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- **Draft (D)**: describes planned contents and main structure of the different sections. Document is between 0% - 50% completed.
- **Intermediate (I)**: document is approximately between 50% - 100% completed. It is the previous step before it could be released.
- **Released (R)**: document is 100% completed, reviewed and authorized for release by the partner responsible of the deliverable or the WP leader.

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Executive summary

The aim of this document is to describe in detail the trials (pre and full/final trials) that we are going to carry out in Spain, Ireland and United Kingdom after the release of the desired features of the BREATHE platform developed in both WP2 (AAL home system) and WP3 (Informal caregiver tool). Moreover, this document includes the scope of each trial stage as well as the following related topics: general framework for trials, validation methodologies, indicators, technology components and delivery schedule (components, elements and functionalities), inclusion and exclusion criteria for the participants, supportive research material (protocols, informed consent, questionnaires, etc.), ethics approvals from external ethics committees and possible hazards and risks. There are four important deliverables which are the starting point of this document and whose reading is highly recommended: (1) the internal (access from third parties is not allowed) document called BREATHE architecture definition[1] which describes, from a technical point of view, the whole platform and the relationship between its main components, (2) the trials strategic plan[2] which describes, from the ethics and privacy perspective, those commonalities for involving real end-users in test pilots, (3) the first release of the AAL home system (restricted) and (4) the first release of the informal caregiver tool (restricted) which describes the different components, interfaces and features as well as the whole BREATHE platform which will be available for testing with real end-user during the pre-trial stage.

Initially when the DoW was written, it was assumed that the requirements for setting the pre-trials and (full and final) trials up were the same. Nevertheless, although the objectives pursued for the validation plan, the methodology and empirical investigation (independent and dependent variables, research indicators, hypothesis, research recommendations, etc.) were the same as well as there are some shared processes and commonalities regarding the supporting material for carrying out the research (inform consent, information leaflet, inclusion/exclusion criteria, validation methodologies, analysis of data, recruitment strategies, etc.) between both trials stages, as the pre-trial report (D4.2 – Pre-trial report) which will collect the most important conclusions and findings of the pre-trial stage will not be released until M17 (September, 2014), the BREATHE Consortium agreed on take advantage of the deliverable D4.1 for (1) defining the pre-trials as well as the global things (pre-trials and trials commonalities like the research methodologies, for instance) in detail and (2) defining the required planning (work plan/roles) for the full and final trials (M21 and beyond). These information will be elaborated between M17 and M19 and wrote down on the deliverable D4.3 (Trials midterm report) in M20 (December, 2014).

[1] [Redmine, private] http://redmine.breathe-project.eu/dmsf/files/321/download
[2] [Website, public] http://breathe-project.eu/gallery/16/D13_-_Trials_strategic_plan_v10.pdf

1 About this document

1.1 Structure of this document

This document has been structured in three different main sections as follows:

- Section 3 (Introduction and objectives of the validation plan) aims to define those global things or commonalities which are shared between both the pre-trials and trials stages as a first step of the research process and before the involvement of the real end-users.
- Section 4 (Pre-trials) describes, in a very detailed way, all the requirements and procedures which will be taken into account by all the partners in charge for setting the pre-trials up as well as for preparing the required material which will support the investigation (e.g. questionnaires, recruitment process, inform consents, interview scripts, sheets for gathering and analysing data, etc.) during the pre-trials which will be carried out in M15 in Spain, UK and Ireland.
- Section 5 (trials) describes the required specific steps (milestones, work plan and involved roles) in order to achieve the following objectives: to prepare the required material for supporting the research during the trials (sampling, inclusion/exclusion criteria, sites capabilities, functionalities, detailed scripts, questionnaires, training material, ethics requirements (if proceed), etc.) and to get the Ethics approval from the TCD Ethics Committee which it is expected in M21.

2 Introduction

As can be read in our Document of work (DoW) and the public deliverable D1.3 (Trials strategic plan), the BREATHE system is planned to be developed and released in three different approaches:

- First release or pre-trial (M15).
- Second release or trial (M22).
- Third release or trial (M26).
- Final release (M30).

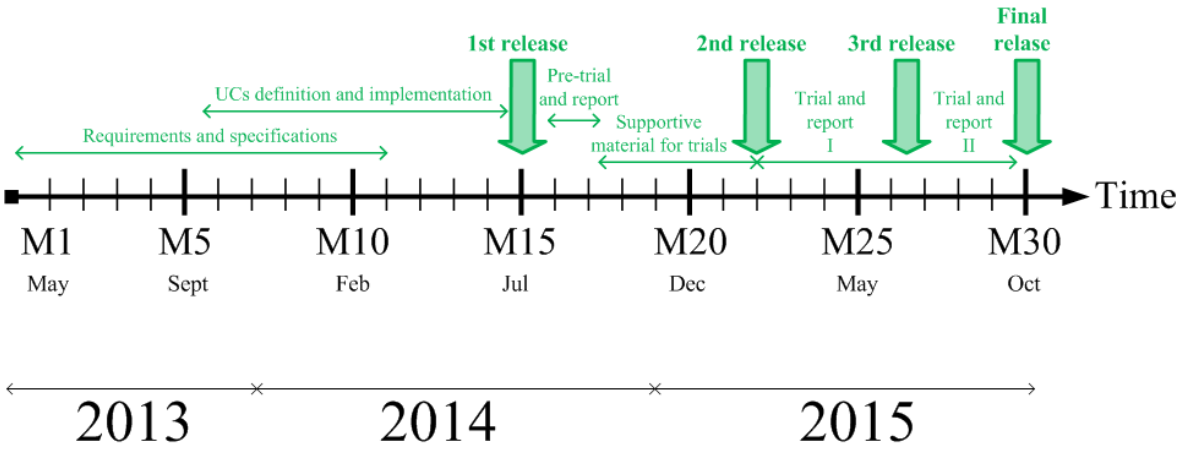

Figure 1 - Envisaged release schedule and trials for the BREATHE platform

The main difference between the aforementioned approaches is the location where the developed technology will be deployed. While in the pre-trials the validation of the developments will be carried out in enclosed (in terms of risks) environments like living laboratories or smart rooms, the full and final trials will be done in real spaces under real conditions: the end-user´s home. BREATHE Consortium agreed on following an agile and iterative testing process which covers the whole creation process from the beginning until the end as follows:

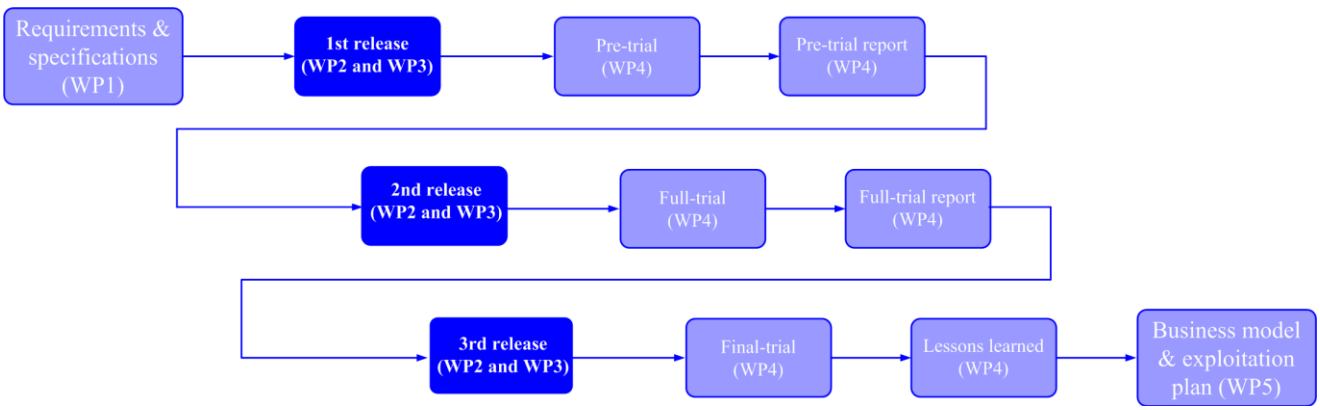

Figure 2 - Relationship between WPs and trials (from WP1 to WP5)

3 Objectives of the validation plan

3.1 Introduction

The important social-demographic changes in Europe over the last decades, as a result of the ageing of the population, as well as the decrease in the extended family model has been brought into focus the importance of the role of the formal carer, who often works under severe stress levels and with multiple difficulties.

The progressive incorporation of technology to the care of people needing that help is generating an improvement in the care of the most needy, but can forget those who are giving this care, the formal and informal carers. This oversight of the carers' importance and the search of specific solutions for them has a direct repercussion on the quality of the care assisted people receive, since improving the life quality of the former results in the improvement of the care and thus also on the life quality of the latter. The development of resources for carers is turning them into a priority issue.

This research will show us the reality of this carers' group and the people for whom they care, by proposing the **BREATHE solutions**. To do it, we will evaluate the factors that impact on their daily life, paying attention to their necessities. This means that relevant information will be taken from the carers and from the assisted people. Hence, we can state that this research will bring up useful data on a European level, given the transnational character, the each member state, the individual institutions and all the academic organizations as they utilise the newfound health and social knowledge.

3.2 Methodology and empirical investigation

3.2.1 Introduction

The social research that underpins the BREATHE Project is a quantitative form of social research and therefore is based on an empirical methodology that, using the best precision possible, determines the path and steps to be taken to improve the knowledge of what we have proposed to study and to enhance subsequent discourse. Ultimately there is a recognition for that respect for ethical values is required and that this permeates all social research especially with vulnerable subjects. As BREATHE requires research with people, the effort put into respect for ethical procedure must be optimal.

3.2.2 General purpose

To study the participation of carers and assisted people, relative to the technological resources and solutions that are provided by BREATHE, and how these aspects affect, alter or enhance their **quality of life**. In such a way and also considering the installation of devices in homes (sensors and image filters), as well as interface utilization (app) for support and a specific web application.

3.2.3 Concrete goals

1. To evaluate the participants' interaction (carers or assisted people) with the proposed devices in BREATHE.
2. To determine the participants' (carers or assisted people) degree of satisfaction, relative to the proposed solutions.
3. To utilise the applicable results in order to improve the Pilot Sites installed in a further phase.

3.2.4 Main questions

1. How does the carer or assisted person cope with giving or receiving of care respectively?
2. What options does he/she have at his/her disposal? Does he/she know them? Do they bring solutions to his/her daily life?
3. Which are the elements that make it difficult or easy the incorporation of BREATHE's solutions about the process of giving or receiving care? The installation requirements? The cost? Need of formation or learning about its use? Privacy needs? Degree of trust on its tools?

3.3 Research indicators

3.3.1 Variables: definitions and indicators

- Independent variable:

Carers of people with Long Term Conditions (LTC).

- Dependent variables:

Dependent variable	Concept definition	Operational definition	Indicators
Type of carer	Carer's typology in function of whether he/she is paid in exchange for services or provides free service by being a friend or family member of the assisted person.	Informal care or formal care.	1. The carer is family or not of the assisted person. 2. The carer receives or does not receive reimbursement for the care he/she provides. 3. The carer has received adequate training or information or not, about caring.
Type of assisted person	The type of illness that is shown by the assisted person and which will determine the benefit or not in the use of BREATHE technology.	Existence of physical and/or mental illnesses that implies long term conditions.	1. Mental illnesses. 2. Chronic physical illnesses. 3. Non chronic illnesses.

Degree of autonomy of the assisted person	The assisted person's degree of autonomy in the specific daily activities.	Autonomy degree (autonomous, almost autonomous, not autonomous), that the person with LTC shows in basic daily activities.	1. Autonomy level in basic daily activities (go to the bathroom, eat, dress, move, climb stairs, personal hygiene, etc.).
Social network connection of the carer	Existence or not of the carer's ability to get in touch with peers.	Belonging to carers' social networks.	1. Computer knowledge. 2. Availability or absence of Internet connection. 3. Access or not to computers, tablets, smartphones. 4. Social network knowledge. 5. Availability to use specific carers' social networks.
Self-perception of the carer facing the care stress	Degree of self-acceptance of the carer in the performance of their work, facing the physical and emotional exhaustion that is implicit to care.	Balances the necessary elements to correct self-esteem and minimize the degree of physical and emotional exhaustion.	1. Stress level. 2. Psycho-social risks. 3. Emotional stability. 4. Socialization level. 5. Caring burden level. 6. Personal relationship with the assisted person. 7. Social isolation degree relative to their personal life.
Formative resources	Knowledge of the available resources that are adequate to the carer situation.	Relation between the quantity and the quality of the information that the carer has about where to go, what to do, how to face a situation appropriate to the third person care.	1. Resources reference. 2. Value of the resources he/she knows. 3. Availability (if it occurs) of Access to the mentioned resources.
Institutional support	Carer's perception relative to whether he/she feels supported or not in an institutional level during the time as a career.	How the carer lives the institutional social environment and difficulties that he/she might have had or not relative to him/herself.	1. Existence or absence of economic support. 2. Existence or absence of emotional support. 3. Existence or absence of technological support (phone assistance devices). 4. Existence or absence of external services for the caring promoted by public institutions.

Carer´s empowerment at collective level	Position in which the individual is placed relative to the need of a bigger empowerment.	Mentions the degree of control about his/her life and the surrounding reality.	1. Degree of belonging to the collective group of carers (besides that, participation in occasions, frequent collaborator). 2. Present expectations (or absence of these) relative to the elements that may ease a bigger life quality.
Proposed technology	Any technological device that is part of the BREATHE solution for the support of the carers' work.	Evaluation by the carers and assisted people of the proposed and developed technological solutions as BREATHE in Pre-Trials and Trials.	1. Evaluation of interface for the mobile or tablet (app). 2. Evaluation of the web application for carers. 3. Attitudes to the possible use of spatial localization devices. 4. Attitude face to the possible use of sensors
Image filtering	Filtered image by the computer software that allows information about the assisted person to be obtained.	Election of the filter type selected by carers and assisted people with LTC, bonded to a concrete space of the home.	1. Elected option relative to the final image filtered or not by the image caption device and altered by the software: normal, silhouette, stick figure and cartoon.
Information sending to the carers	The information can be received in one way or another.	Way in which the BREATHE applications inform the carers.	1. Warning to the smartphone. 2. Warning to the web application.
Technophobia	Existence and rejection degree to the use of technologies by part of the assisted people and carers.	Opinion of the participants relative to the trust degree in the use of technologies related to BREATHE and personal compromise in providing information to the system.	1. Trust degree in the use of Internet; 2. Trust degree in the use of the web application; 3. Trust degree in the use of the app; – Positioning in favour or against to implement information taking from BREATHE technologies.

Table 1 - Dependent variables (Research indicators)

3.3.2 Hypothesis

We go from the central hypothesis that the process of caring for people with long term conditions to the aggregate denominated carers (formed by the people that give care to other people that need them) is an extremely difficult and complex process due to the specific needs of the carers. This situation could improve by the introduction of technologies that support the carers in their job and in this way result also in the quality and duration of the assisted person's care in their own home.

By the previous, our starting hypothesis for the research related with the BREATHE Pre-Trials and Trials sets in action how the incorporation of specific technologies in the BREATHE Trial make easy:

- Provide innovative solutions to the caring task.

- The precocious detection to problems related to caring, present in the carers.
- Improve the knowledge about the care that the carers have.
- Support the carer and allowing him/her to reduce the overcharge in the caring.
- Extend the time in which the people with Long Term Conditions (LTC) can remain in their own homes (without being derived to an external resource, e.g. elder residence).

3.3.3 Acquiring data from interviews

3.3.3.1 Design of the research

The qualitative research will be done in three European countries: Ireland, United Kingdom and Spain. It will elaborate on the relevant information documents that **guarantee the ethical rights of the participants** and will require the reading and signing of a consent document. The participants' selection will take into account the limitations that will be established between BREATHE partners and on the last phase a questionnaire will be elaborated for the informal carers and other questionnaire for the assisted people that will gather all the dependent variables aforementioned, with the purpose of giving answers to the work hypothesis that has been set up.

The interviews will take place, whenever possible, in a laboratory where the technologies of BREATHE will be applied. If it is not possible, these will take place in the homes of the contacted people. They will be recorded by audio and it will observe the adequate ethical procedures relative to the treatment and storage of personal and sensitive personal data.

3.3.3.2 Data gathering model

The answers will be collated in a form that will be determined by the partner responsible of such activity. The variables which are the products of the operations proposed in this document and which were previously introduced in the questionnaires for their further study and analysis will be collected. Detailed information related to the specific content of the information material, the interviews, the data gathering document and other specifics, they are included in Sections 4 and 5 of this deliverable, by there we forward to such sectors for a deep reading on such contents.

3.3.4 Research recommendations

We strongly recommend inclusion of the variables obtained in this research with the purpose of validating the hypothesis, as well as following the ethics processes recommended by the BREATHE Ethics Board.

3.3.5 Validation plan check list

3.3.5.1 Check list

Briefly a testing list of a qualitative social research developed for the Pre-Trials and (Full/Final) trials, for the BREATHE project:

Activity	Yes	No
Search and selection of secondary sources	X	
Elaboration of empirical research study	X	
Adequacy of the operationalization to the documentation of utilization	X	
Elaboration of investigation documents	X	
Elaboration of data gathering document	X	
Translation of documents (if relevant)	X	
Correction and partners' input	X	
Participants' selection	X	
Realization of interviews	X	
Transcription (if relevant)	X	
Obtaining data and their processing	X	
Data analysis	X	
Facing data to the hypothesis	X	
Conclusions	X	

Table 2 - Qualitative social research check-list

3.3.5.2 Ethical check list

Such as it was commented, in other sections of this Deliverable 4.1 (specifically, section 4 and 5) the detailed information about the processes and procedures accomplished by this social research will be accessed, according to its own AAL rules, international rules and own participant member state rules. A brief list for testing the ethical activities related to the qualitative investigation is given below:

Activity	Yes	No
AAL ethical requirements' elaboration	X	
Study of the secondary sources for the ethical researches	X	
Implementation of unified ethical criteria	X	
Elaboration of research documents relative to the ethical aspects	X	
Presentation of the investigation to ethical committees (if relevant)	X	
Presentation of the investigation to external ethical experts (if relevant)	X	
Approval of ethical committees and/or external auditors	X	
Testing of whether the ethical requirements are accomplished with the participants	X	
Signed consent form signing	X	
Storage of the information obtained complying with the ethical rules and data protection of each country	X	
Elaboration of the final report about ethical procedures	X	

Table 3 - Qualitative social research (ethical activities)

4 Pre-trials

4.1 Introduction

The BREATHE platform will be developed and deployed in the first instance in two different and supplementary environments: (1) in a more controlled infrastructures also called living laboratories in United Kingdom and Spain and (2) in real spaces (private homes) also called home based trials in Ireland. Although the nature in both are slightly different (living laboratories are more enclosed spaces with a higher tolerance of error since the BREATHE technology will not be installed in the end-user´s homes), the research objectives, settings, supportive materials, inclusion/exclusion criteria and availability of technological devices will be exactly the same. Pre-trials carried out in living laboratories would consist of the components and elements which compounds the whole architecture (i.e. indoor video-based monitoring system, array of multi-function sensors, local servers, interaction device and the server side system of the informal caregiver tool) in a property which resembled an assisted person's home, however it would provide access for researchers and technicians to manage the system and carry out checks with some reasonable threshold of tolerance from the end-users point of view.

Some of the issues which emerged during the plenary meeting in Dublin (Trinity College, May 2014) regarding the pre-trials stage were:

- [Potential risk] Ethics approval for installation of the AAL home system in assisted people's homes for TCD could delay the trial (since they must to achieve an ethics approval from their local ethics committee).
- Potential disruption to private homes for installation of the BREATHE AAL home system.
- A requirement to thoroughly test the BREATHE AAL home system could be impaired if it is in the home of an assisted person.
- Cost of the BREATHE AAL home system was in excess of the budgets available for the three countries: Spain, Ireland and United Kingdom.
- Technical implementation and dependencies between different elements of the BREATHE AAL home system.
- Control of the data on the BREATHE AAL home system for the pre-trials (who is the owner).
- Physical location on the cloud infrastructure for the storage of the gathered in the pre-trials.
- Each pre-trial would have a minimum of 6 pairs of informal caregivers and assisted persons visiting the laboratory and doing the interviews (12 people in total per country).

- The system is best suited to people living alone – multiple people in the same home is possible but requires extra processing.
- Pets living together with the assisted person are allowed.

The objectives pursued by pre-trials will be covered from two different perspectives: (1) technical point of view and (2) end-users point of view. In the first one, the major challenge is to be able to produce a functional and stable first version of the BREATHE platform and to identify those problems and concerns which may arise as consequence of carrying out its installation in a real environment. On the other hand, the goal of the pre-trial is to involve real end-users (both assisted persons and informal carers) from three different countries whose feedback about the acceptance, usability and added value of the BREATHE platform is paramount for us in order to ensure that the job done is in the right way.

4.2 Technical point of view

Specifically, the objectives pursued by the pre-trials from the technical point of view are:

- To acquire the physical elements which makes up both the video-based monitoring system and the array of multi-function sensors as well as the interaction device and the local server (**feasibility**).
- To deploy both the video-based monitoring system and the array of multi-function sensors infrastructures in real premises.
- To set up the back-end server side system of the informal caregiver tool which enables us to store the RAW data automatically gathered from the AAL home system (**scalability**).
- To automatically recognize some primitive human activities (specifically, indoor location at room level) from both the indoor-video based monitoring system and the array of multi-function sensors and to properly upload them to the server side system of the IC tool (**reliability**).
- To develop and test under real conditions the interfaces which enables the exchange of information between the components and elements of the whole platform, namely: the interaction device and the home version of the IC tool.
- To improve our understanding and expertise in order to reach a better performance in the second release (which includes some additional features in the IC tool as well as the supporting of video in real-time).

4.3 End-users point of view

Specifically, the objectives pursued by the pre-trials from the end-user´s point of view are:

- To collect some feedback from the assisted persons (APs):

  - After being surrounded by the AAL home system technology (i.e. real devices/components): one camera and four sensors (**model/human acceptance**).
  - In order to check his/her impressions after being monitored in real-time for his/her main carer.
  - In order to verify if he/she really understands what is happening around him/her and to research which is the best way for setting the privacy filters of the cameras up.

- To collect some feedback from the informal carers (ICs):
  - After using the informal caregiver tool (home version) in order to find out the real added value of that kind of platforms (**technological acceptance**).
  - So that we can discover his/her willingness to fill in questionnaires which helps us to measure his/her level of burden and emotion automatically.
  - About watching through the video-based monitoring system what the assisted person is doing in real-time (**ethics vs privacy vs peace of mind**).
  - About the level of importance of several activities and events automatically gathered in the assisted person´s home (**added value**).

4.4 Expected outcomes from the pre-trials

The expected outcomes from the trials carried out in Spain, United Kingdom and Ireland as consequence of the first release of software are (these outcomes will be later on linked to the specific actions/functionalities carried out during the pre-trials in order to achieve the aforementioned pursued objectives):

- Feedback about which activities and alerts the informal caregivers like the most to see about their loved ones and themselves.
- Feedback on how do they (informal carers and assisted persons) feel with having devices at home and being surrounding by them. Acceptances of the technological infrastructure.
- Feedback on how the assisted person feels about controlling when to be watched. The same opinion from the IC side.
- Feedback on the overall solution and model.
- Feedback on some specific screens and preferences (look and feel).
- Feedback on how they perceive self-assessment tools like questionnaires (i.e. Zarit burden interview, Barthel index, etc.) and non-structured sources of information like writing a personal diary or responding direct short-questions about his/her feelings and impressions (e.g. how do you feel?, how are you?, etc.).

- Extract our own experience in dealing with the installation of all these devices in three different locations: identify main technical problems installing and uninstalling technological components.
- A first version of the whole system partially running: PCs at home acting as gateways, server side system of the IC tool storing RAW data automatically gathered from the trial sites, a dashboard for the IC and a tablet app for the AP which lets him/her to manage the indoor video-based monitoring system without the support of the IC.

ID	Outcome
O1	To receive feedback about which activities and alerts the ICs like the most/less (about their loved ones and themselves).
O2	To receive feedback about the feeling of having devices at home and being surrounding by them.
O3	To receive feedback from the AP about the possibility to be watched in real-time.
O4	To receive feedback from the AP and IC about the overall solution and model.
O5	To receive feedback about the look and feel of the application.
O6	To receive feedback from the ICs about how they perceive the self-assessment tools (e.g. Zarit questionnaire, Barthel index, etc.) and non-structured sources of information (e.g. writing a personal diary or answering short-questions about their feelings).
O7	To extract our own conclusions and improve our experience dealing with the installation/uninstallation of the BREATHE technology in three different locations in order to identify problems and constrains before the full trials arrive (real environment installations).
O8	To set up an important technological milestone which releases a first version of the whole system partially running under real conditions.
O9	To determine attitudes of carers and cared for persons towards the BREATHE platform in order to oversee the development and installation of the following stages (second and final release).

Table 4 - Summary of specific outcomes from the pre-trials

4.5 Initial timeframe

The first release will enable the informal carer (IC) to receive some basic information about the activities of daily living of his/her loved one (also called assisted person, AP) thanks to the availability of both the AAL home system and the informal caregiver tool (always within the reach of the AP´s main carer). Moreover, the first release will set up all interfaces between sub-systems and their components in order to be able to exchange data between all of them in a proper way. Pre-trials will be carried out in parallel in Spain, Ireland and United Kingdom (starting on 25th August 2014 and finishing before the first fortnight of September 2014) and they will be a great opportunity to get a first feedback from the involved end-users. Once the pre-trial ends, a report (deliverable D4.2 – Pre-trial report) will be drawn up with the most important conclusions, hazards, risks and findings in order to influence the next development stage and to ensure that

the final solution will fit the initial end-users requirements found out in WP1 (D1.1 – Whitepaper on Needs and requirements of AAL and ICT solutions for informal LTC of elderly people[3]).

After the agreements reached in the second plenary meeting hosted in the Trinity College (Dublin, Ireland) and attending the Gantt chart available in our DoW (page 16, BREATHE main document of work), there are some temporal restrictions that we have to take into account for planning the initial timeframe and allocate the next steps:

Task	Deadline
Stop the pre-trials experiments (interviewing end-users) in the three different countries.	Friday 12th September 2014
Release for the internal review of the deliverable D4.2: pre-trials report.	Friday 26th September 2014
Final release of the deliverable D4.2: pre-trials report (which involves the following steps: writing, internal review and release).	Tuesday 30th September 2014

Table 5 - Initial timeframe

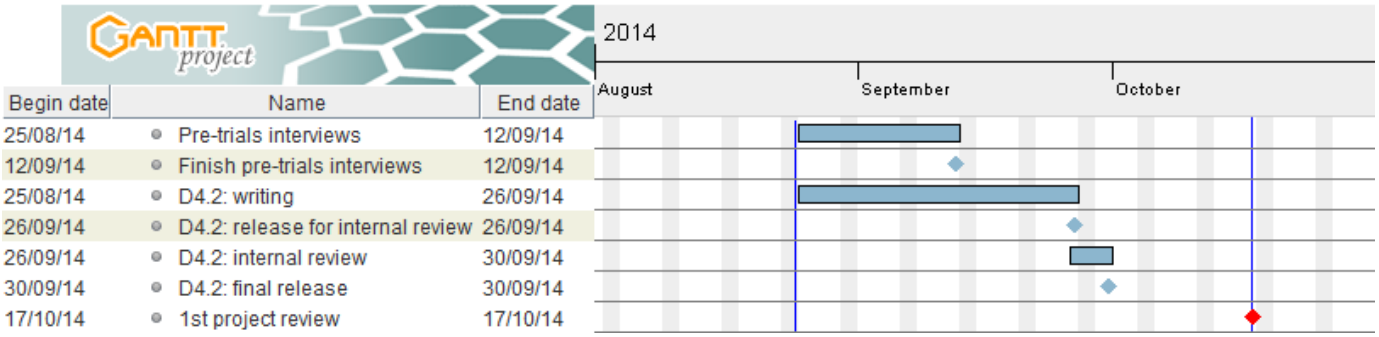

Figure 2 - Initial timeframe (Gantt chart)

4.6 Set up

4.6.1 Aim

The aim of this research is to assess attitudes to technology that has been developed in response to the needs identified in the requirements and needs assessment phase (WP1, Requirements and specifications). Participants (assisted person and informal carers) will provide feedback on the feasibility and usability of technology as well as feedback on how they perceive structured self-assessment tools like questionnaires (i.e. Zarit, etc.) and non-structured sources of information (e.g. diaries, etc.).

[3] http://breathe-project.eu/en/publications (Accessed on July, 2014)

4.6.2 Facts

- Pre-trials will be carried out in three different countries and they will run in parallel: Spain, Ireland and United Kingdom.
- Pre-trials will be set up in testing environments (living laboratories or smart rooms) and private homes.
- At least 6 pairs of informal caregivers and assisted persons will be recruited and interviewed per country (there are no restrictions on the upper limit).
- Assisted persons and informal caregivers will be separately interviewed (in different rooms by different interviewers).
- In addition to our own ethics review from our Ethics Board, an ethical review will be done by third-parties: the Faculty Research Ethics Committee in TCD[4], the Cybermoor Ethics Committee in United Kingdom and the Polytechnic University of Valencia in Spain.
- In no way whatsoever, video neither images will be recorded or stored in our servers.
- Real devices (cameras and sensors) will be used in pre-trials.
- Real software deployments will be carried out in the testing environments.
- Inclusion and exclusion criteria, research objectives as well as the supportive materiel (questionnaires, scripts, etc.) used in pre-trials will be the same in the three different countries.
- If we initiate the experiments and we identify that there are aspects that do not work and require a change, we will stop the experiment, modify those aspects that we consider feasible to change and continue the experiments with the new system.
- A common calendar exists (table 2 and figure 3) with some timing restrictions as we agreed in our last plenary meeting (Dublin, May 2014) and according the information available in our DoW. This calendar will be completed subsequently with those detailed steps that we will follow until the release of the pre-trial report (deliverable D4.2).
- The informal caregiver can only watch the real-time video after an alert event sent from the assisted person´s home and always with the consent of the assisted person.
- The assisted person is the actor who has the last word for setting up the privacy levels of the real-time video (what privacy filter will be assigned to each alert).
- During pre-trials, both the indoor video-based monitoring system and the array of multi-function sensors will be able to recognise only activities related to the location (room level) of the assisted person at home and send a textual description/message

[4] http://www.healthsciences.tcd.ie/research-ethics-committee (Accessed on July, 2014).

to the informal caregiver tool (e.g. going to the toilet, etc.) which will be stored in the server side-system (back-end) of the home version of the IC tool.

- Power outages as well as low battery alerts from installed devices will not be taken into account during the pre-trial stage but in the trials (second and final release where the software will be configured to automatically restart when power is restored).
- Pre-trials will put the focus on (sections 4.2, 4.3 and 4.4) the user´s acceptance/tolerance about the technological deployment in the assisted person´s home as well as the real added-value of the BREATHE platform as a whole. Pre-trials will serve us for discovering how to deploy the technological solution without harming the user´s premises: how the sensors and the cameras will be attached and removed to the environment, which are the limits with wires, etc.

4.6.3 Timeframe

The pre-trial stage is scheduled to commence mid-August 2014 (M15) and it is scheduled to end mid-September 2014 (M16).

4.6.4 Sampling and inclusion/exclusion criteria

Approximately 6 informal caregivers and recipient of care dyads (12 interviews/country which means n = (6+6) x 3 = 36 interviewed people) will be conducted for this study. The number of interviews needed to reach data saturation (where no new themes emerge) will be considered alongside feasibility issues (resources and timing). A convenience sample of participants will be recruited through a voluntary organisations (e.g. Carers Association) working with carers and/or people with LTCs and with a technology company who provide an emergency response service to people being cared for. All eligible participants will be invited to participate by formal letter, including study information leaflet. This will provide the participant with the necessary information required to make the decision whether to participate or not. The participant will also have the opportunity to discuss the study with a member of the research team. If the person is happy to participate in the study, the consent form will be signed in person at the point of the interview. If the person does not wish to participate, they will be given no further details about the research (although the study procedure is low risk, participants will be given a week to 10 days to decide whether or not to participate). At any point a participant is free to leave the study if they so wish.

Regarding the inclusion and exclusion criteria, they must be the same than those used for the interviews carried out in WP1 to ensure coherence in the research process:

INCLUSION CRITERIA	
Carers	**Care recipients**
• Informal carers, e.g. relative or partner of the person with an LTC (stroke survivors, frail older persons, people with musculo-skeletal disease, or mobility problems). • Formal carers: an officially employed, paid carer	• People with a LTC for at least six months (stroke survivors, frail older persons, people with musculo-skeletal disease, or mobility problems).

of the person with a LTC. • Aged 18-90. • Can be living together or separately from care recipient. • Ability to communicate clearly in English.	• Aged 18-90. • Ability to communicate clearly in English.

Table 6 - Inclusion criteria for pre-trials

EXCLUSION CRITERIA	
Carers	**Care recipients**
• Individuals under 18. • Have significant cognitive impairment or physical illnesses which are likely to impair their ability to participate in the study or their ability to give informed consent. • Not fluent English.	• Individuals under 18. • Have significant mental or physical illness which is likely to impair their ability to participate in the study or their ability to give informed consent. • Not fluent English. • Have a severe communication impairment (e.g aphasia), which prevents them from clearly communicating with an interviewers.

Table 7 - Exclusion criteria for pre-trials

4.6.5 Research design

A cross-sectional descriptive research study design will be used. Data will be collected via one to one semi-structured interviews. Interviews will provide specific, individual attitudes and feedback in relation to a demonstration within the individual's home of a prototype of the BREATHE system. At present, this prototype consists of several features of the whole platform which will be tested under real conditions and with real end-users (both assisted persons and informal carers). The interviewer will demonstrate and explain how BREATHE platforms works and which are its most important innovations (and always taking in mind the specific list of goals pursued by the trials). The interviewer will then ask the informal carer participants to provide feedback on two structured self-assessment tools (the Zarit burden interview short form (12-item) and Barthel Index, Appendix A) and use of these measures within the main trial. This will then be repeated for the non-structured components.

4.6.6 Data collection

Qualitative data will be collected via one to one structured interviews and demonstrations (approximately 1 hour in duration) with carers (informal) and care recipients. All interviews will be audio-recorded and transcribed verbatim. Quantitative survey based socio-demographic background information will be completed as part of the interview schedule.

4.6.7 Sites capabilities

4.6.7.1 Spain (ISI)

The laboratory was set up on the premises of the company Iniciativa Social Integral (ISI), due to its location in the city. ISI is good situated just in the city center with good communications, including public transport. The testing environment has been set up in two different areas:

- Room 1 (IC´s space) where the laptop which runs the home version of the IC tool and connects with the indoor video-based monitoring system located in the other room. This area is reserved for the IC and his/her interviewer (BREATHE researcher).

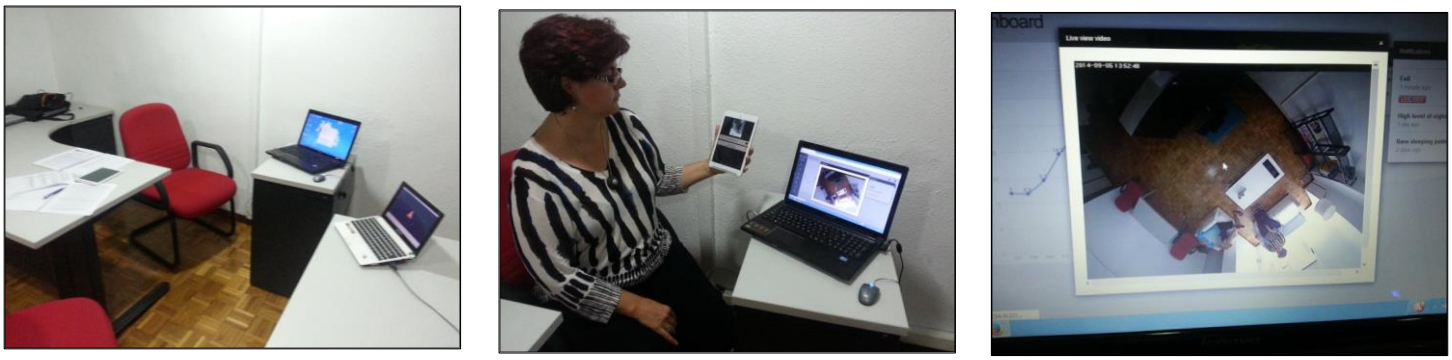

Figure 3 - IC´s area (Spanish living lab)

- Room 2 (AP´s space), which is located next to the other room, simulates the AP´s home (specifically his/her living room) and it is where the interview with the assisted person has been carried out.

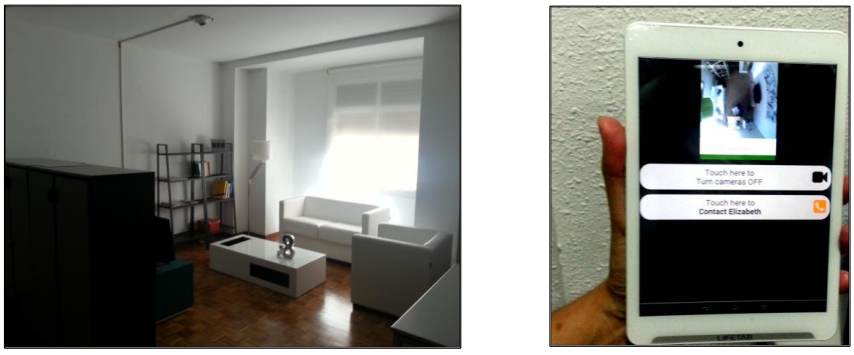

Figure 4 - AP´s area (Spanish living lab)

4.6.7.2 Ireland (TCD)

The Irish pre-trial interviews were conducted in the homes of 6 assisted people and their respective informal carers. In all cases the informal carer lived with the assisted person. The interviews were conducted separately with the informal carer and the assisted person in all but 2 cases. In these instances, the option to interview separately

was not feasible for the participants. The interviews took 45-60 minutes per participant to complete. All houses had their own broadband connection. No technology was installed during this pre-trial. This pre-trial consisted of a web based demonstration, and visual demonstration of samples of an app, sensors and cameras.

The informal carer was shown the home version of the informal caregiver tool, on a laptop, brought to the home by the research team. The assisted person was also shown the web based prototype of the BREATHE informal carer web tool, in conjunction with the opportunity to assess an app currently designed to remotely control the on/off feature of the camera, and to facilitate calls to the carer when needed. The app was demonstrated using an Android OS tablet. Participants then answered a list of questions regarding current living circumstances, and their response to the IT that was demonstrated to them. Interviews were conducted in Dublin City, North County Dublin, West County Dublin and Wicklow.

4.6.7.3 United Kingdom (CYB)

The UK pre-trial system has been set up in one of the assisted living flats in the Grisedale Croft, Alston (Cumbria, UK). This is a controlled environment where no one is living. The flat is within a secure residential block in the centre of town and has a small bedroom, kitchen and toilet opening into a main living area.

The flat has a fibre optic broadband connection (10Mbs synchronous) with a wireless router and the BREATHE system has been installed in the corner on the outside facing wall. The camera has been installed in the living room of the flat, which gives a complete view of the living area. Motion sensors have been fitted in the bedroom and kitchen, a door sensor has been installed on the front door and the plug sensor installed in the kitchen. There is a communal sitting room located along the corridor from the flat, which has a TV and this will be used for carrying out contemporaneous interviews with carers and assisted persons.

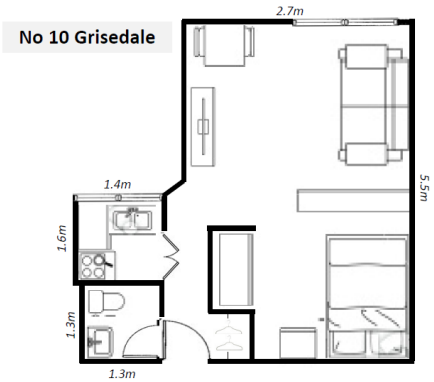

Figure 5 – Outside view of the Grisedale Croft Care home (UK living lab)

The twelve assisted living flats are managed by Eden Housing Association[5] and are attached to Grisedale Croft Residential Care Home. The assisted living flats are available to people over the age of 55 who have a support need of some kind. The flats have a 24 hour emergency support back-up facility and support available from a local independent living advisor if required. There are one bedroom flats and studio flats, situated over two floors serviced by a lift and stair lift. Modern walk in shower rooms have also just been installed in some of the flats.

Figure 6 - Inside view of the Grisedale Croft Care home (UK living lab)

[5] Eden Housing Association - http://www.edenha.org.uk (Accessed on July, 2014)

4.6.8 Supporting material

4.6.8.1 Letter of invitation

Dear [named individual],

We would like to invite you to take part in a research study being conducted by [Add the appropriate name here]. The study aims to develop technology that will help to support carers. This technology will be part of a system called BREATHE that could provide:

- Monitoring of someone with a Long Term Condition at home, based on technology installed in their home.
- Support and guidance for informal carers.

Some technology already exists which can monitor people with long term conditions and pass important information to their carers. However, the new BREATHE technology aims to use new types of sensors which could provide better support and reassurance to carers while maintaining the privacy of people with long term conditions. We would like to know what you think about this, in order to make the technology as useful as possible. If you decide to take part in the study, you will be asked to participate in a one to one interview. The interviews will ask you to view a video and to look at motion sensors. They will then seek your opinion on the feasibility and usefulness of these technologies in your home. An information sheet about the study is included in this pack.

You can register your interest in participating with the [Add appropriate name here] and if you wish, a member of the research team will contact you in a week to ten days after you receive this letter to discuss the study with you. If you have any questions in the meantime, please contact [Add appropriate name here] using the contact details below.

Thank you for your time and interest,

[Add contact name here]

4.6.8.2 Participant information leaflet

For the interviews with people with LTC

Introduction – What is the BREATHE study about?

You are invited to participate in a study that aims to develop technology that will help to support carers. This technology will be part of a system called BREATHE that could provide:

- Monitoring of someone with a Long Term Condition at home, based on technology installed in their home.
- Support and guidance for informal carers.

Some technology already exists which can monitor people with long term conditions and pass important information to their carers. However, the new BREATHE

technology aims to use new types of sensors which could provide better support and reassurance to carers while maintaining the privacy of people with long term conditions.

Who will take part in the study?

- This study aims to find out what support is needed by carers of people with long-term conditions.
- This is being done by asking relevant people, like you for their views of the system.

How will you find out my view of the system?

- We hope to find out your opinion during a brief one to one interview between yourself and a researcher from [Add appropriate name here] at [Add appropriate location here].
- This interview would take place after you have had the opportunity to view a pre-recorded demonstration of the BREATHE system.
- At the start of the interview you will be asked to fill in some short background questions about yourself. You will then be asked questions about the BREATHE system which is being developed, and you will be given the opportunity to discuss and ask questions about this topic.
- The demonstration and interview will last between 60-90 minutes. The interview will be audio recorded. This will enable the researchers to study the answers that you give. The recordings will be kept confidential, and any quotations that are published will be anonymised.
- We will then be able to include this information in the future design of the BREATHE system, in order to make the technology as helpful as possible for carers.

What's involved in the 'demonstration' of the system?

- The demonstration consists simply of researchers bringing along their laptop and using this to show you a pre-recorded example of how the system would work in a home setting. This would only take place with your full consent.
- This will consist of a basic step by step visual guide through the login and make-up of the BREATHE system.
- This will be followed up by displays of different options on the system (e.g. ability to detect activity/movement in the home).
- It is important to know that this will not be live activity but a pre-recorded demonstration example only developed by the BREATHE technical team).

What are the benefits of taking part?

The study aims to develop technology that will help to support carers in looking after people with long-term conditions. There are no direct benefits to you of taking part in this study, but by participating in this study, you will contribute to making the design of such technology as useful as possible.

What are the risks of taking part?

The potential for risks from taking part in this study are minimal. You will be asked some questions about your own experiences with long term conditions and care and how the BREATHE system may be best design to support the informal caregiving process. These questions will be asked sensitively, and your answers will be treated in confidence.

Who have we asked to participate in the interviews?

We are inviting people with Long Term Conditions who receive informal care at home. In particular, we are looking for people with Long Term Conditions who:

- Are from 18 to 90 years old.
- Can give written, informed consent.
- Are physically well enough to participate in an interview.
- Have had their Long Term Condition for at least six months.
- Have at least one Long Term Condition which fits into these categories:
    - Stroke survivors.
    - Frail older people.
    - People with musculo-skeletal disease, or mobility problems.

Who must we exclude?

You cannot participate in this study if any of the following are true:

- You are not a fluent speaker of English.
- You have significant cognitive impairment or physical illnesses, which would prevent you from participating in the study and giving consent.
- You have a severe communication impairment (e.g. aphasia), which prevents you from clearly communicating with an interviewer.

How will we maintain your privacy and confidentiality?

Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the study group. If you consent to participate in this study, you will be given a study ID number.

Compensation

This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

Voluntary participation

If you decide to volunteer to participate in this study, you may withdraw at any time. If you decide not to participate, or if you withdraw, you will not be penalised and will not give up any benefits that you had before entering the study.

Stopping the study

You understand that the investigators may withdraw your participation in the study at any time without your consent.

Who is organising and funding the research?

The research is organised by a European research group which has been brought together to design the BREATHE system. The research group is supported by a European Union grant which is concerned with developing technology that will make independent living at home possible for people with long term health conditions. Funding is provided by the European Ambient Assisted Living (AAL) Joint Program.

Permission

This study has ethical approval from the Faculty of Health Sciences Research Ethics Committee, Trinity College Dublin.

What if I have questions about the project?

You can get more information or answers to your questions about the study, your participation in the study, and your rights from [Add name here] who can be telephoned at [Add telephone number here] or email your query to [Add email address here]. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

For the interviews with informal carers

What is this BREATHE Study about?

You are invited to participate in a study that aims to develop technology that will help to support carers. This technology will be part of a system called BREATHE that could provide:

- Monitoring of someone with a Long Term Condition at home, based on technology installed in their home.
- Support and guidance for informal carers.

Some technology already exists which can monitor people with long term conditions and pass important information to their carers. However, the new BREATHE technology aims to use new types of sensors which could provide better support and reassurance to carers while maintaining the privacy of people with long term conditions.

Who will take part in this study?

- This study aims to find out what support is needed by carers of people with long-term conditions.
- This is being done by asking relevant people like you, for their views, of the system.

How will you find out my view of the system?

- We hope to find out your opinion during a brief one to one interview between yourself and a researcher from [Add the appropriate name] at [Add the appropriate location].
- This interview would take place after you have had the opportunity to view a pre-recorded demonstration of the BREATHE system.
- At the start of the interview you will be asked to fill in some short background questions about yourself. You will then be asked questions about the BREATHE system which is being developed, and you will be given the opportunity to discuss and ask questions about this topic.
- The demonstration and interview will last between 60-90 minutes. You will not be asked to reveal any identifying or personal information about the people you care for. The interview will be audio recorded. This will enable the researchers to study the answers that you give. The recordings will be kept confidential, and any quotations that are published will be anonymised.
- We will then be able to include this information in the future design of the BREATHE system, in order to make the technology as helpful as possible for carers.

What's involved in the 'demonstration' of the system?

- The demonstration consists simply of researchers bringing along their laptop and using this to show you a pre-recorded example of how the system would work in a home setting. This would only take place with your full consent.
- This will consist of a basic step by step visual guide through the login and make-up of the BREATHE system.
- This will be followed up by displays of different options on the system (e.g. ability to detect activity/movement in the home).
- It is important to know that this will not be live activity but a pre-recorded demonstration example only developed by the BREATHE technical team).

What are the benefits of taking part?

The study aims to develop technology that will help to support carers in looking after people with long-term conditions. There are no direct benefits to you of taking part in this study, but by participating in this study, you will contribute to making the design of such technology as useful as possible for people like you.

What are the risks of taking part?

The potential for risks from taking part in this study are minimal. You will be asked some questions about your own experiences with long-term conditions and care. These questions will be asked sensitively, and your answers will be treated in confidence.

Who have we asked to participate in the interviews?

We are inviting people who are caregivers (both formal i.e. paid and informal) for people with long-term conditions at home to participate. In particular, we are looking for formal carers who:

- Are from 18 to 90 years old.
- Can give written, informed consent.
- Have been a carer for at least six months for people with LTCs in a domestic setting.
- Have some experience of caring for people in one or more of these categories:
    - Stroke survivors.
    - Frail older people.
    - People with musculoskeletal disease, or mobility problems.

Who must we exclude?

You cannot participate in this study if any of the following are true:

- You are not a fluent speaker of English.
- You have significant cognitive impairment or physical illnesses, which would prevent you from participating in the study and giving consent.
- You have a severe communication impairment (e.g. aphasia), which prevents you from clearly communicating with an interviewer.

How will we maintain your privacy and confidentiality?

Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the study group. If you consent to participate in this study, you will be given a study ID number.

Compensation

This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

Voluntary participation

If you decide to volunteer to participate in this study, you may withdraw at any time. If you decide not to participate, or if you withdraw, you will not be penalised and will not give up any benefits that you had before entering the study.

Stopping the study

You understand that the investigators may withdraw your participation in the study at any time without your consent.

Who is organising and funding the research?

The research is organised by a European research group which has been brought together to design the BREATHE system. The research group is supported by a European Union grant which is concerned with developing technology that will make

independent living at home possible for people with long term health conditions. Funding is provided by the European Ambient Assisted Living (AAL) Joint Program.

Permission

This study has ethical approval from the Faculty of Health Sciences Research Ethics Committee, Trinity College Dublin.

What if I have questions about the project?

You can get more information or answers to your questions about the study, your participation in the study, and your rights from [Add name here] who can be telephoned at [Add telephone number here] or email your query to [Add email address here]. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

4.6.8.3 Consent form

PROJECT TITLE: BREATHE

Principal Investigators Name: [Add names here]

Researchers: [Add names here]

Corresponding Researcher [Add contact name, email and telephone number here]

Background

The aim of this study is to develop technology that will help to support carers. This technology will be part of a system called BREATHE that could provide:

- Monitoring of someone with a Long Term Condition at home, based on technology installed in their home.
- Support and guidance for informal carers.

Some technology already exists which can monitor people with long term conditions and pass important information to their carers. However, the new BREATHE technology aims to use new types of sensors which could provide better support and reassurance to carers while maintaining the privacy of people with long term conditions. The purpose of this research is to explore the experience of providing care for someone with a long-term condition and the potential contribution that a system like BREATHE could make in supporting this:

- To achieve this we need the help of people like you, who are either providing care, or in receipt of care, to provide us with feedback on our new system. Your input at this stage in the process is invaluable to us.
- If you consent to take part, you will be shown a video based demonstration of the BREATHE system, using a laptop provided by the researcher, within your home setting and then asked to comment on the system within a caregiving context.

- This feedback would take place via a one to one confidential interview with a researcher and yourself. This entire process would not take longer than 60-90 minutes.
- This will not involve any monitoring or assessment of either the carer or the person being cared for. This is simply a demonstration to get your feedback on the proposed system.
- Finally you will be asked about possible areas of relevance to you as either the person providing care, or the person in receipt of the care.

All interviews will be dealt with in the following way:

- The interview will be recorded using a digital recorder. All audio recordings will be stored securely on the researcher's password protected computer and then transcribed.
- You may view your transcript, if you wish, and are free to change or withdraw any information shared during the course of the discussion.
- All recordings and subsequent transcripts will be anonymously labelled and will not be used for any purpose other than that of this study. The data will be confidential and stored in a secure manner in keeping with the requirements of the Ethics Committee of Trinity College.
- All views shared by contributors will be treated confidentially and all comments will be reported anonymously. The information gained during the study will not be used in future unrelated studies without your specific permission.

Declaration

I have read, or had read to me, the information leaflet for this project and I understand the contents. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I understand that I may withdraw from the study at any time and I have received a copy of this agreement.

Participant's name: [Add here]

Contact details: [Add here]

Participant's signature: [Add here]

Date: [Add here]

Statement of investigator's responsibility

I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

Investigator's signature: [Add here]

Date: [Add here]

4.6.8.4 Letter of request for interview

Dear [Add name here]

Further to our contact about conducting the research as part of the BREATHE study, I wish to follow up with you, regarding carry out this interview in [Add appropriate location here].

It is necessary to facilitate the interview demonstration is a natural home environment to explore feasibility of technology in this environment.

The proposed date for this interview is xx/xxxx/xxxx.

A researcher from [Add name here] will be in touch with you to confirm your availability on this date.

Thank you for considering this request,

Yours sincerely,

[Add name here]

4.6.8.5 Detailed script

As has been said before, the assisted person and the informal carer will be separately interviewed in two different rooms and by two different interviewers. The next table shows the specific steps that we are going to carry out during the pre-trials (in order to get a better understanding about how the APs and ICs will be involved, please carefully read the Questionnaires section):

Step	Action	Expected time (minutes)
0	Welcome AP and IC together and detailed explanation of the experiment (review of the script, creation of unique identifier, etc.). In case the subject accepts (signature of the informed consent), the experiment will continue and the pre-trial will start.	5
1	Baseline establishment. The AP and the IC will be separated in two different groups with two researchers/interviewers. The interviews will run in parallel.	5
2A	Interview with the IC. Start recording voice. Review of general assessments and expectations of the interview. Warming up: description of the whole questionnaire and expected time.	5
2B	Interview with the AP. Start recording voice. Review of general assessments and expectations of the interview (human acceptance). Warming up: description of the whole questionnaire and expected time.	
3A	Interview with the IC (questionnaire available in the next section). Start recording voice. Questions about themselves and their circumstances, about their most important concerns as carer, about the BREATHE technology (real demonstration of the features available for the first release) and about their acceptability of installing the BREATHE system in their loved one´s homes.	45
3B	Interview with the AP (questionnaire available in the next section). Start	

	recording voice. Questions about themselves and their circumstances, about some of their experiences as consequence of being cared by someone, about the BREATHE technology (real demonstration of the features available for the first release) and about their acceptability of installing the BREATHE system in their homes.	
4A	Interview with the IC. Final assessments and conclusions.	5
4B	Interview with the IC. Final assessments and conclusions.	
5	AP, IC and the two interviewers will meet together. Thank you and good bye.	5
6	Interviewers will wrap things up and will complete the XLS sheets for the data analysis with the appropriate answers.	25
7	Final XLS sheets, filled in questionnaires and voice records will be properly uploaded and stored in our Project repository on Redmine [restricted and safety access].	5
8	Interviewers will check that the uploaded files have been successfully stored on the server.	5
	TOTAL TIME (minutes)	120

Table 8 - Detailed script and expected time

4.6.8.6 Questionnaires

Interview schedule for informal carers of people with LTCs

Thank you for agreeing to take part in this study. Your involvement will help us to understand what potential users of the BREATHE technology think about it, and will indicate how to make the technology as useful as possible for carers of people who have Long Term Conditions (LTCs). We will be asking people who have Long Term Conditions what they think too, but this is an opportunity to tell us what you think from your point of view as a career. Do feel free to ask any questions during the session – the interviewer will be happy to provide you with any more information about the work and explain the questions in more detail.

SECTIONS	DESCRIPTION
SECTION A ABOUT YOUR CIRCUMSTANCES (21 QUESTIONS)	In Section A, we would like to ask you some questions about you and your circumstances. This will help us to understand your views, and will help us to make the best use of the answers that you provide.
SECTION B THE BREATHE SYSTEM AND MONITORING (24 QUESTIONS)	Section B asks for your feedback on a demonstration prototype of the working BREATHE solution.
SECTION C YOUR ROLE AS A CARER (2 QUESTIONS)	Section C asks about some of your experiences as a carer and the main issues that cause you concern in your role as a carer.
SECTION D THE BREATHE SYSTEM GIVING	Section D contains questions about the BREATHE system offering guidance and support to informal carers.

GUIDANCE AND SUPPORT (5 QUESTIONS)	
SECTION E ACCEPTABILITY OF THE BREATHE SYSTEM: (10 QUESTIONS)	Section E contains questions about the acceptability of installing the BREATHE system in the home.

SECTION A – ABOUT YOUR CIRCUMSTANCES

In Section A, we would like to ask you some questions about you and your circumstances. This will help us to understand your views, and will help us to make the best use of the answers that you provide. Your answers will only be used anonymously – your name will not be associated with any comments that you make.

1. Your gender Male □ Female □

2. Your date of birth ……..

3. Where do you live? (Place name, e.g. "Dublin")
……

4. Who is the person who you care for?
Husband □ Wife □ Mother □
Father □ Grandfather □ Grandmother □

Other:
…….

5. How many hours do you spend per week caring for this person?
Approximately ……hours

6. What type(s) of conditions does this person have?
……
……
……
……

7. How would you describe your own current health status?
Excellent □ Good □ Average □ Fair □ Poor □

8. Do you live with the person who you provide care for?
Yes □ No □

9. If you do not live with the person who you provide care for, how far away do you live?

……

Miles □ Kilometres □

10. If you do not live with the person who you provide care, do they live alone?
Yes □ No □

11. How often you are in contact with the person who you provide care for by phone?
Every day □ 2 or more times a week □ Once a week □
2 or more times a month □ Once a month □ Less often than once a month □

12. Do you or the person you care for currently have any home help or healthcare or social care support, in addition to the informal care that you provide?
Yes □ No □
If yes, please specify:
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13. Does the person who you provide care for have any medical cover? e.g. medical card, private health insurance
Yes □ No □
If yes, please specify:
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14. Could you tell me whether you:
Work full-time outside the home □
Work part-time outside the home □
Have moved from full-time work to part-time work due to your caring role □
Do not work outside the home due to your caring role □
Do not work outside the home due to unemployment or redundancy □
Do not work outside the home due to illness or disability □
Do not work outside the home because you are retired □
Have never worked outside the home □

15. If you work or have worked outside the home, what is your current or main previous occupation?
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IT RELATED QUESTIONS:

Now we have a few questions about using technology:

16. Do you ever use the internet?
Yes □ No □ [*if no, go to question 21*]

17. If you do use the internet, what type of internet connection do you have?
Broadband □
Other: ……

18. If you do use the internet, what device(s) do you use for this?
Desktop computer □ Laptop □ Smartphone □
Tablet computer, like an iPad □
Other: ……....

19. If you do use the internet, how confident do you feel when you use the internet?
Very confident □ Quite confident □ Neutral □
Not very confident □ Not confident at all □

20. If you do use the internet, how often do you use it?
Every day □ Every week □ About once a month □
Less than once a month □

21. Do you or the person you provide care for already use any assistive technology (for example any technology which helps with practical or medical needs, or which monitors safety or health at home, including mobile phone "apps")?
If yes, please specify:
……
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SECTION B: THE BREATHE SYSTEM & MONITORING

Now we would like to demonstrate the different functions of the BREATHE system and then ask you for your feedback on what you have seen.

[*Step 1. Demonstrate 'Access to adapted video signals in real time': (1) Log in to web tool and (2) Access 'Dashboard'*]

This is the main panel on the prototype that should show the most relevant things about what is happening at the home of the person you care for. It should also show some information summarizing your own status as an informal carer. You can see:

1. A vertical menu on the left side.
2. An example of a graphical representation.
3. A component with dummy 'Important Notes'.
4. Two icons: a notifications icon – a bell in red background with '1'; and an icon to access configuration.

A smart phone version is currently being developed where you can access some common contents with the website, but not everything because of the limitations of the device.

[*Click on the notifications icon Select the 'fall' notification Click 'live view' to access the video IE skype video demonstration This will be done via a laptop and a smartphone to demonstrate on-demand live video. The interviewer will remain in the room with the carer. They will open up the skype facility on their laptop and they will ring their colleague using skype. (Its important for interviewer to ensure that they have their skype account up to date and accessible for the meeting, likewise for their colleague). Their colleague will be situated in a nearby room or hall, and will answer the skype call using their smartphone. This will demonstrate to the carer that they can see the other person in the other room and provides a real example of the 'live' camera feed they have just seen on the video demonstration*]

22. Is the idea of watching real time/live video beneficial for you?

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23. When would you like to be able to access real-time/live video of the person you care for: anytime you wish, or only when there is an alert (for example a fall, or the assisted person leaving the home)?

Anytime □ Only when there is an alert □ Never □

24. Do you have any concerns about the privacy of the assisted person in the case of using real-time/live video?

Yes □ No □

If you have concerns, could you describe them?

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25. Do you think that the assisted person would find it acceptable for you to access the real-time/live video anytime you wish?

Yes □ No □

Could you give me some reasons for your answer?

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26. Do you think that the assisted person should be able to control when they can be observed?
Yes □ No □
Could you give me some reasons for your answer?
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I would now like to show you some images that illustrate the possible ways that the BREATHE system might monitor people in their homes, in order to provide support to carers.

[Show the informal carer images A to D].

27. Which 'masked' video to you prefer?
A. Normal video □ B. Silhouettes □C. Stick figure □ D. Cartoon like □

28. Which masked video do you think the assisted person would accept?
A. Normal video □ B. Silhouettes □C. Stick figure □ D. Cartoon like □

[*Step 2. Demonstrate 'Visualize the current status of the AP'. Close the video box, to remove video from screen. Click on the bell icon to remove the box with notifications. Once in 'Dashboard', click on 'Status'*]

On the screen, you can see:

- Information about the level of activity of the assisted person (equal to amount of time spent in the different rooms of the house. '20% higher' means that the overall activity level of the last day is 20% higher than the average of the last month.
- Information about bathroom occupancy. This is the number of times the assisted person entered the bathroom during the day compared to the average of the last month.
- Information about sleeping patterns and nightly activity.
- Information about the assisted person leaving the house.
- Information about use of kitchen appliances.

In the final version of the BREATHE system, when you click on one of the round-bordered squares, you can access more detail on that specific aspect. The five activities shown can be changed for each informal carer. For example, I could be more interested in 4 of the five activities (let's say level of activity, bathroom occupancy, nightly activity and leaving the home' and add a different fifth activity (let's say 'watching TV').

29. Are you interested in information displayed for activity during the day, activity during the night, or both?

Activity during the day □ Activity during the night □ Both □

30. Are you interested in information displayed for the previous day, the previous week, or trends from the last month?

Previous day □ Previous week □ Trends from the last month □

31. Are there any relevant activities that are important for you to know about regarding the status of the assisted person that we have not included?

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32. Can you rank the top 5 activities that could be displayed on the current status of the assisted person?

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[*Step 3. Configuring the pre-defined alerts from the assisted person. Click on 'Dashboard' Click on 'Configuration' (the cog-shaped icon on the top right)*]

An alert is a real-time notification that arrives on your smart phone or on your computer. You can be notified about any detected activity. It is not recommended to set up the system so that you are alerted by any detected activity, as you will have a high volume of alerts and it will reduce the impact of individual alerts from the system.

[*Have a printed list of the alerts that can be sent by the system ready. Show the informal carer the printed list of alerts*]

33. Which of the alerts listed are the most important for you? [*If the informal carer identifies more than 5 alerts, ask them to rank their top 5 alerts in order of importance*]

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34. Are there any alerts not listed that you would like to see included?

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35. Do you like the ease with which alerts can be set?

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36. If information could be sent to you about X, would you prefer the information to be:

a. Sent to your Smartphone automatically (like a text message) □
b. Available for you to look at whenever you like (like looking at a webpage in your own time) □
c. Neither □
d. Both □

[*Step 4. Completion of self-assessment questionnaires*]

37. If you were using the BREATHE system, and it asked you to spend a few minutes to complete on-screen questionnaires as part of the system, would you be prepared to do this? *[For example, the questions might be about whether you needed any information about X's condition]*

Yes □ No □

Could you provide some more detail about your answer?

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38. Similarly, if the system worked in a way that meant you had to complete brief on-screen diaries, would you be prepared to do this? *[For example, the questions might be about how you felt that day about your caring role.]*

Yes □ No □

Could you provide some more detail about your answer?

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39. As part of the study we are also aiming to have individual's complete questionnaires around key areas of the caregiving experience. Below we have outlined some of the areas we aim to assess in the main trial. Would you be willing to be assessed on these areas and spend time necessary to complete brief questionnaires assessing these areas on a regular basis?
[*Table will be guided and completed by the researcher in response to participant answers*]

No.	Area	Relevance to carer Y/N	Complete on a regular Basis Y/N	Rank Yes responses in Priority from (1-9)
1	Caregiver confidence/self-efficacy			
2	Positive Aspects of Caring			
3	Caregiver burden			
4	Emotional response to caregiving			
5	Depression			
6	Anxiety			
7	Stress			

40. How long would you be willing to spend answering assessment data (e.g. 10, 20, 30, 60

minutes)?

……

41. Would you prefer to answer assessment data once a week, once every two weeks, or once a month?

Never □ Once a week □ Once every two weeks □ Once a month □

[*Print out a copy of the Zarit Burden Interview and the BARTHEL Index. Ask that the informal carer completes these questionnaires. Do not focus on the individual's end score of the questionnaires in this interview. Ask the informal carer to read through the questionnaire and then answer the following questions*]

42. Would you find it acceptable to complete an instrument such as the Zarit Burden Interview? If yes, how often?

Never □ Once a week □ Once every two weeks □ Once a month □

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43. In addition to your answers above would it be useful to you to know about the social activity of the assisted person? Which activities in particular? *[for example going out, talking on the telephone, having visitors]*

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44. Would you want health professionals to see any of the monitored data about X, for example data about activity levels or a record of any emergencies?

Yes □ No □

45. If yes, what kinds of information would be useful to send to a health professional?

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SECTION C – YOUR ROLE AS A CARER

As you know, this project is about designing some technology that might help to support carers. So, we would like to ask you about some of your experiences as a carer, to help us to understand what you think the real needs are for this kind of technology. So, thinking about your role as a carer:

46. What are the main things that cause you the most worry about X, and what do you think might help with these? [*if needed, some examples are: what financial/practical support you receive, any emergency when X is alone at home, the quality of care that others provide to X, how to deal with acute episodes relating to X's LTC, what to do if X's condition gets worse*]

Main Issues Causing Worry about X:

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What might help:

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47. What are your main concerns you have in relation to yourself as a caregiver, and what do you think might help with these?

[*if needed, some examples are: time pressure, your own health and wellbeing, your knowledge of X's LTC, your social life, how to seek support, how to cope with current or*

future situations]

Main concerns:

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What might help:

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SECTION D – THE BREATHE SYSTEM GIVING GUIDANCE & SUPPORT

As we have described already, the BREATHE system could provide you with monitoring information about X. However, BREATHE could also potentially provide you with guidance and support as a carer.

48. Do you think it would be useful if the system could provide you with information about X's long term condition? (*e.g. how to deal with particular aspects of their care, or what to do in an emergency)*

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49. If yes, what kinds of information do you think could be useful?

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50. Would you want the system to provide support to X if you were not available? *[for example, contact numbers for services, or a way to alert another person that help were needed]*

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Some carers find that caring for someone with a Long Term Condition can affect their health and wellbeing.

51. Do you think it could be useful if the BREATHE system could monitor the health and wellbeing of carers in relation to their caring role? *For example, the system could regularly ask the carer about their health and wellbeing and provide some relevant resources to help them based on their answers.*

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52. Do you think that it would be useful if the system could help carers to get in touch with other carers for peer support?

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SECTION E – ACCEPTABILITY OF THE BREATHE SYSTEM

This final part is about how the technology might be provided, and how people might be involved in using it.

53. If you were interested in using this system, who do you imagine might provide it and pay for it?

Private purchase □ Paid for by the government □
Private health insurance □ Other □

If you selected the 'other' option could you provide further information about who should provide and pay for the BREATHE system?

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54. If you were interested in using this system, would you be happy to install it in X's home if you were given enough training?

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[*The next section should only be asked of carers living with the assisted person*]

Finally, we would like to ask you some questions about how acceptable you find the idea of the

BREATHE system being installed in your home.

55. Do you accept having cameras installed in the home?

Yes □ No □ [If no, skip to Question 57]

56. Which rooms in the home would you like a camera installed in? [*Interviewer complete the following table with the informal carer*]

Room	Camera Y/N	Number of cameras acceptable
Bedroom		
Bathroom		
Living room		
Dining room		
Kitchen		
Hall		
Conservatory		

57. Do you accept having sensors installed in the home?

Yes □ No □

58. Which rooms in the home would you like a sensor installed in? [*Interviewer complete the following table with the informal carer*]

Room	Sensor Y/N	Number of sensors acceptable
Bedroom		
Bathroom		
Living room		
Dining room		
Kitchen		
Hall		
Conservatory		

59. Do you accept having a concealed mini-computer installed in your home

Yes □ No □

60. Please describe the main challenges to installing the BREATHE system. Are there any barriers to installing the system in your home?

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Thank you. That is the end of our questions.

61. Is there anything else you would like to ask, or anything else you would like to tell us?

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62. Is there anything else you would like to ask, or anything else you would like to tell us?
    a. Your attitude to technology in the home
    b. Your experience as a carer

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Thank you very much for taking part in this research, we value your views and will respect your privacy by keeping your answers anonymous. We will only use this information in relation to the BREATHE project.

Interview schedule for assisted person

Thank you for agreeing to take part in this study. Your involvement will help us to understand what potential users of the BREATHE technology think about it, and will indicate how to make the technology as useful as possible for carers of people who have Long Term Conditions (LTCs). We will be asking carers what they think too, but this is an opportunity for you to tell us what you think from your point of view as someone who has a long-term condition. Do feel free to ask any questions during the session – the interviewer will be happy to provide you with more information about the work and explain the questions in more detail.

There are 4 SECTIONS IN THIS INTERVIEW (A – D), with a total of 31 questions.

SECTIONS	DESCRIPTION
SECTION A ABOUT YOUR CIRCUMSTANCES (19 QUESTIONS)	In Section A, we would like to ask you some questions about you and your circumstances. This will help us to understand your views, and will help us to make the best use of the answers that you provide.
SECTION B THE BREATHE SYSTEM AND MONITORING (32 QUESTIONS)	Section B asks for your feedback on a demonstration prototype of the working BREATHE solution.
SECTION C YOURSELF AND YOUR	Section C asks about some of your experiences as someone who has care provided to them, to help us understand what you think

CARER (2 QUESTIONS)	the real needs are for this kind of technology.
SECTION D ACCEPTABILITY OF THE BREATHE SYSTEM (9 QUESTIONS)	Questions about the acceptability of installing the BREATHE system in the home.

SECTION A – ABOUT YOUR CIRCUMSTANCES

In Section A, we would like to ask you some questions about you and your circumstances. This will help us to understand your views, and will help us to make the best use of the answers that you provide. Your answers will only be used anonymously – your name will not be associated with any comments that you make.

1. Your gender Male □ Female □

2. Your date of birth ……..

3. Where do you live? (Place name, e.g. "Dublin")
…….

4. Who is the person who cares for you (your "informal carer")?
Husband □ Wife □ Son □ Daughter □ Grandchild □

Other (please state)
…….

5. How many hours a week does this person care for you?
Approximately ……hours

6. I understand that you have at least one Long Term Condition. What type of condition(s) do you have?
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7. How would you describe your current health status?
Excellent □ Good □ Average □ Fair □ Poor □

8. Do you live with the person who provides your care?
Yes □ No □

9. If you do not live with the person who provides your care, how far away do they live?
……
……

Miles □ Kilometres □

10. If you do not live with the person who provides your care, do you live alone?
Yes □ No □

11. How often are you in contact with your carer by phone?
Every day □ 2 or more times a week □ Once a week □
2 or more times a month □ Once a month □ Less often than once a month □

12. Do you currently have any home help or social care support, in addition to your informal carer?
Yes □ No □

If yes, please specify:
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13. Do you have any medical cover? e.g. medical card, private health insurance
Yes □ No □

If yes, please specify:
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IT RELATED QUESTIONS:

Now we have a few questions about using technology:

14. Do you ever use the internet?
Yes □ No □ [if no, go to question 19]

15. If you do use the internet, what type of internet connection do you have?
Broadband □

Other (please specify):

……

16. If you do use the internet, what device(s) do you use for this?
Desktop computer □ Laptop □ Smartphone □
Tablet computer, like an iPad □
Other (please specify):
……

17. If you do use the internet, how confident do you feel when you use the internet?
Very confident □ Quite confident □ Neutral □
Not very confident □ Not confident at all □

18. If you do use the internet, how often do you use it?
Every day □ Every week □ About once a month □
Less than once a month □

19. Do you or the person who provides your care already use any assistive technology (for example any technology which helps with practical or medical needs, or which monitors safety or health at home, including mobile phone "apps")?
If yes, please specify:

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SECTION B – The BREATHE SYSTEM AND MONITORING

The idea of the BREATHE system, which is being designed, is to support carers by doing two things:

- Providing some information to a carer from some monitoring equipment in the home of the person with a Long Term Condition – this would reassure a carer, and let them know if there were any problems or emergencies.
- Providing some information and support to the carer so that they would know how best to provide care to the person with a Long Term Condition.

Now we would like to demonstrate the different functions of the BREATHE system and then ask you for your feedback on what you have seen.

STEP 1. Demonstrate 'Access to adapted video signals in real time'.

[Log in to web tool and access 'Dashboard']

This is the website that an informal carer will log in to and view information about what is happening in your home. This prototype will show the relevant events with information summarizing the activity of the informal carer. You can see:
1. A vertical menu on the left side
2. An example of a graphical representation
3. A component with example 'Important Notes'
4. Two icons: a notifications icon – a bell in red background with '1'; and an icon to access configuration/system settings.

A smart phone version is currently being developed where you can access some common content with the website, but not everything because of the limitations of the device.

[Click on the notifications icon Select the 'fall' notification and Click 'live view' to access the video. In Ireland, at this point the interviewer will initiate a skype call with the 2nd interviewer in another room. This will be done via a laptop and a smartphone to demonstrate on-demand live video. The interviewer will remain in the room with the carer. They will open up the skype facility on their laptop and they will ring their colleague using skype. It is important for interviewer to ensure that they have their skype account up to date and accessible for the meeting, likewise for their colleague. Their colleague will be situated in a nearby room or hall, and will answer the skype calling using their smartphone. This will demonstrate to the carer that they can see the other person in the other room and provides a real example of the 'live' camera feed they have just seen on the video demonstration].

20. Would you find it acceptable for your informal carer to watch real time/live video of you?
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21. If yes, in which rooms would you be happy to be monitored? And which you would not? Please explain why?
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22. When do you think an informal carer should be able to access real-time/live video of the person they care for/support: anytime you wish, or only when there is an alert (for example a fall, or you leaving the house)?
Anytime □ Only when there is an alert □ Never □

23. Do you have any concerns about your privacy in the case of using real-time/live video?
Yes □ No □

If you have concerns, could you describe them?

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24. Would you like to be able to control when you can be observed?
Yes □ No □

Could you give me some reasons for your answer?

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I would now like to show you some images that illustrate the possible ways that the BREATHE system might monitor people in their homes, in order to provide support to carers. [Show the assisted person images A to D].

25. Which 'masked' video do you prefer?
A. Normal video □ B. Silhouettes □ C. Stick figure □ D. Cartoon like □

STEP 2. Demonstrate 'Carer Visualizing the current status of the AP'

[Close the video box, to remove video from screen. Click on the bell icon to remove the box with notifications. Once in 'Dashboard', click on 'Status']

On the screen, you can see:

- Information about the level of activity of an assisted person (equal to amount of time spent in the different rooms of the house. '20% higher' means that the overall activity level of the last day is 20% higher than the average of the last month.
- Information about bathroom occupancy. This is the number of times the assisted person entered the bathroom during the day compared to the average of the last month.
- Information about sleeping patterns and nightly activity.

- Information about the assisted person leaving the house.
- Information about use of kitchen appliances.

In the final version of the BREATHE system, when you click on one of the round-bordered squares, you can access more detail on that specific aspect. The five activities shown can be changed for each informal carer. For example, I could be more interested in 4 of the five activities (let's say level of activity, bathroom occupancy, nightly activity and leaving the home' and add a different fifth activity (let's way 'watching TV').

26. Are you interested in information displayed for activity during the day, activity during the night, or both?

Activity during the day □ Activity during the night □ Both □

27. Are you interested in information displayed for the previous day, the previous week, or trends from the last month?

Previous day □ Previous week □ Trends from the last month □

28. Are there any relevant activities that are important for a carer to know about regarding your status that we have not included?

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29. Can you rank the top 5 activities that you would like to see displayed as your current status, to your caregiver?

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STEP 3. Configuring the pre-defined alerts from the assisted person

[Click on 'Dashboard'. Click on 'Configuration' (the cog-shaped icon on the top right)].

An alert is a real-time notification that arrives on your smart phone or on your computer. You can be notified about any detected activity. It is not recommended to set up the system so that

you are alerted by any detected activity, as you will have a high volume of alerts and it will reduce the impact of individual alerts from the system. [Have a printed list of the alerts that can be sent by the system ready. Show the assisted person the printed list of alerts].

30. Which of the alerts listed are the most important for you? [If the assisted person identifies more than 5 alerts, ask them to rank their top 5 alerts in order of importance]

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31. Are there any alerts not listed that you would like to see included?

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32. Do you like the ease with which alerts can be set?

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33. If information could be sent to X about you, would you prefer the information to be:

e. Sent to a Smartphone automatically (like a text message) □
f. Available for them to look at whenever they like (like looking at a webpage in your own time) □
g. Neither □
h. Both □

STEP 4 Demonstrate the app for the assisted person

[Start up the Assisted Person app on the tablet]
This is your control panel. This is a way that you can personally control the video monitoring system. You can turn on and off the cameras at your discretion.

[Demonstrate how to turn off and on the cameras]
You can also send a notification to your carer to ring you.

[Demonstrate how to contact the informal carer]
When you send a notification to your carer, he or she will get a receipt of message.

34. Would you find it useful to be able to turn on and off the cameras?
Yes □ No □

Could you give me some reasons for your answer?
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35. Did you find it easy to turn on and off the cameras on the control panel?
Yes □ No □

Could you give me some reasons for your answer?
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36. Would you find it useful to be able to send a message to your informal carer?
Yes □ No □

Could you give me some reasons for your answer?
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37. Did you find it easy to send a notification to your informal carer on the control panel?

Yes □ No □

Could you give me some reasons for your answer?

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38. How confident do you feel about using the control panel?

Very confident □ Quite confident □ Neutral □

Not very confident □ Not confident at all □

Could you give me some reasons for your answer?

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39. Did you find the control panel easy to use?

Yes □ No □

Could you give me some reasons for your answer?

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40. Are there any other aspects of the BREATHE system that you would like to control that we have not included on the control panel?

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Step 5. Completion of self-assessment questionnaires

41. If you were using the BREATHE system, and it asked you to spend a few minutes to complete on-screen questionnaires as part of the system, would you be prepared to do this? [For example, the questions might be about whether you had eaten a meal.]

Yes □ No □

Could you provide some more detail about your answer?

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42. Similarly, if the system worked in a way that meant you had to complete on-screen brief diaries, would you be prepared to do this? [For example, the questions might be about how you were feeling or whether you needed any help.]

Yes □ No □

Could you provide some more detail about your answer?

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43. As part of the study we are also aiming to have individual's complete questionnaires around key areas of the caregiving experience. Below we have outlined some of the areas we aim to assess in the main trial. Would you be willing to be assessed on these areas and spend time necessary to complete brief questionnaires assessing these areas on a regular basis? [Table will be guided and completed by the researcher in response to participant answers]

No.	Area	Relevance [Y/N]	Complete on a regular basis [Y/N]	Rank yes responses in Priority from (1-5)
1	Assisted Person (AP) memory and behaviour checklist			
2	Functional ability of AP			
3	Activities of daily living of AP			
4	Depression (both caregiver and AP)			
5	Anxiety (both caregiver and AP)			
6	Stress			
7.	Quality of Care			
8.	Perceived social support			

44. How long would you be willing to spend answering assessment data (e.g. 10, 20, 30, 60 minutes)?

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45. Would you prefer to answer assessment data once a week, once every two weeks, or once a month?

Never □ Once a week □ Once every two weeks □ Once a month □

[Print out a copy of the BARTHEL Index. ES+UK: Ask that the assisted person completes these questionnaires. Do not focus on the individual's end score of the questionnaires in this interview. IE: Ask the assisted person to read through the questionnaire and then answer the following questions]

46. Would you find it acceptable to complete an instrument such as the Barthel Index?

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47. Would you be happy for a health professional to see some of the monitored data about you, for example data about activity levels or a record of any emergencies?

Yes □ No □

48. If yes, what kinds of information would be useful to send to a health professional?

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49. As well as visual information, the BREATHE system could send information reports to X, perhaps on a Smartphone, for example "N is fine today", or "N has not been to the bathroom since yesterday". This information could be based on specific information that you have chosen together in advance. If information could be sent to X about you, would you prefer the information to be:

Sent to a Smartphone automatically (like a text message) □

Available for you to look at whenever you like (like looking at a webpage in your own time)? □

Neither □

Both □

50. Would you want the system to provide some care support to you if your carer was not available? [for example, contact numbers for services, or a way to alert another person that help were needed]

Yes □ No □

51. If yes, what sort of care support would be useful for you?

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Section C – Yourself and your carer

As you know, this project is about designing some technology that might help to support carers. So, we would like to ask you about some of your experiences as someone who has some care provided to them, to help us to understand what you think the real needs are for this kind of technology. So, thinking about the care that your informal carer provides:

52. What do you think causes concern for your carer, in relation to their role as a carer? [if needed, some examples are: time pressure, X's own health and wellbeing, X's knowledge of your LTC, X's social life, how to seek support, how to cope with current or future situations]

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53. What do you think might help to support your carer in their role?

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Section D – ACCEPTABILITY OF THE SYSTEM

This final part is about how the technology might be provided, and how people might be involved in using it.

54. If you or your informal carer were interested in using this system, who do you imagine might provide it and pay for it?

Private purchase □ Paid for by the government □

Private health insurance □ Other □

If you selected the 'other' option could you provide further information about who should

provide and pay for the BREATHE system?

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Finally, we would like to ask you some questions about how acceptable you find the idea of the BREATHE system being installed in your home.

55. Do you accept having cameras installed in the home?

Yes □ No □ [If no, skip to Question 57]

56. Which rooms in the home would you like a camera installed in? [Interviewer complete the following table with the informal carer]

Room	Camera Y/N	Number of cameras acceptable
Bedroom		
Bathroom		
Living room		
Dining room		
Kitchen		
Hall		
Conservatory		

57. Do you accept having sensors installed in the home?

Yes □ No □ [If no, skip to Question 59]

58. Which rooms in the home would you like a sensor installed in? [Interviewer complete the following table with the informal carer]

Room	Sensor Y/N	Number of sensors acceptable
Bedroom		
Bathroom		
Living room		
Dining room		
Kitchen		
Hall		
Conservatory		

59. Do you accept having a concealed mini-computer installed in your home?

Yes □ No □

60. Please describe the main challenges to installing the BREATHE system. Are there any barriers to installing the system in your home?

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Thank you. That is the end of our questions.

61. Is there anything else you would like to ask, or anything else you would like to tell us?

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62. Is there anything else you would like to ask, or anything else you would like to tell us?

- Your attitude to technology in the home.
- Your experience as someone receiving informal care.

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Thank you very much for taking part in this research, we value your views and will respect your privacy by keeping your answers anonymous. We will only use this information in relation to the BREATHE project.

4.6.9 Technological deployment

4.6.9.1 Scenario

Since the aim of the pre-trials is to conduct some interviews with real end-users (assisted persons and their main carers) in order to get a first feedback about the expected final solutions (currently under development), at this time of the project it has not sense to waste our time deploying complicated infrastructures which reduces the time spent with users. For that reason, the components installed in the pre-trials environments which will be deeply tested during the pre-trials are:

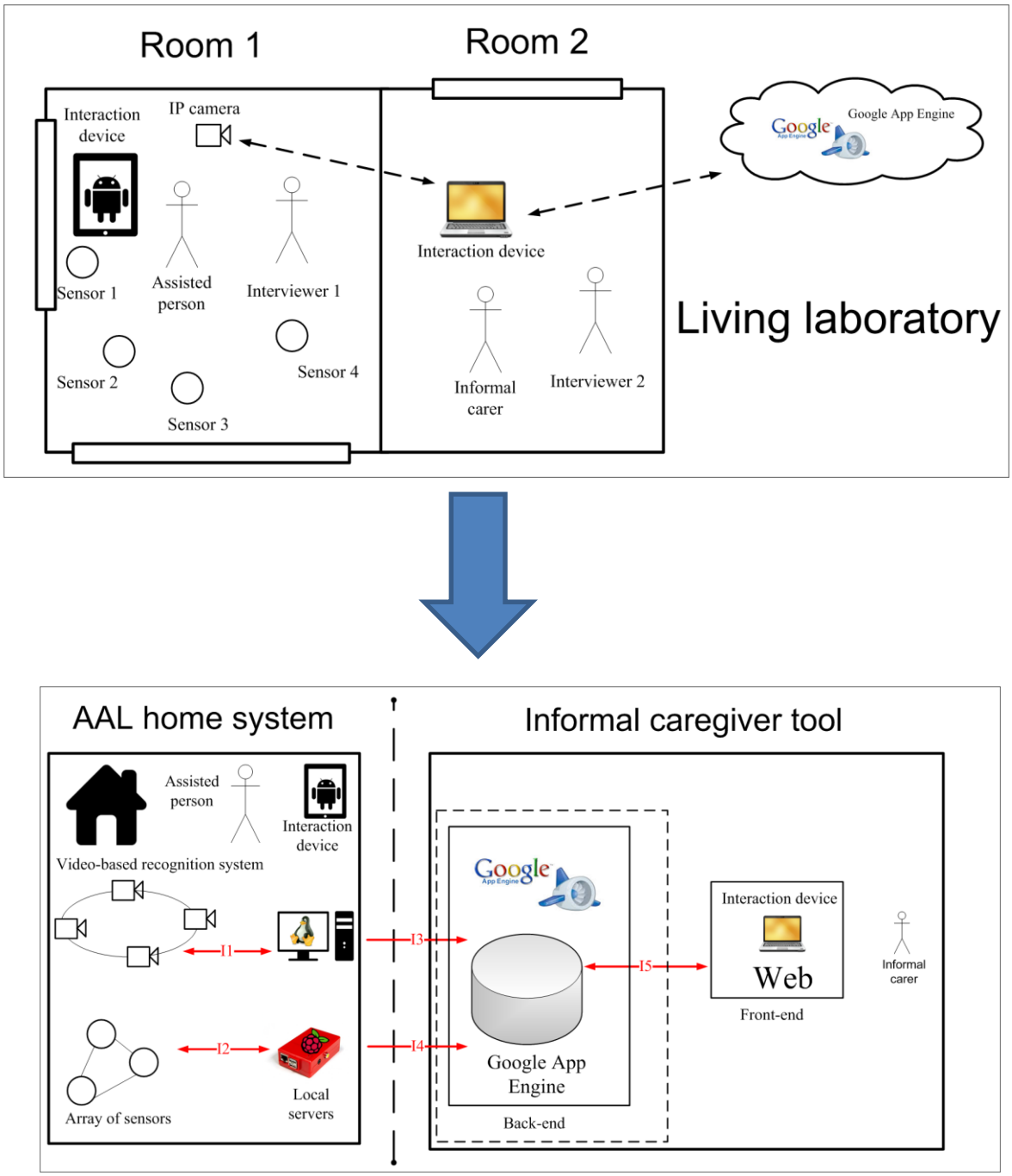

Figure 7 - Scenario deployed and simulated architecture during pre-trials

Specifically, the elements which will be ready for testing during the pre-trials are:

AAL HOME SYSTEM			
Element	**Number of devices**	**Location**	**Aim**
Indoor video-based monitoring system			
IP camera (with webserver enabled)	1 per room	Room where the AP will be interviewed. Ceiling of each room.	To simulate during trials the feature of real-time access from a remote platform. Instead of showing sample videos and in order to improve the understanding of the IC about the final solution, we will connect to the IP camera at some specific time of the interview.
Array of multi-function sensors			
Sensors	4 sensors per room	Room where the AP will be interviewed. Properly distributed along the room.	Although the sensors will not be gathering neither exchanging date between them (simulation) we want to ask the AP about his/her impression as consequence of being surround by some technological devices. The sensors available in the room where the AP will be interviewed should be the same we are planning to set up the final array of multi-function sensors. Furthermore, the AP should not know that the sensors are not working.
Interaction device			
Low cost tablet PC and holder/stand	1 per room	Room where the AP will be interviewed. Commonly used area.	Enable the AP to interact with the some screens which will be running in the interaction device and to discuss about his/her feeling.
INFORMAL CAREGIVER TOOL			
Back-end			
Google App engine datastore	1 datastore per team: AP and IC	Google cloud infrastructure	To store RAW data automatically gathered from the AP´s home and to feed the informal caregiver tool
Front-end			
Laptop or desktop PC	1 per room	Room where the IC will be interviewed. Commonly used area within the reach of the IC.	To access to the informal caregiver tool (home version) in order to get a better understanding about the screens and GUI components available. The laptop/desktop has to be connected to the Internet so that Internet access from the room where the IC will be interviewed is required.

Table 9 - Available elements for testing

4.6.10 Functionalities

The AAL home system is the system in charge for gathering information of the AP in an automatically way (without human intervention) thanks to the indoor video-based monitoring system and the array of multi-function sensors. Although it is planned that different activities, alerts and events will be collected at the end of the project (final release), the challenge for the first release (pre-trial) is to only collect information about the location (room level) of the AP at home and to set up all the involved interfaces which will enable the exchange of data and information between components.

The following table matches the features which will be tested during the pre-trials and the motivation of the BREATHE Consortium for delivering them in the first release:

Actor	Use case name	ID	Short-description	Motivation	How	Responsible
Informal caregiver	Home version of the IC caregiver tool					
	Access to adapted video signals in real-time	UC-W-4	After receiving an alert from the AP´s home (notification in the IC tool), the IC will be able to watch in real-time what the AP is doing.	Technological acceptance: to collect some feedback from the IC after using the informal caregiver tool in order to find out the real added value of that kind of platforms.	An alert will be simulated so a notification will pop-up in the home version of the IC tool. Then the IC will be able to connect (in real-time) to the IP camera installed in the room where the AP is being interviewed.	TSB and KU
	Visualize the current status of the AP and IC	UC-W-14	After accessing to the appropriate section into the informal caregiver tool, the application will show to the carer in a very user-friendly way his/her current status (burden and emotion) as well as the current status of the AP (mobility, social, mental and functional). During pre-trials, the information will be simulated.		The section which will show information about the current status of both the AP and IC will be ready but the information contained simulated. Additionally and before the trials, we have to discuss how to transform the list of activities gathered from the AP´s home into the following categories: mobility, social, mental and functional.	TSB and Designability
	Configure predefined alerts of the AP	UC-W-15	After accessing to the appropriate section into the informal caregiver tool, the IC will set up those relevant alerts which will send automatic notifications from the AP´s home to both versions of the informal		Any implementation will be required. The aim of this is to discuss with the main carers the number of alerts they want to receive and with which frequency	TSB, Designability and KU

Actor	Use case name	ID	Short-description	Motivation	How	Responsible
			caregiver tool (mobile and home).		so that we can manage the whole process.	
	Complete self-assessment questionnaires	UC-W-16	After accessing to the appropriate section in the home version of the IC tool, the IC will be invited to fill-in some questionnaires in order to measure his/her level of burden in a properly way.		The aim of this UC is to discuss with the IC which is the best way to answer that kind of questions so that the IC can measure his/her level of burden/risk. Additionally, the IC will be answered about the possibility to answer some free and asynchronous questions which give us the opportunity to measure his/her level of emotion.	TSB and ISI
Assisted person		Interaction device				
	AP turns OFF the AAL home system	UC-H-27	After pressing the appropriate option in the interaction device, the AP is able to turn ON/OFF the video-based monitoring system so that he/she can decide when being monitored. The GUI will be ready but not the exchange of information (real control) with the video-based monitoring system.	To see how the assisted person feels when he/she knows that can be monitored in real-time but he/she has to power to decide when and under which conditions.	During pre-trials, the screen with the appropriate GUI will be ready so that the AP can interact with the device. This GUI will not be connected to the video-based monitoring system.	CYB and Des
	AP turns ON the AAL home system	UC-H-29				CYB and Des
	A message is shown in the interaction device to inform the AP that he/she is being	UC-H-32	The interaction device pops-up a message informing him/her that he/she is being monitored in real-time by the main carer.	To see the reaction of the assisted person when he/she knows that is being remotely monitored by the main carer.	During pre-trials, a timer or a hidden component for the AP will trigger the message to the screen. With the interview the	CYB and Des

Actor	Use case name	ID	Short-description	Motivation	How	Responsible
	watched in real-time				idea is to discover if the AP really understand what is happening and he/she agrees for being watched in real-time.	
	The AP sends an alert to the IC in a deliberate way	UC-H-33	After pressing the appropriate option in the interaction device, the assisted person is able to send an alert in a deliberate way in order to call the attention of the main carer.	To discover the real added value of this feature and under which circumstances it makes real sense.	During pre-trials, the screen with the appropriate GUI will be ready so that the AP can interact with the device.	CYB

Table 10 - Feature vs motivation for testing

4.6.11 Demonstration videos

Sometimes the assisted person is unable to reach the places where the pre-trials are being carried out due to a lack of mobility or other personal circumstances. In order to avoid exclude or harm them, we have recorded some demonstration videos[6] which explains the BREATHE platform and lets the interviewers to carry through the interview with the AP as they will be located in the living laboratories.

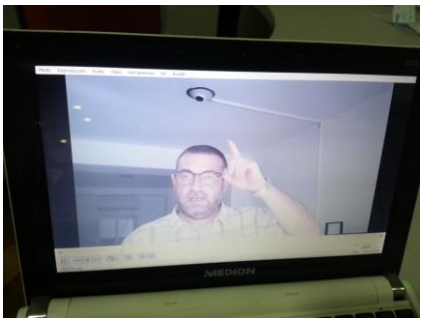

Figure 8 - Demonstration video snapshot

4.6.12 Training material for interviewers

Before the pre-trials stage will be launched, it is mandatory to train the staff people in charge for driving the interviews so that the objectives pursued by the pre-trials will be achieved. For that reason, the BREATHE Consortium have prepared the following training material[7]:

- Webinar on the Informal carer tool (conducted by TSB on August 6th 2014).
- Webinar on the interaction device (conducted by Cybermoor Services on August 6th 2014).

The main objectives of the online training sessions are:

- To explain how the current version (first release) of both the informal caregiver tool and the interaction device works.
- To give some tips and indications on the type of feedback the BREATHE project Consortium would like to receive from the involved actors (APs and ICs).

[6] [Redmine, restricted] http://redmine.breathe-project.eu/projects/breathe/dmsf?folder_id=170

[7] [Redmine repository, restricted] http://redmine.breathe-project.eu/projects/breathe/dmsf?folder_id=158 (Accessed on July, 2014)

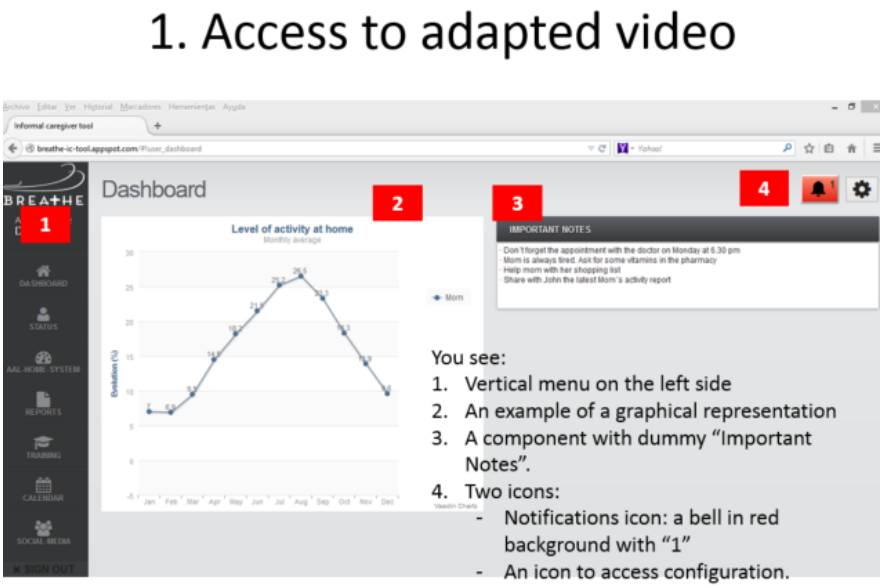

Figure 9 - Snapshot of the training session about the IC tool

4.6.13 Practical considerations

- The informal caregiver can only watch the real-time video after an alert even and always with the consent of the assisted person.
- During pre-trials, both the indoor video-based monitoring system and the array of multi-function sensors will be able to recognise only activities related to the location (room level) of the assisted person at home and send a textual description/message to the informal caregiver tool (e.g. going to the toilet, etc.)
- Fake videos will be developed by KU partner just to demonstrate the service for the pre-trial and getting some feedback about the user´s acceptance/tolerance which means that no video images will be stored on the cloud infrastructure of the system for the pre-trial (images will be only buffered for on the local equipment during the time the trial will be carry out).
- PC noise and lights. Elderly users can be very distracted by PC noise and by lights. Similarly lights on the PC and sensors can prompt older people to unplug them at night. These requirements will be taken into account before the acquisition of the components which will be deployed in the AP´s home.
- Power outages as well as low battery alerts from installed devices will not be taken into account during the pre-trial stage but in the trials (second and final release where the software will be configured to automatically restart when power is restored).
- Pre-trials will put the focus on the user´s acceptance/tolerance about the technological deployment in the assisted person´s home as well as the read added-value of the BREATHE platform as a whole. Pre-trials will serve us for discovering how to deploy the technological solution without harming the user´s premises: how the sensors and the cameras will be attached and removed to the environment, which are the limits with wires, etc.

4.7 Ethics and ethical requirements

Although the BREATHE project has established its own Ethics Board (EB)[8], each of the partner sites are governed by different structures and requirements for approval from institutional ethics committees as outlined below.

4.7.1 Ethical committee requirements at partner sites

4.7.1.1 Ireland (TCD and TER)

Ethical approval is required for TCD from the Faculty of Health Sciences Research Ethics Committee (REC) at TCD[9]. Applicants must complete a detailed Ethics Application Form (MS Word, 157 kB)[10] which describes the study aims, objectives and methodologies, alongside any supplementary materials (e.g. participant information sheets, questionnaires) for review at an Ethics Committee meeting (usually held monthly). The outcome of the meeting is usually known within a month and the committee may approve the application with/without amendments or reject the application. If they require amendments, these must addressed and re-submitted to the committee before a letter of official approval will be issued. For the BREATHE study, the process has been split into two separate applications as these will require different methodological approaches and will pose different ethical challenges:

- Application to conduct field pre-trials during WP4 in Ireland:
    - Submission: Friday 6th June 2014.
    - Outcome received from the Ethics Committee: July 15th 2014.
    - Amended proposal resubmitted: July 18th 2014.
    - Final approval from the Ethics Committee[11]: July 31st 2014.

4.7.1.2 UK (CYB and KU)

CYB does not require ethical approval from an external board. Approval for participation was obtained from the Cybermoor Ethics Board for conducting the interviews and focus groups for the user-requirement stage of this research. The BREATHE Ethics Board will provide guidance on ethical issue during this project.

[8] http://breathe-project.eu/en/governance/#Board (Accessed on July, 2014.)
[9] Faculty Research Ethics Committee: http://www.healthsciences.tcd.ie/research-ethics-committee (Accessed on April, 2014).
[10] Download the Ethics application form: http://www.healthsciences.tcd.ie/assets/doc/Ethics-Form-Revised-August%2012%20(3).docx (Accessed on April, 2014).
[11] [Redmine, restricted] http://redmine.breathe-project.eu/projects/breathe/dmsf?folder_id=156 (Accessed on July, 2014)

4.7.1.3 Spain (ISI and TSB)

ISI does not require ethical approval from an external board so will therefore not be required to submit an application for data collection for the user-requirements stage or to conduct the field trials. During the Ethics Board meeting in Dublin, TCD and KU felt that it would be appropriate for ISI to obtain some external input to the ethics of their pre-trial. For that reason, ISI and TSB as Spanish partners agreed to facilitate this external ethics review with the Polytechnic University of Valencia (UPV). Specifically, the review will be conducted by Mrs. María-Pilar Sala-Soriano, a Telecommunications engineer, who has been ethics reviewer in many European AAL Projects. Furthermore, at all stages of the study, the BREATHE Ethics Board will provide guidance and support to the aforementioned person on any ethical aspects of the project. This review will be ready on Tuesday 24th June 2014.

4.8 Pre-trials data protection and data privacy

Overall the Project Consortium will follow EU Directive 95/46/EC on both personal and local data protection laws and will ensure that personal data will be treated in line with that legal directive. In terms of protection of personal data this research Project will enforce the EU Directive 2002/58/EC on Privacy and Electronic Communications (amending Directive 97/66/EC). Within each specific country special attention will be paid to the national laws and regulations derived from this EU Directives, in case they are more restrictive. An outline of these National Laws presented in this below. Where possible, any specific recommendations with regard to the use of cameras (predominantly this is in reference to CCTV use) will be presented.

4.8.1 Ireland (TCD and TER)

In Ireland the collection, storage and utilization of personal data are subject to the provisions outlined in the Irish Data Protection Act 1988 and the Data Protection (Amendment) Act 2003[12,13]. The Acts set out the general principle that individuals should be in a position to control how data relating to them is used. All research conducted must follow the constraints as outlined in this document. In particular, all participants need to provide consent to participate, to be informed as to who will access their data and how data will be stored securely in line with Data Protection guidelines. The Data Protection Commissioner is responsible for upholding the rights of individuals as set out in the Acts, and enforcing the obligations upon data controllers. There are eight rules which must be followed by Data Controllers (individuals/legal person who controls and is responsible for the keeping and use of personal information). The data controller for the pre-trial will be TCD.

[12] Data Protection Act 1988: http://www.irishstatutebook.ie/1988/en/act/pub/0025/index.html (Accessed on April, 2014).

[13] Data Protection Act 2003: http://www.irishstatutebook.ie/2003/en/act/pub/0006/index.html (Accessed on April, 2014).

CCTV and images

Recognisable images captured by CCTV systems are personal data and are therefore subject to the provisions of the Data Protection Acts. The processing of personal data kept by an individual and concerned solely with the management of his/her personal, family or household affairs or kept by an individual for recreational purposes is exempt from the provisions of the Acts. This exemption would generally apply to the use of CCTVs in a domestic environment. However, the exemption may not apply if the occupant works from home.

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4.8.2 UK (CYB and KU)

In the UK, the Data Protection Act 1998 (DPA) is the Act which defines the law on the processing of data on identifiable living people[14]. All research conducted must follow the constraints as outlined in this document. Under this Act, every data controller (e.g. organisation, sole trader) who is processing personal information is required to register with the Information Commissioner's Office (ICO)[15]. Cybermoor is registered with the Data Protection Officer and will be the data controller for the pre-trial.

In this case, the eight principles/rules to the Data Protection Act are:

- Rule 1: Personal data shall be processed fairly and lawfully.
- Rule 2: Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes.
- Rule 3: Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed.
- Rule 4: Personal data shall be accurate and, where necessary, kept up to date.
- Rule 5: Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes.
- Rule 6: Personal data shall be processed in accordance with the rights of data subjects under this Act.

[14] Data Protection Act 1998: https://www.gov.uk/data-protection (Accessed on April, 2014).
[15] Data Protection and Freedom of Information advice: http://ico.org.uk (Accessed on April, 2014).

- Rule 7: Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.
- Rule 8: Personal data shall not be transferred to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.

CCTV and images

The use of images of people is covered by the Data Protection Act, and organisations who use CCTV must comply with the Data Protection Act 1998. The Data Protection Act does not apply to individuals' private or household purposes. For example, if a camera is installed in a home to protect it from burglary, the Act will not apply.

4.8.3 Spain (ISI and TSB)

In Spain, the collection, storage and utilisation of personal data are subject to the provisions outlined in the Organic Law 15/1999 December 13th on the Protection of Personal Data (LOPD) and amendments pertaining to Law 2/2011, March 4th[16]. Under the provisions of these Laws, when an organisation collects personal data, it must inform the individual explicitly beforehand of the following:

- The existence of a file collecting his or her data, the objectives of storing the data and the recipients of this information.
- The mandatory or the optional character of the information collected.
- The consequences of providing or not providing the data.
- The rights to access, rectify, delete or oppose the data stored.
- The identity of the individual responsible for the treatment and the storage of the data or his or her representative.
- If the personal information has been collected indirectly, there is the obligation to inform the person within 3 months from the initial data storage.

CCTV and images

Under the provisions of these laws, images constitute personal data when they refer to identified or identifiable persons. Therefore, personal data protection principles should be applied to the use of cameras under the following circumstances[17]:

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[16] Spanish Data Protection Agency: http://www.agpd.es/portalwebAGPD/canaldocumentacion/publicaciones/common/pdfs/AEPD_en.pdf (Accessed on July, 2014).

[17] Spanish Data Protection Agency. Guide on Video Surveillance: https://www.agpd.es/portalwebAGPD/canaldocumentacion/publicaciones/common/pdfs/guia_videovigilancia_en.pdf (Accessed on July, 2014).

- There is recording, capturing, transmission, preservation or storage of the images, including their reproduction or broadcasting in real time or the processing of the personal data derived from these images.
- These activities refer to the data of identified or identifiable persons.

The LOPD is not applicable to image processing in the personal and domestic spheres, understanding this to be image processing performed by an individual in the context of an exclusively private or family-based activity.

4.8.4 General issues around data protection

Since the raw data automatically gathered from both the indoor video-based monitoring system and the array of multi-function sensors which will be set up in the assisted person´s home will be stored on a cloud infrastructure owned by Google Inc, we have to ensure that the storage of this data is within the EU region and it is in accordance with the EU laws about privacy[18] and its terms of service[19] (Appendix B). Regarding the deployment of the cloud application, this can be done in the United States or in the European Union[20]. BREATHE Consortium will ensure that its deployments and the end-user content will be stored within the European Union so that there will be less network latency since the data will be closer to the end-users.

4.8.5 Insurance and liability

The BREATHE platform prototype will be validated with real end-users in the partner countries during the field pre-trials. During the field pre-trials, the research sites will be responsible for prior arrangements for insurance and indemnity: TCD is covered by the College Professional Indemnity Scheme[21] and Cybermoor and ISI have public liability insurance.

4.9 Conclusion

4.9.1 Involved partners and expected roles

Partner	Responsibilities
TSB	• Draw up the pre-trial initial guide document and coordinate the job between partners. • Development of the interfaces: I3, I4 and I5. • Design, development and deployment of the server side system of the IC tool on the Google infrastructure.

[18] Google terms of privacy: http://www.google.com/policies/privacy/ (Accessed on May, 2014).
[19] Google terms of service: https://developers.google.com/cloud/terms/ (Accessed on May, 2014).
[20] An application can run in the USA or in the EU. If you have an App Engine Premier Account, you choose where the application runs when you create it in the Administration Console. Non-premier users can run their application from the EU if they fill out a request form (https://docs.google.com/spreadsheet/viewform?formkey=dDllb3FHLS1IdXVIcjVKR3FScklka1E6MQ) (Accessed on May, 2014).
[21] Royal College of Nursing: https://www.rcn.org.uk/support/legal/indemnityscheme (Accessed on April, 2014).

	• Development of the home version of the IC tool (those use cases tagged for the first release). • Involved in the pre-trials carried out in Spain: set up the Spanish testing environment. • Draw up the technical report highlighting those problems which may arise as consequence of carrying out the installation/uninstallation of the BREATHE platform in a real environment.
KU	• Development of the interface I1. • Development and deployment of the indoor video-based monitoring system. • Development of those algorithms which will monitor the location of the AP at home (room level). • Ethics review and approval of the trials. • Responsible for filling in and submit the ethics application form to the ethics committee (if proceed). • Responsible for implementing the required amendments in the submitted ethics application form (if proceed) until approval. • Involved in the pre-trials carried out in UK: set up the UK testing environment.
ISI	• Guiding and implementation the whole process of the pre-trials carried out in Spain (elaboration of the required material, recruitment of the target users, etc.). • Ethics review and approval of the trials. • Interviewer (main driver, recruitment, note taker, etc.) in the Spanish pre-trials.
TCD	• Guiding and implementation the whole process of the pre-trials carried out in Ireland (elaboration of the required material, recruitment of the target users, etc.). • Responsible for filling in and submit the ethics application form to the ethics committee. • Responsible for implementing the required amendments in the submitted ethics application form (if proceed) until approval. • Ethics review and approval of the trials. • Responsible of the writing and release of the D4.2 (pre-trials report).
Designability	• Development of the interface I2. • Development and deployment of the array of multi-function sensors. • Development of those algorithms which will monitor the location of the AP at home (room level). • Involved in the development (external advisor) of those GUIs which will be running in the interaction device. • Involved in the pre-trials carried out in UK: set up the UK testing environment. • Draw up the technical report highlighting those problems which may arise as consequence of carrying out the installation/uninstallation of the BREATHE platform in a real environment.
CYB	• Development of the Android application which will be running in the interaction device (those use cases tagged for the first release). • Implementation of the pre-trials carried out in United Kingdom (elaboration of the required material, recruitment of the target users, etc.).
TER	• Implementation of the pre-trials carried out in Ireland: set up the Irish testing environment. • Draw up the technical report highlighting those problems which may arise as consequence of carrying out the installation/uninstallation of the BREATHE platform in a real environment.

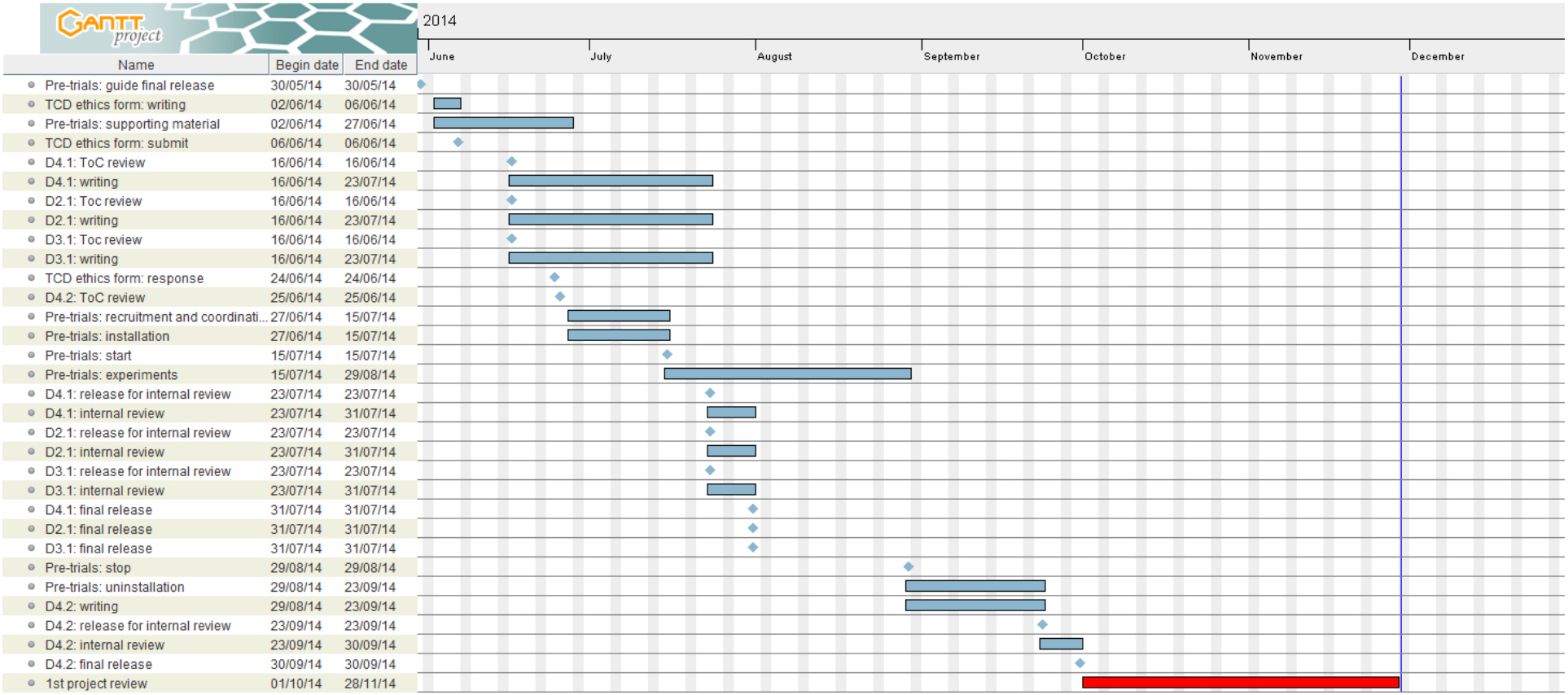
Table 11 - Involved partners and expected roles

4.9.2 List of specific steps

Step	Task	Deadline	Responsible
0	Document describing and defining in detail the pre-trials: pre-trials guide.	Friday 30th May 2014	TSB
1	Complete and submit the TCD ethics application form.	Friday 6th June 2014	TCD
2	D4.1: table of contents (ToC) ready for internal review.	Monday 16th June 2014	ISI
3	D2.1: table of contents (ToC) ready for internal review.	Monday 16th June 2014	KU
4	D3.1: table of contents (ToC) ready for internal review.	Monday 16th June 2014	TSB
5	Response from the TCD ethics committee. Amendments and update the TCD ethics application form in accordance (if proceed) until approval.	Tuesday 24th June 2014	TCD
6	External ethics review from the Polytechnic University of Valencia.	Tuesday 24th June 2014	TSB and ISI
7	D4.2: table of contents (ToC) ready for internal review.	Wednesday 25th June 2014	TCD
8	Preparation of the supporting material for conducting the interviews: inform consent, questionnaires, detailed script, roles, templates, etc.	Friday 27th June 2014	ISI
9	End-users recruitment, selection and schedule the visits to the test laboratories depending on their availability	Friday 15th July 2014	ISI: Spain TCD: Ireland CYB: UK
10	Set up the pre-trial infrastructure (technical installation and configuration) in the testing environments.	Friday 15th July 2014	TSB: Spain TER: Ireland CYB/Des: UK
11	Technical report about the main findings, problems and concerns as consequence of carrying out the installation of the BREATHE platform in a real environment (part of D4.2).	Friday 22nd July 2014	TSB: Spain TER: Ireland Des: UK
12	D4.1: release for the internal review.	Wednesday 23rd July 2014	ISI
13	D3.1: release for the internal review.	Wednesday 23rd July 2014	KU
14	D2.1: release for the internal review.	Wednesday 23rd July 2014	TSB
15	D4.1: final release after internal review.	Thursday 31st July 2014	ISI
16	D3.1: final release after internal review.	Thursday 31st July 2014	KU
17	D2.1: final release after internal review.	Thursday 31st July 2014	TSB
18	Pre-trials experiments (interviewing end-users).	Friday 29th August 2014	ISI: Spain TCD: Ireland CYB: UK
19	Uninstallation of the pre-trial infrastructure and update of the technical report done in step 6	Tuesday 23rd September 2014	TSB: Spain TER: Ireland Des: UK
20	Release for the internal review of the deliverable D4.2: pre-trials report.	Tuesday 23rd September 2014	TCD

21	Final release of the deliverable D4.2: pre-trials report (which involves the following steps: writing, internal review and release).	Tuesday 30th September 2014	TCD
22	First project review in Valencia (Spain).	October 7th 2014	All

Table 12 - List of specific steps



Name	Begin date	End date
Pre-trials: guide final release	30/05/14	30/05/14
TCD ethics form: writing	02/06/14	06/06/14
Pre-trials: supporting material	02/06/14	27/06/14
TCD ethics form: submit	06/06/14	06/06/14
D4.1: ToC review	16/06/14	16/06/14
D4.1: writing	16/06/14	23/07/14
D2.1: Toc review	16/06/14	16/06/14
D2.1: writing	16/06/14	23/07/14
D3.1: Toc review	16/06/14	16/06/14
D3.1: writing	16/06/14	23/07/14
TCD ethics form: response	24/06/14	24/06/14
D4.2: ToC review	25/06/14	25/06/14
Pre-trials: recruitment and coordinati...	27/06/14	15/07/14
Pre-trials: installation	27/06/14	15/07/14
Pre-trials: start	15/07/14	15/07/14
Pre-trials: experiments	15/07/14	29/08/14
D4.1: release for internal review	23/07/14	23/07/14
D4.1: internal review	23/07/14	31/07/14
D2.1: release for internal review	23/07/14	23/07/14
D2.1: internal review	23/07/14	31/07/14
D3.1: release for internal review	23/07/14	23/07/14
D3.1: internal review	23/07/14	31/07/14
D4.1: final release	31/07/14	31/07/14
D2.1: final release	31/07/14	31/07/14
D3.1: final release	31/07/14	31/07/14
Pre-trials: stop	29/08/14	29/08/14
Pre-trials: uninstallation	29/08/14	23/09/14
D4.2: writing	29/08/14	23/09/14
D4.2: release for internal review	23/09/14	23/09/14
D4.2: internal review	23/09/14	30/09/14
D4.2: final release	30/09/14	30/09/14
1st project review	01/10/14	28/11/14

Figure 10 - List of specific steps (Gantt chart)

4.9.1 Cross-check table

The following table checks that the objectives pursued by the pre-trials are covered through the appropriate questions available on the questionnaires:

ID	Outcome	How/where
O1	To receive feedback about which activities and alerts the ICs like the most/less (about their loved ones and themselves).	Section B (24 questions from the IC´s questionnaire).
O2	To receive feedback about the feeling of having devices at home and being surrounding by them.	Section D (9 questions from the AP´s questionnaire).
O3	To receive feedback from the AP about the possibility to be watched in real-time.	Section B (32 questions from the AP´s questionnaire).
O4	To receive feedback from the AP and IC about the overall solution and model.	Section B, D and E (IC´s questionnaire) and sections B and D (AP´s questionnaire).
O5	To receive feedback about the look&feel of the application.	Section B and D (IC´s questionnaire).
O6	To receive feedback from the ICs about how they perceive the self-assessment tools (e.g. Zarit questionnaire, Barthel index, etc.) and non-structured sources of information (e.g. writing a personal diary or answering short-questions about their feelings).	Section D and E (IC´s questionnaire).
O7	To extract our own conclusions and improve our experience dealing with the installation/uninstallation of the BREATHE technology in three different locations in order to identify problems and constrains before the full trials arrive (real environment installations).	Specific sections reported on deliverable D4.2. These conclusions will be properly reported by the technical people in charge of setting the trials up in the testing environments.
O8	To set up an important technological milestone which releases a first version of the whole system partially running under real conditions.	Deeply reviewed in both D2.1 (First release of the AAL home system) and D3.1 (First release of the IC tool) which will be released in M15.
O9	To determine attitudes of carers and cared for persons towards the BREATHE platform in order to oversee the development and installation of the following stages (second and final release).	Section A (21 different questions from the AP´s and IC´s questionnaires) and section A and C (AP´s questionnaire).

Table 13 - Final cross-check table (goals vs questionnaires)

5 Trials

5.1 Introduction

As has been said before, the BREATHE technology will be released in three different phases namely first (M15), second (M21) and third release (M26). Each of them will be intensively tested with end-users under real conditions in order to verify that the technological outcomes fit the expected needs and requirements found out in WP1. This is the best possible approach to reach the final of the project (M30) with quality enough to be ready to the market in a reasonable period of time. Originally when the proposal was written, we envisaged that the validation methodologies and the indicators to be measured during the trials with the end-users would be the same independently of the release phase as well as the country where the trial will be carried out. Unfortunately, there are some particularities between countries and releases which makes, at this point, impossible for us to take advantage of D4.1 for defining the global procedures and supporting material (questionnaires, technological scenarios, technological components, ethics reviews, etc.) to be used in the research during the whole process. For that reason and in order to be as much pragmatic as possible, the BREATHE Consortium have agreed on the following approach:

- The pre-trial stage will arrive on M15 and will involve the technological deployments carried out as part of the job done in the first release. Pre-trials will be set up in living labs, smart-rooms or real homes (depending on the preferences of the people participating in the research process) and they will run in parallel in three different countries: Spain, Ireland and United Kingdom. The validation methodologies, research indicators, pursued objectives and supporting material have been deeply covered in the above sections (specifically sections 3 and 4) of this document. The most important conclusions and findings of the pre-trial stage will be reported on D4.2 (Pre-trials report), which will be released in September 2014.
- The (full/final) trials will arrive on M22 and M26, respectively, and they will cover the job done in the second and third release. Both full and final trials will be set up in the end-user´s homes and, as the pre-trials, they will run in parallel in Spain, Ireland and United Kingdom. The objectives of the validation plan, methodologies, indicators, hypothesis, empirical investigation as well as how to acquire data from the interviews will be **exactly the same** than those used during the pre-trial stage (widely described in Section 3, page 10). The only difference with the research job carried out during the pre-trial stage is about the supportive material. Specifically, it is important to review/prepare from scratch the following items: the objectives pursued by the trials from both the users and the technical point of view, the expected outcomes, the timeframe, the sampling range (minimum/maximum number of dyads to be interviewed per country), questionnaires, detailed script, sites capabilities and how to deploy/install the technology and training material for both the interviewers and the end-users. Additionally, since the objectives pursued by the research and the way the users will be involved is not the same than in the pre-trial stage, we will have to get the approval from the Ethics Committees as we did in the

past before setting up the scenarios for the pre-trials. These new material will be widely reported on D4.3 in M20. Table below shows the **specific list of the supportive material for the TRIAL research** which has to be ready before the submission deadline for its Ethics review:

Step	Task description	Deadline
Supportive material for the TRIAL research		
1	List of specific objectives pursued by the trials from a technical point of view.	November 7th 2014
2	List of specific objectives pursued by the trials from the end-users point of view.	
3	Expected outcomes from the trials	
4	Timeframe.	
5	Sampling of dyads (assisted person/informal caregiver) to be interviewed per country and inclusion/exclusion criteria.	
6	Design of the research process (how data will be collected, BREATHE innovations to be tested with the person interviewed, etc.)	
7	Detailed description of sites capabilities in Ireland, Spain and United Kingdom.	
8	Letter of invitation (after recruitment).	
9	Participation information leaflet (after recruitment) for the assisted people and the informal carers.	
10	Consent form (after recruitment).	
11	Letter of request for interview (after recruitment).	
12	Detailed script to be followed during the interviews with the assisted person and the informal carers. Ideally, the script will be the same in the three different countries but it could be slightly different depending on the particular conditions of each site.	
13	Questionnaires for the assisted people and the informal carers.	
14	List of use cases (functionalities) which will be released for the second and third release (properly scheduled).	
15	How to set up the scenario where the technology will be deployed and the trials conducted (list of components included).	
16	Training material for the interviewers.	
17	Training material for guiding the users during the guided phase in the trials.	
18	Practical considerations (lessons learned from the pre-trials stage).	
19	Ethics application form (which includes the research aims and objectives as well as the above material) to get the ethical approval from the Faculty of Health Sciences Research Ethics Committee at TCD (Ireland).	
20	Ethics application form submission deadline.	
21	Expected outcome received from the TCD Ethics Committee.	November 18th 2014
22	Amended proposal resubmission deadline (if proceed) to the TCD Ethics Committee.	November 25th 2014
23	Expected final ethical approval received from the TCD Ethics	November 28th

	Committee.	2014
24	After the ethics approval from the TCD Ethics Committee, the above steps/supportive material will be reported on deliverable D4.3 (trials midterm report).	December 19th, 2014

Table 14 – Required supportive material for the TRIAL research

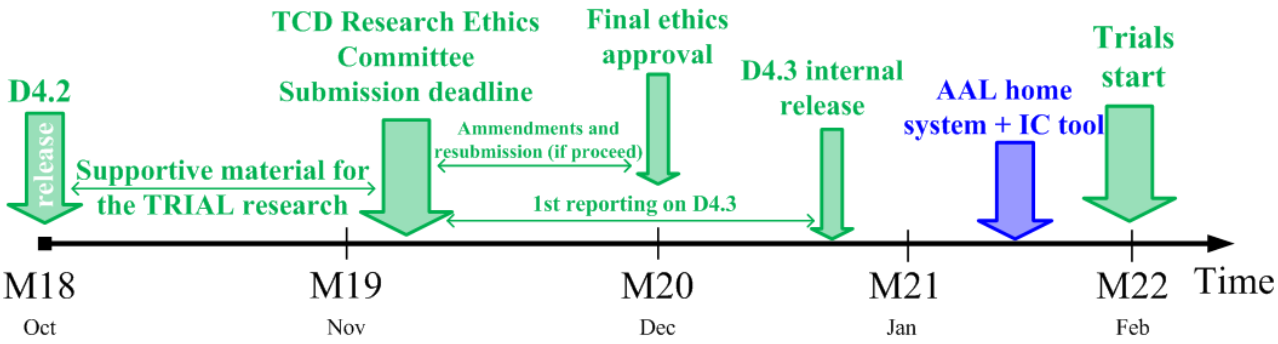
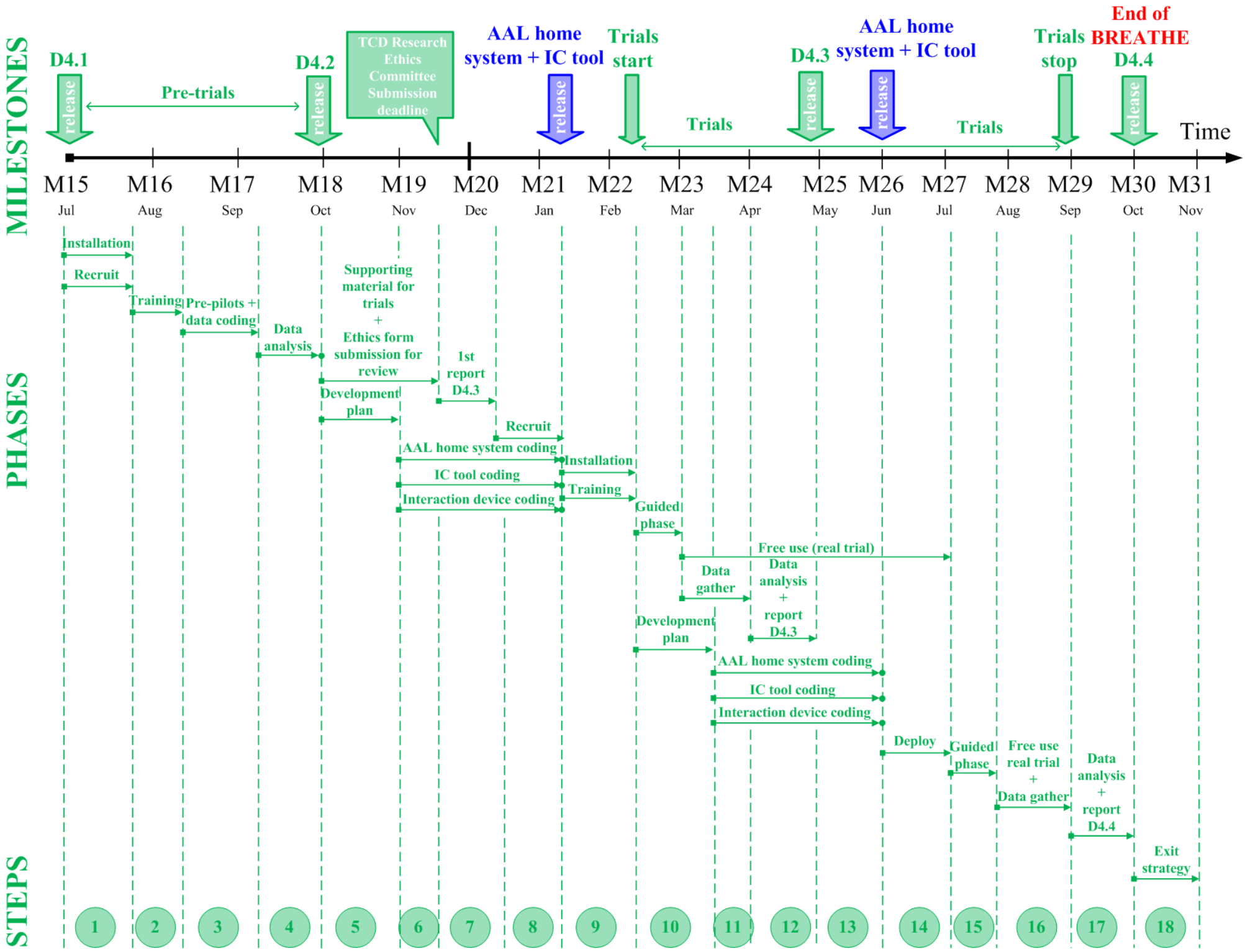


Figure 11 - Timeline between M18 and M22

5.2 Full trial work plan

The next period of time covers from M18 (when the deliverable D4.2 with the conclusions and findings of the pre-trials will be released, October 2014) to M30 (the end of BREATHE project, October 2015). Table below shows the most important milestones which have to be taken into account in the aforementioned period of time:

Milestone	Partners	Deadline
Release of D4.2 (Pre-trial report). D4.2 will wrap up the most important findings and conclusions from the pre-trials carried out in Spain, UK and Ireland from M15 to M18. These learned lessons will help the Consortium to conduct the next steps in the right way: trial phase.	TCD, ISI, CYB and TSB	M18
TCD Research Ethics Committee Submission deadline. Before the trials stage, we need to get a new approval from the TCD Ethics Committee. For that reason we have to design the research process in detail as well as to prepare all the supportive material to be used during the trials in order to be reviewed and approved by the Ethics Committee.	All	M19
2nd and 3rd release of software. Specifically, those use cases (functionalities) and technological developments that have to be released for testing with real end-users during the trials.	TSB, KU, ERREMME, CYB and Designability	M21/M26
Trials. This stage will cover the period of time from M22 until the end of the project. Trials pilots will be set up in real environments only (i.e. the end-user´s homes) and they will intensively test the new BREATHE features deployed in M21 and M26.	All	M22/M30
Release of D4.3 and D4.4 reports (Trials midterm report). These reports will include the data analysis after the data gathering during the trials.	TCD, ISI, CYB and TSB	M24/M30
Final release and end of BREATHE. The final release will arrive as consequence of the technical job carried out from the beginning as well as the involvement of end-users during the trials (pre-trials stage included). The final release (outcome) will include those features and components developed which better fit the needs and requirements of our target users.	All	M30


MILESTONES
PHASES
STEPS
D4.1
release
Pre-trials
D4.2
release
TCD Research Ethics Committee Submission deadline
AAL home system + IC tool
release
Trials start
Trials
D4.3
release
AAL home system + IC tool
release
Trials
Trials stop
End of BREATHE
D4.4
release
Time
M15 M16 M17 M18 M19 M20 M21 M22 M23 M24 M25 M26 M27 M28 M29 M30 M31
Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov
Installation
Recruit
Training
Pre-pilots + data coding
Data analysis
Supporting material for trials + Ethics form submission for review
1st report D4.3
Development plan
Recruit
AAL home system coding
IC tool coding
Interaction device coding
Installation
Training
Guided phase
Free use (real trial)
Data gather
Data analysis + report D4.3
Development plan
AAL home system coding
IC tool coding
Interaction device coding
Deploy
Guided phase
Free use real trial + Data gather
Data analysis + report D4.4
Exit strategy
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18

Regarding the work plan (phases) to be followed until the end of the project as well as the roles of the required people at each phase, a detailed image is shown above. Each of them is detailed below in the following table[22]:

Step	Phase	Description/Roles	Deadline
5	Definition	Preparation of the required material (objectives, detailed script, questionnaires, etc.) for supporting the research process carried out in the trials. Lead by the overall manager: TCD.	M19
		To complete the Ethics form which has to be submitted to the TCD Ethics Committee as prior step to the trials stage. The Ethics form has to include all the supportive material and the description (in detail) of the testing environments and how the end-users will be involved). The specific objective pursued by this action is to get the ethics approval from the TCD Ethics Committee in order to start with the recruitment of our target users. Lead by the overall manager: TCD.	
		To discuss and prepare the development plan for the 2nd release, which will schedule the next release of features to be deployed and intensively tested during the trials with real end-users. This development plan will specifically cover the BREATHE functionalities which will be tested before M26 (3rd release). Lead by the technical manager: TSB.	
6	Technological development	Development of the technological features/use cases agreed and reported on the development plan (internal document) which will be ready for M22. Specifically, new features will be developed and deployed around the following sub-systems: AAL home system (both indoor video-based monitoring system and array of multi-function sensors), interaction device for the AP, home and mobile versions of the IC tool. This development stage will cover the following period of time: M19 – M21 (BREATHE Consortium will take advantage of these three months for creating new features as well as for adapting what it was already implemented for the next wave of trials). Lead by the technical manager: TSB (supported by the team leader of each technical partner site).	M21
7	Definition	The aim of the deliverable D4.3 (trials midterm report) is	M20

[22] Steps 1-4 (installation, recruitment, training, pre-pilots, data encoding, data analysis and release of D4.2 with the most important conclusions/findings/hazards/risks of the whole pre-pilots process) have been excluded of this table for simplicity (please, take into account that this table/section is only focused on the TRIAL stage which will cover the period of time from M18 (end of pre-trials) – M30 (final release and end of the project).

Step	Phase	Description/Roles	Deadline
		to describe in detail all the required steps for preparing the trials and to summary the most important conclusions after the analysis of the data gathered during trials. According our work plan, the final version of the deliverable D4.3 has to be released in M24 and it will include information about the definition, data collection and data analysis phases. In M20, the information about the definition process will be reported on D4.3. Lead by the overall manager: TCD (contributors supporting the process are the technical manager and the recruitment manager at each testing site).	
8	Recruitment	Once the TCD Ethics approval from the TCD Ethics Committee arrive, BREATHE Consortium will be able to start with the recruitment phase. The aim of this stage is to involve a specific number of eligible end-users into the research process. The minimum/maximum number (sampling/inclusion and exclusion criteria) of users to be recruited per country will be previously defined in the step 5. Lead by the WP4 leader: CYB (contributors supporting the process are the recruitment managers at each testing site: ISI in Spain and TCD in Ireland).	M21
9	Installation	This phase will cover the physical installation of the equipment which will compound the BREATHE platform in the recruited end-user´s homes. One installation will cover a dyad: AP + IC. Lead by the technical manager: TSB (supported by one people per country with a technical profile: ISI, CYB and TER).	M22
	Training for BREATHE staff	The aim of the training stage is to teach the BREATHE staff who will be in contact with the end-user´s about the material which will support the research process as well as how to interact with the technical devices and software features under test. Each technical team will prepare the training material which will be shared with the rest of the Consortium (especially with the interviewers) through a series of webinars. The following training sessions will be set up: (1) video-based indoor system, (2) array of multi-function sensors, (3) interaction device for the AP, (4) home version of the IC and (5) mobile version of the IC. Lead by the technical manager (TSB) and the rest of the partners in charge of the technological developments (ERREMME, KU and CYB).	
10	Guided phase: end-users´ training	The objective pursued by the guided phase is to help the end-users to start using the BREATHE technology available at their home on a daily basis. This step is like a training process but for the end-users instead of the people in charge of guiding the trials. Lead by the overall manager: TCD (contributors supporting the process are the training managers at each testing site: ISI and CYB).	M23

Step	Phase	Description/Roles	Deadline
		The training manager is a single contact person who is called by the end-users in case of necessity (something happens) and he/she is the person in charge for fixing the problem within the shortest period of time.	
	Development plan	To discuss and prepare the development plan for the 3rd release, which will schedule the next release of features to be deployed and intensively tested during the trials with real end-users. This development plan will specifically cover the BREATHE functionalities which will be tested before M30 (end of the project). Lead by the technical manager: TSB.	
	Data collection	The data collection step will gather information about the feedback of the end-users as consequence of the intensive usage of the technological systems that they have within their reach. The information will be safety and anonymously gathered and it will match with the objectives pursued by the trial. This step will cover the following period of time: M23 – M24. Lead by the overall and data manager: TCD.	M24
	Free use phase	Once the guided phase finishes, the free use stage will start. The idea behind this is to really find out if the technological solutions developed by the BREATHE Consortium fit the real needs and requirements of the recruited dyads (AP + IC) and it is intuitive and attractive enough to be used on a daily basis. This step will cover the following period of time: M23 – M27. Lead by the training manager: ISI in Spain, TCD in Ireland and CYB in UK.	M27
11	Technological development	Development of the technological features/use cases agreed and reported on the development plan (internal document) which will be ready for M26. Specifically, new features will be developed and deployed around the following sub-systems: AAL home system (both indoor video-based monitoring system and array of multi-function sensors), interaction device for the AP, home and mobile versions of the IC tool. This development stage will cover the following period of time: M23 – M26. Lead by the technical manager: TSB (supported by the team leader of each technical partner site).	M26
12	Data analysis	The aim of this step is to analyse the data gathered between the period of time which covers M23 – M24 of the trials carried out in Spain, UK and Ireland. The idea behind this is to cross data between countries and compare information in order to extract conclusions which help us to develop a useful product for our target end-users group. Lead by the data manager: TCD with the support of the D4.3 leader (CYB).	M25
	Final reporting	The conclusions and main findings of the data analysis	

Step	Phase	Description/Roles	Deadline
		step will be reported in the deliverable D4.3. This document will summarize our most important actions before the first period of full trialling and it will help the technical partners of BREATHE to really understand the usability of their developments. The conclusions reported here will guide the next (final) intensive testing period. Lead by the D4.3 leader: CYB.	
14	Technological deployment	As consequence of the technological development scheduled in step 11, in M27 the technical partners in charge of the development of the technological systems which will compound the BREATHE platform will be ready for deploying new features and services. Lead by the technical manager: TSB (supported by the team leader of each technical partner site).	M27
15	Guided phase: end-users´ training	Since new features will be available at the end-user´s disposal for testing, a new guided phase will start. This step will be focused on the new developments and no others. Lead by the overall manager (TCD) and the training managers at each testing site: ISI in Spain and CYB in UK.	M28
16	Data collection	The data collection step will gather information about the feedback of the end-users as consequence of the intensive usage of the technological systems that they have within their reach. The information will be safety and anonymously gathered and it will match with the objectives pursued by the trial. This step will cover the following period of time: M28 – M29. Lead by the overall and data manager: TCD.	M29
	Free use phase	Once the guided phase finishes, the free use stage will start. The idea behind this is to really find out if the technological solutions developed by the BREATHE Consortium fit the real needs and requirements of the recruited dyads (AP + IC) and it is intuitive and attractive enough to be used on a daily basis. This step will cover the following period of time: M28 – M29. Lead by the training manager: ISI in Spain, TCD in Ireland and CYB in UK.	M30
17	Data analysis	The aim of this step is to analyse the data gathered between the period of time which covers M29 – M30 of the trials carried out in Spain, UK and Ireland. The idea behind this is to cross data between countries and compare information in order to extract conclusions which help us to develop a useful product for our target end-users group. Lead by the data manager: TCD with the support of the D4.4 leader (TCD).	
	Final reporting	In M30 and before the project ends, a new report will be released (D4.4 – lessons learned) summarizing our findings and difficulties trying to deploy a technological	

Step	Phase	Description/Roles	Deadline
		system which improves the quality of life and working conditions of the ICs who are regularly caring his/her loved ones (APs). These documents will emphasise the last period of trialling and it will highlight the conclusions and risks of the whole process (M1 – M30). Lead by the D4.4 leader: TCD.	
End of BREATHE Project			
18	Exit strategy	The objective pursued by the exit strategy is to avoid a curtness finishing of the trials (managing potential dependencies created with the end-users using the platform) and uninstall all the BREATHE equipment available in the end-users homes without disturbing the users and harming their personal environment. The exit strategy of the full trials was widely described in the DoW (section 1.5, page 10) and it is expected to give (to those users really interested in) the opportunity to extend, at least, for 1 additional year the use of the platform. Lead by the overall manager (TCD), the technical manager (TSB) and the project coordinator (TSB).	M31

Table 15 - Work plan for the trial stage

References

[1] BREATHE architecture definition. Internal document. BREATHE Consortium. http://redmine.breathe-project.eu/dmsf/files/321/download

[2] Deliverable D1.3 – Trials strategic plan. Public document. BREATHE Consortium. http://breathe-project.eu/gallery/16/D13_-_Trials_strategic_plan_v10.pdf

[3] Deliverable D2.1 – First release of the AAL home system. Internal document. BREATHE Consortium.

[4] Deliverable D3.1 – First release of the informal caregiver tool. Internal document. BREATHE Consortium.

Appendix A

A.1 Barthel index of activities of daily living for ICs of people with LTCs

Barthel Index of Activities of Daily Living

Instructions: Choose the scoring point for the statement that most closely corresponds to the patient's current level of ability for each of the following 10 items. Record actual, not potential, functioning. Information can be obtained from the patient's self-report, from a separate party who is familiar with the patient's abilities (such as a relative), or from observation. Refer to the Guidelines section on the following page for detailed information on scoring and interpretation.

The Barthel Index

Bowels
0 = incontinent (or needs to be given enemata)
1 = occasional accident (once/week)
2 = continent
Patient's Score: _____

Bladder
0 = incontinent, or catheterized and unable to manage
1 = occasional accident (max. once per 24 hours)
2 = continent (for over 7 days)
Patient's Score: _____

Grooming
0 = needs help with personal care
1 = independent face/hair/teeth/shaving (implements provided)
Patient's Score: _____

Toilet use
0 = dependent
1 = needs some help, but can do something alone
2 = independent (on and off, dressing, wiping)
Patient's Score: _____

Feeding
0 = unable
1 = needs help cutting, spreading butter, etc.
2 = independent (food provided within reach)
Patient's Score: _____

Transfer
0 = unable – no sitting balance
1 = major help (one or two people, physical), can sit
2 = minor help (verbal or physical)
3 = independent
Patient's Score: _____

Mobility
0 = immobile
1 = wheelchair independent, including corners, etc.
2 = walks with help of one person (verbal or physical)
3 = independent (but may use any aid, e.g., stick)
Patient's Score: _____

Dressing
0 = dependent
1 = needs help, but can do about half unaided
2 = independent (including buttons, zips, laces, etc.)
Patient's Score: _____

Stairs
0 = unable
1 = needs help (verbal, physical, carrying aid)
2 = independent up and down
Patient's Score: _____

Bathing
0 = dependent
1 = independent (or in shower)
Patient's Score: _____

Total Score: _____

(Collin et al., 1988)

Scoring:

Sum the patient's scores for each item. Total possible scores range from 0 – 20, with lower scores indicating increased disability. If used to measure improvement after rehabilitation, changes of more than two points in the total score reflect a probable genuine change, and change on one item from fully dependent to independent is also likely to be reliable.

Sources:

- Collin C, Wade DT, Davies S, Horne V. The Barthel ADL Index: a reliability study. *Int Disabil Stud.* 1988;10(2):61-63.
- Mahoney FI, Barthel DW. Functional evaluation: the Barthel Index. *Md State Med J.* 1965;14:61-65.
- Wade DT, Collin C. The Barthel ADL Index: a standard measure of physical disability? *Int Disabil Stud.* 1988;10(2):64-67.

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Guidelines for the Barthel Index of Activities of Daily Living

General

- The Index should be used as a record of what a patient *does*, NOT as a record of what a patient *could do*.
- The main aim is to establish degree of independence from any help, physical or verbal, however minor and for whatever reason.
- The need for supervision renders the patient not independent.
- A patient's performance should be established using the best available evidence. Asking the patient, friends/relatives, and nurses will be the usual source, but direct observation and common sense are also important. However, direct testing is not needed.
- Usually the performance over the preceding 24 – 48 hours is important, but occasionally longer periods will be relevant.
- Unconscious patients should score '0' throughout, even if not yet incontinent.
- Middle categories imply that the patient supplies over 50% of the effort.
- Use of aids to be independent is allowed.

Bowels (preceding week)

- If needs enema from nurse, then 'incontinent.'
- 'Occasional' = once a week.

Bladder (preceding week)

- 'Occasional' = less than once a day.
- A catheterized patient who can completely manage the catheter alone is registered as 'continent.'

Grooming (preceding 24 – 48 hours)

- Refers to personal hygiene: doing teeth, fitting false teeth, doing hair, shaving, washing face. Implements can be provided by helper.

Toilet use

- Should be able to reach toilet/commode, undress sufficiently, clean self, dress, and leave.
- 'With help' = can wipe self and do some other of above.

Feeding

- Able to eat any normal food (not only soft food). Food cooked and served by others, but not cut up.
- 'Help' = food cut up, patient feeds self.

Transfer

- From bed to chair and back.
- 'Dependent' = NO sitting balance (unable to sit); two people to lift.
- 'Major help' = one strong/skilled, or two normal people. Can sit up.
- 'Minor help' = one person easily, OR needs any supervision for safety.

Mobility

- Refers to mobility about house or ward, indoors. May use aid. If in wheelchair, must negotiate corners/doors unaided.
- 'Help' = by one untrained person, including supervision/moral support.

Dressing

- Should be able to select and put on all clothes, which may be adapted.
- 'Half' = help with buttons, zips, etc. (*check!*), but can put on some garments alone.

Stairs

- Must carry any walking aid used to be independent.

Bathing

- Usually the most difficult activity.
- Must get in and out unsupervised, and wash self.
- Independent in shower = 'independent' if unsupervised/unaided.

(Collin et al., 1988)

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Figure 12 - Barthel index of activities of daily living for ICs

A.2 Zarit self-report burden of care measure for ICs of people with LTCs

THE ZARIT BURDEN INTERVIEW

Please circle the response the best describes how you feel.

	Never	Rarely	Sometimes	Quite Frequently	Nearly Always	Score
1. Do you feel that your relative asks for more help than he/she needs?	0	1	2	3	4	
2. Do you feel that because of the time you spend with your relative that you don't have enough time for yourself?	0	1	2	3	4	
3. Do you feel stressed between caring for your relative and trying to meet other responsibilities for your family or work?	0	1	2	3	4	
4. Do you feel embarrassed over your relative's behaviour?	0	1	2	3	4	
5. Do you feel angry when you are around your relative?	0	1	2	3	4	
6. Do you feel that your relative currently affects our relationships with other family members or friends in a negative way?	0	1	2	3	4	
7. Are you afraid what the future holds for your relative?	0	1	2	3	4	
8. Do you feel your relative is dependent on you?	0	1	2	3	4	
9. Do you feel strained when you are around your relative?	0	1	2	3	4	
10. Do you feel your health has suffered because of your involvement with your relative?	0	1	2	3	4	
11. Do you feel that you don't have as much privacy as you would like because of your relative?	0	1	2	3	4	
12. Do you feel that your social life has suffered because you are caring for your relative?	0	1	2	3	4	
13. Do you feel uncomfortable about having friends over because of your relative?	0	1	2	3	4	

14. Do you feel that your relative seems to expect you to take care of him/her as if you were the only one he/she could depend on?	0	1	2	3	4	
15. Do you feel that you don't have enough money to take care of your relative in addition to the rest of your expenses?	0	1	2	3	4	
16. Do you feel that you will be unable to take care of your relative much longer?	0	1	2	3	4	
17. Do you feel you have lost control of your life since your relative's illness?	0	1	2	3	4	
18. Do you wish you could leave the care of your relative to someone else?	0	1	2	3	4	
19. Do you feel uncertain about what to do about your relative?	0	1	2	3	4	
20. Do you feel you should be doing more for your relative?	0	1	2	3	4	
21. Do you feel you could do a better job in caring for your relative?	0	1	2	3	4	
22. Overall, how burdened do you feel in caring for your relative?	0	1	2	3	4	
Total Score (out of 88)						

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Interpretation of Score:	
0 – 21	little or no burden
21 – 40	mild to moderate burden
41 – 60	moderate to severe burden
61 – 88	severe burden

Score values and interpretation are guidelines only, as discussed in:
Hebert R, Bravo G, and Preville M (2000). *Canadian J Aging* 19: 494-507.

Figure 13 - Zarit burden interview for ICs

A.3 Sheet explaining BREATHE and possible monitoring technology

The BREATHE system will be a way of supporting carers of people with long term conditions, and will include some types of monitoring of the person who they provide care for:

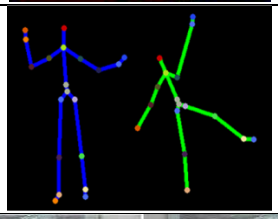
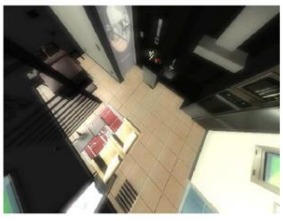
A	Normal video. Shows real footage of person in room	
B	Silhouettes. Shows only silhouettes of person in room	
C	Stick figure	
D	Cartoon like	

Table 16 - Filters for the indoor video-based monitoring system (people)

Alternatively, the whole room could be shown as a "virtual room", to show the context of the room that the person was in with these options:

E	Show an empty room if there is no cause for concern, so that the person with long term condition has complete privacy	
F	Show the person's location within the room if there is a query about the person's safety or wellbeing	

G	Show the person's position and posture, or even real footage, if the system thinks that the person needs help	

Table 17 - Filters for the indoor video-based monitoring system (environment)

Appendix B

B.1 Google cloud platform terms of service[23]

These Google Cloud Platform Terms of Service apply to all new accounts for any Cloud Platform services created after February 1, 2014 and will apply to all Google App Engine accounts after May 1, 2014 and to all Google Cloud Storage, Google Prediction API, Google BigQuery Service, Google Cloud SQL, Google Compute Engine and Google Cloud Datastore accounts after March 2, 2014.

For Google App Engine accounts created before February 1, 2014, the Terms of Service located here https://developers.google.com/cloud/terms/deprecated-appengine-terms will apply until May 1, 2014, at which time these Google Cloud Platform Terms of Service will apply.

For Google Cloud Storage, Google Prediction API, Google BigQuery Service, Google Cloud SQL, Google Compute Engine and Google Cloud Datastore accounts created before February 1, 2014, the Terms of Service located here https://developers.google.com/cloud/terms/deprecated-terms will apply until March 2, 2014, at which time these Google Cloud Platform Terms of Service will apply.

Google Cloud Platform

LICENSE AGREEMENT

This Google Cloud Platform License Agreement (the "Agreement") is made and entered into by and between Google and the business entity agreeing to these terms ("Customer"). "Google" means either (i) Google Ireland Limited, with offices at Gordon House, Barrow Street, Dublin 4, Ireland, if Customer's billing address is in any country within Europe, the Middle East, or Africa ("EMEA"), (ii) Google Asia Pacific Pte. Ltd., with offices at 8 Marina View Asia Square 1 #30-01 Singapore 018960, if Customer's billing address is in any country within the Asia Pacific region ("APAC"), or (iii) Google Inc., with offices at 1600 Amphitheatre Parkway, Mountain View, California 94043, if Customer's billing address is in any country in the world other than those in EMEA and APAC.

This Agreement is effective as of the date Customer clicks the "I Accept" button below (the "Effective Date"). If you are accepting on behalf of Customer, you represent and warrant that: (i) you have full legal authority to bind Customer to this Agreement; (ii) you have read and understand this Agreement; and (iii) you agree, on behalf of Customer, to this Agreement. If you do not have the legal authority to bind Customer, please do not click the "I Accept" button below. This Agreement governs Customer's access to and use of the Service. For an offline variant of this Agreement, you may contact Google at http://www.google.com/enterprise/cloud/contact.html for more information.

1. Licenses.

1.1 From Google to Customer. Subject to this Agreement, Google grants to Customer a worldwide, non-sublicensable, non-transferable, non-exclusive, terminable, limited license during the License Term to: (a) use the Services, (b) integrate the Services into any Application and provide the Services, solely as integrated into the Application, to users of the Application, and (c) use any Software provided by Google as part of the Services.

1.2 From Customer to Google. By submitting, posting, generating, or displaying any Application and/or Customer Data on or through the Services, Customer gives Google a worldwide, non-sublicensable, non-transferable, non-exclusive, terminable, limited license to use any Application and/or Customer Data for the sole purpose of enabling Google to provide, maintain, protect, and improve the Services in accordance with the Agreement.

2. Provision of the Services.

[23] Last modification on December, 2013: https://developers.google.com/cloud/terms (Accessed on May, 2014)

2.1 Console. Google will provide the Services to Customer. As part of receiving the Services Customer will have access to the Admin Console, through which Customer may administer the Services.

2.2 Facilities and Data Transfer. All facilities used to store and process an Application and Customer Data will adhere to reasonable security standards no less protective than the security standards at facilities where Google processes and stores its own information of a similar type. Google has implemented at least industry standard systems and procedures to ensure the security and confidentiality of an Application and Customer Data, protect against anticipated threats or hazards to the security or integrity of an Application and Customer Data, and protect against unauthorized access to or use of an Application and Customer Data. Google may process and store an Application and Customer Data in the United States or any other country in which Google or its agents maintain facilities. By using the Services, Customer consents to this processing and storage of an Application and Customer Data. The parties agree that Google is merely a data processor.

2.3 Accounts. Customer must have an Account and a Token (if applicable) to use the Services, and is responsible for the information it provides to create the Account, the security of the Token and its passwords for the Account, and for any use of its Account and the Token. If Customer becomes aware of any unauthorized use of its password, its Account or the Token, Customer will notify Google as promptly as possible.

2.4 Privacy Policies. The Services are subject to Google's Privacy Policy. Changes to the Privacy Policy will be made as stated in the applicable policy. In addition, Google is enrolled in the U.S. Department of Commerce Safe Harbor Program and will remain enrolled in this program or another replacement program (or will adopt a compliance solution which achieves compliance with the terms of Article 25 of Directive 95/46/EC) throughout the Term of the Agreement.

2.5 New Applications and Services. Google may: (i) make new applications, tools, features or functionality available from time to time through the Services and (ii) add new services to the "Services" definition from time to time (by adding them at the URL set forth under that definition), the use of which may be contingent upon Customer's agreement to additional terms.

2.6 Modifications.

a. To the Services. Subject to Section 9.4 (Termination for Convenience), Google may make commercially reasonable Updates to the Services from time to time. If Google makes a material change to the Services, Google will inform Customer, provided that Customer has subscribed with Google to be informed about such change.

b. To the Agreement. Google may make changes to this Agreement, including pricing from time to time. Unless otherwise noted by Google, material changes to the Agreement will become effective 30 days after they are posted, except if the changes apply to new functionality in which case they will be effective immediately. If Customer does not agree to the revised Agreement, please stop using the Services. Google will post any modification to this Agreement to the Terms URL.

c. Service Specific Terms. The Service Specific Terms are hereby incorporated by reference into the Agreement.

3. Payment Terms.

3.1 Free Quota. Certain Services are provided to Customer without charge up to the Fee Threshold, as applicable.

3.2 Online Billing. Google will issue an electronic bill to Customer for all charges accrued above the Fee Threshold based on (i) Customer's use of the Services during the License Term (including, if any, the relevant Fee for TSS set forth in the Fees definition below); (ii) any Reserved Units selected; (iii) any Committed Purchases selected; and/or (iv) any Package Purchases selected. For use above the Fee Threshold, Customer will be responsible for all Fees up to the amount set in the Account and will pay all Fees in U.S. Dollars or in such other currency as agreed to in writing by the parties. Customer will pay all Fees in accordance with the payment terms applicable to the Fees. Google's measurement of Customer's use of the Services is final.

3.3 Taxes. Customer is responsible for any Taxes, and Customer will pay Google for the Services without any reduction for Taxes. If Google is obligated to collect or pay Taxes, the Taxes will be invoiced to Customer, unless Customer provides Google with a timely and valid tax exemption certificate authorized by the appropriate taxing authority. In some states the sales tax is due on the total purchase price at the time of sale and must be

invoiced and collected at the time of the sale. If Customer is required by law to withhold any Taxes from its payments to Google, Customer must provide Google with an official tax receipt or other appropriate documentation to support such withholding.

3.4 Invoice Disputes & Refunds. To the fullest extent permitted by law, Customer waives all claims relating to Fees unless claimed within sixty days after charged (this does not affect any Customer rights with its credit card issuer). Refunds (if any) are at the discretion of Google and will only be in the form of credit for the Services. Nothing in this Agreement obligates Google to extend credit to any party.

3.5 Delinquent Payments. Late payments may bear interest at the rate of 1.5% per month (or the highest rate permitted by law, if less). Google reserves the right to suspend Customer's Account for any late payments.

4. Customer Obligations.

4.1 Compliance. Customer is solely responsible for its Applications, Projects, and Customer Data and for making sure its Applications, Projects, and Customer Data comply with the Acceptable Use Policy. Google reserves the right to review the Application, Project, and Customer Data to ensure Customer's compliance with the Acceptable Use Policy. Customer is responsible for ensuring all End Users comply with Customer's obligations under the Agreement.

4.2 Privacy. Customer will protect the privacy and legal rights of its End Users under all applicable laws and regulations, which includes a legally adequate privacy notice communicated from Customer. Customer may have the ability to access, monitor, use, or disclose Customer Data submitted by End Users through the Services. Customer will obtain and maintain any required consents from End Users to allow Customer's access, monitoring, use and disclosure of Customer Data. Further, Customer will notify its End Users that any Customer Data provided as part of the Services will be made available to a third party (i.e. Google) as part of Google providing the Services.

4.3 Restrictions. Customer will not, and will not allow third parties under its control to: (a) copy, modify, create a derivative work of, reverse engineer, decompile, translate, disassemble, or otherwise attempt to extract the source code of the Services or any component thereof (subject to Section 4.4 below and except to the extent such restriction is expressly prohibited by applicable law); (b) use the Services for High Risk Activities; (c) sublicense, resell, or distribute the Services or any component thereof separate from any integrated Application; (d) use the Services to create, train, or improve (directly or indirectly) a substantially similar product or service, including any other machine translation engine; (e) create multiple Applications, Accounts, or Projects to simulate or act as a single Application, Account, or Project (respectively) or otherwise access the Services in a manner intended to avoid incurring Fees; (f) unless otherwise set forth in the Service Specific Terms, use the Services to operate or enable any telecommunications service or in connection with any Application that allows End Users to place calls or to receive calls from any public switched telephone network; or (g) process or store any Customer Data that is subject to the International Traffic in Arms Regulations maintained by the Department of State. Unless otherwise specified in writing by Google, Google does not intend uses of the Services to create obligations under HIPAA, and makes no representations that the Services satisfy HIPAA requirements. If Customer is (or becomes) a Covered Entity or Business Associate, as defined in HIPAA, Customer agrees not to use the Services for any purpose or in any manner involving Protected Health Information (as defined in HIPAA) unless Customer has received prior written consent to such use from Google.

4.4 Third Party Components. Third party components (which may include open source software) of the Services may be subject to separate license agreements. To the limited extent a third party license expressly supersedes this Agreement, that third party license instead governs Customer's agreement with Google for the specific included third party components of the Services, or use of the Services (as may be applicable).

4.5 Documentation. Google may provide Documentation for Customer's use of the Services. The Documentation may specify restrictions (e.g. attribution or HTML restrictions) on how the Applications may be built or the Services may be used and Customer will comply with any such restrictions specified.

4.6 DMCA Policy. Google provides information to help copyright holders manage their intellectual property online, but Google cannot determine whether something is being used legally or not without their input. Google responds to notices of alleged copyright infringement and terminates accounts of repeat infringers according to the process set out in the U.S. Digital Millennium Copyright Act. If Customer thinks somebody is violating

Customer's or its End Users' copyrights and wants to notify Google, Customer can find information about submitting notices, and Google's policy about responding to notices at http://www.google.com/dmca.html.

4.7 Application and No Multiple Accounts, Bills, Tokens. Any Application must have material value independent from the Services. Google has no obligation to provide multiple bills, Tokens (if applicable), or Accounts to Customer under the Agreement.

5. Suspension and Removals.

5.1 Suspension/Removals. If Customer becomes aware that any Application, Project (including an End User's use of a Project), or Customer Data violates the Acceptable Use Policy, Customer will immediately suspend the Application or Project (if applicable), remove the applicable Customer Data or suspend access to an End User (as may be applicable). If Customer fails to suspend or remove as noted in the prior sentence, Google may specifically request that Customer do so. If Customer fails to comply with Google's request to do so within twenty-four hours, then Google may suspend Google accounts of the applicable End Users, disable the Project or Application, and/or disable the Account (as may be applicable) until such violation is corrected.

5.2 Emergency Security Issues. Despite the foregoing, if there is an Emergency Security Issue, then Google may automatically suspend the offending End User account, Application, Project, or the Account. Suspension will be to the minimum extent required, and of the minimum duration, to prevent or terminate the Emergency Security Issue. If Google suspends an End User account, Application, Project, or the Account, for any reason, without prior notice to Customer, at Customer's request, Google will provide Customer the reason for the suspension as soon as is reasonably possible.

6. Intellectual Property Rights; Brand Features.

6.1 Intellectual Property Rights. Except as expressly set forth herein, this Agreement does not grant either party any rights, implied or otherwise, to the other's content or any of the other's intellectual property. As between the parties, Customer owns all Intellectual Property Rights in Customer Data and the Application or Project (if applicable) and Google owns all Intellectual Property Rights in the Services and Software.

6.2 Brand Features Limitation. If Customer wants to display Google Brand Features in connection with its use of the Services, Customer must obtain written permission from Google through the process specified in the Trademark Guidelines. For the purpose of providing the Services, Customer permits Google to display any Customer Brand Features that may appear in Customer's use of the Services. Any use of a party's Brand Features will inure to the benefit of the party holding Intellectual Property Rights to those Brand Features. A party may revoke the other party's right to use its Brand Features pursuant to this Agreement with written notice to the other and a reasonable period to stop the use.

6.3 Customer Feedback. If Customer provides Google feedback or suggestions about the Services, then Google may use that information without obligation to Customer, and Customer hereby irrevocably assigns to Google all right, title, and interest in that feedback or those suggestions.

7. Technical Support Services

7.1 By Customer. Customer is responsible for technical support of its Applications and Projects.

7.2 By Google. Subject to payment of applicable support Fees, Google will provide TSS to Customer during the License Term in accordance with the TSS Guidelines. Certain TSS levels include a minimum recurring Fee as described in the "Fees" definition below. If Customer downgrades its TSS level during any calendar month, Google may continue to provide TSS at the same level and TSS Fees before the downgrade for the remainder of that month.

7.3 Deprecation Policy. Google will announce if it intends to discontinue or make backwards incompatible changes to the Services specified at the URL in the next sentence. Google will use commercially reasonable efforts to continue to operate those Services versions and features identified at https://developers.google.com/cloud/terms/deprecation without these changes for at least one year after that announcement (or in the case of Google App Engine, until the later of: one year after that announcement or April 20, 2015), unless (as Google determines in its reasonable good faith judgment):

(i) required by law or third party relationship (including if there is a change in applicable law or relationship), or

(ii) doing so could create a security risk or substantial economic or material technical burden.

The above policy is the "Deprecation Policy."

8. Confidential Information. The recipient will not disclose the Confidential Information, except to Affiliates, employees, agents or professional advisors who need to know it and who have agreed in writing (or in the case of professional advisors are otherwise bound) to keep it confidential. The recipient will ensure that those people and entities use the received Confidential Information only to exercise rights and fulfill obligations under this Agreement, while using reasonable care to keep it confidential. The recipient may also disclose Confidential Information to the extent required by applicable Legal Process; provided that the recipient uses commercially reasonable efforts to: (i) promptly notify the other party of such disclosure before disclosing; and (ii) comply with the other party's reasonable requests regarding its efforts to oppose the disclosure. Notwithstanding the foregoing, subsections (i) and (ii) above will not apply if the recipient determines that complying with (i) and (ii) could: (a) result in a violation of Legal Process; (b) obstruct a governmental investigation; and/or (c) lead to death or serious physical harm to an individual. As between the parties, Customer is responsible for responding to all third party requests concerning its use and its End Users' use of the Services.

9. Term and Termination.

9.1 Agreement Term. This Agreement will remain in effect for the License Term.

9.2 Termination for Breach. Either party may terminate this Agreement for breach if: (i) the other party is in material breach of the Agreement and fails to cure that breach within thirty days after receipt of written notice; (ii) the other party ceases its business operations or becomes subject to insolvency proceedings and the proceedings are not dismissed within ninety days; or (iii) the other party is in material breach of this Agreement more than two times notwithstanding any cure of such breaches.

9.3 Termination for Inactivity. Google reserves the right to terminate the Services for inactivity, if, for a period exceeding ninety days, Customer: (a) has failed to access the Admin Console; (b) a Project has no active virtual machine or storage resources or an Application has not served any requests; and (c) no electronic bills are being generated.

9.4 Termination for Convenience. Customer may stop using the Services at any time. Customer may terminate this Agreement for its convenience at any time on prior written notice and upon termination, must cease use of the applicable Services. Google may terminate this Agreement for its convenience at any time without liability to Customer. Subject to Section 7.3, Google may discontinue any Services or any portion or feature for any reason at any time without liability to Customer.

9.5 Effect of Termination. If the Agreement expires or is terminated, then: (i) the rights granted by one party to the other will immediately cease; (ii) all Fees (including Taxes) owed by Customer to Google are immediately due upon receipt of the final electronic bill; (iii) Customer will delete the Software, any Application, Instance, Project, and any Customer Data; and (iv) upon request, each party will use commercially reasonable efforts to return or destroy all Confidential Information of the other party.

10. Publicity. Customer is permitted to state publicly that it is a customer of the Services, consistent with the Trademark Guidelines. Google may include Customer's name or Brand Features in a list of Google customers, online or in promotional materials. Google may also verbally reference Customer as a customer of the Google products or services that are the subject of this Agreement. This section is subject to the "Brand Features Limitation" section of the Agreement. For clarification, neither party needs to seek approval from the other if the party is repeating a public statement that is substantially similar to a public statement that has been previously approved.

11. Representations. Each party represents that: (a) it has full power and authority to enter into the Agreement; and (b) it will comply with all laws and regulations applicable to its provision, or use, of the Services, as applicable. Google warrants that it will provide the Services in accordance with the applicable SLA (if any).

12. Disclaimer. EXCEPT AS EXPRESSLY PROVIDED FOR HEREIN, TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, GOOGLE AND ITS SUPPLIERS DO NOT MAKE ANY OTHER WARRANTY OF ANY KIND, WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE AND NONINFRINGEMENT. GOOGLE AND ITS SUPPLIERS ARE NOT RESPONSIBLE OR LIABLE FOR THE DELETION OF OR FAILURE TO STORE ANY CUSTOMER DATA AND OTHER COMMUNICATIONS MAINTAINED OR TRANSMITTED THROUGH USE OF THE SERVICES. CUSTOMER IS SOLELY RESPONSIBLE FOR SECURING AND BACKING UP ITS APPLICATION, PROJECT, AND CUSTOMER DATA. NEITHER GOOGLE NOR ITS SUPPLIERS, WARRANTS THAT THE OPERATION OF THE SOFTWARE OR THE SERVICES WILL BE ERROR-FREE OR UNINTERRUPTED. NEITHER THE SOFTWARE NOR THE SERVICES ARE DESIGNED, MANUFACTURED, OR INTENDED FOR HIGH RISK ACTIVITIES.

13. Limitation of Liability.

13.1 Limitation on Indirect Liability. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, NEITHER PARTY, NOR GOOGLE'S SUPPLIERS, WILL BE LIABLE UNDER THIS AGREEMENT FOR LOST REVENUES OR INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, OR PUNITIVE DAMAGES, EVEN IF THE PARTY KNEW OR SHOULD HAVE KNOWN THAT SUCH DAMAGES WERE POSSIBLE AND EVEN IF DIRECT DAMAGES DO NOT SATISFY A REMEDY.

13.2 Limitation on Amount of Liability. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, NEITHER PARTY, NOR GOOGLE'S SUPPLIERS, MAY BE HELD LIABLE UNDER THIS AGREEMENT FOR MORE THAN THE AMOUNT PAID BY CUSTOMER TO GOOGLE DURING THE TWELVE MONTHS PRIOR TO THE EVENT GIVING RISE TO LIABILITY.

13.3 Exceptions to Limitations. These limitations of liability do not apply to breaches of confidentiality obligations, violations of a party's Intellectual Property Rights by the other party, or indemnification obligations.

14. Indemnification.

14.1 By Customer. Unless prohibited by applicable law, Customer will indemnify, defend, and hold harmless Google from and against all liabilities, damages, and costs (including settlement costs and reasonable attorneys' fees) arising out of a third party claim: (i) regarding any Application, Project, Instance, Customer Data or Customer Brand Features; or (ii) regarding Customer's, or its End Users', use of the Services in violation of the Acceptable Use Policy.

14.2 By Google. Google will indemnify, defend, and hold harmless Customer from and against all liabilities, damages, and costs (including settlement costs and reasonable attorneys' fees) arising out of a third party claim that Google's technology used to provide the Services (excluding any open source software) or any Google Brand Feature infringes or misappropriates any patent, copyright, trade secret or trademark of such third party. Notwithstanding the foregoing, in no event will Google have any obligations or liability under this Section arising from: (i) use of any Service or Google Brand Features in a modified, unauthorized, or unintended form or in combination with materials not furnished by Google, (ii) Customer's violation of this Agreement, (iii) use of non-current versions of the Services or Google Brand Features, and (iv) any Customer Data.

14.3 Possible Infringement.

a. Repair, Replace, or Modify. If Google reasonably believes the Services infringe a third party's Intellectual Property Rights, then Google may, at its sole option and expense: (a) obtain the right for Customer to continue using the Services; (b) provide a non-infringing functionally equivalent replacement; or (c) modify the Services so that they no longer infringe.

b. Suspension or Termination. If Google does not believe the foregoing options are commercially reasonable, then Google may suspend or terminate Customer's use of the impacted Services.

14.4 General. As a condition to indemnification for a claim, the party seeking indemnification must promptly notify the other party of the claim in writing and cooperate with the other party in defending the claim. The indemnifying party has full control and authority over the defense, except that: (a) any settlement requiring the party seeking indemnification to admit liability or to pay any money will require that party's prior written

consent, such consent not to be unreasonably withheld or delayed; and (b) the other party may join in the defense with its own counsel at its own expense. Notwithstanding the foregoing, if the indemnified party settles without the prior written consent of the indemnifying party, the indemnifying party has no obligation of contribution. THE INDEMNITIES ABOVE ARE THE ONLY REMEDY UNDER THIS AGREEMENT FOR VIOLATION OF A THIRD PARTY'S INTELLECTUAL PROPERTY RIGHTS.

15. Federal Agency Users. The Services were developed solely at private expense and are commercial computer software and related documentation within the meaning of the applicable Federal Acquisition Regulation and agency supplements thereto.

16. Miscellaneous.

16.1 Notices. All notices must be in writing and addressed to the other party's legal department and primary point of contact. The email address for notices being sent to Google's Legal Department is legal-notices@google.com. Notice will be treated as given on receipt as verified by written or automated receipt or by electronic log (as applicable).

16.2 Assignment. Neither party may assign any part of this Agreement without the written consent of the other, except to an Affiliate where: (a) the assignee has agreed in writing to be bound by the terms of this Agreement; (b) the assigning party remains liable for obligations under the Agreement if the assignee defaults on them; and (c) the assigning party has notified the other party of the assignment. Any other attempt to assign is void.

16.3 Change of Control. If a party experiences a change of Control (for example, through a stock purchase or sale, merger, or other form of corporate transaction): (a) that party will give written notice to the other party within thirty days after the change of Control; and (b) the other party may immediately terminate this Agreement any time between the change of Control and thirty days after it receives that written notice.

16.4 Force Majeure. Neither party will be liable for failure or delay in performance to the extent caused by circumstances beyond its reasonable control.

16.5 No Agency. This Agreement does not create any agency, partnership or joint venture between the parties.

16.6 No Waiver. Neither party will be treated as having waived any rights by not exercising (or delaying the exercise of) any rights under this Agreement.

16.7 Severability. If any term (or part of a term) of this Agreement is invalid, illegal, or unenforceable, the rest of the Agreement will remain in effect.

16.8 No Third-Party Beneficiaries. This Agreement does not confer any benefits on any third party unless it expressly states that it does.

16.9 Equitable Relief. Nothing in this Agreement will limit either party's ability to seek equitable relief.

16.10 Governing Law.

a. For City, County, and State Government Entities. If Customer is a city, county or state government entity, then the parties agree to remain silent regarding governing law and venue.

b. For Federal Government Entities. If Customer is a federal government entity then the following applies: ALL CLAIMS ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE SERVICES WILL BE GOVERNED BY THE LAWS OF THE UNITED STATES OF AMERICA, EXCLUDING ITS CONFLICT OF LAWS RULES. SOLELY TO THE EXTENT PERMITTED BY FEDERAL LAW: (I) THE LAWS OF THE STATE OF CALIFORNIA (EXCLUDING CALIFORNIA'S CONFLICT OF LAWS RULES) WILL APPLY IN THE ABSENCE OF APPLICABLE FEDERAL LAW; AND (II) FOR ALL CLAIMS ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE SERVICES, THE PARTIES CONSENT TO PERSONAL JURISDICTION IN, AND THE EXCLUSIVE VENUE OF, THE COURTS IN SANTA CLARA COUNTY, CALIFORNIA.

c. For All Other Entities. If Customer is any entity not set forth in Section 16.10(a) or (b) then the following applies: ALL CLAIMS ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE SERVICES WILL BE GOVERNED BY CALIFORNIA LAW, EXCLUDING THAT STATE'S CONFLICT OF LAWS RULES, AND WILL BE LITIGATED EXCLUSIVELY IN THE FEDERAL OR STATE COURTS OF SANTA

CLARA COUNTY, CALIFORNIA, USA; THE PARTIES CONSENT TO PERSONAL JURISDICTION IN THOSE COURTS.

16.11 Amendments. Any amendment must be in writing, signed by both parties, and expressly state that it is amending this Agreement.

16.12 Survival. The following Sections will survive expiration or termination of this Agreement: 6.1 (Intellectual Property Rights), 8 (Confidential Information), 9.5 (Effects of Termination), 13 (Limitation of Liability), 14 (Indemnification) and 16 (Miscellaneous).

16.13 Entire Agreement. This Agreement sets out all terms agreed between the parties and supersedes all other agreements between the parties relating to its subject matter. In entering into this Agreement, neither party has relied on, and neither party will have any right or remedy based on, any statement, representation or warranty (whether made negligently or innocently), except those expressly set out in this Agreement. The terms located at a URL referenced in this Agreement and the Documentation are hereby incorporated by this reference. After the Effective Date, Google may provide Customer with an updated URL in place of any URL in this Agreement.

16.14 Conflicting Terms. If there is a conflict between the documents that make up this Agreement, the documents will control in the following order: the Agreement, and the terms located at any URL.

16.15 Definitions.

"Acceptable Use Policy" or "AUP" means the acceptable use policy set forth here for the Services: developers.google.com/cloud/terms/aup. "Account" means Customer's Google account (either gmail.com address or an email address provided under the "Google Apps" product line), subject to those terms of service, as may be applicable. "Admin Console" means the online console(s) and/or tool(s) provided by Google to Customer for administering the Services. "Affiliate" means any entity that directly or indirectly Controls, is Controlled by, or is under common Control with a party. "Application(s)" means any web or other application Customer creates using the Services, including any source code written by Customer to be used with the Services, or hosted in an Instance. "Brand Features" means the trade names, trademarks, service marks, logos, domain names, and other distinctive brand features of each party, respectively, as secured by such party from time to time. "Committed Purchase(s)" have the meaning set forth in the Service Specific Terms. "Confidential Information" means information that one party (or an Affiliate) discloses to the other party under this Agreement, and which is marked as confidential or would normally under the circumstances be considered confidential information. It does not include information that the recipient already rightfully knew, that becomes public through no fault of the recipient, that was independently developed by the recipient, or that was lawfully given to the recipient by a third party. Customer Data is considered Customer's Confidential Information. "Control" means control of greater than fifty percent of the voting rights or equity interests of a party. "Customer Data" means content provided, transmitted, or displayed via the Services by Customer or its End Users; but excluding any data provided as part of the Account. "Documentation" means the Google documentation (as may be updated from time to time) in the form generally made available by Google to its customers for use with the following Services:

- Google App Engine, set forth here: https://developers.google.com/appengine/
- Google Cloud SQL, set forth here: https://developers.google.com/cloud-sql
- Google Cloud Storage, set forth here: https://developers.google.com/storage
- Google Prediction API, set forth here: https://developers.google.com/prediction
- Google BigQuery Service, set forth here: https://developers.google.com/bigquery/
- Google Compute Engine, set forth here: https://developers.google.com/compute/
- Google Cloud Datastore, set forth here: https://developers.google.com/datastore/

"Emergency Security Issue" means either: (a) Customer's or its End User's use of the Services in violation of the Acceptable Use Policy, which could disrupt: (i) the Services; (ii) other Customers' or its End Users' use of the Services; or (iii) the Google network or servers used to provide the Services; or (b) unauthorized third party access to the Services. "End Users" means the individuals Customer permits to use the Services, Application, or

Project. "Fee Threshold" means the threshold (as may be updated from time to time), as applicable for certain Services, as set forth here: https://developers.google.com/cloud/pricing. "Fees" means the applicable fees for each Service and any applicable Taxes. The Fees for each Service are set forth here: https://developers.google.com/cloud/pricing. "High Risk Activities" means uses such as the operation of nuclear facilities, air traffic control, or life support systems, where the use or failure of the Services could lead to death, personal injury, or environmental damage. "HIPAA" means the Health Insurance Portability and Accountability Act of 1996 as it may be amended from time to time, and any regulations issued thereunder. "Instance" means a virtual machine instance, configured and managed by Customer, which runs on the Services. Instances are more fully described in the Documentation. "Intellectual Property Rights" means current and future worldwide rights under patent law, copyright law, trade secret law, trademark law, moral rights law, and other similar rights. "Legal Process" means a request for disclosure of data made pursuant to law, governmental regulation, court order, subpoena, warrant, governmental regulatory or agency request, or other valid legal authority, legal procedure, or similar process. "License Term" means the term of the Agreement, which will begin on the Effective Date and continue until the Agreement is terminated as set forth herein. "Package Purchase" has the meaning set forth in the Service Specific Terms. "Privacy Policy" means Google's privacy policy located at: http://www.google.com/policies/privacy/. "Project" means a grouping of computing, storage, and API resources for Customer, and via which Customer may use the Services. Projects are more fully described in the Documentation. "Reserved Unit Term" has the meaning set forth in the Service Specific Terms. "Reserved Units" have the meaning set forth in the Service Specific Terms.

"Services" mean, as applicable: (a) Google App Engine; (b) Google Cloud SQL; (c) Google Cloud Storage; (d) Google Prediction API; (e) Google BigQuery Service; (f) Google Compute Engine; and (g) Google Cloud Datastore, and such other services as set forth here: https://developers.google.com/cloud/services (including any associated application program interfaces; and (h) TSS. The Services do not include Google Translate API. "Service Specific Terms" means the terms specific to one or more Services set forth here: https://developers.google.com/cloud/terms/service-terms, except the terms relating to (a) Google Translate API; and (b) Fees for Google Cloud Datastore, do not apply.

"SLA" means the Service Level Agreement as applicable to:

- Google App Engine set forth here: https://developers.google.com/appengine/sla
- Google Cloud Storage set forth here: https://developers.google.com/storage/sla
- Google Prediction API set forth here: https://developers.google.com/prediction/sla
- Google BigQuery Service set forth here https://developers.google.com/bigquery/sla
- Google Cloud SQL set forth here: https://developers.google.com/cloud-sql/sla
- Google Compute Engine set forth here: https://developers.google.com/compute/sla
- Google Cloud Datastore set forth here: https://developers.google.com/datastore/sla

"Software" means any downloadable tools, software development kits or other such proprietary computer software provided by Google in connection with the Services, which may be downloaded by Customer, and any updates Google may make to such Software from time to time. "Taxes" means any duties, customs fees, or taxes (other than Google's income tax) associated with the purchase of the Services, including any related penalties or interest. "Terms URL" means the following URL set forth here: https://developers.google.com/cloud/terms. "Token" means an alphanumeric key that is uniquely associated with Customer's Account. "Trademark Guidelines" means Google's Guidelines for Third Party Use of Google Brand Features, located at the following URL: http://www.google.com/permissions/guidelines.html. "TSS" means the technical support service provided by Google to the administrators pursuant to the TSS Guidelines. "TSS Guidelines" means Google's technical support services guidelines then in effect for the Services. TSS Guidelines are at the following URL: http://support.google.com/enterprise/terms (under Google Cloud Platform Services). "Updates" means the periodic software updates provided by Google to Customer from time to time. Updates are designed to improve, enhance and further develop the Services and may take the form of bug fixes, enhanced functions, new software modules and completely new versions.

Disclaimer

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