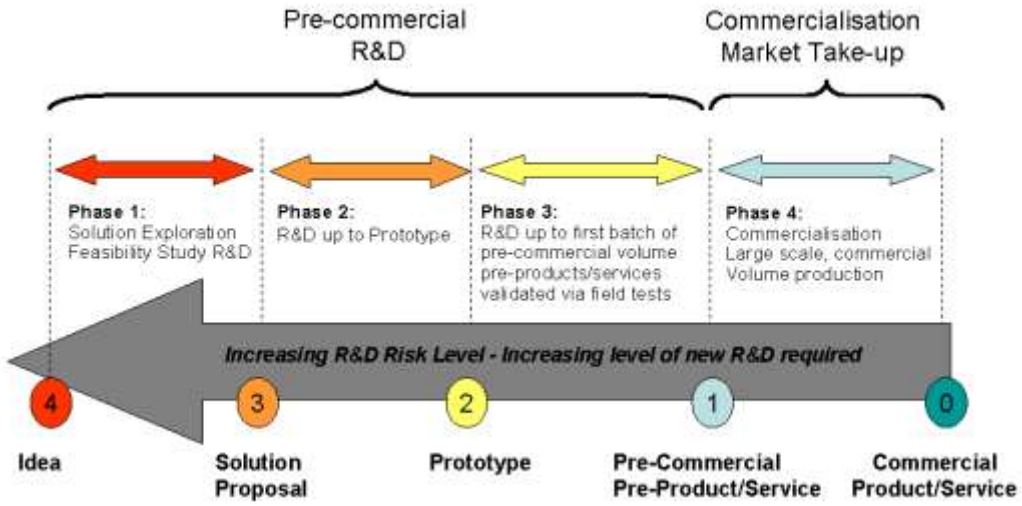
1 Introduction

The DECIPHER PCP Questions and Answers will be updated every time new relevant topics arise. All interested parties should therefore visit www.decipherpcp.eu for the most recently updated version of the DECIPHER PCP Frequent Questions and Answers.

In case your organisation / company is interested to get ready to participate to DECIPHER PCP tender and you are not able either to attend individual meetings with any of the Consortium partner or to come to the next Market Consultation Days (to be held in UK and in Italy in November 2013), please send an e-mail to the mail box decipher.aquas AT gencat.cat sharing with us your questions or comments on the tender process and making sure we will keep you informed about the tender process..

2 Challenge

Question	Answer
2.1 What is DECIPHER PCP project?	The DECIPHER (Distributed European Community Individual Patient Healthcare Electronic Record) project challenges the industry to develop a mobile solution which enables secure cross-border access to existing patient healthcare portals. The new user-friendly application acquired through PCP will enable efficient and safe medical care of mobile patients in EU member states. It is funded by the European Commission under the 7th Framework Programme for research and technological development (FP7).
2.2 Which are DECIPHER PCP main objectives?	The objective of the project is to develop solutions addressing for example the management of long term conditions of patients with chronic diseases or unplanned care episodes.
Which is DECIPHER PCP main challenge?	Despite of the prevailing globalization trends, health delivery systems and health records are still severely limited by national borders. DECIPHER will take the challenge of leading the development of an innovative mobile application connecting with health information repositories of different countries. As the healthcare infrastructures are variable, a flexible solution compatible with multiple standards and open interfaces is required. Moreover, legislation and rules concerning security and privacy are country-dependent and shall be carefully taken into account.
2.3 Which are the public authorities involved in DECIPHER PCP?	The three procuring authorities are ESTAV Centro (Italy/Tuscany), TicSalut (Spain/Catalonia) and Central Manchester University Hospitals NHS Foundation Trust (UK/Manchester). AIAQS (Agency for Health Information, Assessment and Quality, Catalonia) (Spain/Catalonia) will act as single procuring authority launching the PCP tender process on behalf of the three aforementioned public bodies.
2.4 What is a pre-commercial procurement (PCP) process?	The pre-commercial procurement consists in the purchase of research and development used to align the supply with the demand. It consists of a staged competitive process development whose risks and benefits are shared between among the public procurers and the technology providers. The outcome of the PCP is a technology that still will need to go through further development to be deployed and to be ready for commercial use. According to the EU definition: "*Pre-commercial procurement involves direct public R&D*

	investment in the first three phases (pre-commercial part) of a typical R&D project life cycle (Figure 1). Innovative Procurement, corresponding to phase 4 in the typical R&D project life cycle, is a very important complement to Pre-commercial procurement to ensure wide take-up of newly developed pre-commercial R&D pre-products/services. It is clear that pre-commercial procurement involves a higher degree of risk than Innovative Procurement; both in terms of technological risks (require earlier stage R&D, prototyping, testing, etc) and/or in terms of non-technological risks (more uncertain return on investment period, higher risk of uncertainty in cost estimations, etc). The way to get pre-commercial procurement going is to share, not only the risks, but also the benefits of the R&D between procurers and suppliers."  ***Figure 1: Typical Research and Innovation life-cycle transforming an idea into a product/service***
2.5 Can we discuss an example of the use cases you are working with?	*A use case scenario is available for consultation here : http://www.decipherpcp.eu/sites/default/files/attachments/decipher_pcp_user_case_scenario.pdf*
2.6 Is DECIPHER PCP aligned to any other European initiative?	DECIPHER project refers to epSOS, CALLIOPE, eHGI and LOD2.
2.7 Can you briefly describe epSOS?	Smart Open Services for European Patients – epSOS, (previously known as S.O.S. –"Smart Open Services") is an Open eHealth Initiative for a large scale European pilot of patient summary and electronic prescription is a Europe-wide project organized by 27 beneficiaries representing twelve EU-member states, including ministries of health, national competence centres and numerous companies. The overarching goal of epSOS is to develop a practical eHealth framework and an Information & Communication Technology (ICT) infrastructure that will enable secure access to patient health information, particularly with respect to basic patient summaries and ePrescriptions between different European healthcare systems. The project is co-financed by the European Commission within the Competitiveness and Innovation Programme (CIP). For more information please visit http://www.epsos.eu/

2.8 At this moment in time the adoption of epSOS is up to the member states and is voluntary. Why DECIPHER refers to this standardisation framework?	In supporting directives, Commission proposes voluntary standards that will be implemented if stakeholders want to. Standardisation is successful when the definition has been joined by stakeholders. DECIPHER will push for the adoption of standards like epSOS
2.9 Will the industry adopt epSOS as a standard or will it create its own one?	Some market uptakes created by non profit organisations have been adopted by public authorities because they have criteria that match with organisation needs. epSOS is a nation-to-nation communication. If a country is interested in developing a NHR-S (National Health Record - System) and wants to be involved in it, it needs to be able to collect information in a structured way and to define which information has to be exchanged and how to do it. It will allow the country to converge and to use standardisations in epSOS.
2.10 Is there an example of epSOS service DECIPHER will make use of?	Yes. epSOS has defined a constraint set of rules for translation services for any kind of documents.
2.11 Can you briefly describe Calliope?	CALLIOPE stands for “CALL for InterOPErability” with the focus on eHealth. CALLIOPE is a network of collaborating organisations mandated with the planning and implementation of eHealth. CALLIOPE has been initiated by 28 founding members comprising 17 organisations representing national governments, eHealth centres and 11 EU-level stakeholder organisations of health professionals, patients, health insurers and industry. CALLIOPE has now produced final results, in terms of a collaboration platform successfully applied and ready to migrate and be further developed in other initiatives. The relevance of CALLIOPE to this PCP proposal is with the Networking and Co-ordination activities, including building stakeholder co-operation and can also support EU level co-operation of public entities. One of its main achievements has been the establishment of a trusted, efficient platform for collaboration of organisations representing different interests around a shared goal. It has not produced standards (but a very useful standardization report) nor applications or services, but a Roadmap for eHealth Interoperability. This Roadmap, of course, can also be a factual basis for making some decisions in the DECIPHER Project. For more information please visit http://www.calliope-network.eu/
2.12 Can you briefly describe eHGI?	The eHealth Governance Initiative (eHGI) is working to establish a governance structure for eHealth within Europe in order to ensure continuity of healthcare both at home and across borders. It is achieving this through the development of strategies, priorities, recommendations and guidelines designed to deliver eHealth in Europe in a co-ordinated way. The Initiative seeks a strong coordinated political leadership and the integration of eHealth into national health policies through its links to the Article 14 eHealth Network that brings together national authorities responsible for eHealth on a voluntary basis to work on common orientations in this area and to promote an interoperable and sustainable eHealth implementation across Europe.

	Priority Areas of the eHealth Network are: • eID EU Governance for eHealth Services • Semantic and Technical Interoperability • Data Protection • Patient Summary and Other Priorities For more information please visit http://www.ehgi.eu/
2.13 Can you briefly describe LOD2?	LOD2 is a large-scale integrating project co-funded by the European Commission within the FP7 Information and Communication Technologies Work Programme. Commencing in September 2010, this project comprises leading Linked Open Data technology researchers, companies, and service providers (15 partners) from across 11 European countries (and one associated partner from Korea). Over the past 3 years, the semantic web activity has gained momentum with the widespread publishing of structured data as RDF. The Linked Data paradigm has therefore evolved from a practical research idea into a very promising candidate for addressing one of the biggest challenges in the area of intelligent information management: the exploitation of the Web as a platform for data and information integration in addition to document search. To translate this initial success into a world-scale disruptive reality, encompassing the Web 2.0 world and enterprise data alike, the following research challenges need to be addressed: improve coherence and quality of data published on the Web, close the performance gap between relational and RDF data management, establish trust on the Linked Data Web and generally lower the entrance barrier for data publishers and users. With partners among those who initiated and strongly supported the Linked Open Data initiative, the LOD2 project aims at tackling these challenges by developing: • enterprise-ready tools and methodologies for exposing and managing very large amounts of structured information on the Data Web, • a testbed and bootstrap network of high-quality multi-domain, multi-lingual ontologies from sources such as Wikipedia and OpenStreetMap. • Algorithms based on machine learning for automatically interlinking and fusing data from the Web. • Standards and methods for reliably tracking provenance, ensuring privacy and data security as well as for assessing the quality of information. • Adaptive tools for searching, browsing, and authoring of Linked Data. LOD2 project will integrate and syndicate linked data with large-scale, existing applications and showcase the benefits in the three application scenarios of media and publishing, corporate data intranets and eGovernment. The resulting tools, methods and data sets have the potential to change the Web as we know it today. For more information please visit http://lod2.eu/Welcome.html
2.14 In wellness the security requirements are just a user and a password. What level of security requirements will DECIPHER adopt?	As public authorities, Consortium has to assure a high security level which has to be combined with interoperability and an easy use of technologies developed. Some regulations could be seen as a barrier comparing to people sharing personal data in internet. So it could be interesting to work in next generation of data protection, this is health data protection and security level that can change depending on the information and the user.

2.15 What is the value of solving these problems? What is the cost benefit of solving these problems?	DECIPHER will help in designing solutions to the mobility of European citizens with a chronic health condition, by providing them with the capacity of accessing and sharing their PHR with any health professional that will attend him/her. This accessibility will save time and cost as it will reduce duplication of tests and duration of care time. At the same time DECIPHER is promoting treatment adherence among patients with tools such as alerts and reminders.
2.16 How technologies developed by DECIPHER PCP will change things (e.g. better patient outcomes, care delivery, other measures)?	One of the main objectives of the project is to support SMEs in their R&D activities by sharing with them the related costs and risks of this investment. These technological solutions will be closer to market and health procurers will have access to innovative products that has been designed according to their specific requirements, while at the same time entrepreneurs will develop commercially competitive solutions.
2.17 Which are the intended users of the technology and their roles (e.g. there may be an end user, a clinical user or a carer who will help to operate it)?	*The intended end users are European citizens with a chronic health condition but who have an active life. Concrete situation such as cross-border travelling, emergency care, but most importantly treatment management will benefit largely from DECIPHER's solution. Other functionalities can be investigated in order to facilitate the communication of the patient with a medical professional when he/she is being attended in a different health care system or/and in a different language.*
2.18 What regulatory class will the product be and will there be a need for clinical trials?	DECIPHER consortium is envisaging to procure technologies that will not be classified as medical devices according to the EC Medical Device Directive

3 Procedure

Question	Answer
3.1 Which will be the DECIPHER PCP process?	The DECIPHER PCP Consortium will deploy a single, joint PCP Call. As part of the dissemination strategy, each Commissioning Authority will engage with their national and international networks and invite suppliers from throughout the EU to compete to win a contract. The joint PCP will be conducted ensuring that the competition is conducted using an open, fair and transparent tendering process. Successful bidders will be awarded a contract, and this contract will be performance-managed by a project coordinator, representing one of the Consortium Partners. Suppliers will own all IP that arises from their contracted work; and the Commissioning Authority and Consortium will be granted rights to use the IP.

	At the end of each of the three planned phases, the Commissioning Authority will plan for the next phase. Consideration will be given to the evaluation evidence from the completed work, the new requirements going forward, and best-fit procurement methodologies. This flexibility to procurement will help to reduce risk and provide opportunities for new suppliers to compete for work in an open, fair and transparent competition, held at the start of each phase. The DECIPHER PCP project covers the process up to Phase 3, after which the participating procurers will be responsible for the commercial procurement actions.
3.2 What is the duration of each of the PCP phases?	PCP process starts in Q1 2014 and Phase 1 will last three months, Phase 2 six months and Phase 3 9 months.
3.3 Will be possible for any technology provider to step directly into phase 2 or phase 3?	No, providers for Phase 2 will only be selected from Bid winners of Phase 1. Subsequently bidders participating in Phase 3 will be selected from Phase 2 providers only.
3.4 When the PCP Information to Tender will be issued?	DECIPHER PCP consortium is working to launch PCP tender in Q1 2014.
3.5 How will the successful tenders be chosen?	Throughout the next months, DECIPHER PCP consortium will define selection criteria and inform about them during the tender process.
3.6 Which regulations apply to PCP?	In spite PCP is out of the European Public Procurement regulation, DECIPHER PCP will end just before a public procurement process which is regulated by the EC public procurement legislation. The Public Procurement Directives, 2004/18/EC and 2004/17/EC provides the legal bases under which PCP are covered. PCP is an R&D procurement that is considered as exception to the Public procurement Directives and WTO's definition of Public Procurement and State Aid. According to official EU publications: *"Pre-commercial procurement is an R&D procurement of the type 'public service contract' because it refers to acquisition of knowledge – collected by the supplier by carrying out intellectual investigation services (R&D services) consisting of critical solution analysis, prototyping, field testing and small scale pre-product/service development – with the objective to prove the feasibility or unfeasibility to transform a technologically innovative idea into a first working batch of pre-commercial volume and quality pre-products/services according to the requirements in the tender specifications. As the definition of R&D services in the Directives ranges from 'research (laboratory) services' through 'experimental development services' up to 'design and execution of research and development', the R&D public service contract can cover all three pre-commercial phases of the typical R&D project life cycle."*

3.7 What will happen if in the middle of the process a company launches a similar solution?	If a fully functional commercial solution is made available and this solution meets the requirements that DECIPHER PCP established in phase 0, the PCP will be cancelled. This is an inherent risk of R&D activities and DECIPHER PCP is no exception, however the DECIPHER consortium is providing an updated state-of-the-art report that includes a technology watch to ensure genuinely innovative technology will be developed in DECIPHER's PCP.

4 Bidders

Question	Answer
4.1 What kind of organization can participate to the PCP? Can my organization participate alone or is it better to submit a proposal as a consortium?	All European organizations delivering technologies applicable to the eHealth sector are invited to join DECIPHER PCP process. On the other hand non European companies are invited to join if at least the 51% of the R&D carried out during the DECIPHER PCP programme is performed in Europe. All kind of organizations that demonstrate the interest and the ability to exploit the developed technologies, independently of their size, are invited to join. In the case of a university, for example, it can join the call in a consortium with a business organisation or a spin-off of the university that exploits the results of the developed technology.
4.2 What are the characteristics of the bidding organizations will you look at? Taking into account the complexity of the mobile health ecosystem, what is your target group? Integrators, software developers, SMEs, etc?	Bidding organizations will be active in the following sectors: eHealth, mobile applications, security, interoperability, semantic interoperability, accessibility, etc Bidders should be entities that are willing to share R&D risks and benefits with the DECIPHER consortium and whose main objective should be the development of a competitive solution that can be presented to any public commercial procurement eventually. A bidder should look beyond DECIPHER PCP bid and be aiming at 'Regular' Public procurement by using DECIPHER's pre-commercial procurement programme to reach a commercial off-the-shelf and ready-made solution

5 Finance

Question	Answer
5.1 Which is the budget of the project and how it will be distributed?	DECIPHER Project will run a PCP competition with a global amount of 900,000€.. This joint PCP competition will be undertaken to select an initial group of 9 suppliers. Each supplier will receive up to a maximum of 25,000€ to participate in Phase 1. The cohort will be reduced to 6 bidders for Phase 2 and each supplier will be awarded up to 52,500€ each. 3 of those bidders will be selected to participate in Phase 3 and will receive up to 120,000€.
5.2 Is it possible to reduce the number of companies in the phase 1 of the PCP process in order to pay more the selected proposal?	No The key aspect in the PCP process is a co-financing approach. Companies must be aware that all the cost of the pre-commercial R&D will not be covered by the DECIPHER project. The DECIPHER consortium is taking part in the early phases of the process to share the risks related to R&D with the scope of sharing also the benefits if a solution is reached. DECIPHER competition will select the best possible solutions the market can offer. The financial participation will be at market value so as to avoid distortion under the Public Procurement Directives and WTO Agreement. If the R&D is not at market price, it will be considered as State Aid.
5.3 How will you design an appropriate business model to ensure the large enterprises see the value to join the DECIPHER PCP?	DECIPHER PCP Consortium is already working in defining one or more business cases that will support the industry to draw on top of it the appropriate business models. , In Phase 0, the procuring authorities are building their business cases. All companies participating in the PCP, will be evaluated on different criteria, involving their technical, organisational and also economic feasibility. Companies will be expected to develop business models based on the results from each of the phases.
5.4 If I am successful how will I be paid	All contracted companies will be paid on a drawdown milestone payment basis in accordance with their submitted project plans.

6 Management

Question	Answer
6.1 During the PCP process how will be the interaction between you and the bidders?	A PCP tool will be set up as a communication and tracking mechanism. All communications between bidders and DECIPHER's Consortium will be held through the PCP tool so as to share and record all information that will be made available, for higher transparency. The project development in the different phases will be reported through the PCP tool which will provide project tracking over time

6.2 Are citizens involved in the requirement elicitation phase?	Yes. DECIPHER PCP will develop technology that will respond to peoples' needs. Throughout the next months, moderated workshops with the participation of patients and healthcare professionals will be conducted in Barcelona, Manchester and Florence to complete the functional requirements definition that will be the frame for DECIPHER PCP call and its use cases.
6.3 Are all the European Ministries of Health involved in this initiative?	3 Commissioning authorities from 3 European regions are participating as core partners in the DECIPHER project (Tuscany, Manchester, Catalonia). DECIPHER's Advisory Board includes representatives from French Health Ministry and experts on Greek Health Ministry. At the same time DECIPHER will interact with other Health Ministries from Spanish regions and other European Regions to validate DECIPHER consortium needs and business case.
6.4 Who should I contact if I have any other questions?	For more questions, please contact to decipher.aquas AT gencat.cat