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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"

D7.1 – Greek Pilot Report v1

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D7.1 – Greek Pilot Report v1

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1 Executive Summary

The Greek Pilot of the SMART BEAR project consists of two distinct legal entities, one representing the Regional Government Sector (RoP – Region of Peloponnese) and one the Local Government Sector (MPF – Municipality of Palaio Faliro). The two pilot sites, albeit legally distinct, share a common project management plan for the implementation of the project with different operational plans depending on the various needs of the participants in the two sides. At the same time, both sides share common challenges though: the ageing of the population and the general digital illiteracy of the elderly, the decreasing fertility rates and the emigration of younger and skilled people in richer Western Countries (Brain Drain effect).

This is a situation that characterizes Greece as a whole and is a threat of existential magnitude. Compared with 1951, the proportion of people in Greece aged 15-64 compared with 2020 was down by 1.4 per cent, but that number is going to balloon in the coming decades. In 1951 the proportion of people aged up to 19 years was 38.6 per cent, but in 2020 it was only 19.4 per cent. In 1951 the number of people aged 65 and over was 6.8 per cent, but by 2020 it was 22.3 per cent, a number which is projected to increase to 28 per cent by 2040. Moreover, the proportion of people of working age will have shrunk from 58.5 per cent in 2020 to 54 per cent by 2040[1]. The demographic time-bomb has serious implications for the sustainability of the Health and Social Protection System as the very old people need more and more costly resources when they are in need of healthcare services, especially during their late years when the chronic disease challenge is more prominent.

The success of SMART BEAR may be, therefore very significant for the Greek pilot for many reasons: **Firstly**, because it will be important to showcase based on Real World Evidence, that digital health technologies can support active and healthy aging in a personalized manner for the elderly population in the study but for individuals as well. **Secondly**, the analysis of the results in the MPF and RoP sites, may allow for replicability based on an emerging model of chronic disease management in Greece, where the regional and local administration are important stakeholders in the prevention of chronic diseases facilitated by integrated care teams of professionals, supported by feasible and evidence based clinical protocols, outcomes-oriented interventions and supportive, easy to use, digital tools for independent living and improved self-care. MPF and RoP, can become pioneers in this field. **Finally**, some results may be exploitable by the Greek partners, both in terms of research but also commercially based on the business models created, hence allowing for sustainability beyond the end of the project. This deliverable, D7.1, will focus on the **achievements** of the Pilots towards success, the **challenges** encountered and the plans until the next deliverable D7.2 “Greek Pilot Report v2” in month 60 (August 2024) of the project.

[1] https://balkaninsight.com/2022/09/08/greeces-ticking-demographic-time-bomb/

2 Introduction

SMART BEAR is a multi-centre patient-centred research project aiming at implementing state-of-the- art technology in the everyday life of elderly citizens with specific multimorbidities, 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 elderly and their ability to live independently, while also contributing to a continuous and objective monitoring with personalized interventions towards optimizing disease and associated risks' management.

The Greek pilot includes two clinical sites, Municipality of Palaio Faliro (MPF), which is a local government authority, and the Region of Peloponnese (RoP), which is a Regional Government Authority. Despite their differences in terms of the structure of the population (urban vs rural), demographics, epidemiology of chronic diseases etc, the two sites share one common objective: to respond swiftly and effectively to the projected chronic disease epidemic, through personalized interventions in community settings and supported by state of the art digital tools that promote active and healthy aging, especially at later years of life, thereby improving the health status, quality of life and well – being of old people with multimorbidities, adding more healthy years to their lives. In this Deliverable D7.1, the Greek pilot site clinical partners RoP and MPF, outline and discuss the various challenges and achievements until March 2024 as well as the plan until the submission of the next Deliverable D7.2 in August 2024.

2.1 Purpose of the document

Deliverable D7.1 "Greek Pilot Report v1" is the 1st report with respect to the deployment activities of the SMART BEAR Greek Pilot site partners, RoP and MPF. In this report, the **ACHIEVEMENTS** are related to:

- Organization and progress of patient pre-recruitment, recruitment, inclusion baseline and specific assessment;
- Establishment of recruitment centres and staffing with healthcare personnel.
- SMART BEAR and Synergies Device uptake, preparation for use and delivery to participants.
- Training of participants in the use of the app and the devices delivered.
- Tools and methodologies to monitor implementation progress in pilot sites (beyond the Clinical KPI's that will be reported in D7.2). Also, in D7.1, the CHALLENGES encountered by RoP and MPF clinical teams during the reported period covered in D7.1 are outlined and the means used to overcome them are presented. Finally, the plans of the 2 pilot sites of the Greek Pilot, until the next deliverable D7.1 are discussed.

2.2 Objectives of the Smart Bear Greek Pilot

The objectives of the Greek Pilot (RoP (Leader of the Greek Pilot) and MPF in WP7, are as follows:

- To ensure timely and appropriate recruitment of study participants according to the study ethical documents and ethical procedures,
- To deliver training to the involved health professionals in the study clinical pathways, the use of the required SMART BEAR and Synergy's Devices and the implementation of the digital interventions through the app,
- To ensure that the SB devices and the app interoperate and are fully functional for use by

participants and for collection of project data,

- To monitor the progress of the participants in the use of the digital interventions,
- To continuously provide lvl-1 & lvl-2 support to participants through the operation of a physical and over the telephone help desk service and to motivate them to continue in the study and avoid high dropout rates.

2.3 SWOT Analysis of the Greek Pilot Sites participating in Smart Bear (MPF, RoP)

INTERNAL FACTORS	
STRENGTHS +	WEAKNESSES –
• A culture of Innovation in the Pilot Sites • The Public Authorities participating in the project, the General Directorate of Public Health and Social Welfare of the Region of Peloponnese and the Municipality of Palaio Faliro are institutions that represent a solid social footprint to the citizens, which creates easier and quicker confidence relations with the potential participants. • Leaders, Political and Clinical, are experienced in deployment and monitoring of similar projects • Highly skilled and committed healthcare and managerial workforce	• Due to the under-staffing of public institutions, there is a lack of adequate human resources to support digital, personalized health prevention interventions for active and healthy ageing • Elderly people are not digitally literate, and they need a lot of support • The health profile of the population is unknown, so it is very hard to recruit participants with the according to the envisaged comorbidity stratification.
EXTERNAL FACTORS	
OPPORTUNITIES +	THREATS –
• To become centers of excellence for digitally provided, integrated, prevention services directed to elderly people with chronic diseases in Greece at local and regional level since this contributes to the reform taking place in the NHS. • To convince decision makers based on the clinical and technical results of the project, to adopt the SmartBear service as a regular prevention service in NHS Primary Health Centers financed by national funds and European Structural Funds.	• To compete for financial support against other digitally supported, integrated care prevention projects that will strive to get financing from the Resilience and Recovery Fund and European Social Fund in Greece. Once the project is concluded there is no business model in place that can allow for continuation.

Table 1: SWOT Analysis of the Greek Pilot Site

3 Achievements of the reek Pilot

3.1 Pre – Recruitment and Recruitment in the Pilot

Both RoP and MPF faced a difficult task to recruit the required number of participants in the SMART BEAR Project. The main problem was that since they are not NHS providers, but their activities pertain to public health and health promotion and prevention, they do not have a comprehensive analysis of the epidemiology in their capture areas related to the conditions SMART BEAR targets. Both authorities decided to start a comprehensive pre-recruitment campaign, using various communication channels and tools, in community settings. Pre-recruitment, started in October 2022, a long time before the actual recruitment kicked off. The idea was to stimulate the interest of potential participants before recruitment, and build a comprehensive database of interested participants, that could be recruited in the pilot fast when the recruitment centres were set up and the clinical teams were trained and fully operational.

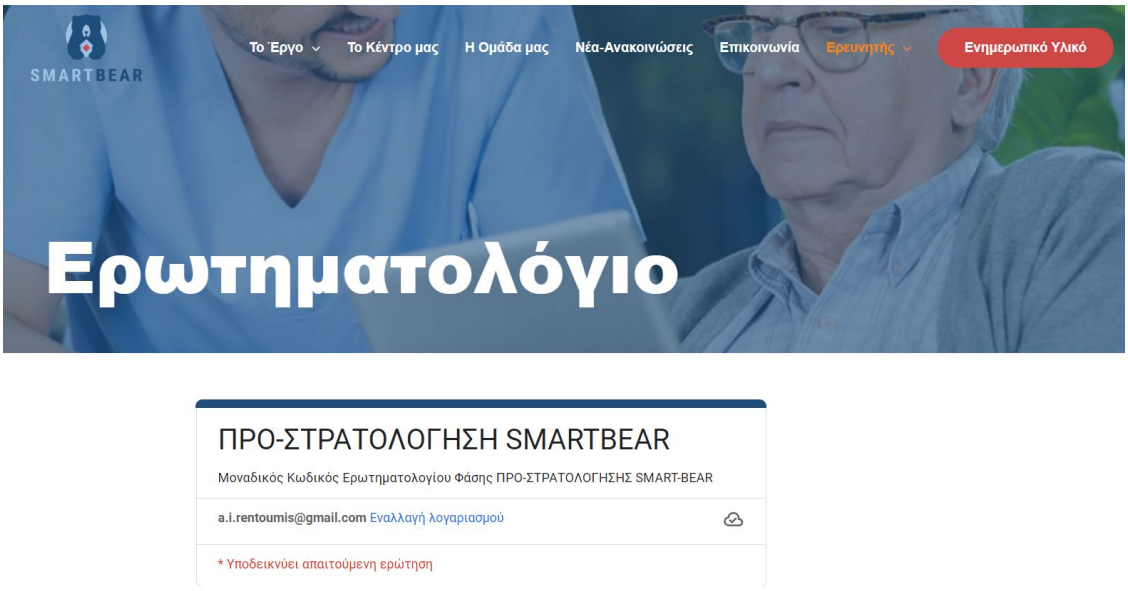


Figure 1: MPF Pre-Recruitment mini-site

To facilitate pre-recruitment, RoP developed a pre-recruited questionnaire to be completed by potential participants during pre-recruitment events, containing demographic and contact information, current diseases and co-morbidities, medication, lifestyle habits and level of digital literacy. This allowed for safe and secure patients' data collection and comorbidities categorization and gave a clear picture of the population in perspective. MPF developed a page within the project website (www.smart-bear.gr), in order to collect all answers from a pre-recruitment questionnaire that was developed early in the project by MPF officials and clinicians, quite similar to that of RoP. A screenshot of the mini-site is presented below.

The Region of Peloponnese launched an official cooperation with the Municipal Authority of Tripoli allowing for recruitment of beneficiaries from the ΚΑΠΗ (Open Protection Centres for the Elderly). All ΚΑΠΗ were open to RoP Clinical Team Members to carry out recruitment processes.

MPF focused on a two – pronged pre-recruitment approach. Firstly, by implementing communication and awareness raising actions through various communication channels within

the municipality and secondly by engaging health and social services in neighbouring municipalities, i.e. the municipalities of Alimos, Agios Dimitrios, Egaleo and Nea Smyrni. After an initial high-level meeting at policy makers level, the neighbouring municipalities organized communication events in their own ΚΑΠΗ, while MPF healthcare professionals and volunteers, informed potential participants about the project aims, benefits, inclusion and exclusion criteria, and then proceeded to completion of the pre-recruitment questionnaire together with the citizen.

At MPF, the first phase of pre-recruitment lasted from September 2022 to July 2023 and progressed slowly. During this first phase, MPF pre-recruited 357 potential participants through the pre-recruitment survey tool provided at https://smart-bear.gr/. After the Clinical Team was assembled at the Municipal Center for Digital Health Prevention – Kentro Psiphiakis Proliptikis Iatrikis (KE.PSI.P.I.), in the middle of July 2023, the second phase of pre-recruitment started.

	First Pre-recruitment Period	Second Pre-recruitment Period
Appointments	46,9% (n=168)	**76,7% (n=268)**
No appointments	52,9% (n=189)	22% (n=77)
Later appointment	0,2% (n=1)	1,1% (n=4)
No response	0% (n=0)	0% (n=0)
Out of age	16% (n=57)	**1,4% (n=5)**

Table 2: Pre-recruitment progress, comparison of 1st and 2nd phase (MPF)

A systematic effort was dedicated by one psychologist / health visitor and a nurse, to create a pre-recruitment plan, that was set forth in September 2023 and was renewed in January 2024, when it was presented to the Mayor of MPF. According to the plan, six action pillars were identified as crucial for pre-recruitment success:

- Pre-recruitment at the Elderly Centres for the Elderly (KAPI) and the MPF Sport Centre (ΠΟΑΚΕ).
- Pre-recruitment of MPF personnel and municipal counsellors relatives.
- Pre-recruitment through the operation of 2 Smart Bear Info Kiosks positioned at central locations of MPF.
- Pre-recruitment at Private HealthCare Sector units (Diagnostic Centres, Private Medicine Practices, Pharmacists etc)
- Pre-recruitment of beneficiaries in other Municipalities through formal MOU implementation.
- Pre-recruitment at Local Enterprises.

Figure 2: Pre-Recruitment Action Plan Pillars at MPF

Realizing that recruiting 560 participants in the project (increased in the latest amendment to 640 early in 2023), would be a difficult task, MPF focused on pillars 1, 3 and 5 of its pre-recruitment strategy. More specifically, the main focus from January 2024 (M53) onward, was on activating cooperation agreements with the health and social services of neighbouring municipalities, such as the municipalities of Alimos, Agios Dimitrios, Egaleo and Nea Smyrni. The neighbouring municipalities organized communication events in their own Elderly Care Services while KE.PSI.P.I. professionals informed participants about the project and pre-recruited interested potential participants in the pre-recruitment platform for further analysis and scheduling of appointments for eligibility assessment at KE.PSI.P.I.

Through these activities, it was possible to broaden the pre-recruitment base and by the end of May 2024 (M57), 831 potential participants were pre-recruited from all 5 municipalities. From these 831 potential participants, KE.PSI.P.I. contacted 707 potential participants and arranged for 61.6% eligibility and recruitment appointments (436 potential participants), while 37,9 % of contacts did not culminate in appointments at KE.PSI.P.I. for various reasons. It is important to mention when recruitment finally started, 86 individuals were already out of age range (mainly citizens from the first phase of pre-recruitment). Pre-recruitment data analysis showed that it would be difficult to reach the numbers related to some clinical entities of Smart Bear. Figure – 3 below, shows the numbers of pre-recruited potential participants per self – reported clinical entity of Smart Bear. For example, the frequency of self-reported frailty in our sample, is about 9%. These data are updated and cover the period until May the 29th, 2024.

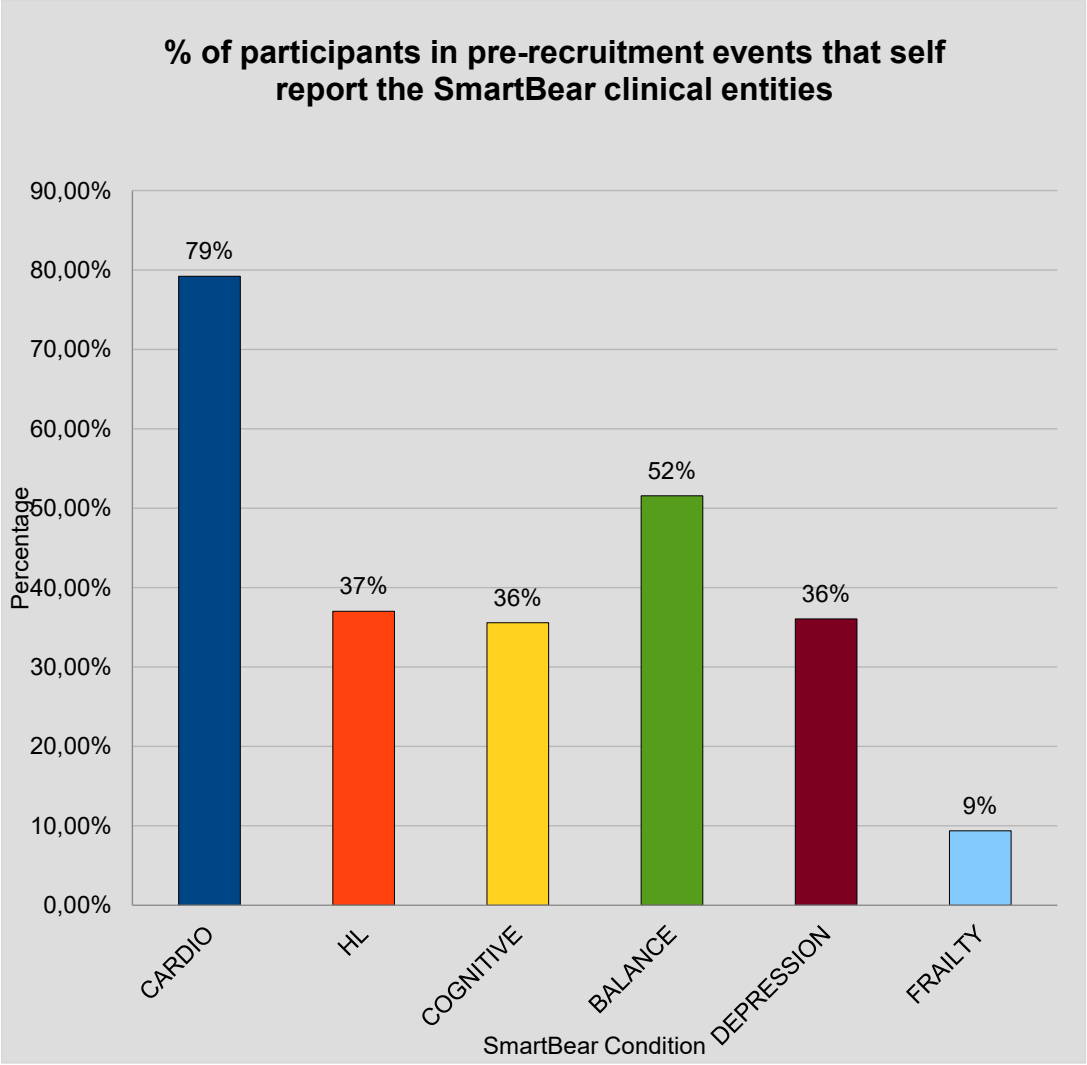


Figure 3: % of participants in pre – recruitment events that self – report Smart Bear clinical conditions

RoP started the first pre-recruitment phase in August 2022 (M36), through the participation in the 50th Panpeloponnesian exhibition of Tegea, to raise awareness in the public about the Smart Project. In the following period up to January 2023, contacts were slow and in small-scale meetings as the situation was constantly changing, with delays regarding the readiness of the SMART BEAR platform, the mobile application and the delivery of the equipment to be provided, a dire situation that could have caused unwillingness from potential participants to take part in the recruitment process. From January 2023 to August 2023, pre-recruitment data analysis indicated that the number of potential participants was sufficient for the needs of the project and the goal of the RoP Team. During this period, RoP professionals encountered more than 240 individuals, and officially included 103 potential participants in the pre-recruited selection process of which:

- 43 were suffering from Hearing Loss,
- 21 were suffering from Balance Disorders,
- 67 were suffering from Cardiovascular Diseases,
- 10 were suffering from (Mild) Cognitive Impairments &
- 22 were suffering from Frailty.

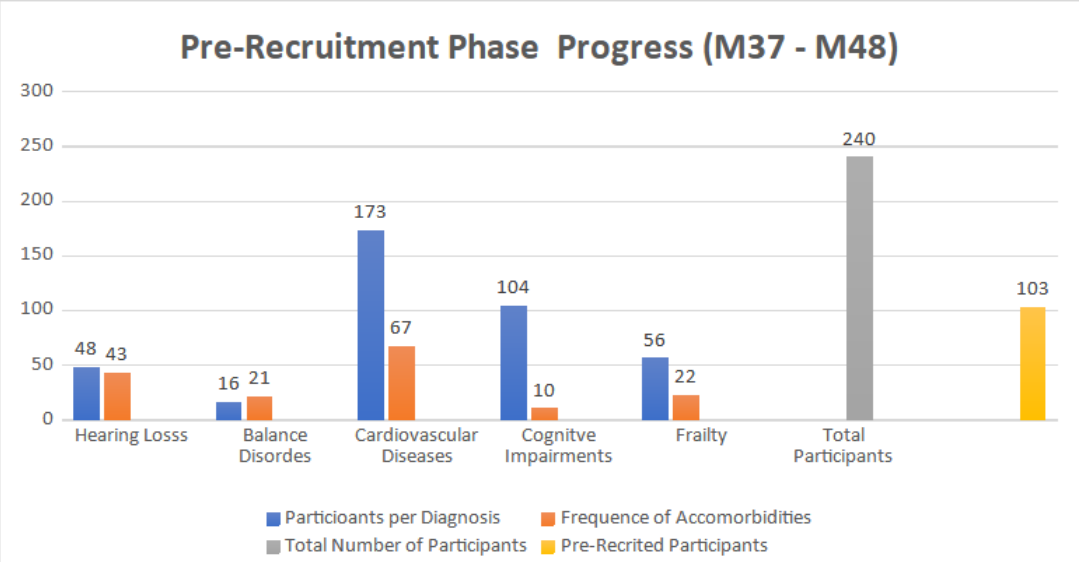


Figure 4: RoP Pre-Recruitment Progress

The following months, these numbers increased rapidly as the understanding of the high scientific level of the program, the help it can offer in the daily life, as well as the prestige of the Institution of the Region of Peloponnese, were all important boosting factors.

Table 3: RoP Dissemination Activities

Month	Categorization	Description
M43	Region of Peloponnese Facilities	Awareness-raising action for the general population about the European HORIZON "SMART BEAR" project. Distribution of printed material. Completion of a pre-requitement questionnaire.
M47	Open Protection Centres for the Elderly of the Municipality of Tripoli	Awareness-raising action for the general population about the European HORIZON "SMART BEAR" project. Distribution of printed material. Completion of a pre-requitement questionnaire.
M47	Open Protection Centres for the Elderly of the Municipality of Tripoli	Awareness-raising action for the general population about the European HORIZON "SMART BEAR" project. Distribution of printed material. Completion of a pre-requitement questionnaire.
M47	Local Community of Steno, Municipality of Tripoli	Awareness-raising action for the general population about the European HORIZON "SMART BEAR" project. Distribution of printed material. Completion of a pre-requitement questionnaire.
M47	Local Community of Kerasitsa, Municipality of Tripoli	Awareness-raising action for the general population about the European HORIZON "SMART BEAR" project. Distribution of printed material. Completion of a pre-requitement questionnaire.

M47	FIRE DEPARTMENT OF TRIPOLI	Verbal briefing to staff. Distribution of printed material.
M48	51st PanPeloponnesian Exhibition of Tegea	Awareness-raising action for the general population about the European HORIZON "SMART BEAR" project. Distribution of printed material. Completion of a pre-requitement questionnaire.

3.2 Establishment of recruitment centres and staffing with healthcare personnel

From early 2022 and after the Covid-19 Pandemic, both sides of the Greek Pilot identified the need to create a specially designed one - stop service point to welcome, inform, recruit, assess and deliver interventions to participants and their informal caregivers.

For this purpose, RoP refurbished and re-designed some of the already available facilities to allow for a comfortable and relaxing space where the assessment, intervention and monitoring activities of the interdisciplinary project team took place. RoP's premises consisted of a Physician's office, two Nurse offices, a Psychologist's office, and a Help Desk office for the Project under the coordination of the Regional Public Health Directorate.

The following services are planned to be provided to SMART BEAR study participants:

- Pre-Recruited information office;
- Recruiting participants for baseline assessment, conducted by a multidisciplinary team of health professionals, according to the study protocol, for Hearing Loss, Balance Disorders, CVD's, Frailty, MCI and Depression;
- Specialized assessment for Balance Disorders, HL and CVD's;
- Allocation of participants to set of devices according to condition profile;
- Training of participants to the use of the SB devices and the app;
- Help desk (telephone centre and physical service) for lvl - 1 and lvl - 2 support to participants;
- Smart Home Device Preparation, Installation at home and support (external services)
- assessment of study participants;

Figure 5 RoP Team

Figure 6 RoP Indoor Spaces

At MPF, the Municipal Authority, decided to modify the use of a municipal building that was previously used as a cultural centre, into KE.PSI.P.I., the Municipal Center for Digital Prevention Medicine. This was a difficult endeavour since MPF needed to take a political decision and convince all political parties in the Municipal Council about the benefits of this initiative both in the short and in the long term. After 7 months of refurbishment work based on the municipal budget, KE.PSI.P.I. was ready to host the Smart Bear Clinical Team and recruit participants from middle July 2023 (M47) onward.

The clinical team consisted initially of 2 Physicians, 1 nurse, 1 health visitor, 1 psychologist/health visitor, 1 audiologist, 2 physiotherapists. The clinical team members were contracted out based on their qualifications and experience through a public recruitment service tender and started working at KE.PSI.P.I. on July the 13th, 2023.

Figure 7: KE.PSI.P.I. Clinical Team Members and Indoor Spaces

KE.PSI.P.I was established and started operating official at MPF on September 5th, 2023, based on no. 247/05-09-2023 Mayor's Decree, providing the following services to Smart Bear study participants only:

- Scheduling of appointments for baseline assessment;
- Baseline assessment, with support of the SB Dashboard, conducted by a multidisciplinary team of health professionals, according to the study protocol, for Hearing Loss, Balance Disorders, CVD's, Frailty, MCI and Depression;
- Specialised assessment for Balance Disorders, HL and CVD's;
- Allocation of participants to set of devices according to condition profile;
- Training of participants to the use of the SB devices and the app, according to the disease entities;
- Help desk (telephone centre and physical service) for lvl - 1 and lvl - 2 support to participants;
- Smart Home Device Preparation, Installation at home and support (external services through indirect costs);
- Intervention delivery for Synergies (Holobalance, not S4H);
- Reassessment of study participants at 6 and 12 months.

3.3 Development of Tools to Organize and Monitor the Project Progress

To monitor and evaluate the progress of the Greek Pilot study related processes, both RoP & MPF organized and created appropriate tools, and more specifically:

3.3.1 Standard Operations Guide

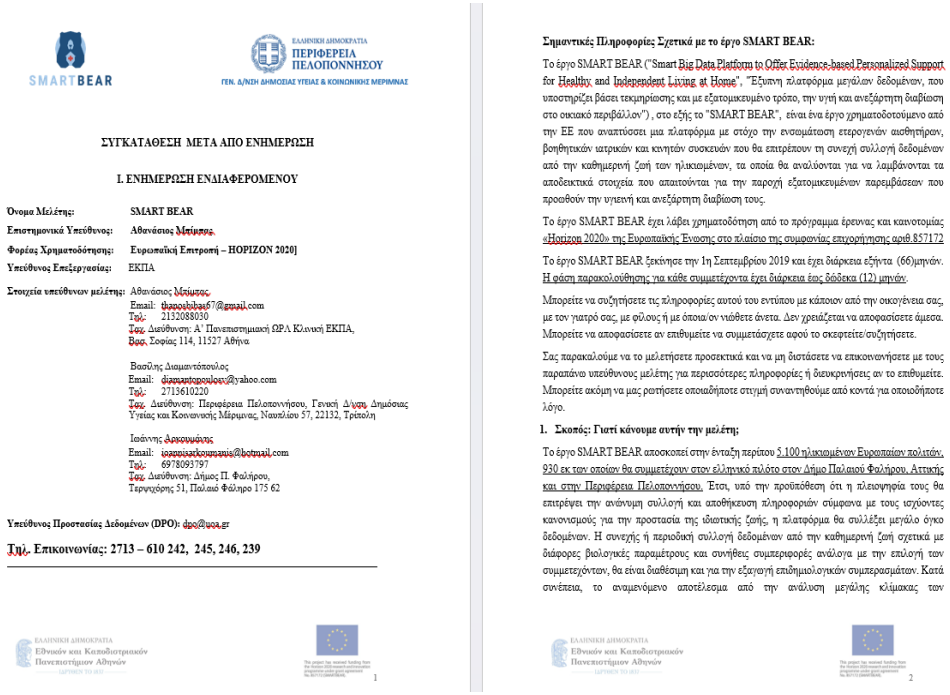
Greek Pilot's Clinical Team Members have developed a detailed guide, with all processes that are undertaken by the Clinical Team Members. This Operations guide contains an analysis of the following processes:

- Contacting potential participants after pre-recruitment events, procedures for Eligibility Assessment, Baseline Assessment and Specialty Assessment, training of participants in the use of devices and the app, managing Adverse Events, meetings of the Clinical Team Members, managing Complaints, managing Registered Volunteers, safety issues in case of emergencies.

Figure 8: KE.PSI.P.I. Operations Procedures Guide

3.3.2 Patient Consent Form

The Greek Pilot Site partners RoP and MPF, under the supervision of the National and Kapodistrian University of Athens (NKUA), translated the Informed Consent Form into Greek and optimized it for use in the Greek pilot settings. According to the Standard Operating Procedures guide developed, these documents are printed before a potential participant is included but after eligibility assessment, assigned to potential participants to read when in the premises or at their own time, signed and returned and finally kept in lockers at each pilot site.



ΣΥΓΚΑΤΑΘΕΣΗ ΜΕΤΑ ΑΠΟ ΕΝΗΜΕΡΩΣΗ

I. ΕΝΗΜΕΡΩΣΗ ΕΝΔΙΑΦΕΡΟΜΕΝΟΥ

Όνομα Μελέτης: SMART BEAR

Επιστημονικά Υπεύθυνος: Αθανάσιος Μπίμπος

Φορέας Χρηματοδότησης: Ευρωπαϊκή Επιτροπή – HORIZON 2020]

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Σημαντικές Πληροφορίες Σχετικά με το έργο SMART BEAR:

Το έργο SMART BEAR ("Smart Big Data Platform to Offer Evidence-based Personalized Support for Healthy and Independent Living at Home", "Έξυπνη πλατφόρμα μεγάλων δεδομένων, που υποστηρίζει βάσει τεκμηρίωσης και με εξατομικευμένο τρόπο, την υγιή και ανεξάρτητη διαβίωση στο οικιακό περιβάλλον") , στο εξής το "SMART BEAR", είναι ένα έργο χρηματοδοτούμενο από την ΕΕ που αναπτύσσει μια πλατφόρμα με στόχο την ενσωμάτωση ετερογενών αισθητήρων, βοηθητικών ιατρικών και κινητών συσκευών που θα επιτρέπουν τη συνεχή συλλογή δεδομένων από την καθημερινή ζωή των ηλικιωμένων, τα οποία θα αναλύονται για να λαμβάνονται τα αποδεικτικά στοιχεία που απαιτούνται για την παροχή εξατομικευμένων παρεμβάσεων που προωθούν την υγιεινή και ανεξάρτητη διαβίωση τους.

Το έργο SMART BEAR έχει λάβει χρηματοδότηση από το πρόγραμμα έρευνας και καινοτομίας «Horizon 2020» της Ευρωπαϊκής Ένωσης στο πλαίσιο της συμφωνίας επιχορήγησης αριθ 857172

Το έργο SMART BEAR ξεκίνησε την 1η Σεπτεμβρίου 2019 και έχει διάρκεια εξήντα (66)μηνών. Η φάση παρακολούθησης για κάθε συμμετέχοντα έχει διάρκεια έως δώδεκα (12) μηνών.

Μπορείτε να συζητήσετε τις πληροφορίες αυτού του εντύπου με κάποιον από την οικογένεια σας, με τον γιατρό σας, με φίλους ή με όποιο/ον νιώθετε άνετα. Δεν χρειάζεται να αποφασίσετε άμεσα. Μπορείτε να αποφασίσετε αν επιθυμείτε να συμμετάσχετε αφού το σκεφτείτε/συζητήσετε.

Σας παρακαλούμε να το μελετήσετε προσεκτικά και να μη διστάσετε να επικοινωνήσετε με τους παραπάνω υπεύθυνους μελέτης για περισσότερες πληροφορίες ή διευκρινήσεις αν το επιθυμείτε. Μπορείτε ακόμη να μας ρωτήσετε οποιαδήποτε στιγμή συναντηθούμε από κοντά για οποιοδήποτε λόγο.

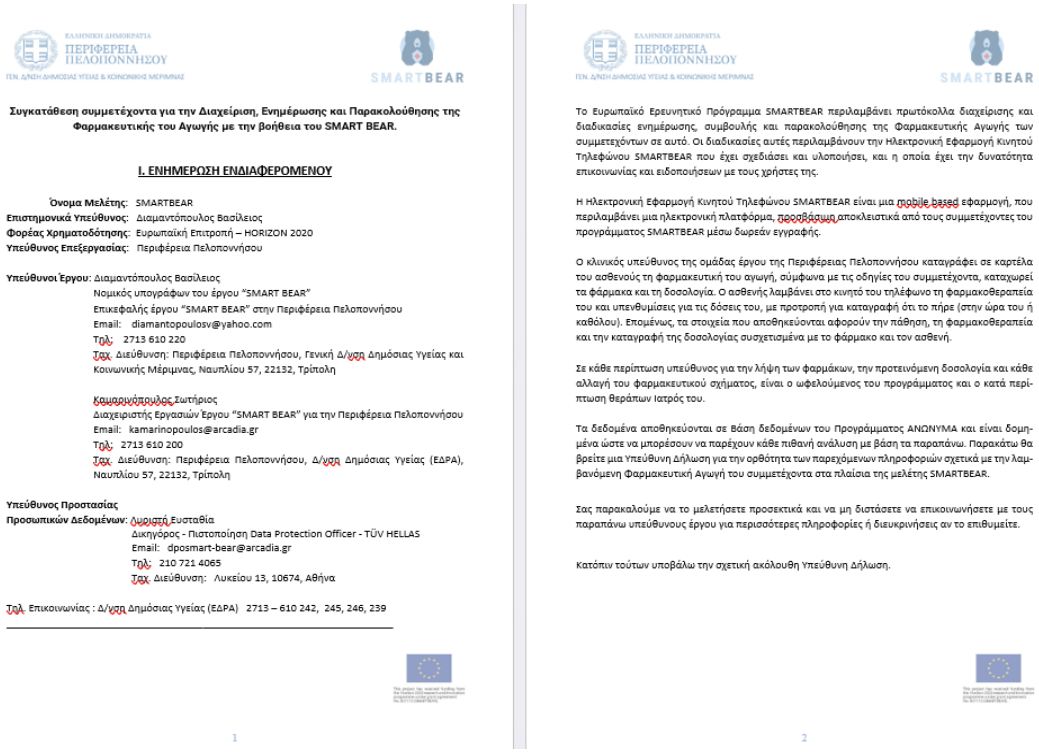
1. **Σκοπός: Γιατί κάνουμε αυτήν την μελέτη;**

Το έργο SMART BEAR αποσκοπεί στην ένταξη περίπου 5.100 ηλικιωμένων Ευρωπαίων πολιτών, 930 εκ των οποίων θα συμμετέχουν στον ελληνικό πιλότο στον Δήμο Παλαιού Φαλήρου, Αττικής και στην Περιφέρεια Πελοποννήσου. Έτσι, υπό την προϋπόθεση ότι η πλειοψηφία τους θα επιτρέψει την ανώνυμη συλλογή και αποθήκευση πληροφοριών σύμφωνα με τους ισχύοντες κανονισμούς για την προστασία της ιδιωτικής ζωής, η πλατφόρμα θα συλλέξει μεγάλο όγκο δεδομένων. Η συνεχής ή περιοδική συλλογή δεδομένων από την καθημερινή ζωή σχετικά με διάφορες βιολογικές παραμέτρους και συνήθειες συμπεριφορές ανάλογα με την επιλογή των συμμετεχόντων, θα είναι διαθέσιμη και για την εξαγωγή επιδημιολογικών συμπερασμάτων. Κατά συνέπεια, το αναμενόμενο αποτέλεσμα από την ανάλυση μεγάλης κλίμακας των

Figure 9: ICF at RoP

3.3.3 Medication Uptake Responsibility Statement

The pilot site partners, developed a statement, signed by the Physician and the Participant, regarding the correctness of information provided for one's medication. According to the statement, the participant is responsible for the correctness of the most current information provided in relation to the Medication taken upon inclusion and when the initial medication profile is set in the Dashboard. This is due to the fact that the project's physicians are not the patients attending physicians, and do not therefore, have by National Legislation, access to the National e-prescription web app. Also, the statement indicates to each participant that they are responsible to notify the project physicians when a change in the medication takes place so that the correct notifications are generated in the app. The statement has been approved for use by both the RoP and MPF DPO's.



ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΠΕΡΙΦΕΡΕΙΑ ΠΕΛΟΠΟΝΝΗΣΟΥ
ΓΕΝ. Δ/ΝΣΗ ΔΗΜΟΣΙΑΣ ΥΓΕΙΑΣ & ΚΟΙΝΩΝΙΚΗΣ ΜΕΡΙΜΝΑΣ

SMARTBEAR

Συγκατάθεση συμμετέχοντα για την Διαχείριση, Ενημέρωσης και Παρακολούθησης της Φαρμακευτικής του Αγωγής με την βοήθεια του SMART BEAR.

Ι. ΕΝΗΜΕΡΩΣΗ ΕΝΔΙΑΦΕΡΟΜΕΝΟΥ

Όνομα Μελέτης: SMARTBEAR
Επιστημονικά Υπεύθυνος: Διαμαντόπουλος Βασίλειος
Φορέας Χρηματοδότησης: Ευρωπαϊκή Επιτροπή – HORIZON 2020
Υπεύθυνος Επεξεργασίας: Περιφέρεια Πελοποννήσου

Υπεύθυνοι Έργου: Διαμαντόπουλος Βασίλειος
Νομικός υπογράφων του έργου "SMART BEAR"
Επικεφαλής έργου "SMART BEAR" στην Περιφέρεια Πελοποννήσου
Email: diamantopoulosv@yahoo.com
Τηλ: 2713 610 220
Ταχ. Διεύθυνση: Περιφέρεια Πελοποννήσου, Γενική Δ/νση Δημόσιας Υγείας και Κοινωνικής Μέριμνας, Ναυπλίου 57, 22132, Τρίπολη

Καμαρινόπουλος Σωτήριος
Διαχειριστής Εργασιών Έργου "SMART BEAR" για την Περιφέρεια Πελοποννήσου
Email: kamarinopoulos@arcadia.gr
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Ταχ. Διεύθυνση: Περιφέρεια Πελοποννήσου, Δ/νση Δημόσιας Υγείας (ΕΔΡΑ), Ναυπλίου 57, 22132, Τρίπολη

Υπεύθυνος Προστασίας Προσωπικών Δεδομένων: Δωριστή Ευσταθία
Δικηγόρος - Πιστοποίηση Data Protection Officer - TÜV HELLAS
Email: dposmart-bear@arcadia.gr
Τηλ: 210 721 4065
Ταχ. Διεύθυνση: Λυκείου 13, 10674, Αθήνα

Τηλ. Επικοινωνίας : Δ/νση Δημόσιας Υγείας (ΕΔΡΑ) 2713 – 610 242, 245, 246, 239

1

ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΠΕΡΙΦΕΡΕΙΑ ΠΕΛΟΠΟΝΝΗΣΟΥ
ΓΕΝ. Δ/ΝΣΗ ΔΗΜΟΣΙΑΣ ΥΓΕΙΑΣ & ΚΟΙΝΩΝΙΚΗΣ ΜΕΡΙΜΝΑΣ

SMARTBEAR

Το Ευρωπαϊκό Ερευνητικό Πρόγραμμα SMARTBEAR περιλαμβάνει πρωτόκολλα διαχείρισης και διαδικασίες ενημέρωσης, συμβουλής και παρακολούθησης της Φαρμακευτικής Αγωγής των συμμετεχόντων σε αυτό. Οι διαδικασίες αυτές περιλαμβάνουν την Ηλεκτρονική Εφαρμογή Κινητού Τηλεφώνου SMARTBEAR που έχει σχεδιάσει και υλοποιήσει, και η οποία έχει την δυνατότητα επικοινωνίας και ειδοποιήσεων με τους χρήστες της.

Η Ηλεκτρονική Εφαρμογή Κινητού Τηλεφώνου SMARTBEAR είναι μια mobile based εφαρμογή, που περιλαμβάνει μια ηλεκτρονική πλατφόρμα, προσβάσιμη αποκλειστικά από τους συμμετέχοντες του προγράμματος SMARTBEAR μέσω δωρεάν εγγραφής.

Ο κλινικός υπεύθυνος της ομάδας έργου της Περιφέρειας Πελοποννήσου καταγράφει σε καρτέλα του ασθενούς τη φαρμακευτική του αγωγή, σύμφωνα με τις οδηγίες του συμμετέχοντα, καταχωρεί τα φάρμακα και τη δοσολογία. Ο ασθενής λαμβάνει στο κινητό του τηλέφωνο τη φαρμακοθεραπεία του και υπενθυμίσεις για τις δόσεις του, με προτροπή για καταγραφή ότι το πήρε (στην ώρα του ή καθόλου). Επομένως, τα στοιχεία που αποθηκεύονται αφορούν την πάθηση, τη φαρμακοθεραπεία και την καταγραφή της δοσολογίας συσχετισμένα με το φάρμακο και τον ασθενή.

Σε κάθε περίπτωση υπεύθυνος για την λήψη των φαρμάκων, την προτεινόμενη δοσολογία και κάθε αλλαγή του φαρμακευτικού σχήματος, είναι ο ωφελούμενος του προγράμματος και ο κατά περίπτωση Θεράπων Ιατρός του.

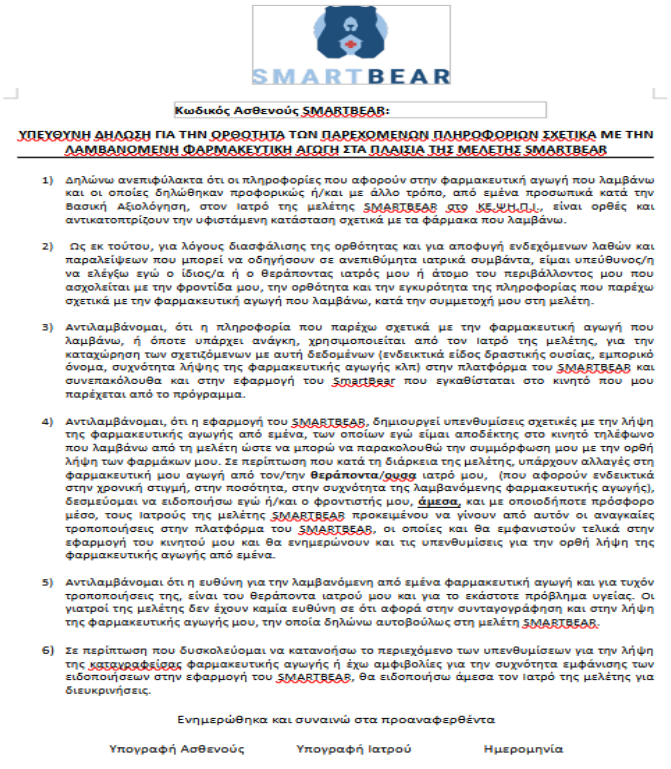
Τα δεδομένα αποθηκεύονται σε Βάση δεδομένων του Προγράμματος ΑΝΩΝΥΜΑ και είναι δομημένα ώστε να μπορέσουν να παρέχουν κάθε πιθανή ανάλυση με βάση τα παραπάνω. Παρακάτω θα βρείτε μια Υπεύθυνη Δήλωση για την ορθότητα των παρεχόμενων πληροφοριών σχετικά με την λαμβανόμενη Φαρμακευτική Αγωγή του συμμετέχοντα στα πλαίσια της μελέτης SMARTBEAR.

Σας παρακαλούμε να το μελετήσετε προσεκτικά και να μη διστάσετε να επικοινωνήσετε με τους παραπάνω υπεύθυνους έργου για περισσότερες πληροφορίες ή διευκρινήσεις αν το επιθυμείτε.

Κατόπιν τούτων υποβάλω την σχετική ακόλουθη Υπεύθυνη Δήλωση.

2

Figure 10: RoP Medication Uptake Responsibility Statement



SMARTBEAR

Κωδικός Ασθενούς SMARTBEAR:

ΥΠΕΥΘΥΝΗ ΔΗΛΩΣΗ ΓΙΑ ΤΗΝ ΟΡΘΟΤΗΤΑ ΤΩΝ ΠΑΡΕΧΟΜΕΝΩΝ ΠΛΗΡΟΦΟΡΙΩΝ ΣΧΕΤΙΚΑ ΜΕ ΤΗΝ ΛΑΜΒΑΝΟΜΕΝΗ ΦΑΡΜΑΚΕΥΤΙΚΗ ΑΓΩΓΗ ΣΤΑ ΠΛΑΙΣΙΑ ΤΗΣ ΜΕΛΕΤΗΣ SMARTBEAR

1) Δηλώνω ανεπιφύλακτα ότι οι πληροφορίες που αφορούν στην φαρμακευτική αγωγή που λαμβάνω και οι οποίες δηλώθηκαν προφορικώς ή/και με άλλο τρόπο, από εμένα προσωπικά κατά την Βασική Αξιολόγηση, στον Ιατρό της μελέτης SMARTBEAR στο ΚΕ.ΨΗ.Π.Ι., είναι ορθές και αντικατοπτρίζουν την υφιστάμενη κατάσταση σχετικά με τα φάρμακα που λαμβάνω.

2) Ως εκ τούτου, για λόγους διασφάλισης της ορθότητας και για αποφυγή ενδεχόμενων λαθών και παραλείψεων που μπορεί να οδηγήσουν σε ανεπιθύμητα ιατρικά συμβάντα, είμαι υπεύθυνος/η να ελέγξω εγώ ο ίδιος/α ή ο Θεράποντας ιατρός μου ή άτομο του περιβάλλοντος μου που ασχολείται με την φροντίδα μου, την ορθότητα και την εγκυρότητα της πληροφορίας που παρέχω σχετικά με την φαρμακευτική αγωγή που λαμβάνω, κατά την συμμετοχή μου στη μελέτη.

3) Αντιλαμβάνομαι, ότι η πληροφορία που παρέχω σχετικά με την φαρμακευτική αγωγή που λαμβάνω, ή όποτε υπάρχει ανάγκη, χρησιμοποιείται από τον ιατρό της μελέτης, για την καταχώρηση των σχετιζόμενων με αυτή δεδομένων (ενδεικτικά είδος δραστικής ουσίας, εμπορικό όνομα, συχνότητα λήψης της φαρμακευτικής αγωγής κλπ) στην πλατφόρμα του SMARTBEAR και συνεπακόλουθα και στην εφαρμογή του SmartBear που εγκαθίσταται στο κινητό που μου παρέχεται από το πρόγραμμα.

4) Αντιλαμβάνομαι, ότι η εφαρμογή του SMARTBEAR, δημιουργεί υπενθυμίσεις σχετικές με την λήψη της φαρμακευτικής αγωγής από εμένα, των οποίων εγώ είμαι αποδέκτης στο κινητό τηλέφωνο που λαμβάνω από τη μελέτη ώστε να μπορώ να παρακολουθώ την συμμόρφωση μου με την ορθή λήψη των φαρμάκων μου. Σε περίπτωση που κατά τη διάρκεια της μελέτης, υπάρχουν αλλαγές στη φαρμακευτική μου αγωγή από τον/την **Θεράποντα/ουσα** ιατρό μου, (που αφορούν ενδεικτικά στην χρονική στιγμή, στην ποσότητα, στην συχνότητα της λαμβανόμενης φαρμακευτικής αγωγής), δεσμεύομαι να ειδοποιήσω εγώ ή/και ο φροντιστής μου, **άμεσα,** και με οποιοδήποτε πρόσφορο μέσο, τους Ιατρούς της μελέτης SMARTBEAR προκειμένου να γίνουν από αυτόν οι αναγκαίες τροποποιήσεις στην πλατφόρμα του SMARTBEAR, οι οποίες και θα εμφανιστούν τελικά στην εφαρμογή του κινητού μου και θα ενημερώνουν και τις υπενθυμίσεις για την ορθή λήψη της φαρμακευτικής αγωγής από εμένα.

5) Αντιλαμβάνομαι ότι η ευθύνη για την λαμβανόμενη από εμένα φαρμακευτική αγωγή και για τυχόν τροποποιήσεις της, είναι του θεράποντα ιατρού μου και για το εκάστοτε πρόβλημα υγείας. Οι γιατροί της μελέτης δεν έχουν καμία ευθύνη σε ότι αφορά στην συνταγογράφηση και στην λήψη της φαρμακευτικής αγωγής μου, την οποία δηλώνω αυτοβούλως στη μελέτη SMARTBEAR.

6) Σε περίπτωση που δυσκολεύομαι να κατανοήσω το περιεχόμενο των υπενθυμίσεων για την λήψη της καταγραφείσας φαρμακευτικής αγωγής ή έχω αμφιβολίες για την συχνότητα εμφάνισης των ειδοποιήσεων στην εφαρμογή του SMARTBEAR, θα ειδοποιήσω άμεσα τον Ιατρό της μελέτης για διευκρινήσεις.

Ενημερώθηκα και συναινώ στα προαναφερθέντα

Υπογραφή Ασθενούς Υπογραφή Ιατρού Ημερομηνία

Figure 11: MPF Medication Uptake Responsibility Statement

3.3.4 Promotional Material

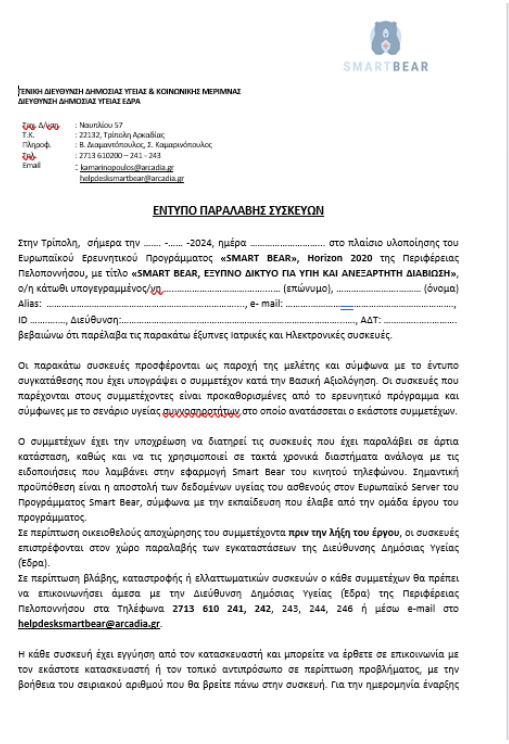
ROP renewed and reprinted the existing flyers for the presentation of the project. Also developed new promotional material for the needs of the project. To better serve the participants and to implement the Device Delivery Phase paper bags were designed and printed. This is also the case for MPF that bought ecological bags for participants to carry all SMART BEAR devices after they have received training in their use and the use of the app and created additional flyers, posters and a roll up banner, very much needed when pre-recruiting in neighbouring municipalities.

Figure 12: MPF & RoP bags for transfer of Smart Bear Devices by patients

3.3.5 Other Forms

3.3.5.1 Device Delivery Form:

To follow the rate and frequency of SB delivery and installation to patients, a form was created and both RoP and MPF clinical team staff were responsible for managing this form. This form is filled out by the project team and signed by the participant to have proper control over the delivery of the devices.



ΓΕΝΙΚΗ ΔΙΕΥΘΥΝΣΗ ΔΗΜΟΣΙΑΣ ΥΓΕΙΑΣ & ΚΟΙΝΩΝΙΚΗΣ ΜΕΡΙΜΝΑΣ
ΔΙΕΥΘΥΝΣΗ ΔΗΜΟΣΙΑΣ ΥΓΕΙΑΣ ΕΔΡΑ

Ταχ. Δ/νση : Ναυπλίου 57
Τ.Κ. : 22132, Τρίπολη Αρκαδίας
Πληροφ. : Β. Δεφραντσούλος, Σ. Καμαρινόπουλος
Τηλ. : 2713 610200 – 241 - 243
Email : kamarinopoulos@arcadia.gr
helpdesksmartbear@arcadia.gr

ΕΝΤΥΠΟ ΠΑΡΑΛΑΒΗΣ ΣΥΣΚΕΥΩΝ

Στην Τρίπολη, σήμερα την ..... -..... -2024, ημέρα ..... στο πλαίσιο υλοποίησης του Ευρωπαϊκού Ερευνητικού Προγράμματος **«SMART BEAR», Horizon 2020** της Περιφέρειας Πελοποννήσου, με τίτλο **«SMART BEAR, ΕΞΥΠΝΟ ΔΙΚΤΥΟ ΓΙΑ ΥΓΙΗ ΚΑΙ ΑΝΕΞΑΡΤΗΤΗ ΔΙΑΒΙΩΣΗ»**, ο/η κάτωθι υπογεγραμμένος/νη ..... (επώνυμο), ... (όνομα) Alias: ....., e- mail: ....., ID ....., Διεύθυνση:....., ΑΔΤ: ..... βεβαιώνω ότι παρέλαβα τις παρακάτω έξυπνες ιατρικές και Ηλεκτρονικές συσκευές.

Οι παρακάτω συσκευές προσφέρονται ως παροχή της μελέτης και σύμφωνα με το έντυπο συγκατάθεσης που έχει υπογράψει ο συμμετέχον κατά την Βασική Αξιολόγηση. Οι συσκευές που παρέχονται στους συμμετέχοντες είναι προκαθορισμένες από το ερευνητικό πρόγραμμα και σύμφωνες με το σενάριο υγείας συγγνωστοτήτων στο οποίο ανατάσσεται ο εκάστοτε συμμετέχων.

Ο συμμετέχων έχει την υποχρέωση να διατηρεί τις συσκευές που έχει παραλάβει σε άρτια κατάσταση, καθώς και να τις χρησιμοποιεί σε τακτά χρονικά διαστήματα ανάλογα με τις ειδοποιήσεις που λαμβάνει στην εφαρμογή Smart Bear του κινητού τηλεφώνου. Σημαντική προϋπόθεση είναι η αποστολή των δεδομένων υγείας του ασθενούς στον Ευρωπαϊκό Server του Προγράμματος Smart Bear, σύμφωνα με την εκπαίδευση που έλαβε από την ομάδα έργου του προγράμματος.
Σε περίπτωση οικειοθελούς αποχώρησης του συμμετέχοντα **πριν την λήξη του έργου**, οι συσκευές επιστρέφονται στον χώρο παραλαβής των εγκαταστάσεων της Διεύθυνσης Δημόσιας Υγείας (Εδρα).
Σε περίπτωση βλάβης, καταστροφής ή ελλαττωματικών συσκευών ο κάθε συμμετέχων θα πρέπει να επικοινωνήσει άμεσα με την Διεύθυνση Δημόσιας Υγείας (Έδρα) της Περιφέρειας Πελοποννήσου στα Τηλέφωνα **2713 610 241, 242**, 243, 244, 246 ή μέσω e-mail στο **helpdesksmartbear@arcadia.gr**.

Η κάθε συσκευή έχει εγγύηση από τον κατασκευαστή και μπορείτε να έρθετε σε επικοινωνία με τον εκάστοτε κατασκευαστή ή τον τοπικό αντιπρόσωπο σε περίπτωση προβλήματος, με την βοήθεια του σειριακού αριθμού που θα βρείτε πάνω στην συσκευή. Για την ημερομηνία έναρξης της εγγύησης παρακαλώ επικοινωνήστε με τα γραφεία της Διεύθυνση Δημόσιας Υγείας (Έδρα) της Περιφέρειας Πελοποννήσου στα Τηλέφωνα **2713 610 241, 242**, 243, 244, 246.

Υπεύθυνος για τις έξυπνες ιατρικές συσκευές του Ερευνητικού Προγράμματος Smart Bear παραμένει η Γενική Διεύθυνση Δημόσιας Υγείας και Κοινωνικής Μέριμνας καθώς και το Ευρωπαϊκό Πρόγραμμα Smart Bear **μέχρι και την λήξη του προγράμματος (28/02/2025).**

Έξυπνες Ιατρικές και Ηλεκτρονικές Συσκευές που παρέλαβα:

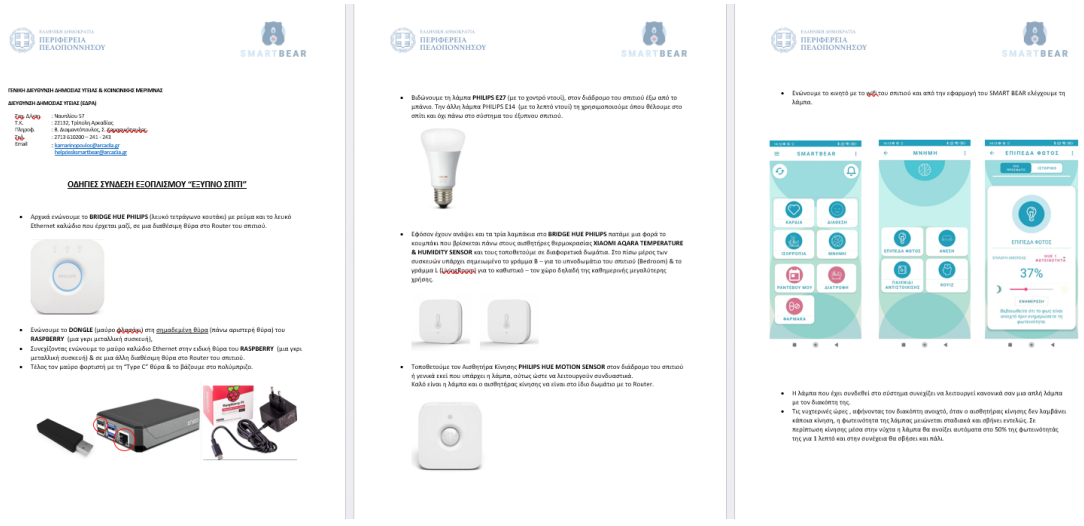
☐ **HOME HUB DEVICES** | **1** PHILLIPS HUE (bridge-κεντρική μονάδα), **1** PHILLIPS HUE λάμπα led (λαμπτήρας E27), **1** PHILLIPS HUE λάμπα led (λαμπτήρας E14), **1** PHILLIPS HUE motion sensor (ασύρματος αισθητήρας κίνησης & φωτός), **2** XIAOMI AQARA temperature & humidity sensor (ασύρματοι αισθητήρες θερμοκρασίας & υγρασίας), **1** RASPBERRY pi 4model B 4gb with case & psu (integration hub kit), **1** ZIGBEE usb cc2531 (usb dongle), **1** integral high-speed micro sd card (κάρτα μνήμης micro – sd 32gb), **1** πολύπριζο (4 θέσεων Σούκο), **1** καλώδιο ethernet(μήκος 2μ). **Σύνολο 11 εξαρτήματα.**

■ **SMARTPHONE** | XIAOMI REDMI 10C 4/128GB BLUE (Έξυπνο Τηλέφωνο)
■ **FITNESS TRACKER - SMARTWATCH** | Garmin vivosmart 5 Black (Έξυπνο Ρολόι)
☐ **SMART SCALE** | iHealth HS2S (Έξυπνο Ζυγαριά)
■ **SMART THERMOMETER** | iHealth NT13B (Έξυπνο Θερμόμετρο)
■ **SMART OXIMETER** | iHealth PO3M (Έξυπνο Οξύμετρο)
■ **SMART BLOOD PRESSURE** | Omron M7 (Έξυπνο Πιεσόμετρο)
☐ **SMARTPHONE** | Samsung Galaxy A13 (Έξυπνο Τηλέφωνο)
☐ **HEARING AIDS** | Beltone Achieve (Έξυπνα Ακουστικά Βοηθήματα)

Ο/Η ΠΑΡΑΛΑΒΩΝ	Ο ΠΡΟΪΣΤΑΜΕΝΟΣ ΔΙΕΥΘΥΝΣΗΣ ΔΗΜΟΣΙΑΣ ΥΓΕΙΑΣ ΚΑΜΑΡΙΝΟΠΟΥΛΟΣ ΣΩΤΗΡΙΟΣ
.....	.....

3.3.5.2 Home Hub Manual:

In some cases of patients who were in outlying areas of the Peloponnese Region and had good digital literacy and direct collaboration with attendants, we needed to design a guide to install the programmed smart home devices.



ΟΔΗΓΙΕΣ ΣΥΝΔΕΣΗ ΕΞΟΠΛΙΣΜΟΥ "ΕΞΥΠΝΟ ΣΠΙΤΙ"

3.3.6 Audiovisual material

For the needs of dissemination of the program, the Region of Peloponnese team together with the responsible project partners, created audiovisual material which was shared on the Peloponnese Region's YouTube channel.

Greek M40 https://www.youtube.com/watch?v=XjdPDnwfR5U&t=1s

Greek M42 https://www.youtube.com/watch?v=iOcmkf8jTOA&t=4s

Engilsh M42 https://www.youtube.com/watch?v=oD4neV1YfgQ&t=28s

3.3.7 Data Analysis tools

For the needs of the proper functioning of the project, the appropriate tools were created to record daily statistics on the candidates and participants of the project in the corresponding Excel sheets on the central server of the Region of Peloponnese, and complete analysis of these data on a weekly frequency. MPF created an xl worksheet, to gather statistics related to the daily operation of KE.PSI.P.I. and another one to record delivery of Smart Bear devices to patients and to schedule further delivery. These tools are further presented in section 3.3.11. below.

3.3.8 Physical Documents Archive

Recruitment, baseline assessment and specific assessment started in October 2023 (M50) while the Dashboard was not fully functional. The Region of Peloponnese team created a hard copy version of the platform entry fields, in order to be able to proceed with the evaluation rapidly, recording and archiving each participant's clinical file. These documents are stored in a dedicated space in the offices at the Public Health Directorate (EDRAS) of the Peloponnese Region, to safeguard the personal data of the participants, as instructed by the legal partner.

MPF did not use a physical twin of the dashboard. However, each participant has a specific physical file, with the following information: Informed Consent Form, Medication Uptake Responsibility Form, Informed Consent Revocation Form. The file is stored at a locker inside the office of the physicians at KE.PSI.P.I.

3.3.9 Recruiting and Assessing Participants

The Recruitment phase started in October 2023, with RoP recruiting the first participant on October 6 2023 while MPF followed on October the 11th, when the SMART BEAR Dashboard for clinicians, was nearly fully functional. However, due to the considerable delay in the delivery of the SMART BEAR devices to the pilot, the Greek clinical partner sites, had to change their implementation planning. Moreover, recruitment and assessment using the Dashboard, was in many cases problematic as several technical issues were discovered and needed immediate attention by the clinical partners. The issues discovered were mainly recorded as tickets in WP6 and later in WP7. For these reasons RoP decided to carry out the assessments in stages starting from the basic assessment which includes a clinical picture of the patient, signing the consent form for participation in the project, mental and cognitive assessment, and identification and recording of daily habits.

After 5 months of baseline assessment in the purpose-designed space of RoP and in the cooperating areas of the Elderly Care Centres of the municipality of Tripoli from October 2023 to March 2024 (M55) 270 participants have completed the Basic Evaluation with an average of about 45 patients per month. The appointments that have been made to reach this number of participants were 306. All the above patients after their clinical examination and assessment are recorded in the database of the RoP project team and are divided into co-morbidity scenarios according to the indications of the specially designed SMART BEAR Dashboard platform that has been designed and implemented by the collaboration of all relevant project partners for the needs of the project.

For KE.PSI.P.I the following statistics are available (until 07/06/2024):

Indicator	KE.PSI.P.I Result
Number of registrations in the SB Platform	451
Citizens not eligible for participation	63
Citizens pending for ICF submission	15
Eligible citizens not providing informed consent	52
Dropouts	4 (due to loss of sight, TIA)
Citizens allocated to SB scenarios	317
Citizens with Hearing Loss	119
Citizens with Cardiovascular Disorders	234
Citizens with Depression	102
Citizens with Balance Disorders	263
Citizens with Frailty	10
Citizens with MCI	248

Table 4: KE.PSI.P.I. Statistics until 1st week of June, 2024

3.3.10 Joint Procurement

The Joint Procurement is a coordinated tender procedure, which is based on an agreement between the parties to appoint an awarding authority and is aimed to purchase the same devices for all the pilots. While the advantages include uniformity in the acquired devices and potentially lower costs due to bulk purchasing, challenges arose in adapting the procedure to comply with the regulations in each pilot site, which can vary significantly.

Especially the project delays due to the Covid-19 pandemic caused the procurement contracts to be necessarily changed several times, the agreed devices to need replacement, and several big problems and delays. In fact, ICCS was responsible for the procurement of the whole Greek pilot and, as a public administration, has had the duty to comply both with European and national regulations, in addition to reporting procedures.

For the two clinical sites of the Greek Pilot the first devices were delivered on October 26, 2023, and included mobile phones and @HomeHub kits. Since then, the following devices have been delivered to the Greek Pilot clinical partners RoP and MPF according to the table below.

Table 5: Device Delivery to Greek Clinical Partners

Device	Delivery	no	Date
Smartphone 2 Cosmote	1	320	26/10/2023
	2	240	11/12/2023
	3	80	16/02/2024
	4	104	6/3/2024
Smart scale	1	476	1/3/2024
Smart thermometer	1	692	1/3/2024
Smart Oximeter	1	668	1/3/2024
Smart home devices	1	148	26/10/2023
	2	111	20/12/2023
	3	37	21/02/2024

Both clinical partners of the Greek Pilot have already delivered some sets of smart home devices as trial kits to 5 participants in cooperation with the project's technical partner and the external partners of each team. The remaining devices will be delivered en masse to the participants until October 2024, and as soon as they become available to the pilot clinical partners.

MPF has delivered the following numbers of devices to participants:

Table 6: Device delivery to participants at MPF

Smart Bear Devices Delivered	Numbers (Until 07/06/2024)
Redmi Smartphone	167
Smart Scale	118
Digital Thermometers	167
Digital Oximeters	167
Smart Home device kits	31
Redmi Smart Phone that needs replacement	2

4 Challenges of the reek Pilot Clinical Sites

During the reporting period, the Greek pilot clinical sites had to face several challenges. Some of these challenges have been collaboratively managed with the respective project partners involved; however, some others are expected to be encountered soon.

The table below shows a list of these challenges, their causes, their area of influence, their impact in the pilot effectiveness, the remedy, and the partners contributing to their elimination or reduction.

Table 7: Greek Pilot Clinical Sites Challenges

CHALLENGE	CAUSE	INFLUENCE	IMPACT	REMEDY	PARTNERS
Delayed Deliveries of Devices	Initially COVID – 19 related. Later, issues with procurement	Pilot participant numbers not easily reached	Dissatisfaction & Loss of interest of participants	Continuous pressure to ICCS, delivery to participants in batches	ICCS, RoP, MPF
Lack of a Single Point of Service Delivery	Fragmented Public Health services	Recruitment, assessment and Intervention effectiveness	Dissatisfaction among participants, decreased efficiency and coordination of team members	Redesign of facilities & creation of new ones to serve as a single point of interest	RoP, MPF
Lack of technical expertise in clinical partners	Public health workers not having technical skills	Use of devices and app and data provision	Problems in efficient and timely training of participants,	External expertise where needed, Rigorous and contunuous training of Clinical Team Members by ATC	RoP, MPF, ATC
Digital illiteracy of beneficiaries	Digital Illiteracy withing the targeted age group beneficiaries	Use of devices and app and data provision	Continuous need for support, limited provision of data for analysis	Extensive and repeated training of participants, mainly face to face	RoP, MPF

4.1 Delayed Deliveries of Devices

ICCS was the responsible partner for the procurement of the whole Greek pilot and as a public administration, has had the duty to comply both with European and national regulations, in addition to reporting procedures, is also the institution that has been called to carry the whole responsibility for these actions. MPF and RoP where in constant and continuous contact with ICCS to solve collaboratively problems arising. Greek clinical partners also supported ICCS with comments during the Smart Bear devices tender documents preparation. MPF and RoP where the first Large Scale Pilots (apart from the PoP) that started receiving devices in the last trimester of 2023 and had prepared appropriate mechanisms and storage places to store the devices with safety and to distribute them to participants in an organized manner.

4.2 Lack of a Single Point of Service Delivery

An integrated care service for elderly people, needs to have a focal point of delivery, due to the need to have the multidisciplinary team always connected and the need to have a seamless flow of services from one specialty, to another so that the beneficiaries are better served with comfort. At MPF, there was no such infrastructure available, and that has been a constant worry for the Municipal Authority until July 2023 (M47), when the Municipal Center for Preventive Services (KE.PSI.P.I.) started its operation.

4.3 Lack of highly skilled team members to support the Project

Both MPF and RoP Teams have social and public health departments focusing on health promotion, prevention and public health protection.

During the period covered in this report, the General Directorate of Public Health & Social Welfare of the Region of Peloponnese which is the competent authority of the Region of Peloponnese for the implementation of the project, under the direction of the General Director and Signatory of the project for the Greek Pilot Doctor Mr. Diamantopoulos Vasilios and Supervisor Director of Public Health Mr. Kamarinopoulos Sotirios reconstituted the RoP project team according to the new requirements of the project with a team of project manager, doctors, nurses, and health visitors. Moreover external partnerships with a Hearing Aid specialist and a technical expert for the preparation and installation of the @HomeHub devices were established.

The health department of the Municipality of Paleo Faliro consists of Nurses, Health Visitors and Social Workers and in some case public health doctors. The needs of the project are extensive for the clinical specialties to accomplish the tasks outlined in WP7 in its entirety. However, physicians, audiologists and physiotherapists are not currently permanently employed.

The challenge was, therefore, to cover this need with sufficient and highly skilled personnel that have had previous experience in similar research projects. MPF developed public tenders for recruiting clinical specialties that are required in the project but at the same time, engaged public health experts from the permanent staff, to assist and to gain experience and knowledge that can be used after the project has ceased to exist.

4.4 Lack of necessary equipment and IT infrastructure to support the single point of service delivery.

Since the beginning of the project, the Greek Pilot clinical partners recognized the need to create dedicated premises for its successful completion.

In RoP, the General Directorate of Public Health & Social Welfare upgraded the medical office and reconfigured the Public Health Department's facilities in order to provide better care services to the participants.

MPF identified early in 2022 the need to procure specialized medical and hotel equipment as well as consumables in order to support the operation of KE.PSI.P.I. Since MPF is not a specialized institution in healthcare delivery, this has been a difficult task, as the requirements for procuring the equipment needed time to be elicitated.

4.5 Lack of technical expertise to support the deployment of the Smart Bear devices and particularly the HomeHub solution

Both sides of the Greek pilot consist of public Health and Social Welfare Services and consequently did not have the technical expertise to prepare, install and monitor the progress of the HomeHub solution in the homes of the eligible participants.

Moreover, there were worries regarding the readiness and the willingness of elderly beneficiaries to allow for installation of the solution at their homes, since they had to be reassured by the clinical site personnel, related to safety and privacy issues before the solution was installed. To accomplish this need, both sides assigned an external partner to work in collaboration with the relevant technical partners of the project and a clinical supervisor, to prepare the devices and install them in the participants' residences.

Furthermore, many participants did not envisage that the solution was a healthcare innovation for them, since its use would not create any notifications in the app related to indoors and outdoors situations they would encounter, and this has created some worries related to the uptake of the solution.

4.6 Digital illiteracy of beneficiaries

Another challenge that was encountered by the RoP and MPF clinical team members, was the widespread digital illiteracy in the related target age group. This was related to the use of smart mobile phones but also the lack of familiarity with the use of digital health devices (maybe except Blood Pressure Monitors). As a result, many elderly people were not confident that they could really accomplish well the tasks they had to do, and as a result, continuous motivation and support was provided by clinic team members to accommodate their hesitation and fears.

4.7 Setting up a Help Desk service that would support beneficiaries both face to face and through telephone contact

Despite discussions related to the creation of a digital help desk within WP6, MPF decided not to proceed with a virtual help desk service and a ticketing system. Due to the delay in delivery of the devices and finalization of the SB app, there were concerns related to the development of the knowledge base and the troubleshooting guide needed for the help desk personnel by technical partners. Due to high number of applicants expected, a multichannel help desk was established to manage the requests for level – 1 and – 2 supports for the Greek Pilot. The prior tasks of this tool is contact prediction (forecast for contact distribution, contact length, contact complexity), phone and email channels setup and trouble data base design.

RoP Team Locally, has organized Help Desk service at level 1 - i.e. a call centre for the information of the participants, info about daily routine or “something is not working”). First level will be provided in real time (if by phone) or asynchronously (if by email). If the first level is not able to provide support, the input is sent to the second level.

Later, when the devices have been delivered to the users, its operation will focus mainly on the solution of problems remotely - during the opening hours of the offices of the Public Health Department (Headquarters) of the Region of Peloponnese (08:30 a.m. - 15:00 p.m.).

The user feedback processing and the platform issue or incident investigation a managed at central level from the platform integration team (WP6). A preliminary forecast of the expected contacts has been defined together with a preliminary plan for the service setup.

This is followed by level 2 service on-site assistance at the offices of the Public Health Department (Headquarters) of the Region of Peloponnese for solving more serious problems such as the following - reconnection or retraining of devices or replacement of devices. Replacement will only be possible as long as a few more devices are available from the volume of supply we have available.

Both help desk operators and patients will be provided with comprehensive training materials encompassing both technical and patient-specific content. RoP side of the Pilot has a help desk service operative since summer of 2022 with the Call Information Center and since August of 2023 the RoP Help Desk is fully operational for supporting study participants, care givers, clinical and technical operators. From April 2024 when device delivery will begin, the RoP team will carry out periodic analysis of the problems recorded through the help desk to propose new platform requirements, local process updates or focused communication with patients.

MPF has a help in place for both lvl – and lvl – 2 support at KE.PSI.P.I. The service is supported by one clinician and operates both face to face on weekdays, 09:00 – 12:00 or via the telephone. To help with operation of the help desk, MPF has developed a help desk manual for operator (s).

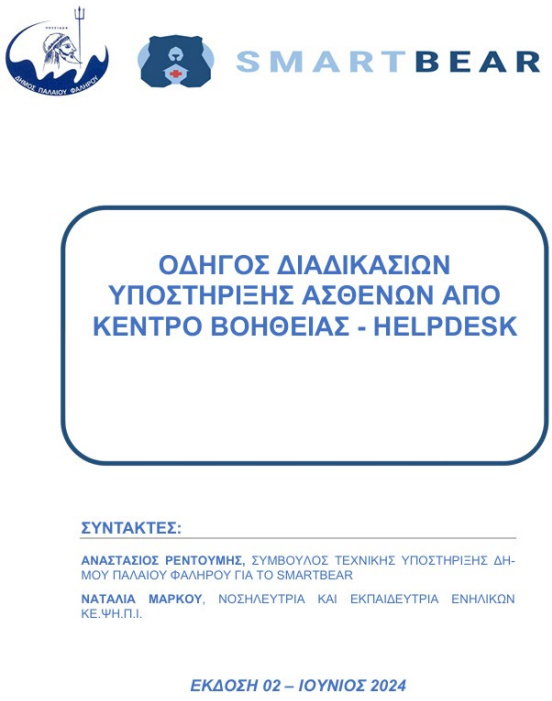


Figure 13: Help Desk manual for Operators at MPF

5 Next Steps

The Greek Pilot has started the recruitment of participants since October 2023 and has already actively contributed to the proper continuation of the project, the necessary monitoring, reporting and updating of the web app designed by the partners for the Smart Bear solution, the monitoring and suggesting improvements to the Smart Bear application for smart mobile phones, the monitoring and reporting of the set of smart home devices and generally in all aspects of the project.

The results of all this work are displayed throughout the above report. As detailed within this document, the consistent delays stem from various factors, collectively contributing to the deviation from the original timeline. This made many of the processes that were already established to require extensive changes and corrections by all project partners. Each pilot's clinical teams are the ones that are in direct contact with the target population daily and are under a lot of pressure to get the project working properly.

The next steps until D7.2 and until D7.3 are as follows:

- To continue recruitment until the number of participants agreed in the recent Amendment is reached in October 2024 (M62).
- Deliver the devices to the Participants in batches, as they are delivered.
- Set the HL devices and start training Participants in their use until end of October 2024.
- Train Participants in the use of the Smartwatch and Blood Pressure Monitoring Devices starting in the third week of June 2024 (M58).
- Set up and start the intervention of HOLOBALANCE (MPF only) by end of June 2024, provided the dashboard is fully functional.
- Start 6 month and 12-month assessment - late June 2024 for MPF Team and late August 2024 (M60) for RoP Team.
- Operation of the Help Desk - RoP will continue with the same strategy, MPF will start in 2nd week of June of 2024.
- Preparation and organization of the next Project Review Meeting at MPF/RoP, second week of September 2024.