health economics, from Paris-Saclay in public health, did an internship in health economic research at Columbia University and Versailles University, and worked two years in a clinic administration team in London.

## 9.2.11 HR – Croatian Health Insurance Fund (HZZO)

## Organization 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. HZZO was involved in few cross-european projects such as the epSOS, EXPAND, ENJECT, INCA, AdriHealthMob, JAseHN 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.

#### CV of key persons

*Jelena Curać* Bsc in Physics, graduated from the University of Zagreb, Faculty of Science, Department of Physics. She has 18+ 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.

*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 was highly involved in national projects such as the CEZIH, ePrescriptions, smart card, etc.

Hrvoje Jezidžić, Bsc EE graduated from the University of Zagreb, Faculty of Electrical Engineering and Computing. Within 23+ 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..

Hrvoje Belani, MSc EE, graduated from the University of Zagreb, Faculty of Electrical Engineering and Computing in 2003 where he majored in telecommunications and informatics. He is an experienced software engineer and architect, with advanced knowledge in software methods and processes, requirements engineering and business process modelling, as well as EU project management. From 2010, he works as a senior inspector for informatics in IT division of HZZO and as information security officer there. He was the project manager for Croatia in epSOS project in period 2012-2014, and from the end of 2014 he is the management committee substitute in COST TD1405 on "European Network for the Joint Evaluation of Connected Health Technologies (ENJECT)". He was also active in preparing proposals for IN3CA (CIP ICT PSP) and ASSESS CT (H2020) projects cofinanced by the European Commission. He is also part of the OpenNCP community and organizational member representative in HL7 Croatia.

## 9.2.12 HU – National Healthcare Service Center (NHSC)

## Organization profile

The National Healthcare Service Center – (Állami Egészségügyi Ellátó Központ - ÁEEK) - is a public institution established by the ministry responsible for health (MoH) to govern more than 100 public hospitals and other 20 health service providers owned by Hungarian State and to support the implementation of the health care reform in Hungary. Hospitals maintained by ÁEEK cover the majority (ca. 80%) of Hungarian inpatient capacities. ÁEEK's mission is to ensure the construction of well-focused methodological and development policy strategy for the healthcare sector. The institution is the main methodological centre for organizational and system development, quality management and e-Health. 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. ÁEEK is responsible for coordinating health sector IT strategy, ensuring the multi-purpose use of sectorial data assets accumulated in the health sector, as well as - together with the EU Project Management Directorate - acting as project manager, coordinator and consultant in numerous Hungarian and EU health informatics projects. ÁEEK operates the national eHealth Infrastructure (EESZT) and acts as the appointed National Contact Point for eHealth. ÁEEK participates in several international cooperation programmes, e.g. FP7, LLL and Health programme, in Joint Action projects also in the field of eHealth (for example epSOS, CEF, eHGI, JAseHN). 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.

## CV of key persons

**Sára MARTON** JD works at the EU Project Management Directorate of ÁEEK. She is a health law and health management specialist and works as a legal expert and strategic planner. She has been involved in the project management of several EU and national health care development and eHealth related projects. Sára

Marton was the Hungarian delegate of the e-Health Network legal subgroup and a core team member of JAseHN T6.2.

István CSIZMADIA works at the EU Project Management Directorate of ÁEEK. He is Head of International Programmes and Projects. He has extensive 27 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.

**Dr. Béla MUZSIK** MD is Head of Department for Data Analysis and Data Supply at National Healthcare Service Center (ÁEEK), Hungary. He has extensive 15 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.

Barnabás Margitai MD, MBA, MSc graduated from the Medical University, Debrecen in 1989. He became a specialist as a gynaecologist in 1993. He has a 15-year clinical experience. He has a MBA and MSc Diploma in Health Care Management and Qualification as a Quality System Manager. He has an experience in pharmaceutical industry, and providing medical service in public and private healthcare. He has had several positions in the past 10 years. He worked as a Senior Consultant in Performance Improvement at Healthcare National Health Service Centre; as a Medical Advisory Board & Medical Council Executive, Chief Quality and Safety Manager at Euromedic / Affidea International, as Deputy Director of the Department of Biological and Patient Safety, Quality and Safety Improvement Division, Szabolcs-Szatmár-Bereg County Hospitals; as a General Director of Institute for Healthcare Quality Improvement and Hospital Engineering (EMKI); and as a Director of National Association of Manufacturers and Distributors of Assistive Devices (NAMDAD): His main interests are e-health related solutions, quality and safety in health care.

## Semmelweis University – Affiliated entity profile

Semmelweis University has over 240 years of tradition of medical treatment, education (nowadays in English, German and Hungarian languages) and clinical & preclinical research, supported by its 5 faculties, 27 clinics and theoretical institutions. The development of research activities (basic and applied research, experimental development, technological innovation) has received increasing attention over the past decade, this experience and expertise serves as the basis for innovation and the application of modern technologies. With a total staff number of 7500 - many of whom are young talents, around 1000 academic employees -Semmelweis University is a leading academic medical institution of Central Europe. Semmelweis University continuously expands the participation in exchange of knowledge, professional international collaborations, policy development and representation of academic sphere in decision making processes, thus allowing to successfully fulfil its mission in education, research and healthcare. Health Services Management Training Centre (HSMTC) with its 20 years, is one of the youngest, dynamic developing departments with substantial project and knowledge management experience, assisting the development of health services by generating better management knowledge and practice. The Health Services Management Training Centre is organising MSc and BSc courses for younger and already practicing professionals, the colleagues of Centre involved in the PhD education as supervisors and they teach different courses for students from other faculties of the Semmelweis University and for residents on several health management topics. Beside the education activities, the institute is involved in or is leading numerous international and national research and development projects. The colleagues of the institute represent a unique set of skills in the fields of management, change management, operation of health care institutes, HR, quality and patient safety, and the scientific evaluation of health care providers. It organises and improves the education activities according to The Standards and Guidelines for Quality Assurance in the European Higher Education Area (ESG). HSMTC is a member of several international professional organisations, like the European Health Management Association (EHMA) and the European Health property network (EUHPN). The Centre has a strong collaboration among others with the World Bank and the World Health Organisation

## CV of key persons

*László Bencze*, JD has got a background in law 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. Since 2015 international policy expert and project coordinator at Semmelweis University – Health Services Management Training Centre

*Miklós Szócska*, Dr. is the director of Semmelweis University, Health Services Management Training Centre. He holds a Master of Public Administration degree from John F. Kennedy School of Government at Harvard University, and a Ph.D. from the Semmelweis University in the field of change management. Between 2010-14 Dr. Szócska served a full electoral term as Minister of State for Health of the Hungarian Government.

*Márton Kis*, MBA, MSc is originally a financial economist, and gathered his experience in the field of banking, telecommunication, IT, media, trade and healthcare, in the management of different Hungarian and international companies. Since joining HSMTC in the fall of 2014 he is coordinating a number of Hungarian and international projects (including eHealth Joint Action, Ecoquip and Hungarian National level healthcare reorganization), and an active member of the eHealth team of HSMTC

Edmond Girasek, Dr. graduated at the Eötvös Lóránt University (ELTE) as sociologist in 2006. He interested in quantitative methods and the topic of health workforce already in his student years. His thesis was written about career choice of medical doctors. During his university years, he was one of the founders and operation of the ELTE Special College for Social Sciences and. As a demonstrator taught quantitative methods for first and second years sociology students and the member of Special College. His Ph.D. thesis was defended in 2013 in the Semmelweis University. Edmond joined to the HSMTC team in January 2007 as a junior fellow. He is working in the team since 2009 as an assistant lecturer and since 2013 as assistant professor. Edmond took part in several national and international research, training and advisory projects e.g. the Health Professional Mobility in the EU Study lead by the European Observatory on Health Systems and Policies. In the course of this project he spent one year in an internship in Brussels. Recently he is leader expert in the Joint Action on Health Workforce Planning and Forecasting project WP4 lead by the HSMTC. This work package responsible for the data and terminology. Edmond is also the professional leader of the Semmelweis University Graduated Tracking System and working hard on preparation projects on eHealth topic.

## 9.2.13 IE – Department of Health (DoH)

## Organization 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.

#### CV of key persons

**Kevin Conlon** has worked in health ICT for more than 25 years and is currently head of ICT eHealth and Information Policy Unit in the Irish Department of Health. He has an MSc in health information system. He led out on the development of the *eHealth Strategy for Ireland* and the organization of the EU eHealth Week Conference in Dublin in 2013.

*Mary Cleary* has significant National and International experience in eHealth development and worked closely with the Department on Irelands EU Presidency eHealth Week in 2013. Mary is co-lead in JAseHN Task 7.5 - Patient Access to Electronic Health Records working as part of the National team. Mary is Deputy CEO of the Irish Computer Society/ICS Foundation and Chair of the CEN Workshop on ICT Skills. She oversees ICT professionalism and digital inclusion policy and initiatives for ICS, coordinating the Irish Digital Jobs and Skills Coalition and advising the ICS CIO Forum on professionalism and Continuous Professional Development for all domains, with particular emphasis on eHealth. She holds a Master's Degree

in Education, and has extensive experience of ICT professional programme design and implementation. She has worked on several national education initiatives, promoting ICT as a teaching and learning tool and is an active member of ECDL Foundation Expert Working Group. She manages education outreach initiatives, as well as the professional and advocacy activities of HISI (Healthcare Informatics Society of Ireland), and delivers 8 national conferences annually. She is a delegate to the NSAI (National Standards Authority of Ireland) ICT SCC, and represents the NSAI on the CEN Technical Committee 428.

*Caitriona Wray* 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.

## 9.2.14 IT – Ministero della Salute (MINSAL)

## Organization 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.

## CV of key persons

Lidia Di Minco Graduated in Mathematics, Head of National Healthcare Information System (SISN) Unit within Directorate General of Digitization, Health Information System and Statistic of the Ministry of Health. She is responsible for design and development of healthcare information systems aimed to appropriateness and expenditure monitoring, data warehouse and decision support systems for clinical investigation and epidemiologic analysis; implementation of telemedicine services in the NHS; health information data management, semantic interoperability and national coordinator of eHealth projects; management of the national governance of the implementation of Electronic Health Record and ePrescription; responsible of the EU project managed by the Directorate General (eHGI, PARENT, EESSI, JAseHN); delegate at the Technical Commission for the Coordination of Social Security Systems of the CE.

*Valeria Proietti* 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.

*Morgan Romanelli* works in the National Health 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; technical support for design and development of healthcare information systems; technical expert in exchange data relating patients' international mobility.

## 9.2.15 LT – Ministry of Health of the Republic of Lithuania (SAM)

## Organization profile

The Ministry of Health of the Republic of Lithuania (National Health Insurance Fund - VLK) 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 is to form and implement health policy that ensures public health, high quality health promotion activities, and rational use of resources

## CV of key persons

Ssaulius Štarolis, IT Officer. Graduated from Kaunas Technological University in 1993. He has been working at the Information and Communication Technology (ICT) sector of Lithuania, in various positions since 1993. Currently he is in charge of the Head of IS development Division of Information Technology department of VLK, which consists of seven IT officers. Current responsibilities include: apply the VLK strategy in terms of ICT Systems, managing all projects and Tenders in progress for developing ICT systems various co-funded projects, participation in EU working groups.

*Natalija Jelenskienė*, IT Officer. Graduated from Kaunas Technological University in 2000. She has been working at the Information and Communication Technology (ICT) sector of Lithuania, in various positions since 1989. Currently she is in charge of the Head of the Health insurance register Division of Information Technology department the VLK, which consists of five IT officers. Current responsibilities include: managing health insurance register and other Systems in the VLK.

**Dovilė Ekaitė**, Expert. Graduated from Vilniaus University in 2012 and Mykolas Romeris University in 2016. She was appointed in the public service as an Information Technology expert since 2015. Current duties include the following: testing, administrating and maintaining information systems, preparation of technical specifications.

## 9.2.16 LU – Agence eSanté (AeS)

## Organization profile

Agence eSanté is Luxembourg's national eHealth agency for the exchange and sharing of data in the healthcare sector, whose main mission it is to

- develop and implement a common interoperability platform to support such data sharing and exchange and
- define a national strategy to promote and enhance interoperability between healthcare information management systems.

The services offered through the national eHealth platform include amongst others secure mail between healthcare professionals, a collaborative space and a healthcare provider directory. The eHealth platform's principal tool to facilitate the sharing of medical information is the so-called "Dossier de Soins Partagé" (DSP), a patient's secure electronic health record allowing authorised healthcare providers to have easy access to his relevant health related information.

## CV of key persons

Heiko Zimmermann, Senior advisor, worked as a software architect and developer in the IT sector for several years, before joining CRP Henri Tudor in Luxembourg in 2009. There he worked on different eHealth related projects for the Ministry of Health in Luxembourg. In 2012 he joined Agence eSanté, where he is leader of the interoperability department. He is involved in the specification and implementation of the national eHealth platform, an IT platform providing different eHealth services for the healthcare sector in Luxembourg. He was working as the national project coordinator for the epSOS project and was member of the Luxembourg consortium for eSens. He is involved in Trillium Bridge II and the CEF eHDSI project, where he currently also acts as one of the co-chairs of eHMSEG.

*Jean-Claude Karasi*, Senior advisor, joined Agence eSanté in May 2013 as the project manager and expert in the medical domain for the implementation of the Luxembourg national e-health platform and its services. He started his professional career at the Ministry of Health in Rwanda. As a civil servant, he served as a healthcare provider at the referral hospital (Centre Hospitalier Universitaire de Kigali - CHUK) in Rwanda from 1999-2004.

*Pascale Lucas*, Senior advisor, joined Agence eSanté in September 2012 as Head of Project Management, including leading the eSanté Platform. Holder of a Master degree in management, she has overall 30 years' experience in Sales, Product Marketing and Project Management for international groups (Konica, INTEL, Clearstream, SopraGroup) and national entities in France and Luxembourg (Public Research Centre-LIST, SMEs and eHealth national Agency in Luxembourg).

*Julien Sassella*, Junior advisor, Julien Sassella is a lawyer and data protection officer at Agence eSanté since June 2015. Prior to that, he worked as a lawyer in various law firms in Luxembourg. He holds a master's degree in business law from the University of Strasbourg.

Daisy Smet, Project coordinator / advisor, Daisy Smet joined Agence eSanté in March 2012 where she is head of the administrative and communication pool. She holds a Master degree in translation English-French-Dutch, and a Master degree in Marketing and corporate communication. She started her professional career in the communication department of (former) Paribas Bank's head office in Brussels. She then moved to Luxembourg where she worked for more than 16 years in the financial sector, in the administrative and communication/marketing area, before joining the healthcare sector. She is involved in the JASeHN work since 2015, and is involved in the CEF eHDSI project.

## 9.2.17 LV – The National Health Service (NHS)

## Organization profile

The National Health Service (NHS) is the operating direct administrative institution subordinate to Ministry of Health. It was established on 1st November 2011. NHS took over the functions formerly carried out by The Centre of Health Economics and Health Payment Centre. The aim of the NHS 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 programme according to the policy decided by the State.

## CV of key persons

*Linda Freimane*, Deputy director of information and communication technology, she has held various management and programme positions in the field of IT healthcare management since 2013. She has more than 8-year experience with EU fund projects, including 4-year experience in development and implementation of E-health system in Latvia.

**Peteris Erbs**, Head of IT division, he joined NHS in 2016 as project manager in E-health and standard division to ensure all technical issues regarding implementation of E-health system are managed and the system "go live" on September 2016. Now he is in charge for all IT division which ensure the needs of all systems managed by NHS.

## 9.2.18 MT – Ministry for Health (MFH)

#### Organization profile

The Ministry for Health (MFH) of the Government of Malta is responsible for the planning, delivery and evaluation of health care services in Malta. The Information Management Unit within MFH is responsible for the formulation of national eHealth and Digital Health strategy and for the implementation of national eHealth and Digital Health projects, and Health IT systems in the Government health services.

MFH has offered to support the 3rd Joint Action on eHealth by providing quality assurance of documents prepared in technical work packages and by engaging in strategic aspects of the preparation of input for the meetings of the eHealth Network.

## CV of key persons

Hugo Agius Muscat is a consultant public health physician with over 25 years of experience in the field of health informatics. Dr Agius Muscat qualified in Medicine and Surgery in 1985, and in 1990 he was awarded a Master of Science degree by the University of Warwick (UK) with distinction. He also holds other formal qualifications related to health informatics. He currently works on national eHealth and Digital Health projects in the Information Management Unit of the Ministry for Health. For five years he was Director for Information Management & Technology at Mater Dei Hospital, Malta's main acute hospital, and for ten years he directed the Department of Health Information & Research. He is also a Visiting Senior Lecturer at the University of Malta.

*Vivian Brincat* is an ICT Officer in the Ministry for Health with 7 years of experience in the administrative management of eHealth Projects, epSOS, PARENT, JAseHN and other local projects. She currently works on national eHealth projects in the Project Management office of the Information Management Unit. She is a certified PRINCE2 Practitioner, Enterprise Content Management Master & Specialist, ITIL Intermediate in Service Design, Offerings & Agreements and Release Control & Validation, Middle Management – University of Malta and currently sitting for a BA Hons Degree in Public Projects Management.

## 9.2.19 NL – Stichting Nationaal ICT Instituut in de Zorg (NICTIZ)

## Organization profile

Nictiz is the Dutch national 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. In the past years Nictiz has managed the national EHR programs and supported the development of national interoperability standards and profiles. To this end Nictiz has close cooperation with the international Standardization Organizations: IHE, HL7, IHTSDO, Continua Health Alliance, ISO. Nictiz is the National Release Center for SNOMED CT. Nictiz has designed and developed the National Infrastructure for health information exchange. This is complemented with a qualification process. Nictiz is an active beneficiary and participant in the EC projects (epSOS, Antilope, eStandards, eSENS, ASSESS CT and Expand). Nictiz is an adviser for the Ministry of Health of the Netherlands, on national and international affairs, such as the eHealth Network. Nictiz is a member of EHTEL and participates in the network for European competence centers (EHTEL/ELO)

## CV of key persons

*Michiel Sprenger*, Michiel Sprenger holds a PhD in Physics, and has been active in Physics, Medical technology, Informatics and IT from 1986 to 2008 in an Academic Medical Center. He joined Nictiz in 2008, being active in strategic advice to all parties involved in the development of IT in Healthcare. He was the coordinator of the program that brings regional organisations together and in cooperation with Nictiz for the achievement of national transparency in information exchange for the Netherlands. He is the chairman of the platform of the Dutch branches of SDOs in the Netherlands. He is one of the leaders of the joint UMC program "registration at the source". He is a member of the subgroup of the eHealth network on CEF proposals.

*Elise Peters* has Master degrees in Communication and Information Sciences (MA) and Public Information Management (MSc). She worked for several health projects in an Academic Medical Center and followed an information management traineeship. She joined Nictiz in 2016 as medior advisor, being active in JAseHN 2 WP5 and task 7.5 and other national projects.

#### 9.2.20 NO – Norwegian Directorate of eHealth (NDE)

#### Organization profile

The Norwegian Directorate of eHealth (NDE) is a sub-ordinate institution of the Norwegian Ministry of Health and Care Services. Established on January 1st, 2016, NDE is a sub-ordinate institution of the country's Ministry of Health and Care Services. The former eHealth division of The Norwegian Directorate of Health provided the nucleus from which the new Directorate of eHealth has evolved. NDE will implement the national policy on eHealth, establish the requisite standards, and administrate the use of eHealth methodology nation-wide. The organisation's primary responsibilities are 1) the national steering and coordination of eHealth through close cooperation with regional health authorities, local authorities, technical organisations, and other interested parties, and 2) to develop and administrate digital solutions that will improve and simplify the national health and care sector.

## CV of key persons

*Morten Lier Svendsen*, Senior Advisor, he has a Master of Laws (University of Oslo, Norway) and Bachelor in Computer Science (From Lewis & Clark College, Portland, OR, U.S.A. and NTNU, Trondheim, Norway). Have worked in the Directorate of Health (now transferred to the Directorate of e-Health) since 2012 with

law and IT, mainly in the intersection in-between law and IT - assessing IT-solutions with regards to current legislation and also developing new legislation and change in existing one in the e-health-field (e.g. for the Norwegian solution for e-prescription and patient summary records). Also works with IT-contracts, data-protection and privacy and have contributed to JASEHN (EU) – mainly in its efforts to create a multilateral agreement for enabling cross-border health data exchanges. Was on a secondment to the Norwegian Ministry of Health (2016-2017) mainly for contribution to new legislation for coming services in e-health. **Fields of knowledge or expertise:** Privacy law, IT and health-data laws governing the digitalization of the health-sector, contract law, intellectual property law

*Irene Olausse*, Phd, Science and Technology Studies, University of Oslo, she is Senior Advisor Directorate for eHealth at Divison Strategy. **Relevant areas of experience:** International relations, Knowledge Management, Strategy office.

*Helge T. Blindheim*, Senior Advisor Directorate of eHealth at Division Strategy. His present focus is: Technology specialist (mHealth, cloud computing, api-economy, big data, technology trends), strategy development, knowledge management, speaker. He was worked as Technical Manager, Product and Project manager in Unit 4 Agresso (Norway). Technology strategist and account manager for health care in Microsoft (Norway). **Relevant areas of experience:** ICT in politics, ICT-driven business development.

## 9.2.21 RS – Institut za javno zdravlje Srbije "Dr Milan Jovanović Batut" (IPHS)

## Organization profile

The Institute of Public Health of Serbia "Dr Milan Jovanović Batut" was established on the Republic level and represents an expert institution for Public Health, which provides advice, support and guidance for the Serbian government and all departments for public health and conducts independent researches on issues related to public health in Serbia. The activity of the Institute is defined by the Health Care law which under public health considers realization of public interest by creating conditions for the preservation of public health through organized comprehensive social activity aimed at preserving the physical and mental health, and environmental protection, and prevention of risk factors for disease and injuries, which is accomplished by application of health technologies and measures aimed at promoting health, preventing disease and improving quality of life. Regarding that, Institute's main areas of activity are: analysis, planning and organization of health care, information with biostatistics, health promotion, control and disease prevention, hygiene and human ecology and microbiology.

## CV of key persons

*Ivan Ivanovic*, MD, Public Health Specialist, Head of Department of informatics and biostatistics in IPH of Serbia. I completed Faculty of Medicine at the University of Belgrade and specialist training and became specialist of Social Medicine. Currently I am PhD candidate. Main fields of interest and activities in my professional work are: coordination of development and realization of Integrated Health Information System (IHIS) in Republic of Serbia, organization and implementation of health statistical research including responsibility for correctness of data, their timely publishing, accessibility and protection of data, organization and implementation of targeted research projects on health, development and maintenance of databases on national level and data analysis and reporting on population health, healthcare system performance and resources.

Lidija Stankovic is a programmer. She finished Belgrade University, Faculty of Organizational Sciences in Belgrade, Serbia and Master of Information systems and technologies at Belgrade University, Faculty of Organizational Sciences in Belgrade, Serbia. She is employed at IPH of Serbia and holding the position Head of Biostatistics at Informatics and Biostatistics Department. She has over 9 years of experience working in the area of health care system. She is responsible for creating and maintaining national relational databases in MS Access, creating and maintaining databases in SPSS and reporting regarding request.

## 9.2.22 SI – National Institute of Public Health of the Republic of Slovenia (NIJZ)

#### Organization profile

NIJZ is the central Slovenian institution for public health practice, research and education. As such, NIJZ is engaged in numerous activities covering the areas of epidemiology, health promotion, statistics, and national coordination of preventive health programmes. The vast majority of important public health functions and services in Slovenia are provided by NIJZ and its 9 regional offices. Being centred on all aspects of the public health, NIJZ presents a capable partner in practically all health-related projects. In eHealthAction NIJZ could facilitate valuable professional expertise and play an important role, namely it could provide significant support in facilitating the pertinent information for an integrated view of the patient, including all health determinants. NIJZ, as the manager of the numerous national health-related databases, could facilitate health care data sets in order to provide dynamic exploitation of data sources. Moreover, through the innovative approaches, gradually being established within the eHealth project, NIJZ could support the development of proactive personalized care services across the complete health ecosystem.

At the same time, NIJZ could engage in wide-ranging dissemination of the project results and knowledge gained in the project implementation process. Inclusive engagement and promotion of lessons learnt could ensure better national and transnational transferability and applicability of the project results, and other outputs generated by the project partners. On the other hand, the project results could be used as a beneficial platform in related ongoing national and international projects, programmes and joint actions.

In the last years NIJZ has participated in numerous Joint Actions and has successfully managed and coordinated some bigger projects as EPAAC – European Partnership for Action Against Cancer, PARENT – Cross-border Patients Registries Initiative and CANCON – Development of a European Guide on Quality Improvement in Comprehensive Cancer Control.

#### CV of key persons

Dalibor Stanimirovic, (1976) 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, CrowdHEALTH - 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: Assistance for the blind and visually impaired (ALICE), Humane technology for enhanced user experience (Emphatic Products), etc."

*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 projects Cosy - Cognitive systems for cognitive assistants (2007-2008) and 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 robotics."

*Lucija Tepej Jočić* is a member of Centre for healthcare informatics 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 currently focused on the Electronic Health Record in Slovenia where she is involved in different activities on many viewpoints of interoperability. Her previous work experience includes management of complex ICT projects in different industries."

*Mate Beštek* PhD Candidate at IT University of Copenhagen is involved with the national eHealth since 2010. His focus has been on semantic interoperability and overall architecture. Lately, he is focused more on strategies for achieving a more successful implementation on national level. He is an experienced research and development engineer with almost 15 years of experience mostly in the industry but also in academia and lately at the National Institute of Public Health of the Republic of Slovenia (NIPH) where he is in charge of the national Electronic Health Record and Information Security. He works in role of a gatekeeper of the overall national eHealth architecture. He has worked on many important projects like the ePSOS and PARENT and has been working hard on brining the standards into the Slovenian national eHealth."

## 9.3 External and internal risk analysis and contingency planning

Identified Risk	Likelihood	Impact	Contingency planning
Delays in providing deliverables by WPs	Medium	Low	Preliminary reporting; detailed responsibilities; clear process, output and outcome indicators; link reimbursement to delivery
Changes in JA key personnel	Low	High	Existence of Standard Operating Procedures (SOPs); procedure in case of withdrawal of a partner prior to the start of the JA (in the consortium agreement)
MS/C and stakeholders not sufficiently engaged	Medium	Medium	Nomination of in-country knowledge brokers; establishment of a Stakeholder Forum
Low response rate for evaluation surveys	Medium	Medium	Establishing a steering committee/Core Working Group, to facilitate communication
Deliverables not used by MSs (not attractive nor appropriate)	Medium	Medium	Content provided by core WPs formatted and edited centrally by WP2 taking into account stakeholder analysis and input from in-country knowledge brokers
Unclear authoring or intellectual property rights	Low	Medium	Clear decision on those rights before the start of the JA (in the consortium agreement)

Note: Likelihood and Impact: Low, Medium, High

## 9.4 Financial management

The Coordinator is responsible for the financial management of the JA and shall ensure the disbursement of funds to the partners in accordance with the Grant and Consortium Agreements, the collection of regular cost statements and audit certificates (if needed).

The Coordinator provides two senior project managers, each with several years of experience in project management and project coordination as well as the Financial Department of SPMS, headed by the SPMS LEAR and Financial Signatory. The project senior officers will be in charge of the ongoing overall financial management, the implementation of an ongoing reporting mechanism for the associated partners as well as consortium financial meetings. The Financial Department is responsible for the establishment of a proper reporting mechanism including the creation of respective reporting templates, the collection, analysis and evaluation of financial data from all project partners as well as continuous budget planning and budget monitoring. In case of any deviations or major financial issues, the Financial Department will implement appropriate solutions in accordance with the rules set out in the GA and CA.

The Coordinator creates a separate bank account for the JA transactions, being able to identify easily at any time transfers received from CHAFEA and transfers made to partners. The EU financial contribution to the JA will be distributed by the Coordinator according to:

- the consortium budget as included in the JA proposal,
- the approval of reports by CHAFEA and

• the payment strategy stated in the CA to be signed by all partners and their affiliated entities in the beginning of the JA.

#### 10. BUDGET

## 10.1 Content description and justification

## 10.1.1 Overall budget

The consortium of the JA is composed of 1 partner as coordinator plus 22 other partners and 8 affiliated entities. This made it a challenge to distribute effort to all involved in the respective Tasks and Work Packages, and to set up a corresponding budget per WP and per partner in parallel. After the definition and agreement on objectives, purpose and deliverables of horizontal and core WPs and their corresponding Tasks, participants indicated their skills and desired contributions to the different tasks, and the corresponding number of PMs they could allocate to the project over its entire duration. From this exercise resulted the following total budget:

Item	Value	Percentage
Direct costs	4,205,591.38 €	93.46%
Personnel costs	3,150,591.38 €	70.01%
Subcontracting	333,000.00€	7.40%
Other direct costs	722,000.00 €	16.04%
o Travel	689,200.00 €	15.32%
o Equipment	0.00 €	
<ul> <li>Other goods and services</li> </ul>	32,800.00 €	0.73%
Indirect costs (7%)	294,391.40 €	6.54%
Total eligible costs	4,499,982.78 €	
• EU-funding (60%)	2,699,989.67 €	
• Partners co-funding (40%)	1,799,993.11 €	
Total	4,499,982.78 €	100.00%

Budget distribution in terms of percentage is of 70.01% for personnel costs, 16.04% for other direct costs (including travels and subsistence and other goods and services), and 7.4% for subcontracting (details on the latter are included in the sections below). The remaining 6.54% are for the indirect costs, calculated, as per CHAFEA rules, to be 7% of the direct costs.

According to the CHAFEA rules, each partner is responsible for its affiliated entities (AE) in terms of ensuring that the foreseen work is done, with the budget of the AE in each country being aggregated to the respective partner's budget. EC funding is 60% of the total eligible costs, while partners, as well as affiliated entities, are responsible for co-funding the remaining 40%.

#### 10.1.2 Personnel costs

The total of personnel costs amounts to 3,150,591.38 € (70.01% of the total budget). The rational to calculate and distribute the Personnel costs per WP was based on the perspective of participants on effort allocation needed, taking into consideration their skill, experience, and their stated desired contributions to the project, as well as the total amount of work estimated to be needed to achieve the set objectives of each work package. The following table shows the agreed upon distribution of personnel effort per WP:

Workpackage Name	Effort (PMs)	Budget (€)	Percentage of Total Budget
WP1 - Coordination	108.00	402,689.69 €	8.95%
WP2 - Dissemination	34.10	136,336.83 €	3.03%
WP3 - Evaluation	9.00	82,800.00 €	1.84%
WP4 - Empowering people	97.04	559,384.82 €	12.43%
WP5 - Innovative use of health data	77.50	339,141.24 €	7.54%
WP6 - Enhancing continuity of care	115.70	635,754.70 €	14.13%
WP7 - Implementation challenges and impact	154.50	635,344.75 €	14.12%
WP8 - Integration in National policies and sustainability	61.78	359,139.35 €	7.98%
Total	657.62	3,150,591.38 €	70.01%

## 10.1.3 Subcontracting costs

The total of subcontracting costs amounts to  $333,000 \in (7.4\% \text{ of the total budget})$ . This budget is used to cover various specific partner needs, as follows (more details are available in the respective partners' detailed budgets):

Partner	Amount	% of Total Subcontracting	Reasoning
SPMS	130,000 €	39.04%	This subcontracting amount is expected to cover various costs incurred through the project, calculated as follows:  • 5,000.00 € to support of WP3 with the project's evaluation activities  • 17,000.00 € integration of specific expert knowledge (not available within the project) for WP4  • 17,000.00 € integration of specific expert knowledge (not available within the project) for WP5  • 17,000.00 € integration of specific expert knowledge (not available within the project) for WP6  • 17,000.00 € integration of specific expert knowledge (not available within the project) for WP7  • 17,000.00 € integration of specific expert knowledge (not available within the project) for WP7  • 17,000.00 € integration of specific expert knowledge (not available within the project) for WP8  • 10,000.00 € to improve ability to respond to eHN requests and/or follow-up activities
			<ul> <li>30,000.00 to subcontract external support to answer currently unforeseen project needs not covered by the above funds</li> </ul>
ATNA	36,000 €	10.81 %	Integration of specific expert knowledge (not available within the partner) for WP3, WP5, WP7 with the support of activities such as analysis and review of relevant materials, interaction with other project partners as well as expert opinion and consultation services.

Partner	Amount	% of Total Subcontracting	Reasoning
3rd RHA	55,000 €	16.52%	The amount is to subcontract the Aristotle University of Thessaloniki to support the WP7 work. The organisation has extensive expertise in the area covered by that workpackage, and its support is deemed important to achieve the desired work objectives set for the former
MSSSI	12,000 €	3.6%	Funds are for contracting an external consultant expert in European project participation to support MSSSI in its work This subcontracting is higher since for eHAction, the own resources are limited. Therefore, this is currently the availability of internal resources and then, subcontracting is necessary in the proportion proposed. However, this estimate could be altered in the future, with the possibility of allocating more own resources to the eHAction (because of, for instance, new recruits or changes of existing resource dedications.)
MoH-FR	100,000 €	30.03%	This subcontracting is meant entirely for affiliate organisation ASIP Santé. The goal is for their internal experts to focus on strategic tasks, and subcontract the remaining work to external experts. These funds will allow the subcontractors to contribute to the creation of content for deliverables, as well to attend the different meetings and calls, and to keep ASIP Santé own experts informed of the work in progress.  ASIP Santé 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.  Yet, ASIP Santé has recently designated a full-time employee to reinforce the management of subcontractors for European projects and be able to get all relevant resources when needed, in addition to the team already working for European projects, such as CEF, JAseHN or EURO-CAS. In particular, the tasks related to governance issues always remain under the control of ASIP Santé
Total	333,000.00€	100.00%	

#### 10.1.4 Other Direct costs

#### 10.1.4.1 Travel costs

The total costs considered for travelling represent 15.32% of the total budget and amount to  $689,200 \in$ . This amount is the sum of all the individual partner budgets for travels for meetings, plus an amount  $(35,000 \in)$  to support the travel of external experts to the project workshops.

The travel budget for each partner was based on its type (project coordinator, workpackage leader, or other), to which a correction was added in a case-by-case basis to account for some partners extra costs due to geographic distance or other factors. The reasoning was as follows:

- It was considered that, on average, each travel will cost an average 900€ per business trip, which includes all expenses (flight, hotel, and other travel-related costs)
- Each partner is expected to take on average 2 persons to each event they attend. The coordinator is expected to take, on average, 3 persons.

- During the project, a total of around 24 events will occur that will require a trip from some or all partners. This number results from adding the following events:
  - o 6 Steering Council (SC) meetings, to which all partners are required to participate
  - o 6 Leadership Council (LC) meetings, to which workpackage leaders are required to participate. While an effort will be made to align these meetings with the Steering Council meetings in order to save on travel costs, this may not be possible or desirable depending on the circumstances.
  - o 12 workshops (WS), to which only some of the partners are required to attend, the specific selection depending on the workshop subject matter.
- Based on the previous point, it was considered that some partners, such as Workpackage leaders, will necessarily have to travel more than others. As such, the partners were organized in three types, each with a specific estimation of the number of trips they will need. In addition, it was also considered that external experts, such as speakers invited to the workshops, will constitute a fourth type. The estimation of the total amount of travel needed by each type is as follows:

Type of partner	Number of trips	Total Events	Persons per Event	Travel Budget
Coordinator	6 SC + 6 LC + 12 WS	24	3	64,800.00 €
WP Leader/co-Leader	6 SC + 6 LC + 8 WS	20	2	36,000.00 €
Other	6 SC + 6 WS	12	2	21,600.00 €
CP & EE	-	40	1	35,000.00 €

- The budget destined to support the travel of the external experts will be managed by the coordinator, and as such is part of the latter's travel budget. The travel budget for this partner is hence calculated as 64.800€ + 35,000€ = 99,800€
- The partners other than the coordinator have their base travel budgets be either 36,000€ (for WP leaders or co-leaders), or 21,600€ (for all other partners). However, a few partners had their travel budget altered to take into consideration other factors that impact travel cost, such as the geographical location, or the low amount of work they will have in the project. The partners in these conditions are:

Partner	Reasoning	Variation	Travel Budget
ATNA	Extra 3 trips due to having 2 affiliates	+2,700 €	38,700 €
3 <sup>rd</sup> RHA	Extra 3 trips due to having 2 affiliates	+2,700 €	38,700 €
MSSSI	Low effort, hence only 1 person will attend each event	-10,800€	10,800 €
THL	Higher flight costs, average trip budgeted at 1,200€	+12,000€	48,000 €
MINSAL	Low effort, less travel expected	-8,800 €	12,800 €
AeS	Lower travel costs due to proximity to Brussels	-11,600€	10,000 €
MFH	Low effort, less travel expected	-8,800 €	12,800 €

## 10.1.4.2 **Equipment**

The realization of the proposed work does not require the purchase of equipment, and as such no allocation of funds is done in this category.

## 10.1.4.3 Other goods and services

The total of other goods and services costs amount to  $32,800 \in (0.73\%)$  of the total budget). This budget is used to cover various specific partner needs, as follows:

Partner	Amount	% of Total Subcontracting	Reasoning
			This amount is expected to cover various costs incurred through the project, as follows:
SPMS	31,300 €	95.43%	• 3,300 € to help support the costs of meetings that involve 40 participants or more, which will potential require the renting of rooms
			• 20,000 € to support meeting services, such as catering, technical equipment, and other such services
			• 8,000€ to support professional quality review and language proof of deliverables
ATNA	1,500 €	4.57%	Amount to provide the partner with support for the organization and hosting of one consortium meeting
Total	32,800 €	100.00%	

## 10.2 Summary of staff effort

Partner	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	Total PM per partner
1 - SPMS	105.00	27.00	0.00	4.50	3.50	7.50	7.50	1.50	156.50
2 - ATNA	0.00	0.00	9.00	10.00	7.50	8.00	2.50	1.50	38.50
3 - MoH-CY	0.00	1.10	0.00	8.80	0.00	9.90	12.10	4.05	35.95
4 - MZCR	0.00	0.00	0.00	0.00	0.00	4.00	23.00	1.00	28.00
5 - Gematik	0.00	0.00	0.00	3.00	0.00	23.00	5.00	6.00	37.00
6 - MoSA	0.00	2.00	0.00	12.00	0.00	4.00	8.00	1.00	27.00
7 - 3rd RHA	0.00	0.00	0.00	0.00	8.00	0.00	23.77	8.75	40.52
8 - MSSSI	0.00	0.00	0.00	0.00	0.00	1.30	0.00	1.00	2.30
9 - THL	0.00	0.00	0.00	3.00	14.00	3.00	1.00	1.00	22.00
10 - MoH-FR	3.00	0.00	0.00	4.75	1.50	5.50	7.63	7.23	29.61
11 - HZZO	0.00	0.00	0.00	7.00	4.00	5.00	6.00	2.00	24.00
12 - NHSC	0.00	0.00	0.00	8.00	26.50	5.00	10.50	0.75	50.75
13 - DoH	0.00	0.00	0.00	6.99	2.00	21.00	2.00	2.00	33.99
14 - MINSAL	0.00	0.00	0.00	0.00	0.00	1.50	0.00	2.50	4.00
15 - SAM	0.00	0.00	0.00	6.00	4.50	3.00	11.50	1.00	26.00
16 - AeS	0.00	1.00	0.00	1.00	0.00	3.00	3.00	2.00	10.00
17 - NHS	0.00	0.00	0.00	7.00	3.00	3.00	8.00	0.50	21.50
18 - MFH	0.00	3.00	0.00	0.00	0.00	0.00	0.00	1.00	4.00
19 - NICTIZ	0.00	0.00	0.00	12.00	0.00	0.00	4.00	1.00	17.00
20 - NDE	0.00	0.00	0.00	0.00	0.00	0.00	0.00	10.00	10.00
21 - IPHS	0.00	0.00	0.00	0.00	0.00	5.00	11.00	3.50	19.50

Partner	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	Total PM per partner
22 - NIJZ	0.00	0.00	0.00	3.00	3.00	3.00	8.00	2.50	19.50
Totals	108.00	34.10	9.00	97.04	77.50	115.70	154.50	61.78	657.62

## 10.3 Detailed budget

Applicant Number/ Short Name	1 - SPMS					
(If affiliated entity: Affiliated to which	<sup>c</sup> h -					
Applicant number/Short name)						
(A) Direct personnel costs						
Staff function	Montl	hly Cost	Estimated Person-month	Sum Cost (€)		
President		8,367.13	6.40	53,584.65		
Directorate		5,519.00	5.03	27,770.84		
Chief of office		4,552.21	58.18	264,835.98		
Technical experts		2,474.28	86.89	214,981.54		
			Total person	<b>Total Costs (€) for</b>		
			month	(A)		
			156.50	561,173.01		
	Justificatio	n				
				nsible for both WP1		
			rganisation of the w			
	management of the funds related to all of these tasks					
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/Just				
	5,000.00	Because of the ongoing work proper independent being inverted to be the proper independent by T3.1. Integration of within the proof deliverable analysis and with other present consultate. Integration of the properties of the pro	ne WP3 constant invited of the project it is condent evaluation sure olved on a constant for external expertion of specific expert knowledge of the project for WP4 with the external corresponding review of relevant respect partners as we conservices.	crucial to also ensure apport from someone basis. The concrete ise are to be worked owledge (not available the support of creation ag activities such as materials, interaction ell as expert opinion owledge (not available		
	17,000.00	analysis and review of relevant materials, interaction with other project partners as well as expert opinion and consultation services.  Integration of specific expert knowledge (not available within the project) for WP6 with the support of creation of deliverables and corresponding activities such as				
	17,000.00	and consultate Integration of		owledge (not available		

		with	in the project) for WP7 with the support of creation	
			eliverables and corresponding activities such as	
		analysis and review of relevant materials, interaction		
			other project partners as well as expert opinion	
			consultation services.	
			gration of specific expert knowledge (not available	
			in the project) for WP8 with the support of creation	
	17,000.00		eliverables and corresponding activities such as	
			ysis and review of relevant materials, interaction	
			other project partners as well as expert opinion	
			consultation services.	
			ause the JA's main objective is to support the work	
			e eHN, it needs to be in the position to react	
	10,000.00		kly on eHN requests and/or follow-up activities	
			result from its decisions and discussions and that	
			not be covered within the project's own resources.	
			ng project execution, it is possible that	
			nticipated technical or logistical needs beyond those	
			idered above arise that cannot be answered by the	
			ortium expertise or resources (for example a need	
	30,000.00		technical, legal, or other analysis in an area	
			ide of the skills of all the consortium partners).	
			se funds will be used by the coordinator to answer	
			unexpected needs by contracting external experts	
		to fu	lfil them	
<b>Total Costs (€) of (B)</b>	130,000.00			
	Justificatio	n		
	See above			
1	200 400 10			
(C) Other direct costs				
(C) Other direct costs (C.1) Travel	Costs (t	E)	Justification	
` /		€)	64,800€ for the travel of 3 people for 24 events (6	
` /	Costs (f		64,800€ for the travel of 3 people for 24 events (6 SC meetings, 6 LC meetings, 12 workshops), plus	
` /			64,800€ for the travel of 3 people for 24 events (6 SC meetings, 6 LC meetings, 12 workshops), plus 35,000€ to support the travel of external experts	
(C.1) Travel	<b>Costs (6</b> 99,800.0	00	64,800€ for the travel of 3 people for 24 events (6 SC meetings, 6 LC meetings, 12 workshops), plus 35,000€ to support the travel of external experts to the workshops	
` '	Costs (f	00	64,800€ for the travel of 3 people for 24 events (6 SC meetings, 6 LC meetings, 12 workshops), plus 35,000€ to support the travel of external experts	
(C.1) Travel (C.2) Equipment	99,800.0 Costs (6	00 €)	64,800€ for the travel of 3 people for 24 events (6 SC meetings, 6 LC meetings, 12 workshops), plus 35,000€ to support the travel of external experts to the workshops  Justification  -	
(C.1) Travel	<b>Costs (6</b> 99,800.0	00 €)	64,800€ for the travel of 3 people for 24 events (6 SC meetings, 6 LC meetings, 12 workshops), plus 35,000€ to support the travel of external experts to the workshops  Justification  Justification	
(C.1) Travel (C.2) Equipment	Costs (6	(E)	64,800€ for the travel of 3 people for 24 events (6 SC meetings, 6 LC meetings, 12 workshops), plus 35,000€ to support the travel of external experts to the workshops  Justification  - Justification help support the costs of meetings that involve 40	
(C.1) Travel (C.2) Equipment	99,800.0 Costs (6	(E)	64,800€ for the travel of 3 people for 24 events (6 SC meetings, 6 LC meetings, 12 workshops), plus 35,000€ to support the travel of external experts to the workshops  Justification  - Justification  help support the costs of meetings that involve 40 participants or more, which will potential require	
(C.1) Travel (C.2) Equipment	Costs (6	(E)	64,800€ for the travel of 3 people for 24 events (6 SC meetings, 6 LC meetings, 12 workshops), plus 35,000€ to support the travel of external experts to the workshops  Justification  Justification  help support the costs of meetings that involve 40 participants or more, which will potential require the renting of rooms	
(C.1) Travel (C.2) Equipment	Costs (6  99,800.0  Costs (6	(E) (E)	64,800€ for the travel of 3 people for 24 events (6 SC meetings, 6 LC meetings, 12 workshops), plus 35,000€ to support the travel of external experts to the workshops  Justification  -  Justification help support the costs of meetings that involve 40 participants or more, which will potential require the renting of rooms support meeting services, such as catering,	
(C.1) Travel (C.2) Equipment	Costs (6	(E) (E)	64,800€ for the travel of 3 people for 24 events (6 SC meetings, 6 LC meetings, 12 workshops), plus 35,000€ to support the travel of external experts to the workshops  Justification  -  Justification  help support the costs of meetings that involve 40 participants or more, which will potential require the renting of rooms  support meeting services, such as catering, technical equipment, and other such services	
(C.1) Travel (C.2) Equipment	Costs (6  99,800.0  Costs (6  3,300.0  20,000.0	(E) (O) (O)	64,800€ for the travel of 3 people for 24 events (6 SC meetings, 6 LC meetings, 12 workshops), plus 35,000€ to support the travel of external experts to the workshops  Justification  - Justification  help support the costs of meetings that involve 40 participants or more, which will potential require the renting of rooms  support meeting services, such as catering, technical equipment, and other such services support professional quality review and language	
(C.1) Travel  (C.2) Equipment  (C.3) Other goods and services	Costs (6  99,800.0  Costs (6  3,300.0  20,000.0  8,000.0	000	64,800€ for the travel of 3 people for 24 events (6 SC meetings, 6 LC meetings, 12 workshops), plus 35,000€ to support the travel of external experts to the workshops  Justification  -  Justification  help support the costs of meetings that involve 40 participants or more, which will potential require the renting of rooms  support meeting services, such as catering, technical equipment, and other such services	
(C.1) Travel  (C.2) Equipment  (C.3) Other goods and services  Total Costs (€) of (C)	Costs (€  99,800.0  Costs (€  3,300.0  20,000.0  8,000.0  131,100.	000	64,800€ for the travel of 3 people for 24 events (6 SC meetings, 6 LC meetings, 12 workshops), plus 35,000€ to support the travel of external experts to the workshops  Justification  - Justification  help support the costs of meetings that involve 40 participants or more, which will potential require the renting of rooms  support meeting services, such as catering, technical equipment, and other such services support professional quality review and language	
(C.1) Travel  (C.2) Equipment  (C.3) Other goods and services  Total Costs (€) of (C)  (D) Indirect Costs	Costs (6  99,800.0  Costs (6  3,300.0  20,000.0  8,000.0  131,100.  Total Costs	00 €) 0 0 0 0 0 0 8 (€)	64,800€ for the travel of 3 people for 24 events (6 SC meetings, 6 LC meetings, 12 workshops), plus 35,000€ to support the travel of external experts to the workshops  Justification  - Justification  help support the costs of meetings that involve 40 participants or more, which will potential require the renting of rooms  support meeting services, such as catering, technical equipment, and other such services support professional quality review and language	
(C.1) Travel  (C.2) Equipment  (C.3) Other goods and services  Total Costs (€) of (C)	Costs (€  99,800.0  Costs (€  3,300.0  20,000.0  8,000.0  131,100.	00 €) 0 00 00 s (€)	64,800€ for the travel of 3 people for 24 events (6 SC meetings, 6 LC meetings, 12 workshops), plus 35,000€ to support the travel of external experts to the workshops  Justification  - Justification  help support the costs of meetings that involve 40 participants or more, which will potential require the renting of rooms  support meeting services, such as catering, technical equipment, and other such services support professional quality review and language	

Applicant Number/ Short Name	2 - ATNA	
(If affiliated entity: Affiliated to		
which Applicant number/Short name)	-	
(A) Direct personnel costs		

Staff function	<b>Monthly Cost</b>	Estimated Person-month	Sum Cost (€)	
Senior level manager	12,000.00	5.18	62,068.97	
Project manager	8,000.00	4.98	39,862.07	
Expert level	6,000.00	10.34	62,068.97	
		Total person month	Total Costs (€) for (A)	
		20.5	164,000.00	
	Justification			
		r of WP3, and has extensive p	participation in all the	
	remaining primary			
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/Justification		
	36,000.00	Integration of specific expert knowledge (not available within the partner) for WP3, WP5, WI with the support of activities such as analysis ar review of relevant materials, interaction with other project partners as well as expert opinion and consultation services.		
<b>Total Costs (€) of (B)</b>	36,000.00			
	Justification			
	See above			
(C) Other direct costs				
(C.1) Travel	Costs (€)	Justification		
	27,000.00	Amount to cover the travel of events (6 SC meetings, 6 LC workshops)		
(C.2) Equipment	Costs (€)	Justification		
	-	-		
(C.3) Other goods and services	Costs (€)	Justification		
<b>Total Costs (€) of (C)</b>	27,000.00			
(D) Indirect Costs	<b>Total Costs (€)</b>			
(Max. 7% on A, B and C)	15,890.00			
<b>Total estimated eligible costs</b>	242,890.00			

Applicant Number/ Short Name	ELGA				
(If affiliated entity: Affiliated to which Applicant number/Short name)	2 - ATNA				
(A) Direct personnel costs					
Staff function	<b>Monthly Cost</b>	Estimated Person-month	Sum Cost (€)		
Senior consultant	14,500.00	3.00	43,500.00		
Consultant	8,500.00	3.00	25,500.00		
Technical expert	10,400.00	3.00	31,200.00		
	Total person month    Total Costs (€) for (A)				
	9 100,200.00				
	Justification				
	This affiliate will provide direct support to ATNA in WP4 and				
	WP6, which is their area of expertise				
(B) Direct costs of sub-contracting	Costs (€) Task	(s)/Justification			

	, , , , , , , , , , , , , , , , , , , ,	
	-	
<b>Total Costs (€) of (B)</b>	-	
	Justification	
(C) Other direct costs		
(C.1) Travel	Costs (€)	Justification
	5.850.00	Amount to cover the travel of 1 person for 6
	3.830.00	events (6 workshops)
(C.2) Equipment	Costs (€)	Justification
	-	-
(C.3) Other goods and services	Costs (€)	Justification
	-	
<b>Total Costs (€) of (C)</b>	5.850.00	
(D) Indirect Costs	<b>Total Costs</b>	(€)
(Max. 7% on A, B and C)	7,423.50	
Total estimated eligible costs	113,473.50	

Applicant Number/ Short Name	GÖG					
(If affiliated entity: Affiliated to which Applicant number/Short name)	2 - ATNA					
(A) Direct personnel costs						
Staff function	Monthly Cost		Estimated Person-month	Sum Cost (€)		
Senior consultant	15,5	11.00	2.20	34,048.30		
Project manager/expert	11,92	28.00	1.92	22,910.30		
Junior expert/researcher	6,70	65.00	4.88	33,041.40		
			Total person month	Total Costs (€) for (A)		
			9	90,0000.00		
	Justificati					
	This affiliate will provide direct support to ATNA in WP4 and					
	WP5, which is their area of expertise					
(B) Direct costs of sub-contracting	Costs (€)   Task(s)/Justification					
	-					
<b>Total Costs (€) of (B)</b>	-					
	Justificati	on				
(C) Other direct costs	<b>G</b>	<u> </u>	T- 100 10			
(C.1) Travel	Costs (	€)	Justification	0.1		
	5,850.0	00	Amount to cover the travel of 1 person for 6			
(CA) E			events (6 workshops)			
(C.2) Equipment	Costs (	€)	Justification			
(C.3) Other goods and services	Costs (	C)	Justification			
(C.5) Other goods and services	Costs (	C)	Amount to provide the part	ner with current for the		
	1,500.00		organization and hosting of			
			meeting	one consortium		
<b>Total Costs (€) of (C)</b>	7,350.0	)()	meeting			
(D) Indirect Costs	Total Cost					
(Max. 7% on A, B and C)	6,814.5					
Total estimated eligible costs	104,164					
	101,107					

Applicant Number/ Short Name	3 - MoH-0	CY			
(If affiliated entity: Affiliated to which					
Applicant number/Short name)	-				
(A) Direct personnel costs					
Staff function	Mont	hly Cost	t	Estimated Person-month	Sum Cost (€)
Senior consultant		5,50	00.00	3.95	21,725.00
				Total person	Total Costs (€) for
				month	(A)
				3.95	21,725.00
	Justificati	_			
					P4, WP6, and WP7,
	which all fall in its area of expertise				
(B) Direct costs of sub-contracting	Costs (€)	Task(s)	)/Justi	fication	
	-				
<b>Total Costs (€) of (B)</b>	-				
	Justificati	on			
	-				
(C) Other direct costs					
(C.1) Travel	Costs (	<b>(€)</b> Ju	ustific	ation	
	21,600.	()()		t to cover the travel	* *
	21,000.	ev		6 SC meetings, 6 w	orkshops)
(C.2) Equipment	Costs (	€) Ju	ustific	ation	
	-	-			
(C.3) Other goods and services	Costs (	(€) Ju	ustific	ation	
	_				
<b>Total Costs (€) of (C)</b>	21,600.	00			
(D) Indirect Costs	<b>Total Cost</b>	ts (€)			
(Max. 7% on A, B and C)	3,032.7	75			
<b>Total estimated eligible costs</b>	46,357.	75			

Applicant Number/ Short Name	University	of Cyprus			
(If affiliated entity: Affiliated to which Applicant number/Short name)	3 - MoH-(	CY			
(A) Direct personnel costs					
Staff function	Mont	hly Cost	Estimated Person-month	Sum Cost (€)	
Senior consultant		5,500.00	15.00	82,500.00	
Project manager		4,000.00	3.00	12,000.00	
Senior IT officer		4,000.00	14.00	56,000.00	
			Total person	<b>Total Costs (€) for</b>	
			month	(A)	
			32	150,500.00	
	Justification				
	This affiliate will provide direct support to MoH-CY in WP7 and WP8, which is its area of expertise				
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/Justi	fication		
	-				
<b>Total Costs (€) of (B)</b>	-				
	Justification				

(C) Other direct costs		
(C.1) Travel	Costs (€)	Justification
	-	
(C.2) Equipment	Costs (€)	Justification
	-	-
(C.3) Other goods and services	Costs (€)	Justification
	-	
<b>Total Costs (€) of (C)</b>	-	
(D) Indirect Costs	<b>Total Costs (€)</b>	
(Max. 7% on A, B and C)	10,535.00	
<b>Total estimated eligible costs</b>	161,035.00	

Applicant Number/ Short Name	4 - MZCR	•			
(If affiliated entity: Affiliated to which					
Applicant number/Short name)	-				
(A) Direct personnel costs					
Staff function	Mont	hly Cost	Estimated Person-month	Sum Cost (€)	
Senior Director		3,412.0	0 28	95,536.00	
			Total person month	Total Costs (€) for (A)	
			28	95,536.00	
	Justificati	-			
			ader of WP7, and als	o has extensive	
	participation in WP6				
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/Ju	stification		
	-				
<b>Total Costs (€) of (B)</b>	-				
	Justification				
(C) Other direct costs					
(C.1) Travel	Costs (	,	ication		
			int to cover the travel		
	36,000.		events (6 SC meetings, 6 LC meetings, 8		
(3.4)	<b>S</b>		hops)		
(C.2) Equipment	Costs (	€) Justii	ication		
	-	- T 1.1	p 1 •		
(C.3) Other goods and services	Costs (	E) Justii	ication		
Total Costs (f) of (C)	26,000	00			
Total Costs (€) of (C) (D) Indirect Costs	36,000.				
· /	Total Cost				
(Max. 7% on A, B and C)	9207.5				
Total estimated eligible costs	140,743	.52			

<b>Applicant Number/ Short Name</b>	5 - GEMATIK		
(If affiliated entity: Affiliated to which			
Applicant number/Short name)	-		
(A) Direct personnel costs			
Staff function	Monthly Cost	Estimated	Sum Cost (F)
Stall function	Monthly Cost	Person-month	Sum Cost (€)

Senior Project Coordinator		7,400.	.00	10.28	76,055.56
Project Expert	5,700.0		.00	18.50	105,450.00
Project Coordinator		4,800.	.00	8.22	39,466.66
				Total person	<b>Total Costs (€) for</b>
				month	(A)
				37	220,972.22
	Justification	on			
	gematik will be involved in WPL and TL position for WP6 Enhancing continuity of care as well as taking the expert role in several content-related tasks				
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/J			
	-	-			
<b>Total Costs (€) of (B)</b>	-				
	Justification				
	-				
(C) Other direct costs					
(C.1) Travel	Costs (	€) Just	tifica	ation	
		Amo	ount	to cover the travel	of 2 people for 20
	36,000.0		events (6 SC meetings, 6 LC meetings, 8		
			workshops)		
(C.2) Equipment	Costs (	€) Just	tifica	ation	
	-	-			
(C.3) Other goods and services	Costs (	€) Just	tifica	ation	
	-	-			
Total Costs (€) of (C)	36,000.0				
(D) Indirect Costs	Total Cost	_ ` ´ _			
(Max. 7% on A, B and C)	17,988.0				
Total estimated eligible costs	274,960.	.28			

Applicant Number/ Short Name	6 - MoSA			
(If affiliated entity: Affiliated to which Applicant number/Short name)	-			
(A) Direct personnel costs				
Staff function	Mont	hly Cost	Estimated Person-month	Sum Cost (€)
Senior consultant		6,000.00	12.46	74,769.00
Project manager		4,500.00	14.54	65,423.00
			Total person	<b>Total Costs (€) for</b>
			month	(A)
			27.00	140,192.00
	Justificati	on		
	The partne in WP6 and		ler of WP4, and has	extensive participation
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/Justi	fication	
	-			
<b>Total Costs (€) of (B)</b>	-			
	Justificati	on		
(C) Other direct costs				
(C.1) Travel	Costs (	<b>€)</b> Justific	ation	

	36,000.00	Amount to cover the travel of 2 people for 20 events (6 SC meetings, 6 LC meetings, 8 workshops)
(C.2) Equipment	Costs (€)	Justification
	-	-
(C.3) Other goods and services	Costs (€)	Justification
	-	
<b>Total Costs (€) of (C)</b>	36,000.00	
(D) Indirect Costs	<b>Total Costs (€)</b>	
(Max. 7% on A, B and C)	12,333.44	
<b>Total estimated eligible costs</b>	188,525.44	

Applicant Number/ Short Name	7 – 3 <sup>rd</sup> RH	<b>A</b>			
(If affiliated entity: Affiliated to which	7 3 101	11			
Applicant number/Short name)	-				
(A) Direct personnel costs					
(A) Direct personner costs			77.41		
Staff function	Mont	hly Cost	Estimated Person-month	Sum Cost (€)	
Senior IT engineer 1	3,200.00			32,520.00	
Senior IT engineer 2		3,400.0		24,186.75	
Project manager		4,200.0	0 15.24	· · · · · · · · · · · · · · · · · · ·	
			Total person	Total Costs (€) for	
			month	(A)	
			32.52	120,730.50	
	Justification	on			
	The partner is the leader of WP7, and has extensive participation in				
	most of the remaining primary workpackages				
(B) Direct costs of sub-contracting	Costs (€)   Task(s)/Justification				
		The amount is to subcontract the Aristotle University of			
		Thessaloniki to support the WP7 work. The organisation			
	55.000.00	has extensive	ve expertise in the are	ea covered by that	
		workpackag	ackage, and its support is deemed important to		
		achieve the	desired work objecti	ves set for the former	
Total Costs (€) of (B)	55.000.00				
	Justification	on			
(C) Other direct costs					
(C.1) Travel	Costs (	€) Justif	ication		
		,	nt to cover the travel	of 2 people for 20	
	38,700.0		s (6 SC meetings, 6 L		
			hops), plus 3 trips fo	•	
(C.2) Equipment	Costs (		ication		
	-	-			
(C.3) Other goods and services	Costs (€) Ju		Justification		
g = == g = == <b>g</b> = = <b>g</b> = <b>g</b> = = <b>g</b> =	-	, , ,			
<b>Total Costs (€) of (C)</b>	38,700.0	00			
(D) Indirect Costs	Total Cost				
(Max. 7% on A, B and C)	15,010.				
Total estimated eligible costs	229,440				
Total colliacta engible costs	227,770	.07			

Applicant Number/ Short Name	General H	lospital Pap	ageorgiou	
(If affiliated entity: Affiliated to which Applicant number/Short name)	$7-3^{\rm rd}$ RH.			
(A) Direct personnel costs				
Staff function	Mont	hly Cost	Estimated Person-month	Sum Cost (€)
Senior IT engineer		3,000.0	0 6.0	,
			Total person month	Total Costs (€) for (A)
			6.00	18,000.00
	Justificati	on		
(B) Direct costs of sub-contracting	Costs (€)   Task(s)/Justification			
	-			
<b>Total Costs (€) of (B)</b>	-			
	Justificati	-		
				3 <sup>rd</sup> RHA in WP7, which
	is their are	a of expertis	e	
(C) Other direct costs		0   -		
(C.1) Travel	Costs (	€) Justii	fication	
(CA) T	- C + (	T (1)	De 4 •	
(C.2) Equipment	Costs (	€) Justii	fication	
(C 2) Other goods and services	Contac	- T a4:4	fication	
(C.3) Other goods and services	Costs (	t) Justii	ncauon	
<b>Total Costs (€) of (C)</b>	_			
(D) Indirect Costs	Total Cost	ts (E)		
(Max. 7% on A, B and C)	1,260.0	` '		
Total estimated eligible costs	19,260.			
Total Commated engine costs	19,400.	UU		

Applicant Number/ Short Name	General H	ospital of The	essaloniki George l	Papanikolaou	
(If affiliated entity: Affiliated to which Applicant number/Short name)	$7 - 3^{rd}$ RH.	A			
(A) Direct personnel costs					
Staff function	Mont	hly Cost	Estimated Person-month	Sum Cost (€)	
Senior IT engineer		3,000.00	2.00	6,000.00	
			Total person	<b>Total Costs (€) for</b>	
			month	(A)	
			2.00	6,000.00	
	Justification				
	This affiliate will provide direct support to 3 <sup>rd</sup> RHA in WP7, which				
	is their are	a of expertise			
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/Justi	ification		
	-				
Total Costs (€) of (B)	-				
	Justificati	on			
(C) Other direct costs					
(C.1) Travel	Costs (	€) Justific	ation		
	-				
(C.2) Equipment	Costs (	€) Justific	ation		

	-	-
(C.3) Other goods and services	Costs (€)	Justification
	-	
<b>Total Costs (€) of (C)</b>	-	
(D) Indirect Costs	<b>Total Costs (€)</b>	
(Max. 7% on A, B and C)	420.00	
<b>Total estimated eligible costs</b>	6,420.00	

Applicant Number/ Short Name	8 - MSSSI				
(If affiliated entity: Affiliated to which					
Applicant number/Short name)	_		1		
(A) Direct personnel costs					
Staff function	Mont	hly Cost	Estimated Person-month	Sum Cost (€)	
Vice-Directorate		5,048.40	0.08	387.76	
Chief of department		4,383.60	0.08	336.75	
Consultant		3,872.00		7,121.59	
Project manager		9,196.00	0.31	2,824.89	
			Total person month	Total Costs (€) for (A)	
			2.3	10,670.99	
	Justification				
	The partne	r will have a	minor participation i	n WP6 and WP8	
(B) Direct costs of sub-contracting	Costs (€) Task(s)/Justification				
	Funds are for contracting an external consultant expert in European project participation to support MSSSI in its work				
<b>Total Costs (€) of (B)</b>	12,000.00				
	Justificati	on			
(C) Other direct costs					
(C.1) Travel	Costs (	-,	cation		
	10,800.		nt to cover the travel (6 SC meetings, 6 w		
(C.2) Equipment	Costs (	€) Justif	cation		
	-	-			
(C.3) Other goods and services	Costs (	€) Justif	ication		
	-				
<b>Total Costs (€) of (C)</b>	10,800.				
(D) Indirect Costs	Total Cost				
(Max. 7% on A, B and C)	2,342.9				
Total estimated eligible costs	35,813.	96			

Applicant Number/ Short Name	9 - THL		
(If affiliated entity: Affiliated to which Applicant number/Short name)	-		
(A) Direct personnel costs			
Staff function	Monthly Cost	Estimated Person-month	Sum Cost (€)
~ .	7.500.00	2.00	22 500 00
Senior expert	7,500.00	3.00	22,500.00

Experts/WP co-leader		5,900	0.00	16.00	94,400.00
				Total person	Total Costs (€) for
				month	(A)
				22	136,400.00
	Justification				
	The partner is the co-leader of WP5, and participates in all the				ticipates in all the
	remaining primary workpackages				
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/	/Justi	fication	
	-				
<b>Total Costs (€) of (B)</b>	-				
	Justification	on			
(C) Other direct costs					
(C.1) Travel	Costs (	€) Jus	stific	ation	
		An	noun	t to cover the travel	of 2 people for 20
	48,000.0	00 eve	ents (	6 SC meetings, 6 L	C meetings, 8
		wo	orksh	ops)	
(C.2) Equipment	Costs (	€) Jus	stific	ation	
	-	-			
(C.3) Other goods and services	Costs (	€) Jus	stific	ation	
	-				
<b>Total Costs (€) of (C)</b>	48,000.	00			
(D) Indirect Costs	<b>Total Cost</b>	ts (€)			
(Max. 7% on A, B and C)	12,908.	00			_
<b>Total estimated eligible costs</b>	197,308	.00			

Applicant Number/ Short Name	10 – MoH	-FR			
(If affiliated entity: Affiliated to which Applicant number/Short name)	-				
(A) Direct personnel costs					
Staff function	Mont	hly Cost	Estimated Person-month	Sum Cost (€)	
Senior strategist		10,680.00	2.62	27,928.20	
Project manager		8,400.00	2.62	21,966.00	
			Total person	Total Costs (€) for	
			month	(A)	
			5.23	49,894.20	
	Justification				
	The partner is the leader of WP8, and participates in all the				
		primary work	packages		
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/Just	ification		
	-				
<b>Total Costs (€) of (B)</b>	-				
	Justificati	on			
(C) Other direct costs					
(C.1) Travel	Costs (	€) Justific	cation		
		Amour	nt to cover the travel	of 2 people for 20	
	36,000.	00 events	(6 SC meetings, 6 L	C meetings, 8	
		worksh	orkshops)		
(C.2) Equipment	Costs (	€) Justific	cation		
	_	-			

(C.3) Other goods and services	Costs (€)	Justification
	-	
<b>Total Costs (€) of (C)</b>	36,000.00	
(D) Indirect Costs	<b>Total Costs (€)</b>	
(Max. 7% on A, B and C)	6,012.59	
<b>Total estimated eligible costs</b>	91,906.79	

Applicant Number/ Short Name	ASIP Santé	Š		
(If affiliated entity: Affiliated to which Applicant number/Short name)	10 – MoH-F	₹R		
(A) Direct personnel costs				
Staff function	Month	nly Cost	Estimated Person-month	Sum Cost (€)
Senior expert	10,735.00		5.96	64,023.54
Project manager		7,300.00	11.93	87,074.40
Risk manager		7,300.00	1.99	14,512.40
			Total person month	Total Costs (€) for (A)
			19.88	165,610.34
	Justificatio			
	This affiliate will provide direct support to MoH-FR in all the WPs the latter participates on			
(B) Direct costs of sub-contracting	Costs (€) Task(s)/Justification			
	ASIP Santé's internal experts to focus on strategic tasks, and subcontract the remaining work to extern experts. These funds will allow the subcontractors to contribute to the creation of content for deliverables well to attend the different meetings and calls, and keep ASIP Santé own experts informed of the work progress.			the subcontractors to tent for deliverables, as ings and calls, and to
<b>Total Costs (€) of (B)</b>	100,000.00	T - G		
	Justificatio	n		
(C) Other direct costs				
(C.1) Travel	Costs (€	(a) Justifi	cation	
	-	) = .40		
(C.2) Equipment	Costs (€	(E) Justifi	cation	
(C.3) Other goods and services	Costs (	Justifi	cation	
T-4-1 C-44 (C) of (C)	-			
Total Costs (€) of (C) (D) Indirect Costs	Total Casts	· (C)		
\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	<b>Total Costs</b> 18,592.7			
(Max. 7% on A, B and C) <b>Total estimated eligible costs</b>	284,203.0			
Total estimated engible costs	204,203.	UU		

Applicant Number/ Short Name	CNAM		
(If affiliated entity: Affiliated to which Applicant number/Short name)	10 – MoH-FR		
(A) Direct personnel costs			
Staff function	Monthly Cost	Estimated Person-month	Sum Cost (€)

Senior consultant		9,540.0	n	4.50	42,930.00
Schiol consultant		7,540.0	U		Total Costs (€) for
				Total person	<b>\</b> /
				month	(A)
				4.50	42,930.00
	Justificati	on			
	This affiliate will provide direct support to MoH-FR in all the V			IoH-FR in all the WPs	
	the latter participates on				
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/Jus	stif	fication	
	-				
<b>Total Costs (€) of (B)</b>	-				
	Justificati	on			
(C) Other direct costs					
(C.1) Travel	Costs (	€) Justif	ica	ation	
	-				
(C.2) Equipment	Costs (	€) Justif	ica	ation	
	-	-			
(C.3) Other goods and services	Costs (	€) Justif	ica	ation	
	_				
<b>Total Costs (€) of (C)</b>	-				
(D) Indirect Costs	<b>Total Cost</b>	ts (€)			
(Max. 7% on A, B and C)	3,005.	1			
Total estimated eligible costs	45,935	.1			

Applicant Number/ Short Name	11 - HZZ(	)		
(If affiliated entity: Affiliated to which				
Applicant number/Short name)	-			
(A) Direct personnel costs				
Staff function	Mont	hly Cost	Estimated Person-month	Sum Cost (€)
Senior consultant		2,500.00	4.00	10,000.00
Project manager		2,500.00	8.00	20,000.00
Consultant		2,000.00	12.00	24,000.00
			Total person month	Total Costs (€) for (A)
			24	54,000.00
	Justification	on		
	The partner participates in all the primary workpackages			orkpackages
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/Justi	stification	
	-			
<b>Total Costs (€) of (B)</b>	-			
	Justification	on		
(C) Other direct costs				
(C.1) Travel	Costs (	<b>€)</b> Justific	ation	
	1 / 1 (50) 1 (1) 1		Amount to cover the travel of 2 people for 12 events (6 SC meetings, 6 workshops)	
(C.2) Equipment			<b>Justification</b>	
	-	-		
(C.3) Other goods and services	Costs (	<b>€</b> ) Justific	ation	
	_			
<b>Total Costs (€) of (C)</b>	21,600.	00		

(D) Indirect Costs	<b>Total Costs (€)</b>	
(Max. 7% on A, B and C)	5,292.00	
Total estimated eligible costs	80,892.00	

Applicant Number/ Short Name	12 - NHSC	2			
(If affiliated entity: Affiliated to which					
Applicant number/Short name)	_				
(A) Direct personnel costs					
Staff function	Mont	hly Cos	t	Estimated Person-month	Sum Cost (€)
Project manager			00.00	6.09	17,062.50
Financial manager		2,6	00.00	6.09	15,843.75
Senior consultant/expert		2,2	00.00	4.06	8,937.50
				Total person	Total Costs (€) for
				month	(A)
				16.25	41,843.75
	Justification				
				of WP5, and partici	pates in all the
	remaining primary workpackages				
(B) Direct costs of sub-contracting	Costs (€)	Task(s	)/Justi	fication	
	-				
<b>Total Costs (€) of (B)</b>	-				
	Justificati	on			
(C) Other direct costs					
(C.1) Travel	Costs (		ustific		
				to cover the travel	
	36,000.			6 SC meetings, 6 L	C meetings, 8
			vorksho	1 /	
(C.2) Equipment	Costs (	<b>€</b> ) J	ustific	ation	
	-	-			
(C.3) Other goods and services	Costs (	<b>€</b> ) J	ustific	ation	
	-				
Total Costs (€) of (C)	36,000.				
(D) Indirect Costs	Total Cost	_ ` /			
(Max. 7% on A, B and C)	5,449.0				
Total estimated eligible costs	83,292.	81			

Applicant Number/ Short Name	<b>Semmelweis University</b>		
(If affiliated entity: Affiliated to which Applicant number/Short name)	12 - NHSC		
(A) Direct personnel costs			
Staff function	Monthly Cost	Estimated Person-month	Sum Cost (€)
Senior expert 1	5,824.52	3.83	22,327.33
Senior expert 2	3,148.39	3.83	12,068.83
Senior expert 3	2,624.97	4.60	12,074.86
Project manager	3,541.94	6.13	21,723.90
Junior expert 1	2,164.52	4.60	9,956.79
Junior expert 2	1,574.19	5.75	9,051.59
Junior expert 3	2,833.55	3.83	10,861.94

E 1 CC.		2.450.6	0	1.02	4.71.4.20
Financial officer		2,459.6	8	1.92	4,714.39
				Total person	<b>Total Costs (€) for</b>
				month	(A)
				34.50	102,779.56
	Justificati	on			
	This affilia	te will provi	de e	extensive direct su	pport to NHSC in
	WP5, which	h is their are	a o	of expertise, as wel	l as support the latter in
	the other w	orkpackages	s it j	participates on	
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/Jus	stifi	ication	
	-				
<b>Total Costs (€) of (B)</b>	-				
	Justificati	on			
(C) Other direct costs					
(C.1) Travel	Costs (	€) Justif	ica	tion	
	-				
(C.2) Equipment	Costs (	€) Justif	ica	tion	
	-	-			
(C.3) Other goods and services	Costs (	€) Justif	ica	tion	
	_				
<b>Total Costs (€) of (C)</b>	-				
(D) Indirect Costs	<b>Total Cost</b>	ts (€)			
(Max. 7% on A, B and C)	7,194.5	57			
Total estimated eligible costs	109,974	.13			

Applicant Number/ Short Name	13 - DoH			
(If affiliated entity: Affiliated to which	_			
Applicant number/Short name)				
(A) Direct personnel costs				
Staff function	Mont	hly Cost	Estimated Person-month	Sum Cost (€)
Principal		7,368.00	5.05	37,227.32
Assistant principal		6,307.00	3.67	23,175.67
Legal expert		6,307.00	1.84	11,587.83
Senior administrator		4,671.00	1.84	8,582.02
eHealth expert		7,000.00	17.45	122,180.27
Technical expert		6,577.00	2.30	15,104.88
Assistant Secretary General		11,138.00	1.84	20,463.82
			Total person	<b>Total Costs (€) for</b>
			month	(A)
			33.99	238,321.80
	Justificati	on		
	The partne	r is the co-lead	ler of WP6, and par	ticipates in all the
		primary work		
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/Justi	ification	
	_			
<b>Total Costs (€) of (B)</b>	-			
	Justificati	on		
(C) Other direct costs				
(C.1) Travel	Costs (	<b>€)</b> Justific	ation	
	36,000.	00 Amoun	t to cover the travel	of 2 people for 20

		events (6 SC meetings, 6 LC meetings, 8 workshops)
(C.2) Equipment	Costs (€)	Justification
	-	-
(C.3) Other goods and services	Costs (€)	Justification
	-	
<b>Total Costs (€) of (C)</b>	36,000.00	
(D) Indirect Costs	<b>Total Costs (€)</b>	
(Max. 7% on A, B and C)	19,202.53	
Total estimated eligible costs	293,524.33	

Applicant Number/ Short Name	14 - MINS	SAL		
(If affiliated entity: Affiliated to which				
Applicant number/Short name)	-			
(A) Direct personnel costs				
Staff function	Mont	hly Cost	Estimated Person-month	Sum Cost (€)
Head of office		12,589.94	1.00	12,589.94
Official		5,801.64		11,603.28
Administrative		3,661.79		3,661.79
			Total person month	Total Costs (€) for (A)
			4.00	27,855.01
	Justificati	-		
			minor participation i	n WP6 and WP8
(B) Direct costs of sub-contracting	Costs (€) Task(s)/Justification			
	-			
<b>Total Costs (€) of (B)</b>	-			
	Justificati	on		
(6) 6.1				
(C) Other direct costs	C + (	O) T (**	4.	
(C.1) Travel	Costs (	- ,	cation	£1 £ 10
	12,800.	events	nt to cover the travel (6 SC meetings, 6 w	•
(C.2) Equipment	Costs (	€) Justifi	cation	
	-	-		
(C.3) Other goods and services	Costs (	€) Justifi	cation	
	-			
<b>Total Costs (€) of (C)</b>	12,800.			
(D) Indirect Costs	Total Cost			
(Max. 7% on A, B and C)	2,845.8			
Total estimated eligible costs	43,500.	86		

<b>Applicant Number/ Short Name</b>	15 - SAM		
(If affiliated entity: Affiliated to which			
Applicant number/Short name)			
(A) Direct personnel costs			
Staff function	Monthly Cost	Estimated	Sum Cost (€)
Staff function	Within Cost	Person-month	Sum Cost (E)
Senior expert	2,000.00	26.00	52,000.00
		Total person	<b>Total Costs (€) for</b>

				month	(A)
				26.00	52,000.00
	Justification	on			
	The partne	r has ex	tensive	participation in all	the primary
	workpacka	iges			
(B) Direct costs of sub-contracting	Costs (€)	Task(s	)/Justi	fication	
	-				
<b>Total Costs (€) of (B)</b>	-				
	Justification				
(C) Other direct costs					
(C.1) Travel	Costs (€) Jus		Justification		
	21,600.00		Amount to cover the travel of 2 people for 12		
	21,000.	e e	events (6 SC meetings, 6 workshops)		
(C.2) Equipment	Costs (	<b>(€)</b> J	ustific	ation	
	-	-			
(C.3) Other goods and services	Costs (€)		Justification		
	_				·
<b>Total Costs (€) of (C)</b>	21,600.	00			
(D) Indirect Costs	<b>Total Cost</b>	ts (€)			
(Max. 7% on A, B and C)	5,152.0	00			
Total estimated eligible costs	78,752.	00			

Applicant Number/ Short Name	16 - AeS			
(If affiliated entity: Affiliated to which				
Applicant number/Short name)	-			
(A) Direct personnel costs				
Staff function	Mont	hly Cost	Estimated Person-month	Sum Cost (€)
Senior consultant		10,350.00		46,000.00
Junior consultant		6,800.00		22,666.67
Project manager/consultant		9,000.00	2.22	20,000.00
			Total person	<b>Total Costs (€) for</b>
			month	(A)
			10.00	88,667.00
	Justification	-		
	The partne	r will have a r	ninor participation i	n several workpackages
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/Just	ification	
	-			
<b>Total Costs (€) of (B)</b>	-			
	Justification	o <b>n</b>		
(C) Other direct costs				
(C.1) Travel	Costs (	€) Justifi	cation	
	10,000.0	Amour	nt to cover the travel	of 2 people for 12
	10,000.	events	(6 SC meetings, 6 w	orkshops)
(C.2) Equipment	Costs (	€) Justifie	cation	
	-	-		
(C.3) Other goods and services	Costs (	€) Justifi	cation	
	-			
<b>Total Costs (€) of (C)</b>	10,000.	00		
(D) Indirect Costs	<b>Total Cost</b>	ts (€)		

(Max. 7% on A, B and C)	6,906.69	
<b>Total estimated eligible costs</b>	105,573.69	

Applicant Number/ Short Name	17 - NHS					
(If affiliated entity: Affiliated to which						
Applicant number/Short name)	-					
(A) Direct personnel costs						
Staff function	Mont	hly Cost	Estimated Person-month	Sum Cost (€)		
IT department		3,200.00	10.75	34,400.00		
Project department		3,200.00	10.75	34,400.00		
			Total person	<b>Total Costs (€) for</b>		
			month	(A)		
			21.50	68,800.00		
	Justification	-				
	The partner	r participates	in all the remaining	primary workpackages		
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/Just	ification			
	-					
<b>Total Costs (€) of (B)</b>	-					
	Justification	on				
(C) Other direct costs						
(C.1) Travel	Costs (	€) Justifi	<b>Justification</b>			
	21,600.0	14 1	Amount to cover the travel of 2 people for 12 events (6 SC meetings, 6 workshops)			
(C.2) Equipment	Costs (	€) Justifi	tification			
	-	-				
(C.3) Other goods and services	Costs (	€) Justifi	cation			
	-					
<b>Total Costs (€) of (C)</b>	21,600.	00				
(D) Indirect Costs	<b>Total Cost</b>	ts (€)				
(Max. 7% on A, B and C)	6,328.0	00				
Total estimated eligible costs	96,728.	00				

Applicant Number/ Short Name	18 - MFH						
(If affiliated entity: Affiliated to which Applicant number/Short name)	-						
(A) Direct personnel costs							
Staff function	Mont	hly Cost	Estimated Person-month	Sum Cost (€)			
Senior consultant		7,000.00	2.00	14,000.00			
Project manager	3,000.00		2.00	6,000.00			
			Total person	Total Costs (€) for			
			month	(A)			
			4.00	20,000.00			
	Justificati	on					
	The partne	r will have a n	ninor participation is	n WP2 and WP8			
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/Justi	ification				
	-						
<b>Total Costs (€) of (B)</b>	-						
	Justificati	on					

(C) Other direct costs		
(C.1) Travel	Costs (€)	Justification
	12,800.00	Amount to cover the travel of 1 person for 12 events (6 SC meetings, 6 workshops)
(C.2) Equipment	Costs (€)	Justification
	-	-
(C.3) Other goods and services	Costs (€)	Justification
	-	
<b>Total Costs (€) of (C)</b>	12,800.00	
(D) Indirect Costs	<b>Total Costs (€)</b>	
(Max. 7% on A, B and C)	2,296.00	
<b>Total estimated eligible costs</b>	35,096.00	

Applicant Number/ Short Name	19 - NICT	IZ					
(If affiliated entity: Affiliated to which							
Applicant number/Short name)	-						
(A) Direct personnel costs							
Staff function	Mont	hly Cost		Estimated Person-month	Sum Cost (€)		
Senior advisor		12,00	0.00	8.50	102,000.00		
Medior adviser		9,00	0.00	8.50	76,500.00		
				Total person	<b>Total Costs (€) for</b>		
				month	(A)		
				17.00	178,500.00		
	Justificati						
	The partne WP8	r is the lea	ader	of WP4, and also pa	articipates in WP7 and		
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/	/Justi	fication			
	-						
<b>Total Costs (€) of (B)</b>	-						
	Justificati	on					
(C) Other direct costs							
(C.1) Travel	Costs (	-,	stific				
				nount to cover the travel of 2 people for 20			
	36,000.		events (6 SC meetings, 6 LC meetings, 8				
			workshops)				
(C.2) Equipment	Costs (	€) Ju	stific	ation			
(62) 04 1 1 1	-	- T	1.00	4.			
(C.3) Other goods and services	Costs (	€) Ju	stific	auon			
Total Costs (C) of (C)	26,000	00					
Total Costs (€) of (C)	36,000.						
(D) Indirect Costs	Total Cost						
(Max. 7% on A, B and C)	15,015.						
Total estimated eligible costs	229,515	.00					

Applicant Number/ Short Name	20 - NDE	
(If affiliated entity: Affiliated to which	_	
Applicant number/Short name)		
(A) Direct personnel costs		

Staff function	Mont	hly Cost		Estimated Person-month	Sum Cost (€)	
Senior consultant		7,200.	00	3.00	21,600.00	
Project manager		8,600.	00	7.00	60,200.00	
				Total person	<b>Total Costs (€) for</b>	
				month	(A)	
				10.00	81,800.00	
	Justification	on				
	The partner	r is the co-l	ead	ler of WP8, and par	ticipates in several	
	other work					
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/J	usti	ification		
	-					
<b>Total Costs (€) of (B)</b>	-					
	Justification	on				
(C) Other direct costs						
(C.1) Travel	Costs (	€) Just	ific	ation		
				t to cover the travel		
	36,000.		events (6 SC meetings, 6 LC meetings, 8			
			orkshops)			
(C.2) Equipment	Costs (	€) Just	Justification			
	-	-				
(C.3) Other goods and services	Costs (	€) Just	ific	ation		
	-					
<b>Total Costs (€) of (C)</b>	36,000.					
(D) Indirect Costs	<b>Total Cost</b>	ts (€)				
(Max. 7% on A, B and C)	8,246.0					
Total estimated eligible costs	126,046	.00				

Applicant Number/ Short Name	21 - IPHS				
(If affiliated entity: Affiliated to which					
Applicant number/Short name)	-				
(A) Direct personnel costs					
Staff function	Mont	hly Cost	Estimated Person-month	Sum Cost (€)	
Senior researcher/coordinator		1,650.00	3.90	6,435.00	
Senior researcher		1,100.00	11.70	12,870.00	
Junior researcher		1,100.00	3.90	4,290.00	
			Total person	<b>Total Costs (€) for</b>	
			month	(A)	
			19.50	23,595.00	
	Justificati	on			
		r has extensive all in its area o		P6, WP7, and WP8,	
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/Justi	ification		
	-				
<b>Total Costs (€) of (B)</b>	-				
	Justificati	on			
(C) Other direct costs					
(C.1) Travel	Costs (	€) Justific	ication		
	21,600.	00 Amoun	t to cover the travel	of 2 people for 12	

		events (6 SC meetings, 6 workshops)
(C.2) Equipment	Costs (€)	Justification
	-	-
(C.3) Other goods and services	Costs (€)	Justification
	-	
<b>Total Costs (€) of (C)</b>	21,600.00	
(D) Indirect Costs	<b>Total Costs (€)</b>	
(Max. 7% on A, B and C)	3,163.65	
Total estimated eligible costs	48,358.65	

Applicant Number/ Short Name	22 - NIJZ					
(If affiliated entity: Affiliated to which						
Applicant number/Short name)	_		_			
(A) Direct personnel costs						
Staff function	Mont	hly Cost	Estimated Person-month	Sum Cost (€)		
Senior researcher		3,800.00		62,084.00		
Senior consultant		5,000.00	3.16	15,811.00		
			Total person month	Total Costs (€) for (A)		
			19.50	77,895.00		
	Justificati	-				
	The partne	r has extensiv	e participation in all	the primary		
	workpacka					
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/Just	ification			
	-					
<b>Total Costs (€) of (B)</b>	-					
	Justificati	on				
(C) Other direct costs	G + (	(C) T (100)				
(C.1) Travel	Costs (			0.0 1.0 10		
	21,600.	( )( )	Amount to cover the travel of 2 people for 12			
(C 2) E	(C4 (		events (6 SC meetings, 6 workshops) <b>Justification</b>			
(C.2) Equipment	Costs (	€) Justino	cation			
(C.3) Other goods and services	Costs (	€) Justific	cation			
( • • • • • • • • • • • • • • • • • • •	-	( )				
<b>Total Costs (€) of (C)</b>	21,600.	00				
(D) Indirect Costs	Total Cost					
(Max. 7% on A, B and C)	6,964.6					
<b>Total estimated eligible costs</b>	106,459	.65				

# 11. Previous and Current Grants Relevant to the Programme (limited to the last 3 years)

- JAseHN
- PARENT JA
- CEF eHDSI

- EXPAND
- ProEmpower
- Trillium II
- EURO-CAS
- e-SENS
- eStandards
- VALUeHEALTH
- ASSESS CT
- ESIF
- Study on Big data in Public Health and Telemedicine

## 12. CURRENT APPLICATIONS RELEVANT TO THE PROGRAMME

- **JA-06-2017** Joint Action on Health Information towards a sustainable EU health information system that supports country knowledge, health research and policymaking (€4 million EU co-funding)
- **JA-02-2017** Joint Action Innovative Partnership on Action against Cancer (€4,5 million EU cofunding)

## 13. EXCEPTIONAL UTILITY

Not relevant as the JA will not request a higher co-funding rate than 60%.

#### 14. COLLABORATING STAKEHOLDERS

Institution	Contact person (First name and last name)	City & Country
Ministry of Health - Health Information and Communication Policy Directorate (MoH-HICPD)	Nayden Chivarov	Bulgaria
The Danish Health Data Authority (DHDA)	Kenneth Ahrensberg	Denmark
National Center Pre-hospital Emergency Medical Assistance (NCPEMA)	Ruslan Turcan	Moldova
Ministry of Health (MoH-PL)	Arleta Zaremba	Poland
National Public Health House (NPHH)	Andreea Gărăiacu	Romania
eHälsomyndigheten, The Swedish eHealth Agency (SEHA)	Rebecca Tornqvist	Sweden
National Health Information Centre (NHIC)	Jan Cap	Slovakia
UK Department of Health (DH)	Rob Dickman	United Kingdom
NHS Digital	Jeremy Thorp	United Kingdom
eHealth Suisse (eHS)	Stefan Wyss	Switzerland
Health Service Executive (HSE)	Richard Corbridge	Ireland

# ANNEX - ORDER FROM THE MINISTRY OF HEALTH OF LITHUANIA

# ESTIMATED BUDGET FOR THE ACTION (page 1 of 6 Associated with document Ref. Ares(2018)3532486 - 03/07/2018

	Estimated eligible costs (per budget category)				,	EU contribution	<b>0. 0</b>	Action's estimated receipts			
					m . 1		20 contribution				
	A. Direct personnel costs	B. Direct costs of subcontracting	C. Other direct costs	D. Indirect costs <sup>2</sup>	Total costs	Reimbursement rate % <sup>3</sup>	Maximum EU contribution <sup>4</sup>	Maximum grant amount <sup>5</sup>	Income generated by the action	Financial contributions given by third parties to the beneficiaries	Action's total receipts
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract and seconded persons		C.1 Travel C.2 Equipment C.3 Other goods and services								
Cost form <sup>6</sup>	Actual	Actual	Actual	Flat-rate <sup>7</sup> 7%							
	a	b	С	$d = 0.07 \times (a +b+c)$	e = a+b+c+d	f	$g = e \times f$	h	i	j	k = i + j
1. SPMS	561173.01	130000.00	131100.00	57559.11	879832.12	n\a	n\a	527899.27	0.00	0.00	0.00
2. ATNA	164000.00	36000.00	27000.00	15890.00	242890.00	n\a	n\a	145734.00	0.00	0.00	0.00
- GOeG	90000.00	0.00	7350.00	6814.50	104164.50	n\a	n\a	62498.70	0.00	0.00	0.00
- ELGA	100200.00	0.00	5850.00	7423.50	113473.50	n\a	n\a	68084.10	0.00	0.00	0.00
Total beneficiary	354200.00	36000.00	40200.00	30128.00	460528.00	n\a	n\a	276316.80	0.00	0.00	0.00
3. MoH-CY	21725.00	0.00	21600.00	3032.75	46357.75	n\a	n\a	27814.65	0.00	0.00	0.00
- UCY	150500.00	0.00	0.00	10535.00	161035.00	n\a	n\a	96621.00	0.00	0.00	0.00
Total beneficiary	172225.00	0.00	21600.00	13567.75	207392.75	n\a	n\a	124435.65	0.00	0.00	0.00

# ESTIMATED BUDGET FOR THE ACTION (page 2 of 6 Associated with document Ref. Ares(2018)3532486 - 03/07/2018

	Estimated eligible costs (per budget category)					EU contribution	<b>0. 0, 1. 1.</b>	Action's estimated receipts			
	A D'				Til						
	A. Direct personnel costs	B. Direct costs of subcontracting	C. Other direct costs	D. Indirect costs <sup>2</sup>	Total costs	Reimbursement rate % <sup>3</sup>	Maximum EU contribution <sup>4</sup>	Maximum grant amount <sup>5</sup>	Income generated by the action	Financial contributions given by third parties to the beneficiaries	Action's total receipts
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract and seconded persons		C.1 Travel C.2 Equipment C.3 Other goods and services								
Cost form <sup>6</sup>	Actual	Actual	Actual	Flat-rate <sup>7</sup> 7%							
	a	b	С	$d = 0.07 \times (a +b+c)$	e = a+b+c+d	f	$g = e \times f$	h	i	j	k = i + j
4. MZCR	95536.00	0.00	36000.00	9207.52	140743.52	n\a	n\a	84446.11	0.00	0.00	0.00
5. GEMATIK	220972.22	0.00	36000.00	17988.06	274960.28	n\a	n\a	164976.17	0.00	0.00	0.00
6. MoSA	140192.00	0.00	36000.00	12333.44	188525.44	n\a	n\a	113115.26	0.00	0.00	0.00
7. 3rd RHA	120730.50	55000.00	38700.00	15010.14	229440.64	n\a	n\a	137664.38	0.00	0.00	0.00
- HGP	6000.00	0.00	0.00	420.00	6420.00	n\a	n\a	3852.00	0.00	0.00	0.00
- Нрара	18000.00	0.00	0.00	1260.00	19260.00	n\a	n\a	11556.00	0.00	0.00	0.00
Total beneficiary	144730.50	55000.00	38700.00	16690.14	255120.64	n\a	n\a	153072.38	0.00	0.00	0.00
8. MSSSI	10670.99	12000.00	10800.00	2342.97	35813.96	n\a	n\a	21488.38	0.00	0.00	0.00

# ESTIMATED BUDGET FOR THE ACTION (page 3 of 6 Associated with document Ref. Ares(2018)3532486 - 03/07/2018

		Estimated elig				EU contribution			Action's estimated receipts		
	Estimated eligible costs (per budget category)					20 Contribution					
	A. Direct personnel costs	B. Direct costs of subcontracting	C. Other direct costs	D. Indirect costs <sup>2</sup>	Total costs	Reimbursement rate % <sup>3</sup>	Maximum EU contribution <sup>4</sup>	Maximum grant amount <sup>5</sup>	Income generated by the action	Financial contributions given by third parties to the beneficiaries	Action's total receipts
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract and seconded persons		C.1 Travel C.2 Equipment C.3 Other goods and services								
Cost form <sup>6</sup>	Actual	Actual	Actual	Flat-rate <sup>7</sup> 7%							
	a	b	с	$d = 0.07 \times (a +b+c)$	e = a+b+c+d	f	$g = e \times f$	h	i	j	k = i + j
9. THL	136400.00	0.00	48000.00	12908.00	197308.00	n\a	n\a	118384.80	0.00	0.00	0.00
10. MoH-FR	49894.20	0.00	36000.00	6012.59	91906.79	n\a	n\a	55144.07	0.00	0.00	0.00
- ASIP	165610.34	100000.00	0.00	18592.72	284203.06	n\a	n\a	170521.84	0.00	0.00	0.00
- CNAM	42930.00	0.00	0.00	3005.10	45935.10	n\a	n\a	27561.06	0.00	0.00	0.00
Total beneficiary	258434.54	100000.00	36000.00	27610.41	422044.95	n\a	n\a	253226.97	0.00	0.00	0.00
11. HZZO	54000.00	0.00	21600.00	5292.00	80892.00	n\a	n\a	48535.20	0.00	0.00	0.00
12. NHSC	41843.75	0.00	36000.00	5449.06	83292.81	n\a	n\a	49975.69	0.00	0.00	0.00
- SU	102779.56	0.00	0.00	7194.57	109974.13	n\a	n\a	65984.48	0.00	0.00	0.00

# ESTIMATED BUDGET FOR THE ACTION (page 4 of 6 Associated with document Ref. Ares(2018)3532486 - 03/07/2018

		Estimated alia	ible <sup>1</sup> costs (per bu			EU contribution			Action's estimated receipts		
						EO CONTIDUCION					
	A. Direct personnel costs	B. Direct costs of subcontracting	C. Other direct costs	D. Indirect costs <sup>2</sup>	Total costs	Reimbursement rate % <sup>3</sup>	Maximum EU contribution <sup>4</sup>	Maximum grant amount <sup>5</sup>	Income generated by the action	Financial contributions given by third parties to the beneficiaries	Action's total receipts
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract and seconded persons		C.1 Travel C.2 Equipment C.3 Other goods and services								
Cost form <sup>6</sup>	Actual	Actual	Actual	Flat-rate <sup>7</sup> 7%							
	a	b	С	$d = 0.07 \times (a +b+c)$	e = a+b+c+d	f	$g = e \times f$	h	i	j	k = i + j
Total beneficiary	144623.31	0.00	36000.00	12643.63	193266.94	n\a	n\a	115960.17	0.00	0.00	0.00
13. DoH	238321.80	0.00	36000.00	19202.53	293524.33	n\a	n\a	176114.60	0.00	0.00	0.00
14. MINSAL	27855.01	0.00	12800.00	2845.85	43500.86	n\a	n\a	26100.52	0.00	0.00	0.00
15. SAM	52000.00	0.00	21600.00	5152.00	78752.00	n\a	n\a	47251.20	0.00	0.00	0.00
16. AeS	88667.00	0.00	10000.00	6906.69	105573.69	n\a	n\a	63344.21	0.00	0.00	0.00
17. NHS	68800.00	0.00	21600.00	6328.00	96728.00	n\a	n\a	58036.80	0.00	0.00	0.00
18. MFH	20000.00	0.00	12800.00	2296.00	35096.00	n\a	n\a	21057.60	0.00	0.00	0.00
19. NICTIZ	178500.00	0.00	36000.00	15015.00	229515.00	n\a	n\a	137709.00	0.00	0.00	0.00

# ESTIMATED BUDGET FOR THE ACTION (page 5 of a Associated with document Ref. Ares(2018)3532486 - 03/07/2018

	Estimated eligible costs (per budget category)					EU contribution			Action's estimated receipts		
	A. Direct personnel costs	B. Direct costs of subcontracting	C. Other direct costs	D. Indirect costs <sup>2</sup>	Total costs	Reimbursement rate % <sup>3</sup>	Maximum EU contribution <sup>4</sup>	Maximum grant amount <sup>5</sup>	Income generated by the action	Financial contributions given by third parties to the beneficiaries	Action's total receipts
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract and seconded persons		C.1 Travel C.2 Equipment C.3 Other goods and services								
Cost form <sup>6</sup>	Actual	Actual	Actual	Flat-rate <sup>7</sup> 7%							
	a	b	с	$d = 0.07 \times (a +b+c)$	e = a+b+c+d	f	$g = e \times f$	h	i	j	k = i + j
20. NDE	81800.00	0.00	36000.00	8246.00	126046.00	n\a	n\a	75627.60	0.00	0.00	0.00
21. IPHS	23595.00	0.00	21600.00	3163.65	48358.65	n\a	n\a	29015.19	0.00	0.00	0.00
22. NIJZ	77895.00	0.00	21600.00	6964.65	106459.65	n\a	n\a	63875.79	0.00	0.00	0.00
Total consortium	3150591.38	333000.00	722000.00	294391.40	4499982.78	607	2699989.67	2699989.67	0.00	0.00	0.00

# ESTIMATED BUDGET FOR THE ACTION (page 6 of 6 Associated with document Ref. Ares(2018)3532486 - 03/07/2018

- (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). A beneficiary that receives an operating grant during the action's duration cannot claim any indirect costs for the year(s)/reporting period(s) covered by the operating grant (see Article 6.2.D).
- (3) See Article 5.2 for the reimbursement rate.
- (4) This is the theoretical amount of the EU contribution, if the reimbursement rate is applied to all the budgeted costs. This theoretical amount is capped by the 'maximum grant amount'.
- (5) The 'maximum grant amount' is the maximum grant amount decided by the Agency. It normally corresponds to the requested grant, but may be lower.
- (6) See Article 5 for the cost forms.
- (7) Flat rate: 7% of eligible direct costs.

**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 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

Ministry of Health of the Republic of Cyprus (MoH-CY), established in 1 Prodromou Street & 17 Chilonos Street 1 & 17, Nicosia 1448, Cyprus, ('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 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

**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 ('4')

in Grant Agreement No 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

**GEMATIK GESELLSCHAFT FUR TELEMATIKANWENDUNGEN DER GESUNDHEITSKARTE MBH (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 ('5')

in Grant Agreement No 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

**SOTSIAALMINISTEERIUM (MoSA)**, 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 ('6')

in Grant Agreement No 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

**DIOIKISI 3IS YGEIONOMIKIS PERIFEREIAS MAKEDONIAS (3rd RHA)**, established in ARISTOTELOUS 16, THESSALONIKI 54623, Greece, VAT number: EL999122114, ('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 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD (MSSSI), established in PASEO DEL PRADO 18-20, MADRID 28014, Spain, ('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 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

**TERVEYDEN JA HYVINVOINNIN LAITOS (THL)**, established in MANNERHEIMINTIE 166, HELSINKI 00271, Finland, VAT number: FI22295006, ('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 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

**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 ('10')

in Grant Agreement No 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

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 ('11')

in Grant Agreement No 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

**ALLAMI EGESZSEGUGYI ELLATO KOZPONT (NHSC)**, 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 ('12')

in Grant Agreement No 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

**DEPARTMENT OF HEALTH (DoH)**, established in poolbeg St, Hawkins House, Dublin dn 6, Ireland, ('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 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

**MINISTERO DELLA SALUTE (MINSAL)**, 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 ('14')

in Grant Agreement No 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

**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 ('15')

in Grant Agreement No 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

**AGENCE ESANTE (AeS)**, established in ALLEE MARCONI - VILLA LOUVIGNY, LUXEMBOURG 2120, Luxembourg, VAT number: LU25854803, ('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 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

**NACIONALAIS VESELIBAS DIENESTS (NHS)**, 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 ('17')

in Grant Agreement No 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

Ministry for Health - Government of Malta (MFH), established in Palazzo Castellania, Merchants Street 15, Valletta VLT 200, Malta, VAT number: MT12979127, ('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 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

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 ('19')

in Grant Agreement No 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

**DIREKTORAT FOR E-HELSE (NDE)**, established in VERKSTEDVEIEN 1, OSLO 0277, Norway, ('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 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

**INSTITUT ZA ZASTITU ZDRAVLJA SRBIJEDR MILAN JOVANOVIC BATUT (IPHS)**, established in DR SUBOTICA STREET 5, BEOGRAD 11000, Serbia, VAT number: RS102000930, ('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 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

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 ('22')

in Grant Agreement No 801558 ('the Grant Agreement')

**between** SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

for the action entitled Joint Action supporting the eHealth Network (eHAction).

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

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**

#### MODEL ANNEX 4 CHAFEA MGA — MULTI

#### FINANCIAL STATEMENT FOR [BENEFICIARY [name]/AFFILIATED ENTITY [name]] FOR REPORTING PERIOD [reporting period]

	Eligible <sup>1</sup> costs (per budget category)					Receipts			EU contribution		
	A. Direct personnel costs	B. Direct costs of subcontracting	C. Other direct costs	D. Indirect costs <sup>2</sup>	Total costs	Income generated by the action	Financial contributions given by third parties to the beneficiaries	Total receipts	Reimburseme nt rate % <sup>3</sup>	Maximum EU constribution <sup>4</sup>	Requested EU contribution
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract and seconded persons		C.1 Travel C.2 Equipment C.3 Other goods and services								
Cost form 5	Actual	Actual	Actual	Flat-rate 6 7%							
	а	b	с	d = 0,07 * (a + b + c)	e= a+ b + c + d	f	g	h= f + g	i	j	k
[short name beneficiary / affiliated entity]											

#### The beneficiary/affiliated entity 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 12, 13 and 17).

For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

① 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.

<sup>&</sup>lt;sup>1</sup> See Article 6 for the eligibility conditions.

<sup>&</sup>lt;sup>2</sup> The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme). A beneficiary that receives an operating grant during the duration of the action cannot claim any indirect costs for the year(s) covered by the operating grant (see Article 6.2.D).

 $<sup>^{3}</sup>$  See Article 5.2 for the reimbursement rate

<sup>&</sup>lt;sup>4</sup> 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 have to be less.

<sup>&</sup>lt;sup>5</sup> See Article 5 for the cost forms.

<sup>&</sup>lt;sup>6</sup> Flat rate: 7% of eligible direct costs.

#### ANNEX 5

### MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENT (CFS)

### This document sets out:

- the objectives and scope of the independent report of factual findings on costs declared under a EU grant agreement financed under the Health Programme (2014-2020) or Consumer Programme (2014-2020) and
- a model for the certificate on the financial statement (CFS).

### 1. Background and subject matter

[OPTION 1 for actions with one RP and NO interim payments: Within 60 days of the end of the reporting period, the coordinator must submit to the Commission a final report, which should include (among other documents and unless otherwise specified in Article 15 of the Grant Agreement) a certified financial statement (CFS; see proposed model below) for each beneficiary and (if applicable) each affiliated entity, if:

- it requests an EU contribution of EUR 325 000 or more as reimbursement of actual costs and
- the maximum EU contribution indicated for that beneficiary/affiliated entity in the estimated budget (see Annex 2) as reimbursement of actual costs is EUR 750 000 or more.]

[OPTION 2 for actions with several RPs and interim payments: Within 60 days of the end of each reporting period, the coordinator must submit to the Commission a **periodic report**, which should include (among other documents and unless otherwise specified in Article 15 of the Grant Agreement) a **certified financial statement** (CFS; see proposed model below) for each beneficiary and (if applicable) each affiliated entity, if:

- the cumulative amount of EU contribution the beneficiary/affiliated entity requests as reimbursement of actual costs is EUR 325 000 or more and
- the maximum EU contribution indicated for that beneficiary/affiliated entity in the estimated budget (see Annex 2) as reimbursement of actual costs is EUR 750 000 or more.

The CFS must be submitted every time the cumulative amount of payments requested (i.e. including in previous financial statements) reaches the threshold (i.e. a first certificate once the cumulative amount reaches 325 000, a second certificate once it reaches 650 000, a third certificate once it reaches 975 000, etc.).

Once the threshold is reached, the CFS must cover all reporting periods for which no certificate has yet been submitted.]

The beneficiary must provide the CFS for itself and, if applicable, for its affiliated entity(ies).

The **purpose** of the audit on which the CFS is based is to give the Agency 'reasonable assurance' that costs declared as eligible costs under the grant (and, if relevant, receipts generated in the course of the action) are being claimed by the beneficiary in accordance with the relevant legal and financial provisions of the Grant Agreement.

The **scope** of the audit is limited to the verification of eligible costs included in the CFS. The audit must be conducted in line with point 3 below.

Certifying auditors must carry out the audits in compliance with generally accepted **audit standards** and indicate which standards they have applied. They must bear in mind that, to establish a CFS, they must carry out a compliance audit and not a normal statutory audit. The eligibility criteria in the Grant Agreement always override normal accounting practices.

The beneficiary and the auditor are expected to address any **questions on factual data or detailed calculations** before the financial statement and the accompanying certificate are submitted. It is also recommended that the beneficiary take into account the auditor's preliminary comments and suggestions in order to avoid a qualified opinion or reduce the scope of the qualifications.

Since the certificate is the main source of assurance for cost claims and payments, it will be easier to consider amounts as eligible if a **non-qualified certificate** is provided.

The submission of a certificate does not affect the Agency's right to carry out its **own assessment or audits**. Neither does the reimbursement of costs covered by a certificate preclude the Agency or the Commission, the European Anti-Fraud Office or the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 17 of the Grant Agreement.

The Agency expects the certificates to be issued by auditors according to the highest professional standards.

# 2. Auditors who may deliver a certificate

The beneficiary is free to choose a **qualified external auditor**, including its usual external auditor, provided that:

- the external auditor is **independent** from the beneficiary and
- the provisions of **Directive 2006/43/EC**<sup>2</sup> are complied with.

Independence is one of the qualities that permit the auditor to apply unbiased judgement and objective consideration to established facts to arrive at an opinion or a decision. It also means that the auditor works without direction or interference of any kind from the beneficiary.

This means a high degree of confidence.

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 or similar national regulations (OJ L 157, 9.6.2006, p. 87).

Auditors are considered as providing services to the beneficiary/affiliated entity under a **purchase contract** within the meaning of Article 9 of the Grant Agreement. This means that the costs of the CFS may normally be declared as costs incurred for the action, if the cost eligibility rules set out in Articles 6 and 9.1.1 of the Grant Agreement are fulfilled (especially: best value for money and no conflict of interests; see also below eligibility of costs of other goods and services). Where the beneficiary/affiliated entity uses its usual external auditor, it is presumed that they already have an agreement that complies with these provisions and there is no obligation to find new bids. Where the beneficiary/affiliated entity uses an external auditor who is not their usual external auditor, it must select an auditor following the rules set out in Article 9.1.1.

**Public bodies** can choose an external auditor or a competent public officer. In the latter case, the auditor's independence is usually defined as independence from the audited beneficiary 'in fact and in appearance'. A preliminary condition is that this officer was not involved in any way in drawing up the financial statements. Relevant national authorities establish the legal capacity of the officer to carry out audits of that specific public body. The certificate should refer to this appointment.

### 3. Audit methodology and expected results

# 3.1 Verification of eligibility of the costs declared

The auditor must conduct its verification on the basis of inquiry and analysis, (re)computation, comparison, other accuracy checks, observation, inspection of records and documents and by interviewing the beneficiary (and the persons working for it).

The auditor must examine the following documentation:

- the Grant Agreement and any amendments to it;
- the periodical and/or final report(s);
- for personnel costs
  - salary slips;
  - o time sheets;
  - contracts of employment;
  - o other documents (e.g. personnel accounts, social security legislation, invoices, receipts, etc.);
  - o proofs of payment;
- for subcontracting
  - o the call for tender;
  - o tenders (if applicable);
  - o justification for the choice of subcontractor;
  - o contracts with subcontractors;
  - o invoices;
  - o declarations by the beneficiary;
  - o proofs of payment;
  - o other documents: e.g. national rules on public tendering if applicable, EU Directives, etc.:
- for travel and subsistence costs
  - o the beneficiary's internal rules on travel;

- o transport invoices and tickets (if applicable);
- o declarations by the beneficiary;
- o other documents (proofs of attendance such as minutes of meetings, reports, etc.);
- o proofs of payment;
- for equipment costs
  - o invoices;
  - o delivery slips / certificates of first use;
  - o proofs of payment;
  - o depreciation method of calculation;
- for costs of other goods and services
  - o invoices:
  - o proofs of payment; and
  - o other relevant accounting documents.

# General eligibility rules

The auditor must verify that the costs declared comply with the general eligibility rules set out in Article 6.1 of the Grant Agreement.

In particular, the costs must:

- be actually incurred;
- be linked to the subject of the Grant Agreement and indicated in the beneficiary's estimated budget (i.e. the latest version of Annex 2);
- be necessary to implement the action which is the subject of the grant;
- be reasonable and justified, and comply with the requirements of sound financial management, in particular as regards economy and efficiency;<sup>3</sup>
- have been incurred during the action, as defined in Article 3 of the Grant Agreement (with the exception of the invoice for the audit certificate and costs relating to the submission of the final report);
- not be covered by another EU or Euratom grant (see below ineligible costs);
- be identifiable, verifiable and, in particular, recorded in the beneficiary's accounting records and determined according to the applicable accounting standards of the country where it is established and its usual cost-accounting practices;
- comply with the requirements of applicable national laws on taxes, labour and social security;
- be in accordance with the provisions of the Grant Agreement (see, in particular, Articles 6 and 9-11a) and
- have been converted to euro at the rate laid down in Article 15.6 of the Grant Agreement:
  - o for beneficiaries with accounts established in a currency other than the euro:
    - Costs incurred in another currency must be converted into euros at the average of the daily exchange rates published in the C series of the <u>EU Official Journal</u> determined over the corresponding reporting period.

To be assessed in particular on the basis of the procurement and selection procedures for service providers.

If no daily euro exchange rate is published in the EU Official Journal for the currency in question, the rate used must be the average of the monthly accounting rate established by the Commission and published on its website;

o for beneficiaries with accounts established in euro:

Costs incurred in another currency should be converted into euros applying the beneficiary's usual accounting practice.

The auditor must verify whether expenditure includes **VAT** and, if so, verify that the beneficiary:

- cannot recover the VAT (this must be supported by a statement from the competent body) and
- is not a public body acting as a public authority.

The auditor should base his/her audit approach on the **confidence level** following a review of the beneficiary's internal control system. When using sampling, the auditor should indicate and justify the sampling size.

# Specific eligibility rules

In addition, the auditor must verify that the costs declared comply with the specific cost eligibility rules set out in Article 6.2 and Articles 9.1.1, 10.1.1, 11.1.1, 11a.1.1 and 11a.2.1 of the Grant Agreement.

#### Personnel costs

The auditor must verify that:

- personnel costs have been charged and paid in respect of the actual time devoted by the beneficiary's personnel to implementing the action (justified on the basis of time sheets or other relevant time-recording system);
- personnel costs were calculated on the basis of annual gross salary, wages or fees (plus obligatory social charges, but excluding any other costs) specified in an employment or other type of contract, not exceeding the average rates corresponding to the beneficiary's usual policy on remuneration;
- the work was carried out during the period of implementation of the action, as defined in Article 3 the Grant Agreement and
- the personnel costs are not covered by another EU or Euratom grant (see below ineligible costs);
- for additional remunerations: the 2 conditions set out in Article 6.2.A.1 are met (i.e. that 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 and that the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used);
- for in-house consultants: the 3 conditions set out in Article 6.2.A.2 of the Grant Agreement are met (i.e. that the in-house consultant works under the beneficiary's instructions, that the result of the work carried out belongs to the beneficiary, and that the costs are not significantly different from those for personnel performing similar tasks under an employment contract).

The auditor should have assurance that the management and accounting system ensures proper allocation of the personnel costs to various activities carried out by the beneficiary and funded by various donors.

# Subcontracting costs

### The auditor must verify that:

- the subcontracting complies with best value for money (or lowest price) and that there was no conflict of interests;
- the subcontracting was necessary to implement the action for which the grant is requested;
- the subcontracting was provided for in Annex 1 and Annex 2 or agreed to by the Agency at a later stage;
- the subcontracting is supported by accounting documents in accordance with national accounting law
- public bodies have complied with the national rules on public procurement.

#### Travel and subsistence costs

The auditor must verify that travel and subsistence costs:

- have been charged and paid in accordance with the beneficiary's internal rules or usual practices;
- are not covered by another EU or Euratom grant (see below ineligible costs);
- were incurred for travels linked to action tasks set out in Annex 1 of the Grant Agreement.

### Equipment costs

### The auditor must verify that:

- the equipment is purchased, rented or leased at normal market prices;
- public bodies have complied with the national rules on public procurement;
- the equipment is written off, depreciation has been calculated according to the tax and accounting rules applicable to the beneficiary and only the portion of the depreciation corresponding to the duration of the action has been declared and
- the costs are not covered by another EU or Euratom grant (see below ineligible costs).

### Costs of other goods and services

### The auditor must verify that:

- the purchase complies with best value for money (or lowest price) and that there was no conflict of interests;
- public bodies have complied with the national rules on public procurement;
- the costs are not covered by another EU or Euratom grant (see below ineligible costs).

### Ineligible costs

The auditor must verify that the beneficiary has not declared any costs that are ineligible under Article 6.4 of the Grant Agreement:

- costs relating 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 Agency;
- excessive or reckless expenditure;
- deductible VAT;
- VAT incurred by a public body acting as a public authority;
- costs incurred during suspension of the implementation of the action;
- in-kind contributions from third parties;
- costs declared under other EU or Euratom grants (including those awarded by a
  Member State and financed by the EU or Euratom budget or awarded by bodies other
  than the Agency 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;
- costs incurred for permanent staff of a national administration for activities that are part of its normal activities (i.e. not undertaken only because of the grant);
- costs incurred for staff or representatives of EU institutions, bodies or agencies.

# 3.2 Verification of receipts

The auditor must verify that the beneficiary has declared receipts within the meaning of Article 5.3.3 of the Grant Agreement, i.e.:

- income generated by the action (e.g. from the sale of products, services and publications, conference fees) and
- financial contributions given by third parties, specifically to be used for costs that are eligible under the action.

# 3.3 Verification of the beneficiary's accounting system

The auditor must verify that:

- the accounting system (analytical or other suitable internal system) makes it possible to identify **sources of financing** for the action and related expenses incurred during the contractual period and
- expenses/income under the grant have been recorded systematically using a numbering system that **distinguishes** them from expenses/income for other projects.

### **Certificate on the financial statement (CFS)**

To [Beneficiary/affiliated entity's full name address]

We, [full name of the audit firm/organisation], established in [full address/city/country], represented for signature of this audit certificate by [name and function of an authorised representative],

### hereby certify

#### that:

- 1. We have **conducted an audit** relating to the costs declared in the financial statement of [name of beneficiary/affiliated entity] (the ['beneficiary']['affiliated entity']), to which this audit certificate is attached and which is to be presented to the Consumers, Health, Agriculture and Food Executive Agency under Grant Agreement No [insert number] [insert acronym], covering costs for the following reporting period(s): [insert reporting period(s)].
- 2. We confirm that our audit was **carried out in accordance with generally accepted auditing standards** in compliance with ethical rules and on the basis of the provisions of the **Grant Agreement** and its Annexes (and in particular the audit methodology described in Annex 5).
- 3. The financial statement was examined and all necessary tests of [all]/[X]%] of the supporting documentation and accounting records were carried out in order to obtain reasonable assurance that, in our opinion and on the basis of our audit
  - total **costs** of **EUR** [**insert number**] ([insert amount in words]) are eligible, i.e.:
    - actual;
    - determined in accordance with the [beneficiary's][affiliated entity's] accounting principles;
    - incurred during the period referred to in Article 3 of the Grant Agreement;
    - recorded in the /beneficiary's//affiliated entity's/ accounts (at the date of this audit certificate);
    - comply with the specific eligibility rules in Article 6.2 of the Grant Agreement;
    - do not contain costs that are ineligible under Article 6.4 of the Grant Agreement, in particular:
      - costs relating to return on capital;
      - debt and debt service charges;
      - provisions for future losses or debts;
      - interest owed;
      - doubtful debts:
      - currency exchange losses;

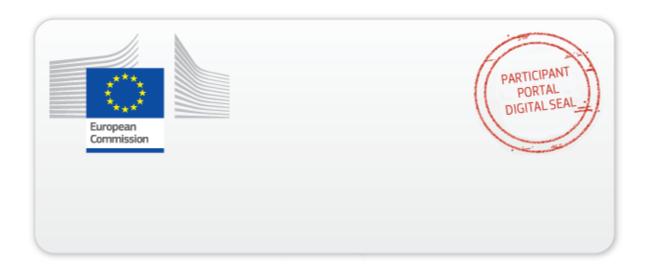
- bank costs charged by the [beneficiary's][affiliated entity's] bank for transfers from the Agency;
- excessive or reckless expenditure;
- deductible VAT;
- VAT incurred by a public body acting as a public authority;
- costs incurred during suspension of the implementation of the action;
- in-kind contributions provided by third parties;
- costs declared under other EU or Euratom grants (including those awarded by a Member State and financed by the EU or Euratom budget or awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the [beneficiary][affiliated entity] is already receiving an operating grant financed by the EU or Euratom budget in the same period;
- costs incurred for permanent staff of a national administration, for activities that are part of its normal activities (i.e. not undertaken only because of the grant);
- costs incurred for staff or representatives of EU institutions, bodies or agencies;
- [are claimed according to the euro conversion rate referred to in Article 15.6 of the Grant Agreement;]
- total receipts of EUR [insert number] ([insert amount in words]) have been declared under Article 5.3.3 of the Grant Agreement and
- the [beneficiary's] [affiliated entity's] accounting procedures are in compliance with
  the accounting rules of the state in which it is established and permit direct
  reconciliation of the costs incurred for the implementation of the action covered by the
  EU grant with the overall statement of accounts relating to its overall activity.

[However, our audit opinion is qualified for:

- costs of EUR [insert number]
- receipts of EUR [insert number]

which in our opinion do not comply with the applicable rules.]

- 4. We are qualified/authorised to deliver this audit certificate [(for additional information, see appendix to this certificate)].
- 5. The /beneficiary//affiliated entity/ paid a **price** of EUR [insert number]) (including VAT of EUR [insert number]) for this audit certificate. [OPTION 1: These costs are eligible (i.e. incurred within 60 days of the end of the action referred to in Article 3 of the Grant Agreement) and included in the financial statement.][OPTION 2: These costs were not included in the financial statement.]



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