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Revised (R): The final released document has been modified/updated with new content.

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List of Abbreviations

API	Application Programming Interface
CABIE	Context Aware Brokering and Inferencing Engine (data aggregator)
FC	Formal Carer
GP	General Practitioner
HCP	Healthcare professional
IC	Informal Carer
ICT-AT	Information Communication Technology – Assistive Technology
MDT	Multidisciplinary team
PHN	Public Health Nurse
PoC trial	The main Proof of Concept trial of ProACT with end users with multimorbidity and their care network
PwM	Person with Multimorbidity
PwM kit	The technology that the PwM will receive at home
SIMS	Subject Information Management System

Executive Summary

The purpose of this deliverable is to provide implementation plans for testing and evaluating the ProACT system. To reflect the iterative project implementation cycle, this document will be reviewed and updated twice during the life cycle of the project (M23 and M39).

The current version of this deliverable **outlines the framework for implementing the friendly trial** and for **evaluating its results.** We define a friendly trial as a trial to test the robustness of a technology ecosystem, prior to deployment to real end users. Participants of the friendly trial will be members of research teams at trial sites. During the friendly trial, participants will 'act' as ProACT stakeholders, testing an end-to-end integrated ProACT ecosystem. This deliverable outlines the technology to be deployed in the friendly trial, how data will be managed, the study design, and what we will evaluate. The latter includes technology robustness (for example, data flow between sensors, the ProACT back end architecture and end user interfaces; reliability of technology), system analytics (usage and system performance), and user feedback (usefulness, satisfaction, user burden). Outcomes from the friendly trial will contribute to refinement of the technology ecosystem and the protocol for the main Proof of Concept (PoC) trial.

It is important to note that this document describes the formal friendly trial. In reality, as new devices are introduced (e.g. novel sensors) and new applications are designed, developed and iterated upon leading up to the PoC trial, researchers at trial sites will retain a kit and continue to test when any new piece of technology is introduced into the ProACT ecosystem.

As described in the grant agreement, this deliverable is designed to be an iterative document, with updates due for submission at M23 and M39. These updates to the deliverable will include additional protocols for conducting the main PoC trial and the transfer feasibility study.

1 Introduction - Friendly Trial Overview

The purpose of this deliverable is to **outline the framework for implementing the friendly trial** and for **evaluating its results.** We define a friendly trial as a trial to test the robustness of a technology ecosystem, prior to deployment to real end users. Given the various pieces of technology that will integrate to make up the ProACT platform, testing the robustness of this integration in the real world is crucial. This is particularly important in the case of ProACT, where the health and wellbeing of older persons with multimorbidity (PwM) is the focus. During the friendly trial we will test the flow of data between sensors (that will be used to monitor the PwM's health and wellbeing status), the ProACT back end architecture (CABIE and the InterACT cloud) and end user interfaces, ensuring that data is displayed as expected. A robust system will also foster trust among its end users for the main Proof of Concept (PoC) trial, including PwMs, and members of their informal and formal care network. In addition it will give the field researchers at trial sites hands-on experience with the system, which will enable a better evaluation during the main PoC trial, and will also allow for testing deployment procedures, and procedures around obtaining consent, questionnaire delivery, and user evaluation strategies.

For the purposes of the friendly trial, the prototype ProACT ecosystem will be deployed and evaluated in the two main trial sites (Ireland and Belgium) and to a smaller extent at the transferability pilot site (Italy) for a period of 12 weeks (1 action research cycle). Participants will be members of the research teams. Each participant at the main trial sites will 'act' as multiple ProACT end users (e.g. PwM, informal carers (IC) and formal carers (FC), healthcare professionals (HCPs)):

- **PwM** - The ProACT PwM kit including sensors and a tablet will be deployed to the participant's home. Activity sensors will be placed around the home, they will wear a smart watch and be asked to take vitals (e.g. blood pressure and weight) and to view their data on the PwM interface on the tablet.
- **IC** – The participant will use the interface developed for carers, interacting with the data collected from the PwM kit.
- **HCPs and/or others** – The participant will also take on the role of other stakeholders, for example a GP, pharmacist, or formal carer, interacting with the data taken from the PwM kit.

Having each participant take on multiple roles will support the very detailed level of testing required to test integration, flow of information and robustness in real-world settings. Both trial sites have previous experience in running large health and wellbeing trials with older adults and HCPs and have found friendly trials are essential to resolving any issues prior to deployment.

1.1 Aims and Objectives

The aim of the friendly trial is to deploy an integrated ProACT platform to pilot participants and to determine any issues with deployment or connectivity during the pilot period. The platform deployed will include devices and sensors identified as important for ProACT participants in

managing their conditions (e.g. blood pressure, blood glucose, activity etc.) as well as interfaces for displaying data and educational material to participants.

Specific objectives include:
- Recruit 5 participants at each of the two main trial sites to take on multiple ProACT roles.
- Recruit 5 participants at the transferability site, each of whom will take on 1 role.
- Deploy a PwM kit to all participants acting as a PwM.
- Deploy other stakeholder interfaces (e.g. for clinicians, informal carers) to participants, to test flow of data from sensors through to end user interfaces.
- Instantiate CABIE to collect data from each pilot site.
- Evaluate data flow between all modules of the system – i.e. the sensors (inputs), CABIE, the InterACT cloud and interfaces.
- Evaluate the reliability of the data and technologies.
- Evaluate the overall usability of the platform in real-world environments.
- Evaluate / pilot the outcome measures identified for use in the trial

Outcomes from the friendly pilot trial will be fed directly into WP2 and WP3 through multidisciplinary team calls between trial site researchers and the technical team, to support the iterative re-development/improvement of the ProACT system. In parallel to the friendly trial, sensors, devices and interfaces will be evaluated as part of WP2's iterative design and testing process with end users (PwM and other support actors) who have been recruited to research panels at trial sites as part of WP1. A revised deployment plan and protocol for the final PoC trials will also be produced as an output of the friendly trial.

1.2 Deliverable Description

This deliverable will have close links with a number of other deliverables in the project, and outputs from those deliverables will inform further iterations of D1.4. In particular, close attention will be paid to:

- **D2.1** – Technical Reports (also due M9 with subsequent updates): provides technical descriptions of the various systems that are being developed and integrated into the ProACT architecture, and that are referred to throughout this deliverable.
- **D2.2** – Deployment Plan for ICT-AT (also due M9 with subsequent updates): Describes the deployment plan for ICT-AT contained within the ProACT ecosystem, including deployment of the technology required for the friendly trials.
- **D2.3** – Report on Training Tools (also due M9 with subsequent updates): This report contains details of training materials for the ProACT system, including those that will be evaluated as part of the friendly trial.

2 Friendly Trial Deployment Details

2.1 Participants

2.1.1 Ireland and Belgium

Five participants will be recruited at each main trial site. Participants will be recruited from within the research teams. Initially it was planned to include some healthy older adults as participants during the friendly trial. However, during a consortium meeting workshop to plan the friendly trial, trial partners felt it would be best to solely recruit researchers, primarily for the following reasons:

1. Researchers within the team have an understanding of exactly what will be required in terms of testing, and this knowledge is critical for an effective pilot implementation; furthermore, researchers at trial sites will gain first-hand experience of deploying, using and testing the technologies which will be valuable for their involvement in deployment and maintenance during the main PoC trial;
2. The level of effort and feedback required to fully test the system will be quite taxing on participants (see Study Design below);

Usability testing of devices and interfaces will happen in parallel with the friendly trial; this testing will be conducted with representatives of ProACT end user groups in a controlled environment, ensuring they are continually contributing to the design and refinement of the system.

Each of the 10 participants will take on multiple 'roles' during the friendly trial, to support testing of interfaces for the different ProACT support actors in addition to the PwM. A number of clusters of participants will be set up. Possible examples of clusters are shown in Table 2.1. For example, in cluster C1, participant 1 will play the role of a PwM who has a care network of an informal carer and a formal carer also involved in ProACT, whereas in cluster C4, participant 4's lead role will be a heart failure CNS, who is also acting as a PwM, and IC and a PHN.

The setup of the clusters will replicate the planned recruitment process at trial sites during the main PoC trials. The lead role is therefore important in terms of setting up different ProACT actors on the SIMS participant management system (described further in Section 2.3.1). With C4 for example, this cluster will replicate recruitment through a heart failure clinic, where the CNS will help to recruit PwMs onto ProACT. The heart failure CNS then will be able to view data for multiple PwMs.

Each person acting as a PwM will be 'assigned' two or more of the ProACT conditions, which will determine what sensing kit they receive as well as the frequency with which they need to take readings (for example, a person with CHF will need to take daily weight whereas weekly weight would be sufficient for a person with diabetes). Roles other than the PwM will only require a web interface. As all of our participants are members of research teams, ethical approval will not be required.

Table 2.1: Sample Participant Clusters

Cluster	Participants	Lead Role	Additional Roles
C1	P1_Ire	PwM	IC, FC,
C2	P2_Ire	PwM	FC, pharmacist,
C3	P3_Ire	Geriatrician (with MDT)	PwM, IC, GP
C4	P4_Ire	Heart failure CNS	PwM, IC, PHN
C5	P5_Ire	GP	PwM, IC, pharmacist
C6	P6_Be	PwM	IC, FC
C7	P7_Be	PwM	FC, pharmacist
C8	P8_Be	GP	PwM, pharmacist
C9	P9_Be	Hospital specialist	PwM, GP
C10	P10_Be	FC	PwM, IC

2.1.2 Italy

In Italy, the transferability site, 5 participants will be recruited from the research team. Each participant will take on one role. Therefore, one PwM kit will be tested in Italy, alongside additional web interfaces. This will allow researchers at the transferability site to also gain experience in using and deploying the ProACT ecosystem.

2.2 Technology to Deploy

The friendly trial will test an integrated ProACT system over a 12-week period. In reality, however, there will be continuous in-lab and in-home testing if and when new devices/sensors/applications are added to the ProACT ecosystem leading up to the main PoC trial. Please see D2.1 (Technical Reports) for specific details on the technologies for testing at this phase.

Table 2.2 indicates the hardware to be deployed for the friendly trial, while Table 2.3 indicates the end user applications to be deployed. Participants acting as a PwM will receive a selection of the vital signs monitoring equipment dependent on their conditions, the wellbeing monitoring equipment and a tablet (outlined in Table 2.2), as well as the ProACT health and wellbeing application. The Withings devices and the Smart Things kit are connected devices that will automatically transfer data to CABIE (already implemented), whereas the blood glucose monitor and pulse oximeters are not connected and thus will require the participant to manually enter their readings through the ProACT health and wellbeing application (hereafter referred to as the ProACT App). The primary reason to evaluate manual entry for these devices is that many of the PwMs interviewed as part of the scoping phase of ProACT (WP1) indicated that they already had these devices and would wish to continue using them, rather than being given new devices for a ProACT trial.

Participants will use the ProACT App to review their vital signs and wellbeing data. From this application, the participant will also answer a short number of daily questions and questionnaires (for example, to measure breathlessness for COPD, mood, general wellbeing and any others determined necessary through the requirements gathering process).

Table 2.2: Hardware to be deployed

Vital signs monitoring	Wellbeing Monitoring	Other
Withings Blood Pressure monitor Blood Glucose monitor Withings Weight Scale Pulse oximeter (blood oxygenation)	Smart Things Passive Infrared (PIR) Kit (ambient activity) Withings Active Pop watch (step count and sleep)	Tablet Broadband Peripheral supplies (batteries, extension leads etc.)

Table 2.3: Software to be deployed

End User Application	
ProACT health and wellbeing application for PwM	Displays data gathered through various sensors as well as training material and behaviour change education and tips.
ProACT Informal Carer's app	Displays data gathered through various sensors from the PwM, as well as training material and education
ProACT Formal Carer's app	Only displays wellbeing data
ProACT HCP app	Displays data for multiple PwM

The ProACT App will also deliver educational material tailored to the individual and their conditions, as well as behaviour change interventions and techniques defined as part of WP4. For example, one behaviour change intervention that will be evaluated during the friendly trial is the daily use of the ProACT system. This will be evaluated by tracking participant's engagement through usage statistics within ProACT and also through qualitative feedback from friendly trial participants.

Alongside the health and wellbeing application, digital training tools being developed in D2.3 (Report on Training Tools) to help participants in using and navigating the system will be integrated and tested as part of the friendly trial. Additional applications for the PwM will be designed and developed over the coming months, based on the requirements emerging from WP1, and will be tested in a similar manner (for example a medication application).

Participants in the friendly trial will also be able to log in and view data through the additional applications outlined in Table 2.3, depending on what roles they are playing during the friendly trial.

Each device or piece of technology will need to be appropriately set up prior to deployment in the friendly trial, and assigned to a participant ID. For example, each Smart Things sensor needs to be digitally assigned to a room in the home (e.g. bedroom, kitchen etc.) prior to deployment and then labelled so the researcher deploying the kit knows where to place it. Details on how the technology kit needs to be prepared for deployment are provided in D2.2 (Deployment Plan for ICT-AT) and researchers at trial sites will follow these instructions when

deploying kits to friendly trial participants. This will allow researchers to have a number of 'practice runs' to resolve any deployment issues prior to the main PoC trial.

2.3 2.3 Data Management

There are two aspects of data management to consider during the friendly trial:

1. Managing participants
2. Managing the end to end data transfer from participant devices to end user applications.

2.3.1 Managing Participants

SIMS (Subject Information Management System) will be available to each trial site, and researchers will be trained on its use. SIMS supports the management of participants on the trial, including the kit assigned to them, daily / weekly questions assigned to them and their schedule, and the educational material / training assigned to them (tips) and its schedule (Figure 2.1). SIMS also has the capability to allow the researcher to generate various reports about participants. For example, for a particular participant, the researcher can query their responses to daily questions for a particular date range, or view graphs of sensor data readings over time (e.g. weight, sleep score etc.) Testing this during the friendly trial will allow the researchers at trial sites to determine what additional reports might be useful for the main PoC trial. Further technical details on SIMS can be found in D2.1 (Technical Reports).

Figure 2.1: SIMS web interface

2.3.2 Managing Data Transfer

The friendly trial should ensure that data is transferred accurately and consistently. Table 2.4 outlines the data to be captured and the expected frequency. The following points outline the expected transfer sequence:

1. Data is recorded manually by the participant (vitals) and automatically (wellbeing) on a daily basis. Manual measurements should vary in frequency from 1 to 3 times daily. Note, manual here refers to the participant engaging in taking a measurement, for

example standing on the weight scales, taking blood pressure, as opposed to manual entry of a reading.

2. Physiological devices for measuring vitals are paired with the tablet and should display a reading on the tablet interface at the time measurement has been taken (locally). CABIE runs a check (via broadband connection) to detect the presence of data at intervals throughout the day. CABIE processes this data and transfers it to the InterACT cloud. This is then transferred to online interfaces.

3. Ambient and wearable devices, Smart Things and Smart Watch continuously capture data throughout the day and/or night. CABIE checks for the presence of this data at intervals, and processes the information. This is transferred to the InterACT cloud and retrieved by the tablet applications on demand.

4. If data is not sent/received by the server an email alert will be automatically sent to technical team members. The email report should include details of:
   a. The participant ID(s) that have not sent/received data
   b. The devices that have not sent/received data
   c. Reason for transfer issue if identifiable (e.g. connection error, CABIE error)
   d. The time and date of last successful data transfer for the relevant measure

5. Any issues that arise during the trial, and the steps taken to resolve these issues will be recorded by the technical team using a suitable tracking tool.

6. Privacy checks - Prior to the friendly trial, partners IBM and DkIT will complete their work on defining processes for anonymizing participant data before it is sent to the InterACT cloud for storage. The anonymization process will ensure that participant identity cannot be inferred from InterACT cloud data. IBM have begun the process of advising DkIT on the requirements for this process, and prior to the friendly trial, methods of evaluating anonymization success will be finalized. The methods used will be detailed in subsequent iterations of this deliverable.

Table 2.4: Device type and frequency of data to be recorded during friendly trial

Measurement Device	Data Captured	Frequency
Smart Watch	• Steps • Distance • Sleep quality • Hours in bed • Hours asleep • Timeline of sleep activity • Restlessness	• Daily
Ambient Sensors	• Time inside/outside home • Time in different rooms of house	• Daily
Blood Pressure Cuff	• Blood Pressure • Heart Rate	• 1-3 times daily
Digital Weight Scales	• Weight (Kg)	• 1 time daily
Blood glucose	• Blood glucose level	• Mealtimes daily

Pulse oximeter	• Blood oxygenation level	• 1-3 times daily
Tablet for self-report questions	• Mood • Sleep • Pain • Social	• Daily

2.4 Study Design

All objectives should be evaluated by this study design within the action cycle of 12 weeks. It is important to note that a detailed study design protocol will be developed in month 10, to provide concrete instructions to implement Steps 1 to 3 below as well as finalising any questionnaires and interview protocols that will be used for the evaluation (see Section 3). Prior to defining this protocol, it is necessary to finalise the technology development for the friendly trial, as well as reflect on the analysis of requirements data outlined in D1.2 (Stakeholder Report) to understand what measures are important to capture pre- and post-trial.

2.3.3 Step 1: Evaluate recruitment and initial set-up

Step 1.1 : Recruitment of participants:

The project participants are determined within the teams at trial sites, as well as the multiple roles they will take and the ProACT conditions to be monitored, before the friendly trial starts. A document with participant names and contact details will be created at each trial site.

Step 1.2: Evaluate recruitment material

- Participants will read the information brochure on the pilot, and complete the informed consent documents. The purpose is only to evaluate the material that will be used in the main PoC trial as true consent is not required by participants of the friendly trial. However, each participant will be aware of where data is stored and who has access.
- The participants will give feedback using track changes on the relevant documents for each role they are taking in the trial.
- Based on this feedback, the documentation for the PoC trial will be updated, and added to addendum for the Ethical Committee.

Step 1.3 Kit preparation and deployment

- Each trial site will prepare each PwM kit for deployment, following instructions from the technical team (e.g. pairing devices, assigning room IDs to ambient sensors).
- Each trial site will use SIMS to add and manage their participants, and to assign a PwM kit to each participant.
- Once activated, a field researcher at each trial site will deploy the kits to participants. They will follow a deployment protocol, developed in conjunction with the technical team, outlining how to deploy the kit (for example, connecting to broadband in the home, where to place sensors etc.). This protocol will be developed in month 10 once

the technical development for the friendly trial has been finalised, and will be included as an Appendix in the next update of this deliverable in month 23.

Step 1.4: Test and evaluate education and training material set-up and use

- The educational material for the set up will be scheduled (through SIMS) for distribution to the participants as is foreseen in the PoC trial.
- A short survey (Google form) will be used for each participant to evaluate the educational material, seen from the roles he or she fulfils.

Once all steps in section 1 are complete we can continue with the evaluation of the system.

2.3.4 Step 2: Evaluate data flow between all modules of the system, and the reliability of data and technologies

Step 2.1: Evaluate the data flow between all modules – i.e. the sensors (inputs), CABIE, the InterACT cloud and interfaces

- By month 11, a set of test tasks will be defined and provided for each participant role by the providers of the tools and interfaces.
- This will include information about how often and at what time of day they are expected to take measurements and complete tasks with the system, for each role.
- The participants will complete the tasks by a predefined date.
- The technical partners will check if the flow of the data for each role is error-free.

Step 2.2: Evaluate the reliability of the data and technologies

- An automatic email will be sent to technical and trial site partners if data transfer does not take place.
- The participant will be provided with templates to record any issues, for example if they don't see the data they are expecting to see (see Step 3.2 and Section 2.5 below for these templates).

2.3.5 Step 3: Evaluate usability, support of system, and outcome measures

Step 3.1: Evaluation after training/first use

- Participants will be asked to fill in a usability scale (such as the System Usability Scale[1]), and free text feedback fields for all interfaces will be available, specific to each role.

Step 3.2: Continuous logging of everyday problems using the tools and interfaces

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[1] https://www.usability.gov/how-to-and-tools/methods/system-usability-scale.html

- An online form will be available to report issues or problems in a semi-structured format.

Step 3.2: Evaluation after 12 weeks of use

- Every two weeks each participant will receive an email asking them to fill in a structured online form for each role they are acting in, to evaluate the usability, the experience of the communication support, and if the outcome measures are appropriate. Extra open fields will be provided to give feedback on usability, features and the outcome measures.
- At the end of the 12 weeks, field researchers will test the evaluation instruments (e.g. questionnaires, draft interview protocols) by conducting an evaluation with the friendly trial participants.

Step 3.3: Synthesis of input from evaluation and prioritisation of adaptations in design

After every evaluation cycle of 3.2, a synthesis and comparison of the feedback will be performed across the different trial sites. During an interdisciplinary meeting with a representative of each trial site, and all technical partners, a list of questions/issues will be discussed and prioritised, with timing provided for when issues will be resolved. The trial sites will be updated when an issue has been resolved, and will continue to test this to ensure the issue is resolved, and that a new issue has not been introduced.

2.5 Templates for Collecting User Feedback

Participants will be provided with templates (outlined below) for recording their experiences of taking readings and viewing this data on their interface. There will be two templates:

(1) Participants will be required to record the date and time they are taking a measurement, to verify whether this data appears on the relevant interface and to report any issues that they experienced. For ambient and wearable devices, participants will be required to verify that that activity has been recorded and is displayed correctly.
(2) Participants will be provided an 'issues' checklist to complete if any problems occur with recording data. The checklist will contain common issues that participants can check for, and also a space for other issues, actions taken to resolve issues and further comments.

Participants will fill these out online; the responses will be reviewed regularly by the trial site researchers and communicated to the technical team during interdisciplinary calls.

	Blood Pressure		Blood Glucose		Weight		Spirometer		PIR Motion		Watch		Sleep		Self-Report	
Date	Time taken	Display *yes/no*	Time taken	Display *yes/no*	Time taken	Display *yes/no*	Time taken	Display *yes/no*	Activity *yes/no*	Display *yes/no*	Activity *yes/no*	Display *yes/no*	Activity *yes/no*	Display *yes/no*	Time taken	Display *yes/no*
	Comments		Comments		Comments		Comments		Comments		Comments		Comments		Comments	
Date	Time taken	Display *yes/no*	Time taken	Display *yes/no*	Time taken	Display *yes/no*	Time taken	Display *yes/no*	Activity *yes/no*	Display *yes/no*	Activity *yes/no*	Display *yes/no*	Activity *yes/no*	Display *yes/no*	Time taken	Display *yes/no*
	Comments		Comments		Comments		Comments		Comments		Comments		Comments		Comments	
Date	Time taken	Display *yes/no*	Time taken	Display *yes/no*	Time taken	Display *yes/no*	Time taken	Display *yes/no*	Activity *yes/no*	Display *yes/no*	Activity *yes/no*	Display *yes/no*	Activity *yes/no*	Display *yes/no*	Time taken	Display *yes/no*
	Comments		Comments		Comments		Comments		Comments		Comments		Comments		Comments	

Issue Record *(provide details of any issues that occurred during testing)*								
Date	Measurement Type	Data not accurate	Measure failed	Battery failure	Broadband/ bluetooth connection	Sensor not positioned correctly	Power outage/un plugging	Other / Actions taken / Comments

3 Evaluation Goals and Success Metrics

It is important to remember that this is a friendly trial, the aim of which is to deploy testing in order to determine at an early stage whether the ProACT system is, to a certain extent, robust, reliable, usable, and responding to the needs of all support actors. Where possible metrics will be introduced to help assess the performance of the ProACT system in the friendly trial.

3.1 System Analytics

A detailed specification for ProACT system analytics is currently being developed, and will be available in Month 10 as part of D3.3 (A set of analytic methods to measure ecosystem performance). Additional information on how system analytics will be leveraged to evaluate system performance can be found in D2.1 (Technical Reports). System analytics which are expected to be in place for, and evaluated during, the friendly trial include:

- **Usage statistics:** Requests to underlying APIs will be logged and processed to compile daily statistics on participant interaction with ProACT systems. Using this data, the research team will be able to determine how often a participant has opened their ProACT application, when they last took readings, viewed educational material, or failed to complete a scheduled questionnaire. A variety of logging levels will be employed to ensure a rich data set is available for inspection, and to allow for future expansion of system analytics. Statistics gathering will be automated on the CABIE data aggregator, compiled at regular intervals, and results will be available to the research team through SIMS. Where appropriate, analysis of system statistics will be used to automatically generate alerts: for example, relevant stakeholders will receive an email notification when a participant has not generated any readings over a 24-hour period, or when they fail to complete a scheduled questionnaire in a reasonable time period.
- **Performance analysis:** Requests to underlying APIs will be logged and processed to compile daily statistics on the performance of the core ProACT system. Using this data, the technical team will be able to determine how stable and responsive underlying technologies are in a real-world trial. A variety of logging levels will be employed to ensure a rich data set is available for inspection, and to allow for future expansion of system analytics. The ProACT system components (e.g. InterACT, CABIE etc.) all log their respective performance information separately. In advance of the friendly trial, the feasibility of aggregating and centralizing this information in SIMS will be investigated. The friendly trial will provide a unique and invaluable opportunity to evaluate the stability and performance of information transfer between individual components of the system in an unpredictable environment, which would be difficult to replicate artificially.

System analytics will be monitored by both the research team and the technical team, and findings will be discussed on a regular basis in the interdisciplinary team meetings, noted above, with trial site partners as necessary.

3.2 Technology

3.2.1 Reliability of data and technologies

The following questions will be addressed during the friendly trial:

- Are the number of readings displayed equal to number of measurements taken?
- Is the ambient data displaying as expected (e.g. length of time in bed)?
- Are the dates of readings taken displaying correctly?
- Are the times of readings taken displaying correctly?
- Are data issues reported by participants aligned with email alerts?
- Are questionnaires and surveys deployed by the ProACT system received correctly by the PwM?
- Are completed questionnaires and surveys recorded accurately by the ProACT system?
- Are any training/educational materials deployed and viewed correctly?
- Tests should also be made on the health data upper and lower limit checking algorithms. Sensor readings should be occasionally entered that are outside the prescribed safe areas.
- The correct generation of alerts should also be checked.

3.3 User Feedback

During the friendly trial we will evaluate the user experience of the ProACT-system as a whole and of the different components and/or functions. Once these components and functions are defined, we will be able to further specify the evaluation metrics accordingly. The main topics we will focus on in the evaluation are the usability, ease of use and learning, user burden, meeting of expectations and satisfaction.

The daily questionnaires that will be used in the ProACT-system (e.g. to measure breathlessness, mood etc.) will also be tested and evaluated during the friendly trial. The system will automatically log how often the questionnaires are filled in, at what time and date, and how long it took to complete them. As part of the evaluation metrics, the perception of the length and experienced burden of the questionnaires will be captured.

During the friendly trial only, the participants will fill in shorter questionnaires every two weeks as indicated above. These questionnaires will be provided online, and participants will get e-mail notifications as a reminder. At the beginning and at the end of the 12-week friendly trial we will conduct a more extensive questionnaire and interview using a draft interview protocol. These will be conducted in person, replicating what will happen in the PoC trial.

3.3.1 Expectations

At the start of the trial, after the ProACT system is installed and explained, the following open-ended questions will be asked to get a more in-depth view on participants' expectations:

1) What do you expect from the ProACT-system?

2) What do you hope the ProACT-system to help you with?

At the end of the friendly trial the following open-ended questions will be asked to see if expectations were met, by comparing these to the earlier mentioned questions on expectations:

1) What did the ProACT-system help you with?

2) Were your expectations on the ProACT-system met?

3.3.2 User evaluation of overall ProACT-system

To measure the usefulness, satisfaction and ease of learning, and use of the overall system, an adapted USE Questionnaire[2] will be administered after the first week of use, after six weeks and at the end of the friendly trial, to give a detailed insight in the user experience, and how it develops throughout the trial. The questionnaire will be adapted, taking into account that friendly trial participants are not end real end users, and thus responses to certain aspects of the questionnaire, such as usefulness, may not be relevant.

In the two-weekly questionnaire on the user experience the After Scenario Questionnaire[3] will be used. This 3-item questionnaire measures ease of use, satisfaction in time spend and satisfaction with supporting information. It will be useful in mapping possible changes in experience following alterations in the ProACT system during the trial.

3.3.3 Evaluation of training materials

Participants will be asked to evaluate training and education materials that will be provided to them (see D2.3: Report on Training Tools for further details). The purpose of the training materials will be to demonstrate to the participant how the technology should be used, including taking measurements and interpreting data. The Patient Education Materials Assessment Tool for Printable Materials (PEMAT-P) (http://www.ahrq.gov/sites/default/files/publications/files/pemat-p.pdf) will be used to assess printable materials used, and PEMAT-A/V for audio visual materials (http://www.ahrq.gov/sites/default/files/publications/files/pemat-av.pdf). The survey examines training material for content, word choice, organisation, layout and design, and the use of visual aids. Participants will also be asked to note any errors and/or suggestions directly into the documents.

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[2] http://garyperlman.com/quest/quest.cgi?form=USE
[3] http://garyperlman.com/quest/quest.cgi?form=ASQ

3.4 Outcomes

Analysis will be ongoing during the friendly trial, with regular calls between trial site researchers and the technical team. Each site will standardise findings and produce a report to share with partners who can learn from the outcomes. Outcomes from the friendly pilot trial will be fed directly into WP2 and WP3 to support the iterative re-development/improvement of the ProACT system. The aim will be to produce a revised plan for the final PoC trials to facilitate their deployment and development, ensuring best practice and coordination between trial sites.

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