DECIPHER PCP

FP7 – 288028
Framework Programme (FP) 7
ICT -2011.5.3
Patient Guidance Service (PGS), safety and healthcare record information reuse
Combination of CP & CSA

Deliverable D4.1
Phase 0: Evaluation Report

FP7 – 288028
Framework Programme (FP) 7
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Patient Guidance Service (PGS), safety and healthcare record information reuse
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Responsible Author	Cari Almazan	e-mail: calmazan@gencat.cat
	Partner: AIAQS	Phone: +34 935513900

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Authors	**Name**	**Partner**
Main author	C.Almazán	AQuAS
Co-authors	M.Moharra, M.Decool, C. Sampol, P. Adam, I. Caamiña, A. Garcia Altes, C. Coll, R. Alessandrello	AQuAS
	R. Deed, P. Hanmer	CMFT
	M.Spinu; M.Faviere; S.Papiani; L.Cattaneo; T.Lanis	ESTAVC
	Garcia - Milá	TICSALUT
	J. Lähteenmäki	VTT
	M.C. Corradini, F. Tistarelli, A. Saliaj, G. Cangioli, G. Mennuti, S. Bertagnini	ATS
	S. Ikavalko, K. Huhtinen	CULMINATUM
	E. Casals, V. J.Ribas	BD

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Abstract (for dissemination)	Deliverable 4.1 deals with the DECIPHER project evaluation. It is split into two parts: first one refers to the evaluation framework and programme for DECIPHER and the second part shows the results of the evaluation of Phase 0 (Needs Assessment Phase). The Evaluation of DECIPHER project has been planned at two levels: 1) a short term evaluation based on intermediate evaluations at the end of each Phase of the PCP. The main aim is to get information and to assess the achievement of goals previously established for this phase and secondly to elaborate recommendations for next phase. 2) A medium term evaluation to assess whether DECIPHER will reach the overall objectives of the project according to the end users needs. The second part of this Deliverable deals with the evaluation of Phase 0. (Needs Assessment Phase)- The results produced by DECIPHER during this phase will definitely provide some evidence in PCP field at European level, specifically concerning the methods and processes followed during this phase.

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1 Background

PCP is essentially an “approach to procuring R&D services”. It is triggered by procurers identifying the need to find a solution to a specific problem of public interest for which they cannot yet find "commercially ready or nearly-ready" solutions on the market and which requires significant amount of R&D investment (step-change innovations, not incremental adaptations) to get the solution developed[1.] Specifically PCP refers to: 1) R&D services following the product innovation cycle life. Thus, R&D can include activities such as solution exploration and design, prototyping, up to the original development of a limited volume of first products, 2) It’s based on risk-benefit sharing, among public authorities and industry, and elaboration of R&D needed to develop innovative solution, 3) it combines the risk-benefit sharing and the procurement process to ensures maximum competition, transparency, openness, fairness and pricing at market conditions to allow the public purchaser to chose/ identify the best solutions [1-2.]

First PCP initiative was launched in 1982 in USA and is still running. It’s called ‘Small Business Innovation Research´ (SBIR). During the first decade of the new millennium two national initiatives were launched in Europe inspired by pre-commercial part of the US SBIR: the cases of UK SBIR (2001) and Netherlands SBIR (2004)[3], followed by other countries such as Finland, Denmark and Hungary more recently Spain, Italy and Sweden have strong commitments to implement PCP practices[4].

The objective of DECIPHER project is to promote the development of a mobile solution that enables secure cross-border mobile access to existing patient healthcare portals and efficient and safe medical care of mobile patients in EU member states. This solution shall be of special interest in the management of long term conditions of patients with chronic diseases or unplanned care episodes. To reach this challenge at this time, R&D activities are needed to promote innovation in this field and a PCP approach has been proposed. Thus, DECIPHER will deploy a PCP to create and

1 “Draft PCP Manual – A practical guide to PCP Implementation for PROGR-EAST WP4 Pilots” PROGR-EAST FP7-ICT-2009-4
2 Pre-comercial Procurement: Driving innovation to ensure sustainable high quality public services in Europe. Commision of the European Communities. {SEC (1007) 1668}
3 Wolfgang Knapp, Nina Widmark, Stephen Hughes, ILiona Lundström, Angelica Roschier. Desing options paper. Part of Deliverable D3.3-D3.6. Pre-Comercial Procurement of Innovation (PCP).Pro Inno Europe. INNONETS. INNO_Partnering Forum. October 2011
4 PreCO. Policy Recommendations for advancing Pre-Commercial Procurement in Europe.

innovative mobile application connecting with health information repositories from different countries.

DECIPHER PCP process will take place over 3 Phases: Design (Phase 1), Prototype (Phase 2) and Small-Batch Production (Phase 3). Prior to PCP, there is a Need Assessment Phase (Phase 0) to identify end-users needs (patients and healthcare professionals) and to define functionalities of innovation. Each phase of the PCP includes a series of activities described in the accompanying graph. The PCP begins with a PCP-ITT contract issued by the Contract Authority. Also, establishing a competition between a cohort of suppliers throughout each of the three PCP phases. This cohort begins in phase 1 and competes to advance to phase2. Those which are selected on completion of phase 2 will enter phase 3 competition. In this PCP process defined by the EC, at the end of each Phase (following the life cycle of innovation) an intermediate evaluation is carried out.
In the context of DECIPHER project the objectives of WP4 are:

- To design a framework to be used to evaluate the different bidders in terms of process and impact measures
- To design a framework to be used to evaluate the different selected proposals covering technical and pre-pilot aspects and to be used generically when procuring pre-commercial solutions in the mobile health domain
- To generate detailed standard reports of the evaluations
- To prepare an impact evaluation of the project through a summative evaluation that will cover success and failure issues.

The aim of the WP4 is to provide information to the contracting authorities to assess if the objectives defined for each phase and the overall objective of the project are finally reached. It should be considered that the Specification development and ITT notice, the evaluation of submissions, the contracts awards and the legal documentation are out of scope of WP4.

To meet WP4 objectives, a literature review of the state of the art of current PCPs, its have been conducted, which should to allow a definition of the evaluation programme (evaluation framework, intermediated evaluation process and an overall evaluation process during the PCP).

2 Literature review

2.1.1 Background

To evaluate the development and implementation of DECIPHER, an evaluation framework and programme need to be elaborated. The purpose of the evaluation is to provide information to decision makers to assign a value judgement, in that case, about the process and methods used in the DECIPHER PCP. Therefore, valid and reliable information is necessary to help stakeholders make informed decisions to enable continuous improvement of the PCP process.

This report is a review of the literature about evaluation on Pre-Commercial procurement (PCP). The EU Commission definition of the PCP concept is: "Pre-commercial procurement consists of a procurement of R&D services that involves a risk-benefit sharing at market conditions and in which a number of companies develop in competition new solutions for mid-to long term public sector needs" [5].

The purpose of this literature review is not to give a comprehensive overview on all PCP literature. It is not intended either as an evaluation of PCP programmes; rather the purpose of the review is to draw lessons for the PCP evaluation process since concrete experiences in Europe.

2.1.2 Objectives

- To describe the most frequent evaluation frameworks used in PCP setting in order to identify the most appropriate framework for DECIPHER
- To examine the possibilities to define a standard statement of selection and evaluation criteria methods based on the evidence of experience.

2.1.3 Methods

A literature review was carried out in evaluation frameworks of PCP process by means of a computerized literature search performed using several data sources: ISI Web of Knowledge and Google scholarship

5 Guide to community rules on public procurement of services other than in the water, energy, transport and telecommunications sectors directive 92/50/EEC.

The search strategy was focus in Europe and it included as main mesh terms(Annex 1):

> "precommercial procurement"; "pre-commercial procurement";"public sector procurement";"public procurement", "small business research";"small business innovation";"public procurement";"innovat

The review was completed by consulting some websites of relevant international organizations and manual review of the bibliographic references of articles.

Data extraction and synthesis

The data extracted from PCP publications were: title of the document, year of publication, scope of the document, main contents and conclusions. The data extracted from the PCP call for tenders were: tender characteristics (main goal of PCP challenge, contracting authorities, time, call for tender); and evaluation dimensions for award criteria (impact, quality and price).

Narrative synthesis was used to integrate findings. The results of this review are presented according to the characteristics of reports, contents and main remarks. Data extracted were summarized into tables presented in Annexes 2 and 3.

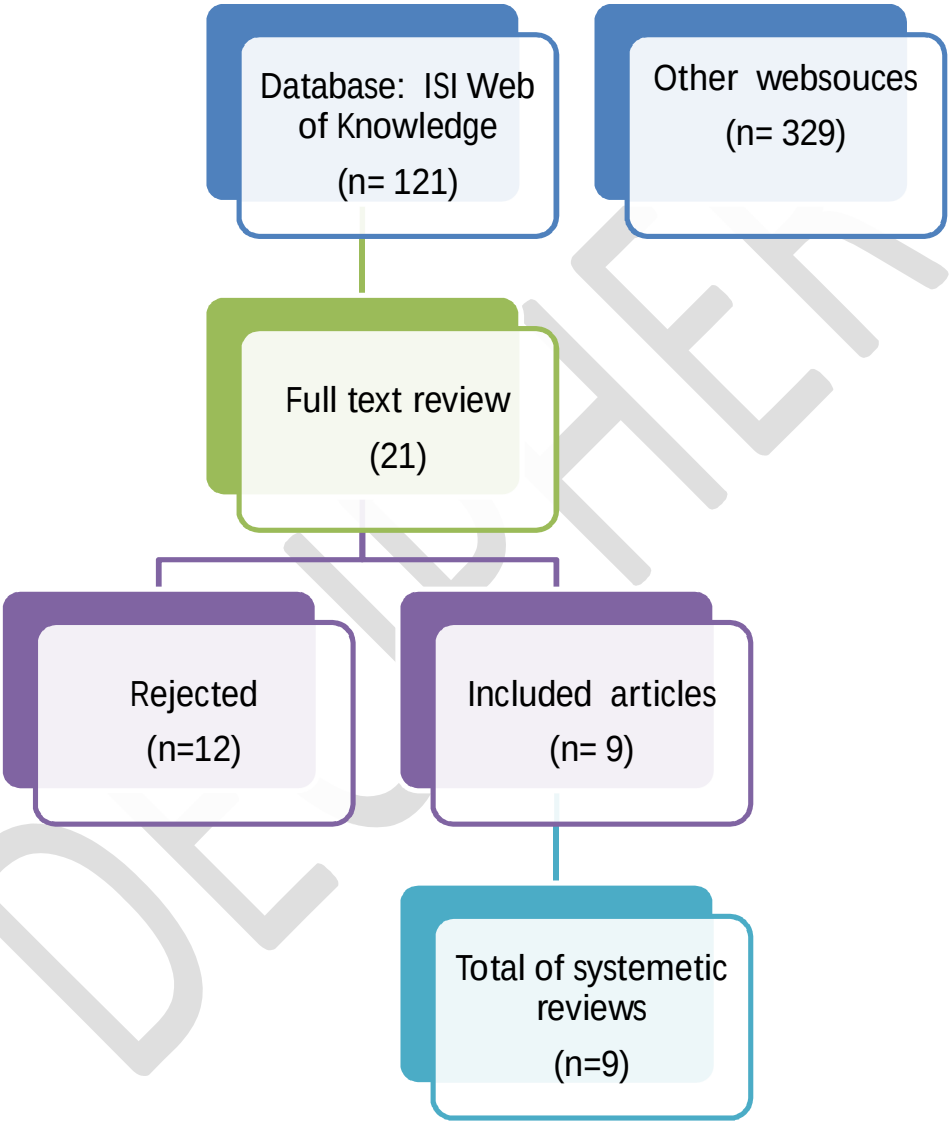
2.1.4 Results

Literature review overview

The literature search located 450 electronic citations and 21 relevant full text documents were selected for review. Finally, 9 publications were included in this literature review. Most of the papers contained in the search were not concern with PCP and a big amount of titles dealing with public procurement around the world were excluded of the review.

The selection of references of the review was classified into two categories of documents: policy papers, directives and general guidelines on PCP and European PCPs on course.

Figure 1 shows the process of study selection.



Policy papers, Directives and general guidelines on PCP

Six documents related to a comprehensive view of PCP were identified (Table 1). These documents were analysed to identify the characteristics of the PCP, the terms of procedure and legal framework. Table 1 also includes a comparative analysis on other models of procurement. The overall purpose of the publications are to provide guidance to better implement innovation services for stakeholders, and to discuss different design options or improving initiatives in the area of Pre-Commercial Public Procurement. Although, this review is focused on European experience, one report related to the SBIR of US policy directive was included.

Table 1. Policy papers, Directives and general guidelines on PCP

Europe reports
Directive on Pre-commercial procurement: Driving innovation to ensure High quality public services in Europe. Brussels. EC communication [SEC (2007) 1668]
Knapp W, Widmark N, Hughes S, Lundström I, Roschier A. Design options paper, Pre-commercial Procurement of innovation INNONET, Austria.2011.
Sloth M, D2.1 Analysis of public Pre-Commercial Procurement models and mechanisms. Belgium: 2011.
Lucas R, Vulcano A, Jacobsen B.A practical guide to PCP. Implementation for PROGR-EAST pilots. Italy: 2012.
Rigby J, Review of pre-commercial procurement approaches and effects on innovation. Compendium of evidence on the effectiveness of innovation policy intervention. Manchester: Manchester Institute of Innovation Research Manchester Business, School, University of Manchester. 2013.
US reports
Small Business Administration Office of Investment and Innovation [Internet web page]. Small Business Innovation Research (SBIR) Program, Policy directive.2012. Available at: http://www.sbir.gov/about/sbir-policy-directive.pdf

Directive on Pre-commercial procurement. Driving innovation to ensure high quality public service in Europe (2007)[6], was published by the European Commission. This document on PCP raises the awareness on how R&D services can be procured in a way that applied risk-benefit sharing between procurers and suppliers. Highlight the importance of public procurement in reinforcing the innovation capabilities on the EU whilst improving the quality and efficiency of public services. This document provide guidance on good practise to promote the potential of public

6 Pre-commercial procurement: Driving innovation to ensure High quality public services in Europe. Brussels. EC communication [SEC (2007) 1668]

procurement for stimulating innovation, aiming to draw the attention of Member States to the existing but underutilised opportunity of PCP. This Directive defined the framework of PCP, following the Phases of the product innovation life cycle and identify two intermediate evaluations after phase 1 (solution design) and phase 2 (prototyping), in order to select progressively the best solution. The Directive proposed the following award criteria: "ability to address the problem posed in the tender", "technological quality and innovativeness of the proposal", "added value for society/economy of the proposal" and proposes a continuous evaluation using the same criteria for the contract award.

Design options paper, Pre-commercial Procurement of innovation, INNONET [7] has been prepared in the context of the INNO-Partnering Forum project. The document suggests and discusses different design options in the area of PCP, and it's intended as a guide or tool for any innovation agency, department or similar organisation that is considering, or has decided to offer a PCP initiative. It identifies 5 stages in the PCP: activation stage, identification stage, PCP stage, commercial stage and follow-up stage along side the project. It describes the differences of PCP stages between US SBIR, Nederland's SBIR and EU Commission. The document presents an interesting approach on the follow-up stage of the PCP, as continuous activities that comprise a general follow-up such an approach includes short term monitoring, medium term evaluation and long term impact analysis. The published document proposes four award criteria: 1) Solution of public challenge and Entrepreneurship; 2) Degree of innovation and technological quality; 3) Economic perspective; 4) added value for society.

Analysis of *Pre-commercial Public Procurement models and mechanisms (P3ITS)* [8] is a report which establishes the legal framework for public procurement and PCP and then moves on to describing how procurement of innovation has been implemented in practise in different Member States in the EU. This report describes the reason why new PCP programmes are basing their general and evaluation framework on already existing ones to avoid uncertainties as regard on methods and to the legal aspect. For European countries the concept of PCP is still new to most procurers. England and the Netherlands are the first one making it usable for all procurers and other European countries are starting up programmes on their own, experiences and

7 Knapp W, Widmark N, Hughes S, Lundström I, Roschier A. Design options paper, Pre-commercial Procurement of innovation INNONET, Austria.2011.
8 Sloth M, D2.1 Analysis of public Pre-Commercial Procurement models and mechanisms. Belgium: 2011.

recommendations from these programmes are not yet available as the programmes have only just started in 2010.

***Practical guide to PCP. Implementation for PROGR-EAST* pilots[9],** is a manual on PCP for policy makers and public procurers for participating countries of PROGR-EAST programme. To elaborate the manual, European and US experiences on PCP were analysed. Also, a desk research, interviews to procurers and procurement experts, were carried out. Publication highlights the needs of having a practical manual on PCP for policy makers and public procurers and to define a practical approach of how to implement PCP and legal issues associated with it. The PCP framework and the main steps of evaluation are those defined by EC. As regards to the award criteria, the manual recommends to define it prior to evaluating submissions and should be made explicit in the PCP Call for Tender. The award criteria may take into account the price and additionally three dimension: 1) quality, refers to the ability to address the problem posed in the tender; 2) Implementation, related to the quality and effectiveness of the proposed R&D work plan and allocation of resources; 3) impact refers to the added value for society/economy, the soundness of the commercialisation plan of the bidder.

Review of pre-commercial procurement approaches and effects on innovation. Compendium of evidence on the effectiveness of innovation policy intervention[10]. It's a review of literature on government procurement of R&D services, published by the Manchester University that seeks to stimulate innovation. This report examines the rationales of PCP, its context, operation and impact. Furthermore, it analyses the definition and purpose of PCP, special conditions as well as how PCP is implemented within the EU. The principal finding on evaluation methods is that it doesn't exist a formal framework. Despite the recent interest in PCP outside the US, there are no formal extensive evaluations that use effective methods to assess impact. It points out the limited evaluation of PCP programmes for a variety of reasons and while much has been written about US scheme, there remain uncertainties about its operation and impacts upon innovation. It emphasise that a small number of evaluations have examined the net impact by using control groups.

9 Lucas R, Vulcano A, Jacobsen B.A Practical guide to PCP. Implementation for PROGR-EAST pilots. Italy: 2012.
10 Rigby J. Review of pre-commercial procurement approaches and effects on innovation. Compendium of evidence on the effectiveness of innovation policy intervention. Manchester: Manchester Institute of Innovation Research Manchester Business, School, University of Manchester. 2013.

The ***Small Business Innovation Research (SBIR) Program - Policy Directive***[11] . It's an US Policy Directive (PD) that fulfils Small Business Act statutory obligation. The aim is to provide guidance to the participating Federal Agencies for the general operation of the Small Business Innovation Research Program (SBIR). This PD details the statutory requirement to simplify and standardise the program proposal, selection, contracting compliance, and audit procedures for SBIR program, while allowing the SBIR agencies flexibilities in the operation of their individual SBIR program.

The statutory purpose of the SBIR program is to strengthen the role of innovative small business concerns in Federally-funded research or research and development Specific Program. SBIR Agencies are obligated to follow the guidance provided by this PD. The standard statement on evaluation is developed in the PD on a general basis.

The PD establishes that SBIR Agency must make the awards through the following uniform three-phase process:

- to determine insofar as possible, the scientific and technical merit and feasibility of ideas that appear to have commercial potential,
- awards to further develop work from phase 1 that meets particular program needs and exhibits potential for commercial application,
- awards where commercial applications of SBIR-funded R/R&D are funded by non-Federal sources of capital; or where products, services of further research intended for use by the Federal Government are funded by follow-on-non-SBIR Federal Funding Agreements.

The SBIR Agency standardized the method in its evaluation process and provides five evaluation criteria:

- the technical approach and the anticipated agency and commercial benefits that may be derived from the research,
- the adequacy of the proposed effort and its relationship to the fulfilment of requirements of the research topic or subtopics,

11 Small Business Administration Office of Investment and Innovation [Internet web page]. Small Business Innovation Research (SBIR) Program, Policy directive.2012. Available at: http://www.sbir.gov/about/sbir-policy-directive.pdf

- the soundness and technical merit of the proposed approach and its incremental progress toward topic or subtopic solution,
- qualifications of the proposed principal/key investigators, supporting staff, and consultants,
- evaluations of proposals require, among other things, consideration of a proposal's commercial potential.

Other US reports identified on the evaluation of PCP are those elaborated by the National Research Council, such as 'An Assessment of the SBRI program'. But these reports are focused on the evaluation of the impact (in terms of effectiveness and cost) of SBIR program, rather than in the evaluation of specific projects. Therefore, these reports are out of the scope of this review[12].

European PCPs currently active

Two studied programmes[13-14] of active European PCP projects funded by the EC under the Seventh Framework Programme for research and technological development (FP7) were identified. The principal aims of those projects are to demonstrate the effectiveness of the PCP approach to address societal and governmental needs with the purpose of developing a new product or solution. A descriptive summaries content table of the PCP is presented in Annex 2.

One of the PCP, Supporting Independent Living for the Elderly through Robotics **SILVER** challenge to develop new innovative robotic solutions that target assisting the elderly and those caring for them with personal activities of daily living. In this PCP a Technology Strategy Board (from UK) act as the Authority on behalf and in the name of the group of contracting authorities for a cross border group of SILVER contracting authorities (City of Eindhoven – Netherland; City of

12 Charles W. Wessner, Editor, Committee on Capitalizing on Science, Technology, and innovation: An Assessment of the Small Business Innovation Research Program, National Research Council. ISBN: 0-309-11087-4. http://www.nap.edu/catalog/11989.html.
13 SILVER [web page] Generic Pre-Commercial Procurement Process. http://www.silverpcp.eu/

14 CHARM [web page] Invitation to Tender.
http://www.rijkswaterstaat.nl/en/about_us/business_opportunities/charm_pcp/

Odense- Denmark; City of Oulu- Finland; City of Stockport United Kingdom; City of Vantaa- Finland; city of Västeras – Sweden; Region of Southern Denmark). The time schedule for the PCP is from February 2013 to May 2016.

The **CHARM** consortium is another European PCP currently active which intends to help development of the market for Traffic Management Centres. It also tries to reduce the cost of ownership and create a more flexible and adaptable traffic management system.
The Secretary of State for Transport (HA) from England and Rijkswaterstaat (RWA) from the Netherlands are the contracting Authorities both are governmental agencies responsible for the strategic road networks in England and Netherlands. Building on this perspective, 3 separate Pre-Commercial Procurement (PCP) challenges have been proposed to achieve substantial improvement of traffic management services:

Challenge 1: Advanced distributed network management: To realise a module that provides automated support for management of large (nationwide) traffic networks. The module should be a multi-layered, self-learning engine that is able to manage large networks and balances between different types of goals
Challenge 2: Detection & Prediction of Incidents: To realise a module that provides early identification and prediction of near future events on the network (accidents, queues, etc.), called "virtual patrolling". Detection and prediction should be targeted at the top 3 incidents: accidents, car breakdowns and queues.
Challenge 3: Support of Cooperative ITS Functions: To realise a module that supports the implementation of cooperative system services requiring a participation of intelligent infrastructure, in order to optimise the performance of the road network.

Those PCP trajectories typically consist of three phases: concept/solution design, prototype development and pilot phase (development of first pre-products on a small scale that are tested in the field).

The assessment criteria and their weighting and scoring model published per phases in the Invitation to tender for both PCP are very similar. The same criteria and method for evaluating the tenders in each phase will be used but may be elaborated or developed in further detail within those frames. The weights per criterion differ according to the process evolution.

Review limitations

Few documents on evaluation of the PCP process have been found. PCP is a new process in Europe and few documents have been published. In general, a kind of guideline is often developed and published by the public procurer aiming to compile the experience in a tool guideline for future PCPs; hence the studied documents (guideline, hand book, policy paper, deliverable, invitation to tender) are most of them very practical ones. Few scientific studies have been performed on evaluation measures of PCP processes. Big amounts of US publication on SBIR experience is available but were excluded in the review because the scope of this study was the European PCP experience.

2.1.5 Main remarks

2.1.5.1 Evaluation frameworks used in PCP setting

Although, the approach adopted has been to scan very large literature very few documents were fitted with the selection criteria previously defined.

The results showed a descriptive and well documented methodology on tender's process but there is very little evidence for follow up monitoring and overall evaluation. The results of the literature review identified two main guidelines describing PCP programme processes in Europe. However these documents are not based on the experience of a PCP programme at European level like DECIPHER but are rather focused on national PCP experiences.

These documents provided some general guidelines to be followed in the evaluation PCP process:

- The frameworks should be applied in a flexible way, taking into account different contexts and purposes, stakeholder's point of view, phases in PCP process, device development, and evaluation methods.
- The methodology of the evaluation must be designed at the first stage of the project to assess the lead body to follow-up stages and the ongoing activity. This evaluation framework includes monitoring the PCP process, and evaluating initiative as a whole.
- "Within the literature on the evaluation of the US SBIR programme, and in relation to other pre commercial procurement schemes from around the world, three major issues have arisen: a) the difficulty of ensuring and emphasising the comparability of findings; b) the

evaluation process; and c) the apparent absence of evaluations early in the lifetime of the measures used."[15]

2.1.5.2 General considerations on selection and evaluation criteria methods

The results on PCP projects have helped to identify a set of common and standard evaluation dimensions for the DECIPHER PCP-ITT. In this report, the evaluation dimensions for the award criteria are considered important features that organise, give shape and support the proposal for the evaluation criteria during the PCP process however it should be noted that the two PCPs currently active (SILVER and CHARM) are not developing an innovation solution in the health field.

Additionally some conclusions on the selection, process and evaluation methods have been identified:

- Award criteria must be linked to the subject matter of the contract, disclosure must extend to all factors which will be taken in consideration by the procurer in evaluating. The award criteria must be pre-determined prior to evaluating submissions, and these criteria should be made explicit in Invitation to Tender.
- All offers have to be evaluated according to the same objective criteria regardless of the nationality of the bidder and these criteria must be understandable, quantifiable and verifiable.
- Establishment of a numerical scoring system is vital; each criterion should be assigned specific score and be given a different weight. A score sheet should be distributed to the experts based on the criteria and scoring model. A ranking list should be produced and used by the evaluating panel.
- The intermediate evaluations can make use of the same criteria used for the contract award. The tender specifications can become progressively more specific with each phase. It's recommended that flexible approach is taken regarding the criteria used.

15 John Rigby (2007) Review of Pre-commercial Procurement Approaches and effect on innovation

3 Evaluation framework

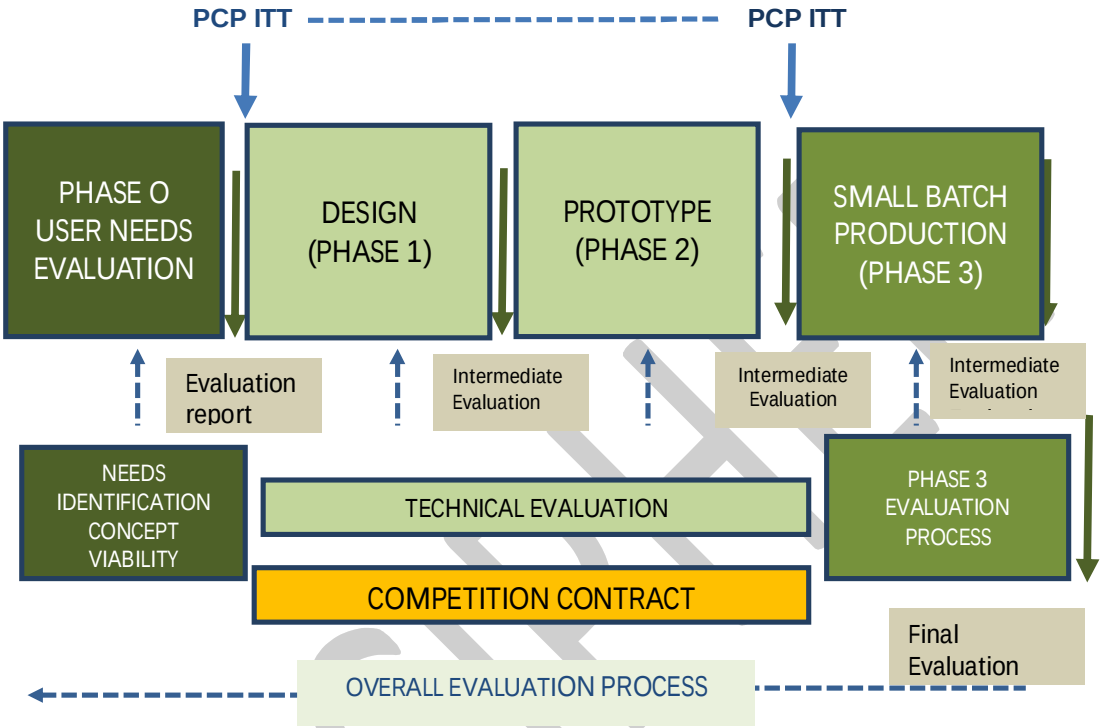
To ensure DECIPHER PCP meets the objectives set by Contracting Authorities and is devised according the basic principles of PCP established (by EC Treaty Principles), such as competition, transparency, openness, fairness and pricing at market conditions, an evaluation program is designed during the three years of the project. Evaluation should provide valid and reliable information to the Contracting Authority, known as the DECIPHER PCP, and will allow the procurers to meet their strategic objectives. In that sense, Contracting Authority needs to consider what information is required to make informed decisions. If some changes in the process are required, this change should be managed in a controlled process. Following the guide "A practical Guide to PCP. Implementation for PROGR-EAST pilots" several questions, which cover the activities developed in the DECIPHER PCP can help to decision makers to make informed decisions, such as:

- Was the need clearly defined and prioritised by the Contracting Authority?
- Did a Concept Viability exercise identify if a solution to the need already exists in the marketplace, or if it is technically and pragmatically possible to create a step-change solution?
- Was the PCP Call for Tender outcome focused?
- Was the competition conducted in an open, fair and transparent manner?
- Were contracts designed to ensure that the supplier remained focussed on delivering the outcome identified in the PCP CT?
- Were contracts performance managed, to ensure milestone deliverables, and that risks and issues were managed optimally?
- Did the PCP ensure that Intellectual Property was managed well?
- Were innovations developed that met the need identified in the PCP CT?

The results of the literature review (section 2) and the consensus of WP4 partners allow to define the DECIPHER Programme Evaluation which includes the evaluation framework, the intermediate evaluations and the overall evaluation PCP process.

The DECIPHER evaluation framework is based mainly in previous PCP experiences and practical guides for PCPs within the EC environment. Figure 2 shows the evaluation framework defined for DECIPHER during the three years of the project.

Figure 2. DECIPHER Evaluation Framework



DECIPHER evaluation approach is a continuous process carried out to obtain information of the task developed during the PCP, at two levels and periods of time: a **short term evaluation** based on the **intermediate evaluation** (after the solution design, prototype development and small batch production stages) and **medium term related to the overall evaluation**. In addition, DECIPHER will include an evaluation of Needs Assessment Phase 0 before starting the PCP. More specifically, intermediate evaluations will be conducted after:

- Phase 1: Solution Design
- Phase 2: Prototype development
- Phase 3: Proof of concept

Furthermore, an **overall PCP evaluation** throughout the project will assess whether the PCP will achieve its goals according the user needs and whether the project has run based in the principles of competition, transparency, openness, fairness, characteristic of PCP.

3.1 Intermediate evaluations

3.1.1 Evaluation Phase 0

Objective

To evaluate the method used in Phase 0 in order to meet the objectives previously defined in Phase 0. The evaluation criteria to assess the needs identification phase will be based on methodology appropriate and also in the quality of the methods used.

Main task:

This activity will be evaluated by means of accomplishment and objectives met: the solution meets the needs identified in the first step (end users needs).

Evaluation process

An assessment of the activities performed by procuring authorities during Phase 0 will be provided. This evaluation will take into account the type of methodologies used to achieve the objectives previously defined for Phase 0.

Responsible of evaluation

WP4 will be responsible for providing an evaluation of the methodologies followed and activities performed during Phase 0.

Timing of evaluation

The evaluation of Phase 0 will be performed as soon as the official deliverables including expected activities to be performed during Phase 0 have been submitted.

Output of evaluation

A report (Deliverable 4.1) on the evaluation of Phase 0 with results, conclusions and recommendations will be prepared. See Section 4.1 for additional information.

3.1.2 Evaluation Phase 1

Objective Phase 1 Design.

This evaluation aims to verify the technical, economic and organizations feasibility of each company's proposal against pros and con of the potential alternatives solutions. The output of this phase typically includes a technology evaluation, a first solution design, an organisational plan for Phase 2.

Main tasks of Phase 1 (DoW)

- To run the PCP-ITT via open, fair and transparent process.
- To select suppliers by a process of competition and awarded contracts to participate in phase 1.
- To manage the contract. A Member State will project manage the development of the innovation of the supplier to which it has been assigned.

Evaluation process

The **review of each of the main tasks** of Phase 1 will provide information to decision makers to assess the achievement of the main objective of this phase, which is developing the design of the solution. Therefore, the information to assess the technical, economic and organizational feasibility of the proposals will be obtained from:

– Results of the assessment of final solutions done by DECIPHER PCP Tendering Board and DECIPHER PCP Experts Board, based on the award criteria. These criteria and the score are show in the Table 1

– Additionally, it will include results of other technical criteria. These criteria are described and proposed in Annex 3 and should be adapted to each specific phase. These criteria will be related to the technical feasibility including the quality of technology, technical validity, security and usability. Also criteria about the cost and the benefit of the proposal could be considered in order to approach a cost/ benefit evaluation.

The data collected from the PCP tool Management System will be **used to monitor the competition, transparency, openness and fairness characteristics of the PCP.** The PCP tool Management System will allow DECIPHER to obtain information about: the invitation to bidders, the upload of proposals, to audit the interactions between bidders and procurers, to highlights risks/issues, to follow milestones, and to monitor financial payment

Table 2. Evaluation Criteria for the design solutions in Phase

Criteria	
FUNCTIONALITY Score: 25 points maximum	1.- Functionalities required by the technical specifications, meeting the needs/goals described in such specifications: sharing information, no duplication of clinical tests, self-care, etc 2.-Additional functionalities proposed by the bidder, meeting the needs that result from patients mobility for care givers and care receivers.
INNOVATION Score: 20 points maximum	1.- Description of existing solutions for the needs/goals described in the technical specifications 2.- Explanation/support of the technical and functional innovation of the solution with regard to existing solutions (please note that at least 50% of the services under PCP should be R&D services)
QUALITY Score: 25 points maximum	Quality in the solution design: 1.- Work planning 2.- Identification and management of risks (regulatory risks, data protection, e-health, etc)
TECHNICAL FEASIBILITY Score: 15 points maximum	Quality of technology/technical validity (Annex 3)
FINANCIAL FEASIBILITY Score: 15 points maximum	1.- Saving costs advantages for healthcare providers 2.-Commercial exploitability: market analysis and market identification (business plan) 3.-Explotability costs ;third party dependencies (patents, licences)

Responsible of evaluation

BD and VTT will evaluate all technical requirements and functional satisfaction.

AQuAS will monitor all process.

Few selected end users will be invited to participate in the evaluation process on functional satisfaction.

Timing of evaluation

It will take place after the solution design, before to Phase 2.

Output of evaluation

A report (Deliverable 4.2) of evaluation with results of the process evaluation and recommendations about the next step. The report will be divided into two parts:

- Review of the process and results of the assessment solution.
- Monitor the competition, transparency, openness and fairness of the PCP regarding Phase 1.

3.1.3 Evaluation Phase 2

Objective

The aims of the evaluation are to verify to what extent the main features exhibited by the prototype meet the functional and performance requirements set forward by the public purchaser for the desired solution. The main output of this phase normally includes a prototype specification and demonstration, as well as a plan for limited first product development and testing and an updated cost/benefit evaluation.

Main tasks of Phase 2 (DoW)

- To run ITT Phase 2. Six suppliers will be offered a contract to continue participating in the PCP. Each contract will state the terms and conditions of the work, including the deliverables, milestones, and financial payment schedule.
- To select suppliers by a process of competition and awarded contracts to participate in phase 2.
- To manage the contract. A Member State will project manage the development of innovation of the supplier assigned to it.

Evaluation process

The **review of each of the main tasks** of Phase 2 will provide information to decision makers to assess the achievement of the main objective of this phase, which is developing of a prototype. Therefore, the information to assess the technical, economic and organizational feasibility of the proposals will be obtained:

- Results of the assessment of prototypes done by DECIPHER PCP Tendering Board and DECIPHER PCP Experts Board, based on the award criteria. These criteria and the score are show in the Table 2
- Additionally, it will included results of other technical criteria . These criteria are described and proposed in (Annex4) and should be adapted to each specific phase. These criteria will be related to the technical feasibility including the quality of technology, technical validity, security and usability. Also criteria about the cost and the benefit of the proposal could be considered in order to develop a cost/ benefit evaluation.

Data collected from the PCP tool Management System will be **used to monitor the competition, transparency, openness and fairness characteristics of PCP**.. This Management Tool will allow DECIPHER to obtain information about: the invitation to bidders, the upload of proposals, to audit the interactions between bidders and procurers, to highlights risks/issues, to follow milestones, and to monitor financial payments.

Table 3. Evaluation Criteria for the prototype in Phase 2

Criteria	Definition
FUNCTIONALITY	Assessment of grade of compliance of the prototype with the functionalities described in the correspondent solution selected
INNOVATION	Checking the innovative elements in the prototype
QUALITY	Quality in the solution implementation: technical and personal resources devoted to prototyping
TECHNICAL FEASIBILITY	Prototyping technical issues: reliability, stability
FINANCIAL FEASIBILITY	Cost analysis
FORMER PHASES	Quality of End of Phase 1 report

Responsible of evaluation

BD and VTT will evaluate all technical requirements and functional satisfaction.

AQuAS will monitor all process.

Few selected end users will be invited to participate in the evaluation process on functional satisfaction.

Timing of evaluation

It will take place after the solution design. It must allow a progressive selection of companies with the best design solution to jump into Phase 3.

Output of evaluation

A report (Deliverable 4.3) of evaluation with results of the process evaluation and recommendations about the next step.

The report will include two parts:

- Review of the process and results of the assessment solution.
- Monitoring of the competition, transparency, openness and fairness of the PCP regarding Phase 3

3.1.4 Evaluation Phase 3

Objective

The evaluation aims to verify and compare the performance (interoperability, scalability, etc) of different solutions in simulated real-life operational conditions of the targeted public service. The main output of this phase usually includes a test product specification, a field test and an updated cost/benefit evaluation.

Main tasks of Phase 3 (DoW)

- To run ITT Phase 3. Three suppliers will be offered a contract to continue participating in the PCP. Each contract will state the terms and conditions of the work, including the deliverables, milestones, and financial payment schedule.
- To select suppliers by a process of competition and awarded contracts to participate in phase 3.
- To manage the contract. Member State will manage the development of the innovation of the supplier assigned to it.

- To perform a proof of concept of the designed solution.

Evaluation process

The **review of each of the main tasks of Phase 3** will provide information to decision makers to assess the achievement of the main objective of this phase: The proof of concept.
Therefore, the information to assess product specifications, field test and economic evaluation will be obtained:

- Results of the assessment criteria and the assessment of the test done by DECIPHER PCP Tendering Board and DECIPHER PCP Experts Board, bases in the award criteria. These criteria and the score are show in the Table 3

Data collected from the PCP tool Management System will be used to monitor the competition, transparency, openness, and fairness characteristics of PCP. This Management Tool will allow DECIPHER to obtain information about: the invitation to bidders, the upload of proposals, to audit the interactions between bidders and procurers, to highlights risks/issues, to follow milestones, and to monitor financial payments.

Table 4. Evaluation criteria for prototype in Phase 3.

Criteria	Definition
FUNCTIONALITY	Assessment of grade of compliance of series with the functionalities described in the correspondent solution selected
INNOVATION	Checking of innovative elements in series
QUALITY	Quality in the solution implementation: technical and personal resources devoted to small scale producing
TECHNICAL FEASIBILITY	Production technical issues: reproducibility of the solution in an industrial process, reliability, stability
FINANCIAL FEASIBILITY	Cost analysis
FORMER PHASES	Quality of End of Phase 2 report

Proof of concept

The proof of concept will be conducted in simulation conditions in each country, a sample of 20 patients with chronic conditions and ability of using mobile solution should be selected.

Following the testing of the solution, patients will complete a questionnaire on usability, accessibility, semantics aspects. The questionnaires will be developed ad hoc for the project. Also five patients in each group will be asked to participate in a semi-structured interview to identify barriers and enablers of the solution, experience and perceptions (Table 5).

Table 5. Proof of concept: dimensions and metrics.

Dimension	Measures	Methods
Service aspects	Usability: extent to which the solution is used and attractive to the user Access: extend to which the technology can provide wider access for patients to public information data portals using mobile platforms. Semantics	Review of available usability questionnaires Ad hoc questionnaire
Perceptions and acceptance	To identify barriers and enablers, experience and perception	Semi-structured interview

Responsible of evaluation

BD and VTT will evaluate all technical requirements and functional satisfaction.

AQuAS will monitor all process.

A total of 60 end users will be invited to participate in the evaluation process on functional satisfaction.

Timing of evaluation

It will take place after the prototype.

Output of evaluation

A report (Deliverable 4.4) of evaluation with results of the process evaluation and recommendations will be elaborated. This report will include three parts:

- Review of the process and results of product testing.
- Monitoring of the competition, transparency, openness and fairness of the PCP regarding Phase 3.
- Evaluation results of the proof of concept.

3.2 Overall PCP evaluation

The aim of this evaluation will be to assess whether the PCP will achieve its goals according to the end-user needs and whether the project has run based on the principles of competition, transparency, openness, and fairness, characteristic of PCP.

To achieve this aim, it will included the intermediate evaluations and a set of indicators elaborated by means of a literature review and discussion and consensus work among the project partners.

4 Phase 0: Needs Assessment Phase

This section includes a description of the main objectives and methods expected to be used during this phase, the description of activities performed by the Commissioning Authorities within the DECIPHER Consortium and the evaluation of the activities and results performed during this phase.

4.1 Main tasks during Phase 0

The Needs Assessment phase embraces two steps, the Needs identification and the Concept Viability exercises (Figure 1) which are essential preparatory starting steps to the PCP process. During the Needs Assessment Phase, the DECIPHER Consortium will identify a concrete challenge engaging citizens and healthcare professionals in order to define the Consortium's PCP requirement. The expected outcome in the use case exercise is the relevant use case scenario including the functional specifications.

Step 1. Needs Identification:

The main objective during this phase is:

- To identify the need

Methods

There are different methodologies to identify the need:

- o Literature review of scientific, technical and policy publications.
- o Interviews (Key informant individual interviews or focus group, involving service end-users: citizens, patients' healthcare providers and end users in the needs assessment process).
- o Participatory techniques (consensus group)

The main output of the needs identification will be the use-case scenarios that will be then fed into the second step validation exercise called Concept Viability where evidence on the technical viability is expected to be collected.

Step 2. Concept Viability

There are two objectives in the concept viability exercise:

- o To assess whether it is technically possible to create a solution to meet the needs identified in the first step.

- To check whether the need can be met with products/services already available in the market.

Methods

To achieve these objectives, there are two possible approaches:

- Market/patent search: to cross check the needs identified with the state-of-the art of the industrial development.
- To share the identified needs with the industry

4.2 Evaluation

4.2.1 Background

Evaluation is a key activity that needs to be carried throughout the PCP process in order to ensure that the PCP is on course to meet the objectives set by the Contracting Authorities.

The evaluation criteria to assess Phase 0 will be based on the achievement of objectives previously defined and in the quality of methods used during this phase to achieve both steps: needs identification and concept viability exercise.

The following sections contain the main results reported in phase 0 and an assessment of the activities performed.

Deliverable 2.1_Phase0_NeedsAssessmentReport; *Deliverable 5.1EHR_PHR interfaces and PHR platforms state of the art report* and *Deliverable 6.3 Engaging Suppliers* to the PCP tender have been used as background material to evaluate the Needs Assessment phase.

4.2.2 Results

Phase 0 embraces different phases (needs identification phase; needs verification phase, feasibility analysis and concept viability and the Market consultation Day). To reach the objectives previously defined for Phase 0, different activities have been performed which are described in D2.1; D 5.1and D6.3. The following section shows a brief description of the activities performed.

4.2.2.1 Activities performed

Literature review

A state of the art study was performed to provide technical information for the development and procurement of the DECIPHER app. This study included cross-border aspects (including the targeted architecture and legal aspects), a review on existing PHR services (platforms and ecosystems) and the related EU initiatives and RTD activities. In addition, a first approach of how the DECIPHER partners (Spain/Catalonia; UK/Manchester and Italy/Tuscany) should access the EHR systems was also provided.

Surveys, stakeholder meetings and interviews

In general, a wide range of methods (Surveys, stakeholder meetings and interviews) were performed to answer the initial and specific objectives (Table 6). The main actors involved for these activities were ICT stakeholders, GPs and opinion leaders.

Table 7. Description of activities performed in Phase 0

Methods	**Objective**	**Content**	
Literature review	- To provide technical information for the development and procurement of the DECIPHER app.	- Cross-border aspects for personal health records - Existing PHR services - Standards and open specifications - Access to the HER systems of the DECIPHER partners.	
Methods	**Objective**	**Actors**	**When**
Stakeholder meeting	- To identify use cases	- Those with responsibility for personal health record	April 2013
Survey	- Definition of DECIPHER use case	NA	May 2013
Primary Research: interviews, structure questionnaires	- State of the art of HER - HER/PHR availability and use case in the NHS system	- GPs - Accident and Emergency services staff - Opinion leaders	April 2013
Secondary Research	- IT state of the art in the NHS	- --Literature research - Face to face interviews with stakeholders	April 2013
Workshop* (through nominal technique, brainstorming and metaplan)	- To validate the functional requirements of the DECIPHER application	- Clinical Professionals - Patients	NA
Market Consultation Day	- To validate the procuring authorities requirements with the market.	- Industry - Universities	June 2013

Methods	Objective	Process
Business case	To develop a list of specifications for pre-competitive bidding	
Functional specification exercise	To develop a list of specifications for pre-competitive bidding	FAST methodology: (functional; analysis; system; technique). Training to partners was provided on the FAST methodology
Horizon Scan	To analyse the state of the art of regulatory frameworks described To determine the protection and exploitability of the technologies.	

*Moderated workshops were carried out in Barcelona, Manchester and Florence. NA: not available

As described in Table 7, a survey was conducted by procuring authorities with the objective of defining the DECIPHER use cases. The following information was extracted:

- *General context where DECIPHER would operate in each country/region* (i.e. personal health channel, Summary Care Records among others). The results of this general context showed that there were some research shared aspects/requirements (secure access to the PHR/HER, chronic disease related and unplanned care).
- *PHR/HER availability and usage in each country/region*: a full description of the different architectural systems was provided by each procuring authority and an analysis of the common needs concerning exchange of medical information and privacy and access was also provided.

Finally a set of use cases was proposed and analysed according to the potential implementation complexity and subsequently they were ordered by priority level (high, medium and low).

Workshops

The main aim of conducting the workshops was to validate the functional mobile application. A total of 60 participants (30 patients and 30 clinical professionals) participated in the workshops that were held in Barcelona, Florence and Manchester. There were criteria defined for attendance of clinical professionals (medical specialities, clinical practice approach or management responsibilities) and for patients (use of technology, chronic level and patients with different health problems).

Table 8 shows that most of healthcare participants were physicians from a wide range of specialities and all participants were working at varying hospital levels but all from the public healthcare sector. The methodology for the workshops was based on a combination of techniques such as brainstorming, nominal group technique and metaplan. The results of the workshops showed three main blocks of conclusions: the usability key points, the function prioritization and the added model functionalities.

Table 8. Number and profile of actors participating in the workshops

Medical speciality	Physician (N=21)	Nurses (N=6)	Social Assistant (N=1)
Emergency care	2		
Transversal to different specialities	6	2	
Family Care	1		
Intensive care	3	2	
Mental Health / Orthopaedics / Cardiovascular / Pediatrics / Diabetis Units	6		
Social Problems			1
Long term conditions	1	2	
General Practise	2		
Level of care			
Hospital/Primary care	5		
Hospital Care	11	5	
Primary Care	5	1	
Social Care			1
Public/Private healthcare provider			
Public	20	6	1
Public/Private	1		

Main geographic situation (rural/urban)			
Urban	16	5	1
Urban/Rural	5	1	

Business case

Currently, the business case model for the proposed DECIPHER solution has been provided on a theory basis, the following section presents a brief description of the business case model currently described for DECIPHER.

The main interest of the DECIPHER programme is to get as many bids as possible and to make the outreach to be broad to make sure that all kinds of solutions for the problem are envisaged. The benefits of participating to the PCP should also be advertised to potential suppliers. To that end, it is important to highlight that participants will obtain positive results no matter how far they go in the process. For all participants, it is important to highlight that the PCP will lead towards a new market. At first, the suppliers may fell unsure how the PCP process might be beneficial for them. They will be put in competition with other suppliers to develop a product, which they are not sure they will eventually sell. It is therefore advised to develop a business case that has to include:

- The forecasted market development
- Other potential buyers or sources of profit
- the actions to enhance the market conditions for the wide adoption of innovations.
- other measures to be taken to help the winners of the PCP process to commercialise their new product or service, and not only through the subsequent tender.

  Business Case is the term usually used to refer to the project document which shows the estimates of expected timing of costs and revenues.
- In the analysis of the economic feasibility of a project is essential to take account of differences in the timing of costs, all of which are concentrated in the implementation phase of the project, compared to the benefits that will be available only after activation of the operating functions that the product the project will provide . The costs to consider are:
  - costs of design, construction and commissioning of the final products
  - the project costs in terms of human resources and technological equipment ;
  - The operating costs after the start of the new operating system processes: including human resource costs, maintenance costs and costs of using infrastructure components.

The economic benefits to consider are any higher revenues and lower costs resulting from higher efficiencies and lower costs arising from decommissioning of existing systems and processes that will be discontinued as replaced by the products of the project.

- To take account of the different distribution of costs compared to that of revenues, all flows must be discounted in order to make them comparable. The analysis of discounted cash flows, will highlight the “breakeven point“ (Break Even Point), that is the moment in time when the revenue curve intersects the cost curve, and therefore the point at which the total income estimated equalized costs. The project will be considered "value-added " to the organization if the economic break-even point will be prior to the scheduled time of product life of the project.
- The projects should be approved through a business case, which tries to answer the following question "Why should I invest in a particular project ? " Explain the characteristics of the project, the reasons why you should develop, the benefits that would arise and the costs to support it , as well as any other information necessary to decide whether or not to implement the project.
- The business case must identify the benefits. 1) Benefits of a financial - revenue, reduction or elimination of costs. 2) Other measurable benefits - customer service, employee satisfaction, error rates, levels complaints , etc. . 3) Intangible Benefits - strategic alignment , development of skills. Not all you can report on financial criteria and not everything can be measured, the intangible results must, however, ' to be the most realistic and meaningful as possible.
- Identify costs: 1) the costs to carry out and complete the project such as personnel costs , those related to the materials used , and any external resources necessary to structure; 2) the costs relating to any investment project involving; 3) operating costs that the organization will support once implemented the project

The business case must be supported by a document that responds to these questions

- Why the project needs to be done, what benefits bring , how to reach them
- What is the level of risk of the project? What are the risks relating to the construction, implementation and business?
- From what assumptions they go to realize the business case? Check that they are reasonable and consistent with the other present organization 4) What aspects are present in the business case sensitive? Some aspects of costs and benefits may vary by producing

a limited impact on the business case , but there are others who, even after a minimum variation , may change sign at the business case (from positive to negative or vice versa)

Functional specification exercise

The functional specification exercise was performed using the FAST methodology (Functional Analysis System Technique). The basic element of this system is the Function that describes the original intent or purpose that a product, process or service expected to be performed. In order to perform the analysis and work together on the definition of DECIPHER functional specifications there was a training proposal for all partners in the project. The training was performed in Barcelona (October 2013), Italy (November 2013) and Finland (November 2013).

The results of this exercise have helped to redefine the first set of functional requirements. See Table 9.

Horizon scan

The Horizon scan activity was performed through two main activities: an analysis of the state of the art concerning the regulatory frameworks described in D 5.1 and the patent search determining the protection and exploitability of the technologies.

The patent search query was mainly focused on United States of America patent database UPSTO.gob and in the European Patent Register.
The results of this query resulted in a total of 56 patents, 9 out of these 50 patents were relevant to DECIPHER.

Market Consultation

Three Pre-Commercial Procurement Market Consultation days have been organised in Barcelona (Catalonia), Tuscany (Italy) and Manchester (UK). The main aim of this activity was the engagement of suppliers to the PCP tender. The Market Consultation Days were planned as “preparation of a public procurement” and organised in a way no to preclude or distort competition. Thus, the announcement of the Market Consultation Day was made in advance through webs, mailing lists and OJEU. There was an open dialogue between the participants and the DECIPHER project partners and finally, information was provided at the same time by recording and broadcasting online.

Additionally and after the Market Consultation Days, a questionnaire was sent to all the participants attending the Market Consultation Days. The aim was to know about the profile (experience in developing technologies, SME versus large companies) of organisation/companies attending the meeting; opinion about PCP process (questions about PCP phases, criteria to evaluate bidders' proposals; interest in participating in PCP).

Data analysis coming from these questionnaires showed that there are about 20 companies interested in participating in the DECIPHER project. The results of the Excel questionnaire also showed some relevant aspects reported by companies concerning the evaluation criteria.

4.2.3 Evaluation of Phase 0 activities

This section includes an evaluation of the methodologies performed and reported during Phase 0 and is based on the information reported in previous section 4.2.2

4.2.3.1 Methods and activities performed

A wide range of methods and activities (literature review, surveys, interviews and workshops) have been performed by the procuring authorities to reach the objectives previously defined. However, there is still some information not clearly defined in the process and timing of the activities, for instance it is not clear when the interviews with stakeholders and opinion leaders or when the survey to define the use cases was launched (Table 7).

Table 7. Checklist of methods and activities performed during Phase 0

PHASE 0	Yes	No
Needs identification phase		
Methods		
Literature review	✓	
Surveys	✓	
Workshops	✓	
Actors		
Were stakeholders, opinion leaders involved during this phase?	✓	
Were healthcare professionals (GPs; nurses) involved during this phase?	✓	
Were patients involved during this phase?		✓

Needs verification phase		
Workshops	⌐	
Actors		
Were healthcare professionals (GPs; nurses) involved during this phase?	⌐	
Were patients involved during this phase?	⌐	
Feasibility analysis and concept viability	**Yes**	**No**
Methods		
Functional specification exercise	⌐	
Horizon scan	⌐	
Business case	⌐	
Market day	⌐	
Outputs		
Functional requirements	⌐	

4.2.3.2 Outputs achieved

The activities performed have yielded to some outputs that were expected to be reached in Phase 0. The main output of this phase is the set of functional requirements defined for the DECIPHER App. In addition, this exercise has been completed and achieved through a wide range of methodologies, including qualitative approach through focus groups and interviews techniques. Table 9 shows a description of the functional requirements

Table 9 List of functional requirements defined by the DECIPHER app.

FUNCTIONAL REQUIREMENTS
Secure PHR-S Access
Share information (semantics)
Manage treatments (calendar and reminders; Alerts, tasks tracking)
Inform in Emergency Situations

4.3 Conclusions

- **Pre-Commercial Procurement (PCP) in EU is a relatively new model of procurement** and is gaining usage among the Member States but little case experience and best practice is available. The Needs Assessment phase processes and the results produced by DECIPHER will definitely provide some evidence in the PCP field.

- **The two main objectives defined for Phase 0 have been achieved**: the identification of the needs through different activities and subsequently the concept viability analysis through the business case and functional exercise among other activities. Finally, a set of functional requirements has been defined within the project.

- **The set of four functionalities requirements have been identified** through performing different activities which were based on the one hand through qualitative approach (interviews with stakeholders and moderated workshops among others) and on the other hand within the feasibility analysis and concept viability phases.

- **In general there is high variability in the methods and results reported during Phase 0.** The results reported during the Needs Identification Phase showed high variability in the type of methods used and in the quantity and quality of data reported by the three procuring activities. The activities (i.e workshops) organised by the Project Coordinator showed similar methods and therefore results were consistent and comparable. However, other activities organised by the procuring activities (interviews with stakeholders and opinion leaders) were difficult to be compared due to the difference in methods used and results reported. This needs more attention with regard to the upcoming evaluation phases, specifically given the multi-cultural and pluralistic societies across Europe.
- **The Functional Requirements exercise was successfully achieved through FAST methodology.** The first approach of this exercise brought a first set of functional requirements that was validated by the procuring authorities.

- **There were some delays in the Needs Identification and Needs Assessment phases.** The delay in these phases caused that the feasibility concept analysis started later

than it was planned. Thus, the horizon scanning activity produced some unexpected results concerning the number of patents relevant to DECIPHER (about 56 patents were identified, 9 of these patents were relevant to DECIPHER).

5 Annex 1. Bibliography search

A total of 121 references by title were found in the ISI Web of Knowledge

6 39 ((Title=(precommercial procurement) OR Title=(pre-comercial procurement)) OR Title=(public sector procurement))

5 10 Title=((precommercial procurement) OR (pre-commercial procurement)) OR Title=("public sector procurement")

4 2 Title=(precommercial OR pre-commercial) AND Title=(innovat* OR research* OR technolog*)

3 17 Title=("public procurement") AND Title=(innovat* OR research* OR technolog*)

2 63 Title=("small business research") OR Title=("small business innovation")

1 11 Title=("public procurement") AND Title=(innovat*)

A total of 329 documents have been identified through the google scholarship search

evaluation OR evaluated OR assessment "precommercial procurement" OR "precommercial procurement" filetype:pdf (Result: 329 documents)
https://www.google.es/search?as_q=%7C+%22precommercial+procurement%22+%7C+%22Small+Business+Research+Initiative%22&as_epq=precommercial+procurement&as_oq=&as_eq=&as_nlo=&as_nhi=&lr=&cr=&as_qdr=all&as_sitesearch=&as_occt=any&safe=images&as_filetype=pdf&as_rights=#as_qdr=all&lr=&q=evaluation+OR+evaluated+OR+assessment++%22precommercial+procurement%22++OR+%22precommercial+procurement%22+filetype:pdf

"Small Business Research Initiative" evaluation OR evaluated OR assessment filetype:pdf
https://www.google.es/search?as_q=%7C+%22precommercial+procurement%22+%7C+%22Small+Business+Research+Initiative%22&as_epq=precommercial+procurement&as_oq=&as_eq=&as_nlo=&as_nhi=&lr=&cr=&as_qdr=all&as_sitesearch=&as_occt=any&safe=images&as_filetype=pdf&as_rights=#as_qdr=all&lr=&q=%22Small+Business+Research+Initiative%22+evaluation+OR+evaluated+OR+assessment+++filetype:pdf

6 Annex 2. Description of Policy papers, Directives and general guidelines on PCP

DOCUMENT TITLE	TYPE OF DOCUMENT	SCOPE	METHODS	MAIN CONTENT	CONCLUSION
Pre-commercial procurement: Driving innovation to ensure high quality public service in Europe. December 2007	Communication from the commission to the European Parliament, the council, the European economic and social committee of the regions.	- Describe an approach to procuring R&D services, by PCP programme. -D the attention of Member States to the existing but underutilised opportunity of PCP.	-	-Define the scope on R&D and highlighted the importance of public procurement in reinforcing the innovation of the Union. -Explain PCP and risk-benefit sharing at market condition in legal framework. -Draw a phased PCP progress in a Typical product innovation life cycle.	Addressed the need for more innovation in the public sector and provides an approach to procure R&D services (PCP). Public authorities and the Commission could evaluate the potential role of PCP strategies in meeting the relevant policy objectives. The Commission will consider to propose a set of actions in relation to PCP in areas of policy priority based on relevant impact assessment, and explore possible need of new platforms for cooperation on PCP.

Design Options Paper. Pre-commercial Procurement of Innovation (PCP) INNO-Partnering Forum coordinated by VINNOVA (Sweden) European Commission/Enterprise and Industry. October 2011	Guide for any innovation agency, department or similar considering a PCP initiative	-To suggest and discuss different design options in the area of PCP. -It is targeted at organisations (innovation agencies, ministries) involved in procurement.	Peer reviews of 2 programmes: NL Agency and the Technology of Strategy Board and SBRI (UK).	- Background on PCP - Design PCP initiatives - Design process - PCP stage	*Service delivery system:* - Important to create early support and interest for PCP initiative to ensure that relevant actors understand and buy the concept - A lead body is recommended to perform a risk analysis for the PCP initiative *Design process:* - A structured marketing and communication plan is needed to ensure that the initiative reaches the main target group. - It is advisable to design the initiative with a maximum number of phases (two or three) and employ these in a flexible way. *Qualification criteria for tenderers:* - It is important to avoid criteria that might put certain companies at an unfair advantage (i.e make sure that SMEs are not excluded).

Pre-commercial Public Procurement for ITS innovation and deployment. WP2 Analysis of PCP models and mechanisms. P3ITS. May 2011	Analysis of PCP models and mechanisms, as deliverable contracting document.	-Describe the legal framework for public procurement and PCP. Describe how procurement of innovation has been implemented in practise in different Member States in the EU.	Focused on 5 public procurement programmes, analyse the models and mechanisms used for PCP and purpose a comparative analyse.	Analyse legal aspect of PCP and seek to discover best practise for PCP implementation. -Comparative analysis on PCP and others public procurements methods.	- PCP programmes are basing their general and evaluation framework on already existing ones to avoid uncertainties as regard on methods and to the legal aspect. -The inclusion of a preparatory phase is expected to deliver better results in the PCP programme. -Better planned the projects on procurement part of a longer term political strategy. -Challenged properly analysed, will ensure funding throughout the project life time, and allow procurers to have their material evaluated by experts assigned to the programme.

Small Business Innovation Research (SBIR) Program; Small Business Administration. Office of Investment and Innovation; October 2012	-Policy Directive (PD)	-To provide guidance to the participating Federal Agencies for the general operation of the SBIR program.	-The PD simplifies and standardizes the program proposal, selection, contracting, compliance and audit procedures for the SBIR program.	-Competitively Phased structure of the Program -Program Solicitation Process - Eligibility and Application Requirements - Funding process - Terms of Agreement Under SBIR awards	Specific program purposes: - To stimulate technological innovation - Uses mall business to meet Federal R/R&D needs - Foster and encourage participation by socially and economically disadvantaged small businesses - Increase private sector commercialization of innovations derived from Federal R/R&D.

A practical guide to PCP. Implementation for PROGR-EAST pilots. May 2012.	Contracting document under the Seventh Framework Programme.	Manual on PCP for policy makers and public procurers for PROG-EAST target countries.	Analysis carried out within the Progr -EAST initiative as background study schemes and practise in Europe and US though literature review, desk research, interviews to procurers and procurement experts.	-Definition of PCP -Present the needs of practical Manual on PCP for policy makers and public procurers . -Define a practical approach of how implement PCP and legal issues	- In the model proposed is organised in step-wise manner, structured in 5 major steps. -Evaluation & dissemination are presented as constant activities essential to the process. -Information requested must be sufficient to enable evaluators to make informed decisions as to which suppliers should advance to the next phase. -The award criteria must be pre-determined prior to evaluating submissions, & these criteria should be made explicit in the PCP CFT. All offers have to be evaluated according to the same objective criteria regardless of the nationality of the bidder and these criteria must be understandable, quantifiable and verifiable

Review of PCP approaches and effects on innovation. Compendium of evidence on the effectiveness of innovation policy intervention. University of Manchester. January 2013	Review of the literature on government procurement of R&D services .	- Examines the rationales of PCP, its context, operation and impact. - Analyse the definition and purpose of PCP, special conditions, context and justification as well as how PCP is implemented within the EU.	- Literature Review of bibliography on SBIR and PCP documents.	- Definition on PCP - Justification for PCP - Implementation models. EU observation of PCP initiative. -Evaluation on procurement, impact.	-The principal finding on evaluation methodologies is given the recent interest in PCP outside the US is on going, - Evaluation of PCP is challenging because PCP activities are a diverse set of activities and do not constitute a single model of intervention. - The first issue raised is that of the need for evaluation in the case of SBIR and the critical role evaluation could play in the operation of the programme. - Within the literature on the evaluation of the US SBIR programme, and in relation to other PCP three major issues have arisen: a) the difficulty of ensuring and emphasising the comparability of findings; b) the evaluation process; c) the apparent absence of evaluations early in the lifetime of the measures used.

7 Annex 3. Description of European PCPs on course

PCP	TENDER CARACTERISTICS				EVALUATION DIMENSSION FOR AWARD CRITERIA		
	Main goal of PCP challenge	**Contracting Authorities**	**Time**	**Call for Tender**	**IMPACT**	**QUALITY**	**PRICE**
SILVER Supporting Independent Living for the Elderly through Robotics	Develop new innovate robotic solution that target assisting the elderly and those caring for them with personal activities of daily living	Denmark, Finland, the Netherlands, Sweden and United Kingdom. The consortium includes research institutions and public sector organizations. The public procurers in consortium are: City ofEindhoven, City of Odense, City of Oulu, City of Stockport, City of Vantaa, City of Västerås and Region of Southern Denmark	1st of March 2013- 31st of March 2016.	Up to 8 companies will participate in Phase 1: Solution Design (budget up to 350.000 EUR, duration 6 months), up to 4 companies in Phase 2: Prototype development (budget up to 720.000 EUR, duration 1 year) and up to 3 companies in Phase 3: Pre-Commercial small scale product/service development (budget up to 1.080.000 EUR, duration 1 year)	I. The extent of how well the proposed idea/ solution/technology meets the challenge as detailed in the Brief and whether it will have the desired impact II. Potential of the proposal to address future/ wider challenges in the challenge area in an innovative way (e.g. by developing or employing novel concepts, approaches, methodologies, tools, or technologies) III. Amount of time saving the solution will realise = III.1 x III.2 III.1 Amount of time saving the solution will realise in a(n imaginary) city of 100.000 people according to the tenderer's calculations (in Phase 1 and Phase 2	VI. Validity of the technical approach that will be adopted. VII. The extent to which the tender shows a clear plan for the development of a working solution, and whether it is a reasonable plan to finish Phase 3 in time. VIII. Effectiveness of the project management IX. The extent to which the tenderer and/or subcontractor shows or demonstrates to have dedicated the resources (e.g. human capital, equipment, etc.) necessary to perform the scope of the tender. X. The extent to which crucial risks (technical, commercial and other) to project success are identified, and how	XI. Formula for Phase 1. For tenders with prices between 20,000 – 40,000 Euros the scoring will be calculated with the following formula: points = 5 x [10 - (9/20,000)*(tender price - 20,000)] Tenders with prices below 20,000 Euros score the maximum points.
				Public	detailed information will	effectively these will be	

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					be provided to make more precise calculations in a real city. III.2 Validity of the indicated time saving IV. The extent of how usable (ISO3 definition usability) the solution will be for the target group (care givers or care receivers) V.1The extent to which the approach analyses the economic and financial needs of the contracting authorities procuring the to be developed solution and whether it is a realistic analysis. V.2 The extent to which the approach demonstrates commercial feasibility, and whether it is a realisticcommercialisation plan / route to market(In Phase 2 and 3 the following phrase will be added:"taking into account the analysis under V.1")	managed.	
CHARM	The CHARM Pre-Commercial Procurement	Highways Agency - HA (England) Rijkswaterstaat-		Tenderers should aim at a market introduction of	I. The panel assess how well the proposed idea/ solution/ technology meets the challenge as	IV. The panel assess the validity of the technical approach that will be adopted.1	X. The price of the tender (exclusive of VAT)

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	project (PCP) intends to stimulate innovations to improve Traffic Management Centres (TMCs) promoting safe, fast and reliable (interurban) road mobility	RWS (The Netherlands) The Flanders Department of Mobility and Public Works (Mobiliteit en Openbare Werken - MOW); the UK-based Technology Strategy Board and Agentschap NL s are preferred partner supporting the consortium with their expertise in procurement and innovation projects.		their new solution a maximum 3 years after the end of the PCP. In total, € 2.880.000,- (exclusive of VAT) is reserved for the PCP contracts. Phase 1 is intended to demonstrate feasibility. Phase 2 is for the development and evaluation of prototypes or demonstrators. Phase 3 is intended for the original development and testing of a limited volume of first products/ services (test series).	detailed in the brief. II.The panel assess to what extent the approach demonstrates commercial feasibility. Is there a realistic commercialisation plan / route to market? III.The panel assess to what extent the tender has the potential to address future/ wider challenges in the area.	V. The panel assess to what extent the tender shows a clear plan for the development of a working solution. Is it a reasonable plan to finish the project in time? VI. The panel assess how effectively the project will be managed? VII. The panel assess to what extent the tenderer and/or subcontractor appear to have dedicated the resources (e.g. human capital, equipment, man hours etc.) necessary to perform the scope of the tender. VIII.The panel assess to what extent the crucial risks (technical, commercial and other) to project success appear to have been identified and how effectively will these be managed. IX. For Phase 2 the quality of the end of Phase report of Phase 1 is assessed. For Phase 3 the quality of the end	determines the points awarded. 0 points are awarded at the maximum price for that Phase. Maximum point at a price of € 0,-. In between a linear scale is used (to one decimal point).

						of Phase report of Phase 2 is assessed	

8 Annex 4. Definitions of the evaluation criteria.

Criteria	Definition
FUNCIONALITY	Description of the functionalities required by the CB, meeting the needs/goals described in such specifications: sharing information, no duplication of clinical tests, selfcare, etc. Description of additional functionalities proposed by the bidder, meeting the needs that result from patients mobility for care givers and care received.
INNOVATION	Description of existing solutions for the needs/goals described in the CB. Explanation and support of the technical and functional innovation of the solution with regard to existing solutions, as well as of the research and development (R&D) nature of the services offered to ensure that the procurement keeps under the explicit exemption for this type of services set out in the EU directive 2004/18/EU.
QUALITY	Description of quality aspects of the solution design, with special reference to the work planning, personal and material resources and identification and management of logistic, regulatory and legal risks (data protection, e-health, etc).
TECHNICAL FEASIBILITY	Description of the technical feasibility of the solution, and identification and management of technical risks (for example: security of the solution in terms of data protection and reliability of the information to accede).
FINANCIAL FEASIBILITY	Description of financial advantages of the solution for patients and healthcare providers, in terms of costs savings, as well as of its commercial exploitability (market analysis and market identification). Analysis of exploitability costs (third party dependencies: patents, licences, etc)

9 Annex 5. Checklist of criteria to assess the technical feasibility

There are four main aspects related with the technical feasibility: quality of technology, technical validity, security and usability. The following list includes a set of criteria to take into account for the evaluators in the review process of the proposals.

Technical evaluation:

Quality of technology

- Functionality coverage. Level of coverage of the functionality as defined in the use cases and usage scenarios defined in the brief, for both mandatory and optional functionalities
- Scalability. Level of difficulty of scaling up the solution, including technical requirements, increase in resources, processes changes, and any other requirement that may limit the increase of the usage of the system
- Maintenance. Cost of keeping the system in working order at a commercial level, including technical amortization, human resources, licensing, and legal requirements.
- Internationalization. Feasibility and cost of localizing the system to countries other than the Countries of Affiliation, including technical requirements, certifications, local regulatory.
- Adaptability. Capability of the system to tackle future challenges in the scope of the remote access to patient data, and to include new services.
- Integration into existing systems. Adaptation of the system to the current health information systems available in the Countries of Affiliation.
- Feasibility. Evaluation of the feasibility of the solution
- Third party dependencies (OS, hardware, components, patents, licenses)

Technical validity

Validity of the technical approach will be based on the panel assessment of the relevant technical documentation such as:

- Architecture design
- Process flow (registration, authentication, use cases)
- Risk analysis of the solution (compromised data, lost phone, re-authentication, omission of service, data corruption, etc.)
- Regulatory compliance
- Maturity of the technological parts that compose the solution
- Reliability level
- Quality processes during development
- Testing strategy for pilot prototypes (unit testing, integration testing, stress test, rogue client test, etc.)

Security.

Level of security of the solution based on the methods and apparatus used to ensure proper authentication and data protection.

Usability.

Defined in ISO3

Cost/ benefit evaluation

- Ex ante evaluation of the cost-benefit analysis that calculates all costs and all benefits in monetary terms. Compare alternatives to measuring the cost and benefit in the same unit.
- This method allows to calculate the profitability of innovation proposal: subtracted the benefits and costs (both calculated in monetary units) and if the result of the subtraction is positive means that the benefits outweigh the costs and that the intervention is cost effective and if the result is negative means that it is advisable to carry out
- Cost/ benefit analysis should consider :
  - Perspective of evaluation: to help define what costs and what the results will be considered in the evaluation.
  - Cost. To identify measure and evaluate the components of the relevant costs in relation to the perspective adopted.
  - Results. To identify, measure and evaluate the results in relation to the approach taken

Technical evaluation proposed by companies

- Covering real end-users needs
- Security, interoperability
- Experience in the fields of eHealth and IT domain
- Adequate work-plan
- Functional coverage
- Usability
- Scalability
- Cost
- Technical feasibility
- Universal access