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Personal Health ICT Systems to Support Integrated Care Solutions

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Abstract – **Because of the increasing ageing population, the frequency of chronic diseases has been growing in Europe over the past decades. In addition, the ever-growing demand for acquiring, managing and exploiting patient health related information has led to the development of many electronic health (eHealth) systems and applications. However, despite the number of systems already developed and the apparent need for such systems, end-users can collect online and exploit only a limited set of information for health purposes in the context of personalized, preventive and participatory medicine. To this direction, the authors describe work relevant to the development of a core personal health record (PHR) software, needed to support teams providing healthcare, including the patient as a member of the team, paying emphasis on wellbeing, home care and the management of chronic diseases. Outcome of this work has become part of the Integrated Care Solutions™ suite, developed by the Institute of Computer Science of the Foundation for Research and Technology-Hellas (FORTH), towards enhancing tools available in support of personalized care. This technical and research report presents the PHR concept, related work and best practices for the development of PHR systems, based on information and communication technology (ICT) in a coherent manner by adopting international standards and best practices where available. The report concludes by providing directions towards achieving wider PHR adoption and use, based on accumulated experience from many European Union (EU) research projects. Detailed description of how to address issues relevant to the different disease functionalities, the diverse bi-directional interoperability with external data sources, user engagement and security, is included together with key modules needed for improving the efficiency and quality of self-management.**

Keywords – Electronic Health Record, Personal Health Record, Interoperability, Coordinated Care, Personal Health Systems, Health Data Integration, Quality Care

Introduction

PHR refers to a representation of health records related to the care of a patient, managed by the patient, with the goal to promote continuity of care in a reliable, accessible and secure fashion. The main

expected benefit is both patient and healthcare professionals' empowerment towards a more synergistic, patient-centric healthcare, promoting shared and personalized care throughout a citizen's lifespan.

The concept of the PHR has been developed in parallel with the development of the electronic health record (EHR). PHR was first mentioned in an early report from the US Institute of Medicine called "The Computer-Based Patient Record: An Essential Technology for Health Care" [1]. The report described the envisaged requirements of such an endeavor. In Europe, the PHR concept has been introduced through European directive 95/ 46/ EC [2] which first allowed, and at the same time proposed, the direct interaction of the person with his/ her health record including input of data from home, work and leisure places.

The advancements in healthcare practice, the limitations of the traditional healthcare processes and the need for flexible access to health information, create an ever-growing demand for electronic health systems everywhere. To this direction, PHR systems provide citizens with the ability to become more active in their own care combining data, knowledge and software tools. PHR systems are citizen centric, in the sense that their management is the primary responsibility of the citizen [3]. Through a PHR application, the citizen/ patient is able to provide daily life-status information, maintain his/ her own record of medical exams and define the access rights to their personal data, leveraging that access, to improve health and disease management. Over the last twenty years, a large number of PHR-like systems have been developed [4], many of which have been abandoned. A non-exhaustive account of currently available systems is presented in Table 1.

Table 1: Indicative list with available PHR products and corresponding websites.

PHR product	**Website**
CareZone PHR	https://carezone.com/
The Dossia Health Manager™	http://dossia.com/products/health-manager.html
eclinicalWorks Patient Portal	https://www.eclinicalworks.com/products-services/patient-engagement/
Epic MyChart	https://www.epic.com/software#PatientEngagement
Indivo™	http://indivohealth.org/
kindredPHR	https://kindredphr.com/v2/launch.jsp
Medfusion iHealthRecord	http://www.medfusion.net/ihealthrecord/
MedHelp PHR	http://www.medhelp.org/
MedicAlert	http://www.medicalert.org/
Microsoft HealthVault	https://international.healthvault.com/
MyALERT® Personal Health Record	http://www.alert-online.com/myalert
myPHR	http://www.myphr.com/
NoMoreClipboard	https://www.nomoreclipboard.com/
OpenMRS	https://openmrs.org/
Patient Ally	https://www.patientally.com/
Patient Fusion	https://www.patientfusion.com/

PatientsLikeMe	https://www.patientslikeme.com/
WebMD Health Manager	https://www.webmd.com/phr
zweena PHR	http://zweenahealth.com/

To receive the benefits of a PHR, citizens need to be able to access their health information on demand. The minimum core objectives for a PHR, connected to an EHR, include a mechanism to provide patients the ability to view online, download and transmit their health information, and a secure electronic messaging system to communicate. Having guaranteed data capture and sharing, PHR products aim towards improved outcomes through the advancement of healthcare processes.

Despite the wide variety of potential benefits [5][6], the uptake of personal health records (PHRs) has been rather slow [7][8]. This is partly because only a small subset of the PHR applications are free, web-based and open-source [4][9]. In addition, the variety of existing business models, fee-based or commercial, complicate even more the selection of an appropriate PHR. Other important issues that complicate even further the selection and use of PHR systems include:

- **Interoperability:** PHR systems are rarely integrated and interoperable with other electronic services and systems [10][11]. In most cases, end-users need to enter all their health data manually.
- **Usability/ Adaptability:** The majority of PHR systems follow the approach "one system fits all". However, different persons with different primary diseases have different needs and PHR systems so far fail to adapt to specific needs [12]. User needs and requirements from both the patient and healthcare provider perspectives need to be addressed.
- **Trust:** There are limitations in the methodologies used for sharing information among patients, and their relatives, doctors and researchers. There is a sense of lack of trust as well as inefficient access control and security mechanisms [4][13].
- **Added Value:** The majority of PHR systems are not linked with specific health services. In addition, the benefit for citizens to maintain a personal health file through manual input of data has not been adequately demonstrated [4][9].

To face these challenges, guidelines and standards are starting to emerge to support the development of quality PHR systems. This technical report focuses on the presentation of a state-of-the-art PHR system, which is interoperable, personalized, and adaptable for various diseases. It has been designed for easy integration with existing clinical information systems. Its development has been based on the outcomes of various EU research projects and exhibits a high technology readiness level. Integrated Care Solutions™ for the Citizen (ICS-C) provide a number of software modules to support effective and efficient access control mechanisms and many added-value services. The goal is to provide an innovative ecosystem for enhancing the self-management capacity of patients through the involvement of all stakeholders participating in the therapeutic process.

Methods

In order to conduct this work, literature review was performed on established work, and additional information was retrieved from published material and web sites towards identifying current trends and

good practices. The subsections provide short presentations of the Health Level Seven (HL7[1]) PHR system (PHR-S) functional model (FM) [14], the quality criteria set by the European institute for health records (EuroRec[2]), related EU research and development projects, as well as key international standardization activities. A model for software quality assurance is also presented. All of them have guided the design and development of the PHR for the Citizen (PHR-C), which is part of the ICS-C group of the Integrated Care Solutions™ suite of products. The different models and projects selected emphasize the functionalities that are required to support efficient PHR adoption.

The implementation of PHR-C was based on scrum, an agile methodology, focusing on iterative incremental processes for software development. Short iterations helped to keep quality under control by reaching a releasable state frequently, preventing the team from collecting a large backlog of defect correction work. Key drivers, for defining the overall architecture, were patients, and clinical care providers. Physical meetings with relevant stakeholders were focused on practice and usage in the healthcare domain. Information discussed during these meetings provided feedback for system improvements and version releases. Functionality of each component and communication interfaces between components were specified. The solution focuses on the combination of a group of services into one technology. The modular architecture of the PHR makes the platform easily expandable to include additional roles, diseases and phenotypes.

HL7 Personal Health Record System Functional Model, Release 1 PHR-S FM

The HL7 PHR-S FM[3], which is a draft international standard: ANSI/ HL7 PHRSFM, R1-2014; ISO/ FDIS 16527:2013 (E) [14][15], defines a standardized model of the functions that may be present in a PHR-S. According to HL7, the PHR is the underlying record (e.g., data, information, pictures, sounds, graphs, videos, etc.) that the software functionality a PHR-S maintains. Depending on the functionalities applicable for a particular business case, certain PHR functions and criteria in the PHR-S FM will apply to any single PHR-S implementation. This, more concrete, expression of usable subsets of functions from the PHR-S FM is called *functional profile*. This profile is the standard description and common understanding of the requested or available functions in a given environment. The intention is for all functions describing the behavior of a system, in a consumer-oriented language, to be recognizable to all key stakeholders of a PHR-S. PHR-S FM consists of three main sections: Personal Health, Supportive, and Information Infrastructure, as outlined in Table 2. The *Personal Health* (PH.1.0-PH.6.0) section functions are the subset of PHR-S functions that manage information and features, related to self-care and provider-based care over time. PH section functions can yield a summary record of an individual's care, including ad hoc views of the overall PHR.

Table 2: The PHR-S functional outline.

PHR-S function list sections	**ID#**	**Superset of functions**
Personal Health	PH.1.0	Account Holder Profile
	PH.2.0	Manage Historical Clinical Data And Current State Data
	PH.3.0	Wellness, Preventive Medicine, and Self Care

[1] http://www.hl7.org/
[2] http://www.eurorec.org/
[3] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=88

PHR-S function list sections	**ID#**	**Superset of functions**
	PH.4.0	Manage Health Education
	PH.5.0	Account Holder Decision Support
	PH.6.0	Manage Encounters with Providers
Supportive	S.1.0	Provider Management
	S.2.0	Financial Management
	S.3.0	Administrative Management
	S.4.0	Other Resource Management
Information Infrastructure	IN.1.0	Health Record Information Management
	IN.2.0	Standards Based Interoperability
	IN.3.0	Security
	IN.4.0	Auditable Records

The *Supportive* (S.1.0-S.4.0) section functions are the subset of PHR-S functions that assist the PHR account holder with administrative and financial requirements. Also included are PHR-S functions that provide input to systems that perform clinical research, promote public health and seek to improve the quality and outcome of health care delivered.

The *Information Infrastructure* (IN.1.0-IN.4.0) section consists of PHR-S functions that support Personal Health and Supportive section functions. These functions ensure that the PHR-S provides information privacy and security, interoperates with other information systems (including PHR and EHR systems), and helps make PHR-S features accessible and easy to use.

According to HL7 PHR-S FM, in order to ensure the necessary functions in selecting or developing PHR systems, it is important to create accurate, clear and impartial functional profiles by selecting functions from the HL7 EHR-S FM. A functional profile is a selected set of functions that are applicable for a particular purpose, group of users, degree of interoperability, etc. The profile consists of the choice of certain functions that can be mandatory (SHALL), prohibited (SHALL NOT), optional recommended (SHOULD), optional, or permissible (MAY). The goal of creating a functional profile is to support a business case for PHR-S use by selecting an applicable subset of functions from the PHR-S FM. A formal process exists for registering and balloting functional profiles. Testing and certification procedures are then required to ensure that the subsystems and the general PHR-S conform to the selected functional profile and meet the characteristics for the proper operation of the system. A PHR-S does not conform directly to the PHR-S FM; rather, a PHR-S conforms to a functional profile (i.e., a subset – more specifically, a tailored subset) of the PHR-S FM. Conformance to the PHR-S FM is defined for functional profiles.

HL7 PHR-S FM guided the development of PHR-C in order to ensure that the core functionalities have been developed into a coherent software.

EuroRec EHR Quality Seal

EuroRec is an independent not-for-profit organization, promoting in Europe the use of high quality electronic health records (EHRs). One of its main missions is to support, as the European certification body, EHRs quality labelling and defining functional and other criteria for EHRs. Level 2 of the EuroRec EHR Quality Seal[4] encompasses 50 functional quality criteria, addressing various essential functions of the EHR: access and security management of the systems, basic functional requirements on medication, and clinical data management focusing on trustworthiness of the clinical data. These criteria are also very relevant to PHR systems and have been used to guide the development of the proposed PHR. These criteria are presented in Table 3.

Table 3: EuroRec EHR quality seal level 2 criteria.

Criteria	**Description**
1	The system enables to link a role to a user.
2	The system shall include the information necessary to identify each patient, including the first name, surname, gender and date of birth.
3	The system enables the capture of all patient demographic data necessary to meet legislative and regulatory requirements.
4	The system displays all current health problems associated with a patient.
5	Each version of a health item has a date and time of data entry.
6	Each version of a health item identifies the actor who has actually entered the data.
7	Each update of a health item results in a new version of that health item.
8	The system supports the use of clinical coding systems, where appropriate, for data entry of health items.
9	The system presents a current medication list associated with a patient.
10	The system presents a medication history associated with a patient.
11	The current medication list can be printed.
12	The system provides a catalogue of medicinal products.
13	Each version of a health item has a status of activity, e.g. active or current, inactive, history or past, completed, discontinued, archived.
14	The system presents a list of the allergens with an active status.
15	Deletion of a health item results in a new version of that health item with a status "deleted".
16	Each version of a health item has a person responsible for the content of that version. The person responsible for the content can be a user or a third party.
17	Each change of status of a health issue results in a new version of that health issue.
18	A complete history of the versions of a health item can be presented.
19	The system enables to document a patient contact.
20	The system is able to present all the documentation associated to a contact for that patient.

[4] http://www.eurorec.org/services/seal/

21	The system is able to present the history of the individual results for discrete lab test.
22	Each version of a health item has a date of validity.
23	The system supports concurrent use.
24	The system makes confidential information only accessible by appropriately authorised users.
25	The system enables the implementation of a privilege and access management policy.
26	The audit trail contains the registration of users logging in or out.
27	The audit trail contains the registration of security administration events.
28	Audit trails cannot be changed after recording.
29	The system enables a user to change his password.
30	Security service issues and operation of the system are well documented.
31	Each health item is uniquely and persistently associated with an identified patient.
32	Each version of a health item is uniquely and persistently identified.
33	Each user is uniquely and persistently identified.
34	The system enables to assign different access rights to a health item (read, write,...) considering the degree of confidentiality.
35	All patient data can be accessed directly from the patient record.
36	The system distinguishes administrators, privileged users and common users. Administrators assign privileges and/or access rights to privileged and common users. Privileged users assign privileges and/or access rights to common users.
37	The system is available in the languages required by the regulatory authorities.
38	Each patient and his EHR is uniquely and persistently identified within the system.
39	The system is able to make a distinction between patients with same name, first name, gender and date of birth.
40	The system takes the access rights into account when granting access to health items, considering the role of the care provider towards the patient.
41	The system offers to all the users nationally approved coding lists to assist the structured and coded registration of health items.
42	Data entry is only done once. Entered health items are available everywhere required.
43	The system displays patient identification data (name, first name, age and sex) on each data entry interface.
44	The system displays, when prescribing a medicinal product, known allergies of the patient, if it does not alert the user for a specific allergen.
45	The system enables the user to modify patient's administrative data.
46	The system distinguishes actual or active medication items from past medication items when including and displaying medication items in lists or in a journal.
47	The system enables the user to modify health items, if legally admitted.
48	The system has a timeout function, terminating a session after a configurable period of inactivity.

49	The system has a consistent way to present clinical alerts, e.g. red color for abnormally and/or high lab results.
50	A medication list presents at least the following elements: identification of the medicinal product (package), starting date, date of the latest prescription, dosing instructions (structured or as an expression)

The criteria focus on access and security management of systems, and basic functional requirements on medication, and clinical data management focusing on trustworthiness of the clinical data.

European Projects

Several European Union projects design and develop personalized health applications for the management of chronic diseases for patient empowerment and self-management. These projects provided significant experience gains on PHR development and offered the background of implementing health apps for cancer patients. Some of them are briefly presented below:

REACTION: "Remote Accessibility to Diabetes Management and Therapy in Operational healthcare Networks" ran between 2010 and 2014[5]. The project conducted research and developed an intelligent service platform for professional remote monitoring and therapy management of diabetes patients in different health systems across Europe. As such, the platform was not a general-purpose PHR system but optimized especially for the empowerment of diabetic patients. The constructed platform could execute various clinical applications for monitoring of vital signs, context awareness, feedback to the point of care, integrative risk assessment, event and alarm handling as well as integration with clinical and organizational workflows and external Health Information Systems [16].

P-Medicine: "From data sharing and integration via VPH models to personalized medicine" ran between 2011 and 2015[6]. The project created an infrastructure that facilitates the translation from current medical practice to personalized medicine. Essential to the realization of personalized medicine is the development of information systems capable of providing accurate and timely information about potentially complex relationships between individual patients, drugs, and tailored therapeutic options. In the context of the project, a range of services were designed and developed on top of a PHR system. The p-medicine PHR was based on a general purpose PHR (Indivo-X), with extensions towards the directions of cancer patient profiling and clinical decision support for personalized oncology [17]. Furthermore, the project implemented a secure mechanism for informed secondary use of patient's biomaterial and personal data via the PHR [18]. The p-Medicine tools and technologies were validated within the concrete setting of advanced clinical research with pilot cancer trials based on clear research objectives, in the domains of Wilms tumor, breast cancer and leukemia.

EURECA: "Enabling information re-Use by linking clinical REsearch and Care" ran between 2012 and 2015. The goal of the project was to enable seamless, secure, scalable and consistent linkage of healthcare information residing in EHR and PHR systems with information in clinical research information systems, such as clinical trials. Achieving semantic interoperability among PHR and clinical trial systems was at the core of the EURECA project, as it was the basis for enabling many of the software services and tools developed in the project. Data management services were implemented

[5] http://www.reaction-project.eu/
[6] http://www.p-medicine.eu/

for a variety of EHR and clinical trial systems (e.g. Obtima, OpenClinica) in order to achieve semantic interoperability with the Indivo-X PHR using terminology standards and HL7 mechanisms for exporting and importing data [11][13].

MyHealthAvatar: "A Demonstration of 4D Digital Avatar Infrastructure for Access of Complete Patient Information" ran between 2013 and 2016[7]. The project was an attempt for the digital representation of patient health status [19]. The goal was to create a "digital avatar", i.e. a graphical representation/ manifestation of the user, acting as a mediator between the end-users and health related data collections, focusing on the interoperability and the data integration aspect. It was designed as a lifetime companion for individual citizens to facilitate the collection, the access and the sustainability of health status information over the long-term. Among others, key questions that are answered in this context is how to develop optimal frameworks for large-scale data-sharing, how to exploit and curate data from various EHRs and PHRs, assembling them into ontological descriptions relevant to the practice of systems medicine and how to manage the problems of large scale medical data.

iManageCancer: "Empowering patients and strengthening self-management in cancer diseases" ran between 2015 and 2018[8]. The project objective was to provide a cancer specific self-management platform designed according to the needs of patient groups. At the same time, it focused on the wellbeing of the cancer patient with special emphasis on avoiding, early detecting, and managing adverse events of cancer therapy but also importantly, on the psycho-emotional evaluation and self-motivated goals [20]. In this context, the project developed cancer specific apps that allow patients, through an easy-to-use interface for mobile devices, to keep track of their health and disease status and to keep a health diary on personal clinical observations such as side effects of therapies, which the patient can share with his healthcare providers. Health and disease status included therapies and results of clinical interventions or tests.

BOUNCE: "Predicting Effective Adaptation to Breast Cancer to Help Women to BOUNCE Back" started in 2017 and is scheduled to run until 2021[9]. The project delivers a unified clinical model of modifiable factors, associated with optimal disease outcomes and advanced computational tools, to be deployed for a prospective multi-center clinical pilot at four major oncology centers. The overreaching goal of the project is to incorporate elements of a dynamic, predictive model of patient outcomes in building a decision-support system used in routine clinical practice to provide physicians and other health professionals with concrete, personalized recommendations regarding optimal psychosocial support strategies.

The European research projects offer results that provide valuable scientific insights about the appropriate modules that are necessary to enhance care and promote patient empowerment and self-management practices. The experience accumulated and the tools developed have rendered PHR-C as an important tool not only for health management but also for clinical research. Advance work in progress includes modules that allow authorized end-users to make cohort analysis on all patient data, to visualize graphically the psycho-emotional profile of patients using various graphical paradigms, to perform advanced searches in specialized databases using natural language (advanced search engine tools), and to allow researchers to generate requests for specific cohorts.

[7] http://www.myhealthavatar.eu/
[8] http://imanagecancer.eu/
[9] https://www.bounce-project.eu/

Standardization Efforts

Technical challenges for the implementation and adoption of EHRs and PHRs, have mostly to do with issues relevant to interoperability, device connectivity, security, compliance with national and international legislation regulation, as well as with local policies, usability and accessibility from different devices by users with different profiles [21][22]. Interoperability enables two directional communication between systems and is based on commonly accepted data standards, ensuring accurate data transmission in a secure way. Interoperability between systems is an imperative need in order to better support both clinical work but also economic and social aspects of health care.

At the lowest level, systems transmitting and receiving data from one another must conform to agreed communication protocols. At a middle level, interoperable systems demonstrate both syntactic as well as semantic interoperability. Systems use conventions for data description, message or document structures. Organizations such as HL7 International[10] and Personal Connected Health Alliance (PCHAlliance) Continua[11] help towards the delivery of standards-based, open specifications that can support the flow of data from the point of capture into EHRs in the same format and coded content. Consensus on systems requirements is also important. Integrating the Healthcare Enterprise (IHE[12]) describes how standards may be used effectively.

Third party terminologies such as the Current Procedures Terminology (CPT) code set[13], SNOMED CT[14], Logical Observation Identifiers Names & Codes (LOINC[15]), and International Classification of Diseases (ICD[16]) codes are currently available. In addition, several ontologies have been defined for specific conditions such as cancer, trying to integrate other existing biomedical ontologies such as the ACGT MO [23] and the MHA Semantic Core Ontology [19].

In the context of HL7 and lightweight semantic interoperability, it is important to mention Fast Healthcare Interoperability Resources (FHIR) (pronounced 'fire'), which is a next generation standards framework. FHIR combines the best features of HL7's v2 , HL7 v3 and CDA [24] product lines while leveraging the latest web standards and applying a tight focus on implementability.

The development of PHR-C followed standards-based, open specifications to support the flow of data captured in EHRs and other third party systems, in the same format and coded content. Some of the standards used are HL7, DICOM, XML, and ICD10.

Software Quality Assurance

Software quality assurance consists of a methods and tools to monitor the software engineering processes in order to ensure quality. Software validation and verification activities should be conducted throughout the entire software life cycle. The scope of verification is to check that a product, service, or system (or portion thereof, or set thereof) meets a set of initial design requirements, specifications, and regulations. In the development phase, verification procedures involve performing special tests to

[10] http://www.hl7.org/
[11] http://www.pchalliance.org/
[12] http://www.ihe.net/
[13] https://www.ama-assn.org/practice-management/cpt-current-procedural-terminology
[14] https://www.snomed.org/snomed-ct
[15] https://loinc.org/
[16] http://www.who.int/classifications/icd/en/

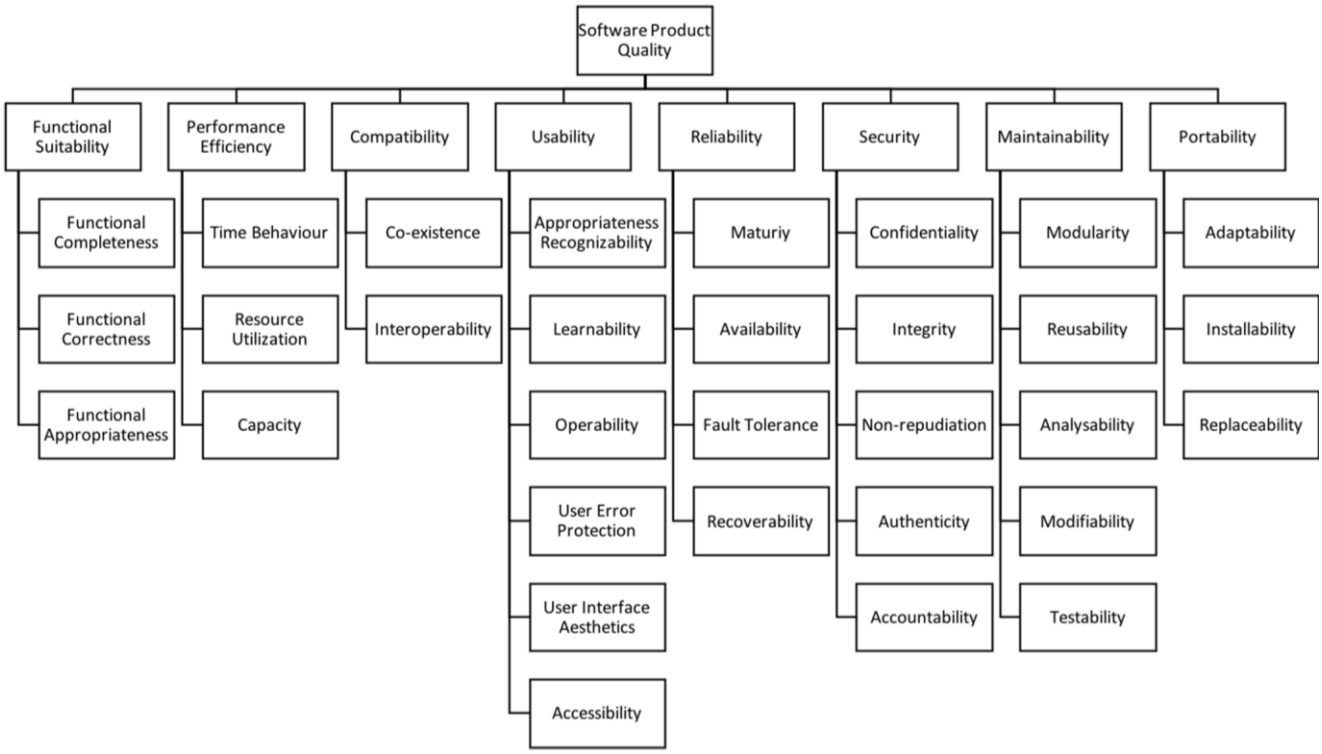
model or simulate a portion, or the entirety, of the application. Validation is the process of evaluating software during or at the end of the development process to assure the quality of the desired outcome.

Common conformity assessment schemes for interoperability of health systems needs to be in place in order to promote the adoption and take-up of interoperability testing of eHealth solutions against identified eHealth standards and profiles. In addition, quality assurance through quality labeling is very important to promote the design, development and implementation of functional and effective applications.

Software quality assurance principles, as they are presented in this section, guided the PHR-C development throughout all its iteration cycles.

The design and evaluation of any app should adhere to certain principles of systems and software engineering, such as the ones defined by ISO 25000 series for systems and software quality requirements and evaluation[17]. A set of functional and non-functional requirements have to be collected by the development team (based on the needs of the end users), implemented and validated (by the development team) and evaluated (by end users). Different requirements exist for different components such as the security mechanism, the application programming interfaces (mainly for the communication with the databases) and end user interface (UI). ISO/ IEC 25010[18] [25] has organized the requirement into eight main categories, and its respective sub-categories, including functional suitability, performance efficiency, compatibility, usability, reliability, security maintainability and portability (Figure 1).

Figure 1: Software product quality model in ISO/ IEC 25010.



[17] https://www.iso.org/standard/64764.html
[18] https://www.iso.org/standard/35733.html

The product quality model can be applied to just a software product, or to a computer system that includes software, as most of the sub-characteristics are relevant to both software and systems. The product quality model categorizes product quality properties into eight characteristics, as presented in Figure 1: functional suitability, reliability, performance efficiency, usability, security, compatibility, maintainability and portability. Each characteristic is composed of a set of related sub-characteristics, naming:

Functional Suitability

Functional suitability is the degree to which a product or system provides functions that meet stated and implied needs when used under specified conditions.

Functional completeness: The degree to which the set of functions covers all the specified tasks and user objectives.

Functional correctness: The degree to which a product or system provides the correct results with the needed degree of precision.

Functional appropriateness: The degree to which the functions facilitate the accomplishment of specified tasks and objectives.

Performance Efficiency

Performance relative to the amount of resources used under stated conditions.

Time behavior: The degree to which the response and processing times and throughput rates of a product or system, when performing its functions, meet requirements.

Resource utilization: The degree to which the amounts and types of resources used by a product or system when performing its functions meet requirements.

Capacity: The degree to which the maximum limits of a product or system parameter meet requirements.

Compatibility

The degree to which a product, system or component can exchange information with other products, systems or components, and/ or perform its required functions, while sharing the same hardware or software environment.

Co-existence: The degree to which a product can perform its required functions efficiently while sharing a common environment and resources with other products, without detrimental impact on any other product.

Interoperability: The degree to which two or more systems, products or components can exchange information and use the information that has been exchanged.

Usability

The degree to which a product or system can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use.

Appropriateness recognizability: The degree to which users can recognize whether a product or system is appropriate for their needs.

Learnability: The degree to which a product or system can be used by specified users to achieve specified goals of learning to use the product or system with effectiveness, efficiency, freedom from risk and satisfaction in a specified context of use.

Operability: The degree to which a product or system has attributes that make it easy to operate and control.

User error protection: The degree to which a system protects users against making errors.

User interface aesthetics: The degree to which a UI enables pleasing and satisfying interaction for the user.

Accessibility: The degree to which a product or system can be used by people with the widest range of characteristics and capabilities to achieve a specified goal in a specified context of use.

Reliability

The degree to which a system, product or component performs specified functions under specified conditions for a specified period of time.

Maturity: The degree to which a system meets needs for reliability under normal operation.

Availability: The degree to which a system, product or component is operational and accessible when required for use.

Fault tolerance: The degree to which a system, product or component operates as intended despite the presence of hardware or software faults.

Recoverability: The degree to which, in the event of an interruption or a failure, a product or system can recover the data directly affected and re-establish the desired state of the system.

Security

The degree to which a product or system protects information and data so that persons or other products or systems have the degree of data access appropriate to their types and levels of authorization.

Confidentiality: The degree to which a product or system ensures that data are accessible only to those authorized to have access.

Integrity: The degree to which a system, product or component prevents unauthorized access to, or modification of, computer programs or data.

Non-repudiation: The degree to which actions or events can be proven to have taken place, so that the events or actions cannot be repudiated later.

Accountability: The degree to which the actions of an entity can be traced uniquely to the entity.

Authenticity: The degree to which the identity of a subject or resource can be proved to be the one claimed.

Maintainability

The degree of effectiveness and efficiency with which a product or system can be modified by the intended maintainers.

Modularity: The degree to which a system or computer program is composed of discrete components such that a change to one component has minimal impact on other components.

Reusability: The degree to which an asset can be used in more than one system, or in building other assets.

Analysability: The degree of effectiveness and efficiency with which it is possible to assess the impact on a product or system of an intended change to one or more of its parts, or to diagnose a product for deficiencies or causes of failures, or to identify parts to be modified.

Modifiability: The degree to which a product or system can be effectively and efficiently modified without introducing defects or degrading existing product quality.

Testability: The degree of effectiveness and efficiency with which test criteria can be established for a system, product or component and tests can be performed to determine whether those criteria have been met.

Portability

The degree of effectiveness and efficiency with which a system, product or component can be transferred from one hardware, software or other operational or usage environment to another.

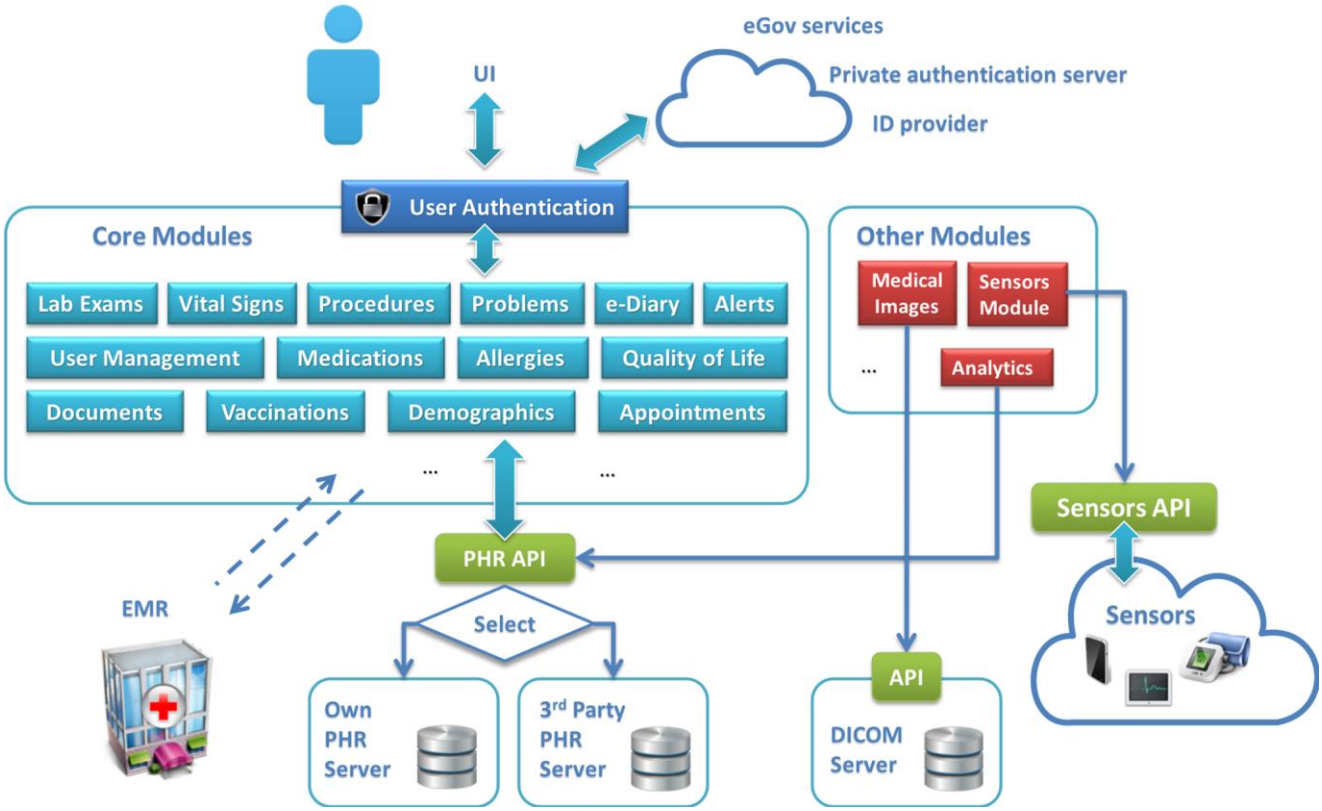
Adaptability: The degree to which a product or system can effectively and efficiently be adapted for different or evolving hardware, software or other operational or usage environments.

Installability: The degree of effectiveness and efficiency with which a product or system can be successfully installed and/or uninstalled in a specified environment.

Replaceability: The degree to which a product can be replaced by another specified software product for the same purpose in the same environment. EXAMPLE The replaceability of a new version of a software product is important to the user when upgrading.

Quality in use is the degree to which a product or system can be used by specific users to meet their needs to achieve specific goals with effectiveness, efficiency, freedom from risk and satisfaction in specific contexts of use.

Figure 2: High-level architecture of the PHR. The GUI layer consists of several core modules (individual apps) tailored to support administration, patient and disease specific needs.

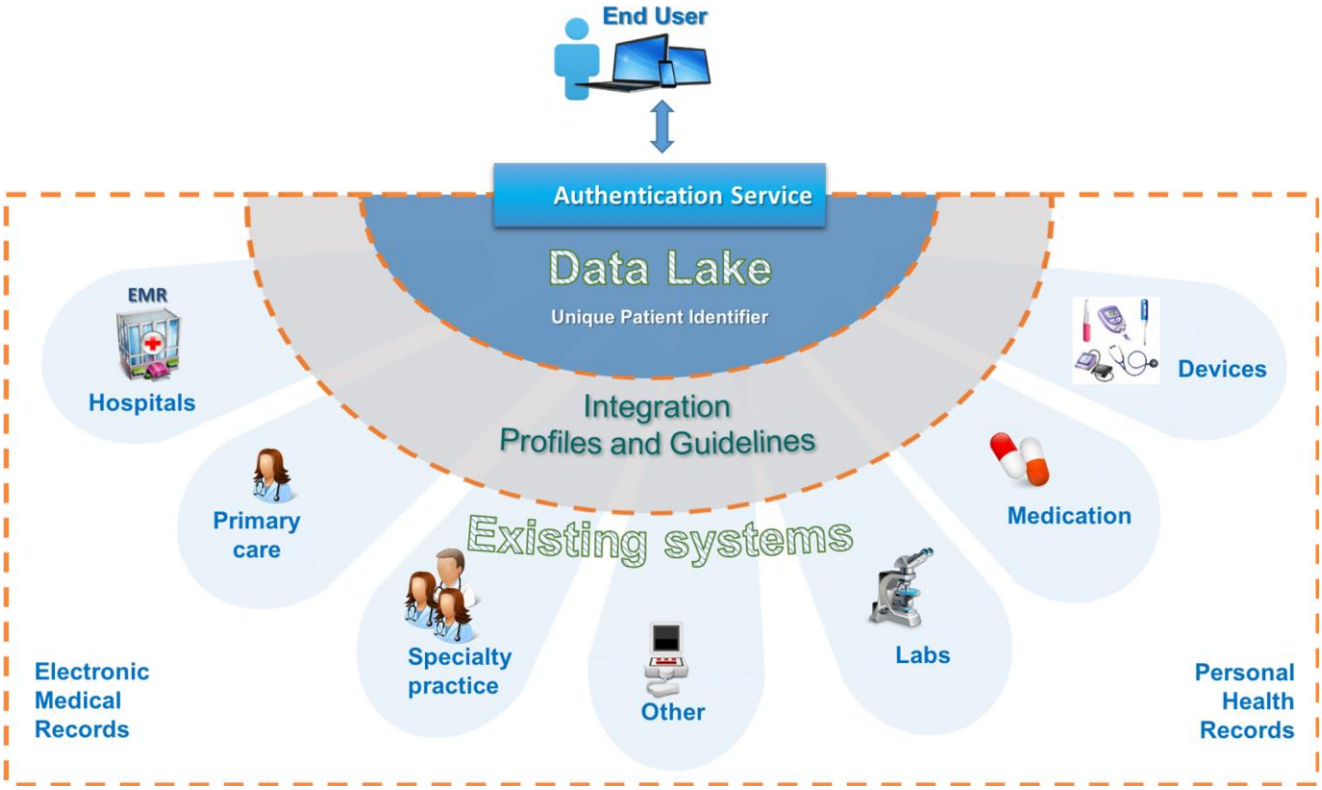


An independent team (excluding members of the development team) apply an evaluation procedure for the developed software components in order to verify that they meet all the anticipated requirements, regulations and quality standards, and that PHR apps were developed in a well-structured way, based on the ISO 25000 series. The evaluation questionnaire provided in Annex I includes the crucial sub-characteristics of software quality measures, translated into simple questions in natural language. The evaluation form provides a list of questions where the evaluator will have to answer with a degree of satisfaction (Likert scale). This methodology has already been used to evaluate PHR components that have been developed within the framework of European research projects. This methodology is currently being applied for the evaluation of the PHR-C.

Personal Health Record for the Citizen (PHR-C)

The implementation of a PHR adaptable to user needs requires an integrated, modular and extensible architecture. The PHR builds on an open architecture to maximize the benefits of combining technologies available in the organizations and health systems relevant to the citizen. A high-level, two-layer architecture facilitates the development of a multitude of interrelated apps, based on common modules that should be available. Figure 2 provides a high-level architecture of the PHR-C and its core modules. A data management layer, shown in Figure 3, is collecting and integrating all available data. The graphical user interface (GUI) layer, shown in Figure 2, includes many individual apps offering three kinds of services, administration apps, core patient apps and disease specific apps. Generic services (admin and core patient ones), as well as disease management services are supported by the data layer that underlines them. The list of services can be extended with the addition of any relevant module to support clinical and administrative needs such as insurance eligibility notification and others.

Figure 3: The end user will be able to transparently accesses (through apps) high quality information, integrated at the data lake layer by means of certain integration profiles and guidelines, applied in a standardized manner (e.g. through regulation).



The PHR-C provides a multilingual, disease self-management platform designed for the specific needs of patient groups, focusing on the wellbeing of the patient with special emphasis on adherence, healthy lifestyle patient education and treatment. The platform is centered on a PHR for the individual patient surrounded by mobile health applications designed to encourage the patient to become more involved in his/ her treatment management, enhance clinician-patient communication, maximize compliance to therapy, predict, detect and manage side effects, and provide information about drug interactions. PHR-C facilitates the communication and use of data among different supporters including patients, health providers, family, friends, researchers and policy makers.

The PHR-C provides an integration framework to support access to existing systems such as Electronic Medical Record (EMR) systems of public health authorities. Integration with existing systems is based on standardized middleware components as well as de-facto industrial standards. At the same time, it allows importing and exporting some data from and to available electronic medical records (EMRs) and/ or other available ICT tools. IHE profiles and Continua guidelines have the potential to support the sharing of health information in a secure, reliable and incremental manner across the different points of care, through authorized and validated interaction with existing systems and tools (Figure 2). As described in [26] ontologies and semantics can play a key role and big data management infrastructures can help in efficiently processing big amounts of information.

In addition to the modular architecture and the integration solution described previously, a privacy and security layer wraps the whole architecture, data flow and interactions. Privacy and data protection constitute core values of individuals and of democratic societies. Data protection and compliance form an underpinning building block in the PHR. The PHR enables privacy and security technologies and

ensures that the data sharing constraints of each data source are at all times respected. Privacy needs have been considered from the very beginning of system development, following the Cavoukian term "Privacy by Design" [27][28]. The privacy by design approach dictates that data protection safeguards need to be built into products and services from the earliest stage of development. The European Commission has included this approach in the General Data Protection Regulation (GDPR) [29] aiming primarily to strengthen and unify data protection for all individuals within the EU, while at the same time give control back to citizens and EU residents over their personal data. Privacy by design ensures privacy of patients and compliance with laws and ethical rules, while facilitating technology acceptance.

Functional Requirements and Software Components

According to recent reviews [4][9][30], the most frequently occurring data elements in PHRs include health history, treatments, patient general information and diagnostics. In many cases, those are formed as individual apps each one focusing on problems/ diagnoses, treatments, procedures, laboratory results, allergies, immunizations, demographics, vital signs and measurements. Those data elements are able to capture individual patient health information similar to the structure of the information in EHRs. As such, they are essential for recording individual health status. In addition, tools for enhancing communication between patients and doctors (appointments, reminders, offline messages) are also required, whereas psychosocial status and educational resources are also key to a useful personal health system.

The developed software consists of the back-end server, and the front-end client, which are described in the subsequent subsections, together with the description of all the implemented core modules and their link with PHR-S FM.

The back-end server

The back-end server is responsible for operations (business logic) that are necessary for the system to work properly. These operations include getting the data from the database and providing that data to the front-end, user authentication and authorization, retrieval of inserted data from the front-end and others. The service oriented architecture (SOA[19]) style of software design was adopted for the back-end to provide a flexible and adaptable environment. Extensibility and interoperability among different types of client applications (web based and mobile) are provided as well as a module-based implementation.

A set of modules are available through a representational state transfer (REST) application program interface (API). The REST API[20] is available through a set of endpoints that accept hypertext transfer protocol (HTTP[21]) requests to GET, POST, PUT and DELETE data from and to the database. Each of the described modules is supported by a set of request and response methods organized in controllers. The controllers are software modules that were implemented and attached to the system, providing scalability and extensibility. The REST API provides all the methods for the necessary business logic

[19] http://www.opengroup.org/standards/soa
[20] https://restfulapi.net/
[21] https://www.w3.org/http/

to the front-end applications. The data exchange format is the java script object notation (JSON[22]) as the most common and lightweight format in the industry.

Table 4 lists the API calls implemented, as part of the presented work. Special end user apps for which no custom API was implemented, such as the one for e-Diary, the use of 3rd party software by providers such as Apple[23], Google[24], and Microsoft[25] is supported. Two additional functionalities developed to support Addresses (*place-controller: Place Controller*) and Reporting (*reports-controller: Reports Controller*) are not listed in Table 4. Annex II includes further API documentation.

Table 4: Mapping of functionality modules to API calls.

Functionality Module	**API Calls**
Alerts	alerts-controller : Alerts Controller
Allergies	allergy-controller : Allergy Controller
Appointments	appointments-controller : Appointments Controller
Demographics	records-controller : Records Controller
Documents	file-upload-controller : File Upload Controller
Lab Exams	exam-controller : Exam Controller
Medications	drugs-controller : Drugs Controller
Problems	problem-controller : Problem Controller
Procedures	procedure-controller : Procedure Controller
Quality of Life	questionnaire-controller : Questionnaire Controller
User Authentication	token-endpoint : Token Endpoint
User Management	accounts-controller : Accounts Controller
	roles-controller : Roles Controller
Vaccinations	vaccination-controller : Vaccination Controller
Vital Signs	blood-glucose-controller : Blood Glucose Controller
	blood-pressure-controller : Blood Pressure Controller
	cholesterol-controller : Cholesterol Controller
	height-controller : Height Controller
	weight-controller : Weight Controller

A basic reporting mechanism to support the extraction of quality information for communication purposes has also been implemented. This mechanism was based on JasperReports reporting engine[26].

[22] https://www.json.org/
[23] https://www.icloud.com/
[24] https://calendar.google.com
[25] https://outlook.live.com
[26] https://github.com/TIBCOSoftware/jasperreports

That means that every report is generated based on a template file and then is being filled with data dynamically. All the user input (e.g. measurements, exams, problems, etc.) can be documented and exported as a portable document format (PDF) file. The reporting mechanism allows for the creation of different types of reports for the same datatypes. Therefore, reports can be easily tailored to specific end user needs. A number of templates were implemented by means of the iReport designer tool[27], an eclipse based interactive development environment (IDE) that allows easy creation and management of Jasper templates. The user is able to select from the front-end client a specific report (e.g. the one for lab exams) through a link. The reporting mechanism parses the generated template and fills the data dynamically. The list of available reports that can be exported as PDF documents by each patient is listed below:

- Allergies
- Appointments
- Drugs
- Exams
- Problems
- Procedures
- Vital signs (blood glucose, blood pressure, cholesterol, height, weight)
- Vaccinations

The front-end client

The front-end client consists of a GUI, which enables end-user interactions. It provides the interface to input information in the system and representations of the information (e.g. views) in human readable manner (e.g. web pages). The majority of the front-end client is built using the single-page application (SPA) paradigm, based on a state of the art JavaScript framework (i.e. AngularJS[28]), in order to provide a user experience similar to that of a desktop application.

Applications build based on a SPA paradigm, either have all necessary code – hypertext markup language (HTML[29]), JavaScript[30], and cascading style sheets (CSS[31]) – retrieved with a single page load, or the appropriate resources are dynamically loaded and added to the page as necessary, usually in response to user actions. This allows faster interaction times, minimal network load and a better user experience.

Figure 4, Figure 5, Figure 6, and Figure 7 provide a view of the GUI developed to accommodate functions ran on different configuration environments. Figure 8 provides a visual sample of the mobile screens of the PHR.

[27] https://community.jaspersoft.com/project/ireport-designer
[28] https://angularjs.org/
[29] https://www.w3.org/html/
[30] https://www.javascript.com/
[31] https://www.w3.org/css/

Figure 4: Tablet view of the PHR-C solution.

Figure 5: Depiction of vital signs management screens.

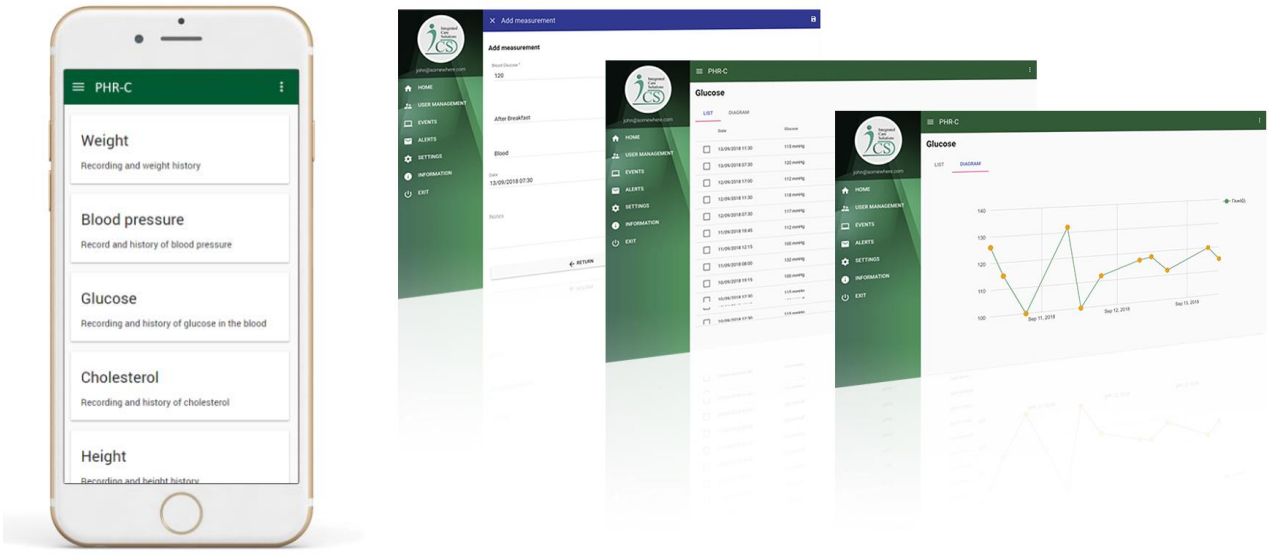


Figure 6: The end user interface provides the patients with options to access core modules for managing Alerts, Allergies, Appointments, Demographics, Documents, e-Diary, Lab Exams, Medications, Problems, Procedures, Quality of Life, User Management, Vaccinations, and Vital Signs. Support of multiple languages is provided by design. The figure depicts the Greek GUI.

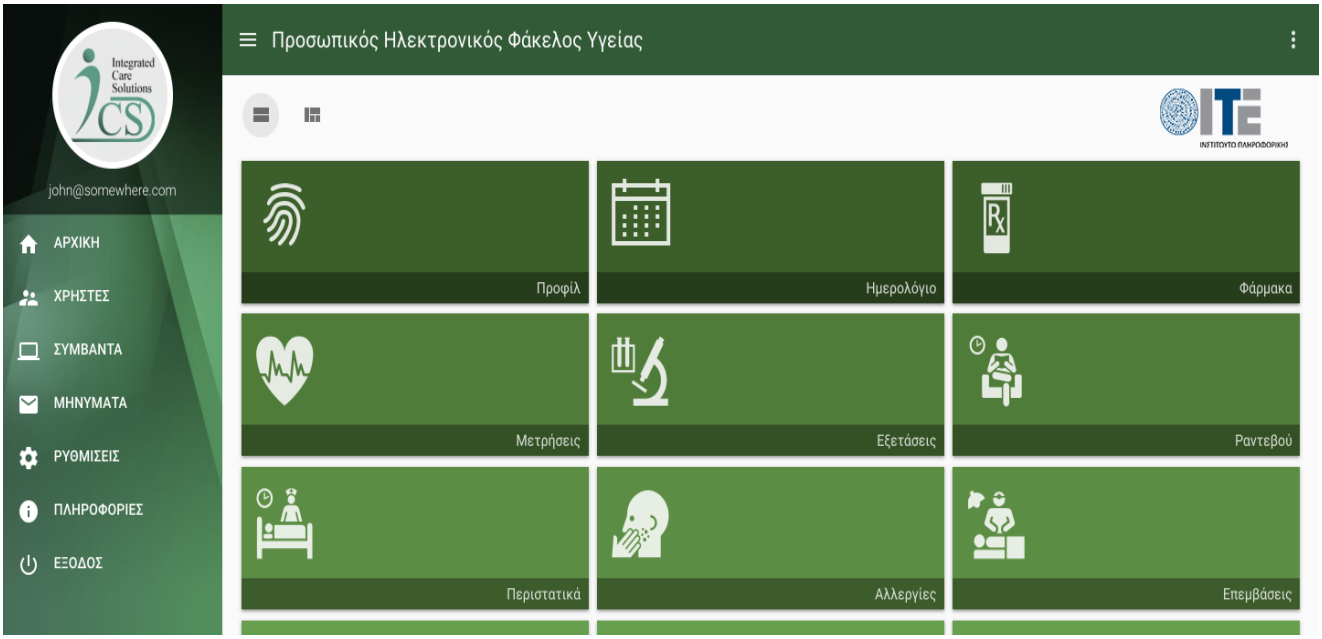
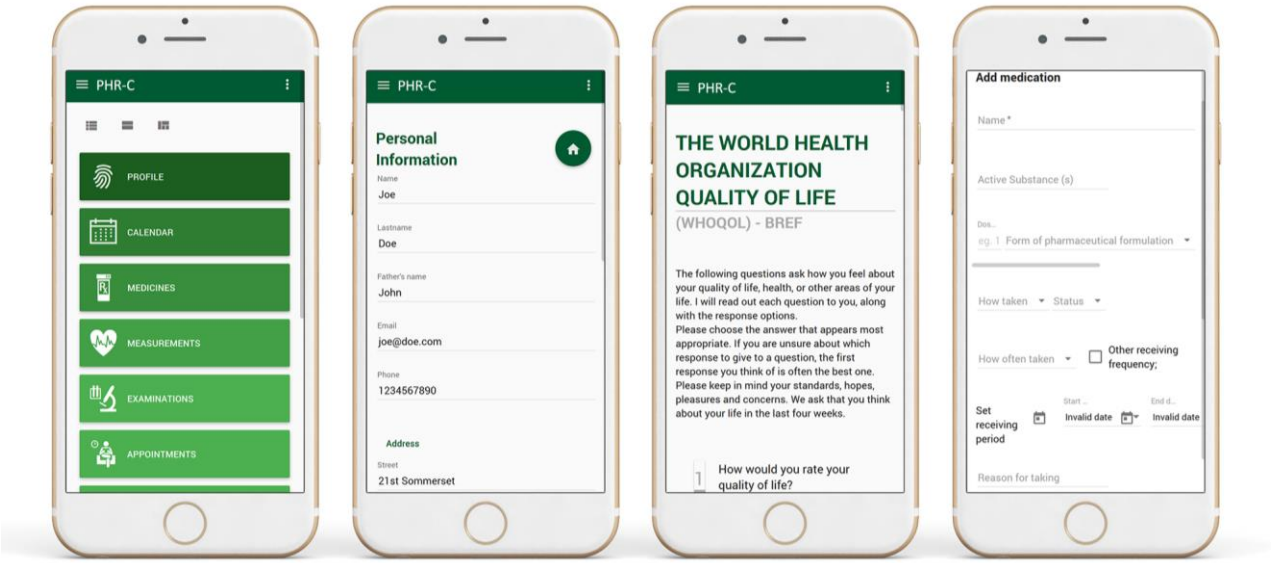


Figure 7: Desktop view of the World Health Organization Quality of Life questionnaire[32] [31][32][33] incorporated in PHR-C.

[32] http://www.who.int/mental_health/publications/whoqol/en/

Figure 8: Mobile phone views of PHR-C.



Core Modules Description, Actions and Fields

The PHR application follows a modular architecture. Table 5 describes the initial set of software modules supported by the PHR application and the fields that accompany them.

Table 5: Core Modules, description, actions and fields.

Module	**Description**	**Actions**	**Fields**
Alerts	This app enables healthcare providers to set the appropriate alert rules and the corresponding messages that appear to the patients when certain conditions are met.	- Display appropriate message if alert conditions are met	- Preconditions - Text message
Allergies	Known allergies of the patient.	- List of allergies - Add new allergy - Edit existing allergy - Delete allergy	- Allergy name (autocomplete field) - Allergy type (drop down list) - Severity (drop down list) - Notes (free text)
Appointments	Appointments of the patient. The patient is able to schedule appointments with his general practitioner(s) and receive a notification before the appointment based on a reminder time before	- List of appointments - Add new appointment - Edit existing appointment - Delete appointment	- Appointment name (free text) - Date (date-time field) - Doctor's name (free text) - Doctor's phone (free text) - Reminder (drop down list) - Notes (free text)

Module	**Description**	**Actions**	**Fields**
	the event (e.g. 1 hour before).		
Demographics	Personal information of the patient.	- List of patients (administrative role) - Add new (administrative role) - Edit personal information - Delete (administrative role)	- First name (free text) - Last name (free text) - Father's name (free text) - Email (free text) - Phone (numerical field) - Address (free text) - Postal code (free text) - City (free text) - State (free text) - Country (free text) - Date of birth (date field) - Gender (drop down) - Smoker (drop down) - Blood type (drop down)
Documents	This app enables storing personal documents in the patient profile (discharge letters, prescriptions, PDFs, ECGs, DICOM images etc.).	- Upload new document - Delete document - Share document - Open document	- Document title (free text) - Date added (date) - File (file) - Organization (free text) - Responsible doctor (free text) - Reasons (free text) - Diagnosis (free text) - Type (drop down) - Comments (free text)
e-Diary	This app allows the diary visualization of all information related to problems, medications, procedures and appointments available in a user profile. It offers an intuitive way of visualizing and interacting with the aforementioned information.	- Select problems, medications, procedures, appointments to appear in the calendar - Select Calendar or Timeline View - Navigate to specific date - Alert users about specific appointments - Add problems, medications, procedures and appointments	It offers a graphical way to interact with: - problems - medications - procedures - appointments
Lab Exams	Laboratory exams the patient has undergone.	- List of lab exams - Add new - Edit - Delete	- Exam name (autocomplete field) - Status (drop down field) - Abnormal interpretation (drop down field) - Date (date field) - Value (free text)

Module	**Description**	**Actions**	**Fields**
			- Unit (free text) - Minimum (numerical field) - Maximum (numerical field) - Laboratory (drop down) - Notes (free text)
Medications	Medications prescribed to the patient.	- List of prescribed meds - Add new - Edit - Delete	- Drug name (autocomplete field) - Substances (autocomplete field) - Dosage (free text) - Pharmaceutical type (autocomplete field) - Dose route (drop down) - Status (drop down) - Frequency (drop down) - Start date (date field) - End date (date field) - Reason (free text) - Instructions (free text) - Notes (free text)
Problems	Health problems that the patient has had or is having.	- List of problems - Add new problem - Edit problem - Delete problem	- Name (free text) - Doctor's name (free text) - Hospital (drop down) - Address (free text) - Notes (free text)
Procedures	Procedures that the patient had done in the hospital.	- List of procedures - Add new procedure - Edit procedure - Delete procedure	- Procedure (autocomplete field) - Date (date field) - Doctor (free text) - Hospital (drop down) - Address (free text) - Notes (free text)
Quality of Life	This app includes a standardized questionnaire for monitoring the quality of life of individual patients.	- Record answers to questionnaire - List current score - List past scores	- Answers to individual questions (select fields) - Accumulated scores
User Authentication	This module enables user authentication. Connected to local and national authentication services.	- Authenticate user - Return user id of an authenticated user	- Username (free text) - Password (free text)
User Management	Administration of users. Only users with administrative roles have access to this module.	- List of users - Add new user - Edit user - Delete user	- Username (free text) - Password (free text) - Repeat password (free text) - Full name (free text) - Email (date field) - Photo (image file)

Module	**Description**	**Actions**	**Fields**
			- Roles (checkboxes)
Vaccinations	Vaccinations that the patient has received.	- List of vaccinations - Add new vaccination - Edit vaccination - Delete vaccination	- Name (free text) - Manufacturer (free text) - Sequence number (numerical field) - Provider (free text) - Date received (date field) - Adverse effects (free text) - Administration method (drop down) - Body location (free text) - Notes (free text)
Vital Signs	Measurements of the patient. The patient is able to view measurement history in tabular and graphical way as well as to edit them. The measurement types are: - Blood glucose - Blood pressure - Cholesterol - Height - Weight	For each of the measurement type the patient actions are: - List of measurement in tabular and graphical way - Add new measurement - Edit existing measurement - Delete measurement	- Blood glucose - Value (numerical field) - Unit (drop down field) - Period (drop down field) - Type (drop down field) - Date (date-time field) - Notes (free text) - Blood pressure - Systolic (numerical field) - Diastolic (numerical field) - Pulses (numerical field) - Date (date-time field) - Notes (free text) - Cholesterol - LDL (numerical field) - HDL (numerical field) - Total (numerical field) - Date (date-time field) - Notes (free text) - Height - Value (numerical field) - Unit (drop down field) - Date (date-time field) - Notes (free text) - Weight - Value (numerical field) - Unit (drop down field) - Date (date-time field) - Notes (free text)

PHR Functions and Modules as they link to the PHR-S FM

PHR-C functionalities and modules can be linked directly to the PHR-S FM. In an effort to depict the relation of core functionality modules with EHR-S FM, towards establishing an initial approach for defining an initial profile to test compatibility against, we have come up with the links depicted in Table 6.

Table 6: PHR-C Core Functionality Modules Links to PHR-S FM R1 Personal Health Functions.

Name	**Potential Sources**	**Description**	**PHR-S FM ID#**	**PHR-S FM Statement**
Alerts	PHR, external sources	This app allows the implementation of care management alerting rules to appear in end-user(s) account.	PH.3.5.5	Notify the PHR Account Holder of an event or situation that may need immediate action.
Allergies	PHR, EHR	For recording allergies and related information (allergy name, severity, allergen, adverse reactions, etc.).	PH.2.5.4	Manage the PHR Account Holder's list of known allergens and adverse reactions with all pertinent information.
Appointments	PHR, external providers	To allow an end-user to schedule his appointments. Appropriate reminders are then issued to remind him a specific appointment.	PH.3.5.1	Provide a health calendar to record and display health care events.
Demographics	PHR, eGov Service	For recording demographic information (address, gender, date of birth, etc.).	PH.1.2	Enable the PHR Account Holder to manage information about demographics.
Documents	PHR	For storing personal documents as attachments (discharge letters, prescriptions, PDFs, ECGs, DICOM images etc.).	PH.3.1.1	Provide the ability for the PHR Account Holder to enter personally sourced data and to make it available electronically to authorized health care provider(s) or other authorized users or applications.
e-Diary	PHR, external providers	This app allows the diary visualization of all information available in a user profile.	PH.3.5.4	Present the PHR Account Holder with reminders either sent by external sources (such as from provider(s)), or internally generated from information in the PHR-S (such as guideline-based reminders, prescription refills, appointment reminders, or other calendar entries).
Lab Exams	Patient, EHR, commercial laboratories	For recording laboratory results and related information (lab test name, date, value, abnormal values, etc.).	PH.2.5.3	Manage results of diagnostic tests including inpatient, ambulatory and home monitoring tests.

Medications	PHR, EHR, claims history	For recording medication prescribed medicines taken and related information (drug name, quantity, unit, date etc.).	PH.2.5.2	Manage the PHR Account Holder's medication list.
Problems	PHR, EHR	For recording problems and related information (start date, category, details, etc.).	PH.2.5.1	Manage the PHR Account Holder's health problem list and provide the ability to manage the problem list over time in accordance with organizational policy and/or jurisdictional law.
Procedures	PHR, EHR, or claims	For recording medical procedures and related information (name of the procedure, date performed, institution, cost etc.).	PH.2.5.7	The list of past procedures is a useful summary of what has been done in the past and anatomic changes have occurred that might influence current assessments and treatments. It is important to capture any surgical implants and associated lot/ serial numbers for tracking/ reporting purposes.
Quality of Life	PHR	For recording responses to validated questionnaires to assess the quality of life of individuals.	PH.3.1	Provide the ability for the PHR Account Holder to enter personally sourced data and to make it available electronically to authorized health care provider(s) or other authorized users or applications.
User Authentication	PHR, external services	To allow proper user authentication.	PH.1.1	Unambiguously identify the PHR Account Holder; correctly link the information with the PHR Account Holder and vice-versa.
User Management	PHR, external services	To enable effective management for the administrator (role definitions etc).	PH.3.5.3	Each individual that accesses the PHR should be registered in a directory with his or her contact information and granted specific access rights.
Vaccinations	PHR, EHR	Dates and types of (childhood) vaccinations.	PH.2.5.5	Manage the Account Holder's immunization data and associated capabilities including reminders, alerts, compliance, and administration.
Vital Signs	PHR	For recording vital signs such as pulse, temperature etc. and related information (date, unit etc.).	PH.3.1.1	Provide the ability for the PHR Account Holder to enter personally sourced data and to make it available electronically to authorized health care provider(s) or other authorized users or applications.

Non-Functional Requirements

Technologies have the potential to change health care as well as life style for people with chronic conditions when tailored to individual needs taking into consideration social and cultural characteristics. The solution presented has used a user-centered design approach, based on outcomes of projects that

have already involved all relevant stakeholders throughout the process of technology design, development, implementation and evaluation.

Non-functional requirements for a PHR system are requirements that describe not what the software will do, but how the software will do it, e.g. performance requirements, design constraints and software quality attributed.

During development emphasis was paid on formulating an open, modular framework of tools and services, so that PHR-C can be adopted gradually, including efficient secure sharing and handling of large personalized data sets, building standards-compliant tools and models. Since the underlying infrastructure is based on a modular SOA reference architecture, the system can easily be tailored to support different chronic diseases such as cancer, diabetes, chronic pain, and others. The solution is responsive by design, and provides a user-friendly interface, accessible to all users.

In order to ensure that privacy and personal data of patients are protected, GDPR[33] obligates data controllers to adopt data protection by design and by default when developing systems that process personal data. The GDPR [34] is a regulation of general application and is principles-based. It includes the principle that the protection of personal data shall be a default property of personal data information systems, which is captured in an obligation of data controllers to implement data protection by design and by default. This means that data controllers must implement the data protection principles, facilitate the enforcement of the data subjects' rights, as well as implement technical and organizational measures to secure the personal data under their care. Seven fundamental privacy by design principles suggest strategies for implementing privacy by design systems. The European Union Agency for Network and Information Security (ENISA) has also published several documents on strategies and ways of implementing privacy by design[34] [35][36].

A fundamental principle of a personal health record is that the patient is the owner of his/ her own data and controls the access for others like healthcare professionals and family, friends. Apart from the data sharing issue, which rise due to this principle, a secure framework for the authorization, authentication, delegation, and auditing is mandatory for secure access and communication between services and patient interaction with the platform. Every patient registered to the platform can upload all kind of data into his/ her account. As these data are private and sensible, specific requirements for data protection have to be addressed. Specifically, apps should support:

- Roles and rights management to control access to the platform.
- Secure upload of data via a Hyper Text Transfer Protocol with Secure Sockets Layer (HTTPS).
- Data storage in an encrypted way.
- Patient full control over his/her data. He/ she can upload, edit and delete his/ her data at any time without giving a reason.
- Uploaded data belong to the patient.
- Secondary usage of data is only possible after anonymization of the data [20].

[33] http://eur-lex.europa.eu/eli/reg/2016/679/oj

[34] https://www.enisa.europa.eu/publications/handbook-on-security-of-personal-data-processing

- Signing of contracts for secondary usage of anonymized data between the patient (data provider) and the data user [16].
- Patient capacity to sharing of data with other people at any time. These people are not allowed to download, edit or delete the data. They gain only the allowance to read the data after signing a contract with the patient.
- An audit trail system monitoring all the actions in the platform.

Based on the existing technologies OAuth v2.0 is the de facto standard for authorization and communication with a web based or mobile application[35]. With OAuth users can revoke a specific API client without affect other API clients, nor does user need to change password (e.g. In case one API party's server is hacked).

For the PHR-C implementation, an API was created based on OAuth 2.0 security for each module of PHR-C front-end client and a detailed documentation was created about each API call. Specifically, the PHR-C front-end client is integrated with the PHR-C back-end system through the API and OAuth 2.0 provider.

Data interoperability: A collection of APIs for data interoperability was created and integrated with the OAuth 2.0 security layer. Through the available services of the API, different applications can store and retrieve data. The data retrieval is accomplished using specific criteria and date filtering. Services for storing and retrieving user answers to tests for the validation of the PHR-C were also developed.

Sharing & interoperability: Multiple roles are supported such as patients, health professionals, companions and researchers allowing the secure and seamless sharing of selective information, enhancing the patient/doctor and patient/ patient interaction and communication and enabling researches to access statistical information.

The development process of the PHR-C system has encompassed ISO 27001 [34] objectives and controls. ISO 27001[36], which is the main international standard for information security[37], has a set of recommended security objectives and controls to ensure that information security is an integral part of the system lifecycle, including the development lifecycle. By considering these controls during the software development process, the effectiveness of the PHR-C system, regarding information protection, is enhanced. ISO 27001 controls have been applied to ensure that system security requirements are considered during system analysis and design and that the desired results were achieved and no negative impact resulted from the changes.

Additionally, ISO 27001 defines three controls for the testing phase:

- Acceptance testing against the requirements is mandatory – against functional and non-functional ones.
- There must be security tests during the overall development process.
- Development, test, and operational environments must be separated.

[35] https://oauth.net/
[36] https://www.iso.org/standard/54534.html
[37] https://www.iso.org/isoiec-27001-information-security.html

The information security management system that FORTH has developed, as part of its information security policy, guarantees the proper monitoring of software development in line with its provisions for secure development and maintenance of procedures for applications, systems and services.

Internal acceptance Testing was conducted with respect to ISO/ IEC 25010 quality characteristics of the PHR-C. Acceptance criteria have been defined in order to cover the functional and non-functional requirements of the system. Based on the acceptance criteria, the quality assurance team performed the tests taking into account functionality, efficiency, compatibility, usability, reliability, portability, maintainability, and security issues. A separate team conducted penetration tests in order to evaluate the security of PHR-C by trying to exploit system vulnerabilities.

Discussion

Healthcare systems around the world are becoming increasingly interested in strengthening the role of patients in their own care. Empowerment occurs when patients increase their capacity to think critically and make autonomous, informed decisions. In that process, the role of healthcare providers, technology providers, citizens, and policy makers is of paramount importance.

Despite the wide availability of PHRs, their adoption has been so far limited. A key factor contributing to this is the fact that PHRs are generic, whereas specific needs emerge in individual disease domains. Various comorbidities make the problem even worse. As such, disease oriented modules are required, focusing on specific key areas of an individual disease. This need has already been widely identified by recent research, leading to developing solutions customized on specific diseases such as pain [37][38] and cancer [20]. However, instead of building customized solutions, it would be better if generic solutions were available that would be adaptable to specific diseases and comorbidities. Users would be able to select and use different modules according to their individual needs. As such, individualization and adaptability are two key characteristics of an ideal PHR system. More than this, using the notion of functional profiles, a general purpose PHR can be instantiated for specific types of diseases and the individual needs of the citizens.

Additional reasons for the limited adoption of PHR systems include lack of interoperability, low usability and adaptability, and limited value added [38]. Lack of wider acceptance and fragmentation in efforts remain obstacles for wider adoption and consequently all the expected benefits are yet to be experienced. However, there are success stories to present as a proof of concept. In Australia, more than 6 million people have registered for My Health Record[38]. This success story indicates that the vision of PHR is indeed feasible under strict regulatory strategies such as strong governmental persistence. In Europe, the key issue to success is standardization, in terms of functionality offering and interoperability, calling for a coordinated governance framework and process.

In order to address the need for an interoperable and adaptable PHR, PHR-C has been developed as an expandable PHR that includes modules such as home care services, and connection to wellness applications for automatic input of data (e.g. steps/ day, water/ day, sleep patterns and others). Links to the EHR of the citizen, the national e-prescription service, and other connections to third party apps for accessing data from clinical/ hospital information systems are also available. In addition, PHR-C can be configured to incorporate new personalized medicine modules to address emerging new data,

[38] https://myhealthrecord.gov.au/

including genetic information, medical advice and recommendations, and prevention information. Specialized modules based on specific chronic conditions are under development to support patient empowerment and self-management. Home monitoring, enhanced communication with health providers, and information on guidelines for prevention and life style have been shown to reduce comorbidities and improve quality of life.

The Integrated Care Solutions^{TM} software suite comprises a series of IT applications and services based upon an open, scalable and evolvable architecture. It is an innovative service platform for electronic and mobile health applications and services across heterogeneous networks, focusing on a patient centered clinically driven, healthcare delivery system. Scalability, modularity, and robustness are some key characteristics of the applications suite. Applications are subsystems of an integrated solution that can be installed either as stand-alone systems or in combination with other applications to support automation of business processes both within and between healthcare facilities. They can electronically interface with third party applications and open devices, based on standards such as HL7, DICOM, XML, and web services. Figure 9 provides a high-level overview of the landscape currently covered. Integrated Care Solutions^{TM}, through its various tools and applications may contribute significantly to clinical decision support for disease management and treatment planning.

PHR-C has followed a structured development using common established set of criteria and functionalities and has the potential to be widely adopted in a coordinated care environment. Based upon the PHR-S FM, it offers a realistic and applicable proportion of functionality and interoperability components. Focusing on solving actual end-user needs can lead to a wider adoption and use of PHR systems. Using the notion of functional profiles, a general purpose PHR can be instantiated for specific types of diseases and the individual needs of the citizens. Adaptability and personalization are key to the successful deployment of any large-scale PHR infrastructure, bearing in mind that interoperability is not possible without following standards and adhering to specifications.

Future Directions

Clinical data standards enable healthcare institutions to share clinical information. The permanent availability and accessibility of this information is essential. Standardization in medical informatics enables the interconnection and the interoperability between both care and research systems, as well as the alignment of local clinical systems for easier data integration. In other words, it is very important that the specific meaning is preserved across information systems. Semantic interoperability guarantees that both transmitter and recipient interpret the shared information identically. Indeed, clinical data standards should enable the exchange of data and their metadata between healthcare organizations in different geographical locations, with possibly different local languages, in such a way that continuity of medical care and aggregation of medical research is made possible.

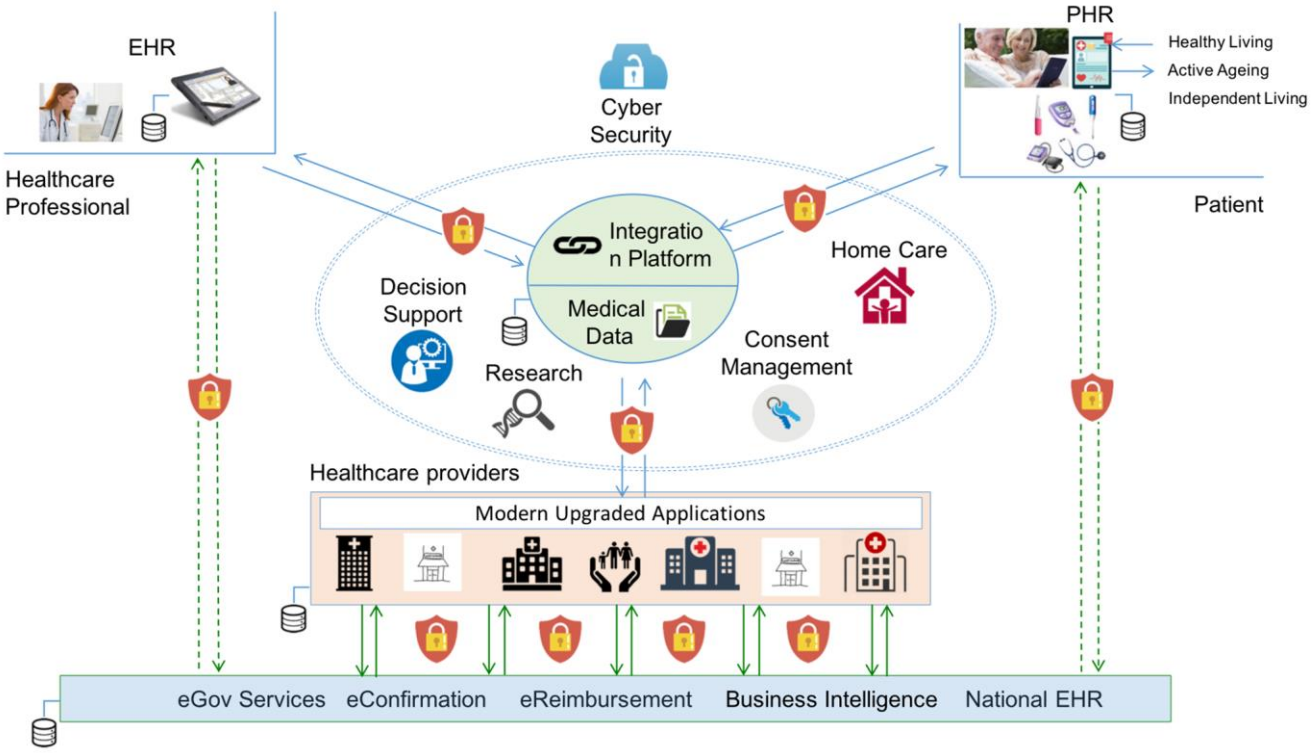
Fully interoperable PHR, EHR and EMR systems are not yet a wide reality. Some degree of standardized transmission has been achieved but true semantic interoperability exists only in limited settings including EHR components.

Interoperability can advance only through sustained legal, organizational, semantic and technical efforts to address clinical needs and financial constraints. A broader view of interoperability is required, as consumers move towards alternative approaches of care including mobile, wearable and home based technologies.

Figure 9: Integrated Care Solutions™ consists of several applications designed for both primary and hospital care, pre-hospital emergency care, welfare, as well as for self-management.

Wide commercial availability of health care apps, sensor systems, and wearable technologies as well as the new home monitoring and communication systems technologies require viewing interoperability as an integration of entertainment, communication, home management and health. Interoperability is a primary consideration to achieve communication of applications, medical devices, health care providers, and citizens. In addition, the growing demand to secondary use of clinical and administrative data renders the pressure towards solving interoperability challenges more imperative. Figure 10 demonstrates a typical overview of an integration platform for the sharing of medical information between citizens/ patients and healthcare professionals, within the context of a national health system.

Figure 10: Medical information integration platform to support coordinated care within a National Health System.



Future solutions should support Internet of Things (IoT) and cope with fast-paced changes by functioning in a heterogeneous environment, using components from different vendors and organizations. Applications and services will have to be able to cope with both new and legacy components and handle different versions of the components minimizing the impact of adding new protocols. In addition, they will have to support modelling, storing and retrieving big, heterogeneous disparate data sources that are expect to change and evolve through time. If built on top of state-of-the art interoperability standards, uninterrupted adaptation of the solution in heterogeneous environments will be easier to maintain. Any such platform should be capable of communicating with different types of devices/ sensors/ actuators, but also with other data sources such as feeds, reference data, and others.

With the proposed approach, PHR-C has the capacity for integration and harmonization with almost any connected device and respective applications. PHR-C is also able to communicate with different sensors and interoperate with different IoT systems. Finally, PHR-C supports connectivity with wearable technology, an important aspect especially for the support of citizens with chronic diseases.

The promotion of a meaningful net of digital solutions requires coordinated actions. As described in [39] EU has already set out its intentions to take further actions focusing on:

- citizens' secure access to and sharing of health data across borders,
- better data to advance research, disease prevention and personalized health and care, and
- digital tools for citizen empowerment and person-centered care.

In the following subsections, the authors present a brief description of some key, evolving, state of the art, technologies and tools they consider important for the development of personal ICT systems towards the delivery of integrated care solutions to support faster diagnosis, treatment, and research.

FHIR

Our orientation is towards the effort to use the current interoperability standards but also prepare proactively for the adoption of the state of the art interoperability standards. Early adopters are the innovators who usually set the guidelines and mark the prototypes to be widely used. With that perspective in mind, the plan is for PHR-C to support the FHIR standard in its future releases and seek to conform to the SMART on FHIR specifications.

FHIR® – Fast Healthcare Interoperability Resources[39] is a next generation interoperability standard for electronic exchange of healthcare information. FHIR was developed by HL7, a not-for-profit organization accredited by the American National Standards Institute that develops and provides frameworks and standards for the sharing, integration and retrieval of clinical health data and other electronic health information. FHIR combines the best features of HL7's v2, HL7 v3 and CDA product lines while leveraging the latest web standards and applying a tight focus on implementability.

FHIR solutions are built from a set of modular components called "Resources". These resources can easily be assembled into working systems that solve real world clinical and administrative problems at a fraction of the price of existing alternatives. FHIR is suitable for use in a wide variety of contexts – mobile phone apps, cloud communications, EHR-based data sharing, server communication in large institutional healthcare providers, and much more.

As health IT and EHRs continued to be plagued by interoperability problems, FHIR emerged in 2014 as a draft standard for trial use to enable health IT developers towards the development of more quickly and easily build applications for EHRs and faster exchange and retrieval of application data.

While FHIR at first was a somewhat experimental project for HL7, it quickly acquired support from many EHR vendors. That resulted to the creation of the Argonaut Project[40], an HL7 backed consortium, which sprung up and moved FHIR forward to the point at which, in February 2017, it became a full standard.

Another significant effort towards the establishment of the FHIR framework is SMART on FHIR[41], which is based at Boston Children's Hospital, and has gained broad industry support. SMART on FHIR is a set of open specifications to integrate apps with EHRs, portals, health information exchanges and other health IT systems, according to the organization and will be further described at its corresponding section bellow. Another is HAPI FHIR[42], a new library for adding FHIR messaging to applications. It was developed at University Health Network in Ontario, Canada. HAPI FHIR is open source and free to use.

FHIR frameworks are built around the concept of resources -- basic units of interoperability and modular components that can be assembled into working systems to try to resolve clinical, administrative and infrastructural problems in healthcare. FHIR provides software development resources and tools for administrative concepts such as patients, providers, organizations and devices, as well as a variety of

[39] http://www.hl7.org/fhir/
[40] http://argonautwiki.hl7.org/
[41] http://docs.smarthealthit.org/
[42] http://hapifhir.io/

clinical concepts including problems, medications, diagnostics, care plans and financial issues, among others.

Unlike HL7's most widely used formal standard (also called HL7), FHIR is designed specifically for the web and provides resources and foundations based on XML, JSON, HTTP, Atom and OAuth structures. Tools can be reused to improve interoperability to retrieve the history of a specific resource or a specific version. The specification is online, fully hyperlinked and can be linked from the resource of a property to the data type of that property. FHIR can be used in mobile phone applications, cloud communications, EHR-based data sharing and among institutional healthcare providers.

The FHIR specification is broken into three parts: general documentation, implementation and resource list. General documentation describes how resources are defined and gives background material including definitions of data types, codes and XML and JSON formats. Users can use resources with the RESTful architecture-programming interface as clinical documents or in a service-based architecture.

FHIR defines a framework for extending and adapting resources, which can be read by any system, regardless of the way they were developed but can also be easily read by humans as each resource carries text representation based on HTML. Extension definitions can be retrieved using the same framework as retrieving other resources.

SMART

SMART on FHIR[43] is a set of open specifications to integrate apps with EHR systems, portals, health information exchanges, and other health IT systems. SMART contains:

- Clean, structured data: **FHIR**
- Easy-to-use, resource-oriented **REST API** for structured clinical data.
- Scopes and permissions: **OAuth2**
- When an EHR user launches an app, a “launch request” notification is emitted. By providing the proper permissions via OAuth scopes (eg. patient/*.read) the user is authorized and provided with an access token with the needed permissions– including access to clinical data and context like:
    - which patient is in-context in the EHR
    - which encounter is in-context in the EHR
    - the physical location of the EHR user
- Simple sign-in: **OpenID Connect**
- Lightweight UI integration: **HTML5**
- Exceptional support for integration with existing EHR user interfaces, as SMART on FHIR allows web apps to run inside browser widgets or inline frames, so users can interact without leaving the EHR environment.
- Native and mobile applications are also supported.

[43] http://docs.smarthealthit.org/

The SMART on FHIR JavaScript client library[44] helps in the creation of browser-based SMART apps that interact with a FHIR REST API server. SMART apps get authorization tokens, provide information about the user and patient record in context, and API calls to fetch clinical data. Annex III contains a list of already available SMART on FHIR applications.

IHE Patient Care Coordination

According to IHE[45], the Patient Care Coordination (PCC) domain was established in 2005 to deal with integration issues that cross providers, patient problems or time. It deals with general clinical care aspects such as document exchange, order processing, and coordination with other specialty domains. PCC also addresses workflows that are common to multiple specialty areas and the integration needs of specialty areas that do not have a separate domain within IHE.

Integration profiles defined by the PCC Technical Committee are published in the IHE PCC Technical Framework[46] [40][41]. Brief descriptions of each of these profiles, as well as its current implementation status for each one of them, are presented in Annex IV. Certain profiles leverage HL7® FHIR, applying a tight focus on implementability.

Conclusions

The ultimate goals underlying the development and implementation of electronic health systems are to allow citizens to stay healthy, effectively manage chronic conditions, reduce comorbidities and improve quality of life. The PHR has the potential to become the life-long companion of citizens that can truly transform health care and establish continuity of care. PHRs offer the potential to improve patient-clinician interactions, empower citizens to become co-producers of their health, and alleviate the cost of healthcare by maximizing on-line interactions and avoiding unnecessary hospitals visits. The vision is to achieve a better health service for all citizens and a better outcome for patients. In order to do that any PHR solutions must be carefully designed anticipating future integration capabilities with third party systems in a secure, meaningful, and trustworthy manner. Therefore, any information and communication technology support needs to consider current technology developments and demonstrate flexibility and capacity, by adopting related best practices and international standards and architectures. PHR-C has the potential to offer such a state of the art system to facilitate individualized citizen needs for life long continuity of care.

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[44] https://github.com/smart-on-fhir/client-js
[45] https://www.ihe.net/ihe_domains/patient_care_coordination/
[46] https://www.ihe.net/resources/technical_frameworks/#pcc

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Annex I – Software Evaluation Form

Proposed evaluation questionnaire used for acquiring the degree of satisfaction.

Name of evaluator(s):						
Evaluator's expertise:						
Name and Version of the software component:						
Evaluation date :						
	FORM A *(Software quality characteristics)*	**Rating**				
		strongly agree	agree	neutral	disagree	strongly disagree
Functionality	The set of functions covers all the specified tasks and user objectives.					
	The system provides the correct results with the needed degree of precision.					
	The functions facilitate the accomplishment of specified tasks and objectives.					
Efficiency	The system responds quickly.					
	The system utilizes resources efficiently.					
Compatibility	The system shares resources without loss of its functionality.					
	The system shares information/data with other components					
Usability	The users can recognize easily whether the system is appropriate for their needs.					
	The users learn to use the system easily.					
	The users use the system without much effort.					
	The system protects users against making errors.					
	The user interface enables pleasing and satisfying interaction for the users.					
Reliability	Most of the faults in the software been eliminated over time.					

	The software is capable of handling errors.					
	The software resumes working & restores lost data after failure.					
Security	The system provides identification access wherever is needed.					
	Data are accessible only to authorized users					
	The system traces actions uniquely.					
	The system prevents unauthorized access.					
Maintainability	Faults can be easily diagnosed.					
	The system is composed of discrete independent components.					
	An asset can be used in more than one system, or in building other assets.					
	The software can be tested easily.					
Portability	The software can be moved to other environments easily.					
	The software can be installed easily.					
	The software can easily replace other software.					
Quality in use	The software is accurate and complete for the intended use.					
	The software improves the time or reduces resources for the intended goal.					
	The software satisfies the perceived achievements of pragmatic goals.					
	The software cannot harm people in the intended contexts of use.					

Selected sub-characteristics for the evaluation form of the components and its translation into a simple question for the end user.

Functionality	Suitability	Can software perform the tasks required?
	Accurateness	Is the result as expected?
	Interoperability	Can the system interact with another system?
	Compliance	Is the system compliant with standards?

Efficiency	Time Behaviour	How quickly does the system respond?
	Resource utilization	Does the system utilize resources efficiently?
Compatibility	Co-existence	Can the system share resources without loss of its functionality?
	Interoperability	Can the system share information/data with other components?
Usability	Understandability	Does the user comprehend how to use the system easily?
	Learnability	Can the user learn to use the system easily?
	Operability	Can the user use the system without much effort?
	Attractiveness	Does the interface look good?
Reliability	Maturity	Have most of the faults in the software been eliminated over time?
	Fault tolerance	Is the software capable of handling errors?
	Recoverability	Can the software resume working & restore lost data after failure?
Security	Authentiticity	Does the system provide identification access wherever is needed?
	Confidentiality	Are data accessible only to authorized users?
	Accountability	Can the system trace actions uniquely?
	Integrity	Does the system prevent unauthorized access?
Maintainability	Analysability	Can faults be easily diagnosed?
	Changeability	Can the software be easily modified?
	Stability	Can the software continue functioning if changes are made?
	Testability	Can the software be tested easily?
Portability	Adaptability	Can the software be moved to other environments?
	Installability	Can the software be installed easily?
	Conformance	Does the software comply with portability standards?
	Replaceability	Can the software easily replace other software?
Quality of Use	Effectiveness	How accurate and complete is the software for the intended use?
	Efficiency	Does the software improve the time or reduce resources for the intended goal?

	Satisfaction	Does the software satisfy the perceived achievements of pragmatic goals?
	Health and safety risk	Can the software harm people in the intended contexts of use?

Annex II – API Documentation

End point and call functions for each of the controllers developed.

accounts-controller : Accounts Controller	
/api/accounts/	getAccounts
/api/accounts/	createAccount
/api/accounts/	updateAccount
/api/accounts/demographics/{username}	getAccountDemographics
/api/accounts/search	searchAccounts
/api/accounts/{id}	deleteAccount
/api/accounts/{username}	getAccount
alerts-controller : Alerts Controller	
/api/alerts/{allergyId}	deleteAlert
/api/alerts/{recordId}	getAlertByRecord
/api/alerts/{recordId}	createAlert
/api/alerts/{recordId}	updateAlert
allergy-controller : Allergy Controller	
/api/allergies/{allergyId}	deleteAllergy
/api/allergies/{recordId}	getAllergiesByRecord
/api/allergies/{recordId}	createAllergy
/api/allergies/{recordId}	updateAllergy
appointments-controller : Appointments Controller	
/api/appointments/{appointmentId}	deleteAppointment
/api/appointments/{recordId}	getAppointmentsByRecord
/api/appointments/{recordId}	createAppointment
/api/appointments/{recordId}	updateAppointment
/api/appointments/{recordId}/{from}/{to}	getAppointmentsByDateRange
blood-glucose-controller : Blood Glucose Controller	
/api/bloodGlucose/{bloodGlucoseId}	deleteBloodGlucose
/api/bloodGlucose/{recordId}	getBloodGlucoseByRecord
/api/bloodGlucose/{recordId}	createBloodGlucose
/api/bloodGlucose/{recordId}	updateBloodGlucose
blood-pressure-controller : Blood Pressure Controller	
/api/bloodPressure/{bloodPressureId}	deleteBloodPressure

/api/bloodPressure/{recordId}	getBloodPressureByRecord
/api/bloodPressure/{recordId}	createBloodPressure
/api/bloodPressure/{recordId}	updateBloodPressure
cholesterol-controller : Cholesterol Controller	
/api/cholesterol/{cholesterolId}	deleteCholesterol
/api/cholesterol/{recordId}	getCholesterolByRecord
/api/cholesterol/{recordId}	createCholesterol
/api/cholesterol/{recordId}	updateCholesterol
drugs-controller : Drugs Controller	
/api/drugs/{drugId}	deleteDrug
/api/drugs/{recordId}	getDrugsByRecord
/api/drugs/{recordId}	createDrug
/api/drugs/{recordId}	updateDrug
exam-controller : Exam Controller	
/api/exam/{examId}	deleteExam
/api/exam/{recordId}	getExamByRecord
/api/exam/{recordId}	createExam
/api/exam/{recordId}	updateExam
file-upload-controller : File Upload Controller	
/api/fileUpload/{fileUploadId}/{recordId}	deleteFileUpload
/api/fileUpload/{recordId}	getFileUploadByRecord
/api/fileUpload/{recordId}	createFileUpload
/api/fileUpload/{recordId}	updateFileUpload
height-controller : Height Controller	
/api/height/{heightId}	deleteHeight
/api/height/{recordId}	getHeightByRecord
/api/height/{recordId}	createHeight
/api/height/{recordId}	updateHeight
place-controller : Place Controller	
/api/place/	getPlaces
/api/place/	createPlace
/api/place/	updatePlace
/api/place/active	getActivePlaces
/api/place/{id}	deletePlace

/api/place/{id}	getPlace
problem-controller : Problem Controller	
/api/problems/{problemId}	deleteProblem
/api/problems/{recordId}	getProblemByRecord
/api/problems/{recordId}	createProblem
/api/problems/{recordId}	updateProblem
/api/problems/{recordId}/{from}/{to}	getProblemsByDateRange
procedure-controller : Procedure Controller	
/api/procedures/{procedureId}	deleteProcedure
/api/procedures/{recordId}	getProcedureByRecord
/api/procedures/{recordId}	createProcedure
/api/procedures/{recordId}	updateProcedure
/api/procedures/{recordId}/{from}/{to}	getProceduresByDateRange
questionnaire-controller : Questionnaire Controller	
/api/questionnaire/{questionnaireId}	deleteQuestionnaire
/api/questionnaire/{recordId}	getQuestionnaireByRecord
/api/questionnaire/{recordId}	createQuestionnaire
/api/questionnaire/{recordId}	updateQuestionnaire
records-controller : Records Controller	
/api/records/	getAllDemographics
/api/records/	createDemographics
/api/records/	updateDemographics
/api/records/{recordId}/demographics	getDemographics
reports-controller : Reports Controller	
/api/reports/allergies/{recordId}	createAllergiesReport
/api/reports/appointments/{recordId}	createAppointmentsReport
/api/reports/bloodGlucose/{recordId}	createBloodGlucoseReport
/api/reports/bloodPressure/{recordId}	createBloodPressureReport
/api/reports/cholesterol/{recordId}	createCholesterolReport
/api/reports/drugs/{recordId}	createDrugsReport
/api/reports/exams/{recordId}	createExamsReport
/api/reports/height/{recordId}	createHeightReport
/api/reports/problems/{recordId}	createProblemsReport
/api/reports/procedures/{recordId}	createProceduresReport

/api/reports/vaccinations/{recordId}	createVaccinationsReport
/api/reports/weight/{recordId}	createWeightReport
roles-controller : Roles Controller	
/api/roles/	getRoles
/api/roles/	createRole
/api/roles/	updateRole
/api/roles/{id}	deleteRole
/api/roles/{id}	getRole
/api/roles/{name}	getRole
token-endpoint : Token Endpoint	
/oauth/token	getAccessToken
/oauth/token	postAccessToken
vaccination-controller : Vaccination Controller	
/api/vaccination/{recordId}	getVaccinationByRecord
/api/vaccination/{recordId}	createVaccination
/api/vaccination/{recordId}	updateVaccination
/api/vaccination/{vaccinationId}	deleteVaccination
weight-controller : Weight Controller	
/api/weight/{recordId}	getWeightByRecord
/api/weight/{recordId}	createWeight
/api/weight/{recordId}	updateWeight
/api/weight/{weightId}	deleteWeight

Annex III – SMART on FHIR Application List

Application Title	App Developer	Description	Supported Devices/ Environments	Designed For	App Link
1upHealth - Aggregated Patient Data	1upHealth	Helps providers view patient data aggregated from external health systems. Patients can connect their medical data sources using FHIR.	Web	Clinicians & patients	https://apps.smarthealthit.org/app/aggregated-patient-data
ACT.md	ACT.md	ACT.md extends EMR's across the community, removing the silos that prevent you from addressing social determinants of health.	iOS, Android, Web	Clinicians & patients	https://apps.smarthealthit.org/app/actmd
Adherence - Surescripts Medication Management Solution	Surescripts, LLC	Improves patient medication management via patient-specific insights, health plan-generated messages, and streamlined physician feedback.	Web	clinicians & patients	https://apps.smarthealthit.org/app/surescripts-medication-management-solution
Arrest Assist - Reversible Causes of PEA Arrest Tool	MedStar Institute for Innovation (MI2)	A tool that searches a patient's medical history for reversible causes of PEA arrest. Great for hospital based code teams.	Web	clinicians	https://apps.smarthealthit.org/app/reversible-causes-of-pea-arrest
ASCVD Risk Calculator	Cerner Corporation	The ASCVD Risk Calculator is a tool that estimates a 10-year and/or lifetime cardiovascular risk score and how to potentially reduce risk.	Web	clinicians & patients	https://apps.smarthealthit.org/app/ascvd-risk-calculator
Atrial Fibrillation Stroke Risk - CHA2DS2-VASc Score	MedStar Institute for Innovation (MI2)	Autofilling decision tools for CHA2DS2-VASc Score.		clinicians	https://apps.smarthealthit.org/app/atrial-fibrillation-stroke-risk-cha2ds2-vasc-score
Bilirubin Chart	Intermountain Healthcare	Demonstration app designed to help clinicians treat	Web	clinicians	https://apps.smarthealthit.

Application Title	App Developer	Description	Supported Devices/ Environments	Designed For	App Link
		newborn hyperbilirubinemia appropriately.			org/app/bilirubin-chart
BP Centiles v1 (Open Source)	Boston Children's Hospital	Calculate a child's blood pressure percentiles, normalized by age, sex, and height	Web	clinicians	https://apps.smarthealthit.org/app/bp-centiles
BP Centiles v2	Interopion	Updated version of the open source BP Centiles app.	Web	clinicians	https://apps.smarthealthit.org/app/bp-centiles-v2
Cardiac Risk	Boston Children's Hospital	Estimate a patient's 10-year risk of heart attack or stroke (Reynolds Risk Score) with an intuitive interactive display.	Web	clinicians & patients	https://apps.smarthealthit.org/app/cardiac-risk
Carefluence	Carefluence	Clinical Decision Support and Workflow	Web	clinicians	https://apps.smarthealthit.org/app/carefluence
Carefluence Patient Portal	Carefluence	Aggregates patient data from connected facilities giving patients access to all of their records in one single SMART patient portal.	Web	patients	https://apps.smarthealthit.org/app/carefluence-patient-portal
CarePassport Portal	CarePassport Corp.	A Complete patient portal allowing clinicians & patients to view all medical records, reports & imaging studies using FHIR.	Web, Android, iOS	clinicians & patients	https://apps.smarthealthit.org/app/paxeramed-portal
Chest Pain Application	Regenstrief Institute	The Chest Pain App is a new way to present patient data in the electronic medical records based on the chief complaint.	Mac, Linux, Windows, Web	clinicians	https://apps.smarthealthit.org/app/chest-pain-application
CHF Predictive Analytics	SFO Technologies	CHF(Congestive Heart Failure) Predictive Analytics application helps users to identify and test their chronic cardiac risks.	Web	patients	https://apps.smarthealthit.org/app/chf-predictive-analytics

Application Title	App Developer	Description	Supported Devices/ Environments	Designed For	App Link
ClinDat	Health Report Services	Patient and clinician facing interfaces to monitor and score rheumatic disease symptoms.	Web	clinicians & patients	https://apps.smarthealthit.org/app/clindat
Clinical Knowledge Summary	University of Utah	The CKS app finds and summarizes the results of high quality clinical trials and systematic reviews on specific disease treatments.		clinicians	https://apps.smarthealthit.org/app/clinical-knowledge-summary
Diabetes Monograph	Boston Children's Hospital	Displays information about the patient in a diabetes-specific monograph.	Web	clinicians	https://apps.smarthealthit.org/app/diabetes-monograph
Diabetes Predictive Analytics	SFO Technologies	App for calculating the risk of patients having Type 2 Diabetes Mellitus	Web	clinicians & patients	https://apps.smarthealthit.org/app/diabetes-predictive-analytics
Disease Monograph	Boston Children's Hospital	Displays information about the patient in a configurable disease-specific monograph.	Web	clinicians	https://apps.smarthealthit.org/app/disease-monograph
Doctella	Doctella	Powerful platform that uses provider-customizable Smartlists to engage and empower patients.	iOS, Android	clinicians & patients	https://apps.smarthealthit.org/app/doctella
DoseMeRx	DoseMe	Quick, simple and easy-to-use precision dosing software specifically developed for clinical use at the point-of-care.	Windows, Web	clinicians	https://apps.smarthealthit.org/app/dosemerx
Doximity on FHIR	Doximity	Doximity provides detailed profiles on providers and a secure messaging platform.	iOS, Mac, Web, Android, Linux, Windows	clinicians	https://apps.smarthealthit.org/app/doximity-on-fhir
Duke PillBox	Duke Medicine	Trains patients on use of prescribed medications to improve compliance and adherence results.	Web	clinicians & patients	https://apps.smarthealthit.org/app/duke-pillbox

Application Title	App Developer	Description	Supported Devices/ Environments	Designed For	App Link
ED Pulmonary Embolism Auto-Filling Calculator	MedStar Institute for Innovation (MI2)	A calculator that auto-completes the Revised Geneva and PERC rules based on patient information in FHIR.	Web	clinicians	https://apps.smarthealthit.org/app/ed-pulminary-embolism
ePRISM | Health Outcomes Sciences	Health Outcomes Sciences Inc.	Provides healthcare organizations a fully automated means to enable personalized predictive content and seamlessly adapt it to any workflow	Web	clinicians	https://apps.smarthealthit.org/app/eprism-or-health-outcomes-sciences
Forecast Health Risk Prediction and Prevention App	Forecast Health	Identifies high risk patients, highlights the causes of risk, and provides patient-specific guidance to reduce risk and costs.	Web	clinicians	https://apps.smarthealthit.org/app/forecast-health-risk-prediction-and-prevention-app
Growth Chart	Boston Children's Hospital	Concise, interactive view of a child’s growth over time.	Web	clinicians	https://apps.smarthealthit.org/app/growth-chart
Growth Chart and Immunizations	Prairie Byte Solutions	Growth Chart app has been developed for parents and pediatricians. It allows to view child's growth over time as well as immunizations.	Web	clinicians & patients	https://apps.smarthealthit.org/app/growth-chart-and-immunizations
Hale Health Remote Care Platform	Hale Health	Hale connects clinical teams and their patients between visits through live video visits, secure messaging, photo + video sharing, and more.	Android, Web, Mac, Windows, iOS	clinicians & patients	https://apps.smarthealthit.org/app/hale-health-remote-care-platform
HealthDecision	HealthDecision, Inc.	HealthDecision provides decision support and shared decision-making tools for clinicians and patients at the point of care.	Web	clinicians & patients	https://apps.smarthealthit.org/app/healthdecision

Application Title	App Developer	Description	Supported Devices/ Environments	Designed For	App Link
Healthsuite	SFO Technologies	Healthsuite application helps users to identify and test their cardiac and diabetes risks.	Web	clinicians & patients	https://apps.smarthealthit.org/app/healthsuite
HMS Library of Evidence	Harvard Medical School	The HMS Library of Evidence App provides evidence-based decision rules to guide appropriate imaging in the context of patient clinical data.	Web	clinicians & patients	https://apps.smarthealthit.org/app/hms-library-of-evidence
Krames On FHIR	StayWell	Krames On FHIR® is a robust solution suite that integrates into the EHR to deliver patient education materials at the point of care.	Web	clinicians & patients	https://apps.smarthealthit.org/app/krames-on-fhir
LHC-Forms on FHIR	Lister Hill National Center for Biomedical Communications (LHNCBC)	Widget that creates input forms for Web-based medical applications or to integrate into electronic health records.	Web	clinicians & patients	https://apps.smarthealthit.org/app/lhc-forms-on-fhir
Lush SMART on FHIR Mobile Clinical Data App	Lush Group Inc.	This application demonstrates capability in connecting to multiple EMRs, using FHIR, to provide clinical data for a specified patient.		clinicians & patients	https://apps.smarthealthit.org/app/lush-smart-on-fhir-app
Meds Price Compare	Technosoft Healthcare Solutions	Compare prices, print free coupons & save up to 80% on prescription and non prescription meds.	Linux, Windows, Web, Mac	clinicians & patients	https://apps.smarthealthit.org/app/meds-price-compare
Meducation RS	First Databank	Patient-specific medication instructions, simplified and 20+ languages to reduce medication errors & improve adherence.	Web	clinicians & patients	https://apps.smarthealthit.org/app/meducation-rs
Meducation TimeView	Polyglot Systems	Displays a patient's medication adherence history in intuitive formats, enabling quick	Web	clinicians	https://apps.smarthealthit.org/app/meducation-timeview

Application Title	App Developer	Description	Supported Devices/ Environments	Designed For	App Link
		& appropriate interventions.			
MPR Monitor	Boston Children's Hospital	Calculates medication possession ratios and predicts adherence based on patient's prescription and fill history.	Web	clinicians	https://apps.smarthealthit.org/app/mpr-monitor
MyFHR	CareEvolution	Full-featured patient health record app.	Web, iOS	patients	https://apps.smarthealthit.org/app/myfhr
MyLinks	PatientLink Enterprises, Inc.	MyLinks is a platform linking patients with their physicians, researchers, pharmacists, caregivers, friends, and family.	Windows, Linux, Mac, Web	clinicians & patients	https://apps.smarthealthit.org/app/mylinks
OpenHRE on SMART	Lightbeam Health Solutions	Resource and tools for implementing secure, sustainable Health Information Exchange.	Web	clinicians	https://apps.smarthealthit.org/app/openhre-on-smart
OpNote	mTuitive	Web-based postoperative report that provides correct procedural codes, quality indicators and immediate sign out.	Web	clinicians	https://apps.smarthealthit.org/app/opnote
Patient Chart	Prairie Byte Solutions	Patient Chart app allows physicians to view a longitudinal patient record on any device (laptop, tablet, mobile) using OpenID or OAuth2.	Web	clinicians & patients	https://apps.smarthealthit.org/app/patient-chart
PDemo	CareEvolution	Patient Demographics: query and display list of patients	Web	IT	https://apps.smarthealthit.org/app/pdemo
Pediatric Growth Chart for iOS	Boston Children's Hospital	A pediatric growth charts app for iPhone and iPad	iOS	clinicians & patients	https://apps.smarthealthit.org/app/pediatric-growth-chart-for-ios

Application Title	App Developer	Description	Supported Devices/ Environments	Designed For	App Link
Premier AKI Staging	Premier, Inc.	Assists clinicians aiming to follow the clinical practice guidelines for effective care of acute complex conditions such as AKI	Web	clinicians	https://apps.smarthealthit.org/app/premier-aki-staging
Rimidi Diabetes+Me	Rimidi	Diabetes+Me is a cloud-based enterprise solution for diabetes management.	Windows, Mac, Web, iOS	clinicians & patients	https://apps.smarthealthit.org/app/rimidi-diabetesme
RxOrbit InWorkflow App	Leap Orbit	The RxOrbit InWorkflow App embeds medication lists, alerts, or other relevant information from your state PDMP directly in the EHR.	Linux, Web, Mac, Windows	clinicians	https://apps.smarthealthit.org/app/rxorbit-inworkflow-app
Sepsis Watch	GA Tech College of Computing / Emory Department of Biomedical Informatics	Predicts six lab values which are advance indicators of sepsis, so that the progress of sepsis can be prevented by proactive treatment.	Web	clinicians	https://apps.smarthealthit.org/app/sepsis-watch
SMART Analytics Adapter	Qlik	Embed data insights in the clinician workflow for seamless navigation between patient records and analytical apps for data-driven decision.	iOS, Windows, Web, Mac	clinicians	https://apps.smarthealthit.org/app/smart-analytics-adapter
SMART Precision Cancer Medicine	Vanderbilt University Medical Center	Compares a patient's diagnosis-specific somatic gene mutation(s) to a population-level set of comparable data.		clinicians	https://apps.smarthealthit.org/app/smart-precision-cancer-medicine
Swellbox	Swellbox	Aggregates and facilitates the collection and exchange of student health records, in a simple and secure lifetime health account.	Web, iOS	patients	https://apps.smarthealthit.org/app/swellbox
TriVox Health	Boston Children's Hospital	TriVox Health gathers patient reported outcomes, provides real-time analysis,	Web, iOS, Android	clinicians & patients	https://apps.smarthealthit.org/app/trivox-health

Application Title	App Developer	Description	Supported Devices/ Environments	Designed For	App Link
		symptom tracking and monitors response to therapy over time.			
VisualDx Diagnostic CDS	VisualDx	Web-based clinical decision support system designed to enhance diagnostic accuracy, aid therapeutic decisions, and improve patient safety.	Web, Android, iOS	clinicians	https://apps.smarthealthit.org/app/visualdx-diagnostic-cds

Annex IV – IHE Patient Care Coordination Profiles

Profiles with final text are stable. Trial implementation profiles are frozen for trial use. Certain profiles, such as CMAP, DCTM, PMDT, QEDm, RECON and RIPT, leverage HL7® FHIR, applying a tight focus on implementability.

Profile State	**Acronym**	**Profile Name**	**Brief Description**	**IHE Wiki Link**
Final Text	XDS-MS	Cross Enterprise Sharing of Medical Summaries	Describes the content and format of Discharge Summaries and Referral Notes.	https://wiki.ihe.net/index.php/Medical_Summaries_Profile
Final Text	EDR	Emergency Department Referral	Communicates medical summary data from an EHR System to an EDIS System.	https://wiki.ihe.net/index.php/Emergency_Department_Referral_Profile
Final Text	XPHR	Exchange of Personal Health Record	Describes the content and format of summary information extracted from a PHR system for import into an EHR system, and visa versa.	https://wiki.ihe.net/index.php/Exchange_of_Personal_Health_Record_Content_Profile
Final Text	IC	Immunization Content	Describes the content and format of documents for exchange of immunization data.	https://wiki.ihe.net/index.php/Immunization_Content
Trial Implementation	APE	Antepartum Education	Records educational material provided during the office visit(s) for the antepartum episode.	https://wiki.ihe.net/index.php/Antepartum_Profiles
Trial Implementation	APHP	Antepartum History and Physical	Records data often collected at the initial ambulatory office visit for a pregnant patient.	https://wiki.ihe.net/index.php/Antepartum_History_and_Physical_Profile
Trial Implementation	APS	Antepartum Summary	Records the aggregation of significant events, diagnoses, and plans of care during an antepartum episode.	https://wiki.ihe.net/index.php/Antepartum_Care_Summary_Profile
Trial Implementation	APL	Antepartum Laboratory	Records results from standard laboratory tests administered during an antepartum episode.	https://wiki.ihe.net/index.php/Antepartum_Profiles
Trial Implementation	BED	Bed Management	Augments ITI PAM to communicate bed management for admissions.	https://wiki.ihe.net/index.php/Bed_Management
Trial Implementation	CM	Care Management	Exchanges information to manage care for specific conditions.	https://wiki.ihe.net/index.php/Care_Management_Profile
Trial Implementation	CDA-DSS	CDA Document Summary Sections	Describes the different types of CDA section templates that summarizes content in the CDA document or add	https://wiki.ihe.net/index.php/CDA_Document_Summary_Sections_Profile

Profile State	Acronym	Profile Name	Brief Description	IHE Wiki Link
			summary content that is not already included in the CDA document.	
Trial Implementation	CMAP	Clinical Mapping	Translates codes from one terminology to another for exchange of information between systems. (FHIR profile)	https://wiki.ihe.net/index.php/Clinical_Mapping
Trial Implementation	XCHT-WD	Cross Enterprise Cardiovascular Heart Team	Orchestrates the creation of a dynamic network of cardiovascular professionals called a Heart Team.	https://wiki.ihe.net/index.php/Cross_Enterprise_Cardiovascular_Heart_Team
Trial Implementation	XBeR-WD	Cross-enterprise Basic eReferral Workflow Definition	Establishes a common set of rules to share between participants involved in an eReferral workflow	https://wiki.ihe.net/index.php/Cross-enterprise_Basic_eReferral_Workflow_Definition
Trial Implementation	XTHM-WD]	Cross-enterprise TeleHome Monitoring Workflow Definition	Establishes a common set of rules to share between participants involved in a telemonitoring workflow	https://wiki.ihe.net/index.php/Cross-enterprise_TeleHome_Monitoring_Workflow_Definition
Trial Implementation	XTB-WD	Cross-enterprise Tumor Board Workflow Definition	Defines an XDW based workflow aimed to manage the creation and the execution of a tumor board.	https://wiki.ihe.net/index.php/Cross-enterprise_Tumor_Board_Workflow_Definition
Trial Implementation	DCTM	Dynamic Care Team Management	Shares information about a patient's care teams. (FHIR profile)	https://wiki.ihe.net/index.php/Dynamic_Care_Team_Management
Trial Implementation	CTNN	Emergency Department Encounter Summary Composite Triage and Nursing Note	Records both triage and nursing care delivered to a patient in the emergency department.	https://wiki.ihe.net/index.php/Emergency_Department_Encounter_Summary
Trial Implementation	EDPN	Emergency Department Encounter Summary ED Physician Note	Records care delivered to a patient in the emergency department.	https://wiki.ihe.net/index.php/Emergency_Department_Encounter_Summary
Trial Implementation	ETS	EMS Transport Summary	Shares information during situations where patients are being transported to a hospital emergency department facility.	https://wiki.ihe.net/index.php/EMS_Transport_Summary

Profile State	Acronym	Profile Name	Brief Description	IHE Wiki Link
Trial Implementation	ITS	Interfacility Transport Summary	Shares information during situations where patients are being transported between two healthcare facilities.	https://wiki.ihe.net/index.php/Interfacility_Transport_Summary
Trial Implementation	LDHP	Labor and Delivery History and Physical	Records data often collected during initial admission to a birthing facility.	https://wiki.ihe.net/index.php/Labor_and_Delivery_History_and_Physical
Trial Implementation	MCV	Multiple Content Views	Tags CDA text to achieve different rendering behaviors.	https://wiki.ihe.net/index.php/Multiple_Content_Views
Trial Implementation	PMDT	Point-of-Care Medical Device Tracking	Records medical device information acquired at the point-of-care. (FHIR profile)	https://wiki.ihe.net/index.php/Point-of-Care_Medical_Device_Tracking
Trial Implementation	QED	Query for Existing Data	Queries for clinical data elements, including observations, allergy and intolerances, conditions, diagnostic results, medications, immunizations, procedures, encounters and provenance.	https://wiki.ihe.net/index.php/Query_for_Existing_Data
Trial Implementation	QEDm	Query for Existing Data for Mobile	Queries for clinical data elements, including observations, allergy and intolerances, conditions, diagnostic results, medications, immunizations, procedures, encounters and provenance. (FHIR profile)	https://wiki.ihe.net/index.php/Query_for_Existing_Data_for_Mobile
Trial Implementation	RECON	Reconciliation of Clinical Content and Care Providers	Communicates lists of clinical data that were reconciled, who did the reconciliation and when. (FHIR profile)	https://wiki.ihe.net/index.php/Reconciliation_of_Clinical_Content_and_Care_Providers
Trial Implementation	ROL	Referral Order Linking	Communicates and links the referral and/or order number in documentation and metadata associated with services requested by an order placer	https://wiki.ihe.net/index.php/Referral_Order_Linking
Trial Implementation	RCK	Retrieval for Clinical Knowledge	Describes how Health IT systems, Person Health Records, and HIEs can retrieve clinical knowledge on the topics for presentation to a clinician or patient.	https://wiki.ihe.net/index.php/Retrieval_for_Clinical_Knowledge
Trial Implementation	RIPT	Routine Interfacility Patient Transport	Supports interoperability between systems used on transport vehicles between healthcare facilities. (FHIR profile)	https://wiki.ihe.net/index.php/Routine_Interfacility_Patient_Transport