D2.2

User Requirements

for cross-border HR integration

V2

ABSTRACT

This report describes the second version of final users' requirements of InteropEHRate platform and related open specifications. It includes the initial definition of clinical content to be supported by a S-EHR, expressed in three different reference scenarios. The results of the second cycle of focus groups are also reported, including suggestions and comments on InteropEHRate functionalities and user interface, in the three different categories: patients and family caregivers, healthcare professionals, clinical researchers.

Delivery Date	April 29th, 2020
Work Package	WP2
Task	T2.1
Dissemination Level	Public
Type of Deliverable	Report
Lead partner	FTGM

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826106.

This document has been produced in the context of the InteropEHRate Project which has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826106. All information provided in this document is provided "as is" and no guarantee or warranty is given that the information is fit for any particular purpose.

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LOGTABLE

Version	Date	Change	Author	Partner
0.1	2020-02-04	TOC initial version	Stefano Dalmiani, Paolo Marcheschi,	FTGM
0.2	2020-02-20	Initial Draft	Stefano Dalmiani, Paolo Marcheschi,	FTGM
0.3	2020-03-10	Users focus groups results	Paolo Marcheschi, Stefano Dalmiani, Paul De Raeve, Efthimya Papadopoulou, Ioanna Prasini, Christina Kotsiopoulou, George Petrescu, Marcela Chavez, Patrick Duflot, Theodora Zacharia, Thanos Kalligeris	FTGM, HYG, SCUBA, CHU, ISA, EFN
0.3	2020-03-31	Updates to scenarios	Francesco Torelli, Stefano Dalmiani, Paolo Marcheschi, Gabor Bella, Simone Bocca	ENG, FTGM, UNITN
0.4	2020-04-09	Second version of requirements	Francesco Torelli	ENG
0.5	2020-04-10	Final draft	Paolo Marcheschi, Stefano Dalmiani	FTGM
0.6	2020-04-22	First internal Review	Thanos Kiourtis, Simona Bica	UPRC, SIMAVI
0.7	2020-04-23	Addressed review comments	Paolo Marcheschi, Stefano Dalmiani	FTGM
0.8	2020-04-25	Quality Review	Argyro Mavrogiorgou	UPRC
0.9	2020-04-27	Addressed Quality review comments	Paolo Marcheschi, Stefano Dalmiani	FTGM
1.0	2020-04-28	Final Release	Stefano Dalmiani	FTGM
VFinal	2020-02-29	Final check and version for submission	Laura Pucci	ENG

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-HER	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
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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. 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, uses Narrative Scenarios methodology to describe 3 instances of health data exchange in a secure and interoperable environment.

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

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 [D2.1][13] .

- Section 2 "Approach for requirement analysis"

- Updated version to distinguish user requirements that apply to the InteropEHRate framework from requirements that apply to any realisation of the InteropEHRate standard architecture. Moreover, the concept of epic has been introduced.
- A new action (PI of the study) has been added.

- Section 3 “S-EHR Content”
  - Added reference to eHDSI and EU indications on EHR data management.
  - Added subchapter on Consent management.
  - Added subchapter on Digital signature of documents and health data.
- Section 4 “Reference Scenarios”
  - The titles of previously defined scenarios have been updated to make clearer the clinical context.
  - Scenario S2 has been improved.
  - Scenario S3 has been completely redefined, removing the need of the S-EHR Cloud and introducing the new concept of InteropEHRate Open Research Network.
  - Added the new “Scenario S4 - Semantic data management”, describing the activities performed by data scientists for representing the semantics of the health data stored within an EHR and needed for supporting the cross-border exchange.
- Section 5 “User Requirements”
  - Added the analysis of scenarios S2, S3, S4.
  - All requirements from number ‘73’ to ‘155’ are new with respect to v1. In particular they now specify the requirements of the S-EHR Cloud, both for backup and access to health data in emergency situations, and the requirements of the S-EHR for sharing health data with researchers.
  - Includes some updates to requirements specified in the first version of this document [D2.1][13] and still to be implemented.
  - The descriptions distinguish requirements targeted only by the InteropEHRate Open Specification, requirements also implemented in the InteropEHRate framework and requirements classified out of scope of both.
- Old section 6 “Knowledge Management Tool” has been merged with section 5.
- Section 6 “Users Focus Groups” (previously numbered section 7) has been updated to include the new 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 and of additional applications (e.g. “Knowledge Management Tool”) that are 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 implementation, 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 version v1 of the InteropEHRate framework (the reference implementation of the InteropEHRate architecture) and other ones that are candidates for inclusion in v2 and 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 [D3.1] [1] “Specification of S-EHR mobile privacy and security conformance levels” 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 the 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 [D4.2][14] and [D4.8][15] .

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 three 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 fourth 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 more fine 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. The first year is dedicated to the analysis of the scenario “Device to Device HR exchange” (focusing mainly on the exchange of data during face to face clinical encounters).

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 sections describe the usage scenarios and the user requirements specified during the first 6 months of the project.

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 the actors of 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	
-	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) Medical imaging and bio-signals:
    a) contains DICOM images and movies;
    b) contains bio-signals (e.g. SCP and DICOM waveform);
5) Reports and digitally signed documents (e.g. PaDES);
6) Hospital discharge reports;
7) Personal notes of the patient (wellness and activity data).

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 future, there will be 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][12]).

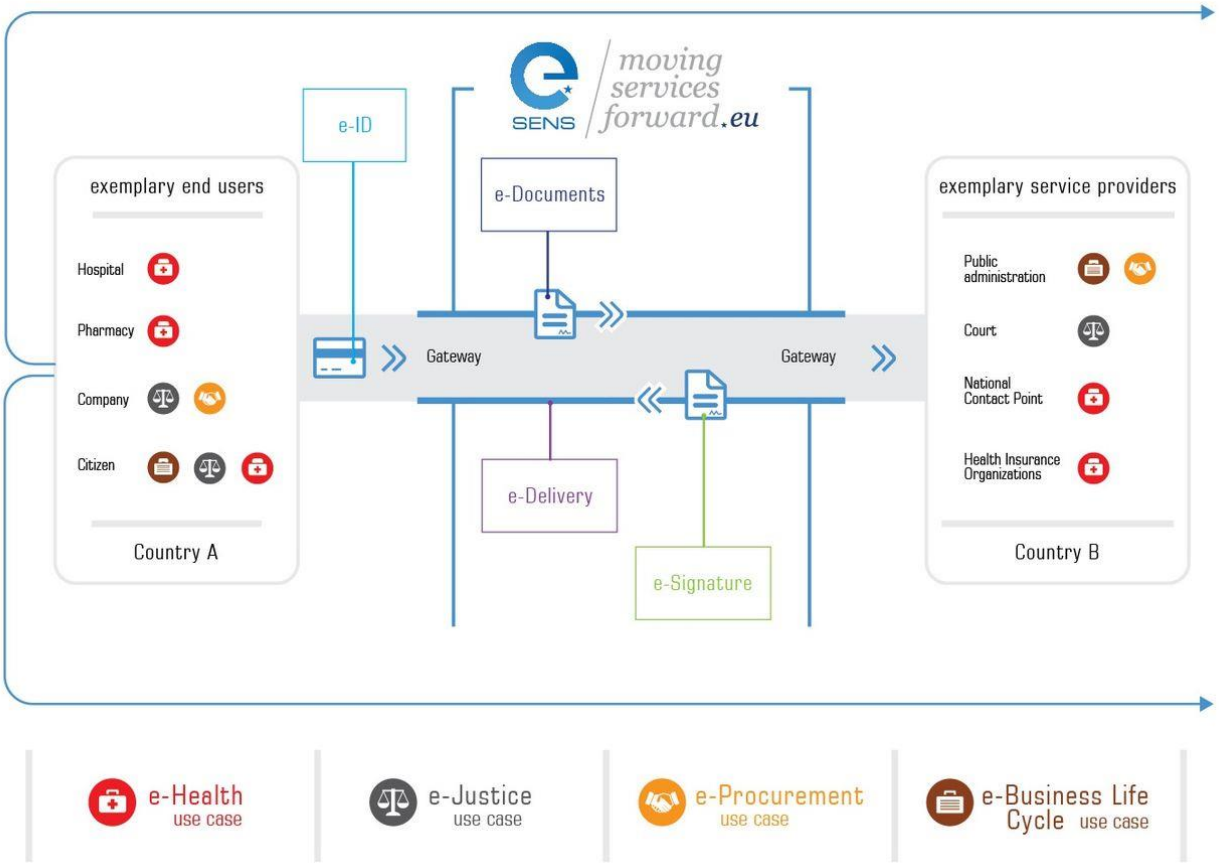


Figure 1. *Example of use for digital signature cross-borders*

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][10] 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][11] . 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 platform assigning EU trial number 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][7] 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][8] .

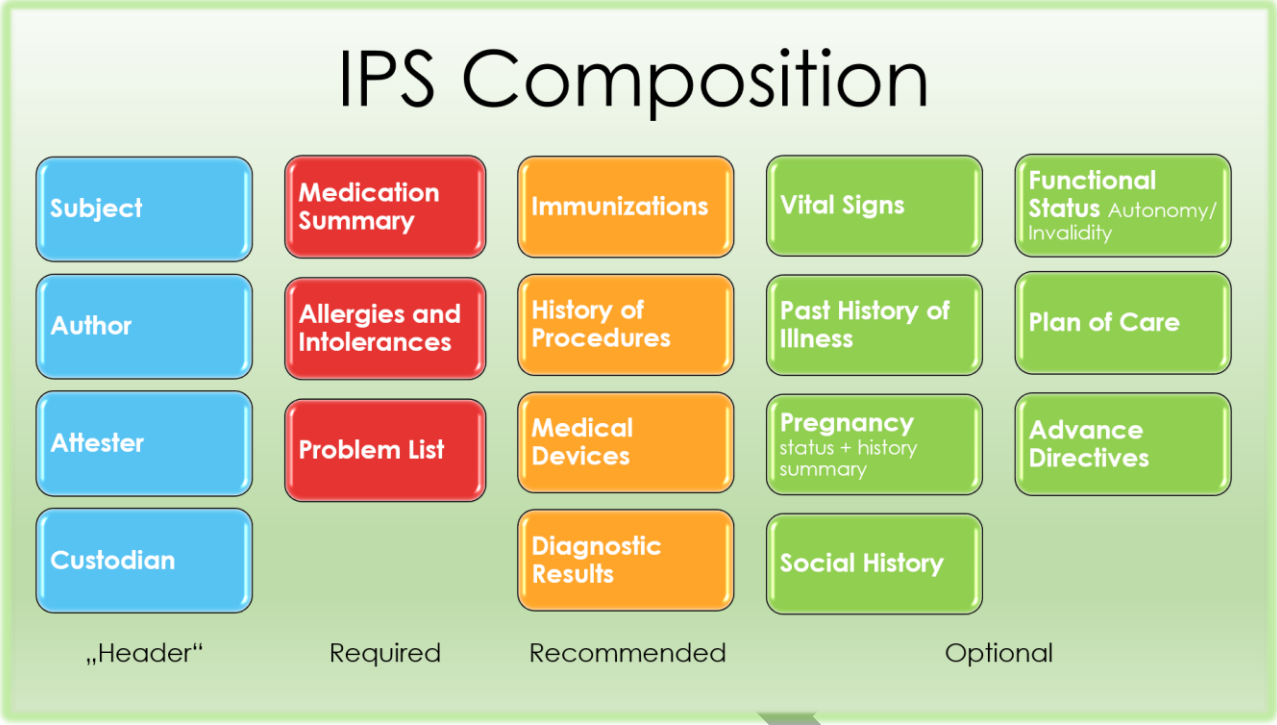


Figure 2.*IPS composition*

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][6]

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

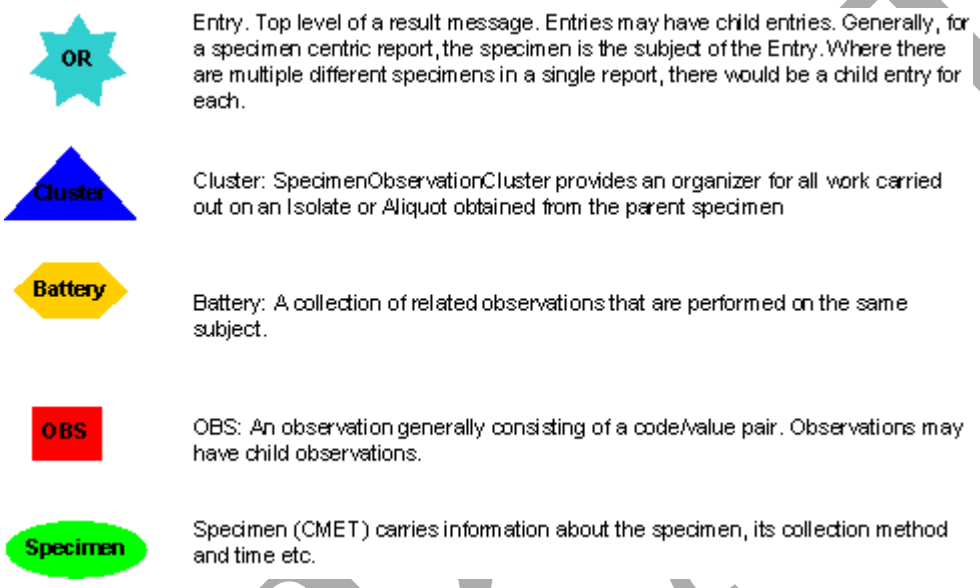


Figure 3. *Example of structure for laboratory exams*

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:

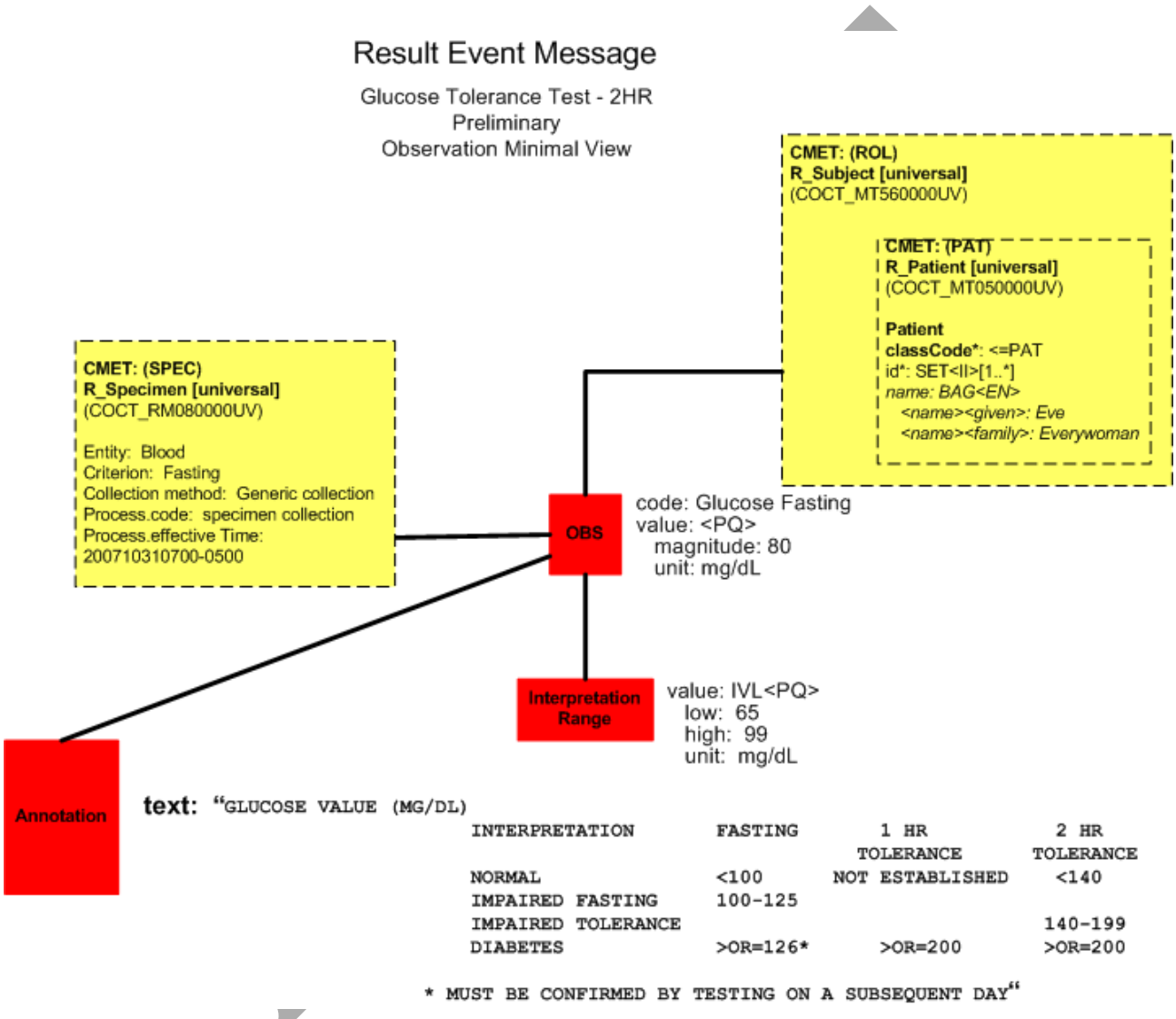


Figure 4. *Example of information model for laboratory exams*

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		Non-reactive	11/20/2019 0730	11/20/2019 08:00
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:

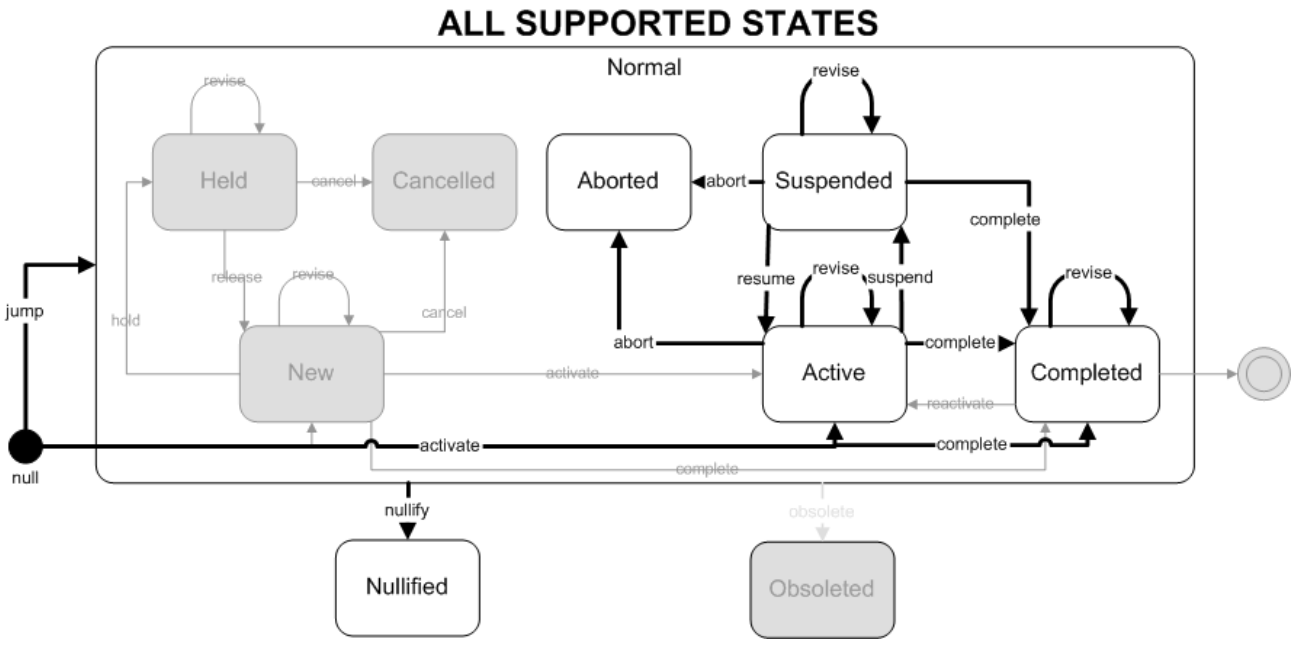


Figure 5. *Example of states diagram for laboratory exams*

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.

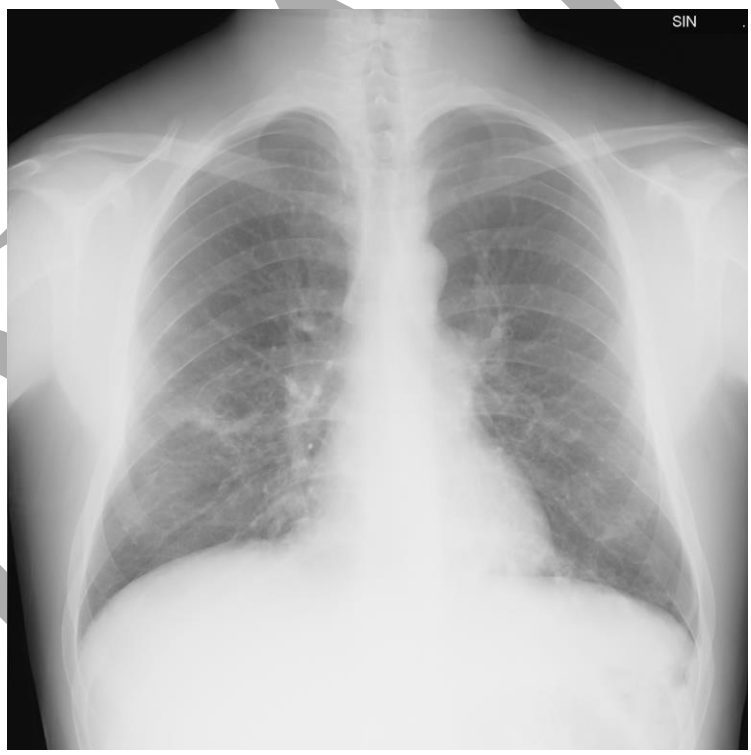


Figure 6.*X-ray Medical Image*

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][9] . 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][16] .

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.

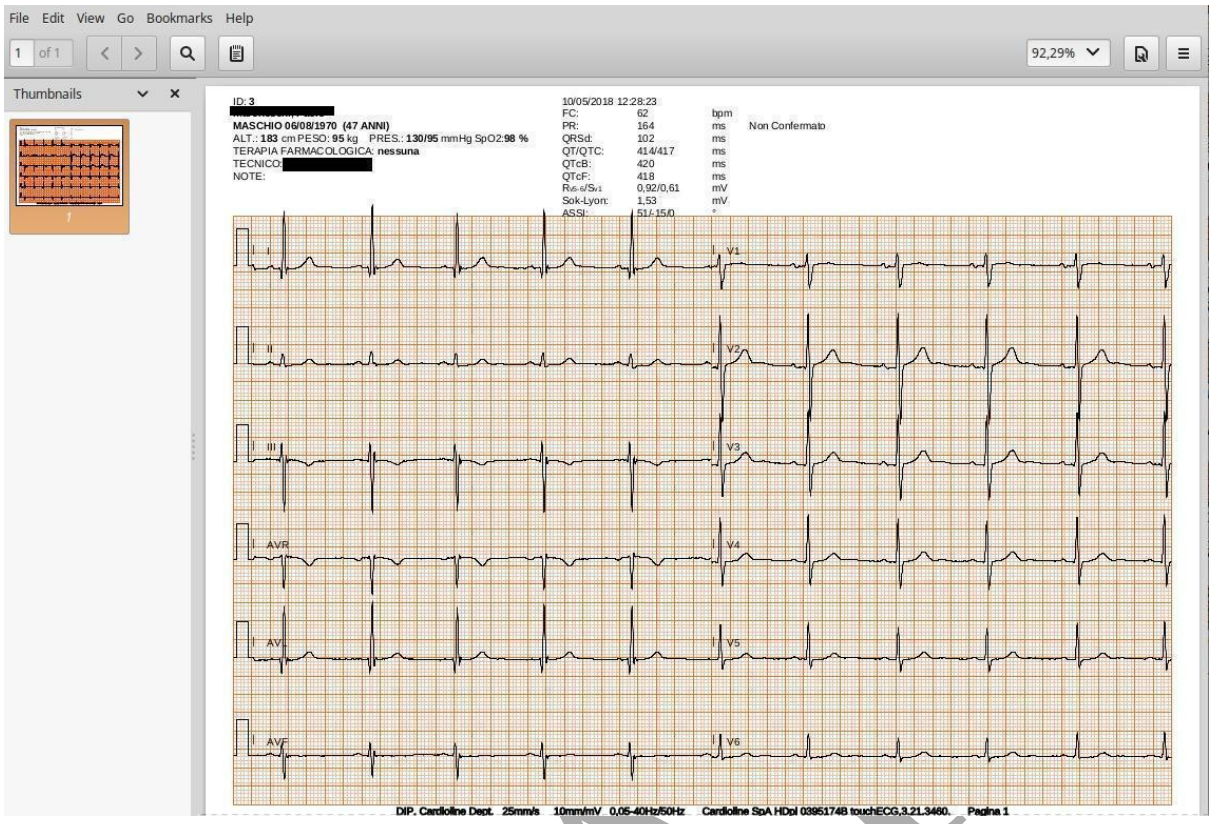


Figure 7. *Example of digital ECG*

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:	1.3.6.1.4.1.5962.99.1.3577849546.1829541192.1575535912650.4611.0
(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:	1.3.6.1.4.1.5962.99.1.3577849546.1829541192.1575535912650.4612.0
(0020,000E)	SeriesInstanceUID:	1.3.6.1.4.1.5962.99.1.3577849546.1829541192.1575535912650.4613.0
(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 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

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

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.

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.

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

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

In the following chapter it is reported short descriptions of the reference scenarios, where a sample usage of the S-EHR platform is described.

4.1 *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/smartphone, or phablet), 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.

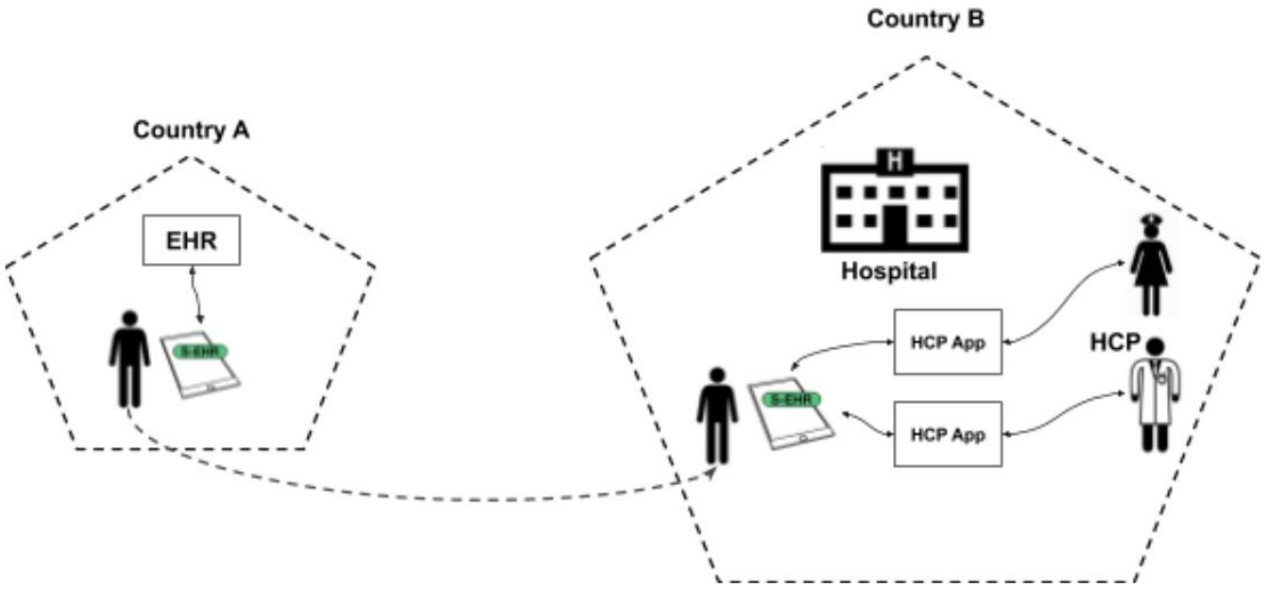


Figure 8.*Scenario S1 - Medical visit abroad: Device to Device HR exchange*

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.

4.1.1.1 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 has been 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 complains of mild lower limbs edema, dyspnoea and reduction in exercise tolerance.

4.1.1.2 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. [Sub-Scenario] The data about the health history 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. [Sub-Scenario] 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 the S-EHR system by an author/actor is registered (logged) by both the S-EHR and the HCP App and associated permanently with the unique identification of the involved patient and HCP author/actor.

J. The patient has already configured on his/her S-EHR a set of default permissions for any HCP that he/she authorizes to access his/her data.

K. [Scenario S4] The health care organization has described the semantic codes used locally by the organization (national and local codes) using the Knowledge Management Tool.

L. [Scenario S4] The domain expert of the healthcare organization has defined the mapping between the local codes and the international codes.

M. All the information is related to its producer/author.

N. The HCP cannot repudiate the produced information.

O. The Patient cannot repudiate the produced information.

P. The data contained in the S-EHR are safe and represents a legal consistency on which it relies for diagnosis/treatment/prognosis/prevention.

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

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

4.1.2 Scenario Description

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

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 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. Are 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 are 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.

The HCP2 accompanies the patient 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.

Data produced by the HCP3 during the evaluation are collected in the HCP App of HCP3.

During the evaluation of HCP3, S-EHR is able to exchange data with 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.

20) HCP3 starts to visit the patient: download the patient's history from the S-EHR app (translated into the HCPs 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, compare them with current values (collected by HCP2) and recognize a relevant gain in body weight.

23) HCP3 asks for a chest X-ray at local imaging facilities.

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

b) HCP3 compares them 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.

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 HCP Terminal:

a) image and report of chest X-rays

b) evaluation report

c) drug prescription for furosemide 25 mg

4.1.3 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.

4.1.4 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
- 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)

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),
- jugular vein distension (presence/absence);
- Cardiac & lung auscultation (normal/abnormal)

Latest EKG:

- heart rate (bpm),
- PR,
- QRS intervals (msec)
- QTc intervals (msec),
- left bundle branch block (presence/absence);

Latest echocardiogram:

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

Latest chest X-ray:

- report and images;

Latest Holter monitoring:

- mean heart rate (bpm),
- number of premature ventricular beats,
- number of ventricular tachycardias (with max length in bpm),
- atrial fibrillation (presence/absence);

Latest device report:

- rate of biventricular pacing (if available),
- appropriate device interventions (ATP and shock);
- Latest cardiopulmonary exercise testing:
    - workload (Watt),
    - VO2 peak (ml/min/Kg),
    - VE/VCO2 slope;

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 (if available) including:

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

4.2 *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.

[Related Scenario] 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.

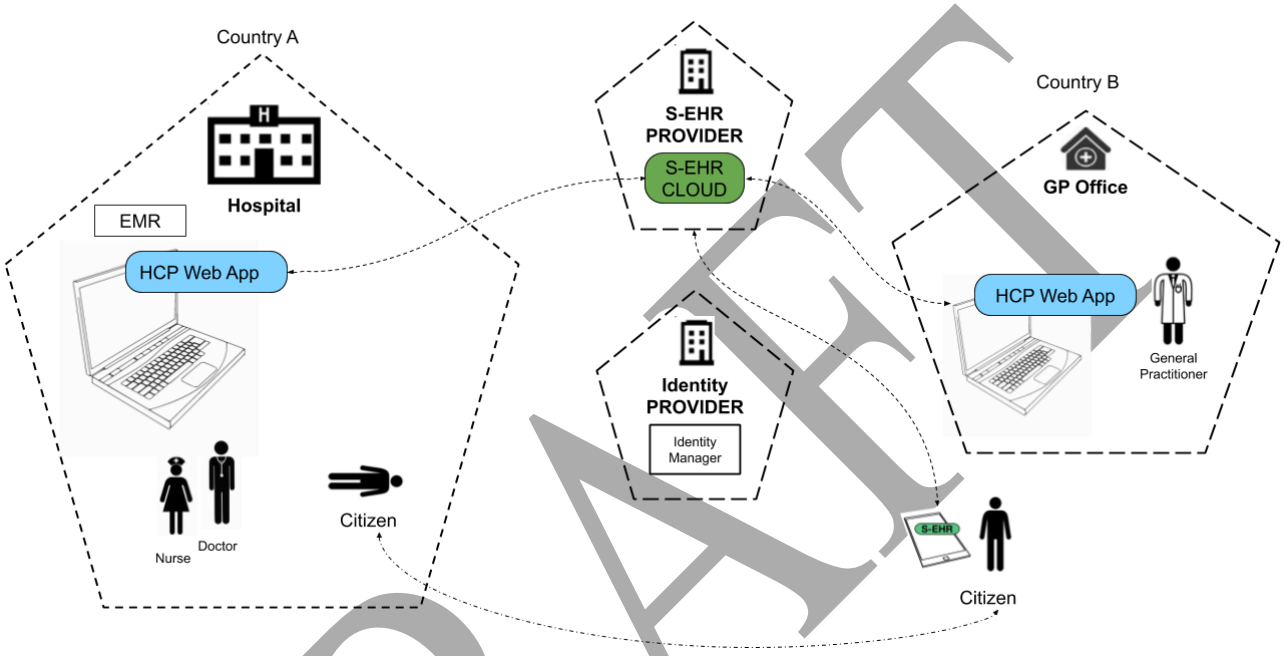


Figure 9 *Scenario S2 - Emergency access: R2D Scenario*

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 the scenario is operating.

4.2.1.1 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.

4.2.1.2 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 and to share them with people and at moments explicitly authorised by the patient.

C. [Sub-Scenario] 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.

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. The patient has no access to the device containing his\her own S-EHR.

H. or the patient has his own phone and has an internet connection (abroad)

I. or the patient has his own phone and hasn't internet connection (abroad)

J. 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 to that patient by the S-EHR Cloud.

    b. the token is used 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

K. [Sub-Scenario] The patient gave his/her consent to the emergency identification by means of an emergency identity token.

L. [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.

M. 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 cloud.

N. 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.

O. 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.

P. The hospital has full access to internet connection and to S-EHR cloud infrastructure

Q. 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.

R. All the information is related to its producer/author

S. The HCP cannot repudiate the produced information.

T. The Patient cannot repudiate the produced information.

U. The data contained in the S-EHR are safe and represents a legal consistency on which it relies for diagnosis/treatment/prognosis/prevention

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

W. There is a mutual trust between Patient and HCP

4.2.2 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 (height, eye colour) contained in the identification data with the 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 on the left anterior descending coronary artery is mentioned.

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 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 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, prescriptions, visits and recommendations, therapy and prescriptions.

4.2.3 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, new data is downloaded from S-EHR Cloud to the patient's phone.

4.2.4 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 *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 purpose.

Citizens and researchers may decide to participate in the InteropEHRate Open Research Network. The InteropEHRate Open Research Network is constituted by consentient patients and by 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.

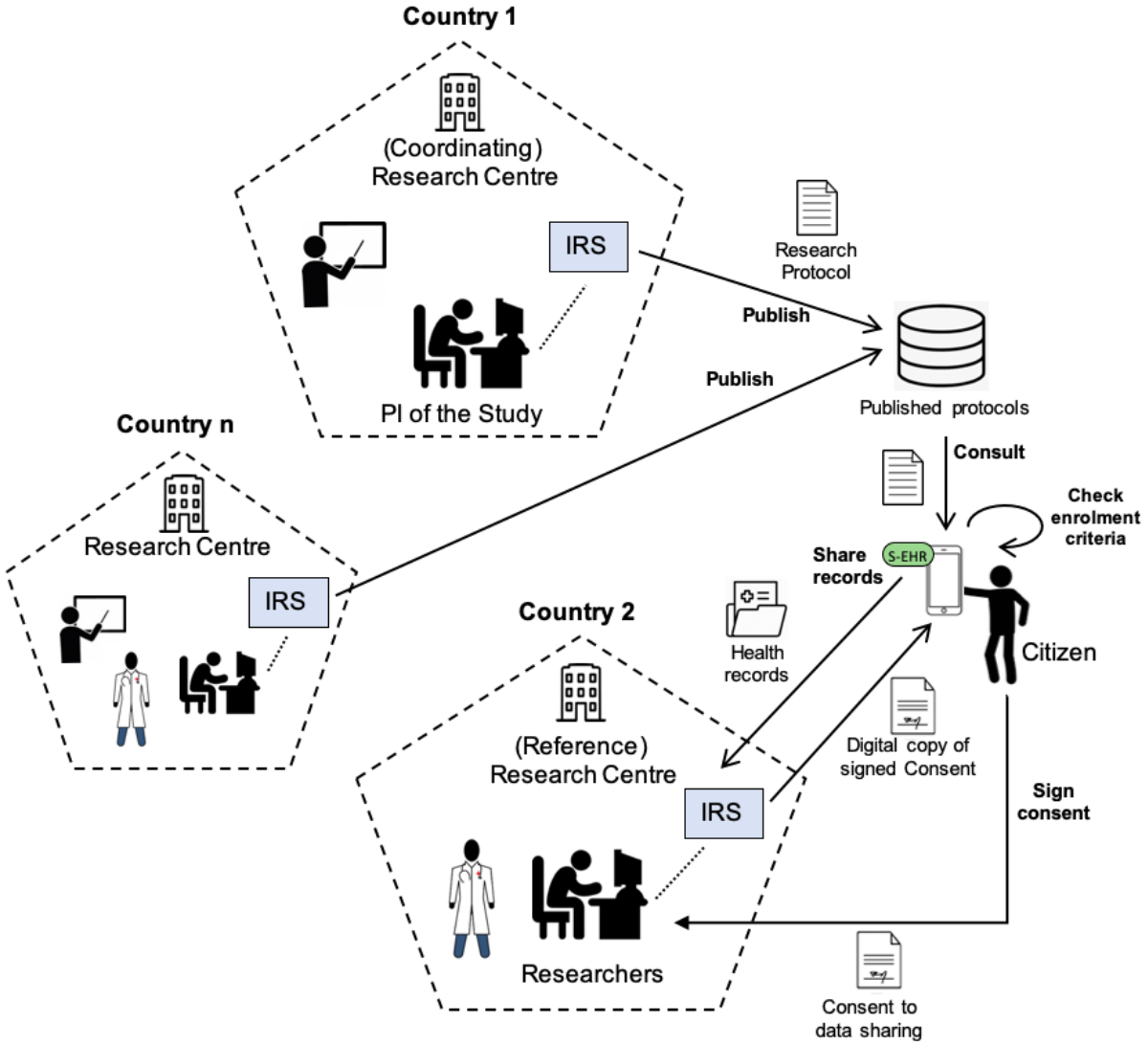


Figure 10. *Scenario S3 - Health research study: Research Scenario*

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.

4.3.1 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.

4.3.1.1 Clinical preconditions and assumptions

- A population of patients have a collection of clinical data related to their status and clinical condition.
- The research protocol has been approved by the ethical committee and its feasibility has been verified.

4.3.1.2 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.

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.

L. Patients can withdraw from their participation in the InteropEHRate Open Research Network at any moment (and someone does it).

4.3.2 Scenario Description

1) Patients (including 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 "Female hypertension study" using the InteropEHRate format:
    a) the protocol involves female patients with age > 65 years, with hypertension and treated with ACE inhibitors, 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 healthcare treatment and vital signs and 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.
4) The research protocol is transmitted to the S-EHR apps of the patients.
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.
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 is excluded from the research's possible candidates and receives no notification.
7) Eve accesses on the S-EHR app a list showing the studies she may participate in and selects the invitation called "Female hypertension 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 "Female hypertension 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
    a) In the case of this protocol, the data of the previous 5 year are sent.
    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) In the case of this protocol, pseudonymized data are sent for the next two years.
    c) The Reference Research Centre selected by Eve forwards any new health data set to the Coordinating Research Centre (if different).
13) Eve may choose to be notified each time that new health data are sent to the Principal Investigator.
14) Eve can withdraw her participation at any time.
    a) In case of withdrawing, the event is notified to the Reference Research Centre of Eve.
15) 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.

4.3.3 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).

4.3.4 Dataset

Research 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 for cardiology domain (Latest bio-humoral exams)

5. Surgical history

6. Current medications.

4.4 *SUB-Scenario S4 -Semantic data management*

The purpose of this scenario is to describe the preparatory operations that are necessary to enable the conversion of local health records into their interoperable form and thus ensure their syntactic and semantic interoperability.

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.

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.

4.4.1 Data integration background definition

The InteropEHRate Framework aims to provide a solution working in different countries, with different health systems, using different languages and coding systems. A large data knowledge is needed to allow the interoperability of the components inside the InteropEHRate Framework, and obtain the desired data integration. The knowledge is defined as the description, in several languages, of each code and health-related concept present in each local and international standard used in the data exchanged, as well as the definitions of the data schemas used to represent health records in each country considered, and FHIR standard format, used as data exchange standard format within InteropEHRate Framework.

Having the knowledge related to the data to be exchanged, is possible to create mappings and data conversions from different representations of data (e.g. different data schema), as well as translate the data description in other languages.

InteropEHRate offers services and tools to upload, manage and exploit the knowledge described above. The most important component called *Health Data Integration (HDI) Platform*, is an innovative knowledge-based data integration platform able to organize in an efficient way the knowledge uploaded and allow the other components of the framework to exploit it.

The part of the InteropEHRate framework called *InteropEHRate Health Tools (IHT)* are interactive tools that serve the purpose of configuring and adapting the *HDI Platform*, to the specific needs of the local institution (e.g., hospital) managing the knowledge described above. Configuration and adaptation involve supporting:

- Local language;
- Local health-related terminology;
- Locally used coding systems and their mapping to international ones;
- Local data structures and their mapping to FHIR.

4.4.2 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.

4.4.2.1 Data preconditions and assumptions

A. The healthcare organization represented in the following example uses national natural language. The health data of the healthcare organization are described using official national language, while the language used to describe the data in international standards is often English.

B. The description of the knowledge to be imported, or knowledge data, is uploaded using structured files. These files, most of the time, are created by the DS, or in case a huge quantity of data have to be structured, the data scientist can be assisted by a *software developer* in charge of programmatically automating the files creation.

C. The international Knowledge that defines and describes InteropEHRate interoperability standards (InteropEHRate FHIR profiles) is *a priori* built into the HDI Platform, all the while remaining adaptable and extensible.

D. The local knowledge that defines health-related terminology and health codes for local data is not yet present in the HDI Platform. If the knowledge already exists in the HDI Platform, the DS doesn't need to import new knowledge to be able to correctly convert local data to an international version. If instead, the local knowledge doesn't exist in the HDI Platform, the DS has to import it before starting to integrate the local data.

E. The local institution (e.g. a Hospital) maintains the health data of its patients. These data, represented by a set of health records, are stored locally in the Hospital. The Hospital aims to integrate its health data with the data already exchanged within InteropEHRate framework.

F. The Hospital's local data are described using several health-related coding systems (used at local, regional, national or international level) and expressed through a specific data schema used by the Hospital to internally manage health data. The data schema of the institution is different from the international data schema adopted by InteropEHRate (InteropEHRate FHIR profiles).

4.4.2.2 IT preconditions and assumptions

G. The HDI Platform as well as the Knowledge Management Tool (KMT) and Data Mapping Tool (DMT) are installed and correctly settled up in the Hospital system.

4.4.3 Scenario Description

1) An Italian Hospital wants to integrate the health records of its patients, stored locally 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.

3) The DS starts to manage the content of the health records. He analyses the local data, in order to identify the medical terminology and codes used in the Hospital's EHRs. The concepts related to the terminology and health codes represent the knowledge used locally to describe a health record.

a) An example of the local health data, describing an observation on blood analysis report, is reported below:

```
<entry typeCode="DRIV">
    <organizer classCode="CLUSTER" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.22.4.9"/> <!-- Results organizer template -->
        <id root="31616000-1bea-440e-bad0-ae8996a1139e"/>
        <code code="18723-7" displayName="Analisi del sangue" codeSystemName="LOINC" codeSystem="2.16.840.1.113883.6.1"/>
        <statusCode code="completato"/>
        <effectiveTime value="20171117"/>
        <component>
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.22.4.10"/> <!-- Result observation template -->
                <id root="2f8c412f-a58b-40c3-b56d-0b6305b5c115"/>
                <code code="67151-1" codeSystem="2.16.840.1.113883.6.1" displayName="troponina T. cardiaca "/>
                <statusCode code="completato"/>
                <effectiveTime value="201711170845"/> <!-- YYYY[MM[DD[HH[MM[SS[.SSSS]]]]]][+/-ZZZZ] -->
                <value xsi:type="PQ" value="15.36" unit="ng/L"/>
            </observation>
        </component>
    </organizer>
</entry>
```

Figure 11. *CDA Local data example*

The data example reported above, is structured using the data schema (CDA) adopted locally by the Hospital, and the data are described in the language of the Hospital (Italian). Within the structure there are two codified concepts, related to the LOINC medical coding system, describing respectively "*blood analysis*" and "*Troponina T*". These concepts represent the local knowledge (related to the portion of data) to be imported.

4) The DS, once collected all the local knowledge used in the data to be integrated, verify if this knowledge already exists in the HDI Platform, using the KMT.
    a) From the portion of data reported in step 3.a, the DS understands that it is necessary to import in HDI Platform all the definitions of the LOINC medical coding system, in order to be able to recognize the codes present in the health records.
5) The DS has to import the local knowledge in the HDI Platform. For this operation, the DS creates and import a structured file, called import file, defining relevant concepts and their relatedness (underlying the meanings of terms, data attributes, coded values, etc., that are used by the local institution or on regional or national levels) for the terminology and health codes identified in steps 3 and 4.
6) Having the local knowledge imported in the HDI Platform as well as the international knowledge (as indicated by the assumption B), the DS has to verify, using the KMT, if the local data schema (used to define the health records of the Hospital) can be mapped correctly to the international data schema (InteropEHRate FHIR profiles).
7) Having the local knowledge imported and the needed definitions of types and attributes for the international data schema, the DS uses the DMT to create the mapping between the local health records and the S-EHR version of them (expressed in FHIR).
    a) This operation sees the local data as input of DMT, while the outputs are:
        i) a model (which can be reused in future) which defines the mapping between the local data schema and the international one.

ii) The health records data type and coding, to be integrated in the HDI Platform, annotated following the mapping model defined by the DS.

8) The DS, using a functionality offered by DMT, integrates the health records data type and coding, generated in the previous step, in the HDI Platform.

4.4.4 Post-conditions and notes

- The knowledge imported in the HDI platform can be used to convert and translate the data exchanged, both new health data generated by an HCP at the moment of data exchange and pre-existing health data coming from legacy systems.

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.

The first version of this document provided an analysis of just one scenario. This second version updates the analysis of the first scenario and includes a first analysis of all the other scenarios, including the new scenario "S4 - Semantic Data Management".

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.

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 application that the requirement applies to. The prefix S-EHR-A means "S-EHR App", HCP-A means "HCP App", KMT means "Knowledge Management Tool", DMT means "Data Mapping Tool", S-EHR-C means "S-EHR Cloud", IRS means "InteropEHRate Research Services", S-H-A means that the requirement applies to "both S-EHR App and HCP App", S-A-C means that the requirement involves the "combination S-EHR App and HCP App", S-IRS means that the requirements involves the "combination of S-EHR App and InteropEHRate Research Services", S-H-C means that the requirements involves the "combination of HCP App and S-EHR Cloud".

#	Scenario S1 step	Implied requirements
A	[Sub-scenario] The Patient owns a S-EHR app,	S-EHR-A-1, S-EHR-A-2
	installed on his smartphone, and pertinent consent is granted	S-EHR-A-3, S-EHR-A-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).	S-EHR-A-6, S-EHR-A-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.	S-EHR-A-5
D	[Sub-Scenario] The data about the health history and current pharmacological therapy of the patient has already been imported from the EHR system of his referral centre to the S-EHR of the patient.	S-EHR-A-13, S-EHR-A-14, S-H-A-73, S-EHR-A-74, S-EHR-A-15, S-EHR-A-17

E	[Sub-Scenario] The patient selected a subset of data to be shared with HCP, i.e. he/she hides some personal data for HCP viewing.	HCP-A-9
F	[Sub-Scenario] HCP uses the software "HCP App", able to access a S-EHR app by using a Device to Device connection.	
G	[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.	HCP-A-7, HCP-A-79, HCP-A-80
H	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.	HCP-A-10, HCP-A-11, HCP-A-12
I	[Sub-Scenario] 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.	HCP-A-8
J	Every action performed on the S-EHR system by an author/actor is registered (logged) by both the S-EHR and the HCP App and associated permanently with the unique identification of the involved patient and HCP author/actor.	S-EHR-A-19, HCP-A-21, S-EHR-A-76
	and associated permanently with the unique identification of the involved patient and HCP author/actor.	S-EHR-A-20, HCP-A-22, S-EHR-A-77
K	The patient has already configured on his/her S-EHR a set of default permissions for any HCP that he/she authorizes to access his/her data.	HCP-A-9
L	Patient data is contained in the EHR system of the referral centre (Hospital, Healthcare provider, etc.)	
M	The latest up-to-date EHR data is present in the S-EHR device of the patient.	
N	[Scenario S4] The health care organization has described the semantic codes used locally by the organization (national and local codes) using the Knowledge Management Tool.	KMT-23
O	[Scenario S4] The domain expert of the healthcare organization has	DMT-24

	defined the mapping between the local codes and the international codes.	
P	All the information is related to its producer/author.	S-H-A-69
Q	The HCP cannot repudiate the produced information.	S-EHR-A-19, S-EHR-A-20, S-H-A-69
R	The Patient cannot repudiate the produced information	S-EHR-A-19, HCP-A-22, S-H-A-69
S	The data contained in the S-EHR are safe and represents a legal consistency on which it relies for diagnosis/treatment/prognosis/prevention	S-H-A-69
T	The HCP can verify the origin and validity of the information shared by the citizen.	S-H-A-69
U	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 makes an appointment for a visit and on the agreed day, he goes to the hospital. The patient is initially admitted. 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.	S-EHR-A-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.	S-EHR-A-28, S-H-A-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 his/her identifying data with the HCP1	S-EHR-A-29, S-H-A-73
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	HCP-A-30, S-H-A-73, HCP-A-75

	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.	HCP-A-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.	HCP-A-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	HCP-A-32, HCP-A-67
8	The admission data is stored by the HCP app for future traceability.	HCP-A-33, HCP-A-34
9	Using his/her phone, the patient sees on the S-EHR the description of the healthcare organization that just identified him/her.	S-EHR-A-28, S-H-A-73
10	He/She 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.	S-EHR-A-35, S-H-A-73
11	By means of the S-EHR the patient gives his/her consent, implicitly giving the default view/transmission permissions he/she may have previously configured on the S-EHR (see the assumptions under 5.1).	S-EHR-A-36
	Every other HCP scoped by the Healthcare Organization and involved in patient care/treatment are authorized to access S-EHR	S-EHR-A-35
12	The consent is transmitted to the HCP App and recorded by it for future traceability.	HCP-A-38, HCP-A-39, S-H-A-73
13	A preconfigured (by the HCP on the HCP App) dataset of patient's data	HCP-A-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	HCP-A-41, S-EHR-A-36, HCP-A-67

	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).	HCP-A-42, HCP-A-44
15	Downloaded patient's data are translated into HCPs natural language. HCPs natural language is the one officially related to the Healthcare provider. Are downloaded from S-EHR:	HCP-A-49, HCP-A-50, KMT-25, KMT-26, HCP-A-51, HCP-A-52
15.a	personal evaluation of symptoms, entered by the patient	S-EHR-A-95, HCP-A-96
15.b	body weight measurements of the last week, entered by the patient	
16	HCP1 measures vital signs, body weight, BP, pulse, respiratory rate, SPO2, Temp, AVPU and alertness.	HCP-A-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. The HCP2 accompanies the patient in a waiting room where he/she can wait to have a specialistic evaluation.	HCP-A-54, HCP-A-67, S-H-A-73
18	Another HCP, HCP3, is assigned to evaluate the patient in a different room. Data produced by the HCP3 during the evaluation are collected in the HCP App of HCP3. During the evaluation of HCP3, S-EHR are able to exchange data with HCP App	S-EHR-A-27, HCP-A-54, S-H-A-73
19	Once the patient is in the visiting room, the consulting HCP3 asks the patient the reasons for his need for the visit.	HCP-A-58
20	HCP3 starts to visit the patient: download the patient's history from the S-EHR app	HCP-A-61, HCP-A-66, HCP-A-67, S-H-A-73, HCP-A-65
	(translated into the HCPs language)	HCP-A-51, HCP-A-52
	and import it into HCP app.	HCP-A-42, HCP-A-66, S-H-A-73, S-EHR-A-94

21	HCP3 updates on the HCP app the patient's clinical history reporting new symptoms.	HCP-A-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.	HCP-A-66, HCP-A-47, HCP-A-71, S-H-A-73, HCP-A-63
23	HCP3 asks for a chest X-ray at local imaging facilities. HCP3 downloads from the S-EHR app images of a previous exam, performed in Belgium the year before, HCP3 compares them with the current exam and recognizes signs of increased interstitial congestion.	HCP-A-64, HCP-A-45, S-H-A-73
24	The HCP3 retrieves information from S-EHR on prescribed drugs. 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).	HCP-A-62, HCP-A-43, HCP-A-60, S-H-A-73
25	The HCP3 finalizes the visit by compiling an evaluation report on the HCP app.	HCP-A-60
26	The HCP3 provides a drug prescription for furosemide 25 mg on the HCP app.	HCP-A-59
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 HCP Terminal:	HCP-A-152, HCP-A-67, S-H-A-73
28	image and report of chest X-rays evaluation report drug prescription for furosemide 25 mg	HCP-A-56, HCP-A-54, HCP-A-57, HCP-A-55
28	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.	HCP-A-67, HCP-A-68

Table 9 - Requirements associated to "Scenario S1 - Device to Device HR exchange"

#	Scenario S2 step	Implied requirements
A	[Sub-Scenario] The Patient owns a S-EHR, installed on his/her smartphone, and pertinent consent is granted.	S-EHR-A-1, HCP-A-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 and to share them with people and at moments explicitly authorised by the patient.	S-EHR-A-5, S-A-C-98, S-EHR-A-106
C	[Sub-Scenario] 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.	S-EHR-A-14, S-EHR-A-16, S-H-A-70
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.	S-A-C-97, S-A-C-133, S-EHR-A-135
E	The content of the Patient's S-EHR is currently aligned with the content of the S-EHR Cloud.	S-A-C-97, S-A-C-133
F	The kind of data included in the emergency data set is the same defined by the International Patient Summary.	
G	The patient has no access to the device containing his\her own S-EHR.	
H	or the patient has his own phone and has an internet connection (abroad)	
I	or the patient has his own phone and hasn't internet connection (abroad)	
J	The patient has an emergency identity token.	S-EHR-A-134
J.a	S-EHR generates a unique emergency code (also called "emergency identity token") and a corresponding QR-code that has been associated to that patient by the S-EHR Cloud.	S-EHR-A-134
J.b	the token is used to access to the data contained in S-EHR Cloud	S-EHR-A-134
J.c	the token cannot be used to access to data contained in patient's smartphone S-EHR	S-EHR-A-134

	app	
K	[Sub-Scenario] The patient gave his/her consent to the emergency identification by means of an emergency identity token.	S-A-C-98
L	[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.	S-H-C-138
M	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 cloud.	HCP-A-141
N	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.	S-H-C-139
O	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, like the IPS, for emergency reasons.	S-A-C-149, S-EHR-C-101, S-EHR-C-105, S-EHR-C-102, S-EHR-C-140, S-EHR-C-137
P	The hospital has full access to internet connection and to S-EHR cloud infrastructure	
Q	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.	HCP-A-142
R	All the information is related to its producer/author	S-H-A-69
S	The HCP cannot repudiate the produced information.	S-H-A-69
T	The Patient cannot repudiate the produced information.	S-H-A-69
U	The data contained in the S-EHR are safe and represents a legal consistency on which it relies for diagnosis/treatment/prognosis/prevention	S-H-A-69, S-H-A-70
V	The HCP can verify the origin and validity of the information shared by the citizen.	S-H-A-69
W	There is a mutual trust between Patient and HCP	S-H-C-138

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 read with a QR-code scanner) the code contained in the emergency identity token on the HCP App.	S-H-C-143
4	HCP1 using the same HCP App, request access to the associated health data for emergency reasons.	S-H-C-99, S-H-C-104, HCP-A-45, S-EHR-C-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.	S-H-C-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.	S-H-C-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).	S-H-C-99, S-H-C-144
9	The Patient's health data are imported in a few seconds (5 to 10) from the S-EHR cloud to the HCP App.	S-H-C-145
9.a	Data are visualized (and imported) by the HCP App used by HCPs currently authorized to treat patient's data (i.e. involved in patient's treatment process), translated into HCPs natural language.	HCP-A-51, HCP-A-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.	HCP-A-51

12	From S-EHR cloud patient history is also reported diabetes as chronic illness, under treatment with insulin.	HCP-A-51
13	Despite the absence of typical cardiac symptoms (patient has diabetes) the HCP1 performs a 12-lead EKG, showing 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 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 Discharge Report containing the cause of admission, discharge diagnostic assessment,	S-H-C-100, HCP-A-136, HCP-A-46, HCP-A-151, HCP-A-152
19	prescriptions, visits and recommendations, therapy.	S-EHR-C-103, S-EHR-A-148, S-EHR-A-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.	HCP-A-146
PCB	When the S-EHR App of the patient is connected again with the internet, new data is downloaded from S-EHR Cloud to the patient's phone.	S-A-C-133

Table 10 - Requirements associated to "Scenario S2 - Emergency access"

#	Scenario S3 step	Implied requirements
A	Patients gave their consent (informed consent) to store data into their S-EHR app.	S-EHR-A-5
B	Patients have their most recent and updated health data stored in the S-EHR app.	S-H-A-70
C	Patients data stored on the S-EHR app have a strict correlation to the patient's owner and data authorship.	S-H-A-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 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.	IRS-93
J	Health data sets shared for research purposes can be accessed/queried only by the authorized researchers.	IRS-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.	S-EHR-A--
L	Patients can withdraw from their participation in the InteropEHRate Open Research Network at any moment (and someone does it).	S-IRS-109
1	Patients (including 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	S-EHR-A-107

	notified, in case of positive match, of the possibility to apply as participant to the study.	
2	A Research Organization, Coordinating Research Centre, formalises the research protocol called “Female hypertension study” using the InteropEHRate format:	S-IRS-110, S-IRS-111
2.a	the protocol involves female patients with age > 65 years, with hypertension and treated with ACE inhibitors, defined a research protocol specifying a required clinical dataset;	S-IRS-112, S-IRS-114, S-IRS-113
2.b	the protocol requires a set of pseudonymized health data that includes:	S-IRS-115
2.b.i	the prospective collection of treatment plans, for 2 years after patient enrolment,	S-IRS-116, S-IRS-117
2.b.ii	the retrospective evaluation of data up to 5 years before enrolment;	S-IRS-119, S-IRS-118
2.c	the protocol specifies a set of participating Reference Research Centres belonging to specific regions.	S-IRS-120
3	Using the InteropEHRate Research Service, the Coordinating Research Centre publishes the research protocol on the InteropEHRate Open Research Network.	IRS-81
4	The research protocol is transmitted to the S-EHR apps of the patients.	S-IRS-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.	S-IRS-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:	S-IRS-121
6.a	Eve may participate and is invited to the research;	S-IRS-121
6.b	Adam is excluded from the research’s possible candidates and receives no notification.	S-IRS-121
7	Eve accesses on the S-EHR app a list showing the studies she may participate in and selects the invitation called “Female hypertension study”.	

8	The S-EHR app shows to Eve the details of the research protocol , including details about:	S-EHR-A-89
8.a	the Coordinating Research Centre	S-EHR-A-89, S-IRS-122, S-EHR-A-90
8.b	the Local Research Centre (belonging to the Reference Region she previously selected),	S-IRS-122
8.c	reference contacts for further details,	S-EHR-A-85, S-IRS-120
8.d	the requested health data (type of data and covering period),	S-EHR-A-85
8.e	the purpose of the research,	S-EHR-A-85, S-IRS-124
8.f	the data retention period,	S-EHR-A-85, S-IRS-123
8.g	the level of anonymization of the requested data.	S-IRS-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.	S-EHR-A-89, S-IRS-125, S-IRS-117, S-IRS-118
10	Eve accepts to participate in the research.	S-IRS-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;	S-EHR-A-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;	S-IRS-127
10.c	Eve selects a Reference Research Centre;	S-IRS-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	S-IRS-125

	protocol.	
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.	S-IRS-128, S-EHR-A-86, S-IRS-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 “Female hypertension study”.	S-EHR-A-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.	IRS-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	S-IRS-91
12.a	In the case of this protocol, the data of the previous 5 year are sent.	S-IRS-91, S-IRS-118
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.	S-IRS-91
12.b.	In the case of this protocol, pseudonymized data are sent for the next two years.	S-IRS-91, S-IRS-117
12.c	The Reference Research Centre selected by Eve forwards any new health data set to the Coordinating Research Centre.	IRS--
13	Eve may choose to be notified each time that new health data are sent to the Principal Investigator.	S-EHR-A-132
14	Eve can withdraw her participation at any time.	S-EHR-A-88
14.a	In case of withdrawing, the event is notified to the Reference Research Centre of Eve.	IRS-84
15	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	IRS-82

15.a	In this case, health data are sent for the next 2 years.	S-IRS-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 11 - Requirements associated to "Scenario S3 - Health research study"

#	Scenario S4 step	Implied requirements
A	An Italian local healthcare provider (The Hospital) wants to integrate the health records of its patients, stored locally in the Hospital's DB, in the HDI Platform offered by InteropEHRate Framework, in order to convert these data in an international version (defined by the InteropEHRate FHIR profiles), which is supported and interpretable by the S-EHR.	
B	The Hospital assigns to a DS the task to complete the data integration procedure.	
C	The DS starts to manage the content of the health records. He analyses the local data, in order to identify the health-related terminology and health codes used in the health records descriptions. The concepts related to the terminology and health codes represent the knowledge used locally to describe a health record.	KMT-153
D	The DS, once collected all the local knowledge used in the data to be integrated, verify if this knowledge already exists in the HDI Platform, using the KMT.	KMT-153
E	The DS has to import the local knowledge in the HDI Platform. For this operation, the DS creates and import a structured file, called import file, defining relevant concepts and their relatedness (underlying the meanings of terms, data attributes, coded values, etc., that are used by the local institution or on regional or national levels) for the terminology and health codes identified in steps 3 and 4.	KMT-153
F	Having the local knowledge imported in the HDI Platform as well as the international knowledge (as indicated by the assumption B), the DS has to verify, using the KMT, if the local data schema (used to define the health records of the Hospital) can be mapped correctly to the international data schema (InteropEHRate FHIR profiles).	KMT-153, KMT-154
G	Having the local knowledge imported and the needed definitions of types and attributes for the international data schema, the DS uses the DMT to create the mapping between the local health records and the international version of them (international version of health records expressed in FHIR).	DMT-155

J	The DS, using a functionality offered by DMT, integrates the health records data, mentioned in the previous step, in the HDI Platform.	DMT-155

Table 12 - Requirements associated to "Scenario S4 - Semantic data management

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 (Dec 2020)
    - v3 = InteropEHRate Framework v3 (Dec 2021)
    - s2 = InteropEHRate Open Specification v2 (Dec 2020)
    - s3 = InteropEHRate Open Specification v3 (Dec 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[4].

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. Other modifications and the addition of further requirements will happen during the next months to take into account feedback from focus groups and experts and in the next years when other defined scenarios will be refined and analysed.

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

5.1 *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 S1, S2 and S3. The table lists the requirements that involve only the S-EHR App, while the following sections list the requirements that involve respectively also the HCP App, the S-EHR Cloud, and the InteropEHRate Research Services.

ID	Title	Main actor	Requirement description	F/NF	Target
S-EHR-A-4	S-EHR runs on iOS smartphone	-	The S-EHR is a mobile app that can run on IoS version X	NF	s2
S-EHR-A-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
S-EHR-A-5	Consent to S-EHR data management	Citizen	At installation the S-EHR obtains from the Citizen his/her consent (informed consent) to store and manage his/her personal health data on the smart device.	F	v1
S-EHR-A-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
S-EHR-A-35	D2D consent by the Citizen for temporary S-EHR access to Healthcare organization	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 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.	F	v1
S-EHR-A-27	D2D device pairing	Citizen	The Citizen connect/pair his/her smart device to the HCP computer/device	F	v1
S-EHR-A-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	F	OOS

			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.		
S-EHR-A-15	R2D import of (portion of) Laboratory result from national health care system on S-EHR	Citizen	Citizen health data (portion of Laboratory results) can be imported from the Citizens national health care system on Citizen S-EHR.	F	v2
S-EHR-A-16	R2D import of (portion of) Medical images and reports from national health care system on S-EHR	Citizen	Citizen health data (portion of reports and Medical images) can be imported from Citizen's national health care system on Citizen S-EHR.	F	v2
S-EHR-A-17	R2D import of (portion of) Hospital discharge reports from national health care system on S-EHR	Citizen	Citizen health data (portion of Hospital discharge reports) can be imported from the Citizens national EHR on Citizen S-EHR.	F	v3
S-EHR-A-18	R2D import of (portion of) health data from all national health care systems on S-EHR	Citizen	(A portion of) Citizen health data can be imported from all remote national health care systems on Citizen S-EHR.	F	OOS
S-EHR-A-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
S-EHR-A-6	Enabling of Citizen identification from S-EHR (without CA)	Citizen	The S-EHR store and send 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	F	v1

			Citizen).		
S-EHR-A-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
S-EHR-A-13	R2D import of (portion of) Patient Summary from national health care system on S-EHR (without security)	Citizen	Citizen health data (portion of Patient Summary) can be imported from the Citizens national health care system on Citizen S-EHR.	F	v1
S-EHR-A-14	R2D import of (portion of) Prescription import from national health care system on S-EHR	Citizen	Citizen health data (portion of Prescriptions) can be imported from the Citizen national health care system on Citizen S-EHR.	F	v2
S-EHR-A-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
S-EHR-A-3	S-EHR runs on Android smartphone	Citizen	The S-EHR is a mobile app that can run on Android version X	NF	v1
S-EHR-A-20	Consultation of auditing health data modification for Citizen on S-EHR	Citizen	Any audited modification on health data (creation, reading, updating, deleting) is consultable from the Citizen that is the owner the data	F	v1
S-EHR-A-74	R2D import of (portion of) Patient Summary from national	Citizen	Citizen health data (portion of Patient Summary) can be imported from the Citizen national health care system on Citizen S-	F	v2

	health care system on S-EHR (with security)		EHR.		
S-EHR-A-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
S-EHR-A-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
S-EHR-A-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	v2
S-EHR-A-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
S-EHR-A-86	Digitally signature by Reference Research Centre of Citizen's consent	Citizen	The Citizen receives on his/her S-EHR a digital copy of the consent (to participate in a research he/she has been invited to) signed at the Reference Research Centre. The digital copy is digitally signed by the Research Centre using a legal binding mechanism.	F	v3
S-EHR-A-87	Citizen's digital signature of consent to share health data for a	Citizen	The Citizen can give his/her consent to participate to a research he/she has been invited to and digitally sign it (in a legally binding way) directly on his/her S-EHR.	F	v3

	given study				
S-EHR-A-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 a clinical 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
S-EHR-A-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 than the citizen is invited to share his/her health data to the research study.	F	v2
S-EHR-A-90	Reminder of invitation to participate to a research study	Citizen	If there is some invitation to which the citizen has still to answer, a notification is displayed periodically to remember him to decide.	F	v3
S-EHR-A-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	v2
S-EHR-A-95	Update from the patient of personal health information		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	v2
S-EHR-A-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

S-EHR-A-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 the 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
S-EHR-A-130	Pseudoidentity restricted to single research protocol.	-	When a citizen gives a digital consent to participate to a research protocol, a specific pseudo-id for that patient will be generated, to be used only for the pseudonymisation of data shared within that specific research protocol.	NF	v2
S-EHR-A-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
S-EHR-A-134	Citizen's access to emergency token	Citizen	Citizens may use their S-EHR to access 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. To this end, the Citizen will have to print, preferably on a medal or bracelet, and worn the emergency token provided by the S-EHR.	F	v2
S-EHR-A-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

S-EHR-A-147	Storage and download of medical images on S-EHR	Citizen	A Citizen can also enable 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
S-EHR-A-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

Table 13 - Requirements for the S-EHR App

5.2 *S-EHR App and HCP App*

ID	Title	Main actor	Requirement description	F/NF	Target
S-H-A-69	Non reputable data provenance tracking	Data user	The author and data origin of any health data is verified (i.e. non reputable), tracked, visible to any authorized user and legally valid.	NF	v2
S-H-A-70	Integrity of information	Data user	Users are guaranteed that the managed health data (stored or transferred) hasn't been modified maliciously or accidentally.	NF	v3
S-H-A-73	Compliance to IEHR profiles	Data user	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

Table 14 - Requirements that applies to both the S-EHR App and the HCP App

5.3 *S-EHR App and S-EHR Cloud*

ID	Title	Main actor	Requirement description	F/NF	Target
S-A-C-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
S-A-C-98	Sharing of health data with	Citizen	Citizens can consent HCPs of Healthcare organisations to access, only for	F	v2

	qualified HCPs for emergency by means of S-EHR Cloud		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.		
S-A-C-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 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
S-A-C-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

Table 15 - Requirements that combine the S-EHR App and the S-EHR Cloud

5.4 *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 sections describes additional requirements which implementation involves both the HCP App and respectively the S-EHR-Cloud and the InteropEHRate Research Services.

ID	Title	Main actor	Requirement description	F/NF	Target
HCP-A-2	S-EHR download from iOS store	Citizen	S-EHR is downloadable from IoS store. The Citizen downloads the S-EHR from the Android store and installs it on its iOS device.	NF	OOS
HCP-A-21	Auditing for healthcare organization	-	Any operation on health data (creation, reading, updating, deleting, sharing,	NF	v1

			authorization) is tracked from the HCP App		
HCP-A-33	Auditing of admission data by HCP App	-	The Citizen's admission data are stored by the HCP app for future traceability.	F	v1
HCP-A-38	Auditing on HCP app of consent by Citizen for temporary S-EHR access	-	The HCP app stores the temporary consent given by the Citizen to download data from the S-EHR and upload the updated/acquired data back to the S-EHR	F	v1
HCP-A-34	Consultation of admission data on HCP App	HCP	The HCP can view the admission data on HCP App	F	v1
HCP-A-22	Consultation of auditing for healthcare organization	HCP	Any operation on health data (creation, reading, updating, deleting, sharing, authorization) is consultable from the HCP on the HCP App	F	v1
HCP-A-39	Consultation on HCP app of consent by Citizen for temporary S-EHR access	HCP	The HCP app view the temporary consent given by the Citizen to download data from the S-EHR and upload the updated/acquired data back to the S-EHR	F	v1
HCP-A-41	D2D download on HCP App from S-EHR of initial data set	-	The set of Citizen's health data, previously configured by the HCP, are automatically downloaded on the HCP App at connection time of the HCP App with the S-EHR. If some of this data is hidden by the patient, they are not downloaded.	F	v1
HCP-A-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/hers 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 transactions, e.g. D2D data exchange.	F	v2
HCP-A-32	D2D Request of consent	HCP	The HCP can ask, contextually to the		v1

	from HCP for download and storage of data from S-EHR and upload new data to S-EHR		identification (i.e. without further interaction) the temporary consent for the healthcare organization of the HCPs to download and store, for the amount of time required and allowed from the national law, and to upload the updated/acquired data back to S-EHR. 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.		
HCP-A-30	D2D Visualization of Citizen identity to HCP (without certificate)	HCP	The HCP can see the identification data of the Citizen on the HCP app in order to confirm the Citizen's identity	F	v1
HCP-A-7	Enabling of HCP identification from HCP app (without CA)	HCP	The HCP app sends to the S-EHR a description of the identity of the HCP.	F	v1
HCP-A-8	Enabling of healthcare organization identification from HCP app	HCP	The healthcare organization obtains a qualified certificate (release by a CEF eID trusted certification authority) that is stored on HCP app	F	v1
HCP-A-12	HCP app Android support	-	HCP app is provided as an Android application	NF	OOS
HCP-A-10	HCP app desktop cross platform support	-	HCP app is provided as a desktop cross-platform application	NF	v1
HCP-A-11	HCP app iOS support	-	HCP app is provided as an iOS application	NF	OOS
HCP-A-42	Patient Summary consultation on HCP App	HCP	A Doctor can view the Patient Summary (a portion of it) shared with him/her by a Citizen using the HCP App.	F	v1
HCP-A-40	Setup on HCP App of initial health data to download by D2D	HCP	The HCP can configure what are the Citizen's health data that will be automatically downloaded at connection time of the HCP app with the S-EHR	F	v1
HCP-A-43	Prescription consultation on HCP App	HCP	A Doctor can view the Prescription (a portion of it) shared with him/her by a Citizen using the HCP App	F	v2

HCP-A-44	Laboratory result consultation on HCP App	HCP	A Doctor can view the Laboratory result (a portion of it) shared with him/her by a Citizen using the HCP App	F	v2
HCP-A-45	Medical images and reports consultation on HCP App	HCP	A Doctor can view the Medical images and reports shared with him/her by a Citizen using the HCP App	F	v3
HCP-A-46	Hospital discharge reports consultation on HCP App	HCP	A Doctor can view the Hospital discharge (a portion of it) reports shared with him/her by a Citizen using the HCP App	F	v3
HCP-A-47	Vital signs and other measure consultation on HCP app	HCP	A doctor can view vital signs and other measurement using the HCP App	F	v2
HCP-A-48	Selection of language on the HCP App	HCP	The HCP selects the language in which he/she prefers the S-EHR to appear.	F	v2
HCP-A-53	Authoring of initial assessment on HCP App	HCP	An HCP may author and store an initial assessment of the Citizen, as part of a visit, on the HCP app. The assessment includes the registration of vital signs, body weight, BP, pulse, respiratory rate, SPO2, Temp, AVPU and alertness	F	v3
HCP-A-54	D2D upload by HCP of evaluation report on S-EHR	HCP	An HCP may upload an evaluation report on the S-EHR of the subject Citizen using the D2D protocol	F	v3
HCP-A-55	D2D upload by HCP of Vital Signs on S-EHR	HCP	An HCP may upload Vital Signs (part of initial assessment) on the S-EHR of the subject Citizen using the D2D protocol	F	v2
HCP-A-56	D2D upload by HCP of X-ray image and report on S-EHR	HCP	An HCP may upload an X-Ray image and related report on the S-EHR using D2D protocol	F	v3
HCP-A-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
HCP-A-58	Clinical History authoring on HCP App	HCP	An HCP may author and store the clinical history on the HCP app to report the reason of a visit, new symptoms and findings identified during the visit.	F	v3

HCP-A-59	Prescription authoring on HCP App	HCP	An HCP may author and store an Prescription on the HCP app	F	v2
HCP-A-60	Evaluation Report authoring on HCP App	HCP	An HCP may author and store an evaluation report on the HCP app, including new recommended pharmacological therapy	F	v3
HCP-A-61	D2D download on HCP App from S-EHR of a portion of Patient Summary	HCP	A portion of Patient Summary is automatically downloaded at connection time of the HCP app with the S-EHR	F	v2
HCP-A-62	D2D download on HCP App from S-EHR of a portion of Prescriptions	HCP	A portion of Prescriptions is automatically downloaded at connection time of the HCP app with the S-EHR	F	v2
HCP-A-63	D2D download on HCP App from S-EHR of a portion of Laboratory results	HCP	A portion of Laboratory results are automatically downloaded at connection time of the HCP app with the S-EHR	F	v2
HCP-A-64	D2D download on HCP App from S-EHR of a portion of reports and Medical imaging	HCP	A portion of reports and Medical imaging (X-Rays) are automatically downloaded at connection time of the HCP app with the S-EHR	F	v3
HCP-A-49	Display on HCP App of a portion of Patient Summary codes	HCP	An HCP can see a portion of the semantic codes in the Patient Summary mapped to international standard codes	F	v2
HCP-A-50	Display on HCP App of a portion of Prescription codes	HCP	An HCP can see a portion of the semantic codes in the Prescriptions mapped to international standard codes	F	v2
HCP-A-51	Automated translation on HCP App of information extracted from natural language in Patient Summary	HCP	An HCP can see a translated version of information extracted from natural language in Patient Summary	F	v2
HCP-A-52	Automated translation on HCP App of information extracted from natural language in Prescription	HCP	An HCP can see a translated version of information extracted from natural language in Prescription	F	v2

HCP-A-65	D2D download on HCP App from S-EHR of a portion of Hospital discharge reports	HCP	A portion of Hospital discharge reports are automatically downloaded at connection time of the HCP app with the S-EHR	F	v3
HCP-A-66	D2D download on HCP App from S-EHR of the vital signs and other measures	HCP	The vital signs and other measures taken during previous medical visits are downloaded from the S-EHR at the request of the HCP app	F	v3
HCP-A-67	D2D authorization to download and upload S-EHR data from HCP App	HCP	Download and upload of health data on S-EHR from an authorized HCP App is possible only if the Citizen's consent is valid and includes the specific operation performed by the HCP. If consent is not valid, a new consent request should be triggered in the S-EHR.	NF	v3
HCP-A-68	Consent to store Citizen's data	HCP	Citizen's data can be stored by authorized HCP App and only until the Citizen's consent expires.	NF	v3
HCP-A-71	Comparing of vital signs on HCP App	HCP	The HCP may see and compare in the same view on the HCP App the values of vital signs collected during different visits	F	OOS
HCP-A-75	D2D Visualization of Citizen identity to HCP (using certificate)	HCP	The HCP can see the identification data of the Citizen on the HCP app in order to confirm the Citizen's identity	F	v2
HCP-A-79	Enabling of HCP identification from HCP app (with CA)	HCP	The S-EHR asks the HCP and stores on the HCP app a certificate that identifies the HCP. The certificate is released by a CEF eID trusted certification authority.	F	v2
HCP-A-80	Enabling of healthcare organization identification from HCP app (withCA)	HCP	The healthcare organization obtains a qualified certificate (release by a CEF eID trusted certification authority) that is stored on HCP app	F	v2
HCP-A-96	Download from the HCP of health information provided from the patient	HCP	The HCP can download from the S-EHR, using the D2D protocol, health data produced directly by the citizen.	F	v2

HCP-A-136	Encryption of health data written by HCP on S-EHR Cloud.	-	Every data sent by an HCP App to the S-EHR Cloud is encrypted by the HCP App, 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	v3
HCP-A-141	Support of multiple client applications for HCP	-	Different instances or sessions of the HCP App running on different devices can be used by different HCPs or by the same HCP simultaneously.	NF	v1
HCP-A-142	Compliance to organisational regulations	-	An HCP App must comply with regulations about HCPs' access and mechanisms to check and control access to the data that are in place in the specific hospital where it is used.	NF	v3
HCP-A-146	Permanent storage of emergency health data	HCP	Data imported from S-EHR Cloud on the HCP App may be stored safely by the Hospital for future access to authorized users, if authorized by the patient or by the law.	F	v3
HCP-A-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
HCP-A-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 the Discharge Report to the Citizen's language.	F	v3

Table 16 - Requirements for the HCP App

5.5 *HCP App and S-EHR Cloud*

ID	Title	Main actor	Requirement description	F/NF	Target
S-H-C-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 healthcare 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
S-H-C-100	Storing of Discharge Report on Citizen's S-EHR Cloud by the HCP	HCP	At patient discharge, the Discharge Report is generated and stored in the Citizen's S-EHR Cloud	F	v3
S-H-C-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
S-H-C-138	Legal identification and authentication of qualified HCPs	-	Only HCP belonging to a recognised Healthcare organisation 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 assure the Healthcare role of the organisation.	NF	v3
S-H-C-139	Legal identification and authentication of qualified Healthcare organisations	-	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) the health data of the Citizen.	NF	v2
S-H-C-143	HCP' access to Citizen identity by means of Citizen's token	-	In case of a health 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
S-H-C-144	Authorisation to healthcare team	-	When a qualified HCP gains access to the health data for emergency reasons, also the rest of the	F	v3

	for emergency.		healthcare team that treats that patient for that specific emergency encounter automatically gains access to the same health data.		
S-H-C-145	High transfer rate of IPS transmission in emergency	-	When an HCP accesses the Citizens' IPS, it is imported in a few seconds (5 to 10) from the S-EHR cloud to the HCP App.	NF	v2

Table 17 - Requirements that involves the combination of HCP App and S-EHR Cloud

5.6 *HCP App and InteropEHRate Research Services*

ID	Title	Main actor	Requirement description	F/NF	Target
S-IRS-91	Automatic anonymization and sharing of citizen's health data for research.	-	After a citizen accepts 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
S-IRS-109	Citizen's withdrawing from research network	Citizen	A Citizen may withdraw in any moment, using the S-EHR, from his/her participation in the InteropEHRate Research Network.	F	v2
S-IRS-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
S-IRS-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

S-IRS-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
S-IRS-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
S-IRS-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
S-IRS-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
S-IRS-116	Support of drug treatment plan within data set definition.	-	A formal publishable specification of a research protocol allows to include the treatment plan 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
S-IRS-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 to the described study.	NF	v2

S-IRS-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
S-IRS-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
S-IRS-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 described study. The Research Centres are identified by a simple unique ID and described by name, specialty, address and contact information.	NF	v3
S-IRS-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 matching is found.	F	v3
S-IRS-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 and of the specific research centre (Local Research Centre) that will receive and process the shared health data.	NF	v3

S-IRS-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
S-IRS-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
S-IRS-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
S-IRS-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 protocol, accepting the condition described within the formal published specification of that research protocol. The electronic consent will be successively signed on paper by the citizen.	F	v2
S-IRS-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
S-IRS-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	v2

S-IRS-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 refers to a research protocol already accepted by the Patient on the S-EHR.	NF	v3

Table 18 - Requirements that combine the S-EHR App and the InteropEHRate Research Services

5.7 *S-EHR Cloud*

The S-EHR Cloud allows the Citizen to backup 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
S-EHR-C-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
S-EHR-C-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	v2
S-EHR-C-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
S-EHR-C-105	Auditing of HCPs that gained access to the Medical Images	HCP	The S-EHR Cloud keeps track of the HCPs that gained access to the Citizen's Medical Images	F	v3
S-EHR-C-137	Auditing of Organisations that gained access to health data for emergency	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	NF	v3

	reasons		recognised by the S-EHR Cloud.		
S-EHR-C-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 19 - Requirements of S-EHR Cloud

5.8 *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
IRS-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
IRS-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
IRS-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
IRS-84	Notification to Researcher that a Citizen revoked his/her consent	Researcher	When a Citizen revokes the consent previously released, his/her reference research centre is notified.	F	v3
IRS-92	Disposition of health data after expiration of the	-	At the end of the research, shared health data will no longer be available on IRS. Exported data stored in RO infrastructure	NF	v3

	consent period		is under responsibility of RO.		
IRS-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	NF	v3
IRS-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	v2

Table 20 - Requirements of the InteropEHRate Research Services

5.9 *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 fulfil in order to fully realize the scenarios.

ID	Title	Main actor	Requirement description	F/NF	Target
KMT-23	Description of local codes by Domain Expert	Data scientist	The domain expert uses the Knowledge Management Tool to store and describe in a formal way the semantic codes used locally from the organization where the HCP app is used.	F	v1
KMT-25	International codes support for Patient Summary	-	International codes for Patient Summary mapping are already described and stored in the Knowledge Management Tool	F	v1
KMT-26	International codes support for Prescription	-	International codes for Prescription mapping are already described and stored in the Knowledge Management Tool	F	v2
KMT-153	EHR Local Knowledge Importation	Data scientist	The Data Scientist, using the Knowledge Management Tool as well as standard software development tools, converts, imports (from external (open) standards definitions), and manages the local knowledge (terminology and health codes) used by the Hospital in local EHR, as well as the mappings of the above to international terminology and codes.	F	v2
KMT-154	S-EHR FHIR Knowledge Importation	Data scientist	The Federation 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 S-EHR content, in order to correctly convert the local version of EHR into the International version (S-EHR).	F	v2

Table 21 - Requirements for the Knowledge Management Tool

5.10 *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 Scientist 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
DMT-24	Mapping between local codes and international codes by Domain Expert	Data scientist	The domain expert using the Data Mapping Tool defines the mappings between local codes and international codes	F	v1
DMT-155	EHR Data Integration	Data scientist	The Data Scientist, using the Data Management Tool, creates a mapping between the local EHR and the S-EHR. Then, for testing purposes, the Data Scientist integrates a test set of local EHR data into the HDI Platform, verifies the correctness of mappings, and fine-tunes them if necessary.	F	v3

Table 22 - 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 attend. 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 23 - 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[5].

6.1 *Patients Focus Groups*

Patients Focus Groups was the most challenging focus group for this project. It consisted in 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 condition 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.

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.

For each of the hospitals selected focus group members were:

- ISA: 16 Patients

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

- HYG: 17 Patients
- FTGM: 7 Cardiological patients
- CHU: 19 Patients
- SCUBA: 5 Patients.

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 Survey Questions
Gender
Age
My preferred feature of the software application you use to access or manage my health data: I can store clinical data by myself.
If you can choose, would you like to have the possibility to hide some health data for a certain Healthcare provider or admission/visit/treatment?
Would you like to have a localization of Healthcare facilities nearby?
Would you like to have a localization of Healthcare facilities that are supporting IEHR platform?
After a visit (when you are no more at the healthcare facility), would you like to receive your report in your app, as soon as the report is ready?
After an instrumental exam (when you are no more at the healthcare facility), would you like to receive the final report in your app, when the report is ready?
I think that I will need technical assistance available to solve problems associated with the use of S-EHR.
Would you be willing to send your health data to a research institution for a health-related study (after a detailed explanation of research and purposes, and using anonymized/pseudonymized data)?
Are you willing to allow research organizations authorized in the SEHR platform to contact you using the APP only for the researches who may apply your health status?
Are you willing to add specific data in your SEHR, requested by a research organization, only to participate in a research? (e.g. visits, blood tests, instrumental examinations)
Should a notification be visualized to you before sending any periodic update with new health data to researchers (when requested by the clinical research protocol)?

Table 24 - Patient Questionnaire

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 were 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

In the following section there are reported results summarized by Focus group activity, expressed in questionnaires compiled during meetings or afterwards.

In Annex 1 it is reported analytical results of questionnaires.

1) My preferred feature of the software application you use to access or manage my health data: I can store clinical data by myself.

This question was based on a rating scale from 1 (strongly disagree) to 5 (totally agree), and the majority (88,5%) agreed with an answer of 4 and 5. So this is the most important feature the software must have. From a preliminary investigation it has been seen that this choice is linked to the patient's need to register many of the documents that are delivered to him in paper form and that do not have an electronic counterpart, in fact not all hospitals manage to have an information system capable of exporting the results in digital format.

2) If you can choose, would you like to have the possibility to hide some health data for a certain Healthcare provider or admission/visit/treatment?

The answer to this question has had about an equal number of positive and negative answers. This shows that in half of the patients surveyed this is an important feature.

3) Would you like to have a localization of Healthcare facilities nearby?

This question was based on a rating scale from 1 (strongly disagree) to 5 (totally agree), and the majority (92,6%) agreed with an answer of 4 and 5. *This shows a great interest in this feature*.

4) Would you like to have a localization of Healthcare facilities that are supporting IEHR platform?

This question was based on a rating scale from 1 (strongly disagree) to 5 (totally agree), and the majority (91,1%) agreed with an answer of 4 and 5. *This shows a great interest in this feature*.

5) After a visit (when you are no more at the healthcare facility), would you like to receive your report in your app, as soon as the report is ready?

To this question more than half (52,5%) of the interviewees answered that they wanted the answers of the exams within the day, this timing not being very narrow allows to use hardware and software without exacerbating the realization costs.

6) After an instrumental exam (when you are no more at the healthcare facility), would you like to receive the final report in your app, when the report is ready?

Nearly half of patients want an answer within the day and 23,7% can wait 7 days,

7) I think that I will need technical assistance available to solve problems associated with the use of S-EHR.

61% of patients are positive about the user experience with the app, although they expect to have good support of the software with extensive documentation and FAQ (frequently Asked Question). Someone thinks they may need assistance in connection with a new hospital or in solving technical problems.

8) Would you be willing to send your health data to a research institution for a health-related study (after a detailed explanation of research and purposes, and using anonymised/pseudonymized data)?

The majority (83,1%) of patients believe that this is an important possibility to be able to face new scientific problems and to provide the possibility to develop new therapies and solve new research themes. Furthermore, a patient thinks it is important to have data not only from the clinical environment but also directly from the patient.

The remaining patients are afraid that the transmission of data may be insecure and do not trust much to disclose data that is valuable to them.

9) Are you willing to allow research organizations authorized in the SEHR platform to contact you using the APP only for those researches who may apply your health status?

This question was based on a rating scale from 1 (strongly disagree) to 5 (totally agree), and the majority (78,5%) agreed with an answer of 4 and 5. This shows a great interest in this feature.

10) Are you willing to add specific data in your SEHR, requested by a research organization, only to participate in a research? (e.g. visits, blood tests, instrumental examinations)

This question was based on a rating scale from 1 (strongly disagree) to 5 (totally agree), and the majority (78,4%) agreed with an answer of 4 and 5. This shows a great interest in this feature.

11) Should a notification be visualized to you before sending any periodic update with new health data to researchers (when requested by the clinical research protocol)?

86,4% strongly agree to the sentence.

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: 318 Health Care Professionals
- HYG: 20 Health Care Professionals
- FTGM: 12 Health Care Professionals
- CHU: 16 Health Care Professionals
- EFN: 12 Health Care Professionals
- SCUBA: 5 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.

Question
Sex
Age Range
Are you used to share electronic information with your patients?
I think that use of data within the IEHR platform would be easy.
I think that in my Healthcare Facility I will have technical assistance available to solve problems associated to IEHR
I think that my interaction with the patient using IEHR PLATFORM will require much effort for my share
I think IEHR PLATFORM will be compatible with other systems that I use
Would you like to access the S-EHR platform (NICOBAR) using the national authentication services tools?

Table 25 - 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 were 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

1) Are you used to share electronic information with your patients?

The majority (65,9%) of the HCP are used to share electronic information with patients.

2) I think that use of data within the IEHR platform would be easy.

This question was based on a rating scale from 1 (strongly disagree) to 5 (totally agree), and the 39,4% were uncertain with a score of 3, only the 13.2% strongly agreed with an answer of 5. This shows a particular distrust in platforms of this type, probably due to the current software used by the great majority of operators in the healthcare sector. Therefore, particular care must be taken in the creation of this type of software, taking care of the functional ergonomics of the application that interfaces with the user.

3) I think that in my Healthcare Facility I will have technical assistance available to solve problems associated with IEHR.

This question was based on a rating scale from 1 (strongly disagree) to 5 (totally agree), in this case only the 13,2% put a score of 5 and the 35,7% put a score of 4, this shows not a particular trust in technical assistance of HCP's healthcare facilities. The distrust in the possibilities of help from the local ICT organizations must be supported in some way by other technical bodies that must be created so as not to drop expectations regarding the success of the product.

4) I think that my interaction with the patient using IEHR PLATFORM will require much effort for my share.

This question was based on a rating scale from 1 (strongly disagree) to 5 (totally agree), 23,8% of HCP put a 5 score and 33,5 put a 4 score, this means that the majority of HCPs think that using the IEHR platform will require a lot of effort. This type of problem must be addressed by making the application as simple and easy to manage as possible.

5) I think IEHR PLATFORM will be compatible with other systems that I use

This question was based on a rating scale from 1 (strongly disagree) to 5 (totally agree), The majority (65,3%) agreed on this topic.

6) Would you like to access the S-EHR platform (NICOBAR) using the national authentication services tools?

The use of a single authentication platform attracts most of the respondents, and this is also an indication of great confidence in the national IT services of their countries. 86% of the respondents replied yes.

In Annex 1 the analytical results of questionnaires are reported.

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: 5 researchers.
- HYG: 10 researchers.
- FTGM: 11 researchers.
- EFN: 3 researchers.
- CHU: 8 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.

Questions
Age Range
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 system look for new patients to invite to one specific study?
Should a notification be sent to the researcher when receiving any periodic update with new health data?
Do you need the ability to reach a patient (for example to contact him in case of important health information to communicate)?

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
Select your Hospital?

Table 26 - 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 were 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.)

6.3.3 Response Analysis and Interpretation

1) 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)

The majority 37,5% of researchers think the maximum delay for having new collected data of the period is 1 to 10 days, and the 31,3% think that depends on study design. The 12,5% otherwise would like to have real-time data.

2) How often should the system look for new patients to invite to one specific study?

The majority 56,3% of researchers think that the best timing is once a week during enrolment period, 28,1% would like it once a day, and 15,6 would like one time at the beginning of the study.

3) Should a notification be sent to the researcher when receiving any periodic update with new health data?

87,5% replied yes to this question.

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

Most of the interviewed (59,4%) agreed to contact the patient directly, 31,3% would like to use the SHER app to contact the patient, maintaining anonymity.

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

59,4% would like to send general results of the research, 21,9% do not want to send results of the research.

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

The withdrawal from the study is considered optimal to be done in real time 75%, other researchers would like 1-10 days and 9,4% consider 1 month.

In Annex 1 is reported analytical results of questionnaires

7 CONCLUSIONS AND NEXT STEPS

This report described the second version of the InteropEHRate user requirements.

Similarly to other reports of the InteropEHRate project, this document reflects the current understanding by the project consortium and will be further updated. The final version of this report is planned for March 2021.

This second version of the report added a new scenario S4, updated the research scenario S2 and elicited the requirements coming from the analysis of scenarios from S2 to S4. Also some update to requirements reported on the first version and not yet implemented is included. All the scenarios and requirements follow from the goals of the project and from the indications of focus groups, also reported in this deliverable. In total more than 80 new requirements have been identified, more than doubling the total number of requirements. Some of the requirements apply only to the InteropEHRate Open Specification, while others apply also (or only, in the case of Knowledge management and data management tools) to the implementation of the InteropEHRate Framework. Some other requirements are considered out of the scope of both the specification and the implementation, but are also reported for completeness and for future consideration. For each requirement a tentative plan for specification and implementation is indicated.

Minor updates are expected within the final version. It will report new feedback from focus groups with possible recommendations for future evolutions, and will report the final version of the InteropEHRate scenarios, taking into account both indications of focus groups and from reference ethical committees involved in InteropEHRate pilots. Also, the requirements will be updated on the base of new feedback, and to exploit technologies to be developed in Y3, in particular blockchain for distributed authorisation.

8 REFERENCES

[1] **[D3.1]** InteropEHRate consortium. D3.1: Specification of S-EHR mobile privacy and security conformance levels, March 2020. https://www.interopehrate.eu/resources/#dels

[2] **[D5.1]** InteropEHRate consortium. Software requirements specification of an integrated EHR web app for HCP, June 2019. https://www.interopehrate.eu/resources/#dels

[3] **[D5.7]** InteropEHRate consortium. Design of the data integration platform, September 2019. https://www.interopehrate.eu/resources/#dels

[4] **[D6.1]** InteropEHRate consortium. Software requirements & architecture specification of a S-EHR, June 2019. https://www.interopehrate.eu/resources/#dels

[5] **[HHSS]** M. M. Hennink, "International Focus Group Research: A Handbook for the Health and Social Sciences", 2007, p. 277.

[6] [EPRSC] "06. Make ePrescription available - eHealth DSI Operations - CEF Digital." [Online]. Available: https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/06.+Make+ePrescription+available. [Accessed: 11-Jun-2019].

[7] **[IPS]** International Patient Summary http://international-patient-summary.net.

[8] **[CDA]** HL7 Version 3 Clinical Document Architecture (CDA®) https://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

[9] **[DICOM]** DICOM® (Digital Imaging and Communications in Medicine) https://www.dicomstandard.org/

[10] **[EIDAS]** https://www.cryptomathic.com/news-events/blog/qualified-electronic-signatures-for-eidas

[11] **[CTR]** https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

[12] **[NORA]** http://www.noraonline.nl/wiki/NORA_licentie - http://www.noraonline.nl/wiki/Bestand:E-SENS_architecture.jpg (https://www.esens.eu/), CC BY 3.0, https://commons.wikimedia.org/w/index.php?curid=58324456

[13] **[D2.1]** InteropEHRate Consortium, User Requirements for cross-border HR integration - V1, June 2019. https://www.interopehrate.eu/resources/#dels

[14] **[D4.2]** InteropEHRate Consortium, Specification of remote and D2D protocol and APIs for HR exchange - V2, March 2020. https://www.interopehrate.eu/resources/#dels

[15] **[D4.8]** InteropEHRate Consortium, Specification of protocol and APIs for research health data sharing - V1, March 2020. https://www.interopehrate.eu/resources/#dels

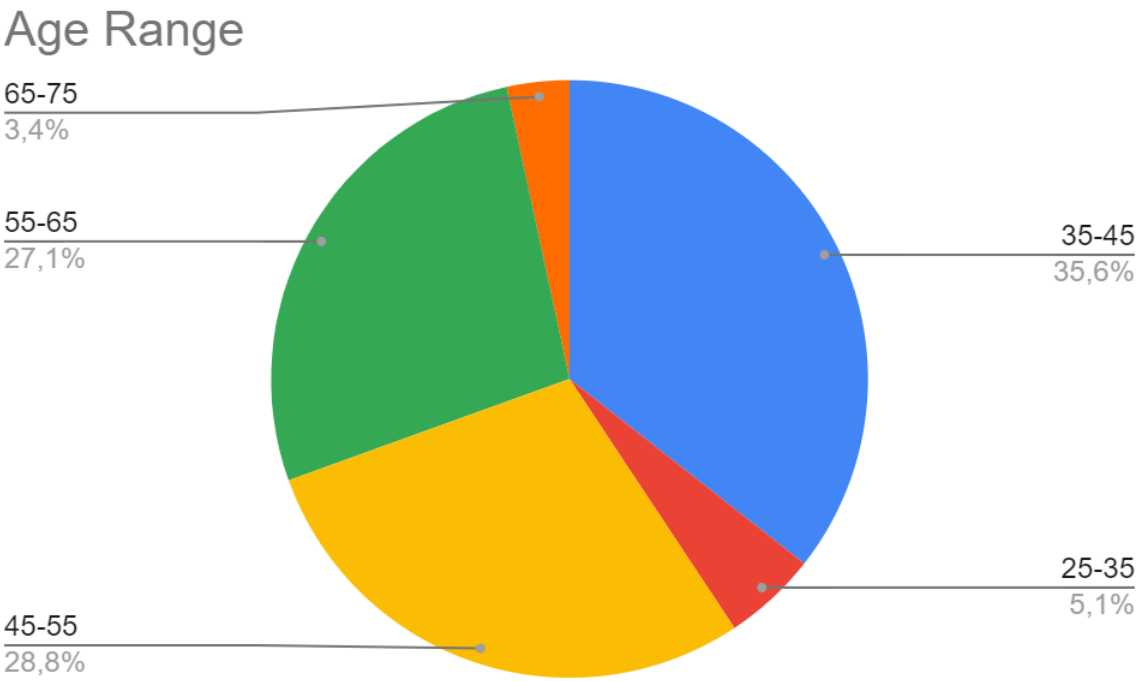
[16] **[BIR]** https://wiki.ihe.net/index.php/Basic_Image_Review

9 ANNEX 1

9.1 *Patient Focus groups Response*

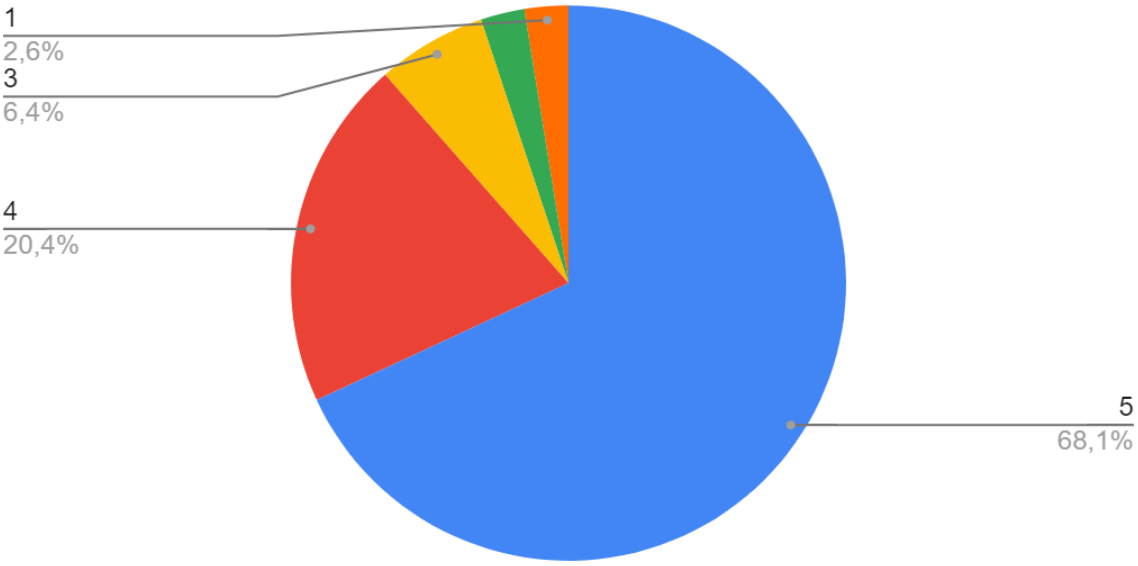
In the following graphs are presented the analytical results of questionnaires.

- Age Range

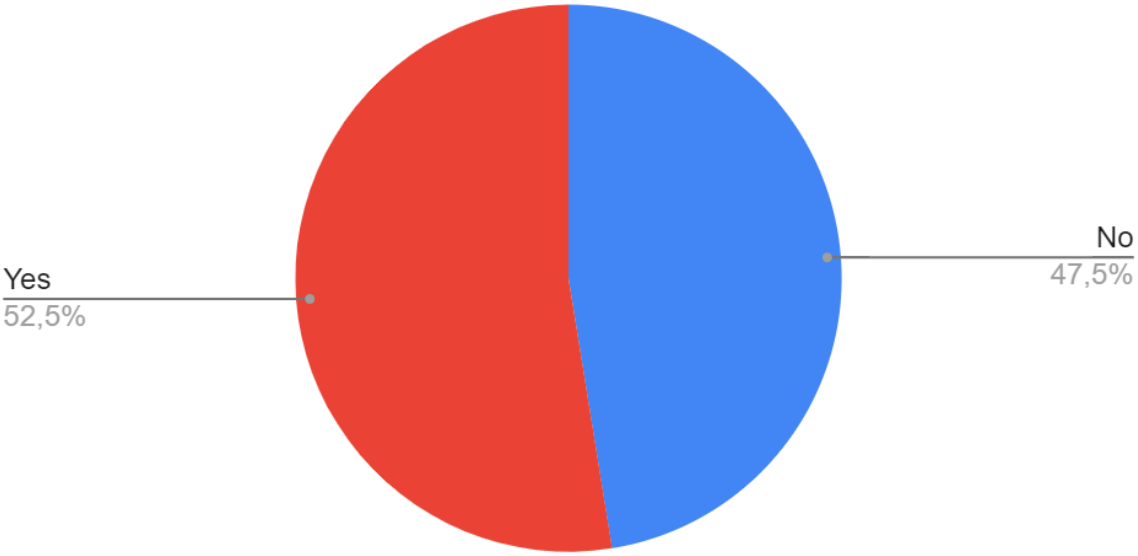


- My preferred feature of the software application you use to access or manage my health data: I can store clinical data by myself.

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

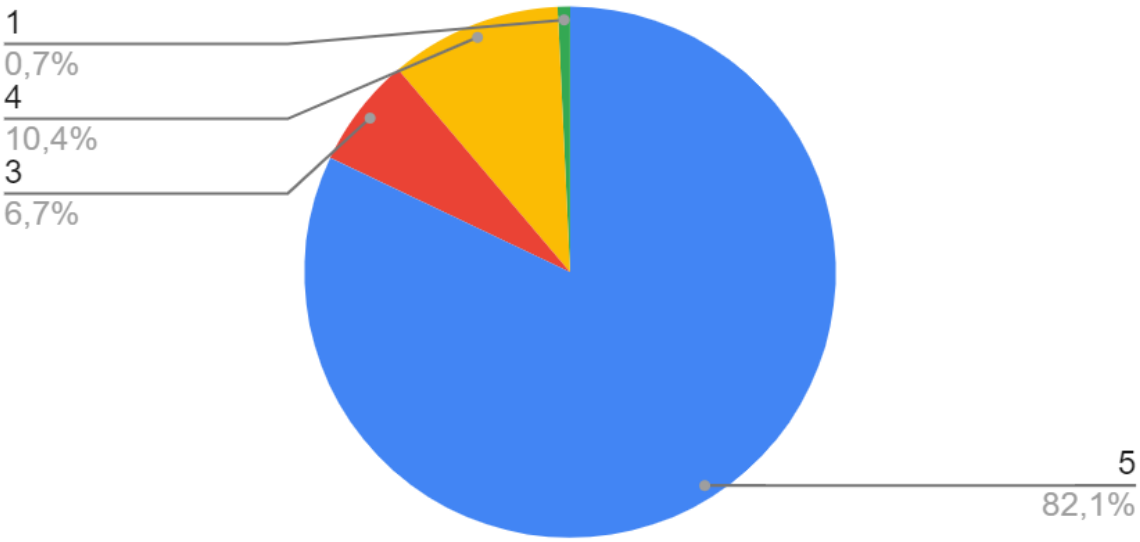


- If you can choose, would you like to have the possibility to hide some health data for a certain Healthcare provider or admission/visit/treatment?



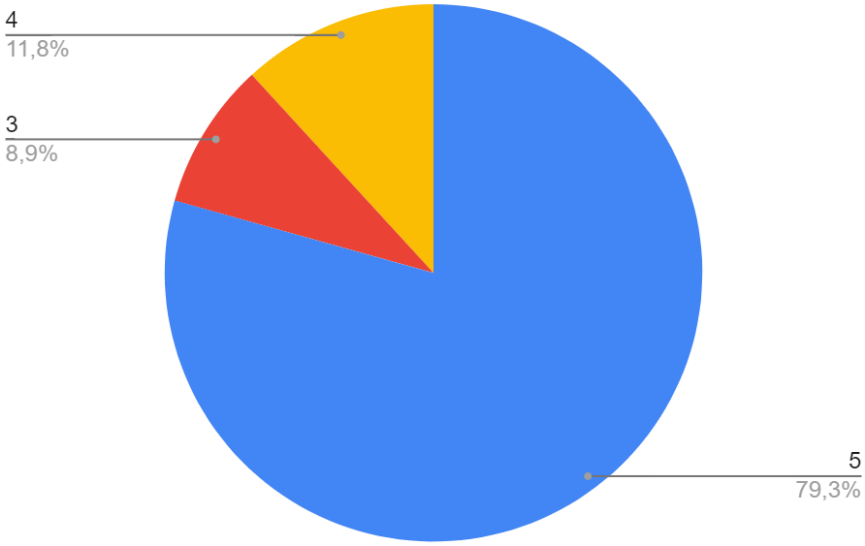
- Would you like to have a localization of Healthcare facilities nearby?

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

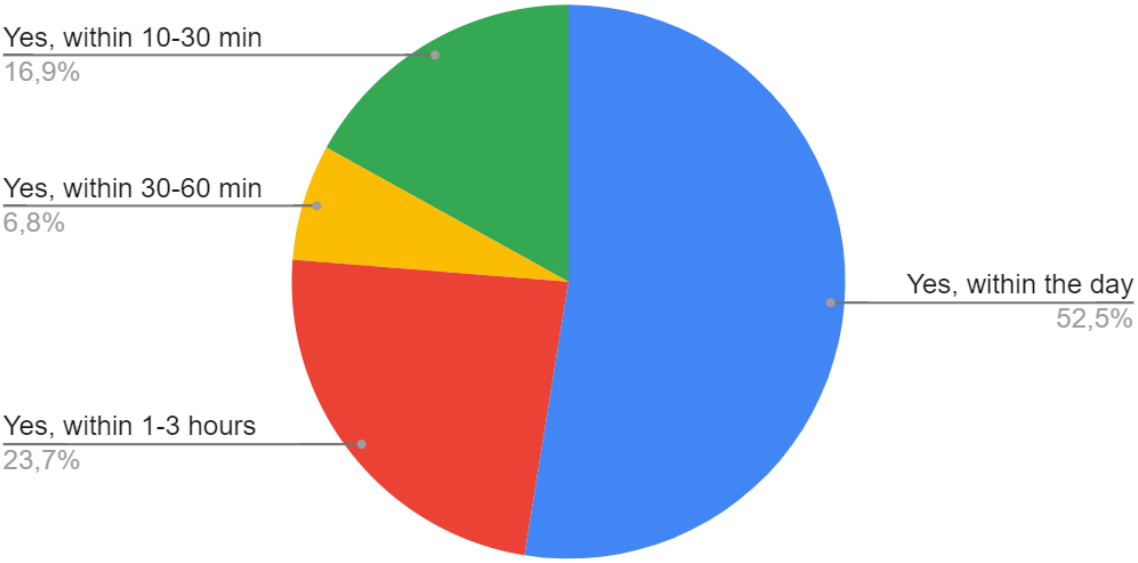


- Would you like to have a localization of Healthcare facilities that are supporting IEHR platform?

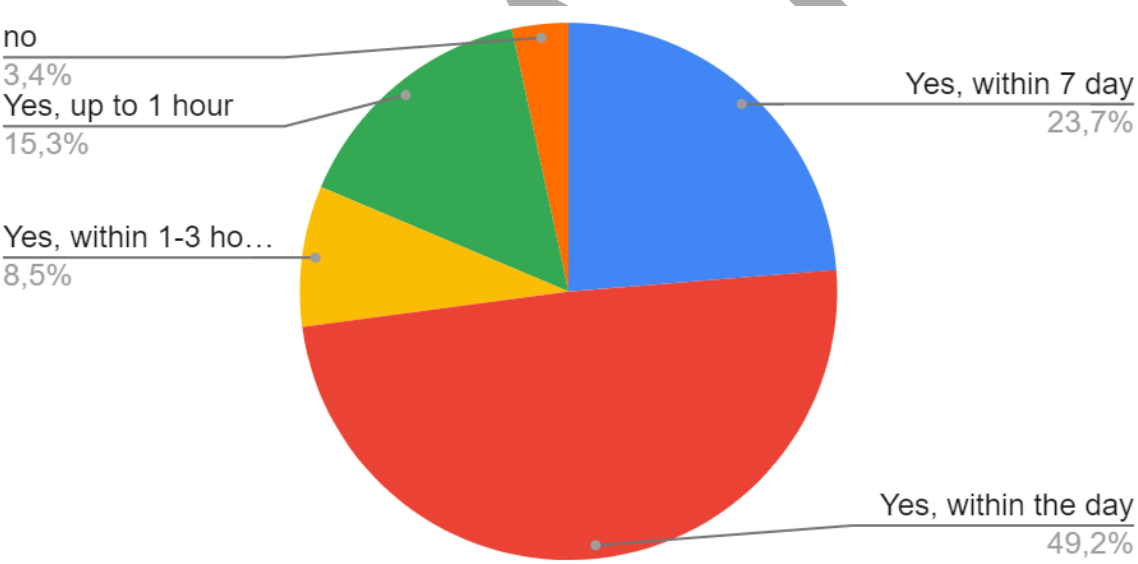
Answer= 1 to 5: 1= strongly disagree, 5= totally agree



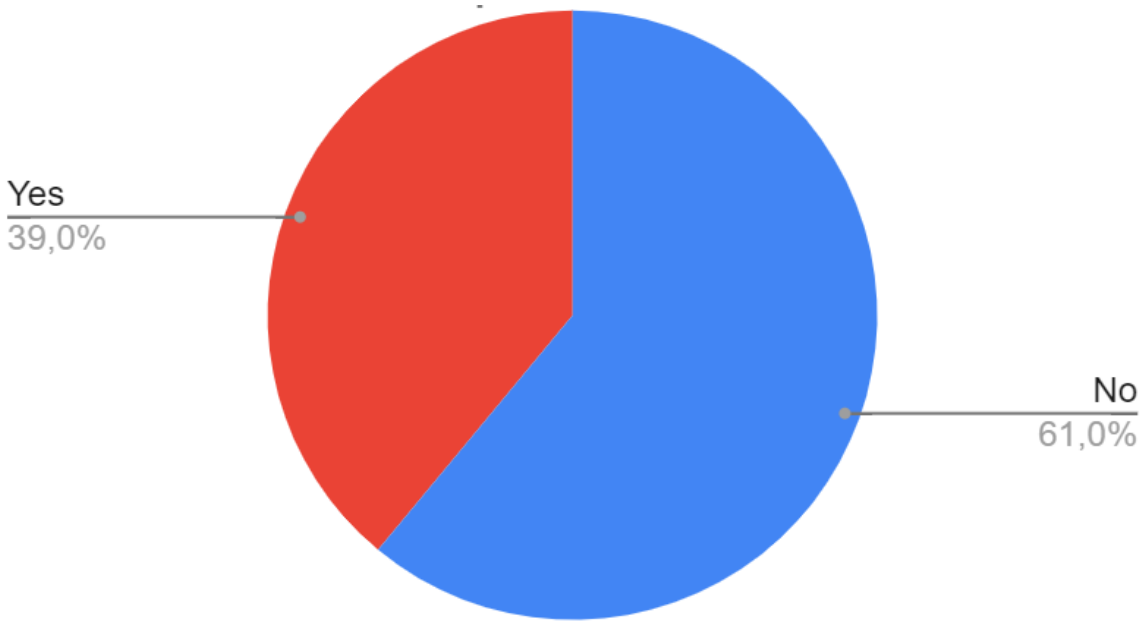
- After a visit (when you are no more at the healthcare facility), would you like to receive your report in your app, as soon as the report is ready?



- After an instrumental exam (when you are no more at the healthcare facility), would you like to receive the final report in your app, when the report is ready?



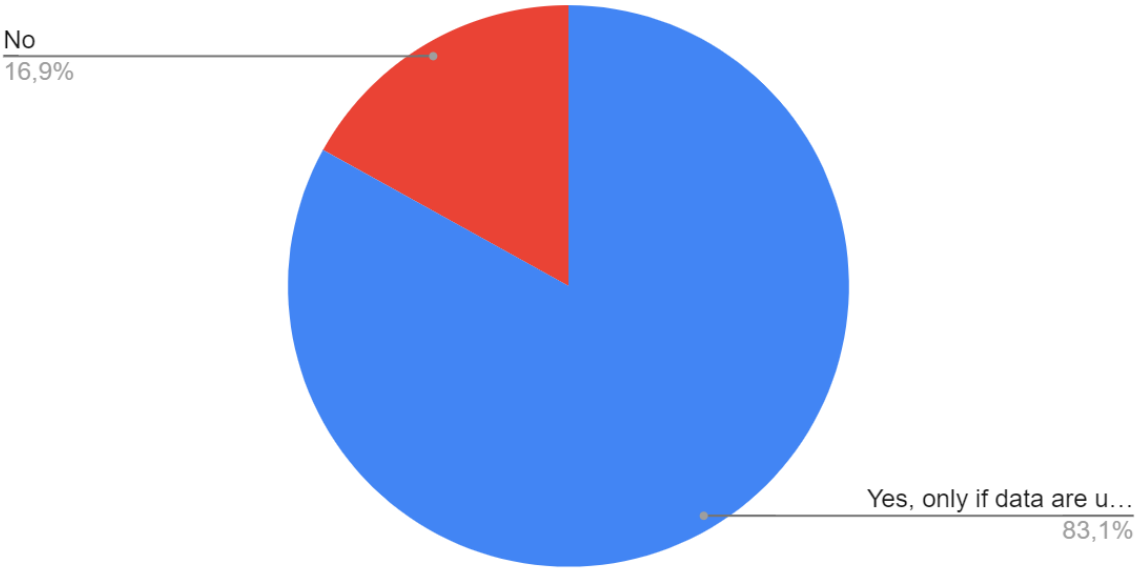
- I think that I will need technical assistance available to solve problems associated with the use of S-EHR.



Notes:

- Yes, if it's too complicated.
- Yes, problems to connect with a new hospital
- Yes, to solve technical problems
- Yes, if I can't find the answer in a FAQ
- Yes, it depends of the difficulty
- Yes, in case of need
- Yes, to solve technical problems.

- Would you be willing to send your health data to a research institution for a health-related study (after a detailed explanation of research and purposes, and using anonymised/pseudonymized data)?



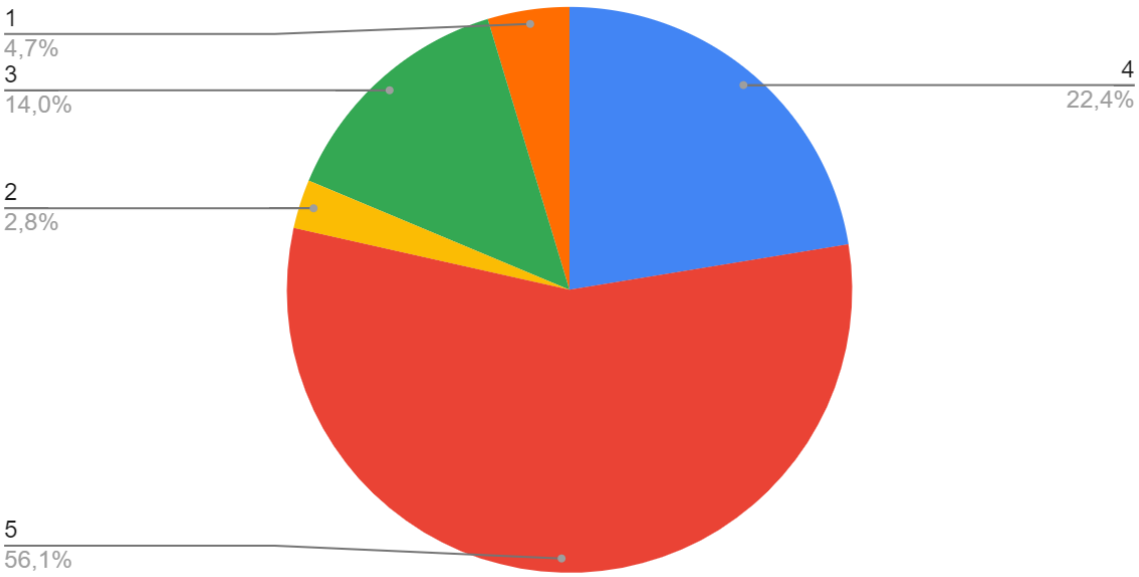
Suggestions and notes:

- I want to keep control of my medical data
- Because I want to keep my data under my control
- Not trusting the data anonymization
- I don't trust the anonymization system
- Don't want to share all my medical information
- I need proof that it is anonymous
- Too dangerous for my private data
- Yes, with strict rules on the security of my personal data and their use for strictly scientific purposes.
- I don't want my personal information to leak and I don't want to bother me
- I would like to assist in research
- If my data were to help develop new therapies to help more patients it would be a welcome project
- I would also like a more specialized view
- I'm interested in helping.
- Because I think they will bother me often and I don't want to.
- Study and research can help more patients.
- I would not seek it, but it does not bother me as long as the anonymity is respected.
- I think the collection of complete information from a research foundation will help to the fastest resolution of the research issues.
- For better information and troubleshooting.

- Concerning the two diseases I have, the one is rare and I think sharing opinions, or therapies is very useful. As for the second disease, information is always needed such as patients amongst themselves e.g. I got this and I no longer have nausea. From my doctor these suggestions would be well documented and what you might expect and have heard advice are always best addressed.
- I would like to have a second opinion
- I agree to send my medical record data to help with medical research to advance science
- It is important for researchers to have actual patients medical data and not only in a clinical environment

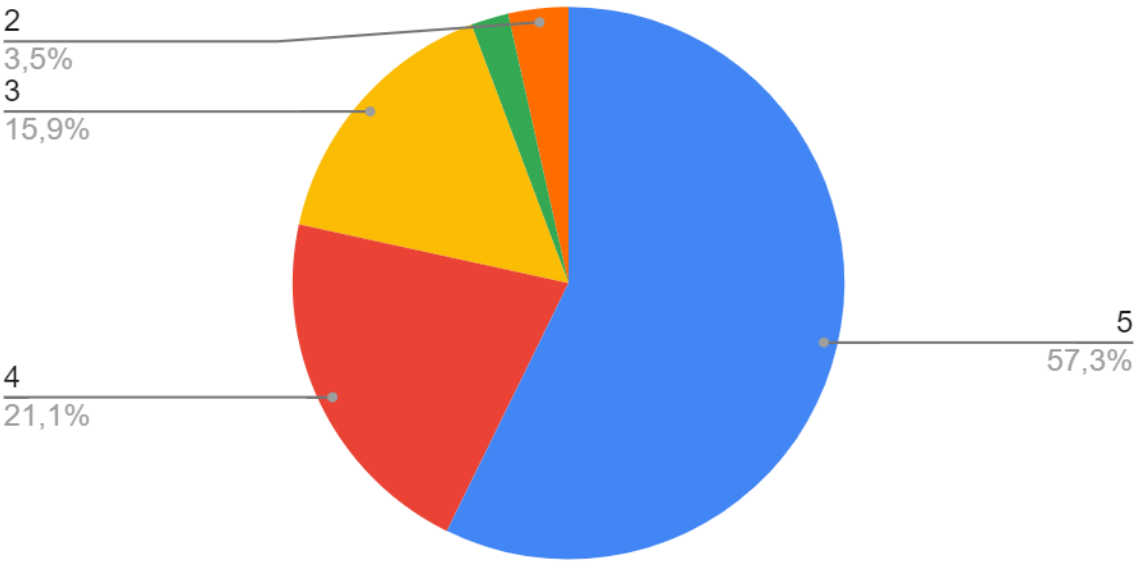
- Are you willing to allow research organizations authorized in SEHR platform to contact you using the APP only for those researches who may apply your health status?

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

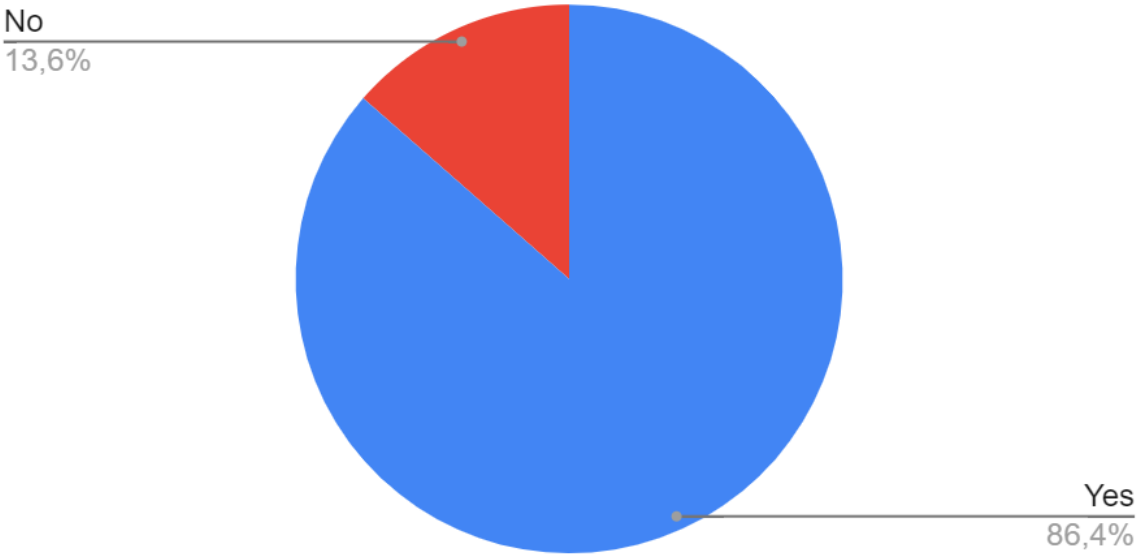


- Are you willing to add specific data in your SEHR, requested by a research organization, only to participate in a research? (e.g. visits, blood tests, instrumental examinations)

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



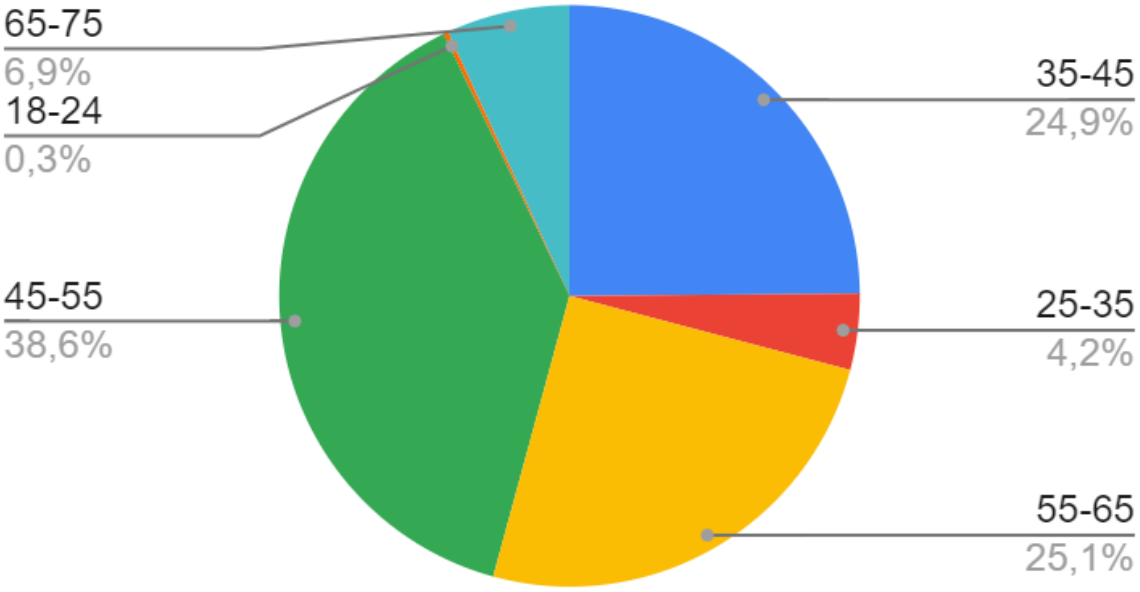
- Should a notification be visualized to you before sending any periodic update with new health data to researchers (when requested by the clinical research protocol)?



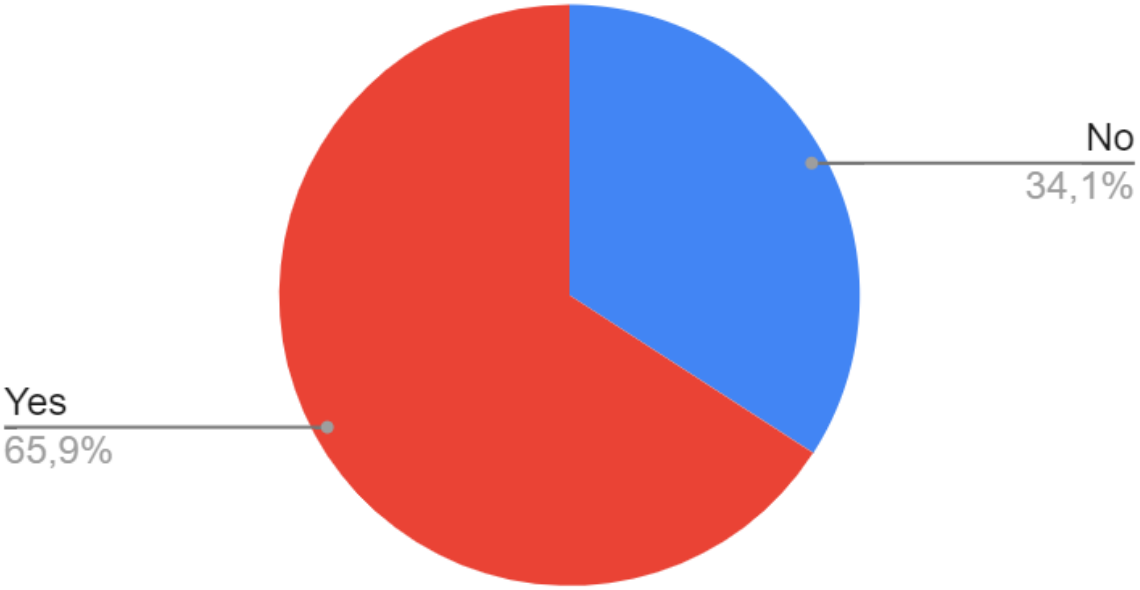
9.2 *HCP Focus groups Response*

In the following graphs are presented the analytical results of questionnaires.

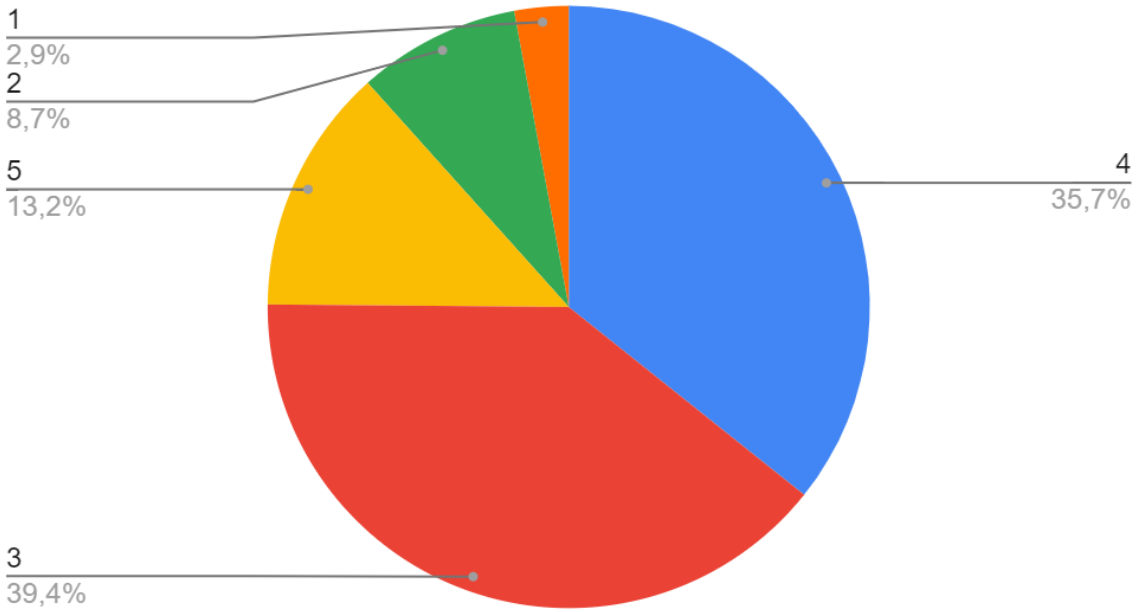
- Age Range:



- Are you used to share electronic information with your patients?

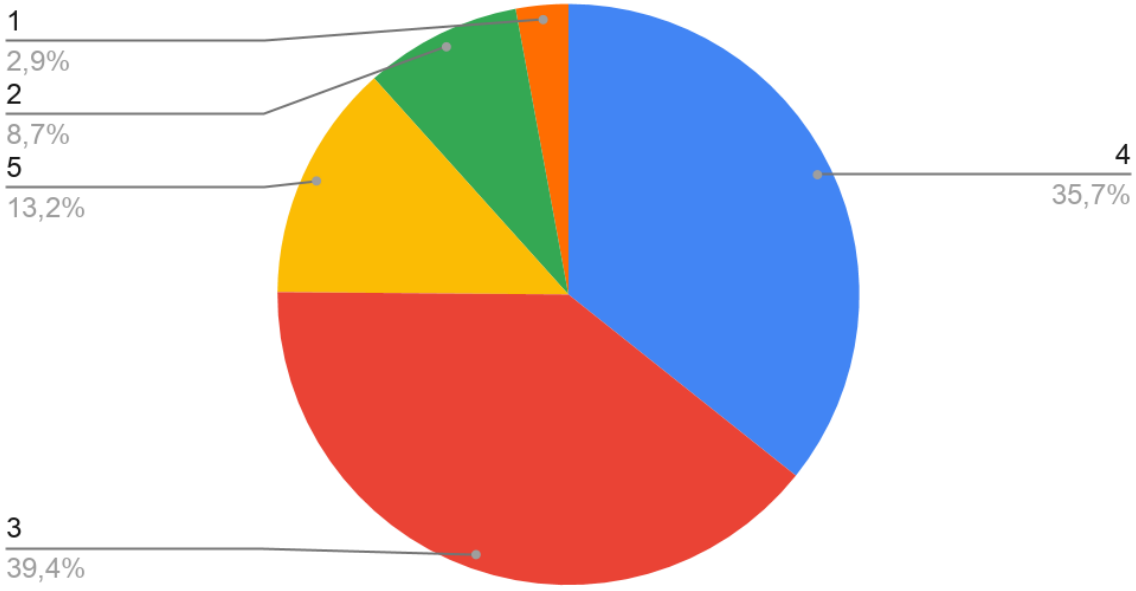


- I think that use of data within IEHR PLATFORM would be easy.



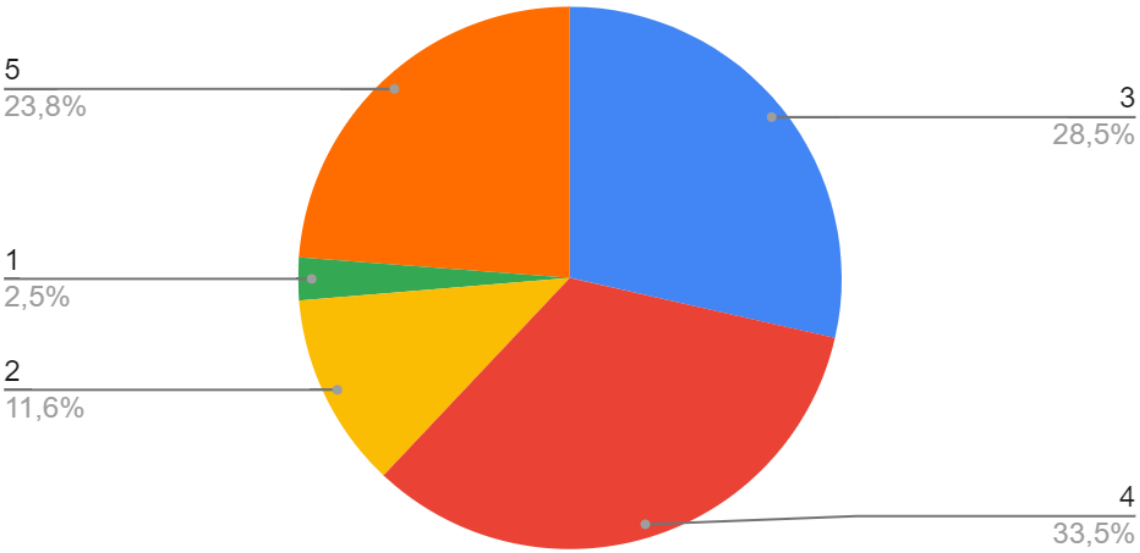
- I think that in my Healthcare Facility I will have technical assistance available to solve problems associated with IEHR.

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



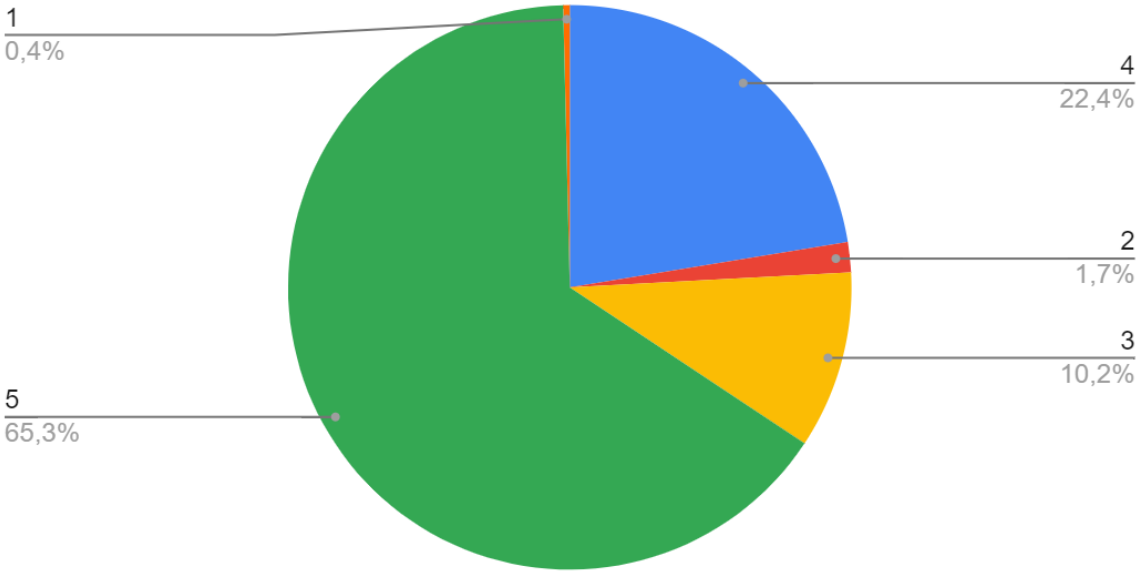
- I think that my interaction with the patient using IEHR PLATFORM will require much effort for my share

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

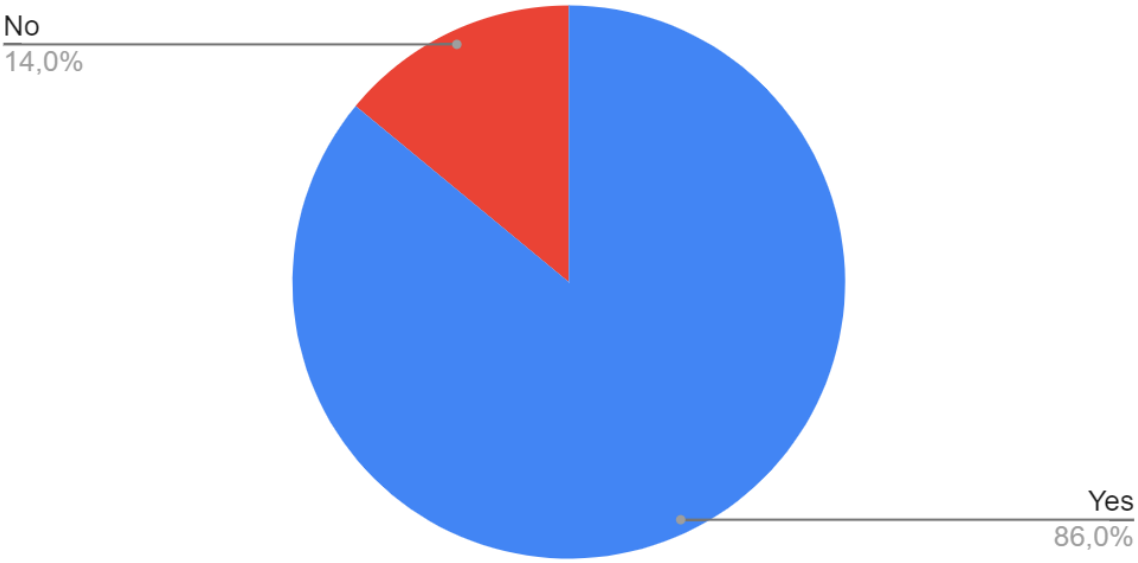


- I think IEHR PLATFORM will be compatible with other systems that I use

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



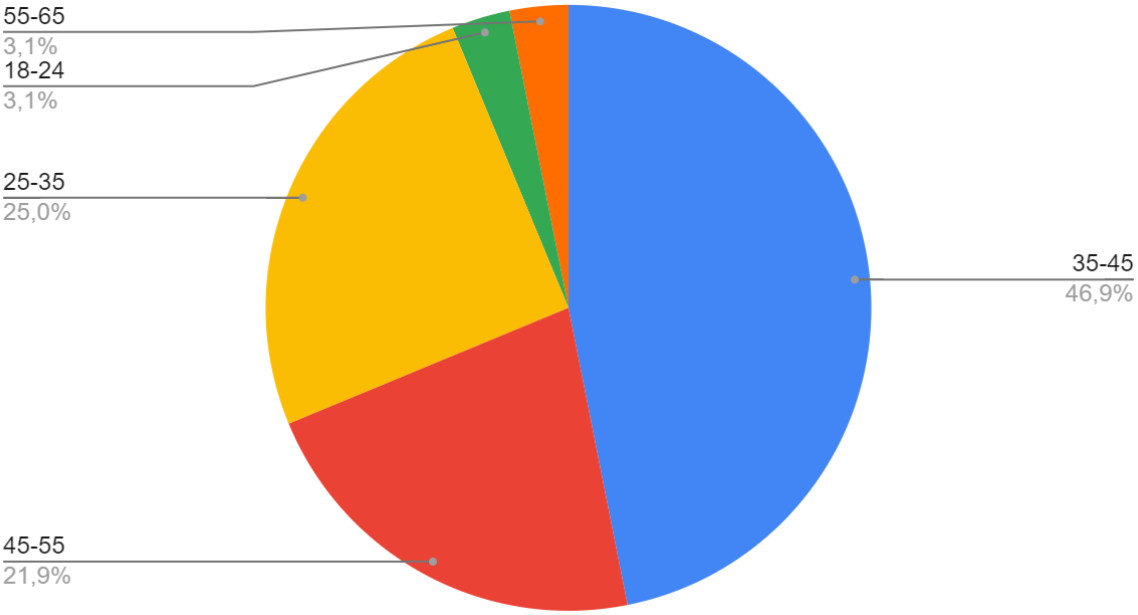
- Would you like to access the S-EHR platform (NICOBAR) using the national authentication services tools?



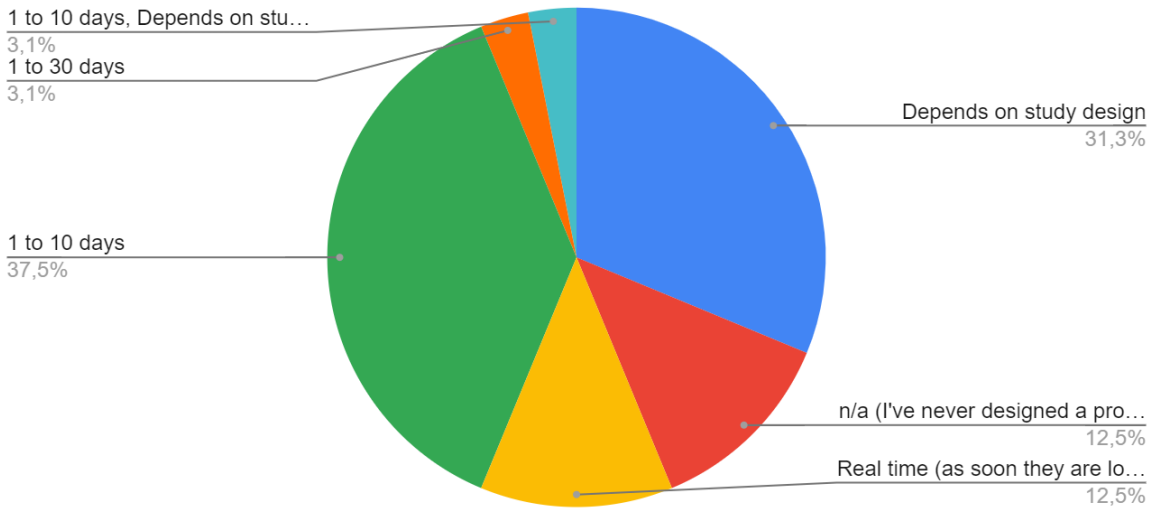
9.3 *Researchers Focus groups Response*

In the following graphs are presented the analytical results of questionnaires.

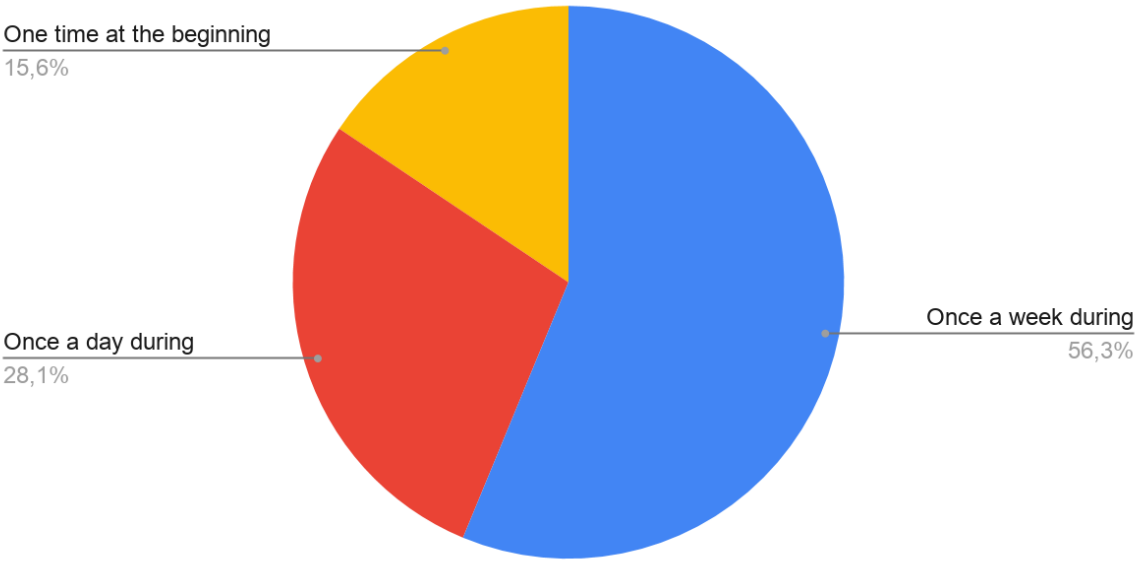
- Age Range



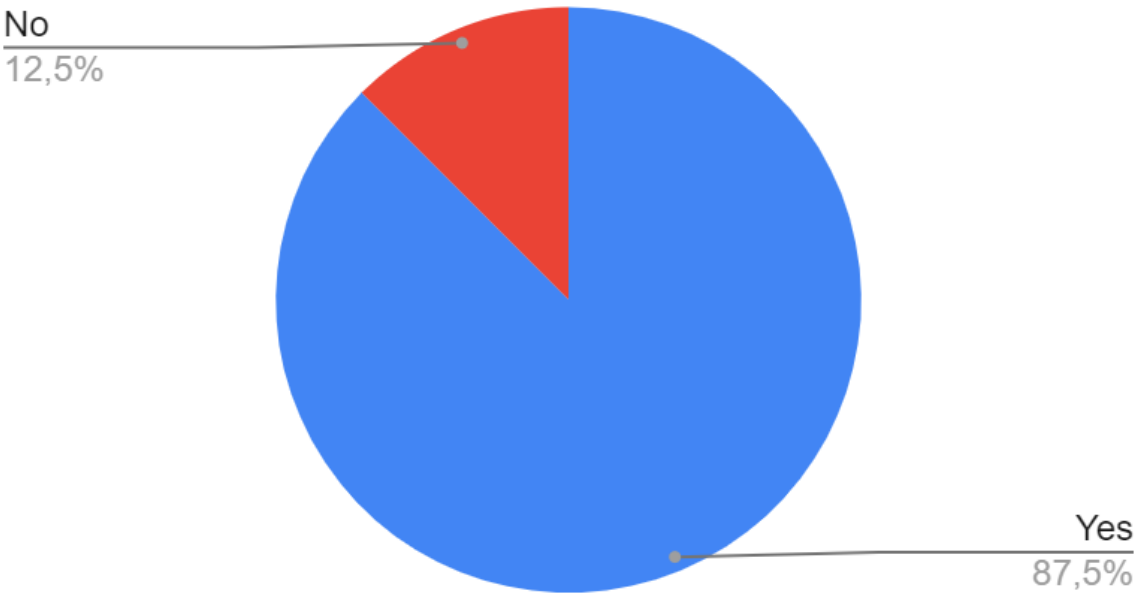
- For a prospective Research with periodic assessment of the patient, specify the maximum delay for having new collected data of the period (from the App S-EHR of the patient)



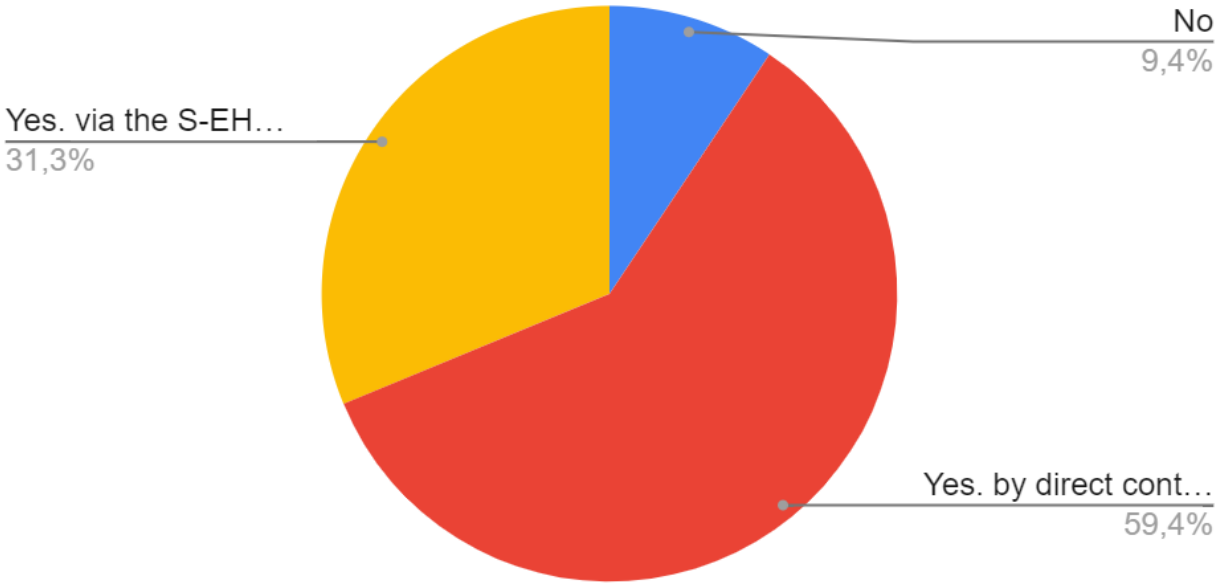
- How often should the system look for new patients to invite to one specific study?



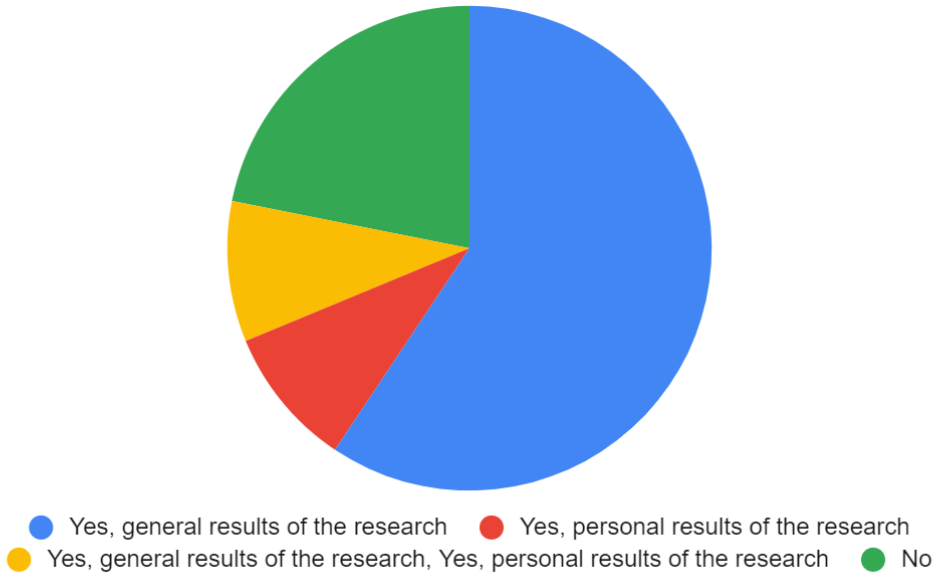
- Should a notification be sent to the researcher when receiving any periodic update with new health data?



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



- 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.