

Healthier and Independent Living of the Elderly: Interoperability in a Cross-Project Pilot

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Abstract

The ageing of the population creates new heterogeneous challenges for age-friendly living. The progressive decline in physical and cognitive skills tends to prevent elderly people from performing basic instrumental activities of daily living and there is a growing interest in technology for aging support. Digital health today can be exercised by anyone owning a smartphone and parameters such as heart rate, step counts, calorie intake, sleep quality, can be collected and used not only to monitor and improve the individual's health condition but also to prevent illnesses. However, for the benefits of e-health to take place, digital health data, either Electronic Health Records (EHR) or sensor data from the IoMT, must be shared, maintaining privacy and security requirements but unlocking the potential for research an innovation throughout EU. This paper demonstrates the added value of such interoperability requirements, and a form of accomplishing them through a cross-project pilot.

Keywords

Digital health, health data interoperability, smart devices, IoMT, privacy by design

1. Introduction

The ageing of the population creates new heterogeneous challenges for age-friendly living. Older people have greater health and long-term care needs than younger people, and are less likely to work when unhealthy [1]. It is recognised that the elderly have a high prevalence of multiple chronic

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conditions, with multimorbidity being a cause for increased number of contacts with physicians [2]. The progressive decline in physical and cognitive skills tends to prevent the elderly from performing basic instrumental activities of daily living. In addition, many developed countries are facing increasingly high medical costs and a growing financial problem to social support and pension systems. For these reasons, there is a growing interest in technology for aging support [3].

With the shift to digital technology that brings computers, smartphones, and a myriad of wearable sensing and actuating devices to our daily activities, technology for older adults now includes smart technological solutions that allow to effectively monitor health conditions, support interventions, and even improve prevention. Data from wearable smart devices have been used in a wide range of tasks, including, for example, tracking gait, monitoring vital signs, blood glucose, etc [4, 5]. Still, one of the main challenges in the wide adoption of such technologies in healthcare is the extraction of useful and actionable health-related information from the large volume of data [6]. There is a unique opportunity with the many health related platforms popping throughout Europe and beyond, that in order to create a real impact, should be interoperable and enable data sharing and stakeholder collaboration. Wellbeing services' and precision medicine are increasingly important and enabled by the power of omics approaches and personalisation in the so-called Digital Health.

2. Digital health

Digital health refers to a range of technology innovations put in service to the health sector and medicine [7]. Examples include e-health practices such as telemedicine and telehealth, health informatics, Electronic Health Records (EHR), and patient self-care and monitoring. Currently, e-Health systems are information and communication technologies that meet the needs of citizens, patients, healthcare professionals, healthcare providers, as well as policy makers. Concepts such as the Internet of Things (IoT), Internet of Medical Things (IoMT), data collection, big data, data analytics, and interoperability between health platforms play a significant role and are immense facilitators for e-Health services.

IoT is a key enabler for the digital health. Physical objects, uniquely identified, and equipped with embedded sensors to collect and store data are able to communicate with other objects, sharing data to act depending on the processed information that is received. This unveils a world of possibilities such as the IoMT, with a connected infrastructure of (wearables) medical devices, software applications, health systems and services on the cloud [8]. IoMT systems are nowadays able to monitor citizens and patients and notify health professionals, providing information that may be relevant for the detection or monitoring of a health situation, hence enabling personalised interventions.

Such use of technology is enabling a shift in health systems development. Digital health today can be exercised by anyone owning a smartphone [9]. The work on Digital Twins in healthcare has significantly advanced, mostly empowered from innovations in science and technology, allowing to model patient characteristics and simulate the impact of drugs, treatments, therapies, etc [10, 11]. Requiring the mapping and link of actors and initiatives, and a blueprint of an inclusive ecosystem to share knowledge and facilitate understanding between developers, users, and decision-makers, the digital twin in the healthcare domain, represents a significant step forward towards tightening and improving the interactions between systems, caregivers and patients. In fact, the increasingly higher availability of IoMT devices, digital twins, and also the integrated use of data-driven methods such as machine learning, artificial intelligence, is enabling many European-funded projects and initiatives to develop technology and health-related platforms for preventing, slowing the development of, or dealing effectively with effects of the health impairments [12]. All can have a significant improvement on the quality of life and bring significant savings in the cost of healthcare services in modern society.

For the benefits of e-health, digital health data, EHR or sensor data from the IoMT, must be shared, maintaining privacy and security requirements but unlocking the potential for research an innovation throughout EU. Next, three projects are introduced as an example of some of this ongoing innovation.

2.1. SMART BEAR project

SMART BEAR (SB) is a large scale patient-centred research project that is aiming to provide an intelligent and personalised digital solution for sustaining and extending health and independent living of the elderly with a specific set of comorbidities, such as cardiovascular diseases, cognitive impairments, hearing loss, or balance disorders. When focusing on the elderly, aspects such as motivation, behavioural change, active user engagement, and interfacing are critical for the implementation and acceptance of any digitally enabled solutions. Numerous barriers (e.g. physical, economic, social and psychological factors) have been identified, which together with a lack of motivation often caused by complex interfaces and/or obtrusive solutions that require extensive and tedious explicit data insertion, may prevent active engagement. To deal with this, SB is attempting to extrapolate the models and best practices achieved in sectors such as the fitness and well-being, where smart devices and commercial analytics applications work together in a continuous monitoring of the user and are capable of providing extremely valuable information regarding the results, new objectives and progress.

As in an IoMT network, SB seeks to integrate data from off-the-shelf friendly medical and consumer devices into an innovative health solution that will leverage big data analytics and learning capabilities to generate the evidence required for making decisions about personalised interventions. Through the smartphone, patients involved in the project pilot cases have access to an integrated set of wearables and smart devices used to gather measurable health indicators, and receive personalised messages generated by the SB platform on such indicators. Through the platform dashboard, clinicians can analyse patients' data, also considering their clinical history and EHR data. Data scientists can also analyse the pseudonymised data, collected following the HL7 FHIR standard for health care data exchange [13], by using the big data analytics engine. Privacy-preserving and secure by design data handling capabilities, covering data at rest, in processing, and in transit, will cover comprehensively all platform components.

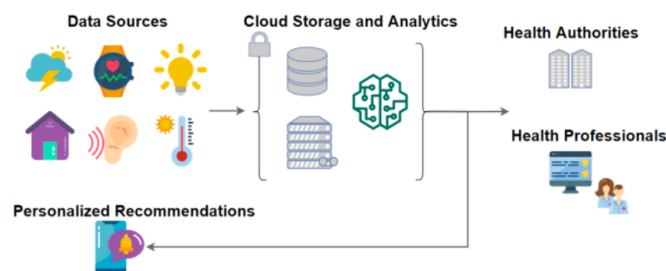


Figure 1: Overview of SMART BEAR architecture (as in [14])

The technical solution being implemented (**Error! Reference source not found.**) consists of different and heterogeneous data sources (smart home sensors and wearable mobile devices) connected using standard protocols (e.g. MQTT, REST) to a cloud system backend that will perform the big data management and is responsible for the generation of insights for the different stakeholders. For instance, the trajectories of Intrinsic Capacity [15] can be obtained from the produced data by using the methodology that is described in [16]. The backend relies on a secure infrastructure with a data repository (ensuring data anonymisation), a big data analytics engine, and a Decision Support System (DSS). The data repositories have been developed using interoperability standards FHIR to store medical data, SNOMED CT [17] to for the codes, terms and definitions, and OpenAPI specifications. During the project, according to predefined rules set by clinical research team, SB DSS-generated interventions in the form of personalised recommendations will be delivered through the patient's mobile phone, and adjusted to the individual profile of each participant, taking into account the personal preferences and the medical conditions [14].

2.2. Smart4Health project

More and more frequently Europeans are living in one country, working in another, and spending their leisure time and holidays in various others. Smart4Health (S4H) is an European project aiming to develop, test and validate a secure cloud-based interoperable health data platform, providing to

citizens, patients and health care professionals, the possibility of collaborating in a integrated and digital process, and enabling a secure, easy-to-use, accessible and portable health data services worldwide.

In S4H citizen-centred approach, one is able to upload data using FHIR standard from: (i) EHR as well as data from health care providers; (ii) Health data gathered in a work environment context; (iii) Personal collected health data (i.e. wearables, personal medical devices, applications). The solution being developed is comprehensive but, for the sake of demonstration, low-back pain (LBP) is considered as one of the data provisioning scenarios. Within the project, a physiotherapy medical device (MedX-LE) is used to train deeper muscles, reinforcing them and helping to decrease the patient backpain. It is being smarterized so that it can also serve the purpose of data provider [18], and connected to automatically feed the project platform with a low-back pain assessment and physiotherapy training data. With this information at the platform, the citizen is then in power of sharing it, becoming interoperable with any health care providers independently of the place or country he/she is in, or even donating it to research.

2.3. HOLOBALANCE project

The HOLOBALANCE (HB) platform delivers a holistic tele-rehabilitation programme for older adults with balance disorders and in risk of fall. HB intervention programme is designed to ensure an evidence-based, multi-sensory balance rehabilitation training exercises and gamified versions (i.e. exergames), aiming to improve postural and functional independence and preserve their physical, cognitive, mental and social well-being, through a comprehensive set of physical, cognitive and auditory training activities [19]. The HB intervention combines novel hologram-based projection technologies through a virtual Augmented Reality (AR) surrogate physiotherapist for enhanced coaching and machine-user interactions (Holobox), with an advanced monitoring platform, which consists of a set of wearable sensors and other interconnected monitoring IoT devices [20].

Patients are continuously recorded while performing their exercises and exergames via a combination of body worn sensors to assess task performance, including two IMU sensors, an ECG sensor, two pressure insole sensors, and a stand-alone depth camera. AI techniques are used to evaluate performance in two different modes. The online monitoring is used to provide real-time analytics on task execution and allow the AR physiotherapist to intervene and stop the patient when necessary. The offline monitoring is activated when a training session has been successfully completed to assess performance and provide a score, rating patient capacity to reach the current level of activity required. Feedback is provided to the supervising physiotherapist through the HB dashboard with detailed evaluations of automated task performance metrics, emotional analytics (i.e. AI-based estimation of frustration, arousal and pleasure) and user feedback if symptoms were provoked.

3. The SMART BEAR pilot of the pilots

The SB project includes five large-scale pilots, spanning six different countries (France, Greece, Italy, Portugal, Romania and Spain) to demonstrate project achievements. Prior to the kick-off of the large-scale pilots, the project initiated a “Pilot of the Pilots” (PoP) in Portugal (in the Autonomous Region of Madeira), that will run for 12 months, setting the scene for 100 patients. The main objective of the PoP is to provide insights on the requirements for setting up the full scale study in all five pilots and identify potential critical points and challenges (e.g., how to deal with safety regulations, how to work on recruitment, how to swiftly deploy the necessary technical infrastructure, what are the main problems faced, etc.). In its early stages, the PoP is also demonstrating the first release of the SB infrastructure, and in addition, it targets to prove that different systems and platforms can work together, sharing data and providing new and improved health services to the patients. Hence, the SB PoP was developed to serve as a real interoperability demonstrator of digital health technologies and projects, in particular with those of S4H and HB.

At clinical level, the PoP is introducing LBP as a common comorbidity to all participants, in addition to the ones anticipated in the SB project, including balance disorders also addressed by HB

(see left side of Figure 2). Hence PoP participants (patients) should be recruited with LBP and a set of 2 other comorbidities.

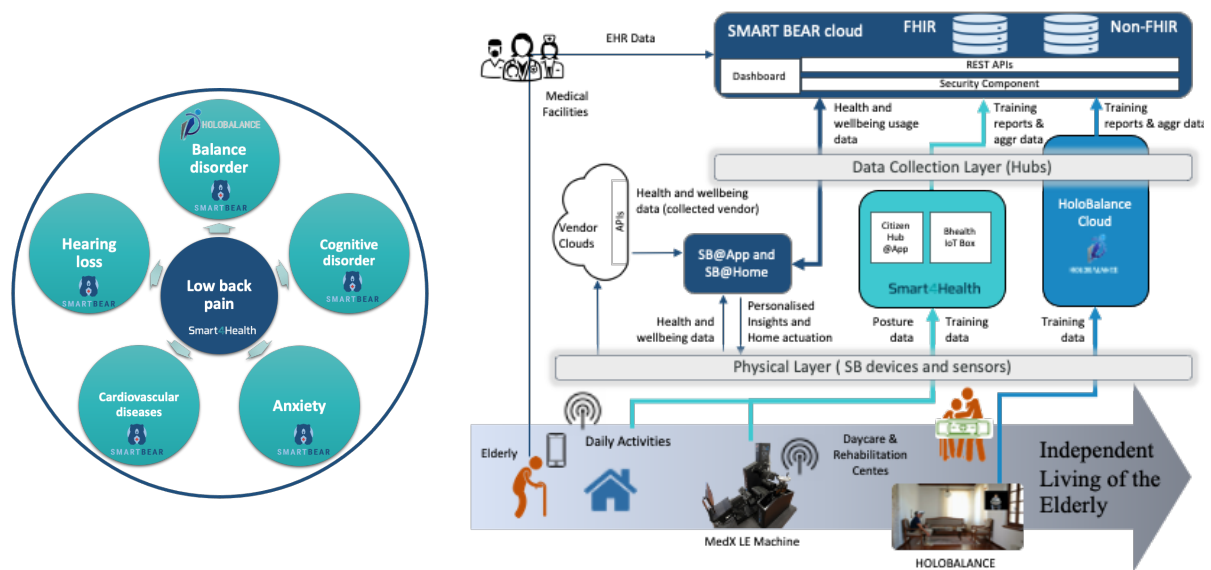


Figure 2: Comorbidities addressed in the PoP (left) and technical overview for data sharing (right)

3.1. Data interoperability and cross-project collaboration

Starting from the identified common clinical aspects mentioned before, the PoP collaboration is sharing device data and infrastructures involved in the low back pain prevention and treatment, namely the smarterized MedX machine being used in S4H, and the virtual AR physiotherapist and the HoloBox for the balance disorders being used in HB. On a technical level (right side of Figure 2), middleware interoperability is ensured, enabling integrated data collection and cross-project system development.

The elderly participants are assessed by the clinical staff in appropriate medical facilities at different times during the pilot execution (baseline, 6 and 12 months), and using the SB platform dashboard, they provide the initial health records to the platform. Then, as illustrated through the bottom arrow, the patient is continuously monitored throughout his/her daily activities with wearable devices, at the day-care or rehabilitation centers, as well as in their homes. The SB mobile app (SB@App) is responsible to gather health and wellbeing data from the wearable devices and provide it to the cloud, where AI and ML models can provide some personalised insights to the patients, in support to a more healthy and independent living. The SB home hub (SB@Home) is only provided to patients with cognitive disorders, and being interoperable with the SB@APP, it is capable of performing some home actuation, e.g., managing light environments, based on health and wellbeing parameters.

To enable effective data interoperability on top of the cross-project collaboration, it was necessary to identify which specific components were required to be integrated, so that the SB cloud could receive the relevant information in the appropriate format. In more detail, the data to be exchanged between projects is facilitated by the S4H BHealth IoT Box [18], the Citizen Hub mobile app [21], as well as the HB cloud platform. Such data is sent to SB in FHIR using dedicated RESTfull APIs, and includes:

1. **MedX force tests**, a diagnostic exam to assess current health of the back muscular strength. The test also helps to define the parameters of the LBP exercises that compose the actual MedX training that will follow in the subsequent weeks.
2. **LBP questionnaires** used to assess the level of pain experienced in each week of training.
3. **MedX training data**, including the number of repetitions, weight and angle of the LBP exercises being performed.

4. **HB training data**, including exercise performance score, number of repetitions, exercise duration, provoked symptoms (i.e. headache, dizziness, blurry vision, disorientation), detailed reports on whole body motion and body parts movement.
5. **Additional wearables data (external to SB)**, in particular posture data which is collected by the S4H Citizen Hub. Posture information might be of interest to patients with LBP or even balance disorders to evaluate the impact of the different physiotherapy programmes in their physical posture.

3.2. Preserving privacy while supporting health data interoperability

The SB project is motivated by the need for personal data management and services that fully comply with the General Data Protection Regulation (GDPR). Adhering to this, in the case of co-operation of projects that have in place different technical approaches to this compliance obligation, and at the same aiming for health data interoperability, the PoP applies the principles of Privacy by Design. Thus, choosing well known standards (in particular the HL7 FHIR standard, FHIR resource profiles to define constraints and extensions to the FHIR base model, SNOMED-CT for semantic enrichment of the data, ICD-10 medical terminology and others) provides a harmonization solution on how data sources are stored and managed to support structural interoperability for the exchange of information and its use without changing the content of the data [22].

The management of personal data and Personally identifiable information (PII), its confidentiality, integrity, and availability involves relevant protection mechanisms, as they are derived from the various standards such as Common Criteria Evaluation Methodology (CEM) (ISO/IEC 15408 1996-2018), the Open Source Security Testing Methodology Manual (ISECOM 1988-2918), and related research efforts [23]. A dedicated component has been implemented to allow and monitor interactions between components, manage Role Based Access Control (RBAC) authentication/authorisation procedures, and administer a separated data repository in which all personal data, PIIs and keys associations reside in an encrypted fashion for privacy reasons. There are three different categories of data collected: a) IoMT/sensor usage data or questionnaires' answers collected via the SB@App, b) medical data collected via the SB Dashboard, and c) usage/medical devices data transmitted from cooperating projects (S4H, HB). Ids management and Personal Identifiable Information removal techniques used were introduced in [24] and properly enhanced to meet SB needs (Figure 3)

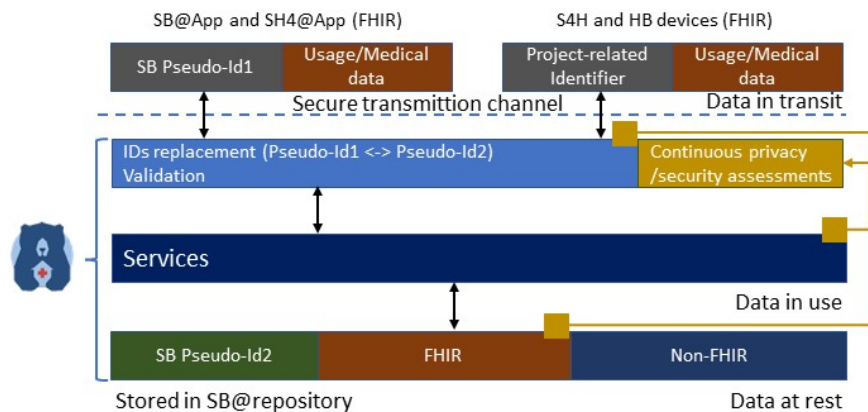


Figure 3: Adhering to “Privacy by design” principle: a SB@Cloud component replaces different IDs to a SB-generated one (Pseudo-Id2) by which data record is stored in SB@Repository

4. Preliminary achievements and results

The first months of the PoP was more of technical nature, envisaging to demonstrate a significant set of functionalities, namely data collection through the selected wearables devices, storage, security, as well as launch the discussion on personalisation strategies provided by the SB platform. It also

seeks to exploit the infrastructure, devices and sensors specifically put in place for balance and LBP training, hence making use of the collaboration with the S4H and HB projects.

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. The pre-pilot phase dealt with the testing and acquisition of complete sets of consumer devices that can support the monitoring of certain health conditions, e.g., a blood pressure monitor, a smart scale, etc. An initial demographics assessment of the target population was made, and a small-scale procurement including all the necessary devices and logistics for the PoP has been done according to the estimates of comorbidities to be present. At the moment, such devices are integrated with the SB@App using vendor provided SDKs and 50 device sets are already available in Madeira to be delivered to the PoP participants.

The baseline assessment of patients is being conducted in 2 health centres, where the clinical team carries the procedures and necessary activities for the assessment, from the presentation of questionnaires to the physical and nutritional exams. Based on the results, the patients are included or excluded in the study, and the first data becomes available in the platform. For the participants with balance disorders, a Holobox arrived in Madeira to perform a virtual reality training and two MedX machines have been installed for participants to carry out the training on the prevention and treatment of LBP. These physiotherapy infrastructures have been prepared and configured to send training data for the SB platform through dedicated RESTfull APIs as described in the previous section.

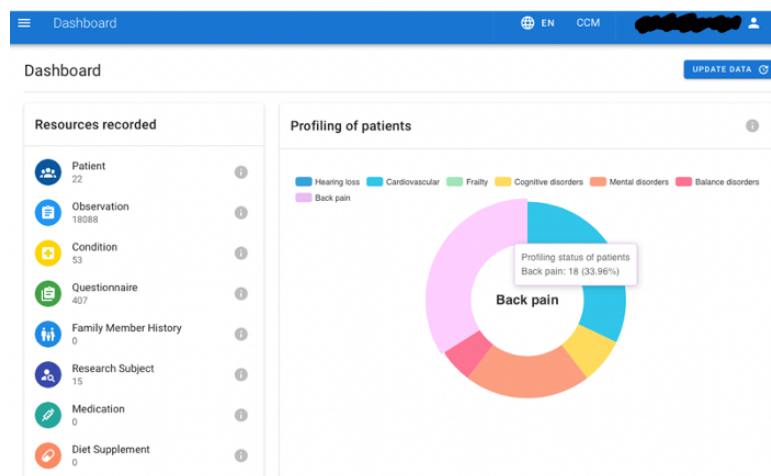


Figure 4: Included participants and sum of comorbidities presented (via the SB clinicians' dashboard)

At this point in time, with 4 months of PoP execution 22 recruited participants were fully evaluated in the baseline assessment and presented several comorbidities (Figure 4). After analysing the comorbidities presented by the participants, it is clear that the participants with the combination of LBP, cardiovascular disease and mental illness are undoubtedly high in number. In fact, from the seriation carried out among potential participants, these patients are the ones who are likely to collect the best benefit from the 12-month follow-up in SB. According to the high incidence of LBP and cardiovascular disease in the Portuguese population, a high number of participants with these comorbidities was already expected and if we add the fact that we are currently experiencing a worldwide pandemic, the high incidence of anxiety and mental health diseases is also not surprising.

18 participants already are already following the MedX physiotherapy sessions protocol. In total, 83 MedX sessions have been executed. Therefore, from the total 22 recruited patients, 18 have begun the training programme sharing data between S4H and SB. The data from the force tests and training sessions are being sent automatically to the SB platform through the installed infrastructure. The number of patients recruited with balance disorders are lower than with LBP. Nevertheless, the synergy with HB is also effective, since out of the 4 patients recruited, 3 of them are already in the Holobox physiotherapy sessions. In total 13 Holobox sessions have been executed. In Figure 5 it is possible to visualize some of the MedX force test and HB training data being collected.

As mentioned in section 3, the PoP will provide the basis of the full scale implementation of all five SB pilots. All the preliminary objectives have been accomplished, with technical and clinical infrastructure set-up, the first patients recruited, and data being collected and shared with SB using a secure infrastructure applying the privacy by design paradigm. It is worthwhile mentioning that even if outside of the scope of this paper, in addition to the data being collected through the cross-project interoperability, patients are using the SB@APP to collect health data (e.g. blood pressure, weight, steps, etc.) outside of day-care or rehabilitation centers. This path is actually providing the majority of data into the platform (around 100 observations per day and increasing) and there is still ongoing developments (even replacing device vendors due to lack of stability of SDKs and APIs provided) to ensure a seamless integration and flow of data into the platform that will allow to implement AI-based recommendations and interventions, as well as study ethical and clinical issues arising when addressing multimorbidity in vulnerable populations.

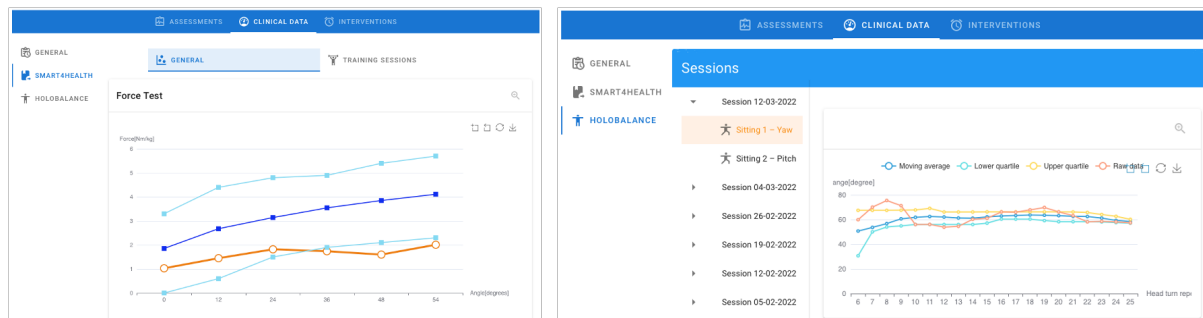


Figure 5: Sample data collected from cross-project collaboration (via the SB clinicians' dashboard)

Additionally, and as part of future work, bidirectional interoperability scenarios between SB and the other projects may also bring considerable benefits for unlocking the full potential of Digital Health, e.g., in order to become the reference platform for citizens to manage their EHR data, S4H has all the interest that the elderly involved in the PoP could save and share their data through the S4H platform.

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