SMARTBEAR

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Trusted digital solutions and Cybersecurity in Health and Care
TOPIC DT-TDS-01-2019
Smart and healthy living at home

SMART BEAR

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

D11.1 – Romanian Pilot Report v1

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D11.1 – Romanian Pilot Report v1

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Executive Summary

The ageing of the population creates new heterogeneous challenges for age-friendly living, and digital health, today, can be exercised by anyone owning a smartphone. Parameters such as heart rate, step counts, blood pressure, sleep quality, can be collected and used not only to monitor and improve the individual's health condition but also to prevent illnesses. SMART BEAR is a multi-centre patient- centred research project aiming at implementing state-of-the-art technology in the everyday life of older adults with specific health challenges, by integrating off-the-shelf friendly to use devices into the smartphone and to an intuitive platform, the SMART BEAR platform.

The research project and its protocol are designed to be replicated under the same philosophy in all involved pilot countries (Greece, Italy, Portugal, France, Romania), where the consortium plans to recruit 4100 older adults in 5 large scale pilots spanning several centres in some countries.

This deliverable reports the status of the Romanian pilot as of May 2024 (M57).

Deliverable D11.1 is the first deliverable for the Romanian Pilot, and the deliverable structure is based on an early version (v0.5) of the WP8 (Pilot 2, Italy-Portugal) reports (D8.5), which set the reporting structure and detailed the existing procedures for device procurement and preparing the clinical and technical infrastructure.

Deliverable D11.1 highlights several pilot-specific activities and challenges in relation to **participants' recruitment and enrolment, helpdesk configuration for continuous participants' support, device kits procurement and preparation, ethics approval, and monitoring of the pilot progress, with lessons learnt**.

At this point in time, in an effort to meet the required targets, the Romanian pilot has already started to recruit participants ensuring the readiness of the pilot, while waiting for the delivery of the devices, given some delays in procurement and ethical approval. An initial pilot assessment will be included in version 2 of this report.

This report will be superseded by deliverable D11.2 "Romanian Pilot Report v2" due in month 60 (August 2024) of the SMART BEAR project.

Contents

List of acronyms

AI: Artificial Intelligence
CS-BM: Centre for Seniors of the Bucharest Municipality
CVD: Cardiovascular Disease
DPIA: Data Protection Impact Assessment
EC: European Commission
ECG: Electrocardiogram
EthSR: Ethics Screening Report
EU: European Union
FHIR: Fast Healthcare Interoperability Resources
GCP: Good Clinical Practices
GDPR: General Data Protection Regulation
GDS-15: Reduced version of the Geriatric Depression Scale
GDSS: General Directorates for Social Services (local administration)
GP: General Practitioner
IADL: Lawton–Brody Instrumental Activities of Daily Living scale
IC: Informed Consent
IoMT: Internet of Medical Things
LBP: Low-Back Pain
MCI: Mild Cognitive Impairment disorder
MDR: EU Regulation 2017/45, a.k.a. Medical Device Regulation
MedX LE: MedX Lumbar Extension Machine
MePA: Public Administration Electronic Market
ML: Machine Learning
MNA: Mini Nutritional Assessment
MoCA: Montreal Cognitive Assessment
MoH: Ministry of Health
NAMMDR: National Agency for Medicines and Medical Devices in Romania
NAPPR: National Agency for Public Procurement in Romania
PHQ-9: Depression Test Questionnaire
PoP: Pilot of the Pilots
RDN: Registered Dietitian and Nutritionist
RDO: Request of Offer
RGA: Rapid Geriatric Assessment
SB: SMART BEAR
SB@App: SMART BEAR mobile Application
SB@Home: SMART BEAR Home hub
SDK: Software Development Kit
SQS: Single item sleep Quality Scale
TLS: Transport Layer Security
VAS: Pain Visual Analogue Scale

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1 Introduction

SMART BEAR is a multi-centre patient-centred research project aiming at implementing state-of-the- art technology in the everyday life of older adults with specific health challenges, by integrating off-the-shelf friendly to use devices into an intuitive platform, the SMART BEAR platform. It will deliver a solution offering measurable improvements to the Quality of Life of the older adults and their ability to live independently, while also contributing to a continuous and objective monitoring with personalised interventions towards optimising disease and associated risks' management.

Project and Project Protocol design renders a common direction for all pilots (participating: Greece, Italy, Portugal, France, Romania). The consortium plans to recruit 4100 older adults in 5 large-scale pilots spanning 5 member states and several centres in some countries.

In the M15 review meeting, the results presented demonstrated that the pilot work has been modified to address the COVID-19 situation by reducing at home and on-site visits for guidance and installation. However, at the time, the intended interactions between doctors, carers and users were not fully detailed and integrated with the technology being developed. For these reasons the review team and the EC suggested the implementation of a smaller scale pilot in a controlled environment, prior to the start of the five large-scale pilots, to obtain real life data and guide the system designs.

Therefore, given the recommendations received and the pandemic crisis, the project started a Pilot of the Pilots (PoP) in Portugal, at the pilot site in the Autonomous Region of Madeira, started officially on October 20, 2021 at M26. Thanks to the previous experience gained by PoP, recommendations, and suggestions regarding various aspects of pilot setup and activation have been made available to all pilots.

The Romanian pilot includes a single site, covering the metropolitan area of Bucharest and the adjacent counties. The start of the Romanian pilot was first planned in M31.

Unfortunately, delays from the original plan occurred due to the COVID-19 pandemic, to the need to wait for ethical approval, and, especially during year 4, to platform migration complications and to procurement delays.

As of now (May 2024), the pilot site in Romania was successfully initiated (in M52), but is still pending device deliveries in order to start preparing device kits and device allocation to recruited participants.

1.1 Purpose of the document

The deliverable D11.1 "Romanian Pilot Report v1" is the evaluation report of the deployment activities of the SMART BEAR Romanian Pilot. It demonstrates the developments and procedures followed at the ANA clinical facility (The Excellence Memory Centre for Brain Health and Longevity Medicine), as well as the progress, initial findings and lessons learnt. Unfortunately, as the device deployment in the Romanian Pilot has not started yet, this report cannot provide a comprehensive assessment of the pilot; the first full pilot evaluation should be provided in the version 2 of this report.

After a brief introduction, the document begins with a definition of the Romanian Pilot and its objectives in section 2, after which enters in detail in the different procedures adopted. Section 3 reports the procurement of the devices and the hardware material required for the implementation. The Romanian Pilot timeline is explained in section 4, that details the core piloting milestones, from infrastructure setup to participants' enrolment and users' training. Section 5 presents the dissemination activities, while section 6 is summarising the ethical approval process. Finally, section 0 covers lessons learnt during pilot implementation so far.

This report will be superseded by deliverable D11.2 "*Romanian Pilot Report v2*" at M60 (August 2024) of the SMART BEAR project.

2 Romanian Pilot

To achieve its goal, SMART BEAR is implementing an e-health monitoring system, through state-of- the-art technologies for the continuous medical and environmental sensing, assistive technologies, and big data analytics, to enable healthy and independent living for older adults. Five large-scale pilots, spanning five different EU member states (Greece, Italy, Portugal, France, Romania), in addition to the Pilot of the Pilots (in Madeira, Portugal), are being developed to demonstrate project achievements.

WP11 addresses the various activities planned for the successful preparation, implementation and outcomes evaluation of the Romanian pilot, centred around the ANA clinical facility, namely The Excellence Memory Centre for Brain Health and Longevity Medicine in central Bucharest. Patients (potential participants) come from the Bucharest metropolitan area (2.63 million inhabitants spread in an area of 1,804 km^2 as reported by Bucharest-Ilfov Regional Development Agency) and the surrounding counties (3.17 million inhabitants over an area of about 34,400 km^2, as reported by South-Muntenia Regional Development Agency).

Project activities, including participants' recruitment, enrolment, and monitoring, happen in this clinical facility. Specifically, participants are recruited among the list of chronic patients being treated or referred to the Excellence Memory Centre for Brain Health and Longevity Medicine.

2.1 Synergies

The demonstration of the synergy with the Smart4Health[1] EU projects is a secondary objective of our pilot, attempting the implementation of it at a technical level from the clinical perspective; developments (tools) are expected to be shared between projects in an attempt to establish a sustainable framework for health and wellbeing initiatives. Smart4Health is sharing device data and infrastructures involved in the low back pain prevention and treatment. The Smart4Health project ended in October 2023, and resulted in a number of outcomes, among which a machine that can be

[1] https://smart4health.eu/

deployed to support low back training, and the IoT Box for data storage will be reused in the pilot.

As the national regulatory framework would have most likely stalled the ethical approval procedure for the HOLOBALANCE[2] synergy beyond the practical deadlines set for SMART BEAR, ANA had to opt out of implementing this synergy (reasons to be detailed in sections 3.1.2-Synergies for the Romanian Pilot and 6-Ethics Approval).

3 Procurement procedures and strategy adopted

Having in mind to purchase the exact same devices for all pilot sites at potentially lower costs (expected for bulk purchases) the consortium decided on a Joint procurement. Contract execution was challenging, as compliance needs to be ensured with both EU and national regulations. The decision to proceed with a Joint Procurement procedure was unanimously agreed upon by all project partners during a Project Coordination Committee meeting on 30/11/2021.

However, when trying to align this procedure with the National legislative requirements we were faced with the fact that in Romania, Law no. 98/2016 does not provide for the possibility of a centralised transnational procurement and imposes the condition of approving the centralisation of procurement of several contracting authorities by Government decision.

Therefore we formally contacted the National Agency for Public Procurement in Romania (NAPPR) asking for clarifications in this matter; we obtained and provided the consortium with a written response on methodology guidance from the NAPPR, (reg. no. 6277 dated Aug 11th, 2023 - month 48) stating:

- ”*a contracting authority in Romania which is partner in a cross-border project, may purchase products/services based on a framework agreement drafted by the Greek partner involved in the public procurement procedures, not necessitating a new procurement awarding procedure****, only if this partner is a centralized purchasing body according to the national legal provisions in force in the Member State where said partner is located***”;
- ”*for all procurements made as part of the project that are expected to be conducted on Romanian territory, the provisions of Romanian legislation on public purchases are mandatory, as they transpose EU directives in force, but for all other procurements, unless if the funding agreement stipulates otherwise, the applicable provisions are those relevant for public procurements which are in force in the Member State where said procurements are conducted*”
- ”*as regards the preparation of a joint procurement and the liabilities of each contracting party within the awarding of the procurement, (…) these are set forth in the formal act concluded between said entities (i.e. association agreement, protocol, partnership agreement etc*);”

[2] https://holobalance.eu/

Given ANA's inability to proceed according to the joint procurement model as in the case of the other pilots, on the coordinator's suggestion, ANA has agreed to delegate the purchase and transportation of devices for the Romanian pilot to the ICCS partner, so as to comply with local regulations. Accordingly, ANA entered a trilateral agreement in M52 with ICCS and CNR, according to which ICCS will procure and provide the devices for the Romanian Pilot.

However, device delivery for the Romanian Pilot stalled, pending the signing of the amendment requested for the Grant Agreement, which was needed by ICCS to give them the legal coverage to proceed with the purchase, and pending (ongoing) clarifications on the legal and financial means to lawfully provide the devices to the Romanian Pilot.

3.1 Joint Procurement

Having in mind to purchase the exact same devices for all pilot sites at potentially lower costs (expected for bulk purchases) the consortium decided on a Joint procurement. Contract execution was challenging, as compliance needs to be ensured with both EU and national regulations. ANA, together with all other pilots has supported the joint procurement initiative proposed by the Consortium, provided it complies with EU and national legislation. In October 2022, we agreed to the joint procurement based on the European Commission's favourable response. However, upon consulting with NAPPR in July 2023 about the transposition of the EU Directive into Romanian law, we learned that joint procurement is currently unfeasible. NAPPR (as detailed in Annex 5.1 & 5.2) indicated that national regulations only permit joint procurement under specific conditions that were not those implemented in the project model, with a single authority for the tenders but contracts signed by the pilots. Consequently, ANA had to revise its position to align with these requirements, while remaining committed to supporting the project within the bounds of national regulations. In particular, the contract execution proved to be the most difficult part for ANA, given specific national requirements (Annex 5 lists selectively relevant legislation). In fact, ANA was unable to procure itself the devices for the Romanian pilot.

To enable the procurement process in Romania, otherwise impossible, as proposed by Coordinator and in order to comply with local regulations, ANA entered a "Trilateral agreement for the transfer of ANA's budget to ICCS" (signatories: ANA, ICCS, CNR). For the Romanian Pilot, device delivery was delayed, pending the signing of the amendment requested for the Grant Agreement and pending clarifications on whether the devices will need to be retrieved from participants at the end of the project.

This trilateral agreement also implies that all indirect costs associated with the procurement budget have been transferred to ICCS, leaving ANA unable to allocate funds needed to cover the costs of the complex logistics behind device allocation (receipt, storage rental and security for storage, shipment from storage to clinical facility, service operations, retrieving said devices from participants and shipping them back to ICCS/Greece, insurance etc).

ANA is currently working intensely and closely with CNR and ICCS on finding out legal and financial solutions for this conundrum, to expedite device allocation and piloting activities; we are relying on ICCS to identify a workable solution (of course we will provide all the support needed that does not require additional funds).

Once the devices are well received ANA and ITSS will assure the device preparation and allocation to the volunteers, the technical training and the help-desk support for the proper implementation of piloting.

Dealing with a trilateral document makes the signing procedure more challenging as such agreements need to identify common grounds while also meeting tri-national (i.e., Romanian, Greek and Italian) as well as common EU requirements.

3.1.1 SMART BEAR Devices for the Romanian Pilot

Once we finalize solving all legal/financial issues, devices should become available for delivery. ANA has been in close contact with ITSS (Romanian tech partner) in an attempt to fine-tune all following stages (i.e. device reception, setting up (pre-configuring) kits of devices per use case scenarios.

A custom software solution is being perfected as a joint effort (ANA-ITSS), which will facilitate tracking participants (appointments for clinical & administrative purposes, i.e. contracts for device allocation) and support requests (enabling remote collaboration between ANA and ITSS staff).

As of May 2024, according to the new Amendment of the Grant Agreement, the products needed for the Romanian Pilot are listed in Table 1. No tentative schedule for delivery and procurement updates can be provided as ANA could not participate in the joint procurement.

Lot No	Description	Devices needed
1	Hearing Aids	*376*
2	Smartphone 1	188
3	Smartphone 2	752
4	Smart BP	704
5	Smart scale	816
6	Smart thermometer	940
7	Smart Oximeter	940
8	Smart watch	940
9	Smart home devices	223

Table 1: Devices needed for the Romanian Pilot

3.1.2 Synergies for the Romanian Pilot

For the Romanian Pilot, the only viable synergy was with the Smart4Health EU project, serving as a technical complement to demonstrate interoperability feasibility.

The national regulatory framework would have stalled the ethical approval procedure for the HOLOBALANCE synergy beyond the (already) tight schedules set for SMART BEAR, so ANA was forced to opt out of the implementation of this synergy (also see section 6-Ethics Approval).

As already explained, ANA was prevented (given local regulations - Annexes 5.1 & 5.2) from participating in the joint procedure; the Joint Procurement will be performed by ICCS, same as for the SMART BEAR devices. This synergy will only be implemented for demonstrative purposes.

According to our partners, the call for tenders for Smart4Health was published by ICCS on February 24, 2023, and was awarded to ITTM SA (Information Technology for Translational Medicine), based in in 27, Rue Henri Koch - House of BioHealth, L-4354 Esch-sur-Alzette (Luxemburg).

ANA is only expected to provide ITTM the address for delivery.

4 Pilot preparation

For pilot set-up, it was necessary to carry out a set of activities involving all the project partners, both at technical, clinical, and even administrative level, that are described in detail through this section of the deliverable.

Prior to Pilot setup and functioning ANA contributed to Smart Bear platform setup, in close collaboration with WP3, WP4, WP6, being directly involved in drafting the requirements and guidelines as part of WP2 and WP12. A general user test was performed by the Pilot of pilots, where pilot processes and first version of SB platform (v0.1) has been used for a first batch of participants.

The flow of local / pilot setup is suggested in Figure 1:

- **Local procedures**: needed for enforcing WP11, due observance being paid to local specificities (albeit regulatory, ethical, cultural, socioeconomical particularities etc).
- **Support system**: designed to be reachable via multiple channels (phone, email, physically) and to allow in-sync problem solving (collaborative solution with clinical and technical teams). Should support both the clinical teams (recruiters) and participating volunteers (recruits).
- **Technical preparations**: device setup / connectivity in kits, according to already established use case scenarios.

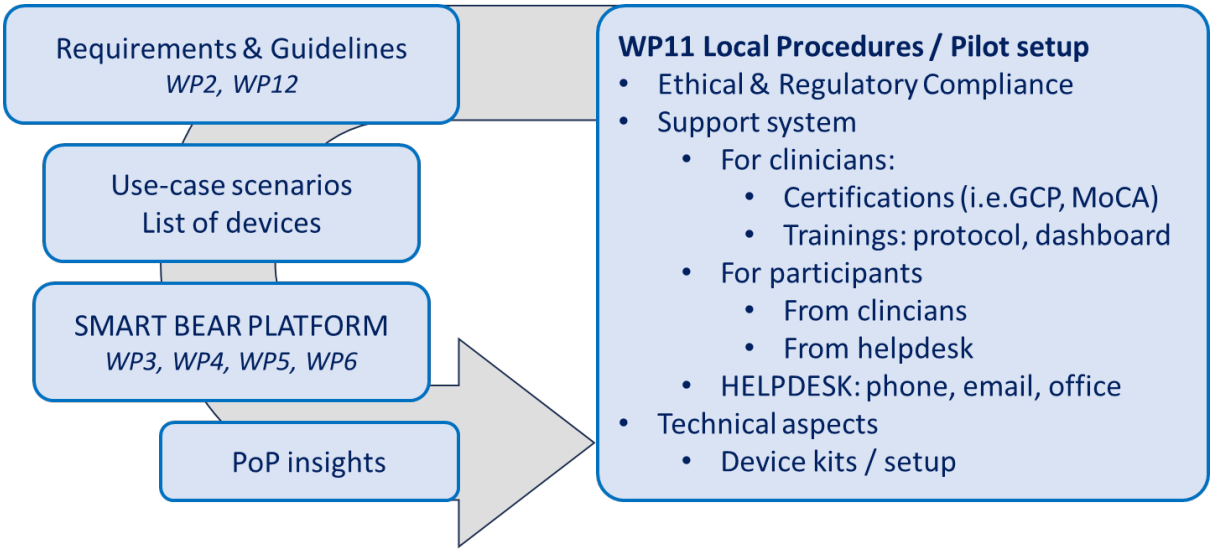

Figure 1: Pilot Set-Up

For a unitary approach of the clinical protocol in all pilots and clinical assessments of SMART BEAR participants, the WP11 clinical team was trained by domain experts in the comorbidities under study and technical staff for devices and platform use.

Given the specific challenges and delays encountered so far, as a mitigation plan aimed to prevent any additional delays in piloting, the Romanian Pilot completed all tasks (i.e. national ethical and legal requirements) for running the pilot ahead of device delivery.

All certifications and authorizations were requested and obtained for properly functioning in the new clinical headquarters and ethical approval was obtained (M50).

As agreed by Consortium in regular meetings, the Romanian Pilot was initiated in M52 (first patient recruited) and has so far recruited 241 patients by the end of May 2024 (M57), ahead of receiving/deploying any single device for piloting.

Resuming pre-recruitment activities in full force is pending the receipt of devices. Potential participants/volunteers are expected from (1) educational sessions set up with local partners (i.e. social care directorates etc) and (2) participating healthcare professionals involved in primary care delivery (GP's, diabetologists, psychiatrists, geriatricians etc).

4.1 Baseline Definition

The Romanian pilot is based on our primary clinical resource, the Excellence Memory Centre for Brain Health and Longevity Medicine, situated in central Bucharest and serving as major clinical hub, serving patients from the Bucharest metropolitan area (2.63 million inhabitants) and the surrounding districts (yielding another 3.17 million inhabitants).

Health Institutions: The main SMART BEAR clinical hub is our Excellence Memory Centre for Brain Health and Longevity Medicine. A new, more accommodating facility (with clinical examination rooms large enough to accommodate volunteer examination as requested in mini-BEST) was identified and contracted, as previously

reported (M36). The facility features enough storage space for device allocation (can store ~100 device kits).

Local support: We ensured local support (signed partnership agreements) from the Centre for Seniors of the Bucharest Municipality (M5) and with the General Directorates for Social Services in all 6 districts of Bucharest: Sector 1 (M34), Sector 2 (M34), Sector 3 (M34), Sector 4 (M28), Sector 5 (M25) and Sector 6 (M34). Basic follow-up with municipality representatives is ongoing, constantly reminding of the project inclusion criteria and providing updates about SMART BEAR; this is expected to boost recruitments after device delivery.

We also signed a strategic partnership agreement with GP associations in Bucharest-Ilfov area (M6), and we are in the process of initiating several more GP's (1 GP initiated as of M57, more to follow). As a result of dissemination activities reaching out to primary care physicians, we also initiated 2 other specialists (1 diabetologist, 1 geriatrician).

Population Data: The Romanian pilot aims to recruit 940 participants. Pre-recruitment of participants started since M30 and a tentative 381 pre-screened participants have been contacted and invited to participate in SMART BEAR as of May 2024. So far, 241 were recruited out of them.

Targeted Population Clinical Profile: The Romanian pilot complies with the SMART BEAR piloting requirements: patients aged 65-80 with at least two of the five specified comorbidities: hearing loss, cardiovascular diseases, mild cognitive impairment, mental health (anxiety/depression), balance disorders, as well as frailty. Specifically, eligible participants reside in Bucharest metropolitan area and the surrounding regions.

Clinical Team: The Romanian pilot core team consists of highly skilled clinicians. All underwent specific training for the purpose of SMART BEAR (training /certification month numbers provided in Table 2:

Name	Role	GCP	MoCA	SB training
Dr. Razvan Ioan Trascu	Lead Clinical Case Manager	M44	M51	M51
Dr. Adriana Manea	Clinical Case Manager	M30	M51	M51
Dr. Mihaela Minea	Clinical Case Manager	M30	M51	M51
Dr. Oana Druga	Clinical Case Manager	M51	M50	M51
Dr. Oana Parliteanu	Clinical Case Manager	M22	M55	M56
Dr. Irina Miron	Clinical Case Manager	M54	M55	M56
Dr. Cosmina Haisan	Clinical Case Manager	M55	M55	M56

Table 2: ANA core clinical team of the Romanian Pilot

4.2 Planning and Workflows

4.2.1 Pre-Recruitment (User Engagement and Screening)

Given the local support secured from the Centre for Seniors of the Bucharest Municipality and the General Directorates for Social Services in all 6 districts (M5-M34), ANA clinical teams held informative sessions reaching out to several hundreds of seniors in the target age group (65-80 years old); a pre-recruitment form was submitted, compliant to GDPR, enquiring specifically about the conditions which were part of the SMART BEAR eligibility criteria (see above, section 4.1).

However, a major source of recruitment is direct, targeted referral from healthcare professionals aware of the SMART BEAR eligibility criteria, thus ensuring the referred patients pass the screening and eligibility checkups; this allows a more effective time management for the core clinical team.

The pre-recruitment and screening process is shown in Figure 2.

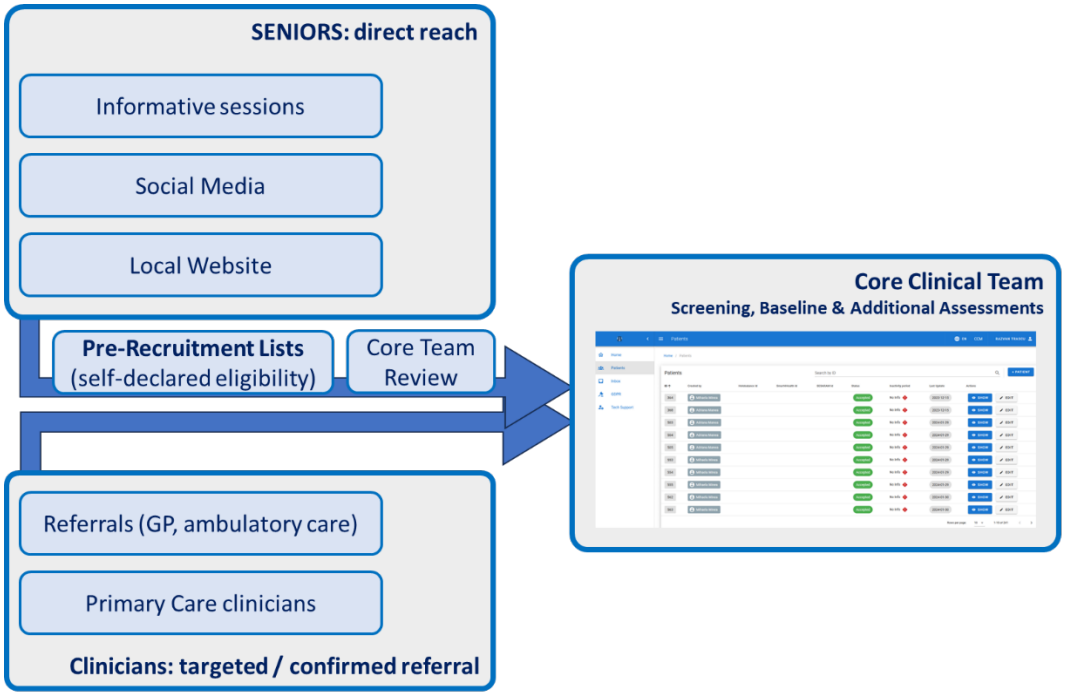

Figure 2: Prerecruitment and screening diagram

ANA recruitment process relies on two main sources of potential participants:

I. Self-assessed: participants attending the informative / educational sessions held in partnership with Centre for Seniors of the Bucharest Municipality (M5) and with the General Directorates for Social Services filled in GDPR forms and pre-recruitment structured questionnaires, based on the eligibility criteria (which comorbidities the attendants *declare* they have) and contact details; pen & paper forms filled in by potential participants were then archived and a centralized list of potential self-assessed eligible participants is drafted in Excel.

- Romanian Pilot website (https://smartbear.anaaslanacademy.ro/) provides comprehensive information about the SMART BEAR Project (consistent with latest updates and approved by the local ethics committee), including the Informative letter and the Informed consent form (Figure 3); potential participants are invited to a smart, responsive adhesion form designed to collect the same information provided in the pre-recruitment (pen & paper) forms. If based on self-declared data the volunteer fails any of the eligibility requirements, submission of the form is impossible (this ensures no data is collected for non-eligible volunteers - Figure 4 and Figure 5). All data collected from website is centralized as part of the pre-recruitment list; clinicians review lists before sending them to front desk staff for double-checking and making appointments.
- ANA social media channels direct to the Romanian pilot website; channel of choice was Facebook (based on preference shown by the community of older adults involved in prior and ongoing ANA projects related to AAL), but all ANA social media channels were used to direct potential participants to the website, namely:
    - A dedicated project Facebook page was launched in M39 and constantly updated, cross-referencing other SMART BEAR Pilots' available pages (Portuguese, Italian, Greek) and the main project page;
    - Ana Aslan International Foundation Facebook page and the Senior Community Facebook Group as well ANA Linked-In and YouTube channel/podcast contain posts linking to the Romanian Pilot website; most ANA clinicians and researchers shared such posts to their personal network (profiles and pages), to ensure project dissemination.

All volunteers self-assessed as eligible are called by the front desk staff instructed on SMART BEAR specificities; volunteers' answers are double-checked over the phone and if apparently eligible they are invited for detailed project presentation; if still interested, after informed consent for participation is given, appointments are made so they can be screened and recruited; baseline and additional assessments are performed in one or more appointments, depending on availability. Since no devices were received, all participants go through all additional assessments for all eligible comorbidities.

II. Healthcare referrals: based on prior partnerships, primary healthcare workers working with older adults with chronic conditions (i.e. general practitioners, internists, psychiatrists, geriatricians, diabetologists etc.) present the project, obtain informed consent and, depending on availability, screen patients and/or refer them to our clinical facility; this latter, referral-based model yields best results, as the partner clinicians referring their patients typically perform screening tests as part of routine care and fill up for ANA (on pen & paper forms) some of the data required for screening, baseline and additional assessments, allowing our core team to focus on checking if all data is current and to perform specific tests, as per clinical protocol.

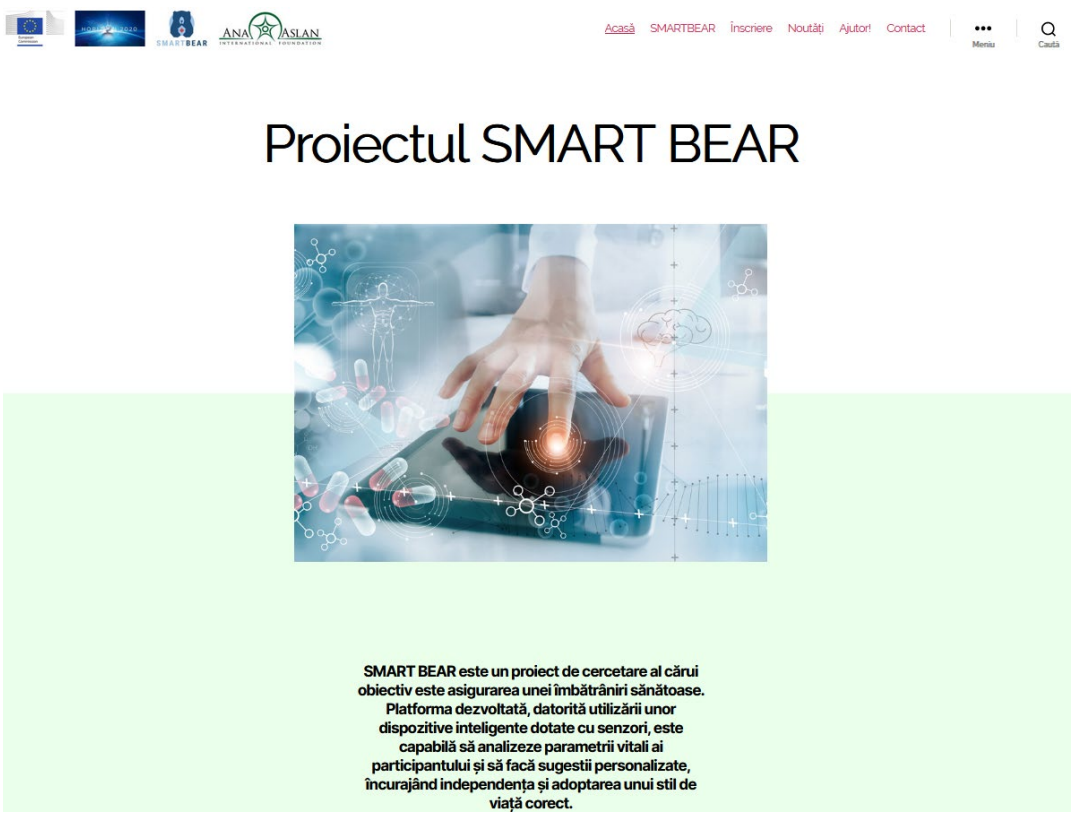

Figure 3: SMART BEAR Romanian website – first page

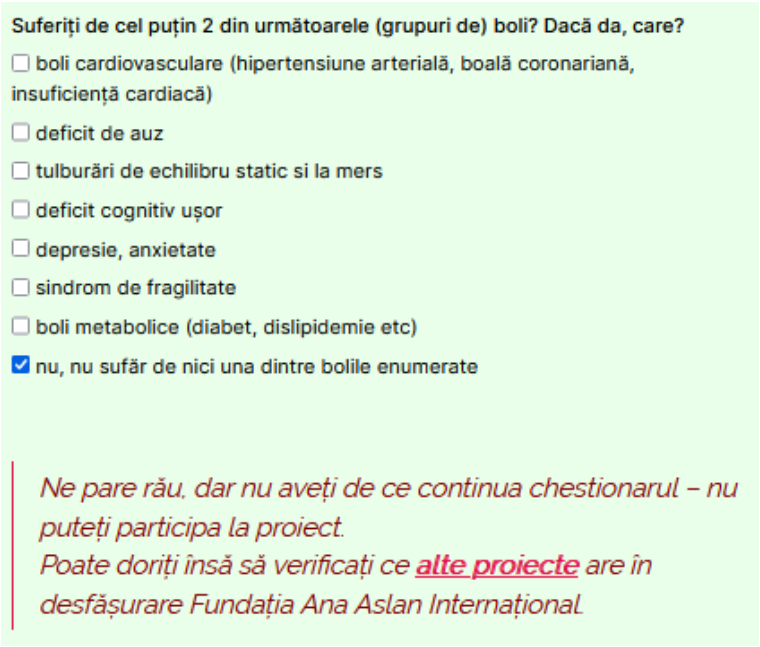

Figure 4: SMART BEAR Romanian website: responsive form (if selecting "none of listed comorbidities" volunteer is directed to other ANA projects).

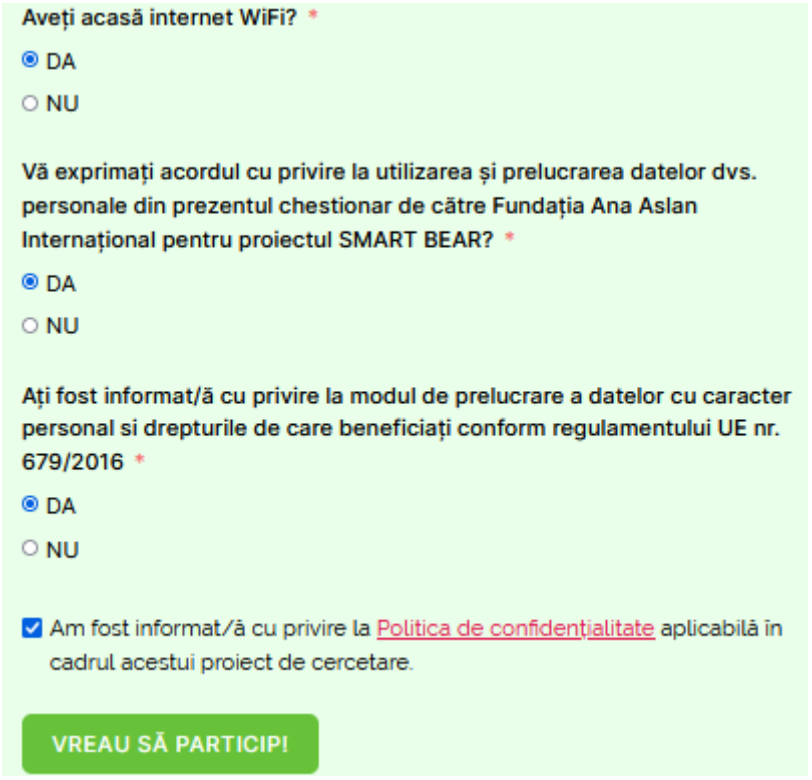

Figure 5: SMARTBEAR Romanian website: submission possible only if volunteer choices comply to eligibility criteria.

A tentative 381 pre-screened and filtered (from the initial attendance lists) potential participants have been contacted and invited to participate in SMART BEAR as of May 2024. Adhesions via the website (responsive smart form) are still open and the process is ongoing.

Although large numbers of participants showed interest and appeared to be eligible for participation, things changed due to the time lag between pre-recruitment events and the actual date the invitation was issued to participate. Interest decreased, a lot of potential participants had to cut expenses and gave up internet subscriptions; some potential participants moved away from Bucharest (countryside or abroad) and some even deceased meanwhile. However, we used the pre-recruitment lists to kickstart the pilot and simultaneously reached out to our network of GP's and partners for boosting referrals of potential participants.

Our clinicians typically handle dashboard data registration based on GP-provided data cross-checked with each participant; communication between GP's and our internal team is possible electronically, secured by user/password authentication, via https. Each GP can submit patient data in online questionnaires observing study protocol for each patient, and each clinician has access to this data during participants' appointments.

We expanded the number of medical staff / clinicians and available examination rooms to be capable of assuring in-house assessments for each participant, according to study protocol, in order to compensate for the decreased time-availability of Romanian GP's.

4.2.2 Infrastructure Installation Plan

Given the complexity of SMART BEAR and the synergy with another EU Project (i.e., Smart4Health), the planning for infrastructure installation was considering ever since selecting our current location for piloting.

Infrastructure preparations considered:

- **Setting up the Helpdesk**: this activity is ongoing and meant to provide support to participants and clinicians. A core group of two volunteers started devoting their personal time to learning about protocol framework and tech issues, and they are expected to assist and coordinate volunteer helpdesk team when the helpdesk is to be initiated. Both were required to pursue GCP and MoCA certification and training and regularly attend clinical team meetings. Helpdesk is minimally functional, supporting clinicians and is pending device delivery for becoming fully operational. Helpdesk is covered in section 4.3.2.
- **Set-up of Clinical Facility:** A new, more accommodating facility (with clinical examination rooms large enough to accommodate volunteer examination as requested in mini-BEST) was identified and contracted (M36).

  All required authorizations and certifications were requested and obtained in preparation of lawfully performing all clinical piloting tasks there:
  - Public Health Directorate authorised the premises on M41;
  - College of Physicians authorised the use of the facilities in M40, and re-authorized it in M53 (addition of new medical specialties);
  - ISO certification for conducting clinical studies was issued on M45 (to be renewed in M57);
  - NAMMDR authorised the facilities for conducting clinical studies in M51 (authorization request file was submitted in M43)

  Participants' enrolment is described in section 4.2.3.

  Pending more details on the Smart4Health synergy, recently approved, the same facility is expected accommodate this technical, demonstrative synergy.
- **Device Kit Preparation** will occur before allocating devices/kits to volunteers. Pre-configuration of smartphones, pre-pairing the devices, etc should reduce the time needed to be spent with participants and should allow an initial focus on users' training on expected tasks and activities as part of SMART BEAR. This activity is pending device delivery.

4.2.3 Patient Enrolment (Recruitment and Initial Assessment)

As previously anticipated in section 4.2.1, the SMART BEAR core clinical team will actively reach pre-recruited volunteers and cross-check their findings with the self-reported clinical history in the pre-recruitment questionnaires. If matching the criteria in pre-recruitment AND during phone call verifications, volunteers are scheduled to an extensive presentation of the project, according to ethics and GDPR regulations; following their consent (informed consent + consent to data processing) they are finally screened and, following that, undergo baseline and additional assessments.

The streamlined flow of eligible volunteers is depicted in Figure 6.

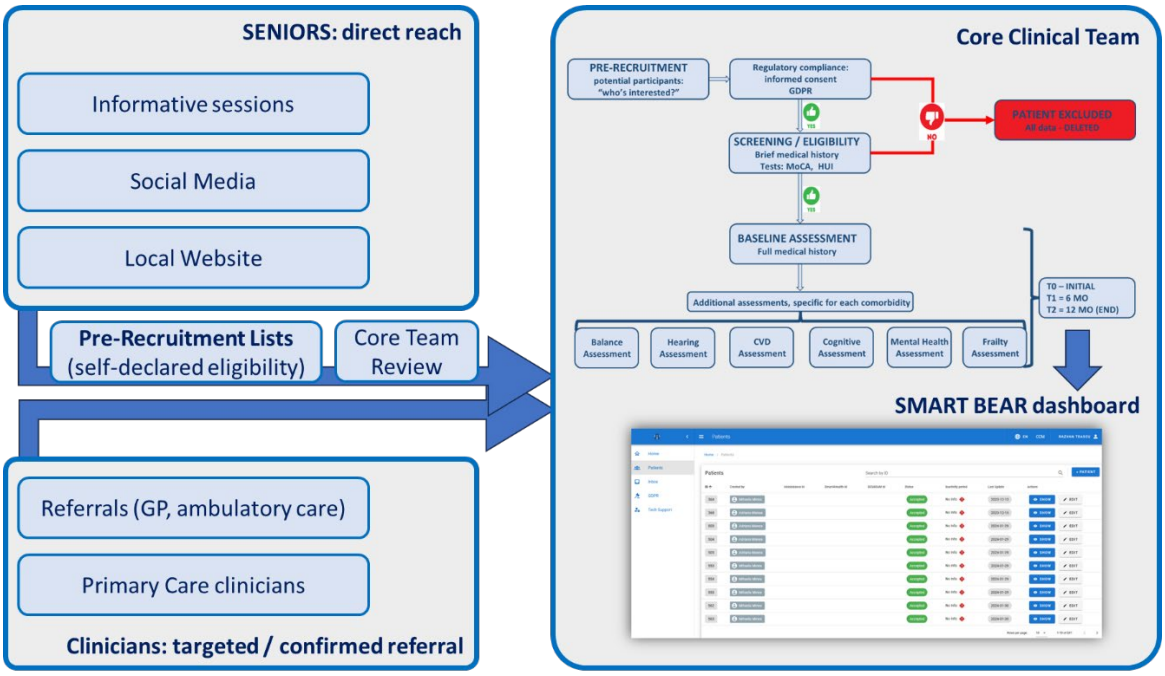

Figure 6: Recruitment process

More medical professionals are invited onboard the Romanian Pilot in various social media channels (Facebook closed groups on professional topics, linked in profiles) as well as in various local medical events.

Primary healthcare physicians are expected to screen their own patients and check their eligibility (inclusion & exclusion criteria), and to provide us with a medical history of their patients, including current medication & dietary restrictions, comorbidities, demographics and digital literacy assessments (since these are already available to them as part of regular care); all info provided is cross checked for each participant (saving additional time when targeting questions instead of open questions).

Our clinicians conduct informative sessions (for obtaining the informed consent and ensure GDPR compliance), then depending on the older adult's consent they confirm screening eligibility and perform baseline and additional assessments (based on appointment/s agreed with each participant).

If not available from participant's primary health care provider, ANA clinicians collect demographics and assess MoCA and dexterity scores (Figure 6). This confirms the inclusion / eligibility criteria and completes the recruitment process, being assigned a SMART BEAR ID in the dashboard.

Recruitment, initially planned to start earlier, was unfortunately delayed:

- It was a pre-requirement for the ethical approval of the Romanian pilot to have an official position on MDR status (see section 6 - Ethics Approval)
- Delayed Joint Procurement (see section 3.1 - Joint Procurement)
- Technical challenges related to dashboard usability and migration (staging environment accounts were only provided in M49)

The first participant in the Romanian pilot provided informed consent and was later screened in M52. As of May 2024 (M57), an overall 241 volunteers have been recruited as part of the Romanian Pilot.

4.2.4 User's Training and Feedback Management

For the patients that meet the eligibility criteria and that are enrolled in the pilot, pending on device delivery and preparation of device kits, additional appointments will be needed for device allocation based on use-case scenarios.

Core Helpdesk team will work closely with ITSS to ensure smooth device allocation and to ensure there will be enough pre-configured device kits to perform device allocation, both to already recruited participants and to ongoing/next recruitments.

Device allocation will consider the time needed to train participants on device usage and common problems. All questions and issues raised by participants will be collected in a structured manner to be added as "Frequently asked questions" to the Romanian pilot website.

All clinicians will have a minimal knowledge of how devices work (technology, data transfer protocols) and will have access to user guides, as they are expected to be the first ones contacted by study participants, even before contacting the Helpdesk.

The demonstrative setup of Smart4Health synergy location is pending further clarifications as new amendment was only recently signed (M57).

Expected participants' management diagram is depicted in Figure 7 and is subject to continuous review and optimization.

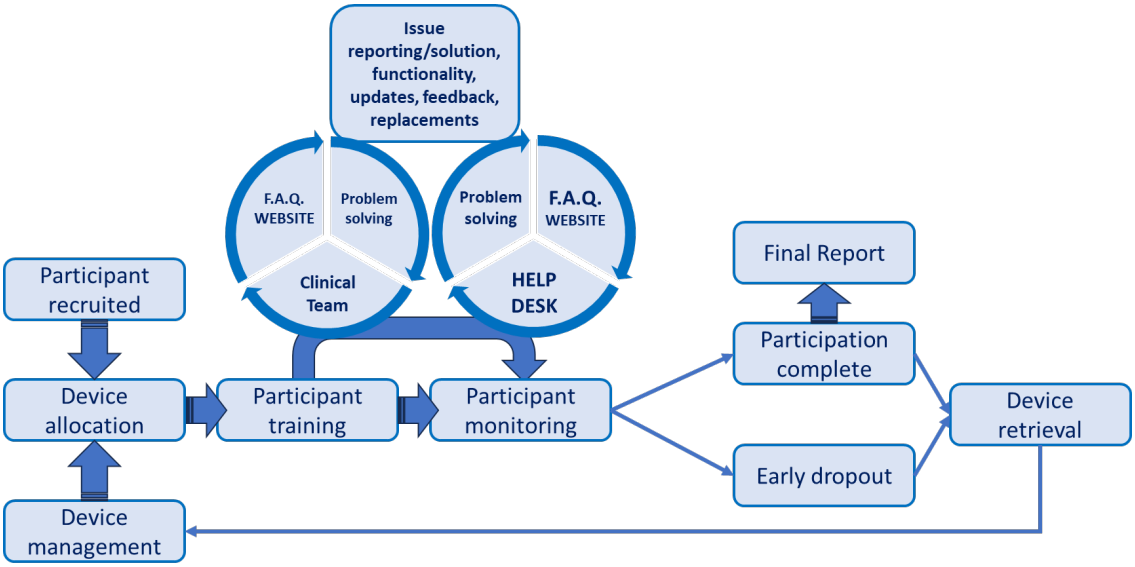

Figure 7: Participants' management diagram

4.3 Infrastructure Preparation

4.3.1 Preliminary Devices' Testing

ITSS contributed significantly to early identification and testing (M13-M14) of devices providing feedback to WP3 partners; the following devices were tested:

- Smartphone (Samsung S10)
- Smartwatch (Fitbit Charge 4)

- Smart thermometer (Withings Thermo)
- Smart BP monitor (Withings BPM Core)
- Smart scale (Withings Body+)
- Smart pulseoximeter (iHealth)

As a joint effort, both ANA and ITSS contributed to SB@App design (ANA – cognitive /serious games selection for SB@App), translation (ongoing) and testing of the SB@App (ITSS - M38) and dashboard (staging environment), providing insights from both technicians' and clinicians' perspective.

There was some additional (proof of concept) testing performed on Raspberry Pi /OpenHub configurations including various sensors (in anticipation of home kit preparation), identifying potential interference between 2.4 GHz WiFi networks and CC2531 dongle Zigbee connectivity in areas with high density (i.e. apartment blocks), duly reported to WP3 partners; both ANA and ITSS had contributions in documenting home sensing devices for MCI use case and the HomeHub technical manual.

Further testing is needed for the Romanian Pilot, pending delivery of devices making it to the final procurement list/finalization of joint procurement.

4.3.2 Helpdesk

The support team was initiated by designating 2 part-time collaborators, expected to assist the clinical team with appointments and office management issues; they were trained on minimally understanding the project (i.e. project requirements and goals, inclusion criteria) to better pre-screen potential participants before making appointments for the presentation of the study (=obtaining the informed consent) and/or clinical assessments within the project (Table 3).

Two volunteers (Table 3) were identified and instructed as they are expected to be the core helpdesk team, responsible for coordinating with ITSS (tech partner for Romania) and with all ANA clinicians and for coordinating the volunteer-based helpdesk to be initiated upon device delivery.

Name	Role	GCP	MoCA	SB training
Daiana Muller	Front-desk / Support	-	-	M56
Petruta Paraschiv	Front-desk / Support	-	-	M56
Dr. Ana Cherciu	Helpdesk / Support	M55	M55	M56
Dr. Vlad Barbulescu	Helpdesk / Support	M55	M54	M56

Table 3: Core helpdesk / front-desk teams of the Romanian Pilot

Helpdesk is expected to function on volunteers (medical residents and students) and is standing by for initiation, upon device delivery initiation. An in-house software solution is being developed in collaboration with ITSS for the sole purpose of integrating volunteer appointments, device management and helpdesk support.

ANA helpdesk will cover:

1. **first level assistance**: end user support, to be provided by ANA via **dedicated phone and/or email**. All issues solved will be categorized and ranked and, if

frequent, will be submitted for publication in the *Frequently Asked Questions* section of the Romanian pilot website.

If unable to solve issues, end-user input is forwarded to next level.

2. **second level support**: local troubleshooting will be done by ANA working closely with ITSS.

User feedback processing and any platform issues/incidents are centrally managed by the platform integration team (WP6).

Helpdesk contacts will be provided to:

- study participants
- clinicians involved in the project (referrals / recruitments)

The final helpdesk setup will be presented in D11.2, as updates and adjustments are expected following the receipt of devices to be tested.

4.3.3 SMART BEAR Patient Kits

The exact content of the SMART BEAR device kits will vary according to the health conditions and comorbidities assessed by the clinical team. Specific devices are only relevant if particular conditions are present (i.e., blood pressure monitor only available to cardiovascular patients).

To save time, as previewed in section 4.2.2 - Infrastructure Installation Plan, ANA and ITSS intend to use pre-paired kits of devices fitting specific patient profiles, as suggested by the PoP. As of June 2024 (M58), no devices are available to ANA/ITSS.

Based on partner's reports, we expect a two-stage device allocation process:

- Device kit preparation (preconfiguring / pre-pairing devices), and
- Device deployment (training and actual delivery to participant).

As for device preparation, two tentative distinct workflows are expected:

- wearables kit, derived from a general-purpose kit (smartphone type 2, smart watch, smart oximeter and smart thermometer), plus additional devices, on a per-needed base (i.e. smart scale plus blood pressure monitor for cardiovascular conditions).
- home kit (includes besides the general-purpose kit, the Raspberry Pi running on OpenHab, the smart home hub and sensors, the light bulbs).

Pending device delivery, we expect the following flow:

1. creation of Google accounts for smartphone initialization and setup
2. smartphone setup, including installation of SMART BEAR App and wearable providers' connectivity apps (account creation & login for proprietary apps)
3. device pairing
4. Individual packaging and labelling

4.4 Users Training

SMART BEAR training includes different target groups: clinicians, support team/staff, helpdesk, participants, technical operators.

Technical training is based on the documentation provided by partners in implementation WPs as project deliverables and additional materials. Since all the staff involved in ANA activities is proficient in English, no translation from English into Romanian was needed.

Training materials tailored to local needs, based on the use-case scenarios and general training content provided by WP2 and WP12 are pending device delivery for finalization (they will include user manuals, to be provided by vendors in Romanian).

- The **support/front desk team** was initiated by designating 2 part-time collaborators, expected to assist the clinical team with appointments and office management issues; they were trained on minimally understanding the project (i.e. project requirements and goals, inclusion criteria) to better pre-screen potential participants before making appointments for the presentation of the study, for obtaining their informed consent and/or for the purpose of clinical assessments within the project.
- Two volunteers were identified and instructed as they are expected to be the **core helpdesk team**, responsible for coordinating with ITSS (tech partner for Romania) and for coordinating the volunteer-based helpdesk to be initiated upon device delivery. Both are devoting their personal time to learning about protocol framework and tech issues, and they are expected to assist and coordinate any volunteers joining the helpdesk team later, upon device delivery and helpdesk initiation. Both were required to pursue GCP and MoCA certification and training and regularly attend clinical team meetings
- The **core clinical team** underwent online clinical training with NKUA in M51; all are GCP and MoCA certified. Core clinicians (especially the lead case manager) were in constant contact with PoP (clinical aspects) and UMIL (tech aspects/dashboard training) and are fully capable to assist any newly-joining clinicians in case they needed help with either protocol or dashboard usage.

The overall training concept is provided in Figure 8:

- WP11 representatives (clinical lead, project manager and / or lead clinical case manager) attend regularly consortium meetings then update the core teams in regular (weekly) meetings about central (consortium-level) decisions, pilot evolution, next steps. Feedback and any possible local issues are relayed to consortium partners;
- Core teams participate to drafting local support materials (i.e. translation, adaptation and design of materials for participants: website updates, manuals for use of the devices etc). They also get involved in training and updating new team members.

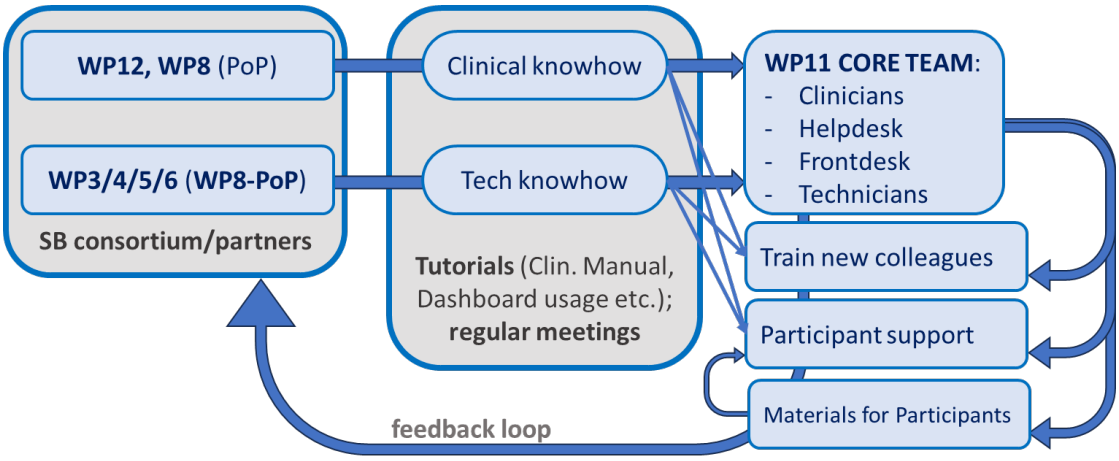

Figure 8: Training and change management activity diagram

4.4.1 Clinical Staff

Proper training of the clinical team was essential for initiating the pilot. All core clinical team members were provided all ethical and clinical protocol documents, any relevant manuals and technical documents; they were also required to have proper certifications and trainings as per protocol/design (i.e. GCP, MoCA). They were provided access to SMART BEAR staging environment before going through the clinical & dashboard training lead online by WP12 partners in M51.

The core clinical team was already listed and presented in Table 2: ANA core clinical team of the Romanian Pilot (page 14, Baseline Definition); all are experienced, licensed medical doctors, well versed with older adults (i.e. family practitioners, geriatricians etc).

The Ethics Application & Piloting Protocol & Evaluation Framework was translated into Romanian, as it was needed in the WP11 ethical approval (covered in section 6, Ethics Approval), and is provided as ANNEX 1: D12.1 (D52) - RO.

4.4.2 Participants

According to ethical regulatory requirements all potentially eligible participants were provided in depth explanations about the protocol requirements and expected usage of devices as per the SMART BEAR ethical framework and testing protocol.

A website was designed to allow a centralized, transparent point of access for all participants, recruited or not. Website includes updates about the project, frequently asked questions (we already centralized all frequent issues encountered while obtaining the informed consent, and we intend to update it with usage /troubleshooting also, after receiving devices and initiating device allocation).

We also intend to provide a translated manual for SB@App and provide the manuals in Romanian for all the different devices (pending delivery).

5 Dissemination & Communication Activities

An exhaustive description of WP11 dissemination and communication activities was provided in SMART BEAR annual project reports (deliverables D1.2, D1.8, D1.4 and D1.9). Briefly categorized, the ones relevant to WP11 were:

- **national/local dissemination activities** were targeted at raising interest and awareness amongst primary healthcare doctors, working in Romania, which would potentially either (1) refer their (chronic/eligible) patients to ANA for SMART BEAR eligibility check/recruitment or (2) get involved in piloting as part of the ANA clinician team (SB assessments for participants/volunteers). Such events included:
    - our annual conference STRESS CONGRESS, featuring presentations and / or panels / workshops dedicated to SMART-BEAR project in 2021, 2022, 2023
    - dedicated, recurrent panel featuring SMART BEAR presentations in BeHealth, the annual RO-HEALTH conference (Romanian Gold Cluster), 2021, 2022, 2023 editions
    - national conferences dedicated to mental health professionals (i.e. CNAlz2023 – National Conference on Dementias and Alzheimer), GPs (Conference on Family Practice)
    - recurring telcos and meetings with local GP representatives (over 30) during the COVID pandemic, following the strategic partnership with local GP associations (M6), exhaustively listed in the periodic technical reports.
    - ANA newsletters / podcasts targeted at healthcare professionals.

- **communication activities**: following the partnerships with the Centre for Seniors of the Bucharest Municipality and with the General Directorates for Social Services in all 6 districts of Bucharest, there were in excess of 40 meetings with GDSS and CS-BM representatives (physical/telcos), resulting in about 20 large-scale meetings with older adults, attendance lists summing up to 600 participants, which were the basis of pre-recruitment lists mentioned in section 4.2.1. In addition to these, ANA was a constant presence in various newsletters, TV / radio shows, podcasts and newspaper articles dedicated to smart healthy ageing, constantly mentioning this project in an attempt to raise awareness.

Dissemination and communication activities are ongoing at a local/national level, aiming at keeping and boosting interest in project participation. However, this is challenging as no estimates can be provided, neither to clinicians nor to participants, about device deliveries.

6 Ethics Approval

Getting the ethical approval for piloting in Romania was particularly challenging, as the implementation of Directive 2005/28/EC laying down principles and detailed

guidelines for GCP into Romanian legislation corroborated with national legislation fine-tuning the implementation of the MDR required as a mandatory step contacting the national authority (NAMMDR) and obtaining a written decision stating SMART BEAR is not subject to MDR; depending on SMART BEAR qualification as MDR / non-MDR, the ethical approval needed to be obtained from the national ethics committee or, respectively, from an independent / institutional committee.

In order to clarify particularities of national legislation, ANA representatives consulted NAMMDR as part of a high-level audience held on M45 regarding the MDR classification of SMART BEAR, attended on behalf of ANA by the lead clinical case manager, ANA pilot manager and ANA legal advisor and on behalf of NAMMDR by the vice-president and the director for market regulation and surveillance department.

Following the Consortium statement position adopted in M43 and the Statement of the Coordinator signed in M46, and based on the lessons learnt from the meeting held on M45, the ANA team of experts successfully obtained the first (amongst SMART BEAR pilots) written position of a national authority regarding the MDR status of the SMART BEAR project (in M47).

There were quite a few legislative changes in national legislation, most being issued by the Ministry of Health (abbr. MoH), potentially impacting the project, which ANA team had to consider and reflect in all procedures, processes and flows:

- M40: Methodology for market approval for medical devices and registration of medical devices in EUDAMED
- M41: Methodology for evaluating, appointing and notifying medical device assessment bodies (MoH, #3969/2022, last amended in M50)
- M42: Methodology for medical device clinical evaluation & investigations (MoH, #330/2023)
- M50: Amendments to MoH 3969/2022 (MoH #3277/2023)
- M50: Romanian version of harmonised standards for medical devices (MoH 3362/2023)
- M51: Changes and amendments to medical device regulations (MoH #3876/2023)

All these local legislative changes had to be considered and implemented, triggering conformity amendments for all documents and flows.

As requested in the guidance provided by the NAMMDR and as approved by the Coordination team, ANA applied to obtain the ethical approval for SMART BEAR using a slightly modified protocol (i.e. no notifications allowed in the Smart Bear app), to keep the project out of scope of MDR.

6.1 Documents Submitted

The ethical approval was first issued by the Local Ethics Committee in M50, then subsequently revised in M56; the documentation provided to obtain the ethical approval included the following, attached hereto:

- Deliverable D52 (D12.1), Ethics Application & Piloting Procol & Evaluation Framework (provided as original in English, plus the translation into Romanian: ANNEX 1: D12.1 (D52) - RO);

- NAMMDR decision no. 304210E/2023, stipulating that SMARTBEAR is not subject to MDR 2017/745(EU), except for the patient alerting module of the SB@App (ANNEX 2: NAMMDR Decision)
- Templates for Information Letter and Confidentiality Policies, as well as template for Informed Consent for Participating to SMARTBEAR Research Project and Informed Consent for Processing Personal Data (versions current as of May 2024 provided in ANNEX 3: Participant pack

Ethical approval (v1 / M50 and v2 / M56) is provided in ANNEX 4: Ethical approval
Ethical and regulatory compliance is an ongoing process, and ANA revises ethical documentation as often as required to ensure all participants' rights are observed, especially since SMART BEAR targets a vulnerable population.

7 Lessons Learnt and Next Steps

Even ahead of receiving devices, ANA gained (and shared with consortium partners) in-depth insights about local and EU regulations and their applicability in research projects; this allowed the whole consortium to proactively address the EC recommendation enquiring about project qualification as a medical device, which expedited clinical & ethical approval) and effectively aided in anticipating issues and in problem-solving. We also learned to adjust promptly to the frequently changing regulatory aspects and to design a flexible, rapidly adaptable piloting framework / setup. Proper communication and regular networking with consortium partners are crucial in problem-solving, as shown by:

- **Procurement:** efficient expedited coordination of effort is crucial to ensure success; whenever multiple parties are involved (i.e. trilateral agreements), reaching satisfactory agreements can be time-consuming, as regulatory requirements may differ between member states or between public and private entities. All specific requirements need to be timely formalized in terms of guarantees, offers, invoicing, shipment & delivery schedule etc.
- **Pilot preparation:** a thorough understanding of both clinical and technical aspects of the project is required from both clinical and technical partners; common terminology and mutual updates, regular contact and having a joint strategy should offload/switch certain device training and troubleshooting tasks between clinical and technical staff.
- **Ethical approval:** Since "directives" are legislative acts that set out goals for EU member states to achieve, it is up to individual member states to devise their own laws – which makes GCP compliance extremely challenging in projects involving several member states. Some countries are stricter than others (apparently this being the case for Romania), and syncing up documents and requirements across member states / partners can be crucial for timely ethical approval. It was particularly challenging for SMART BEAR to have the MDR enter into force in 2021, after the project was approved and kicked off.

Both partners in the WP11 (Romanian Pilot involves ANA and ITSS) are in sync and ready to make any necessary adjustments; next foreseeable steps are:

- **help desk** is standing by, pending device delivery; will provide support to participants, clinical and technical operators. An in-house ticketing solution will allow a feedback loop with technical partners, and the consortium-wide schedule of regular pilot board meetings is set in place, allowing coordinated efforts of tech and clinical teams from all pilots.
- **recruitment/enrolment**: it is hoped that device delivery, kit preparation and device allocation start soon, as there is an imminent risk of having the participants lose interest in the project (first participant was recruited months ago – M52).
- **ethical / regulatory compliance:** this is an ongoing process of the outmost importance, since SMART BEAR does target a vulnerable population.

8 References

[1] National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) - CDC, "COVID-19 in the Madeira Islands." [Online]. Available: https://wwwnc.cdc.gov/travel/notices/covid-2/coronavirus-maderia-islands. [Accessed: 03-Feb-2022].

[2] SMART BEAR Consortium, "Deliverable D3.1 - SMART BEAR @ Home Enabling Components v1," SMART BEAR EU Project (H2020-857172), www, 2021.

[3] SMART BEAR Consortium, "Deliverable D3.2 - Report on SMART BEAR @ Home Enabling Components v1," SMART BEAR EU Project (H2020-857172), 2021.

[4] SMART BEAR Consortium, "Deliverable D12.1 - Ethics Application & Piloting Protocol & Evaluation Framework," SMART BEAR EU Project (H2020-857172), 2020.

[5] SMART BEAR Consortium, "Deliverable D6.3 - Report on SMART BEAR @ Home Enabling Components v1 (Draft)," SMART BEAR EU Project (H2020-857172), 2021.

[6] Smart4Health Consortium, "Deliverable D4.4 - 1st Provision of tools, software and instruction notes for interoperability and integration of components in the CUCs," Smart4Health EU Project (H2020-826117), 2019.

[7] K. T. F. Barbosa and M. das G. M. Fernandes, "Elderly vulnerability: concept development," *Rev. Bras. Enferm.*, vol. 73, no. suppl 3, 2020.

[8] L. Mary, L. Boggs, L. Whelan, and F. Baka, "ICH Good Clinical Practice E6 (R2)," *Global Health Training Centre*. [Online]. Available: https://globalhealthtrainingcentre.tghn.org/ich-good-clinical-practice/. [Accessed: 03-Feb-2022].

[9] Nasreddine, Z. S., Phillips, N. A., Bédirian, V., Charbonneau, S., Whitehead, V., Collin, I., ... & Chertkow, H. (2005). The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. Journal of the American Geriatrics Society, 53(4), 695-699.

[10] SMART BEAR Consortium, "Deliverable D14.3 - POPD - Requirement No. 3," SMART BEAR EU Project (H2020-857172), 2020.

[11] SMART BEAR Consortium, "Remarks on the Review Report - PMOC-857172-1 (ver 2.0)," 2020.

9 ANNEX 1: D12.1 (D52) - RO

This is SMART BEAR deliverable D12.1 (D52) – Ethics Application & Piloting Protocol & Evaluation Framework, translated into Romanian.

Annex 1. D52 (D12.1) – RO
"Ghid privind avizarea etică, protocolul de testare și evaluare" (108 pages)

This Annex is provided as a separate embedded PDF file.
To open this Annex:

- *double click left image (editable/DOCX version)*
- *browse & open attachments (PDF version)*

10 ANNEX 2: NAMMDR Decision

The formal response of the National Authority in Romania (NAMMDR) regarding the MDR classification of SMART BEAR project and a certified translation, provided to all partners.

Annex 2.1. NAMMDR response on MDR
Original Response (in Romanian) – 1 page

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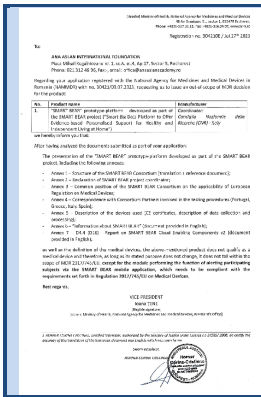

Annex 2.2. NAMMDR response on MDR
Certified Translation (into English) – 1 page

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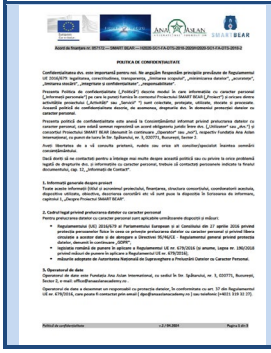
11 ANNEX 3: Participant pack

The participant pack consists of the following documents (provided as external attachments, in Romanian, versions current as of May 2024, as approved by the Ethics Committee):



Annex 3.1. Confidentiality Policy (in Romanian), provided to SB participants before obtaining GDPR consent (5 pages)

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Annex 3.2. Informative Letter about project activities, provided before obtaining the Informed Consent (12 pages).

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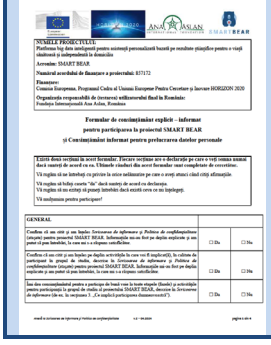

Annex 3.3. Informed Consent Documents (in Romanian), including GDPR and Informed Consent sections, compliant to normal regulatory requirements (4 pages).

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12 ANNEX 4: Ethical approval

Ethical approval documentation for the Romanian Pilot of SMART BEAR, was issued as a bilingual version.

Annex 4.1. Initial ethical approval: M50
Issued in Oct. 2023, bilingual (Romanian / English), 3 pages.

This Annex is provided as a separate embedded PDF file.
To open this Annex:

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Annex 4.2. Ethical approval, as revised in M56
Issued in Apr. 2024, **b**ilingual (Romanian / English), 3 pages.

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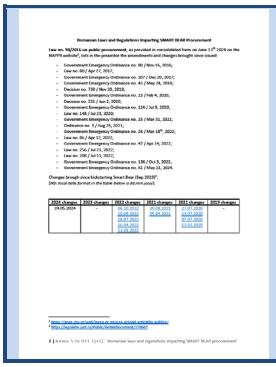
13 ANNEX 5: Particularities of Romanian regulatory framework

Documents relevant for the particularities of the national regulatory framework in Romania.



Annex 5. Selected list of Romanian Laws and Regulations Impacting SMART BEAR Procurement (4 pages)

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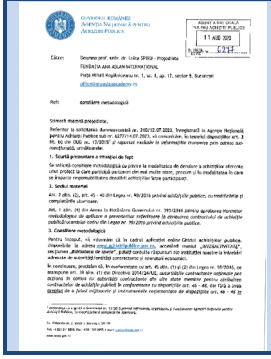

Annex 5.1. NAPPR methodology guidance about national regulations on joint procurement (Romanian) (2 pages).

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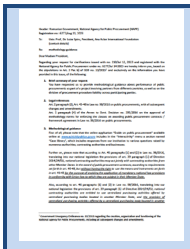

Annex 5.2. NAPPR methodology guidance about national regulations (translated into English, 2 pages).

This Annex is provided as a separate embedded PDF file.
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- *browse & open attachments (PDF version).*