



DECIPHERPCP

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 D1.1 Project Initiation Documentation



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DECIPHER PCP

Work Package:
WP1 – Management Activities

Deliverable D1.1

Project Initiation Documentation

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Abstract (for dissemination)	The present document (D1.1 Project Initiation Documentation) contains and describes the procedures to be followed during the DECIPHER project implementation in order to achieve the project objectives. It formalizes the approach of the DECIPHER consortium to assure the quality of the project outcome as of the project management.

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1 Purpose

The Project Initiation Document is aimed to provide DECIPHER consortium with all the information related to the project management plan and to all the procedures and processes that will be followed to ensure an efficient execution of DECIPHER project and its PCP programme.

This document is comprehensive of a Quality Management Plan in compliance with the general principles and policies defined in the underlying basic regulations (7th Framework Programme General Rules for participation), National contracts, the Consortium agreement and other guidelines detailed on References ([Ref. 1], [Ref. 2], [Ref. 4], [Ref. 5], [Ref. 5]).

The Project Initiation Document, hereafter PID, contains the following information:

1. Project Organisations Structure
2. Conflict resolution
3. Work plan
4. Document procedures, standards and control
5. Reporting procedures, frequency and format
6. Communication procedures
7. Risks management

The PID is considered a living document and will be updated regularly throughout the project.

Where necessary, the PID makes reference to the relevant project's documents such as Grant Agreement and Annexes including Description of Work (DoW) and Consortium Agreement (CA). When ambiguity of interpretation among these documents arises, this PID is superseded. Therefore, priority is given to the documents in the following order:

- Grant Agreement [Ref. 1], the amendment No. 1 [Ref. 2] and the DoW [Ref. 3]
- Consortium Agreement [Ref. 5]
- Project Initiation Document (the present document)

If doubts persist, they have to be resolved by the established project authority, the Programme Board.

2 Legal Basis

The project **Distributed European Community Individual Patient Healthcare Electronic Record**, whose acronym is **DECIPHER**, is a combination of CP & CSA partially funded by the ICT Work Programme 2011 of the European Commission FP7 Framework Programme. Its Grant Agreement number 288028 [Ref. 1] was initially signed on December 21st, 2011 but then it got suspended on January 24th, 2012 by the European Commission. The suspension got lifted on January 24th, 2013 after the approval of the Amendment No 1 [Ref. 2] submitted on January 4th, 2013.

3 Consortium Partners

No.	Partner Name	Short Name	Country
1	AGENCIA D'INFORMACIO AVALUACIO I QUALITAT EN SALUT	AIAQS	ES
2	FUNDACIO TICSALUT	TICSALUT	ES
5	CULMINATUM INNOVATION OY LTD	CULMINATUM	FI
6	TEKNOLOGIAN TUTKIMUSKESKUS VTT	VTT	FI
7	ENTE PER I SERVIZI TECNICO-AMMINISTRATIVI DI AREA VASTA CENTRO	ESTAVC	IT
8	ANCITEL TOSCANA S.R.L.	ATS	IT

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9	CENTRAL MANCHESTER UNIVERSITY HOSPITALS NHS FOUNDATION TRUST	CMFT	UK
10	BARCELONA DIGITAL CENTRE TECNOLOGIC	BD	ES

4 Project Definition and Objectives

DECIPHER will deploy Pre-commercial Procurement (PCP) to create step-change innovations in mobile patient ICTs. Using electronic patient records as the key enabling technology, this joint PCP will create technology-led service transformation in cross-border mobile healthcare, delivering significant benefits to patients and healthcare organisations. The Consortium consists of three leading commissioning authorities: ESTAVC (Italy), TICSALUT (Spain/Catalonia) and CMFT (UK). A single, joint PCP activity will be issued. Suppliers will be challenged to build on outputs from epSOS, CALLIOPE, eHGI and LOD2, and advances in mobile technology.

The overarching objective of the DECIPHER Project is to enable secure cross-border mobile access to existing patient healthcare portals which are individually supported by national (governmental) bodies.

The three main objectives of the project are:

1. To deploy a single, cross-border joint PCP Call to commission suppliers from throughout the EU to develop fully interoperable and secure mobile solutions accessing health information data
2. Produce a common framework and requirements specification for producing interoperable, mobile, cross-border European PHR services within the selected application domain or application domains
3. Research, evaluate and improve the success of the Pre-Commercial-Procurement method as a viable and successful process for ICT-oriented service development for the health care sector.

According to the current DoW the DECIPHER contribution to FP7 Programme call objectives will be evaluated as follow:

Call Objectives, DECIPHER Contribution, and Method of Evaluation

Objective	DECIPHER Contribution	Method of Evaluation
More forward-looking, concerted, public sector approach to societal challenges.	PCP processes will be used to engender a spirit of fast-moving completion amongst suppliers. The best innovations will advance to and complete Phase 3 (small-batch production and evaluation). As these innovations were commissioned to meet clearly defined end-user requirements and Functional Specifications, the step-change benefits that such innovations generate should be evidenced in the independent evaluation.	An independent evaluation of each commissioned innovation will be undertaken. This evaluation will include the success to which the innovation meets end-user requirements and Functional Specifications. Unanticipated impacts will also be measured during the evaluation of the programme and projects. The final evaluation report will document what has worked well and why, and where and how there are opportunities for further improvement in future. The evidence and case studies will be used to encourage wide and rapid take-up of successful innovations across the European healthcare sectors.

<p>Increased opportunities for wide market uptake and economies of scale for the supply side by forming critical mass on the public demand side, wide publication of results of cross border PCP activities and contribution to standardization of jointly defined public sector PCP solution requirement specifications</p>	<p>Use-Case Scenarios will bring citizens and healthcare providers together from throughout the EU to describe a common vision for step-change innovations. The shared ‘Wouldn’t it be Great if...’ visions will be documents as Use-Case Scenarios.</p> <p>At Programme level, a Concept Viability exercise will validate the Use-Case Scenarios to ensure that they are technically challenging yet realistically achievable. This will lead to the development of an agreed, pan-European Functional Specification, which will form the basis of the single and joint PCP Invitation to Tender, resulting commissions. Each participating Member State will engage in a coordinated Project Implementation and be actively engaged in implementing the Dissemination Plan.</p> <p>These activities will involve using the shared platform, standards, documents, and business processes. All this cooperative effort will help innovations get traction in the market-place and to speed diffusion of beneficial innovations across the EU.</p>	<p>The Programme Board will be responsible for providing an environment that encourages cross-border cooperation. The following metrics will be collected to identify levels of achievement:</p> <ul style="list-style-type: none"> • Use and Development of the Shared EU DECIPHER Platform: pending to be selected • Use and Development of Shared Standards: epSOS, LOD2, CALLIOPE, eHGI, W3, ISO9001, Medical Device Legislation & Certification. • Use and Development of Shared Documents: Functional specifications; Use-case scenarios; R&D contracts; NDA agreements. • Use and Development of Shared Business Process: Programme Plan, including use of above platform, standards, documentation; Programme Board Meetings; Project Management Metrics, including documentation of a) number of local ideas submitted, developed, and diffused (take-up); level of onward investment and number of jobs created for each innovation on platform.
<p>Common platform for a wide range of ICT-based healthcare services</p>	<p>The Initiative will benefit from the use of the platform the consortium will select at the beginning of the project</p>	<p>The independent evaluation of the Initiative will consider carefully the extent to which all Stakeholders have benefited from use of a common online Innovation Management System. Results from this ongoing evaluation will be disseminated widely and used by the Programme Board to keep improving the common platform.</p>

<p>Improve sustainability of Healthcare services by enabling better use of resources</p>	<p>Patient use of mobile devices to complement other forms of care will help to improve healthcare services to patients. Such benefits to patients including improvements in speed and access to healthcare records, especially when away from home.</p>	<p>The experience of patients, citizens and healthcare professionals will be assessed as part of the process, impact and outcome evaluation for each innovation developed in the PCP. The results of these evaluations will inform and improve future work.</p>
<p>Increased international competitiveness of European Healthcare Information Services and Software industry</p>	<p>The challenges will develop new technologies that leverage opportunities emerging from epSOS, CALLIOPE, eHGI, and LOD2, combined with new advances in mobile ICT devices. As such, this Initiative will position European SME's in a defining role, and at the cutting-edge of nextgeneration mobile devices in healthcare.</p>	<p>The Initiative will assess the outcome of each innovation, including amount of investment attracted, jobs created, and sales across the EU and globally. This information will contribute to a performance metric, which will be available for key stakeholders to access.</p>
<p>Better medical expertise access in remote areas, via improved decision-support systems</p>	<p>The mobile innovations developed during this Initiative will be designed to deliver improved access to medical expertise and improved decision-support systems when the citizen is mobile and in remote areas.</p>	<p>Innovations will be assessed to determine the extent to which they enable patents to get access to medical expertise when they are in remote areas. The results will be reported.</p>
<p>Accelerated establishment of interoperability standards and of secure, seamless communication of health data between all involved partners, including patients</p>	<p>The Initiative will be built around established open and interoperable standards, including those from:</p> <ul style="list-style-type: none"> -epSOS -LOD2 -CALLIOPE -W3 -medical device certifications -ISO9000 standards. 	<p>The use and development of open interoperability standards will be assessed and reported throughout the duration of the Initiative.</p>
<p>Wide-scale epidemiology based on European-wide Healthcare information system</p>	<p>The Initiative will benefit for engagement with epSOS. It will also link to large datasets via LOD2. It is therefore probable that some innovations developed during the PCP will contribute to widescale epidemiology based on Europeanwide healthcare information systems.</p>	<p>Innovations will be assessed by what benefits they offer key stakeholders. As such, innovations that deliver widescale epidemiology based on European-wide healthcare information systems will be assessed and reported throughout the duration</p>

		of the Initiative.
Support for patient mobility and patient safety through PHR accessed throughout Europe	Innovations developed as a result of this Initiative will generate significant improvements in patient mobility and patient safety. Using a mobile innovation arising from this Initiative, patients will be able safely and securely to get access to their own Patient Health Records within the secure epSOS environment.	Innovations will be assessed to determine the extent to which they offer support for patient mobility and patient safety through PHR accessed throughout Europe. The results will be reported.
Improved disease management and treatment through provision of personalised services	Applications will exploit developments from the epSOS, CALLIOPE, eHGI and LOD2 Initiatives, enabling improved patient centric disease management and treatment. For example, when abroad and using the mobile innovation developed from this Initiative, patients with diabetes will be able to get access to their healthcare record via epSOS, while LOD2 information will enable the patient to find local hospitals.	Innovations will be assessed to determine the extent to which they offer Improved disease management and treatment through provision of personalised services. The results will be reported.
Reinforced participation of patients in care processes and health management	Innovations will leverage epSOS and LOD2 opportunities in ways that enable patients to participate actively in their care.	Innovations will be assessed to determine the extent to which they reinforce participation of patients in care processes and health management. The results will be reported.
Faster medication innovation and lower costs through a more efficient research process	The innovations will contribute to the construction of semantic and ontological resources that will enable researchers to find and use information in a highly context-specific and efficient manner.	Innovations will be assessed to determine the extent to which they can assist the development of faster medication innovation and lower costs through a more efficient research process. The results will be reported.
Wider access for patients to public health information data portals using mobile platforms	This Initiative will leverage epSOS, CALLIOPE, eHGI, LOD2 and W3 capability to enable patients to access semantically enhanced public health information data portals using mobile devices and platforms.	Innovations will be assessed to determine the extent to which they can provide wider access for patients to public health information data portals using mobile platforms. The results will be reported.
Standard mobile solutions for future implementations of closed loop applications	Innovations will be based on open standards used in epSOS and LOD2, contributing to the development of next generation mobile devices.	Innovations will be assessed to determine the extent to which they enable standard mobile solutions for future implementations of closed loop applications. The results will be reported.

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5 Project Management Structure

As defined in the Annex I Document of Work [Ref. 3] and in the Consortium Agreement [Ref. 5] the Initiative will be supported by a **Programme Board**, comprised of Work package Leads and the PCP Coordination Team Leads from each participating Member State.

The Programme Board will establish governance procedures and ensure that the Initiative progresses to plan. Each of the above functional areas will have agreed terms of reference at the outset of the programme and will be maintained within the Programme Initiation Document.

Any changes to the programme plan will be conducted via agreed configuration management processes. The Programme Board will make decisions to ensure that the programme runs to plan, with consideration given to time, cost and quality criteria.

Quality Management will be provided by the Programme Board with review and acceptance procedures on all project deliverables.

Regular **Programme Board meetings** take place at least quarterly and are chaired by the Coordinator. Such meetings can be either face-to-face or virtual (by telephone or video conferences). At least one meeting per year will be face-to-face. The partner representative will be in principle be maintained throughout the project, where this is possible. Any change in a partner's representative to the Programme Board should be informed in writing to the Coordinator at least ten (10) days before a meeting of the Programme Board meeting takes place, indicating the reason for substitution, identifying the new representative and explaining whether the substitution will be temporary or permanent. The Coordinator shall give notice in writing of a meeting to each Member as soon as possible and at least **forty five (45)** calendar days preceding an ordinary meeting and fifteen (15) calendar days preceding an extraordinary meeting. The agenda of the Programme Board meetings should be sent twenty one (21) calendar days before the ordinary meetings. Any Member of a Programme Board may add an item to the original agenda by written notification to all of the other Members up to fourteen (14) calendar days preceding the meeting. The agenda may be modified during the meeting without limitation in meetings where all Members of the Programme Board are present and it is unanimously accepted or approved.

The following items will be part of the standard agenda for all Programme Board meetings:

- Progress
- Ensure compliance with Programme directives
- Consider and decide milestone changes
- Consider and decide specification deviations
- Review of key risks and issues
- Review of financial reports
- Review of Consortia Resources

The Coordinator shall produce written minutes of each meeting which shall be the formal record of all decisions taken. The draft minutes shall be sent to all Members within ten (10) calendar days of the meeting. The minutes shall be considered as accepted if, within fifteen (15) calendar days from sending, no Member has objected in writing to the chairperson with respect to the accuracy of the draft of the minutes.

The consortium will be supported by an **Advisory Group** that will act in strong co-operation with other funded FP7 ICT PCP projects. The members of Advisory Group will be recognized experts in topics like mobile devices, interoperability, PHR and pre-commercial procurement. They will provide critical information to ensure strategic and operational effectiveness, including:

- Legislative constraints are being observed
- Quality assurance are being adhered to
- Focus on the business need is being maintained
- The project remains viable
- An acceptable solution for PCP is being developed
- The scope of the project is not creeping upwards unnoticed.

At the beginning of the project the following experts have confirmed their availability and willingness to make part of DECIPHER advisory board:

- Dr Niilo Saranummi (Finland: eHealth technology innovation)

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- Dr Michèle Thonnet (France Ministry of Health: Information security)
- Jeremy Thorp (UK Connecting for Health: epSOS)
- Dr Zoi Kolitsi (Greece Aristotelean University of Thessaloniki: Legal and regulatory issues)
- Dr Michael Hausenblas (Ireland DERI: Linked data standards)
- Mr. Antti Kivelä (Sitra: Finnish PHR)

At local level all the activities are coordinated by the **Coordination Teams** from each of the participating Member States. Each of them will report to the Programme Board.

The **Coordinator** is the legal entity acting as the intermediary between the Parties and the European Commission. The Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the Grant Agreement and this Consortium Agreement, specifically:

- Monitoring compliance by the Parties with their obligations;
- Keeping the address list of Members and other contact persons updated and available
- collecting, reviewing to verify consistency and submitting reports and other deliverables (including financial statements and related certifications) to the European Commission;
- transmitting documents and information connected with the Project to any other Parties concerned;
- Administering the financial contribution of the Union and fulfilling the financial tasks described in Article 7 of the Consortium Agreement;
- Providing, upon request, the Parties with official copies of documents which are in the sole possession of the Coordinator when such copies are necessary for the Parties to file claims.

The **WP Leaders** (WPL) have the responsibility of implementation of each WP work, including:

- Monitor the technical progress of work in comparison with the agreed schedule, propose actions in case of under-performance of an individual partner;
- Communicate problems and/or issues from the partners that need to be referred to the Coordinator and the Programme Board;
- Prepare with support of the Partners the summary technical reports and/or periodic technical reports as required

The **Task Leader** is responsible for defining each task and managing the progress within time and resource limits. The **Task Leader** will define the actual work to be done within the tasks and will ensure the outcome quality of all tasks by deadlines. Task goals are outlined in the Grant Agreement. If the task definition changes the title, scope or duration in comparison with what initially defined in the Grant Agreement, this change must be justified and approved first by the WP Leader and the Coordinator.

The sub-tasks will generally be the work of one individual or a small group of individuals. The TC may break down the work in actions as required to ensure progress is controlled in the environment of his or her workplace, and in accordance with their normal operating practice.

6 Conflict resolution

Regarding the conflict resolution, as a general rule, the Coordinator will aim at a consensus building, promoting mediation over voting in order to ensure the maximum cooperation within the consortium.

In case of conflict between two or more parties, the Programme Board can play the role and assume the authority of arbitrator if accepted unanimously by all Parties involved in conflict about a specific matter. The Parties requiring the arbitration of the Programme Board for the resolution of a conflict commit oneself to accept and carry out the Programme Board decision. In case one of the Parties involved in the conflict doesn't intend to use the Programme Board arbitration, the conflict will be solved according with the Grant Agreement provisions. Specific provision for conflict resolution, rights and obligations of all participants are covered by the Consortium Agreement.

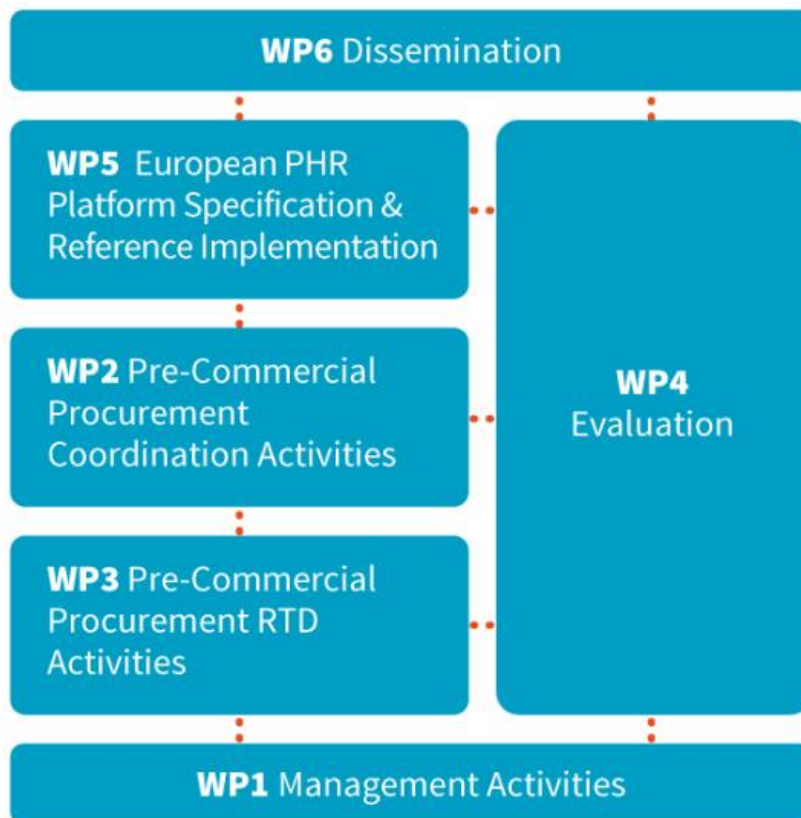
All disputes arising out of or in connection with the Consortium Agreement, which cannot be solved inside the DECIPHER Consortium, shall be finally submitted to mediation in accordance with the WIPO Mediation Rules. The place of mediation shall be Brussels unless otherwise agreed upon. The language to be used in the mediation shall be English unless otherwise agreed upon. The award of the arbitration will be final and binding upon the Parties.

7 Meetings

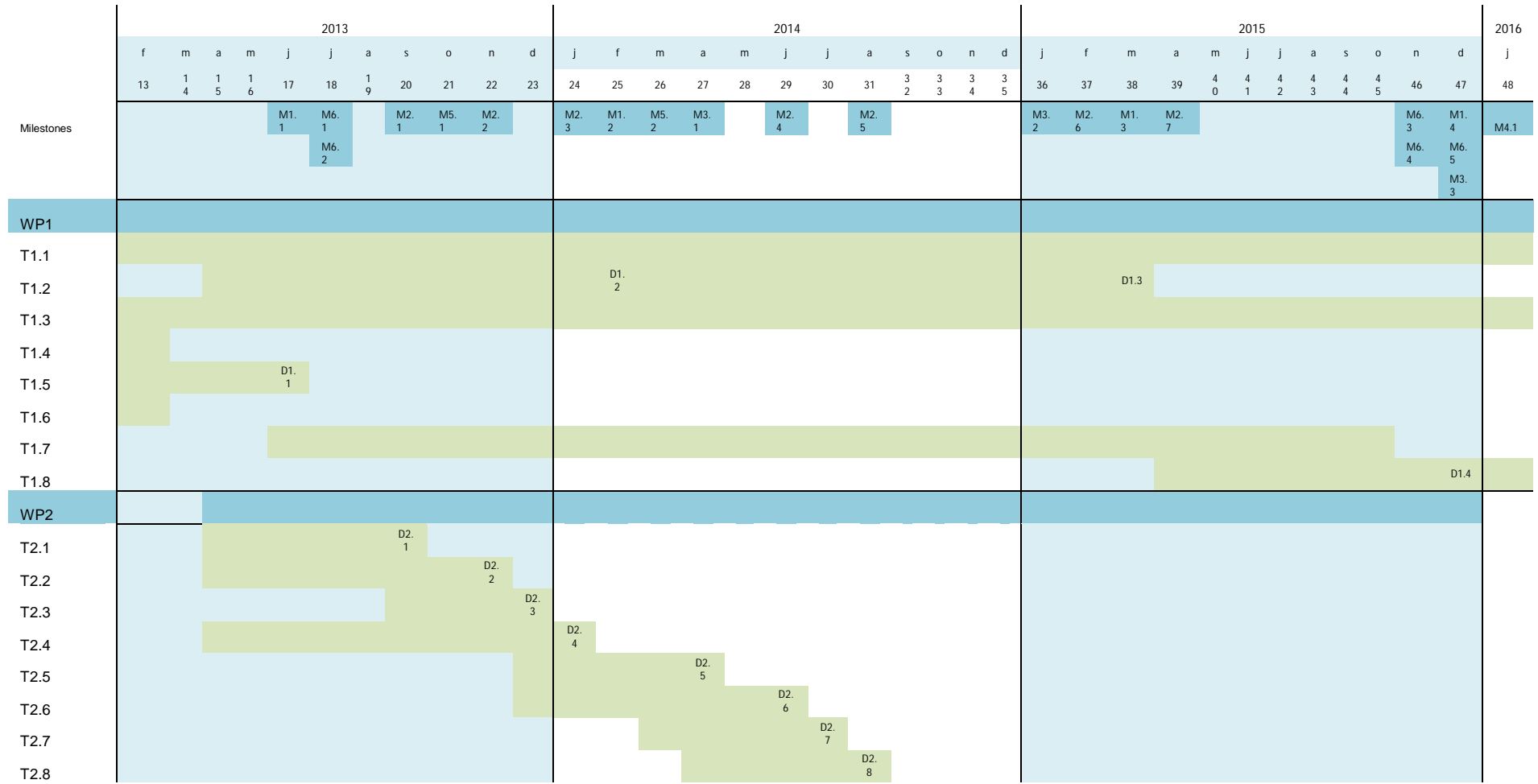
Throughout the Project the different members can identify the need to set up ad-hoc meetings to go through different topics or issues that could either affect the Coordination Team, the WP Team or the specific Tasks and Deliverables. These meetings will be either face-to-face or virtual (by telephone or video conferences). The chairperson will give notice in writing to each of the invited members no later than fourteen (14) calendar days preceding the meeting and will send the agenda seven (7) days before the meeting. The chairperson shall produce written minutes of each meeting which shall be the formal record of all decisions taken. The draft minutes should be sent to all Members within ten (10) calendar days of the meeting. The minutes shall be considered as accepted if, within fifteen (15) calendar days from sending, no Member has objected in writing to the chairperson with respect to the accuracy of the draft of the minutes. The chairperson shall send the accepted minutes the Coordinator, who shall safeguard them. If requested the Coordinator shall provide authenticated duplicates to Parties

8 Work plan

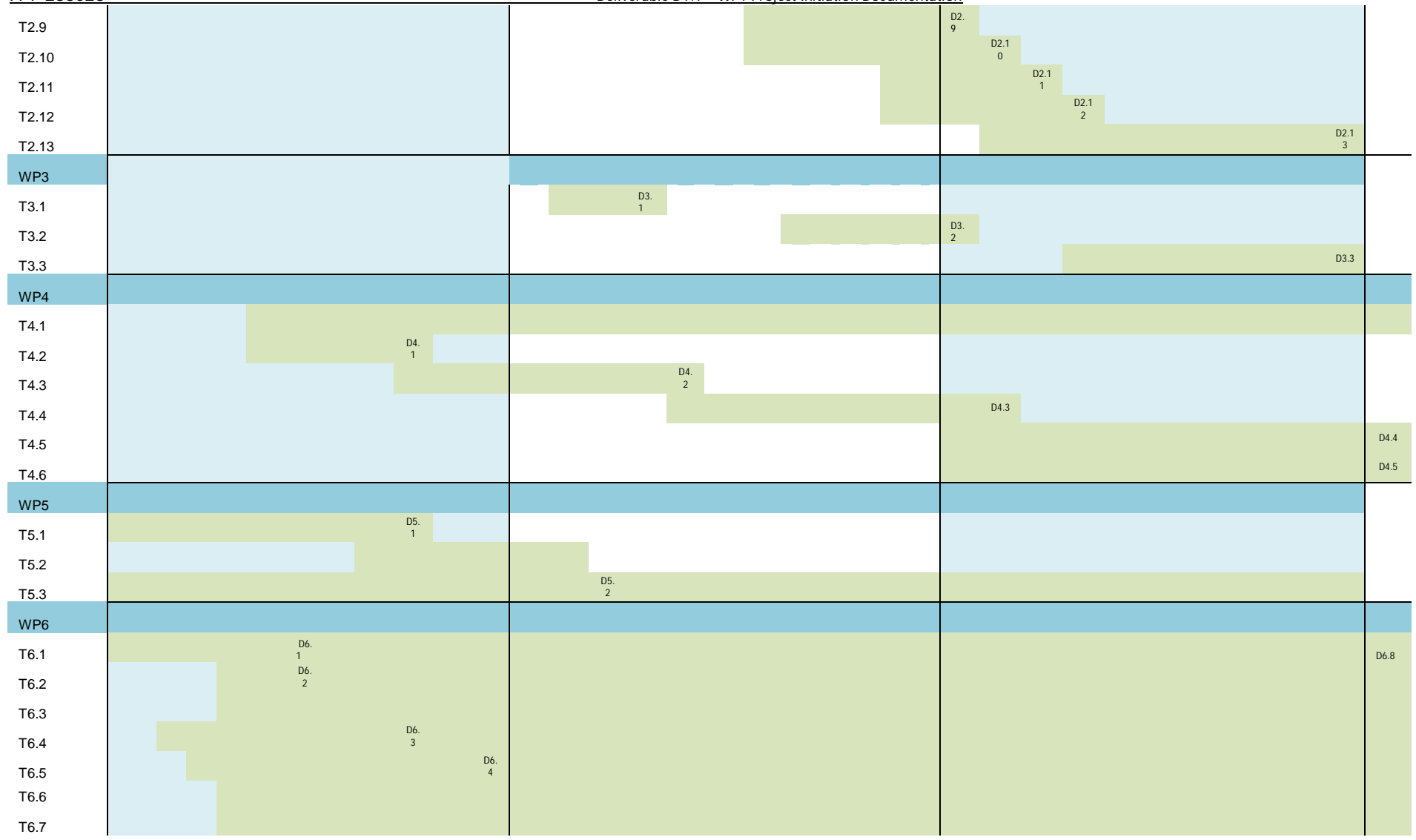
8.1 Project workpackages structure



8.2 Workplan Chart



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5 D6.7
D6.
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8.3 List of Deliverables

Deliverable Number	Title	WP Number	Nature	Dissemination level	Delivery date*
D1.1	Project Initiation Document	WP 1	O	PU	17
D1.2	1st year programme report	WP 1	R	PU	25
D1.3	2nd year programme report	WP 1	R	PU	38
D1.4	Final programme report	WP 1	R	PU	47
D2.1	Phase 0: Needs assessment report	WP 2	R	PU	20
D2.2	Phase 1: Specification complete & ITT notice	WP 2	R	PU	22
D2.3	Phase 1: Submissions evaluated	WP 2	R	PU	23
D2.4	Phase 1: Contracts awarded and signed	WP 2	O	PU	24
D2.5	Phase 1: End user feedback report	WP 2	R	PU	27
D2.6	Phase 2: Specification complete & ITT notice	WP 2	R	PU	29
D2.7	Phase 2: Submissions evaluated	WP 2	R	PU	30
D2.8	Phase 2: Contracts progressed	WP 2	O	PU	31
D2.9	Phase 2: End user feedback report	WP 2	R	PU	36
D2.10	Phase 3: Specification complete & ITT notice	WP 2	R	PU	37
D2.11	Phase 3: Submissions evaluated	WP 2	R	PU	38
D2.12	Phase 3: Contracts progressed	WP 2	O	PU	39
D2.13	Phase 3: Final end user feedback report	WP 2	R	PU	47
D3.1	Phase 1: Prototypes designed	WP 3	R	PU	27
D3.2	Phase 2: Prototype produced	WP 3	P	PU	36
D3.3	Phase 3: Deployment of demonstrator	WP 3	D	PU	47
D4.1	Phase 0: Evaluation Report	WP 4	R	PU	21
D4.2	Phase 1: Evaluation Report	WP 4	R	PU	28
D4.3	Phase 2: Evaluation Report	WP 4	R	PU	37
D4.4	Phase 3: Evaluation Report & Summary Evaluation Report	WP 4	R	PU	48
D4.5	Final Evaluation Published	WP 4	R	PU	48
D5.1	PHR platforms state-of-the-art report	WP 5	R	PU	21
D5.2	PHR test environment set up	WP 5	O	PU	26
D6.1	Information Dissemination Strategy	WP 6	R	PU	18
D6.2	Information Dissemination: Website & Social Media	WP 6	O	PU	18
D6.3	Engaging suppliers to the PCP Tender	WP 6	O	PU	21, 26, 36
D6.4	Papers, guides & presentations on Lessons Learned	WP 6	R	PU	23, 29, 37, 48

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D6.5	Innovative Public Procurement: Policy development Seminar for EU27	WP 6	O	PU	48
D6.6	Exploit PCPI: Seminar for eHealth providers	WP 6	O	PU	48
D6.7	Final Seminar	WP 6	O	PU	47
D6.8	Post-project information dissemination	WP 6	R	PU	48

8.4 List of Milestones

EC Number	Milestone Number	Milestone Name	Delivery Date*	Means of verification
MS1	M1.1	Project Initiation Document	17	Signed contract between EC and Consortium
MS2	M1.2	1st year programme report	25	Document approved by Programme Board
MS3	M1.3	2nd year programme report	38	Signed contracts with Consortium members
MS4	M1.4	Final programme report	47	Document approved by Programme Board
MS5	M2.1	Phase 0: Needs assessment report completed	20	Document approved by Programme Board
MS6	M2.2	Phase 1: ITT issued	22	Document approved by Programme Board
MS7	M2.3	Phase 1: Contracts awarded and signed	24	Signed contract with suppliers
MS8	M2.4	Phase 2: ITT issued	29	Document approved by Programme Board
MS9	M2.5	Phase 2: Contracts progressed	31	Programme Board approve stage gate progression of selected suppliers
MS10	M2.6	Phase 3: ITT issued	37	Document approved by Programme Board
MS11	M2.7	Phase 3: Contracts progressed	39	Programme Board approve stage gate progression of selected suppliers
MS12	M3.1	Phase 1: Designs completed	24	Designs completed and verified against specification by Programme Board
MS13	M3.2	Phase 2: Prototypes completed	33	Prototypes completed and verified against specification by Programme Board
MS14	M3.3	Phase 3: Demonstrators completed	45	Demonstrators completed and verified against specification by Programme Board
MS15	M4.1	Final Evaluation Published	47	Report approved by the Programme Board
MS16	M5.1	PHR platforms state-of-the-art report	21	Document approved by Programme Board
MS17	M5.2	PHR test environment set up	26	Platform completed and verified against specification by Programme Board
MS18	M6.1	Information Dissemination Strategy completed	18	Document approved by Programme Board

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MS19	M6.2	Information Dissemination: Website set up	18	Website working in live environment
MS20	M6.3	Innovative Public Procurement: Policy-development Seminar for EU27 held	48	Seminar held
MS21	M6.4	Exploit PCPI: Seminar for eHealth providers held	48	Seminar held
MS22	M6.5	Final Seminar held	47	Seminar held

8.5 Deliverables Revision Protocol

Quality assurance for deliverables is implemented by review procedures for the approval of all deliverables to the Commission. If necessary, for a deliverable one or two reviewers are appointed by the Programme Board either from consortium members, from Advisory Panel members or by seeking specific external review (appropriate confidentiality ensured). The WPL to whom the deliverable belongs will propose suitable reviewers to the Programme Board. The proposal will be deemed accepted if no objections have been received within 7 days after making the proposal. Reviewers will evaluate the deliverable’s contents and report their findings to the Programme Board. The Programme Board / Coordinator will subsequently decide on acceptance. In case of approval, the deliverable will be signed by the Coordinator and sent to the Commission, in case changes need to be made, the partners responsible for the deliverable will be informed at shortest possible notice about the actions to undertake. All deliverables must be sent to the reviewer in advance to the deadline in order to facilitate the correct and efficient revision of the deliverable according to the deliverable revision protocol.

From	To	Object	Document Status	Date
Main Author	WP Leader and co-authors	Table of contents	Draft	45 days before deadline
Programme Board	Main Author	One or two Reviewer(s) Assignment		45 days before deadline
WP Leader and co-authors	Main Author	Table of contents	Review comments	40 days before deadline
Main Author, WP Leader, co-authors	Programme Board and Coordinator	Table of contents	Review completed	35 days before deadline
Main Author and co-authors	WP Leader and Reviewer(s)	Deliverable	Draft	15 working days before deadline
WP Leader and Reviewer(s)	Main Author and co-authors	Deliverable	Review comments	10 working days before deadline
Main Author and co-authors	WP Leader and Reviewer(s)	Deliverable	Review completed	2 working days before deadline
Coordinator	Project Officer	Deliverable	Final	Deadline

9 Document procedures, standards and control

Wherever possible, documents should adhere to the layout and contents style that remains the same throughout the project. Document templates (in MS-Word and MS-PowerPoint format) that can be used are made available on the DECIPHER Internal Web site.

File naming should follow the specifications below:

- Deliverables: DECIPHER DX.Y DeliverableName V y y.docx
- Minutes: DECIPHER YYYYMMDD_XthTB_MeetingMinutes_V y y.docx (where 'TB' stands for 'Type of Board': in the case of Programme Board 'TB' will be replaced with 'PB')

In the creation of documents the version numbering is maintained. Version numbers consist of a maximum of three fields, denoting the major version, the minor version, and the update version, respectively. For example, "Version 3.2.1" indicates major version 3 of the document, minor version 2, and update version 1. Major version number 0 is used for (draft) documents prior to submission to the Commission. Formally, each new version supersedes all earlier versions. The naming convention for filenames includes the version at the end of the filename (e.g., "DECIPHER D1.2 ProjectInitiationDocumentationV2.1.1.doc")

The differences between major, minor, and update versions are as follows:

- Major Version: A major version represents significant additions to the document, including but not limited to major additions to the contents. A major version is published on as wide as possible forum (within the restrictions set by the Grant Agreement and Consortium Agreement), e.g., as deliverable to the Commission. A major version consolidates all errata and corrigenda to data. The publication of a major version supersedes any prior documentation for major, minor, and update versions.
- Minor Version: A minor version also represents significant additions to the document. It may include small or large additions to the contents or other significant normative changes. A minor version is typically distributed only within the Consortium. A minor version incorporates selected errata as appropriate.
- Update Version: An update version represents relatively small changes to the document, focusing on linguistic, layout, or minor content-related changes. An update version never involves any additions to actual scientific or technical contents. It is distributed within the working group (authors, editors, reviewers) that works on the document. An update version incorporates selected errata.

The version history is reflected by a table at the start of each document, identifying version number, date, authors, reviewers and summary of the document's status.

10 Reporting procedures, frequency and format

The activities in the work packages are subdivided into tasks and subtasks. Technical and co-ordination meetings, when needed, are organised by the WPL. He/she is responsible for the deliverables of his work package, as defined in the Grant Agreement (Annex I).

Each WPL provides at least monthly a Project Status Report to the Coordinator indicating the progress for their work package. This can be done by copying the minutes of work package meetings to the Coordinator.

Work Package Progress Reports are to be submitted to the Coordinator once per three months. These are included in the Periodic Reports which are sent to the Commission. Work Package Progress Reports are to be made according to the provided template (will be available on the internal website), their contents can be incrementally updated every third month.

The Coordinator further prepares reports to the Commission for formal review purposes, as and when required by the contract.

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Useful information on many administrative aspects of project management can be obtained from the documents listed in section 13.FP7 projects Management main tasks are indicated in Articles II.2, II.4 and II.16.5 of the Grant Agreement.

The administrative execution period is fractioned into 3 main reporting periods (RP):

RP1: from Month 1 to Month 24 (February 2012 – January 2014)

RP2: from Month 25 to Month 36 (February 2014 – January 2015)

RP3: from Month 37 to Month 48 (February 2015 – January 2016)

Within each of the execution periods the reporting, deliverable and planning cycles consist of:

- Resource reporting (Intermediary Financial report): internal report of the project partners to the Coordinator on the effort dedicated and cost assigned by each partner to the work packages of DECIPHER
- Periodic reports to the EC have to be generated for every reporting period and are due 60 days after the end of the corresponding reporting period. The reports contain cost claims.
 - o Certificate on Financial Statement shall be submitted for claims of interim and final payments when the amount of the cumulate (with all previous payments for which a certificate on the financial statements has not been submitted) Community financial contribution claimed by a beneficiary under the form of reimbursement of costs is equal to or superior to 375.000 EUR.
 - o Cost reimbursement and payments: The received payments (pre-financing at the beginning of the project implementation and reimbursement of justified cost after project evaluations) are distributed to the beneficiaries by the Coordinator.
- Project deliverables are due according to the detailed work plan defined in the DoW and are delivered to the Coordinator at this date. The Coordinator takes care of their issue to the EC Project Officer and the project reviewers according to contractual obligations established in the contract and to particular agreements with the Project Officer. Deliverable generation process is described in section 8.5.
- The final report to the EC has to be generated after the last reporting period and is also due not later than 60 days after RP3. This report shall comprise a final publishable summary report covering results, conclusions, impact and wider societal implications of the project.

Project reviews are meetings between part of the consortium led by the Coordinator and the EC (eventually assisted by External Project Reviewers) and form part of the yearly EC project review procedure to be finished normally at the latest 90 days after the reporting period. In the case of the final review the meeting normally takes place before the final reports are finished, i.e. at the latest 60 days after the end of the project, in order to provide input and support to the generation of the final reports.

- RV1: Month 20 (September 2013 – initially planned in June 2013)
- RV2: Month 26 (March 2014)
- RV3: Month 38 (March 2015)
- RV4: Month 48 (January 2016)

11 Communication procedures

All contacts with the EC about any matter will be made via the Coordinator. Communications with the European Commission will be in spoken or written English.

All the e-mails related to the project shall include the subject starting with “DECIPHER Tj” where „j” is the Task identifier, followed by a more specific description of the subject.

When sending e-mails with file attachments, please consider the size of the attachment. Very large attachments may not be accepted by the recipient server and even modest size attachments (around a few MB) might rapidly cause e-mail quotas to be exceeded, particularly where recipients are away from the office for an extended period. Therefore, consideration should be given to uploading the relevant file to a shared folder in subversion instead of

attaching it to the e-mail. Finally, as a courtesy, please include your contact details on every e-mail that you initiate.

A listing of all the mail addresses of the members of the project can be found at the private area of DECIPHER web portal.

It is recommended that all individuals install the Internet voice- based facility “Skype” and communicate their Skype unique name to other partners, so that all members of the Consortium are able to communicate freely and directly with each other.

A central storage point for all public project-related information is established in the DECIPHER WWW page: <http://www.decipherpcp.eu>. Maintenance of external website is the responsibility of Culminatum, Leader of WP6. The Programme Board will approve the contents of the external website.

The central repository of all internal project meeting reports, publications, document templates, task lists, contact information, and any other additions brought in by project members is established in the DECIPHER intranet webpage: <http://decipher.estav-centro.toscana.it/>. The internal site can only be accessed via a password distributed to project members either by the Coordinator or the web master. Maintenance of internal project website is the responsibility of ESTAVC, Italian Contracting authority.

12 Risks management

ID	Risk	Likelihood	Impact	Contingency	Likelihood After Contingency	Impact After Contingency	When Identified	When Closed
1	Programme Team do not engage with programme plan	Low	High	Establish, with the Programme Team, an agreed approach for Governance. Agree Cooperation agreements	Low	Low	Proposal submission	
2	Programme Team do not share common understanding of PCP and innovation development	Medium	High	Provide training on PCP, project and programme management. Hold web and face-to-face meetings.	Low	Medium	Proposal submission	
3	Project Teams not updating progress of Projects	Medium	High	Provide training on use of the online Innovation Management System. Hold web and face-to-face meetings.	Low	Low	Proposal submission	
4	The Initiative does not engage with other related EU programmes	Medium	Medium	Hold regular meetings and attend conferences to disseminate progress and to network.	Low	Low	Proposal submission	

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5	None of the procurers is already piloting epSOS and during the PCP project epSOS compliancy is not fully validated	High	Medium	In the Evaluation WP it will be taken into consideration to evaluate epSOS requirements in a built-in synthetic demo environment.	Low	Low	Kick off/1st Programme Board Meeting
6	One or more awarded SMEs go bankrupt while expected to produce their deliveries	Medium	High (one = Medium; more = high)	Criteria of selection will include the review of the accountancy books and the delivery of the commercialization plan. In the call definition it will be made clear that the payment will be phased according to the progress of the delivered work and specific clauses will be introduced (e.g.: in case an awarded SME cannot complete the delivery, the money will be re-assigned to the next bidder in the ranking list or re-distributed between the remaining bidders)	Low	Low	Kick off/1st Programme Board Meeting
7	It is not clear whether we can have a 4th procurer from Finland with access to a personal health record (as FSHS had with Taltioni)	Medium	High	Criteria of selection of 4th procurer will include an entity that is currently using at least a patients' health information system although not yet regionally deployed	Low	Low	Kick off/1st Programme Board Meeting

13 References

Ref. 1 Grant Agreement N° 288028 DECIPHER, dated 21/12/2011

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- Ref. 2 Approval of Amendment No.1 to grant agreement No. FP7-ICT-288028 – DECIPHER, dated 24/01/2013
- Ref. 3 Annex I of the Contract no. 288028 – “Description of Work”, dated 05/12/2012
- Ref. 4 Annex II of the Contract no. 288028 – “General Conditions”, version 6 dated 24/01/2011
- Ref. 5 DECIPHER Consortium Agreement v5 Signature Version, dated from 07/12/2012
- Ref. 6 Project web site: <http://www.decipherpcp.eu> (under construction)
- Ref. 7 Guidance Notes on Project Reporting, (7th Framework Programme, European Commission) version 2012
- Ref. 8 Template for final Report, (7th Framework Programme, European Commission), version November 2008
- Ref. 9 Guidance notes and templates for Project Technical Review involving Independent Expert(s), (7th Framework Programme, European Commission), version 10/11/2008
- Ref. 10 Guide to financial issues related to indirect actions of the Seventh Framework Programmes, (7th Framework Programme, European Commission), version 18/03/2013
- Ref. 11 Certificates issued by external auditors guidance notes for beneficiaries and auditors, (7th Framework Programme, European Commission), version 03/09/2009

14 List of Key Words/Abbreviations

CA	Consortium Agreement
CP	Collaborative Project
CSA	Coordination & Support Action
DoW	Grant Agreement Annex I - Document of Work
FP7	Framework Programme 7
GA	Grant Agreement
ICT	Information and Communication Technologies
PCP	Pre Commercial Procurement
PHR	Patient Health Record
PID	Program Initiation Document
SME	Small & Medium Enterprises
WP	Work Package
WPL	Work Package Leader