EUROPEAN COMMISSION
Directorate General for Communications Networks, Content and Technology

Sustainable and Secure Society
Health and Well-being

GRANT AGREEMENT

NUMBER — 690492 — EMPATTICS

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

on the one part,

*the **European Union** ('the EU'), represented by the European Commission ('the Commission')*[1],

represented for the purposes of signature of this Agreement by Head of Unit, Miguel GONZALEZ-SANCHO,

and

on the other part,

1. 'the coordinator':

Conselleria de Sanidade de Galicia (Sanidad Galicia), LG1979/26, established in Edificio Administrativo San Lázaro sn, Santiago de Compostela 15781, Spain, ESS1511001H represented for the purposes of signing the Agreement by Ministry, Jesús VAZQUEZ ALMUIÑA

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

2. **REGION MIDTJYLLAND (CDR)**, 29190925, established in Skottenborg 26, VIBORG 8800, Denmark, DK29190925

3. **SERVICIO ARAGONES DE LA SALUD (SALUD)**, N/A, established in VIA UNIVERSITAS 34, ZARAGOZA 50071, Spain, ESQ5000442C

4. **GROUPEMENT DE COOPERATION SANITAIRE POUR LE DEVELOPPEMENT DES SYSTEMES D'INFORMATION PARTAGES EN ILE DE FRANCE (GCS D-SISIF)** FR46, 513654715, established in 10 RUE DU FAUBOURG MONTMARTRE, PARIS 75009, France, FR41513654715

5. **SPLOSNA BOLNISNICA SLOVENJ GRADEC JAVNI ZAVOD*GENERAL HOSPITAL SLOVENJGRADEC (SB-SG)** SI2, 5054958000, established in GOSPOSVETSKA CESTA 1, SLOVENJ GRADEC 2380, Slovenia, SI34697390

6. **THE EUROPEAN HEALTH FUTURES FORUM (EHFF)** GB5, 08447376, established in KINGATES FARM NEWPORT ROAD, VENTNOR PO38 2QP, United Kingdom

7. **KOKOMO HEALTHCARE LIMITED (KKM)** LTD, 526649, established in 33 ANNAVILLA RANELAGH DUBLIN 6, DUBLIN 6, Ireland, IE2986375SH

8. **M&C SAATCHI MADRID SL (Saatchi)** SL, M392135, established in CALLE GRAN VIA 27 PLANTA 3, MADRID 28013, Spain, ESB84428754

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

1 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

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

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

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Forms

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

Annex 7 Model for the commitment on availability of resources

Annex 8 Model for the statement on the use of the previous pre-financing instalment

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 '***EMpowering PAtients for a BeTTer Information and improvement of the Communication Systems — EMPATTICS***' **('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 *1 February 2016* ('**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 budget category (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

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

CHAPTER 3 GRANT

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

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR 3,500,000.00** (three million five hundred thousand EURO).

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses ***70% 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 **5,000,000.00** (five million EURO).

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

(a) for **direct costs of *PCP* subcontracting**: as actually incurred costs (**actual costs**);

(b) for **direct personnel costs for related additional coordination and networking activities**:

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

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points B.1.4 and B.1.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(c) for **direct costs for subcontracting of related additional coordination and networking activities**: as actually incurred costs (**actual costs**);

(d) for **other direct costs of related additional coordination and networking activities**: as actually incurred costs (**actual costs**);

(e) for **indirect costs for related additional coordination and networking activities**: on the basis of a flat-rate applied as set out in Point B.4(a), (b) and (c) of Article 6.2 ('**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 *Commission* — when the payment of the balance is made (see Article 21.4) — in the following steps:

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

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

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

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

5.3.2 Step 2 — Limit to the maximum grant amount

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

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

The grant must not produce a profit.

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

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

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

The following are considered **receipts**:

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

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

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

The following are however not considered receipts:

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

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

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

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

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *Commission* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

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

- the amount obtained following Steps 1 to 3 or

- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

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

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

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *Commission* for the beneficiary concerned;

- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

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

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

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

(a) for **actual costs**:

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

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

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

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

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

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

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

(b) for **unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, PointA)}

multiplied by

{the number of actual units};

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

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

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

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

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

6.2 Specific conditions for costs to be eligible

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

A. Direct costs of *PCP* subcontracting
B. Costs for related additional coordination and networking activities

'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 B.4 below).

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

A. Direct costs of *PCP* subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1 are met.

B. Costs for related additional coordination and networking activities are eligible up to EUR *1,500,000.00*, if they comply with the following:

B.1 **Direct personnel costs for related additional coordination and networking activities**

Types of eligible personnel costs

B.1.1 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 related additional coordination and networking activities ('**costs for employees (or equivalent)**'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[2] may also declare as personnel costs **additional remuneration** for personnel assigned to the related additional coordination and networking activities (including payments on the basis of supplementary contracts regardless of their nature), if:

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

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

Additional remuneration for personnel assigned to the related additional coordination and networking activities is eligible up to the following amount:

(a) if the person works full time and exclusively on the related additional coordination and networking activities during the full year: up to EUR 8 000;

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

(c) if the person does not work exclusively on the related additional coordination and networking activities up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

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

multiplied by

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

B.1.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel cost, 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.

B.1.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs, if the conditions in Article 11.1 are met.

B.1.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**') who are working on the related additional coordination and networking activities and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in

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

Annex 2 multiplied by the number of actual hours worked on the related additional coordination and networking activities.

B.1.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the related additional coordination and networking activities.

B.1.6

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

number of actual hours worked on the related additional coordination and networking activities},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the related additional coordination and networking activities under the conditions set out above (Point B.1.1)}.

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

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

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

minus

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

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

(a) for personnel costs declared as **actual costs:** the hourly rate is the amount calculated as follows:

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

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

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

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

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

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

plus

overtime worked

minus

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

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

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

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

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

For all options, the actual time spent on **parental leave** by a person assigned to the related additional coordination and networking activities may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points B.1.4 and B.1.5 above), or

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

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

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

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

and

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

B.2 **Direct costs of subcontracting for related additional coordination and networking activities** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.2.1 are met.

B.3 **Other direct costs for related additional coordination and networking activities**

B.3.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

B.3.2 *The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

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

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

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

B.3.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the related additional coordination and networking activities and in accordance with Article 10.1.1 or

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

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

B.3.4 **Capitalised and operating costs of 'large research infrastructure'**[3] *directly used for the related additional coordination and networking activities are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure[4]*);*

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

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

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

B.4 **Indirect costs for related additional coordination and networking activities**

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points B.1 to B.3), from which are excluded:

(a) costs of subcontracting and

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

(c) *not applicable.*

Beneficiaries receiving an operating grant[5] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

B.5 ***Specific cost category(ies)***

Not applicable

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

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

[5] 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.

6.3 Conditions for costs of linked third parties to be eligible

Not applicable

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

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

6.5 Ineligible costs

'**Ineligible costs**' are:

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

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

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

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

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

(b) costs reimbursed under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *Commission* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

6.6 Consequences of declaration of ineligible costs

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

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

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

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

7.2 Consequences of non-compliance

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

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

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

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

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

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

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

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

Not applicable

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

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

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

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

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

10.2 Consequences of non-compliance

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

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

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

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

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

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

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

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

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

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

11.2 Consequences of non-compliance

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

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[6] 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).

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

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

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

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

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

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

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

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

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

12.2 Consequences of non-compliance

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

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

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 *Rules for the pre-commercial procurement of research and development services*

*13.1.1 The beneficiaries will award subcontracts for the PCP research and development services (‘**PCP R&D services**’) that are necessary to address the ‘**common challenge**’ set out in Annex 1.*

The subcontracts must be awarded as one single joint procurement by the beneficiaries concerned (i.e. the ‘lead procurer’ and the ‘buyers group’).

The lead procurer must be a ‘contracting authority’ or ‘contracting entity’ within the meaning of Directives 2004/18/EC[8] and 2004/17/EC[9].

[8] 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, 30.4.2004, p. 114).

The buyers group must constitute a 'total jointly committed budget' for payment of the subcontracts.

The 'buyers group', the 'lead procurer', the services to be subcontracted (for each implementation phase ('PCP phase')), their estimated costs and the estimated financial contribution per beneficiary to the 'total jointly committed budget' must be set out in Annex 1. The estimated costs of PCP subcontracting per beneficiary must be set out in Annex 2.

Classified results may be subcontracted only after explicit approval (in writing) from the Commission (see Article 37).

The beneficiaries concerned must — throughout the action —:

- *guarantee equal treatment of tenderers and subcontractors and avoid any restrictions or distortions of competition;*

- *avoid any conflict of interest (see Article 35);*

- *allow for all communications to be made in English (and any additional language(s) they may have chosen).*

The subcontracts for pre-commercial procurement must provide for the following:

- *the ownership, by the subcontractors, of the intellectual property rights on the results that they generate;*

- *the right of the buyers to access results — on a royalty-free basis — for their own use;*

- *the right of the buyers to grant (or to require the subcontractors to grant) non-exclusive licences to third parties to exploit the results — under fair and reasonable conditions — (without the right to sub-licence);*

- *the obligation of the subcontractors to transfer back to the buyers the ownership of intellectual property generated by subcontractors during the PCP, if subcontractors fail to commercially exploit the results within the period set out in the subcontract;*

- *the right of the buyers to publish — at the time of the contract award notice — the identity of the winning tenderers and a project summary provided by the winning tenderers, and to publish — after R&D has finished and after consulting the subcontractors — summaries of the results as well as the identities of the subcontractors that successfully completed the last phase of the PCP.*

The beneficiaries concerned must ensure that the majority of the research and development work done by the subcontractor(s) (including the work of the main researchers) is located in the EU Member States or associated countries ('place of performance obligation').

*The beneficiaries concerned must **prepare**, **procure** and **implement** the subcontracts in accordance with the following requirements:*

*(a) For the '**preparation stage**':*

[9] 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, 30.4.2004, p. 1).

*(i) agree (in writing) on their internal procedures for carrying out the joint PCP procurement ('**joint procurement agreement**');*

*(ii) make an '**open market consultation**', which:*

- *is published — two months in advance — in the Official Journal of the European Union (via a '**prior information notice (PIN)**', drawn up in English and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *is summarised on the project website and other web-sites requested by the Commission, together with a list of Q&As raised during the open market consultation;*

*(iii) prepare '**common tender specifications**'*

*(b) For the '**procurement/tendering stage**':*

*(i) **Step 1** make a '**contract notice**', which*

- *is published by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*
- *specifies that the procurement concerns a pre-commercial procurement that is exempted from Directives 2004/18 and 2004/17*[10]
- *specifies a time-limit for receipt of tenders of at least two months;*
- *allows for the submission of tenders in English (and any additional language(s) chosen by the buyers group);*
- *is promoted and advertised widely;*
- *indicates how potential tenderers can obtain the 'request for tenders';*

*and the **request for tenders** inviting all interested economic operators to tender, which:*

- *identifies the lead procurer, the buyers group and, if applicable, third parties involved in the PCP ;*
- *informs potential tenderers about the outcome and list of Q&As of the market consultation (see above);*
- *describes the common challenge (using functional or performance based specifications and taking into account the outcome of the open market consultation);*

[10] See Article 16(f) of Directive 2004/18/EC, Article 24(e) of Directive 2004/17/EC.

- *describes the process for the evaluation and selection of the tenders for the first PCP phase and the intermediate evaluations after each following PCP phase;*

- *describes the practical set-up for the implementation of the subcontracts;*

- *describes the minimum requirements that subcontractors must comply with during the PCP;*

- *describes the arrangements for intellectual property rights, confidentiality, publicity (information about contract award and publication of summaries of R&D results) and rules on applicable law and dispute settlement;*

(ii) ***Step 2**: make an **evaluation of the tenders**, ranking them, on the basis of the common tender specifications (see above), according to best value for money criteria and ensuring that the price corresponds to market conditions;*

(iii) ***Step 3**: **award the subcontracts** to a minimum of three tenderers offering best value for money and a price corresponding to market conditions.*

*The **framework agreements** (one agreement per selected tenderer) must be signed by the lead procurer and set out the terms and conditions that govern the specific contracts.*

*The **specific contracts** (one agreement per selected tenderer and PCP phase) must be signed by the lead procurer and set out the details of the PCP R&D services purchased by each buyer (in particular, their quantity and price);*

(iv) ***Step 4**: make a '**contract award notice**' which is published — within 48 days after conclusion of the framework agreements — by the lead procurer in the Official Journal of the European Union (in English and any additional language(s) chosen by the buyers group);*

*(c) For the '**contract implementation stage**':*

(i) *monitor that the PCP R&D services are implemented in compliance with the objectives of the action set out in Annex 1;*

(ii) *ensure compliance with the planning of resources set out in Annex 1 and the estimated budget indicated in Annex 2;*

(iii) *ensure payment of the subcontractors.*

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

13.1.2 In addition, the beneficiaries concerned must ensure that their obligations under Articles 17.1, 18, 34, 35, 37, 36, 38, 39 and 46 also apply to the subcontractors.

The beneficiaries concerned must also ensure that every prior information notice, contract notice or contract award notice published in relation to the subcontracting includes the following disclaimer:

"This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No 690492. The EU is however not participating as a contracting authority in this procurement."

13.2 Rules for subcontracting of related additional coordination and networking activities

13.2.1 If necessary to implement the action, the beneficiaries may award subcontracts for the 'related additional coordination and networking activities' described in Annex 1.

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

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

- they are specifically justified in the periodic or final 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.

Classified results may be subcontracted only after explicit approval (in writing) from the Commission (see Article 37).

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

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

Beneficiaries acting as contracting authorities within the meaning of Directive 2004/18/EC or as contracting entities within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1 or 13.2.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2 or 13.2.2, the grant may be reduced (see Article 43).

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

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

Not applicable

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

Not applicable

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

16.1 Rules for providing trans-national access to research infrastructure

Not applicable

16.2 Rules for providing virtual access to research infrastructure

Not applicable

16.3 Consequences of non-compliance

Not applicable

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

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

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

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

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

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

(i) changes in its legal, financial, technical, organisational or ownership situation

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

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

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

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

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

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

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

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

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

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

18.1.2 Records and other documentation to support the costs declared

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

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

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

In addition, **for direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate

records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

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

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

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

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

18.2 Consequences of non-compliance

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

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

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit:

- 5 days before its publication: a copy of the prior information notice (PIN) (see Article 13);
- 30 days before its publication: a copy of the contract notice (see Article 13);
- at the end of the tender evaluation *(and after the intermediate evaluations that precede the start of each new PCP phase (see Article 13))*:
    - **information on the total number of bids received**, in particular the data on the winning tenderer(s) and abstracts of the winning tenders for publication and evaluation purposes;

- **information on the evaluation of tenders**: the final ranking list of the selected projects, final scores and qualitative assessment per evaluation criterion for each received bid, minutes of the evaluation meeting;

- *an **assessment by the buyers group of the results achieved** by each participating tenderer in the previous PCP phase (except for the initial evaluation of tenders at the start of the PCP);*

- *the coordinator must submit in month 6 a progress report containing:*

  - *a '**periodic summary technical report**' for publication by the Commission;*

  - *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;*

- at the end of the action: **information on each subcontract** financed by the procurement, including data on each contractor that participated in the procurement and overview of the results, for publication and evaluation purposes.

  This must include an assessment by the buyers group, based on the validation of solutions, of the final results of each participating tenderer in terms of achieving the performance and functionality requirements of the common tender specifications;

- any **other deliverables** identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

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

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

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

20.2 Reporting periods

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

- RP1: from month 1 to month 6
- RP2: from month *7* to month *36*

20.3 Periodic reports — Requests for second pre-financing payment

The coordinator must submit a periodic report within 60 days following the end of the 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 other deliverables identified in Annex 1.

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

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

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

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

(b) **call for tender documents**, including the contract notice, invitation to tender, procurement contracts;

(c) a **report on** the outcome of the **preparation phase** of the procurement (e.g. the open market consultation) and their impact on the call for tender;

(d) from each beneficiary participating in the joint procurement, a formal and duly signed '**commitment on availability of resources**' (see Annex 7), and

(e) a '**statement on the use of the first pre-financing instalment**' (see Annex 8), including the **request for a second pre-financing payment**.

The coordinator must certify that the information provided is full, reliable and true; and it can be substantiated by adequate supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22).

20.4 Final report — Request for payment of the balance

The coordinator must submit the final report within 60 days following the end of the last reporting period.

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

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

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

(ii) the conclusions on the action, and

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

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

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary, for all reporting periods.

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

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

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

Each beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (in particular, that the costs for subcontracts comply with the conditions in Article 13);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- all the receipts have been declared (see Article 5.3.3);

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

(iii) *not applicable;*

(iv) a '**summary financial statement**', created automatically by the electronic exchange system, consolidating the individual financial statements and including the **request for payment of the balance**;

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Point B.1 of Article 6.2)

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

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

20.7 Language of reports

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

20.8 Consequences of non-compliance — Suspension of the payment deadline — Termination

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

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *Commission*, the Agreement may be terminated (see Article 50).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- a **first pre-financing** payment;
- a **second pre-financing** payment, on the basis of the request for a second pre-financing payment (see Article 20);
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

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

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

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

The *Commission* will — within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest

— make a first pre-financing payment to the coordinator of EUR **666,233.75** (six hundred and sixty six thousand two hundred and thirty three EURO and seventy five eurocents), except if Article 48 applies.

From this amount, an amount of EUR **175,000.00** (one hundred and seventy five thousand EURO), corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *Commission* and transferred into the '**Guarantee Fund**'.

The *Commission* will — within 60 days after receiving the request (see Article 20) — make a second pre-financing payment to the coordinator of EUR **2,483,766.30** (two million four hundred and eighty three thousand seven hundred and sixty six EURO and thirty eurocents), except if Articles 47 or 48 apply.

If the statement on the use of the previous pre-financing instalment shows that less than 70 % of the previous instalment paid has been used to cover the costs of the action, the amount of the new pre-financing to be paid will be reduced by the difference between the 70 % threshold and the amount used.

21.3 Interim payments — Amount — Calculation

Not applicable

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

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

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

If the total amount of earlier payments is lower than the final grant amount, the *Commission* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

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

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

{final grant amount (see Article 5.3)

minus

pre-financing made}.

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

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;

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

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

21.5 Notification of amounts due

When making payments, the *Commission* will formally notify to the coordinator the amount due, specifying whether it concerns the second pre-financing payment or the payment of the balance.

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

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 45.

21.6 Currency for payments

The *Commission* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

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

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

Pre-financing may however be distributed only:

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

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

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: BANCO DE ESPANA
Address of branch: 16, CL.DURAN LORIGA LA CORUNA (A CORUNA), Spain
Full name of the account holder: XUNTA DE GALICIA
Full account number (including bank codes):
IBAN code: ES1490000022100350000022

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

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

21.10 Date of payment

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

21.11 Consequences of non-compliance

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

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

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

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

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

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

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

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

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

22.1 Checks, reviews and audits by the Commission

22.1.1 Right to carry out checks

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

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

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

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

22.1.2 Right to carry out reviews

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

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

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

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

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Commission may request beneficiaries to provide such information to it directly.

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

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

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

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

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

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

22.1.3 Right to carry out audits

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

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

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

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

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

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

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

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

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

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

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

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

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

Under Regulations No 883/2013[17] and No 2185/96[18] (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] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[18] 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).

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

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012[19], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

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

22.4 Checks, reviews, audits and investigations for international organisations

Not applicable

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

22.5.1 Findings in this grant

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

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

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

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

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

22.5.2 Findings in other grants

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

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

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

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

22.5.3 Procedure

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

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

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

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

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

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

(ii) does not submit revised financial statements.

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

The Commission will determine the amounts to be rejected on the basis of the revised financial statements, subject to their approval.

If the Commission does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify the beneficiary concerned the application of the initially notified correction rate for extrapolation.

If the Commission accepts the alternative correction method proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative correction method.

22.5.3.2 If the findings concern **improper implementation** or a **breach of another obligation**: the formal notification will include:

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

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

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

If the Commission does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify the beneficiary concerned the application of the initially notified flat-rate.

If the Commission accepts the alternative flat-rate proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative flat-rate.

22.6 Consequences of non-compliance

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

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

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

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

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

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

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

23.2 Consequences of non-compliance

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

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

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

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[20].

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

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

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

23a.2 Consequences of non-compliance

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

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

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

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

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

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

24.2 Consequences of non-compliance

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

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

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

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

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

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

Waivers of access rights are not valid unless in writing.

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

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

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

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

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

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

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

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

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

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[21] established in an EU Member State or '**associated country**'[22], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

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

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

25.5 Access rights for third parties

Not applicable

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[21] For the definition, see Article 2.1(2) of the Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is under the direct or indirect control of a participant, or under the same direct or indirect control as the participant, or that is directly or indirectly controlling a participant.
'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.
However the following relationships between legal entities shall not in themselves be deemed to constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

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

25.6 Consequences of non-compliance

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

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

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

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

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

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

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

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

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

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

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

26.3 Rights of third parties (including personnel)

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

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

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

26.4 *EU* ownership, to protect results

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

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

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

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

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

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

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

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

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

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

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

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

26.5 Consequences of non-compliance

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

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

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

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

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

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

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

27.2 *EU* ownership, to protect the results

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

27.3 Information on EU funding

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

> "The project leading to this application has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 690492".

27.4 Consequences of non-compliance

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

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

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

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

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

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

(c) creating and providing a service, or

(d) using them in standardisation activities.

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

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

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

> "Results incorporated in this standard received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 690492".

28.3 Consequences of non-compliance

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

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

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

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

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

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

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

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

29.2 Open access to scientific publications

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

In particular, it must:

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

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

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

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

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

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

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

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

29.3 Open access to research data

Not applicable

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

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

(a) display the EU emblem and

(b) include the following text:

"This project has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 690492".

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

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

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

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

29.5 Disclaimer excluding *Commission* responsibility

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

29.6 Consequences of non-compliance

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

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

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

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

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

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

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

30.2 Granting licenses

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

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

(b) *not applicable.*

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

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

30.3 *Commission* right to object to transfers or licensing

Not applicable

30.4 Consequences of non-compliance

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

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

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

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

The conditions set out in Article 25.1 apply.

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

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

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

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

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

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

31.4 Access rights of affiliated entities

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

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

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

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

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

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

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

31.6 Access rights for third parties

Not applicable

31.7 Consequences of non-compliance

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

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

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

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

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[24], in particular regarding:

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

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

32.2 Consequences of non-compliance

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

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

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

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

33.2 Consequences of non-compliance

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

ARTICLE 34 — ETHICS

34.1 Obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[25] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States.

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

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

(a) aim at human cloning for reproductive purposes;

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

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

34.2 Activities raising ethical issues

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

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the *Commission* copy of:

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

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

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

[25] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out only if:

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

34.4 Consequences of non-compliance

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

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

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

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

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

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

35.2 Consequences of non-compliance

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

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

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

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

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

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

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

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

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

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

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

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

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

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013[26], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

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

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

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

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

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

36.2 Consequences of non-compliance

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

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

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

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

Not applicable

37.2 Classified results

*Activities related to 'classified results' (see Annex 1) must comply with the '**security requirements**' (Security Aspect Letter (SAL) and the Security Classification Guide (SCG)) set out in Annex 1 until they are declassified.*

Action tasks related to classified results may not be subcontracted without prior explicit written approval from the Commission.

The beneficiaries must inform the coordinator — which must immediately inform the Commission — of any changes in the security context and — if necessary —request for Annex 1 to be amended (see Article 55).

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

Not applicable

37.4 Consequences of non-compliance

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

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

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

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

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

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

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

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

(a) display the EU emblem and

(b) include the following text:

> For communication activities: "This project has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 690492".
>
> For infrastructure, equipment and major results: "This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 690492".

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

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

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

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

38.1.3 Disclaimer excluding the *Commission* responsibility

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

38.2 Communication activities by the *Commission*

38.2.1 Right to use beneficiaries' materials, documents or information

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

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

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

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

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

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

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

(d) **translation**;

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

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

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

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

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

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

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

38.3 Consequences of non-compliance

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

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

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the Commission

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

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

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

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

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 'service specific privacy statement(s) (SSPS)' that are published on the Commission websites.

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

39.2 Processing of personal data by the beneficiaries

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

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

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

39.3 Consequences of non-compliance

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

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *COMMISSION*

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

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

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

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

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

41.1 Roles and responsibilities towards the *Commission*

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

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

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

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

(a) Each **beneficiary** must:

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

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

(iii) submit to the coordinator in good time:

- individual financial statements for itself and, if required, certificates on the financial statements (see Article 20);

- the data needed to draw up the technical reports (see Article 20);

- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);

- any other documents or information required by the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Commission.

(b) The **coordinator** must:

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

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

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

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

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

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

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

41.3 Internal arrangements between beneficiaries — Consortium agreement

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

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

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

41.4 Relationship with complementary beneficiaries — Collaboration agreement

Not applicable

41.5 Relationship with partners of a joint action — Coordination agreement

Not applicable

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

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

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The *Commission* will — **at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full.

If the *Commission* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *Commission* of its disagreement and the reasons why.

If the *Commission* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the *Commission* rejects costs **at the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the summary financial statement (see Article 20.4). It will then calculate the payment of the balance as set out in Article 21.4.

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

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The *Commission* may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The *Commission* may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

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

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

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

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

43.3 Effects

If the *Commission* reduces the grant 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 Articles 5.3.4 and 21.4).

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

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

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

Each beneficiary's financial responsibility in case of recovery is limited to its own debt, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

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

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

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

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

(b) *not applicable;*

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

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

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

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

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

44.1.2 Recovery at payment of the balance

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

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

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

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

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

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

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

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

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

divided by

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

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing received by the beneficiary}}.

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

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

divided by

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

multiplied by

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

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

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

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

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

(i) *not applicable;*

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

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

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

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

44.1.3 Recovery of amounts after payment of the balance

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

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

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

divided by

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

multiplied by

the final grant amount (see Article 5.3)}.

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

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

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

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

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

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

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

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

(i) *not applicable;*

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

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

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

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

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the *Commission* may impose **administrative** and **financial penalties** if a beneficiary:

(a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or

(b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the Commission may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the *Commission*.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *Commission* may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *Commission* may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the *Commission* will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *Commission* does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

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

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

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

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

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

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

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

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *Commission*

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

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

46.2 Liability of the beneficiaries

46.2.1 Conditions

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

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages - Calculation

The amount the *Commission* can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the *Commission* will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *Commission* does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

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

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

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

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

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

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

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

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

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

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

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

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

47.2 Procedure

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

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

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

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

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

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *Commission* may — at any moment — suspend, in whole or in part, the pre-financing payment for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

(a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or

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

48.2 Procedure

Before suspending payments, the *Commission* will formally notify the coordinator:

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

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

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

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

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

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

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

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

49.1.2 Procedure

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

- the reasons why and

- the expected date of resumption.

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

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

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

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

49.2 Suspension of the action implementation, by the *Commission*

49.2.1 Conditions

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

(a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

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

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

49.2.2 Procedure

Before suspending implementation of the action, the *Commission* will formally notify the coordinator:

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

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

The suspension will **take effect** five days after confirmation notification is received by the coordinator (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 will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

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

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *Commission* (see Article 46).

Suspension of the action implementation does not affect the *Commission's* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

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

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *Commission* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit: the final report (see Article 20.4).

If the *Commission* does not receive the reports within the deadline (see above), no costs will be taken into account.

The *Commission* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *Commission* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the

addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *Commission* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for all the reporting periods until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Articles 20.3 and 20.4).

The information in the termination report must also be included in the final report (see Article 20.4).

If the request for amendment is rejected by the *Commission*, (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *Commission*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *Commission* will **calculate** — on the basis of the termination report and the report on the distribution of payments — if the pre-financing payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary and approved by the *Commission*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *Commission* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *Commission* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases (in particular if termination takes effect after the period set out in Article 3), the *Commission* will formally notify a **debit note** to the beneficiary concerned. If payment

is not made by the date in the debit note, the Guarantee Fund will pay to the *Commission* the amount due and the *Commission* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the final payment.

If the *Commission* does not receive the termination report within the deadline (see above), no costs will be taken into account.

If the *Commission* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the *Commission*

50.3.1 Conditions

The *Commission* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

  (i) resumption is impossible, or

  (ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) *not applicable;*

(j) *not applicable;*

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary 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**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *Commission* will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and

- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *Commission* of the measures to ensure compliance with the obligations under the Agreement.

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

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the coordinator.

50.3.3 Effects

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

The coordinator must — within 60 days from when termination takes effect — submit a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *Commission* does not receive the report within the deadline (see above), no costs will be taken into account.

The *Commission* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the report submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *Commission's* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the *Commission* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for all the reporting periods until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the final report (see Article 20.4).

If the request for amendment is rejected by the *Commission* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *Commission*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *Commission* will **calculate** — on the basis of the termination report and the report on the distribution of payments — if the pre-financing payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary and approved by the *Commission*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *Commission* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *Commission* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases, in particular if termination takes effect after the period set out in Article 3, the *Commission* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *Commission* the amount due and the *Commission* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the final payment.

If the *Commission* does not receive the termination report within the deadline (see above), no costs will be taken into account.

If the *Commission* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that

- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

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 'Terms and Conditions of Use of the electronic exchange system'. 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 Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

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

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

The *Commission* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *Commission*** must be sent to the following address:

European Commission
Directorate General for Communications Networks, Content and Technology
Health and Well-being
BU25 03/175
B-1049 Brussels Belgium

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 'Beneficiary Register'.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

Not applicable

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[30], periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

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

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents;
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *Commission* may request additional information.

[30] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8.6.1971, p. 1).

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *Commission* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58).

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *Commission's* right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

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

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

If a dispute concerns administrative or financial penalties, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU.

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

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

SIGNATURES

For the coordinator

Jesús VAZQUEZ ALMUIÑA with ECAS id nvaqueje signed in the Participant Portal on 03/12/2015 at 10:29:34 (transaction id SigId-7579-Udb8pEQqDkiMFVbPDzlUCVeBFqcSTUJv6p1IAcbByNTRtf1ncV9geZgzzhfsv4JEQv11LNkumn0C0FYwRwV2Vzu-Jj71zxYb8yr9TOHuN2x1OS-W8zUpnCEBkVxGdD6slocO9B91wr1dXLALmQLQhDcKBP).
Timestamp by third party at
Thu Dec 03 10:29:42 CET 2015

For the *Commission*

Signed by Griet VAN CAENEGEM with ECAS id caenegr as an authorised representative on 11-12-2015 16:38:20 (transaction id SigId-1253-5zbwi0zjo0J7YxqP2AGOJv3VANDK2ctHqtzpsm4kmfc4YRwHdt5Pmce2dXEDPPNG6UqxpbDXXT2IFfcaUAg3Vum-PHslUMVSXYCswcv4WdCzfp-qD4S4uzfOEGQ6PC6OwNKNBJyNRKLPILoTEYK69JB7xC)
Fri Dec 11 16:38:25 CET 2015

EUROPEAN COMMISSION

Directorate General for Communications Networks, Content and Technology

Health and Well-being

ANNEX 1 (part A)

COFUND (PCP)

NUMBER — 690492 — EMPATTICS

Table of Contents

1.1. The project summary

Project Number [1]	690492	Project Acronym [2]	EMPATTICS

One form per project

General information	
Project title [3]	EMpowering PAtients for a BeTTer Information and improvement of the Communication Systems
Starting date [4]	01/02/2016
Duration in months [5]	36
Call (part) identifier [6]	H2020-PHC-2015-single-stage
Topic	PHC-27-2015 Self-management of health and disease and patient empowerment supported by ICT
Fixed EC Keywords	MEDICAL AND HEALTH SCIENCES
Free keywords	Empowerment, adherence, chronic diseases, PCP

Abstract [7]

This project will research and define how health and care professionals and patients will use ICT technologies to plan interventions with patients and to monitor the progression of their physical and mental state. It will investigate and document the requirements for Decision Support Tools that can be created, deployed and embedded into the daily routines of patients and Health and Care Professionals to deliver quality standardised care across a large population of chronic and elderly patients. This will include the technology requirements and use cases for sharing Care Plans between professionals and patients as well as the scope and depth of integration between new productivity and care coordination toolsets and current EMR recording software.
EMPATITCS will undertake further research and collate current global examples of self-management services that have been clinically proven to positively impact the health of a population. It will study the socio-economic and age dependency factors that affect awareness, uptake and adherence to self-management services. This will define and design a best in class self-management service that provide the educational and informational services that a large population of elderly and chronic patients require to self-manage. The emphasis will be of the use of appropriate technology to scale the service and to connect with population groups that are difficult to reach due to geographic or demographic factors.

1.2. List of Beneficiaries

Project Number [1]	690492	Project Acronym [2]	EMPATTICS

List of Beneficiaries

No	Name	Short name	Country	Project entry month[8]	Project exit month
1	Conselleria de Sanidade de Galicia	Sanidad Galicia	Spain	1	36
2	REGION MIDTJYLLAND	CDR	Denmark	1	36
3	SERVICIO ARAGONES DE LA SALUD	SALUD	Spain	1	36
4	GROUPEMENT DE COOPERATION SANITAIRE POUR LE DEVELOPPEMENT DES SYSTEMES D'INFORMATION PARTAGES EN ILE DE FRANCE	GCS D-SISIF	France	1	36
5	SPLOSNA BOLNISNICA SLOVENJ GRADEC JAVNI ZAVOD*GENERAL HOSPITAL SLOVENJGRADEC	SB-SG	Slovenia	1	36
6	THE EUROPEAN HEALTH FUTURES FORUM	EHFF	United Kingdom	1	36
7	KOKOMO HEALTHCARE LIMITED	KKM	Ireland	1	36
8	M&C SAATCHI MADRID SL	Saatchi	Spain	1	36

1.3. Workplan Tables - Detailed implementation

1.3.1. WT1 List of work packages

WP Number [9]	WP Title	Lead beneficiary [10]	Person-months [11]	Start month [12]	End month [13]
WP1	Project Management, Financial Coordination and Quality Assurance	1 - Sanidad Galicia	30.00	1	36
WP2	Reviewing evidence base ad supply-side status and identifying buyer needs	6 - EHFF	19.00	1	12
WP3	PCP training and industry dialogues	2 - CDR	31.00	1	12
WP4	Contract Implementation	1 - Sanidad Galicia	35.00	1	36
WP5	PCP test sites and technology validation	3 - SALUD	65.00	4	36
WP6	Communication, explotation and dissemination of results	8 - Saatchi	16.00	1	36
		Total	196.00		

1.3.2. WT2 list of deliverables

Deliverable Number [14]	Deliverable Title	WP number [9]	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D1.1	Project management plan	WP1	1 - Sanidad Galicia	Report	Confidential, only for members of the consortium (including the Commission Services)	1
D1.2	Project quality assurance plan	WP1	1 - Sanidad Galicia	Report	Public	3
D1.3	Evaluation plan	WP1	1 - Sanidad Galicia	Report	Public	3
D1.4	Internal website and communication protocols	WP1	1 - Sanidad Galicia	Websites, patents filling, etc.	Confidential, only for members of the consortium (including the Commission Services)	3
D1.5	First report	WP1	1 - Sanidad Galicia	Report	Public	6
D1.6	Trial Protocols	WP1	1 - Sanidad Galicia	Demonstrator	Public	8
D1.7	Partner meetings	WP1	1 - Sanidad Galicia	Demonstrator	Public	36
D1.8	Progress reports	WP1	1 - Sanidad Galicia	Report	Public	36
D1.9	Final report WP1	WP1	1 - Sanidad Galicia	Report	Public	36
D2.1	Interim report on the operationalization of the common challenge	WP2	6 - EHFF	Report	Confidential, only for members of the consortium (including the Commission Services)	4
D2.2	Interim report on the regional context and the strategic needs analysis	WP2	6 - EHFF	Report	Confidential, only for members of the consortium (including the Commission Services)	4
D2.3	Interim report on the market scope on tools, practices and ICT solutions	WP2	6 - EHFF	Report	Confidential, only for members of the consortium (including the Commission Services)	7
D2.4	Final report WP2	WP2	6 - EHFF	Report	Public	8

Deliverable Number [14]	Deliverable Title	WP number [9]	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D3.1	Map of potencial companies and networks	WP3	2 - CDR	Report	Public	6
D3.2	Information material about PCP	WP3	2 - CDR	Report	Public	3
D3.3	Newsletters	WP3	2 - CDR	Report	Public	6
D3.4	Workshops	WP3	2 - CDR	Demonstrator	Public	6
D3.5	PCP conference	WP3	2 - CDR	Demonstrator	Public	7
D3.6	Open market consultation report	WP3	2 - CDR	Report	Public	5
D3.7	Press releases	WP3	2 - CDR	Report	Public	8
D4.1	Call of expresión of interest for new buyers	WP4	1 - Sanidad Galicia	Report	Public	2
D4.2	Action plan for PCP execution	WP4	1 - Sanidad Galicia	Report	Public	2
D4.3	Five committees of regional experts (CRE)	WP4	1 - Sanidad Galicia	Other	Confidential, only for members of the consortium (including the Commission Services)	1
D4.4	Buyers evaluation Board (BEB)	WP4	1 - Sanidad Galicia	Other	Confidential, only for members of the consortium (including the Commission Services)	1
D4.5	Evaluation guidelines to be followed by CREs and BEB	WP4	1 - Sanidad Galicia	Report	Public	5
D4.6	Short report describing the support of buyers for technology take-up	WP4	1 - Sanidad Galicia	Report	Public	5
D4.7	FAQs report about the use of PCP	WP4	1 - Sanidad Galicia	Report	Public	7
D4.8	Tender specifications document	WP4	1 - Sanidad Galicia	Report	Classified Information: CONFIDENTIEL UE (Commission Decision 2015/444/EC)	6
D4.9	PCP evaluation tenders report Phase 1	WP4	1 - Sanidad Galicia	Report	Public	13
D4.10	Up to 10 contracts phase 1	WP4	1 - Sanidad Galicia	Other	Confidential, only for members	13

Deliverable Number [14]	Deliverable Title	WP number [9]	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
					of the consortium (including the Commission Services)	
D4.11	Updated technology description and solution design reports up to 10 offers at the end of phase 1	WP4	1 - Sanidad Galicia	Other	Confidential, only for members of the consortium (including the Commission Services)	17
D4.12	Updated Commercialization and impact plan up to 10 offers Phase 1	WP4	1 - Sanidad Galicia	Other	Confidential, only for members of the consortium (including the Commission Services)	17
D4.13	PCP evaluation tenders report Phase 2	WP4	1 - Sanidad Galicia	Report	Public	17
D4.14	Up to 5 contracts phase 2	WP4	1 - Sanidad Galicia	Other	Confidential, only for members of the consortium (including the Commission Services)	18
D4.15	Up to 5 authorizations ethics committee & others aplicable requirements to initiate phase 3	WP4	1 - Sanidad Galicia	Other	Confidential, only for members of the consortium (including the Commission Services)	23
D4.16	Up to 5 organisational plan and 5 developed/ tested prototype	WP4	1 - Sanidad Galicia	Other	Confidential, only for members of the consortium (including the Commission Services)	27
D4.17	PCP evaluation tenders report Phase 3	WP4	1 - Sanidad Galicia	Report	Public	27
D4.18	Up to 3 contracts phase 3	WP4	1 - Sanidad Galicia	Other	Confidential, only for members of the consortium (including the Commission Services)	28
D4.19	Up to 3 impact and Validation report of Phase 3 results	WP4	1 - Sanidad Galicia	Report	Confidential, only for members of the consortium (including the	34

Deliverable Number [14]	Deliverable Title	WP number [9]	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
					Commission Services)	
D4.20	Report from suppliers	WP4	1 - Sanidad Galicia	Report	Public	34
D4.21	Up to impact and comparison report of Phase 3 results	WP4	1 - Sanidad Galicia	Report	Public	36
D5.1	Phase 3 preparatory report	WP5	3 - SALUD	Report	Confidential, only for members of the consortium (including the Commission Services)	8
D5.2	Definition case for evaluation of clinical effectiveness	WP5	3 - SALUD	Report	Confidential, only for members of the consortium (including the Commission Services)	20
D5.3	Definition case for evaluation of patient and clinician perspectives	WP5	3 - SALUD	Report	Confidential, only for members of the consortium (including the Commission Services)	20
D5.4	Definition case for evaluation of economic aspects	WP5	3 - SALUD	Report	Confidential, only for members of the consortium (including the Commission Services)	20
D5.5	Phase 3 final report	WP5	3 - SALUD	Report	Public	36
D6.1	Dissemination, exploitation and communication estrategias	WP6	8 - Saatchi	Websites, patents filling, etc.	Public	2
D6.2	Project logo and external webside	WP6	8 - Saatchi	Websites, patents filling, etc.	Public	2
D6.3	Social media strategy and profile	WP6	8 - Saatchi	Report	Public	3
D6.4	Stakeholder analysis	WP6	8 - Saatchi	Report	Confidential, only for members of the consortium (including the Commission Services)	3

Deliverable Number [14]	Deliverable Title	WP number [9]	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D6.5	Stakeholder relationship management tool/list	WP6	8 - Saatchi	Websites, patents filling, etc.	Confidential, only for members of the consortium (including the Commission Services)	3
D6.6	Marketing material for print and online	WP6	8 - Saatchi	Websites, patents filling, etc.	Public	3
D6.7	Meeting with local stakeholders in each region	WP6	8 - Saatchi	Websites, patents filling, etc.	Public	36
D6.8	Publications for academic journals	WP6	8 - Saatchi	Websites, patents filling, etc.	Public	36
D6.9	Conference papers	WP6	8 - Saatchi	Websites, patents filling, etc.	Public	36
D6.10	Dissemination and exploitation interim reports	WP6	8 - Saatchi	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D6.11	Final conferences	WP6	8 - Saatchi	Websites, patents filling, etc.	Public	36
D6.12	Final report dissemination	WP6	8 - Saatchi	Report	Public	36

1.3.3. WT3 Work package descriptions

Work package number [9]	WP1	**Lead beneficiary** [10]	1 - Sanidad Galicia
Work package title	Project Management, Financial Coordination and Quality Assurance		
Start month	1	**End month**	36

Objectives

The objective of this work package is to ensure proper and effective management of the proposed project and activities. As well, it will help ensure that the project meets its objectives within the identified budget, resources and schedule. This Work Package will undertake coordination between Consortium members as well as with the European Commission, ensuring effective communication, the proper flow of information both internally and externally, and the ongoing tracking of deliverables. The Work Package will also coordinate assessment and reporting procedures on behalf of the consortium related to the progress being made to both Consortium members and the European Commission.

Description of work and role of partners

WP1 - Project Management, Financial Coordination and Quality Assurance [Months: 1-36]
Sanidad Galicia, CDR, SALUD, GCS D-SISIF, SB-SG, KKM
All Sub Tasks of WP1 will commence at M1 and continue for the entire project period.
Task 1.1: Consortium Management/Project Office – Consellería Sanidade
Kokomo will have overall responsibility to establish the project office for the consortium, including the contract with the Commission, internal communication and management structure. Responsibilities and activities will include:
- Establishing the Steering Committee, Executive Committee, and Strategic Advisory Board
- Establishing and managing the Project Plan
- Coordinating activity/communication with Work Package leads and Buyers
- Managing project time lines and schedules, including identifying corrective actions where appropriate
- Liaising with the Steering Committee, Project Management Board and Scientific Advisory Committee
- Establishing and implementing appropriate standards of project management and quality assurance
- Preparing required management reports, and arranging partner meetings

Task 1.2 Financial and administrative co-ordination – Consellería de Sanidade
- Liaising with the Project Officers from Buyers Group
- Submitting financial deliverables to the European Commission
- Collecting and consolidating financial statements
- Distributing EU contribution among the partners

Task 1.3 Quality Assurance, risk management analysis and evaluation methodology – Kokomo
- Producing a project Quality Assurance Plan, which will reference the working methods to be used in the project as well as other standards in use
- Monitoring and identifying risks for project report
- Addressing ethical and security issues
- Developing the evaluation plan, in conjunction with WP4 and WP5
- Monitoring the proper maintenance of quality records
- Ensuring that requirements are met in a cost effective and traceable manner through the use of an established quality systems in line with ISO 9001:2000 “Quality management systems - Requirements”
- Assuring the quality of the project in its different aspects according to the Quality Assurance Plan and the quality norms agreed among the Consortium members
- Providing feedback to the Project Management about possible deviations from plans or from agreed quality standards and recommending corrective actions

Participation per Partner

Partner number and short name	WP1 effort
1 - Sanidad Galicia	22.00

Partner number and short name	WP1 effort
2 - CDR	1.00
3 - SALUD	1.00
4 - GCS D-SISIF	1.00
5 - SB-SG	1.00
6 - EHFF	0.00
7 - KKM	4.00
Total	30.00

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D1.1	Project management plan	1 - Sanidad Galicia	Report	Confidential, only for members of the consortium (including the Commission Services)	1
D1.2	Project quality assurance plan	1 - Sanidad Galicia	Report	Public	3
D1.3	Evaluation plan	1 - Sanidad Galicia	Report	Public	3
D1.4	Internal website and communication protocols	1 - Sanidad Galicia	Websites, patents filling, etc.	Confidential, only for members of the consortium (including the Commission Services)	3
D1.5	First report	1 - Sanidad Galicia	Report	Public	6
D1.6	Trial Protocols	1 - Sanidad Galicia	Demonstrator	Public	8
D1.7	Partner meetings	1 - Sanidad Galicia	Demonstrator	Public	36
D1.8	Progress reports	1 - Sanidad Galicia	Report	Public	36
D1.9	Final report WP1	1 - Sanidad Galicia	Report	Public	36

Description of deliverables

D1.1 Project management plan (M1)
D1.2 Consortium agreement and Grant Agreement (M2)
D1.3 Terms of Reference of Project Management Board and Scientific Advisory Committee (M2) D1.4 Project quality assurance plan (M3)
D1.5 Gender action plan (M3)
D1.6 Evaluation plan (M3)
D1.7 Internal website and communication protocols (M3) D1.8 Project meeting (M5)
D1.9 Trial protocols (M8)
D1.10 Partner meetings (M12, 24, 36)
D1.11 Periodic reports (M6, 12, 18, 24, 30, 36)
D1.12 Final report (M36)

D1.1 : Project management plan [1]

Plan activities agreed among partners, including deadlines and responsibles

D1.2 : Project quality assurance plan [3]

Document used as reference of the working methods implemented in the project as well as other standards in use

D1.3 : Evaluation plan [3]

Document to guide the evaluation protocols as well as responsibles necessary for the evaluation of proposals

D1.4 : Internal website and communication protocols [3]

Plan uses as internal communication channels to manage the projects

D1.5 : First report [6]

First reporting period (M1-M6)

D1.6 : Trial Protocols [8]

Definition of the test disease types, inclusión/exclusion criteria ...

D1.7 : Partner meetings [36]

Partner meetings

D1.8 : Progress reports [36]

Periodic reports (M6, M12, M18, M24, M30, M36)

D1.9 : Final report WP1 [36]

Final report from the Coordinator summarizing main conclusions of the EMPATTICS project. Second reporting period (M7-M36)

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS1	Project management plan	1 - Sanidad Galicia	1	
MS3	Evaluation plan	1 - Sanidad Galicia	3	
MS4	Launch of project office and management structures	1 - Sanidad Galicia	3	
MS5	Trial protocols	1 - Sanidad Galicia	8	

Work package number [9]	WP2	Lead beneficiary [10]	6 - EHFF
Work package title	Reviewing evidence base ad supply-side status and identifying buyer needs		
Start month	1	End month	12

Objectives

The main objective of this WP is to briefly describe the literature and scope the existing IT market solutions to identify limitations to cover regional needs and to support the PCP process to create a state-of-the-art technology that meets the needs of the Buyers Group. Tasks include the combination of various types of analysis and the engagement of stakeholders at different levels of the healthcare system.

Description of work and role of partners

WP2 - Reviewing evidence base ad supply-side status and identifying buyer needs [Months: 1-12]
EHFF, Sanidad Galicia, CDR, SALUD, GCS D-SISIF, SB-SG
Task 2.1. Review of evidence and existing EU projects – Task leader: FAD, Participant: Diane Whitehouse. M1-M3
Desk review of scientific literature on the application of ICT tools and solutions to self-management in chronic diseases and specifically on the selected area that the Buyers selected for operazionaling the common challenge at the beginning of the project. The review will be focused on evidence of effectiveness and limitations (including identification of barriers for the adoption). It will be centred on the evidence presented in systematic reviews of the last 8 years and key documents of key institutions regarding health and chronic care (WHO, King's Fund, Health Foundation...). Milestones: Wp starting meeting with partners on M1 and Summary of scientific evidence M3
Task 2.2. Analysis of joint health and care needs – Task leader: EHFF + Regional partners. Participants: FAD, Diane Whitehouse. M1-M3
The objective is to perform regional and combined Strategic Needs Assessment by: 1) identifying regional self-management policy and community implementation as related to the agreed prioritised area and specific disease/target population and 2) understanding the regional situation about barriers for the adoption of ICT for self-management from a citizen's perspective. This task will perform the analysis and aggregation of the information provided by the regions including data on:
- Results on the wider determinants of health and social care as they relate to chronic diseases
- Analysis of their health care plans and other policy documents,
- Their knowledge on socio-economic, environmental and technology acceptance barriers to adoption of self-management
The resulting qualitative and quantitative data will provide a picture of what is needed to enable citizens to become empowered and further indicators to establish the future self-care needs of the local populations and the drivers of innovation for the PCP. The PCP will then be able to support better targeting of self-care interventions to reduce health and care inequalities and establish self-care technologies as a vital component of local competencies to produce a high standard of regional chronic care management. Milestones: Analysis of joint health and care needs onM3
Task 2.3. Identification of initial key areas of interest Task leader: EHFF. Participants: FAD + Diane Whitehouse + Regional partners. M3-M4
3.1. Identification of the specific topics and variables of interest according to the Buyers priorities to be covered in the market scope by combining the results from the review of the scientific basis and the analysis of the regional context.
Task 2.4. Market scope – Task leader: EHFF. Participants: Diane Whitehouse M4-M7
4.1 Build and agree on the contents of the market scope
In this task we will develop the basis for the evaluation of the various products and related services offered including the areas that will be included. Each product-service combination will be examined at least from the perspective of payers. In this task we will agree the contents of the market scope including perspectives of authorities dealing with legislation and regulation, financiers/investors, end- users and service providers. Existing patents will also be explored.
4.2 Research best practice global tools, products and solutions and their limitations.
Various methodologies for business modeling will be used to assess their appropriateness and the role of end-users, payers and stakeholders.
4.3 Summary of current tools, practices and ICT solution for self-management (and their limitations) that will that will inform the definition of detailed specifications for the PCP
Task 2.5. Gap Analysis – Task leader: FAD Participants: EHFF, Diane Whitehouse.M7
Analysis of the gaps between literature findings and tools on ICT for self-management and the regional policies and context. Based on the findings from previous tasks a reference model and basic contents for optimal use of advanced

ICT systems and services for self-care will be defined. This will be done by comparing the existing regional settings (technology infrastructure, stakeholders, products, services, healthcare and social system characteristics) with best practices. The resulting PCP specification will then be tested among experts and buyers
Task 2.6. Report – Task leader: EHFF. Participants FAD and Diane Whitehouse.M8
6.1 Report adapted to the needs of the procurement process that will serve to launch an Open Challenge for the technology community to respond. Milestone: Summary of buyers needs according to the combined results of previous tasks (Completion of the Gap Analysis) M7

Participation per Partner

Partner number and short name	WP2 effort
1 - Sanidad Galicia	2.00
2 - CDR	2.00
3 - SALUD	2.00
4 - GCS D-SISIF	2.00
5 - SB-SG	2.00
6 - EHFF	9.00
7 - KKM	0.00
Total	19.00

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D2.1	Interim report on the operationalization of the common challenge	6 - EHFF	Report	Confidential, only for members of the consortium (including the Commission Services)	4
D2.2	Interim report on the regional context and the strategic needs analysis	6 - EHFF	Report	Confidential, only for members of the consortium (including the Commission Services)	4
D2.3	Interim report on the market scope on tools, practices and ICT solutions	6 - EHFF	Report	Confidential, only for members of the consortium (including the Commission Services)	7
D2.4	Final report WP2	6 - EHFF	Report	Public	8

Description of deliverables

D.2.1 Interim report on the scientific evidence (restricted circulation) M4
D.2.2 Interim report on the regional context and the strategic needs analysis (restricted circulation) M4
D.2.3 Interim report on the market scope on tools, practices and ICT solutions (restricted circulation) M7

D.2.4 Final WP2 Report M8

D2.1 : Interim report on the operationalization of the common challenge [4]
Report from EHFF focused on the analysis of operarionalization of the common challenge

D2.2 : Interim report on the regional context and the strategic needs analysis [4]
Report from EHFF focused on the analysis of regional needs and challenges related to the project

D2.3 : Interim report on the market scope on tools, practices and ICT solutions [7]
Analysis of the technology state-of-the-art on the challenge

D2.4 : Final report WP2 [8]
Final report of WP2. Conclusions will guide Tender documents

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS6	Operationalization of the common challenge	6 - EHFF	1	
MS7	Review of evidence and existing EU projects	6 - EHFF	1	
MS8	Analysis of joint health and care needs	6 - EHFF	1	
MS9	Market scope	6 - EHFF	13	
MS10	Summary of buyers needs according to the combines results of previous tasas (completion of the gap analysis)	6 - EHFF	5	

Work package number [9]	WP3	Lead beneficiary [10]	2 - CDR
Work package title	PCP training and industry dialogues		
Start month	1	End month	12

Objectives

The WP intends an open Market Consultations that will serve us to draft all the functional specifications for an Innovation Call. The goal is to create awareness among companies to participate in the PCP process but also to create awareness amongst the public partners with regards to the PCP process.

Description of work and role of partners

WP3 - PCP training and industry dialogues [Months: 1-12]
CDR, Sanidad Galicia, SALUD, GCS D-SISIF, SB-SG, KKM, Saatchi
Task 3.1: Open Challenge/technical dialogues with the Market. Task leader: Central Denmark Region (M1-8), participation all buyers
The open challenge intends an open and transparent discussion with companies about key requirements and functional specifications found in previous WP. Before publishing the final contract, we must organize several informative industry technical sessions/hackathons across different cities and regions in Europe. These sessions should be organised like highly intense "innovation sessions of 1-2 days": designed to propose and develop answers. They will also serve to foster joint ventures/alliance between SMEs, entrepreneurs, start-ups and big companies. The proposed sessions will also act as excellent marketing tools to announce our future PCP call and at the same time they can serve us to gather feedback from companies before the final contract publication
PCP is a quite innovative tool to promote applied research and there are not many companies with enough experience and resource to participle in these calls. They do not about financial and technical requirements, legal contract processes and so on and so forth. In order to increase the level of awareness of potential tenderers we propose informative sessions (in parallel with task 1) to inform companies about risks and benefits of PCP tenders. Sessions will also help us to anticipate our PCP project to companies engineering and R&D departments. We propose to introduce in these technical dialogues a PCP training of 3-4 hour from an experimented organisation. This partner could lead the PCP training part and subcontract a company with experience in Hackathon organisation. This strategy will certainly increase the number of tenderers, the quality of the solutions, and promotes entrepreneurship in the ICT health sector.
1. Mapping of potential ICT companies and developers and other creative companies (M1-3)
2. Production of information material to both on-line and social medial including guidelines and recommendations about PCP (M1-3)
3. Establishing of a Linked-in group for interested companies and procurers (M4)
4. Marketingoftheinformationdirectlytopotentialtenderers(fromthemapping)abouttheinitial conclusions gathered in WP2 and indirectly through websites and professional media networks (M4-5
5. Webinars about basic PCP and PPI (M4-M7)
6. Seminars, workshops and personal meetings (M6-7)
7. Facilitation of new consortiums/collaborations and matchmaking amongst interested companies with have the right motivation and competencies (M6-8)
8. Innovation conferences and hackathons to be held in France, Spain; Slovenia and Denmark (M6-7)
9.Modificationoftenderspecificationsaccordinglytoinputfromtheinnovationconferencesandoneto one meetings (M7)

Participation per Partner

Partner number and short name	WP3 effort
1 - Sanidad Galicia	5.00
2 - CDR	11.00
3 - SALUD	5.00
4 - GCS D-SISIF	3.00
5 - SB-SG	5.00

Partner number and short name	WP3 effort
6 - EHFF	0.00
7 - KKM	1.00
8 - Saatchi	1.00
Total	31.00

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D3.1	Map of potencial companies and networks	2 - CDR	Report	Public	6
D3.2	Information material about PCP	2 - CDR	Report	Public	3
D3.3	Newsletters	2 - CDR	Report	Public	6
D3.4	Workshops	2 - CDR	Demonstrator	Public	6
D3.5	PCP conference	2 - CDR	Demonstrator	Public	7
D3.6	Open market consultation report	2 - CDR	Report	Public	5
D3.7	Press releases	2 - CDR	Report	Public	8

Description of deliverables

D3.1: Map of potential companies and networks (M2)
D3.2: Information material (guidelines, previous PCP cases, website) to companies & public procurers (M3)
D3.3: Newsletters (M3 and M5 and M7)
D3.4: Workshops and meetings with companies from France, Spain and Denmark (M7)
D3.5 PCP conferences with 150 attendees and 30 companies interested in joining the PCP process (M7)
D3.6: Guidelines for implementing a joint PCP process (M8)
D3.7: Press-releases (M8)

D3.1 : Map of potencial companies and networks [6]

Lists and contacts of potential companies: Companies will be gathered during the activities programmed during WP3

D3.2 : Information material about PCP [3]

Leaflet resuming the main aspects of the PCP tender like guidelines, previous PCP cases and website to companies & public procurers

D3.3 : Newsletters [6]

Periodical Newsletters explaining the evolution of the project and other relevant information

D3.4 : Workshops [6]

Workshops and meetings with companies

D3.5 : PCP conference [7]

Big event to officially present the tender

D3.6 : Open market consultation report [5]

Outcomes report after Open Market Consultation

D3.7 : Press releases [8]

Periodical Press releases explaining the evolution of the project and other relevant information

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS11	Analysis of the market	2 - CDR	3	
MS12	Information material about PCP process and content	2 - CDR	3	
MS13	Workshops with companies	2 - CDR	4	
MS14	PCP conference	2 - CDR	7	
MS15	Guidelines for implementing a joint PCP process	2 - CDR	8	

Work package number [9]	WP4	Lead beneficiary [10]	1 - Sanidad Galicia
Work package title	Contract Implementation		
Start month	1	End month	36

Objectives

The core task of WP4 is the preparation and subcontracting phase and accompanying the PCP execution phase. The detailed structure of the PCP tendering process will be defined in this WP including the solution design, prototype phase and test/validation phase. A fair and transparent procedure will be ensured by conducting the PCP on the basis of the principles governing public procurement procedures. The Consellería de Sanidade will be responsible for managing the contracts with companies on the national level under overall coordination of the Project Management Board. Through WP, Buyers will ensure that the development of new technologies addressed the self-care Functional Specification of the PCP contract in a transparent and competitive methodology that involves 3 phases
The specific objectives of the WP3 are:
Coordinate an EU joint PCP process including contracts and arrangements;
Set up a common agreement on the indicators for the evaluation of the offers received;
Launch an EU open call for tender and evaluate proposals from companies
Execute contracts

Description of work and role of partners

WP4 - Contract Implementation [Months: 1-36]
Sanidad Galicia, CDR, SALUD, GCS D-SISIF, SB-SG, KKM
This WP will be led by Consellería de Sanidade (Lead Procurer) and EMPATTICS Buyers will be involved and contribute to the development of the PCP tasks. Contributions from other partners such as EHFF and the results of WP2 and WP3 will be essential to prepare the PCP according to the Functional Specifications of the Health Challenges and industrial standards. The estimated duration of the WP4 is of 36months, starting on M1 and lasting until the end of the project EMPATTICS (M36). The following tasks are previewed:
Task 4.1: Leader: Consellería d Sanidade with all Buyers and Kokomo, MC&Saatchi. Publication of an Open Call for expression of interest to include new Buyers in the EMPATTICS Buyers Group M1-M3
A call for new members of the Buyers group will be announce on the EMPATTICS project website and at the website of the Lead procurers. Members of the Buyers group expect the reception Expressions of Interest from other European Public Health Authorities. The expressions of interest will incorporate a description of the Organization profile, current projects on Patient Empowerment technologies and financial commitments. Up to 2 Public Authorities will be incorporated to the EMPATTICS Buyers group, enlarging Networking and Coordination activities
Task 4.2: Leader: Consellería de Sanidade with All Buyers. PCP design phase. M1-M4
At the beginning of the project, BUYERS will work on the PCP design phase. Several actions will be executed during this task:
- Drafting of an action plan through a meeting plan with buyers group to discuss all procedural details
- Clarification of the legal framework with buyers group
- Drafting of the framework of the PCP: how the joint evaluation of offers will be organised,
- Creation of contact list in Buyer Organizations.
CreationofCommitteesofRegionalExperts(CRE)
CreationofaBuyersEvaluationBoard(BEB)
Secure enough resources within the Buyers group for the execution o the PCP tender: staff, legal experts, IPR experts, procurement staff, industrial contacts, IT professionals, Clinicians, etc.
Agree on the financial transactions required for the publication of PCP tender.
Prepare a contract Notice for early dissemination of the PCP contract.
Decide whether about electronic process or paper based process. The Lead procurer is now implementing an electronic procurement system and it expects to be operational at the end of 2015.
Task 4.3: Leader: Consellería Sanidade with All Buyers. PCP Planning and set-up of the framework M4-M8
During this task Buyers will draft the framework of the PCP contract, ensuring that the joint evaluation of offers will be organised, which type of best value for money evaluation criteria to use, preparation and quality check of technical specifications, preparation of formal tendering documents, etc.
Incorporating the socio-economic and technical analysis carried our during WP2
Incorporating the innovation readiness levels of the industry (acquired through WP2 and WP3)

Incorporating the technical aspects of the available IT systems in EMPATTICS regions (WP2)
Describe the Functional Specifications of the Health Challenges
Define with all details the scope and objectives of each PCP phase
Define the selection criteria for participating in the PCP (experience of bidders, technical and economic requirements, etc)
Decide on the contract details (share the IPR , requests of right of use, royalties, information on the applicable law, time line of the contract, languages accepted, Payment timelines, use of personal data and its protection, bidder responsibility, piggybacking clauses for other purchasers etc)
Define indicators for evaluating the offers received at the different phases(indicators will include, among others criteria to asses innovation level, R&D feasibility, R&D management plan, time management, expected impact on health systems, potential to become a global solution, Business and commercialization plan)
Task 4.4: Leader: Consellería de Sanidade with All Buyers and MC&Saatchi. Publication of the PCP Contract and related dissemination activities.M8-M11
An open call for tenders will be launched on EU TED journal. The PCP tender will also be published on National and regional procurement portals aiming the maximum dissemination of the contract opportunity. Offers for Phase 1 will be received no later than M11. The publication of the PCP tender will be accompanied of other publications/actions:
- Explanatory note of the award criteria for the PCP tender
- Evaluation Guidelines to be followed by Committee of Regional experts and Buyers Evaluation Board.
- Report on the information collected during WP2 and WP3
- Short report describing the support of Buyers for technology take-up.
- FAQs report about the use of PCP
- PCP Business Case.
- Several disseminations actions carried out by MC&Saatchy to maximize tender publication awareness
- Answering questions of bidders (all questions raised by bidders will be published on Lead Procurer Website).
Task 4.5: Leader: Consellería de Sanidade with All Buyers. Evaluation of proposals.M11-M13
The CREs and BEB will be formed by representatives of all members of the Buyers groups. Evaluation Reports will be presented to the Public authority that administers the contract by consensus. CRE and BEB will evaluate according to the set of indicators and guidelines defined in Task2 and Task3.Other actions includes:
- Evaluation templates
- Evaluation Report forms
Task 4.6: Leader: Consellería de Sanidade. Administration of the contracts.M13-M36.This task includes the communication notices and the preparation of the contracts with the winning bidders. Contracts will be prepared according to the PCP framework defined in task 4.3 and the national laws of the Lead procurer.

Participation per Partner

Partner number and short name	WP4 effort
1 - Sanidad Galicia	30.00
2 - CDR	1.00
3 - SALUD	1.00
4 - GCS D-SISIF	1.00
5 - SB-SG	1.00
6 - EHFF	0.00
7 - KKM	1.00
Total	35.00

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D4.1	Call of expresión of interest for new buyers	1 - Sanidad Galicia	Report	Public	2
D4.2	Action plan for PCP execution	1 - Sanidad Galicia	Report	Public	2
D4.3	Five committees of regional experts (CRE)	1 - Sanidad Galicia	Other	Confidential, only for members of the consortium (including the Commission Services)	1
D4.4	Buyers evaluation Board (BEB)	1 - Sanidad Galicia	Other	Confidential, only for members of the consortium (including the Commission Services)	1
D4.5	Evaluation guidelines to be followed by CREs and BEB	1 - Sanidad Galicia	Report	Public	5
D4.6	Short report describing the support of buyers for technology take-up	1 - Sanidad Galicia	Report	Public	5
D4.7	FAQs report about the use of PCP	1 - Sanidad Galicia	Report	Public	7
D4.8	Tender specifications document	1 - Sanidad Galicia	Report	Classified Information: CONFIDENTIEL UE (Commission Decision 2015/444/ EC)	6
D4.9	PCP evaluation tenders report Phase 1	1 - Sanidad Galicia	Report	Public	13
D4.10	Up to 10 contracts phase 1	1 - Sanidad Galicia	Other	Confidential, only for members of the consortium (including the Commission Services)	13
D4.11	Updated technology description and solution design reports up to 10	1 - Sanidad Galicia	Other	Confidential, only for members of the consortium (including the	17

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
	offers at the end of phase 1			Commission Services)	
D4.12	Updated Commercialization and impact plan up to 10 offers Phase 1	1 - Sanidad Galicia	Other	Confidential, only for members of the consortium (including the Commission Services)	17
D4.13	PCP evaluation tenders report Phase 2	1 - Sanidad Galicia	Report	Public	17
D4.14	Up to 5 contracts phase 2	1 - Sanidad Galicia	Other	Confidential, only for members of the consortium (including the Commission Services)	18
D4.15	Up to 5 authorizations ethics committee & others aplicable requirements to initiate phase 3	1 - Sanidad Galicia	Other	Confidential, only for members of the consortium (including the Commission Services)	23
D4.16	Up to 5 organisational plan and 5 developed/ tested prototype	1 - Sanidad Galicia	Other	Confidential, only for members of the consortium (including the Commission Services)	27
D4.17	PCP evaluation tenders report Phase 3	1 - Sanidad Galicia	Report	Public	27
D4.18	Up to 3 contracts phase 3	1 - Sanidad Galicia	Other	Confidential, only for members of the consortium (including the Commission Services)	28
D4.19	Up to 3 impact and Validation report of Phase 3 results	1 - Sanidad Galicia	Report	Confidential, only for members of the consortium (including the Commission Services)	34
D4.20	Report from suppliers	1 - Sanidad Galicia	Report	Public	34

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D4.21	Up to impact and comparison report of Phase 3 results	1 - Sanidad Galicia	Report	Public	36

Description of deliverables

D4.1 Call of Expression of Interest for new Buyers (M2)
D4.2 Action plan for PCP execution. (M2)
D4.3 Five Committees of Regional Experts (CRE) (M1)
D4.4 One Buyers Evaluation Board (BEB) (M1)
D4.5 Evaluation Guidelines to be followed by CREs and BEB (M5)
D4.6 Short report describing the support of Buyers for technology take-up (M5)
D4.7 FAQs report about the use of PCP (M7)
D4.8 A PCP Business Case. (M8)
D4.9 Launch of European PCP open tender (M8)
D4.10 Up to 10 contracts phase 1(M13)
D4.11 Updated Technology description report up to 10 offers at the end of Phase 1 (M17)
D4.12 Updated Solution design report up to 10 offers Phase 2 (M17)
D4.13 Updated Commercialization and Impact plan up to 10 offers Phase 2 (M17)
D4.14 Up to 5 contracts phase 2 (M18)
D4.15 Up to 5Authorizations Ethics committee & others applicable requirements to initiate phase 3 (M23)
D4.16 Up to 5 organisational plan for Phase 2 (M27)
D4.17 Up to 5 developed/ tested prototypes (M27)
D4.18 Up to 3 contracts phase 3 (M28)
D4.19 Up to three Organisational plan for Phase 3
D4.20 Up to Impact and comparison report of Phase 3 results

D4.1 : Call of expresión of interest for new buyers [2]

Public Document with the Terms and conditions to attract new Buyers

D4.2 : Action plan for PCP execution [2]

Detailed Plan with all steps, calendar, activities, compromises and responsibles for the publication of the PCP tender

D4.3 : Five committees of regional experts (CRE) [1]

Document of Constitution of 5 committees (one per buyer)

D4.4 : Buyers evaluation Board (BEB) [1]

Document of Constitution of the Board that will evaluate proposals from companies. One member per buyer

D4.5 : Evaluation guidelines to be followed by CREs and BEB [5]

Documents to guide evaluators on the assessment of the received proposals

D4.6 : Short report describing the support of buyers for technology take-up [5]

Report for potential companies explaining the support of buyers for the validation of technologies

D4.7 : FAQs report about the use of PCP [7]

Document with FAQs to easily explain main aspects of the tender

D4.8 : Tender specifications document [6]

Common tender specifications

D4.9 : PCP evaluation tenders report Phase 1 [13]

The buyers will report about final ranking list of the select projects, final scores and qualitative assessment per evaluation criterion for each received bid, minutes of evaluating meeting. Moreover information on the total number of bids received (data and abstracts of the winning tenderer(s) will be reported in a format specified by the EC, for publication and evaluation purposes

D4.10 : Up to 10 contracts phase 1 [13]

Number of expected contacts to be signed with companies at the beginning of Phase 1

D4.11 : Updated technology description and solution design reports up to 10 offers at the end of phase 1 [17]

Companies should present at the end of Phase 1 a technology description report and a solution design report. The best 5 proposals will enter in Phase 2

D4.12 : Updated Commercialization and impact plan up to 10 offers Phase 1 [17]

Companies should present at the end of Phase 1 a commercialization and impact plan. The best 10 proposals will enter in Phase 2

D4.13 : PCP evaluation tenders report Phase 2 [17]

Info on the PCP evaluation of tenders: - final ranking list of the select projects, final scores and qualitative assessment per evaluation criterion for each received bid, minutes of evaluating meeting. - information on the total number of bids received (data and abstracts of the winning tenderer(s) will be reported in a format specified by the EC, for publication and evaluation purposes. Inof on results achieved in previous PCP phase: - assessment by buyers group of the results achieved of the results achieved by each participating tenderer in the previous PCP phase

D4.14 : Up to 5 contracts phase 2 [18]

Number of expected contacts to be signed with companies at the beginning of Phase 2

D4.15 : Up to 5 authorizations ethics committee & others aplicable requirements to initiate phase 3 [23]

Document presented by companies to initiate Phase 3 Validation with patients and clinicians

D4.16 : Up to 5 organisational plan and 5 developed/tested prototype [27]

Companies should present at the end of Phase 2 an Organisation plan. The best 3 proposals will enter in Phase 3 Companies should present at the end of Phase 2, a prototype specification and demonstration document, as well as a plan for limited first product development, involvement and testing, The best 3 proposals will enter in Phase 3.

D4.17 : PCP evaluation tenders report Phase 3 [27]

Info on the PCP evaluation of tenders: - final ranking list of the select projects, final scores and qualitative assessment per evaluation criterion for each received bid, minutes of evaluating meeting. - information on the total number of bids received (data and abstracts of the winning tenderer(s) will be reported in a format specified by the EC, for publication and evaluation purposes. Inof on results achieved in previous PCP phase: - assessment by buyers group of the results achieved of the results achieved by each participating tenderer in the previous PCP phase

D4.18 : Up to 3 contracts phase 3 [28]

Number of expected contacts to be signed with companies at the beginning of Phase 3

D4.19 : Up to 3 impact and Validation report of Phase 3 results [34]

Companies must report on the validation results and impact.

D4.20 : Report from suppliers [34]

Info on each project and its achievements in a format specified by the EC, for publication and evaluation purposes

D4.21 : Up to impact and comparison report of Phase 3 results [36]

Report about the efficiency of each technology in the different test sites, including a comparison of the impact of the technologies in a variety of European regions. Demonstration to the EC.

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS2	Consortium agreement and grant agreement	1 - Sanidad Galicia	6	
MS16	Publication call for new buyers	1 - Sanidad Galicia	1	

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS17	Creation of CREs and BEB	1 - Sanidad Galicia	1	
MS18	Plan for definition of PCP	1 - Sanidad Galicia	4	
MS19	Definition of PCP indicators, selection criteria and main contract clauses	1 - Sanidad Galicia	7	
MS20	Publication of PCP tender	1 - Sanidad Galicia	8	
MS21	Evaluation and award of phase 1	1 - Sanidad Galicia	13	
MS22	Evaluation and award of phase 2	1 - Sanidad Galicia	17	
MS23	Evaluation and award of phase 3	1 - Sanidad Galicia	27	
MS24	Impact and comparison results	1 - Sanidad Galicia	36	
MS32	Publication of the PIN	1 - Sanidad Galicia	2	Publication of the Prior Information Notice (PIN) for the open consultation

Work package number [9]	WP5	Lead beneficiary [10]	3 - SALUD
Work package title	PCP test sites and technology validation		
Start month	4	End month	36

Objectives

WP includes the monitoring and validation of self-care solutions. Therefore this work package covers activities of the companies during Phase 3. Monitoring activities will be assumed by the buyers group according to the MAST methodology. WP5 leader will ensure that MASTmethodology is correctly used in the pilot sites and analysis of data is done in accordance with the MAST guidelines.

Description of work and role of partners

WP5 - PCP test sites and technology validation [Months: 4-36]
SALUD, Sanidad Galicia, CDR, GCS D-SISIF, SB-SG
Task 5.1 Phase 3-test sites and technology Monitoring Preparatory stage (Phases from M4-M8)
This task will address the preparation of all technical aspects that will be part of the validation studies. Among other things the WP leaser will work on the analysis of main aspects of the Health challenges and basic characteristics of the potential technologies that will be tested. The inputs received from WP2 and WP 3 will be incorporated to this task. The definition report will also include epidemiology of the target health challenge, resources available at the different test sites, technical readiness level ofparticipating test sites, interoperability and integration needs (EMRs), anticipated needs of training if applicable, contact listsat test sites, patient sample sizes, etc. The result of this Phase 3 preparatory report will help EMPATTICS to prepare the ground for initiating monitoring and validadtion studies with companies.
Task 5.2 Definition studies for evaluation of Clinial effectiveness (M4-M20)
During the first months of the EMPATTICS the comsortum will decide the number and disease to be testet. The comsortium has already agreed that a minimum of 2 diseases, ideally 3 will be tested. After decision on the diseases that will be tackled by platforms, WP5 will start to work on the definition of linical effectiveness. The effectiveness refers to the performance of EMPATTCICS technologies in Phase3 application in regular clinical practice. Some examples of outcome masures are (diseases not defined yet):
Diabetes: HbA1c; SF-36; Diabetes quality of life score DQOL; SF-12; VAS:; the five item Centre for Epidemiologic Studies Depression Scale; (CESD), Number of hospitalizations; Number of rehospitalisations; Number of bed days for hospitalised patients; Number of primary clinic visits; Number of specialist visits; Number of visits at emergency department.
Heart failure: All-cause deaths, Heart failure related deaths, Revised Heart Failure Self-Care Behaviour Scale, MLHFQ: The 21-item Minnesota Living with Heart Failure Questionnaire,6 minute walk test, Health Failure Self-Efficacy; Hospital Anxiety and Depression Score, Number of hospitalizations, Number of heart failure related rehospitalisations, Number of bed days for hospitalised patients, Number of primary clinic visits, Number of specialist visits, Number of heart failure related visits at emergency department
COPD: All caused deaths,the SGRQ, Chronic Respiratory Questionnaire (for QoL), Clinical COPD Questionnaire for health related quality of life, SF-36, Minnesota Living with Heart Failure Questionnaire; Number of hospitalizations, Number of rehospitalisations, Number of bed days for hospitalised patients, Number of primary clinic visits, Number of specialist visits, Number of visits at emergency department, Number of office visits, Number of home visits
Task 5.3 Definition studies for evaluation of Patient and Clinician perspectives (M4-M20)
Within this task, the consortium aims the creation of relevant documents to evaluate the end user perspectives (clinicians, patients and caregivers): The consortium is especially interested in data and performance indicators about technology satisfaction and acceptance, ability to use theapplications and capacity to of empowerment and self-management. Basic surveys, questionaires and interviews in accordance with MAST methodology will be prepared to measure end-user satisfaction
Task 5.4 Definition studies for evaluation of Economic Aspects (M4-M20)
Economic evaluation wil be mostly focused on healthcare systems. Patient's economic aspects such as savings in patient travel costs or caregiver's bubsistance savings will not be considered due to time and resources constrains. The focus will be paid on the analysis of resources used when delivering the assessed technologies (investments in new equipments if applicable, use of hospital staff,....) and the related changes in use of health care resources (savings in bed days, savings in Hospitalization costs,variation on the number of outpatient visits)
application and its comparators in the health care sector and other sectors
Task 5.5 Training companies on MAST methodology (M28)

The outcomes of Tasks 5.1-5.4 will be transferred to companies training workshops. Companies will be responsible for the preparation of documentation and reports providing to healthcare organizations enough information about the clinical effectiveness, patient and clinician perspectives and impact on healthcare systems.
Note. Substantial financial support has been devoted to Phase 3. Companies will have to work in this performance assessment relying on external consultants and specialized staff, if they lack of specialized resorces. Buyers expect a proactive attitude from Companies in Phase3. Buyers also expect that this phase will serve to train companies in issues related to medical practice. The learning experiences gained through phase 3 will probably help companies to improve their technologies (improvements will not be covered by the funded PCP) and and to prepare their organizations for future commercialization activities.
Task 5.6 Test sites validation and monitoring reports (M28-M36)
The tree companies selected for phase 3 will present their results to WP5 leader

Participation per Partner

Partner number and short name	WP5 effort
1 - Sanidad Galicia	13.00
2 - CDR	7.00
3 - SALUD	25.00
4 - GCS D-SISIF	7.00
5 - SB-SG	13.00
6 - EHFF	0.00
7 - KKM	0.00
Total	65.00

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D5.1	Phase 3 preparatory report	3 - SALUD	Report	Confidential, only for members of the consortium (including the Commission Services)	8
D5.2	Definition case for evaluation of clinical effectiveness	3 - SALUD	Report	Confidential, only for members of the consortium (including the Commission Services)	20
D5.3	Definition case for evaluation of patient and clinician perspectives	3 - SALUD	Report	Confidential, only for members of the consortium (including the Commission Services)	20

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D5.4	Definition case for evaluation of economic aspects	3 - SALUD	Report	Confidential, only for members of the consortium (including the Commission Services)	20
D5.5	Phase 3 final report	3 - SALUD	Report	Public	36

Description of deliverables

D5.1 Phase 3 preparatory report (M8)
D5.2 Definition case for evaluation of Clinial effectiveness (M20)
D5.3 Definition case for evaluation of Patient and Clinician perspectives (M20)
D5.4 Definition case for evaluation of Economic Aspects(M20)
D5.5 Phase 3 final report (M36)

D5.1 : Phase 3 preparatory report [8]

Internal document anticipating guidelines to validate technologies

D5.2 : Definition case for evaluation of clinical effectiveness [20]

Document with all relevant indicators that will be used to test the effectiveness of technologies participating in Phase 3

D5.3 : Definition case for evaluation of patient and clinician perspectives [20]

Document with all relevant indicators and activities that will be used to test the perspectives of end users of technologies participating in Phase 3

D5.4 : Definition case for evaluation of economic aspects [20]

Document with all relevant indicators and activities that will be used to evaluate the economic aspects of the of technologies participating in Phase 3

D5.5 : Phase 3 final report [36]

Final report summarizing main conclusions of the EMPATTICS Phase 3

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS25	Test site and monitoring plan	3 - SALUD	8	
MS26	Definition of test site and monitoring criteria	3 - SALUD	20	
MS27	Test sites and monitoring reports	3 - SALUD	36	

Work package number [9]	WP6	Lead beneficiary [10]	8 - Saatchi
Work package title	Communication, explotation and dissemination of results		
Start month	1	End month	36

Objectives

The objective of this work package is to create, evaluate and disseminate the knowledge generated in this project, and to enable the means and channels for communication, among the project partners, the stakeholders and the broader public. In particular this work package aims at changing the mind-set of public procurers that wants to use PCP as a powerful vehicle for innovation procurement. Through the contracted reporting mechanisms, we will demonstrate the full potential of PCP to the European Union decision makers, and show that EU SMEs will respond with world class solutions when openly challenged to solve real world health and care obstacles. This WP will generate recommendations on upgrading the human resource skills amongst procurement, legal, clinical and social care personnel, within local, regional and national purchasers/providers as they relate to innovative chronic disease self-care.

Description of work and role of partners

WP6 - Communication, explotation and dissemination of results [Months: 1-36]
Saatchi, Sanidad Galicia, CDR, SALUD, GCS D-SISIF, SB-SG, EHFF
Task 6.1 Dissemination and exploitation strategies (M1 – M2)
WP6 will develop a detailed dissemination and exploitation strategy in partnership with all partners and buyers. This will include determining the optimal local, regional, national and European dissemination channels. The strategy will including time lines and schedules for deliverables and identify key inputs required from each WP throughout the PCP process. The strategy will be shared with WP lead and partners.
Task 6.2 Digital, Social Media and Web Strategy (M1 – M3, ongoing)
WP6 will develop and implement a digital, social media and web presence for the project. This will include a dedicated project web site, digital presentations and brochures. A key deliverable will be a targeted social media strategy which will include a local, regional, national and EU-level audience analysis to assess the best social media approach for the project. This will be done through consultation with project partners as well as industry experts. This task will then include the execution of the strategy, including ongoing monitoring and evaluation to ensure effectiveness across channels and with key stakeholders.
Task 6.3 Stakeholder analysis and management (M1 – M3, ongoing)
WP6 will undertake a stakeholder analysis to identify key local, regional, national and EU-level stakeholder profiles as well as publications and medial channels. This will include identifying key policy and industry organisations, thought leaders, market segments, industry organisations, magazines, forums. This will correspond to working undertaken in WP3 related to open market consultations/engagement. In addition, W6 will develop a stakeholder relationship management tool or process to ensure information is captured throughout the project and used by all project partners. Appropriate steps will be taken to manage any personal information collected.
Task 6.4 Marketing Material and Publications (M1 – M3)WP6 will develop print and marketing material for the project for dissemination by all partners. In addition, all partners will target publishing 2 articles per year in online or print media over the life of the project. WP6 will assist in identifying publications and forums at different levels and assist with the application and publication process.
Task 6.5 Meetings and Conferences (M4 – M36)
WP6 will arrange meetings with local stakeholders in each of the Buyer regions. This will target 20-40 key stakeholders, including online and print media. Venues will be determined by the local partner. In addition. WP6 will develop and update a list of relevant conferences. All project partners will be expected to attend a local, regional, national or international conference per year that the project is ongoing. This can be combined with publication activities in Task 6.4.
Task 6.6 Dissemination reporting (M8 – 36)
WP6 will prepare interim reports on dissemination and exploitation activities to project partners on an on a regular basis which will include an evaluation of activities and adjustments required to the overall strategy. Reports will also incorporate a summary of all dissemination activities conducted by each project partner. A final report, including all activities and an assessment of their effectiveness will be developed for distribution to all project partners.

Participation per Partner

Partner number and short name	WP6 effort
1 - Sanidad Galicia	1.00
2 - CDR	1.00
3 - SALUD	1.00
4 - GCS D-SISIF	1.00
5 - SB-SG	1.00
6 - EHFF	1.00
7 - KKM	0.00
8 - Saatchi	10.00
Total	16.00

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D6.1	Dissemination, exploitation and communication estrategias	8 - Saatchi	Websites, patents filling, etc.	Public	2
D6.2	Project logo and external webside	8 - Saatchi	Websites, patents filling, etc.	Public	2
D6.3	Social media strategy and profile	8 - Saatchi	Report	Public	3
D6.4	Stakeholder analysis	8 - Saatchi	Report	Confidential, only for members of the consortium (including the Commission Services)	3
D6.5	Stakeholder relationship management tool/ list	8 - Saatchi	Websites, patents filling, etc.	Confidential, only for members of the consortium (including the Commission Services)	3
D6.6	Marketing material for print and online	8 - Saatchi	Websites, patents filling, etc.	Public	3
D6.7	Meeting with local stakeholders in each region	8 - Saatchi	Websites, patents filling, etc.	Public	36
D6.8	Publications for academic journals	8 - Saatchi	Websites, patents filling, etc.	Public	36

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D6.9	Conference papers	8 - Saatchi	Websites, patents filling, etc.	Public	36
D6.10	Dissemination and exploitation interim reports	8 - Saatchi	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D6.11	Final conferences	8 - Saatchi	Websites, patents filling, etc.	Public	36
D6.12	Final report dissemination	8 - Saatchi	Report	Public	36

Description of deliverables

D6.1 Dissemination and exploitation strategies (M2)
D6.2 Project logo and website (M2)
D6.3 Social media strategy and profile (M3)
D6.4 Stakeholder analysis (M3)
D6.5 Stakeholder Relationship Management tool/list (M3 and ongoing)
D6.6 Marketing material for print and online (brochures, newsletters, articles) (M3)
D6.7 Meeting with local stakeholders in each region (M4, 8, 12, 18, 24, 28, 32, 36)
D6.8 Publications for academic journals (M24, M36)
D6.9 Conference papers (M8, 20, 36)
D6.10 Dissemination and exploitation interim reports (M8, 24)
D6.11 Final conferences (M30-36)
D6.12 Final report dissemination (M36)

D6.1 : Dissemination, exploitation and communication estrategias [2]

Document with main details about the dissemination strategy to be followed during the project and including deadlines and responsibles.

D6.2 : Project logo and external webside [2]

Creation of project logo and website

D6.3 : Social media strategy and profile [3]

Plan to disseminate the project in Internet

D6.4 : Stakeholder analysis [3]

Analysis of relevant companies that can participate in the PCP tender

D6.5 : Stakeholder relationship management tool/list [3]

Tool to manage better relationship with stakeholders

D6.6 : Marketing material for print and online [3]

Materials for disseminate all project obejectives. To be disseminated in workshops and online (through Web and social media).

D6.7 : Meeting with local stakeholders in each region [36]

Workshops open to companies and relevant organizations that can participate in the tender or further disseminate objectives and expected benefits

D6.8 : Publications for academic journals [36]

Publications in different academic journals

D6.9 : Conference papers [36]

Documents presented in relevant PPI or Health Innovation events explaining project objectives, strategy and execution

D6.10 : Dissemination and exploitation interim reports [24]

Internal documents collecting the activities done by different partners across Europe

D6.11 : Final conferences [36]

Disseminating main results in the Final Conference

D6.12 : Final report dissemination [36]

Final report from WP6 Coordinator summarizing main dissemination activities and impact

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS28	Dissemination and exploitation strategy	8 - Saatchi	2	
MS29	Project website	8 - Saatchi	2	
MS30	First PCP conference	8 - Saatchi	8	
MS31	Final report on dissemination	8 - Saatchi	36	

1.3.4. WT4 List of milestones

Milestone number [18]	Milestone title	WP number [9]	Lead beneficiary	Due Date (in months) [17]	Means of verification
MS1	Project management plan	WP1	1 - Sanidad Galicia	1	
MS2	Consortium agreement and grant agreement	WP4	1 - Sanidad Galicia	6	
MS3	Evaluation plan	WP1	1 - Sanidad Galicia	3	
MS4	Launch of project office and management structures	WP1	1 - Sanidad Galicia	3	
MS5	Trial protocols	WP1	1 - Sanidad Galicia	8	
MS6	Operationalization of the common challenge	WP2	6 - EHFF	1	
MS7	Review of evidence and existing EU projects	WP2	6 - EHFF	1	
MS8	Analysis of joint health and care needs	WP2	6 - EHFF	1	
MS9	Market scope	WP2	6 - EHFF	13	
MS10	Summary of buyers needs according to the combines results of previous tasas (completion of the gap analysis)	WP2	6 - EHFF	5	
MS11	Analysis of the market	WP3	2 - CDR	3	
MS12	Information material about PCP process and content	WP3	2 - CDR	3	
MS13	Workshops with companies	WP3	2 - CDR	4	
MS14	PCP conference	WP3	2 - CDR	7	
MS15	Guidelines for implementing a joint PCP process	WP3	2 - CDR	8	
MS16	Publication call for new buyers	WP4	1 - Sanidad Galicia	1	

Milestone number [18]	Milestone title	WP number [9]	Lead beneficiary	Due Date (in months) [17]	Means of verification
MS17	Creation of CREs and BEB	WP4	1 - Sanidad Galicia	1	
MS18	Plan for definition of PCP	WP4	1 - Sanidad Galicia	4	
MS19	Definition of PCP indicators, selection criteria and main contract clauses	WP4	1 - Sanidad Galicia	7	
MS20	Publication of PCP tender	WP4	1 - Sanidad Galicia	8	
MS21	Evaluation and award of phase 1	WP4	1 - Sanidad Galicia	13	
MS22	Evaluation and award of phase 2	WP4	1 - Sanidad Galicia	17	
MS23	Evaluation and award of phase 3	WP4	1 - Sanidad Galicia	27	
MS24	Impact and comparison results	WP4	1 - Sanidad Galicia	36	
MS25	Test site and monitoring plan	WP5	3 - SALUD	8	
MS26	Definition of test site and monitoring criteria	WP5	3 - SALUD	20	
MS27	Test sites and monitoring reports	WP5	3 - SALUD	36	
MS28	Dissemination and exploitation strategy	WP6	8 - Saatchi	2	
MS29	Project website	WP6	8 - Saatchi	2	
MS30	First PCP conference	WP6	8 - Saatchi	8	
MS31	Final report on dissemination	WP6	8 - Saatchi	36	
MS32	Publication of the PIN	WP4	1 - Sanidad Galicia	2	Publication of the Prior Information Notice (PIN) for the open consultation

1.3.5. WT5 Critical Implementation risks and mitigation actions

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
R1	Deliverables or WP has delay or issues	WP1	Project manager has to moniot and communicate with WP leaders who will have a clear area of responsibility
R2	No coherency between WPs according to lack of unified communication including all partners involved in task	WP1	Project Office (PRO) will develop an internal communication plan to follow. The project manager will inform partners and keep them updated on milestones regarding information / communication
R3	The proposed PCP call does not attract enough SME to compete	WP3	WP leader 3 and 7 will activate SME with workshops and stakeholder analysis with communication and information
R4	During several tasks in order to prepare PCP a common decision or evaluation is required, this might result in disagreements which will delay activities	WP3	If no consensus is found in time , the Scientific Advisory Board (SAB) as well as Steering Committee (SC) will take a decision
R5	Some partners might not respect their commitments or milestones, no quality work is delivered	WP1	The project manager will inform this partner in a proactive way in order to let the partner improve. Otherwise measures will be taken to rearrange the tasks or remove the partner
R6	Existing background IPR of proposed ICT solution	WP4	Contract manager makes a background IPR search on all ICT suppliers
R7	Monitoring ICT pilots complexity due to geographical range of suppliers	WP5	Contract manager will use RAG system to support both contract manager and suppliers to stay on track
R8	Some proposed technology does not function properly	WP5	Continuously monitoring of Contract manager using agile project leadership with reports every 15 days from suppliers
R9	The design and performance of the ICT tool	WP4	Create an award criteria with less technical and

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
	is too much influenced by the public procurers		functional demands for suppliers
R10	The contribution from each public procurer will increase	WP4	Contact with national agencies in participating countries, detecting national/ regional calls on PCP 2015 – 2018.

1.3.6. WT6 Summary of project effort in person-months

	WP1	WP2	WP3	WP4	WP5	WP6	Total Person/Months per Participant
1 - Sanidad Galicia	22	2	5	30	13	1	73
2 - CDR	1	2	11	1	7	1	23
3 - SALUD	1	2	5	1	25	1	35
4 - GCS D-SISIF	1	2	3	1	7	1	15
5 - SB-SG	1	2	5	1	13	1	23
6 - EHFF	0	9	0	0	0	1	10
7 - KKM	4	0	1	1	0	0	6
8 - Saatchi	0	0	1	0	0	10	11
Total Person/Months	30	19	31	35	65	16	196

1.3.7. WT7 Tentative schedule of project reviews

Review number [19]	Tentative timing	Planned venue of review	Comments, if any
RV1	6	Brussels	Before Tender publication
RV2	16	Brussels	After Phase 1
RV3	27	Brussels	After Phase2
RV4	36	Brussels	After Phase 3

1.4. Ethics Requirements

Ethics Issue Category	Ethics Requirement Description
PROTECTION OF PERSONAL DATA	- The applicant must explicitly confirm that the existing data are publicly available and/or if a specific authorisation is mandatory.
PROTECTION OF PERSONAL DATA	- Data protection policy is not described. The applicants must provide details on how data will be stored (electronic format or paper), how long it will be retained and how it will be anonymised.
HUMANS	- Details must be provided about the measures taken to handle the vulnerability of the groups targeted in the project proposal as declared on p. 126.
HUMANS	- Details on the procedures for recruiting participants must be given. The inclusion/exclusion criteria and the number of participants must be defined.
HUMANS	- Behavioural data collected during participants' observation can bring to incidental findings. The policy to be adopted must be defined.
HUMANS	- Detailed information must be provided on the informed consent procedures that will be implemented.
PROTECTION OF PERSONAL DATA	- The applicant must specify which type of sensitive personal data will be collected and justify the collection of such data.
PROTECTION OF PERSONAL DATA	- The applicant must confirm that no project activity will commence before obtaining the ethical approvals from the relevant authorities. In addition, the applicant must specify which relevant authorities will approve the research and within which time frame.
PROTECTION OF PERSONAL DATA	- In case of data not publicly available, relevant authorisations must be provided.
PROTECTION OF PERSONAL DATA	- A detailed description of the procedure and of the content of the informed consent form must be provided.

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	

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.

Table of Changes

Change E.N.T.E.R. for M&SAATCHI	**50, 54, 55, 68, 69, 70, 72, 75 107-112**
3.1.1. Graphical representation of work packages	**60-62**
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5.1. Ethics	**112 to 116**

Table of Contents

1. Excellence

1.1. State of the art

1.1.1. State of the art: Supply side

Informed motivated patients are those with sufficient information to become wise decision makers in the treatment of their disease. They are active in their role of managing their condition and they are motivated to make effective decisions to improve their personal prognosis. The service objective is to support and equip patients to become active self-managers, regardless of education level. The idea of expert patients, who use technology to understand and respond in real time to changes in their medical condition, is becoming more wide-spread as the mobile savy generation have reached the over 40 age bracket that is normally associated with the on-set of chronic diseases.

This project will research and define how health and care professionals and patients will use ICT technologies to plan interventions with patients and to monitor the progression of their physical and mental state. It will investigate and document the requirements for Decision Support Tools that can be created, deployed and embedded into the daily routines of patients, caregivers and healthcare professionals to ensure quality standardised care across a large population of chronic and elderly patients. This will include the technology requirements and use cases for sharing Care Plans between professionals and patients as well as the scope and depth of integration between new productivity and care coordination toolsets and current EMR recording software.

EMPATTICS will undertake further research and collate current global examples of self-management services that have been clinically proven to positively impact chronic patients. It will study the socio-economic and age dependency factors that affect awareness, uptake and adherence to self-management services. This will define and design a best in class self-management service that provide the educational and informational services that a large population of chronic patients requires to self-manage. The emphasis will be of the use of appropriate technology to scale the service and to connect with population groups that are difficult to reach due to geographic or demographic factors.

Patient empowerment is a top priority. Public health authorities across Europe recognize that the current paternalistic model to manage most disease is clearly outdated. Current paternalistic approach is especially non-operational – and too expensive - for chronic and pluri-patological patients. The private sector is naturally aware of this shift in the public sector and it has started to develop private initiatives cantered on patient focused solutions.

A short check on the literature demonstrates the existence of numerous technologies to help patients to manage their health. Almost all of them could be classified in 5 groups (a) medical content via internet; (b) e-mail, phone reminders and other communication tools with short messages to improve health management; (c) online communities; (d) patient portals (e) data-capture tools such as pedometers, sensors, weight management systems.

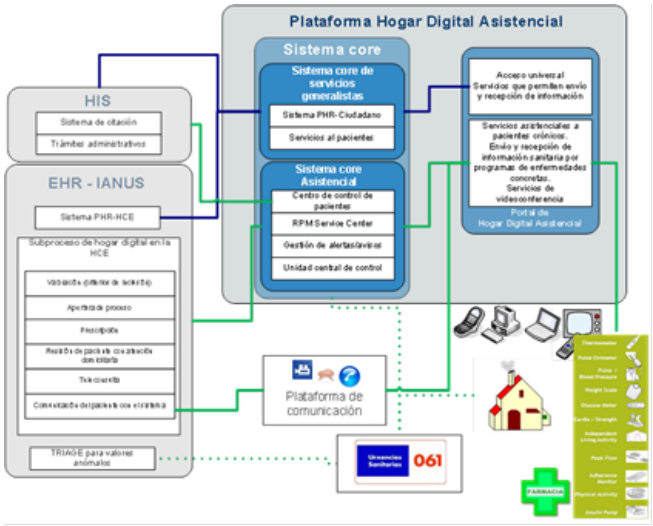
Some constructive examples of these private initiatives are:

- 1) MyCare program from Mayo Clinic (US):[1] A program developed to empower patients affected by cardiac surgery. The program includes different modules A “Plan of Stay” with a daily patient “To Do” list that was linked to personalized patient clinical status and the recovery events: a module with Educational Material about their surgery, medical conditions, and expected care events in the hospital, a module to Promote Strength through a set of daily expectations for physical activities and finally a Recovery Planning module with information on how patients should care for themselves in the long term.

[1] http://webcast.aats.org/2013/files/Saturday/20130504_audrm2_0800_08.25%20David%20A.%20Cook.pdf

- 2) Health Buddy Mobile from Bosch healthcare: solution was built to promote patient engagement through a mobile patented and commercialized by Bosch. The system is targeted to patients with different chronic disease (Chronic Obstructive Pulmonary Disease (COPD), Heart Failure, Diabetes, Heart Failure/Depression, Coronary Artery Disease and Hypertension. Working as a platform, the system works through health recommendations and materials sent by BOSCH to patient/Bosh cell phones. The patient then starts an interactive session that includes: reporting vital sign data, answering a brief set of questions about medication compliance. The session also includes recommendations for physical and mental health, activities as well as educational and coaching resorces for their specific condition and health profile.

- 3) Hogar Digital promoted by Consellería de Sanidade through its healcare service provider (SERGAS) involved a PPI contract gained by a Joint venture formed between Telefonica and Indra Company.[2] HogarDigital Platform created to empower patients affected by various chronic diseases. Patients can send and receive health information to/from clinicians. The platform allows the development of a care and self-care and medication agenda, prescribe diets, offer recommendations for exercise, and it can include a variety of multimedia content like videos, presentations, etc. to support the patient and/or caregiver.



Hogar Digital also includes seamless integration with a sensor network to monitor some basic patient features and it represents a powerful tool to establish a double communication between patient and doctors. The system works effectively with patients that introduce their health data, symptoms and diets in the Platform. One of the existing challenges is making the system useful for a population without knowledge of IT or disabilities. Besides, Hogar Digital is likely to be connected in the future to social media and third party medical apps providing a powerful tool for patients and clinicians, as it has the capability to be connected to EMR systems. Despite the current powerful and relevant features, the system should be completed with more advanced tools and methods for assessing adherence, detection of the defaulting patient, analysis of the factors that determine the failure or implementation of strategies directed to the patient or caregiver. It also lacks of "smart algorithms" to provide reactive information (like alerts of inappropriate adherence by patients, of absence of enough exercise, etc) to patients and clinicians.

Other technologies related to Patient empowerment and adherence:[3]

- Vaxtrak, Novartis V&D – iPhone app to track and plan vaccinations includes schedule, reminders, locations of vaccination centers and information about vaccines and diseases
- GoMeals, Sanofi-aventis – iPhone app for diabetes condition – help patients to measure calories, fats, carbs, etc.
- Glucotrol, Pfizer – Type II Diabetes – long acting drug – once a day dosing
- Vitality GlowCap – pill bottle equipped with a wireless transmitter – tracks compliance and
- reminds patients by flashing the bottle top and playing reminder melody at time of medication

[2] http://www.indracompany.com/noticia/indra-y-telefonica-disenan-hogar-digital-asistencial
[3] https://www.pt.capgemini.com/resource-file-access/resource/pdf/Patient_Adherence__The_Next_Frontier_in_Patient_Care.pdf

- HopeLab's Re-Mission and Bayer's DIDGET engage patients in fun games and help them manage their condition and side effects
- Zeck Attack, Novartis Vaccines – game to raise awareness for tick borne encephalitis (TBE)
- Quest Diagnostic tools and Care 360 EHR module, which allow physicians and nurses to instantly monitor patients' lab results, prescriptions and medication history
- Novartis partnered with Proteus Biomedical to produce high *tech pills* with embedded ingestible sensors, which tracks medication adherence by time-stamping patient's ingestion of medication. Smart pills records the time of ingestion and brings about patient adherence by informing the patient of the next medication period by communicating through a sensor (usually worn as a skin patch or embedded under the skin). This information can be uploaded to a smart phone or sent to the physician via the internet.

Unfortunately most of these technologies have not succeeded in the market because they are **unable to provide automatic, smart and reactive solutions**. Evidence shows that there is no single intervention strategy, or package of strategies that has been shown to be effective across all patients, conditions and settings. Furthermore, most of the initiatives only cover one – or a few – of the needs that patients suffering from a long term condition has. Hence patients are obliged to relate to different solutions, eg a patient with COPD who has to use one tool for monitoring, another for exercise and a third for decision support. Finally, technologies are fragmented stand-alone solutions that are only configurable to either the specific patients' needs or an update of clinical instructions by involving the supplier. From EMPATTICS point of view, technology developer should work together with healthcare providers and patients to increase the usability of the innovative technologies.

Similarly, most of the technologies available in the market are not designed to be integrated in the Electronic Medical Record systems of Public Health Authorities. Lack of integration with different European EMRs limit the capacity of clinicians to follow up patient's behaviours, their adherence to treatments, etc. The reduced connectivity with EMRs also limits dialogues and tele-care interventions from clinicians to patients. EMPATTICS is conscious of the large number of EMRs in Europe. Almost each European region has todays its own EMR system, and sometimes the private sector finds enormous difficulties to promote technologies in accordance with the different IT standards of the different EMRs.

Finally, we see a huge opportunity in social networks. Many current technologies available in the market for empowering chronic patients lack of tools to foster exchange of health knowledge and health experiences among patients. EMPATTICS consider social networks essential to facilitate interaction among patients, and contributing to the development of more informed and conscious patients.

The proposed development model of EMPATTICS goes in those directions trying to overcome the main gaps identified in current technologies and promoting developments targeted to chronic patients and adapted to clinicians needs.

1.1.2. State of the art: Demand side

In Europe there is a strategic interest on the deployment of technologies that facilitate chronic patient management and his adherence to treatments. The Strategic Implementation Plan of the EIP on AHA identified the area to be addressed: "Health literacy, patient empowerment, ethics and adherence programs, using innovative tools and services".[4] In particular the Action Plan, that involved 34 multi-stakeholder commitments from national, regional and local authorities, research centres, academia, industry, enterprises and existing consortiums across the EU, worked on the

- Development of adherence action at regional level, supported by innovative tools.

[4] ACTION PLAN on 'Prescription and adherence to treatment'. 6 November 2012, Conference of Interested Partners, Brussels. European Innovation Partnership on Active and Healthy Ageing

- Development of innovative tools and applications to promote health literacy and patient empowerment for informed lifestyle choices, including a pan-European online community using ICT based solutions and social marketing models.

All members of the EMPATTICS consortium are already working on the development of patient empowerment e-health solutions/services.

- In **Galicia**, through InnovaSaude and H2050 Innovation Plans, more than 100 entities (95% of them private companies) participated in technical dialogues created around the hospital of the future and patient centered technologies. The Galician Public Health System received almost 300 technical proposals. Technical dialogues with the industry provided insightful information about the current state of the art of a variety of ICT technologies for patient empowerment and as well as a clear vision about the cost and expected benefits of the potential technologies developed through more than 25 PCP and PPI tenders.
- In **Central Denmark Region** especially two initiatives focuses on empowering patients through e-health
  - Shared Service Centre is a Public Private Innovation project launched by Central Denmark Region in corporation with the 19 municipalities in the region and one hospital. The scope is to design a shared service centre that will provide services such as technical support, logistics and maintenance as well as hotline for users. The shared service centre will enable the patient to use e-health solutions and the staff to dedicate their time to core tasks such as treatment and care.
  - Developing and implementing patient-reported outcome (PRO) via TelePRO[5]. PRO used for consultation support provides patient-centered care, ensuring that patient-reported symptoms guides the clinical decisions, and it has been found that PRO and clinical judgments produce complementary data, which, when combined, provide a more accurate description of the patients' symptoms[6].
- In **Aragon**, the SALUD works on patient empowerment e-health solutions and services leaded by the Healthcare Innovation Unit at Barbastro Area. Some of the most remarkable initiatives includes:
  - SUSTAINS project. A set of administrative and clinical services based on patient access to his/her EHR (Electronic Health Record).
  - A vital signs telemonitoring platform used, evaluated and enhanced in four different projects related to chronic patients monitoring.
  - The definition of a public procurement method called, e-RESATER (telemedicine network for rural areas), that fosters the participation of public and private procurers, several providers, individual users and associations, educational institutions and third sector organisations
  - MASTERMIND project for patient empowerment about mental disease and by providing ICT tools that underpins traditional therapies for people with depression.
- In **Ile de France**, the GCS D-SISIF, founded in 2008, is a Health care cooperation consortium which aims to develop the shared health information systems within the Ile-De-France region. The GCS D-SISIF is in charge of building the e-health domain, in deep collaboration with end users, social organisations and private companies. The target is the regional cyberspace of health called ENRS. This ENRS (Health Regional Digital Space) is defined as computerized services and applications undertaken by the health regional Agency (ARS) and piloted by the GCS D-SISIF. It is compliant with

[5] TelePRO is a PRO assessment to evaluate the need for a hospital visit. The PRO data is obtained while the patient is at home either via a paper- or a webbased survey, that is fully integrated into the HER and available to the patient via sundhed.dk .

[6] Hjollund NHI, Larsen LP, Biering K, Johnsen SP, Riiskjær E, Schougaard LM; Use of Patient-Reported Outcome (PRO) Measures at Group and Patient Levels: Experiences From the Generic Integrated PRO System, WestChronic Interact J Med Res 2014;3(1):e5

the interoperability framework and the national methods promoted by the national health information Agency (ASIP Santé). The GCS D-SISIF works on e-health solutions and services including Healthcare Innovation. Different regional project led by the GCS D-SISIF illustrate its activity:

- ROR project. A set of administrative services permitting to obtain the references of all health professionals and health structure of the Ile de France Region
- The S-PRIM project whose objective is to implement PACS on the different hospital structure of the region but also share the images among all health professionals and the patients.
- Telemedicine platform implemented to support different projects like emergency in neurology, dermatology, multi handicapped patients monitoring or diabetic retinopathy follow up.
- The TerriSanté project whose objective is to implement a platform permitting information sharing and delivery of services for the coordination of patient care, prevention and education. This project counts with the participation of public and private sanitary and medico-social institution, city health professionals, individual patients and associations, educational institutions and third sector organisations

- In **Slovenia**, General Hospital Slovenj Gradec (SB-SG) is a telemedicine service provider for diabetic patients (DM) and patients with congestive heart failure (CHF). It provides a support to tose patients through its CEZAR telemedicine centre located in the hospital. In April 2015 almost 500 patients were supported (350 DM and 140 CHF), some of them more than a year. Both services have proven to be very beneficiary to the patients as well as to the health professionals working with them. Positive experience encourages the SB-SG management to start considering new telemedicine services to support self-management at home in other chronic conditions e.g. in pre and postoperative in obesity (gastric band installation in a bariatric surgery), operations with heart or kidney transfer, self-treatment of haemophilia patients etc. The services would increase number of patients gaining intensive support from health professionals at a distance. From the CEZAR telemedicine centre perspective it would extend the offer of the centre. As the centre has ambitious to operate national wide, it is the SB-SG interest to add new services.

Even though, EMPATTICS Buyers have demonstrated broad deployment of technologies for chronic patient management, Buyers also recognize the absence of effective smart technologies, especially in the area of adherence. Buyers agreed that they have already reached a great level of efficiency on drugs and diagnostic technologies but unfortunately many patients across Europe do not adhere to the treatment and healthy recommendations prescribed by their doctors, or do not receive adequate information and do not have access to decision support tools. In fact the EU has recently estimated that the Non-adherence cost reaches €1.25 billion annually to the European Union. We therefore need a suitable mix of people, processes and technologies to give patients the control of their disease, and create effective mechanisms to get regular medication and promote healthy lifestyles.

1.1.3. State of the art: Framework Conditions

Galicia

The Consellería de Sanidade is the Public health authority with competences in the area of health. The organisation is therefore subjected to the national and regional policies that promote innovation in our autonomous region (Galicia) and in our country, Spain.

At National level, he Spanish Law 14/2011, of June 1st, Law for Science Technology and Innovation and the Spanish Law 2/2011, of March 4th, Law of Sustainable Economy (LES) considers Public Procurement as an opportunity to foster Innovation and technology development in our country.

Later, the Spanish Ministry of Economy and Competiveness published on July 8th, 2011 the Guide for innovative public procurement. This Guide is addressed to all public authorities and other public sector entities and it served to guide public authorities in the articulation of the first PPI and PCP contracts.

At regional level the Autonomous law 14/2013, published on December 27 for the rationalization of the public sector in Galicia, addresses several concepts, and plans to promote the strategic use of public procurement in the autonomous community of Galicia. The 14/2013 law of the Regional Government of

Galicia includes in its seventh provision the mandate of the legislature for the Galician Regional Administration to develop a guide of good practices to promote innovative public procurement in Galicia. The first version of the Guide is already under revision, facilitating the development of new projects under the framework of PCP contracts. Both Guidelines have been published according to the Directive 2014/24 / EU on public procurement.

The Regional Health Government of Galicia has played a key role in the development of the Galician Guide as a result of its experience in PPI and PCP projects (more than 30 tenders opened in 3 three years). Part of the success in the management of such large number of PPI and PCP tenders in short time is due to the involvement of the lawyers that defined the Procurement policies for the Autonomous region. This group of lawyers has been incorporated to the EMPATTICS project. The team created by Public procurement officers of the health ministry and Lawyers from the Galician Autonomous Government specialized in regional, national and European policies for innovation procurement is a valuable asset to guarantee the feasibility of the EMPATTICS project.

Besides The Consellería de Sanidade through SERGAS, is currently implement two major innovation plans (Innovasaúde and Hospital2050)[7] that introduce ICT developments focused on patient centred services. With a total budget of €90Million, these two innovation plans have helped the organisation to acquire large knowledge on the promotion of health technologies in innovative companies and help them to acquire enough standards and certifications to reach the market and it served to the Spanish Ministry of Economy and Competitiveness[8] and DG Connect to disseminate good practices about PPI and PCP on the area of health across Spain and Europe.

In this regard the Consellería de Sanidade has recently being awarded with €21,5M of EDRF funds to continue with Public Procurement of Innovation activities in the area of health. Around 20% of this funding will be exclusively for PCP projects in the area of personalized medicine (therapies and diagnostic tools).

Denmark

By the initiative: "The citizens' healthcare system – our healthcare system" Danish Regions, Local Government Denmark, patient associations and healthcare professionals have started a movement towards patient engagement and patient empowerment. The initiative is to be ratified in May 2015 and subsequently implemented during the following years. Hence, there exists both a politically, ethically and clinically demand for tools and technologies addressing patient empowerment in Denmark.

Technologies that are to be adopted in Denmark have to follow decisions form The National eHealth Authority (NSI)[9,] who creates the framework for all ICT solutions developed or used in the healthcare sector in Denmark. In June 2013 The National Board of eHealth adopted a reference architecture on how to share documents and images and collect health data in patients' homes. The reference architecture indicates how standards (technical as well as content) should be used in order to have the desired effect.

The Danish Government, Danish Regions and Local Government Denmark has reached an accord on deploying a national Home monitoring database (KIH DB) that collects, stores and makes available telemedicine measuring and monitoring data across systems and sectors. Accordingly, Danish Regions has recently decided on the Open Tele infrastructure as an open source component for home monitoring data.

Finally, Central Denmark Region is part of 4S[10], which is an open source ecosystem for telemedicine providers and consumers. Members include the National eHealth Authority, three out of the five Danish regions (who operate all public hospitals and secondary care), municipalities (primary health care and social care), software providers, Aarhus University and the Alexandra Institute. 4S is working to promote

[7] http://publications.jrc.ec.europa.eu/repository/bitstream/JRC94502/jrc94502.pdf
[8] http://ec.europa.eu/enlargement/taiex/dyn/create_speech.jsp?speechID=27614&key=58ee1ea2644dd2eecda74d3dadd5f1af
[9] http://www.ssi.dk/English/HealthdataandICT.aspx
[10] http://4s-online.dk/english.php

collaboration on and around health related data, across public and private sectors. 4S is currently focusing on the use domains of telemedicine and tele-health. Through the use of open technologies, reference architectures and international standards, the goal of the 4S ecosystem is to make it easier, faster and cheaper to practically achieve better healthcare IT solutions.

Aragón (SALUD)

Aragón has been one of the latest regions in Spain to join the official actions about Public Procurement that have already been described in the Galicia section. Nevertheless there is a raising concern about PPI and PCP and a set of initiatives are being set up at the regional government: the collaboration with the Public Regional Observatory of Public Procurement, the activation of a new profile for PPI in the regional website for public procurers, the support to individual initiatives in this area and the inclusion of the CPI at the regional strategy of research and innovation.

The SALUD has worked enhancing the innovation process in e-health for more than ten years. A set of strategic lines drive this process: telemedicine (tele-advice, tele-consultation and tele-monitoring), health promotion and prevention, safety and security, e-learning programs and decision support systems. Two main pillars underpin the innovation in the region: the segmentation of the innovation process and the continuous assessment under an integral perspective.

The innovation process has been divided into phases in order to improve its effectiveness and its adherence within the organisation. The first step involved the establishment of strategic alliances to share knowledge, experience and to create business opportunities, the second phase is the validation of services under a real small environment and the latter stage is the deployment to other settings (if and only if the validation has proved the real effectiveness and the long-term sustainability of the solution) .

The Barbastro Healthcare Area SALUD-BHA played a significant role as validator of e-Health services for the whole region. The results of this work are being disseminated through different distribution channels as the collaborations with the EIP-AHA and the SIMHPS3 initiatives.

Ile de France

With 11 746 000 inhabitants, that is 19 % of the French population, the Ile-de-France is to the rank of the biggest regions at the world level. Particularly dynamic, it represents 22,6 % of the Gross domestic product French (GDP). The regional agency of health (ARS) of Ile-de-France was created on April 1st 2010. The ARS agency is in charge of the implementation of the health politic in the region. The regional agency of health is a public institution of the State, placed under the supervision of the Minister for Health. ARS agency is administered by a General Director and endowed with a supervisory board chaired by the prefect of region.

On December 3rd, 2013, Ministries of Social Affairs and health, industrial recovery and delegated ministry loaded with small and medium-sized enterprises, innovation and digital economy as well as general commissionership in the investment announced the launch of a national call for projects within the framework of the Investments of future. Joining the National Strategy of Health, the program "Territoire de soins Numériques" has the ambition of the emergence of excellent, experimental territories regarding use of the digital technology, in the service of the improvement and regarding the modernization of the system of care. A 80 million euro investment is dedicated to this program within the framework of the Investments of future to support 5 projects carried by the Regional Agencies of Health of Aquitaine, Bourgogne, Ile-de-France, Rhône-Alpes and Indian Ocean.

These projects apply to territories of 200 000 to 400 000 inhabitants and propose an innovative range of services aimed at the general public, the healthcare professionals and the patients, implying industrials in the digital sector. Taking place over the period 2014 - on 2017, this project has for main objective the contribution of new services on the following dimensions:· The organization and the performance of the health system: knowledge of the resources of the territory, the real time visibility on the availability of the resources to favour their optimization, qualification of the pressure of the demand on these resources, organization and securisation of the drug circuit;·The improvement and the fluidification of

care: in situation of mobility, remote expertise, remote consultation or monitoring, patients follow up at home; services provided to the healthcare professionals: information exchange in the perspective of coordination, appointment setting via the new technologies for example; The prevention, the information and the education of the patient: proactive initiatives of prevention, general information and advice to the patient, therapeutic education, transmission of information to the patients via the new technologies

The long term objective is to spread the range of services, deployed on these five experimental territories, to bigger set territories even national territory.

With the project TerriSanté, the Regional Agency of Health (ARS) Ile-de-France proposes conjugating the improvement of the health of the population of Big Paris and development of the digital economy. The main objective of this project is the improvement of the coordination of the routes of care, thanks to the massive deployment of digital solutions, while watching the reduction of the disparities of health.

Besides all these related initiatives, the Ile de France region has extensively cooperated in the development of European PCP tenders, mostly through the Reseau des Acheteurs Hospitaliers D'Ile de France. Some examples of this cooperation are the Happi-project,[11] the INNOCAT project[12] and the INSPIRE network.[13]

Slovenia

In Slovenia eHealth programme started in 2009 and has been supported by the EU through structural funds. It is focused on institutional health care system for more efficient work of health professionals. Two structural projects have been started: national Health Network (zNET) to connect all healthcare institutions on the national level and some application projects as e.g. ePrescription, eDischarge letter, eReferral, teleradiology and telestroke. None of the projects has been completed and solutions being developed have been tested and implemented only at some institutions. No service aiming at improving patient's self-management as home telemedicine services is planned to be developed under the eHealth programme 2009-2013 although in integrated home care project had been a part of the action plan. The Ministry of Health has started to prepare a national resolution on health but not yet the eHealth strategy 2020. A civil society organisation The Slovenian Medical Informatics Association prepared in 2012 a foundation document for a national strategy on telehealth services that was passed to the MoH as a support of professionals in preparation of the national strategy on telehealth.

As a result of the absence of strategies and related action plans activities in the area of telehealth, Slovenia lacks of concerted action on the national level to develop these types of services. Some national pilot projects in the past extinguish proving only feasibility of technological solutions. The only project (still ongoing until the end of 2015) is an EU project "United4Health" with the SB-SG as the partner that has already resulted in a side product – the CEZAR telemedicine centre at the SB-SG offering support to DM and CHF patients. The management of the SB-SG is determined that despite unfriendly conditions develops and offer several types of telemedicine services at a regional and later at the national level.

1.2. Clarity and pertinence of the objective of the PCP – The common challenge

1.2.1. The Common Challenge

As it was stated on point 1.1.2, all Buyers have already initiated several projects targeted to more empowered patients and caregivers. Activities embrace different diseases and groups of patients providing and extensive knowledge within EMPATTICS partner. EMPATTICS Buyers considers "Empowerment" as a patient-centred, collaborative approach tailored to match the fundamental realities of disease care. Patient empowerment helps patients to discover and develop the inherent

[11] http://www.happi-project.eu/
[12] http://www.sustainable-catering.eu/home/
[13] http://inspirecampus.eu/

capacity to be responsible for one´s own life. Although health professionals are experts on disease care, patients are expert on their own lives. EMPATTICS approach recognizes that knowing about an illness is not the same as knowing about a person´s life and that, by default, patients are the primary decision-makers in control of the daily self-management of their own illness.

In the last decades there has been a growing interest on the general field of patient empowerment and particularly on self-management not only in the 5 regions that participate in the EMPATTICS project but also in many other European rehions. This growing interest is associated with assumptions that empowered individuals will (a) make more rational healthcare decisions to maximize their health and wellness (b) decrease dependence on healthcare services and (c) ultimately contribute to more cost-effective use of healthcare resources, but still substantial evidence is needed in this field(4).

Although there is still no systematic evidence of patient empowerment as a whole, it has been proven that the successful empowerment of patients in the self-management of their disease has a potential positive effect on multiple outcomes. The process of empowerment has been also associated with a perceived improvement of the relationship and interaction between patients, healthcare and social professionals and the health and social care systems as a hole.

However, despite the large number of initiatives that have been undertaken in the last decade, self-care programs are still not available for the majority of citizens and patients in Europe and most experiences so far have been isolated and not linked to policy developments covering overall population of a region/state. Currently available self-care support tools are narrow point solutions that have not succeed to overcome the socio-economic, gender and age-dependent differences in digital literacy and therefore have not been adopted as large scale solutions that will impact the health of Europeans.

The qualitative Eurobarometer of May 2012 "Patients Involvement"[14], indicate that patients with chronic diseases are both motivated and sufficiently knowledgeable to be involved in decision making and self-management (e.g. section 7.6 on self-care) and the Epposi Barometer 2013 shows that approximately 90% of consumers from 10 European countries view self-care as a vital part of the management and prevention of both chronic conditions and diseases. Still, only 20% feel very confident in managing their own health, which stresses the importance of adequate support of self-care.

Focusing on patient empowerment it is also important to support the patients' adherence and minimize non-adherence. Adherence is understood as "*the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider*[15]*".*

The distinction between adherence and compliance is that adherence requires the patient's agreement to the recommendations. Adherence is a multidimensional phenomenon determined for five factors:

1. Socioeconomic factors: age is a factor that influences reported adherence irregularly. But two major groups regarding this parameter are:
   - Adolescents: adherence is lower than in younger children. While they are capable of greater autonomy struggle with self-esteem, body image, defining social functions...
   - Elderly: aged population growth and increased prevalence of chronic diseases
2. Factors related to clinicians or the Health Care System: a good provider-patient relationship can improve adherence
3. Factors related to the disease: its repercussion depends on how the perception of risk influences in the patient, importance of follow-up treatment and the priority given to adherence.
4. Factors related to treatment: Complexity of medical regimen, duration of treatment, previous treatment failures, frequent changes of treatment, side effects and the availability of medical support to treat them.

[14] Eurobarometer Qualitative Study. Patient involvement. 2012.
[15] Adherence to long –term therapies: evidence for action. World Health Organisation 2003

5. Patient-related factors: knowledge and beliefs of the patient about their disease, to treat motivation, confidence in their ability to engage in therapeutic behaviour of the disease

The magnitude of nonadherence is estimated close to 50% in patients with chronic diseases. There is strong evidence that many patients with diabetes have difficulty to adhere. This causes ethical and psychosocial complications of disease, reduces the quality of life of patients and resources wasted health care. Overall, this diminishes the ability of worldwide health care systems to achieve the goals of population health. A simple way to classify nonadherence can be:

- Primary: this prescription fails to withdraw from the pharmacy
- Secondary: alteration of the correct dose, changing dosing intervals, eg. los in the drug intake or increased frequency of doses and suspension of treatment before the recommended time.
- Intentional: where the patient makes a conscious decision not to fill, pick up from the pharmacy, or take a medication as prescribed
- Unintentional: the result of forgetfulness and so on

Some of the key drivers for nonadherence are patient related factors such as: the patient beliefs about their provider, condition(s), medication(s), level of knowledge about their condition(s), previous health experiences, health literacy, trust, emotional state, ability to pay, and demographics and the physician related factors such as: the physicians attitudes and assumptions about patients as well as his or her patient communication skills, e.g., their ability to engage patients, elicit their illness perspectives, and involve the patient in decisions about their health care[16].

Addressing nonadherence from primary care should be:

1. Awareness of the problem by the health professional
2. Effort motivation to change the situation
3. Reasoned Prescription
4. Selection of simple, effective and rapid methods for assessing adherence
5. Detection of the defaulting patient
6. Analysis of the factors that determine the failure through structured interview
7. Implementation of strategies directed to the patient or caregiver

It is expected that implementing ICT technologies to support patient empowerment will influence both factors that improve adherence as well as factors that reduce the risk of nonadherence. Furthermore, it has been observed that the most effective approaches are multiple levels, focusing on more than one factor with more than one input.

An intervention that encompasses multiple levels would be one that has as its objectives:

- Awareness and knowledge about adherence
- Tools to support adherence
- Information for self-care
- Tool to help patients develop healthy adaptive behaviors to change the problematic ones
- Better communication between patients and health professionals

Through this PCP the EMPATTICS partners will achieve new service innovations that will allow increased co-creation and co-operation between health, social care and patients/families that will increase the patient's adoption and adherence using ICT self-care technologies and enhance professionals in the use of decision support systems. All relevant data obtained with the different solutions will be collected in electronic medical records.

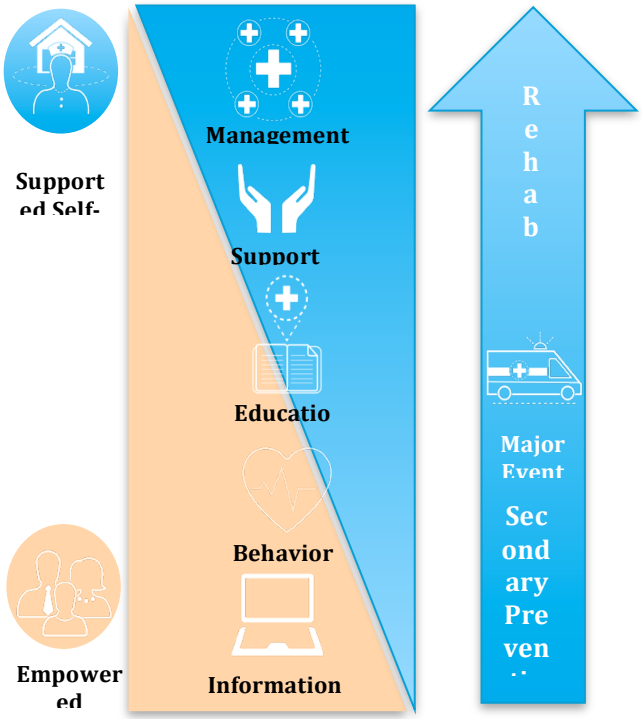
[16] Wilkins, S.; "The key to better medication adherence is better physician-patient communication"; Mind the Gap Academy Publishing; 2014

What is the common challenge?

To enhance self-management for people with chronic illnesses through innovative ICT tools and test them at a large scale and integrated as part of the strategic development of health policies in **all buyer regions**. The goal is a system that will be broadly applicable to a variety of disease types.

Health management will be addressed holistically, including healthy lifestyles and prevention as well as disease management, leading to better experience and outcomes alongside more effective and efficient use of services. The project will identify specific gaps to be addresses in the regions. For each one we will seek innovative personalised health technologies to demonstrate applicability of our approach to different target populations.

We will collectively achieve this by investing-to-save in self-management as well as to scope the behavioural, social and professional barriers that currently block their adoption. Overall the tendering process will consider interventions at all levels:



Citizens/patients giving them the opportunity to act as co-managers and equipping them to do so by, stimulating treatment adherence, enhance health literacy, providing information and supporting their skills for self-determination and behaviour change.

Healthcare professionals raising their awareness of how to support health literacy and self-determination through training and tools for supporting collaborative shared decision making with people living with a chronic condition eg. diabetes across all stages of their condition.

Health systems introducing coordination and follow up through ICT mediated Health systems introducing coordination and follow up through ICT mediated mechanisms

Social systems, by specifically targeting the demographic and socioeconomic barriers to the optimal treatment of chronic disease.

This is a multi-faceted challenge for which we will seek innovative ICT tools that enable new self-care models to support people with selected conditions. All ICT solutions should address access barriers and health behaviours associated with ICT tools, particularly age related barriers, gender inequities and socioeconomic barriers.

The solution designed will be a universal platform with fully customizable services belonging to either preventive, therapeutic, rehabilitation or palliative care. Plattform will include horizontal integration tools interoperable, based on DSS and taking into account clinical safety so as to enhance the organisations involved with quality, efficient and effective services.

What impact will solving this Common Challenge have on advancing the health care needs on the provider (demand) side?

Through this PCP we will achieve new service innovations which will allow for increased co-creation and co-operation between health, social care and patients/families. This will increase the adoption and adherence to disease management recommendations through ICT self-care

- *At patients' level* the most direct outcomes would be: 1) increased participation of patients (and their carers) in their care; 2) increased of the health literacy and perceived self-efficacy; 3) increased adherence to the management their condition; 4) improved quality of life, 5) improved functional level and 6) improved disease progression (reducing the appearance and severity of episodes and complications)
- *At professionals' level the most direct outcomes would be: 1) increased skills to engage patients in shared decision-making. And 2) increase the confidence in incorporating ICT self-management support systems in their daily work*
- *At system level*, the empowerment of people with chronic diseases to improve the use of health services (reducing ER visits, maximizing the professionals time…), and overall facilitate a cost-effective management of the health system. At societal level, targeting the most relevant barriers to the optimal management of diabetes can help reduce the health inequities of the participating regions.

Ultimately the piloting of the ICT solutions that will result from the tendering process are expected to provide the evidence for healthcare managers to adopt the innovative solutions to their healthcare and social systems.

By this collective and innovation procurement to overcome our Common Challenge, we will increase the participation of citizens in their care process, and we will prove the impact of better management of co-morbidities, on the quality of lives of patients and the delivery costs of care, to the target groups and we will develop a common learning process that could be extrapolated to other regions in Europe.

Why Chronic Disease?

Europe has the highest burden of chronic diseases which are responsible for 86% of all deaths[17] and result in premature morbidity and loss of healthy life years. In fact, WHO considers the rise in chronic diseases an epidemic and estimates that this epidemic will claim the lives of 52 million people in the European Region by 2030[18] which calls for adequate prevention and sustainable disease management.

Also it is widely acknowledged that 70% to 80% of healthcare costs in Europe are spent on the management of chronic diseases. This corresponds to €700 billion in the EU Member states budget and this number is expected to increase in the coming years[19]. This represents a major challenge for health systems across Europe and it also impacts on the wider social system and Member States economies.

Scalable Solutions – Tested on a minimum of two diseases ideally at least 3

Within the area of chronic diseases the involved regions agree that this proposal would use diabetes (type 1 and 2) as one of the test disease types, the other type of disease has not yet been decided. This focus has been selected due to the relevance of this disease both in the specific regions and across al Europe. Currently there are about 60 million people with diabetes in the European Region, which represents about 10.3% of men and 9.6% of women aged 25 years and over[20]. The prevalence is even estimated to increase by a 22.4% in Europe by the year 2035[21].

Not only is diabetes relevant due to its prevalence, one should also take into account its high impact on the lives of those affected. The WHO estimates that that 50% of people with diabetes die of

[17] Global Status Report on Noncommunicable Diseases (2010) Geneva: World Health Organisation. http://www.who.int/chp/ncd_global_status_report/en/

[18] United Nations General Assembly 19 May 2011 Report by Secretary-General on the prevention and control of non-communicable diseases (A/66/83)

[19] United Nations General Assembly 19 May 2011 Report by Secretary-General on the prevention and control of non-communicable diseases (A/66/83)

[20] http://www.euro.who.int/en/health-topics/noncommunicable-diseases/diabetes/data-and-statistics

[21] International Diabetes Federations; IDF Diabetes Atlas, 6th edition http://www.idf.org/sites/default/files/EN_6E_Atlas_Full_0.pdf

cardiovascular disease (primarily heart disease and stroke), and 10-20% of people with diabetes die of kidney failure. So, the overall risk of dying among people with diabetes is at least double the risk of their peers without diabetes[22].

In addition 50% of people with diabetes suffer diabetic neuropathy and after 15 years of diabetes, approximately 2% of people become blind, and about 10% develop severe visual impairment[23].

Furthermore diabetes is particularly relevant to the self-management focus because as the WHO highlights, studies of the diabetes epidemic suggest that modifiable risk factors explain about 80% of the increase in prevalence[24] of type 2 diabetes, the most common type of diabetes.

Finally, diabetes is also particularly relevant to the challenge due to the important role of socioeconomic factors in explaining its prevalence. The WHO highlights that socioeconomic disadvantage contributes to the development of diabetes and its complications through inequitable access to quality treatment and environmental conditions that promote unhealthy choices[25].

High rates of diabetes are found among the lower-income groups in many middle- and high-income countries. For example, morbidity from diabetes complications is three and a half times higher among the poorest people in the United Kingdom than the richest[26]. When explaining those differences the WHO insists that it can't be solely attributed to individual choices in terms of lack of exercise or unhealthy food. Far from this, the WHO insists that policy has a crucial role in promoting an environment that makes healthier choices easier[27].

So, to sum up, diabetes is particularly relevant to the challenge posed by Horizon 2020 due to its:

- High prevalence
- High impact in the lives of those affected
- Modifiable risk factors
- Inequities to prevent and treat it

Enhancing the importance of diabetes prevention and treatment with innovative solutions in the agendas of the participant regions, can lead to a significant and meaningful change in all of the highlighted areas: reduce prevalence (tackling the modifiable risk factors), reduce the impact on the lives of those affected and reduce the inequities in the prevention and treatment of the disease.

Specifically addressing diabetes there is conclusive evidence that several types of educational interventions have had multiple positive outcomes. For example in a series of systematic reviews Steinsbeck et al.[28]; Klein et al.[29] analysed different types of educational interventions and all found at least positive results in clinical outcomes. There is also promising evidence on the use of ICT technologies to enhance self-management of diabetes (see for example Poolsup et al.[30]; Liang et al.[31]).

[22] http://www.euro.who.int/en/health-topics/noncommunicable-diseases/diabetes/data-and-statistics

[23] http://www.euro.who.int/en/health-topics/noncommunicable-diseases/diabetes/data-and-statistics
[24] http://www.euro.who.int/en/health-topics/noncommunicable-diseases/diabetes/data-and-statistics
[25] idem
[26] idem
[27] idem
[28] Steinsbekk A, Rygg LØ, Lisulo M, Rise MB, Fretheim A. Group based diabetes self-management education compared to routine treatment for people with type 2 diabetes mellitus. A systematic review with meta-analysis. BMC Health Serv Res. 2012
[29] Klein HA, Jackson SM, Street K, Whitacre JC, Klein G. Diabetes self-management education: miles to go. Nurs Res Pract. 2013
[30]Poolsup N, Suksomboon N, Kyaw AM. Systematic review and meta-analysis of the effectiveness of continuous glucose monitoring (CGM) on glucose control in diabetes. Diabetol Metab Syndr. Diabetology & Metabolic Syndrome; 2013
[31] Liang X, Wang Q, Yang X, Cao J, Chen J, Mo X, et al. Effect of mobile phone intervention for diabetes on glycaemic control: a meta-analysis. Diabet Med. 2011

The WHO has been done the same studies for other chronic diseases, such as stroke, COPD (Chronic Obstructive Pulmonary disease), Coronary Artery Disease, Hypertension, Dementia and Depression. The developed solution will have to scope all of them. In the first phase of the project the buyers who are involved in the project would discuss in which chronic diseases they test the solution. As we are mentioned before, the developed solution will have cope with the different levels of development of EMRs and EHRs that exist in Europe today and add value as efficient and intuitive tools for both patients and clinicians. Finally the developed ICT solutions must be connected to social networks and they must include innovative technologies and gaming attitudes to engage patients and clinicians.

Why tackle chronic disease through patient empowerment and self-management?

The UK Department of Health defines self-management as: "*The actions individuals and careers take for themselves, their children, their families and others to stay fit and maintain good physical and mental health; meet social and psychological needs; prevent illness or accidents; care for minor ailments and long term conditions; and maintain health and wellbeing after an acute illness or discharge from hospital"*[32].

As this definition implies, self-management is associated with a transition from strict professional care to new combinations including self-care and informal care and enhancing health care integration supported by the use of innovative technology.

Specifically addressing diabetes there is conclusive evidence that several types of educational interventions have had multiple positive outcomes. For example in a series of systematic reviews Steinsbeck et al.[33]; Klein et al.[34] analysed different types of educational interventions and all found at least positive results in clinical outcomes. There is also promising evidence on the use of ICT technologies to enhance self-management of diabetes (see for example Poolsup et al.[35]; Liang et al.[36])

However, even for the educational interventions and the ICT-supported self-management interventions there is remarkably less contextualized information (what were the barriers of adoption of ICT technologies? What strategies are most effective to implement a self-management program outside the clinical trial context?, etc.)

The large scale scope of this project will identify the most relevant barriers to self-management in the context of 4 European regions and target them with innovative ICT solutions. This process will be part of the strategic development of the participant regions, therefore overcoming the main limitation to the evidence on self-management interventions so far: the siloed experiences. With a more ambitious and systemic approach the 5 regions will advance the well-being of their citizens by taking advantage of the most innovative ICT solutions and from learning from each other's experiences.

Even more, the experience with this large-scale demonstrations will provide evidence on the best ICT solutions for self-management and implementation processes that will be valuable across all Europe.

1.2.2. The Common Challenge: Meeting a concrete need

EMPATTICS consortium involves public health authorities and hospitals with highly diverse level of innovation on the deployment of patient centred solutions. Since 2011, SERGAS, the healthcare service provider of the Consellería de Sanidade, has invested more than 30 million Euros in different PPI projects

[32] Department of Health (2005). *Self care – a real choice*. London: Department of Health

[33] Steinsbekk A, Rygg LØ, Lisulo M, Rise MB, Fretheim A. Group based diabetes self-management education compared to routine treatment for people with type 2 diabetes mellitus. A systematic review with meta-analysis. BMC Health Serv Res. 2012

[34] Klein HA, Jackson SM, Street K, Whitacre JC, Klein G. Diabetes self-management education: miles to go. Nurs Res Pract. 2013

[35] Poolsup N, Suksomboon N, Kyaw AM. Systematic review and meta-analysis of the effectiveness of continuous glucose monitoring (CGM) on glucose control in diabetes. Diabetol Metab Syndr. Diabetology & Metabolic Syndrome; 2013

[36] Liang X, Wang Q, Yang X, Cao J, Chen J, Mo X, et al. Effect of mobile phone intervention for diabetes on glycaemic control: a meta-analysis. Diabet Med. 2011

aiming to transform current relationship and care models between providers, professionals and patient and the creation of **a safe, fast and intelligent patient-centred healthcare system.**[37] Other organisations like GCS D-SISIF, SALUD_Aragon, Slovenia or the Region of Central Denmark have developed interesting ideas in this regard. Some examples from these regions/organisations about their experience in patient empowerment are therefore presented.

Galicia

Several activities have been implemented in Galicia to promote Patint Empowerment. Initiatives could be classified as non-technological and technological related activities.

Regarding the former group, the Consellería de Sanidade created in n 2009 the **Galician School of Health for Citizens** project was initiated. It has a comprehensive communication web, updated, attractive and easy to maintain. The school seeks to promote the exchange of knowledge between citizens and health professionals and increase visibility and improve access to courses organized by the school. The main objectives are:

- to provide knowledge and skills about caring to carers, patients and families
- to exchange and share experiences and expertise in health and disease processes to generate guides for patients with the same process
- to inform and educate patients associations as a means for help and self-help and for its members

Later in 2011, it has also created a **Patients´ Advisory Council**, whose aim is to advance the improvement of safety for patients, family and caregivers, acting as a structure that serves to increase the quality of health services, encouraging levels of participation and providing patients with the necessary information for decision-making and anything else of interest.

Regarding the group of technological initiatives deployed for patient empowerment, we highlight the Innovation plan InnovaSaude (€45 Million). **InnovaSaude** plan is composed of 14 different subprojects aiming a safe, fast and intelligent patient-centred healthcare system. More specifically the list of the innovasaude plan are: Mobile diagnostic-therapeutic healthcare points, Medical imaging centre, Hospital at home, Multi-speciality teleconsultation products, Digital (care) home assistance, Patient expert 2.0., Smart multilevel alert system, Advanced medical simulation centre, Computer-aided diagnosis systems, Professional 3.0, Innovation space for healthcare services, Integrated information and management system for clinical end epidemiological data for research, Transfer of the results of research and innovative healthcare projects and the Integrated system for digitalisation, indexation, storage and management of clinical information

Central Denmark Region

In the period 2013-2017 The Healthcare Plan in Central Denmark Region is focusing on the delivery of healthcare in three parallel tracks of which one of the tracks; "On the patients' terms" is overriding the entire plan. Only by acknowledging the patient as an active partner who is allowed and enabled to participate in his/her own treatment can we expect to achieve the best quality in healthcare. Some of the initiatives following The Healthcare plan are mentioned below.

- Central Denmark Region is conducting a large scale implementation of patient-reported outcome (PRO) via TelePRO[38]. In a recent comprehensive review of randomized trials, it was concluded that PRO used for consultation support provides patient-centered care, ensuring that

[37] Guidebook Series: How to support SME Policy from Structural Funds. Public Procurement as a Driver of Innovation in SMEs and Public Services. ISBN 978-92-79-40344-6, ISSN 1977-6683, DOI 10.2769/3747, © European Union, 2014. URL: http://ec.europa.eu/enterprise/policies/innovation/policy/public-procurement/index_en.htm

[38] TelePRO is a PRO assessment to evaluate the need for a hospital visit. The PRO data is obtained while the patient is still at home via either a paper- or a webbased survey, that is fully integrated into the EHR.

patient-reported symptoms guides the clinical decisions, and it has been found that PRO and clinical judgments produce complementary data, which, when combined, provide a more accurate description of the patients' symptoms[39]. TelePRO is implemented across the hospitals in the region to all patients within three diagnoses and will be expanded to eight diagnoses within the next three years.

- The project Clinically Integrated Home Monitoring sets out to test home monitoring on a wide range of patient categories in a large-scale setting. By home monitoring patients with COPD, diabetes and complicated pregnancies e.g. pre-eclampsia we have reduced the number of hospitalizations and ambulant treatments, encouraged patients to master their own health and patient have felt empowered. The project is a co-operation between Central Denmark Region and The Capitol Region of Denmark.

- Region Aarhus University and Aarhus University Hospital conducts "The Aarhus research programme in patient involvement". The international literature, the Danish Health and Medicines Authority, the Danish Regions and the Danish Institute for Health Services Research have clearly outlined the need for more knowledge and a better understanding of programmes that will strengthen the involvement of patients and their relatives in the diagnostics, treatment, care and rehabilitation and improve the patients' safety, well-being and self-care in daily life. The reasons are demographic (aging population and multi-morbidity), democratic (patient rights), medical (increasing treatment possibilities; patient involvement improves treatment outcomes) and socioeconomic (lack of health care professionals and economic resources).

  Many challenges remain in providing a health service that systematically, reliably and demonstrably provides patient-centred care. If the experience of patients who take care of themselves is to be improved, they must be recognised as active co-producers of their own health and supported to develop the knowledge and skills needed to become confident self-managers of their conditions.

  The aim of the research programme is to produce research-based, applicable knowledge on patient attributes (motivation, opportunity and ability to involvement in treatment and care); provider behaviour (attitude towards and interaction with patients and relatives); and health system (cultural and organisational capacity and suitability).

  The research programme in patient involvement addresses the patients' learning, influence and autonomy. It is established to improve the recognition of facilitators and barriers to different types of patient involvement as a measure for optimising care and treatment across sectors, populations and medical conditions.

Aragón

Aragón concern for chronic attention has been visible through several initiatives like the "Information Systems and Telemedicine Plan" of Aragon's Government, the "Strategic Plan for Aragon Social Services 2012_2015", the "Aragon Social Law", and "the Strategy of Attention to chronics" among others.

From the practical point of view, several initiatives have been developed in the SALUD as services and at the SALUD-BHA as projects (after successful validation deployed into services) , and there is a clear need to integrate the successful initiatives under a common umbrella that provides a unique access point to the citizen suffering from chronic pathologies :

- The e-Prescription tool, that includes all the prescription process for the Aragón citizens, including prescription from the clinicians, delivery from the pharmacy, logistics from the pharmaceutical college and user interaction

[39] Hjollund NHI, Larsen LP, Biering K, Johnsen SP, Riiskjær E, Schougaard LM; Use of Patient-Reported Outcome (PRO) Measures at Group and Patient Levels: Experiences From the Generic Integrated PRO System, WestChronic Interact J Med Res 2014;3(1):e5

- The access to EHR that is now possible thanks to the HCDSNS initiative (Electronic Health Record from the National Healthcare System) and which was tested at the SUSTAINS project
- The clinical and administrative services asessed at the SUSTAINS project.
- Two websites including regional care services: The SALUD INFORMA website for healthcare and the SOCIAL INFORMA website for socialcare. The SALUD INFORMA website includes also a set of services under the « Citizen Folder »
- The telemonotoring platform which are already integrated with the EHR.
- The Integrated Care platform which is being developed at the SMARTCARE project.
- Training programmes and information focused on chronic attention and healthy lifestyle

The challenge is to enhance all these services and integrate horizontally to improve their quality, efficiency and effectiveness.

Ile de France

Even though there are several initiatives to foster patient Empowerment in the Ile De France Region, the TerriSanté outstands in terms of funding and expected impact on the population. The challenge is to develop a platform of exchange and integrated services aimed at the healthcare professionals and at the population. One of the major stakes of the TerriSanté project will involve the management of expectations of the users and the healthcare professionals. Other Key aspects include:

- Improve the information in health of the population;
- Increase the educational offer in the health and educational therapeutic through the e-learning and the serious games(sets)
- Favour the prevention and optimize the actions;
- Improve the orientation of the users within the sanitary and medical and social offer;
- Organize readable fitness trails and favour the observance of treatments;
- Favour the return in the autonomy and the preservation at home.
- Allow the professionals to reach a shared information;
- Allow the professionals to be actors of prevention campaigns;
- Foster collaborative practices and the coordination of multi-professional actors within the framework of complex fitness trails;
- Simplify the administrative tasks, to the advantage of the time spent with the patient;
- Increase the offer of training(formation) through the e-learning and the serious games(sets);
- Organize and structure the management of data large-scale patients, being able to contribute to the research, to the health monitoring and the public health.

The implementation of such a shared information system involves an evolution of the cultures and requires a reflection on organizations and support of the change. To answer these stakes, the project rest on the implementation of a toolkit of interoperability and exchanges, agile, the real technological base of the project, allowing the sharing of information collected within the territory from the working tool of the professional and the Web portal for the patient. This toolkit must be opened towards the outside and allow to integrate into "plug and play" mode of the services developed within the territory, which the patient and the professional must be able to reach, by respecting their uses and the tools of their jobs. To this end, the toolkit will lean on a set of common reference tables (Id patients, directory of the PS, etc.) and a universe of interoperability allowing the provision of "normalized" connectors every time to make can assuring this integration of the various services interacting directly with the platform. The interoperability will be also assured in the absence of "normalized" connectors.

Concerning the innovative services, an experiment of collection of information from devices and from communicating objects and from systems of analysis allowing the remote follow-up of the patient will be led for example with tools of remote surveillance or of serious games for purposes of therapeutic

education. These technologies will be experimented on restricted perimeters (chronic patients) to make sure of their relevance and their feasibility.

This toolkit as well as the services will have to integrate the advanced technologies, in particular as regards the user interface and allow, for example, the use of Smartphones or mobile terminals. The toolkit will have to cover a broad spectrum of services of the field of the well-being and the primary prevention up to the field of the coverage of the complex routes including the support at home for the users and the caregivers there.

Slovenia

SB-SG has been a telemedicine service provider for diabetic patients (DM) and patients with congestive heart failure (CHF) for over one year. As already presented in the chapter on the state-of-the-art at the demand side (1.1.2) the SB-SG is, encourage by the positive experience with DM and CHF telemedicine service provision, determined to introduce new services to enable self-management to patients at home living with other chronic conditions e.g. obesity, heart or kidney transplantation, haemophilia and others. There is an immediate need to develop and introduce pre and postoperative monitoring of patients with obesity following gastric band installation in a bariatric surgery. Further on pre and postoperative monitoring of patients passing heart or kidney transplantation. The services would increase number of patients gaining intensive support from health professionals at a distance. From the CEZAR telemedicine centre perspective it would extend the offer of the centre. As the centre has ambitious to operate national wide it is the SB-SG interest to add new services and to cover needs of other institutions (e.g. the University Clinical Centre Ljubljana).

Health professionals at the Internal Clinic of SB-SG hospital have been challenged for years by high blood pressure patients reporting so called “white colour syndrome”. Such patients claim to have too high blood pressure measurement values if the measurement is done in a healthcare institution. This could be true, but some patients just want to hinder their non-adherence to their doctor’s recommendation for healthier living style. Introducing telemetric measurements of blood pressure at home e.g. for a months would discover the mystery of the “white colour syndrome”. For CEZAR centre providing blood pressure monitoring is a daily routine, but a programme has to be formed with the telemedicine monitoring embedded that would become a clinically proven service.

There is an additional internal reason for SB-SG to broaden its spectrum of services. The hospital tends to promote their most successful and renown departments nationally and internationally to attract patients from other regions and countries. A part of the promotion strategy there is also getting a European accreditation for the Centre for obesity at SB-SG. There is a trend in European healthcare sector that specialist departments seek an international nomination for “Centre of excellence” through accreditation. One of the conditions for gaining that nomination is a permanent and regular follow-up of patients treated by the candidate centre (70% coverage requested). Tele monitoring of gastric patients using telemedicine services is an ideal means of fulfilling the requisite. SB-SG is determined to seek accreditation for the Centre for obesity, so introduction of the telemedicine service for those patients is a strong need.

As it was demonstrated before, all partners have substantial experience in the implementation of patient empowerment policies and technologies. Through EMPATTICS, partners look for a global scale solution adapatable at patients and clinicians needs , with a high level of interoperability with existing EMR systems, with smart algorythms to detect and alert end users (aptients and clinicians) about the evolution of their disease, treatment (especially adherence) and lifestyles. Solutions should be also compatible with powerful social networks. Following the principles of PCP methodology, Buyers don’t want to commit the error of describing excessively the technical aspects of the expected solutions. Buyers expects state-of-the art plattforms compatible with various diseases and adaptable to pluri-patological patients

1.3. Progress beyond state of the art

1.3.1. State of the art: Demand side

During the preparation of this proposal EMPATTICS buyers sufficiently discussed about actual and future needs in relation with patient empowerment solutions. In these discussions, the input and experience of European Health Futures Forum (EHFF) was also very valuable. As a not-for-profit independent organisation created to improve the health of European citizens, the EHFF worked on several projects and initiatives through an open, interactive and inclusive approach, engaging citizens by employing methods, techniques & expertise in thinking, debating and shaping the future of health in Europe. EHFF bring to the discussion its experience on present and future patient's needs, enriching buyer's unmet needs deliberations and the definition of the EMPATTICS challenge of the PCP contract.

EMPATTICS debates also involved the different level of development regarding current Electronic Medical Record systems. Buyers participating in EMPATTICS show different levels of EMRs. On the one hand, we have regions like Galicia, which has achieved massive deployment of its EMR system. Consellería de Sanidade EMR systems is now used in 100% of total interventions between patients and clinicians with more than 20,000 healthcare professionals using EMR system and more than 1,300 Galician pharmacies providing thousands of e-prescriptions to patients daily.

The same kind of deployment you will find in Central Denmark Region which has a 100% implemented EHR at the hospital level but the records at the municipality and GP level are different and not integrated at all. The Shared Medication Record is a national service that enables health care providers and patients to see the patients' complete and current medication information at the point of care. The Shared Medication Record is in operation and is fully implemented at all hospitals, municipalities and general practitioners in 2014. Even though the HER and The Shared Medication Record are fully implemented in Denmark, there exists no decision on how to integrate home monitoring into the EHR's.

In the other hand, other EMPATTICS Buyers have achieved less deployment of its EMR systems making to be completed with inputs from other organisations. In Aragón patient's clinical information is accessible for both primary care professionals and specialists from the whole region through the same tool: the HCE. SaALUD-Aragon also uses e-prescription services to facilitate the delivery of the services around the region. Aragón is also deeply involved in the project HCDSNS (Electronic Health Record from the National Health System) which allows the patient access to the personal clinical information.

In Ile de France patient's clinical information concerning coordination of care should be accessible for a first territory in 2016 for both primary care professionals and specialists through a TerriSanté EHR. Besides this application, other applications as the e-prescription should facilitate the delivery of the services around the region. Ile de France is also deeply involved in project concerning syntaxes and semantic interoperability which allows the access to shared clinical information.

The eHealth information system in Slovenia has been in its developing phase since 2009. Its core components are: zNET healthcare communication network, electronic health records (EHR) and a national healthcare portal (zVEM). The purpose of zNET and zVEM is to establish a national infrastructure, which will support patient treatment on a national level and ensure secure data exchange among several different existent information systems of health care providers. zVEM will serve as a central point for cooperation, where different users will access, communicate and use eHealth informational solutions in a secure and traceable way. The eHealth project anticipates gradual development and implementation of the different eHealth solutions within zVEM framework. Currently, both telemedicine services provided by CEZAR are within the SB-SG hospital secure information environment and will be integrated into zNET and zVEM when the national network is fully established and is operational.

Current differences on the development of EMR and EHR systems across EMPATTICS buyers emphasize the need of Patient empowerment solutions platforms with capacity to act at European scale.

Companies participating in EMPATTICS PCP will therefore be forced to provide technical solutions and services adaptable to different EMRs and EHR's development levels represented in the EMPATTICS consortium. This means that international ICT standards must be used. Also in order to increase the sales potential to other relevant buyers not included in EMPATTICS consortium.

Another key feature of the proposed technology aims the inclusion of social networks promoting the interaction of patients within the community. The e-community should include functionalities to promote the participation of clinicians, nurses and clinical staff of healthcare providers.

1.3.2. State of the art: Supply side

At the beginning of the project the EMPATTICS consortium will work on a more detailed analysis of existing technologies, potential developers, and current EMRs state-of the art of EMPATTICS buyers. Among other things, the consortium will describe the state-of-the art and scope of the existing IT solutions to identify limitations to cover regional needs of the Buyers and to ensure that the PCP process creates truly innovative technologies that meet the needs of the enterie Buyers Group. Tasks will include the combination of various types of analysis and the engagement of different stakeholders like clinicians, IT developers, Innovation managers, Pharmacists and of course patients.

First conclusions of EMPATTICS consortium resolved that we must seek a solution that should act as a platform that will: 1) increase the awareness and knowledge about **treatment adherence**, 2) provide valuable information for **self-care management** of patient diseases, 3) help patients to develop **healthy adaptive behaviours** to change the problematic ones and 4) facilitate the **communication between patients and health professionals**

	Expected Costs	**Expected benefits**
Phase 1	€25.000 per company. Costs estimated for travelling and consulting working hours. Cost estimated based on previous PCP contracts developed in Europe and particularly considering the experience of the Consellería de Sanidade and its healthcare service provier, SERGAS, in PCP contract.	Feasibility studies proposed by firms. Companies will gather a good understanding health system and patients' needs that is essential for the appropriate development of the project. It will also provide a new vision of current e-health market. Phase 1 output includes a feasibility study that includes a technology description, a first solution design, an organisational plan for Phase 2 and a costs/benefit evaluation of the proposed solution.
Phase 2	€330,000. Cost estimated for the salary of 3-5 engineers, consulting services, travelling and internal development costs (hardware and software). Cost calculated over the 31 PPI tenders published by Consellería de Sanidade and SERGAS since 2011, and hours of R&D of a team of experienced IT engineers	It aims the verification of the main features exhibited by a technology prototype. At the end of Phase 2, 5 companies will have a prototype with potential to be commercialized after appropriate certification. The output of phase 2 will guarantee absence of monopolistic positions in this business. Phase 2 expected outcomes includes a prototype specification and demonstration, as well as a plan for limited first product development and testing and an updated cost/benefit evaluation in Phase 3
Phase 3	€533,333 Cost estimated for validation tests with a cohort of 100-200 patients dispersed across Europe. Costs includes hour of clinical trial management, taxes and insurance for clinical trials. Costs don't include other Buyers contribution to EMPATTICS (hour of clinicians, data managers, for clinical trials, etc)	Verification and comparison of technology performance in real scenarios. The project will end here providing information about the efficiency of each technology in the different test sites, including a comparison of the impact of the technologies in a variety of European regions.

The new platform will be tested in some diseases during the development of EMPATTICS but it should have to be open to other "disease modules" adaptable to other chronic illnesses like stroke, COPD (Chronic Obstructive Pulmonary disease), Coronary Artery Disease, Hypertension, Dementia, Depression, etc. The developed solution will have to cope with the different levels of development of EMRs and EHRs that exist in Europe today and add value as efficient and intuitive tools for both patients and clinicians. Finally the developed ICT solutions must be connected to social networks and they must include innovative technologies and gaming attitudes to engage patients and clinicians.

All technologies must be tailored to particular illness related demands experienced by the patient. To accomplish this, participating companies need to develop the means of accurately assessing all factors that influence the management t of the disease (adherence to treatment, diet, physical activity, etc). It is also highly recommendable to include systems that promote patient disease monitoring by health systems (nurses, healthcare professionals, pharmacists). There are proven studies about a higher efficiency of patient empowerment technologies when patients are also monitored by health professionals.

It is the belief of the consortium that creation of new and relevant solutions to real everyday challenges grows out of a challenge based dialogue and call rather than through a narrow technical specification that hardly relates with the complexity of the challenge. Rather than time consuming detailed specifications this PCP will engage in asking the right innovation questions. The consortium prioritise to invest time in the framing of the problem and user needs before specifications of technical requirements and to qualify the challenge and the derived solution in a joint public- private exploration of new solutions with a generic and commercial potential. EMPATTICS will involve other partners than 'the usual suspects' we already know pretty well. Hopefully this approach will demonstrate that there can be defined a variety of relevant and useful solutions to the common challenge.

1.4. Credibility of the proposed approach

1.4.1. Overall Approach

EMPATTICS project has sought to take a deliberate and logical approach to addressing the Buyers' common challenge, the division of work into distinct but interrelated work packages, and the overall management of these activities.

The project is divided into the following Work Packages, with the associated high-level objectives:

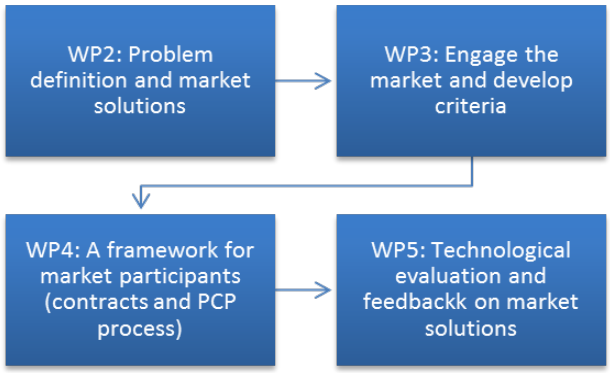
- **WP1: Project Management, Financial Coordination and Quality Assurance**: To ensure proper management of the overall project in a manner that is accountable, reliable and responsible to the Buyers and the EU
- **WP2: Reviewing evidence base and supply-side status and identifying buyer needs**: To scope the existing market to ensure that the PCP process creates state-of-the-art technology that meets the needs of the Buyers Group
- **WP3: PCP training and Industry dialogues**: To engage with market participants to develop in an open and effective manner with industry solutions that will address the buyers' needs
- **WP4: Contract Implementation**: To ensure the development of new technologies to address the self-care Functional Specification through appropriate contract management and oversight
- **WP5: PCP test sites and Technology validation** To ensure activities of the companies who apply and win a contract as part of the PCP call are delivery technologically sound and innovative solutions to the buyers
- **WP6: Communication, exploitation and dissemination of the results:** To create, evaluate and disseminate the knowledge generated in this project

Each WP package will have a designated lead that will coordinate and manage those activities. WP1 will operate across the entire initiative to ensure appropriate project management and aid the Work Package Leads and Buyers Group members to deliver an innovative PCP process. WP1 will also then ensure that that EU regulations and reporting are conducted appropriately throughout the project.

Each WP leader is responsible the activities, deliverables and milestones within their WP. The list below demonstrates the primary tasks from each WP, each designed to ensure that the project is delivering a strong PCP process that delivers innovation for the Buyers Group:

WP1 Project Management, Financial Coordination and Quality Assurance	•Task 1.1: Consortium Management/Project Office •Task 1.2 Financial and administrative co-ordination •Task 1.3 Quality Assurance, risk management analysis and evaluation methodology
WP2 Reviewing evidence base and supply-side status and identifying buyer needs	**•Task 2.1. Operationalization of the common challenge** **•Task 2.2 Review of evidence and existing EU projects** **•Task 2.3 Analysis of joint health and care needs** **•Task 2.4 Identification of initial key areas of interest** **•Task 2.5 Market scope** **•Task 2.6 Gap Analysis** **•Task 2.7 Final Report**
WP3 PCP Training and Industry Dialogues	•Task 3.1: Mapping of potential ICT companies and developers &creative companies •Task 3.2: Production of information material •Task 3.3: Establishing of a Linked-in group for interested companies and procurers •Task 3.4: Marketing of the information directly to potential tenderers •Task 3.5: Webinars about basic PCP and PPI •Task 3.6: Seminars, workshops and personal meetings •Task 3.7: Facilitation of new consortiums/collaborations and matchmaking amongst interested companies •Task 3.8: Innovation conferences and hackathons •Task 3.9: Modification of tender specifications accordingly to input
WP4 Contract Implementation	**•Task 4.1: Publication of an Open Call for expression of interest** **•Task 4.2: PCP design phase** **•Task 4.3: PCP Planning and set-up of the framework** **•Task 4.4: Publication of the PCP Contract and related dissemination activities** **•Task 4.5: Evaluation of proposals** **•Task 4.6: Administration of the contracts**
WP5 PCP test sites and Technology validation	•Task 5.1 Phase 3-test sites and technology Monitoring Preparatory stage •Task 5.2 Definition studies for evaluation of Clinial effectiveness •Task 5.3 Definition studies for evaluation of Patient and Clinician perspectives •Task 5.4 Definition studies for evaluation of Economic Aspects •Task 5.5 Training companies on MAST methodology •Task 5.6Test sites validation and monitoring reports
WP6 Communication, exploitation and dissemination of results	•Task 6.1 Dissemination, exploitation and communication strategies •Task 6.2 Digital, Social Media and Web Strategy •Task 6.3 Stakeholder analysis and management •Task 6.4 Marketing Material and Publications •Task 6.5 Meetings and Conferences •Task 6.6 Dissemination reporting

The PCP method will aim to engage the market participants directly to foster innovative approaches to meeting the needs of the Buyers Group. EMPATTICS as part of each PCP Phase, there will be an evaluation and assessment of the outcomes of the tender process and the outputs resulting from the tender.



While WP1 and WP6 are horizontal in natures to ensure the management of the project, and the dissemination of the results, the approach taken is that the others will operate in a complementary fashion to ensure the execution of the PCP process. Below is a general flow of activity, with each sub task in work packages interacting to deliver the outcome for the Buyers Group.

1.4.2. Confirmation of Requirements

It is the intention of the EMPATTICS project consortium to comply with all Horizon 2020 requirements and standards, as well as the appropriate EU and participant country procurement requirements.

The PCP process will follow the Horizon 2020 definitions, using a consistent approach to buy R&D from competing providers to identify the best innovative solutions. This process will split the procurement into three phases, conducted in a fair and open tendering process. This PCP will focus on the R&D phase prior to commercialisation of activity. All parties will be made aware that the tender for R&D services is separated from the purchase of any end-products. That said, a determination will be made to ensure the appropriate management of IPR, consistent with EU and national regulations, while appropriately ensuring the value for money of the Buyers Group in supporting the R&D services.

As part of this process, the EMPATTICS project will engage with market participants in an open dialogue, which will be used to adjust and focus the tender specifications to ensure that the PCP process will result in state-of-the-art R&D services that go beyond the work already being undertaken in the marketplace.

The PCP call for tender will be launched by Consellería de Sanidade, the Lead Procurer, who meets the EU public procurement directives 2004/18/EC, 2004/17/EC, and 2009/81/EC. The tender will be published in English, and all tenders will be judged by fair, openly available, consistent criteria. Publication will be widely distributed across appropriate national, EU and international forums. Qualifications will be set to identify the best solution without undue focus on cost though ensuring value for money is achieved for the Buyers.

As it was anticipated before, the Lead procurer has played a key role in the development of Public Procurement of Innovation in the area of health (more than 30 tenders opened in 3 three years 2012-2015). [40] Part of the success in the management of such large number of PPI and PCP tenders in short time is due to the day-to-day involvement of the lawyers that defined the Innovation Procurement policies and recommendations publiched in early 2015 Galician Autonomous Region. This group of lawyers has been incorporated to the EMPATTICS project .The team created by Public procurement officers from Galician Health Ministry and the Lawyers from the Galician Autonomous Government (Xunta de Galicia) are specialized in regional, national and European policies for innovation procurement, bringing a high valuable asset to guarantee the feasibility of the EMPATTICS project.

The PCP contract that will be concluded with each selected tenderer shall take the form of one single framework agreement covering all PCP phases, which does not involve contract renegotiations after contract award. This framework agreement shall contain information on the future procedure for implementing the different phases (through specific contracts), including the format of the intermediate evaluations (incl. evaluation criteria and weightings) after the solution design and prototype development phases.

1.4.3. Lead Procurer

The Conselleria de Sanidade will act as lead procurer in this project sharing with the rest of buyers its large experience in Public Procurement of Innovation. The Consellería de Sanidade developed wit the private sector several patient centred projects promoted by PPI and PCP tenders through its affiliate organization, SERGAS, responsible for delivering healthcare services in Galicia. With an annual budget of €3,400 million, SERGAS provides healthcare services to 95% of the Galician population (2,7 Million, 23% of its population over 65 years old). Consellería de Sanidade/SERGAS resources comprise 14 secondary care trusts and hospitals, 493 primary care centres, 90 emergency centres and 165 homes for the elderly. It employs more than 36,000 people, including 2,200 primary care physicians and 4,741 secondary care physicians.

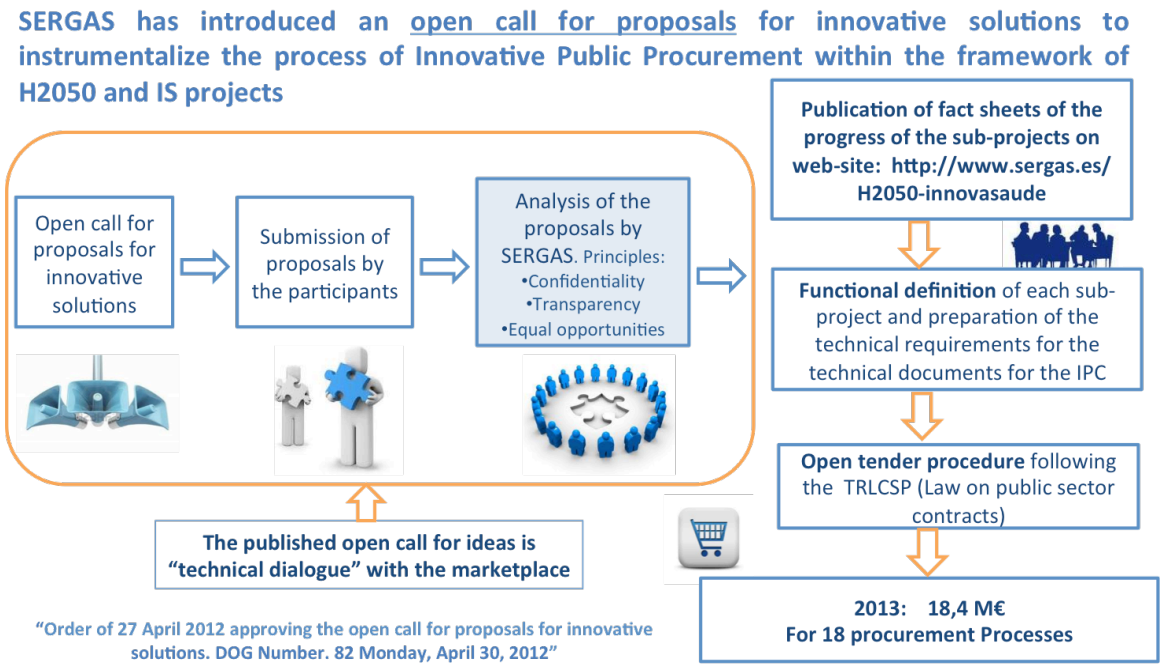
[40] http://publications.jrc.ec.europa.eu/repository/bitstream/JRC94502/jrc94502.pdf

Since early 2011, the Galician Healthcare system has promoted several PPI initiatives. Thus two major innovation plans, InnovaSaúde (IS) and Hospital 2050 (H2050), have been put in place. InnovaSaúde (IS) and Hospital 2050 (H2050) have been established through an agreement with the Spanish Ministry of Economy and Competitiveness with €90 million from the European Regional Development Funds (ERDF). Both innovation plans alone mobilized more than €30 million in PPI contracts during the last 3 years. IS and H2050 innovation plans aim to transform both the care model and the relationship model between providers, professionals and patients through:

- A change from a reactive care model to a proactive one.
- Measures that ensure the continuum of care.
- The evaluation of the health and cost impact of technologies and treatments.
- Bringing care closer to citizens through technology, and making the home a place of care.

The PPI initiatives developed in Galicia under the above innovation plans includes Public (commercial) Procurement of (Innovative) Technology and Pre-commercial Public Procurement of technology.

Consellería de Sanidade accumulates considerable experience in contract and implementation of PPI process. The model developed in Galicia includes distinctive features that aim the promotion of an effective integrated care model through the application of innovative ICT solutions. Public Commercial Procurement of Innovative Technology (PPIT) involved a two consecutive steps process. The first one is a technical dialogue with the market and the second is the procurement process of the innovative technology, which is informed by the results of the previous phase.



Technical dialogues with the market aimed to enable the Galician Healthcare system in a transparent and open dialogue to become familiar with the best, most beneficial and most up-to-date technical, technological and organisational solutions on the ICT market. It also allowed the contracting authority to compare its needs against the capacity of a constantly changing market to meet those needs. The results of the technical dialogue led to the drafting of a demand-driven tender map, through Public Procurement of Innovative Technology.

The first group of tenders (March 2013) included 18 tenders with a total budget of €18.4 million while the second tenders group (April 2014) provided information on 12 tenders with a total budget of €13.9 million. All PPIT tenders are characterised by some specific elements which reflect the innovative aspect of Th Galician Health System strategy such as Intellectual and industrial property rights, Royalties offer, Evaluation criteria of the proposals, etc.

In addition to experience in PPIT, the organisation also launched a Pre-commercial Public Procurement (PCP), named InnovaSuMMa. This PCP project is also part of the aforementioned Innovasaude and Hospital2050 major innovation plans. The final aim of InnovasuMMa PCP initiative is to incorporate elements of personalised medicine, i.e. diagnostic and prognostic biomarkers for colon, lung and prostate cancers, into the hospital protocols in the oncological field. The total budget for this PCP contract was €628,000 and the maximum amount for each individual contract with a company was €110,000. InnovaSumma involved collaboration with the heads of oncology units at the Galician public hospitals and with the Galician Oncology Society. Seven oncology units acted as "test places" of the proposed technologies.

- PCPP InnovasuMMa involved a PCPP contract of R+D services in the competitive phases with risks and the benefits shared between companies and Galician Public Health System
- Phase 1 - Demonstration of the viability of the proposal. The objective is to guarantee the adaptation of the initial proposal to the clinical and organisational contexts of Galician Hospitals and especially to the services where the technology has to be developed and/or tested. During this phase, approvals from Regional Ethics Committees and other organisations with regulatory responsibilities in this kind of investigation will be obtained. This phase lasts one month and a maximum of 4 companies can participate.
- Phase 2 - Development of a prototype of the solution proposed. The objective is to improve prototypes of the technology proposed considering the actual context of the oncological services of Galicia and to obtain preliminary results with real patients, validating technologies and associated diagnostic services. This phase lasts 6 months and a maximum of 3 companies can participate.
- Phase 3 - Development of a full demonstrator. The aim of this phase is to evaluate the proposal's viability with regard to incorporating the tests developed into the current hospital protocols, considering any adjustments and complementary tests needed. A maximum of 2 companies can participate in this phase that lasts 6 months.

A key aspect of the PPI/PCP contracts in Galicia is the way intellectual property rights of the research developed have been defined. These rights are given or transferred to the companies. As compensation for this transfer of rights, The Galician Healthcare system receives a percentage of the net profits of the commercial exploitation of the products developed during the contract, which cannot exceed 20%. This facilitates company sales and development in the healthcare and biotech sectors, an industry particularly concerned with IP rights. In this scheme Consellería de Sanidade/SERGAS keeps the option to retrieve these rights in the case that the company does not exploit them commercially within 5 years, thus ensuring public availability of the technology. The possibility has also been considered of licensing out the developed solutions to third party suppliers under fair and reasonable market conditions.

The Buyers Group

Central Denmark Region

Central Denmark Region (CDR) is one of five administrative regional units in Denmark. The primary responsibility of CDR is healthcare, involving responsibility for hospital services, including psychiatry, health insurance, general practitioners and specialists. In addition the region operates a number of social institutions. Around 30.000 employees work to carry out regional tasks at all levels.

The population in CDR amounts to 1,3 million. The annual healthcare budget is Euro 3,350 million. The Region has 5 hospitals of which one of them is a university hospital. There are 31 psychiatry departments. The Region has 19 municipalities who have their own healthcare budgets but there is a strong cooperation between the municipalities and the hospital. The General Practitioners are autonomous and with own budgets.

Healthcare innovation and business development

Central Denmark Region has experimented with the Public-Private Innovation set-up during the last 6 years. This has resulted in the creation of an autonomous company MedTech Innovation Center (MTIC) which is supported by the regional growth forum (and also from 2014 12 municipalities, the university of Aarhus and the profession university VIA) in order to develop new solutions within life science in public private partnerships. MTIC has project managers with commercial experiences that are outsourced to the hospitals and working inside-out as an ordinary hospital employee together with hospital local innovation managers but with the goal of building bridge between the hospital and the companies in public private partnerships. Two of the main conclusions from these 6 years of work are that top management back-up and involvement is absolutely necessary and that multidisciplinary capabilities make the solutions more innovative and create better speed in the projects.

Public Procurement in Central Denmark Region

Department of Procurement & Clinical Engineering is a central unit responsible for procurement and supply to the 5 regional hospital units, combining relevant areas as research, clinical engineering, technical service and logistics.

Central Denmark Region has a great deal of experience within Public-Private Innovation in healthcare, among others from a regional fund. Evaluations points out that PPI often are a resource demanding innovation method struggling to fulfil the commercial potentials and lack of implementation extent. As an alternative the region sees a great potential in increasing procurement of innovation in order to create new innovative healthcare solutions in close public-private collaboration in an involving, dialogue and trust based, transparent process. In order to improve the initial (technical) dialogue for all participants the region experiments and documents in the pre-phases that leads to the actual request for tender. The specific choice of tender form is based on an individual assessment according to the specific needs and circumstances.

As described in the regional strategy for intelligent public procurement, Central Denmark Region currently focuses on improving procurement within the following overall themes:

1. Efficiency/effectiveness
2. Innovation and quality
3. Sustainability

Aragón Region

Servicio Aragonés de Salud (SALUD) is the public health provider for Aragón, having the responsibilities of overall management and co-ordination of the existing healthcare resources in the territory, provide Primary care, Secondary care, mental care and geriatric care management, including homecare, and to the promotion and protection of individual and public health.

SALUD's mission is to provide an integral healthcare attention, to ensure the services accessibility, to promote healthy lifestyles, the prevention and protection and to maintain patients' autonomy and their social inclusion.

SALUD has a network composed of 12 General Hospitals, 110 Primary Health Centres and 5 Geriatric hospitals. It has introduced innovation on the professionals' regular practice through the integration of telemedicine solutions thanks to the collaboration on several strategic projects.

Barbastro's Healthcare Area (SALUD-BHA) has worked in a very active manner in the last decade in the deployment of several telemedicine solutions in the sector. Firstly, and thanks to several European projects, the sector was provided with devices and systems creating a niche of technology, communications and information systems needed to deploy telemedicine solutions across the area. SALUD-BHA was provided with a wide band communication network connecting all centres in the territory. Then, SALUD-BHA worked on the deployment of basic telemedicine services that allow a two-way communication between specialists to offer healthcare assistance across the whole territory.

The region has also started to test the benefits of PCP and PPI projects participating in discussion's with the Spanish Ministry of Economy and Competiveness, and starting strategic alliances with other autonomous regions in Spain to develop joint PCP and PPI actions.

Finally, the regions also count with a specific Observatory in Public Procurement of Innovation.[41] Sponsored by the Autonomous Government of Aragon, this initiative has become a reference in Spain to guide procurement officers and procurement managers in the legal aspects of PCP and PPI contracts.

Ile de France

Founded in 2008, the GCS D-SISIF (www.gcsdsisif.fr) is a Health care cooperation consortium which aims to develop the shared health information systems within the Ile-De-France region. The GCS D-SISIF is in charge of building the e-health domain. The target is the regional cyberspace of health called ENRS.

This ENRS (Health Regional Digital Space) is defined as computerized services and applications undertaken by the health regional Agency (ARS) and piloted by the GCS D-SISIF. It is compliant with the interoperability framework and the national methods promoted by the national health information Aggency (ASIP Santé). It meets the objectives defined by the national and regional health policies.

The GCS D-SISIF is composed of 8 colleges of members which represent all the health organizations and General Practioneers in the region. The GCS D-SISIF aims to improve the work conditions of its members by facilitating:

- The interoperability and the mutualization among members
- The administrative, legal and financial office delivery
- The operational project management activities

Slovenj Gradec General Hospital

The Slovenj Gradec General Hospital (SB) is a public health care institute which performs secondary-level health-care activities and other activities stipulated by its Founding Act, primarily for the Carintia (Koroška) and the Savinjsko-Šaleška statistical regions. Its founder is the Republic of Slovenia.

Health-care activities at the secondary level are as follows:

- Hospital health-care activities in the field of internal medicine, paediatrics, gynaecology and obstetrics, traumatology with orthopaedic surgery, general and abdominal surgery and urology. Its operational plan is implemented in four large surgical theatres and two smaller ones with a day surgery office.
- Specialist outpatient activities are performed in all basic medical fields, in the field of physical medicine and rehabilitation, and in the field of classical radiology with ultrasound and CT diagnostics and mammography diagnostics.

The Slovenj Gradec General Hospital admits each year around 15,000 patients and 160,000 outpatients. It employs 727 people: 142 doctors, including 77 specialists, 59 residents and 6 interns. In the field of nursing, it employs 131 registered nurses with a bachelor's degree in nursing, 192 middle-level nurses and 5 medical technicians doing internships. In the medical field, there are also 9 pharmacists and 57 employees from other related health-care fields. The non-medical staff comprises of 55 employees in the field of health-care administration, 65 employees in the field of provisions/supply and catering and 57 employees in the fields of technical maintenance and administration. Being a teaching and research institution SB-SG participates in international projects and studies.

SB-SG gained its first experiences in providing telemedicine support to patients at home within the United4Health project (ICT PSP 2013-2015). Telehealth Centre called CEZAR (Center za zdravje na daljavo Koroške regije) runs within the SB-SG hospital. It provides currently support almost 500 patients with

[41] http://www.obcp.es/

diabetes mellitus (DM) and patient with congestive heart failure (CHF) in the region of Carintia (Koroška), Slovenia. To set up the services from "green field" SB-SG, as a public institution, went through a technology solution procurement process implementing a legal mechanism of direct negotiations with potential providers.

The organisation has recently entered in a new strategic based on international collaboration participating in high-level discussions with international partners. The Hospital is also interesting in new ways to promote e-health innovation in Slovenia through PPI/PCP projects.

1.4.4. PCP Preparation Stage

EMPATTICS Project will involve an open Market Consultations to qualify functional specifications for an Innovation Call, in order to benefit both qualification of the common challenge and development of new implementable solutions. The dialogue will also include key questions regarding the commercialisation on and development of technologies (such as potential royalties to share with buyers and IP management, since the commercial potential is of decisive interest to both the demand and supplier side. When the 'common challenge' is defined in WP2 this will form the basis of a number of innovation sessions/intensive hackathons in European hotspots:

Task 1 - Open Challenge/technical dialogues with the Market:

Goal: to ensure innovative solutions to the 'common challenge' that are implementable and of great value to both buyers and suppliers.

1) Share the initial conclusions of Buyers' debates and get valuable feedback from companies in order to qualify the final tender specification. There will be an open and transparent discussion that will be supplemented, challenged and improved by competent knowledge partners on for example new technologies but also other relevant knowledge in other relevant sectors than the traditional ICT sector (this could be for example knowledge about design, learning, edutainment, gaming, motivation of lifestyle changes, service management).
2) Inform potential tenderers about the following call. The marketing of the sessions and the sessions themselves will also act as an excellent marketing tool to announce our future PCP call.
3) Facilitate new consortiums/collaborations. The session will also serve to foster joint-ventures/alliances between SMEs, entrepreneurs, start-ups and big companies, also across sectors.
4) Get an impression of the potential partners and solutions to be expected in the following phases of the project.

Output will be qualification of the 'common challenge', first ideas/concepts for relevant solutions, impression of the market and differences in the overall approach, new multidisciplinary consortiums etc. Even if the companies do not win the tender they will access new knowledge, insights (public strategy and future scenarios, user needs and limitations) and network with interesting people that could lead to new business opportunities. If they are chosen to further development of a solution, they will also benefit from direct feedback on their ideas and prototypes from highly qualified patients, nurses, doctors and healthcare managers throughout the process.

Task 2 - Increase PCP awareness:

Goal: increase the number of tenderers, the quality of the final solutions, and promote entrepreneurship in the ICT health sector.

PCP is one of the new tools to promote applied research and therefore a new discipline to both the public and private partners. There is a general lack of knowledge and experience with PCP and other innovative procurement models in both sectors. Development of basic understanding and skills are vital for harvesting the essential improvements. Public private (resource saving) development of new mutual

beneficial solutions requires awareness of for example financial requirements, technical requirements, legal contract processes, cultural differences, facilitation of PPI processes, practical tools, recommendations, cases, expectation management, management of common goals etc.

Only few companies have enough experience and resources to participate in these calls. Companies often lack knowledge about financial requirements, technical requirements, legal contract processes and so on and so forth. In order to unlock the potential in new procurement of innovation we need to increase the level of awareness of potential tenderers. Therefore we will propose informative sessions (in parallel with task 1) to inform companies about risks and benefits of PCP tenders and other innovative tender forms. Sessions will also help us to anticipate our PCP project to the companies' engineering and R&D departments. The initiatives will be both:

1) Facilitated through personal meetings/informative sessions as a part of the technical dialogue.
2) Digital and print material that informs companies of the PCP potential and challenges. We will work on numerous platforms such as social medias, local business networks and of course the EMPATTICS website.

The goal of our procurement activities is (including prerequisites):

1) Development of innovative and relevant solutions that will benefit both citizens (people living with diabetes), health care providers (regions and municipalities) and private enterprises.
2) To mature both market and demand.

   2.a) Ensure that we get the best private innovation partners that can contribute to an optimum tender specification and following solutions. Create awareness and attract a broad range of private companies in Europe.

   2.b) To mature a demand for visionary solutions within the health care sector/public procurers.
3) To motivate and educate/enable both private and public partners to participate successfully in PPC/innovative procurement/PPI.

Activities

Several Networking and Coordination activities will be developed at EMPATTICS to increase awareness and define a successful PCP tender document.

1) Announcement of upcoming tender on relevant platforms, especially on-line and new media such as Twitter and Linked-in and other healthcare forums. Invitation to one-day innovation conferences (dialogue meetings) in chosen European cities will be offered. Besides the announcements relevant companies will be addressed through network, desk research, and alliances with local business/growth initiatives/hubs/clusters.
2) General information, guidelines and recommendations about PCP will be made accessible to all interested companies through the internet and relevant business on-line media.
3) A linked-in group for interested companies and procurers will be established and marketed through the Buyers Group's network and internet pages.
4) Seminars and webinars about basic PCP and PPI will be planned, prepared and offered to all interested companies.
5) Awareness about advantages of new procurement methods will be created and marketed directly to SME's known from desk research and cluster analysis.
6) Innovation conferences will be prepared and held in different cities throughout Europe.
7) Execution of PCP seminars for different segments such as practitioners and decision makers/ executives in both public and private sectors (procurers, suppliers).
8) Facilitation of innovation conferences and matchmaking.

9) Follow up on one to one meetings with chosen companies/consortiums. Documentation.

10) Modification of tender specifications accordingly to input from the innovation conferences and one to one meetings.

11) Evaluation of the process.

12) Coordination with relevant WP and internal meetings.

1.4.5. PCP Initial approach to R&D and evaluation

EMPATTICS will foster competition among companies, guaranteeing transparency and involving all members of the buyer's group in the evaluation process.

EMPATTICS will produce a PCP contract in three different phases.

- EMPATTICS solution design and business plan
- EMPATTICS Prototype
- R&D plan for test series

The evaluation criteria will imply different indicators that will be grouped in three categories.

1) EMPATTICS will have the minimum technical specifications and R&D requirements to participate in the tender that will be evaluated in a Go-Non-Go basis. Bidders will be of course forced to demonstrate that they can accomplish the minimum requirements of EMPATTICS tender. Accomplishment of these criteria will be compulsory for all bidders and they will not be punctuated. In their proposals, bidders will present different technologies and solutions to face EMPATTICS health challenge. After fulfilling compulsory requirements, the strategy and activities decided by each bidder will be measured and valuated according to Automatic Indicators and Non-Automatic Indicators that will be punctuated by the evaluation committee.

2) Second group of EMPATTICS indicators are associated to technical and non-technical aspects that can be evaluated automatically. The list of Automatic Indicators intends to measure those indicators that can be presented by bidders with a number. Automatic indicators consist of tender price, time of prototype development, maximum number of patients managed, percentage of potential royalties in future sales to be shared with buyers, number of test sites required for optimal validation studies, etc. Automatic Indicators will represent around 10% of final bidder's punctuations.

3) EMPATTICS will work on the definition of indicators that cannot be evaluated automatically. Non-Automatic Indicators will represent the higher percentage of bidders final evaluation. Around 90% of the final punctuation will be associated to Non-Automatic Indicators. Non Automatic Indicators will include, among others, the evaluation of better management of patients, business model of the proposed solution, quality of the proposed R&D plan, adequacy of the proposed solution, improvements in patient's management by clinicians, expected saving costs for health systems, expected improvements in adherence to treatments by patients, innovative approach, etc. Some of non-automatic indicators will be not be part of the evaluation of all phases. For instance, whereas business models, price and expected saving costs will be evaluated in phase 1, the R&D plan and improvements in patient's management by clinicians and by the patients themselves will be evaluated in phase 3.But also TCO calculations/considerations, implementation costs and time, ease of integration to existing systems, flexibility as for instance build up in components, based on international ICT standards and therefore easy to integrate etc. must be evaluated. During the preparation of the tender, all buyers will discuss and agree the list of Non-automatic Indicators to be evaluated: initial discussions expects around 20 different Non automatic indicators grouped in at least 4 categories (expected impact of Health Organisations, Expected Impact on Patients, Management and execution of the project by bidders and business and commercialization plans of the proposed technologies).

EMPATTICS evaluation will impy Clinicians, IT specialists and Innovation profiles recruited among the Buyers group. Each Buyer will create a balanced and diverse committee of regional experts (CRE) that will evaluate all technical proposals. Each CRE will appoint a chair and a co-chair that will participate in

the Buyer Evaluation Board (BEB). The Buyer Evaluation Board will have 2 representatives per buyer and up to 3 external experts. The decisions taken on the BEB will be finally communicated to the Procurement department of Leader Procurer.

EMPATTICS consortium will create guidelines and templates to assist CRE and BEB on their evaluation processes. The evaluation documentation package will be uploaded to the website before Tender publication. Companies will know in advance evaluation criteria, process and recommendations to better address their proposals.

1.4.6. PCP Phases

EMPATTICS involves a single procurement contract managed in various phases. EMPATTICS will open a discussion among all members of the buyers group to decide if just one contract (subjected to the terms and conditions of the PCP tender) is signed between the Lead procurer and all companies that initiate the EMPATTICS' activities in Phase 1 or if several contracts are signed before commencing each PCP phase.

In EMPATTICS we are very conscious about the importance of a fair and natural competition. The numbers of competitors involved and retained vary among 3 phases.

- Phase 1 (4 months) M13-M16: Aim to verify the technical, organisational feasibility, impact on health organisations and expected economic/market projections of future commercialization of each company's proposal against the pros and cons of potential alternative solutions. The total budget for Phase 1 will be €250.000. Each company will have a maximum budget of €25.000 for Phase 1. According to these amounts, we expect 10 companies in Phase 1 but the number of companies could increase if the economic proposals are inferior and there are sufficient resources within the identified budget to include more firms. Buyers expects detailed studies about the implementation of their technologies. Companies will have the possibility to interact with Buyers organizations in a open and transparent procedure. This phase will help companies to learn about the real EMPATTICS scenarios
- Phase 2 (9 months) M18-M27: Aims to verify to what extent the main features exhibited by the prototype, meet the functional and performance requirements set forward by the Buyers Group for the desired solution. The total budget for Phase 2 will be €1.650.000. This will fund the successful firms to manufacture the first prototype. Similarly we will allocate a maximum amount of €330,000 per company expecting a competition among 5 companies.
- Phase3 (8 Months) M28-M36: Original development of a first batch of devices/technologies will be developed and later validated through field tests. Phase 3 will aims to verify and compare the performance (interoperability, scalability, etc.) of different solutions in real-life/real clinical operational conditions of the targeted public service.
  Buyers will significantly contribute to the validation of new technologies, participating with clinicians, clinical data managers, patient asociations, HTA agencies, advising on Ethics Committees issues. The total budget for phase 3 will be €1.600.000 with 3 companies and approximately €533k of maximum budget per company.

1.4.7. PCP Phases: Outcomes

As noted earlier, Patient empowerment is defined as helping patients discover and develop the inherent capacity to be responsible for one´s own life. Patient empowerment approaches recognize that knowing about an illness is not the same as knowing about a person´s life and that, by default, patients are the primary decision-makers in control of the daily self-management of their own illness. Europe has the highest burden of chronic diseases which are responsible for 86% of all deaths and result in premature morbidity and loss of healthy life years. In fact, WHO considers the rise in chronic diseases an epidemic and estimates that this epidemic will claim the lives of 52 million people in the European Region by 2030 which calls for adequate prevention and sustainable disease management.

Also it is widely acknowledged that 70% to 80% of healthcare costs in Europe are spent on the management of chronic diseases. This corresponds to €700 billion in the EU Member states budget. The number is expected to increase in the coming years. Chronic diseases represent a major challenge for health systems across Europe, impacting on the wider social system and economies of Member States.

Opportunely, chronic patients are growing more empowered as they become proactive participants in their own healthcare experience. ICT health technologies are enabling that change, with a number of significant advances playing a big role in future patient management. Unfortunately most of these ICT advances reach the market through R&D projects entirely developed by the private sector. Companies grow their technologies without any contact with end users or clinicians and the solutions resulted are isolated initiatives that support neither the patients nor the systems needs as a whole.

Consequently the new technologies proposed by companies reach the market with insuperable gaps and deficiencies from patient's point of view and incompatible with different EMR technical specifications. Insufficient collaborative R&D between companies and health organisations harvest new technologies that cannot be deployed across Europe. In fact, many of these promising technologies never reach patients. Product development constraints and failures are particularly difficult for innovative SMEs. SMEs lack of resources to develop their technologies in collaboration with health services and they have serious financial limitations to validate their products with real patients.

Collaborative R&D through a PCP can help companies to overcome aforementioned barriers helping procurers to identify real needs/challenge that affects Health Organisations. Previous experiences from EMPATTICS buyer's group members demonstrated that there are not solutions in the market to cover the proposed Health Challenge. We therefore need to procure an R&D development that will involve different phases (exploration and design, prototyping and development of a limited volume of first products or services + validation/test studies).

Accordingly, a PCP process is required to cover health organisational need s and to guarantee European scale solutions for patient management. The expected outcomes of each PCP are explained here:

Phase 1 Expected Outcomes

Phase 1 aims the verification of the feasibility proposed by companies. It also aims at a good understanding of the impact of such technologies not only on health organisations but also on the e-health market. The expected output of phase 1 includes a feasibility study that includes a technology description (mock-up and fast prototypes), a first solution design, an organisational plan for Phase 2 and a costs/benefit evaluation of the proposed solution. Finally it also aims at a quick response from invited patients to get their feedback on the usability.

Phase 2 Expected Outcomes

It aims at the verification of the main features exhibited by a technology prototype which is evaluated by patients. Phase 2 expected outcomes includes a prototype specification and demonstration, as well as a plan for limited first product development, involvement and testing by both hhealtcare professionals and patients and not least an updated cost/benefit evaluation in phase 3

Phase 3 expected outcomes

It aims at the verification and comparison of technology performance in real scenarios involving patients and healthcare professionals. The main output of this phase includes a test product specification study that should provide enough evidences for complete cost/benefit evaluation on both quantitative and qualitative measures. The project will end here with a report of the efficiency of each technology in the different test sites, including a comparison of the impact of the technologies in a variety of European regions. Heath Technologies assessment organisations would help to define technical specifications to allow companies to develop their test in agreement with common requirements of health systems.

1.4.8. PCP Monitoring and Execution

Each PCP contract phase will be evaluated in 2 stages: Each buyer will create a committee of regional experts (CRE) composed of at least 5 people. CRE will involve an IT expert with proven track record in

the development and implementation of e-health technologies for patient empowerment, a clinician with expertise in chronic diseases, a second clinician with competency in a related field (such as oncology, Cardiology, Psychiatry), a pharmacist with enough knowledge to valuate improvements in the area of adherence, and finally, an innovation professional with experience in economics and commercialization of health technologies. CREs could be extended with other professionals (experts in health economics, health system executives, health technology assessment). Each Regional committee will decide on additional members, appointing a regional Chair and a regional co-Chair.

CREs will evaluate all proposals. During the implementation of WP1 and WP2, EMPATTICS consortium will prepare detailed guidelines for common evaluation procedures. At the conclusion of this regional evaluation, proposals will be ranked according with the criteria of the PCP contract.

After this regional evaluation, results will be confronted and debated within the EMPATTICS Buyers Evaluation Board (BEB). Regional Chair and Regional Co-chair of CRE will have a seat on EMPATTICS Buyers Evaluation Board (BEB). Each buyer will have 2 representatives in this board with one vote per Buyer. The Evaluation Committee will have 2-3 independent external experts so 7-8 people will participate on EMPATTICS Evaluation Committee.

EMPATTICS BEB will hold at least 3 meetings to decide the companies selected for each PCP phase. In these meetings, EMPATTICS BEB will discuss regional results and propose 1 technical report by consensus. The report will be presented to the contracting authority, which will communicate final decision to companies.

In the first 2 phases of the PCP contract companies will work also alone with little interaction with Health Professionals. However, the Buyers group members will appoint a Regional contact person (RCP. RCP will facilitate information and solve doubts to companies: This contact person will act with total transparency, publishing all information provided to one company in the website. This contact person will certainly facilitate the development of proposals with fresh information form the participating regions. It will also guide potential candidates in the guidelines and recommendations of PCP contracts.

In Phase 3 a more detailed R& D Monitoring methodology is required. WP5 leader (SALUD ARAGON) will assume this responsibility designing a test a monitoring protocol for all companies in phase 3. This protocol will allow the implementation of common test sites in the different European locations. EMPATTICS consortium will work from the very beginning on the definition of guidelines for effective execution (by companies) and monitoring (by test sites buyers). Such guidelines will be of course subjected to the evaluation criteria and key performance indicators included in the PCP contract.

Aggregation of data and comparability of results among pilot sites will be made possible by the use of the same evaluation methodology, MAST (Model for ASsessment of Telemedicine), in all the pilot sites. MAST, which was originally designed under contract to the European Commission in the context of the MethoTelemed Project, is a new model to be used as a basis for decision making in EU and the European countries in decisions on use of telemedicine and eHealth applications. We will use MAST with the purpose of describing effectiveness and contribution to quality of care by EMPATTICS technologies.

1.4.9. Removing Barriers

PCP involves a procurement process that facilitates interaction with companies and it fosters truly innovative technologies adapted to the needs or challenges of public systems. EMPATTICS consortium conceives Europe as a microcosm of the ‘global village’. Europeans live and work in highly dynamic and diverse geographic area with very different regions, singularities. EMPATTICS consortium represents very well European diversity. We have on the consortium large metropolis like Paris, dispersed and aged regions like Galicia, low and high performance innovation regions, medium size and big hospitals, etc.

Despite the enriching European diversity, we have also many points in common, and especially on the area of healthcare. In EMPATTICS everybody agrees that for various well-understood reasons, the current model of healthcare delivery is not sustainable at all. Unfortunately no-one is sure how to provide an alternative that will be effective.

EMPATTICS look for disruptive technologies focused on the promotion of an empowered patient, conscious of his disease and equipped with technologies and of self-management plans that facilitate relationships with health care professionals. This idea requires a totally disruptive paradigm that involves redefinition of healthcare procedures, relationships, disease education, etc. Challenges ahead are titanic because we will need also innovative models that will only move forward with powerful and scalable patient empowerment technologies.

Thus health systems, health professionals, patients associations and technology developers must urgently create mechanisms and initiate profound debates to agree on solutions with global scale. EMPATTICS Networking activities are therefore critical to identify health systems needs and to anticipate issues related with regional differences, local legislations, demographics, economic constraints or technology readiness levels (e.g. different electronic medical records systems)

Following the example of EHFF, in EMPATTICS we would like to get global solutions with capacity to create an impact in very diverse European regions. In order to attain that goal we propose a helicopter (EMPATTICS PCP contract) viewpoint and begin with the future of healthcare quality – because that is a common thread for all the elements – structure, process and outcomes for all regions involved here.

EMPATTICS' Networking and Coordination Activities (N&CA) will be very much focused on the facilitation of SMEs. We believe that EMPATTICS will be very attractive for highly innovative small companies. Our dialogues (hackathons) with companies will anticipate general PCP goals. They will also serve to foster joint ventures of two or more partners to reduce project risk as well as they will be very instructive tools to learn about the PCP project. The introduction of test sites will also facilitate companies' access to patients, testing in real scenarios their technologies (Phase3 of the PCP). The last phase of PCP is very valuable for SMEs. EMPATTICS Buyers will open their hospitals to companies to test and validate technologies with their clinicians and patients. This validation phase will of course facilitate the development and future deployment of technologies across Europe.

Besides, EMPATTICS will have also on board the visions and recommendations of very diverse profiles including the recommendations of Health Technology Assessment agencies, like AVALIA-T.[42] AVALIA-T was established in 1999 by the Galician Health Regional Government to promote the introduction, dissemination and use of health technologies using clinically proven efficacy, effectiveness and safety criteria. HTA contribution to N&CA will provide insights and guidelines to develop PCP R&D orientated to the market. HTA will also facilitate regulation and standardization recommendations about future introduction and promotion of health technologies in hospitals.

1.4.10. Procurement, Coordination and Networking Objectives

EMPATTICS aims to use the PCP process to identify new technologies and services to a enhance self-management for people with diabetes through innovative ICT tools and test the new technologies at a large scale and very different European sites located in all consortium regions.

The overall objectives of the EMPATTICS projects include different goals that address the objectives of the administration, clinicians, patients and companies.

Administration Goal 1:
Introduce PCP in the DNA of 5 European regions through the preparation and evaluation of a joint PCP contract developed with the participation of 5 European regions.

Administration Goal 2:
Execute a PCP contract in collaboration with other European regions, modernizing current procurement process and sharing best procurement practices with other European regions.

Companies Goal 3

[42] http://www.sergas.es/MostrarContidos_N3_T01.aspx?IdPaxina=60977

Develop at least 5 technologies/services prototypes with capacity to impact the European Diabetes market through innovative solutions specifically designed to satisfy the technology and patient management challenges already existing in 4 very different European regions.

Companies Goal 4
Test 3 technologies in real environments and with real patients

Patients Goal 5
Contribute to the promotion of ICT technologies that will help them to control the evolution of their diseases, stimulating their treatment adherence and supporting their skills for behavior change.

Clinicians Goal 6

Contribute to the promotion of technologies that increase the efficiency of their patient management practices, allowing the management and coordination of more patients with higher quality standards.

1.4.11. Procurement, Coordination and Networking Objectives

Goals	Key Performance indicators
Administration Goal 1: Introduce PCP in the DNA of 5 European regions through the preparation and evaluation of a joint PCP contract developed with the participation of 4 European regions.	• 1 PCP Business case with benefits is developed, including specific PCP guidelines for companies, and evaluators. • At least 5 regional PCP conferences arranged for policy involvement • Creation of at 4 regional Evaluation Committees • Creation of 1 International Evaluation Committees • One common assessment criteria agreed by consortium • 2 arranged study visits from successful PCP best practice • Open a 3 months period for engagement of a new member of buyers group. • 8 training workshop for public procurement technicians • 1 intentional cooperation agreement involving minimum 4 countries for further future PCP cooperation and projects • 6 Electronic newsletter s to minimum 400 stakeholders European wide • 2 final conferences with 300 people attended • articles published by each project partner, • One website produced • 4 video clip produced • 20 communications to the general pres/media
Goal 2. Administration Execute a PCP contract in collaboration with other European regions, modernizing current procurement process and sharing best procurement practices with other European regions	• Initiate open dialogues with minimum 80 SMEs • One framework for PCP contracts is developed • One industrial workshop is arranged in order to open the PCP call • One European call open during 3 months via TED database • 12 meetings of the Regional Evaluation Committee • 4 meetings of the International Evaluation Committee • Perform 3 PCP phases according regulations Gather

	up to 10 tenders during Phase 1) Solution design • R&D of up to 5 ICT prototypes in Phase 2) Prototype development • R&D of up to 3 ICT solutions in Phase 3) limited test products
Companies Goal 3 Develop at least 5 technologies/services prototypes with capacity to impact the European Diabetes market through innovative solutions specifically designed to satisfy the technology and patient management challenges already existing in 4 very different European regions.	• R&D of up to 5 ICT prototypes in Phase 2) Prototype development • One conference with at least 8 Venture capitalists for presentation of minimum 5 promising opportunities offered by SMEs involved in PCP project.
Companies Goal 4 Test 3 technologies in real environments and with real patients	• Establishment 4 test sites in minimum 4 European regions • Up to 3 validated ICT solutions ready to commercialize on the market 1 report on Guidelines for validation studies of ICT solutions
Patients Goal 5 Contribute to the promotion of ICT technologies to control the evolution of diseases, stimulating treatment adherence and supporting skills for behaviour change.	• At least 160 patients in Europe recruited for validation studies. • 160 diabetes follow up studies • Establishment of appropriate indicators values according to the monitoring protocols
Clinicians Goal 6 Contribute to the promotion of technologies that increase the efficiency of patient management practices, allowing the management and coordination of more patients with higher quality standards.	• Feedback form at least 20 clinicians across Europe on the ICT solutions • Feedback form at least 20 Pharmacist across Europe on the ICT solutions • At least 40 professionals trained in Europe for the validation of 3technologies

Impact of additional Networking and coordination activities

EMPATTICS consortium involves several regions and organisations with strong experience in patient empowerment solutions in the area of ICT. Many of these organisations have already participated in the development of sophisticated technologies in the area of health, participating with different experts and departments in the field. The consortium aims to positively impact in their regions with future developments financed by PCP funds.

Regions like Galicia (lead procurer) will initiate in mid-2015 a new program that will mobilize €21,5 million in Public Procurement of Innovation in the area of heath (2015-2020). Around 20% of this budget will be targeted to PCP projects in personalized medicine.

In Spain, Aragon has also initiated discussions with the Spanish ministry for Economy and competitiveness to participate in joint PPI projects with other Spanish regions like Galicia. Other regions like Paris and Central Denmark have already participated in PPI projects.

The consortium has already found synergies regarding common health challenges and common objectives. All buyers are also interested in common PCP projects compromising part of their resource to develop technologies adapted to the real needs of patients and clinicians.

To foster new developments in the area of health, Buyers sill contribute to the EMPATTICS project with an equal cash contribution. This demonstrate the real compromise of all buyers to this initiative.- Besides cash contributions, some buyers will participate with dedicated experts from HTA agencies, IT departments, clinicians and innovation experts to guide the development of technologies according to the perspectives of the European markets and European standards.

1.4.12. Relation to Challenge and Scope

The Buyers Group of Project EMPATTICS will encourage innovation regional R&D teams to work on providing solutions on these major themes:

- Empowering citizens to manage their own health and disease
- Research into personalised health technologies, and co-operative ICTs
- Holistic approach, from healthy lifestyle, dietary habits and disease management
- Patient centred with education, patient empowerment, secondary prevention and self-management of conditions
- Age-dependent differences in health, behaviour and handling of devices

EMPATTICS will ensure that that the solutions engage citizens in their health, wellbeing and prevention of diseases using ICT tools and personalised services that support behavioural change and promote health literacy. The project will create an innovative procurement framework that encourages R&D organisations to create Self-management solutions that can be embedded into the real pathways of care that the Buyers Group operate locally.

EMPATTICS will ensure that that the solutions allow for professional support for Self-Managing patients where patients are encouraged to become the prime actor in management of their own care. The role of the healthcare Buyers Group is to develop support tools for the self-managing patient. The project is established to ensure these support tools offer the Buyers Group:

1. A portfolio of techniques and tools to help patients choose and live healthy behaviours
2. A fundamental transformation of the patient–caregiver relationship into a collaborative partnership.

EMPATTICS will seek to ensure that professionally supported self-management tools allow the patients, to achieve and maintain a high level of education, information and motivation about their conditions. The tools that will be developed from Project EMPATTICS will make patients more knowledgeable, more skilful and more self-confident on medication regimes and self-appraisal techniques. Project EMPATTICS will create the environment for product development where the interactions between care provider and patient become more meaningful and each touch-point has a material impact on slowing the progression of a person's chronic disease.

EMPATTICS will ensure that self-managing patients can be offered the opportunity to co-create a personalised self-management plan based on the principles of:

- Have knowledge of their conditions
- Follow a treatment plan created and agreed with their health professional
- Actively share in decision making with health professionals
- Monitor and manage signs and symptoms of their condition
- Manage the impact of their condition on their physical emotional and social life
- Adopt lifestyles that promote health
- Have the confidence, the access and the ability to use support services

EMPATTICS Health Authorities will seek the development of self-management tools and services that have the objective to provide the necessary support for a population of self-managing patients.

1.4.13. National and International Activities

Spain:

There is a huge interest in **Galicia** and Spain for the promotion of Public Procurement of Innovation projects[43] and particularly PCP contracts as mechanism to promote research and innovation from public to private sectors.

Since early 2011, The Cobnsellería de Sanidade has mobilized more than 30 million Euros in PPI contracts focused on patient centred solutions and Hospital of the future. Among these contracts Galicia launched a PCP contract for the promotion of personalized medicine protocols through cancer biomarkers. For all this initiatives, the institution received several Public Procurement awards,[44] becoming a reference institution at national level.

At regional level the Galician Government is currently working on the publication of Guidelines for the promotion of PCP and PPI contracts in the region. Consellería de Sanidade is currently cooperating with the RegionalGalician Government to translate its experience on PPI/PCP to other strategic sectors like renewable energy or aquiculture. The Regional Galician Government is also interested in the promotion of Health innovation through PPI/PCP initiatives. A considerable amount of its RIS3 funds will be allocated to this purpose.[45]

Spanish government is currently discussing its new strategic plan to promote PPI projects with the allocation of around €150M to competitive calls exclusively developed in the area of health. Some of these projects will be developed through consortiums of Public health authorities of different Spanish regions. **Aragon** is actively participating in these discussions and it has started to propose projects in the area of patient empowerment and establishing alliances with other Spanish regions like Galicia..

Denmark

In 2012, the Government, Danish Regions and Local Government Denmark embarked on the ambitious National Action Plan for Dissemination of Telemedicine[46.] The action plan consists of five initiatives (projects) on either national scale, large-scale or pilot project scale. A total of DKK 80 million (EUR 11 million) has been allocated to completely or partially finance the initiatives. With the projects, the Danish healthcare system is currently building up important experience about the use of telemedicine for e.g. citizens with chronic obstructive pulmonary disease (COPD), diabetes, and depression, as well as for pregnant women with and without complications.

Likewise Danish Regions has agreed on a set of common indicators across the five regions to advancing ICT solutions within healthcare. More of these indicators address developing and implementing telemedical solutions to improve patient's access to healthcare and patient empowerment. Accordingly Danish Regions has established a Forum for Telemedicine and ICT Supported Patient empowerment.

During the last 5 years Central Denmark Region has worked with several creative procurement models both in theory and in practice in order to promote more innovative solutions and better decision making in choosing the right commercial partners. PCP is one of several means as for instance Public Private Innovation Partnership (PPI) is another. Central Denmark Region has tested the different models in order to get an insight into the different outcomes of the methods.

Central Denmark Region is exchanging experiences with tender models at a national level in a procurement committee where for instance law experts from commercial law firms are invited to discuss solutions and future actions. The region will ensure relevant dialogue with the remaining other 4

[43] http://www.idi.mineco.gob.es/portal/site/MICINN/menuitem.7eeac5cd345b4f34f09dfd1001432ea0/?vgnextoid=281c12c94d364410VgnVCM1000001d04140aRCRD&lang_choosen=en

[44] http://www.idi.mineco.gob.es/portal/site/MICINN/menuitem.edc7f2029a2be27d7010721001432ea0/?vgnextoid=9c3ee67e19ce6410VgnVCM1000001d04140aRCRD&vgnextchannel=cf091f4368aef110VgnVCM1000001034e20aRCRD

[45] http://www.ris3galicia.es/wp-content/uploads/2014/03/ris3_folleto.pdf

[46] http://www.digst.dk/Servicemenu/English/Policy-and-Strategy/Strategy-for-Digital-Welfare/Telemedicine

Danish regions regarding both sharing of knowledge and inputs both ways, among others in the Regional Forum for Collaboration regarding Health Innovation.

The second largest city in Denmark – Aarhus - is going to be European Cultural Capital in 2017 and is located in Central Denmark Region. The region and the remaining municipalities are very active in the preparations and it will be natural to promote EMPATTICS in relation to some of the many activities, venues and conferences. It is also possible for the project to get feedback from both civilian and professional participants during 2017.

France: There is a huge interest in Ile de France and France for the promotion of digital innovation in health. French government promotes the development of informatics in health trough the digital modernization of public and private health institutions and the development of regional HER solutions like "Territoire de soins numériques" project (TSN) mobilizing 80 million Euros and promotion of research and innovation in the public sectors.

At regional level the Ile de France health Agency is currently working with RESAH Ile de France in the promotion of Health innovation through PPI and PCP initiatives. For example, the RESAH participate to the TerriSanté project and a 2 Million Euros funds dedicated to innovative projects should be operationally managed by the RESAH

Competences and experience demonstrated by RESAH IdF in the development of PPI and PCP contracts are valuable assets to continue with the promotion of patient empowerment technologies in France. Ile de France cooperated in the development of European PCP tenders, through the RESAH, such as the Happi-project,[47] the INNOCAT project[48] and the INSPIRE network.[49]

Slovenia: SB-SG has been pioneering in the field of telemedicine introduction and provision in Slovenia beyond a piloting phase. CEZAR telemedicine centre at SB-SG has been investigating not only methods of service delivery to diabetic patients and patients with congestive heart failure but also means of incorporation of the new services into the existing healthcare processes in the hospital. Additionally, CEZAR has been preparing variety of financial models for the service reimbursement for equipment use, disposals (e.g. glucose tests strips), connectivity costs and the staff work compensation.

SB-SG, being an innovative public hospital, highly supports the mechanism of PCP and will promote it in Slovenia where it has not yet been in use. It will seek support to the approach not only at the Ministry of Health but also at other national institutions e.g. National Institute for Public Health, the state owned compulsory health insurance company, Health Insurance Institute of Slovenia (ZZZS), private insurance companies as Vzajemna, Triglav, Adriatic-Slovenia, and at regional levels at general and specialised hospitals e.g. Geriatric Clinics of Ljubljana, being part of the University Clinical Centre; Ljubljana (UKC LJ).

2. Impact

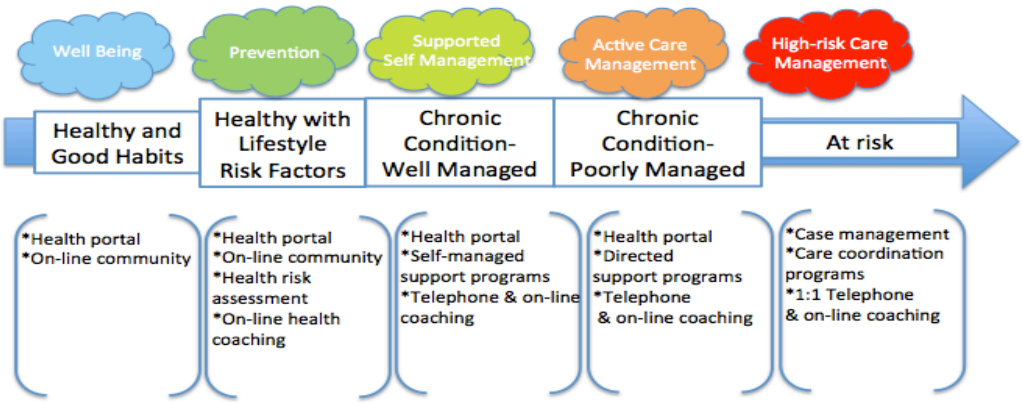
2.1. Expected impacts

The overarching strategy of EMPATTICS Project is to ensure the creation of tools that can be used by Buyers to an automatic, smart deliver self-management service that moves away from reactive, unplanned and episodic approach to care, and to create new community care systems that gives patients the most intensive care in the least intensive setting. Tools developed in EMPATTICS will be designed with the particular problems presented by lifestyle chronic diseases and the volumes of patients who might join such a service. EMPATTICS allows innovative European R&D companies to work alongside Buyers into which they will eventually sell services. Whilst the information tools design and R&D will belong with the SMEs, the services will be designed with Health Authorities and must provide a patient-centric service delivery with shared professional and patient roles. EMPATTICS will allow the creation of personalised self-management care plans that involve and that have been agreed by all

[47] http://www.happi-project.eu/
[48] http://www.sustainable-catering.eu/home/
[49] http://inspirecampus.eu/

clinical stakeholders. The developed tools must be appealing to GPs, their practice nurses and other community health and social care staff. The project must allow the R&D companies to create tools that provide a service that off-loads the oversight and disease management of LTC patients, to patients, but does not decrease the quality of care they receive.

EMPATTICS will promote the creation of tool sets for prepared proactive clinical teams that are multi-disciplinary and tasked and staffed to undertake chronic care in the community. The Project EMPATTICS will create technologies to help community based nurses, plan self-care with patients and to monitor the effects. Project EMPATTICS will encourage the creation of tools across the whole disease journey



EMPATTICS will encourage the creation of tools based on web and mobile technology to provide effective communication between clinicians and with patients. Mobile technologies allow new follow up processes that will improve the service efficiency and help EMPATTICS designed solutions, to cost effectively achieve a population scale.

EMPATTICS will therefore seek solutions that contain the following components:

- Population identification processes which identify the people who are good candidates for disease management intervention (Risk Strat tools)
- Evidence-based practice guidelines, decision support tools and patient care plans
- Collaborative clinical models involving GP's and providers of support services
- Patient self-management support including education, disease prevention, behaviour modification programmes, and compliance monitoring
- Enhanced protocols for post-discharge planning and follow up that allow care to transition from hospital to home, overseen by staff
- Service process and outcomes measurement, evaluation and management
- Routine reporting and feedback mechanism which includes communications to patients, GPs, Hospital Consultants as well as service Commissioners
- Services connected to a variety of EMR systems deployed at very different Euroepan test sites
- E-community services formed by chronic patients for better patient management

2.2. Measures to maximise impact

EMPATTICS buyers have already discussed various ways to promote the expected outcomes of the R&D funded through this PCP project. The detailed elements of this plan will be outlined as part of the dissemination and exploitation plans, as well as communication activities throughout the life of the EMPATTICS project.

2.2.1. Demand side measures to encourage wide deployment of solutions

2.2.1.1. Overview

EMPATTICS envisages two general categories of measures to encourage wide deployment of solutions:

Internal promotion of the Demand side. Internal discussions among Buyers have confirmed the intention of the participants to implement a new care model based on a more empowered patient that it's conscious of his disease and who has accepted the total control of his treatment. If the R&D proposed in this project demonstrates efficiency, we will deploy several measures to implement the outcomes of funded R&D:

1) All buyers are already moving funds "from acute care to long term care" and promoting policies that foster, preventing and patient empowerment solutions. Similar further policies in their regions should certainly contribute to the deployment of the more successful EMPATTICS technologies.
2) EMPATTICS buyers will incorporate clinicians, IT engineers and pharmacists in EMPATTICS Networking and Coordination activities. This strategy will serve to anticipate to key people and end users the benefits of EMPATTICS solutions. These Influencers in Buyer organisations will collaborate in the elaboration of internal EMPATTICS reports and they have already confirmed their collaboration in further dissemination activities if necessary.
3) Buyers with the capacity to determine new regional policies will force the adoption of the best technologies: EMPATTICS technologies will probably co-exist with current chronic disease protocols, hopping to become the standard in a short future. Some of the buyers (Consellería de Sanidade, SALUD and Region of Central Denmark) have already thought about the possibility of public co-funding of the final price if patients are the end consumer of the successful EMPATTICS technologies.
4) Buyers with the capacity to implement technologies at a hospital level will also force in their hospitals the introduction of the wining technologies. The results obtained in one hospital could later be transferable to other hospitals in the region or in the country. In previous conversations these buyers expect to foster the size of pool technologies and overcome with other hospitals in their regions/countries economy of scale issues of the most successful EMPATTICS technologies
5) Buyers also expect the establishment of reliable key performance indicators for better management of chronic patients and the publication of Annual figures reporting the main outcomes of the deployed technologies resulted from the EMPATTICS projects. This follow up will certainly serve to scale up the resulted technologies.

At the EMPATTICS consortium we also foresee several measures to implement external promotion of the Demand side.

1) The first measure will be implemented at the beginning of the project through the publication of a call targeted to other buyers outside the EMPATTICS consortium. The EMPATTICS consortium would like to increase the number of buyers. Buyers will contribute to co-finance the 30% of the PCP not covered by EC. This participation will give them some benefits like percentage of royalties or discount prices on future contracts. The final conditions for new buyers will be determined during the first months of the project.
2) EMPATTICS also consider the possibility of participation of other organisations not interested in co-financing the proposed R&D. These organisations could participate in some evaluation committees or during the definition phase increasing the market dimension and scope of the technologies to be developed during the EMPATTICS project.
3) At the end of the project, EMPATTICS buyers will also facilitate information to other buyers interested in the resulted technologies about the results and impact of the funded R&D. An appropriate monitoring system and reliable information about the impact of the resulted technologies (number of consults reduced, number of treatments reduced, etc) is essential to

facilitate the deployment of these technologies in other healthcare organisations outside the EMPATTICS consortium.

Besides the aforementioned measures, EMPATTICS universal challenge ensures that many healthcare organisations in Europe will have the same need and as such a great incitement to engage. Since the engagement is obvious most of the job to mobilise the demand side is about information, participation on conferences, participating in networking activities and marketing by telling about the solutions and what results the solutions are capable of delivering both economically and qualitatively. Information letters and leaflets will be produces just as the website will have all this content available to interested managers.

The ICT solutions that will be created build on a solid knowledgebase across different countries, cultures and how to do things.

EMPATTICS Buyers all participate with their different knowledge of the challenge and which solutions already exists and how they work. Buyers have different experiences which again will generate solutions that will be comprehensive according to the needs. This solid knowledge is of utmost importance in order to create new solutions that meet the common challenge in a new and more creative way..

Involvement of Patients in the project will create a second and strong demand side:

The healthcare sector experiences that patients have new demands as new consumer ICT solutions are growing and the access to information and knowledge is much easier for patients. At the same time the question of the patients bringing their own devices and how to handle this is important to incorporate in the solutions. Thanks to the methodologies and know-how of EHFF, EMPATTICS project intends to involve patients in the procurement process both in order to get their ideas and needs and to crate solutions that the patients like and demand. This will create a consumer (patients) demand from influential patient cooperation and organisations as for instance diabetes patient organisations that are quite influential politically in several countries. Furthermore they are very often capable of making their statements clear through the press as illness is very interesting in public relations.

The different regions in the Buyers Group have all a very positive back-up from the top management which is necessary when it comes to innovation but also to deployment. The common challenge is a heavy burden on the different regions both economically where it counts for a large proportion of the local healthcare budgets and in terms of resources where a lot of man power and hospital beds are spent on chronically ill patients. This ensures interest from decision makers who naturally must have foreseen budgets within this well-known and big challenge. At the same time Patients' organisations demand the possibility of self-management as do younger patients to whom ICT is a prerequisite.

The project managers from each region will make it a team focus on how best to influence the budgets in the different regions in order to make sure that the solutions will be deployed after the PCP. Therefore there will be exchanges of experiences of business cases, patient satisfaction reports, efficiency reports and they will be available to others outside the consortium.

The politicians will also be influenced and made aware of the new solutions by invitations to the politicians to talks and presentations. The Buyers will discuss how best to gain political influence so that there will come a political pressure on the administrators with regards to procurement and deployment.

2.2.1.2. Measurement

In order to maximise impacts of the PCP process, the introduction of KPIs is essential and control measures is essential for the management of the project EMPATTICS. EMPATTICS will work with a number of selection criteria that should be addressed in choosing the companies that are involved in the different PCP stages. Furthermore a number of evaluation criteria both quantitative and qualitative will be used as a protocol in testing the solutions and these will be known to the companies before one stage will start. The results of the tests will be crucial for the decisions related to the next PCP stage. Companies will know the expectations from the specific goals and they can focus their efforts which will create better improvements.

The criteria that will be used to qualify the companies that are chosen to participate are amongst others knowledge of the healthcare sector, experiences from working with the healthcare sector, experience with innovation projects, earlier successful innovation cases and references, examples of business cases from earlier work, experiences with working with innovation methods, experiences with working with patients as end-users etc.

The Key Performance Indicators used in the evaluation of the outcome of each PCP stage will comprehend ease of use, motivation created in the patients to actually use the solution, positive feedback from clinicians on the worthiness of the solution (for instance on a scale from 1 to 5 which will make et quantifiable), concrete tasks are moved from professional clinicians to patients, cost savings on tasks that are moved from professional clinicians to patients etc.

EMPATTICS will establish 2 groups of KPIs. **first group of KPIs** will be related to the monitoring and control of the EMPATTICS buyers project as a whole, with special emphasis in the evaluation of the different C&N activities that will end in the publication and execution of a successful PCP contract.

List of KPIs for monitoring the PCP contract
KPIS during the preparation of the PCP tender
Number of companies and/or people attending seminars and innovation conferences.
Number of companies/consortiums interested in joining the concept development.
Number of visits in the EMPATTICS buyers website
Number of contact emails requesting information about the PCP tender
Monthly Google Analytics report about the visualization of EMPATTICS buyers project key words
Number of potential buyers participating in the call for buyers
Number of references and quotations at national level related to EMPATTICS buyers N&C activities (workshops, technical dialogues, etc)
Number of references and quotations in twitter, linkedin and other social networks.
KPIs during the execution of the PCP tender
Number of companies that download tender documents
Number of companies that respond to the final tender.
Countries of origin of the companies that participate in the PCP tender
Number of questions raised about the PCP contract
days of delay for execution of phase 1
Days of delay for execution of phase 2
Days of delay for execution of phase 3
Complaints received about the PCP process
% of companies satisfaction score (it will be obtained through online tests)
% of buyers satisfaction score (it will be obtained through online tests)

The **second group of KPIs** will be more related to the execution of the R&D tasks that will be accomplished by companies. Buyers have already discussed some KPIs to monitor the development of R&D by companies but the final list of KPI will be defined during WP2 (consultations to patients, clinicians, hospitals, healthcare providers, researchers…) and WP3 (company engagement through technical dialogues with companies, company clusters, VC firms, etc)

List of KPIs for monitoring the PCP R&D
Medication adherence, using an appropriate adherence score (e.g Moriskyi)
% of Empowerment scale, through appropriate scale to measure disease-related psychosocial self-efficacy.
% of Disease knowledge of the selected chronic disease for test study
% of increase of self-care behaviours (diet, physical activity, blood sugar testing, and food care).
% of participation in disease debates in social networks
Saving costs for the Public health system (surgeries and visits to clinicians reduced, etc)
Number of regions that can participate as test sites with the technology
Detailed KPIs will be established during WP2 and WP3 to monitor the successful construction of technology prototype and technology valuation

2.2.1.3. Remove barriers

EMPATTICS aims the creation of innovative but generic solutions that can easily be adopted in several European countries. EMPATTICS strategy is therefore based on the development of a multidiseases platform that can be adapted to the different health environments, and especially to different EMRs.

In order to create innovative but generic solutions that aim to penetrate a wider market there will be offered training and marketing activities in several countries throughout Europe. The goal is to involve and create awareness, and get into dialogue and activate clinicians and executives in the healthcare sector in order to create a demand side.

EMPATTICS Buyers will work together on removing barriers for a wider market introduction and this will be discussed at joint meetings in order to get ideas from one another, but also to make joint efforts towards policy makers both regional, national and in EU. Time to market is often very long within healthcare industry because evidence is needed. Therefore the protocol for the test results is important because it must provide evidence for the outcome of the solutions. Much effort will be put on the protocol that is absolutely central for a wider market introduction. It will be publicized and used in conferences and networking activities throughout Europe.

Besides good test results, there will be produced a number of use cases that will explain and describe how the solutions have been used, what were the results, good advice on implementation based on experiences etc.

The interoperability of the solutions will be secured by involving ICT architects from different countries in each PCP phase so that they can give their inputs to selection criteria. The ICT architects cooperate across countries to make a joint contribution that can be used anywhere. Also the architects will work with the companies along the process in order to get the ICT architecture on the right tracks. International ICT standards will be one of the answers to interoperability and coherence. After the third stage the ICT architects will produce a document on the experiences containing advice on standards, architecture, coherence to existing ICT systems etc. This can be used directly by ICT departments throughout Europe but it can also be used to influence national and EU bodies of decision makers.

The EMPATTICS consortium has planned several C&N activities that will contribute to the full deployment of technologies across Europe:

1) Buyers will provide to companies technical specifications and ICT compliance. The high diversity regarding ICT deployment within the consortium is a good example of the European diversity.

2) Buyers will also participate in the validation of technologies (Phase 3 of the PCP contract) as test sites. Companies will therefore validate their technologies in close contact with technicians, improving their developments in a real co-design and co-production scenarios

3) Buyers will be confronted to patients from very different European regions. Habits, diets and cultural behaviours are very different in Paris (France), Slovenia, Denmark and Aragon or Galicia in Spain. Companies will test their technologies with very different patients target groups. This is an unique “advantage” of the joint PCP

4) Companies will be also challenged to the different cultural environment of the different regions. The level of ICT knowledge and deployment in Paris is very different from Slovenia. The aged and dispersed population of Galicia is very different from the Denmark or Aragon. Companies will have also to deal with different languages, different regulations, different markets, etc

5) During WP2, WP3 and WP5 EMPATTICS buyers will also support companies to obtain certifications and standards to facilitate commercialization across Europe. The role of Health Technology Assessment Organisations is very important in this point. AVALIA-T, the Health Technology Assessment Agency of the lead Procurer (Consellería de Sanidade), will collaborate with companies in the evaluation and recommendations at European level of the standards required for their technologies. This support will certainly accelerate market penetration of the EMPATTICS successful technologies across Europe.

2.2.1.4. Optimising results

During the project period many lessons will be learned and the importance on learning right from the beginning. For instance it will be effectuated in the form of writing summaries after meetings and networking activities. And it will be organized with someone in the project organisation who will be held responsible for the learning throughout the project. Focused activities on learning will be held in order to make tacit knowledge into explicit knowledge. Otherwise it cannot be spread for further use.

The results obtained during the project will be publicized on different levels in order to reach different groups. The groups comprise healthcare managers, healthcare professionals, politicians, patients and relatives. The different groups will be reached through different media (including conferences, networking, social media) and with different means. A marketing and media plan will be produced in cooperation within the consortium. The table shows just the top level of this.

Group	Media
Healtcare managers	At the strategic level the interest is on efficiency and quality and not so much on the ICT solutions themselves. Executive summaries will be produced and press releases will be published to create awareness. Documents that address the strategic level will be produced and distributed. They will also be published on websites and linked-in.
Healthcare professionals	At this tactical level the pressure is on making an effective operation so this will be addressed through journals and on-line media.
Politicians	At the political level the interested is both on "what can we do for the citizens" in order to attract votes but also on economy/budgets. So there will be at least to angles in attracting politicians' interests. Media is primarily meetings, conferences, twitter and networking activities.
Patients and relatives	At the patients and relatives level the focus is on what they can achieve from self-management through using the new ICT solutions. Media is on-line media as facebook and internet websites. Communication with patients also includes associations. EHHF(partner of the EMPATTICS have broad experience in communication with patients, bringing to the consortium an real value for companies and patients)
VC Firms	We will also incorporate the lessons of the INSPIRE project trying to propose and develop specific actions for VC/ investors engagement. This group of activities can help companies in their future growth and should certainly help us to understand the industry and to develop IPR policies accordingly.
Company clusters and Associations	We also want to disseminate the benefits of PCOP among companies. Based on the experience of Consellería de Sanidade. The strategic use of PCP can easily be accomplished through appropriate dissemination through cluster and company associations. Besides this dissemination is carried out in a transparent and open format, fostering rivalry and competition among companies.

EMPATTICS aims to become a successful Europe's health collaboration setting an example in new types of procurement carried out by organisations from different EU Member States. Appropriate dissemination with private organisations like M&SAATCHI and EHFF will certainly guarantee the expected dissemination of project results. A final Conference for the dissemination of project results and lessons learn will be held at the end of the project. Potential Conference venues are Brussels, Madrid or Paris.

2.2.2. Measures to encourage wide exploitation of results by the supply side

2.2.2.1. Intellectual Property Rights approach

The management of Intellectual Property Rights (IPR) in health is complex and the EMPATTICS consortium understands that Intellectual Property Rights are a key aspect of the PCP contract and of the EMPATTICS project success as a whole. In the area of health, developers must integrate existing and new technologies. R&D. IPR scope and definition is usually complicated and particularly in large ambitious health platforms like the proposed by the EMPATTICS health challenge. In order to avoid conflicts, questions and misunderstandings both on the demand and supply sides, EMPATTICS proposes a clear and simple framework for the management of IPRs.

All buyers agree that the IPR resulted of this project should belong to the companies that participate in the tender and develop the technologies. As private organisations created to commercialize products, companies have more capacity to exploit funded IPR. The organisations that compose EMPATTICS buyers Buyer's group don't want to compete with companies. EMPATTICS buyers are very much concerned with the promotion of technologies to cover their assistance needs and to manage their patient's. They are interested in co-design technologies and services that offer better cos-efficiency performance. But EMPATTICS Buyers don't want to sell or exploit IPRs results. Commercialization is out of its "core business". Therefore Intellectual and industrial property rights related to the goods and

services developed under the PCP contract will belong to companies. In other words, the exercise of the rights of use, reproduction, distribution, and transformation will belong exclusively to the company which wins the tender

At the same time, all buyers agree that the PCP contract should avoid monopolies, guarantee the use of the funded R&D services by other EU public authorities and foster wide exploitation of the developed technologies for the benefit of patients across Europe.

With these basic principles and taking advantages of the wide experience of the Lead procurer in the management of IPR rights (more than 25 PCP/PPI tenders published during 2011-2014), EMPATTICS proposes the following IPR management approach:

1. The exercise of the rights of use, reproduction, distribution, and transformation will belong exclusively to the company which wins the tender.
2. Winning companies will offer rights to all members of EMPATTICS buyers group to use the funded IPRs on a non-exclusive basis
3. Winning companies will assume all costs related to the registration and exploitation as well as all responsibilities resulted of technology exploitation.
4. The PCP contract will include a a call-back provision to ensure that the funded IPRs could return back to EMPATTICS Buyer's if the companies that do not succeed in the exploitation phase do not execute this task with enough efforts or exploit funded IPR against general public interest.
5. IPR evaluation in health might also be a complex task since it is difficult to estimate the value of a potential market deployment of the technologies demanded by EMPATTICS. Therefore, the PCP contract will include a clause to stipulate a royalty payment. Companies will have to offer Buyers group a percentage of participation in the future commercialisation benefits resulted from funded IPR.
6. IP generated during the project shall be isolated from the IP held by the company (or the buyer) before the start of the project. Companies will disclose all background intellectual property rights of which it is aware which are required to implement the proposed solution (background knowledge). Existing IPRs which are not funded by the PCP project must be also licensed to the Buyer's group on terms which enable them to be used in the same way as the Funded IPRs.
7. The EMPATTICS consortium will carry out patent searches and the evaluation of existing IP on know how related to the background knowledge proposed by the companies. The consortium will use technology software tools or consultants to verify free use of the background knowledge to implement the proposed solution.

The following table explain the main aspects of the management of IPR funds by EMPATTICS:

Question	Answer	Rationale
Who will be the owner of funded IPR?	Companies	Companies have more capacity to exploit funded IPR
Will buyers have future access to the new technologies?	Yes, they a non-exclusive license from companies	PCP implies a risk- and benefits for buyers and developers
Will you include a call back provision of the funded IPR?	Yes	We are looking for the benefits of patients, an the protection of general public interest. Based on Lead Procurer experience the call back provision could be stipulated in 5 years.
There are economic risks for buyers but what about the expected benefits?	Evaluation of of health technologies is complex and royalties seem the fairest concept to provide benefits.	Companies must assume that PCP is not a grant agreement or subsidy. They are in a contract for R&D services with shared risks and benefits. Initially companies should pay a royalty if there is any commercial use of funded IPR. Royalties will be decided by each company within some limits imposed by EMPATTICS. The royalty is calculated on % of the revenue (exclusive of tax) received by the beneficiary of the contract, after deduction of the costs of production and marketing.
Will Royalties reduce the attractiveness of the PCP contract?	No	According to EU law, we must guarantee that the PCP includes shared risks and benefits. According to Lead procurer experience (more than 25 PPI/PCP tenders managed in 3 years), Big multinationals, SMEs, start-ups, etc understands and accepts royalties.
Will royalties limit the evolution & natural growth of companies?	No	The PCP contract will include an amount to get liberated of future royalty payment. The exact amount will be decided in WP2 after debates with companies, clusters, VCs, etc.
How will you ensure that companies duly inform about their background knowledge?	Through the PCP contract	As part of the Invitation to Tender requirements, there will be an obligation on the entrant to disclose all background intellectual property rights of which it is aware which are required to implement the proposed solution. This includes third party intellectual property needed before the solution can be implemented. In this regard the EMPATTICS will use innovation tools and databases such as Goldfire InnovatorTM to carry out substantial patent searches on related know-how.

As it was stated before, IP management is complex. Although the lead procurers have demonstrated substantial experience on the management of funded IPR or resulted from Public Procurement of Innovations, it is always convenient to adapt the clauses and obligations included in the PCP contract to the health challenge an expected technology that will solve the problem.

The EMPATTICS consortium will address and discus the main clauses in WP-2 and WP-3. Discussions will involve buyers, a variety of companies (Multinationals, SMES, start-ups), Companies cluster, companies associations, VC firms, angel investors, etc. the combined vision of key aspects like percentage of royalties, liberation payments, etc, will be reflected in the final document. This strategy should ensure enough attractiveness in the PCP contract guaranteeing competition and final project success.

2.2.2.2. First customer reference

From the very beginning the EMPATTICS consortium understood the importance of the collaboration with companies: all buyers accepted their inclusion in the project as a first customer reference of the developed solutions. We are conscious that for many companies, especially for SMEs, the existence of very diverse first customer references is essential to gain international leadership in new markets.

EMPATTICS consortium provides at least five customer references: Consellería de Sanidade, GCS D-SISIF, the Central Denmark Region, SALUD-Aragon and General hospital Slovenj Gradec (SB-SG).

All EMPATTICS Buyyers will participate in the test and monitoring studies of PCP phase 3.In this phase the first prototypes will be tested in real clinical environments and with real patient cohorts. Companies will have in their marketing materials customer references from highly diverse organisations: a healthcare provider that works in one of the European region with higher aged population (Consellería de Sanidade), an institution that operates in Paris, one of the biggest and most dynamic European cities (GCS D-SISIF), an organisation that works in one of the regions with the highest innovation performance indicators in Europe (Central Denmark Region), a region that is transforming its entire health system SALUD-Aragon and finally one of the biggest Hospitals in eastern Europe (General hospital Slovenj Gradec (SB-SG)).

The EMPATTICS consortium will of course work on the participation of more organisations in the buyers group. Potential buyers in Limoges (France) and the UK have already demonstrated their interest if the project is finally granted. The five current sites can be already consider as excellent references to exploit and deploy the technology across Europe but the consortium is aware of the value of credible reference customer for companies and it will select additional sites accordingly.

2.2.2.3. Encourage Interest

In order to encourage interest and involvement from the industry to the PCP both WP3 and WP6 will have activities. The activities will comprehend both a wider and open/indirectly marketing approach to reach the companies that we do not know but also a directly marketing approach based on the analysis of the relevant stakeholders.

The wider approach will mainly be based on on-line media such as lined-in, twitter and web pages. The direct approach will be invitations to companies to attend workshops and meetings.

The messages and the dialogue to the market are about what they will gain from the PCP. First of all they will be told that there is a need already for the solutions so that we are talking about demand driven innovation that will be followed by procurement if the right solutions are developed. The market size will be demonstrated. Next there will be the possibility to discuss the PCP process at workshops at least in Denmark, Spain, Slovenia and France in order to demystify PCP but also to get feedback on the expected processes from the industry and finally to motivate the involvement from companies. In these workshops the benefit from joining the PCP will be communicated; lots of feedback from the relevant customer group, the companies will get a lot of information that can be used in product development in general, they will get a new network and direct access to the clinic and they will be compensated for their development costs. Third there will be held meetings in Denmark, Spain, Slovenia and France with companies that the project team find interesting and who have a product portfolio and competences within the wanted areas. Finally there will be a conference in Denmark, Spain, Slovenia and France where companies will meet patient organisations, clinicians and hospital managers that will tell about the needs for new solutions. There will be the possibility to ask questions to a panel consisting of both patient organisations and clinicians/hospital managers. If companies have any questions and ideas after this that they will like to discuss a telephone and email hotline will be established in a limited period.

Companies should understand the unique opportunity that offers the EMPATTICS consortium. EMPATTICS challenge is not only to assure financial returns through R&D funded PCP at market prices but also shift companies output and social development through an outstanding set of Networking and

Coordination activities facilitating the establishment of joint ventures with other industrial partners, relations with investors and VC firms, access to different EMR systems, etc.

2.2.3. Communication activities and dissemination of results

The successful dissemination and exploitation of project results in terms of sustainable use and impact of outcomes, especially after the development and testing implementation of the outputs has ended, is very dependent upon a number of crucial key factors and criteria, which are the basis for a successful communication strategy. From our experiences (M&SAATCHI specialist in dissemination) we consider the following key factors to be relevant:

a) **Output quality:** To achieve a high degree of valorisation and use, the outputs produced need to be of a very high quality. It is important to pay considerable attention to the output quality during the entire project development, and therefore it is always advisable to introduce procedures and responsibilities for quality management in project processes in order to guarantee a high quality final output. Outputs must be up to date and appealing to the customers otherwise dissemination and further use cannot be expected.
b) **Adaptability of outputs to country and organisation specific circumstances:** From our point of view it is an important precondition that the results and outputs of the project are adaptable to a high degree in relation to the circumstances of different countries, systems and industry/SMEs. This is particularly important as the developed materials and approaches should be relevant to different types of organizations and target groups.
c) **Clear definition of advantages for users:** A high degree of use is, in our opinion, mainly dependent on the capacity of the project and the partnership to clearly show the advantages of using the instruments and outputs for the final target group. For this reason all partner institutions should always try to make the advantages of the project and its results transparent and evident, in relation to all events and possibilities. In particular the project website should make very clear what the added value of the output is and its use to the potential customer.
d) **Early identification of stakeholders and potential users:** It is vital that relevant stakeholders and potential users (customers) of the project results are clearly identified and defined very early in the project's life. It is not advisable to change user groups during the project process. Identified stakeholders should be contacted and kept informed throughout the whole project process so as to ensure the sustainable use of results after the project ends. Thereby, the focus should not only be in involving them in the activities but to engage them on a long-term perspective.

By considering these preconditions in all working phases the aim of the entire communication plan is:

- To promote and raise awareness with regard to the project contents and developments –self management for patients as holistic innovative ICT solution and PCP as appropriate method
- To provide information on the quality, relevance and effectiveness of the results
- To successfully transfer the results to appropriate decision-makers in order to achieve their sustainable promotion and support
- To convince individual end-users to adopt and/or apply the results after the project has ended.

In general the dissemination approach provided by M&SAATCHI. is built on two dimensions.

Horizontal dimension

The horizontal dimension contains all activities to strengthen the communication and dissemination between the project partners. This includes all internal activities to provide information and instruments for further individual dissemination of each partner. This is considered as especially important because not all partners are involved in all activities at the same level. Therefore, the internal communication process needs to ensure that all participants are continuously up to date with the project's process and activities. Only then, the partners in the individual countries can successfully implement dissemination activities at all levels (local, regional, national, EU and international) The project coordinator together

with M&SAATCHI carries the main responsibility for the horizontal dimension but also the project partners are requested to actively take part in these processes.

Vertical dimension

The vertical dimension concentrates on all activities designed to actually reach the target groups and final users. This includes all activities that will be carried out individually by each partner such as the involvement of their own partners, networks and stakeholders and the implementation of the individual dissemination activities. M&SAATCHI is also responsible for the vertical dimension in terms of providing concepts, encouraging and controlling the activities, although the actual success is very much dependent upon the support and cooperation of the project partners.

Both the horizontal as well as the vertical dimension will be carried out by using different approaches, methods and instruments of dissemination, always dependent upon the most adequate means and possibilities of each project partner.

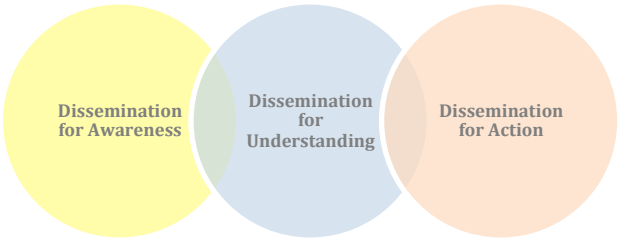
Basically, they can be structured as follows:

- **Face-to-face activities**
  Presentations, round tables, workshops, seminars, conference …
- **Internet-based activities**
- **Paper-based**
- **Media-based**
- **Promotional products**
- **Project activities** (pilot implementation, testing phases, evaluation, surveys, focus groups, workshops, seminars…)

The dissemination WP and concept runs parallel to all other phases of the work programme and is specifically adjusted according to the main activities of each phase. Thereby the main focus is to ensure that all outcomes/instruments reach the right target audiences in a format and at a time, that provides greatest benefit.

Dissemination concept

The dissemination approach is built on 3 phases that are closely linked with the other WPs of the project. As dissemination is a process running during the entire project period those phases are not to be completed and the next one is starting. There is always an overlapping period from one phase to the next one. Therefore, the correlation concerning the time schedule can only be seen as orientation according to the time schedule of other WPs.



Dissemination for awareness

Main activities:

- Identification of dissemination channels in each partner country and at EU and the international level
- Identification of stakeholder profiles
- Set up of dissemination and exploitation strategy
- Set up of social media strategy

- Set up of project website
- Production of first dissemination material
- First involvement of stakeholders and target groups

When? M 1-7 closely linked with activities of WP2

Why? To raise awareness on the project itself in a first step and in a second step on the PCP method and the state of the art versus needs of the use of ICT based self-management tools for patients. To "prepare the soil" for next activities.

What? The project and its activities, the partnership, the funding programme, the PCP method, self-management tools for patients as innovative ICT solution

Who to disseminate to? TG1) procurers: political actors, public funding authorities **TG2)** suppliers: Industry/ SMEs**TG3)** Healthcare professionals **TG4)** patients, relatives **TG5)** broad public involved in the sector

Who will do it? All partners

How? project website, press release, set up of social media profiles, newsletters

Dissemination for understanding

Main activities:

- Direct contact with stakeholders in face-to-face meetings ("from involvement to engagement")
- Organisation of local stakeholder meetings with press conference
- Intensive presence in print and online media at local and EU/international level
- Enlargement and update of dissemination strategy at national and EU levels ((internal evaluation of possible improvements or adaptations)
- Enlargement and update of social media presence (internal evaluation of possible improvements or adaptations)

When? Months 6-25, closely linked with the activities of WP3 – PCP Training and Industry dialogues, WP5 – PCP execution and monitoring

Phase 1: Months 4-8 focus on WP3

Phase 2: Months 8-25: focus on WP4 and WP5

Why? To promote the European call and all 3 phases, to promote pilot testings, to recruit participants, to engage stakeholders

What? The outcomes of WP2, the European call, the test series, (additionally ongoing promotion of the partnership, the funding programme, the PCP method, self-management patients' tools as innovative ICT solution)

Who to disseminate to?

Phase 1: focus on TG1,2) procurers, Industry/ SME

Phase 2: focus on TG3,4,5) Healthcare professionals, patients, relatives, broad public involved in sector

Who will do it? All partners

How? Articles, local stakeholder meetings combined with press conference, seminars, webinars, information events, project website, social media

Dissemination for action

Main activities:

- Organisation of final conferences with press conference
- Intensive presence in print and online media at local and EU/international level
- Update of dissemination strategy at national and EU levels with regards to "after funding period" (internal evaluation of improvements and adaptations, incl. issues of maintenance, partners activities and plans)
- Update of social media presence and strategy with regards to "after funding period" (internal evaluation of improvements and adaptations, incl. issues of maintenance, partners activities and plans)

When? Months 25-36, closely linked with the activities of WP5 – PCP execution and monitoring **Why?** To present final products, to set concrete steps for exploitation, to convince stakeholders, to reach out to a broader field in ICT and healthcare systems at the European level (additionally ongoing promotion of the partnership, the funding programme, the PCP method, patients' self-management tools as innovative ICT solution)

What? Digital solutions based on outcomes of test series, PCP strategy for public purchasers

Who to disseminate to? Focus on stakeholders and TG1 (possible purchasers such as municipalities, local/reg./national authorities, ministries; decision-makers, politicians, EC) and TG3,4,5) ICT solution schools, teachers, head teachers and teacher education, also TG2) suppliers in related fields

Who will do it? All partners

How? Final conferences in different partner countries (Brussels, Madrid or Paris) with press conference

Overall activities:

- The project will develop its own branding in form of a corporate identity used for all public outcomes. The outcomes will not only follow the own CI but also the requirements of the funding programme in form of disclaimers, logos and further guidelines.
- A continuous enlargement of stakeholders will be undertaken during the entire project period.
- During all activities a clear process of monitoring, reporting will be established from the beginning on. The system is based on national reports by each partner and will be summarised and analysed for interim and final reports.
- The direct interaction with all TGs and stakeholders will focus on active engagement. Thereby, the collection of feedback as well as exchange and interaction via social media is considered as important outcome of the activities.
- The reporting of dissemination activities will also include the documentation of dissemination activities.

2.2.4. Policy-makers and legal stakeholders

Regional, national and international policy makers, health administrators and legal experts in Europe represent a key target audience for the project, and will be reached through formal and informal outreach and presentations in a number European projects Consortium members participate, including and others. Additional channels include the European Connected Health Alliance (which convenes various local mHealth ecosystems for exchange of experience) and the on-going procurement projects at the EU and national levels.

Concerning the removal of barriers the consortium will engage in on-going actions oriented to procurement, legal and other experts in other countries to promote best practices and standards on:

1. Joint regulatory action phases/actions
2. Contribution to standardisation
3. Appropriate consultation of stakeholders (e.g. experts in industrial protection and IPR rights between purchasers and companies participating in the PCP)

2.2.5. Clustering

We propose "Clustering" activities with the following relevant EC projects to exchange knowledge and networking. This will include engaging with PCP projects that were funded in previous rounds (such as SILVER), as well as any projects that are successful under PHC27.

2.2.6. Other channels of dissemination

We will increase the impact of the project with different instruments:

1. Through certification of the solutions concerning interoperability and the eventual needed extension of the profiles once the project prototype is accepted.
2. Through certification of the implied devices in delivering the services requested in the PCP which are needed to communicate with the mobile such as glucometers, which should be compliant with relevant EU and regional guidelines.
3. Through the dissemination channels of industry organisations which operate internationally, and have members dedicated to mhealth and self-care.

The industrial/commercial involvement to ensure wide exploitation of the results is guaranteed making the public call accessible to all sector SMEs in the participating regions and through all newsletters and webinars. We will also engage with the large operators in Europe all work with local integrators that almost always are SMEs. The opportunity of involving SMEs has been considered via the following channels:

- Certified SMEs which are already providers to local health economies in France, Spain and Demark will receive a communication and notice in the related websites as well as Journals or other publications
- The associated companies industry associations will receive the respective notifications (newsletters and websites)
- The usual channels that the operators have over Europe, and for which we will design an agreed formal communication of the project simultaneously when the PCP notice is published

2.2.7. Appropriate consultation of stakeholders and ensuring industrial/commercial involvement for a wide exploitation of the results

The goal is to be very open and concrete about what the companies can gain from a PCP process and what conditions must be met in order to be able to have a PCP process. The stakeholders will be told about the advantages in joining the PCP in several ways – through websites, workshops, meetings and conferences.

Any company who joins a PCP will get insight into concrete needs in the public sector that is expected to be met my new ICT solutions. These needs are international needs as France, Spain and Denmark all together have the same needs which makes a very large potential market. So there will be an access to needs that are generally known throughout Europe. These needs will be specified throughout the process and any questions and ideas that any of the companies must have can be discussed both with patient organisations (and "test" patients), clinicians and healthcare managers. This will give the industry even more insight and there will often be a spillover of knowledge to other areas if the companies are creative and good listeners and are capable of changing the information into needs and solutions. This change can be discussed with the project managers and at workhops with Buyers.

Beside insight into the need the companies will be able to get insight into another market. For instance a Spanish company that are well known in Spain for good solutions will get insight into the French and

Danish market. How they operate and how they thing and what sales arguments can be used in those market also what systems they use already.

Networking is a third valuable advantage the companies. Companies will meet new people with all sorts of responsibilities and positions in the healthcare sector. This network can be incredible valuable in future operation.

A final advantage that the companies will get is knowledge of PCP in general and this can be used also in future projects.

The advantages will be described in use cases in order to make them more tangible.

The commercial involvement can only be assured if the Public sector first adopts willingly the developed solution, and once the industrial sectors willingly starts not from scratch but with a MoU among competitors. This will be a key element of the Competitive Dialogue lead in Work Package 4.

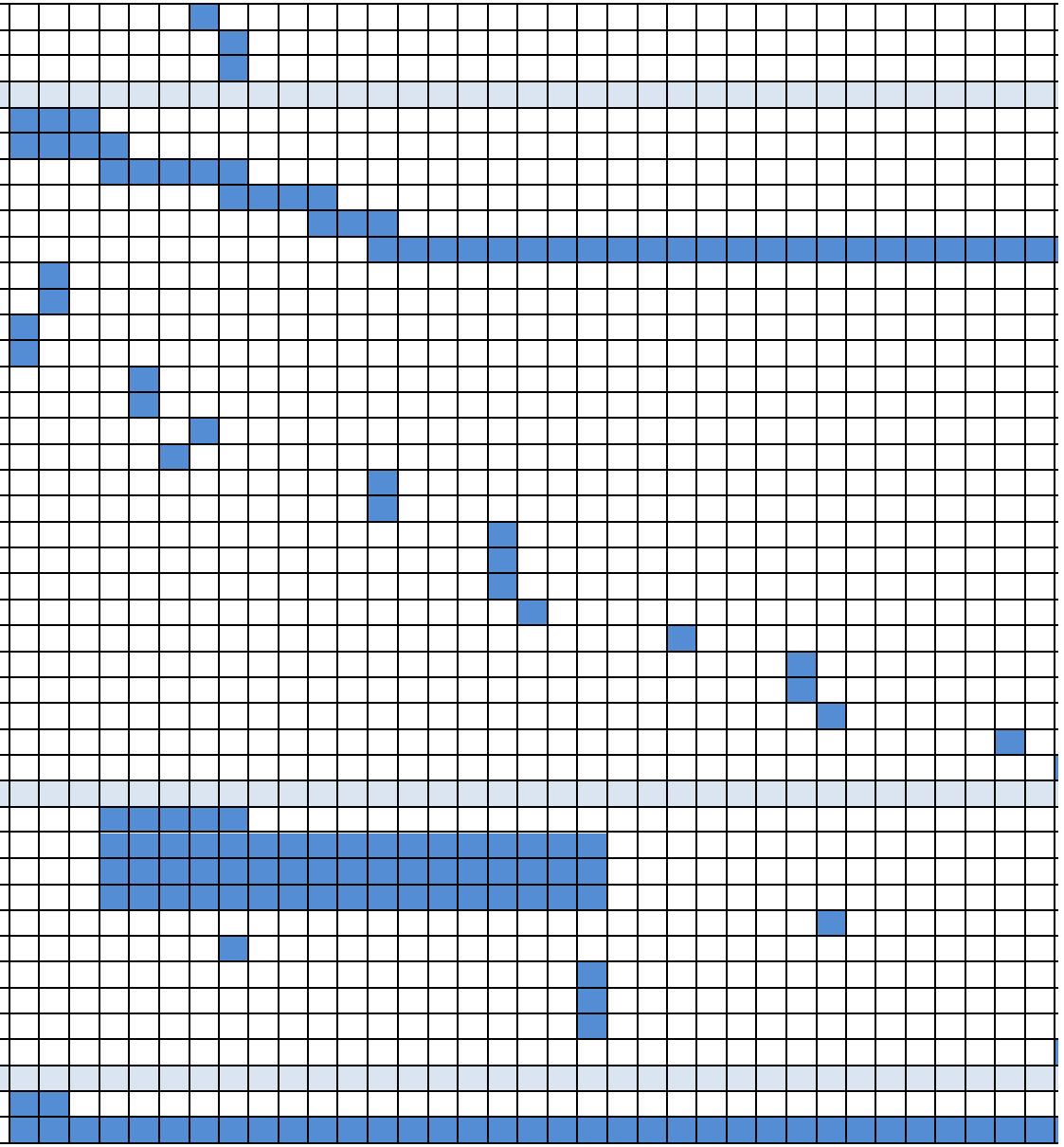
In this way we expect that this public pre-commercial procurement of R&D services that have the objective to develop breakthrough solutions for public sector problems for which there are no solutions can reach local and global SMEs of the ICT sector.

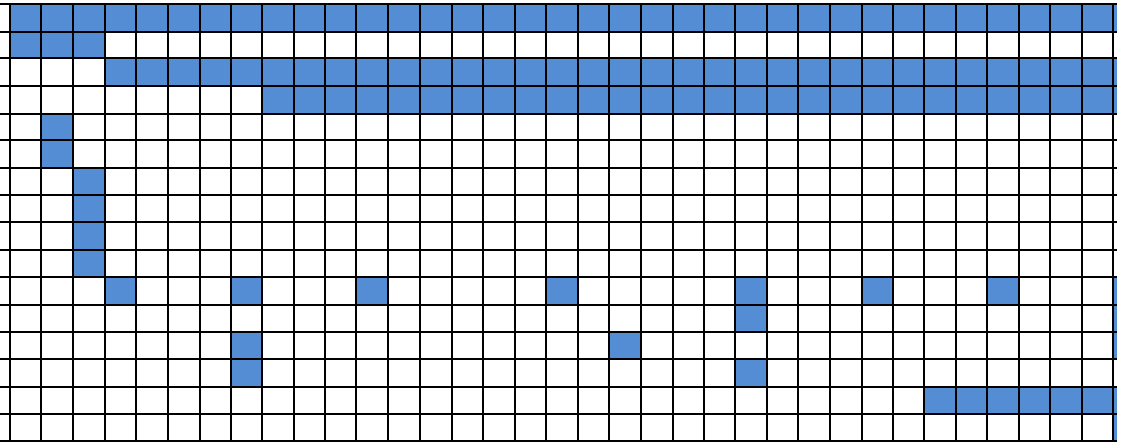
3. Implementation

3.1. Project plan

3.1.1. Graphical representation of work package

		Month																																		
		Year 1												Year 2												Year 3											
Nr		1	2	3	4	5	6	7	8	9	10	11	1	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
WP1	**Project Management, Financial Coordination and Quality Assurance**																																			
Task 1.1	Consortium management/project Office																																			
Task 1.2	Financial and administrative co-ordination																																			
Task 1.3	Quality assurance, risk management analysis and evaluation methodology																																			
D1.1	Project management plan																																			
D1.2	Joint procurement agreement, commitment on availability resources																																			
D1.3	Project quality assurance plan																																			
D1.4	Gender action plan																																			
D1.5	Evaluation plan																																			
D1.6	Internal website and communication protocols																																			
D1.7	First periodic report																																			
D1.8	Trial protocols																																			
D1.9	Partner meetings																																			
D1.10	Progress reports																																			
D1.11	Final report																																			
WP2	**Reviewing evidence base and supply-side status and identifying buyer needs**																																			
Task 2.1	Review of evidence and existing EU projects																																			
Task 2.2	Analysis of joint health and care needs																																			
Task 2.3	Identification of initial key areas of interest																																			
Task 2.4	Market scope																																			
Task 2.5	Gap Analysis																																			
Task 2.6	Report																																			
D2.1	Interim report on the scientific evidence																																			
D2.2	Interim report on the regional context and the strategic needs analysis																																			
D2.3	Interim report on the market scope on tools, practices and ICT solutions																																			
D2.4	Final WP2 report																																			
WP3	**PCP training and Industry dialogues**																																			
Task 3.1	Open Challenge/technical dialogues with the Market																																			
D3.1	Map of potential companies and networks																																			
D3.2	Information material (guidelines, previous PCP cases, website) to companies & public procurers																																			
D3.3	Newsletters																																			
D3.4	Workshops																																			

D3.5	PCP conferences with 150 attendees and 30 companies interested in joining the PCP process	
D3.6	Internal guidelines	
D3.7	Press-releases	
WP4	**Contract Implementation**	
Task 4.1	Publication of an Open Call for expression of interest to include new Buyers in the EMPATTICS Buyers Group	
Task 4.2	PCP design phase	
Task 4.3	PCP Planning and set-up of the framework	
Task 4.4	Publication of the PCP Contract and related dissemination activities	
Task 4.5	Evaluation of proposals	
Task 4.6	Administration of the contracts	
D4.1	Call of Expression of Interest for new Buyers	
D4.2	Action plan for PCP execution	
D4.3	Five Committees of Regional Experts (CRE)	
D4.4	Buyers Evaluation Board (BEB)	
D4.5	Evaluation Guidelines to be followed by CREs and BEB	
D4.6	Short report describing the support of Buyers for technology take-up	
D4.7	FAQs report about the use of PCP	
D4.8	Tender specifications document	
D4.9	PCP evaluation tenders report Phase 1	
D4.10	Up to 10 contracts phase 1	
D4.11	Updated Technology description and solution design reports up to 10 offers at the end	
D4.12	Updated Commercialization and Impact plan up to 10 offers Phase 1	
D4.13	PCP evaluation tenders report Phase 2	
D4.14	Up to 5 contracts phase 2	
D4.15	Up to 5 Authorizations Ethics committee & others applicable requirements to initiate	
D4.16	Up to 5 organisational plan and 5 developed/tested prototypes for Phase 3	
D4.17	PCP evaluation tenders report Phase 3	
D4.18	Up to 3 contracts phase 3	
D4.19/D4.20	Up to 3 Organisational plan for Phase 3/ Report from suppiers	
D4.21	Up to Impact and comparison report of Phase 3 results	
WP5	**PCP test sites and Technology validation**	
Task 5.1	Phase 3-test sites and technology Monitoring Preparatory stage	
Task 5.2	Definition studies for evaluation of Clinial effectiveness	
Task 5.3	Definition studies for evaluation of Patient and Clinician perspectives	
Task 5.4	Definition studies for evaluation of Economic Aspects	
Task 5.5	Training companies on MAST methodology	
D5.1	Phase 3 preparatory report	
D5.2	Definition case for evaluation of Clinical effectiveness	
D5.3	Definition case for evaluation of Patient and Clinician perspectives	
D5.4	Definition case for evaluation of Economic Aspects	
D5.5	Phase 3 final report	
WP6	**Communication, exploitation and dissemination of the results**	
Task 6.1	Dissemination and exploitation strategies	
Task 6.2	Digital, Social Media and Web Strategy	

Task 6.3	Stakeholder analysis and management	
Task 6.4	Marketing Material and Publications	
Task 6.5	Meetings and Conferences	
Task 6.6	Dissemination reporting	
D6.1	Dissemination and exploitation strategies	
D6.2	Project logo and website	
D6.3	Social media strategy and profile	
D6.4	Stakeholder analysis	
D6.5	Stakeholder Relationship Management tool/list	
D6.6	Marketing material for print and online (brochures, newsletters, articles)	
D6.7	Meeting with local stakeholders in each region	
D6.8	Publications for academic journals	
D6.9	Conference papers	
D6.10	Dissemination and exploitation interim reports	
D6.11	Final conferences	
D6.12	Final report dissemination	

3.2. Management structure and decision making procedures

3.2.1. Critical risks for implementation

Project risk is primarily a management responsibility. Project risk includes constraints, external interfaces, supplier relationships, or contract restrictions. Other examples are unresponsive vendors and lack of organisational support. Perceived lack of control over the projects external dependencies makes project risk difficult to manage PCP part of EMPATTIC – includes both management and technical work procedures.

Financial risks
Public procurers from our buyers group are committed to finance 30% of the PCP part of the project. This sum is divided among the buyers. The amount of money involves a risk for each public procurer as no guarantee of successful product is stated. If one public procurer leaves the consortium, the amount of contribution increases for the rest of the partners. A contract will be made in order to allow more public procurers take part in PCP of ICT solution once project is started. For example there is an interest from Luxemburg to take part in developing the product.

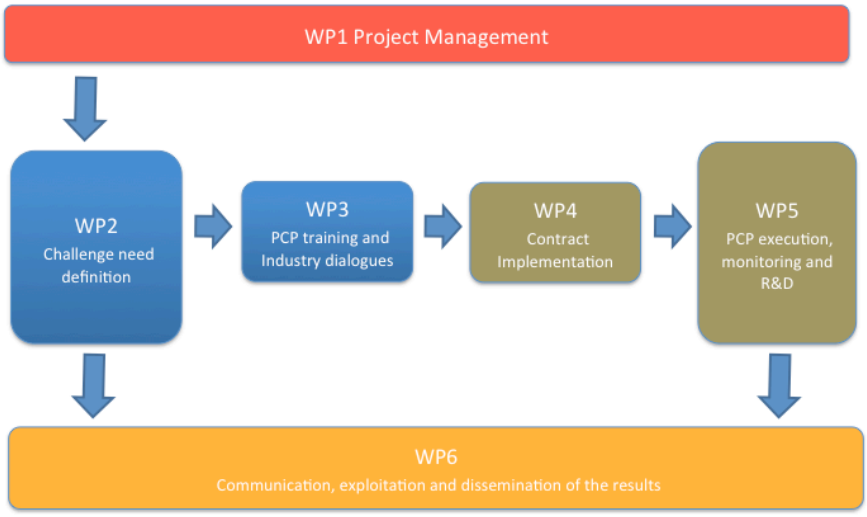
Management procedures
In the management procedures, there is risk in activities such as planning, staffing, tracking, quality assurance and configuration management. This will be managed by Contract manager and Project manager.

Technical work procedures
In technical procedures, risk is found in engineering activities, design, programming, and testing. Planning is the management process most often found in risk assessments.

Product Risk
This part contains intermediate and final work product characteristics. Risk will be found in the stability of the requirements, design performance, software complexity, and test specifications. Because the system requirements are often perceived as flexible, product risk is difficult to manage. This is therefore a crucial risk for the Contract manager to monitor as the project impact depends on developing the ICT tool.

3.2.2. Organisational Structure

The project has been broke down into 6 work packages:



- WP1: Project Management, Financial Coordination and Quality Assurance
- WP2: Reviewing evidence base and supply-side status and identifying buyer needs
- WP3: PCP training and Industry dialogues
- WP4: Contract Implementation
- WP5: PCP test sites and Technology validation
- WP6: Communication, exploitation and dissemination of the results
- There are two horizontal activities: Project Management, Financial Coordination and Quality Assurance and Communication, exploitation and dissemination of results.

Project Co-ordination, Management and Quality Assurance
All the activities of co-ordination (financial, contractual and administrative issues), general management (technical and operational) and quality management of the project are included in WP1, which interacts with all the other work packages. In particular, all the reporting activities towards the Commission are included in this WP.

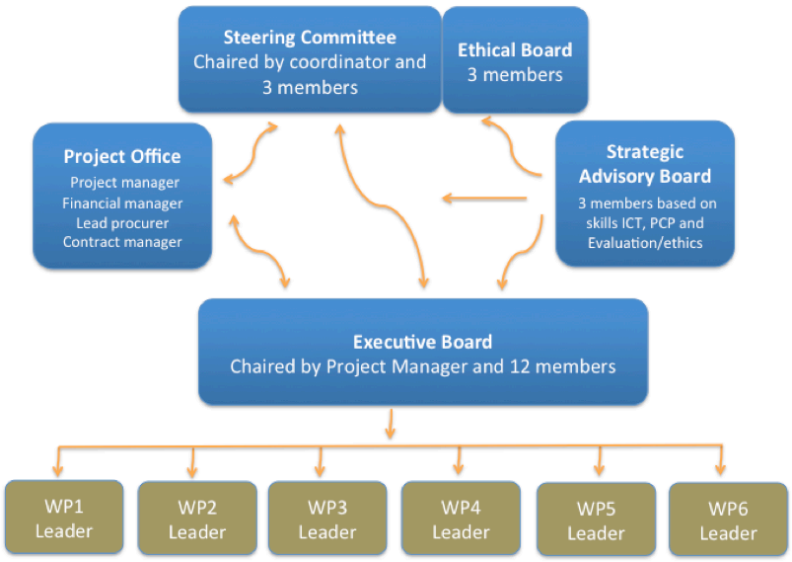
Communication, exploitation and dissemination of results

All the dissemination and communication activities are grouped in a single work package (WP6) which will utilise various communication channels.

These activities will be aimed, on one hand, dissemination of PCP as method and dialogue and training of companies and at creating two different networks of interested partners for further deployment of ICT solutions related to health.

Dissemination and communication activities will also target to the general public through articles in newspapers and magazines and coverage by local and national and regional Radio and TV channels.A dissemination team will be made up of representative of each WP, with the mission to stimulate and support local and national dissemination, working with the Advisory Board.

The guiding principle determining all project management activities was to ensure decentralised, flexible decision-making, while maintianing the appropriate level of oversight. While day to day control of the project is in the hands of the coordinator, the responsibility for the project as a whole lies with the Project Steering Committee (PSC).



The project management structure will be responsible for:

- producing the Project and Quality Plan
- controlling the execution of the project plan
- keeping the overall project on schedule, by applying the appropriate corrective actions in case of shift in relation to the project plan
- guaranteeing that the appropriate standards of project management and quality assurance are applied
- applying all the regulatory prescriptions in terms of data confidentiality and integrity
- discussing project objectives and results with the patients and Professionals Advisory Boards, and take inspiration from their advice for the implementation of the project.

The need to keep an overall co-ordination, while catering for autonomous work package management and descentralised decision power, implies a two level management structure, which addresses the need for both consistency at project level and flexibility in the field. In this scheme, the upper level of management is responsible for the overall supervision of the project, while the lower level has the mandate to carry out the individual work packages and the activities in the countries.

The upper level of management is represented by the Project Steering Committee, by the Project Office, the Strategic Advisory Board and by the Executive Board.

3.2.3. Project Steering Committee and Ethical Board

The Steering Committee (chaired by coordinator and including 6 other members) gives strategic guidelines to the Project Office and the Executive Board and steers the project according to the agreed objectives. The Steering Committee is responsible for the approval of the financial budgets, and making decisions which can modify the distribution of funding among beneficiaries.

Decisions on managerial, and technical issues are made following standard procedures of circulation of agenda items, discussion and agreement at meetings. Virtual meetings through videoconferencing, tele-conferencing and e-mail will be held to improve efficiency and reduce travelling costs.

The Steering Committee will also address legal, confidentiality and security issues emerging during the lifeclycle of the project. The ethical issues will be addressed by the Ethical Board. At least 3 members from the buyers group will constitute this Ethical Board.

The Steering Committee and the Ethical Board will meet once per semester.

Detailed rules for the functioning of the Steering Committee will be laid down in a Consortium Agreement. It can be anticipated however that decisions will be taken by majority and the quorum is a minimum of 2/3 of the Buyers Group. In voting, each Buyer has one vote.

3.2.4. Strategic Advisory Board

The Scientific Advisory Committee (2 member from each buyer based on skills ICT, PCP and Evaluation/Ethics) will ensure the project will be based on sound scientific inputs and current health policy-oriented recommendations according to e-health Action Plan and the European Innovation Partnership on Active and Healthy Ageing. The Scientific Advisory Committee supports in comprehensive approach every phase of project and will provide periodical recommendations to the Project Steering Committee for its consideration in amending the direction or implementation of the PCP and/or monitoring and validation of technologies in order to ensure the objectives and expected impact are achieved. Taking into account the production of different WPs, will provide recommendations that should also provide a clear picture of available options and possible scenarios for economic assessment, useful implementation and economic grow. The main objective of the SAB is to ensure the PCP leads to scientific and technological breakthroughs in areas of self-care for chronic disease increasing the quality of life of European citizen, improving the sustainability of health systems and the competitiveness of European Industry.

Members: Reputed experts from different sectors and from the different regions. Ideally member profile should be diverse, recruited from the following pool:

- evidence based policy analyst and/or HTA expert,
- e-health specialist,
- health professional planning health care or manager;
- nurse expert on self-management programmes, pharmacist;
- engineer and ICT developer,
- economic assessment;
- business and competitiveness specialist;
- legal expert on innovative procurement
- at least 1 patient/patient group representative

The SAB members must be able to demonstrate evidence of the skills, knowledge and experience.

Total 10-12 members, chair included, proposed by regional authorities from different countries and gender balance. The Chair would review the CVs and would propose the members to the Management Board who finally approved them. Meetings will be scheduled upon request of Management Board and a least once/ year, before every review.

3.2.5. Executive Board

The Executive Board will contribute to all stages of the project, and should give feedback on several aspects of this. Its objectives will be:

- ensuring the compliance of the project with the regions´needs
- providing the Steering Committee and project with constructive feedback

The Board will also serve as a bridge between the upper and lower level of management.

The Executive Board Members are Procurement Department, Legal Department, IT Department and Health Policy officers from the Buyers Group organisations. Various project teams will be set up both on a regional basis, including: Project Assurance, Procurement Team, Evaluation Team, and Clinical Forum. A Programme

Director will be appointed for this project who reports directly to the Program Board, provides updates to the Scientific Advisory Committee, and will co-Chair the Work Package.

3.2.6. Project Office

The Project Office controls the daily administration and management of the project. The objectives are to coordinate all work conducted in the project, to oversee the tasks and work packages, to ensure sound financial management of the project and production of deliverables, and to report to the EC via the contracted reports. The Project Office members are a Project Manger, a Financial Manager, a Lead Procurer and a Contract Manager.

3.2.7. Word Packages leaders

Each WP has a designed WP leader who has the responsibility to coordinate and communicate the activities within their work packages. The WP leaders also contribute to planning and integration between different objectives of EMPATTIC as well as are being responsible for the achievement of the WP objectives, activities and deliverables in cooperation with other partners.

3.2.8. Organisational structure justification

The organisational structure outlined above is intended to reflect the need to ensure regional views are represented, decision-making is delegated to the correct level or group, and that the project will ultimately be accountable to the Buyers and the EU. Terms of reference will be set out and published for each element of the governance structure. In addition, Buyers will collectively approve the members of the Steering Committee, the Strategic Advisory Board, and the Executive Board (which will include representation from all Buyers).

In selecting this structure, care was taken to reflect the need for scientific, technology and health expertise, as well as procurement and legal expertise. In addition, the Executive Board will be able to approve financial and other reporting elements to ensure that the Buyers are fully accountable for the procurement process to the EU as well as the participating countries.

In addition, the use of function experts will allow the consortium to ensure that all elements of the procurement process, as well as the services being procured meet the agreed upon standards of quality amongst the partners and those expected by the EU.

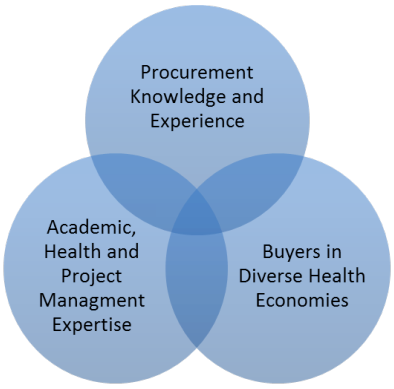
3.2.9. Consortium Agreement

As part of WP1, all Consortium members undertake to complete a Consortium Agreement and finalise the Grant Agreement. This will include all financial arrangements, the handling of IPR rights, and all other administrative elements required for the project to be implemented in a fair, open and deliberate manner as well as meet all legal and financial requirements of the EU and member countries.

3.3. Consortium as a whole

There are new technologies and solutions in Self-care sought by the Buyers Group in Project EMPATTICS. Within the Healthcare authorities they represent, the PCP has so far been an under-utilised tool for promoting innovation. One of the aims of this project is to demonstrate the effectiveness of this approach to as a method for procuring R&D services, or of the results of R&D services, for the purpose of developing the new Self-care products or solutions that the Project EMPATTICS Buyer's need for their patients.

We have leveraged the experience of the Lead Procurer (***Consellería de Sanidade***) and their experience with PCP and PPI contracts to help diffuse the PCP approach to other organisations which represent large health care authorities. We have built up the Spanish experience with the Buyers Group with a complementary innovative skill set with the other members of the Consortium.



The ***Central Region of Denmark*** also brings experience with innovative market engagement experience that will serve as leaders for our competitive dialogue sessions. We have balanced this with the PCP a selection of large and small scale health Buyers in regions that believe that PCP could be an in important new way for them to engage openly with the market and regional SMEs.

As the largest health authority in France, the region of Ile de France, through ***GCS D-SISIF*** is interested to engage with a PCP to learn can it stimulate supplier product development from the demand side to address the requirements and the needs of the people of metropolitan Paris.

Like all buyers they want solutions that can be deployed to address a strong demand to improve services through innovation. ***Slovenj Gradec General Hospital*** is a large and innovative centre that includes teaching and research facilities – focussed on bringing technology and innovation into the delivery in a region with complex needs, and where chronic disease presents an on going challenge. Similarly, ***SALUD-Aragon*** have extensive experience engaging with chronic health service delivery and are actively engaged in leveraging complementary national projects in Spain to incorporate ICT solutions to improve care.

In addition, to the Buyers, the consortium has brought on academic health experts and private firms to assist in the horizontal elements of the project structure. The ***European Healthy Futures Forum*** represents a collection of health and technology experts that can leverage their experience and networks to define health and market challenges. ***Kokomo Healthcare*** is a healthcare consultancy with specialist expertise in the emerging area of Connected Health, and provides advice, support, and training to technology multinationals, telecommunications corporations, medical companies, and national health authorities. Their services will be used to assist with project management and oversights.

M&SAATCHI is an independent communication agency formed by 45 professionals specialist in communication, adversating, digital enviroments and in the creation of contents for the brands. In EMPATTICS **M&SAATCHI** will lead the dissemination and communication.

The Project has been structured to ensure the public and private sector share the risks and benefits of engaging in exploratory research, which has the potential to innovate public services from the early stages of pre-commercial product development up to the stage where products are ready for commercialisation.The design of Project EMPATTICS, ensures that innovative public procurers assist with new PCP regions and that Healthcare IT teams can play their role, more as technologically demanding first buyers and less as developers of new in-house solutions.

3.4. Resources to be committed

EMPATTICS' consortium is formed by a balanced gropup of organizations, from different regions across Europe and with different competences in the innovation value chain of e-health technologies (including Public Procurement experts, lawyers, clinicians, validation technologies, communication, communication with patients, etc).

Considering the high expertise and the balanced profiles of participanting organizations, most of the resources commited to the project will rely on personnel contributions. The management and planning of the project is based on the content and compromises described in the different Work Packages (WP).

The total budget of the project is 5.000.000€. Following PHC-27 call, 70% of the total budget (3.500.000€) will be exclusively dedicatted to the PCP contract. EMPATTICS' partners will participate with additional Networking & Coordination activities essential to developthe documents and processes that wil facilitate companies R&D activities and to share the lessons learnt with other Public Procurers across Europe. Networking & Coordination activities include personnel, direct costs and a minimum subcontracting activities (total 1.500.000€). The Table below shows the general distribution of financial resources:

Participant	(A) Direct Costs of PCP subcontracting /€	(B) Costs for related additional coordination and networking activities				(C) Total costs/€ (=A+B)	(E) Maximum EU contribution /€ (=C*D)
		(B1) Direct personnel costs/€	(B2) Other subcontracting costs/€	(B3) Other direct costs/€	(B4) Indirect costs/€ (=(B1+B3)*25 %)		
SERGAS	700.000,00	371.000,00	48.750,00	16.000,00	96.750,00	1.232.500,00	862.750,00
Central Denmark Region (CDR)	700.000,00	150.000,00		14.500,00	41.125,00	905.625,00	633.937,50
Aragón	700.000,00	150.000,00		14.500,00	41.125,00	905.625,00	633.937,50
GCS D-SISIF	700.000,00	101.000,00		14.500,00	28.875,00	844.375,00	591.062,50
General hospital Slovenj Gradec (SB-SG)	700.000,00	101.000,00		14.500,00	28.875,00	844.375,00	591.062,50
European Health Futures Forum	0,00	60.000,00		1.000,00	15.250,00	76.250,00	53.375,00
Kokomo Healthcare	0,00	45.000,00		8.000,00	13.250,00	66.250,00	46.375,00
MC&Saatchi	0,00	60.000,00		40.000,00	25.000,00	125.000,00	87.500,00
Total	3.500.000,00	1.038.000,00	48.750,00	123.000,00	290.250,00	5.000.000,00	3.500.000,00

Personnel Costs

Personnel costs are the main resource commited to the project (more than 70% of EMPATTICS N&C activities represent Personnel Costs). EMPATTICS Personnel Costs have been calculated according to the Man Month distribution required by each WP and and the average personnel cost for each organization. The EMPATTICS project participates with 199 Personal Months contribution. The highest contribution is assumed by the public authorities that participate in project (EMPATTICS Buyers group), representing 84% of all human resources of the project. The high Personnel costs of Buyers demonstrate the large commitment of all public authorities with the EMPATTICS project. In fact, all Buyers have highlighted that they will participate in this project with even more human resources (clinicians, IT engineers, Project managers, legal experts, …) than the personnel costs financed with the EC contribution.

All Buyers will participate in all WPs. This high participation from Buyers adds a hughe value to the EMPATTICS project. The impact of N&C activities will be higher and all organizations will learnt from other experiences (e.g Paris and Aragon will know the best practices regarding industrial involvement of Central Denmark Region, Slovenia will learn from PCP methodologies already implemented in Galicia, etc)

WP4 seems critical for the evolution of the project. The Consellería de Sanidade will assume its leaderships, compromising significant human reources to the project. This considerable effort will guarantee early PCP tender publication. The rest of Buyers will participate in the definition of main PCP clauses and PCP phases evaluation. The Consellería de Sanidade will also assume the Leadership of WP1 (Project Management). Kokomo will collaborate with the Consellería de Sanidade in some management

activities, but the Consellería de Sanidade will assume the management of all financial aspects with the rest of partners and acting as a unique contact point with the EC.

WP5, PCP test sites and Technology validation, accounts for the larger personnel contribution. More than 33% of Personnel resources will be dedicated to WP5 for testing and validating technologies. With this approach, companies will benefit from multidisciplinary teams to validate their technologies in real clinical environments. Companies will receive highly valuable inputs to better address the health challenge and to fine-tune their technologies. The validation phase is especially attractive for SMEs. Similarly, the EMPATTICS comsortium expects technologies well adapted to their organizations. For that reason, all Buyers will significantly contribute with their efforts to the development of Phase 3 during WP5.

WP3 is also critical for a successful PCP tender. Company engagement (especially SMEs) is essential to guarantee competitive technologies. The consortium will rely on the experience and knowledge of the Central Denmark region. The EMPATTICS also considerably contribute with human resources to the appropriate development of this WP.

Under this scheme, four of the six EMPATTICS WPs will be led by members of the Buyers group. Two specific WPs will be led by private organizations that collaborate extensively in European projects. The EMPATTICS consortium will rely on the experiences and methodologies of two organizations with an exceptional European projects track record. For the WP2, the EHFF network will collaborate to fine-tune the common health challenge, analysing the inputs of the literatue, patients, and Buyer organizations. Similarly M&SAATCHI will assume the leadership of dissemination activities.

Subcontracting

EMPATTICS project relies on the demonstrated capacities of the members of the comsortium, mainly the members of the buyers group. The busdget for subcontracting activities is limited. The consortium only reserved a minimum amount of money for specific actions (Advice on legal isusues related exclusively to the management of IPR, technology surveillance studies that will guarantee truly innovative PCP R&D, and translation services). Independently of the subcontracting activities, Buyers will probably assume other subcontracting costs (videos and printing materials, Conference and workshops venues, etc) that have not been added to the proposal as a consequence of the limited N&C budget.

Other Direct Costs

This account is also very limited (mainly travelling). The reduced travelling budget will force the EMPATTICS consortium to work remotely and concentrating all efforts on the set of activities that will originate higher impact on patients and companies.

PCP tender and Global Financial Plan

The PCP tender constitutes the core of the EMPATTICS project. The Lead Procurer, Consellería de Sanidade will assume the activities related to the publication and management of the legal aspects of the tender, including the management of contracts with the selected companies. Under the EMPATTICS scheme, the five buyers will contribute equally to the PCP budget (210.000€ each). This equal distribution also confirms the high interest of all Buyers in the technologies to be developed within the EMPATTICS. Independently of current commitment from Buyers, EMPATTICS also anticipates that the network of public procurers will be probably enlarged with more Buyers. During the preparation of the proposal, several institutions in France, UK and Italy demonstrated their interest in the EMPATTICS project. An open call for new buyers (WP4) will be opened at the beginning of the project. We expect a higher number of Buyers in the EMPATTICS consortium in Month3. This will help to reduce (pro-rata) the commited financial contributions of Buyers.

The PCP tender and the project management will be therefore responsibily of the Lead Procurer (Consellería de Sanidade). The Lead procurer has published during the period 2011-2014 more tha 30 PPI tenders (including PCP) for a total budget that exceeded 30Million Euros. Most of these tenders were exclusively related to the promotion of e-health technologies. The procurement department of the

Lead Procurer is therefore ready to tackle the critical aspects of the PCP tender. The Procurement department of the Conselllería de Sanidade has also the experience to prepare the necessary documents and it has become a leading institution in Spain in the development of Public Procurement of Innovation.

In addition to the Procurement department of the Conselllería de Sanidade, the Lead Procurer will rely on the Legal cabinet of the Galician Regional Government. Their lawyers are currently collaborating with the Consellería de Sanidade to extend the lessons learned during these years to other strategic sectors in the region. The lawyers of the Regional Government of Galicia are also a reference at national level, collaborating with other national authorities to translate the PPI and PCP rules and policies implemented in Galicia to other Spanish regions.

With this large, experience and qualified team of lawyers, procurement officers and innovation managers, the Lead Procurer will guarantee a prompt publication of the PCP tender as well as a transparent and efficient evaluation process. The rest of buyers will collaborate with the Consellería de Sanidade in the definition of the main points of the PCP tender and the evaluation of proposals from companies. The Lead Procurer will assume the publication of the tender, and according to the national laws, it will assume the responsibilities/liabilities associated to this publication. All buyesr will share the financial cost associated to this tender.

Regarding the existance of additional national or regional funding, we may anticipate the Galicia and Aragon Regions (both in Spain), are currently negotiating with representatives of MINECO, the Spanish Ministry of Economy and Competitiveness, a new programme to finance the development of health technologies through PPI or PCP. During the preparation of the proposal, Galicia received confirmation of an award of 21,5Million ERDF for this purpose. We will initiate conversations to allocate part of this funding to the EMPATTICS project. We expect an agreement about this commitment before the resolution of the PHC-27 call. Similarly, the Central Denmark region will initiate conversation with national authorities to achieve additional funding for the EMPATTICS project. We expect similar moves in Paris and Slovenia. All these negotiations are still pending, so we could not provide financial commitments from national/regional institutions at this point.

3.4.1. Direct 'costs of PCP subcontracting' – Total jointly committed budget for the PCP (Table 3.4a)

Participant Number / Short Name	Country	(a) Contribution from participant's own resources to the part of the PCP subcontracting costs cofunded by Horizon 2020 [€] (min d*30%)	(b) EU Contribution from Horizon 2020 [€] (max d*70%)	(c) Indicative possible additional Contribution cofunded by ESIF (including contribution from participant's own resources to the part of the PCP subcontracting costs cofunded by ESIF) (optional) [€]	(d) Minimum total jointly committed budget for payment of the PCP subcontracts = Maximum amount of subcontracting costs that can be eligible for cofunding by Horizon 2020 [€] (a + b)	(e) Maximum total jointly committed budget for payment of the PCP subcontracts [€] (a + b + c)
1. CS	Spain	210.000	490.000		700.000	700.000
2. CDR	Denmark	210.000	490.000		700.000	700.000
3. SAR	Spain	210.000	490.000		700.000	700.000
4. GCS	France	210.000	490.000		700.000	700.000
4. GHSG	Slovenia	210.000	490.000		700.000	700.000
Total		1.050.000	2.450.000		3.500.000	3.500.000

3.4.2. Direct costs of 'subcontracting of related additional coordination and networking activities' (Table 3.4c)

Participant Number/Short Name 1. Consellería de Sanidade	**Cost (€)**	**Justification**
Subcontracting of coordination and networking activity 1	28.750	External assistance for legal advice on IPR issues
Subcontracting of coordination and networking activity 2	10.000	Translation services
Subcontracting of coordination and networking activity N	10.000	Technology intelligence and Patent search
Total	**48.750**	

3.4.3. 'Other direct cost' items (travel, equipment, large research infrastructure, goods and services) of related additional coordination and networking activities (Table 3.4d)

Participant Number/Short Name 1. Consellería de Sanidade	**Cost (€)**	**Justification**
Travel	**14.500**	This budget corresponds to the normal amount assigned to each partner to allow them to attend all the Project and Evaluation meetings, the hackatons to provide their input and to be taken up to speed with the evolution of the Project and attend dissemination events
Equipment		
Other goods and services	**1.500**	
Total	**16.000**	

Participant Number/Short Name **2.** Central Denmark Region	**Cost (€)**	**Justification**
Travel	**14.500**	This budget corresponds to the normal amount assigned to each partner to allow them to attend all the Project and Evaluation meetings, the hackatons to provide their input and to be taken up to speed with the evolution of the Project and attend dissemination events
Equipment		
Other goods and services		
Total	**14.500**	

Participant Number/Short Name 3. Servicio Aragones de Salud	**Cost (€)**	**Justification**
Travel	**14.500**	This budget corresponds to the normal amount assigned to each partner to allow them to attend all the Project and Evaluation meetings, the hackatons to provide their input and to be taken up to speed with the evolution of the Project and attend dissemination events
Equipment		
Other goods and services		
Total	**14.500**	

Participant Number/Short Name **4.** Le Groupement de Coopération Sanitaire pour le Développement des Systèmes d'Information partagés en Santé en Ile-de-France	**Cost (€)**	**Justification**
Travel	**14.500**	This budget corresponds to the normal amount assigned to each partner to allow them to attend all the Project and Evaluation meetings, the hackatons to provide their input and to be taken up to speed with the evolution of the Project and attend dissemination events
Equipment		
Other goods and services		
Total	**14.500**	

Participant Number/Short Name 5. General Hospital Slovenj Gradec	**Cost (€)**	**Justification**
Travel	**14.500**	This budget corresponds to the normal amount assigned to each partner to allow them to attend all the Project and Evaluation meetings, the hackatons to provide their input and to be taken up to speed with the evolution of the Project and attend dissemination events
Equipment		
Other goods and services		
Total	**14.500**	

Participant Number/Short Name 6. European Health Futures Forum	**Cost (€)**	**Justification**
Travel	**1.000**	This budget corresponds to the amount assigned to this partner to allow them to attend some of the Project meetings to provide their input in the WP2.
Equipment		
Other goods and services		
Total	**1.000**	

Participant Number/Short Name 7. Kokomo Healhtcare	**Cost (€)**	**Justification**
Travel	**8.000**	This budget corresponds to the amount assigned to this partner to allow them to attend some of the Project meetings and dissemination events
Equipment		
Other goods and services		
Total	**8.000**	

Participant Number/Short Name 8. M&SAATCHI	Cost (€)	Justification
Travel	**5.000**	This budget corresponds to the amount assigned to this partner to allow them to attend some of the Project meetings to provide their input and to encourage dissemination events
Equipment		
Other goods and services	**35.000**	Leaflets, website...
Total	**40.000**	

4. Members of the consortium

4.1 Participants (applicants)

4.1.1 Consellería de Sanidade (Spain)

4.1.1.1 Description of the legal entity

XUNTA DE GALICIA
CONSELLERÍA DE SANIDADE

Galicia is located at the Northwest of Spain, and it also borders by Portugal on its north side. Its population is close to three million people (2,795,422 inhabitants), and it must be noted that people over 65 years old represent 22%, that is 5% more than the average in Spain. Furthermore, there is a wide dispersion of the population, 3,775 locations, that is to say, people are not located in medium or big cities, but in small villages all around the region. Many of them connected by small roads and far from hospitals. This means that healthcare resources and infrastructure spread widely across the region. The best approach for improving services in our region is the development of ICT solutions to improve the healthcare processes. This has been successfully proven in several projects such as the electronic medical record, electronic prescription and digital imaging that are being used in Galicia. That is why Galicia is fully compromised towards European Innovation Partnership on Active and Healthy Ageing (EIP AHA) goals (provide better health and social care at an affordable cost) being one of the Reference Sites of the EIP AHA and it is totally aligned with the Challenge 3, “New healthy lifestyle model based on active ageing of population”, of Smart Specialisation Strategy in Galicia, RIS3 Galicia.

Consellería de Sanidade is the Public Health Authority in Galicia, whose mission is defining and promoting strategies and guidelines consistent with health policy formulated by the Government of Galicia. In Galicia Healthcare services are provided mainly by a public institution, SERGAS. The main resources for SERGAS consist of 7 hospitals trusts with tertiary care services, and 7 rural hospitals with secondary care services. Another 460 primary care centres complete the network of healthcare facilities in the Region. About 38,000 professionals work at SERGAS, which is considered the biggest organization in Galicia. The Public Health Authority and the Public Healthcare Provider, SERGAS, work in close collaboration towards the goal of providing sustainable healthcare services with the highest levels of quality, using ICT as an essential tool.

In 2010, the Public Health Authority of Galicia developed a strategic plan, SERGAS 2014 Strategic, which defines seven strategic objectives. One of these main strategic objectives is promoting technology and information in the public health service network. An average of 30 M€ funding has been incorporated

during the last 10 years to provide new models, based in the introduction of new technologies and tools to support organizational changes: Electronic Health record, named IANUS, e-Prescription or Digital imaging provide successful experiences that have provided and are currently providing benefits for quality and sustainability of health services.

Moreover, since early 2011 and following this strategic plan, the Public Health Authority and SERGAS have promoted several PPI initiatives under the above innovation plans includes Public Procurement of Technology and Pre-commercial Public Procurement of technology. More information in 1.4.3. Lead Procurer.

For these two reasons, using ICT as an essential tool to take care of our patients and our experience in PPI initiatives, Galicia´s profile matches fully the Common Challenge and the action of this proposal, Pre-commercial procurement co-fund action.

4.1.1.2 Nominated lead in the following areas: Legal, Procurement, IT and Health Policy

	Name	Title	Department	Contact information
Legal	Beatriz Allegue Requeijo	CIO	Advisory and support cabinet for legal and regulatory updates of Galician Regional Government	beatriz.allegue.requeijo@xunta.es
Procurement	Paula Camba Loureda	Deputy	General Subdepartment of purchases and services	paula.camba.loureda@sergas.es
IT	Javier Quiles del Río	Chief	General Subdepartment of Information and Commucations Technology	javier.quiles.delrio@sergas.es
Health Policy	Julio García Comesaña	Deputy	General Subdepartment of Care Management and Organizational Innovation	julio.garcia.comesana@sergas.es

4.1.1.3 CV of the key people

Beatriz Allegue Requeijo

She graduated with a degree in Law from the University of Santiago de Compostela (Spain) in 2000, spending part of their studies at the Faculty of Law and Economics from the University of Maine (France). She finalizes her doctor's degree courses in 2006, reaching the sufficiency researcher in 2007.

She has completed her education with several Master's degrees in the areas of administrative and public law at University of Coruña and University of Barcelona.

In 2005, she joined the Galician Administration`s Legal Service. She has filled diverse jobs since 2005 as legal Advisor of the Economic and Financial Department, legal Advisor in the General Direction's Legal Service and legal advisor-chief of the territorial legal service in Lugo.

Likewise, she has taken charge of the advice of diverse public companies and public foundations.

From 2013 she has been holding the role of legal coordinator in the General Direction's Legal Service, where she develops functions of advice and coordination of the advisory and normative Area of the different Galician Departments.

She is nowadays member of the Administrative Contracts Consultation Board of the Region of Galicia and coordinator of the work group of Public Procurement of Innovation. As a result of this group of work has been the making of a Guide of good practices to encourage the innovation in the CCAA of Galicia.

She works like a former-teacher at Galician School of Public Administration (EGAP) and at Galician School of Health Administration (FEGAS), especially giving courses and workshops on public contracts and public aids.

She has written diverse articles on the subject of administrative law, public procurement, agreements of collaboration, etc.

María Jesús Lamas Díaz

She graduated with a degree in Pharmacy from the University of Santiago de Compostela in 1989. She got her doctorate on pharmacogenetics in 2011, with cum laude and distinction at the University of Santiago de Compostela. She has been accredited as a Clinical Oncology Pharmacist by the Board of Pharmaceutical Specialties of the USA.

From 1991-1994 she completed her pharmacy residency in the Complejo Hospitalario of Santiago de Compostela.

From 1995-1996, she was the technical director of pharmacy in the Hospital Santa Teresa, where she has implemented and developed systems and software for management of pharmacy and health products.

From 1997-2003, she has worked in the Pharmacy Dpt of Hospital de Conxo, in charge of the department of compounding and oncology. At the same time she has been involved in development projects as Management by the use of GRDs and Implementation of the first automated dispensing system with controlled prescription by pharmacists in Europe.

From 2003-2013, she has been the head of the Oncology Unit Pharmacy in the Complejo Hospitalario of Santiago de Compostela, turning it into a benchmark comprehensive cancer patient care in Spain, dispensing individualized dosages and monitoring of patients with oncological new oral therapies with high therapeutic and economic impact.

From 2010 to present, she holds the position of Director of the Pharmacy Dpt in the Xerencia de Xestión Integrada of Santiago de Compostela. She assists pharmacy managers with the integration of clinical pharmacy services, drug utilization programs, and pharmacy operations throughout the institution, she develops and maintains quality training opportunities and relationships for teaching and precepting pharmacy students and residents. She actively participates in medication safety systems, regulatory compliance initiatives, patient quality services, and disease outcomes programs. She delivers general and specialty medication therapy management consult services and disease state management services as needed and proactively participates in all areas of medication use as appropriate to optimize patient outcomes.

She has participated in several research projects and scientific societies; she has published several articles (∑IF=45.065), reports and communications in national and international congresses in the field of the pharmacogenetics and therapeutic adherence. She has been collaborator and investigator in more than 100 clinical trials. She is, currently, head of the Research Group of Clinical Pharmacology in the Health Research Institute of Santiago de Compostela, Director of Research in the Spanish Society of Hospital Pharmacy (SEFH) and teacher and coordinator in several courses or teaching programs (Oncology Pharmacy Preparatory Course BCOP and Master in Oncology Pharmacy at Valencia University).

Paula Camba Loureda

She holds a degree in Telecommunications Engineering from the University of Vigo, in 1999. On March 1999 she finished her Final Year Research Project (thesis), titled Deep building penetration effects on wireless communication systems, developed with an Erasmus grant in the K.U Leuven, Belgium.

From July 1999 to October 2001, she worked in Telecom network designs for cable operators like R and Jazztel. On November 2001 she moved to Madrid and started working as Purchase Manager in the Environmental and Telecom sectors. Since 2004, Executive Master in Business Administration from IE (Instituto de Empresa). On February 2004 she became Purchase and Logistic Director of a company that developed international Projects financed by DAF (Development Assistance Fund) credits in the areas of Health and Education.

On October 2005 she returned to Galicia and applied for a job as a permanent official form the Galician Civil Service. In 2007 she started working in the Galician Health Service in the resolution of appeals and complaints related to recruitment procedures.

From February 2009 to January 2011 she worked as the Head of Section in the Dependency and Personal Autonomy Service in the Social Services Territorial Department of Vigo.

Since February 2011 she is the Deputy Director General of Purchases and Services in the Galician Health Service. This department deals with the Public Procurement Proceedings in the field of sanitary and non sanitary products and services that are demanded by hospitals and health centres. They draft all the tender documentation for corporate telecommunication purchases and services contracts (electronic medical records, e-prescription and digital medical imaging, among others). They have developed more than 29 public procurement procedures of innovative technology with a total tender sum of more than 23,9 million Euro (VAT not included) and one pre- commercial public procurement. She participates as specialist in Public Procurement in some national associations and forums.

Beatriz Pais Iglesias

She graduated with a degree in Medicine and Surgery from the University of Zaragoza in 1990. She finalised her doctorate courses in 1993 reaching the sufficiency researcher in 1994. She obtained the title of specialist in Nephrology in 1994. She spent 4 months in the Hospital Clínico from Barcelona, developing a formative stay in its Kidney Transplantation Unit.

She has been practising as a nephrologist in the Hospital Arnau de Vilanova of Lleida and in the Hospital of Figueres, Girona, both in Cataluña, Spain.

In 1995 she moved to Galicia, where she started an investigation project in Molecular Biology, about “Mutations in the PKD2 gene adult polycystic kidney disease,” in the University of Santiago de Compostela and the Institute of Molecular Biology.

In 1996 she joined the Galician health service in the General Hospital of Santiago de Compostela, in the role of Emergency Physician. She worked in Extrahospitalary Emergencies from 1996 to 1997 (061 Foundation). Then she obtained the post of physician in the Hospital of Barbanza (Ribeira), in 1998. In 2001 she became Chief of the Emergency Room. In 2006 she hold the post of Medical Director, in that same hospital.

Since 2010 she has worked in the general department of Quality and Safety in the SERGAS, coordinating the development and implantation of corporate systems, as an adverse events report system in all the hospitals and part of the Primary care in Galicia (SiNASP), a Corporative Model of Patient Safety, a Safety Audits Program for all the hospitals in Galicia, and others projects related with Safety Patient and Risk Managemen.

She has participated in different programs from the PaSQ, leaded by the Health Ministry and the Joint

Action (check list in surgery, adverse events reports) from 2013 until now.

She has developed a Master in Quality and Safety from the University Miguel Hernández (Murcia), directed by the National Health Ministry in 2013, in which context she developed the document "Guide for the management of Adverse Events in the sanitary centres of the Galician Health System".

She has imparted courses about Safety Patient and Risk Management in the FEGAS (Fundation School for Healthcare) from 2010 to 2015. She is responsible for two editions of a course about Lean Healthcare and Six Sigma, what are going to be held during 2015.

From February 2015 she holds the post of General Subdirector of Patient Care and Quality in the SERGAS. She is also the director of the Galician School in Public Health for Citizens.

She is member of the directive team of the scientific society SOGALCA, (Galician Society of Quality Management) from January 2015 and member of the Technical Committee AENOR from 2015.

Julio García Comesaña

He graduated with a degree in Physical Sciences from the University of Santiago de Compostela in 1993. He finalizes his doctorate courses in 2003. He has the Medical Physicist title by the Helath Ministry of Spain in 1997. He has the Sanitary Administration Master Degree by the National Health School in 2008. He is actually developing the program "Leader and Strategic Management for policy makers in Health of the IE Business School, in Madrid.

After several years working as Medical Physicist in Radiation Therapy Departments (Hospital Vall d`Hebron in Barcelona) he joined the Galician health service in the Central Offices in 2001, developing the actual Radiological Information System, which include the digital management of the image, in the frame of the Radiological Protection Program of the community. In 2003 assume the Radiological Protection Chef in the Hospitalary Complex of Vigo, starting the digitalization of the its Radiological Department. In 2005 he became the Director of the center. He coordinate the healthcare activity of the Endocrine Department and his relationship with the primary car level in that field. He manage with all the departments directly related with the management of the diabetic patients. In 2009 he became the medical Director of the Hospital Complex of Vigo.

In 2011 he start to work as the coordinator of the Galician Cancer Strategy, with one of its principal aims to became a cancer network. Currently, he is the Deputy Director of Healthcare in SERGAS, in the areas of Integration, health order and Organizational Innovation and a member of the Health Innovation Platform and coordinator of several projects in healthcare innovation projects.

From here he have an active role in the coordination of the healthcare aspects of the management of patients in 14 hospitals and 420 health centers, electronic medical records, e-prescription and digital medical imaging, among other duties.

In 2011 he also became involved in the Health Innovation Platform, becoming part of a multidisciplinary team that is constitutes in the public health authority in Galicia and the Galician health care service, in order to stimulate innovation projects, such as two big projects of innovation health: Hospital 2050 and Innova Saúde, both of which were initiated in 2011. The two projects will develop until 2015, with a ERDF funding of €63 M.

In that projects and in others he have a important role in aspects directly related with the mobile devices, the integrated care, the tele monitorization of the patients form their usual habitat (house, work, social care houses, comunitary pharmacy) and their active role in the management of their illness.

He has participated in several research projects and scientific societies in the field of Health management and ICT in the Health field. : He has become member of ETHEL, and has been a member of Managerial Board IHE-Spain, a member of ESR: European Society of Radiology from 2007 and a member

of the Technical Committee AENOR from 2008. He has published several articles, reports and communications in national and international congresses in the field of the electronic medical records and digital medical imaging projects.

From his actual position as Deputy Director of Healthcare in SERGAS, in the areas of Integration, health order and Organizational Innovation he has developed and is responsible of several initiatives related with the project:

- Developing of strategies for the active integration between the primary car level and the hospitaly level in several disciplines like Endocrine
- Developing specific tools for the professionals using ICT like the e-interconsultation, an asynchronous communication software that allow to the primary care level physician comment patients concrete issues and have an electronic response directly in the HCE that increase the coordination level and the resolution capability. With this tool from January 2014 all the patients of one health area are management in the endocrine issues only by this method
- Developing specific tools for the patients using ICT or even more, something so simple like telephone. Using an HCE that integrated all the information, in all the levels, he has started to use in last year the phone consultation service for patients in primary car level in all the region. The system allow the patient ask for a non presential consultation via telephone and in the scheduled time the professionals call him and they can make the consultation without need to go to the primary care center, always over the base that all the information relevant is in the HCE. Even when the result of the consultation is a prescription, as the comunitary pharmacies are connected with the HCE, the patient can go directly there to achieve the medicines.
- Developing several projects in the field of the use of m-health in chronic diseases like COPD, Diabetes, cardiac Insufficiency, dementia or no Chronic like the follow-up of the healthy child or the pregnant. Both directly with the patients or his relatives, and with other resources like the comunitary pharmacies or social beds.
- Developing the strategy for the future relationship of the patient with the Health system, using the ICT tools both for the management of the health problems, and for to know his opinion, preferences, uses or accessibility.

Javier Quiles del Río

He graduated with a degree in Physical Sciences from the University of Santiago de Compostela in 1996. It finalises his doctorate courses in 1998, reaching the sufficiency researcher in 1999. He has been a scholar of investigation of the Institute of Health Carlos III, funded by the Health Research Fund (1997-1999). He has studied computer engineering at the National University of Distance Education (UNED) and has completed several direction courses of ICT and project management.

In 1998 he spent 6 months in the German National Cancer Research (DKFZ), Heidelberg for the development of computer programs of medical imaging.

In 2000 he joined the Galician health service in the Hospitable Complex of Santiago de Compostela, in the role of technician.

Since 2005 he has worked in the general department of technology and system of information, coordinating the development and implantation of corporate systems in the SERGAS.

From 2010 to present, he holds the post of head of service of project management information systems being the manager of development and implantation of corporate projects. For example, the management of patients in 14 hospitals and 420 health centres, electronic medical records, e-prescription and digital medical imaging, among other duties.

In 2011, he obtained the rank of technical superior of technology and system of information. In this he also became involved in the Health Innovation Platform, becoming part of a multidisciplinary team that is constitutes in the public health authority in Galicia and the Galician health care service, in order to stimulate innovation projects, such as two big projects of innovation health: Hospital 2050 and Innova Saúde, both of which were initiated in 2011. The two projects will develop until 2015, with an ERDF funding of 90 M€. Javier is currently the coordinator of these two projects.

He has participated in several research projects and scientific societies in the field of ICT in health: He has recently become member of ETHEL, and has been a member of Managerial Board IHE-Spain, a member of ESR: European Society of Radiology from 2007 and a member of the Technical Committee AENOR from 2008. He has published several articles, reports and communications in national and international congresses in the field of the electronic medical records and digital medical imaging projects.

Susana Fernández Nocelo

Susana Fernandez Nocelo joined the Innovation Platform in March 2011 as part of a multidisciplinary team that is constituted in the public health authority in Galicia and the Galician health care service in order to evaluate proposals to identify high impact projects and manage health innovation projects. She is the Coordinator of European Projects and has worked on proposals for health innovation projects, including the Hospital 2050 and Innova-saúde, which was recently awarded 90 million Euros from the European Regional Development Fund, ERDF.

In 2006, she joined the public health laboratory in Ourense, belonging to the public health authority and accredited under the standard UNE-EN-ISO/IEC 17025:2005; where she is responsible for the microbiology area since beginning until present.

From 2004 to 2006 she worked with a research contract in the R & D, funded by the Direction General of R & D entitled "development of a non invasive system for monitoring the tumor growth in genetically modified mice". She is currently collaborating on the other research project funded with public funds. She has published several articles, reports and communications in national and international congresses.

She has an honours degree in Chemistry, specialising in Analytical Chemistry at the University of Santiago de Compostela and a degree in Science and Technology of Food at the University of Vigo. She is also a graduate in health and has a PhD from the Faculty of Medicine at the University of Santiago de Compostela.

4.1.1.4 List of relevant publications, products, services or other achievements

- Public Procurement as a Driver of Innovation in SMEs and Public Services. Guidebook Series: How to support SME Policy from Structural Funds. European Commission. Directorate-General for Enterprise and Industry. Unit B.3: Innovation Policy for Growth. E-mail: ENTR-INNOVATION-POLICY-FOR-GROWTH@ec.europa.eu.
  http://ec.europa.eu/enterprise/policies/innovation/policy/public-procurement/index_en.htm
- Strategic Intelligence Monitor on Personal Health Systems Phase 3 (SIMPHS3). Healthcare PPI, Galicia (Spain) Case Study Report. Author: Ramon Sabes-Figuera. Editor: Fabienne Abadie. European Commission. Joint Research Centre. Institute for Prospective Technological Studies
- On may 2014, the Galician Health Service was awarded with the National Innovation and Design 2013 Award by de Ministry of Economy and Competitiveness in the field of Innovative Public Procurement for developing the best project, innovating in the administrative procedure at the design, preparation and execution stages.

- Diario Medico Award 2014 to the best Public Health Policy in relation to the InnovaSumma project. The Innovasumma project aims the introduction of Cancer Biomarkers through Precomercial Public Procurement to promote Personalized Medicine protocols in the area of Oncology. Diario Medico is a private organization focused on Health dissemination at national level.
- A.A.V.V, "La preparación de los contratos en la nueva ley 30/2007, de 30 de octubre, de contratos del sector público" Revista de la Asesoría Juridica de la Xunta de Galicia. Num 5. Especial contratación. 2009 ISSN: 1689-6563.
- Allegue Requeijo, B, "La contratación de las administraciones públicas como estímulo de la responsabilidad social corporativa". Congreso Internacional CIRIEC. 2008
- A.A.V.V, "Comentarios a la ley 30/1992 comentada por Letrados de la Xunta de Galicia". 2007. ISBN 84-8408-416-7.
- Quiles, J. Rosón, B. Prado, J. Galicia leeds the way with a sucessful EHR deployment. HIMSS Insights. HIMMS Europe. November 2012; 1(1); 52-55.
- P. de Toledo, J.C. Albillos, J. Quiles, Los estándares en Sistemas de Información Sanitarios en Europa: la visión de IHE, I+S, Informatica de la Salud. (2008): 68; 17-25.
- Engelmann U, Schröter A, Schwab M, Eisenmann U, Vetter M, Lorenz K, Quiles J, Meinzer HP. A User driven Architecture for Teleradiology and PACS. European Radiology. 10(2) (2000) S232-S233.

4.1.1.5 List of relevant previous projects or activities

- CIP-ICT-PSP-2013-7 MASTERMIND, "MAnagement of mental health diSorders Through advancEd technology and seRvices – telehealth for the MIND ". Grant agreement no: 621000 (2014-2016).
- CIP-ICT-PSP-2012 UNITED4HEALTH, "UNIversal solutions in TElemedicine Deployment for European HEALTHcare ". Grant agreement no: 325215 (2012-2015).
- BER-NIL-2013-01. Adherence study with nilotinib in patients with chronic myeloid leukemia. Fundation IDICHUS. 2013-2014.
- BER-CAP-2011-01 Adherence study with capecitabine in patients with advanced colorectal or gastric cancer. Fundation IDICHUS. 2011-2012.
- INNOVASUMMA Project 600.000 € 2011-2015. Pre-comercial Procurement funded innovation projects in Health care.
- EIP-AHA Innitiative. Galician Health Service Reference Site.

4.1.1.6 Description of significant infrastructure and/or major items of technical equipment

Galician healthcare network connects all primary care centres and secondary care centres. More than 1,800 private communication lines conform this network. This situation allows connection to the same electronic health record system to all healthcare professionals (14,900 users in December 2011, all using digital signature under PKI infrastructure), sharing online the same information, including discharge reports, laboratory results, prescription, digital imaging from any centre, primary care information. Total access to Primary care information is available online from any hospital, and also is hospital information from any primary care centre.

E-Prescription has also finished deployment and is available for 99,7% of population and more than 1300 pharmacies are connected and 93% of prescriptions are registered in electronic format, both from primary and secondary care centres. Patients are also users of Galician Electronic Health Record System,

and they can access information with digital certificates. Finally, Galicia will finish the connection process for joining the National System for EHR in June 2012, reaching the capability to interact with other European regions through epSOS project. Moreover a program of quality improvement in care for chronic patients with polypharmacy is being developed in the Galician Health Service as part of the common policies of the National Health System. Its main goal is to improve the quality of care and the pharmaceutical provision to polypharmacy chronic patients by advising on the use of drugs, health education and proper collaboration between health professionals. The program has target population polypharmacy of chronic patients, taking 6 or more medications, continuously for a period not less than 6 months. These patients are usually people over the age of 65.

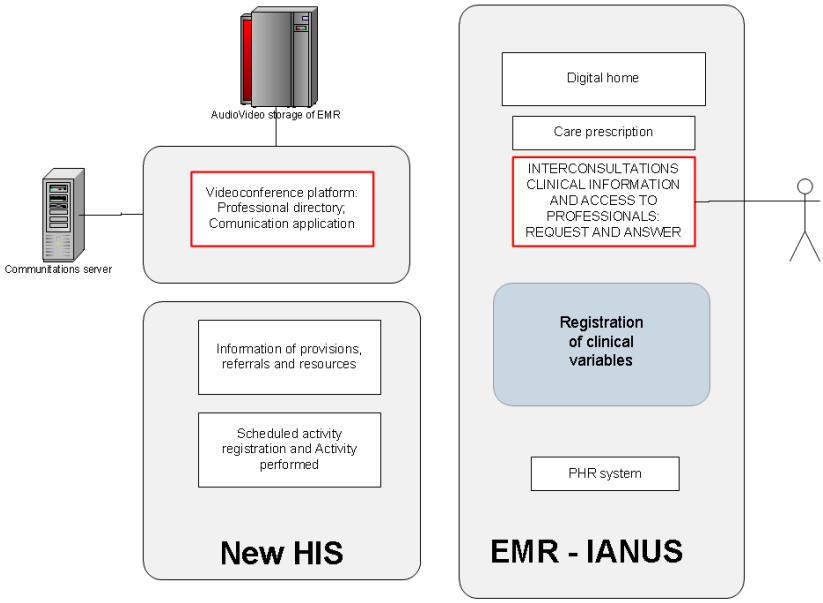
ICT Funding is expected to cover 100% of hospital centres with wireless network and mobile devices that will be incorporated during the next three years. These elements have been identified as an essential infrastructure to provide communication, interaction and traceability for professionals and patients and will be widely used as a basis on innovative telemedicine projects.

Telemedicine services are mainly implemented on an off-line model, where GPs and request diagnosis and treatment consultations to Clinicians at hospitals. More than 10.000 teleconsultations are performed on serveral areas: Dermathology, Cardiology, Neumology, Ophtalmology on the national electronic health infrastructure.

Videoconference system is available since 2010 for communication among professionals, connecting GP and secondary and tertiary centres. Several programs are currently undergoing such as: Tele-Ictus, or Diabetes programs where endocrinologists and GP collaborate in patients follow-up processes. Also, COPD programmes are using videoconference to connect patients at their home.

The Region is currently focusing on establishing integration to social care systems at e.g. physically and mentally handicapped residences and to psychiatric institutions, thus expanding the electronic communication flow among all relevant parties.

Currently, two main innovation programs named “Hospital 2050” and “Innova Saúde” are being carried out with 90 M€ of ERDF funding each, for the period 2011-2015. There is a specific project aimed to deploy a videoconference wide infrastructure that will provide ubiquitous videoconference services in June 2014.



4.1.1.7 List of other EU projects

We are planning to participate in H2020:

- PHC-21-2015: Advancing active and healthy ageing with ICT: Early risk detection and intervention (CONFIDENTIAL INFORMATION)
- PHC-30-2015: Digital representation of health data to improve disease diagnosis and treatment (CONFIDENTIAL INFORMATION) Moreover, we are planning to participate in COST actions. We have already summited our proposal. The challenge of this Proposal will tackle within a networking approach how e-Government facilitates on-line public reporting, two-way communication and will debate, on-line citizen participation in decision-making, and citizen satisfaction with ongoing e-participation processes. The networking action will try to explore and take an advantage about the impacts from governments that have engaged their citizens on-line within three macro-regional strategies (Eastern Baltic Sea Region; Euro-Region "Galicia-Northern Portugal" and Greater Region in Luxembourg); discusses issues and challenges in adopting and implementing on-line civic engagement initiatives globally. We are currently participate in: MASTERMIND, "**MAnagement of mental health diSorders Through advancEd technology and seRvices – telehealth for the MIND** ". The MasterMind Consortium intends:
- to implement at scale evidence-based computerised Cognitive Behavioural Therapy (cCBT) services for depressed adults across a number of EU and Associated Countries, and from this implementation: · identify the barriers and success factors to implement cCBT on a large scale in different political, social, economic and technical health care contexts and from the perspective of different stakeholders such as patients, professionals and health insurances · recommend successful strategies for implementing cCBT in these different contexts/settings
- to implement video-conference-enabled blended care for patients with depression treated in General Practice which uses video conferences of the patient, the GP and a specialist in order to educate both the patient and the GP on depression and its treatment, validate the diagnosis, plan the treatment and monitor course of symptoms during and after treatment.

UNITED4HEALTH, "**UNIversal solutions in TElemedicine Deployment for European HEALTHcare** ".

United4Health aims to reaching new frontiers in the evaluation and deployment of ICT services for the management of people living with chronic diseases in home settings, on a large scale. It uses as a starting point the experience accumulated in the RENEWING HEALTH Pilot A which has similar objectives to United4Health, but a wide range of interventions due to the obligation to start from running pilots.

The services which are going to be piloted in United4Health have been already validated in the framework of RENEWING HEALTH, which is due to be completed in December 2013 even if the different design (United4Health is a deployment while RENEWING HEALTH is a Randomised Controlled Trial) has imposed some adaptations. This means that all the services have been abundantly tested from the point of view of functionality and robustness of the technical solution.

Out of the large basket of services used in RENEWING HEALTH, three have been selected by the

United4Health Consortium, and will be evaluated in the framework of multicentre trials. The services selected are:

Life–long management of diabetes; Short-term follow-up after hospital discharge for COPD patients; Remote monitoring of Congestive Heart Failure.

CHRODIS-JA, **Joint Action on Chronic Diseases and promoting healthy ageing across the life cycle**

CHRODIS is a Joint Action (JA), which is co-financed by the European Commission and is managed by the Consumers, Health and Food Executive Agency (CHAFEA) within the framework of the Community's 2008- 2013 public health programme. The goal of CHRODIS-JA is to integrate chronic diseases as a priority in current and future European research and action programmes and to take into account the outcome of the reflection process into the implementation of the EU 2020 initiative. In this sense, CHRODIS-JA is intimately linked to the reflected recommendations and actions defined by the EU especially those contributing to healthy ageing.

The organisations participating in CHRODIS-JA have been designated by their national governments due to their expertise.

ACT, **Advancing care coordination and telehealth deployment**

The ACT programme brings together a pan-European consortium of leading companies, universities, hospitals and healthcare authorities. Initiated in February 2013, the 2,5 year programme will define best practices in care coordination and telehealth. The objective of this EU co-funded project is to overcome the structural and organizational barriers of the deployment of coordinated care.

The ACT programme addresses a primary challenge facing healthcare systems in EU member states: the ageing population and the related burden of chronic disease. By specifically investigating four key drivers, influencing the effective deployment of coordinated care and telehealht services and generating best practice examples, ACT provides the foundation to help overcome organisational and structural issues in patient stratification, patient and staff engagement, optimisation of organisational structures, and efficacy and efficiency.

Hospital 2050, **H2050 and Innova-saúde6**

H2050 project includes the design and planning of several subprojects aimed at developing an efficient future hospital in the management of his resources, safe for patients, profesionals and citizens, respectful with the environment and adapted to new technologies and especially focused on patients. The Project will develop infrastructure and user-centered demonstration scenes, in which are assessed and validated new health innovation projects, using a real environment integrated in the hospital complex of high capacity and using advanced methodologies of Living lab.

The project will constitute an innovation ecosystem to facilitate technology development and implement new technology solutions, not just to solve problems of Galician health system, but to develop new products and services to compete in the global healthcare market. The final result of this project is a scale demonstration of the facilities of the future hospital that it will be held physically in a new area of innovation within the Hospital of Ourense, belonging to SERGAS, and the production of different deliverables the subprojects of innovation.

Innova-saúde, H2050 and Innova-saúde6

Innova-saúde project will promote the implementation of 14 innovation subprojects in care delivery while facilitating of innovative business around the health sector of the Galician Autonomous Community. Among these subprojects it is worth to mention InnovaSuma Project, which is aligned with

the current policy strategies of SERGAS which focus on personalised medicine. The final aim of the Project is to incorpórate elements of personalised medicine, i.e. diagnostic and prognostic biomarkers for colon, lung and prostate cancers into the hospital protocols in the oncological field. The total budget for this Project is the 628.00€ and the maximun amount of each individual contract with a company is 110.000€. The Project and the related contract have been divided into three competitive phases: the demonstration of the viability of the proposal, the development of a prototype of the solution proposed and the development of a full demonstrator.

The aim is to transform the healthcare model towards a new model:

- patient centred approach: a developing new delocalised tools(telecare, telehealth, telemonitoring, web portals 2.0 for patients and professionals...) that avoid unnecessary hospitalisation and the overload of hospital services but at the time allow agile communication and access

- safe and agile healthcare services: applying new technological solutions to reduce as much as possible human errors interaction

- smart: changing structure of assistance services that certify an optimum capability in services as to quality and security

- make the health sector become an engine of socio-economic development, delivering value in the Autonomous Community of Galicia.

4.1.1.8 National or international activities or initiatives linked with the action

The national program for encouraging the PPI has a budget of 300 M€ ERDF funds. Of these 300 M€, about 50M€ will go towards cooperation among various Spanish regions. Galicia has been chosen by the ministry to lead 22% of that budget.

At the regional level, Galicia also has a plan to promote the PPI in line with the strategic priorities of its RIS3 (ris3galicia.es). It is expected to can manage 24M€ these funds on projects related to the health sector, led by the Authority of Public Health of Galicia. This implies that there is a possibility that a portion of this budget will be used to launch the purchase of the prototype that will generate with this proposal and to deploy it across our health system.

4.1.2 Central Denmark Region (Denmark)

4.1.2.1 Description of the legal entity

Central Denmark Region is one of five administrative regional units in Denmark. The primary responsibility of Central Denmark Region is healthcare, involving responsibility for hospital services, including psychiatry, health insurance, general practitioners and specialists. In addition the region operates a number of social institutions. Around 30.000 employees work to carry out regional tasks at all levels.

The population in Central Denmark Region amounts to 1,3 million. The annual healthcare budget is Euro 3,350 million. The Region has 5 hospitals of which one of them is a university hospital. There are 31 psychiatric departments. The Region has 19 municipalities who have their own healtcare budgets but

there is a strong cooperation between the municipalities and the hospital. The General Practitioners are autonomous and with own budgets.

Central Denmark Region is actively working with health care solutions that revolves around the patient, including patient involvement and empowerment. All hospitals have 100% implementation of a shared EMR (Electronic Medical Record).

In addition to being part of the buyers group in Empattics, Central Denmark Region is leading WP3 – PCP training and Industry dialogues. Central Denmark Region prioritises healthcare innovation in combination with business development and has a vast and relevant experience with Public-Private innovation. The regional Department of Procurement & Clinical Engineering has a constant focus on improving a valueadding and transparant dialogue in procurement – both of innovation and traditional. The team represents many different relevant professional backgrounds to secure a competent handling of the jobs included in the WP (see CVs).

4.1.2.2 Nominated lead in the following areas: Legal, Procurement, IT and Health Policy

	Name	Title	Department	Contact information
Legal	Janni Hadulla Nielsen	Lawyer	Department of Procurement & Clinical Engineering	janni.nielsen@stab.rm.dk . Phone: +45 7841 4519
Procurement	Tine Park	Innovation Manager	Procurement Department of Procurement & Clinical Engineering	Tine.Park@rm.dk. Phone: +45 7841 4734
IT	Lars Simesen	ICT architect	ICT Development and Architectural Design	lars.simesen@stab.rm.dk. Phone. + 45 3046 3694
Health Policy	Rikke Skou Jensen	Appoiented Deputy Director of Healthcare planning	Department of Healthcare planning	information rikke.skou.jensen@midt.rm.dk. Phone+45 7841 2000

4.1.2.3 CV of the key people

Lisbeth Kallestrup, MD. Centre Director

Centre Director, Aarhus University Hospital, Denmark. Responsible for 10 departments including 2500 staff.
During the career of Dr. Lisbeth Kallestrup empowerment in health care and health promotion has been a central focus area and a concept for all developmental initiatives.
In her current position as centre director Dr. Lisbeth Kallestrup is also responsible for af Patient involvement Programme at Aarhus University Hospital in Denmark leading and facilitating activities across the hospital – so far in 25 departments.
Lisbeth Kallestrup has always considered Empowerment as a leading principle working with strategic planning and implementation of different health programmes in all parts of the world. Dr. Lisbeth Kallestrup has a many years experience in developing health solutions with a participatory approach

worldwide as a Senior Programme Adviser in HIV/AIDS to United Nations Populations Fund (UNFPA) Head Quarter in New York, earlier as Head of Health Advisers to the European Commission in Zimbabwe, as a Consultant in HIV/AIDS at US Centres for Disease Control and Prevention and as Technical Adviser in Health Management Information System and Surveillance to Zimbabwe; employed by Danida, Ministry of Foreign Affairs Denmark.
Basic and practical experience with empowerment Lisbeth Kallestrup achieved as Adviser at the IMCC Primary Health Care project in a rural district in Bolivia dealing with health promotion, education of community health workers and empowerment of communities.

Klaus Veng, former firefighter, nurse, clinical research training and MSc IT and organization. Project manager.

Project manager for innovation at MedTech Innovation Consortuim and Aarhus University Hospital. Has experience from a wide variety of innovation projects. Everything from developing apps for clinicians and patients, new approach to patient admission and new hospital beds.
Clinical experience from emergency departments, cardiac unit and closed psychiatric ward. Worked with product development, design and innovation for several private companies and has experience as a clinical product designer from a health IT company working with clinical logistics.

Thea Boje Windfeldt, Cand. Mag. Anthro. Innovation Consultant

User Driven Innovation expert with nearly 10 years of experience within PPI, user driven innovation and digitalization of workflow and services. Special focus on Design Thinking and Design Anthropology within the development processes and on Strategic Design throughout the process.
Extensive expertise from both private (7 years) and public sector (3,5 years).
Leader expertise of both ideation processes, large scale projects and teams/departments.

Gitte Kjeldsen,Project Manager

Public Private Innovation (PPI) expert at MedTech Innovation Consortium and the regional hospital at Horsens. 6 years of experience with PPI within healthcare ICT solutions.
18 years of experience from private companies – finance and IT, of which 10 years of management responsibility in a large private company within change management, sales and conceptualization of new solutions to the public sector.
Plans and coordinates WP3. Publication: Larsen S B; Soerensen N, Grøndahl M, **Kjeldsen G**: Toward a shared service center for telemedicine – Telemedicine in Denmark, and a possible way forward. (is submitted and accepted by Health Informatics Journal and will be published later this year)

Kirsten Lomborg, Professor of Health Science, Aarhus University PhD Nursing Science

Manager of the Research Programme in Patient Involvement, Aarhus University Hospital. 121 publications. Among others: Zøylner A. Christiansen P, Kirkegaard P, **Lomborg K**: Patient involvement in the development of individualized care for women with breast cancer. ; Bove D G, Overgaard D, Lindhardt B Ø, **Lomborg K**, Midtgaard J: Development and Evaluation of a Brief Psychoeducative Supportive Intervention in Patients with Advanced COPD.

Britta Ravn, Head of department at Centre for Telemedicine and Telehealthcare in Central Denmark Region

Nurse with extensive experiences in implementation and scalability within health- and socialcare at both national and regional level. Responsible for implementing telemedicine and for co-operation between municipalities, hospitals and GP's in Central Denmark Region. Is a member of The National Forum for Telemedicine and ICT-supported Patient Empowerment, established by Danish Regions and of The National Co-ordination of Telemedicine, established by The Danish Agency for Digitisation. Publications: 4 book chapters and 5 articles on implementation and "Check! Telehealthcare at Scale", a self-evaluation tool to asses readiness for scaling up e-health solution, at http://www.rm.dk/sundhed/faginfo/center-for-telemedicin/in-english/tools/

Egelund Antonsen, Nurse, diploma in management and governance, IPMA certified level D. Innovation Consultant and Project Manager

Specialist with implementing technological solutions in a hospital setting where the technologic solutions ensure a better quality for the patient and a better efficiency in the hospital.
Specialist in Organization development with a focus on ensuring the coherence and cooperation between the health professionals and bringing new structures in to the hospital.
Expertise from public sector (15 years)

Tine Park, Innovation Manager, Department of Procurement & Clinical Engineering

Responsible for internal and external innovation activities, among others implementation of the new regional strategy for intelligent public procurement (procurement for innovation) and general optimisation of conditions for and effects from Public-Private collaboration. Vast experience with health care innovation in both private and public sector and within Public-Private innovation. Educated an Industrial Designer with experience within planning, facilitation and performance of international ethnographic user studies, user involvement and co-creation, concept- and product development, commercial development, innovation management and project management of complex development projects with many multidisciplinary partners.

Janni Hadulla Nielsen, Specialist lawyer in public procurement, Department of Procurement & Clinical Engineering

Vast experience with Public procurement, open procedures and restricted procedures. Experience with negotiations and dialogue before, during and after the tender procedure. Thorough knowledge about the legal aspects of public private innovation and research and development.
One of the driving forces at national level in new dialogue based tender forms that benefit both public health care and private R&D.
Highly involved in the preparation and implementation of the new procurement directive in Denmark.

Olav Bjørn Petersen, MD, Ph.D. Associate professor Dr

Head of Fetal Medicine Unit, Aarhus University Hospital. >6 years of experience with clinical telemedicine/telehealth.
Initiator- and project manager of 2 large obstetric telemedicine/home monitoring projects at Aarhus University Hospital including home-monitoring of women with pregnancy complication: ABT-project and KIH-project.
Initiator- and project manager of ongoing telemedicine project at Aarhus University Hospital regarding home-monitoring during induction of labour.
Co-inventor and developer of the current national telemedicine platform in Denmark (OpenTele).
Project manager of project regarding development of real-time Cardio-Toco-Graph for telemonitoring of pregnant women (cooperation with companies Monica, Milou and SilverBullet)
Board member of 4S: National Foundation of Software Services (http://4s-online.dk/english.php).
President of Danish Fetal Medicine Society 2012-2014
President of Steering committee, Danish National Fetal Medicine Database 2014-
Received > 1,2 million € in public funding for telemedicine/telehealth projects since 2010.
118 publications, 5 book chapters. Speaker/organizer at 6 national telemedicine conferences since 2014.
Ph.D. 1999
Supervisor of 4 completed and one ongoing PhD-projects.
H-index: 7

4.1.2.4 List of relevant publications

- ICT architecture for Telemedicine (Decision at national level)
- Shared Service Centre concept: http://www.rm.dk/sundhed/faginfo/center-for-telemedicin/telemedicinske-projekter/falles-servicecenter/

4.1.2.5 List of relevant previous projects

- Central Denmark Region Public-Private Innovation Fund: Funding, monitoring and evaluation of Public-Private Innovation projects which has contributed with learning of what makes PPI successfull and the opposite. This new knowledge has accelerated the interest for procurement of innovation in order to increase the effects from PPI both in a commercial and an implementation aspect. Furthermore the experiences has resulted in recommendations to the EU funded national project OPI-Lab (www.opilab.dk) and to the national agenda regarding more effective (and efficient) developments projects in the public sector.
- Clinical Logistics: A competitive dialogue for clinical logistics including R&D of the solution has resulted in an commercial successful IT solution on several regional hospitals. The solution creates a user friendly overview, optimises time consumption and consumption of resources and heightens quality.
- Horsens: at the forefront of health. This long term project has been initiated to create value adding telemedicine solutions for patients living with chronic diseases, focusing on one userfriendly platform that secures coordination and coherence across sectors. The project has been an involving process including Central Denmark Region (hospital), the municipality of Horsens, patients, GPs and private companies in both design, prototyping and test of the IT solution. The project has among others contributed with relevant experience regarding

matchmaking and consortiums. The project results are about to be the basis of a tender specification.

4.1.2.6 Description of significant infrastructure and/or major items of technical equipment

a. ICT infrastructure in Central Denmark Region: All hospitals have the same EHR and exchange of data between hospitals, general practitioners and municipalities is done according to a common standard
b. The Shared Medication Record is a mandatory national service that enables health care providers and patients to see the patients' complete and current medication information at the point of care
c. www.sundhed.dk is a healthcare portal for patients where they can find their own data

4.1.2.7 National or international activities or initiatives linked with the action

a. A national forum for regional and national telemedicine will participate in the knowledge sharing from EMPATTICS
b. Knowledge sharing on a national level also includes the Regional Forum for Collaboration regarding Healthcare Innovation.
c. Implementation of Strategy for Intelligent Public Procurement on both regional and national level.
d. Expected implementation of the new procurement directive in Denmark in October 2015.

4.1.3 Servicio Aragonés de Salud (Spain)

4.1.3.1 Description of the legal entity

The Autonomous Region of Aragón is located on the northeast of Spain, with a rate of 50% inhabitants living in the capital and the rest sparsely spread among the rest of the municipalities in the territory.

Servicio Aragonés de Salud (SALUD) is the public health provider for Aragón, having the responsibilities of overall management and co-ordination of the existing healthcare resources in the territory, provide Primary care, Secondary care, mental care and geriatric care management, including homecare, and to the promotion and protection of individual and public health.

SALUD's **mission** is to provide an integral healthcare attention, to ensure the services accessibility, to promote healthy lifestyles, the prevention and protection and to maintain patients' autonomy and their social inclusion.

SALUD has a network composed of 12 General Hospitals, 110 Primary Health Centres and 5 Geriatric hospitals. It has introduced innovation on the professionals' regular practice through the integration of telemedicine solutions thanks to the collaboration on several strategic projects.

Barbastro's Healthcare Area (SALUD-BHA) has worked in a very active manner in the last decade in the deployment of several telemedicine solutions in the sector. Firstly, and thanks to several European projects, the sector was provided with devices and systems creating a niche of technology, communications and information systems needed to deploy telemedicine solutions across the area.

SALUD-BHA was provided with a wide band communication network connecting all centres in the territory. Then, SALUD-BHA worked on the deployment of basic telemedicine services that allows a two-way communication between specialists to offer healthcare assistance across the whole territory.

SALUD-BHA has been key to provide IT services to the organization, as the clinic intranet, a portal available to all staff in the healthcare sector that gives access to the applications of each service. And has been working on the definition of integrated care programs to patients, mainly older people with chronic conditions, starting with telemonitoring programs in rural environments, enhancing them to other ranges of populations, expanding the basket of services and enrolling care providers and empowering citizens to achieve a better quality integrated care and co-responsabilizating agents in the management of the health status.

SALUD also works on policies of patient empowerment where users have online access to resources and services, permitting users to assume a more active role in the management of their own health through a platform to have access to their EHR and clinical results.

The sector is working on creating a technological platform with global access to provide health services and tele-assistance throughout the world, based on advances in video collaboration solutions. This environment will be able to integrate units from different centres with the aim to integrate virtual specialised assistance services, including home hospitalisation.

All services are evaluated with clinical and economic indicators, and assure patients' privacy and security following the guidelines described by the ethical evaluation team.

4.1.3.2 Nominated lead in the following areas: Legal, Procurement, IT and Health Policy

	Name	Title	Department	Contact information
Legal	Ángel Sanz Barea	Manager of the Aragonais Healthcare Service (SALUD)	Healthcare, Social Welfare and Family	Servicios Centrales del SALUD, Edificio Plaza de la Convivencia- Plaza de la Convivencia, 2-50071 Zaragoza (Zaragoza)
Procurement	Jose Luis Aguado Ipiens	Manager of the CGIPC	CGIPC SALUD (Integrated Management of Corporative Projects Centre at the SALUD)	jlaguado@salud.aragon.es
IT	Juan Coll Clavero	Innovation and New Technologies Manager	Barbastro Healthcare Area (SALUD)	jcoll@salud.aragon.es
Health Policy	Juan Coll Clavero	Innovation and New Technologies Manager	Barbastro Healthcare Area (SALUD)	jcoll@salud.aragon.es

4.1.3.3 CV of the key people

Juan Coll Clavero

Juan Coll is the responsible for innovation and new technologies at Barbastro Hospital, Barbastro Health Care Sector since 2002. Juan Coll holds a Degree in Medicine and Surgery granted by the University of Zaragoza in 1983. From 1990-2002, he was the Computer and Information Systems Manager at Barbastro‟s Hospital. Juan Coll has participated in several projects in the fields of telemedicine, telecare and new technologies. Some of the most representative are the national project PITES T-Ayuda, EU projects such as eTEN HEALTH OPTIMUM and HEALTH OPTIMUM ID. Now he is involved in two pilot A projects: SMARTCARE (Joining up ICT and service processes for integrated care in Europe) and MASTERMIND (Management of mental health disorders with advanced technology and services). He participates in a very active manner in congresses, conferences, forum and scientific days through discussions, oral communications and posters, being very active in the dissemination of the projects also in written publications. Juan and the Innovation and New Technologies Department have been awarded with several prizes, such as the "Sanitaria 2000" prize 2011 for their technological contribution to the Aragonais Public Health System, the "National Prize of Informatics and Health" 2011 by the Health Informatics Spanish Society (SEIS) recognising "their contribution to the development of teleHealth at a National and European level, thanks to the leadership of the unit in new technologies and health innovation" and recently the national "Barea Professor Award" for the work developed under the field of "Innovation, development and new technologies".

Jose Luis Aguado Ipiens

Jose Luis Aguado is the responsible of the CGIPC (Integrated Management of Corporative Projects Centre) at the SALUD (Aragonais Healthcare Service).

Jose Luis has a degree as Industrial Engineer from the ETSI at Zaragoza. He has also performed courses in the area of business management and planning from the CEPADE.

He has been responsible for the Systems and Technological Communications Area at Fujitsu Spain in the Aragón región. He has also worked as a freelance in technical support, consultancy and project management for the regional administration in Aragón in the areas: Informatics, Local Administration and Regional Policy, Industry and SMEs.

4.1.3.4 List of relevant publications

- Coll J., Anglés R. Chapter two of the book. Aragonais Healthcare Service: results of PITES project on social and health care for chronic dependent elders in Aragón. Monografias. NIPO 725-14-015-2 Madrid 2014.
- Is Ambient Assisted Living the Panacea for Ageing Population? ISBN: 978-1-61499-190-8, Ed. IOS Press (results of the DREAMING project).
- SIMPHS3 - Strategic Intelligence Monitor on Personal Health Systems. SIMPHS3 DREAMING (Spain) Case study report. The SIMPHS3 research looks at integrated care services - including telehealth, telecare and independent living solutions - for older patients with chronic conditions.

This research aims to define operational guidelines for further implementation in European regions. The SALUD has participated in the DREAMING chapter and also in the guidelines definition.

- Hernandez C., Coll J, several authors. IT Innovation for elders. Situation, requirements and solutions for integral attention to chronicity and dependency. Ed. Fundación Vodafone. ISBN: 84-934740-6-1

4.1.3.5 List of relevant previous projects

- **SUSTAINS** CIP-ICT-PSP PN 297206 (2012-2014). Support USers To Access INformation and Services. The major aim of SUSTAINS was the patient empowerment through the online access to clinical and administrative services related to healthcare, and more specifically to EHR. SUSTAINS contributed to three major healthcare related issues: empowerment of patients, quality of care and efficiency of the healthcare systems.
- **PITES**. PI09-90549 (2010-2012). PITES "Innovation Platform of new telemedicine and e-health services for chronic-dependent patients" (PN: PI09-90110), aim was to design an integrated service of social and health care to fragile chronic dependent elderly people. PITES was funded by a FIS Grant in collaboration with the National Health Institute Carlos III. PITES was awarded with the national Prize "Profesor Barea 2014" in the "Innovation, Development and New Technologies category"
- **DREAMING** CIP-ICT-PSP PN225023 (2009-2012). elDeRly-friEndly Alarm handling and MonitorING. The main goal of DREAMING was to demonstrate how new services can support independent living of elderly people. The major aim of DREAMING project was keeping elderly people in their home environment as long as their physical and mental conditions allow it. DREAMING strategy was centred around the goal of measuring the real impact of the monitoring and eInclusion services on the quality of life of the elderly people, the cost of social and health care delivered to them and on a number of clinical indicators.

4.1.3.6 Description of significant infrastructure and/or major items of technical equipment

SALUD owns nodes and data centres that host patient's clinical information with a total capacity of 137TB and 468 servers. Nodes host all departmental and corporate applications and databases for each sector. A fibre optic cable links nodes between hospitals and ASDL lines in centres.

SALUD provides multiple systems and services the most important being:

- The users database (BDU) that identify users in the region.

- Primary care electronic health record (OMI AP) in centres and medical offices.

- Clinic Intranets: Every hospital has a corporate intranet for professional use integrated with OMI-AP.

- Salud Informa: A web page oriented to citizens

- Hospital management system (HIS) that hosts all clinical activity at the centres and provision units.

- Emergencies services information system (PCH) deployed in all sectors.

- Radiology images digitisation: an images storage and management system (PACS) and an radiology information system (RIS)

- Others such as the e-prescription, telemedicine solutions, nursing care IS, data warehouse and business intelligence, patients manager, knowledge portal, online training tool, user's call centre, management and support to systems centre.

4.1.3.7 List of other EU projects

SALUD is working in several Europeans projects related to the attention to chronics. Starting in 2013, the ICT-PSP-CIP project **SMARTCARE** "Joining up ICT and service processes for quality integrated care in Europe" (Grant agreement no.: 325158) aims to provide integrated care by collaboration and coordination of care attention, involving all care providers into an integration of services and care.

MASTERMIND ICT-PSP-CIP project "MAnagement of mental health diSorders Through advancEd technology and seRvices – teleHealth for the MIND" (Grant agreement no: 621000) efforts are to oriented to patients with depression, and pretends to implement at high scale evidence based computerised Cognitive Behavioural Therapy (cCBT) services for depressed adults across 9 EU and Associated Countries.

e-Resater is an European Project that permitted to develop local networks of healthcare providers in 6 territories across South–European regions and pool their experiences in e-Health provision through a dedicated transnational platform. This platform gathered exchange tools, an observatory of health in rural areas, together with tutorials on how to create projects of local health networks in rural areas and tools to assess and evaluate eHealth projects.

4.1.3.8 National or international activities or initiatives linked with the action

The importance of searching new mechanisms to ensure the health services in Aragon territory is shown as the Servicio Aragonés de Salud, and the Aragones' Health and Welfare Department is currently working on the creation of a Centre of Excellence in Telemedicine and e-Health that will provide to a niche of technological companies and industries with local, regional, national and international scope and that will be available to cooperate thorough collaboration frameworks contributing with added value and high quality ICT solutions.

Moreover, other regional policies that contribute to the social and health services are the "Information Systems and Telemedicine Plan" of Aragon's Government, the "Strategic Plan for Aragon Social Services 2012_2015", the "Aragon Social Law", and "the Strategy of Attention to chronics".

SALUD is the body of the Aragon's Health, Welfare and Family Department that takes care of the health services of the region and has the responsibilities to overall manage and co-ordinate the existing healthcare resources in the territory of Aragón, Primary Care and Secondary Care management, including homecare and promotion and protection of individual and collective health.

The Aragon Government, together with the Canarian Region, has applied to a National Spanish Innovative Public Procurement with the aim of promoting the development of ICT solutions focused on implementing new health services. SALUD also search to provide citizens with a Health Council and Multidevice Triage service, 24 hours a day, 365 days a year, together with a solution that allows the choice of the most suitable, available health care resource at a certain moment and place, suitable to all health services on a healthcare center with which Primary care, Specialized care and Chronic Patients assistance is performed.

Also, a new variant of this implementation of the Health Council and Multidevice Triage service and, compatible with it, will be developed. This variant will permit to proceed to an integral enhancement of the emergencies and medical urgencies process, by using real-time information of the availability of the healthcare resources, human and material. That is, since citizens access that Health Council and Multidisciplinary Triage service or even before that occurs, so that the acute of the pathology of the chronic condition and current inefficient referrals to Emergency units are avoided, and until discharge form the process can be proceed or the patient is admitted.

4.1.4 Le Groupement de Coopération Sanitaire pour le Développement des Systèmes d'Information partagés en Santé en Ile-de-France (GCS D-SISIF) (France)

4.1.4.1 Description of the legal entity

Founded in 2008, the GCS D-SISIF (www.gcsdsisif.fr) is a Health care cooperation consortium which aims to develop the shared health information systems within the Ile-De-France region. The GCS D-SISIF is in charge of building the e-health domain. The target is the regional cyberspace of health called ENRS.

This ENRS (Health Regional Digital Space) is defined as computerized services and applications undertaken by the health regional Agency (ARS) and piloted by the GCS D-SISIF. It is compliant with the interoperability framework and the national methods promoted by the national health information Aggency (ASIP Santé). It meets the objectives defined by the national and regional health policies.

The GCS D-SISIF is composed of 8 colleges of members who represent all the health organizations and General Practioneers in the region.

4.1.4.2 CV of the key people

Eric Lepage

He is the Head of the Innovation department at the GCS D-SISIF and Professor of Medical Informatics at Paris 12 University. He was medical CIO for 10 years of the AP-HP institution regrouping 37 public university hospitals. His current research interest focus on semantic interoperability, medical decision making and evaluation of HIS impact.

4.1.4.3 List of relevant publications

LEPAGE E: Sharing information between 72 000 health care professionals across 37 public university hospitals :

a review of AP-HP experiences**.**

eHealth Week 2011 – HIMSS, Budapest, 2011

LEPAGE E, DANIEL Ch, CORMONT S, BUEMI A.

A global European approach for sharing medical information : Dream or reality ?

eHealth Week 2011 – HIMSS, Budapest, 2011

Vandenbussche PY, Cormont S, André C, Daniel C, Delahousse J, Charlet J, Lepage E

Implementation of a platform dedicated to the biomedical analysis terminologies management.

J Am Med Inform Assoc, 2013, 10.1136/amiajnl-2012-001410

Joulakian M, Griffon N, Schuer M1, Lepage E, Savoy-Collet C, Skalli S, Massari P, Darmoni S

Indicateurs en biologie et en imagerie au sein des systèmes d'information de santé

Journées francophone d'Informatique Médicale, 2014

Schuersa M, Joulakiana M, Griffon N, Pachécoa N, Périgarda N, Lepage E, WatLEB l, Massari P, Darmoni S

Quality indicators from laboratory and radiology information systems

Medinfo, 2015, accepted for presentation

4.1.4.4 Description of significant infrastructure and/or major items of technical equipment

The GCS D-SISIF aims to improve the work conditions of its members by facilitating:

- The interoperability and the mutualization among members
- The administrative, legal and financial office delivery
- The operational project management activities

The GCS D-SISIF is composed of 6 departments. One of them, headed by Pr Eric Lepage, is in charge of the introduction of new technologies in the medical practice. In this perspective, projects concerning connected objects, patient education through the serious games, mobility, and management of care by the patient are studied. This department is also in charge of conducting the TerriSanté project whose objective is to share information among all the health professional (including medico-social structure) but also deliver services to health users and the patient (scheduling, lab and imaging results, care management, hospital admission, e-order, on line payment). This project should be experimented on a sub population of 300 000 before generalization on the Ile de France region (12 Millions people).

4.1.4.5 List of other EU projects

The GCS D-SISIF has led several projects or activities connected to the subject of the GPS4IC proposal, such as :

Region sans film project permitting to implement the PACS solution on more than 20 hospitals in the Ile de France region, the next step is to share all the images performed in the Ile de France region

PAERPA project whose objective is to increase the management of care of the elderly person. This project is also based on sharing information concerning the follow up of the elderly person.

The GCS D SISIF is also involved in the interoperability management and its usage for sharing the information. In this perspective, he conducts a project permitting the exchange of laboratory results based on LOINC nomenclature and the integration of these lab results in the professional tool.

4.1.5 General Hospital Slovenj Gradec (Slovenia)

4.1.5.1 Description of the legal entity

The Slovenj Gradec General Hospital (SB-SG) is a public health care institute which performs secondary-level health-care activities and other activities stipulated by its Founding Act, primarily for the Carintia (Koroška) and the Savinjsko-Šaleška statistical regions. Its founder is the Republic of Slovenia.

Health-care activities at the secondary level are as follows:

- Hospital health-care activities in the field of internal medicine, paediatrics, gynaecology and obstetrics, traumatology with orthopaedic surgery, general and abdominal surgery and urology. Its operational plan is implemented in four large surgical theatres and two smaller ones with a day surgery office.
- Specialist outpatient activities are performed in all basic medical fields, in the field of physical medicine and rehabilitation, and in the field of classical radiology with ultrasound and CT diagnostics and mammography diagnostics.

The Slovenj Gradec General Hospital admits each year around 15,000 patients and 160,000 outpatients. It employs 727 people: 142 doctors, including 77 specialists, 59 residents and 6 interns. In the field of nursing, it employs 131 registered nurses with a bachelor's degree in nursing, 192 middle-level nurses and 5 medical technicians doing internships. In the medical field, there are also 9 pharmacists and 57 employees from other related health-care fields. The non-medical staff comprises of 55 employees in the field of health-care administration, 65 employees in the field of provisions/supply and catering and 57 employees in the fields of technical maintenance and administration.

Being a teaching and research institution SB-SG participates in international projects and studies.

Telehealth Centre called CEZAR (Center za zdravje na daljavo Koroške regije) runs within the hospital. It provides currently support to 450 patients with diabetes mellitus (DM) and patient with congestive heart failure (CHF) in the region of Carintia (Koroška).

Name	Gender	Short CV or description of the profile
Prim. Cirila Slemenik-Pušnik, MD, Spec. Int. Med.	female	Prim. Cirila Slemenik-Pušnik is internal medicine specialist and the key staff at the hospital department of Internal medicine running daily practice since 1991. Her expertise is in management of preventative and curative programmes for persons with chronic heart failure, planning of curative programmes and education of patients. She has participated several research projects and has run medical trials in the hospital. She is also the lead cardiologist for telemedical support of patients with congestive heart failure from the CEZAR telemedicine centre at SB-SG. Additionally, she coaches two patient's associations for active and healthy living of patients with heart diseases. Role of Mrs. Pušnik will be linked to CHF patients (identification, inclusion, medical support) in all stages of the services development: planning, designing, setting-up, testing and evaluating the solutions. She will work closely with CHF patients' organisations on the telemedicine services promotion.
Metka Epšek-Lenart, MD, Spec. Int. Med.	female	Metka Epšek-Lenart is lead diabetologist at the hospital Internal medicine department running diabetes department in the SB-SG and several regional healthcare centres. She is also responsible for telemedical support of diabetic patients from the CEZAR telemedicine centre at SB-SG. During the last 12 years she has been involved in several clinical trials within the research activities of the GH Slovenj Gradec. She has gained reach working experience with hospitalized patients with diabetes and other endocrinology diseases. She has been very active in education of diabetic patients for sustainable life with diabetes and has established her own preventative and curative programmes for diabetes. Role of Mrs. Epšek-Lenart will be linked to DM patients (identification, inclusion, medical support) in all stages of the services development: planning, designing, setting-up, testing and evaluating the solutions. She will also guide the development of activity monitoring system as a part of the telemedicine support to DM patients. She will also work with DM patients' organisations on the services promotion.
Maja Rakuša	female	Maja Rakuša is a senior graduated nurse specializing in telehealth. She is a telehealth centre coordinator at SB-SG (CEZAR) and runs daily tasks related to CHF and DM patient recruitment, training and inclusion into the telemedicine services. She also provides professional support to the patients and work in cooperation with the medical specialist. She is also telemedicine data manager.

Stanislav Pušnik, MSc, MD, spec.		Stanislav Pušnik is a physician – Specialist of Occupational, Traffic and Sports Medicine. Employed at Primary Healthcare Centre Ravne na Koroškem since 1982 and acts as a director since 1994. He works as a specialist of occupational medicine, serves in emergency medical services and runs general medical practice. His commitment in the project will be part time bringing expertise in primary care services. Mr.Pušnik will work on business models, promotion of the services at primary level, incorporation of the services into the existing healthcare system in Slovenia and on reimbursement issues.
Ph.D. student	tbd	Telemedicine data analysis, dissemination of the results.
Quality manager	tbd	System analysis and the services quality improvements, accreditation of services
District nurse	tbd	Home visits to patients - telemedicine service users.

4.1.5.2 Nominated lead in the following areas: Legal, Procurement, IT and Health Policy

	Name	Title	Department	Contact information
Legal	Janez Lavre	Director	Management	Same as for the institution
Procurement	Ivanka Linasi	CFO	Finances	Same as for the institution
IT	Drago Rudel	CIO	IT	Same as for the institution
Health Policy CHF	Cirila Slemenik-Pušnik	Prim.MD,Spec.	Department of Internal Medicine	Same as for the institution
Health Policy DM	Metka Epšek-Lenart	MD,Spec.	Department of Internal Medicine	Same as for the institution
Health Policy Obesity	Brane Breznikar	MD, Spec.	Department of Surgery	Same as for the institution

4.1.5.3 CV of the key people

Prim. Cirila Slemenik-Pušnik, MD, Spec. Int. Med.

Prim. Cirila Slemenik-Pušnik is internal medicine specialist and the key staff at the hospital department of Internal medicine. She graduated in 1983 at the University of Ljubljana, Slovenia and works towards her M.Sc. degree at the University of Rijeka, Croatia. Since 1983 she works at the General Hospital Slovenj Gradec.

Her expertise is in management of preventative and curative programmes for persons with chronic heart failure, planning of curative programmes and education of patients. From 1991 to 2006 she held a position of the head of the Intensive care unit of the internal department at the General Hospital Slovenj Gradec. In 2010 she chaired the "Association of physicians of Carinthia". In 2006 she chaired "The Commission for drugs" at the hospital.

Dr. Slemenik-Pušnik has participated several research projects and has run medical trials in the hospital e.g. United4Health EU project (2013-2015), *Shift* (2008), "*Beautiful* (2006). She is also the lead

cardiologist for telemedical support of patients with congestive heart failure from the CEZAR telemedicine centre at SB-SG. She also coaches two patient associations for active and healthy living with heart diseases.

4.1.5.4 List of relevant publications

Rudel D, Slemenik-Pušnik C, Epšek-Lenart M, Pušnik S, Lavre J. Patient Inclusion in a Diabetic and CHF Telemedicine Services – The United4Health Slovenia Experience, In: Jordanova M, Lievens F, editors. Global telemedicine and eHealth updates: knowledge resources, Vol. 7, 2014, 58-61.

Rudel D, Slemenik-Pušnik C, Epšek-Lenart M, Pušnik S, Lavre J. From a green field to a telemedicine service supporting 400 patients in one year – the Slovenian experience, In: Jordanova M, Lievens F, editors. Global telemedicine and eHealth updates: knowledge resources, Vol. 8, 2015.

4.1.5.5 List of relevant previous projects

United4Health - UNIversal Solutions in Telemedicine Deployment for European HEALTH care. EU project CIP-ICT PSP-2012-3 325215. Available at: http://united4health.eu/ (last accessed 2014-02-08).

4.1.4.6 Description of significant infrastructure and/or major items of technical equipment

The key infrastructure used by the CEZAR will be the telemedicine centre with all its infrastructure that consists of an office with ICT infrastructure, service application and data servers located in the SB-SG informatics centre, sets of measuring equipment for each patient including a smart phones as gateways.

4.1.5.7 List of other EU projects

a) In 2014, the Department of Anaesthesiology, Intensive Therapy Unit, will be included in the project titled CREACTIVE (**C**ollaborative **RE**search on **Ac**ute **T**raumatic Brain **I**njury in Intensi**ve** Care Medicine in **E**urope). The aim of the project is to conduct a longitudinal follow-up of patients with moderate (GCS 9-12) and severe (GCS<9) brain injuries over the next 50 months and to define those genetic and phenotypic characteristics that affect the neurological outcomes in injured patients. The purpose of the project is to compare the results and quality of treatment with those of other centres, i.e. to implement so-called benchmarking (Italy, Cyprus, Hungary, Poland, Greece), and to indirectly participate in research work (with blood samples) that will be carried out in Milan, Italy (a genetic and phenotypic analysis). The project is financed with European funds. (value €130,000)

b) In 2013, it participated in an international study under the auspices of the European Society of Anaesthesiology, ESA: **ETPOS**: European Transfusion Practice and Outcome Study: A multi-central evaluation of the standard of transfusion care and clinical outcomes for elective surgical patients. Observational Study. The study was conducted during the period from 1 April to 30 June 2013. A total of five patients were enrolled and the study was successfully concluded. (value €200,000)

c) The Department of Internal Medicine participated in the HGT REP-060 study (open extension of the TKT028 study)

d) The Department of Internal Medicine also participated in a multi-centric, open, randomised study on the safety and clinical results of treatment with Replagal® as part of enzyme

substitution therapy in adult patients with Fabry disease. (The total project value was around €2 million and the SB-SG share was €500,000).

e) The Department of Urology is participating in a 4-year study titled *Prospective register of patients with a confirmed diagnosis of prostate adenocarcinoma manifested as metastasised castration-resistant prostate cancer* – Study No. 212082PCR4001 (2013-2016), client Janssen-Cilag International NV.

4.1.6 European Health Futures Forum (UK/Spain)

4.1.6.1 Description of the legal entity

Lead organisation: **The European Health Futures Forum** (EHFF) is an NGO dedicated to helping improve the health of the citizens of Europe, by creating a network of networks, knowledge exchange on the future of health and healthcare in Europe, promoting the active employment of futures methodology in the context of European Health and Healthcare, promoting transformational change through multi stakeholder collaboration and creating a virtual intergenerational community of healthcare innovators. 19 countries are represented within EHFF and the individuals and the organisations they represent are listed with brief CVs in the Community section of the EHFF website: www.ehff.eu. EHFF has been involved in a number of EC initiatives including those related to the patient empowerment and self-care since 2013, listed below. EHFF is also involved in connected Healthcare and developing the education of Healthcare professionals as demonstrated by working relationships with the ECHAlliance, Mobile World Capital Barcelona, and EHMA and EFPC. Registration number, Companies House UK : 8447376 **PIC no :937661753**

Fundacion Avedis Donabedian (FAD), is a non-profit organization that has supported quality efforts in Health and Social Care since 1989 (www.fadq.org). Over time FAD has participated in many national projects related to chronic care, health care integration and patient and citizens empowerment. FAD is currently part of the Spanish Network of Health Services and Chronicity (REDISSEC). FAD has undertaken a number of European projects, being the leader of the EU Framework research projects MARQuIS and DUQUE on effectiveness of quality mechanisms (including patients' safety and patients' empowerment). FAD has also participated as a partner in HANDOVER (7th FM) and PATIENT (Erasmus) in the last three years and has contributed to the ongoing Joint Action on quality and safety, PaSQ. FAD co-led the EMPATHIE-project on self-management in chronic diseases, recently published and is currently a partner in another DG-SANTE tender on self-care, PISCE.

The European Patients' Forum (EPF) was founded in 2003 to ensure that the patients' community drives policies and programmes that affect patients' lives to bring changes empowering them to be equal citizens within the EU (www.eu-patient.eu). EPF currently represents 61 members, which are national coalitions of patients organizations and disease-specific patient organizations working at European level, and. EPF reflects the voice of an estimated 150 million patients affected by various chronic diseases throughout Europe. EPF's vision for the future is that all patients with chronic and/or lifelong conditions in the EU have access to high quality, patient-centered equitable health and social care. The EPF strategic goals focus on areas such as health literacy, healthcare design and delivery, patient involvement, patient empowerment, sustainable patients' organizations and non-discrimination. EPF is involved in many European initiatives.

UMCU: With over a 1,100 beds and more than 12,000 employees and an annual turnover of one billion Euros the University Medical Centre Utrecht is the largest academic centre in the Netherlands (www.umcutrecht.nl). Patient care and biomedical research are closely linked, which creates an environment where scientific advancements quickly move from bench to bedside, advancements that improve patients' lives and that matter internationally. The scientific output from the UMC Utrecht has a 1.68 citation score between 2007 and 2010/11. This implies a scientific impact 68% higher than world average. Besides a hospital based living lab, UMCU has community based living labs for healthcare innovation R&D projects in the local communities.The target population here are the elderly with and without chronic conditions in the community and at work. UMCU is acknowledged for their interaction with patients and society, which creates an 'innovation loop' where societal issues guide scientific research, putting patient needs at the heart of our scientific endeavour.

Dr Diane Whitehouse (Consultant) is a partner in The Castlegate Consultancy, a UK-based public services and eHealth policy and analysis group. She works actively in the research, policy, and deployment fields of eHealth with a variety of groups and associations. Until February 2007, Diane was a Scientific Officer in the 'ICT for Health' Unit of the European Commission's General Directorate Information Society and Media (now called Connect). In 2009/10, she was particularly involved in writing the Value+ handbook for project coordinators about patient involvement. Since 2010, in EHTEL, she has concentrated on areas including policy development, stakeholder engagement, telehealth and interoperability. She is an active participant in the active and healthy ageing domain of the European Innovation Partnership, including work in the action group on integrated care. Diane is a social scientist whose work focuses on the social, organisational, and ethical aspects of ICT, and has included market-related studies. Her several books e.g., most recently the co-edited volume, "*Managing eHealth: from Vision to Reality*", are well-known.

4.1.6.2 CV of the key people

Dr David Somekh

Trained:

Oxford University and Middlesex Hospital (MA Physiology and MB, BCh) 1969

London University (PhD in Experimental Psychology) 1974

FRCPsych (post-graduate training at Maudsley Hospital, London) 1975-1982

Kleinian Psychoanalyst (training with British Psychoanalytic Society completed 1982, retired from clinical work in psychoanalysis 2010)

Consultant Forensic Psychiatrist with specialist registration in UK NHS since 1982

Clinical practice and managerial experience:

NHS regional secure services (Ravensbourne NHS Trust and Kings College Hospital) 1982-1995

Clinical director for Mental Health, Ravensbourne NHST (1991-3)

Clinical Director Forensic services (Riverside NHS Trust) 1995-7

CEO Blenheim House Ltd. (forensic division of Westminster HC) (1997-2001)

Retired from NHS and full clinical practice 2002. Continues to present day as independent forensic psychiatry expert.

Forensic Advisor to HASCAS since 2002 (Health and Social Care Advisory Service: NGO specialising in consultancy projects for NHS in MH, elderly and CAMS services) e.g since 2008, once or twice per year on average medical member on statutory external enquiry panel on homicides by mental health patients conducted by HASCAS as preferred provider commissioned by NHS

Quality activities:

National (UK): Chair national NGO for quality in healthcare from 1995 (was AQH, then merged with IQA to become IQA-HC) to 2004 (joined Board in 1989)

In above capacity became Member of Executive of European Society for Quality in Healthcare (representing UK) since its inception in 1998.

Member of NICE (National Institute for Clinical Excellence) Partners Council since its inception in 1999 to 2004/5

President, Royal Society of Medicine Quality Section 2010-2012.

At EU Level: As member of ESQH Executive gave evidence (on quality related to cross-border issues) to HLRP on Health in 2003.

President ESQH: April 2005-March 2007. Past President for two years to April 2009, now Life Member of Executive.

Involved in EU health policy projects on Quality e.g. Simpatie project 2005-7 on Patient Safety (see ESQH website www.esqh.net)

Involved in setting up of successor to Simpatie, Eunetpas, at end 2007 which was in turn succeeded by current JA in PS and quality, PASQ.

Recognised as expert advisor on quality by DG SANCO D2 and in early 2009, with others, gave confidential advice on setting up of mechanism for EC reflection process on Health Quality. Has represented ESQH on PSQWG since its inception later in 2009.

Set up ESQH Lisbon Office for Health Futures Nov.2011 and constituted ESQH Lisbon office as independent European NGO, the European Health Futures Forum (EHFF), registered as Not for Profit Company in UK, March 2013, with representatives from 19 EU countries (www.ehff.eu).

Representing EHFF, convened EMPATHiE network (Empowering Patients managing their health in Europe) in Jan. 2013 (now 22 organisations, representing academic experts in quality, patient organisations, professional bodies and others with an interest in patient empowerment). Successfully bid on behalf of network for interest in Action Plan B3 (integrated care) within the EIP on AHA, and active, representing the EMPATHiE network, within B3 since June 2013 to provide cross-cutting expertise in patient empowerment.

More recently involved in wider, cross-EIP activities on patient empowerment in partnership with Dr Guldemond, lead for Action Plan A2.

For EHFF joined JA on work force planning (EUWFP) April 2013 as collaborating partner in WP6 (horizon scanning). Has consultancy contract as EHFF advisor to UK Centre for Workforce Intelligence (CfWI) since July 2013.

Supported FAD Barcelona to lead successful consortium (representing 10 EMPATHiE network members) in bid for SANCO tender on self-management in chronic diseases, which kicked off December 2013, completed October 2014.

Successfully convened, with CBO Utrecht, larger follow-on consortium for tender on self-care in minor conditions, PISCE, kick-off September 2014

Dr. Rosa Sunol

M.D. PhD is the Director of Avedis Donabedian Institute-Universitat Autònoma de Barcelona (FAD). In this position, she oversees this non-profit organization that has supported quality improvement efforts in health and social care in Spain since 1989. Additionally, Dr. Sunol holds the Donabedian Research Chair in Quality at the Faculty of Medicine at UAB Barcelona. She is a deputy editor of the International Journal for Quality in Health Care since 1991. Dr. Sunol has published several articles and books and has over 25 years of experience in health and social care research. She has participated in several EU funded research projects and was recently the coordinator of the EU project "Deepening our Understanding of Quality Improvement in Europe" (DUQuE). Other projects she has been active in as Director of FAD are mentioned under the attached

Walter Atzori

Senior Programme Officer at the European Patients' Forum (EPF). He has several years of experience in managing and implementing European projects, especially in the eHealth and integrated care field. As a result of this he has gathered extensive experience in areas which are critical to the successful deployment of eHealth and integrated care services such as user acceptance, patient empowerment, and identification and integration of user requirements into designing and delivering healthcare services. At EPF he has been involved in the RENEWING HeALTH telemedicine project, SUSTAINS on patient's access to Electronic Health Records, SmartCare on ICT based integrated health and social care services for older people. He also co-led the Chain of TRUST project looking at patient and health professionals' perspective on telehealth, and represents EPF in the eHealth Governance Initiative and the eHealth Stakeholder Group set up in 2012 by the European Commission. Walter has developed extensive expertise in strategic planning, needs assessment, as well as monitoring and evaluation.

Dr Nick Guldemond M**D, PhD, DSc**

Clinical researcher (1969, Voorburg, the Netherlands) was trained in engineering and medicine (clinical physiology). He obtained his PhD with a focus on orthopaedic complications due to diabetes. He worked at various universities and hospitals as researcher, coordinator and principal investigator in projects regarding healthcare innovation, medical technology and eHealth. As founder and CEO of the 'Medical Field Lab' he received great acknowledgement for creating business through public private partnerships by the Ministry of Economic Affairs. Dr. Guldemond is currently Associate Professor Integrated Care & Technology and Chief Innovation Officer at the University Medical Centre Utrecht, He is advisor for the Dutch House of Representatives and board member of the Innovative Medical Device Initiative IMDI.nl and member of the commission on the national eHealth implementation agenda. He is coordinator of

EIP-AHA A2 Action Group Falls Prevention and associated with thematic networks ProFouND and E-NO-FALLS

4.1.6.4 List of relevant publications

For ESQH/EHFF Dr Somekh was one of three invited external experts who contributed to the recent report of the EXPH (expert panel on effective ways on investment in healthcare) on future EC investment in quality and safety: published Oct. 2014

http://ec.europa.eu/health/expert_panel/opinions/docs/006_safety_quality_of_care_en.pdf

EHFF was co-coordinator with FAD in the delivery of the DG-SANCO tender 'empowering patients in the management of chronic diseases', completed late 2014 and finally published Mar. 2015 : http://ec.europa.eu/health/patient_safety/key_documents/index_en.htm

4.1.6.5 List of relevant previous projects

As above. In addition, partners in the WP, in particular FAD, EPF and UMCU all have other relevant projects, some identified in the organisation descriptions in section 2, above, but each has more that could be listed.

4.1.6.7 List of other EU projects

EIP on AHA: see Dr Somekh's CV for description of Empathie Network activities which he currently co-ordinates.

EHFF is collaborating partner in Chrodis JA (WPs 5, 6 and 7).

EHFF is collaborating partner in JA EUWF (horizon scanning)

4.1.7 Kokomo Healthcare (Ireland)

4.1.7.1 Description of the legal entity

Expert, real-world consultancy

Kokomo is in the business of consultancy. We work with clients – healthcare providers and technology companies – to design connected health solutions. We begin by helping clients to define their approach and articulate their strategy. We facilitate workshops to discuss client requirements from business, clinical, and technical perspectives. The outputs from these workshops are detailed documents that capture the scope and proposed architecture of the desired solutions. We continue to work with clients on all aspects of healthcare service design, taking into account local needs and national policy, while keeping sight of overall objectives and desired benefits as articulated at the beginning of the process. The service design culminates in a program for implementation that takes into account change management, program management, and stakeholder management. Genuine stakeholder participation throughout the process ensures that the final service design relates to the client requirements articulated at the initial workshops.

Experienced resources

Kokomo can provide healthcare consultancy services to your organisation. We can supply temporary staff or dedicated teams to work on projects or to prepare tender responses. Our consultants have been involved in healthcare IT and Connected Health since the beginning. The breadth and depth of their expertise allows Kokomo to provide unparalleled insight, practical advice, and timely support. As experienced consultants, they have the engagement, project management, and communication skills to deliver connected health projects to the highest level of quality.

4.1.7.2 CV of the key people

Dr. Malachy Rice

After a long career in telecommunications and healthcare IT, managing director Dr. Malachy Rice founded Kokomo to help healthcare providers and technology companies take advantage of the opportunities made possible by developments in connected health. Kokomo offers original perspectives that challenge conventional approaches and helps clients implement bespoke solutions based on the latest innovative technologies. Many healthcare providers are intuitively aware that developments in technology-led connected healthcare can lead to better patient outcomes while reducing cost, but they are unsure about how to harness those developments. Likewise, many technology companies are aware of the market opportunities that exist, but they are unsure about how to apply their products and technologies to connected health. Kokomo provides essential insight at senior management and board level, enabling healthcare providers and technology companies to devise strategies to implement connected health solutions.

4.1.8 M&SAATCHI (Spain)

4.1.8.1 Description of the legal entity

We are a company created in 1995 by the Saatchi brothers with offices all over the world. M&C Saatchi gathers together many of the people who revolutionized this sector not so long ago. The company has positioned itself by adding the value of the experience and the potential of teams what are already leading the way in many markets at international level.

M&C SAATCHI MADRID is an independent communication agency formed by 45 professionals specialist in communication, advertising, digital environments and in the creation of contents for the brands. We develop global strategies, we create, we design, we produce, we manage... We do what is necessary to help our clients reach their marketing and communications objectives, whatever the sector they operate in and in any place of the world.

In order to achieve this, we have the support of the international M&C SAATCHI network, with 24 independent offices in Europe (London, Paris, Geneva, Madrid, Stockholm, Berlin, Milan, Moscow), America (New York, LA, Sao Paolo), Africa (Johannesburg, Cape Town), Asia (Tel Aviv, Istanbul, New Delhi, Kuala Lumpur, Singapore, Shanghai, Tokyo), Australasia (Sydney, Melbourne) and Middle East (Abu Dhabi, Beirut).

At www.mcsaatchi.com you can find detailed information about this global network formed by more than 100,000 professionals who share a philosophy:

It is easier to complicate than simplify. Simple ideas are easier to assimilate and remember, brutal simplicity of thought is a necessity. Check it on www.brutalsimplicityofthought.com

4.1.8.2 CV of the key people

Javier Cavanillas - CEO

Javier finished his Degree in Advertising in the Complutense University of Madrid in 1992.

During his first years, he developed his professional career in different agencies, such as Link 7 or Lintas, building communication campaigns in different fields.

In 1999, Javier joined SEGA as an Advertising Manager, promoting to Marketing Director one year later. Two years afterwards, he signed up for the MSN Division of Microsoft where he worked for more than three years as a Marketing Director.

His return to the creative agency took place in 2005, when he founded Bungalow25. In the year 2010, this agency was ranked 7th in the world in advertising innovation. Nine years later, he has joined M&C Saatchi Madrid as a CEO.

During his 20 years of professional experience he got several achievements such as the launch of Dreamcast (SEGA) or Windows 7.

Some of the clients Javier has worked with are Unilever, Winston (RJR Tobaccos) , Renault, Barclays, San Miguel, Texaco, Servicom, Uni2, Línea Directa Aseguradora, Compaq, Microsoft, FOX International Channels, Expert, Sony Pictures, Santa Mónica Sports, Cajastur, CCM, Casino Gran Madrid, OCU, Alain Afflelou, Bristol-Myers Squibb and Coca-Cola.

Andrés Martínez – Executive Creative Director

Andrés holds a degree in Fine Arts by the Escuela Superior de Artes y Oficios (School of Arts and Crafts) of Madrid.

In 1992, he began his advertising career in Lowe Lintas Spain, first as an Art Director, and and two years later as a CopyWriter. There, he participated in the development of the digital area. 6 years later, he arrived at McCann-Erickson as a General Creative Director, and in 2005, he led the creative direction of BBDO Madrid, agency where he remained for four years. In 2010, he joined Grey Mexico as a Creative VP placing the agency in the No. 1 of the creative ranking of Grey in the world. Andrés was a member of the Global Creative Council of GREYGROUP and one year later, he was appointed Regional Creative Director of Grey Latam. In 2012, he joined JWT Mexico as an Executive Creative Vicepresident. From January 2015, Andrés is a partner and Executive Creative Director of M&C Saatchi.

Over the years, Andrés has worked for virtually all the possible categories of clients: banks, insurance companies, retail, sport brands, cars, etc. Just to mention a few examples, we could include: BBVA, Santander, HSBC, ING, Nike, Puma, MTV, Renault, Fiat, BMW, Toyota, Coca-Cola, Pepsi, P&G, Unilever, Hasbro, Modelo, Heineken, Movistar, Telmex, Diageo, Walmart, Nestle, Cruz Roja, Once, etc.

In 2005, while working for BBDO Madrid, the agency obtained the recognition of “Agency of the Year”, winning the first platinum Sol of the history. In 2007, he was appointed “Creative of the Year in Spain”.

Andrés has won more than 25 Lions at Cannes and hundreds of prizes in different international festivals. In 2014, he was selected, for the second time, as a member of the jury in the Cannes Festival. At Cannes Lions 2014, JWT Mexico was the Mexican agency most awarded of the history in this festival, winning 7 Lions.

Susana Outeiriño – Client Service Director

Susana has a degree in Marketing, Advertising and Public Relations by the Institute of Marketing, Saragossa (Spain). She also holds a CAM Diploma in Digital Marketing by The Chartered Institute of Marketing, UK (2012-2013). In 2013, she has been chosen from over 300 candidates to take part in Proyecto Promociona. This program is carried out with Norwegian funds within the framework of the European Economic Area, coordinated and co-funded by CEOE (Spanish Confederation of Business Organizations), with the participation of the Ministry of Health, Social Services and Equality, and collaboration of ESADE Business School (Top 3 Business Schools in Europe), who intends to change the situation of the senior Management in our country, adapting to changing times. The aim is to improve access of women to management positions and Boards of Directors of our companies, and thus keep progressing to create a shared leadership.

Susana has more than 17 years' experience in client and strategic management of global and local brands, including Pan-European campaigns.

She started her career in JWT working for clients such us Rolex, De Beers and TNT. In 1999 she joined Young&Rubicam as an Account Supervisor, handling accounts with high activity across all media and managing Pan-European projects. In 2005 she joined *SCPF, one of the tops creative agencies in Spain, as an Account Director with top responsibility over top-performing teleco brands handling high level of activity within dynamic environments. Later on, in 2012 she arrived at JWT to led campaign implementation to ensure consistency across all media, providing strategic vision and advice for Vodafone's Spanish Board. In 2015 she joined M&C Saatchi Madrid as a Client Service Director.

Over the years, Susana has worked for clients such us: Movistar, J&B, Kraft Foods, Via Digital Cable Channel, Schweppes, Vodafone, Nokia, Openbank (part of Santander Bank Group), Nivea Men, Invisaling, etc.

She received an EFI Silver Award for the Schweppes Citrus Launch Campaign in 2002.

Oskar Arriola – Brand Manager

Oskar graduated in Advertising and Public Relations at the University of Navarra. He started his professional career at Tiempo BBDO Madrid as an Account Executive. Two years later, he joined the team of Zapping Activities (BTL division), managing not only corporate and promotional events but also the special activities for the clients of the group. Four years later, he became part of the ATL team. Since 2013, he has worked in the M&C Saatchi Account Department.

During his 10 years of experience, Oskar has worked with brands such as Ministry of Infraestructures, MTV, Nickelodeon, Paramount Comedy, Viacom Media, RGA insurance, Kia Motors, Mercedes-Benz,

Santillana Editorial, Camilo José Cela University, Adif, Aldeasa, Banca Cívica, Orange, BBVA Innovación, Correos, Western Union, MoneyGram, Ballantine's.

4.1.8.3 List of relevant publications

"Brutal simplicity of thougt" is our work philosophy, our thoghts, what guide us. It is easier to complicate than to simplify. Simple ideas are easier to assimilate and remember for a longer time. Brutal simplicity of thought is therefore a necessity. That's why we publicate two books:

- "Brutal Simplicity of Thought: How It Changed the World" (2013) - This book presents stunningly simple examples of concepts that have changed the world - from the single piece of paper that became the American Declaration of Independence, giving birth to the most powerful nation in the history of the world, to the symbol and line that enables us to write music. Thought-provoking and incisive, "Brutal Simplicity of Thought" is the distillation, in words and pictures, of the Saatchi method of creativity.
- "Brutal Simplicity of Thought: How It Changed our clients" (2014) – This book presents how M&C Saatchi implement his philosophy around the world, show real examples of our client's works.

With the creativity, M&C Saatchi wins in 2015 some representative worldwide achievements:

- Cannes Lions: 2 Golds, 2 Silver y 5 Bronze
- "The one Show": 8 Gold, 6 Silver y 3 Bronze

4.1.8.4 List of relevant previous projects

"Banca civica" Bank Launch Campaign

- Due to the financial crisis around the globe and the bursting of the housing bubble in our country, saving banks have entered into a mortgage crisis that leads to a reorganization of the Spanish financial market: the merge of several saving banks, becoming banks.
- To launch a new bank, called Banca Cívica, creating a brand with specific values such as transparency, client participation and changes in the traditional banking.
- Banca Cívica must be different because of two tributes linked to its DNA: Transparency (this bank tells its clients the benefit it obtains with them) and Involvement (the customers themselves decide which social project will receive part of the money). To make this value proposal trustworthy, we transformed the communication of Banca Cívia into a great survey at national level, asking people how they wanted their bank to be. There was a roadshow in 16 Spanish cities, using digital graffiti screens where participants left their opinions.
- Our work: Events, TV, radio, press, advertising tarpaulins, billboards, buses, POS, internet and social media.

Ficod (International Forum of Digital Content)

- Ficod is the digital content event referent in UE with more than 4.000 attendees: companies, professionals, entrepreneurs and investors. The agenda was based on 5 pillars: industry,

financing, talent, congress and awards and the contents reach numbers such us: 70 speakers, 42 corporate presentations,16 workshops and 23 masterclasses.

- Our work was to create the event identity, creating and producing all the digital materials, website and apps, producing of audiovisual materials, coordination of event: speakers and content selection, manage all the logistic issues, and Public Relations call and coordination of media.

Ballantines – "Nervo's Fan-Tasia"

The European Legislation limits the promotion of alcoholic drinks; consequently, Internet contents are a key tool for this category, above all when the target public is so young.

We created a unique experience for the NERVO fans. Ballantine's decided to transform the community of fans "NERVO Nation" into a real planet, inviting the DJ's fans to join them in the shooting of a video clip. A special app was created for the event, through which the fans sent pictures that were projected on a screen with just one click, adding an emboss effect that changed with the music.

This content was the communication excuse, through which audiovisual and photographic content was created and all the brand communication in Social Media during the year 2015.

4.1.8.5 List of other EU projects

- FICOD (International Forum of digital contents) – financiated by the Spanish Government
- BALLANTINE'S – "Nervo Fantasía Campaign" – Development of campaign with digital platform and social media promotion plan, in coordination of all the European M&CSaatchi Network.
- NORWEIGIAN AIRLINES – Launch of "European Campaign" – Conventional campaign in TV and digital media. All the European M&CSaatchi Network work coordinated to track the consumer insights in each country for developing the campaign.

4.1.8.6 National or international activities or initiatives linked with the action

RED BULL – Trafalgar Battle in Social Media

More than 200 years later, Red Bull recreates the historic battle that took place in the waters of Cape Trafalgar. Same place, same countries involved, but different weapons. This time the battle is for the supremacy of kitesurf. Red Bull encouraged kitesurf fans, giving them the opportunity to register in one of the teams and compete with the best riders of the moment, such as, the world champion Gisela Pulido. There were more than 12,000 registrations, and although the most part of them only participated virtually, their participation also scored. By the way, this time Spain was the winner.

Results: within 20 days…, 22,179 visits, 81.81% new visits 8,958 registrations 1,046 brand references 1,592 Facebook fans 93,050 brand visualizations 230 Twitter followers, with the participation of relevant people like the writer Arturo Pérez Reverte and the journalist Sara Carbonero.

SCHIBSTED - SchibstedNext

After the acquisition of Anuntis (Segundamano, Infojobs, Fotocasa…), Schibsted Media Group needs to be part of the media groups outlook in Spain, achieving a place in the field of big data and in wide range of possibilities offered by the future of digital media.

For this purpose, Schibsted celebrated the largest training event on big data and the future of the Internet: Schibsted Next, to show the market how the future in the Internet was going to be and the possibilities of the group offer.

We developed a call plan that included the presence in the main media of the sector, professional associations and the use of external databases. The main advertisers, media agencies and creative agencies of the country were invited. In addition, we managed the presence and coverage of the media in the advertising sector and the qualitative monitoring of the messages.

MAPFRE – Ycar

YCar is an specific Car Insurance product of the company Mapfre, geared to a young target (18-25 years old) with an particular preferences and particular way to drive his cars.

We developed the communication strategy 2011- 2014 in social media, corporate blog (creation of community contents) and newsletters, community management and active listening, online reputation.

Results VS previous agency: Facebook: 663 fans vs. 4.000 fans, + 488 %; Twitter: 847 followers vs. 3.600 followers + 295 %; Blog: 550 visits to the most visited post vs 1724 visits to the most visited post, + 313 %.

4.2 Third parties involved in the project (including use of third party resources)

4.2.1 Consellería de Sanidade

No third parties involved

4.2.2 Central Denmark Region

No third parties involved

4.2.3 Servicio Aragonés de Salud

No third parties involved

4.2.4 Le Groupement de Coopération Sanitaire pour le Développement des Systèmes d'Information partagés en Santé en Ile-de-France (GCS D-SISIF)

No third parties involved

4.2.5 General Hospital Slovenj Gradec

No third parties involved

4.2.6 European Health Futures Forum

No third parties involved

4.2.7 Kokomo Healthcare

No third parties involved

4.2.8 M&SAATCHI

No third parties involved

5. Ethics and Security

The EMPATTICS consortium is aware of the enormous importance of properly handling ethics-related issues with the proposed EMPATTICS solutions. The services that EMPATTICS wants to introduce are intended for vulnerable groups of people, who are impaired due to disease or disability. This is why ethical principles and values, like dignity, justice, equality, inclusion, access to services regardless of health state, age, gender, nationality, education, financial abilities, location of residing, should be carefully managed within the project. In particular, "remoteness" of the provider and the receiver of a healthcare service represent a special challenge for the project and thus demands special attention in stating user/patient position within the project. The population selected will be people with a chronic disease who could have some disabilities but who are fresh enough to participate .who could have some disabilities. The judgement of that will be made by professional clinicians. The overall protection of vulnerable patients will be in the inclusion and exclusion criteria. Clinical professional will be part of making the inclusion criteria and a clinical professional is responsible for judging the patients' ability to participate. And the Ethics Committees will have accepted the inclusion criteria. So, the research project selected must included the next measures in the protocols:

- A detailed list of inclusion and exclusion criteria which defines the population selected. Only competent person will be included.

- A description of the procedure to select the participants: The invitation will be given when the patients visit to the hospital or healthcare centre. The patients will receive both oral and written information about the project. They will also receive the Informed Consent Form and a stamped and addressed envelope for the answer. The patients will have 2 days to decide whether to participate or not. Participants will be recruited by a healthcare professional who evaluates the protocol adequacy to their clinical situation and the inclusion/exclusion criteria. If a patient does not wish to participate he/she will continue with his/her usual care pathway.

- The prototypes designed will be easy to use and friendly in order to minimize harm or discomfort in subjects. Invasive prototypes will not be selected.

All these measures will be taken into account in the tender documents.

As this Project concerns health and social issues, law and maximum guarantees shall be considered regarding ethical, confidentiality, privacy and security issues. Furthermore there exist big concerns regarding the use of patient data, monitoring of personal habits, social and community behaviour, or sharing of personal data between patients, carers and professionals, in which privacy must be guaranteed.

The EMPATTICS project will involve the monitoring of individuals' activities and handling of sensitive personal data. Thus the prototype evaluation will comply with principles laid down in the Helsinki Declaration and the Oviedo Convention and with the rules set out in European directive 2001/20/EC on the implementation of good clinical practice in the conduct of clinical trials. EMPATTICS participants will be informed of risks identified by this work and will sign informed consent statements that clearly state their rights as subjects. The pilot should fully respect the fundamental right to the protection of personal data, in particular of personal data related to health and the relevant EU and national legislation.

The consortium has long proven and standing experience in the implementation of the EU Directives on personal data protection and local data protection laws and will ensure that personal data will be treated in line with the legal requirements.

The Clinical Study Protocols and the related Technical Requirements will incorporate organisational and technical measures in order to ensure the privacy of the individuals participating in the project. All records and other information about subjects participating in the pilots will be treated as confidential.

5.1 Ethics

The medical-legal issues linked to the world of telemedicine and monitoring applications are, in reality, directly linked to the much wider field of the management of patient's personal and clinical data.

Any telemedicine application should ultimately be considered as a medical act: this means that the patient must be appropriately informed of the characteristics of the services that will be used, and aware of the possible risks involved and the precautions that the organisation intends to adopt to reduce these risks and in particular, to guarantee the confidentiality of the information gathered. On the basis of such information, the patient should be able to agree or not to receiving healthcare through a telemedicine system and the supplier of the service has to guarantee a high level of security in the treatment, storage and transmission of clinical data.

Specifically, the following issues will be addressed:

Data protection issues: The EMPATTICS project will avoid handling unnecessary personal data but some handling of personal data will be needed, we will ensure that all personal data is protected to ensure the subjects right to freedom, dignity and privacy. This will be applied to all data that could be potentially seen and misused. The design of EMPATTICS prototypes will ensure this principle holds for all systems developed by the EMPATTICS project.

On EMPATTICS, data will be collected in electronic format for the two kinds of data repositories that will be used in the Project:

1) The repository "A" will contain data of the application that will be used to collect patient data and provide followance information to healthcare professionals. This repository will contain personnel data, and patients will be asked for consent for their data to be stored. Data in repository "A" will be stored at least five years, according to the rules applied to healthcare data.

Regarding data protection policy, the EU's 1995 Data Protection Directive set a milestone in the history of personal data protection and will be applied in this project. Its basic principles, ensure an effective protection of the fundamental right of individuals to data protection, are as valid today as they were 17 years ago. But differences in the way that each EU country implements the law have led to an uneven level of protection for personal data, depending on where an individual lives or buys goods and services.

This information should comply the EU data protection Directive plus the National Rules regarding data protection in the country where the developer company is settled.

Companies what will be awarded to implement the application should apply the European laws for data protection and the corresponding regulation. Moreover, they will be considered in the HIGH level of data privacy and security. This file should be declared in the National Agency for Data Protection, all

accesses to data should be registered for audit and control, a strong policy for user access and authorization should be applied, and the user has the rights to request accessing to its information, and also for cancellation of part or all the information that is stored.

2) The repository "B" containing data for the research study and evaluation of the results of the project, will aggregate information from all participants from patients in different regions and will allow extracting result indicators of the overall Project. This second repository will contain anonymized data.

A protocol will be defined to extract homogenous objective data from the health application used by patients and measure the use and benefits of the system.

Data will be introduced into repository "B" by the healthcare professionals participating in the project into a specific datamart that will not allow the storage of personal data or personal identifiers. Only anonymized data will be introduced into this database. This database will be used to obtain statistics and results of the prototype usage by patients.

Precommercial procurement should allow the participants to define the final solutions. The following data set is described here as an example of the type of information that will be stored, as the final variables cannot be stablished before the final prototypes will be selected.

- UserRegisterID

- Time and date of access to the prototype. -> This will allow to obtain the daily or monthly profile of use

- Number of registers of personal health data introduced

- Results obtained from tests or games included in the prototype

- Number of times the user had a visit in emergency for the disease that is being treated through the prototype.

- Numer of times the user had a visit in GP for the disease that is being treated

- Number of times the patient did not adhere to the treatment.

- ...

Any data stored, either directly acquired from the prototype or derived from this data, will not be publicly available. Data will be accessed only by the organizations that sign the Grant agreement, and a third party organization could access this data only by authorisation of the Steering Board committee with a positive evaluation made by the Ethics committee.

Data minimization: Collected data will be limited to the minimum required to carry out the EMPATTICS project plan

Informed consent: All volunteers will be able to give their informed consent. All participants in the EMPATTICS prototype tests will have the right to withdraw and have all data destroyed should they so wish. Application for ethical approval at the test sites, where needed, will be commenced as soon as feasible from the start of the project.

To participate in the project an Informed Consent Form and Information Sheet about the procedure will be given to the patient. Their physician will give all the information about the project in order to make the patients understand properly what the purpose of the project is. Patients have 2 days to take the decision and return the Consent Form. The patients will be encourage to contact the healthcare professionals for further information before giving consent if needed.

If patients decide to give their consent, they will be included in the project and if not, they continue with their usual care pathway. All participants in the EMPATTICS prototype tests will have the right to

withdraw and destroy all their data if they want. If a patient wishes to withdraw, traditional healthcare services will be offered to them.

The number of participants will be defined according to the nature of the tests and the technology that will be tested. In order to develop and test prototypes it is more relevant to have a widespread field of patients with different profiles (different age groups have different needs and different competences within using technology, different needs and behaviour) to participate than to have a large number. We estimate an average of 50 patients will be involved in the different tests.

The participation in the project will be voluntarily and the main inclusion criteria will be people diagnosed with a chronic disease and who are able to understand and provide the written consent. The local healthcare professionals will be asked to assess and nominate patients who meet the following inclusion and exclusion criteria:

Inclusion criteria:

- The patient must be over the age of eighteen years of age
- The patient must be able to consent for her/himself
- The client must be in a stable phase of his/her mental illness as determined by the local psychiatric team based on their professional knowledge
- …

Exclusion criteria:

- Involuntary patients
- Mentally disabled patients who are not able to give an informed consent.

No payment or other inducement will be offered to participants in the research.

Depending on the projects/proposals selected, more detailed inclusion and exclusion criteria for participating in the project will be adapted to the prototype tested and the main objective selected in the protocol. This information will be included in the protocol sent to the Ethics Committees. Moreover, final protocol will be sent to the Commission as a deliverable too, deliverable 1.9.

The Informed Consent will include the information recommended in Declaration of Helsinki (Fortaleza, 2013) and the International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002).

The Informed Consent templates included these points:

- Purpose and description of the project

- A clear mention that the participation is voluntary, that the refusal to participate will involve no penalty or loss of benefits, and that they may decide, at any time, to discontinue participation.

- Why we offer to participate in the project

- What is the patient role in the project

- The duration of the subject´s participation

- A description of any reasonably foreseeable risk, discomfort or disadvantages

- Information about it is not expected that the patient gets direct benefit from participating in the project

- Information of what will happen with the data as the end of the project. Publication of the results

- Description of the procedures adopted for ensuring data protection/confidentiality/privacity.

- A reference to who is the responsible person for the safekeeping of the data

- A reference that the data will be anonymized at the end of the process

- A reference to whom to contact for answers to pertinent questions about the procedure. Patients have the opportunity to ask questions and to remove at any time from the procedure without consequences.

Patients have the opportunity to ask questions and to withdraw at any time form the project without consequences.

The final Informed Consent Forms (ICFs) will be adapted to the procedures included in the projects/proposals. The ICFs will be forwarded to the Ethics Committees for their approval. Moreover, final informed consent will be sent to the Commission as a deliverable too, deliverable 1.9.

Management of Ethical-related risks: EMPATTICS will ensure strict protocols for personal data handling are adhered to at various levels, ranging from the acquisition, transmission, storage, access, publication and general use according to national and international regulations.

Any incidental findings detected will be revised by Ethical Board. Ethical Board will make a report with the recommendations about the findings. Such recommendations include continuing or terminating the research project, or modifications to the protocol and informed consent forms.

Below we self-assess the EMPATTICS project from the perspective of each of the questions we responded positively to in the Ethics section in the proposal forms.

- **Are they volunteers for prototype test in social or human sciences research?** The EMPATTICS project aims to asses the effectiveness of a range of interventions in the self-management of chronic diseases thus the volunteers are participating in human sciences research. This will be made clear to the participants in the consent form we will design as part of the project. Participants will have full control over data collected by the study and will have the right to withdraw and have their data destroyed at any point in the test study.
- **Are they persons unable to give informed consent?** No.
- **Are they children/minors?** No.
- **Are they patients?** Yes, only people suffering from chronic diseases will be recruited for the study.
- **Are they healthy volunteers for medical studies?** No, only people suffering from chronic diseases will be recruited for the study.
- **Does your research involve personal data collection and/or processing?** Yes we will gather sensitive personal data during the EMPATTICS test. Data collected and our proposed processing of the data will be clearly explained in the consent form all participants are required to sign before joining the test. The architecture of the EMPATTICS prototypes are to hold data in a Personal Health Record that the participant has control over. If the participant chooses to withdraw from the test they have the capacity to destroy all their personal data completely and permanently.
- **Does it involve the collection and/or processing of sensitive personal data (e.g.: health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?** Yes, such data will be held in the Personal Health Record. Levels of security and privacy enforced on the Personal Health Record will be at best current practice levels and that will be maintained throughout the duration of the project.

  One of the main deliverables of the Project will be a prototype which will be designed

specifically to collect and process data from patients.

Two kinds of data and two repositories are defined and will be used in the Project:

- **Does your research involve human participants?** The objective of test prototypes is to study the effectiveness of an approach to the self-management of chronic disease with the support of ICT. The study will augment existing services. Accordingly, we do not intend to change the current level of support given to the subject of the test. The goal is to gather both qualitative and quantitative data on the experience of the service users. The data will be used to determine if the prototype has a positive effect on a number of aspect including wellbeing, quality of life, health conditions. All potential subjects will be provided with full information on what they are expected to do during the study and will only be included under the provisioning of a fully informed consent. The goal of the test is to assess the effectiveness of prototype approach to self-management of chronic disease and, if the results are positive, it will have direct benefit to the participants in the study. The architecture of the EMPATTICS prototypes will be designed to ensure personal control over data gathered by the system and to ensure privacy and data protection are ensured at the strongest possible level.

  1) The repository "A": data of the application that will be used to collect patient data and provide followance information to healthcare professionals. This repository will contain personal data. This data is required to monitor and check the results of the use of the prototype in the health behaviour of the patients. Only Healthcare professionals and clinicians in charge of the patients included in the project will have access to this repository. Access to information will only be allowed according to security rules and policies of healthcare organizations involved in the project. Taking into account the definition of data Repositories, only personal data will be collected and stored in the Repository "A", and the type of data introduced in this repository will be equivalent to Health Record information.

  The level of privacy and security to be applied to this data is HIGH and will share the same policies applied to Electronic Health Record information.

  According to the declaration of personal data files stated by Galician Health Service in Order of the Regional Parliament published in June 14th 2007 the type of data included is:

  a) Demographic data: age, gender, social: carers informal/formal...

  b) Clinical data: data related to selected pathologies

  2) The repository "B": data of the statistical study, used to aggregate information from all participants and will allow extracting results indicators of the overall Project. This second repository will contain anonymized data, and will guarantee that any person will not be identified, directly or indirectly, by data contained in this repository.

  Companies and healthcare organizations involved in the project will have access to this repository.

  These two repositories will be connected through a code but only the Healthcare professionals and its clinicians will have access to this code.

- **Does it involve tracking or observation of participants?** Yes, an important part of the data collected will be behavioural data streams. This will be made clear to the participants and they will have an opportunity to inspect the data and decide if it is intrusive and have data deleted that is judged to be intrusive.
- **Does your research involve further processing of previously collected personal data (secondary use)?** The project will enable the possibility of linkage between data collected by the project and existing health records. The consent form will make this clear to participants and participants will be provided with a list of all potential associations as part of the consent process.

Ethics documents: since the detail of the proposed proptotypes will be finalized as part of the project we cannot as yet present the detailed ethical approvals that are necessary prior to commencing the tests. The project partners have considerable experience in preparing ethics approval documents and have good relationships with their Local Research Ethics committees. Once the details of the pilots have been finalized appropriate partners will make detailed ethics applications in their locality.

Local, regional or national authorities will approve the research for instance, local, regional or national Ethics Committees. Furthermore each regional or national Medical Device Department of the buyers group regions will make sure that the prototypes and information technology solutions are safe enough to test according to international guidelines and standards.

The project activity will not commence before obtaining the ethical approvals from the relevant authorities.

5.2 Security

As reports and opinions issued have legal value, their archiving is mandatory in order to preserve and maintain their form and content unaltered and readable over time. In fact they undergo an archive procedure following national laws currently in force for document dematerialization.

The transmission of the patient's personal and clinical data must take place using systems and instruments which can guarantee the reliability of the data received (i.e. guarantee that what is received is identical to what has been transmitted) and its privacy (i.e. guarantee that the data transmitted cannot be tapped by third parties and then interpreted). In order to guarantee also the inalterability of the clinical data contained in the documents transmitted, the document is digitally signed and encrypted.Given the sensitivity of personal data stored in and used by the prototypes, definition and implementation of a security concept is one of the fundamental components of platform design.

Security framework

- The solution will use either open source Apache Shiro or the Spring Security framework. These are the leading java/java EE frameworks that provide authentication, authorization and other security services for enterprise solutions.
- The security framework will be used to restrict and protect all web services resources and functionalities of the system.

System access

- The security framework will support single point of access (SPA).
- The framework and the named components will also offer a JNDI based interface to a Lightweight Directory Access Protocol (LDAP) repository in the HIS system. This will deliver the needed properties to provide security mechanisms.

Content access

- The access to content will be given on a "need to know" basis. The screens and content that a user can see and their read and write privileges will be defined in relation to their allocated user role and the job tasks they need to perform. The security framework and the LDAP repository help provide a structured approach for implementation and definition of user roles and their associated profiles.

Standards

- The security framework provides the needed SSL/TSL components to secure all HTTP browser connections to the web application (https).

Logging

- To support the needed logging functionality the integration platform provides the IHE defined ATNA Audit Trail and Node Authentication component. These have been identified by Continua as a standard logging utility for healthcare system.
- The two possible runtime environments OSGi or a Webserver for the Open eHealth Integration Platform 2.x both support the SOA architecture of the overall web application.
- As an alternative, the Open Health Tools OpenATNA implementation will be taken into account for providing the needed logging.

Please indicate if your project will involve	
activities or results raising security issues:	NO
'EU-classified information' as background or results	NO

Legislative issues in EMPATTICS

Considering the understanding of healthcare service domains, telehealth services are a subdomain of eHealth services. It could be therefore assumed that legal grounds for eHealth services apply also to telehealth or telemedicine services. According to the legal department of the European Commission for the field of eHealth[i], the legal grounds for the implementation of eHealth services have already been given in number of documents of the current European legislation. Directive on a Transparency Mechanism for Information Society Services defines EHealth services as »e-services in the European information society«. They have the right to the free flow of services, which in turn applies also to telemedicine or telehealth (articles 56 and 57 of the Treaty of the Functioning of the European Union). The Directive on eCommerce 2000/31/ES applies to telemedicine services. A working document is being prepared, explaining the adequacy of the current European legislation for the field of telemedicine (telehealth).

The field of eHealth services is regulated also by »soft legislation«, given in the strategies and views of the European Commission, like:

- Communication on eHealth – making healthcare better for European citizens: „An action plan for the European eHealth Area" - COM(2004)356, article 152; article 95(3).
- Communication on "A lead market initiative for Europe" COM(2007)860.
- Communications from the Commission to the European Parliament, the Council, the European Economic and Social committee and the Committee of Regions about the Benefits of Telemedicine for Patients, healthcare Systems and Society - COM(2008) 689 final [i].
- Staff Working Paper on telemedicine for the benefit of patients, healthcare systems and society - SEC(2009) 943 final [i]..

The fields, which mostly need legal regulation, are:

- Registration (accreditation), authorisation and licences for the providers of healthcare
- Liability of providers
- Reimbursement of expenses
- Personal (healthcare) data protection
- Oppositions in the legislative regulation of individual countries of the EU and contradicting laws
- Treatment with personal contact between the patient and healthcare worker (face-to-face).

The current legislation of the European Community is followed by only a few member states. Telemedicine services are being implemented by most of the countries of the EU, yet almost none includes these services into their healthcare system systematically, or acknowledges them legally, which would enable its routine use. The reason for the lack in legal clarity is constituted of numerous ethical and legal dilemmas with the deployment of telemedicine as noted the European Commission in the document "Telemedicine for the benefit of patients, healthcare systems and society" COM(2008)689 final[i] and the Commission staff working paper "Telemedicine for the benefit of patients, healthcare systems and society SEC(2009)943 final"

There is a lack of clarity on liability lies in the field of implementing telehealth services across the borders of member states. Virtual providers of services have to respect their national legislation. Number of European regulations (Rome I, Rome II, Brussels I) determines general liabilities, yet numerous instructions do not determine liabilities in a uniform way. It is expected that this subject, together with the subject of cross-border healthcare service implementation, will be arranged in the near future through EU projects like epSOS.

ESTIMATED BUDGET FOR THE ACTION (page 1 of 2)

	Estimated eligible[1] costs (per budget category)									EU contribution			Additional information		
	A. Direct costs of PCP subcontracting	B. Costs for related additional coordination and networking activities							Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]	Information for indirect costs	Information for auditors	Other information:
		B.1 Direct personnel costs				B.2 Direct costs of subcontracting	B.3 Other direct costs	B.4 Indirect costs[2]							
		B.1.1 Employees (or equivalent) B.1.2 Natural persons under direct contract B.2.3 Seconded persons [B.1.6 Personnel for providing access to research infrastructure]		B.1.4 SME owners without salary B.1.5 Beneficiaries that are natural persons without salary			B.3.1 Travel B.3.2 Equipment B.3.3 Other goods and services B.3.4 Costs of large research infrastructure						Estimated costs of in-kind contributions not used on premises	Declaration of costs under Point D.4	Estimated costs of beneficiaries/ linked third parties not receiving EU funding
Form of costs[6]	Actual	Actual	Unit[7]	Unit[8]		Actual	Actual	Flat-rate[9] 25%							
	(a)	(b)	Total (c)	No hours	Total (d)	(e)	(f)	(g)=0,25x ((a)+(b)+ (c)+(f) +[(h1)+(h2)]- (m))	(i)= (a)+(b)+(c)+ (d)+(e)+(f)+ (g)+(h1)+(h2)+(h3)	(j)	(k)	(l)	(m)	Yes/No	
1. Sanidad Galicia	700000.00	371000.00	0.00			48750.00	16000.00	96750.00	1232500.00	70.00	862750.00	862750.00	0.00	No	
2. CDR	700000.00	150000.00	0.00			0.00	14500.00	41125.00	905625.00	70.00	633937.50	633937.50	0.00	No	
3. SALUD	700000.00	150000.00	0.00			0.00	14500.00	41125.00	905625.00	70.00	633937.50	633937.50	0.00	No	
4. GCS D-SISIF	700000.00	101000.00	0.00			0.00	14500.00	28875.00	844375.00	70.00	591062.50	591062.50	0.00	No	
5. SB-SG	700000.00	101000.00	0.00			0.00	14500.00	28875.00	844375.00	70.00	591062.50	591062.50	0.00	No	
6. EHFF	0.00	60000.00	0.00			0.00	1000.00	15250.00	76250.00	70.00	53375.00	53375.00	0.00	No	
7. KKM	0.00	45000.00	0.00	0.00	0.00	0.00	8000.00	13250.00	66250.00	70.00	46375.00	46375.00	0.00	No	
8. Saatchi	0.00	60000.00	0.00			0.00	40000.00	25000.00	125000.00	70.00	87500.00	87500.00	0.00	No	
Total consortium	3500000.00	1038000.00	0.00		0.00	48750.00	123000.00	290250.00	5000000.00		3500000.00	3500000.00	0.00		0.00

ESTIMATED BUDGET FOR THE ACTION (page 2 of 2)

(1) See Article 6 for the eligibility conditions
(2) The indirect costs covered by the operating grant (received under any EU or Euratom funding programme; see Article 6.5.(b)) are ineligible under the GA. Therefore, a beneficiary that receives an operating grant during the action's duration cannot declare indirect costs for the year(s)/reporting period(s) covered by the operating grant (see Article 6.2.E).
(3) This is the theoretical amount of EU contribution that the system calculates automatically (by multiplying all the budgeted costs by the reimbursement rate). This theoretical amount is capped by the 'maximum grant amount' (that the Commission/Agency decided to grant for the action) (see Article 5.1).
(4) The 'maximum grant amount' is the maximum grant amount decided by the Commission/Agency. It normally corresponds to the requested grant, but may be lower.
(5) Depending on its type, this specific cost category will or will not cover indirect costs. Specific unit costs that include indirect costs are: costs for energy efficiency measures in buildings, access costs for providing trans-national access to research infrastructure and costs for clinical studies.
(6) See Article 5 for the forms of costs
(7) Unit : hours worked on the action; costs per unit (hourly rate) : calculated according to beneficiary's usual accounting practice
(8) See Annex 2a 'Additional information on the estimated budget' for the details (costs per hour (hourly rate)).
(9) Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs
(10) See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit).
(11) See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit, estimated number of units, etc)
(12) Only specific unit costs that do not include indirect costs
(13) See Article 9 for beneficiaries not receiving EU funding
(14) Only for linked third parties that receive EU funding

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

REGION MIDTJYLLAND (CDR), 29190925, established in Skottenborg 26, VIBORG 8800, Denmark, DK29190925 ('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 690492 (‘the Agreement’)

between Conselleria de Sanidade de Galicia **and** *the European Union (‘the EU’), represented by the European Commission ('the Commission'),*

for the action entitled ‘EMpowering PAtients for a BeTTer Information and improvement of the Communication Systems (EMPATTICS)’.

and mandates

the *coordinator* to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Carsten TAUL with ECAS id ntaulcar signed in the Participant Portal on 14/12/2015 at 08:37:56 (transaction id SigId-310-zUpSA7qQYiwuwyzxcjKVKIYGSjjk8KwIVaMcKIYkTVEzlVtBf9tIxGSSbzZ3zLwokNDwSA0U71tW2xI3tK1615e-Jj71zxYb8yrnTly9NGmq5u-jxHaRitvTM8dK3iemTm6dBe4qGO1KTzzLRWqgzgH3ZRu).
Timestamp by third party at
Mon Dec 14 08:38:06 CET 2015

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

SERVICIO ARAGONES DE LA SALUD (SALUD), N/A, established in VIA UNIVERSITAS 34, ZARAGOZA 50071, Spain, ESQ5000442C ('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 690492 (‘the Agreement’)

between Conselleria de Sanidade de Galicia **and** *the European Union (‘the EU’), represented by the European Commission ('the Commission'),*

for the action entitled ‘EMpowering PAtients for a BeTTer Information and improvement of the Communication Systems (EMPATTICS)’.

and mandates

the *coordinator* to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Miguel CARROQUINO BAZÁN with ECAS id ncaroqmi signed in the Participant Portal on 17/12/2015 at 14:54:48 (transaction id SigId-3787-ehkhv34TaAmeSIcYbTM9PLYxUrH46hsX6AkRdS2cbiQA1QskUAYW1WivO2AwVwgqlbJadpNamMAAgnYhZ86dTm-PHslUMVSXYCswcv4WdCzfp-W5l7arKxs2ZV9s2YnZJzydX7QzO18znXJZzdClzu47IaG). Timestamp by third party at
Thu Dec 17 14:54:52 CET 2015

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

GROUPEMENT DE COOPERATION SANITAIRE POUR LE DEVELOPPEMENT DES SYSTEMES D'INFORMATION PARTAGES EN ILE DE FRANCE (GCS D-SISIF) FR46, 513654715, established in 10 RUE DU FAUBOURG MONTMARTRE, PARIS 75009, France, FR41513654715 ('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 690492 (‘the Agreement’)

between Conselleria de Sanidade de Galicia **and** *the European Union (‘the EU’), represented by the European Commission ('the Commission'),*

for the action entitled ‘EMpowering PAtients for a BeTTer Information and improvement of the Communication Systems (EMPATTICS)’.

and mandates

the *coordinator* to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Pierre BOIRON with ECAS id nboiropi signed in the Participant Portal on 21/12/2015 at 14:10:19 (transaction id SigId-7-MfAmUxqdWTmlei6JNoCdZH1ozNGPK8M8QkpEAzsOgznFA6EjXNaZGR1nYrO7eKzwp2moVdSypzfQqn2NdZyZVSO-Jj71zxYb8yr0LxKCzZHb4o-VwdOrOmFhy0EzPrVARHAKbzTDHxW7gToeJpl5mBXMCXm).
Timestamp by third party at
Mon Dec 21 14:10:24 CET 2015

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

SPLOSNA BOLNISNICA SLOVENJ GRADEC JAVNI ZAVOD*GENERAL HOSPITAL SLOVENJGRADEC (SB-SG) SI2, 5054958000, established in GOSPOSVETSKA CESTA 1, SLOVENJ GRADEC 2380, Slovenia, SI34697390 ('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 690492 (‘the Agreement’)

between Conselleria de Sanidade de Galicia **and** *the European Union (‘the EU’), represented by the European Commission ('the Commission'),*

for the action entitled ‘EMpowering PAtients for a BeTTer Information and improvement of the Communication Systems (EMPATTICS)’.

and mandates

the *coordinator* to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

THE EUROPEAN HEALTH FUTURES FORUM (EHFF) GB5, 08447376, established in KINGATES FARM NEWPORT ROAD, VENTNOR PO38 2QP, United Kingdom ('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 690492 (‘the Agreement’)

between Conselleria de Sanidade de Galicia **and** *the European Union (‘the EU’), represented by the European Commission ('the Commission'),*

for the action entitled ‘EMpowering PAtients for a BeTTer Information and improvement of the Communication Systems (EMPATTICS)’.

and mandates

the *coordinator* to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

David SOMEKH with ECAS id nsomdavi signed in the Participant Portal on 11/12/2015 at 20:29:20 (transaction id SigId-37-1LlNvzZpVzGKHSaI3VIO5tUVwEzSlmehUzYoKSP70Tvhg1mPjjVbyHMj5okHVeHXzYrOeZJCQH1N30Jp1eZtFpt-Jj71zxYb8yrnTly9NGmq5u-WrCzYM2aS5fo0gSixfbnhQ02Ozn6mZfLFruHqglvp5N0). Timestamp by third party at
Fri Dec 11 20:29:25 CET 2015

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

KOKOMO HEALTHCARE LIMITED (KKM) LTD, 526649, established in 33 ANNAVILLA RANELAGH DUBLIN 6, DUBLIN 6, Ireland, IE2986375SH ('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 690492 (‘the Agreement’)

between Conselleria de Sanidade de Galicia **and** *the European Union (‘the EU’), represented by the European Commission ('the Commission'),*

for the action entitled ‘EMpowering PAtients for a BeTTer Information and improvement of the Communication Systems (EMPATTICS)’.

and mandates

the *coordinator* to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

M&C SAATCHI MADRID SL (Saatchi) SL, M392135, established in CALLE GRAN VIA 27 PLANTA 3, MADRID 28013, Spain, ESB84428754 ('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 690492 (‘the Agreement’)

between Conselleria de Sanidade de Galicia **and** *the European Union (‘the EU’), represented by the European Commission ('the Commission'),*

for the action entitled ‘EMpowering PAtients for a BeTTer Information and improvement of the Communication Systems (EMPATTICS)’.

and mandates

the *coordinator* to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ⓘ print format A4 landscape

MODEL ANNEX 4 FOR H2020 MGA PCP/PPI COFUND — MULTI

FINANCIAL STATEMENT FOR *[BENEFICIARY [name]/LINKED THIRD PARTY [name]]* FOR REPORTING PERIOD [reporting period]

	Eligible[1] costs (per budget category)												Receipts	EU contribution			Additional information
	A. Direct costs of *[PCP][PPI]* subcontracting	B. Costs for related additional coordination and networking activities									Total costs		Receipts	Reimbursement rate %	Maximum EU contribution[3]	Requested EU contribution	Information for indirect costs :
		B.1 Direct personnel costs			B.2 Direct costs of subcontracting	B.3 Other direct costs		B.4 Indirect costs[2]	*[B.5 Costs of …]*				Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
		B.1.1. Employees (or equivalent) B.1.2 Natural persons under direct contract B.2.3. Seconded persons *[B.1.6. Personnel for providing*	B.1.4 SME owners without salary B.1.5 Beneficiaries that are natural persons without salarv			B.3.1 Travel B.3.2 Equipment B.3.3 Other goods and services	*[B.3.4.Costs of large research infrastructure]*		*[B.5.1 Costs of …]6*	*[B.5.2 Costs of …]6*							
Form of costs[4]	Actual	Actual	Unit	Unit		Actual	Actual	Actual	Flat-rate[5] 25%	Unit		Unit					
	a	b	Total c	No units	Total d	e	f	*[g]*	h=0,25x(b+c+d+f+*[g]* + *[i1]*[6] +*[i2]*[6] -o)	No units	Total *[i1]*	Total *[i2]*	j = a+b+c+d+e+f+*[g]* +h +*[i1]* +*[i2]*	k	l	m	n	o
[short name beneficiary /linked third party]																	

The beneficiary/linked third party hereby confirms that:
The information provided is complete, reliable and true.
The costs declared are eligible (see Article 6).
The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).
For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘ Please declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace other costs that are found to be ineligible.

[1] See Article 6 for the eligibility conditions

[2] The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.2.B.4). If you have received an operating grant during this reporting period, you cannot claim any indirect costs.

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying the reimbursement rate by the total costs declared). The amount you request (in the column 'requested EU contribution') may have to be less (e.g. if you and the other beneficiaries are above budget, etc).

[4] See Article 5 for the forms of costs

[5] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, and unit costs declared under budget category F if they include indirect costs (see Article 6.2.B.4)

[6] Only specific unit costs that do not include indirect costs

ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data**

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Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the Financial Statement(s)[1] drawn up by the *[Beneficiary] [Linked Third Party]* for the Horizon 2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a Certificate on the Financial Statements' ('CFS') referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement has been concluded under the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*

[1] By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union][Euratom][Agency]* is not a party to this engagement.

1.1 Subject of the engagement

The coordinator must submit to the *[Commission][Agency]* the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the coordinator the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement..

The CFS is composed of two separate documents:

- The Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;
- The Auditor's Independent Report of Factual Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures ('the Procedures') to be performed by the Auditor, and the standard factual findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the *[Commission,][Agency,]* the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

1.2 Responsibilities

The *[Beneficiary] [Linked Third Party]:*

- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the *[Beneficiary's] [Linked Third Party's]* accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- accepts that the Auditor cannot carry out the Procedures unless it is given full access to the *[Beneficiary's] [Linked Third Party's]* staff and accounting as well as any other relevant records and documentation.

The Auditor:

- *[Option 1 by default:* is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations*]*.
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer:* is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary*].*
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation:* is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation*].*

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[2]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the *[Commission][Agency]* requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]*, and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the [*Commission*] [*Agency*], the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [*the European Union*] [*Euratom*] budget. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the *[Commission] [Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by *[*dd Month yyyy*]*.

[2] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

1.6 Other terms

[*The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.*]

[legal name of the Auditor]	[legal name of the *[Beneficiary][Linked Third Party]*]
[name & function of authorised representative]	[name & function of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary][Linked Third Party]*

Independent Report of Factual Findings on costs declared under Horizon 2020 Research and Innovation Framework Programme

(To be printed on the Auditor's letterhead)

To

[name of contact person(s)], [Position]

[[*Beneficiary's*] [*Linked Third Party's*] name]

[Address]

[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')],*

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)[3] of the *[Beneficiary] [Linked Third Party]* concerning the grant agreement

[insert grant agreement reference: number, title of the action and acronym] ('the Agreement'),

with a total cost declared of

[total amount] EUR,

and a total of actual costs and 'direct personnel costs declared as unit costs calculated in accordance with the [*Beneficiary's*] [*Linked Third Party's*] usual cost accounting practices' declared of

[sum of total actual costs and total direct personnel costs declared as unit costs calculated in accordance with the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practices] EUR

and **hereby provide our Independent Report of Factual Findings ('the Report')** using the compulsory report format agreed with you.

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') examined.

The Procedures were carried out solely to assist the [*Commission*] [*Agency*] in evaluating whether the [*Beneficiary's*] [*Linked Third Party's*] costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The *[Commission] [Agency]* draws its own conclusions from the Report and any additional information it may require.

[3] By which the Beneficiary declares costs under the Agreement (see template 'Model Financial Statement' in Annex 4 to the Agreement).

The scope of the Procedures was defined by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the *[Beneficiary's] [Linked Third Party's]* Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

Not applicable Findings

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

Explanation (to be removed from the Report):

*If a Finding was not applicable, it must be marked as '**N.A**.' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related Procedure(s) did not have to be carried out.*

The reasons of the non-application of a certain Finding must be obvious i.e.

i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable;

ii) if the condition set to apply certain Procedure(s) are not met the related Finding(s) and those Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the Procedure and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.

….

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

Explanation (to be removed from the Report):

- *If the Auditor was not able to successfully complete a procedure requested, it must be marked as '**E**' ('Exception') in the corresponding row on the right-hand column of the table. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the Procedure must be indicated below.*
- *If the Auditor cannot corroborate a standard finding after having carried out the corresponding procedure, it must also be marked as '**E**' ('Exception') and, where possible, the reasons why the Finding was not fulfilled and its possible impact must be explained here below.*

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.

….

Example (to be removed from the Report):

1. *The Beneficiary was unable to substantiate the Finding number 1 on … because ….*
2. *Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: …*
3. *After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____ EUR. The difference can be explained by …*

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. *Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because …*
2. *In order to be able to confirm the Finding number 15 we carried out the following additional procedures: ….*

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the *[Beneficiary] [Linked Third Party]* and the [*Commission*] [*Agency*], and only to be submitted to the [*Commission*] [*Agency*] in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the *[Beneficiary] [Linked Third Party]* or by the [*Commission*] [*Agency*] for any other purpose, nor may it

be distributed to any other parties. The [*Commission*] [*Agency*] may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the *[Commission] [Agency]* by the *[Beneficiary] [Linked Third Party]* for the Agreement. Therefore, it does not extend to any other of the [*Beneficiary's*] [*Linked Third Party's*] Financial Statement(s).

There was no conflict of interest[4] between the Auditor and the Beneficiary *[and Linked Third Party]* in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR _____ (including EUR_____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]

[name and function of an authorised representative]

[dd Month yyyy]

Signature of the Auditor

[4] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The European Commission reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

The 'result' column has three different options: 'C', 'E' and 'N.A.':

- 'C' stands for 'confirmed' and means that the auditor can confirm the 'standard factual finding' and, therefore, there is no exception to be reported.
- 'E' stands for 'exception' and means that the Auditor carried out the procedures but cannot confirm the 'standard factual finding', or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- 'N.A.' stands for 'not applicable' and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than the euro' the Procedure related to 'beneficiaries with accounts established in euro' is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A	**ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE**		

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A. (*The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)* The Auditor sampled _____ people out of the total of _____ people.		
A.1	**PERSONNEL COSTS** <u>For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs)</u> To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: ○ a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract; ○ the payslips of the employees included in the sample; ○ reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system; ○ information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent;	1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary's sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary's usual practices.	
		2) Personnel costs were recorded in the Beneficiary's accounts/payroll system.	
		3) Costs were adequately supported and reconciled with the accounts and payroll	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ the Beneficiary's usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); ○ applicable national law on taxes, labour and social security and ○ any other document that supports the personnel costs declared. The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA) and recalculated the personnel costs for employees included in the sample.	records.	
		4) Personnel costs did not contain any ineligible elements.	
		5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.	
	Further procedures if 'additional remuneration' is paid To confirm standard factual findings 6-9 listed in the next column, the Auditor: ○ reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory obligations, the Beneficiary's usual policy on additional remuneration, criteria used for its calculation…); ○ recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, etc.) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 'Productive hours' and A.4 'Time recording system').	6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.	
		7) The amount of additional remuneration paid corresponded to the Beneficiary's usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	IF ANY PART OF THE REMUNERATION PAID TO THE EMPLOYEE IS NOT MANDATORY ACCORDING TO THE NATIONAL LAW OR THE EMPLOYMENT CONTRACT ("ADDITIONAL REMUNERATION") AND IS ELIGIBLE UNDER THE PROVISIONS OF ARTICLE 6.2.A.1, THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION UP TO THE FOLLOWING AMOUNT: *(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR;* *(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR* *(C) IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.*	8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used.	
		9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000 per FTE/year (up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).	
	Additional procedures in case "unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices" is applied: Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5 and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard factual findings 10-13 listed in the next column:	10) The personnel costs included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. This methodology was consistently used in all H2020 actions.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs;. ○ reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; ○ verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records; ○ verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts; ○ verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents.	11) The employees were charged under the correct category.	
		12) Total personnel costs used in calculating the unit costs were consistent with the expenses recorded in the statutory accounts.	
		13) Any estimated or budgeted element used by the Beneficiary in its unit-cost calculation were relevant for calculating personnel costs and corresponded to objective and verifiable information.	
	<u>For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no subcontractors).</u> To confirm standard factual findings 14-18 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary: ○ the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary;	14) The natural persons reported to the Beneficiary (worked under the Beneficiary's instructions).	
		15) They worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ the employment conditions of staff in the same category to compare costs and; ○ any other document that supports the costs declared and its registration (e.g. invoices, accounting records, etc.).	16) The results of work carried out belong to the Beneficiary.	
		17) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		18) The costs were supported by audit evidence and registered in the accounts.	
	<u>For personnel seconded by a third party and included in the sample (not subcontractors)</u> To confirm standard factual findings 19-22 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: ○ their secondment contract(s) notably regarding costs, duration, work description, place of work and ownership of the results; ○ if there is reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the amount invoiced by the third party did not include any profit;	19) Seconded personnel reported to the Beneficiary and worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		20) The results of work carried out belong to the Beneficiary.	
		If personnel is seconded against payment: 21) The costs declared were supported with documentation and recorded in the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll; ○ any other document that supports the costs declared (e.g. invoices, etc.).	Beneficiary's accounts. The third party did not include any profit.	
		If personnel is seconded free of charge: 22) The costs declared did not exceed the third party's cost as recorded in the accounts of the third party and were supported with documentation.	
A.2	**PRODUCTIVE HOURS** To confirm standard factual findings 23-28 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that: ○ the annual productive hours applied were calculated in accordance with one of the methods described below, ○ the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated.	23) The Beneficiary applied method [*choose one option and delete the others*] [**A**: 1720 hours] [**B**: the 'total number of hours worked'] [**C**: 'annual productive hours' used correspond to usual accounting practices]	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	If the Beneficiary applied method B, the auditor verified that the correctness in which the total number of hours worked was calculated and that the contracts specified the annual workable hours. If the Beneficiary applied method C, the auditor verified that the 'annual productive hours' applied when calculating the hourly rate were equivalent to at least 90 % of the 'standard annual workable hours'. The Auditor can only do this if the calculation of the standard annual workable hours can be supported by records, such as national legislation, labour agreements, and contracts. *BENEFICIARY'S PRODUCTIVE HOURS' FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS:* ***A.*** *1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)* ***B.*** *THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL NUMBER OF HOURS WORKED' IN THE NEXT COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE).*	24) Productive hours were calculated annually.	
		25) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.	
		If the Beneficiary applied method B. 26) The calculation of the number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary.	
		If the Beneficiary applied method C. 27) The calculation of the number of 'standard annual workable hours' was verifiable based on the documents provided by the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	C. THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL ANNUAL PRODUCTIVE HOURS' IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS. *'ANNUAL WORKABLE HOURS' MEANS THE PERIOD DURING WHICH THE PERSONNEL MUST BE WORKING, AT THE EMPLOYER'S DISPOSAL AND CARRYING OUT HIS/HER ACTIVITY OR DUTIES UNDER THE EMPLOYMENT CONTRACT, APPLICABLE COLLECTIVE LABOUR AGREEMENT OR NATIONAL WORKING TIME LEGISLATION.*	28) The 'annual productive hours' used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the 'annual workable hours'.	
A.3	**HOURLY PERSONNEL RATES** <u>I) For unit costs calculated in accordance to the Beneficiary's usual cost accounting practice (unit costs):</u> If the Beneficiary has a "Certificate on Methodology to calculate unit costs " (CoMUC) approved by the Commission, the Beneficiary provides the Auditor with a description of the approved methodology and the Commission's letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary. If the Beneficiary does not have a "Certificate on Methodology" (CoMUC) approved by the	29) The Beneficiary applied [*choose one option and delete the other*]: [Option I: "Unit costs (hourly rates) were calculated in accordance with the Beneficiary's usual cost accounting practices"] [Option II: Individual hourly rates were applied]	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	Commission, or if the methodology approved was not applied, then the Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the unit costs (hourly rates) of staff included in the sample following the results of the procedures carried out in A.1 and A.2. II) For individual hourly rates: The Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the hourly rates of staff included in the sample following the results of the procedures carried out in A.1 and A.2. *"UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES":* *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2.* *HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS:* *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH*	*For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC):* 30) The Beneficiary used the Commission-approved methodology to calculate hourly rates. It corresponded to the organisation's usual cost accounting practices and was applied consistently for all activities irrespective of the source of funding.	
		For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission: 31) The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	
		For option II concerning individual hourly rates:	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2.	32) The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	
A.4	**TIME RECORDING SYSTEM** To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records: o description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system); o its actual implementation; o time records were signed at least monthly by the employees (on paper or electronically) and authorised by the project manager or another manager; o the hours declared were worked within the project period; o there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below) ;	33) All persons recorded their time dedicated to the action on a **daily/ weekly/ monthly** basis using a **paper/computer-based** system. (*delete the answers that are not applicable)*	
		34) Their time-records were authorised at least monthly by the project manager or other superior.	
		35) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ the hours charged to the action matched those in the time recording system. *ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).*	36) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.	
	<u>If the persons are working exclusively for the action and without time records</u> For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.	37) The exclusive dedication is supported by a declaration signed by the Beneficiary's and by any other evidence gathered.	
B	**COSTS OF SUBCONTRACTING**		
B.1	**The Auditor obtained the detail/breakdown of subcontracting costs and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 38-42 listed in the next column, the Auditor reviewed the	38) The use of claimed subcontracting costs was foreseen in Annex 1 and costs were declared in the Financial Statements under the subcontracting category.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	following for the items included in the sample: o the use of subcontractors was foreseen in Annex 1; o subcontracting costs were declared in the subcontracting category of the Financial Statement; o supporting documents on the selection and award procedure were followed; o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment). In particular, i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement. ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement.. For the items included in the sample the Auditor also verified that: o the subcontracts were not awarded to other Beneficiaries in the consortium;	39) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
		40) The subcontracts were not awarded to other Beneficiaries of the consortium.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	○ there were signed agreements between the Beneficiary and the subcontractor; ○ there was evidence that the services were provided by subcontractor;	41) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.	
		42) There was evidence that the services were provided by the subcontractors.	
C	**COSTS OF PROVIDING FINANCIAL SUPPORT TO THIRD PARTIES**		
C.1	**The Auditor obtained the detail/breakdown of the costs of providing financial support to third parties and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). The Auditor verified that the following minimum conditions were met: a) the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex 1; b) the financial support to third parties was agreed in Annex 1 of the Agreement and the other provisions on financial support to third parties included in Annex 1 were	43) All minimum conditions were met	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	respected.		

D	OTHER ACTUAL DIRECT COSTS		
D.1	**COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). The Auditor inspected the sample and verified that: ○ travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy; ○ travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference; ○ no ineligible costs or excessive or reckless expenditure was declared.	44) Costs were incurred, approved and reimbursed in line with the Beneficiary's usual policy for travels.	
		45) There was a link between the trip and the action.	
		46) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.	
		47) No ineligible costs or excessive or reckless expenditure was declared.	
D.2	**DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). For "equipment, infrastructure or other assets" [from now on called "asset(s)"] selected in the	48) Procurement rules, principles and guides were followed.	
		49) There was a link between the grant agreement and the asset charged to the action.	

	sample the Auditor verified that: ○ the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures; ○ they were correctly allocated to the action (with supporting documents such as delivery note invoice or any other proof demonstrating the link to the action) ○ they were entered in the accounting system; ○ the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table); The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary's country and with the Beneficiary's usual accounting policy (e.g. depreciation calculated on the acquisition value). The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).	50) The asset charged to the action was traceable to the accounting records and the underlying documents. 51) The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy. 52) The amount charged corresponded to the actual usage for the action. 53) No ineligible costs or excessive or reckless expenditure were declared.	
D.3	**COSTS OF OTHER GOODS AND SERVICES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). For the purchase of goods, works or services included in the sample the Auditor verified that: ○ the contracts did not cover tasks described in Annex 1;	54) Contracts for works or services did not cover tasks described in Annex 1. 55) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment.	

	○ they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting); ○ the goods were not placed in the inventory of durable equipment; ○ the costs charged to the action were accounted in line with the Beneficiary's usual accounting practices; ○ no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA). In addition, the Auditor verified that these goods and services were acquired in conformity with the Beneficiary's internal guidelines and procedures, in particular: ○ if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement. ○ if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement. For the items included in the sample the Auditor also verified that: ○ the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment); *SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE*	56) The costs were charged in line with the Beneficiary's accounting policy and were adequately supported. 57) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups. 58) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were made in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the*	

	AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.	*caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	
D.4	**AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE** The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020. ***In the cases that a positive ex-ante assessment has been issued*** *(see the standard factual findings 59-60 on the next column)****,*** The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment; ***In the cases that a positive ex-ante assessment has NOT been issued*** *(see the standard factual findings 61 on the next column),* The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category;	59) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology described in the positive ex-ante assessment report. 60) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly. 61) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure.	

	In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes *(see the standard factual findings 61 on the next column),* • The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large Research Infrastructures or issued recommendations.		
E	**USE OF EXCHANGE RATES**		
E.1	a) For Beneficiaries with accounts established in a currency other than euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO AT THE AVERAGE OF THE DAILY EXCHANGE RATES PUBLISHED IN THE C SERIES OF OFFICIAL JOURNAL OF THE EUROPEAN UNION (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.* *IF NO DAILY EURO EXCHANGE RATE IS PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION FOR THE CURRENCY IN QUESTION, CONVERSION SHALL BE MADE AT THE AVERAGE OF THE MONTHLY ACCOUNTING RATES ESTABLISHED BY THE COMMISSION AND PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm),*	62) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final figures.	

	DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.		
	b) For Beneficiaries with accounts established in euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY'S USUAL ACCOUNTING PRACTICES.*	63) The Beneficiary applied its usual accounting practices.	

[legal name of the audit firm]

[name and function of an authorised representative]

[dd Month yyyy]

<Signature of the Auditor>

ANNEX 6

MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data.**

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Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and claiming direct personnel costs declared as unit costs ('the Methodology') in connection with grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] ('the Agreement(s)')

The Agreement(s) has(have) been concluded between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*.

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union] [Euratom] [Agency]* is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, beneficiaries *[and linked third parties]* that declare direct personnel costs as unit costs calculated in accordance with their usual cost accounting practices may submit to the *[Commission] [Agency]*, for approval, a certificate on the methodology ('CoMUC') stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which is composed of two separate documents:

- the Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

- the Auditor's Independent Report of Factual Findings ('the Report') issued on the Auditor's letterhead, dated, stamped and signed by the Auditor which includes; the standard statements ('the Statements') evaluated and signed by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') performed by the Auditor and the standard factual findings ('the Findings') assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.

The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the *[Beneficiary] [Linked Third Party]* and the Auditor.

The *[Beneficiary] [Linked Third Party]:*

- is responsible for preparing financial statements for the Agreement(s) ('the Financial Statements') in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the *[Beneficiary's] [Linked Third Party's]* accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading 'Statements to be made by the Beneficiary/ Linked Third Party' in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the *[Beneficiary] [Linked Third Party]* providing full and free access to the *[Beneficiary's] [Linked Third Party's]* staff and to its accounting and other relevant records.

The Auditor:

- *[Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations]*.
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary]*.
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation]*.

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the Beneficiary's *[and Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with these ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out and the Findings to be endorsed by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[1]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there was no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report, and must specify – if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the Commission, *[the Agency]*, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are claimed from [*the European Union*] [*Euratom*] budget. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the Commission*, [the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by [dd Month yyyy].

[1] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

1.6 Other Terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]	[legal name of the [Beneficiary] [Linked Third Party]]
[name & title of authorised representative]	[name & title of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor Signature	Signature of the *[Beneficiary] [Linked Third Party]*

Independent report of factual findings on the methodology concerning grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

(To be printed on letterhead paper of the auditor)

To

[name of contact person(s)], [Position]

[[Beneficiary's] [Linked Third Party's] name]

[Address]

[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]*,

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the agreed-upon procedures ('the Procedures') and provide hereby our Independent Report of Factual Findings ('the Report'), concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and declaring direct personnel costs declared as unit costs ('the Methodology').

You requested certain procedures to be carried out in connection with the grant(s)

[title and number of the grant agreement(s)] ('the Agreement(s)').

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes: the standard statements ('the Statements') made by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the *[Beneficiary] [Linked Third Party]*.

The Report covers the methodology used from [dd Month yyyy]. In the event that the *[Beneficiary] [Linked Third Party]* changes this methodology, the Report will not be applicable to any Financial Statement[2] submitted thereafter.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not

[2] Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.

give a statement of assurance on the costs declared on the basis of the *[Beneficiary's] [Linked Third Party's]* Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

…..

Explanation of possible exceptions in the form of examples (to be removed from the Report):

i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number … because…;

ii. the Auditor could not carry out the procedure … established because …. (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);

iii. the Auditor could not confirm or corroborate the standard Finding number … because ….

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates …

Regarding standard Finding 15 it has to be noted that …

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner: …

Annexes

Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the Commission:

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;
2. Brief description of the time recording system in place;
3. An example of the time records used by the [*Beneficiary] [Linked Third Party*];
4. Description of any budgeted or estimated elements applied, together with an explanation as to why they are relevant for calculating the personnel costs and how they are based on objective and verifiable information;
5. A summary sheet with the hourly rate for direct personnel declared by the [*Beneficiary*] [*Linked Third Party*] and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the [*Beneficiary*] [*Linked Third Party*] in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:

- is confidential and is intended to be submitted to the Commission by the [*Beneficiary*] [*Linked Third Party*] in connection with Article 18.1.2 of the Agreement;
- may not be used by the [*Beneficiary*] [*Linked Third Party*] or by the Commission for any other purpose, nor distributed to any other parties;
- may be disclosed by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the [*Beneficiary*] [*Linked Third Party*].

No conflict of interest[3] exists between the Auditor and the Beneficiary *[and the Linked Third Party*] that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR _____ (including EUR _____ of deductible VAT).

[3] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:

- was involved in the preparation of the Financial Statements;

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]

[name and title of the authorised representative]

[dd Month yyyy]

Signature of the Auditor

- stands to benefit directly should the certificate be accepted;

- has a close relationship with any person representing the beneficiary;

- is a director, trustee or partner of the beneficiary; or

- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Statements to be made by the Beneficiary/Linked Third Party ('the Statements') and Procedures to be carried out by the Auditor ('the Procedures') and standard factual findings ('the Findings') to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party's usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
A. Use of the Methodology I. The cost accounting practice described below has been in use since *[*dd Month yyyy*]*. II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy*]*.	**Procedure:** ✓ The Auditor checked these dates against the documentation the Beneficiary has provided. **Factual finding:** 1. The dates provided by the Beneficiary were consistent with the documentation.
B. Description of the Methodology III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures. *[Please describe the methodology your entity uses to calculate personnel costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]* *[If the statement of section "B. Description of the methodology" cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of*	**Procedure:** ✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology. **Factual finding:** 2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed. 3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
Factual Findings: - *…]*	
C. **Personnel costs** <u>General</u> IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act; V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility; VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means that personnel costs are charged in line with the Beneficiary's usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to the European Union or Euratom, unless explicitly provided for in the grant agreement(s); VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice; VIII. Personnel costs are based on the payroll system and accounting system. IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements and were based on objective and verifiable information. *[Please describe the 'budgeted or estimated elements' and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate].* X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses	**Procedure:** *The Auditor draws a sample of employees to carry out the procedures indicated in this section C and the following sections D to F.* *[The Auditor has drawn a random sample of 10 full-time equivalents made up of employees assigned to the action(s). If fewer than 10 full-time equivalents are assigned to the action(s), the Auditor has selected a sample of 10 full-time equivalents consisting of all employees assigned to the action(s), complemented by other employees irrespective of their assignments.].* For this sample: ✓ the Auditor reviewed all documents relating to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax , labour and social security law and any other documents corroborating the personnel costs claimed; ✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that: i. they were employed directly by the Beneficiary in accordance with applicable national legislation; ii. they were working under the sole technical supervision and responsibility of the latter; iii. they were remunerated in accordance with the Beneficiary's usual practices; iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary's usual cost accounting practices; ✓ the Auditor verified that any ineligible items or any costs claimed under other costs categories or costs covered by other types of grant or by other grants financed from the European Union budget have not been taken

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary's bank for transfers from the Commission/Agency; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action. XI. Personnel costs were not declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU budget and grants awarded by bodies other than the Commission/Agency for the purpose of implementing the EU budget). <u>If additional remuneration as referred to in the grant agreement(s) is paid</u> XII. The Beneficiary is a non-profit legal entity; XIII. The additional remuneration is part of the beneficiary's usual remuneration practices and paid consistently whenever the relevant work or expertise is required; XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding; XV. The additional remuneration included in the personnel costs used to calculate the hourly rates for the grant agreement(s) is capped at EUR 8 000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action). *[If certain statement(s) of section "C. Personnel costs" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of*	into account when calculating the personnel costs; ✓ the Auditor numerically reconciled the total amount of personnel costs used to calculate the unit cost with the total amount of personnel costs recorded in the statutory accounts and the payroll system. ✓ to the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, the Auditor carefully examined those elements and checked the information source to confirm that they correspond to objective and verifiable information; ✓ if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8 000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s). ✓ the Auditor recalculated the personnel costs for the employees in the sample. **Factual finding:** 4. All the components of the remuneration that have been claimed as personnel costs are supported by underlying documentation. 5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility. 6. Their employment contracts were in line with the Beneficiary's usual policy; 7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month's pay, etc.); 8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records; 9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
Factual Findings: - *…]*	relevant for calculating the personnel costs and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values). 10. Personnel costs contained no ineligible elements; 11. Specific conditions for eligibility were fulfilled when additional remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to objective criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8000 per full-time equivalent (or up to up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).
D. Productive hours XVI. The number of productive hours per full-time employee applied is *[delete as appropriate]*: A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time). B. the total number of hours worked in the year by a person for the Beneficiary C. the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours. <u>If method B is applied</u> XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave). XVIII. 'Annual workable hours' are hours	**Procedure (same sample basis as for Section C: Personnel costs):** ✓ The Auditor verified that the number of productive hours applied is in accordance with method A, B or C. ✓ The Auditor checked that the number of productive hours per full-time employee is correct and that it is reduced proportionately for employees not exclusively assigned to the action(s). ✓ If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts. ✓ If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90% of the standard number of working hours per year.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation. XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> XX. The standard number of productive hours per year is that of a full-time equivalent; for employees not assigned exclusively to the action(s) this number is reduced proportionately. XXI. The number of productive hours per year on which the hourly rate is based i) corresponds to the Beneficiary's usual accounting practices; ii) is at least 90% of the standard number of workable (working) hours per year. XXII. Standard workable (working) hours are hours during which personnel are at the Beneficiary's disposal preforming the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence. *[If certain statement(s) of section "D. Productive hours" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *…]*	**Factual finding:** <u>General</u> 12. The Beneficiary applied a number of productive hours consistent with method A, B or C detailed in the left-hand column. 13. The number of productive hours per year per full-time employee was accurate and was proportionately reduced for employees not working full-time or exclusively for the action. <u>If method B is applied</u> 14. The number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary and the calculation of the total number of hours worked was accurate. 15. The contract specified the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> 16. The calculation of the number of productive hours per year corresponded to the usual costs accounting practice of the Beneficiary. 17. The calculation of the standard number of workable (working) hours per year was corroborated by the documents presented by the Beneficiary. 18. The number of productive hours per year used for the calculation of the hourly rate was at least 90% of the number of workable (working) hours per year.
E. Hourly rates The hourly rates are correct because: XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel	**Procedure** ✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used. ✓ The Auditor has obtained a list of all the relevant employees, based on which the

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above. *[If the statement of section 'E. Hourly rates' cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *…]*	personnel rate(s) are calculated. For 10 full-time equivalent employees selected at random (same sample basis as Section C: Personnel costs): ✓ The Auditor recalculated the hourly rates. ✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding. **Factual finding:** 19. No differences arose from the recalculation of the hourly rate for the employees included in the sample.
F. Time recording XXIV. Time recording is in place for all persons with no exclusive dedication to one Horizon 2020 action. At least all hours worked in connection with the grant agreement(s) are registered on a **daily/weekly/monthly** basis *[delete as appropriate]* using a **paper/computer-based system** *[delete as appropriate]*; XXV. For persons exclusively assigned to one Horizon 2020 activity the Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time; XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly; XXVII. Measures are in place to prevent staff from: i. recording the same hours twice, ii. recording working hours during absence periods (e.g. holidays, sick leave), iii. recording more than the number of productive hours per year used to calculate the hourly rates, and	**Procedure** ✓ The Auditor reviewed the brief description, all relevant manuals and/or internal guidance describing the methodology used to record time. The Auditor reviewed the time records of the random sample of 10 full-time equivalents referred to under Section C: Personnel costs, and verified in particular: ✓ that time records were available for all persons with not exclusive assignment to the action; ✓ that time records were available for persons working exclusively for a Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a Horizon 2020 action; ✓ that time records were signed and approved in due time and that all minimum requirements were fulfilled; ✓ that the persons worked for the action in the periods claimed; ✓ that no more hours were claimed than the productive hours used to calculate the hourly

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
iv. recording hours worked outside the action period. XXVIII. No working time was recorded outside the action period; XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates. *[Please provide a brief description of the time recording system in place together with the measures applied to ensure its reliability to the Auditor and annex it to the present certificate[4]].* *[If certain statement(s) of section "F. Time recording" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* *- …]*	personnel rates; ✓ that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period; ✓ the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been effective. In addition, the Auditor has verified that no more hours were charged to Horizon 2020 actions per person per year than the number of productive hours per year used to calculate the hourly rates, and verified that no time worked outside the action period was charged to the action. **Factual finding:** 20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements. 21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available; 22. For the random sample the time records were signed by the employee and the action manager/line manager, at least monthly. 23. Working time claimed for the action occurred in the periods claimed; 24. No more hours were claimed than the number productive hours used to calculate the hourly

[4] The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as it information flow up to its use for the preparation of the Financial Statements.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
	personnel rates; 25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the action period. 26. Working time claimed is consistent with that on record at the human-resources department.

[official name of the** [Beneficiary] [Linked Third Party]**]	***[official name of the Auditor]***
[name and title of authorised representative]	***[name and title of authorised representative]***
[dd Month yyyy]	***[dd Month yyyy]***
<Signature of the** [Beneficiary] [Linked Third Party]**>	***<Signature** of the Auditor**>***

ANNEX 7

MODEL FOR THE COMMITMENT ON AVAILABILITY OF RESOURCES

- **For options *[in italics in square brackets]*: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data**

COMMITMENT ON AVAILABILITY OF RESOURCES

Grant Agreement: [Insert grant agreement number and acronym]

(To be filled out by each beneficiary of the buyers group, and each linked third party linked to (a) beneficiary/ies, that is providing financial commitments that are needed to carry out the PCP or PPI call for tender.)

The undersigned [name of the authorised representative] declares that [name of beneficiary or linked third party] can commit and **make available financial resources** totalling EUR […] to finance its share of the *[R&D services] [innovative solutions]* to be procured, based on the estimated value of planned *[PCP][PPI]* procurement.

The undersigned [name of the authorised representative] declares that [name of beneficiary or linked third party] authorizes [names of the beneficiary that is the lead procurer] to **act in his name and on his behalf** as lead procurer for the planned *[PCP][PPI]* procurement.

Name and signature Date and stamp

(To be filled out by linked third parties that provide in-kind contributions necessary to carry out the call for tender)

The undersigned [name of the authorised representative] declares that [name of linked third party] can commit and make **available resources** by means of contributions in kind totalling EUR […] to the [name of beneficiary/ies] for carrying out the *[PCP] [PPI]* procurement, based on the indicated amounts of planned contributions.

Name and signature Date and stamp

ANNEX 8

MODEL FOR THE STATEMENT ON THE USE OF THE PREVIOUS PRE-FINANCING INSTALMENT

➢ **For fields in [grey in square brackets]: enter the appropriate data**

STATEMENT ON THE USE OF THE *[FIRST][SECOND]* PRE-FINANCING INSTALMENT

(To be filled out by the coordinator)

The undersigned [*Name of the authorised representative*]

- declares that […] % of the *[first][second]* pre-financing instalment of EUR [insert amount] paid for Grant Agreement [insert grant agreement reference: number, title of the action and acronym] have been used,
- declares that this is based on substantiated data (bank slip/treasury account) provided by each beneficiary,
- certifies that the information contained in the periodic report is full, reliable and true, and is substantiated by adequate supporting documentation that will be produced upon or in the context of checks, reviews, audits and investigations,
- requests a [second][third] pre-financing payment of EUR [insert amount] for [insert grant agreement reference: number, title of the action and acronym].

Name and signature Date and stamp

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