D8.1 Trial definition and planning
POLYCARE Project

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1　EXECUTIVE SUMMARY

This deliverable describes the processes to be carried out in each site and its timeline to make the deployments and proofs of concepts fully operational.

All sites will have to implement specific activities accordingly to their local context, legal requirement, organisational model and administrative procedures. Considering these differences of the local contexts, all sites have to answer the following same set of questions:

- Definition of operational planning (work plan).
- Introduction of systems and services.
- Plan for the recruitment of users.
- Plan for the training of users.

WP6 and the related activities are connected to the previous POLYCARE work packages 2, 3 and 4. This means that the individual conclusions and previous work sections per site reflect many issues that are already explained in the previous WP deliverables (e.g. ICT infrastructure, the service model, use cases requirements, legislation, etc.)

This document will gather the plans for the preparation of the pilots, and the risks identified to perform the activities to have the Proofs of Concept ready to be tested with real users by June 2017 when the provision of POLYCARE integrated care services will start.

2   DOCUMENT INFORMATION

2.1   Target audience

This document is oriented to:

- POLYCARE Consortium partners
- European Commission
- Public in general

2.2   Overview of the document

This document describes the preparation process of deployment; that is, the plans that the sites will have to perform to make the deployment fully operational. The current document describes the activities that will have to be implemented for the concrete deployment implementation and be able to provide integrated care services to the patients.

2.3   Reference documents

- R1. Grant agreement nº: 690367 for the POLYCARE Project. [November 2015]
- R2. Proposal number: SEP-210271031 POLYCARE

2.4   Terminology

2.4.1   Abbreviations and acronyms

- CE: Collaborative Environment
- EC: European Commission
- EHR: Electronic Health Record
- GP: General Practitioner
- HCP: Healthcare Professional
- HIS: Hospital Information System
- LPT: Local POLYCARE Team
- PoC: Proof of concept
- SCP: Social Care professional
- TSCP: Third Sector Party
- UKB: University Hospital of Bonn

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3   INTRODUCTION

It is important to note that the methodology for the provision of POLYCARE integrated care services will be described in deliverable WP6 D6.5 ("D6.5 Definition of the new methodology and the process models for integrated care in home hospitalization supported with ICT").

This deliverable is due to a future moment and will contain the detailed description of all activities that need to be performed to have the Proof of Concept ready for testing with real users by the planned start date. This includes not only technology, devices and communication technologies but also the identification of users and enrolment of professionals.

That document (WP6 D6.5) will describe in detail the strategies and methodology to follow. The present document defines the work plan for those activities.

More information about specific aspects in:

- On ethics and data protection regulations available at WP2 D2.3 Data protection, Privacy, Legislation and Ethics
- On the POLYCARE system requirements available at WP2 D2.2 Requirements Analysis
- On the system specification and modules on WP2 D2.5 System specification
- On the technical designs of the POLYCARE components on WP3, 4, 5
- On WP7 about the integration of ICT technology.

This document will also be handled to WP7 leaders for the preparation of the integration testing plan so as to fulfil the deadlines present at this paper.

4   TRIAL PLAN: ARAGON

4.1   Introduction to the pilot site- LOCAL CONTEXT

A detailed description of the deployment service has been made available in previous deliverables in relation to the service delivery process (see WP2 deliverables & D6.1 deliverables) and the ICT infrastructures to be utilised for service delivery (see WP3 and WP4 deliverables). In the following, a short summary of the deployment service to be operationally implemented under filed conditions is to be provided in order to set the scene for further operational planning.

4.1.1   Background

Servicio Aragones de Salud (SALUD) provides healthcare service to the whole Aragon region, which comprises an area with a population of approximately 1.100.000 inhabitants. The SALUD is a public organization, funded by regional budget coming from the inhabitants' taxes. The tissue of private healthcare providers in almost non-existent, falling the provision of health services in the public supplier. The SALUD provides healthcare services on a universality and cost free basis.

Operationally, the SALUD is divided into 8 healthcare areas, providing services to the inhabitants in the 8 demarcation subareas. The POLYCARE integrated care services will be first tested into the Barbastro's healthcare area, with a population of approximately 110.000 inhabitants, with very poor communications and a rate of over 65 years-old patients of 20%, and mainly on the area around of Barbastro city, with a population of 17.000 inhabitants.

The tissue of social providers is wider, with public and private suppliers providing a wide range of services to the population. Currently, there is no coordination of actions between social providers, neither between social providers and SALUD. Therefore, the attention can be considered as in silos structured.

4.1.2   Main contact person at the deployment site

The contact details for the person responsible for the trial planning and operation of the PoC at the Aragon site is:

Name of deployment site:	ARAGON site
Name of main contact person:	Juan I. Coll Clavero
Organisation:	Servicio Aragones de Salud (SALUD)
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4.1.3   Summary of the deployment service to be implemented

The Aragon integrated care services will be firstly deployed on one of the 8 subareas of the SALUD, Barbastro's Healthcare Area, to evaluate the impact of the POLYCARE service on the population and on the sustainability of the Welfare Systems. Population from the area of Barbastro city will be enjoying from integrated care.

The target group is elders over 65 years old with medical and social needs. The medical and social inclusion and exclusion criteria can be read in more detail on "D6.5 Definition of the new methodology and the process models for integrate care in home hospitalizations supported by ICT", covering in any case, chronic patients suffering from COPD or Heart Failure. Social needs include fragile old people, socially or physically excluded due to illness or disability of any condition with home care needs and living in the cities of the Barbastro Healthcare area.

The healthcare provider in Aragon is Servicio Aragones de Salud (SALUD), as the only healthcare provider in Aragon. Social providers involved on the deployment of integrated care will be the local county council Social Service, Comarca del Somontano's Social Services, partner of the POLYCARE consortium. If any other social stakeholder is required on the provision of integrated care services, their participation will have to be sealed under collaboration agreements between the SALUD, Comarca del Somontano Social Services and the new social providers for the framework of the POLYCARE project.

Among the objectives of POLYCARE project in Aragon, is to enhance the services by the sharing of information and the collaboration among actors by the elimination of silos. Therefore, each provider will put in common the information required to enhance the services identified as integrated care services. Moreover, the agents will be using the common platform created in POLYCARE WPs 3, 4 &5 to create plans and schedule actions of provision of care and collaborate on the attention to users. Common databases and online platforms will be used as collaboration tools and when possible, the providers that own information systems will permit the integration of systems to permit the interoperability of data.

The main benefits expected to achieve in Aragon with the POLYCARE project are to provide integrated care services in home hospitalization situations, narrowing the current provision of care in silos, enhancing the collaboration between agents, sharing information that enhance the services and to provide online tools that permit agents to work together on the creation and execution of integrated care plans and coordinate on the provision of care.

The Aragon deployment site plans to test the POLYCARE solution in 100 patients. The PoC will run for 15 months, with a maximum of 5 patients at the same time receiving the POLYCARE service.

4.2 Preparation of systems & resources

4.2.1 Contractual setup

Comarca del Somontano is partner of the POLYCARE Project, and therefore, responsible of the provision of social services to the project's users. If new care providers are required to participate on the POLYCARE project, different actions will have to be performed as:

- If required, SALUD will have to sign contractual measures within the same organization to prepare the service deployment
- if required, collaboration agreements between the SALUD and the social providers will have to be signed.

Activities	Time line
Collaboration agreements between the SALUD and the social providers will have to be signed.	June 2017.
Collaboration agreements within the different SALUD departments to implement the integration of services	June 2017.

4.2.2 ICT components

4.2.2.1 ICT procurement

SALUD, as public body of the Aragon Government, embraces in its operation to the legislation of the Administrations, in particular to the Royal Legislative Decree 3/2011 and Law 30/2007 of Contracts in the Public Sector. This legislation is to regulate the acquisitions in the public sector, to ensure principles of freedom to access to tenders, publicity and transparency of procurements etc..

In order to prepare the service implementation and set in place the collaboration tool, online platform and integration of services, several procurements will have to be performed:

- Provide staff to help on the integration with the SALUD information systems
- Acquisition or extension of the support, management and hosting services of the information systems involved on the project.
- Acquisition of the biomedical devices, IT technology and licenses required.
- Hiring or extension of the maintenance and support services to permit the integration of other legacy information systems non-dependent from SALUD, but of his property.

Time line for achieving the implementation of the procurement measures

The deadline to perform the actions related to the preparation of the service deployment:

Activities	Time line
Identify staff to help on the integration with the SALUD information systems	April 2017
Acquisition or extension of the support, management and hosting services of the information systems involved on the project (if required)	April 2017
Launch and resolution of 1st tender for the acquisition of the biomedical devices, IT technology and licenses required.	Latest in March 2017
Launch and resolution of 2st tender for the acquisition of the biomedical devices, IT technology and licenses if required.	March 2018
Hiring or extension of the maintenance and support services to permit the integration of other legacy information systems non-dependent from SALUD, but of his property	April 2017

Description of any measures to be conducted for setting up and maintaining a call centre

No procurement measures have to be taken to maintain a technical call center in Aragon, as it is already covered by the call centre (CAU) and Barbastro Hospital IT call centre. See helpdesk section.

4.2.2.2   Technical adaptation of existing ICT components / systems

SALUD owns a wide IT network that connects all information systems and permits to share all applications and data available for the healthcare professionals. The POLYCARE system will have to be installed into that network and will have to be integrated with the already existing databases and information systems. Therefore, integration with the systems is a requirement for SALUD.

All integration activities will be further detailed in WP7 deliverable D7.1 Integration Testing plan that will be published in May 2017, so the plan for the envisaged activities to achieve integration is susceptible to change in that future deliverable.

Activities	Time line
Integration of POLYCARE ICT with SALUD information systems	May 2017
Implementation of the integration of the already SALUD existing information systems with the patient's EHR	May 2017
Updated versions of the POLYCARE platform according to the testing results and new user's requirements	June 2017- December 2017

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4.2.2.3   Testing of ICT components / systems under field conditions

Two different phases of testing are to be differentiated. The first testing phase will be performed while the development of the POLYCARE applications. This testing phase will be done prior to the provision of POLYCARE services to real users (before the start of the Proof of concept). The output of that test is to have available a first version of the software developments ready and validated with its basic functionality. This testing is out of the scope of WP8 and will be done as activities of WP2, WP3 and WP4.

The second testing phase will run during the PoC and while the provision of POLYCARE services to real users. Its aim is to test the validated basic functionality of the first version and collect the feedback of all users. These tests will permit to implement new requirements or software adaptations, if needed, resulting on new versions (v2.0, v3.0 etc..). This testing will run with the purpose of the evaluating the POLYCARE project, according to the evaluation framework defined in WP6.

As the new systems have to be integrated with the already existing information systems in SALUD's network, a prior testing phase will be performed to check the integration before the PoC starts.

Activities	Time line
Testing of the integration between POLYCARE platforms with the already existing SALUD infrastructure	May 2017 – June 2017
Test with real users.	June 2017 – December 2018

4.2.3   Installation of system and services

4.2.3.1   The installation team

Different teams will be responsible for the installation of the information systems and the technology at the patients' homes. The composition of them will be described in Deliverable "D6.5 Definition of the new methodology and the process models for integrated care in home hospitalisation supported with ICT".

The different teams (AST, CGIPC, Barbastro's Hospital IT department) are already formed up as part of the Aragon Government and Servicio Aragones de Salud departments. People will have to be nominated from these departments to form up the POLYCARE installation teams.

Moreover to these team, SALUD providers will have to identify their key people to lead the integration of the already existing technology with the POLYCARE new system (as the telemonitoring portal or videoconference services etc) that will have to participate on the update of the actual services and testing phases.

Moreover, the POLYCARE technological partners will be the final responsible for the installation of POLYCARE system.

Activities	Time line
Identify key people in AST	March 2017
Identify key people for installation in CGIPC	March 2017
Identify key people in SALUD Barbastro Hospital IT Department	March 2017
Identify key people among SALUD providers	March 2017
Set up of installation team by POLYCARE technical consortium members	March 2017
Texts of the applications available for translation	March 2017
Text of the applications translated	May 2017

4.2.3.2   Installation procedures

The installation tasks to be performed will be done during the Spring 2017 to set the systems ready for testing.

Activities	Time line
Installation of POLYCARE Aragon local databases and implementation of new interfaces to integrate data from SALUD databases holding patient's data	April 2017
Installation and set-up of Aragon POLYCARE servers	April 2017
Installation of POLYCARE applications in servers	May 2017
Installation of POLYCARE applications in tablets	May 2017

A description of the teams responsible for the installation and integration of the information systems will be found on D6.5.

4.2.3.3   Installation procedures at patients home

Several ICT may be needed to be installed at the patient's home as those of communications, installation of devices or configuration of devices.

The time expected for the installation of technology would be 1 hours per home.

Activities	Time line
Installation and configuration of technology at patients home	Before referral of patient to their home.

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4.3   Help desk

4.3.1   Help desk set-up

The different help desks available to support POLYCARE project on the implementation and deployment phases are described on the service process model, deliverable D6.5.

The timeline for activities to set-up the helpdesk are as follows:

Activities	Time line
Define responsibilities of Aragon's Government Attention to Users Call Center (CAU) regarding to the POLYCARE project	May 2017
Define responsibilities of Barbastro's Hospital IT Help Desk regarding to the POLYCARE project	May 2017
Set up POLYCARE users Help Desk	May 2017
Set up Comarca of Somontano POLYCARE users Help Desk	May 2017

4.4   Recruitment of patients

Detailed activities and planning of the enrolment of users will be available on WP6, deliverable "D6.5 Definition of the new methodology and the process models for integrate care in home hospitalizations supported by ICT".

4.4.1   Identification of service users potentially to be recruited

The POLYCARE proof of Concept will run starting in June 2017 for 15 months. Previous experiences say that the shortest time between identification, enrolment and the start of service provision is essential to avoid drop-outs. Moreover, the identification of potential users will be performed when exacerbations occur, and in most occasions, when an admission at Emergency units occurs at Barbastro Hospital.

The commitment of Aragon is to test the POLYCARE proof of concept in 100 users. Therefore, a continuous inclusion of participants will last during 15 months, with a maximum of 5 patients receiving POLYCARE services in parallel. Any potential user identified during the lifetime of the project can be enrolled as soon as it is identified.

The period of time between the identification of the potential users, the acceptance and the start of the provision of care must be the shortest.

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Activities	Time line
Identify potential participants	Starting in June 2017during the whole duration of the PoC

4.4.2   Assessment of users

The assessment of users is essential to evaluate the properness to include the patient into the POLYCARE program and to identify their needs and create a proper care plan according to their requirements and clinical and social status. Therefore the assessment of users will be performed as following

Activities	Time line
Development of electronic tools to ease the assessment of users admitted in POLYCARE and integrated with the SALUD IT infrastructure and SALUD Information Systems	May 2017
Definition of the assessments instruments	April 2017
Assess the clinical status of the patient (adequation to POLYCARE inclusion criteria)	Starting in June 2017during the whole duration of the PoC, after the identification process
Assess the social status of the patient (adequation to POLYCARE inclusion criteria)	Starting in June 2017during the whole duration of the PoC, after the identification process
Assess the clinical needs of the patient (medical assessment)	Starting in June 2017during the whole duration of the PoC, after the inclusion
Assess the social needs of the patient (social assessment)	Starting in June 2017during the whole duration of the PoC, after the inclusion

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4.4.3   Formal ethics approval of the local deployment & other ethical principles of involving human beings in the deployment

Description of any measures to be conducted for obtaining a formal ethics approval of the deployment.

Please, refer to WP2 "D2.3 Data protection, privacy, legislation and Ethics" and its update on WP6 "D6.3. Privacy and Ethics definition", for a more detailed description.

Aragon's institutions have to follow the Regional legislation on Ethics, supervised by the Aragon Committee for Clinical Research in Aragon (Comité de Ética en Investigación Clínica de Aragon-CEICA). This organism is in charge of evaluating all clinical research projects to be performed in Aragon and the post-authorization studies. It sets the rules to perform research in the territory and all projects need to have their acceptance before performing any type of research. An information sheet and a consent form draft documents will be sent for their approval, together with the purposes of the project.

Before starting POLYCARE project, a description of the project, objectives and purpose, methodologies and team involved will be sent to the CEICA to be evaluated and approved. Information sheet and consent forms draft documents will be sent for approval.

If is important to note that the CEICA approval was already asked for before the signature of the Grant Agreement. SALUD received its approval by Sept 2015.

Description of any measures to be conducted for meeting ethical principles for involving human beings in the deployment

The actions to be performed on this section are headed to obtain the approval from the CEICA to perform the POLYCARE project and provide integrated care services to real users. This same organism will have to provide the approval for the draft documents (information sheet and consent form) before the start of the provision of services.

Moreover, the professionals will have to commit to the regulations on data protection and deontological medical rules.

Same wise, activities for ensuring the data protection by the social agents will have to be certified.

Activities	Time line
Healthcare professional's commitment to the data protection regulations and access to health data.	June 2017
Healthcare professional's commitment to compliance with the deontological medical rules.	June 2017
Signature by all agents involved on the project of the "Authorization of access to POLYCARE data" which provides	June 2017

access to the patient's data on the scope of the POLYCARE project and acceptance of compliance of the data protection & ethics national regulations.	

4.4.4   Informed consent

Description of any measures to be conducted for obtaining informed consent by the deployment users

Two documents will be written: an information sheet and an informed consent document. These documents will have to be approved by the CEICA to ensure the ethics & data protection regulations compliance before handling them to the users. These documents were written before the start of the POLYCARE project and approval from CEICA was executed before as a mandate of the Commission. The information sheet will explain the POLYCARE project and the implication of enrolment by the users, what might happen etc. This information document is handled to participants and their relatives by healthcare professionals or social agents before their enrolment in the project.

Group information sessions may be performed before handling the consent form to inform and answer questions to the users and relatives, if required, and as many as required.

The timeline for these tasks are planned during the project lifetime. All actions have to be performed before the start of the provision of services and in concordance to the enrolment of users.

Activities	Time line
CEICA approval of the POLYCARE project. the information sheet and consent form documents	April 2017
Information meeting/interview	After identification, prior to handling consent form
Signature of the consent form by the patients	After identification and information meeting. Before enrolment

4.5   Recruitment of professionals & stakeholders

4.5.1   Identification of potential professionals & stakeholders to be enrolled

Information meetings will be organized to identify potential professionals that may be interested in the participation of POLYCARE program and the provision of integrated care in home hospitalization cases. Different agents will participate on these

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meetings to create a multidisciplinary team, covering all required professional profiles.

Activities	Time line
Information sessions with Primary Care & Continuous Care	March 2017
Information sessions with Specialized Care	March 2017
Information sessions with Emergency Units	February 2017
Information sessions with SALUD Social worker	March 2017
Information sessions with Comarca de Somontano Social services	March 2017
Enrolment of GPs, Primary Care nurses & continuous care staff	April 2017 and during the whole duration of PoC
Enrolment of Emergency Team	By April 2017
Enrolment of SALUD social worker	April 2017
Enrolment of Comarca de Somontano social workers and social agents	April 2017

4.6   Training of users

Like the enrolment of users, the preparation, conduct and follow up of each of the training measures envisaged at this stage and the parties at the site responsible for implementing any of the measures mentioned below will be described in deliverable "D6.5 Definition of the new methodology and process model for integrated care in home hospitalization supported with ICT". This deliverable will be published in June 2017, and therefore, the current plan is susceptible to change.

4.6.1   Staff training

Different activities will be performed in order to empower agents. These training programs will be adapted to the different users and roles in the project.

- Training programs on the use of the biomedical devices will be performed to social agents.
- Training programs on the use of POLYCARE collaboration platform will be performed to the care providers' agents.
- Programs on the use of the POLYCARE telemonitoring platform and integrated tools will be performed to the healthcare call center staff and Emergency doctors.
- Programs on the use of the POLYCARE assessment tools for the Barbastro's Hospital social agent.

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- Programs on the protocols of resolution of medical incidences to the medical call center staff.
- Dedicated training programs on the procedures of provision of care will be performed by Comarca del Somontano.

Time line

Before the provision of care to the user and as close as possible to the starting date.

Activities	Time line
Training programs on the use of the biomedical devices to social agents	May 2017
Training programs on the use of POLYCARE collaboration platform to the care providers' agents.	May 2017
Programs on the use of the POLYCARE telemonitoring platform and integrated tools to the healthcare call center staff and Emergency doctors.	May 2017
Programs on the use of the POLYCARE assessment tools for the Barbastro's Hospital social agent	May 2017

4.6.2   End user training

Training programs on the use of the biomedical devices and gamification applications will be performed to end-users and their relatives supported by paper material and best-practices recommendations.

Activities	Time line
Training programs on the use of ICT and gamification application	After enrolment, before the provision of care & the closest to the starting date

4.6.3   Training materials

The training programs will be conducted on a basis of 3-hours face-to-face classes, taught by healthcare professionals/ POLYCARE technological partners and with real technology/biomedical devices. Classes will be supported by presentations and written material.

Material provided can be handled as: use of biomedical devices, best-practices recommendations, use of telemonitoring portals, use of POLYCARE platform, protocols of attention by the medical call center, etc..

Activities	Time line
Training material for professionals ready	April 2017

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| Training material for patients ready | April 2017 |

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4.7   Risks assessment and contingency plans- Aragon site

Risk no.	Risk	Categorisation	Impact	Probability	Remedial action	Manager	Deadline
1	Delay to achieve ethical approval committee	Legal / regulatory	☐ low ☐ medium ☒ high	☒ low ☐ medium ☐ high	Send pilot protocol, information sheets and consent form draft before date of ethical committee meeting	Aragon Pilot staff	Before PoC starts
2	Drop out of participants	User-related	☒ low ☐ medium ☐ high	☒ low ☐ medium ☐ high	Increase sample size, perform information sessions to population to recruit potential users, perform information sessions to GPs and Specialists..	Aragon POLYCARE management team, all Comarca de Somontano agents	All pilot lifetime
3	Improper functioning of devices	Technological	☐ low ☒ medium ☐ high	☐ low ☒ medium ☐ high	Technological support	Barbastro's Hospital IT department	During pilot
4	Delay to achieve technical adaptations	Technological	☐ low ☒ medium ☐ high	☒ low ☐ medium ☐ high	Constant monitoring of technical adaptations during pilot time line	Aragon Pilot management team, Barbastro's Hospital IT department And POLYCARE technological partners	When all technical adaptation is finished

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6	Delay in the development of POLYCARE collaboration platform by the time of start of provision of IC services	Technological	☐ low ☐ medium ☒ high	☐ low ☐ medium ☒ high	First version of the POLYCARE platform will have to be available and tested by 1st June 2017 with basic functionality. Other versions may follow including more functionality	POLYCARE Technological partners	During PoC
7	Delay in the development of POLYCARE biomedical devices by the time of start of provision of IC services	Technological	☐ low ☐ medium ☒ high	☐ low ☐ medium ☒ high	First version of the POLYCARE biomedical devices will have to be available and tested by 1st June 2017.	POLYCARE Technological partners	During PoC
8	Delay in the integration with already existing SALUD IS	Organisational/ Technical	☒ low ☐ medium ☐ high	☐ low ☐ medium ☒ high	The POLYCARE platform will be develop so as to store the maximum of data (although could be duplicated) so if integration cannot be achieved.	Salud + POLYCARE Technological partners	During pilot
9	Delay in the integration with already existing IS from social providers	Organisational/ Technical	☒ low ☐ medium ☐ high	☐ low ☐ medium ☒ high	The POLYCARE platform will be develop so as to store all the information provided and the database will be configured to be able to store the maximum of data so if integration cannot be performed with certain social providers, i.e, those not owning IS or without possibility to develop integration interfaces. Commitment from the social providers to enter data into the platform, if	Comoarca de Somontano + POLYCARE Technological partners	During pilot

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					integration of IS cannot be performed.		
10	Lack of potential participants	User-related	☐ low ☒ medium ☐ high	☒ low ☐ medium ☐ high	Perform information sessions to population to recruit potential users, to GPs, specialists, emergency units, to social providers and to patient's associations in the region.	Aragon Pilot management team, Comarca de Somontano	All pilot lifetime

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5   TRIAL PLAN: BONN AND SURROUNDING AREA

5.1   Introduction to the pilot site

In the following, a summary of the most relevant characteristics of this site and its specific conditions regarding the proof of concept will be provided. The implementation of the POLYCARE-service in Bonn under field conditions has to be provided in order to set the scene for further operational planning and modifying if necessary.

Previous deliverables also contain specific descriptions of this site (i.e. deliverables of WP2, WP3, WP4 as well as deliverable 6.1).

5.1.1   Background

Bonn is a medium-sized large city in the county North Rhine-Westphalia with nearly 320.000 inhabitants within its administrative city boundaries including the surrounding suburbs. It is embedded in a rural environment with the hilly regions Eifel, Bergisches Land and Siebengebirge. As in the rest of Germany every fifth person in this region is older than 65 years old with a rising trend.

Although the region offers a provision of medical care at a high level there is only a weak integration between the in- and out-patient-sector as well as within the out-patients-sector. The ladder concerns the different healthcare providers (e.g. doctors and nursing services as well as GPs and Specialists).

Communication between the different healthcare providers is mainly taking place via telephone and faxes and more and more – but still with slow pace – via email.

Although the government recently has passed a decree to strengthen the mutual use of electronic health records, there is still much effort necessary to establish sufficient coverage of real integrated care for patients not only but especially in rural areas. This also applies for the use of telemedicine structures and home hospitalization facilities.

Taken together in Bonn efforts will be needed to establish the POLYCARE setting but also to prepare an environment required for the conduct of the POLYCARE pilot.

5.1.2   Main contact person at the deployment site

The contact details for the persons responsible for the trial planning and operation of the PoC at the Bonn site is:

Name of deployment site: BONN AND SURROUNDING AREA

Name of main contact persons: Klaus Weckbecker, Martin Coenen

Organisation: Universitätsklinikum Bonn

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5.1.3   Summary of the deployment service to be implemented

The service of integrated care by the POLYCARE service will be deployed at the practices of 5 to 7 GPs of Bonn and the surrounding area (which also covers the northern area of the county of Rhineland Palatinate). Besides Bonn, the significantly smaller cities of Troisdorf, Linz and Bad Honnef are accommodating the GPs that have been recruited so far. Other potential towns for the recruitment of GPs are Mayen, Bornheim, Siegburg, Sankt Augustin, Alfter, Königswinter and Meckenheim as well as many small communities around and between those mentioned before.

The service will focus on elderly people over 65 years of age suffering from chronic conditions with an acute illness exacerbation respectively. The definite inclusion and exclusion criteria will be described in detail in deliverable D6.5. However, in general the conditions will be COPD and heart failure as well as any chronic condition accompanied by acute infections as pneumonia, pyelonephritis or erysipel.

There will be an assessment of social needs as well to evaluate if the deployment of a social carer will be necessary as well. Furthermore it is important to note that the service is exclusively piloted in the primary care sector without interfaces to the secondary (specialists) and tertiary (hospitals) sectors within the POLYCARE environment, so the regular care of the three different levels (sectors) will be totally unimpaired and independently continuing.

Since the different stakeholders in Germany all have their own information system (e.g. there are almost one hundred different software solutions for GPs) without interfaces to exchange and access patient's data neither with specialists and hospitals nor with nursing and social services, some important objectives of the POLYCARE-service are for one thing to evaluate if and how enhancement of integrated care by the support of ICTs can take place and for another to detect and overcome obstacles related to integrated care.

Therefore each care provider will share the information required by each other to gain a better coordination of the provision of care. Moreover, the stakeholders will use a common platform created and provided by the technical partners of the POLYCARE project. This platform will contain features as creating (care-) plans, defining and scheduling specific actions and other tools to ease the collaboration between care providers. Due to technical and legal issues there will be no interfaces between the POLYCARE platform and existing systems.

The site of Bonn and the surrounding area is going to test the system in 30 patients with an estimated maximum at 3 patients at the same time. Each patient will be included in the project for approximately one to two weeks.

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5.2 Preparation of systems & resources

5.2.1 Contractual setup

Within the POLYCARE project different external care providers will be involved.

According to the current status different GPs, nursing services and social workers will participate. Before any of those providers will join the project an agreement has to be signed to define the obligations and reimbursement of the participating care providers.

Activities	Time line
Signed agreement between University Hospital Bonn and the different providers.	June 2017

5.2.2 ICT components

5.2.2.1 ICT procurement and technical adaptation of existing ICT components

In Germany, many different electronic systems for doctor's practices exist with each GP using a different one. They cannot all be integrated into the project. Therefore, with the current state of planning for the German pilot no interconnections to those external systems in the clinical environment is intended.

Since the recruitment of patients will take place via the GPs practices there is no integration of ICT components of the UKB necessary.

5.2.2.2 Testing of ICT components under field conditions

The timeline of the testing of the ICT components by staff of the LPT will be performed during the whole duration of the software development. By the start of the proof of concept, by June 2017, the first version of the software development will be ready and validated with basic functionality. During the first phase of the pilot some patients without exacerbations will also be included. This will help to setup the project and the according systems since there has not been established any service like this before. It is supposed to gain first experiences in an elective situation for the patients, the GPs and the LPT. Moreover, the pure functionality of the devices can be analysed more easily comparable to the testing phase of the functionality of the new POLYCARE platform of the other sites. Furthermore, it will help to strengthen the awareness of the service for the GPs. Those patients are supposed to be additionally included to the 30 patients with exacerbations. The testing and development phases will continue so as to collect the feedback of all the users and implement any new requirements or software adaptation, if needed, resulting on new versions (v2.0, v3.0 etc..)

Activities	Time line
Testing of the functionality of the new POLYCARE platform by	May 2017 – July

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staff of the LPT.	2017
Testing of the functionality with real users without acute exacerbations	July 2017 – December 2017
Test with real users in acute phases.	June 2017 – December 2018

5.2.3   Installation of system and services

5.2.3.1   The installation team

The POLYCARE technological partners will be the final responsible for the set up the POLYCARE system. However, the LPT will be responsible for both the installation of all components at the patient's home and the continuous support of the care providers and patients.

The particular composition of the team will be described in deliverable D6.5 "Definition of the new methodology and process models"

Activities	Time line
Set up of installation team by POLYCARE technical consortium members	March 2017
Texts of the applications available for translation	March 2017
Texts of the application translated	May 2017
Determine the composition of the LPT	May 2017

5.2.3.2   Installation procedures

Installation of the POLYCARE database and servers for Bonn will be done by Fraunhofer whereas the installation of the application in tablets will be performed by the LPT.

Activities	Time line
Installation of POLYCARE application in tablets	May 2017
Installation of POLYCARE database and servers for Bonn	May 2017

5.2.3.3   Installation procedures at patients home

The LPT will provide and install the tablet, wearables and other technical equipment (e.g.HUB) at the patient's home.

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Activities	Time line
Installation and configuration of technology at patients home	After enrolment of patient

5.3   Help desk

5.3.1   Help desk set-up

The POLYCARE help desk available to support POLYCARE project on the implementation and deployment phases are described on the service process model in deliverable D6.5.

Activities	Time line
Define responsibilities of the POLYCARE Help Desk	May 2017
Set up POLYCARE Help Desk	June 2017

5.4   Recruitment of patients

5.4.1   Identification of service users potentially to be recruited

The identification of users is exclusively taking place via the before recruited GPs working in Bonn and the surroundings.

As it is needed to recruit patients with exacerbations which occur (in most cases) unpredictable at any time it is most important that the GPs are aware of the service (see also section 6.5.)

The PoC starts in July 2017 and is running for 15 months. The recruitment of patients is taking place continuously over this period of time with a maximum of 4 patients at the same time. As stated above the service is tested on 30 users plus 1 user per participating GP without an exacerbation.

Activities	Time line
Identify potential participants with exacerbations	During the whole duration of the PoC (July 2017 – September 2018)

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5.4.2   Assessment of users

The assessment of users in both medical and social fields is taking place directly after including the patient into the POLYCARE-Service and is crucial to create an individual and exact care plan for each patient as soon as he/she is enrolled. Consequently the assessment of users will be the basis for further planning and will be performed during the lifetime of the PoC. It continues until the discharge of the patient from the pilot.

Activities	Time line
Definition of assessment instruments	April 2017
Assessment of the medical status of the patient	During the whole duration of the PoC (July 2017 – September 2018)
Assessment of the medical needs of the patient	During the whole duration of the PoC (July 2017 – September 2018)
Assessment of the social status of the patient	During the whole duration of the PoC (July 2017 – September 2018)
Assessment of the social needs of the patient	During the whole duration of the PoC (July 2017 – September 2018)

5.4.3   Formal ethics approval of the local trial

In Germany the responsible ethic committee depends on the city/area where the clinical research project will be performed. The GPs who will participate in the POLYCARE project are localized in the surrounding area of Bonn and two ethics committees are responsible. For GPs who belong to North Rhine-Westphalia the

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Ethic Committee of the Medical Association of North Rhine is responsible. The southern surrounding of Bonn belongs to Rhineland-Palatinate and for GPs located in this area the competent ethic committee is the Ethic Committee of the Medical Association of Rhineland-Palatinate.

The ethic committees are responsible for ensuring that clinical research projects will comply with ethic and data protection regulations and the protection of rights, safety and well-being.

Before starting the POLYCARE project a description of the project, objectives and purpose, methodologies, team involved and documents which will be handed out to the patient (e.g. questionnaires, training material etc.) have to be approved by the ethic committees – in particular the informed consent form.

Activities	Time line
Ethic committee approvals of the POLYCARE project	May 2017

5.4.4   Informed consent

The informed consent form includes patient information and the consent document. The patient information will explain the POLYCARE project and the implication of enrolment.

The informed consent form will be handed over to the patient during the information interview in which the GP informs the patient of the POLYCARE project. Before the patient will sign the infomed consent form he will have enough time to ask all open questions.

All actions have to be performed before the enrolment of patients.

Activities	Time line
Information interview	After identification, prior to handling informed consent form
Signature of informed consent form by the patient	After identification and information interview. Before enrolment

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5.5 Recruitment of professionals & stakeholders

5.5.1 Identification of potential professionals & stakeholders to be enrolled

Recruitment of care providers has already started in July 2016. The POLYCARE project was introduced to eligible and interested GPs localized in Bonn and surrounding area by telephone and to some GPs by a focus group. Moreover, nursing services and social workers cooperating with the GPs have been contacted for participation. Until March 2017 GPs will be asked about their interest of participation. All stakeholders will be introduced to the POLYCARE project by a face to face meeting until June 2017.

If necessary care providers could additionally be enrolled during the trial as well.

Activities	Time line
Enrolment of care providers	June 2017 & during the trial if necessary

5.6 Training of users

5.6.1 Staff training

All involved providers will be trained on a face to face course before start of the trial or if any provider will join POLYCARE at a later point in time he will be trained before starting work. These training programs will be adapted to the different users and roles in the project.

Before the provision of care to the user and as close as possible to the starting date.

Activities	Time line
Training programs on the use of the biomedical devices to the care providers	May/June 2017
Training programs on the use of POLYCARE collaboration platform to the care providers	May/June 2017
Training programs for the Help desk staff	May/June 2017

5.6.2 End user training

Training programs on the use of the devices and the tablet (containing the Mobile App with the gamification applications) will be performed to end-users and their relatives on a face to face training directly after enrolment and supportive written material will be handed out as well.

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Before those training documents will be handed over to the patient it has to be approved by the responsible ethic committee.

Activities	Time line
Training programs on the use of devices and gamification application	After enrolment, before the provision of care & the closest to the starting date

5.6.3   Training materials

The trainings mentioned above will be supported by presentations and written material. Those materials will be developed after at least a reasonably final version of the devices and the app has been developed. They have to be approved by the responsible ethic committee.

Activities	Time line
Training material for professionals ready	April/May 2017
Training material for patients ready	March/April 2017

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5.7   Risks assessment and contingency plans: Bonn Site

Risk no.	Risk	Categorisation	Impact	Probability	Remedial action	Manager	Deadline
1	Delay to achieve ethical approval committee	Legal / regulatory	☐ low ☐ medium ☒ high	☒ low ☐ medium ☐ high	Send pilot protocol, information sheets and consent form draft before date of ethical committee meeting	Bonn POLYCARE management team	Before PoC starts
2	Drop out of participants	User-related	☒ low ☐ medium ☐ high	☐ low ☒ medium ☐ high	Increase sample size, improvement of information/training for patient and care provider	Bonn POLYCARE management team	All pilot lifetime
3	Improper functioning of devices	Technological	☐ low ☒ medium ☐ high	☐ low ☒ medium ☐ high	Technological support	LPT, Fraunhofer	During pilot
4	Delay to achieve technical adaptations	Technological	☐ low ☒ medium ☐ high	☒ low ☐ medium ☐ high	Constant monitoring of technical adaptations during pilot time line	Bonn POLYCARE management team And POLYCARE technological partners	When all technical adaptation is finished
6	Delay in the	Technological	☐ low	☐ low	First version of the POLYCARE platform	POLYCARE	During PoC

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	development of POLYCARE collaboration platform by the time of start of provision of IC services		☐ medium ☒ high	☐ medium ☒ high	will have to be available and tested by 1st June 2017 with basic functionality. Other versions may follow including more functionality	Technological partners	
7	Delay in the development of POLYCARE biomedical devices by the time of start of provision of IC services	Technological	☐ low ☐ medium ☒ high	☐ low ☐ medium ☒ high	First version of the POLYCARE biomedical devices will have to be available and tested by 1st June 2017.	POLYCARE Technological partners	During PoC
8	Lack of potential participants	User-related	☐ low ☐ medium ☒ high	☐ low ☒ medium ☐ high	Perform information sessions or face to face meetings to GPs who are responsible for recruitment of potential users,	Bonn POLYCARE management team	All pilot lifetime

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6   TRIAL PLAN: COUSERANS

6.1   Introduction to the pilot site- LOCAL CONTEXT

6.1.1   Background

ECHOSANTÉ (France, Occitanie Region) is an organization founded in 2003 as a hospital-city services network in the territory of the Couserans, an initiative that already represented a first milestone in the care integration journey in which the organisation is still immersed.

Nowadays, it gathers together the main local players in a view to deliver integrated social and health interventions, promoting care pathways on the basis of a holistic understanding of each person's needs and a personalized treatment. Likewise, ECHOSANTÉ strives for promoting patient's autonomy, their empowerment and capabilities for self-management of care and disease.

ECHOSANTÉ is conceived as a collaborative and co-creative space where the main care providers and actors can promote and carry out joined-up innovative initiatives and projects for providing better care services. To this end, the composition of the Administration Board reflects this philosophy, and it is made up by the Ariège Couserans Hospital, representatives of several municipalities, nursery homes and facilities for elderly people, as well as Medicine, Nursery and Physiotherapist private practices. In what concerns the multidisciplinary team realms, they are mostly Medicine, Nursery, Psychology, Social Intervention and Project Management.

The Couserans Region is a rural and mountainous area in the south of France with a weak population density (18h/km² foothill, 7h/km² in the mountains), and plenty of isolated houses where many elderly people live alone, being mostly +75 years old. The extremely pronounced ageing trend in the area has placed the promotion of innovative solutions for achieving a more efficient and sustainable management of chronic diseases and comorbidities at the forefront of ECHOSANTÉ's organizational strategy. In this sense, it is expected that POLYCARE will allow to provide a better care coordination amongst the different stakeholders in the HAH services and to face the difficulties bound to its territory, improving care accessibility and health democracy.

6.1.2   Main contact person at the deployment site

The contact details for the person responsible for the trial planning and operation of the PoC at the Couserans site is:

Name of deployment site: COUSERANS site

Name of main contact person: Catherine Vicq

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Organisation:	ECHOSANTÉ
E-mail address:	c.vicq@ch-ariege-couserans.fr
Skype:	ECHOSANTÉ_innovation
Telephone number:	+33.5.61.96.28.80

6.1.3   Summary of the deployment service to be implemented

The ECHOSANTÉ HAH services started in 2007 and were built upon a collaborative hospital-city network. The coordination amongst the different stakeholders is evolving since then towards an integrated care, progressively being developed in the catchment area. Intrinsically, the HAH practice involves comprehensive and coordinated care, gathering together social and health professionals coming from different public and private organizations and structures in the territory. The multidisciplinary team is composed of   liberal doctors, nurses, formal and non-formal caregivers, pharmacists, psychologists, geriatrists, physiotherapists, medical equipment providers, ergo-therapists, palliative care providers, social services, catering providers, domiciliary carers, etc. All these professional profiles are deeply involved and coordinated in the HAH care pathway according to the organization's missions. Namely, these are: to avoid or reduce admissions and hospitalization stays, assuring quality of care in an equivalent manner as in traditional hospitals; allowing patients to stay at their preferred or usual environments (at home or in other social or health housing alternatives), fostering independent living, provide psychological support and health education and accompanying near end of life patients with specific care and support.

The main objective of POLYCARE in the COUSERANS is to initiate a Research and Innovation work line in integrated care for people with chronic conditions and more concretely in the HAH domain. Specifically, the PoC will be aimed to test the viability of the POLYCARE concept as :

- One-time care, aimed at patients that need complex and high technique healthcare, presenting a stabilized disease and for a limited period of time.
- Re-adaptation care for a limited period of time following the discharge process, addressed to people after for example going through surgery, or to avoid Emergencies overload.

Regarding the settings/environments for the POLYCARE PoC, the inclusion criteria it will consider (to be developed in D. 6.5) both patient's home and elderly care facilities (in France, EHPAD). 100 patients are expected to participate in the study all along the 15 months of the PoC duration.

The main benefits expected are:

- To gather evidence from integrated care improvements in HAH related to the implementation of an innovative ICT based tool conceived for enhancing

communication amongst stakeholders, tele-monitoring and decision support systems, compared to traditional treatment in HAH.

- To improve the drugs circuit (greater safety, derived from the collaborative environment)
- To further develop HAH possibilities, for instance, including re-adaptation care services to avoid emergencies overload

6.2   Preparation of systems & resources

6.2.1   Contractual setup

Activities	Time line
Collaboration agreements between ECHOSANTÉ and the Hospital Ariège-Couserans	June 2017.
Collaboration agreements with elderly people facilities (EHPADs)	June 2017.

6.2.2   ICT components

6.2.2.1   ICT procurement

ECHOSANTÉ, as a private entity, will comply the EU directives on procurement since POLYCARE is a public funded project

At the day being, these procurement procedures are envisaged :

- Extension of the support, management and hosting services of the IT provider
- Acquisition of the biomedical devices
- IT technology and licenses required
- Other equipment (tablets, etc.)

The deadlines to reach the formalized contracts with the different providers are:

Activities	Time line
Extension of the support, management and hosting services of the IT provider	April 2017
Acquisition of the biomedical devices, IT technology and licenses required	April 2017
IT technology and licenses required	April 2017
Other equipment (tablets, etc.)	April 2017

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Description of any measures to be conducted for setting up and maintaining a call centre

No procurement measures have to be taken to maintain a technical call center

6.2.2.2   Technical adaptation of existing ICT components / systems

One of the greatest operational challenges for any health innovative technology is to achieve interoperability with other Health Information Systems. The pilot in the Couserans area will intend to demonstrate interoperability with the EHR and to this end, some modifications in the systems could be performed. However the EHR (DPI) in France is not fully implemented what can lead to difficulties in attaining this purpose. Therefore, a viability analysis has to be performed beforehand.

The integration activities, if any, will be further detailed in WP7 deliverable D7.1 Integration Testing plan that will be released in May 2017, so the plan for the envisaged activities to achieve integration is susceptible to change in that future deliverable.

Activities	Time line
Viability of EHR and POLYCARE integration	January 2017
Implementation of the EHR and POLYCARE integration	May 2017

6.2.2.3   Testing of ICT components / systems under field conditions

Before the PoC implementation in an HAH context, it is important to test the different POLYCARE components as well as its integrations firstly within the LPT team and afterwards with real end-users to assure safety, to address usability issues and to provide significant and structured inputs to the technical partners to allow them to carry out further improvements and enhancements. For ethical considerations, end-users at this stage will be defined as elderly people with chronic conditions, not suffering from exacerbations.

Activities	Time line
Testing of the POLYCARE partial prototypes and components before the PoC	Dec 2016- June 2017
Pre-Pilot: Testing of the Integrated POLYCARE concept before PoC by professionals and end-users (not suffering from chronic conditions)	June 2017 – December 2017
Test with real users in HAH environments	June 2017 – September 2018

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6.2.3   Installation of system and services

6.2.3.1   The installation team

In this deliverable, the technical workflow will specify competencies and responsibilities at a local level regarding providers that will collaborate with the POLYCARE technical partners in order to achieve a successful installation. These ones will be the final responsible for the delivery and installation of POLYCARE system.

Activities	Time line
Technical workflow defined	March 2017
Set up of installation team by POLYCARE technical consortium members	March 2017
Texts coming from the different POLYCARE modules available for localization	March 2017
POLYCARE system localized	May 2017

6.2.3.2   Installation procedures

Activities	Time line
Installation of POLYCARE local databases in the Couserans and implementation	April 2017
Installation and set-up of the Couserans servers	April 2017
Installation of POLYCARE applications in servers	May 2017
Installation of POLYCARE applications in tablets	May 2017

6.2.3.3   Installation procedures at patients home

Activities	Time line
Installation and configuration of technology at patients home	Before referral of patient to their home/ EHPAD (residence facilities)

6.3   Help desk

6.3.1   Help desk set-up

The timeline for activities to set-up the helpdesk are as follows:

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Activities	Time line
POLYCARE Help desk set-up	May 2017

6.4   Recruitment of patients

6.4.1   Identification of service users potentially to be recruited

Potential users will be identified according to three sources of recruitment: 1- The GPs that refer patients to HAH services 2- The EHPADs (residence facilities) medical coordinator that demands an HAH service for one resident and 3- An admission that occurs at the Hospital Ariège Couserans' Emergency services

The commitment of the COUSERANS is to carry out a proof of concept with 100 users. Therefore, the inclusion of participants will be active during 15 months. An additional 20% of patients will be recruited as a provision to compensate potential drop-outs.

The mean of active patients in the POLYCARE systems will range between 3-5 with a maximum of 5 patients receiving POLYCARE services at the same time. The mean duration of the intervention is expected to be around two weeks.

Activities	Time line
Identify potential participants	Starting in June 2017 and active during the whole duration of the PoC

6.4.2   Assessment of users

Once identified, the patient/future user of the POLYCARE system will be informed about the PoC essential characteristics, implications, rights and commitments, and will have to sign the informed consent. Afterwards, and in order to determine if the patient fulfils the inclusion criteria (and to check out that none of the exclusion criteria occurs), he will undergo an assessment process covering health and social status to evaluate the inclusion of the patient into the POLYCARE program, as well as to identify their integrated care needs that are at the core of a personalized care plan. Therefore, the assessment of users will be performed according to the following deadlines.

Activities	Time line
Assess the overall clinical status of the patient (adequation to POLYCARE inclusion criteria)	Starting in June 2017during the whole duration of the PoC, after the identification

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	process
Assess the overall social status of the patient (adequation to POLYCARE inclusion criteria)	Starting in June 2017during the whole duration of the PoC, after the identification process
Assess the clinical needs of the patient (medical assessment)	Starting in June 2017during the whole duration of the PoC, after the inclusion
Assess the social needs of the patient (social assessment)	Starting in June 2017during the whole duration of the PoC, after the inclusion

6.4.3   Formal ethics approval of the local deployment & other ethical principles of involving human beings in the deployment

Description of any measures to be conducted for obtaining a formal ethics approval of the deployment

The French institutions in charge of Ethical surveillance in the case of researches involving humans are the Committees for the Protection of Persons (CPP - Comités de Protection des Personnes). These bodies stablish the pieces of information that the main researcher (being the methodology of the study and the protocol the most crucial elements for the decision-making process) has to provide in order to obtain the ethical approval. These regional ethics committees will issue a positive/negative report to the researchers regarding the protection of the participants and whether any subsequent amendments to the research protocol are required. After the research protocol is approved by a CPP, it is then referred for approval to either the Ministry of Health or the Agency for the Sanitary Security of Health Products.

Description of any measures to be conducted for meeting ethical principles for involving human beings in the deployment

These measures and their time-line are:

Activities	Time line
Care professional's commitment to data protection regulations, access to health data procedures and ethical guidelines	June 2017

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An "authorization of access to POLYCARE data" which provides access to the patient's data on the scope of the POLYCARE, will have to be signed by social and health professionals.	June 2017
Ethical file to be sent to the CPP (Comité de Protection des Personnes)	February/March 2017
Ethical approval by the CPP	April 2017

6.4.4   Informed consent

Description of any measures to be conducted for obtaining informed consent by the deployment users

Two documents have already been created: an information sheet and an informed consent document. These documents will have to be approved by the CPP to ensure the ethics & data protection regulations compliance before handing out them to the users. The information sheet will describe in plain language the POLYCARE project, its objectives, phases, technology, PoC and the implication of the patient's enrolment, his rights, etc. Before giving these documents to the patient, his representative or family, one member of the LPT will hold a meeting with them to explain the contents of these sheets verbally and in an understandable way, and will respond to all the questions posed by the potential participant. Clarifying that any consequence will take place if the patient withdraws at any time in the study, is one of the most important aims of this meeting. Finally, collecting the signature of the informed consent is indispensable before proceeding to carry out any PoC actions.

Time line

During the project lifetime. All actions have to be performed before the start of the provision of services and in concordance to the enrolment of users.

Activities	Time line
CPP approval of the POLYCARE study, and the information sheets and consent form documents	April 2017
Information meeting/interview	After identification, prior to handling consent form
Signature of the consent form by the patients	After identification and information meeting. Before enrolment

6.5   Recruitment of professionals & stakeholders

6.5.1   Identification of potential professionals & stakeholders to be enrolled

One joint information session will be organized to update all the HAH internal professionals and stakeholders in the COUSERANS, previously identified as interested in collaborating within the framework of the POLYCARE project and its PoC study. Since POLYCARE it is not only a technology but also (and mainly) an integrated care model adapted to HAH services, the care pathway as well as the tasks and roles of each participants within, it will be presented. A "who does what, when, where and how" diagram will help to clarify and to organize the integrated care chain.

Activities	Time line
Identification of professionals and stakeholders to be enrolled in the POLYCARE PoC and organization of the care chain and actions	February 2017
Joint information sessions for professionals and stakeholders	March 2017

6.6   Training of users

6.6.1   Staff training

Different training courses will be organised to build capacity and motivation amongst the professionals, researchers and stakeholders

- One joint training action on the use of the POLYCARE system. Following a hands-on approach, the participants will be taught on how to utilize the different components of the POLYCARE System.
- One training action about the POLYCARE research methodology and the handling/organization/treatment of data for the conduction of statistical analysis.
- One training action about protocols for the resolution of medical incidences at the call centers and managing alarms.

Activities	Time line
One joint training action on the use of the POLYCARE system.	May 2017

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| One training action about the POLYCARE research methodology and data management. | May 2017 |
| One training action about protocols for the resolution of medical incidences at the call centers | May 2017 |

6.6.2   End user training

The training and information provided to the end-user/patient and his informal caregivers is indispensable for the success of the PoC and will greatly determine his motivation and adherence to the service. Due to the high vulnerability of the patient and the particular situation that an hospitalisation at home represents, the LPT will pay especial attention to the moment of the introduction of the technology to the patient, to avoid overwhelming him, what could directly lead to a drop-up.

A short and practical training session will be carried out with the patients and their informal caregivers to enable them to use the tablet and its different functionalities as well as the biomedical devices. A short presentation video will be shown to the patient that will be also be available on the mobile application (health information part) as a reminder.

Activities	Time line
Training session for patients and informal caregivers	After enrolment, before the provision of care & the closest to the starting date

6.6.3   Training materials

The training actions addressed to professionals will be conducted on a basis of 3-hours on-site sessions by healthcare professionals of the LPT.

The materials provided will be:

- A professional user guidelines/manuals
- Printed training materials in form of fiches (a fiche per content unit) and proposed links to interesting web information
- Practical exercises

In the case of the training session with patients and informal caregivers, the training materials will be:

- A user manual for patients
- A video showing the operation of the Tablet and mobile application, monitoring devices, etc.

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Time line

Activities	Time line
Training material for professionals ready	April 2017
Training material for patients ready	April 2017

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6.7 Risks assessment and contingency plans- Couserans site

Risk no.	Risk	Categorisation	Impact	Probability	Remedial action	Manager	Deadline
1	Delay to achieve ethical approval committee	Legal / regulatory	☐ low ☐ medium ☒ high	☒ low ☐ medium ☐ high	Send pilot protocol, information sheets and consent form draft before may	LPT Couserans	Before PoC starts
2	Drop out of participants	User-related	☐ low ☒ medium ☐ high	☐ low ☒ medium ☐ high	20% of additional participants (above the 100 committed) provision as a countermeasure for drop outs. Motivating and avoiding overcharge. Using best practices to promote patient's adherence to the system	LPT Couserans	All pilot lifetime
3	Improper functioning of devices	Technological	☐ low ☒ medium ☐ high	☐ low ☒ medium ☐ high	Technological support	Local technical providers and POLYCARE technical partners	During pilot
4	Delay to achieve technical adaptations	Technological	☐ low ☒ medium ☐ high	☒ low ☐ medium ☐ high	Constant monitoring of technical adaptations during pilot time line	Local technical providers and POLYCARE technical partners	When all technical adaptation are finished
6	Delay in the development of POLYCARE collaboration	Technological	☐ low ☐	☐ low ☐ medium	First version of the POLYCARE platform will have to be available and tested by 1st June 2017 with basic functionality. Other versions may follow including more	POLYCARE Technological partners	During PoC

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	platform by the time of start of provision of IC services		medium ☒ high	☒ high	functionality		
7	Delay in the development of POLYCARE biomedical devices by the time of start of provision of IC services	Technological	☐ low ☐ medium ☒ high	☐ low ☐ medium ☒ high	First version of the POLYCARE biomedical devices will have to be available and tested by 1st June 2017.	POLYCARE technological partners	During PoC
10	Lack of potential participants	User-related	☐ low ☒ medium ☐ high	☒ low ☐ medium ☐ high	Perform information sessions to population to recruit potential users, to GPs, specialists, emergency units, to social providers and to patient's associations in the region.	Couserans LTP	All pilot lifetime

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