SmartHealth: a Service-based Platform for Information Integration and Clinical Evaluation Support

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***Abstract*— The stringent regulations related to eHealth products and software design and manufacture can be difficult to overcome. Many businesses can create innovative prototypes, but costs and technical demands for compliance often hinder the process of industrialization and commercialization. SmartHealth is a service-oriented platform for information integration. It aims to support medical device manufacturers in generating new insights from their devices and health apps to assist in the clinical evaluation process while assuring regulatory compliance throughout the entire product development lifecycle. To demonstrate the viability of SmartHealth, the system will be tested against two use case scenarios: an ECG-based device and a Sleep/Room monitoring device. These two products are from two different manufacturers, and the goal is to certify them as medical devices.**

I. Introduction

The development of eHealth devices and software has a very demanding regulatory requirement regarding know-how, development practices and financial costs [1,2]. Many companies can develop innovative prototypes, but industrialization and commercialization are completely at stake due to these entry-to-market barriers [3, 4].

With the introduction of the new Medical Device Regulation (MDR) in 2021 [5], regulatory compliance became even stricter. Manufacturers have found themselves particularly challenged in classifying their medical devices, identifying the required compliance requirements, collecting and managing clinical evidence, and collecting post-market surveillance data [6]. Although large companies tend to be more capable of supporting the financial cost of regulatory training and addressing these new demands, it is not the case for small-size companies [4]. Furthermore, regardless of the size, companies feel there is a lack of centralized information and tools to support regulatory compliance [4].

In this sense, the SmartHealth system aims to lower the entry-to-market barriers in the development of new eHealth and Ambient Assisting Living (AAL) products by offering a set of integrated services that promote compliance with the main medical device standards as well as facilitate innovation activities through the combination of data originated from different products. In addition, it seeks to reduce development costs, by supporting the evaluation of devices and services throughout the different development phases, from proof of concept to the preparation of tests (usability tests, clinical trials, etc.) and post-market monitoring.

The underlying objective is to promote endogenization, on the part of the national health value chain entities, in their strategies, projects and R&D and innovation activities of criteria related to demand, entrance, and adoption in global markets. These aspects can be decisive for the commercial success of a given product/service.

II. Related Work

The market provides diversified solutions to support the medical device development process and its standard compliance. However, supporting medical device manufacturers always implies the adoption/purchase of different services and products from different manufacturers with non-existent interoperability.

Below, we present the types of solutions currently available in the market and the literature:

- *Requirements management systems:* software tools that simplify the requirement engineering process, enabling more organized and formalized requirements management, change control, and traceability [6,7]. Some tools, such as the Jama Connect platform [8], go one step beyond and can align with mandatory requirements on standard-specific regulations, including in the medical device context—a paramount aspect of the compliance and maintenance of a company's quality management system.
- *Compliance automation systems:* platforms that ensure regulations and standards defined by governing bodies align with the organization's policies and procedures using automated mechanisms [9]. These mechanisms, which help track compliance procedures in a single platform, include continuous data and/or documentation monitoring and alerts in case of compliance violations. As a result, it reduces compliance risks and facilitates implementing and

maintaining an organization's regulatory requirements [9]. However, there is a lack of these types of systems, which include the most relevant medical device regulatory standards, such as ISO13485 (Quality System for medical devices industry), ISO14971 (Risk Management for medical devices), IEC 62366 (Usability in medical devices), IEC 62304 (Software lifecycle for medical devices), and IEC 60601 series (Medical electrical equipment). However, some attempts are being made, despite being only documentation templates/checklist platforms [10,11,12].

- *Clinical trial management systems (CTMS):* software systems that support the clinical trial portfolio's planning, management, and tracking [13]. It also facilitates the analysis and statistics of clinical trial data [13]. There are many CTMSs available in the market [13], and despite not being developed to address regulatory compliance, if used properly, they can answer many requirements demanded by the clinical evaluation phase for medical devices, including in the AAL domain.

The systems mentioned above address different phases of the medical device development process. As different manufacturers provide different systems, a company might need to acquire one of each to get the support needed for efficient compliance with regulatory requirements. This can be difficult to achieve and highly costly. Furthermore, these systems lack information integration, allowing for a more holistic view of the status of an organization and product(s) regulatory compliance status.

III. SmartHealth System

The SmartHealth system can be defined as a service-based platform for integrating information while making it interoperable and adhering to medical device regulatory standards. This solution responds to companies that require access to services to support the most challenging aspects of the software development process, namely product innovation activities and implementation/maintenance of applicable regulatory requirements – where it includes product evaluation. There are two fundamental factors for the commercialization success of a product.

As depicted in Fig. 1, the SmartHealth system is composed of five distinct components: (1) the Clinical Trials Module (clinical trial management tool); (2) the Data Analytics tool; (3) the Data Visualization tool; (4) Health Data Repository; and (5) the Medical Device Certification Support Module. In the following subsections, we describe each component in detail.

A. Clinical Trials Module (CTM)

The Clinical Trials Module (CTM) aims to support health professionals and trial managers from the initial stages of a trial to its conclusion. It enables compliance with policies for the use and safety of medical devices and facilitates assessing the device's performance on a functional and clinical level.

The CTM is represented by two applications: web and mobile. The Web Component allows the trial team (trial manager, health professionals) to set clinical trials or usability tests and monitor them. The mobile component is made available to trial participants to collect patient-reported outcomes, adverse events, or other information set by the trial team (e.g., instructions of use).

Data collected by the CTM is pseudonymized and sent to the Health Data Repository (see subsection III-C) to be then used for analysis (III-D) and visualization (see subsection III-C). The pseudonymization process strips trial data of identifiable information (e.g., name, localization, contact, etc.), but it is kept an app-generated ID to allow the analysis of all data made available by each participant.

Due to the system's characteristics, by enabling the remote participation and monitoring of users, this system can also include clinical studies and tests for post-market surveillance purposes.

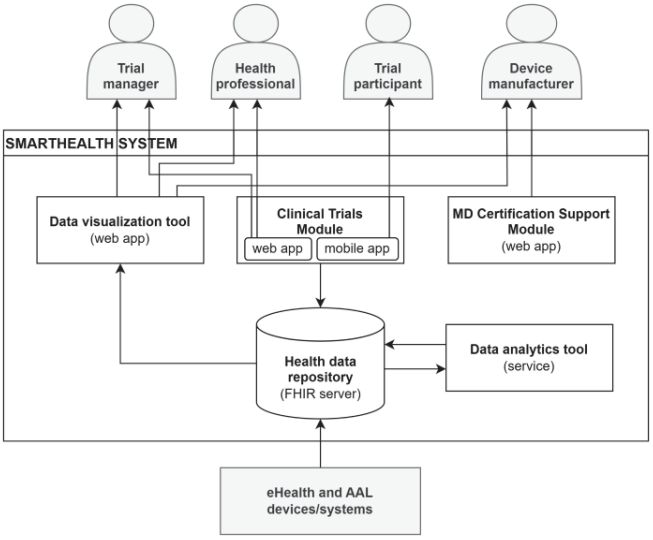

Fig. 1. SmartHealth system high-level architecture

B. Data Analytics tool

The Data Analytics tool is an automated Python service that provides new insights and conclusions based on data in the Health Data Repository (subsection III-D). This data originates from the CTM (subsection III-A), AAL, and eHealth devices/systems.

Data processing is performed in three distinct stages, as depicted in Fig. 2.

1) Data identification and pre-processing: data from the repository is identified based on a protocol schema file provided to the service. This schema file contains information regarding the structure of the clinical study and tests (e.g., number of sessions, number of planned visits, type of activities on each session, etc.), and the types of health data expected from the medical devices (e.g., ECG, PPG, EMG, EEG, temperature, weight, blood pressure, questionnaires, medication intake, etc.). Then, the service automatically

identifies the different data formats and handles missing values by removing them. This pre-processing technique was selected for simplicity due to the heterogeneity of health data that can be available.

2) Signal analysis and delineation: from the pre-processed data, instances that contain time series data are analyzed according to their type. The tool can process and delineate ECG signals by adapting the ECGkit [14] to Python. This ECG analysis component extracts P-Q-R-S-T wave peaks, onsets, and offsets, which translate into features commonly used to perform the clinical evaluation of ECG devices, such as QRS durations, RR intervals and heart rate [15,16]. This component was validated using PhysioNet's QT database [17] to assess its delineation capacity, achieving an overall sensitivity of 99,42% and a positive predictivity of 93,73%. It is also capable of processing EEG signals using the MNE-Python library [18].

3) Statistical processing: time series data originating from to-be-certified medical devices accompanied by an equivalent gold-standard device is subjected to kappa statistics and limits of agreement. More conventional metrics are extracted for other data, such as absolute or relative frequency, median, maximum, minimum, deviation, etc.

Finally, the data extracted from the analytics tool is injected into the health data repository for visualization (subsection III-C).

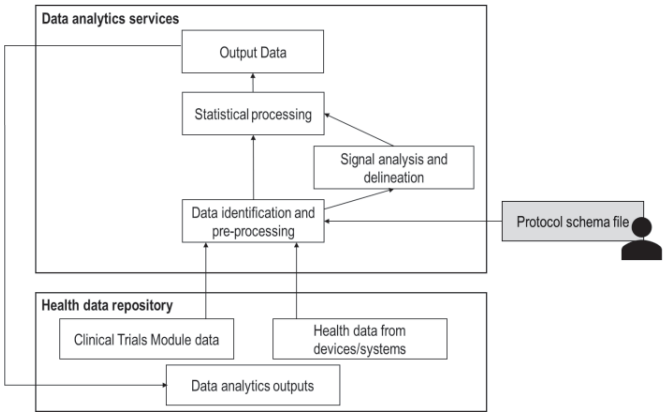

Fig. 2. Data analytics tool service: data flow diagram

C. Data Visualization tool

The data visualization tool of the SmartHealth system allows for the visualization of data available at the Health Data Repository. This tool is an instantiation of the open-source software named Trial Monitor [19] developed by our Fraunhofer researchers.

Trial Monitor is a software tool that facilitates researchers, trial managers and developers in creating personalized Web dashboards for monitoring participants in technology-enabled field trials or usability tests. With minimal configuration files, Trial Monitor automatically generates these dashboards, saving time which would otherwise have to be channelled into creating or adopting different dashboards for every system to be assessed.

D. Health Data Repository

The Health Data Repository aims to store data originating from AAL and eHealth devices in assessment and data collected from the Clinical Trials Module (subsection III-A). It also stores new data insights resulting from the data analytics tool over the existing data at the repository.

The repository is a fully contained FHIR server developed by the open-source project HAPI FHIR [20]. HAPI FHIR provides a complete Java implementation of the HL7 FHIR standard [21], which defines rules and specifications for exchanging electronic health information between different systems regardless of how they are stored at the source.

E. Medical Device Certification Module

The Medical Device Certification Support Module arises as a response to an identified need to support medical device manufacturers in conducting the certification process of their medical devices, for future commercialization, in compliance with the guidelines and regulatory standards of the market. This module is a questionnaire that allows for a rapid assessment of the compliance status of the devices in question.

III. Case Studies

To demonstrate the viability of the SmartHealth system, we plan on performing two studies with two medical devices that aim to be certified. To register a participant into the SmartHealth system, the CTM mobile app must be installed. This app will also allow participants to follow clinical study procedures step by step.

The first clinical study assesses a three-lead ECG band with patches accompanied by a mobile application for visualization. The goal of this device is to collect biometric data relevant to monitoring chronic cardiovascular diseases. The device can collect ECG, respiratory rate, heart rate variability, and the user position (laying or seated, based on inertial sensors).

The study will be composed of 4 sessions. Three sessions shall be performed in a clinical setting by a nurse to the participant, followed by the participant unguided. They will have to execute four tasks: seated at rest (2 minutes), laid down at rest (2 minutes), walking (2 minutes), and getting up and sitting down (five times). These tasks shall be done using simultaneously the gold-standard ECG device and the device in question. At the end of each session, the nurse and participant must answer a usability questionnaire. One session is to be done remotely exclusively by the participant. It is expected the recruitment of 20-50 participants.

The second study is a technical, proof-of-concept test to evaluate the accuracy and performance of a Sleep/Room monitoring device. The aim of this device is to monitor sleep quality for the detection of paroxysmal nocturnal dyspnoea or orthopnoea. The system is composed of a pillow that collects EEG, respiratory rate, body movements/agitation, sleep duration, humidity, temperature, noise detection and head position; and room sensor devices that collect room temperature, room humidity, room sound/noise, agitation levels, presence/absence

of one or two users. Data shall be collected in a temperature-humidity-controlled room for three consecutive days.

Both studies are expected to occur between May and June.

V. Conclusions and Future Work

Compliance with regulatory requirements is one of the most overwhelming aspects of the medical device development process, especially in the clinical evaluation phase. The market and the literature provide different systems and services to answer these challenges. However, they lack information integration, complicating maintenance procedures for regulatory compliance.

With the proposal of the SmartHealth system, we intend to facilitate the implementation and maintenance of regulatory requirements by providing a set of interoperable tools and services that allow for information integration. Due to its flexible nature using minimal configuration settings, it can easily adjust to different product specificities and support different product development phases, including product conceptualization/innovation activities and post-market surveillance.

Nevertheless, the SmartHealth system still has space for improvement. First, it should include a DevOps module to automatize test processes (from unit tests to system tests) and software deployment to ensure guarantees of continuous system conformity. This feature was expected to be included, but it was not implemented due to project constraints. Second, the data analytics tool should support advanced analytics based on forecasting techniques while explaining the root causes of trend lines. This would enhance the insights currently provided. Third, the Medical Device Certification Module must evolve towards an automated tool that allows for the planning, implementing, and maintaining the MDR regulatory requirements, going beyond the questionnaire-filling method for identifying risks and gaps. Finally, due to time constraints, it was impossible to plan additional clinical studies with more devices and, therefore, provision the data analytics tool with more biosignal analysis components. By evolving the SmartHealth system to include the aspects mentioned earlier, we believe it can be revolutionary for facilitating organizations' compliance with regulatory requirements and supporting innovation activities.

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