Research design documentation

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In this document, the following partners have contributed to the creation of this deliverable: UIBK, EURAC, UNILJ, VILANS, FAWO, JOAFG, COOP, ERT, 2PCS, M&A

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Consortium Partners

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1. INTRODUCTION AND PURPOSE

This deliverable gives a condensed overview of all results document related to task 2.2 “Development of final research design” of the i-evAALution project. It presents the main results of the task - the detailed sub-task results are attached to this document and inserted as links in the respective chapters.

1.1 DESCRIPTION OF TASK AND RELATION TO WORKPLAN

The detailed task planning and execution was based on the task description in the original project proposal (p.15):
“Based on D2.1 “Literature review on scientific evaluation methods”, the final research design for i-evAALution is developed. This includes the selection of evaluation methods for each dimension of analysis (cf. section 2.5 in this proposal), the planning of the sequencing of research activities as well as the preparation of all material that is needed to conduct the research (questionnaires, interview guidelines, feedback forms etc.). In order to guarantee the quality of the evaluation, the rationales behind the research designs have to be documented and key performance indicators (KPIs) have to be finalised for all research activities (cf. sect. 2.5 for an initial planning of KPIs). Additionally, pre-tests will be employed with a small sample of end-users in order to ensure the properness of the evaluation material. As not all persons conducting research activities are necessarily trained in scientific methods (e.g. employees of end-user organisations), this task does also include the development of comprehensive training material and quality management strategies to ensure a high-quality data collection in T2.3. Finally, this task does also involve the establishment of a data management strategy answering questions such as where and in which formats evaluation data is stored.”

2. RESULTS OF SUB-TASKS

2.1.. RESEARCH QUESTIONS (TASK 2.2.1)

Based on the proposal, the research questions have been defined consortium-internally in a joint process in order to ensure the involvement and acceptance by all partners. First, every partner defined research questions within the four dimensions of the proposal, which are as follows:

- System design
- System acceptance
- System impact
- Business perspective.

The research questions were summarized and brought together by the work package leader UIBK. This served as the basis for a joint discussion with all project partners involved in WP2 (via Skype). To finalise the questions, a workshop was specially organised in Bolzano on 9 July 2018 (participants were from EURAC, UIBK, UNILJ, VILANS and JOAFG). During the workshop, we prioritized the questions, jointly decided which ones should be included and which ones would be beyond the scope of the project. The result of this subtask is an Excel file with the research questions of the project i-evAALution, which can be found in figure 1 and figure 2.

#	Research question	Subquestions	Preliminary description of data collection method	Time planning	Operationalization responsibility
		SYSTEM DESIGN			
1	How reliable and secure is the i-evAALution bundle?	How reliable do the use cases offered by the bundle work? How secure is the system?	developer tests logs / metrics of software tests (use cases) security evaluation	prior to pilot	UIBK + 2PCS
2	How do users rate the user experience of the i-evAALution bundle and what are design suggestions to increase user experience?	utility ease of use satsifaction desirability / attractiveness learnability and memorability errors / reliability signs of frustration	1) usability expert evaluation (consortium-internal) a) heuristic evaluation b) reliability and performance (test environment) c) reliability and performance (real life simulation) 2) end-user workshops think-aloud and experience observation	prior to pilot	UIBK
3	What is the performance of the i-evAALution bundle during field use?	frequency and content of bugs frequency and content of help desk consults	log files of bugs log files of help desk consults	during pilot phase	UIBK
4	How attractive is the the i-evAALution bundle for care giving organisations and their professional carers and how can attractiveness be increased?	a: What are the most relevant key performance indicators for the i-evAALution bundle to improve the quality, efficiency and effectiveness of the care provided? b: Which type of costs / savings are expected to be reduced by the provided solution bundle? How can the bundle can contribute to more potential savings? c: Which services should be technically supported / connected in order to increase the integration and incorporation within your organisation and the general social / care system in your country?	focus groups with caregiving organisations	prior to pilot	UIBK + 2PCS
5	Which privacy and data protection criteria are obligatory for the test sites and their users and to what extent does the i-evAALution system fulfill them?	security and privacy protection concerning system architecture, processes and communication, data flow, permissions, etc.	lab testing / screening based on a concepts and defined indicators for the whole system and each solution; national ethical-legal frameworks as well as national health and care systems have to be analysed.	prior to pilot	UIBK + 2PCS
6	Which legal, ethical, market and customer criteria are relevant for the test sites and their users in each country? To what extent does the i-evAALution bundle meet this requirements and does it offer a high chance of solution adoption probability?	intended technology readiness level retrofitting capability capability of remote control need for maintenance and repairs degree of interoperability with bundle solutions and other common technologies potential to remain attractive (open platform approach, consideration of existing standards and state-of-the-art technologies) disoperation / failures financial and general viability (usage of affordable components/technology, retrofittable)	lab testing / screening based on a concepts and defined indicators for the whole system and each solution (e.g. process model, effectiveness analysis) analysis during implementation / supporting	prior to pilot / during implementation	UIBK + 2PCS

Figure 1 Research questions related to the system design

	SYSTEM ACCEPTANCE				
7	What factors influence the acceptance of the bundle and how do social, environmental/contextual and personal aspects determine the acceptance of the bundle?	What is the influence of personal factors (e.g. demographics, socio-economic status) on acceptance of the bundle? What is the influence of environmental/contextual (e.g. social norm) factors on acceptance of the bundle? What is the influence of technology-related factors on acceptance?	quantitative acceptance questionnaire	during pilot	
8	What features are most frequently used and what are the main characteristics of the older adults regarding the use of features?		log files of use	during pilot	
9	How well is the bundle integrated into the daily lives of the test persons and what are aspects of disturbance?		self-reported	during pilot	
	SYSTEM IMPACT				
10	What is the effect of the i-evAALution bundle on quality of life of older adults?	subjective QoL effects on autonomy freedom of choice freedom of movement decisional autonomy social inclusion / participation activity and mobility home environment and safety	quantiative measurement instrument (tbd), RCT setting	during pilot	
11	What is the effect of the i-evAALution bundle on frailty and functional independence of older adults?	effects on IADL level effects on physical frailty status	quantiative measurement instrument (tbd), RCT setting, for frailty only self-reported questionnaires	during pilot	
12	What is the effect of the i-evAALution bundle on quality-adjusted life expectancy and health and care resource use?			during pilot	
13	What is the effect of the i-evAALution bundle on caregiver burden?		quantiative measurement instrument (tbd), RCT setting	during pilot	
	BUSINESS PERSPECTIVE				
14	What are older adults and informal carers willing to pay for the i-evAALution bundle and how does it differ across demographic characteristics?		tbd, quantitative measurement	during pilot	
15	Which customer segments for the i-evAALution bundle can be identified?		tbd, quantitative measurement	during pilot	
16	What is the preferred acquistion model, (rent / buy), what are possible service models and what is the related willingness to pay (maintenance, user service, support)?		tbd, quantitative measurement	during pilot	
17	What impact does the i-evAALutoin bundle have on care organisations and care systems?	Impact on efficiency and effectiveness which result in saving expenses or by not having to increase expenses in the mid and long term? Impact on quality of care? Impact on satisfactions of staff? Impact on image and competitiveness (increase of demand etc.) ?	questionnaire + cost-benefit analysis; process analysis	during pilot	
18	Under what conditions would municipalities /care insurance companies be interested in providing the bundle and what would they be willing to pay for the i-evAALution bundle?		focus groups?	during pilot	
19	What roles does the bundle require and who are the stakeholders in the i-evAALution ecosystem that could fulfill these roles?		analysis of application environment	prior to pilot	

Figure 2 Research questions related to the system acceptance, system impact and the business perspective

2.2.. RESEARCH DESIGN OPERATIONALISATION (TASK 2.2.2)

Based on the research questions, we developed a detailed research design for the project i-evAALution. It presents the overall research models for all evaluation stages (pre-alpha phase, alpha phase, trial phase) and for all involved end users. Based on the research questions from sub-task 2.2.1, research hypotheses that we intend to test are presented. Based on the literature and measures research in task 2.1, it specifies the selected (standardized and validated) instruments (questionnaires, methods) that we will use and indicates where self-developed items are necessary. Furthermore, several confounding variables are listed that we consider important and will therefore be collected in the trial phase. In the last chapter we also give an overview of the layout of all steps in the pre-testing and testing phase.

2.2.1. FRAMEWORK MODELS WITH VARIABLES

At first, two framework models were created, as illustrated in figure 3 and figure 4, that build the basis for the research hypotheses and provide an overview of various predictor and outcome variables. The framework models were developed on the basis of the Senior Technology Acceptance Model (STAM) of (Renaud and van Biljon 2008) and the Cycle of Technology Acquirement by Independent-Living Seniors (C-TAILS) (Peek et al. 2017) as well as a detailed literature research.

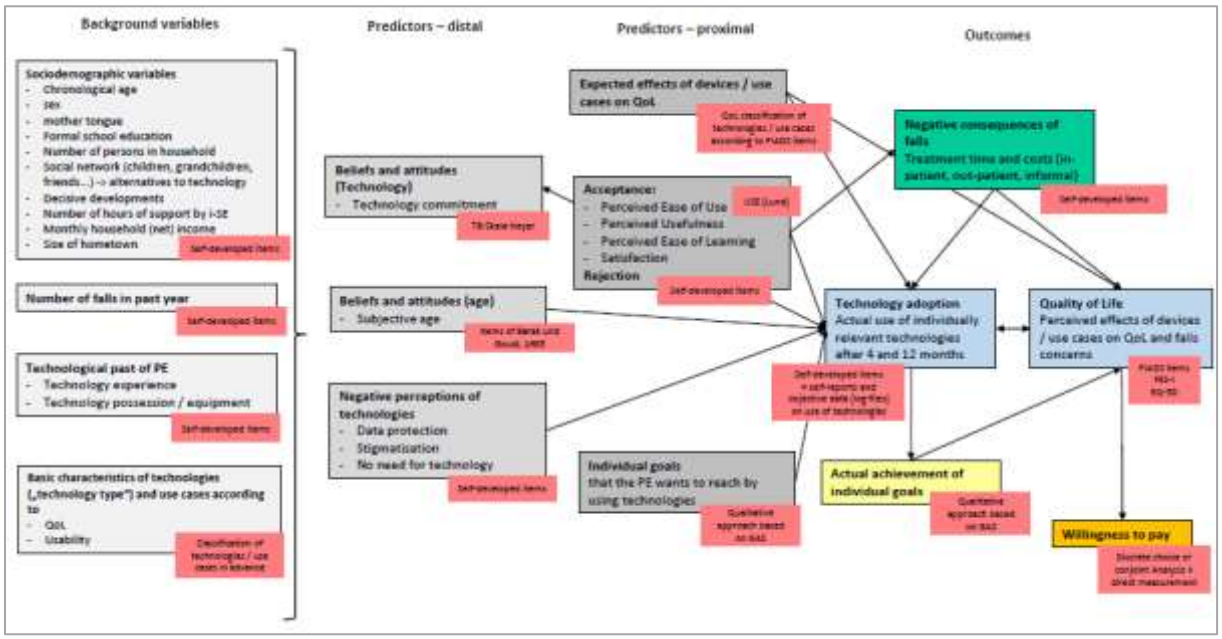

Figure 3 Framework model for PEs

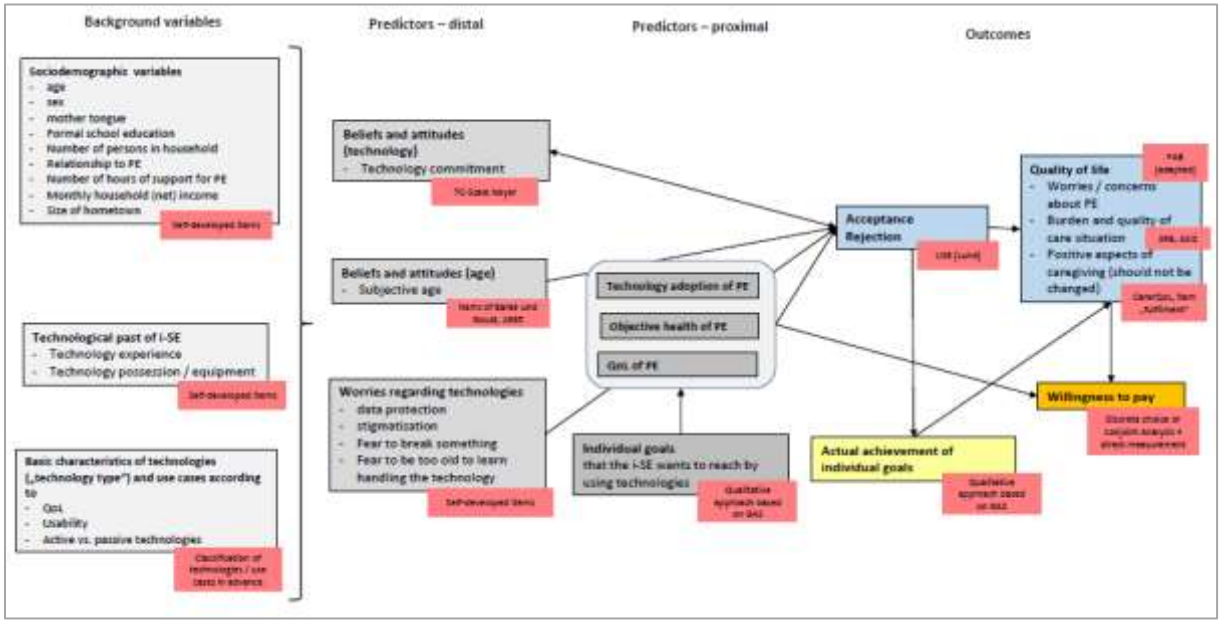

Figure 4: Framework model for i-SEs

2.2.2. HYPOTHESES AND RESEARCH QUESTIONS

The classification of the following hypotheses and research questions is based on the four "dimensions of analysis" of the project proposal: system design, technology acceptance, technology impact and business perspective

2.2.2.1. DIMENSION 1: SYSTEM DESIGN

The research questions (Task 2.2.1), developed jointly by the project partners, serve to find out how usable the i-evAALution bundle is according to PE, i-SE and f-SE, and how high its technical quality (reliability, safety) is. The system design will be improved as much as possible in the pre-alpha and alpha-phase by iterative feedback to the software development team of the consortium. During the pilot phase, the system design, especially its reliability, will be consequently monitored to receive data on the technological performance of the bundle. In case there are periods of technical problems, this fact can be included into the data analysis as a confounding variable.

	Research Question	Subquestions	Preliminary description of data collection method
1	How reliable and secure is i-evAALution?	• How reliable and secure do the products / devices work? • How reliable and secure is the bundle / the different use cases?	**Developer tests in alpha phase** a) logs / metrics of software tests (use cases) b) security evaluation
2	How do users rate their experience of the i-evAALution bundle and what are design suggestions to increase user experience?	• utility • ease of use • satisfaction • desirability / attractiveness • learnability and memorability • errors / reliability • signs of frustration	**1) Usability expert evaluation (consortium-internal) in pre-alpha phase** a) heuristic evaluation b) reliability and performance (test environment) c) reliability and performance (real life simulation)

			2) End-user feedback in alpha phase (PE) User-tests plus experience observation **3) End-user feedback (PE and i-SE) at the end of the pilot phase**
3	What is the performance of the i-evAALution bundle during field use?	• frequency and content of bugs • frequency and content of help desk consults	**Developer tests during pilot** a) log files of bugs b) log files of help desk consults
4	How attractive is the i-evAALution bundle for care giving organisations and their professional carers and how can attractiveness be increased?	• What are the most relevant key performance indicators for the i-evAALution bundle to improve the quality, efficiency and effectiveness of the care provided? • Which type of costs / savings are expected to be reduced by the provided solution bundle? How can the bundle can contribute to more potential savings? • Which services should be technically supported / connected in order to increase the integration and incorporation within your organisation and the general social / care system in your country?	**Focus groups with caregiving organisations during the recruitment phase ("awareness sessions") and the pilot phase** (organisations which are included into the project as well as external organisations. More details on the focus groups will be defined during the business modelling process / WP4)
5	Which privacy and data protection criteria are obligatory for the test sites and their users and to what extent does the i-evAALution bundle fulfill them?	• security and privacy protection concerning system architecture processes and communication • data flow • permissions • etc.	**1) Lab testing / screening in alpha phase** based on a concept and defined indicators for the whole system and each solution **2) Analysis of national ethical-legal frameworks as well as national health and care systems in alpha phase**
6	Which legal, ethical, market and customer criteria are relevant for the test sites and their users in each country? To what extent does the i-evAALution bundle meet these requirements and does it offer a high chance of solution adoption probability?	• intended technology readiness level retrofitting capability • capability of remote control • need for maintenance and repairs • degree of interoperability with bundle solutions and other common technologies • potential to remain attractive (open platform approach, consideration of existing	**1) Lab testing / screening during the pilot phase** based on a concepts and defined indicators for the whole system and each solution (e.g. process model, effectiveness analysis) **2) Analysis during the pilot phase**

		standards and state-of-the-art technologies) • Incorrect functioning / failures • financial and general viability (usage of affordable components/technology, retrofittable)	

Table 1 Research questions system design

2.2.2.2. DIMENSION 2: TECHNOLOGY ACCEPTANCE

The main theoretical foundations for this project are the following two models:

- The **Cycle of Technology Acquirement by Independent-Living Seniors (C-TAILS)** (Peek et al. 2017): The model was developed in an explorative qualitative field study. It explains which influencing factors lead older people to acquire (assistive) technologies and which consequences can result from the acquisition. The authors still see a research gap for the clarification of the complex influences of many factors on technology acquisition (and use) of older adults.
- The **Senior Technology Acceptance Model (STAM)** (Renaud and van Biljon 2008), which is based on the Technology Acceptance Model (TAM) (Davis 1985). Davis defines technology acceptance as "system use" (Davis 1989) (p. 319), including other variables described in TAM, TAM2 and TAM3, which lead to the actual use of a system. The STAM goes further though, a) by specifying the model concerning the population group of older adults, and b) by distinguishing technology acceptance and technology adoption. The authors do not assume a complete adoption, i.e. acceptance of a device, until the intention to use it has in fact become actual long-term use (testing and experimenting must confirm the usefulness of the device to the user). This takes into account the process character of technology acceptance: only if there is the permanent conviction of the usefulness and also an ongoing actual use, one can speak of the long-term acceptance of a device.

The two most important components which influence the (long-term) use of technology are **Perceived Usefulness (PU)** and **Perceived Ease of Use (PEOU)**, defined by (Davis 1989) (p.320) as „the degree to which a person believes that using a particular system would enhance his or her job performance" (PU) and the "degree to which a person believes that using a particular system would be free of effort" (PEOU). The influence of these two variables on technology usage has been demonstrated in many studies (summarised for example in the review of Chen and Chan (2011)).

Overall, for i-evAALution we regard **usability** according to ISO 9241-11:2018, where it is defined as "the extent to which a system, product or service can be used by particular users in a particular context of use in order to achieve particular objectives effectively, efficiently and satisfactorily" (p.9 in Europäisches Komitee für Normung (2008)). The concept of "usability" is intertwined with "technology acceptance": PU and PEOU show similarities with the concepts of **effectiveness** ("accuracy and completeness with which users achieve specific goals", p.18) and **efficiency** ("resources used in relation to the results achieved", p.18). According to ISO 9241-11:2018 (Europäisches Komitee für Normung 2018) they determine the usability of a system together with **satisfaction** („the extent to which the [...] reactions of the user [...] correspond to the user requirements and user expectations", p.20). The following table shows a classification of the four variables.

	TAM constructs, which influence technology acceptance	ISO 9241-11 constructs, which determine (amongst others) usability
Quality of goal achievement	PU: „degree to which a person believes that using a particular system would enhance his or her job performance“	Effectiveness: “accuracy and completeness with which users achieve specific goals”
Effort in relation to goal achievement	PEOU: “degree to which a person believes that using a particular system would be free of effort“	Efficiency: “resources used in relation to the results achieved“

Table 2 Classification of four acceptance / usability variables

Concerning the assessment of **„objective usability”** Venkatesh and Davis (1996) propose that experts perform tasks on a technical system (e.g. a software programme). Their performance (e.g. duration of time to solve the task) is then related to the performance of novices, which results in a number between 0 and 1. As this process is very time- and resource-consuming we will ensure the objective usability of the i-evAALution bundle in a different way: in the pre-alpha phase of the project, it will be estimated through heuristic evaluation by internal and external usability experts. According to Quiñones and Rusu (2017), it is important that usability heuristics used by experts refer as specifically as possible to the system to be evaluated. In their review, they give an overview on heuristics developed between 2006 and 2016, including also the domains to which they refer.

The validity of the expert assessments / evaluation is thus ensured in two ways for i-evAALution:

- The widely accepted heuristics of Nielsen (1994) is enriched by several heuristics extracted from a literature research (see separate working document on procedure and content of the i-evAALution usability evaluation)
- Our internal experts (staff of the consortium partners) are not only usability experts, but also domain experts, i.e. people with many years of (practical) experience in the field of AAL. Thus, the main disadvantage in applying usability heuristics that (Quiñones and Rusu 2017) name are minimised.

Furthermore, we will obtain **qualitative feedback of PE** in the (pre-)alpha phase of the project by observing them use the different parts of the bundle – which requires no additional cognitive effort of the older users (as would the thinking-aloud method) (Sarodnick and Brau 2011). Both the experts’ and the PEs’ feedback will be forwarded in various iterative loops to the software developers of the project who will improve the bundle as much as possible before it is tested on a bigger scale in the pilot phase.

Arning and Ziefle (2007) distinguish an attitude component of technology acceptance with affective and cognitive aspects, and a behavioural component which refers to the actual use of a certain device. This leads to the following matrix:

	Attitude component of acceptance	Behaviour component of acceptance
Specific technologies	Specific measures (Usefulness, Satisfaction, and Ease of use questionnaire, Lund (2001))	Actual use measured by log data and / or self-reports by users
Technology in general	General measures (Technology commitment scale, Neyer et al. (2012))	-

Figure 3 Matrix of measures for technology acceptance

Within the project i-evAALution, we will measure all three aspects of technology acceptance. They are included in different ways in the following research hypotheses.

HYPOTHESES „INFLUENCE OF TECHNOLOGY COMMITMENT - PE“	
1	People (PE) with a higher technological commitment a) use more i-evAALution devices and use cases, and b) use the i-evAALution technologies and use cases more frequently. The relationship remains present even if it is controlled for by the variable "actual technology competence": Older persons in the intervention group with higher technology commitment at the beginning of the pilot phase should differ in the use of i-evAALution technologies from persons who have a lower technology commitment at the beginning, independent of their actual technology competence.
2	The commitment to use technology is increased through the use of the i-evAALution technologies and use cases (prepared through adequate and individual training). The willingness to use technology is higher in the intervention group than in the control group at the first intermediate measurement (4 months) and at the end of the test phase (12 months) among older people.
Evidence for the hypothesis	
	Neyer et al. (2012) see technology commitment as "an attitude characteristic that reflects the subjective evaluation of technological progress" (p. 88). They developed a model of technology commitment including a measurement tool with three components / scales: technology acceptance, technology competence and technology control. Although it can be assumed that the older people who actually agree to participate for one year in i-evAALution already have a higher readiness for technology than the average, their attitudes and experience in dealing with modern technology (above all the competence and control subscales) should increase during the project in the intervention group (but not in the control group). The authors state the need for research concerning the relationship of the construct to the actual technical competences of a person: the commitment to use technology should continue to predict the actual use of technology, even if the actual competence is controlled for.
	In a rather explorative study with 52 older people, Berkowsky et al. (2018) only found a small connection between the technology commitment of a person and the intention to use it. They measured the technology commitment with the Technology Readiness Scale 2.0 (TRI2.0) of

	(Parasuraman and Colby 2015), which includes competence and control perceptions only marginally. Therefore, in the project i-evAALution the construct and its measurement will be done according to (Neyer et al. 2012).
How will the hypotheses be tested?	
• Measurement of technology commitment via the Brief Measure for Technology Commitment (TC Scale) (Neyer et al. 2012) • The use of technology during the pilot phase is determined by objective data (log data) and subjective data (self-report) • The actual technical competence is measured by the experiences with technology and technology ownership (possibly also by the results of the initial technical training: e.g. length of the training until everything is understood, or errors in test tasks).	

HYPOTHESIS „INFLUENCE OF TECHNOLOGY COMMITMENT – I-SE“	
1	The technology commitment of i-SE is increased by the acceptance of the i-evAALution technologies and use cases (prepared through adequate and individual training) and vice versa. The acceptance of the i-evAALution technology is higher in the intervention group than in the control group at the first intermediate measurement (4 months) and at the end of the test phase (12 months).
Evidence for the hypothesis	
	Neyer et al. (2012) see technology commitment as "an attitude characteristic that reflects the subjective evaluation of technological progress" (p. 88). They developed a model of technology commitment including a measurement tool with three components / scales: technology acceptance, technology competence and technology control. Although it can be assumed that the informal secondary end-users who actually agree to participate for one year in i-evAALution already have a higher readiness for technology than the average, their attitudes and experience in dealing with modern technology (above all the competence and control subscales) should increase during the project in the intervention group (but not in the control group). The authors see a need for research about the technology commitment of informal support persons. Within the framework of i-evAALution, the hypothesis is put forward that there is a positive effect with i-SE, as with the older test subjects themselves.
	In a rather explorative study with 52 older people, Berkowsky et al. (2018) only found a small connection between the technology commitment of a person and the intention to use it. They measured the technology commitment with the Technology Readiness Scale 2.0 (TRI2.0) of (Parasuraman and Colby 2015), which includes competence and control perceptions only marginally. Therefore, in the project i-evAALution the construct and its measurement will be done according to (Neyer et al. 2012).
How will the hypotheses be tested?	
• Measurement of technology commitment via the Brief Measure for Technology Commitment (TC Scale) (Neyer et al. 2012); one sub-scale might be deleted due to feedback from the alpha-phase • The acceptance of i-SE will be measured by self-developed items (the USE scale does not work for i-SE)	

- The actual technical competence is measured by the experiences with technology and technology ownership (possibly also by the results of the initial technical training: e.g. length of the training until everything is understood).

HYPOTHESIS „INFLUENCING FACTORS FROM THE TAM-TRADITION“

The acceptance, i.e. the actual usage of the i-evAALution bundle / the i-evAALution use cases (after 4 and after 12 months) by older adults is determined by the predictors

1) Perceived usefulness (PU)
2) Perceived ease of use (PEOU)
3) Ease of learning
4) Satisfaction
5) Confidence in one's own ability

Evidence for the hypothesis

In two studies about the variables Perceived Usefulness (PU) and Perceived Ease of Use (PEOU) (Davis 1989) showed that both were correlated with the actual use of technologies (with PU being significantly more correlated than PEOU). In the study of (Berkowsky et al. 2018), PU was a robust factor for the intention to use (ITU).

The variable „satisfaction with the technology“ plays an important role when evaluating a technology – it is part of the ISO concept of usability (Europäisches Komitee für Normung 2018) as well as the research of Demers et al. (2002), who developed a satisfaction questionnaire on assisitve services and devices. Embedding satisfaction into a technology acceptance model to our knowledge has not yet been done.

(Berkowsky et al. 2018): in this explorative study, confidence in one's own ability to deal with technologies is a robust predictor of willingness to use technologies (usage intention). Here it is assumed that it also influences the actual use of technologies over a period of one year. (Neyer et al. 2012) explicitly extend the TAM model with the development of their TC scale (subscale technical competence conviction and control conviction). During the development of the Usefulness, Satisfaction and Ease of Use Questionnaire (USE), (Lund 2001) realised that the factor Ease of Learning was complementing Ease of Use.

How will the hypotheses be tested?

- The use of technology is determined by objective data (log-files, possibly performance in training tasks) and subjective data (self-reports)
- Data on the five variables are collected as follows:
    1) USE subscale Perceived Usefulness
    2) USE subscale Perceived Ease of Use
    3) USE subscale Perceived Ease of Learning
    4) USE subscale Satisfaction
    5) TC subscales belief about one’s own technical competence and control (Neyer et al. 2012)

HYPOTHESIS „INFLUENCE OF SUBJECTIVE AGE“

Subjective age influences technology acceptance, depending on the type of technology (cognitive, instrumental technologies; emotional, social technologies; assistive technologies).
Evidence for the hypothesis
"Subjective age is a multidimensional construct that indicates how old a person feels and into which age group a person categorizes himself or herself" (Kleinspehn-Ammerlahn et al. 2008) (p.377). The effects of the variable chronological age on technology acceptance have been investigated in a large number of studies and appear to be rather weak overall. Hauk et al. (2018), for example, conclude from their meta-analysis that acceptance strongly depends on the type of technology: there are no age effects on acceptance concerning technologies that enable growth, knowledge acquisition, or facilitation of everyday tasks. However, there are effects on technologies that enable entertainment and leisure, health and safety as well as communication and social needs. Künemund (2016) on the other hand postulates that age effects disappear if variables such as gender, education and previous technical experience are kept constant. Based on their results, Hauk et al. (2018) recommend that future studies also include subjective age, which could have a higher predictive power than chronological age. Chéron and Kohlbacher (2018) show in a **review of 8 studies** that measure subjective age in connection with (technical) innovations that **none includes the actual use of those innovations**. In their own study, they conducted a large-scale questionnaire survey among middle-aged and older people in Japan on the use of electronic consumer goods (high-end TV, digital camera, high-end rice cooker...). They found that subjective age plays a **mediating role** on technology anxiety and global consumer innovativeness. The investigation of the influence of subjective age on the actual long-term use (e.g. collected via log files) of assistive technologies hasn't been carried out up to now and will therefore be included in the i-evAALution project. What needs to be considered is that the i-evAALution sample will consist of persons who already have a positive attitude about assistive technologies. Therefore, they might use (some of the) technologies less, if they feel younger as they might not perceive the need for the technologies.
How will the hypothesis be tested?

• Measurement of chronological age (self-developed item) as well as subjective age (four items based on Barak and Gould (1985)) with PE and i-SE
• The three aspects of technology acceptance measured by
  • TC Scale, i.e. the commitment to use technology (acceptance, technology competence, technology control)
  • USE Questionnaire
  • Actual usage measured by log files and self-reports

HYPOTHESIS „SOCIAL INFLUENCES"
The more adult children are worried about their older parents at baseline, the higher the technology commitment and acceptance of the i-evAALution bundle by the older adults. This effect will not be present if the i-SE is the partner, grandchild or in another relationship (friend, neighbour...) with the older person.
Evidence for the hypothesis
In their qualitative study (Luijkx et al. 2015) investigate the influence of different family members on the use of electronic devices by older people. They found out that adult children sometimes urge their parents to use technological devices and that older adults sometimes give in and use devices

because they recognise their children are concerned and therefore push them. They observed these effects for computer devices, mobile phones and personal alarms. These effects could not be found in relationships of older people with their spouses or grandchildren.

How will the hypotheses be tested?

- The level of worry of i-SE will be measured by the Filial Anxiety Scale B (Cicirelli 1988)
- The general technology acceptance of PE and i-SE will be measured by the TC scale (Neyer et al. 2012)
- The acceptance of the i-evAALution bundle will be measured by the USE scale (Lund 2001)
- The actual use of the i-evAALution technologies will be measured by log-files and self-reports.

HYPOTHESIS „FURTHER FACTORS“

The technology acceptance of people who use the technologies / use cases for 4 or 12 months is negatively influenced by the following variables:

- Data protection concerns
- Perceived stigmatisation by the technologies
- Perception of no personal need for a technology.

Evidence for the hypothesis

Peek et al. (2014) extracted from a review of 16 studies (before 2011) various factors which influence the acceptance of older people who actually have used technical devices (“post-implementation research”, p.236), partly over a longer period:

- Concerns about data protection
- Stigmatisation
- Perception of the personal need for a technology
- Benefits through increased safety
- Occurrence of false alarms
- non-functioning of the technology
- Availability of personal support as an alternative to technologies
- Satisfaction with the technology
- Affective factors concerning the technology
- You could break something
- You could be too old to learn how to deal with each other

According to a review of Yusif et al. (2016), the following barriers can hinder technology adoption by older adults:

- Privacy concerns
- Perception of no need
- Stigma
- Limited training tailored to older learners
- Fear of dependence
- Loss of Dignity
- Trust
- Functionality / added Value
- Cost
- Ease of use and suitability for daily use

• Feeling of embarrassment • Autonomy • Lack of accessibility and social inclusion It won't be possible to research all factors within the project i-evAALution. Therefore, we are planning to concentrate on three variables that both research groups found to be influential on technology adoption.
How will the hypotheses be tested?
• Concerns about the test phase and the technologies will be assessed qualitatively in the questionnaires at baseline • We will assess qualitatively at month 4 and month 12 of the testing phase, why certain use cases were not used by the PEs.

The following table contains practice-oriented research questions that provide information about the perceived quality of the i-evAALution bundle and whose answers are important, for example, for the market entry of the product.

	Research Questions	Sub-questions	Preliminary description of data collection method
1	What features are most commonly used and what are the main characteristics of older adults in terms of using features?	/	a) Sociodemographic data b) The usage data for the technologies / applications are collected via self-disclosure and technical data (log data)
2	How well is the bundle integrated into the everyday life of the test persons and what are aspects of disturbance?	/	The usage data for the technologies / applications are collected via self-disclosure and technical data (log data)

Table 3 Research questions technology acceptance

2.2.2.3. DIMENSION 3: TECHNOLOGY IMPACT

Bayer et al. (2007) are warning researchers to be overenthusiastic about expected short- or even medium-term effects of assistive technologies – even though since the publication of this article some randomised controlled trials have been conducted and published, which provide empirical data on these effects. A review of those studies (Czaja et al. (2017), Cartwright et al. (2013), Hirani et al. (2014), Mortenson et al. (2013), Mortenson et al. (2018), Mann (1999), Khosravi and Ghapanchi (2016), Slegers et al. (2008)) seems to confirm the need to be cautious with the assumption of clear and strong impacts, still some effects could be found and i-evAALution will contribute even more meaningful results to this body of research.

In their randomised controlled trial Slegers et al. (2008) showed that internet and computer usage of **older adults** had no effects on their QoL and well-being (physical and mental functioning, loneliness, satisfaction with life, depression etc.). Other researchers have focused more on the effect of technological devices which are designed for older adults, with the aim to enhance their autonomy and well-being. The results are mixed, even though there are some studies with an elaborate methodological design, which are described briefly in the following sections.

Hirani et al. (2014) summarise their results of testing „telecare“ in the large British study “Whole Systems Demonstrator” (WSD) in the following way: The technologies tested do not radically change the lives of older people, but appear to have some positive effects on psychological and health-related aspects of quality of life. No effects were shown using the ICEpop CAPability measure for older people (ICECAP) (Coast et al. 2008) with its five dimensions attachment, security, role, enjoyment and control / independence. As a limitation of their study, the authors state the fact that only the whole intervention and not the effects of specific devices (e.g. the fall sensor) were investigated. During i-evAALution we will take up those shortcomings and study QoL-effects in a more detailed way.

Basically no effects on health-related QoL aspects at all could be demonstrated in the “telehealth” part of the WSD (Cartwright et al. 2013), conducted with older persons with chronic conditions. The authors’ conclusion therefore is that telehealth “should not be used as a tool to improve health related QoL or psychological outcomes” (p. 9). Within i-evAALution we focus on “normal” older adults, i.e. older adults who don’t necessarily have a certain condition or illness. Even though chronic conditions and comorbidity are rather common in older persons we can assume that effects on non-health-related aspects of QoL could still be found by using the i-evAALution bundle.

Czaja et al. (2017) report from the test of the software PRISM (Personal Reminder Information and Social Management) that after a one-year test phase there were no group differences regarding loneliness, social support and well-being amongst older people, which were actually expected through the use of the software. A curious effect was that after 6 months there was very well a positive group effect (the intervention group scored higher on QoL variables as the control group), but after 12 months only a positive time effect remained (both groups scored higher at the end of the trial compared to the baseline). The authors provided two possible explanations for this outcome: either it could have been a kind of novelty effect (technologies are perceived more positive as long as the older adults hadn’t got used to them) or it was a study participation effect (the mere participation in the study and contact with the staff lead to positive impacts).

Through a complex intervention with demand-oriented technologies including counselling and training, a study by Mortenson et al. (2018) was supposed to demonstrate positive effects of these technologies on older people (an exploratory study of the same authors suggested effects on some QoL-related aspects (Mortenson et al. 2013)). However, no group effects could be demonstrated – probably a major problem was that the intervention and control groups were too similar.

In a relatively old randomised controlled trial (Mann 1999) found out that assistive technology was able to slow down functional decline and prevent an increase of pain perceptions of older adults over an 18 months period.

During the project i-evAALution, not only the influence of assistive technologies on the quality of life of older people, but also on their **informal caregivers** will be examined. Up to 2012, there were no methodologically adequate studies on the effects of assistive technologies on informal caregivers, as Mortenson et al. (2012) show in their review. No randomised controlled trials had been conducted and in none of the studies the actual use of the technologies by i-SE was assessed. The authors conclude that “the evidence provided by these studies is limited” (p.12 in author manuscript).

The randomised controlled trial by Mortenson et al. (2018) aimed at demonstrating positive effects of assistive technologies not only on older adults but also on their informal caregivers. However, also for informal caregivers no group effects could be shown due to the methodological problems mentioned above. What could be shown though was that in the intervention as well as in the control group the burden of i-SE decreased over time, which leads to the implication that assistive technologies have an effect – which is not necessarily different or bigger than the one of conventional care though. The rather positive effects confirmed the outcomes of the previous exploratory study in which the research team (Mortenson et al. 2013) showed that part of the i-SE burden decreased due to the use of assistive technology.

Czaja et al. (2013) name advantages that assistive technologies can have on the burden of informal supporters, which will also be addressed by the i-evAALution bundle: logistical barriers can be overcome more easily and access to services can be facilitated, and communication with relatives, other caregivers or health facilities can be improved.

In summary, the findings of assistive technologies on older adults and their informal caregivers are mixed and not under all conditions and for all technologies huge effects can be expected. Still, the research process can't be considered to be concluded yet and therefore more research is needed. For many stakeholders – not only older adults and their family members but also policy makers and public health authorities – it is crucial to survey in a detailed way which QoL-effects can be expected from the use of assistive technologies.

HYPOTHESIS „QUALITY OF LIFE OF PE"
After 4 and 12 months, the perceived quality of life of the older persons in the intervention group is better, or less severely declined than that of persons in the control group.
Evidence for the hypothesis
Like it was demonstrated by the "telecare" branch of the WSD (Hirani et al. 2014) and Mortenson et al. (2018) (see above), we expect to find positive effects on some aspects of quality of life, also depending on the kinds of technologies which are actually used by the older test persons and their i-SE.
How will the hypotheses be tested?
• The impact of the i-evAALution technologies / use cases will be assessed in the intervention group by the Psychosocial Impact of Assistive Devices Scale (PIADS) (Jutai and Day 2002) • Agree and Freedman (2011) have extracted three QoL-concepts, which are particularly affected by the use of assistive technologies. Each concept is represented by an item which measures the impact of assistive devices in that domain. Based on those three items (on safety, control and participation) we developed a QoL-measure which will possibly be used by the intervention group as well as the control group. • The EQ-5D-5L (van Reenen and Janssen 2015) with its five items and a visual analogue scale will be used to assess effects of the technologies / use cases on health related quality of life. Even though previous research hasn't found clear effects of assistive technologies on the EQ-5D domains, the questionnaire is widely recognised among tertiary end-users. As it is a parsimonious measure, it will therefore be used in the project.

- The Falls Efficacy Scale International (FES-I) (Yardley et al. 2005) assesses the fear of falls / concern of falling when performing activities inside or outside the home. We expect it to be reduced by the long-term use of the safety-relevant technologies and use cases of the i-evAALution bundle.

HYPOTHESIS „QUALITY OF LIFE OF I-SE“
After 4 and 12 months, the perceived quality of life of the older persons in the intervention group is better, or less severely declined than that of persons in the control group.
Evidence for the hypothesis
A first systematic review on (positive) effects of assistive technologies on caregivers was done by Mortenson et al. (2012): “the findings suggest that AT use helps caregivers by diminishing some of the physical and emotional effort entailed in supporting individuals with a disability” (p.1 in author manuscript) – though all studies had methodological problems which limits their explanatory power. A more recent review (Madara Marasinghe 2016) showed that in many studies the burden (concerning concrete care tasks as well as emotional burden) of caregivers could be decreased by assistive technologies.
How will the hypotheses be tested?
Three of the measures used to assess the effects of i-evAALution on informal carers are part of the iMTA Valuation of Informal Care Questionnaire (iVICQ) (Hoefman et al. 2013): • Assessment of Informal care Situation (ASIS) • Self-rated burden scale (SRB) • The “fulfilment of care” item of the Care-related Quality of Life instrument (CarerQol) (Brouwer et al. 2006; Hoefman et al. 2011) • Furthermore, we use the Filial Anxiety Scale B (Cicirelli 1988) in a slightly modified version to assess worries of informal carers about the persons they assist (the PEs).

HYPOTHESIS „ACTUAL TECHNOLOGY USE“
The actual use (after 4 and 12 months) of a particular i-evAALution technology / use case is determined by its expected and perceived impact on quality of life.
Evidence for the hypothesis
In their explorative study, Berkowsky et al. (2018) found the factor “perceived impact on quality of life” was a robust predictor for the willingness to use technologies (usage intention). Here, we assume that both the expected impact and the actual perceived impact influence the actual use of technologies over a period of one year.
How will the hypotheses be tested?
• In the pre-alpha phase of the pilot we classify all i-evAALution devices and use cases according to their assumed impact on quality of life (according to the PIADS items) and cluster the use cases which should have similar effects (on security, on the ability to participate etc.) • At the baseline of the trial phase (but after their technology training), the PE assess the expected impact of the i-evAAlution bundle by using the PIADS • The actual use of technology by the older adults is assessed by objective data (log data, possibly performance in tasks) as well as subjective data (self-reports)

- After 4 and 12 months we analyse the PIADS values of PEs and compare them to the actual use of the respective use case / use cases cluster. We hypothesise that after 4 / 12 months the PIADS values are more positive than at baseline if the PEs actually used the respective use cases / clusters of use cases.

HYPOTHESIS „TECHNOLOGY COMMITMENT“
Older adults and informal carers who have a high readiness / commitment to use technology at the end of the pilot phase also have a high quality of life.
Evidence for the hypothesis
(Neyer et al. 2012) see technological readiness as an "attitude characteristic that reflects the subjective assessment of technological progress" (p. 88). They developed a model of technology commitment including a measuring instrument with three subscales: technology acceptance, technology competence and technology control. The correlation of technology commitment and indicators of successful ageing (e.g. life satisfaction and attitude towards ageing) was demonstrated by the authors. The authors cite the need for more research as proof that technology commitment mediates the use of technology and thus contributes to a better quality of life in old age – to our knowledge, this has not been achieved up to now.
How will the hypotheses be tested?
• Measurement of technology readiness via the short scale for the assessment of technology commitment (TC scale) (Neyer et al. 2012) • Quality of life for PE is measured with PIADS, possibly the self-developed QoL measure, EQ-5D and FES-I • Quality of life for i-SE is measured with SRB, ASIS, CarerQol (item “fulfilment”) and FAB.

HYPOTHESES „GOAL ACHIEVEMENT PE”
a) The objectives regarding the use of the i-evAALution technologies of the PE lead to the use of the respective technologies / use cases b) The objectives of the older adults are achieved after 4 and especially after 12 months because they actually used the respective (goal-relevant) technologies / use cases. c) The goal achievement leads to an increase in the respective quality of life domains.
Evidence for the hypothesis
As described above, the impact of technologies on QoL-aspects of older adults demonstrated by quantitative measures in randomised controlled trials is sometimes not very clear / large. Therefore, we decided to use a qualitative approach as well, which is based on the Goal Attainment Scale (GAS) (Turner-Stokes 2009) The GAS was developed to measure the individual effectiveness of a variety of interventions in clinical research, therapy and rehabilitation research. We expect it to be a rather sensitive measure, which should be able to demonstrate an impact of the used technologies / use cases.
How will the hypotheses be tested?
At baseline we will ask the participants (PEs as well as i-SE) what their most important goals are that they would like to achieve by using the bundle. The respondent can name a maximum of three goals. After 4 and 12 months we will assess the achievement of those goals by asking the participants to

what extent they have reached their goals (using the scaling method proposed in GAS: 0 means achievement of the goal, -1 and -2 mean underachievement, and +1 or +2 mean overachievement).

HYPOTHESIS „GOAL ACHIEVEMENT I-SE"
The objectives of the informal caregivers are achieved after 4 and especially after 12 months because of the actual use of the technologies / use cases by the PE.
Evidence for the hypothesis
As described above, the impact of technologies on QoL-aspects of informal caregivers demonstrated by quantitative measures in randomised controlled trials is sometimes not very clear / large. Therefore, we decided to use a qualitative approach as well, which is based on the Goal Attainment Scale (GAS) (Turner-Stokes 2009) The GAS was developed to measure the individual effectiveness of a variety of interventions in clinical research, therapy and rehabilitation research. We expect it to be a rather sensitive measure, which should be able to demonstrate an impact of the used technologies / use cases.
How will the hypotheses be tested?
At baseline we will ask the participants (PEs as well as i-SE) what their most important goals are that they would like to achieve by using the bundle. The respondent can name a maximum of three goals. After 12 months we will assess the achievement of those goals by asking the participants to what extent they have reached their goals (using the scaling method proposed in GAS: 0 means achievement of the goal, -1 and -2 mean underachievement, and +1 or +2 mean overachievement).

HYPOTHESES „CONSEQUENCES OF FALLS"
a) Parts of the i-evAALution technology bundle (the emergency call and fall prevention components) have a positive effect on the consequences of falls (treatments, hospital stays, concern of falls are diminished); older people in the intervention group suffer less from them after 12 months (4 months is too short) than older people in the control group. b) Older people in the intervention group, who have experienced at least one fall during the year prior to the i-evAALution trial suffer less from fear of falling after 12 months (4 months is too short) than older people in the control group.
Evidence for the hypothesis
• Steventon et al. (2013) reported the outcomes of the "telecare" arm of the Whole Systems Deomstrator trial as hospital admissions (due to falls), general practitioner contacts, domiciliary care weeks amongst others. They couldn't find significant effects of their technology bundles, which included pendant alarms amongst others; some methodological limitations, like the intention to treat approach and the fact that fall detectors were assigned by local teams to the persons, have to be considered though. We therefore assume that it could be possible that during i-evAALution the demonstration of effects is verified. • Mann et al. (2002) give a small overview about several studies, which have shown that Personal Emergency Response Systems (PERS) "delay institutionalization, reduce admissions and shorten hospital stays, and reduce duration of personal aide services" (p.92). • Yardley et al. (2005) showed that fear of falls (measured with the FES-I) is significantly higher in persons who have experienced one or more falls during the past year than people who haven't had any falls.

In summary, we think it might be possible to find some positive effects of falls-relevant i-evAALution components on consequences of falls, especially for persons who have experienced falls in the past.
How will the hypotheses be tested?
• The number of falls and their treatments (in-patient, out-patient, informal) will be assessed for the 12 months prior to the trial phase and for the 12-month trial phase • Concerns about falling / fear of falls will be assessed by the short Falls Efficacy Scale International (FES-I)

HYPOTHESIS „EFFECT OF TECHNOLOGY TYPE“
Different technologies / use cases affect different areas of quality of life: The classifications / assessments of the technologies / use cases with regard to effects on the quality of life established at the beginning of the test phase (pre-alpha phase) are confirmed by the empirical data, i.e. the measurements in the intervention group.
Evidence for the hypothesis
According to Schulz et al. (2013) many technology classifications lack areas of quality of life. The quality of the classifications of the i-evAALution technologies is confirmed by the expert classification and the subsequent confirmation by empirical data, thus laying the foundation for further statements about connections and effects of certain technologies (with certain classification characteristics).
How will the hypotheses be tested?
• The i-evAALution devices and use cases will be classified according to the dimensions / items of the PIADS. At the end of the trial phase, these classifications will be compared with the QoL-improvement of persons who used the respective devices and use cases.

2.2.2.4. DIMENSION 4: BUSINESS PERSPECTIVE

An important person-centred variable, which will be included into the i-evAALution research, is the willingness to pay for devices and functionalities of the bundle by older persons and their informal caregivers. The health and care market is a regulated one, and many expenses in western countries are covered by public health and welfare agencies either completely or partly. At the moment, however, those agencies rarely fund innovative assistive technology devices for community-dwelling older adults. Therefore, more research on how much (older) users of assistive technologies as well as their family members would pay out of their own pocket is needed.

Older adults' willingness to pay for assistive technologies out of their own pocket is probably limited (Schulz et al. 2014). Many studies have only assessed the WTP for single technologies like hearing aids (Grutters et al. 2008), wearable devices (Kekade et al. 2018), a fall prevention smartphone app (Rasche et al. 2018) or activity trackers (Mercer et al. 2016). An interesting study with representative samples of the Irish population was carried out by Callan and O'Shea (2015). The participants involved rated different telecare as well as non-technological community care programmes and were also asked about their personal willingness to pay for such programmes. The study was only an interview survey though – none of the respondents had actually taken part in one of the care programmes. All randomised controlled trials which we reviewed (e.g. Czaja et al. (2017), the WSD studies, Mortenson et al. (2018)) did not assess the WTP of older adults for the respective assistive technologies. Thus, i-evAALution can

be regarded as the first randomised controlled trial in which WTP of older adults as well as their informal carers is systematically assessed.

HYPOTHESIS „WILLINGNESS TO PAY (WTP) OF PE“
The actual use (4 and 12 months) of devices or use cases of the i-evAALution bundle (=acceptance) leads to a higher willingness in older adults to pay for them (mediated by the variable quality of life).
Evidence for the hypothesis
• Not many studies assess the WTP of older adults for assistive technological devices or services that those have acutally tested or used. Grutters et al. (2008) researched the WTP of older users for hearing aids, and Mercer et al. (2016) gave older adults five activity trackers for at least three days of testing each. Many other studies just surveyed older adults about their WTP for (ficticious) products and services as different as (wearable) e-health devices and services (Kekade et al. (2018), Mann et al. (2002), Tsuji et al. (2006)), online services for primary care (Roettl et al. (2016), Adler (2006)), a fall prevention smart phone app (Rasche et al. 2018), or quality of life technologies (Schulz et al. 2014). The WTP for those ficticious devices or products which could not be tested by the participants was generally rather low. For i-evAALution we do not expect that the WTP will be very high, but that participants who actually experience a quality of life improvement by devices or use cases they used will be inclined to pay more for them than persons who did not use them. • Berkowsky et al. (2018) deduct the possibility of a different relationship from their study: they request further research on the hypothesis that the willingness to pay for a device (and the actual cost of the device) might actually influence the willingness to adopt and use it.
How will the hypotheses be tested?
• According to Breidert et al. (2006) indirect measures to assess person's willingness to pay for a product should be preferred over direct measures as those imply methodological problems and most probably lead to biases – even though the direction of those biases (over- or underestimation of the true WTP) could not be clarified yet. Therefore, in addition to direct questions about how much older adults and their family members are willing to pay for the i-evAALution technologies, we will carry out either conjoint or discrete choice analyses.

HYPOTHESES „WILLINGNESS TO PAY (WTP) OF I-SE“
a) Positive QoL-effects of used devices / use cases on older adults lead to a higher willingness to pay in i-SE. b) Less perceived burden and PE-related worries of the i-SE result in their higher willingness to pay for the devices / used cases used by the PE.
Evidence for the hypothesis
There aren't many studies that have researched the willingness to pay of informal caregivers for assistive technologies. Mahoney et al. (2008) conducted a small-scale study with 27 working family care-givers who could test a computerised monitoring and alerting tool for their older relatives on their workplaces for six months. 38% of the participating caregivers were willing to pay a monthly sum of 60US$ for the system they had tested.

Schulz et al. (2016) conducted a larger-scale survey on 512 caregivers and asked them about their WTP for hypothetical monitoring and assisting technologies in the fields of kitchen and personal care tasks. 80% of their participants were willing to pay something, the mean being 50 to 70US$. None of the studies has included analyses on the relationships between WTP and variables like QoL, burden, or care-related worries. During the i-evAALution project we will research these relationships.
How will the hypotheses be tested?
• WTP is measured by discrete choice and / or conjoint analysis • Burden and worries are measured by ASIS, SRB and FAS-B

The table below contains the research questions that were developed for this dimension.

	Research Question	Subquestions	Preliminary description of data collection method
1	Which customer segments for the i-evAALution bundle can be identified?	/	tbd, quantitative (qualitative?) measurement
2	What is the preferred acquisition model, (rent / buy), what are possible service models and what is the related willingness to pay (maintenance, user service, support)?	/	tbd, quantitative (qualitative?) measurement; conjoint or discrete choice analysis
	What impact does the i-evAALution bundle have on care organisations and care systems?	Impact on efficiency and effectiveness which result in saving expenses or by not having to increase expenses in the mid and long term? Impact on quality of care? Impact on satisfactions of staff? • Impact on image and competitiveness (increase of demand etc.)?	questionnaire + cost-benefit analysis; process analysis Focus Groups with formal secondary end users, decision makers, management
	Under what conditions would municipalities / care insurance companies be interested in providing the bundle and what would they be willing to pay for the i-evAALution bundle?	/	Focus groups
	What roles does the bundle require and who are the stakeholders in the i-evAALution ecosystem that could fulfill these roles?	/	analysis of application environment

Table 4 Research questions business perspective

2.2.3. METHODOLOGY

In the following chapter, the methodological approach to answer the defined research questions and to test the developed hypotheses is presented.

We decided to follow a person-centred assessment schedule, which means that we do not indicate fixed date in this schedule but treat every entry of a test person individually as time point zero. This allows a

gradual rollout of bundles and a gradual scale-up of participants, which is necessary for administrative, logistical and resource-related reasons.

2.2.3.1. INSTALLED TECHNOLOGIES

The following devices will be installed in the homes of the primary end-users of the intervention groups (in the four pilot countries Austria, Italy, Slovenia and the Netherlands):

- 2PCS emergency watch and SOS pendant (2PCS Funkfinger)
- Different smarthome devices
- Tablet with the funcionalities:
    - Calendar
    - Useful websites
    - Alarm button
    - Light control
    - Games
    - Care documentation

2.2.3.2. USE CASES

The following use cases have been developed by the project consortium and will be realised by the (interoperating) technologies described above. They are presented in detail within the deliverables of work package 1.

- UC01A – APPOINTMENT AND TASK MANAGEMENT
- UC03A – SERVICE CALLS
- UC03B – REQUEST FOR CARE SERVICES
- UC05 – SWITCHING ON/OFF THE LIGHTS
- UC06 – PLAYING GAMES
- UC07 - MANUAL ALERTING
- UC08 – FINDING MISSING PERSON
- UC09A – FALL DETECTION INDOOR AT HOME
- UC09B – FALL DETECTION OUTDOOR
- UC10 – NO MOVEMENT ALERT (AT HOME)
- UC11 – FEELING FINE?
- UC12 – FIRE PROTECTION

2.2.3.3. CLASSIFICATION

The technologies and use cases will be classified regarding their usability as well as their hypothesised impacts on the quality of life of older adults and informal caregivers. The classifications will be carried out by internal and external persons in the (pre-) alpha phase of the project.

Classification levels	**Evaluators**	**Methods**

Usability	Experts PE i-SE	The adapted Nielsen's 10 usability heuristics (Nielsen 1994), which will be carried out by (internal) usability experts.
QoL	Experts	Expected effects of individual devices / use cases on different quality of life domains (according to PIADS and FAS-B).

Table 5 Classification levels of technologies / use cases

2.2.4. SAMPLE

Within the framework of the project, it will not be possible to create a representative sample. All pilots will recruit end-users with the help of various end-user organisations, local senior clubs, personal contacts as well as adverts on local newspapers or magazines. Therefore, various demographic variables and other possible interference factors will be systematically assessed and included in the data analysis. A further description of the sample including the test persons and the inclusion criteria will be given below (description of sub-task 2.2.3).

2.2.5. MEASURES

Derived from the framework models illustrated in Chapter 2.2.1., the variables measured for this study are presented in the following.

2.2.5.1. MEASURES PE

All variables, which are considered relevant, i.e. which will be assessed during the pilot phase (baseline measurements, measurements at 4 and 12 months) are presented here with their according assessment measures.

Table 6 Background variables PE

Sociodemographics	
Self-constructed items	In the iVICQ (page 1-5) (Hoefman et al. 2013) it is advised to assess • Gender • Age • Relationship to PE • Duration of informal care in years • Number of hours of informal care per week (Peek et al. 2017) stress the importance of social network (children, grandchildren, friends...) -> do PE have alternatives to technology? Further questions: • Formal school education • Number of persons in household

	• Monthly household (net) income • Employment status • Distance from PE to i-SE • Type of housing • Etc.
Falls	
Self-constructed items	• No. of falls in past year • Necessary treatments because of falls
Technology experience and possession	
Self-constructed items	• Perceived technology competence • No. and types of technologies in household • Frequency of technology use • Possession of other assistive devices

Table 7 Predictor variables distal PE

Technology commitment	
TC scale (Neyer et al. 2012)	Has three dimensions: technology acceptance technology competence technology control
Subjective Age	
4 items developed by Barak and Schiffman (1981)	• Feel-age / psychological age: e.g. I feel … years old. • Look-age: e.g. When I look at myself in the mirror I feel … years old. • Do-age: e.g. I do the things a person who's... years old does. • Interest-age: e.g. My interests are those of a person who's... years old.
Worries and concerns regarding the i-evAALution bundle and the study	
Self-constructed open questions	Qualitative assessment

Table 8 Predictor variables proximal PE

Expected effects of bundle on QoL	
Psychosocial Assessment of Assistive Devices Scale (PIADS)	Was developed as self-report measure on effects of assistive technologies (Day and Jutai 1996b) Has three dimensions:

	- competence - adaptability - self-esteem
Acceptance	
Usefulness, Satisfaction, and Ease of Use (USE) questionnaire on usability	Items of USE questionnaire (Lund 2001): The questionnaire was designed in such a way that the items are as general, short and applicable as possible for many technologies. This is an advantage in comparison to the TAM items (Venkatesh and Bala 2008), whose wording is specific for a professional context.
Individual goals which the PE wants to achieve by using the bundle	
Procedure based on the Goal Attainment Scaling (Turner-Stokes 2009)	Qualitative measure, PE name three goals max.
Rejection (premature ending of participation in pilot phase)	
Self-developed items	In case a PE decides to leave the test phase, the following questions will be asked: Quantitative: e.g. "My fears (data protection etc.) have come true" yes - no; "My situation has changed and I cannot take part any more" yes – no Qualitative: e.g. "What exactly has changed in your situation?"

Table 9 Dependent variables / outcomes PE

Falls	
Negative consequences of falls	Treatment time due to falls during the 12-month trial phase (in-patient, out-patient, informal)
Technology adoption	
Self-constructed items + log data	The i-evAALution study does not follow an Intention To Treat (ITT) approach: We won't study the effects of the bundle as a whole but assess the effects of the single devices and use cases which really have been used by the older adults and their informal carers. Therefore, we not only assess technology use by self-report (e.g. "How often (= hours per week) have you used ... within the last ... months?") but also by objective data (log files).

	Furthermore, by classifying devices and use cases according to their assumed effects on QoL, we create detailed hypotheses in advance, which will then be tested.
QoL	
Several scales + self-constructed items	• PIADS (Day and Jutai 1996a) • Short Falls Efficacy Scale International (FES-I) (Kempen et al. 2008) • EQ-5D (*https://euroqol.org/*) • Three QoL items based on Agree and Freedman (2011)
Individual goals which the PE achieved	
Procedure based on the Goal Attainment Scaling (Turner-Stokes 2009)	Qualitative measure: stated goals at baseline are related to their actual achievement after having used the technologies.
Willingness to pay for bundle	
• Conjoint or discrete choice analysis • Direct measurement	According to Breidert et al. (2006) indirect measures provide more valid results than direct measures. More research has to be done to develop the concrete questions for the different measurement points

2.2.5.2. MEASURES I-SE

All variables which are considered relevant, i.e. which will be assessed during the pilot phase (baseline measurements, measurements at 4 and 12 months) are presented here with their according assessment measures.

Table 10 Background variables i-SE

Socio-demographics	
Self-constructed items	In the iVICQ (page 1-5) (Hoefman et al. 2013) it is advised to assess • Caregiver's gender • Caregiver's age • Caregiver's health (EQ-5D) • Relationship to PE • Duration of informal care • Number of hours given per week • Household composition • Do you have paid work? • Do you have unpaid work (except informal care of PE)? • Financial compensation for providing informal care • Monthly net household income
Technology experience and possession	

Self-constructed items	• Perceived technology competence • No. and types of technologies in household • Frequency of technology use

Table 11 Predictor variables distal i-SE

Technology commitment	
TC scale (Neyer et al. 2012)	Has three dimensions: technology acceptance technology competence technology control
Subjective Age	
4 items developed by Barak and Schiffman (1981)	• Feel-age / psychological age: e.g. I feel … years old. • look-age: e.g. When I look at myself in the mirror I feel … years old. • do-age: e.g. I do the things a person who's... years old does. • interest-age: e.g. My interests are those of a person who's... years old.
Worries and fears concerning the i-evAALution bundle	
Self-constructed open questions	Qualitative assessment

Table 12 Predictor variables proximal i-SE

Expected effects of bundle on QoL	
Four scales which assess care related QoL	• CarerQoL (fulfilment-from-care item) (Brouwer et al. 2006) • Assessment of informal care Situation (ASIS) (Hoefman et al. 2013) • Self-rated Burden Scale (SRB) (Hoefman et al. 2013) • Filial Anxiety Scale – B (FAS-B) (Cicirelli 1988)
Individual goals which the i-SE wants to achieve by using the bundle	
Procedure based on the Goal Attainment Scaling	Qualitative measure, i-SEs name three goals max.

Table 13 Dependent variables / outcomes i-SE

Evaluation of the i-evAALution bundle: acceptance

Usefulness, Satisfaction, and Ease of Use (USE) questionnaire on usability (Lund 2001)	Four dimensions: • Usefulness • Ease of use • Ease of learning • Satisfaction
Rejection	
Self-developed items	In case i-SE decides to leave the test phase, the following questions will be asked: Quantitative: e.g. "My fears (data protection etc.) have come true" yes - no; "My situation has changed and I cannot take part any more" yes – no Qualitative: e.g. "What exactly has changed in your situation?"
Quality of life	
Four scales which assess care related QoL	• CarerQoL (fulfilment-from-care item) • ASIS • Self-rated Burden Scale (SRB) (• Filial Anxiety Scale – B (FAS-B) (Cicirelli 1988)
Individual goals which the i-SE achieved	
Procedure based on the Goal Attainment Scaling (Turner-Stokes 2009)	Qualitative measure: stated goals at baseline are related to their actual achievement after having used the technologies.
Willingness to pay for bundle	
• Conjoint or discrete choice analysis • Direct measurement	According to Breidert et al. (2006) indirect measures provide more valid results than direct measures. More research has to be done to develop the concrete questions for the different measurement points

2.2.5.3. CONFOUNDING VARIABLES

Different factors might have an influence on the results of the data analysis and will therefore be included as variables. They might bias the results and will therefore be controlled for in the statistical data analysis.

Table 14 Possible confounding variables

Variable	Measures
Type and duration of conducted training	Learning for older people should always be self-directed and not too fast. Therefore, when introducing the technical equipment, the duration / number of lessons will be adapted to the needs of the PE (and if necessary to the i-SE). The duration of training lessions should reflect the initial technology experience of a person (the less experience, the more training will be required). Thus, during the data analysis phase, the training variable should be related to prior technology experience as well as to acceptance and usability variables.
Personal visits at the particpants' homes	Technical problems during the pilot phase are solved either by telephone or, if this isn't possible, by visits of project staff at home, to ensure the use of the equipment for the rest of the test phase. These telephone calls and visits can be seen as necessary service delivery, which would also have to be carried out if the devices were offered on the regular market. But as visits could be regarded as pleasant by the participants (as a change in everyday life, exchange with other people, communication over a cup of coffee...) we will document all telephone calls and personal visits which have been made and assess the appraisal of the visits by questions like: "I thought the visits of the test supervisors were very pleasant - pleasant - neither - nor - unpleasant - very unpleasant" "I thought the telephone calls with the test supervisors were very pleasant - pleasant - neither - nor unpleasant - very unpleasant"
Technical problems	Technical problems could (negatively) influence the appraisals of the technologies and will therefore be assessed after both 4 and 12 months: • By a rating scale: how much did the participants have the impression a) that there were technical problems and b) how much did these affect the course of the study / their own quality of life.... By objective measures (e.g. number of technical interventions by project staff)
Triggered interest in technology	Influences that could manifest themselves between the different measurement points will be surveyed, e.g. whether the participants in the control group have been in contact with AAL technologies during the trial phase. It may not be possible to (statistically) control these influences - but they should be taken into account when interpreting the results. Possible question: "Did you feel the participation in the study triggered an interest for AAL technologies in you?"

Technology acquirement during the trial phase	It could be possible that (due to the participation in our study) PEs from the intervention or control group acquire new technologies by their own initiative during the 12-month trial period. Therefore, at the end of the trial we should ask participants again about the number / kinds of technologies they possess (and compare them to the baseline measurement).
Contact between intervention and control group	It could happen that participants from the intervention and control group know each other (private relationship or living in the same building) and exchange opinions and experiences about the technologies during the project. Possible questions: „Have you met and talked to someone who takes part in the study as well (e.g. via Palette)?" "Have you exchanged opinions about technologies with a person in the intervention group / control group in the past months?"
Study participation effect	The mere fact that the participants received attention and recognition through the study (got the possibility to make a contribution to science) can lead to positively biased effects. Possible question: "To participate in the study… …has made me very proud …has burdened me very much …has not had much influence on me"
Effort of taking part in assessment points	The fact that several questionnaires have to be filled in at one measurement point could be experienced as stressful. Possible questions: "Filling out the questionnaires at the beginning / after 4 months / after 12 months was very pleasant - pleasant – neither / nor - unpleasant - very unpleasant." "The questionnaires were… …too many / too long …often incomprehensible …too private …not particularly pleasant, but as a contribution to research I accepted it …interesting / pleasant to fill in"
Filling in the questionnaires with	In some of the pilot countries / on some of the measurement points, data collection via questionnaires is conducted by mailing materials by post. It could therefore happen that older people do not complete the questionnaires

the help of relatives (e.g. i-SE)	on their own but ask for help and are therefore influenced by other people (e.g. younger relatives, the i-SE). Possible question: “Did you fill in the questionnaire alone / with the help of another person?”
Social desirability	Older adults show a higher social desirability than younger adults (Fastame and Penna 2012). In general the bias should be equally present in the intervention and in the control group. Concerning the acceptance of the i-evAALution bundle in the intervention group we will not only ask participants via self-report (which could be biased by social desirability) but also collect objective usage data (log files), which is free from this bias.

In an Excel file we have compiled all measures for both PE and i-SE in both the intervention and control group. Below, there is an image of this assessment schedule.

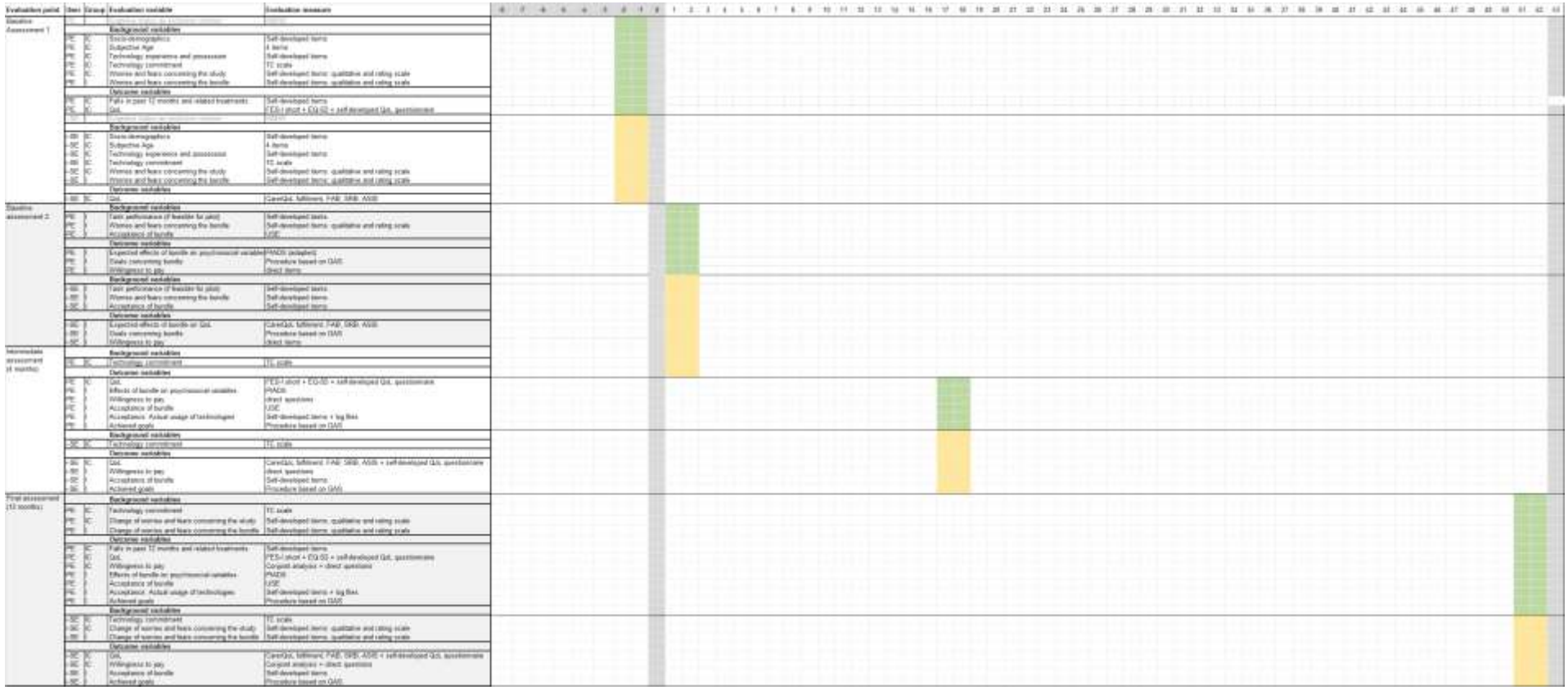

Figure 4 Person-centred assessment schedule

2.2.6. PREPARATIONS

The preparations and the main test phase of i-evAALution are described in the following sections.

Before the 12-month trial phase, several preparations must be made to achieve the following goals:

- Compilation of a systematic classification of the technical devices / functionalities / use cases, which can later be used for comparison with acceptance and quality of life (separate Excel file created)
- Translations of the standardised questionnaires into the project languages. A detailed description of this topic will be given below in the chapter of sub-task 2.2.6.
- Test of the equipment as well as the planned measures in pre-tests and implementation of changes for the main test phase (the pre-alpha and alpha phase will be described in the deliverables 3.1 and 3.4.)
- Development, test and implementation of guidelines for all internal and external project staff involved in the technical installation and data collection, in order to ensure a uniform approach and the greatest possible objectivity (methodological quality criterion). A more detailed description of this topic will be given below in the chapter of sub-task 2.2.7.
- Development and test of trainings for all participants involved (PE and i-SE) in order to ensure the greatest possible benefit and effect through the technologies / use cases. A detailed description of this topic will be given in deliverable 3.4.
- Check fulfilment of the inclusion criteria (see deliverable 3.1) of all interested PEs and i-SEs.

2.2.7. MAIN STUDY

2.2.7.1. RANDOMISATION

After signing the informed consent document and the assessment of cognitive fitness (will be checked by pilot partners optionally), the dyads of PE and i-SE will be randomised into either the intervention or the control group. A detailed description will be given below in the chapter of sub-task 2.2.3.

2.2.7.2. TRAINING OF PROJECT STAFF

Before the pilot activities start, all involved internal project staff will read the script / guidelines for project staff and all external staff (subcontracted by the pilot partners) will be trained according to the developed script / guidelines. A report on how the staff trainings were carried out will be given in the deliverable of WP3.

2.2.7.3. INSTALLATION OF TECHNOLOGIES

The installation of the technology bundle in the homes of the elderly will be carried out by internal or external employees of the project partners according to the developed script / guidelines (see above) and according to the pre-defined installation plan developed by WP1.

2.2.7.4. TRAINING OF PE AND I-SE

The training for study participants, which also was developed in the preparation phase, will be conducted with all PEs and i-SEs of the intervention group, including a written manual, which participants can keep throughout the trial phase in their folder with the project documents. After the training sessions, the PEs'

competences in handling the i-evAALution technologies will be assessed (self-reports and assessment by training staff).

2.2.7.5. DATA COLLECTION (CONTROL AND INTERVENTION GROUP)

In the **control group**, the participants (PEs and i-SEs) will receive a bundle of questionnaires at three points in time:

- at the beginning (baseline)
- after four months
- at the end of the twelve-month test phase.

In the **intervention group**, the participants (PEs and i-SEs) will receive a bundle of questionnaires at four points in time:

- at the beginning (baseline 1)
- directly after technology training (baseline 2)
- after four months
- at the end of the twelve-month test phase

The questionnaires both in the intervention as well as the control group will be distributed and filled in by participants either when researchers or care staff personally visit the test persons (e.g. for the installation of the devices) or after having received the questionnaires as paper copies by post (stamped and addressed envelope is included). In Slovenia, is planning to send a link of online questionnaires to participants where possible (e.g. to i-SE who will more likely use e-mail and the internet). Oral presentations of the questionnaires via telephone will not be conducted, as memory limits could influence the answers strongly (Krosnick and Presser 2010). Assistance via telephone might be given to older participants if they struggle to fill in the questionnaires by themselves.

2.2.7.6. INFORMATION EVENTS

During the trial phase, in every pilot region three information events on non-technological topics for older adults are planned (e.g. on nutrition, travelling, literature…). These events will be organised as incentive for the control group to participate in the study and stay in. To minimise bias by different treatment of the control and intervention group, also participants from the intervention group will be invited to the events.

2.2.7.7. END OF PILOT PHASE

After having filled in the last questionnaires, the AAL devices will be uninstalled and collected from the participants' homes, unless other individual agreements about keeping (some of) the devices were made. At the end of the 12-month trial period, the older participants in the control group are given the opportunity to try out the AAL bundle in a workshop or a short test phase at home.

2.2.7.8. DATA ANALYSIS

The data of all pilots will be collected via a common data entry tool, compiled with SPSS or Excel. The statistical analysis will be carried out in a way that allows testing the different research hypothesis presented in this document.

2.3.. TASK 2.2.3: TEST PERSONS, INCLUSION CRITERIA, SCREENING, RANDOMIZATION, DROPOUTS, INCENTIVES

Task 2.2.3 includes all decisions concerning the selection and integration of test persons to the planned randomized controlled trials. In the following sections, the inclusion criteria for PEs and i-SEs, the necessary screenings to ensure that inclusion criteria are met, the randomization strategy and chosen incentives for the control group to minimize dropouts are outlined.

2.3.1. INCLUSION CRITERIA

The project's consortium members, especially the research institutions and the end-user organisations, defined the inclusion criteria for the i-evAALution trial jointly in order to ensure a selection that allows for both, scientific rigor, but also recognizes issues of practical feasibility in the recruitment process. The aim was to derive a set of inclusion criteria that is as inclusive as possible to reach the high number of end-users and as exclusive as necessary to enable a targeted sampling and the retrieval of valid effects for a clearly defined population cohort.

We therefore firstly, based on the inclusion criteria already mentioned in the proposal, collected input on those and further potential criteria by the consortium members. Those were peer-reviewed to and reduced to a short-list that served as a basis for final decision-making. The final discussion and decision on inclusion criteria was made during the PMB meeting at the 2nd consortium meeting in Vienna. On overview of the final inclusion criteria is shown in table 15.

Table 15 Summarized inclusion criteria

Inclusion Criteria for Primary End-users (PE)

1	65 or older
2	Lives in private household or assisted living apartment (non-stationary care environment)
3	The PE should have adequate cognitive capacities.
4	75% live in single households
5	Willingness and ability to take part in the trial for 12 months in alignment with the conditions of participation • agrees with installation of whole bundle • agrees on random assignment to control or intervention group • able to participate in the language(s) of the trial site • able to sign the informed consent
6	The PE needs to have an i-SE (according to our definition of i-SE) who is willing to take part

Informal Secondary End-useres (i-SE)

1	18 or older
2	The SE should have adequate cognitive capacities.
3	Is a family member or other person the PE knows privately (no volunteer from a care or end-user organisation)

4	Is a person who is seen as a point of reference in everyday life by the older adult and is concerned about the well-being of him / her. An i-SE provides emotional and / or practical support to the older adult on a regular basis.
5	Willingness and ability to take part in the trial for 12 months in alignment with the conditions of participation • agrees with installation of whole bundle • agrees on random assignment to control or intervention group • able to understand directions and participate in the protocol in the supported languages of the trial site • able to sign the informed consent • is available for a personal introduction at the beginning of the trial phase.

2.3.2. SCREENING

The inclusion criterion “cognitive status” is the only one that requires necessary screening. In the proposal, we defined that persons with moderate to severe cognitive impairments, especially forms of dementia have to be excluded from our trial, as our intervention is not targeted at them specifically and as obtaining consent from these persons is ethically sensitive. The proposal defines a threshold of Reisberg Scale >3. While in the proposal we originally planned that the end-user organisations confirm whether an exclusion due to cognitive impairments applies, we decided during the consortium meeting in Vienna that this is not possible for all pilot regions. End-user organisations in the consortium in Austria, Italy and Slovenia do not have data regarding cognitive impairments and there will most likely be participants who live independently without support of an end-user organisation. In those regions, the screening instrument Mini Mental State Examination (Folstein et al. 1975) will be conducted. In the Netherlands, the setting will be closely related to professional care organizations who have either the data or the necessary project members with experience to do a subjective screening and confirm whether an exclusion due to cognitive impairments applies.

2.3.3. RANDOMIZATION

The randomization process will take place after the participant has signed the informed consent and has conducted the initial questionnaire. Randomization will be done automatically within the i-evAALution management database.

This means that for each eligible person the respective pilot partner adds a new entry to the database containing the following information:

- Pilot site
- Household size
- Test person ID.

When the entry is saved, the system automatically assigns the person to either the intervention group (code=1) or to the control group (code=0). This is achieved by adjoining random permuted blocks of 1 and 0 to the open spots in the database in the respective strata (see below for stratification and permutation criteria).

For the randomization process, we need to meet the following criteria:

- Randomization must not be prone to manipulation (e.g. if the randomization logic in the database would be 1-0-1-0-1-0, assignment of persons to the groups could easily be manipulated by any person entering the data).
- However, randomization should lead to equally sized groups already within smaller sub-groups and not only when the full number of test persons in a pilot is reached (e.g. we should make sure that for every 10 persons, there is an equal division between 1 and 0). This is necessary, as in the i-evAALution project we will presumably have a longer recruitment and roll-out period and within that period installation effort should be predictable (e.g. if a pilot site recruits 10 persons, it should be sure that this means to have 5 installations).
- We need to stratify the samples for household size. Single households and multi-person households fall in two different randomization pools. The multi-person-household pool is limited to 25 % of the overall number of test persons per pilot.

We will therefore use a stratified, permuted and random block design[1]

Stratification

The stratification factors used for randomization are:

- Pilot site
- Household size

Within the randomization process, the stratification makes sure that in each pilot region we have an equal size of intervention and control group and that single and multi-person households are equally assigned to either intervention group .
This means a weighted assignment as shown in Table 4:

Table 16 Group assignment scheme per pilot site

Pilot Site		
	I	C
S	0,75 to 1,00 * 0,5	0,75 to 1,00 * 0,5
M	0,00 to 0,25 * 0,5	0,00 to 0,25 * 0,5

I=intervention group
C=control group
S=single-person-household
M=multi-person-household

The table reads as follows: Of the total persons in a pilot site, a minimum of 75 % must be single households – This means that 75 % to 100 % of the total persons fall in the randomization pool “S”.

[1] See guidelines on randomisation sequence generation: http://www.spirit-statement.org/sequence-generation/

They are assigned to intervention and control group with a probability of 50 %. 0 % to 25 % of the total persons fall in the randomization pool "M". They are assigned to intervention and control group with a probability of 50 %. For example, if pilot Italy has a total of 100 persons, of which 20 % are living in multi-person households the distribution would be as shown in.

Table 17 Group assignment scheme - example

Pilot Site IT_EURAC: n=100		
	I	C
S	(100 * 0,8) * 0,5= 40	(100*0,8) * 0,5= 40
M	(100 *0,2) *0,5= 10	(100 *0,2) *0,5= 10

Permuted block design

The permuted random block design ensures that study groups of the same size will be generated with an allocation ratio of 1:1 and that close balance of the numbers in each group are ensured at any time during the trial. In order to minimize the risk of manipulation by discovery of block sizes, we will randomly vary block size. We obtain random block design by using an SPSS random case selection function with filter for unselected cases (1/0)[2]

Table 18 Summary – Key characteristics of the randomization process

Key element of random sequence generation	Specification for i-evAALution trial
Method of sequence generation	Computerized random number table (SPSS random number function)
Allocation ratio	1:1
Type of randomization	Stratified, permuted block randomization
Stratification factors	Pilot site Household size

2.3.4. PREVENTION OF DROPOUTS AND INCENTIVES

Dropouts may likely occur during the i-evAALution pilot phase for different reasons and we must therefore make sure to implement a strategy to reduce dropouts, (already outlined within D3.1 – measures to keep end-users motivated throughout the pilot phase). As long as the pilot phase still allows for a replacing of participants without the need to cut the length of trial for the respective test persons, replacements will be sought. For the remaining dropouts, we must ensure to account for any missing values in the analysis process within the analysis plan produced in WP2 – sub-task T2.2.2. Within this sub-task, we also have defined incentives that we can offer the control group like information events and the possibility to try out the technologies after the trial phase. Furthermore, pilots can decide to organise a raffle at the end of the trial phase, in which all participants of the control group can take place who have filled in all questionnaires.

[2] For details on random allocation and case selection using SPSS see: Arifin, W. (2012): "Random sampling and allocation using SPSS. Education In Medicine Journal, 4(1). DOI: 10.5959/eimj.v4i1.4

2.3.5. MOTIVATION AND PROPOSALS

For the intervention group, we foresee frustration with the technology as the main danger for dropouts. Frustration will likely develop if persons using the technology do not receive proper training and related training material in the first place and if test persons experience technological problems and do not have the chance to receive technological support during the trial.

For the control group, we foresee a missing feeling of engagement and relation to the overall project as the main danger for dropouts. In order to minimize dropout rates in the control group throughout the trial, we will provide the control group with a set of incentives. The goals of these incentives are to keep the control group engaged throughout the trial by information events and keep their awareness high. However, at the same time the incentives must not interfere with the technology intervention in order to make sure they do not intermingle with the effects of the technology. Discussing this, we came up with ideas for suitable incentives that were informed by the consortium members' former experiences.
Table 19 gives an overview of all options discussed for prevention of dropouts in intervention and control group. A detailed explanation of the measures and incentives is given in the paragraphs below.

Table 19 Overview of measures against dropouts – all options

	Measure / Incentive	Pre	During	Post	Intervention	Control
1	Technology training	X			X	
2	Technological support		X		X	
3	Information events and newsletters		X		X	X
4	Technology try-out session			X		X
5	Raffle at end of trial phase					X

1. Appropriate technology training for the intervention group

Based on recent research findings, a training manual, which ensures adequate training for the older adults as well as their informal secondary end-users, will be developed. The training should be carried out in at least one face-to-face session, during which all technological devices and functionalities of the 12.03.2019 190312_T2.2.3_Results_v5.docx 12 / 15 i-evAALution bundle will be introduced and explained thoroughly. Then, participants will get the occasion, to try out all active technologies (passive smart home devices cannot be tried out) themselves, according to a standardised protocol. Furthermore, all participants will be provided with a paper manual designed clearly and attractively, to be able to look up information themselves during the trial phase.

2. Technical support

During the trial phase, technical support will be provided for the test persons in the intervention group. The definition of support structures, the organisation and operative management will be conducted within WP3.

3. Information events and newsletters

Information events are organised in the pilot sites, open for both, the intervention, and control group. These events should provide the participants with interesting (local) information, e.g. lectures or presentations of local stakeholders. Examples for topics are:

- The city's offers for senior citizens

- The city's public transport system for senior citizens
- Leisure time activity offers
- …

However, the information events must not deal with the i-evAALution bundle technologies or with any kinds of digital or AAL technology.

The events should take place throughout the pilot phase. Every pilot site organises three events, the topic selection is free to choose (respecting the above defined topic restrictions) by the respective pilot partner.

Regular newsletters should complement the information events. Those can be sent out more often and contain other interesting information for the target group (e.g. other interesting events for seniors in the city) as well as organisational details regarding any upcoming assessment periods (e.g. the appointments for the next questionnaires will be made soon). The newsletters should also be the invitation to the information events organised by the pilot partners within the project.

Decision at consortium meeting Vienna:
Each pilot site offers at least 3 information events during the pilot phase, which are open for both, the control and intervention group, but not topic-wise related to AAL or our project. Regular newsletters compliment this.

4. Post-treatment try-out session

In order to ensure access to the technology of the i-evAALution project also for the control group, each pilot site will organise a workshop open for the control group after the pilot phase (this means after the last follow-up questionnaire). During this workshop, the control group participants have the opportunity to try out the i-evAALution technology bundle and be informed about any related issues.

Decision at consortium meeting Vienna:
After the pilot phase, the control group is invited to another information event, where they can try out the technologies (post-treatment try-out session).

5. Raffle

All participants of the control group will be told that they will participate in a raffle at the end of the trial phase if they fill in the questionnaires (at month 4 and 12). Examples of prices could be books or a voucher; every pilot site will use this means individually.

2.4.. TASK 2.2.5: ETHICAL AND LEGAL QUESTIONS

Task 2.2.5 comprises the establishment of ethical and legal guidelines for our project and especially the pilot phases.

2.4.1. DATA FLOW ANALYSIS

We analysed the dataflow within the i-evAALution bundle as well as the dataflow that occurs during the pilot phases (for administration and evaluation purposes) in an Excel spreadsheet, as shown in the

figures 6 to 9. For every data processing system, we documented the following properties in order to ensure a transparent data flow:

- Solution / solution area
- Type of data (e.g. personal, localization data, etc.)
- Collected data in detail
- Storage location
- Usage of data
- Processing system
- Processing provider

This information has been inserted to the informed consent to ensure that test persons receive transparent information on what data is being collected.

Please check:	Solution / Solution area	Type of data	Collected data	Storage location	Usage of data	Processing system	Processing provider
	Module A: ICT / Infrastructure						
	Local Internet WiFi / LAN	Access data for the respective systems that are connected to the Internet	Password, Internet activity; time/date	Externally via the respective Provider	A WiFi infrastructure is required as a prerequisite for use for 2PCS and tablet.	Modem, Hotspots	Provider
2PCS	**M2M Sim Card**	Localization and communication data	Time / date, telephone communication, transmission of the outdoor localization data	Externally via the respective Provider	SIM prepaid cards (M2M) for use of 2PCS telephony	2PCS	2PCS, Provider
JOAFG for AT EURAC for IT VILANS (Tangenborgh, Lyvore) for NL ERT for SI	**Alarm & communication server**	Personal data	Name, assigned employee, alarm chain (MA name, date / time), acknowledgment (MA name, date / time)	Server-Cloud	The alarm server can be used for work flows and in the alarm area. (e.g. NovaAlert, NL AVICS)	Alarmserver	
JOAFG for AT EURAC for IT VILANS (Tangenborgh, Lyvore) for NL ERT for SI	**Callcenter Software**	Personal data	Name, assigned employee, alarm chain (MA name, date / time), acknowledgment (MA name, date / time), i-SE phone number, e-Mail adress	Server-Cloud			
AT-JOAFG	**Alarm & communication server**	Personal data, Localization	Name, assigned employee, alarm chain (MA name, date / time), acknowledgment (MA name, date / time), location	Server-Cloud	The alarm server can be used for work flows and in the alarm area. (e.g. NovaAlert), Alarmserver forwards localizatio data to emergency control center via eMail	Alarmserver	
AT-JOAFG	**Callcenter Software**	Personal data, Localization	Name, assigned employee, alarm chain (MA name, date / time), acknowledgment (MA name, date / time), location	Server-Cloud	Callcenter Software gets data from alarm server and is transforming this in an alarm signal according to the standards of the call center. A ticket system should be available or at least documentation of call acceptance, duration of call and responas to call	local callcenter software/server	local callcenter/AT-JOAFG
ITALY	**Alarm & communication server**	Personal data	Name, assigned employee, alarm chain (MA name, date / time), acknowledgment (MA name, date / time)	Server-Cloud	The alarm server can be used for work flows and in the alarm area. (e.g. NovaAlert, NL AVICS)	Alarmserver	
ITALY	**Callcenter Software**	Personal data (Name, adress, living situation, phone number, contact person, received a key yes/no), Phone number of the watch	Name, assigned employee, alarm chain (MA name, date / time), acknowledgment (MA name, date / time)	Server-Cloud		the same as in gAALaxy	
NL-Lyvore, Tangenbourgh	**Alarm & communication server**	Personal data, Localization	Name, assigned employee, alarm chain (MA name, date / time), acknowledgment (MA name, date / time), i-SE phone number, i-SE e-mail adress	Server-Cloud		Alarmserver (AVICS integration fort the emergency alarms)	
NL-Lyvore, Tangenbourgh	**Callcenter Software**	Personal data, Localization	Name, assigned employee, alarm chain (MA name, date / time), acknowledgment (MA name, date / time), i-SE phone number, i-SE e-mail adress	Server-Cloud		Alarmserver	

Figure 5 Data processing Module A: ICT / Infrastructure

	Modul B: HomeTab						
ERT	**HomeTab**	All user accounts, App-related data	User name, password, name, date of birth, e-mail, address, language, phone number, tablet usage time / date	Tablet storage			Google?
ERT	**HomeTab Fun**						
ERT	**HomeTab ...**						
ERT	**HomeTab ...**						
ERT	**HomeTab care documentation**	personal data	name, address, birth date, health data, activity data	depending on software?	Entry of nursing documentation	depending on software (CareCenter, MyVitali, usw.)	Enduser-Organization
ERT	**HomeTab User Interface**	User accounts on the provided apps and APP related data	User name, password, name, date of birth, e-mail, address, language, phone number, tablet usage time / date	Tablet storage Software Userinterface	A HomeTab user interface (user interface), which itself is an application (APP), makes it easy to use standard apps or the tablet's own apps.	HomeTab	ERT
ERT	**HomeTab Calendar**	Personal access data for the calendar account, personal appointments	Username, password, name, event title, date / time, location, appointment description, invited persons to the appointment, subscribers and cancellations	Tablet storage app provider xy (google calendar?)	With this function, it should be possible to record, display and remind appointments, especially for recurring appointments or important appointments.	Termin-APP	ERT? Third party providers?
ERT	**Google Suche**	Personal searches, personal access data	Username, password, name, search history or behavior, date / time	Tablet storage, third party (e.g., Google)	This application allows a quick and easy search for information.	Browser-App	Google
ERT	**Skype**	Personal data	Username, password, name, date of birth, e-mail, address, language, phone number, when and for how long, date / time	Skype, tablet storage	Easy collection and management of circles / groups (interaction in communities such as: formal supervisors, informal caregivers, neighbors, friends, etc.) Skype is used to send messages and make video calls	Skype-App	Microsoft
ERT	**Game-based multi-media applications**	Personal data, depending on access rights	Username, password, name, date of birth, e-mail, address, language, phone number, tablet usage time / date	Tablet storage, third party	Users can play different games	Fun-App	ERT? Third party providers?
ERT	**Service Anfragen**	Personal data	Name, address, email, phone number, location	Tablet storage, third party	Über diese Anwendung soll es möglich sein div. Services anzufragen.	Drittanbieter-AAP	Serviceanbieter
UIBK	**Helferbörse 2.0**	Personal data	Name, address, email, phone number, location	Tablet storage, UIBK	This application allows that users can request voluntary services and can offer voluntary services on their own	Drittanbieter-AAP	UIBK

Figure 6 Data processing Module B: HomeTab

	Modul C: Home Automation SHA						
UIBK	**Light control**	Access data Smarthome Austria, Logfile Smarthome, current situation by control	Username, password, name, e-mail, address, language, phone number, transaction data, activity data, activity and status of each sensor, preferences and time on / off light	Tablet, innogy Cloud	Smarthome Austria's lighting control system controls the lights in a variety of ways: - Switching on / off via individually placed wall buttons or flush-mounted sockets - switching on / off using individually defined rules (for example, if the motion detector detects motion, then certain lights should be turned on)	Smarthome Austria (innogy)	innogy
~~UIBK~~	~~**Control light color**~~	~~Access data Smarthome Austria, Logfile Smarthome, current situation by control~~	~~Username, password, name, e-mail, address, language, phone number, transaction data, activity data, activity and status of each sensor, preferences and date / time of light color~~	~~Tablet, innogy Cloud, Philips HUE~~	~~Lit according to the setting~~	~~Smarthome Austria (innogy), Philips HUE base station~~	~~innogy~~
~~UIBK~~	~~**Switch SHA**~~	~~Status switch~~	~~Username, password, name, e-mail, address, language, phone number, transaction data, activity data, activity and status of the respective sensors, preferences and time of light color, date / time when switch is pressed~~	~~innogy Cloud~~	~~controls Philips HUE LED-lamp or lamps attached to smart plug~~	~~Smarthome Austria (innogy), Philips HUE base station~~	~~innogy~~
UIBK	~~**Philips HUE LED**~~	~~Brightness (in%), light color~~	~~Username, password, name, e-mail, address, language, phone number, transaction data, activity data, activity and status of the respective sensors, preferences and time of light color, date / time~~	~~innogy Cloud, Philips HUE~~	~~Lit according to the setting~~	~~Smarthome Austria (innogy), Philips HUE base station~~	~~innogy~~
UIBK	**Door and window sensor**	Status door / window		innogy Cloud	Send signal about door status to SHA	Smarthome Austria (innogy)	innogy
UIBK	**Smart Plug**	state of the attached device		innogy Cloud	Controls switch actuator	Smarthome Austria (innogy)	innogy
UIBK	**burglary protection**	Access data Smarthome Austria, Logfile Smarthome, current situation by control		innogy Cloud	Verifies presence or movement in the apartment at certain times	Smarthome Austria (innogy)	innogy
UIBK	**notification processes**	Access data Smarthome Austria, Logfile Smarthome, current situation by control	Username, password, name, e-mail, address, language, phone number, transaction data, activity data, activity and status of each sensor, time / date	Tablet, innogy Cloud	Smarthome Austria provides the following options for notification processes against additional booking of a notification package: □ SMS □ Email This can be a notification when a person has not moved for a defined period of time or a particular device has not been used for a defined period of time. This scenario has a low priority.	Smarthome Austria (innogy)	innogy
UIBK	**light signal**	Condition of the infected device, transmitted information	Username, password, name, e-mail, address, language, phone number, transaction data, activity data, activity and status of each sensor, time / date	innogy Cloud	A command lamp from Smart Home Austria activates a lamp to give a signal to the user.	Smarthome Austria (innogy)	innogy

Figure 7 Data processing Modul C: Home Automation SHA

	Modul D: Alerting						
2PCS / ERT	**Mobile Alerting**	Personal data: at least necessary for the use of the system is first and last name and the assigned device ID. The maximum with regard to the collection of further person-specific data is at the discretion of the respective test facility; the system can provide the respective fields as required. Location position: the person is issued by the software only in case of an officially triggered emergency; on the 2PCS terminal the last 2 positions are deleted continuously; a triggered emergency by a secondary end user is always documented and must be completed as specified in the software; Processing: After each emergency an emergency protocol (PDF) is generated and is available in the system for all authorized employees; the further registration of this PDF is the responsibility of the respective test facility; Integration with external systems is possible but not offered in the standard	Name, address, activity data, location data, access data	2PCS server locally at the test facility or centrally at the provider;	Each test facility can define the type of alarm in certain emergency scenarios (info, warning, alarm) 1. Triggering SOS Button: With the 2PCS solution, the end user can make an emergency or service call via a mobile device. In addition, locating the end user when triggering an alarm is possible both indoor and outdoor. The created alarm chain starts automatically. 2. Person is missing: If a person is left out, authorized persons may locate the person 3. automatic fall detection: The created alarm chain starts automatically. 4. Geofencing: entry / exit of defined areas of residence. The created alarm chain starts automatically. 5. Check-In / Out: Time-based alert if a return time has been created for the person in the software. 6. Triggering SOS button on HomeTab 6. Triggering emergency via voice recognition	2PCS, HomeTab, gAALax middleware, Google Home	2PCS, ERT, UIBK, Google
2PCS	**Automatic fall detection**	Personal data	Name, address, activity data, activities of the sensors	2PCS watch	automatic fall detection via 2PCS acceleration sensor	2PCS	2PCS
2PCS	**GeoFencing**					2PCS	2PCS
	Modul E: Voice control						
ERT	**Google Home**					Google Cloud	Google-App

Figure 8 Data processing Module D: Alerting

2.4.2. ETHICAL ANALYSIS (MEESTAR)

In addition, the task comprised an ethical analysis of the project and pilot phases in order to safeguard the ethical integrity of all tasks and measures pursued within the project and large-scale pilots. We used the MEESTAR model (Model for the Ethical Evaluation of Socio-Technical Arrangements) as an analysis framework. In the following an introduction to the MEESTAR model, a summary of the application of the MEESTAR model to the i-evAALution project as well as a description of the evaluation process will be given.

2.4.2.1. MEESTAR MODEL

The MEESTAR (Model for the Ethical Evaluation of Socio-Technical Arrangements, Manzeschke et al. (2013) is an analysis framework for the ethical evaluation of the implementation of assistive technologies in life worlds. It can be used to identify ethically sensitive effects or characteristics of the technology and find solutions for these issues. As the ethical minimum requirement for assistive technologies is that they must not produce harm, the model focuses on negative effects. MEESTAR proposes one neutral and three negative degrees of ethical sensitivity but no positive one. This ensures that the analysis safeguards that negative effects are identified and not counterbalanced with potential positive effects of the system.

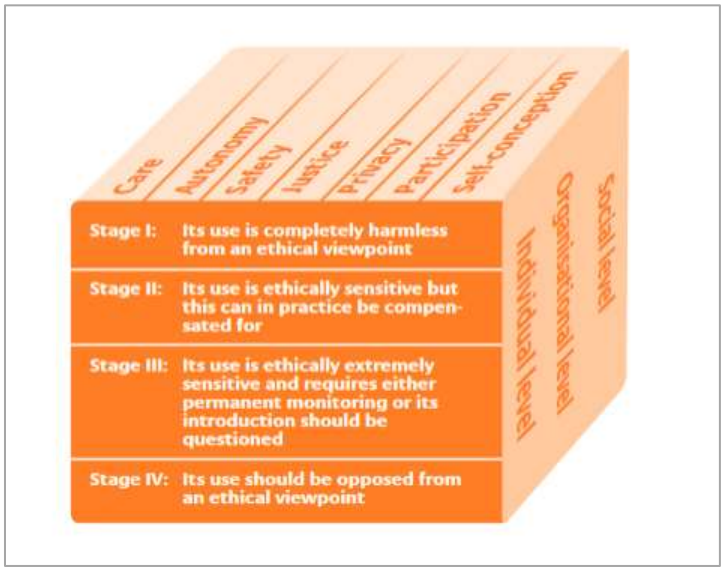

Figure 9 MEESTAR model

The MEESTAR model consists of three axes (see Figure 10). The x-axe contains seven ethical dimensions: care, autonomy, safety, justice, privacy, participation and self-conception. The y-axe contains the four degrees of ethical sensitivity assessment and the z-axe contains three possible perspectives (individual, organisational, societal).

2.4.2.2. ETHICAL GUIDELINES CARE

On the basis of the MEESTAR model, the study authors formulated 15 ethical guidelines with clear recommendations for the design and implementation of assistive technology. We use these guidelines

and recommendations for the evaluation of ethically sensitive issues within the project (Manzeschke et al. 2013, p.22).

1. Autonomy: Age appropriate assisting systems should help users to lead an autonomous life.

2. Restricted autonomy: Age appropriate assisting systems should only be used to help cognitively impaired people following a special assessment and taking into consideration the probable wishes of such people.

3. Participation: Age appropriate assisting systems should support participation in social life and integration into social relationships.

4. Justice: Access to age appropriate assisting systems should be without discrimination.

5. Safety: The use of age appropriate assisting systems has to be safe and secure for all user groups, both in normal usage and if faults and breakdowns occur which affect the whole system or certain parts of the process.

6. Privacy: Age appropriate systems should not have a negative effect on the way people shape their own lives.

7. Data privacy: Personal data and other confidential data collected, documented, evaluated and stored in the context of age appropriate assisting systems should be protected in the best possible way against access by unauthorised third parties and against misuse.

8. Notifications and informational self-determination: Users of age-appropriate technical assisting systems should be informed in full about the function and collection of data relating to them and the function of the system and should not be asked to give their consent except on that basis.

9. Liability: Responsibilities and liability in the event of a malfunction in age appropriate assisting systems have to be transparent and regulated in a binding way.

10. Concepts of age: Age appropriate assisting systems should permit as many different concepts of age as possible.

11. Avoiding discrimination and standardization: Stigmatisation and discrimination are undesirable in the context of using age appropriate assisting systems. Similarly, undesirable are direct or indirect standardization that issue from such systems.

12. Usability: Age appropriate assisting systems should be designed so that their use is simple, intuitive and easy to follow.

13. Contractual regulations: When using age appropriate assisting systems, it should be possible to exit from contractual relations if users feel insecure, unhappy, observed, or impaired in their privacy, or concerned in any other way.

14. Qualifications and further training: All of those involved in the field of age appropriate assisting systems should participate in regular training and educational activities.

15. Responsibility and the best possible support through technology: Suppliers of age appropriate assisting systems should behave responsibly; assistive technologies should always be employed for the benefit and wellbeing of users.

2.4.2.3. EVALUATION PROCESS

The above-described guidelines have been inserted to an evaluation matrix and further specified by establishing detailed factors per guideline. Based on existing project experiences as well as based on the i-evAALution solution design and project set-up, the UIBK team has performed the evaluation by answering the following questions:

- How does a specific guideline relate to our project? In which parts of the project does it apply?

- Which degree of ethical sensitivity according to the definitions of the MEESTAR model applies for a certain factor?
- What measures can we take to avoid, prevent or control the ethical risks?

The used evaluation matrix contains the following information:

Table 20 Explanation of evaluation matrix

Column	Explanation
Guideline	Title of guideline and core sentence according to MEESTAR guidelines (Mazeschke et al. 2015, p.22)
Factor	A factor that can affect the integrity of the guideline (mostly negatively)
Description	Description of sub-factor. What does it incorporate?
Relation to project	How does the described factor relate to our project, what parts of the project does it touch?
Measures	What measures do we take to ensure the factor is recognized within the project work? In what documents / tasks do we incorporate the factor?
Ethical sensitivity assessment	What degree of ethical sensitivity (1-4) according to the MEESTAR-model does this factor in our project belong to? (Figure 1)
Responsibility	Who is responsible for implementing the measures (according to the general task / project plan)?
Status	What is the status of implementing the measure?
Reference to document	Optional: links to the documents where the measures are implemented

2.4.2.4. APPLICATION TO I-EVAALUATION PROJECT

Table 21 contains the results of the ethical analysis of the i-evAALution project using the MEESTAR model.

Table 21 Evaluation of ethical aspects using the MEESTAR model

	Guideline	Factor	Description	relation to project	Measures	Ethical sensitivity assessment	Responsibility	Status	Reference to documents	Source of proof
1	**Autonomy** Age appropriate assisting systems should help users to lead an autonomous life.	automatic decision making system	automatic decision making by technical system must be transparent for the users; no automatic decision making processes without prior user agreement	solution design: automatic decision making in use cases: - Automatic alerting (2PCS fall detection) - automatic notification (I'm fine function) - Automatic light scenarios	Add and highlight information on automatic decision making in informed consent templates, summarize information on automatic decision-making distinctly at the end of the informed consent	2	WP3	open	informed consent	nothing highlighted, Summary p. 50
		Shutdown by user	the user should be able to shut off the systems (temporarily or permanently), the user and provider should be informed about switch-off mechanisms responsibilities and liabilities in case of system shut-down by user must be clarified and communicated	solution design: ability to switch off: central box 2PCS HomeTab GoogleHome	solution implementation: switch-off possible by pulling one plug (the one at the box) HomeTab: switch-off possible? 2PCS: no charging of battery, pulling central plug to disable 2PCS antenna Google Home: disconnect from power supply	2	WP1 solution providers WP3 implementation		informed consent bundle implementation description	missing information p.18
2	**Limited self-determination / autonomy** Age appropriate assisting systems should only be used to help cognitively impaired people following a special assessment and taking into consideration the probable wishes of such people.	-	-	does not apply as persons with cognitive impairments are excluded from the trial	define exclusion criterion and screening methods	1	UIBK / WP2	done	T2.2.3 - Results	
3	**Participation** Age appropriate assisting systems should support participation in social life and integration into social relationships.	facilitated access	The system should support (easier) access to social life.	solution design: Voice Calls / Skype Calls / Helferbörse 2.0 / Service Calls via 2PCS or HomeTab	inherent to bundle design, active invitation to participation	1	WP1 / WP3	open		
		systemic steering of preferred mode of participation	Individual preferences of participation must be recognized, the system must not steere the preferred mode of participation / communication by users and reference persons.	solution design: Voice Calls / Skype Calls / Helferbörse 2.0 / Service Calls via 2PCS or HomeTab	Explain the available functions during recruitment and in informed consent, encourage test persons to use the devices, but make clear that test persons decide on usage frequency and intensity	2	WP3	done	informed consent	p.13
		repression of other forms of participation	the system should not hinder or repress other forms of participation (e.g. personal friendships)	solution design: Voice Calls / Skype Calls / Helferbörse 2.0 / Service Calls via 2PCS or HomeTab	Explain the available functions during recruitment and in informed consent, encourage test persons to use the devices, but make clear that test persons decide on usage frequency and intensity	2	WP3	done	informed consent	p.36
4	**Justice** Access to age appropriate assisting systems should be without discrimination.	discrimination based on income	persons independent of their income status should have access to the system	during pilot phase	communicate that test persons have to bear no costs for the pilot phase, secure that budget for each pilot site is available to equip all test households, for the post-project phase the conditions and cost of keeping the technology must be made clear (exit strategy) and should be in favour of the test persons	1	WP3	done	informed consent	p. 11, 13
		discrimination based on social status	persons independent of their social status should have access to the system	during pilot phase: no differentiation on the basis of social status	different recruitment channels should be used to reach a variety of target groups, social status is no demarcation criterion for participation	1	WP3	open	recruitment strategies D3.1	
		discrimination based on age	persons independent of their age should have access to the system	during pilot phase: inclusion criterion	A cut-off age is necessary for scientific study, clear communication about the reason for having this cut-off age, try to find alternatives for persons that must be excluded due to age if necessary (information about alternative services etc.)	3	WP2	done	T2.2.3 - Results	
		discrimination based on gender	persons independent of their gender should have access to the system	during pilot phase: no differentiation on the basis of gender	both genders can participate, use of gender-inclusive language in all project material, and especially in communication material	1	WP2/WP3/WP4	in progress	T2.2.3 - Results recruitment material informed consent	
		discrimination based on education level	persons independent of their education level should have access to the system	during pilot phase: no differentiation based on education level	all education levels can participate	1	WP2	done	T2.2.3 - Results	
		discrimination based on technical affinity	persons independent of their technical affinity should have access to the system	no differentiation based on technical affinity	communicate clearly that no prior experience with technology is necessary to take part in the trial, establish and implement training concept for users, provide good instructions and user manuals for test persons	2	WP3	in progress	training concept	
5	**Safety** The use of age appropriate assisting systems has to be safe and secure for all user groups, both in normal usage and if faults and breakdowns occur which affect the whole system or certain parts of the process.	impairment of the physical and mental integrity of the users and providers	Age-appropriate assistance systems should not compromise safety in terms of physical or mental integrity of users and providers.	usage of technical systems during pilot	conduct alpha testing to reduce errors and malfunctions and increase reliability, communicate that existing systems are not replaced by the bundle, communicate that during pilot phase no absolute reliability can be guaranteed,	3	WP3	done	informed consent	p. 16 emergency handle p. 8 dementia
		health impairments due to system failures	Errors, malfunctions, process interruptions, network problems or other technical defects or human error must not impair or endanger the health of the participants.	usage of technical systems during pilot	conduct alpha testing to reduce errors and malfunctions and increase reliability communicate that existing systems are not replaced by the bundle, communicate that during pilot phase no absolute reliability can be guaranteed,	3	WP3	done	informed consent	p. 15 nothing is going to be replaced
		additional physical or psychological burden	Age-appropriate technical assistance systems must not lead to additional physical or psychological stress, such as stress, excessive demands, discrimination or stigmatization.	solution design usage of technical systems during pilot	provide support options and options for personal contact in case any burdens occur, make clear that test persons can exit anytime if they feel uncomfortable with the technology, encourage test persons to name such negative effects during evaluation, take feedback seriously solution design: use options that reduce stress, e.g. option to stop failure alarms (2PCS)	3	WP3 / WP1	in progress		

6	**Privacy** Age appropriate systems should not have a negative effect on the way people shape their own lives.	data processing	Collection and further processing of data, which are passed on from the private environment of users of age-appropriate assistance systems to third parties, must be processed in such a way that no further information (eg linking of the data) can be derived.	usage of technical systems during pilot	ensure pseudonymized data collection, secure data storage, implement limited access rights for different actors and stakeholders, conduct close monitoring of data quality and integrity localization data: only the two last GPS positions are stored, olders are deleted -- > release of localization data only in case of emergency	2	WP2	open		
		warnings and notifications	Warning signals or messages should be pseudonymised and - wherever possible - anonymised.	usage of technical systems during pilot	clear and transparent escalation plans, each warning or alert is documented and process flow is retraceable, use of pseudonymized identification data and separate link to personal data only on level of pilot site	2	WP2 / WP3	open		
		sensitive user data	The collection and transmission of data from the core area of user privacy through age-appropriate assistance systems must be safeguarded by special protective measures, as is the case with all data processing systems.	data collection	no sensitiv data (according GDPR) will be collected	1	WP2	done		
7	**Data privacy** Personal data and other confidential data collected, documented, evaluated and stored in the context of age appropriate assisting systems should be protected in the best possible way against access by unauthorised third parties and against misuse.	unauthorized access and processing	Third parties may not unauthorized access or process personal information from users. This also includes access to data of the medical or nursing staff (employee data protection).	usage of technical systems during pilot	systems are protected and user have differnt access rights	2	WP3	done		
		privacy statement	Privacy statements should be written in a simple and clear way and should be communicated transparently.	recruitment phase	clear and transparent information in informed consent	2	WP3	done	informed consent	p. 50
8	**Notifications and informational self-determination** Users of age-appropriate technical assisting systems should be informed in full about the function and collection of data relating to them and the function of the system, and should not be asked to give their consent except on that basis.	consent follows transparent information	The users should be informed about the scope, depth, functionality and data usage of the respective age-appropriate assistance systems in a comprehensive, comprehensible and appropriate manner. Only on the basis of this information and information should users decide on the use of assistance techniques.	recruitment phase	informed consent contains clear description of scope, depth, functionality and data usage of the bundle and parts	2	WP3	in progress	informed consent	p. 15, 16 17, 21(missing), 23, 24, 26, 27, 50, 51, 56, 57, 58, 59, 60
9	**Liability** Responsibilities and liability in the event of a malfunction in age appropriate assisting systems have to be transparent and regulated in a binding way.	liability definition	detailed definition of responsibilities and liability for all system parts, no "responsibility vacuums"	usage of technical systems during pilot	market ready products -> product liability is clear for stand-alone products, clarify process between systems	2	WP3	open		
10	**Concepts of age** Age appropriate assisting systems should permit as many different concepts of age as possible.	transport manifold pictures of age	A one-sided image of the old person, which is characterizes persons as deficient, should be avoided as well as a unilaterally positively drawn picture of the old person as vital, efficient and disciplined.	recruitment, overall project dissemination	make sure that marketing material, recruitment information, etc. is inclusive of a variety of pictures of age	2	WP4/WP3	open	communication strategy recruitment material	
11	**Avoid discrimination and standardization** Stigmatisation and discrimination are undesirable in the context of using age appropriate assisting systems. Similarly undesirable are direct or indirect standardization that issue from such systems.	(hidden) standardization	Use of technology can lead to (hidden) standardization e.g. if persons adapt to technical rhythms and routines or orient their daily lifes towards measures produced by the system Such subtile effects must be clearly revealed and must be declinable by the user.	solution design	hidden standardization could take place, e.g. with the 'are you okay function' (people could adapt their behaviour to fulfill this function) or in case of failure alarms (people adapt their behaviour to not produce failure alarms). clear information at the beginning and opt-out-option for those use cases during project (e.g. deactivation of are you okay function), users decide on usage behaviour, proactively communicate to users that producing failure alarms is no problem and should not lead them to change their behaviour, user training should include training on how to disable (failure) alarms	3	WP3	open	informed consent	problem after the project, people used to the technologie
12	**Usability** Age appropriate assisting systems should be designed so that their use is simple, intuitive and easy to follow.	user-centered design	Decisive for the serviceability and friendliness of age-appropriate assistance systems is a simple and catchy operation, in which the relieving and / or supporting property of the system can be recognized. This has to be taken into consideration above all against the background of the potentially older users, who eg. B. by impaired sensorimotor, limited mobility or reduced cognitive abilities (such as memory) other usage requirements for technical systems.	solution design	realize alpha-testing phase, end-user workshops pre pilot, expert evaluation of usability and make sure that feedback is taken seriously and incorporated into the solution design	2	WP1/WP2	open	evaluation of usability in WP2 and develpment in WP1	
13	**Contractual regulations** When using age appropriate assisting systems it should be possible to exit from contractual relations if users feel insecure, unhappy, observed, or impaired in their privacy, o rare concerned in any other way.	withdrawal from contract		exits during pilot phase	exit of test persons in project possible anytime without any reason communicate this info in informed consent, recruitment material, all communication material with end-users	1	WP3	open	exit strategie, informed consent	
14	**Qualification and further education** All of those involved in the field of age appropriate assisting systems should participate in regular training and educational activities.	provider education	providers of assistive technology should attend regular further education regarding user requirements as well as legal, economic, ethical and social questions	usage of technical systems during pilot	adoption through feedback from alpha test phase, close monitoring of ethical and legal requirements during project and ensure sensibility of all project members by sharing this document	2	WP1/WP2	open	evaluation and development ethical and legal monitoring (e.g. this document)	
15	**Responsibility and the best possible support through technology** Suppliers of age appropriate assisting systems should behave responsibly; assistive technologies should always be employed for the benefit and wellbeing of users.	communicate benefits and added value for users	Technology should not restrict the execution of life in an undesirable way or require users to adapt too much. It is therefore particularly important that the benefits and added value of technical assistance systems are clear and comprehensible to all involved.	recruitment	clear and transparent communication about the functions, the possibilities and the limits of the i-evAALution bundle, do not "talk persons into" testing the bundle	2	WP3	open		
		employ services / technical options after consent	Services and / or technical options should always be used only with the consent of the respective users.	recruitment	no installation without signed informed consent, date of signature has to be entered to central management database	2	WP3	open	informed consent	the whole informed consent?

2.4.3. APPLICATION AT ETHICS COMMISSIONS

The third part of this task was to prepare the applications to the ethical commissions to obtain ethical approval for our study. A documentation was prepared by UIBK. After consulting all ethics committees in the pilot regions, the following application process turned out to be necessary:

Pilot region Austria Johanniter	Application by UIBK team to the University of Innsbruck Ethical Review Board is valid for the pilot. The description must include the pilot setting of Johanniter.
Pilot region Austria FAWO	Application by UIBK team to the University of Innsbruck Ethical Review Board is valid for the pilot.
Pilot region Italy Eurac / SOS Coop	The application to the South Tyrolean Ethical Board has been made, the decision is expected on 17 September 2019.
Pilot region Netherlands Vilans	For the Netherlands a separate application to the regional ethical committee has been made. The committee stated that no full application was needed since the study does not fall under the Medical-Scientific Research with People Act (WMO).
Pilot region Slovenia Eurotronik	Application by UIBK team to the University of Innsbruck Ethical Review Board is valid for the pilot. The description must include the pilot setting of Eurotronik.

The University of Innsbruck prepared an application draft. The applications were sent to the Ethical Boards in April 2019.In the following, the draft for the application to the regional ethical committees is presented.

1. PURPOSE

This document contains draft texts in English and German for the project description needed to apply to the regional ethical committee.
The draft text includes information on:

1. Description of research goals and background
2. Methods and research design
3. Inclusion and exclusion criteria
4. Ethically sensitive issues
5. Funding
6. Argumentation of (non)necessity study participant insurance

Please consider the comments and check for necessary adaptions to align with national legislation.

2. ACCOMPANYING DOCUMENTS

At least in Austria, this project description needs to be handed in together with

1. Informed consent for study participants (in progress)
2. Overview on collected data and data collection instruments used (in progress)

Optionally, the following documents can be attached:

1. Ethical evaluation of the project (MEESTAR model – excel sheet) (ready)

2. Data quality management within project (ready)

3. PROJECT DESCRIPTION ENGLISH

The present research and development project 'i-evAALution' with a budget of 3.066.726,44 € is funded within the call 2017 of the "AAL Programme" by the Forschungsförderungsgesellschaft mbH (FFG), further national funding agencies as well as the European Union. The Institute for Strategic Management, Marketing and Tourism acts as consortium leader of an international consortium (Netherlands, Italy, Slovenia, Austria) consisting of ten partners including three research institutions, three support institutions, two technical system integrators and two solution providers. The aim of the project is to develop an interoperable bundle of AAL (Active Assisted Living) solutions and smart home systems, to evaluate them in a 12-month pilot phase and to test the effects of the bundle on quality of life, technology acceptance and care costs.

The new value of the present project is reflected in the (1) technical development approach and above all in the (2) evaluation approach. (1) The existing market offer in the area of AAL solutions is characterised by a high degree of fragmentation and specialisation. Individual AAL solutions are tailored to the special needs of older people, but can often not be combined with other systems per se, which represents a considerable usage barrier due to increased information requirements, operating costs, etc. By comparison, consumer products such as smart home systems offer a sufficient degree of integration possibilities, are usually modular in design and easy to operate. However, they are not designed to meet the special needs of older people or to be used in the context of outpatient care. By integrating both solution types, the advantages of the systems can be combined and relevant application scenarios can increase the security of the living environment. (2) While the evaluation focus of AAL projects so far has mostly been on technical aspects, the concentration on system effects on the quality of life is still an emerging researched field. So far, some qualitative studies have been carried out on the basis of which effects on the quality of life can be assumed[1,2]. Few randomised controlled studies in the literature demonstrate the positive effects of technologies[3]. The present study is intended to contribute to proving the effect of the technologies on aspects of quality of life and prolonged independence and thus to strengthen the promotion of mobile care before stationary care. In addition, data on the perceived relief and quality of life of the caregivers are to be collected.

The core of the research design is a randomized controlled trial with 810 test subjects distributed among intervention and control groups as well as 810 associated informal caregivers (relatives, neighbours, acquaintances or other caregivers). The test participants in the intervention group receive the technology bundle described above. This consists of five subsystems: (1) A mobile emergency call device with localisation and voice connection options as well as automatic fall detection (by acceleration sensor), which forwards triggered emergency calls directly to professional emergency call service providers (in Austria the Johanniter emergency call centre). (2) The Smart Home System enables light and device control to prevent falls and increase surrounding safety. (3) A tablet solution with an interface suitable for senior citizens serves as a medium for communication and entertainment services and as access to a (4) matching platform for voluntary services, on which test participants can both offer and receive voluntary services. (5) To create multimodal interaction possibilities, speech recognition software is integrated in the tablet. The test participants are distributed among five pilot regions with an equal division into intervention and control group: Pilot region Vienna with 130 test households (supervised by Johanniter Austria), pilot region Carinthia and Innsbruck with 130 test households (supervised by

system integrator FAWO GmbH and affiliated outpatient care providers), pilot region South Tyrol Bolzano with 100 test households (supervised by outpatient care provider Cooperativa SOS Onlus), pilot region Slovenia with 200 test households (supervised by Eurotronik Kranj d.o.o. and affiliated care organisation) and the pilot region of the Netherlands with 250 test households (care by Vilans - Centre of expertise for long-term care and the care organisations Tangenborgh and Lyvore). The technology bundle will therefore be installed for a total of 405 persons, randomly assigned to the intervention group and tested over a period of 12 months. Data collection takes place within the framework of interviews with participants from the intervention and control groups prior to installation (baseline) and as a four- and twelve-month follow-up. The data collection includes socio-demographic data, the quality of life status of the person and factors of technology acceptance. Details can be found in the attached research design overview. In addition to the surveys, log data of the technical devices are recorded during the test period in order to be able to evaluate the frequency and behaviour of use of the test subjects as control variables for effect analyses. The functionality, reliability and user-friendliness of the technology bundle as well as of all illustrated scenarios developed in the first project phase will be ensured in an alpha test phase prior to the planned broad roll-out to 405 households. This includes the expert-based usability evaluation (testing of the bundle by internal consortium experts) using heuristics and short-term test deployments as well as a 4-6 week alpha test phase with a small number of older test subjects (5-10). The aim of this phase is to eliminate errors in the system design and relevant usability problems in advance in order to exclude errors as best as possible for the later intervention study.

Participants in the intervention study must be 65 or older, live in private or assisted (i.e. outpatient) housing and have an informal caregiver who agrees to participate in the test phase. In addition, potential participants must be willing and able to follow the study protocol, which means in particular: (1) willingness to be randomly assigned to an intervention or control group, (2) willingness to have the entire product bundle installed in their own home and (3) the ability to participate in the evaluation measures in the respective supported language of the pilot region. Exclusion criteria for participants* are (1) residence in inpatient care facilities and (2) moderate to severe cognitive impairment, especially dementia (optional screening by Mini Mental State Examination MMSE). In addition, 75% of the test participants must be living alone, i.e. as soon as this threshold value per test region is reached during the recruitment of the participants, living in multi-person households is an exclusion criterion. Informal caregivers must be 18 years of age or older, have a private relationship with the subject, and provide regular practical or emotional support. In addition, caregivers must have a mobile phone in order to receive messages about the respondent's well-being status during the test phase. Moderate to severe cognitive impairments are exclusion criteria for caregivers.

Within the framework of the project, ethical aspects with regard to the solution development as well as with regard to the course of the project, in particular the test phases, are taken into account. An ethical evaluation based on the MEESTAR model[4], which is often used in the context of technology-assisted care, results in an ethically sensitive status of the project, the ethical risks of which can be largely controlled or compensated. An overview of the seven dimensions of the model and the measures taken to safeguard them can be found in the table below:

Dimension	**Evaluation**

Care	The normative right to care is not replaced, but supported by technology within the project. In addition, care activities, e.g. in emergencies, can be made more efficient by localization possibilities and a direct speech connection.
Self-determination	Maintaining the self-determination of the test persons is one of the main objectives of the project. This will be achieved through the technological support of the test subjects in their everyday lives. It is ensured that technical systems can be switched off at any time, if the test person wishes to. Test persons are not obliged to use the technical devices and can withdraw their consent to participate in the test phase any time without stating any reason.
Safety	The improvement of objective safety and the perception of safety is promoted in the project primarily through the use of emergency systems and home automation technologies. Potential negative effects, such as the reduction of functional capabilities through excessive automation, are taken into account, for example through control and information mechanisms instead of automation. Reliability of the technology cannot be fully guaranteed during the test phase, which requires clear communication and the necessity of test persons to keep their already available safety measures in place during the test phase.
Privacy	Securing privacy and data protection is a key aspect of measures to ensure an ethically unobjectionable approach. In addition to providing the test subjects with comprehensive information about the way in which the technical systems collect and process data and the evaluation processes, several measures are taken to ensure the privacy of the test subjects. For example, no general localisation of the test subjects is carried out, but only a selective localisation after an emergency trigger. Sensitive personal data is only transmitted in encrypted form. All evaluation data is processed in pseudonymised form. Access to personal data is exclusively the responsibility of the respective organization. The approaches pursued in the project are in conformity with GDPR legislation.
Justice	Justice refers to the distribution and access to support solutions regardless of a person's socio-economic status, gender or social status. Distributive justice is ensured during the project as test persons do not have to bear any costs. Moreover, the project team is sensitive to apply gender-neutral language to all communication material to encourage persons regardless of gender to take part in the test phase. Recruitment channels should be widespread in order to reach different social backgrounds.
Participation	The user-centred development approach allows maximum participation of the test persons in the development process.
Self-conception	The use of assistive technology could be perceived as a stigma by the test subjects. Therefore, the project attaches particular importance to the ambient use of technology. This is taken into account, for example, through the use of a piece of furniture containing the system headquarters. Sensitive communication protocols during the test phase ensure that concerns of test persons are heard.

The use of medical devices or tele-medical systems as a component of AAL system solutions is completely dispensed within this research project. No patients are involved in this sense. Participation is voluntary, free of charge and can be cancelled at any time without giving reasons. As we do not pursue a clinical trial in the sense of the German Medicines Act (AMG) or the Medical Devices Act

(MPG) and do not apply invasive or stressful procedures, a test subject insurance is not necessary for this project. In the event of potential damage resulting from the use of the individual technical products, the product liability of the solution providers applies.

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2.5.. TASK 2.2.6: PREPARATION OF EVALUATION MATERIAL, TRANSLATION AND PRE-TESTS

This task contains the description of the approach for preparing the evaluation material, the translation of the standardised questionnaires and the regional pre-tests.

2.5.1. PREPARATION OF EVALUATION MATERIALS

2.5.1.1. STANDARDISED QUESTIONNAIRES

The standardised questionnaires that will be used for evaluation purposes were checked for their availability and cost. In cases where the questionnaire was generally free of cost, the authors were contacted by EURAC to obtain permission to use the questionnaire. For questionnaires requiring a registration process (e.g. EQ-5D), this was done centrally by UIBK. The following table shows an overview of standardised questionnaires and the status.

Name	Name long	Authors	Status / permission
ASIS	Assessment of informal care Situation	Hoefman, R. J.; van Exel, N.J.A.; Foets, M.; Brouwer, W.B.F. (2011): Sustained Informal Care: The Feasibility, Construct Validity and Test-Retest Reliability of the CarerQol-Instrument to Measure the Impact of Informal Care in Long-Term Care. In Aging & mental health 15 (8), pp. 1018–1027.	Cost: free Author: contacted Permission to use given
CarerQoL-7D **fulfilment from caregiving item**	Care-related Quality of Life instrument	Brouwer WB, van Exel NJ, van Gorp B, Redekop WK. The CarerQol instrument: a new instrument to measure care-related quality of life of informal caregivers for use in economic evaluations. Qual Life Res. 2006 Aug;15(6):1005-21. Hoefman, R. J.; van Exel, N.J.A.; Brouwer, W. B. F. (2013): iMTA Valuation of Informal Care Questionnaire (iVICQ). Erasmus Universiteit Rotterdam, Institute of Health Policy & Management / Institute for Medical Technology Assessment.	Cost: free Author: contacted Permission to use given

EQ-5D-5L		Euroqol group Devlin, N. J., & Brooks, R. (2017). EQ-5D and the EuroQol group: past, present and future. Applied health economics and health policy, 15(2), 127-137. Herdman, M., Gudex, C., Lloyd, A., Janssen, M. F., Kind, P., Parkin, D., ... & Badia, X. (2011). Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of life research*, *20*(10), 1727-1736.	Cost: free Registration done
FAB	Filial Anxiety Scale B	Cicirelli, Victor G. (1988): A measure of Filial Anxiety Regarding Anticipated Care of Elderly Parents. In The Gerontologist 28 (478-482).	Test author is 93 years old, no other authors could be reached. The questionnaire will be used citing the original publication.
(Short) FES-I	Falls Efficacy Scale - International (short)	Delbaere, Kim; Close, Jacqueline C. T.; Mikolaizak, A. Stefanie; Sachdev, Perminder S.; Brodaty, Henry; Lord, Stephen R. (2010): The Falls Efficacy Scale International (FES-I). A comprehensive longitudinal validation study. In Age and ageing 39 (2), pp. 210–216. Kempen, Gertrudis I. J. M.; Yardley, Lucy; van Haastregt, Jolanda C. M.; Zijlstra, G. A. Rixt; Beyer, Nina; Hauer, Klaus; Todd, Chris (2008): The Short FES-I: a shortened version of the falls efficacy scale-international to assess fear of falling. In Age and ageing 37 (1), pp. 45–50.	Cost: free Author: contacted Permission to use given
MMSE (optional)	Mini Mental State Examination	Folstein, M. F.; Folstein, S. E.; McHugh, P. R. (1975): "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. In Journal of psychiatric research 12 (3), pp. 189–198.	Cost: not free Partners in Italy and Austria will purchase the required copies
PIADS	Psychosocial Impact of Assistive Devices Scale	Jutai, Jeffrey W.; Day, Hy (2002): Psychosocial impact of of Assistive Devices Scale (PIADS). In Technolgy and Disability 14, pp. 107–111.	Cost: free Author: contacted Permission to use given

SRB	Self-rated burden scale	Hoefman, R. J.; van Exel, N.J.A.; Foets, M.; Brouwer, W.B.F. (2011): Sustained Informal Care: The Feasibility, Construct Validity and Test-Retest Reliability of the CarerQol-Instrument to Measure the Impact of Informal Care in Long-Term Care. In Aging & mental health 15 (8), pp. 1018–1027.	Cost: free Author: contacted Permission to use given
TC scale	Short scale of technology commitment	Neyer, F. J., Felber, J., & Gebhardt, C. (2012). Entwicklung und validierung einer kurzskala zur erfassung von technikbereitschaft. *Diagnostica*.	Cost: free Author: contacted Permission to use given
USE	Usefulness, Satisfaction, and Ease of Use (USE) questionnaire on usability	Lund, A. M. (2001). Measuring usability with the USE questionnaire. Usability Interface, 8(2), 3-6	Cost: free Author: contacted Permission to use given

2.5.1.2. SELF-DEVELOPED ITEMS

Self-developed items were prepared by Eurac and discussed and reviewed within the WP2 team. To date (25.10.2019) the baseline 1 and 2 questionnaires are finished.

Baseline 1: see attached document D2.2a

Baseline 2: see attached document D2.2b

2.5.2. TRANSLATIONS

In the following the guidelines on the translation and validation of the questionnaires used in the i-evAALution project is presented. On that basis, a methodology was proposed on how the responsible project partners can organise and conduct the translation and validation of the questionnaires.

2.5.2.1. COMMON TRANSLATION GUIDELINES

WHO Guidelines:

The World Health Organisation (WHO) developed a guideline on how to translate questionnaires on the management of substance abuse, which is based on previous WHO studies. It consists of several phases.
https://www.who.int/substance_abuse/research_tools/translation/en/ (retrieved on 20 March, 2019)

Forward translation: a single translator translates it from English to the preferred language. Several aspects are important:

- Language to which it is translated is his/her native language
- He/she has sufficient English knowledge

- He/she is familiar with the topic/terminology of the questionnaire and has interview expertise
- Focus on conceptual instead of word for word translation
- Use common language, adapted to the target group, not jargon
- Clear, simple, concise phrases.

Expert panel

The number of experts varies (original translator + expert on topic + expert questionnaire development / translation)

- Group of bi-lingual experts
- Identify insufficient expressions/words and inconsistencies between the original and translated questionnaire (eventual compare with existing previous translations)
- Results: complete translation of the questionnaire

Back-translation

- A single translator (mother tongue is English) translates it from the preferred language to English. The same aspects as in step 1 should be considered (mother tongue differs).
- In WHO questionnaires, the back-translation is limited to selected items which are particularly sensitive or cause often problems. Discrepancies are discussed with the an “editor-in-chief”

Pre-testing and cognitive interviewing:

- Pre-test respondents are representative for the target group
- Minimum 10 persons, male / female, different socio-economic status
- Debriefing with respondent: discuss terms & understanding of questions
- Compare answers of questionnaire to actual response
- Discuss misunderstood/unacceptable terms
- Discuss alternatives
- In-depth interview or Focus group
- Conducted by experienced interviewer

Final version and documentation

The result of the above process has to be described and documented in detail.

FES-I Guidelines:

The University of Manchester provides a very informative website on the Falls Efficacy Scale International (FES-I), which also includes a systematic protocol of how to translate it into a different language.

https://sites.manchester.ac.uk/fes-i/ (retrieved on 20 March 2019)

- The English version of the FES-I is always point of departure. Translate the full 16 item FES-I. Once these 16 items are translated the seven items that make up Short FES-I can simply be selected from this text. However, ensure that the instructions for Short FES-I are also translated as they are slightly different from FES-I instructions.
- Make use of the translator / interviewer notes for interpretations of different items.
- The English version of the FES-I will be translated from English into the local language by at least **two translators independently**. These translators need to be (a) native speakers of the local language, and (b) familiar with the concept fear of falling.
- A **first consensus meeting** of the translators is held which has to result in a provisional local version.

- Each of the translators will **select two older persons for a try-out** of the FES-I in written form. The questionnaire needs to be filled in by each older person separately without any disruption of the translator. Afterwards, the 16 items are discussed between the translator and the older person (Were all items clear? Is it necessary to reformulate items?).
- Each of the translators may adjust the wording of items.
- A **second consensus meeting** is held to create consensus about a next preliminary local version of the FES-I.
- A **back translation** from the local language into English is done by a professional translator whose native language is English.
- A **third consensus meeting** of the translators is held to review the back translation. Important for the reviewing is the intentional meaning of the back translation, not the literal meaning. The objective is a valid translation of the local version of the FES-I, not a new English one. If necessary, the professional back translator will be consulted for additional information.
- We always need to be informed about the final local version. E-mail *fes-i@manchester.ac.uk*

Guidelines of the international test commission:

International Test Commission. (2017). The ITC Guidelines for Translating and Adapting Tests (Second edition).
https://www.intestcom.org/files/guideline_test_adaptation_2ed.pdf (retrieved on 20 March 2019)

The 18 guidelines consist of the following sub-items: Pre-condition (3), test development (5), confirmation (4), administration (2), scoring and interpretation (2), and documentation (2).

Pre-condition:

- PC-1 Obtain the necessary permissions from the holder of the **intellectual property rights** relating to the test before carrying out any adaptation. Obtain official (signed) permission (Copyright) from the owner before start
- PC-2 Evaluate that the amount of **overlap in the definition and content of the construct** measured by the test in the populations of interest is sufficient for the intended use (or uses) of the scores. Experts should evaluate the constructs in each language group: does the construct make sense in each group? (focus-groups, surveys, etc.)
- PC-3 Minimize the **influence of any cultural and linguistic differences** that are irrelevant to the intended uses of the test in the populations of interest. (item format, use of computer, etc) To overcome this problem, the “cultural and linguistic distance” between the original and target language should be assessed with interviews/focus groups (understanding, experience with these tests, familiarity with scales, etc.)

➔ Importance of translators who are native speakers of the target language

Test development:

- TD-1 Ensure that the **adaptation process considers linguistic, psychological, and cultural differences** in the intended populations through the choice of experts with relevant expertise. Cultural knowledge. Minimum of **2 translators** per forward/backward translation.

➔ "expert" is a person or a team with sufficient combined knowledge of (1) the languages involved, (2) the cultures, (3) the content of the test, and (4) general principles of testing, to produce a professional quality translation/adaptation of a test.

- TD-2 Use appropriate translation designs and procedures to maximize the suitability of the test adaptation in the intended populations.

➔ Focus on functional instead of literal meanings
➔ Forwards & Backward translations
➔ Expert Panel
➔ Use multiple translations designs (forward & backward translations, expert panels)

- TD-3 Provide evidence that the **test instructions and item content have similar meaning** for all intended populations.

➔ (1) reviewers should be native in local culture and language; (2) use of samples of bilingual respondents; (3) use of local surveys to evaluate the test; and (4) use of non-standard test administrations to increase acceptability and validity.
➔ local site (bilingual) pre-test
➔ Ask bilingual persons to rate the difficulty of a question in both languages

- TD-4 Provide evidence that the item formats, rating scales, scoring categories, test conventions, modes of administration, and other procedures are **suitable for all intended populations**.

➔ familiarity of item-format equal in all countries?
➔ check if the respondents have the required level of experience to give a valid response

- TD-5 **Collect pilot data** on the adapted test to enable **item analysis, reliability assessment and other small-scale validity studies**, so that any necessary revisions to the adapted test can be made.

[Symbol] test the translated questionnaire reliability / validity, using at least a modest sample size

Confirmation:

- C-1 Select **sample with characteristics that are relevant** for the intended use of the test and of sufficient size and relevance for the empirical analyses.

➔ collect a larger sample to identify possible biased items, minimum 200 respondents.
➔ representative sample of the target population

- C-2 Provide relevant statistical evidence about the construct equivalence, method equivalence, and item equivalence for all intended populations.

➔ Carry out an analysis on construct equivalences of the original language and the translated language. Does did the construct remain the same after the translation?[Symbol]Equivalent at item level after the translation (language & culture)?

- C-3 Provide evidence supporting the norms, reliability and validity of the adapted version of the test in the intended populations.

➔ five sources of validity evidence based on: test content, response processes, internal structure, relations to other variables, and consequences of testing

- C-4 Use an appropriate equating design and data analysis procedures when linking score scales from different language versions of a test.

➔ In general, it is problematic to link test-results/scores of different (language) versions.
➔ Is there evidence that the same construct is being measured in the source and target language versions of the test? Does the construct have the same relationship with other external variables in the new culture?

- ➔ Evaluate the functioning of common items across multiple language groups, when they are used in a single evaluation.
- ➔ True Bilingual test-persons could help verify this.

Administration:

- A-1 Prepare administration materials and instructions to minimize any culture- and language-related problems that are caused by administration procedures and response modes that can affect the validity of the inferences drawn from the scores.
- ➔ Anticipate potential problems: Clarity of test instructions (including translation of those instructions), the answering mechanism (e.g., the answer sheet), the allowable time (one common source of error is the failure to allow sufficient time for test-takers to finish), motivation for candidates to complete the test, knowledge about the purpose of the test, and how it will be scored.
- A-2 Specify testing conditions that should be followed closely in all populations of interest.
- ➔ Also meant for administrators, standard instructions
- ➔ Make sure that everybody fills it out in a similar condition, but suitable to the culture. Trainings

Scoring and interpretation:

- SSI-1 Interpret any group score differences with reference to all relevant available information.

Even when translating perfectly, cultural differences or differences may still be present.

- SSI-2 only compare scores across populations when the level of invariance has been established on the scale on which scores are reported.
- ➔ Make comparative statements between groups, based on the amount of validity evidence between the original and translated version (highest level).

Documentation:

- Doc-1 Provide technical documentation of any changes, including an account of the evidence obtained to support equivalence, when a test is adapted for use in another population.
- Carefully document all changes of the process. Should give enough details for replication. (might be requested later on)
- Doc-2 Provide documentation for test users that will support good practice in the use of an adapted test with people in the context of the new population. Written for persons who use the test

<u>Other guidelines:</u>

van de Vijver and Hambleton (1996):

Different kinds of biases should be taken into account when translating questionnaires:

- **Construct bias**: a construct may be evaluated / seen differently in a different country (being a good son / daughter in China, is when they take good care of their parents. In Westerns countries this norm is much broader)
- **Method bias**: different answers due to the method. Socially desirable answers due to response formats may differ in countries. Communication problems between interviewer and interviewee.

- **Item bias** or differential item functioning: problems, which are related to the translation of individual items (wording etc.)

Behr et al. (2015):

- Translations don't have to be word-for-word – they should rather "work" as well as possible in the target language
- To translate in a team can be considered as state of the art
- They recommend the TRAPD approach (Harkness 2003):
    - **Translation** by two independent translators (at least one of them should be professionally trained)
    - **Review** in a joint meeting, which is hosted by a facilitator. Every item is being discussed and if possible, solutions are found already
    - **Adjudication**: if there are still unclear / open issues, an experienced survey- / questionnaire expert is asked for help
    - **Pre-test**: The translated questionnaire is tested with a small sample of the target group to get information about how / if the translated items are understood in the intended way.
    - **Documentation**: The whole translation process should be documented.
- They advise against backtranslation of questionnaires as this approach is controversially discussed as it has some disadvantages (as successful translations can turn out by this method as wrong, and bad translations can remain undetected).
- A newly translated questionnaire should be validated as thoroughly with the target group as the original questionnaire (by qualitative and / or quantitative methods, which test the psychometric properties, e.g. confirmatory factor analysis).
- The authors stress the point that sometimes not only translations but also adaptations to the cultural context of a target country are necessary (e.g. if a questionnaire is about the local health system or includes measures like miles / metres).

2.5.2.2. I-EVAALUTION TRANSLATION

Responsibilities:

The following partners are responsible for the translation of the questionnaires into the four project languages:

Table 22 Translation responsibilities

Partner	Language
UIBK	German
EURAC	Italian
UNILJ	Slovenian
VILANS	Dutch

I-evAALution Guidelines

Here we propose the guidelines for translating standardized and validated questionnaires for the use in i-evAALution. They are based on the above-described translation processes as well as on considerations regarding the feasibility and availability of resources in our project.

Translation

- The **original** questionnaire is always the point of departure
- One of the translators should be **professionally trained**
- The translators should have good **knowledge in the language of origin**
- At least one of the two translators should **have knowledge about the concept** of the questionnaire
- The focus on **conceptual meaning** of the translation instead of word-to-word translation
- **The new questionnaire** should encompass common words, easy understandable phrases, be concise
- **Two translators** with the above requisites **independently** translate the questionnaire to their **mother tongue** (Slovenian, German, Dutch or Italian)

Consensus meeting

- The two translators **discuss their translations** (especially the meaning of questions and potential discrepancies) together **with a researcher of the i-evAALution consortium** until consensus in reached
- Outcome is a fully translated questionnaire, including all instructions

Pre-testing and cognitive interviewing

- **Three older test persons** (PE or i-SE, >65 years) fill in the questionnaire in individual sessions (one test person + i-evAALution researcher) without disruption by the researcher
- The researcher discusses the **actual meaning / understanding of each item** with the test person in order to answer the following questions:
    - Was the item clear?
    - Were there incomprehensible words or phrases?
    - Is it necessary to reformulate the item?
- If the researcher thinks it necessary, he / she applies the techniques of **probing** (e.g. “What exactly do you understand by the term ‘social integration’ in item 3?” or **paraphrasing** (e.g. “Could you rephrase item 3 in your own words for me?”) (see Lenzner et al. (2015))
- If change requirements arise from the pre-testing, they are **discussed by the researcher with the two translators** (another joint meeting is only necessary in case the changes would be substantial or controversial)
- The **final version** of the questionnaire is compiled

Validation

- After having used the translated questionnaires in the respective pilot countries during the one-year trial phase, the collected data will be used to assess the psychometric criteria of the measures (in particular its reliability and validity).

Documentation

- Every project country describes the actual translation, testing and validation processes for all questionnaires
- The project consortium will let the project authors know about the translations and send them to them
- The descriptions will be collected and included in an appropriate deliverable of WP3.

The overview of the questionnaires to be translated is provided here:

https://seresunit.sharepoint.com/:x:/r/sites/ievAALution/Documents/WP2_STUDY_EVAL/02_work/T2.2_STUD_DES/2.2.6_Prep_translate_pre-tests/190405_i-evAAL_Translation_Overview.xlsx?d=w250fecc4a508585bb3ce7f3ddcda9d0b&csf=1&e=xQJid3

2.5.3. PRE-TESTS

Several pre-tests of the devices as well as the questionnaires and other data collection methods will be run with a small group of elderly people and informal caregivers before the main trial phase. The aim is to obtain information of problems in the processes (difficulties to understand introductory texts, questionnaire scales experienced as inappropriate, etc.) as well as the technologies, and to solve as many as possible for the main test phase.

As described in Deliverable 3.1 "Strategic approach plan for pilots", the pre-tests are carried out in three different phases:

1. Pre-alpha phase (members of the consortium):

First, the consortium will test the individual devices and the overall system for a few days. This way we can assess how user-friendly it is, if everything works the way it should, what kind of bugs occur, what aspects are missing, etc. Furthermore, Nielsen's usability heuristics (plus adaptations) will be used to systematically evaluate the devices. Adjustments will then be made by the project development team, based on the feedback.

2. Pre-alpha phase (older adults):

In a second step, several PEs who will not take part in the main trial phase will be invited to sessions in which they test the individual devices and the complete bundle. At first, they will receive the training according to the developed protocol, so we can verify if it fits the older peoples' needs. Then, we will let them try out the devices and observe them handling them. In this way, problems can be identified and be forwarded to the software developers who will try to solve them. At the end of the workshop, PEs will fill in a usability questionnaire.

3. Alpha Phase (older adults):

The detailed approach for conducting the alpha phase has been defined and contains the following content:

- PROCEDURE OF THE APLPHA PHASE
  - Every pilot should have the beginning of the pilot phase, which will be simulated during the Alpha test, planned out according to the local conditions and resources. In Italy, for example, there are three appointments planned for the participants of the intervention group:
    - appointment: informed consent document, optional MMSE, Baseline 1 questionnaire
    - appointment: technology installation, technology training
    - appointment: further technology training, Baseline 2 questionnaire
  - During the Alpha phase we will arrange these three appointments with the PEs and their i-SEs and thus get an estimate on how much time will be roughly needed and if any adjustments should be made to this procedure.

- INFORMED CONSENT DOCUMENT

- All content of the informed consent document (project information and parts to be signed by the participants) should be explained thoroughly by the project staff to PEs and i-SEs in the Alpha phase. Enough time to read the document should be given (at least one day, better several days).
- When asking the participants of the Alpha phase for feedback, the following questions should be asked:
  - Was everything clear in the document(s)?
  - If not, what was unclear and how could it be made clearer?
  - Do you have any other suggestions on how the document should be improved?
- Notes of the answers, preferably in a spare copy of the informed consent document should be made

- MMSE (optional)
  - The countries which use the MMSE should also try the administration out in the Alpha phase (especially if the project staff has no or little experience with it).
  - Feedback on the MMSE administration should be written down in the Excel feedback file (see below).

- QUESTIONNAIRE BASELINE 1
  - PREPARATIONS
    - Before giving the questionnaires for Baseline 1 to the PEs and i-SEs in the Alpha phase, carry out the following preparatory activities:
      - Make sure that the questionnaire testing will not be interrupted (take into account that the entire interview for one person will take approximately 60 minutes).
      - Get your watch or smartphone ready to measure the time for filling in the questionnaire (only in case of the retrospective think-aloud method).
  - HOW THE INTERVIEWING WILL LOOK LIKE
    - Before the project staff start with the first questionnaire, it is obligatory to review and study the complete B1 questionnaire, so that they can easily give a short presentation of the questionnaire and its purpose. During the Alpha phase, project staff need to conduct the testing of the questionnaire in person, i.e. they need to be with the PE and i-SE at the same table. The respondent fills out the questionnaire independently. No other way of interviewing is allowed.
    - The interviewing will take place according to one of two scenarios. Choose one scenario for one PE and i-SE of the Alpha phase and the other scenario for the second PE and i-SE of the Alpha phase.

<u>Scenario 1: This approach gives more information on the content</u>

- Ask the PE and i-SE to complete the questionnaire by himself/herself and encourage him/her at the beginning to comment the questionnaire out loud while reading and answering each question (e.g. comment on the unclear terms, ambiguity of statements, unclear instructions, etc).
- Feedback: During the interview, have a version of the questionnaire prepared for yourself, to write down the respondent's comments:

- If you detect any kind of problem during the respondents answering the questions (e.g. the respondent does not understand the question, he/she thinks about the answer for a long time; the respondent could not answer the question with the suggested options), describe the problem in a short comment.
- Furthermore, try to identify the cause of the problem with the respondent, and also describe/write this in the comment. Give the respondent the possibility to express and describe the problem on his own (using his words), and also (this is preferable) to give suggestions for the improvement of the content and/or the form of the questionnaire.
- Although it is preferred to have short descriptions of the problems, please make sure that they are clearly and unambiguously described. Try to summarize the respondent's comments consistently and literally.
- The descriptions of the problems within each separate question should be added to the separate questionnaire straightaway.

Scenario 2: This approach gives information on the time needed

- The testing will be done with the retrospective think-aloud method, which means that you ask the respondent to fill out the questionnaire on his/her own and report any problems in a comprehensive commentary after the end of completing the survey. The respondent may mark the places in the questionnaire, where he had problems, so that he can easily summarize the issues after he completes the whole survey.
- Measure the time (start the stopwatch before the respondent begins answering the questionnaire and do not forget to stop the stopwatch when he is finished).
- You are not allowed to talk to the respondent while he/she is filling in the questionnaire, unless he/she is stuck and needs clarifications. Provide them short help according to the guidelines for project staff (separate working document – T2.2.7).
- When the respondent gives his/her comments regarding the problems at the end of the questionnaire, you need to behave as a value-neutral researcher, so do not engage in a discussion regarding the questions or comment on the respondent's opinions, views or answers he/she has chosen in the questionnaire. The only exception can be made if it helps you to clarify a problem in the questionnaire.
- Feedback: During the interview, have a version of the questionnaire prepared for yourself, to write down the respondent's comments. Include the feedback of both (all) PEs and i-SEs into the English basis versions of the B1 and B2 which will be provided on Sharepoint, removing double issues. The feedback should contain the following information:
  - the problem identified, a suggested solution (e.g. the respondent could not answer the question, the question contained sensible information, the question was not clear, etc.)
- Include the feedback of both (all) PEs and i-SEs on the following issues in the Excel file on Sharepoint:
  - A general impression of the interviewing: What was the respondent's reaction to the B1 questionnaire (positive/negative)?

- The duration of the questionnaire (only in case of the retrospective think-aloud method).

- TECHNOLOGY INSTALLATION
  - After having prepared and carried out the technology installation in the homes of the PEs of the alpha phase, write down in the Excel file on Sharepoint if you have encountered any problems concerning:
    - Organisation / logistics
    - Time management
    - Placing the devices in the apartment
    - Setting the use cases up

- TECHNOLOGY TRAINING
  - After the installation of the technologies, the training with the PE (and i-SE) can take place. Please refer to the training guidelines and materials which have been compiled.
  - When asking the participants of the Alpha phase for feedback on the technology introduction / training, ask them the following questions:
    - Was everything clear in the training materials?
    - Where the explanations of the training instructor clear?
    - Was anything missing?
    - Do you have any suggestions on how the training materials and procedures should be improved?
  - Make notes on the answers and insert them to the Excel file on Sharepoint.

- QUESTIONNAIRE BASELINE 2
  - The preparations and procedure of the interviewing will be the same as described for baseline 1: Carry out scenario 1 with one PE + i-SE and carry out scenario 2 with the other PE + i-SE.
  - Also collect and write down the feedback as described for the questionnaire of Baseline 1.

- PERIOD OF TECHNOLOGY TESTING
  - Tell your Alpha test persons to contact you during the technology testing at home if they have any problems or questions. You can also simulate different scenarios / emergencies during this time to check the functioning of the use cases.
  - If any problems arise during the testing phase, write them down in the Excel file on Sharepoint indicating clearly to which
    - Device
    - Use Case
    - Middleware / platform
  - the problem relates. Provide solutions to the problems where possible.

- TECHNOLOGY DE-INSTALLTION
  - At the end of the Alpha phase, de-install the technologies in the flats of the PEs. Thank the participants for their valuable help and don't forget to mention that they will be informed about the project's results at the end of the trial phase (in about 1,5 years).

- Thus, all pilot partners can write down the feedback from their Alpha tests in those documents, which everyone (developers, researchers and pilot partners) can access, discuss feedback and make changes where necessary to
  - Technologies
  - Questionnaires
  - Procedures

Table 23 Template of worksheet for general feedback from the Alpha-phase

Pilot	Feedback no.	Informed consent document	Quest. B1	Technology installation	Usage of technologies	Technology training	Quest. B2	Further feedback
	Feedback no.1							
	Feedback no.2							
	Feedback no.3							
	Feedback no.4							
	Feedback no.5							
	Feedback no.6							
	Feedback no.7							
	Feedback no.8							
	Feedback no.9							
	Feedback no.10							

After the pre-alpha and alpha phase, the technology bundle and other test materials should be ready for the pilot phases. The pilot phase will not start until all major problems are resolved.

2.6.. TASK 2.2.7: DEVELOPMENT OF TRAINING MATERIALS FOR DATA COLLECTORS

2.6.1. INTRODUCTION

In this working document we're outlining the rules and guidelines for all project staff members, who will be in contact with the primary and informal secondary end-users during the trial phase. Many of the provided information here is based on / taken from the works of the Comparative Survey Design and Implementation (CSDI) Guidelines Initiative[3] and the Interview Training Manual of the Eurofamcare project[4].

Project partners who recruit external project staff for subtasks have the responsibility to train this staff thoroughly according to this working document. Also project internal staff should make sure, that the content of this document is understood and all necessary information (manuals, templates…) are ready to be used.

2.6.2. GENERAL GUIDELINES

[3] http://ccsg.isr.umich.edu/index.php/chapters/interviewer-recruitment-selection-and-training-chapter#four
[4] https://www.uke.de/extern/eurofamcare/deli.php#deli3

The following list of general rules of conduct will be respected during all visits at the homes of PEs or i-SEs by **all internal as well as external project staff**:

- We will arrange all appointments at the PEs' or i-SEs' homes in advance by phone or e-mail, if possible at least one day ahead, to give the test participants time to prepare for our visits
- We will make visits with two project persons at maximum to make the situation as comfortable as possible for the older persons and avoid "overcrowding" in the apartment
- We will be on time for visits. If we are delayed for some reason we will call the PE or i-SE on time and notify them about the delay
- When we enter the homes of the test persons, we make a personal presentation with our full name and our organisation right at the beginning. Then we briefly repeat the purpose of the visit.
- During our visits we avoid technical and scientific terms, especially English ones, and try to explain everything in a clear and concise way
- During visits, we always act in a friendly and helpful way, but avoid excessive private conversations or extensions of phone calls or visits which have nothing to do with the project-related purpose.

2.6.3. TECHNOLOGY INSTALLATION AND SUPPORT

Project-external installation staff will get

- A thorough technological introduction on all i-evAALution technologies
- Copies of the technology user manuals
- All contact details of the technology providers to be able to get information on the devices or request replacement devices if necessary (support process will be described in D3.4)
- Templates of documentation files, in which all contacts with PEs or i-SEs (personally or via telephone) have to be documented in detail.

2.6.4. INTERVIEWING

Research has shown that interviewer staff should be trained to improve the quality of interview and questionnaire data:

- It reduces item nonresponse (Billiet and Loosveldt 1988)
- It increases the amount and accuracy of information (Billiet and Loosveldt 1988)
- It increases participation commitment by knowing how to identify and respond to the test persons' concerns (O'Brien et al. 2002)

All interviewer staff will be provided with the full questionnaire documents (Baseline 1, Baseline 2, Intermediate, Final, for PE as well as i-SE) beforehand and read them thoroughly, including the instructions for oral administration, in case an older test person prefers this mode. In case manuals are available for validated questionnaires which are used in the four measurement points, these will be provided to interviewers as well.

Furthermore, **external interviewers** will be given the following information in a face-to-face introductory session:

- An overview of the project, the consortium and the test phase
- The project information folder (which the test persons get as well) and the informed consent document

- Information on the roles of the interviewers and the project staff as supervisors during the test phase
- An overview of the different possible interview modes (face-to-face and delivering self-administer survey materials), and the tasks each poses for the interviewer
- An overview of the sample design and associated implications and tasks for the interviewer

All questionnaires should be filled in by the test persons (PE and i-SE) autonomously. The following prescribed procedures will be included in the interviewer training (Fowler and Mangione 1990), so the interviewer staff can help test persons filling the questionnaires in, in case this is requested by them (the test person is not able to fill in the questionnaire by himself / herself):

- **Standardized question-asking.** Interviewers will be trained to read each question exactly as written and to read the questions slowly. They will ask all questions exactly in the order in which they are presented in the questionnaire.
- **Questionnaire format and conventions.** Interviewers will be taught how to enter the answers to both open-ended and closed-ended questions, i.e. write down as exactly as possible what the person said.
  They should follow interviewing conventions such as emphasizing words in the questionnaire which appear in bold or are underlined, recognizing and not reading aloud interviewer instructions, reading or not reading optional words as appropriate, and selecting correct fill choices (e.g., he/she, has/have, etc.).
- **Clarification.** Interviewers will be trained to repeat all or a specified part of the question verbatim when respondents ask for clarification. Interviewers should not make up their own definitions to any word, phrase, or question in the questionnaire. Interviewers will be asked to notify their project organisation responsible for the test phase about any questions which were confusing to PE / i-SE and require further clarification.
- **Probing.** If a respondent's answer to an open question is inadequate and it is legally, ethically and culturally permissible to probe, interviewers are trained to employ unbiased techniques to encourage answers that are more complete, appropriate, and thoughtful. Probes must be neutral; that is, they must avoid "sending a message" about what is a good or a bad response. Such strategies of probing for more information may include:
  - A pause to encourage the person to fill the silence or a direct request for further information.
  - Verbal probes chosen from a stock list of phrases such as "Could you explain what you mean by that?" or "Can you tell me anything else about _____ ?"
- **Feedback.** Interviewers will be trained to provide the test persons with culturally appropriate feedback when they are doing well in order to encourage them to listen carefully and to give thoughtful answers.
  - This feedback may be in the form of a nonverbal smile or nod or a short encouraging phrase.
  - Verbal feedback should be selected from a prepared list of stock phrases such as "That's useful information" or "Thank you, that's helpful" to ensure that the feedback is not evaluative of the content of the answer. For example, in English the word "okay" is discouraged for use in feedback because it could be construed as agreement with or approval of the respondent's answer.

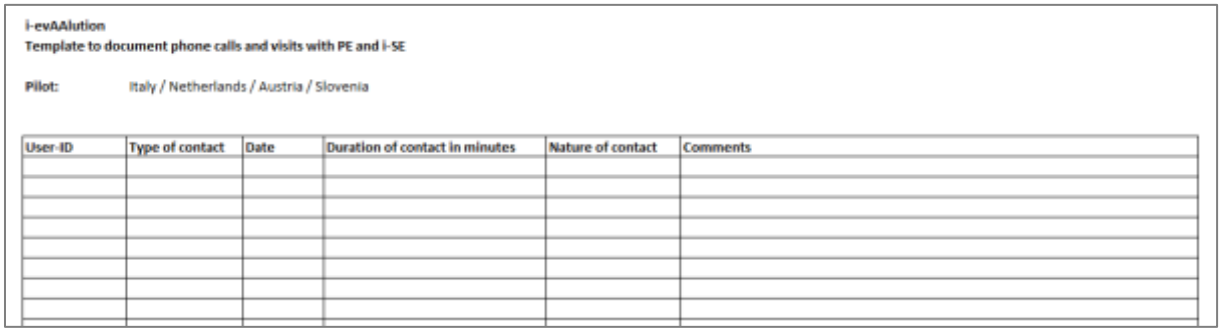
- As a general rule, give nonverbal or short feedback to short answers and longer feedback phrases to longer answers.

- **Recording answers.** To reduce measurement error, interviewers will be trained to record answers to open questions exactly as given.

The local project staff will keep in touch regularly with the interviewers, for solving any doubt or difficulty that may arise, as well as taking note of how many interviews have been completed. They encourage project-external interviewers to hand in completed interviews regularly and check every paper copy for completeness. Every paper copy of the questionnaire should be scanned in promptly and be kept as electronic file to prevent data loss.

2.6.5. DOCUMENTATION OF CONTACTS

The project staff in every pilot region make sure, that all personal contacts as well as contacts by phone with PE or i-SE will be documented. These contacts include information meetings, the technology installation, technology trainings of the PE and i-SE (a manual for this will be elaborated in a different working document), interview / questionnaire meetings and technical support contacts. A template of a file Excel will be provided, so all calls or meetings with test users can be documented in detail.



i-evAAlution
Template to document phone calls and visits with PE and i-SE

Pilot: Italy / Netherlands / Austria / Slovenia

User-ID	Type of contact	Date	Duration of contact in minutes	Nature of contact	Comments

Figure 10 Cut-out of documentation template

In the “Type of contact field” the following options can be chosen from a drop-down list:

- call to arrange appointment
- information
- technology installation
- technology training
- interview / questionnaire
- technical support
- other

The “Nature of contact” can be one of the following:

- by phone
- personally

2.7.. TASK 2.2.8: EXECUTION OF TRAINING FOR DATA COLLECTORS

In some pilot regions, project-external staff will be subcontracted to assist with installing the technologies and / or data collection. These persons will be trained by the staff of i-evAALution consortium members in face-to-face training sessions according to the guidelines elaborated in subtask 2.2.7 (see above). Furthermore, all project partners will make sure that their internal staff is familiar with the guidelines as well and will act accordingly.

The description of the training execution will be provided in the pilot reports (pre-alpha, alpha and main phase) within WP3.

2.8.. TASK 2.2.9: DEVELOPMENT OF QUALITY MANAGEMENT STRATEGY FOR DATA COLLECTION

2.8.1. INTRODUCTION

This section describes the data quality management strategy implemented in the i-evAALution trial to ensure the quality of the collected data. We understand data quality as comprised by six operational dimensions elaborated by Brown (2007) and adapted by Gass et al. (2017)

Table 1: Data quality dimensions (taken from Gass et al. 2017)

Dimension	**Description**
Accuracy	Data are correct and reflect the truth
Reliability	Data are consistently collected and entered in a standard way across data collectors
Timeliness	Data are current to routine data entry and available for near real-time reporting
Completeness	There are no missing essential data elements
Precision	Data have necessary detail to address research questions and management requirements
Integrity	Data are secure and protected from bias or manipulation

2.8.2. DATA QUALITY MANAGEMENT EXCEL

An excel document for data quality measures is used to track and document potential adverse events that could affect data quality and states related prevention and monitoring measures. The table lists the following information:

- Phase: What phase / aspect of the trial is affected?
- Event: What adverse events could affect data quality?
- Measures: description of measures to be taken
- Timing: when are those measures implemented
- Effect on data quality dimensions (see table 1)

It is a descriptive summarizing document that gives an overview of measures that are implemented throughout the project and should be used for quick overview and identification of missing measures or additional adverse events throughout the project.

The Excel document for data quality measures can be found here:
https://seresunit.sharepoint.com/:x:/r/sites/ievAALution/Documents/WP2_STUDY_EVAL/02_work/T2.2_STUD_DES/2.2.9_Data_quality_management/190108_Data_Quality_Management_v2.xlsx?d=w1962e4cc82545969bcfa330960e67678&csf=1&e=FdUYb9

2.8.3. OVERVIEW ON DATA QUALITY MEASURES BY DIMENSION

1. Accuracy

How do we ensure that questionnaire data is accurately entered to the system?

- Upon data entry of a new person to the database, the initials and birthdate of the test person must be entered in order to prevent switches of identification numbers after randomization.
- On-site live entry of data?
- Standard restrictions in online questionnaires (e.g. check for correctness of format etc.) only allow ticking options
- Thorough training of data collectors + detailed written instructions for assessment interviews
- Plausibility checks
- Pre-tests

2. Reliability

How do we make sure that data is consistently collected and entered in a standard way across data collectors?

- Standardized and obligatory training for data collectors
- Standard data entry tool (online survey)
- Adherence to respective written instructions

3. Timeliness

How do we make sure that questionnaires are collected in a timely manner?

- In the i-evAALution database the date of questionnaire completion must be entered.
- Dependent on that date the database will generate reminders when the next questionnaire for the respective test person is ready.
- In the i-evAALution database, regular reports can be generated that display for which test persons the assessment is due at a given time point.

4. Completeness

How do we ensure that questionnaires are completed fully?

- Thorough selection on questionnaires in the first place
- Accompanied data collection planned with trained interviewers
- Adherence to manuals and administration guidelines of the respective questionnaires

5. Precision

How do we ensure that data has all necessary details to address the research questions?

- Thorough selection on questionnaires in the first place based on scientific criteria
- Ensure statistical validity: create hypotheses that lead the scientific process, define adequate scientific descriptive and inferentical analysis methods (Döring & Bortz, 2016)
- Installation of complete standardized bundle and provision of all use cases
- Effect hypotheses are based on detailed level of use cases (what use cases can have which effects?)
- Training of data collectors to make sure questionnaires are completed precisely (see completeness)

6. Integrity

How do we ensure that data is stored securely and safe from manipulation?

- Questionnaire data is pseudonymized with the test person identification number
- There is no direct connection of TP-ID and personal data
- Personal data is stored only locally by the respective pilot site organisation and only given out to persons who accompany the test persons on site (data collectors, installation personnel, support personnel on site)

2.9.. TASK 2.2.10: DEVELOPMENT OF DATA MANAGEMENT STRATEGY (STORAGE, PROCESSING)

In this section, the management of data underpinning i-evAALution is described and a data management plan outlined. It shows that the topic of data management and protection is taken seriously, and that personal and sensitive data is treated confidentially. It demonstrates not only *that*, but also *how* data management will be carried out. The data management plan will be communicated to the test persons (PEs, i-SEs and other stakeholders) via the project information materials and the informed consent document and will thus enhance their feelings of safety and trust in the project. In this way, also the quality of the collected data will be ensured. The i-evAALution data management plan is based on the checklist made available by the Digital Curation Centre (2013).

2.9.1. RELEVANT POLICIES AND PROCEDURES

All i-evAALution activities concerning test persons or involved stakeholders are based on the European Data Protection Regulation No. 679/2016. Furthermore, in every pilot country the respective national legislation will be taken into account.

Furthermore, the European Code of Conduct for Research Integrity is an important reference for the project (ALLEA - All European Academies, 2017). The data collection and analysis will be oriented on its four fundamental principles (p.4):

- **Reliability** in ensuring the quality of research, reflected in the design, the methodology, the analysis and the use of resources.
- **Honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair, full and unbiased way.
- **Respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment.
- **Accountability** for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts.

Furthermore, the consortium will apply the "Data Practices and Management" as described in the code of conduct (p.6):

- Researchers, research institutions and organisations ensure appropriate stewardship and curation of all data and research materials including unpublished ones, with secure preservation for a reasonable period.
- Researchers, research institutions and organisations ensure access to data is as open as possible, as closed as necessary, and where appropriate in line with the FAIR Principles (Findable, Accessible, Interoperable and Re-usable) for data management.
- Researchers, research institutions and organisations provide transparency about how to access or make use of their data and research materials.
- Researchers, research institutions and organisations acknowledge data as legitimate and citable products of research.
- Researchers, research institutions and organisations ensure that any contracts or agreements relating to research outputs include equitable and fair provision for the management of their use, ownership, and/or their protection under intellectual property rights.

2.9.2. DATA COLLECTION

In this section, an outline is given on which data will be produced and collected in the project, and how this will be done.

2.9.3. TYPES OF DATA

Within i-evAALution, mainly **personal data** of older adults, their relatives, volunteers, various stakeholders, and representatives of companies and service providers will be collected.

Sensitive data will be collected by some pilot partner via the screening of participants with the Mini Mental State Examination (MMSE). No data regarding the MMSE-results will be stored / saved together with the name or other personal data of the respective person.

There is **no existing data** that can be reused in the project.

2.9.4. WAYS TO COLLECT DATA

During i-evAALution, data will be collected in the following ways:

- Questionnaires (given to participants directly, sent by post or given online)
- Open questions (face-to-face interviews)
- Activity data concerning the involved technological devices, which will be stored in log files

2.9.5. QUALITY ASSURANCE

SEE SUBTASK 2.2.9 ON DATA QUALITY MANAGEMENT (PREVIOUS CHAPTER OF THIS DELIVERABLE).

2.9.6. DOCUMENTATION AND META DATA

All results and outcomes of the project will be accessible for the project partners via a shared online platform, which is password protected and divided by the project leader as well as the work package leaders into folders and subfolders with clear and unambiguous labels. Furthermore, all partners will save documents related to data collection in separate folders with clear and distinct labelling on their respective servers. Project partners will also create user-codes for the test persons in a homogenous way and use these codes for labelling relative files.

Original hardcopy versions of documents will be archived in a dedicated location in the respective partner organisations until after the inspection by the national funding authorities.

2.9.7. ETHICS AND LEGAL COMPLIANCE

2.9.7.1. ETHICAL ISSUES

Before the tests, all PEs and i-SEs will give their consent regarding data preservation and sharing by signing a declaration of agreement (see templates of informed consent documents). Test persons will be extensively informed about the i-evAALution data management by information sheets as well as oral explanations and will subsequently give their written consent to

- collecting and processing of personal data by the project partners
- transferral of information about them in an anonymous and encrypted way to external institutions and for research purposes.

The identity of test participants will be protected through pseudonomization of the collected data. Sensitive data will be stored and transferred securely via a safe connection. Moreover, ethical concerns will be managed by involving project partners' internal experts on ethics.

2.9.7.2. COPYRIGHT AND INTELLECTUAL PROPERTY RIGHTS (IPR)

All collected data (e.g. questionnaire, usage data…) in coded form will be stored centrally on SharePoint by all project partners. Dissemination activities which rely on this data (e.g. publications) must be coordinated with the project partners in time, especially with the partners who have collected the data.

Since i-evAALution is a multi-partner project, the IPR ownership is covered by the consortium agreement.

2.9.8. STORAGE AND BACKUP

In this section, the storage of i-evAALution data is described as well as the consequences this has on data backup, access and security.

2.9.8.1. STORAGE AND BACKUP DURING THE PROJECT

Data will be stored in separate files on each pilot partners' servers. Documents like questionnaires or interviews / user test records will not be stored together with the name of the person, but only with a

user code. A list with the assignments of the user codes to the persons will be saved separately. Some data will be published for statistical and research purposes; this data will be entirely anonymized.

Test data of end users
Qualitative and quantitative data will be stored on the computers and servers of the respective pilot partners. The organizations take into account the legal and organizational framework conditions (e.g. retention requirements, security measures ...). In addition, standards and certifications that already exist will be fulfilled (e.g. EURAC ISO 27001 certified) Only anonymized data will be shared with the research partners.

2.9.8.2. MANAGEMENT OF ACCESS AND SECURITY

Risks to data security will be managed by the technical team and solution providers of the i-evAALution project. It is at the discretion of all project partners that data is secured. It also each user's own responsibility to protect his or her own privacy so that access to confidential data (e.g. user profile) is controlled through a password. Through 'Sharepoint', the secure access of the data by collaborators and project partners is ensured, as 'Sharepoint' is also password-protected. Moreover, the technical teams of the pilot providers will take IT-security measures by always keeping the servers up-to-date.

2.9.9. DATA SHARING

As in the i-evAALution project small and medium enterprises are involved, which are interested in bringing the technology-bundle on the market in their respective countries, collected data will generally be kept within the consortium. An overall summary of results will be published, using the anonymized data. Disclosure of information to secondary users is possible, but data will be entirely anonymized, i.e. data can never be traced back to individual persons.

Furthermore, i-evAALution ensures sufficient protection for confidential data and IPR through a non-disclosure agreement amongst all partners, which is part of the consortium agreement.

The formats and software chosen by the i-evAALution project partners do not enable sharing and long-term access to the data.

2.9.10. RESPONSIBILITIES AND RESOURCES

The University of Innsbruck (Institut für Strategisches Management, Marketing und Tourismus), will be responsible for the supervision and coordination of the i-evAALution data management activities. The responsibility lies with the organization (project partner) or the respective data protection officer of the organization.

Resources, i.e. staff working hours concerning data management, were not specified explicitly in the project proposal but the project partners will be able to cover the necessary work load within their foreseen number of staff hours.

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