EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY Directorate General
Health systems and products
Director

SERVICE CONTRACT

CONTRACT NUMBER – SANTE/2015/D2/021 – SI2.722481

The European Union (hereinafter referred to as "the Union"), represented by the European Commission (hereinafter referred to as "the contracting authority"), which is represented for the purposes of the signature of this contract by Andrzej Rys, Director of SANTE.DDG1.D., Direction of Health Systems and Products at Directorate-General for Health and Food Safety

on the one part, and

The Pro-Step Consortium, consisting of

European Patients' Forum
ASBL
Rue Dicks 14
1417 Luxemburg
Luxemburg
Statutory registration number : F448
VAT registration number : BE0807.605.667

AND

Danish Committee for Health Education – DCHE
Non-Profit association
Classensgade 71,5
2100 - Copenhagen East
Registration number 14035338
VAT : 14035338

European Health Futures Forum – EHFF
NGO
Kingates farm, Ventnor
IOW PO38 2QP UK
Registered 8447376

Fundacion Avedis Donabedian para la Mejora de la Calidad Asistencial – FAD
Non Profit Private Entity
Provenca 293 Principal
08037 Barcelona

Spain
Registration 645
VAT ESG59026716

Institute for Medical Technology Assessment of Erasmus University of Rotterdam – iMTA
Limited Company
Burgemeester Oudlaan,50
3062PA Rotterdam
The Netherlands
Registration 24257138
VAT NL804735529B30

(hereinafter referred to as 'the contractor'), represented for the purposes of the signature of this contract by Mrs Anke Seidler, Head of Office, European Patients' Forum Brussels

The parties identified above and hereinafter collectively referred to as 'the contractor' shall be jointly and severally liable vis-à-vis the contracting authority for the performance of this contract.

on the other part,

HAVE AGREED

to the **special conditions,** the **general conditions for service contracts** and the following annexes:

Annex I – Tender specifications (reference No SANTE/2015/D2/021 of 7 July 2015)

Annex II – Contractor's tender (reference of 29 September 2015)

Annex III - Powers of Attorney

which form an integral part of this contract (hereinafter referred to as "the contract").

- The terms set out in the special conditions shall take precedence over those in the other parts of the contract.
- The terms set out in the general conditions shall take precedence over those in the annexes.
- The terms set out in the tender specifications (Annex I) shall take precedence over those in the tender (Annex II).

I – SPECIAL CONDITIONS

ARTICLE I.1 – SUBJECT MATTER

I.1.1 The subject matter of the contract is "pilot project on the promotion of self-care systems in the European Union in the field of chronic diseases".

I.1.2 The contractor shall execute the tasks assigned to it in accordance with the tender specifications annexed to the contract (Annex I).

ARTICLE I.2 – ENTRY INTO FORCE AND DURATION

I.2.1 The contract shall enter into force on the date on 15 January 2016.

I.2.2 Under no circumstances may performance commence before the date on which the contract enters into force.

I.2.3 The duration of the execution of the tasks shall not exceed 24 months. Unless otherwise specified, all periods specified in the contract are calculated in calendar days. Execution of the tasks shall start from the date of entry into force of the contract.

The period of execution of the tasks may be extended only with the express written agreement of the parties before the expiration of such period.

ARTICLE I.3 –PRICE

I.3.1 The maximum total amount to be paid by the contracting authority under the contract shall be 949.912 EUR (nine hundred forty-nine thousand nine hundred and twelve Euros) covering all tasks executed.

I.3.2 Price revision

The total amount referred to in the Article I.3.1 shall be fixed and not subject to revision during the first year of performance of the contract.

ARTICLE I.4 – PAYMENT ARRANGEMENTS

I.4.1 First interim payment

The contractor shall submit an invoice for an interim payment of EUR 237.478 (two hundred thirty-seven thousand and four hundred seventy-eight Euros) equal to 25 % of the total amount referred to in Article I.3.1. 6 months after signature of the contract.

Invoices for interim payment shall be accompanied by a progress report or any other document in accordance with the tender specifications. The contracting authority shall make the payment within 60 days from receipt of the invoice. The contractor shall have 15 days in which to submit additional information or corrections or a new progress report or documents if required by the contracting authority.

I.4.2 Second interim payment

The contractor shall submit an invoice for an interim payment of EUR 237.478 (two hundred thirty-seven thousand and four hundred seventy-eight Euros) equal to 25 % of the total amount referred to in Article I.3.1. 10 months after signature of the contract.

Invoices for interim payment shall be accompanied by a progress report or any other document in accordance with the tender specifications. The contracting authority shall make the payment within 60 days from receipt of the invoice. The contractor shall have 15 days in which to submit additional information or corrections or a new progress report or documents if required by the contracting authority.

I.4.3 Third interim payment

The contractor shall submit an invoice for an interim payment of EUR 237.478 (two hundred thirty-seven thousand and four hundred seventy-eight Euros) equal to 25 % of the total amount referred to in Article I.3.1. 17 months after signature of the contract.

Invoices for interim payment shall be accompanied by a progress report or any other document in accordance with the tender specifications. The contracting authority shall make the payment within 60 days from receipt of the invoice. The contractor shall have 15 days in which to submit additional information or corrections or a new progress report or documents if required by the contracting authority.

I.4.4 Payment of the balance

The contractor shall submit an invoice for payment of the balance.

The invoice shall be accompanied by the final progress report or any other document in accordance with the tender specifications. The contracting authority shall make the payment within 60 days from receipt of the invoice. The contractor shall have 15 days in which to submit additional information or corrections, a new final progress report or other documents if it is required by the contracting authority.

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Where VAT is due in Belgium, the provisions of the contract constitute a request for VAT exemption No 450, Article 42, paragraph 3.3 of the VAT code (circular 2/1978), provided the contractor includes the following statement in the invoice(s): "Exonération de la TVA, Article 42, paragraphe 3.3 du code de la TVA (circulaire 2/1978)" or an equivalent statement in the Dutch or German language.

ARTICLE I.5 – BANK ACCOUNT

Payments shall be made to the contractor's bank account denominated in euro, identified as follows:

Name of bank: ING Belgique

Full address of branch: Agency Marnix, Avenue Marnix 24, 1000 Brussels

Exact designation of account holder: European Patient's Forum

Full account number including bank codes: BE95310167632658

ARTICLE I.6 – COMMUNICATION DETAILS AND DATA CONTROLLER

For the purpose of Article II.6, the data controller shall be the head of unit SANTE.DDG1.D2.

Communications shall be sent to the following addresses:

Contracting authority:

European Commission

Directorate-General Health and Food Safety

Directorate D – Health Systems and Products

Unit D2 – Healthcare Systems

B-1049 Brussels

Email: aurelien.perez@ec.europa.eu

Contractor:

Mrs Valentina Stramiello

European Patients' Forum

Rue du Commerce 31

B-1000 Brussels

Email: valentina.stramiello@eu-patient.eu

ARTICLE I.7– APPLICABLE LAW AND SETTLEMENT OF DISPUTES

I.7.1. The contract shall be governed by Union law, complemented, where necessary, by the law of Belgium.

I.7.2. Any dispute between the parties in relation to the interpretation, application or validity of the contract which cannot be settled amicably shall be brought before the courts of Belgium.

ARTICLE I.8 - EXPLOITATION OF THE RESULTS OF THE CONTRACT

I.8.1 Modes of exploitation

In accordance with Article II.10.2 whereby the Union acquires ownership of the results as defined in the tender specifications (Annex I), these results may be used for any of the following purposes:

(a) use for its own purposes:

(i) making available to the staff of the contracting authority

(ii) making available to the persons and entities working for the contracting authority or cooperating with it, including contractors, subcontractors whether legal or natural persons, Union institutions, agencies and bodies, Member States' institutions

(iii) installing, uploading, processing

(iv) arranging, compiling, combining, retrieving

(v) copying, reproducing in whole or in part and in unlimited number of copies

necessary, the contractor shall in turn seek the agreement of any creator or other right holder. The contractor shall reply to the contracting authority within one month and shall provide its agreement, including any suggestions of modifications, free of charge. The creator may refuse the intended modification only when it may harm his honour, reputation or distort integrity of the work.

I.8.2 Pre-existing rights and transmission of rights

All pre-existing rights shall be licensed to the Union in accordance with Article II.10.3.

The contractor shall provide to the contracting authority a list of pre-existing rights and third parties' rights including its personnel, creators or other right holders as provided for in Article II.10.5.

ARTICLE I.9 – TERMINATION BY EITHER PARTY

Either party may, unilaterally and without being required to pay compensation, terminate the contract by formally notifying the other party by giving [one month's] notice. Should the contracting authority terminate the contract, the contractor shall only be entitled to payment corresponding to part-performance of the contract before the termination date. The first paragraph of Article II.14.3 shall apply.

SIGNATURES

For the contractor,

Walter Atzori
Head of Office Brussels
EPF

signature: Walter Atzori

Done at Brussels, date 22/12/15

For the contracting authority,

Andrzej Rys
Director
Health Systems and Products Directorate

signature: P.O. S. Cini

Done at Brussels, date 22/12/2015

In duplicate in English.

(b) distribution to the public:

(i) publishing in hard copies

(ii) publishing in electronic or digital format

(iii) publishing on the internet as a downloadable/non-downloadable file

(iv) broadcasting by any kind of technique of transmission

(v) public presentation or display

(vi) communication through press information services

(vii) inclusion in widely accessible databases or indexes

(viii) otherwise in any form and by any method

(c) modifications by the contracting authority or by a third party in the name of the contracting authority:

(i) shortening

(ii) summarizing

(iii) modifying of the content

(iv) making technical changes to the content:

- necessary correction of technical errors
- adding new parts or functionalities
- changing functionalities
- providing third parties with additional information concerning the result (e.g. source code) with a view of making modifications

(v) addition of new elements, paragraphs titles, leads, bolds, legend, table of content, summary, graphics, subtitles, sound, etc.

(vi) preparation in audio form, preparation as a presentation, animation, pictograms story, slide-show, public presentation etc.

(vii) extracting a part or dividing into parts

(viii) use of a concept or preparation of a derivate work

(ix) digitisation or converting the format for storage or usage purposes

(x) modifying dimensions

(xi) translating, inserting subtitles, dubbing in different language versions:

- English, French, German
- all official languages of EU
- languages used within EU
- languages of candidate countries
- [*list other languages*]

(d) the modes of exploitation listed in article II.10.4

(e) rights to authorise, license, or sub-license in case of licensed pre-existing rights, the modes of exploitation set out in any of the points (a) to (c) to third parties.

Where the contracting authority becomes aware that the scope of modifications exceeds that envisaged in the contract the contracting authority shall consult the contractor. Where

II – GENERAL CONDITIONS FOR SERVICE CONTRACTS

ARTICLE II.1 – PERFORMANCE OF THE CONTRACT

II.1.1 The contractor shall perform the contract to the highest professional standards.

II.1.2 The contractor shall be solely responsible for taking the necessary steps to obtain any permit or licence required for performance of the contract under the laws and regulations in force at the place where the tasks assigned to it are to be executed.

II.1.3 Without prejudice to Article II.4 any reference made to the contractor's personnel in the contract shall relate exclusively to individuals involved in the performance of the contract.

II.1.4 The contractor must ensure that the personnel performing the contract possesses the professional qualifications and experience required for the execution of the tasks assigned to it.

II.1.5 The contractor shall neither represent the contracting authority nor behave in any way that would give such an impression. The contractor shall inform third parties that it does not belong to the European public service.

II.1.6 The contractor shall be solely responsible for the personnel who executes the tasks assigned to the contractor.

The contractor shall stipulate the following employment or service relationships with its personnel:

(a) personnel executing the tasks assigned to the contractor may not be given orders directly by the contracting authority;

(b) the contracting authority may not under any circumstances be considered to be the employer of the personnel referred to in point (a) and the personnel shall undertake not to invoke against the contracting authority any right arising from the contractual relationship between the contracting authority and the contractor.

II.1.7 In the event of disruption resulting from the action of one of the contractor's personnel working on the contracting authority's premises or in the event that the expertise of a member of the contractor's personnel fails to correspond to the profile required by the contract, the contractor shall replace him without delay. The contracting authority shall have the right to make a reasoned request for the replacement of any such personnel. The replacement personnel must have the necessary qualifications and be capable of performing the contract under the same contractual conditions. The contractor shall be responsible for any delay in the execution of the tasks assigned to it resulting from the replacement of personnel.

II.1.8 Should the execution of the tasks be directly or indirectly hampered, either partially or totally, by any unforeseen event, action or omission, the contractor shall immediately and on its own initiative record it and report it to the contracting authority. The report shall include a description of the problem and an indication of

the date on which it started and of the remedial action taken by the contractor to ensure full compliance with its obligations under this contract. In such an event the contractor shall give priority to solving the problem rather than determining liability.

II.1.9 Should the contractor fail to perform its obligations under the contract, the contracting authority may - without prejudice to its right to terminate the contract - reduce or recover payments in proportion to the scale of the unperformed obligations. In addition, the contracting authority may claim compensation or impose liquidated damages in accordance with Article II.12.

ARTICLE II.2 – MEANS OF COMMUNICATION

II.2.1 Any communication relating to the contract or to its performance shall be made in writing and shall bear the contract number. Any communication is deemed to have been made when it is received by the receiving party unless otherwise provided for in this contract.

II.2.2 Electronic communication shall be deemed to have been received by the parties on the day of dispatch of that communication provided it is sent to the addressees listed in Article I.6. Without prejudice to the preceding, if the sending party receives a message of non-delivery to or of absence of the addressee, it shall make every effort to ensure the actual receipt of such communication by the other party.

Electronic communication shall be confirmed by an original signed paper version of that communication if requested by any of the parties provided that this request is submitted without unjustified delay. The sender shall send the original signed paper version without unjustified delay.

II.2.3 Mail sent using the postal services is deemed to have been received by the contracting authority on the date on which it is registered by the department responsible referred to in Article I.6.

Any formal notification shall be made by registered mail with return receipt or equivalent, or by equivalent electronic means.

ARTICLE II.3 – LIABILITY

II.3.1 The contractor shall be solely responsible for complying with any legal obligations incumbent on it.

II.3.2 The contracting authority shall not be held liable for any damage caused or sustained by the contractor, including any damage caused by the contractor to third parties during or as a consequence of performance of the contract, except in the event of wilful misconduct or gross negligence on the part of the contracting authority.

II.3.3 The contractor shall be held liable for any loss or damage sustained by the contracting authority in performance of the contract, including in the event of subcontracting, and for any claim by a third party, but only to an amount not exceeding three times the total amount of the contract. Nevertheless, if the damage or loss is caused by the gross negligence or wilful misconduct of the contractor or of its personnel or subcontractors, the contractor shall have unlimited liability for the amount of the damage or loss.

II.3.4 The contractor shall indemnify and hold the Union harmless for all damages and costs incurred due to any claim. The contractor shall provide compensation in the event of any action, claim or proceeding brought against the contracting authority by a third party as a result of damage caused by the contractor during the performance of the contract. In the event of any action brought by a third party against the contracting authority in connection with the performance of the contract, including any alleged breach of intellectual property rights, the contractor shall assist the contracting authority. Such expenditure incurred by the contractor may be borne by the contracting authority.

II.3.5 The contractor shall take out an insurance policy against risks and damage relating to the performance of the contract, if required by the relevant applicable legislation. It shall take out supplementary insurance as reasonably required by standard practice in the industry. A copy of all the relevant insurance contracts shall be sent to the contracting authority should it so request.

ARTICLE II.4 - CONFLICT OF INTEREST

II.4.1 The contractor shall take all the necessary measures to prevent any situation of conflict of interest. Such situation arises where the impartial and objective performance of the contract is compromised for reasons involving economic interest, political or national affinity, family or emotional ties, or any other shared interest.

II.4.2 Any situation constituting or likely to lead to a conflict of interest during the performance of the contract shall be notified to the contracting authority in writing without delay. The contractor shall immediately take all the necessary steps to rectify the situation. The contracting authority reserves the right to verify that the steps taken are appropriate and may require that additional steps be taken within a specified deadline.

II.4.3 The contractor declares that it has not granted and will not grant, has not sought and will not seek, has not attempted and will not attempt to obtain and has not accepted and will not accept, any advantage, financial or in kind, to or from any party whatsoever, when such advantage constitutes an illegal practice or involves corruption, either directly or indirectly, in so far as it serves as an incentive or reward relating to the performance of the contract.

II.4.4 The contractor shall pass on all the relevant obligations in writing to its personnel and to any natural person with the power to represent it or take decisions on its behalf and ensure that it is not placed in a situation which could give rise to conflicts of interest. The contractor shall also pass on all the relevant obligations in writing to third parties involved in the performance of the contract including subcontractors.

ARTICLE II.5 – CONFIDENTIALITY

II.5.1 The contracting authority and the contractor shall treat with confidentiality any information and documents, in any form, disclosed in writing or orally in relation to the performance of the contract and identified in writing as confidential.

The contractor shall:

(a) not use confidential information and documents for any purpose other than fulfilling its obligations under the contract without prior written agreement of the contracting authority;

(b) ensure the protection of such confidential information and documents with the same level of protection it uses to protect its own confidential information, but in no case any less than reasonable care;

(c) not disclose directly or indirectly confidential information and documents to third parties without prior written agreement of the contracting authority.

II.5.2 The confidentiality obligation set out in Article II.5.1 shall be binding on the contracting authority and the contractor during the performance of the contract and for five years starting from the date of the payment of the balance unless:

(a) the concerned party agrees to release the other party from the confidentiality obligation earlier;

(b) the confidential information becomes public through other means than in breach of the confidentiality obligation through disclosure by the party bound by that obligation;

(c) the disclosure of the confidential information is required by law.

II.5.3 The contractor shall obtain from any natural person with the power to represent it or take decisions on its behalf, as well as from third parties involved in the performance of the contract, an undertaking that they will comply with the confidentiality obligation set out in Article II.5.1.

ARTICLE II.6 – PROCESSING OF PERSONAL DATA

II.6.1 Any personal data included in the contract shall be processed pursuant to Regulation (EC) 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. Such data shall be processed by the data controller solely for the purposes of the performance, management and monitoring of the contract without prejudice to its possible transmission to the bodies charged with monitoring or inspection tasks in application of Union law.

II.6.2 The contractor shall have the right to access its personal data and the right to rectify any such data. The contractor should address any queries concerning the processing of its personal data to the data controller.

II.6.3 The contractor shall have right of recourse at any time to the European Data Protection Supervisor.

II.6.4 Where the contract requires the processing of personal data by the contractor, the contractor may act only under the supervision of the data controller, in particular with regard to the purposes of the processing, the categories of data which may be processed, the recipients of the data and the means by which the data subject may exercise his rights.

II.6.5 The contractor shall grant its personnel access to the data to the extent strictly necessary for the performance, management and monitoring of the contract.

II.6.6 The contractor undertakes to adopt appropriate technical and organisational security measures having regard to the risks inherent in the processing and to the nature of the personal data concerned in order to:

(a) prevent any unauthorised person from gaining access to computer systems processing personal data, and especially:

(i) unauthorised reading, copying, alteration or removal of storage media;

(ii) unauthorised data input, as well as any unauthorised disclosure, alteration or erasure of stored personal data;

(iii) unauthorised use of data-processing systems by means of data transmission facilities;

(b) ensure that authorised users of a data-processing system can access only the personal data to which their access right refers;

(c) record which personal data have been communicated, when and to whom;

(d) ensure that personal data being processed on behalf of third parties can be processed only in the manner prescribed by the contracting authority;

(e) ensure that, during communication of personal data and transport of storage media, the data cannot be read, copied or erased without authorisation;

(f) design its organisational structure in such a way that it meets data protection requirements.

ARTICLE II.7 – SUBCONTRACTING

II.7.1 The contractor shall not subcontract without prior written authorisation from the contracting authority nor cause the contract to be de facto performed by third parties.

II.7.2 Even where the contracting authority authorises the contractor to subcontract to third parties, it shall nevertheless remain bound by its contractual obligations and shall be solely responsible for the proper performance of this contract.

II.7.3 The contractor shall make sure that the subcontract does not affect rights and guarantees granted to the contracting authority by virtue of this contract, notably by Article II.18.

ARTICLE II.8 – AMENDMENTS

II.8.1 Any amendment to the contract shall be made in writing before fulfilment of any new contractual obligations and in any case before the date of payment of the balance.

II.8.2 The amendment may not have the purpose or the effect of making changes to the contract which might call into question the decision awarding the contract or result in unequal treatment of tenderers.

ARTICLE II.9 – ASSIGNMENT

II.9.1 The contractor shall not assign the rights, including claims for payments, and obligations arising from the contract, in whole or in part, without prior written authorisation from the contracting authority.

II.9.2 In the absence of such authorisation, or in the event of failure to observe the terms thereof, the assignment of rights or obligations by the contractor shall not be enforceable against the contracting authority and shall have no effect on it.

ARTICLE II.10 – OWNERSHIP OF THE RESULTS - INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS

II.10.1 Definitions

In this contract the following definitions apply:

(1) 'results' means any intended outcome of the performance of the contract which is delivered and finally accepted by the contracting authority;

(2) 'creator' means any natural person who contributed to the production of the result and includes personnel of the contracting authority or a third party;

(3) 'pre-existing rights' means any industrial and intellectual property rights, including background technology, which exist prior to the contracting authority or the contractor ordering them for the purpose of the contract execution and include rights of ownership and use by the contractor, the creator, the contracting authority and any third parties.

II.10.2 Ownership of the results

The ownership of the results shall be fully and irrevocably acquired by the Union under this contract including any rights in any of the results listed in this contract. Those rights in the results may include copyright and other intellectual or industrial property rights, as well as all technological solutions and information contained within these technological solutions, produced in performance of the contract. The contracting authority may exploit them as stipulated in this contract. All the rights shall be acquired by the Union from the moment the results are delivered by the contractor and accepted by the contracting authority. Such delivery and acceptance are deemed to constitute an effective assignment of rights from the contractor to the Union.

The payment of the price as set out in the contract is deemed to include any fees payable to the contractor in relation to the acquisition of rights by the Union including all forms of use of the results.

The acquisition of rights by the Union under this contract covers all territories worldwide.

Any intermediary sub-result, raw data, intermediary analysis made available by the contractor cannot be used by the contracting authority without the written consent of the contractor, unless the contract explicitly provides for it to be treated as a self-contained result.

II.10.3 Licensing of pre-existing rights

The Union shall not acquire ownership of the pre-existing rights.

The contractor shall license the pre-existing rights on a royalty-free, non-exclusive and irrevocable basis to the Union which may use the pre-existing right as foreseen in Article I.8.1. All the pre-existing rights shall be licensed to the Union from the moment the results were delivered and accepted by the contracting authority.

The licensing of pre-existing rights to the Union under this contract covers all territories worldwide and is valid for the whole duration of intellectual property rights protection.

II.10.4 Modes of exploitation

The Union shall acquire ownership of each of the results produced as an outcome of this contract which may be used for any of the following purposes:

(a) giving access upon individual requests without the right to reproduce or exploit, as provided for by Regulation 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents;

(b) storage of the original and copies made in accordance with this contract;

(c) archiving in line with the document management rules applicable to the contracting authority.

II.10.5 Identification and evidence of granting of pre-existing rights and rights of third parties

When delivering the results, the contractor shall warrant that they are free of rights or claims from creators and third parties including in relation to pre-existing rights, for any use envisaged by the contracting authority. This does not concern the moral rights of natural persons.

The contractor shall establish to that effect a list of all pre-existing rights and rights of creators and third parties on the results of this contract or parts thereof. This list shall be provided no later than the date of delivery of the final results.

In the result the contractor shall clearly point out all quotations of existing textual works. The complete reference should include as appropriate: name of the author, title of the work, date and place of publication, date of creation, address of publication on internet, number, volume and other information which allows the origin to be easily identified.

Upon request by the contracting authority, the contractor shall provide evidence of ownership of or rights to use all the listed pre-existing rights and rights of third parties except for the rights owned by the Union.

This evidence may refer, inter alia, to rights to: parts of other documents, images, graphs, tables, data, software, technical inventions, know-how etc. (delivered in paper, electronic or other form), IT development tools, routines, subroutines and/or other programs ("background technology"), concepts, designs, installations or pieces of art, data, source or background materials or any other parts of external origin.

The evidence shall include, as appropriate:

(a) the name and version number of a software product;

(b) the full identification of the work and its author, developer, creator, translator, data entry person, graphic designer, publisher, editor, photographer, producer;

(c) a copy of the licence to use the product or of the agreement granting the relevant rights to the contractor or a reference to this licence;

(d) a copy of the agreement or extract from the employment contract granting the relevant rights to the contractor where parts of the results were created by its personnel;

(e) the text of the disclaimer notice if any.

Provision of evidence does not release the contractor from its responsibilities in case it is found that it does not hold the necessary rights, regardless of when and by whom this fact was revealed.

The contractor also warrants that it possesses the relevant rights or powers to execute the transfer and that it has paid or has verified payment of all due fees including fees due to collecting societies, related to the final results.

II.10.6 Creators

By delivering the results the contractor warrants that the creators undertake not to oppose that their names be recalled when the results are presented to the public and confirms that the results can be divulged. Names of authors shall be recalled on request in the manner communicated by the contractor to the contracting authority.

The contractor shall obtain the consent of creators regarding the granting of the relevant rights and be ready to provide documentary evidence upon request.

II.10.7 Persons appearing in photographs or films

If natural, recognisable persons appear in a result or their voice is recorded the contractor shall submit a statement of these persons (or of the persons exercising parental authority in case of minors) where they give their permission for the described use of their image or voice on request by the contracting authority. This does not apply to persons whose permission is not required in line with the law of the country where photographs were taken, films shot or audio records made.

II.10.8 Contractor's copyright for pre-existing rights

When the contractor retains pre-existing rights on parts of the results, reference shall be inserted to that effect when the result is used as set out in Article I.8.1 with the following disclaimer: © - year – European Union. All rights reserved. Certain parts are licensed under conditions to the EU.

II.10.9 Visibility of Union funding and disclaimer

When making use of the results, the contractor shall declare that they have been produced within a contract with the Union and that the opinions expressed are those of the contractor only and do not represent the contracting authority's official position. The contracting authority may waive this obligation in writing.

ARTICLE II.11 – FORCE MAJEURE

II.11.1 'Force majeure' means any unforeseeable and exceptional situation or event beyond the parties' control which prevents either of them from fulfilling any of their obligations under the contract, which was not attributable to error or negligence on their part or on the part of subcontractors and which proves to be inevitable in spite of exercising due diligence. 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, as well as labour disputes, strikes or financial difficulties, cannot be invoked as force majeure.

II.11.2 A party faced with force majeure shall formally notify the other party without delay, stating the nature, likely duration and foreseeable effects.

II.11.3 The party faced with force majeure shall not be held in breach of its contractual obligations if it has been prevented from fulfilling them by force majeure. Where the contractor is unable to fulfil its contractual obligations owing to force majeure, it shall have the right to remuneration only for the tasks actually executed.

II.11.4 The parties shall take all the necessary measures to limit any damage due to force majeure.

ARTICLE II.12 – LIQUIDATED DAMAGES

The contracting authority may impose liquidated damages should the contractor fail to complete its contractual obligations, also with regard to the required quality level, according to the tender specifications.

Should the contractor fail to perform its contractual obligations within the time-limits set by the contract, then, without prejudice to the contractor's actual or potential liability or to the contracting authority's right to terminate the contract, the contracting authority may impose liquidated damages for each and every calendar day of delay according to the following formula:

0.3 x (*V/d*)

V is the amount specified in Article I.3.1;

d is the duration specified in Article I.2.3 expressed in calendar days.

The contractor may submit arguments against this decision within 30 days of receipt of the formal notification. In the absence of a reaction on its part or of written withdrawal by the contracting authority within 30 days of the receipt of such arguments, the decision imposing the liquidated damages shall become enforceable.

The parties expressly acknowledge and agree that any sums payable under this article are in the nature of liquidated damages and not penalties, and represent a reasonable estimate of fair compensation for the losses incurred due to failure to fulfil obligations which may be reasonably anticipated.

ARTICLE II.13 – SUSPENSION OF THE PERFORMANCE OF THE CONTRACT

II.13.1 Suspension by the contractor

The contractor may suspend the performance of the contract or any part thereof if a case of force majeure makes such performance impossible or excessively difficult. The contractor shall inform the contracting authority about the suspension without delay, giving all the necessary reasons and details and the envisaged date for resuming the performance of the contract.

Once the circumstances allow resuming performance, the contractor shall inform the contracting authority immediately, unless the contracting authority has already terminated the contract.

II.13.2 Suspension by the contracting authority

The contracting authority may suspend the performance of the contract or any part thereof:

(a) if the contract award procedure or the performance of the contract prove to have been subject to substantial errors, irregularities or fraud;

(b) in order to verify whether presumed substantial errors, irregularities or fraud have actually occurred.

Suspension shall take effect on the day the contractor receives formal notification, or at a later date provided in the notification. The contracting authority shall give notice as soon as possible to the contractor to resume the service suspended or inform the contractor that it is proceeding with the termination of the contract. The contractor shall not be entitled to claim compensation on account of suspension of the contract or of part thereof.

ARTICLE II.14 – TERMINATION OF THE CONTRACT

II.14.1 Grounds for termination

The contracting authority may terminate the contract in the following circumstances:

(a) if a change to the contractor's legal, financial, technical or organisational or ownership situation is likely to affect the performance of the contract substantially or calls into question the decision to award the contract;

(b) if execution of the tasks has not actually commenced within three months of the date foreseen, and the new date proposed, if any, is considered unacceptable by the contracting authority, taking into account Article II.8.2;

(c) if the contractor does not perform the contract as established in the tender specifications or fails to fulfil another substantial contractual obligation;

(d) in the event of force majeure notified in accordance with Article II.11 or if the performance of the contract has been suspended by the contractor as a result of force majeure, notified in accordance with Article II.13, where either resuming performance is impossible or the modifications to the contract might call into question the decision awarding the contract or result in unequal treatment of tenderers;

(e) if the contractor is declared bankrupt, is being wound up, is having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, is the subject of proceedings concerning those matters, or is in any analogous situation arising from a similar procedure provided for in national legislation or regulations;

(f) if the contractor or any natural person with the power to represent it or take decisions on its behalf has been found guilty of professional misconduct proven by any means;

(g) if the contractor is not in compliance with its obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which it is established or with those of the country of the applicable law of this contract or those of the country where the contract is to be performed;

(h) if the contracting authority has evidence that the contractor or natural persons with the power to represent it or take decisions on its behalf have committed fraud, corruption, or are involved in a criminal organisation, money laundering or any other illegal activity detrimental to the Union's financial interests;

(i) if the contracting authority has evidence that the contractor or natural persons with the power to represent it or take decisions on its behalf have committed substantial errors, irregularities or fraud in the award procedure or the performance of the contract, including in the event of submission of false information;

(j) if the contractor is unable, through its own fault, to obtain any permit or licence required for performance of the contract.

II.14.2 Procedure for termination

When the contracting authority intends to terminate the contract it shall formally notify the contractor of its intention specifying the grounds thereof. The contracting authority shall invite the contractor to make any observations and, in the case of point (c) of Article II.14.1, to inform the contracting authority about the measures taken to continue the fulfilment of its contractual obligations, within 30 days from receipt of the notification.

If the contracting authority does not confirm acceptance of these observations by giving written approval within 30 days of receipt, the termination procedure shall proceed. In any case of termination the contracting authority shall formally notify the contractor about its decision to terminate the contract. In the cases referred to in points (a), (b), (c), (e), (g) and (j) of Article II.14.1 the formal notification shall specify the date on which the termination takes effect. In the cases referred to in points (d), (f), (h), and (i) of Article II.14.1 the termination shall take effect on the day following the date on which notification of termination is received by the contractor.

II.14.3 Effects of termination

In the event of termination, the contractor shall waive any claim for consequential damages, including any loss of anticipated profits for uncompleted work. On receipt of the notification of termination, the contractor shall take all the appropriate measures to minimise costs, prevent damages, and cancel or reduce its commitments. The contractor shall have 60 days from the date on which termination takes effect to draw up the documents required by the special conditions for the tasks already executed on the date of termination and produce an invoice if necessary. The contracting authority may recover any amounts paid under the contract.

The contracting authority may claim compensation for any damage suffered in the event of termination.

On termination the contracting authority may engage any other contractor to execute or complete the services. The contracting authority shall be entitled to claim from the contractor all extra costs incurred in this regard, without prejudice to any other rights or guarantees it may have under the contract.

ARTICLE II.15 – REPORTING AND PAYMENTS

II.15.1 Date of payment

Payments shall be deemed to be effected on the date when they are debited to the contracting authority's account.

II.15.2 Currency

The contract shall be in euros.

Payments shall be executed in euros or in the local currency as provided for in Article I.5.

Conversion between the euro and another currency shall be made according to the daily euro exchange rate published in the *Official Journal of the European Union* or, failing that, at the monthly accounting exchange rate established by the European Commission and published on its website, applicable on the day on which the payment order is issued by the contracting authority.

II.15.3 Costs of transfer

The costs of the transfer shall be borne in the following way:

(a) costs of dispatch charged by the bank of the contracting authority shall be borne by the contracting authority,

(b) cost of receipt charged by the bank of the contractor shall be borne by the contractor,

(c) costs for repeated transfer caused by one of the parties shall be borne by the party causing repetition of the transfer.

II.15.4 Invoices and Value Added Tax

Invoices shall contain the contractor's identification, the amount, the currency and the date, as well as the contract reference.

Invoices shall indicate the place of taxation of the contractor for value added tax (VAT) purposes and shall specify separately the amounts not including VAT and the amounts including VAT.

The contracting authority is, as a rule, exempt from all taxes and duties, including VAT, pursuant to the provisions of Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union.

The contractor shall accordingly complete the necessary formalities with the relevant authorities to ensure that the supplies and services required for performance of the contract are exempt from taxes and duties, including VAT exemption.

II.15.5 Pre-financing and performance guarantees

Pre-financing guarantees shall remain in force until the pre-financing is cleared against interim payments or payment of the balance and, in case the latter takes the form of a debit note, three months after the debit note is notified to the contractor. The contracting authority shall release the guarantee within the following month.

Performance guarantees shall cover performance of the service in accordance with the terms set out in the tender specifications until its final acceptance by the contracting authority. The amount of a performance guarantee shall not exceed the total price of the contract. The guarantee shall provide that it remains in force until final acceptance. The contracting authority shall release the guarantee within a month following the date of final acceptance.

Where, in accordance with Article I.4, a financial guarantee is required for the payment of pre-financing, or as performance guarantee, it shall fulfill the following conditions:

(a) the financial guarantee is provided by a bank or an approved financial institution or, at the request of the contractor and agreement by the contracting authority, by a third party;

(b) the guarantor stands as first-call guarantor and does not require the contracting authority to have recourse against the principal debtor (the contractor).

The cost of providing such guarantee shall be borne by the contractor.

II.15.6 Interim payments and payment of the balance

The contractor shall submit an invoice for interim payment upon delivery of intermediary results, accompanied by a progress report or any other documents, as provided for in Article I.4 or in the tender specifications.

The contractor shall submit an invoice for payment of the balance within 60 days following the end of the period referred to in Article I.2.3, accompanied by a final progress report or any other documents provided for in Article I.4 or in the tender specifications.

Upon receipt, the contracting authority shall pay the amount due as interim or final payment within the periods specified in Article I.4, provided the invoice and documents have been approved and without prejudice to Article II.15.7. Approval of the invoice and documents shall not imply recognition of the regularity or of the authenticity, completeness and correctness of the declarations and information they contain.

Payment of the balance may take the form of recovery.

II.15.7 Suspension of the time allowed for payment

The contracting authority may suspend the payment periods specified in Article I.4 at any time by notifying the contractor that its invoice cannot be processed, either because it does not comply with the provisions of the contract, or because the appropriate documents have not been produced.

The contracting authority shall inform the contractor in writing as soon as possible of any such suspension, giving the reasons for it.

Suspension shall take effect on the date the notification is sent by the contracting authority. The remaining payment period shall start to run again from the date on which the requested information or revised documents are received or the necessary further verification, including on-the-spot checks, is carried out. Where the suspension period exceeds two months, the contractor may request the contracting authority to justify the continued suspension.

Where the payment periods have been suspended following rejection of a document referred to in the first paragraph and the new document produced is also rejected, the contracting authority reserves the right to terminate the contract in accordance with Article II.14.1(c).

II.15.8. Interest on late payment

On expiry of the payment periods specified in Article I.4, and without prejudice to Article II.15.7, the contractor is entitled to interest on late payment at the rate applied by the European Central Bank for its main refinancing operations in Euros (the reference rate), plus eight points. The reference rate shall be the rate in force on the first day of the

month in which the payment period ends, as published in the C series of the *Official Journal of the European Union.*

The suspension of the payment periods in accordance with Article II.15.7 may not be considered as a late payment.

Interest on late payment shall cover the period running from the day following the due date for payment up to and including the date of actual payment as defined in Article II.15.1.

However, when the calculated interest is lower than or equal to EUR 200, it shall be paid to the contractor only upon request submitted within two months of receiving late payment.

ARTICLE II.16 - REIMBURSEMENTS

II.16.1 Where provided by the special conditions or by the tender specifications, the contracting authority shall reimburse the expenses which are directly connected with execution of the tasks on production of original supporting documents, including receipts and used tickets, or failing that, on production of copies or scanned originals, or on the basis of flat rates.

II.16.2 Travel and subsistence expenses shall be reimbursed, where appropriate, on the basis of the shortest itinerary and the minimum number of nights necessary for overnight stay at the destination.

II.16.3 Travel expenses shall be reimbursed as follows:

(a) travel by air shall be reimbursed up to the maximum cost of an economy class ticket at the time of the reservation;

(b) travel by boat or rail shall be reimbursed up to the maximum cost of a first class ticket;

(c) travel by car shall be reimbursed at the rate of one first class rail ticket for the same journey and on the same day;

In addition, travel outside Union territory shall be reimbursed provided the contracting authority has given its prior written consent.

II.16.4 Subsistence expenses shall be reimbursed on the basis of a daily subsistence allowance as follows:

(a) for journeys of less than 200 km for a return trip, no subsistence allowance shall be payable;

(b) daily subsistence allowance shall be payable only on receipt of supporting documents proving that the person concerned was present at the destination;

(c) daily subsistence allowance shall take the form of a flat-rate payment to cover all subsistence expenses, including meals, local transport which includes transport to and from the airport or station, insurance and sundries;

(d) daily subsistence allowance shall be reimbursed at the flat rates specified in Article I.3;

e) accommodation shall be reimbursed on receipt of supporting documents proving the necessary overnight stay at the destination, up to the flat-rate ceilings specified in Article I.3.

II.16.5 The cost of shipment of equipment or unaccompanied luggage shall be reimbursed provided the contracting authority has given prior written authorisation.

II.16.6 Conversion between the euro and another currency shall be made as specified in Article II.15.2.

ARTICLE II.17 – RECOVERY

II.17.1 If an amount is to be recovered under the terms of the contract, the contractor shall repay the contracting authority the amount in question according to the terms and by the date specified in the debit note.

II.17.2 If the obligation to pay the amount due is not honoured by the date set by the contracting authority in the debit note, the amount due shall bear interest at the rate indicated in Article II.15.8. Interest on late payments shall cover the period from the day following the due date for payment, up to and including the date when the contracting authority receives the full payment of the amount owed.

Any partial payment shall first be entered against charges and interest on late payment and then against the principal amount.

II.17.3 If payment has not been made by the due date, the contracting authority may, after informing the contractor in writing, recover the amounts due by offsetting them against any amounts owed to the contractor by the Union or by the European Atomic Energy Community or by calling in the financial guarantee, where provided for in Article I.4.

ARTICLE II.18 – CHECKS AND AUDITS

II.18.1 The contracting authority and the European Anti-Fraud Office may check or have an audit on the performance of the contract. It may be carried out either directly by their own staff or by any other outside body authorised to do so on their behalf.

Such checks and audits may be initiated during the performance of the contract and during a period of five years which starts running from the date of the payment of the balance.

The audit procedure shall be deemed to be initiated on the date of receipt of the relevant letter sent by the contracting authority. Audits shall be carried out on a confidential basis.

II.18.2 The contractor shall keep all original documents stored on any appropriate medium, including digitised originals when they are authorised by national law and under the conditions laid down therein, for a period of five years which starts running from the date of payment of the balance.

II.18.3 The contractor shall allow the contracting authority's staff and outside personnel authorised by the contracting authority the appropriate right of access to sites and premises where the contract is performed and to all the information, including information in electronic format, needed in order to conduct such checks and audits. The contractor shall ensure that the information is readily available at the

moment of the check or audit and, if so requested, that information be handed over in an appropriate form.

II.18.4 On the basis of the findings made during the audit, a provisional report shall be drawn up. It shall be sent to the contractor, which shall have 30 days following the date of receipt to submit observations. The final report shall be sent to the contractor within 60 days following the expiry of that deadline.

On the basis of the final audit findings, the contracting authority may recover all or part of the payments made and may take any other measure which it considers necessary.

II.18.5 By virtue of Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspection carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities and Regulation (EC) No 1073/1999 of the European Parliament and the Council of 25 May 1999 concerning investigation conducted by the European Anti-Fraud Office (OLAF), the OLAF may also carry out on-the-spot checks and inspections in accordance with the procedures laid down by Union law for the protection of the financial interests of the Union against fraud and other irregularities. Where appropriate, the findings may lead to recovery by the contracting authority.

II.18.6 The Court of Auditors shall have the same rights as the contracting authority, notably right of access, for the purpose of checks and audits.

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Healthcare systems

SPECIFICATIONS ATTACHED TO THE INVITATION TO TENDER

Call for tender n° *SANTE/2015/D2/021*

Pilot project on the promotion of self-care in chronic diseases in the European Union.

1. Title of the contract

Pilot project on the promotion of self-care systems in the European Union in the field of chronic diseases

2. Introduction

The burden on healthcare systems is growing significantly as populations increase and life expectancies rise. An ever increasing number of people are living longer and at the same time living with one or more chronic conditions. As healthcare systems continue to struggle with the growing burden being placed upon them, the funding of these systems is also increasingly difficult to sustain.

For health systems to not just survive but to thrive, it is clear that changes are necessary and that demand for services must be appropriately managed. One area that can support the effective and cost-effective use of healthcare systems and resources is the promotion of safe self-care and patient empowerment.

For the purpose of this request, self-care is defined as *"what individuals, families and communities do with the intention to promote, maintain, or restore health and to cope with illness and disability with or without the support of health professionals such as pharmacists, doctors, dentists and nurses. It includes but is not limited to self-prevention, self-diagnosis, self-medication and self-management of illness and disability"*. This was the definition specified in the cost/benefit analysis of the first pilot project[1].

3. Background

Commission Decision C(2013)4940 of 2 August 2013 specified the initial framework for the promotion of self-care systems in the European Union within the scope of self-limiting diseases (minor diseases). On the basis of this decision, a contract was signed which included the setting up of a platform of experts in self-care with regards to **minor and self-limiting conditions**; this project is expected to be completed, once the platform of experts has concluded its work, in February 2016.

By Commission Decision C(2014)4127 of 25 June 2014 the Commission seeks to expand these activities by extending its scope from minor self-limiting diseases to **chronic diseases** (including chronic conditions and chronic disorders).

4. Subject of the contract

The subject of this contract is the promotion of self-care for chronic diseases in Europe. To reach this goal, the contractor will have to conduct a study (consisting on a literature review and cost-benefit analysis) and to set up a platform of experts in self-care in the field of chronic diseases to explore and propose possible methods of promotion of self-care for chronic diseases, while taking into account and complementing the following:

[1] http://ec.europa.eu/dgs/health_food-safety/funding/docs/call_sanco-2013-d2-027_tender-specifications_en.pdf

- the previous works carried out within the Action group of Integrated care (B3) of the European Innovation Partnership on Active and Healthy Ageing (EIP-AHA) [2];
- the results of the activities carried out under the contract (call SANCO/2013/D2/027) referred to under point 3; and
- the results of the EMPATHiE study on "Empowering patients in the management of chronic diseases"[3].

The expert platform shall be run by the Contractor and be composed of cross-functional stakeholders. The expert platform shall at least be composed of recognised experts in chronic diseases, healthcare and self-care, gathering cross-functional stakeholders, such as policy makers, patients groups, health professionals, healthcare providers, educators, healthcare insurers, academics, communication experts and other relevant stakeholders.

The expert platform shall have a balanced geographical coverage and consist of minimum 20 people.

DG SANTE shall be consulted and agree on the composition of the platform of experts.

4.1. Tasks

4.1.1. Study

The study shall cover self-care systems already in place in EU Member States in the following areas:

- Chronic metabolic diseases;
- Chronic gastro-intestinal diseases;
- Chronic dermatologic diseases;
- Chronic respiratory diseases;
- Chronic cardiovascular diseases;
- Chronic circulatory diseases.

4.1.1.1. Literature review

The study referred to in 4.1.1 shall start with an **extensive literature review of existing studies and data.** The literature review methodology with at least a search strategy including keywords, databases, and inclusion/exclusion criteria shall be presented in the offer.

[2] http://ec.europa.eu/health/ageing/innovation/index_en.htm

[3] http://ec.europa.eu/health/patient_safety/docs/empathie_frep_en.pdf

The tasks of the contractor are:

- to **review** the scientific evidence on **the added value** of self-care in the above mentioned areas taking into account the different dimensions of self-care as defined under section 2 above, e.g. self-prevention, self-diagnosis and self-management of diseases
- to **identify best practices** related to self-care in the above-mentioned areas. The offer shall contain explicit criteria to assess what is a best practice in the field of self-care;
- to **identify and review key elements allowing to scale up best practices** from one country to another, and from one disease to another; e.g establish a **taxonomy** of existing good practices by taking into account the evidence of its results and break down by type of intervention and characteristics of the disease

4.1.1.2. Cost-benefit analysis

The study referred to in 4.1.1 shall include a cost/benefit analysis covering the areas defined under point 4.1.1.

This cost-benefit analysis shall be conducted from both a patient and health system perspective. For patients cost shall include non-financial costs and benefits also, as for instance time spent or saved, fears or assurances, health-benefits or losses. Equally, from a health systems perspective, benefits shall include for example lesser burdens on society in general due to a healthier population.

4.1.2. Platform of experts

In light of the results of the above-mentioned study, the contractor shall:

- Select at least 6 diseases, preferably one in each of the above-mentioned areas, where self-care brings added value in terms of cost-benefits;
- On the basis of this selection, set up a platform of experts to
    - Identify any barrier that may hinder the development of self-care;
    - Develop guidelines for national and local policy makers on how to promote self-care;
    - Propose scenarios for EU collaboration;
    - Propose innovative approaches for the development of self-care;
    - Propose and design communication tools to patient/consumers to improve prevention and disease management;
- Set up a work-plan for the platform of experts;
- Bear all costs with setting up and running the platform of experts (for instance travel expenses, secretarial services, communication, coordination).

- The platform will be abolished after delivery by the contractor and acceptance by the contracting authority of all deliverables under this contract,

4.1.3. Dissemination of results

The contractor shall:

- put in place a strategy to ensure dissemination of results at European, national and local level;
- organize a closing/concluding conference in Brussels to present the outcome of the work. This conference should bring together at least 100 participants representing relevant stakeholders and Member States. Results from other former projects, such as the EIP-AHA, the first Pilot project on self-care (call SANCO/2013/D2/027), and the EMPATHiE study (see point 4 above) shall be taken into account to the relevant extent.

5. Reports and documents to be submitted

The work carried out by the Contractor will be the subject of the following reports, which must be sent to the Commission.

* **Interim reports or documents**:

The reports or documents will describe the work carried out, detailing the methodology applied, and the results obtained during each phase, the duration of which is specified below, and state in particular:

- the effects, if any, of the results obtained on the overall work covered by the contract;
- the work programme planned for the following phase.

Interim reports or documents must be sent to the Commission no later than the deadline stated in the overall timeframe table.

* **Final report**:

The final report will describe the work carried out and the results obtained under the contract.

The draft must be submitted to the Commission no later than 24 months after signature of the contract. The Commission will then either inform the Contractor that it approves the draft or will send him its comments.

The Contractor shall have 20 days to submit additional information or corrections, a new final report or other documents if it is required by the contracting authority.

The report shall have following standard disclaimer:

"The information and views set out in this report are those of the author(s) and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein."

5.1. Deliverables and timeframe:

D0 - Inception Report: An inception report must be sent to the contact person in unit SANTE.D.2 within 10 working days after the kick-off meeting. The kick-off meeting shall take place within one month after the signature of the contract. The inception report shall include what was agreed during the kick-off meeting, including the work plan and timing.

D1 - Interim report 1 – Study composed of a literature review and a cost/benefit analysis

This interim report shall contain the results of the literature review and the cost/benefit analysis of the self-care systems already in place in the EU in the following areas:

- Chronic metabolic diseases;
- Chronic gastro-intestinal diseases;
- Chronic dermatologic diseases;
- Chronic respiratory diseases;
- Chronic cardiovascular diseases;
- Chronic circulatory diseases;

D2 - Interim report 2 – Selected diseases

This interim report shall contain the following:

- The **duly justified selection of at least 6 diseases**, preferably one in each of the above-mentioned areas, where self-care brings added value in terms of cost-benefits;

D3 – Interim report 3 - Platform of experts

This interim report shall contain the following:

- The **composition of the platform of experts and its work plan.** For each member, the report should include their CVs as well as a summary of their main achievements/publications in the field of self-care or related fields and a short explanation on the added value that their experience and/or knowledge can bring to the work of the platform. The report shall also include a detailed work plan.

DG SANTE D.2 shall agree to the selected conditions, the composition of the proposed platform and the proposed work plan.

D4 - Interim report 4 – Barriers, guideline, scenarios and communication tools

For each of the selected conditions, the interim report shall contain:

- the identification of any barrier that may hinder the development of self-care;
- guidelines for national and local policy makers on how to promote self-care;
- possible scenarios for EU collaboration;
- communication tools to patient/consumers to improve prevention and disease management.

D4 – Interim report 5 – Strategy for dissemination of results

This interim report shall contain:

- a strategy to ensure dissemination of results at European, national and local level;
- the details concerning the organisation of the closing/concluding conference, including a Gantt chart for the administrative preparations such as invitation, registration, management of travel and accommodation of participants, booking of room and interpretation for the conference, preparation of documents and reports, catering, hostesses, visual identity, list of speakers, working plan (work groups, parallel sessions, plenary sessions), interaction with stakeholders and members of the platform, communication plan for the conference.

D5 – Dissemination of results

- **Implementation of the strategy** to ensure dissemination of results at European, national and local levels;
- Results of the **closing/concluding conference** in Brussels.

D6 – Final report

The pilot project shall be finished with a final report.

The report shall encompass the full study. Findings from the first pilot project on minor conditions shall also be taken into account. The report shall also include:

- an **executive summary in English, French and German** of the main results obtained;
- an **abstract** of no more than 200 words;
- a summary of the outcome of the closing/concluding conference;
- the 4 interim reports.

The overall indicative timeframe is the following:

Month	Deliverable	Description	Payments
M1	**D0**	**Kick off meeting** with DG SANTE D2 in Brussels, Belgium **Inception report**	
M6	**D1**	Interim report 1 – Study composed of a literature review and a cost/benefit analysis	First payment
M7	**D2**	Interim report 2 – Selected conditions	
M10	**D3**	Interim report 3 - Platform of experts	Second payment
M17	**D4**	Interim report 4 – Barriers, guideline, scenarios and communication tools	
M17	**D5**	Interim report 5 – Strategy for dissemination of results	Third payment
M22	**D6**	Dissemination of results	
M24	**D7**	Final report	Final payment

A detailed timetable respecting the above timeframe should be provided in the offer.

Where necessary, further discussion between the Contractor and DG SANTE D.2 will be organised via telephone or video conferences.

6. Participation in the tendering procedure

6.1. Access to the market

Participation in this tendering procedure is open on equal terms to all natural and legal persons coming within the scope of the Treaties and to all natural and legal persons in a third country which has a special agreement with the Union in the field of public procurement on the conditions laid down in that agreement. Where the Multilateral Agreement on Government Procurement[4] concluded within the WTO applies, the participation to the call for tender is also open to nationals of the countries that have ratified this Agreement, on the conditions it lays down.

6.2. Joint tenders

Requests to participate/tenders can be submitted by consortia of two or more economic operators ("joint tender"). Joint tenders may include subcontractors in addition to the joint tenderers.

Consortia must not have a given legal form in order to be allowed to submit a tender or request to take part, but the consortium selected may be required to adopt a given legal

[4] See http://www.wto.org/english/tratop_E/gproc_e/gp_gpa_e.htm

form after it has been awarded the contract if this change is necessary for proper performance of the contract.

In case of joint tender, all economic operators in a joint tender assume joint and several liability towards the Contracting Authority for the performance of the contract as a whole.

The consortium shall nominate one legal entity as single point of contact for the Contracting Authority who will have full authority to bind the consortium and each of its members, and will be responsible for the administrative management of the contract (invoicing, receiving payments, etc.) on behalf of all other entities.

Tenders from consortia of economic operators must specify the identity, role and division of tasks, qualifications and experience of each member.

After the award, the Contracting Authority will sign the contract either with all members of the group, or with the member duly authorised by the other members via a power of attorney, which shall be attached to the contract.

Any change in the composition of the consortium during the procurement procedure may lead to the rejection of the corresponding tender. Any change in the composition of the consortium after the signature of the contract may lead to the termination of the contract.

6.3. Subcontracting

Subcontracting is allowed in the tender but the contractor shall retain full liability towards the Contracting Authority for performance of the contract as a whole.

Tenderers must give an indication of the proportion of the contract that they intend to subcontract (e.g. expressed as a percentage of the total value of the contract).

Tenderers are required to identify subcontractors whose share of the contract is above 5% of the total value of the contract. Tenders must specify the role, activities and responsibilities of these subcontractors.

Any change in subcontracting during the procurement procedure may lead to the rejection of the corresponding tender.

During contract execution, the change of any subcontractor identified in the tender will be subject to prior written approval of the Contracting Authority. Any change in subcontracting after the signature of the contract may lead to the termination of the contract.

6.4. Supporting documents for the identification of the legal status and capacity of the tenderer, the members of the group in case of joint tender and of specified subcontractors

The tender must include a cover letter (tender submission form, see Annex I to these tender specifications) presenting the name of the tenderer (including all entities in case of joint offer) and identified subcontractors if applicable, the name of the single contact person in relation to this tender and the name and position of the person authorised to sign the contract.

In case of joint tender, the cover letter must be signed by a duly authorised representative for each tenderer, or by a single tenderer duly authorised by the other tenderers (with power of attorney attached).

Subcontractors must provide a letter of intent stating their willingness to provide the service foreseen in the offer and in line with the present tender specification.

In order to prove their legal capacity and their status, all tenderers (in case of joint tender each member of the group) must provide a signed Legal Entity Form with its supporting evidence (indicating in which country they have their headquarters or domicile as well as their VAT number and registration number). The form is available on: http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm (Annex III to these tender specifications).

The tenderer (or the single point of contact in case of joint tender) must provide a Financial Identification Form and supporting documents indicating their account number and bank address. Only one form per offer should be submitted (no form is needed for subcontractors and other joint tenderers). The form is available on: http://ec.europa.eu/budget/contracts_grants/info_contracts/index_en.cfm (Annex II to these tender specifications).

Tenderers must provide the following information if it has not been included with the Legal Entity Form (see Annex III):

- For legal persons, a legible copy of the notice of appointment of the persons authorised to represent the tenderer in dealings with third parties and in legal proceedings, or a copy of the publication of such appointment if the legislation which applies to the legal entity concerned requires such publication. Any delegation of this authorisation to another representative not indicated in the official appointment must be evidenced.

- For natural persons, where applicable, a proof of registration on a professional or trade register or any other official document showing the registration number.

7. Variants

The technical offer must cover all aspects and tasks required in the technical specification and provide all the information needed to apply the award criteria. Offers deviating from the requirements or not covering all requirements may be excluded on the basis of non-conformity with the tender specifications and will not be evaluated.

8. Volume of contract

Price band from EUR 800.000 up to a maximum of EUR 1.000.000.

The duration of the contract is **24 months**; the tasks covered by the contract shall be completed within **24 months** after the signature of the contract by the last contracting party.

9. Price

- Prices must be quoted in Euro using, if necessary, the conversion rates published in the C series of the Official Journal of the European Union on the day when the contract notice was published (if no notice was published, on the day when the invitation to tender was sent out).
- Prices must be fixed amounts in Euro.
- Estimated travel and subsistence expenses must be indicated separately.

  This estimate should be based on Article I.3.2 of the contract annexed to these specifications and include any travel required to meet representatives of DG SANTE. In

any event, it should represent the maximum amount of travel and subsistence expenses payable for all the services provided.

- Prices should be quoted free of all duties, taxes and other charges, including VAT, as the Union is exempt from such charges under Articles 3 and 4 of the Protocol on the privileges and immunities of the European Union; the amount of VAT should be shown separately.
- Prices are firm and not subject to revision.

10. Terms of payment

See attached draft contract

11. Contractual terms and guarantees

In drawing up his bid, the tenderer should bear in mind the provisions of the standard contract attached to this invitation to tender (Annex VII).

Submission of a tender implies acceptance of all the terms specified in the present specifications and in particular in the attached standard contract including the general conditions applicable to contracts (Annex VII).

All documents presented by the tenderer become the property of the European Commission and are deemed confidential.

The Commission will not reimburse expenses incurred in preparing and submitting offers.

12. Requirement as to the tender

The tender must include:

(a) an administrative part including all the information and documents required by the contracting authority for the appraisal of tenders on the basis of the exclusion and selection criteria set out under paragraphs 14 and 15 respectively of these specifications;

(b) a technical part including all the information and documents required by the contracting authority for the appraisal of tenders on the basis of the award criteria set out under paragraph 16 of these specifications;

(c) a financial part setting out prices in accordance with paragraph 17 of these specifications.

13. Exclusion criteria

13.1. Candidates or tenderers shall be excluded from participation in a procurement procedure if:

(a) they are bankrupt or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;

(b) they have been convicted of an offence concerning their professional conduct by a judgment which has the force of res judicata;

(c) they have been guilty of grave professional misconduct proven by any means which the contracting authority can justify including by decisions of the European Investment Bank and international organisations;

(d) they have not fulfilled obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the contracting authority or those of the country where the contract is to be performed;

(e) they have been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Union's financial interests;

(f) they are currently subject to an administrative penalty for being guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in a procurement procedure or failing to supply this information, or having been declared to be in serious breach of its obligations under contracts covered by the Union's budget.

Points (a) to (d) of the first subparagraph shall not apply in the case of purchase of supplies on particularly advantageous terms from either a supplier which is definitively winding up its business activities, or from the receivers or liquidators of a bankruptcy, through an arrangement with creditors, or through a similar procedure under national law.

Candidates or tenderers must certify that they are not in one of the situations listed above by completing and signing the form in Annex IV, "Certification with respect to the Exclusion Criteria".

The tenderer to whom the contract is to be awarded must **also** provide **evidence** that they are not in any of the situations described in points (a), (b), (d) and (e) above within the time limit stipulated by the contracting authority. This evidence must be in one of the forms described in paragraph 14.2 below.

13.2. Evidence

a) The contracting authority shall accept as satisfactory evidence that the candidate or tenderer to whom the contract is to be awarded is not in one of the situations described in point (a), (b) or (e) of paragraph 14.1, a recent extract from the judicial record or, failing that, an equivalent document recently issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied. Where the tenderer is a legal person and the national legislation of the country in which the tenderer is established does not allow the provision of such documents for legal persons, the documents should be provided for natural persons, such as the company directors or any person with powers of representation, decision making or control in relation to the tenderer.

b) The contracting authority shall accept, as satisfactory evidence that the candidate or tenderer is not in the situation described in point (d) of paragraph 14.1, recent certificates or letters issued by the competent authorities of the State concerned. These documents must provide evidence covering all taxes and social security contributions for which the tenderer is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions.

For any of the situations (a), (b), (d) or (e), where any document described in two paragraphs above is not issued in the country concerned, it may be replaced by a sworn or, failing that, a solemn statement made by the interested party before a judicial or administrative authority, a notary or a qualified professional body in his country of origin or provenance.

c) Depending on the national legislation of the country in which the candidate or tenderer is established, the documents referred to in paragraph 13.2 shall relate to legal persons and/or natural persons including, where considered necessary by the contracting authority, company directors or any person with powers of representation, decision-making or control in relation to the candidate or tenderer.

13.3. Contracts may not be awarded to candidates or tenderers who, during the procurement procedure:

(a) are subject to a conflict of interest;

(b) are guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in the contract procedure or fail to supply this information;

(c) find themselves in one of the situations of exclusion, referred to in paragraph 14.1, for this procurement procedure.

Candidates or tenderers must certify that they are not in the situation in point (a) by completing and signing the form in Annex IV, "Certification with respect to the Exclusion Criteria".

14. Selection criteria

14.1. Evidence of access to contracts (proof of eligibility)

The tenderer indicates in which State it has its headquarters or domicile and presents the supporting evidence normally acceptable under its own law (see annex I).

Moreover, the tenderers are requested to:

- indicate their VAT number (see annex I);
- indicate the name and position of the person authorised to sign the contract (see annex I);
- indicate their account number and bank address (R.I.B. or standard form in annex II);
- for natural persons, the standard form in annex III must also be completed and returned.

14.2. Economic and financial capacity

1. Proof of economic and financial capacity may be furnished by one or more of the following documents:

(a) appropriate statements from banks or evidence of professional risk indemnity insurance;

(b) the presentation of balance sheets (or extracts from balance sheets) and profit and loss accounts for at least the last two years for which accounts have been closed, where publication of the balance sheet is required under the company law of the country in which the economic operator is established (Mandatory for contracts with a value of 130,000 EUR or more);

(c) a statement of overall turnover and turnover concerning the works, supplies or services covered by the contract during the last three financial years.

2. For contracts with a value of 130,000 EUR or more, tenderers (and in case of a consortium, the consortium leader and the consortium members) are also requested to fill in the 'simplified balance sheet' and the 'simplified profit and loss accounts' enclosed in the 'Simplified Presentation' form in Annex VI for the last year for which accounts have been closed. Alternatively, the tenderers may fill in only the fields marked in bold and the ones marked in italics. All amounts must be expressed in Euro using the conversion rate as per section 9 (Price) of these tender specifications.

3. On the basis of the data from the 'Simplified Presentation' form in Annex VI, a number of values and ratios will be calculated in order to evaluate the economic and financial capacity of the tenderers.

4. The following values will be calculated:

Value	Formula/source	Unfavourable if:
own funds	from the balance sheet	negative
	own funds - paid-up capital	negative
working capital	permanent capital - fixed assets	negative
gross operating surplus	from the P&L accounts	negative
net result	from the P&L accounts	negative
self-financing capacity (SFC)	net result after tax + amortization – capitalized production	negative

There is no favourable value score for these categories

5. Following ratios are calculated:

Ratio	Formula	Unfavourable if	Average if	Favourable if
general liquidity	current assets/short-term debts	below 1	between 1 and 1.25	Above 1.25
financial independence	own funds/total liabilities	below 0.20	between 0.20 and 0.40	above 0.40
indebtedness	own funds/medium & long-term debts (MLT)	below 0.30	between 0.30 and 0.60	above 0.60
coverage of deposits and borrowed funds by the SFC	SFC / MLT debts	below 0.25	between 0.25 and 0.50	above 0.50
profitability	gross operating surplus / turnover	below 0.10	between 0.10 and 0.20	above 0.20

6. Each type of evaluation has a corresponding scoring (number of points) as follows:

Scoring	
Unfavourable value/ratio	0 points

Favourable value	1 point
Average ratio	1 point
Favourable ratio	2 points

7. In order to meet the financial capacity criterion, the tenderer must obtain a score of at least 8 points (out of a total of 16 points), which corresponds to 50% of the maximum number of points.
8. If, for some exceptional reason which the contracting authority considers justified, the tenderer or candidate is unable to provide the references requested by the contracting authority, or if he feels that the financial viability check does not provide an accurate picture of his organisation's financial status, he may prove his economic and financial capacity by any other means which the Commission considers appropriate.

14.3. Technical and professional capacity

Technical and professional capacity of economic operators shall be evaluated and verified in accordance with this paragraph.

The Contractor should propose an appropriate team consisting of minimum six persons - including the team leader - who fulfils the requirements set in out in i and ii below to perform the specific services.

The tenderer must meet the following criteria

i. The team leader must have a university degree and at least 8 years of relevant professional experience in the field of public health and health economics, and with knowledge of self-care. The team leader must have experience in overseeing European project delivery, quality control of delivered service, client orientation and conflict resolution.

ii. All team members listed below shall, with the exemptions for f), have a university degree and at least 5 years work experience after the relevant professional qualifications, in one of the following areas:

   a. at least one member with professional experience in developing and/or implementing self-care strategies;
   b. at least one member with professional experience in the field of patient rights;
   c. at least one member with professional experience in collaborating with health professional organisations and patient organisations;
   d. at least one member with professional experience in work at EU level in the area of health;
   e. at least one member with professional experience in health economics;
   f. at least one member with experience in organising and running EU conferences and working groups;
   g. at least one member with professional experience in journalism and/or communication.

   Team members can fulfil several of the points a) – g).

iii. Team members can receive support; such as performance of clerical tasks; by other professionals not having the above mentioned requirements as long as they are under the supervision of a team member who fulfils the above mentioned requirements.

iv. All above team members shall have a proven adequate working knowledge of **English**.

Technical and professional capacity of tenderers shall be evaluated and verified.

Evidence of the technical and professional capacity of tenderers shall be furnished on the basis of the following documents:

Criterion	Evidence to be provided	Comments
i	reference of performed projects	
i and ii,	Curriculum vitae proving the minimum requirements requested	Preferably in EU-pass format, but at least 2 pages long per person. Summaries will not be accepted.
i, ii and iv	A filled-in checklist on the technical and professional capacity under the selection criteria listing all team members with their function in the team and also specifying their competences in English	Language competences should be attested by certificates or by documenting study or work experience in an English-speaking environment

14.4. Tenders from consortiums of firms or groups of service providers, Contractors or suppliers

Tenders from consortiums of firms or groups of service providers, Contractors or suppliers must specify the role, qualifications and experience of each member or group.
Proof of eligibility, Certification with respect to the Exclusion Criteria and documents on exclusion and selection criteria must be supplied by each member of the consortiums of firms or groups of service providers (or Contractors or suppliers, depending on the type of contract) submitting a single tender.

TECHNICAL PART

15. Award criteria

The contract will be awarded to the tenderer who submits the most economically advantageous bid, as assessed on the basis of the following factors:

(a) Technical evaluation criteria in their order of importance as weighted by percentage:

N°	Qualitative Award criteria	Weighting (max. points)
1	Quality of the proposed methodology for the study (section 4.1.1)	20
2	Quality and appropriateness of the proposed methodology for the establishment of the platform of experts (section 4.1.2).	30
3	Quality of the suggested dissemination strategy including a preliminary outline of conference program (section 4.1.3)	20
4.	Organisation of the work	30
	Total points	100

The criteria are detailed as follows:

Quality of the proposed methodology for task 4.1.1 "the study" (20 points)

This criterion will assess the relevance and quality of the methodology proposed in relation to the tasks described in section 4.1.1 and in particular :

- the scope and design of the desk research and analysis method requested in task 4.1.1.1., taking into account the selected keywords, databases and criteria.
- the methodology and approach proposed to carry out the cost–benefit analysis requested in task 4.1.1.2.
- well justified methodology choices
- comprehensive and detailed description of the methods.

.Quality and appropriateness of the proposed methodology for task 4.1.2 "platform of experts" (30 points)

This criterion will assess the relevance and quality of the methodology proposed in relation to the tasks described in section 4.1.2 and in particular :

- the criteria and selection methodology proposed to establish the platform of experts and to select the experts
- the structure suggested for the running and the management of the work of the platform
- well justified methodology choices
- comprehensive and detailed description of the methods.

Quality of the suggested dissemination strategy (20 points)

This criterion will assess the relevance and quality of the methodology proposed in relation to the tasks described in section 4.1.3 and in particular :

- relevance and quality of the strategy suggested at national and local level
- quality and structure of the preliminary outline of the conference
- well justified methodology choices
- comprehensive and detailed description of the methods.

Organisation of the work (30 points)

This criterion will assess the relevance and feasibility of the approach for the management of the work in general, the concrete work plan and timetable, as well as the adequacy of roles, responsibilities and work allocation.

Tenders must score minimum 50% for each criterion and sub-criterion, and minimum 60% in total. Tenders that do not reach the minimum quality thresholds will be rejected and will not be ranked.

b) Price.

Method used to determine the most economically advantageous offer:

The quality/price ratio will be applied only to bids which reach or exceed the threshold defined under point 15(a).

General evaluation:

The contract will be offered to the most economically advantageous bid, taking into account the quality of the service, striking a balance between the technical quality of the bid and price proposed according to a quotient of 70/30.

This will be done by multiplying:

- the points awarded for technical quality by 0.70
- and the points awarded for the price of the bid by 0.30.

The points for technical quality and those for price thus obtained are then added together, and the contract will be awarded to the tenderer obtaining the highest total number of points.

Offer score (i) = (0.70 x Q(i)) + (0.30 x P*/P(i)] x 100)

Where:
Q(i) is the score obtained in the technical (quality) evaluation of the offer (i)
P* is the lowest price among all the offers conforming to the admissibility criteria and which obtained the minimum scores requested.
P(i) is the reference price for offer (i).

FINANCIAL PART

16. Financial part

Prices must be presented in the standard format of annex V.

The price for the tender must be quoted in euro. Tenderers from countries outside the euro zone have to quote their prices in euro. The price quoted may not be revised in line with exchange rate movements. It is for the tenderer to assume the risks or the benefits deriving from any variation.

Prices must be quoted free of all duties, taxes and other charges, including VAT, as the European Union is exempt from such charges under Articles 3 and 4 of the Protocol on the privileges and immunities of the European Union. The amount of VAT may be shown separately.

Annexes:

Annex I - Tender submission form
Annex II - Financial Identification form
Annex III - Legal identification:
- Privacy Statement
- Legal Entity form - Private Company
- Legal Entity form - Public Company

Annex IV - Certification with respect to the exclusion criteria
Annex V - Budget
Annex VI - Simplified financial statements
Annex VII - Draft Contract

Contracting Authority:
EUROPEAN COMMISSION
Health and Consumers Directorate-General
Call for tender SANTE/2015/D2/021

Volume B

Technical part

Pilot project on the Promotion of Self-care in Chronic Diseases in the European Union

30 September 2015

Title of the tender:

Pilot project on the Promotion of Self-care in Chronic Diseases in the European Union (PRO-STEP – Promoting Self-management for chronic diseases in Europe)

Contents

1. Composition of the team

Title of the tender:	Pilot Project on Promoting Self-management for Chronic Diseases in the European Union
Proposal acronym:	PRO-STEP
Type of funding scheme:	Tender (no. SANTE/2015/D2/021)
Type of tenderer:	Consortium
Leader of consortium:	Nicola Bedlington, European Patients' Forum

The consortium brings together organisations with a broad range of expertise in fields and backgrounds relevant for self-care in chronic disease in the European Union. The consortium is led by a patients' organisation (EPF) and includes key stakeholders in relevant fields: health education (DCHE), research and implementation (FAD), and health policy (EFHH) as well as translation of knowledge (advisors to the steering committee).

Table 1: Participating organisations

Number	Name of the organisation	Country	Role
1.	European Patients' Forum (EPF)	Belgium	Consortium leader
2.	Fundacion Avedis Donabedian – Avedis Donabedian Research Institute (FAD)	Spain	WP leader
3.	Danish Committee for Health Education (DCHE)	Denmark	WP leader
4.	Institute for Medical Technology Assessment, Erasmus University (iMTA)	Netherlands	WP leader
5.	European Health Futures Forum (EHFF)	United Kingdom	WP leader

The team brings together strong and proven expertise in health promotion, health literacy, health education, self-care, chronic disease self-management, patient empowerment, patient participation, design and implementation of integrated care models and quality and safety of care both in health and social care. It has the capacity to combine feasible research scenarios with professional practice and EU policy. Most of the team members have participated in the consortia which were responsible for previous tenders EAHC/2013/Health/04 (hereafter referred to as the 'EMPATHiE project') 'Empowering patients in the management of chronic diseases' and SANCO/2013/D2/027 (hereafter referred to as the 'PiSCE project').'Pilot project in the promotion of self-care systems in the European Union'.

Representatives from other key stakeholder groups, including health professionals, disease-specific experts and patient representatives, industry, policy-makers and other experts as appropriate, will be invited to join the Platform of Experts following selection of the diseases based on the literature review and CBA, and after consultation with the Commission.

Through its networks, the team maximises synergies with previous and ongoing projects and initiatives, as well as outreach to stakeholders both at European and national/local levels. Members of the consortium are currently engaged in relevant international and national initiatives in the European Union; they also have extensive experience in the development and evaluation of best practices, qualitative and quantitative methods, and policy strategies (see WP1 description, below).

2. Executive summary

This is a tender designed to explore the added value of self-management in chronic diseases. The requirement for this work originates in the Council acceptance of the final report of the reflection process on chronic diseases: 12983/13 and its endorsement by the European Parliament during its session of 2013 (reaffirmed in 2014) in committing funds for the pilot projects which these tenders represent.

The study benefits from a thorough analysis of patient empowerment, including the relationship between self-management, joint decision-making and health literacy, stemming from the EMPATHiE project, the first of two previous tenders, and the experience of a platform of experts addressing the issues around the promotion of self-care; both guidelines for individual minor diseases and concrete policy actions related to promoting self-care, in the another ongoing study (the PiSCE project), in minor and self-limiting conditions. A cost-benefit analysis of self-care systems for minor conditions e.g. the UK NHS Choices system, produced limited results.

The project will contribute to the aim, expressed in the original Commission Decision, C (2013)4940 on a Pilot Project: 'Promotion of self-care systems in the European Union' to put in place a framework for action to enhance self-care at EU level and develop strategies to support the broader implementation of effective self-care.' The Consortium intends to meet the tender specifications by work that is divided into four phases over a 24 month period.

The overall requirement is to conduct a study (consisting of a literature review and cost-benefit analysis) and to set up a platform of experts in self-care in the field of chronic diseases to explore and propose possible methods of promotion of self-care for chronic diseases, taking into account previous and on-going policy work in this field.

Phase 1 Taking six broad chronic disease groups as a starting point the team responsible for the literature review (WP2) will examine the scientific evidence for the added-value of self-care/self-management, taking into account actions patients carry out in prevention, monitoring and managing their condition. The review includes identifying best practices, which entails developing explicit criteria for identifying such practices. A taxonomy of existing good practices will be produced and finally, in line with the priorities of the European Innovation Platform on Active and Healthy Ageing, having identified best practices, the task is to review key elements of them which would allow the scaling up of best practices from country to country or from disease to disease. The team undertaking this element of the project previously delivered the literature review on empowerment in chronic diseases (in the EMPATHiE project) so that some of their previous work can be incorporated.

In parallel and in synergy with this work, a separate team of health economists (WP3), dealing with the same group of conditions, will provide a cost-benefit analysis, looking at both a patient and a health system perspective. They are required to consider both monetary costs related to self-care but also non-financial costs and benefits. The combined results of the two work streams will form the basis for starting the second phase.

Phase 2 The first element of this phase (WP4) is, on the basis of the above work, to select six or more diseases, preferably one from each of the broad disease groups, where there is the best evidence that self-care creates added-value in terms of cost-benefits (and to seek approval from the

Commission for their choices). Then the Consortium is required to set up a cross-functional expert stakeholder platform, comprised of recognised experts in chronic diseases, healthcare and self-care, with a balanced geographic representation also. Again, the Commission's agreement will be sought for the final selection of the 20 or so members of the Platform. The team that would be responsible for this have previous experience of undertaking such a task as they created the expert platform currently completing the work for the PiSCE (self-care in minor conditions) project. The final part of this phase is to create and seek Commission approval for a comprehensive work plan for the Platform to carry out during its active period of seven months.

Phase 3 The Expert Platform, using the selected diseases as a basis are required to deliver a number of outputs:

- Identify any barrier that may hinder the development of self-care;
- Develop guidelines for national and local policy makers on how to promote self-care;
- Propose scenarios for EU collaboration;
- Propose innovative approaches for the development of self-care;
- Propose and design communication tools to patient/consumers to improve prevention and disease management

The work will be divided and handled by WP leaders in WP5 and 6 who have experience of managing a platform of experts, in the previous tender (PiSCE). Because WP5 have a high level of expertise in health promotion and guideline development, they will deal with items 1, 2 and 5 from the above list whereas WP6 leaders, with experience in the policy field at EU level, will deal with items 3 and 4. Throughout this phase there will be close communication between the two working groups, to ensure that we obtain maximum benefit from the accumulated skills of the expert platform.

Phase 4 The last phase relates to dissemination: putting in place a strategy to ensure dissemination of results at European, national and local level and organising a closing/concluding conference in Brussels to present the outcome of the work. This conference will bring together at least 100 participants representing relevant stakeholders and Member States. The results of the conference will be evaluated and incorporated into the project Final Report as well as evidence regarding the implementation of the dissemination strategy. This phase (WP7) is led by EPF, the leading NGO in the European Union for patient representation. They also lead WP1, which oversees and coordinates the management of the project. It seems very appropriate that an organisation dedicated to patients' rights, and involved at a policy level on that issue, also recently having launched a European campaign on patient empowerment, should lead this project.

3. Self-care and self-management in the European context

Chronic diseases are conditions of long duration and generally slow progression, which result in significant morbidity and loss of healthy life years. They represent the major share of the burden of disease in Europe[1], affecting more than 80% of people aged over 65, and are responsible for 86% of all deaths in the region. Given that the population of Europe aged 65 and above is estimated to rise from 87.5 million (in 2010) to 152.6 million by 2060, addressing chronic diseases is one of the key objectives of EU health policy for the next years.

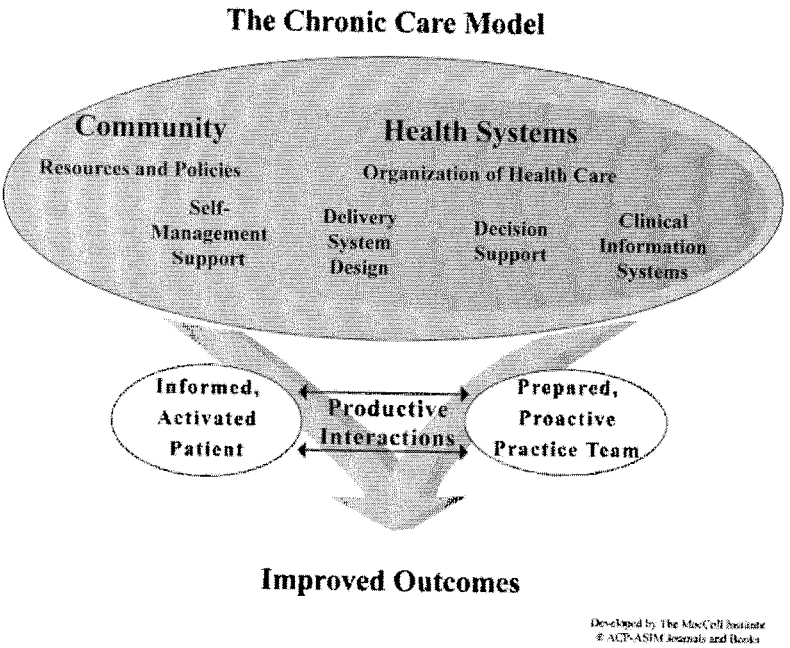
This development, coupled with the need to restructure healthcare systems to increase their cost-effectiveness and ensure their long-term sustainability while providing high-quality care, represents a paradigm shift from acute, hospital-based care towards community-based, integrated, longer-term care where patients are expected to have a crucial role. This approach aims for patients to move from being passive recipients of care to being active partners in chronic disease self-management, and ultimately towards "co-production" of health. (e.g. Realpe and Wallace, 2010)

The 2012 qualitative Eurobarometer on patient involvement found that patients with chronic conditions are more likely and willing than other healthcare users to get actively involved in their healthcare. "Policy-makers in many countries ... are looking for ways to empower people to manage their own health and health care, by providing them with effective self-management support." (Coulter et al, 2008).

The Chronic Care Model developed by Ed Wagner and his colleagues in the United States has been highly influential internationally as a framework for the management of chronic diseases, which recognises the central role of the informed, motivated patient alongside with a prepared and proactive care team. At the heart of this model is the importance of providing patients with effective self-management support for long-term health problems. (Bodenheimer et al, 2002; Wagner EH, 1988) The Stanford chronic disease self-management programme (http://patienteducation.stanford.edu), for example, is based on the chronic care model.

[1] Herein after 'Europe' substitutes the European Union, as in certain contexts it is more appropriate to refer to Europe in geographical terms.

Figure 3.1. Wagner's Chronic care model



There is good evidence that support for self-management has an impact both in terms of improving health outcomes and reducing costs. For example, a recent comprehensive review on self-management literature of more than 550 articles of high quality research the authors concluded that, "whilst the findings of individual studies are mixed, the totality of evidence suggests that supporting self-management can have benefits for people's attitudes and behaviours, quality of life, clinical symptoms and use of healthcare resources." (de Silva, The Health Foundation, 2011).

However, while understanding of the importance of self-management in improving health outcomes has been available in the policy arena for a number of years, translating policy into concrete actions is taking some time.

3.1. Definition of self-care

The definition of self-care as described in the call for this tender is: *"what individuals, families and communities do with the intention to promote, maintain, or restore health and to cope with illness and disability with or without the support of health professionals such as pharmacists, doctors, dentists and nurses. It includes but is not limited to self-prevention, self-diagnosis, self-medication and self-management of illness and disability..."*

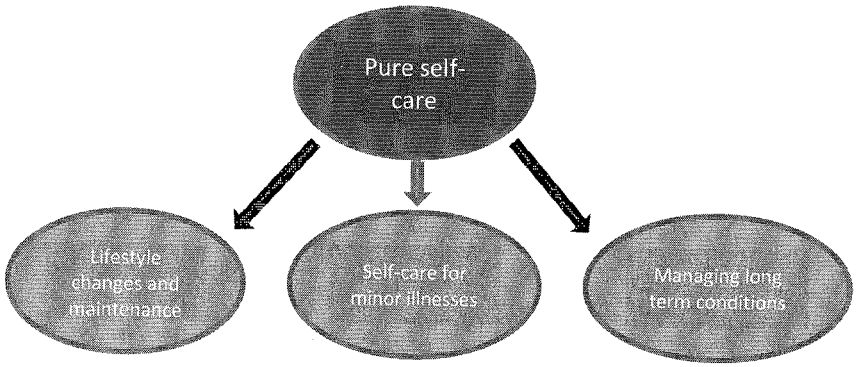
This definition was developed by the previous CBA project, elaborating on the definition used in the tender calls for both the CBA and PiSCE projects of self-care as *"the actions people take for themselves, their children and their families to prevent and care for minor ailments and long-term conditions and maintain health and well-being after an acute illness or discharge from hospital."* (UK Department of Health, 2005). The CBA project team had 8 experts (including one Austrian patient representative) perform a Delphi exercise to extend the definition as above.

The Consortium believes that for the consideration of chronic disease, simplicity has virtue, although the definition used needs to reflect the key elements of what is to be studied.

To that end we would start with fundamentals: Coulter and Ellins (2006) define self-care as "practices undertaken by individuals towards maintaining health and managing illness." However, they go on to say, "the terms self-care and self-management are often used interchangeably, although they are not strictly the same." While not explicitly defining the difference, it is possible to infer that, in the case of chronic diseases, "the goal of self-management support is to enable patients to perform three sets of tasks: i) medical management of their illness (e.g. taking medication, adhering to a special diet; ii) carrying out normal roles and activities; and iii) managing the emotional impact of their illness." (Lorig and Holman, 2003)

This could be seen as a subset within self-care which by their definition "entails people's active involvement in all aspects of their own healthcare and that of their families." The following graph from a recent BMA paper on self-care illustrates a similar concept.

Fig.3.2 Self-care (from BMA, 2008: self-care Q and A)



Related concepts

In our view there are at least two facets of self-management of chronic illnesses that are relevant to the present study: the *prevention* element referred to earlier, i.e., the capacity of the patient (both in terms of motivation and knowledge) to make life-style choices which maintain overall health and combat deterioration of the condition; and secondly what psychologists call *"self-efficacy"* (Bandura, 1977), which is the confidence and knowledge to make sensible decisions and which can be supported or undermined by the nature of interactions with health professionals. This concept is central to *patient empowerment* and figures strongly in work on the Stanford model of chronic disease management referred to above.

This reference to patient empowerment and self-efficacy provides a natural link to the next point. Why spend so much time talking about definition? For work of this kind to have an impact on policy and contribute to improvement, it has to have as strong an evidence-base as possible. Without a definition of relevant terms, one cannot make meaningful comparisons. This was recognised for example in the wording of the EMPATHiE tender call: "the concept of patient empowerment is not clear and is often used interchangeably with such terms as 'patient involvement' or 'patient-centred care'. Moreover, it is often perceived only as the use of eHealth tools by patients."

During the course of the EMPATHiE project, the utility of its chosen conceptual model was amply validated. This sees patient empowerment as having three key (inter-related and overlapping) dimensions: health literacy/education; shared decision–making; and self-management. The literature review showed that reliable studies were more frequent in regard to the last mentioned and least available in regard to the second.

The essential message here in regard to chronic diseases is that self-management is a key element of patient empowerment, but is closely linked to other aspects, which go beyond simply managing illness. Therefore, the definition of self-care/self-management will need to be developed during the first few months of the project.

3.2. EU policy in the area of self-care and chronic diseases

The present tender flows from the Reflection process on chronic disease initiated in follow-up to the 2011 Council conclusions on "Innovative approaches for chronic diseases in public health and

healthcare systems". The final report of the Reflection process, published in the autumn of 2013, identified two main pillars in its recommendations: (i) disease prevention and health promotion, where the exchange of good practices in this area is highlighted together with two specific initiatives the European Innovation Partnership for Active and Healthy Ageing (EIP-AHA) and the Joint Action on chronic diseases, CHRODIS; and (ii) management of chronic diseases. This latter section describes the circumstances in which the EMPATHiE tender study on patient empowerment was commissioned and recognises the important role of patient empowerment in chronic disease management: "Patient empowerment integrates multiple concepts that enable a person to effectively self-manage their disease. Many chronically ill people are not hospitalised and are still functioning actively in all aspects of society and therefore self-care and care in the home setting are important. For this to work effectively, patients need to be empowered to make decisions about their healthcare in close collaboration with the healthcare providers." Important characteristics of patient-centred chronic disease management include "optimal cooperation between multiple healthcare professionals with the right skills, from different disciplines, and different institutions." (Report 12983/13, p. 18-19)

The three tenders that have arisen from the Commission decision (C(2013) 4940 final) represent an interlinked exploration of an area which has important implications for potential cost savings, but also expresses a shift of emphasis in the overall approach to chronic diseases.

Looking outside the activities of DG SANTE unit D2 on health systems, there are other relevant activities which need to be taken into account. In addition to the Joint Action on chronic diseases (CHRODIS), which is managed by Directorate C (public health), relevant activities on health literacy are taking place involving different Commission Directorates as well as stakeholders. The European Innovation Partnership on Healthy and Active Ageing (EIP-AHA) is jointly managed between DG SANTE and DG CNECT. There are also new projects under Horizon 2020, particularly topics PHC27, 28 and 29, all dedicated to developing new technology related to improving self-management. It is vital to optimise synergies and sharing of information between these initiatives.

The tender consortium has already excellent connections with pieces of this jigsaw. For example, EPF and EHFF have made presentations at a recent WP7 meeting of CHRODIS, in which EPF is a partner and EHFF a collaborating partner. CHRODIS WP7 is an in-depth study of diabetes management practices across the European Union. Similarly, the involvement of EPF and EHFF in the patient empowerment sub-group of the EIP-AHA B3 action area has allowed sharing of good practices at national level and regional level. There has been useful additional interaction with another aspect of the EIP, namely the Reference Site Collaborative Network, which recently held a two-day seminar on management of chronic respiratory diseases. We have excellent links with the Maastricht Health Literacy Project through their involvement in the current Expert Platform of the PiSCE project.

This project provides an opportunity to pull together the work of the three tenders, to provide some answers and to raise pertinent new questions. The growth of knowledge in this important area of health care, namely patient empowerment, self-management and self-care is an incremental process. This study can provide a direction for further work, taking into account the projects going on in other Commission Directorates, but can also highlight important knowledge gaps where further research and development might be concentrated.

3.3. Additional issues in regard to self-management in chronic disease

There are three specific areas that need to be considered, which contribute to the effectiveness and equity of self-management activities.

1. *Health literacy*

Health literacy is a critical dimension of empowerment (WHO, 2006) and self-management (WHO, 2013), which are competencies required of citizens in 21st century society. Health literacy is both a means and an outcome and it encompasses accessing, comprehending and evaluating health information, but also relating the information to oneself and one's health and transforming it into appropriate actions. (Sorensen et al, 2012) It is known that limited health literacy has a negative impact on health, service use and costs to the healthcare system. (WHO, 2013; Eichler et al., 2009)

Interest in health literacy has been growing at European level. Regulation 282/2014, setting up the 3rd EU health programme 2014-2020, acknowledges that: "Patients need to be empowered, *inter alia* by enhancing health literacy, to manage their health and their healthcare more pro-actively, to prevent poor health and make informed choices." The European Commission's communication on the EIP-AHA recognised health literacy as an important social determinant of health. (COM(2012)83 final) The European Health Literacy project HLS-EU (2009-2012) showed that nearly half of the respondents in the eight Member States studied had limited health literacy. Drawing on these results, an informal multi-stakeholder group of patients, researchers, health professionals and industry published a consensus paper calling for more EU action ("Making health literacy a priority in EU policy", June 2013).

Most recently, in June 2015, the results of a mapping study commissioned under the 3rd Health Programme were published. The FP7-project IROHLA, a large study of health literacy in the older population, will have its closing conference in November 2015. This study promises to deliver a guideline on how to promote health literacy in older people. IROHLA research stresses that health literacy and self-management are strongly related (data to be available in November).

During discussions at the kick-off meeting with the Commission, if we are successful in our bid, it could be explored to what extent and how health literacy might be addressed more directly in this tender.

2. *Education of health professionals to support self- management*

Improving the communication skills of health professionals also plays an important role in achieving patient-centred health care. This is something that has emerged strongly from the PiSCE interim results, as well as the conclusions of the EMPATHiE and IROHLA projects. The Expert Panel on Effective Ways of Investing in Health (EXPH) report on Quality and Safety, published in October 2014, includes this topic in its high-priority recommendations for future policy: "to promote the training of health professionals in their new role of 'trainers' for patients with chronic conditions and in addition develop ways, means, time and motivation for professionals to learn better communication skills to engage and involve patients in their care." (EXPH, 2014, p. 71) It would seem important to pursue this theme during the course of the study, even though, like health literacy, it is not explicitly referred to in the tender call.

3. The role of technology

Finally there is the uncertain role of eHealth and mHealth in self-management. The Commission's eHealth Action Plan 2012-2020 "Innovative healthcare for the 21st century" acknowledges that "ICT applied to health and healthcare systems can increase their efficiency, improve quality of life and unlock innovation in health markets. However this promise remains largely unfulfilled....."

In analysing the barriers to deployment of eHealth, the first mentioned is: lack of awareness of, and confidence in eHealth solutions among patients, citizens and healthcare professionals. (e.g., Chain of Trust project final report, 2013) Particularly but not exclusively, in the eHealth field, new systems or devices that may improve the effectiveness of health systems are introduced as "empowering patients", when patients have not been consulted in the development of the "innovation" and there is no data to support the assertion that the new tool will actually improve the ability of patients to manage their care. (ibid; EIP-AHA Synergies group, unpublished minutes from Jan 2015).

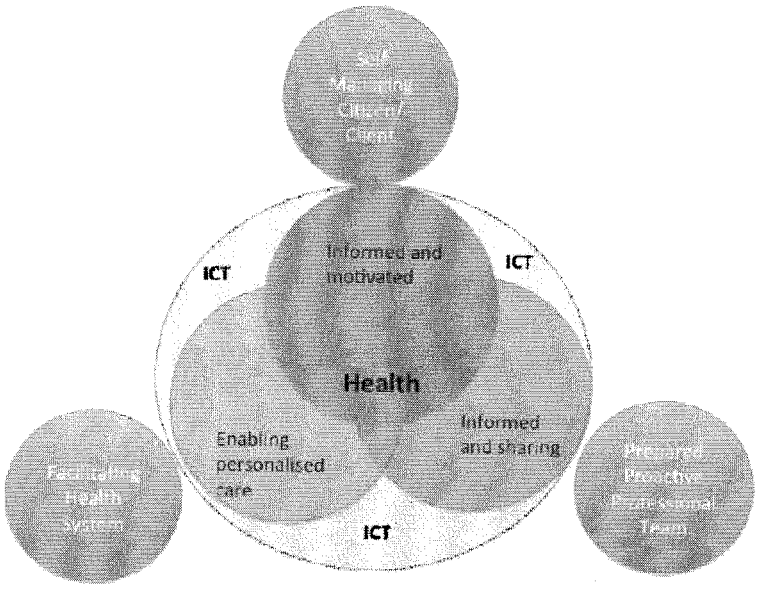
Nevertheless, the rapid increase in the number of software applications for mobile devices (apps) offers potential for developing information and diagnostic tools, possibilities to "self-quantify" as well as new modalities of care. They are blurring the distinction between the traditional provision of clinical care by physicians, and the self-administration of care. (COM(2012)736 final, p. 9)

Optimising and tailoring of interventions, e.g. providing personalised support promoting easy access to understandable health information, tools for self-monitoring and providing social support, has been shown to be a promising strategy to improve self-management especially of vulnerable people with low health literacy. (De Winter AF, Reijneveld SA et al. 2013, Understanding Health Literacy and the Development of an Intervention Model, The IROHLA consortium, UMCG, Groningen, The Netherlands. Personal communication). The widespread adoption of mobile devices – smartphones, tablets etc. – and their technical possibilities provide an opportunity to address societal challenges regarding health and wellbeing of low health literacy adults.

The vision of the Action Plan has as its first named priority "to improve chronic disease and multimorbidity management and to strengthen effective prevention and health promotion practices". The most relevant aspect of the operational objectives of the Plan to this project is the support for R and D in eHealth and well-being "to address the lack of availability of user-friendly tools and services."

In line with these observations, we would be wise to bear in mind this dimension of the current environment in reviewing self-management practices and making policy recommendations. The following model, adapted from the UK NHS (https://www.whittington.nhs.uk/default.asp?c=7402), demonstrates well the relations between the above-discussed concepts.

Fig.3.3. Self-management support model (UK NHS)



There is a final, important caveat about lack of data. Following the European Commission's Green paper on mHealth (2014) and the public consultation completed this year, the Commission is committed to pursuing the appropriate safeguards to allow some kind of regulation, especially of the mobile apps market. But in terms of taking the *usage* of such tools into consideration for policy purposes, there is not enough adequate information about the impact of apps on either wellness or on self-management in chronic care. In addition, there is limited data on the extent or nature of citizens' use of Internet-based information, apps or social media for self-care or as a part of self-management in chronic disease. There is a substantial amount of research that needs to be done. This will be addressed in our literature review.

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4. Objectives of the study

4.1. General and specific aspects

General aspects:

This is the second of two tenders related to Commission Decision C (2013)4940 on a pilot project: "Promotion of self-care systems in the EU". The wording of the original Decision refers to a cost-benefit analysis "of self-care oriented health systems in the EU and the current frameworks in place to enhance self-care systems and patients' empowerment". Referring to the platform of Experts it says: "In the process of analysing further action to take at EU level, the platform shall build on the outcomes from the above mentioned cost/benefit analysis and shall take account of the call for tender in work plan 2013 to the Health Programme (2008-2013) 'Empowering patients in the management of chronic diseases'." It seems, therefore, that self-care and patient empowerment were seen as closely related by those drafting the Decision. One can conclude that the general objective is as stated in the original decision: *"...to put in place a framework for action to enhance self-care at EU level and develop strategies to support the broader implementation of effective self-care."* This tender speaks to a major component of that framework, namely self-care/self-management in chronic diseases.

The specific objectives of the study, as in the previous tenders, include the identification of good practices, development of guidelines and tools for promotion of self-care and concrete policy actions, which will help professionals and policymakers take the next steps in implementation. The tender also asks more searching questions such as; what is a good or best practice? Can we define explicit criteria by which good or best practices can be identified? What is added value? Furthermore, the tender refers to identifying key elements which would allow the scaling-up or transferability of good practices, either from one country to another or from one disease to another. This echoes the current phase of the European Innovation partnership on Active and Healthy Aging (EIP-AHA), which is the move, following identification of good practices, into the scaling-up strategy.

Specific aspects:

The tender has 4 phases:

Phase 1: The first six months entail *an extensive literature review* of the scientific evidence on *the added-value* of self-care in six major disease areas (WP2). The review is to take into account the different dimensions of self-care, including self-prevention, self-diagnosis and self-management. Clearly a significant objective for this section is to decide early on how to define added-value.

We can relate this work to the previous studies: in terms of the cost-benefit analysis, the previous CBA study (EHAC/2013/026) did not explicitly look at non-financial cost and benefits, whereas this tender will address these. For example, for patients this could mean time spent or saved, fears or assurances, health benefits or losses; and for the health systems, reduced burden on society in general due to a healthier population.

In the previous self-care tender (PiSCE), the platform of experts were asked to make proposals for actions and collaboration at EU level on self-care "which will give an added value", without defining added value specifically. In the present tender, the emphasis will be on "the effective and cost-

effective use of healthcare systems and resources", which inevitably will influence our eventual choice of definition of added-value.

The six disease areas represent a large field of literature and in addition this first stage of the contract must also take into account the identification of *best practices* related to self-care, which also requires a definition of *explicit criteria to assess what a good practice (or bad practice) is*.

Following on from this, this component includes identifying and reviewing *key elements which allow the scaling up of best practices* from country to country or from disease to disease. This work would be undertaken during the period when the EIP participants (in particular for B3, the integrated care area) are in process of setting this in motion, so that in the six months of this proposed study within the tender the results of these activities will not yet be available in any concrete form, although there should be indications. We will take into account also the proposed methodology to assess/validate the transferability of good practices on patient empowerment (GPPEs) developed in EMPATHiE.

Finally the literature reviewers are required to establish *a taxonomy of existing good practices* by taking into account the evidence of its results and breaking them down by type of intervention and disease characteristic. The group at FAD who will lead this substantial task were those who delivered the literature review on patient empowerment in the EMPATHiE study, half of whose results related to self-management in chronic disease, which is an obvious advantage but will need to be expanded.

Parallel with the literature review is *the cost-benefit analysis* (WP3) to be conducted from both a patient and a health system perspective. The review would require a mechanism whereby non-financial costs and benefits were quantified, in order for the combination of the two parallel studies to provide data on which the second part of the study would be based. The potential synergies between these two Work Packages is a fundamental, and one of the objectives of the management team (WP1) is to continuously review that interchange of information between the relevant WPs and provide mechanisms to facilitate it.

Phase 2: For the second phase, the objective is, on the basis of the outputs from WP2 and 3, *to select at least six diseases where self-care brings added-value in terms cost-benefits.* Although the steering group as a whole will address this, guided by the WP2 and 3 leaders, the process will be managed by WP4, which also has the responsibility of *selecting potential members of the platform of experts* and gaining Commission approval for the final composition of the platform *and an appropriate work plan.* This phase will last three to four months.

Phase 3: The third phase comprises deployment of the Platform of Experts to tackle the five tasks described in the tender call and we have chosen to tackle these by splitting the platform into two groups, WP5 and WP6, although the platform members not directly working on a particular task will be regularly informed on progress. Having had experience of working with a large platform, in the current PiSCE tender we felt that having two inter-connected work groups is a better model than having a smaller group tackling a specific task and then consulting with the larger platform. We believe that the greater number of tasks here could be dealt with more effectively by this division of labour.

WP5 will therefore deal with *identifying barriers to the development of self-care in chronic diseases, developing guidelines for regional and local policy-makers on promotion of self-care and propose and*

design communication tools that supported patients in prevention and disease management. We felt that this was one possible logical cluster and WP6 were assigned the tasks *of proposing or identifying innovative approaches to the topic* and *scenarios for EU collaboration, reflecting also* no doubt the scenarios explored at the end of the EMPATHiE project and the concrete policy proposals required from the PiSCE project, which would be known prior to the seven months of this phase.

Phase 4: The final phase would be managed by the WP1 team, who, as well as providing overall leadership, would handle, in the last seven months of the project, *the strategy for dissemination, as well as organising and delivering a closing/concluding conference which would present the outcome of the work* and be convened as specified in the tender call. It is expected that feedback from the conference will contribute to the contents of the final report, which would be completed by the WP1 team and would also contain evidence of the effectiveness of the dissemination strategy.

5. Added value of our proposal

This project has significant added value for the European society in general and in particular for people living with one or more long-term conditions. The importance of developing effective strategies for promoting self-care by patients and citizens is growing, as governments seek to develop healthcare systems that guarantee high quality care whilst facing the challenges of ageing populations, increase in chronic diseases and rapid technological development in the context of constrained finances.

5.1. Adequacy of the proposal with social, cultural and political context

Patient empowerment and self-management in chronic diseases is a cross cutting challenge that affects society, health professionals, the medical technology industry and political life through the government budgets dedicated to the healthcare systems. According to the WHO Health 2020 Strategy, all countries have to adapt to changing demography and patterns of disease, especially mental health challenges, chronic diseases and conditions related to ageing.

The qualitative Eurobarometer on patient involvement found that attitudes of citizens and professionals towards patients' involvement in their own care vary significantly between different regions of the EU. Similarly, the EMPATHiE study identified the attitudes of health professionals as a major barrier to patient empowerment. Cultural differences across European member states are addressed more fully in section 5.2. (below).

In attempting to shift the attitudes, knowledge and skills of both citizens and health professionals towards a different model of working together, which can improve effectiveness of treatment and the prevention of deterioration and reduce the costs to the EU healthcare systems, this project like those preceding it aspires to contribute to that adaptation.

Innovative solutions provided by new technology can also play their part, not via reinforcing established practices – rather by creating better ways of working which include more access of patients to their health data through tools which support them in being less dependent on professionals. Professionals will need to re-examine their roles, which also may have economic benefits.

The proposal recognises these additional issues, which are not solely in the control of policymakers or those delivering healthcare. Mobile Health is one striking example of a new element in the equation of self-management which is much more bottom-up in its development, and such emerging and less predictable factors will be borne in mind.

Key to this positive shift of focus and in promoting the engagement of patients/citizens in that change, is the involvement of them and their representatives at all stages of the change process. This consortium is led by an umbrella patient organisation, a cross-disease European NGO that represents 65 patient organisations across the EU, is active in the patient's rights field, health literacy, and is currently engaged in a Europe-wide campaign on patient empowerment. EPF's membership includes patient organisations in most of the specific disease-areas addressed in this tender: chronic metabolic, gastrointestinal, dermatologic and respiratory diseases. In addition, through their national platforms chronic cardiovascular and circulatory diseases can be addressed. With this leadership, the role of patient involvement from grass roots to the European policy level will be at

the centre of our work.

5.2. Pertinence of geographical coverage

Health systems in Europe, although based on similar fundamental principles (e.g. universal access, equity), vary significantly in the way they are structured and their state of development, which is affected by political, economic and cultural factors related to the size, position and history of that country. The five Consortium members represent Member States that have shown leadership in the field of self-care and patient empowerment: the UK, the Netherlands, Denmark, Spain and Italy (EIP-AHA B3 Action Group, compendium of good practices; PASQ Joint Action repository of good practices, www.pasq.eu/Wiki.aspx). However, for policy recommendations to have any force, in terms of potential for effectiveness, they would need to take into account factors that represent barriers to progress in different health systems, and in order to do this knowledge of what is happening in these environments is needed. For example, The HLS-EU survey showed striking differences between the Member States from "Eastern" and "Western" regions of the EU. The mapping study on patient's rights, being carried out by the European Observatory and Maastricht University, is likely to underline this point in its conclusions.

Rather than having a wide geographic spread represented within the Consortium itself, as was the case in EMPATHiE and PiSCE, we have chosen to have a smaller but highly experienced group leading the project. The tender consortium has the advantage of extensive networks reaching across the EU and beyond, which will enable us to establish connections with "champion" medical professionals, self-care experts, policy-makers and others in different Member States of the EU, who are committed to changing the culture in their particular countries and regions.

In addition, we will ensure that our knowledge and the attention we pay to geographic and cultural differences is enhanced in the selection of members to the Expert platform. We know that real expertise in the chronic disease field is spread widely across Europe, from working with colleagues currently engaged in the CHRODIS Joint Action, e.g. from Member States such as Lithuania, Slovenia etc., and are confident that the coverage issue will be dealt with very well in this way.

5.3. Adding modified requirements to the tender delivery

Although mental health was not identified separately as one of the main groups of chronic diseases when the tender was issued, we are well aware of the impact that chronic mental health makes on wellbeing, employment and health resources and this was well recognised in the formulation of the EC work plan for public health 2008-13. Mental health examples were represented in the good practice examples provided by the literature review, WP1 of the EMPATHiE project. This is an issue, were we to be successful in the tender bid that could be discussed at the kick-off meeting with the Commission.

The other two elements not referred to in the tender specification have already been addressed in section 3, above. We would intend to incorporate into the thinking behind our delivery of the required variables, knowledge of what is currently happening in the health literacy field, as we see it as so relevant to the success of what we are being asked to propose and a similar argument applies to on-going work in the fields of eHealth and mHealth.

6. Project development

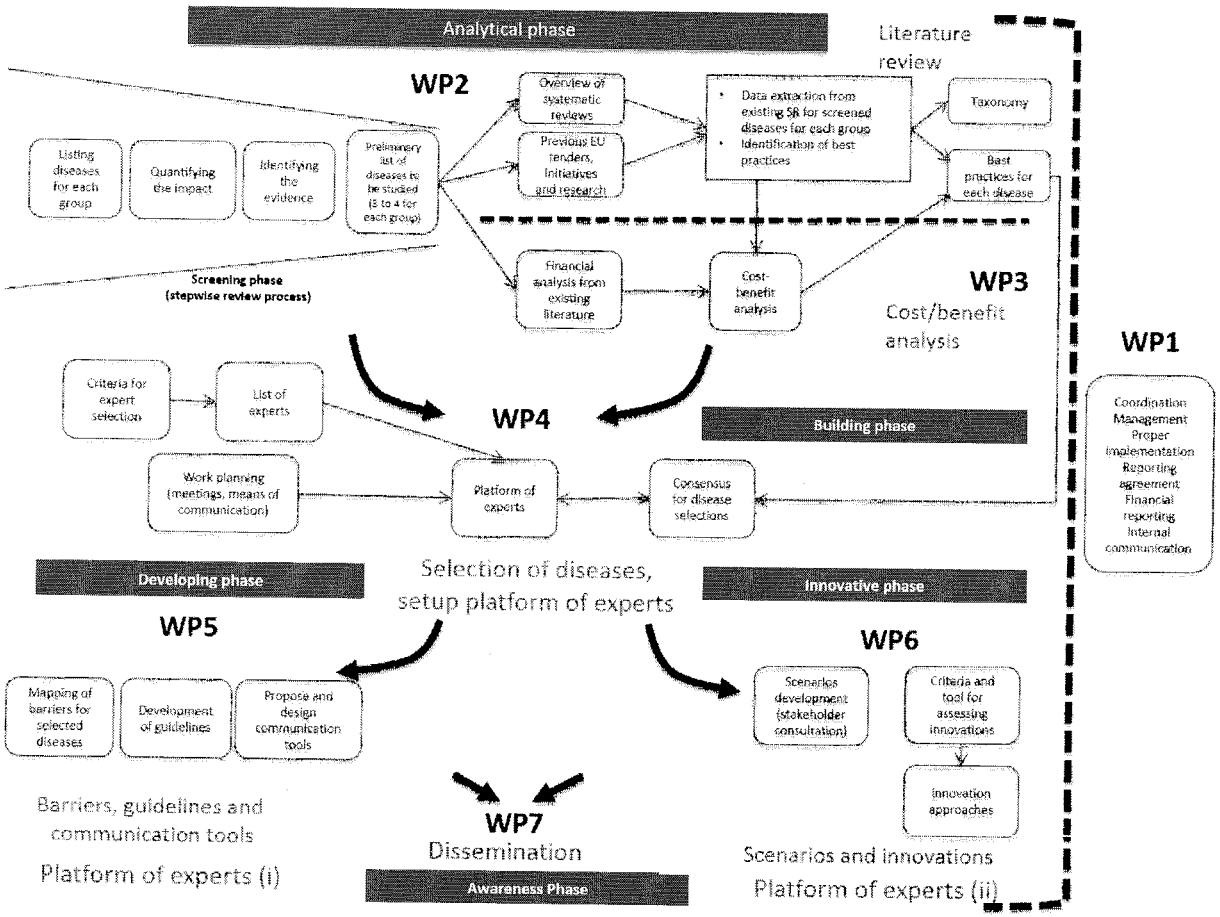
6.1. Overview of the project structure and interactions

The project structure aims to maximise the synergies between the work of the different partners and work packages and is structured in seven work packages, representing broadly four phases:

1. Analysis phase:
   - WP2 Literature review
   - WP3 Cost-benefit analysis
2. Selection phase:
   - WP4 Selection of diseases, and setting up the Platform of Experts and its work plan
3. Execution phase:
   - WP5 Guidelines on policymakers, mapping of barriers, communication tools to promote self-care
   - WP6 Innovative practices and scenarios for EU collaboration
4. Dissemination phase:
   - WP7 Closing conference and dissemination strategy

For optimum effectiveness and efficiency, project management is structured as a cross-cutting work package of its own. See detailed description of WP1. *Figure 6.1* (overleaf) demonstrates the flow and inter-relations of the work packages.

Fig.6.1 Overview of the project structure



6.2. Work package 1: Project management

Work package title: Project management

Start Month number: 1

End Month number: 24

Duration in number of months: 24

Work package leader: EPF

Partners involved: EHFF, FAD, DCHE, and iMTA

Description of the work package

Actions undertaken to manage the project effectively and make sure that it is implemented as planned, including financial management.

Scope and objectives

The objectives of WP1 are to ensure smooth operation of all aspects of the project and proper implementation of the contract; to comply with the provisions of the contract and Consortium Agreements in respect of reporting, including financial reporting; to manage internal communications and ensure the timely organisation of consortium meetings; and to monitor the progress and quality of the project.

Proper delivery on all aspects of the project is to be assured by the management team, as is compliance with provisions of the contract and the Consortium Agreement. Management also covers internal communications including meetings; governance, including chairing of the steering committee; planning; tasks coordination; internal progress monitoring and managing eventual risks; financial management including distribution of payments; and timely reporting to the European Commission.

Proposed methodology and work process

EPF is responsible for the project management, including reporting, and management of the platform of experts jointly with EHFF. In consultation with DG SANTE, EPF will ensure an excellent administrative handling of the project. EPF will also take care of external communication and is coordinating WP 7 (dissemination of results).

The main management requirements for the successful completion of the project are described in this chapter:

- Team composition, capacities and responsibilities
- Governance and management structure
- Work plan
- Risk analysis and control mechanisms
- Meetings and communication with the contracting authority

- External communication

The first and second parts of the project focus on the study (literature review and cost-benefit analysis), based on which in the second phase, specific diseases will be selected and the platform of experts put in place. The third phase focuses on coordination of the work of the experts resulting in the deliverables. The fourth phase of the project focuses on dissemination of the results and organisation of the final conference.

Reasons for methodological choices

The methodology of this work packages is based on EPF's strong track record gained over ten years both as participant (partner) in and the leader or coordinator of several EU projects funded under the Health Programmes, the 7th Framework Programme, Horizon 2020 and other programmes – EPF was the project leader in "Value+" on patient involvement, "Chain of Trust" on eHealth; "EMPATHY: Europe meets Young Patients" under the Youth in Action programme; and "EUPATI" , The European Patient Academy on Therapeutic Innovation, under the IMI-JU. In addition, we are or have been partners in the European Union Network for Patient Safety and Quality of Care (PaSQ); the Joint Action on Chronic Diseases (CHRODIS); WE CARE- Towards Sustainable and Affordable Healthcare; InterQuality- International Research on Financing Quality in Healthcare; SmartCare – Delivering integrated eCare; ERASMUS+ project on young patients' empowerment: eHGI; Renewing Health; and SUSTAINS. The methodology also benefits from the fact that the same partner (EPF) is responsible for managing the overall project and the important WP7 on dissemination, which will ensure maximum synergies between these work packages.

Team composition and capacities

The level of expertise in the composition of the project team and the quality of the collaboration with the experts is a key aspect of quality. Our consortium is composed of 5 organisations with extensive experience in carrying out European projects and in influencing policy-making at both the national and European levels. Their expertise covers areas such as health promotion, health literacy and health education, self-care, self-management, patient empowerment, quality of care, translating research to practice, and scenario planning and policy making.

A brief summary of the expertise that these organisations deliver to the project is given below.

Organisation	*Mission and core business*
The European Patients' Forum (EPF)	The European Patients' Forum 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 in the EU. EPF currently represents 65 members, which are national coalitions of patients organisations and disease-specific patient organisations working at European level. 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-centred 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' organisations and non-discrimination. EPF is involved in many European initiatives, platforms and projects, including the European Commission Expert Group on Patient Safety and Quality of Care; the Joint Actions CHRODIS and PaSQ; SmartCare and WeCare (integrated care), PiSCE (self-care in minor conditions) and SUSTAINS (eHealth and patient empowerment). EPF is a member of ENOPE, the European Network on Patient Empowerment which focuses on evidence-based programmes for chronic disease self-management and capacity-building.
The European Health Futures Forum (EHFF)	The European Health Futures Forum is a non-government organisation, constituted in March 2013. It is 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 inter-generational community of healthcare innovators. Specifically in relation to patient empowerment and self-care, the organisation led the setting up of the EMPATHiE network, which bid for involvement in the EIP on AHA and has been active within the B3 (integrated care) Action area, offering expertise on patient empowerment. EHFF supported FAD in managing the EMPATHiE tender on patient empowerment in chronic diseases and is also a collaborating partner in the JA on workforce planning (horizon scanning WP) and in the JA on chronic diseases. Currently it participates in the steering committee of the PiSCE tender and is involved in several consortium bids related to empowerment of patients through use of eHealth tools.
Fundacion Avedis Donabedian para la mejora de la Calidad (FAD)	FAD's mission is collaborating with health and social care professionals, organisations, public's institutions and professionals and citizens associations to improve the quality of the health and social care. FAD has been participating in many projects related with chronic care and health care integration. These projects have been related with the field of patient safety and assessment, clinical indicators both in health and social care and patients and citizens empowerment. A highlight is the evaluation of Primary Care reform in Catalonia, including more than 100 indicators. FAD is currently part of the Spanish Network of Health Services and Chronicity (REDISSEC). FAD has participated in several European projects, being the leader of the EU research projects MARQuIS and DUQUE on effectiveness of quality mechanisms (including patients' safety and patients' empowerment) (6th and 7th framework. FAD has also participated as partner in HANDOVER (7th FM) and PATIENT (Erasmus). FAD led the Consortium for the EMPATHiE-project. FAD has wide experience in professional consensus and supporting professional change strategies. FAD also conducts its main strategic activity in the social area including different initiatives related to patient rights.

The Danish Committee for Health Education (DCHE)	The Danish Committee for Health Education represents all public organisations and unions of all the health care professionals in the health care system, DK. The Committee is the only organisation in Denmark that develops, evaluates and implements evidence-based healthcare interventions in the Danish healthcare system within the area of patient empowerment, focusing on patient education and self-management programmes. The work is carried out in collaboration with the National Board of Health. The Committee implements evidence-based programmes from other countries. An example is the Chronic Disease Self-Management Programme from Stanford University that has been implemented in 71 of 98 municipalities in DK by the Committee within a 3 year period. In the area of Patient Empowerment the Committee works as an advisor for the Ministry of Health and the National Board of Health as well as the Committee contribute to national Health Technology Assessments and national guidelines on the area. The Committee is the chair of the National group on patient education and one of the founders of the European Network of Patient Empowerment (ENOPE).
Institute for Medical Technology Assessment (iMTA)	Since its foundation in 1988, iMTA has played a key role in HTA research in the Netherlands, in Europe and worldwide. iMTA offers expertise in economic evaluation, cost analysis, and outcomes research and is dedicated to the use of cost-effectiveness information in healthcare decision making. Its staff consists of about 40 scientists from different disciplines, including economics, econometrics, medicine, psychology, epidemiology, mathematics and pharmacy. iMTA was at the forefront of developments in the societal perspective for economic evaluation in health, including the development of the friction cost-method for productivity losses, (Koopmanschap, 1995) measurement of presenteeism (Brouwer, 1999), questionnaire development for productivity losses (Bouwmans, 2013), measurement of caregiver costs and burden (Hoefman 2013) including specifically developed questionnaires to measure these items (the iMTA valuation of informal care questionnaire, including the CarerQoL, Brouwer, 2006, Hoefman 2011). iMTA is based at Erasmus University of Rotterdam.

The capacity of the representatives of the organisations involved in carrying out the work in this project complies with the required capacities as stated in the Tender specifications. A CV of each participating organisation is provided in the Administrative part. All team members have a proven adequate working knowledge of English, as is specified in their CVs and for the lead partners in the table below.

Table 6.1: English proficiency of leading team members

Name	UNDERSTANDING		SPEAKING		WRITING
	Listening	Reading	Spoken interaction	Spoken production	
Nicola Bedlington (EPF, Leader)	C2	C2	C2	C2	C2
Kaisa Immonen-Charalambous (EPF)	C2	C2	C2	C2	C2
David Somekh (EHFF)	C2	C2	C2	C2	C2
Rosa Sunol (FAD)	C2	C2	C2	C2	C2
Carola Orrego (FAD)	C1	C1	C2	C2	C1
Lars Munter (DCHE)	C2	C2	C2	C2	C2
Job van Exel (iMTA)	C2	C2	C2	C2	C2

Table 6.2: Capacity of key consortium members

	Developing and/or implementing self-care strategies	Patient rights	Collaborating with health professional	Work at EU level in the area of health	Health economics	Organising and running EU conferences and working groups	Journalism and/or communication
Nicola Bedlington /EPF (leader)		x	x	X		x	x
Kaisa Immonen-Charalambous /EPF		x	x	X		x	x
Valentina Strammiello/EPF		x	x	X		x	x
David Somekh /EHFF	x		x	X		x	
Rosa Sunol /FAD	x	x	x	X		x	
Carola Orrego/FAD	x		x	X		x	
Job van Exel /iMTA				X	x		
Lars Munter /DCHE	x		x	X		x	x

Management structure

Project leader

The leader of this project is Nicola Bedlington, Secretary- General of the European Patients' Forum (EPF). She has over a decade of experience in the field of public health and especially on the rights of

patients and people with disabilities. She has overseen numerous European projects and has extensive experience in policy development, high-level negotiation and conflict resolution.

EPF is assisted in the coordination, for advice and support in collecting, reviewing and submitting the interim and final reports and associated documents and forms to the European Commission as required in the contract, by Dr David Somekh of the European Health Futures Forum (EHFF).

The project leader is responsible for:

- Chairing the project Steering Committee (SC)
- Acting as the primary contact with the European Commission for all formal written and verbal communication on behalf of the consortium, including the coordination of administrative and financial requirements
- Coordinating of external communication in consultation with the European Commission
- Collecting, reviewing and submitting the interim and final reports and associated documents and forms to a the European Commission as required in the contract
- Organising the meetings and agenda for the SC, acting as the primary contact between WP leaders
- Overseeing the distribution of the interim payments to the partners as agreed in the Consortium Agreement.

A ***project support office*** is set up at the site of the project leader. The project support office consists of the project leader, a project officer, a senior policy adviser, an administrative assistant and a financial controller (head of office). The primary task of the support office is to assist the leader in the financial, technical and administrative management of the consortium. It will supply advice, prepare documents, obtain information and documents from participants (and other parties), and act as point of contact for information flows and queries. For the delivery of the dissemination strategy and final conference, the office will be expanded with team members having events management and communications expertise. The financial controller will assist the project leader in the budget monitoring and the financial reporting to the European Commission and will be available to the consortium for questions of a financial/budgetary nature.

Work package leaders

All work package leaders collectively work with the project leader in ensuring that the objectives of the project as a whole are met. The appointed work package leaders for each work package are primarily responsible for the coordination of the work, including the organisation of technical meetings as required, reporting work in progress to the project management, preparation and submission of the technical deliverables and reporting (major) changes to the project plan. WP leaders organise communication and exchange of knowledge and documents regarding their WP with the project partners and experts involved. In case of new insights or problems that require alterations in the planning and execution of activities, WP leaders are responsible for proposing adequate changes within the work package schedule and possible reallocation of responsibilities and reporting it to the Steering Committee (SC). Problems that cannot be resolved within the work package, are reported to the project leader, who will undertake appropriate actions to resolve the problem.

Experts involved in the panel of experts have an important role to play in the delivery of the work:

the role is described under WP4. Experts are also invited to give advice on all the work within the project that could benefit from their input.

Governance and decision-making

In order to ensure the delivery of the deliverables within the agreed budget, timeframe and the required quality, an adequate management structure is proposed to distinguish the various management activities and responsibilities within this contract and to ensure a smooth process in carrying out the work by the WPs and the reporting to DG SANTE. Consequently, a clear division of internal responsibility and decision-making levels within the consortium is required and a system for monitoring the progress of the work in the WPs must be put in place.

All WP leaders together form the project's ***Steering Committee*** *(SC),* which reflects the consortium's collective experience in carrying out European projects and the required expertise. The SC is chaired by the Project Leader and is the highest decision-making unit within the consortium. Its main responsibility is to ensure the correct implementation of the contract with the European Commission. Specifically, the steering committee decides over the following issues:

- Quality assurance: the SC agrees on the completeness and quality of all formal reports to the European Commission and ensures that a good validation of reports takes place.
- List of nominated experts and consortium composition: steering members will collectively agree on the list of nominated experts for the platform which will be submitted to DG SANTE.
- Corrective measures: the SC is responsible for identification of and corrective measures to (including termination of defaulting partners and partners' tasks modification).
- Disputes: in case of dispute between two or more partners, the SC decides on any resolving measures.
- Changes in technical reports: in case of major deviations in the course or objectives of the activities that require consulting with the European Commission.
- Changes in the Consortium Agreement: in case of changes in the rights and obligations of the partners and/or decision-making procedures that necessitate amendments in the consortium agreement.

The SC takes major decisions regarding the direction and progress of the project. Decisions are taken in a collaborative manner and unanimously wherever possible. In case unanimity is not achieved through discussions, the project leader is responsible for taking the decision.

Consortium agreement

A consortium agreement describing the co-operation and project coordination will be developed at the start of the project. This will include for example voting procedures, veto rights, representations in meetings and agreed procedures for distributing meeting documents, reports and other products of the project. It will also include the details of financial management of the project.

Financial management

As project leader, EPF will be responsible for financial management. This will include administration of the interim and final payments linked to the completion and approval by the EC of specific deliverables:

M6 first payment, linked to approval of interim report 1

M10 second payment, linked to approval of Interim report 3
M17 third payment, linked to approval of Interim report 5
M24 final payment, linked to approval of final report

EPF will also handle the reimbursement of individual experts participating in the Panel of Experts; reimbursement of costs related to the working meetings of the Panel and meetings of the Steering Group; and all costs related to the final the conference, including subcontracting where relevant. EPF will fulfil these responsibilities based on our strong track record in sound financial management, principles of efficiency, transparency and equal treatment of potential contractors including avoidance of any conflict of interest.

Meetings with the contracting authority

In order to be of maximum value to the European Commission, a continuous consultation takes place between the management of the project and DG SANTE. All communication towards DG SANTE will be directed through the project Leader.

It is expected that after the kick-off meeting, presentation of the interim reports and other discussions will be managed through videoconferencing, unless otherwise requested by DG SANTE. DG SANTE will be invited to provide advice and feedback to the project team during the course of the project. This will take place both through (formal) reporting to DG SANTE and via informal ways of communication (mail, telephone or video conferences).

Internal and external communication

In addition to the kick-off meeting, the SC will meet physically during the working meetings of the Panel of Experts and at the final conference. A face-to-face meeting will take place once during the second phase of the project, to decide the selection of specific diseases and choice of experts to be invited on the Platform. Meetings will be prepared by the leader, including the timely distribution of the agenda and supporting documents.

Internal monitoring and updates through the organisation of monthly teleconferences (TC) or web meetings ensure that the project is being implemented as planned and reaches its objectives. Internal reporting and review of project progress will be undertaken in good time before submission of interim reports to DG SANTE. The Internet-based communication platform will be used to ensure internal flow of documents and information. When necessary, an extra face-to-face meeting will be scheduled.

This project aims to put in place a framework for action that is directed at supporting the broader implementation of effective self-care in chronic disease at the EU and national levels, complementing and building on previous work in this area. External communication will address all involved stakeholders, including the organisations involved in the consortium and in the expert panel, their wider networks, policy-makers at EU, national and local levels, and the scientific community. External communication during the project will be managed by the Project Leader in consultation with DG SANTE.

A specific Dissemination strategy will be developed to ensure the effective dissemination of the results of the project, including the final conference (WP7). The fact that WP7 and WP1 are led by the same consortium partner (EPF) will optimise coordination and synergies between these work

packages.

Risk management plan

A complex project involving seven work packages and approximately 20-25 experts giving important input in the different parts of the project and the validation of reports and deliverables, requires a risk management plan. Below are some risks we have anticipated (table).

Table 6.3: Risk analysis and contingency planning

Risk event	Probability	Impact	Contingency Plan
Lack of proper participation and voice of certain stakeholder groups/ experts in the platform	Medium	Medium-High	The consortium and its existing network from projects such as PiSCE and EMPATHiE provides a good starting point for setting up an expert platform. A separate Work Package (WP4) is designed to guarantee an adequate selection of motivated experts by developing criteria, seeking for additional expertise, etc.
Poor performance, delays in reporting or management issues of a particular partner	Low	High	All partners have proven experience and committed themselves to deliver the expertise for the project and take responsibility over the tasks as described in the management structure. Competent project management will anticipate any issues in advance so they can be resolved. In case of withdrawal of a partner or failure to accomplish, the others will cover their tasks.
Insufficient involvement of citizens and patients in the different WPs	Low	High	Each WP leader in consultation with EPF has explicitly looked at this risk and incorporated it in the methodology.
Lack of synergy between the Work packages	Low	High	Special attention is given to the facilitation of communication between the WP leaders, and the WP leaders and experts. This will take place in several ways such as a web-based meetings, plenary meetings, small group working meetings, etc. Previous experience in working together in similar projects (EMPATHiE, PiSCE) ensures smooth project coordination.
Underestimation in planning of human resources for specific tasks	Low	Medium	Timely identification of issues by WP leaders will ensure that case of any issues tasks can be re- assigned promptly and consequent re-allocation of resources will take place.

Serious underperformance of one of the beneficiaries	Low	Low	The Consortium Agreement caters for this situation and the corresponding clauses will be applied (warnings, and in case of prolonged underperformance, contract termination with the beneficiary concerned and reallocation of tasks and budget to another or a new beneficiary).
Lack of engagement by the experts in the work of the platform	Low	Medium-high	Each expert will be approached in a personal way. We will regularly check the experts are engaged with their tasks and with the wider group; and whether they feel fully informed, included, and are comfortable using the web based communication platform.
Insufficient and/or imbalanced participation in final conference	Medium	Medium	The planning for the final conference will ensure a balanced selection of stakeholders receive invitations; effective follow-up and support will maximise participation. Reimbursement of travel and accommodation costs will be a strong incentive, targeted particularly towards key stakeholder representatives. The conference programme will be designed to be attractive and stimulating.

Other possible risks will be continuously monitored through management coordination and in the Steering Committee and will be addressed immediately during the course of the project development. The Steering Committee is responsible for monitoring the progress and quality of the work and they will decide whether re-assignment of tasks and consequent re-allocation of resources is necessary. In case of withdrawal of one of the partners or failure to accomplish what has been agreed upon, the others will cover their tasks.

Partners have substantial collective experience in developing and delivering EU projects. The overall coordination is the responsibility of the project coordinator and the WP leaders, which are also responsible to assure the quality of the results of the activities. When an activity has finished the WP-leaders will review the results and deliver them to the project coordinator, who will review these results again before presenting it to the Commission.

Reporting and Deliverables

Reporting will be carried out and submitted to the Commission at each period or phase of the project. The reports will contain a description of the work that has been carried out and the results that have been obtained during the past period. The reports will also describe the possible effects of the results obtained on the overall work of the consortium partners in the project and a planning of the work for the following period.

Inception report (D0) – M1

An inception report will be delivered To DG SANTE within 10 working days after the kick-off meeting. The report shall include what was agreed during the kick-off meeting, including the work plan and timing.

Interim report 1 (D1) Study composed of a literature review and a cost-benefit analysis – M6

Interim report 1 contains the results of the literature review and the cost-benefit analysis of the self-care systems already in place in the EU in the six disease areas specified in the tender: chronic metabolic diseases; chronic gastro-intestinal diseases; chronic dermatologic diseases; chronic respiratory diseases; chronic cardiovascular diseases; and chronic circulatory diseases.

Interim report 2 (D2) Selected conditions – M7

Interim report 2 contains the selection of at least six diseases, duly justified, where self-care brings added value in terms of cost-benefits.

Interim report 3 (D3) Platform of experts – M10

Interim report 2 contains the composition of the proposed Platform of Experts; the CVs and main achievements/publications of each expert in the field of self-care or related fields, and a short explanation on the added value that their experience and/or knowledge can bring to the work of the platform. The report also includes a detailed work plan for the platform.

Interim report 4 (D4) Barriers, guideline, scenarios and communication tools – M17

Interim report 4 contains, for each of the selected diseases, the identification of any barriers that may hinder the development of self-care; guidelines for national and local policy makers on how to promote self-care; possible scenarios for EU collaboration; and communication tools to patients/consumers to improve prevention and disease management.

Interim report 5 (D5) Strategy for dissemination of results – M17

Interim report 5 contains a strategy to ensure the dissemination of results of the project at European, national and local levels; details concerning the organisation of the closing conference, including a Gantt chart for the administrative preparations; interaction with stakeholders and members of the platform, and the detailed communication plan for the conference.

Interim report 6 (D6) Dissemination of results – M22

Interim report 6 contains the implementation of the dissemination strategy and the results of the closing conference in Brussels.

Final report (D7) – M24

The final report encompasses the full study, including: an executive summary in English, French and German; an abstract of max. 200 words; a summary of the outcome of the closing conference; and the four interim reports. The draft report will be submitted to the Commission no later than 24 months after signature of the contract.

Resources required

The main resources required by this work package are mainly human resources:

- Project management expertise
- Financial management expertise
- Administrative resources
- Communication support for drafting of reports

In addition:

- Internet-based communication platform

Work plan (fig. 6.2)

			YEAR 1												YEAR 2											
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
WP1 – Project management	1.1	Consortium Agreement																								
	1.2	Kick-off meeting																								
	1.3	SC Teleconference/web-meeting																								
	1.4	Interim Report D1 - Literature review & CBA																								
	1.5	Interim report D2 - Selected conditions																								
	1.6	Interim report D3 - Platform of experts																								
	1.7	Interim report D4 - Barriers, guideline, scenarios, comm tools																								
	1.8.	Final Report to DG SANTE																								
WP2 – Literature review	2.1	Scoping the study																								
	2.2	Comprehensive review of systematic literature reviews from screened diseases																								
	2.3	In-depth review of previous related research at EU level																								
	2.4	identify and review key elements allowing to scale up best practices																								
	2.5	Interim report 1 providing the data for selecting the conditions for the PoE																								
	2.6	Refine lit.review and in-depth analysis based on the results of 2.4																								
	2.7	Further analysis of key elements allowing to scale up best practices																								
	2.8	Develop a taxonomy of existing good practices																								
WP3 – Cost-benefit analysis	3.1	Build detailed CBA structure parallel to awaiting results of WP2																								
	3.2	Receive description of interventions from literature review work-package																								
	3.3	Literature review on CBA specific input parameters																								
	3.4	Apply input parameters identified through literature research in Excel CBA																								
	3.5	Additional targeted search for missing variables in scientific/grey literature																								
	3.6	Conduct CBA for all long-list conditions & scenario analyses																								
	3.7	Rank order all long-list conditions of CBA result																								
	3.8	Contribute to Interim Report 1																								
	3.9	Respond to additional questions by the Commission on CBA related matters																								
WP4 – Platform of experts	4.1	Criteria for selection of diseases																								
	4.2	Definition of selection criteria for composition of Expert Platform																								
	4.3	List of potential experts and liaison re: availability, documentation																								
	4.4	Interim report D2 and agreemtn on final composition of the PoE																								
	4.5	First working conference of PoE																								
	4.6	Work of the PoE (see WP5, WP6)																								
	4.7	Second working conference of Expert Platform																								
WP5 – Barriers, Guidelines, communication	5.1	TC with Platform of experts																								
	5.2	Discussions on communication tools and needs for development																								
	5.3	Earlier draft version- Guidelines for Policy Makers, Barriers, Communication Tools																								
	5.4	Integrating comments, discussions via TC																								
	5.5	Guidelines for policy - full structure, Barriers-voting/grading, Early tool prsentation																								
	5.6	New draft version - policy, barriers, communication tools																								
	5.7	Pre final versions presented at 2nd working conference, new drafts																								
	5.8	Final review before closing conference - policies, barriers, communication tools																								
WP6 – EU scenarios, innovation	6.1	Consolidation of material for (a) scenarios and (b) innovation; development of criteria and rating tool for assessing value																								
	6.2	Preliminary allocation of core groups for the two tasks																								
	6.3	1st meeting of platform – agreement on core groups for tasks																								
	6.4	Agreement for new core group on definition of innovation & form of rating tool																								
	6.5	Scenarios: Phase 1 proposals for policy actions																								
	6.6	Collection of examples of innovation starts																								
	6.7	Scenarios: phase 2 proposals for policy actions																								
	6.8	Examples of innovation circulated to wider group																								
	6.9	Scenarios: final proposals for policy actions																								
	6.10.	Innovation: final rating and ranking of examples																								
	6.11	Delivery of Interim report 4																								
WP7 – Dissemination, conference	7.1	Development of visual identity (logo, templates)																								
	7.2	Wordpress webpage																								
	7.3	Promotional activities																								
	7.4	Interim report D5 – Strategy for dissemination																								
	7.5	Closing conference																								
	7.6	Follow up																								
	7.7	Interim report D6 – Dissemination of results																								

6.3. Work package 2: Literature review

Work package title: Extensive literature review of existing studies and data

Start Month number: 1

End Month number: 16

Duration in number of months: 16

Work package leader: FAD

Partners involved: EHFF, EPF, DCHE, iMTA

Description of the work package

Scope and objectives

The aim of this work package is to evaluate the scientific evidence on the added value of self-care, identify best practices already in place and the key elements allowing to scale up best practices in the selected areas of this call including: chronic metabolic diseases, chronic gastro-intestinal diseases, chronic dermatologic diseases, chronic respiratory diseases, chronic cardiovascular diseases and chronic circulatory diseases.

The alignment between WP2 and WP3 is an important part of the research activities prior to the first interim report. Prior to month three, WP3 will have designed the CBA structure and commenced a preliminary review on CBAs of self-care programmes in general. Before month three, WP2 will have screened a set of diseases for further research. After month three both teams (from WP2 and WP3) will agree on a common structure to identify and study interventions within the screened diseases. This structure will be used as input for WP2 and WP3 to identify interventions for further study into their cost to benefit ratio and effectiveness.

Proposed methodology for realisation of the objectives

This WP builds upon the methodologies used in previous projects EMPATHiE and PISCE, whose development w by the same members of this proposal, therefore building synergies from the previous work and further developing the approach and strategies used in those projects.

In this work-package we will identify the diseases (including conditions and chronic disorders) for which self-care can have the most added-value based on currently available evidence. Those diseases will be included in the extensive literature review of 1) articles published in peer-reviewed journals; 2) EU previous works carried out in the EMPATHiE and PiSCE project as well as the Action Group of Integrated Care (B3) of the European Innovation Partnership on Healthy Ageing (EIP-AHA); and 3) other research projects conducted so far at EU level. The literature review will be performed using overviews (reviews of systematic reviews), identifying practices with added value in terms of self-care and the best practices among those. We will carry out a content analysis centred on the key elements enabling to scale-up the identified best practices.

The results of this WP together with WP 3 (cost-benefit analysis) will support the selection of the six (or more) diseases, preferably one for each chronic disease-area mentioned previously, around

which the platform of experts will be selected and build its work.

Reason for the choice of methodology

A stepwise process is an efficient way to study a large number of diseases and prioritise the most relevant in term of their prevalence, burden for patients and health systems and the experts' consideration of the modifiability of the behaviours that would be targeted with a self-care practice.

An overview, or review of systematic reviews, is a useful methodology to synthesize a large amount of information. This allows a rapid examination of as well as a comprehensive analysis of reviews of interventions relevant for this project.

Directed content analysis will be useful to identify the key elements which allow scaling-up of the best practices to be considered for the further work packages on exploring and proposing methods on self-care. And, where the material is available, to identify and provide a narrative description of barriers and facilitators of studied interventions.

Work process

Task one: Scoping the study: diseases screening for each chronic disease-area

Each one of the selected chronic disease-areas for the call has a large number of chronic diseases that potentially could be included in this study. For example, metabolic disorders can include rare inherited diseases such as Tay-Sachs disease, hereditary fructose intolerance or Gaucher's disease or more frequent diseases such as diabetes type I and 2, conditions linked to alcohol abuse, kidney failure or gout.

In this task we will use a step-wise approach to identify chronic diseases that are potentially more effectively addressed with self-care to further analyse them in the in-depth literature review for each group. We envisage the following actions:

- To identify the chronic diseases in each chronic disease-area (including chronic conditions and chronic disorders and multi-morbidity profiles) through a review of clinical manuals and consultation with experts
- To identify the diseases potentially most effectively addressed by self-care practices for further review. Three or four diseases per chronic disease-area will be selected for the literature review based on the following key variables:
    - *Frequency of the disease/condition.*
    - *The disease burden.* We will use available data considering different variables to quantify the impact of the chronic conditions. To characterize the burden of each disease, we will use available indicators such as morbidity and mortality, mean age of onset of the disease and quality of life (quality and disability adjusted life years, if available).
    - *Available evidence. B*ased on key and Mesh terms, a structured search in Database of Abstracts of Reviews of Effects of Interventions (DARE) and MEDLINE (accessed through PubMed) will be performed in order to quantify the amount of literature available for each disease.

- *Modifiable behaviours in term of self-care.* Based on the literature scanning process and team criteria, each disease will be grouped in terms of the level of dependence between disease outcomes and self-care behaviours. (High, medium and low dependence on patient/caregivers behaviours) Self-care behaviours will include actions to prevent, diagnose and manage the studied chronic diseases.

A league table ("Prioritisation matrix") presenting the results for the above-mentioned key variables by disease will be prepared. An explicit scoring system will be developed to facilitate the data presentation and discussion.

Task 2. To perform a comprehensive review of systematic literature reviews for the pre-selected diseases

For each of the pre-selected diseases an individual overview of systematic literature reviews will be performed. This study design is a relatively recent tool of literature synthesis, designed to gather evidence from multiple systematic reviews of interventions within a single document for ease of use and access. The work will build on the previous EMPATHiE literature review, performed by the leader of the WP, using similar methodological approach and taking advantage of the already scanned evidence while complementing it with new articles and conditions.

Inclusion criteria:

- *Language:* No language restriction will be applied to this review. Systematic literature reviews in all EU languages will be included, if the abstract is available in English.
- *Publication date:* Systematic literature reviews published between 2002 and 2015.
- *Type of studies:* We will include systematic literature reviews that evaluate the effect of self-care interventions/methods and assess the impact of such interventions on at least one of the following key outcomes groups: clinical outcomes, cost/use of health services or patient reported outcomes.

  We will also consider as an inclusion/exclusion criterion the methodological quality of all systematic reviews. The methodological quality will be assessed with the *AMSTAR tool: A Measurement Tool to Assess Reviews* (Shea 2007). This instrument is an 11-item tool to assess the methodological quality of systematic reviews that has been internally and externally validated and it has proven its validity for assessing risk of bias in systematic reviews (Shea 2009).

  The scores resulting from the AMSTAR review will be recorded and taken into account first as an inclusion criterion, as only systematic reviews with lower risk of bias (AMSTAR> 5) will be included for the analysis. In addition the AMSTAR scores will aid in the development of the conclusions of the literature review and the prioritisation of the information.
- *Type of participants:* Systematic reviews in which the self-care practice was aimed at patients dealing with any (or multiple) of the pre-selected diseases, or at health care professionals working with those patients.
- *Type of interventions:* Systematic reviews of practices aiming to evaluate the effect of self-care interventions/practices related to the pre-selected chronic conditions, taking into

account different dimensions of self-care: self-prevention, self-diagnosis and self-management.

For the purpose of selecting systematic reviews, the definition of self-care included in the tender specification will be used:

"What individuals, families and communities do with the intention to promote, maintain, or restore health and to cope with illness and disability with or without the support of health professionals such as pharmacists, doctors, dentists and nurses. It includes but is not limited to self-prevention, self-diagnosis, self-medication and self-management of illness and disability." (UK Dept. of Health, 2005)

Interventions being carried out at any level of care (community care, primary care, hospital or long-term care) will be included.

- *Type of outcomes: as self-care can potentially have an* **added value in self-care** in several types of outcomes the inclusion criteria will be adapted accordingly. Therefore systematic reviews that present results in at least one of the stated key outcomes:
    - Patient empowerment measures (ex. self-efficacy, Health literacy level, patient activation)
    - Quality of life measures
    - Clinical outcomes (ex. mortality, morbidity, labs results, symptoms and signs)
    - Cost/use of health services (ex. Cost, Length of stay, number of visits, ED consultations)

Search Sources

The proposes overview will include systematic reviews published in The Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects of Interventions (DARE), MEDLINE (accessed through PubMed), CINAHL.

Search strategy

A Boolean search strategy for PubMed will be performed, including keywords for patient self-care and chronic care (presented below using the PICO framework). This strategy will include keywords of text words and Medical Subject Headings (MESH terms) as well as search operators. The keywords will aim at a broad search in order to ensure that all relevant systematic reviews are detected. Following this goal the keywords used will refer to the different aspects of self-care (including at least self-care, self-prevention, self-diagnosis, self-medication and self-management) as well as key words related to the selected diseases for the review.

Those keywords will be searched in the titles of the systematic reviews and/or abstracts.

The structure of the search for PubMed will be adapted for other databases.

Figure 6.3: Keyword for the search strategy: PICO table

Patient or Problem	Intervention (at least are the following)	Comparison	Outcomes (at least are the following)
Key words related to the selected 3-4 diseases per chronic area.	Key words related to self-care including at least: Self-care Self-prevention Self-diagnosis Self-medication Key words for interventions oriented to enhance self-care: Knowledge and attitudes (Education, written information,..) Behavioural change (virtual support, decision aids, incentives, self-monitoring, e-health, virtual support..) Professional change: incentives, multidisciplinary teams, monitoring performance..)	Not restricted by comparison group	○ Clinical Outcomes ○ Cost/Use of Health Services (ER, Cost, time...) ○ Patient empowerment level ○ Quality of life

Data extraction

The systematic reviews identified in the search will be scanned following the inclusion criteria. The references of the selected systematic review will be registered in a database to organise information. From these systematic reviews, full text will be extracted for a thorough analysis.

For all the systematic reviews that meet the inclusion criteria, there will be a data extraction of its main features. A data extraction table will be built combining both information on the systematic reviews (reference, information on the research process and methodological quality) and information on the interventions reported in the systematic review (patients/professionals targeted, description of the programme, reported outcomes and other variables of interest).

As a guide, the data extracted would include at least:

- Disease/s or condition/s for which the intervention is implemented
- Type of the evaluated intervention/s
- Objective
- Inclusion criteria for the individual studies
- Search date
- Methodological quality of the systematic review (Amstar)
- Information on the included studies (number, number of participants, country/ies of implementation...)
- Patient characteristics
- Description on the self-care interventions
- Outcome variables of interest
- Major results and conclusions.

The results of the described analysis will be presented in summary tables and via detailed narrative description.

Task 3. To perform an in-depth review of previous related DG SANCO Tenders EMPATHiE and PISCE, Action group of Integrated care (B3) of the European Innovation Partnership on Active and Healthy Ageing (EIP-AHA) and other research and initiatives at EU level related to self-care of chronic conditions

The consortium which is presenting this proposal includes the PiSCE main partners and EMPATHiE coordinators and key partners. Thanks to the experience of the leaders and partners of this proposal in both EMPATHiE and PiSCE projects we will be able to take full advantage of the methodologies and results previously obtained. On that basis will be able to update, complement and amplify the review of relevant European experiences.

The objective of this review will be to complement information for the scaling up from one country to another for the studied interventions.

This extension of the review of European initiatives will include a desk review of at least the following initiatives:

- Activities of the different groups of the European Innovation Partnership on Active and Healthy Aging and especially the good practices provided by the Action Group for prevention of functional decline and frailty (A3) and the Action Group for Integrated Care for Chronic Diseases (B3)
- The results of the Joint Action addressing chronic diseases and promoting healthy ageing across the life cycle (CHRODIS-JA 2014) as well as other EU joint actions partially addressing chronic care: such as the Joint Action on Patient Safety and Quality (PaSQ)
- Research projects under Horizon 2020 and 7th Framework linked to chronic care management (e.g. the CARRE project: patients manage their chronic heart and kidney disease, Smartcare),
- We will also link to integrated care initiatives reported in The European Files (July 2014) to identify self-care initiatives (https://webgate.ec.europa.eu/eipaha/initiative/index/show/id/280) and ICT-initiatives linked to chronic care (INSPIRE, PALANTE etc.); http://www.palante-project.eu/home

Task 4. To identify and review key elements which allow scaling up of best practices

A mixed design process (qualitative and quantitative) will be used to analyse the selected best practices.

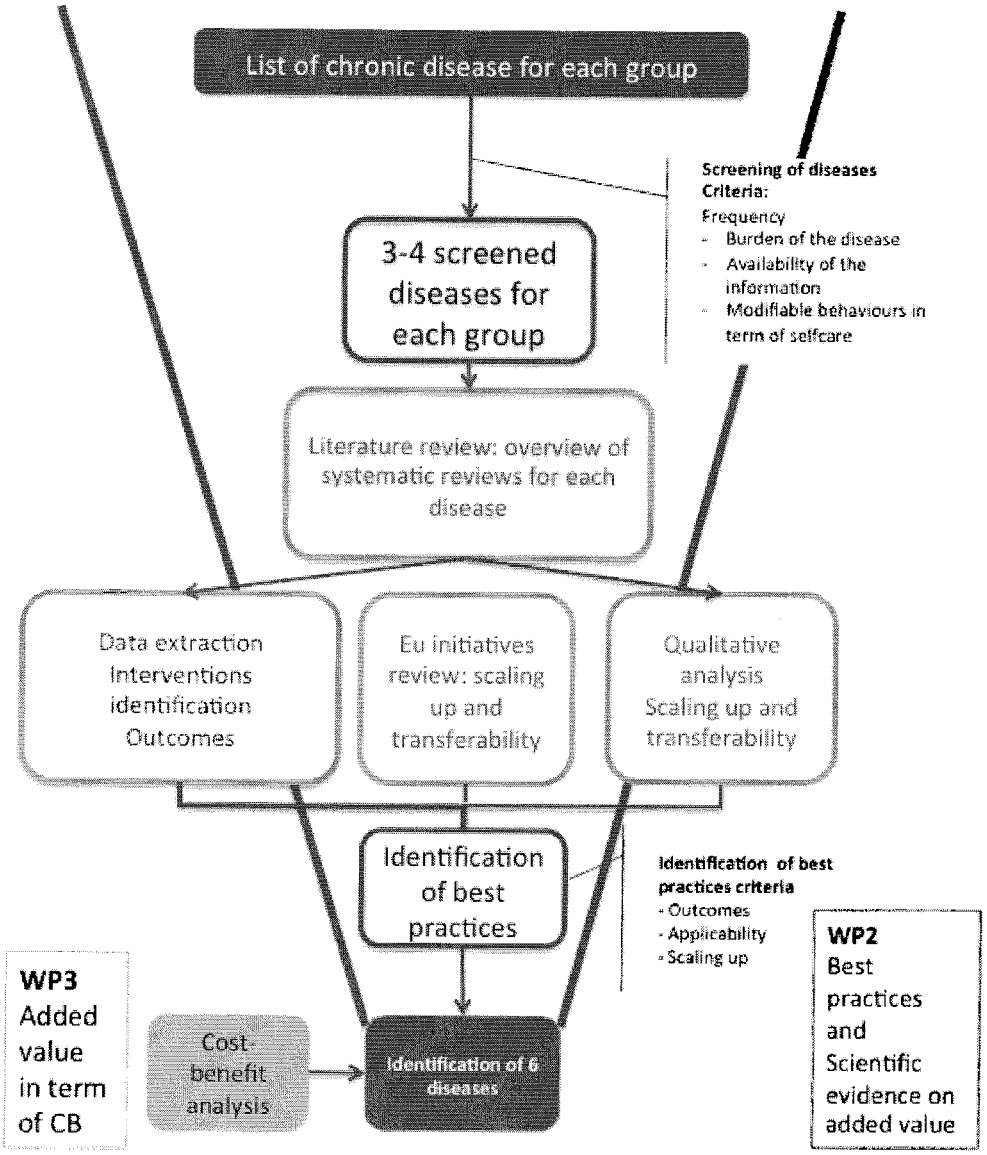
For the qualitative part, directed content analysis from the results and discussion will be performed. Coding categories (i.e. patient knowledge, intervention characteristics) will have been previously decided from the existing literature (including categories and variables used for EMPATHIE project). The content analysis will be focused on ***scaling up*** from one country to another and from one disease to another (variables of the implementation process, feasibility to be implemented in EU countries of lower incomes, etc.). This will be complemented with other *transferability* considerations (context, patient and professional characteristics, intervention characteristics, when available).

From results of this WP as well as WP-3 (cost-benefit analysis) we will present a proposal of key elements allowing to scale up best practices to be discussed in the expert platform.

In addition suggestions to facilitate the ease of scaling-up will be proposed and/or developed, such

as **a taxonomy of existing best practices** by taking into account the evidence of its results and break down by type of intervention and characteristics of disease. For the development of this task, our team will consider the existing classification developed for the EMPATHiE project as well as classification of good practices included in the Compilation of Good Practices of Action Group for Integrated Care for Chronic Diseases (B3). Different categories and dimensions could be included, covering elements such as: patient population, intervention recipient, intervention content, delivery personnel, method of communication (personal, e-health, IT systems), type of self-care behaviours, intensity and complexity, context, clinical outcomes, etc.

Figure 6.4 Schematic of WP2 processes



Task 5. Identification of best practices and their added value

The literature review and review of European research and initiatives will enable the identification of best practices related to self-care.

For the purposes of this project, and building on the previous EU projects on self-care and chronic diseases (EMPATHIE; JA-CHRODIS, etc.) the **best self-care practices** will be selected considering the criteria of outcomes, applicability (implementation) and scalability.

For these criteria, an evaluation using a 0 to 5 Likert scale will be performed to rank interventions and identified diseases where they "best" work and have most potential to be applicable and scalable to other diseases and other countries. Two independent members of the team will perform the evaluation.

- **Impact on outcomes** compared to usual care or other interventions. (Patient empowerment level, Quality of life measures, clinical outcomes, cost/use of health services). Practices will be better evaluated depending the number and type of outcomes (intermediate /short term outcome v/s final /long term outcomes)
- **Evidence to be scalable up within EU**. Based on the information gained from previous tasks (WP2, 3 and 4) specific variables will be considered to determine the level of scalability. (EU existing initiatives, experience in its development, number of countries where it has been applied).
- **Evidence for applicability and implementation** in the real life situation: Based on the information gained from previous tasks (WP2, 3 and 4) and the Good Practices on Patient empowerment matrix developed within the EMPATHiE project, specific variables will be taken into account to define the level of applicability (Disease characteristic, context, intervention characteristic, patient and professional characteristic). This analysis will be performed for those practices/interventions where outcomes had been evaluated as positives.

This information **("scientific evidence on added value")** will be combined with results from WP3 **(added value in terms of cost-benefit)** – see WP3- in order to facilitate the process of selecting the six conditions.

Task 6. Provide information to decide the six conditions to be included in the expert platform.

The information from the previous tasks will be summarised in tables for each disease and prepared to facilitate the discussion and the final decision process of selecting the six or more conditions.

Reporting and Deliverables

Results will be presented identifying the effect of each intervention evaluated for the outcome variables defined previously and presented in synthesised tables for each disease.

For each of the studied diseases, a list of effective practices and highlighted best practices will be structured taking into account their effectiveness, EU applicability, scaling-up potential and recommendations for implementation.

Calendar

M1-2

- Task 1: Scoping of chronic areas and pre-selection of diseases

M2-5

- Task 2: Comprehensive literature review of systematic reviews for the pre-selected diseases, identification of self-care added-value for the chronic areas
- Task 3: Review of previous related DG SANCO Tenders and related EU research
- Task 4: identify and review key elements allowing to scale up best practices (first part)
- Identify best practices and their added value

M6

- D1 – Interim report 1

M7-9

- Continuation task 4: refine literature review and key element to scaling-up of best practices

M 9-12

- Taxonomy of existing practices

M11

- First meeting of the platform of experts

M16

- Second meeting of the platform of experts

Resources required

The principal expenditures related to completion of this WP may be categorized under "Staff cost, travel subsistence and other cost":

Staff costs:

a) Design and implementation of search strategies
b) Reviewing of included studies
c) Quality assessment
d) Report development
e) Work management

Travel and subsistence:

a) Scheduled meetings

Other costs:

a) Payment for access to databases, handling and obtaining the results of relevant studies
b) Translation services for relevant studies in foreign languages (other than English and partners languages)

c) Obtaining relevant literature for the project (relevant studies and methodological bibliography)

References

http://epoc.cochrane.org/epoc-resources

Becker LA Oxman AD: *Chapter 22: Overviews of reviews*.

In *Cochrane Handbook for Systematic Reviews of Interventions Version 501* Edited by Higgins JPT, Green S. 2008.

Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration

Ryan RE, Hill S. Developing an overview of Cochrane systematic reviews: a framework for synthesising the evidence on interventions to improve people's involvement in healthcare. (Poster) XIII Cochrane Colloquium, Melbourne October 2005.

http://www.imbi.uni-freiburg.de/OJS/cca/index.php?journal=cca&page=article&op=view&path%5B%5D=1324

Shea BJ, Grimshaw JM, Wells GA, Boers M, Andersson N, Hamel C, Porter AC, Tugwell P, Moher D, Bouter LM. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. BMCMedical Research Methodology 2007;15(7):10.

Shea BJ, Hamel C, Wells GA, Bouter LM, Kristjansson E, Grimshaw J, Henry DA, Boers M. AMSTAR is a reliable and valid measurement tool to assess the methodological quality of systematic reviews. J Clin Epidemiol. 2009 [Epub ahead of print; PMID: 19230606].

6.4. Work package 3: Cost-benefit analysis

Work package number: WP3

Work package title: Cost-benefit analysis

Start Month number: 1

End Month number: 7

Duration in number of months: 7

Work package leader: iMTA

Partners involved: FAD, EPF, DCHE, EHFF

Description of the work package

The cost-benefit work package shall rank the selection of self-care interventions, which was generated in the literature study work-package according to the size of 'value added' from the patient and the health care perspective. We base this analysis on existing evidence gathered through literature study, we synthesize the outcomes using a common denominator (the DALY) and supplement missing data with expert opinion.

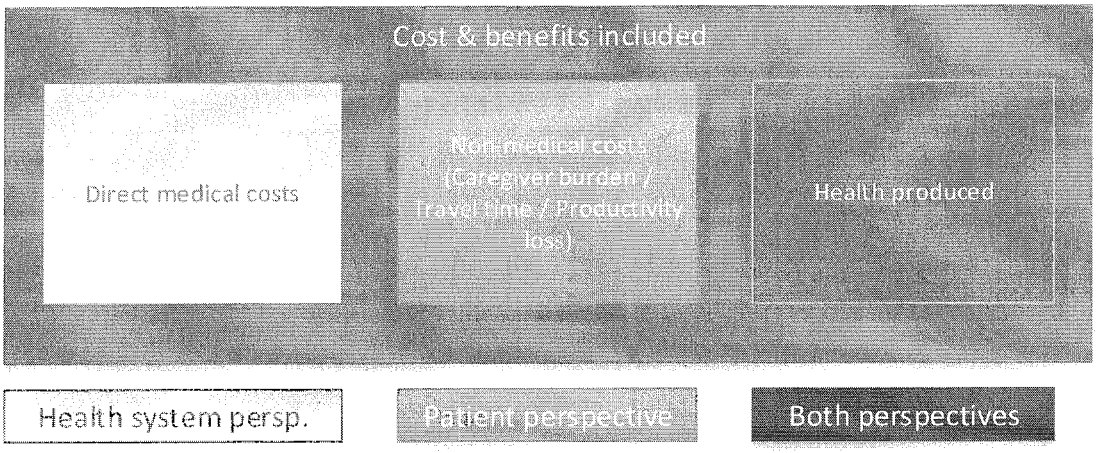
Scope and Objectives

The objective of this work package is to identify where self-care can bring added value within a long list of conditions in six disease areas identified in the tender call by ranking the self-care practices selected through the literature search and hence identifying those for which evidence of added value is available.

The scope is focussed on the health system perspective and the patient perspective as described below. The approach described here uses previously existing data where parameters are available, or generates new parameters based on combining existing parameters. For example, one may conceive the construction of average cost prices for patient time or the value of caregiver time.

We propose to start the cost-benefit work-package with a mutually agreed on systematic framework for cost-benefit analysis to be applied to all 6 chronic conditions to ensure maximum comparability. This will be the topic of discussion during the kick-off meeting, where the consortium will propose to use the framework described in the sections below and would be happy to receive comments from the Commission. The systematic framework shall have the generic properties captured in *figure 6.5* below.

Figure 6.5: systematic framework for CBA



An adequate scoping strategy requires consensus on the relevant costing categories. The scoping of these categories is described below.

Costing categories

There are several cost categories: direct medical costs and non-medical costs, described further below. Indirect medical costs in life years gained are not included in this CBA as they are not part of the call for tender and are currently still under discussion amongst health economists in several Member States.

Direct medical costs

Direct medical costs are most important for the health systems perspective. Medical costs unit prices are derived/calculated from the scientific literature, for which the research method is detailed further on, supplemented with expert opinion and publicly available sources such as EUROSTAT. Medication, devices and tests will be valued with market prices. When available in published CBA dossiers, prices will be taken from these studies. Volumes will be taken from public sources such as EUROSTAT, WHO CHOICE, or from peer-reviewed published literature.

Medical consumption categories consist of:

- Hospital admissions and length of stay
- Ambulatory care (e.g. GP visits)
- Medication use
- Use of (diagnostic) tests
- Use of medical devices

Non-medical costs

In this study, we adopt the terminology commonly used in health economics, where it is common to adopt a societal perspective in which both financial costs (direct medical costs within the health care budget) and non-financial costs (non-medical costs outside the health care budget) are included. Non-financial costs refer to those costs which are not direct cash-inflow/outflow that fall within the budget of the health care decision maker. Examples of non-medical costs that do not impact the health care budget but do impact society are informal care, productivity costs, health losses and travel and patient time.

Informal care. Informal care, where relevant, will be valued using the shadow price method, which means that substitution costs are used (i.e. the price of paid help).

Productivity losses. Absence from work, reduction in productive days due to illness (absenteeism) or reduced productivity while present (presenteeism) are part of productivity losses. Productivity losses will be valued from the perspective of the patient, being lost-wages. Wage rates will be corrected for age and gender.

Travel & patient time. Similar to productivity losses, the cost of the patient's time to travel for treatment or manage his or herself need to be calculated when adopting the patient perspective.

Health losses. The quantification of the health loss will be expressed in costs per disability adjusted life year avoided: a common denominator for different types of health loss in the different types of disease. This common denominator is required to be able to rank across diseases rather than within diseases and to avoid the politically sensitive issue of monetizing health benefits directly. This strategy is exemplified in *table 6.8,* on page 47.

Proposed methodology for realisation of the objectives

Task 1: Defining the framework

In a cost-benefit analysis (CBA), monetary units are used to assess if benefits outweigh costs to identify the preferable (policy) option, i.e. the option that improves the welfare of a society the most. Hence, the distinguishing element of CBA versus another policy evaluation instrument is that it captures all effects, including health effects, in monetary terms, i.e. a common comparator in the form of a single monetary unit to facilitate comparisons of policy options. If the benefits of a practice exceed the costs, there is a net social benefit in the practice (Drummond, 2005).

CBA, by default, compares two policy situations, one with the intervention/practice (self-care in this case) and one without, referred to as the base case. The base case situation is the 'usual care', e.g. health care services such as prescription medicines, GP visits, and day care (hospital visits). Note that the comparator 'usual care' is different in different countries.

Defining added value

The added value of a self-care programme as compared to usual care with monetized health outcomes is described with the following decision rule of equation 1):

$$\Delta B - \Delta C > 0 \qquad 1)$$

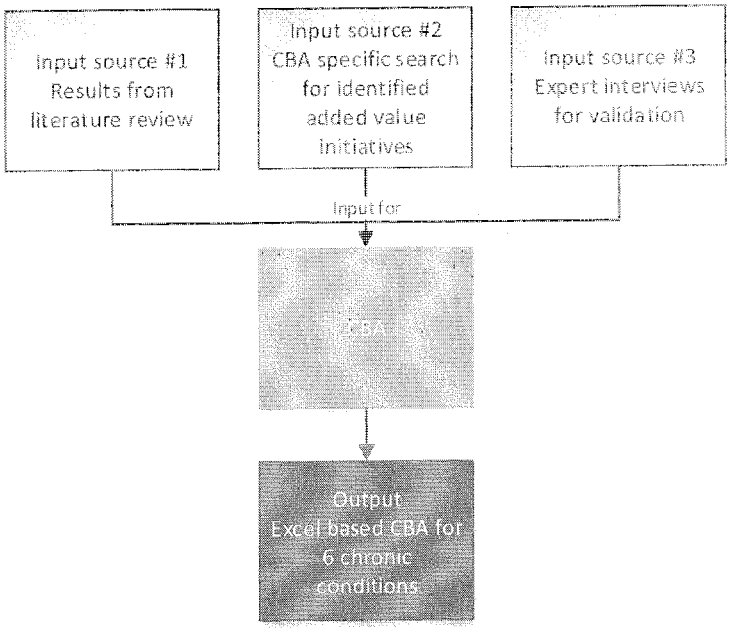
where ΔC describes the difference in costs of self-care compared to usual care and ΔB describes the difference in benefit. The result of the formula has to be larger than 0 to indicate added value, or net societal benefit. To compare effects now and in the future, discounting is usually applied. This means that net present value of future costs and benefits are calculated. By means of discounting an overall measure of profitability can be calculated. The outcome of the CBA can be subjected to a sensitivity/scenario analysis. Note that we will use the cost per DALY avoided method, which means that the benefit in the above decision rule is expressed in DALYs rather than direct monetary units.

Task 2 Calculating CBA for each one of the potential added-value diseases identified in WP2

The CBA will use input from the literature review task described in section 4.1.1.1 of the Call for Tender

supplemented with additional input from experts and concise literature searches to identify missing data as captured in the flow chart in *figure 6.6.*

Figure 6.6: Flow-chart of CBA



Approach to identifying additional information

The additional search will focus on health economic specific sources accessed through, for example, the TUFT CEA registry, and a systematic search in the scientific literature through PUBMED, NHS EED and MEDLINE. When insufficient data is available in existing cost-benefit studies, an additional search will be performed in the scientific and grey literature to identify missing parameters. In some instances contact will be sought with international experts through a questionnaire. Key words will resemble the following line (("Cost-benefit" OR "cost benefit") AND [disease area] AND [intervention]). The search will be conducted from publications since 2002 in at least 4 European languages (English, French, German and Dutch). If required by the Commission this language scope can be extended. When the literature is insufficient for identifying all required parameters, experts will be consulted through semi-structured interviews by telephone.

Search strategy

The employed search strategy will make use of the possibilities of the search operators such as AND, OR, NEAR. For an example, see table 6.7 below. The NEAR/10 operator searches key-words within 10 related words of the original search.

Table 6.7: Example of easily reproducible search strategy

		Number of publications per database	
Search for each database		ABI/Inform - EconLIT	Pubmed
Search #1	A NEAR/10 B	11,059	138,043
Search #2	C NEAR/10 D	17,042	40,164
Search #3	E NEAR/10 F	14,792	189,283
Search #4	G NEAR/10 H	4,020	19,788
Search #5	#1 AND (#3 OR #4)	386	5,973
Search #6	#2 AND (#3 OR #4)	852	3,532
Search #7	#5 AND #6	57	146

Output of CBA

We will provide, for each of the long-listed chronic diseases, the summarized output in a standard table as shown below (table 3.4) and this will be included in the rationale to be put to the Commission in WP4 for selection of the 6 or more diseases to be used as the basis for the work of the platform of experts. As the quantification of health benefit is politically sensitive, we propose an alternative approach that is more acceptable and includes expert opinion. First, based on the literature review we identify whether or not there is a health benefit associated with the self-care option. If there is, indeed a health benefit but increased costs from the perspective of the patient, the table outputs the key consequence, i.e. what the monetary value of the "health benefit" would have to be for it to have a positive net impact on the patient (this value equals the net health loss from the non-medical costs). Where possible, we will express this monetary value as cost-per DALY-avoided to have a uniform quantification of the health outcome, but we would like to note that this requires sufficient data on the effect size of the intervention/practice, which might require more data than is available for some of the self-care interventions.

Table 6.8: Output of CBA analysis for a hypothetical practice

Hypothetical example			
	Difference option 1 and option 2	**Option 1**	**Option 2**
Intervention		*Usual care*	*Self care program*
Direct medical costs			
Hospital admissions and length of stay	€ -23.400,00	€ 56.400,00	€ 33.000,00
Ambulatory care	€ 15.487,00	€ 50.400,00	€ 65.887,00
Medication	€ 500,00	€ 74.000,00	€ 74.500,00
Tests	-	-	-
Use of medical devices	-	-	-
DALY gained	€ 2,00		
Net benefit Direct medical costs	€ 7.413,00		
Non-medical costs	€ -		
Informal care	€ -	€ 15.600,00	€ 15.600,00
Productivity losses	€ -9.130,00	€ 542.000,00	€ 532.870,00
Travel time	€ -10.365,00	€ 14.365,00	€ 4.000,00
Patient time	€ 20.000,00	€ 15.000,00	€ 35.000,00
DALY gained	€ 2,00		
Net loss Non-medical costs	€ 505,00		
Benefit from health system perspective	€ 3.706,50		
Cost per DALY avoided patient perspective	€ 252,50		

Ranking of outcomes

Basic ranking

Based on the standardised cost-benefit table for each of the long-listed conditions, we can rank-order the conditions on their cost to benefit ratio in terms of cost per DALY avoided. We propose to colour-code the ranked conditions based on the data-quality underlying the CBA: red for poor data-quality, orange for sufficient but low data quality and green for sufficient data-quality. The data-quality of the parameter will be based on the study design characteristics, where case-reports are the lowest quality and randomized blinded controlled trials are the highest quality (note that in self-care interventions it is likely only possible to blind the data assessor, not the patient). This ranked list adjusted for quality will inform the selection of 6 conditions for further study.

Criteria based ranking

We supplement the basic ranking with criteria based ranking: not all elements in the cost-benefit analysis may receive equal weight. For example, from a health care system perspective we may want to attribute more weight to reducing hospitalisations, due to a normative assumption that more patient centred care in the first line (i.e. family doctors) is preferable. We will make explicit these criteria and discuss the desired weighting approach with the European Commission.

Reason for the proposed methodology

As mentioned before, the key contested issue of applying cost-benefit analysis in health care is the monetization of health benefits. There are several strategies for this quantification, rooted in welfare theory, of which willingness to pay (WTP) is one of the most common ones (Bobinac, 2010). However, the estimates for WTP studies are known to vary widely (Brazier, 2007). Alternatives are contingent valuation studies, or human capital approaches. All these approaches, however, require either some form of preference elicitation – not feasible in this study – or revealed preferences for which data often is not available. It is for this reason that we suggest to not directly value health but to use two approaches: the cost per DALY avoided and the, and to determine what the value of health would have to be in society in order for a practice to have 'added value'. Following the hypothetical example above: a practice that is EURO 505 more costly than the situation without the practice, but is judged by experts (and/or literature) to be more health improving than the alternative, the "added value of health" would have to equal EURO 505. This approach is less politically sensitive and more transparent in its valuation of health.

Work process

The staff working on the CBA will work closely together with the staff working on the literature review (WP2) as these two sections are closely intertwined. First of all, the literature review work-package will generate the long-list of conditions of potentially more "added-value" conditions on which CBA will be conducted. When these have been selected, the CBA staff will conduct an additional search to identify relevant parameters for the CBA such as medical costs with and without the self-care intervention, but also additional parameters for non-medical costs such as patients' travel costs and their time. The results of the CBA will be grouped with the literature review in the first interim report, which will contain the results of the CBA.

Reporting and Deliverables

The results of the Cost benefit analysis will be included in the first interim report.

Calendar

M1

- Kick-off with European Commission

M2

- Build more detailed CBA structure parallel to awaiting results of the literature review work-package

M3

- Receive description of interventions from literature review work-package.
- Literature review on CBA specific input parameters.

M4

- Apply input parameters identified through literature research in Excel CBA format;
- Identify missing parameters and conduct additional targeted search for missing variables in scientific and grey literature. Potentially contact experts to address information gaps

M5

- Conduct CBA for all long-list conditions.

M6

- Perform scenario analyses
- Rank order all long-list conditions of CBA results

M7

- Contribute to first interim report.

Resources required

- The results of the literature review including a long-list of conditions selected through the literature review.
- Access to online databases of cost-effectiveness / CBA studies (available at iMTA/Erasmus University)

References

Drummond, Michael F. Methods for the economic evaluation of health care programmes. Oxford university press, 2005.

Bobinac, Ana, N. J. A. Van Exel, Frans FH Rutten, and Werner BF Brouwer. "Willingness to Pay for a Quality-Adjusted Life-Year: The Individual Perspective." Value in Health 13, no. 8 (2010): 1046-1055.

Brazier, John. Measuring and valuing health benefits for economic evaluation. Oxford University Press, 2007.

6.5. Work package 4: Creation of the platform of experts

Work package number: WP4

Work package title: Selection of target diseases, creating a platform of experts and work plan for the Platform

Start Month number: 6

End Month number: 10

Duration in number of months: 5

Work package leader: EHFF

Partners involved: EPF, DCHE, FAD, iMTA

Description of the work package

Scope and objectives

The three objectives of this work package are as follows:

a) the selection of six or more specific diseases which show added value in terms of cost-benefit where self-management by patients is in place or it has been effectively promoted.

b) the creation of a platform of recognised experts in chronic diseases, self-care and healthcare. The platform is to have a balanced geographical coverage and consist of a minimum of 20 people. The expert platform is to be selected from experts representing cross- functional stakeholders such as policy makers, healthcare providers, healthcare professionals, patient groups, educators, healthcare insurers, academics, communication experts and other relevant stakeholders. The composition and establishment of the platform will take place via consultation and agreement with DG SANTE.

c) setting up a work-plan for the platform of experts.

Work process

a) Selection of 6 or more diseases

The process of selection of the target diseases depends on the outputs of WP2, the extensive literature review, and of WP3, the cost-benefit analysis. Given the awareness of those responsible for delivering the combined report for interim report 1 (Deliverable D1) by M6, it is anticipated that the identification of the proposed target diseases will be all but completed by M6. If during M6 it appears that there are more candidate diseases than were expected, a weighting mechanism (based on added value to both patients and to the health systems) which will have been previously developed will be applied. This will allow a logical selection of those diseases to be put forward as part of interim report D2, so that the choice of diseases to be the focus of the latter part of the project will be a transparent process to external sources – in the first case to DG SANTE. To review the findings of the interim report and decide whether the weighting mechanism needs to be employed, a face-to-face meeting of the steering group is planned for M6.

b) Creation of a platform of experts

It is to be borne in mind that the majority of the Consortium were (and are currently) members of the steering group of the previous tender on self-care in minor conditions, PISCE (SANCO/2013/D2/027). It is also evident that apart from the logical specification of expertise in the subject area, chronic diseases generally and the specific chronic diseases, the stakeholder profile required is more or less identical to that described in the previous call (with the addition of policy makers and academics, both groups represented in the final composition of the PiSCE platform). Nevertheless, for self-care in chronic diseases the composition of this expert platform will inevitably feature areas of expertise not present in the previous one.

We propose to use the following methodology for the creation of such a platform within the timeline of the project:

1. *Selection criteria for experts for the platform on self-care*

Essential to the quality of the expert platform on self-care in chronic diseases is the selection of appropriate representatives that will be able to give input for the five tasks specified in the call that are to be performed and delivered on by the Expert Platform (see WP5 and WP6 , below).

The selection of experts will start in M7/8, following agreement as to the specific chronic diseases to be addressed, assuming no delay in agreeing these with DG SANTE following the acceptance of interim report 2 (Deliverable D2), with the development of criteria for inclusion and obtaining consensus from our steering group partners regarding those criteria. The expertise as described in the tender specifications (14.3 Technical and professional capacity) will be used as a starting point and additional criteria will be included. The group of experts will also need to have a balanced geographical coverage and include some experts who are active at national and local levels. The consortium will carefully examine the additional expertise that is required, given the tasks, and we will seek out the availability of potential platform members and their motivation to be included (subject to DG SANTE approval) prior to M10. Once possible experts are identified, they will receive information about the project and the objectives of the platform and they will be invited to apply for provisional membership of the platform. This in essence is the process followed for selection of the PISCE project platform of experts and has proved to work well if a very personal approach is adopted for each individual.

2. *List of nominated experts with CV, summary of achievements and explanation on the added value.*

A list of nominated experts will be drafted. We anticipate that this list of nominated experts will be derived from the following sources:

- The consortium members that have developed this project application.
- Experts selected using the criteria for selection that have been agreed
- Suggestions for additional experts from DG SANCO / the Commission.

A CV, a summary of achievements and an explanation on the added value to the platform of each expert will be provided.

3. *Selection of the experts for the platform*

Following submission of Deliverable D2 to DG SANTE and their agreement on the experts to be selected, the members of the Platform will be advised of the proposed work plan. The minimum

number for the platform is 20 members, but we anticipate that 20-25 experts will join the platform for participation in this project.

DG SANTE will be invited to participate in the platform and be advised of the agenda and outcome of each meeting of the platform and be invited to react.

4. Setting up means for communication

Once the experts for the platform have been chosen, it is important to put in operation a set of effective means for communication. A web based communication platform will be selected and put in place that will facilitate:

- Communication within the project team. Within the project team, it is important to keep track of each other's findings, share documents and exchange administrative and financial information.
- Communication between the project team and the experts. The experts are a major source of input for developing the deliverables in WP5 and 6. During the course of the project, they will be informed about the progress of the work on a continuous basis. Moreover, the communication platform will enable us to carry out Delphi-procedures for exchanging knowledge between experts and building consensus about the subject that is covered in the WP concerned.
- Communication between the project team and DG SANTE. The programme will enable DG SANCO to follow the project progress and will also disclose the agenda of project meetings, draft reports, etc.

  Communication with interested parties outside the project. In order to anticipate a broader implementation of self-care in Europe in the future, interested parties may make themselves known during the course of the project. These parties will be updated on a regular basis via newsletters or other means of communication (to be determined). These identified parties may also serve as one of the sources from which participants for the closing conference would be selected.

c) Work plan for the platform of experts

As will be seen from the descriptions of the succeeding WPs, the work plan which will involve different members of the expert platform is already laid out in principle, although it may be modified prior to delivery of interim report 2 (D2). Each WP will have a defined methodology for developing its own deliverables. While separating the five tasks identified in the tender call into two groups to facilitate management of the processes seems a rational way forward, inevitably there will be cross-over between the tasks. Therefore, to strengthen the commonality of the platform as a whole, two face to face meetings of the whole expert platform will be organised, in M11 and M16. In the first meeting, experts can participate in and advise on the way the tasks of the WP's are to be carried out. In the second meeting, the focus will be on the draft documents that have to be delivered.

To elaborate further on the activities to be undertaken in the course of the first meeting of the Platform, the WP leaders for WP5 and 6 will have assessed the expertise of the individuals that make up the Platform following approval by DG SANTE of the final structure. Given the five tasks that have to be undertaken, they will agree a draft allocation of members of the Platform to each of the tasks that they are required to deliver so that there is a more or less balanced distribution of contributors,

bearing in mind their expertise. In other words, between four and seven (say) individuals would form a core group, coordinated by the WP leader concerned, for delivery of each task.

At the first meeting in M11, the whole platform will be invited to arrive at a consensus over the draft allocation of tasks, and a final version will be agreed. This will enable the individual members of the platform get to know each other and to familiarise them with the work required from the platform within WP5 and WP6. Other activities in that meeting will principally comprise a round of introductions and a briefing on the work done so far (the results of WP2 and WP3) as well as on the context of the overall project.

Reason for the proposed methodology

The creation of a high-quality expert platform on self-care is the key to the success of this project and may point the way to further work that might be carried out to develop the various elements/ themes at a future date. The platform of experts and the knowledge that they bring is an important complement to the data collected and synthesized in WP2 and WP3. It will be the reservoir of knowledge necessary to deliver the five tasks defined in the tender. Moreover, the expert platform will be selected in such a way that it is linked to cross-functional stakeholders from a balanced geographical background, including both national and regional perspectives. The diversity in demonstrated expertise and geographical and stakeholder backgrounds will assure that the network will have credibility not only for the delivery of guidelines and communication tools but also to propose possible scenarios for EU collaboration. As referred to above, this is familiar ground for the consortium, having carried out a similar exercise successfully in the course of the PiSCE project. We our able to incorporate the learning from that experience into the proposed activities in order to maximize the effectiveness of the proposed methodology.

Reporting and Deliverables

Please refer to the reporting arrangements described under project management (WP1). As is required by the terms of the tender call, the activities carried out and the results obtained in the work package will be the subject of general reports which will submitted to DG SANTE at each period or phase of the project.

Moreover, DG SANTE will be expected to be in attendance at the two general platform meetings and be informed on the agenda and outcome each time and will have the opportunity to feed in their views as they see fit. Finally, DG SANTE will be connected to the web-based communication platform which will be put in place for internal communication during the project.

Calendar

M6

- Selection criteria for selection of the six or more target diseases.
- Face to face meeting of the steering group to discuss the implications for the above of the outputs of WP1 and WP2.

M 8

- Following agreement with DG SANTE begin defining selection criteria for composition if Expert Platform

M 9

- Using agreed criteria, construct a list of potential members of the Platform and make contact with individuals to ascertain their willingness and availability during M11-17 (through to M24) and obtain for each the necessary CV list of achievements

M 10

- Submit Deliverable D2 and negotiate and agree final composition of the Platform

M 11

- Arrange First working conference of Expert Platform.
- Communication plan describing objectives, target groups and means for communication such a newsletters, website, LinkedIn, etc.

M 11-16

- Work of the Platform via WP5 and WP6: see below
- Development of (drafts of) supporting documents in preparation of setting up a sustainable platform in the future.
- Scenarios for utilizing the platform in enhancing self-care at EU level and in developing strategies to support the broader implementation of effective self-care.

M 16

- Second working conference of Expert Platform.

Resources required

The resources that are key for the success of this Work Package are:

- Appropriate criteria for selection of self-care experts for both guideline development and for advising on policy actions regarding the broader implementation of self-care.
- A strong statement regarding the role and functioning of the platform, so that it will be attractive for experts and organisations to join the platform or have a connection to it.
- A web-based communication platform that will facilitate communication within and outside the expert platform, including an automated Delphi technique.

6.6. Work Package 5: Platform of experts (i)

Work package number: WP5

Work package title: Guidelines for policy, mapping of barriers, and communication tools

Start Month number: 10

End Month number: 17

Duration in number of months: 7

Work package leader: DCHE

Partners involved: EPF, EHFF, FAD, iMTA

Description of the work package

Building upon:

- the previous work carried out within the Action group of Integrated care (B3) of the European Innovation Partnership on Active and Healthy Ageing (EIP-AHA);
- the results of the activities carried out under the contract (call SANCO/2013/D2/027) referred to under point 3 (PISCE); and the results of the EMPATHiE study; and
- the results of WP2, WP3 and WP4 of this project

The work package involves the Platform of Experts, for the six or more selected diseases, to:

- Conduct a mapping of barriers that might hinder the promotion of self-care
- Develop guidelines for national and local policy makers on how to promote self-care
- Propose and design communication tools to patients/consumers to improve prevention, diagnosis and disease management.

Scope and objectives

To develop guidelines for national and local policy makers on promotion of self-care, gather proposals for innovative approaches and communications tools to improve the field – drawing upon the full experience and knowledge of the Platform of Experts.

Proposed methodology for realisation of the objectives

The Platform of Experts will have ample experience at a national level on self-care and promotion of good health practices. In this work package we will have three simultaneous work flows to both ensure each goal and also provide overview of the progress for the Platform of Experts.

Following the allocation of the experts as described above in WP4, the work flows will be based on an iterative process that would involve a monthly Skype or similar meeting of the core group from M11 through to M16. Following each meeting, draft proposals are agreed within the group and circulated to the wider Platform for comments in M12, 14 and 16, to gain consensus on the final version for delivery in M17.

Workflow 1 – Barriers

Barriers are perhaps often met, but not necessarily mapped. So a key task in this workflow will be to create an overview of barriers found by different stakeholders across the field at macro, meso, and micro levels.

Some of these barriers may be commonly recognized, others will be identified through the discussions of work flow 2 and 3 – as well as the work of WP6. To begin with, however, we would ask the experts to name/describe key barriers they have found nationally or locally and map these. Following a series of discussion there barriers will be categorized, measured in terms of severity and prioritized.

This work will produce a catalogue of barriers that will also be discussed as to its form, as the presentation of such barriers and possible solutions to counter these will have significant potential for further discussion at a policy making level. The process will take into account the mapping of barriers and facilitators done in the EMPATHiE project, and will include other/ more specific barriers identified by the platform.

Workflow 2 – Guidelines

To develop guidelines for national and local policy makers on how to promote self-care we would use the results of the literature review and the cost-benefit analysis to target specific potential opportunities and challenges for self-care that can be improved by policy changes at a national or local level.

Following the process of expert allocation in WP4, we will use an iterative feedback-model that starts by drawing upon the Platform of Experts to provide all and any examples of policies at a national or local level that have proven;

a. to promote self-care
b. that can be implemented by policymakers at a national or local levels
c. that have potential for transferability/scaling-up

Following this process we will make a series of draft guidelines on the promotion of self-care for policymakers. The draft-versions will then be discussed with the experts at regular joint sessions by teleconference or during face-to-face meetings, upon which new versions – and eventually a final version – will be made. This will be presented first to the entire group of experts during the 2nd working meeting, and will then be finalised and presented at the closing conference.

Workflow 3 – Communication Tools

Building upon the earlier EU projects on self-care, the Platform of Experts will propose and design communication tools to improve prevention and disease management – including self-prevention, self-diagnosis, self-medication and self-management of illness and disability. The selection of the six or more specific diseases within this project will have a strong impact on the composition of the Platform of Experts, but also on the relevant communication tools. Some areas will have many, proven communication tools – other areas might lack good working tools.

We suggest that the Experts allocated following the WP4 process will solve this requirement by choosing a set number (to be discussed at the kick-off meeting) of communication tools - e.g. six – to be proposed and developed for download/manual for production to enable ease of use through a common platform.

The communication tools will then serve as examples to support the promotion of self-care on a policy level, or as a way to start innovative approaches. Based upon these assumptions we would ask the Platform of Experts to give their feedback as to

a. The best communication tool they have experienced
b. A type of communication tools that they have felt lacking in their work (that they perhaps have seen working with good effect in other, similar fields)
c. Basic do's and don'ts that should be included in the proposals

Following this discussion, the allocated experts would then have an initial discussion to decide which types of communication tools they want to propose and develop. They would then develop a series of drafts for other experts to comment on. Final versions will be presented at the closing conference and placed online for download and use.

Reason for the proposed methodology

The Platform of Experts will need to gather and discuss various barriers, examples of policies, and good communication to ascertain the potential for change in each and all. The formation of the Platform of Experts is therefore not only the gathering of many bright minds, but also a necessary process of analysis, discourse, and careful selection.

Earlier experience suggests that having an iterative system of discussions and suggestions is a good tool to manage this abundance of expertise and to synthesize the required results during the project.

Work process

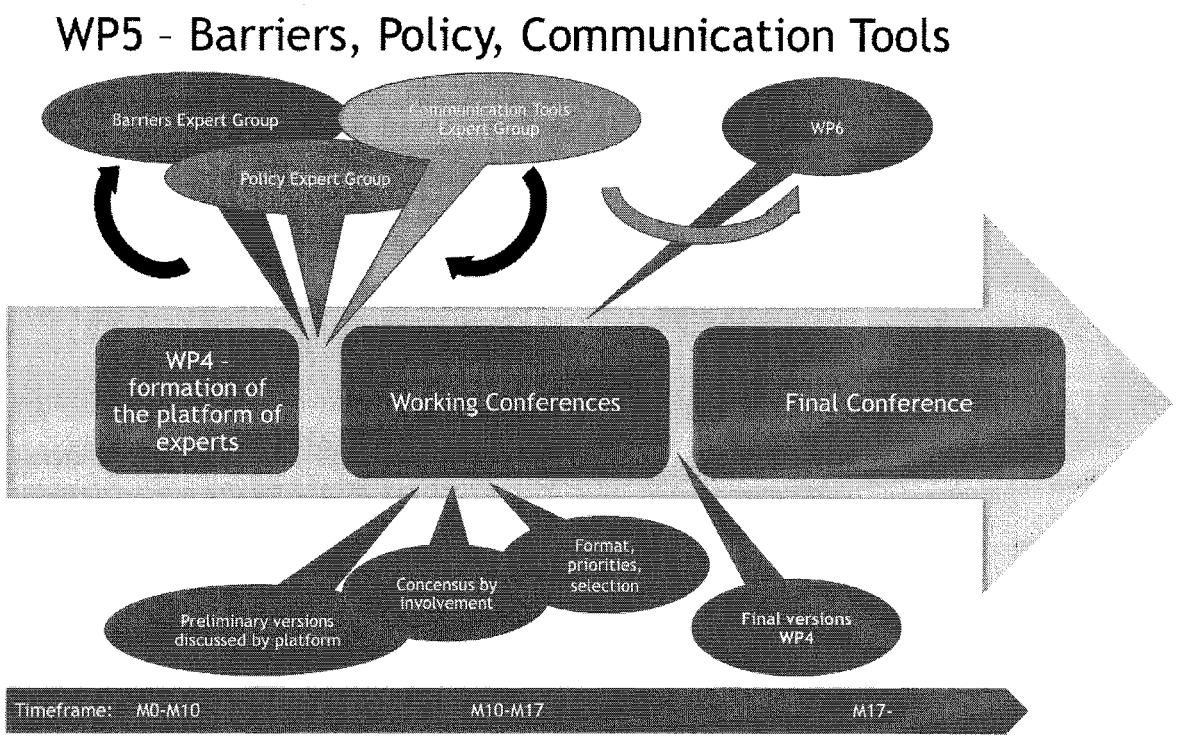
Following the formation of the Platform of Experts, the literature review and the cost-benefit analysis the WP5 will involve:

1) A scoping exercise involving the Platform of Experts, but also relevant other (earlier) projects, authorities and organisations in Member States specifically with a view towards:
    a. gathering examples of good self-care policies, innovative approaches, and examples of good communication tools in this area
    b. identifying barriers at a national/local levels
    c. identifying the level of ambition for communication and effort across the EU in this field – looking also for "champion cases" to be used in either in the development of guidelines for policy, solving barrier challenges, or communication tools, and linking these to the future dissemination of the project results.
2) Production of a catalogue of barriers – covering
    a. Types
    b. Level
    c. Severity
    d. Suggested priority as seen by the platform of experts
    e. Suggested Solutions

3) Production of guidelines on policy –suggested content to include:
   a. Type of policy level
   b. Type of policy change
   c. Goal of policy change – and possibilities for further policy changes if national or local trends and developments (outside the remit of this project) leads to different results.
   d. How to engage national/local target groups (patients/citizens, other relevant stakeholders) to take part in the specific policy implementation and development.
   e. Measuring the effects of policy changes
   f. Dissemination of results (local or national)

4) Production of proposals for communication tools to improve self-care – to an extent fitting with the results of the earlier stages of the project and the decisions of Platform of Experts as to policy guidelines and barriers – this will also look to and involve the work being done in WP6 for the six chosen diseases. This will include
   a. Identifying and involving local target groups in the development process
   b. Implementing the communication tools
   c. Fundamental requirements for the communication tools to have effect – and possibilities for local adaptation as to specific needs
   d. Suggestions on how to measure and evaluate results for both dissemination and benchmarking purposes

The work process is illustrated by the following figure:



Reporting and Deliverables

Each version will be labelled - and thus serve as a report on the status of the work package.

Calendar

M10

- Teleconference with the Platform of Experts

M11

- Initial results of scoping exercise presented by mail for comments for the Platform of Experts
- Discussions on communication tools and needs for development
- 1st Working Conference of platform of experts

M12

- Guidelines for Policy Makers earliest draft version
- Barriers Catalogue earliest draft version
- Sketches of communications tools presented and discussed

M13

- Integrating comments, discussions be teleconferences and recirculation of draft versions

M14

- Guidelines for Policy Makers expected with full structure – content still to be developed further
- Barriers Catalogue voting/grading session
- Elaborate communication tools presented – selection of priorities as to types and goals

M15

- Guidelines for Policy Makers comments, new draft versions circulated, comments taken
- Barriers Catalogue new draft versions circulated and comments taken
- Communication Tools circulated and comments taken

M16

- 2nd Working Conference with presentation of pre-final versions – and discussions on needed extra work
- New draft versions circulated

M17

- Guidelines for Policy Makers Final version presented to the Platform of Experts for final comments and adaptation before closing conference
- Barriers Catalogue Final version presented to the Platform of Experts for final comments and adaptation before closing conference
- Communication Tools presented to the Platform of Experts for final comments and adaptation before closing conference

M21

- Final versions presented at closing conference

Resources required

- The formation of the platform of experts
- The results of the literature review and the cost-benefit analysis
- A graphic designer/Layout assistance

References

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Abraham and Michie (2008). A Taxonomy of Behaviour Change Techniques Used in Interventions, Health Psychology, Vol. 27, No. 3, 379–387

6.7. Work package 6: Platform of experts (ii)

Work package title: Scenarios for EU collaboration and innovative approaches for the development of self-care

Start Month number: 10

End Month number: 17

Duration in number of months: 8

Work package leader: EHFF

Partners involved: EPF, FAD, DCHE, iMTA

Description of the work package

In parallel with the activities of WP5, described above, WP6 is tasked to use the Platform of Experts to propose scenarios for EU collaboration and to propose innovative approaches for the development of self-care.

In relation to the first of these tasks, the work can build on previously carried out work related to patient empowerment in the management of chronic disease (the EMPATHiE project) which is referred to in the introduction to this tender call and was a tender within the 2013 Health Programme EAHC/2013/Health/04. WP4 of this project was entitled 'to develop scenarios of EU future collaboration on patient empowerment'. Similarly, in the previous PiSCE tender on self-care (which dealt with minor, self-limiting conditions, referred to in the introduction to this call as SANCO/2013/D2/027), WP3 was tasked to 'provide proposals of actions which will give added value' with the caveat that 'the proposals of actions should not only be of organisational nature but on concrete policy actions.' This WP is yet to report but the methodology proposed in that successful tender bid will be taken into account.

As to the second task, there is a wealth of information about self-management in chronic diseases, some of which has been the subject of the tenders referred to above, some of it being considered as part of the current Joint Action on Chronic Disease (CHRODIS-JA) and some as part of the activities within the Innovation Partnership on Active and Healthy Ageing (EIP-AHA). The question inevitably arises, is any of this activity genuinely innovative? This is a question which will tax the Platform, even given its collective expertise, but it should be well placed to make a good start to answering this question.

Scope and objectives

The first task can be seen as being part of a sequence. Patient empowerment as identified in the EMPATHiE tender is envisaged as comprising three key (overlapping) dimensions: health literacy/education, shared decision-making and self-management. The second tender focused on self-care, but in minor, self-limiting conditions primarily. The current tender complements this by examining self-care in chronic diseases. There may well be overlap between the proposed scenarios

for EU collaboration in all three studies, but equally it will be of interest to see whether the specific nature of self-management of the identified chronic diseases leads to differences in the scenarios proposed as part of Deliverable D4.

In relation to innovation, this term is used so widely and yet so loosely, that one objective undoubtedly will be to attempt to define criteria by which to judge or rate examples as being "innovative" or not.

Work Process

Proposed methodology for realisation of the objectives

a) Scenarios

In WP4 of the EMPATHiE project, the methodology for identifying scenarios for future EU collaboration used a model of stakeholder consultation which included: building on the information from the previous WPs to provide an outline of the possible scenarios; followed by a consultation, which took the shape of two stakeholder workshops, an online survey, and a number of personal interviews with representatives of key stakeholder organisations. Stakeholders were selected on the basis of a stakeholder mapping, aiming for broad representation of different stakeholder groups and focusing on EU-level organisations. Although producing an excellent result, the model used was perhaps too resource-intensive and a more streamlined approach might have produced a similar outcome.

In WP3 of the PiSCE project, the process was built on the outcomes of the cost/benefit analysis study, the tender on patient empowerment, evidence and data regarding health literacy, and took forward through a collaborative approach existing policies on self-care and self-medication, proposing concrete synergies with added value at EU level. The suitability of the report regarding feasible policy actions was to be achieved by involving project partners and external stakeholders (pharmacists, consumers, the self-medication industry) within the platform of experts and, therefore, in the consensus building process required to produce the concrete policy actions. Although the main interactions were via reiteration of the structured initial report, some teleconference meetings took place between the core team steering the process and there was one additional stakeholder (face to face) focus group.

The work process proposed for this tender builds on the experience gained from the above work, which most of the current consortium were also involved in. It would start with the consolidation of information from previous projects, in this case the policy recommendations arising from the two previous tenders (assuming the PiSCE project's report is accepted by DG SANTE by the time this WP is initiated) as well as relevant data from other sources, such as the outputs of WP2 and 3 available in Interim report 1 as well as other current ongoing work related to the management of chronic diseases, such as that of the CHRODIS-JA. The core group that has been agreed following the Platform meeting in M11 (see WP4) will then begin reviewing possible scenarios. The expected iterative process would involve a monthly Skype or similar meeting of the core group from M11 through to M16 and following each meeting, when draft proposals are agreed within the group, circulation to the wider Platform for comments in M12, 14 and 16, to gain consensus on the final version for delivery in M17.

The second Platform meeting in M16 will allow review by the whole stakeholder group of synergies or any anomalies arising by consideration side by side of the five nearly completed drafts of the required outputs from the Platform for M17.

b) Innovative approaches

A similar approach will be applied for this task. As indicated in the previous section (Scope and Objectives) a crucial first step for the core group will be to attempt a means of defining innovative approaches, e.g. looking at the distinction between incremental (in effect, improvement methods) and step-innovation, i.e. transformational change. Likely sources to support this will be a review of the self-care/empowerment examples in the inventory collected as part of the EIP-AHA, the discussion of transferability of good practice examples from WP3 of EMPATHiE, the literature reviews from WP2 which will include consideration of the EMPATHiE literature review, and the DG SANTE-commissioned report of the Expert Panel on Effective Ways of Investing in Health (EXPH) on disruptive innovation, which is likely to be released in the late Autumn of 2015. This would naturally lead to consideration of a means of rating approaches to the development of self-care in the different disease entities as innovative or not.

After circulating the results of this exercise to the wider Platform to obtain their opinions and get a consensus on use of the tool, the next step for the core group would be to assemble a series of examples to rate and subsequently to circulate this to the Platform to seek additional examples to be included in the process.

The third phase would be to rate and rank the material and prepare a final list as a draft product for submission in Interim report 4 and again circulate this for comments to the wider Platform prior to their second meeting in M16.

Reasons for methodological choices

The method of using the expertise of the Platform that has been proposed both for this WP and for WP5, as was emphasized in the equivalent section of the WP4 description, arises from experience of handling large groups of Experts in the previous tenders, EMPATHiE and PiSCE. As was also mentioned earlier, we have learned lessons regarding the need to check at regular intervals the engagement of the individuals within the Platform as well as the most effective means of internal communication of documents. These lessons will be applied here.

Reporting and Deliverables

The draft reports from both processes will be scrutinized by the Steering group as a matter of routine and the final reports will be included in Interim report 4 at M17.

Calendar

M 10

- Consolidation of previous material for both tasks a) scenarios and b) innovation and development of criteria and rating tool for assessing innovation value of approaches to development of self-care
- Agree likely composition of membership of core groups for task a) and b).

M 11

- Following agreement with DG SANTE, convene first meeting of Platform and gain agreement on core groups for tasks
- Get agreement for new core group b) on definition of innovation and form of rating tool

M 12

- For task a) phase 1 proposals for policy actions for circulation to Platform
- For task b) start collection of examples of innovation from various sources

M 14

- For task a) phase 2 proposals for policy actions for circulation to Platform
- For task b) completion of collection of examples and circulation to wider group for additional examples

M 16

- For task a) phase 3 (final) proposals for policy actions for comments from Platform members
- For task b) final rating and ranking of examples circulated to Platform for approval
- Second working conference of Expert Platform.

M 17

- Delivery of Interim report 4

M 21

- Final conference where Expert Platform members will participate.

Resources required

The resources that are key for the success of this Work Package are:

- Effective subdivision of the Platform in to core working groups
- Responsiveness of individual Platform members to requests for opinions on circulated drafts
- A useful and pragmatic consensus on definitions of innovation and the means for rating examples
- A strong statement regarding the role and functioning of the platform, so that it will be attractive for experts and organisations to join the platform or have a connection to it
- Workable and plausible scenario proposals.

6.8. Work package 7: Dissemination and conference

Work package title: Dissemination, including final conference

Start Month number: M6

End Month number: 24

Duration in number of months: 13

Work package leader: EPF

Partners involved: EHFF, DCHA, FAD, iMTA

Description of the work package:

Scope and objectives

The objective of this work package is to develop and implement a strategy to ensure dissemination of the project's results at European, national and local levels; and to organise a closing conference in Brussels.

The dissemination strategy will encompass European, national and local levels. The conference will include at least 100 participants representing relevant stakeholders and Member States. Results of other projects, such as the EIP-AHA, PiSCE and EMPATHiE will be taken into account to the relevant extent.

Proposed methodology for realisation of the objectives

According to CHAFEA, dissemination "refers to the process of making the results and deliverables of a project available to the stakeholders and to the wider audience. Dissemination is essential for take-up, and take-up is crucial for the success of the project and for the sustainability of outputs in the long term."

This section elaborates the dissemination strategy chosen for the PRO-STEP project to ensure that dissemination of the project results is effective particularly towards the national and local levels.

The dissemination strategy will revolve around the following elements:

- Defining the objectives of the dissemination actions (why disseminate);
- Defining the dissemination "products" (what will be disseminated);
- Defining a timeline for the activities (when it will be disseminated);
- Identifying the target groups (to whom it will be disseminated);
- Identifying the means for disseminating the "products" to the identified target audience (how it will be disseminated);
- Establishing the roles and responsibilities of partners in relation to the various activities (who will disseminate).

Reasons for the methodological choices

The complexity of the envisaged dissemination strategy rests on the assumption that the purpose of the dissemination activities is to inform a wide range of target groups and at different levels:

European, national and local. For this reason we aim to conceive and produce dissemination tools tailored on target groups and their level of expertise on self-care and healthcare-related issues.

This includes the production of:

- WordPress webpage to allow easy access to the main information about the project development and promotion of the final event
- Concise report (potentially the Executive Summary of the project's final report)
- Infographic/factsheets or leaflets showing the main findings in English and most other languages of the European Union;
- Collection of good practices or case studies classified by type, Member State, etc. and accessible via web.

All dissemination materials will be produced in a digital version to allow easier access through social media and websites. A limited number of copies will be printed out for distribution at the final conference.

All consortium partners have an extensive and well-established network of contacts encompassing a variety of different stakeholders at local, national and EU levels. Since many of them are/were also involved in the PiSCE tender and the previous EMPATHiE study, as well as the EIP-AHA action group B3, we will be able to leverage these networks also. The consortium will be able to reach national and regional health institutions also through existing networks such as CHRODISJA, where EPF is a partner.

Over the last 10 years, EPF has gained extensive experience in organising high-level conferences on diverse health policy topics as well as European projects. We have developed a conference format that works very well and can be adopted to individual topics and audiences; this combines plenary sessions with interactive working sessions that enable in-depth discussion between the participants and leads to jointly developed outcomes, thus creating a sense of "ownership".

Work process

The development of the dissemination strategy will be done in close interaction with all other work packages and will take into account the different tasks, the results achieved and the challenges encountered.

Based on this input, we will identify the goals for successful dissemination. A stakeholder analysis, drawing on knowledge gained in the EMPATHiE project and the PiSCE tender, will identify key target audiences at European, national and local levels. Key messages will be identified for each target audience in close collaboration with the relevant WP and agreed by the project *steering committee*.

Methods of dissemination will then be selected for each level to optimise outreach to each major stakeholder group. With the leverage the networks of the entire consortium as well as the panel of experts to achieve the widest possible coverage.

Dissemination channels

Key dissemination channels to ensure effective dissemination of the project will include: an online presence through WordPress and through leveraging consortium partners' own websites; press

releases; and use of social media to support dissemination of key messages (Twitter, Facebook, blogs). The project will aim to develop papers and/or presentations of the results, to be given at conferences following the project's conclusion; and potentially papers for publication in peer-reviewed journal(s) as well as online newsletters such as the Health-EU e-newsletter. This will be further detailed in Interim Report D5.

The dissemination strategy

The strategy (Interim Report D5) in M17 will elaborate in detail the following elements:

Part I: strategy for dissemination of results

- Dissemination objectives
- Target audiences and key messages tailored to these audiences
- Dissemination channels and methods
    - Internet: EPF will build a WordPress webpage with a dedicated web address. Information to be published will be subject to agreement with DG SANTE. The tool can be used also to promote the final conference.
    - Press releases: versions targeted to the national level will be adapted to national contexts and include case studies and testimonials where relevant.
    - Social media: used in a two-way dialogue with target audiences: to disseminate the study results, promote the final conference and identify potential good practices.
    - Executive summary of the final report in three EU languages (English, French, German)
    - Possible papers or presentations given at conferences following the project, subject to approval from DG SANTE
    - Possible paper developed for (a) peer-reviewed publication(s)
- Visual identity:
    - logo
    - reporting templates
    - PowerPoint template and standard public presentation
- Optimising interactions with stakeholders, including the EIP-AHA, ENOPE and other relevant initiatives
- Interacting with members of the platform and leveraging their networks
- General principles to ensure the quality of the dissemination materials, respect of all partners' work, confidentiality of the results, approval by DG SANTE, etc.

Part II: planning of the closing conference

- Conference objectives
- Promotional activities: e.g., save the date, webpage to raise interest and incentivise stakeholders.
- Logistics, including invitations, registrations process, venue booking, interpretation, catering, travel and accommodation, FAQ, etc.
- Conference structure: plenary sessions and parallel sessions/working groups

- Conference facilitation and reporting (subcontracting via tender)
- Communication plan, including public relations, press, documents
- Draft agenda and speakers
- Target audience: list of invitees, achieving a balanced representation of stakeholders
- Live interactive video streaming to allow a larger attendance and greater interaction. Possibility of posting recordings of key sessions online.
- Gantt chart of activities

Ensuring effective dissemination at national and local levels

The consortium will actively disseminate the findings through their own existing networks and membership and rely on a cascade effect at regional and local level.

EPF has a large and well-established membership of 65 member patients' organisations, 15 of which are national coalitions of patient organisations. The 15 national coalitions are from Belgium (Flanders), Bulgaria, Croatia, Cyprus, Estonia, France, Hungary, Malta, Latvia, Lithuania, Poland, Romania, Slovakia, Spain, and the United Kingdom, and they do have their own networks at regional and local levels.

Nationalities that are not represented via the coalitions are represented via the European-level disease-specific organisations, which have again their own networks of members across the Union. In addition to members, EPF has developed since 2008 direct relations also with disease-specific patient organisations working at national, regional and local level. This network currently counts over one thousand contacts. We will also work closely with a number of networks and platforms such as ENOPE (European Network for Patient Empowerment, focusing on chronic disease self-management education in several EU and non-EU countries, in which EPF is a member).

Other partners will also provide contacts of their extensive networks at European and national levels to widen and diversify the target audience. For example, FAD may contribute to the dissemination as partner of the Reference Research Network in Chronic Care in Spain.

The final conference

The final conference will take place during M21 in Brussels. The objectives of the final conference will be:

- to bring together relevant stakeholders to raise awareness of the PRO-STEP project, its outputs and results;
- to explore specific issues, such as barriers, opportunities and needs of different stakeholders, different EU Member States to realise effective self-care strategies; and
- to collectively reflect on follow up actions needed to promote self-care in Europe.

The conference will include at least 100 participants, representing a balanced breakdown of stakeholder groups and geographical presence. These will include:

- patient representatives in the selected disease areas (a balanced geographic and disease representation will be sought);

- health professionals, including doctors, nurses, pharmacists, health managers and other professionals relevant for promoting self-care generally and in the selected diseases;
- payers, e.g. national health insurance organisations;
- Member States' policy-makers at national /regional levels;
- EU-level decision-makers (European Commission relevant DGs, European Parliament);
- industry and commercial actors, e.g. pharmaceutical, MedTech, ICT industry

Self-care will also be examined from the perspectives of particular (groups of) people that may be potentially in a vulnerable position (e.g. old/young patients, socially excluded or marginalised persons, those with low health literacy) as well as from a gender lens. We shall endeavour to ensure appropriate representation from these groups.

The conference will take place over two days (with a speakers' dinner on the evening before the first day) and will be structured as a mix of plenary sessions and interactive working sessions to encourage high- quality, interactive working that will facilitate more meaningful understanding of the topic, and its relevance and applicability. (See "Conference outline", page 74) The conference will be professionally moderated by an experienced facilitator subcontracted through tender.

Pre-reading documents will be circulated subject to Commission approval. After the event, a comprehensive conference report will be produced by a professional rapporteur, which will include the key outcomes and recommendations flowing from the event.

The conference will be evaluated internally in accordance with key indicators linked to the objectives of the meeting. These will be elaborated in the dissemination strategy, Interim Report D5. Participants will receive an evaluation questionnaire. Key indicators may include: effective planning and preparation of the conference; optimal and balanced attendance by the targeted stakeholder groups (number of participants, number of Member States represented); conference pre-read material completed; Conference report produced by M22.

Reporting and Deliverables

D5 – Interim report 5 – Strategy for dissemination of results (M 17)

This interim report will contain the strategy to ensure dissemination of results at European, national and local level and a detailed description of the organisation of the closing/concluding conference, including a Gantt chart of activities as described above.

D6 – interim report 6 – Dissemination of results (M 22)

This interim report will describe the implementation of the dissemination; and the results of the closing conference in Brussels.

Calendar

M 2-3

- visual identity and template

M 8-9

- Wordpress webpage

M17

- Interim report 5 – dissemination strategy, conference plan

M21

- Closing conference, Brussels

M22

- Interim report 6 – results of the conference, implementation of the dissemination strategy

Resources required

This work package requires the following key resources:

a) Communications expertise
b) WordPress Internet platform
c) Conference organisation logistical support
d) Conference communications support
e) Conference moderation (to be subcontracted via tender)
f) Conference reporting (to be subcontracted via tender)
g) Conference interpretation services
h) Translation services for "key messages" tool into most EU language

Conference preliminary outline

(Day 0)

Speakers' and organisers' dinner, venue to be confirmed

Day 1

a.m.

Registration & coffee
Conference opening, interventions from high-level representatives (E.g. EC, EU Presidency)
Keynote from patient representative on self-care and empowerment

Plenary session 1
Keynote presentation(s) followed by discussion panel and/or moderated Q&A with the audience.
Networking coffee
Plenary session 2 as above
Networking lunch

p.m.

Parallel working sessions (repeated twice)
Three or four priority topics selected to be explored in-depth with participants; this can include key issues around promoting self-care in different Member States; "role playing" of different stakeholders to implement a specific case study or potential strategy - identification of key barriers and success factors...

Workshop moderators facilitate (methods, e.g. brainstorm, prioritising, SWAT..), each workshop has a rapporteur and note taker.

- Option 1: working sessions are run twice with different groups. The benefit is that participants can select two sessions and have a broader view of the issues. The drawback is lack of continuity and shorter time, potential overlap between the groups.
- Option 2: working sessions are run twice but with the same group. The benefit is continuity; the second session can focus on developing recommendations after the brainstorming in the first session. The drawback is that each participant can only participate in one topic.

Conference Dinner, probably at the conference venue.

Day 2

a.m.

Plenary session 1: Feedback from the parallel working groups

- Presentations from all working sessions – key points
- Moderated Q&A with the audience

Coffee and networking break

Plenary session 2: Conclusions and the way forward

- Presentation(s) and take-home messages

Networking and goodbye lunch.

7. Ethical and gender considerations

7.1. General information

This tender does not involve any clinical trial or other physical intervention on humans, human tissues, animals or flora from protected environments. In the project people will be interviewed, participate in focus group discussions and provide feedback on interventions. These people will be asked for consent before participating. Children and persons not being able to give their consent will not be include in any activity. No personal information is collected that can be traced back to individuals.

7.2. Ethical considerations specific to the tender proposal

PRO-STEP aims to put in place a framework for action to enhance self-care in chronic diseases at EU level and develop strategies to support the broader implementation of effective self-care. The interviews, focus groups and workshops will address potentially sensitive health and socioeconomic issues for patients and healthcare professionals. For this reason, we will be careful to ensure voluntary participation, as well as to protect the confidentiality of all participants. The recruitment will begin with the prepared consent script. This script emphasizes that participation is voluntary and all involved persons may withdraw at any time. To ensure the confidentiality of subject data all participants ID will be removed after data validation and interview data will be password-protected.

The work of the consortium, platform of experts as well as each WP individually takes into account the ethical impact of the proposed deliverables. This is represented throughout the tender description through criteria of equity, non-discrimination and inclusiveness.

Horizontal criteria of equity and non-discrimination are directly referenced within the proposal. The guidelines for policy (WP5) include an assessment of needs of patients by mapping barriers based on the above mentioned criteria. The communications tools will also include a needs assessment with regard to target audiences that may be vulnerable to barriers to access and health inequalities (vulnerable groups). The innovative approaches and scenarios for EU collaboration (WP6) will equally reflect these criteria.

All WPs have a common process of external validation/review of their work, aimed to also take into account the ethical perspective. All WP leaders as well as the leader of the consortium (EPF, a patient organisation) are committed to an inclusive process that considers the impact of the actions developed and proposed on the patient/person from an ethical standpoint.

7.3. Gender and other considerations

Gender considerations are directly referenced within the proposal. All PRO-STEP participants support the principle of equality between men and women as a common value of the European Union.

The overall aim of then project is to further develop self-care in chronic conditions. Gender considerations will be included within the guidelines for policy on promotion of self-care, communication tools as well as the EU scenarios. More broadly, the principle of non-discrimination as outlined in Art. 19 of the Treaty on the Functioning of the European Union (TFEU) will be incorporated when determining the needs of the target audience.

On project development, we aim to include equal groups of men and women for the focus groups, surveys and participating groups. Gender considerations will also be included in the project development. The project coordinator is a woman and we expect that the project Consortium membership will also achieve gender equality.

7.4. Compliance with international and national norms and legislation

National regulations and international codes of conduct

The consortium will fulfil all legal requirements of each stage. The applicant certifies that the consortium will adhere most strictly to all existing ethical and safety provisions of the individual states and of the EU. Participants will conform to relevant EU legislation including:

- Art. 19 of the Treaty on the Functioning of the European Union.
- The Charter of Fundamental Rights of the EU.
- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
- Council Directive 83/570/EEC of 26 October 1983 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation laid down by law, regulation or administrative action relating to proprietary medicinal products.
- Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.
- Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms.
- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

Furthermore, each consortium member will be held responsible for fulfilment of all legal and ethical requirements in his/her country.

International conventions and declarations

Participants will respect the following international conventions and declarations:

- The Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (last amended in Fortaleza, Brazil in October 2013 at the 64TH World Medical Association General Assembly).
- Convention of the Council of Europe on Human Rights and Biomedicine signed in Oviedo on 4 April 1997, and the Additional Protocol on the Prohibition of Cloning Human Beings signed in Paris on 12 January 1998.

- UN Convention on the Rights of the Child.
- Universal Declaration on the human genome and human rights adopted by UNESCO.
- Participants should take into account to the opinions of the European Group of Advisers on the Ethical Implications of Biotechnology (1991 -1997) and the opinions of the European Group on Ethics in Science and New technologies (as from 1998).
- The Council of Europe additional Protocol to the European Convention on Human Rights and Biomedicine on Biomedical Research (CETS No. 195).
- Provision of the arrangements made for providing information to persons and for obtaining informed consent.

Special arrangement made for the inclusion of children in the studies performed

Children are not a primary focus group and data collection from children is not anticipated.

Description of the arrangements for protecting the confidentiality of personal data

In our study no names of persons or other participants' information that will permit their identification will be kept. Information will be arranged, so that individual information cannot be traced back to that person. Identifying data will be stored separately from the main PRO-STEP Database and securely stored by an independent source (a University Department). All person-related data will receive a pseudonym (a participant number). Pseudonym creation will be unique, i.e. there will never be the same pseudonym for two different persons. The code lining the personal identification data to pseudonyms (participant numbers) will be kept locally at the health care centre were the patient was attended. Codes will be used in all stages of the project after data collection.

Encrypted Data Transfer

All data will be transferred using encryption (SSL and/or HTTPS as technical protocols [HTTPS], [SSL3]).

Client/Server Authentication

When using remote data entry, the entering site (device) will be authenticated to the server in the data centre, to avoid so-called man-in-the-middle attacks (HTTPS provides this).

Specification of any payments, inducements or other benefits to be given to the persons concerned

No payments or inducements will be given to any person enrolled in this study.

ANNEX V

BUDGET (in EURO, excluding VAT) Ref. Ares(2015)2839811 - 07/07/20

1. Total cost in EURO (VAT exclusive) 949,912

2. Breakdown of cost

A. SERVICE SUPPLY FEES

	Staff expenditure	Remarks/info	No of Units*	Units* rate	Total
	Secretary General EPF	Nicola Bedlington	14	700.0	9,800
	Senior Policy Advisor, EPF	K. Immonen-Charalambous	114	450.0	51,300
	Programme Officer, EPF	Valentina Stramiello	120	300.0	36,000
	Admimistrative Assistant, EPF	Danielle Flores	60	210.0	12,600
	Communications Officer, EPF	Valentina Stylianou	48	350.0	16,800
	Events coordinator, EPF	Véronique Tarasovici	70	300.0	21,000
	Head of Office, EPF	Anke Seidler	25	500.0	12,500
	Director, EHFF	David Somekh	120	700.0	84,000
	Senior Advisor, EHFF	Matthijs Zwier	72	500.0	36,000
	Programme Director, IMTA	Nicolaas Jacob Arnold van Exel	73.6	950.0	69,920
	Director, DCHE	Charan Neladner	15	500.0	7,500
	Editor, DCHE	Lars Münter	125	500.0	62,500
	Director, FAD	Rosa Sunol Sala	50	509.7	25,485
	Researcher, FAD	Marta Ballester Santiago	264	185.5	48,972
	Junior Researcher, FAD	Eva Frigola Capell	205	160.4	32,890
	Expert (Deputy Director), FAD	Maria del Pilar Hilarion Madariaga	60	306.2	18,374
	WP-Leader Deputy Director, FAD	Carola Orrego Villagran	125	306.3	38,281
Sub-Tot					583,922

B. OPERATIONAL COSTS / OVERHEADS

	Operational costs (Closing conference, two days in Brussels, 100 participants+20 speakers/panellists with interpretation and other costs, organisation and delivery of expert panel)	320,000
	Overheads (Telephone, fax, paper, envelopes, photocopies, etc.)	0
Sub-Total B		320,000
Sub-Total A + B (VAT exclusive)		903,922

C. TRAVEL AND SUBSISTENCE

		No of trips	Travel expenses (flight, train)	Subsistence allowance **	Total costs
	Commission in Brussels				0
	Other destinations/project work (to be specified)				0
	destination : Brussels	2 expert panel meetings of two days with 35 people including 20 experts, SG and consortium members	Flights	427	29890
	destination: Brussels...	2 expert panel meetings of two days with 35 people including 20 experts, SG and consortium members	Accomodation and subsistence	230	16100
	destination : Brussels				
	destination: Brussels...				
Sub-Total C					45,990
GRAND Total A + B + C (VAT exclusive)					949,912

15

* Complete the unit of measurement as appropriate: hourly, daily, weekly, monthly ...

** The maximum daily subsistence allowance shall be (in €):

This allowance is deemed to cover accommodation, breakfast and main meals, local travel (including taxis) and sundries.

ANNEX XX
POWER OF ATTORNEY[1]

I, the undersigned,

Charan Nelander

representing,

Danish Committee for Health Education, DCHE
Non-profit association
Registration Number 14035338
Classensgade 71, 5. – 2100 Copenhagen East
VAT: 14035338

hereinafter referred to as "the consortium member",

for the purposes of the signature and the implementation of the contract "Pilot project on the promotion of self-care systems in chronic diseases in the European Union" - SANTE/2015/D2/021 with the European Commission (hereinafter referred to as "the contract")

hereby:

1. grant power of attorney to

European Patients' Forum-EPF

Asbl governed by Luxemburg law

F448

Rue Dicks 14, 1417 Luxemburg

represented by Anke Seidler, Head of Office of the European Patients' Forum,

(hereinafter referred to as "the consortium leader")

to sign in my name and on my behalf the contract and its possible subsequent amendments with the European Commission.

2. Grant power of attorney to the consortium leader to act on behalf of the consortium member in compliance with the contract.

---

1 One original version of this Annex is to be included for each consortium member except for the member acting as single point of contact.

I hereby confirm that the consortium member accepts all terms and conditions of the contract and, in particular, all provisions affecting the consortium leader and the other consortium members.

The consortium shall nominate one legal entity as single point of contact for the Contracting Authority who will have full authority to bind the consortium and each of its members, and will be responsible for the administrative management of the contract (invoicing, receiving payments, etc.) on behalf of all other entities.

I hereby accept that the consortium member will do everything in its power to help the consortium leader fulfil its obligations under the contract, and in particular, to provide to the consortium leader, on its request, whatever documents or information may be required. I also accept that all economic operators in this joint tender assume joint and several liability towards the Contracting Authority for the performance of the contract as a whole.

I hereby declare that the consortium member agrees that the provisions of the contract, including this power of attorney, shall take precedence over any other agreement between the consortium member and the consortium leader which may have an effect on the implementation of the contract.

This power of attorney shall be annexed to the contract and shall form an integral part thereof.

SIGNATURE

Charan Nelander, Director

Done in Copenhagen, September 23rd 2015

ANNEX XX
POWER OF ATTORNEY[1]

I, the undersigned,

Dr David Somekh

representing,

European Health Futures Forum (EHFF)
A Company Limited by Guarantee (NGO)
Registered at Companies House UK no.8447376
Address: Kingates farm, Ventnor, IOW PO38 2QP UK
VAT number (N/A)

hereinafter referred to as "the consortium member",

for the purposes of the signature and the implementation of the contract (tbc) related to tender no: SANTE/2015/D2/021 with the European Commission (hereinafter referred to as "the contract")

hereby:

1. grant power of attorney to
The European Patient's Forum (EPF)

A European NGO

[*official registration No*][2]

31, Rue du Commerce, B-1000, Brussels

[*VAT number*],

Represented by: Nicola Bedlington, EPF Secretary-General

(hereinafter referred to as "the consortium leader")

to sign in my name and on my behalf the contract and its possible subsequent amendments with the European Commission.

2. Grant power of attorney to the consortium leader to act on behalf of the consortium member in compliance with the contract.

---

1 One original version of this Annex is to be included for each consortium member except for the member acting as single point of contact.

2 To be deleted or filled in according to the "Legal Entity" form

I hereby confirm that the consortium member accepts all terms and conditions of the contract and, in particular, all provisions affecting the consortium leader and the other consortium members.

The consortium shall nominate one legal entity as single point of contact for the Contracting Authority who will have full authority to bind the consortium and each of its members, and will be responsible for the administrative management of the contract (invoicing, receiving payments, etc.) on behalf of all other entities.

I hereby accept that the consortium member will do everything in its power to help the consortium leader fulfil its obligations under the contract, and in particular, to provide to the consortium leader, on its request, whatever documents or information may be required. I also accept that all economic operators in this joint tender assume joint and several liability towards the Contracting Authority for the performance of the contract as a whole.

I hereby declare that the consortium member agrees that the provisions of the contract, including this power of attorney, shall take precedence over any other agreement between the consortium member and the consortium leader which may have an effect on the implementation of the contract.

This power of attorney shall be annexed to the contract and shall form an integral part thereof.

SIGNATURE 

Dr David Somekh Network Director, EHFF

Done at Ventnor, UK 28/09/15

In duplicate in English

ANNEX XX
POWER OF ATTORNEY[1]

I, the undersigned,

Rosa Sunol,

representing,

FUNDACION AVEDIS DONABEDIAN PARA LA MEJORA DE LA CALIDAD ASISTENCIAL (FAD)
NON PROFIT PRIVATE ENTITY[2]
official registration No 645[3]
full official address: PROVENÇA 293 PRINCIPAL – 08037 BARCELONA (SPAIN)
VAT number:ESG59026716,

hereinafter referred to as "the consortium member",

for the purposes of the signature and the implementation of the contract **Pilot project on the promotion of self-care in chronic diseases in the European Union, tender n° *SANTE/2015/D2/021*** with the European Commission (hereinafter referred to as "the contract")

hereby:

1. grant power of attorney to

European Patients' Forum-EPF

Asbl governed by Luxemburg law

F448

Rue Dicks 14, 1417 Luxemburg

represented by Anke Seidler, Head of Office of the European Patients' Forum,

(hereinafter referred to as "the consortium leader")

to sign in my name and on my behalf the contract and its possible subsequent amendments with the European Commission.

2. Grant power of attorney to the consortium leader to act on behalf of the consortium member in compliance with the contract.

---

1 One original version of this Annex is to be included for each consortium member except for the member acting as single point of contact.

2 To be deleted or filled in according to the "Legal Entity" form

3 To be deleted or filled in according to the "Legal Entity" form

I hereby confirm that the consortium member accepts all terms and conditions of the contract and, in particular, all provisions affecting the consortium leader and the other consortium members.

The consortium shall nominate one legal entity as single point of contact for the Contracting Authority who will have full authority to bind the consortium and each of its members, and will be responsible for the administrative management of the contract (invoicing, receiving payments, etc.) on behalf of all other entities.

I hereby accept that the consortium member will do everything in its power to help the consortium leader fulfil its obligations under the contract, and in particular, to provide to the consortium leader, on its request, whatever documents or information may be required. I also accept that all economic operators in this joint tender assume joint and several liability towards the Contracting Authority for the performance of the contract as a whole.

I hereby declare that the consortium member agrees that the provisions of the contract, including this power of attorney, shall take precedence over any other agreement between the consortium member and the consortium leader which may have an effect on the implementation of the contract.

This power of attorney shall be annexed to the contract and shall form an integral part thereof.

SIGNATURE

Rosa Sunol
Director

AVEDIS
DONABEDIAN
FUNDACIÓN

× × × × ×
× × × × ×
× × × × ×
× × × × ×
× × × × ×

[signature]

Done at Barcelona, 23/09/2015

In duplicate in English

ANNEX XX
POWER OF ATTORNEY[1]

I, the undersigned,

Matthijs Versteegh, PhD,

representing,

institute for Medical Technology Assessment *[iMTA]*
Limited company[2]
Registration number 24257138][3]
Burgemeester Oudlaan 50, 3062PA, Rotterdam, The Netherlands
VAT number NL804735529B30,

hereinafter referred to as "the consortium member",

for the purposes of the signature and the implementation of the contract **Call for tender n° *SANTE/2015/D2/021* Pilot project on the promotion of self-care in chronic diseases in the European Union** with the European Commission (hereinafter referred to as "the contract")

hereby:

1. grant power of attorney to

European Patients' Forum-EPF

Asbl governed by Luxemburg law

F448

Rue Dicks 14, 1417 Luxemburg

represented by Anke Seidler, Head of Office of the European Patients' Forum,

(hereinafter referred to as "the consortium leader")

to sign in my name and on my behalf the contract and its possible subsequent amendments with the European Commission.

2. Grant power of attorney to the consortium leader to act on behalf of the consortium member in compliance with the contract.

---

1 One original version of this Annex is to be included for each consortium member except for the member acting as single point of contact.

2 To be deleted or filled in according to the "Legal Entity" form

3 To be deleted or filled in according to the "Legal Entity" form

I hereby confirm that the consortium member accepts all terms and conditions of the contract and, in particular, all provisions affecting the consortium leader and the other consortium members.

The consortium shall nominate one legal entity as single point of contact for the Contracting Authority who will have full authority to bind the consortium and each of its members, and will be responsible for the administrative management of the contract (invoicing, receiving payments, etc.) on behalf of all other entities.

I hereby accept that the consortium member will do everything in its power to help the consortium leader fulfil its obligations under the contract, and in particular, to provide to the consortium leader, on its request, whatever documents or information may be required. I also accept that all economic operators in this joint tender assume joint and several liability towards the Contracting Authority for the performance of the contract as a whole.

I hereby declare that the consortium member agrees that the provisions of the contract, including this power of attorney, shall take precedence over any other agreement between the consortium member and the consortium leader which may have an effect on the implementation of the contract.

This power of attorney shall be annexed to the contract and shall form an integral part thereof.

SIGNATURE

in replacement.

Prof Carin Uyl-de Groot, Statutory director iMTA / Prof. M. Rudberg-van Möllen.

[signature]

Done at Rotterdam, 24-09-2015

In duplicate in English