EUROPEAN COMMISSION
Directorate-General for Communications Networks, Content and Technology

eHealth, Well-Being and Ageing

ANNEX 1 (part A)

Innovation action

NUMBER — 857172 — SMART BEAR

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1.1. The project summary

Project Number [1]	857172	Project Acronym [2]	SMART BEAR

One form per project

General information	
Project title [3]	Smart Big Data Platform to Offer Evidence-based Personalised Support for Healthy and Independent Living at Home
Starting date [4]	01/09/2019
Duration in months [5]	48
Call (part) identifier [6]	H2020-SC1-FA-DTS-2018-2
Topic	DT-TDS-01-2019 Smart and healthy living at home
Fixed EC Keywords	Healthy ageing, Internet of Things
Free keywords	Big data, Independent Living, Connected Health, Intelligent interventions

Abstract [7]

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. Within Europe's ageing population, Hearing Loss, Cardio Vascular Diseases, Cognitive Impairments, Mental Health Issues and Balance Disorders, as well as Frailty, are prevalent conditions, with tremendous social and financial impact. Preventing, slowing the development of or dealing effectively with effects of the above impairments can have a significant impact on the quality of life and lead to significant savings in the cost of healthcare services. Digital tools hold the promise for many health benefits that can enhance the independent living and well-being of the elderly. 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 personalised interventions promoting their healthy and independent living. The platform will also be connected to hospital 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 personalised 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. The SMART BEAR solution will be validated through five large-scale pilots involving 5.000 elderly living at home in Greece, Italy, France, Spain, and Romania.

1.2. List of Beneficiaries

Project Number [1]	857172	Project Acronym [2]	SMART BEAR

List of Beneficiaries

No	Name	Short name	Country	Project entry month[8]	Project exit month
1	CONSIGLIO NAZIONALE DELLE RICERCHE	CNR	Italy	1	48
2	ATOS SPAIN SA	ATOS	Spain	1	48
3	PHILIPS ELECTRONICS NEDERLAND B.V.	PHILIPS	Netherlands	1	48
4	IBM ISRAEL - SCIENCE AND TECHNOLOGY LTD	IBM	Israel	1	48
5	AZIENDA REGIONALE PER L'INNOVAZIONEE GLI ACQUISTI S.P.A.	LISPA	Italy	1	48
6	PERIFEREIA PELOPONNISOU	ROP	Greece	1	48
7	MUNICIPALITY OF PALAIO FALIRO	MPF	Greece	1	48
8	COMUNITA SOCIALE CREMASCA ASC	CSC	Italy	1	48
9	FONDAZIONE CENTRO SAN RAFFAELE	FCSR	Italy	1	48
10	ASSOCIATION CATEL CLUB DES ACTEURS DE LA TELEMEDECINE	CATEL	France	1	48
11	IDCQ HOSPITALES Y SANIDAD SL	QUIRON	Spain	1	48
12	FUNDATIA ANA ASLAN INTERNATIONAL	ANA	Romania	1	48
13	FOUNDATION FOR RESEARCH AND TECHNOLOGY HELLAS	FORTH	Greece	1	48
14	ETHNIKO KAI KAPODISTRIAKO PANEPISTIMIO ATHINON	NKUA	Greece	1	48
15	PANEPISTIMIO IOANNINON	UOI	Greece	1	48
16	UNIVERSITA DEGLI STUDI DI MILANO	UMIL	Italy	1	48
17	UNIVERSIDAD DEL PAIS VASCO/ EUSKAL HERRIKO UNIBERTSITATEA	UPV/EHU	Spain	1	48
18	CITY UNIVERSITY OF LONDON	CITY	United Kingdom	1	48
19	INSTITUTE OF COMMUNICATION AND COMPUTER SYSTEMS	ICCS	Greece	1	48
20	SPHYNX TECHNOLOGY SOLUTIONS AG	STS	Switzerland	1	48
21	STREAM VISION	SV	France	1	48
22	IT SUPPORT SOLUTIONS SRL	ITSS	Romania	1	48
23	INNOVATEC SENSORIZACION Y COMUNICACION, S.L.	INV	Spain	1	48
24	ATHENS TECHNOLOGY CENTER ANONYMI BIOMICHANIKI EMPORIKI KAI TECHNIKI ETAIREIA EFARMOGON YPSILIS TECHNOLOGIAS	ATC	Greece	1	48

1.2. List of Beneficiaries

No	Name	Short name	Country	Project entry month[8]	Project exit month
25	BIRD & BIRD	2B	France	1	48
26	UNINOVA-INSTITUTO DE DESENVOLVIMENTO DE NOVAS TECNOLOGIAS-ASSOCIACAO	NOVA	Portugal	1	48
27	SECRETARIA REGIONAL DA SAUDE	SRS	Portugal	1	48

1.3. Workplan Tables - Detailed Implementation

1.3.1. WT1 List of work packages

WP Number[9]	WP Title	Lead beneficiary[10]	Person-months[11]	Start month[12]	End month[13]
WP1	Project Management	1 - CNR	65.00	1	48
WP2	Requirements & Platform Design	24 - ATC	87.00	1	9
WP3	Evidence-based Health & Well-being Monitoring	15 - UOI	124.00	7	33
WP4	Analytics & Decision-making for Personalised Interventions	3 - PHILIPS	212.00	7	33
WP5	Secure & Privacy-aware Data Handling	20 - STS	98.00	7	48
WP6	Platform Integration & Testing	2 - ATOS	116.00	12	36
WP7	Pilot 1 – Greece	6 - ROP	132.00	3	45
WP8	Pilot 2 – Italy-Portugal	16 - UMIL	203.00	3	45
WP9	Pilot 3 – France	10 - CATEL	136.00	3	45
WP10	Pilot 4 – Spain	11 - QUIRON	308.00	3	45
WP11	Pilot 5 – Romania	12 - ANA	136.00	3	45
WP12	Cross-Pilot Validation & Final Evaluation	14 - NKUA	107.00	2	48
WP13	Dissemination, Exploitation, Standardisation & Sustainability	19 - ICCS	178.00	1	48
WP14	Ethics requirements	1 - CNR	N/A	1	48
		Total	1,902.00		

1.3.2. WT2 list of deliverables

Deliverable Number[14]	Deliverable Title	WP number[9]	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D1.1	Initial Quality, Innovation and Data Management Plan	WP1	1 - CNR	Report	Confidential, only for members of the consortium (including the Commission Services)	4
D1.2	Year 1 project report and project plan updates	WP1	1 - CNR	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D1.3	SMART BEAR Open Call	WP1	1 - CNR	Report	Public	28
D1.4	Year 3 project report and project plan updates	WP1	1 - CNR	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D2.1	SMART BEAR Requirements	WP2	16 - UMIL	Report	Public	3
D2.2	SMART BEAR Architecture	WP2	18 - CITY	Report	Public	9
D3.1	SMART BEAR @ Home Enabling Components v1	WP3	15 - UOI	Demonstrator	Public	17
D3.2	Report on SMART BEAR @ Home Enabling Components v1	WP3	15 - UOI	Report	Public	17
D3.3	SMART BEAR @ Home Enabling Components v2	WP3	15 - UOI	Demonstrator	Public	30
D3.4	Report on SMART BEAR @ Home Enabling Components v2	WP3	15 - UOI	Report	Public	30
D3.5	SMART BEAR @ Home Enabling Components v3	WP3	15 - UOI	Demonstrator	Public	33
D3.6	Report on SMART BEAR @ Home Enabling Components v3	WP3	15 - UOI	Report	Public	33

Deliverable Number[14]	Deliverable Title	WP number[9]	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D4.1	SMART BEAR Cloud Enabling Components v1	WP4	3 - PHILIPS	Demonstrator	Public	17
D4.2	Report on SMART BEAR Cloud Enabling Components v1	WP4	3 - PHILIPS	Report	Public	17
D4.3	SMART BEAR Cloud Enabling Components v2	WP4	3 - PHILIPS	Demonstrator	Public	30
D4.4	Report on SMART BEAR Cloud Enabling Components v2	WP4	3 - PHILIPS	Report	Public	30
D4.5	SMART BEAR Cloud Enabling Components v3	WP4	3 - PHILIPS	Demonstrator	Public	33
D4.6	Report on SMART BEAR Cloud Enabling Components v3	WP4	3 - PHILIPS	Report	Public	33
D5.1	Continuous Security Assurance & Privacy by design - enabling mechanisms v1	WP5	20 - STS	Demonstrator	Public	17
D5.2	Report on Continuous Security Assurance & Privacy by design - enabling mechanisms v1	WP5	20 - STS	Report	Public	17
D5.3	Continuous Security Assurance & Privacy by design - enabling mechanisms v2	WP5	20 - STS	Demonstrator	Public	30
D5.4	Report on Continuous Security Assurance & Privacy by design - enabling mechanisms v2	WP5	20 - STS	Report	Public	30
D5.5	Continuous Security Assurance & Privacy by design - enabling mechanisms v3	WP5	20 - STS	Demonstrator	Public	33
D5.6	Report on Continuous Security Assurance & Privacy by design - enabling mechanisms v3	WP5	20 - STS	Report	Public	33
D5.7	Final Security Assurance Report	WP5	20 - STS	Report	Public	48

Deliverable Number[14]	Deliverable Title	WP number[9]	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D6.1	Integrated SMART BEAR platform v1	WP6	2 - ATOS	Demonstrator	Public	18
D6.2	Report on integrated SMART BEAR platform v1	WP6	2 - ATOS	Report	Public	18
D6.3	Integrated SMART BEAR platform v2	WP6	2 - ATOS	Demonstrator	Public	31
D6.4	Report on integrated SMART BEAR platform v2	WP6	2 - ATOS	Report	Public	31
D6.5	Integrated SMART BEAR platform v3	WP6	2 - ATOS	Demonstrator	Public	36
D6.6	Report on integrated SMART BEAR platform v3	WP6	2 - ATOS	Report	Public	36
D7.1	Greek Pilot Report v1	WP7	14 - NKUA	Report	Public	26
D7.2	Greek Pilot Report v2	WP7	14 - NKUA	Report	Public	32
D7.3	Greek Pilot Report v3	WP7	14 - NKUA	Report	Public	39
D7.4	Greek Pilot Final Evaluation Report	WP7	14 - NKUA	Report	Public	45
D8.1	Italian-Portuguese Pilot Report v1	WP8	9 - FCSR	Report	Public	26
D8.2	Italian-Portuguese Pilot Report v2	WP8	9 - FCSR	Report	Public	32
D8.3	Italian-Portuguese Pilot Report v3	WP8	9 - FCSR	Report	Public	39
D8.4	Italian-Portuguese Pilot Final Evaluation Report	WP8	9 - FCSR	Report	Public	45
D9.1	French Pilot Report v1	WP9	10 - CATEL	Report	Public	26
D9.2	French Pilot Report v2	WP9	10 - CATEL	Report	Public	32
D9.3	French Pilot Report v3	WP9	10 - CATEL	Report	Public	39
D9.4	French Pilot Final Evaluation Report	WP9	10 - CATEL	Report	Public	45
D10.1	Spanish Pilot Report v1	WP10	11 - QUIRON	Report	Public	26
D10.2	Spanish Pilot Report v2	WP10	11 - QUIRON	Report	Public	32
D10.3	Spanish Pilot Report v3	WP10	11 - QUIRON	Report	Public	39
D10.4	Spanish Pilot Final Evaluation Report	WP10	11 - QUIRON	Report	Public	45
D11.1	Romanian Pilot Report v1	WP11	12 - ANA	Report	Public	26

Deliverable Number[14]	Deliverable Title	WP number[9]	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D11.2	Romanian Pilot Report v2	WP11	12 - ANA	Report	Public	32
D11.3	Romanian Pilot Report v3	WP11	12 - ANA	Report	Public	39
D11.4	Romanian Pilot Final Evaluation Report	WP11	12 - ANA	Report	Public	45
D12.1	Ethics Application & Piloting Protocol & Evaluation Framework	WP12	14 - NKUA	Report	Public	6
D12.2	Evaluation Framework	WP12	14 - NKUA	Report	Public	26
D12.3	Cross-Pilot Evaluation Report v1	WP12	1 - CNR	Report	Public	28
D12.4	Cross-Pilot Evaluation Report v2	WP12	16 - UMIL	Report	Public	38
D12.5	Cross-Pilot Evaluation Report v3	WP12	15 - UOI	Report	Public	48
D13.1	Communication, Dissemination, Impact Creation, Exploitation & Standardisation plan	WP13	13 - FORTH	Report	Public	4
D13.2	Interim Communication, Dissemination, Impact Creation, Exploitation & Standardisation Report	WP13	19 - ICCS	Report	Public	24
D13.3	Interim Stakeholder Engagement Report	WP13	12 - ANA	Report	Public	24
D13.4	Data Valorisation Model & Open Call Requirements	WP13	17 - UPV/EHU	Report	Public	28
D13.5	Final Communication, Dissemination, Impact Creation & Standardisation Report	WP13	19 - ICCS	Report	Public	48
D13.6	Final Stakeholder Engagement report	WP13	12 - ANA	Report	Public	48
D14.1	H - Requirement No. 1	WP14	1 - CNR	Ethics	Confidential, only for members of the consortium (including the Commission Services)	3
D14.2	H - Requirement No. 2	WP14	1 - CNR	Ethics	Confidential, only for members of the consortium	5

Deliverable Number[14]	Deliverable Title	WP number[9]	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
					(including the Commission Services)	
D14.3	POPD - Requirement No. 3	WP14	1 - CNR	Ethics	Confidential, only for members of the consortium (including the Commission Services)	15

1.3.3. WT3 Work package descriptions

Work package number [9]	WP1	**Lead beneficiary** [10]	1 - CNR
Work package title	Project Management		
Start month	1	**End month**	48

Objectives

Co-coordinate all technical, innovation and administrative project activities; Ensure compliance with the project contract, description of work and quality plan; Plan and facilitate communication and interactions within the consortium; Produce reports on project progress and ensure the effective use of resources for realizing project activities; Manage the innovation created within the project; Handle the Open Call.

Description of work and role of partners

WP1 - Project Management [Months: 1-48]
CNR, ATOS, PHILIPS, IBM, LISPA, ROP, MPF, CSC, FCSR, CATEL , QUIRON, ANA, FORTH, NKUA, UOI, UMIL, UPV/EHU, CITY, ICCS, STS, SV, ITSS, INV, ATC, 2B, NOVA, SRS
Task 1.1 – Project Coordination [M1-M48] (Lead: CNR, Partners: ALL): This task will provide the overall project coordination, performing self-assessment activities (resources planning and distribution, project monitoring, corrective actions if needed), quality assurance, risk management, and consideration of external factors. This task will also have responsibility for setting up an appropriate communication and collaborative environment for the consortium members (e.g., mailing lists, project repository, internal wikis, and reporting tools). Deliverables: D1.1, D1.2, D1.4.

Task 1.2 – Clinical Coordination [M1-M48] (Lead: NKUA, Partners: -): The project clinical coordination will involve the clinical oversight of all Piloting activities, from Protocol definition to the final evaluation. Deliverables: D1.1, D1.2, D1.4.

Task 1.3 – Scientific & Technical Coordination [M1-M48] (Lead: STS, Partners: -): The project's scientific and technical coordination will ensure the quality and soundness of the scientific and technical work performed in the project. It will also involve continuous identification and mitigation of technical risks and complying to the Data Management Plan (D1.1). Deliverables: D1.1, D1.2, D1.4.

Task 1.4 – Innovation Management [M1-M48] (Lead: LISPA, Partners: -): The project innovation management will define innovation management and IPR handling (D.1.1), while ensuring that internal as well as external opportunities for innovation are subject to regular reviews. Deliverables: D1.1, D1.2, D1.4.
Task 1.5 – Open Call [M25-M32] (Lead: CNR, Partners: -): This task will organize and run the SMART BEAR Open Call to engage new partners bringing new types of data and devices to the platform. The Open Call will be announced on M28 and will be open until M32 at the latest. Deliverables: D1.3.

Participation per Partner

Partner number and short name	WP1 effort
1 - CNR	23.00
2 - ATOS	1.00
3 - PHILIPS	1.00
4 - IBM	1.00
5 - LISPA	6.00
6 - ROP	1.00
7 - MPF	1.00
8 - CSC	1.00

Partner number and short name	WP1 effort
9 - FCSR	1.00
10 - CATEL	1.00
11 - QUIRON	1.00
12 - ANA	1.00
13 - FORTH	1.00
14 - NKUA	6.00
15 - UOI	1.00
16 - UMIL	1.00
17 - UPV/EHU	1.00
18 - CITY	1.00
19 - ICCS	1.00
20 - STS	6.00
21 - SV	1.00
22 - ITSS	1.00
23 - INV	1.00
24 - ATC	1.00
25 - 2B	2.00
26 - NOVA	1.00
27 - SRS	1.00
Total	65.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D1.1	Initial Quality, Innovation and Data Management Plan	1 - CNR	Report	Confidential, only for members of the consortium (including the Commission Services)	4
D1.2	Year 1 project report and project plan updates	1 - CNR	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D1.3	SMART BEAR Open Call	1 - CNR	Report	Public	28
D1.4	Year 3 project report and project plan updates	1 - CNR	Report	Confidential, only for members of the consortium (including	36

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
				the Commission Services)	

Description of deliverables

Deliverables of WP1:

D1.1 : Initial Quality, Innovation and Data Management Plan [4]

This deliverable will include the Quality Management Plan (QMP), the Innovation Management Plan (IMP), as well the Data Management Plan (DMP). Any updates of QMP, IMP and DMP that may be deemed necessary in the course of the project will be included in the annual project reports.

D1.2 : Year 1 project report and project plan updates [12]

This document will include project management report and financial report for year 1. It will report on all management achievements and actions during the report interval, as well as cost statements of the project, and allocation of funds according to contracted schedule, and plans for the next period. The deliverable will also include necessary updates of QMP, IMP and DMP.

D1.3 : SMART BEAR Open Call [28]

The announcement of the SMART BEAR Open Call.

D1.4 : Year 3 project report and project plan updates [36]

This document will provide a report of all project execution aspects.

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification

Work package number [9]	WP2	**Lead beneficiary** [10]	24 - ATC
Work package title	Requirements & Platform Design		
Start month	1	**End month**	9

Objectives

To gather and analyse all the user requirements for the SMART BEAR solution; define and analyse the system requirements of the envisioned SMART BEAR integrated solution; identify and provide critical updates in terms of available tools and technologies, arising in the period between proposal submission and project's ini-tiation; design the initial architecture and specification of the SMART BEAR solution.

Description of work and role of partners

WP2 - Requirements & Platform Design [Months: 1-9]
ATC, CNR, ATOS, PHILIPS, LISPA, ROP, MPF, CSC, FCSR, CATEL , QUIRON, ANA, FORTH, NKUA, UMIL, CITY, ICCS, STS, SV, ITSS, INV, NOVA, SRS
Task 2.1 – Health & Well-being Requirements [M01-M03] (Lead: UMIL, Partners: ATOS, PHILIPS, ROP, MPF, CSC, FCSR, CATEL, QUIRON, ANA, NKUA, UMIL, NOVA, SRS): This task will define the requirements of the SMART BEAR solution from the perspective of the health and well-being of the elderly. These will cover re-quirements 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, inde-pendent living and improving the quality of life of the elderly will be considered. Deliverables: D2.1

Task 2.2 – User & Platform Requirements [M01-M03] (Lead: ATC, Partners: CNR, ATOS, PHILIPS, LISPA, ROP, MPF, CSC, CATEL, QUIRON, ANA, CITY, ICCS, STS, SV, ITSS, INV, SRS): This task will focus on defining the platform requirements from technical perspective (e.g. interfacing cap)abilities, supported in-teractions, compute and networking capabilities), conducting an up-to-date analysis of the pertinent techno-logical landscape (based on the State of the Art presented in Section 1.4.1), and the identification, specifica-tion and prioritisation of system requirements for it. It will also define an initial list of user-related require-ments, such as user interfacing, visualization, and intervention delivery preferences which will be further re-fined in T2.3 and during the Piloting stages (WP7-WP12). Finally, this task will also specify the security & privacy, as well as continuous assurance requirements, considering the regulatory landscape in each of the participating countries and the EU as a whole. Deliverables: D2.1

Task 2.3 – User-centred SMART BEAR Architecture & Design [M02-M09] (Lead: CITY, Partners: CNR, ATOS, PHILIPS, LISPA, FORTH, UMIL, CITY, ICCS, STS, ITSS, ATC, NOVA): This task will focus on specifying the initial reference architecture for the SMART BEAR platform and the digital services that it will offer. This will involve: (i) the identification of the different components/tools required to realise the SMART BEAR vi-sion; (ii) the definition of the interfaces of these components to enable communication and data exchanges between them; (iii) the definition of the basic interactions and data flows between them, which are required in order to address the requirements identified in T2.1 and T2.2. The developed architecture and functional specification will drive the work of WP3, WP4, WP5 and WP6. The definition will include open APIs and da-ta representations aligned with existing interoperability standards, while providing a baseline for data valorisa-tion and sharing purposes which will be further refined in T13.3. Part of the system design will focus on providing accessible human-computer interactions and follow the principles for usable and intuitive user in-terfaces. To this end, from the early stages of the project potential end-users will be recruited to provide guidelines on how to improve system usability. The later will facilitate bridging system functionalities with friendly HCI interfaces after considering the diverse backgrounds and needs of the different users (patients, caregivers, clinicians). Following the iterative evaluation of the integrated system by the five pilots considered in SMART BEAR, all human computer interaction issues will be periodically revised in order to thoroughly improve system usability. Deliverables: D2.2

Participation per Partner

Partner number and short name	WP2 effort
1 - CNR	4.00

Partner number and short name	WP2 effort
2 - ATOS	8.00
3 - PHILIPS	6.00
5 - LISPA	4.00
6 - ROP	3.00
7 - MPF	4.00
8 - CSC	3.00
9 - FCSR	2.00
10 - CATEL	3.00
11 - QUIRON	3.00
12 - ANA	4.00
13 - FORTH	2.00
14 - NKUA	2.00
16 - UMIL	6.00
18 - CITY	6.00
19 - ICCS	4.00
20 - STS	4.00
21 - SV	2.00
22 - ITSS	4.00
23 - INV	2.00
24 - ATC	6.00
26 - NOVA	3.00
27 - SRS	2.00
Total	87.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D2.1	SMART BEAR Requirements	16 - UMIL	Report	Public	3
D2.2	SMART BEAR Architecture	18 - CITY	Report	Public	9

Description of deliverables

Deliverables of WP2:

D2.1 : SMART BEAR Requirements [3]

This report will include a prioritised definition of the requirements of the SMART BEAR solution.

D2.2 : SMART BEAR Architecture [9]

This report will provide the overall architecture of the SMART BEAR platform, including @ Home and Backend Cloud instances, and a detailed design specification of the key hardware and software components of it, including their functionalities, interfaces and main security and privacy constraints regarding their use. At least 5 individuals from each pilot site will participate in the process, per KPI-22.

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS1	MS1	24 - ATC	9	Final ANEMOS architecture. Means of verification: Release of D2.4.

Work package number [9]	WP3	**Lead beneficiary** [10]	15 - UOI
Work package title	Evidence-based Health & Well-being Monitoring		
Start month	7	**End month**	33

Objectives

To provide efficient and secure out of the box federation of smart devices present in the SMART BEAR eco-system; to provide monitoring capabilities for end user activities, their conditions and the interventions ap-plied; to provide the local analytics needed to infer higher level information from the raw data monitored; to summarize data prior to transmission to the backend cloud; to develop the SMART BEAR mobile application and associated submodules.

Description of work and role of partners

WP3 - Evidence-based Health & Well-being Monitoring [Months: 7-33]
UOI, CNR, PHILIPS, LISPA, FCSR, FORTH, NKUA, UMIL, STS, SV, ITSS, INV, ATC, NOVA
Task 3.1 – Smart Home, IoT and eHealth devices Federation [M07-M033] (Lead: UOI, Partners: LISPA, FORTH, UMIL, STS, SV, ITSS, INV, ATC): This task will encompass all activities required to seamlessly integrate the available smart consumer and medical devices, as well as the smart city and relevant sources into the SMART BEAR @ Home ecosystem, interfacing them with the SMART BEAR Hub that will be deployed for that purpose and which will be used, along with the Mobile Application (developed in T3.2), to relay the aggregated data to the SMART BEAR Cloud (see WP4). Efforts will particularly focus on providing a secure out-of-the-box setup and configuration process for all deployed devices. Deliverables: D3.1, D3.2, D3.3, D3.4, D3.5, D3.6

Task 3.2 – Activities, Conditions & Interventions Monitoring [M07-M033] (Lead: CNR, Partners: PHILIPS, FCSR, NKUA, UOI): This task will involve the development of the mechanisms that will allow the platform to monitor (from the raw data aggregated by the smart devices) the everyday activities of the end-users, the environmental context, as well as the parameters related to the conditions covered by the project, as well as the interventions suggested by the platform (if they were followed by the end-user, what their effect was, etc.). Deliverables: D3.1, D3.2, D3.3, D3.4, D3.5, D3.6

Task 3.3 – Data Summarisation & Local Analytics [M07-M033] (Lead: UMIL, Partners: LISPA, UOI, ITSS): This task will also involve the development of summarization, merging and filtering operations at the SMART BEAR Hub, to compress the volume of data to be stored and transmitted to the backend Cloud. It will also develop the local analytics capabilities that are needed to infer higher level information about the users from the data collected in T3.2 and T3.3. Deliverables: D3.1, D3.2, D3.3, D3.4, D3.5, D3.6

Task 3.4 – SMART BEAR @ Home Mobile Application, Visualisation & User Interfacing [M07-M033] (Lead: ATC, Partners: UOI, UMIL, SV, ITSS, INV, ATC, NOVA): This task will develop the SMART BEAR mobile application, including the visualisation and user interfacing mechanisms needed to allow for seamless interactions between the end-users and the SMART BEAR platform. The primary functions of the application will be to: (a) collect data from the elderly about their activities and the phones' embedded sensors (e.g., accelerometer), (b) provide alerts and suggestions for personalised interventions to the end users, (c) receive commands and collect feedback on interventions suggested by SMART BEAR, and (d) provide access to personal data held by the SMART BEAR platform on them as well as the ability to request their modification or deletion (per GDPR requirements). The application will be the main source of input to the backend Cloud when the patient is not at home (in contrast, when at home most data collection functions will happen via the Hub). The application will include modules for delivering: (1) questionnaires (e.g. for screening potential participants), (2) cognitive games, (3) balance training (via HoloKit), (4) hearing aid management, (5) mental health profiling and monitoring, (6) CVD risk factor assessment and management, (7) social and physical activity enhancement, and (8) nutrition monitoring. As with all components developed in this WP, three main versions of the mobile application will be released, with the final version of the application being delivered after significant testing and user feedback has been gathered from the Pilots. Deliverables: D3.1, D3.2, D3.3, D3.4, D3.5, D3.6

Participation per Partner

Partner number and short name	WP3 effort
1 - CNR	6.00

Partner number and short name	WP3 effort
3 - PHILIPS	12.00
5 - LISPA	7.00
9 - FCSR	3.00
13 - FORTH	3.00
14 - NKUA	6.00
15 - UOI	22.00
16 - UMIL	17.00
20 - STS	3.00
21 - SV	5.00
22 - ITSS	11.00
23 - INV	5.00
24 - ATC	22.00
26 - NOVA	2.00
Total	124.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D3.1	SMART BEAR @ Home Enabling Components v1	15 - UOI	Demonstrator	Public	17
D3.2	Report on SMART BEAR @ Home Enabling Components v1	15 - UOI	Report	Public	17
D3.3	SMART BEAR @ Home Enabling Components v2	15 - UOI	Demonstrator	Public	30
D3.4	Report on SMART BEAR @ Home Enabling Components v2	15 - UOI	Report	Public	30
D3.5	SMART BEAR @ Home Enabling Components v3	15 - UOI	Demonstrator	Public	33
D3.6	Report on SMART BEAR @ Home Enabling Components v3	15 - UOI	Report	Public	33

Description of deliverables

Deliverables of WP3:

D3.1 : SMART BEAR @ Home Enabling Components v1 [17]

This deliverable will include the first version of the implementation of SMART BEAR @ Home Enabling Components. These components will be the basic SMART BEAR Hub communication software (contributed by T3.1), the monitor (contributed by T3.2), the component supporting the summarization and local analytics of data

at the SMART BEAR Hub (contributed by T3.3), and the SMART BEAR mobile application, visualisation and user inter-faces (contributed by T3.4).

D3.2 : Report on SMART BEAR @ Home Enabling Components v1 [17]

This deliverable will be a report documenting the components included in D3.1. The task responsible for the development of each of these components, as identified in the description of D3.1, will also be responsible for the provision of the documentation of the relevant component in this deliverable. The delivered components will include: at least 2 heterogeneous devices covered by the monitoring solution (KPI-1); at least 3 parameters inferred by basic analytics (KPI-4); application for screening potential participants (KPI-12); will integrate at least 2 sensing and actuation mechanisms such as those described in Table 2 (KPI-20).

D3.3 : SMART BEAR @ Home Enabling Components v2 [30]

This deliverable will include the second version of the implementation of SMART BEAR @ Home Enabling Components. These components will be the basic SMART BEAR Hub communication software (contributed by T3.1), the monitor (contributed by T3.2), the component supporting the summarization and local analytics of data at the SMART BEAR Hub (contributed by T3.3), and the SMART BEAR mobile application, visualisation and user inter-faces (contributed by T3.4).

D3.4 : Report on SMART BEAR @ Home Enabling Components v2 [30]

This deliverable will be a report documenting the components included in D3.3. D3.4 will be an amended version of D3.2, which in addition to the material included in D3.2, will include the documentation of all the new capabilities of the relevant components. The task responsible for the development of each of these components will also be responsible for the provision of the documentation of the component in this deliverable. The delivered components will include: at least 4 heterogeneous devices covered by the monitoring solution (KPI-1); at least 6 parameters inferred by basic analytics (KPI-4); application for monitoring participants (KPI-12); will integrate at least 4 sensing and actuation mechanisms such as those described in Table 2 (KPI-20).

D3.5 : SMART BEAR @ Home Enabling Components v3 [33]

This deliverable will include the third version of the implementation of SMART BEAR @ Home Enabling Components. These components will be the basic SMART BEAR Hub communication software (contributed by T3.1), the monitor (contributed by T3.2), the component supporting the summarization and local analytics of data at the SMART BEAR Hub (contributed by T3.3), and the SMART BEAR mobile application, visualisation and user inter-faces (contributed by T3.4).

D3.6 : Report on SMART BEAR @ Home Enabling Components v3 [33]

This deliverable will be a report documenting the components included in D3.5. D3.6 will be an amended version of D3.4 and D3.2, which in addition to the material included in these earlier deliverables, will include the documentation of all the new capabilities of the relevant components. The task responsible for the development of each of the relevant components will also be responsible for the provision of the documentation of the component in this deliverable. The delivered components will cover all aspects defined in the relevant KPIs, including at least 5 types heterogeneous devices covered by the monitoring solution (KPI-1); all 9 parameters inferred by basic analytics (KPI-4); applications for participant screening and monitoring, and delivery of the SMART BEAR platform interventions (KPI-12); and integration of all needed sensing and actuation mechanisms such as those described in in Table 2 (KPI-20).

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS2	MS2	15 - UOI	15	CRSA specification language. Means of verification: Release of D3.1.
MS3	MS3	3 - PHILIPS	22	Initial version of tools, models and integrated platform. Means of verification: Release of D3.2,

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
				D4.1, D5.1, D3.3, D4.2, D5.2, and D6.1.

Work package number [9]	WP4	Lead beneficiary [10]	3 - PHILIPS
Work package title	Analytics & Decision-making for Personalised Interventions		
Start month	7	End month	33

Objectives

To provide all the components needed to implement the SMART BEAR Cloud, including the (i) data reposito-ry, (ii) analytics & decision models, (iii) decision support system, (iv) big data analytics, (v) interventions as-sessment & learning, and (vi) visualisation and interfacing components.

Description of work and role of partners

WP4 - Analytics & Decision-making for Personalised Interventions [Months: 7-33]
PHILIPS, ATOS, IBM, ROP, MPF, CSC, FCSR, CATEL , QUIRON, ANA, NKUA, UOI, UMIL, CITY, ICCS, ITSS, ATC, NOVA

Task 4.1 – Data Repository & hosting [M07-M33] (Lead: ICCS, Partners: ATOS, PHILIPS, IBM, NKUA, CITY, ITSS): This task will be responsible for the design and development of the data repository of the SMART BEAR platform, which will be receiving data from all the different external data sources (SMART BEAR @ Home hubs, corresponding repositories of the pilot providing partners, medical records from healthcare service providers, the SMART BEAR mobile application). The task will specify a unified schema for these data in a manner that can support effectively the operation of the data analytics and learning/evolution components of SMART BEAR (see Task 4.4 and Task 4.5, respectively), and its scalable deployment, in line with the data sharing and valorisation requirements that will also drive the corresponding Open Call. The design and implementation of the data repository will consider standards for health records (e.g., HL7) as well as security & privacy standards and regulations, such as GDPR. Deliverables: D4.1, D4.2, D4.3, D4.4, D4.5, D4.6.

Task 4.2 – Analytics & Decision Models for Personalised Interventions [M07-M33] (Lead: PHILIPS, Partners: ROP, MPF, CSC, FCSR, CATEL, QUIRON, ANA, NKUA, UOI, ICCS): This task will focus on the development of a language for the specification of the SMART BEAR models (including the analytics models, the intervention decision making models, and the user personalization models) offering constructs for specifying: (a) the decision-making process for suggesting interventions of different types, (b) the evidence that is needed for deciding to suggest interventions of different types, (c) the process of monitoring the adoption or rejection of interventions and learning from their effect, and (d) the personal, medical and preference profiles of individual users. In defining this language, various approaches will be considered including ontology-based languages such as the EVOTION language for specifying to public health policy decision-making models [21], mark up languages for specifying machine learning and analytics computations (e.g., PMML and PFA, respectively). A tool will also be built to enable the specification of decision models using the defined language. This task will also be responsible for the design and development of the decision-making models for identifying and realising appropriate interventions for the health and well-being of the elderly. Where applicable relevant medical and health and safety guidelines will be catered for within the models. Monitoring tools (Task 3.2) will be used to monitor the adoption and application of such interventions and learning tools (see Task 4.5) will be used to analyse their effects and tune the relevant decision models accordingly. Finally, this task will also develop the core data analytics components needed to support the processing of both static (aka batch) data and dynamic (real-time) data. This component will be developed as a bridge between SMART BEAR @ Home instances, existing open IoT platforms and the SMART BEAR repository (Task 4.1). Deliverables: D4.1, D4.2, D4.3, D4.4, D4.5, D4.6.

Task 4.3 – Decision Support System development [M07-M33] (Lead: ICCS, Partners: PHILIPS, UOI): This task will focus on the development of the SMART BEAR Decision Support System (DSS) that will realise the process of deciding upon the adoption and execution of interventions driven by the decision models specified in Task 4.2. DSS will consider the wider profile of individual end users, their medical profile, their preferences profile, as well as historical evidence and analysis of the effects arising from the adoption of interventions from individuals with similar profiles. The latter will enable it to reason and identify interventions with poor results and adopt the relevant decision-making process accordingly. Deliverables: D4.1, D4.2, D4.3, D4.4, D4.5, D4.6.

Task 4.4 – Big Data Analytics Engine [M07-M33] (Lead: UMIL, Partners: IBM): This task will apply Model-Based BDaaS on the data produced by the assortment of inputs aggregated by the SMART BEAR Cloud to correlate and analyse the participants' health and environment conditions, as well as their preferences, so as to suggest the most appropriate interventions for them. The task will develop the mechanisms needed to translate the SMART BEAR models

(Task 4.2) to executable scripts in the Big Data Analytics engine in order to enable their execution in this engine and store the outcomes of the analysis in the data repository as an instance of the decision model. Examples of such engines include the Hadoop ecosystem, offering HBase on data storage management, Spark and Storm for iterative batch and real-time data processing, Flume and Kafka for data integration and Mahout, MLlib, H2O and SAMOA for machine learning. Deliverables: D4.1, D4.2, D4.3, D4.4, D4.5, D4.6.

Task 4.5 – Intervention Assessment, Learning & Evolution [M07-M33] (Lead: CITY, Partners: PHILIPS, NKUA, CITY, ICCS): This task will develop the intervention assessment elements of the backend Cloud which, by aggregating and analysing the effectiveness of proposed interventions, along past interventions on participants and participants with similar profiles, will enable the establishment of their (short and long -term) effectiveness, the conditions that affect this effectiveness, along with the acceptability of different types of interventions (for a given participant and participants with similar profiles), and their long-term adoption. The evaluation will consider both the subjective and objective effectiveness of interventions, from a technical, user-based and clinical experts' -based perspective. This will allow for a continuous improvement on the suggested interventions, while helping highlight deficits in the current best practice in managing the conditions and risks targeted by the project in the everyday lives of the elderly. Deliverables: D4.1, D4.2, D4.3, D4.4, D4.5, D4.6.

Task 4.6 – Visualisation [M07-M33] (Lead: UMIL, Partners: ICCS, ITSS, ATC, NOVA): This task will focus on the development of web accessible dashboard for the SMART BEAR platform. This dashboard will provide access to all key capabilities of the platform including data management, core data analytics, learning and evolution, decision model creation and decision models, decision making and interventions, activity and interventions monitoring, and different types of visualisation. Access to these capabilities will be restricted according to the roles and access rights of different types users (e.g., clinical experts, administrators, technical support), whilst preserving the strong privacy constraints applying to SMART BEAR. Deliverables: D4.1, D4.2, D4.3, D4.4, D4.5, D4.6.

Participation per Partner

Partner number and short name	WP4 effort
2 - ATOS	16.00
ATOS IT	2.00
3 - PHILIPS	44.00
4 - IBM	12.00
6 - ROP	2.00
7 - MPF	3.00
8 - CSC	3.00
9 - FCSR	3.00
10 - CATEL	3.00
11 - QUIRON	3.00
12 - ANA	3.00
14 - NKUA	8.00
15 - UOI	8.00
16 - UMIL	22.00
18 - CITY	18.00
19 - ICCS	40.00
22 - ITSS	14.00
24 - ATC	6.00
26 - NOVA	2.00

Partner number and short name	WP4 effort
Total	212.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D4.1	SMART BEAR Cloud Enabling Components v1	3 - PHILIPS	Demonstrator	Public	17
D4.2	Report on SMART BEAR Cloud Enabling Components v1	3 - PHILIPS	Report	Public	17
D4.3	SMART BEAR Cloud Enabling Components v2	3 - PHILIPS	Demonstrator	Public	30
D4.4	Report on SMART BEAR Cloud Enabling Components v2	3 - PHILIPS	Report	Public	30
D4.5	SMART BEAR Cloud Enabling Components v3	3 - PHILIPS	Demonstrator	Public	33
D4.6	Report on SMART BEAR Cloud Enabling Components v3	3 - PHILIPS	Report	Public	33

Description of deliverables

Deliverables of WP4:

D4.1 : SMART BEAR Cloud Enabling Components v1 [17]

This deliverable will include the first version of the following components of SMART BEAR: the data repository (contributed by T4.1); the language for specifying the SMART BEAR analytics, intervention decision making and user personalization models, the tool enabling the specification of models using this language, and actual models of these three types (contributed by T4.2); the core data analytics component needed to support the processing of both static and dynamic data (contributed by T4.2); the decision support system (contributed by T4.3); the big data analytics engine (contributed by T4.4); and the intervention assessment component (contributed by T4.5), and the visualisation component (contributed by T4.6).

D4.2 : Report on SMART BEAR Cloud Enabling Components v1 [17]

This deliverable will be a report documenting the components included in D4.1. The task responsible for the development of each of these components, as identified in the description of D4.1, will also be responsible for the provision of the documentation of the component in this deliverable. The delivered solution will cover data analytics and learning capabilities tailored to datasets collected from a first set of the devices used for monitoring participants (KPI-6) and decision support capabilities will cover at least 1 medical area (KPI-9).

D4.3 : SMART BEAR Cloud Enabling Components v2 [30]

This deliverable will include the second version of the components included in D4.1. The task, which had responsibility for developing the earlier version of each of these components for D4.1 will also be responsible for providing the new version of the component in this deliverable.

D4.4 : Report on SMART BEAR Cloud Enabling Components v2 [30]

This deliverable will be a report documenting the components included in D4.3. D4.4 will be an amended version of D4.2, which will include the documentation of all the new capabilities of the relevant components. The task responsible for the development of each of these components for D4.3 will also be responsible for the provision of

the documentation of the component in this deliverable. The delivered solution will cover data analytics and learning capabilities tailored to datasets collected from an extended set of the devices used for monitoring participants (KPI-6) and decision support capabilities will cover at least 3 medical areas (KPI-9).

D4.5 : SMART BEAR Cloud Enabling Components v3 [33]

This deliverable will include the third version of the components included in D4.3. The task, which had responsibility for developing the earlier version of each of these components for D4.1 and D4.3 will also be responsible for providing the new version of the component in this deliverable.

D4.6 : Report on SMART BEAR Cloud Enabling Components v3 [33]

This deliverable will be a report documenting the components included in D4.5. D4.6 will be an amended version of D4.4 and D4.2, which will include the documentation of all the new capabilities of the relevant components. The task responsible for the development of each of these components for D4.2 and D4.4 will also be responsible for the provision of the documentation of the component in this deliverable. The delivered solution will cover the full set of data analytics and learning capabilities as well as decision support capabilities, as defined in the corresponding KPIs (KPI-6 & KPI-9).

Schedule of relevant Milestones

Milestone number[18]	**Milestone title**	**Lead beneficiary**	**Due Date (in months)**	**Means of verification**
MS3	MS3	3 - PHILIPS	22	Initial version of tools, models and integrated platform. Means of verification: Release of D3.2, D4.1, D5.1, D3.3, D4.2, D5.2, and D6.1.

Work package number [9]	WP5	Lead beneficiary [10]	20 - STS
Work package title	Secure & Privacy-aware Data Handling		
Start month	7	End month	48

Objectives

To provide the security and privacy by design enabling mechanisms that will be integrated into the SMART BEAR platform; to provide the continuous security assurance framework that will provide continuous guaran-tees about the security posture of the SMART BEAR Cloud.

Description of work and role of partners

WP5 - Secure & Privacy-aware Data Handling [Months: 7-48]
STS, IBM, FORTH, CITY, SV, ITSS, INV, ATC
Task 5.1 – Security & Privacy by design - enabling mechanisms [M07-M33] (Lead: FORTH, Partners: IBM, CITY, STS, SV, ITSS, INV, ATC): This task will focus on the developing the necessary mechanisms (aka controls) to ensure the security and privacy of the data held in the SMART platform and the integrity of the platform itself (both @ Home and its Cloud). The security properties will focus on the integrity, confidentiality and availability of data at rest, in transit and in processing. The techniques and mechanisms that will be used for this purpose will include encryption, role and attribute-based access control, with privacy-related features embedded into the corresponding authorisation policies. Strong confidentiality and authentication mechanisms will cover communications between the peripheral components of the SMART BEAR @ Home platform (smart consumer and medical devices, the SMART BEAR Hub, the smartphone) and the backend (Cloud instance and healthcare service providers). Lightweight mechanisms will be employed where needed, based on the analysis of relevant capabilities and gaps of the existing components (used mobile phone, sensors). Furthermore, data anonymisation techniques, differential privacy and selective data obfuscation and randomisation both for raw data and for outcomes of the platform's analytics will be employed to facilitate the privacy-aware data sharing and processing (e.g., to infer knowledge from processing intervention data of users with similar profiles). The core security controls, including secure setup and configuration of all involved devices, will be implemented before issuing the project hardware (e.g. smart devices, mobile application) to the elderly for the start of the real-time data collection pilot activities. Deliverables: D5.1, D5.2, D5.3, D5.4, D5.5, D5.6

Task 5.2 – Continuous Security Assurance [M07-M48] (Lead: STS, Partners: IBM, FORTH, CITY, SV, ITSS, INV, ATC): This task will focus on the developing the Continuous Security Assurance solution integrated into the SMART BEAR platform, to ensure the security and privacy of the data held in the platform and the protection of the platform itself, providing a real-time view of the security posture of the organisation where SMART BEAR is deployed, The runtime operations of the platform will be continually monitored based on the STS's security assurance platform to detect security and privacy threats. The platform will provide a certifiable view of the system's security posture, with accountability provisions for changes that occur in said posture, as it will process generic timestamped events representing the operation of different components in the implementation stack of a system and support the runtime checking of conditions expressed in the powerful temporal logic language of Event Calculus. Finally, a security assessment will be carried out on the integrated platform to ensure any omission are detected and amended prior to final release. Deliverables: D5.1, D5.2, D5.3, D5.4, D5.5, D5.6, D5.7.

Participation per Partner

Partner number and short name	WP5 effort
4 - IBM	22.00
13 - FORTH	15.00
18 - CITY	12.00
20 - STS	32.00
21 - SV	4.00
22 - ITSS	4.00

Partner number and short name	WP5 effort
23 - INV	4.00
24 - ATC	5.00
Total	98.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D5.1	Continuous Security Assurance & Privacy by design - enabling mechanisms v1	20 - STS	Demonstrator	Public	17
D5.2	Report on Continuous Security Assurance & Privacy by design - enabling mechanisms v1	20 - STS	Report	Public	17
D5.3	Continuous Security Assurance & Privacy by design - enabling mechanisms v2	20 - STS	Demonstrator	Public	30
D5.4	Report on Continuous Security Assurance & Privacy by design - enabling mechanisms v2	20 - STS	Report	Public	30
D5.5	Continuous Security Assurance & Privacy by design - enabling mechanisms v3	20 - STS	Demonstrator	Public	33
D5.6	Report on Continuous Security Assurance & Privacy by design - enabling mechanisms v3	20 - STS	Report	Public	33
D5.7	Final Security Assurance Report	20 - STS	Report	Public	48

Description of deliverables

Deliverables of WP5:

D5.1 : Continuous Security Assurance & Privacy by design - enabling mechanisms v1 [17]

This deliverable will include the first version of the implementation of the mechanisms (controls) to ensure the security and privacy of the data held in the SMART platform and the integrity of the platform itself (contributed by T5.1); and the component supporting the continuous assessment of the security and privacy state of the platform (contributed by T5.2).

D5.2 : Report on Continuous Security Assurance & Privacy by design - enabling mechanisms v1 [17]

This deliverable will be a report documenting the components included in D5.1. The task responsible for the development of each of these components, as identified in the description of D5.1, will also be responsible for the provision of the documentation of the component in this deliverable. The privacy-preserving and secure by design

data handling capabilities delivered will ensure at least 2 key security and privacy properties (KPI-14), covering at least 1 data state (KPI-15), as defined in the corresponding security policies (KPI-16) and following relevant guidelines (KPI-17).

D5.3 : Continuous Security Assurance & Privacy by design - enabling mechanisms v2 [30]

This deliverable will include the second version of the components included in D5.1. The task, which had responsibility for developing the earlier version of each of these components for D5.1 will also be responsible for providing the new version of the component in this deliverable.

D5.4 : Report on Continuous Security Assurance & Privacy by design - enabling mechanisms v2 [30]

This deliverable will be a report documenting the components included in D5.3. D5.4 will be an amended version of D5.2, which will include the documentation of all the new capabilities of the relevant components. The task responsible for the development of each of these components for D5.3 will also be responsible for the provision of the documentation of the component in this deliverable. The privacy-preserving and secure by design data handling capabilities delivered will ensure at least 4 key security and privacy properties (KPI-14), covering at least 2 data state (KPI-15), as defined in the corresponding security policies (KPI-16) and following relevant guidelines (KPI-17).

D5.5 : Continuous Security Assurance & Privacy by design - enabling mechanisms v3 [33]

This deliverable will include the third version of the components included in D5.3. The task, which had responsibility for developing the earlier version of each of these components for D5.1 and D5.3 will also be responsible for providing the new version of the component in this deliverable.

D5.6 : Report on Continuous Security Assurance & Privacy by design - enabling mechanisms v3 [33]

This deliverable will be a report documenting the components included in D5.5. D5.6 will be an amended version of D5.4 and D5.2, which will include the documentation of all the new capabilities of the relevant components. The task responsible for the development of each of these components for D5.2 and D5.4 will also be responsible for the provision of the documentation of the component in this deliverable. The privacy-preserving and secure by design data handling capabilities delivered will ensure all relevant security and privacy properties (KPI-14), covering all 3 data states (KPI-15), as defined in the corresponding security policies (KPI-16) and following relevant guidelines (KPI-17).

D5.7 : Final Security Assurance Report [48]

This deliverable will provide the final report on the security assurance aspects (issues detected, mitigation actions etc.) faced in the duration of the project. It will also validate that the security framework provides application-specific and multi-domain certifications and license requirements per the ISO/IEC 27000 family of standards (KPI-19).

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS3	MS3	3 - PHILIPS	22	Initial version of tools, models and integrated platform. Means of verification: Release of D3.2, D4.1, D5.1, D3.3, D4.2, D5.2, and D6.1.

Work package number [9]	WP6	Lead beneficiary [10]	2 - ATOS
Work package title	Platform Integration & Testing		
Start month	12	End month	36

Objectives

To integrate all the tools and components defined in WP2 and developed in WP3, WP4 and WP5, in order to provide the integrated SMART BEAR solution; to test and ensure the quality of the platform; to define a framework of criteria for evaluating SMART BEAR; to document and provide usage guidelines for the platform.

Description of work and role of partners

WP6 - Platform Integration & Testing [Months: 12-36]
ATOS, LISPA, UMIL, CITY, ICCS, STS, SV, ITSS, INV, ATC, NOVA
Task 6.1 – Integration of tools and components into the SMART BEAR platform [M12-M36] (Lead: ATOS, Partners: LISPA, UMIL, CITY, ICCS, STS, SV, ITSS, INV, ATC, NOVA): This task will focus on the integration and delivery of the core SMART BEAR solution. The integration process will be driven and enabled by the architecture defined in WP2. This architecture may need to be refined to reflect and accommodate the exact implementations of components in WP3, WP4 and WP5. If this happens, the amended architecture will be documented and supplied along with the three releases of the platform. The integrated version of the framework will provide the basis for evaluating the effectiveness of the SMART BEAR approach in the pilots of the project (see WP7 – WP11). Deliverables: D6.1-D6.6

Task 6.2 – Technical Testing & Quality Assurance of the integrated platform [M12-M36] (Lead: LISPA, Partners: ATOS, UMIL, SV, ITSS, INV, ATC, NOVA): This task will focus on testing the integrated platform. Test cases and unit tests will be developed for this purpose. These will be driven by the platform requirement specifications and the architecture model developed in WP2. It will also consider all KPIs defined in the proposal (Section 1.1.3) and at Task 12.1 that depend on the integrated platform. Testing will verify the proper interfacing of the core SMART BEAR platform with the external components. It will also cover the security evaluation of the SMART BEAR platform itself. Deliverables: D6.2, D6.4 D6.6

Task 6.3 – Documentation & Guidelines for the usage of SMART BEAR platform [M12-M36] (Lead: ICCS, Partners: ATOS, STS): This task will be concerned with the production of an end-user guide for installing, deploying and using the SMART BEAR solution and its components. The target user groups for this purpose will be as identified in WP2, including doctors, supporting medical staff and end users. Deliverables: D6.4

Participation per Partner

Partner number and short name	WP6 effort
2 - ATOS	32.00
ATOS CCSU	2.00
ATOS IT	3.00
5 - LISPA	10.00
16 - UMIL	14.00
18 - CITY	4.00
19 - ICCS	11.00
20 - STS	8.00
21 - SV	5.00
22 - ITSS	5.00
23 - INV	5.00

Partner number and short name	WP6 effort
24 - ATC	14.00
26 - NOVA	3.00
Total	116.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D6.1	Integrated SMART BEAR platform v1	2 - ATOS	Demonstrator	Public	18
D6.2	Report on integrated SMART BEAR platform v1	2 - ATOS	Report	Public	18
D6.3	Integrated SMART BEAR platform v2	2 - ATOS	Demonstrator	Public	31
D6.4	Report on integrated SMART BEAR platform v2	2 - ATOS	Report	Public	31
D6.5	Integrated SMART BEAR platform v3	2 - ATOS	Demonstrator	Public	36
D6.6	Report on integrated SMART BEAR platform v3	2 - ATOS	Report	Public	36

Description of deliverables

Deliverables of WP6:

D6.1 : Integrated SMART BEAR platform v1 [18]

This deliverable will provide the first version of the integrated SMART BEAR platform involving all the first release of components of WP3, WP4 and WP5 developed until M17.

D6.2 : Report on integrated SMART BEAR platform v1 [18]

A report documenting the integrated platform's (a) functionalities and any amendments made to its architecture and design, (c) the outcomes of testing the platform and (d) installation, deployment and usage guidelines for the platform. The integrated smart adaptive living solution will provide interfaces to the platform for at least 2 types of people (KPI-21).

D6.3 : Integrated SMART BEAR platform v2 [31]

his deliverable will provide the second version of the integrated SMART BEAR platform involving all the second release of components of WP3, WP4 and WP5 developed until M30.

D6.4 : Report on integrated SMART BEAR platform v2 [31]

Update on D6.2 for the second version of the integrated platform. The integrated smart adaptive living solution will provide interfaces to the platform for at least 3 types of people (KPI-21)

D6.5 : Integrated SMART BEAR platform v3 [36]

This deliverable will provide the final version of the integrated SMART BEAR platform involving all the final release of components of WP3, WP4 and WP5 developed until M36.

D6.6 : Report on integrated SMART BEAR platform v3 [36]

Update on D6.4 for the final version of the integrated platform, including validation of all criteria defined in pertinent KPIs, including KPI-19 and KPI-21.

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS3	MS3	3 - PHILIPS	22	Initial version of tools, models and integrated platform. Means of verification: Release of D3.2, D4.1, D5.1, D3.3, D4.2, D5.2, and D6.1.
MS4	MS4	14 - NKUA	26	Initial prototype demonstration and pilot validation. Means of verification: Release of D6.2, D7.1, D8.1, D9.1, D10.1 and D11.1.
MS6	MS6	14 - NKUA	32	Second prototype demonstration and pilot validation. Means of verification: Release of D6.4, D7.2, D8.2, D9.2, D10.2 and D11.2.
MS7	MS7	2 - ATOS	36	Final prototype delivery and demonstration. Means of verification: Release of D6.6, D7.3, D8.3, D9.3, D10.3 and D11.3.

Work package number [9]	WP7	**Lead beneficiary** [10]	6 - ROP
Work package title	Pilot 1 – Greece		
Start month	3	**End month**	45

Objectives

To carry out (i) the SMART pre-piloting (equipment procurement, pre-recruitment, screening), (ii) setup (plat-form setup, user recruitment), (iii) piloting (including monitoring and support) and (iv) evaluation activities, in the context of the Greek pilot environment.

Description of work and role of partners

WP7 - Pilot 1 – Greece [Months: 3-45]
ROP, MPF, NKUA, ATC, 2B
Task 7.1 – Equipment Procurement, End-user Pre-Recruitment & Screening – Greece [M03-M33] (Lead: MPF, Partners: ROP, NKUA): This task will implement Phase 1 of the Pilot, i.e. the pre-recruitment and screening of end-users, as described in Section 1.3.4.1.1, for the Greek Pilot. It will also involve the Calls for Tenders to acquire the equipment (smart devices, smart phones, smart hearing aids, etc.) needed for setting up the piloting environment. Deliverables: D7.1, D7.2, D7.3, D7.4

Task 7.2 – Pilot Setup, Equipment Procurement & End-user Recruitment – Greece [M18-M34] (Lead: MPF, Partners: ROP, NKUA, ATC): This task will implement Phase 2 of the Pilot, i.e. the recruitment of end-users, as described in Section 1.3.4.1.2, for the Greek Pilot. Moreover, it will involve procuring the needed equipment and setting up SMART BEAR in the Pilot environment of the involved local sites. Deliverables: D7.1, D7.2, D7.3, D7.4

Task 7.3 – Piloting, Privacy, Legal and Ethics - Monitoring & Support – Greece [M19-M42] (Lead: ROP, Partners: MPF, NKUA, 2B): This task will implement Phase 3 of the Pilot, i.e. the actual Piloting phase, as described in Section 1.3.4.1.3, for the Greek Pilot, involving 1.000 end-users. A significant part of the effort in this task will be dedicated to supporting the end-users (technical and clinical support) and continuously monitoring the Pilot execution in terms of regulatory and ethics compliance. Deliverables: D7.1, D7.2, D7.3, D7.4

Task 7.4 – Pilot specific evaluation – Greece [M23-M45] (Lead: NKUA, Partners: ROP, MPF): This task will involve Phase 4 of the Pilot, i.e. the evaluation of the Greek pilot, as described in Section 1.3.4.1.4, via the methodology and KPIs defined in Task 12.1. Deliverables: D7.1, D7.2, D7.3, D7.4

Participation per Partner

Partner number and short name	WP7 effort
6 - ROP	32.00
7 - MPF	68.00
14 - NKUA	15.00
24 - ATC	15.00
25 - 2B	2.00
Total	132.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D7.1	Greek Pilot Report v1	14 - NKUA	Report	Public	26
D7.2	Greek Pilot Report v2	14 - NKUA	Report	Public	32
D7.3	Greek Pilot Report v3	14 - NKUA	Report	Public	39
D7.4	Greek Pilot Final Evaluation Report	14 - NKUA	Report	Public	45

Description of deliverables

Deliverables of WP7:

D7.1 : Greek Pilot Report v1 [26]
First evaluation report of the Greek SMART BEAR Pilot

D7.2 : Greek Pilot Report v2 [32]
Second evaluation report of the Greek SMART BEAR Pilot

D7.3 : Greek Pilot Report v3 [39]
Third evaluation report of the Greek SMART BEAR Pilot

D7.4 : Greek Pilot Final Evaluation Report [45]
Final evaluation report of the Greek SMART BEAR Pilot

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS4	MS4	14 - NKUA	26	Initial prototype demonstration and pilot validation. Means of verification: Release of D6.2, D7.1, D8.1, D9.1, D10.1 and D11.1.
MS6	MS6	14 - NKUA	32	Second prototype demonstration and pilot validation. Means of verification: Release of D6.4, D7.2, D8.2, D9.2, D10.2 and D11.2.

Work package number [9]	WP8	**Lead beneficiary** [10]	16 - UMIL
Work package title	Pilot 2 – Italy-Portugal		
Start month	3	**End month**	45

Objectives

To carry out (i) the SMART pre-piloting (equipment procurement, pre-recruitment, screening), (ii) setup (platform setup, user recruitment), (iii) piloting (including monitoring and support) and (iv) evaluation activities, in the context of the Italian-Portuguese pilot environment.

Description of work and role of partners

WP8 - Pilot 2 – Italy-Portugal [Months: 3-45]
UMIL, CNR, LISPA, CSC, FCSR, 2B, NOVA, SRS
Task 8.1 – Equipment Procurement, End-user Pre-Recruitment & Screening – Italy-Portugal [M03-M33] (Lead: UMIL, Partners: CNR, LISPA, CSC, NOVA, SRS): This task will implement Phase 1 of the Pilot, i.e. the pre-recruitment and screening of end-users, as described in Section 1.3.4.1.1, for the Italian-Portuguese Pilot. It will also involve the Calls for Tenders to acquire the equipment (smart devices, smart phones, smart hearing aids, etc.) needed for setting up the piloting environment. Deliverables: D8.1, D8.2, D8.3, D8.4

Task 8.2 – Pilot Setup, Equipment Procurement & End-user Recruitment – Italy-Portugal [M18-M34] (Lead: UMIL, Partners: CNR, LISPA, CSC, FCSR, NOVA, SRS): This task will implement Phase 2 of the Pilot, i.e. the recruitment of end-users, as described in Section 1.3.4.1.2, for the Italian-Portuguese Pilot. Moreover, it will involve procuring the needed equipment and setting up SMART BEAR in the Pilot environment of the involved local sites. Deliverables: D8.1, D8.2, D8.3, D8.4

Task 8.3 – Piloting, Privacy, Legal and Ethics - Monitoring & Support – Italy-Portugal [M19-M42] (Lead: UMIL, Partners: CNR, LISPA, CSC, 2B, NOVA, SRS): This task will implement Phase 3 of the Pilot, i.e. the actual Piloting phase, as described in Section 1.3.4.1.3, for the Italian-Portuguese Pilot, involving 1.000 end-users. A significant part of the effort in this task will be dedicated to supporting the end-users (technical and clinical support) and continuously monitoring the Pilot execution in terms of regulatory and ethics compliance. Deliverables: D8.1, D8.2, D8.3, D8.4

Task 8.4 – Pilot specific evaluation – Italy-Portugal [M23-M45] (Lead: FCSR, Partners: CNR, LISPA, UMIL, NOVA, SRS): This task will involve Phase 4 of the Pilot, i.e. the evaluation of the Italian-Portuguese pilot, as described in Section 1.3.4.1.4, via the methodology and KPIs defined in Task 12.1. Deliverables: D8.1, D8.2, D8.3, D8.4

Participation per Partner

Partner number and short name	WP8 effort
1 - CNR	10.00
5 - LISPA	25.00
8 - CSC	29.00
9 - FCSR	18.00
16 - UMIL	72.00
25 - 2B	2.00
26 - NOVA	36.00
27 - SRS	11.00
Total	203.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D8.1	Italian-Portuguese Pilot Report v1	9 - FCSR	Report	Public	26
D8.2	Italian-Portuguese Pilot Report v2	9 - FCSR	Report	Public	32
D8.3	Italian-Portuguese Pilot Report v3	9 - FCSR	Report	Public	39
D8.4	Italian-Portuguese Pilot Final Evaluation Report	9 - FCSR	Report	Public	45

Description of deliverables

Deliverables of WP8:

D8.1 : Italian-Portuguese Pilot Report v1 [26]
First evaluation report of the Italian-Portuguese SMART BEAR Pilot

D8.2 : Italian-Portuguese Pilot Report v2 [32]
Second evaluation report of the Italian-Portuguese SMART BEAR Pilot

D8.3 : Italian-Portuguese Pilot Report v3 [39]
Third evaluation report of the Italian-Portuguese SMART BEAR Pilot

D8.4 : Italian-Portuguese Pilot Final Evaluation Report [45]
Final evaluation report of the Italian-Portuguese SMART BEAR Pilot

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS4	MS4	14 - NKUA	26	Initial prototype demonstration and pilot validation. Means of verification: Release of D6.2, D7.1, D8.1, D9.1, D10.1 and D11.1.
MS6	MS6	14 - NKUA	32	Second prototype demonstration and pilot validation. Means of verification: Release of D6.4, D7.2, D8.2, D9.2, D10.2 and D11.2.

Work package number [9]	WP9	**Lead beneficiary** [10]	10 - CATEL
Work package title	Pilot 3 – France		
Start month	3	**End month**	45

Objectives

To carry out (i) the SMART pre-piloting (equipment procurement, pre-recruitment, screening), (ii) setup (plat-form setup, user recruitment), (iii) piloting (including monitoring and support) and (iv) evaluation activities, in the context of French pilot environment.

Description of work and role of partners

WP9 - Pilot 3 – France [Months: 3-45]
CATEL , SV, 2B
Task 9.1 – Equipment Procurement, End-user Pre-Recruitment & Screening – France [M03-M33] (Lead: CATEL, Partners: -): This task will implement Phase 1 of the Pilot, i.e. the pre-recruitment and screening of end-users, as described in Section 1.3.4.1.1, for the French Pilot. It will also involve the Calls for Tenders to acquire the equipment (smart devices, smart phones, smart hearing aids, etc.) needed for setting up the piloting environment. Deliverables: D9.1, D9.2, D9.3, D9.4

Task 9.2 – Pilot Setup, Equipment Procurement & End-user Recruitment – France [M18-M34] (Lead: CATEL, Partners: SV): This task will implement Phase 2 of the Pilot, i.e. the recruitment of end-users, as described in Section 1.3.4.1.2, for the French Pilot. Moreover, it will involve procuring the needed equipment and setting up SMART BEAR in the Pilot environment of the involved local sites. .Deliverables: D9.1, D9.2, D9.3, D9.4

Task 9.3 – Piloting, Privacy, Legal and Ethics - Monitoring & Support – France [M19-M42] (Lead: CATEL, Partners: SV, 2B): This task will implement Phase 3 of the Pilot, i.e. the actual Piloting phase, as described in Section 1.3.4.1.3, for the French Pilot, involving 1.000 end-users. A significant part of the effort in this task will be dedicated to supporting the end-users (technical and clinical support) and continuously monitoring the Pilot execution in terms of regulatory and ethics compliance. Deliverables: D9.1, D9.2, D9.3, D9.4

Task 9.4 – Pilot specific evaluation – France [M23-M45] (Lead: CATEL, Partners: SV): This task will involve Phase 4 of the Pilot, i.e. the evaluation of the French pilot, as described in Section 1.3.4.1.4, via the methodology and KPIs defined in Task 12.1. Deliverables: D9.1, D9.2, D9.3, D9.4

Participation per Partner

Partner number and short name	WP9 effort
10 - CATEL	112.00
21 - SV	22.00
25 - 2B	2.00
Total	136.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D9.1	French Pilot Report v1	10 - CATEL	Report	Public	26
D9.2	French Pilot Report v2	10 - CATEL	Report	Public	32

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D9.3	French Pilot Report v3	10 - CATEL	Report	Public	39
D9.4	French Pilot Final Evaluation Report	10 - CATEL	Report	Public	45

Description of deliverables

Deliverables of WP9:

D9.1 : French Pilot Report v1 [26]
First evaluation report of the French SMART BEAR Pilot

D9.2 : French Pilot Report v2 [32]
Second evaluation report of the French SMART BEAR Pilot

D9.3 : French Pilot Report v3 [39]
Third evaluation report of the French SMART BEAR Pilot

D9.4 : French Pilot Final Evaluation Report [45]
Final evaluation report of the French SMART BEAR Pilot

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS4	MS4	14 - NKUA	26	Initial prototype demonstration and pilot validation. Means of verification: Release of D6.2, D7.1, D8.1, D9.1, D10.1 and D11.1.
MS6	MS6	14 - NKUA	32	Second prototype demonstration and pilot validation. Means of verification: Release of D6.4, D7.2, D8.2, D9.2, D10.2 and D11.2.

Work package number [9]	WP10	**Lead beneficiary** [10]	11 - QUIRON
Work package title	Pilot 4 – Spain		
Start month	3	**End month**	45

Objectives

To carry out (i) the SMART pre-piloting (equipment procurement, pre-recruitment, screening), (ii) setup (platform setup, user recruitment), (iii) piloting (including monitoring and support) and (iv) evaluation activities, in the context of Spanish pilot environment.

Description of work and role of partners

WP10 - Pilot 4 – Spain [Months: 3-45]
QUIRON, UPV/EHU, INV, 2B
Task 10.1 – Equipment Procurement, End-user Pre-Recruitment & Screening – Spain [M03-M33] (Lead: QUIRON, Partners: -): This task will implement Phase 1 of the Pilot, i.e. the pre-recruitment and screening of end-users, as described in Section 1.3.4.1.1, for the Spanish Pilot. It will also involve the Calls for Tenders to acquire the equipment (smart devices, smart phones, smart hearing aids, etc.) needed for setting up the piloting environment. Deliverables: D10.1, D10.2, D10.3, D10.4.

Task 10.2 – Pilot Setup, Equipment Procurement & End-user Recruitment – Spain [M18-M34] (Lead: QUIRON, Partners: INV): This task will implement Phase 2 of the Pilot, i.e. the recruitment of end-users, as described in Section 1.3.4.1.2, for the Spanish Pilot. Moreover, it will involve procuring the needed equipment and setting up SMART BEAR in the Pilot environment of the involved local sites. Deliverables: D10.1, D10.2, D10.3, D10.4.

Task 10.3 – Piloting, Privacy, Legal and Ethics - Monitoring & Support – Spain [M19-M42] (Lead: QUIRON, Partners: EHU, INV, 2B): This task will implement Phase 3 of the Pilot, i.e. the actual Piloting phase, as described in Section 1.3.4.1.3, for the Spanish Pilot, involving 1.000 end-users. A significant part of the effort in this task will be dedicated to supporting the end-users (technical and clinical support) and continuously monitoring the Pilot execution in terms of regulatory and ethics compliance. Deliverables: D10.1, D10.2, D10.3, D10.4.

Task 10.4 – Pilot specific evaluation – Spain [M23-M45] (Lead: QUIRON, Partners: EHU): This task will involve Phase 4 of the Pilot, i.e. the evaluation of the Spanish pilot, as described in Section 1.3.4.1.4, via the methodology and KPIs defined in Task 12.1. Deliverables: D10.1, D10.2, D10.3, D10.4.

Participation per Partner

Partner number and short name	WP10 effort
11 - QUIRON	278.00
17 - UPV/EHU	6.00
23 - INV	22.00
25 - 2B	2.00
Total	308.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D10.1	Spanish Pilot Report v1	11 - QUIRON	Report	Public	26

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D10.2	Spanish Pilot Report v2	11 - QUIRON	Report	Public	32
D10.3	Spanish Pilot Report v3	11 - QUIRON	Report	Public	39
D10.4	Spanish Pilot Final Evaluation Report	11 - QUIRON	Report	Public	45

Description of deliverables

Deliverables of WP10:

D10.1 : Spanish Pilot Report v1 [26]
First evaluation report of the Spanish SMART BEAR Pilot

D10.2 : Spanish Pilot Report v2 [32]
Second evaluation report of the Spanish SMART BEAR Pilot

D10.3 : Spanish Pilot Report v3 [39]
Third evaluation report of the Spanish SMART BEAR Pilot

D10.4 : Spanish Pilot Final Evaluation Report [45]
Final evaluation report of the Spanish SMART BEAR Pilot

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS4	MS4	14 - NKUA	26	Initial prototype demonstration and pilot validation. Means of verification: Release of D6.2, D7.1, D8.1, D9.1, D10.1 and D11.1.
MS6	MS6	14 - NKUA	32	Second prototype demonstration and pilot validation. Means of verification: Release of D6.4, D7.2, D8.2, D9.2, D10.2 and D11.2.

Work package number [9]	WP11	**Lead beneficiary** [10]	12 - ANA
Work package title	Pilot 5 – Romania		
Start month	3	**End month**	45

Objectives

To carry out (i) the SMART pre-piloting (equipment procurement, pre-recruitment, screening), (ii) setup (platform setup, user recruitment), (iii) piloting (including monitoring and support) and (iv) evaluation activities, in the context of Romanian pilot environment.

Description of work and role of partners

WP11 - Pilot 5 – Romania [Months: 3-45]
ANA, ITSS, 2B
Task 11.1 – Equipment Procurement, End-user Pre-Recruitment & Screening – Romania [M03-M33] (Lead: ANA, Partners: -): This task will implement Phase 1 of the Pilot, i.e. the pre-recruitment and screening of end-users, as described in Section 1.3.4.1.1, for the Romanian Pilot. It will also involve the Calls for Tenders to acquire the equipment (smart devices, smart phones, smart hearing aids, etc.) needed for setting up the piloting environment. Deliverables: D11.1, D11.2, D11.3, D11.4.

Task 11.2 – Pilot Setup, Equipment Procurement & End-user Recruitment – Romania [M18-M34] (Lead: ANA, Partners: ITSS): This task will implement Phase 2 of the Pilot, i.e. the recruitment of end-users, as described in Section 1.3.4.1.2, for the Romanian Pilot. Moreover, it will involve procuring the needed equipment and setting up SMART BEAR in the Pilot environment of the involved local sites. Deliverables: D11.1, D11.2, D11.3, D11.4.

Task 11.3 – Piloting, Privacy, Legal and Ethics - Monitoring & Support – Romania [M19-M42] (Lead: ANA, Partners: ITSS, 2B): This task will implement Phase 3 of the Pilot, i.e. the actual Piloting phase, as described in Section 1.3.4.1.3, for the Romanian Pilot, involving 1.000 end-users. A significant part of the effort in this task will be dedicated to supporting the end-users (technical and clinical support) and continuously monitoring the Pilot execution in terms of regulatory and ethics compliance. Deliverables: D11.1, D11.2, D11.3, D11.4.

Task 11.4 – Pilot specific evaluation – Romania [M23-M45] (Lead: ANA, Partners: -): This task will involve Phase 4 of the Pilot, i.e. the evaluation of the Romanian pilot, as described in Section 1.3.4.1.4, via the methodology and KPIs defined in Task 12.1. Deliverables: D11.1, D11.2, D11.3, D11.4.

Participation per Partner

Partner number and short name	WP11 effort
12 - ANA	112.00
22 - ITSS	22.00
25 - 2B	2.00
Total	136.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D11.1	Romanian Pilot Report v1	12 - ANA	Report	Public	26

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D11.2	Romanian Pilot Report v2	12 - ANA	Report	Public	32
D11.3	Romanian Pilot Report v3	12 - ANA	Report	Public	39
D11.4	Romanian Pilot Final Evaluation Report	12 - ANA	Report	Public	45

Description of deliverables

Deliverables of WP11:

D11.1 : Romanian Pilot Report v1 [26]
First evaluation report of the Romanian SMART BEAR Pilot

D11.2 : Romanian Pilot Report v2 [32]
Second evaluation report of the Romanian SMART BEAR Pilot

D11.3 : Romanian Pilot Report v3 [39]
Third evaluation report of the Romanian SMART BEAR Pilot

D11.4 : Romanian Pilot Final Evaluation Report [45]
Final evaluation report of the Romanian SMART BEAR Pilot

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS4	MS4	14 - NKUA	26	Initial prototype demonstration and pilot validation. Means of verification: Release of D6.2, D7.1, D8.1, D9.1, D10.1 and D11.1.
MS6	MS6	14 - NKUA	32	Second prototype demonstration and pilot validation. Means of verification: Release of D6.4, D7.2, D8.2, D9.2, D10.2 and D11.2.

Work package number [9]	WP12	Lead beneficiary [10]	14 - NKUA
Work package title	Cross-Pilot Validation & Final Evaluation		
Start month	2	End month	48

Objectives

To lay the groundwork for the Pilots of the project (ethics application, equipment procurement, pilot protocol & evaluation methodology definition); to carry out the cross-pilot validation & evaluation activities, covering technical, clinical, and regulatory aspects; to assess the impact of the platform's extensive pilots in the context of EC's horizontal pilot activities.

Description of work and role of partners

WP12 - Cross-Pilot Validation & Final Evaluation [Months: 2-48]
NKUA, CNR, ATOS, PHILIPS, LISPA, ROP, MPF, CSC, CATEL , QUIRON, ANA, UOI, UMIL, UPV/EHU, CITY, ICCS, STS, ITSS, ATC, 2B, NOVA, SRS
Task 12.1 – Pilots Ethics Application, Protocol & Evaluation Methodology definition [M02-M26] (Lead: NKUA, Partners: PHILIPS, ROP, MPF, CSC, 2B): The task will involve the preparation of the documentation needed for obtaining ethics approval for the SMART BEAR pilots, submit the ethics approval applications to relevant authorities as required by the five pilot coordinators (ROP, UMIL, CATEL, QUIRON, ANA) and their relevant national regulatory frameworks, and oversee the progress of the relevant ethics approval process. Moreover, it will focus on the definition of the Piloting Protocol to be followed in all the Piloting activities, as well as the definition of criteria for the evaluation of the SMART BEAR solution, finalizing the targeted outcome measures for the different types of evaluation, extending and refining the KPIs identified in this proposal. Deliverables: D12.1, D12.2

Task 12.2 – Cross-Pilot Technical Validation & Final Evaluation [M23-M48] (Lead: CNR, Partners: PHILIPS, LISPA, UMIL, CITY, ICCS, STS, ITSS, ATC, NOVA): This task will carry out a cross-pilot analysis and an overall assessment of the SMART BEAR solution from a technical perspective, covering all pertinent evaluation KPIs identified in this proposal and the ones defined in Task 12.1 as well as the MAFEIP framework. The expansion of the SMART BEAR approach and implemented solutions to also cover additional smart consumer and medical devices, and ecosystems, thus expanding coverage to additional verticals (e.g. smart energy) and additional medical conditions (e.g., epilepsy), will be analysed. Deliverables: D12.3, D12.4, D12.5

Task 12.3 – Healthy, Independent ageing and Well-being Cross-Pilot Evaluation [M23-M48] (Lead: UMIL, Partners: CNR, PHILIPS, ROP, MPF, CSC, CATEL, QUIRON, ANA, NKUA, NOVA, SRS): The focus of this task will be on identifying issues and trends cross-cutting across the different pilots and their related intricacies and providing evaluation conclusions based on them. Special attention will be given to covering all different evaluation KPIs, including both those identified in this proposal and any additional that may have been identified whilst developing the evaluation framework in Task 12.1, as well as to qualitatively and quantitatively assess the gains in the medical attention and the health and well-being of the elderly from the adoption of the developed solution. The impact assessment will include socio-economic parameters following the approach detailed in Section 2.1.6. Deliverables: D12.3, D12.4, D12.5

Task 12.4 – Legal & Business Cross-Pilot Evaluation [M23-M48] (Lead: EHU, Partners: STS, 2B): This task will deal with the SMART BEAR evaluation from the legal & regulatory perspective. Moreover, it will consider business aspects (benefits, complications etc.), stemming from the deployment of the SMART BEAR solution. Deliverables: D12.3, D12.4, D12.5

Task 12.5 – Digital Platforms/Pilots Horizontal Activities Evaluation [M23-M48] (Lead: UOI, Partners: CNR, ATOS, STS, ITSS, ATC): This task will involve the evaluation of the SMART BEAR platform from the perspective of its compatibility, applicability and linking with EU-wide activities pertaining to horizontal pilots and digital platforms (e.g. CSA). Deliverables: D12.3, D12.4, D12.5

Participation per Partner

Partner number and short name	WP12 effort
1 - CNR	8.00

Partner number and short name	WP12 effort
2 - ATOS	1.00
ATOS CCSU	3.00
3 - PHILIPS	7.00
5 - LISPA	2.00
6 - ROP	3.00
7 - MPF	4.00
8 - CSC	4.00
10 - CATEL	4.00
11 - QUIRON	4.00
12 - ANA	2.00
14 - NKUA	12.00
15 - UOI	5.00
16 - UMIL	8.00
17 - UPV/EHU	6.00
18 - CITY	3.00
19 - ICCS	3.00
20 - STS	6.00
22 - ITSS	4.00
24 - ATC	6.00
25 - 2B	5.00
26 - NOVA	6.00
27 - SRS	1.00
Total	107.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D12.1	Ethics Application & Piloting Protocol & Evaluation Framework	14 - NKUA	Report	Public	6
D12.2	Evaluation Framework	14 - NKUA	Report	Public	26
D12.3	Cross-Pilot Evaluation Report v1	1 - CNR	Report	Public	28
D12.4	Cross-Pilot Evaluation Report v2	16 - UMIL	Report	Public	38
D12.5	Cross-Pilot Evaluation Report v3	15 - UOI	Report	Public	48

Description of deliverables

Deliverables of WP12:

D12.1 : Ethics Application & Piloting Protocol & Evaluation Framework [6]

This deliverable will include the Piloting protocol, together with the application submitted with all enclosures (such as information letters, recruitment advertisements, consent forms etc.) to the relevant Ethics Committees for approval.

D12.2 : Evaluation Framework [26]

This deliverable will define the refined set of KPIs, criteria and methodology to evaluate the SMART BEAR platform.

D12.3 : Cross-Pilot Evaluation Report v1 [28]

This deliverable will provide the cross-pilot evaluation report of the first version of the SMART BEAR integrated platform, extending the results of the individual pilot evaluation with cross-cutting issues, trends and effectiveness results, and covering technical, healthy and independent living, as well as legal, business and pilot horizontal activities aspects. All KPIs focusing on the establishment of baseline values will be satisfied (namely, KPI-28, KPI-29, KPI-30, KPI-31).

D12.4 : Cross-Pilot Evaluation Report v2 [38]

Update on D12.1 for the second version of the SMART BEAR integrated platform. All relevant KPIs will be evaluated, including the accuracy of the monitoring solution in terms of state identification with respect to each of the individual devices when that device is used in isolation (KPI-2), drop-out rates (KPI-3), comprehension of individual health status and condition (KPI-5), health delivery services cost (KPI-7), provision of evidence useful to at least 3 types of stakeholders (KPI-8), reduction of unnecessary interventions (KPI-10), speed-up of delivery of interventions (KPI-11), application acceptance (KPI-13), platform usability (KPI-23), usage percentage (KPI-24), recommendation rating (KPI-25), effectiveness of personalised care (KPI-26), and reduction of visits to healthcare providers (KPI-27).

D12.5 : Cross-Pilot Evaluation Report v3 [48]

Update on D12.3 for the final version of the SMART BEAR integrated platform. All relevant KPIs will be evaluated, reaching the target values (as defined in Table 1) in all areas, including the accuracy of the monitoring solution in terms of state identification with respect to each of the individual devices when that device is used in isolation (KPI-2), drop-out rates (KPI-3), comprehension of individual health status and condition (KPI-5), health delivery services cost (KPI-7), provision of evidence useful to at least 4 types of stakeholders (KPI-8), reduction of unnecessary interventions (KPI-10), speed-up of delivery of interventions (KPI-11), application acceptance (KPI-13), platform usability (KPI-23), usage percentage (KPI-24), recommendation rating (KPI-25), effectiveness of personalised care (KPI-26), and reduction of visits to healthcare providers (KPI-27).

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS5	MS5	1 - CNR	28	1st Cross-Pilot Evaluation. Means of verification: Release of D12.3.
MS8	MS8	16 - UMIL	38	2nd Cross-Pilot Evaluation. Means of verification: Release of D12.4.
MS9	MS9	15 - UOI	48	Cross-Pilot validation & Final Evaluation. Means of verification: Release of D12.5.

Work package number [9]	WP13	Lead beneficiary [10]	19 - ICCS
Work package title	Dissemination, Exploitation, Standardisation & Sustainability		
Start month	1	End month	48

Objectives

To raise awareness about the project concept, developments and findings to all key stakeholders; to develop the dissemination and communication strategy of the project, including social presence, participation in EU events, collaboration with other related projects; and implement it; to implement an interactive SMART BEAR user-friendly portal to inform the general public and relevant stakeholders about SMART BEAR; to develop the business model for SMART BEAR and strategies for incentivising/promoting project adoption by various stakeholders within the healthcare community; to enhance and demonstrate the sustainability and wider adoption of the platform through the definition of an Open Call for the SMART BEAR data valorisation model.

Description of work and role of partners

WP13 - Dissemination, Exploitation, Standardisation & Sustainability [Months: 1-48]
ICCS, CNR, ATOS, PHILIPS, IBM, LISPA, ROP, MPF, CSC, FCSR, CATEL , QUIRON, ANA, FORTH, NKUA, UOI, UMIL, UPV/EHU, CITY, STS, SV, ITSS, INV, ATC, 2B, NOVA, SRS
Task 13.1 – Communication & Dissemination activities [M1-M48] (Lead: ICCS, Partners: All): This task contains all the communication and dissemination activities for SMART BEAR. Details on the communication activities are described in Sect. 2.2.6 whereas details on dissemination activities in Sect. 2.2.2. Dissemination and communication activities will be planned and monitored through periodic plans and monitoring reports. These plans and reports will be produced at the half and the end of the project. In this task will also actively seek to collect feedback from attendees of our dissemination activities (e.g., seminars, workshops and conference presentation) and use them to assess the take of our results and the effectiveness of our dissemination strategy. Deliverables: D13.1, D13.2, D13.5

Task 13.2 – Impact creation, Exploitation & Standardisation activities [M03-M48] (Lead: FORTH, Partners: CNR, ATOS, PHILIPS, IBM, LISPA, ROP, MPF, CSC, CATEL, QUIRON, ANA, NKUA, UOI, EHU, CITY, ICCS, STS, SV, ITSS, ATC, NOVA, SRS): To facilitate the market sustainability and Business continuity of SMART BEAR, this task will (i) investigate the market prospects for the project's outputs in the short and long term (i.e., 1, 3 and 5 years after the project). This will be based on performing a rigorous, multi-stakeholder analysis on the total costs revealing the real costs of operating the platform on a day-to-day business. We will also develop a detailed business plan and marketing strategy to address the relevant KPIs identified in Task 12.1 and deliver a report on the exploitation activities carried out within the project's duration. This task will also identify and evaluate the SMAR BEAR's IPR production and potentials and prepare a plan for joint protection and exploitation of it after the end of the project. The plan will include the IPR overview and describe the planned post-project innovation activities. Moreover, the task will continuously investigate opportunities for SMART BEAR to contribute to existing medical, health and well-being services standards, as well as healthcare policies related to the elderly. Deliverables: D13.1, D13.2, D13.5

Task 13.3 – Data Valorisation Model & Open Call Requirements [M08-M28] (Lead: EHU, Partners: PHILIPS, ROP, MPF, CSC, CATEL, QUIRON, ANA, NKUA, UMIL, CITY, NOVA, SRS): This task will refine the baseline model for data valorisation to provide the final data sharing specification and data valorisation models that will form as the basis for the associated open call (see T1.5). This will enable new partners to leverage SMART BEAR, bringing new types of data and devices to the platform, and linking it to additional vertical domains and relevant piloting activities, towards the creation of a sustainable solution for the health and well-being of the elderly, with lasting impact. Deliverables: D13.4

Task 13.4 – Cross-cutting Pilot Activities & EC projects' Laisons [M03-M48] (Lead: UOI, Partners: CNR, PHILIPS, FCSR, FORTH): The main focus of this task will be to engage stakeholders involved with relevant horizontal piloting activities within pertinent EC initiatives, as well as create laisons with other projects with complementarities to SMART BEAR. Deliverables: D13.3, D13.6

Task 13.5 – Stakeholder Engagement – End-user & Healthcare Laisons [M03-M48] (Lead: ANA, Partners: ATOS, PHILIPS, LISPA, ROP, MPF, CSC, FCSR, CATEL, QUIRON, ANA, NKUA, NOVA): This task will focus on the engagement of end-users that could potentially adopt the SMART BEAR solution, as well as healthcare stakeholders and policymakers who can provide valuable feedback but also promote the wider adoption of the SMART BEAR approach. Deliverables: D13.3, D13.6

Participation per Partner

Partner number and short name	WP13 effort
1 - CNR	6.00
2 - ATOS	6.00
3 - PHILIPS	15.00
4 - IBM	5.00
5 - LISPA	6.00
6 - ROP	7.00
7 - MPF	13.00
8 - CSC	10.00
9 - FCSR	6.00
10 - CATEL	9.00
11 - QUIRON	9.00
12 - ANA	10.00
13 - FORTH	7.00
14 - NKUA	7.00
15 - UOI	8.00
16 - UMIL	4.00
17 - UPV/EHU	8.00
18 - CITY	6.00
19 - ICCS	5.00
20 - STS	4.00
21 - SV	4.00
22 - ITSS	4.00
23 - INV	2.00
24 - ATC	4.00
25 - 2B	2.00
26 - NOVA	7.00
27 - SRS	4.00
Total	178.00

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D13.1	Communication, Dissemination, Impact	13 - FORTH	Report	Public	4

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
	Creation, Exploitation & Standardisation plan				
D13.2	Interim Communication, Dissemination, Impact Creation, Exploitation & Standardisation Report	19 - ICCS	Report	Public	24
D13.3	Interim Stakeholder Engagement Report	12 - ANA	Report	Public	24
D13.4	Data Valorisation Model & Open Call Requirements	17 - UPV/EHU	Report	Public	28
D13.5	Final Communication, Dissemination, Impact Creation & Standardisation Report	19 - ICCS	Report	Public	48
D13.6	Final Stakeholder Engagement report	12 - ANA	Report	Public	48

Description of deliverables

Deliverables of WP13:

D13.1 : Communication, Dissemination, Impact Creation, Exploitation & Standardisation plan [4]

This document will describe a concrete plan for SMART BEAR dissemination, communication, Impact Creation, exploitation and standardization activities. It will provide estimations on the activities to be performed, like presentations, papers publications, articles in popular media, participation in standardization bodies etc. It will also provide the project's business plan.

D13.2 : Interim Communication, Dissemination, Impact Creation, Exploitation & Standardisation Report [24]

Report on dissemination, communication, impact creation, exploitation and Standardisation activities for the first half of the project. It will also include an assessment of the project's progress in terms of the relevant KPIs (i.e., KPI-32, KPI-33).

D13.3 : Interim Stakeholder Engagement Report [24]

Report including all the Stakeholder Engagement activities for the first half of the project. It will also include an assessment of the project's progress in terms of the relevant KPIs (i.e., KPI-34), reporting on at least on cluster-ing/ concentration activity, per the aforementioned KPI.

D13.4 : Data Valorisation Model & Open Call Requirements [28]

The specification of the SMART BEAR data valorisation model and the requirements for the relevant open call.

D13.5 : Final Communication, Dissemination, Impact Creation & Standardisation Report [48]

Final report on dissemination, communication, impact creation, exploitation & standardisation activities of the project. The project's satisfaction of pertinent KPIs (i.e., KPI-32, KPI-33) will be validated.

D13.6 : Final Stakeholder Engagement report [48]

Final Report on Stakeholder Engagement activities. The project's satisfaction of pertinent KPIs (i.e., KPI-34) will be validated.

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification

Work package number [9]	WP14	**Lead beneficiary** [10]	1 - CNR
Work package title	Ethics requirements		
Start month	1	**End month**	48

Objectives

The objective is to ensure compliance with the 'ethics requirements' set out in this work package.

Description of work and role of partners

WP14 - Ethics requirements [Months: 1-48]
CNR
This work package sets out the 'ethics requirements' that the project must comply with.

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D14.1	H - Requirement No. 1	1 - CNR	Ethics	Confidential, only for members of the consortium (including the Commission Services)	3
D14.2	H - Requirement No. 2	1 - CNR	Ethics	Confidential, only for members of the consortium (including the Commission Services)	5
D14.3	POPD - Requirement No. 3	1 - CNR	Ethics	Confidential, only for members of the consortium (including the Commission Services)	15

Description of deliverables

The 'ethics requirements' that the project must comply with are included as deliverables in this work package.

D14.1 : H - Requirement No. 1 [3]

2.6. The applicant must clarify whether vulnerable individuals/groups will be involved, and the measures and implementastion approach to protect them and minimise the risk of their stigmatisation must be submitted as deliverable in month 3.

D14.2 : H - Requirement No. 2 [5]

2.1. The procedures and criteria that will be used to identify/recruit research participants must be submitted as a deliverable. 2.2. The informed consent procedures that will be implemented for the participation of humans must be kept on file (to be specified in the grant agreement). Files kept for respective pilots are addressed by/under the pilot WP and deliverables accordingly. 2.3. Templates of the informed consent/assent forms and information sheets (in language and terms intelligible to the participants) must be kept on file (to be specified in the grant agreement). Files kept for respective pilots are addressed by/under the pilot WP and deliverables accordingly. 2.9. Copies of opinions/ approvals by ethics committees and/or competent authorities for the research with humans must be kept on file (to be specified in the grant agreement). Files kept for respective pilots are addressed by/under the pilot WP and deliverables accordingly.

D14.3 : POPD - Requirement No. 3 [15]

4.1 The beneficiary must check if special derogations pertaining to the rights of data subjects or the processing of genetic, biometric and/or health data have been established under the national legislation of the country where the research takes place and submit a declaration of compliance with respective national legal framework(s). 4.2 The host institution must confirm that it has appointed a Data Protection Officer (DPO) and the contact details of the DPO are made available to all data subjects involved in the research. For host institutions not required to appoint a DPO under the GDPR a detailed data protection policy for the project must be submitted as a deliverable. 4.4 The beneficiary must explain how all of the data they intend to process is relevant and limited to the purposes of the research project (in accordance with the 'data minimisation 'principle). This must be submitted as a deliverable. 4.6 A description of the technical and organisational measures that will be implemented to safeguard the rights and freedoms of the data subjects/research participants must be submitted as a deliverable. 4.7 A description of the security measures that will be implemented to prevent unauthorised access to personal data or the equipment used for processing must be submitted as a deliverable. 4.8 Description of the anonymysation/pseudonymisation techniques that will be implemented must be submitted as a deliverable.

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification

1.3.4. WT4 List of milestones

Milestone number[18]	Milestone title	WP number[9]	Lead beneficiary	Due Date (in months)[17]	Means of verification
MS1	MS1	WP2	24 - ATC	9	Final ANEMOS architecture. Means of verification: Release of D2.4.
MS2	MS2	WP3	15 - UOI	15	CRSA specification language. Means of verification: Release of D3.1.
MS3	MS3	WP3, WP4, WP5, WP6	3 - PHILIPS	22	Initial version of tools, models and integrated platform. Means of verification: Release of D3.2, D4.1, D5.1, D3.3, D4.2, D5.2, and D6.1.
MS4	MS4	WP10, WP11, WP6, WP7, WP8, WP9	14 - NKUA	26	Initial prototype demonstration and pilot validation. Means of verification: Release of D6.2, D7.1, D8.1, D9.1, D10.1 and D11.1.
MS5	MS5	WP12	1 - CNR	28	1st Cross-Pilot Evaluation. Means of verification: Release of D12.3.
MS6	MS6	WP10, WP11, WP6, WP7, WP8, WP9	14 - NKUA	32	Second prototype demonstration and pilot validation. Means of verification: Release of D6.4, D7.2, D8.2, D9.2, D10.2 and D11.2.
MS7	MS7	WP6	2 - ATOS	36	Final prototype delivery and demonstration. Means of verification: Release of D6.6, D7.3, D8.3, D9.3, D10.3 and D11.3.
MS8	MS8	WP12	16 - UMIL	38	2nd Cross-Pilot Evaluation. Means of verification: Release of D12.4.
MS9	MS9	WP12	15 - UOI	48	Cross-Pilot validation & Final Evaluation. Means of verification: Release of D12.5.

1.3.5. WT5 Critical Implementation risks and mitigation actions

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
1	Underperforming partner	WP1, WP10, WP11, WP12, WP13, WP14, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	All consortium partners are highly committed to the project and it is hardly to expect this situation. Manage grace periods initially and WP Leaders to improve the planning of activities for upcoming deliverable. If it occurs, the flexible project management structure and Consortium Agreement (see Sect. 3.2) allow a quick shift of resources to alternative project partners (see also below).
2	Partner leaving the project	WP1, WP10, WP11, WP12, WP13, WP14, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	This unlikely case would only temporarily disrupt the project, as the consortium features overlapping coverage in critical areas of expertise; the affected tasks can be allocated to another partner. Otherwise, the management structure allows quick inclusion of new partners.
3	Key-person left or is temporarily not available	WP1, WP10, WP11, WP12, WP13, WP14, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	Key consortium partners are involved with more than one experienced staff member (see Sect. 4), ensuring an immediate substitution. Furthermore, the consortium has technical excellence in related disciplines spread across partners, providing additional substitution possibilities.
4	Threat of Brexit for eligibility of UK partners	WP1, WP10, WP11, WP12, WP13, WP14, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	UKRO's (U.K Research Office, British H2020 NCP) information HM Treasury statement issued on 13 August 2016 confirms: "Where UK organisations bid directly to the European Commission on a competitive basis for EU funding projects while we are still a member of the EU, for example universities participating in Horizon 2020, the Treasury will underwrite the payments of such awards, even when specific projects continue beyond the UK's departure from the EU".
5	Needed partners' resources are underestimated	WP1, WP10, WP11, WP12, WP13, WP14, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	In this case, the project management bodies will analyse the following possibilities to ensure that planned work can be completed: (i) re-arranging resources among the partners as needed, (ii) committing further internal resources of organizations in project activities (if possible), and (iii) re-planning work on the activities in accordance with previous measures.
6	Project schedule is partly not appropriate	WP1, WP10, WP11, WP12, WP13, WP14, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	The project management will continuously monitor performed work vs. project plan (see WP1 and Sect. 3.2) and are entitled to perform corrective actions – change of the project plan – if necessary, which also apply for this case (see also below). In crucial cases, the PM will work on the plan adaptation in close cooperation with EC.
7	Project milestones or deliverables are delayed	WP1, WP10, WP11, WP12, WP13, WP14, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	In the scope of project management monitoring activities (see Sect. 3.2), detailed analysis will be done on both global project and lower (WP/ Task) project implementation levels. Thus, it

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
			will be ensured that such cases are recognized in early stages, ensuring timely and effective implementation of necessary corrections in the work plan.
8	Low technical quality of deliverables	WP1, WP10, WP11, WP12, WP13, WP14, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	Addressed through regular quality review and peer reviews for each deliverable (see Sect. 3.2.7), also following the Quality Management Plan defined at M4 (see D1.2).
9	Agreement among partners is difficult to achieve	WP1, WP10, WP11, WP12, WP13, WP14, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	Collaboration spirit in the consortium targets achieving consensus among partners on the open issues and the project management bodies will work in this direction. However, to avoid long consensus making processes, which might affect the project plan, the related management procedures for decision making and conflict resolution (Sect. 3.2.9) will be timely applied.
10	Not satisfactory interaction among WP's and tasks	WP1, WP10, WP11, WP12, WP13, WP14, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	The regular synchronization of work among WP's (as well as among tasks within WP's) will be performed in the scope of project management activities (Sect. 3.2), so that these cases should not occur or should be timely recognized allowing implementation of corrective actions without significant impact on the project plan. If the problems continue, the PM together with STPM and WP leaders will analyse problems in interactions and propose additional procedures for improvement of the interactions.
11	Necessary coordination level is not achieved	WP1, WP10, WP11, WP12, WP13, WP14, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	Similar as it will be done for monitoring of the technical project activities, including analysis of work done and implementation of the corrective actions, the project coordination and management will be observed as well. Thus, if necessary the responsible management bodies will propose the corrective actions improving overall project coordination. If needed, management of the Coordinator organization will be involved to solve the problems.

1.3.6. WT6 Summary of project effort in person-months

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	WP10	WP11	WP12	WP13	WP14	Total Person/ Months per Participant
1 - CNR	23	4	6	0	0	0	0	10	0	0	0	8	6	✓	57
2 - ATOS	1	8	0	16	0	32	0	0	0	0	0	1	6		64
· ATOS CCSU	0	0	0	0	0	2	0	0	0	0	0	3	0		5
· ATOS IT	0	0	0	2	0	3	0	0	0	0	0	0	0		5
3 - PHILIPS	1	6	12	44	0	0	0	0	0	0	0	7	15		85
4 - IBM	1	0	0	12	22	0	0	0	0	0	0	0	5		40
5 - LISPA	6	4	7	0	0	10	0	25	0	0	0	2	6		60
6 - ROP	1	3	0	2	0	0	32	0	0	0	0	3	7		48
7 - MPF	1	4	0	3	0	0	68	0	0	0	0	4	13		93
8 - CSC	1	3	0	3	0	0	0	29	0	0	0	4	10		50
9 - FCSR	1	2	3	3	0	0	0	18	0	0	0	0	6		33
· OSR	0	0	0	0	0	0	0	0	0	0	0	0	0		0
10 - CATEL	1	3	0	3	0	0	0	0	112	0	0	4	9		132
11 - QUIRON	1	3	0	3	0	0	0	0	0	278	0	4	9		298
· QS IDCSVISA	0	0	0	0	0	0	0	0	0	0	0	0	0		0
· QS IDCSVSA	0	0	0	0	0	0	0	0	0	0	0	0	0		0
· QS IDCSMSA	0	0	0	0	0	0	0	0	0	0	0	0	0		0
· QS PGSA	0	0	0	0	0	0	0	0	0	0	0	0	0		0
· QS IPSTSA	0	0	0	0	0	0	0	0	0	0	0	0	0		0
· QS IIISL	0	0	0	0	0	0	0	0	0	0	0	0	0		0
· QS USPMSL	0	0	0	0	0	0	0	0	0	0	0	0	0		0
· QS USPIDSA	0	0	0	0	0	0	0	0	0	0	0	0	0		0

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	WP10	WP11	WP12	WP13	WP14	Total Person/ Months per Participant
· QS CSSL	0	0	0	0	0	0	0	0	0	0	0	0	0		0
· QS ISBSL	0	0	0	0	0	0	0	0	0	0	0	0	0		0
· QS TRIANA	0	0	0	0	0	0	0	0	0	0	0	0	0		0
12 - ANA	1	4	0	3	0	0	0	0	0	0	112	2	10		132
13 - FORTH	1	2	3	0	15	0	0	0	0	0	0	0	7		28
14 - NKUA	6	2	6	8	0	0	15	0	0	0	0	12	7		56
15 - UOI	1	0	22	8	0	0	0	0	0	0	0	5	8		44
16 - UMIL	1	6	17	22	0	14	0	72	0	0	0	8	4		144
17 - UPV/EHU	1	0	0	0	0	0	0	0	0	6	0	6	8		21
18 - CITY	1	6	0	18	12	4	0	0	0	0	0	3	6		50
19 - ICCS	1	4	0	40	0	11	0	0	0	0	0	3	5		64
20 - STS	6	4	3	0	32	8	0	0	0	0	0	6	4		63
21 - SV	1	2	5	0	4	5	0	0	22	0	0	0	4		43
22 - ITSS	1	4	11	14	4	5	0	0	0	0	22	4	4		69
23 - INV	1	2	5	0	4	5	0	0	0	22	0	0	2		41
24 - ATC	1	6	22	6	5	14	15	0	0	0	0	6	4		79
25 - 2B	2	0	0	0	0	0	2	2	2	2	2	5	2		19
26 - NOVA	1	3	2	2	0	3	0	36	0	0	0	6	7		60
27 - SRS	1	2	0	0	0	0	0	11	0	0	0	1	4		19
Total Person/Months	65	87	124	212	98	116	132	203	136	308	136	107	178		1902

1.3.7. WT7 Tentative schedule of project reviews

Review number [19]	Tentative timing	Planned venue of review	Comments, if any
RV1	6	Luxembourg	
RV2	18	Luxembourg/Italy-Portugal	possibly at pilot site for demonstrations
RV3	30	Luxembourg/Greece-Romania	possibly at pilot site for demonstrations
RV4	42	Luxembourg/Spain-France	possibly at pilot site for demonstrations
RV5	48	Luxembourg	

1. Project number

The project number has been assigned by the Commission as the unique identifier for your project. It cannot be changed. The project number **should appear on each page of the grant agreement preparation documents (part A and part B)** to prevent errors during its handling.

2. Project acronym

Use the project acronym as given in the submitted proposal. It can generally not be changed. The same acronym **should appear on each page of the grant agreement preparation documents (part A and part B)** to prevent errors during its handling.

3. Project title

Use the title (preferably no longer than 200 characters) as indicated in the submitted proposal. Minor corrections are possible if agreed during the preparation of the grant agreement.

4. Starting date

Unless a specific (fixed) starting date is duly justified and agreed upon during the preparation of the Grant Agreement, the project will start on the first day of the month following the entry into force of the Grant Agreement (NB : entry into force = signature by the Commission). Please note that if a fixed starting date is used, you will be required to provide a written justification.

5. Duration

Insert the duration of the project in full months.

6. Call (part) identifier

The Call (part) identifier is the reference number given in the call or part of the call you were addressing, as indicated in the publication of the call in the Official Journal of the European Union. You have to use the identifier given by the Commission in the letter inviting to prepare the grant agreement.

7. Abstract

8. Project Entry Month

The month at which the participant joined the consortium, month 1 marking the start date of the project, and all other start dates being relative to this start date.

9. Work Package number

Work package number: WP1, WP2, WP3, ..., WPn

10. Lead beneficiary

This must be one of the beneficiaries in the grant (not a third party) - Number of the beneficiary leading the work in this work package

11. Person-months per work package

The total number of person-months allocated to each work package.

12. Start month

Relative start date for the work in the specific work packages, month 1 marking the start date of the project, and all other start dates being relative to this start date.

13. End month

Relative end date, month 1 marking the start date of the project, and all end dates being relative to this start date.

14. Deliverable number

Deliverable numbers: D1 - Dn

15. Type

Please indicate the type of the deliverable using one of the following codes:

R	Document, report
DEM	Demonstrator, pilot, prototype
DEC	Websites, patent fillings, videos, etc.
OTHER	
ETHICS	Ethics requirement
ORDP	Open Research Data Pilot
DATA	data sets, microdata, etc.

16. Dissemination level

Please indicate the dissemination level using one of the following codes:

PU	Public
CO	Confidential, only for members of the consortium (including the Commission Services)
EU-RES	Classified Information: RESTREINT UE (Commission Decision 2005/444/EC)
EU-CON	Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC)
EU-SEC	Classified Information: SECRET UE (Commission Decision 2005/444/EC)

17. Delivery date for Deliverable

Month in which the deliverables will be available, month 1 marking the start date of the project, and all delivery dates being relative to this start date.

18. Milestone number

Milestone number:MS1, MS2, ..., MSn

19. Review number

Review number: RV1, RV2, ..., RVn

20. Installation Number

Number progressively the installations of a same infrastructure. An installation is a part of an infrastructure that could be used independently from the rest.

21. Installation country

Code of the country where the installation is located or IO if the access provider (the beneficiary or linked third party) is an international organization, an ERIC or a similar legal entity.

22. Type of access

VA	if virtual access,
TA-uc	if trans-national access with access costs declared on the basis of unit cost,
TA-ac	if trans-national access with access costs declared as actual costs, and
TA-cb	if trans-national access with access costs declared as a combination of actual costs and costs on the basis of unit cost.

23. Access costs

Cost of the access provided under the project. For virtual access fill only the second column. For trans-national access fill one of the two columns or both according to the way access costs are declared. Trans-national access costs on the basis of unit cost will result from the unit cost by the quantity of access to be provided.

History of changes

#	Section	Description	Date
		PART A	
1	1.3.3	Fixed cross-reference in T7.1 to the pilot phase 1 description (1.3.4.1.1)	29/03/2019
2	1.3.3	Fixed cross-reference in T8.1 to the pilot phase 1 description (1.3.4.1.1)	29/03/2019
3	1.3.3	Fixed cross-reference in T9.1 to the pilot phase 1 description (1.3.4.1.1)	29/03/2019
4	1.3.3	Fixed cross-reference in T10.1 to the pilot phase 1 description (1.3.4.1.1)	29/03/2019
5	1.3.3	Fixed cross-reference in T11.1 to the pilot phase 1 description (1.3.4.1.1)	29/03/2019
6	1.3.3	Fixed cross-reference in T7.2 to the pilot phase 2 description (1.3.4.1.2)	29/03/2019
7	1.3.3	Fixed cross-reference in T8.2 to the pilot phase 2 description (1.3.4.1.2)	29/03/2019
8	1.3.3	Fixed cross-reference in T9.2 to the pilot phase 2 description (1.3.4.1.2)	29/03/2019
9	1.3.3	Fixed cross-reference in T10.2 to the pilot phase 2 description (1.3.4.1.2)	29/03/2019
10	1.3.3	Fixed cross-reference in T11.2 to the pilot phase 2 description (1.3.4.1.2)	29/03/2019
11	1.3.3	Fixed cross-reference in T7.3 to the pilot phase 3 description (1.3.4.1.3)	29/03/2019
12	1.3.3	Fixed cross-reference in T8.3 to the pilot phase 3 description (1.3.4.1.3)	29/03/2019
13	1.3.3	Fixed cross-reference in T9.3 to the pilot phase 3 description (1.3.4.1.3)	29/03/2019
14	1.3.3	Fixed cross-reference in T10.3 to the pilot phase 3 description (1.3.4.1.3)	29/03/2019
15	1.3.3	Fixed cross-reference in T11.3 to the pilot phase 3 description (1.3.4.1.3)	29/03/2019
16	1.3.3	Fixed cross-reference in T7.4 to the pilot phase 4 description (1.3.4.1.4)	29/03/2019
17	1.3.3	Fixed cross-reference in T8.4 to the pilot phase 4 description (1.3.4.1.4)	29/03/2019
18	1.3.3	Fixed cross-reference in T9.4 to the pilot phase 4 description (1.3.4.1.4)	29/03/2019
19	1.3.3	Fixed cross-reference in T10.4 to the pilot phase 4 description (1.3.4.1.4)	29/03/2019
20	1.3.3	Fixed cross-reference in T11.4 to the pilot phase 4 description (1.3.4.1.4)	29/03/2019
21	1.3.4	ESR - Updated project Milestone table.	29/03/2019
22	1.3.3	ESR - Removed redundant deliverables for WP1 (periodic reports) and updated their references to task updates accordingly	29/03/2019
23	1.3.3	ESR - Added more details description for WP3 deliverables.	29/03/2019
24	1.3.3	ESR - Added more details description for WP4 deliverables.	29/03/2019
25	1.3.3	ESR - Added more details description for WP5 deliverables.	29/03/2019
26	1.3.3	EthSR 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8 – Accounted in T14.3, with results in deliverable D14.3.	02/04/2019
27	1.3.3	EthSR 2.6 – Accounted in T14.3, with results in deliverable D14.3	02/04/2019
28	1.3.3	EthSR 2.1 – Accounted in T14.2, with results in deliverable D14.2	01/04/2019
29	1.3.3	Updated deliverables' descriptions to show their relation with the KPIs of Table 1, and their incremental evaluation throughout the deliverables' iterations, per the POs request.	22/04/2019
30	1.2, 1.3	The partner MUT (Spain) is replaced with QUIRON (Spain), NOVA and SRS (Portugal). The grant amount remains unaffected. The total cost/effort of the project increases. QUIRON replaces MUT in the Spanish pilot. NOVA and SRS are	22/05/2019

		included with CNR into the Italian Pilot, which becomes Italian-Portuguese (+100 users).	
PART B			
31	1.3.4.1	Added missing heading for Phase 3 of Pilots	28/03/2019
32	3.4	Inserted Table 15: Equipment Budget calculation for the pilots	29/03/2019
33	3.4	Added references to Table 15 for pilot equipment budget justification for (ROP)	29/03/2019
34	3.4	Table 14: Corrected justification for CSC (was mentioned Greece but it is the Italian-Portuguese Pilot)	29/03/2019
35	3.4	Table 14: UMIL corrected cost justification (91200 for visits to 700 persons) and other goods and services is for audit. (these changes are typos, they do not affect the project budget)	29/03/2019
36	4.2.2	Added details about the project tasks performed by the linked third parties of the partner ATOS Spain S.A. (ATOS)	01/04/2019
37	4.2.8	Added the Ospedale San Raffaele (OSR), PIC number 953176030, as third party of Fondazione Centro San Raffaele (FCSR).	01/04/2019
38	5.1.10	EthSR 2.8 - Added the Smart Bear Incidental Findings Policy	02/04/2019
39	5.1.3	EthSR 2.2 - The informed consent procedures that will be implemented for the participation of humans will be kept on file.	02/04/2019
40	5.1.3	EthSR 2.3 - All the informed consent/assent forms that will be implemented for the participation of humans, together with the information sheets, will be written in language and terms intelligible to participants and will be kept on file.	02/04/2019
41	5.1.5	EthSR 2.9 – All ethics approvals and/or opinions/approvals by competent authorities for the research with humans will be kept on file.	02/04/2019
42	4.1.13	Updated FORTH's profile (key personnel)	18/04/2019
43	1.1.2	Updated KPI-19 and KPI-21 of Table 1 to point to correct deliverable (D6.6)	22/04/2019
44	1.1, 1.2, 1.3	The five pilots now involves 5100 users over six countries (+100 cases in Portugal).	22/05/2019
45	1.3.4.3.4	Pilot 4 – Spain, is carried out across all the country, not only on the Basque country	24/05/2019
46	2.2.4, 3.3, 4.1	Added NOVA and SRS, replaced MUT with QUIRON	24/05/2019
47	3.4	Updated effort and costs due to the new partners QUIRON, MUT and SRS. Updated the CNR travel budget. The project grant amount remains unaffected.	24/05/2019
48	4.2	Added details of the linked third parties of ATOS, QUIRON and FCSR, contributions in kind for UMIL	24/05/2019
49	3.4	Added section 3.4.3 with the description of the Open Call, update of tables 13 and 14 in CNR other direct costs	08/07/2019

Table of contents

Prevalent Health Threats and Factors Deteriorating the Quality of Life of the Elderly

- Hearing loss, cardio vascular diseases, cognitive impairments, balance disorders and mental health conditions are amongst the ten most prevalent health challenges, which people over 65 – a constantly increasing age sub-group of EU citizens – experience [9].
- These conditions, along with the prevalence of frailty in this age group, lead to a deteriorated quality of life (e.g., inactive life style, isolation, loneliness) and life threats for the individuals (e.g., physical injury, death, self-harm)

Cost

The management of the above conditions by healthcare systems is characterized by high and rising costs as well as gaps in quality, safety, equity, and access.

- The annual cost of managing Hearing Loss in the European Union is €213bn [1]
- The total economic cost of dementia worldwide increased from US$279 bn in 2000 to $948 bn in 2016, with an annual growth rate of 15.94% [2]
- The total cost of cognitive disorders in Europe in was 240bn [3]
- Estimated cost of falls in Europe is 25bn Euro annually and fall-related expenditures exceeding 45 billion euros by the year 2050 [4]

Digital tools hold promise for many health benefits that can enhance the independent living and well-being of the elderly. Yet, their use is often perceived to have technological and privacy risks.

What SMART BEAR will do

SMART BEAR will deliver a solution offering:

- ✓ Continuous and objective monitoring and interventions for 21st century precise and personalised medicine towards optimising disease and associated risks' management
- ✓ Measurable improvements to the Quality of Life of the elderly and their ability to live independently

The *SMART BEAR* solution will

- ✓ Integrate off-the-shelf smart consumer and medical devices to provide a Connected Health environment,
- ✓ Provide an affordable, user-friendly, and accountably secure and privacy-preserving service to the elderly, and
- ✓ Increase the efficiency of healthcare delivery and reduce resource waste

1 Excellence

1.1 Objectives

1.1.1 Background and motivation

Prevalent medical conditions affecting the independent and healthy living of the elderly.

The European population growth is slowing down, while population ageing accelerates [5]. 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** [6]. 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** [7]. 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 DP) for pensions, 8.3% of GDP for health care and up to 3.4% of GDP for long-term care [8].

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 [9] are the following:

Hearing Loss (HL) is one of the most prevalent chronic conditions and the third most common health condition affecting older adults after heart disease and arthritis, and currently the fifth leading cause of years lived with disability worldwide [10][11]. Approximately one in three people between the ages of 65 and 74 has hearing loss, and nearly half of those older than 75 has difficulty hearing. Hearing loss increases the risk of cognitive decline, mental illness, and depression, and leads to social isolation.

Cardio Vascular Diseases (CVDs; namely hypertension, ischemic heart disease, heart failure) are the number one cause of death globally; an estimated 17.9 million people died from CVDs in 2016, representing 31% all global deaths, out of which 85% were due to ischemic heart disease and stroke and this number is expected to increase to

approximately 23.6 million by 2030 [12]. According to the European Society of Cardiology (ESC), CVDs have a significant economic impact estimated to cost to the EU economy €210 billion a year. The diseases affect many levels: physical, social, and emotional, especially in elder adults.

Cognitive Impairments (CI) affecting the ability of people to think, learn and remember are also prevalent amongst the elderly. Approximately 47.5 million people worldwide have dementia (one of the most common cognitive health issues faced by the elderly) and this number is forecasted to nearly triple by 2050. CI is particularly prevalent in heart failure (HF) and deficits of varying severity may appear in several cognitive domains, e.g., memory, attention, executive function and psychomotor speed. People with HF have a more than four-fold risk of cognitive deficits compared to people without HF and approx. 25% of patients may have moderate-to-severe CI [13].

Mental Health issues (MH) is profoundly influenced by experiences in later life and has an impact on physical health and vice versa. Social isolation, lack of mental stimulation, and physical activity exacerbate risks of poor mental health and cognitive impairment. Older adults with physical health conditions such as heart disease have higher rates of depression than those who are healthy. Additionally, untreated depression in an older person with heart disease can negatively affect its outcome. Depression, affecting 7% of the world's older population, has also been shown to increase the risk of converting Mild Cognitive Impairment (MCI) to dementia. Anxiety disorders affect 3.8% of the older population, substance use problems affect almost 1%, and around a quarter of deaths from self-harm are among people aged 60 or above.

Balance Disorders (BD) seen as a global epidemic by the World Health Organization, caused by the age-related progressive loss of functioning of sensory information and inability to control body movements. Balance disorders lead frequently to falls, physical injury and death (one elderly person dies from falling every 29 minutes [14].

In tandem with the above, the prevalence of **Frailty** in the 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 [15]. Frailty and comorbidity are clinical manifestations of 2 distinct aging-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 [16]. Wong et al [17] recently reported that among community dwelling seniors who are frail 82% have comorbidities, 29% have disability in at least one activity of daily living (ADL), and 93% have disability in at least one instrumental activity of daily living (IADL). Similar overlap between frailty, comorbidity, and disability has been reported among Cardiovascular Health Study participants (Figure 1) [18].

Preventing, slowing the development of, or dealing effectively with effects of the above health impairments can have a significant improvement on the quality of life of the elderly and bring significant savings in the cost of healthcare services in modern society. Smart technology solutions enabling the monitoring of the elderly and immediate intervention upon the above conditions can improve prevention and more effectively manage the above conditions, leading to more independent and healthy living of the elderly.

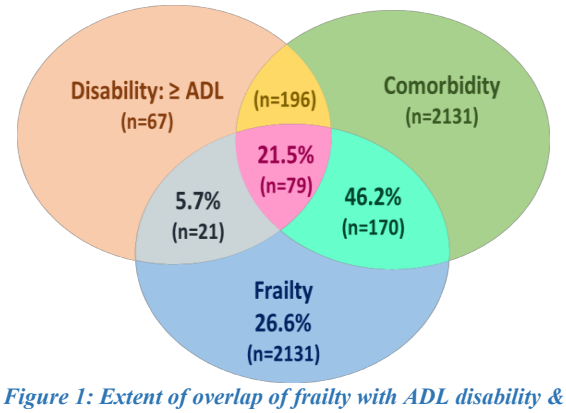

Figure 1: Extent of overlap of frailty with ADL disability & comorbidity (≥2 diseases.

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 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 the 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.

Challenges and barriers to large-scale deployment of technology enabled care: In spite of advances in Smart Homes and Ambient Assisted Living (AAL) technologies, the realisation of the vision of an integrated fully functional smart home providing technology enabled care (TEC) for the elderly faces still technological and societal challenges that pose barriers for large-scale deployment. These challenges arise due to: (1) budget constraints and

non-availability of low-cost technology solutions affecting the overall project sustainability; (2) the need to provide modular, interoperable and expandable solution that would enable the incorporation of new and upcoming devices and sensors produced by different manufacturers and avoid vendor lock-in; (3) the ability to timely communicate the vast amounts of data generated by the different types of sensors, medical devices and actuators; (4) the ability of the platforms to provide personalised and adaptive interventions, which typically require the gathering of relevant data and machine learning capabilities, (5) the ability to ensure the level of user trust in health apps and platforms, preserve key security and privacy conditions, as well as data protection to enable the acceptability of the technology by both the elderly, care takers and the providers of health care services; (6) the ability to support co-creation to enhance uptake as many solutions are derived by technologists working independently from actual users; (7) concerns from Healthcare professionals (HCP's) on the evidence on outcomes and economic benefits.

1.1.2 Aim and Vision

SMART-BEAR will provide an intelligent and personalised digital solution for sustaining and extending healthy and independent living by:

Implementing an **affordable, accountably secure and privacy-preserving innovative platform** with off-the-shelf smart and medical devices, **at TRL9,** to support the healthy and independent living of elderly people with five prevalent health-related conditions; **Hearing Loss, Cardio Vascular Diseases, Cognitive Impairments, Mental Health Issues and Balance Disorders,** as well as **Frailty.** This will be achieved through intelligent, evidenced-based interventions on lifestyle, medically-significant risk factors, and chronic disease management, enabled by the utilisation of continuous and objective **medical and environment sensing, assistive technologies and big data analytics**.

The *SMART BEAR* platform will be tested and validated through **five large scale pilots**, spanning **six different countries** and **5100 individuals**. The pilots will enable the evaluation of the platform in the context of healthcare service delivery by private and public providers at regional, state and EU level, and demonstrate its **efficacy, extensibility, sustainability, and cost effectiveness** for the individual and the healthcare system.

To achieve the above, *SMART-BEAR* will build on the platform developed by the H2020 project EVOTION to support evidence based public health policies formation and monitoring (h2020evotion.eu), which supports: (a) the continuous collection of medical, physiological and lifestyle data from heterogeneous resources (hospitals, biosensors, advanced hearing aids and mobile phones), and (b) the analysis of these data, driven by high level big data analytics and decision models to generate evidence useful for making public health policy level interventions [19][20][21]. The EVOTION platform is in 5 hospitals in Greece and the UK, collecting data from 1000+ hearing aid users.

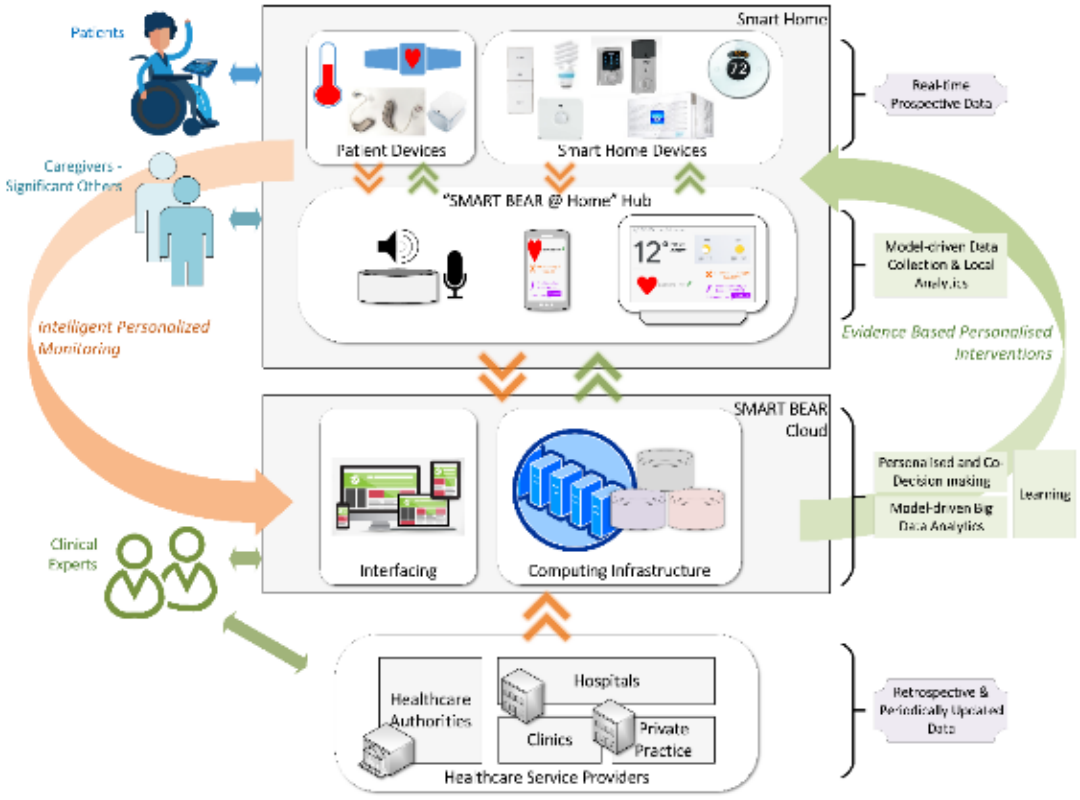

Figure 2. The SMART BEAR Concept

SMART BEAR will extend the EVOTION platform through: (1) integration with IoT enablers and platforms (e.g. FI-

WARE, Copernicus, consumer smart ecosystems), *SMART BEAR* will extend the connectivity of the EVOTION platform to support new medical devices, wearables, smart home/IoT sensors and actuators, and smart environment infrastructures; (2) development of new high level data analytics and decision models to support the intelligent and personalised interventions required for enhancing the healthy and independent living of the elderly; (3) integration of the EVOTION platform with a continuous security and privacy assurance platform to provide the continuous auditability and transparency needed for ensuring the *SMART BEAR* platform's trustworthiness by its end users, and; (4) testing and validation of the above at a much greater scale, involving 5100 participants spanning 6 countries. In developing the above extensions, special consideration will be given to creating an extensible and sustainable platform, open for wider adoption in the connected health ecosystem.

1.1.3 Specific Objectives

To achieve its overall aim, *SMART BEAR* will pursue the following objectives:

Objective 1: Continuous participant monitoring, environment sensing, data collection & interoperability.

Description: This objective concerns the identification, deployment and integration of off-the-shelf smart consumer and medical devices enabling the continuous monitoring of parameters pertinent to the health and well-being of the elderly. The raw data needed for *SMART-BEAR* will be collected through functional monitoring (measurement of general activities, motion, resting, sleeping, meal and medication intake), physiological monitoring (heart rate, respiration, blood pressure, hearing aid responsiveness), behavioural monitoring (fatigue, discomfort, stress), medical device usage (e.g., hearing aid usage) and compliance, as well as social interaction monitoring (e.g., number of phone calls, time spent in social media, sound processing to infer social interactions, etc.) of the elderly. To collect these data, *SMART-BEAR* will use assistive medical devices (smart hearing aids and blood pressure meters); wearable body sensors (smart watches with integrated PPG-based tracking), virtual assistants for cognitive and balance training; smart home sensors and actuators (movement, light, humidity sensors, smart thermostats and lighting), and mobile devices (mainly smartphones, but also smart TVs/tablets if already present) along with their embedded sensors (GPS, accelerometer). The device integration will be done so as to ensure the platform is interoperable with existing smart home platforms (in particular the Open Connectivity Foundation home platform and FI-WARE), smart city infrastructures, and the Copernicus European Union Earth Observation Programme. Furthermore, the *SMART-BEAR* platform will offer open APIs and data representations aligned with existing interoperability standards (e.g., HL7), defining a baseline for data valorisation and sharing purposes. [**KPIs: KPI-1** to **KPI-3** and **KPI-19** in Table 1].

Objective 2: Data analytics, decision making for intelligent and personalised interventions enhancing the well-being and independent living of participants.

Description: *SMART-BEAR* will offer: (a) **basic analytics** to infer **higher level monitoring parameters** and the **state of the elderly** from device/sensor raw data; (b) **advanced data analytics** to generate the **evidence** required for making decisions about personalised interventions from the monitoring parameter values obtained in (a); and (c) **decision support capabilities** that will enable the identification and delivery of **personalised, intelligent interventions** to support the healthy and independent living of the elderly in line with existing medical knowledge.

The **basic analytics** capabilities under (a) will help infer basic profiles of the elderly participants (their functional, physiological and behavioural state, their social interactions, cognitive, sensory, and balance profiles), and safety and risk-related parameters (e.g., strip and fall reduction, mental health and other hazards detection).

The **advanced data analytics** will correlate and detect patterns in the monitoring and state data that indicate the need for interventions to support the healthy and independent living of the participants; creating knowledge and an observational evidence base that can be leveraged to offer personalized health care and medicine in clinical practice, and evaluating the impact of health policies and national health services. [**KPIs: KPI-4** to **KPI-8** in Table 1].

The final decision on whether to make an intervention, will be made by the SMART BEAR **decision support system** (DSS), which will harness the evidence generated by analytics. A major challenge in implementing it will be to provide meaningful and highly personalized guidance to support individual users' decision-making processes and deliver appropriate intelligent interventions considering the social and well-being needs and potential health risks of the elderly. Furthermore, the DSS will need to support interventions of different modalities (e.g., automated, vetted by clinicians, vetted by the elderly). A key element of decision making that will be developed in *SMART-BEAR* will be the ability to **extract knowledge** from the models built from the mining of monitoring and state data (e.g., neural networks) that can offer the needed **explainability** of why the evidence can support different decisions/interventions.

Interventions delivery will be achieved by developing new or customizing existing **end-user applications**, covering: (1) screening potential participants, (2) cognitive games, (3) balance training, (4) hearing aid management, (5) mental health profiling and monitoring, (6) CVD risk factor assessment and management, (7) social and physical activity enhancement, and (8) nutrition monitoring. Moreover, the platform will extend and integrate existing tools and platforms available from the consortium: the EVOTION platform (connectivity with hearing aids and model driven data

analytics), and HOLOBALANCE (virtual balance training and coaching). [**KPIs: KPI-9** to **KPI-13** in Table 1].

Objective 3: Security, Privacy and Trustworthiness of the platform.

Description: This objective will be concerned with the implementation of **privacy and security preserving controls** to cover all the components and connections in the *SMART-BEAR* platform. These mechanisms will follow a **privacy** and **security-by design** approach, in which a thorough security analysis of the *SMART-BEAR* solution will be carried out from the early stage of the platform design, considering security, privacy and regulatory compliance requirements (e.g. GDPR, NIS directive) that should be met to ensure not only legitimate operation of the *SMART-BEAR* platform but also its acceptance and usability by the involved users. Existing security standards for the different types of platform components and devices (e.g., ISO standards and Common Criteria profiles) will be considered in selecting and implementing and testing security and privacy controls, ensuring that all the key properties of anonymity, confidentiality, availability, integrity and privacy are comprehensively covered. This analysis will guide the efforts of developing the mechanisms supporting the privacy-aware and secure by design operation of the platform, catering for the different involved user types. Furthermore, *SMART-BEAR* will advocate a **continuous security and privacy assurance** approach. This will involve developing probes for continuous monitoring and dynamic testing of the platform to generate evidence that can support the continuous assessment of the security and privacy provisions of the platform, making it transparent, audible and trustworthy. [**KPIs: KPI-14** to **KPI-18** in Table 1].

Objective 4: User-centric implementation and integration of the platform.

Description: Pursuing this objective will involve the integration of the capabilities developed in **Objectives 1-3** into **an innovative, affordable and sustainable smart adaptive living solution** to improve the healthy and independent living of elderly people and their Quality of Life. As part of this objective, we will also: (a) **integrate sensing and actuation mechanisms** needed for realising interventions at the smart home level, (b) **build and host** a **big data repository** to store data collected by sensors, devices and the mobile applications, and (c) **develop** appropriate **data visualisation** and **interfacing mechanisms** to enable the use of the platform by different types of users with different needs, including elderly users, their caregivers and medical experts. The work planed in *SMART-BEAR* regards the integration of technologies and interfacing with existing platforms to develop a unified system targeting TRL 9.

To provide a **user-centric solution**, *SMART-BEAR* will adopt a rapid prototyping approach, enabling end-users to be involved in system design from the very early stages. In particular, multiple interviews, demos and Wizard of Oz assessments will provide insight into the complementary perspectives of different users. The focused evaluation of the system under the user-centred KPIs that will be specifically defined for that purpose will provide guidelines for making the developed technology usable and easily accessible by end-users [**KPIs: KPI-20** to **KPI-24** in Table 1].

Objective 5: Demonstrate and validate the use of the *SMART-BEAR* platform at TRL 9 via five large scale pilots, involving 5100 participants across six EU countries.

Description: The project will demonstrate and validate its technology in real smart home environments engaging all relevant actors (elderly, health care professionals, and significant others), aiming to support co-creation and maximize user acceptance and trust in the system, revolutionizing consumption of digital services at home and in particular enabling new self-management care systems for better quality of life for the elderly in general and in particular for those groups covering the five main health conditions and frailty addressed by the project. In this context, the *SMART-BEAR* platform will be validated in **five different pilots**, spanning **six different European countries** and involving **5,100 end users**, whilst considering the effect of the platform in promoting healthy and independent living and well-being in the context of **different organisational models** for providing public and private healthcare services within regions, countries and across Europe. Thus, beyond supporting **healthy and independent living interventions for individuals**, the platform of *SMART-BEAR* will also support the **analysis of potential public health policies** at regional, national and international levels regarding such interventions. [**KPIs: KPI-26** to **KPI-31** in Table 1].

Objective 6: To maximise the project's impact and create a sustainable solution.

Description: The consortium will maximise the project's impact through innovation, exploitation and standardisation of the *SMART-BEAR* approach, and by raising awareness of the project's outcomes to healthcare stakeholders, organisations and individuals, whilst pursuing links and synergies with pertinent initiatives and piloting activities. Societal impact assessment (see section 2.1.6) will provide feedback for the project. This objective concerns also the effective dissemination and communication of project outcomes in scientific conferences, industrial exhibitions and other related fora, and social media (**WP13**). Moreover, to create a sustainable solution, *SMART-BEAR* will develop a **data sharing and valorisation model** (DSVM). This model will identify ways, at a technical and organisational 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 personalisation of its relation with its end users, develop new services, and monetise 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. [**KPIs: KPI-32** to **KPI-34** in Table 1].

Table 1. SMART BEAR Key Performance Indicators

KPI ID	Description and target value	Validation
KPI-1	The monitoring solution will comprise at least 5 heterogeneous devices (smart home devices/RFID sensors/hubs, wearable devices, smartphones, and medical devices like hearing aids, smart pillboxes, blood glucose meters, as described in Table 2, to effectively demonstrate its general applicability.	Reported in D3.6. Validated in pilots.
KPI-2	The monitoring solution will increase accuracy of state identification at least 25% with respect to each of the individual devices when that device is used in isolation.	Validated in pilots. Reported in D12.5
KPI-3	The monitoring solution will help keep drop-out rates due to various reasons (interoperability, usability, data security/privacy issues, user acceptance) low (<5%).	Validated in pilots. Reported in D12.5.
KPI-4	Deliver basic analytics to infer high level parameters regarding the (1) functional, (2) physiological, and (3) behavioural state of each participant, as well as their (4) safety, (5) risk, (6) social interactions, (7) cognitive, (8) sensory, and (9) balance profiles.	Reported in D3.6. Validated in pilots.
KPI-5	The basic analytics will improve the comprehension of individual health status and condition by 20% compared to using raw sensor data.	Validated in pilots. Reported in D12.5
KPI-6	Deliver advanced data analytics and learning capabilities for large scale analysis of the comprehensive datasets collected from all pilots and participants, which are capable of dealing with the volume and velocity of data collected by the various devices used for monitoring participants.	Reported in D4.6. Validated in pilots.
KPI-7	The advanced data analytics and learning capabilities will produce evidence enhancing existing health delivery services for the targeted 5 health conditions and their related comorbidities, by reducing their overall delivery cost by at least 20%.	Reported in D12.5.
KPI-8	The advanced data analytics and learning capabilities will provide evidence useful to at least 4 types of stakeholders (HCP, businesses, national governments, professional societies).	Validated in pilots. Reported in D12.5.
KPI-9	The decision support capabilities will cover at least 5 medical areas: (i) hearing loss, (ii) cardiovascular diseases, (iii) cognitive impairments, (iv) mental health issues, and (v) balance disorders.	Validated in pilots. Reported in D4.6.
KPI-10	The decision support capabilities will reduce unnecessary interventions by at least 20% in hearing loss and balance disorders, and 10% in CVDs, cognitive impairments, and mental health issues.	Validated in pilots. Reported in D12.5.
KPI-11	The decision support capabilities will speed-up the delivery of appropriate medical interventions by healthcare providers by at least 20% of the current time needed.	Validated in pilots. Reported in D12.5.
KPI-12	Deliver applications for participant screening and monitoring, and delivery of the *SMART BEAR* platform interventions.	Reported in D3.6.
KPI-13	Acceptance of the application interventions by the users, reporting a score higher than 80 in Software Usability Scale (SUS) and higher than 80% in Technology Assessment Methodology (TAM).	Reported in D12.5.
KPI-14	The privacy-preserving and secure by design data handling capabilities delivered will ensure the key properties of: (i) anonymity, (ii) confidentiality, (iii) privacy, and (iv) integrity of data.	Validated in pilots. Reported in D5.6.
KPI-15	The privacy-preserving and secure by design data handling capabilities delivered will ensure the aforementioned key properties for data: (i) in transit, (ii) at-rest, and (iii) in processing.	Reported in D5.6.
KPI-16	The privacy-preserving and secure by design data handling capabilities delivered will have demonstrable security monitoring policy compliance and auditability for all properties contained in respective security policies.	Reported in D5.6.
KPI-17	The privacy-preserving and secure by design data handling capabilities delivered will be compliant with the encryption guidelines of NIST.	Reported in D5.6.
KPI-18	The security framework will respect all ISO/IEC 27000 family of standards and also be able to operate in different security domains for various identifications, by providing application-specific certifications and license requirements.	Reported in D5.7.
KPI-19	The integrated smart adaptive living solution will interoperate with existing open source smart platforms, specifically with FIWARE.	Validated in pilots. Reported in D6.6.
KPI-20	The integrated smart adaptive living solution will integrate sensing and actuation mechanisms such as these described in Table 2.	Validated in pilots. Reported in D3.6.
KPI-21	The integrated smart adaptive living solution will provide interfaces to the platform for at least 4 types of people: (i) elderly users, (ii) their caretakers, (iii) health-care professionals, and (iv) health-care managers & business/regional decision makers.	Validated in pilots. Reported in D6.6
KPI-22	At least 5 individuals from each pilot site will participate during the design of the user-centric platform (either in focus groups, individual interviews, etc.).	Reported in D2.2.
KPI-23	At least 90% of the participants will evaluate the final *SMART BEAR* platform usability as greater than or equal to 8 in a range of 1-10 in at least 80% of the questions in the evaluation questionnaires.	Reported in D12.5.
KPI-24	At least 95% of the participants will be using the *SMART BEAR* platform for the whole duration of the pilot, indicating a drop-out rate of less than 5%.	Reported in D12.5.
KPI-25	At least 90% of the participants will be willing to recommend the *SMART BEAR* platform to a friend by the end of the project	Reported in D12.5.
KPI-26	The integrated smart adaptive living solution will improve the effectiveness of personalized care by at least 30% compared to what is currently achievable.	Validated in pilots. Reported in D12.5.
KPI-27	The integrated smart adaptive living solution will reduce visits to healthcare providers by at least 40%.	Validated in pilots. Reported in D12.5.
KPI-28	Delivery and demonstration of the TRL-9 integrated *SMART BEAR* platform to each of the partners supporting the pilots.	Validated in pilots. Reported in D12.3.
KPI-29	At the end of the first three months of a pilot, metrics will be collected for each individual, according to their health conditions and their related comorbidities. These metrics should be improved by at least 10% by the end of the pilot.	
KPI-30	At the end of the first three months of a pilot, metrics will be collected for all individuals in the pilot site,	

	according to their health conditions and their related comorbidities. The metrics should be improved by at least 10% by the end of the pilot.	
KPI-31	At the end of the first three months of a pilot, metrics will be collected across all pilot sites. These metrics should be improved by at least 10% by the end of the pilot.	
KPI-32	Achieve the project's dissemination targets as defined in Table 11 of Sect 2.2.6.	Reported in D13.5.
KPI-33	Contribute to standards, such as CEN ISO 13606 EHR-communication standard, and to the series of standards known as Concurrent-Use-Standards (CEN: EHR-communication, Health Information Service Architecture and System of Concepts for Continuity of Care) – see Sect. 2.2.3.	Reported in D13.5.
KPI-34	At least 2 clustering/concentration activities with the CSA supporting the activities defined under "DT-ICT-13-2019: Digital Platforms/Pilots Horizontal Activities". The activities will take place at M03 before the design of the solution and then at M27 in order to report on the initial results of the pilots.	Reported in D13.6.

1.2 Relation to the work programme

[…] *foster large-scale deployment of integrated digital solutions which will bring improved quality of life to citizens while demonstrating significant efficiency gains in health and care delivery across Europe.*

Hearing loss (HL), cardio vascular diseases (CVDs; i.e., hypertension, ischemic heart disease, heart failure), cognitive impairments (CI), mental health (MH), as well as postural impairments (PI) and frailty (FR) that often lead to independence status changing physical injuries, are amongst the ten most prevalent health challenges that elderly people are faced with and affect their ability to have a healthy and independent living. *SMART-BEAR* will implement an integrated, smart and adaptive living digital platform (**KPI-19**, **KPI-20, KPI-28**) offering personalised monitoring and interventions to support elderly people with such conditions, in tandem with healthcare professionals (HCPs) (**Objective 4**). The solution will be tested and validated through five large scale observational and interventional pilots involving 5.100 elderly citizens, in six different countries: France, Greece, Italy, Romania, Spain and Portugal (**Objective 5**). The pilots will enable the validation of the solution and its ability to bring significant efficiency gains (**KPI-26**, **KPI-27**, **KPI-29, KPI-30, i-KPI-4, i-KPI-5, i-KPI-6, i-KPI-7, i-KPI-8, i-KPI-10, i-KPI-13**) in the context of healthcare service delivery by private and public providers at regional, state and European level.

The pilots should build on open platforms, standardised ontologies, APIs and results from IoT-based smart living environments, service robotics and smart wearable & portable systems.

The *SMART-BEAR* solution implementation will be based on smart off-the-shelf wearables and hearing aids and mobile devices. It will also use specific enablers of the FIWARE open IoT platform to support connectivity with existing clinical systems (**Objective 4**). The solution will be offered as an open shell platform at the end of the project. The offering will include the full range of data analytics, decision making, device connectivity and decision-making capabilities (note: data collected during the project will not be part of the offering due to security and privacy reasons). These capabilities will be offered through open APIs supporting access to data in the platform. The data representation will conform to HL7 (in particular HL7-FHIR where contributions will be made towards special applications of non-invasive self-monitoring at home) (**Objective 1**). This will enable data sharing and valorisation.

go beyond current SOTA in terms of scale, the capabilities for personalisation, adaptation, and user acceptance

SMART-BEAR will advance the state of the art in offering **personalised decision support** and **interventions** by analysing user needs at multiple time scales and using reasoning algorithms to develop successful personalized recommendations without obstructing users' ordinary daily activities. Another key element of decision making will be the ability to **extract knowledge** from the models built from the mining of monitoring and state data (e.g., neural networks) that can offer the needed **explainability** of why the evidence supports different decisions/interventions (**Objective 2**). The number of users involved and duration of pilot services should be sufficient to ensure significance in impact analysis, with a minimum of 4 pilot sites in 4 countries. The *SMART-BEAR* platform will be deployed and validated by 5100 users in six different countries: France (1000 users), Greece (1000 users), Italy (1000 users), Spain (1000 users), Romania (1000 users) and Portugal (100 users) (**Objective 5**). The overall period over which recruited participants in the different pilots will be using the platform will be 24 months (see **T7.2, T8.2, T9.2, T10.2** and **T11.2**) to ensure the significance of the evaluation outcomes and the related impact analysis.

The proposed pilots should also demonstrate feasibility of integration with other relevant application domains such as energy, transport, or smart cities, including interoperability, along with data security and integrity, and models for data sharing and valorisation are to be developed in order to create incentives for data aggregation across different platforms and application areas.

The deployment of the *SMART-BEAR* solution in the pilots will involve integration with different types of: (1) assistive medical devices; (2) body sensors; (3) smart/virtual assistants; (4) smart cities sensors (environmental sensors); (5) smart homes sensors and actuators (light, sound, temperature, humidity and motion sensors); (6) smartphones; and (7) existing participant data available from local healthcare service providers (**Objective 1**). The solution will also utilise: (a) related data representation and sharing standards, as well as FIWARE to implement connectivity with the above components and devices (**Objective 4**); and (b) FIWARE security and privacy enablers (controls). The

latter will be enhanced by continuous security and privacy assurance monitoring and certification mechanisms based on related security and privacy standards such as ISO 27000 (**Objective 3**). Through adherence to existing data representation, communication and security/privacy standards, *SMART-BEAR* will demonstrate the feasibility of a baseline for data valorisation. In addition, based on experience obtained through the large-scale validation of the baseline solution in the pilots, *SMART-BEAR* will develop and propose models for data valorisation, and will use an open call to engage new partners with new types of data and devices to the platform, to further enhance the spectrum and effectiveness of the targeted interventions for the well-being and independent living of the elderly (**Objective 6**).

Regulatory aspects and legal aspects of data ownership should be addressed. Relevant ethics and gender issues should be taken into account.

Regulatory and legal aspects of data ownership and sharing will be addressed in *SMART-BEAR* by an early analysis of related standards and legislation. This will be complemented by related requirements of different types of users including the elderly, healthcare service providers and regional and national authorities involved in the pilots. The outputs of this process will be used in developing the ethics approval applications for the different pilots, and approved by this process. During the deployment of *SMART-BEAR* in the pilots, the adherence of the solution to security and privacy requirements and standards will be continuously assessed through the platform assurance components (**Objective 3**). Ethical issues will be addressed through the ethics approval application and continuous ethics monitoring in the project. Gender issues will be addressed as the project targets an elderly population (67 years +) in which the ratio of male-to-female is 7-to-10 [22]. This ratio becomes 6-to-10 when considering the 80+ years old [22].

Intelligent and personalised digital solutions for sustaining and extending healthy and independent living.

Through the collection and analysis of health, physiological, life style and environmental data from the participants, and the incorporation of intelligent decision-making capabilities, *SMART-BEAR* will identify and deliver personalised interventions (Table 3) increasing the independent living and overall well-being of the participants (**Objective 1, Objective 2**). The targeted interventions will bring the following efficiency gains in health and care delivery in Europe (**KPI-26**, **KPI-27**, **KPI-29, KPI-30, i-KPI-4, i-KPI-5, i-KPI-6, i-KPI-7, i-KPI-8, i-KPI-10, i-KPI-13**).

Innovative ways for ensuring user-friendly and accessible interface design and new intuitive ways of citizen interaction and trust creation are needed.

Through a user-centred design and development methodology, *SMART-BEAR* will develop user-friendly interfaces for the different user accessible devices and components of the platform (**Objective 4**). These will offer enhanced accessibility, to address the special needs of the elderly users of the platform (e.g., different types of sensory and cognitive impairments). *SMART-BEAR* will incorporate SotA security and privacy controls and continuously validate adherence to security and privacy standards/properties (**Objective 3**) to ensure the trustworthiness of the platform.

Special emphasis should be given to viable concepts that ensure security and privacy by design, data protection, safety, security and trust in the resulting system and service delivery inside and outside the home.

To ensure that the privacy and security of sensitive data is preserved end-to-end and data are only accessible to authorised entities, state of the art security and privacy controls (e.g., relevant FIWARE enablers) will be used (**Objective 3**). These will be tailored to the different types of the platform users (elderly, caregivers, clinical experts), and in line with special requirements established through *SMART-BEAR*'s user-centred development approach, as well as related requirements, legislation and standards. *SMART-BEAR* will ensure that security and privacy is addressed by-design and will incorporate a security assurance component, to continuously assess the platform's adherence to security and privacy requirements and standards throughout its deployment in the pilots (**Objective 3**).

Pilot projects are expected to contribute to the consolidation and coherence work that will be implemented by the CSA supporting the activities defined under "DT-ICT-13-2019:Digital Platforms/Pilots Horizontal Activities"

SMART-BEAR will interact with and contribute to the CSA supporting the activities defined under "DT-ICT-13-2019: Digital Platforms/Pilots Horizontal Activities" (**Objective 6**). A dedicated task (**T12.5**) is included for this.

1.3 Concept and methodology

1.3.1 Overall concept and approach

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 large-scale pilots involving 5.100 elderly living at home in Greece, Italy, Portugal, France, Spain, and Romania.

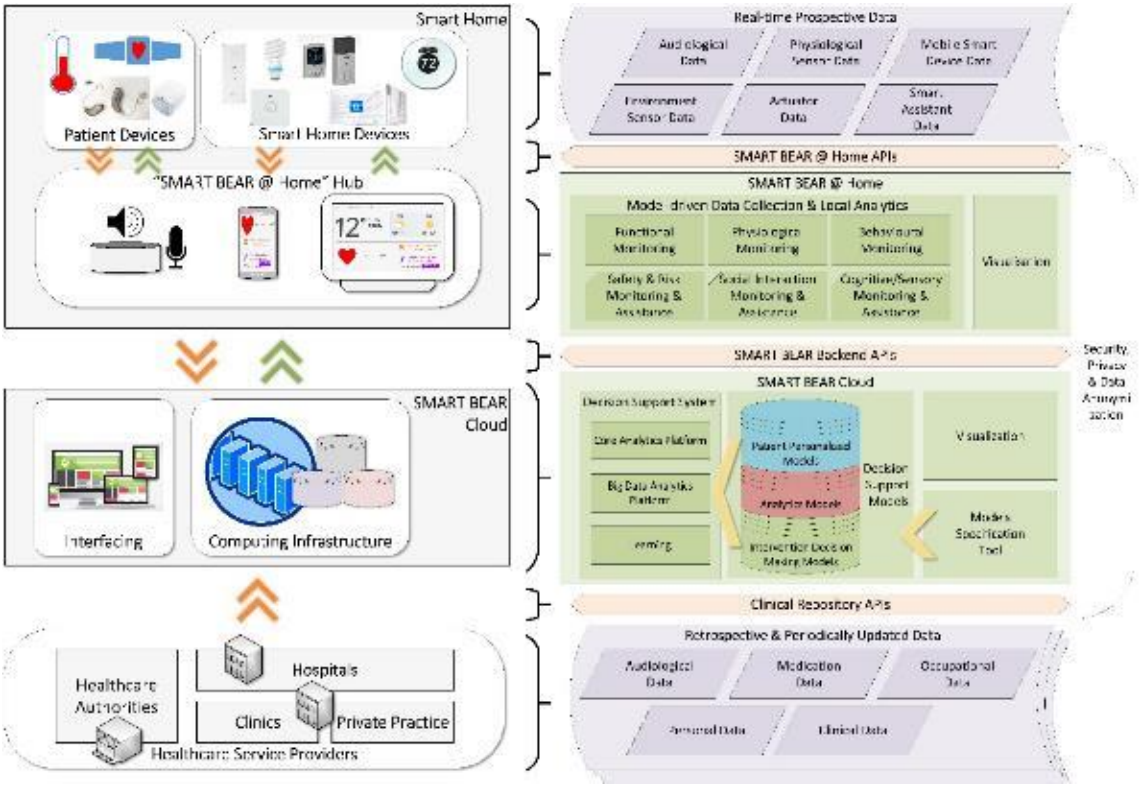

Figure 3: Envisaged SMART BEAR platform

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.

1.3.1.1 *Technological Aspects*

1.3.1.1.1 *SMART BEAR @ Home*

SMART BEAR is a technologically elevated solution for the elderly leveraging the smart home IoT ecosystem to enhance the well-being and independent living of individuals facing challenges from Frailty and the five prevalent medical conditions targeted in the project. Towards this, the platform will incorporate an assortment of heterogeneous off the shelf smart and medical devices (cf. Table 2), to gather Real-time Prospective Data from the end user. Specifically, the *SMART BEAR* platform will exploit data from wearable smart watches to deduce user physical activity, such as heart rate, oxygen saturation, activity tracking (e.g. steps taken, floors climbed, intensity of exercise), as well as sleep tracking (including identification of sleep cycles and stages; e.g., REM, light sleep) and burned calories assessment. Moreover, a smart home ecosystem will be set up, featuring devices such as smart switches, smart lights, motion and environmental conditions' sensors, door and window monitoring through magnetic sensors, as well as object RFID tracking. In addition to these a smart pillbox (to track pill consumption) and a smart blood pressure meter (to automatically upload measurements) will be integrated as well. As some of the targeted end users will have hearing loss, sophisticated smart hearing aids will be integrated as well into the SMART BEAR ecosystem, leveraging the consortium's expertise from project EVOTION. A small computing platform, the SMART BEAR Hub, will be installed in the home, for local data aggregation, pre-processing and local analytics (to infer higher level information such as functional and behavioural monitoring, from raw sensor data) and communication to/from the SMART BEAR Cloud. Finally, all end users will be provided with a smart phone, which will run the SMART BEAR mobile application. This will be the main interface and visualisation element that end users will interact with. It will also be used to track the necessary parameters and communicate with the SMART BEAR Cloud when the user is outdoors. The SMART BEAR @ Home ecosystem will be tailored to be unobtrusive and trouble-free to the extent possible, with secure out of the box configuration, and with minimal effort required to add additional devices.

Table 2. Candidate off-the-shelf devices for integration into the SMART BEAR ecosystem

Type		Functions / Characteristics	Off-the-shelf solutions	
			Product	API/SDK
Smart Home	Devices	✓ Smart light control (on/off, intensity, light temperature) ✓ Motion/presence sensing ✓ Ambient light sensing ✓ Temperature/Humidity monitoring ✓ Magnetic door/window monitoring ✓ Smart switching to control appliances / lights / trigger functions	PHILIPS hue Hue ecosystem	Available API & SDK
			SAMSUNG SmartThings SmartThings	Available API, Groovy IDE
			mi Xiaomi Mi Smart Home	Available API
	RFID	✓ Detection of indoor location ✓ Proximity ✓ Object tracking	OpenBeacon.org OpenBeacon	Open Source
	Integration Hub	✓ Integration of heterogeneous connected smart devices / ecosystems ✓ Open Source	openHAB	Source code
			Home Assistant	Source code
Wearable	Smart Watch	✓ 24/7 heart rate monitor ✓ Sleep & sleep stages tracking ✓ Activity tracking ✓ Calorie burn monitoring ✓ 3-Axis accelerometer & gyroscope ✓ Vibration motor ✓ GPS / smart-phone connected GPS	empatica Embrace	N/A
			fitbit Charge 3	Available API, SDK
			OMRON Generation Zero	N/A
Mobile	Smartphone (D)	✓ Typical smartphone characteristics (touch screen, voice calls, messaging, location, accelerometer etc.) ✓ Android O/S ✓ Data Plan	android O/S	Available API, SDK
Medical	Smart Hearing Aid (E)	✓ Soft Speech Boost ✓ Transient Noise & wind noise Management ✓ Multiple Directionality Options ✓ Adaptation Management ✓ Acoustic Notification	oticon PEOPLE FIRST OPN	Access to APIs
	Smart Pillbox	✓ Pill consumption detection ✓ Progress tracking over time ✓ Alerts ✓ Connectable/stackable	tricella Pillbox	N/A
	Blood pressure	✓ Blood pressure measurement ✓ Reading average / memory ✓ Online upload/ data extraction ✓ Irregular heartbeat detection	OMRON M7	Available API (Omron Connect)

1.3.1.1.2 *SMART BEAR Cloud*

At the SMART BEAR Cloud, i.e. the backend system of the cloud, the following key functions will be included.

1.3.1.1.2.1 Data collection

Data will be collected, analysed and monitored in real time. Beyond the data collected from the *SMART BEAR @* Home instance and environmental parameters (e.g. from the smart city infrastructure), the *SMART BEAR* backend will also collect and analyse data through medical assessments and questionnaires (standard and/or extended as required for the purposes of the project) conducted by medical experts; questionnaires given to the elderly; medical data obtained from healthcare providers (e.g. medical records), and; the continuous monitoring of the compliance to and the effects of the undertaken interventions. Participants, Family or General Practitioners (FGPs) will be notified by the platform in case of significant alteration of individualized data profiles or abnormal health parameters. FGPs will be able to evaluate the platform's output against standard practice and provide feedback to the research team at a later stage. Intervention data will be fed back to the platform for further analysis. All interventions will be registered, stored and further processed as part of the backend data analytics. Static and real time data will be collected such as Patient's medical history (aided by validated questionnaires) and/or HER, sensors (wearable and fixed) and devices present in the smart environment (IoT and IoMT), open-access data, self-reported data, intervention data.

1.3.1.1.2.2 Data Synthesis & Analysis

Incoming data will be constantly monitored and used to trigger warnings in two ways: (i) Predefined abnormal parameter values (e.g., a warning will be issued if the pulse oximeter records a heart rate value of >120 in a single measurement or records a 20% increase in heart rate for 3 consecutive days) for profiling with the application of machine learning techniques. (i) Identification of deviation from a participant's data profile through machine learning techniques (e.g., a warning will be issued when sensors record limited mobility compared to previous days).

As mentioned above, notifications or warnings will be issued to the user, the responsible FGP or any significant other depending on the consent provided by each participant. Feedback of the action taken will also be recorded and further analysed. In case the user attends to a non-collaborating healthcare center, the information of the actions taken there will be also filed. Finally, ignoring the notification will also be recorded and evaluated.

1.3.1.1.2.3 Personalised monitoring, modelling & decision support for intelligent interventions

The evidence arising from data analytics will be fed into decision models, which will identify and suggest or automatically trigger interventions that can prevent the appearance of such factors or reduce their effect in order to improve the health and well-being of the elderly. These models will enable hybrid forms of decision making in which predictions and classifications provided by the computed models of the data analytics layer, will be further filtered based on medical and clinical knowledge, and safety parameters in order to provide plausible interventions. To enable the decision making, the models that we envisage in SMART BEAR will consist of: (i) an analytics (sub) model – This sub model will determine that data to be analysed in order to identify risk factors and potential interventions and specify the exact data analytics workflows that will be applied to the data in order to produce the evidence related to these factors and interventions.; (ii) an intervention decision making (sub) model – This sub model will define alternative interventions, the types and extend of evidence that will need to be obtained through analytics for exploring the plausibility of an intervention, the exact criteria that the collected evidence will need to satisfy in order to confirm the plausibility of an intervention, further clinical knowledge that should be taken into account before undertaking an intervention, and the stakeholder(s) who will have responsibility for making the final decision upon a suggested intervention or choose amongst alternatives, and the recipient/target of the intervention, and (iii) a patient personalisation (sub) model - SMART BEAR regards its seamless adaptation to the needs of the individual users but also their habits and preferences, in order to accomplish minimally annoying and effective interventions that fit seamlessly with their lifestyle.

To this end, the history of past interaction sessions between the implemented systems and each individual user will be exploited to develop (i) a time-trackable user history of how (s)he has accepted system recommendations at given times and contexts (ii) an interaction-profile of the user to provide insight on the *SMART BEAR* features and interaction modalities (s)he is most willing to use (iii) a usability-profile-based user association mechanism to facilitate transferring knowledge gained through the interactions with a given user to other similar users. Well tested tools are already available to support *SMART BEAR* in these directions. The merit of a recent decision model-driven approach developed for evidence-based decision-making in the area of health policy [21] will be investigated in defining the SMART BEAR decision models. Moreover, the Episodic Memory module developed by FORTH [31] adequately supports information-rich and time-stamped representations of past episodes, providing build-in mechanisms to not only query the past but also make probabilistic inference on user's profile features. The latter will provide the means for selecting and optimally adapting the communication channel of *SMART BEAR* with each individual user. The transfer of knowledge between users can effectively rely on the well-known Collaborative Filtering approaches that make successful predictions about the preferences of a user by collecting information from many users.

1.3.1.1.2.4 Big Data Analytics and Learning

Thanks to IoT smart sensors, the *SMART BEAR* platform will continuously monitor the health status and activities of the elderly, as well as monitor the safety and security of the environment. *SMART BEAR* will also connect to hospitals and other healthcare service systems to obtain data of the elderly medical history. This continuous flow of data can support personalized diagnosis and assistance and help automate important tasks, such as the creation of statistical data archives or the scheduling and management of routine or emergency visits. Equally importantly, this data will be extremely valuable in establishing the effectiveness of the interventions performed by the platform and the conditions under which they are most effective. Ensuring a highly reliable, accurate and robust implementation of a technological infrastructure for recording, storing, processing, and analysing the continuous flow of data is today practicable thanks to the advancements in Artificial Intelligent and Big Data processing technologies.

Big data analytics in *SMART BEAR* will be carried out using a model driven approach. More specifically data analytics will be based on *intervention decision making models*, which steer the decision-making process by defining the data that need to be collected, the ways in which they should be analysed to produce the evidence useful for making intelligent decisions about interventions, how this evidence may support or contradict various interventions, and how healthcare service providers should be involved in the decision-making process. To support this, the *SMART BEAR* platform will be designed with the following requirements: **(i) Modular and interoperable data ingestion**,

to support devices from different manufacturers through a common data model for integrating different data structures from all types of devices; **(ii) Parallelization and data stream processing**, through a Big Data processing approach for distributing data acquisition, processing, and storage, to allocate resources elastically and process computational tasks of any complexity; **(iii) Data analytics and artificial intelligence**, to support automatic monitoring, alerting and decision making by integrating advanced data analytics and artificial intelligence capabilities and to offer explanations for interventions suggested by these algorithms; **(iv) Privacy-aware data processing**, to ensure consistent data encryption, database security, as well as secured communication channels, as data collected by smart homes contain sensitive information, protected by the GDPR, which is critical for the *SMART BEAR* platform.
The expertise established by some of the partners in the consortium through the H2020 RIA projects EVOTION and TOREADOR (cf. Table 5) will guide the implementation of the above.

1.3.1.1.2.5 Monitoring & Visualisation

Participant's online status and notifications will be monitored through a dashboard- type front end. It will be regularly updated automatically by incoming data or manually with entries by the users and the different collaborating health care centres. Depending on the type of alert, the administrators and/or corresponding health care centre will receive a notification as well. The dashboard will present the users' personal details, the responsible doctor/health care centre, user's connection situation (online or not) and a "there are events that need attention" button, as shown below.

User's Name	Contact Details	Responsible Doctor's Contact Details	Emergency Contact Details	Connection Status*	! Red Flag Notification
X.X.	Area Tel. number	Name / Tel. number Corresponding health Center	Name / Tel. number	Online / offline Last registration	Type of event Action to be taken

*e.g. if at least 1 sensor or device is not transmitting at a particular moment: the connection status is characterized as "user offline".

By clicking the "User's name" cell, the corresponding data tab will open. Information of, both real time and previously stored, sensors measurements, environmental data, along with user's and responsible doctor's manual entries will be displayed. Data will be appropriately updated, and data on each sensor function mode will be visible as well.

1.3.1.1.3 *Security & Privacy*

Multiple entities and associated interactions are expected during typical, everyday use of the *SMART BEAR* solution, including interactions of the elderly and their caregivers with the platform, interactions of the smart devices with the *SMART BEAR @* Home instance, interactions of said instance with the backend cloud and interactions of the various entities there (e.g. administrative staff, clinical experts, backend systems interacting with hospital systems). These complex interaction schemes, along with the private sensitive nature of the handled data, necessitate the integration of strong security and privacy provisions, including seamless authentication and authorization services, for the protection of the framework's Machine-to-Machine (M2M) and Machine-to-Human (M2H) interactions.

These challenges are exacerbated since the small, low cost, off-the-shelf devices used to collect sensing data may not have mature security functions, having been designed primarily for ease of set-up, use and interconnection and having relatively low processing capacity. Since smart homes will be a key point of intersection between people and technology, an approach to information security in this context requires a particular input from social, political and economic perspectives. Smart homes may include sensitive systems related to the occupants' healthcare, finances and systems related to the physical security of the home, which may be open to dangerous manipulation by attackers.

The above define a set of requirements for providing a secure and privacy-preserving technology-enabled care at home. Namely: Constrains of small, low cost, interconnected devices without mature security functions; low latency of network connectivity to allow uploading of computationally intensive real-time tasks (e.g. condition reasoning, command processing) to the cloud; secure communication within the smart home (*SMART BEAR @* Home instance), which may use a range of protocols (WiFi, Bluetooth, NFC, ZigBee, etc.), and thus have a number of open vectors for exploitation; privacy protection as smart home sensors generate a large amount of highly personal data and metadata; consent for data sharing, secure and anonymised information, coordination of cooperative action; safety for sensitive systems related to the occupants' healthcare and systems related to the physical security of the home; secure communications with the backend processing systems (*SMART BEAR* cloud); secure and privacy-preserving interactions (communication, processing, storage) with third parties (hospitals, clinics) and their data and metadata; Authentication, Authorization and Accounting mechanisms tailored to each type of entity (from elderly, caregivers, clinical experts, but also devices such as sensors and backend systems); guaranteed and reliable availability of information from back-end databases and real time data streams.

The information sources to be protected include: data from smart devices, including raw data, logs, metadata (headers, content type, dates, etc.), events (alerts, warnings, errors, etc.), rules, settings and preferences (which may disclose information about the end user's conditions), updates to and from smart devices, post-processed data and interactions of the *SMART BEAR @* Home instance with the backend *SMART BEAR* cloud, as well as interactions of the latter with the various healthcare service providers (hospitals etc.).

All adopted security & privacy mechanisms will have to meet these requirements, and a key characteristic will be

the capability to adapt in real-time to various usage requirements (context, privacy preferences, risk profile, etc.).

1.3.1.2 *Clinical Aspects*

The WHO defines health as a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity. As more than 80% of the elderly population suffer from at least one of the targeted conditions (CVD, HL, CI, MH and BD), the way these conditions are managed, the efficacy of interventions and the holistic philosophy of the overall approach highly influence quality of life and well-being. The home environment is critical for the development of serious NCDs, since more than 70% of time is spent at home, exposing older adults to a series of risk factors which may influence more than one conditions.

Motivated by this, the role of smart technologies in SMART BEAR is to monitor related metrics, prevent or delay deterioration, facilitate aspects of everyday life, motivate healthy life style, suggest healthy diet, avoid risks and improve safety, provide reliable information, daily coach with use of serious games and holograms, close the gap between patient and healthcare, and help people live more independently despite the presence of the conditions. The integration in SMART BEAR IoT ecosystem of devices providing data for the functional, physiological, safety/risk, behavioural and cognitive/sensory monitoring, will also allow evaluating Frailty and providing appropriate interventions. Frailty is a syndrome of compromised energetics with five core clinical features [23]: (1) low grip strength, (2) slowed walking speed, (3) low physical activity, (4) self-reported exhaustion, and (5) unintentional weight loss.

Moreover, according to WHO guidelines for physical activity, citizens over 65 should include dedicated balance exercises in their weekly physical activity, together with muscle strengthening exercises [24] and SMART BEAR will motivate patients via apps and serious games to meet this goal. Physical activity is also highly indicated in CVDs, which are the leading cause of death globally, causing 17.9 million deaths (32.1%) in 2015. At the same time in 2009, costs related to CVD amounted to €106 billion, representing approximately 9% of the total healthcare expenditure across the EU. Another smart technology used will be apps improving adherence to medication as well as to diet.

Another targeted intervention is the implementation at home of evidence-based Balance Physiotherapy (BP) exercises [25]. BP is a structured intervention and considered the most effective way to improve posture and prevent falls [26]. Participants identified as at risk of fall during their initial assessment will be provided with an affordable and easy to use device (i.e. the HoloKit, developed in project HOLOBALANCE where some partners are actively participating), presenting a hologram through augmented reality in their familiar, home environment, which will show them suggested exercises, guide and motivate them. Improvement will be monitored with use of validated tools correlated with risk of falls (Functional Gait Assessment). Approximately one out of three people aged over 65 fall annually, whereas almost half of them fall more than once in the same period. One out of five falls are related to serious injuries, including bone fractures and hematomas of the brain, increasing morbidity [27][28], hospitalization and further complications. Complications of falls comprise loss of mobility and potentially fatal pulmonary embolism, pneumonias, serious COPD deterioration, pulmonary infections, depression and malnutrition, completing a vicious cycle of frailty [29] and directly costing €25 billion annually in the EU [30], with far higher indirect costs.

Finally, SMART BEAR will provide participants diagnosed with HL with high end hearing aids with directional microphones and specialised profiles tailored to different environments during the first weeks of their participation. The HA usage will be monitored, whereas they will be motivated through apps to refer problems, to increase HA acceptance. Cognitive Impairment will be supported with safety apps and with serious games for memory/reasoning.

1.3.1.3 *SMART BEAR Interventions*

SMART BEAR will feature a variety of interventions, tailored to the individual's needs and current state, in line with existing medical knowledge and protocols, towards comfortable and independent living and quality of life improvement. Some examples of risk factors and associated indicators to be monitored, their links to health conditions, the means of measurement and the corresponding interventions are shown in Table 3 and some scenarios are depicted in Figure 4

Table 3. Monitored conditions & corresponding interventions

Risk Factors / Indicators	Related Health Condition(s)	Means of Measurement	Intervention(s)
Noise exposure	Hearing loss, tinnitus, Mental health (depression, fatigue)	Noise level sensors embedded in hearing aids and/or smartphones	Personal alert/notification Alert to clinical experts -> adjust hearing equipment
Frequent Falls	Balance Disorders, Postural Impairment/Presbystasis, Frailty	Accelerometers/gyroscopes in smartphone & smart watch	Serious games and virtual physical trainer for balance disorders delivered via HoloKit Automated calls to significant others (in cases of fall detection).
Cognitive Decline	Dementia, Alzheimer's Disease, Memory loss	MOCA, Mini Mental Test	Cognitive Games (Digit Recall test etc.)

Physical inactivity	Frailty, Obesity, CVDs, Depression	Smart watch/fitness tracker	Personal alert/notification Serious games with built in reward mechanisms (badges, score board etc.). Physical Activity Apps to ensure minimum daily activity (duration, frequency and intensity) and suggest exercise scheme tailored to needs and capacities of end user (with special considerations for patients with conditions like heart failure).
Air particles / Smoke/ Gas/ External Temperature / Pollen	COPD (Chronic Obstructive Pulmonary Disease), CVDs	Air quality sensors, Data retrieved from Smart Cities (particles' concentration in local area)	Personal alert / notification Trigger of connected air conditioning / filtering / ionisation (where present) Alert to clinical experts -> notify about status of environment
Sleep disturbances	Mental health (fatigue, anxiety, burnout, depression, cyclothymic disorders), Cis (memory, attention, alertness)	Smart watch sleep tracking	Alert user for sleep deprivation levels, provide sleep suggestions / exercises and recommendations for improved sleep Alert to clinical experts -> notify about sleep patterns
Malnutrition	Obesity, CVDs, Metabolic syndrome, Vitamin deficiencies, anaemia, mental health (eating disorders, anxiety)	App to monitor nutrition intake	Suggest dietary program based on medical history and cultural background. Gamification elements when goals are reached.
Weight Loss/Gains	Obesity, Frailty, CVDs, Metabolic syndrome, Depression, Eating disorders	Weight scale, self-reporting	Suggest dietary program based on medical history and cultural background. Special consideration for patients with heart failure. Alert to significant others / clinical experts.
Abnormal Blood Pressure levels	CVDs (hypertension, low blood pressure)	Blood Pressure Meter, self-reporting	Personal notification, use of apps to ensure medication intake, daily activities. Consider medication side-effects. Alert to significant others / clinical experts
Cardiovascular & Respiratory Symptoms (Angina, breathing disorders)	CVDs, COPDs	Questionnaire/self-reporting	Alert to significant others / clinical experts
Abnormal Blood glucose levels	Diabetes (Hyperglycemia/ hypoglycemia)	Blood Glucose Meter	Personal notification, use of apps to ensure medication intake, daily activities. Consider medication side-effects. Alert to significant others / clinical experts
Non-compliance to medication scheme	Adverse effects, deterioration of chronic diseases, suboptimal therapeutic effect	Pill intake monitoring (e.g. via Smart Pillbox)	Personal notification, use of apps to ensure proper medication intake
Non-ideal light levels	Falls, increased injury risk, sleep disturbances (Digital device extra-usage + Blue light extra exposure) hormonal deregulation (continuous light exposure) delayed circadian rhythm connected with a cognitive dysregulation (evening light exposure) depression, stress (light underexposure)	Light sensitivity sensors	Personal alert/notification Alert to clinical experts -> notify patient about the importance of proper lighting When detecting a change of position, lights will automatically be switched on (dimmed during night-time).
Social isolation	Mental health (depression, anxiety, suicidal risk, eating disorders)	UCLA Loneliness Scale; sound sensor to detect frequency of discussions HCI events with mobile device	Notifications to enhance social activity; alerts to the clinical experts
Family isolation	Mental health (depression, anxiety, fatigue, Suicidal risk), CIs (memory)	Social networks, use of smart phone/calls HCI events with mobile device	Personal Reminders Alert to significant others
Extreme Temperatures / weather conditions	Dehydration, increased risk of CVDs, Mental health (depression, fatigue), CIs (attention, alertness), eye-related syndromes	Home temperature/humidity sensors, Environmental data acquisition through Copernicus services	Temperature & humidity regulation suggestions (air condition, opening windows, heating system setting etc.), suggestions to stay at home (in extreme weather conditions).
Behavioural changes	CIs (memory, attention), Mental health (depression, anxiety, fatigue, suicidal risks)	Screening Questionnaires (e.g., PH2), HCI events with mobile device	Alert to significant others Suggest treatment options, contact clinical expert & significant others (automatically in critical cases)

Emotional changes	Mental health (depression, anxiety, fatigue, suicidal risks)	Screening Questionnaires (Geriatric Depression Scale, BECK Depression Inventory, BECK Anxiety Inventory)	Suggest contact with significant others/clinical expert, Automated calls to significant others in critical cases
Habitual substance use (Smoking/passive smoking, Alcohol, legal sedatives)	CVDs, COPD, Diabetes, Cognitive Impairment, Depression	Monitoring, Screening Questionnaires	Alerts / suggestions to cessation or reduce frequency. Alert significant others / clinical experts.

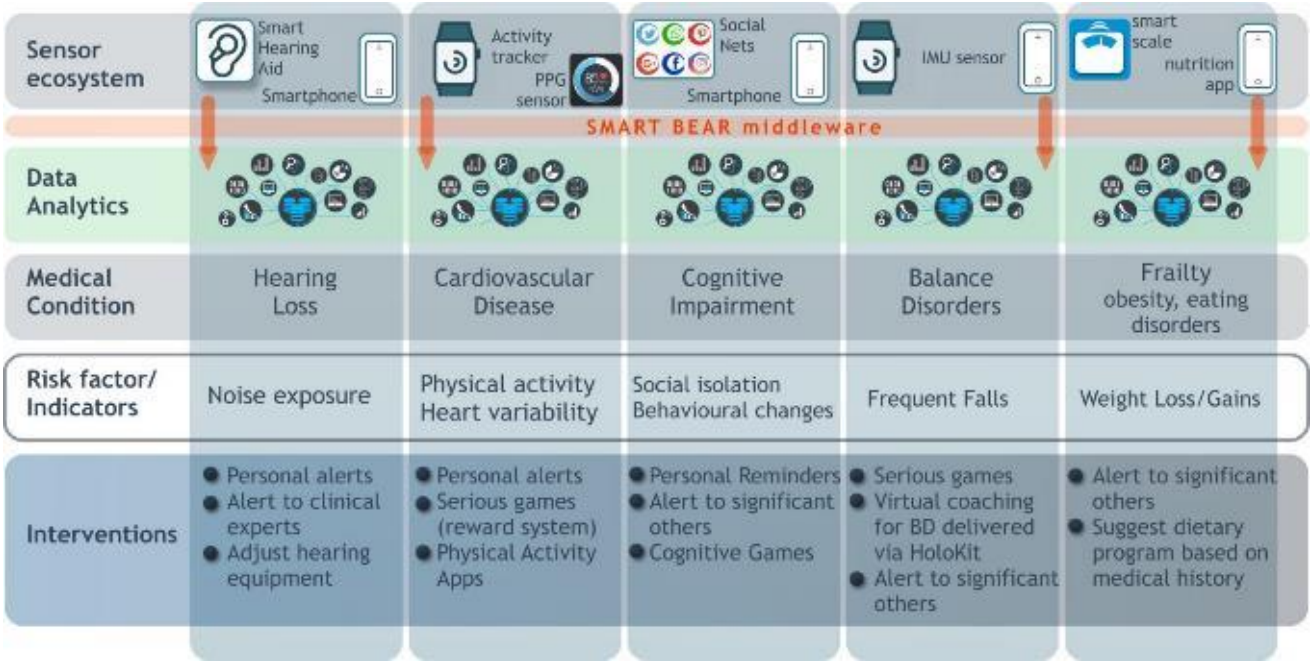

Figure 4: SMART BEAR intelligent intervention scenarios

1.3.1.4 *SMART BEAR Cloud*

1.3.2 Project Positioning in Technology Readiness Spectrum

The *SMART BEAR* platform consists of the integration of different components, knowledge, models and tools, customized, trained and integrated in the overall platform (Table 4).

Table 4. SMART BEAR technological building blocks and their TRL progression

Pre-existing technology and owner	TRL		Justification
	Start	End	
Model-based BDA-as-a-service (UMIL)	7	8	The MBDAaaS Platform developed in the H2020 Toreador project will be exploited in the large-scale setting of *SMART BEAR*.
Open Data Portal of Health Data in Lombardy (LISPA)	8	9	Aggregated data generated from the Italian-Portuguese Pilot will be exploited to enrich the set of Open Data distributed by LISPA and to equip the portal with examples of data-driven policies that are applied by Regione Lombardia.
Machine learning analyser. (UMIL)	5	7	Customize the machine learning – based analyser for classification and clustering of clinical data aggregated through sensing devices in *SMART BEAR*.
Personalised decision support models and tools (ICCS)	4	6	The personalised aspect of *SMART BEAR* will be achieved through training with user's data and interaction with decision support modelling. Also, knowledge from clinical experts as well corporate-related entities will be combined with data driven models to deliver the final personalised approaches and tools.
Behavioural and Emotional Algorithms (ICCS)	5	6	Behavioural modelling and emotional computing algorithms and approaches currently exist and they have been validated in several different environments. Within *SMART BEAR*, these algorithms will be trained using relevant data and applied in a proof of concept study in the relevant environment.
Personalized interfaces and tools (FORTH)	4	6	Personalization in *SMART BEAR* will be achieved through home mobile application and training with user's data and interaction with behavioural models. Also, knowledge from physicians and psychiatrists will be combined with data driven models to deliver the final hybrid motivational approaches and tools.
Auditory training tools (EVOTION)	4	6	Knowledge and tools from partners' previous research and projects will be utilized and integrated with the relevant ICT tools and applied in a proof of concept study in the relevant environment.
Analysis and intelligence tool. (NKUA)	7	8	System on top of systems for consolidated data acquisition from different sources at home for further analysis via sophisticated algorithms translating raw information of performance indexes to decision

			making for improvements in elderly's well-being. Big data analysis and machine learning techniques will be incorporated into *SMART BEAR* platform. Integration is expected to advance system to new standards.
IoT Tool (UOI)	6	7	*SMART BEAR* will use the existing IoT knowledge and extend it to comprise functionalities related to intervention management and monitoring.
Security assurance platform (STS)	6	7	Security assurance platform: (a) combines runtime monitoring and dynamic runtime testing to ensure to correct and effective operation of security controls in cloud and distributed systems; (b) can be hooked to different systems programmatically through probes (e.g., event captors, test tools) to obtain the monitoring and/or test evidence required for assurance and/or certification assessments; (c) operates based on models that determine the operational evidence that should be captured and how it should be assessed (e.g., what conditions it should satisfy) in order to assess the correctness and effectiveness of implemented system security controls; (d) enables the runtime assessment of temporal event patterns and rules that can express signature or anomaly-based patterns. The Security assurance platform will be used as a basis for developing the activity and intervention monitoring capabilities of *SMART BEAR*.
Indoor Localization Tools (UOI)	7	8	The ICT expertise will be customised so that it can be exploited within *SMART BEAR* in terms of localization and assistance for the pilot applications that will be carried out in house.

1.3.3 Relevant National & International research activities

Several EU, national and international R&D projects and initiatives investigate topics relevant to *SMART BEAR*, while some of the *SMART BEAR* partners already participate in these EU projects. This will help the project to exchange experience, tools and knowledge in cyber security, IoT, activities monitoring, multi-sensor learning, analytics and other scientific areas with these projects. Table 5 lists the ones with the highest relevance, outlining relations to *SMART BEAR* and how it will progress beyond them and more details are provided in Section 4.1.

Table 5: Related EU and national projects and initiatives

Related Project	SMART BEAR Relation
EVOTION aims to enable the seamless collection of big data from all actors and related to treatment of hearing loss to inform, support, and develop hearing health care policies. This is achieved by developing a multi-stakeholder demonstrator platform that combines and analyses heterogeneous big data from clinical repositories and from patients' everyday hearing aid use and clinical treatment. **Partners involved:** UMIL, ICCS, NKUA, ATC, CITY	*SMART BEAR* will build on the EVOTION platform, used to collect data from the smart hearing aids of 1000 end users, monitored by 5 hospitals. The EVOTION's backend model-driven data analytics will be enhanced to accommodate new types of data covering additional medical conditions and frailty, and providing enhanced personalisation & user acceptance features, trialled at a large scale (5.100 end users), with a more comprehensive impact evaluation and special consideration for the sustainability of the platform.
TOREADOR takes a model-based BDA-as-a-service providing models of the entire Big Data analysis process and of its artefact which are open and suitable for standardisation, supporting substantial automation and commoditisation of Big Data analytics, while enabling it to be easily tailored to domain-specific customer requirements. **Partners involved**: UMIL, CITY	SMART BEAR will incorporate TOREADOR's model-based BDA-as-a-service (MBDAaaS) approach , in regards to standardization, so that SMART BEAR can be easily tailored to the senior citizens specific requirements. The architectural framework and set of components for model-driven set-up and management of Big Data analytics processes will be a valuable tool for SMART BEAR.
I-BIDaaS aims to empower users to utilize and interact with big data technologies by designing and demonstrating a framework that increases the speed of data analysis. **Partners involved:** FORTH, IBM, ATPS	*SMART BEAR* will integrate the expertise gained from the integration of the various data processing modules of the **I-BiDaaS** platform, and the exploitation and processing of heterogeneous data sources architecture and workflow.
SNSECog aims to improve mental well-being for elderly Europeans with sensory impairment. **Partners involved:** NKUA	*SMART BEAR* aims to incorporate interferences at personal level in order to improve the quality of living and the mental of elderly with chronic diseases in a non-obtrusive way.
EMBALANCE aims to develop a data repository and decision support system (incorporating data mining) for the diagnosis of human balance problems. **Partners involved:** NKUA**,** ICCS	*SMART BEAR* will deal with seniors' specific needs for living independently at home related to cognitive decline, cardiovascular risk, hearing loss and balance disorders, integrating data analytics, monitoring systems and feedback capabilities
HOLOBALANCE aims to deliver a radically new cost-effective virtual coach, consisting of a hologram based surrogate balance physiotherapist, an augmented reality cognitive game, combined with auditory exercises and a physical activity planner. **Partners involved:** UOI**,** NKUA, ICCS, STS	*SMART BEAR* will exploit the expertise gained on monitoring and coaching of Postural Impairment to provide targeted intervention via the HoloKit to elderly which exhibit balance deterioration.
ACTOVAGE objective is to enable the deployment and operation at large scale of Active & Healthy Ageing IoT based solutions and services, supporting and extending the independent living of older adults in their living environments, and responding to real needs of caregivers, service providers and public authorities. **Partners involved:** ATOS	*SMART BEAR* will capitalize on the background knowledge and outcomes of the aforementioned project regarding the IoT based solutions and services, supporting and extending the independent living of elderly in their environments, the reuse and scale up open and proprietary IoT platforms, technologies and standards and the new developed interfaces providing interoperability across heterogeneous IoT platforms.
CEATE-IoT objective is to stimulate collaboration between IoT initiatives, foster the take up of IoT in Europe and support the development and growth of IoT ecosystems based on open technologies and platforms. **Partners involved:** ATOS	*SMART BEAR* will receive feedback from Create-IoT regarding the technological and validation issues of common interest across the various application domains and use cases. It will also capitalize on the provides tools to ensure consistency and linkages between different IoT LSPs.

ALFRED allows older people to live longer at their own homes with the possibility to act independently and participate in society by providing the technological foundation. **Partners involved:** ATOS	*SMART BEAR* will take input from ALFRED project as far as it concerns the interventions provided for social inclusion, personalized care, physical activity and cognitive impairments prevention.
LISTEN central objective is to design and implement a complete system, including both the software and hardware components, enabling robust hands-free large-vocabulary voice-based access in smart homes. **Partners involved:** FORTH	*SMART BEAR* will exploit the developed voice recognition software for the envisaged communication with the elder adults through the *SMART BEAR* apps to control the provided actuators.

Other relevant National and International Research Activities that must be highlighted include the *ORCATECH Life Laboratory* which is a resource used to explore technologies to support independent living, to assess new behavioral markers, and to evaluate approaches for assessing neurological and other relevant health changes, all in the participant's home. *Lab-of-Things (LoT) by Microsoft Research* is a computing platform that makes predictive decisions about the home environment or resident's health status. This platform utilizes an operating system named HomeOS for monitoring, managing, and controlling all interconnected devices that exist in homes. It also analyzes information that are collected from the sensors. *SPHERE (Sensor Platform for Healthcare in a Residential Environment)* is *a*n EPSRC-funded interdisciplinary research project with collaboration of research teams from the Univ. of Bristol, Univ. Reading and Univ. of Southampton, that regards the development of a smart home platform of non-medical networked sensors. These sensors can gather and integrate various types of data about the home environment, including behaviors of home's residents in order to further understand a variety of healthcare needs.

1.3.4 Evaluation framework: The *SMART BEAR* Pilots

To achieve its goal, *SMART BEAR* will implement an e-health monitoring system, through state of the art technologies for the continuous medical and environment sensing, assistive technologies, and big data analytics, to enable healthy and independent living for the elderly. **Five large-scale pilots, spanning six different countries** (Greece, Italy, Portugal, France, Spain, Romania), will be used to demonstrate project achievements. Given the scale of the pilots and each country's specificities, each pilot will be driven by a dedicated Work Package (WP7-WP11). A detailed protocol will be defined in the early stages of the project (WP12, Task 12.1), which will be followed by all pilots.

1.3.4.1 *Pilot Phases*

Piloting will be conducted in four phases detailed in the subsections below.

1.3.4.1.1 *Phase 1 - Pre–Recruitment and screening phase*

With a recruitment target of 1,000 participants per pilot, special consideration will be given to the recruitment procedures so as to achieve this target. Initially, a series of events will be organized in the regions where the pilots will be conducted, to increase awareness of chronic diseases (HL, CVDs, CIs, MH and BD). These events will also include activities pertinent to public health issues, e.g. chronicity of diseases, self-monitoring, new developments, etc. These open days will aim to identify potential participants. During these actions medical information will be presented in a manner easily understood by the general public and the target groups will be informed about the project aims.
Inclusion criteria are: (a) Age 67-80, (b) willingness to participate in the study, (c) history of at least two of the following conditions: Hypertension, coronary disease, heart failure, hearing loss, balance disorders, postural impairment, vestibular disorders, depression, anxiety disorder, (d) willingness to receive an initial set up visit and follow up visits at home, (e) adequate cognitive function (Montreal Cognitive Assessment score>18), (f) adequate mobility based on the validated and universally used Health Utility Index (HUI3) [32].
A brief, structured screening questionnaire will be filled in by potential participants. The questionnaire will automatically suggest inclusion/exclusion of participants, but the final decision will be taken by the pilot clinicians. Data collected in these questionnaires will be stored in line with current GDPR recommendations.
Other ways to recruit participants include, but are not be limited to, direct contact of citizens affiliated in Open Day Centers, Help at Home Programs, Municipality Outpatient Clinics and Social Support Services, where the personnel promoting the study have established relationships of trust, and thus we expect increased recruitment rates. Of course, these personnel will not be involved in the recruitment procedures per se, only its promotion.
Moreover, leaflets and advertising materials will be given out in the outpatient clinics of the involved healthcare organisations as well as local hospital and Primary Health Care centers.
Relevant links advertising the project to potential participants and their significant others will be posted in the social media accounts of ***SMART BEAR* ambassadors**, i.e., popular personalities (actors, singers, athletes) with hundreds of thousands of followers cumulatively – a practice with very good results in past similar projects. In all cases, potential participants will fill in the pre-screening questionnaire, either physically (in the cases of the Municipality Centers and Social Programs) or online after signing an online informed consent according to GDPR regulations.
Questionnaires will categorize sources of potential participants, map geodemographical data, and assess relevant KPIs by considering (a) the number of events organized prior to the main recruitment period, (b) the percentage of

citizens who sign the initial informed consent and provide data for the initial questionnaire, (c) the percentage of them who are eligible for the pilot, and (d) the percentage of them who enter the study.

1.3.4.1.2 *Phase 2 – Recruitment*

Recruitment will take place at local level, in the facilities of the organizations involved. Potential participants deemed eligible in the pre-recruitment phase will be contacted and be invited at recruitment days, organised by clinical personnel (doctors, nurses, social workers) involved in the project.

A presentation of the project (participant obligations and their expected benefits, data management and safety, duration of the study etc.) will take place and a detailed information leaflet will be handed out, giving potential participants enough the time to read it and ask questions. Subsequently, individual bilateral meetings will be held, for potential participants to resolve any further questions. Practical issues, timelines and obligations will be explained. It will also be made clear that participants can leave the pilot at any time, without having to provide any explanation and without any effect to their medical care or to the relationship with the social supportive structures (e.g., municipality programs for Elderly). Moreover, a set of questions on the inclusion and exclusion criteria will be presented, to validate the pre-screening questionnaire outcome. Authorized personnel may make extra questions to validate potential areas of uncertainty, before deciding if an individual is suitable to participate in the project or not.

For those who sign the informed consent, an extended medical history questionnaire will be filled in by the responsible clinicians. Information will be recorded in structured e-forms and contain detailed medical history, medication used, specific history about the medical entities targeted, dietary and life style habits, smoking history, history of falls and near fall incidents, history of hospitalization and contact with health care services. A baseline clinical assessment will also be conducted, especially on hearing, frailty, and postural impairment.

Participants who have declared hearing loss will undergo pure tone audiometry, to decide whether to fit them with a hearing aid. Hearing aid fitting for up to 200 patients will take place in the most appropriate setting for each Pilot setup.

For postural disorders and frailty, the assessment will include a specific history and where indicated by the history a clinical assessment with the Functional Gait Assessment [33]– a functional trial of universal acceptance and relatively brief duration (<10 min), evaluating ten different tasks to establish the risk of falls.

The assessment will also contain an evaluation of cognitive function through Montreal Cognitive Assessment (MOCA) and Mini Mental Questionnaire, of frailty with FRAIL questionnaire [34], of hearing with the Hearing Handicap Inventory for Adults, of depression with the Geriatric Depression Scale (GDS), and of overall quality of life with the EQ-5D questionnaire. Finally, patients will be informed about the levels of notification (personal, significant others, directly to health care services in case of acute potentially life-threatening diseases), and be asked to nominate the person(s) who they consider as their significant others, and select from a suggested list of events, incident and threats that should trigger notifications to them. Informed consent by the significant others will be obtained as well. The same (choice out of a suggested list) will be performed about acute situations, as these are defined by the medical team of the project. The patients will have the right to exclude some or all situations, although it will be highlighted to them that this is not considered safe.

1.3.4.1.3 *Phase 3 – Pilot & Interventions*

Participants, after signing the informed consent will be given an appointment with the technical support team. The team will visit their houses, install the equipment, explain its use, ensure safety, explain what is expected by the participants, go through the relevant interfaces, establish Internet & WiFi connectivity, resolve all questions, provide contact details and explain the time plan and the expected outcome. This visit will be planned to last 6 hours in order to ensure that all issues have been resolved.

Patients will have to state whether any significant others and/or the primary healthcare physician will be notified for the recording findings, however this will be optional and, in any case, informing the participants will be obligatory. Notifications will be divided in four different categories:

1. The first category are summaries of the findings in the form of a report. It will be automatically produced and will be sent to the patient in weekly or monthly basis, subject to their preference.
2. The second category are intervention notifications, e.g., suggesting times to open windows based on air pollution, motivation messages to conduct some physical activity to meet week targets, or suggestions for a healthy meal.
3. The third category are suggestions about contacting healthcare services. These might be either acute, when sensors detect potentially dangerous conditions or not acute. In the latter case, the platform will automatically extract some data, encouraging participants to point them out during their next visit to their physician, or even arranging appointments in the light of these findings, if deemed necessary. This decision will be made by the participant.
4. The fourth category are invitations to participate in serious games, i.e., self-assessment tests targeting the improvement of identified deficiencies, like conducting balance physiotherapy exercises for patients at risk of falls or the digit recall memory game to reduce risk of memory loss.

Each participant will remain in the study for 12 months, during which their three planned follow up visits will take place, to resolve any technical issues and obtain their views on SMART BEAR through a structured questionnaire.

1.3.4.1.4 *Phase 4 – Evaluation*

Evaluation is the final pilot stage, taking place within the individual pilot environments initially. An initial list of outcomes and metrics are shown in Table 6, to be finalized in Task 12.1 and validated by Pilot and Cross-Pilot Evaluation Reports (D8.1-D8.4, D9.1-D9.4, D10.1-D10.4 and D11.1-D11.1). The pilot-specific evaluations will be iterative, happening at M26, M32, M39 and, finally, at M45. An extended cross-evaluation will also take place (in the context of WP12), to compare outcome measures across countries and identify patterns of subgroups across countries. These will take place at M28, M38, and, finally, at M48. This cross-pilot evaluation of the *SMART BEAR* solution will consider technical aspects (T12.2), the platform's effect in improving the Healthy, Independent ageing and Well-being of the end users (T12.3), the legal & business aspects (T12.4), and the interoperability and impact of the platform in the context of EC's Digital Platforms/Pilots Horizontal Activities (T12.5).

Table 6. Indicative list of SMART BEAR Pilots' monitored KPIs

Feature addressed	Metric	KPI
Everyday life was hindered by platform?	Structured Questionnaire filled by the participant	No or minimum effect
Connectivity	Connectivity Records	No loss of connectivity
Usability (easiness to use wearables, apps, etc.)	System Usability Scales filled by the participant	High
Diet	Records of daily nutrition diary	Improvement of food quality; Fat, glucose, and salt restriction
Physical Activity	Fitness watch app, duration, intensity and type of physical activity	Goals set by guidelines, adapted per medical entity
Cognitive function	Validated Questionnaires (MOCA, Mini Mental test), Memory games (digit recall test), reasoning games (pattern recognition)	Improvement in tests
Balance, tendency to fall	Functional Gait Assessment, number of falls	Improvement in FGA, decrease in number of falls
Hearing Handicap	HHI for adults, Glasgow Hearing Aid Benefit Profile (if fitted w hearing aid)	Improvement
Frailty	Weight, FRAIL questionnaire	Weight increase, improve in FRAIL questionnaire.
Mental Health	GDA, M.I.N.I. Mental test, etc.	Improvement
Overall Quality of Life	EQ5D, HUI3	Improvement
Compliance	Number of notifications whose suggestions were adhered to.	More than 80%
Contact with health care services	Number of visits, number of remote contacts with family doctor or other facilities. Structured questionnaire will be used. Attempt to compare data from electronic patient files will be made.	Decrease in healthcare use
Acute events and incidents correlated or not with targeted incidents (e.g., falls, hypertensive crisis, strokes, cardiac infraction)	Dedicated questionnaire, medical file if possible	Contribution to prevention/assessment by the platform
Evaluation of platform contribution by health care providers	Questionnaire for family doctors to evaluate reliability and usefulness of medical data provided by the platform and compliance of participants	Overall satisfaction, evaluation of most useful parameters, improvement suggestions
Subjective well-being (affection levels, behavioral confirmation, status, comfort & stimulation); Empirical validation of wellbeing.	Gallup-Healthways Well-being 5, SPL-IL scale	Improvement in scores
Emotional well-being (measure of subjective quality of life and, despite its positive wording, as a screen for depression)	WHO-5 Well-Being Index.	Improvement in WHO-5 Well-being Index

1.3.4.2 *Management of Dropouts*

A certain dropout rate is expected, as in any relevant project, and can be as high as 15%, although in a similar project with 6 *SMART BEAR* consortium members (EVOTION) drop-out rates were less than 3%. In case of dropouts, a special recruitment phase to cover the required number of participants will be allowed. This has already been taken into account in the timeline of the project. Moreover, when a participant drops out in the first 6 months of their participation, equipment will be returned and be given to a replacing participant.

1.3.4.3 *Targeted Pilots Environments*

The subsections below provide more details on the individual piloting environments of *SMART BEAR*..

1.3.4.3.1 *Pilot 1 – Greece*

Pilot Lead: MPF, **Technical Support:** ATC, **Clinical Lead:** NKUA, **Other Partners Involved:** ROP, ICCS

Areas Covered: The Greek pilot will run in two regions with different characteristics in order to evaluate the efficiency of SMARBEAR solution in as many social cum socioeconomic conditions as possible. These will be the Municipality of Palaio Faliro (MPF; a metropolitan area with an estimate of approximately 10.000 people being over 65 years of age) and the Region of Peloponese (ROP; a rural area with a significant portion of elderly population). ROP is a public state authority, supervises the delivery of health and social care services (for which responsible are the municipalities) to the citizens in collaboration with the Greek Ministry of Health and Social Services. SMARTBEAR will benefit from this diversity as we will be able to collect and evaluate data coming from all of them.

Delivered Services: Nutrition and Physical Activity department; Municipal Surgeries; Social Welfare; Blood Bank; Education and School Subsistence; Financially deprived support; Open Day Care Centres for the Elderly; Centre for Mental Health (under the auspices and supervision of the Psychiatric Hospital of Attica "Dromokaiteio")

Delivered Services: Nutrition and Physical Activity department; Municipal Surgeries; Social Welfare; Blood Bank; Education and School Subsistence; Financially deprived support; Open Day Care Centres for the Elderly; Centre for Mental Health (under the auspices and supervision of the Psychiatric Hospital of Attica "Dromokaiteio")
Region of Peloponnese: One of the 13 Peripheries of Greece covering the area of Peloponnese apart from Achaia region. According to Kallikratis legislative framework, the periphery of Peloponnese as a Public state authority, supervises the delivery of health and social care services (for which responsible are the municipalities) to the citizens in collaboration with the Greek Ministry of Health and Social Services.

Peloponnese, is characterised with a diversity of landscapes ranging from urban areas to remote and isolated areas on the mountains. SMARTBEAR will benefit from this diversity as we will be able to collect and evaluate data coming from all of them.

Population Data: Greek participants will recruit in total approximately 1000 people.
MPF: Out of a total population of approximately 10.000 (for the 65+) almost 6.000 are enlisted in the municipality's services for the elderly, mainly the Open Day Care Centres (KAPH in Greek). MPF currently operates 3 centres but from the 1st of January 2019 a fourth centre will open its gates to welcome the members of the community. Pre-recruitment as well as recruitment phase will take place in the KAPH premises, recruiting 700 participants

ROP: A detailed and thorough localisation of recruitment plan for the area of 15.490 klm2 will be done, in order to ensure the most efficient distribution of these 300 SMARTBEAR participants. The total population of the area is 577.903 (2011 census) with a higher percentage for the 65+ reaching approximately 20%.

Population Clinical Profile: The sites of both MPF and the Region of Peloponnese target the same conditions as these are considered belonging to the highest prevalence ones amongst elderly population: Balance disorders – aiming at falls prevention; Hearing Loss; Cardiovascular diseases (ischaemic heart disease, hypertension); Mental issues (depression and anxiety); Cognitive Impairment (mild levels)

1.3.4.3.2 *Pilot 2 – Italy-Portugal*

Pilot Lead: UMIL, **Technical Support:** LISPA, FCSR, NOVA, **Clinical Lead:** UMIL, **Other Partners Involved**: CNR, CSC, SRS

Partners cover two countries, Italy and Portugal. In Italy, both **rural** and urban **territories** in Lombardy, so as not to restrict the sampling of this pilot to a single geographical area. Two areas are covered by the pilot: the **metropolitan area of Milan** (8.2 million habitants over an area of about 13,000 km^2) and the **District of Crema** (150.000 habitants over an area of about 573 km^2). The two areas are very different because of their extension, environmental conditions, urban services, and population. In Portugal, the area covered is the Portuguese Madeira **archipelago**.

The organizational structure of the Italian-Portuguese pilot is composed of four pillars: **(i) LISPA** is in charge of the **technical coordination** of the Pilot, i.e. managing the internal communication, defining guidelines for the procedures to be followed; handling procurement of the material and the setup of a help-desk for supporting the clinical operators working with the recruited patients. Moreover, LISPA, as an ICT service provider for the regional health care system, will activate all the appropriate channels to reach all the stakeholders related to the Pilot activities and to disseminate the results in the Italian context; it will be supported by **NOVA**, which has recognized research and development results on big data, interoperability of systems and applications, trusted digital solutions and cyber physical in IoT solutions; **(ii) UMIL** is in charge of the **scientific coordination** of the Pilot, supported by **CNR**, i.e. training the clinical and technical staff on the use of the smart devices and the project infrastructure; controlling the data acquisition process to verify that the **data quality** is high; verifying possible improvements in the data acquisition procedures; analysing collected data in coordination with the project and the clinical staff; **(iii) FCSR** is in charge of the **engineering aspects** of the pilot to define the project solution/service by involving field experts (clinicians, bioengineers, researchers, etc.) and final end users (+65). FCSR will, for example, support the **requirement elicitation** stage, the deployment of the *SMART BEAR @* Home Hub, the **testing** of the solution in a controlled environment, the monitoring and the validation of results in coordination with UMIL; the linked third party OSR will be involved in the activities by supporting the FCSR team in the design of the clinical requirements as well as to analyse the results

of piloting activities. **(iv) UMIL and CSC** will **recruit patients** involved in their health care services and assist them during the implementation of the experimental monitoring in Italy; **SRS** will recruit patients and assist them in Portugal.

Population Clinical Profile Dependent persons, in frailty, with pathologies in progress, or assisted at home: 65-year-old patients with pluri-pathologies (in the first half of 2018, the elderly assisted, from the ADI service, were 919 with a decent percentage in care for 2/3 years.); adult patients who, due to clinical-functional problems, are considered equivalent to elderly subjects (180 patients in the first half of 2018). The most prevalent pathologies of the elderly assisted by ADI are: malnutrition, diabetes mellitus, dementia, Parkinson's disease, chronic ischemic heart disease, COPD, fracture outcomes, stroke and cerebral outcomes. In young and adult patients: stroke outcomes, ALS, MS. Almost all assisted subjects are affected by two or more pathologies. In the District of Crema an estimated 4,900 dependent people over 65, only 16% supported by the national service. There is frailty due to diseases, conditions of loneliness, or families unable to cope with the need for assistance. It is necessary to improve the effectiveness of home-care action, focusing on strengthening the functions and assessment skills in the various phases (reception, drafting of the individual project, adherence to the protocol, monitoring). Focus on a greater diversification/articulation of the service, both in terms of the skills offered (educational, therapeutic employment) and the type of user reached. Improving the monitoring capability of delivered action can significantly support a redesign of the service.

Delivered Services: Territorial Service, Assistenza Domiciliare Integrata (ADI), integrated home care and social-health interventions at home; U.U.O.O. of Neuromotor Rehabilitation, Cardiology and Respiratory Hospital of Rivolta (Protected resignation to domicile)

Approach: Planning of health and social-health interventions at home after multi-dimensional evaluation (Inter RAI Home Care) and definition of personalized project (PAI). The professionals involved are: doctors, nurses, rehabilitation therapists, educators, socio-health workers (OSS) and socio-health auxiliaries (ASA). Home care pathways consisting of the organized set of medical, rehabilitative, nursing and nursing assistance necessary to stabilize the clinical picture, limit functional decline and improve quality of life. These interventions are integrated with social assistance and family support services and professional protection for the person.

1.3.4.3.3 *Pilot 3 – France*

Pilot Lead: CATEL, **Technical Support:** SV, **Clinical Lead:** CATEL, **Other Partners:** none

Areas Covered: CATEL will chose representatives areas in France to address a large number and different kind of elderly people. Two regions are considered as possible and interesting experimentation areas: (i) Ile-de-France (the Paris Region), the area with the largest number of elderly people (and thus, of dependant elderly people); (ii) Nouvelle Aquitaine (particularly the "Creuse" department), the region where the population is the oldest, and where many innovative e-health programs and projects are developed for elderly people and (iii) Bretagne, where the elderly people are the healthiest, and which is an innovative and dynamic region in the e-health field.

Population Data: In 2015, 879,000 people (27% of the total population) were 60 years old and over in **Bretagne**, 95% living at home. Their life expectancy was 0.4 year under the national average age. The elderly population could reach 1.4M people in 2050. Bretagne is an innovative and dynamic region, with a strong interest for new technologies. It is both a rural and urban region, with middle size cities and several isolated islands. In 2014, there were 1,692,000 people (29% of the population) over 60 years old in **Nouvelle Aquitaine**, one of the oldest populations in France. By 2050, the number of people over 75 years old should double. The care organization for dependant elderly people is consequently a major issue in that region. **Ile-de-France** is the area with both the largest number of elderly people and the largest number of dependant elderly people. This is a very dense urbanized area with easy access to internet and facilities. (source: figures issued from Insee reports available on https://www.insee.fr/fr/accueil)

Population Clinical Profile: Possible relevant orientations that can be led: (i) prevention and well-being; (ii) patient orientation and pathway in the health system; and (iii) patient care and monitoring.

Targeted users: Depend/Independent elderly users living at home (+65 years old): prevent isolation, reassure and ensure a better health monitoring to avoid a premature retirement home placement; Seniors (+65 years old) living in a remote area (medical desert): reduce feelings of isolation and monitor chronic diseases; Seniors (+65 years) living in collective structures such as senior residences: reassure, prevent and ensure a better health monitoring

Major uses: Chronicle disease monitoring (heart and breath insufficiency, diabetes, etc.): A study showed that French seniors tend to favour devices measuring heart rate and blood pressure; Facilitate home support on a daily basis with remote assistance: medication recall (electronic pillbox), fall detection sensors, geolocation of objects or people; Encouraging the practice of physical activities by monitoring progress

Possible connected tools used in the frame of the experiences: Connected tablets, high-tech patient calls, light paths, bio-medical sensors, geolocating tools, all-in-one diagnostic support armchair

French seniors versus connected objects: *"Older French seniors (aged 70 and over) are as concerned about connected objects as younger seniors (50-60 years old). Nearly 1/3 of 50+ have already used connected objects. They seem to find a real added value since 81% always use them. A very high score that says their satisfaction "[35]*

"84% of French seniors want to communicate the results directly to their doctor. 68% of them would apply to him to choose a connected object."

1.3.4.3.4 *Pilot 4 – Spain*

Pilot Lead: QUIRON, **Technical Support**: INV, **Clinical Lead:** QUIRON, **Other Partners Involved:** EHU/UPV

Aging profile: Number of people over 64 years old for every 100 children under 16 years of age: 39.5 at 1980, 103.3 at 2000 and 118.4 at 2017 (*source: Adecco Foundation*).

Areas Covered: Demographic projections by INE (Instituto Nacional de Estadistica) explained in the proposal are confirmed by the number of older people (more than 65 years-old) in Spain which currently is near 19% of the total population and it seems that will be more than the 30% in 2050. There are also some more pessimistic estimations from United Nations that states Spain as the oldest population country in the world in 2050 (Population Ageing and Development 2009: www.unpopulation.org). The repercussions of the aging process on the active Spanish population are of such magnitude that they could not be offset by increased activity rates or the later retirement age only. None of the measures on their own would compensate this problematic decrease of the active population. Furthermore, there is very big support from Spanish public administrations on silver economy and active ageing with even an investment plan with the creation of the Nagusi Intelligence Center, NIC, a center that will turn the challenge of the aging population into an opportunity to develop a new sector of activity and employment, the Silver Economy, that responds to the needs of the elderly. There are three main challenges for the NIC: to have professionals with specific training oriented to aging, especially in bioengineering and medical technology; generate new technologies at the service of the elderly, that improve their quality of life, which is aligned to *SMART BEAR* Project; and create a big data platform that transforms the data stored by administrations into knowledge to better serve people, always guaranteeing privacy and security.

Population Data: In 2018, the population over the age of 65 in Spain was 19.3%, including regions as the Basque Country which is above these numbers with the 22.4% or Madrid region that has increased its elderly population in more around 4% in the last ten years (an increase of more than 260,000 people over 65 years old). In comparison with Europe, only Italy has higher figures than the Basque Country, by barely three tenths; 10 years ago, the proportion in the Basque Country was more than 3 percentage points below. 83 municipalities exceed the average percentage of the Basque Country, whilst 168 presented the same or a lower percentage. Amongst those that exceed it are Bilbao, Donostia-San Sebastián and Barakaldo. Over the course of the last ten years, the proportion of people aged over 65 decreased in 76 municipalities, even though they only make up 3.4% of the total population. For older age groups, people aged 85 and above went from 2.1% of the total population in 2007 to 3.7% of the total population in 2017, which is an increase of 1.6 percentage points over those 10 years. This process has been very dramatic for the centenarian population, with a rise in the number of centenarians from 341 in 2007 to 624 ten years later, which is almost double. In the Autonomous Community of the Basque Country, there was a ratio of 1.5 people aged 65 or more to every person under 16, exceeding the ratio for Spain as a whole, which is 1.2, but still far from the ratio in Asturias, which is 2.1.*(source: EUSTAT, Basque Institute of Statistiques)*

Population Clinical Profile: Possible orientations: (i) prevention and well-being; (ii) patient orientation and pathway in the health system; (iii) patient care and monitoring; and (iv) active and independent living support and orientation.

Targeted users: Independent elderly users living at home (+65 years old): prevent isolation, reassure and ensure a better health monitoring to avoid a premature retirement home placement; Seniors (+65 years old) living in rural areas (medical desert): reduce feelings of isolation and monitor chronic diseases; Seniors (+65 years) living in collective structures such as senior residences: reassure, prevent and ensure a better health monitoring;

Major uses: Chronicle disease monitoring (heart and breath insufficiency, diabetes, etc.); Facilitate home support on a daily basis with remote assistance: medication recall (electronic pillbox), fall detection sensors, geolocation of objects or people, activity monitoring; Encouraging the practice of physical activities by monitoring progress and encouraging participation in social/ group activities

Possible connected tools used in the frame of the experiences: Connected tablets, mobile devices, high-tech patient calls, bio-medical sensors, geolocating tools, fitness trackers, smart watches, IoT home sensors

Other data: In Spain there are different initiatives aimed at the population over 65 years old, such as the Basque Strategy for Active Aging, the Euskadi Lagunkoia initiative to promote friendly municipalities for the elderly, the forms of Governance for people over 65 years of age or the public service of Beti On teleassistance used by more than 42 thousand elderly people who use an emergency button-device to contact an incident tracking team avoiding critical situations. Regarding the Active Aging index, or comparative measurement between countries about the potential of the elderly to have an active and healthy aging and that measures the independent level of life that elderly

people have, their participation in paid work and in activities social, Euskadi ranks seventh among countries and states of Europe. Euskadi occupies the second position after Sweden and followed by Denmark in active aging capacity – a concept defined by the World Health Organization (WHO) as the process of optimization of health, participation and security opportunities, to improve the quality of life as people get older.

1.3.4.3.5 *Pilot 5 – Romania*

Pilot Lead: ANA**, Technical Support:** ITSS**, Clinical Lead:** ANA**, Other Partners:** National Society of GP's (snmf.ro); Association of GP's Bucharest (amf-b.ro): General Directorate for Social Assistance Bucharest (dgas.ro)

Number of people over 65 years old for every 100 children under 15 years of age is on average 115 [36]
Areas Covered: ANA will select the participants to the Romanian pilot mainly from Bucharest, the capital of Romania. The recruitment of participants will be achieved both directly from the database of existing patients of ANA and indirectly through the network of GPs and specialists that were trained by ANA during the large medical educational project held between 2010-2013. Also, the project concept will be shared with both the National Society and the local Association of the GPs from Bucharest. Furthermore, it will be shared with the local municipality of Bucharest for extended recruitment (we collaborated with them in the AAL projects which require the participation of seniors for ICT driven solutions). Other cities that could be chosen in order to ease the selection of testing patients, and/or to match with clinical testing objectives are Cluj-Napoca, Timisoara and Constanta.

Population Data: Population of Bucharest on 2018/1/1 was 2,113,483 people, of which 17% were over 65 (359,182). Bucharest is the area with both the largest number of elderly people (3 times higher than in any other administrative region of the country), and the largest number of dependant elderly people. This is a very dense urbanized area with easy access to internet and facilities. Also, the adoption of new technologies has increased significantly in the last 4-5 years; this is reflected in the usage of smartphones that was about 22% from people at 55+ years old in 2016.

Population Clinical Profile: Possible relevant orientations that can be led: (i) prevention and well-being; (ii) patient orientation and pathway in the health system; and (iii) patient care and monitoring.

Targeted users: Independent/Dependent elderly users living at home (+65 years old): prevent isolation, reassure and ensure a better health monitoring to avoid a premature retirement home placement; Elderly seniors (+65 years) living in collective structures such as senior residences: reassure, prevent and ensure a better health monitoring.

Major uses: Chronic disease monitoring (heart and breath insufficiency, diabetes); facilitate home support on a daily basis with remote assistance: medication recall (electronic pillbox), fall detection sensors, geolocation of objects or people; Encouraging the practice of physical activities by monitoring progress

Possible connected tools used in the frame of the experiences: Connected tablets, high-tech patient calls, light paths, bio-medical sensors, geolocating tools, all-in-one diagnostic support armchair

Other aspects: One important aspect to address is the motivation of the participants to join the trials and to stay committed for the whole 12 months' length of the pilot. The incentive of keeping the devices after the closing of the pilots is significant; however, it might make sense to have additional incentives. Also, it should be noted that, unfortunately, the Romanian healthcare system has been ranked almost the lowest in 2017 in terms of EHCI (European Healthcare Consumer Index), for parameters such as: respecting the patient rights and informing them, accessibility to treatment (waiting time), results of treatments, range of medical services offered, preventive measures and pharmaceuticals. Under these circumstances using innovative ICT technologies might help improve significantly the area of preventive interventions. We have seen in some of our AAL projects that the solutions developed were received with interest both by the elderly and by the representatives of municipalities or private associations, once they tested them and perceived the potential benefits (despite initial attitudes being quite conservative).

1.3.5 Gender Dimension

Gender affects the risk for different conditions to appear. For example, fear of falling [37]is more frequent in female older adults than in male counterparts, even when adjusted for other known risk factors. Female gender is also a risk factor for late-life depression [38]and older women also rate self-report health complaints significantly higher than men and report a lower health related quality of life [43]. It is believed that women may experience more balance problems and a higher risk of injury from falling compared to men due to poorer lower limb strength, greater difficulties performing activities of daily living and a higher osteoporosis prevalence, approximately 40% higher in older men than women after taking age into account. These differences may be noted because older men and women may vary in their behaviours, risk factors and prevalence of medical conditions and physical activities associated with postural imbalance and falls [44]. Further data are needed to investigate gender specific differences regarding the characteristics and associations of self-perceived disability and psychological sequelae in people with postural instability to identify potential gender-specific obstacles to the intervention or benefits from the intervention.

During the *SMART BEAR* project, retrospective and prospective data will be analysed for gender specific parameters in relation to the aforementioned characteristics and associations with regards to treatment outcome as well as factors

affecting outcome will be examined, to assess if interventions/commendations for overall health and well-being differ between men and women. Currently, prevention interventions are not gender based. Sex and gender analysis will be completed considering the ethical and equity impacts assessment, approaching, with a qualitative and a quantitative research tool, both the determinants of accessibility to the technology, and the determinants of social and health care costs in the two populations of potential users.

1.4 Ambition

1.4.1 State of the Art and beyond

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.

1.4.1.1 *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 [51]. As stated in [52] 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. UniversAAL[53], developed in the context of Ambient Assisting Living) or general-purpose platforms (e.g. FI-WARE [54] and the GoogleApp engine [55], 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 affect 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.

Progress beyond the state of the art: *SMART BEAR's Smart Home/IoT infrastructure adopted in SMART BEAR will enable: (a) the integration of smart objects by exploiting open source technology agnostic solutions (Homeassistant, openHab) that allow the interoperable connection of heterogeneous IoT devices, systems and technologies to the SMART BEAR ecosystem and efficient real-time data streaming; (b) 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; (c) the deployment of summarization, merging and filtering operations in real-time and at the back-end to compress the volume of data to be stored and transmitted; and (d) 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). The SMART BEAR infrastructure will be developed by using open standards and a modular design. This is necessary to ensure that the infrastructure will be able to: (a) communicate and interoperate with existing IoT platforms, either application-agnostic (e.g., FI-WARE [54], UniversAAL [53]) or vertical, exploring the suitability of e-health specific platforms (e.g. Researchdroid, ResearchStack [55]) and (b) evolve to accommodate technological changes and IoT standards that may emerge in the future. The IoT data management is divided into an online, real-time front-end that interacts directly with the interconnected IoT objects and sensors and an offline backend that handles the storage and in-depth analysis of IoT data.*

1.4.1.2 *Personalised modelling & Decision support*

Many knowledge technologies have been proposed for modelling medical procedures, processes and medical data and knowledge management [56], because medical decision support systems are in general very challenging due to their complexity and richness of the medical knowledge involved. Building a personalised decision support system, which can make diagnosis, prognosis and therapy more effective and reliable for the patient, and which is optimal in the use of medical and clinical resources, is yet an unattained goal and still presents a great challenge [57].

As far as multivariate statistical methods are concerned regarding longitudinal data, which are of main interest in *SMART-BEAR*, it is assumed that the variables are independent and that data can be modelled using linear combinations of these variables [58]. This is strongly related to the ability of those methods to cope well with conditionally

dependent variables and non-linearities of a system. These methods are broadly divided into supervised, unsupervised, semi-supervised and reinforcement learning methods [59]. The majority of the ML methods related to DSS's development is based on supervised learning: artificial neural networks (ANN), decision trees (DT), genetic algorithms (GA) and Support Vector Machines (SVM). The application of SVM to datasets allow applications to make statistical inferences at the level of the individual rather than the group of patients, which is also connected to feature selection methods are most commonly applied to eliminate noisy and irrelevant features. Furthermore, feature selection decreases the chance of overfitting and increases the chance of producing more understandable results. As clinical information acquired at baseline could be used to make individualized predictions about long-term clinical and functional outcomes in people [60]. As there are several clinical forms of disease, of which symptoms vary depending on the age and ethology, application of Case Based Fuzzy Cognitive Map (CBFCM, a cognitive process applying the main features of fuzzy logic and neural processors to situations involving imprecision and uncertain descriptions, in a similar way to intuitive human reasoning [61]) was shown to have positive results. Moreover, examples have shown in [62] [63] it can further enhance the development of a real-time data capture and personalized DSS.

Progress beyond the state of the art: *To determine interventions that not only offer the best outcome but are also seamlessly accepted by users and HCPs, the system needs to reason with uncertain knowledge to gain insights into historical data and predict future situations or to detect abnormalities in the data that may trigger further investigation. SMART-BEAR will advance the state of the art in personalized decision support by implementing abstractions summarising 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.*

1.4.1.3 *Big Data Analytics and Learning in eHealth*

Today, Big Data Analytics (BDA) are more and more made available through Cloud Platforms using an as-a-Service approach we will subsequently refer as Big Data as-a-Service (BDaaS). In fact, these infrastructures encompass the traditional task of data analytics as they extend their scope to data processing in general, including procedures such as Data Ingestion, Preparation, Transformation and Storing [50]. Research on Big Data as-a-Service (BDaaS) [65] has been tackled from four main perspectives, which vary on the degree of automation supporting the execution of a Big Data campaign: (i) *Big Data Platform-as-a-Service* considers those approaches offering support for deploying the core platform (e.g., Hadoop and Spark with interactive query services) as a service [66]. Azure and Amazon are probably the most prominent representatives of this perspective. (ii) *Performance-Oriented BDaaS* considers approaches where the deployment of a Big Data campaign is guided by optimization criteria aimed to take the computational workload under control [67][68]. (iii) *Application-Oriented BDaaS* considers those approaches where the deployment of a Big Data campaign is guided by specific business cases, including requirements on data management or analytics to be executed [65][68]. (iv) Finally, *Model-based BDaaS* is the closest line of research to the work in this projects. It considers approaches aimed to provide models for representing the different stages of a Big Data pipeline and improving the capability of verifying solutions against requirements. The high complexity and side-costs of designing, developing and deploying Big Data infrastructures suggest the adoption of model-driven approaches that foster modularity, reusability, and automatisation of design and implementation tasks. MBDAaaS [69] aims to address the above needs. Recent contribution has been developed on top of platform-specific configuration libraries. KeystoneML [70], for example, introduced an approach for large-scale pipeline optimization extending Spark ML libraries [64]. The authors focus on capturing end- to-end pipeline application characteristics that are used to automatically optimize execution at both the operator and pipeline application levels. Other works, such as [71], have focused on testing and monitoring Machine Learning going beyond error rate but focusing on system reliability, i.e., reducing technical debt, and lowering long-term maintenance cost. In addition to these aspects, a key ingredient for successfully applying big data analytics in practice, especially for applications such as healthcare interventions, is to be able to understand the concepts identified by learning algorithms and to explain the decisions that they have taken for specific inputs. This is an active area of research (see [72][73] for two recent surveys and [74] for a recent Dagstuhl seminar), with various applications [72], such as in (i) validating ML and (ii) debugging ML results [75][76] (a need identified early on even for algorithms producing decision trees [77]), (iii) knowledge extraction [73][78][79] [80][84][94], (iv) decision explanation [81][82][83], and (v) model distillation/compression [84] [85][86].

Progress beyond the state of the art: *Although the Big Data as-a-Service (BDaaS) perspectives has been considered in the literature, there is a lack of a comprehensive approach tailored to the medical conditions and intelligent interventions towards the health and well-being of individuals, as targeted by SMART BEAR. The development of such a platform is an important contribution of the project given that although several standalone systems, such as vital sign monitoring, emergency call and reminding systems are available, a fully-fledged smart home platform is still far from the reality. The expertise established by some of the partners in the consortium through relevant H2020 RIA projects (see Section 1.3.4) 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 studied by the project during the design of the SMART BEAR big data analytics. SMART*

BEAR will also apply knowledge extraction & decision exploration techniques based on our past expertise (e.g., [74][80][84][94]), to increase our confidence that the decisions made for interventions are appropriate and well-understood by HCPs.

1.4.1.4 *Personalised Human-Computer Interactions*

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 [87][1] or properly structured, time-stamped hierarchical ontologies, called episodes [88]. 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 [89] 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 system's functionality. Comparing multiple events simultaneously, the learning system is able to generalize knowledge [90] [91]. 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 [92][93]. Decisions which were useful in the past may be employed to solve current situations. Decisions which did not succeed may be avoided.

Progress beyond the state of the art: *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. 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.*

1.4.1.5 *Security, Privacy & Ethics in eHealth*

Security & Privacy mechanisms: Basic security tasks such as mutual authentication, encryption, and data integrity remain challenging in IoT. Encryption using elliptic curves and signatures have been shown to be possible on some embedded devices but not on every sensor or actuator [56]. Confidentiality and integrity protection mechanisms also require strong authentication and authorisation mechanisms. This requires assigning an identity to sensors and actuators, i.e. a sensor must store some secret to authenticate to a field device. In the past, this was, for example, solved with a second channel and user involvement [85] or using certificates [96]. However, these solutions all lack scalability and support for dynamic, unobtrusive smart environments. Concerning security and privacy at the backend, since the *SMART BEAR* application will require distribution of sensitive data and its processing, it will need to adopt new distributed and/or collaborative paradigms of cloud computing. Among the first techniques to prevent sensitive cloud information leakage is the obfuscation and anonymization of uploaded data [97]. However, these techniques affect the data and possibly render them unusable for applications. Puttaswamy et al. [98] propose a mechanism for identifying and encrypting sensitive user data, without limiting the functionality of cloud applications. Additionally, in this context, many other cryptographic techniques have been proposed for preserving data confidentiality; the approach of Craig Gentry [99] who proposed the first fully holomorphic encryption scheme, privacy preserving encryption [100] and attribute-based encryption (ABE) have been proposed for the cloud. In Liu et al. [101] a proxy re-encryption scheme based on ABE is proposed, allowing the cloud to re-encrypt user data without knowing the actual content. Such cryptographic mechanisms are used not only for protecting data in the cloud, but also as end-to-end mechanisms for protecting data in transit. However, cryptography alone cannot sufficiently preserve user privacy and that other forms of privacy enforcement must be employed [102], such as proper identity and authorization management, by specifying and enforcing security, access control, and privacy policies. Indeed, an ENISA report [103] on security and resilience of e-Health infrastructures and services (an area very relevant in the case of the *SMART BEAR* solution), identifies that access control is a very significant priority in securing applications. Among the studied authorization schemes proposed for systems with different requirements and properties, a cross-platform solution that meets the requirements of all types of embedded systems and provides interoperability is the eXtensible Access Control Markup Language (XACML [104]), the de-facto standard for specifying and evaluating access control policies [105], also supporting its extension with privacy-aware features [106]. The EU project Internet-of-Things Architecture (IoT-A) worked on the adoption of XACML in the IoT [107], while in [108], the authors utilize XACML in the context of the privacy of eHealth data within the mobile environment.

Progress beyond the state of the art: *To address security and privacy concerns, SMART-BEAR will combine novel and standardized technologies to provide lightweight and usable mechanisms for authentication of its entities (de-*

vices, applications, users etc.) and protection of their resources through strong, unambiguous and fine-grained authorization services. The XACML authorization engine will form the basis of this work, developing dynamic authorization services and providing the necessary variables (operational or situational context, as well as privacy requirements and other scenario/use case peculiarities). Privacy-aware features will be embedded into the policy definitions. Developed solutions for SMART-BEAR´s back-end security will allow the creation of secure and privacy-preserving communications within and from the SMART-BEAR cloud infrastructure to the SMART-BEAR @ Home instance, as well as the healthcare service providers in an end-to-end manner. The privacy controls will also include differential privacy and selective data obfuscation and randomisation, both for raw data and data analytics outcomes, learning and evolution processes. These efforts will also leverage/extend the access control privacy- and context-aware policies of SMART-BEAR. Moreover, via the combination of its advancements with the above guarantees and visibility of the system's status, and consequent enhanced operator control and accountability, SMART-BEAR will provide a significantly higher level of security and privacy than what is currently available in the domain.

1.4.2 Innovation potential

Beyond the advancements to the state of the art in individual technology and scientific areas indicated in Sect. 1.4.1, the overarching ground-breaking objective of *SMART BEAR* is to deliver a smart adaptive living solution that, through continuous and unobtrusive personalised monitoring, will enable intelligent interventions towards supporting the healthy and independent living of elderly people. SMART-BEAR offers great innovation potential, as it will advance the state of the art in offering personalised decision support and interventions by implementing abstractions that summarize user needs at multiple time scales and by utilizing temporal causality and reasoning algorithms that exploit the past to develop successful personalized recommendations without obstructing the ordinary daily activities of users. Also, through the algorithms of decision making, the platform will offer the ability to extract knowledge from the models built from the mining of monitoring and state data, offering the necessary interpretation ability and evidence. Some keys aspects are detailed below.

1.4.2.1 *Ground-breaking objectives, Novel concepts*

SMART BEAR will deliver a solution offering continuous and objective monitoring and interventions for precise and personalised medicine towards optimising disease and associated risks' management in order to provide measurable improvements to the Quality of Life of the elderly and their ability to live independently. The solution will integrate off-the-shelf smart consumer and medical devices to provide a Connected Health environment, and provide an affordable, user-friendly, and accountably secure and privacy-preserving service to the elderly in order to increase the efficiency of healthcare delivery and reduce resource waste. The objectives of the project have been designed in such a way so as to cover the necessary activities of this large scale project and pilot. The user centric implementation (Objective 4) of the platform will allow to build a solution that will be accepted by the users, as they will be the co-designers of it and address their preferences, proper-ties and specificities. Based on this initial user centric design, the platform will offer monitoring and sensing capabilities, in an interoperable manner, to allow extension and integration with different sensors, systems and platforms (Objective 1). The monitoring data will be analysed with state of the art data analytics and decision making techniques in order to offer personalised interventions enhancing the well-being and independent living of participants (Objective 2). The necessary privacy and security preserving controls will be implemented to cover comprehensively all the components and connections utilized by the SMART-BEAR platform. These mechanisms will be developed based on a privacy and security-by design approach, in which a thorough security analysis of the SMART-BEAR solution, considering security, privacy and regulatory compliance requirements (e.g. GDPR, NIS directive) will be applied (Objective 3). The innovation of the platform will be tested in a large pilot study via five large scale pilots, involving 5.100 participants across six EU countries (Objective 5) and finally its sustainability and impact will be measured (Objective 6).

1.4.2.2 *Relevant market leading products and services*

A smart home in order to be fully-fledged requires the integration of healthcare and monitoring systems along with a wide range of physiological and environmental sensors to a common platform, where issues related to the management of the large volume of information, interoperability, privacy and security should be appropriately addressed. Smart homes for elderly healthcare, either in the form of prototype or in the form of commercially available solutions, have been presented in the literatures and in the market, respectively. A review of these prototype and commercial solutions is presented in the work of [110] and [111]. The reported smart homes focus on different aspects of the daily living of elder people including safety, health and nutrition, physical activity, personal hygiene and care, social engagement and leisure. They address each aspect either separately or in combination of two.

Some of commercial available solutions are GreatCall, MobileHelp and Grand Care that safeguard an elderly at home and on-the-go, BeClose which keeps elderly in close contact with their family and caregivers, Care Link Advantage that tracks the activities of the elderly residing at home, identifies the areas of concern and programs the system to

generate notifications accordingly. Additionally, Independa offers communication services such as video chat, photo sharing, message and alert call between the elderly and the family members. Also, it reminds key events such as important activities of daily living (ADL), appointments with doctors, social engagements, and medication schedule.

Currently, many leading communications and media companies such as Rogers Communications [112], Bell Canada[113], AT&T [114]and British Telecom [115] are offering smart home solutions to their customers. Although these solutions offer excellent services for monitoring the safety and security and controlling the environment and the appliances of the home, they still lack comprehensive healthcare monitoring services. Some technology companies such as Philips [116], ABB [117] and Iqarus [118] are offering remote healthcare services and medical solutions. However, these solutions are primarily designed for large-scale clinical environments.

Samsung has been working to create a unified platform for elderly care solutions, designed to be interoperable with non-Samsung devices. TrueSensekits are tailored specifically to those with symptoms of common chronic conditions. The Independent Living Kit is designed to enable seniors to continue living safely in their own homes longer. Finaly, Zanthion provides services/products for senior care monitoring for those who live at home, a complete help call, fall detection, and notification system for communities of all sizes bringing the necessary services to residents.

1.4.2.3 *Sustaining Innovation*

The main innovation sustainability of SMART BEAR lays in its multidisciplinary approach which leverages on a variety of state-of-the-art technologies or methodologies such as, projective interfaces, deep learning, biosensors, to name but a few. The radically new nature, the multi-disciplinary consortium will naturally foster emerging of further innovation by hybridisation of existing approaches within new contexts with potentially very high innovation potential. Last, but not least, the constant involvement of users will ensure that any emerging innovation will be included in the context of real-life demand and response scenario, with obvious immediate benefit for the achievements of the project. The IoMT-based elderly's well-being and health enhancement Innovation value chain is enacted by an open ecosystem of small and large enterprises, pilot centres, individual inventors, research institutes and universities. Large enterprises are experimenting with a variety of schemes to stimulate and benefit from entrepreneurial activities outside their organisations. Similarly, national and European research programmes are trying out new instruments designed to encourage participation by small companies and to grow this sector of the market, namely the penetration of IoMT-based technologies in the smart and adaptive environments that support well-being and health improvement of elderly. Information gathering and analysis is still in progress, but it appears that while the general philosophy of Open Innovation is shared, there is considerable variation in how it is interpreted and applied, and a consensus on best practice has yet to emerge. SMART BEAR, through its envisioned model-driven monitoring and intervention platform, aims to foster innovation in well-being and health enhancement of the elderly at Smart Home (and also in any similar living- environments) by providing the basis towards the establishment of a well-being and health point of reference for elderly through a complete database. It will comprise thorough information about the current status (in terms of existing risks, well-being levels and health levels) in order to provide the validation and evaluation basis for any future effort of ICT-based enhancement of these levels. The envisioned platform can be directly linked to specific standards thus, building an ecosystem of large industries and small-medium entities that comprise challenging living environments in various fields of operation and on top of multiple technologies, will maximise innovation potential and may assist towards the vision of the enhancement of elderly's health and well-being.

2 Impact

2.1 Expected impacts

2.1.1 Expected Impact in reference to the work programme

EU industry and society have changed radically over the last 10-15 years, towards high productivity, stronger innovation, considerable reorientation of the workforce and the development of innovative products and services for new and emerging markets. Having faced the worst crisis since the 1930s, with a recent 4% contraction of the EURO Zone Economy, today's scientific and engineering health-based research communities are undergoing a profound transformation, with fresh thinking needed towards empowering citizens to more effectively manage their own health and diseases and to reduce the human and cost pressures on national and European healthcare. According to pillars under the European Societal Challenge strategy and targets under the Europe 2020 strategy, the *SMART-BEAR* care science approach is an important research and innovation contributor, providing the basis for significant opportunities to (i) demonstrate how the integration of established ICT-based concepts and approaches for ageing people is fit for global scale up, (ii) facilitate adoption within healthcare systems, (iii) strengthen the research of our academic community, and most importantly, (iv) benefit society and our ageing citizens through improved quality of life and significant, sustained efficiency gains in health and care delivery. *SMART-BEAR* will share its results and the technology behind them to other researchers, academic communities, and industries through an open, HL7 compatible API.

SMART BEAR addresses all the call impact criteria – the following text describes the impact of *SMART BEAR* in the short/long term, and discusses the transferability of our results to other critical sectors.

Impact expected by the call: *Emergence of European-led platform for smart and healthy and independent living at home* ***[Impact#1]***

SMART BEAR's adaptive smart-living platform for smart and healthy and independent living at home will have the following characteristics: (i) continuous monitoring of the health and well-being of the elderly and environment sensing via the incorporation of heterogeneous devices (Obj.1); (ii) data analytics, smart decision making, and interventions for intelligent and personalised interventions enhancing the well-being and independent living of participants (Obj.2); (iii) platform security, privacy, and trustworthiness (Obj.3); and (iv) user-centric platform implementation and integration (Obj.4). *SMART BEAR*'s European-led dimension is ensured by the structure of the consortium featuring key-European players of their respected fields, and the effort made to capitalize on European initiatives such as EIPAHA, AAL, etc. [**KPIs: iKPI-1** to **iKPI-18** in Table 7].

Impact expected by the call: *Increased competitiveness of the European ICT industry in the domain, through enhanced interoperability, best practices for viable business and financing models and scalable markets.* ***[Impact#2]***

SMART BEAR consortium by demonstrating and validating the use of the platform at TRL9, via five large scale pilots, involving 5.100 participants across six EU countries (Obj. 5), will increase the competitiveness not only of its members but also of the general European ICT industry in the domain, as it will serve as a catalyst for demonstrating both the feasibility and the utility of the approach to the EU health and care delivery market.

SMART BEAR development principles include open APIs and data representations aligned with existing interoperability standards. The platform will extend existing solutions for data analytics, decision making, and promote interoperability with existing smart home platforms, smart city applications, and the Copernicus European Union Earth Observation Programme (Obj. 8). [**KPIs: iKPI-1**, **iKPI-2** and **iKPI-5** in Table 7].

Impact expected by the call: *Demonstrate links and build synergies with Member States' and regional initiatives in this area.* ***[Impact#3]***

SMART BEAR's demonstration and validation itself is built around synergies within regions, countries and across Europe. Specifically, regular meetings to search for cross-business/initiatives synergies will be organized (Obj. 5). These meetings should typically include related stakeholders where synergies could be expected. Engagement in a "receiver-based communication" style, allowing stakeholders to share information about their activities, and follow up as they see appropriate [**KPIs: iKPI-1** to **iKPI-3** in Table 7].

Impact expected by the call: *Improved and evidence-based efficiency of health and care systems with demonstrated added-value of underlying technologies.* ***[Impact#4]***

The evidence for making decisions on personalised interventions will be generated through advanced data analytics and learning capabilities for large scale analysis of the comprehensive datasets collected from all pilots and participants (Obj.4). The demonstration and validation of *SMART-BEAR* involving 5.100 participants across six EU countries can deliver an advanced, evidence-based healthcare platform incorporating services based on new, open technologies that will serve as a platform diagnostic prototype. (Obj. 9) [**KPIs: iKPI-4** to **iKPI-8** in Table 7].

Impact expected by the call: *Improved quality of life and health status for involved users and carers, with demonstrated added-value of underlying technologies* ***[Impact#5]***

Improvement of quality of life and health status is obtained by developing mechanisms for the continuous monitoring of the health and well-being of the elderly via heterogeneous devices, such as: (i) assistive medical devices; (ii) body sensors; (iii) smart/virtual assistants; (iv) environmental sensors and actuators of smart homes (IoT sensors); and (v) smartphones (Obj. 1). The data analytics on the data collected along with smart decision making and interventions will enhance the well-being and independent living of participants. The customization or development of existing applications like those used for (i) screening potential participants for whom the platform will be useful, (ii) cognitive games, (iii) balance training, (iv) hearing aid management, (v) mental health profiling and monitoring, (vi) CVD risk factor assessment and correction, and (vii) social and physical activity enhancement will enable participant monitoring and delivery of the *SMART-BEAR* interventions (Obj. 2). **[KPIs: iKPI-6** to **iKPI-13** in Table 7**]**.

Impact expected by the call: *User accepted, validated innovative solutions addressing* ***accessibility, privacy****, security, vulnerability, liability, and trust in connected data spaces.* ***[Impact#6]***

SMART-BEAR will develop privacy-preserving and secure by design data handling capabilities, covering data at rest, in processing, and in transit, and all components and connections (Obj. 3), and follow a user-centric platform implementation and integration approach (Obj. 4). *SMART-BEAR* will be tested and validated through five large scale pilots, spanning six different countries and 5100 individuals. The pilots will enable evaluation in the context of healthcare service delivery by private and public providers at regional, state and European level (Obj. 5). *SMART-BEAR* will offer a real-time healthcare monitoring framework, under which key functional, quality, usability, security and privacy conditions will be fulfilled to ensure the acceptability of *SMART-BEAR* by its targeted users. *SMART-BEAR* will be built upon a security-driven design foundation, empowering it to become a standard basis for a secure and trustworthy, user-accepted healthcare solution [**KPIs: iKPI-14** to **iKPI-18** in Table 7].

2.1.1.1 *Additional Impacts*

Impact #7*: Enhancement of the trust and engagement of individuals and enterprises to critical ICT systems for connected healthcare.*

SMART BEAR contributes to the establishment of the following tools: (i) functional monitoring; (ii) physiological monitoring; (iii) behavioural monitoring; (iv) safety and risk monitoring and assistance; (v) social interaction monitoring and assistance; and (vii) cognitive/sensory assistance. The benefits from the *SMART BEAR* platform are not restricted to public and private organisations, but extend to citizens and the society at large, through the enhanced preparedness and thus increased protection of governmental, private-sector, and personal data, which strengthens citizens trust and engagement in the Healthcare sector. [**KPIs: iKPI-14** to **iKPI-18** in Table 7].

Impact #7*: Enhancement of the trust and engagement of individuals and enterprises to critical ICT systems for connected healthcare.*

SMART-BEAR contributes to the establishment of the following tools: (i) functional monitoring; (ii) physiological monitoring; (iii) behavioural monitoring; (iv) safety and risk monitoring and assistance; (v) social interaction monitoring and assistance; and (vii) cognitive/sensory assistance. The benefits from the *SMART-BEAR* platform are not restricted to public and private organisations, but extend to citizens and the society at large, through the enhanced preparedness and thus increased protection of governmental, private-sector, and personal data, which strengthens citizens trust and engagement in the Healthcare sector. [**KPIs: iKPI-14** to **iKPI-18** in Table 7].

Impact #8: *Life quality improvement, feeling of independence and safety for the citizens and professionals through advanced services in Healthcare, to be validated through 5 pilots.*

Individuals' quality of life and work will be enhanced by the secure and smooth operation of healthcare industries, essential to the economy and society. Protecting and ensuring the resilience of the critical infrastructures is essential to national security, public health and safety, economic stability, and way of life [**KPIs: iKPI-18** in Table 7].

Contribution to Impacts of DT-ICT-13-2019: Digital Platforms/Pilots Horizontal Activities

Impact #9: *SMART-BEAR will provide for "Tangible contributions from European key players to actively engage with the platform building"*

SMART-BEAR's consortium comprises key-European players such as CNR, ATOS, Philips, and IBM. Regarding the *SMART-BEAR* platform building, the corresponding tangible contributions are: Healthcare services and applications, Security Assurance, Privacy Enhancing Technologies, Machine Learning, Big Data Analytics, Internet of Things, and Decision Support System.

Impact #10: *SMART-BEAR will allow for "Efficient information sharing across the programme stakeholders for horizontal issues of common interests"*

SMART-BEAR will establish processes and criteria (privacy, security, and intellectual property) for publishing project results (data) within and outside the consortium. It will also define data quality related parameters, how data will be collected, stored, accessed, exchanged, as well as how data approved for publication can be used by others.

Impact #11: *SMART BEAR will maintain and extend an active co-system of relevant stakeholders, including start-ups and SMEs*

SMART BEAR's ecosystem consists of industrial partners as well as academic and research organizations. *SMART BEAR* participants collectively constitute a consortium capable of achieving the project objectives and the tasks assigned to them. The *SMART BEAR* consortium consists of 9 academic /research organisations and 5 end-users' sites across EU in the targeted healthcare domain. On the ICT side, *SMART BEAR* relies on a leading technology provider in the field of health-related devices (Philips) and five technology providers directly related to technologies and services required for the *SMART BEAR* platform, which by itself places *SMART BEAR* in an advantageous position for creating and maintaining an ecosystem around its approach. The dissemination actions planned will also aim to grow the number of interested parties and demonstrate to SMEs in particular how they can also link with the platform and use it to develop and commercialise their own products.

Impact #12: *SMART BEAR will validate in usage context of usability, risk and security assessment and identification of gaps related to trust, security and privacy, respect for the scarcity and vulnerability of human attention, and liability and sustainability*

SMART BEAR will demonstrate and validate its technology in real environments engaging all relevant actors (elderly, health care professionals, carers, family members, etc.), aiming to support the co-creation of the platform with all stakeholders and maximize user acceptance and trust in the system, revolutionizing consumption of digital services at home. Special emphasis will be given to security and privacy by design, offering data protection, safety, security and trust in the resulting system and service delivery inside and outside the home. All *SMART BEAR* partners have existing communication channels to ensure the project's sustainability. *SMART BEAR* will offer a real-time healthcare monitoring framework fulfilling the quality, usability, security and privacy conditions needed for the acceptance of *SMART BEAR* as a secure and trustworthy, user-accepted health and care delivery solution.

Impact #13: *SMART BEAR will strengthen the role of EU on the global scale, in particular in terms of standardisation activities and access to foreign markets*

SMART BEAR is a solution at TRL9 offering personalised monitoring and interventions to support the healthy and independent living of elderly people with five prevalent health-related conditions for that age group. The wide spreading of the pilots involved, the nature of the data acquired and their analysis leaves opportunities for *SMART BEAR* to contribute to standardisation activities. Towards this, initiatives will be undertaken targeting renewal of the CEN ISO 13606 EHR-communication standard. Contribution is also foreseen to the series of standards known as Concurrent-Use-Standards (CEN: EHR-communication, Health Information Service Architecture and System of Concepts for Continuity of Care). Health Informatics Interoperability standards will be used such as HL7 – FHIR, where contributions could be made towards special applications of non-invasive self-monitoring at home. In addition, behavioural changes identification standards related to the interaction with smart devices such as the *SMART BEAR* system will be proposed. To the consortium's best knowledge such an integrated solution is missing from the market and the potential a validated platform would have is very interesting. The quality of the consortium that ensures the success of the project constitutes a market opportunity and can establish EU as the "big player" in the domain. The project's impact will be maximised through innovation, exploitation and standardisation and through raising awareness of the project's outcomes to healthcare stakeholders, organisations and individuals, whilst pursuing links and synergies with pertinent initiatives and piloting activities, opening therefore new paths in the global market regarding *SMART BEAR*.

Table 7: The** SMART BEAR **Impact KPIs

Impact KPI ID	Description and target value	Validation
iKPI-1	Number of healthcare standards contributed by SMART BEAR. Targeted value: At least 2 standards	Reported in D13.5
iKPI-2	Number of external partnerships promoting the deployment of the final product in related markets. Targeted value: At least 2	Identified synergies and cross-collaborative side-projects. Reported in D13.5, D13.6.
iKPI-3	Number of meetings with relevant stakeholders. Targeted value: At least 6 per year	Reported in D13.6
iKPI-4	Decrease of total individualized cardiovascular risk score for users with non-established CVD as defined by the European Society of Cardiology [39] Targeted value:<5%	Outcomes of final cross-pilot evaluation reported in D12.5
iKPI-5	Increase of prospective potential of evidence-based platform agnostic technology in the healthcare industry. Targeted value: >10%	Impact assessment and outcomes of pilots-based validation as reported in D12.5, D13.5
iKPI-6	Improved percentage of adherence in prescribed medical treatment [40]. Targeted value: Increase by 20%	Outcomes of final cross-pilot evaluation reported in D12.5
iKPI-7	Decrease in patient-to-doctor visits. Targeted value: 20% fewer visits annually.	Outcomes of final cross-pilot evaluation reported in D12.5
iKPI-8	Decrease in disease related number of admittances and hospitalisation time for participants suffering from ischaemic heart disease and heart failure. Targeted value: 15%	Outcomes of final cross-pilot evaluation reported in D12.5

iKPI-9	Achievement and maintenance of hypertension treatment targets defined by the European Society of Hypertension. [41]	Outcomes of final cross-pilot evaluation reported in D12.5
iKPI-10	Achievement of increased and optimised hearing aid use through objective recordings and consequent analytics of the SMARTBEAR platform. Targeted value: 25%	Outcomes of final cross-pilot evaluation reported in D12.5
iKPI-11	Improve users' social well-being. Targeted value: >20%	Outcomes of final cross-pilot evaluation reported in D12.5
iKPI-12	Participants will meet the following WHO guideline: Older adults should do at least 150 minutes of moderate-intensity aerobic physical activity throughout the week or do at least 75 minutes of vigorous intensity aerobic physical activity throughout the week or an equivalent combination of moderate- and vigorous-intensity activity	Outcomes of pilots-based validation reported in D8.4, D9.4, D10.4, D11.1, D12.5
iKPI-13	Increase in QALY index. Targeted value: >0.5 SD (standard deviation) change [42]	Outcomes of final cross-pilot evaluation reported in D12.5
iKPI-14	Increase in user interaction satisfaction index (QUIS). Targeted value: >75	Outcomes of final cross-pilot evaluation reported in D12.5
iKPI-15	Number of presentations at scientific events. Targeted value: >20	Reported in D13.5
iKPI-16	Number of meetings with research institutions. Targeted value: >20	Reported in D13.5, D13.6
iKPI-17	Increase the degree of usability of the platform. Targeted value: >80 in SUS and >80% in TAM	System Usability Scale (SUS) questionnaire and the Technology Assessment Methodology (TAM)
iKPI-18	Faster and smarter identification of exploitable errors and data breaches in a healthcare platform. Targeted value: Number of identified errors and breaches <10%	Functional, Integrations and Penetration testing Reports, Integrity, Confidentiality and Availability, Security Assurance Reports (reported in D5.7)

2.1.2 Impact Delivery

During its execution, *SMART BEAR* will ensure it meets its ambitious objectives and achieves expected impacts with a three-stage impact assessment approach. According to it, impact assessments occur at: (1) the project level to ensure project partners deliver the required outputs to test the business case; (2) the pilot level with involved local and national stakeholders to produce outcomes that test and refine the value proposition and improve the business case for *SMART BEAR*; and (3) a European level encompassing wider society to aggregate and spread social and economic benefits that result from the business case. Of particular importance to (2) and (3) will be the engagement of the Advisory Board of the project which will involve representatives of key stakeholders, external to the consortium (see Sect. 2.2.1), and liaising with related EU initiatives (see Task 13.4).

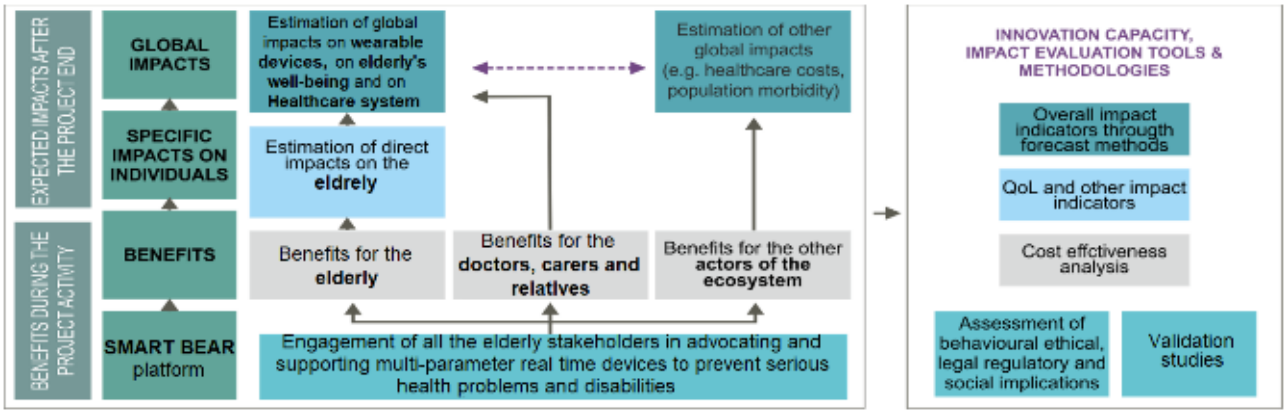

Figure 5. SMART BEAR platform Engagement

2.1.3 Barriers

Introduction of an IoT-based smart living environment supporting elderly citizens entails key Barriers.

Life Style Barriers: Elimination of modifiable risk factors including unhealthy lifestyle has the potential for prevention of 77% of HL, CVD, CI, MH and BD cases. The present study focuses on revealing reasons for maintaining specific lifestyle choices, by exploring associations between these choices and various sociodemographic and health-related characteristics.

Elderly characteristics as Barriers: They can be distinguished between individual (internal) barriers, for example socio-psychological factors and physiological characteristics, and demographic/societal (external) ones, such as infrastructure, cultural, economic, and institutional barriers. Socio-cultural Barriers refer to specific social and cultural practices, beliefs, and traditions within a community or society and how these impact on self-perceptions and the perceptions of others.

Practical Barriers refer to the physical, medical and economic obstacles to activity that individuals encounter in their daily lives. Issues such as cost, safety, access, time pressures and health issues are significant for each group (although

different groups are impacted in different ways).

Regulatory factors: Ethical and legal factors play an important role in digital health systems. Securing the privacy rights of patients will be an integral and important aspect. A task is defined in each pilot WP for ensuring ethical and security compliance while WP5 is responsible for continuous data and privacy assurance. Old people's safety and responsible clinical practice is also an important consideration. Two European Regulations, Directives and their transpositions into National laws and regulations are particularly important: (a) Privacy: the General Data Protection Regulation (EU) 2016/679, and (b) Medical devices and Patient's safety: Medical device directive legislation with extensions to software, whose new form has entered in force at the same time as the GDPR. The *SMART BEAR* project will take these regulations into consideration in the design of the *SMART BEAR* platform and data architecture and operationalisation in respect to the health environment

2.1.4 Impact in innovation capacity, competitiveness, and growth

Improvement in innovation capacity of the participants and of the consortium as a whole, is achievable by: (i) multidisciplinary (physiotherapy, clinical, data analysis, accessible user interaction, software engineering, health economics,) effort to the demanding research and innovation activities, (ii) Pilot partners participation to perform proof of concept studies, usability, user acceptance testing and validation of the platform, (iii) breakthrough idea of integrating different tools and components for supporting healthy and independent living of elderly at home. Strengthening the competitiveness and growth of companies by developing innovations meeting the needs of European and global markets; and, where relevant, by delivering such innovations to the markets. The SME partners of SMARTBEAR (STS, SV, ITSS, INV, ATB, 2B) will enhance their competitiveness and increase their market share. The direct link between research activities and outcomes to the market which is expected to lead to a competitive spin-off company that will exploit the results of the project and mainly the delivered SMARTBEAR platform and services. The CNR as the coordinator may activate research based start-up, a portfolio with numerous national and international patents, several with industrial application and a technology transfer office that continuously supports the results of research and plays an active role in the coordination and promotion of research-enterprise joint activities. Details of the exploitation intentions are provided in section 2.2.4.

2.1.5 Societal & Environmental Impact

Introduction of ICT integrated systems solutions in smart adaptive living is even more pronounced where a variety of actors at different involvement levels (elder people, health professionals, carers, municipality staff) are intrinsically involved. The primary enabling requirements for the adoption of ICT are: security, confidentiality, interoperability, scalability and standards. Subsequent fundamental requirements for the adoption of an innovative technological solution into elderly's habits are: (i) the solution is being implemented and tested within the smart-home; (ii) the solution is bringing a change in elderly's monitoring, (iii) the solution is having an impact on elderly's quality of life and ultimately health, (iv) the solution is having the capacity to transfer the experience to other organisations and systems. Those health-related ICT implementations that achieve the above fundamental requirements, in addition to assessment requirements, could scale-up to the healthcare system. Assessment requirements are related to the measure of the impact of the ICT solution. 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 policy making (Task 12.2).

2.2 Measures to maximise impact

2.2.1 External Advisory Board

SMART BEAR solutions do not only address requirements of the healthcare domain, but also smart home and, consequently, smart city domains. We feel that this will significantly increase the acceptance of novel and innovative solutions for the healthy and independent living and well-being of elderly individuals. Additionally, and External Advisory Board (EAB) will help *SMART BEAR* connect with possible adopters (e.g. healthcare organisations) 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. Sivo1apenko**, University of Patras; **Athanasios Manos**, Director PD neurotechnology; **Anastasios Tagaris**, President and Managing Director, IDIKA S.A.

2.2.2 Dissemination Plan

2.2.2.1 *Online dissemination*

The consortium intends to: set up and maintain, both throughout as well as for at least a period of two years after the project end, the project web site. This will incorporate a public area, through which public information will be disseminated (e.g. public deliverables, news, etc.), as well as a private area for the distribution of restricted information amongst the consortium members and for the management of the work to be undertaken. The consortium will also engage the utilisation of social media for the dissemination of information, and thus create Facebook, LinkedIn and Twitter accounts from where public important information will be disseminated, as well as a Wikipedia page. The consortium will also take advantage from the distribution of multimedia material through YouTube, which will include informative and demonstration videos of the *SMART BEAR* platform.

There will be a dedicated web site with *SMART BEAR* information, objectives, results, partners and events. A restricted area on the site will provide secure access to the participants and the EC only – it will host an electronic discussion forum, a project agenda and an e-library with the project's confidential management documents. Furthermore, the website will include a portal for sustained longitudinal studies and participant engagement.

Digital and social media has tremendous potential for reaching some of the targeted audiences and engaging people with the *SMART BEAR* brand. A social media grid will be drawn up that will plot the most appropriate social media channel/sites for targeting specific audiences. Appropriate pages will be designed for each channel and a content maintenance plan will be put in place for management the streaming of information across these channels to secure and maintain followers. Social and digital media will be particularly powerful in helping to create 'communities of support' for the project. The project will create interest on social media and digital platforms by using visual media, videos, animations, info-graphic imagery, and importantly, mobile enabled and richer content experiences for users.

2.2.2.2 *Scientific Publications*

Partners will disseminate the research results of the project through publications in journals and dissemination targeted conferences. A preliminary list of those prepared by the consortium is presented below:

Journals: IEEE Transactions (on Big Data, on Knowledge and Data Engineering, on Signal Processing, on Image Processing, on Intelligent Systems, on Biomedical Engineering) and other IEEE journals (Multimedia, Biomedical and Health Informatics), IEEE/ACM Transactions on Audio, Speech, and Language Processing, Cognitive Psychology, International Journal of Virtual and Augmented Reality, Multivariate Behavioural Research, Cognitive Sciences, Genomics and Bioinformatics, Behaviour Research and Therapy, International, Journal of Big Data and Analytics in Healthcare, Motivation and Emotion, Image and Vision Computing, International Journal of Big Data, Research in Organizational Behaviour, International Journal of Cloud Computing, BMC Medical Informatics and Decision Making, Springer Quality and User Experience, Contemporary Nurse, Journal of Nutrition Education and Behavior, Information Processing and Management, Multimedia Tools and Applications, Age and Ageing, International Journal of Nursing Studies, Nursing Standard, Journal of Health Services Research and Policy

Conferences: ACM Conference on Human Factors in Computing Systems, IEEE Engineering in Medicine and Biology Conference, ACM Symposium on Spatial User Interaction Biomedical and Health Informatics conference, IEEE Symposium on 3D User Interfaces, IEEE Big data congress, International Conference on Healthcare & Life-Science Research, International Conf. on Artificial Intel. Apps and Innovations, IEEE Int Conference on E-Health and Bioengineering, IEEE Conference on Quality of Multimedia Experience, ICMR/ACM International Conference on Multimedia Retrieval, ACM Conference on Human-Computer-Interaction with Mobile Devices and Services, ACM International Conference on Research and Development on Information Retrieval, International Conference on Information and Knowledge Management

2.2.2.3 *Organization of international scientific events*

We will use innovative ways, including video and digital media, to communicate the results of the project at the targeted events, conferences and seminars. The *SMART BEAR* consortium is planning to organize minimum two (2) workshops targeted to the relevant research communities, as well as the domain stakeholders. The consortium in order to target a better effect on the phase strategy is focusing also at different levels of promotion to approach the target audiences identified with an EU, international, micro-level focus. Table 8 depicts our initial plan to connect specific type of events with specific audiences and prioritize our yearly activities.

Table 8. Events and audience breakdown

What	Who	How	Evaluation
European Events	Technological & Research communities, Educational and Clinical Research communities, relevant media etc.	Networking while representing *SMART BEAR* at events, Organize or attend Workshops, Give *SMART BEAR* oriented presentations, Attendance with a roll up / exhibition	Increased awareness. Increased website visits, social media interaction Feedback received via events evaluation forms
Micro-level Events	Technology experts, educational and clinical networks, Hearing aid industry, Sensors manufacturers	Organize events at a regional level, participate in local events with a targeted presentation etc.	Concerned citizens, geographically secluded audience, local policy makers and law experts etc.
International Events	Awareness initiatives, technology experts, relevant media	Events attendance, presentation, distribution of material, representation at events.	Policy makers, software development experts etc.

2.2.2.4 *System-level demonstrations*

Demonstrations in fairs and exhibitions: *SMART BEAR* will seek to organize at least one demonstration of the project results in major international fairs and exhibitions. Demonstrations in EU related events: *SMART BEAR* will seek to organize and at least two demonstrations of the project technical results in EU related events. Demonstrations in major international conferences: *SMART BEAR* will seek to organize at least two demonstrations of the project technical results in major international conferences. Table 9 quantifies the project's dissemination activities and sets a basis for verifying whether the project dissemination objectives have been met via key performance indicators (KPIs).

Table 9: SMART BEAR dissemination KPIs

Tool	Description	Success Indicators
Online Dissemination		
Project Website	Web access to deliverables, technical results and presentation materials of ***SMART BEAR***	≥1.000 accesses annually ≥100 downloads
Social Media	Regular push announcements through social media (Twitter, LinkedIn, ResearchGate)	≥50 posts
Newsletter	Regular quarterly newsletter with the technical activities of ***SMART BEAR***	≥9 newsletters
Brochure	High–quality electronic brochure with the scientific approach and activities of ***SMART BEAR***	≥2.000 hard copies distribution in ≥ 10 events ≥500 downloads
Scientific Publications		
Journal publications	Publications in International referred in smart home and assisted living	≥10 publications
Magazine publications	Publications in International magazines in smart home and assisted living	≥10 publications
Conference publications	Publications in International referred technical and non-technical conferences in smart home and assisted living	≥12
Special issues	Preparation of special issues in international referred technical and non-technical journals and magazines	≥2 ≥10 selected papers/issue
Organization of International Scientific Events		
Workshops	Organization of workshops	2 workshops ≥30 attendees

2.2.3 Standardisation and open source engagement

The wide spreading of the source involved, the nature of the data acquired and their analysis leaves opportunities for *SMART BEAR* to contribute to standardisation activities. Towards this, initiatives will be undertaken targeting renewal of the CEN ISO 13606 EHR-communication standard. Contribution is also foreseen to the series of standards known as Concurrent-Use-Standards (CEN: EHR-communication, Health Information Service Architecture and System of Concepts for Continuity of Care). Health Informatics Interoperability standards will be used such as HL7 – FHIR where contributions could be made towards special applications of non-invasive self-monitoring at home. In addition, behavioural changes identification standards related to the interaction with smart devices such as the *SMART BEAR* system will be proposed.

SMART BEAR has identified a set of standardization bodies and EU directives that have to be closely monitored during the project lifetime, while in part of them, specific contributions are envisaged to be provided. These bodies and announced strategies include:

The eHealth Standardization Coordination Group (eHSCG), supported by ITU-T Study Group 16, maintains a list of standards in both technical and non-technical areas of eHealth on the WHO web site, with the main initiatives summarized in the ITU-T standards report. *SMART BEAR* will investigate all standards and initiatives identified and related to the envisioned intervention services based on IoT-enabled decision support systems.

The ISO/TC 215 Technical Committee: ISO's Technical Committee 215 addresses health informatics [41]. ISO/TC 215 focuses primarily on electronic health records. Various Working Groups (WGs) within TC 215 address topics such as data structure, messaging and communication, security, pharmacy and medication, devices, and business requirements for electronic health records, like ISO/TS 25237:2008 addressing pseudonymization principles and requirements for privacy protection of electronic health records [42]. Many of ISO's standards are collaborations or endorsements of standards developed by other standards organizations such as HL7 or IEEE. For example, ISO/HL7 27931:2009, "Data Exchange Standards -- Health Level Seven Version 2.5" establishes an application protocol for electronic data exchange in healthcare environments. *SMART BEAR* will contribute to its most relevant standards.

ETSI standards on eHealth: The two main ETSI standards related to eHealth are TR 102 764 [43] (eHEALTH; Architecture; Analysis of user service models, technologies and applications supporting eHealth) and SR 002 564 [44] (Applicability of existing ETSI and ETSI/3GPP deliverables to eHealth). *SMART BEAR* will investigate the possibility to contribute to both these standards.

Open Source Policy: *SMART BEAR* intends to enable commercial partners to build closed-source solutions based on open source components and to minimise the difficulty of the potential customer to understand a licence. By satisfying these requirements, we allow an early adoption of the developed technologies by a broad community of interested users and in parallel we do not restrict consortium members and third parties from extending the available technology to develop new tools and applications available via closed licenses. *h)* **Data management**: part of the collected data will be made available to the public, provided that privacy and security issues are addressed, adhering to legal and ethical guidance for handling personally identifying data. In order to do that, we will work on a Data Management Plan (DMP) quite early in the project (i.e. D1.1 on M04), which will determine the type of generated data, as well as their exploitation and curation strategy. To maintain adherence to guidelines for the management and protection of personally identifying data, a nominated data controller role within the project steering board has also been included. This will include ensuring any personal data that are collected or stored by the project adheres to the principles of informed consent for a clear and specific purpose, using secure storage, with right of access; and where data collected is adequate; it is relevant and not excessive. Three general types of data have been identified as part of the project: (i) accessed personal and clinical data, (ii) captured and tracked sensor data (including audio/visual, motion and physiological readings) and user provided responses (e.g., feedback), and (iii) created data (such as the labour task performance, fatigue estimation, etc) as content within *SMART BEAR* or the secondary output from data analytics performed on the primary captured data. The DMP will identify best practises and specific standards for these major data types and assess their suitability for sharing and reuse in accordance with official guidelines. Identified datasets for sharing will be made discoverable, accessible, assessable and intelligible, useable and interoperable to specific quality standards, using data sharing services such as OpenData (open-data.europa.eu/en/data/) or EUDAT (www.eudat.eu/) for open access.

2.2.4 Exploitation Strategy

Having a big innovative idea like *SMART BEAR* is not the end of the journey. Objective is to make a profitable product out of it. The process of transforming that idea into a marketable product is a path full of challenges. Challenges that need to be addressed to reach the biggest goal: bringing the big idea to the market.

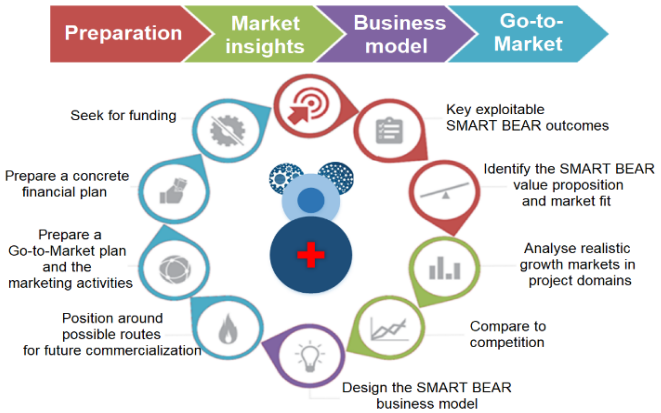

Figure 6: SMART BEAR Exploitation Plan adapting Deloitte's Fast track to innovation programme

All *SMART BEAR* partners have strong interest in participating in this project not-only because it fits with their strategic individual plans but also and mainly because they foresee strong potential for the joint exploitation of the project results and the creation of a sustainable tight collaboration. They all share the vision of cooperating in a win-win manner. Although during the project lifetime, novel business models will be defined, already from the proposal-writing phase, *SMART BEAR* partners have carried out an initial exploitation strategy, following Deloitte's Fast Track programme to Innovation [73]. Fast Track is an intensive program in which firms bring an innovative idea to life together with clients and work on predefined phases towards a concrete business model and a go to market plan (see Figure 6). Building upon the Deloitte's programme, the components of articulating

SMART BEAR exploitation plan are detailed below.

The *SMART BEAR* consortium identifies three main stakeholders categories that may be interested in the exploitation of the project results: 1) The **industrial community,** with a commercialisation interest of products and/or services that may be developed and delivered on top of the project open source results, 2) The **research and academic community**, including universities and other research organisations, and 3) The **end-users community,** which includes municipalities, private sector and clinical organizations interested in delivering high quality solutions to their beneficiaries. The *SMART BEAR* consortium recognizes three main exploitation models for the project results: 1) **The commercial exploitation model**, which implies the paid provision of the project results to the end users, complying with a licensing scheme which will be defined in the *SMART BEAR* business plan, 2) The **research exploitation model**, which implies the re-utilisation of the research know-how acquired in future research activities, and 3) **The technological exploitation model**, which implies the re-utilisation of the technological know-how acquired for the development of innovative products and the provision of advanced services built on top of them. However, not all project partners and interested stakeholders need exploit all project results using these three models.

The exploitation models of the *SMART BEAR* project results will be dependent upon three main parameters: a) the nature and interests of the project partners and stakeholders in general (Figure 7), b) the distribution model (commercial or non-commercial) of the project results and c) the distribution of the IPRs amongst the project partners. Based on these limitations, 1) the *SMART BEAR* industrial partners are mainly interested in commercially exploiting the project results, 2) the consortium (as well as external) academic and research organizations are mainly interested in adopting the research exploitation model for project results that will be provided as open source components, integrating them in their research and/or teaching activities and/or setting up future research projects further promoting the project results, and 3) external industrial partners are mainly interested in adopting the technological exploitation model for the project results. Partners' exploitation interests be provided as open source components for know-how transfer in other products/services. The *SMART BEAR* consortium has already drafted a plan for the commercial exploitation (Figure 8) of the *SMART BEAR* components and its results. However, it should be noted that this is a first, preliminary approach, while the detailed business plan that will be followed, will be defined within the project evolution. This preliminary approach foresees the commercial exploitation of the *SMART BEAR* reference implementation, upon which additional commercial features can be delivered. Towards this end, the SMART BEAR reference implementation per se, incorporating the developed software artefacts, the provided novel software development paradigm and the business intelligence, along with the proper information modelling techniques and the exploitation of the programmable infrastructure capabilities, can be provided with an open source license and free of charge. The same can apply for a basic version of the highly-distributed applications that will be delivered within the project.

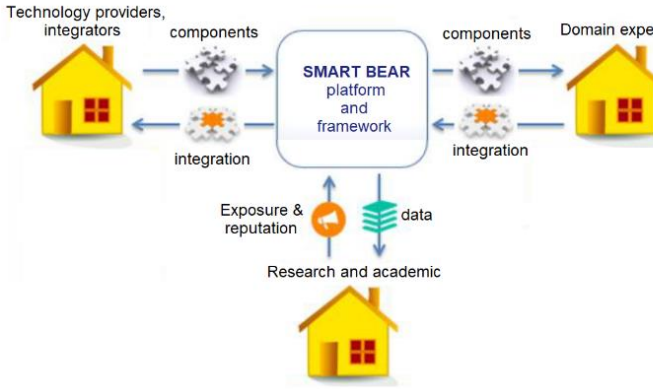

Figure 7: SMART BEAR Exploitation Models

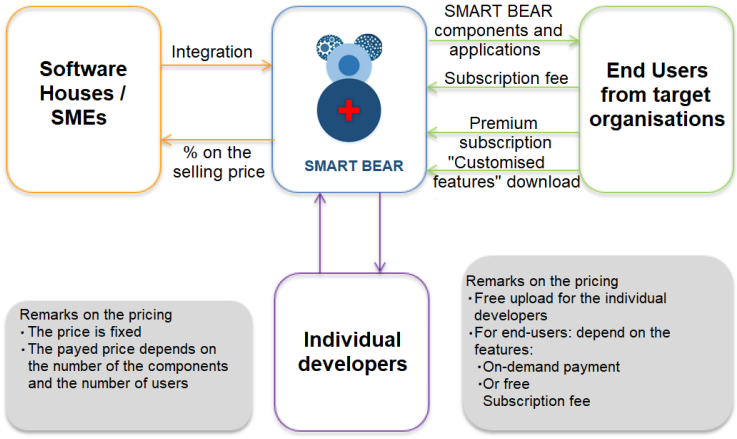

Figure 8: SMART BEAR Commercial Exploitation

In addition, external industrial organisations (e.g. business critical application development SMEs) can develop applications delivered by advanced versions of the *SMART BEAR* components, for which they will have to pay royalties to the *SMART BEAR* consortium. This will facilitate the development of (another) ecosystem of industrial stakeholders generating value through the exploitation of the *SMART BEAR* components and tools. Thus, the **revenue** of the *SMART BEAR* components and tools can be generated from a variety of sources which include: 1) digital services providers acquiring "premium" versions of the *SMART BEAR* components and the applications delivered over it, 2) external partners providing added value services and applications in the area of education and eLearning for people with disabilities and especially cognitive, 3) investors and external funders, 4) advertisements, donations, etc.

CNR	CNR-ICAR will reuse the project's results in its active research activities and in future projects focusing in the area of advanced ICT solutions for healthcare, and will support the project partners in the transition from research to exploitation.
ATOS	ATOS, as a system integrator and big data services company, is interested in the technical outcomes from *SMART BEAR* or apply them to solve specific needs of its customers. In particular, ATOS is very interested on aspects tackled by the project such as the development of a data analytics component to support the processing of both static (aka batch) data and dynamic (real time) data. In this sense, it is worth mentioning that ATOS provides big data solutions through Atos Codex, our big data analytics brand. We will explore the combination of big data analytics using Atos Codex and the techniques provided by *SMART BEAR*, especially related to data stream analytics to enhance our Atos Codex portfolio of services. These services will be including learning and evolution capabilities as results of the assets generated in the context of *SMART BEAR*. Finally, we will increase expertise as multi supplier integrator in healthcare context.
PHILIPS	Philips' exploitable outcome will build on our expertise in semantic interoperability, analytics, information management, infrastructure development, optimization and modelling of clinical workflows, and development of tools for clinical decision support for healthcare professionals and patients.
IBM	With specialists in application, infrastructure, analytics and cyber security domains, IBM aims to maintain its outstanding reputation for delivering value and excellence to all their clients. The *SMART BEAR* project will give to IBM the opportunity to develop and then exploit healthcare analytics, anomaly detection and security solutions within the company relevant products and services in the AI, healthcare and security sectors. *SMART BEAR* technologies can be relevant to improve many IBM products and services, such as: IBM Watson Healthcare Platform, IBM Watson IoT Platform and IBM Bluemix Platform services. The new technologies that will be developed in the *SMART BEAR* project will enhance existing Bluemix services and create opportunities for new emerging services development.We may also use IBM's connections in Israel analytics and security community to present *SMART BEAR* innovative ideas.
LISPA	LISPA participation to R&D projects is strictly related to the project goals and the current services or the strategic planning of future services LISPA will include in its portfolio. As such, the exploitation goal is to obtain results easily integratable in the eGov, eHealth platform and services for Lombardy citizens. Since the requirement specifications, LISPA will keep in consideration the future adoptability/integrability in the Lombardy eHealth platform, to make easier the exploitation at the end of the project, if results fulfil the requirements, after a consolidation of TRL to at least Level 8.
ROP	It will support SMART BEAR Greek pilot activities. Through the adoption of SMART BEAR solution it will enhance the social and healthcare services that provides to the elder population of the region of Peloponnese.
MPF	It will support SMART BEAR Greek pilot activities. Besides of the innovative social and healthcare services that will provide to the citizens of municipality through the utilization of SMART BEAR solutions and services. Toward this direction will contribute all the relevant to healthcare sectors of the municipality. Additionally, the integration of the SMART BEAR services to the Telehealth Unit of the Palaio Faliro will take place.
FCSR	FCSR will technically support SMART BEAR Italian-Portuguese pilot activities, while it will enhance its R&D activities. Furthermore, it will promote SMART BEAR services to elder population facing hearing loss, balance disorders, cognitive impairment and cardiovascular diseases through its cooperation with IRCCS San Raffaele Hospital.
CSC	The helpline system for home care managed by CSC will be integrated with the project monitoring infrastructure. This way the CSC personnel will support the *SMART BEAR* activities and CSC will be able to study innovative models for managing this service, possibly improving effectiveness and reducing costs.
CATEL	Catel's aim (e-health resource and skills center) is to make the best possible use of the results from the *SMART BEAR* project in line with its 20 year old motto: "let digital technology be used by the greatest number of healthcare professionals and patients for an improved health and a better well-being.» In this context, Catel will be interested in the results obtained for improving in particular the elderly users' quality of life and health status as well as those of the carers involved. The implementation of innovative and accessible solutions validated and accepted by users, while respecting the conditions of security and confidentiality, will also be of major interest. Furthermore, Catel will leverage on the methodologies deployed and validated to reinforce its solutions for a successful deployment of e-health on a large scale. To do so, Catel will rely both on the experience of interventions on the spot and the knowledge resulting from R&D works implemented. In particular, an interesting line of intervention has been identified on schemes of organization favoring a dynamic cooperation between stakeholders and dissemination of uses.
ANA	The research exploitation will be targeted towards developing further projects in which to assess the individual and societal benefits of applying ICT in the area of healthy and active aging. This will be accomplished both within the internal research department and through cooperative projects with partners interested and experienced in the same area. The commercialization will be realized directly through our clinical facilities and indirectly through partnerships with companies acting in this sector. In our combined roles of research- based and end-user organization we envision to re-utilize the research know-how acquired in future research activities and to get involved in the commercialization of the projects' results towards the Romanian end-users.
FORTH	The work in the *SMART BEAR* project will be undertaken by the Unit of Medical Technology & Intelligent Information Systems (MedLab). MedLab is a highly innovative and self-contained research unit strongly activated in the fields of Biomedical Engineering and development of Intelligent Information systems. It has an internationally acknowledged excellence in conducting high quality scientific research and developing innovative Information Technology (IT) applications, products and services. Personalization in *SMART BEAR* will be achieved through home mobile application and training with user's data and interaction with behavioral models.
NKUA	NKUA exploitation vision is to create a holistic, safe, evidence based platform which will objectively monitor high impact morbidity, timely detect risks, improve lifestyle and facilitate primary health case as a cheap, easy to use supportive tool. NKUA will exploit the outcomes of *SMART BEAR* project in terms of critical findings on occupational health and mental health, in order to enhance similar research already taking place within the University. Also, it will build on the experience gained from the application of innovative technologies related to the monitoring and improving well-being and health of employees in challenging environments, to be incorporated in teaching activities of the University and enhance the institution's strong track record of publications in prestigious medical journals.
UOI	UOI as a well-known university research organisation and specifically Medical Technology & Intelligent Information Systems (MEDLAB) primarily acts as a technology and innovation provider for national and international partners from industry and commerce. In this regard our primary focus is to partner with system providers and facilitate a supply chain for the final product. Finally, the new

	knowledge and technical knowhow will directly be exploited into a number of graduate and postgraduate courses taught by researchers involved in the project and will be used for academic curriculum development at the University of Ioannina.
UMIL	UMIL mostly focuses on Big Data Analytics, Artificial Intelligence, System Design. In this context, the goal of the university will be to test the MBDAaaS Methodology in a large experimental setting, including performance and stability tests, acceptance tests, and perceived quality. Moreover, *SMART BEAR* will allow UMIL to extend the opportunities for training activities addressed to master or PhD students of multiple disciplines, and to industry. The activities of the project will be connected to teaching activities at the UNIMI master on Data science and economics and at the PhD level. The results of the project will also be exploited to foster the discussion on MBDAaaS at the scientific and industrial level.
CITY	CITY is interested in exploiting the results of the project in its taught postgraduate (MSc) courses on cyber security, big data science, health informatics, and software engineering, where students will be able to see advanced case studies and solutions for a domain as important as healthcare. We are also interested in consulting services to SMEs and other companies that would want to enter the market, and exploring other ways of monetizing the results of the project (e.g., forming start-ups around specific project outcomes).
ICCS	ICCS exploitation vision is to at least maintain if not gain more momentum for funded research at national and European level by producing scientific results that could find their way into new and innovative solutions. ICCS goal is to design and develop the *SMART BEAR* DSS module focusing on comorbidities and easily parametrisable for any combination that the clinicians would like to further explore. ICCS primarily focuses on the scientific community and especially the clinical community for DSS results validation prior to any commercialization action. The approach to be adopted includes synergies with clinicians for DSS validation using as a basis the results achieved through *SMART BEAR*.
EHU	Capitalization of project outcomes and escalability of results to our R&D actions and networks on Healthy aging, Quality assistance, Internet of Things, and Active ageing. Moreover, the capitalization of technologies, will allow for the development of training contents and more efficient impact monitoring on the provided services.
STS	STS will use the outcomes of ANEMOS for strengthening its service and product portfolio. STS plan is to augment the capabilities of its security assurance and certification platform in ways that allow it to support the delivery of preci-sion digital healthcare services at smart home environments and backend cloud infrastructures supporting said services. From a technical perspective, the strategy of STS for achieving this exploitation route is to develop mechanisms sup-porting the implementation of continuous assurance by executing the assurance models and developing appropriate APIs for its platform to provide access to the monitoring/testing evidence and checks required, from an assortment of off the shelf smart consumer and medical devices. From a business perspective, SPHYNX's strategy will be to explore ways of making use of its platform as a continuous assurance framework for increasing the security awareness of end-users and system administrators in the healthcare domain
SV	Stream Vision first aim is to exploit *SMART BEAR* directly as part of our e-health solutions. We expect to be able to integrate results from *SMART BEAR* into our future range of Patient Self-Monitoring products and thus address the senior health market. The French market for patient self-monitoring and -management is rapidly growing and requires more adaptable and personalized solutions. One of the main Stream Vision's targets for its e-health developments is senior residence groups and this project offers a large audience in this field.
ITSS	The advance of technology should be implemented in solutions that help and provide the answer for people to be more independent and more connected to each other or support staff. We are interested in e-health solutions that are safe, reliable and want to learn how we can develop this growing area. ITSS will be interested in the results obtained so that it can improve the safety and health of people who are in need of technology to make their life simpler and comfortable. Also we will document the technical solutions so we can learn an further improve out services
QUIRON	Quironsalud will exploit project result among its network of associates and will incorporate the solutions in its daily work regarding active ageing promotion.
INV	INV exploitation goals are to scale up SMART BEAR solutions (in the field of IoMT, Silver Economy and Active Ageing) adapting them to the Spanish market for commercial uptake. The involvement of potential end-users during the pilots will help INV guiding its work towards the commercial adaptation of SMART BEAR outcomes.
ATC	ATC will focus on the development of the SMART BEAR mobile application, an endeavour which will give the company significant insights into the smart IoT as well as digital healthcare ecosystems. Moreo-ver, the user-centered approach followed in the project will allow the company to gain important in-sights on user acceptance and usability aspects from a large number of participants. These will allow the company to exploit the knowledge to enter the abovementioned new markets and also improve its product portfolio as a whole.
2B	2B has a high number of clients involved with disruptive technologies, both on the provider side and on the customer side. Several international leading companies have been assisted by the firm on issues relating to cyber-security and privacy, on judicial and extra-judicial matters, and more general with their aim of providing novel, yet legally compliant, products and services on the EU market. In the context of its work within the *SMART BEAR* project, 2B is able to keep abreast of the many legal and regulatory changes. It is also able to position itself on the legal market as a market leader by researching the most innovative legal issues and providing legal advice in relation thereto, with a practical and business mind. Not only does this provide to 2B a competitive advantage and enables it to position itself towards its international clients, but it also gives 2B the ability to showcase its first-hand knowledge and expertise and to get involved in EU policy making. Business development opportunities are expected by leveraging on the research results and the practical know-how gained during the project. This should hopefully allow enlarging 2B's current work in relation to its targets and reduce investments in relation to the research of novel legal issues. For instance, in relation to privacy, the research performed on the application of new obligations under the GDPR can be re-used in other contexts and for an array of targets in various sectors
NOVA	NOVA works closely with the international industry and universities developing reference research and innovation in technology. SMART BEAR technological innovations will be transferred into profitable business concepts with novel services and products further developed to match new industrial requirements and linking up with standardisation and European harmonisation approaches includ-ing the electronic EHR exchange format and corresponding actions under European funding.
SRS	SRS, through SMART BEAR, will be able to apply innovative models for managing home services, targeting an improvement in effectiveness and a reduction of the costs.

2.2.4.1 *Identification of targeted stakeholders for SMART BEAR exploitation*

SMART BEAR considers dissemination, communication and exploitation activities as a tightly bound grid which carries the project results to the society and the market, through the appropriate channel and at the appropriate timing depending on the result maturity. **At the start** of *SMART BEAR*, as no results will be available, the communication strategy will focus on raising awareness among the stakeholders' community, then as first *SMART BEAR* results will become available, dissemination of project outputs will start and last until the end of the project. As *SMART BEAR* **evolves**, the outreach activities get more intense and their orientation is turned from awareness creation to outcomes' validation and market creation. **During the last quarter of the** *SMART BEAR*, the project results will be available to the wider audience to be used in future research activities and further exploited.

Dissemination material will be produced for the communication of results and experiences beyond the limits of *SMART BEAR* partnership into the maximum number of potential beneficiaries, stakeholders and policy makers in the participating areas and the whole European region. Structuring the target audiences will have real impacts on the message to be produced, and how this information is written. For example, the language style used in the different products will vary, generally becoming more specialised at deeper levels utilizing technical language and terms. Content is crucial in successful dissemination and communication. Content has to be aligned with audience classes and differs from: Paediatricians, Families, Schools, Educators, National and European Health Authorities, Scientific & Research on nutritional genomics, Catering services, Food and beverage industry, Distribution chains, Media & Advertising, Technology experts / providers.

2.2.4.2 *Building strong collaborations with other PPPs*

On 9 and 10 March 2015, the first European Summit on Innovation for Active and Healthy Ageing took place in Brussels. Over 1400 leaders from government, civil society, investment and finance, industry and academia discussed how Europe can transform demographic change into opportunities for economic growth and social development. The event was organized by the European Commission, representing public states in collaboration with the Active and Assisted Living (AAL) Programme, AGE Platform Europe, the European Connected Health Alliance (ECHAlliance) and Knowledge for Innovation (K4I). The summit built on the achievements of ongoing EU initiatives (https://ec.europa.eu/research/innovation-union/pdf/active-healthy-ageing/ageing_summit_report.pdf):

The European Innovation Partnership on Active and Healthy Ageing (EIP-AHA - https://ec.europa.eu/eip/ageing/home_en) launched in 2012; *SMART BEAR* will active contribute to five of its working groups (A1: Adherence to Prediction, A2: Falls Prevention, B3: Integrated Care, C2: Independent Living Solutions, D4: Age friendly environments)

"More Years, Better Lives-https://www.jp-demographic.eu/", the Joint Programming Initiative (JPI) which enhances coordination and collaboration between European and national research programmes related to demographic change; *SMART BEAR* partners from Italy (coordinator), France (pilot site), Israel (industry), Spain (pilot site, industry) will pursue collaboration with this joint programme through their national contact points.

Horizon 2020, the EU Research and Innovation Framework programme, in particular funding under Societal Challenge 1 for innovative ICT solutions for active and healthy ageing; *SMART BEAR* is a H2020 proposal and its members will participate in all relevant activities.

The Active and Assisted Living Programme (http://www.aal-europe.eu/), where Member States in cooperation with the European Commission fund projects on applied research for innovative ICT-based products, services and systems for ageing well. *SMART BEAR* will seek participation in the yearly organised AAL forum in order to increase visibility of its progress and results.

SMART BEAR's multi-disciplinary balance between privately and state-owned entities ensures that all possible collaborations with organisations and initiatives pertinent to healthy and independent living of the elderly will be exhaustively pursued.

2.2.4.3 *Fast Track: Bringing Ideas to Life*

The *SMART BEAR* business model is a multi-sided one, i.e., there is more than one type of customers that have interest on the service provided. All the details of the preliminary business model are presented in Figure 10 summarizing the key partners and activities, the project's value propositions, the way that customers' relationships will be built, the customer segments, and the channels to be used, also defining some preliminary revenue streams.

The *SMART BEAR* partners recognize that a well-coordinated plan to realize the aforementioned business canvas model is essential for a sustained influence and penetration of the project outcomes to the market. Accordingly, the partners will create a comprehensive, well-coordinated exploitation plan. The preparation of the plan will be led by the Innovation Manager of the project (Sect.3.2.1), in collaboration with all project partners, and will follow a methodology that has been proven successful in previous projects. The exploitation plan will be elaborated and continuously updated, aiming at maximizing the exploitation levels of the project, from the involved stakeholders. It includes

eight phases: (i) market insights and business requirements, in which a draft is provided at proposal phase and will serve as the starting point; (ii) define projects value proposition; (iii) business requirements validation, during the period up to M12 of the project a survey to test market readiness of the first results of the project will be performed. The results will be validated by the External Advisory Board (Sect.2.2.1) ; (iv) elucidate business model/scenarios based on an initial version already presented and a revision will be provided in M24; (v) identify and explore open issues; (vi) seek partners buy in, where partners will state which resources and investments they can commit to the project, and which roles they will accept in the post-project sustainability scenario; (vii) consolidation; (viii) go-to-market, long-term sustainability and potential commercialization (Figure 9).

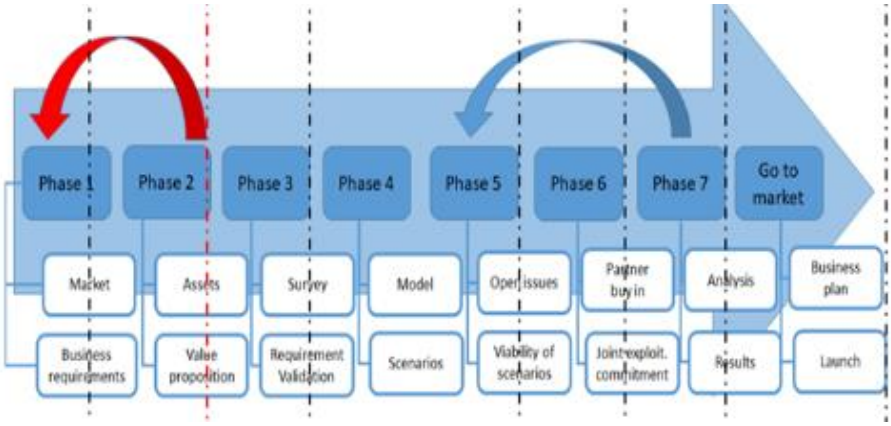

*Figure 9: SMART BEAR **plan for market outreach***

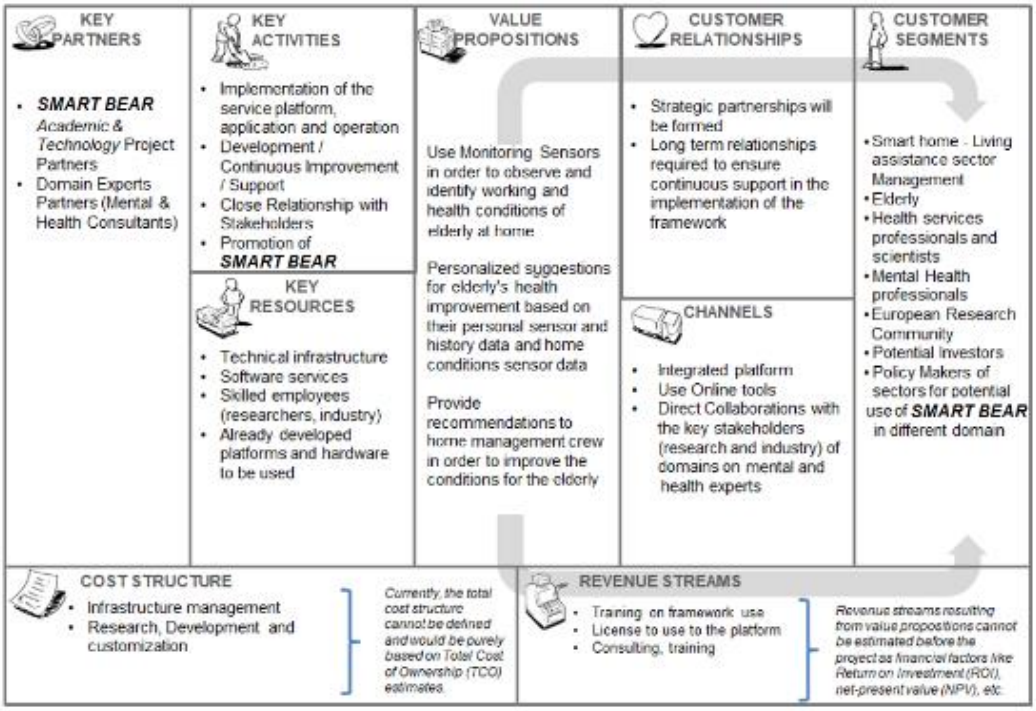

*Figure 10: SMART BEAR **Business Model Canvas***

2.2.5 IPR Knowledge and Open Access Management

IPR Policy: To safeguard Intellectual Property Rights (IPR) of *SMART BEAR* partners, while ensuring impact of project results within the wider community, *SMART BEAR* strives balance between public information and confidential information – both as inputs to the project and output that is disseminated or considered for later reuse. Thus, as part of the overall IPR policy of *SMART BEAR*, the knowledge produced will be continually tracked and registered to the respective owners, as follows:

IP Ownership: Results shall be owned by the project partner carrying out the work leading to such Results. If any Results are created jointly by at least two project partners and it is not possible to distinguish between the contributions of each of the project partners, such Results, including inventions and all related patent applications and patents, will be jointly owned by the contributing project partners. Further details concerning jointly owned Results, joint

inventions and joint patent applications will be addressed in the Consortium Agreement.

Transfer of Results: As Results are owned by the project partner carrying out the work leading to such Results, each project partner shall have the right to transfer Results to their affiliated companies without prior notification to the other project partners, while always protecting and assuring the Access Rights of the other project partners. Such use of Results will encourage competitiveness of the EU market by creating broader uses of the Results and opening up the markets for the Consortium's Results in all markets.

Open Source and Standards: A central aim of this consortium is to provide benefit to the European community. Some of the project partners may be either using Open Source code in their deliverables or contributing their deliverables to the Open Source communities. Alternatively, some of the partners may be contributing to Standards, be they open standards or other. Details concerning open source code use and standard contributions will be addressed in the Consortium Agreement.

The *SMART BEAR* knowledge management and protection strategy aims to be as open as possible to achieve maximum impact of the project results, so the default rule is for results to be public. This will not be so if it is explicitly required by legitimate explicit interests of *SMART BEAR* partners. In particular, for what concerns IPR developed within the *SMART BEAR* experiments, the following pattern will be followed as part of each of the experiments: Delivering public reports (deliverable of type "R, PU") about the requirements, KPIs, principle solutions, as well as lessons learned for each of the pilots; Performing confidential piloting activities (deliverable of type "DEM, CO"), to ensure IPR protection, while offering controlled release of IPR and knowledge as part of the aforementioned public reports. In terms of the policy, if open source is used Apache 2.0 license or a similar license will be the minimum expectation and GPL or similar viral licenses are explicitly forbidden since it dramatically restricts the uptake of open source by commercial parties which will be extremely influential for TT. However, *SMART BEAR* orientation is towards Open Interfaces and Specifications and Open-Source is simply seen as one of many implementation environments that are up to partners and subsequent practitioners to choose. IPR Management: Before project start, partners will have signed a Consortium Agreement (CA) that lays down rights and obligations concerning IPR and project participation. It has al-ready been decided to base this upon model consortium agreements specifically developed by the EU – most likely the most recent version of the DESCA 2020 model (version 1.2, February 2016). Acknowledging the size of the *SMART BEAR* consortium, initial negotiations by partners on this have already begun.

Publication of Foreground (Results): Parties are encouraged to publish material related with public deliverables. Any publication or communication is required to indicate the contribution made by each of the Parties. For the avoidance of doubt, a Party may not publish Foreground or Back-ground of another Party, even if such Foreground or Background is amalgamated with the Party's Fore-ground, without the other Party's prior written approval. Detailed rules about the publication of Foreground are specified in the Consortium Agreement. Access to knowledge: The principal interface for knowledge access, internally (within the consortium) as well as externally, will primarily be through the *SMART BEAR* project website. The primary goal is to inform about the project, and to disseminate its results to be attractive to practitioners, the website will be presented in terms of product and service offerings, and not in terms of the standard EU project websites. Thereby, even though the website will provide access to deliverables and in-formation about the project, the main visible material will be success stories about pilot execution, important lessons learned, access to tangible results in the form of the aforementioned open source software modules, as well as means to directly become engaged with project partners (e.g., if interested in post project replication).

Open Access Publications: For maximizing the impact of the projects activities and results obtained, the consortium will provide free on-line access to its published research and innovative outcomes in prestigious conferences, journals and books. The consortium is convinced that such free on-line access strategy will help not only other projects to benefit from the results of *SMART BEAR* but also lead to a better exchange with others which will in return be a benefit for the project. As such, and in line with the H2020 guidelines to grant open access to publications produced by the project, the project will follow an open access approach for all its scientific publications. To make maximum use of its budget, *SMART BEAR* will opt for "green access" whenever possible and guaranteeing that results will be immediately available (based on publisher's policies). In cases, where the timely open-access dissemination is not possible by following the "green access" model, *SMART BEAR* will opt for 'gold' open access

2.2.6 Communication Activities

A dissemination and communication plan will be developed (Figure 11) to ensure appropriate activities are in place to inform, engage, create awareness, and promote information about *SMART BEAR*, its aims, its outputs and impacts and the wider societal implications. *SMART BEAR* will implement a dissemination and communication strategy with the following key characteristics: **audience driven, proactive, targeted & focused, with measurable performance and European visibility**. Communication will be implemented right from the project start and throughout *SMART BEAR* life -cycle, differentiated in terms of actions, tools and target groups addressed, according to the project's stage of implementation, e.g. linking the communication with the task in progress. The exploitation plan will

serve as the basis of *SMART BEAR* business model design and future commercialization strategies defined within it. In fact, part of the exploitation effort will involve initial exploration of possible business models that could help advance future commercialization efforts in different industries and applications. Figure 11 represents the framework of communication, dissemination and exploitation activities corresponding to the different project periods.

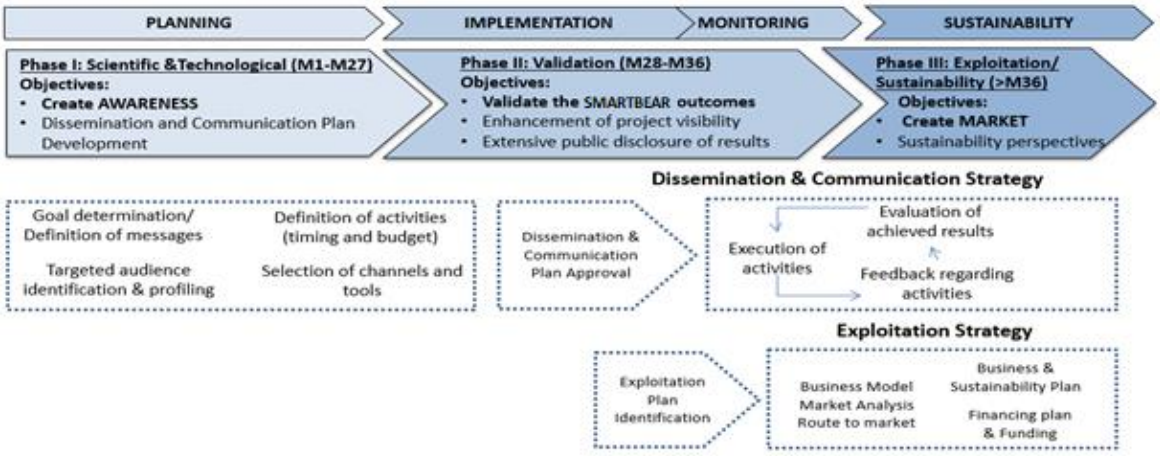

***Figure 11:** SMART BEAR framework of communication, dissemination and exploitation activities*

Table 11. Dissemination and Communication activities and measurable indicators.

Communication channels	Measurable indicators
International Conferences and Events: SMART BEAR partners will participate in European and international conferences that are considered as significant channels for presenting the results and innovative aspects to the healthcare and scientific community and also for creating awareness of the SMART BEAR project to the community of experts.	11 papers submitted in conferences, 1 workshop organized by the consortium (present novel guidelines and the platform)
Exhibitions and Horizon 2020 events: The consortium, namely the scientific partners, will participate at Horizon 2020 events and exhibitions.	Participation in 1 exhibitions and 1 Horizon 2020 event
Publications in Scientific Journals: The submission and publication of SMART BEAR research work and consolidated results to scientific journals is a significant channel for reaching the scientific community. Selected journals to disseminate SMART BEAR concepts, tools and results include, but are not limited to, biomedical engineering, occupational medicine etc.	3 green open access publications
Online dissemination through Internet: An advanced and up-to-date website will be released at month 3 of the project. In addition, electronic newsletters reporting on SMART BEAR deliverables, events and results will be issued stakeholders in English and in the local languages of the consortium on the project's website allowing a wide community of potential.	1 website, 1 lay summary, 3 press releases and 3 promotional campaigns
Biomedical Communities and Social Research Networks: Research Networks (i.e. Twitter, LinkedIn, BiomedTown, ResearchGate, BiomedExperts). The dissemination manager will be responsible for the SMART BEAR building into the BiomedTown where all the public information about the SMART BEAR on going activity will be published. Also, Twitter will be used to publish news, SMART BEAR achievements, etc. and stay connected to the worldwide scientific community. An account and a project group will be created to LinkedIn, ResearchGate and BiomedExperts.	5 accounts on social networks, over 50 followers on Twitter and over 50 connections on other networks
SMART BEAR Presentation Material: SMART BEAR flyer, brochure and poster will be developed to serve as an essential tool for the dissemination at external events targeting academic and research institutes, industrial partners and clinical experts. They will present the project results in an appealing and structured manner and will be updated and published at prefixed time intervals to provide the latest achievements of SMART BEAR.	3 posters and 3 brochures and that will be utilized in workshops and conferences
Traditional communication channels: The consortium will make use of the traditional channels including non-specialized magazines, newspapers and television (TV) to reach the general public and present the objectives, innovative aspects and benefits of the SMART BEAR project without emphasizing technical details.	2 articles to national non-specialized magazines per participating country
Collaboration with other gender projects: SMART BEAR plans to network with other research groups and concertation activities with other Smart and Healthy Living at Home projects, in the same (DT-TDS-01-2019) as well as in other calls.	Establish synergies with at least two EC projects
Collaboration with policy makers: SMART BEAR platform and socio-economic analysis will be presented to the relevant health policy makers to discuss potential update of the SMART BEAR outcomes.	At least one meeting with health policy makers, in 1 of the 5 pilot site countries

2.2.6.1 *Outreach, communication and engagement of healthcare communities*

SMART BEAR considers a wide set of outreaches means expanding traditional means with interactive and on-line based ones. Considering that communication activities differ from dissemination activities mainly in the targeted audience, they require specific attention. Dissemination activities chiefly aim at peers, scientific communities and technology experts and providers familiar with the areas related to the *SMART BEAR* platform and its individual

features (IoT, IoMT, DSS, WSNs, Health gaming, collaboration platforms), scientific and research community on Ambient Assisted Living and the medical specialties of ENT (hearing loss and/or balance training) cardiologists (CVDs), Mental health professionals (cognitive and or mental issues), while communication activities aim at non-specialists and address wider groups e.g. people seeking work in the care giving sector, National and European Health Authorities, municipalities, distribution chains, media & advertising. Although communication activities may use the same pool of dissemination channels and means (even with different intensity) their intricacies need to be dealt with by marketing experts. This includes creating a framework for dialogue and participation in the general public debate. As a result, *SMART BEAR* will use the well-established concept of dissemination in its strategy, albeit in a broader, dialogue-oriented sense. *SMART BEAR* dissemination and communication strategy is based on a five-step approach as depicted in Figure 11. i) Determination of the information to be provided (WHAT?), ii) Identification of the target audiences (WHO?), iii) Identification of the different stages of the project's cycle and the dissemination phases (WHEN?), iv) Identification of the dissemination channels and the communication activities (HOW?), v) Identification of the effectiveness and quality of the dissemination and communication activities (HOW MUCH?)

2.2.6.2 *Outreach and communication to broader communities*

It is important to develop content for those target audiences that do not require a detailed knowledge of the project but it is helpful for them to be aware of the activities and outcomes. Creating such an awareness message of *SMART BEAR* work will help build a wide recognised identity and profile. **General public** and societal target groups need general information that is easy to understand.

It is important to develop content for those audiences that need to be targeted directly because they can benefit from what *SMART BEAR* project offers. Creating such content will help build a deeper understanding of the project's work. Researchers want to have in-depth information on methodology, results springing from the proposed services and uncertainties of those offerings. It is important to develop content for those audiences that are in a position to adopt or use any product/approach/output offered by *SMART BEAR* project. Creating such content will help those people that are in a position to act in some way. Health provider organisations, Care givers associations need information that relates to their actual role and work (e.g., how and to what level do provided models, tools and framework contribute to their goals and methodologies). To ensure the impact of the project, *SMART BEAR* will develop an **EU wide recognised brand** that becomes synonymous with audience's interest for the areas worked and contributed in the project. To ensure the mobilisation of all key stakeholders behind the project vision, goals and activities will require the development of a brand strategy for *SMART BEAR* that will define its positioning, values, attributes and benefits. A brand story and identity will be produced that will underpin all creative communications. The objective of the dissemination and communication strategy of *SMART BEAR* is to identify and organise the activities to be performed in order to promote the widest dissemination of knowledge from the project. As such, the strategy is expanded in three directions towards: (i) raising public awareness and ensure maximum visibility of *SMART BEAR* key facts, outputs and findings among public and society at large; (ii) supporting the notification of *SMART BEAR* results in the scientific, EC and general R&D sector; (iii) enhancing the commercial potential of the results.

3 Implementation

3.1 Work plan — Work packages, deliverables

The work plan of *SMART BEAR* is aligned with the concept and objectives of the project; the innovation programme of *SMART BEAR* is organized into eight interlinked work packages (WPs), as depicted in Figure 12. The Gantt diagram in Figure 13 shows the timing of the work packages and the respective tasks of the *SMART BEAR* project.

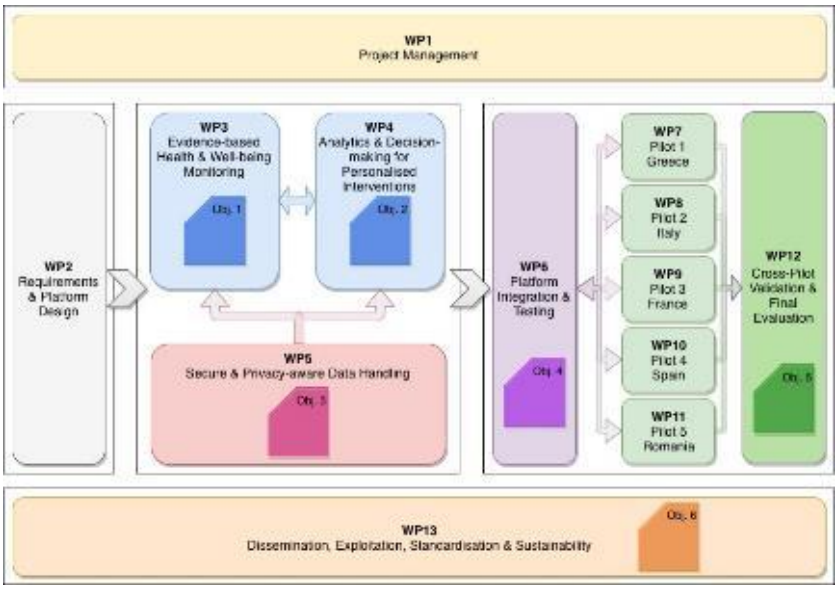

Figure 12.** SMART BEAR **work package structure & relation to Objectives

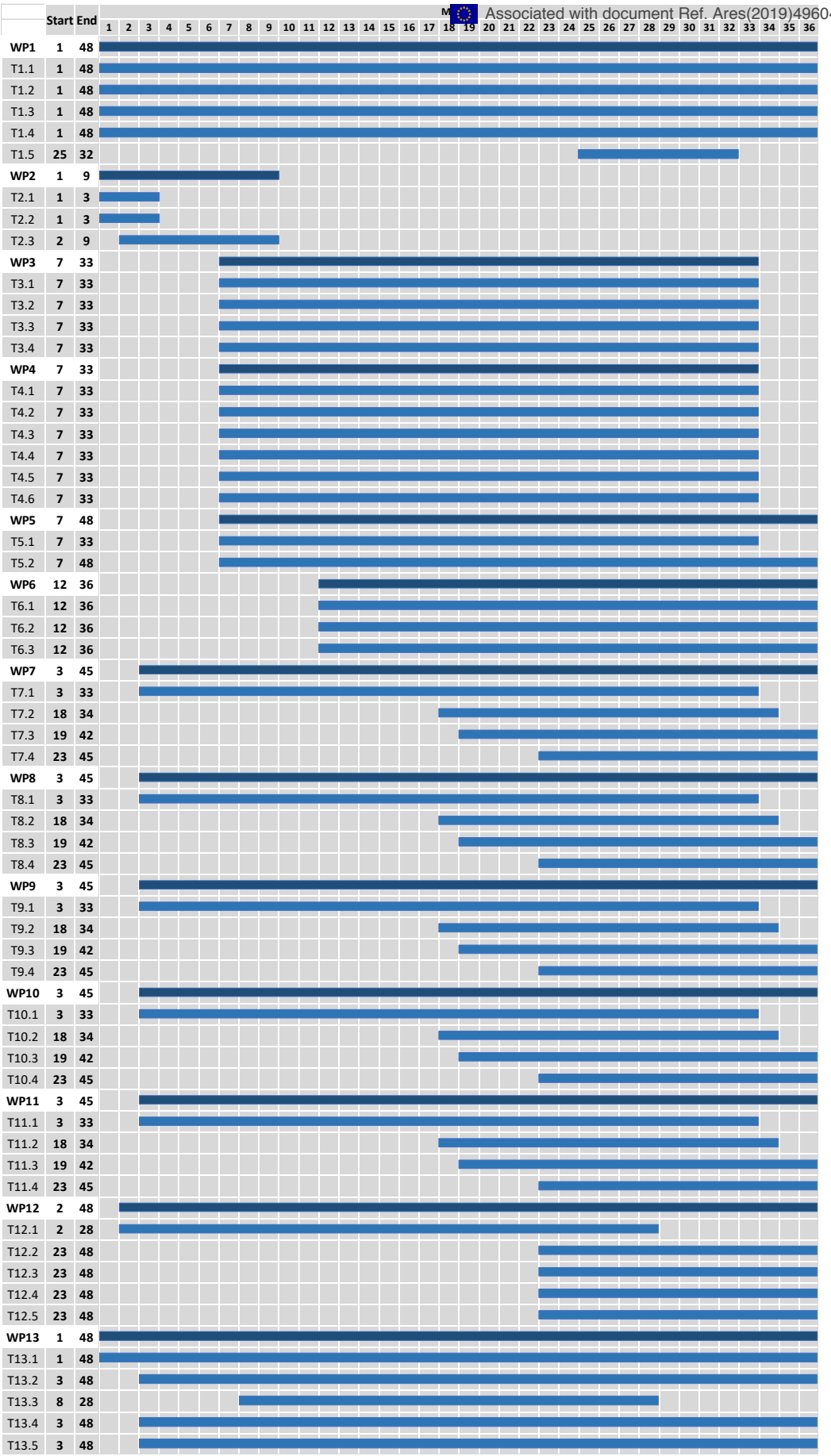

Figure 13. SMART BEAR Gantt diagram