D5 – SMART BEAR Requirements

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D2.1 (D5) – SMART BEAR Requirements

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Executive Summary

It is a fact that the European population growth is slowing down, while the population ageing accelerates. Rapid increases in the elderly population are predicted for the coming decades due to the ageing of post-war baby births. Motivated by the above, the aim of the SMART BEAR platform is to integrate 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 personalized interventions promoting their healthy and independent living. The platform will also be connected to hospitals and other health care service systems to obtain data of the end-users (e.g., medical history) that will need to be considered in making decisions for interventions.

SMART BEAR will leverage big data analytics and learning capabilities, allowing for large scale analysis of the above-mentioned collected data, to generate the evidence required for making decisions about personalized interventions. Privacy-preserving and secure by design data handling capabilities, covering data at rest, in processing, and in transit, will cover comprehensively all the components and connections utilized by the SMART BEAR platform.

This deliverable describes the process to elicit and classify the SMART BEAR requirements. From the perspective of the health and well-being of the elderly, this will cover requirements related to managing the five main medical conditions covered, as well as Frailty, in the everyday lives of the elderly, and the corresponding risks. Moreover, aspects such as promoting active (physically and cognitively) living, healthy nutritional and social habits, and providing conditions that facilitate safe, independent living and improving the quality of life of the elderly are considered. From the perspective of platform requirements, we investigate the interfacing capabilities, computing and networking capabilities, conducting an up-to-date analysis of the pertinent technological landscape, and the identification, specification, and prioritization of system requirements for it. We also include an initial list of user-related requirements, such as user interfacing, access control, and visualization. Finally, we specify the legal requirements to comply with data protection regulation in the EU. The results of this deliverable will be further refined in D2.2 and during the Piloting stages (WP7-WP12).

More specifically, this document is organized in the following way. Section 1 provides an introduction to the background of the projects and to the goals of this deliverable. The state of the art is introduced Section 2, addressing Smart and eHealth technologies, in the framework of the WHO guidelines on intrinsic capacity, in Section 2.2 and medical treatments in Section 2.4. The requirement elicitation methodology adopted in SMART BEAR is introduced in Section 3. The dimensions and complexity of the project required to organize the requirement elicitation process in multiple stages. The domain analysis is addressed by the results of Section 2; requirement gathering is addressed by focus groups and questionnaires submitted to different stakeholders of the project such as clinicians, patients, legal experts and experts in technological solutions for Ambient Intelligence and Smart eHealth solutions; requirement integration, validation, and prioritization is addressed by workshops aimed at analysing the results achieved in the different pilots. Section 4 collects the materials produced in the requirement gathering of clinical requirements and offers a focus on the results obtained within the different activities organized by the project. Section 5 collects the materials produced in the requirement gathering of technological requirements and offers a focus on the evaluation of their consistency and awareness within the consortium. Section 6 proposes a detailed focus on the legal aspects that are inherent to the project and must be reflected in the SMART BEAR platform to get compliance with the GDPR regulations. Section 7 goes to the conclusions highlighting that the requirement elicitation process will not be stopped with this deliverable but is an ongoing activity of the project consciously updated.
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<td>ABPM</td>
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<td>ADL</td>
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<td>AF</td>
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<td>API</td>
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1 Introduction

1.1 Background and motivation

The European population growth is slowing down, while population ageing accelerates [1]. In particular, rapid increases in the elderly population are predicted for the coming decades, due to the ageing of post-war baby boomers. Eurostat projects that the ratio of people aged 65 and over relative to those of working age (15-64 years), namely the old-age dependency ratio, is projected to increase from 28.8% to 51.6% between 2015 and 2060 in the EU-28’s populations [2].

In parallel, due to the slightly declining proportion of children, the total age dependency ratio, is projected to rise from 53.2% in 2016 to 79.7% in 2080 [3]. The progressive decline in physical and cognitive skills prevents elderly people from living independently and from performing basic instrumental activities of daily living. These trends are putting significant pressure on age-related public expenditure in the 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 GDP for long-term care [4]. Amongst the ten most prevalent health challenges leading to physical injuries that elderly people are faced with and which affect their ability to have a healthy and independent living [5] are hearing loss (HL), Cardio Vascular Diseases (CVDs; namely hypertension, ischemic heart disease, heart failure), Cognitive Impairments (CI), , Balance Disorders (BD).

In tandem with the above, the prevalence of Frailty in elderly people ranges from 33% to 88% depending on the criteria used and increases steadily with age. When people are frail it takes only a minor life incident to tip them from independence to dependence [6]. Frailty and comorbidity are clinical manifestations of 2 distinct ageing-related processes, namely diminished functional reserve and accumulation of pathological processes. Nevertheless, frailty and comorbidity often overlap in the elderly and lead to impairment in quality of life and functional status [7]. Wong et al [8] recently reported that among community dwelling seniors who are frail 82% have comorbidities, 29% have a disability in at least one activity of daily living (ADL), and 93% have a disability in at least one instrumental activity of daily living (IADL). A similar overlap between frailty, comorbidity, and disability has been reported among Cardiovascular Health Study participants (Figure 1) [9].

Over recent years, there has been an increase in interest in e-health monitoring systems situated at homes, leading to the creation of Health Smart Homes. Such technologies can facilitate the monitoring of patients’ activities and enable healthcare services at home. They improve the quality of elder population well-being in a non-obtrusive way, allowing greater independence, maintaining good health, preventing social isolation for individuals and delay their placement in institutions such as nursing homes and hospitals. Their development was enabled by major advances in wireless technology and computing power, leading to an increasing number

![Figure 1: Extent of overlap of frailty with ADL disability & comorbidity ≥ 2 diseases](image)
of connected medical devices that can generate, collect, analyse and transmit data. 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. The IoMT is rapidly transforming healthcare delivery. More specifically, connectivity between sensors and devices is enabling health care organisations to streamline their clinical operations and workflow management, and improve older adults care, even from remote locations, such as their home.

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 platform will also be connected to healthcare service providers’ systems to obtain data (e.g., medical history) that may need to be considered in making decisions for interventions. SMART BEAR will leverage big data analytics and learning capabilities, allowing for large scale analysis of the abovementioned collected data, to generate the evidence required for making decisions about personalised interventions. Privacy-preserving and secure by design data handling capabilities, covering data at rest, in processing, and in transit, will cover comprehensively the SMART BEAR platform. The SMART BEAR solution will be validated through five largescale pilots involving 5,100 elderly living at home in Greece, Italy, Portugal, France, Spain, and Romania.

Figure 2: The SMART BEAR concept

Figure 3 shows the envisaged SMART BEAR platform high-level architecture, highlighting the basic building blocks realising each of the main elements of the SMART BEAR concept, as presented in Figure 2. The platform will feature a SMART BEAR @ Home instance, deployed in the monitored living environment of each of the end-users, as well as the backend SMART BEAR Cloud, where all aggregated data will be collected and analysed to enable the intelligent personalised interventions covering the targeted conditions as well as the general health and well-being of the elderly, extending their independent living. The key aspects of the envisaged concept are detailed in the subsections below.
Figure 3: Envisaged SMART BEAR platform
1.2 Goals of the deliverable

This deliverable describes the process to elicit and classify the SMART BEAR requirements. From the perspective of the health and well-being of the elderly, this will cover requirements related to managing the five main medical conditions covered, as well as Frailty, in the everyday lives of the elderly, and the corresponding risks. Moreover, aspects such as promoting active (physically and cognitively) living, healthy nutritional and social habits, and providing conditions that facilitate safe, independent living and improving the quality of life of the elderly are considered. From the perspective of platform requirements, the aim is to investigate the interfacing capabilities, computing and networking capabilities, conducting an up-to-date analysis of the pertinent technological landscape, and the identification, specification, and prioritization of system requirements for it. The deliverable also includes an initial list of user-related requirements, such as user interfacing, access control, and visualization. Finally, we specify the legal requirements to comply with data protection regulations in the EU. The results of this deliverable will be further refined in D2.2 and during the Piloting stages (WP7-WP12).

As explained in Section 3 the requirement elicitation methodology adopted in SMART BEAR is organized in multiple stages. Domain analysis is initially addressed. Requirement gathering is addressed by focus groups and questionnaires submitted to different stakeholders of the project such as clinicians, patients, legal experts and experts in technological solutions for Ambient Intelligence and Smart eHealth solutions. Requirement integration, validation, and prioritization are addressed by workshops aimed at analysing the results achieved in the different pilots. Section 4 collects the materials produced in the requirement gathering of clinical requirements and offers a focus on the results obtained within the different activities organized by the project. Section 5 collects the materials produced in the requirement gathering of technological requirements and offers a focus on the evaluation of their consistency and awareness within the consortium. Section 6 proposes a detailed focus on the legal aspects that are inherent to the project and must be reflected in the SMART BEAR platform to get compliance with the GDPR regulations.

It is important to underline that the SMART BEAR requirement elicitation process will not be stopped with this deliverable but is an ongoing activity of the project that will consciously be updated by the results archived in the Piloting stages that the consortium will develop.

2 State of The Art (Technologies)

The current state of the art and practice in these areas and the innovations that SMART BEAR will bring are reviewed in the following subsections.

2.1 Leveraging Smart Home/IoT Environments in eHealth

In the domain of health smart homes several sensing systems have been developed for monitoring and assessing the abilities of persons. However, most of them operate in isolation from the real requirements of the healthcare institutions which contributes to a high incidence of unsuccessful projects [10]. As stated in [11] none of the current approaches systematically consider the person’s context (health status and behaviour) as defined by the medical domain of geriatrics regarding the dependency concept. This missing link creates a high uncertainty in the adoption of such e-health systems. Therefore, it is important to improve context-aware HMS for ensuring their integration into health institutions. One aspect regards the interconnection and networking of large numbers of heterogeneous smart objects and IoT solutions, covering different communication technologies (Bluetooth, RFID, Zigbee, 802.11, 802.15.4 etc.), running a variety of often proprietary protocols and applications, with limited exposed interfaces. Aiming to alleviate the interoperability issues, various IoT platforms are emerging, either domain-specific (e.g. AAL [12], developed in the context of Ambient Assisting Living) or general-purpose platforms (e.g. FI-WARE [13] and the Google App engine [14], developed to provide technical services for different domains). This situation makes it difficult to introduce a brand-new platform; applications and developers rely on existing platforms and their services; thus, future platforms need to be able to be interoperable with the existing ones. Beyond interoperability traditional monitoring systems tend
to manage all sensed data with unconditional processing. Most of them adopt a continuous monitoring strategy that negatively affects resource usage and relevance of decisions. Such long-term monitoring consumes storage, uses energy for multiple sensors, increases computational costs required to analyze data, and increases network usage leading to transmission failures. Handling huge amounts of data can also impair the system in triggering relevant and quick decisions. In order to enhance the reliability of data transmission and the availability of high relevant contextual information, there is a need to define efficient data summarizing and filtering mechanisms applied with a conditional scheme.

Intelligent assistive technologies extend the scope of recovery programs by fostering rich interactions with the user, such as games and cognitive or locomotor tests [68] to know if the patient has progressed in his medical recovery or to drive personalized plans.

Successful treatment of patients requires exploiting not only their individual medical profiles, but also their habits, wills, and dislikes. To achieve this, it is necessary to keep track of the history of user activities, properly abstracted at a level that facilitates revisiting and processing of the past, in order to make predictions and decisions about the present. Typically, raw data are represented as time-series of entities, called events and defined by time-points, while their high-level representation is implemented by temporal abstractions [46] or properly structured, time-stamped hierarchical ontologies, called episodes [47]. A critical issue on knowledge deduction and abstraction from past experiences regards the storage of associations between events and episodes. These can be effectively revealed with the use of Temporal Association Rules [48] that identify frequent antecedent-consequent relations between events. The representation of past episodes between SMART BEAR and the human can significantly enhance the personalization of the system's functionality. Comparing multiple events simultaneously, the learning system is able to generalize knowledge [49] [50]. In addition, the representation and recall of past events provides a way of exploiting previous positive and negative states, which can be useful later for decision-making [51][52]. Decisions which were useful in the past may be employed to solve current situations. Decisions which did not succeed may be avoided.

2.2 **WHO Guidelines on Integrated Care for Older People**

The World Health Organization (WHO) has set the goal of enabling healthy ageing by sustaining the functional abilities elderly people. To achieve the goal, the WHO is advocating the contribution of outreach health workers in enabling elderly people to live a healthy life. The idea should be to not only focus on the medical ailment but also conduct a thorough assessment of the needs of the elderly people, and primary care workers have a crucial role to play. A, special emphasis is given to the integration of available services for varied conditions. The recently released guidelines by the WHO has recommended for better coordination between health and social care providers. In this context, evidence-based approaches for performing a comprehensive assessment and formulation of appropriate care plans are also recommended.

WHO has recognized that technology can play a key role in achieving the goal of providing integrated services in proximity of the patient, using evidence-based guidance. Due to its support for the integration and cost-effective delivery of services, technology is also recognized as a key asset in order to move closer to the achievement of universal health coverage for all at all ages.

The WHO Guidelines on Integrated Care for Older People (ICOPE) [69] was reflected in a mobile App1 helping the health and social care providers, and the patient itself, in monitoring and coordinating care plans. The ICOPE approach embodies the focus on optimizing intrinsic capacity and functional ability as the key to healthy ageing. Following the guidelines this mobile App set out six areas, one for each domain of intrinsic capacity, and allow the definition of evidence-based care to carry out person-centred integrated care for older people. The areas supported by the ICOPE App include mobility limitations, malnutrition, visual impairment and hearing loss, cognitive decline, and depressive symptoms (see Figure 4 for a reference). The interactive app guides health and social care workers step-by-step through the process of screening older people at risk of

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care dependency in the community, undertaking a person-centred assessment of older people’s health and social care needs, and designing a personalized care plan. The framework recommends specific actions depending on the extent of existing health and social services.

Figure 4  WHO iCOPE App

2.3 Technological Progress Beyond the State of the Art

SMART BEAR will advance state of the art in several aspects by designing the two focal platforms of the system: **SMART BEAR @ Home** and **SMART BEAR Cloud**.

**SMART BEAR @ Home** provides full specified integration of IoT objects by exploiting open source technology that allows the interoperable connection of heterogeneous devices, for efficient real-time data streaming. The runtime management and adaptation of these objects and the IoT applications they form, to accommodate the needs of users and consider the users’ context. The deployment of summarization, merging and filtering operations in real-time to compress the volume of data to be stored and transmitted and to comply with personal data protection regulation. SMART BEAR will capitalize on user profiling and the flexible and automatic customization of system functionality according to individual user characteristics. To enhance user satisfaction, temporal abstractions and data analytics will be combined to enable aggregating temporal abstraction of individual users to develop temporal abstractions of groups of users and additionally transfer behavioural characteristics and abstractions from one context and one user/group profile to another.

**SMART BEAR Cloud** provides a modular and distributed service for storage and analytics. It supports the extraction of high-level representations by temporal abstractions of data to effectively track the short- and long-term aspects of user behavioural characteristics by exploring associations with past episodes (what, when, how). It supports personalized decision support by implementing abstractions summarizing user needs at multiple time scales and by utilizing temporal causality and reasoning algorithms that develop successful personalized recommendations without obstructing the ordinary daily activities of users. Moreover, information from past sessions will be exploited to predict the outcome of possible courses of actions via dynamic probabilistic reasoning to support adapted HCI policies for effective personalized recommendations, which will enhance users’ trust on the system. The expertise established by some of the partners in the consortium through relevant H2020 RIA projects will guide the achievement of such an ambitious result. In particular, the selection of analytics suitable to the monitoring requirements of the project, together with the configuration of the optimal processing schema, will be studied by the project during the design of the SMART BEAR big data analytics. SMART BEAR will also apply knowledge extraction & decision explanation techniques
based on our past expertise (e.g.,[33][39][43]), to increase our confidence that the decisions made for interventions are appropriate and well understood by HCPs.

2.4 **SMART BEAR Targeted Medical Conditions**

SMART BEAR aims to deliver an integrated technological solution that is easy to use and to maintain and that would enhance the elderly’s independence. In order to obtain this goal 6 major clinical entities have been targeted: hearing loss (HL), balance, cardiovascular diseases (CVDs), dementia, depression and frailty. A multidisciplinary evidence-based approach to the design and development of a technological solution that handles these entities on the basis of the current state-of-the-art is needed.

The SMART BEAR integrated platform will handle these conditions according to a holistic view. The concept of intrinsic capacity (IC) was introduced by the World Health Organization (WHO) in 2015 offers a significant interpretation of the clinical approach adopted by the SMART BEAR project.

In order to assure the quality and innovation of Smart Bear project, the following series of actions have been undertaken. In the first step, the clinical body of Smart Bear Consortium, which consists of a multidisciplinary group of clinical experts, reviewed extensively the literature in order to identify what Smart Bear should focus on. Each partner has centred this background research on the domain of their expertise. Partners’ contribution to identifying the current state of the art is depicted in Figure 5.

Guidelines, test batteries, useful assessment and management tools, indicated interventions, state of the art technological solutions have all been evaluated and described in detail. Once gathered, all chapters have been reviewed by all clinical partners. During this step, comments or additions were integrated into the final version of each section.

![Figure 5: A map of the medical conditions addressed](image)

2.4.1 **The Concept of Intrinsic Capacity**

The concept of intrinsic capacity (IC) was introduced by the World Health Organization (WHO) in 2015 [81] [82]. In the “World Report on Ageing and Health” [82], IC was presented as a new model for capturing in a holistic way the individual’s functions and capacities adopting a life-course approach. IC is defined as the composite of all the physical and mental capacities of the person and represents the amount of resources one can rely upon during his life. By interacting with the surrounding environment, IC largely defines the individual’s
functional ability (i.e., what the person can aspire to do for giving value to his/her abilities and positively act for the society).

IC 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. In fact, by following its trajectory over time, the clinician may identify deviations from normality before the onset of clinical manifestations. This translates into the capacity of preventively acting to promote healthy ageing. At the same time, the assessment of intrinsic capacity may provide a measure for judging the effectiveness of implemented therapeutic interventions. Interestingly, the model might be used to support the detection of specific regions or populations requiring special attention from public health.

The IC model is based on the rationale that the individual’s capacities tend to fade with ageing. At the same time, the environmental barriers become more burdening, increasing the gap between what the person can do and what in reality does. The solution proposed by the WHO model is to increase IC and/or reduce the environmental barriers in order to allow older persons to 1) do what they have reason to value, and 2) make them again active and functional in the society where they live.

It is also noteworthy that the proposed model completely overcome some of the traditional medical paradigms. In particular, the objective of the model is not on the diagnosis and management of diseases. The focus is here given to the person’s function and reserves with the purpose of levering on that for restoring the maximal level of health (in its broadest meaning). This makes sense especially when considering that the WHO is a global agency that should provide recommendations applicable worldwide, independently of the social, cultural, and economic differences. In this context, it is evident the strong socio-economic connotation that the diagnosis of a disease may have because implicitly requiring the evaluation by medical professional and/or diagnostic infrastructures, which may not always be available in areas with limited access to care. At the same time, it is documented in the literature how older persons do not see the absence of diseases as a priority for their wellbeing, whereas other aspects (largely based on functions and neglected in the traditional clinical practice) are seen as pivotal [83] . The monitoring and collection of preclinical parameters descriptive of the individual’s health profile might overcome such limitation, especially if considering the possibilities offered by technological advancements [84] . This approach may enable better targeting of these resources when changes in IC suggest the need for clinical evaluation and expert advice.

**IC assessment and management.** After the theoretical design of the framework, the WHO has worked for translating the IC model into practice. In particular, efforts have been devoted to providing clinicians and researchers to instruments able to capture and render objective IC in the next future. With this final purpose, a review of the literature recently defined the five domains/functions that are critical for adequately and comprehensively capture IC [85] . The identified domains were the locomotion, vitality, sensory (in particular, vision and hearing), cognition, and psychological ones. These domains influence each other and are in turn all influenced by environmental factors. More recent discussions have particularly focused their attention to the concept of vitality [86] , which has been developing over time from one of the five domains defined by the energy metabolic capacity of the person to a kind of background biological reserve from which the other four domains stem and act [87] .

It is noteworthy that the concept of IC finds its natural environment of application in the integration of care services. This link is clearly explained by the fact that IC has a multidimensional, complex, and dynamic structure. As such, its proper clinical management requires the development of a personalized plan of intervention that, to be successful, should be designed in a multidisciplinary way and be respectful of the individual’s priorities and needs. It is thus not surprising that the WHO followed the publication of the World Report of Ageing and Health with a document reporting the guidelines for the implementation of integrated care for older people in order to support the management of the declines in IC [88] . At the same time, with the handbook entitled “Integrated Care for Older People (ICOPE): Guidance on Person-Centred Assessment and Pathways in Primary Care” [89] , the WHO is indicating which are the instruments to be used to measure the different IC domains and suggests how the design a personalized clinical care pathway for the individual. This handbook is accompanied by a dedicated app (currently available for Android in a demo version, soon
available for iOS), which supports the functional assessment, the collection of data, and the clinical monitoring of the person over time.

2.4.2 Hearing Loss

Physiology of Hearing. Hearing is the process by which the auditory system transforms changes of air pressure of the external environment (condensations and rarefactions of sound waves) into nerve impulses and transmits them to the brain, where they will be precepted as sounds [90] [91]. Sound vibrations travel through the external (pinna and external auditory canal) to the middle ear, process that plays a significant role to sound amplification and tuning [92] [93]. Subsequently, changes in pressure arrive to the cochlea, the part of the inner ear that hosts the organ of Corti, that is the sensory organ of hearing. The Organ of Corti consists of a variety of functional and supporting cells, a basilar membrane and fluid content of specific composition and ion (K+ / Na++) concentration [94]. The vibration of the basilar membrane, along with the change in cellular and cochlear potentials, creates neuronal impulses that will travel to the brain and produce there the perception of sound. Damage to a specific type of cochlear cells (inner and outer hair cells) can cause sensorineural hearing loss, today's commonest sensory deficit of people of all ages [95].

Hearing Loss. Young people with normal hearing can hear a range of sounds from 20 to 20000Hz. This hearing capacity declines over the years, fact that makes ageing, along with genetic causes, complications at birth and early life and exposure to ototoxic substances and excessive noise, one of the leading causes of hearing impairment. Hearing loss (HL) is by definition the complete or partial loss of the ability to hear from one or both ears and is manifested by higher hearing thresholds and worsening of the discrimination of speech and sounds.

According to WHO’s estimations, 6% of the global population (466 million people) is affected by handicapping hearing loss. More specifically, it is estimated that one-third of people over the age of 65 is affected by a hearing loss of some degree. Till 2050, hearing loss will affect more than 900 millions of people, reaching 10% of human population [96]. The annual cost for Europe is estimated to be 213 billion Euros per year, while globally it reaches 750 billion dollars [97].

Apart from the financial cost, hearing loss is related to significant societal and personal burden. It should not be considered as an isolated health problem. According to the Global Burden of Disease study, it is one of the 8 leading causes of living years with disability [97]. Multiple studies imply association of hearing impairment with psychological and physical diseases, such as cognitive disorders and dementia (increase of 25dB of hearing threshold corresponds to a 7 cognitive years loss [98]), anxiety and depression [99], accidents [100] and higher mortality rate [101]. Moreover, people suffering from hearing loss are less active and tend to retire sooner than normal hearing people [102]. Elderly with hearing impairment tend to isolate themselves by eliminating any participation to social events [102]. The lack of communication with their environment lowers significantly their quality of life [101].

Noise. Besides ageing as a factor affecting hearing evidently, special mention should be made to the exposure to excessive noise. As mentioned above, overexposure to high levels of noise is one of the leading causes of hearing impairment. Hearing loss caused by noise, or noise-induced hearing loss (NIHL), is defined as the elevation of hearing threshold mostly in frequencies between 3 and 6kHz. It can be manifested after acute acoustic trauma or after years of overexposure to hazardous noise. Urbanization and industrialization of modern society causes inevitably an increase of environmental noise levels. People are exposed to excessive noise during their occupation (occupational noise) and their leisure time (recreational noise). Exposure to loud sounds (noise and music) during activities of free time is mostly voluntary and pleasant. Therefore, it can frequently be underestimated by people, society and stakeholders. On the other hand, reducing the likelihood of noise overexposure at work has been already recognized and led to the design and implementation of mandatory noise exposure and thus hearing loss prevention-related regulations in many countries [103] [104]. Those regulations focus on the reduction of noise levels at the source and of the time each subject is exposed. Solutions such protective equipment (e.g. earplugs), mandatory regular screening are implied [105]. However, the generic and universal character of these measures does not enable their adjustment to each subject needs
and lifestyle. Hence, despite such regulations, approximately 25% of HL cases are still attributed to noise trauma [106].

**Hearing Loss Management.** Concerning available therapeutical solutions for hearing impaired patients, innovative pharmaceutical agents are being tested for their safety and efficacy (Regeneration of inner ear hair cells with Gamma-secretase INhibitors, Horizon 2020 Project). Nevertheless, the only currently available HL management solution is the provision of hearing devices (hearing aids (HA), cochlear implants (CI) and other assistive devices) [96]. In parallel, patients in need of hearing amplification could benefit from hearing therapy and auditory training (specialized activities to improve perception and discrimination of sounds, music and speech), as well.

Key points to the efficacy of the use of such assistive devices and complementary treatments is their proper fitting, the affordability and accessibility of the follow-up services and their proper combination with more collective strategies of HL prevention and management [e.g. implementation of the Occupational Health and Safety (Noise Exposure) Regulations [103]]. Moreover, in order to treat efficiently patients with HL, physicians should take into account their comorbidities, notably cognitive decline and dementia, depression, diziness causing falls, diabetes, thyroid, cerebrovascular and/or cardiovascular disorders and arthritis, as well.

Currently, HA fitting is based on patient’s audiogram, the current gold standard in everyday clinical practice. The technique assesses hearing sensitivity by pointing out the lowest intensity level at which a patient can detect a series of pure tones at octave and sometimes inter-octave intervals between 250 and 8,000 Hz1,18. Hence, fitting is practically oriented in audiological findings rather than the patients’ everyday hearing challenges and overall medical and social profile. Gaining insight on their habits, comorbidities and needs will provide researchers, manufacturers and clinicians with the appropriate information in order to build more holistic and thus useful patients’ profile.

Making a step beyond, designing appropriate public health policies (PHP) is essential for the effective management of HL, as it has been acknowledged in recent documents by the World Health Organization [96]. Deep insight on HAs end-users’ characteristics will enable the design of such focused policies, while real-time feedback on their efficacy will allow better understanding of the tradeoffs between their cost and benefits.

### 2.4.3 Hearing Aids: State of the Art & Beyond

Hearing Aids (HAs) are wearable medical devices designed and developed to be used by people of all ages suffering from hearing loss. They use digital sound systems consisting of 1 or 2 microphones, a digital signal processing (DSP) controlled amplification system and a miniature loudspeaker [108] [109] . This sound system aims to amplify the useful signal (e.g. speech) and to attenuate noise, in order to improve the perception and discrimination of sound [109].

Different environments require different HA functions; in quiet situations, the DSP system of a HA should amplify weak speech in order to make it audible while in noisy conditions the system should attenuate (filter out) the noise in order to help the user receive the clearest sound or speech possible [110] . Modern HAs use a variety of different programs, such as noise reduction or directional microphones, which can be activated by the user or by the HA itself, through a complex system using speech and noise detectors [111].

During the last decades, HAs technology has greatly advanced. However, achieving an efficient balance between making speech audible, attenuating noise, and obtaining comfortable sound levels in order to meet each HA user’s needs is far from optimized [112] [113]. Current solutions include modification of HA settings automatically by the HA itself and/or manually, by means of a switch, remote control or Application for Android/iOS devices [113] . The different settings correspond to preexisting programs that are being chosen during the HA fitting according to the needs of each patient. This approach has already improved the efficacy of HAs, it cannot nevertheless cover all possible situations where dynamic HA adjustments and modifications from a user interaction point of view may be needed (e.g., in cases where hearing sensitivity of a patient has temporarily or permanently deteriorated beyond the level assumed by the initial HA settings or when users change their lifestyle) [113] [115].
Currently, finding the optimal settings for the individual HA user is based on user’s description of difficult hearing scenarios and his/her everyday needs. What comes next is a trial-and-error procedure of settings modification by the clinician and/or the user, a procedure that can be time-consuming and requires a number of comebacks to the clinician’s office [113] [116]. A more collective and accurate solution is needed.

A promising feature of today’s HAs is their ability to log data as it pertains to user habits, device integrity, environmental classification and feature engagement [115]. The collection and analysis of this objective information can be used not only individually for assessing each user’s lifestyle and needs but in a large scale as well. The accumulated seamless collection of data concerning the hours of usage, the frequency of settings modification and the patterns of signal received by the speech and noise detectors, along with the subjective information coming from the user himself, could improve the HA experience, enable the design of more personalized algorithms and settings programs and lead to more accurate assessment of patient’s overall satisfaction [114] [115].

There has been considerable progress in the implementation of Big Data analytics based on HAs acquired data in order to achieve the above purposes. Apart from specific HAs suppliers who conduct Big Data collection and analysis techniques focused on their customers [116] [117], academics and policymakers are also getting actively involved in similar scientific efforts [118]. In a recent study Mellor et al. explore retrospectively connections between subsets of HAs logged varieties of data. Data Mining methods have been applied to a large, anonymized dataset (>300,000 devices, >150,000 wearers) which has been released to independent research from an anonymous hearing-aid manufacturer. This particular approach has identified patterns concerning dispensing behaviour (e.g. significant changes in audiograms between visits), device performance and user preferences. However, the importance of further analysis of HAs data and combination of those data with epidemiological and subjective information from the user’s point of view has been underlined and future research is needed before achieving more accurate, robust conclusions [121].

EVOTION (name originating from ancient Greek «εὖ + ὠτίον» which means “good ear”) is an on-going prospective Big Data project collecting data from more than 1000 users in 5 hospitals in Greece, UK and Denmark. Within the frame of this Horizon 2020 Project a multi-stakeholder demonstrator platform was developed. The platform enables the seamless collection of data from the user’s, manufacturer’s and audiologist’s point of view. At the same time, it combines, and analyses data concerning each user’s clinical management and HAs usage with personal, medical and occupational information coming from clinical repositories. Important clinical information referring among others to hearing deterioration or cognitive decay of the users, along with environmental factors, is taken into account. The collection of such heterogeneous data is achieved through existing repositories of HL-related data, enhanced HAs, wearable sensors, social networks and a mobile application. The analysis of this dataset contributes to better identify contextual and personalized usage profiles. Long-term goal of the project is the optimization of HA settings on both individual and large-scale level and the enhancement of current policies in key hearing loss (HL) technology and clinical management areas.

Although EVOTION has been a pioneer in its domain and its results are yet to be fully discovered, Smart Bear will extend and integrate the available from its consortium EVOTION technology to the new ICT tools and implement it to its goals and aims. Its backend model-driven data analytics will be enhanced in order to incorporate Data covering additional clinical and environmental factors. Combination of those heterogeneous data will expand the current insight on HAs users’ profile and everyday challenges. Such fine-tuning would permit more precise guiding and assessing of current hearing-aid fitting procedures, and thus more efficient HA usage from earlier stages. It would be also a significant tool in developing more individualized HA programs and settings and building more efficiently HL management strategies. On the other hand, HL correlation with other comorbidities and contextual factors will be for the first time evaluated by applying big data analytic techniques to the assorted data, pointing out related risks and effects to HL patients. Achieving the aforesaid goals would be beneficial to clinicians, manufacturers and patients and have consequences at a public health policymaking level.
2.4.4 Auditory Training: State-of-the-Art and Beyond

Auditory Training (AT) involves evidence-based listening activities for people of all ages. These specialized auditory exercises target to enhance brain’s plasticity through re-organization of the brain’s neurons [122][123]. Outcomes of AT are reflected in changes in neuro-imaging and neurophysiologic indices and translates in auditory/language test results and improved listening behaviours [124].

The key to success for every computer-based AT program is the precise control of the training stimulus (phonemes, syllables, words or non-speech sounds), the adaptation of training exercises to the progress made by each user and the use of various competing noise backgrounds similar to real-life acoustic environments [122][123]. To date, there are few computer-based AT programs targeting both bottom-up sensory processing (analytic training) and top-down linguistic and other higher order functions [124].

The efficacy of such training for adult listeners has been assessed in multiple studies [123] [125] [126]. Improvements in speech in noise test performance, auditory memory test performance [123] [128], verbal memory and global cognition [127] [128] have been observed after AT of varied duration. Hearing impaired listeners see particularly benefit from AT and smart HA providing this feature, since they depend largely on their cognitive resources in order to discriminate speech from noise [127] [128]. Nowadays, there is evidence that AT should be initiated as soon as a HA is fitted [130]. However, the current knowledge on the incorporation of such training to appropriate individualized management strategies is still limited. To date, AT programs are proved not sufficiently personalized and thus not sufficiently beneficial when user is exposed to untrained stimuli or has to execute untrained tasks [130]. Analyzing in real-time HAs users’ everyday challenges and needs and taking into account their overall medical history is required in order to design individualized AT strategies that constantly adapt to users’ reality.

In Horizon 2020 EVOTION project, HAs users are encouraged to make use of individualized rehabilitation treatments such as AT, according to their auditory profile. More specifically, EVOTION smart HAs and platform continually monitor specific listening situations in which the user experiences hearing challenges and learns from the collected data how to design the most appropriate and individualized AT strategy (e.g. phoneme discrimination training for individuals missing beginning or ending of words, auditory directives / story in noise training for those with difficulties with auditory memory). In parallel, analysis of those data aims to explore the necessity of personalized auditory rehabilitation services and its affordability by health care systems and consumers, in order to develop decision and simulation (DS) models for public health policymaking related to HL treatments.

Smart Bear goes beyond the state of the art by applying the gained during partners’ previous projects experience and tools on monitoring and coaching hearing-impaired participants in a large number of its participants. The auditory profile of smart HAs users will be seamlessly updated and they will be able to benefit from continuously adjusting AT activities. Information on progress tracking, user’s compliance and real-life performance will be classified and evaluated. Individualized AT strategies will be developed along with collective hearing loss management policies.

2.4.5 Cardiovascular Diseases

Structure and function of a normal heart. The heart is an organ with complex structure responsible for pumping blood and distributing oxygen and nutrients throughout the body. It is divided in four chambers, two atria and two ventricles. The right atrium and ventricle collect venous blood from the body sending it to the pulmonary circulation whereas the left ones collect oxygenated blood from the lungs sending it back to the systemic circulation. The principal cell in the human heart is the cardiac myocyte. Its unique properties allow it to relax and contract in different frequencies creating different work which depend on the metabolic needs. The human heart has an intrinsic conduction system which is consisted of differentiated myocytes responsible for electrical signal creation and transmission from the sinus node (the physiological pacemaker) to the atrioventricular node and then to the ventricles. All the myocytes have an intrinsic property of depolarization however, under normal circumstances, this is undertaken by the aforementioned specific cells. The conduction
system is the origin for the synchronous contraction and relaxation of ventricles and atria, so-called the cardiac circle.

There is a one-way flow of blood through the heart; this flow is maintained by a set of four fibrous valves. The atrioventricular or AV valves (the right tricuspid and left bicuspid or mitral) allow blood to flow only from atria to ventricles. The semilunar valves (pulmonary and aortic) allow blood to flow only from the ventricles out of the heart and through the great arteries. The heart wall consists of three layers. The inner thin one, called endocardium, which covers all the cavities, the valves as well and adjoins that of the arteries. The mid part, called myocardium, is the layer that actually contracts. The left ventricle’s myocardium is much thicker than the right’s one as it has to overcome much higher pressures, those of the systemic circulation. The atrial myocardium is thin. The third, outer layer is called epicardium. It is where the main heart blood vessels are located together with nervous plexuses and fatty tissue. The heart is surrounded by a thin layer called pericardium which acts as a protective membrane.

The failing heart. The heart’s function as a pump is based on its elastic properties to relax and receive passively blood (differ for each of the ventricles) and subsequently contract, pumping it back to the pulmonary and systemic circulation. Dysfunction or malformation at any level of the heart structure may lead to a spectrum of disorder giving rise to the syndrome of heart failure. There are numerous causes congenital or acquired which can be grouped in 3 main categories. Those who refer to a primarily diseased myocardium (like coronary artery disease, cardiomyopathies), others which are related to abnormal loading conditions (among others hypertension, valvular disease, septal defects) and arrhythmias.

Heart failure (HF) is a very diverse clinical syndrome. Many patients will have several different pathologies—cardiovascular and non-cardiovascular—that conspire to cause HF. It is characterized by typical symptoms (e.g. breathlessness, ankle swelling and fatigue) that may be accompanied by signs (e.g. elevated jugular venous pressure, pulmonary crackles and peripheral oedema) caused by a structural and/or functional cardiac abnormality, resulting in a reduced cardiac output and/or elevated intracardiac pressures at rest or during stress. Depending on its aetiology it can occur as an acute event which may resolve (i.e. viral infection – acute myocarditis) or remain as chronic dysfunction (i.e. dilated cardiomyopathy). Additionally, there are other reasons like hypertensive cardiomyopathy which develop over time into the chronic type of the syndrome. Depending on its severity, clinically there are 4 functional classes as adopted by the New York Heart Association classification. (NYHA class I: no limitation in usual everyday activities, NYHA class II: mild limitation on exertion, NYHA class III: significant limitation of everyday activities, NYHA class IV: unable to carry out any activity). They are used to guide prognosis and therapeutic strategies.

Another classification of the syndrome which is predominant in clinical practice refers to the systolic function of the left ventricle (left ventricular ejection fraction – LVEF) defined by imaging studies (Echocardiography or Cardiac Magnetic Resonance study). Heart failure with preserved ejection fraction (HFrEF – LVEF > 50%) roughly refers to a heart which keeps its systolic properties however fails to relax adequately. It is a clinical syndrome which may run for years before the diagnosis due to its non-specific signs and the diversity of the population affected. Heart Failure with reduced ejection fraction (HFrEF LVEF < 40%) is an entity where both the systolic and diastolic properties of the heart are failing. Patients with an LVEF in the range of 40–49% represent a ‘grey area’, which we now define as HFrEF. Differentiation of patients with HF based on LVEF is important due to different underlying aetiologies, demographics, co-morbidities and response to therapies.

The prevalence of HF depends on the definition applied but is approximately 1–2% of the adult population in developed countries, rising to ≥10% among people >70 years of age. Among people >65 years of age presenting to primary care with breathlessness on exertion, one in six will have unrecognized HF (mainly HFrEF). The lifetime risk of HF at age 55 years is 33% for men and 28% for women. The proportion of patients with HFrEF ranges from 22 to 73%, depending on the definition applied, the clinical setting (primary care, hospital clinic, hospital admission), age and sex of the studied population, previous myocardial infarction and the year of publication. Data on temporal trends based on hospitalized patients suggest that the incidence of HF may be decreasing, more for HFrEF than for HFrEF. HFrEF and HFrEF seem to have different epidemiological and etiological profiles. Compared with HFrEF, patients with HFrEF are older, more often women and more...
commonly have a history of hypertension and atrial fibrillation (AF), while a history of myocardial infarction is less common.

There are many diagnostic tools for the syndrome of heart failure which include, medical history, clinical examination, imaging studies (echocardiogram, cardiac MRI), electrocardiogram and several biomarkers. There are also other tests which help to further investigate the underlying reason of cardiac dysfunction (i.e. coronary angiogram, scintigraphy, MRI, stress echocardiography, positron emission tomography, cardiac computed tomography).

There is considerable evidence that the onset of HF may be delayed or prevented through interventions aimed at modifying risk factors for HF or treating asymptomatic LV systolic dysfunction. Hypertensive cardiomyopathy for instance can be prevented if hypertension is promptly treated. Or, a primary percutaneous coronary intervention (PCI) at the earliest phase of an ST segment elevation myocardial infarction (STEMI) to reduce infarct size decreases the risk of developing a substantial reduction in LVEF and subsequent development of HFrEF. In asymptomatic patients with chronically reduced LVEF, regardless of its aetiology, treatment can reduce the risk of HF requiring hospitalization.

Treatment options in chronic heart failure. As mentioned before, there are types of heart failure which are secondary to a non-cardiac problem. An example would be the condition of high output heart failure seen in thyroid disease. In such cases the treatment of the primary disorder will improve cardiac function as well. Additionally, in structural heart disease (congenital defects, valvular disorders) interventional or surgical procedures are necessary to reverse the dysfunction partially or completely. However, in any case, partially reversible or not, some kind of cardiac dysfunction will remain which will require further attention.

The pillars of treatment in chronic heart failure are medications (like diuretics, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, angiotensin receptor-neprilysin inhibitors, mineralocorticoid receptor antagonists, β blockers, vasodilators), percutaneous or surgical interventions (angioplasty, valve repair procedure), devices (cardiac resynchronization therapy, implantable cardioverter defibrillator, left ventricular assist device) and in advanced cases, heart transplantation. This chapter will not be further discussed in this document.

Smart Bear platform – Expectations for the HF population. As aforementioned, heart failure is a complex syndrome that requires certain expertise and experience to be diagnosed and managed promptly. Besides, there are numerous causes of heart failure which when addressed early, its development and progression can be delayed. A great example of this is the entity of HFpEF profile in diabetic, hypertensive women. Multiple epidemiological studies have shown that the incidence of heart failure in this group can be substantially decreased when the individual risk factors are controlled. Despite the fact that early interventions in the field of Cardiology have reduced the prevalence of HFrEF, the number of new diagnoses of HFpEF is increasing, together with life expectancy. The Smart Bear platform aims to detect on an early stage people at high risk of developing heart failure either with being alerted when a major risk factor like blood glucose levels, or blood pressure levels exceeds the normal limits or, by smart calendars assessing their everyday life activity and functional class.

On the other hand, older people with diagnosed heart failure would benefit from a monitoring program in multiple ways. Body weight monitoring is substantial in HF population. A smart scales device could be used to guide the treatment with diuretics and also to prevent hospitalizations as already shown in clinical studies. In fact, early up-titration of medical treatment before the overt decompensation of the syndrome can reduce the need for hospital admission. Additionally, smart calendars could be introduced to HF patients to control their salt intake which has to be limited.

Finally, although being thoroughly investigated, HFpEF is a relatively new entity for clinical grounds. In that sense, big epidemiological data would offer new insights on the pathogenesis and the physical course of the disease.
2.4.6 Epidemiology – aetiology of hypertension and clinical importance of blood pressure control

**Hypertension.** Blood pressure is the tension exerted by circulating blood against the arterial wall. It is determined by three major components which are the blood volume ejected in each cardiac cycle into the arterial conduit, the elastic properties of the arterial wall and the rate at which blood flows out of the arteries. It has been one of the most commonly measured clinical parameters and major components in clinical decision making. Blood pressure can be measured in different ways, interventional or not. It is commonly expressed by systolic and diastolic values in millimetres of mercury.

The circulation conduit of all mammals has several regulatory mechanisms to maintain continuous blood flow to the body tissues in different circumstances. As mentioned before blood pressure is mainly determined by stroke volume (the volume of blood ejected by the heart during each cardiac cycle) and vascular resistance. In healthy state, when the metabolic needs increase, ie during exercise, cardiac output can increase up to 5 times compensating the high oxygen demands. Blood pressure remains stable as vascular resistance decreases. There are four major mechanisms which regulate blood flow: neuro-humoral, myogenic, metabolic and flow mediated changes. These will not be discussed in detail in this document.

Ageing, specific diseases, genetic factors, environmental exposure to several pollutants, drugs, diet, obesity, lack of physical exercise and many other conditions contribute to increased blood pressure as they affect the elastic properties of the arterial tree and attenuate or exacerbate the physiological response of the regulatory mechanisms.

Hypertension, or high blood pressure, is a serious medical condition affecting over 1 billion people worldwide and has been recognized as a principal contributor to cardiovascular and renal morbidity and mortality. In fact, it has been a leading risk factor for premature death, heart attacks, stroke, heart failure, renal failure and other diseases affecting heart, brain and kidneys. Recently, hypertension has also been linked with the development of cardiac arrhythmias, and cognitive decline.

According to the WHO data, in 2015, hypertension was affecting 1 in 4 men and 1 in 5 women around the globe. More importantly, despite the efforts from health organizations, it seems that there are many hypertensives who never had a diagnosis of high blood pressure as well as others who are not adequately treated.

Blood pressure is a continuous biological parameter. Large epidemiological studies have linked the increased levels of arterial pressure (hypertension) with significant morbidity and mortality. The normal values for children and adults are determined as the ones which are related to minimal risk for cardiovascular disease. The majority of hypertensive subjects do not have a specific reason for the development of high blood pressure. This is the commonest scenario and it is referred as essential hypertension. There are many risk factors as discussed below which can predispose to the hypertensive state (i.e. obesity, high salt intake) however there is no direct causative relationship. On the contrary, up to a 5-15% per cent of the hypertensive population express secondary hypertension due to an identifiable and potentially curable cause (i.e. renovascular disease, endocrine diseases). Further discussion regarding secondary hypertension exceeds the purpose of this document.

Hypertension rarely occurs in isolation. It usually clusters with other metabolic disorders like dyslipidemia or blood glucose intolerance. Male sex, ageing, smoking, hyperlipidemia, hyperuricemia, diabetes mellitus, early-onset menopause, obesity, family history of premature cardiovascular disease or early-onset hypertension, sedentary lifestyle, poor psychosocial and socioeconomic situations have all been recognized as factors which further influence the cardiovascular risk in hypertensive patients.

It is highly recommended that hypertensive people are thoroughly investigated for the presence of such conditions. There are many algorithms which can be applied to assess an individual's risk and this process is very important in low – intermediate risk adults because it can influence the treatment strategy. The European Society of Cardiology strongly recommends the use of SCORE system which uses the patient’s age, blood pressure levels and total cholesterol to determine the 10-year estimate for a fatal cardiovascular event. The
total actual risk for all events (fetal and non-fatal), is influenced by the aforementioned risk factors and its much higher than the one provided by the SCORE system.

**Blood pressure measurement.** Indirectly, blood pressure is measured with a device called a sphygmomanometer which consists of an inflatable bladder covered by a cloth sleeve, and a gauge or column of mercury. The cloth is wrapped around the upper arm or thigh in an area that overlies a major artery, so that this artery will be compressed by the inflated sleeve. As the cuff pressure increases and the underlying artery is compressed, the pulsations in the artery gradually increase and then decrease until the artery is occluded. These counter pulsations produce oscillations in cuff pressure which are the basis for oscillometer method of blood pressure recording. The auscultation method can also be used with a bell-shaped stethoscope. The dimensions of the bladder are crucial for a correct reading and they should match the patient’s size.

The direct blood pressure monitoring is performed by using intraarterial catheters in the radial, brachial, axillary or femoral artery. Vascular pressure is transmitted through a fluid-filled plastic tube that connect the arterial catheter to the pressure transducer. The blood pressure is then seen as a continuous waveform in a medical monitor and the systolic, diastolic and mean arterial pressure is determined automatically after being calibrated to the atmospheric pressure. This is the most accurate way of blood pressure monitoring however its use is limited for critically ill patients.

Despite being one of the most frequently performed measurements in clinical practice, the indirect blood pressure determination is depended on the performer or the electronic device which is used. Not trained personnel or non-validated machines can lead to wrong measurements and consequently wrong clinical decisions.

Auscultatory or oscillometer semiautomatic or automatic sphygmomanometers are the preferred method for measuring BP in the outpatient setting. These devices should be validated according to standardized conditions and protocols. BP should initially be measured in both upper arms, using an appropriate cuff size for the arm circumference. A consistent and significant SBP difference between arms (i.e. >15 mmHg) is associated with an increased CV risk, most likely due to atheromatous vascular disease. Where there is a difference in BP between arms, ideally established by simultaneous measurement, the arm with the higher BP values should be used for all subsequent measurements. Three BP measurements should be recorded, 1–2 min apart, and additional measurements only if the first two readings differ by >10 mmHg. BP is recorded as the average of the last two BP readings.

In older people, people with diabetes, or people with other causes of orthostatic hypotension, BP should also be measured 1 min and 3 min after standing. Orthostatic hypotension is defined as a reduction in SBP of ≥20 mmHg or in DBP of ≥10 mmHg within 3 min of standing and is associated with an increased risk of mortality and CV events. Heart rate should also be recorded at the time of BP measurements because resting heart rate is an independent predictor of CV morbidity or fatal events.

According to the latest European guidelines the diagnosis of hypertension can be based upon BP measurements in or out of office. For the office measurements in adults, HTN is defined as BP levels above 140/90mmHg. This is based upon several epidemiological studies which showed benefit when treatment was offered to patients exceeding the aforementioned values. Optimal BP levels for systolic BP are <120mmHg, normal 120-129mmHg and high normal 130-139mmHg. Accordingly, for diastolic BP optimal levels are those <80mmHg, normal 80-84mmHg and high normal 85-89mmHg.

For prognostic and treatment strategy reasons, hypertension has been further classified in grades, according to the untreated BP values on diagnosis. Grade I HTN is defined as systolic BP 140-159mmHg and/or diastolic 90-99mmHg. Grade II as systolic BP 160-179mmHg and/or 100-109mmHg. Grade III as systolic BP ≥ 180mmHg and/or diastolic ≥ 110mmHg.

Use of unattended office BP measurement in a recent clinical trial [the Systolic Blood Pressure Intervention Trial (SPRINT)] generated controversy about its quantitative relationship to conventional office BP measurement (which has been the basis for all previous epidemiological and clinical trial data); its feasibility in routine clinical practice has also been questioned. Presently, the relationship between BP readings obtained with conventional office BP measurement and unattended office BP measurement remains unclear, but
The available evidence suggests that conventional office SBP readings may be at least 5–15 mmHg higher than SBP levels obtained by unattended office BP measurements. There is also very limited evidence on the prognostic value of unattended office BP measurements, i.e. whether they guarantee at least the same ability to predict outcomes as conventional office BP measurements.

Out-of-office BP measurement refers to the use of either Home Blood Pressure Measurement (HBPM) or Ambulatory Blood Pressure Monitoring (ABPM), the latter usually over 24 h. It provides a larger number of BP measurements than conventional office BP in conditions that are more representative of daily life. Home BP is the average of all BP readings performed with a semiautomatic, validated BP monitor, for at least 3 days and preferably for 6–7 consecutive days before each clinic visit, with readings in the morning and the evening, taken in a quiet room after 5 min of rest, with the patient seated with their back and arm supported. Two measurements should be taken at each measurement session, performed 1–2 min apart. Compared with office BP, HBPM values are usually lower, and the diagnostic threshold for hypertension is ≥135/85 mmHg (equivalent to office BP ≥140/90 mmHg) when considering the average of 3–6 days of home BP values.

Compared with office BP, HBPM provides more reproducible BP data and is more closely related to hypertension mediated organ damage, particularly left ventricular hypertrophy. Recent meta-analyses of the few available prospective studies have further indicated that HBPM better predicts cardiovascular morbidity and mortality than office BP. There is also evidence that patient self-monitoring may have a beneficial effect on medication adherence and BP control, especially when combined with education and counselling. Telemonitoring and smartphone applications may offer additional advantages, such as an aid to memory to make BP measurements, and as a convenient way to store and review BP data in a digital diary and transmit them.

ABPM provides the average of BP readings over a defined period, usually 24 h. The device is typically programmed to record BP at 15–30 min intervals, and average BP values are usually provided for daytime, night-time, and 24 h. The diagnostic threshold for hypertension is ≥130/80 mmHg over 24 h, ≥135/85 mmHg for the daytime average, and ≥120/70 for the night-time average (all equivalent to office BP ≥140/90 mmHg). ABPM is a better predictor of HMOD than office BP. Furthermore, 24 h ambulatory BP mean has been consistently shown to have a closer relationship with morbid or fatal events and is a more sensitive risk predictor than office BP of CV outcomes such as coronary morbidity or fatal events and stroke.

BP normally decreases during sleep. Although the degree of night-time BP dipping has a normal distribution in a population setting, an arbitrary cut-off has been proposed to define patients as ‘dippers’ if their nocturnal BP falls by >10% of the daytime average BP value; however, the ‘dipping’ status is often highly variable from day to day and thus is poorly reproducible. Recognized reasons for an absence of nocturnal BP dipping are sleep disturbance, obstructive sleep apnea, obesity, high salt intake in salt-sensitive subjects, orthostatic hypotension, autonomic dysfunction, chronic kidney disease, diabetic neuropathy, and old age. Several studies have shown a prognostic value of dipping phenomenon in hypertensives. No dippers or even worse the reverse dippers exhibit worse outcomes in long term follow up.

**White coat hypertension and masked hypertension.** The white coat phenomenon refers to the condition that an individual’s blood pressure measurements appear to be higher when performed in a clinic environment compared to the ones taken at home or with an ambulatory monitor. People with white coat hypertension can account up to the 30-40% of the population and they have normal BP levels in everyday life, usually slightly higher than the ones with sustained normotension, however they appear to have increased risk of developing sustained HTN. In addition, compared with normotensive subjects, they are at higher CV risk. Out of office BP measurements are essential to recognize this part of the population as the clinic BP checks would misdiagnose the presence of sustained hypertension.

Masked hypertension can be found in approximately 15% of people with normal office BP measurements. It is more common in younger patients and it is associated with alcohol consumption, smoking, increased physical activity and stress. Out of hospital BP monitoring is crucial for the diagnosis, and often, hypertension mediated organ damage can be present. This part of the population exhibits significantly increased CV risk, close to or even higher than the ones with sustained hypertension.
Symptoms of hypertension. Hypertension is frequently called a “silent killer”. Most of the hypertensive population are unaware of their high blood pressure levels due to the fact that the condition usually does not cause any symptoms or warning signs. Not rarely, symptoms related to hypertensive state derive from organ damage as a consequence of chronic hypertension. However, in emergency situations (conditions when very high levels of blood pressure cause acute organ damage) symptoms may include headache, confusion, palpitations, chest pain, dyspnea, blurred vision, vomiting, fatigue.

As many individuals may suffer from sustained hypertension with no warning signs, it is essential that blood pressure is measured regularly as a preventive method in the general population.

Treatment options in hypertension. Hypertensive people are at high risk of developing life-threatening cardiovascular acute or chronic conditions. BP lowering together with addressing other risk factors can substantially reduce the burden of cardiovascular morbidity and mortality. Meta-analyses of randomized controlled trials including several hundred thousand patients have shown that a 10 mmHg reduction in SBP or a 5 mmHg reduction in DBP is associated with significant reductions in all major CV events by ~20%, all-cause mortality by 10 – 15%, stroke by ~35%, coronary events by ~20%, and heart failure by ~40%.

There are two well-established strategies to lower BP: lifestyle interventions and drug treatment. Device-based therapy is also emerging but is not yet proven as an effective treatment option. Lifestyle interventions can undoubtedly lower BP and in some cases CV risk, but most patients with hypertension will also require drug treatment. These include smoking cessation, decrease in salt intake, physical exercise promotion, weight loss and avoidance of alcohol consumption.

Regarding the drug treatment strategies for essential or secondary hypertension there are several options and each of the patients requires a personalized approach according to his comorbidities and profile. Specific drug strategies will not be discussed in this document.

Follow – up in hypertension. The maximum benefit from any of the aforementioned treatments applied requires close monitoring for each of the hypertensive patients. The principal goal is to maintain the normotensive state avoiding overtreatment and addressing at an early stage any side-effects from the medications offered. Additionally, a holistic approach should be offered targeting in comorbidities such as dyslipidemia and diabetes.

Adherence to lifestyle modifications and medication remains a big challenge during follow up. Although there is adequate information available to the public regarding the benefits of controlled blood pressure levels the proportion of people who follow the medical advice is disappointing. There are several reasons leading some hypertensive subjects to discontinue their treatment or to receive it in an intermittent fashion. Poor information given by the health care professionals, specific drug side effects, dementia, economic difficulties, all may lead to treatment discontinuation.

SMART BEAR platform – targeting on multiple tasks. Hypertension is probably the most extensively investigated medical condition globally. Data from several epidemiological studies or randomized controlled trials have adequately shown the benefit from blood pressure control. However, as mentioned before there is a significant proportion of the population who have never been diagnosed and others whose blood pressure levels are not controlled despite the treatment received.

Innovative technologies such as smart devices are already handy tools for patients and health care professionals. However, their use is limited among younger individuals. Smart Bear platform aims to introduce ways of blood pressure monitoring and treatment control to an age group with specific needs. People of older age commonly face multiple comorbidities (diabetes, heart failure, dementia, arrhythmias, depression etc.); they have limited access to information compared with younger patients and often their restricted mobility keeps them longer at home and inactive.

One of the principal pillars of the SMART BEAR platform targets is the detection of hypertension. Arterial stiffening is advancing with age and so does the prevalence of hypertension. It is not uncommon in daily practice to face with patients over the age of 67 who never had a diagnosis of HTN before. Having a diagnostic tool available at home could decrease the proportion of people who are unaware of their high blood pressure levels.
Additionally, for those on treatment, Smart Bear platforms aims to provide a long term, regular monitoring at the convenience of their environment and their choice. It has been proven that adequate monitoring improves blood pressure control, enhances the adherence to medication and adaptation of lifestyle modifications such as salt intake restriction. Nevertheless, side effects of overtreatment such as orthostatic hypotension, will be early detected. In this way, events which can be detrimental, like falls, can potentially be avoided. Finally, during BP monitoring, other conditions which can greatly affect prognosis such as atrial fibrillation can be early detected and addressed.

In the era of personalized medicine, ageing population and multiple comorbidities, innovative technology seems to be an affordable tool to improve the quality of life and reduce the burden of cardiovascular morbidity and mortality.

2.4.7 Balance Disorder

Balance relies on the harmonized integration of different signals which arrive to our brain through several organs (eyes, vestibular system, muscles, touch sensors). Information about gravity and mechanical forces as detected by the balance sensory organ (labyrinth), vision, and proprioception, all contribute to motion and tilt perception. Musculoskeletal system enables controlling the position of the body at rest and in motion. The whole balance system permits keeping a stable visual focus when changing position.

**Sensory Input – Eyes.** Sensory receptors in the retina, that is rods (low light situations) and cones (colour and finer details of the visual scene), send impulses to the brain which provide visual cues identifying our orientation – displacement relative to other objects. Peripheral vision providing information about object size and localization, binocular disparity, visual motion, visual acuity, depth of field, and spatial frequency is believed to dominate both perception of self-motion and postural control.

**Sensory Input – Proprioception.** Proprioception or kinesthesia is our ability to detect the location and movement of parts of our body. Sensory receptors of the muscles, skin and joints that are sensitive to stretch or pressure in the surrounding tissues respond to limb movements and send the information to the CNS. There, the acquired information is combined with other senses.

**Cognitive Function.** Dynamic postural control and cognitive function are closely associated. In multi-tasking and/or dual-tasking situations, safe walking demands additional attention and executive function plays a crucial role for normal gait. Gait impairment are a strong predictor for the development of dementia even 10 years ago. Older adults with moderate cognitive impairment tend to fall twice as often as older adults with no cognitive decline.

**Sensory Input – Vestibular system.** The labyrinth, that is the balance sensory organ, makes part of the inner ear. Each labyrinth is located in the temporal bone of the skull (one in the left and one in the right side) and contains three semicircular canals and two otolithic organs. These important structures are fluid-filled and contain sensory hair cells whose movement creates neural impulses and provides the brain with information about the acceleration of the head. More specifically, the semicircular canals lie in orthogonal planes, meaning that there is an angle of about 90° between any one pair. Horizontal canals are in the same plane and form a synergistic pair. Similarly, the anterior canal on one side and the posterior canal on the other side (and vice versa) function synergistically. This architecture enables the sense of rotational acceleration in all three planes. On the other hand, the horizontally oriented utricle and the vertically oriented saccule sense linear acceleration, that is the position of the head with respect to gravity.

**Integrated output.** Sensory organs provide information that will be processed and integrated within the Central Nervous System (CNS). A complex system will enable the development of sophisticated mechanisms of anticipatory postural adjustments and adaptation strategies to changing environmental and balance task demands. The involved cortical areas, the cerebellum and brain stem nuclei transmit impulses to the muscles that control movements of the eyes, head and neck, trunk, and legs. Cognitive disorders, attention deficits and other behavioural factors, such as fear of falling, are involved.

**Balance disorders.** Maintaining balance at rest and in motion and keeping clear vision while moving is multifactorial and relies on the integration of physical, sensory (visual, somatosensory, vestibular), and cognitive-
behavioural functions. Unavoidably, these functions tend to decline over the years, making age-related progressive loss of sensory information and the inability to control body movements the major factors responsible for the increase in fall risks in older adults. Moreover, older people tend to present additional problems with motor control, such as weakness, slowness, tremor, or rigidity, fact that deprives them from recovering properly from imbalance. As a result, physical inactivity and increased sedentary time are leading causes for functional impairments, fear of falling and frailty. These factors raise the risk of falling and injury and interfere with rehabilitation process.

It is estimated that 1-2 out of 10 people has experienced balance or dizziness problems sometime in their lifetime. This rate increases in the elderly. People suffering from balance disorders may present vertigo (a spinning sensation), staggering, lightheadedness, faintness, floating sensation, blurred vision, confusion or disorientation\textsuperscript{15}. The severity of symptoms varies for each individual. The wide variety of symptoms may lead to their misinterpretation. Many of the cases are erroneously classified as psychogenic and remain untreated.

According to the WHO global report, 1 out of 3 people older than 65 years old fall each year and this prevalence increases for people > 70 years old. Falls are the second leading cause of accidental death after road traffic accidents. In the EU, an average of 35,848 older adults (65 and above) are reported to have died on an annual basis due to serious injuries caused by falls. This figure is expected to be an underestimation of the true deathly falls rate which probably is much higher.

A recent study analyzing data from more than 200 hospitals from across Europe has estimated that every year within the EU, 3.8 million older people attend emergency departments (ED) with a fall-related injury; 1.4 million need to be admitted to hospital for further treatment. This fact makes falls the predominant cause (58%) of injury-related emergency department (ED) attendances and costs to the EU at least 25 billion euros every year. As the population of the elderly in Europe is expected to grow by 60% by 2050, the number of fall-related deaths is expected to increase to almost 60,000 by 2050. This could result in annual fall-related expenditures exceeding 45 billion euros by the year 2050.

Vestibular deficits are diagnosed in the majority of the fallers. 80% of the adults with an unexpected fall suffer by an inner ear pathology affecting postural control.

The necessity to develop more efficient prevention strategies is widely recognized. Worldwide interest has been focused on 4 major areas; Physical activity, Exercise, gait and balance physiotherapy for the enhancement of one’s strength, coordination of limbs, neural plasticity, and self-confidence; vision for the avoidance of further sensorial deprivation and additional reasons of imbalance; concomitant medication for the identification of side effects or potential interactions; and patient’s environment for making everyday environment practically safer. The assessment of these factors should be performed in the context of an individualized multifactorial integrated solution\textsuperscript{21}.

Test and retest of outcome measures, referring to postural control, provide quantification of the rehabilitation outcome. Functional Gait Assessment (FGA) is a dynamic postural functional test, including 10 advanced gait tasks (normal walking, changing speed walking, walking while turning the head vertically and horizontally, turning about, overcoming an obstacle, walking while placing one foot directly in front of the other, walking with eyes closed, walking backwards and climbing stairs). Each task receives a score between 0 and 3 (0 for severe balance deficit, 1 for moderate impairment, 2 for mild impairment and 3 for normal gait pattern).

A balance exercise regime, provided by a physiotherapy and/or a certified health professional, is an effective method for reducing the postural instability, symptoms arising from vestibular deficits, fear of falling and eventually falls as well as for increasing functionality, physical activity and social participation. Balance rehabilitation protocols are personalized and home-based are consisting by a multi-sensory set of exercises, having as a goal the re-weighting of sensory inputs, central nervous adaptation, coordination of the body segments and optimal selection of postural adjustments. Are considering a safe and effective treatment and minor side effects have reported.

Specific exercises for reducing dizziness, unsteadiness, disorientation and motion discomfort are including in the balance rehabilitation standard care, giving an advantage in the effectiveness of the programs, decreasing sessions and consequently time and effort spending. Vestibular exercises are based on three principles,
adaptation, habituation and substitution. In habituation exercises patient constant expose to stimuli, which cause low to moderate symptoms, leading to the correction of the sensory mismatch that the Central Nervous System produce after a vestibular disorder. Habituation exercises are subject to specific instructions and restrictions regarding type and the intensity of symptoms. Adaptation refers to the increase of vestibular-ocular reflex gain as an error visual signal slip to the retina, is frequency dependent, and patient may experience a brief symptoms’ exacerbation during stimulation. Substitution refers to the promotion of alternative strategies (visual and/or proprioceptive) in order to alter the vestibular system to work with the remaining cues and reprogramming neural networks.

Without proper feedback from the physiotherapist, the patient may not follow the correct prescribed exercise instructions leading to either a marked improvement or an excessive increase in symptoms. People with cognitive deficits, moderate or severe symptoms or fear of falling will benefit greatly from supervision. Supervision promotes adherence to the program, ideally improving it, and its absence increases the withdrawal rates from the protocol.

To date there is no personalized solution of hazard assessment and intervention for people with balance disorders that takes into account all the aforementioned factors.

HOLOBALANCE is a state-of-the-art virtual coaching platform whose aim is to engage patients with dizziness and unsteadiness in balance and gait physiotherapy and to encourage them increase their physical activity. Designed and performed by a multidisciplinary consortium (ENTs, physiotherapists, neurologists, gerontologists etc) provides participants in 4 clinical sites with individualized exercises according to their needs. Data from motion capture sensors and wearable sensors (smart bracelet, smart glasses, sensorised soles), physiotherapy exercises movement and emotional and behavioural features help create personalized user profiles. Balance physiotherapy, cognitive training or long term multilevel motivation and physical activity by means of holograms, augmented reality games and vocal instructions help users comply with their treatment plan and coach them in order to achieve maximum effect. Seamless analysis of the collected data and progressive learning algorithms continuously update patients’ profile with information about their compliance to the exercises, their performance and their longitudinal progress.

EMBalance is an EU funded research program with 800 participants with balance disorders. The project delivered an integrated patient-specific decision support system based on retrospective and prospective data for diagnosis and treatment. It targets the improvement of management of undiagnosed or undertreated patients by providing a powerful tool of early diagnosis and efficient treatment planning.

The FP7 project ALFRED provides its aged participants with a Driven Interaction Assistant and enhances their independent living, promotes their social inclusion and prevails age-related physical and cognitive impairments by means of serious games. According to their individual needs and clinical profiles, participants solve everyday problems with the help of an interactive virtual butler, receive information about social events that might interest them and are encouraged to spend essential time on physical and cognitive serious gaming. Wearable sensors which monitor basic physiological and clinical parameters allow medical staff or careers to access elderly’s vital signs and thus enhance their personalized care.

Smart Bear consortium will use the gained during partners’ previous projects know-how and experience and integrate it to its goals. It will prioritize fall prevention and improvement of participants with balance disorders quality of life by means of interventions addressing social inclusion, personalized care, physical activity, balance physiotherapy and fall risk factors reduction.

State of the art sensors will seamlessly monitor physiological and other clinical and environmental parameters and will detect specific risk factors, such as avoidance of physical activity, incomppliance to physiotherapy, low blood pressure or heart rate abnormalities. The integrated Smart Bear platform will promote safer living conditions for its users by regularly informing them and their physicians about its observations and by providing them with individualized clinical suggestions. Smart Bear participants will receive notifications according to their profile and needs. Specific physical exercises, specialized gait and balance physiotherapy, serious gaming, encouragement to visit a physician for further evaluation and possible change of medication.

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are examples of the strategies Smart Bear will use to provide its users with highly personalized and thus more efficiently care.

2.4.8 Mental Health

It is hard to define what “good mental health” is for any people, and particularly for elderly people. Yet, being in good mental health cannot be the “absence of treatment” as often considered by curative psychiatry. The focus of Smart Bear is centred on “how digital health can improve the healthy and independent living of elderly people and their quality of life”.

If we consider mental health in this purpose, many factors contribute to the “good mental health” of elderly people such as: keeping autonomy and independency, maintaining social relationships and emotional life, being connected to the world, feeling part of society, feeling “useful” to their families, friends and to society. Being in good physical health is also one of the major keys to a balanced mental health, with importance of sleep, food, physical activity factors) as well as maintaining good mental activity and skills. WHO reported that those with physical health conditions, such as heart disease, have higher rates of depression than those who are physically well.

All these factors contribute to maintain self-esteem for elderly people, which is on one of the keys to “ageing well” when it comes to mental health.

If, according to the 2018 Barometer of senior well-being in France, 83% of people over 65 are satisfied of their life (a better result than for younger people). One the other hand, 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. 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.

On the general population, mental health problems are a growing public health concern. According to the 2013 Global Burden of Disease study, the predominant mental health problem worldwide is depression, followed by anxiety, schizophrenia and bipolar disorder. In 26 countries, depression was the primary driver of disability. Depressive disorders also contribute to the burden of suicide and heart disease on mortality and disability; they have both a direct and an indirect impact on the length and quality of life.

Moreover, it is important to consider copathologies to depression, that is when the mental disorders are associated with other diseases. Indeed, a recent study by Inserm estimates that in 30% of cases, these psychological manifestations betray the beginning of a neurodegenerative disease, most often an Alzheimer’s disease. They can also be related to micro strokes that have gone unnoticed elsewhere. Finally, in some people, these disorders can promote addiction, hence the importance of taking charge of them as soon as possible.

The global economy loses about 1 trillion USD per year because of depression. As states the introduction of the Interreg North-West Europe project eMEN, “Europe’s main challenge in mental health care is the substantial increase in demand for services. This has increased social and economic costs for the society.” and “e-Mental health, focusing on prevention, faster the treatment and relapse reduction”.

Mental Health treatment and digital health. To prevent these depressive disorders, it is very important to fight against the main factors of depression for seniors on the prevention side, and also to spot as soon as possible the alert signs to talk with a health professional (anxiety, memory loss, behavioural disorders and dementia). Those risk factors can be physical, psychological, social or biological.

The digital uses in the mental health field is really low. The Emen project states that in 2016, “the average use across the Netherlands, France, Germany, UK, Belgium and Ireland was 8%, which is low compared to other healthcare sectors; with the lowest use in FR (less than 1%) and the highest in the Netherlands (15%). Unmet needs were also high, with an EU average of 6.8%”. 

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Yet, digital health can be a lever to:
- work on the factors to prevent seniors from depression,
- give health assistance and treatment online,
- work on the detection of alert signs,
- foster elderly people to “empower” and act on his/her mental health.

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,
- well-being solutions,
- sensors allowing the collection of data, their analysis and the generation of alerts.

Many research projects are working on this field. Here are research fields already explored:
- Real-time monitoring, the collection and analysis of data about individuals’ moods, cognitions, and activities, about their whereabouts, behaviour, and physiological states,
- Current State and Future Directions of Technology-Based Ecological Momentary Assessment and Intervention for Major Depressive Disorder,
- The effectiveness of mHealth to the improvement of healthy behaviours in an elderly population,
- Smartphone and smartphone-sensor based healthcare technologies for seniors
- The use of context sensing to identify mental health-related states,
- The use of machine learning and algorithms to predict the elderly emergency department visits, or to predict the classification of depression groups in older adults living alone,
- Comparative Effectiveness on Internet-based Depression Treatment.

New technologies and seniors. What could discriminate elderly people as potential users of “digital mental health solutions and tools” could be their habits and level of uses in digital tools, information systems, and largely of internet and smartphones.

When introducing a national home telehealth program to the “Veterans Health Administration” in US, the administration was confronted to the fact that “the Elderly patients often encounter difficulties using these technologies. Despite the advances in telehealth and telemedicine and the evolution of the technology, many individuals cannot afford the treatment or the technology. These same individuals and families are part of the digital divide, and they have not embraced the new technology”.

The barrier to the adoption of health information technologies and largely to digital tools could be a massive difficulty to develop and implement the elderly new uses.

Yet, as for the rest of the population, and maybe more, it seems that digital uses are very well considered and adopted amongst senior population, with a fast technology spreading and development of uses.

As states the 2018 Barometer of senior well-being in France, on people over 65 years, Internet is for seniors a way to maintain social relationships:
- 15 % use internet to discuss on skype at least once a week;
- 41 % use social networks at least once a week.

Internet is a major tool for self-esteem (internet gets a 6.9/10 quote as a factor to keep autonomy and get the feeling they are useful). Internet is already largely part of their lives:
- 54 % of elderly people use internet once a month to seek information and discuss on forums;
- 40 % use web sites to get health information once a month.
A study realized in 2016 by Future Thinking for SeniorSphere showed that more and more seniors are connected to internet. In 2016:
- 79% of people between 60 and 69 years old were connected;
- 56% of people over 70 were connected;
as regard to 85% of global population.
Regarding the use of smartphones, seniors are more and more using these devices, seniors are more and more equipped:
- people between 60 and 69-year-old people were 5% to have a smartphone in 2011 (against 17% of global population) and were 42% to have one in 2017 (against 17% of global population);
- people over 70-year-old were 1% in 2011 and 20% in 2016.

The impact of digital mental health prevention on the elderly quality of life to be studied. It has been proven, in an abstract called “Effectiveness of the mHealth technology in improvement of healthy behaviours in an elderly population-a systematic review” that: “The mHealth technology has proven effective for disease prevention, lifestyle changes, management of cardiovascular disease and diabetes, and is a suitable tool for elderly people. In conclusion, it seems that mHealth can facilitate behavioural changes; although, further research is necessary in this regard”.

But, according to this state of art, it appears that:
- there seems to be very few studies on the impacts of digital mental health on the elderly autonomy and quality of life;
- there seems to be few solutions dedicated to mental health disorders for seniors and specially adapted for them;
- in the large scale of mental health digital tools, the impact of prevention on the autonomy and quality of life of seniors is unknown.

This is to be investigated and studied through the SMART BEAR project.

2.5 Smart Bear Expected Impact

The rate of European population growth is dropping, while populations around Europe are rapidly ageing. This demographic evolution is challenging EU since it increases the demand for long-term health care and safer more age-friendly environments. A holistic view of the problem is required [70] [71].
The solution proposed by the WHO model is addressing two major factors creating this augmented need: the fact that, with ageing, individual’s capacities and degree of independency is deteriorating while environmental barriers become more difficult to overcome. Practically, the specific model aims to increase Internal Capacity and/or reduce environmental barriers in order to enhance elderly’s independence, 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.
SMART BEAR is adopting this holistic view throughout its design and deployment activities. It targets these 5 factors by creating an integrated easy-to-use and to-maintain technological solution that is able to monitor and assess valuable personal, physiological and environmental parameters that correlate with them. Six major medical entities have been placed to the centre of interest and state-of-the-art equipment is going to be used according to evidence-based medical algorithms and current guidelines. The need for a holistic view according to the IC model is even more pronounced in Smart Bear since a variety of actors at different involvement levels (elder people, health professionals, caregivers, municipality staff) will be actively involved.
The impact that SMART BEAR creates as a holistic and integrated technological wellbeing solution is based on 5 crucial factors: security, confidentiality, interoperability, scalability and standards. Fundamental requirements for the harmonized adoption of an innovative technological solution into elderly’s habits are:
The solution is being implemented and tested within the smart home: technical body of Smart Bear and trained health care providers will assure the proper implementation and testing of sensors and other technologies provided to the participants.

The solution is bringing a change in elderly’s monitoring: in respect with each participant needs, and according to evidence-based medical guidelines, the technology offered will deal with participants’ unaddressed health challenges, only to improve their management through an alternative and more age-friendly way.

The solution is having an impact on elderly’s quality of life and ultimately health: subjective and objective tools of impact assessment will be used as described below.

The solution is having the capacity to transfer the experience to other organizations and systems: Smart Bear will augment its impact through innovation, exploitation and standardization of its holistic approach. Project’s outcomes will be adequately communicated to healthcare stakeholders, organizations and individuals, whilst pursuing links and synergies with pertinent initiatives and piloting activities will assure its long-term sustainability. Moreover, it will address not only healthcare but also smart home and smart city domains. This will significantly increase the success of the program since it will enhance participants’ compliance to the novel and innovative solutions provided by the technologies offered.

SMART BEAR’s specific impacts will be measured through the elderly’s monitoring results. These results derive from a list of measurable indicators of the outcomes of the SMART BEAR platform. In this way, the specific impacts expected from the system’s use will be quantified in an objective and credible manner. In this effort the MAFEIP framework will be leveraged, to provide evidence for the decision to buy and to invest on Societal impact assessment will provide feedback for the project. This objective also concerns the effective dissemination and communication of project outcomes in scientific conferences, industrial exhibitions and other related forum, and social media. Moreover, so as to create a sustainable solution, SMART BEAR will develop a data sharing and valorization model (DSVM). This model will identify ways, at a technical and organizational level, for extending the data collected in SMART BEAR by integrating new data providers and sources and use the outcomes of data analysis to improve the platform performance, enhance further the personalization of its relation with its end-users, develop new services, and monetize data-intensive services out of the platform. DSVM will be used to issue an Open Call for the inclusion of additional data sources and providers that can bring specific and significant added value to the SMART BEAR offering.

To measure the impact in terms of elderly’s health benefits, cost, social, and market dimensions, a specific research study is needed. Thus, referring to the ICT solutions, the objectives of the solution should be defined alongside with an appropriate methodology for assessing the solution. The SMART BEAR assessment methodology has three steps and involves the skills and contributions of all project partners.

**Step 1: Acceptance assessment.** The engagement of the SMART BEAR users in using the platform and services reflects the degree of acceptance of the platform and its functionalities by the target group. This is an important prerequisite for the overall impact assessment of the project, since evidence revealing the acceptance of the SMART BEAR solution by the target population is fundamental for achieving significant impact during and after the project.

**Step 2: Benefits’ assessment.** The anticipated benefits from the SMART BEAR platform are in five role-based categories: 1. Benefits to elderly’s well-being; 2. Benefits to Healthcare Sector; 3. The market’s benefits; 4. Indirect on Other Actors and/or Stakeholders; 5. Benefits to European Economy – Direct with new Markets into the AAL Market.

**Step 3: Impact assessment.** SMART BEAR’s specific impacts will be measured through the elderly’s monitoring results. These results derive from a list of measurable indicators of the outcomes of the SMART BEAR platform. In this way, the specific impacts expected from the system’s use will be quantified in an objective and credible manner. In this effort the MAFEIP framework will be leveraged, to provide evidence for the decision to buy and to invest on the SMART BEAR solution, as well as to point towards positive changes in the healthcare policymaking.
An External Advisory Board (EAB) will help SMART BEAR connect with possible adopters (e.g. healthcare organizations) and end-users of the developed solutions, other projects and research initiatives, as well as with important standardization bodies in multiple domains. The experts who have already committed their support (letters provided in Appendix 1) are: Mr. Niels Henrik Pontoppidan, Research Area Manager Augmented Hearing, Eriksholm Research Centre, Oticon A/S; Dr. Marco Predazzi, President, Fondazione Il Melo Onlus Luigi Figini, Italy; Prof. Matteo Cesari, MD, PhD, Head of Geriatric Unit, Fondazione IRCCS Ca’Granda - Ospedale Maggiore Policlinico, Milan, Italy; Pascal Bisson, Advance Studies Program Manager, THALES SIX GTS; Sotirios Kostantakis, CEO Aenorasis S.A.; Prof. Gregory B. Sinapenko, University of Patras; Athanasios Manos, Director PD neurotechnology; Anastasios Tagaris, President and Managing Director, IDIKA S.A.

3 Requirement Elicitation Methodology

Requirements elicitation is the first and most critical step in the process of requirement engineering. Indeed, correct and complete requirements lead to the success of a system, whereas ambiguous and wrong requirements may result in its failure [75]. Elicitation consists of the activities that are taken to understand the users and explore their requirements. Elicitation takes account of the finding and some development, in addition to recording those organizational or legal constraints that must be considered in the context of a specific business process or application.

3.1 Techniques for Requirements Elicitation

A number of techniques have been proposed for requirement elicitation [73], such as, for example, interviews, focus groups, questionnaires, document analysis, domain analysis, and requirements workshops. Each is examined in turn below. Though they all have weaknesses and strengths it is well known that optimal results can be achieved only by the integration of multiple techniques.

**Interview.** An interview is a systematic approach to elicit information from a stakeholder or domain expert by face to face conversation. There are two main kinds of interviews: (i) closed or structured interviews, where the interviewer has a predefined set of questions and is looking for their answers, and (ii) open or unstructured interviews, in which the interviewer tries to get the information from the stakeholders in open discussions. Grin and Hauser [72] found that 20/30 stakeholder interviews can source to determine almost 90% of all possible product requirements.

**Focus group.** A focus group is a means to elicit ideas and expectations about a specific product, feature or need in an interactive group environment guided by a moderator. To maximise the effectiveness of this technique, the group participants should have different backgrounds and different skills. As noted by Matzler and Hinterhuber [74], many market research institutes use focus groups to elicit product requirements, assuming that group dynamic effects enable the emergence of a greater number of more diversified stakeholders needs.

**Questionnaire.** Questionnaires allow to gather requirements from a large number of people in short time and little cost. The success of a questionnaire depends on its effective design, as well as the knowledge and honesty of the respondents. However, because incomprehension and ambiguities may arise, the results extracted from the questionnaires should be clearly analysed. Questionnaires may have two types of questions: (i) closed, if the respondent is asked to select from available responses, and (ii) open-ended, if the respondent is free to answer the questions as he/she wishes.

**Domain analysis.** Domain analysis can elicit requirements of an existing system by studying available documentation and previous applications to identify relevant information. Examples of relevant documents are business plans, market studies, existing guidelines, research studies, procedures, customer suggestion logs, existing system specifications. Domain analysis is particularly useful to provide background knowledge about a particular product, feature or technology.
**Requirement workshop.** A requirement workshop is a focused and intensive collection of meetings in which the stakeholders discuss, discover, define and reach closure on requirements for the target system. Well-run workshops are considered one of the most effective ways to deliver high-quality requirements quickly.

Table 1 summarizes strengths and weaknesses of the requirement elicitation techniques presented above.

**Table 1 Strengths and weaknesses of a set of requirement elicitation techniques**

<table>
<thead>
<tr>
<th>Elicitation tech.</th>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interview</td>
<td>- Simple, economical and generic</td>
<td>- Require considerable commitment and preparation of the participants</td>
</tr>
<tr>
<td></td>
<td>- Effective in understanding the questions and answers</td>
<td>- Time-consuming</td>
</tr>
<tr>
<td>Focus Group</td>
<td>- Time and cost-effective as compared to conducting individual interviews</td>
<td>- Trust and privacy issues</td>
</tr>
<tr>
<td></td>
<td>- with the same number of people</td>
<td>- Require well-trained moderator</td>
</tr>
<tr>
<td></td>
<td>- Require well-trained moderator</td>
<td>- Require a heterogeneous group</td>
</tr>
<tr>
<td></td>
<td>- Difficult to schedule the group</td>
<td>- Difficult to schedule the group</td>
</tr>
<tr>
<td>Questionnaire</td>
<td>- Closed questions are easy to analyse</td>
<td>- Questions and answers might be misunderstood</td>
</tr>
<tr>
<td></td>
<td>- Open-ended questions yield more insights and opinions than other</td>
<td>- Require specialised skills in statistical analysis</td>
</tr>
<tr>
<td></td>
<td>elicitation techniques</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Time-effective</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Easily performed remotely</td>
<td></td>
</tr>
<tr>
<td>Domain Analysis</td>
<td>- Capitalise on existing knowledge to discover/confirm requirements</td>
<td>- Available documentation may not be up-to-date or valid</td>
</tr>
<tr>
<td></td>
<td>- Good starting activity of requirement elicitation</td>
<td>- Require lot of expertise and skills</td>
</tr>
<tr>
<td></td>
<td>- Easily performed remotely</td>
<td>- Time-consuming to locate the relevant information</td>
</tr>
<tr>
<td>Requirement Workshop</td>
<td>- Time and cost-effective as compared to conducting individual interviews</td>
<td>- Require well-trained moderator</td>
</tr>
<tr>
<td></td>
<td>- Effective in mutual understanding of the requirements</td>
<td>- Difficult to schedule the workshop</td>
</tr>
<tr>
<td></td>
<td>- Immediate feedback</td>
<td>- Not useful for small projects</td>
</tr>
</tbody>
</table>
3.2 Requirements elicitation in SMART BEAR

The requirement elicitation methodology adopted in SMART BEAR is aimed at exploiting the strengths offered by different techniques to achieve an efficient and effective elicitation procedure. The coordination between different techniques allows getting detailed information without excessive use of resources and time.

The elicitation procedure is organized in three stages.

1. **Domain analysis.** This stage is aimed at surveying the state of the art identifying the progress SMART BEAR has the potential to introduce. It is mainly developed in Section 2 but it is also evolved by the focus groups and questionnaires used by the project in order to get insights about the needs emerging form patients and clinicians and about the best practices and constraints recommended by technical experts about ICT and data protection regulations.

2. **Requirement gathering.** Once the needs and the opportunities have been defined, a better specification of the requirements is requested. The goal to obtain a first list of requirements, trying to answer “what” is to be built. This stage is addressed in Sections 4.3, 5.1, 5.2, and 5.3. Sections 3.3 and 3.4 explain how this procedure is addressed for clinical requirements and technical requirements respectively using a user-centric approach. Section 6 offers an overview of the GDPR and its Implications on the SMART BEAR project taking indeed a normative approach. The requirements emerging from normative constraints should not be elicited with the user but simply deduced by a careful understanding of the documents prescribing these norms.

3. **Requirement integration, evaluation, and prioritization.** Before considering the requirements elicited as valid they must be analyzed to determine consistency between different statements. The relative importance of requirements must also be defined to effectively guide the development process. All these activities drive a stage of integration aimed at generating an effective list of requirements consistent with the goals and organizational factors motivating the project. The D2.1 deliverable presents the results of this stage mainly in Section 4.1.4 for clinical requirements and in Section 5.3.1 for technical requirements. However, the process of evaluation and integration of the requirement is not completed in the project. Further actions will be implemented during the next WP2 activities and during system specification because only by multiple iterations of the validation stage a project can really verify the consistency of the design steps it implements. For example, the SMART BEAR platform specification will require to validate the data quality and integration level of different devices, as more knowledge about the technical specification of devices will be acquired by the technical partners of the projects by means of tests and trials. This will input further evaluation activities. In the same context, the specific workflows driving the use cases will be designed and evaluated with clinician to double-check their consistency to the requirements.

Figure 6 illustrates the requirement elicitation process adopted in SMART BEAR. As described by the workflow presented in Figure 6 each stage will take in input the results produced by the preceding stage. An analysis of the state of the art is the input for the domain analysis that will focus on IoT environments in eHealth, WHO guidelines and medical conditions targeted in the project. Thanks to this domain analysis we identify the SMART BEAR advances to the state of the art that offers a starting point for organizing the different focus groups and the questionnaires used in the requirement gathering stage. Lists of clinical, technological, and legal requirements are this way produced. The first versions are then evaluated to get a consistent integration of the different need emerged in the gathering stage and to organize a documentation on SMART BEAR requirements providing specifications and prioritization for future design activities.
3.3 **Clinical Requirements: Gathering, Evaluation and Prioritization**

In order to gain insight on SMART BEAR target population needs and expectations, several Focus Groups have been performed in the involved countries. Using focus groups in order to collect information on a specific topic by a specific population is a very popular qualitative method in medical research. Focus groups can take many forms, but most frequently, they are a series of structured discussions of 1 hour of duration, around a Draft Example Scenario and a specific set of questions that are explored with small groups of 4-8 people. The discussion is coordinated by a researcher / facilitator / moderator.

In Smart Bear, before conducting Focus Groups, a Focus Group Facilitation Guide along with the Participants information sheet, Written Informed Consent Form, Notes sheet and Questionnaires addressed to Focus Groups participants have been prepared by NKUA in English. This first version of documents has been created by adapting parts of previous used questionnaires for the elderly into the Smart Bear concept. This material was then circulated among partners for comments and additions. After this step, and with the contribution of FCSR, the questionnaires were finalized. Two scales were included:

- **WHO-5 Well-being Index**, in order to gain a more complete perspective on the participant’s quality of life.
- **Caregiver Burden Inventory**, in order to understand how the caregiver is affected by the participant’s medical condition. Indeed, an important stakeholder of the Smart Bear platform is the people who provide care, time and effort in assisting the elderly in their everyday life.

The final version of all documentation is covering 6 major aspects of Smart Bear as described in Figure 7 has been translated by each Pilot. The English version of the finalized documents can be found in Appendix 1 - SMART BEAR PARTICIPANT FOCUS GROUPS FACILITATION GUIDE.

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3 Available in different languages at [https://www.psykiatri-regionh.dk/who-5/who-5-questionnaires/Pages/default.aspx](https://www.psykiatri-regionh.dk/who-5/who-5-questionnaires/Pages/default.aspx)

4 See attachment “Novack1989”
Focus Groups have then been conducted with both participants and clinicians according to the Ethics regulations of each involved institution. Meeting and discussion followed the steps described in the brief Focus Group Facilitation Guide. Smart Bear Focus groups included a small number of participants meeting the following criteria: age over 65 years old and history of at least one of the targeted medical conditions. In the case of clinicians’ Focus groups, specialists in at least one of the targeted medical conditions were invited and included to the discussion according to their availability.

Results have been reported in a predefined form in order to be coherent and harmonized. They were disseminated among clinical partners and discussed indirectly.

In parallel with Focus groups, online User Surveys / Questionnaires have been used in order to gain knowledge on end-users’ beliefs, attitudes and expectations. A set of written questions has been prepared centrally by NKUA according to the same philosophy of the Focus Groups questionnaires and then been revised by all partners (Figure 7). The finalized version was translated in each Pilot’s language and has been disseminated to a sample population of users. The English version of the finalized documents can be found in the Appendix 1 - SMART BEAR PARTICIPANT FOCUS GROUPS FACILITATION GUIDE. Focus groups and online survey results for Patints and Clinicians per Pilot are included in Section 4.3.

The final requirement gathering as well as the integration and evaluation stages have required the organization of meetings with the joint participation of clinical and technical partners form all pilots. In particular, the calendar has included the following dates:

- November 26th online meeting.
- December 3rd online meeting.
- December 10th online meeting.
- December 16th and 17th face to face meeting in Athens.

![Figure 7 Domains covered by Smart Bear Focus Group and Online surveys material.](image)

### 3.4 Technical Requirements: Gathering, Evaluation and Prioritization

As discussed in Section 3.2, the technical properties of the SMART BEAR platform will be identified by a set of activities including the analysis of the domain, the prioritization of the requirements using questionnaires and the clarification of the goals using focus groups. The Kano model [76] was selected as the approach to be used
in order to classify requirements based on their priority level. The Kano model is a useful tool for understanding
the needs and expectations of a stakeholder-based on how they affect his/her satisfaction with a given product
(e.g., a new software system). Proposed in 1984 by Prof. Noriaki Kano, the Kano model has been widely
practised among marketing/ management practitioners as a guide for strategic and tactical decisions to
achieve stakeholders' satisfaction.

The Kano Model (KM) is based upon three premises. First, the satisfaction of a stakeholder with the features
of a product depends on the level of functionality that is provided, i.e., how much or how well the features are
implemented. A feature is a condition or capability of the product that can be captured by a requirement.
Second, requirements can be classified into categories, depending on how the associated features influence
the stakeholder's satisfaction. Finally, the satisfaction of a stakeholder with the fulfilment of a requirement
can be obtained from a questionnaire.

3.4.1 Kano categories

The Kano model classifies requirements based on their location along two dimensions, namely, the degree
of satisfaction and the level of functionality. The degree of satisfaction goes from total satisfaction (also called
delight and excitement) to total dissatisfaction (or frustration). On the other hand, the level of functionality
goes from fully dysfunctional, when no functionality is provided, to fully functional, when the best possible
fulfilment of the requirement is delivered. These two dimensions are the basis of the KM to classify
requirements depending on how stakeholders feel about the provided level of functionality. In his paper [76]
, Kano identified the four categories illustrated in Figure 8 and described below.

Must-be requirements (red line in the figure) are basic requirements of a product. If these requirements are
not achieved, the stakeholder will be severely dissatisfied and not interested in the product at all. On the other
hand, even if the features described by these requirements are implemented with full functionality, this will
not increase the stakeholder's satisfaction as he/she gave them for granted. To put it another way, must-be
requirements are prerequisites of a product, and their achievement can only lead the stakeholder to a state of
‘not dissatisfaction’. Must-be requirements are also called basic, expected, or dissatisfier.

One-dimensional requirements (straight blue line in the figure) are those for which the level of functionality
is proportional to the degree of satisfaction | the better a requirement is achieved, the higher the stakeholder
will be satisfied, and vice versa. One-dimensional requirements are also called performance or satisfier.

Attractive requirements (green line in the figure) are usually unexpected by the stakeholders but have the
greatest influence on how satisfied they will be with the achievement of a given requirement. As the level of
functionality achieved by these requirement increases, the stakeholder's satisfaction increase more than
proportionally. Conversely, if an attractive requirement is not met, there is no feeling of dissatisfaction.
Attractive requirements are also called exciter, delighter, or added value.

Indifferent requirements (grey horizontal line in the figure) are those in which their presence (or absence)
does not affect the reaction of the stakeholder to the product.

The Kano's classification of requirements can provide decision support to product design. In particular, product
designers must ensure that all the must-be requirements are met. However, once a satisfactory level of
functionality is reached, it is not necessary to keep investing in must-be requirements, as the effort does not
translate into a substantial increase in the stakeholder satisfaction. A good performance of the one-
dimensional requirements is instead essential to stay competitive with market leaders, whereas providing
some attractive features allows differentiating the product from competitors. Note that even a limited
achievement of an attractive requirement will induce satisfaction. Kano's categories also provide valuable
guidance in trade-off situations during the product development stage [77] [78]. For example, if two or more
requirements cannot be achieved in the same product release due to technical or financial reasons, their
category will indicate which ones should be prioritised.
3.4.2 Kano questionnaire

The Kano model is constructed using a survey methodology, whereby requirements are first classified at the individual stakeholder level through a questionnaire and then aggregated. The Kano Questionnaire (KQ) contains a list of question pairs for each and every product requirement. The question pair includes a functional question, which asks how the respondent would feel if a certain requirement is met, and a dysfunctional question, which asks how the respondent would feel if a product fails to achieve that requirement. The questions must be understandable by the intended respondents, and, therefore, they require an appropriate and unambiguous terminology.

To answer each part of the question, the respondent can choose one of five different options, which are proposed below (the different wordings are taken from [80]):

- I like it (or I like it that way, This would be helpful to me);
- I expect it (or It must be that way, This is a basic requirement to me);
- I am neutral (or I do not care, This would not affect me);
- I can tolerate it (or I can live with it that way, This would be a minor inconvenience);
- I dislike it (or I dislike it that way, This would be a major problem for me).

The answers above do not reflect a ranking of the correspondent requirement, but rather the means for its classification in terms of Kano categories. It is important to make this difference clear to the respondents, or the answers may be biased by their preferences over certain features. For instance, a respondent may intend the “I like it” answer as “give maximum priority to the fulfilment of this requirement”, which will lead to misleading classifications (e.g., also an “I expect it” answer might refer to a requirement expected to be fulfilled with maximum priority). A good practice to reduce the risk of misunderstanding is to avoid numbering the answers of the Kano questionnaire.

3.4.3 Analysis of the Kano questionnaire

The KQ is administered to a number of stakeholders, and each answer pair is aligned with the Kano Evaluation Table (KET) shown in Figure 9, revealing an individual stakeholder’s perception of a requirement.

The KET identifies two more categories, namely, questionable and reverse. A requirement is questionable if there is a contradiction in the stakeholders’ answers to a question pair (e.g., respondents answered “I like it” to both the functional and dysfunctional question). If a requirement received a substantial number of
questionable scores, probably the question was confusing, and it should be reformulated. On the other hand, a reversal requirement clearly indicates that stakeholders want the opposite of what it describes, as the degree of satisfaction decreases with the level of functionality provided. Of course, no reversal requirement should be included in the final product.

Once having combined the answers to the functional and dysfunctional question in the KET, the classification of the individual requirements is summarized, as we did in Section 5.3.1. The analysis and interpretation of the results in this table can use different techniques. A standard solution is to consider statistical summaries of the categories distribution, especially the mode i.e., the most frequently occurring category. The mode is simple to use and easy to understand but has some limitations in particular cases.

The DuMouchel analysis [79] has in fact identified three categories of requirements, namely, attractive, one-dimensional, and indifferent. However, this classification has been discarded by the DuMouchel analytical model. The high number of positive answers (i.e., “I expect it”) to the dysfunctional question weaken its reliability. This is most certainly due to ambiguities in the phrasing of the dysfunctional question, which failed to highlight its contrasts with the complementing functional question. The one-dimensional classification indicates that the stakeholders’ satisfaction will be proportional to the fulfilment of requirements.

For an overall interpretation of the Kano questionnaire data, the responses have been analysed using the DuMouchel methodology. First, the methodology requires to calculate the Functional and Dysfunctional scores of every set of requirements, by applying the mapping rules listed in Figure 9, to the respondents’ answers summarized in Section 5.3.1. Second, the Importance score is computed by averaging the responses given to the Self-Stated Importance questionnaire administered together with the KQ. Consider for example the must-be category, which can result from three different combinations of answers (“I expect it” – “I dislike”, “I am neutral” - “I dislike”, “I can tolerate it” - “I dislike”). According to this mapping, it is impossible to distinguish must-be requirements with a majority of functional expectations from those with a majority of functional “I can tolerate it”. Section 5.3.1 reports the scores calculated for each set of requirements to carry out the DuMouchel analysis. Boldface numbers indicate the most frequently occurring answer for a given question which is getting more than 50% of the preference, or the two categories getting the most preferences.

The analysis of the results of the Kano model will provide a great support to the alignment of the different point of view and languages of the technical partners. An initial list of requirements will be brainstormed by the technical partners and assessed using the KQ. The requirements listed in KQ are not aimed at offering a complete coverage of the platform requirements but act as representative of class of requirements to be extended by the technical used cases. The analysis of the Kano model will allow us to verify the coverage of all functional areas and to improve our understanding about converging or diverging aspects. The results reported
D5 - SMART BEAR Requirements

In Table 32 and Table 33 demonstrate the functional areas we identified are offering a complete coverage of the functionalities brainstormed by the technical partners. At the same time some of the brainstormed requirements resulted irrelevant or undesired. Using this results the definition of the technical use case has benefited of guidelines and limiting factors, minimizing the risk of producing irrelevant specification.
4 Health and Well-Being Requirements

4.1 Use Case Scenarios Methodology
This section provides an overview on the methodologies and procedures used by the research teams and pilots for the definition of the project Focus groups, Use Cases, and Scenarios.

4.1.1 State of the Art – Health
Before designing SMART BEAR activities, clinical partners have exhaustively reviewed literature in order to define guidelines and state of the art technological and medical solutions related to the SMART BEAR targeted entities. The gained knowledge contributed to create the basis on which focus groups, online questionnaires and finally use case scenarios were built. Details on partners’ reviews on hearing impairment, balance disorders, CVDs, cognitive disorders, frailty and mental health problems can be found in Section 3.

4.1.2 Focus Groups
Focus Groups (FGs) with seniors and clinicians were conducted by SMART BEAR pilots. The purpose of these actions was to provide us with insight on attitudes, beliefs, and expectations of SMART BEAR target population. Focus groups discussions are an essential element in qualitative medical research, so special care has been given to the material that was going to be used by all pilots (see Appendixes 1, 2, and 3) and to the structure of the discussion itself. In general, the flow of actions followed the schema in Figure 10.

Some results of the focus groups discussions are mentioned below. Balanced representation of all 6 clinical entities and medical specialities has been achieved (Figure 11), adding value to our results (Figure 12). The discussion with seniors and clinicians along with the online questionnaires has been focused on specific concepts concerning SMART BEAR design and implementation. Interesting conclusions have been reached and facilitated the next steps of SMART BEAR use case scenarios creation and requirements definition.
Both participants’ and clinicians’ majority conclude that the aforementioned conditions are the principal problems that challenge seniors’ and their significant others’ everyday life. They affect seniors’ vital functions, sensorial functionalities, psychological functioning, movement functionalities, and cognitive functionalities. All these problems should be addressed by SMART BEAR technological solution.

Seniors’ experience with smart devices has also been assessed, and responses varied significantly. The majority of participants stated being aware of smart devices such as smartwatches, smartphones or smart bulbs. However, there were many participants with no experience at all. What is interesting is that most of them did not feel that this lack of experience should exclude them from their participation to SMART BEAR. They stated more than willing to be trained and/or use their significant other’s help in order to be able to benefit of SMART BEAR technologies. This is why they suggest that integrated solutions such as a smartwatch or a smartphone would be the best choice for the implementation of SMART BEAR Platform. Key points, but not excluding factors, during the pre-recruitment and recruitment phase should be the dexterity of candidates and their and/or their carers’ ability to use the provided technologies.

Workshops on the provided technologies will be of major importance before the deployment of Smart Bear. This conclusion was in accordance with clinicians’ point of view, as well.
The types of measurements that will be most useful to senior’s everyday life were discussed in both FGs and questionnaires. Physiological measurements such as heart rate and blood pressure were mostly preferred, while environmental factors were less appreciated. Possible benefit of weight monitoring and eating habits tracking has also been reported. Participants felt that they can find this kind of information elsewhere.
Furthermore, participants using hearing aids suggested that noise exposure levels and number of changes of HA program during a day would be helpful for them and their audiologist. Overall, participants felt that every day self-monitoring at home is more trust-worthy than the one-time measurements at the clinic, where differences in measurements and errors may occur. Remote monitoring was also considered as a useful tool for improvement of therapeutic strategies, due to a higher number of available data, especially for behavioural disorder pathologies (Figure 13).

**Figure 13** Most useful measurements according to Physicians and Seniors.

SMART BEAR aims to interact with its users, while alerting referring clinicians or significant others is also considered. **Discussion concerning regular reports provided by the SMART BEAR platform has concluded that reports should be adjusted to the nature of each health issue or event** e.g. hypertension-related observations should be reported more frequently (once per week) than fall detection (once per month). In some countries,
such as Romania, Italy, or France, referring doctors find it useful to receive comprehensive reports of their patient’s health. In Greece, where having a family doctor is not common, participants and clinicians have all agreed that those reports should be addressed to the user and he/she should communicate them to their referring doctors (who are more than one). Everyone agreed that this Smart bear feature will facilitate both the self-management of users’ everyday health issues and the patient-doctor relationship (Figure 14).

Figure 14 Regular reports reaching directly the referring physician have had varied acceptance among physicians and seniors.

When asked about their major concerns in the case they decide to participate to SMART BEAR and make use of the platform, the participants expressed their awareness that little effort is requested from their part, respectively learning how to use the smart tools and the platform. Once more it has been stated by both clinicians and seniors that what concerns them the most is the technical issues of the devices that could lead to wrong measurements and thus wrong notifications. The lack of a direct contact of a health provider with the patient was also considered a limitation. The need to assure safety and respect of participants’ privacy were also highlighted (Figure 15).

Receiving alerts and notifications according to platform’s observations was also highly appreciated as very useful by the participants. Nevertheless, all participants agreed that they would be more than willing to follow instructions only as long as the reliability of the devices is proved, the notifications are within reasonable limits and agree with their doctor’s advice. This underlines the fact that SMART BEAR devices should be cautiously chosen among certified medical devices and that notifications should include only simple evidence-based strategies of management. Through every stage of the deployment of the project, it should be clarified that the integrated solution that SMART BEAR provides does not replace medical advice.

Participants were also asked if they would like to participate or recommend to others the participation to the project. The vast majority consider SMART BEAR as a useful technological solution, not only in individual level but as a long term innovative Big Data research study that will provide invaluable insight on varied medical conditions as well and they would like to be involved.
4.1.3 Online and paper-based surveys

In addition to Focus Groups discussions, several Pilots have used online and paper-based questionnaires in order to gain insight on their target population attitudes and beliefs. The relevant material can be found in Appendix 1 and covers the same domains that are described in Figure 12.

Feedback provided by these questionnaires shed light on specific matters of SMART BEAR. Although the level of experience with smart devices varies among physicians and seniors, they have all agreed that implementation of state-of-the-art technology in daily routines of seniors would be of increased value (Figure 26).
Figure 16 Experience of responders of Smart Bear questionnaires with smart devices and degree of acceptance of a state-of-the-art technological solution such as Smart Bear.
Concerning one’s expectations of a project like SMART BEAR, it was evident that its goals and priorities as described thoroughly in this deliverable are well harmonized with target population’s needs and expectations. Both seniors and clinicians aim to less unnecessary visits to health care related structures, frail senior’s safety, better auto-management of health issues, elimination of social isolation, independency, detection of mood deterioration, enhancement of self-esteem, improvement of overall health and patient-doctor communication (Figure 27).

*Figure 17 Expectations of a possible participation in Smart Bear, harmonized with Smart Bear goals.*
Finally, concerning the most useful measurements, results of Focus Groups discussions were confirmed (Figure 18).

Figure 18 Most Useful measurements according to Smart Bear survey results.
4.1.4 Use Case Scenarios and Requirements

In order to create use case scenarios, clinical partners have undertaken a series of actions. Initially, each partner has contributed several scenarios spontaneously, in their domain of expertise and according to their point of view and priorities. Information gathered from the literature (see Section 2), feedback from the online questionnaires (see Section 3 and Appendix 1), and insight gained through elderly’s and clinicians’ focus groups have been combined with partners’ expertise in order to create feasible but valuable and innovative integrated solutions for the support of specific issues elderly face in their everyday routine. A template has been provided to all partners in order to assure the harmonized structure of all scenarios.

Once finalized by each partner, scenarios have been gathered and a first internal evaluation has been conducted. At first, each scenario has been evaluated for its integration, feasibility, priority and relation with project goals. Consequently, all partners had the time to evaluate the selected scenarios as a whole. Opinions and ideas have been exchanged during a relevant teleconference. Following this, a list of additional scenarios has been created, in order to cover all SMART BEAR concepts that were remaining unaddressed. Those scenarios have also been evaluated as described above. The diversity of partners in the Consortium has assured the quality and multidimensionality of scenarios internal validation. In order to empower their quality furthermore a number of discussions and focus groups have been organized, with the aim to discuss the scenarios with external to the project experts and stakeholders’ representatives. A first external validation has also been achieved in specific pilots, as described in Appendix 4.

The project technical and user teams have then collectively decided whether the scenarios are feasible, if they meet SMART BEAR objectives and add value for the target stakeholders. These discussions were held indirectly, through Skype meetings and during a face to face meeting hold in Athens on 16 and 17 December 2019.

At the end of the aforementioned procedures, a list of representative user scenarios has been identified. These scenarios cover all six SMART BEAR target medical entities and reflect the perception of project partners on how the project could achieve its goals and support the independence of its elderly participants by means of the technologies offered.

The procedure that has been followed in order to assure the quality, feasibility and relevance of scenarios along with the steps of extracting from these scenarios the final user requirements is described in Figure 19.

![Figure 19 Procedure followed for the definition of Use Cases and Scenarios.](https://www.ietf.org/rfc/rfc2119.txt)

For the creation of the scenarios, a template inspired to a standardized formal language in RFC2119 (https://www.ietf.org/rfc/rfc2119.txt) has been used. It includes textual description of parameters such as pre-conditions and post-conditions, actors, triggers and flow of events.
4.2 Clinical Use Case Scenarios

The goal of SMART BEAR Project, to create and deliver an integrated technological solution to enhance the independence of the elderly and the self-management of their everyday challenges, can be achieved by targeting six medical entities (hearing loss, balance disorders, CVDs, frailty, cognitive and mental disorders) by remote monitoring, individualized assessment and personalized evidence-based intervention.

Within the SMART BEAR Platform, data will be collected from different sources: sensors (home, wearables, medical devices), online open-access data (weather, social activities, etc.), self-reporting (questionnaires, health diary, medical history), and health care providers (screening visit, follow-ups and current health e-records in specific Pilots). In order to organize the collection and visualization of these data, SMART BEAR interface could present specific icons as shown in Figure 20, where each icon represents a specific application. According to each user’s profile, specific icons will be activated, while MyDiary, MyAppointments, MyDiet, MySMART BEAR and MyMedication will be active for everyone. A brief description of each App is described in Table 2.

![Figure 20 Smart Bear suggested Interface.](image-url)
### Table 2 Smart Bear Apps – Basic Elements.

**Notification** = text that reaches user’s mobile without needing a reaction  
**Alert** = Patient must react/respond to the alert (Relevant Systems Scenarios should be created for the case manager and caregivers)

<table>
<thead>
<tr>
<th>Application</th>
<th>Medical Condition</th>
<th>Feature 1</th>
<th>Device</th>
<th>Notification</th>
<th>Intervention</th>
</tr>
</thead>
</table>
| MyHeart     | CVD               | – Blood pressure<br>- Heart Rate<br>- Weight<br>- Weather<br>- Medication<br>- Physical activity - individualized goals<br>- Blood Glc Level (only if available) | 1. Smart Blood Pressure tracker<br>2. Heart rate tracker<br>3. Smart Weight scales<br>4. Weather station<br>5. Smart Pillbox<br>6. Physical activity tracker<br>+ Smart Glucose monitor (only if available)<br>+ Office BP checks by means of clinician’s BP tracker | Notifications according to the following scenarios, corresponding to the interventions in the next cell  
1. Blood pressure monitoring Module A - Hypertensive user  
   A1. SBP > 140 mmHg  
   (value set at first visit)  
   A2. DBP > 90 mmHg  
   (value set at first visit)  
   A3. weekly average SBP > 140 mmHg or < 120 mmHg (value set at first visit)  
   A4. weekly average DBP > 90 mmHg or < 70 mmHg (value set at first visit)  
   A5. SBP ≧ 180 mmHg, DBP ≧ 110 mmHg  
   A6. SBP < 100 mmHg  
   A7. weekly average SBP 120-140 mmHg, DBP 70 - 90mmHg (values set at first visit)  
Module B - Not known hypertensive user  
B1. weekly average BP > 140/90 mmHg | Green code: 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. I get an alert to seek medical advice. The same notification is sent to the case manager and/or informal/formal caregivers based on the patient’s profile.  
Smart Bear asks if alert was attended.  
A1, A2 Platform advises user to repeat measurement once. If same result
B2. Weekly average BP > 130/85 mmHg
6. Heart rate monitoring
   6.1. periodical (i.e daily) average HR < 50 bpm or > 110 bpm (values set at first visit)
   6.2 episodes of fast heart rate (> 110 bpm), at rest during BP measurement (value set at baseline visit)
   6.3 episodes of fast heart rate recorded (> 140 bpm) from smartwatch lasting more than 1 min (values set at baseline visit)
7. Weather forecast regarding high temperature (> 30 °C) or low temperature (< 20 °C (values set at first visit)
8. Patient sets his height value - Weight gain (weekly average)
9. Patient sets his height value - weight loss (weekly average)
10. If medication is missed
11. weekly activity assessment
12. Arrhythmia alert - optional at baseline visit to set
13. Office BP measurements will be added by clinician during visits. These will persists, diet app activation, smart pill-box activation.
A3, A4 Yellow code activated.
Notification to seek medical advice.
A5, A6. Platform advises end-user to repeat measurement once. If the same result persists, red code activated.
A7. Green code
B1. Yellow code activated (advice to arrange review)
B2. Diet app activation. Yellow code activated if same results for > 2 weeks.
6. 1, 6.2 Red code activation
6.3 red code - high heart rate alert
7 A. warning about hot weather - previous advice given from own doctor should be applied if any
7 B. warning about cold weather - previous advice given from own doctor should be applied if any
8a. general population - advice to install diet app - set targets with a follow-up visit with the clinician - increase physical activity. If BMI is in overweight/obese level advice to see specialist given
8b. heart failure subjects/pathway - apply previous advice given by own doctor
9a. general population - Green code - If BMI is in underweight level advice to see specialist given
<table>
<thead>
<tr>
<th>MyBalance</th>
<th>Balance Disorder</th>
<th>include attended and unattended ones.</th>
<th>9b. heart failure subjects/pathway - apply previous advice given by own doctor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Heart Rate tracker</td>
<td>2. Smart Blood Pressure tracker</td>
<td>10. pill box notifies user to take tablet. If several doses (&gt; than 5) are missing, yellow code.</td>
<td></td>
</tr>
<tr>
<td>3. Smart weight Scale</td>
<td>4. Smart Pillbox</td>
<td>11a. weekly activity goal reached - green code</td>
<td></td>
</tr>
<tr>
<td>Notification to user</td>
<td>1. to complete serious games (daily) (30’ before each session, 1h later if omitted)</td>
<td>11b. weekly activity goal missed - motivation to increase activity given</td>
<td></td>
</tr>
<tr>
<td>2. to inform them for environmental risks (e.g. if weather forecast = rainy: notification for slippery road)</td>
<td>12. if irregular heart rate detection activated - red code</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Attended office BP checks will overall guide antihypertensive treatment. Unattended measurement results will be obtained for research purposes. Significant notice SMART BEAR platform does not substitute the medical consultation and examination - any acute or warring symptom should be reviewed promptly with a visit to own doctor - AE dpt</td>
<td></td>
<td></td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>MyBalance</th>
<th>Balance Disorder</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Heart Rate tracker</td>
<td>2. Smart Blood Pressure tracker</td>
</tr>
<tr>
<td>3. Smart weight Scale</td>
<td>4. Smart Pillbox</td>
</tr>
<tr>
<td>Notification to user</td>
<td>1. to complete serious games (daily) (30’ before each session, 1h later if omitted)</td>
</tr>
<tr>
<td>2. to inform them for environmental risks (e.g. if weather forecast = rainy: notification for slippery road)</td>
<td>1. Test and questionnaires</td>
</tr>
<tr>
<td>2. Holo Balance (limited number of patient)</td>
<td></td>
</tr>
</tbody>
</table>
### MyMo

<table>
<thead>
<tr>
<th>Mental Disorders</th>
<th>1. Mood change questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. Physical activity tracker and connected weight scale with impedance</td>
</tr>
<tr>
<td></td>
<td>3. Smart light sensors / bulbs</td>
</tr>
<tr>
<td></td>
<td>4. Sensors on the fridge and/or sensors in the kitchen and/or connected weight scale</td>
</tr>
</tbody>
</table>

**1 - Mood change**
- Notification to user:
  1. To fill questionnaire - daily reminder - recall 1h later
  2. To do actions if the score is under 60%
  3. To do actions according to the answers to questions
- Notification to the senior's referent:
  4. If the score is under 50%

**2 - Physical activity and sleep**
- Notification to user:
  1. if 25% less activity for 24h

### MyHeart

1. to avoid physical activity / serious gaming if BP or HR abnormal (see MyHeart)
2. to give feedback on games (scale 0-10)
3. to user and clinician if >2 sessions missed

Notification to significant other to take contact with user:
If fall to take contact with user trustee (e.g. medical doctor, family member)

### SMART BEAR Requirements

<table>
<thead>
<tr>
<th>Physical activity tracker</th>
<th>Accelerometer</th>
<th>GPS equipped sole (Uninova)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notification to significant other to take contact with user:</td>
<td>If fall to take contact with user trustee (e.g. medical doctor, family member)</td>
<td></td>
</tr>
</tbody>
</table>
with impedance”
5. HCI = number of calls, use of messenger/skype, use of phone for calls and hearing deterioration (see pilot)
6. sensors in the bathroom
7. sensors on the door + GPS tracker
8. blood tests

<table>
<thead>
<tr>
<th>Notification to senior’s referent:</th>
<th>2.1 notification suggesting an activity such as “Moving would be good for you! Why not go out for a walk today, or play the game... available on the platform?”</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 - if 25% less activity for 48h</td>
<td>2.2 - notification stating the muscle loss and reminding it is important for him/her to move more to keep fit, confident and positive. And Why not going out for a walk or playing an activity game on the platform?</td>
</tr>
<tr>
<td>3 - if significant muscle loss for one week (% to be defined)</td>
<td>2.3 and 2.4 notification that the senior has moved less than usual / has lost muscles this week. It is important for him/her to move more to keep fit, confident and positive. You should check everything is OK, and why not proposing a walk together if possible?</td>
</tr>
<tr>
<td>Alert sent to senior’s referent:</td>
<td>2.5 alert that there might be a problem with the senior, and to call the senior rapidly to check everything is ok, and/or call a clinician in case of problem.”</td>
</tr>
<tr>
<td>4 - if 50% less activity for 24h</td>
<td></td>
</tr>
<tr>
<td>5 - if important muscle loss for a month (% to be defined)</td>
<td></td>
</tr>
</tbody>
</table>

3 - **Light levels**
Notification to user:
3.1 if more than 3 light switch on at night
3.2 - if the daily average brightness in the bedroom decreases more than 25% for 48h

<table>
<thead>
<tr>
<th>Notification to user:</th>
<th>3.1 notification to get advice in order to get a better sleep</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - If the fridge has not been opened for a day</td>
<td></td>
</tr>
<tr>
<td>2- and/or if there has been 50% less activity for the last 24h</td>
<td>3.2 notification suggesting to open stores in the bedroom. Data stored in the platform could be cross-checked with physical activity in order to adjust the mood questionnaire</td>
</tr>
<tr>
<td>3- if the weight gain or loss of more than 1 kg for a week</td>
<td></td>
</tr>
</tbody>
</table>

4 - **Nutrition**
Notification to user:
1 - If the fridge has not been opened for a day and/or if

4.1 and 4.2 Notification to ask a question such as "What are you going
<table>
<thead>
<tr>
<th><strong>5 - Social activities</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Notification to user:</strong></td>
</tr>
<tr>
<td>- if the HCI shows a reduction of -50% of total time spent on communications with others for one week</td>
</tr>
<tr>
<td><strong>Notification to senior’s referent:</strong></td>
</tr>
<tr>
<td>- if the HCI shows a reduction of -50% of total time spent on communications with others for one week</td>
</tr>
<tr>
<td>- if a hearing deterioration has been detected</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>6 - Hygiene</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Notification to user:</strong></td>
</tr>
<tr>
<td>- if reduction of activity in the bathroom over 70% for a week</td>
</tr>
<tr>
<td><strong>Notification to the senior’s referent:</strong></td>
</tr>
<tr>
<td>- if reduction of activity in the bathroom over 70% for a week</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>7 - Movements in and out the housing</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5.1 notification to suggest a social activity:</strong> invite a friend, call a relative, meet someone outside...</td>
</tr>
<tr>
<td><strong>5.2 notification to suggest a phone call and/or a visit to the senior</strong></td>
</tr>
</tbody>
</table>

| **7.1 Notification to suggest the senior to go out for a walk, shopping, to meet someone, to visit someone** |
| **7.2 Notification to inform and recommend checking if everything is ok for the senior, and to suggest/propose the senior to go out** |

there has been 50% less activity for the last 24h"

to eat today? Fresh food is a source of vitamins and pleasant to eat!"

4.3 notification stating the weight change, and proposing to adjust the meals and/or to contact the GP

4.4 notification stating the senior seems to have a difficulty regarding his/her meals + data collected. Suggests contacting the senior to check everything is ok, and/or to contact the GP if necessary.

5.1 notification to suggest a social activity: invite a friend, call a relative, meet someone outside...

5.2 notification to suggest a phone call and/or a visit to the senior

6 No notification but data stored in the platform could be used to add a question about hygiene in the mood questionnaire

7.1 Notification to suggest the senior to go out for a walk, shopping, to meet someone, to visit someone

7.2 Notification to inform and recommend checking if everything is ok for the senior, and to suggest/propose the senior to go out"
### MyMemory

**Cognitive Disorders**
- Daily activities
- Social Activities
- Medication
- Light Levels
- Habitual substances usage
- GPS data?
- Environmental comfort

#### Activity of Daily Living Scale and Instrumental Activities of Daily Living Scale
1. Activities of Daily Living Scale and Instrumental Activities of Daily Living Scale
2. Smart Pillbox
3. Light sensors / smart bulb
4. Self-reporting questionnaire

### Use of medication and drugs

**Notification to user**
- if no activity outside the housing for 48h

**Notification to the senior's referent**
- if no activity outside the housing for 72h

#### Use of medication and drugs

**Notification to user**
- if drugs (THC, alcohol) or high cortisol rate are detected (rates to be defined)

**Notification of the senior's referent**
- if drugs (THC, alcohol) or high cortisol rate are detected (rates to be defined)

#### Use of medication and drugs

**Notification to user**
1. To complete daily activities (every morning)
2. If medication is missed
3. If light levels inadequate
4. As a reward when abstinence from habitual substance
5. To complete MOCA questionnaire (once per month, chosen day and time and then once every week)

1. Digit Recall
5. Activities of Daily Living Scale and Instrumental Activities of Daily Living Scale
5. Home temperature monitor  
6. Home humidity monitor  

(thus once for the next 3 weeks) if omitted)
6. if indoor humidity is above 50% or below 30% 
7. if indoor temperature exceeds 30°C or is below 20°C

Notification to user, significant other, clinician when
1. Medication is missed five consecutive days
2. No contact between user and family for five days
3. Excessive habitual substances usage (self-reporting)

<table>
<thead>
<tr>
<th>MyHearing</th>
<th>Hearing Loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Hours of HA usage</td>
<td>– Benefit of HA usage</td>
</tr>
<tr>
<td>– Number / frequency of changes of HA program</td>
<td></td>
</tr>
<tr>
<td>1. MOCA and GHAB questionnaires</td>
<td>2. Satisfaction of Auditory Training (AT)</td>
</tr>
<tr>
<td>3. Hours of HA usage (data from cloud or directly HA)</td>
<td>4. No of changes of HA</td>
</tr>
<tr>
<td>Notification to user when</td>
<td>4. Auditory Training</td>
</tr>
<tr>
<td>1. Low HA usage (&lt;40h/week or no use 2 consecutive days)</td>
<td></td>
</tr>
<tr>
<td>2. 30’ before specific time of AT session</td>
<td></td>
</tr>
<tr>
<td>2. If no AT session is completed for 2 consecutive days</td>
<td></td>
</tr>
<tr>
<td>3. to fill GHAB and MOCA questionnaire</td>
<td></td>
</tr>
</tbody>
</table>

---

| **My Diary** | All | - Specific questionnaire / medical history created by Smart Bear Clinical Partners | 1. Specific questionnaire / medical history created by Smart Bear Clinical Partners containing predefined questions with predefined multiple choices for the user + free text boxes | Notification if diary not filled 2 consecutive days | - |
| **My Diet** | CVDs, Mental Cognitive disorders | - Weight | 1. Smart weight scales  
2. Self-reporting which suggestion has been chosen  
3. User inserts his height at first visit - BMI automatically calculated  
4. BP values | Suggest options of menu recipes according to BMI, diabetic status, BP, previous choices, previous meals  
Options (Database of healthy recipes - SMART BEAR ambassador to be considered)  
types of diet:  
A. Balanced diet (Mediterranean style)  
B. Salt restriction  
C. High calorie / protein rich  
D. Balanced diabetic | Periodic notifications as follows:  
1 - A  
2 - C  
3, 4 - A and B  
5. A and B or C  
6. D |
<table>
<thead>
<tr>
<th>MyMedication</th>
<th>CVDs Balance Disorders</th>
<th>List of medication (name, dose, form, administration route)</th>
<th>1. Smart Pillbox</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>- Defined by user</td>
<td>1. Notification 30’ before each medication time</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2. Notification and buzzer on the smart pillbox if wrong pillbox case is opened</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3. Notification if missed medication (1h later)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>*for more details see each condition separately</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MySMART BEAR</th>
<th>All</th>
<th>Real-time overview of user’s profile in the form of graphs and lists</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>MyAppointments</th>
<th>All</th>
<th>Synchronizes patient calendar with clinician’s (Audiologist, Cardiologist, GP)</th>
<th>Notification reaches user’s mobile 1d and 30’ before each appointment (regular or not, SMART BEAR related clinician or not)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1. User / caregiver books appointment with clinician when needed</td>
<td>2. User can log manually appointments with other doctors</td>
</tr>
</tbody>
</table>
Apart from Notifications, SMART BEAR will create regular reports as described in Table 3. Reports will be sent to the user and caregivers / clinicians involved or will be sent exclusively to the user who will have to present it to clinician during the next appointment (according to each pilot’s capacities). The time frames here provided an indicative basis. During the meetings involving technical and clinical partners it was underlined that notifications are an element that must be parameterized depending on the acceptance level of each specific end-user adopting the SMART BEAR framework.

Table 3 Regular reports to user / clinician / carer.

<table>
<thead>
<tr>
<th>Mobile Application</th>
<th>Included elements in regular report</th>
<th>Time frame</th>
</tr>
</thead>
<tbody>
<tr>
<td>MyHearing</td>
<td>Hours of usage, GHAB scores, No of program changes, feedback from possible remote fine-tuning appointments</td>
<td>Every month</td>
</tr>
<tr>
<td>MyBalance</td>
<td>Number of falls, physical activity, physiotherapy feedback (progress, specific segment status etc.); in case of MedX use: Low back physiotherapy training monitoring (number of sessions attended, weight used, accomplishments, pace of movement, access to the physiotherapy training pain questionnaire to monitor the level of pain in time; allow user to answer the pain questionnaire in specific timings defined by medical doctor or physiotherapist)</td>
<td>Weekly At the end of MedX (18 months)</td>
</tr>
<tr>
<td>MyHeart</td>
<td>BP, HR, Medication, weight, physical activity, GLC levels</td>
<td>Weekly</td>
</tr>
<tr>
<td>MyMood</td>
<td>Social activity, physical activity, medication, questionnaire scores, compliance to daily activities</td>
<td>Weekly</td>
</tr>
<tr>
<td>MyMemory</td>
<td>Social activity, physical activity, medication, questionnaire scores, compliance to daily activities</td>
<td>Weekly</td>
</tr>
<tr>
<td>MyDiet</td>
<td>Weight, nutritional value of diet summary</td>
<td>Weekly</td>
</tr>
</tbody>
</table>

The aforementioned elements are described in detail in the following subsections.
4.2.1 Hearing

4.2.1.1 Poor Compliance to HA usage

Mario is a 75 years old man from Italy, who worked in the military for all his life. Fifteen years ago, he has retired and now enjoys spending time with his family and friends, watching plays in theatre, going to the cinema, and watching matches of his favourite football team. He agrees to see a clinician who diagnoses hearing loss. Since Mario has history of high blood pressure as well, his clinician suggests that he participates in SMART BEAR, a project that could provide him with an integrated technological solution for both these problems.

Indeed, Mario contacts SMART BEAR research team and communicate his decision to participate to the project. During his work-up visit he meets project’s Audiologist and discuss about SMART BEAR hearing aids and overall technology. During this visit the Audiologist explains to Mario that using his HA is important for improving his experience and satisfaction with his new device and that he should start with few hours and then increase. In any case, he should use the HA every day, till he reaches a level where he uses it all day.

A week after this first visit, MyHearing App detects that Mario has not used his HA the last 48h. A notification is sent to his mobile saying that he has not used his HA for 48h and asking if he needs to book an appointment with the Audiologist. Mario clicks on “No” and decides to wear his HA.

Three weeks later the App sends him a notification to fill GHAB questionnaire. When it is completed, Mario can visualize his score with a brief explanation of how he can easily improve his experience (general tips, not yet personalized).

One month after the first visit to the Audiologist, a report is created by SMART BEAR platform using data collected from the HA: it presents the hours of usage, the number of changes of programs and the past and current scores of GHAB questionnaire (graph day/score). He sees that his score is not high enough, and he remembers what Audiologist told him about using his HA as much as possible.

The report of the 2nd month found Mario a lot happier with his HA. His GHAB score was higher, he uses his HA inside and outside his home. **He did not need an extra visit to the Audiologist’s office and the problem of poor compliance was detected and handled before his 6th month follow up. Seamless monitoring of Mario’s experience with HA did not permit to waste no time.**

<table>
<thead>
<tr>
<th>Use Case:</th>
<th>Poor compliance to HA usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Created By:</td>
<td>NKUA</td>
</tr>
<tr>
<td>Last Updated By:</td>
<td>NKUA, all partners</td>
</tr>
<tr>
<td>Date Created:</td>
<td>10/11/2019</td>
</tr>
<tr>
<td>Last Revision Date:</td>
<td>17/12/2019</td>
</tr>
<tr>
<td>Description:</td>
<td>Identification of poor compliance to HA usage. GHAB questionnaire for detecting poor experience with HA usage. Encouragement to use HA more frequently.</td>
</tr>
<tr>
<td>Actors:</td>
<td>Hearing aid User&lt;br&gt;Audiologist</td>
</tr>
<tr>
<td>Preconditions:</td>
<td>Use of SMART BEAR Platform and SMART BEAR Hearing Aid. Concurrent use of HAs, mobile phones and apps. Patient education and engagement. I (user) have been educated on how to use my HA during my fitting appointment with SMART BEAR Audiologist.</td>
</tr>
</tbody>
</table>
### D5 - SMART BEAR Requirements

#### Trigger:
Patient does not use HA for more than 48h or <40h/week.

#### Flow:
1. Hours of usage are logged and visualized in the relevant App.
2. If I do not use my HA adequately (<40h per week or have not used it for 2 days consecutively), I receive a notification.
3. If I continue not to comply (24h later), a new notification reaches my app. If I do not comply for 7 consecutive days an alert is created and sent to the case manager subject to the existence of such a manager and acceptance to receive such a notification and ICF and/or the formal/informal caregiver. The alert suggests taking contact with me about this specific matter.
4. Periodically, I receive a notification on MyHearing App reminding me to fill my GHAB questionnaire.
5. The questionnaire is displayed in a form of an interactive interface (part of the MyHearing App). Even if I wish to complete the questionnaire later, it is available via the MyHearing App as well. This questionnaire is activated periodically and stays available for a specific period of time.
6. I am able to visualize my current and previous scores (score history).
7. Periodically I receive MyHearing report with my hours of usage and GHAB score with a brief explanation. A report is sent to my Audiologist and the case manager subject to the existence of such a manager and acceptance to receive such a notification and ICF.

#### Alternative Flows:
1. If user faces any issue, a call (between user and audiologist) will be booked via MyAppointments as described in the following scenario.

#### Exceptions:

#### Postconditions:
HA user learns the benefits of wearing his/her HA every day. Better and faster communication between the Hearing Aid user and the Audiologist, real-time fine-tuning and better adaptation to user’s everyday routine through the SMART BEAR Platform. No need to wait till 1st follow-up in order to detect poor compliance, enhancement of compliance to HA use without wasting time.

#### Requirements:
Hearing assessment and initial fitting onsite. First on-site education on AT by an Audiologist: Audiologist logs user’s initial assessment (hearing history, audiogram, speech audiometry, MOCA) on Smart Bear MyHearing App.

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### 4.2.1.2 Remote real-time fine-tuning and verification of hearing aid through the Smart Bear Platform

Andrei is a 73 years old man from Romania, who lives happily with his wife in a village one hour from the nearest town and who has been a worker in wood industry for 35 years. The last 10 years his ability to discriminate speech is declining. The last few months it has become unbearable, especially when he is having his coffee with his friends in a crowded coffee shop with a lot of background noise. This is why she decided to visit an Otolaryngologist and have his hearing tested. He had to call his daughter who lives in the nearest town to pick him up and drive him to the Clinician’s office. During his clinical examination (otoscopy, tympanometry, pure tone audiometry, speech audiometry), presbycusis was diagnosed. The Hearing
Handicap Index for the Elderly questionnaire showed that Andrei is not happy with the current status of his hearing. His clinicians (ENT and Audiologist) have proposed that he uses the SMART BEAR Hearing Aid. They suggested that the first fitting is done onsite, and further change of programs and fine-tuning is done remotely, since it will not be easy for him to visit Audiologist’s office frequently. This will give him the opportunity to adjust hearing aid configurations in his everyday routine without bothering his family every time he needs to visit his Audiologist.

A few weeks after starting using the smart Hearing Aid, Andrei is very happy with his hearing when talking with his family or when watching TV. However, he still finds it challenging when he tries to follow a conversation among friends at his local coffee shop. He decides to book an appointment with his Audiologist through the SMART BEAR relevant application. He is capable of using his smartphone for doing so, but he is asking for his wife help as well, since they both had the training by the Audiologist. He checks the availability and books a specific time. He is planning to be at the coffee shop for this particular appointment so that his Audiologist can directly fine-tune the HA in real-life conditions. He also chooses from a variety of options, the reason for booking this appointment.

The day of the appointment, SMART BEAR Audiologist initiates a call and activates the remote fine-tuning function of Andrei’s hearing aid. He/she gains access to user’s fitting software and initiates a video call with Andrei. He performs an in-situ audiometry and starts adapting HA according to the environment challenges. Three months later, Andrei is very satisfied by his HA. It is shown by his scores on the GHAB questionnaire that MyHearing App notifies him to fill it every month. He can use his HA all day long no matter where he is. He has not needed any further adjustment or going again to the town for meeting his Audiologist.

Table 5 Use Case: Remote real-time fine-tuning and verification of hearing aid through the Smart Bear Platform

<table>
<thead>
<tr>
<th>Use Case:</th>
<th>Remote real-time fine-tuning and verification of hearing aid through the Smart Bear Platform</th>
</tr>
</thead>
<tbody>
<tr>
<td>Created By:</td>
<td>NKUA</td>
</tr>
<tr>
<td>Date Created:</td>
<td>10/11/2019</td>
</tr>
<tr>
<td>Description:</td>
<td>In order to facilitate the communication between the Hearing Aid user and the Audiologist, a real-time individualized fitting solution in real everyday routine conditions would provide value. An appointment for remote direct fitting of the Hearing Aid by an Audiologist will be arranged through the relevant application of the SMART BEAR platform (MyAppointments). This application will provide to the user the possibility of selection among a series of possible problems and issues that he/she might have encountered. This text would be in form of predefined multiple-choice text. During this appointment, SMART BEAR Audiologist can activate the remote fine-tuning function of user’s hearing aid. He/she gains access to user’s fitting software and initiates a video call with the user or their caregiver. Video call permits real-time communication and feedback between user – Audiologist. Apart from receiving subjective input from each user’s point of view, Audiologist will be able to perform in situ audiometry or sensogram, alternate the gain of each specific channel or the Master Gain. He/she will have the ability to add or remove specific programs (e.g. specific noise environment programs).</td>
</tr>
</tbody>
</table>
This functionality addresses a huge practical issue, reduces the number of visits to the Audiologist’s office and would add to the attractiveness of SMART BEAR platform when the latter will enter the commercial market.

<table>
<thead>
<tr>
<th>Actors:</th>
<th>Hearing Aid User / Significant other Audiologist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preconditions:</td>
<td>Concurrent use of Hearing Aids, Fitting Link (hardware that allows the connection the mobile phone and the hearing aid) and mobile phones.</td>
</tr>
</tbody>
</table>
| Flow: | 1. I have an issue or concern about the current fitting of my Hearing Aid.  
   a. Option 1  
      i. I open the MyAppointments App of the smart Bear interface  
      ii. I select by clicking among a series of options concerning the reasons that the current fitting of my Hearing Aid does not satisfy me (multiple choice text).  
      iii. An interface opens up showing a calendar. It is synchronized with Audiologist’s calendar. I arrange an appointment with the Audiologist, according to our availability, by clicking on a specific date/time box  
      iv. The day of the appointment, 30 minutes before, a notification reaches my mobile as a reminder  
      v. I click on the MyAppointments App and have a call with the Audiologist (in or outside the App feature).  
   b. Option 2  
      i. I call my audiologist and I request an appointment  
      ii. I record the appointment into MyAppointments app  
   2. Audiologist records into SMART BEAR the appointment  
   3. During the appointment I am wearing my neck loop (FittingLink type) device.  
   4. During the appointment Audiologist activates the remote fine-tuning function of my Hearing Aid.  
   5. Audiologist performs all the appropriate Fine-tunings (as described in text) through the HA’s relevant application.  
   6. I give him real-time feedback through the video call.  
   7. At the end of the appointment, data from this appointment are logged. |
| Trigger: | Patient who needs fine-tuning and verification of his/her Hearing Aid without visiting Audiologist’s office. |
| Alternative Flows: | 3. In case that the user is not capable of using the SMART BEAR interface or adequately communicate his concerns to the Audiologist, these actions could be facilitated by his/her significant other (carer). |
| Exceptions: |  |
4.2.2 Individualized auditory training (AT).

Yianis is a 75 years old man from Greece, who worked as a teacher all his life. Last 15 years he has retired and now enjoys spending time with his family and friends, going to the cinema and watching matches of his favourite football team. His family is telling him that his hearing is getting worse and worse. Communication has been difficult with him the last few years, especially when the background noise is too loud. He agrees to see a clinician who diagnoses presbycusis and addresses him to a SMART BEAR Audiologist. During his visit to Audiologist’s office, he has audiological and cognitive tests. Audiologist explains to him that these scores will be logged in MyHearing App and Yianis could track those scores and future ones there. He also gives him information about the features and benefits of Auditory Training (AT), another feature of SMART BEAR, and why it is important to stick to it throughout the following few months. Yianis agreed to wear the smart HA in and out of the house, but he is a bit worried that he will not succeed in completing the AT tasks.

The first day after this first visit, Yianis receives a notification reminding him to complete his AT of the day. He ignores it for the moment since he does not feel ready. The next day, since he is still trying to get used to the new HA, he is ignoring the second notification as well. One day after that, a notification reaches Yianis mobile reminding him that he did not complete any AT task for the last 48h and that explains once more in plain language its benefits. Yianis decides to comply with the AT program that is suggested and starts his first AT task. He admits that it is not that difficult and moreover he feels that it has an effect on his overall HA experience.

One month after the first HA fitting, he receives a new notification in order to complete a new MOCA test. His score is logged on his mobile and can be visualized in MyHearing App. A few weeks later he feels that this is as good for his brain and alertness as physical activity for his heart. AT becomes a pleasant routine.

During his first follow-up appointment 3 months later, he discusses his progress with the Audiologist. He is glad to continue receiving notifications whenever he misses an AT session, and he will continue filling MOCA questionnaire every month.

Table 6 Use Case: Individualized auditory training (AT). Short term goal: optimization of HA benefits. Long term goal: prevention or delay of cognitive and auditory processing deterioration

<table>
<thead>
<tr>
<th>Use Case:</th>
<th>Individualized auditory training (AT). Short term goal: optimization of HA benefits. Long term goal: prevention or delay of cognitive and auditory processing deterioration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Created By:</td>
<td>NKUA</td>
</tr>
<tr>
<td>Date Created:</td>
<td>10/11/2019</td>
</tr>
<tr>
<td>Description:</td>
<td>This use case captures scenarios regarding determination of individualized auditory training in cases. AT will be determined on the basis of real-life HA user experienced communication difficulties and association of such difficulties with HA usage. Auditory training will aim towards improvement of speech in noise perception, auditory</td>
</tr>
</tbody>
</table>
memory and localization abilities of the SMART BEAR user. Learning to interpret auditory information can assist with the development of other skills, such as communication, literacy, and mobility. To this end, the system will employ a mixture of artificially listening scenarios and dynamically selected real listening scenes that the specific HA user has experienced and found it challenging to handle, which will be presented to the HA user for training purposes. The training material will include words, non-words, and sentences: short stories will be recorded and delivered to the user via MyHearing App and then he/she will be encouraged to answer a series of contextual questions. Tasks using speech components of frequently repeated linguistic and non-linguistic stimuli and language components, such as vowels, consonants, and syllables should be adapted to each user’s profile in order to improve language processing.

Implementation of AT in SMART BEAR platform is expected to increase compliance and adapt AT in specific user’s needs.

**Actors:** Hearing aid User  
Audiologist

**Preconditions:** Use of SMART BEAR Platform and SMART BEAR Hearing Aid. Concurrent use of HAs, mobile phones and apps.  
Initial onsite hearing aid fitting session/appointment by ENT/AVM/Audiologist  
Patient education and engagement.

**Trigger:** Access to SMART BEAR Platform. Concurrent use of HAs, mobile phones and apps. Patient education and engagement. Patients engaging with AT. Patients returning for 6-month additional follow up.

**Flow:**

1. During my first clinical assessment, an Audiologist performs initial hearing and cognitive tests, including pure tone audiometry, speech in noise tests and Montreal Cognitive Assessment (MOCA). Audiologist performs initial open mould hearing aid fitting.
2. Audiologist records MOCA and speech in noise tests as normal
3. Standard hearing aid usage education is provided to me by audiologist/audiological scientist
4. I start using my HA and sensors in a variety of environments (single speaker noise, multiple talker noise, non-speech noise). Environmental / behavioural parameters will be recorded. SMART BEAR HA system records ambient noise level, duration of noise exposure and patient physiological data, such as skin conductance or blood pressure.
5. SMART BEAR HA system provides data in cumulative diagrams and charts format: skin conductance (listening effort) is increased in certain noise (e.g. multi-talker noise) or in other noisy situations after prolonged noise exposure (need to rely on memory resources).
6. Patient returns for 6 months follow up. Audiologist performs outcome measures (Audiogram, etc.)
7. SMART BEAR system provides HA usage data for different combinations of noise types/levels/duration of exposure
8. Audiologist accesses automatically recorded data
9. Audiologist educates me in auditory training
10. Audiologist prescribes auditory training dependent on automatically recorded data (user profile)
11. Periodically a notification reaches my smartphone to remind me to perform auditory training (at home, using words, sentences and other material.)
12. Progress in AT is recorded, and feedback is provided by the SMART BEAR platform (user/Audiologist)
13. When certain milestones are reached (discrimination, discrimination in noise), AT steps up in more difficult program.
14. Feedback is also provided by the patient (self-reporting)
15. Patient returns for 12 months follow up and performs outcome measures

<table>
<thead>
<tr>
<th>Postconditions</th>
<th>Requirements:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audiologist will use this information in order to determine individualized AT. Outcome measures (HA use and MOCA in particular) and AT related data (type of training, dosage) are recorded in the Smart Bear platform for several HA users. Successive stages of analysis will inform public health case scenario: does AT help improve HA use (and which type/dosage of AT), prevent cognitive decline, enhance listening effort</td>
<td></td>
</tr>
<tr>
<td>AT tool requirements:</td>
<td></td>
</tr>
<tr>
<td>1. First on-site education - motivation building on AT by an Audiologist.</td>
<td></td>
</tr>
<tr>
<td>2. Material in each user’s language</td>
<td></td>
</tr>
<tr>
<td>3. Variety of tasks should be prepared and delivered to avoid boredom / repetition</td>
<td></td>
</tr>
<tr>
<td>4. User works on tasks “on the edge of competence”: The tasks should be presented systematically, progressively and adapted to the subject’s performance (A success/failure criterion ratio of 7:3 before changing level of difficulty)</td>
<td></td>
</tr>
<tr>
<td>5. min 10 hours in total over 6 - 8 weeks</td>
<td></td>
</tr>
<tr>
<td>6. AT tool provides monthly feedback to user and Audiologist</td>
<td></td>
</tr>
</tbody>
</table>

4.2.3 Balance

4.2.3.1 Back Muscle Loss and Balance Disorders

Rubina, aged 72 lives in Funchal city centre after her husband passed away 3 years ago. She decided to live alone and not join a retirement home, as she still manages to keep an independent lifestyle and keeps a very active social life.

One month ago, she realized that she is having recurrent falls at home together with some problems on carrying shopping bags, this started to worry Rubina as she already noticed that she is mixing up the medication she needs to take daily. These issues prompted some anxiety to Rubina.

Rubina met her doctor and shared her concern on the falls and memory losses. He diagnoses balance disorder needing rehabilitation. Rubina is worried that she will not be able to perform physiotherapy tasks due to her back pain that limits her mobility.

---

6The following scenario describes a possible synergy of SMART BEAR project with EU funded Smart4Health (Horizon 2020) and concerns back muscle physiotherapy in participants with balance disorders.
The medical doctor informs Rubina of SMART BEAR and the physiotherapy training focused strengthening low back muscles. This training is not physically intensive, however as it is focused only on the low back muscles it will allow Rubina to develop her low back muscles, improving her capacity to follow balance physiotherapy and decreasing the probability of falls.

Rubina accepts to participate to SMART BEAR and along with her balance rehabilitation will benefit of low back muscle physiotherapy training. Wearables will be used in her daily routines tracking her physical activity and a smart medication dispenser / application will provide support on her daily medication schedule.

As Rubina lives in Funchal, she will perform her trainings in one of the MedX Lumbar extension machines, located in the city centre. Initially Rubina will have an interview with the MedX physiotherapist to understand if she doesn’t have any medical issue that prevents her to attend the training followed by a mental-health and back-health checkup (exclusion criteria: Herniated disc with root irritation symptoms, Operated disc herniation up to 3 months postoperatively, Acute / unstable fractures of the spine in the last 6 months, Osteoporosis, Cortisone intake above 5 mg per day, Coronary heart disease with limited load capacity, Relative heart failure, thrombosis in the last 6 months, Current tumour disease, Aortic aneurysm, Eye surgery or abdominal surgery 6 weeks before the start of therapy). Once her participation validated, she was enrolled in 18 weeks back muscle strengthening physiotherapy program. During this training Rubina will perform once a week a 3 minutes training focused on her low back muscles. The training is supported by a physiotherapist and a gamification application that allows keeping Rubina engaged on performing the exercise in the best way. The gamification setup also provides Rubina a very positive feedback on how her training is going on, improving her self-esteem and reducing anxiety.

Rubina also received a smart band and/or smartwatch, that collects information on her vital signs, physical activity, falls and localization. Moreover, SMART BEAR @ Home will provide a smart medication dispenser / application, this will provide Rubina a notification at the correct time to take specific medications. These notifications will be in the form of a ring tone in the device, on her mobile telephone (alarm and indication of the medication) and in the form of an alert to her emergency contact in case she misses the medication. Rubina selected her daughter and her medical doctor as emergency contacts, both will receive an alert in case Rubina sensor detects a fall, lack of medication intake or heart rate failure (as described in Table 1).

During the following weeks Rubina’s Medical Doctor (MD) has access to her training report and to the data from the wearable. The MD notices that Rubina’s heart rate is constant during the day, except at Saturday afternoons when a higher rate is identified, moreover he realizes that she has two reports where she missed the morning medication. In parallel he notices that she is not performing enough exercise as she doesn’t leave home so often and only exercises during the MedX training.

The MD calls Rubina and talks with her about these questions. She points out that Saturday afternoons she goes out to do the weekly shopping, so sometimes she gets tired with the weights. This leads to an increase of anxiety and she is more often afraid to leave home to meet her friends or to go for a walk. The MD advises her to change her routine, for example to do the shopping when she attends the MedX training and include a 45-minute walk per day in Funchal city centre. Physical exercise will support her on improving her self-esteem and decrease anxiety.

In the following weeks Rubina’s doctor follows her signs via the SMART BEAR Platform reports and identifies that she indeed changed her routine and practices daily walks, in parallel with her vital signs are more constant. He decides to have a phone call to ask her on her anxiety and memory losses, Rubina indicated that her anxiety decreased as well as her memory losses are not so frequent.

At the end of the 18 weeks Rubina receives a final report on her training and on her final strength test for back health. She realizes that she has indeed increased the strength of her back muscles, leading to improve her balance issues and prevent falls. Moreover, she is feeling more confident to go shopping and meet her friends. The medical doctor advises Rubina to keep using the Smart Bear platform to track her vital signs and support her on the medication intake.
### Table 7 Use Case: Back health issues and its effect in balance disorder

<table>
<thead>
<tr>
<th>Use Case:</th>
<th>Back health issues and its effect in balance disorder</th>
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<tr>
<td>Created By:</td>
<td>UNINOVA / SRS</td>
</tr>
<tr>
<td>Last Updated By:</td>
<td>NKUA</td>
</tr>
<tr>
<td>Date Created:</td>
<td>25/11/2019</td>
</tr>
<tr>
<td>Last Revision Date:</td>
<td>16/12/2019</td>
</tr>
</tbody>
</table>

**Description:**

Human balance is the ability to control body posture during standing or moving the body. Balance has a strong impact in daily life, these can make you feel dizzy, unsteady, or lightheaded. This disorder will influence your daily life, and it can even induce the appearance of anxiety. Balance disorder becomes of importance in elderly citizens. The loss of back muscle strength has been correlated with balance disorders in elderly people and the increase of anxiety.

Users of SMART BEAR platform diagnosed balance disorders and frequent falls will take advantage of sensors to monitor movement and physical activity. A first meeting with the patient will explain the objectives and showcase the features of the platform.

Once having the sensors installed and access to the MedX training, patients will be receiving notifications on their physical activity and localization. Via the SMART BEAR application, they will be monitored and encouraged to increase their physical activity and update their therapy. This interaction very close interaction with the GP will be a way to increase patient confidence, mitigate balance disorder and overcome some cognitive impairments.

**Actors:** SMART BEAR Platform User, Clinician

**Preconditions:** MedX Lumbar extension⁷ machine, wearable sensors, Smartphone

**Trigger:** Patient who needs improvement of posture and balance rehabilitation.

**Flow:**

1. I (user) was introduced to the Smart Bear project by my MD to monitor my balance disorder.
2. I decided to register in the SMART BEAR programme, agreeing to be self and home-monitored and to enrol in the MedX physiotherapy to improve my low back muscles health.
3. My physical activity is monitored as described in UC 2.2.
4. I provided access to the data collected (in form of periodic reports) to the case manager subject to the existence of such a manager and acceptance to receive such a notification and ICF. We have all signed the relevant ICF, before my participation in SMART BEAR starts.
5. I perform, with the help of a MedX physiotherapist, a low back health checkup and a health questionnaire to enrol in the Smart Bear pilot + a balance rehabilitation program.

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⁷ [https://www.medxonline.co.uk/equipment/erhaltliche-stationen/le-lumbar-extension/](https://www.medxonline.co.uk/equipment/erhaltliche-stationen/le-lumbar-extension/)
6. I start the 18 weeks physiotherapy training, 10 minutes per session, one session per week. Each session is also monitored with sensing devices to evaluate my progress and gamified to promote my motivation.

7. At the end of each session I get orally general information on my performance, e.g. number of calories consumed, equivalent number of steps, etc. This information is visible on my mobile phone as well (related App).

8. At the end of the program, I get the final report on the improvement of my back muscles which is also shared with the case manager subject to the existence of such a manager and acceptance to receive such a notification according to ICF.

Alternative Flows:

Exceptions:

Postconditions: Stronger low back muscles, higher self-esteem, better compliance to balance rehabilitation program, less falls.

Requirements: First onsite clinical assessment: clinical examination + questionnaire

4.2.4 Fall prevention

Angelica is a 72 years old woman from Spain, who worked as a bank consultant for 35 years. She enjoys outdoor activities (walking, dancing, hiking) and she also maintains her social contacts. The last 6 months she has gradually begun to feel unsteady during her daily activities, with two recent falls make her truly anxious. That was the main reason she visited the neuro-otology clinic. During her clinical examination (neurologic and neuro-otologic examination, electro-hysterography, caloric test, video head impulse test), a unilateral vestibular hypofunction was revealed. The Functional Gait Assessment test showed a high risk of falling (FGA < 18/30), score in the of Falls Efficacy – International (FES-I) revealed a moderate concern about falls (FES-I < 20/64) and her answers in the Rapid Assessment of Physical Activity (RAPA) questionnaire placed her as person with moderate physical activity. Her clinicians have proposed to set the SMART BEAR platform in her house for a year. This will give the opportunity to monitor her daily activities, with respect to balance and posture, and give real-time notifications when the risk of falling increases sharply. Also using the platform will give her the opportunity to access a personalized rehabilitation balance program which will emphasize in increasing motivation and participation. Finally, her physical activity (steps) will be systematically recorded through a mobile phone and she will be rewarded when she achieved her goals as they are specified by her clinicians.

Angelica agreed to install the sensors in her home, to wear sensors and to use a mobile phone. Every morning at a specific time, a buzzer sounds to start the rehabilitation program. After checking for security measures (object-free space, proper mounting of equipment-head mounted display, wearable sensors, insoles, or bracelet) the program starts. It includes personalized exercises for vestibular-ocular reflex adaptation, habituation in sitting and standing positions, eye-head-arm coordination, gait, and coordination of body segments in activities with high balance needs. All exercises are gamified and provided in a mixed reality environment. The rehabilitation program lasts 20 minutes daily, presents a progressive difficulty in exercises and includes game-based cognitive exercises in order to improve multitasking activities. She has the ability to choose between a plethora of serious games, with respect to her preferences.
At the end of the exercise session, Angelica, after resting for a few minutes, continues her common activities (household activities, shopping in the nearest supermarket), with her **cell phone recording steps** constantly. At the end of the day she has recorded 7,896 steps and her physical activity is rated as moderate. She earns a badge which has appeared in her cell phone screen, because she avoided prolonged sedentary time. However, she remains low in the overall scoreboard of users as she rarely achieves the 10,000-step goal per day. An indication of an increase in physical activity begins to appear daily before the completion of the rehabilitation program in order to increase the motivation for it.

One rainy day in mid-November, Angelica receives a **message** from the SMART BEAR. The message warns her of the high risk of falling she may face today. The platform recommends that she can do her outdoor activities, but she has to wear trainers or use a walking stick or postpone activities if possible. She decided to follow her daily routine but to take all the necessary precautions platform indicates.

One year later, Angelica visits again the neuro-otologic clinic for assessment. All this time she has not fallen again, and this is what fills her with confidence about her posture. She also feels that she is more stable in most of her daily activities, which they have been increased significantly but not in the expected level, even if she is more autonomous and functional than before. Her score on the Functional Gait Assessment test improved by 6 points, which is the meaningfully significant clinical difference (**FGA = 24/30**). Nevertheless, the fact that in some circumstances she continues to feel unsteady and, as she wants to maintain a good quality of life, she decides, after clinician recommendation, to continue using the SMART BEAR platform’s equipment and then to be re-assessed. Her scores in the Falls Efficacy – International (FES-I) test has increased but she remains at a level of moderate concern of falls risk. Improving physical activity is something that satisfies her, and the daily feedback, from the physical activity application, to achieve her daily goals finds her perfectly in agreement. This result makes her satisfied and persuades her to continue using the platform.

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**Table 8 Use Case: Fall prevention**

<table>
<thead>
<tr>
<th>Use Case:</th>
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<td>Last Updated By:</td>
<td>NKUA</td>
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<tr>
<td>Date Created:</td>
<td>10/11/2019</td>
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<td>Last Revision Date:</td>
<td>17/12/2019</td>
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<tr>
<td>Description:</td>
<td>Maintaining balance at rest and in motion is multi-factorial and relies on the integration of physical, sensory (visual, somatosensory, vestibular), and cognitive – behavioural functions. These functions tend to decline over the years. Moreover, environmental barriers become more burdening over years. Users of SMART BEAR Platform with diagnosed balance disorders and frequent falls will benefit of continuous monitoring of movement, posture and physical activity. A first onsite assessment session is necessary to set goals and explain the features of the platform. Once having SMART BEAR @ Home installed, users will be receiving notifications for caution every time it is needed (e.g. slippery roads). They will be regularly encouraged to increase their physical activity and complete tasks of an individualized dynamically adapted balance rehabilitation program. Encouragement and motivation will be by means of simple awards every time a set goal is achieved.</td>
</tr>
<tr>
<td>Actors:</td>
<td>SMART BEAR Platform User</td>
</tr>
<tr>
<td></td>
<td>Clinician</td>
</tr>
</tbody>
</table>
### Preconditions:
Home sensors, Head Mounted Display, Wearable sensors, Smartphone

### Trigger:
Patient who needs improvement of posture, physical activity and balance rehabilitation at home.

### Flow:

1. Baseline assessment defines my (user) risk of falling, fear of falling and physical activity level (user profiling).
2. I (user) have SMART BEAR home sensors, smart wearables and smartphone. Technicians visited me (user) at the setup session and informed me about safety, turn on and off the system, interaction with the different modules, charging of the devices.
3. Periodically, a buzzer/notification reminds me of my daily balance rehabilitation task. The notification clearly states that if I do not feel well, I should not proceed to the task.
4. When I am ready, I activate the rehabilitation program through the relevant application.
5. The platform checks through the aggregated sensors if the environment where I plan to complete my task is safe (object-free space) and if I have taken all the security measures (proper mounting of equipment-head mounted display – wearable sensors – insoles- bracelet) and it provides feedback accordingly. I have to verbally confirm the completion of safety instructions.
6. An avatar (physiotherapy surrogate) appears and gives me instructions on the rehabilitation program to follow.
7. The avatar performs the exercise and I (user) have to perform the exercise as accurately as I can for a specific time and/or repetition.
8. Communication is established between me (user) and the avatar as it appears every time I perform incorrectly, stop, I need extra instruction or to be more motivated.
9. In case I (user) executed incorrectly, the avatar stops the exercise and corrects me repeating the exercise verbally and visually.
10. During execution, it also encourages me and finally scores me at the end of each exercise with respect to symptom severity and performance.
11. I have the opportunity to choose the gamified exercise I want to do today. I also have the opportunity to repeat at any point instructions given to a specific exercise.
12. There is a plethora of serious games as options which are presented by the avatar. Their difficulty adapts to my abilities and activity the last few days. Nevertheless, the rehabilitation program is structured in a strictly evidence-based manner.
14. Metrics of my performance appear in my clinicians’ screen (dashboard) and my mobile app (seamless access).
15. Rewards are provided in the augmented environment I perform the balance routine and my mobile app.
16. As soon as I rest, I start my everyday routine.
17. A notification about environmental risks such as slippery road reaches my mobile phone according to the weather forecast.
18. During the day, my physical activity is recorded since I always carry my smartphone.
19. At the end of the day, I am aware of how many steps and km I have walked, and I can have an overall view on my latest activity.
20. A motivational reward reaches my mobile when my daily goal is reached.
21. Comparing my physical activity scores to other users’ help me staying motivated.
22. I recharge my portable sensors and devices as the technicians taught me at the setup session.

Alternative Flows:
8. A wearable (bracelet) could be also chosen as physical activity tracker

Exceptions:


Requirements: Rehabilitation requirements:
1. First onsite clinical assessment (+FES-I, RAPA questionnaires) – setting goals and then weekly adapting of goals by clinician according to user’s previous performance
2. Min 8 weeks of compliance
3. Monthly follow-up with clinical assessment (+FES-I, RAPA questionnaires) – setting goals

### 4.2.5 Cognitive Disorders

#### 4.2.5.1 Cognitive Decline
Cesare is a 76 years old man from Monza (Italy), who worked as a civil engineer for 40 years. Cesare lives with his wife and has two sons that live in Milan, an hour far from Monza. He likes socializing and was used to hang out weekly with four friends for some hiking and biking in the neighbourhood. Unfortunately, his life changed in 2016 when was diagnosed with Semantic Dementia. Dementia has an important impact on his daily life activities and cognition. Cesare may encounter cognitive symptoms like:

- **Difficulties with semantic memory** (e.g. he often doesn’t know what to wear first: t-shirt or shirt, underpants or pants; he may get confused in choosing between toothbrush and toothpaste when he has to brush his teeth)
- **Reduction in speech fluency** (e.g. he has difficulties in word production, therefore he is mostly silent and doesn’t talk very much)
- **Problems with spatial orientation** (e.g. he gets lost when he does new hikes or new paths; he doesn’t drive anymore)
- **Difficulties with visuospatial memory** (e.g. he never finds his keys, his glasses or his wallet).

Cesare is still independent in doing the daily 15-minute walk to the bakery downtown and to buy the newspaper. He can’t go for a long hike on his own, as he was used to do, due to the spatial disorientation. He still enjoys attending mass at the Duomo of Monza and singing in the choir, but he needs assistance since he doesn’t remember the songs.
Veridiana, his wife, is overwhelmed by assisting Cesare with his personal care, such as dressing and monitoring his medication administration. She is also anxious when Cesare leaves the house, since he might get lost, loses his keys, or mismanages the money when he buys something.

What just described were the main reasons why Cesare underwent a neuropsychological evaluation and neurological visit. During his clinical examination (neurological exam, revision of cognitive tests, blood exams and other medical exams) the neurologist proposed to set the SMART BEAR Platform at Cesare’s house for one year. This will give the opportunity to monitor his daily activities, like getting dressed, personal care, managing finances, using public transportation or doing his walks as well as monitor his cognitive symptoms. This will allow his wife and neurologist to get a weekly report regarding Cesare’s cognitive condition and functional status. The use of the platform will give Cesare the opportunity to access a personalized intervention program which may increase his independence in daily life activities, improve some of his cognitive difficulties and preserve other cognitive abilities which are within normal limits.

Veridiana and Cesare agreed to use a smartphone, tablet and other smart devices on a daily basis. Every morning at a specific time, the SMART BEAR Platform assistant device will commence the day with a good morning to Cesare and proceed with the monitoring and intervention program. The smart assistant will assist Cesare with personal care, such as washing his face, brushing his teeth, and getting dressed in the right clothes. The assistant will help Cesare by answering his questions, clarifying his doubts, and giving advice. Questions and answers will be recorded and included in the weekly report that will be sent to the clinician.

At day one, the smart assistant device will remind Cesare of the cognitive evaluation performed once a month. For this evaluation, will be used a cognitive screening digital test such as MoCA, performed directly on a tablet device. After this test, goals will be set, and a cognitive training program will be implemented daily to work on memory, language and spatial orientation problems. The rehabilitation program will last approximately 45 minutes and designed with a progressive difficulty. Cesare will also be able to choose between a variety of exercises based on his preferences.

At the end of the cognitive training session, Cesare will continue his activities (e.g. walking downtown, buying bread or newspaper, socializing) assisted by a smartphone that will record:
- The route to downtown, the mistakes and hesitations to following the right path;
- The way he manages his money

Veridiana will receive a weekly report from the SMART BEAR Platform that summarizes Cesare’s cognitive difficulties/improvements and his functional difficulties/enhancement regarding his independence in the daily life activities. Before the completion of the cognitive training program, the results achieved by Cesare will appear on the screen of the Smart Bear device in order to increase his motivation.

After 6 months of using the SMART BEAR Platform, Cesare will be accompanied by his wife, to perform a neurological checkup visit. In an ideal scenario the neurologist is surprised by his improvements in managing the smart devices and the results of the cognitive training. Although Cesare functional assessment scores (ADL 4/6 and IADL) are stable compared to the previous neurological exam (6 months ago), the clinician observes a better management of his daily activities as well as reduction of his wife’s burden. In addition, Cesare improved his spatial orientation, acquired skills in coping with his memory difficulties, and remains stable with his speech difficulties. In addition, his wife Veridiana seems more relaxed and happier with Cesare using the smart assistant. After the clinician recommendations, Veridiana and Cesare decide to continue benefiting from the use of the SMART BEAR Platform.
Table 9 Use Case: Cognitive Decline

<table>
<thead>
<tr>
<th>Use Case:</th>
<th>Cognitive Decline</th>
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<td>FCSR</td>
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<tr>
<td>Last Updated By</td>
<td>FCSR</td>
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<tr>
<td>Date Created:</td>
<td>19/11/2019</td>
</tr>
<tr>
<td>Last Revision Date</td>
<td>16.12.2019</td>
</tr>
</tbody>
</table>
| Description:    | Improve or maintain a good independence in daily life activities as well as monitor or train cognitive functioning is considered important actions of intervention in neurodegenerative disorders. Both cognitive functioning and independence in daily life activities in patients with dementia, tend to decline over the years. If no intervention is done this decline is progressive and rapid. Moreover, such difficulties become more burdening for caregivers over years.

Users of SMART BEAR Platform with diagnosed neurodegenerative disorder as well as their caregivers will benefit from continuous monitoring of cognitive functioning and functional status. A first onsite assessment session is necessary to set goals and explain the features of the platform to these users. Once having SMART BEAR @Home installed, patients will be receiving indications on how to follow the intervention program. Notifications to encourage and motivate the patient will be sent with simple verbal rewards when a set goal is achieved.

Caregivers and clinicians will receive weekly reports with patient’s information and results. In addition, caregivers might benefit from devices/apps that locate the patient or detect important objects lots by the patients (keys, glasses, wallet, ...).

<table>
<thead>
<tr>
<th>Actors:</th>
<th>SMART BEAR Platform User (e.g. patient, caregivers)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Clinician</td>
</tr>
<tr>
<td>Preconditions:</td>
<td>Smart assistant devices, Smartphone, tablet, position detector of key lost, cognitive training programs for 3D or 2D devices</td>
</tr>
<tr>
<td>Trigger:</td>
<td>Patient who needs supervision in daily life activities, improvement of the functional status, monitoring and enhancement of cognitive functioning at home.</td>
</tr>
<tr>
<td>Flow:</td>
<td>1. I (user) have SMART BEAR home assistant devices, smartphone and tablet.</td>
</tr>
<tr>
<td></td>
<td>2. Every morning, a SMART BEAR smartphone says, “Good morning”, and starts assisting me with personal care activities. The patient’s questions/doubts as well as the devices’ answers will be recorded and will be included in the weekly report to be sent to my clinician and caregiver (e.g. wife).</td>
</tr>
<tr>
<td></td>
<td>3. After breakfast, a buzzer reminds me of my daily cognitive training and gives me a report with my results and goals achieved in the previous training session.</td>
</tr>
<tr>
<td></td>
<td>4. When I am ready, I activate the rehabilitation program through the relevant application.</td>
</tr>
<tr>
<td></td>
<td>5. I choose which task I want to do today. There is a variety of cognitive exercises as option. Their difficulty adapts to my abilities and level achieved in the previous sessions.</td>
</tr>
<tr>
<td></td>
<td>6. The cognitive training lasts 45 minutes.</td>
</tr>
</tbody>
</table>
7. As soon as I rest, I start my everyday routine (e.g. go downtown for a walk, buy braid and newspaper).
8. Before I go out, my smartphone sends me a notification that reminds me to take the key and where they are located.
9. While I was going downtown, my wife was receiving notifications regarding my location and the trajectory done.
10. During the day, my physical activity is recorded since I always carry my smartphone.
11. At the end of the day, I can have an overall view on my latest activity.
12. Comparing my cognitive results to other users’ help me staying motivated.

**Alternative Flows:**

A wearable (bracelet) could be also chosen as tracking position

**Exceptions:**

Depends on the level of severity of dementia. Not all patients can be included in this study.

**Postconditions:**


**Requirements:**

First onsite clinical assessment – setting goals

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### 4.2.5.2 Sleep Disturbances

Andrea is a 64 years old man from Milan (Italy), who still works as an IT consultant. Andrea lives with his wife and doesn’t have children. He likes social life and physical activity. Last year, Andrea was diagnosed with a non-specified dementia and from 6 months he presents behavioural symptoms (i.e. he is moody, less willing to socialize with others, feels tired and without energy most of the day).

Maria, his wife, is very concerned with the above described changes of Andrea. She often encounters challenges in interacting with Andrea since he is easily irritated and nervous. Another challenge encountered by her is that he feels often tired and doesn’t want to go anywhere when they have some plans of going out (e.g. invitation for dinner, museum visit, etc.) nor to play tennis (i.e. his favourite sport). Maria is very concerned and can’t understand what makes Andrea feel so moody and tired. Therefore, she booked a visit with his neurologist.

During the clinical examination (i.e. neurological exam, revision of cognitive tests, blood exams and other medical exams) the neurologist asked Andrea if he sleeps well during the night. At first, Andrea said that he sleeps well but the clinician found him confused and asked the wife. His wife was unsure about his sleep hygiene since she sleeps in another room because he snores a lot. The clinician explained to Andrea and Maria that prominent research studies have found a lack of quality sleep is linked to deterioration of mental health, memory and may have an impact on social life and leisure activities (due to feeling of tiredness and loss of energy). At this point, the neurologist proposed to Andrea to join the Smart Bear platform project that will provide him with smart sleep trackers to monitor the quality of sleep. The clinician’s weekly reports on Andrea’s sleep symptoms (e.g. snoring, hypersomnia, witnessed apneas, parasomnias, restless
legs, and leg movements during sleep) will be very useful to obtain an accurate sleep history. This will allow the clinician to prescribe a personalized drug therapy with the intent to improve Andrea’s mood and quality of life. In addition, monitoring the sleep activity and behaviours in a patient with unspecified dementia will allow the neurologist to differentiate between different dementia diagnosis.

Maria and Andrea agreed to use a **wearable sleep tracking watch** and **Smartphone** on a daily basis. After a month of using the SMART BEAR sleep devices, Andrea will be accompanied by his wife, to the neurological check-up visit. In an ideal scenario the neurologist, will point out from the sleep tracking reports, that Andrea has fragmented sleep patterns (e.g. he often talks during the sleep and he moves a lot) and leg movements during sleep similar to Rem Behaviour Disorder (RBD). The clinician will explain to Andrea and his wife that this may cause excessive daytime sleepiness and fatigue with a negative impact on mood. At this point, the neurologist will prescribe him a pharmacological therapy. Then, he will recommend Andrea to keep joining the SMART BEAR Platform for a better monitoring of the therapeutic efficacy and to try the SMART BEAR Platform sleep intervention program. At this point, the clinician will introduce to the patient **the role that plays the light on sleep** cycles. For example, the human body reacts to blue lights like bright daytime sunlight. Most of our electronic devices have screens that emanate blue light, and when we sit in front of a glowing screen for hours, our body gets the message it’s time to be awake. Red light is ideal for evenings because it has a low colour temperature, far lower than regular sunlight. Switching to natural red light in the evenings can help our body ease into its sleep cycle more naturally. Therefore, **SMART BEAR light sensors** will be set in his home environment that at certain moment of the evening will switch the light in natural red. Furthermore, a **SMART BEAR assistant device** will remind to Andrea to stop using electronic devices with screens that emanate blue light.

### Table 10 Use Case: Sleep Disturbances

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<th>Use Case:</th>
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<td>FCSR, all partners</td>
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<tr>
<td>Date Created:</td>
<td>18/11/2019</td>
</tr>
<tr>
<td>Last Revision Date:</td>
<td>16/12/2019</td>
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<tr>
<td>Description:</td>
<td>Dementia and many of the neurodegenerative diseases are characterized by frequent sleep and circadian disturbances, which negatively affect patient quality of life and increase caregiver burden. Dementia with Lewy bodies (DLB) has the highest prevalence of sleep and circadian disturbances of any dementia, affecting approximately 90% of patients. Increased sleep fragmentation, insomnia, a combination of prolonged sleep latency and nightmares are the most common sleep disturbances in LBD. REM sleep behaviour disorder (RBD), a parasomnia characterized by potentially violent or injurious dream enactment behaviour, is common in LBD and is a supportive diagnostic criterion for DLB. Since demented people may not recall symptoms accurately, the assessment of sleep and circadian disturbances in dementia it’s a big challenge. Collecting collateral history from caregivers is essential, but patients with dementia often live alone or caregivers are not reliable since they may not share the same bedroom with the patient. Given the substantial difficulties in collecting history on sleep disturbances in patients with dementia, the SMART BEAR Platform might be an ideal and reliable way for monitoring sleep related symptoms. In addition, understanding how patients...</td>
</tr>
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</table>
with unspecified dementia sleep might be helpful for an accurate differentiation between different dementia diagnoses.

A first onsite assessment appointment will be set to explain the features of the platform to these users. Once having SMART BEAR sleep devices, patients will be receiving indications on how to follow the monitoring and intervention program. The patient’s sleep will be systematically recorded through a SMART BEAR mobile phone. Clinicians will receive weekly reports with patient’s sleep history. At the checkup neurological visit the collected sleep symptoms will be discussed with the patient and his/her caregiver. At this point, the clinician will be able to better understand the diagnostic picture and to differentiate between different dementia diagnosis and indicate a drug treatment.

Finally, an intervention with SMART BEAR Platform will be recommended to the patient. For example, the clinician will benefit from keeping monitoring the patient’s sleep activity and behaviour to understand if the drug treatment works or if it needs to be adjusted. In addition, his home environment will be provided by SMART BEAR light sensors that at certain moment of the evening will switch the light in natural red. Furthermore, a SMART BEAR assistant device will remind patients to stop using electronic devices with screens that emanate blue light.

**Actors:** SMART BEAR Platform User (e.g. patient, caregivers)  
Clinician

**Preconditions:** SMART BEAR sleep trackers (e.g. watch and mat), Smartphone, light sensors and assistant device.

**Trigger:** Patients who need sleep hygiene monitoring for a better understanding of their medical condition and enhancement of their quality of life.

**Flow:**

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<tbody>
<tr>
<td>1.</td>
<td>I (user) have Smart Bear sleep device, smartwatch t.</td>
</tr>
<tr>
<td>2.</td>
<td>Every night my Smart Bear sleep devices (e.g. watch t) monitor my sleep activity and motion.</td>
</tr>
<tr>
<td>4.</td>
<td>Every morning I can access my sleep activity report on the Smart Bear mobile phone.</td>
</tr>
<tr>
<td>5.</td>
<td>A weekly report of my sleep activity and behaviours is sent to my neurologist.</td>
</tr>
<tr>
<td>6.</td>
<td>I receive notifications (suggestions-advice) regarding my sleeping activity</td>
</tr>
<tr>
<td>7.</td>
<td>After a check-up neurologic visit, I activate the Smart Bear sleep intervention program.</td>
</tr>
<tr>
<td>8.</td>
<td>Now, my home has <strong>SMART BEAR light sensors</strong> that at a certain moment of the evening switch the light in natural red.</td>
</tr>
<tr>
<td>9.</td>
<td>Every night around 8.30 pm my <strong>SMART BEAR assistant device</strong> reminds me to stop using devices that emanate blue light.</td>
</tr>
<tr>
<td>10.</td>
<td>Every night around 10pm my Smart Bear assistant device switches on the guided meditation audio course</td>
</tr>
<tr>
<td>11.</td>
<td>Each guided meditation audio lasts 55 minutes. A monthly report with my mindfulness activity is sent to my clinician. 10. Every week, the <strong>SMART BEAR questionnaire</strong> asks me on my mood status and social life. A weekly report with my answers is sent to my clinician.</td>
</tr>
</tbody>
</table>
12. At the end of the month, I can have an overall view on my latest sleep activity and mood status.
13. Comparing my sleep activity and mood status with my previous results helps me staying motivated.

Alternative Flows:

Exceptions: Patients with MOCA < 18 will be excluded from this study.

Postconditions: Find a suitable pharmacological treatment for patient’s sleep disturbances in dementia. Understanding better the medical condition and differentiate between different dementia diagnosis. Improve patient’s quality of life. Reducing the burden and concerns of caregivers. Remote monitoring of the patient by the clinician.

Requirements: First onsite clinical assessment and set the monitoring program
Second onsite clinical assessment and initiate the intervention program

4.2.5.3 Non-compliance to medication scheme

Luisa is a 71 years old Tuscan lady from Florence, who has always suffered from epilepsy since she was 10. She was a journalist of National Geographic and she would have never travelled around the world doing her job without her seizure medication. She has never been married and she doesn’t have kids. Since she is retired Luisa enjoys spending her time exploring the beautiful Tuscan nature in the UNESCO park Val D’Orcia.

Three years ago, she was diagnosed with Alzheimer’s disease and in the last 3 months she started having increasing memory challenges during her short exploratory trips. One of the biggest inconveniences due to memory difficulties is that she forgets taking her seizure medication or she forgets them around. Three weeks ago, when she forgot taking them, she collapsed to the ground and broke her wrist.

Luisa likes being independent but now she doesn’t feel safe neither to live alone nor to travel alone. The memory difficulties put her at high risk of having seizures and falls that may exacerbate her condition. That makes her feel sad and demoralized and she decided to set a visit with her neurologist. She has high hopes in finding a solution which may remind her to take the pills and allow her to keep doing what she loves more.

During her clinical examination (neurological exam, revision of cognitive tests, blood exams and other medical exams) the neurologist proposed her to participate in the SMART BEAR project for a duration of a year. The clinician explained to Luisa that SMART BEAR will provide her with a smart pillbox and a mobile phone that will help her with medication management. This will give her the opportunity to have a better management of the daily intake of medicines and to avoid seizures. In addition, another benefit is that the neurologist will get a daily report regarding Luisa’s medication management which will help him to better understand Luisa’s challenges with that. If she will like a weekly report could be sent to one of her dearest friends.

Luisa was very happy to take part of the project and the week after she started the personalized monitoring and intervention program. She believes that SMART BEAR Platform may help her increase independence in daily life activities and start travelling again.

Every morning, at 8 AM, when Luisa wakes up, at a specific time, the SMART BEAR Platform assistant device will commence the day with a “Good Morning Luisa”. Therefore, it will remind her to take the seizure...
medication 30 minutes before breakfast (i.e. she has specific seizure medications that need be taken half an hour before meals). Furthermore, the SMART BEAR assistant device will inform her when 30 minutes passed, and she can have her meal. A reminder on the evening intake of the drug will be sending to her on the SMART BEAR mobile phone as text or will be vocally said by SMART BEAR assistant device. Luisa will also be rewarded when she takes her drugs without reminders or notes from the assistant device. She will also have the opportunity to set in advance her short trips on her intervention program app so the smart assistant can remind her to bring the medicines with her. Furthermore, the SMART BEAR assistant device can be used to find the closest drugstore when she can’t find her medications.

Weekly reports will be sent to the clinician and daily reports will accessible by Luisa on her phone. If she will like a weekly report could be sent to one of her dearest friends.

After 6 months of using the SMART BEAR Platform, Luisa will have a neurological checkup visit. In an ideal scenario the neurologist is surprised by her improvements in managing the smart devices and the good results on drug management. He set a second checkup appointment in 6 months.

### Table 11 Use Case: Non-compliance to medication scheme

<table>
<thead>
<tr>
<th>Use Case:</th>
<th>Non-compliance to medication scheme</th>
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</thead>
<tbody>
<tr>
<td>Created By:</td>
<td>FCSR</td>
</tr>
<tr>
<td>Date Created:</td>
<td>25/11/2019</td>
</tr>
</tbody>
</table>

**Description:**

Alzheimer disease (AD) is characterized by memory and other cognitive deficits which impact on a person’s independence in activities of daily and may increase caregiver burden. Medication adherence is a substantial problem in individuals with AD due to memory problems. A significant number of adverse events (e.g. falls, brain injury, heart attack, stroke, etc.) have been linked to medication non-adherence among subjects with AD that have other medical conditions (epilepsy, cardiovascular problems, diabetes, mood disorders, etc.).

Since subjects with AD have memory challenges, they may forget taking the therapy or may not recall if they took it and take the same medication twice. In both cases, these memory issues in AD bring to devastating adverse problems and may exacerbate the patient’s condition.

SMART BEAR Platform might be an ideal and reliable way for monitoring medication intake and help older adults with AD to enhance/maintain stable their independence in daily living activities.

A first onsite assessment appointment will be set to explain the features of the platform to these users. Once having SMART BEAR pillbox devices, patients will be receiving indications on how to follow the monitoring and intervention program.

The patient’s medication intake will be systematically recorded through a SMART BEAR mobile phone. Clinicians will receive daily/weekly reports on patient’s medication management. At the check-up neurological visit, the collected information will be discussed with the patient and/or his/her caregiver. At this point, the clinician will be able to better monitor the patient’s medication management, adjust the therapy if it’s required and locate the patient if there are any unexpected adverse effects.
Finally, an intervention with SMART BEAR platform will be recommended to the patient. For example, a **SMART BEAR assistant device** will remind patients when to take the therapy and where to find it if it goes lost.

<table>
<thead>
<tr>
<th>Actors:</th>
<th>SMART BEAR Platform User (e.g. patient, caregivers)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Clinician</td>
</tr>
<tr>
<td>Preconditions:</td>
<td>SMART BEAR pillbox, mobile phone, and</td>
</tr>
<tr>
<td>Trigger:</td>
<td>Patients with several medical conditions who need a reliable medication intake monitoring to avoid adverse and to enhance their quality of life</td>
</tr>
<tr>
<td>Flow:</td>
<td>1. I (user) have <strong>SMART BEAR pillbox</strong>, mobile phone</td>
</tr>
<tr>
<td></td>
<td>2. Every morning and evening my <strong>SMART BEAR app</strong> reminds me to take my medication before or after meals.</td>
</tr>
<tr>
<td></td>
<td>3. At any time, I can access my medication management report, on the <strong>SMART BEAR mobile app</strong> (<em>MyMedication</em>), in case I don’t remember if I took my medicines or not.</td>
</tr>
<tr>
<td></td>
<td>4. A report of my medication management is available to the case manager clinician (and to a formal and informal caregiver, according to ICF), according to the medical guidelines. This allows the clinician to adjust the therapy if it’s required and/or to locate</td>
</tr>
<tr>
<td></td>
<td>5. With the use of <strong>SMART BEAR medication adherence intervention program</strong>, I am always reminded to take my medications.</td>
</tr>
<tr>
<td></td>
<td>7. Periodically, the <strong>SMART BEAR mobile app</strong> sends me an overview on how I managed my therapy.</td>
</tr>
<tr>
<td></td>
<td>8. The <strong>SMART BEAR mobile app</strong> compliments me for the goals achieved that helps me staying motivated.</td>
</tr>
<tr>
<td>Alternative Flows:</td>
<td></td>
</tr>
<tr>
<td>Exceptions:</td>
<td>Only for patients with dementia: Not all patients with dementia can be included in this study. It depends on the level of severity: MOCA&lt;18 is excluded)</td>
</tr>
<tr>
<td>Requirements:</td>
<td>First onsite clinical assessment and set the monitoring and intervention program. Explain to patients how does the Smart Bear platform work and give them a few hours of practice under supervision.</td>
</tr>
</tbody>
</table>
4.2.5.4 Non-ideal light levels

Jenna is a 68 years old woman from Italy, who worked as a high-school teacher for 30 years. She lives alone with her beloved cat. She usually spends most of her time reading: she has a deep love for the classic works of French literature. In recent years, encouraged by her former students she becomes interested in more current authors (not only French), too. Despite her lifestyle, Jenna is not a lonely person; she is very curious, and she enjoys being with other people. Jenna is still in contact with her former students that sometimes visit her to share a cup of coffee and she is used to arrange dinners and sightseeing trips with her group of friends.

During the last three months, Jenna has gradually begun to feel unsteady and to experience trouble interpreting visual information during her daily activities. One morning in mid-November, such symptoms result in a fall after which Jenna perceives a sense of dizziness and a painful light sensitivity for days. Jenna, truly worried since she lives alone, decides to go to the hospital, where it emerges that the fall resulted in a concussion, responsible for the light sensitivity; in addition, specialists diagnose her the Lewy Body Dementia (LBD). LBD is a type of progressive dementia that leads to a decline in thinking, reasoning and motor functions because of abnormal microscopic deposits that damage brain cells over time. There are no treatments that can slow or stop the brain cell damage caused by LBD and heal the post-concussion light sensitivity, as well. Current strategies only focus on helping symptoms. In that regard, setting the SMART BEAR Platform at Jenna’s house for a year is proposed.

Jenna agreed to install the sensors at home (e.g. smart lights, smart switches and an assistant device) and to use a mobile phone with dedicated mobile applications. Every morning, Jenna wakes up and the lighting monitoring automatically starts. As usual, Jenna has breakfast and gets ready for her daily routine. According to the weather condition (i.e. natural light), the installed SMART BEAR Platform regulates the indoor lighting (i.e. artificial light) brightness and colour. Such regulation can be further personalized by Jenna thanks to the voice-activated assistant device. In fact, people who suffer from light sensitivity are particularly sensitive to certain wavelengths of light, that is the blue-green spectrum, and this intolerance worsens with brightness. Moreover, while Jenna goes from a room to another during the day, the SMART BEAR Platform automatically turns on the lights needed to guarantee a full visibility of nearby objects/obstacles. It’s evening and Jenna is using her mobile phone gathering new ideas for her next trip when the lights dim and the colour of display of her mobile becomes warm to ensure a better mood and a protection against the effects of an excessive blue light exposure (difficulty falling asleep, for instance). However, Jenna does not like such lighting and turns on the lights completely. A while passes and SMART BEAR Platform provides an alert. In the meantime, Jenna receives a message on her mobile phone, and she becomes aware that the light levels are not ideal, or rather, they can be harmful for her. Understanding the importance of a proper lighting, Jenna, therefore, decides to dim the lights.

A year later, Jenna returns again to the hospital. During the visit, Jenna reports feeling an enormous sense of relief since the painful light sensitivity is noticeably alleviated. In addition, she declares to perceive a smaller fear of falling although she continues to experience balance problems. The specialist, based on the clinical examinations, verifies the progress of LBP and prescribes a pharmacological therapy that needs to be monitored in the following months. Furthermore, considering Jenna’s enhanced awareness about the importance of a proper lighting and her improved sense of safety, he recommends her to continue using the Smart Bear platform and Jenna agrees to it.
Use Case: Non-ideal light levels

Created By: FCSR
Last Updated By: FCSR, all partners
Date Created: 18/11/2019
Last Revision Date: 16.12.2019

Description: Human eyes are continuously exposed to light. Lighting impacts human health and performances by enabling visual tasks and, through the control of the body’s circadian rhythm, affecting mood and perception. Light is therefore essential for both physiological responses (light is necessary for the vision) and psychological ones. Inadequate levels of light do not only cause symptoms as eyestrain, dry eye and blurred vision. Indeed, improper lighting is also implicated in augmenting depression, increasing fatigue, reducing alertness and enhancing sleepiness. Finally, the exposure to the light emitted by the electronic devices at night can delay or even stop nocturnal melatonin production which may disrupt sleep or pose a health risk.

Users of SMART BEAR Platform could benefit of continuous monitoring of light exposure at their homes. The Smart Bear platform will get users aware of the quality of the lighting and in case of non-ideal levels of light (e.g. environment too dark or too bright), the platform will suggest, through notifications and/or alerts, the users to adopt a solution (e.g. turn on a lamp or dim the light) in order to meet the compliance environment.

Actors: Smart Bear Platform User
Clinicians

Preconditions: Home sensors, mobile phone

Trigger: Entire older population

Flow:
1. I (user) have SMART BEAR home sensors and Smartphone
2. Every morning, the monitoring automatically starts if I am at home
3. When I am at home, SMART BEAR Platform updates the data of the monitoring (light brightness, light colour, flicker frequency)
4. Whenever I want, I can open the dedicated application to access the collected data that are represented in a meaningful form for me (e.g. comfort level)
5. SMART BEAR Platform detects low quality (e.g. light brightness and duration of exposition > certain thresholds)
6. SMART BEAR Platform alerts me
7. I notice the alert (e.g. buzz, sound or visual alert from the Smart Bear platform)
8. I access to the dedicated application to know relevant information (e.g. compliance parameters, the problem, the cause, the possible solution)
9. I perform an action (e.g. turn on a lamp, dim the light) in order to face the low quality of the lighting
10. As soon as the monitoring entered again into the compliance parameters, the SMART BEAR Platform notifies me (e.g. buzz, sound or visual alert from the Platform)

Alternative Flows:

1. If alerts are off, skip the step 6 and 7 of the basic flow
2. Users can decide to postpone and/or to disable alerts.
3. Users do not perform any action; the platform automatically regulates the smart light to ensure ideal levels of light

Exceptions:

- 

Postconditions:

Visualization of solutions “performed”/” not performed” and of daily/monthly statistics for users and clinicians. Enhanced awareness and management of the quality of the lighting by users. Better compliance to ideal light levels by users.

Requirements:

4.2.5.5 Behavioural changes

Valentin has just turned 70 years old. He spent all his life in Romania, working as a sport professor for almost 40 years and sharing his life with his wife, who died 4 years ago from pulmonary cancer. His two children are living in USA for more than 10 years now and visit him once a year. He used to enjoy outdoor activities such as fishing and hiking, and had a close relation with his wife’s relatives. Since his wife died, which he recalls as being a shock for him, he has gradually started to change his behaviour. He ceased to go fishing and days would pass till he would walk out from his house just to buy something. His car was rarely used as the traffic annoys him. Even if he used to cook all his life for his family trying to keep alive the traditional recipes he learned at home as a child, he gradually changed his dietary habits and eats irregularly. His relationship with his relatives changed dramatically, as some of them moved into countryside after retirement or live with their children in other cities. Since making any visit became burdensome, he started to insulate himself from other people becoming really anti-social. He started to manifest an increased indifference to others and, after two years from his wife death, he started to show some language difficulties. Soon, he was diagnosed with hyperthyroidism. He gave up to his life habit of playing table tennis claiming that the noise of the falling ball irritates him. He does not have the patience anymore for his friends’ visits and shows apathy during his daily activities. He became a heavy TV watcher, which deepen his sleeping disorders as quite often he wakes up in the middle of the night staring at TV for hours. His children are the only ones he keeps contact with. Through the time, he developed his thyroid disorder and a skin condition. Thanks to his children’s persuasion, he went much into information and communications technologies. His children bought him various devices and encourage him to learn how to use them. He constantly refused to go to the doctor and to accept any non-pharmacologic intervention, though he agreed to take some online psychological tests.

When his daughter finally took him to the clinician, it was explained how the neurodegenerative disorders are correlated, such as a thyroid disorder, trauma, and mild depression and the importance of taking preventive actions. At the end of the meeting, Valentin agreed to use SMART BEAR Platform. The platform will monitor and constantly evaluate some of his cognitive functions such as memory, social interaction, life at home, personal care, which all have an impact on his ageing well. His daily activities are recorded as well, and the Platform gives real-time notifications when the risks of inactivity increases and stimulates a more active social behaviour. Nevertheless, the platform will offer him the opportunity to access a personalized schedule meant to increase motivation and participation in the life of the city, friends and
relatives. All in all, his physical and cognitive activities will be systematically recorded through a mobile phone and he will be rewarded when he achieves goals.

Valentin approved to install the Platform and to use the mobile phone. The program starts every morning. A buzzer sounds remind him to take the medicine for the thyroid disorder, to diversify his meals, give recommendations for walks when the weather is nice. All exercises are gamified and provided in a mixed reality environment. He wears a smart band to avoid prolonged sedentary time and isolation. Once a month, he answers to the Global Deterioration Scale questionnaire and games with language usage abilities are constantly suggested to him for playing. After all the data is recorded, they are regularly evaluated. Screening questionnaires (e.g., PH2), HCI events with mobile device are filled in and regarded as mandatory.

At the beginning, Valentin did not take seriously the recommendations and felt annoyed by the Platform’s notifications. Through the constant encouragement of his children, he started to engage in various activities (walking, household activities, shopping, visiting), with his cell phone recording his steps constantly and engagement rates. At the end of the day, he used to notice about 900 steps and his physical activity used to be rated as low and very low. However, in time, he started to engage more vividly in the suggested activities and to pay more attention to the recommendations. By visiting and maintaining clean his wife’s grave, he achieved more than 10,000 steps a day. His activities and reached goals became a common subject to every phone conversation with his children. They also started to take part in his tasks, by constantly asking about his progress and achievements and about the adjustments. The physical activity intensified and that was constantly increasing the motivation for his engagement. The alert to significant others is regarded as paramount for Valentin’s feeling of security.

Comprehensive geriatric assessment is undertaken, based on the long-term data gathered on the Platform that covers his personal history and physical - psychological constant monitoring and evaluation. Activities of Daily Living Scale and Instrumental Activities of Daily Living Scale are also useful instruments and insightful for understanding when Valentin need more support and encouragement and to better understand his triggers and environmental factors.

Six months later, taking a preventive approach, self-management tools for HBP (High Blood Pressure) and COPD (Chronic Obstructive Pulmonary Disease) have also been installed. When his daughter visits him, they go together to a geriatric psychiatrist for the Valentin’s psychiatric assessment. He feels that he is doing again things that he loved doing all is life. He is more active in his daily activities, which diversified significantly. His score on the Functional Gait Assessment test improved by 9 points. He continues using the SMART BEAR Platform’s equipment and the result makes him satisfied and persuades him to continue using the platform.

Table 13 Use Case: Behavioural changes

<table>
<thead>
<tr>
<th>Use Case:</th>
<th>Behavioural changes</th>
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<tbody>
<tr>
<td>Created By:</td>
<td>ANA</td>
</tr>
<tr>
<td>Date Created:</td>
<td>20/11/2019</td>
</tr>
</tbody>
</table>
| Description: | Behavioural changes affect physical and cognitive – behavioural functions which tend to decline over the years. A tailor-made multifactorial context-enhancing intervention is useful. Users of SMART BEAR Platform with behavioural changes will benefit of continuous monitoring, evaluation and stimulation of physical and cognitive activities. A first onsite assessment session is necessary to set goals and explain the features of the platform. Once having SMART BEAR @ Home installed,
users will be receiving notifications and recommendations over the day (e.g. going out for a walk, visiting, shopping not at the closest store) and evaluations (e.g. language tests, depression). They will be constantly supported to maintain their physical activity and complete tasks of an individualized dynamically program. Support, cognitive stimulation, encouragement and motivation will be offered through the Platform while the clinician will have a comprehensive overview of the physical and cognitive activities as well as daily habits of the patient.

| Actors: | SMART BEAR Platform User  
| Clinician |
| Preconditions: | Home sensors, wearable sensors, Smartphone |
| Trigger: | Patient who needs to regain enthusiasm and motivate themselves to engage in daily activities, to socialize and to support their physical activity. |
| Flow: | 1. I (user) have SMART BEAR smart wearables and smartphone.  
| | 2. Every morning, I receive a notification that reminds me of my daily activities’ tasks.  
| | 3. I choose the task to which I want to start my day.  
| | 4. During the day, I choose from serious cognitive games as options. Their difficulty adapts to my abilities and activity in the last few days.  
| | 5. I would often start with a physical activity and take the cognitive game over the day.  
| | 6. Notification about weather and suggestions for enhancing social life are very useful.  
| | 7. During the day, my physical activity is recorded since I always carry my smartwatch.  
| | 8. The system notifies me to fill in the questionnaires regarding my mood and quality of life.  
| | 9. Periodically, I am aware of how many steps and km I have walked, and I can have an overall view on my latest activity as well as of my social and cognitive activities.  
| | 10. Comparing my physical and cognitive activity scores to other users’ help me staying motivated. |
| Alternative Flows: | A wearable (smartwatch) could be also chosen as physical activity tracker |
| Exceptions: | |
| Requirements: | Either a first onsite clinical assessment or a family decision for setting goals |
4.2.5.6 Family Isolation

Tomas is in his late 60’s and he continues living alone in the capital of Romania. He retired soon after his wife had died, and it seemed that he manages quite well the changes in his late life. He just started to devote more time to his nephews and to the extended family. He would often take time to do shopping for his older sister, to pick up his two nephews from school and care for them till his daughter returned from work. He didn’t mind cocking and caring and found himself quite busy with the new responsibilities. He would often meet his younger colleagues from work for a drink over the weekend. When his mother died, he took the financial burden of the funeral upon himself and did all that the tradition required. Two months later after the funerals, he heard that his mother herself took care of her legacy and offered the lands and the house to all her children except for him. He was the only one who received nothing. And no explanation was there for him. He tried to make sense for himself, but he couldn’t. The months passed, he felt more isolated from his family and was not able to do the things he used to do. He was silent and alone. His children took him to psychiatric consultations, but nothing worked. He was becoming so silent that after one year he would barely articulate few words per week. In his best moments, he would nod his head if wants to express agreement or disagreement. Call phones became impossible to handle. He remained silenced just as his mother was silence in her grave.

For Tomas, depression was coupled with anxiety and loss of confidence, and, over time, the family could hardly maintain a basic relation with him. When his children proposed to SMART BEAR Platform, Tomas neither agree nor disagree. Together with the geriatric psychiatrist, they set up some preventive measures and took action. A *personalized notification system* was built, and common decisions were agreed upon: they set up a regular family meal once a week, bought a dog for their father, notified the neighbours about his condition and encouraged their father to maintain attendance to the church. The Platform gives *real-time notifications when the activities follow, remind him of his family reunions, and stimulates a more responsible and active behaviour*, such as dog walking or personal hygiene, attending religious services and respecting holy days. Nevertheless, the platform will offer him the opportunity to access the agreed *personalized schedule* meant to increase motivation and participation in the life of the family. *HCI events with mobile device* considerably helps for maintaining his social and family integration. His activities and responsibilities will be *systematically recorded through a mobile phone*. His children will be also notified (*the alert to significant others*) and aware of his daily routine and may call Tomas to motivate to participate in the program.

The program starts every morning when a buzzer sounds remind him to take the dog for the morning walk. Reminders for the religious service, dining time with family, and other small activities were set. He wears a *smart band to avoid getting lost* as he is unable to verbalize his address.

Tomas started to collaborate and to feel more secure in the family setting. Through the constant encouragement of his children, he started to engage in the activities suggested by the platforms (dog walking, religious services, household activities), with his *cell phone constantly recording his engagement rates*. SMART BEAR Platform had a great impact for Tomas and his family. If previously the GPCOG (General Practitioner Assessment of Cognition) screening was hardly performed by Tomas’ geriatric psychiatrist, now, a complete overview and a more comprehensive assessment is carried out by the doctor.

*Table 14 Use Case: Family isolation*

<table>
<thead>
<tr>
<th>Use Case:</th>
<th>Family isolation</th>
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<tr>
<td>Created By:</td>
<td>ANA</td>
</tr>
<tr>
<td>Date Created:</td>
<td>20/11/2019</td>
</tr>
</tbody>
</table>
**Description:** Family isolation is paired with depression and the constant deterioration of the physical and cognitive – behavioural functions. These functions tend to accelerate in deterioration over the years. Moreover, heart diseases and other chronic conditions are coupled with family isolation.

Users of SMART BEAR Platform who insulate themselves from the family will benefit of continuous monitoring and stimulation of physical and cognitive activities with a special focus on enhancing social and family activities. A first onsite assessment session is necessary to set goals and explain the features of the platform. Once having SMART BEAR @ Home installed, users will be receiving notifications and recommendations over the day (e.g. going out, spiritual goals) and their heart diseases will be monitored. They will be regularly encouraged to increase their physical activity and complete tasks of an individualized dynamically program. Constant support, stimulation, encouragement and motivation will be by means of simple awards every time a set goal is achieved.

| Actors: | SMART BEAR Platform User  
|         | Clinician               |
| Preconditions: | wearable sensors, Smartphone |
| Trigger: | Patient who needs to be reintegrated into the family and partake in their activities. |
| Flow: | 1. I (user) have SMART BEAR smart wearables and smartphone.
2. Every morning, I receive a notification that reminds me to take a walk out.
3. I think about the suggestions of various activities (functional assessment) and decide what to do over the day.
6. During the day, my physical activity is recorded since I always carry my smartphone/smartwatch.
7. Meeting my family for every Sunday lunch.
8. At the end of the day, I take a walk out and spend at least 20 minutes outside of the house.
9. Becoming part of the Seniors SMART BEAR Virtual Community (Social community) I will be able to compare my physical and cognitive ability scores to other users of the Virtual Community to help me stay motivated. |
| Alternative Flows: | A wearable (bracelet) could be also chosen as physical activity tracker |
| Exceptions: | |
| Postconditions: | Enhancement of users’ motivation for cognitive activity. Better compliance to cognitive stimulation programs and emotional support. Augmented self-esteem and self-confidence |
| Requirements: | Either a first onsite clinical assessment or a family decision for setting goals |
4.2.5.7 Social Isolation

Jeni is in her early 80s. She spent all her life in a small Transylvanian city, where she accumulated several functions as a professor and director of a high-ranking high school and didn’t have a monotonous work. As a divorced woman, she fully dedicated herself to professional activities, achieved a high-respected social status, enjoyed a good salary and respect, and often even enjoyed being feared by subordinates. Gradually, after retirement, she lost her social privileges and the social capital: generations changed, people would cease to recognize her on the street, some of her friends moved or passed away, while others were busy with supporting their children and grandchildren. Obesity installed and a sharp pain in the knee did not allow her to move too much. She developed a skin condition and she was hospitalized for a week in a dermatology clinic, where no one was allowed to visit her. That accentuated the feeling of loneliness and neurocognitive decline started to show. She was not treated preferentially, as she used to be, and so she found herself unexpectedly alone. Her life begun to look as the epitome of social isolation.

The clinician’s insistence to use the SMART BEAR Platform begun to show its fruits. **UCLA Loneliness Scale** was used as well as a sound sensor to detect frequency of discussions. After three meetings she agreed to use the Platform for maintaining her independent living. Because doctors were the only one, she could rely on, she started to use the SMART BEAR application for her monthly appointments to the doctor. Attending her doctor appointment via a video call was just the beginning. In few months from installing SMART BEAR @ Home, she also agreed to monitor her activities and to answer to notifications. **HCI events with mobile device was installed. A personalized notification system** was put in place. Gradually and slowly, she became more skilled at using the application and much more confident that, if something happens, she can immediately reach the doctor, or the alarm will notify him.

A year later, due to the constant reminders and suggestions for various social activities, Jeni’s self-confidence was stable. The notification system proved valuable for weather broadcast and incitement to walking and partaking into social events every now and then, as well as to be exposed to natural sunlight, which is beneficial to the cognitive functions. Cognitive games were also able to strengthen her self-assurance in her personal ability to handle her own life. The wearables and in-house sensors have also been installed and she is fully confident that the Platform features will help her maintain the independent living and keep her connected to the social world.

<table>
<thead>
<tr>
<th>Use Case: Social isolation</th>
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<tbody>
<tr>
<td>Created By: ANA</td>
</tr>
<tr>
<td>Date Created: 20/11/2019</td>
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</table>

Description: In order to keep the contact with the clinicians in the cases of social isolation, a solution would provide value. Social isolation is associated with cognitive disorders and heart diseases and stroke and elderly who found themselves alone and insulated from the social life would have trouble to continue staying alone and independently. Because the decline in cognitive abilities is generally significant over the years, people who are socially isolated have trouble in preserving their basic abilities. A preemptive model of care would be beneficial to the socially isolated elderly and wearables and in-house sensors for the elderly in their late age, stabilize their confidence and security.

Users of SMART BEAR Platform who are socially isolated will benefit of continuous monitoring and stimulation of physical and cognitive activities. A first onsite
assessment session is necessary to set goals and explain the features of the platform. Once having SMART BEAR @ Home installed, users will be receiving notifications, recommendations, tests and have the possibility for a virtual appointment with the clinician over the day. Their daily activities will be closely monitored, and they will be regularly encouraged to increase their physical activity and complete tasks of an individualized dynamically program.

| Actors:                          | Smart Bear Platform User  
|                                 | Clinician                  |
| Preconditions:                  | Home sensors, wearable sensors, Smartphone |
| Trigger:                        | Patient who needs to regain self-confidence and the feeling of security |
| Flow:                           | 1. I (user) have the SMART BEAR Platform, smart wearables and smartphone.  
|                                 | 2. The mobile app informs/guides me on how to prepare my home environment for enhanced personal safety while undertaking physical activities.  
|                                 | 3. After my morning routine, I choose which cognitive games to play. Their difficulty adapts to my abilities.  
|                                 | 4. I receive periodically notifications to enhance my social activities, that are correlated with my current level of social involvement (as recorded in MyDiary App).  
|                                 | 5. In the mid-day I go for my walk. Before I go out, I check my smartphone for any notification about environmental conditions.  
|                                 | 6. During the day, my physical activity is recorded since I always carry my smartwatch with me.  
|                                 | 7. Once a week I invite someone over at my place. Once a month I attend a social event such as a play theatre. This information is logged on MyDiary App (shared with MyMood and MyMemory App)  
|                                 | 8. At the end of the day, I am aware of how many steps and km I have walked, and I can have an overall view on my latest activity.  
|                                 | 9. Becoming part of the Seniors SMART BEAR Virtual Community (Social community) I will be able to compare my physical and cognitive ability scores to other users of the Virtual Community to help me staying motivated.  
| Alternative Flows:              | 8. A wearable (bracelet) could be also chosen as physical activity tracker  
| Requirements:                  | A first onsite clinical assessment for setting goals  

4.2.5.8 Extreme temperature/Weather conditions

Abe is a 79 years old man from Italy who worked as a railway man for 60 years. He is a very tireless person with many hobbies. Ever since he retired, he has been dedicating himself completely to his main passions and, gradually, he has transformed his house: a large number of books and copious collections of documentary films swarmed the living room while the basement room has become an authentic joiner’s workshop. Indeed, Abe loves spending his days at home switching between reading a book, watching a documentary, and creating wooden objects for his loved ones (e.g. pieces of furniture for his wife and small toys for his grandchildren). Abe lives with Adele, an affectionate, comprehensive, and attentive wife. Adele, unlike her husband, enjoys outdoor activities (go shopping, go to the cinema, dancing) and she often scolds Abe to spend much time at home.

Four months ago, Abe has begun to experience some ailments (as blurred vision, frequent headaches and sporadic episodes of numbness) which have caused concern especially on the part of Adele. Abe, therefore, decides to see a doctor which, based on both clinical examination and symptoms description, suspects the beginning of dry eye syndrome. The clinician recommends Abe to avoid becoming dehydrated by drinking plenty of water (8 to 10 glasses) each day and to ensure a proper ventilation at home being the place where he spends most of his time. The clinician proposes to set the SMART BEAR Platform at his house for a year. The suggested platform will give him the opportunity to monitor the environmental conditions at home, with a focus on air humidity, atmospheric pressure and air temperature (i.e. thermo-hygrometric comfort), to give real-time notifications and alerts in case of risky conditions (i.e. environmental parameters away from the compliance values specified by guidelines) and to provide suggestions to safeguard the thermo-hygrometric comfort and prevent, in this way, the eye dryness aggravation.

Abe agreed to install the environmental sensors at home and to use a mobile phone with a dedicated mobile application. It is a morning in mid-November, Abe just woke up and the monitoring of air humidity, atmospheric pressure and air temperature automatically starts. As usual, Abe has breakfast and gets ready for his daily routine. Since Christmas is approaching, Abe decides to realize homemade gifts and he goes to the basement room taking the mobile phone with him. After several hours, Adele invites Abe to go grocery shopping together and he accepts. Once at home, they have lunch. After lunch, Abe goes back with the mobile phone to the basement room where he spends the entire afternoon. The same happens in the following days. One rainy afternoon, Abe is in the basement room and he receives an alert from the SMART BEAR Platform. Then, Abe accesses to the dedicated mobile application on the mobile phone and he gets aware that in such an environment the temperature and humidity are high while the ventilation rate is poor: the air is actually dry. Abe looks for potential solutions on the mobile applications and he decides to take a break: he walks off the room leaving the door wide open so as to ensure air recirculation and he goes into the kitchen where he helps Adele cooking for the dinner. Meanwhile, the environmental parameters enter again into the compliance range and a message on Abe’s mobile phone arrives. Adele informs Abe that he may go back to the basement room, but he prefers to stay.

A year later, Abe visits again the doctor. The symptoms are still present, but they are not worsened and, according to the clinical examinations, the eye dryness has not advanced substantially: this represents a valuable result. Abe is now more aware about his wrong behaviours and the precautions/actions necessary to promote an increased wellbeing. He has also developed an enhanced perception about the thermo-hygrometric comfort and its impact on the health. Despite periodic medical examinations are needed to control his health condition, Abe decides to continue using SMART BEAR Platform taking advantages for him and, hopefully, for his wife too.
Table 16 Use Case: Extreme temperature/Weather conditions

<table>
<thead>
<tr>
<th>Use Case:</th>
<th>Extreme temperature/Weather conditions</th>
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<td>FCSR</td>
</tr>
<tr>
<td>Last Updated By:</td>
<td>FCSR, all partners</td>
</tr>
<tr>
<td>Date Created:</td>
<td>18/11/2019</td>
</tr>
<tr>
<td>Last Revision Date:</td>
<td>16.12.2019</td>
</tr>
</tbody>
</table>

Description: Air humidity, atmospheric pressure and air temperature, in both outside and inside environments, particularly affect the wellbeing of the elderly which are more sensitive to weather conditions than younger people. Air humidity is mainly related to the perception of air quality while air pressure and temperature impact on coronary heart disease morbidity. Air temperature is also involved in the body dehydration phenomenon that is another important issue in older population. A person suffering from extreme temperatures may be, however, affected cognitively, too. Indeed, s/he might show signs of clumsiness, lack of coordination, confusion and sleepiness.

Users of SMART BEAR Platform could benefit of the continuous monitoring of weather conditions at their homes. The Smart Bear platform will get users aware of the quality of the environment and in case of risky conditions (e.g. too hot or too cold ambient), the platform will suggest, through notifications and/or alerts, the users to adopt a solution (e.g. open the window) in order to meet the compliance environment.

Actors: SMART BEAR Platform User
Caregiver
Clinicians

Preconditions: Home sensors, smartphone

Trigger: Entire older population

Flow:
1. I (user) have SMART BEAR home sensors and Smartphone
2. Every morning, the monitoring automatically starts if I am at home
3. When I am at home SMART BEAR Platform updates the data of the monitoring (air humidity, atmospheric pressure and air temperature: indoor & outdoor conditions)
4. Whenever I want, I can open the dedicated application to access the collected data that are represented in a meaningful form for me (e.g. comfort level)
5. SMART BEAR Platform detects low quality (e.g. humidity, temperature and duration of exposure > certain thresholds as described in Table 1) by means of Smart Bear integrated sensors + Weather forecast

Alternative Flows:

Exceptions:
**Postconditions:** Visualization of solutions “performed”/” not performed” and of daily/monthly statistics for users, caregivers and clinicians. Enhanced awareness and management of the quality of the environment by users. Better compliance to thermo-hygrometric comfort by users.

**Requirements:**
1. MyMood App connects with smart temperature / humidity / atm pressure sensors
2. Logs and visualizes atm pressure air temperature etc
3. A notification is created and sent to user if extreme highs or lows are reached (specific extreme conditions + a suggestion / solution)
4. Information from both sensors and weather forecast are logged and visualized in Smart Bear Interface

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### 4.2.6 Frailty (Obesity/eating disorders)

#### 4.2.6.1 Malnutrition

Janet is an 80-year-old housewife from Italy. Since she became a widow one year ago, she lives alone. Her daughter Julie with her husband John and her three-year-old son David, who live nearby, visit her every day: this is the favourite moment of the day for Janet. Indeed, Janet enjoys John being together with her family, she spoils her grandson David and she would like such visits to last more and more. Janet is an excellent chef and she loves to prepare her delicacies for Julie, John, and David. Julie loves Janet and she is concerned that her mother could feel lonely.

Three months ago, Janet has begun to experience intermittent abdominal pain with the sensation of food or stomach acid stuck into the throat or chest or behind the breastbone and she notices a gradual weight loss and symptoms of dehydration. Julie decides to prepare some more befitting meals for her mother to warm in the conventional microwave oven when she is alone at home. During her habitual visits in the following days, however, Julie finds the meals untouched. Janet and Julie, therefore, visit a gastroenterologist which diagnoses the dysphagia. Such pathology is due to a general wear and tear on the body over time and its treatment, in addition to prescription of oral medications, involves making a change in the typology and the consistency of food eaten. Anyway, the adequate food and fluid intake must be guaranteed, said the clinician. For that reason, he proposes to set the SMART BEAR Platform at Janet’s house for a year. The suggested platform will give the opportunity to monitor the eating and drinking habits, keep track of weight and medications, to give real-time notifications and alerts in case of risky conditions (e.g. inadequate food intake) and to provide suggestions of meal plans for a better awareness and managing of the dysphagia condition. Finally, she will receive a reward when she achieves her goals as they are specified by her referring physician/dietician (e.g. nutrition and fluid intake).

Janet agreed to install the sensors at home (e.g. smart pillbox and smart scale) and to use a mobile phone with dedicated mobile applications. Every morning, as usual, Janet wakes up, weighs herself, has breakfast and gets ready for her daily routine. It’s midday, Janet is going to have lunch when she gets a call from Julie that asks about her meal and whether she has taken a picture with her mobile phone. Once hung up the call, Janet takes a picture of her meal and she finds that it is not adequate; so, she receives suggestions about some additional dishes by the SMART BEAR Platform. When evening falls, Julie, John and David join Janet at home and they decide to stay for dinner. Julie exploits SMART BEAR Platform to verify her mother’s adherence to medication and eating behaviours by means of the two dedicated mobile applications. Then, Julie and Janet set together the nutritional mobile application meal and drink reminders (i.e. eating regularly and in compliance with medications and recording the nutrition intake) and Julie’s phone number as the emergency number since Julie wants to be alerted whether risky conditions occur. Several days are
passed and Janet, more and more confident with the SMART BEAR Platform, reaches her goal and she wins a reward.

A year later, Janet and Julie visit the gastroenterologist again. During the visit, the clinician inspects the data collected by the SMART BEAR Platform (e.g. eating and drinking habits, weight track) and he reassures that the found fluctuations in food intake and weight are not surprising. Julie, on her part, claims to feel more relaxed in monitoring her mother especially when she cannot visit her. Janet, instead, declares to feel more involved and to feel less alone thanks to the gamification elements (e.g. suggestions of new recipes, new ingredients, and rewards) provided by the SMART BEAR Platform. In fact, she says that afternoons pass faster. Janet and Julie, in accordance with the clinician, finally decide to continue using SMART BEAR Platform.

Table 17 Use Case: App to monitor nutrition intake

<table>
<thead>
<tr>
<th>Use Case:</th>
<th>App to monitor nutrition intake</th>
</tr>
</thead>
<tbody>
<tr>
<td>Created by:</td>
<td>FCSR</td>
</tr>
<tr>
<td>Date Created:</td>
<td>15/11/2019</td>
</tr>
<tr>
<td>Description:</td>
<td>Changes in appetite and sense of taste and smell generally decline with age, making it more difficult to enjoy food and keep regular eating habits. Malnutrition, dehydration and unintentional weight loss contribute to health progressive decline, reduced physical and cognitive functional status, increased utilization of health care services, premature institutionalization, and increased mortality. Nonetheless, many health care practitioners address the multifactorial issues that contribute to nutritional risk and malnutrition and dehydration inadequately. A software installed on a Smartphone or on a tablet could provide help with monitoring and correcting nutrition and fluid intake. The app would require the patient’s or the caregiver’s input to record the nutrition intake of the user. The input could be a selection from a wide pool of possibilities among drinks and food or a picture taken with the Smartphone or with the tablet, if equipped with an image recognition algorithm. The software would record the entries relative to every meal of the user. Adherence to this program would be enhanced by a rewarding system comprehending badges and points to keep it more gratifying. In addition, the app could provide useful suggestions regarding the diversity and nutritional intake of ingredients and meals. When the patient is visited by the referring physician / dietician, nutrition and fluid intake would be assessed and corrected, if needed. This function would enhance healthy ageing and would provide value to the follow-up visits performed by referring physician / dietician; moreover, it would enhance the patient’s self-awareness by providing useful suggestions and knowledge about a healthy lifestyle for older people.</td>
</tr>
<tr>
<td>Actors:</td>
<td>User with frailty or eating disorder</td>
</tr>
</tbody>
</table>
**Preconditions:**
Diagnosed frailty or eating disorder, nutrition intake app and Smartphone or smartwatch.

**Trigger:**
Follow-up visit for general health status and nutrition.

**Flow:**
1. I (user) have SMART BEAR @ Home devices and Smartphone
2. Periodically, I receive a notification to use the smart weight scale in order to weigh myself.
3. The data is logged automatically and can be visible on my smartphone
4. Periodically, the platform reminds me of water intake through the mobile application.
5. Whenever I want, I can look for new recipes, ingredients and suggestions to improve my habits.
6. I can input my meals (picture or selection of meals)
7. I get a reward if I am eating correctly or a communication with suggestions if the food is not appropriate (for example too scarce)
8. The platform keeps track of my weight and hydration
9. SMART BEAR Platform detects an alarming decline in weight for the last period
10. SMART BEAR Platform alerts me and my caregivers that something should change in my eating and drinking habits
11. I notice the alert (e.g. buzz, sound or visual alert from the SMART BEAR Platform)
12. I can visualize the relevant information (e.g. compliance parameters, the problem, the cause, the possible solution)
13. The SMART BEAR Platform notifies me the next days if the monitored parameters reach the compliance levels or if I need to visit a clinician.

**Alternative Flows:**
8. If alerts are off, skip the step 9, 10 and 11
9. Users can decide to postpone and/or to disable alerts
11. If users do not perform any action, the platform keeps track of time range the users are not within the compliance parameters

**Exceptions:**

**Postconditions:**
Improved health status of the patient (better diet and self-awareness).

**Requirements:**
Fitness condition and dietary habits assessments; initial plan of diet and adjustments at follow-up visits.
1. MyDiet App accessible on Smart bear interface
2. connects with smart scale
3. connects with mobile's embedded camera
4. user receives a notification in the form of text to weigh once per week
5. app logs and visualizes user’s weight
6. a monthly report is created and sent to user, significant other and/or clinician according to ICF
7. an alert is sent to user, significant other and/or clinician if weight is +/-3kg (notification to exclude frailty - Heart failure)
8. database of variety of dishes + nutritional details
9. connects photo taken by mobile’s camera with the database
10. creates notification if menu inadequate (e.g. fat, low calories) and sends it to user’s mobile [2]

4.2.6.2

4.2.6.3 Abnormal blood glucose level

Bogdan is 66 years old. He retired one year ago and felt tired and anxious about what is to come. A visit to the clinician sheds light on a serious issue: abnormal blood glucose level. A heavy smoker with a high body mass index, Bogdan started to feel insecure as the signs of abnormality and frailty were shown much earlier than expected. Actually, that was symptomatic for his world of vices and anxieties. He lived alone all his life in unformalized relationships and has no children.

As soon as his clinician informed him about the SMART BEAR Platform, Bogdan agreed to use it. Learning how to manage all the applications and features was easy to him as he was quite a young old man. Together with the geriatric psychiatrist, they set up some preventive measures with a special focus on his dietary habits and physical exercises. Daily walking and sunbathing became his favourite daily habits and were seen as milestones of his endeavour. The platform will give real-time notifications when the activities start, remind him of his responsibilities and stimulates a more responsible and active behaviour, especially in relation with smoking, lying in the bed and TV watching. The reminders for the agreed personalized schedule were set and meant to increase motivation for a healthier lifestyle. His activities and responsibilities will be systematically recorded through a mobile phone.

Bogdan approved to install the Platform and to use the mobile phone. The program supports self-monitoring and self-management which is of great benefit to him. The recording of data in real-time much supports him in developing healthier habits. Regular monitoring of the blood glucose levels helped Bogdan to act immediately and to have the situation under control. By providing services such as reminders, health monitoring and cognitive stimulation, Bogdan feels assisted in carrying out activities towards which he felt anxious, such as travelling. The platform also notifies him to consider medication side-effects and alerts to significant other clinical experts were set. Now he has a greater control over his life by the use of wearables and smart devices.

After six months of using SMART BEAR Platform, Bogdan few major changes occurred. Aside the healthier lifestyle and controlled dietary intakes, his psychological state also changed. He no longer felt anxious or insecure.

Table 18 Use Case: Abnormal blood glucose level

<table>
<thead>
<tr>
<th>Use Case:</th>
<th>Abnormal blood glucose level</th>
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<tbody>
<tr>
<td>Created By:</td>
<td>ANA</td>
</tr>
<tr>
<td>Date Created:</td>
<td>20/11/2019</td>
</tr>
</tbody>
</table>
### Description:
Abnormal blood glucose levels can be caused by unhealthy lifestyle habits, chronic stress exposure and metabolic disorders. Dietary changes, psychological factors and a more active lifestyle very much support a normalization of blood glucose levels.

Usage of SMART BEAR Platform can be of great benefit for those who manifest abnormal BG. A first onsite assessment session is necessary to set goals and explain the features of the platform both to the user and to the close ones. Once having SMART BEAR @ Home installed, users will be receiving notifications and recommendations over the day based on the set goals.

### Actors:
- SMART BEAR Platform User
- Clinician

### Preconditions:
- Smartwatch, Smartphone, Personal glucometer

### Trigger:
Patient who needs improvement of blood glucose level and dietary changes

### Flow:
1. I (user) have Smart Bear app, smartwatch and smartphone.
2. Every morning, I receive a notification that reminds me of my daily activities’ tasks and suggests few meal plans for the day.
3. When I am ready, I activate the program I selected, through the relevant application.
4. I choose which task I want to do today and what meal plan to follow, always considering its benefit to my health.
5. Twice per week I check my post-prandial blood glucose level (2hrs after lunch) on my glucometer.
6. If the blood glucose levels are high for four weeks, I may contact the case manager subject to the existence of such a manager and according to ICF via a call or ask for an appointment.
7. During the day, my physical activity is recorded since I always carry my smartphone.
8. At the end of the day, I am aware of how many steps and km I have walked, and I can have an overall view on my latest activity.
9. Comparing my physical activity scores to other users’ help me staying motivated.

### Alternative Flows:
A wearable (bracelet) could be also chosen as physical activity tracker

### Exceptions:

### Postconditions:

### Requirements:
Either a first onsite clinical assessment or a family decision for setting goals
4.2.6.4 Physical Inactivity

Bob is a 70-year-old man from Italy who worked as a bricklayer for 45 years. Since Bob’s wife died of cancer 19 years ago, Bob and his daughter Eve are the only people at home. Eve is a lawyer and she is totally dedicated to her job. She is used to leave the house very early in the morning and get home very late in the evening. Bob is very proud of his daughter: she is the most valuable thing in his life. Bob is used to take care of himself, his family and the house, as well. He enjoys outdoor activities (doing the grocery shopping, walking, biking, hiking) since he is a very dynamic and sportsperson.

Five months ago, Bob has begun to experience weakness and loss of stamina which have interfered with his regular physical activity that resulted to be drastically reduced. In order to avoid any kind of concern in his daughter Eve, Bob decides to visit his referring physician. After a clinical examination, the sarcopenia is diagnosed. Sarcopenia is an age-related geriatric syndrome characterized by a progressive loss of muscle mass, strength and function. Sarcopenia is also closely correlated with chronic heart failure (CHF) that is the final stage of various cardiovascular diseases. A combination of physical exercise and pharmacological therapy is therefore prescribed by the physician in order to counter the development of Bob’s medical condition. In that regard, setting the SMART BEAR Platform at Bob’s house for a year is proposed. The suggested platform will give the opportunity to monitor the physical activity performed, to provide a personalized training program to promote physical activity, and to give real-time notifications and alerts in case of risky conditions (e.g. noncompliance to the training program and/or excessive physical inactivity). Finally, Bob will receive a reward when he achieves his goals as they are specified by his referring physician/physiotherapist (e.g. number of steps).

Bob agreed to install devices at home, wear sensors and to use a mobile phone with a dedicated mobile application in a daily basis. Every morning, at a specific time, a buzzer sounds to notify that it is time to train. Bob can choose among outdoor or indoor exercises. In case of indoor activities, after checking for security measures (object-free space, proper mounting of equipment) the training program starts; this includes personalized exercises with weight or resistance bands for increasing muscle strength and customized activities with a high balance need for enhancing the coordination of body segments. Such exercises are gamified and provided with progressive difficulty in a mixed reality environment. In case of outdoor activities, instead, the training program includes tailored aerobic exercises able to ameliorate mitochondria-derived problems due to the sarcopenia. Such exercises are gamified and provided with progressive difficulty in a real-life environment. After the training program, Bob does his routinely activities (e.g. shopping in the supermarket) with his mobile phone which constantly records the steps performed. At the end of the day, he wins a reward since his goal of 10,000 steps per day is achieved: Bob is motivated and encouraged in pursuing his training plan. Several weeks pass and Bob unfortunately begins to feel weaker. He is no longer able to reach his goals, so he decides to skip his daily training sessions. One day, Bob receives a message notifying a scarce daily physical activity in the last period. In the meantime, an email is sent to Eve who also gets alerted about the inactivity of her father. In the evening, Eve understands Bob’s malaise and she encourages him to visit the clinician the day after maybe something is changed, and the training program is not adequate anymore.

One year later, Bob goes back to his clinician for the assessment. He feels well, more stable and more strengthened in most of his daily activities. However, in some circumstances he continues to feel unsteady and exhausted and as he wants to maintain a good self-sufficiency and quality of life, he decides, after clinician recommendation, to continue using the SMART BEAR Platform.
Table 19 Use Case: Physical inactivity

<table>
<thead>
<tr>
<th>Use Case:</th>
<th>Physical inactivity</th>
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<tr>
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<td>15/11/2019</td>
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<tr>
<td>Last Revision Date:</td>
<td>17/12/2019</td>
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</table>

**Description:**
One of the potential effects of frailty is sarcopenia, the degenerative loss of skeletal muscle strength that could undermine someone’s ability to maintain the balance. A direct consequence can be a dangerous increase of falls, which are life-threatening and potentially a cause of chronic impairments.

Daily physical activity can be extremely helpful to maintain a good health status, to prevent falls and age-related morbidities.

An application (Smartphone app or virtual reality system) would allow the user to exercise daily by playing serious games. Different games could be selected by the user in order to keep the application interesting and a rewarding mechanism could be incorporated to motivate adherence to a plan. The training plan is set by the referring physician (or the physiotherapist) depending on the user’s health status, fitness condition and other relevant factors.

At each follow-up visit, the referring physician monitors the user’s progress and his/her adherence to the training plan, adjusting it to ensure its easiness and usefulness.

**Actors:**
Frail user
Caregivers
Physiotherapist / referring physician

**Preconditions:**
Diagnosed frailty, virtual reality training system and Smartphone or smartwatch.

**Trigger:**
Fall detection and patient who needs a follow-up visit for general health status.

**Flow:**
1. I (user) have Smart Bear virtual reality training system and Smartphone
2. Periodically, I receive a notification about which activities are scheduled for the day: a certain number of minutes of walking or an exercise with the physical activity training system
3. SMART BEAR Platform keeps track of my progression and my adherence to the training program
4. SMART BEAR Platform detects scarce adherence to the training program
5. SMART BEAR Platform alerts me
6. I notice the alert (e.g. buzz, sound or visual alert from the Smart Bear platform)
7. I can visualize the relevant information (e.g. compliance parameters, the possible solution)
10. The app rewards me with a badge when I complete the activity
11. If adherence to the program is not respected for days in a row, the system alerts the caregivers with an email
5. If alerts are off, skip the step 6 and 7
6. Users can decide to postpone and/or to disable alerts.

Exceptions:
Postconditions: Improved care of the frail user, better fitness level
Requirements: Fitness condition assessment; initial plan of physical training and adjustments at follow-up visits.

4.2.6.5 Weight Loss/Gains

Pier is 67-year-old man from Italy who still works as an architect. He lives with his wife, Camilla, a retired legal secretary. They have a son, Robert, who lives abroad and, as soon as Pier is free from his work commitments, they join their beloved son in Paris. Pier spends his days between family and work although he enjoys social life and physical activity as well. He is in fact used to play tennis with his friends or his colleagues twice a month, at least. Furthermore, Pier loves to surprise his wife with some dinners out or events such as concerts of some of her favourite musicians.

Last year, as a result of a routine examination, Pier discovers to have a metabolic disorder and his referring clinician recommends monitoring the thyroid hormone functionality prescribing some laboratory tests. Several days passed and Pier begins to experience nervousness, irritability, anxiety, racing heart, increased sweating, difficulty sleeping and weakness in the muscles especially in the upper arms and thighs. In addition, he is gradually losing weight despite a good appetite. Pier and Camilla decide to go back to the clinician, who diagnoses the hyperthyroidism thanks to the results of the laboratory tests. The clinician prescribes a pharmacological treatment, but he is worried about the excessive weight loss of his patient. For that reason, he proposes to set the SMART BEAR Platform at Pier’s house for a year. The recommended platform will give the opportunity to keep track of weight and medications, to give real-time notifications and alerts in case of risky conditions (e.g. excessive weight loss, noncompliance with the medication), and to provide suggestions of food programs based on the medical history (e.g. avoiding food with a great iodine content since they are harmful for who suffer from hyperthyroidism). Finally, Pier will receive a reward when his goals as they are specified by his referring physician/dietician (e.g. compliance to medications and steady weight) are achieved.

Pier agreed to install the devices at home (e.g. smart pillbox and smart scale) and to use a mobile phone with dedicated mobile applications. It is morning and, as usual, Pier wakes up, weighs himself and has breakfast while Camilla is preparing the meal for his lunch break based on the food program suggested by the SMART BEAR Platform: now Pier is ready to go to the office. When evening falls, Pier leaves the office and goes to the tennis court for a match with a friend. Finally, he goes home, and he has dinner with Camilla. After dinner, Camilla checks her husband’s adherence to pharmacological therapy, and she scolds Pier since he has missed to take a pill. They decide to set the adherence mobile application pill reminders (i.e. taking pills in compliance with medications). Pier becomes more involved and the following two weeks; he wins his first reward: he has been compliant to the medication for 10 consecutive days and his first goal has been reached. After three months, Pier receives a message notifying that the weight loss in the last month is considerably greater than in the previous two months. Pier does not understand the reason since he has eaten and continues to eat as usual. In agreement with his wife, therefore, Pier decides to share the notification with the clinician in order to alert him. The clinician schedules an appointment for the next week to evaluate if a modification and/or a custom tailoring to the therapy is needed.

A year later, Pier and Camilla visit the clinician for the follow-up. During the visit, the clinician examines the results of new laboratory tests and Pier’s tracking of weight and medication provided by the SMART BEAR
Platform. The TSH (Thyroid Stimulating Hormone) levels are in a physiological range and the excessive weight loss is held. Although symptoms such as racing heart, increased sweating, difficulty sleeping and weakness in the upper arms still exist, Pier would like to continue using SMART BEAR Platform. The possibility to monitor his weight and medication and to share such information with his referring clinician in case of adverse conditions make Pier and Camilla more confident. Lastly, the clinician highlights the importance of monitoring personalized intervention plans that are able to maximize the benefit for the patient.

Table 20 Use Case: Weight Loss/Gain

<table>
<thead>
<tr>
<th>Use Case:</th>
<th>Weight Loss/Gain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Created By:</td>
<td>FCSR</td>
</tr>
<tr>
<td>Last Updated By:</td>
<td>FCSR</td>
</tr>
<tr>
<td>Date Created:</td>
<td>18/11/2019</td>
</tr>
<tr>
<td>Last Revision Date:</td>
<td>17/12/2019</td>
</tr>
<tr>
<td>Description:</td>
<td>Weight loss and gain among elderly is often overlooked. It is, however, important to pay attention to unintentional weight changes in older adults since they could be due to inadequate food intake, as well as a wide range of other contributing factors that may indicate an underlying health (e.g. gastrointestinal, endocrine disorders, cancer), behavioural (e.g. loneliness, isolation and inaccessibility) or emotional (e.g. anxiety and depression) issue. Moreover, the overweight represents a risk factor of different pathologies prevalent among elderly, as cardiovascular disease for instance. Users of SMART BEAR Platform could benefit of continuous monitoring of their own weight and suggestions of meal plans with food that are good for their medical condition. The SMART BEAR Platform will get users aware of the weight trend over time and will alert the users, the caregivers and the clinicians in case of alarming weight loss or gain. In addition, the rewarding system provided by the Platform every time a goal, as specified by the clinician, is reached, encourage and motivate users to healthy ageing.</td>
</tr>
<tr>
<td>Actors:</td>
<td>SMART BEAR Platform User</td>
</tr>
<tr>
<td></td>
<td>Caregivers</td>
</tr>
<tr>
<td></td>
<td>Clinicians</td>
</tr>
<tr>
<td>Preconditions:</td>
<td>Home devices, smartphone</td>
</tr>
<tr>
<td>Trigger:</td>
<td>Patients who need to keep track of their weight (e.g. elderly suffering from unintentional weight loss/gain and elderly with heart failure)</td>
</tr>
<tr>
<td>Flow:</td>
<td>1. Periodically, the platform sends me a notification reminding me to weigh myself on a smart weight-scale</td>
</tr>
<tr>
<td></td>
<td>2. Data concerning my weight are automatically logged on the platform</td>
</tr>
<tr>
<td></td>
<td>3. My weight is visible for me on my Smartphone</td>
</tr>
<tr>
<td></td>
<td>4. In case my weight measurement deviates significantly from the normal limits according to my profile, a notification reaches my phone.</td>
</tr>
</tbody>
</table>
5. If weight is further lower / higher, an alert is sent to the case manager and/or informal/formal caregiver
6. Data are also available for the case manager subject to the existence of such a manager and according to ICF.

Alternative Flows:
5. If alerts are off, skip the step 5 and 6
6. Users can decide to postpone and/or to disable alerts
7. If users do not perform any action, the platform keeps track of time range the users are not within the compliance parameters

Exceptions: -

Postconditions: Visualization of daily/monthly statistics for users and clinicians.
Enhanced awareness about their own weight and the quality of the food to eat.
Augmented safety perceived.

Requirements: First onsite clinical assessment - setting goals
Follow-up visits - setting adjustments

4.2.7 CVDs

4.2.7.1 Hypertension

Dora is a 69-year-old woman, a retired teacher from France. She lives on her own as her partner passed away. She is hypertensive and has had a stroke two years ago which was related with poor blood pressure control. Fortunately, following six months on a rehabilitation program, her mobility is intact, but she experiences memory problems. In fact, during her last visit in the Cardiology clinic, she was unable to recall whether she was taking her medications on a daily basis or not. She was found to have high blood pressure recordings and she was advised that the optimal blood pressure control would delay the progression of the mild dementia she had at that time. She felt upset with herself, being unable to promise that she would follow the advice as her memory was not helping her with the tablets.

Our clinicians realized that Dora, despite the fact that she was able to look after herself in everyday life aspects, she needed help regarding her blood pressure control. Another stroke as a consequence of suboptimal treatment would be detrimental. Additionally, she was obviously depressed. She refused to have any help from the social services.

She was advised to set the SMART BEAR Platform at her house for a year. This would allow her to monitor the blood pressure levels and also, a smart pillbox would notify her to take her tablets regularly.

Dora agreed to have the SMART BEAR Platform installed in her house. In detail, she had a blood pressure recorder, a smartwatch for movement detection, a smart pillbox and a mobile phone.

Three months later, she came back for a regular clinic review. Both herself and the doctor were pleased with the blood pressure recordings. She admitted that the pill-pox application has given her great convenience. Her self-esteem was much improved, and this was reflected in social life. She offers volunteer work as a teacher in poor children and she will continue to use the platform.
**Table 21 Use Case: Hypertension**

<table>
<thead>
<tr>
<th>Use Case:</th>
<th>Hypertension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Created By:</td>
<td>NKUA</td>
</tr>
<tr>
<td>Last Updated By:</td>
<td>NKUA</td>
</tr>
<tr>
<td>Date Created:</td>
<td>17/11/2019</td>
</tr>
<tr>
<td>Last Revision Date:</td>
<td>17/12/2019</td>
</tr>
<tr>
<td>Description:</td>
<td>Elderly hypertensive patients often suffer from comorbidities like dementia and/or depression. Compliance to medication remains a difficult task on this setting. Users of SMART BEAR Platform will benefit of blood pressure monitoring and will be notified to receive their treatment. A first onsite assessment session is necessary to set goals and explain the features of the platform. Once having SMART BEAR @ Home installed.</td>
</tr>
<tr>
<td>Actors:</td>
<td>SMART BEAR Platform User Clinician</td>
</tr>
<tr>
<td>Preconditions:</td>
<td>Smart pillbox, blood – pressure recorder, Smartphone</td>
</tr>
<tr>
<td>Trigger:</td>
<td>Patient who needs improvement of blood pressure control, reminder to take medications</td>
</tr>
</tbody>
</table>
| Flow:            | 1. Periodically, the Platform reminds me to check my blood pressure levels. This is happening via a visual notification on my Smartphone, which goes off as soon as three valid blood pressure recordings are obtained.  
• If my blood pressure levels are: 
  • > 140 / 90 mmHg, I get advised by the platform/app to repeat the measurement and if this persists, I get notified to take omitted medications. 
  • ≥ 180/110 mmHg, I get advice to repeat the measurement and if this persists, I get notified to take omitted medications. Red code activation. (see Table 1). In this case I will be alerted to seek medical advice. I have to respond to the alert answering acknowledged or not in the SMART BEAR mobile interface. 
  • SBP < 100mmHg, I get advice to repeat the measurement and if this persists, Red code activation. (see Table 1) In this case I will be alerted to seek medical advice. I have to respond to the alert answering acknowledged or not in the SMART BEAR mobile interface. 
  • If my periodic average BP recordings are >140/90 mmHg or < 120/70 mmHg I get advice to visit/call my doctor - Yellow code (see table 1) In this case, the app will notify me to arrange call/visit to my case manager.  
2. I get notifications to receive my tablets from a smart pillbox.  
  • If I miss a dose, the corresponding cell in the smart pillbox remains activated with a visual and sound alarm. I can either deactivate it by switching it off, as I don’t wish/need to take the tablet. The omitting medication record will be stored and available to me/case manager when needed. |
3. I receive notifications about the temperature on a periodic basis, or extra ones, if a heatwave happens, so I can titrate the receiving medication as previously advised by my doctor.

4. During blood pressure recording if the resting heart rate exceeds the threshold value set for the specific patient (i.e. > 110 bpm) or arrhythmia is detected, the Platform sends an alert to the case manager subject to the existence of such a manager and acceptance to receive such a notification and ICF. I get 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. In such case, I have to respond to the alert if acknowledged or not in the SMART BEAR mobile interface.

5. My smartwatch keeps track of my heart rate. In case of arrhythmia detection, I get notification of arrhythmia. The same notification is sent to the case manager and/or informal/formal caregivers based on the patient’s profile. In such case, I have to respond to the alert if acknowledged or not in the SMART BEAR app.

6. I use the Smartwatch to record my daily physical activity.
   - I receive congratulation notification when I reach the goals of weekly exercise as set during the recruitment phase.
   - I receive encouraging notifications to increase my regular exercise when goals are not met.

**Postconditions:**
Better compliance with hypertension treatment. Augmented self-esteem. The optimal blood pressure control and the reduced rate of complications related to treatment encourage me to keep myself active

**Requirements:**
First onsite clinical assessment – setting goals
Follow up visits - making appropriate adjustments

### 4.2.7.2 Heart failure with reduced ejection fraction of left ventricle

Paul is a 69-year-old man, who suffered an anterior myocardial infarction at the age of 54. He had bypass surgery. However, his heart function did not improve significantly, and he has developed the clinical syndrome of heart failure with reduced ejection fraction of left ventricle (HFrEF). He receives optimal medical treatment and has had implanted cardioverter defibrillator to protect him from sudden cardiac death.

He lives with his son as his wife died from cancer. His functional status is significantly impaired as he can walk only short distances due to breathlessness. During the last consultation in the heart failure clinic, he was found to be in deteriorated status, edematous, and breathless. He was subsequently admitted to the hospital for intravenous treatment. Over the last three months this deterioration has been gradual, and he admits that he is not able to cope with it. He was advised to monitor his body weight and increase the dosage of diuretics when he gains weight. He was obviously depressed, and not keen on being hospitalized again. On the other hand, he was experienced side effects like hypotension when he was taking more diuretics than needed. Consequently, he was not able to titrate the dosage correctly.

He was advised to set the SMART BEAR Platform at his house for a year. This would allow him to monitor the **blood pressure levels** and also, a **smart scales system** to monitor his body weight. He agreed that the information collected would be sent to his MD on a weekly basis. An over the phone consultation based on
his symptoms and the monitored parameters would allow a closer monitoring with no need for clinic review.
Three months later, he was interviewed regarding his experience with the Platform. He was pleased to realize that close monitoring of his body weight and subsequent alterations in his medications kept him out of the hospital for so long.

Table 22 Use Case: Heart failure with reduced ejection fraction of left ventricle

<table>
<thead>
<tr>
<th>Use Case:</th>
<th>Heart failure with reduced ejection fraction of left ventricle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Created By:</td>
<td>NKUA</td>
</tr>
<tr>
<td>Last Updated By:</td>
<td>NKUA</td>
</tr>
<tr>
<td>Date Created:</td>
<td>17/11/2019</td>
</tr>
<tr>
<td>Last Revision Date:</td>
<td>17/12/2019</td>
</tr>
<tr>
<td>Description:</td>
<td>Elderly patients with heart failure often find difficulties with self-monitoring. Compliance to medication remains a difficult task on this setting. Users of SMART BEAR Platform will benefit of blood pressure and body weight monitoring. A first onsite assessment session is necessary to set goals and explain the features of the platform.</td>
</tr>
<tr>
<td>Actors:</td>
<td>SMART BEAR Platform User</td>
</tr>
<tr>
<td></td>
<td>Clinician</td>
</tr>
<tr>
<td>Preconditions:</td>
<td>Smart scales system, blood pressure recorder, Smartphone</td>
</tr>
<tr>
<td>Trigger:</td>
<td>Patient who needs improvement of heart failure treatment</td>
</tr>
</tbody>
</table>
| Flow: | 1. Periodically, the platform reminds me to check my blood pressure levels  
   - If my blood pressure levels are:
     - <90/60 mmHg I get advice by the platform to repeat the measurement.  
     - I use these results to guide my treatment, as previously advised.  
     - If my weekly average BP recordings are < 90/65 mmHg the Platform sends an alert to the case manager subject to the existence of such a manager and acceptance to receive such a notification and ICF. I get an alert to seek medical advice. The same notification is sent to the case manager and/or informal/formal caregivers based on the patient’s profile. In this case I will be alerted to seek medical advice. I have to respond to the alert answering acknowledged or not in the SMART BEAR mobile interface.  
   2. During blood pressure recording a high resting heart rate > 110 bpm or arrhythmia is detected, 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. I get 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. In this case I will be alerted to seek medical advice. |
3. I receive notifications about the weather temperature on a periodically basis, or extra ones, if a heatwave happens, so I can titrate the receiving medication as previously advised.

4. Periodically I receive notification to weight myself.
   - In case my weight increases more than 2 kg per week, I get notified. If previously advised, I increase the diuretic dosage. I get notification to follow the fluid input restrictions as set during first visit. Diet app reminds me salt restriction.
   - In case my weight decreases more than 2 kg per week, I get notified. If previously advised, I decrease the diuretic dosage.
   - In case my weight has been unstable over the period of one month, 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. I get 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.

5. My smartwatch keeps track of my heart rate. In case of arrhythmia detection or fast heart rate (limits set at first visit) lasting > 1 min, the Platform sends an alert to the case manager subject to the existence of such a manager and acceptance to receive such a notification and ICF. I get 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. In this case I will be alerted to seek medical advice. I have to respond to the alert answering acknowledged or not in the SMART BEAR mobile interface.

6. I use the smartphone to record my daily physical activity.
   - I receive congratulations when I reach the goals of weekly exercise as set during the first visit.
   - I receive encouraging notifications to increase my regular exercise when goals are not met. The Platform asks me if there are symptoms which restrict mobility. If I answer yes, I get alert to seek medical advice.

7. In case I will get admitted to the hospital I will add this information in my diary.


Requirements: First onsite clinical assessment – setting goals
Follow up visits - making appropriate adjustments
See Table 1 and UC 5.1

4.2.7.3 Heart Failure with preserved ejection fraction

Janis is a 72-year-old woman, who lives with her husband in Spain. She is diabetic and has had hypertension for the last 39 years, not adequately treated. She is overweight and has been hospitalized twice during the last 12 months with symptoms of heart failure.
Subsequently, her treatment has changed according to the diagnosis of hypertensive heart disease – heart failure with preserved ejection fraction. She was advised to lose weight, which she finds extremely difficult. Moreover, her doctor strongly recommended to join a rehabilitation program on the local gym for exercise however she did not like the idea. She feels breathless on exertion. Subsequent blood pressure readings during her last consultation in the clinic confirmed poor blood pressure control which triggers her symptoms.

She was advised to set the SMART BEAR Platform at her house for a year. She would be using a blood pressure recorder to monitor her blood pressure levels, a smart pillbox would notify her to take her tablets regularly and a device to monitor her daily activity.

She agreed to have the SMART BEAR Platform installed in her house. In detail, she had a blood pressure recorder, a smartwatch for movement detection, a smart scales device, a smart pillbox and a mobile phone. Three months later, she came back for a regular clinic review. Both herself and the doctor were pleased with the blood pressure recordings. She admitted that the pill-pox application has given her great convenience. Her daily activity had been gradually improved after the second month that she was using the platform. Her self-esteem was much improved, and this was reflected in social life.

<table>
<thead>
<tr>
<th>Use Case:</th>
<th>Heart Failure with preserved ejection fraction</th>
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</thead>
<tbody>
<tr>
<td>Created By:</td>
<td>NKUA</td>
</tr>
<tr>
<td>Date Created:</td>
<td>24/11/2019</td>
</tr>
<tr>
<td>Description:</td>
<td>Heart failure with preserved ejection fraction affects a significant part of the elderly population. Poorly controlled hypertension is the commonest scenario on this setting. Usually, patients at this stage face difficulties with medication compliance. Users of SMART BEAR Platform will benefit of blood pressure monitoring and will be notified to receive their treatment. A first onsite assessment session is necessary to set goals and explain the features of the platform.</td>
</tr>
<tr>
<td>Actors:</td>
<td>SMART BEAR Platform User Clinician</td>
</tr>
<tr>
<td>Preconditions:</td>
<td>Smart pillbox, blood – pressure recorder, Smartphone</td>
</tr>
<tr>
<td>Trigger:</td>
<td>Patient who needs improvement of blood pressure control, reminder to take medications</td>
</tr>
<tr>
<td>Flow:</td>
<td>Better compliance to heart failure treatment. Augmented self-esteem. Adequate blood pressure control and enhancement of physical activity will reduce the episodes of acute decompensation of heart failure.</td>
</tr>
<tr>
<td>Requirements:</td>
<td>First onsite clinical assessment – setting goals Follow up visits - making appropriate adjustments See 5.1 and Table 1</td>
</tr>
</tbody>
</table>
4.2.7.4 Hypertension treatment – paroxysmal arrhythmias - complications

George is a 74-year-old man from Greece, quite active on his everyday life. He is helping his family grocery and looks after his wife who has impaired vision. He is hypertensive and suffers from paroxysmal atrial fibrillation. Over the last four months he has had several episodes of syncope. All these events happened while he was walking.

Following the first episode, he was admitted to a General Hospital and he was diagnosed with sick sinus syndrome. Subsequently, a permanent pacemaker was implanted. He was on regular treatment with Olmesartan-hydrochlorothiazide for hypertension and dabigatran for stroke prophylaxis.

George was reviewed again in the Cardiology clinic for a pacemaker check. During the last visit, he was found to have profound postural hypotension plus several episodes of atrial flutter with high ventricular rate. After interrogation our clinicians realized that both these conditions were responsible for the syncopal attacks. When his heart rate was too high, his blood pressure was dropping, and he was feeling dizzy. This was related with hot weather too. He was advised to discontinue the antihypertensive medications temporarily. Additionally, they suggested to set the SMART BEAR Platform at his house for a year. This would allow him to monitor his blood pressure levels and use antihypertensive medications as needed. On the other hand, the heart rate monitoring would give real-time notifications when his heart rate exceeded the level that usually his blood pressure drops. This information would enable him to avoid a significant injury from falling by lying / sitting down. Finally, information about the temperature would remind him that in a colder period his blood pressure levels usually require treatment whereas during the hot months of the year he should rather avoid the medications.

George agreed to have the SMART BEAR Platform installed in his house. In detail, he had temperature sensors, a blood pressure recorder, a smartwatch for heart rate monitoring and a mobile phone.

Some months later, he was taking his antihypertensive medications when needed and the blood pressure recordings showed optimal control. Moreover, he was notified several times for the presence of high heart rate. He responded on those by resting on a chair. There were no more syncopal attacks mentioned. His self-esteem and confidence were significantly improved as he was no longer afraid of a potential sudden attack. He was happy to remain able to help his wife and his family on the grocery. As a result, he wishes to continue using the platform.

<table>
<thead>
<tr>
<th>Use Case:</th>
<th>Hypertension treatment – paroxysmal arrhythmias - complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Created By:</td>
<td>NKUA</td>
</tr>
<tr>
<td>Date Created:</td>
<td>10/11/2019</td>
</tr>
<tr>
<td>Description:</td>
<td>Elderly people on antihypertensive medications often experience hypotension which may be related with over-treatment, dehydration, hot weather or other conditions like arrhythmias. Users of SMART BEAR Platform in selected people with blood pressure variability and paroxysmal tachycardia causing hemodynamic instability will benefit of continuous monitoring of heart rate. Additionally, regular recording of blood pressure. A first onsite assessment session is necessary to set goals and explain the features of the platform. Once having SMART BEAR @ Home installed, users will be receiving notifications for caution every time it is needed (e.g. hot weather, high heart rate).</td>
</tr>
</tbody>
</table>
**Actors:**

<table>
<thead>
<tr>
<th>SMART BEAR Platform User</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician</td>
</tr>
</tbody>
</table>

**Preconditions:**

Home devices, wearable sensors, Smartphone

**Trigger:**

Patient who needs improvement of blood pressure control, notifications for paroxysmal tachycardia

**Flow:**

1. Periodically, the platform reminds (notifications) me to check my blood pressure levels.
   - If my blood pressure levels are:
     - $> 140 / 90$ mmHg, I get notified by the Platform to repeat the measurement. If the same result persists, I get notification to check for omitted medications.
     - $\geq 180/110$ mmHg, I get advice to repeat the measurement and if this persists, 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. I get an alert to seek medical advice. The same notification is sent to the case manager and/or informal/formal caregivers based on the patient’s profile. In this case I will be alerted to seek medical advice. I have to respond to the alert answering acknowledged or not in the SMART BEAR mobile interface.
     - SBP $< 110$mmHg, I get advice to repeat the measurement and if this persists, 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. I get an alert to seek medical advice. The same notification is sent to the case manager and/or informal/formal caregivers based on the patient’s profile. In this case I will be alerted to seek medical advice. I have to respond to the alert answering acknowledged or not in the SMART BEAR mobile interface.
     - If my weekly average BP recordings are $>160/90$ mmHg or $< 120/70$ mmHg, the Platform sends a notification to the case manager subject to the existence of such a manager and acceptance to receive such an alert and ICF. I get an alert to seek medical advice. The same notification is sent to the case manager and/or informal/formal caregivers based on the patient’s profile.

2. I receive notifications about the ambient (outdoor) temperature on periodically basis, or extra ones, if a heatwave happens, so I can titrate the receiving medication as previously advised by my doctor.

3. I wear a smartwatch which notifies me via vibration, about high heart rate episodes (limit of HR set at first visit). I respond by resting down to avoid any significant injury from falling.

4. I use the smartwatch to record my daily physical activity.
   - I receive congratulation notifications when I reach the goals of weekly exercise as set at first visit.
I receive encouraging notifications to increase my regular exercise when goals are not met. The Platform asks me if there are symptoms which restrict mobility. If I answer yes, I get alert to visit my doctor.

5. In case I will get admitted to the hospital I will add this information in my diary.

Postconditions: Better compliance with hypertension treatment. Awareness about paroxysms of tachycardia and the subsequent risk of falling. Augmented self-esteem. The optimal blood pressure control and the reduced rate of complications related to treatment encourages me to keep myself active.

Requirements: First onsite clinical assessment – setting goals
Follow up visits - making appropriate adjustments

4.2.7.5 Arrhythmia & Coronary heart disease

Manuela is 78 years old and lives in Madrid with her husband on a ground floor apartment that they bought some years ago. Manuela is moderately overweight; she has been hypertensive for more than 30 years and her blood pressure control has been suboptimal due to poor compliance with the medication and the advice for a healthier lifestyle. She has been a smoker for more than 30 years. She finally quit smoking after she suffered from an acute coronary syndrome five months ago. During this admission, she was diagnosed with atrial fibrillation too.

Over the last few months, it is becoming more difficult for her to leave her home and her mobility and autonomy gradually decline due to the lack of activity. Her daily activity is restricted to visits to the health centre, daily errands and the walk she takes with her husband some afternoons, which are getting shorter, as she feels fatigued and discouraged. In addition, it is increasingly difficult for her to remember the medication she should take. It has been relatively common for her to skip several dosages, which has led to episodes of dyspnea caused by hypertension peaks and tachycardia.

Given this situation, her husband and daughter decided to visit her family doctor and explain the situation. Manuela’s primary care physician told them that a cardiologist, his friend, who works at a Quironsalud Hospital is recruiting patients for a study with wearables. Those target on monitoring patients over 65 years old. After consultation with the cardiologist, Manuela gave her consent to participate in the study and the cardiologist assigned a follow-up plan for a year consisting of:

Initial visit: Manuela had her medical history taken by the clinician. He checked her weight, her blood glucose levels, her cholesterol levels. She had an ECG in the initial visit which confirmed a sinus rhythm and an echocardiogram which showed the scar of the past myocardial infarction. However, the systolic function of the left ventricle was preserved, and the function of the right heart was normal. There were no clinical signs of heart failure present at time and her blood pressure levels were abnormal.

12 months: She would be checking her blood pressure levels and heart rate every morning and evening for 12 months and, also:

- She would be using a smart pill box device to avoid forgetting her medication.
- Her mobility will be monitored via a smartwatch. Her target will be to walk a certain distance as set at first visit.

She would be receiving notifications via Smart Bear platform using a Smartphone.

6-month interim visit: An optional 6-month visit will be held, in which she would be offered clinical examination. The reliability of wearable measurements will be tested.
12 month / end of the follow-up period visit: She would be offered clinical examination in which she will be weighed and data from an optional blood and glucose test will be entered by the case manager or specialist in the patient’s e-record. The reliability of wearable measurements will be tested.

All data related to the monitoring of Manuela are collected on the electronic history platform of the Hospital (CASIOPEA), which is connected to the Quirónsalud Group patient portal, which is the direct contact platform between Manuela and the clinical staff that participate in this project. Through the Manuela’s patient portal, she can consult the clinical staff in real-time and receive daily activity notifications and warnings of possible risk events (arrhythmias, stress peaks ...).

During the follow-up period the intervention criteria are as follows:

- **Blood pressure less than or equal to 140/90 mmHg / resting heart rate less than 90 bpm.** Passive interaction with the patient through a series of periodic recommendations aimed at health care.

- **Blood pressure 141-179 / 90-119 mmHg / Resting heart rate between 90-99 bpm.** Active interaction with the patient. The patient gets an alert to repeat the measurement and if this persists, 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. The case manager of the study contacts the patient and asks if the measurement has been made at rest, how she is doing, if she has taken the medication, etc. The patient is asked to repeat the measurements and, depending on the result, the patient is given the appropriate indications. The patient gets an alert to seek medical advice in case no case manager subject exists in the case. The same notification is sent to the case manager and/or informal/formal caregivers based on the patient’s profile.

- **Blood pressure greater than or equal to 180/120 mmHg / resting heart rate greater than 100 bpm.** The patient gets an alert to repeat the measurement and if this persists, 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. The case manager of the study contacts the patient and asks if the measurement has been made at rest, how she is doing, if she has taken the medication, etc. The patient is asked to repeat the measurements and, in case no error is detected in the measurements, the cardiologist will contact directly with the patient to give the appropriate indications. The patient gets an alert to seek medical advice in case no case manager subject exists in the case. The same notification is sent to the case manager and/or informal/formal caregivers based on the patient’s profile. In the 12-month visit, it is observed that the clinical parameters of Manuela remain at optimal values. During the follow-up period no serious adverse effects were detected, except for a couple of alerts due to measurements not performed at rest. During these months the physical state of Manuela has improved, and she is more agile and less fatigued, thanks to the daily activity program and to her weight reduction to optimal values, following the prescribed diet and the recommendations received periodically oriented to the care of her health. Her mood has also improved considerably. Neither adverse effects have been detected as a result of delays in taking the medication.

### Table 25 Use Case: Arrhythmia & Coronary heart disease

<table>
<thead>
<tr>
<th>Use Case:</th>
<th><strong>Arrhythmia &amp; Coronary heart disease</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Created By:</td>
<td>Quironsalud</td>
</tr>
<tr>
<td>Last Updated By:</td>
<td>NKUA</td>
</tr>
<tr>
<td>Date Created:</td>
<td>28/11/2019</td>
</tr>
<tr>
<td>Last Revision Date:</td>
<td>17/12/2019</td>
</tr>
<tr>
<td>Description:</td>
<td>Cardiovascular diseases are, together with oncological pathology, the main cause of mortality in our environment, which is accentuated as the population ages. Usually,</td>
</tr>
</tbody>
</table>
the symptomatology depends on the affected organ but sometimes it is a silent disease:

- Stroke or cerebrovascular accident: they cause approximately one third of deaths from circulatory diseases, but a high percentage of people who survive after a stroke have serious physical and neurological sequels for the rest of their lives.
- Heart failure and heart attacks: hypertension and excessive salt consumption have direct adverse effects on the heart muscle, favouring diseases such as heart attacks or heart failure.
- Renal impairment: causes loss of renal function.
- Loss of vision due to lesion of the blood vessels of the retina (retinopathy).

Therefore, one of its greatest dangers of this type of disease is that it is a silent evil and sometimes they are insufficiently or inadequately treated. Strategies aimed at improving blood pressure control along with avoiding therapeutic non-compliance entails a very important improvement in patient safety along with a significant reduction in health expenditure in two aspects:

- On the one hand, if the prescribed medications are taken correctly, the antihypertensive effectiveness of the strategy increases, which means that fewer drugs are required.
- On the other hand, the greater reduction in blood pressure figures inexorably leads to better control of hypertension, which means less morbidity.

For this reason, the correct taking of the medication by the patients together with the frequent monitoring of the tension and the heart rate are keys to improve the prognosis of patients with cardiovascular diseases.

---

**Actors:**
- SMART BEAR Platform User
- Clinician
- Case manager (optional)

**Preconditions:**
- Blood pressure monitor, heart rate monitor, smart pill box, smartwatch, Smartphone, cholesterol and glucose monitor, diet app

**Trigger:**
- Patient with moderate overweight, diabetes, coronary artery disease and arrhythmias. Poor medication adherence.

**Flow:**
1. I (user) have portable blood pressure monitor, heart rate monitor, smart pillbox, smartwatch and smartphone. In case I have been previously prescribed glucose monitoring, I will already have also a glucose monitor.
2. My blood pressure and heart rate are measured periodically.
3. If I have already been prescribed glucose monitoring, I will monitor my glucose level twice a week and integrate the data manually.
4. I use a smart pill box to remind me about my medications.
5. If my blood pressure levels are less than or equal to 140/90 mmHg / resting heart rate less than 90 bpm. Green code.
6. If my blood pressure levels are > 140/90mmHg or HR between 90 - 110 bpm I get notification if I missed my medications. If so, I remember to take the
medication from the smart pill box and I also get an alert to check BP and HR after 1 hour. If this persists, 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. The case manager of the study contacts me and asks if the measurement has been made at rest, how I am doing, if I have taken the medication. I am asked to repeat the measurements and, depending on the result, I am given the appropriate indications. The patient gets an alert to seek medical advice in case no case manager subject exists in the case. In that case the patients is asked to acknowledge the alert on the mobile app interface.

7. If my blood pressure levels are > 180/110 mmHg or HR > 110bpm or < 50bpm I get an instant alert to repeat the measurement and if this persists, 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. The case manager of the study contacts me and asks if the measurement has been made at rest, how I am doing, if I have taken the medication, etc. I am asked to repeat the measurements and, in case no error is detected in the measurements, the cardiologist will contact directly with me to give the appropriate indications. The patient gets an alert to seek medical advice in case no case manager subject exists in the case. The same notification is sent to the case manager and/or informal/formal caregivers based on the patient’s profile. In that case the patients is asked to acknowledge the alert on the mobile app interface.

8. I take my tablets using a smart pillbox which reminds me to take my tablets regularly. If I omit a dose, an alert appears from the platform. The smart pillbox alert goes off too, via vocal and visual alert. I can either deactivate the alert, omitting the tablet if I believe so, or I can take it so the alert gets deactivated.

9. Periodically I receive information about my daily activity (walking distance) and reminders to maintain regular exercise. This will be a certain walking distance set at first visit. If I manage to walk it on a daily basis, I will get weekly notifications of congratulations - green code. If I won’t be able to walk the distance, a weekly alert will ask me if I feel unwell/have angina. If so, I will get advice to arrange a clinical review with my doctor. Red code.

10. I follow the diet designed for me. I use the diet app and follow the weekly advice.

11. I attend on-site follow-up visits (6 and 12 months. Being the 6 months visit optional depending on the pilot preferences or possibilities) to check wearables accuracy and monitor patient’s progress. Glucose and cholesterol levels will be incorporated to the patient’s e-record if an analysis has been performed by the centre and check the improvement in the cardiovascular risk score.

| Alternative Flows: | In pilots not involving clinicians apart from 6th (optionally) and 12th month nor national health system: Platform logs and visualizes patient data. If a smartwatch based irregular pulse notification algorithm identified possible atrial fibrillation, a telemedicine visit was initiated and after that, the smartwatch, if has an ECG option integrated, will ask to the participant for perform an electrocardiography (ECG) patch and mailed to the case, 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.

<table>
<thead>
<tr>
<th>Exceptions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requirements: First onsite clinical assessment to set goals, check wearables accuracy and determine patient’s condition. Optional 6 month follow up visit to: check wearables accuracy and monitor patient’s progress. 12 month/end of study visit to: check wearables accuracy and monitor patient’s progress.</td>
</tr>
<tr>
<td>+ see 6.4 and Table 1 MyHeart section</td>
</tr>
</tbody>
</table>

4.2.8 Depression

4.2.8.1 Mood deterioration

Georges is 78-year-old and lives in his own house in Vannes, which is a middle town next to the sea in the west of France. He has lost his wife this summer and has to cope with isolation for a few months, as his children live in the south of France (500 km away). Fortunately, they can talk quite often and see each other on Skype. Georges wife used to do many things in the household, and although he loves cooking for friends and family on special occasions, he is not at all interested in the everyday cooking, and the perspective of eating all alone every day discourages him to take care of his meals.

Yet, Georges suffers heart insufficiency, and he has to be careful on what he eats. Apart from this, George has good relationships in his neighbourhood, and even goes out for a walk almost every morning with his friend living next door.

One day, as he was visiting his cardiologist at hospital, he saw a poster presenting the SMART BEAR project. Georges feels interested and applies to be part of the experimentation. He contacts the medical staff in charge of the experimentation in his region. Once the medical tests are done by this medical team, Georges’ participation is confirmed. A technical supplier comes at home and equips Georges with a smartwatch (or other wearable) he is going to wear every day for one year and a smartphone With the help of the supplier, he answers the mood questionnaire for the first time. He chooses what time daily he wishes to receive the reminder to answer this questionnaire. He is also equipped with a connected scale.

Georges wakes up and starts his routine activities as usual: SMART BEAR Platform monitors the completion of each one of them and rewards him whenever a task is completed. He is asked to complete a mood related questionnaire. For his everyday meal choice, he consults MyDiet App, while his medication is controlled by means of MyMedication App and the smart Pillbox. After a few weeks, by the beginning of wintertime, Georges’ answers to the questionnaires tend to show his mood is slightly deteriorating and he does not enjoy the time spent with others as usual. Information is cross-checked with MyMedication App in order to see if this generates a first level alert on SMART BEAR Platform and a notification is sent to his neighbour friend, and to his son, both appointed by Georges to be his referents during the experimentation.

The analysis of Georges’ data on the platform highlights several changes in his behaviour:

- Georges mood questionnaire scores are under 60% and his daily number of steps is decreasing (25% less activity for 24h);
- Georges’ weight is stable, but diet is not balanced, and he has a significant muscle loss for one month (% to be defined);
- decrease of social activities (self-reported or GPS) or the number of calls shows a reduction of -50 %
  of total time spent on communications with others for one week,

Georges’ son who received a notification on his smartphone, calls Georges in the evening. They stay half an
hour on Skype, and Georges has the pleasure to see his youngest little child singing the song she has just
learnt at school!

The following day, his neighbour friend proposes to Georges to go out for a walk. Georges explains he is
suffering from back pain these days, and that it even awakes him at night! Moreover, it is cold and rainy
today, and he feels a bit tired (and to admit, he is already looking forward to his afternoon nap!). So, he
prefers to remain at home.

Later that morning, the SMART BEAR Platform having detected the abstinence of physical and social activity
sends a notification to Georges reminding him that going out every day and doing exercise is stimulating, a
good way to remain fit, particularly for those suffering from back pain and chronic diseases. Georges calls
back his neighbour friend and they go walking together for an hour.

When he comes back home, Georges is hungry. He cooks a meal, checks off as completed the appropriate
task and proposes to his friend to stay and have lunch with him. During the meal, they decide to go out for
a walk every day. At night, Georges feels less alone than usual and his pain in the back is a bit lower. He
sleeps better.

A report is created and sent to Georges every week documenting mood related parameters (see Table 2).
Georges can hand this report to his GP during his next appointment.

Table 26 Use Case: Following the evolution of a senior’s mental health and suggesting appropriate changes in behaviour
to prevent depression through the SMART BEAR Platform

<table>
<thead>
<tr>
<th>Use Case:</th>
<th>Following the evolution of a senior’s mental health and suggesting appropriate changes in behaviour to prevent depression through the SMART BEAR Platform</th>
</tr>
</thead>
<tbody>
<tr>
<td>Created By:</td>
<td>CATEL</td>
</tr>
<tr>
<td>Date Created:</td>
<td>10/11/2019</td>
</tr>
<tr>
<td>Description:</td>
<td>There are many kinds of weak signals indicating that a senior’s mood is deteriorating, and thus a potential risk of depression, threatening the general health and the autonomy of elderly. In the SMART BEAR project, we have the opportunity to cross various significant data collected through the different connected tools and intelligent solutions implemented. To lead this analysis and to give the patient a proper and reactive assistance, it will be necessary to:</td>
</tr>
</tbody>
</table>
  - **submit periodically questionnaires to the involved seniors**, with a limited number of questions checking how they feel, on a subjective and objective point of view. The questions will request both appreciations and concrete facts on their relationships, their physical activity and their everyday routine. The questionnaire has to be short and will be elaborated with our focus group. It can be based on well-known existing mood scales and frameworks used by psychiatrists, adapted to the needs of the project. It might be possible to integrate and adapt existing solutions meant for this purpose. Through the |
| SMART BEAR Platform, the participant would daily receive a notification to answer the periodical survey through the platform or application. The solution will be able to generate reports to the GP or Clinician in charge of them, and to their personal referent. The solution will send alerts to the senior, encouraging him to adopt a better healthy behaviour (see details in the “Trigger” section).
| automatically collect data, through connected tools, that will be meaningful to observe in the context of the prevention of depression:

- regarding their social relationships and prevention of isolation:
  - Global movements in the housing (less activity, more activity, visits).
  As long as mental health is concerned, it has to be checked how the senior feels regarding the social relationships. Concrete data stating social activities, could be misinterpreted if the senior feels bad regarding those social relations and wants to escape them (particularly if he does not live alone), or if he/she does not participate in the discussions, for example. This feeling regarding relationships has to be part of the subjective questionnaire.

- regarding their ability to move and their physical activity:
  - number of steps,
  - geolocalisation (to check the in-door / out-door movements)
  - detection of frailty signs and balance impairment (that could have impacts on their feeling of autonomy and self-esteem)
  - the time of inactivity/sleep (to study changes in sleeping habits or sleeping disorders that could show anxiety and signs of depression... or trigger them),

As regards to physical activity, on a mental health point of view, it is important to check what the senior feels regarding this physical activity. A daily and regular practice lived as a painful, unpleasant, burdensome or frustrating moment could finally have a bad impact on the mental point of view. The daily questionnaire will check this subjective factor.

- regarding their ability to do their everyday routine:
  - daily routine activities completion

Other data that might be useful to collect would be:

- the use of substance and medications (smoking, drugs, sedatives)

The crossed analysis of data should allow, through the SMART BEAR Platform, to:

- generate reports when a weak sign of change in habits or feeling has been detected, and sent to the previously defined persons;
- generate a high-level alert when a critical sign of change in habits or feeling has been detected, and send an alert to the referent GP;
- inform the senior when alerts have been detected and encouraging him or her to change something in his behaviour taking his mood in consideration.

In conclusion:

- the crossing of subjective information and feelings with factual data, on the above-mentioned criteria, will improve our capacity to better follow and understand the senior’s mood evolution;
- we will also be able to check the impact of the recommendations to adopt healthy and positive behaviours, when those recommendations are sent to seniors by intelligent and connected tools instead of humans;
The questionnaire can also be used as an indicator of the way seniors feel regarding their participation in the Smart Bear project itself, and regarding new technologies in general (how they feel to be that way “connected”).

**Actors:**
- The seniors
- The medical referent (GP or clinician) for each senior.
- The relatives around the senior (neighbour, family, the senior referent in collective senior housing)

**Preconditions:**
- A mobile phone, a Wi-Fi or 4G connection.

Regarding the application generating the daily questionnaire:
- At recruitment, the clinician or the supplier fills-up the first daily survey with the patient as an example. The patient will choose the time schedule when he/she wants to receive the alert. The patient will have to decide on who he/she wants to be advised in case of deterioration of his mood and health; his referent GP or Clinician, possibly someone in his family, someone in his/her neighbourhood and/or a referent in the residence if he/she lives in a collective structure. The clinical staff will also give an information sheet to the senior with a phone number to dial in case of technical problems (supplier phone number or technical Smart Bear staff in the country).

**Trigger:**
A senior who feels concerned by paying attention to his mental health and wellness, and to be advised on the changes he could integrate into his routine to lead a healthy and balanced way of life.

**Flow:**
1. I (user) periodically answer surveys on my mood and healthy behaviours (surveys inspired by eMen or iCOPE projects)
2. If I do not answer the survey, the platforms send periodically a notification to remind me to fill in the survey
3. I fill in the survey
4. Under or above different thresholds then a notification will be sent to me with a suggestion (ie. "meals are not satisfying for you these days, why not cook your favourite meal today, eventually with a relative and eat it together?")
5. I live my daily routine as usual and I’m using my smart weight scale (with impedance) once a week as advised by GP.
6. Through smart bear devices, my physical activity is tracked. I receive periodically notifications according to the analysis of these collected data:
   a. If threshold (e.g 25%) less activity for 24h detected, a notification suggesting me an activity such as” “Moving would be good for you! Why not go out for a walk today, or play the game… available on the platform?”"
   b. If threshold (e.g 25%) less activity for 48h AND if significant muscle loss for one week (% to be defined), a notification suggesting me that it is important to move more to keep fit, confident and positive and why not proposing a walk if possible?
   c. If threshold (e.g 50%) less activity for 48h AND if significative muscle loss for a month (% to be defined), then an alert asking me for contacting my GP quickly. These alerts could be sent to my other significatives according to ICF
7. Through smart bear devices the quality of my sleep is tracked too. In case of low quality of sleep, I receive suggestions to get advice in order to get a better sleep.

**Alternative Flows:**

In case the senior has a difficulty to use the application or other tools, he/she can contact the supplier or technical referent on the application in the Smart Bear project.

**Exceptions:**

No senior suffering a severe depression or anxiety should be implemented.

If a senior wants to adapt his participation, he should be free to contact the pilot in his/her country, to decide to stop using one tool or the other for a time or definitively, or to lower the frequency of answer to the survey.

Adaptations on the senior participation to the project have to be proposed with the patient if signals of serious mood deterioration are detected.

Seniors having difficulties to read will have difficulties to answer the daily questionnaire; thus, the reading ability should be a condition for the senior implementation.

**Postconditions:**

The senior feels satisfied about his way of life and keeps good habits in his routine to be fit and happy. He has confidence in his/her ability to maintain social relationships, to move, and to live independently. He feels secure to get advice on how to maintain his/her good mental health and, if the need should arise, to have the guaranty to be surrounded by relatives and to get medical help.

**Requirements:**

- Ability to use the Smartphone and other connected tools.

### 4.3 Clinical Use Cases Requirements

In this section we report all the requirements resulting from the use case scenario discussed in the previous section.

<table>
<thead>
<tr>
<th>Requirement Code</th>
<th>Description</th>
<th>Priority Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>R-HA-1</td>
<td>The Platform must be able to retrieve HA usage data.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-2</td>
<td>The Platform must be able to support visualization of HA usage data aggregated over different time periods (e.g., daily, weekly, monthly).</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-HA-3</td>
<td>The Platform must be able to monitor HA usage data automatically and check whether usage falls within specified ranges.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-4</td>
<td>The Platform must be able to produce notifications to the user when their HA usage is outside the specified ranges.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-5</td>
<td>The Platform must be able to produce follow-up notifications to the user and/or the case manager and/or the formal/informal caregiver within specific periods after the initial notification, depending on the user’s HA usage and the ICF/actor’s acceptance to receive such notifications.</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-HA-6</td>
<td>The Platform must be able to produce notifications reminding the user to fill in their GHAB questionnaire and do so periodically.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-7</td>
<td>The Platform must be able to display an interactive questionnaire.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-8</td>
<td>The Platform must be able to keep active the interactive questionnaire while it has not been filled in and its time period has not elapsed.</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-HA-9</td>
<td>The Platform must be able to calculate GHAB scores.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-10</td>
<td>The Platform must offer the user of retrieving and visualising their GHAB scores.</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-HA-11</td>
<td>The Platform must be able to compare (and visualise) historic GHAB scores.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-12</td>
<td>The Platform must be able to produce a periodic HA usage report, annotated by brief explanations.</td>
<td>MAY</td>
</tr>
<tr>
<td>R-HA-13</td>
<td>The Platform must be able to notify periodic HA usage reports to (a) the user, (b) audiologists, (c) case managers, subject to their existence and acceptance to receive such notifications/ICF.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-14</td>
<td>The Platform must be able to book a call with the audiologist using the MyAppointments app, following the user’s request.</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-HA-15</td>
<td>The Platform (MyHearing app) must be able to allow the user to select the reasons for being dissatisfied with HA.</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-HA-16</td>
<td>The Platform must be able to allow the user to book an appointment with their audiologist for the issues registered by the user.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-17</td>
<td>The Platform must be able to produce reminders for appointments at specified times.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-18</td>
<td>The Platform may be able to initiate a video call with the appointment’s target (e.g., audiologist) at the time of the appointment after the user has clicked to initiate it.</td>
<td>MAY</td>
</tr>
<tr>
<td>R-HA-19</td>
<td>The Platform must be able to allow the user to record an appointment manually.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-20</td>
<td>The Platform must be able to allow the recipient of an appointment request to confirm and save the appointment.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-21</td>
<td>The Platform must be able to allow the audiologist to activate the remote fine-tuning function of the HA.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-22</td>
<td>The Platform must give the appointment participants the ability to log data relevant to the appointment.</td>
<td>MAY</td>
</tr>
<tr>
<td>R-HA-23</td>
<td>The Platform must be able to allow the audiologist to record MOCA/etc. scores.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-24</td>
<td>The Platform must be able to collect and save environmental/behavioural/physiological data during the use of the HA.</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-HA-25</td>
<td>The Platform must be able to provide visualisations of data in different graph types.</td>
<td>MAY</td>
</tr>
<tr>
<td>R-HA-26</td>
<td>The Platform must be able to provide visualisations of data in different graph types.</td>
<td>SHOULD</td>
</tr>
<tr>
<td>Requirement (R-HA)</td>
<td>Description</td>
<td>Priority</td>
</tr>
<tr>
<td>------------------</td>
<td>-------------</td>
<td>----------</td>
</tr>
<tr>
<td>R-HA-27</td>
<td>The Platform must be able to provide records of HA usage data for different combinations of noise types/levels/duration of exposure.</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-HA-28</td>
<td>The Platform must allow the audiologist to access the automatically recorded data.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-29</td>
<td>The Platform must allow the audiologist to view the patient's profile and select an auditory training program.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-30</td>
<td>The Platform must be able to produce periodic notifications for tasks the user must perform (e.g., auditory training).</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-31</td>
<td>The Platform must be able to collect the results of the auditory training.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-32</td>
<td>The Platform must be able to provide feedback on the auditory training to the user and the audiologist.</td>
<td>MAY</td>
</tr>
<tr>
<td>R-HA-33</td>
<td>The Platform must be able to change the auditory training to the next level when certain milestones are reached (discrimination, discrimination in noise).</td>
<td>MUST</td>
</tr>
<tr>
<td>R-HA-34</td>
<td>The Platform must be able to collect self-reporting on the auditory training by the patient.</td>
<td>MAY</td>
</tr>
<tr>
<td>R-HA-35</td>
<td>The Platform must support different user languages [internationalisation].</td>
<td>MUST</td>
</tr>
<tr>
<td>R-BD-1</td>
<td>The Platform must be able to set access roles and define the use case manager and other users linked to the specific userID. The use case manager should have access to the data for a list of userID.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-BD-2</td>
<td>The Platform must allow the MedX physiotherapist to import data in electronic format from the health check-up and health questionnaire.</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-BD-3</td>
<td>The output device (smartphone) must provide a gamified output to the user. A scenario needs to be developed to implement the gamified aspect. A usable front-end GUI and speech-based interaction should be incorporated (e.g. rely on available open-source solutions).</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-BD-4</td>
<td>The Platform must collect data from sensing devices, aggregate information, perform an analysis of previously collected data to extract progress levels.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-BD-5</td>
<td>The smartphone supports speech-based interaction and text. Methods need to be reviewed for TTS, cloud-based, android-API solutions.</td>
<td>MAY</td>
</tr>
<tr>
<td>R-BD-6</td>
<td>The Platform will collect information from devices and summarize it for the session. Start and stop triggers could be integrated to estimate the session duration.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-BD-7</td>
<td>The mobile device must be able to display the output of the report and notify and deliver the report to the use case manager.</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-BD-8</td>
<td>The Platform must be able to collect weather information from open data repository and derive specific notifications based on weather conditions for the userID that are in the Fall prevention category.</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-BD-9</td>
<td>The profile must include a list of different types on information about, e.g., User (userID, language) Devices, Somatometrics, Heath issues, Physical and mental aspects (steps, heart rate measurements, ...), Incidents, etc.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-BD-10</td>
<td>Information on how to use the system should exist also in electronic form.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-BD-11</td>
<td>The user response on acceptance or not acceptance of the recommended task must be recorded.</td>
<td>MUST</td>
</tr>
<tr>
<td>Requirement</td>
<td>Description</td>
<td>Level</td>
</tr>
<tr>
<td>--------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>R-BD-12</td>
<td>The Platform must be able to notify the user via text on the smartphone and vibration on the smartwatch</td>
<td>MUST</td>
</tr>
<tr>
<td>R-BD-12</td>
<td>The use case manager must be able to update the schedule for tasks for the specific userID</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-BD-13</td>
<td>The Platform must be able to display questions to the user to perform the safety check and record responses.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-BD-14</td>
<td>The Platform must be able to record incorrect executions of the exercise</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-BD-15</td>
<td>The App must be able to trigger instructions upon incorrect execution of the exercise</td>
<td>MAY</td>
</tr>
<tr>
<td>R-BD-16</td>
<td>The Platform should include a list of gamified exercises for the user to select</td>
<td>MUST</td>
</tr>
<tr>
<td>R-BD-17</td>
<td>The Platform must be able to derive analytics and dynamically adapt the difficulty of the exercise.</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-BD-18</td>
<td>The Platform must be able to share performance analytics to the clinicians and the user (need to define what information will be displayed)</td>
<td>MUST</td>
</tr>
<tr>
<td>R-BD-19</td>
<td>The Platform must detect via heart rate and accelerometer information and possibly through self-reporting if the user is at rest.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-BD-20</td>
<td>The Platform collects external weather conditions and provides notification to the mobile device in case of possible critical cases (we need to define the critical cases)</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-BD-21</td>
<td>The steps and heart rate are recorded in the Platform from the devices</td>
<td>MUST</td>
</tr>
<tr>
<td>R-BD-22</td>
<td>The Platform is able to report and display to the user on his/her mobile device of the steps he/she has walked.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-BD-23</td>
<td>The Platform must display to the user rewards when goals are reached.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-BD-24</td>
<td>The clinician should set the goals in the Platform and save this information in the user profile</td>
<td>MUST</td>
</tr>
<tr>
<td>R-CD-1</td>
<td>The mobile app must be able to support digital tests (ie MoCA)</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-2</td>
<td>The Platform must be able to calculate/analyse test results in order to suggest a cognitive training program with a variety of exercises, designed with a progressive difficulty.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-CD-3</td>
<td>The Platform should provide a mechanism for collecting data of different types, as well as geo-located data</td>
<td>MUST</td>
</tr>
<tr>
<td>R-CD-4</td>
<td>The Platform must support a mixed reality visualization</td>
<td>MAY</td>
</tr>
<tr>
<td>R-CD-5</td>
<td>The Platform should be able to support object (i.e. keychain) tracking</td>
<td>MAY</td>
</tr>
<tr>
<td>R-CD-6</td>
<td>The Platform must provide a mechanism to calculate suggested activities results.</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-7</td>
<td>The mobile app must be able to play personalized verbal messages</td>
<td>MAY</td>
</tr>
<tr>
<td>R-CD-8</td>
<td>SMART BEAR @ Home devices should be able to play personalized verbal messages based on specific conditions</td>
<td>MAY</td>
</tr>
<tr>
<td>---------</td>
<td>--------------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>R-CD-9</td>
<td>SMART BEAR should be able to log its interactions with patient</td>
<td>MUST</td>
</tr>
<tr>
<td>R-CD-10</td>
<td>SMART BEAR should be able to send reminders for cognitive training to patients on a periodically basis</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-11</td>
<td>SMART BEAR should be able to send report of training results and goals to patients on a periodically basis</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-12</td>
<td>The mobile app should be able to provide rehabilitation programs to patients</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-13</td>
<td>The mobile app should provide a list of cognitive exercises that supports multiple level of difficulty</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-14</td>
<td>SMART BEAR should be able to analyse patient’s training results of the available cognitive exercises</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-15</td>
<td>SMART BEAR should be able to notify caregivers on patient’s location and trajectory</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-16</td>
<td>SMART BEAR should be able to record the physical activity of a patient</td>
<td>MUST</td>
</tr>
<tr>
<td>R-CD-17</td>
<td>SMART BEAR mobile app should be able to provide an overview of the latest activity</td>
<td>MUST</td>
</tr>
<tr>
<td>R-CD-18</td>
<td>SMART BEAR mobile app should provide list with the top training results/scores of all users</td>
<td>MAY</td>
</tr>
<tr>
<td>R-CD-19</td>
<td>SMART BEAR should be able to monitor sleep activity and motion</td>
<td>MAY</td>
</tr>
<tr>
<td>R-CD-20</td>
<td>SMART BEAR should be able to record and report sleep activity of a patient</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-21</td>
<td>SMART BEAR should provide a mechanism to report patient’s sleep activity for a period of time</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-22</td>
<td>SMART BEAR should be able to provide suggestions/advises on sleep activity to a patient</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-23</td>
<td>SMART BEAR mobile app should be able to provide Closed-ended questionnaire</td>
<td>MUST</td>
</tr>
<tr>
<td>R-CD-24</td>
<td>SMART BEAR should provide a reporting mechanism that will support reports on patients’ data (reports such as patients’ answers on questionnaires)</td>
<td>MAY</td>
</tr>
<tr>
<td>R-CD-25</td>
<td>SMART BEAR should provide a notification/alert mechanism which can be triggered by several events/actions (i.e. patient’s medication schedule, patient’s goal achievement, home sensor thresholds, etc.)</td>
<td>MUST</td>
</tr>
<tr>
<td>R-CD-26</td>
<td>The mobile app should provide a calendar for a patient’s medication schedule</td>
<td>MUST</td>
</tr>
<tr>
<td>R-CD-27</td>
<td>SMART BEAR Platform should be able to start recording home devices data on a scheduled basis.</td>
<td>MUST</td>
</tr>
<tr>
<td>R-CD-28</td>
<td>SMART BEAR Platform should be able to aggregate and represent home device data in a meaning form (e.g. comfort level)</td>
<td>SHOULD</td>
</tr>
<tr>
<td>Requirement ID</td>
<td>Description</td>
<td>Priority</td>
</tr>
<tr>
<td>---------------</td>
<td>-------------</td>
<td>----------</td>
</tr>
<tr>
<td>R-CD-29</td>
<td>SMART BEAR should be able to analyse home sensor data</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-30</td>
<td>SMART BEAR should provide a notification/alert mechanism which can be triggered by several events/actions (ie. patient's medication schedule, patient's goal achievement, home sensor thresholds, etc.)</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-31</td>
<td>SMART BEAR should provide a notification/alert mechanism which can be triggered by several events/actions/conditions (ie. patient's medication schedule, patient's goal achievement, home sensor thresholds, weather, etc.)</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-32</td>
<td>SMART BEAR Platform notification/alert mechanism can be postponed/disabled</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-33</td>
<td>The mobile app should provide a list of cognitive games with different levels of difficulty</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-34</td>
<td>SMART BEAR should provide a notification/alert mechanism which can be triggered by several events/actions/conditions (ie. patient's medication schedule, patient's goal achievement, home sensor thresholds, weather, etc.)</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-35</td>
<td>SMART BEAR should be able to collect physical activity data</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-36</td>
<td>The mobile app should be able to support close-ended questionnaires</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-37</td>
<td>SMART BEAR should be able to report physical activity (i.e. steps, km) and cognitive data</td>
<td>MUST</td>
</tr>
<tr>
<td>R-CD-38</td>
<td>SMART BEAR should provide a scoring system for patients' physical and cognitive activities</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-39</td>
<td>SMART BEAR should provide a notification/alert mechanism which can be triggered by several events/actions (ie. patient's medication schedule, patient's goal achievement, home sensor thresholds, etc.)</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-40</td>
<td>SMART BEAR should be able to record physical activity of a patient</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-41</td>
<td>SMART BEAR should provide a scoring system for patients' physical and cognitive activities</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-42</td>
<td>SMART BEAR should support social community functionalities (such as Social Profile, Resource Library, Events, Groups)</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-CD-43</td>
<td>The mobile app should provide personal safety information about physical activities</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-ED-1</td>
<td>The SMART BEAR application should be able to combine meal plans for each patient taking into consideration the recordings of vitals and physiological characteristics</td>
<td>MUST</td>
</tr>
<tr>
<td>R-ED-2</td>
<td>The mobile app should be able to support either automatic entry of glucometer readings or manual entry by the patient</td>
<td>SHOULD</td>
</tr>
<tr>
<td>R-ED-3</td>
<td>The smartwatch in connection with the smartphone should be able to track physical activity and allocate scores to each user hence to allow a gamified approach to physical activity</td>
<td>MUST</td>
</tr>
<tr>
<td>R-ED-4</td>
<td>The Platform should be able to support virtual communities of patients belonging to the same profile and following similar regimes hence their scores (anonymised) part of a gamification approach could be compared so each patient can assess his/her position in the community</td>
<td>MUST</td>
</tr>
<tr>
<td>R-ED-5</td>
<td>The mobile app should be able to give to the user tips on exercising based on an individualised profile (dynamically adapted with each recording)</td>
<td>MUST</td>
</tr>
<tr>
<td>Requirement</td>
<td>Description</td>
<td>Priority</td>
</tr>
<tr>
<td>-------------</td>
<td>-------------</td>
<td>---------</td>
</tr>
<tr>
<td>R-ED-6</td>
<td>The mobile app should follow a gamified approach for increased user motivation</td>
<td>MUST</td>
</tr>
<tr>
<td>R-CVD-1</td>
<td>The mobile app needs to be able to send periodic notifications/alerts to the participant based on preset parameters</td>
<td>MUST</td>
</tr>
<tr>
<td>R-CVD-2</td>
<td>The mobile app needs to be able to send periodic notifications/alerts to the case manager based on preset parameters</td>
<td>MUST</td>
</tr>
<tr>
<td>R-CVD-3</td>
<td>The mobile app needs to be able to save, analyse data from smartphone, smartwatch and devices</td>
<td>MUST</td>
</tr>
<tr>
<td>R-CVD-4</td>
<td>The mobile app needs to be able to communicate, store, analyse data from the blood pressure recorder</td>
<td>MUST</td>
</tr>
<tr>
<td>R-CVD-5</td>
<td>The mobile app needs to be able to communicate, store, analyse data from the smart pillbox</td>
<td>MUST</td>
</tr>
<tr>
<td>R-CVD-6</td>
<td>The mobile app needs to be able to analyse daily exercise goals and encourage participant</td>
<td>MUST</td>
</tr>
</tbody>
</table>
5 User and Platform Requirements

The stakeholders' satisfaction has become a key factor for the success of a product (e.g., a new service or software system). Satisfaction is related to the achievement of stakeholders' needs, and thereby to the presence and performance of certain stakeholders’ requirements in the product. In the SMART BEAR project, the goal of the requirements elicitation phase is to identify a strategic set of guiding requirements that the SMART BEAR platforms should fulfil. By building requirements, we refer to requirements intended to shape the project aim and means without entering on low-level details about the implementation of specific functionalities or technological infrastructures.

We took into consideration only the technological aspects connected to usability and the platform functionalities even if the clinical aspects drive our work in this area. In particular, we are focusing on three components of the SMART BEAR Platform:

- SMART BEAR @ Home.
- SMART BEAR backend.
- Legal Requirements.

Each component was analysed in three stages. The state of the art developed in Section 2 has provided us with a (i) domain analysis for identifying the progress SMART BEAR has the potential to introduce. For these results, we selected a (ii) list of requirements that our technical experts considered significant to achieve the full SMART BEAR potential. This list is then used to (iii) distribute a questionnaire constructed using the Kano Model among the technical profiles in the project. The results of the questionnaire give us a prioritization of the requirements.

The list of requirements is also associated with the main roles that we expect are cooperating within the SMART BEAR platform. Multiple roles can be associated with a same requirement. In particular, we identified the following roles.

- **System.** It refers to the SMART BEAR platform seen as a whole. We use this role for requirements that are inherent to the comprising set of components making the platform functioning. The SMART BEAR platform will have to adhere to GDPR.

- **System Administrator.** It refers to the role that is responsible for the setup and reliable operation of the SMART BEAR platform. It should be able to ensure that the uptime, performance, resources, and security of the computers they manage meet the needs of the other users. The system administrator may require access to the system components and to the registers accounting for the behaviour of the SMART BEAR platform.

- **Patient.** It refers to the final user of the health care services supported by the SMART BEAR platform. It interacts with SMART BEAR @HOME in order to acquire guidance or information about the treatment and the trajectory of its care plans. It is also the owner of the personal data generated, recorded, and processed by the SMART BEAR platform.

- **Clinical Case Manager.** It refers to a health care professional that works as a primary caregiver of a patient in a hospital, skilled nursing facility, clinic, or patient's home. A clinician diagnoses and treats patients. The Case Manager uses the SMART BEAR platform in order to increase the level of evidence-based practices and care plans.

- **Caregiver.** It refers to anyone who provides care for a person who needs extra help. This could mean a family caregiver, a respite caregiver, a home caregiver, or a primary caregiver, to name but a few. In the context of elderly care, this job title typically refers to a private duty home caregiver or senior caregiver.

- **Data Scientist.** It refers to a professional responsible for collecting, analysing and interpreting the overall amount of data collected by the SMART BEAR Cloud. Data science plays an important role for the effective exploitation of the data collected by the SMART BEAR platform.

- **Policy Maker.** It refers to someone who exploits the statistical report and analytics resulting from the SMART BEAR Cloud to create policies and plans, especially for the good of a territory or community.
- **Auditor.** It refers to someone who accesses the SMART BEAR platform in order to audit its behaviour, especially for monitoring the data processing procedures in terms of compliance with guidelines and regulations.

The list of requirements is finally associated with **Functional Areas (FA)** and **Use Cases (UC)**. FA groups multiple UC that describe the operations a user can execute on the platform. The functional areas we identified are the following.

- **User Management (UM)** describes the ability for administrators to manage user access to various IT resources like systems, devices, applications, storage systems, networks, and more. User management not only establishes a user’s authorization to access secure resources, it also serves as a repository of identities and, if done efficiently, can be the source of all identities for an organization. This includes user and password storage, CRUD (create, update, read, and delete) operations, policy (security, password) management, attribute transformation, and self-service flows such as account recovery and registration. It also defines the applications active for a user and the configuration settings of these applications in terms of views, notifications, interactive actions and visualization preferences.

- **IoT Network Management (INM)** is about coordinate, monitor and connect the SMART BEAR gateway and sensors, and monitoring the functioning of communication channels. IoT management presents the challenge to control and monitoring heterogeneous network elements, physical or logical, that support different protocols and quality of service requirements.

- **Data Management (DM)** includes a combination of different functions that collectively aim to make sure that the data in corporate systems is accurate, available and accessible. It is an administrative process that includes acquiring, validating, storing, protecting, and processing required data to ensure the accessibility, reliability, and timeliness of the data for its users, which its solutions make processing, validation, and other essential functions simpler and less time intensive.

- **Cloud Management (CM)** refers to software and technologies designed for operating and monitoring applications, data and services residing in the cloud. Cloud management tools help ensure cloud computing-based resources are working optimally and properly interacting with users and other services.

- **Data Analysis (DA)** involves the process of cleaning, transforming, and modelling data to discover useful information for business decision-making. The purpose of Data Analysis is to extract useful information from data and taking the decision based upon the data analysis. Data analysis tools make it easier for users to process and manipulate data, analyse the relationships and correlations between data sets, and it also helps to identify patterns and trends for interpretation.

- **Data Visualization (DV)** is the graphical representation of information and data. By using visual elements like charts, graphs, and maps, data visualization tools provide an accessible way to see and understand trends, outliers, and patterns in data. It involves producing charts and infographics that communicate relationships among the represented data to viewers of the images. This communication is achieved through the use of a systematic mapping between graphic marks and data values in the creation of the visualization. This mapping establishes how data values will be represented visually, determining how and to what extent a property of a graphic mark, such as size or colour, will change to reflect change in the value of a data. In the world of Big Data, data visualization tools and technologies are essential to analyse massive amounts of information and make data-driven decisions.

The process adopted in order to gather user and platform requirements is presented in Figure 21. Starting from the results of the domain analysis developed in Section 2, we created a group of experts proposing an initial list of requirements. After multiple refinement stages, the final version of this list was evaluated by proposing a questionnaire to the entire group of technical experts of the SMART BEAR project. The questionnaire was designed and analysed using the Kano model, presented in Section 3.4. The results of this questionnaire are used for organizing workshops aimed at identifying critical requirements and to improve the shared understanding among partners. These workshops are, at the same time, aimed at integrating technical requirements with the clinical requirements emerging from Section 4, and legal constraints presented in
Section 6. The final result is aimed to organize a documentation on SMART BEAR requirements providing specifications and prioritization for future design activities.

![Requirement gathering with user and platform requirements](image)

**5.1 SMART BEAR @ Home**

<table>
<thead>
<tr>
<th>#</th>
<th>Name</th>
<th>Role</th>
<th>Description</th>
<th>Notes</th>
<th>FA</th>
<th>TUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>R101</td>
<td>SDK</td>
<td>System</td>
<td>Selected devices must provide an SDK library</td>
<td>If they do not provide SDK they at least have to comply with R102</td>
<td>INM</td>
<td>TUC2.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>TUC2.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>TUC2.3</td>
</tr>
<tr>
<td>R102</td>
<td>API</td>
<td>System</td>
<td>Selected devices must provide an API for interfacing</td>
<td>If they do not provide API they at least have to comply with R101</td>
<td>INM</td>
<td>TUC2.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>TUC2.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>TUC2.3</td>
</tr>
<tr>
<td>R103</td>
<td>Gateways</td>
<td>System</td>
<td>The prototype gateway device should be light, cheap, easily replaceable.</td>
<td>Indifferent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R104</td>
<td>Monitorable Gateways</td>
<td>System</td>
<td>The prototype gateway is fault tolerant. Components for monitoring the state of the gateway are available</td>
<td>Indifferent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R105</td>
<td>Memory</td>
<td>System</td>
<td>A local data storage must be available to support the scheduling of data transfer operations when the connectivity is on.</td>
<td>Indifferent</td>
<td>INM</td>
<td>TUC2.2</td>
</tr>
<tr>
<td>Requirement</td>
<td>Type</td>
<td>Description</td>
<td>Notes</td>
<td>Functional</td>
<td>Dysfunctional</td>
<td></td>
</tr>
<tr>
<td>-------------</td>
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</tr>
<tr>
<td>R106</td>
<td>System</td>
<td>Artificial Intelligence modules must be available locally to support data classification and summarization.</td>
<td>This requirement is crucial to avoid transferring personal data</td>
<td>INM TUC2.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R107</td>
<td>Administrator</td>
<td>Support multiple types of Health factors at the same time</td>
<td>Non Functional (linear)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R108</td>
<td>Patient</td>
<td>The patient is provided with a Mobile app as a component of SMART BEAR @ HOME</td>
<td>UM TUC 1.4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R109</td>
<td>Clinician</td>
<td>Periodically reports are generated and transmitted to the patient via Mobile app</td>
<td>UM TUC 1.4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R110</td>
<td>Patient</td>
<td>Automatic alerts for dangerous events can be notified to the patient via Mobile app</td>
<td>Indifferent, Reverse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R111</td>
<td>Administrator</td>
<td>Mobile app communicates with the SMART BEAR @ HOME Hub</td>
<td>Functional of R112</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R112</td>
<td>Auditor</td>
<td>Mobile app communicates with each SMART BEAR @ HOME single device</td>
<td>Dysfunction of R111</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>R113</td>
<td>Auditor</td>
<td>Mobile app collect data from SMART BEAR @ HOME Hub only</td>
<td>Functional of R114</td>
<td></td>
<td></td>
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<tr>
<td>R114</td>
<td>Auditor</td>
<td>Mobile app collect data from SMART BEAR @ HOME single device</td>
<td>Dysfunction of R113</td>
<td></td>
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<tr>
<td>R115</td>
<td>Administrator</td>
<td>Mobile app identifies problems in the communication with the SMART BEAR @ HOME Hub only</td>
<td>Functional of R116</td>
<td></td>
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<tr>
<td>R116</td>
<td>Auditor</td>
<td>Mobile app identifies problems in the communication with the SMART BEAR @ HOME single device</td>
<td>Dysfunctional R115</td>
<td></td>
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<tr>
<td>R117</td>
<td>Patient</td>
<td>Users can rate the SMART BEAR @ HOME services</td>
<td>Indifferent</td>
<td></td>
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<tr>
<td>R118</td>
<td>Patient</td>
<td>Users can visualize the history of ratings on the SMART BEAR @ HOME</td>
<td>Indifferent, Reverse</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>R119</td>
<td>Administrator</td>
<td>Multiple Care Plans can be supported by the SMART BEAR mobile app</td>
<td>UM TUC 1.4</td>
<td></td>
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<tr>
<td>Req</td>
<td>Description</td>
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<tr>
<td><strong>R120</strong></td>
<td>Configurability of Care Plans</td>
<td></td>
<td></td>
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<tr>
<td><strong>R121</strong></td>
<td>Care Plans updates</td>
<td></td>
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<tr>
<td><strong>R122</strong></td>
<td>Select SMART BEAR @ HOME devices</td>
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<tr>
<td><strong>R123</strong></td>
<td>Visualize SMART BEAR @ HOME device usage</td>
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<tr>
<td><strong>R124</strong></td>
<td>Clinical Tests</td>
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<tr>
<td><strong>R125</strong></td>
<td>Mobile app connects to the user profile in the social networks</td>
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<tr>
<td><strong>R126</strong></td>
<td>Mobile app stores user consent action for accessing personal data</td>
<td></td>
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<tr>
<td><strong>R127</strong></td>
<td>SMART BEAR Hub records different data streams</td>
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<tr>
<td><strong>R128</strong></td>
<td>Mobile app shows the data stored in the Hub</td>
<td></td>
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<tr>
<td><strong>R129</strong></td>
<td>Analyze patient activity in the social networks</td>
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<tr>
<td><strong>R130</strong></td>
<td>SMART BEAR @ HOME on-demand data upload</td>
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<tr>
<td><strong>R131</strong></td>
<td>Mobile app proposes questionnaire</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>System Administrator</th>
<th>Clinical User</th>
<th>Data Scientist</th>
<th>SMART BEAR Care Plans can be configured by selecting the goals to be achieved</th>
<th>UM</th>
<th>TUC 1.4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care Plans can be updated remotely by updating the SMART BEAR mobile app</td>
<td>Indifferent</td>
<td></td>
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<tr>
<td>SMART BEAR platform should allow clinicians to select a different device, based on patient’s preferences and record this selection</td>
<td>UM</td>
<td>TUC 1.4</td>
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<tr>
<td>SMART BEAR mobile app should support multiple Clinical Tests</td>
<td>UM</td>
<td>TUC 1.4</td>
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<tr>
<td>SMART BEAR mobile app should be able to connect to the user profile in the social networks</td>
<td>Reverse</td>
<td></td>
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<tr>
<td>SMART BEAR mobile app should be able to store the user consent action for accessing personal data</td>
<td>UM</td>
<td>TUC 1.3</td>
<td></td>
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<tr>
<td>SMART BEAR Hub should be able to record different data streams</td>
<td>DM</td>
<td>TUC 3.1 TUC 3.2 TUC 3.3</td>
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<tr>
<td>Mobile app shows the data stored in the Hub</td>
<td>Reverse</td>
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<tr>
<td>SMART BEAR @ HOME should be able to analyze the patient activity in the social networks</td>
<td>Indifferent, Reverse</td>
<td></td>
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</tr>
<tr>
<td>SMART BEAR @ HOME should be able to analyze devices’ data and upload them to SMART BEAR repository in an ad hoc basis in case of an event</td>
<td>DM</td>
<td>TUC 3.2</td>
<td></td>
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<tr>
<td>SMART BEAR mobile app should notify SMART BEAR users to fill in a questionnaire</td>
<td>UM</td>
<td>TUC 1.4</td>
<td></td>
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<tr>
<td><strong>R132</strong></td>
<td>Mobile app extracts personal data in an application-friendly standard format</td>
<td>Data Scientist Auditor</td>
<td>SMART BEAR mobile app should be able to extract, in an application-friendly standard format (ie. txt, csv, xls, etc.), personal data</td>
<td>Indifferent, Reverse</td>
<td></td>
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<tr>
<td><strong>R133</strong></td>
<td>Data upload timing</td>
<td>Data Scientist Auditor</td>
<td>Data upload timing from SMART BEAR @ HOME can be configured by clinicians</td>
<td>Indifferent, Reverse</td>
<td></td>
</tr>
<tr>
<td><strong>R134</strong></td>
<td>Register a new device</td>
<td>System Administrator Auditor</td>
<td>SMART BEAR @ HOME should be able to register a new device</td>
<td>INM TUC 2.1</td>
<td></td>
</tr>
<tr>
<td><strong>R135</strong></td>
<td>Register/update/cancel a new user</td>
<td>System Administrator Auditor</td>
<td>SMART BEAR @ HOME should be able to register/update/cancel a new user</td>
<td>UM TUC 1.3</td>
<td></td>
</tr>
<tr>
<td><strong>R136</strong></td>
<td>Assign a role to the user</td>
<td>System Administrator Auditor</td>
<td>SMART BEAR @ HOME should be able to assign a role to the user</td>
<td>UM TUC 1.3</td>
<td></td>
</tr>
<tr>
<td><strong>R137</strong></td>
<td>Assign access right to roles</td>
<td>System Administrator Auditor</td>
<td>SMART BEAR @ HOME should be able to assign access right to roles</td>
<td>UM TUC 1.3</td>
<td></td>
</tr>
<tr>
<td><strong>R138</strong></td>
<td>Mobile app provides up-to-date communications from clinicians</td>
<td>Clinician Patient Auditor</td>
<td>SMART BEAR mobile app should provide up-to-date communications from clinicians</td>
<td>UM TUC 1.4</td>
<td></td>
</tr>
<tr>
<td><strong>R139</strong></td>
<td>Scalability</td>
<td>System</td>
<td>The performance of SMART BEAR @ Home and its components should not degrade with an increase in the number of the users or/and the available datasets</td>
<td>Non functional (exciter)</td>
<td></td>
</tr>
<tr>
<td><strong>R140</strong></td>
<td>Usability</td>
<td>System</td>
<td>SMART BEAR @ Home and its components should be designed to meet high usability</td>
<td>Non functional (linear)</td>
<td></td>
</tr>
<tr>
<td><strong>R141</strong></td>
<td>Android support</td>
<td>System</td>
<td>SMART BEAR @ Home has to support at least the Android OS</td>
<td>Non functional (mandatory)</td>
<td></td>
</tr>
</tbody>
</table>
## 5.2 SMART BEAR Cloud

Table 29 Smart Bear Cloud

<table>
<thead>
<tr>
<th>#</th>
<th>Name</th>
<th>Role</th>
<th>Description</th>
<th>Notes</th>
<th>FA</th>
<th>TUC</th>
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</thead>
<tbody>
<tr>
<td>R201</td>
<td>Availability</td>
<td>System Auditor</td>
<td>The Backend platform must comply with an availability SLA</td>
<td>CM</td>
<td></td>
<td>TUC 4.1, TUC 4.2, TUC 4.3</td>
</tr>
<tr>
<td>R202</td>
<td>Secure Authentication</td>
<td>System Auditor</td>
<td>Users connecting to the Backend platform must be authenticated via secure channels (HTTPS)</td>
<td>Non functiona (linear)</td>
<td></td>
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<tr>
<td>R203</td>
<td>Filter the relevant studies</td>
<td>Data Scientist, System Administra tor, Auditor</td>
<td>SMART BEAR Backend should be able to filter data based on selected factors</td>
<td>DM</td>
<td></td>
<td>TUC 3.1, TUC 3.2, TUC 3.3</td>
</tr>
<tr>
<td>R204</td>
<td>Cluster the relevant studies</td>
<td>Data Scientist, System Administra tor, Auditor</td>
<td>SMART BEAR Backend should cluster the relevant studies based on potential factors</td>
<td>DM</td>
<td></td>
<td>TUC 3.1, TUC 3.2, TUC 3.3</td>
</tr>
<tr>
<td>R205</td>
<td>Characterize data to define the size of the dataset</td>
<td>System Administra tor</td>
<td>SMART BEAR Backend should provide a mechanism to characterize data, based on the study period and the source of origin, as well as to define the size of the dataset, depending on factors like the time frame of the data to be retrieved (from-to), etc.</td>
<td>Indifferent</td>
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<tr>
<td>R206</td>
<td>Support different types of data analysis</td>
<td>Data Scientist, Auditor</td>
<td>SMART BEAR Backend should be able to support different types of data analysis</td>
<td>Non functional (linear)</td>
<td></td>
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<tr>
<td>R207</td>
<td>Initiate data analysis session</td>
<td>Data Scientist, Auditor</td>
<td>SMART BEAR Backend should be able to initiate data analysis session</td>
<td>DA</td>
<td></td>
<td>TUC 5.1, TUC 5.2, TUC 5.3</td>
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<tr>
<td>R208</td>
<td>Administerate (create, update, delete) analysis outcomes</td>
<td>System Administra tor, Auditor</td>
<td>SMART BEAR Backend should be able to administrate (create, update, delete) data analysis sessions</td>
<td>DA</td>
<td></td>
<td>TUC 5.3</td>
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<tr>
<td>R209</td>
<td>Notification when</td>
<td>System Administra</td>
<td>SMART BEAR Backend should notify end-users when a analysis is complete</td>
<td>Indifferent</td>
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<tr>
<td>Requirement</td>
<td>Description</td>
<td>Responsible Roles</td>
<td>SMART BEAR Backend Responsibility</td>
<td>Acceptance Criteria</td>
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<tr>
<td>R210</td>
<td>Visualizations of the analysis outcome</td>
<td>System Administrator</td>
<td>SMART BEAR Backend should be able to provide visualizations of the analysis outcome</td>
<td>DV</td>
<td>TUC 6.1</td>
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<tr>
<td>R211</td>
<td>Support of progressive notifications and save of the outcomes on data analysis</td>
<td>Data Scientist</td>
<td>SMART BEAR Backend should be able to send progressive notifications and save the outcomes accordingly when (25%, 50%, 75% and 100% of the) minimal data set has been analysed.</td>
<td>Indifferent, Reverse</td>
<td></td>
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<tr>
<td>R212</td>
<td>Access management features for the analysis outcomes</td>
<td>Policy Maker</td>
<td>SMART BEAR Backend should be able to provide features of access management for the analysis outcomes related to a policy formulation process. Outcomes should be able to be accessed by individual stakeholders, who should be able to express their views regarding the analysis outcome</td>
<td>Indifferent</td>
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<tr>
<td>R213</td>
<td>Visualize comparative data analysis sessions</td>
<td>Data Scientist</td>
<td>SMART BEAR Backend should be able to visualize comparative data analysis sessions</td>
<td>DV</td>
<td>TUC 6.1</td>
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<tr>
<td>R214</td>
<td>Data Quality</td>
<td>System</td>
<td>SMART BEAR Backend assess the quality of the data collected and classify them based on the quality reached during data collection and transfer</td>
<td>Non functional (linear)</td>
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<tr>
<td>R215</td>
<td>Different visualization modes of the recorded data</td>
<td>Data Scientist</td>
<td>SMART BEAR Backend should be able to provide different visualization modes of the recorded data, both on a single and an aggregated level</td>
<td>DV</td>
<td>TUC 6.1</td>
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<tr>
<td>R216</td>
<td>Collect timestamped data related to an event or configurable period</td>
<td>Data Scientist, System Administrator</td>
<td>The SMART BEAR Backend should be able to collect timestamped data related to this event for a configurable period between before the event occurrence and after it</td>
<td>Indifferent</td>
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<tr>
<td>R217</td>
<td>Manage and System</td>
<td>SMART BEAR Backend should be able to manage and visualize the detected</td>
<td>Indifferent</td>
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<tr>
<td>Requirement</td>
<td>Action</td>
<td>Responsible Parties</td>
<td>Description</td>
<td>Role</td>
<td>Details</td>
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<td>R218</td>
<td>Visualize a detected event log</td>
<td>Data Scientist</td>
<td>SMART BEAR Backend should be able to visualize a list of data types that are collected in the platform.</td>
<td>DM DA</td>
<td>TUC 3.3 TUC 5.2</td>
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<tr>
<td>R219</td>
<td>Select from a list of data types</td>
<td>Data Scientist</td>
<td>SMART BEAR Backend should be able to allow to select from a list of data types, those that are of interest for them</td>
<td>DM DA</td>
<td>TUC 3.3 TUC 5.2</td>
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<tr>
<td>R220</td>
<td>Record the patient’ responses to various standardized questionnaires</td>
<td>System Administrator Auditor</td>
<td>SMART BEAR Backend should be able to record the patient’ responses to various standardized questionnaires</td>
<td>UM DM</td>
<td>TUC 1.4 TUC 3.1</td>
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<tr>
<td>R221</td>
<td>Create record for SMART BEAR device fitting</td>
<td>System Administrator Auditor</td>
<td>SMART BEAR Backend should be able to Create record for SMART BEAR device fitting</td>
<td>INM</td>
<td>TUC 2.3</td>
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<tr>
<td>R222</td>
<td>SMART BEAR platform deployed on elastic cloud</td>
<td>System</td>
<td>SMART BEAR Backend will be deployed on elastic cloud infrastructures</td>
<td>Indifferent</td>
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<tr>
<td>R223</td>
<td>SMART BEAR platform deployed on redundant cloud infrastructure</td>
<td>System</td>
<td>SMART BEAR Backend will be deployed on redundant cloud infrastructure</td>
<td>Indifferent</td>
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<tr>
<td>R224</td>
<td>SMART BEAR platform analyzes. outcome measures</td>
<td>System Administrator</td>
<td>SMART BEAR Backend should be able to manage outcome measurement units</td>
<td>The measure of heart rate, body temperature, etc.</td>
<td>Indifferent</td>
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<tr>
<td>R225</td>
<td>Associate outcome measures with collected SMART BEAR device usage data and patients’ feedback</td>
<td>System Administrator, Clinician, Auditor</td>
<td>SMART BEAR Backend should be able to associate outcome measures with collected SMART BEAR device usage data and the patients’ feedback</td>
<td>INM</td>
<td>TUC 2.3</td>
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<td>R226</td>
<td>Access to questionnaires’ answers</td>
<td>System Administrator, Auditor</td>
<td>SMART BEAR Backend should provide access to questionnaires’ answers</td>
<td>UM</td>
<td>TUC 1.4</td>
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<tr>
<td>R227</td>
<td>Analyze questionnaires’ answers</td>
<td>System Administrator, Auditor</td>
<td>SMART BEAR Backend should be able to analyze questionnaires’ answers</td>
<td>DM, DA, DV</td>
<td>TUC 3.1 TUC 5.2 TUC 6.1 TUC 6.2 TUC 6.3</td>
<td></td>
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<tr>
<td>R228</td>
<td>Access to objective recording about SMART BEAR device malfunctions and related problems of SMART BEAR device users</td>
<td>System Administrator, Auditor</td>
<td>SMART BEAR Backend should provide access to objective recording about SMART BEAR device malfunctions and related problems of SMART BEAR device users</td>
<td>INM</td>
<td>TUC 2.2</td>
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<tr>
<td>R229</td>
<td>Analyze issues, concerns and problems with SMART BEAR devices reported by SMART BEAR devices users</td>
<td>System Administrator, Auditor</td>
<td>SMART BEAR Backend should be able to analyze issues, concerns and problems with SMART BEAR devices reported by SMART BEAR devices users</td>
<td>INM</td>
<td>TUC 2.2</td>
<td></td>
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<tr>
<td>R230</td>
<td>Register/update/cancel</td>
<td>System Administrator</td>
<td>SMART BEAR Backend should be able to register/update/cancel a new user</td>
<td>UM</td>
<td>TUC 1.1 TUC 1.2</td>
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<tr>
<td>Requirement</td>
<td>Description</td>
<td>Role(s)</td>
<td>SMART BEAR Backend should be able</td>
<td>User Access</td>
<td>TUC Numbers</td>
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<tr>
<td>R231</td>
<td>Assign a role to the user</td>
<td>System Administrator, Auditor</td>
<td>to assign a role to the user</td>
<td>UM</td>
<td>TUC 1.1, TUC 1.2, TUC 1.3</td>
<td></td>
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<tr>
<td>R232</td>
<td>Assign access right to roles</td>
<td>System Administrator, Auditor</td>
<td>to assign access right to roles</td>
<td>UM</td>
<td>TUC 1.1, TUC 1.2, TUC 1.3</td>
<td></td>
</tr>
<tr>
<td>R233</td>
<td>Insert a new algorithm</td>
<td>System Administrator</td>
<td>to insert a new data analytics algorithm</td>
<td>DA</td>
<td>TUC 5.1</td>
<td></td>
</tr>
<tr>
<td>R234</td>
<td>Configure an algorithm (parameters, data sources)</td>
<td>System Administrator</td>
<td>to configure an algorithm (parameters, data sources)</td>
<td>DA</td>
<td>TUC 5.1, TUC 5.2, TUC 5.3</td>
<td></td>
</tr>
</tbody>
</table>
### Legal Requirements

**Table 30 Legal Requirements**

<table>
<thead>
<tr>
<th>#</th>
<th>Name</th>
<th>Role</th>
<th>Description</th>
<th>Notes</th>
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<tbody>
<tr>
<td>R301</td>
<td>Privacy of cloud data</td>
<td>System Auditor</td>
<td>Data stored in the Backend platform are anonymized</td>
<td></td>
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<tr>
<td>R302</td>
<td>Consent for Personal Data</td>
<td>System Auditor</td>
<td>A consent must be signed before to start acquiring personal data</td>
<td></td>
</tr>
<tr>
<td>R303</td>
<td>Implement privacy by design</td>
<td>System Auditor</td>
<td>The SMART BEAR Project and Platform shall implement appropriate technical and organizational measures which are designed to implement the data protection principles (lawfulness, fairness &amp; transparency; purpose limitation; data minimization; accuracy; storage limitation; integrity &amp; confidentiality; accountability).</td>
<td></td>
</tr>
<tr>
<td>R304</td>
<td>Implement privacy by default</td>
<td>System Auditor</td>
<td>The SMART BEAR Project and Platform shall implement, per processing activity, appropriate technical and organizational measures which are designed to implement data-protection principles and that ensure that by default only personal data which are necessary for each specific purpose of the processing are processed.</td>
<td></td>
</tr>
<tr>
<td>R305</td>
<td>Implement measures to demonstrate compliance</td>
<td>System Auditor</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>R306</td>
<td>Respect data subject rights</td>
<td>System Auditor</td>
<td>The SMART BEAR Platform and Project shall, among others by means of appropriate technical and organizational measures, allow for data subjects to exercise their rights in relation to the processing of their personal data.</td>
<td></td>
</tr>
<tr>
<td>R307</td>
<td>Obtain consent</td>
<td>System Auditor</td>
<td>Where appropriate, the SMART BEAR Platform shall, when processing personal data of data subjects, do so on the basis of consent, and will take all necessary measures to allow for that consent to meet the applicable conditions.</td>
<td>Reference to mobile app requirements</td>
</tr>
<tr>
<td>R308</td>
<td>Provide information</td>
<td>System Auditor</td>
<td>The SMART BEAR Platform and Project shall provide, in an appropriate manner, data subjects all required information about the processing of their personal data.</td>
<td></td>
</tr>
<tr>
<td>R309</td>
<td>Prevent transfers of personal data outside the EEA</td>
<td>Data Scientist Auditor</td>
<td>The SMART BEAR Platform and Project shall not transfer any personal data outside of the European Economic Area, except if appropriate legal means are put in place to allow for such international transfer.</td>
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</tr>
<tr>
<td>R310</td>
<td>Address the contractual relationship with processors and joint-controllers</td>
<td>System Auditor</td>
<td>The SMART BEAR Project and Platform shall ensure the required contracts, legal acts or arrangements are put in place when third parties process personal data on its behalf or when personal data are processed jointly with other third parties.</td>
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<td>Auditor</td>
<td>Compliance</td>
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<tr>
<td>R311</td>
<td>Maintain records of processing activities</td>
<td>System Auditor</td>
<td>The SMART BEAR Project shall maintain records of processing activities.</td>
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<tr>
<td>R312</td>
<td>Implement security measures</td>
<td>System Auditor</td>
<td>The SMART BEAR Project and Platform shall, in order to ensure the rights and freedoms of individuals when processing their personal data, implement appropriate technical and organizational security measures appropriate to the risk.</td>
<td></td>
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<tr>
<td>R313</td>
<td>Notify and communicate personal data breaches</td>
<td>System Auditor</td>
<td>The SMART BEAR Project and Platform shall take all necessary measures to detect security and data incidents, and to allow for the notification of personal data breaches to the supervisory authority and, if necessary, to the data subjects.</td>
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<tr>
<td>R314</td>
<td>Conduct data protection impact assessments</td>
<td>System Auditor</td>
<td>The SMART BEAR Project and Platform shall, where necessary, conduct data protection impact assessments.</td>
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<tr>
<td>R315</td>
<td>Implement pseudonymization, anonymization or deletion</td>
<td>System Auditor</td>
<td>The SMART BEAR Platform shall pseudonyms, anonymize or delete personal data, where deemed appropriate, in order to comply with the core data protection principles.</td>
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<tr>
<td>R316</td>
<td>Allow for the DPO to fulfill his tasks</td>
<td>System Auditor</td>
<td>The SMART BEAR Project shall allow for the data protection officer it has appointed to fulfil its tasks.</td>
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<td>R317</td>
<td>Ensure compatibility of software licences</td>
<td>System Auditor</td>
<td>The SMART BEAR Platform shall ensure that the licenses for the software used in the SMART BEAR platform are compatible in order for the SMART BEAR platform to remain, where necessary and deemed appropriate, under a permissive open source license.</td>
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<tr>
<td>R318</td>
<td>Respect third-party rights</td>
<td>System Auditor</td>
<td>The SMART BEAR Project and Platform shall consider and respect the rights of third parties, especially with respect to ownership of data, intellectual property rights on data and databases, confidentiality agreements and/or trade secrets attached to certain data sets.</td>
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</table>

### 5.4 Analysis of the Kano questionnaire

The lists of requirements that we prepared are evaluated by proposing a questionnaire to the entire group of technical experts of the SMART BEAR project. The questionnaire was designed and analyzed using the Kano model, presented in Section 3.4, and will be from now referred as Kano Questionnaire (KQ). The KQ for SMART BEAR has been structured in two independent categories of requirements SMART BEAR @ HOME and SMART BEAR backend.

**Questions formulation.** Questions should be as clear and succinct as possible. Also, questions should avoid polar wording, especially in the dysfunctional form. We have 41 questions for SMART BEAR @ HOME and 34 questions for SMART BEAR backend category. Figure 22 shows an example of question for the SMART BEAR @ HOME requirements.
To answer each question, you can choose one of five different options described in Section 3.4.2. Process and analysis of results: Once having combined the answers to the functional and dysfunctional question in the KET evaluation, the classification of the individual requirements can be summarised. Table 31 shows the number of respondents who responded to the two groups of the KQ for SMART BEAR platform.

Table 31 The number of respondents for two group of KQ for SMART BEAR platform

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<th>Number of respondents</th>
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<td>SMART BEAR backend</td>
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Table 32 summarises the answers of questions in group of SMART BEAR @ HOME and Table 33 summarises the answers of questions in group of SMART BEAR backend. Boldface numbers indicate the most frequently occurring answer for a given question which is getting more than 50% of the preference, or the two categories getting the most preferences.

Table 32 Table of results for SMART BEAR @ HOME requirements

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<tr>
<th>Requirement</th>
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<th>Linear</th>
<th>Exciter</th>
<th>Questionable</th>
<th>Reverse</th>
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Another technique to interpret the KET has been presented by Mike Timko of Analog Devices, who proposed using the Satisfaction and Dissatisfaction coefficients [80]. The coefficients indicate, in numerical terms, how

<table>
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<th>Requirement</th>
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<th>Questionable</th>
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strongly a requirement may influence satisfaction or, in case it is not fulfilled, stakeholders' dissatisfaction. In the original paper, Timko labels the Satisfaction and Dissatisfaction coefficients as “Better” and “Worse”, respectively. By considering the total number of answers in each Kano category for a given requirement, the Better and Worse values can be calculated using the following formulas:

Better coefficient after increase = \( \frac{A+O}{A+O+M+I} \) (2.1)

The worse coefficient after reduction = \( \frac{O+M}{A+O+M+I} \) × (-1) (2.2)

The satisfaction and dissatisfaction coefficients provide a better discrimination among requirements. Better-The worse coefficient is used to measure the effect of a certain function in increasing satisfaction or reducing dislike. Better coefficient measures the satisfaction after some increase. The value of Better is usually positive, representing that if a certain functional quality is present, the users' satisfaction will be improved. The larger the positive value is, the greater the effect in increasing the users' satisfaction and the higher the increase rate will be. The worse coefficient is a measure of dissatisfaction after the reduction. The value of Worse is usually negative, representing that if a certain functional quality is absent, the users' satisfaction degree will lower. The larger the negative value, the greater its effect in lowering the satisfaction degree and the faster the decrease rate will be. The Better and Worse values capture this difference. See Table 34 and Table 35.

The methodologies described above to analyse the results of the KQ are based on the categories resulting from the application of the Kano Evaluation Table 34 and Table 35. However, using the KET leads to the loss of a considerable amount of information: from 21 possible combinations of answers for each requirement of SMART BEAR @ HOME and for 20 possible combinations of answers for each requirement of SMART BEAR Backend and from each respondent to just one of six Kano categories.

Table 34 The customer satisfaction coefficient of the requirements in SMART BEAR @ HOME

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<th>Reverse</th>
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<td>0.00</td>
<td>5.56</td>
<td>5.56</td>
<td>100.0</td>
<td>0.52</td>
<td>-0.82</td>
</tr>
<tr>
<td>Req.31</td>
<td>38.89</td>
<td>33.33</td>
<td>11.11</td>
<td>0.00</td>
<td>5.56</td>
<td>11.11</td>
<td>100.0</td>
<td>0.47</td>
<td>-0.76</td>
</tr>
<tr>
<td>Req.32</td>
<td>38.89</td>
<td>22.22</td>
<td>11.11</td>
<td>0.00</td>
<td>5.56</td>
<td>22.22</td>
<td>100.0</td>
<td>0.35</td>
<td>-0.64</td>
</tr>
<tr>
<td>Req.33</td>
<td>11.11</td>
<td>38.89</td>
<td>27.78</td>
<td>0.00</td>
<td>0.00</td>
<td>22.22</td>
<td>100.0</td>
<td>0.66</td>
<td>-0.5</td>
</tr>
<tr>
<td>Req.34</td>
<td>25.00</td>
<td>30.00</td>
<td>20.00</td>
<td>0.00</td>
<td>0.00</td>
<td>25.00</td>
<td>100.0</td>
<td>0.50</td>
<td>-0.55</td>
</tr>
</tbody>
</table>

According to the values of better-the worse coefficient in Table 34 for SMART BEAR @ HOME, the scatter plot is divided into four quadrants (see Figure 23).
According to the values of better-the worse coefficient in Table 35 for SMART BEAR backend, the scatter plot is divided into four quadrants (see Figure 24).

![Figure 24 Chart of Worse-Better for SMART BEAR backend]

In the first quadrant: the better coefficient is high, while the absolute value of the worse coefficient is low. Requirements (R) fall into this quadrant, indicating that when this function is not provided, the users' satisfaction will not decline; but when these requirements are provided, the users' satisfaction will greatly improve.

In the second quadrant: the better coefficient is low, and so is the absolute value of the worse coefficient. Requirements (R) falls into this quadrant, indicating whether this function is provided or not, the users' satisfaction will not change. The users concern the least with these functions.

In the third quadrant: the better coefficient is low, while the absolute value of the worse coefficient is high. Requirements (R) fall into this quadrant, indicating that when the product provides this function, the users' satisfaction will not improve; but when the product does not provide this function, the users' satisfaction will decline significantly. Thus, the functions falling into this quadrant are the fundamental functions.

In the fourth quadrant: the better coefficient is high and so is the absolute value of the worse coefficient. Requirements (R) fall into this quadrant, indicating that when the product provides this function, the users' satisfaction will increase; if the function is not provided, the users' satisfaction will decline.

The results obtained from our KET analysis show a poor shared vision between the technical experts of the project and call for further integration activities to be developed in the requirement integration workshop the project has scheduled.

The analysis of the results of the Kano model provided a great support to the alignment of the different point of view and languages of the technical partners. The requirements listed in KQ was not aimed at offering a complete coverage of the platform requirements but acted as representative of class of requirements to be extended by the technical used cases. The analysis of the Kano model allowed us to verify the coverage of all functional areas and to improve our understanding about converging or diverging aspects. The results reported in Table 32 and Table 33 demonstrate a the functional areas we identified are offering a complete coverage of the functionalities brainstormed by the technical partners. At the same time some of the brainstormed requirements resulted irrelevant or undesired. Using this results the definition of the technical use case has benefited of guidelines and limiting factors, minimizing the risk of producing irrelevant specification.
5.5  **Technical Use Cases**

5.5.1  **Functional Area: User Management**

5.5.1.1  **TUC 1.1 - Create Account**

*Table 36 Use Case: Create Account*

<table>
<thead>
<tr>
<th>Name</th>
<th>Create Account</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>The Create Account use case allows the Administrator to create an account.</td>
</tr>
<tr>
<td>Actor(s)</td>
<td>System Administrator</td>
</tr>
</tbody>
</table>

**Flow of Events**

**Basic Flow**

1. This use case starts when the Administrator accesses the SMART BEAR platform (system) feature that enables him/her to create an account by entering information that is maintained in the User’s account.
2. The Administrator enters the required *User Account* information, selects the typology of users (Patient, Physician, ...), and saves it.
3. The system validates the entered *User Account* information.
4. The values are stored in the User’s account. The system notifies the Administrator that the new account has been created.
5. The use case ends

**Alternate Flows**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>User Cancels Request</td>
<td>At any time, the Administrator may choose to cancel the account creation. At this point, the processing is rolled back, the user account remains unchanged, and the Administrator is notified that the account management request has been cancelled.</td>
</tr>
</tbody>
</table>
| User Enters Invalid User Account Information | If during *Create Account*, the system determines that the Administrator entered invalid *User Account* information, the following occurs:  
  The system point out which data is not valid and provides the Administrator with suggestions for entering valid data.  
  The system prompts the Administrator to insert again the invalid information.  
  The Administrator re-enters the information and the system validates it again.  
  If valid information is entered, the User Account Information is stored.  
  If invalid information is entered, the *Entered Information is Invalid* alternative flow is executed again. This continues until the Administrator enters valid information or selects Cancel (see the *User Cancels Account Management Request* alternative flow).  
  Invalid *User Account* information:  
  Missing information items  
  Username already exists in the system  
  *User Account* information entered does not comply to its definition in the glossary |
<table>
<thead>
<tr>
<th>Pre-Conditions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td><strong>Description</strong></td>
</tr>
<tr>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Post-Conditions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td><strong>Description</strong></td>
</tr>
<tr>
<td>Success</td>
<td>The inserted data is stored in the user account. (Optional) Confirmation is sent to the appropriate email address.</td>
</tr>
<tr>
<td>The user account was not created</td>
<td>The User entered invalid data or chose to cancel the account creation request. In either case, no account will be created.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Extension Points</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>
5.5.1.2  TUC 1.2 - Sign in

Table 37 Use Case: Sign in

<table>
<thead>
<tr>
<th>Name</th>
<th>Sign in</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>A user signs in the system taking a Role</td>
</tr>
<tr>
<td>Actor(s)</td>
<td>Any Role</td>
</tr>
</tbody>
</table>

Flow of Events

Basic Flow

1. This use case starts when the User accesses the sign-in function of the system.
2. The system prompts the User for his/her username and password.
3. The User enters his/her username and password.
4. The system validates the entered username/password, making sure that they match with the respective user account in the system.
5. The User is signed in. The system displays a message indicating that the user has signed in.
6. The use case ends.

Alternate Flows

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>New User</td>
<td>If the User does not have an account, the System will give the User the opportunity to create an account. See the Create Account use case. Once the account is created, the User is considered signed in.</td>
</tr>
<tr>
<td>User Forgot Username Password</td>
<td>If the User forgets his/her username or password, the System will prompt the user to answer his/her security question provided in the Create Account stage. Provided that it is answered correctly, the username and password are emailed to the email address provided when the account was created.</td>
</tr>
<tr>
<td>User Fails Authentication</td>
<td>If the User entered an invalid username and/or password, the following occurs: The system describes the reasons why the User failed authentication. The system prompts the User to re-enter the valid information. The Basic Flow continues where the User enters new information (see step 2).</td>
</tr>
</tbody>
</table>

Pre-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed Consent</td>
<td>The Informed Consent registration flow allows the User to give his authorization to take part to the Smart Bear experimentation and to give access to his medical data to authorized medical authority. This flow starts when the user reads the informed consent text and signs the document electronically in the User’s account.</td>
</tr>
</tbody>
</table>
1. The User indicates that he/she has read the document and approved the document by cross-checking a button “Read and approved”.
2. The system validates the user’s approval and saves the date of this approval.
3. The values for the user’s approval are stored in the User’s account. The system notifies the User that his approval is validated.

Alternate Flow:
1. The clinician or pilot leader can collect the User’s informed consent. The User signed manually the informed consent document.
2. The clinician or pilot leader scan as PDF the informed consent document.
3. The clinician or pilot leader enters the User’s profile and uploads the scanned informed consent document into the dedicated space.
4. The system notifies the User that his/her decision is validated

Post-Condition
1. The User decides to cancel his informed consent. She/he enters the profile and unclick the box of informed consent.
2. The system validates the user’s decision and saves the date of this decision.
3. The values for the user’s decision to cancel his/her informed consent are stored in the User’s account. The system notifies the User that his/her decision is validated.
4. If the informed consent was scanned and uploaded into the User’s profile by the clinician or Pilot leader. Then, the clinician or Pilot leader must have the User to sign a document which states the his/her decision not to give the informed consent. Finally, the clinician or Pilot Leader must scan this document and upload it into the dedicated space.
5. The system notifies the User that the decision is validated.

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success</td>
<td>The User is authenticated, and the system displays all features available for the role the user is associated with, as defined in his/her user account.</td>
</tr>
<tr>
<td>User not signed in</td>
<td>This can occur because the User repeatedly entered invalid sign in information. The User has been notified of the reason why he/she was not signed in. The User is not authenticated and remains in the Anonymous User role.</td>
</tr>
</tbody>
</table>

### 5.5.1.3 TUC 1.3 - Manage Account

*Table 38 Use Case: Manage Account*

<table>
<thead>
<tr>
<th>Name</th>
<th>Manage Account</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>The Manage Account use case allows the User to update the User Account Information maintained in the User’s account.</td>
</tr>
<tr>
<td>Actor(s)</td>
<td>Registered User</td>
</tr>
<tr>
<td>Flow of Events</td>
<td></td>
</tr>
</tbody>
</table>
### Basic Flow

This use case starts when the User accesses the system function that enables him/her to update the information that is maintained in the User's account.

1. The system displays the User Account information currently stored for the User.
2. The User enters the updated User Account information values and requests that the system saves the entered values.
   1. Applications to be made available for the user.
   2. Notification settings.
   5. Authentication procedure.
3. The system validates the entered User Account information.
4. The values for the User Account information are stored in the User’s account. The system notifies the User that the account has been updated.
5. The use case ends.

### Alternate Flows

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>User Cancels Request</td>
<td>At any time, the User may choose to cancel the account update/deactivation. At which point, the processing is discontinued, the user account remains unchanged, and the user is notified that the account management request has been cancelled.</td>
</tr>
<tr>
<td>User Enters Invalid User Account Information</td>
<td>If during Modify Account, the system determines that the User entered invalid User Account information, the following occurs: 6. The system points out which data were invalid and presents the User with suggestions for entering valid data. 7. The system prompts the User to re-enter the invalid information. 8. The User re-enters the information and the system re-validates it. 9. If valid information is entered, the User Account Information is stored. If invalid information is entered, the Entered Information is Invalid alternative flow is executed again. This continues until the User enters valid information or chooses Cancel (see the User Cancels Account Management Request alternative flow). Invalid User Account information:  - Missing information items  - Username already exists in the system  - User Account information entered does not comply to its definition in the glossary  - Not well-formed e-mail address  - Offending words in any part of the User Account information</td>
</tr>
</tbody>
</table>

### Pre-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>User is signed in</td>
<td>The User must be signed in before the User can edit or deactivate his/her account. See the Sign In use case</td>
</tr>
</tbody>
</table>
### Post-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success</td>
<td>The User entered data is stored in the user account.</td>
</tr>
<tr>
<td>The user account was not</td>
<td>The User entered invalid data or chose to cancel the account management request. In either case, there is no change to the user account.</td>
</tr>
<tr>
<td>updated</td>
<td></td>
</tr>
</tbody>
</table>

### Extension Points

None

---

### 5.5.1.4 TUC 1.4 - Admin Configures Mobile App

**Table 39 Use Case: The Administrator Configures the Mobile App**

<table>
<thead>
<tr>
<th>Name</th>
<th>The Administrator Configures the Mobile App</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>This use case allows the System Administrator to update users’ configuration.</td>
</tr>
<tr>
<td>Actor(s)</td>
<td>System Administrator</td>
</tr>
</tbody>
</table>

**Flow of Events**

**Basic Flow**

This use case starts when the System Administrator accesses the system to configure the Mobile App.

1. The System displays the User Account currently stored in the System.
2. The System Administrator selects the User Account it wants to configure.
3. The System Administrator selects the Application it wants to configure.
4. The System Administrator assigns a value for each parameter that can be configured in the Application.
5. The System Administrator repeats steps 3 and 4 if needed.
6. The System Administrator repeats steps 2 if needed.
7. The use case ends.

**Alternate Flows**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancel action</td>
<td>At any time, the System administrator can cancel its previous action.</td>
</tr>
</tbody>
</table>

### Pre-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
</table>

### D5 - SMART BEAR Requirements

<table>
<thead>
<tr>
<th>Users’ account exists</th>
<th>The user account already exists in the system.</th>
</tr>
</thead>
</table>

#### SMART BEAR Applications are in the system

SMART BEAR Applications are listed in the mobile app.

<table>
<thead>
<tr>
<th>Post-Conditions</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMART BEAR Applications are in the system</td>
<td>SMART BEAR Applications are listed in the mobile app</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-Conditions</td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>Description</td>
</tr>
<tr>
<td>Success</td>
<td>The mobile App is updated and its functioning on the user device changes.</td>
</tr>
<tr>
<td>The user account was not updated</td>
<td>The User entered invalid data or chose to cancel the account management request. In either case, there is no change to the user account.</td>
</tr>
</tbody>
</table>

#### Extension Points
None

---

### 5.5.1.5 TUC 1.5 - User Configures Mobile App

**Table 40 Use Case: The User Configures the Mobile App**

<table>
<thead>
<tr>
<th>Name</th>
<th>The User Configures the Mobile App</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>This use case allows the User to update the configuration settings it has access to.</td>
</tr>
<tr>
<td>Actor(s)</td>
<td>System Administrator</td>
</tr>
</tbody>
</table>

**Flow of Events**

**Basic Flow**
This use case starts when the User accesses the system to configure the Mobile App.

1. The System displays an area dedicated to user configuration settings.
2. The User selects the parameters to configure.
3. The User assigns a value for each parameter that can be configured in the configuration settings area.
4. The User repeats steps 2 and 3 if needed.
5. The use case ends.

**Alternate Flows**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancel action</td>
<td>At any time, the User can cancel its previous action.</td>
</tr>
</tbody>
</table>
### Pre-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Users’ account exists</td>
<td>A configuration setting area exists in the mobile App.</td>
</tr>
</tbody>
</table>

### Post-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success</td>
<td>The mobile App is updated and its functioning on the user device change.</td>
</tr>
<tr>
<td>The user account was not</td>
<td>The User entered invalid data or chose to cancel the account management request. In either case, there is no change to the user account.</td>
</tr>
<tr>
<td>updated</td>
<td></td>
</tr>
</tbody>
</table>

### Extension Points

None

---

### 5.5.1.6 TUC 1.6 Participant registration

*Table 41 Use Case: Participant registration - General user’s information*

<table>
<thead>
<tr>
<th>Name</th>
<th>Participant registration - General user’s information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>The participant registration use case allows the User to fill all the information concerning:</td>
</tr>
<tr>
<td></td>
<td>• profile (name, telephone, email etc.),</td>
</tr>
<tr>
<td></td>
<td>• notification preferences,</td>
</tr>
<tr>
<td></td>
<td>• health insurance data,</td>
</tr>
<tr>
<td>Actor(s)</td>
<td>System Administrator</td>
</tr>
</tbody>
</table>

### Flow of Events

**Basic Flow**

This use case starts when the user fills his personal data included in the User’s account.

1. The System Administrator enters the required information:
   a. user’s profile and preferences (language, health insurance data).
   b. monitoring/intervention functions (and related sensors)
   c. equipment (among a finite number of devices)
   d. notification procedures (frequency, channels (app, tablet), recipients (doctors, caregivers))
   e. interactive activities.
   f. data storage plan (frequency local/remote data are transferred).
2. The system validates the entered *User Account* information.
3. The values for the *User’s personal data* are stored in the User’s account. The system notifies the System Administrator that the editing has been validated.

4. The process ends.

### Alternate Flows

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>User modifies data</td>
<td>At any time, the System Administrator may choose to edit each field of personal data. The user validates the new edited data and is notified by the system that the modifications are taken into account</td>
</tr>
</tbody>
</table>

### Pre-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creation account done</td>
<td>The User can only modify his/her profile preferences once the account is created</td>
</tr>
</tbody>
</table>

### Post-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>The user editing is not</td>
<td>The User chooses to cancel the edited data. In either case, no editing is taken into account and the previously saved information remains valid.</td>
</tr>
<tr>
<td>taken into account</td>
<td></td>
</tr>
</tbody>
</table>

### Extension Points

None

---

**5.5.1.7 TUC 1.7 - Generate Interactive activities**

*Table 42 Use Case: Generate interactive activities*

<table>
<thead>
<tr>
<th>Name</th>
<th>Generate interactive activities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brief Description</strong></td>
<td>Clinicians frequently raise questions about patient. Clinicians may self-select simpler and more urgent questions. Information interventions should allow clinicians to easily estimate the value of information in terms of its perceived benefits and cost, with a high threshold for engaging in information seeking as early as possible with minimal cognitive effort.</td>
</tr>
<tr>
<td><strong>Actor(s)</strong></td>
<td>System Administrator</td>
</tr>
<tr>
<td><strong>Flow of Events</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Basic Flow</strong></td>
<td></td>
</tr>
</tbody>
</table>
This use case starts when the clinicians insert questions in the SMART BEAR platform.

1. The clinicians enter the interactive activity: (Women’s or men’s), (medical history), (history of any mental health problem), (history of a chronic physical health problem), (the quality of patient interpersonal relationships), (living conditions and social isolation), (any family history of mental health problems), (her employment and immigration status), (health insurance), etc.

2. The system validates the entered Clinicians questions.

3. The values for the Clinicians questions data are stored in the Clinicians account. The system notifies the patient that the questions should be answered.

4. The use case ends.

### Alternate Flows

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
</table>
| Creation questions done       | - What additional support is patient likely to need with her/him medicines?  
                                  - support for some groups of people (including older people who are taking multiple medicines), clinicians’ practitioners should explain to patients, and their family members, how to identify and report medicines-related patient safety incidents.  
                                  - What additional support to have suitable tool to help patients, and why?  
                                  - What factors should you consider in patient risk assessment and monitoring?  
                                  - What further action could patient take? |

### Pre-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
</table>

### Post-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
</table>

### Extension Points

None

### 5.5.1.8 TUC 1.8 – Recording the Patient Response

Table 43 Use Case: Recording the Patient Response

<table>
<thead>
<tr>
<th>Name</th>
<th>Recording the Patient Response</th>
</tr>
</thead>
</table>
| Brief Description| Patient answers must be clearly reflected in the domain knowledge included in programs for disease management by clinicians and wellness.  
                                  Patient responses were developed as clinical systems to help improve medical care and for use in medical research. |
| Actor(s)        | System                         |
Flow of Events

Basic Flow

This use case starts when the patient fills answers to the questions that received from clinicians.

1. The patient enters the answers: (Women’s or men’s), (medical history), (history of any mental health problem), (history of a chronic physical health problem), (the quality of patient interpersonal relationships), (living conditions and social isolation), (any family history of mental health problems), (her employment and immigration status), (health insurance), etc.

2. The system validates the entered Patient Responses.

3. The values for the Patient Responses are stored in the User Account. The system notifies the clinicians that the answers have been received.

4. The use case ends.

Alternate Flows

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
</table>
| Communicate with Clinicians                | • Patient response for “What factors should you consider in patient risk assessment and monitoring?”
|                                            | • Whether the person has any risk factors for developing adverse drug reactions (report adverse drug reactions to clinician part).
|                                            | • Patient sends a secure communication to clinician potentially via clinician support |
|                                            | • Clinician support may forward communication to an appropriate clinician |
|                                            | • Message content may be supported by tools to support clinician workflow |
|                                            | • Clinician responds to clinician support and/or directly to the patient; may include patient data; Clinician or clinician support communicates response to the patient |

Pre-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Send response</td>
<td>A patient logs into the SMART BEAR tool using the appropriate login and password. From there, the clinician’s questions can be opened and read. The patient sends his/her answer to clinicians.</td>
</tr>
<tr>
<td>Update tool with result of Communication and response</td>
<td>After reading a clinician’s question, the patient may update existing personal health records. The patient may also take other clinical actions as appropriate based on the communication. SMART BEAR tools typically include the ability for the system to automatically track communications sent and received, providing an audit trail of communications and the ability to revisit past communications as necessary.</td>
</tr>
<tr>
<td>Confirm receipt and evaluation of patient communication</td>
<td>A message receipt confirmation may be automatic within the communication tool and is intended to alert the patient that communication has been received.</td>
</tr>
</tbody>
</table>

Post-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
</table>
• This response may be discussed with the clinician. If a patient communication indicates a need for emergency care or another medical intervention, the clinician should always be notified. The response could occur in SMART BEAR mobile App.

OR

• Forwards the information along with other relevant clinical information to the clinician for a response. This could be accomplished using the workflow capabilities of the clinicians.

Extension Points

None

5.5.2 Functional Area: IoT Network Management

5.5.2.1 TUC 2.1 - Register Device

Table 44 Use Case: Register Device

<table>
<thead>
<tr>
<th>Name</th>
<th>Register Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>The Smart Bear @ Home (SB@H) administrator registers the devices used to acquire data</td>
</tr>
<tr>
<td>Actor(s)</td>
<td>System Administrator</td>
</tr>
</tbody>
</table>

Flow of Events

Basic Flow

This use case starts when the administrator SB@H sign on the platform. The administrator:

1. Selects the settings menu.
2. Selects a method to add the device.
3. Start the pairing phase.
4. The system shows all the interfaces exposed by the device.
5. A communication test for each interface is executed.
6. Add the device to the platform.
7. The process ends.

Alternate Flows

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancel action</td>
<td>At any time, the System administrator can cancel its previous action.</td>
</tr>
</tbody>
</table>

Table 44 Use Case: Register Device
### Communication failure
If the system reports a communication failure the device must be tested.

#### Pre-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creation account done</td>
<td>The Admin can only enter his/her profile data once the account is created</td>
</tr>
</tbody>
</table>

#### Post-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>The SB@H acquires data from the added device</td>
<td>The added device streams data to the SB@H platform</td>
</tr>
</tbody>
</table>

#### Extension Points
None

---

### 5.5.2.2 TUC 2.2 - Configure Device

**Table 45 Use Case: Configure Device**

<table>
<thead>
<tr>
<th>Name</th>
<th>Configure Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>The SB@H administrator configures the devices used to acquire data</td>
</tr>
<tr>
<td>Actor(s)</td>
<td>System Administrator</td>
</tr>
</tbody>
</table>

#### Flow of Events

**Basic Flow**

This use case starts when the SB@H administrator signs on the platform.

The admin:

1. Selects the settings menu.
2. Selects the option “configure device”.
3. Changes the data configuration.
4. Confirms the data.
5. The system runs a communication test.
6. The process ends.

#### Alternate Flows

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancel action</td>
<td>At any time, the System administrator can cancel its previous action.</td>
</tr>
<tr>
<td>Title</td>
<td>Description</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Communication failure</td>
<td>If the system reports a communication failure the device must be tested.</td>
</tr>
</tbody>
</table>

**Pre-Conditions**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creation account done</td>
<td>The Admin can only enter his profile data once the account is created.</td>
</tr>
</tbody>
</table>

**Post-Conditions**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>The SB@H acquires data from the device added</td>
<td>The device functioning is now based on new parameters.</td>
</tr>
</tbody>
</table>

**Extension Points**

None

5.5.2.3  **TUC 2.3 - Test Device**

*Table 46 Use Case: Test Device*

<table>
<thead>
<tr>
<th>Name</th>
<th>Test Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>The SB@H administrator tests the device to verify if the generated data are reliable</td>
</tr>
<tr>
<td>Actor(s)</td>
<td>System Administrator</td>
</tr>
</tbody>
</table>

**Flow of Events**

**Basic Flow**

This use case starts when the SB@H administrator signs on the platform.

The administrator:

1. Selects the settings menu.
2. Selects the option “test device”.
3. Select the test to be executed.
   1. components validation;
   2. function validation;
   3. performance validation;
   4. security and data validation;
   5. communication validation.
4. Record the results.
5. If necessary, repeat step 3.
6. End the process.

### Alternate Flows

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancel action</td>
<td>At any time, the SB@H administrator can cancel its previous action.</td>
</tr>
</tbody>
</table>

### Pre-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered devices</td>
<td>Tested devices must be registered.</td>
</tr>
</tbody>
</table>

### Post-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Devices tested</td>
<td>The devices reliability is acknowledged.</td>
</tr>
</tbody>
</table>

### Extension Points

None

5.5.3 Functional Area: Data Management

5.5.3.1 TUC 3.1 Register Data Source

**Table 47 Use Case: Register Data Source**

<table>
<thead>
<tr>
<th>Name</th>
<th>Register Data Source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brief Description</strong></td>
<td>Throughout the use of the SMART Bear @Home platform, data of various types will be collected. Among them are data collected through patient-wearable sensors. In order to gain value from the collection the data needs not only be collected but also stored for further-on analysis.</td>
</tr>
<tr>
<td><strong>Actor(s)</strong></td>
<td>System Administrator, Data Scientist, Clinician</td>
</tr>
</tbody>
</table>

**Flow of Events**

<table>
<thead>
<tr>
<th>Basic Flow</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The user connects to the cloud platform.</td>
</tr>
<tr>
<td>2. He enters the area “Register Data Source”.</td>
</tr>
<tr>
<td>3. He selects a device to be registered.</td>
</tr>
<tr>
<td>4. He selects a sensor of the device to be registered.</td>
</tr>
</tbody>
</table>
5. He gives a name to the data source.
6. He assigns to it a storage destination.
7. If required, he repeats step 4.
8. If required, he repeats step 3.
9. The process ends.

Alternate Flows

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancel action</td>
<td>At any time, the System administrator can cancel its previous action.</td>
</tr>
</tbody>
</table>

Pre-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Registered</td>
<td>Devices must be registered in the platform.</td>
</tr>
</tbody>
</table>

Post-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Analysis</td>
<td>Use of stored data from generating data collection.</td>
</tr>
</tbody>
</table>

5.5.3.2 TUC 3.2 Register Dataset

Table 48 Use Case: Register Dataset (Target)

<table>
<thead>
<tr>
<th>Name</th>
<th>Register Dataset (Target)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>Multiple data sources can be integrated to generate a data collection.</td>
</tr>
<tr>
<td>Actor(s)</td>
<td>System Administrator, Data Scientist, Clinician</td>
</tr>
</tbody>
</table>

Flow of Events

Basic Flow

1. The user selects the “Create Dataset” menu.
2. The user selects multiple data sources.
3. The user maps the sensors of a data source on the elements of the data collection to be created.
4. If needed a Data Transformation procedure is associated with a sensor acquisition procedure.
5. The user selects the data acquisition procedure between stream or micro-batch.
6. If needed, the user returns to step 3.
7. The process ends.
### 5.5.3.3 TUC 3.3 Define Data Transformation

**Table 49 Use Case: Define Data Transformation**

<table>
<thead>
<tr>
<th>Name</th>
<th>Define Data Transformation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>The data generated by sensors may require to apply a data transformation procedure before being included in a dataset.</td>
</tr>
<tr>
<td>Actor(s)</td>
<td>System Administrator, Clinician</td>
</tr>
</tbody>
</table>

**Flow of Events**

**Basic Flow**

1. The user selects the “Create Data Transformation” menu.
2. The user selects multiple data transformation rules.
3. The user composes these rules to define a procedure.
4. The procedure is listed in a library that can be used for acquiring a data source into a dataset.
5. The process ends.

**Alternate Flows**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancel action</td>
<td>At any time, the System administrator can cancel its previous action.</td>
</tr>
</tbody>
</table>

**Pre-Conditions**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Source</td>
<td>Data Sources must be registered.</td>
</tr>
<tr>
<td>Data Analysis</td>
<td>Use of stored data from patients’ sensors’ to be used for analysis.</td>
</tr>
</tbody>
</table>
### Transformation Rules

A set of Transformation Rules must be available in the system.

### Post-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Analysis</td>
<td>Use of stored data from patients’ sensors’ to be used for analysis.</td>
</tr>
</tbody>
</table>

#### 5.5.4 Functional Area: Cloud Management

#### 5.5.4.1 TUC 4.1 Register Cluster

**Table 50 Use Case: Register Cluster**

<table>
<thead>
<tr>
<th>Name</th>
<th>Register Cluster</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>Registers a cluster referenced from SMART Bear Cloud Platform. Connected users installed into the cluster, and updates in a previously-registered cluster.</td>
</tr>
<tr>
<td>Actor(s)</td>
<td>System Administrator</td>
</tr>
</tbody>
</table>

**Flow of Events**

**Basic Flow**

1. The Administrator sets up and creates a service cluster in private repository and sets up cluster network connectivity in cloud Container Registry.
2. The Administrator securely stores the SMART Bear data communications in cloud Container Registry and shares with all cluster users.
3. The Administrator select a zone in which he wants to host the cluster.
4. After the cluster is created, the configuration of the cluster is started.

**Alternate Flows**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Request</td>
<td>Fulfil requests for more infrastructure, such as adding and removing users, creating default subnets, and provisioning storage volumes in response to persistent volume claims in SMART Bear cloud.</td>
</tr>
<tr>
<td>Resources</td>
<td>Integrate ordered infrastructure resources to work automatically with the cluster architecture and become available to your deployed apps and workloads.</td>
</tr>
</tbody>
</table>
### Similar Operations

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isolate, and recover the cluster.</td>
<td></td>
</tr>
</tbody>
</table>

### Pre-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardware</td>
<td>A hardware farm is available.</td>
</tr>
</tbody>
</table>

### Post-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cluster is operational</td>
<td>A cluster is operational to support data storage and analytics.</td>
</tr>
</tbody>
</table>

#### 5.5.4.2 TUC 4.2 Configure Cluster

*Table 51 Use Case: Configure Cluster*

<table>
<thead>
<tr>
<th>Name</th>
<th>Configure Cluster</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>After the cluster is created, configuring the cluster is started.</td>
</tr>
<tr>
<td>Actor(s)</td>
<td>System Administrator</td>
</tr>
</tbody>
</table>

**Flow of Events**

**Basic Flow**

1. The Administrator gives to the cluster a unique name.
2. The Administrator selects a resource group in SMART Bear cloud in which to create the cluster (A cluster can be created in only one resource group, and after the cluster is created, it is not possible to change the resource group).
3. The Administrator selects a geography in which to deploy the cluster.
4. The Administrator assigns applications to the cluster.

**Alternate Flows**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide Security updates</td>
<td>Manage automation requests to update and recover worker nodes.</td>
</tr>
</tbody>
</table>
Cluster is registered

A cluster is registered and can support data storage and analytics.

**Post-Conditions**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
</table>

### 5.5.4.3 TUC 4.3 Monitor Cluster

Table 52 Use Case: Monitor Cluster

<table>
<thead>
<tr>
<th>Name</th>
<th>Monitor Cluster</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brief Description</strong></td>
<td>Continuous monitoring and logging is the key to detect attacks on the cluster and troubleshoot issues as they arise. By continuously monitoring the cluster, its capacity and the availability of resources that are available in SMART Bear app are shown. With this insight, The Administrator can prepare to protect SMART Bear apps against downtime.</td>
</tr>
<tr>
<td><strong>Actor(s)</strong></td>
<td>System Administrator</td>
</tr>
</tbody>
</table>

#### Flow of Events

**Basic Flow**

1. The Administrator sets up logging and monitoring in SMART Bear cloud Service to help troubleshooting issues and improve the health and performance of the clusters.
2. The Administrator proactively monitors service levels, and processes running in SMART Bear cloud.
3. The Administrator tracks critical cloud monitoring metrics such as CPU usage, network traffic, throttled requests, latency, throughput, read replica, health status, subscription count, etc.
4. The Administrator addresses performance anomalies by obtaining a dashboard view of break-down of system errors, user errors, failed requests, etc.
5. The Administrator reports the status of the clusters in the various interfaces.

#### Alternate Flows

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provisioning</td>
<td>SMART Bear can monitor the provisioning process in the Status of cloud.</td>
</tr>
<tr>
<td>Reloading</td>
<td>SMART Bear can monitor the reloading process in the Status of cloud output.</td>
</tr>
</tbody>
</table>

#### Pre-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clusters are running</td>
<td>Clusters are running and collecting data.</td>
</tr>
</tbody>
</table>
### Post-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitoring</td>
<td>Reports are available.</td>
</tr>
</tbody>
</table>

### 5.5.5 Functional Area: Data Analysis

#### 5.5.5.1 TUC 5.1 Register Analytics

*Table 53 Use Case: Register Analytics*

<table>
<thead>
<tr>
<th>Name</th>
<th>Register Analytics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>Analytics techniques are ways to diagnose and treat patients. It can be exploited for processing large amounts of data, understanding, categorizing and learning from this data for the sake of predicting outcomes or recommending alternative treatments to clinicians and patients.</td>
</tr>
<tr>
<td>• Examples of analytics are:</td>
<td></td>
</tr>
<tr>
<td>• Basic statistics.</td>
<td></td>
</tr>
<tr>
<td>• Classification and regression.</td>
<td></td>
</tr>
<tr>
<td>• Clustering.</td>
<td></td>
</tr>
<tr>
<td>• Dimensionality reduction.</td>
<td></td>
</tr>
<tr>
<td>• Feature extraction and transformation.</td>
<td></td>
</tr>
<tr>
<td>• Frequent pattern mining.</td>
<td></td>
</tr>
<tr>
<td>• Evaluation metrics.</td>
<td></td>
</tr>
<tr>
<td>Actor(s)</td>
<td>System Administrator</td>
</tr>
</tbody>
</table>

#### Flow of Events

##### Basic Flow

1. The Administrator selects the “Add Analytics” section.
2. A new analytics procedure is included. The Administrator:
   1. Defines the name of the data analytics.
   2. Defines the input data type.
   3. Defines setting parameters.
   4. Defines evaluation metrics.
3. If necessary, step 2 can be repeated.
4. The process ends.

##### Alternate Flows

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
</table>
### Cancel action
At any time, the System Administrator can cancel its previous action.

### Pre-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software frameworks</td>
<td>One or more software frameworks supporting statistical analysis and machine learning must be available in the systems.</td>
</tr>
</tbody>
</table>

### Post-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ad hoc analytics</td>
<td>SMART BEAR analytics are defined and listed according to the SMART BEAR terminology.</td>
</tr>
</tbody>
</table>

#### 5.5.5.2 TUC 5.2 Configure Analytics Inputs

*Table 54 Use Case: Configure Analytics Inputs*

<table>
<thead>
<tr>
<th>Name</th>
<th>Configure Analytics Inputs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>Configure analytic healthcare inputs in SMART Bear platform can be leveraged in mobile applications with the aim of turning large amounts of data into actionable information that can be exploited to identify needs, provide services, predict problems and prevent crises for the patients.</td>
</tr>
<tr>
<td>Actor(s)</td>
<td>System Administrator, Data Scientist, Clinician</td>
</tr>
</tbody>
</table>

### Flow of Events

**Basic Flow**

1. The actor selects the “Configure Analytics” section.
2. A new data analytics configuration is included. The actor:
   a. Defines the input data set.
   b. Defines default parameters.
   c. Defines evaluation metrics.
3. The actor verifies if the analytics output is consistent.
4. If necessary, step 2 can be repeated.
5. The process ends.

**Alternate Flows**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancel action</td>
<td>At any time, the User can cancel its previous action.</td>
</tr>
</tbody>
</table>
One or more software frameworks supporting statistical analysis and machine learning must be available in the systems.

SMART BEAR analytics are defined and listed according to the SMART BEAR terminology.

### 5.5.5.3 TUC 5.2 Configure Analytics Outputs

Table 55 Use Case: Configure Analytics Outputs

<table>
<thead>
<tr>
<th>Name</th>
<th>Configure Analytics Outputs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>Healthcare analytics outputs can be used to calculate more accurate measures of patient risk stratification, determining the level of health complication, co-morbidity impact and how serious a patient’s health status will affect the outcome.</td>
</tr>
<tr>
<td>Actor(s)</td>
<td>System Administrator, Data Scientist, Clinician</td>
</tr>
<tr>
<td>Flow of Events</td>
<td></td>
</tr>
<tr>
<td>Basic Flow</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>The actor selects the “Configure Analytics” section.</td>
</tr>
<tr>
<td>2.</td>
<td>A new data analytics configuration is included. The actor:</td>
</tr>
<tr>
<td>3.</td>
<td>Defines the out-data set.</td>
</tr>
<tr>
<td>4.</td>
<td>Defines permissions to this output.</td>
</tr>
<tr>
<td>5.</td>
<td>Defines a default visualization procedure.</td>
</tr>
<tr>
<td>6.</td>
<td>The actor verifies the configuration is consistent.</td>
</tr>
<tr>
<td>7.</td>
<td>If necessary, step 2 can repeated.</td>
</tr>
<tr>
<td>8.</td>
<td>The process ends.</td>
</tr>
<tr>
<td>Alternate Flows</td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>Description</td>
</tr>
<tr>
<td>Cancel action</td>
<td>At any time, the User can cancel its previous action.</td>
</tr>
<tr>
<td>Pre-Conditions</td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>Description</td>
</tr>
</tbody>
</table>
One or more software frameworks supporting statistical analysis and machine learning must be available in the systems.

**Post-Conditions**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ad hoc analytics</td>
<td>SMART BEAR analytics are defined and listed according to the SMART BEAR terminology.</td>
</tr>
</tbody>
</table>

### 5.5.6 Functional Area: Data Visualization

#### 5.5.6.1 TUC 6.1 Define Visualization

*Table 56 Use Case: Define Visualization*

<table>
<thead>
<tr>
<th>Name</th>
<th>Define Visualization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>The user login to the platform and define a visualization procedure.</td>
</tr>
<tr>
<td>Actor(s)</td>
<td>System Administrator</td>
</tr>
</tbody>
</table>

**Flow of Events**

**Basic Flow**

The use case starts when the Administrator logs in to the platform

1. The system shows the dashboard.
2. The Administrator selects a dataset.
3. The system checks the request and control the permissions to access the data.
4. The platform shows a tool to configure the visualization setup.
5. The Administrator configures the setup identifying different visualization directives: 
   1. Data dimensionality.
   2. Data cardinality.
   3. Data Types.
   4. Visualization goals.
   5. Active and default interactions.
6. The Administrators configures the roles having access to this visualization report.
7. The platform shows a preview of the visualization report.
8. The process ends.

**Alternate Flows**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>User permission denied</td>
<td>If the Administrator does not have permission to access the dataset, the platform shows a message.</td>
</tr>
</tbody>
</table>
### Default setting

Some roles may access to the default setting only, without any active interaction.

### Pre-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>User sign into the platform</td>
</tr>
</tbody>
</table>

### Post-Conditions

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success</td>
<td>A data visualization procedure is defined.</td>
</tr>
</tbody>
</table>

#### 5.5.6.2 TUC 6.2 Interact with the Visualization

**Table 57 Use Case: Interact with the Visualization**

<table>
<thead>
<tr>
<th>Name</th>
<th>Interact with the Visualization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>The user login to the platform and explores the dataset collected in SMART BEAR.</td>
</tr>
<tr>
<td>Actor(s)</td>
<td>Patient, Caregiver, Clinician, Policy Maker, System Administrator.</td>
</tr>
</tbody>
</table>

#### Flow of Events

**Basic Flow**

The use case starts when the user is logged in to the platform

1. The user logs in data analysis dashboard.
2. She identifies a visualization report.
3. The default setting for the visualisation are displayed.
4. She starts interacting with a visualization report.
   a. She defines filters on the view, e.g. Temporal, geographical, demographics, clinical condition filters.
   b. She defines the chart or report she want to visualize.
5. If necessary, step 3 is repeated multiple times.
6. The user can request the generation of a report.
   a. Export options of the report includes static pdf, dynamic html, row data in csv and others.
   b. A schedule or a repeat option can be defined for the report.
   c. One or more addresses of the report can be defined.
7. The process ends

#### Alternate Flows
**User permission denied**
If the User does not have permission to access the dataset the platform shows a message.

**Default setting**
Some roles may access to the default setting only, without any active interaction.

**Pre-Conditions**

**None**
User sign into the platform

**Post-Conditions**

**Success**
A data visualization procedure is defined.

### 5.5.6.3 TUC 6.3 Share Report

*Table 58 Use Case: Generate Report*

<table>
<thead>
<tr>
<th>Name</th>
<th>Generate Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Description</td>
<td>The SMART BEAR user can share the reports they receive with other users.</td>
</tr>
<tr>
<td>Actor(s)</td>
<td>Patient, Caregiver, Clinician, Policy Maker, System Administrator.</td>
</tr>
</tbody>
</table>

**Flow of Events**

**Basic Flow**

The use case starts when the user logs in to the platform

1. The user logs in data analysis dashboard.
2. She identifies a visualization report.
3. The user can request to share the report.
   1. Export options of the report includes static pdf, dynamic html, row data in csv and others.
   2. A schedule or a repeat option can be defined for the report.
   3. One or more addresses of the report can be defined.
4. The process ends

**Alternate Flows**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>User permission denied</td>
<td>If the User does not have permission to access the dataset the platform shows a message.</td>
</tr>
<tr>
<td>------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Title</strong></td>
<td><strong>Description</strong></td>
</tr>
<tr>
<td>Default setting</td>
<td>Some roles may access not be allowed to share their reports.</td>
</tr>
</tbody>
</table>

**Pre-Conditions**

<table>
<thead>
<tr>
<th><strong>Title</strong></th>
<th><strong>Description</strong></th>
</tr>
</thead>
</table>
| None       | User signs into the platform |}

**Post-Conditions**

<table>
<thead>
<tr>
<th><strong>Title</strong></th>
<th><strong>Description</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Success</td>
<td>A report is transferred to the dashboards of other users.</td>
</tr>
</tbody>
</table>
6 Introduction to the GDPR and its Implications on the SMART BEAR project

The General Data Protection Regulation (EU) 679/2016 ("GDPR"), which entered into application on 25 May 2018, will be particularly relevant to the SMART BEAR Project. Indeed, in the context of the Project numerous activities will involve the processing of personal data.

This Section aims at providing a general introduction to some of the main requirements provided under the GDPR having an impact on the SMART BEAR Project and the development of the Platform. This overview has been drafted on the basis of the GDPR as well as the commitments in relation to data protection the Project Partners have already made in the Grant Agreement8.

Considering the SMART BEAR Project and Platform will inevitably process considerable amounts of personal data, the applicable requirements laid down in the GDPR will have to be adhered to. Failure to do so could result, in addition to reputational damage, to various sanctions provided under the GDPR:

6.1 The concepts of "personal data" and "processing"

6.1.1 Types of data

In the EU, the concept of “personal data” is rather wide-ranging. According to the GDPR, the concept refers to any information relating to an identified or identifiable natural person (‘data subject’): “An identifiable natural person is one 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 or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person”.9 The GDPR particularly expanded this concept to take account of the online environment.

The fact that the definition refers to any information relating to an “identified or identifiable” individual10 essentially means that it includes the name of a person, mobile phone number, e-mail, location, contacts, credit card and payment data, browsing history, pictures, videos, temperature, blood pressure, insulin level, etc.

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8 Notably Objective 3 of the Project as well as the Ethics requirements in relation to Data Protection and Privacy.
9 GDPR, art 4(1)
10 In addition, it shall be noted that additional requirements apply to “special categories” of personal data, meaning data related to racial or ethnic origins, political opinions, religious or philosophical beliefs, trade union membership and data concerning health or sex life. Special restrictions may be set out under EU national laws for the processing of data relating to offences, criminal convictions, as well as, and under certain national laws, data relating to administrative sanctions or judgments in civil cases.
6.1.2 Sensitive Personal Data

The GDPR distinguishes ordinary and special categories of personal data (formerly referred to also as “sensitive data”). The processing of such types of data is restricted and prohibited in most cases. Accordingly, in order to process such special categories of data, the data controller must find a proper legal ground exhaustively listed in the GDPR.

More specifically, the GDPR includes the following concepts, which are defined: “special categories of personal data”, “data concerning health”, “genetic data”, “biometric data”, “data relating to criminal convictions and offences”.

Given the particular focus of the SMART BEAR Project and in particular the aim of providing health-related services to the elderly population, the concepts of “special categories of data”, but also of “data concerning health”, “genetic data” and “biometric data”, will be of high relevance. Accordingly, particular attention must be paid to the restrictions related to the processing of such types of personal data, as well as the limited grounds permitting their processing.

6.1.3 "Processing" of personal data

The GDPR applies when there is a “processing” of personal data which it defines as “any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction”.

It goes without saying that the activities performed upon “personal data” as foreseen in the context of the SMART BEAR project will necessarily imply a processing within the meaning of the GDPR. Hence, the various principles and obligations set therein will need to be carefully assessed and complied with by the involved stakeholders.

6.2 Various actors, roles and responsibilities

In case personal data is being processed (as it is the case in the context of the SMART BEAR Project), it is important to examine the concrete situation so as to determine precisely the exact role played by the different actors involved in such processing.

As already specified by the Article 29 Working Party in 2010, the various concepts enshrined under EU data protection law and in particular the difference between “data controller” and “data processor”, as well as their interaction, is of paramount importance in order to determine the responsibilities. In the same vein, such concepts are also essential in order to determine the territorial application of data protection law and the competence of the supervisory authorities.

6.2.1 Data controller

Based on Article 4(7) of the GDPR, the following requirements are essential for an actor to be considered as a “controller”:

- First, a controller can be a natural or legal person, public authority, agency or any other body. This implies that the form or nature of the entity is irrelevant.

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11 Genetic data was not expressly included as a sensitive data within the Directive. This was considered as a major backdrop within the Directive for failing to extend such protection to new but important data as genetic information.

12 GDPR, art 4(2)

 Second, the controller determines the purposes, conditions and means of the processing. This is a crucial element and one of the main factors in assessing this aspect is the level of influence that someone has in determining “why” (i.e., purposes) and “how” (i.e., means) certain processing activities should be performed. In establishing controllership, it has to be noted that the factual circumstances are a more relevant factor than a ‘fine tune’ designation based on contract or law. This means, for example, that a clear contractual provision excluding a party from being a controller is not relevant if all the other circumstances indicate otherwise.

The decision regarding the ‘purpose and means’ can be made jointly with others, where several legally separate entities process data together or jointly with others for a shared purpose.

The GDPR has clarified the rules with respect to co-controllership by laying down under Article 26 the rules related to the responsibility of joint controllers. Particularly, it contains an elaborate provision on the obligations when more than one controller determines the purpose and means of processing. First, the controllers are required to determine – in an arrangement – the respective responsibilities in light of compliance with the GDPR, and particularly the rights of data subjects. Second, the arrangement should reflect the effective roles and relationships of each controller, and the essence of the arrangement must be made available to data subjects. Third, the data subjects are granted the right to exercise their rights under the GDPR against each controller, irrespective of the arrangement among the controllers.

Finally, the situation of joint controllership should not be confused with the situation of “controllers in common”, which is not as such regulated under the GDPR. While joint controllers decide together on the purposes and the means of processing, controllers in common process a same data set independently of each other.

6.2.2 Data processor and sub-processor

To be qualified as a “processor”, a natural person or an entity must fulfil the following two elements:

• First, it must be a person or legal entity legally separate from the controller.
• Second, it must process personal data on behalf of the controller. This implies that decisions on the ‘purpose’ and ‘essential means’ should be made by the controller.

The concept of ‘essential means’ gives a margin of manoeuvre to processors (such as cloud providers) to determine technical and organisational issues without being considered ‘controllers’.

The GDPR has reinforced the responsibilities imposed on processors. This development has significant implications for service providers in the information technology sector, which are often considered as data processors.

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14 Ibid
15 GDPR, art 4(8)
16 Ibid 13
17 When considering big data, the Civil Liberties, Justice and Home Affairs Committee of the European Parliament highlighted that “the 2014 European Commission Communication [on data-driven economy] makes clear that the fundamental right to personal data protection applies to Big Data when the data processed can be qualified as personal. Referring to the Commission’s Data Protection Reform package (...), the Commission underlines that it will work with member states and stakeholders to ensure that business, and in particular SMEs, receive adequate guidance, notably on issues such as data anonymisation and pseudonymisation, data minimisation, personal data risk analysis, as well as tools and initiatives enhancing consumer awareness. The European Commission also announces its support to projects aiming to regulate personal data breaches and to ensure that data is used in a manner compatible with its initial collection, recognising that ‘these measures will build the trust that is necessary to exploit the full potential of the data-driven economy.’” Gloria González Fuster and Amandine Scherrer, ‘Big Data and Smart Devices and Their Impact on Privacy. Study for the LIBE Committee’ (European Parliament, Directorate-General for Internal Policies, Policy Department C Citizens’
processors so far as the provider adheres to the instructions of the controller and does not process the data for its own purposes. This entails that processors, such as cloud providers, become directly accountable vis-à-vis regulators as well as data subjects.

More specifically, the GDPR has extended the scope of application of EU data protection law, where certain requirements apply for the first time to “processors”. The GDPR also introduces new rules that apply when engaging processors and when the latter engage sub-processors.

More particularly, data controllers may only appoint data processors that provide sufficient guarantees to implement appropriate technical and organisational measures to ensure processing meets the requirements of the GDPR.\(^\text{18}\) Also, processors are required to process personal data in accordance with the controller’s instructions.

Finally, the relationship between the controller and the processor must also be governed by a binding contract the content of which must meet a minimum content. The obligations placed on the processor must cover the duration, nature and purpose of the processing, the types of data processed and the obligations and rights of the controller. There are also a number of specific requirements, including the processing of personal data only on documented instructions from the controller, and requirements to assist the controller in complying with many of its obligations. The data processor has an obligation to inform the controller if it believes an instruction breaches the GDPR or any other EU or Member State law.

In many instances multiple service providers are included in a chain of processors. The GDPR gives data controllers a wide degree of control in terms of the ability of the processor to sub-contract (engage “sub-processors”). In effect, data processors require prior written consent. This can be general, but even where general consent has been given, the processor is still required to inform the controller of any new sub-processors, giving the controller the opportunity to object. Also, the lead processor is required to reflect the same contractual obligations it has vis-à-vis the controller in a contract with any sub-processors and remains liable to the controller for the actions or inactions of any sub-processor.\(^\text{19}\)

### 6.2.3 Allocation of responsibilities in the context of SMART BEAR

On the basis of the previous sub-Sections, the table below provides an overview of the different relationships that may arise in a data protection context:

<table>
<thead>
<tr>
<th>Controller-Processor relationship</th>
<th>Processor-Subprocessor relationship</th>
<th>Joint-Controller relationship</th>
<th>Controllers 'in common' relationship</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="C-P" /></td>
<td><img src="image" alt="P-SP" /></td>
<td><img src="image" alt="C-C" /></td>
<td><img src="image" alt="C-C" /></td>
</tr>
<tr>
<td>Processor processes data on behalf of controller;</td>
<td>Subprocessor is engaged by the processor to carry out specific processing</td>
<td>Two controllers are acting together to determine the</td>
<td>Two controllers share 1 pool of data; each</td>
</tr>
</tbody>
</table>

---

\(^{18}\) GDPR, art 28(1)

\(^{19}\) GDPR, arts 28(2) and 28(4)
controller solely determines the purposes and the means of the processing

activities on behalf of the controller

purposes and the means of the processing: 1 pool of data and 1 set of same purposes

controller defines the purposes and means of their own processing: 1 pool of data but multiple purposes

<table>
<thead>
<tr>
<th>Article 28 GDPR</th>
<th>Article 28(2) and (4) GDPR</th>
<th>Article 26 GDPR</th>
<th>Undefined / Unregulated</th>
</tr>
</thead>
<tbody>
<tr>
<td>A contract must be put in place (the minimum content is imposed by Art. 28 GDPR)</td>
<td>A contract must be put in place (the same obligations as set out in the contract between the controller and the processor shall be imposed on the subprocessor)</td>
<td>An arrangement must be put in place, the essence of which must be made available to data subjects. The arrangement must define the respective obligations and determine who’s responsible towards the data subjects when they exercise their rights</td>
<td>Each controller must individually comply with the obligations under the GDPR</td>
</tr>
</tbody>
</table>

Table 59: Overview of the different relationships that may arise in a data protection context

In light of the foregoing, it will be particularly important to determine who plays what role in the context of the SMART BEAR Project. Indeed, the various partners of the Project will play multiple roles, depending on the particular processing activities. This will require putting in place the appropriate legal instruments as required under the GDPR. In the same vein, any external service providers (e.g. a cloud service provider) will need to be carefully identified in order to qualify them as processor or sub-processors and put in place the necessary contractual arrangements.

The SMART BEAR Project and Platform shall therefore ensure the required contracts, legal acts or arrangements are put in place when third parties process personal data on its behalf or when personal data are processed jointly with other third parties.

6.3 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 25 below.
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.

### 6.3.1 Lawfulness, fairness & transparency

Personal data must be processed lawfully, fairly, and in a transparent manner in relation to the data subject. The “lawfulness” of the processing will be examined in sub-Section 6.4 below. 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 an 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.

### 6.3.2 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

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20 GDPR, art 5(1)(a)
processing is not based on consent\(^\text{22}\), the GDPR lists five factors that should be taken into account in order to determine compatibility\(^\text{23}\):

- 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.”\(^\text{24}\)

### 6.3.3 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.\(^\text{25}\)

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.\(^\text{26}\) 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\(^\text{27}\):

- 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.

\(^\text{22}\) 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.).

\(^\text{23}\) 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.


\(^\text{25}\) 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 the processing could not reasonably be fulfilled by other means.” See <https://www.autoriteprotectiondonnees.be/node/19242> accessed 22 October 2018

\(^\text{26}\) Ibid 42

\(^\text{27}\) Ibid 41
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.

6.3.4 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.

6.3.5 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 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”.28 In reality, this is seldom the case.29

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 anonymisation, but it is for many organisations often more achievable than full deletion”.30 If 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.

6.3.6 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.31 In this context, the GDPR imposes a risk-based approach. Companies are therefore required to appreciate in an objective manner the

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29 Ibid
30 Ibid
31 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
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.

6.4 Legal grounds to process personal data (lawful processing)

In case the GDPR applies, any processing of personal data must be based on one of the grounds listed in Article 6(1) of the GDPR. In other words, in order for a processing activity to be lawful, from the outset and throughout the activity, it must always be based on one of the grounds exhaustively listed in GDPR. The processing of personal data is lawful only if:

- The data subject has given its consent;
- It is necessary for the performance of a contract with the data subject or to take steps prior to entering into a contract;
- It is necessary for the purposes of legitimate interests of the controller or a third party;
- It is necessary for compliance with a legal obligation to which the controller is subject;
- It is necessary to protect the vital interests of a data subject or another person where the data subject is incapable of giving consent;
- It is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;

In addition, whenever special categories of data are being processed, one must carefully take into consideration Article 9 of the GDPR which sets out a general prohibition to process special categories of data (cf. above on the notion). Article 9(2) however provides for exceptions to the general prohibition, such as for instance in case where (non-exhaustive list):

- the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, except where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject;
- processing is necessary for the purposes of carrying out the obligations and exercising specific rights of the controller or of the data subject in the field of employment and social security and social protection law in so far as it is authorised by Union or Member State law or a

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32 GDPR, art 24 and Recital 76. See also in relation to the risk-based approach Articles 32(1) and 33 to 35
33 Member States are permitted to introduce specific provisions to provide a basis under Articles 6(1)(c) and 6(1)(e) (processing due to a legal obligation or performance of a task in the public interest or in the exercise of official authority) for other specific processing situations (e.g. journalism and research). This is likely to result in a degree of variation across the EU. Also, article 9(2) of the GDPR sets out the grounds on the basis of which the processing of "sensitive personal data", which is otherwise prohibited, may take place.
collective agreement pursuant to Member State law providing for appropriate safeguards for the fundamental rights and the interests of the data subject;
c. processing is necessary to protect the vital interests of the data subject or of another natural person where the data subject is physically or legally incapable of giving consent;
d. processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards (processing must be performed by or under the responsibility of a professional subject to the obligation of professional secrecy under Union or Member State law or rules established by national competent bodies or by another person also subject to an obligation of secrecy under Union or Member State law or rules established by national competent bodies).

e.

In the context of SMART BEAR, it will be of paramount importance to carefully consider the most appropriate grounds for the various processing activities.

6.5  Core obligations under the GDPR

Data controllers (and processors in certain cases) have to implement appropriate measures in order to comply with the GDPR.

6.5.1  Overview of the core obligations

The list below aims to summarise the different obligations imposed upon data controller and/or data processors. All such obligations are relevant to the partners of the SMART BEAR Project individually and/or collectively.

- **Records of processing activities**: controller and processors have a general obligation to keep internal records (registers) of data processing activities and to make such records available to the supervisory authority on request. The information these records should contain is listed in the GDPR and is slightly different for controllers and processors. It is therefore necessary for any company to map all its data processing activities and to keep detailed records.

- **Data Protection Officer**: an organisation may be obliged to appoint a Data Protection Officer ("DPO") if the organisation is a public authority or body, or if it carries out certain types of processing activities. The DPO will notably have to be independent and report to the highest management level of the company. The DPO will have to inform and advise the organisation and its employees, monitor compliance with the GDPR and internal policies, as well as act as the point of contact with the authorities and cooperate with them. The DPO must be independent, an expert in data protection, adequately resourced, and report to the highest management level. In case the organisation concludes it is not required to appoint a DPO, it will need to document its legal assessment and make it available to the authorities upon request. In the event that the organisation does not have an establishment in the EU, but that the GDPR nevertheless applies, it must in principle designate a “representative” in the EU.

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34 Article 30 GDPR.
35 Article 37 GDPR.
36 Article 38 GDPR.
Taking into account the sensitive nature of the processing of personal data the Platform will conduct, the SMART BEAR Project has appointed a DPO, namely Mr Benoit Van Asbroeck from 2B. The Project will take the necessary measures to allow him to fulfil his tasks.

Also, given the particular nature of certain Partners of the SMART BEAR Project, such as for instance the Pilots / Use-cases, their appointed DPO's will also play an important role.

- **Security:** A key requirement of the GDPR is that controllers and processors need to process personal data securely by means of ‘appropriate technical and organisational measures’.\(^{37}\) Doing so requires organisations to consider inter alia measures such as risk analysis, organisational policies, and physical and technical measures. Controllers and processors shall, when deciding which security measures are appropriate, take into account: (i) the state of the art, (ii) the costs of implementation, (iii) the nature, scope, context and purposes of processing; and (iv) the risk of varying likelihood and severity for the rights and freedoms of individuals.

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.

- **Data breach notifications:** The GDPR requires notification of a security breach leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to personal data. Thus, in the case of data breach, the organisation must inform, within a short period of time, as the case may be, the (co-)controller, the supervisory authority and/or the affected individuals. It is therefore necessary to anticipate possible incidents and adopt/review internal policies and implement appropriate measures to detect any such incidents.

As a result, the SMART BEAR Project and Platform shall take all necessary measures to detect security and data incidents, and to allow for the notification of personal data breaches to the supervisory authority and, if necessary, to the data subjects.

- **Transfers of personal data outside the EEA:** The transfer of personal data to recipients in “third countries” (i.e. outside of the European Economic Area, ("EEA") are regulated and restricted in certain circumstances. More specifically, any transfer of personal data should be subject to appropriate legal means listed in the GDPR which allow for such international transfer.\(^{38}\)

As a result, the SMART BEAR Platform and Project shall not transfer any personal data outside of the EEA, except if appropriate legal means are put in place.

- **Data Protection Impact Assessments:** In certain circumstances, an organisation will have to carry out Data Protection Impact Assessments ("DPIA's") and in particular when the processing is “likely to result in a high risk” for individuals, such as for instance when implementing new technologies or in case of processing on a large scale of special categories of data. It is therefore necessary to adopt the

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\(^{37}\) Article 5(1)(f) and 32 GDPR.

\(^{38}\) Chapter V of the GDPR.
necessary internal procedure to determine when DPIA’s are required and carry out such assessment where needed. 39

Where necessary, DPIAs will need to be carried out in the context of the SMART BEAR Project and the development of the Platform.

- **Data protection by design and data protection by default:** any company must adopt adequate technical and organizational measures aimed at effectively implementing the GDPR and ensuring that, by default, only personal data which are necessary for each specific purpose of the processing are processed. In other words, the GDPR imposes a general obligation to implement technical and organisational measures to show that organisations have considered and integrated data protection into their processing activities. 40 Thus, the SMART BEAR Project and Platform shall implement appropriate technical and organisational measures which are designed to implement the data protection principles and that ensure that by default only personal data which are necessary for each specific purpose of the processing are processed.

The below sub-Sections further analyse the last two obligations of the above list, which are particularly relevant for the SMART BEAR Project and the development of the Platform.

### 6.5.2 Data protection impact assessment (DPIA)

The GDPR formally codifies the requirement for Data Protection Impact Assessments to be carried in case a processing presents a “high risk” to the rights and freedoms of natural persons. Although DPIAs are mandated for high risk processing, the Article 29 Working Party recommends that they should be seen as a tool for accountability and could be used in somewhat wider situations as well. In the view of the Working Party, conducting a DPIA will help organisations build compliance (at the outset) and demonstrate compliance at a later date.

This being said, strictly speaking, DPIAs are required in certain cases only, i.e. when processing is “likely to result in a high risk”, taking into account the nature, scope, context and purposes of the processing. 41 While Article 35(1) clearly indicates that processing “using new technologies” is likely to result in a high risk, Article 35(3) and Recital 91 provide a non-exhaustive list of occasions when DPIAs are required:

- systematic monitoring of a publicly accessible area on a large scale (e.g. CCTV) (Article 35(3);
- monitoring publicly accessible areas on a large scale, especially when using optic-electronic devices or for any other operations where the competent supervisory authority considers that the processing is likely to result in a high risk to the rights and freedoms of data subjects, in particular because they prevent data subjects from exercising a right or using a service or a contract, or because they are carried out systematically on a large scale (Recital 91);
- systematic and extensive evaluation of personal aspects relating to natural persons which is based on automated processing, including profiling, and on which decisions are based that produce legal effects concerning the natural person or similarly significantly affect the natural person (Article 35(3);
- processing on a large scale of special categories of data or data relating to criminal convictions and offences (Article 35(3);

39 Chapter IV Section 3 sets out a non-exhaustive list of categories of processing that will fall within this provision. Furthermore, also at Member State level, also supervisory authorities have established so-called ‘black’ and ‘white’ lists, laying down in which circumstances data protection impact assessments need to be carried out.

40 Article 25(1) and (2) GDPR.

41 The Article 29 Working Party suggests that if a controller concludes that processing does not need a DPIA, because it is not likely to result in a high risk, then this should also be documented.
large-scale processing operations which aim to process a considerable amount of personal data at regional, national or supranational level and which could affect a large number of data subjects and which are likely to result in a high risk, for example, on account of their sensitivity, where in accordance with the achieved state of technological knowledge a new technology is used on a large scale as well as to other processing operations which result in a high risk to the rights and freedoms of data subjects, in particular where those operations render it more difficult for data subjects to exercise their rights (Recital 91);

processing for taking decisions regarding specific natural persons following any systematic and extensive evaluation of personal aspects relating to natural persons based on profiling those data or following the processing of special categories of personal data, biometric data, or data on criminal convictions and offences or related security measures (Recital 91).

For other processing activities, the organisation should determine whether it poses a high risk to individuals. In such context, Recital 75 of the GDPR provides some relevant elements that may help determining whether a (high) risk exists. More specifically, it is considered that a risky processing may:

- lead to physical, material or non-material damage;
- give rise to discrimination, identity theft or fraud, financial loss, damage to the reputation, loss of confidentiality of personal data protected by professional secrecy, unauthorised reversal of pseudonymisation, or any other significant economic or social disadvantage;
- occur where data subjects might be deprived of their rights and freedoms or prevented from exercising control over their personal data;
- occur where special categories of data and data relating to criminal convictions is processed;
- occur where personal aspects are evaluated, in particular analysing or predicting aspects concerning performance at work, economic situation, health, personal preferences or interests, reliability or behaviour, location or movements, in order to create or use personal profiles;
- occur where personal data of vulnerable natural persons, in particular of children, are processed;
- occur where processing involves a large amount of personal data and affects a large number of data subjects.

In addition to the above illustrations and elements provided by the GDPR to determine whether a DPIA may be required, Articles 35(4) and 35(5) of the GDPR allow national supervisory authorities to establish a list of processing operations that are necessarily subject to the requirement to conduct a DPIA (“blacklist”) and a list of processing activities for which no DPIA shall be required (“white list”). Although such lists must be submitted to the European Data Protection Board (EDPB) and are subject to the consistency mechanism, the content of such lists may differ between the various Member States. Most competent national supervisory authorities have adopted submitted lists (which have been reviewed by the EDPB).

Recital 91 of the GDPR already considers that "The processing of personal data should not be considered to be on a large scale if the processing concerns personal data from patients or clients by an individual physician, other health care professional or lawyer. In such cases, a data protection impact assessment should not be mandatory".

GDPR, art 63

The WP29 states that while the draft lists of the competent supervisory authorities are subject to the consistency mechanism, this does not mean that the lists should be identical. The competent supervisory authorities have a margin of discretion with regard to the national or regional context and should take into account their local legislation. The aim of the EDPB assessment/opinion is not to reach a single EU list but rather to avoid significant inconsistencies that may affect the equivalent protection of the data subjects.
Finally, the national and European authorities\(^{45}\) may publish guidelines ("grey list") to assist controllers determining whether a DPIA may be required, as well as methodologies and tools to allow them carrying out the required DPIA.

The GDPR provides for strict rules in case a DPIA must be carried out, which must be documented to identify and evaluate the possible risks as well as to determine and propose how risks can be limited or reduced.

- First, with respect to the content (and the methodology) of the DPIA, the Article 29 Working Party recommends an iterative process\(^{46}\), based on Article 35(7) of the GDPR\(^{47}\).
- Second, a DPIA should be carried out at an early enough stage so that recommendations can be acted on. This may entail a need to re-assess later on. Periodic review is also likely although the Article 29 Working Party suggests that they should both be carried out continuously and re-assessed at least every three years or perhaps sooner, if circumstances require doing so.
- Third, the data controller is rather free regarding the form of the DPIA. The Article 29 Working Party is not prescriptive and notes that there are various templates available for this. The guidelines take account of two relevant ISO documents: (i) risk management: ISO 31000:2009 on Risk Management – Principles and Guidelines\(^{48}\) and (ii) Protection Impact Assessments ("PIAs") in an information security context: ISO/IEC 29134 on Information technology – Security techniques – Guidelines for privacy impact assessment (project).\(^{49}\)
- In such context, the Article 29 Working Party proposes criteria to assess whether a DPIA template or methodology is sufficiently comprehensive to comply with the GDPR.
- Fourth, although the Article 29 Working Party notes that the GDPR does not require this, it states that publication should be undertaken, either in full or in part, to demonstrate trust and accountability (in particular where members of the public could be impacted by the processing).
- Finally, if the DPIA demonstrates a high risk for the data subjects involved, the controller must notify the supervisory authority and obtain that authority's opinion on the adequacy of the measures proposed in the framework of the DPIA. This is the case whenever risks cannot be mitigated and remain high - such as where individuals may encounter significant or even irreversible consequences, or when it is obvious that a risk may occur. In addition, Member State law may require that data controllers consult the authority in some cases (e.g. processing in the public interest in relation to public health), irrespective of the level of residual risk.

While the data controller is ultimately responsible for the DPIA, it may be required to seek external assistance. Hence, the data processors involved in the processing activity may be required to help. Also, the Data Protection Officer must be involved and must monitor performance of the DPIA. ‘Where appropriate’ the

\(^{45}\) Article 29 Data Protection Working Party, 'Guidelines on Data Protection Impact Assessment (DPIA) and Determining whether Processing is "Likely to Result in a High Risk" for the Purposes of Regulation 2016/679' (2017) WP248, 7

\(^{46}\) Ibid 14

\(^{47}\) GDPR, art 35(7): “The assessment shall contain at least:
(a) a systematic description of the envisaged processing operations and the purposes of the processing, including, where applicable, the legitimate interest pursued by the controller;
(b) an assessment of the necessity and proportionality of the processing operations in relation to the purposes;
(c) an assessment of the risks to the rights and freedoms of data subjects referred to in paragraph 1; and
(d) the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of personal data and to demonstrate compliance with this Regulation taking into account the rights and legitimate interests of data subjects and other persons concerned.”

\(^{48}\) ISO 31000:2009(en), Risk management – Principles and guidelines

\(^{49}\) ISO/IEC 29134, Information technology – Security techniques – Guidelines for privacy impact assessment
controller should seek the views of data subjects (e.g. via a survey or study). Finally, although not mentioned in
the GDPR, others should be involved if they are a relevant stakeholder (e.g. business unit responsible for the
processing) and/or relevant expert (lawyer, security expert etc.).

6.5.3 Data protection by design and data protection by default

The GDPR includes, in the section related to the obligations of data controllers, a dedicated article related to
the requirement to implement “data protection by design” and “data protection by default” measures. Such
measures are linked to the core principles of the GDPR, and in particular the accountability principle and the
related requirement to implement measures to demonstrate compliance with the GDPR, but also the purpose
limitation, storage limitation and data minimisation principles (see above).

More particularly, the requirement to adopt “data protection by design” measures entails that the controller
must implement appropriate technical and organisational measures (e.g. pseudonymisation techniques)
designed to implement the data protection principles (e.g. data minimisation). Said measures must be
implemented in an effective way so as to integrate the necessary safeguards into the data processing in order
to meet the requirements of the GDPR and to protect the rights of data subjects.

These obligations must be respected both at the time of the determination of the means for processing and at
the time of the processing itself. Some elements to take into account while implementing the measures are (i)
the state of the art; (ii) the cost of implementation; (iii) the nature, scope, context and purposes of the
processing; and (iv) the risks of varying likelihood and severity for rights and freedoms of individuals posed by
the processing.

As for the compliance with the “data protection by default” requirement\[^{50}\], the controller must implement
appropriate technical and organisational measures to ensure that, by default, only personal data necessary for
each specific purpose of the processing are processed. This applies to the amount of data collected as well as
to the extent of processing, period of storage and accessibility of the data. The measures adopted by the
controller must guarantee that, by default, personal data are not made accessible to an indefinite number of
individuals without the data subject’s intervention.

These requirements to implement dedicated ‘by design’ and ‘by default’ measures are particularly relevant in
IT environments, and thus also to big data.

In practice, it requires organisations to ensure that they consider privacy and data protection issues at the
design phase and throughout the lifecycle of any system, service, product or process. The requirements can
therefore be far-reaching and apply to all IT systems, services, products and processes involving personal data
processing, but also require looking into organisational policies, processes, business practices and/or strategies
that have privacy implications, rethinking physical design of certain products and services as well as data
sharing initiatives. Moreover, organisations must focus on the requirement to take technical measures to meet
individuals’ expectations in order to notably delimit what data will be processed for what purpose, only to
process the data strictly necessary for the purpose for which they are collected, implement a "privacy-first"
approach with default settings, to appropriately inform individuals and provide them with sufficient controls
to exercise their rights, and implement measures to prevent personal data from being made public by default.

The GDPR imposes requirements related to “data protection by design” and “data protection by default” only
on data controllers. However, in practice, the entire data value chain is impacted.

Indeed, the GDPR imposes upon controllers a general duty to “use only processors providing sufficient
guarantees to implement appropriate technical and organisational measures in such a manner that processing
will meet the requirements of this Regulation and ensure the protection of the rights of the data subject.”\[^{51}\]

This imposes an indirect obligation to have processors develop services, products and processes in line with
data protection by design and by default. In the same vein, those providers that do not process data but

\[^{50}\] GDPR, art 25(2)
\[^{51}\] GDPR, art 28(1)
develop product and technology for controllers and processors are “encouraged to take into account the right to data protection when developing and designing […] to make sure that controllers and processors are able to fulfil their data protection obligations”. If failing to develop GDPR-compliant tools would in practice push these providers out of the market.

The long-standing research carried out under the concept of “privacy by design” may provide useful insights on how to comply with the “data protection by design” and “data protection by default” obligations. Indeed, the concept of “privacy by design” was developed in the 90’s, notably by the Information & Privacy Commissioner of Ontario in Canada, where “privacy by default” was considered to be one of the seven foundational principles of privacy by design:\footnote{GDPR, Recital 78} “Privacy by design seeks to deliver the maximum degree of privacy by ensuring that personal data are automatically protected in any given IT system or business practice. If an individual does nothing, their privacy still remains intact. No action is required on the part of the individual to protect their privacy — it is built into the system, by default.”\footnote{Ann Cavoukian, ‘Privacy by Design: The 7 Foundational Principles’ (PbD 2011) <https://www.ipc.on.ca/wp-content/uploads/Resources/7foundationalprinciples.pdf> accessed 16 October 2018}

The development of these concepts has served as a fundamental source of inspiration for the creation of dedicated requirements in the EU. In such context, the European Network and Information Security Agency – the only institution at EU level which has been equipped with the competence and resources to perform dedicated research regarding privacy and data protection by design and by default – has published in 2014 and 2015 (prior to the GDPR) some practical insights on the requirements of ‘privacy by design’:


In the latter document, ENISA examines in detail various measures that permit the effective implementation of the privacy by design obligation in a big data context. It notably emphasises the need to shift the discussion from ‘big data versus privacy’ to ‘big data with privacy’.\footnote{Ibid 10} In order to achieve such change, it is key to identify the privacy requirements as early as possible in the big data analytics value chain. ENISA provides in its report two useful tables. First, it is important to determine the most appropriate strategies, and second, to apply such strategies in the different phases of the big data value chain.

In such context, applying anonymisation and pseudonymisation measures, implementing security measures to prevent data misuse, relying on so-called “Privacy-enhancing technologies” or “PETs” allow implementing to a certain extent data protection by design and by default requirements on a technical level. Indeed, such technologies embody fundamental data protection principles by minimising personal data use, maximising data security and aim to empower individuals.

### 6.6 Rights of individuals

The GDPR aims to protect natural person in relation to the processing of personal data and therefore recognises several rights to such persons. A snapshot of the various rights of data subjects can be depicted in Figure 26:
In addition to the above rights, the GDPR further provides for the strict procedures to respond to any data subject request, notably regulating issues with respect to the timing and the form of responses, or the fees that may be requested. It also regulates the right for individuals to lodge a complaint with a supervisory authority, the rights to an effective judicial remedy against a supervisory authority, a controller or a processor, and the possibility for data subjects to mandate a not-for-profit body, organisation or association to lodge a complaint on their behalf.

In the context of SMART BEAR, it will be particularly important to carefully consider the above rights and anticipate their concrete application.

The following sub-Sections aim to highlight some of the most important characteristics of each right.

### 6.6.1 Information

One of the most important rights of data subjects is the right to information.

In order to ensure that personal data are processed fairly and transparently, data controllers must provide certain minimum information to data subjects regarding the collection and further processing of their personal data, such as for instance the purposes for which the data are processed. The data controller must provide information in a concise, transparent, intelligible and easily accessible form, using clear and plain language.\(^{58}\)

It should be borne in mind that new notices may be needed if personal data is processed for a new purpose not covered in the initial notice.

The GDPR however foresees certain (limited) situations where the controller does not have to provide the abovementioned information. This is the case if it would be impossible or if it would involve a disproportionate effort. In these cases, appropriate measures must be taken to protect individuals’ interests and the information notice must be made publicly available.\(^{59}\)

In order to give the information in the most adequate manner, the data controller must carefully assess the best means. In such context, “data protection authorities have long been recommending a ‘layered’ notice informing the data subjects about their data being processed step by step. This means providing the individual

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\(^{58}\) The EU Commission may introduce in the future standardised icons. In such case these would then also need to be displayed to individuals.

\(^{59}\) There is also no need to provide the information notice if there is an obligation under EU or Member State law for the controller to obtain/disclose the information; or if the information must remain confidential, because of professional or statutory secrecy obligations, regulated by EU or Member State law.
with the essential information about the processing at the point where the individual needs to make a decision based on the information (for example, an individual needs to know whether an app downloaded will have access to his location data before he chooses to install it), and providing further information in other formats, for example, via more detailed information on a website.\textsuperscript{60}

6.6.2 Access

Data subjects have the right to file a subject access request and obtain from the data controller a copy of their personal data. The GDPR further requires that the controller responds to any request with supplementary information exhaustively listed under Article 15.

If the request is made in electronic form, the information should be provided in a commonly used electronic form (unless the data subject requests otherwise). This could impose costs on controllers who use special formats, or who hold paper records. Recital 63 also encourages controllers, where possible, to provide a secure system which would grant the data subject direct access to his/her data.\textsuperscript{61}

The GDPR nevertheless recognises some limits in the event that the individual's access may adversely affect third parties. Hence, the GDPR provides that the right to receive a copy of the data shall not adversely affect such rights.

Finally, the GDPR also contains a useful limiting provision in Recital 63. If the controller holds a large quantity of data, it may ask the data subject to specify the information or processing activities to which the request relates. Such provision may thus constitute a ground for the controller to refuse a blanket access to all personal data processed and to grant a limited access to the data specifically identified by the individual. It remains however to be seen what amount of data constitutes a "large quantity of information" as required by Recital 63.

6.6.3 Rectification

Individuals can require a controller, without delay, to rectify inaccuracies in personal data held about them. In some circumstances, if personal data are incomplete, an individual can require the controller to complete the data, or to record a supplementary statement.


6.6.4 Erasure ("right to be forgotten")

Pursuant to Article 17 of the GDPR, individuals have the right to have their data ‘erased’ in certain specified situations; in essence where the processing fails to satisfy the requirements of the GDPR. Such right applies in strictly defined cases such as for instance when data are no longer necessary for the purpose for which they were collected or processed, if the individual withdraws consent to processing or when processing is based on legitimate interests.62

If the controller has made personal data public, and where it is obliged to erase the data, the controller must also inform other controllers who are processing the data that the data subject has requested erasure of those data. In the same vein, if the controller has to erase personal data, then it must notify anyone to whom it has disclosed such data, unless this would be impossible or involve disproportionate effort.

Finally, a few strict exemptions may apply where the obligation would then not apply, such as in particular if the processing is necessary for the exercise of the right of freedom of expression and information, for compliance with a legal obligation or if required for the establishment, exercise or defence of legal claims.

6.6.5 Restriction

In some situations, this right provides an individual with an alternative to requiring data to be erased; in others, it allows the individual to require data to be held in limbo whilst other challenges are resolved. The right to restriction applies in strict cases such as when the accuracy of the data is contested by the data subject and the controller needs time to verify, if the processing is unlawful but the data subject objects to erasure or in case the data subject has objected to the processing and the controller needs time to verify whether its legitimate interests override those of the data subject.

If personal data are ‘restricted’, then the controller may only store the data. It may not further process the data unless: (i) the individual consents; (ii) the processing is necessary for establishment, exercise or defence of legal claims; (iii) for the protection of the rights of another natural or legal person; or (iv) for reasons of important (EU or Member State) public interests. When the controller wishes to lift a restriction, it must notify the individual in advance.

Where the data are processed automatically, the restriction should be effected by technical means and noted in the controller’s IT systems. This could mean moving the data to a separate system, temporarily blocking the data on a website or otherwise making the data unavailable. It is therefore required to take into consideration the possibility for data to be restricted at the conception phase of IT services (including big data analytics systems). This further allows abiding by the “privacy by design” requirement under the GDPR.

If the data have been disclosed to others, then the controller must notify those recipients about the restricted processing, unless this is impossible or involves disproportionate effort.

6.6.6 Portability

While the right to data access provided under the GDPR already gives individuals the right to require their data to be provided in a commonly used electronic form, the right to data portability goes further. It indeed requires the controller to provide information – to the data subject or to another controller – in a structured, commonly used and machine-readable form.63 Whereas data subject access is a broad right, portability is narrower. It only applies to personal data:

62 If the individual objects and the controller cannot demonstrate that there are overriding legitimate grounds for the processing.

which is processed by automated means (no paper records);
- which the data subject has provided to the controller; and
- which is processed on the basis of consent or processed to fulfil a contract or steps preparatory to a contract.

The obligation to port the data is stated to be without prejudice to the rights of other data subjects. Presumably, a controller should not port data to another controller (or to the individual) if this would breach the rights of others.

Given the numerous questions raised by the creation of this new ambitious right, the Article 29 Working Party adopted guidelines on the right to data portability on 5 April 2017.64 Such guidelines clarify the conditions under which this new right applies taking into account the legal basis of the data processing (either the data subject’s consent or the necessity to perform a contract) and the fact that this right is limited to personal data provided by the data subject. The guidelines also provide concrete examples and criteria to explain the circumstances in which this right applies. In this regard, the Article 29 Working Party considers that the right to data portability covers data provided knowingly and actively by the data subject as well as the personal data generated by his or her activity. The Article 29 Working Party clearly advocates for a broad interpretation, where “raw data processed by a smart meter or other connected objects, activity logs, history of website usage or search activities” fall within the scope of the portability right.65 This new right can therefore not be undermined and limited to the personal information directly communicated by the data subject, for example, through an online form.

The Article 29 Working Party further clarified that the right to data portability applies only to data controllers. However, the guidance underlines that data processors will have contractual obligations under the GDPR to assist the controller “by appropriate technical and organisational measures” with responding to requests by individuals to exercise their rights. Thus, the Article 29 Working Party concludes that the data controller should “implement specific procedures in cooperation with its data processors to answer portability requests”.

As a good practice, data controllers (and processors to the extent necessary) should develop the means that will contribute to address data portability requests, such as download tools and “Application Programming Interfaces” (“API”).

### 6.6.7 Objection

Under the GDPR, data subjects have a right to object to processing of their personal data on certain grounds, in addition to the right to object to processing carried out for the purposes of profiling or direct marketing (see below). In case a data subject raises objections, the data controller is required to demonstrate that it either has compelling grounds for continuing the processing, or that the processing is necessary in connection with its legal rights. If it fails to demonstrate that the relevant processing activity falls within one of the permitted grounds, it must cease that processing activity.

There is no right for an individual to object to processing in general. Only three specific rights to object are recognised under the GDPR, all relating to processing carried out for specific purposes, or which is justified on a particular basis. More particularly, data subjects can object to:

- Processing for direct marketing purposes: this is an absolute right; once the individual objects, the data must not be processed for direct marketing any further.
- Processing for scientific / historical research / statistical purposes: less strong than the right to object to direct marketing – there must be “grounds relating to [the data subject’s] particular situation”.

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65 By contrast, “inferred” personal data, such as “the profile created in the context of risk management and financial regulations (e.g. to assign a credit score or comply with anti-money laundering rules)” are outside the scope of the portability right.
There is an exception where the processing is necessary for the performance of a task carried out for reasons of public interest.

- Processing based on two specific purposes: (i) legitimate interest or (ii) because it is necessary for a public interest task/official authority. The controller must then cease processing of the personal data unless (i) it can demonstrate compelling legitimate grounds which override the interests of the data subject; or (ii) the processing is for the establishment, exercise or defence of legal claims.

### 6.6.8 Profiling and automated decision-making

Concepts of "profiling" and "automated decision-making".

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<tbody>
<tr>
<td><strong>Defined under Article 4(4) GDPR:</strong> &quot;'profiling' means any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to a natural person, in particular to analyse or predict aspects concerning that natural person's performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movements&quot;</td>
<td>Indirectly defined under Article 22(1) as &quot;a decision based solely on automated processing, including profiling, which produces legal effects concerning [the data subject] or similarly significantly affects him or her.&quot;</td>
</tr>
<tr>
<td><strong>'Automated' process</strong></td>
<td><strong>'Automated' process</strong></td>
</tr>
<tr>
<td><strong>Three stages:</strong></td>
<td>Ability to make decisions by technological means</td>
</tr>
<tr>
<td>o Data collection</td>
<td>Absence of human intervention</td>
</tr>
<tr>
<td>o Automated analysis to identify correlations</td>
<td>Based on all types of personal data (provided, observed, derived or inferred)</td>
</tr>
<tr>
<td>o Apply correlations to an individual to identify characteristics or behaviour patterns</td>
<td></td>
</tr>
<tr>
<td><strong>The evaluation involves a form of assessment / judgment about a person</strong></td>
<td></td>
</tr>
<tr>
<td><strong>May involve statistical deductions</strong></td>
<td></td>
</tr>
<tr>
<td><strong>May be used to make predictions</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Can take place without automated decisions</strong></td>
<td><strong>Can be made with or without profiling</strong></td>
</tr>
</tbody>
</table>

Table 60: Concepts of "profiling" and "automated decision-making"

These concepts are particularly relevant when considering disruptive technologies, including those developed in the context of the SMART BEAR Project. Indeed, the (vast) amount of data that can be collected about individuals is often used to categorise people based on their characteristics, behaviours, interests and habits, but also to make predictions and decisions.

This being said, these particular concepts of profiling and automated decision-making are not generally regulated by the GDPR. Some specific Recitals or Articles of the GDPR however make explicit reference to these concepts. More generally, the key principles and obligations of the GDPR will apply in the context of "profiling" and "automated decision-making".

**Specific rules on "solely automated decision-making"**

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66 For a complete list, see Article 29 Data Protection Working Party, 'Guidelines on Automated individual decision-making and profiling for the purposes of Regulation 2016/679' (as last revised and adopted on 6 February 2018) WP251rev.01, Annex 2
The GDPR includes strict rules in relation to "solely automated decision-making" under Article 22. Several criteria must be met in order for the regime to apply, which can be summarised in the following diagram:

![Diagram showing legal criteria triggering the application of Article 22 GDPR and restrictions and permitted acts.]

*Figure 27: Legal criteria triggering the application of Article 22 GDPR and restrictions and permitted acts*

It follows from the above that several conditions must be met in order for the strict regime of Article 22 to apply.

In certain circumstances clearly defined in three hypotheses under Article 22, decisions based solely on automated processing are permitted. It follows from Article 22(2) of the GDPR that the decision made solely on automated processing may nonetheless be made provided it is:

- authorised by EU or national law to which the controller is subject, and which also lays down suitable measures to safeguard the data subject’s rights and freedoms and legitimate interests; or
- necessary for entering into, or performance of, a contract between the data subject and a data controller; or
- based on the individual’s explicit consent.

In the event that automated decision-making is permitted on the basis of one of the three hypotheses, the controller shall abide by strict obligations clearly defined in the GDPR: (i) Implement suitable measures to safeguard the rights of the individuals, (ii) Inform the data subject and give access; (iii) Cease processing upon objection; and (iv) Conduct a data protection impact assessment.

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67 Recital 71 of the GDPR specifies the following: "decision-making based on such processing, including profiling, should be allowed where expressly authorised by Union or Member State law to which the controller is subject, including for fraud and tax-evasion monitoring and prevention purposes conducted in accordance with the regulations, standards and recommendations of Union institutions or national oversight bodies and to ensure the security and reliability of a service provided by the controller".

68 "Consent" represents one of the major improvements of the GDPR with respect to the legal regime relating to ‘profiling’. It shall however be reminded that the GDPR approaches consent more restrictively. The requirements related to consent are further detailed in sub-section 6.2.
7 Conclusions

7.1 Continuous Requirement Elicitation

The convergence of the knowledge of designers and end-users in engineering is a well-known issue. Social scientists have measured, in a variety of contexts, that a satisfying alignment between the mental models of two social groups or working teams requires time and multiple interactive sessions. Mismatches at the level of language interpretation or conceptualization of a problem are initially affecting any communication in groups with different backgrounds and goals.

To get rid of these mismatches, several instruments were proposed. Methods and guidelines for clearly introduce the adopted terminology using storytelling and situational introductions were, for example, largely studied and adopted. Glossary, handbook or ad hoc training program can also be adopted to reduce the mismatch. All these techniques may be effective but require a quite long startup period that may not be available in several projects. In other words, eliciting the requirements is traditionally carried out as an ex-ante activity. Recent results advocate that it can be also done at runtime involving the actual users, via users’ feedback.

Continuous requirement elicitation is an approach aiming at reducing the mismatch by a continued and progressive improvement of the definition of requirements. Continuous requirement elicitation has the potential to increase the quality and comprehensiveness and even the economic feasibility of requirements elicitation. This would allow developers, potentially, to gain a wider, and more up-to-date knowledge of how users perceive the system role in meeting their requirements, and to understand how that perception changes over time.

The requirement elicitation procedure adopted on SMART BEAR has three stages:

I. domain analysis;
II. requirement gathering;
III. requirement validation, prioritization, and integration.

The method adopted for preparing this deliverable has focused on implementing multiple iterations of these stages using techniques compatible with the relatively short period of time available, given the dimensions of the project. The requirement elicitation process has been conducted by the clinical and technical partners, initially with independent activities that have been merged by progressively integrating the results. The three stages have been covered by the two groups first independently and subsequently by joint meetings and activities.

The volume of the activities developed by this WP is testified by the materials produced during the preparation of this deliverable. However, we do not consider the developed work as conclusive. Further refinements of the requirements will be defined during the next stages. For example, the SMART BEAR platform specification will require to validate the data quality and integration level of different devices, as more knowledge about the technical specification of devices will be acquired by the technical partners of the projects by means of tests and trials. This will input further evaluation activities. In the same context, the specific workflows driving the use cases will be designed and evaluated with clinician to double-check their consistency to the requirements. Finally, the devices adopted will also be revised based on procurement procedures specific to each pilot.

7.2 Non-Functional Requirements

A further aspect to be highlighted is that the documentation developed by the activities carried out has focused on eliciting functional requirements, but non-functional requirements also emerged during the focus groups and the evaluation meetings involving clinical and technical partners.

A first group of non-functional requirements is related to security and legal aspects. The consortium is aware that these requirements must be brought up to the level of "state of the art". To get a reference the document
published by ENISA on the "state of the art" in IT security provides concrete advice and recommendations for action. These guidelines are intended to provide companies, providers (manufacturers, service providers) alike with assistance in determining the "state of the art" within the meaning of the IT security legislation. The document can serve as a reference for contractual agreements, procurement procedures or the classification of security measures implemented. They are not a replacement for technical, organizational or legal advice or assessment in individual cases.

A second group of non-functional requirements emerged by the interaction with patients and clinicians. The output obtained by the Focus Groups with patients and clinicians has underlined that usability, acceptance and integration aspects must be addressed by the project with specific care. Making the system capable to adapt to different user’s viewpoints is critical of the project.

For example, most of the participants agreed that they do not wish to receive both the smartphone and the tablet. In fact, it would be too burdensome to remember interacting with both and they would find it too confusing. The majority would prefer the smartphone over the tablet due to the portability of the former.

The major point that was discussed was that all the functions must be extremely tailored to the user. This was found the most pressing requirement: all the programs, suggestions, notifications, alerts and sharing of data should be customized and adjustable at will. The SMART BEAR options of “sharing data on senior’s health with the caregiver” or of “sending notifications to caregiver” were considered by participants a possible burden for their family members and a risk of feeling oppressed by relatives. Therefore, we recommend the sharing of reports and notifications mechanism to be flexible (e.g. by giving the possibility to the user of setting the frequency of the notifications and reports to the caregivers).

Also, most of the participants were feeling very unsure about the usability of the functions (i.e. their ability in using them). They all agreed that it will be very useful for them to have one or more assisted training sessions on the use of the devices as well as a gradual introduction to their functions.

An interesting idea that was shared about the visualization of the user’s data, about the possibility to view their parameters and trajectories compared with a clinical practice guideline and with what is medically judged to be the norm for someone in their condition. This would help them giving context to their results.

All the participants found particularly useful to share the data with clinicians through regular reports. Nonetheless, a concern was raised when thinking about their interaction with clinicians through SMART BEAR. Most of them did not think it plausible that their clinicians would be interested in burdening themselves with more work. Their usual experience is that the doctors dismiss what lies beyond their usual clinical practice (e.g. research experimentation) and this may reduce the effectiveness of the SMART BEAR intervention.

As the adaptability of the system is a key aspect of SMART BEAR we plan in the next WP2 activities to specify a methodology for generating the “in use” configuration of the SMART BEAR platform for a specific user as the combination of multiple setting profiles. An initial set of configuration profile to be considered was identified:

- Clinical Use Case: the device setting and the workflow driving the use case.
- Patient Profile: demographic profile, clinical conditions, risk class.
- Notification Preferences: notification preferences of the patient, the case manager, and the caregiver.
- Network Settings: local network standard, network access standard.

<table>
<thead>
<tr>
<th>Device</th>
<th>“In Use” Configuration Profile</th>
<th>Clinical Profile ID1</th>
<th>Clinical Profile ID2</th>
<th>Acceptance Profile ID56</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smartphone</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tablet</td>
<td></td>
<td></td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Smartwatch</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Sleep mat</td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Smart Scale</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Smart pillbox</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

The notifications sent by the system can be organized according to the enforcement level they impose.

- **Notifications (Blue):** Sent to the patient but not tracking the patient's reaction.
- **Notifications (Yellow):** Sent to the patient and case manager or caregiver but not tracking the patient's reaction.
- **Alerts (Red):** Sent to the patient (or in alternative to the case manager, caregiver) and tracking the patient's reaction.

In addition to the notification logs the SMART BEAR platform is provided with a Patient Diary collecting events automatically generated such as notifications and alerts + manual text annotations. The diary can be used by the patient also to let us know he stop the SMART BEAR monitoring (maybe he is on violation or he is hospitalized).
8 References


[125] Strenziok M, Parasuraman R, Clarke E, Cisler DS, Thompson JC, Greenwood PM. Neurocognitive enhancement in older adults: comparison of three cognitive training tasks to test a hypothesis of


9 Appendixes

Appendix 1 - SMART BEAR PARTICIPANT FOCUS GROUPS FACILITATION GUIDE

Appendix 2 - ITALIAN PILOT QUESTIONNAIRE FOR CLINICIANS

Appendix 3 - ITALIAN PILOT QUESTIONNAIRE FOR PARTICIPANTS

Appendix 4 - REPORT: VALIDATION OF SMART BEAR @HOME FEATURES THROUGH USE CASE SCENARIOS

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Appendix 1

SMART BEAR PARTICIPANT FOCUS GROUPS FACILITATION GUIDE
1. Introduction

Collecting data using focus groups is a very popular qualitative method in medical research. A focus group could be briefly described as “a discussion within a small group of people that is focused on a certain topic and is coordinated by a researcher / facilitator / moderator”\(^1\). Facilitator’s role is to stimulate the active engagement of participants in the discussion and to gather as many useful information as possible\(^2,3\). It is a helpful way to gain insight on target audience’s characteristics and opinions before, during or after conducting a research project\(^2–5\).

In the case of Smart Bear, multiple focus groups with older adults and clinicians (separately) will be performed in order to collect information from different participants’ points of view\(^1,6\). Careful detailed planning is required in order to gather, record, understand and explain the ways of thinking, beliefs and cultures that influence the participants’ feelings, attitudes and behaviors\(^2,7\). This deep insight gained from focus groups will be beneficial to the design of core Smart Bear procedures.

This is a brief step-by-step Focus Group Guide designed for Smart Bear Pilots. Its goal is to standardize the procedure across all 6 sites and thus maximize Smart Bear Focus Groups effectiveness.

2. Organizing a focus group

2.1. Ethical considerations

- The question whether ethical approval is required should be addressed to each local Ethics Committee by each Pilot.

- Every participant across all 6 sites should sign a written consent before participating to the focus group. Their option to withdraw their consent at any time should be clearly explained to them.

Comment: Involved researchers should never forget that focus groups are research, and the same ethical requirements apply\(^7\). They need to remember their ethical responsibility to the security and privacy of the focus groups participants. Issues such as audio recording of the focus group discussion should be explicitly communicated to all participants before starting the focus group and should be avoided if it raises minor concerns or objections.

2.2. Resources required:
• Project coordinator • facilitator • note-taker • observer (or 2nd note-taker, optional)

Comment: Focus groups team members should be familiar with Smart Bear basic concept and principles, sensitive and non-judgmental with high communication skills. Ideally they do not know personally the participants.

2.3. Selecting a venue:

• Accessible (close to public transport with adequate parking and disability access)
• Minimal noise, visual and other environmental distractions
• Private

Comment: Venue should make participants feel comfortable. An already familiar place would be ideal.

2.4. Recruiting participants

• Group size: Identify 10 participants to contact with the aim of having 4-8 who will actually participate on the day
• Target groups: Frail aged / Physicians working with the elderly
• Inviting people to participate
  • Via telephone
  • Face-to-face
  • Participants information sheet (see Appendix A), providing brief information about
    • Main topics discussed during the focus group,
    • Goals of the focus group,
    • Procedure and approximate time line
    • Practical details of the appointment (access, time, name of focus group team members, contact details).
  • Payment for participation / reimbursement for expenses incurred: no payment / reimbursement is envisaged.

2.5. Preparing focus group material

• Participants information sheet (see Appendix A. Example Participant Information Sheet)
• Written consent (see Appendix B. Example consent form and confidentiality undertaking).
• Notes sheet containing the principle topics that will be discussed (see Appendix C. Example of Focus Group Notes Template / Final Report).
• Questionnaire addressed to participants – Translated version of Smart Bear Focus Group Participants Questionnaire (see Appendix D. Smart Bear Focus Group Participants Questionnaire and Appendix E. Smart Bear Focus Group Clinicians Questionnaire).

3. Conducting a focus group

3.1. Setting up

• Technical requirements (audio recording etc)
• Venue (U-shaped or semi-circle, comfortable seating, temperature etc)
3.2. Participants arrival

- Presentation of the focus group team and explanation of each member’s role during the focus group
- Encourage brief informal introduction - discussion among participants
- Practical information, such as location of toilets, fire exits, approximate duration of the focus group discussion

3.3. Reading - Signing of the Consent Form (see Appendix B)

Comment: During this step, establishing a group agreement, such as, being respectful and making sure conversation stays ‘in the room’, could facilitate the discussion that will follow and may help participants relax and express themselves freely.

3.4. Focus group core procedure

- Hand to participants the Smart Bear Focus Group Questionnaire
- Promote a type of discussion that will generate a maximum number of different ideas and opinions from as many of the participants in the time allotted.
- Take some time to briefly summarize after some useful thoughts have been vaguely expressed, giving the note-taker some extra time to organize what has been discussed (e.g. Participants input: “Sometimes it is too hot outside and I have to go back home sooner than expected. This irritates me and makes my life even more difficult...”, Facilitator’s brief response – summary: “So, daily information on ambient temperature would help you better organize your day.”)

Useful tips:

- Keep all conversation within the group as a whole: side conversations between group members may distract the flow of discussion.
- Remember that this is not an educational workshop.
- While listening, use eye contact and encouraging non-verbal communication. Avoid interruption, but do not hesitate to make a note of comments that require further clarification.
- Use open-ended prompts and probes that keep the flow going (e.g. ‘Would you give us an example of what you mean?’).
- Before moving to the next participant or next topic, show empathy and thank the person for expressing himself (e.g. “Thank you for sharing that, let’s hear now from someone else.”)

3.5. Ending the session

- Give participants 5-10 minutes to add anything that you may not have considered and to hand back their Smart Bear Focus Group Questionnaire.
- Thank everyone for their participation and explain once more the importance of their opinion and the size of the project that will be based on it.
- Assure participants that the discussion has been confidential and any information will be de-identified.
- Make your contact details available in case there are any questions or willingness to participate in the Smart Bear Project after the focus group.

4. Internal Debriefing meeting

- Right after the focus group and without the presence of participants, focus group team members should briefly discuss outcomes and clarify any confusion.
5. Data collection and analysis

Focus group team should read and discuss thoroughly the notes taken during the focus group and each participant’s answers to the Smart Bear Focus Group Questionnaire, looking for patterns and similarities. Key ideas and most frequently emerged issues should be outlined and create a basis on which a list of operational actions for implementing the gained knowledge to the improvement of Smart Bear design will be developed.

6. Reporting - Providing Feedback to the Smart Bear Clinical Coordinator (NKUA)

For the harmonization of the Smart Bear Focus group results, a Reporting Template (see Appendix C and D) is proposed and should be adopted by all Smart Bear Pilots. Feedback is expected to be communicated to the Clinical Coordinator till the end of October 2019 (see 7. Timeline).

REFERENCES


Dear Citizen of [Pilot’s local community] / Dr

We invite you to participate in a focus group discussion as part of Smart Bear Project, an EU funded research project being undertaken by [Pilot Credentials]. Smart Bear aims to implement state of the art technology in the everyday life of our community’s elderly members, in order to enhance their independent living and improve their quality of life. We are interested in hearing your opinion and beliefs so that we can identify ways to achieve this goal. Before you decide whether you wish to participate in this discussion, please take the time to read the following information carefully.

What is the purpose of these discussions?

- We would like to collect information about participants’ needs and beliefs before the design and execution of Smart Bear Project. This information will be used to choose the best methods of handling the most prevalent and important health issues you have to confront in your everyday life.

Why have you been invited to participate in a discussion?

- As a citizen / member of [Pilot – local community], over the age of 67 years old / As a clinician working with the elderly of [local community], you have been invited to participate in a discussion. Your beliefs and opinion will provide useful information for the design and execution of our project.

How these discussions will be conducted?

- We are conducting focus groups with approximately 4-8 people over the age of 67 / physicians living in [Pilot local community]. Discussion on practical matters and health issues of everyday life will be held among the participants and members of Smart Bear team. No prior preparation or experience is required.
- The discussion will last for about 1.5-2 hours.
- The discussion will involve a series of questions, such as your / your patients’ age, your /their familiarization with technology, your expectations of a project like Smart Bear etc. The questions will be given to you in written form and you will be able to express your opinion and discuss with the other participants and Smart Bear local team.
- If you are willing to participate to the above discussion, prior to our meeting, we will ask you to sign the Participant Consent Form. You are welcome to have a family member or carer with you if you wish. In that case, this person will also be asked to sign the Participant Consent Form (for elderly focus groups only).

Will taking part in the discussion cost me anything? Will I get paid?

- The participation to our focus group is voluntary. No charge or payment is envisaged.

What if I don’t want to take part in a discussion or if I want to withdraw later?

- It is fine if you chose not to take part. Your decision will not disadvantage you in any way. If you decide to participate, you may withdraw your comments at any time without giving a reason.

What if I decide to take part in the discussion?

In case you want to participate to our focus group, please contact our team: [contact details]
APPENDIX B. EXAMPLE CONSENT FORM AND CONFIDENTIALITY UNDERTAKING

Smart Bear Focus Group Participation Consent Form

Participant’s ID number:

<table>
<thead>
<tr>
<th>Please check (✓) all that apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I have understood the information provided by the focus group coordinators. I had the time and space to thoroughly think about this information, express my thoughts and questions about it and receive satisfying answers by the focus group coordinators.</td>
</tr>
<tr>
<td>2. I understand that my participation to the focus group is voluntary and I can withdraw at any time without giving a reason. The fact that my decision to withdraw will not disadvantage me in any way has been clarified by the focus group coordinators.</td>
</tr>
<tr>
<td>3. I consent to participate to the Smart Bear Focus Group.</td>
</tr>
<tr>
<td>4. I understand that no charge or payment is envisaged for my participation to the Smart Bear Focus Group.</td>
</tr>
<tr>
<td>5. I understand that my personal information will remain confidential as outlined in the Participant Information Sheet.</td>
</tr>
<tr>
<td>6. I understand that I may not disclose the group discussions outside the focus group and that I must treat other participants’ private information as confidential.</td>
</tr>
</tbody>
</table>

Participant:

____________________________________
Participant’s name

____________________________________
Participant’s signature

Focus Group Team Member who receives the signed consent form

____________________________________        __/__/____
Name and Signature                      Date of signature

APPENDIX C. EXAMPLE OF FOCUS GROUP NOTES TEMPLATE
**Smart Bear Focus Groups Report – [Pilot credentials]**

1. **Number of focus groups conducted:**

   ___________________________________________________________

2. **Number of attendees at each focus group:**
   (note: minimum one focus group for clinicians and one for clinicians per site)

<table>
<thead>
<tr>
<th>Focus group 1:</th>
<th>Focus group 3:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Focus group 2:</th>
<th>Focus group 4:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. **Demographic details**

   Number of males: __________ Number of females: __________ Number of carers: __________

   Mean age (males): __________ Mean age (females): __________

4. **Major themes and quotes that emerged from results of the focus groups and summary / per question**
   (please attach transcript for analysis if available)

   **Question 1: Do you have or have had any of the following medical conditions?**

   **Notable quotes:**

   ___________________________________________________________

   **Summary - Observations:**

   ___________________________________________________________
SMART BEAR FOCUS GROUP CLINICIANS

QUESTIONNAIRE

Clinician’s characterization

Q1. Clinician’s ID

Q2. Age

Q3. Gender  M ☐  F ☐

Q4. Occupation

Q5. Do you treat any of the following conditions?
Please check (✓) all that apply for you and feel free to add any further comments

- Hearing loss
- Dementia
- Imbalance
- Falls
- Anxiety
- Stress
- High blood pressure
- Depression
- Ischemic heart disease
- Arrhythmias

Q6. Experience
Years spent treating this medical condition

Q7. Remote monitoring
Have you ever been dealing with remote monitoring technology?

Yes ☐  No ☐
Section A – The medical condition from the clinician’s point of view

Describe the current procedure you use for your patients with the indicated medical condition

A1. What kind of treatment is used for this condition? What is the mostly used treatment (e.g. inpatient or outpatient treatment)?

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A2. Does this medical condition require for a personalized treatment? If it does, what should a personalized treatment plan include?

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A3. How many patients do you monitor outside of conventional clinical settings? (e.g. such as in the home or in a remote area, etc.).

Please indicate the percentage of patients

_____________________________________________________________________________________
_____________________________________________________________________________________
_____________________________________________________________________________________
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A4. What do you usually monitor outside your clinical setting? (E.g., pharmacological therapy, cognitive, organic or mood symptoms, etc.)

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A5. How do you communicate remotely with the patient? Please indicate what kind of technology or platforms you use. (E.g., whatsapp, internet platforms, phone calls...)

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A6. Does this remote monitoring cause burden on you? (For example in terms of stress, time...)
Section B – Impact of the medical condition on the patient and his/her caregiver from the clinician’s perspective

[Investigate eventual difficulties /complications/challenges for the patient and his/her caregivers]

B1. What is the impact of this medical condition on the patients’ activities of daily living? Which are the main issues encountered by the patient at home?
For example, does it affect daily life activities, nutrition, sleep, mood, motor capacity, cognition (e.g. memory, attention and language)?

<table>
<thead>
<tr>
<th>Vitality</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(daily life activities, cardio-respiratory functions, nutrition, etc..)</td>
<td></td>
</tr>
<tr>
<td>Sensory</td>
<td></td>
</tr>
<tr>
<td>(vision, hearing, etc..)</td>
<td></td>
</tr>
<tr>
<td>Psychological</td>
<td></td>
</tr>
<tr>
<td>(mood, sleep, etc)</td>
<td></td>
</tr>
<tr>
<td>Locomotion</td>
<td></td>
</tr>
<tr>
<td>(balance, motor capacity, gait, etc..)</td>
<td></td>
</tr>
<tr>
<td>Cognition</td>
<td></td>
</tr>
<tr>
<td>(memory, attention, language, etc..)</td>
<td></td>
</tr>
</tbody>
</table>

B2. Who are the people directly or indirectly affected by the onset of the medical condition? (E.g., family members, relatives, health care providers)

B3. How do these difficulties affect the caregiver’s life? Which are the main issues encountered by the caregivers?
Section C – Pros e cons of the ways of handling the medical condition

[Investigate eventual difficulties in handling the condition for the patient, the people close to him/her and the clinician]

C1. Which are the cons of the current medical procedure for the patient? (E.g., remind to take the drugs, handling the adverse effects related to the medication, etc.)

C2. Which are the cons of the current medical procedure for the people close to the patient? (E.g., anxiety about continuous monitoring, remind about the clinical appointments etc.)

C3. Which are the pros and cons of the current medical procedure for the clinician? (E.g., use of WhatsApp for instant communication considered as pro but the technology invasiveness affects private life, etc.)
Section D – Possible benefits of remote monitoring

[Explore improving solutions]

D1. How would you improve weakness/cons of the current medical procedure?

D2. Which of the following measurements would you consider as more useful to your patients’ everyday life?

Please check (✓) up to 3 boxes and feel free to add any further comments

- Blood pressure
- Heart rate
- House temperature
- Blood sugar
- Air pollution
- Social interaction frequency
- Electrocardiogram
- Dietary habits
- Fall detection
- Levels of noise exposure

D3. What would be the benefit in remote patient monitoring for 24 hours a day, if any?

Section E – Use of technology in medical practice

[Explore the use of technology in medical practice]

E1. Which of the following devices have you used/ prescribed/ suggested to your patients?

Please check (✓) all that apply and feel free to add any further comments

- Nutrition Applications
- Smart pillboxes
E2. How often do you use Smart Devices in your everyday clinical practice?
Please check (✓) only one box and feel free to add any further comments

Never ❌ Rarely ❌ Sometimes ❌ Often ❌ Always ✓

E3. How useful do you find technology for your clinical practice?
Please check (✓) only one box and feel free to add any further comments

Obstructive ❌ Indifferent ❌ Useful ✓ Very useful ❌ Fundamental ❌

E4. How easy do you find technology to use in your clinical practice?
Please check (✓) only one box and feel free to add any further comments

Impossible ❌ Difficult ❌ Neutral ❌ Easy ✓ Very easy ❌
Section F – About an eventual experience with Smart Bear

**F1. Smart Bear** Platform could provide you with regular reports concerning your patients’ health status and measurements. Is that something appealing to you?
*Please check (✓) only one box and feel free to add any further comments*

- Yes ☐
- No ☐


**F2. Smart Bear** Platform could provide you with regular reports concerning your patients’ health status and measurements. Which type of report would you consider as more helpful to them and to you?
*Please check (✓) only one box and feel free to add any further comments*

- Monthly report ☐
- Weekly report ☐
- Daily report ☐


**F3.** How would you like to receive this information? (E.g., background message, text messages, email, etc.)


**F4. Smart Bear** Platform could provide patients with regular notifications – suggestions depending on its observations e.g. “Your blood pressure is regularly higher than the normal for the last 2 weeks. You should visit your referring physician”.

Which type of notifications would you consider as more helpful?
*Please check (✓) only one box and feel free to add any further comments*

- Notifications to the user ☐
Notifications to the user and his/her referring physician*  ○
Notifications to the user and his/her significant other*  ○
* (with user’s consent)

F5. How would you like to receive these regular notifications – suggestions? (E.g., background message, text message, email, etc.)

F6. Would you encourage your patients to participate in a project implementing state of the art technology to their everyday life, such as Smart Bear? Why?
Please check (✓) only one box and feel free to add any further comments

Yes ○  No ○

F7. What are your expectations of a project like Smart Bear?
Please check (✓) up to 3 boxes and feel free to add any further comments

Less unnecessary visits ○
Frail Patients’ Safety ○
Better auto-management of your patients’ health issues ○
Better social interactions ○
Improving of your patients’ overall health ○
Improving your patient – doctor communication ○
F8. If one of your patients asks for your opinion on whether to participate in Smart Bear Project, which would be your major concerns?

Please check (✓) up to 3 boxes and feel free to add any further comments

Privacy  ○
Change of Routine  ○
Erroneous Measurements  ○
Erroneous Notifications – Suggestions by the Platform  ○
Technical Issues of the Devices – Internet Connection  ○
Education on Devices and Platform Usage  ○
Increased stress for the user  ○

Would you like to add any further comments? If yes, please add your comments to the box below.

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Thank you for taking the time to fill our questionnaire!
QUESTIONNAIRE

Participant characterization

Q1. Participant’s ID

Q2. Age

Q3. Gender      M ⃝ F  ⃝

Q4. Occupation (before eventual retirement)

Q5. Education (years of schooling)

Q6. Do you have or have had any of the following conditions?

Please check (✓) all that apply for you and feel free to add any further comments

- Hearing loss
- Imbalance
- Anxiety
- High blood pressure
- Ischemic heart disease
- Dementia
- Falls
- Stress
- Depression
- Arrhythmias
Q7. Housing context

Are you living with someone?  Yes ☐  No ☐

If you do, what is your relationship with him or her? Could you leave his/her contact (telephone number or email address)?

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Section A – Impact of the medical condition on the participant’s and their caregivers’ daily life activities

A1. How do you generally spend your day?

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A2. How has your life changed since the onset of your medical condition?

<table>
<thead>
<tr>
<th>Vitality</th>
<th>__________________________________________</th>
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</thead>
<tbody>
<tr>
<td>(daily life activities, cardio-</td>
<td></td>
</tr>
<tr>
<td>respiratory functions,</td>
<td></td>
</tr>
<tr>
<td>nutrition, etc..)</td>
<td></td>
</tr>
<tr>
<td>Sensory</td>
<td>__________________________________________</td>
</tr>
<tr>
<td>(vision, hearing, etc..)</td>
<td></td>
</tr>
<tr>
<td>Psychological</td>
<td>__________________________________________</td>
</tr>
<tr>
<td>(mood, sleep, etc)</td>
<td></td>
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<tr>
<td>Locomotion</td>
<td>__________________________________________</td>
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<tr>
<td>(balance, motor capacity, gait,</td>
<td></td>
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<tr>
<td>etc..)</td>
<td></td>
</tr>
<tr>
<td>Cognition</td>
<td>__________________________________________</td>
</tr>
<tr>
<td>(memory, attention, language,</td>
<td></td>
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<tr>
<td>etc..)</td>
<td></td>
</tr>
</tbody>
</table>
A3. Do you handle your medical condition independently? Do you need help or assistance?

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A4. Whom do you call when you need someone? (Friends, family or others)

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A5. How do the people close to you help you handling your medical condition? Does your medical condition have an impact on their lives?

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Section B – Handling medical conditions

B1. Which are the daily/weekly/monthly steps you follow to handle your medical condition?
B2. How often do you go to the general practitioner or another health care provider for your medical condition?

B3. Which modality do you use to communicate remotely with your health care provider? (E.g. telephone, app, internet portal to communicate real-time...)

B4. Do you use any monitoring devices for your medical condition?

Section C – Pros and cons of the ways of handling the medical condition

C1. Which are the pros and cons of how you handle your medical condition?

C2. If you use any monitoring devices, are they easy to use? Do you find limitations in the devices you use?
Section D – Possible improvements

D1. How would you improve the way you handle your medical condition?

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D2. Which of the following measurements would you consider as more useful to your everyday life?
Please check (✓) up to 3 boxes and feel free to add any further comments

- Blood pressure
- Heart rate
- House temperature
- Blood sugar
- Air pollution
- Social interaction frequency
- Electrocardiogram
- Dietary habits
- Fall detection
- Levels of noise exposure

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D3. Why would you like to receive this information?

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Section E – Relationship with technology

E1. Describe your experience with the following devices:
*Please check (✓) only one box and feel free to add any further comments about your experience with each device*

- **Smartphones**

<table>
<thead>
<tr>
<th>Very poor</th>
<th>Poor</th>
<th>Normal</th>
<th>Good</th>
<th>Very good</th>
</tr>
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<tbody>
<tr>
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</table>

- **Smart TVs**

<table>
<thead>
<tr>
<th>Very poor</th>
<th>Poor</th>
<th>Normal</th>
<th>Good</th>
<th>Very good</th>
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</table>

- **Smartwatches**

<table>
<thead>
<tr>
<th>Very poor</th>
<th>Poor</th>
<th>Normal</th>
<th>Good</th>
<th>Very good</th>
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<tr>
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</table>

- **Smart light bulbs**

<table>
<thead>
<tr>
<th>Very poor</th>
<th>Poor</th>
<th>Normal</th>
<th>Good</th>
<th>Very good</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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</tbody>
</table>
• Smart thermostats

<table>
<thead>
<tr>
<th>Very poor</th>
<th>Poor</th>
<th>Normal</th>
<th>Good</th>
<th>Very good</th>
</tr>
</thead>
</table>

E2. How useful do you find technology for your daily activities?
Please check (✔) only one box and feel free to add any further comments

<table>
<thead>
<tr>
<th>Obstructive</th>
<th>Indifferent</th>
<th>Useful</th>
<th>Very useful</th>
<th>Fundamental</th>
</tr>
</thead>
</table>

E3. How easy do you find technology to use?
Please check (✔) only one box and feel free to add any further comments

<table>
<thead>
<tr>
<th>Impossible</th>
<th>Difficult</th>
<th>Neutral</th>
<th>Easy</th>
<th>Very easy</th>
</tr>
</thead>
</table>

E4. How often do you forget to charge your mobile phone or leave home without it?
Please check (✓) only one box and feel free to add any further comments

<table>
<thead>
<tr>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always</th>
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<tbody>
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</table>

E5. Would you want to use wearable devices? Have you ever had experiences with them? (E.g. Garmin, smartwatch etc.)?

_____________________________________________________________________________________

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Section F – About an eventual experience with Smart Bear

F1. Smart Bear Platform could provide your referring physician with regular reports concerning your health status and measurements. Is that something appealing to you?

Please check (✓) only one box and feel free to add any further comments

Yes ☑ No ☐

_____________________________________________________________________________________

_____________________________________________________________________________________

F2. Smart Bear Platform could provide you with regular reports concerning your health status and measurements. Which type of report is more appealing to you?

Please check (✓) only one box and feel free to add any further comments

Monthly report ☐ Weekly report ☑

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F3. Who else would you want to have access to reports on your health status?

F4. How would you like to receive this information? (E.g., audio reports, text messages, email...)

F5. **Smart Bear** Platform could provide you with regular notifications – suggestions depending on its observations e.g. “Your blood pressure is regularly higher than the normal for the last 2 weeks. You should visit your referring physician”.

How willing would you be to follow the Platform Instructions? 
*Please check (✓) only one box and feel free to add any further comments*

<table>
<thead>
<tr>
<th>Not willing</th>
<th>Slightly willing</th>
<th>Moderately Willing</th>
<th>Willing</th>
<th>Very Willing</th>
</tr>
</thead>
</table>

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F6. Who else would you want to have access to notifications – suggestions on your health status?

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

F7. How would you like to receive notifications – suggestions on your health status? (E.g., phone alarms, text messages, email...)

________________________________________________________________________
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________________________________________________________________________

F8. Would you participate to a project implementing state of the art technology to your everyday life, such as Smart Bear? Why?

*Please check (✓) only one box and feel free to add any further comments*

Yes  ○  No  ○

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F9. What would your expectations be in case you decide to participate to a project like Smart Bear?

*Please check (✓) up to 3 boxes and feel free to add any further comments*

<table>
<thead>
<tr>
<th>Increase of your daily activities</th>
<th>○</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety</td>
<td>○</td>
</tr>
<tr>
<td>Better auto-management of your health issues</td>
<td>○</td>
</tr>
<tr>
<td>Less visits to your referring physician</td>
<td>○</td>
</tr>
</tbody>
</table>
Better social interactions

Time Saving

Money Saving

Improving your diet habits

Improving your confidence

F10. If you decide to participate to **Smart Bear** Project and make use of **Smart Bear** Platform, which would be your major concerns?

*Please check (✓) up to 3 boxes and feel free to add any further comments*

<table>
<thead>
<tr>
<th>Privacy</th>
<th>☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change of Routine</td>
<td>☐</td>
</tr>
<tr>
<td>Erroneous Measurements</td>
<td>☐</td>
</tr>
<tr>
<td>Erroneous Notifications – Suggestions by the Platform</td>
<td>☐</td>
</tr>
<tr>
<td>Technical Issues of the Devices – Internet Connection</td>
<td>☐</td>
</tr>
<tr>
<td>Education on Devices and Platform Usage</td>
<td>☐</td>
</tr>
<tr>
<td>Increased stress</td>
<td>☐</td>
</tr>
</tbody>
</table>

Would you like to add any further comments? If yes, please add your comments to the box below.
If you are interested in participating to the Smart Bear Project, please leave your contacts here:

Name
.................................................................................................................................................
........

Phone number
.................................................................................................................................................

Email address
.................................................................................................................................................

Thank you for taking the time to complete our questionnaire!
APPENDIX … SMART BEAR ONLINE SURVEY CLINICIANS

The following questionnaire concerns Smart Bear, an EU funded research project (Horizon 2020) that is conducted in 6 European countries.

Smart Bear aims to implement state of the art technology in the everyday life of elderly citizens in 7 European cities’, in order to enhance their independent living and improve their quality of life.

[Pilot Credentials] is participating to this innovative European project and invites physicians working with the elderly members of its community to read and answer the following simple questions concerning their characteristics and needs.

There are 13 questions in this survey.

1. Demographic data

[ ]1. What is your medical domain of expertise? *

Please choose only one of the following:

- □ ENT
- □ Cardiology
- □ General Medicine
- □ Geriatrics
- □ Neurology
- □ Psychiatry
- □ Other

[ ]2. What is your nationality? *

Please choose only one of the following:

- □ Italian
- □ Greek
- □ Romanian
- □ Spanish
- □ Portuguese
- □ French
- □ Other

[ ]3. How often do you use Smart Devices in your everyday clinical practice? *


Please choose only one of the following:

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Everyday

2. Medical Conditions

[] 1. Do you treat any of the following conditions? *

Please choose all that apply:

- ☐ Hearing loss - Tinnitus
- ☐ Falls
- ☐ Imbalance
- ☐ Arrhythmias
- ☐ Stress
- ☐ Depression
- ☐ Ischemic heart disease
- ☐ Hypertension
- ☐ Dementia
- ☐ Anxiety

[] 2. Which of the following measurements would you consider more useful for your patients’ everyday wellbeing? *

Please choose all that apply:

- ☐ Blood Pressure
- ☐ Levels of noise exposure
- ☐ Air Pollution
- ☐ Electrocardiogram
- ☐ Heart Rate
- ☐ Fall Detection
- ☐ Blood sugar
- ☐ House Temperature
- ☐ Diet Habits
3. How often does your average aged patient visits you? *

Please choose only one of the following:

- More than once per month
- Once per 1-3 months
- Once per 6 months
- Once per year

4. Which of the following devices have you used / prescribed/ suggested to your patients? *

Please choose all that apply:

- Nutrition Applications
- Physiotherapy Applications and Smart Devices
- Smart pillboxes
- Physical Activity Applications and Smart Devices
- Smart Blood Pressure Tracker
- Smart Hearing Aids

3. Participation in the Smart Bear Project

1. Would you recommend your patients to participate to a project implementing state of the art technology to their everyday life, such as Smart Bear?*

Please choose only one of the following:

- Yes
- No

2. Which are your major concerns about Smart Bear Project? *

Please choose all that apply:
• Privacy
• Change of Routine
• Erroneous Measurements
• Erroneous Interventions – Suggestions by the Platform
• Technical Issues of the Devices – Internet Connection
• Education on Devices and Platform Usage
• Increased stress

[3. What would your expectations of their participation in Smart Bear Project be?*

Please choose all that apply:

Increase of your daily activities
Safety

Better self-management of your health issues

Less visits to your referring physician

Better relationships with your significant others

Time Saving

Money Saving

Improving your diet habits

Improving your confidence

[4. Do you think that implementing state of the art technology to their everyday life would be overall helpful?*}
Please choose only one of the following:

- Yes
- No

[5] Smart Bear Platform could provide participants and their referring physicians, with regular reports concerning their health status and measurements. How often do you think the system should generate these reports?

Please choose only one of the following:

- Daily
- Weekly
- Monthly
- Only if an abnormality is detected

[6] Smart Bear platform could provide referring physicians access to their patients data and ask for their input after each patient’s visit. Is that something appealing to you?*

Please choose only one of the following:

- Yes
- No

Your answer has been recorded.

We do appreciate your time.

The Smart Bear Project Team

Submit your survey.
Thank you for completing this survey.
APPENDIX ... SMART BEAR ONLINE SURVEY SENIORS

The following questionnaire concerns Smart Bear, an EU funded research project (Horizon 2020) that is conducted in 6 European countries.

Smart Bear aims to implement state of the art technology in the everyday life of elderly citizens in 7 European cities, in order to enhance their independent living and improve their quality of life.

[Pilot Credentials] is participating to this innovative European project and invites its citizens with interest in participating in Smart Bear Project to read and answer the following simple questions.

There are 21 questions in this survey

1. Demographic data

1. What is your age group? *

Please choose only one of the following:

- <67
- 67-73
- 74-80
- 80+

2. What is your sex? *

- Female
- Male

3. What is your nationality? *

Please choose only one of the following:

- Italian
- Greek
- Romanian
- Spanish
- Portuguese
- French
- Other
4. How would you describe your experience with Smart Devices such as Smartphones and Smartwatches? *

Please choose only one of the following:

- [ ] Very poor
- [ ] Poor
- [ ] Normal
- [ ] Good
- [ ] Very good

5. Apart from you, how many people live in your household? *

Please choose only one of the following:

- [ ] I live alone
- [ ] 1
- [ ] More than 1

2. Medical History

1. Do you have or have had any of the following medical conditions?*

Please choose all that apply:

- [ ] Falls
- [ ] Stress
- [ ] Depression
- [ ] Arrhythmias (Heart Rhythm Problems)
- [ ] Hearing loss - Tinnitus
- [ ] Coronary disease (Ischemic heart disease)
- [ ] Hypertension (High Blood Pressure)
- [ ] Dementia
- [ ] Imbalance
- [ ] Anxiety
2. Which of the following measurements would you consider more useful for your everyday wellbeing? *

Please choose only one of the following:

- Blood Pressure
- House Temperature
- Air Pollution
- Electrocardiogram
- Heart Rate
- Fall Detection
- Blood sugar
- Levels of noise exposure
- Diet Habits
- Social Interactions Frequency

3. How often do you visit a health care provider? *

Please choose only one of the following:

- More than once per month
- Once per 1-3 months
- Once per 6 months
- Once per year
- I never go to the doctor

4. How easy is it for you to complete your everyday activities (household, visit friends, grocery shopping)? *

Please choose only one of the following:

- Very difficult
- Difficult
- Moderate
- Easy
- Very easy

5. Thinking about how much contact you’ve had with people you like, which of the following best describes your social situation?*
Please choose only one of the following:

- I feel isolated.
- I have some contact with people, but it does not feel enough.
- I have adequate contact with people.
- I have as much contact with people as I want.

[ ] 6. Are you using or having used a hearing aid?*

Please choose only one of the following:

- Yes
- No
3. Participation to the Smart Bear Project

1. Are you interested in participating to a project implementing state of the art technology to your everyday life, such as Smart Bear?*

   Please choose only one of the following:
   - Yes
   - No

2. Which are your major concerns about using smart devices during your everyday activities? *

   Please choose up to three of the following:
   - Privacy
   - Change of Routine
   - Wrong Measurements
   - Wrong Interventions – Suggestions by the Platform
   - Device Use – Internet Connection
   - Education on Devices and Platform Usage
   - Increased stress

3. Have you ever participated in a similar project?*

   Please choose only one of the following:
   - Yes
   - No

4. What would your expectations of your participation in Smart Bear Project be?*

   Please choose all that apply:
   - Increase of your daily activities
   - Safety
   - Better self-management of your health issues
Less visits to your referring physician

Better social life

Time Saving

Money Saving

Improving your diet habits

Improving your confidence

5. Do you think that implementing state of the art technology to your everyday life would be overall helpful?*

Please choose only one of the following:

- Yes
- No

6. Smart Bear Platform can provide you and your referring physician with regular reports concerning your health status and measurements. How often do you think the system should generate these reports?

Please choose only one of the following:

- Weekly
- Monthly
- Only if an abnormality is detected
7. Smart Bear Platform could provide you with regular notifications – suggestions depending on its observations. How willing would you be to follow Platform’s suggestions?*

Examples of Clinical scenario – Platform’s reaction:

“Air pollution is significantly high today. Closing windows will minimize your exposure.”

Please choose only one of the following:

- ☐ Unwilling
- ☐ Slightly willing
- ☐ Moderately willing
- ☐ Willing
- ☐ Very Willing

8. How do you think this suggestions should be provided to you?*

Please choose only one of the following:

- ☐ Notification on the Smart Bear App the moment of the abnormal observation
- ☐ Daily report via Smart Bear App and/or via email
- ☐ Weekly report via Smart Bear App and/or via email
- ☐ Weekly report to your referring physician
- ☐ Other:

9. How willing would you be to complete simple tasks such as Cognitive or Balance Training Serious Games? ?*

Please choose only one of the following:

- ☐ Unwilling
- ☐ Slightly willing
- ☐ Moderately willing
- ☐ Willing
- ☐ Very Willing

10. Would you be interested in participating in a test regarding your level of acquired knowledge and familiarization with the Smart Bear Platform?*
Please choose **only one** of the following:

- ☐ Yes
- ☐ No

Your answer has been recorded.

We do appreciate your time.

**The Smart Bear Project Team**

Submit your survey.
Thank you for completing this survey.
Appendix 2
ITALIAN PILOT QUESTIONNAIRE FOR CLINICIANS
Appendix 2 - ITALIAN PILOT QUESTIONNAIRE FOR CLINICIANS

SMART BEAR FOCUS GROUP CLINICIANS

QUESTIONNAIRE

Clinician’s characterization

Q1. Clinician’s ID

Q2. Age

Q3. Gender

Q4. Occupation

Q5. Do you treat any of the following conditions?
Please check (✓) all that apply for you and feel free to add any further comments

- Hearing loss
- Dementia
- Imbalance
- Falls
- Anxiety
- Stress
- High blood pressure
- Depression
- Ischemic heart disease
- Arrhythmias

Q6. Experience
Years spent treating this medical condition

Q7. Remote monitoring
Have you ever been dealing with remote monitoring technology?

Yes  No
Section A – The medical condition from the clinician’s point of view

[Describe the current procedure you use for your patients with the indicated medical condition]

A1. What kind of treatment is used for this condition? What is the mostly used treatment (e.g. inpatient or outpatient treatment)?

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A2. Does this medical condition require for a personalized treatment? If it does, what should a personalized treatment plan include?

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A3. How many patients do you monitor outside of conventional clinical settings? (e.g. such as in the home or in a remote area, etc.).

Please indicate the percentage of patients ..........................................................

A4. What do you usually monitor outside your clinical setting? (E.g., pharmacological therapy, cognitive, organic or mood symptoms, etc.)

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A5. How do you communicate remotely with the patient? Please indicate what kind of technology or platforms you use. (E.g., whatsapp, internet platforms, phone calls...)

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A6. Does this remote monitoring cause burden on you? (For example in terms of stress, time...)

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Section B – Impact of the medical condition on the patient and his/her caregiver from the clinician’s perspective

[Investigate eventual difficulties / complications / challenges for the patient and his/her caregivers]

**B1.** What is the impact of this medical condition on the patients’ activities of daily living? Which are the main issues encountered by the patient at home?

For example, does it affect daily life activities, nutrition, sleep, mood, motor capacity, cognition (e.g. memory, attention and language)?

<table>
<thead>
<tr>
<th>Vitality</th>
<th>(daily life activities, cardio-respiratory functions, nutrition, etc..)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensory</td>
<td>(vision, hearing, etc..)</td>
</tr>
<tr>
<td>Psychological</td>
<td>(mood, sleep, etc)</td>
</tr>
<tr>
<td>Locomotion</td>
<td>(balance, motor capacity, gait, etc..)</td>
</tr>
<tr>
<td>Cognition</td>
<td>(memory, attention, language, etc..)</td>
</tr>
</tbody>
</table>

**B2.** Who are the people directly or indirectly affected by the onset of the medical condition? (E.g., family members, relatives, health care providers)

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**B3.** How do these difficulties affect the caregiver’s life? Which are the main issues encountered by the caregivers?

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Section C – Pros e cons of the ways of handling the medical condition

[Investigate eventual difficulties in handling the condition for the patient, the people close to him/her and the clinician]

C1. Which are the cons of the current medical procedure for the patient? (E.g., remind to take the drugs, handling the adverse effects related to the medication, etc.)

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C2. Which are the cons of the current medical procedure for the people close to the patient? (E.g., anxiety about continuous monitoring, remind about the clinical appointments etc.)

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C3. Which are the pros and cons of the current medical procedure for the clinician? (E.g., use of WhatsApp for instant communication considered as pro but the technology invasiveness affects private life, etc.)

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Section D – Possible benefits of remote monitoring

[Explore improving solutions]

**D1. How would you improve weakness/cons of the current medical procedure?**

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**D2. Which of the following measurements would you consider as more useful to your patients’ everyday life?**

*Please check (✔) up to 3 boxes and feel free to add any further comments*

- Blood pressure
- Heart rate
- Blood sugar
- House temperature
- Social interaction frequency
- Air pollution
- Dietary habits
- Electrocardiogram
- Levels of noise exposure
- Fall detection

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**D3. What would be the benefit in remote patient monitoring for 24 hours a day, if any?**

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____________________________________________________________________________________
Section E – Use of technology in medical practice
[Explore the use of technology in medical practice]

E1. Which of the following devices have you used/ prescribed/ suggested to your patients? Please check (✓) all that apply and feel free to add any further comments

<table>
<thead>
<tr>
<th>Nutrition Applications</th>
<th>Smart pillboxes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physiotherapy Applications and Smart Devices</td>
<td>Physical Activity Applications and Smart Devices</td>
</tr>
<tr>
<td>Smart Hearing Aids</td>
<td>Smart Blood Pressure Tracker</td>
</tr>
</tbody>
</table>

E2. How often do you use Smart Devices in your everyday clinical practice? Please check (✓) only one box and feel free to add any further comments

<table>
<thead>
<tr>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
</table>

E3. How useful do you find technology for your clinical practice? Please check (✓) only one box and feel free to add any further comments

<table>
<thead>
<tr>
<th>Obstructive</th>
<th>Indifferent</th>
<th>Useful</th>
<th>Very useful</th>
<th>Fundamental</th>
</tr>
</thead>
</table>

E4. How easy do you find technology to use in your clinical practice? Please check (✓) only one box and feel free to add any further comments

<table>
<thead>
<tr>
<th>Impossible</th>
<th>Difficult</th>
<th>Neutral</th>
<th>Easy</th>
<th>Very easy</th>
</tr>
</thead>
</table>
Section F – About an eventual experience with Smart Bear

F1. Smart Bear Platform could provide you with regular reports concerning your patients’ health status and measurements. Is that something appealing to you?

*Please check (✓) only one box and feel free to add any further comments*

<table>
<thead>
<tr>
<th>Yes ☐</th>
<th>No ☐</th>
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</table>

F2. Smart Bear Platform could provide you with regular reports concerning your patients’ health status and measurements. Which type of report would you consider as more helpful to them and to you?

*Please check (✓) only one box and feel free to add any further comments*

- Monthly report ☐
- Weekly report ☐
- Daily report ☐

F3. How would you like to receive this information? (E.g., background message, text messages, email, etc.)

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F4. Smart Bear Platform could provide patients with regular notifications – suggestions depending on its observations e.g. “Your blood pressure is regularly higher than the normal for the last 2 weeks. You should visit your referring physician”.

Which type of notifications would you consider as more helpful?

*Please check (✓) only one box and feel free to add any further comments*

- Notifications to the user ☐
- Notifications to the user and his/her referring physician* ☐
- Notifications to the user and his/her significant other* ☐

* (with user’s consent)
F5. How would you like to receive these regular notifications – suggestions? (E.g., background message, text message, email, etc.)

F6. Would you encourage your patients to participate in a project implementing state of the art technology to their everyday life, such as **Smart Bear**? Why?  
*Please check (✓) only one box and feel free to add any further comments*

- Yes ☐
- No ☐

F7. What are your expectations of a project like **Smart Bear**?  
*Please check (✓) up to 3 boxes and feel free to add any further comments*

- Less unnecessary visits ☐
- Frail Patients’ Safety ☐
- Better auto-management of your patients’ health issues ☐
- Better social interactions ☐
- Improving of your patients’ overall health ☐
- Improving your patient – doctor communication ☐
F8. If one of your patients asks for your opinion on whether to participate in Smart Bear Project, which would be your major concerns?

*Please check (√) up to 3 boxes and feel free to add any further comments*

- Privacy
- Change of Routine
- Erroneous Measurements
- Erroneous Notifications – Suggestions by the Platform
- Technical Issues of the Devices – Internet Connection
- Education on Devices and Platform Usage
- Increased stress for the user

Would you like to add any further comments? If yes, please add your comments to the box below.

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Appendix 3

ITALIAN PILOT QUESTIONNAIRE FOR PARTICIPANTS
SMART BEAR FOCUS GROUP PARTICIPANTS

QUESTIONNAIRE

Participant characterization

Q1. Participant’s ID

Q2. Age

Q3. Gender  M ☐  F ☐

Q4. Occupation (before eventual retirement)

Q5. Education (years of schooling)

Q6. Do you have or have had any of the following conditions?
Please check (✓) all that apply for you and feel free to add any further comments

- Hearing loss  ☐
- Imbalance  ☐
- Anxiety  ☐
- High blood pressure  ☐
- Ischemic heart disease  ☐
- Dementia  ☐
- Falls  ☐
- Stress  ☐
- Depression  ☐
- Arrhythmias  ☐

Q7. Housing context

Are you living with someone?  Yes ☐  No ☐
If you do, what is your relationship with him or her? Could you leave his/her contact (telephone number or email address)?

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Section A – Impact of the medical condition on the participant’s and their caregivers’ daily life activities

A1. How do you generally spend your day?

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A2. How has your life changed since the onset of your medical condition?

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<tr>
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</thead>
<tbody>
<tr>
<td><strong>Vitality</strong></td>
<td>(daily life activities, cardio-respiratory functions, nutrition, etc..)</td>
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<tr>
<td><strong>Sensory</strong></td>
<td>(vision, hearing, etc..)</td>
</tr>
<tr>
<td><strong>Psycological</strong></td>
<td>(mood, sleep, etc)</td>
</tr>
<tr>
<td><strong>Locomotion</strong></td>
<td>(balance, motor capacity, gait, etc..)</td>
</tr>
<tr>
<td><strong>Cognition</strong></td>
<td>(memory, attention, language, etc..)</td>
</tr>
</tbody>
</table>

A3. Do you handle your medical condition independently? Do you need help or assistance?

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A4. Whom do you call when you need someone? (Friends, family or others)

A5. How do the people close to you help you handling your medical condition? Does your medical condition have an impact on their lives?

Section B – Handling medical conditions

B1. Which are the daily/weekly/monthly steps you follow to handle your medical condition?

B2. How often do you go to the general practitioner or another health care provider for your medical condition?

B3. Which modality do you use to communicate remotely with your health care provider? (E.g. telephone, app, internet portal to communicate real-time...)
B4. Do you use any monitoring devices for your medical condition?

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Section C – Pros e cons of the ways of handling the medical condition

C1. Which are the pros and cons of how you handle your medical condition?

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C2. If you use any monitoring devices, are they easy to use? Do you find limitations in
the devices you use?

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Section D – Possible improvements

D1. How would you improve the way you handle your medical condition?

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D2. Which of the following measurements would you consider as more useful to your
everyday life?

Please check (✓) up to 3 boxes and feel free to add any further comments

Blood pressure □ Heart rate □
House temperature □ Blood sugar □
Air pollution □ Social interaction frequency □
Electrocardiogram □ Dietary habits □
Fall detection □ Levels of noise exposure □
**Section E – Relationship with technology**

E1. Describe your experience with the following devices:

_Please check (✓) only one box and feel free to add any further comments about your experience with each device_

- **Smartphones**
  
<table>
<thead>
<tr>
<th>Very poor</th>
<th>Poor</th>
<th>Normal</th>
<th>Good</th>
<th>Very good</th>
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- **Smart TVs**

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<th>Very poor</th>
<th>Poor</th>
<th>Normal</th>
<th>Good</th>
<th>Very good</th>
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- **Smartwatches**

<table>
<thead>
<tr>
<th>Very poor</th>
<th>Poor</th>
<th>Normal</th>
<th>Good</th>
<th>Very good</th>
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</table>

 **D3. Why would you like to receive this information?**

[Additional content not shown in the image]
• Smart light bulbs

<table>
<thead>
<tr>
<th>Very poor</th>
<th>Poor</th>
<th>Normal</th>
<th>Good</th>
<th>Very good</th>
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</table>

• Smart thermostats

<table>
<thead>
<tr>
<th>Very poor</th>
<th>Poor</th>
<th>Normal</th>
<th>Good</th>
<th>Very good</th>
</tr>
</thead>
</table>

E2. How useful do you find technology for your daily activities?
Please check (✔) only one box and feel free to add any further comments

<table>
<thead>
<tr>
<th>Obstructive</th>
<th>Indifferent</th>
<th>Useful</th>
<th>Very useful</th>
<th>Fundamental</th>
</tr>
</thead>
</table>

E3. How easy do you find technology to use?
Please check (✔) only one box and feel free to add any further comments

<table>
<thead>
<tr>
<th>Impossible</th>
<th>Difficult</th>
<th>Neutral</th>
<th>Easy</th>
<th>Very easy</th>
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</thead>
</table>
E4. How often do you forget to charge your mobile phone or leave home without it? Please check (✓) only one box and feel free to add any further comments

<table>
<thead>
<tr>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
</table>

E5. Would you want to use wearable devices? Have you ever had experiences with them? (E.g. Garmin, smartwatch etc.)?

Section F – About an eventual experience with Smart Bear

F1. Smart Bear Platform could provide your referring physician with regular reports concerning your health status and measurements. Is that something appealing to you? Please check (✓) only one box and feel free to add any further comments

Yes ☑  No ☐

F2. Smart Bear Platform could provide you with regular reports concerning your health status and measurements. Which type of report is more appealing to you? Please check (✓) only one box and feel free to add any further comments

Monthly report ☐  Weekly report ☑
F3. Who else would you want to have access to reports on your health status?

F4. How would you like to receive this information? (E.g., audio reports, text messages, email...)

F5. Smart Bear Platform could provide you with regular notifications – suggestions depending on its observations e.g. “Your blood pressure is regularly higher than the normal for the last 2 weeks. You should visit your referring physician”.

How willing would you be to follow the Platform Instructions?
*Please check (✓) only one box and feel free to add any further comments*

<table>
<thead>
<tr>
<th>Not willing</th>
<th>Slightly willing</th>
<th>Moderately Willing</th>
<th>Willing</th>
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F6. Who else would you want to have access to notifications – suggestions on your health status?

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F7. How would you like to receive notifications – suggestions on your health status? (E.g., phone alarms, text messages, email...)

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F8. Would you participate to a project implementing state of the art technology to your everyday life, such as Smart Bear? Why?
Please check (✓) only one box and feel free to add any further comments

Yes ☐ No ☐

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F9. What would your expectations be in case you decide to participate to a project like Smart Bear?
Please check (✓) up to 3 boxes and feel free to add any further comments

Increase of your daily activities ☐
Safety ☐
Better auto-management of your health issues ☐
Less visits to your referring physician ☐
Better social interactions ☐
Time Saving ☐
Money Saving ☐
Improving your diet habits ☐
Improving your confidence ☐
F10. If you decide to participate to Smart Bear Project and make use of Smart Bear Platform, which would be you major concerns?

*Please check (✓) up to 3 boxes and feel free to add any further comments*

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<thead>
<tr>
<th>Concern</th>
<th>Box</th>
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<tbody>
<tr>
<td>Privacy</td>
<td>✗</td>
</tr>
<tr>
<td>Change of Routine</td>
<td>✗</td>
</tr>
<tr>
<td>Erroneous Measurements</td>
<td>✗</td>
</tr>
<tr>
<td>Erroneous Notifications – Suggestions by the Platform</td>
<td>✗</td>
</tr>
<tr>
<td>Technical Issues of the Devices – Internet Connection</td>
<td>✗</td>
</tr>
<tr>
<td>Education on Devices and Platform Usage</td>
<td>✗</td>
</tr>
<tr>
<td>Increased stress</td>
<td>✗</td>
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</tbody>
</table>

Would you like to add any further comments? If yes, please add your comments to the box below.

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Appendix 4
REPORT: VALIDATION OF SMART BEAR @HOME FEATURES THROUGH USE CASE SCENARIOS
Report: validation of SMARTBEAR @home features through use case scenarios

*Editor: Fondazione Centro San Raffaele*

Sara De Silvestri, Alessia Cristiano, Stela Musteata, Diana Trojaniello
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1 Introduction

The SMARTBEAR @home platform proposes a number of services for its potential users (namely older adults over 65 with age-related pathologies, their clinicians and their caregivers).

First steps undertaken by the clinical partners for the definition of the platform’ clinical requirements included:

- A state of the art research on all the pathologies addressed by SMARTBEAR (cardiovascular diseases, hearing loss, balance and postural impairments, cognitive impairments, mental disorders and frailty).
- An exploratory analysis through online questionnaires for clinicians and older adults;
- Focus groups with clinicians and older adults with the aim of understanding the users’ needs from their own perspective;

All these activities allowed the clinical partners to design the SMARTBEAR clinical use cases taking into account the risk factors/indicators of the addressed pathologies as well as the clinicians and older adults’ inputs collected during the first three months of the project.

A total of XXX has been initially produced. Every use case consisted of a flow of activities that the user performs in relation to the devices, the software functions and the interactions between them.

1.1 Rationale

Once the use cases have been designed by the clinical partners, a validation activity (i.e. use case validation) with both older adults and clinicians was planned in order to check if the produced use cases met the users' needs or additional requirements should be included in the use cases.

1.2 Objectives

The purpose of the use case validation was to validate each of the proposed feature by:

- Stating the conditions that the features should observe, if any;
- Identifying which features are perceived as problematic and demanding,
- Exploring alternative solutions to those features that are perceived as problematic.

2 Methods

Involvement of potential users (i.e. clinicians and older adults) is fundamental in order to validate concepts that will be the foundation for designing of the SMARTBEAR @home platform. In this perspective, presentation of scenarios is a useful tool to elicit the clinical requirements. The use of scenarios (i.e. the fictitious story of a user’s accomplishing an action or goal via a product) allowed both clinicians and older adults to identify themselves with the protagonists of the stories in order to obtain an authentic feedback.
For the *use case validation* process two focus group sessions (each of them with 4-6 older adults and clinicians) have been performed to collect feedbacks on the proposed scenarios and define the final use cases.

Overall, the scenarios covered *all the features* (see chap 2.1) included in the use cases produced so far, in order to promote a separate discussion about each of them, and *all the use cases*, to be sure that the participants could feel involved in at least one of the scenarios and optimize the probability to receive feedback from each of the participants. This crosschecking is summarized in the Appendix (Table 5).

### 2.1. Features of the SMARTBEAR @home platform

The *features* of the SMARTBEAR platform according to the use cases defined by the clinical partners are listed in Table 2 (a brief explanation is included where needed). The *features* have been clustered in three groups: a) those related to the presence of sensors (*Wearable/smart devices*); b) those related to the presence of a mobile application (*Software functions*); c) those related to the interaction of the user with the platform (*Human Computer Interaction*).

<table>
<thead>
<tr>
<th>Wearable/smart devices that are part of the SMARTBEAR @home platform</th>
<th>D1</th>
<th>Smartphone</th>
</tr>
</thead>
<tbody>
<tr>
<td>D2</td>
<td>Tablet</td>
<td></td>
</tr>
<tr>
<td>D3</td>
<td>Smartwatch</td>
<td></td>
</tr>
<tr>
<td>D4</td>
<td>Sleep mat</td>
<td></td>
</tr>
<tr>
<td>D5</td>
<td>Smart Scale</td>
<td></td>
</tr>
<tr>
<td>D6</td>
<td>Smart pillbox</td>
<td></td>
</tr>
<tr>
<td>D7</td>
<td>Smart hearing aid</td>
<td></td>
</tr>
<tr>
<td>D8</td>
<td>Smart home sensors</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Software functions implemented through the SMARTBEAR Apps</th>
<th>S1</th>
<th>Sending reminder (notification through the smartphone to remind the user to do something)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2</td>
<td>Sending regular reports (daily or weekly reports that summarize the activities and the measurements performed through the day or the week)</td>
<td></td>
</tr>
<tr>
<td>S3</td>
<td>Sending regular reports to caregivers</td>
<td></td>
</tr>
<tr>
<td>S4</td>
<td>Sending regular reports to clinicians</td>
<td></td>
</tr>
<tr>
<td>S5</td>
<td>Sending notifications (warning the user that a parameter’s trajectory is going the opposite way of what was recommended by medical staff and/or health guidelines)</td>
<td></td>
</tr>
<tr>
<td>S6</td>
<td>Sending alerts (warning that a parameter has been continuously outside the recommended range defined by medical staff and/or health guidelines)</td>
<td></td>
</tr>
<tr>
<td>S7</td>
<td>Sending notifications to caregivers</td>
<td></td>
</tr>
</tbody>
</table>
2.2. Use case scenarios

Use case scenario are shown to participants by way of a PowerPoint presentation. Each scenario has been explained to the participants with the same scheme:

- The protagonist’s background (his/her health conditions, living context, caregivers etc.);
- The devices provided by the SMARTBEAR platform for the specific user;
- The doctor’s personalized plan, i.e. what the doctor set through the SMARTBEAR Application: things to be monitored, means of intervention, plans to be respected etc., depending on the protagonist’s problems.

An example of the protagonist’s day through his/her interactions with the SMARTBEAR platform is also shown in the presentation in order to give a clearer picture of the functions and expand on what remains to be discussed.

A total of 6 scenarios have been prepared and shown to the participants as in the following table:

<table>
<thead>
<tr>
<th>S8</th>
<th>Sending alerts to caregivers</th>
</tr>
</thead>
<tbody>
<tr>
<td>S9</td>
<td>Displaying registered data, adherence to a program and daily/weekly progress</td>
</tr>
<tr>
<td>S10</td>
<td>Giving caregivers access to data</td>
</tr>
<tr>
<td>S11</td>
<td>Connecting to smart devices for physiological parameters (smart blood pressure monitor/glucometer)</td>
</tr>
<tr>
<td>S12</td>
<td>Tracking sound or GPS via smartphone or smartwatch</td>
</tr>
<tr>
<td>S13</td>
<td>Tracking environmental conditions</td>
</tr>
<tr>
<td>S14</td>
<td>Automatically intervening on environmental conditions</td>
</tr>
<tr>
<td>S15</td>
<td>Delivering personalized plan from the clinician</td>
</tr>
<tr>
<td>S16</td>
<td>Giving reward when an achievement is completed</td>
</tr>
<tr>
<td>S17</td>
<td>Inform with psycho-education content</td>
</tr>
</tbody>
</table>

| I1   | Fill in questionnaires |
| I2   | Interaction: photos of meals |
| I3   | Interaction: serious games |
| I4   | Training sessions (hearing) |
| I5   | Videocalling clinicians |
| I6   | Chatting with clinicians |
| I7   | Planning appointments with clinicians |

Table 2 – Features of the SMARTBEAR @home platform for users over 65
<table>
<thead>
<tr>
<th>#</th>
<th>Name</th>
<th>UCs</th>
<th>Devices</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Giovanni - Diet and physical exercise</td>
<td>• Frequent falls&lt;br&gt;• Physical inactivity&lt;br&gt;• Malnutrition&lt;br&gt;• Weight loss/gains</td>
<td>• Smartphone&lt;br&gt;• Tablet&lt;br&gt;• Smart scale&lt;br&gt;• Smartwatch</td>
<td>• Use of the smartphone (D1)&lt;br&gt;• Use of the tablet (D2)&lt;br&gt;• Use of the smartwatch (D3)&lt;br&gt;• Use of smart scale (D5)&lt;br&gt;• Send regular reports (S2)&lt;br&gt;• Send regular reports to caregivers (S3)&lt;br&gt;• Send regular reports to clinicians (S4)&lt;br&gt;• Display registered data (S9)&lt;br&gt;• Display adherence to the program (S10)&lt;br&gt;• Display daily and weekly progress (S11)&lt;br&gt;• Deliver personalized plan from clinician (S17)&lt;br&gt;• Give reward if achievement is completed (S19)&lt;br&gt;• Interaction: photos of meals (I2)</td>
</tr>
<tr>
<td>2</td>
<td>Isotta - Blood pressure monitoring</td>
<td>• Abnormal blood pressure levels&lt;br&gt;• Cardiovascular/respiratory symptoms&lt;br&gt;• Abnormal blood glucose levels</td>
<td>• Smartphone&lt;br&gt;• Tablet&lt;br&gt;• Smart blood pressure monitor&lt;br&gt;• Glucometer</td>
<td>• Use of the smartphone (D1)&lt;br&gt;• Use of the tablet (D2)&lt;br&gt;• Send reminder (S1)&lt;br&gt;• Send notifications (S5)&lt;br&gt;• Send alerts (S6)&lt;br&gt;• Send notifications to caregivers (S7)&lt;br&gt;• Send alerts to caregivers (S8)&lt;br&gt;• Give access of data to caregiver (S12)&lt;br&gt;• Connect to smart devices for physiological parameters (smart blood pressure monitor/glucometer) (S13)</td>
</tr>
<tr>
<td>3</td>
<td>Federico - Mood and Sleep quality</td>
<td>• Sleep disturbances&lt;br&gt;• Non-compliance to medication scheme&lt;br&gt;• Cognitive decline&lt;br&gt;• Non-ideal light levels&lt;br&gt;• Emotional changes&lt;br&gt;• Extreme temperature/Weather conditions</td>
<td>• Smartphone&lt;br&gt;• Tablet&lt;br&gt;• Smart pillbox&lt;br&gt;• Smartwatch&lt;br&gt;• Smart home environment system</td>
<td>• Use of the smartphone (D1)&lt;br&gt;• Use of the tablet (D2)&lt;br&gt;• Smartwatch (D3)&lt;br&gt;• Other devices: sleep mat (D4)&lt;br&gt;• Smart pillbox (D6)&lt;br&gt;• Home sensors and devices (D8)&lt;br&gt;• Track environmental conditions (S15)&lt;br&gt;• Automatically intervene on environmental conditions (S16)&lt;br&gt;• Fill in questionnaires (I1)&lt;br&gt;• Interaction: serious games (I3)</td>
</tr>
</tbody>
</table>
## Lidia - Habits and socialization

- Habitual substances usage (smoking/passive smoking/alcohol/legal sedatives);
- Social isolation;
- Family isolation;
- Behavioral changes;
- Air particles/smoke/Gas/External Temperature/Pollen.

| 4 | Lidia-Habits and socialization | • Smartphone |  • Use of the smartphone (D1)  
|   |                               |  • Tablet    |  • Use of the tablet (D2)  
|   |                               |             |  • Deliver personalized plan from clinician (S17);  
|   |                               |             |  • Inform with psycho-educational content (S20);  
|   |                               |             |  • Track sound or GPS (S14);  
|   |                               |             |  • Deliver personalized suggestions (S18).  

## Andrea - Hearing

- Inadequate fitting

| 5 | Andrea-Hearing | • Smartphone |  • Use of the smartphone (D1)  
|   |                |  • Tablet    |  • Use of the tablet (D2)  
|   |                |  • Smart hearing aid |  • Smart hearing aid (D7)  
|   |                |             |  • Hearing training (I4);  
|   |                |             |  • Remote communication with clinician (video) (I5);  
|   |                |             |  • Remote communication with clinician (chat) (I6);  
|   |                |             |  • Plan appointment with the clinician (I8).  

All the scenarios are reported in the Appendix as well the presentation shown during the focus groups (translated in English).

During the scenarios’ presentation, a blue question mark highlights the points where a discussion needs to be opened to explore the features involved. The questions used to open the discussions about the features are reported in each section in order to provide a better explanation about how the focus group is planned.

### 2.3 Procedure

Two focus groups of 1h30 each, took place on 4\textsuperscript{th} December 2019 at the Policlinico of Milan (Italy). The first group was composed by 5 participants over 65 (3 male and 2 female) and the second by 6 participants over 65 (3 male and 3 female). Only one clinician assisted to the presentation of these scenarios and contributed to the validation of SMARTBEAR features.

An informed consent form, that explains the type of activity, the anonymization of their personal information/contributions and their right to withdraw at any time, was collected by the participants. All the participants signed the consent form, and none has withdrawn.

A specializing neuropsychologist conducted the presentation and the discussion of the features. Two researchers (biomedical engineers) took notes of the discussions and occasionally intervened to obtain a better explanation of concepts emerged from the discussion. The users’ comments and feedbacks were collected in a sheet form (see Appendix C) where the following metrics for each features were collected:
- The severity of problem (if any) related to each feature was categorized as either “critical”, “serious” or “cosmetic” (Molich, 2000);

- The degree of perceived users’ experience according to the parameters proposed by Morville (2004), i.e. the Morville’s user experience honeycomb: useful, usable, credible, desirable and valuable. The other two parameters proposed by Morville (i.e. Findable and Accessible) has not been included.

The focus groups were audio-recorded.

The first three scenarios (Giovanni, Isotta and Federico) were presented to the first group, while the last two scenarios (Lidia and Andrea) were presented to the second group of seniors.

At the end of the meetings, the participants were asked to leave their contact in case they would be interested in participating to the Pilot study.

<table>
<thead>
<tr>
<th>Focus group</th>
<th>Participants</th>
<th>Gender</th>
<th>Users scenarios</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>5</td>
<td>2F, 3M</td>
<td>1,2,3</td>
</tr>
<tr>
<td>#2</td>
<td>6</td>
<td>3F, 3M</td>
<td>4,5</td>
</tr>
</tbody>
</table>

1 Useful, so the content of the product or service should be original and fulfill a need; Usable, it must be easy to use; Desirable: the image, identity, brand, and other design elements used in the product or service should evoke emotion and appreciation; Findable the content needs to be navigable and locatable onsite and offsite so the user can find what they need; Accessible, the content needs to be accessible to people with disabilities; Credible, the user should be able trust and believe what you tell them; Valuable, the product or service should deliver value to the user and enhance the user satisfaction.
3 Results and discussion

This chapter reports the discussions about the SMARTBEAR platform’s features from the senior participants’ point of view and the recommendations from two clinicians from Policlinico di Milano who participated to the focus groups.

![Focus group at Policlinico of Milan](image)

3.1 Senior participants’ comments

In this section, a general report on the major points of discussion is reported; a detailed report is provided in the Appendix C (Table 6 and Table 7). Note that the scenarios 1, 2 and 3 were presented to the first group and the scenarios 4 and 5 to the second. Therefore, some of the SMARTBEAR features were not enquired in both groups, while the most crucial features were asked to both groups (for example, how much time the users are willing to spend on the phone, or if they find the possibility to share their data with their caregivers appealing).

Every participant contributed in an active and positive way to the discussions.

First of all, a criticality that emerged towards the whole idea of the SMARTBEAR @home platform was the reliability of the system. In fact, the participants experienced technical failures in previous projects involving technology that ruined the whole experience for them and did not encourage their participation; it seems that three experienced failures of the system were enough for them to discourage them. Therefore, a robust technical support is needed for the users in order to keep using the platform.

Apart from doubts on the whole system, participants were generally trusting about the single functionalities.
3.1.1 Wearable/smart devices

All the participants (11/11) agreed that they do not wish to receive both the smartphone and the tablet. In fact, it would be too burdensome to remember interacting with both and they would find it too confusing. The majority (7/11) would prefer the smartphone over the tablet due to the portability of the former and the scarce familiarity of the latter, but they do not refuse the tablet after proper training.

About the smart pillbox, the interviewed agreed (5/5) on the necessity that drawers should be split in different moments of the day. The concept of smart hearing aid was greeted with enthusiasm (6/6), but it should be kept in mind that for some of the participants’ acquaintances aesthetics and comfort have been deal-breakers when their expectations were not met.

When discussing about the best device for sleep tracking, opinions were rather polarized: women (2/5) would prefer the smartwatch because they fear it would be uncomfortable and would not appreciate the idea of having an extraneous object between them and the mattress. The majority of men (2/3) preferred the sleeping mat because sleeping wearing the smartwatch would not feel comfortable for them.

None of the participants did appreciate the idea of smart home sensors, since they would not recognize its usefulness in their lives.

The weight scale’s features of being able to extract extra information other than the weight met the appreciation from all the participants (5/5), especially the ability to discriminate between fat mass and lean body mass.

3.1.2 Software functions

The major point that was discussed was that all the functions must be extremely tailored to the user. This was found the most pressing requirement: all the programs, suggestions, notifications, alerts and sharing of data should be customized and adjustable at will. The SMARTBEAR options of “sharing data on senior’s health with the caregiver” or of “sending notifications to caregiver” were considered by participants a possible burden for their family members and a risk of feeling oppressed by relatives. Therefore, we recommend the sharing of reports and notifications mechanism to be flexible (e.g. by giving the possibility to the user of setting the frequency of the notifications and reports to the caregivers).

Also, most of the participants were feeling very unsure about the usability of the functions (i.e. their ability in using them). They all agreed that it will be very useful for them to have one or more assisted training sessions on the use of the devices as well as a gradual introduction to their functions.

An interesting idea that was shared about the visualization of the user’s data, about the possibility to view their parameters and trajectories compared with a clinical practice guideline and with what is medically judged to be the norm for someone in their condition. This would help them giving context to their results.

All the participants found particularly useful to share the data with clinicians through regular report. Nonetheless, a concern was raised when thinking about their interaction with clinicians through SMARTBEAR. Most of them did not think it plausible that their clinicians would be interested in burdening themselves with more work. Their usual experience is that the doctors dismiss what lies beyond their usual clinical practice (e.g. research experimentation) and this may reduce the effectiveness of the SMARTBEAR intervention.
At first, all the participants were unsure about the usefulness of the **psycho-educational content**, since they thought people with certain problems (e.g. substance abuse) would not care to commit to this function. Later, when explained that some people could be underestimating the effects of their behaviors, they agreed that informative content could be beneficial. Their main concern was the usability of this feature, therefore they recommended the tablet for this. Also, 3/6 of the participants would prefer to receive this information vocally, 3/6 would prefer reading it.

A further function that was discussed was the **tracking of sound of conversations or GPS**, which are potentially critical because of privacy invasiveness. In fact, they would not appreciate this function to be on permanently. On the contrary, they would accept it at the condition of being able to turn it off at will.

### 3.1.3 Human computer interaction

The main concern that was lifted was the time needed to be spent on the platform every day. All the participants clearly expressed that the platform should not feel like a burden, so the interaction should be extremely easy and require the **minimum amount of time spent in front of a screen**.

Answering to questionnaires was judges useful by all the participants (5/5), but they were discordant about the modality of administration (3/5) would prefer to **answer vocally** and the others would prefer to do it manually.

Cognitive training through **serious games** was not generally approved because perceived as too time-consuming. They would consider it if it required not more than 5 minutes per session, and if it was not required every day. They recommended the games to be proposed with increasing difficulty and customized on their results.

Lastly, as expressed for software functions, they were concerned not being able to use the platform effectively, therefore, a training session is recommended.

### 3.2 Clinicians’ recommendations on use case scenarios

The two clinicians were asked to include some comments for each feature discussed during the focus groups.

They reported to **avoid sending many notifications to the patients** since it may cause stress and burden (e.g. personal alert notification for poor compliance to HA usage, physical inactivity, hypertension treatment, etc.). Furthermore, the notifications should be personalized in order to not become intrusive in daily life.

The **environmental monitoring** (e.g. air quality sensors, light intensity and color, temperature) are **not considered very relevant** for the clinical practice by the two clinicians ("I do not see the rational for being informed as clinician about the changing lights of the participant’s house").
The two clinicians are very concerned that the SMARTBEAR App for nutrition or physical activity intervention may give suggestions that **may not be based on medical knowledge** (e.g. “The dietary intake represents an important clinical aspect for both the participant and the investigator/clinician. Nevertheless, intervening on it might be risky in the absence of a professional opinion because potentially impacting on the health status of the individual (and the app is not a medical device)”). The two clinicians also recommend the use of questionnaires on nutrition and hydration monitoring, plus the interaction of these results with the smart scale report.

As recommended by the two clinicians, the devices used by the SMARTBEAR platform must be certified as **medical devices** in order to be used for blood pressure or glucose level measurement/intervention.

The clinicians are concerned of receiving **many false alerts that may cause burden and stress** (e.g. “Do not send the results of the questionnaire to the clinical parties (risk of telemonitoring and need to intervene for every reported abnormality, which may represent a false positive).”)

The clinicians are **not willing to receive weekly reports or notifications** on patient’s adherence to the intervention or progress (e.g. “The clinician should be able to see the changes exclusively at the clinical assessment part of the eventual follow-up. Impossible to follow a large number of patients every time the app is alerting (in particular, if the alert is provided to the participant”).

The clinicians are concerned that the SMARTBEAR platform may be **intrusive in the seniors’ daily life** (e.g. “Please consider that everything should not be intrusive in the daily life and that we are talking about older persons with likely multiple clinical conditions for which they take many drugs several times per day.”).

The clinicians worry that the possibility of the patients to **book appointments with the clinicians** through the SMARTBEAR App would be burdensome for the latter (e.g. “No appointments can be planned for participants outside the eventual follow-up visits. Clinical visits are different from research. It is unfeasible to clinically follow hundreds of persons over several months”).

The **administration of questionnaires for mood monitoring is considered** by clinicians a **possible burden** for older adults. On the contrary, the seniors of the two above-mentioned focus groups agreed on their administration and use.
4 References

5 Appendix A - Platform’s features and the original use case scenarios

<table>
<thead>
<tr>
<th>Features</th>
<th>Scenarios</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smartphone</td>
<td>D1</td>
</tr>
<tr>
<td>Tablet</td>
<td>D2</td>
</tr>
<tr>
<td>Smartwatch</td>
<td>D3</td>
</tr>
<tr>
<td>Other devices: sleep mat</td>
<td>D4</td>
</tr>
<tr>
<td>Smart scale</td>
<td>D5</td>
</tr>
<tr>
<td>Smart pillbox</td>
<td>D6</td>
</tr>
<tr>
<td>Smart hearing aid</td>
<td>D7</td>
</tr>
<tr>
<td>Home sensors and devices</td>
<td>D8</td>
</tr>
<tr>
<td>Send reminder</td>
<td>S1</td>
</tr>
<tr>
<td>Send regular reports</td>
<td>S2</td>
</tr>
<tr>
<td>Send regular reports to caregivers</td>
<td>S3</td>
</tr>
<tr>
<td>Send regular reports to clinicians</td>
<td>S4</td>
</tr>
<tr>
<td>Send notifications</td>
<td>S5</td>
</tr>
<tr>
<td>Send alerts</td>
<td>S6</td>
</tr>
<tr>
<td>Send notifications to caregiver</td>
<td>S7</td>
</tr>
<tr>
<td>Send alerts to caregiver</td>
<td>S8</td>
</tr>
<tr>
<td>Display registered data</td>
<td>S9</td>
</tr>
<tr>
<td>Display adherence to the program</td>
<td>S10</td>
</tr>
<tr>
<td>Display daily and weekly progress</td>
<td>S11</td>
</tr>
<tr>
<td>Give access of data to caregivers</td>
<td>S12</td>
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<tr>
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</tr>
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</tr>
<tr>
<td>Automatically intervene on environmental conditions</td>
<td>S16</td>
</tr>
<tr>
<td>Deliver personalized plan from clinician</td>
<td>S17</td>
</tr>
<tr>
<td>Deliver personalized suggestions</td>
<td>S18</td>
</tr>
<tr>
<td>Give reward if achievement is completed</td>
<td>S19</td>
</tr>
<tr>
<td>Inform with psycho-educational content</td>
<td>S20</td>
</tr>
<tr>
<td>Fill in questionnaires</td>
<td>I1</td>
</tr>
<tr>
<td>Interaction: photos of meals</td>
<td>I2</td>
</tr>
<tr>
<td>Interaction: serious games</td>
<td>I3</td>
</tr>
<tr>
<td>Hearing training</td>
<td>I4</td>
</tr>
<tr>
<td>Remote communication with clinician (video)</td>
<td>I5</td>
</tr>
<tr>
<td>Remote communication with clinician (chat)</td>
<td>I6</td>
</tr>
<tr>
<td>Plan appointment with clinician</td>
<td>I7</td>
</tr>
<tr>
<td>Family activities</td>
<td>I8</td>
</tr>
<tr>
<td>Functional improvement (physical abilities)</td>
<td>I9</td>
</tr>
<tr>
<td>Emotional changes</td>
<td>I10</td>
</tr>
<tr>
<td>Emotional changes (social)</td>
<td>I11</td>
</tr>
<tr>
<td>Social isolation</td>
<td>I12</td>
</tr>
<tr>
<td>Extreme temperature/weather conditions</td>
<td>I13</td>
</tr>
<tr>
<td>Abnormal blood pressure levels</td>
<td>I14</td>
</tr>
<tr>
<td>Cardiovascular/respiratory symptoms</td>
<td>I15</td>
</tr>
<tr>
<td>Abnormal blood glucose levels</td>
<td>I16</td>
</tr>
<tr>
<td>Non-compliance to medication scheme</td>
<td>I17</td>
</tr>
<tr>
<td>Non-ideal light levels</td>
<td>I18</td>
</tr>
<tr>
<td>Extreme temperature/weather conditions</td>
<td>I19</td>
</tr>
<tr>
<td>Emotional changes</td>
<td>I20</td>
</tr>
<tr>
<td>Emotional changes (social)</td>
<td>I21</td>
</tr>
</tbody>
</table>

Table 5 – Crosschecking between the platform’s features and the original use case scenarios
6 Appendix B – Users scenarios

Giovanni – Diet and physical exercise

Giovanni’s background

Giovanni started losing weight and muscular mass since a few years back. One evening he had a terrible fall. Consequently, he started conducting an inactive lifestyle out of fear of falling again. The clinician finds out that Giovanni is malnourished and needs a prolonged monitoring, therefore he proposes Giovanni to participate for a year to the SMARTBEAR project.

Use cases:

- Frequent falls
- Physical inactivity
- Malnutrition
- Weight loss/gains

Devices provided to Giovanni

The clinician provides Giovanni with a smartphone and/or a tablet, a smart scale and a smartwatch.

During the presentation the functions and features offered by the smart scale are first disclosed to the participants (e.g. providing parameters about fat mass and muscular mass, sending all data to the smartphone to be consulted, etc.). Later, the participants are asked if they would appreciate such a feature and if they think it would be easy to use (D5).

The same is asked about the smartwatch (if they would be comfortable wearing it for most of the day, and if they find it useful in some of its functions like activity tracking) (D3).

The clinician’s plan for Giovanni with SMARTBEAR

Giovanni agrees to commit to the diet plan indicated by his clinician in order to regain strength and energy.

The participants are asked what they think about a plan tailored by the clinician that they can consult through the SMARTBEAR App. Also, participants could consult their adherence to the program and the current progress; therefore, a discussion is opened on these themes (S9, S10, S11). Also, the reward mechanism is discussed (usefulness and ease to use, especially) (S19).

Also, Giovanni will keep track of his diet and weight so that the clinician can see his trajectories during the next examination. Therefore, Giovanni is asked to take a picture of his plate at every meal.

It is investigated if the participants would appreciate this feature and if they have other preferences (I2).

Giovanni’s physical activity will be tracked by the use of the smartwatch and he will receive regular reports of such activities.
Regular reports can be delivered to the users’ smartphones or tablets in different ways and at different frequencies. In addition, these reports can be sent to the caregivers and to the clinician. The participants have been asked if these features are desirable (S2, S3, S4).

At this point, the participants have explored different examples in the use of the smartphone and tablet, so their perception and familiarity with these devices is explored, along with pros and cons of each (D1, D2).

**Features:**

- Use of the smartphone (D1)
- Use of the tablet (D2)
- Use of the smartwatch (D3)
- Use of smart scale (D5)
- Send regular reports (S2)
- Send regular reports to caregivers (S3)
- Send regular reports to clinicians (S4)
- Display registered data (S9)
- Display adherence to the program (S10)
- Display daily and weekly progress (S11)
- Deliver personalized plan from clinician (S17)
- Give reward if achievement is completed (S19)
- Interaction: photos of meals (I2)

**Isotta – Blood pressure monitoring**

**Isotta’s background**

*Isotta has high blood pressure and diabetes. Lately, blood pressure levels have been worrying, so her doctor recommends a better control over her condition with SMARTBEAR platform.*

**Use cases:**

- Abnormal blood pressure levels
- Cardiovascular/respiratory symptoms
- Abnormal blood glucose levels

**Devices provided to Isotta**

*Isotta receives a tablet and/or a smartphone, a smart blood pressure monitor and a glucometer. These two devices perform the same functions as the ones that Isotta already has, with the perks of being connected to the platform. For example, with the use of this platform Isotta will be able to efficiently keep track of all the measurements she does.*

The participants are asked what they think of this platforms’ feature and if they associate any problem with it (S13).
The doctor’s plan for Isotta

Isotta will track her blood pressure and her glucose level every day, at the times set by her doctor. A reminder is sent to her phone to notify her that she has to make the measurement.

It is explored if participants would find this feature useful (S1).

Lucia, her daughter, can check Isotta’s levels at any time during the day from her smartphone.

It is asked if participants would be comfortable with this idea and what they would propose as an alternative (S12).

The doctor will set a trajectory as the recommended trend for her blood pressure level. If the platform detects a different pace for a certain period, a warning notification would appear on Isotta’s phone.

The appeal of this feature is investigated, along with the possibility to notifying the caregivers too (S5, S7).

Also, the doctor will set some levels or events (like arrhythmias) that Isotta should pose attention to along with dispositions about what to do when Isotta is warned by an alert.

As before, the caregivers can be alerted the same way too (S6, S8).

Features:
- Send reminder (S1)
- Send notifications (S5)
- Send alerts (S6)
- Send notifications to caregivers (S7)
- Send alerts to caregivers (S8)
- Give access of data to caregiver (S12)
- Connect to smart devices for physiological parameters (smart blood pressure monitor/glucometer) (S13)

Federico – Mood and Sleep quality

Federico’s background

Federico has been feeling tired and low energy for some time now, even when just woken up. Gradually, Federico experiences bad mood most of the day. The doctor prescribed him a therapy for his sleep disturbances but Federico often forgets taking his pills. Therefore, the clinician will keep track of his sleep, mood and compliance to the therapy through SMARTBEAR.

Use cases:
- Sleep disturbances
- Non-compliance to medication scheme
- Cognitive decline
- Non-ideal light levels
- Emotional changes
- Extreme temperature/Weather conditions
**Devices provided to Federico**

The clinician provides Federico with a smartphone and/or a tablet, a smart pillbox, a smartwatch, and a smart home environment system.

It is explained that the smart pillbox can remind the users to take the prescribed medication and automatically keep track of their adherence to the pharmacological therapy, so it is asked if the participants would appreciate this feature and how (D6).

* A smart home system could monitor air quality, light level, temperature, motion and other conditions in Federico’s house.

Questions are posed about an eventual set up of a smart home system sensors in the participants’ houses (D8).

**The clinician’s plan with SMARTBEAR for Federico**

* Keeping track of his compliance to the medication plan;
* Tracking the quality of his sleep with the smartwatch or with an alternative device;  
  In order to monitor sleep, wearing a smartwatch is needed; it is asked if participants would be comfortable with it or if they prefer using a sleep mat instead (D3, D4).
* Monitoring Federico’s home environmental conditions in order to find and control factors that would influence his state of mind and his quality of sleep;  
  It is asked if they would feel comfortable if the platform would monitor environmental conditions all the time and if they would find it useful to let the platform automatically adjust some conditions following the clinician’s indications (S15, S16).
* Periodically recording his mood through questionnaires;  
  The participants are enquired if they would be willing to do this activity if they had a mood disorder (I1).
* Periodically recording his memory capacity through serious games to keep track of his cognitive decline.  
  It is asked if they would use this feature (I3).

**Features:**

* Smartwatch (D3)
* Other devices: sleep mat (D4)
* Smart pillbox (D6)
* Home sensors and devices (D8)
* Track environmental conditions (S15)
* Automatically intervene on environmental conditions (S16)
* Fill in questionnaires (I1)
* Interaction: serious games (I3)
Lidia – Habits and socialization

Lidia’s background

*Lidia* is experiencing a burnout due to the fact that she is taking care of her husband 24h/24h, who has been diagnosed with Alzheimer’s disease. In the last period she has started abusing alcohol, neglecting herself and isolating from family and friends. This change in behaviour made her friends and her daughter worry for her. Lidia agrees with her doctor to use SMARTBEAR to reacquire good habits towards herself and the others.

**Use cases:**

- Habitual substances usage (smoking/passive smoking/alcohol/legal sedatives);
- Social isolation;
- Family isolation;
- Behavioral changes;
- Air particles/smoke/Gas/External Temperature/Pollen.

**Devices provided to Lidia**

The clinicians provides Lidia with a smartphone and/or a tablet and a smartwatch.

**The clinician’s plan for Lidia with SMARTBEAR**

*Regarding the bad habits that Lidia needs to correct, the clinician recommends the following plan:*

- **Committing to a daily routine outlined by her clinician in order to regain healthy habits;**
  The participants are asked if they would find this feature useful and easy to use (S17).
- **Follow online psychoeducation sessions through her smartphone or her tablet in order to learn consequences and behavioral effects of alcohol abuse.**
  The participants were asked how they would like to be informed (i.e. the modality) (S20).

*In order to intervene on her social activities, the clinician recommends:*

- **Sending reminders to help her in setting dates with her friends and family;**
- **Keeping track of her participation to social activities using her smartwatch and/or her phone;**
  This feature presents some criticality about invasiveness and privacy (like tracking sound of conversations and GPS); therefore, this matter is discussed with the participants (S14).
- **Sending personalized suggestions to maintain a better behavior towards the others and herself.** For example, she receives suggestions to go outdoor when it is a sunny day or to invite someone over if it is a cold day.
  It is asked if the participants would find these kinds of feature useful (S18).

**Features:**

- Deliver personalized plan from clinician (S17);
- Inform with psycho-educational content (S20);
- Track sound or GPS (S14);
- Deliver personalized suggestions (S18).
Andrea – Hearing

Andrea’s background

Andrea’s capacity to discriminate sounds decreased significantly in the past ten years. Now, this problem has become unbearable and impacts his social life (e.g., he struggles to conversate with his friends in a crowded bar because of excessive background noise). Andrea, a cheerful and extroverted man, considers this issue a serious limitation for his social life. For this reason, he decides to go to the audiologist, even if the closest one is many kilometers distant.

Use cases:
- Inadequate fitting

Devices provided to Andrea

The clinicians provides Andrea with a smartphone and/or a tablet and a smart hearing aid, remotely adjustable by the clinician.

The facilitator asks the participants if they would be willing to use this device and what they think about it (D7).

The clinician’s plan for Andrea with SMARTBEAR

The SMARTBEAR App will give Andrea the following options:
- To book a remote appointment with the audiologist;
  The participants are asked how they would like this feature and if they would find it easy to use (I7).
- To open a communication with the audiologist at the given appointment;
  It is asked which modality of communication (e.g., texting, phone calling, skype calling through) would be preferable for this feature (I5, I6).
- To remotely adjust and to fine-tune the smart hearing aid options;
- To open hearing training sessions through the smartphone or the tablet.
  It is explored if they would find this feature useful and doable (I4).

Features:
- Smart hearing aid (D7)
- Hearing training (I4);
- Remote communication with clinician (video) (I5);
- Remote communication with clinician (chat) (I6);

Plan appointment with the clinician (I8).
## Validation of use case scenarios

### 7 Appendix C – Results

<table>
<thead>
<tr>
<th>Platform (Devices, 2020)</th>
<th>Critical</th>
<th>Serious</th>
<th>Cosmetic</th>
<th>Useful</th>
<th>Usable</th>
<th>Credible</th>
<th>Desirable</th>
<th>Valuable</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smartphone</td>
<td>Yes</td>
<td>Difficult to learn new things and to use it confidently</td>
<td>Yes (except L)</td>
<td>Participants with active lifestyles find it easy to use</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>6/5, L would prefer smartphone; 4/5, 3/6 would prefer the tablet; 1/5, 3/6 would prefer both PC above all</td>
</tr>
<tr>
<td>Tablet</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>As sleep tracker, 2/5 prefer smartwatch, 2/5 would prefer PC; 1/5, L would prefer PC above all</td>
</tr>
<tr>
<td>Smart Watch</td>
<td>Yes</td>
<td>Yes but they (L) are not familiar with it</td>
<td>Restricts their lifestyle and limits their activities</td>
<td>Yes especially as activity tracker (step counter in particular)</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>As sleep tracker; 2/5 prefer smartwatch, 2/5 would prefer PC; 1/5, L would prefer PC above all</td>
</tr>
<tr>
<td>Sleep mat</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
</tr>
<tr>
<td>Smart Scale</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes, especially as muscular/fat mass</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smart pillbox</td>
<td>Yes (L), extremely</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes, if the day is split into two parts</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smart hearing aid</td>
<td>Critical; usefulness and comfort for hearing-sensitive individuals</td>
<td>Critical; usefulness and comfort for hearing-sensitive individuals</td>
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<td>Critical; usefulness and comfort for hearing-sensitive individuals</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature sensor (home)</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unusually value in remote monitoring</td>
</tr>
<tr>
<td>Light sensor (home)</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unusually value in remote monitoring</td>
</tr>
<tr>
<td>Air quality sensor (home)</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unsure</td>
<td>Unusually value in remote monitoring</td>
</tr>
</tbody>
</table>

### Table 6 – Results: devices and interactions
# Validation of use case scenarios

<table>
<thead>
<tr>
<th>Problem (Molich, 2000)</th>
<th>Morville’s User Experience Honeycomb</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>Sentiment</td>
<td>Usable</td>
</tr>
<tr>
<td>Do they think it has critical problems?</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Do they think it has serious problems?</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Do they think it has less serious problems?</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Do they think it is useful?</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Do they think it is easy to use?</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Do they trust it?</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Do they want it?</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Do they think it is valuable?</td>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Software Apps**

<table>
<thead>
<tr>
<th>Problem (Molich, 2000)</th>
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<th>Comments</th>
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</thead>
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<td>Sentiment</td>
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<td>Do they think it has critical problems?</td>
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<td>Do they think it has serious problems?</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Do they think it has less serious problems?</td>
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<tr>
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</tr>
<tr>
<td>Do they want it?</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Do they think it is valuable?</td>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Table 7 – Results: Software Apps**

<table>
<thead>
<tr>
<th>Problem (Molich, 2000)</th>
<th>Morville’s User Experience Honeycomb</th>
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</tr>
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<tr>
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<td>Yes</td>
</tr>
<tr>
<td>Do they think it is valuable?</td>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Comments**

- Critical: not everyone has a carer
- Serious: may make them feel oppressed
- Cosmetic: someone concerned about false positives, others for false negatives
- Critical: would feel oppressed by carers
- Should be personalized and flexible due to familiar dynamics (e.g. giving information to more than one carer etc.)