D2.3

User Requirements

for cross-border HR integration

V3

ABSTRACT

This report describes the final version of users' requirements of the applications that are constrained by the InteropEHRate open specification and of the additional applications that are part of the InteropEHRate (software) framework. These include, in particular, the definition of clinical content to be supported by a S-EHR, needed to deal with the different reference scenarios. The results of the third cycle of focus groups are also reported, including suggestions and comments on functionalities and user interfaces belonging to the InteropEHRate framework, in the three different categories: patients and family caregivers, healthcare professionals, clinical researchers.

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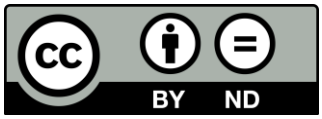

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LOGTABLE

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ACRONYMS

Acronym	Term and definition
API	Application Programming Interface
D2D	Device to Device
DICOM	Digital Imaging and Communication in Medicine
EHR	Electronic Health Record
EU	European Union
GDPR	General Data Protection Regulation
HL7	HL7
HL7-CDA	HL7 Clinical Document Architecture
HL7-FHIR	Health Level 7 - Fast Healthcare Interoperability Resources
IEHR	InteropEHRate project
IPS	International Patient Summary
IT	Information Technology
PaDES	PDF advanced Digital signature
S-EHR	Smart her
SNOMED-CT	SNOMED Clinical Terminology
SCP (SCP-ECG)	ECG Protocol (Standard communications protocol for computer assisted electrocardiography)
CTR	Clinical Trials Regulation
UML	Universal Modelling Language
eHDSI	eHealth Digital Service Infrastructure
FTGM	Fondazione Toscana "Gabriele Monasterio" per la Ricerca Medica e di Sanità Pubblica (Italy)
HYG	DTCA Hygeia – Diagnostic and Therapeutic Center of Athens (Greece)
CHU	CHU de Liege – Centre Hospitalier Universitaire de Liège (Belgium)
EFN	European Federation of Nurses Associations (Belgium)
SCUBA	"Bagdasar-Arseni" Clinical Emergency Hospital of Bucharest (Romania)
ISA	Iatrikos Syllogos Athinon (Greece)

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1 INTRODUCTION

1.1 Scope of the document

The main goal of the present document is to describe the *User requirements for cross-border HR exchange* by means of S-EHRs and related services and applications. It includes both requirements for generic applications that can have different implementations from different vendors (such as the S-EHR and the S-EHR Cloud), constrained by the InteropEHRate open specification, and requirements for specific applications that will be part of the InteropEHRate (software) framework. First of all, this document defines the general content of a S-EHR, reporting correspondence with EU initiatives, ongoing or well established, and then, expressing partners' experience on eHealth systems. It uses Narrative Scenarios methodology to describe four instances of health data exchange in a secure and interoperable environment and one additional scenario related to health data structure and semantic management.

Afterwards it describes how final users express comments and suggestions on proposed functionalities, collecting feedback useful for further refinements in the project's implementation.

1.2 Intended audience

The document is intended to users, policy makers, IT solution architects and developers interested in having an overview of how the InteropEHRate platform requirements were defined to support the exchange of health data among EU parties in a secure and trustworthy way and interested to understand which other reports provide additional details.

1.3 Structure of the document

The document is structured as follows:

- Section 1 (this section) explains the goal and structure of the document and its relation to other reports.
- Section 2 “Approach for requirement analysis” describes the principles applied in the definition of users’ requirements.
- Section 3 “S-EHR Content” describes the clinical content of the S-EHR according to general principles of patient care and international initiative of modelling such kind of data.
- Section 4 “Reference Scenarios” describes the three scenarios used as a reference to represent the typical approach for patient care and research, with explicit preconditions on approaches and sample types of clinical data used for every scenario.
- Section 5 “User Requirements” lists the set of functionalities to be implemented by the different applications of the InteropEHRate platform and derived from the described scenarios.
- Section 6 “Users Focus Groups” describes the general principles of the users’ requirements and refinements collected by Focus Group Activities for three types of focus groups: Patients, Healthcare Professionals, and Researchers.

1.4 Updates with respect to previous version

Here are described which sections have been updated and/or added with respect to the previous version of this deliverable, specifically the deliverable D2.2 **[D2.2]**.

- Section 3 “S-EHR Content”
    - Added new structured sections
- Section 4 “Reference Scenarios”
    - Added Scenario 0, initial feed of the S-EHR. This scenario is used when the patient wants to download on the S-EHR his/her own health-related data from an hospital where he/she had an encounter/admission and some reports or information are available for those.
    - In Scenario 1 is added pre-conditions related to the information authorship, either Patients or HCPs. Also detailed the final expected output from the medial visit, to be uploaded in S-EHR, and the structured list of section for the upload Dataset. A better detailed description of HCPs and related workstation usage is added, especially for the different workstation involved requiring a new authentication/pairing of the S-EHR with HCP App.
    - In Scenario 2 is specified on the pre-condition the inclusion of an ID picture of the patient in the demographic information maintained by the S-EHR and added a condition on information non-repudiation by every author. In the scenario activities is also specified the access of an HCP to some images and videos from patient’s history. The list of sections for the uploaded dataset was also added.
    - In Scenario 3 is added the behaviour of the system for large files, typically from diagnostic and therapeutic imaging, requested by a clinical research protocol but that cannot be maintained on the S-EHR due to the limited amount of available storage. It is also updated the target disease for the sample scenario, now hypertension, and the final objective of the clinical study considering medication side-effects.
    - Scenario 4 was restructured to have a more detailed description of pre-conditions and activities. At the beginning it is added a comprehensive picture describing the architecture of components involved in data management and conversion services (IHT). It is also updated the background section of data integration, describing in a more detailed way the whole process, and it is revised the list of preconditions and activities describing each activity or status in a simplified language.
- Section 5 “User Requirements”
    - According to the updates added to each scenario, and in particular the new Scenario 0, the list of functions is revised and furthermore detailed. A number of 54 new requirements (from n.166 to n.219) have been identified.
    - Target year of each functionality is updated
- Section 6 “Users Focus Groups” has been updated to describe the final release of questionnaires and related results.

2 APPROACH FOR REQUIREMENTS ANALYSIS

This deliverable defines the functionalities required by the users of software applications (e.g., "S-EHR App") that are part of the InteropEHRate standard architecture defined by the InteropEHRate open specification and of additional applications (e.g., "Knowledge Management Tool") that are only part of the InteropEHRate framework. Other than software functionalities, the user requirements describe constraints to be satisfied by the identified software applications.

The InteropEHRate standard architecture refers to an open ecosystem of interoperable applications belonging to well specified categories. Each user requirement, therefore, refers to one entire category of applications, classified as "S-EHR App" and "HCP App", which may operate in the InteropEHRate ecosystem. Each category of applications may have different implementations, developed by different vendors, offering additional functionalities, not included in the described basic model of application, oriented to satisfy additional constraints not included in the InteropEHRate user requirements or project scope.

This document defines functionalities that have already been implemented in the first versions v1 and v2 of the InteropEHRate framework (the reference implementation of the InteropEHRate architecture) and other ones that are candidates for inclusion in v3 of the framework. It also defines functionalities that will be specified by the InteropEHRate open specification but will not be implemented by the InteropEHRate framework. Finally, this document specifies additional functionalities that may be offered by applications of the InteropEHRate standard architecture, but that have been classified as out scope of both the InteropEHRate framework and the InteropEHRate Open specification.

Strictly related to this document is the upcoming report "D3.2 - Specification of S-EHR mobile privacy and security conformance levels - v2" **[D3.2]** that will specify which functionalities and constraints, including also development constraints that are of the scope of the present document, are mandatory for any implementation of the S-EHR App and the S-EHR Cloud.

Concerning other categories of applications included in the InteropEHRate standard architecture, there is only one mandatory constraint that any realisation (e.g., any HCP App) must interact with the S-EHR App and the S-EHR Cloud as specified by the InteropEHRate protocols, specified by deliverables **[D4.3]** and **[D4.9]**.

The definition of user requirements is aligned with the incremental development approach of InteropEHRate, composed of three cycles. Each development cycle lasts one year and incrementally adds results and improvements to results produced in the previous cycle, on the basis of feedback coming from final users and external stakeholders. During each year, a set of candidate user requirements are defined in the first 6 months of the year, possible to be implemented during the following 6 months of the project.

In order to simplify the communication with final users, the analysis of requirements is based on the specification of user scenarios.

A "user scenario" is a storyboard describing the interactions of different actors with the software applications envisioned by the InteropEHRate architecture, in a particular situation to solve a specific problem. The four main user scenarios involve the usage of applications of the InteropEHRate standard architecture for accessing from a European country the health data of patients coming from other European countries. A fifth user scenario involves the usage of additional applications of the InteropEHRate framework aimed to support the conversion and translation of exchanged health data.

Differently from the “use case scenarios” often used in the context of software specifications based on UML use cases, each usage scenario does not describe the interactions for the usage of a single functionality (i.e., a possible execution of a UML use case) provided by a single IT system, but it describes how several actors exploit different functionalities provided by different IT systems, in order to satisfy a complex objective. Usage scenarios are less fine grained and detailed than “use case scenarios”, but thanks to the lower level of technicality they make more evident the value of the functionalities in concrete situations and are more suitable to establish a shared vision with final users.

As InteropEHRate is intended to specify an architecture for an unbounded set of interoperable applications that will run in the full Europe and offered to different citizens, the defined usage scenarios are “generic”, in the sense that they do not refer to a specific local context (e.g., specific country, hospital, legacy system). Also, the reference to specific clinical conditions of the patients is just an exemplification, intended to be representative of many other situations that may involve patients with different pathologies, but requires similar interactions with the described software systems.

Similar to other results of the InteropEHRate project, also the specification of user scenarios is performed collaboratively by all the partners of the project, by both developers and final users. In order to simplify the collaboration, the authoring of the scenarios and the collection of comments are performed using a collaborative word processor, working on shared documents that can be edited simultaneously by all contributors.

The definition of the scenarios and of the architecture proceeds in parallel. During the specification phase, the scenarios are discussed in weekly conference-calls with the final users that belong to the project consortium and, on the basis of their feedback provided during the calls or offline, the scenarios are improved in order to assure that the usage of the new technology is compatible with real needs. As the technical partners of the project better understand the scenarios, they clarify the InteropEHRate Architecture, and in turn the responsibility of the user requirements and the technical partners of the project collaborate to include in the usage scenarios the new insights coming from the clarification of the architecture.

The usage scenarios are successively used for the identification of all required functionalities at a finer level of granularity. The identification of user requirements is a continuous process, lasting along the full project life. In each year, all three scenarios planned by the project are specified and refined, the analysis of user requirements is done more incrementally, focusing each year on a specific scenario, adding the analyses of the new scenario and continuing to improve the analysis of the other scenarios started in the previous years. This last year is dedicated to the analysis of the emergency scenario and the additional Scenario 0 for the initial feed of the S-EHR.

In order to identify the user requirements, the usage scenario to be analysed is split into single sentences and one or more requirements are associated with each sentence. Also, in this case the analysis is performed in a collaborative way, working on a shared spreadsheet. A first version of the requirements is drafted by the main technical partner and afterwards the other technical partners add if needed new requirements and improve the description of already identified ones. As the last step the requirements are submitted to the final users for approval and for identifying the ones with highest value (to be possibly prototyped first).

The requirements are expressed in the form of “epics” in the style of Agile methodologies.

In particular, each functional requirement is represented by a simple sentence describing a specific interaction of a specific user with a specific software application. The sentence clarifies the main goal of

the interaction, the involved actors, the initiators of the actions and the effects or results of the interaction. If, before the development, it is discovered that some aspect of a requirement is not clear it is clarified with discussions traced on an issue tracker. Each epic may require until one year of development to be realised. During the year it is split in more fine-grained user stories, implemented one after the other, in an incremental way.

Also, the usage of epics and user stories has been chosen to simplify the communication with the final users. This style of specification is a good base for organizing also the development phase in incremental steps, focusing each development step on the implementation of few requirements.

The description of requirements may be improved before starting their implementation also to take into account new feedback. The feedback comes from the experience acquired during the development of other requirements or by other two kinds of revision processes. One revision happens within the so-called focus groups. "Focus groups" are selected groups of adult citizens, HCPs and researchers (i.e., end-users) not involved in the day-by-day operation of the project, which meet routinely (max twice a year) at the pilot sites. These individuals are representatives of the pilot sites (i.e., FTGM, HYG, CHU and SCUBA)[1], which will be involved in a more extended final validation to be performed at the end of the third cycle of development.

Following a co-design approach, the InteropEHRate consortium submits intermediate results to focus groups in order to receive their evaluation and validation. Feedback from focus groups may be collected on usage scenarios, requirements, design of user interfaces and intermediate prototypes. The technical partners use the feedback collected from the focus groups to improve the software specification during the current development cycle or during the next one.

The project submits its intermediate results also to an external board of experts in order to receive more strategic recommendations. The recommendations are analysed and exploited by the full consortium to adapt the project roadmap and improve the exploitability of the project results.

The following chapters describe expected S-EHR content, the usage scenarios and the user requirements specified in the final release. The following section report the list of actors involved in the usage scenarios and referred by the entire deliverable.

2.1 Involved actors

The following sections refer to different kinds/roles of final users (called "actors", following the UML terminology) that interact with software applications specified by InteropEHRate. The actors are organized in a generalization hierarchy, where for example a Data User is a more general kind of actor than a Patient. The specification of usage scenarios only refers to the actors Researcher, HCP, and Patient. The user requirements instead also use the other kind of actors to make clearer the interpretation of the scenarios.

[1] InteropEHRate Project Partners. https://www.interopehrate.eu/partners/

Actors	Description	More general actor
Data user	Every person that may perform some operation (creation, reading, updating etc.) on health data	-
Citizen	Every person in a specific country whose health data is managed by an application included in the InteropEHRate architecture	Data user
Patient	Every person that receives healthcare from HCPs. Current requirements consider patients that are also citizens.	Citizen
HCP	All healthcare professionals that produce and/or access health data of a Patient	Data user
Researcher	Every person that desires to exploit the citizens' health data for research purposes	Data user
Data scientist	Every person able to understand specific kind of health data and to express them according to specific standards adopted in the health domain	-
PI of the Study	Principal Investigator of a research study: a researcher internal to the Coordinating Research Centre, who is in charge of leading the study	Researcher
-	Symbol used for Non-Functional requirements	-

Table 1. Actors involved in the definition of usage scenarios and requirements

3 S-EHR CONTENT

In order to make Scenarios express a real use of information stored in S-EHR, a first definition of required content is provided.
Besides an agreement on general management of patient's process and treatments, it was decided by Physicians, Nurses and Researchers of the Hospital partners that, in order to have a meaningful use, S-EHR should be able to contain at least:

1. Patient Summary (used also as Emergency Dataset);
2. ePrescription;
3. Laboratory results;
4. Vital signs;
5. Medical imaging and bio-signals:
    a. contains DICOM images and movies;
    b. contains bio-signals (e.g. SCP and DICOM waveform);
6. Reports and digitally signed documents (e.g. PaDES);
7. Visits reports;
8. Hospital discharge reports;
9. Personal notes of the patient (vital signs, signs, symptoms, wellness and activity data).
10. Emergency contacts;
11. Advance Directive (e.g. do not resuscitate, no blood transfusion, consents for organs donation, etc.)
12. Medical certificates;
13. Treatment plans;
14. Guarantors, accounting and billing data, health insurances;
15. Clinical Research studies participation;
16. Drugs administrations (immunizations)
17. Drugs self- administrations;

This content reflects guidelines and indications contained in eHDSI EU Commission Recommendation of 06/02/2019 on a European Electronic Health Record exchange format, extended with: bio-signals management, documents that are digitally signed, personal notes and data from the patients and his/her caregiver.

S-EHR may contain health data and/or reports and/or documents not expressed in Patient's natural language, because it may be produced by HCPs using different natural language, and this represents a major obstacle for patients and HCPs to use that data.

In this project, it is proposed a translation of data between the language of producers (mostly HCPs) and users: Patient and HCPs in the first instance and Researchers in the second instance.

Eventually text contained in structured data within the S-EHR should be translated, whenever possible with acceptable reliability, to the language of the HCP/Patient. Similar operations will be applicable to unstructured text in raw text format. The problem of extraction of raw text from unstructured data (e.g. scanned or formatted documents such as MS Word doc, PDF) will not be solved as part of the project, and the reference implementation will offer a limited support (in terms of the document formats supported) within the capabilities of third-party text extraction tools.

In the platform it is evaluated the content of a photo of the patient's face in order to assist the identification of him/her within specific scenarios, such as the emergency one.

The following sections provide further details on some of the S-EHR content.

3.1 Medico-Legal validity of S-EHR content

Data contained in S-EHR and managed by HCPs must represent a solid basement of information usable in healthcare processes, from diagnostic assessment to therapy plan decisions, without any doubt on Information Assurance.

In a few words, every data contained in S-EHR has to be solid enough to withstand a court lawsuit.

In order to have a medicolegal validity S-EHR content, especially documents and reports, should comply with **Electronic Signatures Directive** 1999/93/EC and EU Regulation 910/2014 of 23 July 2014 on electronic identification (eIDAS).

In the following figure an example of usage of digital signature to foster the exchange of documents across borders is depicted (ref. **[NORA]**).

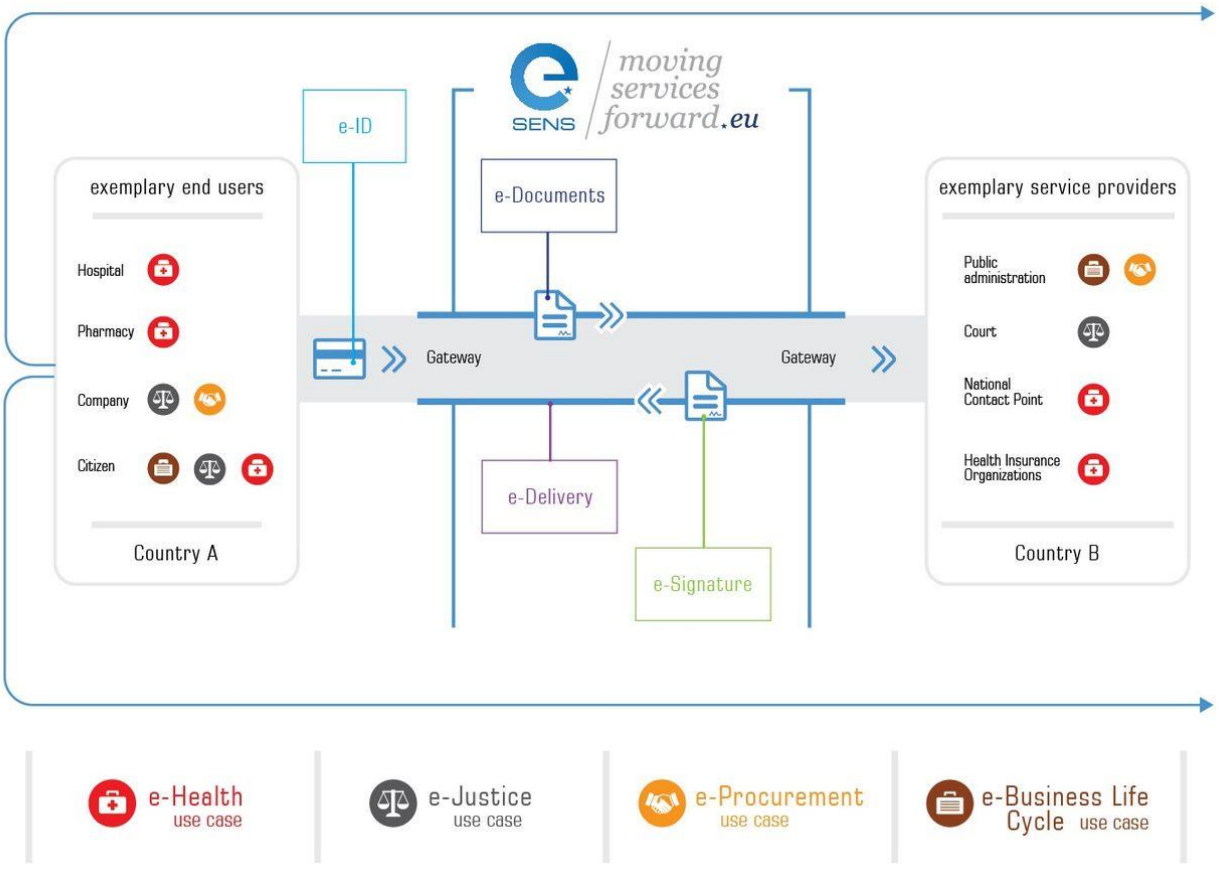

Figure 1. Example of use for digital signature cross-borders

A digital signature is an unforgeable data element, which is logically associated, applied or attached to an electronic document or other information object with the intent or commitment of the signer to sign or otherwise be bound by the terms of the electronic document or other information object.

A digital signature is typically created by "hashing" the electronic document, encrypting the resulting hash (integrity block) using the user's private (secret) key, and appending the encrypted hash to the electronic document or other information object.

A qualified electronic signature is an electronic signature that is compliant to EU Regulation No 910/2014 (eIDAS Regulation) **[EIDAS]** for electronic transactions within the internal European market and is assumed to have at least the legal equivalence of a handwritten signature.

A qualified electronic signature is an advanced electronic signature with a qualified digital certificate that has been created by a qualified signature creation device (QSCD) . Advanced electronic signature is one of the standards outlined in eIDAS for across border security within EU Member States.

An electronic signature, in order to be considered as advanced, must meet the following four requirements:

- The signatory can be uniquely identified and linked to the signature.
- The signatory must have sole control of the signature creation data (typically a private key) that was used to create the electronic signature.
- The signature must be capable of identifying if its accompanying data has been tampered with after the message was signed.
- In the event that the accompanying data has been changed, the signature must be invalidated.

The electronic signature can be implemented through the following three digital signature standards, developed by the European Telecommunications Standards Institute (ETSI), in compliance with the eIDAS Regulation:

- XAdES, XML Advanced Electronic Signatures is a set of extensions to XML-DSig recommendation making it suitable for Advanced Electronic Signatures.
- PAdES, PDF Advanced Electronic Signatures is a set of restrictions and extensions to PDF and ISO 32000-1 making it suitable for Advanced Electronic Signature.
- CAdES, CMS Advanced Electronic Signatures is a set of extensions to Cryptographic Message Syntax (CMS) signed data making it suitable for advanced electronic signatures.

In addition, in order to achieve stronger evidence about the time period in which the signature could have been given, double-sign can be used by both the citizen and the HCP. This will create cryptographic evidence that the outer signature was given in the time period between "Signed on" time of the inner and the outer digital signature containers.

3.2 Patients' Consents for Processing Personal Data

In order to lawfully process personal data a person or entity must be able to point to at least one "legal basis" enumerated in the General Data Protection Regulation (GDPR or the Regulation). These legal bases are specifically to be found in the GDPR's Articles 6 and 9 (for special categories of personal data). The GDPR defines processing as any operation, which is performed on personal data, whether or not by automated means. Pursuant to GDPR's Article 6, the processing of personal data is lawful if at least one of six circumstances is met. Article 9 GDPR prohibits the processing of special categories of personal data such as health data unless one of ten conditions enumerated in paragraph 2 are met.

3.2.1 Consent requirement for personal data processing activities

In terms of Article 6 GDPR, the processing of personal data is lawful in a limited number of circumstances, one of which is based on the consent of the data subject. Article 9 GDPR prohibits the processing of personal data concerning health; however, an exception exists where the explicit consent of the data subject is obtained.

When consent forms the legal basis for processing, no further processing beyond what is covered by the original consent is possible unless further processing is justified by another legal basis (other than consent).

Further processing or re-use would require obtaining new consent or a new legal basis for processing. In the context of scientific research, the GDPR provides some important privileges. The Regulation states in Article 5(1)(b) and Recital 50 a presumption that further processing of personal data for scientific research purposes will be considered compatible with the purpose for which the personal data were originally collected. Article 5(1)(b) requires that the processing be in accordance with Article 89, which only specifies the circumstances of the processing but not the lawfulness.

To lawfully process health data as envisaged in particular, in scenario 1 and 3 of the InteropEHRate project, the explicit and valid consent of patients must be obtained and accurate records of consent statements must be maintained. The GDPR outlines the following elements and conditions required for valid consent:

1. Specific consent – consent must be given in relation to one or more specific, explicit and legitimate purposes determined by the data controller. Furthermore, the procedure for obtaining consent should allow data subjects the freedom to give consent for some processing operations/purposes and not for others. For example, data subjects should be allowed to consent to the storage of health data but not to the exchange of that data. This means that separate consent should be facilitated.
2. Freely Given consent – consent must be freely given; this implies actual control for data subjects.
3. Informed consent – providing information to data subjects prior to obtaining their consent is essential to determine the validity of the consent given. In Article 12 – 14, the GDPR outlines the information that must be provided to data subjects prior to obtaining consent. This information includes the identity of the controllers, the purposes and the legal basis of processing. Furthermore, data subjects should be informed about the type of data collected as well as possible risks in connection with processing and the safeguards to mitigate such risks. Data subjects should be informed of their rights under the GDPR, including the right to withdraw consent at any time. If the data controller fails to provide accessible, relevant information to data subjects, “consent will be an invalid basis for processing”.
4. Unambiguous indication of wishes – consent requires a clear statement from the data subject or a clear affirmative act through an active motion or declaration.
5. Explicit consent – based on Article 9(2) GDPR, explicit consent is required for the processing of personal health data. According to WP29 Guidelines on Consent, the term explicit implies that data subjects must give an express statement of consent. Furthermore, the requirements for valid consent outlined above must be satisfied.

6. Demonstrate consent – the burden of proof rests on data controllers to demonstrate that data subjects have given consent to the processing operations. This imposes an obligation on data controllers to keep accurate records of consent statements.

In terms of Article 7(3), data subjects have the right to withdraw consent at any time and must be informed of this right. The controllers must ensure that consent can be withdrawn as easily as it is given. This implies that when consent is obtained via electronic means for example through one mouse click, data subjects must, in practice, be able to withdraw the consent equally as easily.

If consent is *withdrawn*, all data processing operations previously based on valid consent that took place before the withdrawal *remain lawful*.

However, once consent is withdrawn the controller is obliged to stop the processing actions concerned, unless there is another lawful basis justifying continued processing. Once the InteropEHRate tools are available for public use after the completion of the project, continued processing might be justified based on the 'vital interest of the data subject' in scenario 2, 'public interest in the area of public health' in scenario 1 or for 'scientific research purposes' (during and after the project) in scenario 3.

If there is no other lawful basis justifying the processing of the data, they should be deleted by the controller(s).

3.2.2 Consent requirement for Research Purposes and/or Clinical Studies

Scenario 3 envisages a research protocol facilitating the sharing of personal health data for research purposes. As Scenario 3 has yet to be designed within the InteropEHRate project, it does – as the planning currently stands- not fall within the scope of the Clinical Trials Regulation (CTR) **[CTR]**. This is because the regulation applies to 'clinical trials and not to "non-interventional studies". A non-interventional study means a clinical study that does not fit into the definition of a clinical trial. Based on Article 2 of the CTR, a clinical trial is defined as any clinical study that fulfils any of the following conditions:

a) The subject is assigned to a particular therapeutic strategy. This decision is made in advance and does not fall within the normal clinical practice of the Member State;
b) The subject is prescribed investigational medicinal products. This decision is taken together with the decision to include the subject in the clinical study;
c) Diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects.

However, if at some point during the project or after the project, a clinical trial is intended then further legal considerations are needed and the consent in the S-EHR app must comply with the requirements for informed consent under the CTR (in addition to the GDPR requirements).

Article 29 CTR outlines the specific conditions for informed consent. Consent should preferably be written and must be documented; a copy of such documentation or record must be given to patients. Patients or legal representatives must be given sufficient time to consider the decision.

In terms of Article 29(2) CTR, the information given to patients and their legal representatives must contain:

- The nature, objectives, benefits, implications, risks and inconveniences of the clinical trial;
- The subject's rights, including the right to refuse to participate and the right to withdraw;
- The conditions of the trial, such as its duration;

- The possible treatment alternatives, including the follow-up measures if the participation of the subject in the clinical trial is discontinued.
- The applicable damage compensation systems;
- EU or National or Local trial registration number, the availability of results on the EU database and where possible an indication of when the results may be available. The IT platform to assign EU trial numbers is still under development (ref. Year 2020).

When the information outlined above is presented to subjects, it must be presented in a comprehensive, concise and clear manner. The information provided must be relevant in relation to the clinical trial and understandable to a layperson. The Regulation requires that information be provided in a prior interview with a member of the research team who is appropriately qualified according to the law of the Member State concerned. In this interview, special attention shall be paid to the information needs of specific populations and of individual subjects, as well as the methods used to give the information. In the interview, it shall be verified that the subject has understood the information.

3.2.3 Other Relevant Legal Basis for Processing Health Data in the InteropEHRate Scenarios

Explicit consent is only one of the legal bases provided by Article 9 to process health data. However, this Article states some other legal bases, which may be relevant for the S-EHR Application once it is completed and on the market. Member States may have further conditions for the processing of health data

3.2.3.1 Vital interests of the data subject

In the context of Scenario 2, protecting the vital interests of the data subject in an emergency could form a legal basis for the processing of health data. This legal basis is found in Article 9(2)(c) “processing is necessary to protect the vital interest of the data subject where the data subject is physically or legally incapable of giving consent”. This legal basis is only valid in matters of life and death where the data subject cannot give consent due to being incapacitated or in an altered state of mind. This legal ground is valid in cases of health emergencies where the patient is unconscious. This is in particular relevant for scenario 2 where the patient is not capable of giving his or her consent on the spot. This exception can be applied only to a small number of cases of treatment.

3.2.3.2 Public interest in the area of public health

Article 9 (2)(i) permits the processing of personal data concerning health when processing is necessary for reasons of public interest in the area of public health. Reasons of public interest may include ensuring high standards of quality and safety of health care based on Union or Member State law. This ground applies if the processing is necessary to protect the population against a serious cross-border threat to health, or ensuring high quality standards and safety of healthcare, medicinal products, or medical devices.

3.2.3.3 Scientific Research Purposes

Article 9(2)(j) permits the processing of personal data concerning health when this is necessary for achieving scientific research purposes. In this context, the processing shall be proportional to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the rights of data subject in accordance with Article 89(1) of the GDPR. It is possible this legal basis may be relied on for certain processing activities in the context of scenario 3.

3.2.4 Patients Consent in InteropEHRate

This section will highlight the ways in which InteropEHRate seeks to give effect to the requirements for consent, in the context of patients consent for personal data processing activities during the development of the applications during the pilot phase and when the applications are out on the market in the user case scenarios.

3.2.4.1 Consent in the Pilot Phase

The Project Pilots aim to validate the InteropEHRate framework before a public launch by testing the application with final users who will consist of volunteers from partner hospitals. The pilot phase takes place in year 4 of the project. During the Pilots, these volunteers will freely contribute their personal health data. Project partners are yet to decide how health data will be collected and processed during the Pilots. However, the informed consent of each volunteer will be obtained prior to accessing his or her data. In addition to the consent requests and privacy policy contained in the app, the Project Ethical Committee is tasked with the drafting of a GDPR-compliant informed consent form(s). The informed consent form shall provide volunteers with the research objectives, possible threats and safeguards implemented in the Pilots. The volunteering citizens will be informed of their rights as data subjects including the right to refuse participation or withdraw from the Pilots at any stage without facing consequences.

3.2.4.2 Consent to S-EHR Data Management

When the citizen registers to the application, once it is completed and on the market, consent is required for the purposes of storing and managing personal health data on smart devices. A patient will be given the choice to check a widget to give consent to the core application. By opting to check the widget, the citizen freely gives his or her consent; this action represents an expressed, unambiguous indication of the wish to consent. The controller is obligated to maintain evidence of this. After consent is given, the citizen's account is validated and the citizen is able to access the core functionalities of the app. The citizen is informed of the right to withdraw consent at any time and other important rights in accordance with GDPR requirements. This information is provided in the privacy policy that is included as a link in the consent request.

3.2.4.3 Consent to Data Sharing Functionalities

Once completed and on the market, the S-EHR app allows citizens to share electronic health records (EHR) with health care providers via the HCP app for a limited period. A connection between a patients' phone and the health care providers' computer or network is initiated through the scanning of a QR code that contains the necessary data to establish a Bluetooth enabled connection between the parties. Upon scanning the QR code, the user will receive essential information such as the name, address and a contact person of the HCP organisation. This information is important to establish valid consent and is provided prior to the consent request, in accordance with GDPR requirements. After the provision of information, the consent request is issued. The consent request will contain a clickable link that redirects the citizen to the privacy notice and information about data exchange. In accordance with Articles 12 to 14 GDPR, the privacy policy on the S-EHR app will contain at least information regarding: the purpose of the processing, the contact details of the controller and data protection officer, personal data collection and usage, data sharing, data storage, data security, cloud services, use of cookies and the rights of data subjects. The citizen gives consent to the exchange of personal data through a checkbox widget, connection is fully established when the user accepts the consent request, without consent data sharing is impossible in this scenario.

3.2.4.4 Consent to Data Sharing for Research Purposes

Scenario 3 envisages the use of the S-EHR app as a tool which patients can use should they choose to donate a portion of (or their entire) electronic health data records for the purpose of scientific research. Once completed and on the market, patients will have the option to exchange their clinical data with authorised researchers and institutions in an anonymized or pseudonymized form. Using the S-EHR app and the information present in the informative material (e.g. QR code), or selecting the research from a list of study published in S-EHR, the citizen will be informed about the details of the requested health data, the purpose of the research, data retention periods and about the level of anonymization. Furthermore, the citizen is provided with an information document of the research, containing the contact details of the researcher organisation and principal researchers. Thereafter the citizen is given the option to decide whether to participate in the research. The S-EHR app is used to give patient's consent to donate data to research protocols. Where the citizen freely decides to give consent, he or she may also determine which data sets are shared and restrict their use only to a specific research initiative. As mentioned above, scenario 3 does not fall within the scope of the Clinical Trials Regulation (CTR).

3.3 Patient Summary

In order to fully exploit a complete health profile of the citizen, the "International patient summary", or IPS, is used as a reference for unscheduled encounters and emergency dataset reference.

The International Patient Summary **[IPS]** is a "Minimal and non-exhaustive Patient Summary, specialty-agnostic, condition-independent, but readily usable by all clinicians for the unscheduled (cross-border) care of a patient." Specialty-agnostic implies that this document is not filtered for a particular specialty, while Condition-independent implies that it is not limited to specific circumstances and focuses on the present condition(s) of the patient.

Patient Summary is a standardized collection of fundamental health information, summarized in Figure 1, which contains the most significant clinical facts necessary for safe and secure healthcare.

This summarized version of the health data of the patient provides health experts with the vital information they need to provide in the event of an unexpected or unplanned healthcare scenario (e.g. emergency or accident).

Although this information is largely aimed at helping healthcare professionals to provide unplanned care, it can also be used to provide scheduled healthcare (e.g. for citizen movements or cross-organizational care pathways).

It is possible to implement IPS through the HL7 CDA R2 Document or FHIR document artefacts **[CDA]**.

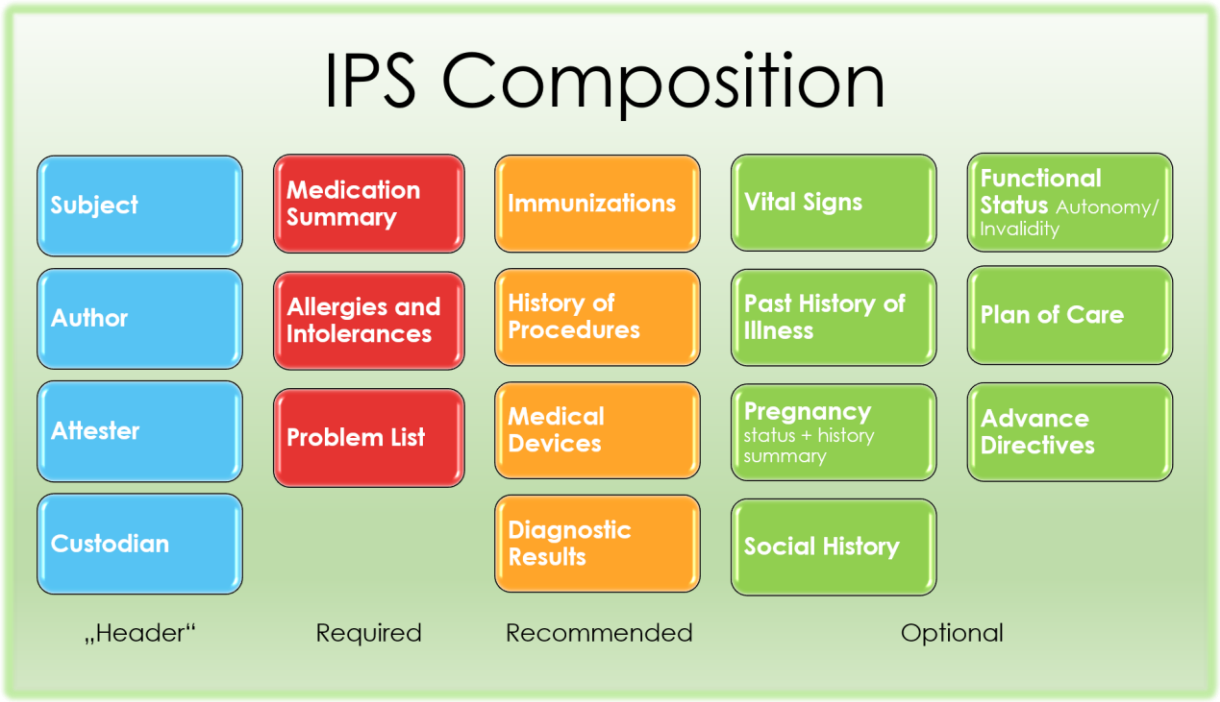

Figure 2. IPS composition

On February 14, 2019 SNOMED and HL7 announced the availability of a set of terms to be used free of charge in support of the IPS. There are about 8000 SNOMED CT terms covering various domains such as allergies, problems and procedures.

The timespan of the contract is set for a period of five years in which updates to SNOMED CT content will be produced in accordance with the release schedule of SNOMED International, which will be publicly available from SNOMED International in Summer 2019.

The IPS templates aim to:

- Serve for both cross-jurisdictional (through adaptation/extension for multi-language and realm scenarios, including translation) and national (through localization) patient summaries.
- Support emergency care and unplanned care in any country (home and foreign), regardless of language
- Define value sets based on international vocabularies that are usable and understandable in any country

The following table describes the standard content of the IPS:

IPS Sections	Description
Medication Summary Section	This section shall contain a characterization of the medication of the patient as part of the overview of the patient, medications are recorded as medication statements in the patient summary.
Allergies and Intolerances Section	This section records the related allergies or intolerances (conditions) for that patient, describing the effect type (e.g. rash, anaphylaxis, ...); preferably the agents that trigger it; and optionally the allergy's criticality and confidence.
Problems Section	The IPS problem section lists and explains for the patient presently being

	monitored clinical issues or conditions. This section can record various types of issues such as chronic diseases (e.g. COPD, diabetes, hypertension); contagious diseases; dietary issues (e.g. metabolic illnesses); and so on.
History of Procedures Section	This section includes a description of previous patient procedures relevant to this document's scope. For instance, procedures can refer to: Invasive Diagnostic Procedure: e.g. Cardiac catheterization; (results of this procedure are documented in the section of results) Therapeutic procedure: e.g. dialysis; surgical procedure: e.g. appendectomy.
Immunizations Section	The Immunizations Section describes the present immunization status of a patient as well as the relevant history of immunizations. The category involves the current status of immunization and may comprise the entire history of immunization appropriate to the time period being summarized.
Medical Devices Section	The section on medical devices includes narrative text and coded entries describing the medical device use patient history. Medical devices include implanted devices and devices for nutrition, but are not restricted to them.
Results Section	This section organizes appropriate observational results gathered on the patient or generated on the patient's collected in-vitro biological specimens. Some of these may be laboratory results, others may be results of anatomic pathology, others, radiology results, and other results.
History of Past Illness Section	This section includes a narrative description and coded entries of the previously encountered conditions of the patient.
Functional Status Section	The section on functional status shall contain a detailed overview of the patient's ability to execute daily living acts, including possible patient needs to be evaluated continuously by third parties.
Plan of Care Section	The section on care plan includes a narrative overview of care requirements including suggestions, objectives, and order requests to monitor, track, or improve the patient's condition.
Social History Section	The section on social history includes an overview of the "lifestyle factors" or "lifestyle observations" linked to the health of the person (e.g. smoke habits; alcohol consumption; diets, risky habits).
History of Pregnancy Section	The section on pregnancy shall include data on whether or not the patient is presently pregnant (optional with the Expected Delivery Date). This may include additional data summarizing the outcome of previous pregnancies.
Advance Directives Section	This section includes advance directives. An advance directive might be “no cardiopulmonary resuscitation”

Table 2. IPS Sections

3.4 Prescriptions

Currently the treatment prescription issued in European countries is recognized in all the other countries of the European Union.

Prescriptions are used to deploy a diagnostic or therapeutic plan, and thus may contain drug provision requests.

To facilitate the recognition of prescriptions in other EU countries, the following data needs to be included:

Item	Description
Identification of the patient	• Surname(s) • First name(s) (written out in full, i.e. no initials) • Date of Birth • optional: gender
Authentication of the prescription	• Issue date
Identification of the prescribing health professional	• Surname(s) • First name(s) (written out in full, i.e. no initials) • Professional qualification • Details for direct contact (email and telephone or fax, the latter both with international prefix) • Work address (including the name of the relevant Member State) • Signature (written or digital, depending on the medium chosen for issuing the prescription)

Identification of the prescribed product, where applicable	• 'Common name' as defined by Article 1 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use or the brand name if:
	  ○ the prescribed product is a biological medicinal product, as defined in point 3.2.1.1.(b) of Annex I (Part I) to Directive 2001/83
	  ○ the prescribing health professional deems it medically necessary; in that case the prescription shall shortly state the reasons justifying the use of the brand name
	• Pharmaceutical formulation (tablet, solution, etc.)
	• Quantity
	• Strength, as defined in Article 1 of Directive 2001/83/EC
	• Dosage regimen

Table 3. Prescription items

ePrescribing is defined as prescribing of medicines in software by a healthcare professional legally authorized to do so, for dispensing once it has been electronically transmitted, at the pharmacy.

eDispensing is defined as the act of electronically retrieving a prescription and giving out the medicine to the patient as indicated in the corresponding ePrescription. Once the medicine is dispensed, the dispenser shall report via software the information about the dispensed medicine(s).

The ePrescription must be submitted in a structured manner, i.e. in organized modular data groups or segments (sorted under the right headers for nesting) each one containing associated information objects.

The main objective of this presentation is to facilitate the understanding of the content of the prescription clinical document and to enable each subset of information to be managed individually when applying semantic services or when applying any kind of translation into the native language of the person requesting the consultation of the clinical document. **[EPRSC]**

3.5 Laboratory results

Laboratory results come from medical diagnostic techniques that evaluate the patient's samples such as blood, urine or other physiological fluids and tissues, highlighting his/her general state of health. Physiological fluid or tissue is taken from the patient and transferred to equipment and analysers to evaluate its composition and factors that indicate problems or pathologies.

Three different information technology systems are involved in producing Laboratory results:

1. Clinical Information Systems (CIS)
2. Laboratory Information Systems (LIS)
3. Laboratory Automation Systems (LAS)

Results sets are organized in groups of data that have a common context of production.

Typically, laboratory findings are produced by laboratories that provide analytical services in fields such as chemistry, haematology, serology, histology, cytology, anatomy (including digital pathology), microbiology, and/or virology.

Laboratory examinations are based on instrumental analysis of a specimen collected from the patient subject. Depending on specimen type, different kinds of containers can be used for preserving specimens during transport to laboratories facilities.

On the same specimen can be performed one single or multiple analyses, and the specimen, or a portion of it, can be stored for further analysis.

A specimen is characterized by a set of properties:

- Patient Identification, Patient ID (gender, age, other clinical parameters)
- date/time of sampling, quantity
- Operator/organization in charge of sampling
- specimen ID and status
- specimen type and source (blood, tissue, urine, etc.)
- priority of sampling

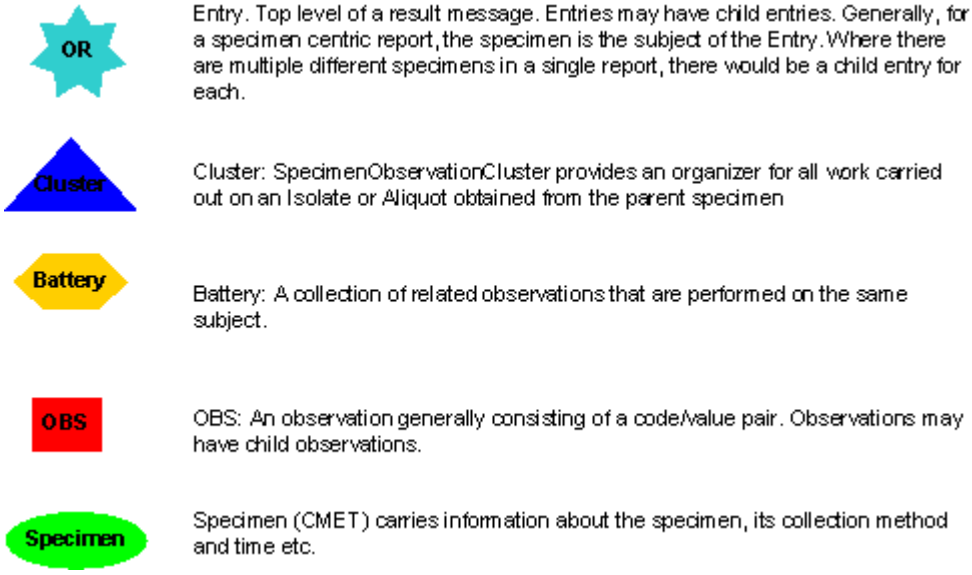

Figure 3. Example of structure for laboratory exams

For each specimen can be requested a set of analysis, described as:

- requested parameter (internal code/LOINC code) (request ID, status)

Once the container and its related specimen are processed by Laboratories devices and processes, results corresponding to clinical requests are produced.

Results can be represented with the minimal following properties:

- Patient Identification, Patient ID (gender, age, other clinical parameters)
- date/time of sampling, quantity
- Operator/organization in charge of sampling
- specimen source
- biohumoral parameter code (corresponding to request, internal code/LOINC code, reflex flag)
- biohumoral parameter value (or reason for missing value) and unit of measure (UCUM)
- interpretation range of normality/pathology/panic/etc. in relation with patient clinical condition/gender/age/etc.
- annotation on the results

In the following figure a graphical representation of a result for glucose on venous blood specimen (glycaemia) is presented:

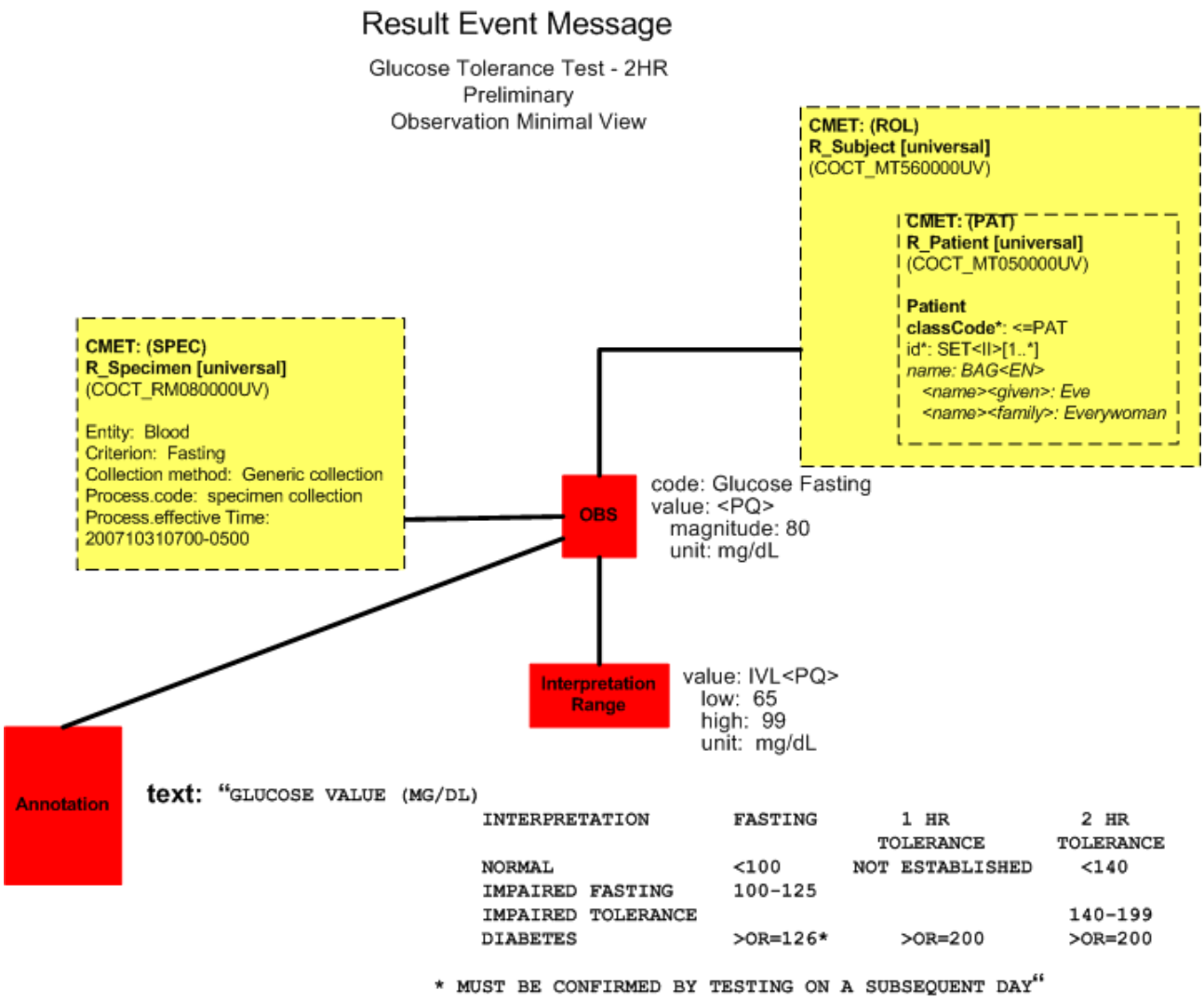

Figure 4.Example of information model for laboratory exams

Results are often represented in a table format, especially when a sequence of measurements is requested (Battery).

In the following table an example of results is presented, including data of specimen sampling:

Hematology Observation/Test Name	Result Value/Flag	Result Comment(s)	Reference Range	Collection Date/Time	Observation Date/Time
Hepatitis A IGM Antibody	Non-reactive	Hepatitis A Core IGM Antibody has been detected in most acute infections and is a reliable marker for	Non-reactive	11/20/2019 0730	11/20/2019 08:00

		acute disease			
Hepatitis B Core IGM Antibody	Reactive / A	Hepatitis B Core IGM Antibody has been detected in most acute infections and is a reliable marker for acute disease.	Non-reactive	11/20/2019 07:30	11/20/2019 08:00
Hepatitis B Surface Antigen	Present	.	Not present	11/20/2019 07:30	11/20/2019 08:30
Hepatitis C Antibody	Non-reactive	.	Non-reactive	11/20/2019 07:30	11/20/2019 08:42

Table 4. LAB Results data example

A specimen sampling request, a specimen sampling and a result can be nullified, updated/revised, or be subjected to other actions. Different status of Results and Specimen are characterized by a state machine, represented on the following figure:

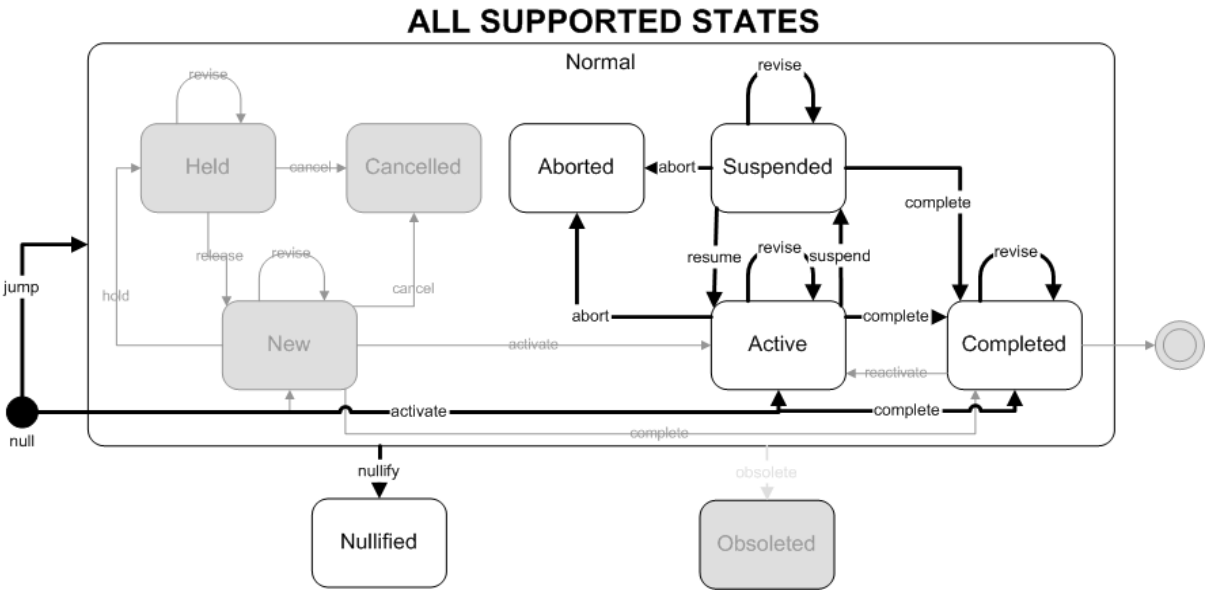

Figure 5. Example of states diagram for laboratory exams

3.6 Images

The dramatic progress of technologies in the field of diagnostic imaging has provided the clinician with an increasingly detailed and accurate diagnostic apparatus.

A digital image can be represented by a matrix of points, called pixels or pels (acronym for Picture ElementS), this matrix is generally rectangular, in medicine square matrices are preferably used, for

example 256x256, 512x512, 1024x1024, and so on. Each pixel or element of this matrix is represented by a number that expresses its brightness. According to the number of bits with which this value is represented, there is a smaller or greater number of possible values. The number of bits with which the colour of the pixel is expressed is called colour depth and its unit of measurement is the bpp (bit per pixel). For example, if we want to represent a maximum number of 256 (2^8) colors, the color depth will be 8 bits, and the representable values will be between 0 and 255, or between 0 and ($2^8 - 1$), if instead we want to represent a maximum number of 65536 (2^{16}) colors, the color depth will be 16 bits, and the representable values will be between 0 and 65535, or between 0 and (2^{16}-1).

The digital radiological images that come from modern diagnostic modalities, such as TAC and MRI, have the characteristic of having a high colour depth (16 bit), in the case of such images that are coloured they are represented in grey tones and the value associated with the pixel is correlated to the value of brightness of the pixel, if n is the depth of colour: 0 is black, that is absence of brightness,$2^n - 1$is white or maximum brightness.

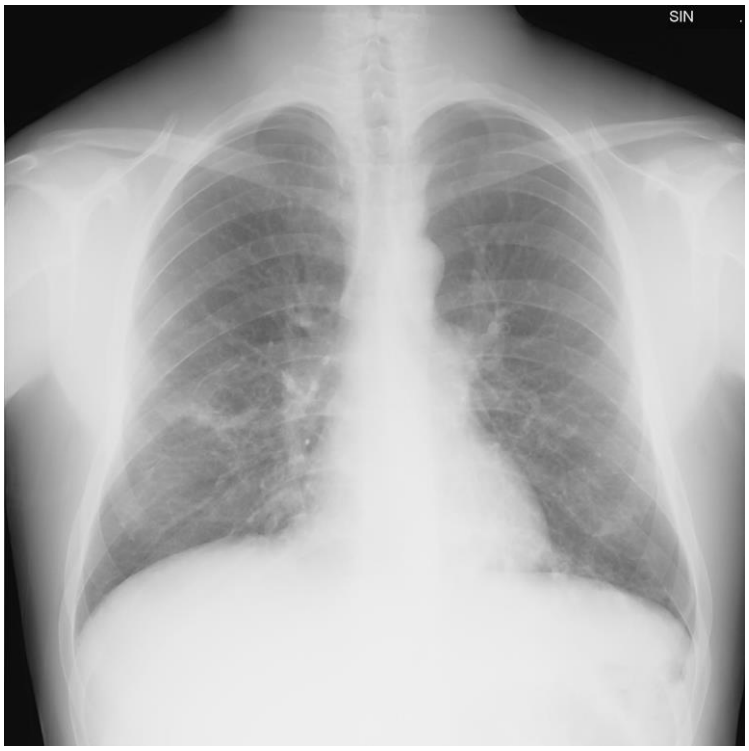

Figure 6.X-ray Medical Image

The ability to obtain images in a single location, to transmit them over a distance, and to view them remotely for diagnostic or consultative purposes has been explored extensively and is part of the more inclusive concept of telemedicine.

In many cases, the use of medical images is necessary both for an overall assessment of the patient's health and for assessing the progress of a disease.

In the example used in this study the patient performs various imaging tests, x-ray angiography, chest radiography, ultrasound imaging (XA, DX, US) among others, and also during the hospital visit, ECG signals are also acquired. These investigations are required both to resolve diagnostic doubts and to establish the severity of an already known pathology.

The availability of medical images is the basis for a correct interpretation of the patient's symptoms and is complementary to the summary of data collected.

There is, besides, the necessity to stick to medical standards of primary importance, which is for instance the Digital Imaging and Communication protocol **[DICOM]**. DICOM, thanks to the high standardization of the processes used in the medical field, allows to overcome the complexity of the sharing of clinical images and signals, and makes it possible to be fully exploited in the treatment of clinical pathologies.

DICOM is a globally recognized standard that defines the criteria for the exchange, communication and archiving of medical information, such as reports, images and videos. Specifically, DICOM uses the TCP/IP protocols to allow communication between the various systems. DICOM data can be exchanged between two different units and almost all system manufacturers use the DICOM standard to produce or modify images, such as X-ray digital images, Magnetic Resonance images, Computed tomography, ultrasound or waveforms. DICOM therefore allows interaction in the medical field between different systems manufacturers and represents the basis for storing digital images both in medical clinics and in hospitals Archive (Picture Archiving and Communication System, PACS).

The DICOM standard is common to all acquisition modalities and it is precisely a lingua franca with which all diagnostic equipment for images and signals can communicate within a modern hospital information network. Thanks to this standard protocol it is possible to be completely independent from the manufacturer of a given medical software or biomedical equipment, for the interpretation or representation of medical images. This is a great advantage for all users of the images whether they are patients, specialists or general practitioners.

In order to be able to view the radiological images hospitals use software that can interpret the standard DICOM format. There are many of these software, both paid and open source, but those used to perform a medical diagnosis, being "medical devices" must be CE marked and associated with diagnostic display monitors, which allow to visualize medical images at best, with high contrast, definition and accuracy.

On the contrary, as far as archiving and communication systems are concerned, there is no need for the CE marking, as they are systems for storing and transferring images and signals, and not medical devices.

It is important to mention how compression algorithms are also used for medical images and how compression algorithms have changed during the spread of PACS systems, lossless algorithms have always been the preferred ones for image analysis as they do not introduce artefacts within the images under study.

They are those used for storing images within PACS. Loss algorithms have also been used where it was useful to show the user images that are similar to the originals, even in the case of limited bandwidth, so DICOM moved from algorithms based on the discrete cosine transform (JPEG, 1992) to more innovative ones based on the Wavelet transform (2000). The latter is known as JPEG 2000 compression and allows for a more effective compression without apparent loss of quality.

Digital imaging in medicine has changed a lot over the years, and has become the main axis of technological change in computerized diagnostics. Since the original information is retained at the time of acquisition, the need for repetition of examinations is reduced, and this leads directly to an economic advantage and a reduction in the ionizing radiation dose given to the patient, making it easy to consult the large amount of data produced, thus increasing the ratio between benefits and costs, to the benefit of community and to the end user.

DICOM Standard permits to include several data processing information along with imaging and signal data. This data is hidden inside DICOM files and protocol messages. Data is organized in data elements, and each data element is tagged with a group and element tag, for example (0010,0010) represents the Patient Name.

The following table contains the structure of SEHR required information of a DICOM Image:

TAG	Description	Example
(0002,0010)	TransferSyntaxUID:	1.2.840.10008.1.2.4.50
(0002,0012)	ImplementationClassUID:	1.3.6.1.4.1.5962.99.2
(0002,0013)	ImplementationVersionName:	PIXELMEDJAVA001
(0002,0016)	SourceApplicationEntityTitle:	IEHR_MATE_11112
(0008,0008)	ImageType:	DERIVED\PRIMARY\INTRACARDIAC
(0008,0020)	StudyDate:	20170209
(0008,0022)	AcquisitionDate:	20170209
(0008,0023)	ContentDate:	20170209
(0008,002A)	AcquisitionDateTime:	20170209083715.680000
(0008,0030)	StudyTime:	083706.000000
(0008,0032)	AcquisitionTime:	083715.680000
(0008,0033)	ContentTime:	083715.680000
(0008,0050)	AccessionNumber:	1171012
(0008,0060)	Modality:	US
(0008,0070)	Manufacturer:	Philips
(0008,0090)	ReferringPhysicianName:	Doctor
(0008,1090)	ManufacturerModelName:	CX50
(0010,0010)	PatientName:	IEHR SAMPLE
(0010,0020)	PatientID:	1171008
(0010,0030)	PatientBirthDate:	19700806
(0010,0040)	PatientSex:	M
(0020,000D)	StudyInstanceUID:	1.3.6.1.4.1.5962.99.1.3577849546.1829541192.1575535912650.4626.0
(0020,000E)	SeriesInstanceUID:	1.3.6.1.4.1.5962.99.1.3577849546.1829541192.1575535912650.4627.0
(0020,0010)	StudyID:	123

(0020,0011)	SeriesNumber:	1
(0020,0013)	InstanceNumber:	1
(0028,0002)	SamplesPerPixel:	3
(0028,0004)	PhotometricInterpretation:	YBR_FULL_422
(0028,0006)	PlanarConfiguration:	0
(0028,0010)	Rows:	600
(0028,0011)	Columns:	800
(0028,0100)	BitsAllocated:	8
(0028,0101)	BitsStored:	8
(0028,0102)	HighBit:	7
(0028,0103)	PixelRepresentation:	0

Table 5. DICOM Results data example

The standards used in order to store images for S-EHR purposes are the following DICOM Media Standards:

- PS 3.10 Media Storage and File Format for Data Interchange
- PS 3.11 Media Storage Application Profiles
- PS 3.12 Media Formats and Physical Media for Data Interchange

3.6.1 DICOM Transfer syntax

A Transfer Syntax is a set of encoding rules able to unambiguously represent one or more Abstract Syntaxes. In particular, it allows communicating Application Entities to negotiate common encoding techniques they both support (e.g., byte ordering, compression, etc.).

It is of manifold importance the support for the following transfer syntax in order to interpreter medical images:

Transfer Syntax UID	Description
1.2.840.10008.1.2	Implicit VR - Little Endian
1.2.840.10008.1.2.1	Explicit VR - Little Endian
1.2.840.10008.1.2.2	Explicit VR - Big Endian
1.2.840.10008.1.2.5	RLE (Run Length Encoding) Lossless
1.2.840.10008.1.2.4.50	JPEG Baseline (Process 1): Default Transfer Syntax for Lossy JPEG 8 Bit Image Compression
1.2.840.10008.1.2.4.51	JPEG Extended (Process 2 & 4): Default Transfer Syntax for Lossy JPEG 12 Bit Image Compression (Process 4 only)
1.2.840.10008.1.2.4.57	JPEG Lossless, Non-Hierarchical (Process 14)
1.2.840.10008.1.2.4.70	JPEG Lossless, Non-Hierarchical, First-Order Prediction (Process 14 [Selection Value 1]): Default Transfer Syntax for Lossless JPEG Image

	Compression
1.2.840.10008.1.2.4.80	JPEG-LS Lossless Image Compression
1.2.840.10008.1.2.4.81	JPEG-LS Lossy (Near-Lossless) Image Compression
1.2.840.10008.1.2.4.90	JPEG 2000 Image Compression (Lossless Only)
1.2.840.10008.1.2.4.91	JPEG 2000 Image Compression
1.2.840.10008.1.2.4.92	JPEG 2000 Part 2 Multi-component Image Compression (Lossless Only)
1.2.840.10008.1.2.4.93	JPEG 2000 Part 2 Multi-component Image Compression
1.2.840.10008.1.2.6.1	RFC 2557 MIME Encapsulation
1.2.840.10008.1.2.4.100	MPEG-2 Main Profile Main Level
1.2.840.10008.1.2.4.101	MPEG-2 Main Profile High Level
1.2.840.10008.1.2.4.102	MPEG-4 AVC/H.264 High Profile / Level 4.1
1.2.840.10008.1.2.4.103	MPEG-4 AVC/H.264 BD-compatible High Profile / Level 4.1
1.2.840.10008.1.2.4.104	MPEG-4 AVC/H.264 High Profile / Level 4.2 For 2D Video
1.2.840.10008.1.2.4.105	MPEG-4 AVC/H.264 High Profile / Level 4.2 For 3D Video
1.2.840.10008.1.2.4.106	MPEG-4 AVC/H.264 Stereo High Profile / Level 4.2

Table 6. DICOM Transfer Syntax UID list

For -SEHR purposes it is important to use a viewer that complies with IHE Basic Image Review (BIR) Integration Profile **[BIR]**.

Average sizes of single DICOM file related to modality are reported in the following table:

Modality	Description	Matrix x	Matrix y	Bit per px	Size (Kbyte)
CD	Color flow Doppler	768	576	8	432
CR	Computed radiography	3520	4280	12	22069
CT	Computed tomography	512	512	16	512
DSA	Digital Subtraction Angiography	512	512	8	256
DX	Digital Radiography	2048	2048	12	6144
DX	Digital Radiography	1024	1024	12	1536
MG	Mammography	4608	5200	14	40950
MR	Magnetic Resonance	256	256	16	128
NM	Nuclear Medicine	70	70	12	7
PET	Positron Emission Tomography – PET	128	128	12	24
US	Ultrasound	512	512	8	256

XA	X-Ray Angiography	512	512	8	256
XA	X-Ray Angiography	1024	1024	16	2048
XA	X-Ray Angiography	2048	2048	16	8192

Table 7. Average sizes of single DICOM file

3.7 Bio-signals

A signal describes the variation of a given quantity as a function of other variables which can be time, space or both. We speak of a biomedical signal when the source that generates these quantities is a living organism.

The measurement of these quantities, the acquisition and analysis of these signals is important in the medical field because it provides useful information for the diagnosis, for the monitoring of therapeutic treatment and in the field of research. They are able to provide additional information to the specialist for a better understanding of the physical, chemical and biological processes under consideration.

Signals can be divided in:

- Spontaneously generated signals from the body
- Evoked potentials or evoked responses, which instead are signals that our body does not spontaneously generate but are evoked when it receives an outside stimulus.

A variety of signals are useful in medicine, and among others these are the most commonly used: ECG (Electrocardiogram), EMG (electromyogram), EEG (Electroencephalogram), ERG (electroretinography), also pressure Holter or Holter ECG.

In cardiology several signals are used: ECG, Holter ECG, and Pressure Holter. While the former is considered essential for patient care, the latter two are usually not considered over their entire duration as they are performed over 24 hours, a subset of the signal is extracted and characterized so as to extract significant parameters and knowledge.

The ECG exam consists of applying electrodes on the chest, wrists and ankles, and records the cardiac electrical activity bringing it back to a graphic pattern known as electrocardiogram (ECG), its reading allows the identification of possible arrhythmias as well as the presence of alterations in the electrical conduction of the heart linked, for example, to a heart attack.

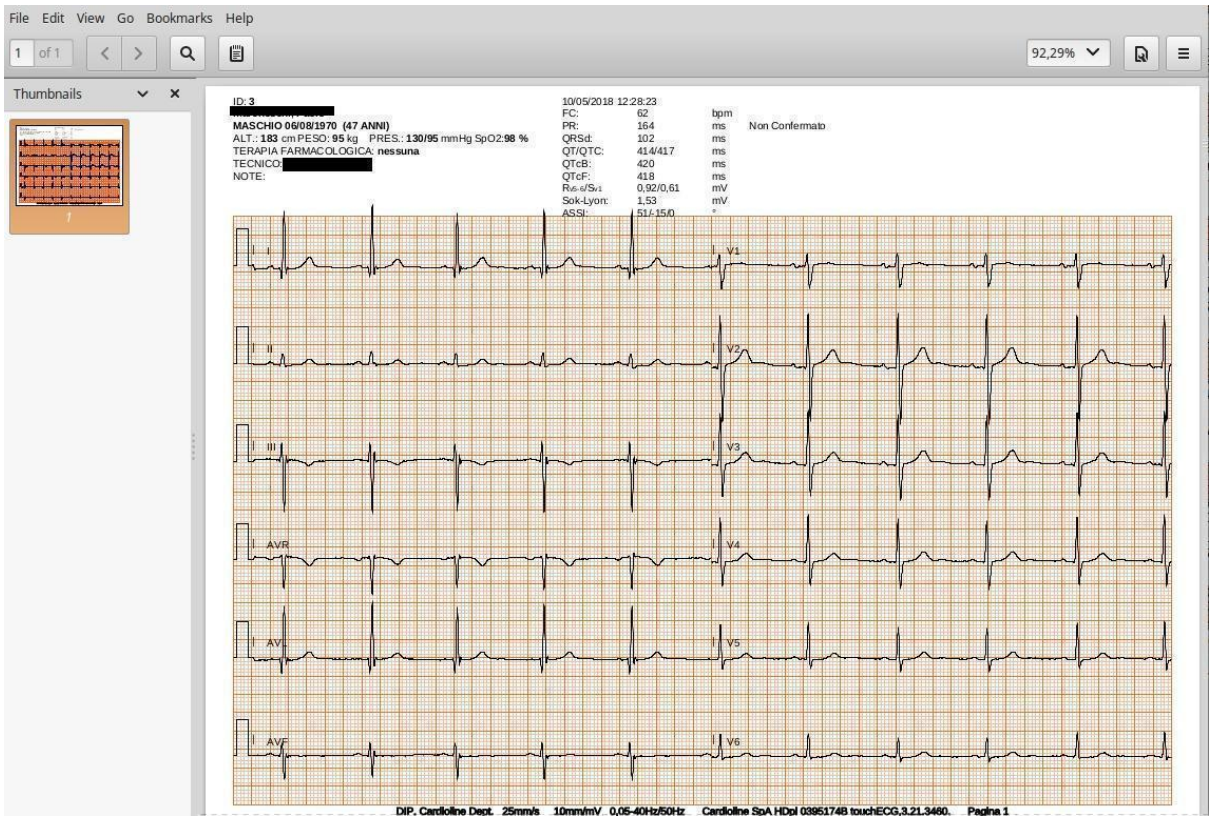

Figure 7. Example of digital ECG

Cardiological examination with ECG plays an important role in the diagnosis of major heart diseases such as arterial hypertension, ischemic heart disease, heart failure, cardiomyopathy, mitral and aortic valve disease.

The transmission of images and signals therefore plays an important role in order to correctly interpret a patient's health, the format of this data is now standardized and the bulk occupation of data is compatible with current mobile phones.

The standard used in order to store DICOM waveforms for S-EHR purposes is the following DICOM Standard: Sup 30 DICOM Waveform http://dicom.nema.org/Dicom/supps/sup30_lb.pdf

A DICOM ECG occupation has an average size of 98 Kbytes.

The following table contains the structure of SEHR required information of a DICOM ECG Waveform:

TAG	Description	Example
(0002,0002)	MediaStorageSOPClassUID:	1.2.840.10008.5.1.4.1.1.9.1.1
(0002,0003)	MediaStorageSOPInstanceUID:	1.3.6.1.4.1.5962.99.1.3577849546.1829541192.1575535912650.4611.0
(0002,0010)	TransferSyntaxUID:	1.2.840.10008.1.2.1
(0002,0012)	ImplementationClassUID:	1.3.6.1.4.1.5962.99.2
(0002,0013)	ImplementationVersionName:	IEHR001

(0002,0016)	SourceApplicationEntityTitle:	IEHR_11112
(0008,0012)	InstanceCreationDate:	20191129
(0008,0013)	InstanceCreationTime:	124129
(0008,0016)	SOPClassUID:	1.2.840.10008.5.1.4.1.1.9.1.1
(0008,0018)	SOPInstanceUID:	1.3.6.1.4.1.5962.99.1.357784 9546.1829541192.157553591 2650.4611.0
(0008,0020)	StudyDate:	20191129
(0008,0023)	ContentDate:	20191129
(0008,002A)	AcquisitionDateTime:	20191129123957
(0008,0030)	StudyTime:	123957
(0008,0033)	ContentTime:	123957
(0008,0050)	AccessionNumber:	1171010
(0008,0060)	Modality:	ECG
(0008,0070)	Manufacturer:	Mortara Instruments Inc.
(0008,0090)	ReferringPhysicianName:	Michele Emdin
(0008,1030)	StudyDescription:	Resting 12-lead ECG
(0008,1090)	ManufacturerModelName:	ELI280
(0010,0010)	PatientName:	IEHR
(0010,0020)	PatientID:	1171008
(0010,0030)	PatientBirthDate:	19700806
(0010,0040)	PatientSex:	M
(0018,1000)	DeviceSerialNumber:	SN000000
(0018,1020)	SoftwareVersions:	2.2.1
(0020,000D)	StudyInstanceUID:	1.3.6.1.4.1.5962.99.1.357784 9546.1829541192.157553591 2650.4612.0
(0020,000E)	SeriesInstanceUID:	1.3.6.1.4.1.5962.99.1.357784 9546.1829541192.157553591 2650.4613.0
(0020,0010)	StudyID:	456
(0020,0011)	SeriesNumber:	1
(0020,0013)	InstanceNumber:	1
(0020,0060)	Laterality:	R
(0032,1030)	ReasonForStudy:	Followup
(0032,1060)	RequestedProcedureDescription:	Resting ECG

(0038,4000)	VisitComments:	Comments
(5400,1004)	WaveformBitsAllocated:	16
(5400,1006)	WaveformSampleInterpretation:	SS

Table 8. Structure of S-EHR required information of a DICOM ECG Waveform

3.8 Health data for research

The aim of this project is to support health research, with an easier way of deployment and conduction of research protocols and studies, inspired by the Open Science approach.

3.8.1 Open Science

Open Science constitutes a "new approach to the scientific process based on cooperative work and new ways of diffusing knowledge by using digital technologies and new collaborative tools."[2]

Unlike traditional science and technology practices, which focus largely on publishing research results in scientific journals, Open Science focuses on sharing and (re-)using all the knowledge and data available during the research process. This includes, inter alia, citizens' most active participation in the citizen science process, open access to peer-reviewed scientific publications and scientific research data, peer reviews and metrics to measure research.

Open Science aims to promote transparency and reproducibility of results, increase and widen the diffusion of knowledge and may overall accelerate scientific progress and innovation.

At the same time, in order to maximize the benefits of Open Science, there are several ethical, legal and social challenges that need to be addressed. Such challenges include:

- possible development of new forms of malpractice
- risk of diluting research results of high quality (emergence of fake science)
- risk of new bias in the assessment of the quality of the research output and impact notably via the alternative metrics
- issues related to content-mining, the privacy of data subjects, potential conflicts with intellectual property and data protection rights
- the emergence of questionable dissemination/publication practices like the proliferation of predatory journals that exploit the open access publishing business model.

The strong connection between Open Science and research integrity has been underlined in the Council conclusions on research integrity, where the Member States recognise "the importance of open science as a mechanism for reinforcing research integrity, while, at the same time, research integrity contributes to open science."

The decision to create a **European Open Science Cloud** (EOSC), a *federated ecosystem of research data infrastructure*, was taken under the European Union's Digital Agenda (2015), followed by an EOSC implementation roadmap in 2018, by a series of dedicated H2020 Calls in 2018-2020 to start prototyping

[2] Horizon 2020 Work Programme 2018-2020 16. Science with and for Society

the EOSC and the launch of an interim governance structure at the end of 2018. This governance is at work to help in the transition to the EOSC Post 2020.

All research builds on former work and depends on scientists' possibilities to access and share scientific information. In the context of Open Science and Responsible Research and Innovation the European Commission therefore strongly supports the optimal open access to and re-use of research data (considering e.g. robust opt-outs). As a concrete action the EC has extended the Open Research Data Pilot to cover all areas of Horizon 2020 (as of the 2017 Work Programme). This will result in more data becoming available for reuse. However, it is necessary to adopt further actions to reach the Commission's overall objective of findable, accessible, interoperable and re-usable (FAIR) data by 2020[3]

Open Science policy of the EU (https://ec.europa.eu/research/openscience) concerns all aspects of the research cycle, from scientific discovery and scientific review to research assessment, publishing and outreach; its cornerstone being open access to publications and research data.

Since 2016, the Commission organises its open science policy according to eight 'ambitions':

- Open Data: FAIR (Findable, Accessible, Interoperable and Re-usable data) and open data sharing should become the default for the results of EU-funded scientific research.
- European Open Science Cloud (EOSC): a 'federated ecosystem of research data infrastructures will allow the scientific community to share and process publicly funded research results and data across borders and scientific domains.
- New Generation Metrics: New indicators must be developed to complement the conventional indicators for research quality and impact, so as to do justice to open science practices.
- Future of scholarly communication: all peer-reviewed scientific publications should be freely accessible, and the early sharing of different kinds of research outputs should be encouraged.
- Rewards: research career evaluation systems should fully acknowledge open science activities.
- Research integrity: all publicly funded research in the EU should adhere to commonly agreed standards of research integrity.
- Education and skills: all scientists in Europe should have the necessary skills and support to apply open science research routines and practices.
- Citizen science: the general public should be able to make significant contributions and be recognised as valid European science knowledge producers.

At global level the EU supports bodies and platforms such as Plan S, the **Research Data Alliance** (RDA), the ISC's Committee on Data of the International Science Council (CODATA), as well as efforts of the OECD, UN and the G20/G7/Carnegie Groups, with the aim of accelerating the transition to full and immediate open access to scientific publications and of making research data as open and reusable as possible, as soon as possible.

3.8.2 Research protocol

Different kinds of scenarios may be described in the clinical research field: clinical protocol feasibility, patient identification and recruitment, clinical trial execution and adverse event reporting.

[3] SwafS-04-2018: Encouraging the re-use of research data generated by publicly funded research projects

In this project we are addressing patient identification/recruitment and clinical trial execution, still considering the need to manage interactions among many information systems in both domain, patient care and clinical research, currently using different schemas and terminology systems.

The collective international efforts of multiple organizations (such as ISO, HL7, CDISC, etc.) currently focuses on defining the various standards required to achieve computable semantic interoperability and to bridge the gap between clinical research and patient care.

3.8.2.1 Retrospective studies

A retrospective study looks backwards and examines exposures to suspected risk or protection factors in relation to an outcome that is established at the start of the study.

The retrospective cohort study compares groups of individuals who are alike in many ways but differ by a certain characteristic (for example, female nurses who smoke and ones who do not smoke) in terms of a particular outcome (such as lung cancer). Data on the relevant events for each individual (the form and time of exposure to a factor, the latent period, and the time of any subsequent occurrence of the outcome) are collected from existing records and can immediately be analysed to determine the relative risk of the cohort compared to the control group.

Many valuable case-control studies, such as Lane and Claypon's 1926 investigation of risk factors for breast cancer, were retrospective investigations.

Most sources of error due to confounding and bias are more common in retrospective studies than in prospective studies. For this reason, retrospective investigations are often criticised. If the outcome of interest is uncommon, however, the size of prospective investigation required to estimate relative risk is often too large to be feasible. In retrospective studies the odds ratio provides an estimate of relative risk. You should take special care to avoid sources of bias and confounding in retrospective studies.

3.8.2.2 Prospective studies

A prospective study watches for outcomes, such as the development of a disease, during the study period and relates this to other factors such as suspected risk or protection factor(s).

The prospective study looks forward, enrolling patients unaffected by the outcome and observing them to see whether the outcome has occurred.

The study usually involves taking a cohort of subjects and watching them over a long period. The outcome of interest should be common; otherwise, the number of outcomes observed will be too small to be statistically meaningful (indistinguishable from those that may have arisen by chance). All efforts should be made to avoid sources of bias such as the loss of individuals to follow up during the study. Prospective studies usually have fewer potential sources of bias and confounding than retrospective studies.

Prospective investigation is required to make precise estimates of either the incidence of an outcome or the relative risk of an outcome based on exposure.

3.8.2.3 Eligibility criteria

Each research protocol design embeds a mandatory specification on features of subjects to be studied, expressed as "eligibility criteria" or simply "selection criteria".

Criteria are formalized as one or more expressions to model the relationships between multiple concepts embedded within eligibility criteria statements, related to collected data.

Criteria can be represented using a formal query language designed to operate on any given model of patient data ("clinical information model") in order to build queries running on EHRs or CDWs (Clinical Data Warehouses).

An example of eligibility criteria is reported in Scenario 3 description, hereby expressed:

1. Gender = FEMALE
2. Pathologies (list) contains hypertension
3. Medical Therapy (list) contains ACE inhibitors.

4 REFERENCE SCENARIOS

The present chapter reports the InteropEHRate reference scenarios, where a sample usage of the software applications (e.g. “S-EHR App”) that are part of the InteropEHRate standard architecture and of additional applications (e.g. “Knowledge Management Tool”) that are part of the InteropEHRate framework are described. In particular, the scenarios S0, S1, S2 and S3 refer to generic software applications covered by the InteropEHRate standard architecture, regardless of the specific implementations, while scenario S4 refers to specific software to be implemented by the InteropEHRate project and to be released as part of the InteropEHRate framework in addition to the reference implementation of InteropEHRate standard architecture.

4.1 Scenario S0 - Initial S-EHR feed

The main purpose of this scenario is to describe how a citizen can download the first content of his/her S-EHR importing his/her health records from a healthcare provider/organisation using Internet communication.

The same process can be used to update the content of his/her S-EHR importing his/her health records from a health organisation using Internet communication.

4.1.1 Preconditions and assumptions

In order to describe health-related processes pertinent to the project's objectives, two main aspects will be considered:

1. Clinical aspects and health-status of the patient
2. IT aspects and description of IT ecosystem around patient and healthcare provider

For each aspect, few assumptions and preconditions are specified in order to represent the common background on which scenarios are operating.

4.1.2 Clinical preconditions and assumptions

Generic Abstract description:

A person suffers from a chronic disease and he/she is regularly followed-up by a referral centre (a healthcare organization) of his/her residence country, where he/she regularly undergoes clinical tests and visits.

Narrative description

A male patient suffering of chronic heart failure is regularly followed-up at the outpatient clinic of a clinical centre in Italy, where he undergoes every six months to an EKG and blood tests, and yearly echocardiogram, cardiopulmonary exercise testing and 24-h Holter monitoring, together with cardiological consultation.

He is currently assuming a drugs-based therapy treatment, in self-administration, with the following drugs:

- bisoprolol 10 mg o.d.,
- sacubitril/valsartan 49/51 mg b.i.d.,
- eplerenone 25 mg o.d.

4.1.2.1 IT and Data Protection preconditions and assumptions

A. The Patient owns a smartphone/tablet and installs a S-EHR app on it

B. The Patient gave his/her approval to the S-EHR app to store and manage his/her personal health data and to share them only with people explicitly authorized by the patient, and for periods authorized by the patient.

C. The Patient had a previous encounter with a Healthcare Organization supporting the InteropEHRate protocol for remote access to the patient's health records maintained by the Organization.

D. Each healthcare organization involved in this scenario has a digital identity that is trusted by the S-EHR app.

E. The Healthcare Organization is registered in eIDAS as an Entity. [eIDAS for service providers][eIDAS SAML AttributeProfile]

F. The maintainer of the S-EHR app received from the healthcare organisation of the previous point the URI to be preloaded the S-EHR App, to access the Hospital's Interface of S-EHR.

G. All the exchanged health information is related to its producer/author.

H. The Healthcare provider cannot repudiate the produced health information.

4.1.3 Scenario Description

1) The patient opens his S-EHR and decides to import in the S-EHR some health-related information from his reference Hospital.
    a) The patient accesses the list of Hospitals connected to the S-EHR and selects his reference Hospital;
    b) The patient chooses if to download automatically in the S-EHR App every new or updated HR data from the selected hospital, or to manually approve any download of new or updated data.
2) The hospital receives the request to download the HR of the person
    a) Hospital requests the identification of the patient using eIDAS, sharing a minimal identification dataset with the national eIDAS identity provider;
    b) the patient identifies himself on eIDAS using the smartphone;
    c) by invoking the R2D service, the patient implicitly authorizes the hospital to collect and transmit health-related data of the patient to S-EHR;
    d) Hospital writes this operation on an audit log, representing both eIDAS authentication and consent for data sharing.
3) After the positive identification of the patient, the Hospital's EHR starts collecting information on the patient and prepares a list of encounters with associated information that can be downloaded on S-EHR. When available the list is downloaded by the S-EHR.
    a) HR data are converted into S-EHR format and translated in the patient's language, and stored in R2D server;
    b) The Hospital publishes the list of encounters and IPS with the patient as subject, with date, type of access;
    c) Every encounter contains one or many items importable in S-EHR (reports, images, prescriptions, vital signs, etc.).

4) The patient selects one or many, or every, encounter to be downloaded in S-EHR, and the patient starts to download documents and data related to the selected encounter clicking on the button "Download" of the S-EHR.
    a) The download may request some time to be completed, also many hours, depending on the amount of information to be transferred and available bandwidth.
    b) Health data with large size, e.g. images and movies related to instrumental examinations and procedures, could not fit the available memory of the smartphone, thus can be transmitted as a reference to the source information (URL/URI) maintained by the source hospital/healthcare provider. The reference to the source can be used later to download the large amount of data on the patient's phone or provided, on patient's request, to other healthcare providers to support the patient's care. On S-EHR this data referred with a link are specifically signalled to the patient with a different notation (text, colour, icons).
    c) Once the download is completed, on the S-EHR the patient is able to view every data downloaded, associated with every encounter and filtered by data and type.
5) The S-EHR App periodically checks for new/updated items published by the selected healthcare provider, and performs selected operations (according to point 1.c) on S-EHR.

4.1.4 Postconditions

The patient is able to delete data on the S-EHR that are obsolete or not needed or simply considered not useful for him/her. The patient can also update information on the S-EHR, manually entered or collected by connected devices (body weight scale, blood pressure monitor, body temperature thermometer, etc.).

The patient can browse on S-EHR the health data that was too large to be downloaded specifically, and, according to memory availability, start downloading them on the phone. Some amount of time will be needed also to transfer the data from the source to the patient's phone.

The patient is able to enter in S-EHR drugs assumptions in self-administration, symptoms, vital signs

4.2 Scenario S1 - Medical visit abroad

The main purpose of this scenario is to show how a citizen and an HCP may exchange clinical data through their devices, using only a "local" link (called Device to Device connection), not involving the use of internet and cloud storage.

A common device owned by a patient is represented by a smartphone (or tablet), on iOS or Android platform, so a first assumption is that the patient described in the scenario owns a mobile device, fully functional and with an installed dedicated app capable to support every aspect of data exchange, and related operations, that will be described in the following chapters. Such an app is called S-EHR (Smart-EHR) Mobile App, or more simply S-EHR.

The device used by the HCP may be a desktop or portable computer or a mobile device, enabled with a Bluetooth adapter.

Exchanged information may be maintained, by the HCP and/or his/her healthcare organization, for a certain amount of time (depending on national regulations and citizen's consent) or deleted immediately after device links are closed.

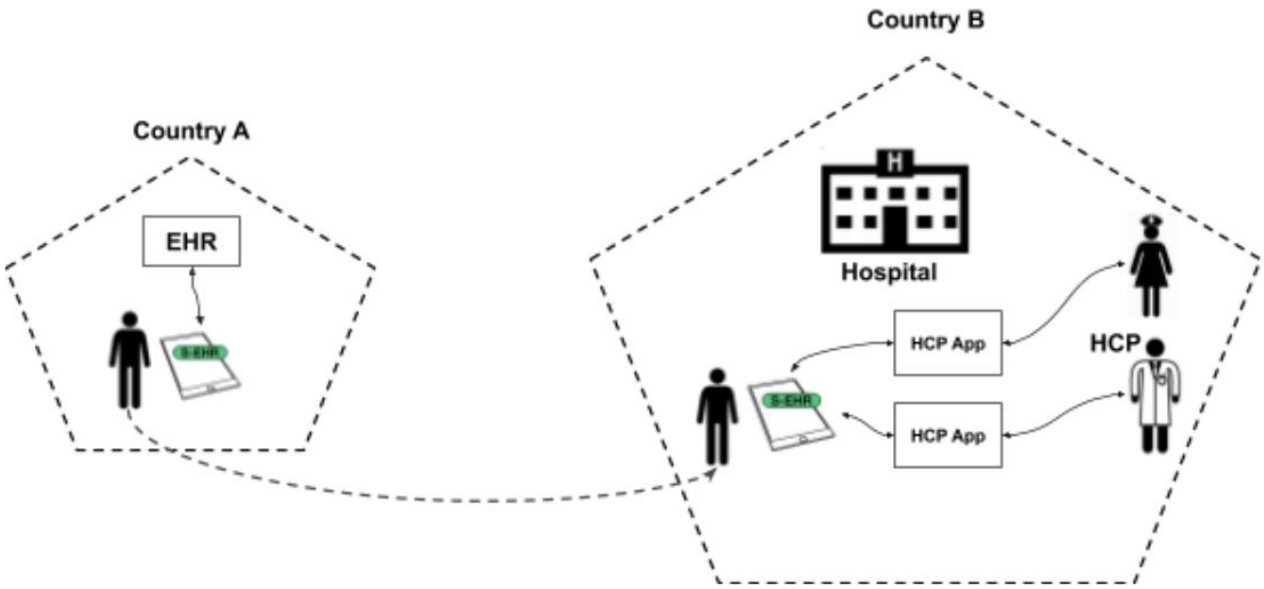

Figure 8. Scenario S1 - Medical visit abroad

4.2.1 Preconditions and assumptions

In order to describe health-related processes pertinent to the project's objectives, two main aspects will be considered:

1. Clinical aspects and health-status of the patient
2. IT aspects and description of IT ecosystem around patient and healthcare provider

For each aspect, few assumptions and preconditions are specified in order to represent the common background on which scenarios are operating.

4.2.1.1 Clinical preconditions and assumptions

Generic Abstract description: A person suffers from a chronic disease and he/she is regularly followed-up by a referral centre (a healthcare organization) of his/her residence country, where he/she regularly undergoes clinical tests and consultations.

A Belgian male suffers from chronic ischemic heart failure (CHF) and atrial fibrillation (AF), both chronic and highly prevalent diseases, in the past 8 years. Because of progressive worsening of the left ventricular systolic function, he was submitted to ICD implantation 3 years ago.

The patient is regularly followed-up at the outpatient clinic of a tertiary centre in Belgium, where he undergoes twice a year EKG and blood tests (including NT-proBNP), and yearly, echocardiogram, cardiopulmonary exercise testing, device control and 24-h Holter monitoring, together with cardiological consultation.

He is currently receiving:

- bisoprolol 10 mg o.d.,
- sacubitril/valsartan 49/51 mg b.i.d.,
- eplerenone 25 mg o.d.,
- atorvastatin 20 mg o.d.,

- rivaroxaban 20 mg o.d.

The patient moved abroad (in Greece), planning a stay of 2 years, during which he progressively complained of mild lower limbs edema, dyspnoea and reduction in exercise tolerance.

4.2.1.2 IT and Data Protection preconditions and assumptions

A. [Sub-Scenario] The Patient owns a S-EHR app, installed on his smartphone, and pertinent consent is granted.

B. [Sub-Scenario] The S-EHR app may store a representation of a digital identity of the citizen that is trusted by the healthcare providers and may be used to identify the patient without the ID card (see step 5).

C. [Sub-Scenario] The Patient gave his/her consent (informed consent) to the S-EHR app to store and manage his/her personal health data and to share them only with people explicitly authorized by the patient, and for periods authorized by the patient.

D. [Scenario 0] The data about the health history (including measurements of vital-signs and bio-signals) and current pharmacological therapy of the patient has been imported from the EHR system of his referral centre to the S-EHR of the patient.

E. HCP uses the software “HCP App”, able to access a S-EHR app by using a Device to Device connection.

F. [Sub-Scenario] Each single HCP involved in this scenario has a digital identity issued by a legal national or local authority, recognized by the S-EHR infrastructure, and associated in a trusted way to his/her qualification.

G. Each HCP involved in this scenario works in a setting/room where he/she uses an HCP workstation (tablet, smartphone, PC, Mac) running the HCP App. Different rooms imply different HCP workstations. The workstation is provided with an interface device/peripheral that allows linkage of the HCP app with the S-EHR.

H. Each healthcare organization involved in this scenario has a digital identity that may be represented within the HCP app and is trusted by the S-EHR app.

I. Every action performed on health data by means of the S-EHR App or HCP app is registered (logged) by the respective app and associated permanently with the unique identification of the involved patient and (HCP or patient) author/actor.

J. The patient has configured on his/her S-EHR the data he/she desires to hide to HCPs. Such hidden data will not be exchanged with the HCP.

K. [Scenario S4] The InteropEHRate data integration platform is available, to support the conversion and translation of structured and unstructured information, and it is configured for the healthcare provider. See Scenario 4.

L. All the information is related to its source/producer/author, where source is the person or organisation that provided the info (not necessarily the original author/producer) and takes (i.e., is accountable) of the information content; Producer organisation is the organisation that the author belongs to; and Author is the person (or device, in case of automatic production) that produced the information.

M. The producer/author (Patient or HCP) of the information stored on the S-EHR cannot repudiate it.

N. The data contained in the S-EHR are safe and integral and represent a legal consistency on which HCPs and patients rely for diagnosis/treatment/prognosis/prevention.

O. The HCP can verify the origin and validity of the information shared by the citizen.

P. There is a mutual trust between Patient and HCP.

4.2.2 Scenario Description

While abroad, a patient decides to refer to a local physician, for a visit related to his/her health situation. He asks for an appointment for a visit and, on the agreed day, he goes to the hospital. The patient is admitted to the healthcare facility.

1) The HCP1 asks the patient if he/she owns a S-EHR. As the patient answers yes, the HCP1 asks him/her to enable Bluetooth connection to his/her Smart Device, and pair with the HCP1 terminal for the identification by means of the D2D protocol.

2) As soon as the connection is successfully completed, the patient may see on the screen of his/her smartphone the data describing the identity of the Health Organization (name, address, etc.) of the HCPs.

3) The patient recognizes that the description corresponds to the organization where he/she is at that moment, so he/she approves the connection to share his/her identifying data with the HCP1.

4) As soon as the connection has been approved by the patient, the HCP1 may see on the screen of his/her HCP app the name, surname, date of birth, location of birth, gender, country of residence (corresponding to the identity document) and social security number (or equivalent identifying data).

5) The HCP1 asks the citizen for his/her identity document and compares it with the information shown on the HCP App.

6) As the data is correct, the HCP1 confirms, using the HCP app, the identity of the patient. If the data is not corresponding, Scenario stops here.

7) HCP1 contextually (i.e. implicitly) asks the citizen for a temporary (limited to this encounter) consent for the healthcare organization of the HCPs to:

- download data from the S-EHR app
- upload the updated/acquired data back to the S-EHR app
- store, for the amount of time required and allowed from the national law, the downloaded data on the systems controlled by the authorized healthcare organization.

8) The admission data is stored by the HCP app for future traceability.

9) Using his/her phone, the patient sees on the S-EHR the description of the healthcare organization that just identified him/her.

10) He sees on screen the request for consent for the admitting organization to download data from the S-EHR app and upload the updated/acquired data back to the S-EHR app.

11) By means of the S-EHR the patient gives his/her consent, implicitly giving the view/transmission permissions. Every other HCP scoped by the Healthcare Organization and involved in patient care/treatment are authorized to access S-EHR

12) The consent is transmitted to the HCP App and recorded by it for future traceability.

13) A preconfigured (by the HCP on the HCP App) dataset of patient's data are transferred from the patient's S-EHR app to the HCP App in a few seconds (5 to 10), up to a couple of minutes if the amount of requested data is relevant (10-20 Mb). Admission is now completed, and the patient moves on to consultation. From this on, the patient interacts with HCP2.

14) Downloaded patient's data may be visualized, using the HCP App, by the HCP2, that is currently authorized by the healthcare organization to treat the data of that patient (i.e. involved in the patient's treatment process).

15) Downloaded patient's data are translated into HCPs natural language. HCPs natural language is the one officially related to the Healthcare provider, and optionally the HCP may manually select a different preferred language. Are also downloaded from S-EHR:

15.a) personal evaluation of symptoms, entered by the patient

15.b) body weight measurements of the last week, entered by the patient

16) HCP2 measures vital signs, body weight, BP, pulse, respiratory rate, SPO2, Temp, AVPU and alertness. Data is entered in the HCP App.

17) During the evaluation, the S-EHR is connected to the HCP App, and the newly collected data (vital signs, body weight, BP, pulse, respiratory rate, SPO2, Temp, AVPU and alertness) are transmitted back to the patient's S-EHR app.

a) HCP2 asks for a chest X-ray at local imaging facilities, to be executed immediately.

b) The HCP2 accompanies the patient to execute the requested chest X-Ray and then in a waiting room where he/she can wait to have a specialist evaluation.

18) Another HCP, HCP3, is assigned to evaluate the patient in a different room.

a) Data produced by the HCP1 and HCP2 during the evaluation are collected in the HCP App and available for HCP3.
b) During the evaluation of HCP3, S-EHR is able to exchange data with the HCP App.

19) Once the patient is in the visiting room, the consulting HCP3 asks the patient the reasons for his need for the visit. The reason is entered on the HCP App.

20) HCP3 starts to visit the patient: download the patient's history from the S-EHR app (translated into the HCPs hospital official language) and import it into the HCP App.

21) HCP3 updates on the HCP App the patient's clinical history reporting new symptoms.

22) HCP3 downloads from S-EHR vital signs and measures from the previous month, compares them with current values (collected by HCP2) and recognizes a relevant gain in body weight.

23) HCP3 asks for a chest X-ray at local imaging facilities, to be executed immediately.

a) HCP3 downloads from the S-EHR app images of a previous exam, performed in Belgium the year before;

b) the chest X-ray exam is performed and its images and report is entered on the HCP App;

c) HCP3 compares the previous exam with the current exam and recognizes signs of increased interstitial congestion.

24) The HCP3 retrieves information from S-EHR on prescribed drugs.

a) HCP3 read about a previous attempt to titrate sacubitril/valsartan, which had failed because of the deterioration of renal function. Given the worsening heart failure signs and symptoms, he decides to initiate a low dose of diuretic (furosemide 25 mg).

25) The HCP3 finalizes the visit by compiling an evaluation report on the HCP app.

25.a) a treatment plan is compiled, that includes a next visit at 3 months from the current and blood analysis.

26) The HCP3 provides a drug prescription for furosemide 25 mg on the HCP app.

27) The HCP3 uploads data from the HCP App to S-EHR (with a consistent identification of HCP responsible for entered data) using the D2D connection already established from the HCP3 workstation's Terminal:

a) image and report of chest X-rays;

b) diagnostic conclusions, evaluation report and treatment plan;

c) drug prescription for furosemide 25 mg;

4.2.3 Postconditions

The temporary consent of the citizen for data exchange automatically expires at the end of the day. The consent for the storage of the data continues.

If large images or data are generated during the visit, a reference to the source information can be uploaded on the S-EHR instead of the source information. This information can be downloaded by the patient later on according to his/her needs and available memory on the S-EHR smartphone.

The citizen uses S-EHR to look at the medication management.

4.2.4 Dataset

In the following section, is reported a dataset of values useful for the evaluation of Chronic Heart Failure (CHF) patients.

General Data:

- Name, Surname, gender
- Date of Birth [place]
- Allergies (transfusion related reactions), intolerance
- Main Chronic Conditions
    - Ischemic heart disease
    - Heart failure
    - Pulmonary disease
    - Abnormal kidney function
    - Abnormal liver function
    - Previous major surgery

- Active malignancy
- Current Medications [previous medications]
- [Backup Contacts]

History:

- Reports of past cardio hospitalizations (discharge report, pdf and structured data) (optional)
- previous visits (pdf and structured data):
  - diagnosis
  - treatment plan (next visits, exams, etc)
  - prescribed drugs

Vital parameters for the last ambulatory visit including:

- weight (Kg), height (cm)
- blood pressure (mmHg),
- resting heart rate (bpm),
- peripheral edema (presence/absence),
- signs of lung congestion and/or pleural effusion (presence/absence),
- sign of ascites (presence/absence) (optional),
- jugular vein distension (presence/absence) (optional);
- Cardiac & lung auscultation (normal/abnormal) (optional)

Latest EKG:

- rhythm (eg sinus rhythm, atrial fibrillation, paced, etc.),
- heart rate (bpm),
- PR,
- QRS intervals (msec) (optional)
- QTc intervals (msec)(optional),
- left bundle branch block (presence/absence) (optional);

Latest echocardiogram:

- LVEF (%),
- left ventricular end systolic/diastolic volume (mL) (optional),
- grade of diastolic dysfunction (0/1/2/3) (optional),
- estimated pulmonary artery pressure (mmHg) (optional),
- degree of mitral and tricuspid regurgitation (no, mild, moderate, severe);

Latest chest X-ray:

- report and images;

Latest Holter monitoring (optional):

- mean heart rate (bpm),
- number of premature ventricular beats,
- number of ventricular tachycardias (with max length in bpm),

- atrial fibrillation (presence/absence);

Latest bio-humoral values:

- hemoglobin (g/dl),
- white blood count,
- creatinine (mg/dl),
- eGFR (ml/min/1.73m2),
- AST,
- ALT,
- GTT,
- bilirubin,
- BNP/NT-proBNP (ng/L);

Latest cardiac magnetic resonance including:

- LVEF (%),
- left ventricular end systolic/diastolic volumes (mL),
- late gadolinium enhancement (presence/absence).

4.2.5 Dataset for upload

list of section from Medical Visit Summary with the associated LOINC code:

- Allergies 48765-2
- History of Medication use Narrative 10160-0
- Problem list - Reported 11450-4
- History of Procedures Document 47519-4
- Relevant diagnostic tests/laboratory data Narrative 30954-2
- Social history 29762-2
- Vital signs 8716-3
- Advance directives 42348-3
- History of Hospitalizations+Outpatient visits Narrative 46240-8
- History of family member diseases Narrative 10157-6
- Functional status assessment note 47420-5
- History of Immunization Narrative 11369-6
- Mental status Narrative 10190-7
- History of medical device use 46264-8
- Diet and nutrition Narrative 61144-2
- Plan of care note 18776-5
- visit discharge DX 11535-2
- prescribed medications 10183-2

4.3 Scenario S2 - Emergency access

The purpose of this scenario is to show how HCPs may access and contribute to Patients' health data when a S-EHR is not available or when the Patient cannot use it, in particular in an emergency situation.

The importing functionality described in the scenario may also be useful in other, non-emergency, situations, to overcome the limitations of a personal phone memory that may not contain the complete set of health-related data belonging to a person. When not in an emergency, a different identification mechanism will be used.

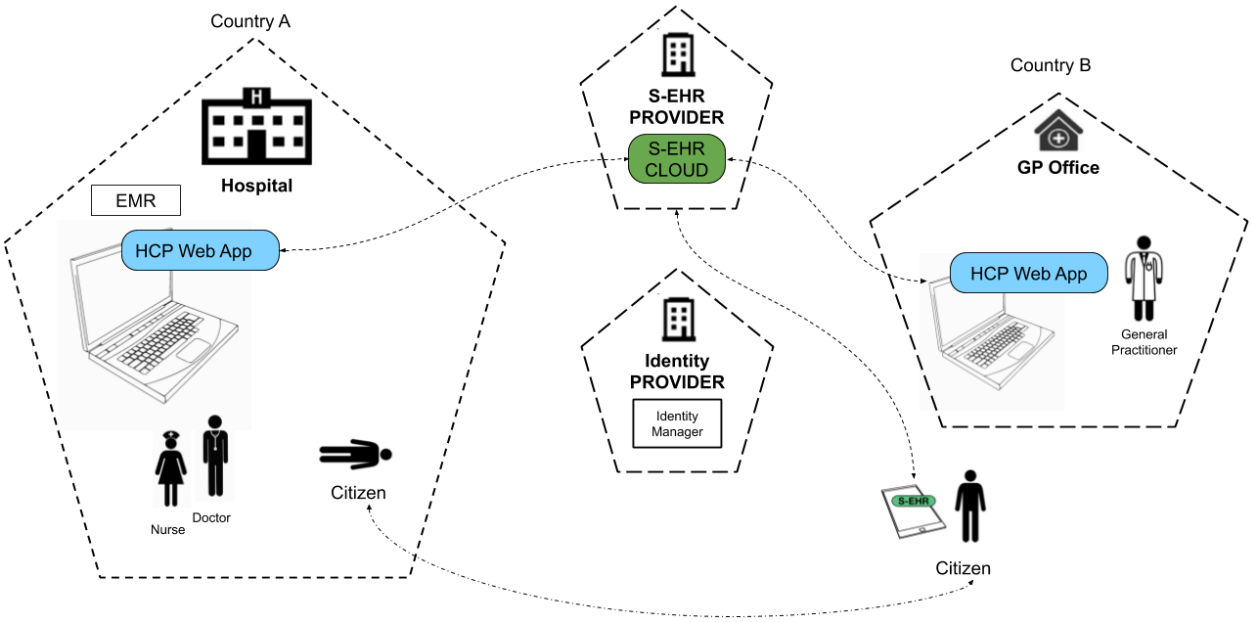

Figure 9.Scenario S2 - Emergency access

4.3.1 Preconditions and assumptions

In order to describe health-related processes pertinent to the project's objectives, two main aspects will be considered:

1. Clinical aspects and health-status of the patient
2. IT aspects and description of IT ecosystem around patient and healthcare provider

For each aspect, few assumptions and preconditions are specified in order to represent the common background on which the scenario is operating.

4.3.1.1 Clinical preconditions and assumptions

Generic Abstract description: A person is abroad and he/she complains symptoms requesting immediate treatment.

Example scenario: A 56 years old male Romanian person is abroad in Belgium, where he complains of nausea, vomiting and mild abdominal pain. The patient is affected by type 2 diabetes treated with insulin.

4.3.1.2 IT and Data Protection preconditions and assumptions

A. [Sub-Scenario] The Patient owns a S-EHR, installed on his/her smartphone, and pertinent consent is granted.

B. [Sub-Scenario] The Patient gave his/her consent (informed consent) to the S-EHR to store and manage his/her personal health data on the S-EHR demographic data and a photo of the patient's face is stored to identify the patient.

C. [Scenario S0] The data about the health history and current pharmacological therapy of the patient have already been imported from the EHR system of his referral centre to the S-EHR of the patient.

D. [Sub-Scenario] The Patient has activated and given his/her consent to the functionality that automatically replicates the content of his/her S-EHR on the S-EHR Cloud and (vice versa) copies on the S-EHR any new data uploaded by authorized actors on the S-EHR Cloud. The alignment happens automatically each time that the smartphone of the Patient is connected to the internet. Also identity data, including a photo of the face of the patient, are uploaded in the S-EHR cloud, to identify the patient

E. The content of the Patient's S-EHR is currently aligned with the content of the S-EHR Cloud.

F. The kind of data included in the emergency data set is the same defined by the International Patient Summary.

G. At the specific moment, the patient has no access to the device containing his\her own S-EHR.

H. The patient has an emergency identity token.

   a. S-EHR generates a unique emergency code (also called "emergency identity token") and a corresponding QR-code that has been associated with that patient. The patient prints the QR-Code on paper and brings the code with her or him in her or his wallet.

   b. the token is used in emergency by HCPs to access to the data contained in S-EHR Cloud

   c. the token cannot be used to access to data contained in patient's smartphone S-EHR app

I. [Sub-Scenario] The patient gave his/her consent to the emergency identification by means of an emergency identity token and to share her or his health data stored on the S-EHR Cloud with HCPs in an emergency.

J. [Sub-Scenario] Each single HCP involved in this scenario has a digital identity issued by a legal national or local authority or healthcare provider recognised by the Hospital and sent to the S-EHR Cloud infrastructure, and associated in a trusted way to his/her qualification.

K. Each HCP involved in this scenario works in a setting/room where he/she uses an HCP workstation (tablet, smartphone, PC, Mac) running the HCP App. Different rooms imply different HCP workstations. The workstation is provided with a network connection with the S-EHR cloud and suitable device to read the emergency token.

L. Each healthcare organization involved in this scenario has a digital identity that may be represented within the HCP app and is trusted by the S-EHR app.

M. Every action performed on the S-EHR Cloud by an author/actor is registered (logged) by both the S-EHR Cloud and the HCP App and associated permanently with the unique identification of

the involved patient and HCP author/actor. This includes obvious "special actions" like accessing an Emergency Dataset.

N. The organization (hospital) has its own regulations in terms of HCPs' access to the data according to each HCP role in the hospital as well as mechanisms to check and control access.

O. All the information is related to its producer/author, both retrieved from and uploaded on the S-EHR cloud.

P. The HCP cannot repudiate the produced information by her or him.

Q. The Patient cannot repudiate the produced information by her or him.

R. The data contained in the S-EHR cloud are whole and not altered in any form, and represents a legal consistency on which it relies for diagnosis/treatment/prognosis/prevention or if any alteration happened the Patient and HCPs will not be able to read the altered data.

S. The HCP can verify the origin and validity of the information shared by the citizen.

T. There is a mutual trust between Patient and HCP

U. [Scenario S4] The InteropEHRate data integration platform is available, to support the conversion and translation of structured and unstructured information, and it is configured for the healthcare provider. See Scenario 4.

4.3.2 Scenario Description

1) The patient is referred to a local emergency department for an evaluation.

2) Once the patient has arrived at the emergency department, an admitting HCP1 discovers that he/she wears an emergency identity token.

3) Whether the patient is responsive or the patient is not responsive (or in an altered state of mind), the HCP1 inputs (or reads with a QR-code scanner) the code contained in the emergency identity token on the HCP App.

4) HCP1 using the same HCP App, requests access to the associated health data for emergency reasons.

5) Initially, the HCP App authorizes the HCP1 to look only at the identification data of the patient associated with the emergency identity token.

6) The HCP1 compares the photo of the patient and relevant physical data (i.e. height, eye colour, etc.) contained in the identification data with the physical characteristics of the patient.

    a) If the patient is responsive, HCP1 can request a direct identification to the patient.

7) The HCP1 confirms the identification on the HCP App.

8) The HCP App authorizes the HCP1 to access the (emergency) health data of the patient (as well as other HCPs involved in the patient's treatment) contained in S-EHR Cloud.

9) The Patient's health data is imported in a few seconds (5 to 10) from the S-EHR cloud to the HCP App.

    a) Data is visualized (and imported) by the HCP App used by HCPs currently authorized to treat patient's data (i.e. involved in the patient's treatment process), translated into HCPs natural language.

10) The admitting HCP1 performs a physical examination on the patient, revealing no significant abnormality at abdominal level.

11) HCP1 consults the patient's history, imported from S-EHR cloud, where coronary artery disease, treated with percutaneous coronary angioplasty (PTCA) on the left anterior descending coronary artery is mentioned.

    a) The Angiography movie of the PTCA procedure is available for download, using the reference contained on S-EHR Cloud. The attending HCP1 downloads it and evaluates the previous PTCA procedure.

12) From S-EHR cloud patient history is also reported diabetes as chronic illness, under treatment with insulin.

13) Despite the absence of typical cardiac symptoms (patient has diabetes) the HCP1 performs a 12-lead EKG, showing on the HCP App a marked ST segment elevation on the inferior leads, supporting the diagnosis of acute myocardial infarction.

14) Blood sample is taken by the HCP1 and results on the HCP App show a significant increase in troponin level.

15) The HCP1 starts heart monitoring and starts an IV therapy.

16) Patient is therefore referred to the Cath lab for urgent coronary angiography and revascularization.

17) HCP1 from the patient's S-EHR noted an allergy to latex, so a latex-free PTCA procedure was set in the cath lab.

18) At patient discharge the S-EHR Cloud is updated with a Discharge Report containing the cause of admission, discharge diagnostic assessment, visits and recommendations, therapy and prescriptions.

4.3.3 Postconditions

[Sub-scenario] Data imported from S-EHR Cloud may be stored safely by the Hospital for future access to authorized users, if authorized by the patient or by the law.

When the S-EHR App of the patient is connected again with the internet, the new data produced by the hospital is downloaded from S-EHR Cloud to the patient's phone.

4.3.4 Dataset

Emergency dataset may contain:

1. Allergies

2. Chronic (or rare) diseases. Main Chronic Conditions:

- Ischemic heart disease
- Heart failure
- Pulmonary disease
- Abnormal kidney function
- Abnormal liver function
- Previous major surgery

- Active malignancy

3. Eventual acute (ongoing) diseases

4. Relevant exams

- Latest EKG (image)
- Latest bio-humoral exams

5. Surgical history

6. Current medications.

4.3.5 dataset for upload

The list of section for the discharge Summary with the associated LOINC code is:

- Hospital Admission Dx 46241-6
- Hospital Admission History And Physical Note 47039-3
- History General 11329-0
- Phisical Examination 29545-1
- Medications On Admission 42346-7
- Hospital Course 8648-8
- Relevant Diagnostic Tests &Or Laboratory Data 30954-2
- Hospital Discharge Studies Summary 11493-4
- Selected Medicine Administered During Hospitalization 8677-7
- Hospital Discharge Dx 11535-2
- Discharge Medications 10183-2
- Treatment Plan 18776-5
- Allergies 48765-2

4.4 Scenario S3 - Health research study

This scenario is intended to show how clinical data owned by a patient and collected during healthcare processes involving the patient as a subject, can be shared for research purposes.

Citizens and researchers may decide to participate in the InteropEHRate Open Research Network. The InteropEHRate Open Research Network is constituted by patients and a group of research organizations (Hospitals, Universities, Research Centres, Institutes) that exploit a common IT infrastructure implementing the communication protocol for Health Data Sharing for Research defined by the InteropEHRate project. The Open Research Network allows the participating researchers to enrol citizens in their research studies (described by specific research protocols) and collect health data for the studies directly from the enrolled citizens. Researchers belonging to the InteropEHRate Open Research Network share a common vocabulary, defined by the InteropEHRate profiles, used to refer to any health data required by the research studies performed on the InteropEHRate Open Research Network.

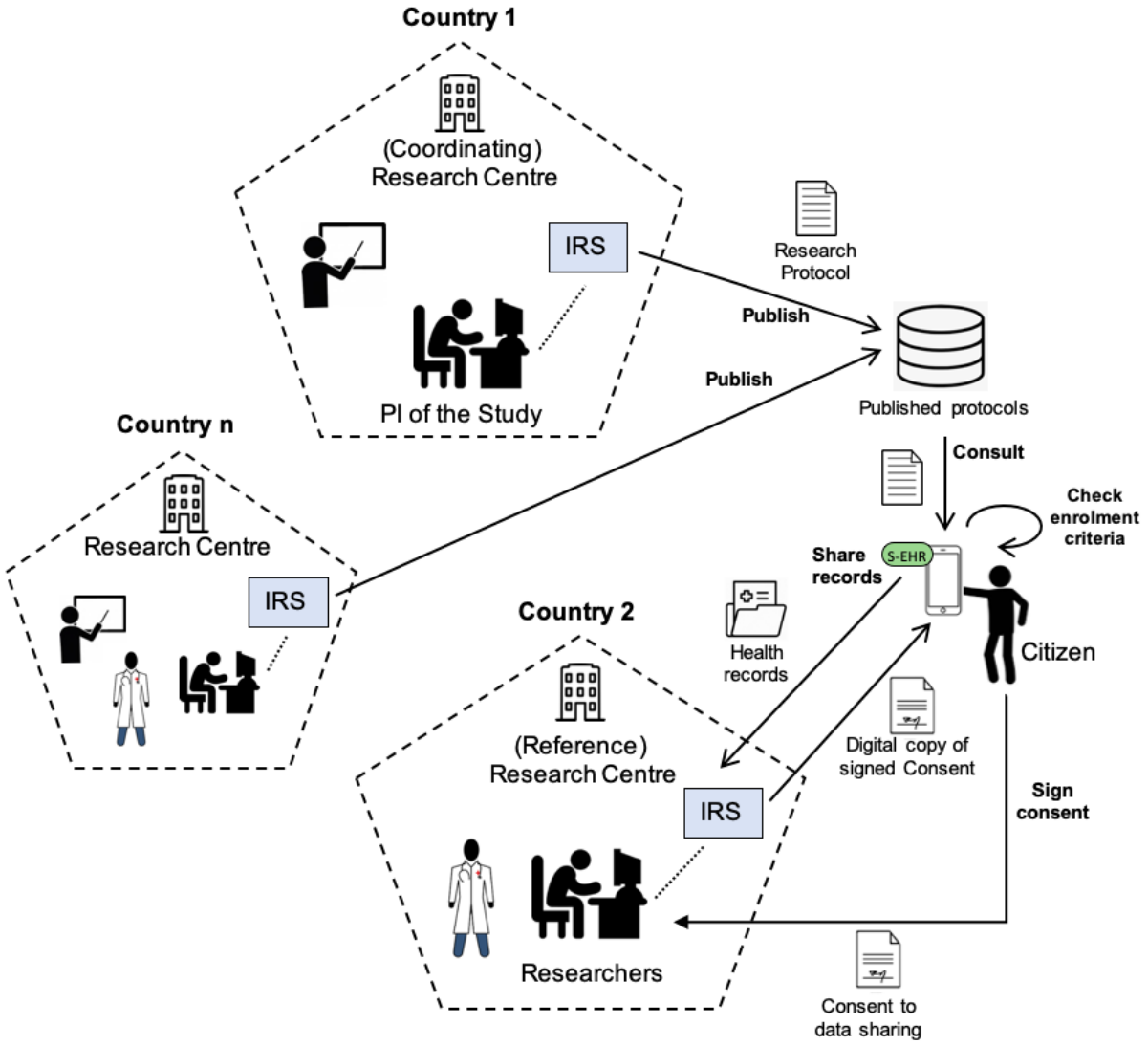

Figure 10. Scenario S3 - Health research study: Research Scenario

Any Research Centre belonging to the InteropEHRate Open Research Network may use the InteropEHRate Research Services (IRS) to publish research protocols and receive health records.

4.4.1 Preconditions

Two main kinds of preconditions will be considered in the two following sections:

1. Clinical aspects and health-status of the patient.
2. IT aspects.

4.4.1.1 Clinical preconditions and assumptions

Generic Abstract description: A population of patients have a collection of clinical data related to their status and clinical condition. A Research Organization defines a research protocol with an associated clinical dataset in relation to some of the data of the patients' collection.

Narrative description

An Italian male, Mr. Adam, and a Belgian female, Mrs. Eve, have their data stored in their S-EHR. They gave consent to be evaluated as a candidate in clinical trials and/or research, donating their data to the researchers. Mrs. Eve suffers from chronic hypertension.

In S-EHR platform is formalized as a Research Dataset Definition (S-EHR-RDD) a vocabulary representing each structured data that can be used by a research protocol. The patient is aware of research dataset content and agreed on his evaluation.

A researcher defines an investigation protocol using data selected from S-EHR-RDD, constraining special filters to select the population of patients that can be enrolled in the study. The research protocol has been approved by the ethical committee and its feasibility has been verified.

4.4.1.2 IT and Data Protection preconditions and assumptions

A. Patients gave their consent (informed consent) to store data into their S-EHR app.
B. Patients have their most recent and updated health data stored in the S-EHR app. Large images or signals or movies related to instrumental examinations or procedures can be entirely contained on the patient's phone, where memory availability allows it, or can be represented by a link pointing to a service of the producing healthcare and allowing the download of the content from the patient or from third parties upon the patient's consent.
C. Patients' data stored on the S-EHR app have a strict correlation to the patient's owner and data authorship.
D. Research Organisations (ROs) belong to the InteropEHRate Research Network.
E. ROs have their own regulations in terms of researchers' access.
F. ROs respect the accountability principles for health data management defined by the GDPR.
G. Researchers have full access to internet connection and to the infrastructure of the InteropEHRate Open Research Network.
H. Researchers own an electronic ID/account, required to access the InteropEHRate Open Research Network, released by an authority, national or local, certifying their identity and qualification.

I. Every action performed by the researchers on the InteropEHRate Open Research Network is registered (logged) and associated permanently with the unique identification of the author/actor and workstation/device.

J. Health data sets shared for research purposes can be accessed/queried only by the authorized researchers.

K. Patients select a reference region/area, i.e., their preferred region/area as location of the research centre that they can contact in case of participation in a research study, when a study is multi-centric.

L. Patients can withdraw from their participation in the InteropEHRate Open Research Network at any moment.

4.4.2 Scenario Description

1) Patients Eve and Adam give consent to be part of the InteropEHRate Open Research Network, i.e. they consent to their S-EHR app to match the health data stored by the app with the enrolment criteria of new research studies and be notified, in case of positive match, of the possibility to apply as participants to the study.

2) A Research Organization, Coordinating Research Centre, formalises the research protocol called "Side effects from hypertensive medication study" using the InteropEHRate format:

    a) the protocol involves patients with age > 18 years, with hypertension and treated with anti-hypertensive drugs, defined a research protocol specifying a required clinical dataset;

    b) the protocol requires a set of pseudonymized health data that includes:

        i) the prospective collection of symptoms, medications, healthcare treatment, vital signs, instrumental examinations results for the next 2 years after patient enrolment, as specified in the clinical research protocol;

        ii) the retrospective collection of data up to 5 years before enrolment, as specified in the clinical research protocol;

    c) The protocol specifies a set of participating Reference Research Centres belonging to specific regions.

3) Using the InteropEHRate Research Service, the Coordinating Research Centre publishes the research protocol on the InteropEHRate Open Research Network. The protocol references requested data and constraints (selection and exit criteria) with InteropEHRate profiles terminologies.

4) The research protocol is transmitted to the S-EHR of the patients.

5) The S-EHR of the patients that have given consent to be invited to new research studies, automatically and silently match the enrolment criteria of the protocol with the content of the S-EHR app, without transmitting any data, in order to determine if the patient may be enrolled in the research.

6) If the evaluation of research criteria is positive, the S-EHR app displays to the owner patient a notification communicating that the patient may participate to the study and that he/she is to adhere to the research:

    a) Eve may participate and is invited to the research;

b) Adam doesn't suffer from hypertension, so he is excluded from the research's possible candidates and receives no notification.

7) Eve accesses on the S-EHR to a list showing the studies she may participate in and selects the invitation called "Side effects from hypertensive medication study".

8) The S-EHR app shows to Eve the details of the research protocol, including details about:

   a) the Coordinating Research Centre

   b) the Local Research Centre (belonging to the Reference Region she previously selected),

   c) reference contacts for further details,

   d) the requested health data (type of data and covering period),

   e) the purpose of the research,

   f) the data retention period,

   g) the level of anonymization of the requested data.

9) The research protocol requires her to share the health data of her previous 5 years and for the next 2 years, restricting their use only to that specific research protocol.

10) Eve accepts to participate in the research.

   a) If supported by the S-EHR App, Eve digitally signs on the S-EHR App the consent to participate in the research study;

   b) The S-EHR App shows to Eve the Reference Research Centres included in the protocol and belonging to the region she previously selected;

   c) Eve selects a Reference Research Centre;

   d) In case Eve cannot sign the consent on the S-EHR App or if required by the research protocol, Eve goes to the selected Reference Research Centre and signs the consent to participate in the research study.

   e) The consent restricts the use of the shared data only to that specific research protocol.

   f) The S-EHR app receives and stores on the mobile device an electronic copy of the consent digitally signed by the Reference Research Centre.

   g) An anonymous identifier is assigned by the S-EHR App to Eve, in order to be used for health data pseudo anonymization only in the research "Side effects from hypertensive medication study".

11) A Reference Research Centre may obtain in any moment a statistic showing the number of citizens that consented to participate in the research protocol.

12) At the start of the research, as indicated within the specification of the research protocol, the S-EHR app sends, in FHIR format, the pseudonymized health data to the Reference Research Centre, according to the clinical protocol design:

   a) The data of the previous 5 year are sent to the Reference Research Centre

   b) Following the specification of the research protocol, the S-EHR app periodically and silently checks the content of the S-EHR app for the new data required by the research

protocol and when available sends a pseudonymized copy of them, in FHIR format, to the Reference Research Centre selected by Eve.

i) pseudonymized data are sent for the next two years.

c) For the previous or current health-related information, If some required data is available but is too large to be contained on the Smartphone, the S-EHR will have to activate the transfer of those information from the remote storage (source healthcare facility or local/regional/national storage service) to the Reference Research Centre, applying the required policy of anonymization / pseudonymization.

d) The Reference Research Centre selected by Eve forwards any new health data set to the Coordinating Research Centre (if different).

13) Eve is asked to fill a questionnaire on self-reported side effects from anti-hypertensive medications.

a) A few months later Eve complained nausea related to the assumption of the anti-hypertensive medications. Eva opens her S-EHR and access to the questionnaire of the research protocol, compiling the questionnaire with the symptom.

b) The questionnaire is sent to the reference research centre.

14) Eve may choose to be notified each time that new health data is sent to the Principal Investigator.

15) Eve can withdraw her participation at any time.

a) In case of withdrawing, the event is notified to the Reference Research Centre of Eve.

16) Every data upcoming to the Reference Research Centre, updated in S-EHR and related to the research, are conveyed to the researcher Database for the period described by the research protocol

a) According to clinical protocol design, health data are sent for the next 2 years.

4.4.3 Post-conditions

A. At the end of the research, data imported from S-EHR are stored safely in the research facilities of the ROs and retained for the period specified by the research protocol or by the local/national regulation, then they are deleted (disposed).

4.4.4 Dataset

Research dataset may contain:

1. Allergies

2. Chronic (or rare) diseases. Main Chronic Conditions:

- Hypertension (mandatory)
- Ischemic heart disease (list of considered ICD9-10 codes)
- Heart failure (list of considered ICD9-10 codes)
- Pulmonary disease (list of considered ICD9-10 codes)

- Abnormal kidney function (list of considered ICD9-10 codes)
- Abnormal liver function (list of considered ICD9-10 codes)
- Previous major surgery (list of considered ICD9-10 codes)
- Active malignancy (list of considered ICD9-10 codes)

3. Eventual acute (ongoing) diseases

- (list of ICD 9-10 codes)

4. Relevant exams for cardiology domain

- Latest bio-humoral exams
- EKG

5. Surgical history

6. list of Current medications:

- ATC code
- Name or description
- Drug Daily Dosage
- administration route

7. The following filled questionnaire on possible side effects of each drug taken

1. Type of symptom(s)

a. Cutaneous symptoms (please describe)
b. Nausea
c. Constipation
d. Palpitation
e. Cough
f. Swollen feet or legs
g. Cold hands or feet
h. Cramps
i. Persistent dry cough
j. Frequent urination
k. Decreased sexual desire
l. Other (please specify)

2. How long does the adverse event last?

- < 1 day
- 1 day to 1 week
- 1 week to 1 month
- > 1 month

3. Did you withdraw the drug? YES/NO
4. Did the adverse reaction require specific treatment? YES/NO

4.5 SUB-Scenario S4 -Semantic data management

Differently from the previous scenarios, this one does not aim to specify the usage of the generic applications considered by the InteropEHRate open specification (that can have different

implementations), but aims to specify the intended usage of specific applications to be provided by the InteropEHRate framework aiming at overall support to data exchange.

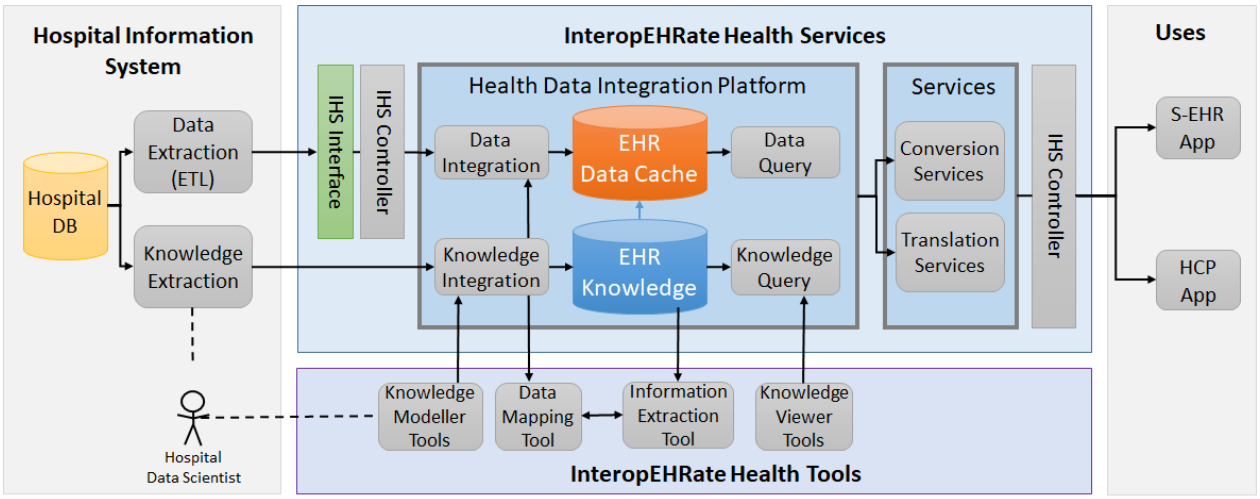

Figure 11. Integration of the InteropEHRate Health Services and Health Tools within a Hospital Information System

More specifically, the purpose of this scenario is to describe the preparatory operations to be offered by the InteropEHRate Health Tools (see Figure 11) and that are necessary to enable the conversion of local health records into their interoperable form and thus ensure their syntactic and semantic interoperability by means of the InteropEHRate Health Services.

The main actor involved in the scenario is the Data Scientist (DS). The data scientist is a highly skilled technical person (e.g. with a computer science or bioinformatics background, typically with a master's degree) who has adequate competences in data manipulation and knowledge engineering. Furthermore, the DS is assumed to have been trained, or have acquired experience, for an adequate understanding of the healthcare data he/she has to manipulate. A DS can be supported by various specialized clinicians (physicians, nurses, etc.) actively engaged in the knowledge management process related to clinical processes.

The DS is typically employed by a hospital and manipulates data and knowledge that relate to that hospital and its Hospital Information System.

While DSs have software development skills, for more complex development tasks they may need to team up with dedicated developers. However, the role of the InteropEHRate Health Tools, whose functionalities are covered in this scenario, is to reduce such software development needs to a minimum.

4.5.1 Data integration background definition

Usually, the healthcare organisations use specific local formats for their health records that are different from the ones required for cross any border interoperability. The InteropEHRate framework addresses the challenges related to the conversion of local health records needed to enable the cross-border interoperability through the *InteropEHRate Health Services (IHS)*. These are deployed at healthcare organizations in order to provide technological support for common interoperability issues such as the use of different data schemas, languages, terminology and coding systems.

The approach adopted by InteropEHRate is that of *agile knowledge-based data integration*. By "knowledge" we understand the computer-readable description of data schemas, coding standards, and language-specific terminology. We distinguish "local knowledge" from "international knowledge": the former describes concepts, schemas, coding, and terms used at a particular healthcare organization (or possibly region or country), while the latter refers to the same elements (concepts, schemas, coding, and terms) defined in international standards and adopted by InteropEHRate for (also cross-border) data transfer and defined by the InteropEHRate *Interoperability Profiles*. Local knowledge should include mapping rules between local and international data and knowledge elements, such as between locally used and international codes of diseases, procedures, active substances, etc.

By "data integration" we refer to a semi-automated method that automates the process of converting the health records of a healthcare organization to its international form and vice-versa. By "semi-automated" we understand a predominantly automated approach that, however, is instructed and generally overseen by a *data scientist* in order to assure the highest quality of the integration methodology. The software component in charge of data integration is called the *Health Data Integration (HDI) Platform.* It is the responsibility of the data scientist to make sure that local knowledge and its mappings are uploaded and represented correctly inside the HDI Platform, and that the system is instructed so that data integration is executed robustly and with less mistakes.

By "agile data integration" we understand a methodology that deals with the evolution of requirements-changes both in local and international data representations, such as the creation of a new local data attribute or a new LOINC code-in a fast and flexible manner. The goal is to be able to adapt the HDI Platform to the evolution of data representations through minor and immediate updates to the knowledge and/or the mapping rules, carried out within hours or days as opposed to weeks and months typical of software update cycles. For this purpose, the project offers the *InteropEHRate Health Tools (IHT):* namely *Knowledge Management Tools* as well as a *Data Mapping Tool.* These are interactive tools that serve the purpose of configuring and adapting the *HDI Platform* through the management of knowledge and mappings described above.

Taking into consideration that the achievement of generating fully interoperable---perfectly converted and translated---health records is not a realistic requirement in the context of all healthcare organizations (due to the amount of effort to be invested into knowledge and data management), InteropEHRate defines three levels of interoperability in increasing order of complexity:

1. secure interoperability: no transformations whatsoever are applied to the data, only the security of data transmission is guaranteed;
2. syntactic interoperability: the data structures are transformed into the FHIR-based schemas required by the Interoperability Profile; however, the data values themselves (e.g. coded values) are not modified and the meanings of data values are not formally defined during the integration process;
3. semantic interoperability: beyond syntactic interoperability, data values are precisely understood during the data integration process and are converted and translated as necessary.

Each healthcare organization can decide which level of interoperability to support. This scenario only applies if one of levels 2 or 3 are targeted by the organization.

4.5.2 Preconditions and assumptions

In order to more concretely describe the operations of the DS, some assumptions are done on the data and on the tools used by DS.

A. The health data of the Healthcare Organization are expressed in local language, and use locally specific terminology, codes, and data schemas to describe, structure, and classify healthcare information.

B. Some portions of patient's health records are expressed as unstructured or semi-structured documents (e.g. PDF, HTML, or text files), while others are structured datasets that are available either in a tabular (e.g. CSV) or in a hierarchical form (e.g. XML or JSON). The DS-driven data integration and conversion process described in this scenario only applies to structured datasets. Unstructured documents, such as PDF files, are not transformed in this process beyond the possible automated machine translation of their textual content. Such files will be embedded as is within the FHIR-based data structure of the converted health records.

C. In case a health record consists of several files or documents, it is assumed that each file is uniquely associated with the identity of the patient (e.g. contains a patient ID). In other terms, from the contents of each file the identity/patient ID of the patient must be certain.

D. In the case of very complex health record files in terms of the number of attributes or XML elements (e.g. hundreds of attributes or deep XML hierarchies), the handling of the file using the interactive *Data Mapper Tool* may be too cumbersome for the DS. In such cases, usually the DS splits such files into several simpler/smaller ones, while maintaining the link among them as described in point C above.

E. Setting up the data mapping and conversion process is a combined top-down (specification-driven) and bottom-up (data-driven) effort. Thus, it is supposed that the DS has at his/her disposition: (1) adequate documentation on the local health record datasets, including all possible kinds of data files, data attributes, and data values; and (2) a significant amount (tens or preferably hundreds) of sample patient health records. This sample should be representative of the complexity of the health records that will be subjected to integration and conversion.

F. The InteropEHRate Health Services, and within it the HDI Platform as well as the Knowledge Management Tool (KMT) and Data Mapping Tool (DMT), are deployed and configured (e.g. local language, HDI Platform communication parameters) within the IT infrastructure of the Healthcare Organization, in order to support the conversion and translation of structured and unstructured health record data.

G. International Knowledge, as defined by the InteropEHRate Interoperability Profile, is *a priori* imported into the HDI Platform.

H. The subset of locally used terms, codes, and data schema elements that are relevant for cross-border interoperability has been identified by local healthcare experts and the DS. In the following, we will not consider any terminology or other metadata that do not fall within this subset. In particular, the meanings of locally used terms, codes, and data schemas---which includes short textual definitions---are either already evident to the DS or they are available to him/her as formal (e.g. Excel sheet) or informal (e.g. human-readable PDF document) documents.

I. This precondition holds only if the Healthcare Organization aims at semantic (and not only syntactic) interoperability. The mappings between locally used terms, codes, and data schema elements and their Interoperability Profile counterparts are available to the DS, expressed either formally (e.g. as a structured mapping file) or informally (e.g. as a human-readable PDF document).

J. The information described under points H and I above have not yet been uploaded into the HDI Platform.

K. The information described under points H and I above have not yet been uploaded into the HDI Platform.

4.5.3 Scenario Description

The scenario is divided into two main phases:

- the *bootstrapping phase*, executed only once, that sets up the initial contents of the HDI Platform and configures it for automated data conversion;
- the *evolution phase*, executed each time that a change either in local data representations (e.g. the introduction of a new local data attribute) or in the international knowledge (e.g. the introduction of a new LOINC code) requires the data conversion process to be updated.

The steps covering the *bootstrapping phase* of the scenario are as follows.

1) An Italian Hospital wants to integrate the health records of its patients, stored in the Hospital's EHR, with the HDI Platform offered by InteropEHRate Framework, in order to convert EHR data in a format supported and interpretable by the S-EHR, defined by the InteropEHRate FHIR profiles.

2) The Hospital assigns a DS the task to complete the data integration procedure.

    a) As mentioned in preconditions F and G, the DS is already familiar with the health record data representations (the interpretation of data structures and values) and related practices of the Healthcare Organization.

3) [This step is executed only if the Healthcare Organization aims at semantic interoperability.] The DS starts by formally describing the locally used terms and codes (but not the data schemas) as well as their mappings to the Interoperability Profile (preconditions F and G), into local knowledge, following the spreadsheet-based Terminology Import Format and using the Knowledge Management Tools to help in verifying the result. The result is one or more spreadsheet files ready to be imported into the HDI Platform, described in detail in Deliverable D5.8. This work is done once and for all, with subsequent minor modifications to keep the knowledge up to date.
4) [This step is executed only if the Healthcare Organization aims at semantic interoperability.] The DS imports local knowledge (i.e. the spreadsheet files using the Terminology Import Format) into the HDI Platform and fixes potential knowledge representation mistakes signalled by the system during the import process. (Examples of mistakes the system is capable of signalling are reference to non-existent concepts, duplicates, loops within hierarchies, etc.) The end result of importing can also be interactively verified using the Knowledge Management Tools (by browsing the imported knowledge).
5) From the set of sample health records made available to the DS, (s)he selects a smaller subset that will constitute the definition set, i.e. the set of health records used as a basis to define the data mapping and conversion operations. The rest of the health records will constitute the validation set, subsequently used to validate the correctness of the same operations.
6) The DS loads a health record file---that may be a portion of a single patient's entire health record (see precondition D)---into the Data Mapper Tool.

a) Using the data Mapper Tool, the DS defines the structural mapping operations from the local data schemas towards the international FHIR schemas. Beyond the mapping of data attributes, this work may also include, if necessary, data value reformatting, splitting, or merging. The Data Mapper Tool records the operations carried out by the DS. Once done, the DS saves the set of operations that will become the Syntactic Data Mapping Recipe (or simply Syntactic Recipe in the following).
b) The DS verifies the Syntactic Recipe by running it automatically over the test set of health record files. In case there are conversion errors (because of a mistake in mapping or because there were unforeseen cases of data heterogeneity within the test set), the DS loads the incriminated file and the Syntactic Recipe into the Data Mapper Tool, fixes the errors, and restarts this step. The DS can also use the Knowledge Management Tools, which contain a so-called Entity Browser Tool, to verify the results of conversion by browsing the integrated health record.
c) If the health record consists of multiple files, steps a-b are executed for each file.

7) [This step is executed only if the Healthcare Organization aims at semantic interoperability.] Once the DS is confident that syntactic conversion is robust enough (i.e. it runs without errors over the entire test set and the Entity Browser Tool is showing correct results), (s)he proceeds to define semantic conversion.
   a) (S)he loads the Syntactic Recipe and the definition set file(s) into the Data Mapper Tool, runs the recipe, and completes it by the semantic conversion step of information extraction. The goal of information extraction is to identify relevant terminology and codes within natural-language labels inside the health record and link such mentions to the corresponding formal knowledge elements defined inside the Platform. The codes and terms to be extracted may be stand-alone (e.g. a single ICD-10 code expressed as a string "I69.3") or embedded within a longer piece of text. The Semantic Recipe that results from adding the information extraction step to the syntactic one is, in turn, saved by the DS.
   b) The DS verifies the correctness of the Semantic Recipe the same way as for the Syntactic Recipe, and confirms its validation. The recipe is put in production by exporting it from the Data Mapper Tool and placing it into a predefined directory and under a predefined name on the server in charge of processing health records.

The steps covering the *evolution phase* of the scenario are as follows.

8) In the case of the evolution of international knowledge---such as the introduction of a new LOINC code or a new FHIR attribute or resource---the knowledge content of the HDI Platform needs to be updated.
   a) The DS can obtain the file(s) to be imported into the HDI Platform from the Central Knowledge Provider, i.e. the Europe-wide entity responsible for maintaining the international knowledge.
   b) The DS simply needs to import the file(s) and, if necessary, update the local-to-international knowledge or data mappings (e.g. mapping of an existing local code to the new LOINC code, or of a local attribute to the new FHIR attribute).
9) In the case of the evolution of the local terminology, codes, or their mappings, the DS needs to create a new Terminology Import Format spreadsheet file that formalises the changes to be applied to local knowledge. The file is then imported into the HDI Platform by the DS.

a) In case the evolution of knowledge results in the evolution of data mapping rules, the DS also needs to update the Data Mapping Recipe(s) accordingly.

10) In case of the evolution of local data structures (e.g. introduction of a new local data attribute) or of the data mapping rules, the DS may need to modify the Data Mapping Recipe(s) accordingly.

a) It is the responsibility of the DS to be aware of the need to update the recipe(s). The way to do this is to load each recipe (syntactic or semantic) into the Data Mapper Tool, apply the modifications, and save the new recipe(s) to the same place as in point 7b above.

4.5.4 Post-conditions and notes

- When set up and maintained as described in the scenario above, the HDI Platform can be used automatically to convert the health records of the Healthcare Organization to the representation defined by the *Interoperability Profile*, including updates made to the health records by an HCP as in scenarios 1 and 2.
- Exception/Errors management: because the approach might not be exhaustive, when the recipe defined by a DS is applied to an EHR and generates an Error/Exception, such event is notified to the DS who has to proceed to an update/correction of the Syntactic/Semantic recipe.

5 USER REQUIREMENTS

As described in the section "Approach for requirements analysis", user requirements are elicited by means of the analysis of user scenarios. More specifically, one or more requirements may be associated with each sentence of a scenario. The analysis is the result of collaborative work done by the technical partners of the project and then approved by the clinical partners.

This third version updates the previous analysis on the basis of new versions of scenarios S1, S2, S3, S4 and adds the analysis of the new "Scenario S0 - Initial S-EHR feed".

The requirements are identified by a prefix and a number. The number represents the order of definition of the requirement. The prefix represents the type of applications that the requirement applies to, according to the following list:

- SA means "S-EHR App",
- SC means "S-EHR Cloud",
- SA-SC means "S-EHR App and S-EHR Cloud",
- SA-HA means "S-EHR App and HCP App",
- SA-RA means "S-EHR App and R2D Access Service"
- SA-IR means "S-EHR App and InteropEHRate Research Services",
- HA means "HCP App",
- HA-SC means "HCP App and S-EHR Cloud",
- HA-IH means "HCP App and InteropEHRate Health Service"
- IH means "InteropEHRate Health Services",
- IR means "InteropEHRate Research Services",
- KM means "Knowledge Management Tool",
- DM means "Data Mapping Tool",
- RA-IH means "R2D Access Service and InteropEHRate Health Services".

The following tables show what are the requirements associated with each portion of the scenarios, while the successive subsections describe the referred requirements, grouped by the type of application that is required to implement them[4].

5.1 Mapping between scenarios and requirements

5.1.1 Requirements from scenario S0 - Initial S-EHR feed

#	Scenario S0 step	Implied requirements
A	The Patient owns a smartphone/tablet and installs a S-EHR app on it	SA-1, SA-2, SA-3, SA-4
B	The Patient gave his/her approval to the S-EHR app to store and manage his/her personal health data and to share them only with people explicitly	SA-5

[4] Different prefixes are now used with respect to previous versions of this report, but the identifying numbers of previously defined requisites remain the same.

	authorized by the patient, and for periods authorized by the patient.	
C	The Patient had a previous encounter with a Healthcare Organization supporting the InteropEHRate protocol for remote access to the patient's health records maintained by the Organization.	SA-RA-166
D	Each healthcare organization involved in this scenario has a digital identity that-is trusted by the S-EHR app.	SA-172
E	The Healthcare Organization is registered in eIDAS as an Entity.	
F	The maintainer of the S-EHR app received from the healthcare organisation of the previous point the URI to be preloaded the S-EHR App, to access the Hospital's Interface of S-EHR.	
G	All the exchanged health information is related to its producer/author.	SA-HA-69
H	The Healthcare provider cannot repudiate the produced health information.	SA-19, SA-20, SA-HA-69
1	The patient opens his S-EHR and decides to import in the S-EHR some health-related information from his reference Hospital.	
1.a	The patient accesses the list of Hospitals connected to the S-EHR and selects his reference Hospital;	SA-172
1.b	the patient chooses if to download automatically in the S-EHR App every new or updated HR data from the selected hospital, or manually approve any download of new or updated data.	SA-RA-174, SA-RA-175
2	the hospital receives the request to download the HR of the person	
2.a	Hospital requests the identification of the patient using eidas, sharing a minimal identification dataset with the national eidas identity provider;	
2.b	the patient identify himself on eIDAS using the smartphone;	SA-RA-166
2.c	by invoking the R2D service, the patient implicitly authorizes the hospital to collect and transmit health-related data of the patient to S-EHR;	SA-173
2.d	Hospital writes this operation on an audit log, representing both eIDAS authentication and consent for data sharing.	HA-21
3	After the positive identification of the patient, the Hospital's EHR starts	SA-RA-166

	collecting information on the patient and prepares a list of encounters with associated information that can be downloaded on S-EHR. When available the list is downloaded by the S-EHR.	
3.a	HR data are converted into IEHR format and translated in the patient's language, and stored in R2D server;	RA-IH-176, RA-IH-177, RA-IH-178
3.b	The Hospital publishes the list of encounters with the patient as subject, with date, type of access;	SA-RA-166
3.c	every encounter contains one or many items importable in S-EHR (reports, images, prescriptions, vital signs, etc.).	SA-RA-166, SA-HA-73
4	The patient selects one or many, or every, encounter to be downloaded in S-EHR, and the patient starts to download documents and data related to the selected encounter clicking on the button "Download" of the S-EHR.	SA-RA-179
4.a	The download may request some time to be completed, also many hours, depending on the amount of information to be transferred and available bandwidth.	SA-RA-13, SA-RA-156, SA-HA-73, SA-RA-74, SA-RA-15, SA-RA-17
4.b	*Health data with large size, e.g. images and movies related to instrumental examinations and procedures, could not fit the available memory of the smartphone, thus can be transmitted as a reference to the source information (URL/URI) maintained by the source hospital/healthcare provider. The reference to the source can be used later to download the large amount of data on the patient's phone or provided, on patient's request, to other healthcare providers to support the patient's care. On S-EHR this data referred with a link are specifically signalled to the patient with a different notation (text, colour, icons).*	*SA-RA-212*
4.c	Once the download is completed, on the S-EHR the patient is able to view every data downloaded, associated to every encounter and filtered by date and type.	SA-180, SA-181
5	The S-EHR App periodically checks for new/updated items published by the selected healthcare provider, and performs selected operations (according to point 1.c) on S-EHR.	SA-RA-174, SA-RA-175
PCA	The patient is able to delete on the S-EHR data that are obsolete or not needed or simply considered not useful for him/her. The patient can also update information on the S-EHR, manually entered or collected by connected devices (body weight scale, blood pressure monitor, body temperature thermometer, etc.).	SA-HA-69, SA-182, SA-183, SA-184

PCB	*The patient can browse on S-EHR the health data that was too large to be downloaded specifically, and, according to memory availability, start downloading them on the phone. Some amount of time will be needed also to transfer the data from the source to the patient's phone.*	*SA-RA-213, IR-216, IR-217*
PCC	The patient is able to enter in S-EHR drugs assumptions in self-administration, symptoms, vital signs	SA-183

Table 9. Requirements from scenario S0 - Initial S-EHR feed

5.1.2 Requirements from scenario S1 - Medical visit abroad

#	Scenario S1 step	Implied requirements
A	[Sub-scenario] The Patient owns a S-EHR app,	SA-1, SA-2
	installed on his smartphone, and pertinent consent is granted	SA-3, SA-4
B	[Sub-Scenario] The S-EHR app may store a representation of a digital identity of the citizen that is trusted by the healthcare providers and may be used to identify the patient without the ID card (see step 5).	SA-6, SA-78
C	[Sub-Scenario] The Patient gave his/her consent (informed consent) to the S-EHR app to store and manage his/her personal health data and to share them only with people explicitly authorized by the patient, and for periods authorized by the patient.	SA-5
D	[Scenario 0] The data about the health history	SA-RA-166
	(including measurements of vital-signs and bio-signals) and current pharmacological therapy of the patient has been imported from the EHR system of his referral centre to the S-EHR of the patient.	
E	HCP uses the software "HCP App", able to access a S-EHR app by using a Device to Device connection.	
F	[Sub-Scenario] Each single HCP involved in this scenario has a digital identity issued by a legal national or local authority, recognized by the S-EHR infrastructure, and associated in a trusted way to his/her qualification.	HA-7, HA-79, HA-80
G	Each HCP involved in this scenario works in a setting/room where he/she uses an HCP workstation (tablet, smartphone, PC, Mac) running the HCP App. Different rooms imply different HCP workstations. The workstation is provided with an interface device/peripheral that allows linkage of the HCP app with the S-EHR.	HA-10, HA-11, HA-12
H	Each healthcare organization involved in this scenario has a digital identity that may be represented within the HCP app and is trusted by the S-EHR app.	HA-8, HA-80

I	Every action performed on health data by means of the S-EHR App or HCP app on the S-EHR system by an author/actor is registered (logged) by the respective app both the S-EHR and the HCP App	SA-19, HA-21, SA-76
	and associated permanently with the unique identification of the involved patient and (HCP or patient) author/actor.	SA-20, HA-22, SA-77
J	The patient has configured on his/her S-EHR the data he/she desires to hide to HCPs. Such hidden data will not be exchanged with the HCP.	SA-9
K	[Scenario S4] The InteropEHRate data integration platform is available, to support the conversion and translation of structured and unstructured information,	KM-23, HA-190, HA-IH-151, HA-IH-152
	and it is configured for the healthcare provider. See Scenario 4.	DM-24
L	All the information is related to its provider/producer/author.	SA-HA-69
M	The producer/author (Patient or HCP) of the information stored on the S-EHR cannot repudiate it.	SA-19, SA-20, SA-HA-69
N	The data contained in the S-EHR are safe and integral integer and represents a legal consistency on which HCPs and patients rely for diagnosis/treatment/prognosis/prevention.	SA-HA-69
O	The HCP can verify the origin and validity of the information shared by the citizen.	SA-HA-69
P	There is a mutual trust between Patient and HCP.	
1	While abroad, a patient decides to refer to a local physician, for a visit related to his/her health situation. He asks an appointment for a visit and, on the agreed day, he goes to the hospital. The patient is admitted to the healthcare facility. The HCP1 asks the patient if he/she owns a S-EHR. As the patient answers yes, the HCP1 asks him/her to enable Bluetooth connection to his/her Smart Device, and pair with the HCP1 terminal for the identification by means of the D2D protocol.	SA-27
2	As soon as the connection is successfully completed, the patient may see on the screen of his/her smartphone the data describing the identity of the Health Organization (name, address, etc.) of the HCPs.	SA-28, SA-HA-73
3	The patient recognizes that the description corresponds to the organization where he/she is at that moment, so he/she approves the connection to share	SA-29, SA-HA-73

	his/her identifying data with the HCP1.	
4	As soon as the connection has been approved by the patient, the HCP1 may see on the screen of his/her HCP app the name, surname, date of birth, location of birth, gender, country of residence (corresponding to the identity document) and social security number (or equivalent identifying data).	HA-30, SA-HA-73, HA-75
5	The HCP1 asks the citizen for his/her identity document and compares it with the information shown on the HCP App.	SA-HA-31
6	As the data is correct, the HCP1 confirms, using the HCP app, the identity of the patient. If the data is not corresponding, Scenario stops here.	SA-HA-31
7	HCP1 contextually (i.e. implicitly) asks the citizen for a temporary (limited to this encounter) consent for the healthcare organization of the HCPs to: - download data from the S-EHR app - upload the updated/acquired data back to the S-EHR app - store, for the amount of time required and allowed from the national law, the downloaded data on the systems controlled by the authorized healthcare organization.	HA-32, HA-67
8	The admission data is stored by the HCP app for future traceability.	HA-33, HA-34
9	Using his/her phone, the patient sees on the S-EHR the description of the healthcare organization that just identified him/her.	SA-28, SA-HA-73
10	He sees on screen the request for consent for the admitting organization to download data from the S-EHR app and upload the updated/acquired data back to the S-EHR app.	SA-35, SA-HA-73
11	By means of the S-EHR the patient gives his/her consent, implicitly giving the view/transmission permissions.	SA-36
	Every other HCP scoped by the Healthcare Organization and involved in patient care/treatment are authorized to access S-EHR	SA-35
12	The consent is transmitted to the HCP App and recorded by it for future traceability.	HA-38, HA-39, SA-HA-73
13	A preconfigured (by the HCP on the HCP App) dataset of patient's data	HA-40
	are transferred from the patient's S-EHR app to the HCP App in a few seconds (5 to 10), up to a couple of minutes if the amount of requested data is relevant (10-20 Mb). Admission is now completed, and the patient moves on to consultation. From this on, the patient interacts with HCP2.	HA-41, SA-36, HA-67
14	Downloaded patient's data may be visualized, using the HCP App, by the	HA-42, HA-44, HA-IH-

	HCP2, that is currently authorized by the healthcare organization to treat the data of that patient (i.e. involved in the patient's treatment process).	157, HA-160, HA-161, HA-162
15	Downloaded patient's data are translated into HCPs natural language. HCPs natural language is the one officially related to the Healthcare provider. Are also downloaded from S-EHR:	HA-49, HA-50, KM-25, KM-26, HA-51, HA-52
15.a	personal evaluation of symptoms, entered by the patient	SA-95, HA-96
15.b	body weight measurements of the last week, entered by the patient	
	optionally the HCP may manually select a different preferred language	HA-48
16	HCP2 measures vital signs, body weight, BP, pulse, respiratory rate, SPO2, Temp, AVPU and alertness. Data are entered in the HCP App.	HA-53
17	During the evaluation, the S-EHR is connected to the HCP App, and the newly collected data (vital signs, body weight, BP, pulse, respiratory rate, SPO2, Temp, AVPU and alertness) are transmitted back to the patient's S-EHR app.	HA-54, HA-67, SA-HA-73
17.a	HCP2 asks for a chest X-ray at local imaging facilities, to be executed immediately.	SA-RA-16
17.b	The HCP2 accompanies the patient to execute the requested chest X-Ray and then in a waiting room where he/she can wait to have a specialist evaluation.	
18	Another HCP, HCP3, is assigned to evaluate the patient in a different room.	SA-27, HA-54, SA-HA-73
18.a	Data produced by the HCP1 and HCP2 during the evaluation are collected in the HCP App and available for HCP3.	
18.b	During the evaluation of HCP3, S-EHR is able to exchange data with HCP App. TBD new authorization/connection/pairing/other.	
19	Once the patient is in the visiting room, the consulting HCP3 asks the patient the reasons for his need for the visit.	HA-58
20	HCP3 starts to visit the patient: download the patient's history from the S-EHR app	HA-61, HA-66, HA-67, SA-HA-73, HA-65
	(translated into the HCPs hospital official language) and import it into the HCP App.	HA-51, HA-52
	and import it into the HCP app.	HA-42, HA-66, SA-HA-73, SA-94
21	HCP3 updates on the HCP App the patient's clinical history reporting new symptoms.	HA-58

22	HCP3 downloads from S-EHR vital signs and measures from the previous month, compare them with current values (collected by HCP2) and recognize a relevant gain in body weight.	HA-66, HA-47, HA-71, SA-HA-73, HA-63
23	HCP3 asks for a chest X-ray at local imaging facilities, to be executed immediately. a) HCP3 downloads from the S-EHR app images of a previous exam, performed in Belgium the year before; b) the chest X-ray exam is performed and its images and report is entered on the HCP App; c) HCP3 compares the previous exam with the current exam and recognizes signs of increased interstitial congestion.	HA-64, HA-45, SA-HA-73, HA-167
24	The HCP3 retrieves information from S-EHR on prescribed drugs. a) HCP3 read about a previous attempt to titrate sacubitril/valsartan, which had failed because of the deterioration of renal function. Given the worsening heart failure signs and symptoms, he decides to initiate a low dose of diuretic (furosemide 25 mg).	HA-62, HA-43, HA-60, SA-HA-73
25	The HCP3 finalizes the visit by compiling an evaluation report on the HCP app. a) a treatment plan is compiled, that includes a next visit at 3 months from the current and blood analysis.	HA-60, HA-168
26	The HCP3 provides a drug prescription for furosemide 25 mg on the HCP app.	HA-59
27	he HCP3 uploads data from the HCP App to S-EHR (with a consistent identification of HCP responsible for entered data) using the D2D connection already established from the HCP3 workstation's Terminal:	HA-IH-152, HA-67, SA-HA-73
	a) image and report of chest X-rays; b) diagnostic conclusions, evaluation report and treatment plan; c) drug prescription for furosemide 25 mg;	HA-56, HA-54, SA-HA-57, HA-55, SA-HA-169, SA-HA-170
PCA	The temporary consent of the citizen for data exchange automatically expires at the end of the day. The consent for the storage of the data continues.	HA-67, HA-68
PCB	*If large images or data are generated during the visit, a reference to the source information can be uploaded on the S-EHR instead of the source information. This information can be downloaded by the patient later on according to his/her needs and available memory on the S-EHR smartphone.*	*SA-RA-213*
PCC	The citizen uses S-EHR to look at the medication management.	SA-171

Table 10. Requirements associated to "Scenario S1 - Medical visit abroad"

5.1.3 Requirements from scenario S2 - Emergency access

#	Scenario S2 step	Implied requirements
A	[Sub-Scenario] The Patient owns a S-EHR, installed on his/her smartphone, and pertinent consent is granted.	SA-1, SA-2
B	[Sub-Scenario] The Patient gave his/her consent (informed consent) to the S-EHR to store and manage his/her personal health data on the S-EHR demographic data and a photo of the patient's face is stored to identify the patient.	SA-SC-185, SA-5, SA-SC-98, SA-106
C	[Scenario S0] The data about the health history and current pharmacological therapy of the patient have already been imported from the EHR system of his referral centre to the S-EHR of the patient.	SA-RA-14, SA-RA-16, SA-HA-70, SA-163
D	[Sub-Scenario] The Patient has activated and given his/her consent to the functionality that automatically replicates the content of his/her S-EHR on the S-EHR Cloud and (vice versa) copies on the S-EHR any new data uploaded by authorized actors on the S-EHR Cloud. The alignment happens automatically each time that the smartphone of the Patient is connected to the internet. Also identity data, including a photo of the face of the patient, are uploaded in the S-EHR cloud, to identify the patient	SA-SC-185, SA-SC-97, SA-SC-133, SA-135, SA-163
E	The content of the Patient's S-EHR is currently aligned with the content of the S-EHR Cloud.	SA-SC-97, SA-SC-133
F	The kind of data included in the emergency data set is the same defined by the International Patient Summary.	
G	At the specific moment, the patient has no access to the device containing his\her own S-EHR.	
H	The patient has an emergency identity token.	
H.a	S-EHR generates a unique emergency code (also called "emergency identity token") and a corresponding QR-code that has been associated with that patient. The patient prints the QR-Code on paper and brings the code with her or him in her or his wallet.	
H.b	the token is used in emergency by HCPs to access to the data contained in S-EHR Cloud	
H.c	the token cannot be used to access to data contained in patient's smartphone S-EHR app	
I	[Sub-Scenario] The patient gave his/her consent to the emergency identification by means of an emergency identity token and to share her or his health data stored on the S-EHR Cloud with HCPs in an emergency.	SA-SC-98
J	[Sub-Scenario] Each single HCP involved in this scenario has a digital identity issued by a legal national or local authority or healthcare provider recognised by the	HA-SC-138, HA-SC-188, HA-SC-

	Hospital and sent to the S-EHR Cloud infrastructure, and associated in a trusted way to his/her qualification.	189
K	Each HCP involved in this scenario works in a setting/room where he/she uses an HCP workstation (tablet, smartphone, PC, Mac) running the HCP App. Different rooms imply different HCP workstations. The workstation is provided with a network connection with the S-EHR cloud and suitable device to read the emergency token.	HA-141
L	Each healthcare organization involved in this scenario has a digital identity that may be represented within the HCP app and is trusted by the S-EHR app.	HA-SC-139
M	Every action performed on the S-EHR Cloud by an author/actor is registered (logged) by both the S-EHR Cloud and the HCP App and associated permanently with the unique identification of the involved patient and HCP author/actor. This includes obvious “special actions” like accessing an Emergency Dataset.	SA-SC-149, SC-101, SC-105, SC-102, SC-140, SC-137
N	The organization (hospital) has its own regulations in terms of HCPs’ access to the data according to each HCP role in the hospital as well as mechanisms to check and control access.	HA-142
O	All the information is related to its producer/author, both retrieved from and uploaded on the S-EHR cloud.	SA-HA-69
P	The HCP cannot repudiate the produced information by her or him.	SA-HA-69
Q	The Patient cannot repudiate the produced information.	SA-HA-69
R	The data contained in the S-EHR cloud are integer and not altered in any form, and represents a legal consistency on which it relies for diagnosis/treatment/prognosis/prevention or if any alteration happened the Patient and HCPs will not be able to read the altered data.	SA-HA-69, SA-HA-70
S	The HCP can verify the origin and validity of the information shared by the citizen.	SA-HA-69
T	There is a mutual trust between Patient and HCP	HA-SC-138
U	[Scenario S4] The InteropEHRate data integration platform is available, to support the conversion and translation of structured and unstructured information, and it is configured for the healthcare provider. See Scenario 4.	
1	The patient is referred to a local emergency department for an evaluation.	
2	Once the patient has arrived at the emergency department, an admitting HCP1 discovers that he/she wears an emergency identity token.	
3	Whether the patient is responsive or the patient is not responsive (or in an altered state of mind), the HCP1 inputs (or reads with a QR-code scanner) the code contained in the emergency identity token on the HCP App.	HA-SC-143
4	HCP1 using the same HCP App, requests access to the associated health data for	HA-SC-99, HA-

	emergency reasons.	SC-104, HA-45, SC-103
5	Initially, the HCP App authorizes the HCP1 to look only at the identification data of the patient associated with the emergency identity token.	HA-SC-143
6	The HCP1 compares the photo of the patient and relevant physical data (height, eye colour) contained in the identification data with the characteristics of the patient.	HA-SC-143
6.a	If the patient is responsive, HCP1 can request a direct identification to the patient.	
7	The HCP1 confirms the identification on the HCP App.	
8	The HCP App authorizes the HCP1 to access the (emergency) health data of the patient (as well as other HCPs involved in the patient's treatment).	HA-SC-99, HA-SC-144
9	The Patient's health data is imported in a few seconds (5 to 10) from the S-EHR cloud to the HCP App.	HA-SC-145, SA-SC-159
9.a	Data is visualized (and imported) by the HCP App used by HCPs currently authorized to treat patient's data (i.e. involved in the patient's treatment process), translated into HCPs natural language.	HA-51, HA-52
10	The admitting HCP1 performs a physical examination on the patient, revealing no significant abnormality at abdominal level.	
11	HCP1 consults the patient's history, imported from S-EHR cloud, where coronary artery disease, treated with percutaneous coronary angioplasty on the left anterior descending coronary artery is mentioned.	HA-51, HA-190
11.a	*The Angiography movie of the PTCA procedure is available for download, using the reference contained on S-EHR Cloud. The attending HCP1 downloads it and evaluates the previous PTCA procedure.*	*HA-SC-214*
12	From S-EHR cloud patient history is also reported diabetes as chronic illness, under treatment with insulin.	HA-51
13	Despite the absence of typical cardiac symptoms (patient has diabetes) the HCP1 performs a 12-lead EKG, showing on the HCP App a marked ST segment elevation on the inferior leads, supporting the diagnosis of acute myocardial infarction.	
14	Blood sample is taken by the HCP1 and results on the HCP App show a significant increase in troponin level.	
15	The HCP1 starts heart monitoring and starts an IV therapy.	
16	Patient is therefore referred to the Cath lab for urgent coronary angiography and revascularization.	
17	HCP1 from the patient's S-EHR noted an allergy to latex, so a latex-free PTCA	

	procedure was set in the cath lab.	
18	[To allow HCPs to display information as effectively as possible, within the S-EHR or the HCP app, information should be shown using priority levels that can be changed on the fly during viewing by the HCP who is using it, creating in this way an adaptive consultation interface that downloads in the background the relevant information of interest and shows it in the fastest way possible.]	
19	At patient discharge the S-EHR Cloud is updated with a Discharge Report containing the cause of admission, discharge diagnostic assessment,	HA-SC-100, HA-136, HA-46, HA-IH-151, HA-IH-152
	prescriptions, visits and recommendations, therapy and prescriptions.	SC-103, SA-148, SA-147
PCA	[Sub-scenario] Data imported from S-EHR Cloud may be stored safely by the Hospital for future access to authorized users, if authorized by the patient or by the law.	HA-146
PCB	When the S-EHR App of the patient is connected again with the internet, the new data produced by the hospital is downloaded from S-EHR Cloud to the patient's phone.	SA-SC-133

Table 11. Requirements associated to "Scenario S2 - Emergency access"

5.1.4 Requirements from scenario S3 - Health research study

#	Scenario S3 step	Implied requirements
A	Patients gave their consent (informed consent) to store data into their S-EHR app.	SA-5
B	Patients have their most recent and updated health data stored in the S-EHR app.	SA-HA-70
C	Patients data stored on the S-EHR app have a strict correlation to the patient's owner and data authorship.	SA-HA-69
D	Research Organisations (ROs) belong to the InteropEHRate Research Network.	
E	ROs have their own regulations in terms of researchers' access.	
F	ROs respect the accountability principles for health data management defined by the GDPR.	
G	Researchers have full access to internet connection and to the infrastructure of the InteropEHRate Open Research Network.	
H	Researchers own an electronic ID/account, required to access the InteropEHRate	IR-93, IR-191, IR-

	Open Research Network, released by an authority, national or local, certifying their identity and qualification.	82
I	Every action performed by the researchers on the InteropEHRate Open Research Network is registered (logged) and associated permanently with the unique identification of the author/actor and workstation/device.	IR-93
J	Health data sets shared for research purposes can be accessed/queried only by the authorized researchers.	IR-150
K	Patients select a reference region/area, i.e. their preferred region/area as location of the research centre that they can contact in case of participation in a research study, when a study is multi-centric.	SA-108, SA-IR-192
L	Patients can withdraw from their participation in the InteropEHRate Open Research Network at any moment.	SA-IR-109
1	Patients Eve and Adam give consent to be part of the InteropEHRate Open Research Network, i.e. they consent to their S-EHR app to match the health data stored by the app with the enrolment criteria of new research studies and be notified, in case of positive match, of the possibility to apply as participants to the study.	SA-107
2	A Research Organization, Coordinating Research Centre, formalises the research protocol called “Side effects from hypertensive medication study” using the InteropEHRate format:	SA-IR-110, SA-IR-111
2.a	the protocol involves patients with age > 18 years, with hypertension and treated with anti-hypertensive drugs, defined a research protocol specifying a required clinical dataset;	SA-IR-112, SA-IR-114, SA-IR-113
2.b	the protocol requires a set of pseudonymized health data that includes:	SA-IR-115, SA-IR-165
2.b.i	the prospective collection of symptoms, medications, healthcare treatment, vital signs, instrumental examinations results for the next 2 years after patient enrolment, as specified in the clinical research protocol;	SA-IR-116, SA-IR-117, SA-IR-119, SA-IR-193, SA-IR-194
2.b.ii	the retrospective collection of data up to 5 years before enrolment, as specified in the clinical research protocol;	SA-IR-118
2.c	the protocol specifies a set of participating Reference Research Centres belonging to specific regions.	SA-IR-120
3	Using the InteropEHRate Research Service, the Coordinating Research Centre publishes the research protocol on the InteropEHRate Open Research Network. The protocol references requested data and constraints (selection and exit criteria) with InteropEHRate profiles terminologies.	IR-81, SA-HA-73, SA-IR-195

4	The research protocol is transmitted to the S-EHR of the patients.	SA-IR-121
5	The S-EHR apps of the patients that have given consent to be invited to new research studies, automatically and silently match the enrolment criteria of the protocol with the content of the S-EHR app, without transmitting any data, in order to determine if the patient may be enrolled in the research.	SA-IR-121
6	If the evaluation of research criteria is positive, the S-EHR app displays to the owner patient a notification communicating that the patient may participate to the study and that he/she is to adhere to the research:	SA-IR-121
6.a	Eve may participate and is invited to the research;	SA-IR-121
6.b	Adam doesn't suffer from hypertension, so he is excluded from the research's possible candidates and receives no notification.	SA-IR-121
7	Eve accesses on the S-EHR app a list showing the studies she may participate in and selects the invitation called "Side effects from hypertensive medication study".	
8	The S-EHR app shows to Eve the details of the research protocol, including details about:	SA-89
8.a	the Coordinating Research Centre	SA-89, SA-IR-122, SA-90
8.b	the Local Research Centre (belonging to the Reference Region she previously selected),	SA-IR-122
8.c	reference contacts for further details,	SA-85, SA-IR-120
8.d	the requested health data (type of data and covering period),	SA-85
8.e	the purpose of the research,	SA-85, SA-IR-124
8.f	the data retention period,	SA-85, SA-IR-123
8.g	the level of anonymization of the requested data.	SA-IR-115
9	The research protocol requires her to share the health data of her previous 5 years and for the next 2 years, restricting their use only to that specific research protocol.	SA-89, SA-IR-125, SA-IR-117, SA-IR-118
10	Eve accepts to participate in the research.	SA-IR-126
10.a	If supported by the S-EHR App, Eve digitally signs on the S-EHR App the consent to participate in the research study;	SA-87
10.b	The S-EHR App shows to Eve the Reference Research Centres included in the protocol and belonging to the region she previously selected;	SA-IR-127

10.c	Eve selects a Reference Research Centre;	SA-IR-127
10.d	In case Eve cannot sign the consent on the S-EHR App or if required by the research protocol, Eve goes to the selected Reference Research Centre and signs the consent to participate in the research study.	
10.e	The consent restricts the use of the shared data only to that specific research protocol.	SA-IR-125
10.f	The S-EHR app receives and stores on the mobile device an electronic copy of the consent digitally signed by the Reference Research Centre.	SA-IR-128, SA-86, SA-IR-129
10.g	An anonymous identifier is assigned by the S-EHR App to Eve, in order to be used for health data pseudo anonymization only in the research "Side effects from hypertensive medication study".	SA-IR-130
11	A Reference Research Centre may obtain in any moment a statistic showing the number of citizens that consented to participate in the research protocol.	IR-83
12	At the start of the research, as indicated within the specification of the research protocol, the S-EHR app sends, in FHIR format, the pseudonymized health data to the Reference Research Centre, according to the clinical protocol design:	SA-IR-91
12.a	The data of the previous 5 year are sent to the Reference Research Centre.	SA-IR-91, SA-IR-118, SA-IR-164
12.b	Following the specification of the research protocol, the S-EHR app periodically and silently checks the content of the S-EHR app for the new data required by the research protocol and when available sends a pseudonymized copy of them, in FHIR format, to the Reference Research Centre selected by Eve.	SA-IR-91
12.b.i	pseudonymized data are sent for the next two years.	SA-IR-91, SA-IR-117
12.c	*For the previous or current health-related information, if some required data is available but is too large to be contained on the Smartphone, the S-EHR will have to activate the transfer of those information from the remote storage (source healthcare facility or local/regional/national storage service) to the Reference Research Centre, applying the required policy of anonymization / pseudonymization.*	*IR-215*
12.d	The Reference Research Centre selected by Eve forwards any new health data set to the Coordinating Research Centre (if different).	
13	Eve is asked to fill a questionnaire on self-reported side effects from anti-hypertensive medications.	SA-IR-218, SA-219
13.a	A few months later Eve complained nausea related to the assumption of the anti-hypertensive medications. Eva opens her S-EHR and access to the questionnaire of the research protocol, compiling the questionnaire with the symptom.	

13.b	The questionnaire is sent to the reference research centre.	
14	Eve may choose to be notified each time that new health data are sent to the Principal Investigator.	SA-132
15	Eve can withdraw her participation at any time.	SA-88
15.a	In case of withdrawing, the event is notified to the Reference Research Centre of Eve.	IR-84
16	Every data upcoming to the Reference Research Centre, updated in S-EHR and related to the research, are conveyed to the researcher Database for the period described by the research protocol	IR-82
16.a	According to clinical protocol design, health data are sent for the next 2 years.	SA-IR-117
PCA	At the end of the research, data imported from S-EHR are stored safely in the research facilities of the ROs and retained for the period specified by the research protocol or by the local/national regulation, then they are deleted (disposed).	

Table 12. Requirements associated to "Scenario S3 - Health research study"

5.1.5 Requirements from scenario S4 - Semantic Data Management

#	Scenario S4 step	Implied requirements
A	The health data of the Healthcare Organization are expressed in local language, and use locally specific terminology, codes, and data schemas to describe, structure, and classify healthcare information.	
B	Some portions of patient's health records are expressed as unstructured or semi-structured documents (e.g. PDF, HTML, or text files), while others are structured datasets that are available either in a tabular (e.g. CSV) or in a hierarchical form (e.g. XML or JSON). The DS-driven data integration and conversion process described in this scenario only applies to structured datasets. Unstructured documents, such as PDF files, are not transformed in this process beyond the possible automated machine translation of their textual content. Such files will be embedded as is within the FHIR-based data structure of the converted health records.	
C	In case a health record consists of several files or documents, it is assumed that each file is uniquely associated with the identity of the patient (e.g. contains a patient ID). In other terms, from the contents of each file the identity/patient ID of the patient must be certain.	
D	In the case of very complex health record files in terms of the number of attributes or XML elements (e.g. hundreds of attributes or deep XML hierarchies), the	

	handling of the file using the interactive Data Mapper Tool may be too cumbersome for the DS. In such cases, usually the DS splits such files into several simpler/smaller ones, while maintaining the link among them as described in point C above.	
E	Setting up the data mapping and conversion process is a combined top-down (specification-driven) and bottom-up (data-driven) effort. Thus, it is supposed that the DS has at his/her disposition: (1) adequate documentation on the local health record datasets, including all possible kinds of data files, data attributes, and data values; and (2) a significant amount (tens or preferably hundreds) of sample patient health records. This sample should be representative of the complexity of the health records that will be subjected to integration and conversion.	
F	The InteropEHRate Health Services, and within it the HDI Platform as well as the Knowledge Management Tool (KMT) and Data Mapping Tool (DMT), are deployed and configured (e.g. local language, HDI Platform communication parameters) within the IT infrastructure of the Healthcare Organization, in order to support the conversion and translation of structured and unstructured health record data.	IH-196, KM-197, DM-198
G	International Knowledge, as defined by the InteropEHRate Interoperability Profile, is a priori imported into the HDI Platform.	KM-154
H	The subset of locally used terms, codes, and data schema elements that are relevant for cross-border interoperability has been identified by local healthcare experts and the DS. In the following, we will not consider any terminology or other metadata that do not fall within this subset. In particular, the meanings of locally used terms, codes, and data schemas---which includes short textual definitions---are either already evident to the DS or they are available to him/her as formal (e.g. Excel sheet) or informal (e.g. human-readable PDF document) documents.	
I	This precondition holds only if the Healthcare Organization aims at semantic (and not only syntactic) interoperability. The mappings between locally used terms, codes, and data schema elements and their Interoperability Profile counterparts are available to the DS, expressed either formally (e.g. as a structured mapping file) or informally (e.g. as a human-readable PDF document).	
J	The information described under points H and I above has not yet been uploaded into the HDI Platform.	
1	An Italian Hospital wants to integrate the health records of its patients, stored in the Hospital's EHR, with the HDI Platform offered by InteropEHRate Framework, in order to convert EHR data in a format supported and interpretable by the S-EHR, defined by the InteropEHRate FHIR profiles.	
2	The Hospital assigns to a DS the task to complete the data integration procedure.	
2.a	As mentioned in preconditions F and G, the DS is already familiar with the health record data representations (the interpretation of data structures and values) and related practices of the Healthcare Organization.	

3	[This step is executed only if the Healthcare Organization aims at semantic interoperability.] The DS starts by formally describing the locally used terms and codes (but not the data schemas) as well as their mappings to the Interoperability Profile (preconditions F and G), into local knowledge, following the spreadsheet-based Terminology Import Format and using the Knowledge Management Tools to help in verifying the result. The result is one or more spreadsheet files ready to be imported into the HDI Platform, described in detail in Deliverable D5.8. This work is done once and for all, with subsequent minor modifications to keep the knowledge up to date.	KM-23, DM-24, KM-153, KM-201
4	[This step is executed only if the Healthcare Organization aims at semantic interoperability.] The DS imports local knowledge (i.e. the spreadsheet files using the Terminology Import Format) into the HDI Platform and fixes potential knowledge representation mistakes signalled by the system during the import process. (Examples of mistakes the system is capable of signalling are reference to non-existent concepts, duplicates, loops within hierarchies, etc.) The end result of importing can also be interactively verified using the Knowledge Management Tools (by browsing the imported knowledge).	KM-153, KM-200, KM-199
5	From the set of sample health records made available to the DS, (s)he selects a smaller subset that will constitute the definition set, i.e. the set of health records used as a basis to define the data mapping and conversion operations. The rest of the health records will constitute the validation set, subsequently used to validate the correctness of the same operations.	DM-202, DM-203
6	The DS loads a health record file---that may be a portion of a single patient's entire health record (see precondition D)---into the Data Mapper Tool.	
6.a	Using the data Mapper Tool, the DS defines the structural mapping operations from the local data schemas towards the international FHIR schemas. Beyond the mapping of data attributes, this work may also include, if necessary, data value reformatting, splitting, or merging. The Data Mapper Tool records the operations carried out by the DS. Once done, the DS saves the set of operations that will become the Syntactic Data Mapping Recipe (or simply Syntactic Recipe in the following).	DM-155, DM-202, DM-203, DM-204
6.b	The DS verifies the Syntactic Recipe by running it automatically over the test set of health record files. In case there are conversion errors (because of a mistake in mapping or because there were unforeseen cases of data heterogeneity within the test set), the DS loads the incriminated file and the Syntactic Recipe into the Data Mapper Tool, fixes the errors, and restarts this step. The DS can also use the Knowledge Management Tools, which contain a so-called Entity Browser Tool, to verify the results of conversion by browsing the integrated health record.	DM-155, IH-158, DM-205, DM-206, DM-207
6.c	If the health record consists of multiple files, steps a-b are executed for each file.	
7	[This step is executed only if the Healthcare Organization aims at semantic interoperability.] Once the DS is confident that syntactic conversion is robust	

	enough (i.e. it runs without errors over the entire test set and the Entity Browser Tool is showing correct results), (s)he proceeds to define semantic conversion.	
7.a	(S)he loads the Syntactic Recipe and the definition set file(s) into the Data Mapper Tool, runs the recipe, and completes it by the semantic conversion step of information extraction. The goal of information extraction is to identify relevant terminology and codes within natural-language labels inside the health record and link such mentions to the corresponding formal knowledge elements defined inside the Platform. The codes and terms to be extracted may be stand-alone (e.g. a single ICD-10 code expressed as a string “I69.3”) or embedded within a longer piece of text. The Semantic Recipe that results from adding the information extraction step to the syntactic one is, in turn, saved by the DS.	DM-208, DM-24, KM-25, KM-26
7.b	The DS verifies the correctness of the Semantic Recipe the same way as for the Syntactic Recipe, and confirms its validation. The recipe is put in production by exporting it from the Data Mapper Tool and placing it into a predefined directory and under a predefined name on the server in charge of processing health records.	IH-158, DM-211, DM-209, DM-210
8	In the case of the evolution of international knowledge---such as the introduction of a new LOINC code or a new FHIR attribute or resource---the knowledge content of the HDI Platform needs to be updated.	KM-154
8.a	The DS can obtain the file(s) to be imported into the HDI Platform from the Central Knowledge Provider, i.e. the Europe-wide entity responsible for maintaining the international knowledge.	
8.b	The DS simply needs to import the file(s) and, if necessary, update the local-to-international knowledge or data mappings (e.g. mapping of an existing local code to the new LOINC code, or of a local attribute to the new FHIR attribute)	KM-153
9	In the case of the evolution of the local terminology, codes, or their mappings, the DS needs to create a new Terminology Import Format spreadsheet file that formalises the changes to be applied to local knowledge. The file is then imported into the HDI Platform by the DS.	KM-153, DM-24, IH-158
9.a	In case the evolution of knowledge results in the evolution of data mapping rules, the DS also needs to update the Data Mapping Recipe(s) accordingly.	
10	In case of the evolution of local data structures (e.g. introduction of a new local data attribute) or of the data mapping rules, the DS may need to modify the Data Mapping Recipe(s) accordingly.	KM-153, DM-155, IH-158
10.a	It is the responsibility of the DS to be aware of the need to update the recipe(s). The way to do this is to load each recipe (syntactic or semantic) into the Data Mapper Tool, apply the modifications, and save the new recipe(s) to the same place as in point 7b above.	
PCA	When set up and maintained as described in the scenario above, the HDI Platform can be used automatically to convert the health records of the Healthcare	RA-IH-176, RA-IH-178, RA-IH-

	Organization to the representation defined by the Interoperability Profile, including updates made to the health records by an HCP as in scenarios 1 and 2.	177, HA-190, HA-IH-151, HA-IH-152
PCB	Exception/Errors management: because the approach might not be exhaustive, when the recipe defined by a DS is applied to an EHR and generates an Error/Exception, such event is notified to the DS who has to proceed to an update/correction of the Syntactic/Semantic recipe.	IH-158

Table 13. Requirements associated to "Scenario S4 - Semantic data management

5.2 Description of requirements

In the next subsections each one of the requirements referred by the previous table is described by means of the following attributes:

- **ID**: the unique identifier of the requirement (used in the previous table to refer to the requirement)
- **Title**: a very short description of the requirement.
- **Main actor**: the user that triggers the functionalities described by the requirements or that is the main beneficiary of the functionality
- **Requirement description**: what is the expected behaviour/action, who triggers the behaviour (a human actor or a system), which are the input data, which are the output data and who will receive them.
- **F/NF**: Indicates if the description refers to a functional or a non-functional requirement. The possible values are F and NF:
    - F: Functional requirement, i.e. any action performed by the SW Application in correspondence of specific events (including user interactions).
    - NF: Non-Functional requirement, i.e. constraint that must be fulfilled by the implementation of several functional requirements
- **Target**: indicates in which version of the project results the functional requirement will be implemented or specified. The possible values are:
    - v1 = InteropEHRate Framework v1 (Dec 2019)
    - v2 = InteropEHRate Framework v2 (March 2021)
    - v3 = InteropEHRate Framework v3 (March 2022)
    - s2 = InteropEHRate Open Specification v2 (Dec 2020)
    - s3 = InteropEHRate Open Specification v3 (June 2021)
    - OOS = Out Of Scope

For a NF requirement *C* the target version indicates when the first functional requirement constrained by *C* will be implemented[5].

The following list of requirements will be subject to possible changes during the development phases. Each of them will be split during the development into more fine-grained user stories implemented in an incremental way.

5.2.1 S-EHR App

The following table describes the requirements that the S-EHR App owned by the Citizen must fulfil in order to realize the scenarios S0, S1, S2 and S3. The table lists the requirements that involve only the S-EHR App, while the following subsections list the requirements that involve respectively also the HCP App, the R2D Access Service, the S-EHR Cloud, and the InteropEHRate Research Services.

ID	Title	Main actor	Requirement description	F/NF	Target
SA-4	S-EHR runs on iOS smartphone	-	The S-EHR is a mobile app that can run on IoS version X	NF	s2
SA-9	Data hiding management on S-EHR	Citizen	The S-EHR allows the Citizen to hide some data to HCPs	F	OOS
SA-19	Auditing health data modification for Citizen on S-EHR	-	Any modification on health data (creation, reading, updating, deleting) performed by any user is tracked by the S-EHR	NF	v1
SA-5	Confirmation to enable the S-EHR data management	Citizen	At first run the S-EHR obtains from the Citizen is informed that: (1) his/her personal health data will be stored and managed by him on the smart device, (2) any data sharing action will require his/her approval. A confirmation is then requested to start to use the S-EHR.	F	v1
SA-29	D2D Access consent to healthcare organization by Citizen	Citizen	The Citizen gives the consent to the healthcare organization to allow the healthcare organization to access his/her (the citizen's) identifying data.	F	OOS
SA-35	D2D consent by the Citizen for temporary S-EHR access to Healthcare	Citizen	The Citizen may give his/her temporary consent, to all HCP belonging to a specific Healthcare Organization and involved in a specific care/treatment, to download data	F	v1

[5] The implementation of the constraint C will be complete only when the last functional requirement constrained by C will be implemented.

	organization		from the S-EHR and upload the updated/acquired data back to the S-EHR. The temporary consent of the Citizen for data exchange automatically expires at the end of the day.		
SA-27	D2D device pairing	Citizen	The Citizen connect/pair his/her smart device to the HCP computer/device	F	v1
SA-37	Customisation of permissions during a specific data exchange	Citizen	Give the possibility to the patient to use permissions different from his default permissions during a specific data exchange. E.g. If an HCP "x" requires weight data and the patient hid the weight in his default permissions, we ask the patient if he wants to share the weight with HCP "x" anyway. If we do this requirement, the "customisation" aspects of data sharing should be included in the consent.	F	OOS
SA-28	D2D Visualization of Healthcare organization to the Citizen	Citizen	The Citizen see on the S-EHR the data describing the identity of the Health Organization	F	v1
SA-6	Enabling of Citizen identification from S-EHR (without CA)	Citizen	The S-EHR stores and sends to the HCP App the identification data of the citizen (the identification data allows the HCP to confirm the identity of the citizen by comparing them with the ID card of the Citizen).	F	v1
SA-36	Implicit application of default S-EHR access permissions for D2D	Citizen	When the Citizen gives the temporary consent to the organization, he/she implicitly gives the default view/transmission temporary permissions he previously configured on the S-EHR.	F	OOS
SA-1	S-EHR download from Android store	Citizen	S-EHR is downloadable from the Android store. The Citizen downloads the S-EHR from the Android store and installs it on its Android device.	NF	v1
SA-3	S-EHR runs on Android smartphone	Citizen	The S-EHR is a mobile app that can run on Android version X	NF	v1
SA-20	Consultation of auditing health data modification for	Citizen	Any audited modification on health data (creation, reading, updating, deleting) performed is consultable from the Citizen that	F	v1

	Citizen on S-EHR		is the owner the data		
SA-76	Auditing health data sharing for Citizen on S-EHR	-	Any sharing operation on health data (sharing, authorization) performed by any user is tracked by the S-EHR	NF	v2
SA-77	Consultation of auditing health data sharing for Citizen on S-EHR	Citizen	Any audited sharing operation on health data (sharing, authorization) is consultable from the Citizen that is the owner the data	F	v2
SA-78	Enabling of Citizen identification from S-EHR (with CA)	Citizen	The S-EHR asks the Citizen and stores on the device a qualified certificate that identifies the Citizen. The certificate is released by a CEF eID trusted certification authority.	F	v3
SA-85	Citizen's consultation of the details of the research study	Citizen	The Citizen can consult the list of received invitations to research studies and see, for each of them, the details of requested health data, the purpose of the research, the data retention periods and the level of anonymization. The Citizen may also consult the information document of the research, containing reference contacts of ORG and principal investigator, to be contacted for further details.	F	v3
SA-86	Digitally signature by Reference Research Centre of Citizen's consent	Citizen	The Reference Research Centre digitally counter-signs the consent (to participate in a research study) signed by the citizen, and sends it back to the citizen.	F	v3
SA-87	Citizen's digital signature of consent to share health data for a given study	Citizen	The Citizen can give his/her consent to participate in a research study he/she has been invited to and digitally sign it (in a legally binding way) directly on his/her S-EHR.	F	v2
SA-88	Citizen's digital revocation of consent to share health data for a given study	Citizen	A Citizen may revoke, directly from his/her S-EHR, a consent previously released to participate in medical research. The revocation of the consent using the S-EHR must be legally binding for the Reference Research Centre also in case the S-EHR does not support the digital signature of the consent by the citizen directly on the S-EHR.	F	v3

SA-89	Invitation of candidate citizens to participate to a research study	Citizen	The S-EHR, upon receiving a notification of the publication of a research study, executes a check to verify if the citizen's profile matches with research study enrolment criteria. If the matching is positive then the citizen is invited to share his/her health data to the research study.	F	v2
SA-90	Reminder of invitation to participate in a research study	Citizen	If there is some invitation to which the citizen still has to answer, a notification is displayed periodically to remind him to decide.	F	v3
SA-94	Patient Summary consultation on HCP App (with citizen update)		The HCP can download from the S-EHR, using the D2D protocol, health data produced directly by the citizen.	F	DEL
SA-95	Update from the patient of personal health information	Citizen	The citizen can update his/her personal health information stored on his/her mobile by updating existing health data, or by adding new health data	F	DEL
SA-106	Adding of new S-EHR Cloud service to the S-EHR	Citizen	The Citizen adds a new S-EHR Cloud service to the list of certified S-EHR Cloud services of the S-EHR by inputting the URL of the service. Only S-EHR Cloud services that are conformant to the InteropEHRate S-EHR conformance levels may be added to the list of certified Cloud services.	F	v3
SA-107	Citizen's consent to be part of InteropEHRate Open Research Network	Citizen	Using their S-EHR, and signing a digital consent, citizens can become part of the InteropEHRate Open Research Network. From that moment, the S-EHR will receive the details of new research studies and will be authorised to match the health data of the citizen with the enrolment criteria of the study (without sending any health data to any party).	F	v2
SA-132	Notification to Citizens of data sharing event for research	Citizen	When the S-EHR of a citizen automatically shares new data as prescribed by a research protocol that the citizen consented to participate in, the citizen will receive a notification.	F	v3

SA-134	Citizen's access to emergency token	Citizen	Citizens may use their S-EHR to access to and exchange with other applications an image containing their "emergency token". The emergency token allows a qualified HCP (authorised by his/her organization) to identify the Citizen and access in case of emergency to his/her health data stored on the S-EHR Cloud, also if the Citizen is unable to provide his/her identity or if the S-EHR is not available.	F	v2
SA-135	Encryption of S-EHR content exchanged with S-EHR Cloud.	-	Every data sent by a S-EHR to the S-EHR Cloud is encrypted by the S-EHR, before of the transmission, with a private key unknown to the S-EHR Cloud provider, so that the S-EHR Cloud provider cannot decrypt any stored data, but only the Citizen and the HCP can.	NF	v2
SA-147	Storage and download of medical images on S-EHR	Citizen	A Citizen can enable also the storage, and import/download of Medical Images from EHR and S-EHR Cloud, on S-EHR if the smart device has enough memory.	F	v2
SA-148	Citizen's access to Medical images from S-EHR	Citizen	A Citizen may access from the S-EHR to his/her Medical images stored on the S-EHR Cloud or on the S-EHR	F	v2
SA-163	Encryption of health data written on S-EHR App	Citizen	The personal data of the Citizen are stored on the mobile device by the S-EHR App in an encrypted format, decryptable only by the citizen, to avoid any unauthorized access on the data.	NF	v3
SA-171	Consultation of treatment plan on S-EHR	HCP	The Citizen can consult the treatment plan from the S-EHR	F	v3
SA-172	Selection of healthcare providers for R2D Access	Citizen	The patient can consult the list of hospitals trusted by the S-EHR that provides an R2D Access Service and can select the ones from which to download his or her health data.	F	v3
SA-173	Notice of R2D Access usage terms	Citizen	When the Citizen asks for the import of health data by R2D Access, the S-EHR gives notice that using R2D Access the Citizen authorises the healthcare provider to convert/translate and transmit health data to the S-EHR.	F	v3

SA-180	Browsing by Encounter of health data on S-EHR	Citizen	The Citizen can browse the health data available on the S-EHR by the associated medical encounter.	F	v3
SA-181	Filtering by date and type of health data on S-EHR	Citizen	When consulting the health data available on the S-EHR the Citizen can filter them by date and type.	F	v3
SA-182	Deletion of selected health data from S-EHR by the Citizen	Citizen	The Citizen can remove from the S-EHR any selected health data.	F	v3
SA-183	Manual input of health data by the citizen on the S-EHR	Citizen	The Citizen can add new health data on the S-EHR	F	v3
SA-184	Import of health data by the citizen on the S-EHR from personal devices	Citizen	The Citizen can import on the S-EHR health data measured by personal devices	F	v3
SA-186	Printing of Citizen's QR-code	Citizen	The Citizen can print the QR-code generated by the S-EHR app	F	v3
SA-219	Execution of questionnaire defined by research protocol	Citizen	At the time specified by the formal specification of the research protocol the citizen is invited to answer on the S-EHR to the defined questionnaire and the answers are stored by the S-EHR.	F	v3

Table 14. Requirements that apply to the S-EHR App

5.2.1.1 S-EHR App and HCP App

ID	Title	Main actor	Requirement description	F/NF	Target
SA-HA-31	D2D Identification and Authentication of the citizen from HCP	HCP	The citizen's identification data (certificate) is used to create or match the citizen's digital identity in the HCP App. The certificate contains the information of the patient from his/her ID card. The certificate is displayed to the HCP and he/she can dismiss or accept the consultation. The match can be persistent in the HCP App in order to avoid the manual confirmation for future use. The citizen's digital identity is used for further	F	v2

			transactions, e.g. D2D data exchange.		
SA-HA-57	D2D upload by HCP of Prescription and report on S-EHR	HCP	An HCP may upload a Prescription and report on the S-EHR using D2D protocol	F	v2
SA-HA-69	Non repudiable data provenance tracking	Data use	The author and data origin of any health data is verified (i.e. non repudiable), tracked, visible to any authorized user and legally valid.	NF	v2
SA-HA-70	Integrity of medical information	Data use	Users are guaranteed that the managed health data (stored or transferred) hasn't been modified maliciously or accidentally.	NF	v3
SA-HA-73	Compliance to IEHR profiles	Data use	The S-EHR and HCP App refuse to accept any health data set including a FHIR resource that declares conformance to an IEHR profile but is not actually conformant to it.	NF	v2
SA-HA-169	D2D upload by HCP of diagnostic conclusions on S-EHR	HCP	An HCP can upload an evaluation report on the S-EHR of the subject Citizen using the D2D protocol	F	v3
SA-HA-170	D2D upload by HCP of Treatment Plan on S-EHR	HCP	An HCP can upload the treatment plan on the S-EHR of the subject Citizen using the D2D protocol	F	v3

Table 15. Requirements that involves the S-EHR App and the HCP App

5.2.1.2 S-EHR App and R2D Access Service

ID	Title	Main actor	Requirement description	F/NF	Target
SA-RA-15	R2D import of (portion of) Laboratory result from healthcare provider on S-EHR	Citizen	Citizen health data (portion of Laboratory results) can be imported from the Citizen healthcare provider on Citizen S-EHR.	F	v2
SA-RA-16	R2D import of (portion of) Medical images	Citizen	Citizen health data (portion of reports and medical images) can be imported from	F	v2

	and reports from healthcare provider on S-EHR		Citizen healthcare provider on Citizen S-EHR.		
SA-RA-17	R2D import of (portion of) Hospital discharge reports from healthcare provider on S-EHR	Citizen	Citizen health data (portion of Hospital discharge reports) can be imported from the Citizen national EHR on Citizen S-EHR.	F	v3
SA-RA-18	R2D import of (portion of) health data from all healthcare providers on S-EHR	Citizen	(A portion of) Citizen health data can be imported from all remote healthcare providers on Citizen S-EHR.	F	OOS
SA-RA-13	R2D import of (portion of) Patient Summary from healthcare provider on S-EHR (without security)	Citizen	Citizen health data (portion of Patient Summary) can be imported from the Citizen healthcare provider on Citizen S-EHR.	F	v1
SA-RA-14	R2D import of (portion of) Prescription from healthcare provider on S-EHR	Citizen	Citizen health data (portion of Prescriptions) can be imported from the Citizen healthcare provider on Citizen S-EHR.	F	v3
SA-RA-74	R2D import of (portion of) Patient Summary from healthcare provider on S-EHR (with security)	Citizen	Citizen health data (portion of Patient Summary) can be imported from the Citizen healthcare provider on Citizen S-EHR.	F	v2
SA-RA-156	R2D import from EHR to S-EHR of the vital signs and other measures	Citizen	The vital signs and other measures taken during previous medical visits can be imported from the EHR of an healthcare provider to the S-EHR of the citizen.	F	v3

SA-RA-166	R2D import of Patient's Encounters and related health data from hospital EHR with eIDAS login	Citizen	The Citizen can import on the S-EHR app the description of any encounter with selected healthcare providers and related health data.	F	v3
SA-RA-174	Automatic check and download of new health data by R2D Access	Citizen	If asked by the Citizen, the S-EHR will automatically import, without any further user confirmation, any new or updated HR data available from the selected healthcare provider.	NF	v3
SA-RA-175	Automatic check and manual approval of download of new health data by R2D Access	Citizen	If asked by the Citizen, the S-EHR will automatically check the availability of new or updated health data from the selected healthcare provider, will notify the Citizen if any and will download them after confirmation by the user.	NF	v3
SA-RA-179	Selection of Encounters to download by means of R2D Access	Citizen	The Citizen can choose to import all the health data available from a selected healthcare provider or just the health data related to specific medical encounters.	NF	v3
SA-RA-212	*R2D-Access to DICOM references*	*Citizen*	*The Citizen may receive from the R2D-Access service health data that contains a reference to a downloadable DICOM studies.*	*F*	*s3*
SA-RA-213	*Download on S-EHR of referred DICOM Studies*	*Citizen*	*The Citizen can download on the S-EHR any DICOM study referred to by previously downloaded health data.*	*F*	*s3*

Table 16. Requirements that involves the S-EHR App and the R2D Access Service

5.2.1.3 S-EHR App and S-EHR Cloud

ID	Title	Main actor	Requirement description	F/NF	Target
SA-SC-97	Activation of automatic backup of S-EHR content on selected S-EHR Cloud	Citizen	Citizens can activate by means of explicit consent the automatic backup, of all the health records stored on their S-EHR, on their preferred S-EHR Cloud service (selected by the list of certified S-EHR Cloud services provided by the S-EHR).	F	v2

SA-SC-98	Sharing of health data with qualified HCPs for emergency by means of S-EHR Cloud	Citizen	Citizens can consent HCPs of Healthcare organisations to access, only for emergency reasons, to their health data stored on the S-EHR cloud. Giving the consent activates the automatic backup of the health data from the S-EHR to the preferred S-EHR Cloud (selected by the list of certified S-EHR Cloud services provided by the S-EHR). The consent authorises the HCP to access health data using an emergency token or the identification data of the citizen.	F	v2
SA-SC-133	Automatic download of health records from S-EHR Cloud to S-EHR	-	When the citizen authorises the backup on the S-EHR Cloud, any new health data written on the S-EHR Cloud by an authorised application are automatically replied to on the S-EHR of the citizen. The alignment happens automatically each time that the smartphone of the Patient is connected to the internet.	F	v2
SA-SC-149	Citizen's consultation on S-EHR of S-EHR Cloud auditing data	Citizen	A Citizen may consult on the S-EHR the auditing data collected by the S-EHR Cloud	F	v3
SA-SC-159	Notification of access to health data on S-EHR Cloud	Citizen	Whenever someone accesses the health data of the citizen stored on the S-EHR Cloud, the citizen is notified so that it can immediately change (i.e. regenerate) the QR code in case that the access was not authorised.	F	v3
SA-SC-185	Consent, exchange and storing of Citizens' face (photo) on the S-EHR and S-EHR Cloud	Citizen	If the patient gives explicit consent the S-EHR and S-EHR Cloud are able to store and exchange with the HCPs also a photo of the citizen's face to identify the patient during the emergencies.	F	v3
SA-SC-187	Update of Citizen's QR-code	Citizen	The citizen can ask the S-EHR app to generate a new QR-code and update the S-EHR Cloud content accordingly	F	v3

Table 17. Requirements that involves the S-EHR App and the S-EHR Cloud

5.2.1.4 S-EHR App and InteropEHRate Research Services

ID	Title	Main actor	Requirement description	F/NF	Target
SA-IR-91	Automatic anonymisation and sharing of citizen's health data for research.	-	After a citizen accepted an invitation to a research study and the study is started according to the specified protocol, the S-EHR automatically queries its content for the data required by the study, once or periodically, depending on the study, and automatically sends the matching data to the IEHR Research Network. The S-EHR anonymises the data before sharing it, if required by the protocol.	F	v3
SA-IR-109	Citizen's withdrawing from research network	Citizen	A Citizen may withdraw at any moment, using the S-EHR, from his/her participation to the InteropEHRate Research Network.	F	v2
SA-IR-110	Support of machine interpretable research protocol for publication.	-	A research protocol that is publishable on the InteropEHRate Open Network must contain a machine interpretable description of the set of health data that the patient will consent to share, of the enrolment criteria. The representation has to be interpretable by the S-EHR for (1) automatically comparing the enrolment criteria with the content of the S-EHR, to check if the patient can be enrolled; (2) automatically share the required data set with authorised Research Organisations.	NF	v2
SA-IR-111	Support of name within publishable research protocol.	-	A formal publishable specification of a research protocol allows to assign a name to the research protocol.	NF	v2
SA-IR-112	Support of constraints on min and max value of patient's attributes within enrolment criteria.	-	A formal publishable specification of a research protocol allows to express enrolment criteria based on constraint on the minimum or maximum allowed value of a specific attribute of the patient.	NF	v2
SA-IR-113	Support of constraints on patient's diagnosis within enrolment criteria.	-	A formal publishable specification of a research protocol allows to express enrolment criteria based on the received diagnosis of the patient.	NF	v2

SA-IR-114	Support of constraints on patient's drug therapy within enrolment criteria	-	A formal publishable specification of a research protocol allows to express enrolment criteria based on one or more active ingredients included in the current or past patient's therapy.	NF	v2
SA-IR-115	Support of description of pseudo-anonymization (yes/no) within data set definition	-	A formal publishable specification of a research protocol allows to express if the citizen is asked to share identity information or pseudonymized health data has to be shared in order to participate in the described study.	NF	v2
SA-IR-116	Support of drug treatment plan within data set definition.	-	A formal publishable specification of a research protocol allows to include the treatment plan (both prescription and consumption of drugs) of the patient among the kind of health data that the citizen is required to share in order to participate in the described study.	NF	v2
SA-IR-117	Support of specification of prospective period within dataset definition.	-	A formal publishable specification of a research protocol allows to specify the period of time in the future during which the required health data will be required to be produced and shared by the citizen, in order to participate in the described study.	NF	v2
SA-IR-118	Support of specification of retrospective period within dataset definition.	-	A formal publishable specification of a research protocol allows to specify the period of time in the past that the required health data refers to and has to be shared by the citizen in order to participate in the described study.	NF	v2
SA-IR-119	Support of evaluation data (blood tests, vital signs, visits, instrumental examination) within data set definition.	-	A formal publishable specification of a research protocol allows to specify the health evaluation data (blood tests, vital signs, visits, instrumental examination) to be shared by the citizen in order to participate in the described study.	NF	v2
SA-IR-120	Support of specification of Reference Centres within research protocol	-	A formal publishable specification of a research protocol allows to specify the list of Research Centres (and relative region) that a patient participating in the study can select as a Reference Research Centre for the specific	NF	v3

			described study. The Research Centres are identified by a simple unique ID and described by name, specialty, address and contact information.		
SA-IR-121	Automatic reception, matching and notification of enrolment criteria on S-EHR.	Citizen	From the moment that a citizen accepted to participate to the InteropEHRate Open Research Network, the S-EHR will receive any new research protocol and will automatically match the health data of the citizen contained within the S-EHR with the enrolment criteria of the new protocol, without sending any personal data of the citizen to any party. The citizen is notified when a positive match is found.	F	v3
SA-IR-122	Inclusion of human readable description of Coordinating and Local Research Centre within research protocol	-	A formal publishable specification of a research protocol refers to a human readable document (PDF) including a description of the research centre that will coordinate the specific study of the specific research centre (Local Research Centre) that will receive and process the shared health data.	NF	v3
SA-IR-123	Inclusion of human readable description of data retention period within the research protocol	-	A formal publishable specification of a research protocol refers to a human readable document (PDF) including a description of the amount of time that the researchers will be authorized to store and use any personal health fata shared by the citizen for that specific research protocol.	NF	v3
SA-IR-124	Inclusion of human readable description of purpose of research within the research protocol	-	A formal publishable specification of a research protocol refers to a human readable document (PDF) including a description of the purpose of the described research study.	NF	v3
SA-IR-125	Inclusion of human readable description of usage restrictions of data within the research protocol	-	A formal publishable specification of a research protocol refers to a human readable document (PDF) including a description of all the allowed and forbidden usages of any personal health data shared by the citizen for that specific research protocol.	NF	v3

SA-IR-126	Citizen's consent to share health data for a research protocol	Citizen	Using the S-EHR a Citizen may give an electronic consent to participate in a specific research study, so accepting the condition described within the formal published specification of that research study.	F	v3
SA-IR-127	Citizens' selection of reference research centre	Citizen	The Citizen selects through the S-EHR, the reference research centre, which is one of those centres within the geographical region previously selected by the Citizen. The selection is notified to the reference research centre.	F	v3
SA-IR-128	Reception and storage of consent, digitally signed from research organisation, on Citizen's S-EHR	Citizen	After that a consent to participate to a research protocol has been signed on paper form the citizen, an electronic copy of it, digitally signed by the research centre where the consent has been given, is sent to and received by the S-EHR of the Citizen, and will be stored permanently within the S-EHR.	F	v3
SA-IR-129	Signed consent refers to the research protocol accepted by the patient.	-	A S-EHR will store the signed consent and will start to share health data on the InteropEHRate Open Research Network only if the signed consent refer to a research protocol already accepted by the Patient on the S-EHR.	NF	v3
SA-IR-130	Pseudoidentity restricted to a single research protocol.	-	When a citizen gives a digital consent to participate in a research protocol, a specific pseudo-id for that patient will be generated, to be used only for the pseudonymization of data shared within that specific research protocol.	NF	v3
SA-IR-164	Encryption on anonymised S-EHR content exchanged with the RRC	Citizen	Every data sent by a S-EHR to the RRC is encrypted by the S-EHR, before the transmission.	NF	v3
SA-IR-165	Authentication of the S-EHR App to the Pseudonym Provider	Citizen	In the second variant of the protocol the user has to authenticate himself to the Pseudonym Provider in order to retrieve the pseudonym	NF	v3
SA-IR-192	Support of multicentric studies within publishable	-	A formal publishable specification of a research protocol allows to define a multicentric protocol.	NF	v3

	research protocol				
SA-IR-193	Support of symptoms within dataset definition of publishable research protocol	-	A formal publishable specification of a research protocol allows to define the information related to citizens' symptoms to be included in the dataset to be retrieved from the S-EHR.	NF	v3
SA-IR-194	Support of healthcare treatments within dataset definition of publishable research protocol	-	A formal publishable specification of a research protocol allows to define the information related to citizens' healthcare treatments to be included in the dataset to be retrieved from the S-EHR.	NF	v3
SA-IR-195	Support of exit criteria within publishable research protocol	-	A formal publishable specification of a research protocol allows to define the exit criteria for the exclusion of a citizen form the research study.	NF	v3
SA-IR-218	Support of questionnaire within dataset definition of publishable research protocol	-	A formal publishable specification of a research protocol allows to define a questionnaire for collecting self-reported health data from the patient (e.g. side effects from anti-hypertensive medications). which answers must to be included in the dataset to be retrieved from the S-EHR.	NF	v3

Table 18. Requirements that involve the S-EHR App and the Research Services

5.2.2 HCP App

The following table describes the requirements that the application used by the HCPs (HCP App) must fulfil in order to fully realize the scenarios S1 and S2. The following two subsections describe additional requirements whose implementation involves both the HCP App and respectively the S-EHR-Cloud, the InteropEHRate Health Services and the InteropEHRate Research Services.

ID	Title	Main actor	Requirement description	F/NF	Target
HA-160	Current Diseases consultation on HCP App	HCP	An HCP can view the Current Diseases shared with him/her by a Citizen using the HCP App	F	v2
HA-161	Pathology History	HCP	An HCP can view the Pathology History	F	v2

	consultation on HCP App		shared with him/her by a Citizen using the HCP App		
HA-162	Document History Consultation	HCP	An HCP can view the Document History shared with him/her by a Citizen using the HCP App	F	v2
HA-167	Previous visit (diagnosis, treatment plan, medications) consultation on HCP App	HCP	An HCP can view the prescriptions shared with him/her by a Citizen using the HCP App	F	v3
HA-168	Treatment plan compilation on HCP App	HCP	During a medical visit an HCP can create and compile a new treatment plan for the patient using the HCP App.	F	v3
HA-190	Automated translation on HCP App of information extracted from natural language in downloaded health history	HCP	An HCP can see a translated version of information extracted from natural language in the full downloaded health history	F	v3

Table 19. Requirements for the HCP App

5.2.2.1 HCP App and S-EHR Cloud

ID	Title	Main actor	Requirement description	F/NF	Target
HA-SC-99	HCP's access to health data of an identified citizen for emergency reasons	HCP	If the Citizen authorised the access to health data for emergency reasons, in case of a medical emergency and after identification of the citizen, a qualified HCP can retrieve the health data of the Citizen from his/her S-EHR Cloud, by using the HCP App, the Citizen's identity data and suitable credentials provided by the healthcare organisation.	F	v2
HA-SC-100	Storing of Discharge Report on Citizen's S-EHR Cloud by the HCP	HCP	At patient discharge, the Discharge Report is created by the HCP using the HCP app and stored in the Citizen's S-EHR Cloud	F	v3
HA-SC-104	HCP's access to Citizen's medical images for emergency reasons	HCP	In the case of an emergency, after gaining access to the Citizen's health records, the HCP may retrieve from the Citizen's S-EHR Cloud any image referred by the accessed health records.	F	v3
HA-SC-	Legal identification	-	Only HCP belonging to recognised Healthcare	NF	v3

138	and authentication of qualified Healthcare organisations		organisations can access emergency data. Each Healthcare organisation is identified by a digital identity issued by a legal national or local authority recognised by the S-EHR Cloud and that assures the Healthcare role of the organisation.		
HA-SC-139	Legal identification and authentication of qualified HCPs	-	Only HCPs having a digital identity issued by a legal national or local authority recognised by the S-EHR Cloud can access (for emergency reasons) to the health data of the Citizen.	NF	s3
HA-SC-143	HCP' access to Citizen identity by means of Citizen's token	-	In case of a medical emergency, an authorised HCP can retrieve the photo and identification data of a Citizen from his/her S-EHR Cloud, using the HCP App, the Citizen's token and suitable credentials provided by the healthcare organisation.	F	v2
HA-SC-144	Authorisation to the healthcare team for emergency	-	When a qualified HCP gains access to the health data for emergency reasons, also the rest of the healthcare team that treats that patient for that specific emergency encounter automatically gains access to the same health data.	F	v3
HA-SC-145	High transfer rate of a 10MB Health Data resource transmission in emergency	-	When an HCP access to the Citizens' Dataset, it is imported in a few seconds (5 to 10) from the S-EHR cloud to the HCP App.	NF	v2
HA-SC-188	S-EHR Cloud authentication based on HCP identity issued by healthcare provider	HCP	The healthcare provider is authenticated and authorised to download emergency data from the S-EHR Cloud on the base of an electronic identity provided by a local or national authority (trusted certification authority) while the specific HCP is authenticated and authorised by the HCP App on the base of its qualification certificated by the healthcare provider. The identity and healthcare provider of the HCP are audited by the S-EHR Cloud.	F	v3
HA-SC-189	S-EHR Cloud authentication based on HCP identity issued by local or national authority	HCP	The HCP is authenticated and authorised to download emergency data from the S-EHR Cloud on the base of an electronic identity provided by a local or national authority (trusted certification authority). The identity and healthcare provider	F	v3

			of the HCP are audited by the S-EHR Cloud.		
HA-SC-214	*Download on HCP App of referred DICOM Studies*	*HCP*	*The HCP can download from the reported URL the DICOM studies referred to by health data contained on S-EHR Cloud.*	*F*	*s3*

Table 20. Requirements that involve the combination of HCP App and S-EHR Cloud

5.2.2.2 HCP App and InteropEHRate Health Services

ID	Title	Main actor	Requirement description	F/NF	Target
HA-IH-151	Automated translation by HCP App of information extracted from natural language in assessment reports to the Citizen's language	-	Before sending it to the S-EHR or to the S-EHR Cloud, the HCP App translates the information extracted from the natural language in image and signal assessment reports Report to the Citizen's language.	F	v3
HA-IH-152	Automated translation by HCP App of information extracted from natural language in Discharge Report to the Citizen's language	-	Before sending it to the S-EHR or to the S-EHR Cloud, the HCP App translates the information extracted from the natural language in Discharge Report to the Citizen's language.	F	v3
HA-IH-157	Distinction between data translated/converted and original data	HCP	The HCP can distinguish which portion of data has been converted or translated and can always see both the original version and the converted or translated one.	NF	v2

Table 21. Requirements HCP App and InteropEHRate Health Services

5.2.2.3 HCP App and InteropEHRate Research Services

ID	Title	Main actor	Requirement description	F/NF	Target
HA-IH-151	Automated translation by HCP App of information extracted from natural language in assessment reports to the Citizen's	-	Before sending it to the S-EHR or to the S-EHR Cloud, the HCP App translates the information extracted from the natural language in image and signal assessment reports Report to the Citizen's language.	F	v3

	language				
HA-IH-152	Automated translation by HCP App of information extracted from natural language in Discharge Report to the Citizen's language	-	Before sending it to the S-EHR or to the S-EHR Cloud, the HCP App translates the information extracted from the natural language in Discharge Report to the Citizen's language.	F	v3
HA-IH-157	Distinction between data translated/converted and original data	HCP	The HCP can distinguish which portion of data has been converted or translated and can always see both the original version and the converted or translated one.	NF	v2

Table 22. Requirements that combine the S-EHR App and the InteropEHRate Research Services

5.2.3 S-EHR Cloud

The S-EHR Cloud allows the Citizen to back-up their health data and allows qualified HCP to access them in case of emergency (if the citizen authorised such an usage). The following table lists the requirements of the S-EHR Cloud elicited from the analysis of scenario S2.

ID	Title	Main actor	Requirement description	F/NF	Target
SC-101	Auditing of HCPs that gained access for emergency reasons to Citizen's health data	HCP	The S-EHR Cloud keeps track of the HCPs that gained access for emergency reasons to the Citizen's health data stored on S-EHR Cloud. Each HCP is identified by a digital identity issued by a legal national or local authority recognised by the S-EHR Cloud.	NF	v3
SC-102	Auditing of changes to health data stored in the S-EHR Cloud	Data user	A S-EHR Cloud keeps track of health records added to or removed from the Citizen's health data stored on it.	NF	v3
SC-103	Storing Citizen's Medical Images in the S-EHR Cloud	Citizen	The Citizen's S-EHR Cloud backups encrypted copies of medical images and references to downloadable images contained in the Citizen's S-EHR.	F	v2
SC-105	Auditing of	HCP	The S-EHR Cloud keeps track of the HCPs that	NF	v3

	HCPs that gained access to the Medical Images		gained access to the Citizen's Medical Images		
SC-137	Auditing of Organisations that gained access to health data for emergency reasons	HCP	A S-EHR Cloud keeps track of the Organisation of any HCP that gained access to the Citizen's health data for emergency reasons. Each Organisation is identified by a digital identity issued by a legal national or local authority recognised by the S-EHR Cloud.	NF	v3
SC-140	Auditing of citizens that gained access to their health data	-	A S-EHR Cloud keeps track of the citizens that accessed their health data. The real identity of the citizen is hidden to the S-EHR Cloud service.	NF	v3

Table 23. Requirements of S-EHR Cloud

5.2.4 R2D Access and InteropEHRate Health Service

The table below describes the requirements that applies to the InteropEHRate Health Services while the following one describes the ones that involves both R2D Access and InteropEHRate Health Services

ID	Title	Main actor	Requirement description	F/NF	Target
IH-158	Logging of unsupported conversions and translations	Data scientist	The conversion and translation services produce a log of any code or other information it is unable to convert or translate in order to be consulted by the Data Scientist to complete or improve the data mapping.	F	v3
IH-196	Configurability of IHS	Data scientist	The Data Scientist can configure the local language and HDI parameters of the InteropEHRate Health Services.	F	v3

Table 24. Requirements for the InteropEHRate Health Services

ID	Title	Main actor	Requirement description	F/NF	Target
RA-IH-176	Automatic conversion of health data for R2D Access	-	Health data imported on the S-EHR by means of R2D Access are converted to InteropEHRate format by the healthcare provider, before sending them to the S-EHR.	F	v3

RA-IH-177	Automatic translation of (portion of) health data for R2D Access	-	A portion (depending on the capability of the healthcare provider) of health data imported on the S-EHR by means of R2D Access are translated in the patient's language by the healthcare provider, before sending them to the S-EHR.	F	v3
RA-IH-178	Automatic Information extraction of health data for R2D Access	-	A portion (depending form the capability of the healthcare provider) of the information contained in unstructured health data imported on the S-EHR by mean of R2D Access is extracted and converted in the InteropEHRate structured format, by the healthcare provider, before sending it to the S-EHR.	F	v3

Table 25. Requirements that involve the R2D Access Service and the InteropEHRate Health Services

5.2.5 InteropEHRate Research Services

The InteropEHRate Research Services (IRS) allows a Research Organisation to invite Citizens having a S-EHR App to participate in a research study. They also allow the research organization to receive the health data shared by the Citizens participating in the research study. The following table lists the requirements of the IRS elicited from the analysis of scenario S3.

ID	Title	Main actor	Requirement description	F/NF	Target
IR-81	Publishing by the Researcher of research protocol on IEHR Open Research Network	PI of the Study	A Researcher publishes a file containing the description of the research protocol conformant to the IEHR specification. An invitation for the S-EHRs of all the Citizens potentially targeted by the protocol is published on the IEHR Open Research Network and will be processed by the S-EHRs.	F	v2
IR-82	Access to shared health data by authorised researchers	Researcher	Health data that citizens have given consent to share are received and stored by IRS of the Research Centres receiving them and the authorised researchers to them.	F	v3
IR-83	Consultation of participation statistics	Researcher	A Reference Research Centre may obtain in any moment a statistic showing the number of citizens that consented to participate in the research protocol.	F	OOS
IR-84	Notification to Researcher that a	Researcher	When a Citizen revokes the consent previously released, his/her reference	F	v3

	Citizen revoked his/her consent		research centre is notified.		
IR-93	Auditing of actions requested to IRS	PI of the Study	Every action requested to the IRS is registered (logged) and associated permanently with the unique identification of the author/actor and workstation/device who performed the action. The author/actor is identified by means of an electronic ID/account, released by an authority, national or local, certifying their identity and qualification.	NF	v3
IR-150	Identification and authorisation of organisations and researchers accessing to IRS	Researcher	Only authorised researchers belonging to organisations belonging to the InteropEHRate Research Network may access specific functionalities, they are authorised for, on the Open Research Network.	NF	OOS
IR-191	Publication of the research machine understandable research protocol on the Open Research Network	Researcher	A qualified HCP can ask to publish a new research study on the Open Research Network. The request is audited by the Open Research Network.	F	v3
IR-215	Download by Researcher of anonymised DICOM Studies referred by health data	Researcher	The Researcher can download from the reported URL the anonymised versions of DICOM studies referred to by health data contained on S-EHR Cloud.	F	s3
IR-216	Anonymisation of unstructured content in DICOM studies	Researcher	The healthcare organisation can anonymise the unstructured content of DICOM studies	F	OOS
IR-217	Anonymisation of structured content in DICOM studies	Researcher	The healthcare organisation can anonymise the structured content of DICOM studies	F	V3

Table 26. Requirements of the InteropEHRate Research Services

5.2.6 Knowledge Management Tool

The scenarios S1 and S2 assume that a Data Scientist has configured the HCP App in order to be able to represent and exchange a specific set of data, according to the InteropEHRate profile. The following table describes the requirements that the application used by the Data Scientist (Knowledge Management Tools) must be fulfilled in order to fully realize the scenarios.

ID	Title	Main actor	Requirement description	F/ NF	Target
KM-153	Health record Local Knowledge Importation	Data scientist	The Data Scientist, using the Knowledge Management Tool as well as standard software development tools, formalizes, imports (from external (open) standards definitions), and manages the local knowledge (terminology and health codes) used by the Hospital in local health record, as well as the mappings of the above to international terminology and codes.	F	v2
KM-154	Health record FHIR Knowledge Importation	Data scientist	The Data Scientist, using the Knowledge Management Tool as well as standard software development tools, converts, imports, and manages the international knowledge (FHIR schema definitions, terminology, and health codes) used in the international health record content, in order to correctly convert the local version of health record into the International one.	F	v2
KM-197	Configurability of KMT	Data scientist	The Data Scientist can configure the local language of the Knowledge Management Tool.	F	v3
KM-199	Knowledge browsing by KMT	Data scientist	The Data Scientist can browse the knowledge imported into the Knowledge Management Tool	F	v1
KM-200	Verification of knowledge imported by KMT	Data scientist	The Knowledge Management Tool signals to the Data Scientist during the import local knowledge (i.e. the spreadsheet files using the Terminology Import Format) potential knowledge representation mistakes (e.g. reference to non-existent concepts, duplicates, loops within hierarchies, etc.). The end result of importing can also be interactively verified using the Knowledge Management Tools (by browsing the imported knowledge).	F	v3
KM-201	Verification of mapping by KMT	Data scientist	The Data Scientist can use the Knowledge Management Tool for verifying the result of mapping of locally used terms and codes to the Interoperability Profile.	F	v3

Table 27. Requirements for the Knowledge Management Tool

5.2.7 Data Mapping Tool

If health data must be exchanged with a legacy application using a representation of the health data that is different from the one defined by the InteropEHRate profile, an automatic conversion of the data from one format to the other must be performed. Data Scientists will use a Data Mapping Tool to configure the correct conversion. The following table describes the requirements of the application used by the Data Management Tool.

ID	Title	Main actor	Requirement description	F/NF	Target
DM-24	Mapping between local codes and international codes by Data Scientist	Data scientist	The data scientist using the Data Mapping Tool can define the mappings between local codes and international codes	F	v1
DM-155	Health record Data Integration	Data scientist	The Data Scientist, using the Data Management Tool, can create a mapping between the local health record and the international health record. Then, the Data Scientist integrates a test set of local health record data into the HDI Platform, verifies the correctness of mappings, and fine-tunes them if necessary.	F	v3
DM-198	Configurability of DMT	Data scientist	The Data Scientist can configure the local language of the Data Mapping Tool.	F	v3
DM-202	Definition of structural mapping rules by DMT	Data scientist	Using the Data Mapper Tool, the Data Scientist can define the structural mapping operations from the local data schemas towards the international FHIR schemas. The Data Mapper Tool records the operations carried out by the Data Scientist.	F	v2
DM-203	Definition of conversion operations by DMT	Data scientist	Using the Data Mapper Tool, the Data Scientist can define, other than the mapping of data attributes, also data value reformatting, splitting, or merging. The Data Mapper Tool records the operations carried out by the Data Scientist.	F	v2
DM-204	Saving of syntactic conversion recipe by DMT	Data scientist	The Data Scientist can save the defined mapping and conversion operations within a so called Syntactic Data Mapping Recipe (also called Syntactic Recipe).	F	v2
DM-205	Loading of syntactic conversion recipe by DMT	Data scientist	The Data Scientist can load a previously created Syntactic Conversion Recipe into the Data Mapper Tool to review and change it.	F	v2

DM-206	Testing of syntactic conversion recipe by DMT	Data scientist	The Data Scientist can verify the Syntactic Conversion Recipe by running it over a test set and see conversion errors (because of a mistake in mapping or because there were unforeseen cases of data heterogeneity within the test set).	F	v2
DM-207	Browsing of integrated health records	Data scientist	The DS can also use the Knowledge Management Tools, which contain a so-called Entity Browser Tool, to verify the results of conversion by browsing the integrated health record.	F	v2
DM-208	Definition of Information Extraction rules	Data scientist	The Data Scientist, after loading the Syntactic Conversion Recipe into the Data Mapper Tool, can complete it by the semantic conversion step of information extraction. Semantic extraction allows to identify relevant terminology and codes within natural-language labels inside the health record and link such mentions to the corresponding formal knowledge elements defined inside the Platform. The codes and terms to be extracted may be stand-alone (e.g. a single ICD-10 code expressed as a string “I69.3”) or embedded within a longer piece of text.	F	v3
DM-209	Saving of semantic conversion recipe by DMT	Data scientist	The Data Scientist can save the defined semantic conversion rules, including information extraction rules.	F	v3
DM-210	Loading of semantic conversion recipe by DMT	Data scientist	The Data Scientist can load a previously created Semantic Conversion Recipe into the Data Mapper Tool to review and change it.	F	v3
DM-211	Testing of semantic conversion recipe by DMT	Data scientist	The Data Scientist can verify the Semantic Conversion Recipe by running it over a test set and see conversion errors (because of a mistake in mapping or because there were unforeseen cases of data heterogeneity within the test set).	F	v3

Table 28. Requirements for the Data Mapping Tool

6 USERS' FOCUS GROUPS

A focus group is a moderated discussion that typically involves 5 to 10 participants. Focus group discussions provide detailed qualitative data, enabling researchers to understand issues in greater depth and understand key user requirements.

Focus groups are a method to generate a great deal of information from a spectrum of different opinions efficiently and at a relatively low cost.

This is a useful way of working with groups who have limited literacy (e.g. elder chronic heart failure patients, nurses with limited experience of EHR, physicians with limited experience of EHR), or those whose first language is not English and more vulnerable. We have to remember that the IEHR project involves different nations with different natural languages spoken by the general population (Patients) and Employees (Healthcare Professionals and Researchers).

InteropEHRate is committed to ensuring that Patients, HCPs and Researchers voices are at the centre of shaping our healthcare platform services. This will mean smaller, more focused sessions developed to listen to individuals, particularly those who don't usually engage in public consultations.

As the "owner" of the patient relationship and health records, the healthcare organization needs to make initial contact with the patients to see if they are comfortable with being contacted by the project's personnel, which will further explain the focus groups objectives and finalize details for patients who are willing to participate. Hospitals cannot hand off patient contact information (even for a focus group) to an outside party, in respect of GDPR.

This constraint makes it truly difficult to have "blind" focus groups (where participants do not know the project and its purposes until the end). However, it is achievable through creative means of recruiting a cross section of participants, for example from the patient's population of healthcare organizations, in order to gain really representative information.

For Patient's focus group recruitment of the pool of patients to draw from, can represent a challenge. For Hospital partners we have to rely upon clinical staff to select possible participants, and this represents a bias to be controlled and evaluated.

It is in human nature to want to select components that might have a more positive spin on their experience at the healthcare provider's facility so that the results of the focus group might turn out to be more positive. Clinical managers have to be diligent about ensuring that the universe of patients used for the recruitment pool is truly diverse, in all ways, including the range and tone of experiences with the organization.

Understanding that focus groups are considered qualitative research rather than quantitative, and that most projects do not have the budget or time to host as many focus groups within any given target as ideal to help address the quantitative margin of error, we chose to conduct focus groups composed of at least 7 persons, within any given target group: Patients, Healthcare Professionals, Researchers.

For each group, we adopted a recruitment policy with the goal of getting 5 to 8 attendees who actually attended. We can have more than this number participate, but it can get unwieldy and for some personality types, intimidating, especially for patients. This gives more reliability for our reported results in case one component truly becomes an outlier due to odd behaviours or responses.

When we create the findings report, we may report about individual "outlier" or "one-off" responses as a matter of interest but unless it is a key finding across the board, or a trend, we do not note it as important in our insights or recommendations.

Focus Group	Description
Patients	Persons who travel abroad and are affected by chronic cardiovascular disease
Healthcare Professionals	Employee of Healthcare service provider (Hospital, Outpatient facility, territorial service) and Stakeholder representatives
Researchers	Investigators interested in, or promoting a, research protocol in clinical or social field

Table 29. Focus Group Types

Applied practical steps are reported in the following list:

1. Focus group activity is promoted by community-based organisations in a familiar and comfortable environment.
2. When running a focus group aims for between 5-12 people and about an hour and a half seminar time.
3. Ensure there is a good facilitator for the focus group with a lived experience or service user/carer insight. It is vital to ensure that all voices are heard (not just the loudest) and that any different perspectives, e.g. where participants disagree with each other, are explored.
4. Develop some topics for discussion in advance – this will structure a guided discussion. The topics should be designed with the overall engagement themes or research questions in mind.
5. Be clear about how the session will be recorded/noted and fed into the wider work programme so that participants are clear about the purpose and outcomes of the focus group.
6. It is essential that participants understand that their participation is voluntary and that there are no consequences in not taking part or answering specific questions.
7. Terms of confidentiality need to be agreed. It can be useful to take the approach of a confidential discussion ("what is shared in the room, stays in the room" and anonymity guaranteed), but in some cases people may want their experiences to be identifiable.
8. Agree ground rules for the group e.g. respect for other people's views and allowing space to talk.
9. Ensure that the findings from the focus group are shared with the participants and that their time and hard work is valued.

To introduce the project and its goal a document is prepared with a brief summary and an exemplary interview of a fictional person belonging to a focus group profile. In that interview, the fictional person just explains a real-life use of the InteropEHRate platform, giving an immediate example and using that as a guide to developing comments and suggestions.

In order to collect answers via the web, FTGM has created an InteropEHRate survey environment, through its online questionnaire platform Google Suite, creating in this way online questionnaires for

patient focus group FTGM, HYG, CHU, for HCP focus groups FTGM, HYG, EFN, CHU and questionnaires for researchers for EFN, FTGM, CHU, HYG. ISA has provided its platform for its patients and doctors[6].

6.1 Patients Focus Groups

Patients Focus Groups was the most challenging focus group for this project. It consists of persons who travel abroad, for business or for leisure, and are affected by the target disease underlying scenario 1 and 2: chronic cardiovascular disease.

The principal elements for this focus group are:

- Explore the need of data exchange when abroad, or anyway out of the usual healthcare provider context.
- Expose current needs, priority and problem of clinical information management.
- Explore the usefulness of the S-EHR platform and expected new functionalities.
- Understand the level of confidence with smart tools and smartphones.
- Receive hints and particular conditions to consider the next steps.
- Understand the level of acceptance related to data donation for clinical research.

For every hospital (FTGM, SCUBA, HYG, CHU) and association (ISA) was designed a focus group manager, in charge of conducting every focus group activity: from selection of candidates, to proposals for participation up to answers collection.

The web execution method was used in this new version of the focus groups, in order to interest the largest number of respondents. The acceptance level was higher than the previous focus groups, and the choice to use a web version of the questionnaires proved successful.

Some hospitals felt they had to translate the questions into the respondents' native language in order to gain a better understanding of the topics. This was done especially for Patients and HCPs who appreciated it.

The age of the patients ranged between 25 and 75, with a higher peak between 35 and 45 years.

6.1.1 Participant Recruitment

Participants were selected by hospitals from a subset of candidates, usually taken by a population of healthcare service customers, under a common condition for patients' selection, to be affected by cardiac chronic diseases. Maximum attention for variety was adopted in order to get the best representation of potential users for the S-EHR platform.

For each of the hospitals or organizations selected focus group members were:

- HYG: 11 Patients
- FTGM: 9 Cardiological patients
- CHU: 11 Patients
- SCUBA: 9 Patients.

[6] InteropEHRate Project Partners. https://www.interopehrate.eu/partners/

6.1.2 Questionnaire design

In order to focus on specific key functionalities of S-EHR, a questionnaire was developed. Every question is driven by a rationale and is related to Projects' objectives.

The original questionnaire is reported in the following table.

Patient Focus group
Select your Hospital?
Gender
Age?
Do you want to create a stable link between you and your preferred healthcare providers (that supports IEHR protocol)?
Do you want to import health information (reports, vital signs, prescriptions, etc.) from a certain/every previous encounter(s) of your preferred healthcare providers (supporting IEHR protocol)?
Do you want to import very large health information (images, videos, signals) in your phone? (this may use most part of smartphone's memory)
Do you want that large health information (images, movies) remain in the producer hospital also providing access to other healthcare providers in order to let them read (with your permission)? (this won't use large amount of smartphone's memory)
Do you want the S-EHR to automatically download new/updated health information from your linked (preferred) healthcare providers (previously selected)?
Do you agree to check manually in the S-EHR for new health data available from your linked (preferred) healthcare providers?
Do you want the S-EHR to receive notifications when new health data can be downloaded from your linked (preferred) healthcare providers?
Would you like to choose which data to download from a healthcare provider or do you prefer to download anything on your smartphone, without worrying for the memory consumption of your phone?
Do you feel confident in choosing your own cloud service (rather than using whatever cloud service is suggested in the S-EHR)?
Would you like to use the S-EHR to remind you to take the therapy?
Travelling across EU do you think is necessary to have a translation of data in the foreign language of target healthcare provider, in order to fully support your healthcare
When abroad you are discharged from a visit/hospital admission, do you think it is a good idea to have a translated version of prescriptions and indications on your phone, along with the original ones?
After a visit (when you are no longer at the healthcare facility), would you like to continue receiving follow-up contacts from the hospitals you visited, to remind future visits and exams that were booked in that provider?
Would you like to have a direct link to your latest COVID test, to be presented to authorized

personnel/officers?
Would you like to have a direct link to your latest COVID immunization, to be presented to authorized personnel/officers?
Do you think that it could be useful to have a checklist for COVID test/symptoms to be presented when travelling abroad (With respect to the destination country)?
How important do you think technical assistance would be needed, in order to solve problems associated with the use of S-EHR?
Are you willing to allow research organizations authorized in the S-EHR platform to contact you using the APP only for those researchers who may apply your health status?
Are you willing to add specific data in your S-EHR, requested by a research organization, only to participate in a research? (e.g.: symptoms, blood tests results, exams results)
Do you want to receive notifications for each data sent to the research centre?
Do you want to receive notifications every time someone accesses your data on the cloud?
Do you like to participate in a research study that is 100% remote/virtual, i.e. without any physical contact with the Research Organization?
Do you like to participate in a research study that is only physical, i.e. with direct access to the healthcare research facilities?
Would you be more likely to share your health data for research if incentivized to do so? If yes, which is your preferred compensation?
Would you need to have personal contact with the investigators of the study before consent to participate?

Table 30. Patients Focus Group

6.1.3 Interactions with Focus Group

The main concept behind interaction with patients was to conduct at least 2 meetings:

- one initial, introductory meeting, where project was explained and scenario described, and where questionnaire was introduced and explained;
- one final meeting, usually at 7-10 days from the initial one, where patient's suggestions and comments were discussed and reported, and where paper or electronic compiled questionnaires were collected.

Different Hospitals managed focus group interactions in different ways, according to local policy of patient's management and members availability for discussion. It was sometimes hard for focus group managers to define a single date for an overall meeting, and in that case more than one initial introductory or final meeting was conducted, according to members' availability of time.

Some countries preferred to perform a translation in national language, in order to have a better compliance for members and a better understanding of contents including national/local variation according to national/local regulation and systems availability (e.g. regional EHR, national GDPR variations, etc.)

6.1.4 Response Analysis and Interpretation

For patients it is very important to create a stable link with the reference hospital (74,4%), even abroad; they would like to be able to import health information in order to have a complete picture of their health at all times, especially for visits that are made abroad, including all kinds of information such as diagnostic images even if they would prefer that this voluminous data remain in the producing hospitals. S-EHR should be able to download all new health information from healthcare providers at least monthly. Patients would also like to be able to check if new data is available. They would like to be notified of new information (64,1%). In order not to occupy the memory of their mobile phone they would also like to understand the size of the data before downloading (56,4%). They would like to use the S-EHR to remind themselves to take the therapy (53,8%). 41% totally agree that it is helpful to have technical assistance in order to solve problems related to the use of S-EHR. It is considered necessary to have a translation of data in the foreign language of the Healthcare Professionals in order to fully support them (76,9%). The possibility of having an automatic translation of the therapeutic indications and prescriptions directly available on mobile phone is considered a valid help to be able to face a course of treatment (to face a treatment path?) in a foreign country with peace of mind (79,5%). 43,6 % of the interviewees would like to receive follow-up contacts from the provider hospital to remind future visits and exams that have been booked there. Also, it is considered useful to have the latest COVID test and immunization on the phone in order to be presented to authorized personnel/officers (82,1%). Regarding the possibility of being enrolled in research projects, they consider it useful to be able to participate even if they have to perform new tests not required by normal clinical practice. 43,6% would like to be able to consult sharing logs to view the data sent to the Research Centre rather than receive notifications for each of them. 41% would prefer to participate in a research study in 100% remote/virtual mode. Only 28,2% would prefer physical contact with the Research Organization. The majority of them (46.2%) do not like to be incentivized to share research information. They would also like to have a personal contact with the investigators of the research study by email (25.5%), by S-EHR APP (28.2%) and also by phone (38.5%).

In Annex 1 are reported analytical results of questionnaires.

6.2 Health Care Professionals Focus Groups

Health Care Professionals Focus Groups was representing employees of healthcare service providers (Hospital, Outpatient facilities, territorial services) and included Stakeholder representatives and members.

For every hospital and stakeholder (FTGM, SCUBA, HYG, CHU and EFN) was designed a focus group manager, in charge of conducting every focus group activity: from selection of candidates, to proposals for participation up to answers collection.

The age of the Healthcare professionals ranged between 25 and 75, with a higher peak between 45 and 55 years.

For each of the hospitals selected focus group members were:

- ISA: 255 Health Care Professionals
- HYG: 11 Health Care Professionals
- FTGM: 15 Health Care Professionals
- CHU: 8 Health Care Professionals
- EFN: 7 Health Care Professionals

- SCUBA: 7 Health Care Professionals.

6.2.1 Participant Recruitment

Participants were selected by Focus group managers from a subset of employees working in out-patient and in-patient facilities. Maximum attention for variety was adopted in order to get the best representation of potential users for the S-EHR platform.

Proposals for participation in the focus group were submitted to every candidate, and consent to manage their personal data, using pseudonymisation techniques, was collected.

6.2.2 Questionnaire design

In order to focus on specific key functionalities of S-EHR, a questionnaire was developed. Every question is driven by a rationale and is related to Projects' objectives.

The original questionnaire is reported in the following table.

HCP Focus group
Select your Hospital:
Sex
Age
Would you like the adoption of a colour code differentiating data registered by patients/family caregivers from other ones certified by hospitals and professional healthcare providers?
Do you expect to have a seamless or simplified connection with patient phone along different HCP workstations, after the initial one?
Do you think that use of data within IEHR PLATFORM would be easy? (Video / demo)
Do you think that interaction with the patient using IEHR PLATFORM will require much effort for your share? (Video / demo)
Do you have credentials for the EU/national personal identification system eIDAS? (SPID in Italy, eID/ItsMe in Belgium)
Do you think that the IEHR platform can facilitate management of foreign patients?
What is your expectation on HCP App? (tick the higher priority for you)
In your ideal APP for patients what are the most desirable features you would like?

Table 31. HCP Questionnaire

6.2.3 Interactions with Focus Group

The main concept behind the interaction with HCP was to organize at least 2 meetings:

- one initial, introductory meeting, where project was explained and scenario described, and where questionnaire was introduced and explained;

- one final meeting, usually at 7-10 days from the initial one, where HCP's suggestions and comments were discussed and reported, and where paper or electronic compiled questionnaires were collected.

Different healthcare providers managed focus group interactions in different ways, according to local policy of employee management and time availability for discussion, according to their duties. It was sometimes hard for focus group managers to define a single date for an overall meeting, and in that case more than one initial introductory or final meeting was conducted, according to members' availability of time.

Some countries preferred to perform a translation in national language, in order to have a better compliance for members and a better understanding of contents including national/local variation according to national/local regulation and systems availability (e.g. regional EHR, national GDPR variations, etc.)

Stakeholders of HCP doctors preferred to involve a larger audience and different categories, submitting questionnaires through a web portal and using the same portal to explain project's objectives and scenarios descriptions.

6.2.4 Response Analysis and Interpretation

Reading the comments written in the open answer, one immediately notices the extreme interest aroused by the issues on the usability of the platform. It suggests an audience of HCP users increasingly detached from the aspects of technological knowledge; the final user depends heavily on the tools that must be fast, usable and always functional. Particular attention must be paid to elderly patients who must have easily usable tools with sound signals, larger bold fonts and few technical S-EHR APP passages for accessing and using the provided data. The manual data entry is not frowned upon by the HCPs but they fear typing errors that can lead to fallacious interpretation of the data. 57,1% of them totally agree about the adoption of a colour code differentiating data registered by patients/family caregivers from other ones certified by hospitals and professional healthcare providers. It is also suggested traceability of origin and validation status of the information. Therefore, the ideal APP should be accurate, intuitive, with full access to patient's history and data, simple to use, with a low percentage of data entered manually. It should have structured information easy to transfer and should provide quick solutions to technical problems. Additionally, it is considered important to have just one "authorization process" to access the information for each individual HCP in the same organization. The main expectation on HCP App is the availability of most patient's data (67,3%). Only 2% of HCPs totally agree that interaction with the patient using IEHR PLATFORM will require much effort. 63,3% totally agree that this platform can facilitate management of foreign patients. The project is considered of great importance especially in all those cases where it is important to have accurate and descriptive data of the patient's pathologies. Especially, the ideal app should allow easy access to essential first-aid information in order to support the emergency scenario. Moreover, many HCPs think that the possibility of having signals and images would be of great advantage. However, it is considered not necessary to have images/videos on the patient's phone but a link to access them may be useful.

6.3 Researchers Focus Groups

Research Focus Groups were representing personnel involved in health-related research (clinical research, social research, etc.), usually employees of a Research Organization that goes from

Universities to Research Hospitals. In this project the main actor is represented by Research Hospital, sometimes belonging to a university.

For every hospital and stakeholder (FTGM, SCUBA, HYG, CHU and EFN) was designed a focus group manager, in charge of conducting every focus group activity: from selection of candidates, to proposals for participation up to answers collection.

Participants were selected by Focus group managers from a subset of employees working in clinical research protocols, and covering different profiles: from physicians to nurses, from IT managers to epidemiologists. Maximum attention for variety was adopted in order to get the best representation of potential users for the S-EHR platform.

Proposals for participation in the focus group were submitted to every candidate, and a consent to manage their personal data, using pseudonymisation techniques, was collected.

The researchers' focus group was formed by professionals performing clinical research in different settings, from pneumology, cardiology, gynaecology, neurosurgery, and cardiac surgery:

- SCUBA: 10 researchers.
- HYG: 5 researchers.
- FTGM: 4 researchers.
- EFN: 5 researchers.
- CHU: 6 researchers.

6.3.1 Questionnaire design

In order to focus on specific key functionalities of S-EHR, a questionnaire was developed.

Every question is driven by a rationale and is related to Projects' objectives.

The original questionnaire is reported in the following.

Researcher focus Group
Select your hospital?
Sex
Age
For a prospective Research with periodic assessment of the patient, specify the maximum delay for having new collected data of the period (from the App S-EHR of the patient)
How often should the S-EHR evaluate selection criteria against the S-EHR content for one specific study?
Should the researcher be notified when receiving any periodic update with new health data from the cohort of enrolled patients?
Do you need the ability to reach a patient (contact him in case of important health information to communicate for example)
Would you like to have the capability to send personal final results of the study to the SHER of the patient?

Specify the delay for notification of patient withdrawal from the study, when applied in S-EHR app
Would you like to receive statistical information about the matching rate of inclusion/exclusion criteria of your studies?
Would you want to receive statistical information about the patient approval rate of your studies?
Do you think S-EHR will be comfortable enough for elderly/unpaired patients when the research requests for a data entry?
For your researches can be useful to have also data on patient's localization?
When you receive requested data would you like to maintain the reference of the author/producer (HCP, Hospital, patient, caregiver, etc.) of that information?

Table 32. Researchers Questionnaire

6.3.2 Interactions with Focus Group

The main concept behind the interaction with researchers was to organize at least 2 meetings:

- one initial, introductory meeting, where project was explained and scenario described, and where questionnaire was introduced and explained;
- one final meeting, usually at 7-10 days from the initial one, where the patient's suggestions and comments were discussed and reported, and where paper or electronic compiled questionnaires were collected.

Different Hospitals managed focus group interactions in different ways, according to local policy of the patient's management and members availability for discussion. It was sometimes hard for focus group managers to define a single date for an overall meeting, and in that case more than one initial introductory or final meeting was conducted, according to members' availability of time.

Some countries preferred to perform a translation in the national language, in order to have a better compliance for members and a better understanding of contents including national/local variation according to national/local regulation and systems availability (e.g. regional EHR, national GDPR variations, etc.)

6.3.3 Response Analysis and Interpretation

In addition to being interested in the possibility of carrying out targeted studies on a very large population, the researchers believe it is important to adapt the application to particular population classes such as the elderly or the impaired, so that they too can use it in the best way without risking losing a slice of the population that is interesting for statistical purposes and for improving the quality of life. They believe that it is still important to have direct contact, mediated by the application, with patients in order to involve them during and after the end of the research study, both to inform them about their state of health, to involve them in subsequent studies and to send final results of the studies. There is some doubt regarding the possibility to reach elderly/unpaired patients for data entry. The reference of the author/producer of the information is considered of manifold importance.

7 CONCLUSIONS AND NEXT STEPS

This report described the third and final version of the InteropEHRate user requirements. Final requirements will be used in the experimental work package to define the activities to be performed in the three pilot to test the platform and the real scenario declined in 4 different hospitals in different nations.

8 REFERENCES

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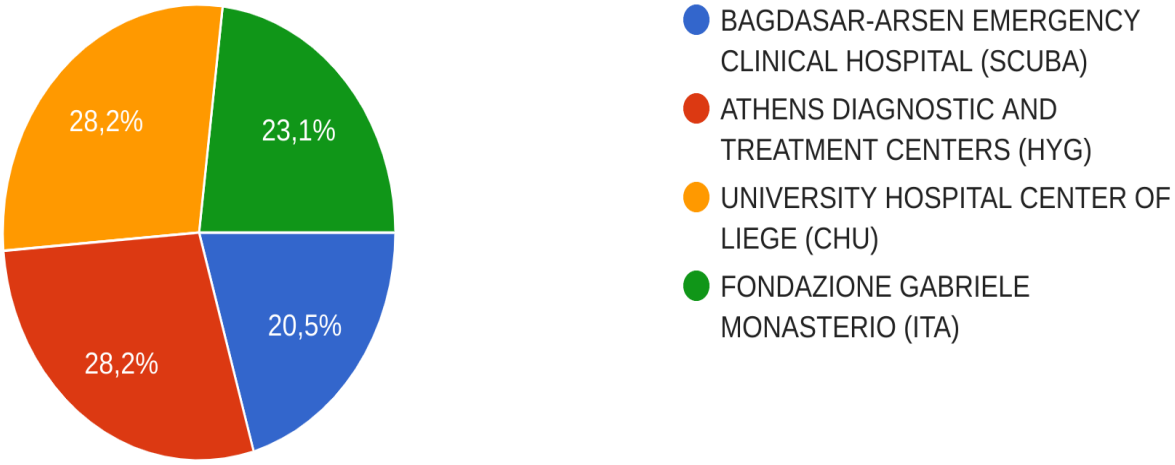
[15] **[D4.9]** InteropEHRate Consortium, Specification of protocol and APIs for research health data sharing, 2021. https://www.interopehrate.eu/resources/#dels

[16] **[BIR]** https://wiki.ihe.net/index.php/Basic_Image_Review

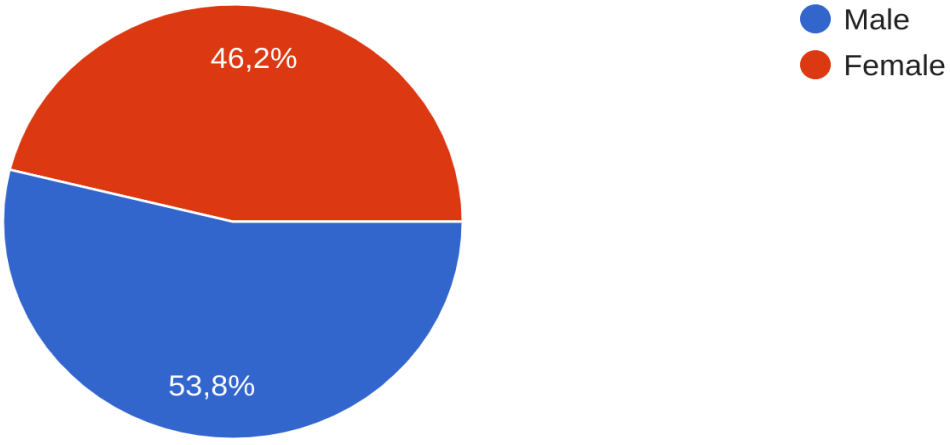
9 ANNEX 1 – Focus Groups responses

9.1 Patient Focus groups Response

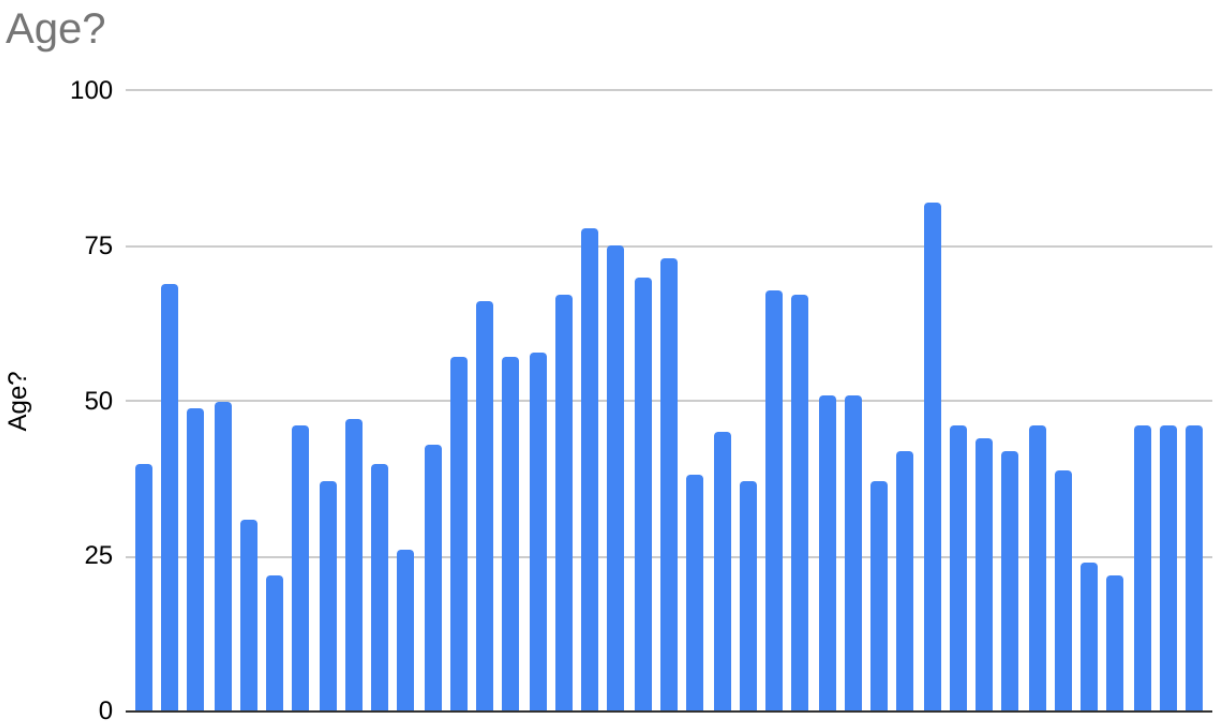
1. Provenance distribution:



2. Gender

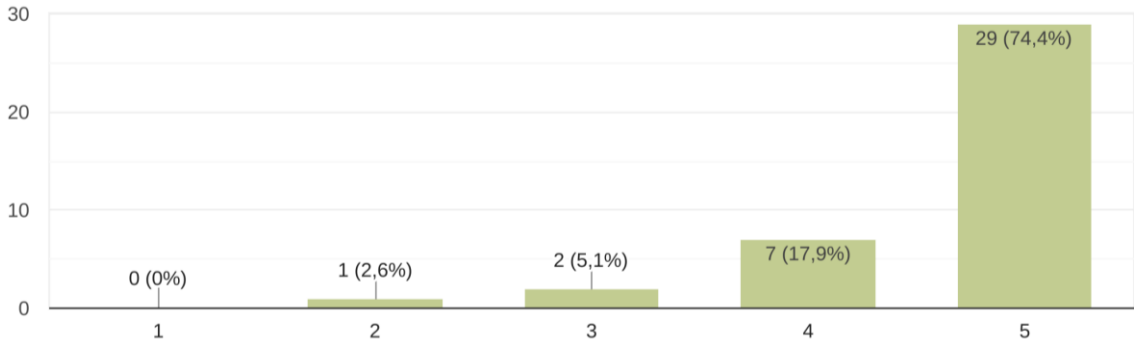


3. Age



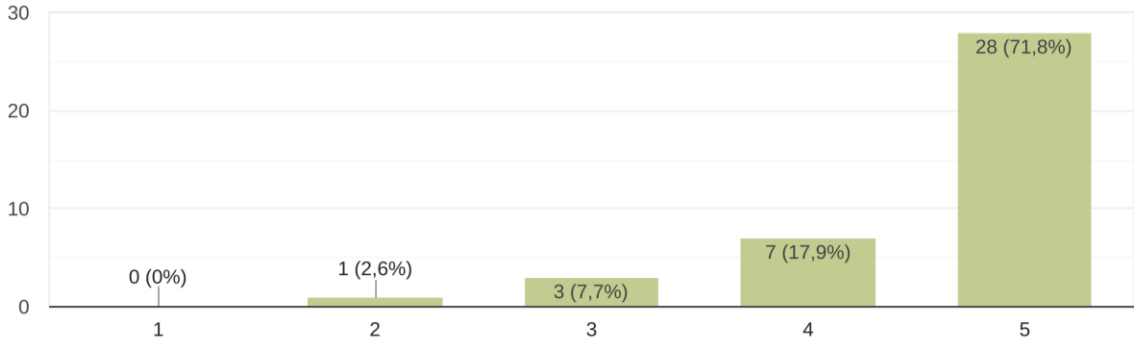
4. Do you want to create a stable link between you and your preferred healthcare providers (that supports IEHR protocol)?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



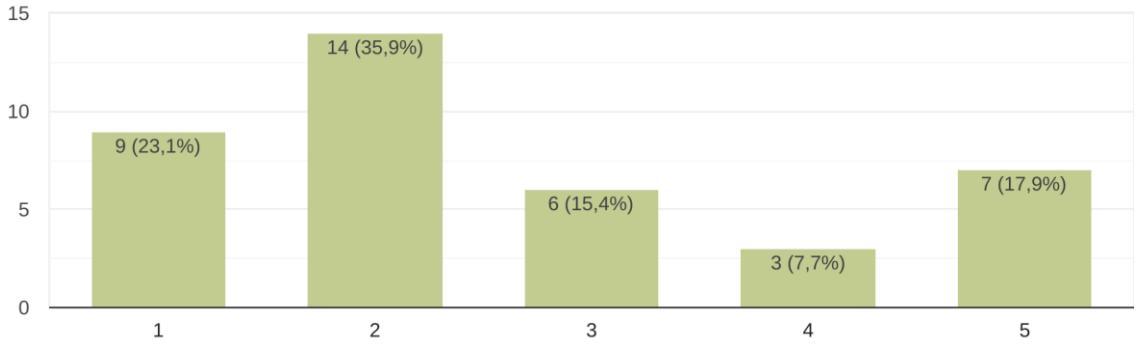
5. Do you want to import health information (reports, vital signs, prescriptions, etc.) from a certain/every previous encounter(s) of your preferred healthcare providers (supporting IEHR protocol)?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



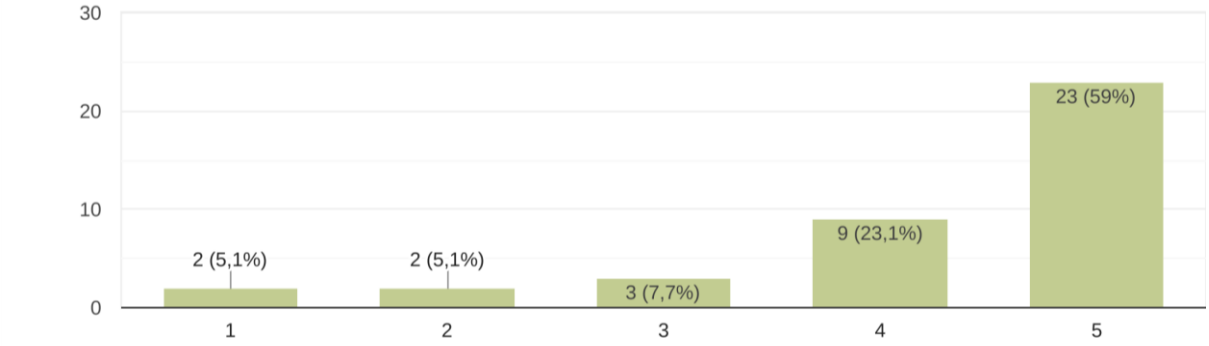
6. Do you want to import very large health information (images, videos, signals) in your phone? (this may use most part of smartphone's memory)

Answer= 1 to 5: 1= strongly disagree, 5= totally agree

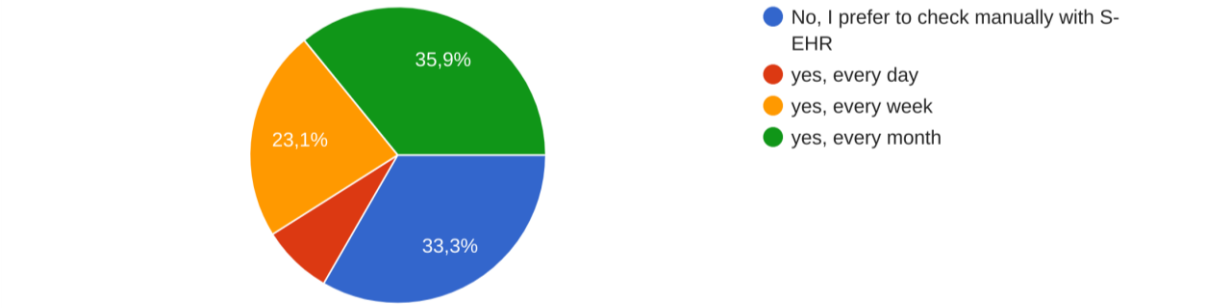


7. Do you want that large health information (images, movies) remain in the producer hospital also providing an access to other healthcare providers in order to let them read (with your permission)? (this won't use large amount of smartphone's memory)

Answer= 1 to 5: 1= strongly disagree, 5= totally agree

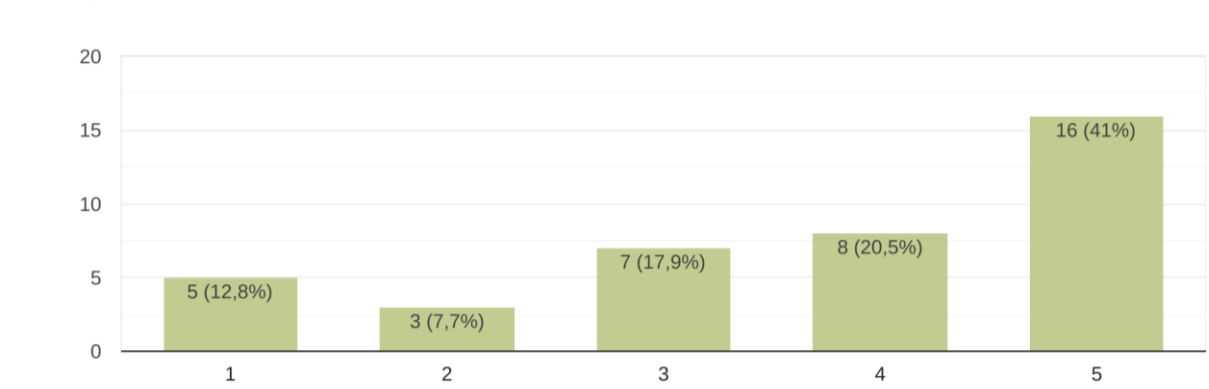


8. Do you want the S-EHR to automatically download new/updated health information from your linked (preferred) healthcare providers (previously selected)?



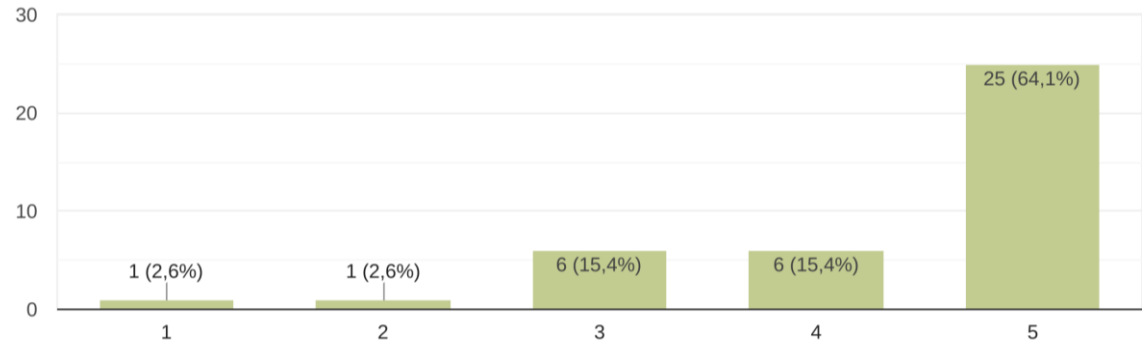
9. Do you agree to check manually in the S-EHR for new health data available from your linked (preferred) healthcare providers?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree

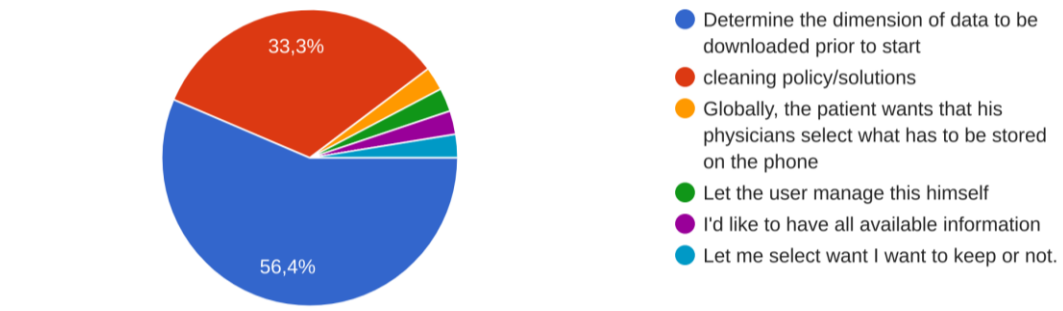


10. Do you want the S-EHR to receive notifications when new health data can be downloaded from your linked (preferred) healthcare providers?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree

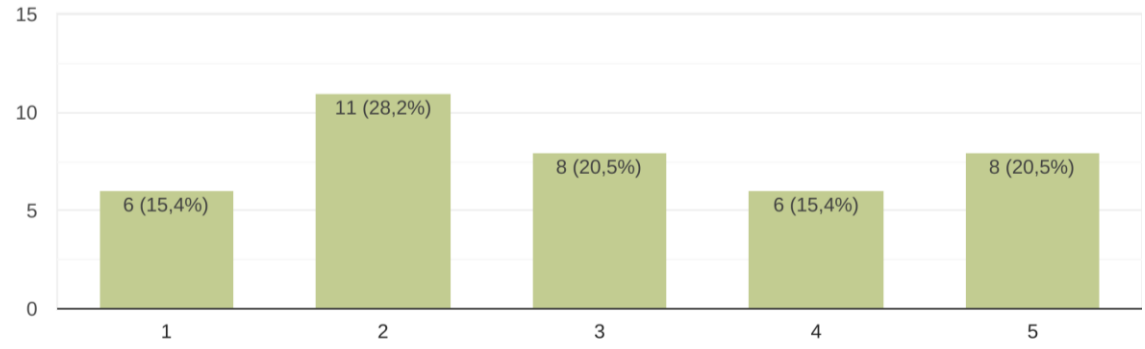


11. Would you like to choose which data to download from a healthcare provider or do you prefer to download anything on your smartphone, without worrying about the memory consumption of your phone?



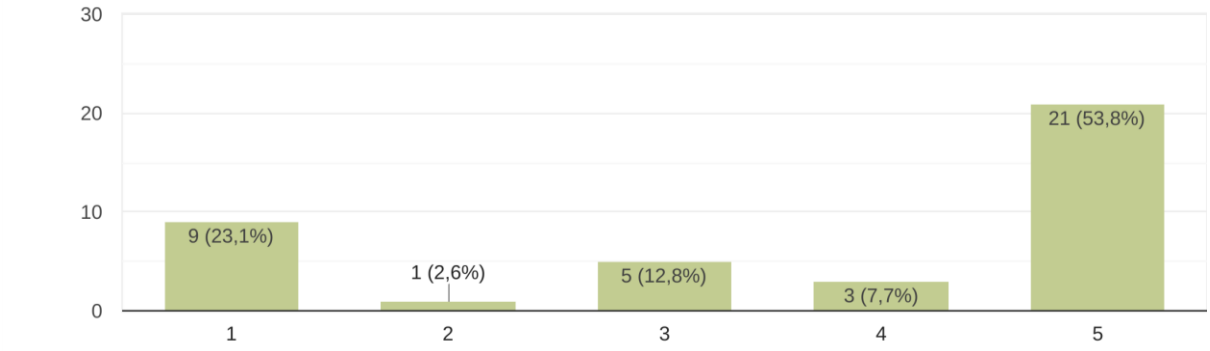
12. Do you feel confident in choosing your own cloud service (rather than using whatever cloud service is suggested in the S-EHR)?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



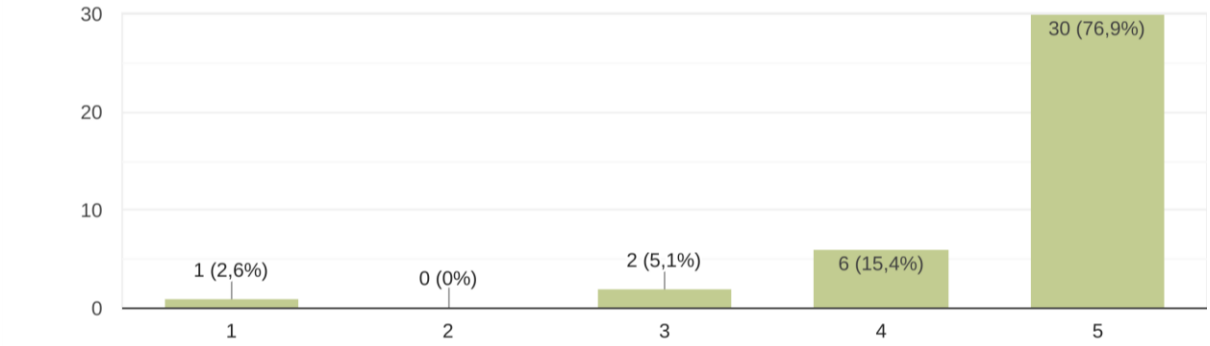
13. Would you like to use the S-EHR to remind you to take the therapy?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



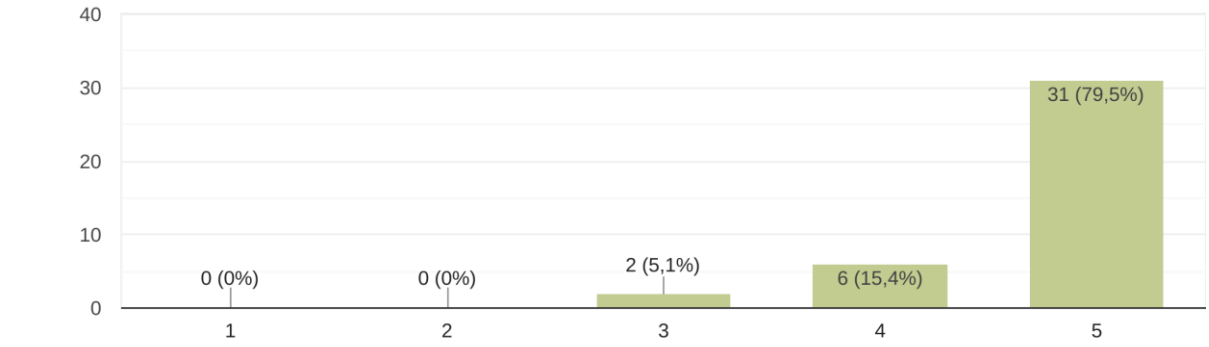
14. Travelling across the EU do you think is necessary to have a translation of data in the foreign language of the target healthcare provider, in order to fully support your healthcare.

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



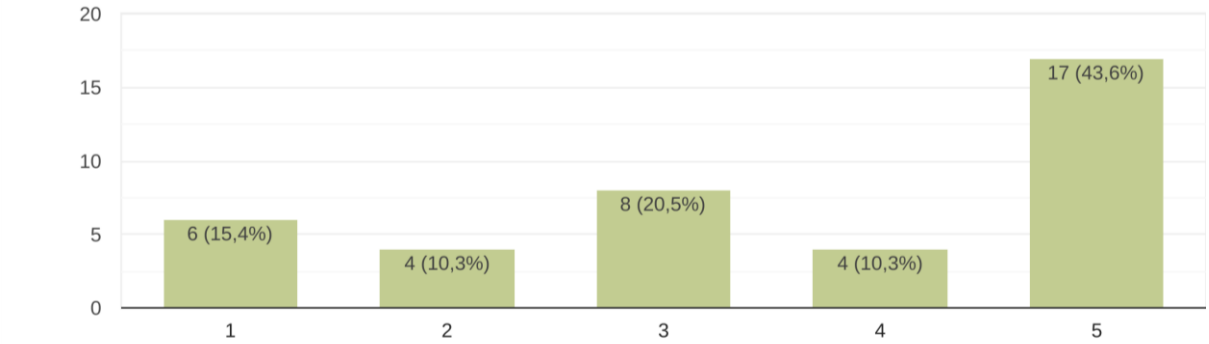
15. When abroad you are discharged from a visit/hospital admission, do you think it is a good idea to have a translated version of prescriptions and indications on your phone, along with the original ones?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



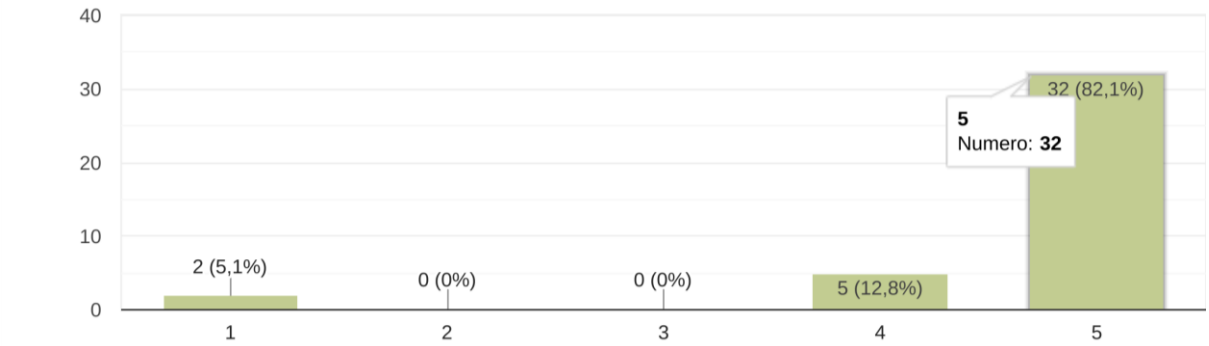
16. After a visit (when you are no longer at the healthcare facility), would you like to continue receiving follow-up contacts from the hospitals you visited, to remind future visits and exams that were booked in that provider?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



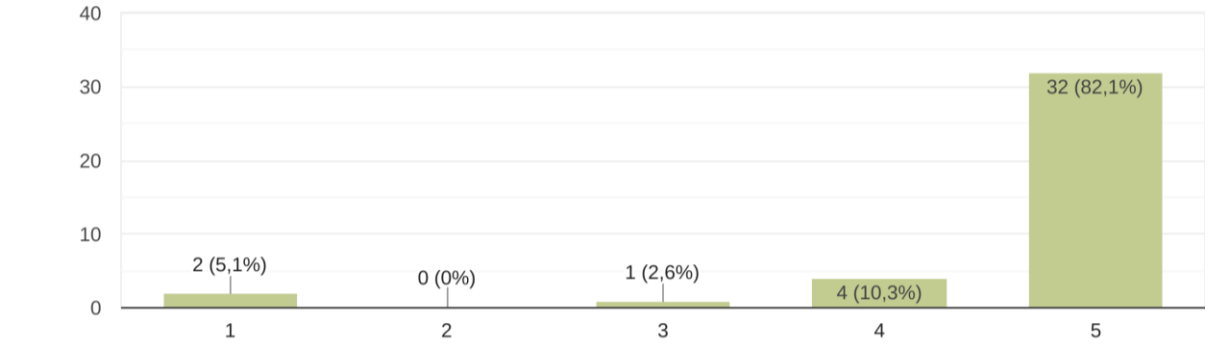
17. Would you like to have a direct link to your latest COVID test, to be presented to authorized personnel/officers?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



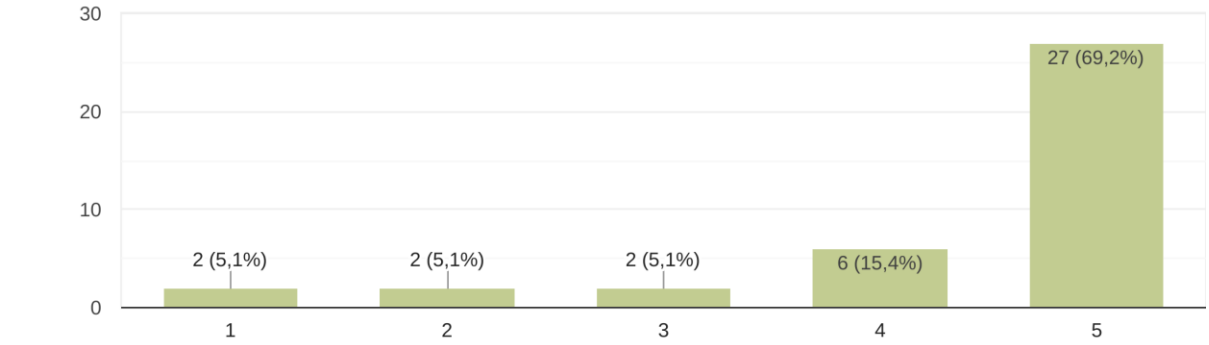
18. Would you like to have a direct link to your latest COVID immunization, to be presented to authorized personnel/officers?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



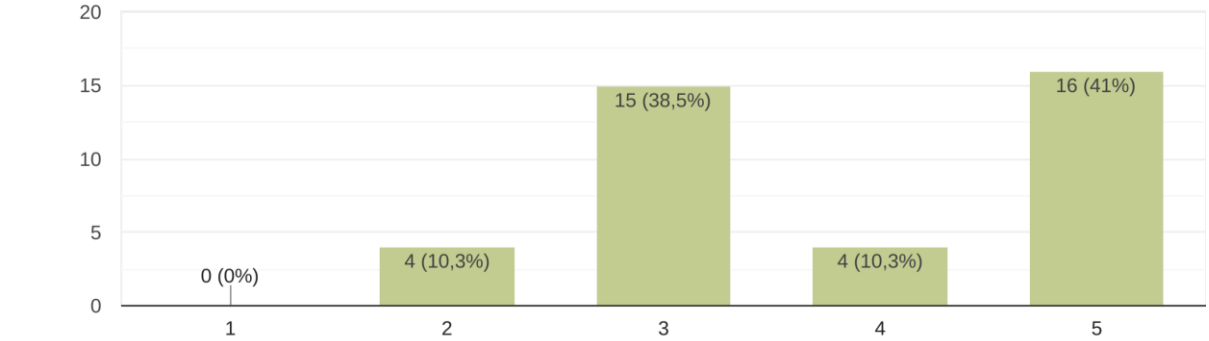
19. Do you think that it could be useful to have a checklist for COVID test/symptoms to be presented when travelling abroad (With respect to the destination country)?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



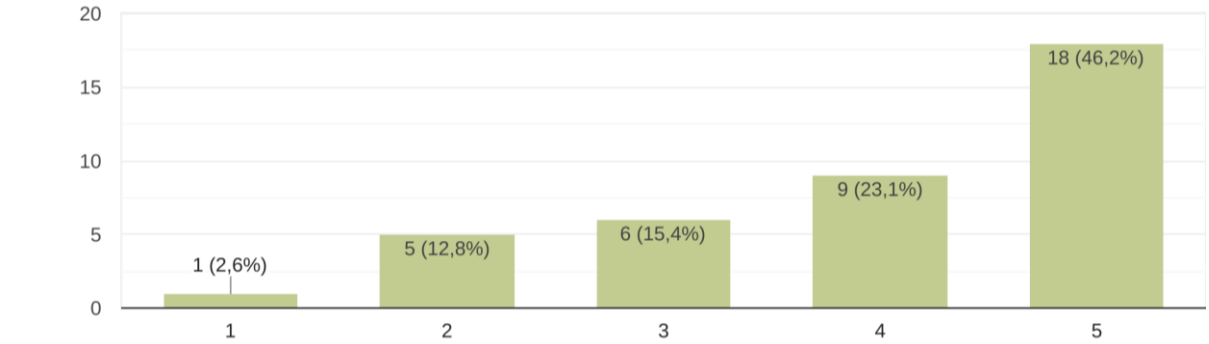
20. How important do you think technical assistance would be needed, in order to solve problems associated with the use of S-EHR?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



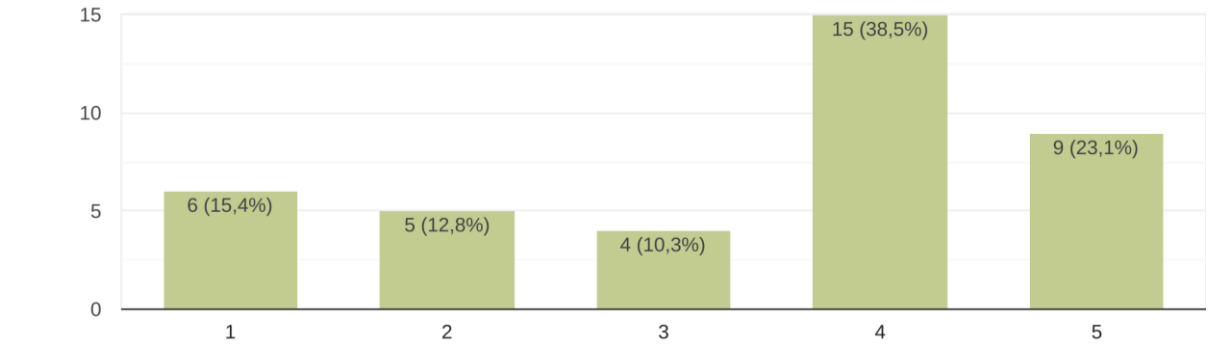
21. Are you willing to allow research organizations authorized in the S-EHR platform to contact you using the APP only for those research who may apply your health status?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



22. Are you willing to add specific data in your S-EHR, requested by a research organization, only to participate in a research? (e.g.: symptoms, blood tests results, exams results)

Answer= 1 to 5: 1= strongly disagree, 5= totally agree

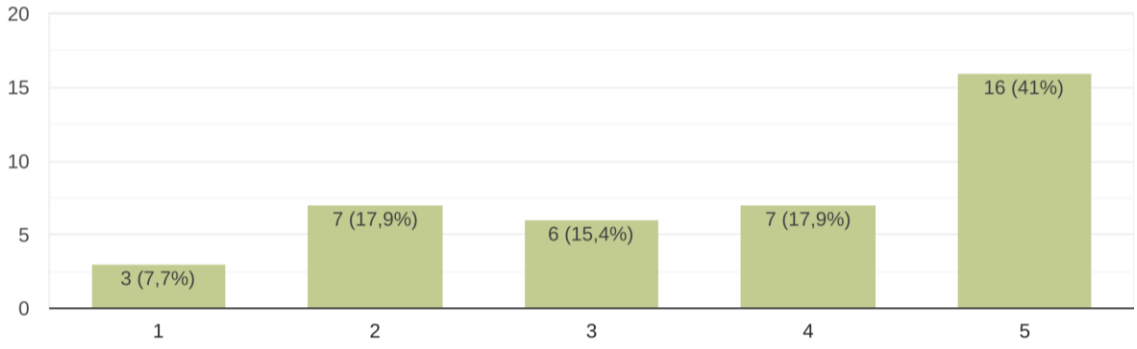


23. Do you want to receive notifications for each data sent to the research centre?

24. Do you want to receive notifications every time someone accesses your data on the cloud?

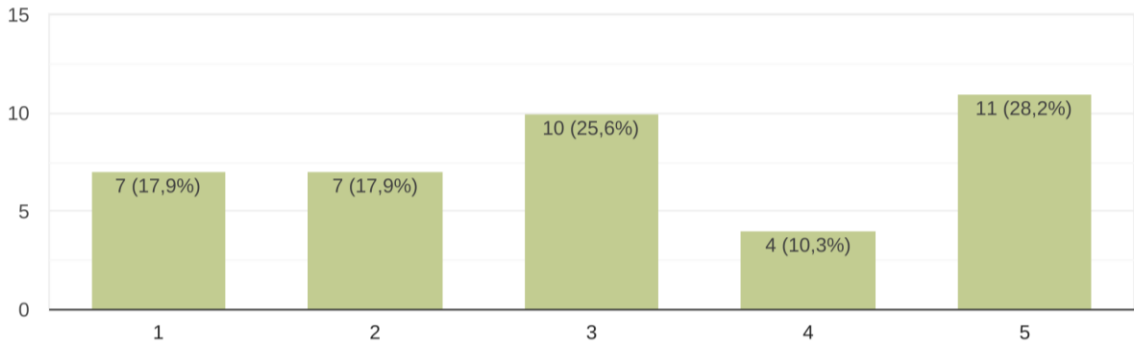
25. Do you like to participate in a research study that is 100% remote/virtual, i.e. without any physical contact with the Research Organization?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree

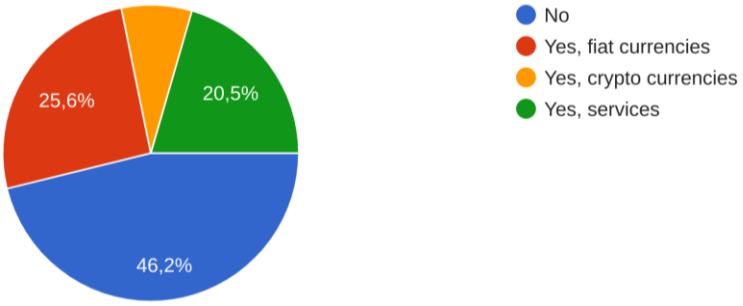


26. Do you like to participate in a research study that is only physical, i.e. with direct access to the healthcare research facilities?

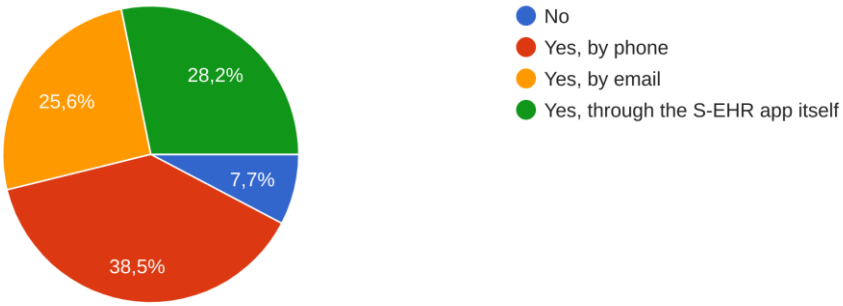
Answer= 1 to 5: 1= strongly disagree, 5= totally agree



27. Would you be more likely to share your health data for research if incentivized to do so? If yes, which is your preferred compensation?

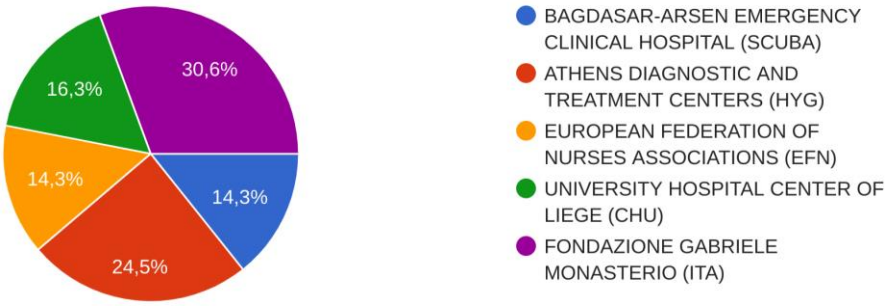


28. Would you need to have a personal contact with the investigators of the study before consent to participate?

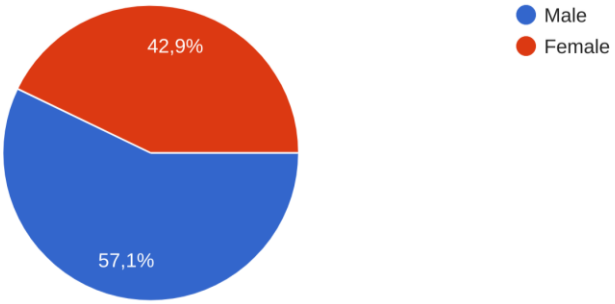


9.2 Health Care Professional Focus Groups

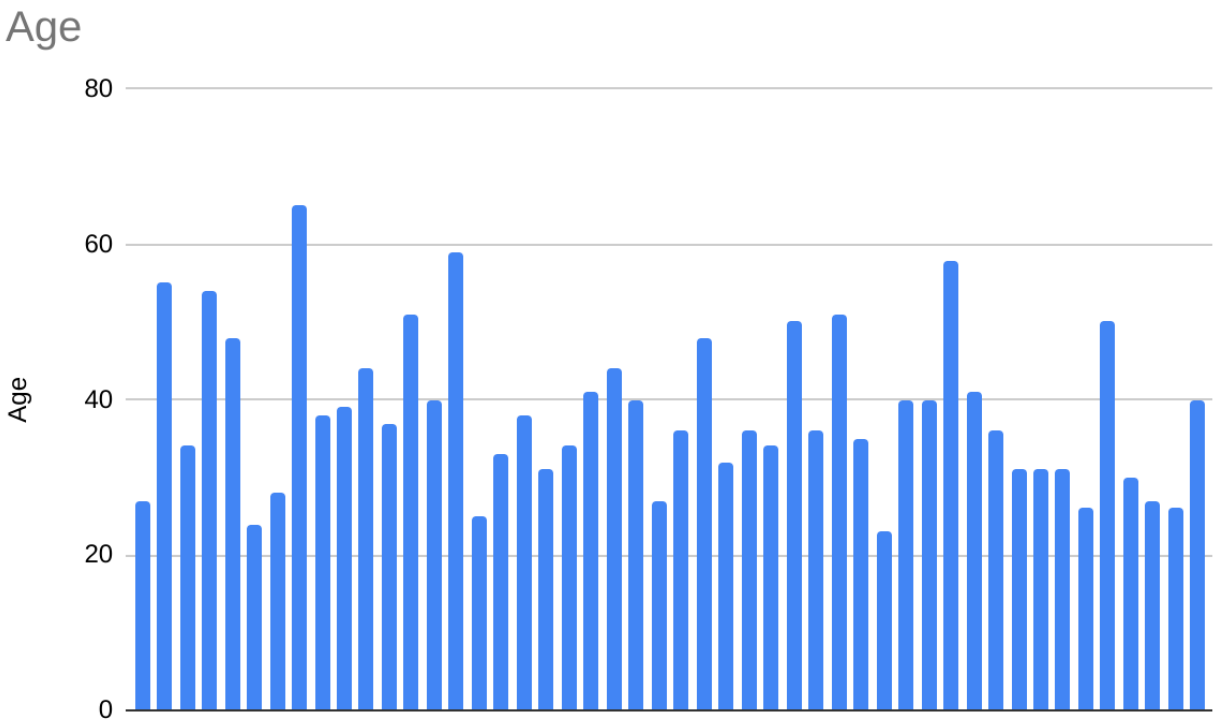
1. Provenance distribution



2. Sex

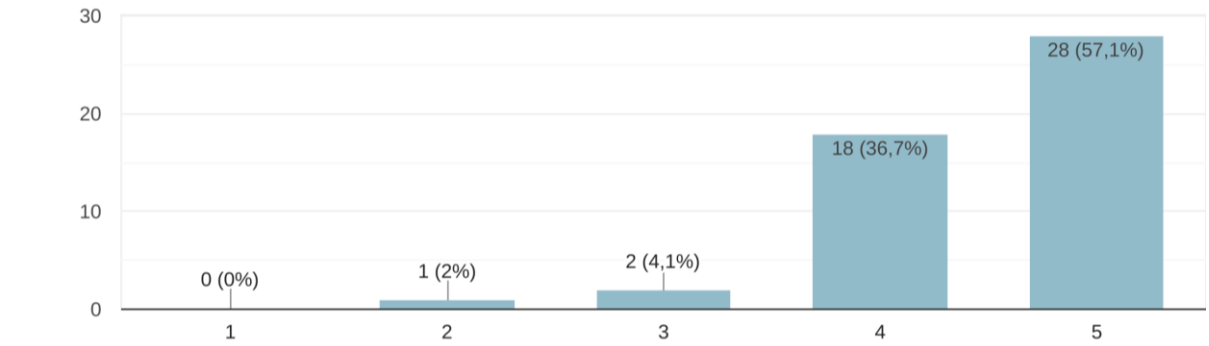


3. Age



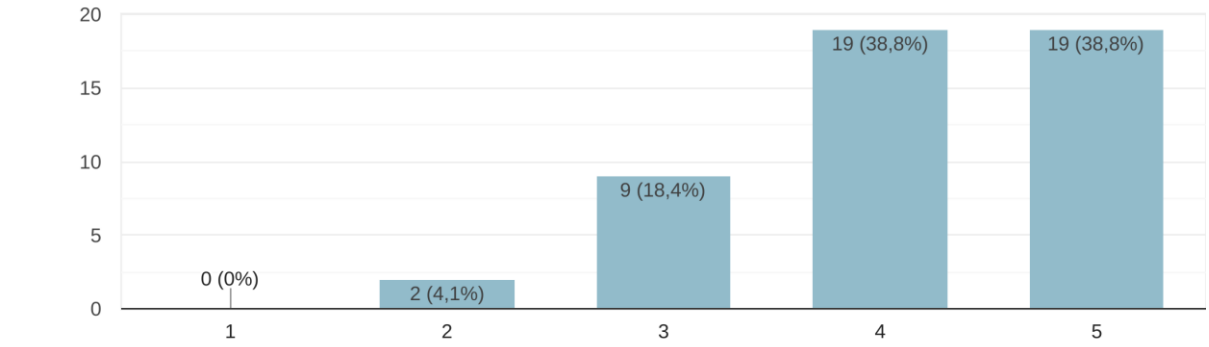
4. Would you like the adoption of a colour code differentiating data registered by patients/family caregivers from other ones certified by hospitals and professional healthcare providers?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



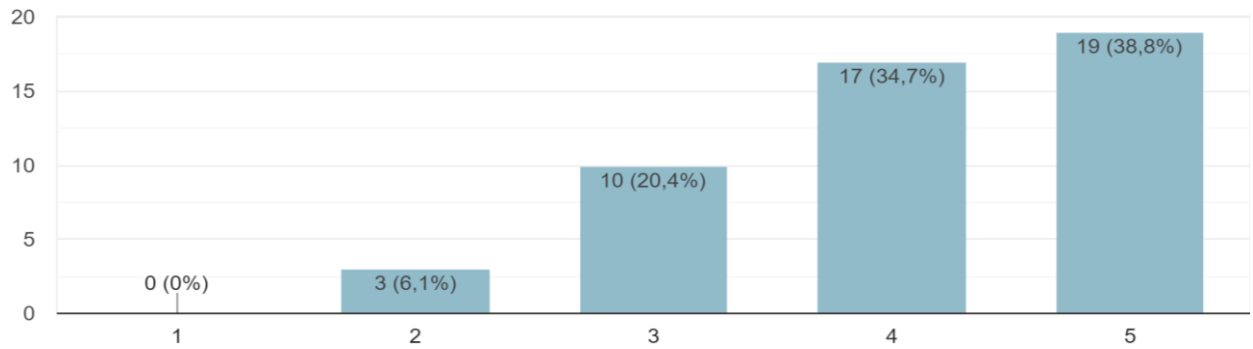
5. Do you expect to have a seamless or simplified connection with patient phones along different HCP workstations, after the initial one?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree

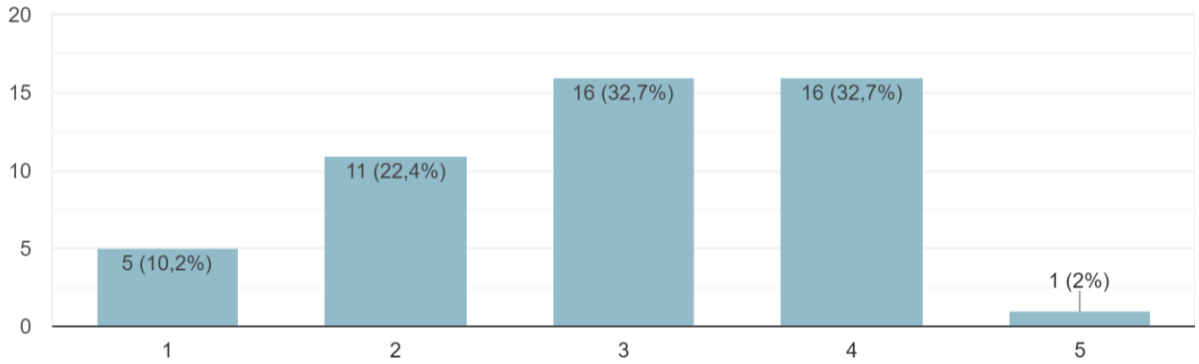


6. Do you think that use of data within IEHR PLATFORM would be easy? (Video / demo)

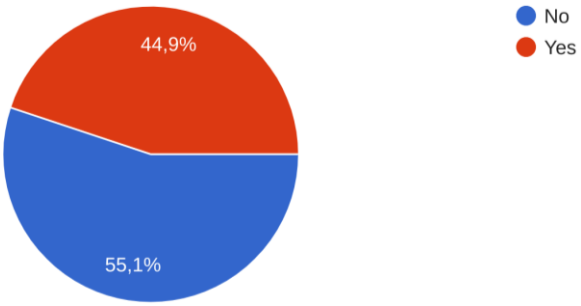
Answer= 1 to 5: 1= strongly disagree, 5= totally agree



7. Do you think that interaction with the patient using IEHR PLATFORM will require much effort for your share? (Video / demo)

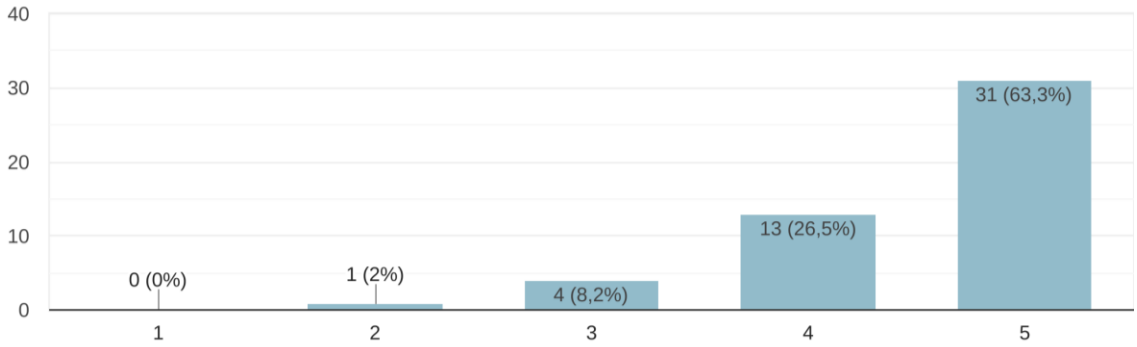


8. Do you have credentials for the EU/national personal identification system eIDAS? (SPID in Italy, eID/ItsMe in Belgium)

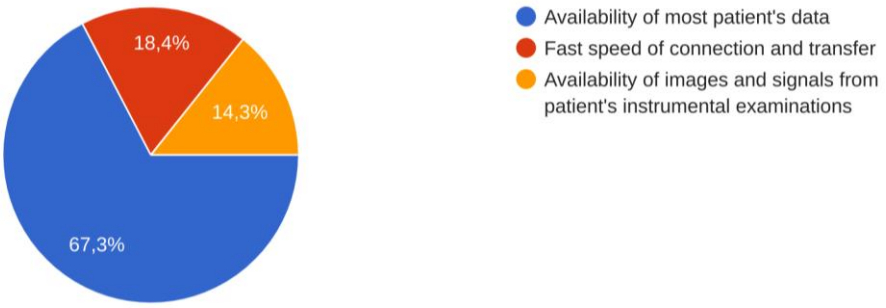


9. Do you think that the IEHR platform can facilitate management of foreign patients?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



10. What are your expectation on HCP App? (tick the higher priority for you)



11. In your ideal APP for patients what are the most desirable features you would like?

These are the responses from Hospitals partners:

- *Availability or access to imaging studies*
- *EASY ACCESS*
- *SIMPLE INSTRUCTIONS FOR USE*
- *WIDE RANGE OF SERVICES AVAILABLE*
- *Low percentage of data registered by patients*
- *Simple to use, intuitive*
- *easy to use*
- *Previous imaging exams*
- *Question 1: yes, it is the role of the physician to assess and re-assess the accuracy of the data at the time of the encounter*
- *Question 2 to 4: I don't want to manipulate smartphones. It is not my job. The data must be made available before the encounter. The encounter is a precious time for face to face exchange with the patient not with a computer.*
- *Question 6: This seems possible in theory. In practice, a lot of barriers will outweigh the benefit.*
- *Question 7: I support the availability of additional communication channels towards patients in healthcare. But it makes no sense to send out a raw copy of the physical exams and analysis to patients. This would compromise the role of GPs and put additional stress on hospitals.*
- *ACCURACY AND REAL-TIME SYNCHRONIZATION*
- *I would like to have and images from studies*
- *The system is very interesting. I would add genealogical information to support genetic and rare diseases both from a care and research point of view.*
- *quick access to information, protocols, guides*
- *Fast availability of patients history and data*
- *The ideal APP would support the emergency scenario. Patients (eventually with the help of their GP) would build up a one-pager that contains essential information for first-aid. This encompasses amongst other allergies, current treatment with a link to the clinical objective!, medical consents, blood group, medical devices...*
- *User friendly technology, adaptations for elderly people - sound signals and big bold fonts.*
- *From what I have seen in videos it is amazing. I am very supportive of data digitalisation in healthcare.*

- *The App should be easy to use, portable (Smartphone, PC...), customizable; it should import clinical data from other databases (hospital DBs, Imaging DBs, Fascicolo Sanitario in Italy...) without the need for manual insertion of data*
- *Intuitive, high speed of health information transfer, quick solution of technical problems*
- *Correct translation of the data. Patients should be able to understand everything. It could also be an option to implement a way to communicate symptoms in an easy way or with easy language. (With pictures of body parts to select and then possible symptoms, select "the arm" and option "pain".*
- *Color palates differentiation specialities, options to change font size, text to speech feature*
- *I don't know*
- *High speed of data transfer*
- *knowing everything about patients, mainly when patients don't carry any data about their clinical status.*
- *simple, fast, complete, interactive*
- *Full access to the entire patient history*
- *structured information quick to transfer; intuitive*
- *ease of use, differentiation of data based on gender, extractability of data, ease of connection with the patient and his doctors*
- *Simplicity and efficiency*
- *easy to use for practitioners*
- *Mobility*
- *Features:*
- *-The focus should be put on patient empowerment to increase adherence to treatments and recommendations.*
- *-The ability to connect a personal health record to connected devices to monitor the patient at home and make those data available during outpatient visit (e.g. blood glucose levels, arterial blood pressure)*

Remarks:
-There are too many manipulations, this should overall be improved for the idea to get accepted.
-It is more important to have the protocol than the image/video from the patient phone during outpatient visit. In some cases, it might be interesting to request access to the images but it is not needed to have them in the initial examination of the patient.

Good communication, speed, images, health data

Availability of data

- Availability of the app AND the health record in the patient native language on the phone.
- Traceability of origin and validation status of the information (entered by patient, entered by nurse, entered/validated by physician ...).
- Automatic synchronization of data collected abroad with reference health organization/network in native language.

To have integrated all the patient data so that the medical personnel will never find themselves again in front of a patient without an accurate medical history.

The first question is indeed of paramount importance! The app should facilitate the coordination of all health care professionals around the patient. More than just showing a raw history of the patient's health, the APP should

allow caregivers to validate, annotate, classify and prioritize the data in order to reflect a recent and trustworthy overview of the patient's health. Incentive and enforcement actions should be explored to influence behavioural changes in the current healthcare model.

1- Strong guarantees about Data security
2- Usability of data: From unstructured text/pdf to codified data using international standards.
3- Nice to have: Get a warning if a prescription to a foreign patient of a drug that is not available in its home country.

Note: it is not necessary to have images/videos on the patient's phone but a link could be useful.

availability of technical assistance

I was unable to watch the videos properly - there was no audio.

In Ireland, the majority of our hospitals do not have digital records and documentation is paper-based. I would be concerned about 'doubling up' the work - i.e. recording a patient's vital signs on paper at their bedside for the hospital records, and then having to make a separate digital entry using the app each time their vital signs are checked; it could be very time consuming.

Additionally, it would be important to have just one 'authorisation process' to access the information - i.e. each individual healthcare worker in the organisation should not have to seek approval to view the data; the patient should authorise healthcare workers in the organisation to view the data.

Full patient's history and medications

simplicity of using

Accuracy of data

history, assessment, contact telephone numbers, diagnosis and treatment, allergies, medication

To get correct and up to date patient's data

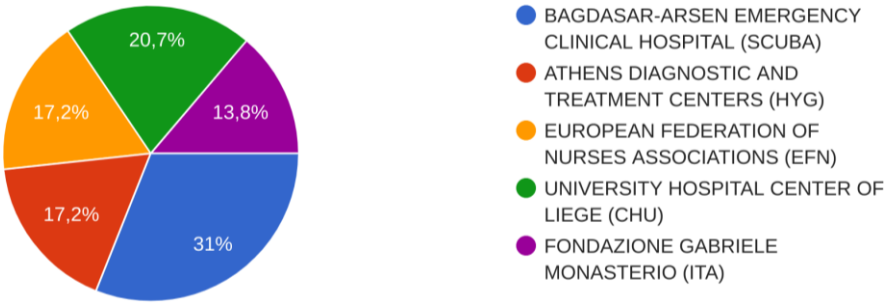
Access to patient's profile

I would like the best ways for treating the patients and all of this process to be much easier.

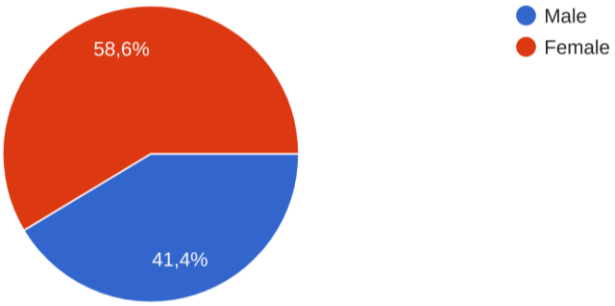
Availability of patient's data (clinical data/blood test/images of instrumental examinations)

9.3 Researcher Focus Groups

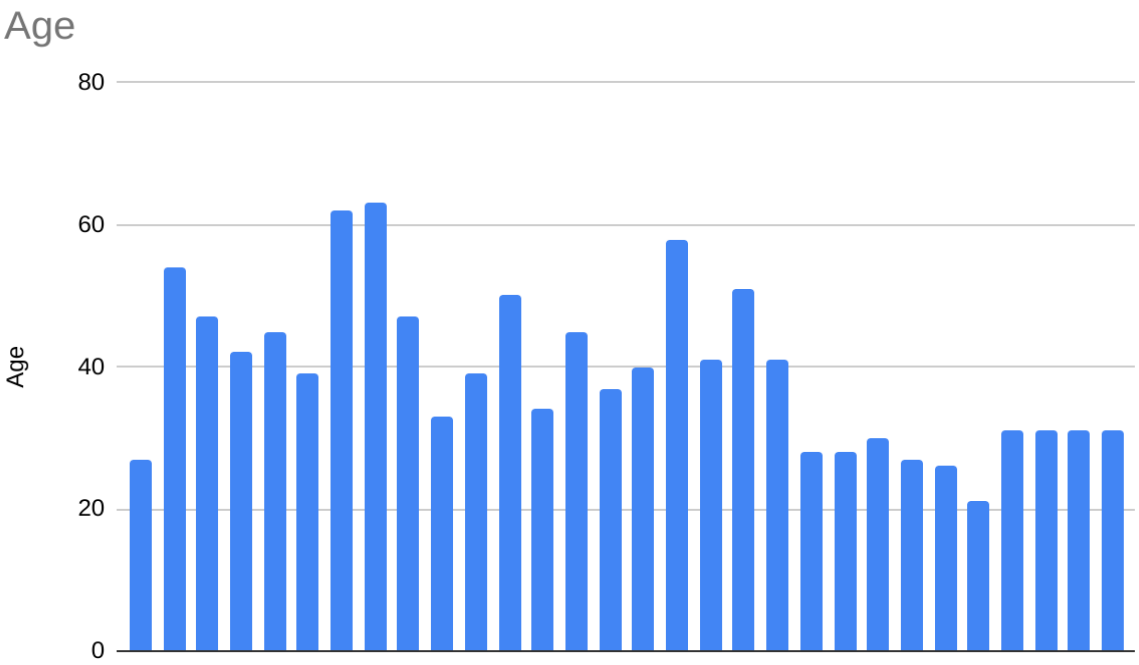
1. Provenance distribution



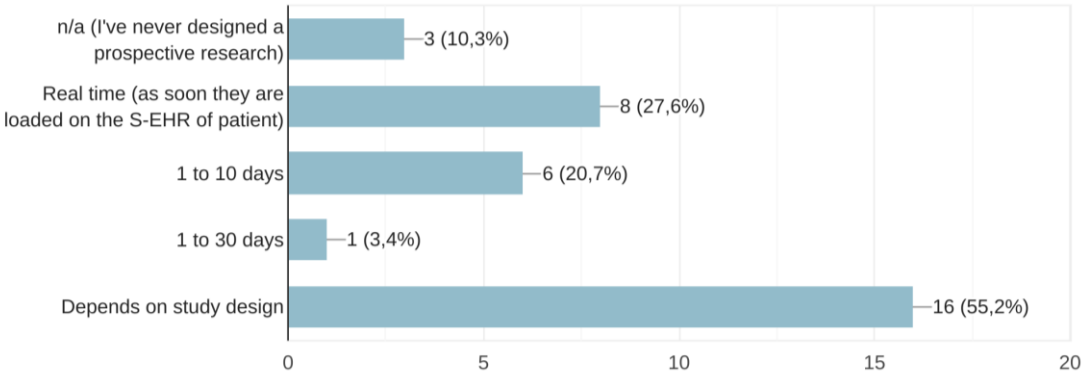
2. Sex



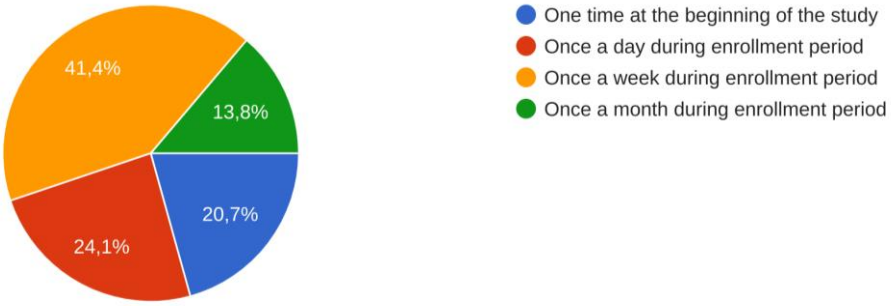
3. Age



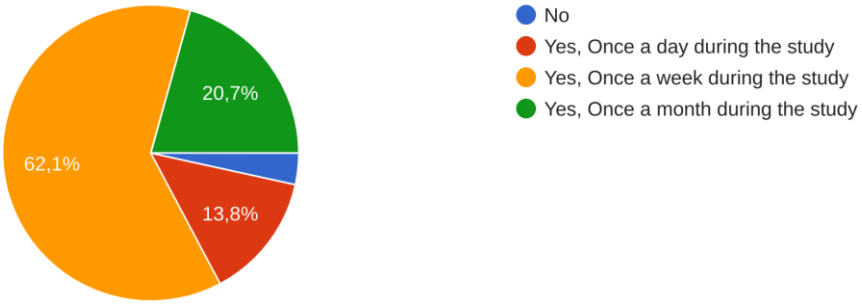
4. For a prospective Research with periodic assessment of the patient, specify the maximum delay for having new collected data of the period (from the App S-EHR of the patient)



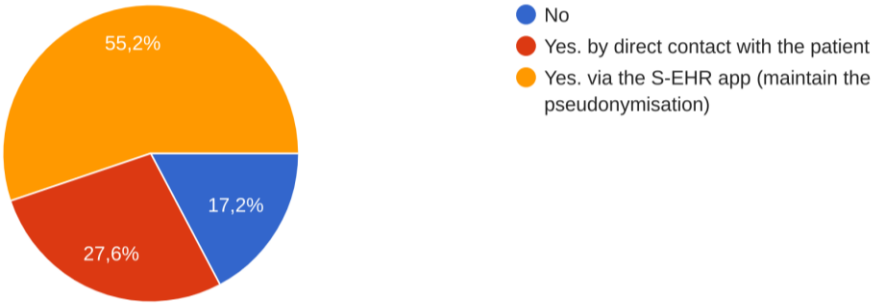
5. How often the S-EHR should evaluate selection criteria against the S-EHR content for one specific study?



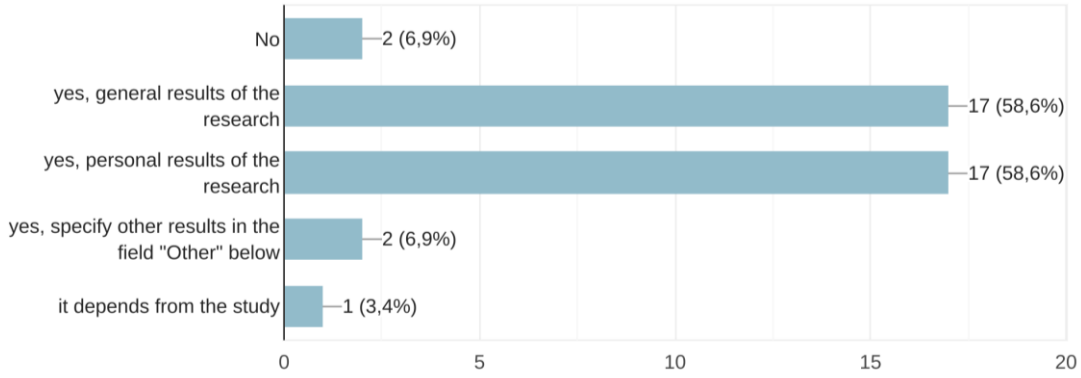
6. Should the researcher be notified when receiving any periodic update with new health data from the cohort of enrolled patients?



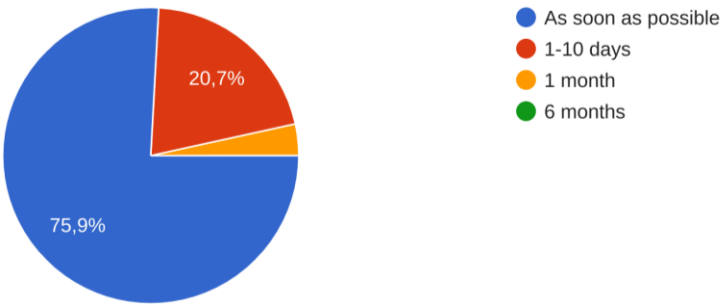
7. Do you need the ability to reach a patient (contact him in case of important health information to communicate for example)



8. Would you like to have the capability to send personal final results of the study to the SHER of the patient?

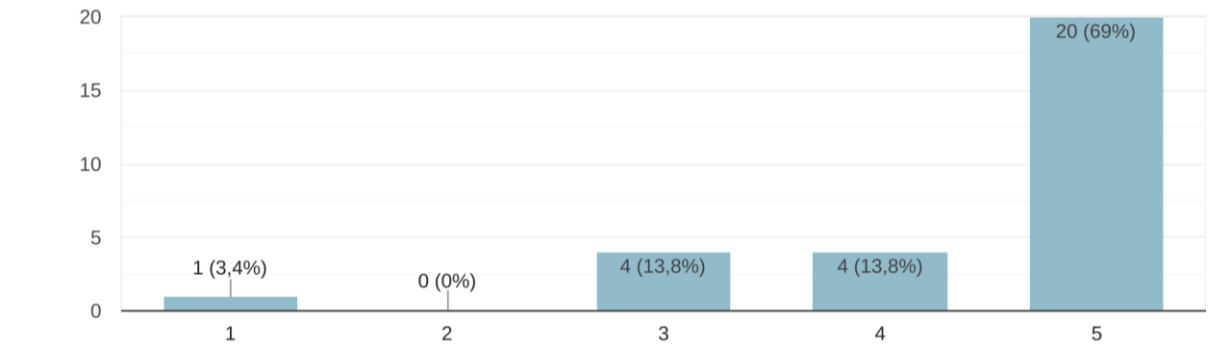


9. Specify the delay for notification of patient withdrawal from the study, when applied in S-EHR app.



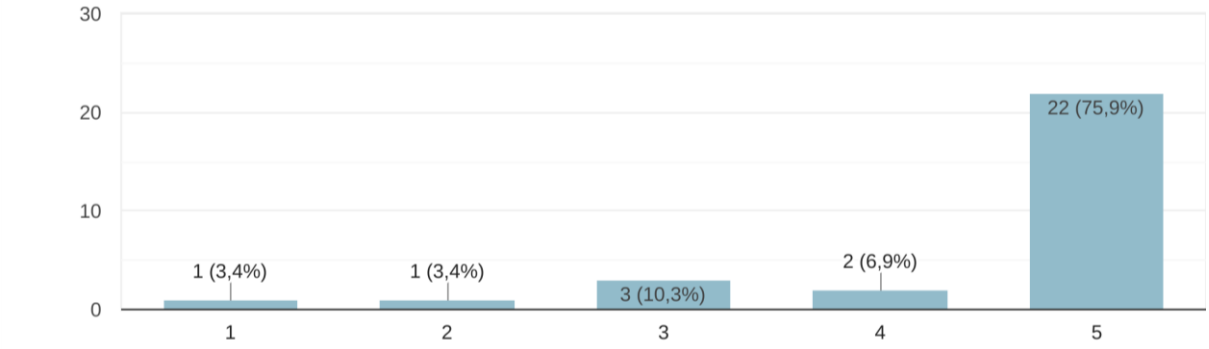
10. Would you like to receive statistical information about the matching rate of inclusion/exclusion criteria of your studies?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



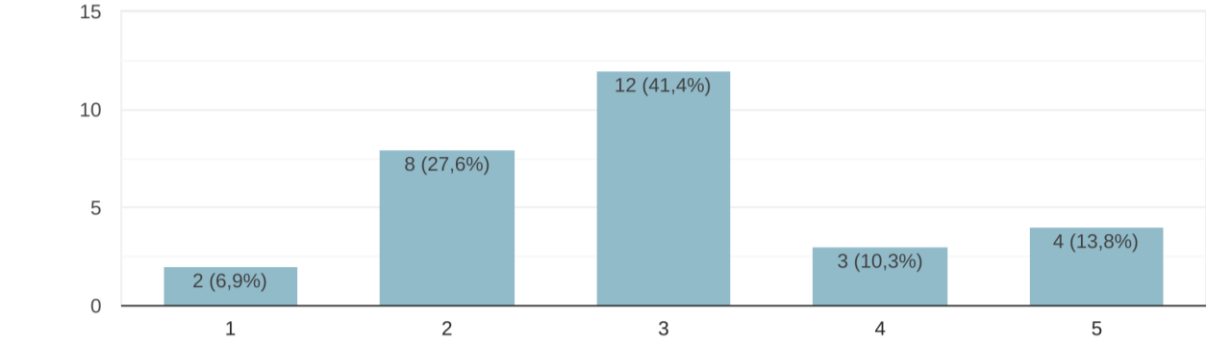
11. Would you want to receive statistical information about the patient approval rate of your studies?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



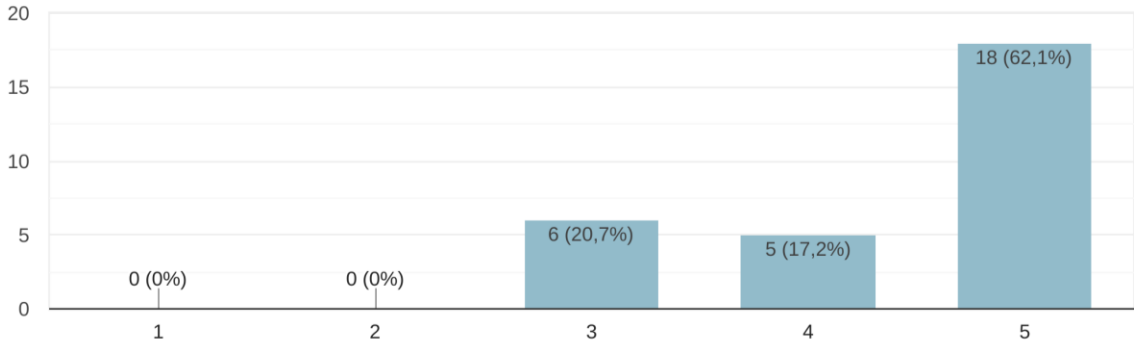
12. Do you think S-EHR will be comfortable enough for elderly/unpaired patients when the research requests for a data entry?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



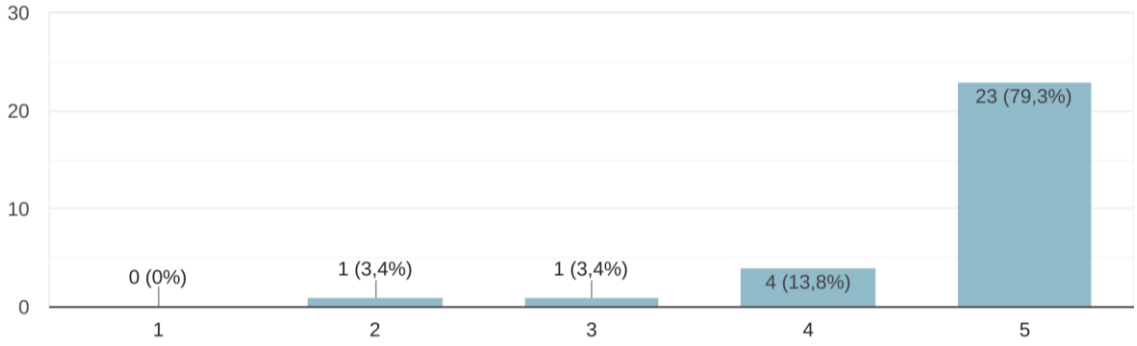
13. For your researches can be useful to have also data on patient's localization?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



14. When you receive requested data would you like to maintain the reference of the author/producer (HCP, Hospital, patient, caregiver, etc.) of that information?

Answer= 1 to 5: 1= strongly disagree, 5= totally agree



9.4 ISA MEDICAL ASSOCIATION OF ATHENS

The report of the focus group of doctors belonging to the ISA of Athens is shown below:

The questionnaire to Healthcare Professionals has been translated along with the localization of the 2 videos explaining the IEHR Platform components and IEHR App, which have been approved by the Special Committee of ISA according to the organization's internal processes.

The Questionnaire was delivered in the format of Google Forms, to a sample of about

1.000 members of ISA, including representatives from various specialties and ages, who either work in their own private practice (i.e. proprietary medlabs) and/or in a hospital, in order to receive answers from various different perspectives.

Furthermore, a helpdesk has been set up in ISA, involving 2 people, responsible for informing the doctors–recipients primarily by direct phone calls, of the informative videos and the questionnaire.

9.4.1 Focus Group of Healthcare Professionals Characteristics

255 doctors replied to the google form questionnaire, who have the characteristics that are included in the following tables and comply to the requirements that have been initially set, concerning the focus group composition:

Age	Number of doctors	Doctors who have their own practice	Doctors who are working or cooperate with a hospital
25-35	12	1	11
35-45	61	28	41
45-55	91	79	42
55-65	63	45	30
65-75	28	22	17
Totals	**255**	**175**	**141**

Specialty	Number of doctors
VASCULAR SURGEON	1
HAEMATOLOGIST	6
DIAGNOSTIC RADIOLOGY	5
RADIOTHERAPY	1
ALLERGOLOGIST	2
ANESTHESIOLOGIST	5
WITHOUT SPECIALITY	20
BIOPATHOLOGIST	9
GASTROENTEROLOGIST	3
GENERAL/FAMILY DOCTOR	12
GYNAECOLOGIST - OBSTETRICIAN	10
DERMATOLOGIST-APHRODISIOLOGIST	7
ENDOCRINOLOGIST	13
OCCUPATIONAL PHYSICIAN	2

CARDIOLOGIST	30
CYTOLOGISTS	2
NEUROLOGIST	3
NEUROSURGEON	2
NEPHROLOGIST	2
ORTHOPEDIC	22
UROLOGIST	6
OPHTHALMOLOGIST	10
PATHOLOGIST	21
PAEDIATRICIAN	10
CHILD PSYCHIATRIST	5
PLASTIC SURGEON	3
PNEUMONOLOGIST	5
NUCLEAR MEDICINE RADIOLOGIST	1
RHEUMATOLOGIST	2
PHYSIATRIST	1
SURGEON	11
THORACIC SURGEON	3
PSYCHIATRIST	14
OTOLARYNGOLOGY	6

AGE	SPECIALTY	NUMBER
25-35	OPHTHALMOLOGIST	1
	UROLOGIST	1
	WITHOUT SPECIALITY	10
25-35 SUM		11
35-45	ANESTHESIOLOGIST	2
	BIOPATHOLOGIST	1
	CARDIOLOGIST	6
	CHILD PSYCHIATRIST	1
	CYTOLOGIST	1
	DERMATOLOGIST-APHRODISIOLOGIST	4
	ENDOCRINOLOGIST	3
	GENERAL/FAMILY DOCTOR	2
	HAEMATOLOGIST	2
	NEUROSURGEON	1
	ORTHOPAEDIC	4
	OTOLARYNGOLOGY	3
	PAEDIATRICIAN	2
	PATHOLOGIST	9
	PNEUMONOLOGIST	2
	PSYCHIATRIST	5
	DIAGNOSTIC RADIOLOGY	1
	SURGEON	3
	THORACIC SURGEON	1

	WITHOUT SPECIALITY	8
35-45 SUM		61
45-55	ALLERGOLOGIST	1
	ANESTHESIOLOGIST	2
	BIOPATHOLOGIST	6
	CARDIOLOGIST	13
	CHILD PSYCHIATRIST	1
	DERMATOLOGIST-APHRODISIOLOGIST	1
	ENDOCRINOLOGIST	3
	GASTROENTEROLOGIST	2
	GENERAL/FAMILY DOCTOR	5
	GYNAECOLOGIST - OBSTETRICIAN	4
	HAEMATOLOGIST	1
	NEPHROLOGIST	1
	NEUROLOGIST	2
	NEUROSURGEON	1
	OCCUPATIONAL PHYSICIAN	1
	OPHTHALMOLOGIST	5
	ORTHOPAEDIC	11
	OTOLARYNGOLOGY	2
	PAEDIATRICIAN	6
	PATHOLOGIST	4
	PHYSIATRIST	1
	PNEUMONOLOGIST	1
	PSYCHIATRIST	4
	RADIODIAGNOSIST	2
	RHEUMATOLOGIST	1
	SURGEON	3
	THORACIC SURGEON	1
	UROLOGIST	4
	VASCULAR SURGEON	1
	WITHOUT SPECIALITY	1
45-55 SUM		91
	BIOPATHOLOGIST	2
	CARDIOLOGIST	9
	CHILD PSYCHIATRIST	2
	DERMATOLOGIST-APHRODISIOLOGIST	2
	ENDOCRINOLOGIST	5
	GASTROENTEROLOGIST	1
	GENERAL/FAMILY DOCTOR	3
	GYNAECOLOGIST - OBSTETRICIAN	4
	HAEMATOLOGIST	1
	NEPHROLOGIST	1
	NUCLEAR MEDICINE RADIOLOGIST	1
	OCCUPATIONAL PHYSICIAN	1
	OPHTHALMOLOGIST	3
	ORTHOPAEDIC	6

55-65	OTOLARYNGOLOGY	1
	PAEDIATRICIAN	2
	PATHOLOGIST	5
	PLASTIC SURGEON	2
	PNEUMONOLOGIST	2
	PSYCHIATRIST	3
	RADIODIAGNOSIST	2
	RADIOTHERAPIST	1
	SURGEON	3
	WITHOUT SPECIALITY	1
55-65 SUM		63
65-75	ALLERGOLOGIST	1
	ANESTHESIOLOGIST	1
	CARDIOLOGIST	2
	CHILD PSYCHIATRIST	1
	CYTOLOGIST	1
	ENDOCRINOLOGIST	2
	GENERAL/FAMILY DOCTOR	2
	GYNAECOLOGIST - OBSTETRICIAN	2
	HAEMATOLOGIST	2
	NEUROLOGIST	1
	OPHTHALMOLOGIST	1
	ORTHOPAEDIC	1
	PATHOLOGIST	3
	PLASTIC SURGEON	1
	PSYCHIATRIST	2
	RHEUMATOLOGIST	1
	SURGEON	2
	THORACIC SURGEON	1
	UROLOGIST	1
65-75 SUM		28
TOTAL		254

9.4.2 Analysis of the results

1. Question : Would you like the adoption of a colour code differentiating data registered by patients/family caregivers from other ones certified by hospitals and professional healthcare providers?

ANSWER	Would you like the adoption of a colour code differentiating data registered by patients/family caregivers from other ones certified by hospitals and professional healthcare providers?	PERCENTAGE
1	3	1,18%

2	2	0,78%
3	20	7,84%
4	59	23,14%
5	171	67,06%
TOTAL	**255**	

2. Question: Do you expect to have a seamless or simplified connection with patient phone along different HCP workstations, after the initial one?

ANSWER	Do you expect to have a seamless or simplified connection with patient phone along different HCP workstations, after the initial one?	PERCENTAGE
1	6	2,35%
2	4	1,57%
3	19	7,45%
4	70	27,45%
5	156	61,18%
TOTAL	255	

3. Question: Do you think that use of data within IEHR PLATFORM would be easy? (Video / demo)

ANSWER	Do you think that use of data within IEHR PLATFORM would be easy. (Video / demo);	PERCENTAGE
1	5	1,96%
2	21	8,24%
3	74	29,02%
4	96	37,65%
5	59	23,14%
TOTAL	255	

4. Question: Do you think that interaction with the patient using IEHR PLATFORM will require much effort for your share? (Video / demo)

ANSWER	Do you think that interaction with the patient using IEHR PLATFORM will require much effort for your share? (Video / demo)	PERCENTAGE
1	16	6,27%
2	28	10,98%
3	97	38,04%
4	80	31,37%
5	34	13,33%

TOTAL	255	

According to the results of the above question, there is a strong possibility that the majority of doctors are not aware of the eIDAS system, which is the basis of the digital signatures used by the majority of doctors who work in the public domain.

5. Question: Do you think that IEHR platform can facilitate management of foreign patients?

ANSWER	Do you think that IEHR platform can facilitate management of foreign patients?	PERCENTAGE
1	7	2,75%
2	7	2,75%
3	43	16,86%
4	89	34,90%
5	109	42,75%
TOTAL	255	

6. Question: What are your expectation on HCP App? (tick the higher priority for you)

ANSWER	What are your expectation on HCP App? (tick the higher priority for you)	PERCENTAGE
Availability of images and signals from laboratory tests of patients	71	27,84%
Availability of most patient data	146	57,25%
High data connection and transfer speed	38	14,90%
TOTAL	255	

7. Question: In your ideal APP for patients what are the most desirable features you would like?

Based on the answers gathered from 255 doctors, focus is given on the speed of the APP, the protection of personal data, available information of the patient's health historic data including laboratory examinations (data and images), chronic diseases, history of allergies, current medication, ease of access and app usability. As outliers, we received some answers which were sceptical of replacing the face-to-face interaction of HCPs and patients (especially elderly people) and a wish for a system that automatically notifies the HCP when certain lab exam results or life sign values are considered dangerous/critical.