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PHC-26-2014

Self management of health and disease: citizen engagement and mHealth

Grant agreement number: 643694

Project Title:

A co-operative mHEALTH environment targeting adherence and management of patients suffering from Heart Failure



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Table of Contents

1. Executive Summary.....	6
2. Introduction	7
3. Contract	8
4. Project Scope	9
5. Management structures and procedures.....	9
5.1. Management Bodies.....	9
5.2. Project Coordinator (PC)	10
5.3. Project Coordination Board (PCB).....	10
5.4. Technical Manager - Scientific Coordinator (TM)	11
5.5. Ethical and Privacy Issues Manager	11
5.6. Project Steering Committee (PSC)	11
5.7. Work Package / Working Group Leaders	12
5.8. Project Technical Board (PTB)	12
5.9. Project Exploitation Board (PEB).....	13
5.10. Working Groups (WGs).....	13
6. Format Specifications.....	14
6.1. Text Documents	14
6.2. Presentations	14
6.3. Tables	14
6.4. Images	14
6.5. Videos.....	14
6.6. Documents Title	14
7. Communication within the consortium.....	15
7.1. Information flow	15
7.2. Meetings.....	15
8. Management process	16
8.1. Reporting Process.....	16
8.2. Biannual Monitoring Report.....	16
8.3. Deadlines for Periodic Reports and Deliverables.....	17
8.4. Deliverable Peer Review Process	18

9.	Research and development process.....	19
9.1.	Work Package Procedure	19
9.2.	Invention Process	19
9.3.	Patient Involvement.....	19
10.	Conflict management.....	20
11.	Instructions for exploitation and dissemination	21
12.	Conclusions.....	23
13.	Appendix.....	24
13.1.	Participating Institutions and Persons.....	24
13.2.	List of Deliverables.....	27
13.3.	List of Milestones.....	30
13.4.	Deliverable Template	32

List of Figures

Fig. 1: Project organization chart.....	10
Fig. 2: Scheme for deliverable preparation procedure	17
Fig. 3: HEARTEN logo	21

List of Tables

Table 1: The appointed members of the Advisory Board	11
Table 2: List of representatives for WP leaders.....	12
Table 3: Assignments of HEARTEN roles to partners and participating persons.	13
Table 4: Timetable for Ordinary Project Meetings	15
Table 5: Timetable for Other Project Meetings	15
Table 6: Deadlines for periodic reports and deliverables	17
Table 7: List of participating institutions, persons, email addresses and role in HEARTEN project.....	24
Table 8: List of deliverables.....	27
Table 9: List of milestones.....	32

1. EXECUTIVE SUMMARY

In accordance with Annex I for the HEARTEN project, the Quality Assurance Plan describes and defines the general coordination, monitoring, and control mechanism of the project.

This deliverable includes official information about the project contract, a description of the project organization and governance structure, a summary of meeting plan, deliverables preparation and submission procedure, research and development process, instructions for internal and external dissemination and exploitation, and a complete list of participating institutions and persons involved in the HEARTEN Project.

The Quality Assurance Plan is intended as a reference material to the project participants, as well as a useful management tool for the project coordinator.

2. INTRODUCTION

HEARTEN is a challenging collaborative research project with a multidisciplinary community of researchers, product developers, and companies that will combine their existing knowledge in the specific fields of their expertise. The achievement of the expected objectives demands commitment and dedication from all project partners.

This document encloses the guidance regarding the project procedures and other useful information that will be used during the project lifetime.

It is important to note that the Quality Assurance Plan does not constitute a legally binding document, so if discrepancies between the signed Grant Agreement and its Annexes, the Consortium Agreement (CA) and the Quality Assurance Plan should transpire, the official signed documents will prevail.

3. CONTRACT

Grant Agreement number: 643694

Project acronym: HEARTEN

Project title: A co-operative mHEALTH environment targeting adherence and management of patients suffering from Heart Failure

Type of project: Collaborative Project

Framework programme: H2020-PHC-2014-single-stage

FP7 Activity code: PHC-26-2014: Self management of health and disease: citizen engagement and mHealth

Start date: January 1, 2015

End date: December 31, 2017

Project duration: 36 months

Project cost: € 4 589 507.49€

Maximum EC contribution: € 4 589 507.00€

List of Annexes to the Grant Agreement:

Annex 1: Description of the action

Annex 2: Estimated budget for the action

Annex 3: Accession Form

Annex 4: Model for the financial statements

Annex 5: Model for the certificate on the financial statements

Annex 6: Model for the certificate on the methodology

4. PROJECT SCOPE

HEARTEN will design, develop and validate an ICT co-operative environment that will enable the HF patients to achieve sustainable behavior change regarding their adherence and compliance, and the ecosystem actors to be engaged and improve the patients' HF management. HEARTEN targets all actors related to the management of patients suffering from HF, including healthcare professionals, caregivers (formal/informal), healthcare providers nutritionists, fitness experts and health insurance experts, towards developing a multi-stakeholder patient centered mHealth ecosystem. The target population of HEARTEN are patients with chronic and acute HF, either post-ischemic or with dilated cardiomyopathy, requiring occasionally re-admittance into hospitals. The idea is to develop biosensors that detect and quantify novel breath and saliva HF biomarkers, being identified through analytical techniques. These biomarkers reflect the health status of the patient and identify whether the patient adheres to the administered drugs. The breath biosensor will be integrated into the smartphone while the saliva biosensor will be integrated into the patient's cup. Additional sensors for monitoring the ECG, the blood pressure and the physical activity constitute the sensor kit of the patient. The input data are complemented with nutrition information from the patient's smartphone, weight monitoring through wireless weight scales as well as the patient's profile and information directly added by the caregivers and the healthcare professionals. The multi-parametric data are transmitted to the HEARTEN cloud architecture, where a knowledge management system analyses them and delivers critical information at hand. HF patients are empowered in self-management, by using their smartphones and tracking their medical vital signs, while the healthcare professionals and the caregivers can issue warnings, coordinate therapies, improve adherence and intervene before frailty incidences occur.

5. MANAGEMENT STRUCTURES AND PROCEDURES

The project organization has been described in more details in the Consortium Agreement. For the reader's convenience and in this document, we provide a short summary of the governance structure, Project boards, and line of managements.

5.1. Management Bodies

For efficiently managing a complex RTD project over a time period of 36 months, a sound, professional but also flexible management structure is of crucial importance. For any project there is a common need for direction, management, control and communication but each project needs a different organization structure to line management. It needs to be more flexible and requires a broad base of specific skills for a comparatively short period of time. The project organization chart is shown in Fig. 1.

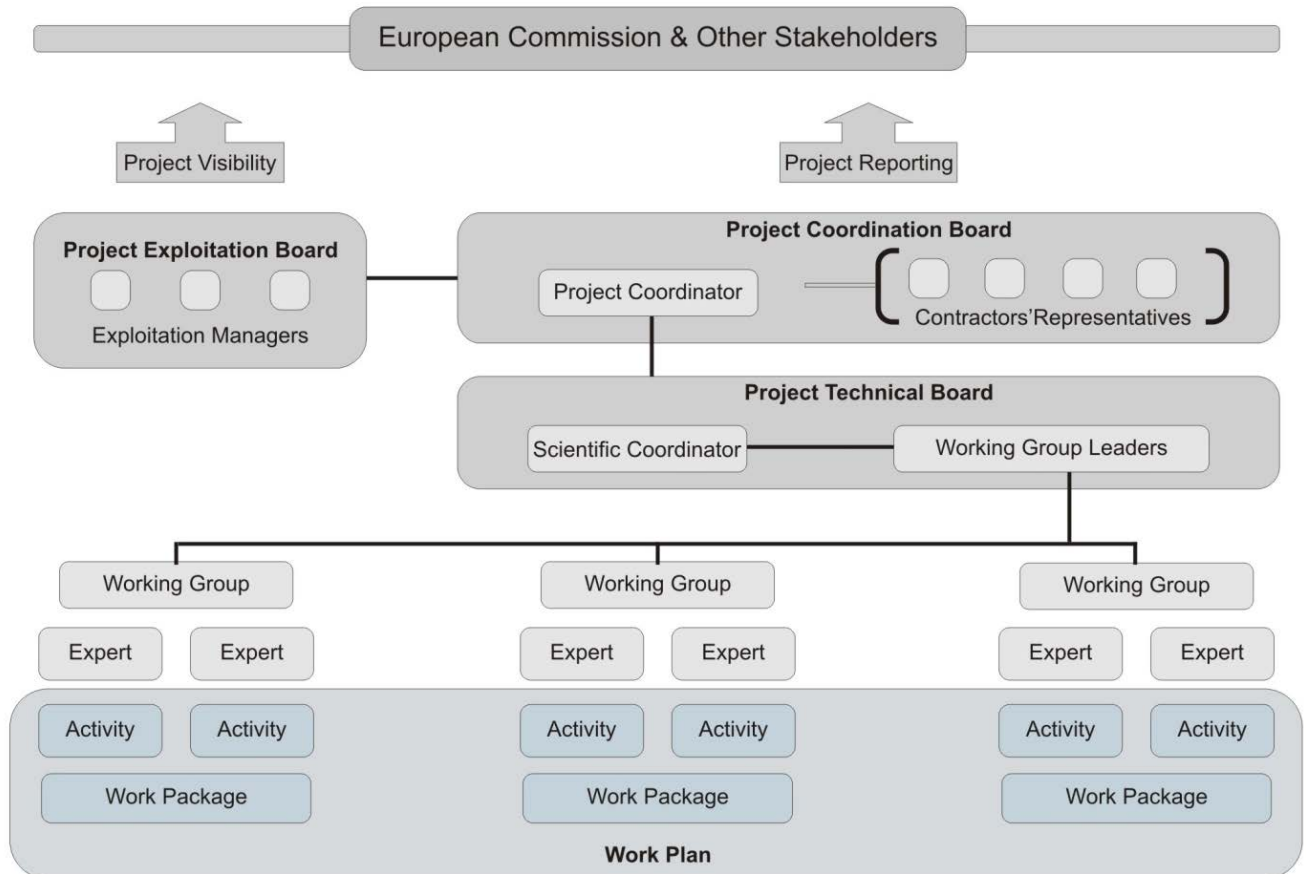


Fig. 1: Project organization chart.

5.2. Project Coordinator (PC)

Head of the project management structure is the **Project Coordinator, Prof. Abdelhamid Errachid** (UCBL) who will be responsible for the overall administrative, financial and technical issues, along with a project manager in Lyon Ingénierie Projets (LIP). Special emphasis within his responsibilities is also to the overall integration of all work package activities. The project coordinator, Prof. A. Errachid, has extensive EU projects participation and coordination capacity, as he has been involved in several European Projects (DEMAC, BARMINT, MICROCARD, MICROTRANS, SPOT-NOSED, MAPTECH, DVT-IMP, BOND, Nano2life, VECTOR, ARAKNES).

5.3. Project Coordination Board (PCB)

The PCB is consisted by the Project Coordinator and one representative of each HEARTEN contractor. PCB is the high level management body and is also the decision body of the Consortium and deliverables approval. It is responsible for all high-level decisions including the project direction, all administrative arrangements, etc.

The PC is the official interface between the European Commission and the consortium. All formal exchanges of information with the European Commission (including documents submission) must therefore be handled through the PC.

5.4. Technical Manager - Scientific Coordinator (TM)

The **Technical Manager – Scientific Coordinator (TM)** for scientific and technical activities is **Prof. Dimitris .I. Fotiadis** (FORTH). His position is to ensure accomplishment of the technical & business objectives and to audit the R&D performance of the project. Among his responsibilities is to resolve the work implementation problems & dead-ends. TM is also the direct link between the Project Coordination Board and the people performing the work. Moreover, he chairs the meetings of the Project Technical Board. The TM shall report to and be accountable to the Project Coordination Board (PCB).

5.5. Ethical and Privacy Issues Manager

The Ethical and Privacy Issues Manager is **Dr M. Giovanna Trivella** from UNIPi. Her main responsibility is to focus on ensuring that all measures have been taken in order for the project to timely identify, analyze and address potential ethical and privacy issues arising from accessing patient health information. She will closely co-operate with the PC and the TM and inform all partners about the necessary measures that have to be taken at all project phases, including project requirements analysis and architecture design, components implementation, platform integration and system evaluation.

Table 1: The appointed members of the Internal Advisory Board.

Project role	Partner short name	Appointed person
Ethical and Privacy Issues Manager	UNIPi	Dr. M. Giovanna Trivella
Technical Manager	FORTH	Prof. D.I. Fotiadis
ICT consultant	EVERIS	Mr. Rafael Ordóñez Benavente
Member of the Spanish Society of Health Informatics	SAS	Mr Carlos Luis Parra Calderón
Legal advisor and litigation attorney in Information Technology & Personal Data Protection	CARE	Mrs. Chrysa Alexea

5.6. Project Steering Committee (PSC)

It will be formed and be chaired by the PC and comprise participants appointed by the Project coordination board - PCB - and shall report to and be accountable to the PCB. The PSC will take decisions with respect to identifying key constraints and implementing actions to compress task timescales and/or actions to expedite the project to maintain or enhance the critical path analysis. The PSC will be responsible for the overall control of the project and for particular key issues, such as monitoring project progress, proposal of changes to the technical programme, financial matters, project performance, resources and exploitation of results. It will also be crucial in ensuring that there is proper integration of activities, strong links between the Work Packages and clear consideration of

the exploitation needs of individual partners. The Committee will meet at least every four months, with the first meeting being held at the commencement of the project.

5.7. Work Package / Working Group Leaders

WP leaders are responsible for the streamlined execution of each Work Package and the management of the corresponding working group. The term refers both to a contractor and its executive. Each WP Leader is also responsible for resolving WP internal problems, reviewing the WP deliverables and reporting to the TM.

Table 2: List of representatives for WP leaders.

Project role	Representative
TM	Prof. D.I. Fotiadis (Forth)
WP1 Leader	Prof. A. Errachid (UCBL)
WP2 Leader	Dr M. Sideri (YourDATA)
WP3 Leader	M. R. Pelliccioli (SESA)
WP4 Leader	Prof. R. Fuoco (UNIFI)
WP5 Leader	Prof. J. Bausells (CSIC)
WP6 Leader	Prof. D.I. Fotiadis (FORTH)
WP7 Leader	M. M. Papadopoulos (APPART)
WP8 Leader	M. S. Zervos (CARE)
WP9 Leader	Carlos Luis Parra Calderón (SAS)

5.8. Project Technical Board (PTB)

The PTB consists of the Scientific Coordinator (TM) and the WP Leaders. It is tasked with the day-to-day management of the project technical activities, the evaluation of working groups performance and the guidance of the project work. In its responsibilities also included the technical - business decision making when a conflict arises.

5.9. Project Exploitation Board (PEB)

The responsibility of PEB is to ensure the value of the project outcomes towards commercialization. Any contractor has to have a qualified Exploitation Manager as representative in the PEB. The PEB uses adequate processes and tools in order to collect the appropriate data for planning & executing the exploitation & dissemination activities of the project.

5.10. Working Groups (WGS)

Each working group is leaded by a WP Leader. Experts or executives by each contractor or subcontractor that constitute a working group with complementary expertise based on the requirements of each work package.

Table 3: Assignments of HEARTEN roles to partners and participating persons.

Project role	Partner short name	Participating person
Project Coordinator	UCBL	Prof. A. Errachid
Technical Manager	FORTH	Prof. D.I. Fotiadis
Ethical and Privacy Issues Manager	UNIPi	Prof R. Fuoco
Dissemination Manager	FORTH	Prof D.I. Fotiadis
Exploitation-Innovation Manager	YOUR DATA SRL	Dr Marco Sideri

6. FORMAT SPECIFICATIONS

In this section, a list of specifications regarding the format of some of the documents that will be used within the project is provided. Each project participants should try to apply to the standards that are described below in order to avoid problems during the circulation of documents and other media.

All documents shall be sent to the PC via email or via the web-site in editable format before submission to the Commission. Only the PC has the right to submit a document to the Commission.

The final documents will have to be in PDF format, especially those that have to be sent to third parties or the Commission.

6.1. Text Documents

All text documents shall be saved in “.doc” or “.docx” format. This can be done either by using Microsoft Word 97-2003 (or later versions) or OpenOffice. All documents edited by several persons should activate the revision tool or at least highlight modified or new text segments. It is important that all modifications are visible and the identity of the person who made the changes is known.

6.2. Presentations

All presentations (slide shows) shall be saved using the “.ppt” or “.pptx” format. This can be done either by using Microsoft PowerPoint 97-2003 (or later versions) or OpenOffice.

6.3. Tables

All tables and calculations shall be saved in “.xls” or “.xlsx” format. This can be done either by using Microsoft Excel 97-2003 (or later versions) or OpenOffice.

6.4. Images

In general all images should either use the JPEG or the PNG format. For more complex images Adobe Photoshop format is suggested.

6.5. Videos

In order to minimize size and optimize quality, all videos should be created using the following video formats: AVI (.avi), WMV (.wmv) or MP4 (.mp4).

6.6. Documents Title

All documents name must start by the project acronym HEARTEN, followed by the type of document (AGD for agenda; MIN for minutes; PPT for presentation; Dxx for deliverable), if necessary including a short specification and ending by the partner short name.

For example:

HEARTEN_D1.1_UCBL.pdf

HEARTEN_AGD kick off meeting_LIP.docx

HEARTEN_PPT kick off meeting_FORTH.ppt

7. COMMUNICATION WITHIN THE CONSORTIUM

7.1. Information flow

Information flow within hearten will be obtained by:

- ✓ notification of relevant new publications in the literature, or by the standard bodies.
- ✓ reports from external meetings.
- ✓ the exchange of internal technical and business documents.

Any technical documentation generated should be able to be exchanged in electronic format, in accordance with a set of guidelines (including guidelines for deliverable naming and configuration management) which should be agreed in an early stage at project start-up. The Project Manager will impose the compliance to these guidelines. The exchange of information will mainly occur by a file transfer over Internet and email. The project communication is considered as restricted for administration and evaluation purposes and otherwise is based upon the adoption of mailing lists mainly for technical and business development matters. Sublists will also be embodied in the communication procedure in order to enhance WP operation and to address specific project related topics.

In general, telephone and fax can be used for urgent needs only. Ordinary mail will be used for strictly formal correspondence, i.e. when executive signatures are required. Urgent correspondence over e-mail will be sent with a request for explicit acknowledge. The Project Coordinator can enforce any adherence to the agreed communications standards.

7.2. MEETINGS

Table 4 summarizes the timetable of the Ordinary Project Meetings. In addition, WP leaders, the ST Manager and the PC can organize technical meetings on specific topics as necessary, according to the indications provided.

Table 4: Timetable for Ordinary Project Meetings.

Consortium body	Ordinary Meetings	Advance Notice	Agenda notification	Minute preparation
Project Coordination Board (PCB)	Once a year	30 calendar days	At least 15 days before the meeting	No later than 21 days after the meeting
Project Steering Committee (PSC)	Every six months	30 calender days	At least 15 days before the meeting	No later than 21 days after the meeting
Project Technical Board (PTB)	Every six months	14 calender days	At least 7 days before the meeting	No later than 21 days after the meeting
Project Exploitation Board (PEB)	Once a year	30 calendar days	No later than 2 weeks before the meeting	No later than 21 days after the meeting

Table 5: Timetable for Other Project Meetings.

Consortium body	Other Meetings	Advance Notice	Agenda notification	Minute preparation
WP Leaders/ST Manager/ PC	As necessary	At least 10 days	No later than 3 weeks before the meeting	No later than 10 days after the meeting

8. MANAGEMENT PROCESS

8.1. Reporting Process

During the course of the project, the consortium should submit to the European Commission the following documents:

- the *deliverables* identified in Annex I of the Grant Agreement, according to the timetable specified in the Deliverables list;
- *periodic activity reports* within 60 days after the end of each reporting period (including the last reporting period).

An overview, including a publishable summary, of the progress of work towards the objectives of the project, including achievements and attainment of any milestones and deliverables identified in Annex I. This report should include the differences between work expected to be carried out in accordance with Annex I and that actually carried out;

- an explanation of the use of the resources;
- a Financial Statement (see the Grant Agreement) from each beneficiary and each third party, if applicable, together with a summary financial report consolidating the claimed Community contribution of all the beneficiaries (and third parties) in an aggregate form, based on the information provided by each beneficiary. Financial statements should be accompanied by certificate that claims of interim payments and final payments when the amount of the Community financial contribution claimed by a beneficiary under the form of reimbursement of costs is equal to or superior to EUR 325000 when cumulated with all previous payments for which a certificate on the financial statements has not been submitted (see 20.4 b ii) of the Grant Agreement). Audit certificates shall be delivered at the same time as the periodic report.
- Reports and deliverables have to be in English and have to be submitted to the EC by the Project Coordinator (PC). The partners will send via email to the PM the required contributions according to the appropriate schedule and template, which will be made available in the web-site.

8.2. Biannual Monitoring Report

Project Partners are obliged to report to the Project Manager every six months. The primary goal of the reports is to allow close supervision and planning of the Project by the PC and the TM. A template will be sent by Lyon Ingénierie Projets at the end of each six month period.

8.3. Deadlines for Periodic Reports and Deliverables

Periodic reports should be submitted **within 60 days after the end of the period**. Other deliverables referred to Annex I "shall be submitted as foreseen therein". Therefore, all deliverables other than period reports should be submitted **at the end of the month indicated in the deliverables list in Annex I**.

In order to avoid possible delays in the submission of periodic reports and deliverables to the PO additional internal deadlines have been identified. Reports and deliverables have to be submitted to the Project Coordinator according to the timetable shown in TABLE 8:

Table 6: Deadlines for periodic reports and deliverables.

Type of document	Submission to PC	Submission to PO
Periodic Activity Report (18 months period)	No later than 30 days after* the end of the reporting period	Within 60 days after the end of the reporting period
Periodic Interim Report (Six month)	No later than 30 days after reception of the template	30 days after the six months period
All other deliverables	At least 15 days before the deadlines specified in Annex I	Within the end of the month indicated in the deliverables list in Annex I

*Deadlines are intended to be strict. However, during the course of the project, the internal deadline for submitting the Periodic Activity Report (18M) to the PC may be anticipated as a consequence of the annual review meeting. As a matter of fact, the PO and Project reviewers need to receive all deliverables and reports **at least two weeks before the review meeting**.

8.4. Deliverable Peer Review Process

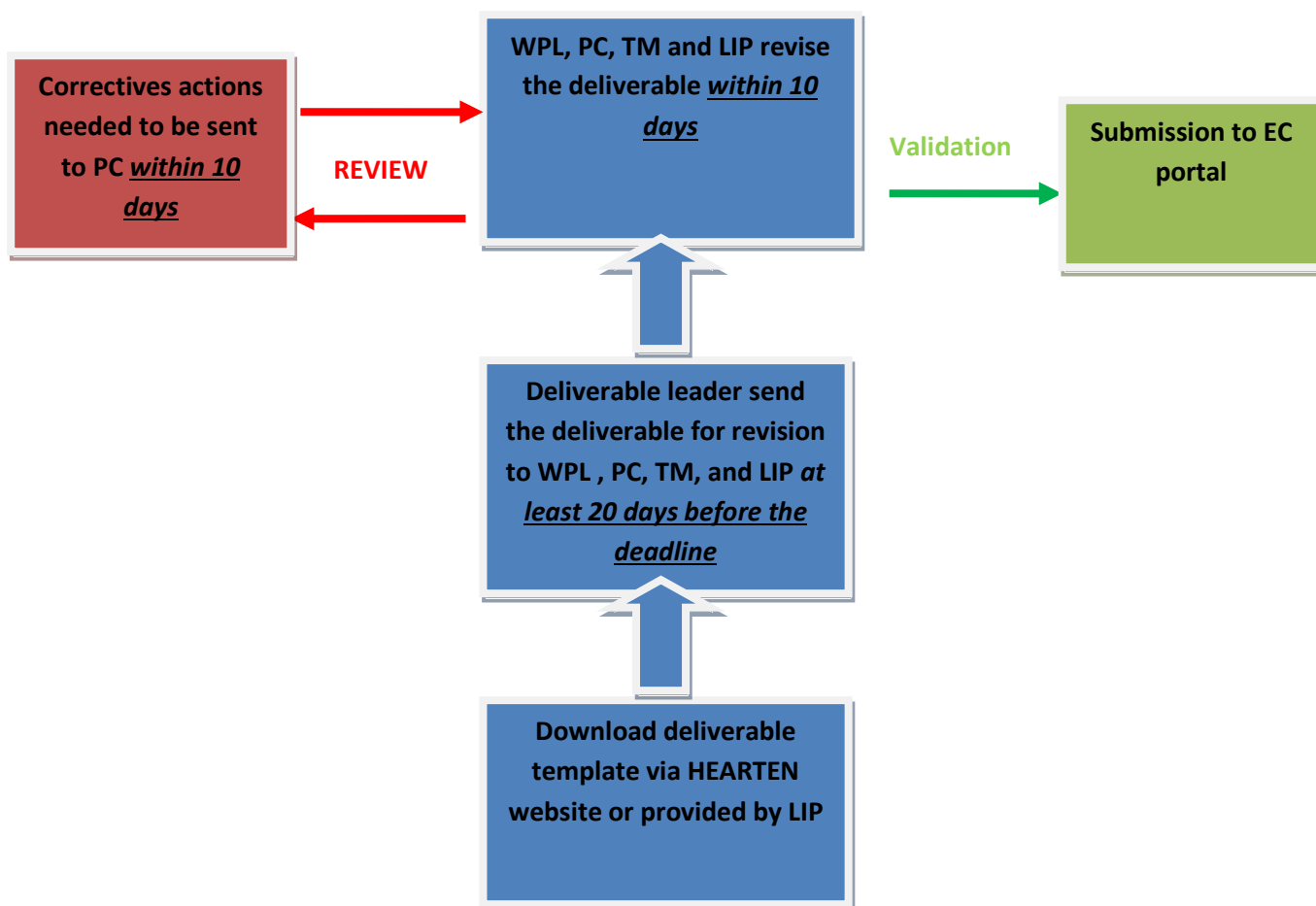


Fig. 2: Scheme for deliverable preparation procedure.

In order to ensure exhaustiveness, clearness and effectiveness, all deliverables shall be made available to the PC for internal reviewing **at least 20 days before the deadline** indicated in the Grant Agreement. The file has to be sent by email to the WP leader, the PC, the TM and LIP. If due to ongoing work this is not possible, at least an early draft containing the table of contents, the abstract and the document structure, shall be sent. The reviewers shall revise the document and assess the scientific and technical quality as well as the editing **within 10 days**. In case corrective actions are needed, they shall send the document back to the partner in charge of the deliverable, pointing out the corrective actions needed. The partner shall make the requested amendments and integrations and send the document back to the PC **within 10 days**.

9. RESEARCH AND DEVELOPMENT PROCESS

9.1. Work Package Procedure

Step 1) The WP leader starts the work package

Step 2) The WP leader communicates with the WP partners about the organization and the distribution of duties and responsibilities, timelines, etc

Step 3) The WP participants conduct the research work for their respective action items in accordance with the provisions outlined in Annex I

Step 4) Research results are then reported to the WP leader, who checks the quality of the research/results and the conformity with standards outlined in Annex I as well as standards defined in the beginning of the WP

Step 5) If there are corrections to be made, he/she can request revisions

Step 6) The WP leader collects the needed information by all partners for the six months reports and sends the consolidated WP report to LIP

It is important to keep communicating within the WP about progress as well as about occurring problems or obstacles throughout the process. If advisable, communication should be extended to neighboring WPs.

9.2. Invention Process

If research activities within the project result in an invention, design or work, which a partner wants to apply a patent, he has to take the following steps:

Step 1) all partners involved in the creation of the invention have to be identified;

Step 2) these co-inventors have to be contacted and an agreement has to be found regarding who will apply where for a patent regarding the invention or part(s) of the invention (there is also the possibility of a joint application);

Step 3) before the application for patent is submitted, the coordinator of the project has to be informed about the topic of the patent and the status of agreement among the project partners involved into the application;

Step 4) if the partner chooses not to apply for a patent for some countries, notice has to be given to the coordinator.

9.3. Patient Involvement

In the project, as reported Annex I, patients will be involved in different activities: breath variables for health monitoring; evaluation of patient psychological support by questionnaires and interviews; empowerment by personalized training. A detailed informed consent will be prepared for patient enrolment. The data protection will be guaranteed by following the national and international EU laws.

It should be noted, that the HEARTEN will help in order to meet the demands for the key human rights, as indicated in the European Charter of Patients' Rights, conducted by the Active Citizenship

Network (ACN), namely that “Every individual has the right of access to all information that might enable him or her to actively participate in the decisions regarding his or her health; this information is a prerequisite for any procedure and treatment, including the participation in scientific research.

10. CONFLICT MANAGEMENT

In a large cooperative project the scientific, technical, commercial ideas and specifications, will have to be agreed and developed by the consortium. It is common for the agreement to be reached by informal contact in the first step, followed by official confirmation via email, letter or agreed written minutes. In case of important issues, the agreement may take the form of a short report which needs to be signed by the decision-makers. Any non-technical factors, such as contractual terms and resource allocation will also need to be agreed and documented in writing. If potential conflict situations arise, the Project Coordinator will be immediately informed by the Scientific Coordinator. Project Technical Committee and the Project Coordinator will discuss and solve the technical issues or conflicts within given contractual commitments that do not involve a change of contract, a change of budget or a change of resources - overall focus. Normally, decisions will be taken in the logic of consensus. If the taken decision is unacceptable to partners found in the minority positions, the problem is elevated to their higher executive officer. If the problem still remains unsolved, the project coordinator has to call for a PCB meeting. In the case of a tie (equality of votes) the project coordinator can use his decisive vote right or again calls a PCB meeting within four weeks' time.

In addition, major conflicts that involve the change of the contract will be discussed and resolved within a PCB meeting. On the PCB level, a decision needs to be achieved with majority vote of the contractor's representatives and the Project Coordinator. In the case of a tie, the vote of the Project Coordinator will be predominant. If no resolution is possible, then the standard Red-Flag procedure will be used as the last resort. The coordinator has to inform the consortium formally (in written) of his decision to impose a final solution by majority vote of the PCB in one week in advance (at least). Moreover, the coordinator will inform the European Commission formally discussing the issues with the Project Officer prior to a final decision is made. It is an explicit right of PCB to change budgets and workloads during the project and to expel a principal contractor or assistant contractor from the consortium. Either the PCB or the Project Coordinator can initiate the conflict resolution procedure. Any changes regarding budget or contractual issues (hard and soft contract amendments) will be reported to and realized only with the approval of the European Commission.

11. INSTRUCTIONS FOR EXPLOITATION AND DISSEMINATION

11.1 Internal Dissemination

11.1.1 HEARTEN Repository Web Space

A private domain has been created in the HEARTEN webpage to share all the HEARTEN documents.

11.2 External Dissemination

11.2.1 Public Website

The address of the public website is: www.hearten.eu

This has been created by FORTH. All partners have to send their contribution to results, people, news, links, press & media, and download pages to the management team (Ms. Marta Esteban). The project partner LIP will be in charge for the maintenance of the site.

11.2.2 Social Media

In accordance to the requirements designated by the EU, the HEARTEN project has also opened social networking websites on:

Facebook

<https://www.facebook.com/pages/HEARTEN-Project/605460052917539>

Twitter

<https://twitter.com/HeartenH2020>

Linkedin

<https://www.linkedin.com/in/heartenproject>

Youtube

<https://www.youtube.com/watch?v=fL6BSboO29w>

11.2.3 HEARTEN Logo

The HEARTEN logo is downloadable from the internal website. Four designs were produced. During the kick off meeting in Lyon, France (5/6-2-2015) the designs were narrowed down to two. Here, a vote was made by the consortium and the final logo that is shown below was chosen.



Fig.3: HEARTEN logo.

11.2.4 HEARTEN Leaflet and Presentation

The official HEARTEN leaflet and presentation will be downloadable from the public website. Leaflets will be updated every 6 months.

11.2.5 Publication Policy

When a partner wants to publish (presentation, article, etc.) results which were obtained within a WP, the WP leader has to be informed.

All contributors have to be asked permission for publication. This includes both WP members as well as members of other WPs and/or contractors who contributed to the material in question.

The WP leader has to make sure, that no material, findings, etc. is disclosed, which is not supposed to be published.

Only when permission is granted from all persons involved, material can be published. The official HEARTEN-logo shall be used for conference presentations.

Acknowledgements to the European Commission to be included in all the publications:

The project leading to this application has received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement No 643694.

All publication activities have to be documented in the periodic report.

Once material is published, it may be used freely in other publications without another request for permission.

11.2.6 Confidentiality Procedure

Four types of documents will be produced according to their dissemination and confidentiality level:

- ☐ **PU:** Public
- ☐ **PP:** Restricted to other programme participants (including the Commission Services)
- ☐ **RE:** Restricted to a group specified by the Consortium (including the Commission Services)
- ☐ **CO:** Confidential, only for members of the Consortium (including the Commission Services)

All Partners are strongly invited to write in the front page the confidentiality level of their documents before their releasing.

The dissemination will be implemented according to the confidentiality level identified by the Intellectual Property Owner/s.

12. CONCLUSIONS

The Project Quality Plan is one of the most important documents of the HEARTEN project. It supports the coordinator and the project management team to manage the project and to clarify matters arising from the Grant Agreement and its Annexes.

It provides practical information that may be referred to throughout the project's life and will also be a useful source of reference to the participant partners. Thereby, the Quality Plan should be considered as a shared resource for all the partners of the project.

13. APPENDIX

13.1. Participating Institutions and Persons

The up to date list of participant contacts is available on the internal website. Table 7 summarizes the current list.

Table 7: List of participating institutions, persons, email addresses and role in HEARTEN project.

Partner	Participants	Role in HEARTEN project	E-mail address
UCBL	Abdelhamid Errachid	Project Coordinator	abdelhamid.errachid@univ-lyon1
	Nadia Zine	Scientific investigator	nadia.zine@univ-lyon1.fr
	Abdellatif Baraket	Scientific investigator	a.baraket@gmail.com
	Michael Lee	Scientific investigator	michael.lee@outlook.es
LIP	Javier Olaiz	Administrative and legal staff	javier.olaiz@lip-lyon1.fr.fr
	Marta Esteban Arnau	Administrative and legal staff	marta.esteban@lip-lyon1.fr
EVERIS	Arturo Henry Torres Zenteno	ICT consultant	Arturo.Torres.Zenteno@everis.com
	Francisco José Fernández Galeano	ICT consultant	francisco.jose.fernandez.galeano@everis.com
	Marcial Valmorisco	ICT consultant	mvalmori@everis.com
	Jesús Pulgarín Paños	ICT consultant	Jesus.Pulgarin.Panos@everis.com
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13.2. List of Deliverables

#	Title	WP	Lead	Type	Dissemination level	Due Date
D1.1	Quality Assurance Plan	WP1	UCBL	Report	Public	3
D1.2	Interim and Periodic progress report 1	WP1	LIP	Report	Confidential, only for members of the consortium (including the Commission Services)	6
D1.3	Interim and Periodic progress report 2	WP1	LIP	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D1.4	Interim and Periodic progress report 3	WP1	LIP	Report	Confidential, only for members of the consortium (including the Commission Services)	18
D1.5	Interim and Periodic progress report 4	WP1	LIP	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D1.6	Interim and Periodic progress report 5	WP1	LIP	Report	Confidential, only for members of the consortium (including the Commission Services)	30
D1.7	Interim and Periodic progress report 6	WP1	LIP	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D1.8	Legal and Ethical Considerations 1	WP1	UNIPi	Report	Confidential, only for members of the consortium (including the Commission Services)	6
D1.9	Legal and Ethical Considerations 2	WP1	UNIPi	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D1.10	Legal and Ethical Considerations 3	WP1	UNIPi	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D1.11	Final project report	WP1	UCBL	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D2.1	Project website, press release, lay summary and twitter account	WP2	FORTH	Website, patents filling, etc	Public	2
D2.2	HEARTEN Presentations and Promotional	WP2	FORTH	Websites, patents	Public	6

	Material 1			filling, etc		
D2.3	HEARTEN Presentations and Promotional Material 2	WP2	FORTH	Websites, patents filling, etc	Public	18
D2.4	HEARTEN Presentations and Promotional Material 3	WP2	FORTH	Websites, patents filling, etc	Public	30
D2.5	HEARTEN Presentations and Promotional Material 4	WP2	FORTH	Websites, patents filling, etc	Public	36
D2.6	Exploitation-Innovation plan 1	WP2	YOUR DATA	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D2.7	Exploitation-Innovation plan 2	WP2	YOUR DATA	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D2.8	Exploitation-Innovation plan 3	WP2	YOUR DATA	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D2.9	Dissemination plan and activities 1	WP2	FORTH	Report	Public	12
D2.10	Dissemination plan and activities 2	WP2	FORTH	Report	Public	24
D2.11	Dissemination plan and activities 3	WP2	FORTH	Report	Public	36
D2.12	Final press release, blog post and project related short film	WP2	FORTH	Websites, patents filling, etc	Public	36
D3.1	Ecosystem actors needs and use cases of the HEARTEN environment	WP3	SESA	Report	Public	5
D3.2	Cooperative ICT environment architecture and ecosystem actors interaction	WP3	SESA	Report	Confidential, only for members of the consortium (including the Commission Services)	9
D4.1	Setup of appropriate methods for saliva and breath biomarker analysis	WP4	UMR	Report	Confidential, only for members of the consortium (including the Commission Services)	5
D4.2	Validated biomarkers for management of HF	WP4	UNIP	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D5.1	First prototypes of the biosensor chips and biosensors	WP5	UCBL	Demonstrator	Confidential, only for members of the consortium (including the	20

	measurement units				Commission Services)	
D5.2	Sensitive layer and/or functionalization for the biosensors	WP5	UCBL	Report	Confidential, only for members of the consortium (including the Commission Services)	22
D5.3	Description and operation manual for the biosensor measurement unit	WP5	CSIC	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D6.1	Data mining and knowledge management framework	WP6	FORTH	Report	Confidential, only for members of the consortium (including the Commission Services)	15
D6.2	Knowledge management system	WP6	FORTH	Other	Confidential, only for members of the consortium (including the Commission Services)	30
D7.1	mHealth app prototype and integration with sensors	WP7	AppArt	Demonstrator	Confidential, only for members of the consortium (including the Commission Services)	20
D7.2	Integration of the mHealth app with knowledge management system	WP7	AppArt	Demonstrator	Confidential, only for members of the consortium (including the Commission Services)	24
D7.3	Final mHealth apps	WP7	AppArt	Other	Confidential, only for members of the consortium (including the Commission Services)	30
D8.1	DynPCP Platform Integrated Architecture and Software Integration Plan	WP8	BIOAXIS	Report	Confidential, only for members of the consortium (including the Commission Services)	30
D8.2	Final integrated Dynamic patient communication protocol and ICT cooperative environment	WP8	FORTH	Demonstrator	Public	36
D9.1	Setup of the pilot studies	WP9	SAS	Report	Confidential, only for members of the consortium (including the Commission Services)	26
D9.2	Pilot studies	WP9	SAS	Report	Confidential, only for	34

	implentation				members of the consortium (including the Commission Services)	
D9.3	Cost effectiveness analysis	WP9	YOUR DATA	Report	Confidential, only for members of the consortium (including the Commission Services)	36

13.3. List of Milestones

#	Name	WP	Date	Means of verification		
M1	Continuous monitoring of specific biomarkers in breath in patients suffering from HF	WP4 WP5	M24	Relevant biomarkers with proof of concept and validation by analytical chemistry Sensitivity in measuring qualitatively and quantitatively the biomarker(s)	Comparison with the User Requirements and state of the art Accuracy in identifying the biomarker Sensitivity in measurements	At least one biomarker selection >90% Accuracy >70% Sensitivity in quantity
M2	Continuous monitoring of vital signals and measurements in patients suffering from HF	WP7	M26	% of acceptability and usability by the users	Compare the provided functionality against the User requirements and gather questionnaires by the patients, the caregivers and the healthcare professionals	>80%
M3	Development of mHealth apps for the patient and the primary ecosystem actors	WP7	M26	% of acceptability and usability by the users	Compare the provided functionality against the User requirements and gather questionnaires by the patients, the caregivers and the medical professionals	>80%

M4	Identification of trends and patterns of non-adherence through knowledge management systems	WP6	M26	Accuracy in identifying high risk conditions, trends, profiles, predictive modelling	Validation in patient specific data	>80%
M5	Integration of the different components and creation of the ICT co-operative environment	WP8	M30	Performance indices (e.g. accuracy) for the target outcomes	Compare the provided functionality against the User requirements and gather questionnaires by the patients, caregivers and healthcare professionals	>80%
M6	Education and guidance of the direct ecosystem actors	WP3, WP9	M36	% of acceptability and usability by the users	Compare the validation procedure against the validation protocol	>80%

13.4. DELIVERABLE TEMPLATE



HORIZON 2020

PHC-26-2014

Self management of health and disease: citizen engagement and mHealth

Grant agreement number: 643694

Project Title:

**A co-operative mHEALTH environment targeting adherence and management of patients suffering from
Heart Failure**



Deliverable Number: DX.X

Title of Deliverable:

WP related to the Deliverable: WPX

Dissemination Level: (PU/PP/RE/CO)*: X

Nature of the Deliverable: (R/P/D/O):** X

Contractual Date of Delivery to the CEC: DD/MM/YYYY

Actual Date of Delivery to the CEC: DD/MM/YYYY

WP responsible for the Deliverable: Partner acronym

Author(s): Name (Partner acronym)

TABLE OF CONTENTS

1. Introduction.....	34
2. Title 1.....	34
3. Title 1.....	34
4. Title 1.....	34
4.1 Title 2.....	34
4.2 Title 2.....	34
4.2.1 Title 3.....	34
5 Conclusion	34
6. References.....	34

1. Introduction

2. Title 1

3. Title 1



Figure 1: HEARTEN logo.

4. Title 1

4.1 Title 2

4.2 Title 2

4.2.1 Title 3

5 Conclusion

6. References