



Personalised Health Monitoring and Decision Support Based
on Artificial Intelligence and Holistic Health Records

D6.3 – Pilot Setup and Implementation of Digital Trials I

WP6 iHelp Validation and Pilot Studies

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Executive summary

Five pilot studies will be carried out as part of iHelp, to help test and validate the solution developed in the project. These pilots' studies that will be further detailed in D6.1 ("Coordination of pilot scenarios for personalised healthcare – early risk identification, prevention and intervention measures I") and in D6.2 ("Coordination of pilot scenarios for personalised healthcare – early risk identification, prevention and intervention measures II") should be set up and implemented by healthcare partners in close collaboration with technical partners.

This series of deliverables, i.e., D6.3 ("Pilot setup and implementation of digital trials I") and D6.4 ("Pilot setup and implementation of digital trials II"), contributes to the description of the set up and implementation process, the former assessing the requisites and milestones to allow the pilots start and the latter assessing the work performed after the end of the pilots (also referred as digital trials). In addition, it describes if the objectives have been reached.

The overall objective of this document is to contain the description of the set-up process for each pilot, and its level of development by M18 of the project, allowing to foresee deviations and potential risks that may jeopardize the pilots start, that is expected around M21 of the project.

1 Work plan

1.1 Introduction

All pilots provide different aspects in relation to disease prevention, personalised health monitoring and decision support. Those differences have implications on the design of the pilots themselves, the setup process and the requirements needed.

But at the same time all of them rely on the same set of technological tools provided by the project and that will be used and assessed in the pilots. And that allowed us to define a common work plan, a set of tasks that is appropriate to report the status of all the pilots and offer a comprehensive view of their readiness status.

The work plan comprises five thematic sections that are listed in the table below. Each of the five sections is divided into tasks and will be described in the following section of the document.

Table 1: Sections of the work plan

Section No	Section Title
1	Pilot definition
2	Ethical approval
3	Wearables
4	Technical assessment
5	Digital trials

1.2 Sections and tasks

Section 1 – Pilot definition: This section is devoted to status the definition of the pilot, which should include not only its description from a clinical or functional point of view, but also various aspects that are related to specific functionalities offered by the iHelp platform and that will allow technology partners to advance in the development and customization of their components for each pilot.

From this approach, this section describes the state of progress in defining the clinical objectives, the criteria and processes for patient selection, and the pilot timing (Tasks 1.1, 1.2, 1.9 and 1.10), the patient data that will be treated (T1.3 and T1.4), the mobile application that patients will use (T1.5 and T1.7), the specific dashboards for doctors that will be implemented (Task 1.6), the need of social media analytics (Task 1.8) and the outcomes expected to be delivered by AI included in iHelp (Task 1.11).

The below table summarizes and showcases the different tasks of this section to further address the scopes and objectives of the pilots' activities under this scope.

Table 2: Tasks of Section 1

Task No	Title	Description
Task 1.1	Pilot abstract and objectives	Definition of the digital trial from a functional approach, explaining the scientific outcomes expected or, in other words, why the pilot makes sense and which is the scientific benefit that will be obtained from it.

Task 1.2	Definition of pilot timeline	Description of when the pilot will start and end, in a way that the timeframe is enough to achieve the scientific results while respecting the iHelp project timetable.
Task 1.3	Primary data definition	Definition of the data that each pilot is going to provide to the project that will not be obtained by tools developed inside the project, in a way that the technical partners are able to start building the data model that will later be used to acquire and store it
Task 1.4	Secondary data definition	Definition of the data that each pilot is going to provide that will be obtained by tools developed inside the project, in a way that the technical partners are able to start building the tools and apps that will later be used to acquire and store that data
Task 1.5	Healthentia APP definition	Definition of the Healthentia app that will be used to perform the patients monitoring. It comprises both the mobile application and the clinical dashboard
Task 1.6	DSS definition	Definition of the specific dashboards inside the DSS tool with the objective of offering the desired views of the data.
Task 1.7	Definition of virtual coach content	Definition of the virtual coach conversations that the patients will have available inside the pilot.
Task 1.8	Definition social media analytics needs	Definition of the needs of social media analytics identified by the pilot.
Task 1.9	Definition of patients inclusion criteria	Definition of the criteria to be applied to select the patients that will be monitored during the pilot execution.
Task 1.10	Definition of patients recruitment process	Definition of the process that should be followed to contact those patients that will be invited to participate in the pilot study, and to formalize their participation in case of their acceptance.
Task 1.11	Definition of AI expected outcomes	Definition of the outcomes that the AI platform included in Healthentia will deliver, to the extent that the technical partners will be able to identify which the model will be and how it will be trained, in order to obtain the desired outcomes.

Section 2 – Ethical approval: The pilots that will be developed in iHelp are clinical studies, in which health data from patients will be processed, which is the most sensitive data in terms of GDPR regulation.

Each pilot acts as the data controller for the data that they will transfer to iHelp and that is why, according to the principle of due diligence, they must be responsible for reviewing and approving the data processing of their patients. Within this parcel of responsibility, three elements have been differentiated that are common to all pilots, and that could be approved or denied independently. In the first place, the approval for the treatment of patient data that will form an active part of the pilot is contemplated (Task 2.1).

Secondly, the approval status of the use of data from patients who are not directly involved in the project is established. This refers to the massive download of data that could be used for the training of AI algorithms of iHelp (Task 2.2).

Finally, the approval status to allow iSPRINT partner act as data processor, which is needed to make use of the Healthentia app (Task 2.3).

The below table summarizes and showcases the different tasks of this section to further address the scopes and objectives of the pilots' activities under this scope.

Table 3: Tasks of Section 2

Task No	Title	Description
Task 2.1	Data of patients directly involved in the trial	The ethical approval for the use of data from patients that will be directly involved in the project has been achieved. Since these patients will voluntarily accept to participate, an explicit consent will be the most used mean of legitimation.
Task 2.2	Data of patients not directly involved in the trial	Some pilots will not use only data from those patients monitored during the trial but will instead offer bulk data from patients (both PC diagnosed and not diagnosed) so the AI algorithms can produce outcomes in terms of predictive analytics, or weight of risk factors. The pilot must obtain the ethical approval for the use of this type of data, which legitimation would be probably different from the previous one.
Task 2.3	Approval for use of data in Healthentia APP, signed with iSPRINT	All the pilots will use the Healthentia APP, developed by iSPRINT, to treat health data. iSPRINT needs a signed consent from each pilot to let the pilots start using the app. In this regard, the pilot acts as data controller and allows iSPRINT to act as data processor.

Section 3 – Wearable devices: The use of IoT devices in healthcare is a trending tendency and has been also addressed by the iHelp project. The use of wearable devices is a shared feature in all the iHelp pilots. With these type of devices the gathering of health data is simplified since they automatically are able to recruit continuous data from physical activity, hearth rate, etc., and also remove the subjectivity for gathering certain type of data, like the quality of sleep.

To be ready to offer those wearable devices to pilot participants, the orders should have been coursed (Task 3.1) and the wearables should have been received (Task 3.2).

The below table summarizes and showcases the different tasks of this section to further address the scopes and objectives of the pilots' activities under this scope.

Table 4: Tasks of Section 3

Task No	Title	Description
Task 3.1	Wearable devices ordered	The purchase order has been executed, which indicates that there is not any administrative problem inside the organization.
Task 3.2	Wearable devices received	The wearables have been received and are available to be used.

Section 4 – Technical assessment: iHelp is a clinical project in which technical tools are used to obtain clinical and scientific outcomes. Therefore, in order to start the pilots, the technical part must be developed, deployed, tested, and ready to be used. This section addresses this technical part. In the first place, two types of pilots are differentiated, depending on whether they are going to deploy an instance of iHelp in

their premises and therefore must report the status of tasks 4.1 and 4.2, or if, on the contrary, they are going to use the central instance of iHelp, in which case it will not be necessary to report the previous mentioned tasks.

The rest of the tasks are common to all pilots and therefore must be completed by all of them.

Different regards are addressed: if the Healthentia application for the pilot has been implemented and translated into the corresponding language (Tasks 4.3 and 4.4), if it has been tested both at basic and advanced levels (Tasks 4.5 and 4.6), and if the pilot has provided a data sample, the technical partners have built the data model for said data sample and it has been tested by loading the data sample provided.

With all these tasks completed, the pilots will be ready both to start monitoring the patients and to import the primary data that will be used in combination with the secondary data in the studies.

The below table summarizes and showcases the different tasks of this section to further address the scopes and objectives of the pilots' activities under this scope.

Table 5: Tasks in Section 4

Task No	Title	Description
Task 4.1	Provision of infrastructure for deployment of iHelp components	The pilot has provided the required infrastructure to deploy the iHelp components inside its premises, instead of using the centralized instance.
Task 4.2	Deployment of iHelp components in hospital premises	The iHelp components have been deployed in the hospital premises and are ready to be used for that pilot, instead of the centralized instance.
Task 4.3	Healthentia APP built	The Healthentia APP has been built following the definition provided by the pilot in Task 1.5
Task 4.4	Healthentia APP translated to required language	The pilot has provided the text in the required language, if any additional language other than English is required.
Task 4.5	Healthentia APP basic tests	The pilot and iSPRINT have jointly performed basic tests of the Healthentia app, covering basic functionalities like inviting users, log in or reporting basic data.
Task 4.6	Healthentia APP advanced tests	The pilot and iSPRINT have jointly performed complete tests of the Healthentia app, covering advanced functionalities like wearable device integration, report of specific pilot tests, or the physician dashboard.
Task 4.7	Primary data sample provided	The pilot has provided a data sample for the primary data defined in Task 1.3.
Task 4.8	Data model for primary data built	The technical partners have built the data model corresponding to the definition (Task 1.3) and the data sample (Task 4.7).
Task 4.9	Primary data sample checked against the model (data ingested)	The technical partners have tested the data model built, successfully ingesting the data sample provided by the pilot.

Section 5 – Internal requirements for digital trials: For the correct development of the pilots, the responsible partners may need internal resources of the organization. For example, a doctor to perform the surveillance of the patients engaged including face to face visits, or a physical room to attend those patients. The detail of these necessary resources is outside the scope of this deliverable, but their definition status and whether they have been guaranteed are included. The goal is to avoid a situation where all

analytical, ethical, and technical requirements have been completed but the start of the pilot may be compromised by bureaucratic issues internal to the organization.

Table 6: Tasks in Section 5

Task No	Title	Description
Task 5.1	Definition of internal resources needed	During the definition of the pilot (Task 1.1) the internal resources needed have been also identified.
Task 5.2	Allocation of internal resources needed	The identified and requested resources have been allocated by the pilot's organization.
Task 5.3	Patient recruitment process	The recruitment process should be performed before the pilot starts, in order to respect the timing of the pilot and let time enough to perform the observational experiments.
Task 5.4	Pilot start	If the digital trial for the pilot study has been started and when, or if it has not been yet started and which is the estimated date to start.
Task 5.5	Pilot end	If the digital trial for the pilot study has finished yet and when, or if it has not been yet concluded and which is the estimated date to finish it.

By gathering the previous defined data for each pilot, their status will be reported in a comprehensive way, identifying those tasks that may cause delays and the stakeholders that should be engaged to avoid further problems.

2 Pilot#1 - UNIMAN

2.1 Pilot definition

The UNIMAN pilot seeks to recruit 700 subjects, aged 50 and above, to perform a cancer risk assessment and stratify the subjects into low, medium, and high risk.

Then all of them will be asked to agree on achievable behavioural changes and will start a follow-up process to monitor their evolution. For high-risk patients a blood sample will be taken and an omics analytics will be performed and repeated at the end of the project to state how the changes in life habits would impact at epigenetic level.

The main definition items of the pilots have been defined, allowing all the technical tasks to proceed and the components to be prepared. Only some items have not been defined but they will not delay the start of the pilot. The detail of each task is provided in the following table.

Table 7: Tasks of Section 1 for UNIMAN pilot

Task No	Title	Description
1.1	Pilot abstract and objectives	Completed. Further detailed in D6.1
1.2	Definition of pilot timeline	Completed. Expected from JUL-22 to SEPT-23.
1.3	Primary data definition	Completed. The primary data definition is those obtained from our cancer risk (REFLECT) study and genetic score.
1.4	Secondary data definition	Completed. The secondary data definition is those obtained from our biomarker study (methylation data) and prevention study
1.5	Healthentia APP definition	Completed. APP has been completely defined.
1.6	DSS definition	Pending. Not yet addressed.
1.7	Definition of virtual coach content	Pending. Not yet addressed.
1.8	Define social media analytics needs	Completed. This pilot will use it and the requirements have been defined.
1.9	Definition of patients inclusion criteria	Completed
1.10	Definition of patients recruitment process	Completed
1.11	Definition of AI expected outcomes	Pending. Not yet addressed.

2.2 Ethical approval

The tasks regarding the ethical approval are being managed and any problem is overseen. All the issues regarding the use of patients' data have been completed and the only item left is the signature of the document that will allow iSPRINT act as data processor in relation to the secondary data used by the Healthentia app.

Table 8: Tasks of Section 2 for UNIMAN pilot

Task No	Title	Description
2.1	Use of data of patients directly involved in the study	Completed. The participant information sheet and consent forms are approved by UNIMAN ethical committee.
2.2	Use of data of patients not directly involved in the study	Completed. That data will be anonymized and thus will not be considered as identified personal data, which was approved by UNIMAN ethical committee review.
2.3	Approval for use of data in Healthentia APP, signed with iSPRINT	In process. In process of clarifying the issue of non-traceable individual with iSPRINT and both partners (UNIMAN and iSPRINT) are satisfied with the agreement therefore DPA is now progressing to the signage state

2.3 Wearable devices

The UNIMAN pilot will make use of wearable devices. The purchase order is being managed following the internal protocols. It is expected that the devices will be available by the time they will be needed in the pilot, which is not at the beginning.

Table 9: Tasks of Section 3 for UNIMAN pilot

Task No	Title	Description
3.1	Wearable devices ordered	In process. Currently processing the enquiry of buying the Fitbit, we anticipate this process may take one month (July).
3.2	Wearable devices received	Pending

2.4 Technical assessment

The UNIMAN pilot will deploy an instance of the iHelp platform in their premises. In this regard the infrastructure has been provided and the deployment tasks are in process. The Healthentia APP has been developed and the basic tests are being performed. The data model for the primary data has been developed but the tasks of providing a data sample and loading it are still in process.

Table 10: Tasks of Section 4 for UNIMAN pilot

Task No	Title	Description
4.1	Provision of infrastructure for deployment of iHelp components	In process. The UNIMAN team will use the local premise of iHelp. We are in the process of setting this up at the university of Manchester however all technical partners were informed
4.2	Deployment of iHelp components in hospital premises	Pending
4.3	Healthentia APP built	In process. The pilot is in constant communication with the Healthentia team and we will try and test the app prior to our implementation
4.4	Healthentia APP translated to required language	N/A. The pilot study doesn't need other language translation
4.5	Healthentia APP tested (basic) (invite users, log in, see basic data reported)	In process
4.6	Healthentia APP tested (advanced) (wearable device integrated, specific pilot tests, physician tools)	Pending

4.7	Primary data sample provided	In process
4.8	Data model for primary data built	Completed. The REFLECT model for cancer assessment will be used and the data model has been defined.
4.9	Primary data sample checked against the model (data ingested)	Pending

2.5 Internal requirements

The UNIMAN pilot has managed the internal needs to correctly develop the study. The internal resources needed have been defined, requested and already allocated, as the patient recruitment process as well.

Table 11: Tasks of Section 5 for UNIMAN pilot

Task No	Title	Description
5.1	Definition of internal resources needed	Completed. Will collaborate with UNIMANS' community partner GFCT.
5.2	Allocation of internal resources needed	Completed
5.3	Patient recruitment process	Completed. UNIMANS' community partner GFCT will help to perform the recruitment of participants.
5.4	Pilot start	Jul-22
5.5	Pilot end	Sept-23

2.6 Risks

If the number of above-average cancer risk participants does not reach UNIMAN's expectations, it will take more time to recruit further participants to achieve pilot's goal.

3 Pilot#2 - FPG

3.1 Pilot definition

The FPG pilot aims to perform a real world data (RWD) analysis using a mobile application connected with Internet of Thing (IoT) devices to systematically acquire Patient Reported Experience Measures (PREMs) and Patient-Reported Outcome Measures (PROMs) for patients affected by pancreatic cancer with indication to radiotherapy, to predict outcomes and toxicity. Therefore, this pilot will recruit only patients diagnosed with PC and are being treated with radio/quimiotherapy.

There are two significant items needed for the start of the project which definition is still in process: the Healthentia APP and the primary data model. But they are in a state of progress that is acceptable and do not pose a risk for the pilot's start. Other items, like the DSS or the AI outcomes are still under discussion but are not needed for the pilot's start.

Table 12: Tasks of Section 1 for FPG pilot

Task No	Title	Description
1.1	Pilot abstract and objectives	Completed. Further detailed in D6.1
1.2	Definition of pilot timeline	Completed. Expected from Sept-22 to Dec-23.
1.3	Primary data definition	In process. Primary data has been defined and extracted from hospital database. Currently working in the identification of standard vocabularies and codes for the codified values
1.4	Secondary data definition	Completed. Physicians defined the secondary data of interest to be reported by the patients during the digital trial
1.5	Healthentia APP definition	In process
1.6	DSS definition	Pending. Not yet addressed.
1.7	Definition of virtual coach content	N/A. This pilot will not use it.
1.8	Define social media analytics needs	N/A. This pilot will not use it.
1.9	Definition of patients inclusion criteria	Completed. Physicians defined the criteria for enrolling patients in the trial
1.10	Definition of patients recruitment process	Completed
1.11	Definition of AI expected outcomes	In process. Toxicity related outcomes have been defined. Discussion between physicians and technical partners about haematological toxicities inclusion

3.2 Ethical approval

The ethical approval has not been yet obtained. The process is ongoing and all the clarifications and information are being provided to the internal ethical committee. That approval is expected to be obtained before September, when the pilot is supposed to start, but there is a risk that it may be delayed and so are being managed and any problem is overseen. All the issues regarding the use of patients' data have been completed and the only item left is the signature of the document that will allow iSPRINT act as data processor in relation to the secondary data used by the Healthentia app.

Table 13: Tasks of Section 2 for FPG pilot

Task No	Title	Description
2.1	Use of data of patients directly involved in the study	In process. The protocol was submitted to the Ethical Committee (hopefully approved by the end of June). Patients will sign an informed consent in order to be enrolled in the trial.
2.2	Use of data of patients not directly involved in the study	In process. Protocol submitted to the Ethical Committee includes also authorities to make available retrospective data in order to train AI models.
2.3	Approval for use of data in Healthentia APP, signed with iSPRINT	In process. DPA between FPG and iSprint has already been signed.

3.3 Wearable devices

FPG has received the wearable devices and they are ready to be shared among patients in the study when the pilot starts.

Table 14: Tasks of Section 3 for FPG pilot

Task No	Title	Description
3.1	Wearable devices ordered	Completed
3.2	Wearable devices received	Completed. Wearables received and ready to be used.

3.4 Technical assessment

The FPG pilot will deploy an instance of the iHelp platform in their premises. In this regard the infrastructure has been provided and the deployment tasks are in process. The Healthentia app has been developed and the only task left is to finalize the translations to Italian. Once the translations will be finished, the tests will be performed. A data sample for primary data has been provided and the technical tasks to build the model are close to be finished. After that, the loading of the data sample will be performed.

Table 15: Tasks of Section 4 for FPG pilot

Task No	Title	Description
4.1	Provision of infrastructure for deployment of iHelp components	Completed. Infrastructure is ready and a simulated learning was performed on synthetic data.
4.2	Deployment of iHelp components in hospital premises	In process. Some components have been already deployed successfully.
4.3	Healthentia APP built	Completed
4.4	Healthentia APP translated to required language	In process. Questionnaires and Healthentia FAQ have been already provided in Italian language, but there are still some texts inside the app that should be translated.
4.5	Healthentia APP tested (basic) (invite users, log in, see basic data reported)	Pending

4.6	Healthentia APP tested (advanced) (wearable device integrated, specific pilot tests, physician tools)	Pending
4.7	Primary data sample provided	Completed. Synthetic primary data were provided to train model. After Ethical Committee approval real primary data will be available to train models.
4.8	Data model for primary data built	In process
4.9	Primary data sample checked against the model (data ingested)	In process

3.5 Internal requirements

The FPG pilot has identified the internal resources needed to correctly develop the study, and those resources are in process to be allocated, once the ethical approval will be achieved.

Table 16: Tasks of Section 5 for FPG pilot

Task No	Title	Description
5.1	Definition of internal resources needed	Completed
5.2	Allocation of internal resources needed	In process
5.3	Patient recruitment process	Jul-22. Depends on ethical approval.
5.4	Pilot start	Sept-22. Depends on ethical approval.
5.5	Pilot end	Dec-23. Depends on ethical approval.

3.6 Risks

Delays in Ethical committee approval could postpone the start of the pilot, affecting the patients recruitment process, allocation of internal resources needed and provision of real primary data. That will cause the pilot to be shortened, what will not be a major problem if the pilot starts before November 2022.

4 Pilot#3 – HDM

4.1 Pilot definition

The HDM pilot seeks to demonstrate if the effect of one of the most relevant risk factor for PC (smoking) can be reverted. This will be studied at epigenomical level, by selecting 15 patients that agreed to quit smoking and studying a tobacco associated epigenomical signature at the beginning of the pilot and then nine months later, to observe if the methylation patters would change.

In parallel HDM will provide medical records of around 100K anonymized patients, including PC diagnosed patients and free cancer patients, to train AI models and try to discover hidden relationships in the provided data that could point to unknown disease factors.

All the relevant aspects of the HDM have been defined, what will allow the pilot start as expected. The DSS dashboards will be defined later once the pilot will start.

Table 17: Tasks of Section 1 for HDM pilot

Task No	Title	Description
1.1	Pilot abstract and objectives	Completed. Further detailed in D6.1
1.2	Definition of pilot timeline	Completed. Expected from SEPT-22 to JUL-23.
1.3	Primary data definition	Completed. The primary data has been defined and a data-sample delivered. Currently working in the identification of standard vocabularies and codes for the codified values
1.4	Secondary data definition	Completed. Physicians already defined the secondary data of interest to be reported by the patients that will participate into the trial.
1.5	Healthentia APP definition	Completed
1.6	DSS definition	Pending. Not yet addressed.
1.7	Definition of virtual coach content	In process. Defined one virtual coach conversation, and in process of revision.
1.8	Define social media analytics needs	N/A. This pilot will not use this tool.
1.9	Definition of patients inclusion criteria	Completed. Patients diagnosed with PC that did smoke and patients PC free that are currently smokers but agreed to quit smoking at the beginning of the pilot.
1.10	Definition of patients recruitment process	Completed. Disseminated to the hospital staff and achieved the desired number of participants.
1.11	Definition of AI expected outcomes	In process. The outcomes will be relations inside the data that are hidden and unknown by now. This specification will be refined.

4.2 Ethical approval

The ethical approval in HDM pilot process is still ongoing. The clinical procedure has been accepted, and also the consents that will serve as legitimation for the use of patients' data. That will allow starting the recruitment process as expected. The approval for the use of anonymized data and the signature of the document that will allow iSPRINT act as data processor in relation to the secondary data used by the Healthentia app are the two items left in this section.

Table 18: Tasks of Section 2 for HDM pilot

Task No	Title	Description
2.1	Use of data of patients directly involved in the study	Completed. Explicit consents that patients will sign have been designed and accepted by the ethical committee
2.2	Use of data of patients not directly involved in the study	In process. HDM will include anonymized data from its patient database. That data will be anonymized and thus will not be considered personal data. In process of gathering the ethical approval, expected by 22 th of July.
2.3	Approval for use of data in Healthentia APP, signed with iSPRINT	In process. Signed consent requested by iSPRINT sent for signature to the ethical committee. Approval expected by 22 th of July.

4.3 Wearable devices

HDM has received the wearable devices and they are ready to be shared among patients in the study when the pilot starts.

Table 19: Tasks of Section 3 for HDM pilot

Task No	Title	Description
3.1	Wearable devices ordered	Completed
3.2	Wearable devices received	Completed. Wearables received and ready to be used.

4.4 Technical assessment

HDM pilot will not deploy an iHelp instance in its premises. It will use the centralized instance. The technical tasks to start the pilot have been completed, with the only exception of the primary data ingestion test that is in process.

Table 20: Tasks of Section 4 for HDM pilot

Task No	Title	Description
4.1	Provision of infrastructure for deployment of iHelp components	N/A. HDM will use the centralized instance of iHelp.
4.2	Deployment of iHelp components in hospital premises	N/A. HDM will use the centralized instance of iHelp.
4.3	Healthentia APP built	Completed
4.4	Healthentia APP translated to required language	Completed. HDM has provided the translation into Spanish, which is the pilot's language.
4.5	Healthentia APP tested (basic) (invite users, log in, see basic data reported)	Completed
4.6	Healthentia APP tested (advanced) (wearable device integrated, specific pilot tests, physician tools)	In process

4.7	Primary data sample provided	Completed. Sent first data sample in April 2022. A new one will be sent including the vocabulary and codes for coded values, but it will not affect the model structure.
4.8	Data model for primary data built	Completed. The data model has been developed and the data ingestion tests are in process.
4.9	Primary data sample checked against the model (data ingested)	In process

4.5 Internal requirements

The HDM pilot has identified the internal resources needed to correctly develop the study, and those resources are in process to be allocated. It is expected to be ready before SEPT-22, when the pilot is planned to start.

Table 21: Tasks of Section 5 for HDM pilot

Task No	Title	Description
5.1	Definition of internal resources needed	Completed. An internal medicine doctor has been requested to be in charge of monitor patients, perform the face to face visits each three months and help them with any issue that may arise.
5.2	Allocation of internal resources needed	In process
5.3	Patient recruitment process	Jul-22
5.4	Pilot start	Sept-22
5.5	Pilot end	Jul-23

4.6 Risks

No major risk that could delay the start of the HDM pilot is foreseen at this stage. The combination of already “Completed” tasks and the planned dates for those that are “In process” will allow the pilot to start in the specified dates.

5 Pilot#4 - MUP

5.1 Pilot definition

The MUP pilot aims to study the weight of different PC risk factors, and its value into the prediction of Pancreatic Cancer development, by performing a regressive study of literature sources and patients with developed Pancreatic Cancer and individuals with several risk factors.

Then, individuals with elevated or high risk of pancreatic cancer will be selected and asked to agree for entering into the iHelp monitoring and real-time decision support program.

The iHelp project will establish the program for raising awareness within healthcare professionals, patients at risk and general population based on the results of the first two phases of the pilot. Expected outcomes of this pilot include Risk predictor for PC; Protocol for diagnosis and monitoring of the patients at risk; Preventive program for patients at risk; Educational and tutorial programs for raising the awareness.

The MUP has successfully finished the definition of the pilot abstract, objectives and primary data to be used, as well as the outcomes expected from the AI provided algorithms and that are explained in D6.1. There are, however, some points left that are needed to successfully start the pilot on the expected dates (Aug-22). These tasks are the definition of the Healthentia APP and the patients' recruitment process. Those ongoing tasks are nevertheless in a stage of progress that will allow finishing them within acceptable due dates.

Table 22: Tasks of Section 1 for MUP pilot

Task No	Title	Description
1.1	Pilot abstract and objectives	Completed. Further detailed in D6.1
1.2	Definition of pilot timeline	Completed. Expected from Sept-22 to Aug-23.
1.3	Primary data definition	Completed. The primary data has been defined and a huge retrospective data-set delivered. Expecting from the technical partners to complete the selection of the variables and to select the codified values.
1.4	Secondary data definition	In process. The team of the MUP has provided their vision regarding the secondary data that could be of interest and could be easily collected from the patients that will participate into the trial.
1.5	Healthentia APP definition	Pending
1.6	DSS definition	Pending
1.7	Definition of virtual coach content	Pending. Required clear definition of the objectives and possible outcomes, as well as its impact on the patients at risk and already diagnosed.
1.8	Define social media analytics needs	N/A. This pilot will not use this tool.
1.9	Definition of patients inclusion criteria	Completed
1.10	Definition of patients recruitment process	In process. Final details of recruitment process is being defined with the collaboration of the clinicians, since its engagement is of vital importance for the success of the pilot.
1.11	Definition of AI expected outcomes	Completed

5.2 Ethical approval

The ethical approval is still ongoing for the use of data from patients not directly involved in the study (bulk and anonymized data) and the signature of the document to let iSPRINT use the data from the Healthentia app is waiting for the Healthentia translations to be finished.

Table 23: Tasks of Section 2 for MUP pilot

Task No	Title	Description
2.1	Use of data of patients directly involved in the study	In process. Explicit consents that patients will sign have been designed and will be presented to the ethical committee.
2.2	Use of data of patients not directly involved in the study	Completed. Anonymised data from patients diagnosed and non-diagnosed were collected and sent for risk predictor creation. The data collection was approved by the respective medical authorities.
2.3	Approval for use of data in Healthentia APP, signed with iSPRINT	Pending. The app has to be translated and presented for approval.

5.3 Wearable devices

The MUP pilot is processing the procurement order according to its internal protocols. MUP has found possible companies that could provide the devices and is currently in conversations with them.

Table 24: Tasks of Section 3 for MUP pilot

Task No	Title	Description
3.1	Wearable devices ordered	In process. Possible companies that could provide the devices have been found.
3.2	Wearable devices received	Pending. The purchase order has not been executed.

5.4 Technical assessment

The technical tasks of the MUP pilot need to be speed up. Basically, the two completed tasks have been the development of the Healthentia APP and the provision of the data sample. But the deployment of the iHelp components in the hospital premises is still in an early stage, and the tests of the Healthentia app could not be started because the translations are still left.

MUP is aware of that and they committed to accelerate these technical tasks in order to start the pilot on the expected dates (Sept-22).

Table 25: Tasks of Section 4 for MUP pilot

Task No	Title	Description
4.1	Provision of infrastructure for deployment of iHelp components	In process. Analysing the requirements with the technical partners.
4.2	Deployment of iHelp components in hospital premises	Pending. Will be started once the platform will be provided.

4.3	Healthentia APP built	Completed
4.4	Healthentia APP translated to required language	Pending. PENDING the translation tasks will be started on week of July 4th.
4.5	Healthentia APP tested (basic) (invite users, log in, see basic data reported)	Pending. Depends on Task 4.4 (translation).
4.6	Healthentia APP tested (advanced) (wearable device integrated, specific pilot tests, physician tools)	Pending. Depends on Task 4.4 (translation).
4.7	Primary data sample provided	COMPLETED
4.8	Data model for primary data built	In process
4.9	Primary data sample checked against the model (data ingested)	Pending

5.5 Internal requirements

The internal resources needed from the MUP pilot are not complex to obtain, have been identified and are expected to be ready for the pilot start in Sept-22.

Table 26: Tasks of Section 5 for MUP pilot

Task No	Title	Description
5.1	Definition of internal resources needed	In process. MUP team is preparing the questionnaire for the survey regarding the medical specialists and patients awareness about Pancreatic cancer
5.2	Allocation of internal resources needed	Pending. They will be allocated after completing the task 5.1.
5.3	Patient recruitment process	Aug-22
5.4	Pilot start	Sept-22
5.5	Pilot end	Aug-23

5.6 Risks

There are three foreseen risks. The first one may cause a delay on the pilot start and is related with a possible delay on receiving Ethical Committee approval for the questionnaire and the survey schedule, but this delay could be easily overcome, if participants into the survey could be attracted to participate into the trial.

The second one is related with the stage of progress of the technical tasks, mainly those needed to deploy the iHelp instance in the MUP premises.

The third one is related to the foreseen reluctance of the medical specialists to participate, which may cause not enough patients be involved and the pilot could not reach statistical value from the survey.

6 Pilot#5 - TMU

6.1 Pilot definition

The aim of the research at TMU is to identify high-risk individuals for pancreatic and liver cancer in order to better manage the disease early on, as well as to investigate the impact of digital therapeutics on these individuals in order to reduce disease risks, improve adherence to risk mitigation strategies, and improve their quality of life and overall well-being. TMU will conduct its work in the following phases: (1) The first phase would comprise of early detection of people who are at high risk for cancer that will help to postpone the progression of the disease for early-stage management of the disease. (2) The second phase will include digital trial, wherein an observational study using a mobile app will be conducted to explore the effects of digital therapeutic solutions on high-risk individuals in order to reduce the chances of disease risks, to improve their quality of life and overall well-being.

The TMU pilot has defined all the relevant items needed to start the pilot, except the secondary data that will be added to the provided primary data, and that is needed to finish the definition of the Healthentia app version for this pilot.

Table 27: Tasks of Section 1 for TMU pilot

Task No	Title	Description
1.1	Pilot abstract and objectives	Completed. Further detailed in D6.1
1.2	Definition of pilot timeline	Completed. Expected from AUG-22 to FEB-23.
1.3	Primary data definition	Completed. The primary data has been defined and a data-sample delivered. Currently working in the identification of standard vocabularies and codes for the codified values.
1.4	Secondary data definition	In process
1.5	Healthentia APP definition	In process. Depends on the definition of the secondary data
1.6	DSS definition	Pending. It has not been yet analysed.
1.7	Definition of virtual coach content	Pending. It has not been yet analysed.
1.8	Define social media analytics needs	N/A. This pilot will not use this tool.
1.9	Definition of patients inclusion criteria	Completed
1.10	Definition of patients recruitment process	Completed
1.11	Definition of AI expected outcomes	Completed

6.2 Ethical approval

The different ethical approvals for the use of the medical data in the TMU pilot are expected to be achieved by the end of July.

Table 28: Tasks of Section 2 for TMU pilot

Task No	Title	Description
2.1	Use of data of patients directly involved in the study	In process. Ethical approval expected by the end of July.

2.2	Use of data of patients not directly involved in the study	In process. Ethical approval expected by the end of July.
2.3	Approval for use of data in Healthentia APP, signed with iSPRINT	In process. The ethical committee is reviewing the document that should be signed and sent to iSPRINT.

6.3 Wearable devices

The TMU pilot will make use of wearable devices to monitor the patients inside the study. But due to organizational reasons those devices will not be directly purchased by TMU, but will be provided by UNIMAN for a specific period of time as part of a joint study.

Table 29: Tasks of Section 3 for TMU pilot

Task No	Title	Description
3.1	Wearable devices ordered	In process
3.2	Wearable devices received	Pending

6.4 Technical assessment

The technical tasks of the MUP pilot regarding the deployment of the iHelp instance need to be speed up. The provision of resources has not yet be completed and therefore the deployment tasks can't be finished. Regarding the other technical tasks, the advanced tests of the Healthentia app could not be started because the wearable devices are not available, and the ingestion test of the primery data is ongoing.

Table 30: Tasks of Section 4 for TMU pilot

Task No	Title	Description
4.1	Provision of infrastructure for deployment of iHelp components	In process. Working with technical partners to prepare the resources needed.
4.2	Deployment of iHelp components in hospital premises	In process. In parallel to task 4.1, working in the deployment of the components.
4.3	Healthentia APP built	Completed
4.4	Healthentia APP translated to required language	Completed
4.5	Healthentia APP tested (basic) (invite users, log in, see basic data reported)	Completed
4.6	Healthentia APP tested (advanced) (wearable device integrated, specific pilot tests, physician tools)	Pending
4.7	Primary data sample provided	Completed. A new one will be sent including the vocabulary and codes for coded values.
4.8	Data model for primary data built	In process
4.9	Primary data sample checked against the model (data ingested)	In process

6.5 Internal requirements

The internal resources needed for the pilot execution have been identified and are in process to be provided. The pilot will start in AUG-22.

Table 31: Tasks of Section 4 for TMU pilot

Task No	Title	Description
5.1	Definition of internal resources needed	Completed
5.2	Allocation of internal resources needed	In process
5.3	Patient recruitment process	Aug-22
5.4	Pilot start	Aug-22
5.5	Pilot end	Feb-23

6.6 Risks

For the TMU pilot, the main foreseen risk is the delay in getting the wearable devices, what may cause a delay on the monitoring activities for the patients involved in the study.

Not reported as a high risk, TMU is aware that the deployment of the iHelp instance needs to be finished before AUG-22, and is working closely with the technical partners to achieve that objective.

7 Resume

The following table resumes the status information for each pilot, with the objective to provide a quick overview of their readiness status, and to compare the same item (task) status for the five different pilots.

Table 32: Partners tasks overview

			UNIMAN	FPG	HDM	MUP	TMU
PILOT DEFINITION	1.1	Pilot abstract and objectives	Completed	Completed	Completed	Completed	Completed
	1.2	Definition of pilot timeline	Completed	Completed	Completed	Completed	Completed
	1.3	Primary data definition	Completed	In process	Completed	Completed	Completed
	1.4	Secondary data definition	Completed	Completed	Completed	In process	In process
	1.5	Healthentia APP definition	Completed	In process	Completed	Pending	In process
	1.6	DSS definition	Pending	Pending	Pending	Pending	Pending
	1.7	Definition of virtual coach content	Pending	N/A	In process	Pending	Pending
	1.8	Define social media analytics needs	Completed	N/A	N/A	N/A	N/A
	1.9	Definition of patients inclusion criteria	Completed	Completed	Completed	Completed	Completed
	1.10	Definition of patients recruitment process	Completed	Completed	Completed	In process	Completed
	1.11	Definition of AI expected outcomes	Pending	In process	In process	Completed	Completed
ETHICAL APPROVAL	2.1	Use of data of patients directly involved in the study	Completed	In process	Completed	In process	In process
	2.2	Use of data of patients not directly involved in the study	Completed	In process	In process	Completed	In process
	2.3	Approval for use of data in Healthentia APP, signed with iSPRINT	In process	Completed	In process	Pending	In process
WEARABLES	3.1	Wearable devices ordered	In process	Completed	Completed	In process	In process
	3.2	Wearable devices received	Pending	Completed	Completed	Pending	Pending
TECHNICAL ASSESSMENT	4.1	Provision of infrastructure for deployment of iHelp components	In process	Completed	N/A	In process	In process
	4.2	Deployment of iHelp components in hospital premises	Pending	In process	N/A	Pending	In process
	4.3	Healthentia APP built	In process	Completed	Completed	Completed	Completed
	4.4	Healthentia APP translated to required language	N/A	In process	Completed	Pending	Completed
	4.5	Healthentia APP tested (basic) (invite users, log in, see basic data reported)	In process	Pending	Completed	Pending	Completed
	4.6	Healthentia APP tested (advanced) (wearable device integrated, specific pilot tests, physician tools)	Pending	Pending	In process	Pending	Pending
	4.7	Primary data sample provided	In process	Completed	Completed	Completed	Completed
	4.8	Data model for primary data built	Completed	In process	Completed	In process	In process
	4.9	Primary data sample checked against the model (data ingested)	Pending	In process	In process	Pending	In process
DIGITAL TRIALS	5.1	Definition of internal resources needed	Completed	Completed	Completed	In process	Completed
	5.2	Allocation of internal resources needed	Completed	In process	In process	Pending	In process
	5.3	Patient recruitment process	Completed	Jul-22	Jul-22	Aug-22	Aug-22

	5.4	Pilot start	Jul-22	Sept-22	Sept-22	Sept-22	Aug-22
	5.5	Pilot end	Sept-23	Dec-23	Jul-23	Aug-23	Feb-23

8 Conclusions

From the above explanation of the actions carried out by project partners in order to set up the pilots, this section offers an overview of each of the five categories studied:

1. Pilot definition: The pilots have been defined and described attending to the main aspects (clinical process, expected scientific outcomes, patients inclusion criteria, primary and secondary data), which will allow to start the pilots within the M19 – M21 period of the project. There are some details regarding DSS panels, social media analytic needs or virtual coaching that are now being defined.
2. Ethical approval: In the iHelp project health data will be treated. That makes mandatory the approval of the respective ethical committees, approvals that in four pilots have not yet been obtained, but are expected for M19 of the project. A delay on this regard may delay the start of the pilots. The partners are aware of it and are closely following these tasks into their respective organizations.
3. Wearables: The pilots will use wearable devices (smart wristbands) to help monitor some data regarding patient status. There are still three pilots that have not available those devices, but in any case that will not compromise the pilot starting, since the most relevant data could be gathered from the Healthentia APP manually.
4. Technical readiness: Four of the five pilots will deploy the iHelp components into their (hospital) premises. In all the cases the tasks corresponding to the provision of required infrastructure and deployment of components are already ongoing. The other relevant point in this section is the development of the personalized version of the Healthentia APP for each pilot. In four of the five pilots it has yet been finished, and in the remaining pilot it is being developed without any major reported issues.
5. Digital trials (internal): In all the pilots the internal resources have been identified and have been allocated or are in process of allocation. No major issues have been raised. The expected starting dates for the pilots are close to the dates of writing this deliverable (M18) and will let time enough to analyze and document the results within the timeline of the iHelp project.

This is the first iteration of two documents that are planned to be released through the project. This first version establishes the baseline and initial descriptions of the tasks and procedures that pilot partners will follow for the implementation of their digital trials. While next iteration, i.e., D6.4 (“Pilot setup and implementation of digital trials II”) will focus on the assessment and evaluation of the digital trials that are planned to be implemented by the pilot partners.

List of Acronyms

AI	Artificial Intelligence
APP	Mobile Application
DPA	Data Processing Agreement
DSS	Decision Support System
FAQs	Frequently Asked Questions
FPG	Agostino Gemelli University Policlinic
GDPR	General Data Protection Regulation
HDM	Hospital de Denia-MarinaSalud
iSPRINT	Innovation Sprint
KI	Karolinska Institutet
LXS	LeanXcale
M	Month
MUP	Medical University Plovdiv
N/A	Not Apply
PC	Pancreatic Cancer
PREMs	Patient Reported Experience Measures
PROMs	Patient-Reported Outcome Measures
RWD	Real World Data
SIE	Siemens
T	Task
TMU	Taipei Medical University
UNIMAN	University of Manchester
UPRC	University of Piraeus Research Centre