SMART BEAR
"Smart Big Data Platform to Offer Evidence-based Personalised Support for Healthy and Independent Living at Home"

D52 – Ethics Application & Piloting Protocol & Evaluation Framework

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D12.1 (D52) – Ethics Application & Piloting Protocol & Evaluation Framework

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Executive Summary

SMART BEAR is a multi-centric patient-centred research project. It is aiming at implementing state-of-the-art technology in the everyday life of elderly citizens with specific health challenges, by integrating off-the-self friendly to use devices into an innovative platform, the SMART BEAR platform.

The project and thus this protocol are designed under the philosophy of a common direction for all involved Pilot countries. This design has to be rigid enough to ensure the undisrupted compliance to SMART BEAR principles and goals, and at the same time flexible enough to be adapted to the capacities and particularities of each Pilot country, its legislation and regulations.

Deliverable D12.1 (D52) includes the Piloting protocol along with all documentation required for the obtainment of approval by the relevant Scientific and Ethics Committees. Indicative templates of advertising material are also included in Appendix.

Comment by authors: Since important designing activities are still ongoing (devices selection, data repositories identification etc), this Study Protocol shall be subject to amendments.
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List of acronyms

ABC: Activities – Specific Balance Confidence Scale
AE: Adverse Event
BMI: Body Mass Index
CC: Clinical Coordinator
CVD: Cardio-Vascular Disease
DD: Device deficiency
EU: European Union
FES-I: Falls Efficacy Scale – International
FA: Functional ait Assessment
GDP: Gross Domestic Product
GDS: Geriatric Depression Scale
HL: Hearing Loss
HRQL: Hearing-specific quality of life
IC: Intrinsic Capacity
ICF: Informed Consent Form
KPI: Key Performance Indicator
MCI: Mild Cognitive Impairment
ML: Machine Learning
ORDP: Open Research Data Pilot
PHQ-8: eight-item Patient Health Questionnaire depression scale
RAPA: Rapid Assessment Physical Activity
SAE: Serious Adverse Event
SG: Serious Games
TTR: Time in Therapeutic Range
USADE: Unanticipated Serious Adverse Device Effect
WHO: World Health Organization
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1 Introduction

1.1 Background

Societies in the contemporary era confront numerous challenging structural and functional changes. Population ageing constitutes a major issue on this aspect. In Europe, current predictions for the near future support a forthcoming increase of the elderly population as the demographic growth is slowing down while ageing accelerates. Estimations coming from Eurostat project that the old-age dependency ratio (the ratio of people aged 65 and over relative to those of working age) will double (28.8% to 51.6%) by 2060 in the EU-28’s populations. Ageing is often accompanied with a progressive decline in physical and cognitive skills and can prevent elderly people from living independently and from performing basic instrumental activities of daily living. The constantly increasing morbidity rates in conjunction with the gradual lack of independence among the older citizens summarize the major burdens that the health and insurance systems are called to deal with. Towards the same direction, family pattern transmission to a looser structure amplifies the problem. These trends reflect to the increase of the demand for long-term health care and safer, more age-friendly environments and are putting significant pressure on age-related public expenditure in the European Union (EU), which is estimated that, by 2060, will reach 12.9% of gross domestic product (GDP) for pensions, 8.3% of GDP for health care and up to 3.4% of Gross Domestic Product (GDP) for long-term care. A holistic and at the same time personalized view of the problem is required.

1.1.1 Hearing Loss

Hearing Loss (HL) is affecting 1/3 of people over 65, while debilitating HL is detected in 6% of the population (WHO, 2019). It is currently estimated that HL will affect more than 900 million people, reaching 1/10 of the global population, by 2050. Its management cost is estimated to 213 billion euros for the European countries and 750 billion dollars, per annum, globally.

At present, the provision and fitting of Hearing Aids (HA) is the major management scheme for the vast majority of patients with HL, as HAs improve patients’ general health-related and hearing-specific quality of life (HRQOL). This improvement is significantly related to patients’ participation in daily activities and their listening ability. Nevertheless, there are still many situations that HA users find significantly challenging, such as listening to poor sound quality, selecting HA’s predefined programs and settings and listening to noisy environments. Consequently, many adults with HL, especially the elderly ones, do not use their HAs. Another factor to consider is the effectiveness of HA use in adults with different degrees of HL. Therefore, HA fitting is a very important process that should (i) continuously adjust the challenges HA users face in their daily life, (ii) consider individual behavioural, cognitive, physiological and other audiological and medical factors and (iii) be accompanied by an individualized rehabilitation program, such as auditory training. Consequently, it seems clear that the selection of a suitable management strategy for HL should consider information beyond just the acoustic characteristics of the various environments in which a HA is used, such as the abovementioned ones.

1.1.2 Balance Disorders

One in three people over the age of 65 falls annually. 80% of elderly people who end up in emergencies with a fall in an unknown cause, suffer from vestibular dysfunction. The effects of balance disorders are manifold in physical, social and economic level and are leading to the increase of frailty, cognitive decline, sedentary behaviour and falls related to death.
Cognitive decline and decrease of the executive function also increases balance dysfunction, instability and likelihood of falls. Behavioural factor such as physical inactivity is leading to weight loss and frailty increasing the fear of falling which is a strong predictor for future falls. Balance rehabilitation is the treatment of choice especially for patients with chronic symptoms of dizziness, instability and falls, with the aim of accelerating brain plasticity and vestibular compensation, reducing the intensity and duration of symptoms, and the incidence of falls and returning to functional activities. Systematic reviews including studies of high methodological validity confirm the above claim. Balance rehabilitation program which includes vestibular exercises (head-eye coordination, habituation exercises, dynamic gait exercises with a high level of balance demands) also seems to improve stability, postural control and decline symptoms related to balance disorders and falls. Cognitive training has also directly demonstrated benefits on balance and gait parameters in older adult fallers.

In SMART BEAR a possible synergy with another EU funded project, that fills this gap, is being considered. A synergy with HoloBalance H2020 program is being considered. HoloBalance platform consists of a surrogate virtual physiotherapist that is projected by a mobile phone attached in a head-mounted display, who is providing an evidence-based balance exercise program, gamified exercises and cognitive games provided in an augmented reality environment in order to improve motivation, cognitive and auditory training exercises as well as incentives to improve physical activity beyond the intended rehabilitation program via a physical activity application installed in a mobile phone. The platform consists of different off-the-shelf devices and equipment. It consists of a special bracelet that records heart rate, pulse volume and sympathetic nerve function factors, special soles that will be fitted to the footwear and will provide information on postural control and gait parameters, a special camera for detecting head movements in space, eye tracking movements, providing guidance and feedback that they will wear during treatment and most importantly a head-mounted display for the surrogate physiotherapist, the gamified exercises and the cognitive games. The HoloBalance rehabilitation program will be implemented daily. An audible signal will alert the participant to start of the platform. The physiotherapist's hologram will appear in the space. The program will start in the form of balance exercise and/or as an electronic game in an augmented environment with balance and cognitive training exercises. Type and progression of the training will depend on the functional level of the participant and always be assessed real-time by the specialized physiotherapist who will have access to the raw data of the participant from the clinic. Despite that algorithms have already been developed so that the participant's motive can be predicted and his/her behaviour to be modified as well as algorithms for treatment progression.

A study of proof of concept has already proven that HoloBalance platform is a safe method for the balance rehabilitation of older adults with balance dysfunction and at the risk of falling. Therefore, this study will assess the effectiveness of the HoloBalance platform in relation to the daily clinical practice (the OTAGO Home Exercise Programme) regarding symptoms decline, increase of balance confidence, functional ability and levels of physical activity community-dwelling older adults.

1.1.3 Cardiovascular Diseases

Cardiovascular disease represents one of the leading causes of morbidity, mortality and disability globally. It affects all the age groups but its dominance among the elderly people is profound. In concordance, depression, dementia, musculoskeletal or vestibular disorders affecting the balance as well as hearing loss represent other significant clinical entities which greatly affect the quality of life and functionality. Combined with frailty, these conditions constitute the main 5 pillars of the SMART
BEAR platform’s target. In terms of intrinsic capacity assessment and maintenance, an initial pre-recruitment evaluation will allow clinicians to identify those profiles which would benefit from enrollment. This refers to the elderly population whose overall capacity is already at risk or expected to deteriorate over time. The platform will accommodate continuous or periodical monitoring of biological parameters, social and physical skills regarding part or all the aforementioned conditions for each of the participants recruited. Based on the situation’s specific needs, suitable validated monitoring or intervention smart devices will be applied accordingly. The platform will integrate all available data and will interact with the end-user via a smartphone interface. During the follow-up period, the intrinsic capacity will be re-evaluated on an individualized and community-based manner. Overall, the platform will facilitate personalized advice and or interventions aiming to promote active living, healthy nutritional and social habits. This intervention is consequently expected to enhance safe and independent living and improve the quality of life of the elderly.

1.1.4 Mental Disorders
As stated in D2.1, depression and anxiety are major threats to the health and quality of life of elderly people with one in five seniors affected by depressive disorders, which is the most common mental disorder for this population. It is estimated that about 20% of 50-85 years are affected by a mental disorder such as chronic depression, suicidal thoughts or psychological distress. One-third of the suicides that occur each year in France concerns persons over 65 years. One-third of those over 65 years old would regularly consume psychotropic medications, not always wisely. One-third of women over 65 consume anxiolytic benzodiazepine. A 2012 systematic review of depression in older adults found that between 4.6% and 9.3% of older adults experience major depression, and an average of 17.1% experience depressive disorders. Although some elderly develop the classic symptoms of depression (persistent sadness and despair), others may present with less typical symptoms (somatic complaints: aches, heart palpitation, dizziness, indigestion etc) that may present as symptoms of other medical illnesses or cognitive disorders.

Many solutions are already available on the market in the mental health industry. Here are different categories of tools and that can be listed in a short review: Portals, gateways and marketplaces for education and orientation, comprehensive wellbeing platforms (integrating education, screening, diagnosis and care), teletherapy, digital care delivery, wearables, virtual reality and analytics (Artificial intelligence), digitized screening, therapies, behaviour change, peer support.

Indeed, considering the general population, there seem to be very few solutions on the market dedicated to prevention in the mental health field. The curative approach is much more deployed in mental health and on a medical point of view, a person who is in “good mental health” is someone who has no treatment yet... consequently, lots of digital tools and solutions proposed in the mental health field are meant to ease the access to care when the persons already suffers from a mental disease (teletherapy, teleconsultations, telepsychiatry), or to detect mental illnesses (screening, help to diagnosis,...), or to propose a help in the cure process (treatment reminders, peer support,...). However very few solutions have the concern to work actively on the depression factors before the person enters real depression.

1.1.5 Cognitive Disorders
Cognitive disorders (CDs), also called as neurocognitive disorders (NCDs), are a category of mental health disorders that primarily affect cognitive abilities including learning, memory, perception, and problem-solving. The term neurocognitive disorder (NCD) was introduced by DSM-5, it encompasses...
acquired cognitive impairment of all causes at all ages and it comprises 2 syndromes, major NCD and mild NCD, distinguished by the severity of the cognitive impairment. Neurocognitive disorders have become more and more common as people are ageing. The foremost frequent is Alzheimer’s disease (AD) - a progressive neurodegenerative disorder characterized by a cascade of pathological events, including abnormal extracellular deposition of amyloid-beta (Aβ) plaques, intracellular tau tangles, and volumetric loss of cortical grey substance. Mild NCD corresponds to the state usually called MCI, and may involve impairment in one or more cognitive domains.

The impact of a diagnosis like neurocognitive disorders is appalling for the elderly people and for his or her caregiver. The impact is felt at different levels for individuals: a variety of emotions and feelings, loss of confidence, depression and anxiety. The diagnosis of neurocognitive disorders could be a great challenge for the informal caregiver like family, friends, life partner with the occurrence risk of burnout syndrome. The requirement for support from a caregiver often starts early within the dementia journey, intensifies because the illness progresses over time, and continues until death. In general, the impact has repercussions at emotional, psychological, social and economic level (increased costs). The overall estimated worldwide costs of dementia were of US$ 818 billion in 2015, akin to 1,09% of the worldwide GDP.

The costs are driven mainly by social care needs; health care costs account for a tiny low proportion of the overall, given the low diagnosis rate, limited therapeutic options, and therefore the underutilisation of existing evidence-based interventions.

Therefore, the interventions within the early, predementia stages, addressing the most risk factors and inspiring changes within the lifestyle represent a sound option. And digital technologies as in Smart Bear could contribute in addressing several areas, with cognitive stimulating serious games, lifestyle coaching (through notifications, advices) in terms of healthy dietary habits, physical and social activities, in measuring the performed activities and monitoring subsequent pathologies and therapy adherence (e.g., hypertension, diabetes, obesity, etc). Additional support may be provided for better indoors orientation (through intelligent lightings and sensors) and safer outdoors travelling (through GPS location trackers).

1.1.6 Frailty

Frailty is a state of pre-dependency that can be conceptualized as “a clinically recognizable state in which the power of older people to deal with daily or acute stressors is compromised by an increased vulnerability brought by age-associated declines in physiological reserve and performance across multiple organ systems”. Frailty can occur as the result of a spread of diseases and medical conditions. Other factors linked with frailty development are: a) socio-demographic influences like living alone, low educational level or poverty, b) psychological factors like depression, c) polypharmacy, d) nutritional issues like malnutrition or poor oral health or e) sedentary lifestyle. In keeping with a scientific review, the reported mean prevalence within the community-dwelling older people is 10,7% (95% confidence interval (CI) = 10.5-10.9; 21 studies; 61,500 participants). A higher prevalence of frailty was associated with the advanced age (a quarter of the individuals aged 80 years older or more are frail) and feminine gender (frailty prevalence among elderly women was reported significantly higher comparatively with frailty prevalence among elderly men). Frailty prevalence is additionally higher among elderly nursing home residents compared to community-dwelling ones.
Frailty is a dynamic process which may be reversible with individually personalized interventions. Frailty screening, evaluation and management are highly important because even small stressors events may expose frail older people to an increased risk of developing significant complications and negative health outcomes such as: falls, dependency, hospitalizations or death.

The frail elderly constitute a complex population in terms of assessment, monitoring, adherence to recommendations, and follow-up. The employment of novel technologies is also considerably helpful for both clinical and research purposes. Specifically, technologies may support interventions preventing disability, improving the quality of life, and enhancing the wellbeing of frail people. Traditional assessment instruments may be complemented or replaced by mobile devices measuring and monitoring frailty domains (e.g., physical performance, cognitive function, physical activity, nutritional status). Novel technologies such as those to be employed in the Smart Bear project have indeed the potential to benefit, assess, monitor, and support frail older people to live independently and improve their quality of life.

1.2 Purpose of SMART BEAR project

The SMART BEAR platform is structured to act as an assisting and personalized tool for the daily routine. It is addressed to the old and the very old proportion of the population and it aims to integrate a wide spectrum of data in order to offer personalized interventions in order to promote the health status and the level of independence. Data collection will require the application of heterogeneous sensors, assistive smart medical devices and the end-users’ input via structured questionnaires and interaction. The platform will also be connected to hospitals and other health care service systems in order to obtain data of the end-users (e.g., medical history) which need to be considered in decision making. The measured parameters and the suggested interventions stand on the grounds of evidence-based medicine and are validated by several medical associations and current guidelines for good medical practice. Emphasis is given so that the smart device interface and function will be friendly to users.

The SMART BEAR project aims to recruit approximately 5100 senior European citizens. Thus, providing that their majority will allow the anonymized information collection and storage under the valid regulations for privacy, the platform will enable big data collection. The continuous or periodical data collection from everyday life regarding several biological parameters and habitual behaviours according to the participants’ choice, will be available also to extract epidemiological reports. Consequently, the expected outcome from the large-scale analysis of the aforementioned parameters will benefit not only the participants but potentially the general public as well.

One of the principal aspects which have influenced the SMART BEAR design is that the intrinsic capacity of each individual fades over time. As declared by the World Health Organization, the
intrinsic capacity refers to the combination of all the physical and mental skills one person has or adopts during his life and enable a healthy and active way of living. **Intrinsic capacity** (IC) oriented model, is addressing both the facts that, with ageing, individual’s capacities and degree of independency are deteriorating and that **environmental barriers** become more challenging. Efficient targeting of those essential points could be valuable for the enhancement of senior’s independency, social interactions and overall well-being. Five domains/functions have been identified as being critical for capturing IC; **locomotion, vitality, sensory (in particular, vision and hearing), cognition, and psychological functions**. These domains evidently influence each other. Additionally, they are all influenced by environmental factors. In clinical grounds, intrinsic capacity assessment becomes increasingly popular. It is fundamental for the required holistic approach in primary and secondary prevention. In fact, it is a dynamic construct and its trajectory over time may inform clinical and public health actions as soon as its monitoring is contextualized at the individual or population level, respectively. On an individualized basis, deviations from baseline overtime may enable preventing actions before the clinical manifestation of a disorder. The same assessment gives the opportunity to reflect on the effectiveness of the implemented therapeutic interventions. On the other hand, the application of this model in the community may enable the detection of specific regions or populations requiring a different approach from the public health perspective.

In SMART BEAR six major medical entities have been placed to the centre of interest: hearing loss, heart failure, arrhythmias, hypertension, balance disorders, depression, frailty and mild cognitive impairment will be targeted. State-of-the-art, off-the-shelf and friendly to use technological equipment is going to be used according to evidence-based medical algorithms and current guidelines and a variety of actors at different involvement levels (elderly, health professionals, caregivers and municipality staff) will be actively involved. The overall aim is the multi-level enhancement of the self-management of everyday health challenges and improvement of Senior’s well-being.
2 Objectives and Research Hypotheses

2.1 Objectives and Hypotheses of the clinical investigations.

2.1.1 Hearing Loss
Regarding hearing aid usage primary objective is to get overall better compliance, improved experience from hearing aids and less follow up visits. Specifically, this will be accomplished by using smart hearing aids (SHAs) that will allow remote fine tuning and closer usage monitoring. In other words, SHAs use can provide a sophisticated, tailored-made solution to HL that can also be applied remotely, reducing therefore patients’ transportation time.

Hypotheses concerning hearing loss are the following:

- Drop – out rate less than 35% (general population 45-50%).
- SMART BEAR participants will use more hours their hearing aids than the general population (10,5 hours per day)²⁰.
- SMART BEAR participants will need fewer visits to Audiologist’s office than the general population (3 visits in the first 6 months)²¹
- For SMART BEAR participants, overall satisfaction from hearing aid usage will increase till the end of the study (according to the results of GHAB)¹⁰.

2.1.2 Balance Disorders
The primary hypotheses regarding balance disorders will be to improve compliance by using a balance rehabilitation protocol for 8 weeks provided by an institutional-based augmented reality platform. Secondary hypotheses will be the decrease in the number of falls annually and the minimization of the fear of falling, the increase of balance confidence, the improvement of postural stability and increase of physical activity level.

Hypotheses related to balance disorders are detailed below:

- Drop-out rate after the completion of the rehabilitation protocol less than 30%
- Decrease in the total number of falls (< 2 falls/ year)
- Decrease of the fear of falling (increase of 8 points at the Falls Efficacy Scale – International after the completion of 8 weeks of rehabilitation program)
- Increase of balance confidence (increase of 11 points at the Activities – Specific Balance Confidence Scale after the completion of 8 weeks of rehabilitation program)
- Improvement of the postural stability (increase of 4 points at the Functional Gait Assessment as well as the mini-BESTest after the completion of 8 weeks of rehabilitation program)
- Improvement of the levels of physical activity measured by the Rapid Assessment Physical Activity questionnaire

2.1.3 Cardiovascular Diseases
Regarding the hypotheses that Smart Bear Project pursues in the area of cardiovascular diseases, we expect to check the impact of the recommendations to adopt healthy behaviours when these recommendations are sent by intelligent and connected tools instead of humans, such as reports or
alerts when a change in habits has been detected, with encouragement to the patient to change something in his behaviour. In detail, these are the different hypotheses that the Project pursues:

- **Decrease in number of non-scheduled visits due to hypertensive peaks (Urgency / Emergency Hypertension) (comparison with baseline)**
- **Improved percentage of adherence in prescribed medical treatment. Targeted value: Increase by 20%**
- **Sustain moderate-intensity aerobic physical activity according to the participant’s profile throughout the week.**
- **Decrease in number of non-scheduled visits due to volume overload in subjects with heart failure (comparison with baseline)**
- **Optimal BP control according to the participant’s profile and 2018 ESH/ESC Hypertension Guidelines. Target: Time in therapeutic range (TTR) >70%**

### 2.1.4 Mental Disorders

There are predictive elements of a senior’s depression such as changes in sleeping habits (the senior sleeps less or worse, sometimes more than usual), appetite variations (less appetite, but sometimes more), physical activity (less active, but sometimes more when he is anxious or agitated), leave out of home (he goes out less or sometimes more). These elements are identified as “weak signals” of depression but are difficult to measure and cannot be considered as isolated markers of depression. However, the observation of gradual changes in the senior’s habits in these areas, especially if these changes are associated, may be relevant for detecting the signs of a senior’s pre-depression.

**Thanks to this experimentation, we will be able to intervene at the onset of the first signs of mood deterioration, in order to limit conversions towards a marked depression. We will try to:**

1. **Better detect the weak signals of a senior’s mood deterioration** through the submission of a regular self-assessment test (PHQ-8) and the collection of data on factors that can impact the senior’s mood (sleep, physical activity, diet, moving out of home). We will be able to visualize more finely the trends in the senior’s mood over time. It will be possible to detect earlier the crossing of thresholds requiring lifestyle changes and/or care, even if they occur between medical appointments. The global vision of these data will give the practitioner a better indication to the diagnosis of depression.

   **Hypothesis:**
   
   => The detection of weak signals and depressions being exhaustive in the Smart Bear experimentation (subject to completion of the PHQ-8 test by seniors), the detection rate of weak signals and depressions in the experimentation is expected to be higher than the rates of depression diagnosed in existing retrospective studies in each of the participating countries. [https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Mental_health_and_related_issues_statistics#Extent_of_depressive_disorders](https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Mental_health_and_related_issues_statistics#Extent_of_depressive_disorders)

   => 2/3 of the clinicians are satisfied with the interest of the platform to help them in their diagnosis.

2. **Study the possibilities of reversibility of these weak signals by sending personalized automatic recommendations to the senior as soon as a drop in morale is detected (PHQ-8 score greater than...**
4). The purpose of these automatic notifications will be to encourage the senior to adopt behaviours that can improve his/her health and psychological well-being. This will test the senior's adaptive capacities.

**Hypothesis:**

=> The overall average of seniors scores on the PHQ-8 questionnaire who take part in the mental health experiment decreases by 15% between the beginning and the end of experimentation, thus showing an improvement in the senior's morale.

=> The incidence and prevalence of depression in the Smart Bear program is 15% lower than these rates in the general population (taking into account differences between countries) (https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Mental_health_and_related_issues_statistics#Extent_of_depressive_disorders)

### 2.1.5 Cognitive Disorders

The primary objective for patients with Cognitive Disorders (MCI) in Smart Bear will be to determine if significant correlations can be found between the compliance with the interventions recommended and the individual evolutions from the baseline on the cognitive status (as reflected by the specific cognitive and functional tests).

The hypothesis is that participants with increased adherence to the recommended interventions (serious games - SG, physical activities, social interactions) will have better outcomes compared to those with lower adherence. The minimum recommended thresholds are of 3 SG sessions / week and 150 min of moderate physical activities / week.

A second objective will be to look for correlations between other continuously monitored lifestyle parameters, such as sleep quality and individual cognitive & functional outcomes.

The hypothesis is that better sleep quality (supported by a better sleep hygiene) will be correlated with better cognitive outcomes.

### 2.1.6 Frailty

The primary objective for frail patients in Smart Bear will be to determine if significant correlations can be found between the compliance with the individualized interventions recommended (in accordance with the poorly performing frailty domains) and the individual evolutions from the baseline on the Edmonton Frailty Scale.

The hypothesis is that participants with increased adherence to the personalized recommended interventions (serious games - SG, physical activities, medication compliance, dietary adjustments, social interactions) will have better outcomes compared to those with lower adherence.
3 Materials and Methods:

3.1 Design of Smart Bear research project

3.1.1 Primary endpoint

- Devices acceptance as defined by successful completion of the whole monitoring period

3.1.2 Secondary endpoints

3.1.2.1 Secondary efficacy endpoints

**Hearing Loss:**
- HA acceptance (number of participants making use of their HA)
- Hours of usage (smart HA log) per week
- Number of visits to Audiologist’s office per 6 and 12 months
- GHAB score at 6 and 12 months

**Balance disorders:** (at 8 weeks)
- Percentage of compliance to the rehabilitation program
- Record of the number of falls
- Falls Efficacy Scale – International (FES-I)
- Activities – Specific Balance Confidence Scale (ABC)
- Functional Gait Assessment (FGA)
- mini-BESTest
- Rapid Assessment Physical Activity (RAPA)

**Cardiovascular disease:**
- Individualized cardiovascular risk score for users of the platform with non-established CVD as defined by the European Society of Cardiology.
- Number of patient-to-doctor visits.
- Percentage of participants with blood pressure under control following ESC guidelines.
- Number of admittances and hospitalization time for participants suffering from ischaemic heart disease, heart failure and stroke.
- Number of patients who developed asymptomatic /silent Atrial Fibrillation
- Number of patients with a CVDs related – deatHs
- Number of non-scheduled visits due to hypertensive peaks
- Hours of moderate-intensity aerobic physical.
- Number of non-scheduled visits due to volume overload in subjects with heart failure
- BP (office, at home)
- Weight and BMI (metric)

**Frailty:**
- Better outcomes on individualized Edmonton Frailty Scale items that are addressed by personalized interventions in higher adherent participants

**Mental Disorders:**
- PHQ-8, GDS, State-Trait Anxiety Inventory
• Sleep quality
• Social interactions

Cognitive disorders:
• MMSE, CDT, VFT, GDS, eCOG, MOCA
• Sleep quality

Overall:
• Adherence in prescribed medical treatment (number of missed medication).
• EuroQoL-5D as a measure of the quality of life and health status

3.1.2.2 Secondary usability endpoints (6th and 12th month)
• The System Usability Scale (SUS)
• Technology Assessment Methodology (TAM)

3.2 Population

3.2.1 Inclusion criteria
• Age: 67 to 80-year-old people (can drop to 65 years old in case of low recruitment rate)
• Gender: Male and female (homogeneous gender distribution amongst the 5000 seniors)
• Medical history: at least 2 of the following conditions (stabilised at the time of the inclusion): hypertension, coronary disease, heart failure, hearing loss, balance disorders, depression, anxiety disorder (Diagnosed based on the medical history/using ICD-10 or DSM5 criteria / using scales (Beck depression Inventory (self-scored), Geriatric Depression scale, State-Trait Anxiety Inventory, Hamilton depression scale, Hamilton Anxiety scale), mild cognitive impairment, frailty.
• Abilities:
  - Adequate cognitive function (Montreal Cognitive Assessment) with a score over 18.
  - Level of mobility based on the validated and universally used Health Utility Index (HUI3), [level 1-4, (moderate disability)].
  - Ability to read
  - Ability to use the basic functions of a smartphone (answer, call, check a notification, open an application)
• Compliance with the experimentation:
The senior
  - has to give his/her consent to take part in the experimentation for a year
  - willingness to participate in all the procedures of the study (including technical and medical follow-up/support, particularly the 3 technical visits at home, and the initial inclusion medical visit)
• Technical conditions:
  Connexion to the internet at home and accepts the use of WIFI all along the experimentation

3.2.2 Exclusion criteria
• If the senior does not comply with the aforementioned inclusion criteria, he will not be recruited.
• Any severe or life-threatening condition at the beginning of the experimentation (ex: severe depression, high risk of heart failure).
• Seniors could be excluded if their medical condition deteriorates during the experimentation, and if he/she does not reach anymore the minimum abilities above mentioned (self-reporting, 6th month follow up).
• Seniors could also be excluded if they do not use the devices and tools they are supposed to experiment. The tools could thus be provided to other seniors in order to reach the experimentation objectives (self-reporting, 6th month follow up).

3.3 The SMART BEAR technological solution

3.3.1 Devices

The table below summarizes the devices selected for the SMART BEAR platform. The selection of the devices has been based on the findings described in “D2.1 SMART BEAR Requirements”. In deliverable D2.1, the main technologies that can be used to monitor each condition were identified and relevant use cases scenarios were described. Analyzing the requirements and the available devices in the market, the following list of device types, main functionalities of the device and relation to the scenarios are described.

Device selection will be performed based on the requirements per scenario of use and based on the average budget for each participant. The final selection for the off-the-shelf devices will be done after an initial period of testing. In that sense, the devices that have been identified to fulfil the requirements of the system (in terms of measurements, usability, GDPR compliance, data extraction, etc), will be purchased and tested in real-life conditions, in a series of setups that will resample the final product. During this period, any potential problems will be identified and the final selection of the devices will be completed.

Table 1: SMART BEAR selected devices

<table>
<thead>
<tr>
<th>SMART DEVICE TYPE</th>
<th>FUNCTIONS</th>
<th>NECESSARY FOR SCENARIO</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMART BLOOD PRESSURE MONITOR</td>
<td>Systolic and diastolic blood pressure; heart rate (pulse); Cuff pressure range: 0-300mmHg; Pressure accuracy: ±3mmHg; Pulse rate range: 40 -180 beats/min, ±5%; Wireless connectivity (WiFi or Bluetooth); API or SDK (for data extraction)</td>
<td>4.2.7.1 Hypertension  4.2.7.2 Heart failure with reduced ejection fraction of left ventricle  4.2.7.3 Heart Failure with preserved ejection fraction  4.2.7.4 Hypertension treatment – paroxysmal arrhythmias - complications</td>
</tr>
<tr>
<td>SMART SCALE</td>
<td>Weighing range: 10 - 180kg, Body Fat (in %), Body Mass Index Skeletal Muscle (in %); Wireless connectivity (WiFi or Bluetooth); API or SDK (for data extraction)</td>
<td>4.2.6.1 Malnutrition  4.2.6.3 Abnormal blood glucose level  4.2.6.5 Weight Loss/Gains  4.2.7.2 Heart failure with reduced ejection fraction of left ventricle  4.2.7.3 Heart Failure with preserved ejection fraction</td>
</tr>
<tr>
<td>Device Type</td>
<td>Functions</td>
<td>Problems/Conditions</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| SMART PILLBOX               | Pill cases for 2/4 days; Locate pillbox; 1 year battery; Bluetooth; API or SDK (for data extraction) | 4.2.5.3 Non-compliance to medication scheme  
4.2.6.3 Abnormal blood glucose level  
4.2.7.1 Hypertension  
4.2.7.4 Hypertension treatment – paroxysmal arrhythmias - complications  
4.2.7.5 Arrhythmia & Coronary heart disease  
4.2.8.1 Mood deterioration |
| SMART HOME DEVICES (inc temp and humidity) | Hub, Light bulb, Smart plug, Motion sensor, Temperature and humidity; Wireless connectivity (WiFi or Bluetooth); API or SDK (for data extraction) | 4.2.5.1 Cognitive Decline  
4.2.5.2 Sleep Disturbances  
4.2.5.4 Non-ideal light levels  
4.2.5.5 Behavioural changes  
4.2.5.6 Family Isolation  
4.2.5.8 Extreme temperature/Weather conditions  
4.2.7.4 Hypertension treatment – paroxysmal arrhythmias - complications |
| SMART WATCH                 | GPS, heart rate monitor, Barometric altimeter, Accelerometer, Thermometer; Heart rate features: HR zones, HR alerts, HR calories, % HR max, HR Broadcast Battery life: Smartwatch mode: Up to 7 days, GPS mode: Up to 13 hours; Wireless connectivity (4G, WiFi, Bluetooth) | 4.2.3.1 Back Muscle Loss and Balance Disorders (in case of Smart4Health Synergy  
4.2.4 Falls Prevention  
4.2.5.2 Sleep Disturbances (alternative to sleep tracker)  
4.2.5.5 Behavioural changes  
4.2.5.6 Family Isolation  
4.2.5.7 Social Isolation  
4.2.6.3 Abnormal blood glucose level  
4.2.6.4 Physical Inactivity  
4.2.6.5 Weight Loss/Gains  
4.2.7.4 Hypertension treatment – paroxysmal arrhythmias - complications  
4.2.7.5 Arrhythmia & Coronary heart disease  
4.2.8.1 Mood deterioration |
| SMART PHONE                 | Compatible with HEARIND AIDS and SMART WATCH; > 5.9in display; 4GB memory; Wireless connectivity (4G, WiFi, Bluetooth); | All |
| ECG                         | All                                                                 | 4.2.7.5 Arrhythmia & Coronary heart disease |
| HEARING AIDS                | Data extraction/transmission capabilities; Bluetooth; Remote fitting;                                              | 4.2.1.1 Poor Compliance to HA usage  
4.2.1.2 Remote real-time fine-tuning and verification of hearing aid through the Smart Bear  
4.2.2 Individualized auditory training (AT)  
4.2.5.7 Social Isolation |
| INDOOR TRACKERS             | Range: 15m; Battery life: >6 months; Wireless connectivity (WiFi or Bluetooth); API or SDK (for data extraction) | 4.2.5.1 Cognitive Decline |
| SLEEP TRACKERS              | Sleep duration, Sleep cycles, Heart-rate; Wireless connectivity (WiFi or Bluetooth); API or SDK (for data extraction) | 4.2.5.2 Sleep Disturbances  
4.2.8.1 Mood deterioration |
Identification and Recruitment of end-users

The target audience for the user evaluation is elderly people between 67 to 80 years old with at least two of the conditions monitored by the SMART BEAR project. The participants will be recruited via a number of clinical / public networks and personal connections, as outlined below.

Once the potential users are identified, personal invitations will be sent via email to outline the project and invite them to participate in the pilot study. When contacting participants, an evaluation and training info sheet will be provided according to the ethics protocol.

The aim of the training session will be to achieve the following:

- Knowledge transfer to end-users of the SMART BEAR devices/platform, with adequate training of the different resources included in the platform
- Training is provided with the aim that end users will then be able to evaluate and validate the applications/platform in a more real-world setting, and input into implementation plans
- Dissemination of the project

The evaluation and training info sheet will be finalized and amended to the Protocol once the selection of devices is completed.

3.3.2 SMART BEAR Platform

SMART BEAR aims at creating an affordable, accountably secure and privacy-preserving innovative platform that integrates state-of-the-art off-the-shelf smart and medical devices. The platform will be capable of

- continuous collection of medical, physiological and lifestyle data from heterogeneous resources (hospitals, biosensors, advanced hearing aids and mobile phones
- integration with IoT enablers and platforms
- analysis of these data, driven by high-level big data analytics and decision models to generate evidence useful for making public health policy level interventions
- integration with a continuous security and privacy assurance platform to provide the continuous auditability and transparency needed for ensuring the SMART BEAR platform’s trustworthiness by its end users.

3.4 Procedures

3.4.1 Pre-recruitment

3.4.2 Screening, Eligibility and Baseline Assessments

All SMART BEAR participants will follow a series of assessments (Standard, common for all participants, and then additional ones according to their profile), till their allocation to profiles and devices. The general scheme of these procedures and a summarizing table of all tests is provided below, while details on each assessment can be found in the corresponding Appendix (15.3).
Figure 2: Approaches and Material for pre-recruitment

Figure 3: Participant Screening and Baseline Assessments Flow of Actions
### Table 2: Overview of Baseline and Additional Assessments

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Procedure</th>
<th>Involves</th>
<th>Baseline visit</th>
<th>6-month visit</th>
<th>Close-out visit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General assessment</strong></td>
<td>Demographics</td>
<td>Participant + study partner</td>
<td>5</td>
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<td>-</td>
</tr>
<tr>
<td></td>
<td>Medical history + medication use</td>
<td>Participant</td>
<td>5</td>
<td>5</td>
<td>5</td>
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<tr>
<td></td>
<td>Physical examination</td>
<td>Participant</td>
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</tr>
<tr>
<td></td>
<td>Life habits - smoking, drinking, hobbies</td>
<td>Participant</td>
<td>5</td>
<td>5</td>
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<tr>
<td></td>
<td>Diet supplement use</td>
<td>Participant</td>
<td>5</td>
<td>5</td>
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<tr>
<td></td>
<td>Godin leisure-time exercise questionnaire</td>
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<tr>
<td></td>
<td>RGA - Rapid Geriatric Assessment</td>
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<td></td>
<td>IADL</td>
<td>Participant</td>
<td>5</td>
<td>5</td>
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</tr>
<tr>
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<td>Social Functioning Scale</td>
<td>Participant</td>
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<tr>
<td></td>
<td>Pittsburgh Sleep Quality Index (PSQI)</td>
<td>Participant (self)</td>
<td>5</td>
<td>5</td>
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<tr>
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<td>Epworth Sleepiness Scale (ESS)</td>
<td>Participant (self)</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Euro Quality of Life (EQ-5D)</td>
<td>Participant (self)</td>
<td>5</td>
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<td></td>
<td>MOCA test</td>
<td>Participant + Clinician</td>
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</tr>
<tr>
<td></td>
<td>Smartphone use</td>
<td>Participant + study partner</td>
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<tr>
<td></td>
<td><strong>TOTAL time (min)</strong></td>
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<tr>
<td><strong>Cognitive impairment</strong></td>
<td>Mini-Mental State Examination (MMSE)</td>
<td>Participant</td>
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</tr>
<tr>
<td></td>
<td>Clock Drawing Test (CDT)</td>
<td>Participant</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Verbal Fluency Test (VFT)</td>
<td>Participant</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Procedure</td>
<td>Involves</td>
<td>Baseline visit</td>
<td>6-month visit</td>
<td>Close-out visit</td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
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<td>---------------</td>
<td>-----------------</td>
<td></td>
</tr>
<tr>
<td>Yesavage Geriatric Depression Scale (GDS)</td>
<td>Participant (self)</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Everyday Cognition - 12 (ECog-12)</td>
<td>Study partner</td>
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<td>5</td>
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<tr>
<td><strong>TOTAL time (min)</strong></td>
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<tr>
<td><strong>Procedures</strong></td>
<td><strong>Involves</strong></td>
<td><strong>Baseline visit</strong></td>
<td><strong>6-month visit</strong></td>
<td><strong>Close-out visit</strong></td>
<td></td>
</tr>
<tr>
<td>Frailty</td>
<td>EDMONTON FRAILTY SCALE (EFS)</td>
<td>Participant</td>
<td>10</td>
<td>10</td>
<td>10</td>
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<tr>
<td><strong>TOTAL time (min)</strong></td>
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<td>10</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td><strong>Assessment</strong></td>
<td><strong>Procedure</strong></td>
<td><strong>Involves</strong></td>
<td><strong>Baseline visit</strong></td>
<td><strong>6-month visit</strong></td>
<td><strong>Close-out visit</strong></td>
</tr>
<tr>
<td>CVD</td>
<td>Number of Visits to the ER due to HTN peak</td>
<td>Participant</td>
<td>5</td>
<td>5</td>
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<tr>
<td>Sleep pattern</td>
<td>Participant</td>
<td></td>
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<tr>
<td>TOBACCO (units per day)</td>
<td>Participant</td>
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<tr>
<td>WEIGHT (kg)</td>
<td>Participant</td>
<td></td>
<td>5</td>
<td>5</td>
<td>5</td>
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<tr>
<td>BMI (Kg/cm²)</td>
<td>Clinician</td>
<td></td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Systolic BP</td>
<td>Participant</td>
<td></td>
<td>5</td>
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<tr>
<td>Diastolic BP</td>
<td>Participant</td>
<td></td>
<td>5</td>
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</tr>
<tr>
<td>HR</td>
<td>Participant</td>
<td></td>
<td>5</td>
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<tr>
<td>ECG</td>
<td>Participant</td>
<td></td>
<td>5</td>
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<tr>
<td>Hb A1c level</td>
<td>Retrospective data, if available</td>
<td></td>
<td>5</td>
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<tr>
<td>LDL/HDL cholesterol level</td>
<td>Retrospective data, if available</td>
<td></td>
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<tr>
<td>Score CV risk</td>
<td>To calculate if all parameters available</td>
<td></td>
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</table>
### Mental disorders

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Involves</th>
<th>Baseline visit</th>
<th>6-month visit</th>
<th>Close-out visit</th>
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</thead>
<tbody>
<tr>
<td>PHQ-8</td>
<td>Participant</td>
<td>5</td>
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<tr>
<td>Yesavage Geriatric Depression Scale (GDS)</td>
<td>Participant (self)</td>
<td>5</td>
<td>5</td>
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<tr>
<td>Hamilton Rating Scale for Depression</td>
<td>Participant</td>
<td>5</td>
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<tr>
<td>State-Trait Anxiety Inventory (STAI)</td>
<td>Participant</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Geriatric Depression Scale (GDS)</td>
<td>Participant</td>
<td>5</td>
<td>5</td>
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</tr>
<tr>
<td>The Beck Depression Inventory (BDI)</td>
<td>Participant</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td><strong>TOTAL time (min)</strong></td>
<td></td>
<td>30</td>
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</tbody>
</table>

### Hearing Loss

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Involves</th>
<th>Baseline visit</th>
<th>6-month visit</th>
<th>Close-out visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>GHABP</td>
<td>Participant</td>
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<td>15</td>
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<tr>
<td>Otoscopy</td>
<td>Participant</td>
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<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Tympanometry</td>
<td>Participant</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Pure Tone Audiometry</td>
<td>Participant</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td><strong>TOTAL time (min)</strong></td>
<td></td>
<td>35</td>
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### Balance Disorders

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Involves</th>
<th>Baseline visit</th>
<th>6-month visit</th>
<th>Close-out visit</th>
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<tbody>
<tr>
<td>MiniBEST- test</td>
<td>Participant</td>
<td>15</td>
<td>15</td>
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</tr>
<tr>
<td>Functional Gait Assessment</td>
<td>Participant</td>
<td>15</td>
<td>15</td>
<td>15</td>
</tr>
</tbody>
</table>
### 3.4.3 Allocation of participants and Subsequent assessments

The devices to be used in SMART BEAR solution will be selected based on the process outlined in Section 3.4.2. For each participant, an initial clinical assessment will be performed by the clinical team of the pilot study, taking into account a number of parameters for each participant, including the number of medical conditions and comorbidities, the severity of them and the general state of each individual.

- if the candidate is not included: he/she is informed that his data will be deleted from Smart Bear database and that he/she can apply again later on if his/her situation changes (in case it is possible).

- if the candidate is included: allocation to the devices, moment of next appointment (fitting, device instalment, follow-ups) and starts the experimentation, addition of ICF parts that refer to the involvement of caregiver – clinician.

Effort will be given in order to evenly distribute the devices to almost equally monitor all the medical conditions, although this target cannot be justified in advance.

---

### Table 1: Time allocation for assessments

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Clinician</th>
<th>Participant</th>
<th>Total (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid Assessment of Physical Activity</td>
<td>10</td>
<td>10</td>
<td>60</td>
</tr>
<tr>
<td>Falls Efficacy Scale International (FES-I)</td>
<td>10</td>
<td>10</td>
<td>60</td>
</tr>
<tr>
<td>The Activities-specific Balance Confidence Scale</td>
<td>10</td>
<td>10</td>
<td>60</td>
</tr>
<tr>
<td><strong>TOTAL time (min)</strong></td>
<td><strong>60</strong></td>
<td><strong>60</strong></td>
<td><strong>60</strong></td>
</tr>
</tbody>
</table>

---

*Figure 4: Overview of participant’s Workflow*
3.4.4 Study Interventions

3.4.4.1 Hearing loss

A smart mobile phone and a smart hearing aid will be provided to participants with hearing loss. Through the mobile phone patients will have access to auditory tasks, such as auditory training. Additionally, mobile phone will be crucial for HA remote fine tuning.

Training on how to use the HAs, mobile application and activate the Remote application for the remote fitting.

At approximately 6 use the HAs, mobile application and activate tited to attend an online follow-up appointment including remote fine-tuning of HAs, if required, Hearing Aid Log checking and completion of the 2nd part of the GHABP. Also, acclimatization mode will be updated. Finally, the individual will have the opportunity to express any concerns and he/she will be consulted appropriately from the Audiologist.

At 6 and 12 months period the HA Log will be checked and remote fine tuning will be performed.

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Notifications</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Compliance (Hours of HA usage)</td>
<td>1. Low HA usage (&lt;40h/week or no use 2 consecutive days)*</td>
<td>4. Auditory Training</td>
</tr>
<tr>
<td>2. Overall satisfaction (GHABP)</td>
<td>*Notification every 24h if no reaction / compliance from user + Notification to Audiologist / significant other if 7 days with no usage</td>
<td>5. Remote fine tuning</td>
</tr>
<tr>
<td>3. Number / frequency of visits to Audiologist’s office</td>
<td>2. 30’ before specific time of AT session</td>
<td></td>
</tr>
<tr>
<td>4. HA log</td>
<td>3. If no AT session is completed for 2 consecutive days</td>
<td></td>
</tr>
<tr>
<td>5. Satisfaction about Auditory training</td>
<td>4. to fill GHAB and MOCA questionnaire</td>
<td></td>
</tr>
</tbody>
</table>
3.4.4.2 Balance Disorders

An augmented reality platform based on an institution will provide an evidence-based balance rehabilitation program 2 days per week for 8 weeks. Additionally, a tailored short home-based exercise programme will be addressed in order to improve levels of physical activity. The platform is designed to improve compliance and motivation of the participants, overall balance function, gait and levels of physical activity. Fifty (50) community-dwelling older adults at the risk of falling will be stratified. Participants will be assessed at the baseline (week 0), at the end of the intervention programme (week 8) and at the end of the follow-up period (2 months). Secondary outcome measures (number of falls, ABC, FGA, miniBEST test, FES-I, RAPA) will be collected in the baseline and at the end of the intervention programme as well as the follow up (2 months).

<table>
<thead>
<tr>
<th>Table 4: Interventions for Participants of HoloBalance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening Session</td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td>Demographics</td>
</tr>
<tr>
<td>The MOCA</td>
</tr>
<tr>
<td>Number of Falls</td>
</tr>
<tr>
<td>The RAPA</td>
</tr>
<tr>
<td>The ABC Scale</td>
</tr>
</tbody>
</table>
3.4.4.3 Cardiovascular Diseases

Participants with known CVDs are ending up in this profile and corresponding scenarios. However, a small number of participants per pilot will also receive a smart BP tracker and be monitored in parallel with participants in CVD categories. The purpose of this small-scale sub-group study is to examine prognostic parameters in participants at high risk of developing CVD. In order to be a candidate for entering this subgroup study, a participant should present diabetes mellitus, obesity and/or sleep apnea.

The general scheme of assessments and actions concerning CVD and high-risk for CVD participants is provided below:

<table>
<thead>
<tr>
<th>Medical Condition</th>
<th>Involved Device</th>
<th>Measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>1. Smart Blood Pressure tracker</td>
<td>Blood pressure</td>
</tr>
<tr>
<td></td>
<td>2. Heart rate tracker</td>
<td>Heart Rate / Heart Rhythm</td>
</tr>
<tr>
<td></td>
<td>3. Smart Weight scales</td>
<td>Weight / BMI</td>
</tr>
<tr>
<td></td>
<td>4. Smart Pillbox</td>
<td>Medication</td>
</tr>
<tr>
<td></td>
<td>5. Physical activity tracker</td>
<td>Physical activity</td>
</tr>
<tr>
<td></td>
<td>6- ECG</td>
<td>Diet</td>
</tr>
<tr>
<td></td>
<td>7- Sleep Trackers</td>
<td>Sleep time / patterns</td>
</tr>
<tr>
<td></td>
<td>8- CV Risk scale (Score)</td>
<td>Blood HbA1c level and Cholesterol (HDL/LDL) level (only if available)</td>
</tr>
</tbody>
</table>

1) HYPERTENSION

*Notifications according to the following scenarios, corresponding to the interventions in the next cell. Notification = text that reaches the user’s mobile without needing a reaction.

*Alerts = Patient must react/respond to the alert (Relevant Systems Scenarios should be created for the case manager and caregivers); there are different types of alert:

- Green code: a message of congratulations and encouragement to continue using the platform sent periodically. / Yellow code: The platform sends a notification to the case manager subject to the existence of such a manager and acceptance to receive such a notification and ICF. End-user gets a
notification to seek medical advice. The same notification is sent to the case manager and/or informal/formal caregivers based on the patient’s profile. / Red code: The platform sends an alert to the case manager subject to the existence of such a manager and acceptance to receive such an alert and ICF. End-user gets an alert to seek medical advice. The same alert is sent to the case manager and/or informal/formal caregivers based on the patient’s profile. Smart Bear asks if the alert was attended.

Table 6: Interventions of SMART BEAR platform in the case of 1) Hypertension, 2) Coronary Disease 3) Heart Failure 4) Silent AF

<table>
<thead>
<tr>
<th>Notification*</th>
<th>Intervention</th>
</tr>
</thead>
</table>
| **Module A - Hypertensive user** | **A1**: Direct advice from the application to repeat measurement, if the same result persists, the platform takes information from *MyMedication App* and/or *Smart Pillbox*: if medication dose is omitted advice is given to receive medication and repeat measurement after an hour. The user is advised to continue monitoring BP - diet app if activated notifies to reduce salt intake, follow healthy lifestyle (avoid smoking tobacco, alcohol consumption, follow balanced diet, if overweight to lose weight). (Yellow alert).  
**A2**: Notification to call/visit clinician. Clinician is receiving BP trends too. (Yellow alert).  
**A3**: Direct notification. Platform advices user to repeat measurement. If the same result persists, platform advices if the user feels unwell to seek for medical advice, information from *MyMedication* or *Smart Pillbox* is reached automatically. If omitted medication, advice to take medication is given. Additionally, advice to arrange a call/visit to own doctor is offered. (Red alert).  
**A4**: Platform advices to repeat measurement. If the same result persists, the platform advices if the user feels unwell to seek for medical advice. If not, advice to arrange a call/visit to own doctor is offered. (Yellow alert).  

| **Module B - Not known hypertensive user** | **B1**: The platform advices user to arrange a visit to own doctor. BP trends can be available to own doctor by user’s request. (Yellow alert).  
**B2**: The platform advices user to follow healthy lifestyle and diet, avoiding alcohol misuse, tobacco smoking and weight control if overweight. Advice to arrange a visit to own doctor if the same results. (Yellow alert).  |

*Guidelines/Task Force of European Society of Cardiology and European Society of Hypertension (ESC/ESH) 2018.*
2) SILENT ATRIAL FIBRILLATION

<table>
<thead>
<tr>
<th>Notification</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1- Daily average HR &lt; 50 bpm or &gt; 110 bpm</td>
<td>C1-C2: Notification to call/ visit significant other or clinician. (Yellow alert).</td>
</tr>
<tr>
<td>C2- Episodes of fast heart rate (&gt; 110 bpm), at rest during BP measurement</td>
<td>C3: Direct notification - high heart rate alert. (Red alert).</td>
</tr>
<tr>
<td>C3- Episodes of fast heart rate recorded (&gt; 140 bpm) from smartwatch lasting more than 5 min</td>
<td>C4: If irregular heart rate detection activated, Smartwatch will ask to the participant for perform an electrocardiography (ECG) patch and mailed to the data manager nurse, who will be able to contact with the patient. Participants with urgent symptoms would be directed to go to an urgent care clinic or emergency department. (Yellow alert).</td>
</tr>
<tr>
<td>C4- Arrhythmia alert</td>
<td></td>
</tr>
</tbody>
</table>

3) CORONARY ARTERY DISEASE

The same notifications and interventions as the previous scenarios (hypertension, atrial fibrillation and heart failure). Furthermore, the following settings:

<table>
<thead>
<tr>
<th>Notification</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>H- Increase of CV risk scale (by SCORE function for predicting 10-year cardiovascular mortality). If available, blood test should be performed at month 0, 6 and 12; Cholesterol (total/LDL) levels plus Hb A1c are necessary to get the scale.</td>
<td>H1: Low CV risk scale reached - award given. (Green alert).</td>
</tr>
<tr>
<td></td>
<td>H2: High CV risk scale reached - motivation to increase activity, improve the diet and encourage to rise better control of traditional CV factors. (Red alert).</td>
</tr>
</tbody>
</table>

4) HEART FAILURE

The same notifications and interventions as the previous scenarios (hypertension and atrial fibrillation). Furthermore, the following settings:

<table>
<thead>
<tr>
<th>Notification</th>
<th>Intervention</th>
</tr>
</thead>
</table>
| D1- If medication is missed | D1. Pillbox notifies user to take tablet: notification 30’ before each medication time; notification and buzzer on the smart pillbox if wrong pillbox case is opened; notification if missed medication (1h later)
If several doses (> than 5) are missing, the platform notifies the clinician. (Yellow alert).
| E1: Advice to install diet app - set targets with a follow-up visit with the clinician and increase physical activity. If BMI is in |
E1. Patient sets his height value - Weight gain (weekly average >2kg)
E2. Patient sets his height value - weight loss (weekly average)

F. Weekly activity assessment

G. Inadequate sleep time / anomalous sleep pattern

Note: Smart Bear platform does not substitute the medical consultation and examination - any acute or warning symptom should be reviewed promptly with a visit to own doctor - AE department.

3.4.4.4 Mental Disorders

The subjective survey based on PHQ-8:

The goal of this questionnaire is to collect up to date consultation and examination - any acute or warning symptom should be reviewed promptly with a visit to own doctor - AE department. By own doctor in 1c are necessary to get the scale. e clinic or emers to give a better understanding of the senior’s difficulties.

- The survey is going to be sent every 3 days, in order to allow the sending of notifications to induce changes in behaviour and try to improve the senior every 3 days, in o

- The analysis and calculation of the PHQ-8 score is going to be done on a 15 days period, every 15 days.

<table>
<thead>
<tr>
<th>Table 7: Questionnaire: How often have you been bothered by the following over the past 3 days?</th>
<th>Not at all</th>
<th>Several days</th>
<th>More than half the days</th>
<th>Nearly every day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interest / pleasure</td>
<td>Little interest or pleasure in doing things?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Happiness</td>
<td>Feeling down, depressed, or hopeless?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Sleep</td>
<td>Trouble falling or staying asleep, or sleeping too much?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Energy</td>
<td>Feeling tired or having little energy?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Food</td>
<td>Poor appetite or overeating?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>--------------------------</td>
<td>------------------------------</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Culpability / self-esteem</td>
<td>Feeling bad about yourself — or that you are a failure or have let yourself or your family down?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Concentration</td>
<td>Trouble concentrating on things, such as reading the newspaper or watching television?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Calmness / restlessness</td>
<td>Moving or speaking so slowly that other people could have noticed? Or so fidgety or restless that you have been moving a lot more than usual?</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

**Score**

Additional question about somatic health/somatic complaints (pains, feeling heart racing, bowel problems, indigestion) or rating scale emphasizing somatic symptoms associated with depression (PHQ-15).

**Additional Question:**
If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

- [ ] Not difficult at all
- [ ] somewhat difficult
- [ ] very difficult
- [ ] extremely difficult

<table>
<thead>
<tr>
<th>Score</th>
<th>Depression severity</th>
<th>Comments</th>
<th>Smart Bear platform protocol refers to...</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-4</td>
<td>Minimal or none</td>
<td>Monitor; may not require treatment</td>
<td>Stage 1</td>
</tr>
<tr>
<td>5-9</td>
<td>Mild</td>
<td>Use clinical judgment (symptom duration, functional impairment) to determine necessity of treatment</td>
<td>Stage 2</td>
</tr>
<tr>
<td>10-14</td>
<td>Moderate</td>
<td>Warrants active treatment with psychotherapy, medications, or combination</td>
<td>Stage 3</td>
</tr>
<tr>
<td>15-19</td>
<td>Moderately severe</td>
<td>Warrants active treatment with psychotherapy, medications, or combination</td>
<td>Out of the mental health program</td>
</tr>
<tr>
<td>20-27</td>
<td>Severe</td>
<td>Warrants active treatment with psychotherapy, medications, or combination</td>
<td>Out of the mental health program</td>
</tr>
</tbody>
</table>

**Analysis and procedure:**

When the senior has filled up a form, he receives a notification to thank him / congratulate him for this completion. The senior could see instantly his score with a graph showing the evolution of his mood for the last weeks, and a reminder of the best and worst scores he ever had.
• Every 10 days, that is after 3 forms are filled-up, we will get an average score on the senior’s mood, and be able to send incentive notifications to the senior according to the data collected (see below).

• Every 15 days, that is after 5 forms are filled-up, we will get a score on the mood of the senior, and know more about the severity of his possible mood deterioration. It would be useful to see graphs showing that both for the senior himself, for the trustees and for the doctor if he/she consults them.

The use of data collected:
Thanks to the devices, it will be possible to collect data on:
- sleep (special device / connected watch)
- weight (connected scale)
- physical activity (connected watch)
- move in/out the housing (smartphone localisation or watch + home sensors)

Those factors and their evolution are not significative signs of depression by themselves, but can give useful complementary information:
Ex. 1: a low score at PHQ-8 + many nights with very early wake-ups
Ex. 2: a low score at PHQ-8 + very few move out of the housing
Ex. 3: a low score at PHQ-8 + weight loss

The information given by the data can make it possible to personalize the incentive notifications sent to the senior, and can be useful and meaningful to the senior’s clinician if he/she may and can check the data (and also to the trustees!).

Details on notifications
Notifications are meant to give proactive recommendations to the elderly based on the information automatically collected, in order to suggest behavioural changes and thus, to improve the person’s mood or avoid its deterioration.

When it is possible, these notifications are personalized according to what the data collected by the devices seem to indicate (see below). If data shows no particular change in the senior’s habit, then a “standard incentive notification” is sent.

Notifications are triggered if necessary, every 10 days, when the average score of the 3 last PHQ-8 forms collected during this period is between 5 and 9 (mild risk of depression).

The notifications may combine several recommendations, under the following conditions:
- 1 single notification for a period of 10 days,
- Maximum 3 recommendations per notification (depending on the data showing biggest changes).

Feedbacks:
- When an alert is sent, in order to check mainly if the senior is willing to follow the recommendations (see figure for different possible options)
- Checking 3 days later, in order to find out whether or not the senior has really followed the recommendation. This will also be a “reminder” in case the senior has not followed the
recommendation yet, and is also meant to allow a more detailed analysis on the impact of notifications on the mood deprived senior.

**Table 8: Types of possible notifications based on the "cases" presented by the data:**

<table>
<thead>
<tr>
<th><strong>Autonomy and ability to move:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 1: went out more than usual</td>
<td>N1: Apparently, you don’t feel very well these days, and it seems like you’ve been very busy lately. Do you feel nervous or worried? What about relaxing and resting at home? Maybe slowing down would do you good!</td>
</tr>
<tr>
<td>Case 2: went out less than usual</td>
<td>N2: Apparently, you don’t feel very well these days, and you’ve been spending more time at home than usual. How about getting some fresh air? What about doing a little walk, a stroll alone or with a friend, a visit to a neighbour, or shopping... This could probably do you good!</td>
</tr>
<tr>
<td>Case 3: did not get out</td>
<td>N3: Apparently, you don’t feel very well these days and you’ve been home for a long time. Is everything alright? If you are experiencing physical difficulties, pain or if something is bothering you, your doctor or your relatives could perhaps help you find solutions adapted to your needs.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Physical activity:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 1: Did less physical activity than usual</td>
<td>N1: Apparently, you don’t feel very well these days, and it seems you have moved less than usual during the last few days. Physical activity is good for your health and also for your morale! Why don’t you go for a walk outside, or do some physical activity that you enjoy (gardening, DIY, swimming, dancing, gym...)?</td>
</tr>
<tr>
<td>Case 2: Did more physical activity than usual</td>
<td>N2: Apparently, you don’t feel very well these days, and you’ve been much more active than usual. Do you feel nervous or worried? Maybe you need some rest and relaxation? After the effort, comfort!</td>
</tr>
<tr>
<td>Case 3: Did not engage in physical activity</td>
<td>N3: Apparently, you don’t feel very well these days, and you’ve done very few physical activity. Is everything alright? Do you suffer from pain, discomfort or unusual fatigue? Moving, even softly, is good for your health and your morale! If you are experiencing physical discomfort or have difficulty finding motivation, your doctor could help you find solutions adapted to your needs.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Sleep:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 1: Sleeps a lot (e.g. long naps, no movement in the afternoon, very long nights)</td>
<td>N1: Apparently, you don’t feel very well these days, and you seem to be sleeping a lot. Is everything all right? Are you too tired? Are you still tired when wake up? Doing physical activity during the day, especially outdoors, often allows people to regain energy... and to sleep better at night! Why don’t you try it for a few days?</td>
</tr>
<tr>
<td>Case 2: Staggered rhythm (e.g. lights are on late at night, inactivity in the housing before 10:00 am)</td>
<td>N2: Apparently, you don’t feel very well these days, and your life rhythms are out of sync. In the long run, do you know that this tires your body and can weigh on your morale? What if you tried for a</td>
</tr>
<tr>
<td>Case 3: Sleeps little or badly (wakes up often, lights on and off several)</td>
<td></td>
</tr>
</tbody>
</table>
times during the night, night-time activity, wakes up very early and does not go back to sleep)  
N3: Apparently, you don’t feel very well these days, and it seems that you have difficulty sleeping. Perhaps you are preoccupied, or perhaps you feel discomfort or physical pain? Do you have nightmares? During night, have your thoughts bothering you? Your doctor could probably help you, don't hesitate to contact him/her!

**Weight / appetite:**

| Case 1: loses weight | N1: Apparently, you don’t feel very well these days, and it looks like you’re losing weight. How’s your appetite? Is eating a pleasuring moment? Do you need help? Don’t hesitate to discuss your diet or appetite or any other difficulty related to meals with your doctor and your family. |
| Case 2: gaining weight | N2 : Apparently, you don’t feel very well these days, and it looks like you’re gaining weight. Are you very hungry or is something else happening? Do you need help? Don't hesitate to discuss your diet or appetite or any other difficulty related to meals with your doctor and your family. |

**General mood**

| Case: no particular change in the data collected, so no clue on why the senior feels bad... | N1: Apparently, you don’t feel very well these days. Do you think something’s wrong? What about planning to do something you usually enjoy, just for your own pleasure? Meeting people, going out, doing crafts, playing games, watching funny movies... Anything you like! If you can’t feel interest in anything and feel preoccupied, your doctor could probably listen and find solutions to help you. |

**Details on the alerts**

Alerts can be generated every 15 days, when the average PHQ-8 scores of the last 2 weeks (i.e. possibly 5 forms completed) is greater than 9, indicating a "moderate risk of depression";

The alert urges the senior to consult his doctor:

"Your score to the mood self-assessment form shows worrisome results over the last 15 days. We highly recommended you to settle an appointment with your doctor.

You can give your doctor access to your data collected on the Smart Bear platform or share your last report with him or her. Thanks to those data, your doctor will have some more information on your health and clues on your possible difficulties. After discussing with you, he will be able to recommend appropriate solutions and/or treatments.

We will get back to you within 8 days to find out if you have been able to contact your doctor".

**Feedbacks:**

- When an alert is sent (see figure for different possible options)
  => *if the senior does not select the option stating he is going to schedule an appointment, a medical referent should be informed (if consent has been given by both participant and medical referent).*
- Checking 8 days later, in order to find out whether or not the senior has made an appointment with his/her doctor, and the result of it (for analysis, as part of the experiment).

=> if the senior has not consulted the doctor (answer “no” to the feedback notification), then, a medical referent should be informed (if consent has been given by both participant and referent).

### 3.4.4.5 Cognitive Disorders

The participants diagnosed with cognitive disorders will receive a **smartphone with cognitive stimulation apps pre-installed**, a **smartwatch for monitoring parameters such as physical activities, sleep quality, and GPS tracking**. Also, in selected cases a **combination of indoor sensors and intelligent lighting system** will be provided (mainly to participants that are willing to accept the deployment of such devices, that imply a perception of larger intrusiveness in their homes).

**Cognitive stimulation should be addressed through serious games apps.** Selection of most useful apps should be implemented in the following months (M07-M10). An important requirement is to have the selected apps either already localized in the 6 languages of the pilots, OR to identify a provider that is willing to assist the consortium with the localization process.

The recommended frequency of app usage will be daily; however, an accepted threshold to see positive effects on cognition is of 2-4 times per week. In case the participant does not use the games for more than one week - 10 days a notification message should be sent from the Smart Bear platform, checking what happened, what possible reasons could exist for this situation and inviting the participant to contact the helpdesk (in case of valid causes of non-compliance).

**Safety when getting out of home** should be assured by the location tracking provided by smartphones and alerts sent to the caregivers (formal or informal) whenever needed.

**Physical activities** (mainly walking for more than 150 minutes per week) should also be tracked through the smartwatch and in case the target is not reached notifications should be sent to the participant, inviting for the achievement of the respective goal.

**Intelligent lighting** using home smart sensor solutions can be used for orientation within the house (e.g. dimmable strip guiding lights towards the bathroom if patients wake up during the night), to provide additional light in task areas (e.g. below cupboards in the kitchen) - all these solutions should be based on a rule-editor and integrated through the OpenHab Gateway.
Information’s about and reminders to engage in social activities should be provided through the mobile phone; also, the notification system will be useful for weather info and invitation to get out, walk and be exposed to natural sunlight when it's the case - natural light exposure and walking have both proven benefits on the cognitive functions.

Follow-up assessments of participants evolution from the clinical perspective on the cognitive area will be performed twice: first at 6 months from enrolment and the second at 1 year (12 months).

3.4.4.6 Frailty
For the participants enrolled in the project with frailty the Smart Bear platform should track physical activities outdoors through the smartwatch, collect BMI & weight-related data, with the help of intelligent scale and use cognitive stimulation apps (for the participants that scored higher on the cognitive domain of the EFS).

Furthermore, the platform should provide educational messages / notifications addressing the dietary choices that can improve the nutritional status in case of weight losses (or suggest corrective measures when weight increases occur) over a defined period of time.

Also, an important aspect that is important to monitor and could be achieved even through Smart Watches is the sleep quality, since sleep disturbances are quite frequent in elderly persons and influence their physical and mental status.

Follow-up assessments of participants evolution from the clinical perspective on the frailty area will be performed twice: first at 6 months from enrolment and the second at 1 year (12 months).

3.4.5 Risks and Benefits of Smart Bear Project

3.4.5.1 Vulnerable Population
SMART BEAR targeted population consists of seniors with specific health challenges. These characteristics place them in a higher risk of risk and created the need for Smart Bear partners to cautiously ensure the security of their rights and freedoms. All pre-recruitment, recruitment and piloting procedures are designed with respect to the principles of anonymity, confidentiality, availability, integrity and privacy-preserving controls will cover all the components and connections in the SMART BEAR platform. The adherence to security, privacy and anonymity standards will be periodically assessed.

3.4.5.2 Anticipated clinical benefits

Hearing loss
Improvement of HA experience by decreasing the number of visits to Audiologist’s office, improvement of speech perception in real-life conditions and increase of hours of usage are the main benefits of the SMART BEAR technological solution.

Balance Disorders
The implementation of HoloBalance in SMART BEAR will provide an evidence-based balance rehabilitation programme which increases adherence and motivation via gamification of the balance exercises. Investigators believe that after an 8-week balance rehabilitation programme provided by an augmented reality platform, compliance, number of falls and fear of falling, postural stability, and levels of physical activity will be improved and that these results will remain for at least a short period of time (2 months follow up).
Cardiovascular health

Cardiovascular disease constitutes a well-recognized burden in the modern era. Morbidity, mortality and disability rates attributed to major cardiovascular events remain significantly high despite the substantial progress in the field of prevention. Health systems around the globe have invested a significant amount of resources in risk stratification techniques. These focus both on primary and secondary prevention. The first refers to asymptomatic individuals and aims to improve a healthier lifestyle and to detect timely subclinical forms of the disease or increased risk to develop a cardiovascular disorder. The second applies for patients with known cardiovascular disease and they focus on risk factors modification and other structured interventions which are imposed in order to increase life expectancy and quality of life.

The SMART BEAR project acknowledges that cardiovascular morbidity is extremely common among the elderly population. Hypertension, Heart Failure, atrial fibrillation and coronary artery disease are the four principle cardiovascular entities of special interest for the project. As previously mentioned, based on the principle of intrinsic capacity maintenance and or improvement, the SMART BEAR platform aims at enrolling several senior citizens in Europe and improving their cardio profile.

First of all, the hypertension issue. Although public awareness about uncontrolled blood pressure levels has significantly risen over the last decades, there is a significant proportion of the population, including people older than the age of 65 who are not aware of being hypertensive. The project will enrol patients with a high possibility of uncontrolled blood pressure levels and will offer according to the current guidelines the necessary advice for monitoring. The expected clinical benefit is profound. People with normal blood pressure levels will be encouraged to keep themselves active and maintain healthy diet habits. Others with abnormal blood pressure levels (known hypertensives or not) will be encouraged to make the necessary amendments to improve them. Finally, participants who experience difficulties with the compliance to the antihypertensive medication or side effects from the treatment will be easily identified and treated as needed.

Secondly, the heart failure target. There are many conditions in Cardiovascular field which can be delayed if not avoided when certain risk factors are timely addressed. Heart failure with a preserved ejection fraction of the left ventricle is one of them. The SMART BEAR project, targeting on risk modification such as healthy diet promotion, increased physical activity, optimal blood pressure control is expected to delay the clinical expression of this disabling condition. Furthermore, participants with diagnosed heart failure (preserved or reduced left ventricular fraction) will also benefit from the project. It has been proven that adequate monitoring enhances the adherence to medication and adaptation of lifestyle modifications such as salt intake restriction, which consequently reduces the risk for hospitalization and the episodes of acute decompensation. Elderly people with heart failure, not infrequently, for multiple reasons, such as coexisting depression or dementia, fail to stick with the clinician’s advice. On the other hand, there are others who fail to early recognize side effects from overtreatment, such as dehydration. These participants are expected to benefit at most from the monitoring schedule. Regular notifications about salt and fluid intake will restrain them from fluid retention. Similarly, notifications about their body weight will reduce the incidence and severity of dehydration and or postural hypotension from overtreatment which can have detrimental results and can lead to falls. Those are some examples of the expected results after the implication of the platform. Overall, elderly heart failure population is extremely vulnerable and require close monitoring and fine tuning of their treatment, a target which the SMART BEAR protocol aims to enhance.
Arrhythmias and particularly atrial fibrillation are the third cardiovascular keystone in the SMART BEAR project. There is established evidence that early detection of the disorder can lead to prompt thromboembolic risk management which in turn reduces the incidence of stroke. Additionally, there is increasing evidence in the literature supporting that atrial fibrillation is strongly related to the development of cognitive decline. The SMART BEAR project is expected to address both these targets. Firstly, improving healthy lifestyle which includes moderation in alcohol consumption, promotion of physical activity and fighting against obesity, optimizing blood pressure control atrial fibrillation development can be delayed. Secondly, regular heart rate monitoring will enable the punctual recognition of those participants with silent arrhythmia. Finally, participants with chronic atrial fibrillation who face difficulties with rate control, will be offered the appropriate monitoring.

Finally, the SMART BEAR project will also address the constantly “hot” cardiovascular aspect of coronary artery disease. As mentioned already, many of the cardiac conditions can be delayed or prevented with early interventions regarding specific risk factors. On this occasion, the project will promote a healthy lifestyle with reminders such as for smoking cessation, optimal blood pressure control, diet modification. This advice, if followed by the participants, will have a great impact on both primary and secondary prevention of coronary disease. In fact, even patients with established disease, fail to achieve a healthier lifestyle and this results frequently in new acute events. The platform though is not addressing only to the disobedient patients. Patients with stable coronary artery disease will be encouraged to follow in a personalized manner an active way of living, under closer monitoring. Early detection of worsening symptoms if reported in the platform will encourage the patient to contact his clinician timely before the occurrence of an unfavourable event. At the same time, elderly people who face difficulties with memory, will be offered ways to avoid to miss their regular medications which occasionally can have detrimental results.

Innovative technologies such as smart devices are already handy tools for patients and health care professionals. The Smart Bear platform aims to introduce ways of cardio telemonitoring and treatment control to an age group with specific needs in the convenience of their environment and their choice. Although hypertension is probably the most extensively investigated medical condition, there are other entities like the one of HFpEF in which big epidemiological data derived by the SMART BEAR project would offer new insights on the pathogenesis and the physical course of the disease.

Mental Disorders

With the Smart Bear project, we stand the hypothesis that digital tools could be a good lever to prevent seniors from depression. The idea through the project is:
  - to identify the detection of mood decay and first signs of depression, through data collected,
  - to foster elderly people, through notifications, to try positive behaviours in order to get a mood improvement.

The Smart Bear project is an opportunity to get a better knowledge on how it is possible to prevent the occurrence of depression factors thanks to digital tools. It could give a better knowledge on the possible actions to help seniors keeping a healthy, dynamic, and positive way of life.

On a second point, there seem to be no mental health solutions designed especially for seniors, taking into account their specific way of life (rhythm, centres of interests, social habits), and the physical and mental troubles associated with ageing.
Through the Smart Bear experimentation, we have the opportunity to focus on the seniors' habits and abilities, and to adapt the solutions to their needs. The notifications, thanks to the “intelligent platform” could be able to take into account the seniors general and individual needs to be happy. Third, we don’t know the impact of automatic incentives to change behaviour on a mood deprived senior. It has been proved that digital health can have an impact on the seniors change in behaviours.

Indeed, changing habits is not easy, especially at an advanced age, when habits can be reassuring, even if they are “bad habits”! But with depression, we add another difficulty there. Depression has the very characteristic of diminishing people’s ability to do their usual routine and to adopt positive behaviours in their everyday life. The advices given by other “humans” to a depressive person, even when it is a relative or a medical staff, are not always effective. But we do not know how a senior who is feeling down, and less and less satisfied with the daily life, will react to automatic incentives to change his/her behaviour.

With the Smart Bear experimentation, the playful aspect of connected tools, their omnipresence, could have an interesting impact to observe on mood deprived persons. The experimentation should allow us to have a better knowledge on how the elderlies, when they enter a low mood period, react to automatic recommendations received from the platform. Will they generally follow the recommendations, or on the contrary, will they drop out of the program? This is to be investigated during the experimentation.

Finally, the Smart Bear Platform could help taking patients in charge earlier. Weak signals of depression are well known by doctors and there are existing tests to detect them. But those tests can only be done when the senior has already decided to consult. The “intelligent platform” could make it possible to detect weak signals of depression before they are really visible to the relatives and professionals around the seniors, potentially before the senior himself is really aware of them, and so before he has even consulted his doctor.

The platform could then encourage seniors to consult their doctor at an earlier stage of the onset of depression, in order to be treated before the symptoms are too advanced. This will be an interesting issue to investigate: how earlier the senior has decided to meet the doctor, in comparison to if he/she would not have been advised to do so by the Smart Bear Platform? And would he/she have consulted the doctor at all, if he/she would not have been advised to do so by the notifications?

**Cognitive Disorders**

SMART BEAR aims to enhance participants’ independency and management of their mild cognitive impairment with a discrete and easy to use technological solution. They will benefit of continuous monitoring of physiological and behavioural parameters and at the same time, stimulation for social and physical activity, serious cognitive games and reminders about environmental parameters such as levels of light or temperature. Geolocation will be also helpful during their outdoor activities.

**Frailty**

SMART BEAR participants challenged by overall frailty will undergo close monitoring of their BMI, stimulation for physical activity and individualized nutritional suggestions. Targeting their frailty at multiple levels is expected to have an augmented impact.
### 3.4.5.3 Adverse events; definitions, assessment (severity, seriousness, causality), safety reporting timelines and requirements

#### Table 9: Definition of Adverse Events

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
</table>
| Adverse Event (AE)                             | Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device.  
**Note 1:** This definition includes events related to the investigational medical device or the comparator  
**Note 2:** This definition includes events related to the procedures involved  
**Note 3:** For users or other persons, this definition is restricted to events related to investigational medical devices  |
| Adverse Device Effect (ADE)                    | Adverse Event related to the use of an investigational devices.  
**Note 1:** This definition includes AEs resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational device  
**Note 2:** This definition includes any event resulting from use error or from intentional misuse of the investigational medical device  |
| Serious Adverse Event (SAE)                    | Any adverse event that:  
• Led to death,  
• Led to serious deterioration in the health of the subject, that either resulted in  
  o a life-threatening illness or injury, or  
  o a permanent impairment of a body structure or a body function, or  
  o in-patient or prolonged hospitalisation, or  
  o medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,  
• Led to foetal distress, foetal death or a congenital anomaly or birth defect  
**Note 1:** Planned hospitalisation for a pre-existing condition, or a procedure required by the CIP, without serious deterioration in health is not considered a SAE.  |
| Serious Adverse Device Effect (SADE)           | An ADE that has resulted in any of the consequences characteristic of an SAE  |
| Unanticipated Serious Adverse Device Effect (USADE) | A SADE which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.  |
Device Deficiency (DD)  
Inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance.  
**Note 1:** this includes malfunctions, use errors, and inadequate labelling

An adverse event does not include

- Pre-existing disease or conditions present at the start of the study that do not worsen in frequency or intensity.
- The condition being studied or signs/symptoms associated with the condition unless more severe than expected for the subject’s condition.

**Adverse events assessment**
A clinician should assess each reported AE. Each adverse event will be assessed for the following criteria:

**Table 10: Severity**

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>The adverse event does not interfere with the subject’s daily routine, and does not require intervention; it causes slight discomfort</td>
</tr>
<tr>
<td>Moderate</td>
<td>The adverse event interferes with some aspects of the subject's routine, or requires intervention, but is not damaging to health; it causes moderate discomfort</td>
</tr>
</tbody>
</table>
| Severe   | The adverse event results in alteration, discomfort or disability which is clearly damaging to health  
*Note: A severity rating of severe does not necessarily categorise the event as an SAE.* |

**Seriousness (As mentioned above).**

**Table 11: Causality**

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>There is evidence to suggest a causal relationship, and the influence of other factors is unlikely</td>
</tr>
<tr>
<td>Possibly</td>
<td>There is some evidence to suggest a causal relationship (e.g. the event occurred within a reasonable time after the procedure). However, the influence of other factors may have contributed to the event (e.g. the patient’s clinical condition, other concomitant events).</td>
</tr>
<tr>
<td>No</td>
<td>There is no evidence of any causal relationship.</td>
</tr>
</tbody>
</table>
Table 12: Expectedness

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expected</td>
<td>An adverse event that is consistent with the information about the devices or clearly defined in the study protocol.</td>
</tr>
<tr>
<td>Unexpected</td>
<td>An adverse event that is not consistent with the information about the devices or defined in the study protocol.</td>
</tr>
</tbody>
</table>

The special design of the SMART BEAR research project does not allow the real-time seamless monitoring of participants. This leads to the fact that AEs may be detected in distance from the moment of their occurrence. Nevertheless, AEs should be referred to the Study Manager of each Pilot and the Sponsor (NKUA) within 7 days, while SAEs within 24h.

3.4.5.4 Risks associated with devices and study procedures

Participant safety will be paramount throughout the study. Risk assessments for each of the tasks to be performed within the study will be completed. The outcome measures used in this study are used commonly in clinical practice and within our research environment, and the research team have extensive experience in ensuring their safe completion.

Anytime an Adverse Event occurs, a case-to-case approach should be followed to assess whether there is a relation of causality between the event occurred and any possible malfunction or misuse. For example, if a patient suddenly leaves the project, we should establish whether a device malfunction or misuse has also occurred and is recognizable as the cause. Therefore, the absence of the anticipated clinical benefits described in subsection 3.4.5.2 can be considered as the only anticipated negative outcomes associated with malfunctioning or misused devices by now. A detailed list of Risk Factors can be found in the Appendix. The Factors described in the list can increase the level of risk and are related to the way the devices function and to how the patients behave during the project.

Table 13: Device Related Risk Factors

<table>
<thead>
<tr>
<th>Situation</th>
<th>Notifications</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>First connection between the device and the network</td>
<td>Data transfer rate = 0</td>
<td>Send an alert from the app to the administrator for approval</td>
</tr>
<tr>
<td></td>
<td>Device ID not recognized</td>
<td></td>
</tr>
<tr>
<td>No wireless connection</td>
<td>Data transfer rate = 0</td>
<td>Send an alert via the app to the smartphone</td>
</tr>
<tr>
<td></td>
<td>Connectivity test failed</td>
<td>Physical warning on the smartphone</td>
</tr>
<tr>
<td>Device not calibrated</td>
<td>The data value sent from the device and from the app are significantly different</td>
<td>Physical warning</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Recalibration via the app performed by the administrator</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device replacement</td>
</tr>
<tr>
<td>Device incompatible</td>
<td>Connectivity test failed</td>
<td>Perform compatibility testing</td>
</tr>
<tr>
<td></td>
<td>The installation of the apps fails</td>
<td>Alert sent to the user</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device replacement</td>
</tr>
<tr>
<td>Situation</td>
<td>Notifications</td>
<td>Interventions</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>----------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Transfer of the data from the devices via the network to the IT system failed</td>
<td>Data transfer rate = 0&lt;br&gt;User ID value recognized&lt;br&gt;Device ID recognized&lt;br&gt;Connectivity test failed</td>
<td>Send an alert to the user&lt;br&gt;Send an alert to the administrator</td>
</tr>
<tr>
<td>Too many data are stored in the device memory</td>
<td>% occupied memory visualized on the app</td>
<td>Perform periodical backup on the cloud&lt;br&gt;Send a periodical alert to end-user for data deletion</td>
</tr>
<tr>
<td>Adverse events occurring to the patient:</td>
<td>Heart rate&lt;br&gt;Blood pressure</td>
<td>Alert sent to the case manager or caregiver according to ICF&lt;br&gt;Periodical check-ups&lt;br&gt;Discontinuation from the study for safety reasons</td>
</tr>
<tr>
<td>Death</td>
<td>Task assigned are ignored</td>
<td>Change personalization strategy&lt;br&gt;Change time and frequency for alerts</td>
</tr>
<tr>
<td>Hyper / Hypotension crisis</td>
<td>Alerts sent and ignored</td>
<td>Have a call with the patient</td>
</tr>
<tr>
<td>Fall</td>
<td>The logs of a specific app register poor usage</td>
<td>Change personalization strategy&lt;br&gt;Change time and frequency for alerts</td>
</tr>
<tr>
<td>Poor interaction</td>
<td></td>
<td>Have a call with the patient</td>
</tr>
<tr>
<td>App not used</td>
<td>Frequent transfer of null data</td>
<td>Alert sent to the user</td>
</tr>
<tr>
<td>Non-Constant use of the device</td>
<td>Data transfer rate (unit missing)</td>
<td>Use frequency testing&lt;br&gt;Check if the patient has been hospitalized&lt;br&gt;Automated withdrawal after 45 days of constant inactivity</td>
</tr>
<tr>
<td>Periodical check-ups missed</td>
<td>Alerts sent and ignored</td>
<td>New alert sent&lt;br&gt;Check if the patient has been hospitalized&lt;br&gt;Automated withdrawal after some consecutive check-ups are missed</td>
</tr>
<tr>
<td>False observation (\rightarrow) false notification / alert to user</td>
<td>False high blood pressure readings – notifications cause frustration to end-user</td>
<td>Periodical check-ups</td>
</tr>
<tr>
<td></td>
<td>False weight readings</td>
<td>Automatic suggestion to repeat measurement</td>
</tr>
<tr>
<td></td>
<td>Office blood pressure readings disproportional to the ones provided during telemonitoring</td>
<td></td>
</tr>
</tbody>
</table>
3.4.5.5 Steps that will be taken to control or mitigate the risks

Risk Factor is any element that can increase or decrease the level of risk where a vulnerability is present or when an adverse unexpected event occurs. A detailed Layer-related list of situations that can put the SMART BEAR at risk in terms of efficiency and security and/or can condition the actual ability of the patients to take part in the program can be found in the corresponding Appendix (15.3). The management of possible risks during the pre-recruitment and piloting phase of SMART BEAR is based on the hierarchical security architecture for cyber-physical systems proposed by Zhu et al (23) and can be found, along with additional identified risks, in detail in Appendix (15.4).

Specifically, in the case of participants of SMART BEAR – HOLOBALANCE solution standard clinical risk management procedures will be followed to ensure patient safety during the outcome measurement sessions. The research group has extensive experience of using these measures and has established risk management strategies that will be followed.

After each exercise, participants will be asked to rate their level of dizziness / disorientation and unsteadiness. If their symptom scores are above mild (scores greater than 1 on a 4-point Likert scale [0-4]) they will be asked to wait until their symptoms subside before continuing with the next exercise. This is in-line with the routine advice given to patients in clinical practice.

Participants will be provided with clear written and pictorial instructions on the appropriate fitting and use of equipment provided. On the initial home visit the Physiotherapist will provide verbal instructions and a demonstration of the correct use of equipment. For the HoloBalance group, the equipment will be individually fitted for each participant by the attending Physiotherapist.

Safety instructions for the completion of home exercise programs will be provided to all participants. These will include instructions for preparing the immediate surroundings where exercises will take place. Further prompts regarding clothing (e.g. ensuring footwear are suitable and fastened), and positioning of the participant for exercises (e.g. stand in the corner of the room).

3.4.5.6 Possible interactions with concomitant medical treatments

The selection of exclusion criteria for this study will limit interactions with pre-existing medical conditions that are associated with high risk of severe depression, life-threatening or uncontrolled hypertension, arrhythmias, heart failure etc. Participants will also be included only when judged as independent or slightly dependent on the safe use of the devices (e.g. visual impairment, cognitive impairment, neurological problems and acute musculoskeletal injury). As this is an observational study with specific rehabilitation solutions for specific subgroups of participants, we do not anticipate any interaction with ongoing medical treatments. SMART BEAR activities do not replace the current healthcare system and will only support the self-management of specific daily health challenges.

3.4.5.7 Risk to Benefit rationale

SMART BEAR clinical study aims at enhancing everyday independency of Seniors with the help of easy to use, widely available, CE approved devices. No interventions or change of medical treatment are envisaged. Concerning the risks of use of the devices, concomitant treatments and study procedures, the model adopted in SMART BEAR is described in 7.4.8.
3.4.6 Definition of end of the project
The study will be completed when the last follow-up outcome measurement session for the last active participant has been completed.

3.4.7 Discontinuation / withdrawal of participants from the study (NKUA)
Throughout the whole SMART BEAR activities it should be clear to participants that they have the right to withdraw their participation and their data at any time. In addition to that, the SMART BEAR investigators may select to discontinue a participant from the study at any time if one of the following issues occur:

- Participant has missed 45 consecutive days of device usage.
- Participant has an acute/severe illness or injury of > 1-week duration that severely impacts upon their ability to continue to fully participate in SMART BEAR activities.
- Participant has suffered acute neurological impairment (e.g. TIA, Stroke) or loss of vision.
- Ineligibility (either arising during the study or retrospective having been overlooked at screening)
- Significant protocol deviation
- Lost to follow up

If participants withdraw from the study or are withdrawn by study personnel, then a member of the research team will be required to complete the Study Discontinuation Form, that will be kept in paper format. The reason for withdrawal will also be recorded in the participant’s file on SMART BEAR platform.

Those that are withdrawn from the study due to non-compliance will be offered the opportunity to provide feedback to the researchers regarding the study and what they perceived led to their lower than expected levels of compliance with the intervention. If the participant is withdrawn due to an adverse event, the investigator will arrange for follow-up telephone calls until the adverse event has resolved or stabilised. Data that has been collected up to the point of withdrawal will be included in subsequent analyses, unless the participant requests that their data is removed from the dataset.

3.5 Statistical Considerations
The General approach of the Smart Bear project aims to implement both statistical and Machine Learning (ML) methods on the datasets that will be created during the different time points. The action plan of data management will allow specific processing to be applied on the regarding all regulations and ethical approvals. In this regard, the process will follow the next steps: a) data preparation, b) data pre-processing, c) application of descriptive statistics, d) extraction of analytics and e) application of ML techniques and methods.

During the data preparation different data sets will be created in order to measure and check the data accuracy and completeness. In this phase plain data querying techniques and data extraction methods from the data stores will be applied and quantification of available datasets will be performed.

The application of data pre-processing tools will be performed after the data preparation to allow the efficient dataset definition while specific operations on the data will be applied including handling of missing or empty values, data imputation and various statistical tests that will measure variable independence and confidence intervals. In addition, the data pre-processing pipeline will include functionalities for outlier detection using both univariate and multivariate methods, as well as,
feature categorization based on their quality in terms of accuracy, relevance, completeness and conformity.

Applying descriptive statistics is a required activity that will enhance the overall Smart Bear project with tools that will be employed to provide frequency-based observational measurements within the collected data. The descriptive statistics will be applied on both datasets of individualized measurements and groups of individuals.

The extraction of data analytics will be performed on the individual datasets using mainly SQL (Structured Query Language) analytics. Data analytics is going to enhance the derived knowledge of descriptive statistics and they will be used as the basis for creating the ML datasets; ML datasets are a major milestone since they will provide predictive rules, extract knowledge from unseen data and classify various unknown variables to meaningful categories. Furthermore, the application of ML methods can associate different types of data and support the implementation of any recommendation mechanism.

In the scope of applying ML tools and methods, the Smart Bear project constitutes a perfect example since it provides an extremely large amount of uncategorized and raw data measurements that are almost impossible to be used as meaningful knowledge or recommendations without appropriate ML handling; both supervised and unsupervised ML methods will be utilized regarding the requirements of the system.

Before applying and utilizing the ML algorithms on the datasets feature extraction and feature selection techniques will be used. As described previously, the extraction of data analytics - that will be carried on the pre-processed datasets - are going to indicate variables or combinations of variable for the feature selection approaches.

The ML technology of the Smart Bear project will be implemented using a variety of previously well-defined and verified scientific methods including: Neural Network (NN) training, Support Vector Machines (SVMs), Decision Trees, Random Forests, Boosting Methods using tree ensembles, such as, gradient boosting trees, Regression Analysis and Naïve Bayes. Among them the focus of ML application will be given to NN, SVMs, Decision Trees and Boost methods. All methods and techniques are data-driven, and the “best” method will be decided after its application. In order to decide “what is best or not” a variety of validation and verification schemes will be used, and the overall process can be early characterized as time-consuming.

3.6 Ethics

3.6.1 Ethical Standards

SMART BEAR aims to enhance elderly’s independency by creating a safe integrated technological environment at home, supporting – not replacing - medical advice. The goal is to enhance and facilitate the daily monitoring of important health parameters and management of everyday health issues.

In pursuing this objective, SMART BEAR undertook to promote the highest ethical, fundamental rights and legal standards. Accordingly, the relevant documents for the six countries involved with the pilots will be prepared in accordance with ethical and regulatory standards for human subject research (e.g., the Helsinki Declaration (WMA Declaration of Helsinki – Ethical principles for medical research involving human subjects, 2018), the CIOMS Guidelines (Van Delden, Revised CIOMS international ethical guidelines for health-related research involving humans, 2017), the Good Clinical Practice Guidelines (Good clinical practice, 2002)), and with the Regulation (EU) 2016/679 of the European
Parliament and of the Council (Regulation, 2016) of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and the free movement of such data and the Organic Law 3/2018, dated 5 December, on the protection of personal data and the guarantee of digital rights. All the ethically relevant issues, like the preparation of pre-recruitment and screening questionnaires, informed consent forms, participants information brochures and study protocols, will be prepared centrally and circulated among clinical partners, who will translate and adapt them to their legislation system. Then, study protocol and documents will be approved by the appropriate Ethical committee, under the responsibility of each Pilot. Each host institution will appoint a Data Protection Officer (DPO), whose contact details will be available to all the data subjects involved in the research. Finally, a regulatory and ethics compliance monitoring of each Pilot execution will take place during the whole project life-cycle.

Two countries that are not members of the European Economic Area (EEA) are involved in SMART BEAR: Israel (with IBM) and Switzerland (with STS). However, the two partners are not directly involved in large scale Pilot activities.

Finally, no blood samples will be taken or stored by SMART BEAR research teams. In the case that blood glucose testing needs to be included in a protocol, they will be the participants themselves to measure by using a personal blood glucose meter via single-use strips.

3.6.2 Internal Ethics Committee

The SMART BEAR Consortium, before its starting date, has appointed a Data Protection Officer (DPO), Mr Benoit Van Asbroeck. In addition to the project DPO, during the piloting phase, each host institution will appoint a Data Protection Officer.

The SMART BEAR DPO acts as a contact point for data subjects and the supervisory authority. He will assist the project partners in monitoring the internal compliance, will inform and advise on the organisation’s data protection obligations, and will provide advice regarding Data Protection Impact Assessments (DPIAs) in accordance with Article 35 of the GDPR.

Moreover, the SMART BEAR DPO heads the SMART BEAR Privacy and Ethics Committee (PEC), which is in charge of all the privacy regulatory and contractual obligations related to ethical issues, such as data protection and anonymity. The PEC also has to ensure that the project is conducted in parallel with each Pilot’s national health system, not overtaking work and responsibility of health providing structures. The SMART BEAR Clinical Coordinator (CC) co-chairs the committee.

All the documents from ethics committees and competent authorities will be stored on the servers and premises of the SMART BEAR partner Bird & Bird (2B), in the specific SMART BEAR matter file. Such documents will be stored employing technical and organisational measures in accordance with the ISO 27001 standard, against which Bird & Bird is certified since 2014. Such documents shall be accessible to the DPO, Mr Benoit Van Asbroeck, as well as the lawyers and staff working on the SMART BEAR Project. Documents from ethics committees and competent authorities will be stored during the entire duration of the project. Afterwards, they will be stored in accordance with the retention requirements laid down in the applicable legislation and/or for the establishment, exercise or defence of legal claims.
3.6.3 Informed Consent

3.6.3.1 Legal framework regarding informed consent

It is being reminded that in the framework of the processing of personal data, 'consent of the data subject' is, pursuant to Article 4(11) of the General Data Protection Regulation (EU) 2016/679, defined as "any freely given, specific, informed and unambiguous indication of the data subject’s wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her".

The GDPR reinforces the requirement that consent must be informed. Based on Article 5 of the GDPR, the requirement for transparency is one of the fundamental principles, closely related to the principles of fairness and lawfulness. Providing information to data subjects prior to obtaining their consent is essential in order to enable them to make informed decisions, understand what they are agreeing to, and for example exercise their right to withdraw their consent. If the controller does not provide accessible information, user control becomes illusory, and consent will be an invalid basis for processing. The consequence of not complying with the requirements for informed consent is that consent will be invalid, and the controller may be in breach of Article 6 of the GDPR.

3.6.3.2 Minimum content requirements for consent to be ‘informed’

For consent to be informed, it is necessary to inform the data subject of certain elements that are crucial to make a choice. Therefore, Working Party 29 ("WP29"), in its Guidelines on consent under the GDPR (Article 29 Working Party, 2018), is of the opinion that at least the following information is required for obtaining valid consent:

1. the controller’s identity;
2. the purpose of each of the processing operations for which consent is sought;
3. what (type of) data will be collected and used;
4. the existence of the right to withdraw consent;
5. information about the use of the data for automated decision-making in accordance with Article 22 (2)(c) where relevant; and
6. on the possible risks of data transfers due to absence of an adequacy decision and of appropriate safeguards as described in Article 46.

With regard to item (i) and (iii), WP29 notes that in a case where the consent sought is to be relied upon by multiple (joint) controllers or if the data is to be transferred to or processed by other controllers who wish to rely on the original consent, these organisations should all be named. Processors do not need to be named as part of the consent requirements, although to comply with Articles 13 and 14 of the GDPR, controllers will need to provide a full list of recipients or categories of recipients including processors. To conclude, WP29 notes that depending on the circumstances and context of a case, more information may be needed to allow the data subject to genuinely understand the processing operations at hand.

In order to lawfully obtain the explicit consent of the participant in the SMART BEAR Project, an "Informed participation and consent form & Information sheet" was drafted. Depending on the purpose for which and the stage at which personal data is collected and processed, there are two versions thereof, namely (i) one in the framework of involvement of the participant in the requirement elicitation for the SMART BEAR Platform and (ii) one for the testing and validation of the SMART BEAR Platform. The sections underneath, concerning the Informed participation and consent form & Information sheet, however, apply to both versions.
3.6.3.3 Purpose of the Informed participation and consent form & Information sheet
The purpose of the Informed participation and consent form & Information sheet is fourfold as follows:
1. Inform all participants about the SMART BEAR Project, the purpose of the processing of their personal data and the personal data processing activities carried out in such a context.
2. Gather the necessary indications that the participant consents to the processing of his personal data in the framework of the SMART BEAR Project.
3. Comply with ethics requirements.
4. Comply with the transparency requirements of the GDPR.

3.6.3.4 Content of the Informed participation and consent form & Information sheet
The content of the Informed participation and consent form & Information sheet is fourfold as follows:
1. About the SMART BEAR Project: This Section shortly describes the SMART BEAR Project, the purposes of the processing of personal data, and the partners of the consortium.
2. About the Participant: This Section aims to collect personal details of the participants, notably for evidentiary purposes.
3. Participation & Consent: This Section aims to collect participants' indications of their wish to participate in the SMART BEAR Project and their consents to the processing of their personal data in such context.
4. Information Sheet (Privacy Policy): This Section informs the participants of the collection and processing of their personal data in the context of their participation in the SMART BEAR Project.

3.6.3.5 How and when to use the Informed participation and consent form & Information sheet
Whenever a Project Partner wishes to gather input from a participant in an offline context in the context of the SMART BEAR Project, the following steps must be followed:
1. The Informed participation and consent form & Information sheet must be submitted for review and completion to the participant before commencing any personal data processing activities.
2. If the participant has any questions about the SMART BEAR Project or the Informed participation and consent form & Information sheet, the Project Partner must ensure that such questions are adequately addressed before commencing the personal data processing activities.
3. The Project Partner must verify that the participant has completed the Sections "About the Participant" and "Consent".
4. The Project Partner must verify that the participant has ticked all the 'Yes'-boxes of the "Participation & Consent" Section. In case the participant has not ticked 'Yes' for each box, do NOT proceed with the personal data processing activities.
5. The Project Partner must ensure to give the participant a copy of the Informed participation and consent form & Information sheet.
6. The Project Partner must be prepared to provide the participant, upon the latter's request, with a copy of the input provided by the participant.
7. The Project Partner must keep the Informed participation and consent form & Information sheet duly completed by the participant on file (a scanned copy saved on the SMART BEAR repository or another appropriate medium).

8. The Informed participation and consent form & Information sheet should be stored during the entire duration of the processing for which the consent was sought. Afterwards, once the retention is no longer necessary for the purpose for which the consent was sought, the document should be stored in accordance with the retention requirements laid down in the applicable legislation and/or for the establishment, exercise or defence of legal claims.

Whenever a Project Partner wishes to gather input from a participant in an online context through a survey in the context of the SMART BEAR Project, the following steps must be followed:

1. Only use the EU Survey questionnaire prepared by Project Partners to conduct the survey.
2. If the participant contacts a Project Partner directly with any questions about the SMART BEAR Project, the personal data processing activities, or the Informed participation and consent form & Information sheet, the Project Partner must ensure that such questions are adequately addressed.

3.6.4 Participant and Data confidentiality

3.6.4.1 Legal assessment: integrity & confidentiality of personal data

Reference is made to Section 11.1.6 regarding the data protection principle of 'confidentiality & confidentiality' pursuant to Article 5(1)(f) of the GDPR.
4 Data Management

This section has already been described in a preliminary report on D1.1 and will be added to Study protocol as soon as devices, infrastructure and repositories are identified. Some general considerations considering the DMP in SMART BEAR are provided below.

4.1 Legal assessment: data protection principles

The data protection principles are at the core of the rules related to the processing of personal data. Article 5(1) of the GDPR lists six key principles relating to the processing of personal data and Article 5(2) provides for a general principle of "accountability", according to which the controller shall be responsible for, and able to demonstrate compliance with, the other six principles. The data protection principles may be depicted in Figure 6 below.

![Figure 6: Overview of data protection principles](image)

The following sub-Sections examine these principles more in-depth, as well as the challenges and opportunities they may pose in relation to big data.

4.1.1 Lawfulness, fairness & transparency

Personal data must be processed lawfully, fairly, and in a transparent manner in relation to the data subject. One of the requirements is for the processing of data to be “fair”, meaning that the data subject must be in a position to learn of the existence of a processing operation and must be given accurate and full information (for instance about the identity of the controller, the purposes of the processing of data, etc.). Fairness is therefore about being open on the processing in order to empower individuals by making them aware of what information about them is being collected and processed.

The principle of “fair and transparent” processing means that the controller must provide information to individuals about its processing of their data, unless the individual already has this information. The information to be provided is specified under Articles 13 and 14 of the GDPR. The controller may also have to provide additional information if, in the specific circumstances and context, this is necessary for the processing to be fair and transparent. Also, the GDPR affirms that the information must be provided in a concise, transparent, intelligible and easily accessible way, using clear and plain language (in particular where the data subject is elderly).

Correspondingly, the SMART-BEAR Platform and Project shall provide, in an appropriate manner, data subjects all required information about the processing of their personal data.

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1 GDPR, art 5(1)(a)
4.1.2 Purpose limitation (and secondary use)

Personal data must be collected for specified, explicit and legitimate purposes; and must not be further processed in a way incompatible with those purposes. Foremost, this requires any processing of personal to have a clearly defined purpose in order to be permitted. This may be particularly difficult in a big data context because “at the time personal data is collected, it may still be unclear for what purpose it will later be used.

Furthermore, the principle includes a second building block: i.e. the prohibition to further process personal data in a way incompatible with the initial purposes (re-purposing). The Article 29 Working Party published a lengthy opinion in 2013 (Opinion 03/2013) – under the Data Protection Directive – on the purpose limitation principle, focuses on this second building block. Article 6(4) of the GDPR has codified some elements of Opinion 03/2013. It sets out the rules on factors a controller must take into account to assess whether a new processing purpose is compatible with the purpose for which the data were initially collected. Where such processing is not based on consent3, the GDPR lists five factors that should be taken into account in order to determine compatibility4:

- any link between the purposes for which the personal data have been collected and the purposes of the intended further processing
- the context in which the personal data have been collected, in particular regarding the relationship between data subjects and the controller
- the nature of the personal data, in particular whether special categories of personal data are processed, (…), or whether personal data related to criminal convictions and offences are processed, (…)
- the existence of appropriate safeguards, which may include encryption or pseudonymisation.
- the possible consequences of the intended further processing for data subjects

The ICO further highlights that a key factor to take into consideration with respect to the compatibility assessment is whether the new purpose is “fair”. This would entail considering “how the new purpose affects the privacy of the individuals concerned and whether it is within their reasonable expectations that their data could be used in this way.”

4.1.3 Data minimisation

The general principle of “data minimisation” enshrined in Article 5(1)(c) of the GDPR provides that personal data must be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed. Also, the period for which the data are stored should be limited to a strict minimum. Finally, personal data should only be processed if the purpose of the processing cannot be fulfilled by other means.6

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3 Or on EU or Member State law relating to matters specified in Article 23 (general article on restrictions relating to the protection of national security, criminal investigations etc.).

4 Further processing of personal data for archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes shall not be considered incompatible with the original processing purposes. However, the conditions of Article 83(1) (which sets out safeguards and derogations in relation to processing for such purposes) must be met.


6 The Belgian Privacy Commission puts emphasis on Recital 39 of the GDPR which provides that the data minimisation principle “requires, in particular, ensuring that the period for which the personal data are stored is limited to a strict minimum. Personal data should be processed only if the purpose of
On such basis, the ICO is of the opinion that having well-managed, up-to-date and relevant data – rather than acquiring and keeping data just in case it may be useful – helps to improve data quality and contributes to the analytics.\(^7\) In such context, the ICO provides some recommendations to abide by the data minimisation principle, in line with the concepts of “privacy by design” and “privacy by default”. More particularly, organisations should\(^8\):

- articulate at the outset why they need to collect and process particular datasets;
- clarify what they expect to learn or be able to do by processing that data;
- ensure that the data is relevant and not excessive in relation to the purposes.

It follows that the data minimisation principle is closely linked to the purpose limitation requirement as any organisation must first determine the purposes of the processing and then establish that the data will be relevant and thus not excessive.

### 4.1.4 Accuracy

Personal data must be accurate and, where necessary, kept up-to-date; every reasonable step must be taken to ensure that inaccurate personal data, having regard to the purposes for which they are processed, are erased or rectified without delay. This principle should be read in conjunction with the data subjects’ rights.

### 4.1.5 Storage limitation

Personal data must be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed. Personal data may be stored for longer periods insofar as the data will be processed solely for archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes in accordance with Article 83(1) and subject to the implementation of appropriate technical and organisational measures.

The GDPR does not specify the exact data retention periods given that these are necessarily context-specific. This being said, considering that data can be kept for “no longer than is necessary” in light of the purpose for which it was originally collected “assumes that each data element is collected only for a single purpose (or perhaps a small number of discrete purposes), and that this purpose was immediately apparent at the outset”.\(^9\) In reality, this is seldom the case.\(^10\)

Despite the challenges, the storage limitation principle requires any organisation to carefully assess the retention periods and determine whether data can be erased, but also whether it can be anonymised or pseudonymised. The requirement to retain data for “no longer than is necessary” indeed only applies to personal data. Data which is not personal falls outside of data protection law and so, in principle, can be retained indefinitely. “Anonymisation throws up its own challenges, especially given European data protection authorities’ strict views on what qualifies as effective

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\(^7\) Ibid 42

\(^8\) Ibid 41


\(^10\) Ibid
anonymisation, but it is for many organisations often more achievable than full deletion”.\textsuperscript{11} If the anonymisation is not achievable, an organisation may consider pseudonymising the data, which will still qualify as personal data but considered to be inherently less intrusive than ‘ordinary’ data.

4.1.6 Integrity & Confidentiality

Article 5(1)(f) of the GDPR concerns the ‘integrity and confidentiality’ of personal data. It says that personal data shall be:

"Processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures."

This can be referred to as the GDPR’s ‘security principle’. It concerns the broad concept of information security.

This means that organisations must have appropriate security to prevent the personal data they hold being accidentally or deliberately compromised. It is recalled that while information security is sometimes considered as cybersecurity (the protection of your networks and information systems from attack), it also covers other aspects such as physical and organisational security measures.

The security principle is to be considered alongside Article 32 of the GDPR, which provides more specifics on the security of your processing. Article 32(1) states:

"Taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, the controller and the processor shall implement appropriate technical and organisational measures to ensure a level of security appropriate to the risk”.

The GDPR does not define the security measures that should be in place. It requires controllers and processors to have a level of security that is ‘appropriate’ to the risks presented by their processing. They need to consider this in relation to the state of the art and costs of implementation, as well as the nature, scope, context and purpose of their processing.

\textsuperscript{11} Ibid
The SMART-BEAR Project and Platform therefore shall, in order to ensure the rights and freedoms of individuals when processing their personal data, implement appropriate technical and organisational security measures appropriate to the risk. These measures shall include, where deemed appropriate, pseudonymisation, anonymisation or deletion of personal data.

More concretely, these measures shall ensure that:

- the data can be accessed, altered, disclosed or deleted only by those have been authorised to do so;
- the data SMART-BEAR holds is accurate and complete in relation to why it is processing it; and
- the data remains accessible and usable, ie, if personal data is accidentally lost, altered or destroyed, it should be able to recover it and therefore prevent any damage or distress to the individuals concerned.

4.1.7 Accountability

The accountability principle relates to the ability to demonstrate compliance with the GDPR's principles, notably through the adoption of certain technical measures, the implementation of policies, the keeping of paper trails of decisions relating to data processing, the introduction of staff training programs, the performance of audits and impact assessments, or the adherence to approved codes of conduct.

The GDPR starts from the postulate that the processing of personal data is a risk for the rights and freedoms of individuals. Such risk must be taken into account and continuously re-assessed. In this context, the GDPR imposes a risk-based approach. Companies are therefore required to appreciate in an objective manner the likelihood and severity of the risk to the rights and freedoms of individuals, taking into consideration the nature, scope, context and purposes of the processing.

Recital 75 of the GDPR provides several examples of risky processing activities which could lead to physical, material or non-material damage. Among such examples, two are particularly relevant to big data analytics. Indeed, the processing is deemed risky where the processing involves a large amount of personal data and affects a large number of data subjects, as well as where data subjects might be deprived of their rights and freedoms or prevented from exercising control over their personal data.

In the context of SMART-BEAR, it will be of paramount importance to carefully consider the various principles, notably in the design and development phases of the Platform. Also, the various decisions and measures taken to comply with the GDPR will need to be kept on file for accountability purposes.

Accordingly, the SMART-BEAR Project and Platform shall implement appropriate measures to ensure and to be able to demonstrate compliance with the data protection and security legal framework.

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12 The risk-based approach is enshrined in Article 24 relating to the responsibilities of the data controller. See also in that context Article 29 Data Protection Working Party, 'Statement on the role of a risk-based approach in data protection legal frameworks' (2014) WP218

13 GDPR, art 24 and Recital 76. See also in relation to the risk-based approach Articles 32(1) and 33 to 35
4.1.8 Opting out from Open Research Data Pilot

Beneficiaries of European Research Council grants must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results. Open access can be defined as the practice of providing on-line access to scientific information that is free of charge to the reader. Open access typically focuses on access to ‘scientific information’ or ‘research results’, which refers to two main categories: Peer-reviewed scientific research articles (primarily published in academic journals) and Research data. However, SMART BEAR opted out from the Horizon 2020 Open Research Data Pilot (ORDP), for two main reasons:

1. Incompatibility with rules on protecting personal data, especially because in SMART BEAR raw and processed data from older citizens at home is foreseen. This incompatibility will be further explored along with ethical issues and protocol approvals as long as sharing the data openly should be clearly mentioned in the information sheets and consent forms according also with GDPR and any reuse of or open access to data should be made perfectly clear to the consenting patients;

2. Incompatibility with the obligation to protect results that can reasonably be expected to be commercially or industrially exploited. This result can only be clearly defined by the end of year 3, and final decisions may have to be made by the end of the project when exploitation aspects will be finalized and agreed among the partners.

In SMART BEAR choice of repository and handling data will follow FAIR Principles (1. Findable, 2. Accessible, 3. Interoperable and 4. Reusable). One possibility being considered is ZENODO while other options are also assessed by each pilot individually and the particular task leader.

**FAIR PRINCIPLES IN SMART BEAR:**

1. **MAKING DATA FINDABLE:** The first step in (re)using data is to find them. Metadata and data should be easy to find for both humans and computers. Machine-readable metadata are essential for automatic discovery of datasets and services, so this is an essential component of the FAIRification process.

2. **MAKING DATA OPENLY ACCESSIBLE:** Once the user finds the required data, she/he needs to know how can they be accessed, possibly including authentication and authorisation. A Creative Commons Attribution-Non Commercial ShareAlike (CC BY-NC-SA) license seems to be the one that fits for SMART BEAR datasets, and especially for the dataset generated within the pilot. Restricted/controlled access means that only authenticated and authorized users whose research proposal has been vetted by the data management Board will be provided access to the pilot dataset.

3. **MAKING DATA INTEROPERABLE:** The data usually need to be integrated with other data. In addition, the data need to interoperate with applications or workflows for analysis, storage, and processing.

4. **INCREASE DATA RE-USE:** The last goal of FAIR is to optimise the reuse of data.
5 Publication Policy

Findings from this study will be written up for submission to high ranking peer-reviewed journals and for an announcement in a high-level public conference. SMART BEAR partners (research/academic, technical and clinical) will carefully select its publication venues based on their scientific excellence and impact. Potential conferences and journals that will be targeted for scientific dissemination are already listed in the D13.1.
6 Deviations from clinical investigation plan

A deviation is considered a departure from the conditions and principles of good clinical practice (GDP) in connection with the study; or the protocol relating to the study.

The Investigator(s) shall not deviate from this protocol except in situations that affect the subject’s rights, safety and well-being, or the scientific integrity of the clinical investigation. All protocol deviations shall be recorded and reported as agreed. A deviation log shall be maintained by the study site and communicated monthly to study Sponsor. All deviations will be included, as required in the final study report.

Specifically, in the case of participants of SMART BEAR – HOLOBALANCE, Deviation from treatment plan will be considered when for 2 consecutive days the participant is not connected to the platform and / or interrupts the exercises before completing them for 2 consecutive days. The responsible therapist will then call the participant by phone to clarify the reason for the interruption. If reported as a side effect, the procedures described will be followed.
7 Monitoring

Monitoring of matters related to the deployment of the study, such as research and professional staff training and certification, subject recruitment, retention, subject compliance, patient safety, data entry and data accuracy is under the responsibility of each Pilot’s Study Manager. The role of Study Manager should be fulfilled by each corresponding WP lead beneficiary.

Lead Site Clinicians shall be the contact persons of each Pilot site. They are responsible for reporting the status of the study and possible problems, adverse events or questions to the Pilot’s study Manager or communicate with Domain Expert if questions of scientific content arise.

The Steering Committee of SMART BEAR comprises of the clinical investigator and the principal investigators of each Pilot and provides a higher-level monitoring of the SMART BEAR project. They should meet, in-person or remotely, quarterly. The main purpose of these meetings is to concentrate on the progress of the study procedures, adherence to the protocol, patient safety and consideration of new information of relevance to the research questions. Recruitment rates and development of strategies to deal with any recruitment problems, along with follow-up rates and strategies to deal with problems including sites that deviate from the protocol shall be discussed. Any amendments to the protocol where appropriate, should be reported and discussed.

The Sponsor of the clinical study will be NKUA. Lead site clinicians directly or through their corresponding Study Manager should inform sponsor for any AEs according to the predefined timeline.

SMART BEAR Domain Experts are members of SMART BEAR consortium with experience in specific medical domains (both clinical practice and research methodology). The main role of Domain Experts will be the consultation of partners on questions or issues with respect to their specific domain of expertise and the organization of trainings – workshops according to the needs of the project.

GDPR compliance will be monitored by each Pilot’s DPO under the guidance and overall supervision of the 2B partner.
8 **Suspension or premature termination of the project**

End of Study Notification will be provided to the EC within 90 days of the completion of the study or within 15 days if the study is stopped for safety reasons\(^{24}\). The clinical study may be prematurely terminated or suspended in one or more sites for several reasons; the data strongly suggests that study participation is unsafe, the protocol or conduct of the study is flawed and may impact upon the safety and/or rights of participants or adversely affect the validity of the study; the ethics committee has withdrawn approval for the study, and poor recruitment.

Prior to terminating / suspending the trial a written report will be produced by the site lead clinician and the Pilot Study Manager stating the reasons for recommending suspension / termination and presenting evidence in support of this. This, in combination with the Declaration of the End of a Clinical Trial Form and a notification of substantial amendment will be circulated to the other recruiting site, sponsor, ethics committee.
9  Project Administration and Statements of Compliance

The SMART BEAR project consortium consists of 27 partners from 10 countries. Despite a large number of members, the project administration structure has been kept simple to avoid a management overhead. Such structure was already defined in the proposal stage and later confirmed at the SMART BEAR kick-off meeting. As described in D1.1 (D1) “Initial Quality, Innovation and Data Management Plan”, the leading coordination roles of the project are:

- **Project Coordinator (PC)** - Giuseppe De Pietro (CNR), responsible for project control and intermediary between the European Commission and the consortium;
- **Technical Coordinator (TC)** - George Spanoudakis (STS), responsible for the technical project management and coordination of project workpackages;
- **Clinical Coordinator (CC)** - Thanos Bibas (NKUA), responsible for the coordination of the clinical partners and pilots;
- **Data Protection Officer (DPO)** - Benoit Van Asbroeck (2B), responsible for data protection and compliance with GDPR requirements;
- **Innovation Manager (IM)** - Daniele Crespi (LISPA), responsible for supporting the innovation-driven research and amplifying the project’s impact.

Besides, each Workpackage/Task has a leader who is responsible for the coordination of the activities and the timely submission of the deliverables. Finally, the SMART BEAR consortium has also established four committees: the Project Coordination Committee, the formal decision-making of the project; the Project Technical Committee, who makes and oversees the technical decisions; the Privacy & Ethics Committee, who is in charge of the obligations related to ethical issues deriving from the usage of clinical data; and, the Advisory Committee, in which international experts, external to the consortium, provide feedback to ensure a proper scientific and technological evolution. One more committee, focused Intellectual Property Rights and chaired by the Innovation Manager, will be established - if deemed necessary - to deal with the definition of access rights and licensing.

In the definition of the piloting protocols, as already reported in D14.2 (D64) “H - Requirement No. 2”, the SMART BEAR consortium will strictly follow the regulatory standards for human subject research: the Declaration of Helsinki (WMA Declaration of Helsinki – Ethical principles for medical research involving human subjects, 2018)\(^{25}\); the CIOMS Guidelines (Van Delden, Revised CIOMS international ethical guidelines for health-related research involving humans, 2017)\(^{26}\); the Good Clinical Practice Guidelines (Good clinical practice, 2002)\(^{27}\). Concerning data protection requirements, all the piloting activities will strictly adhere to the GDPR provisions (General Data Protection Regulation, 2016), as well as to the national legislation implementing the GDPR in the six countries (France, Greece, Italy, Portugal, Romania and Spain) in which such activities will be carried out.

SMART BEAR has already appointed a **Data Protection Officer (DPO)**, Mr Benoit Van Asbroeck. Moreover, an internal Privacy & Ethics Committee (PEC) will be formed to supervise all the privacy regulatory and contractual obligations related to ethical issues. The head of the PEC will be the SMART BEAR’s DPO, while the CC will co-chair. Finally, each host institution involved with the piloting activities will appoint a DPO or at least a Privacy Responsible Person (PRP), whose contact details will be available to all data subjects. As requested in the Ethics Summary Report (EthSR) at point 4.2, the contact details of the DPO, as well as the appointment letters, will be submitted in the deliverable D14.3 (D65) “POPD - Requirement No. 3”.

The DPO or PRP of the host institutions will complete and sign a **Statement of Compliance** in relation to the processing of personal data. The statement will provide assurance to the European Commission and the other SMART BEAR partners on the compliance with applicable data protection legislation of
the personal data processing activities carried out by the host institution in the context of the project. In more details, the statement of compliance will contain a confirmation that the partner will carry out all personal data collection and processing activities in accordance with the applicable data protection legislation, and an acknowledgement and declaration that the all principles and obligations enshrined in the GDPR will be implemented where needed. The Project Coordinator will keep all the statements of compliance on file to ensure the SMART BEAR compliance with the GDPR's principle of accountability.

All the study protocol and documents will be approved by the appropriate Ethical committee, under the responsibility of each Pilot. No piloting activity will be conducted without having first obtained the approval of the responsible authorities. Once obtained, the documents from ethics committees and competent authorities will be stored on the servers and premises of Bird & Bird (Belgium) LLP, by means of technical and organisational measures in accordance with the ISO 27001 standard, against which Bird & Bird (Belgium) LLP is certified since 2014. Such documents will be stored during the entire duration of the project. Afterwards, they shall be stored in accordance with the retention requirements laid down in the applicable legislation and/or for the establishment, exercise or defence of legal claims.
10 References


24. Communication from the Commission — Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (CT-1). :19.


11 Appendix

11.1 Glossary

- **Amyloid-beta (Aβ) plaques**: a naturally occurring protein which in the Alzheimer’s brain appears in abnormal levels and clumps together to form plaques that collect between neurons and disrupt cell function

- **Apps**: a type of software that allows to perform specific tasks. Applications for desktop or laptop computers are sometimes called desktop applications, while those for mobile devices are called mobile apps

- **Auditory Training**: method of using speech and non-speech auditory exercises for enhancing the use of residual hearing and improving perception of sound (speech, music etc).

- **Balance Disorder**: Balance requires collaboration of several body systems: the visual system (eyes), vestibular system (ears) and proprioception (the body's sense of where it is in space). Degeneration or loss of function in any of these systems can lead to balance deficits and to symptoms such as dizziness, falls, unsteadiness.

- **Clinical studies**: A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. Clinical studies can be divided into two broad categories: trials, in which the researcher intervenes to prevent or treat a disease, and observational studies, in which the researcher makes no intervention and patients are allocated treatment based on clinical decisions.

- **Clinical observational study**: Studies in which the researcher observes individuals without manipulation or intervention on the subject.

- **Cognitive domains**: Cognitive performance is typically conceptualized in terms of domains of functioning. There have been defined 6 six key domains (with subdomains included): Learning and Memory, Language, Executive functions, Perceptual-motor function, Complex attention and Social cognition.

- **Community-dwelling**: elderly people that are living independently

- **Compatibility testing**: One or more tests performed to assess the compatibility of devices with the SMART BEAR platform.

- **Connectivity testing**: One or more tests performed to assess the interconnectivity of the devices and the platform.

- **Consent**: Any freely given, specific, informed and unambiguous indication of the data subject’s wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.
- **Data Protection Officer (DPO):** The Data Protection Officer (DPO) must be enrolled by data controllers that are processing large amounts of sensitive data, in order to ensure that an organization applies the laws protecting natural persons’ data. The DPO is responsible for overseeing a company's data protection strategy and its implementation to ensure compliance with GDPR requirements.

- **Data protection:** Also known as data privacy or information privacy, is a legal control over access to and use of data.

- **Data model:** Data model is a way of organizing data elements and standardizing how the data elements relate to one another. A data model explicitly determines the structure of data and is a critical step that must be taken after business requirements.

- **Data subjects:** Any natural person whose personal data is being collected, held or processed.

- **Data Repository:** A data repository is a data library or data archive. It is a general term to refer to a data set isolated to be mined for data reporting and analysis. In that sense, a data repository is a large database infrastructure, or several databases, that collect, manage and store data sets for data analysis, sharing and reporting.

- **Dataset:** A dataset is a set of data and more specific data that are stored in a specific format in a computational system. A dataset in a matrix where each cell presents a unique information. The rows and the columns of a dataset are presenting the same entity (e.x. a row can present the data of a subject and a column can present the gender).

- **Data transfer rate:** The quantity of data that are transferred from a device to the SMART BEAR platform and vice versa in a period of time. This rate can be affected by the efficiency of the network.

- **Decision Support System:** Can be identified as interactive computer-based systems that help decision-makers use data and models to solve structured, unstructured or semi-structured problems. They can incorporate analytical, statistical and forecasting modules or Machine Learning, which are tailored to the problem to be solved.

- **Descriptive Statistics:** A set of statistical methods in the field of mathematics that are used with explicit formulas to quantitative analyse collections of information. Examples of descriptive statistics are including the computation of mean and median in data sample.

- **Device:** Any digital technology such as smartphones, wearable devices and home-based monitoring devices that is distributed to the patients and can be connected to the SMART BEAR platform. The devices are expected to monitor the daily activities and the health data of the patients and allow the platform to predict possible issues and send targeted instructions for personalized interventions.
- **Device incompatible**: A device that has any hardware and/or software feature incompatible with the SMART BEAR requirements.

- **Device not calibrated**: A device that has measurement sensors not calibrated. The data sent by a device not calibrated may be inaccurate or inconsistent.

- **Encryption**: It is the method by which information is converted into secret code that hides the information’s true meaning. In general, encryption refers to the procedure that converts clear text into a hashed code using a key, where the outgoing information only becomes readable again by using the correct key. The data protection authorities of the European Union, represented in the Article 29 Working Party (WP29), consider that the availability of strong and efficient encryption is a necessity in order to guarantee the protection of individuals with regard to the confidentiality and integrity of their data.

- **Evidence-based interventions**: are treatments that have been proven effective (to some degree) through outcome evaluations.

- **Frequency testing**: One or more tests performed to assess whether a user is using his/her devices with a sufficient frequency to continue being part of the program.

- **GDPR (General Data Protection Regulation)**: Legal framework that sets rules and guidelines for the collection and processing of personal information. Any processing of personal data in the context of the activities of an establishment of a controller or a processor in the Union should be carried out in accordance with this Regulation.

- **Hearing aid**: amplification device that assists patients with hearing impairment. Different types of hearing aids exist (in-the-ear (ITE), in-the-canal (ITC), behind-the-ear (BTE), or on the body). **Hearing Aid Fitting** is the initial set of procedures for setting the configurations and programs of a hearing aid. As **Hearing Aid Fine tuning** is defined every refinement of the initial fitting. Both procedures are conducted by Audiologists, according to specific audiometric testing.

- **Hearing Loss**: loss of audibility or clarity. It ranges from mild to profound degree.

- **Information sheet**: It is an information leaflet that researchers must provide to everyone they invite to take part in a research study, to ensure people can make an informed decision about this.

- **Informed consent form**: It is a document that requires a participant's signature in order to participate in a research study. The aim of the informed consent is to provide sufficient information so that a participant can make an informed decision about whether or not to enrol in a study or to continue participation.

- **Intracellular tau tangles**: abnormal accumulations of a protein called tau, that collects inside neurons.
- **Localization**: the process of adapting a product or content to a specific locale or market. (e.g. translation in the local language)

- **Machine Learning**: A set of mathematical and statistical algorithms that are applied to sets of structured data in order to provide knowledge (a broader term defining predictions, unseen data, classification of data, smart recommendations etc) without the need of a specific computer program.

- **Medical monitoring**: Constant or regular medical control of a patient.

- **Non-compliance**: failure to act in accordance with a wish or command.

- **Notification**: in the case of risk factors management, a message sent to the administrator / message reaching the user when specific observations are made by the Platform and associated sensors

- **Ontology**: In computer science, ontology is a formal representation of the knowledge by a set of concepts within a domain and the relationships between those concepts. It is used to reason about the properties of that domain and may be used to describe the domain.

- **Open-source home automation software**: a solution that connects to devices and services from different vendors. Actions, such as switching on lights, can be triggered by rules, voice commands, or controls on the software's user interface.

- **Participant**: Any person who participates, or takes part in the research or observational study.

- **Patient**: A person receiving or expecting to receive medical treatment.

- **Personal data breach**: A breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed.

- **Personal data**: Any information relating to an identified or identifiable natural person. Identifiable meaning, who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier...

- **Physical warning**: a type of warning that is received by the user and consists of vibration, enlightenment or any other sensory signal.

- **Physiological reserve**: the buffer that allows an individual to cope with and recover from stressors. It is gradually declining with ageing but, in frailty, this decline is accelerated and homeostatic mechanisms start failing.
- **Polypharmacy**: refers to the use of a large number of medications, commonly considered to be the use of five or more. Since polypharmacy is a consequence of having several underlying medical conditions, it is much more common in elderly patients. An estimated 30 per cent to 40 per cent of elderly patients take five or more medications. Polypharmacy also can be defined as the use of more medications than are clinically indicated.

- **Predementia stages**: initial stages of cognitive deterioration that do not typically exhibit enough symptoms for a dementia diagnosis.

- **Prevalence**: is a statistical concept referring to the number of cases of a disease that are present in a particular population at a given time, whereas **incidence** refers to the number of new cases that develop in a given period of time.

- **Privacy impact assessment**: The instrument for a privacy impact assessment (PIA) or data protection impact assessment (DPIA) was introduced with the General Data Protection Regulation (Art. 35 of the GDPR). These refers to the obligation of the controller to conduct an impact assessment and to document it before starting the intended data processing. Basically, a data protection impact assessment must always be conducted when the processing could result in a high risk to the rights and freedoms of natural persons.

- **Privacy**: Privacy is a fundamental right, essential to autonomy and the protection of human dignity. Privacy may be defined as the right of the individual to determine when, how, and to what extent he or she will release personal information.

- **Processing**: Any use of personal data (obtaining, recording, storing, organising...). So, it means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means.

- **Pseudonymisation**: The processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.

- **Pure tone audiometry**: main hearing test that is used to identify one’s hearing threshold. A series of pure tones in different frequencies and intensities is being presented to the subject and he/she is requested to respond whenever the tone is audible.

- **Risk Factor**: Any adverse situation that can put the efficiency and security of the SMART BEAR at risk and/or undermine the actual ability of the patients to participate to the program.

- **Recruitment**: The overall process of attracting, shortlisting, selecting and appointing suitable participants.
- **Rule-editor**: a web-based application which enables users to create "trigger-action" rules in an intuitive manner. A "trigger-action" rule is a rule that specifies what should be done (action) when a specific situation or event (trigger) occurs in the current context.

- **Senior residences**: offer services similar to those of a hotel complex for retired people looking for a pleasant life and leisure activities: communal living areas; entertainment and festive moments; catering services; domestic help; remote assistance and repair services; Other personal services are likely to be offered on-demand (deliveries, home hairdresser...) allowing each resident to choose the service according to his or her needs.

- **Sensitive personal data**: Data consisting of racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, biometric data, data concerning health or data concerning a natural person's sex life or sexual orientation.

- **Serious games**: games that have another purpose besides entertainment. They are used to promote learning and behaviour change. Serious gaming is used in various areas such as education, healthcare, marketing and other businesses and industries. The power of serious games is that they are entertaining, engaging and immersive. Serious games combine learning strategies, knowledge and structures, and game elements to teach specific skills, knowledge and attitudes. They are designed to solve problems in several areas and involve challenges and rewards, using the entertainment and engagement components provided when the user is playing games.

- **Sleep hygiene**: habits that help in having a good night's sleep. Common sleeping problems (such as insomnia) are often caused by bad habits reinforced over years or even decades.

- **Supine**: the position of lying horizontally with the face and torso facing up (for measuring blood pressure).

- **Tele-health**: Remote clinical services, such as diagnosis and monitoring. So it is the distribution of health-related services and information via electronic information and telecommunication technologies.

- **Therapy adherence**: In medicine, patient compliance (also adherence, capacitance) describes the degree to which a patient correctly follows medical advice. Most commonly, it refers to medication or drug compliance, but it can also apply to other situations such as medical device use, self-care, self-directed exercises, or therapy sessions.

- **Third country**: A third country is a country other than EU member states and the three additional EEA countries (Norway, Iceland, and Liechtenstein).
- **Transparent information:** The principle of transparency requires that any information addressed to the data subject be concise, easily accessible and easy to understand, by a clear and plain language.

- **Vulnerable:** The concept of vulnerability applies to those sectors or groups of the population that, due to their age, sex, knowledge, physical or mental situation and ethnicity, are at risk of being profiled. Vulnerable people can participate in research studies. However, they need a special protection, in order to avoid stigmatization.

- **Wearables:** Devices that can be worn as accessories, embedded in clothing... So they are devices that can be worn by a consumer or be implemented in their homes. The overarching concept of SMART BEAR is to integrate heterogeneous smart consumer and medical devices, as well as smart city infrastructures, to enable the continuous collection of data from the everyday life of the elderly, which will be analysed to obtain the evidence needed in order to offer personalised interventions to promote their healthy and independent living. The data, along with the devices themselves, are creating the Internet of Medical Things (IoMT) – a connected infrastructure of medical devices, software applications and health systems and services.

### 11.2 Screening and Eligibility Assessment

Screening visit takes place before the ICF for the participation to the project is signed. SMART BEAR clinicians’ team proceeds to:
- a preliminary questionnaire and ICF
- check-list of inclusion / exclusion criteria

**Screening questionnaire**

1) Demographic - 5 MIN
   - Date of birth
   - Gender
   - Ethnicity
   - Referral source
   - Education (highest level attained), registered as number of years of formal education.
   - Living situation (e.g., lives alone, lives with spouse/partner).

2) Medical history and medical use - 40 MIN
   - Diabetes or pre-diabetes
   - Depression or Anxiety disorder (Diagnosed based on the medical history/using ICD-10 or DSM5 criteria / using scales (Beck depression Inventory (self-scored), Geriatric Depression scale, State-Trait Anxiety Inventory, Hamilton depression scale, Hamilton Anxiety scale)
   - Hearing loss
   - Balance disorders, falls
   - CVD history
   - Cognitive issues
• Weight loss
• Other relevant medical history
• Current medication use, pharmaceutical name and dose
• MOCA, HUI:

MoCA is a brief 30-question test that takes around 10 to 12 minutes to complete. It was designed as a rapid screening instrument for mild cognitive dysfunction. It assesses different cognitive domains: attention and concentration, executive functions, memory, language, visuocognitive skills, conceptual thinking, calculations, and orientation. MoCA scores range between 0 and 30. A score of 26 or over is considered to be normal. In a study, people without cognitive impairment scored an average of 27.4; people with mild cognitive impairment (MCI) scored an average of 22.1; people with Alzheimer's disease scored an average of 16.2.

HUI is a rating scale used to measure general health status and health-related quality of life. Dexterity of levels 1-4 are considered adequate for SMART BEAR.

11.3 Inclusion / Exclusion checklist

<table>
<thead>
<tr>
<th>Inclusion Criteria at Screening</th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>[1]: Male or female between 67 and 80 years of age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>[2]: Willing to participate in SMART BEAR monitoring activities for 12 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>[3]: History of 2 of the following medical conditions: hearing loss, arrhythmias, hypertension, heart failure, balance disorders, frailty, mild cognitive impairment, mild depression</td>
<td></td>
<td></td>
</tr>
<tr>
<td>[4]: Wi-Fi connection at home</td>
<td></td>
<td></td>
</tr>
<tr>
<td>[5]: Dexterity according to HUI, levels 1-4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>[6]: Cognitive function according to MOCA score &gt;18/30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>[7]: Ability to read</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Extra criteria for participants – candidates for HoloBalance solution:

<table>
<thead>
<tr>
<th>Inclusion Criteria at Screening</th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>[11] Independent community-dwelling participants able to walk 500 meters independently or with a stick</td>
<td></td>
<td></td>
</tr>
<tr>
<td>[12] No significant visual impairment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>[13] A score of &gt;22 on the MoCA i.e. adults with no or mild cognitive impairment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>[14] At risk of falls (i.e. FGA less than 22/30), have significant fear of falling (FES-I short form &gt;10) or having experienced a fall/s in the last 12 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>[15] Willing to participate and to comply with the proposed training and testing regime.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
By the end of the visit, the candidate is informed if of his/her eligibility. If he/she is still willing to participate to SMART BEAR, he will be guided to the next phase.

### 11.3.1 Baseline Assessments

After the signing of the ICF, participants will undergo a standard assessment common from everyone and then according to their comorbidities they will undergo additional testing.

#### 11.3.1.1 Standard Assessment

All participants will undergo standard medical history and physical examination as described in the corresponding section 3.4.2. Additional tests will adapt to each participant’s profile and comorbidities.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Involves</th>
<th>Duration (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td>Participant + study partner</td>
<td>5</td>
</tr>
<tr>
<td>Medical history + medication use</td>
<td>Participant</td>
<td>5</td>
</tr>
<tr>
<td>Physical examination</td>
<td>Participant</td>
<td>10</td>
</tr>
<tr>
<td>Life habits - smoking, drinking, hobbies</td>
<td>Participant</td>
<td>5</td>
</tr>
<tr>
<td>Diet supplement use</td>
<td>Participant</td>
<td>5</td>
</tr>
<tr>
<td>Godin leisure-time exercise questionnaire</td>
<td>Participant</td>
<td>5</td>
</tr>
<tr>
<td>RGA - Rapid Geriatric Assessment (from St Louis University)</td>
<td>Participant</td>
<td>10</td>
</tr>
<tr>
<td>IADL</td>
<td>Participant</td>
<td>5</td>
</tr>
<tr>
<td>Social Functioning Scale (SFS)</td>
<td>Participant</td>
<td>5</td>
</tr>
<tr>
<td>Pittsburgh Sleep Quality Index (PSQI)</td>
<td>Participant (self)</td>
<td>5</td>
</tr>
<tr>
<td>Epworth Sleepiness Scale (ESS)</td>
<td>Participant (self)</td>
<td>5</td>
</tr>
<tr>
<td>Euro Quality of Life (EQ-5D)</td>
<td>Participant (self)</td>
<td>5</td>
</tr>
<tr>
<td>MOCA test</td>
<td>Participant</td>
<td>15</td>
</tr>
<tr>
<td>Smartphone use</td>
<td>Participant + study partner</td>
<td>5</td>
</tr>
<tr>
<td><strong>TOTAL time (min)</strong></td>
<td></td>
<td><strong>90</strong></td>
</tr>
</tbody>
</table>
Physical examination
- Body height
- Body weight
- Body Mass Index (BMI) and height will be measured at the baseline visit only.
- Blood pressure measured after subject has been lying down for 3-5 minutes; following the supine blood pressure, the subject will stand and blood pressure and heart rate will be taken again after 2-3 minutes.

Life habits - smoking, drinking, hobbies
- **Smoking habits**, including life-time smoking (“when the smoking habit started”) and amount (“how many packs of cigarettes per months were smoked in the last year”)
- **Drinking habits**. Assessment of alcohol use, expressed in unit’s consumption per day
- **Hobbies**, listed as reported number of activities-hobbies / week (i.e., reading, crossword, puzzle-solving, listening or playing music, painting, gardening, backing) for how long time (hour/week)

Diet supplement use
- as indicated by the NIH website a series of supplements are commonly used in ageing, even supporting evidence for their benefits in AD are not conclusive (https://nccih.nih.gov/health/providers/digest/alzheimers). They are: vitamins B, vitamin E, folate, coconut oil, ginkgo, omega-3 fatty acids/fish oil, vitamins B and E, Asian ginseng, grape seed extract, curcumin or other dietary supplements

Godin leisure-time exercise questionnaire
- **for the assessment how many times a series of different kinds of exercise** are performed on average for more than 15 minutes during a typical week

RGA - Rapid Geriatric Assessment: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6140035/
Social Functioning Scale (SFS): https://mh4ot.files.wordpress.com/2012/05/social-functioning-scale.pdf
Euro Quality of Life (EQ-5D): https://euroqol.org/support/how-to-obtain-eq-5d/ (copyright protected - permission to use free for research required)

### 11.3.1.2 Additional Assessments for Hearing Loss
During the first appointment, individuals who have signed the consent form and present hearing loss, they will be asked to undertake the following tasks. Note: They need about 30’ to be completed and therefore, another appointment for the fitting is necessary.

Standard pre-fit assessments include:
• Audiological history (Family history of hearing loss, onset of Hearing loss) occupational history (e.g., history of noise exposure).
• Otoscopy, tympanometry. Otoscopy will be performed on every participant to assess possible wax impaction. Furthermore, tympanometry will confirm the presence the good middle ear condition. The above procedures will be performed by following the BSA recommended procedures (BSA, 2010; BSA, 1992).
• Pure Tone Audiometry will be conducted in order to assess participants’ air and bone conduction hearing thresholds. The frequencies will be tested include 250, 500, 1000, 2000, 3000, 4000, 6000, 8000 Hz and 500, 1000, 2000, 4000 Hz for the air conduction and bone conduction respectively. Additionally, masking will be performed wherever masking rules will be applied.

During the second appointment individuals who have successfully completed the pre-fitting tasks will participate to the fitting procedure. This procedure will last about 1 hour including HA fitting, counselling and training. The fitting procedure, to be followed by the clinicians, is described step by step below:

• Pure Tone Audiometry will be repeated if necessary.
• The Glasgow Hearing Aid Benefit Profile (GHABP): Validated self-report instrument assessing listening difficulty, handicap, HA use and benefit across four everyday listening situations. At this point patient only first part will be completed by the individuals.
• Fitting of smart HAs using the compression fitting rational (NAL-NL2 or Similar, depends on the HA manufacturer). Verification of the HAs using real-ear measurements (objective method).
• For the first time users an acclimatization mode will be activated in order to allow familiarization to the individuals.
• All the HA alerts and indicators will be explained (e.g. low battery etc.).
• Hands-on practice regarding the correct allocation and functionality of the HAs.

11.3.1.3 Additional Assessments for Balance Disorders
Participants with balance disorders will be additionally evaluated with the following outcome measures at the baseline and at the end of the intervention.

MiniBEST- test
The mini BESTest is a 14-item test that assesses dynamic balance components including anticipatory postural adjustments, reactive postural control, sensory orientation and dynamic gait. The data is based on a total score of 28 points. The test takes approximately 20 minutes to complete by an experienced clinician.

Functional Gait Assessment
The (FGA) is a 10-item test that assesses performance on complex gait tasks (e.g. walking with head turns horizontally and vertically or stopping and turning, moving over an obstacle). The test takes approximately 5 minutes to complete by an experienced clinician.

Rapid Assessment of Physical Activity
The Rapid Assessment of Physical Activity (RAPA) is a 9-item, self-administered questionnaire developed to provide an easily administered and interpreted means of assessing levels of physical activity among adults older than 50 years. RAPA evaluates a wide range of physical activity level, from
sedentary to vigorous activity, as well as strength and flexibility training and takes 5-minutes to complete.

**Falls Efficacy Scale International (FES-I)**
The Falls Efficacy Scale International (FES-I) is a short, easy to administer tool measuring an individual’s level of concern regarding falling during social and physical activities inside and outside the home, whether or not the person actually does the activity. Level of concern is measured on a four-point Likert scale (1=not at all to 4=very). It has excellent internal validity and test-retest reliability. Scores of >23 for the long-form and >10 for the short form have been suggested as cut points for indicating high concern about falling.

**The Activities-specific Balance Confidence Scale**
The Activities-specific Balance Confidence Scale (ABC) assesses patient’s perceived confidence for performing 16-activities of daily living without losing balance. Scores ≤67/100% indicate increased falls risk.
The HoloBalance tele-rehabilitation system programme consists of a series of off the shelf, CE marked body-worn sensors (Heart rate monitor, inertial measurement units, pressure detecting insoles, activity monitor) that detect physiological signals, movement and activity levels, and deliver a prescribed training programme via a holographic augmented reality display.

Modules of the HoloBalance platform are presented in the table below.

<table>
<thead>
<tr>
<th>Device</th>
<th>Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head-Mounted Adapter</td>
<td>Docooler AR Headset Box Glasses 3D Holographic Hologram Display Holographic Projector for Smart Phones</td>
</tr>
<tr>
<td></td>
<td><a href="https://www.amazon.com/gp/product/B074NYZZS9/ref=ppx_od_dt_b_asin_title_o0_0_s00?ie=UTF8&amp;psc=1">https://www.amazon.com/gp/product/B074NYZZS9/ref=ppx_od_dt_b_asin_title_o0_0_s00?ie=UTF8&amp;psc=1</a></td>
</tr>
<tr>
<td>Smartphone</td>
<td>Google PIXEL 3 XL</td>
</tr>
<tr>
<td>Edge Computer</td>
<td>Dell Inspiron</td>
</tr>
<tr>
<td><strong>IMUs</strong></td>
<td>MBientLab MMR</td>
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<tr>
<td>------------------</td>
<td>---------------</td>
</tr>
<tr>
<td></td>
<td><a href="https://mbientlab.com/metamotionr/">https://mbientlab.com/metamotionr/</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Depth Camera</strong></th>
<th>Intel Realsense D415</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><a href="https://gr.mouser.com/ProductDetail/Intel/82635ASRCVDKHV?qs=sGAEpiMZZMve4%2fbfQkoj%252bHmpJ4wQb9YPb2aKdrbLy4%3d">https://gr.mouser.com/ProductDetail/Intel/82635ASRCVDKHV?qs=sGAEpiMZZMve4%2fbfQkoj%252bHmpJ4wQb9YPb2aKdrbLy4%3d</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Sensor Insoles</strong></th>
<th>Moticon insoles</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><a href="https://www.moticon.de/science/">https://www.moticon.de/science/</a></td>
</tr>
<tr>
<td>Heart rate monitor</td>
<td>Polar H10</td>
</tr>
<tr>
<td>--------------------</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Wristband</th>
<th>Fitbit Charge 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><a href="https://www.fitbit.com/charge3">https://www.fitbit.com/charge3</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Headphones</th>
<th>Sennheiser HD 200 PRO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component</td>
<td>Description</td>
</tr>
<tr>
<td>--------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>Network cable</td>
<td>UTP ETHERNET CABLE 20 metres</td>
</tr>
<tr>
<td></td>
<td>OEM U/UTP Cat.5e</td>
</tr>
<tr>
<td>Network cable</td>
<td>USB3.0 EXTENSION CABLE 3 metres</td>
</tr>
<tr>
<td></td>
<td>TrustWire USB 3.0 Cable USB</td>
</tr>
<tr>
<td>Tripod</td>
<td>Camera Tripod, K&amp;F Concept 62&quot;</td>
</tr>
<tr>
<td>Bluetooth Dongle</td>
<td>Bluetooth USB Adapter v4.0 konig</td>
</tr>
<tr>
<td>BLE dongle</td>
<td>Bluegiga BLED112</td>
</tr>
</tbody>
</table>
The HoloBalance system will use a head-mounted augmented reality display to deliver exercises and games to participants and will record task performance via a combination of body-worn sensors and a depth camera. The HoloBalance tele-rehabilitation system will provide feedback to the supervising clinical team regarding task performance, participant usage and user feedback. The system will have daily presence in the users’ home with users expected to complete their prescribed rehabilitation on a daily basis, which mirrors the prescribed exercise routines often provided by balance physiotherapists.

HoloBalance is delivering an evidence-based, balance physiotherapy tele-rehabilitation programme including physiotherapist prescribed exercises, cognitive games and activity monitoring for older adults with balance disorders with a high risk of falling. Although participants will have daily interaction with the HoloBalance system, they will be free to choose when to complete their exercises. Participants will be required to wear the full HoloBalance sensor and display system for approximately 30 minutes per day to provide sufficient time to complete all prescribed tasks. In tandem, participants will be required to wear an activity monitor (FitBit Charge 3) throughout the day to record physical activity.
11.3.1.4 Additional Assessments for Cardiovascular Disease

<table>
<thead>
<tr>
<th>MEASUREMENTS</th>
<th>BP</th>
<th>HF</th>
<th>AF</th>
<th>CAD</th>
<th>TIMELINE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Visits to the ER due to HTN peak</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>Baseline, 6 &amp; 12M</td>
</tr>
<tr>
<td>TOBACCO (pack/years)</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>AT 6/12 M</td>
</tr>
<tr>
<td>WEIGHT (kg)</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>CONTINUOUS</td>
</tr>
<tr>
<td>BMI (Kg/cm²)</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>CONTINUOUS</td>
</tr>
<tr>
<td>DIET ADHERENCE</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>CONTINUOUS</td>
</tr>
<tr>
<td>TREATMENT ADHERENCE</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>CONTINUOUS</td>
</tr>
<tr>
<td>SYSTOLIC BP</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>CONTINUOUS</td>
</tr>
<tr>
<td>DIASTOLIC BP</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>CONTINUOUS</td>
</tr>
<tr>
<td>HR</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>CONTINUOUS</td>
</tr>
<tr>
<td>ECG</td>
<td>+</td>
<td></td>
<td></td>
<td></td>
<td>IF HR ALERT</td>
</tr>
<tr>
<td>SLEEP PATTERN</td>
<td>+</td>
<td></td>
<td></td>
<td></td>
<td>CONTINUOUS</td>
</tr>
<tr>
<td>HB A1C LEVEL</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>AT 6/12M (IF AVAILABLE)</td>
</tr>
<tr>
<td>LDL/HDL CHOLESTEROL LEVEL</td>
<td>+</td>
<td></td>
<td></td>
<td></td>
<td>AT 6/12M (IF AVAILABLE)</td>
</tr>
<tr>
<td>SCORE CV RISK</td>
<td>+</td>
<td></td>
<td></td>
<td></td>
<td>AT 6/12M (IF AVAILABLE)</td>
</tr>
</tbody>
</table>

11.3.1.5 Additional Assessments for Mental Disorders

**PHQ-8 test** is an eight-item depression scale which is established as a valid diagnostic and severity measure for depressive disorders.

People with a score under 15 can be included in the mental health experimentation.

People with a score between 15 and 27 won’t be included because of the medical severity (moderately severe or severe).

In the end of the experimentation, the PHQ-8 test has to be filled up by all the participants following the mental health program.

The **Beck Depression Inventory (BDI)** is a 21-item, self-rated scale that evaluates symptoms of depression including mood, pessimism, sense of failure, self-dissatisfaction, guilt, punishment, self-dislike, self-accusation, suicidal ideas, crying, irritability, social withdrawal, indecisiveness, body image change. The BDI-II is scored by summing the ratings for the 21 items. Each item is rated on a 4-point scale ranging from 0 to 3. The maximum total score is 63. No arbitrary cut-off score for all purposes to classify different degrees of depression. The following guidelines have been suggested to interpret the BDI-II: minimal range = 0–13, mild depression = 14–19, moderate depression = 20–28, and severe depression = 29–63.
The Geriatric Depression Scale (GDS) is a self-report test of depression in older adults. Users respond in a “Yes/No” format. The GDS was originally developed as a 30-item instrument. The Geriatric Depression Scale: Short Form is a 15-question screening tool for depression in older adults that takes five to seven minutes to complete and can be filled out by the patient or administered by a provider with minimal training in its use. It is a useful screening tool in the clinical setting to facilitate assessment of depression in older adults especially when baseline measurements are compared to subsequent scores. Answers indicating depression are in bold; score one point for each bolded answer. A score of 0 to 5 is normal. A score > 5 suggests depression. A score ≥ 10 is almost always indicative of depression.

Hamilton Rating Scale for Depression (HRSD), abbreviated HAM-D, is a multiple item questionnaire used to provide an indication of depression, and as a guide to evaluate recovery. Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0–56, where <17 indicates mild severity, 18–24 mild to moderate severity and 25–30 moderate to severe.

State-Trait Anxiety Inventory (STAI) is a psychological inventory based on a 4-point Likert scale and consists of 40 questions on a self-report basis. The STAI measures two types of anxiety – state anxiety, or anxiety about an event, and trait anxiety, or anxiety level as a personal characteristic. The range of possible scores for form Y of the STAI varies from a minimum score of 20 to a maximum score of 80 on both the STAI-T and STAI-S subscales. STAI scores are commonly classified as “no or low anxiety” (20-37), “moderate anxiety” (38-44), and “high anxiety” (45-80). (State anxiety reflects the psychological and physiological transient reactions directly related to adverse situations related to a specific period of time or condition, whereas trait anxiety refers to a trait of personality, describing individual differences with the propensity to state anxiety.)

### 11.3.1.6 Additional Assessments for Cognitive Disorders

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Involves</th>
<th>Duration (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mini-Mental State Examination (MMSE)</td>
<td>Participant</td>
<td>10</td>
</tr>
<tr>
<td>Clock Drawing Test (CDT)</td>
<td>Participant</td>
<td>5</td>
</tr>
<tr>
<td>Verbal Fluency Test (VFT)</td>
<td>Participant</td>
<td>5</td>
</tr>
<tr>
<td>Yesavage Geriatric Depression Scale (GDS)</td>
<td>Participant (self)</td>
<td>5</td>
</tr>
<tr>
<td>Everyday Cognition - 12 (ECog-12)</td>
<td>Study partner</td>
<td>5</td>
</tr>
<tr>
<td><strong>TOTAL time (min)</strong></td>
<td></td>
<td><strong>30</strong></td>
</tr>
</tbody>
</table>

### 11.3.1.7 Additional Assessments for Frailty

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Involves</th>
<th>Duration (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edmonton Frailty Scale (EFS)</td>
<td>Participant</td>
<td>10</td>
</tr>
<tr>
<td><strong>TOTAL time (min)</strong></td>
<td></td>
<td><strong>10</strong></td>
</tr>
</tbody>
</table>
11.4 A hierarchical security architecture for the SMART BEAR project

Risk Factor is any element that can increase or decrease the level of risk where a vulnerability is present or when an adverse unexpected event occurs. Here below some Layer-related situations are listed that can put the SMART BEAR at risk in terms of efficiency and security and/or can condition the actual ability of the patients to take part in the program.

On the one hand the use of SMART BEAR devices represents a promising opportunity to preserve the health and well-being of people, especially the elderly. On the other hand, issues are posed related to the efficiency and the efficacy of devices that can affect the patient’s health both directly and indirectly, therefore it is important to include these issues as risk factors in the Clinical Risk Assessment. Moreover, as many devices can be connected to other devices and healthcare repositories via networking structures, in assessing and managing the risks we must change our focus from the patient using the devices to an integrated system based on the patient, the device, and the network, not being fulfilling the prevision and the management of their respective issues to guarantee the integrity and the security of the whole system. For example, a data breach occurring, or a network being hacked can increase the patient’s vulnerability to adverse events. Thus, our system must be not only secure and resistant but also resilient. To better explain, a resilient cyber-physical system is allowed to attain a given level of operational normalcy, and it concerns issues that stand at the interface between the cyber world and the physical environment. For what concerns the physical world, we need to use controller devices designed to be resilient by incorporating features such as robustness and reliability.

In their article «A hierarchical security architecture for cyber-physical systems», Q. Zhu, C. Rieger and T. Başar proposed a hierarchical viewpoint to address IT security issues related to a power plant in a holistic cross-layer philosophy and ensure dependability, security, and privacy.

<table>
<thead>
<tr>
<th>LAYER</th>
<th>ELEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management</td>
<td>Management Board</td>
</tr>
<tr>
<td>Supervisory</td>
<td>Administrator</td>
</tr>
<tr>
<td>Network</td>
<td>Router</td>
</tr>
<tr>
<td>Communication</td>
<td>Private Network, Internet, Wireless</td>
</tr>
<tr>
<td>Control</td>
<td>Control devices</td>
</tr>
<tr>
<td>Physical</td>
<td>Power Plant</td>
</tr>
</tbody>
</table>

In this model, the supervisory layer coordinates the whole system by designing and sending appropriate commands; Its main function is to perform critical data analysis or fusion to provide an immediate and precise assessment of the situation.
The SMART BEAR project can actually be considered in terms of Risk Assessment and Management as being an integrated system based on an IT structure and physical elements. Therefore, a hierarchical organizational model for the management of the risks related to our system can be defined while performing the patient’s recruitment and the pilot phases. In order to check the effective and safe functioning of the devices the quality of the data must be monitored continuously. In other terms, both the patients and the devices are subject to control. Moreover, the SMART BEAR App allows the user to monitor his/her parameters and the functioning of the devices by him/herself and is connected to the SMART BEAR platform as an additional source of data readily available for testing and monitoring according to a principle of accountability. The respective hierarchy in a patient-centred perspective (PCP) and a device-centred perspective (DCP) is defined in the following table and diagram.

<table>
<thead>
<tr>
<th>LAYER</th>
<th>ELEMENT (PCP)</th>
<th>ELEMENT (DCP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management</td>
<td>Management Board</td>
<td>Management Board</td>
</tr>
<tr>
<td>Supervisory</td>
<td>Administrator</td>
<td>Administrator</td>
</tr>
<tr>
<td>Network</td>
<td>SMART BEAR Hub</td>
<td>SMART BEAR Hub</td>
</tr>
<tr>
<td>Communication</td>
<td>Private Network, Internet, Wireless</td>
<td>Private Network, Internet, Wireless</td>
</tr>
<tr>
<td>Control</td>
<td>SMART BEAR devices</td>
<td>SMART BEAR app</td>
</tr>
<tr>
<td>Physical</td>
<td>Patients</td>
<td>SMART BEAR devices</td>
</tr>
</tbody>
</table>
11.4.1 The SMART BEAR project in an IoT perspective

IoT is an acronym for “Internet of Things”. IoT is a connection of embedded devices, with a network: an embedded device is an object that completely encloses a special-purpose computing system. The SMART BEAR system can be also be considered an IoT-type system because it is made up of personal devices each having a specific purpose and a network that connects them with the SMART BEAR platform.

The 4 common components of an IoT system are:
1. Sensor
2. Application
3. Network
4. Backend (Data Center)

In our case we can identify the following components:
1. SMART BEAR device
2. SMART BEAR and device applications
3. Network
4. SMART BEAR cloud

11.4.2 Different responsibilities in risk evaluation

The phase requiring the greatest attention is the monitoring one, where all the three elements of the integrated system (the patient, the device and the network) are actively involved. Here we are committed to define what role the different elements involved can have to contribute to the evaluation of risks, i.e. recognizing a situation that represents a risk.

Management Board
The Management Board is composed of representatives of the institutions involved and has the important task of performing:

- Health Technology Assessment (HTA), the systematic evaluation of the properties, effects and/or impact of health technologies. Its main purpose is to inform technology-related policymaking in health care, and thus improve the uptake of cost-effective new technologies and prevent the uptake of technologies that are of doubtful value for the health system;
- Data Protection Impact Assessment (DPIA) as required by GDPR to assess where in the SMART BEAR system the integrity and privacy of data can be threatened and what countermeasures can be adopted in case an adverse event occurs;
- Clinical Risk Assessment, the systematic evaluation of the elements contributing to the patient’s well-being and safety during the assessment.

The aforementioned assessment should be performed before the project starts and refined periodically on the basis of the PDCA model with newly discovered risk factors and reassessed risk factors.

**Administrator**

The Administrator is a key figure in our security model because he/she is in charge of coordinating the security system, implementing the needed countermeasures and make the management board aware of possible adverse events occurring.

**Testing of SMART BEAR devices**

IoT testing is a type of testing to check IoT devices. Testing for IoT devices broadly revolves around Security, Analytics, Device, Networks, Processors, Operating Systems, Platforms and Standards. When testing an IoT system we face the following challenges:

- Both the network and internal communication must be checked
- Security is a big concern in IoT platform as many tasks are operated using the Internet
- The complexity of the software may hide the presence of bugs
- Resource such as limitations in memory, processing power, bandwidth, battery life, etc. must be taken into account.

As a consequence, this kind of testing should be implemented as the SMART BEAR system can be considered as an IoT-type. The choice of the procedures and tools to adopt for testing can be discretion.

The broad types of testing are listed below.

**Usability testing**

Usability testing is a technique used in user-centred interaction design to evaluate a product by testing it on users. There are so many devices of different shape and form factors are used by the users. Moreover, the perception also varies from one user to others.

**Compatibility testing**

Compatibility Testing is a type of non-functional software testing to check whether a software is capable of running on different hardware, operating systems, applications, network environments or Mobile devices.
Reliability and Scalability Testing
Reliability testing is a software testing type, that checks whether the software can perform a failure-free operation for a specified period of time in a particular environment. The objective behind performing reliability testing are:

1. To find the structure of repeating failures
2. To find the number of failures occurring in the specified amount of time
3. To discover the main cause of failure
4. To conduct performance testing of various modules of software application after fixing a defect.

Scalability testing is the testing of a software application to measure its capability to scale up or scale out in terms of any of its non-functional capability. The main goals of scalability testing are to determine the user limit for the web application and ensure end-user experience, under a high load, is not compromised. Performance, scalability and reliability testing are usually grouped together by software quality analysts.

Data integrity testing
Data Integrity testing involves:

1. Checking whether or NOT a blank value or default value can be retrieved from the database
2. Validating each value if it is successfully saved to the database
3. Ensuring the data compatibility against old hardware or old versions of operating systems
4. Verifying the data in data tables can be modified and deleted
5. Running data tests for all data files, including clip art, tutorials, templates, etc.

Security testing
Security testing is a type of Software Testing that uncovers vulnerabilities, threats, risks in a software application and prevents malicious attacks from intruders. The purpose of the Security Tests is to identify all possible loopholes and weaknesses of the software system.

Performance testing
Performance testing is a testing practise performed to determine how a system performs in terms of responsiveness and stability under a particular workload.
### 11.4.3 Definition of Layer-related Risks Factor

#### Planning-related Risk Factors

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Presence of a Unity in charge of controlling the devices</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Presence of a DPIA (required by GDPR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adequate number of elements taken into account for the risk evaluation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Definition of formalized procedures for Risk evaluation in the IT system as a whole thing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Definition of procedures to evaluate and assess security problems before a new component is installed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Definition of formalized procedures to perform periodic detection of the risks and the levels of security and data protection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Definition of technical and organizational procedures to protect locally registered data and detect risks</td>
</tr>
</tbody>
</table>

#### Administration-related Risk Factors

<table>
<thead>
<tr>
<th>Situation</th>
<th>Indicators</th>
<th>Countermeasures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unanticipated risks</td>
<td>Frequent logging requests from an ID</td>
<td>Presence of levels of authorization</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Accessibility to the components defined in advance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Existence of logging control mechanisms</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Periodical checks of logging activities</td>
</tr>
<tr>
<td>Uncontrolled credentials spread</td>
<td>Frequent logging requests from an ID</td>
<td>Presence of periodical formalized security tests</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Implementation of periodical data integrity tests</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Necessity to send quick alerts to the end-users (required by GDPR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Presence of a team able to perform quick interventions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>System monitoring</td>
</tr>
<tr>
<td>Security-concerning accidents</td>
<td>Presence of periodical formalized security tests</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Implementation of periodical data integrity tests</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Necessity to send quick alerts to the end-users (required by GDPR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Presence of a team able to perform quick interventions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>System monitoring</td>
</tr>
</tbody>
</table>
### Connection of a new device
- Alert sent from the app to the administrator for approval
- Presence of a formalized procedure for their tracking
- Presence of a mechanism capable to detect and highlight the connection of new devices to the network
- Formalization of compatibility tests
- Management of an inventory of the devices connected to the network
- Possibility for the administrator to perform remote management of the configuration and the features of the devices

### Device not configured
- Data transfer rate = 0 (unit missing)
- Data reception rate = 0 (unit missing)
- Device ID not recognized
- Possibility for the administrator to perform remote management of the configuration and the features of the devices

### Accidents or adverse events in critical areas
- Presence of formalized reliability and scalability tests
- Presence of configurations that allow business continuity

### Accidents or adverse events for all healthcare activities
- Presence of formalized reliability and scalability tests
- Presence of configurations that allow business continuity

### Network-and-Data-Protection-related Risk Factors

<table>
<thead>
<tr>
<th>Situation</th>
<th>Indicators</th>
<th>Countermeasures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is BDA processing an adequate amount of data stored on the IT system?</td>
<td>Data transfer rate</td>
<td>Periodical backup of data from the repositories of the institution to the cloud</td>
</tr>
<tr>
<td></td>
<td>Data amount</td>
<td>Presence of periodical formalized tests on the BDA</td>
</tr>
<tr>
<td>Is the amount of data transferred adequate for the BDA purpose?</td>
<td>Data transfer rate on the app</td>
<td>Periodical backup of data from the devices to the cloud</td>
</tr>
<tr>
<td></td>
<td>Data reception rate</td>
<td>Presence of periodical formalized tests on the BDA</td>
</tr>
<tr>
<td>A significant volume of the data collected by the devices remains stored in the device memory</td>
<td>% occupied memory visualized on the app</td>
<td>Periodical backup on the cloud</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Periodical alert to end-user for data deletion</td>
</tr>
<tr>
<td>Personal data security (integrity, confidentiality, Lawfulness, fairness and transparency, accountability, purpose limitation, data minimization,</td>
<td></td>
<td>Presence of functionality for encrypting registered personal data</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Addition of noise on SMART BEAR hub</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Presence of a DPIA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Presence of periodical formalized data integrity tests</td>
</tr>
<tr>
<td>Issue Description</td>
<td>Proposed Solution</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Accuracy, storage limitation, integrity and confidentiality</td>
<td>Alerts sent to back users in case of data breach or leaks</td>
<td></td>
</tr>
<tr>
<td>Criticisms and adverse situations</td>
<td>Presence of functionalities to detect and signal criticisms and adverse events in function of the data registered in an automated and quick way</td>
<td></td>
</tr>
<tr>
<td>A device is not calibrated</td>
<td>Recalibration via the app by the administrator</td>
<td></td>
</tr>
<tr>
<td>A device is not calibrated</td>
<td>Device replacement</td>
<td></td>
</tr>
<tr>
<td>A device is not sending data</td>
<td>Presence of functionalities allowing to highlight which devices are connected and are sending data</td>
<td></td>
</tr>
<tr>
<td>A device is not sending data</td>
<td>Presence of functionalities allowing to launch an alert</td>
<td></td>
</tr>
<tr>
<td>Access to the different components of the system</td>
<td>Centralized management of the login credentials</td>
<td></td>
</tr>
<tr>
<td>Execution of different functionalities in the different components of the system</td>
<td>Centralized management of the access levels</td>
<td></td>
</tr>
<tr>
<td>Prolonged inactivity</td>
<td>Alert sent to the user</td>
<td></td>
</tr>
<tr>
<td>Prolonged inactivity</td>
<td>Use frequency testing</td>
<td></td>
</tr>
<tr>
<td>Prolonged inactivity</td>
<td>Automated withdrawal after a week of constant inactivity</td>
<td></td>
</tr>
<tr>
<td>Prolonged inactivity</td>
<td>Presence of automated functionalities to block the sessions</td>
<td></td>
</tr>
<tr>
<td>Presence of automated log mechanisms concerning the activities performed by a user</td>
<td>Require a relog</td>
<td></td>
</tr>
<tr>
<td>Necessity to access previous data values at a given moment (deletion right stated in GDPR must be respected)</td>
<td>The date of transfer or storing is an attribute in the database structure</td>
<td></td>
</tr>
<tr>
<td>Necessity to access previous data values at a given moment (deletion right stated in GDPR must be respected)</td>
<td>Complete backup</td>
<td></td>
</tr>
<tr>
<td>Necessity to access previous data values at a given moment (deletion right stated in GDPR must be respected)</td>
<td>Presence of mechanisms that allow to access single data at a certain moment</td>
<td></td>
</tr>
<tr>
<td>Management of an inventory of the devices connected to the network</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Connection of new devices to the network</td>
<td>Data transfer rate = 0 (unit missing)</td>
<td></td>
</tr>
<tr>
<td>Connection of new devices to the network</td>
<td>Alert sent from the app to the administrator for approval</td>
<td></td>
</tr>
<tr>
<td>Connection of new devices to the network</td>
<td>Device ID not recognized</td>
<td></td>
</tr>
<tr>
<td>Establishing a communication between edges of the network</td>
<td>Presence of routing mechanisms that enables the communication</td>
<td></td>
</tr>
<tr>
<td>The communication between the system components is at risk</td>
<td>Use of mechanisms and protocols capable of assure the protection of the communication</td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>No wireless connection</td>
<td>Data transfer rate = 0 (unit missing)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Presence of periodical formalized connectivity testing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alert sent via the app to the smartphone</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Physical warning on the smartphone</td>
<td></td>
</tr>
<tr>
<td>A guest caregiver must connect with the platform</td>
<td>Presence of formalized accessibility requirements</td>
<td></td>
</tr>
<tr>
<td>Presence of dangerous software codes</td>
<td>Alert</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Presence of formalized functionality testing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Presence of devices capable of detecting and removing dangerous software code</td>
<td></td>
</tr>
</tbody>
</table>

### Communication-related Risk Factors

<table>
<thead>
<tr>
<th>Situation</th>
<th>Indicators</th>
<th>Countermeasures</th>
</tr>
</thead>
<tbody>
<tr>
<td>A single component must communicate with a device or a smartphone without routing across SMART BEAR hub in case of emergency</td>
<td>Authorization requested for emergency end-to-end communication</td>
<td>Presence of a device or configuration allowing single components to communicate with external devices the organization network in case of emergency</td>
</tr>
</tbody>
</table>
11.5 Informed Participation & Consent Form and Information Sheet

11.5.1 About the SMART BEAR Project

11.5.1.1 SMART BEAR EU-funded Project

The SMART BEAR (“Smart Big Data Platform to Offer Evidence-based Personalised Support for Healthy and Independent Living at Home”) Project (hereafter the “SMART BEAR Project”) is an EU-funded project developing a platform with the aim of integrating heterogeneous sensors, assistive medical and mobile devices to enable the continuous data collection from the everyday life of the elderly, which will be analysed to obtain the evidence needed in order to offer personalised interventions promoting their healthy and independent living.

The SMART BEAR project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857172.

The SMART BEAR project started on 1 September 2019 and has a duration of 48 months. The monitoring phase for each participant has a duration of 12 months.

11.5.1.2 Project Participation

In the event you would like to participate in the SMART BEAR Project, such participation (hereinafter referred to as "Participation", "to Participate" or "Participating"), will include the following three phases:

1. Screening & Eligibility Assessment Phase. In a first phase, your eligibility for the study will be assessed by means of a brief demographic and medical history questionnaire and of a short testing of your cognition and dexterity.

2. Baseline & Additional Assessment Phase. In a second phase, and once your eligibility is verified, you will have a full assessment (physical examination and additional testing) according to your comorbidities. At the end of this phase, it will be decided which devices will be assigned to you and whether another person (caregiver, partner or clinician) will be involved and may receive notifications or alerts during your participation to the project.

3. Platform Testing & Validation Phase. In a third phase, the SMART BEAR platform will be tested and validated through pilots who will enable the evaluation of the platform in the context of healthcare service delivery by private and public providers at regional, state and EU level, and demonstrate its efficacy, extensibility, sustainability, and cost-effectiveness for the individual. Your data will assist the Partners in the testing and validation of the SMART BEAR Platform. As a result, you may be able to rely on a data privacy governance platform that answers to your expectations as an end-user.

Depending on your eligibility, you may or may not be requested to Participate in subsequent phases of the SMART BEAR Project. Participation is entirely voluntary and does not involve financial compensation. Potential disadvantages or risks of Participating are kept to a minimum. You will have the right to withdraw from the Participation at any time in the SMART BEAR Project.
### 11.5.1.3 SMART BEAR Project Partners

The Partners of the SMART BEAR Project are the following:

*Table 15: SMART BEAR partners*

<table>
<thead>
<tr>
<th>Organisation Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 CONSIGLIO NAZIONALE DELLE RICERCHE</td>
</tr>
<tr>
<td>2 ATOS SPAIN SA</td>
</tr>
<tr>
<td>3 PHILIPS ELECTRONICS NEDERLAND B.V.</td>
</tr>
<tr>
<td>4 IBM ISRAEL - SCIENCE AND TECHNOLOGY LTD</td>
</tr>
<tr>
<td>5 AZIENDA REGIONALE PER L'INNOVAZIONE E GLI ACQUISTI S.P.A.</td>
</tr>
<tr>
<td>6 PERIFEREIA PELOPONNISOU</td>
</tr>
<tr>
<td>7 MUNICIPALITY OF PALAIO FALIRO</td>
</tr>
<tr>
<td>8 COMUNITA SOCIALE CREMASCA ASC</td>
</tr>
<tr>
<td>9 FONDAZIONE CENTRO SAN RAFFAELE</td>
</tr>
<tr>
<td>10 ASSOCIATION CATEL CLUB DES ACTEURS DE LA TELEMEDECINE</td>
</tr>
<tr>
<td>11 IDCQ HOSPITALES Y SANIDAD S.L</td>
</tr>
<tr>
<td>12 FUNDATIA ANA ASLAN INTERNATIONAL</td>
</tr>
<tr>
<td>13 FOUNDATION FOR RESEARCH AND TECHNOLOGY HELLAS</td>
</tr>
<tr>
<td>14 ETHNIKO KAI KAPODISTRIAKO PANEPISTIMIO ATHINON</td>
</tr>
<tr>
<td>15 PANEPISTIMIO IOANNINON</td>
</tr>
<tr>
<td>16 UNIVERSITA DEGLI STUDI DI MILANO</td>
</tr>
<tr>
<td>17 UNIVERSIDAD DEL PAIS VASCO/ EUSKAL HERRIKO UNIBERTSITATEA</td>
</tr>
<tr>
<td>18 CITY UNIVERSITY OF LONDON</td>
</tr>
<tr>
<td>19 INSTITUTE OF COMMUNICATION AND COMPUTER SYSTEMS</td>
</tr>
<tr>
<td>20 SPHYNX TECHNOLOGY SOLUTIONS AG</td>
</tr>
<tr>
<td>21 STREAM VISION</td>
</tr>
<tr>
<td>22 IT SUPPORT SOLUTIONS SRL</td>
</tr>
<tr>
<td>23 INNOVATEC SENSORIZACION Y COMUNICACION, S.L.</td>
</tr>
<tr>
<td>24 ATHENS TECHNOLOGY CENTER ANONYMI BIOMICCHANIKI EMPORIKI KAI TECHNIKI ETAIREIA EFARMOGON YPSILIS TECHNOLOGIAS</td>
</tr>
<tr>
<td>25 BIRD &amp; BIRD</td>
</tr>
<tr>
<td>26 UNINOVA-INSTITUTO DE DESENVOLVIMENTO DE NOVAS TECNOLOGIAS-ASSOCIACAO</td>
</tr>
<tr>
<td>27 SECRETARIA REGIONAL DA SAUDE</td>
</tr>
</tbody>
</table>
11.5.1.4 SMART BEAR Project contact details

Table 16: Contact details of the SMART BEAR project

<table>
<thead>
<tr>
<th>Project Coordinator</th>
<th>Technical Coordinator</th>
<th>Clinical Coordinator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Giuseppe De Pietro</td>
<td>George Spanoudakis</td>
<td>Thanos Bibas</td>
</tr>
<tr>
<td>CONSIGLIO NAZIONALE</td>
<td>SPHYNX TECHNOLOGY</td>
<td>ETHNIKO KAI KAPODISTRIAKO</td>
</tr>
<tr>
<td>DELLE RICERCHE</td>
<td>SOLUTIONS AG</td>
<td>PANEPISTIMIO ATHINON</td>
</tr>
<tr>
<td><a href="mailto:coordinator@icar.cnr.it">coordinator@icar.cnr.it</a></td>
<td><a href="mailto:spanoudakis@sphynx.ch">spanoudakis@sphynx.ch</a></td>
<td><a href="mailto:nkua.smartbear@gmail.com">nkua.smartbear@gmail.com</a></td>
</tr>
</tbody>
</table>

11.5.2 About the Participant

In the event you would like to participate in the SMART BEAR project, please provide us with the following information, which will be processed in accordance with the below Information Sheet (the "Privacy Policy"): 

First name  

Last name  

Organisation  

Title/function  

Email address  

11.5.3 Participation & Consent

Table 17: Template of the Participation & Consent Form

I volunteer to participate in all three phases of the SMART BEAR Project as described above in Section 11.5.1.2.  

Yes ☐ No ☐

I understand that, depending on my eligibility, I may or may not be requested to Participate in subsequent phases of the SMART-BEAR Project.  

Yes ☐ No ☐

I understand that my participation is voluntary (my choice).  

Yes ☐ No ☐

I understand that I will not receive any financial compensation for my participation.  

Yes ☐ No ☐

I am aware that I have the right to withdraw from the Participation at any time in the SMART BEAR Project.  

Yes ☐ No ☐

I understand that participation may involve being interviewed, researched and examined by researchers, doctors and medical assistants.  

Yes ☐ No ☐

I understand that participation may involve being interviewed by researchers and members of the SMART BEAR Project and that I may be recorded during such interview.  

Yes ☐ No ☐

I am aware that the SMART BEAR platform will generate and send notifications, alerts and regular reports to me and to my caregiver or responsible clinician.  

Yes ☐ No ☐

I have read and understood the explanation and documentation provided to me about the SMART BEAR Project.  

Yes ☐ No ☐

I have read and understood the Privacy Policy and I consent to the processing of my personal data as described in the Privacy Policy (see underneath).  

Yes ☐ No ☐

I agree to have my name mentioned in the reports to be submitted to the European Commission.  

Yes ☐ No ☐

I have had all my questions answered to my satisfaction.  

Yes ☐ No ☐
I know who to contact if I have any question about the SMART BEAR Project, my participation thereto or my privacy.

Yes ☐ No ☐

I have been given a copy of this informed participation & consent form.

Yes ☐ No ☐

First name
_____________________________________________________

Last name
_____________________________________________________

Signature
_____________________________________________________

Date
________________ City / Town _________________________

11.5.4 Information Sheet (Privacy Policy)

11.5.4.1 Scope of this policy

This information sheet (hereafter "Privacy Policy") describes how your personal data is collected, used and otherwise processed in the context of the SMART BEAR Project.

This Privacy Policy includes a description of your data protection rights, including a right to object to some of the processing activities we carry out.

In this Privacy Policy:

- "We" or "us" refer to the Partners of the SMART BEAR Project listed in Section 11.5.1.3 above, who will process your personal data as data controllers and as described herein. The SMART BEAR Project Partners can be contacted collectively through the contact details provided in Section 11.5.1.4, and notably by sending an email to [mail contact].

- "Data Protection Legislation" means the Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (the "GDPR")\(^\text{14}\), as well as any legislation and/or regulation implemented or created pursuant to the GDPR and the e-Privacy legislation, or which amends, replaces, re-enacts or consolidates any of them, and all other national applicable laws relating to processing of personal data and privacy that may exist under applicable law.

- The terms "controller", "processor", "third party", "supervisory authority", "personal data", "processing", "data subject", shall have the meanings set out in the applicable Data Protection Legislation.

11.5.4.1.1 What personal data is processed?

In the context of the SMART BEAR Project, your personal data is processed by the Partners, as follows:

- **Processing purpose(s):** for the purpose of Participating in the SMART BEAR Project, as described in Section 11.5.1.2 above.

• **Processed data categories:**
  
  • In the Screening & Eligibility Assessment Phase, the following of your personal data will be processed: *demographics, marital situation, medical history, HUI and MOCA tests.*
  
  • In the Baseline & Additional Assessment Phase, the following of your personal data will be processed: *medical history, medication and nutritional habits, physical examination (height, temperature, blood pressure, heart rate, weight etc) and additional testing (audiological testing, questionnaires related to cognitive function or mood etc) according to your comorbidities.*
  
  • In the Platform Testing & Validation Phase, the following of your personal data will be processed: first name, last name, organisation, title/function, email address, any information you decide to share with us through discussions, interviews, correspondence and questionnaires, clinical information during the baseline and follow-up visits, data providing performance, satisfaction, motivation feedback from participants’ point of view, physiological parameters measured by SMART BEAR devices like blood pressure, habits such as physical activity, hours of usage of devices, frequency of social interactions, environmental data concerning participants region.
  
  • **Source of data:** from you, from discussions with the clinical team of the SMART BEAR project, from clinical assessments during the baseline and follow up visits, your interaction with SMART BEAR platform, measurements/observations of the wearable and medical devices provided to you (such as 3-axis accelerometer, ECG monitors, hearing aids, gyroscope, blood pressure monitor and heart rate monitor), home sensors (light levels, motion sensors, temperature sensors), mobile (embedded camera, time of use) and environmental data through Copernicus or other open access services; from self- or clinician-reporting questionnaires (such as Glasgow Hearing Aid Benefit (GHAB), Montreal Cognitive Assessment (MOCA), mini BESTTest, Spielberger State-Trait Anxiety Inventory (STAI), Functional Gait Assessment (FGA), Activities Specific Balance Confidence Scale (ABC), Falls Efficacy scale international (FES-I), Rapid Assessment of Physical Activity (RAPA)) and from Processed data providing performance, satisfaction, motivation etc. metrics that inform clinician’s decisions.
  
  • **Legal basis:** Your consent, as provided in Section 11.5.3. You may withdraw that consent at any time you choose and at your own initiative by contacting us at [mail contact]. The withdrawal of your consent will not affect the lawfulness of the collection and processing of your data based on your consent up until the moment where you withdraw your consent.

We rely on the following organisations to process your personal data¹⁵:

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<table>
<thead>
<tr>
<th>Organisation (data processor)</th>
<th>Processed data categories</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>[...]</td>
<td>[...]</td>
<td>[...]</td>
</tr>
<tr>
<td>[...]</td>
<td>[...]</td>
<td>[...]</td>
</tr>
</tbody>
</table>

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¹⁵ The list of processors will be filled out by each pilot separately at a later stage.
11.5.4.2 How long is your personal data stored?
We retain your personal data for the duration of the SMART BEAR Project (i.e. until 31 August 2023) or for a shorter period as long as your data are required to fulfil the activities set out in the Participation Form and this Privacy Policy. After such period your personal data may be archived, where possible in an anonymised format, in accordance with applicable legal requirements. We may also retain your personal data if it is reasonably necessary to comply with any legal obligations, meet any regulatory requirements, resolve any disputes or litigation, or as otherwise needed to enforce this Privacy Policy and prevent fraud and abuse.
To determine the appropriate retention period for the information we collect from you, we consider the amount, nature, and sensitivity of the personal data, the potential risk of harm from unauthorised use or disclosure of the data, the purposes for which we process the personal data, and whether we can achieve those purposes through other means, and the applicable legal requirements.

11.5.4.3 How is your personal data shared with third parties?
We only share or disclose information as described in the Participation Form and this Privacy Policy, including with third parties. Your personal data will also be shared with government authorities and/or law enforcement officials if required for the purposes above, if mandated by law or if required for the legal protection of the data controller(s) legitimate interests in compliance with applicable laws.

11.5.4.4 Is your personal data transferred outside the European Economic Area (EEA)?
We do not intend to transfer the data that we collect from you to a destination outside the EEA. Should this however become the case (e.g. as a result of Brexit), we will put in place appropriate safeguards to ensure that such transfers comply with Data Protection Legislation, either by putting in place Standard Contractual Clauses approved by the European Commission as ensuring an adequate protection or by ensuring that the transfer is done to an organisation that complies with Privacy Shield in case the transfer is made to the United States of America. Please note that the data processors listed in Table 18 may store or transfer your personal data outside the EEA. In such event, we will verify that the appropriate safeguards to ensure adequate protection of your data are in place.

11.5.4.5 What are your rights?
Once you have provided your personal data, several rights are recognized under the Data Protection Legislation, which you can in principle exercise free of charge, subject to statutory exceptions. In particular, you have the following rights:

- **Right to withdraw your consent**: you may withdraw your consent at any time you choose and at your own initiative by contacting us at [mail contact]. The withdrawal of your consent will not affect the lawfulness of the collection and processing of your data based on your consent up until the moment where you withdraw your consent.

- **Right to access and rectify your data**: you have the right to access, review, and rectify your personal data. You may be entitled to ask us for a copy of your information, to review or correct it if you wish to review or rectify any information. You may also request a copy of the
personal data processed as described herein by sending an email to [mail contact]. You can access and review this information and, if necessary, ask to rectify your information.

- **Right to erasure**: you have the right to the erasure of all the personal data processed by as described herein in case it is no longer needed for the purposes for which the personal data was initially collected or processed, in accordance with the Data Protection Legislation.
- **Right to object or restriction of processing**: under certain circumstances described in the Data Protection Legislation, you may ask for a restriction of processing or object to the processing of your personal data.
- **Right to data portability**: under certain circumstances described in the Data Protection Legislation, you have the right to receive the Personal Data processed in a format which is structured, commonly used and machine-readable and to transmit this data to another service provider.

These rights may be limited, for example, if fulfilling your request would reveal personal data about another person, or if you ask us to delete information which we are required by law to keep or have compelling legitimate interests in keeping.

To exercise any of these rights, you can get in touch with us using the details set out below. If you have unresolved concerns, you have the right to lodge a complaint with an EU data protection authority where you live, work, or where you believe a breach may have occurred.

11.5.4.6 **What security measures are put in place?**
Appropriate technical and organisational measures are implemented in order to ensure an appropriate level of security of your personal data.

In the event personal information is compromised as a result of a security breach and where the breach is likely to result in a high risk to your rights and freedoms, we will make the necessary notifications, as required under the Data Protection Legislation.

11.5.4.7 **How can we be contacted?**
Questions, comments, remarks, requests or complaints regarding this Privacy Policy are welcome and should be addressed to [mail contact].

11.5.5 **Study Discontinuation Form**
1. Participant ID
2. Pilot / Site Involved
3. Reason for Withdrawal

Participant has missed 15 consecutive days of device usage.

Participant has an acute/severe illness or injury of > 1-week duration that severely impacts upon their ability to continue to fully participate in SMART BEAR activities.

Participant has suffered acute neurological impairment (e.g. TIA, Stroke) or loss of vision.

Ineligibility (either arising during the study or retrospective having been overlooked at screening)
Significant protocol deviation

Consent withdrawn

Lost to follow up

Investigator’s comment:
11.6 *Indicative advertisement material*

**SMART BEAR**

Are you over the age of 67?

Are you facing everyday health challenges such as **hearing loss, heart problems, depression, memory loss or imbalance**?

Are you interested in participating in **SMART BEAR**?

**SMART BEAR** is a **EU H2020** research project that is aiming at implementing state-of-the-art technology such as **smartphones, smart hearing aids, smart home sensors and other smart devices** in the everyday life of **5100 citizens in 6 European Countries**!

For more details, please contact:
Are you over the age of 67?

Are you facing everyday health challenges such as hearing loss, heart problems, depression, memory loss or imbalance?

Are you interested in participating in SMART BEAR?

SMART BEAR is a EU H2020 research project that is aiming at implementing state-of-the-art technology such as smartphones, smart hearing aids, smart home sensors and other smart devices in the everyday life of 5100 citizens in 6 European Countries!

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