D2.1

User Requirements

for cross-border HR integration

V1

ABSTRACT

This report describes final users' requirements of InteropEHRate platform, including the initial definition of clinical content for S-EHR, the description of three different reference scenarios where S-EHR is applied and the methodology applied to refine final users' requirements according to the three different final user categories: patients and family caregivers, healthcare professionals, and clinical researchers.

Refinements and evolution on the clinical definition of S-EHR content and reference scenarios descriptions will be reported in the forthcoming version of this deliverable.

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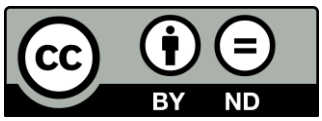

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ACRONYMS

Acronym	Description
API	Application Programming Interface
D2D Device to device	Device to Device
DICOM	Digital Imaging and Communication in Medicine
HER	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	ECG Protocol

TABLE OF CONTENT

LIST OF FIGURES

LIST OF TABLES

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 integration*. First of all, this document defines the general content of S-EHR, reporting correspondence with EU initiative, 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, 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 in the S-EHR app derived from the described scenarios.
- Section 6 "Knowledge Management Tool" lists the set of functionalities to be implemented in the Knowledge Management Tool.
- Section 7 "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 (if any)

Not applicable.

2. APPROACH FOR REQUIREMENT ANALYSIS

The user requirements described in this deliverable defines the functionalities required by the users of software applications included in the InteropEHRate architecture, including both applications that are specific to the InteropEHRate protocols for health data exchange mediated by citizens (e.g. "S-EHR Mobile App" or "S-EHR Broker") and additional applications that are not specific to the InteropEHRate protocols, and for this reason are only part of the reference implementation architecture (e.g. "HCP App"[1] or "Knowledge Management Tool"). Other than software functionalities, the user requirements describe constraints to be satisfied by the identified software applications.

The InteropEHRate 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 (e.g. "S-EHR Mobile App" or "HCP App") that may operate in the InteropEHRate ecosystem. Each category of applications may have different realizations, developed by different vendors, offering other than the standard ones, additional functionalities for satisfying additional constraints not included in the InteropEHRate user requirements. This document does not specify which functionalities are mandatory and which ones are not. This distinction will be done in the next version of this report and in the "Specification of S-EHR mobile privacy and security conformance levels" [D3.1]. The software applications developed by the project will represent the first prototypical realization (i.e. a "reference implementation") of the InteropEHRate requirements. In this document, the term "software application" is indeed a synonym of "category of software application".

The definition of requirements is aligned with the incremental development approach of InteropEHRate, composed by 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, to be possibly 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. In the case of InteropEHRate, all user scenarios involve access by authorized people in a country to the health data of patients coming from other European countries.

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.

[1] While the HCP App is directly involved by the D2D protocol, it is not considered part of the "standard" architecture to emphasize that it is usually not a new kind of application but an extension of existing ones used by HCPs.

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 is performed using a collaborative word processor, working on shared documents that can be edited simultaneously by all contributors.

In order to start the collaboration, the responsible of user requirement analysis drafts an initial version of the usage scenarios, starting from the ones included on the project Grant Agreement, and adds more details on the base of its clinical experience and on the base of the technological goals of the project. The definition of the scenarios and of the architecture proceed afterwards 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 responsible of the user requirements and the technical partners of the project collaborates 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 fined 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 to 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 “user stories” 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.

Also, the usage of 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 operability 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), 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 kind/role 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 uses 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.

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	Citizen

	consider patients that are also citizens.	
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 scientist	Every person able to understand specific kind of health data and to express them according to specific standards adopted in the health domain	-
-	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 and Nurses and Researchers of Hospital partners that, in order to have a meaningful use, S-EHR should be able to contain at least:

1. Patient Summary; (Emergency Dataset)
2. ePrescription;
3. Laboratory results;
4. Clinical 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)

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, itis 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 section provides further details on some of the expected content.

3.1.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.

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

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

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

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

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

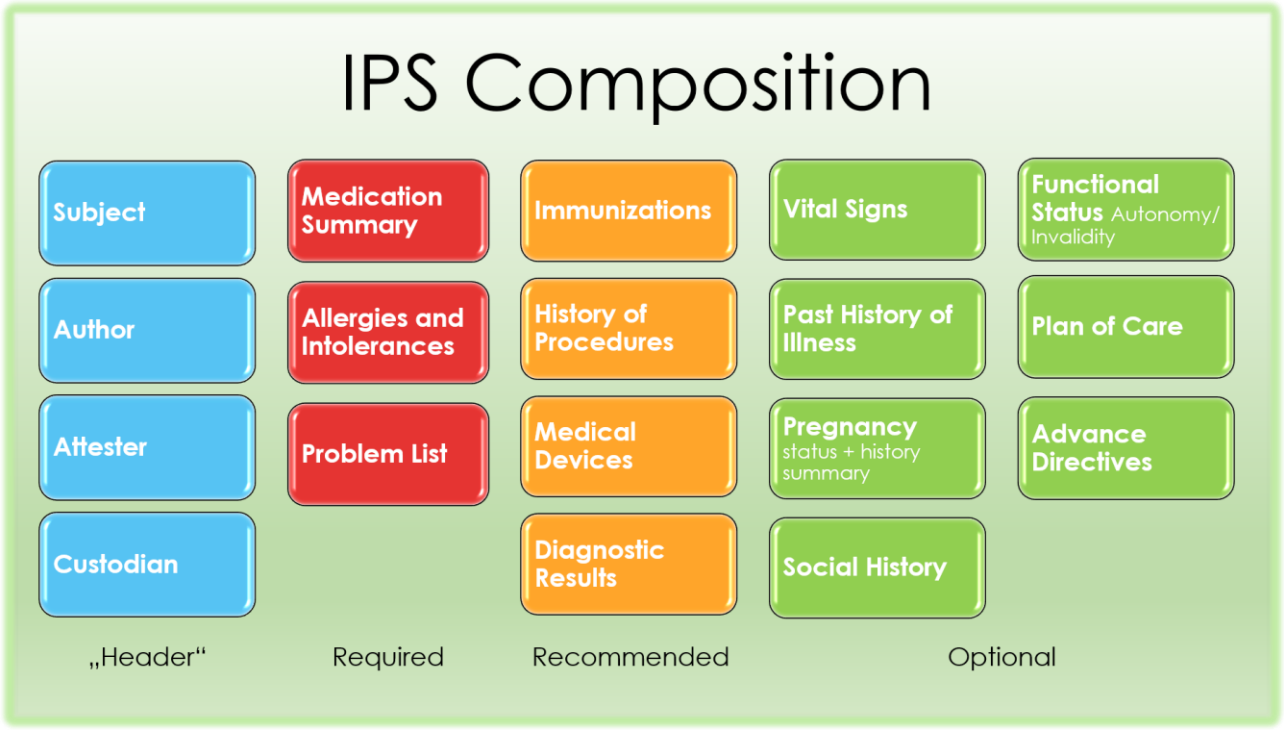

Figure 1. IPS composition

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 length 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 on 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. 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.

IPS Sections	Description
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

3.2. E-prescription

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

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
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

Item	Description
	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 HP clinical document and to enable each sub-set of information to be managed individually when applying semantic services or when applying any kind of translation into the native language of the person requesting the consultation of the clinical document. *[EPRSC]*

3.3.Laboratory results

Laboratory results come from diagnostic techniques that evaluates the patient's samples such as blood, urine, or other physiological fluids and tissues, highlighting his 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.

3.4. 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}) colours, the colour 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.

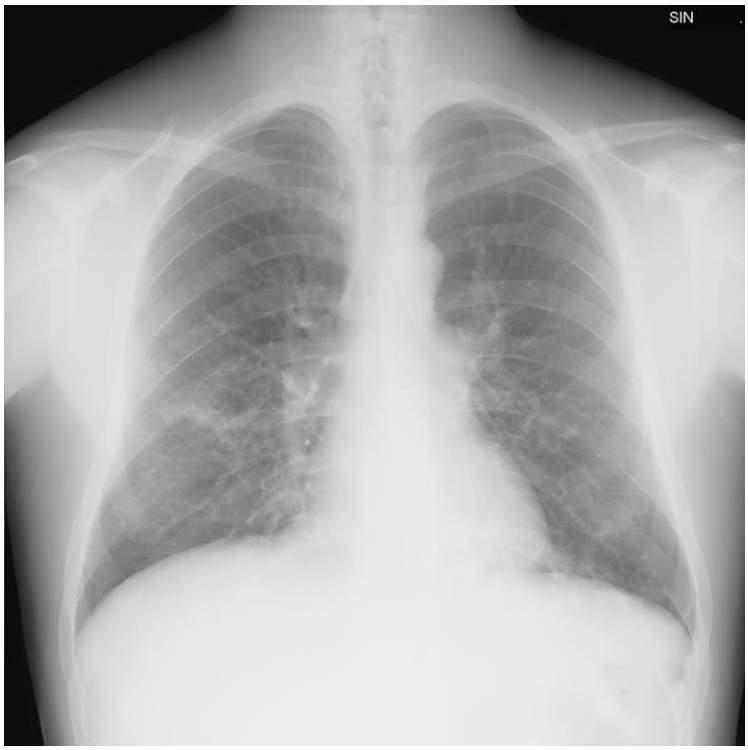

Figure 2. X-ray diagnostic Image

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 diagnostic 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 diagnostic 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 standard of primary importance, which is for instance the Digital Imaging and Communication protocol [DICOM]. DICOM, thanks to the high standardization of the processes used in the healthcare 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 healthcare 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 healthcare 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 healthcare software or biomedical equipment, for the interpretation or representation of diagnostic 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 diagnosis, being "medical devices" must be CE marked and associated with diagnostic display monitors, which allow to visualize diagnostic 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 diagnostic 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.

3.5.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 healthcare 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.

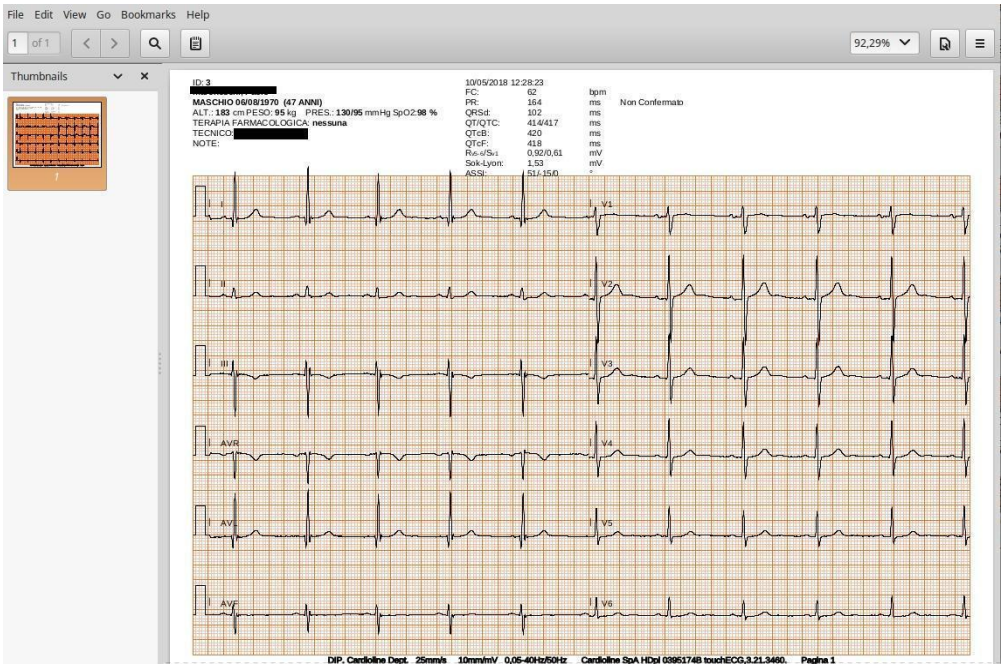

Figure 3. Example of digital ECG

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.

4. REFERENCE SCENARIOS

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

4.1.Scenario S1 - Device to Device HR exchange

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.

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.

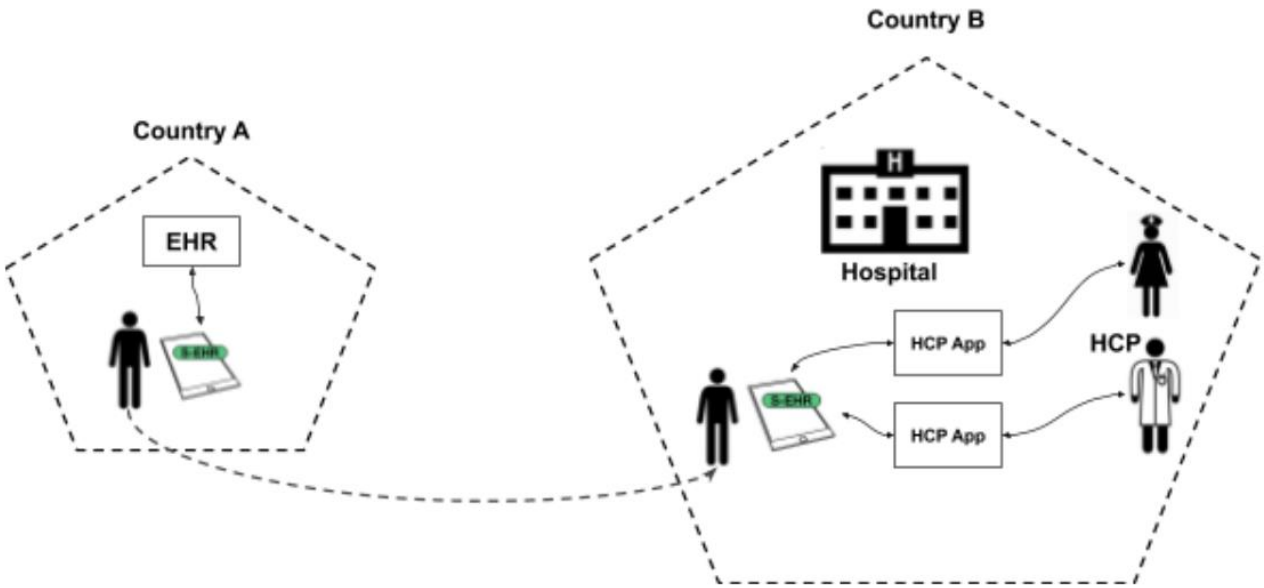

Figure 4. Device to Device HR exchange

4.1.1. Pre-conditions 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, since 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 oedema, dyspnoea and reduction in exercise tolerance.

4.1.1.2 IT and Data Protection preconditions and assumptions

A. [Sub-Scenario] The Patient owns an 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 already been imported from the EHR system of his referral centre to the S-EHR of the patient.
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.
F. [Sub-Scenario] HCP uses the software “HCP App”, able to access an 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.
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.
I. 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.
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.
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.
L. Patient data is contained in the EHR system of 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. The health care organization has described the semantic codes used locally by the organization (national and local codes) using the Knowledge Management Tool.
O. The domain expert of the healthcare organization has defined the mapping between the local codes and the international codes.
P. All the information is related to its producer/author.
Q. The HCP cannot repudiate the produced information.
R. The Patient cannot repudiate the produced information.
S. The data contained in the S-EHR are safe and represents a legal consistency on which it relies for diagnosis/treatment/prognosis/prevention.
T. The HCP can verify the origin and validity of the information shared by the citizen.
U. 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 an 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 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 are 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/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.

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). 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, patient move on to consultation. From this on, patient interacts with HCP2.

14) Downloaded patient's data may be visualized, using the HCP App, by the HCP2, which 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.

16) HCP2 measures vital signs, body weight, BP, pulse, respiratory rate, SPO2, Temp, AVPU and alertness.

Data are entered in HCP App.

17) During the evaluation, the S-EHR is connected to the HCP App, and the newly collected data 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.

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.

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).

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:

- image and report of chest X-rays
- evaluation report
- drug prescription for furosemide 25 mg

4.1.3. Post-conditions

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, are reported a dataset of values useful for the evaluation of Chronic Heart Failure (CHF) patients.

This dataset content is only for HCP interpretation and use, so will not be explained the meaning of each term and acronym.

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 oedema (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 tachycardia (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:

- haemoglobin (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 - Remote to Device HR exchange

The main purpose of this scenario is to show how HCPs may access and contribute to Patients' health data when an 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.

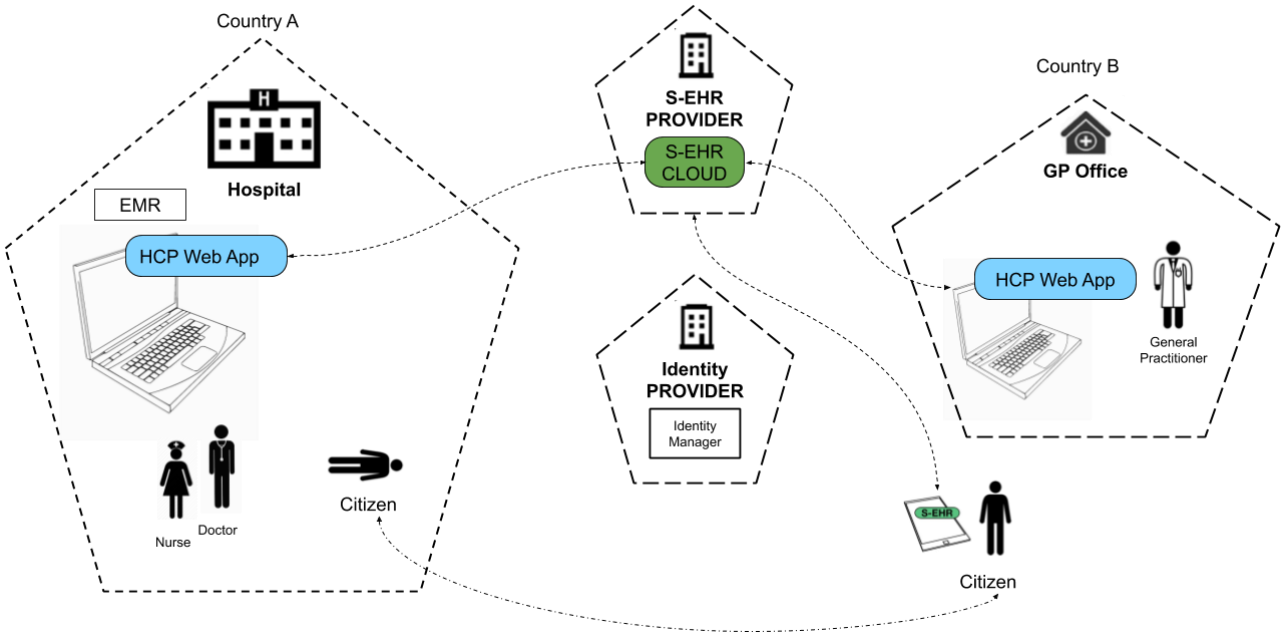

Figure 5. R2D Scenario

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.

A 56 years old male Romanian person is abroad in Belgium, where he complains 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 an 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. [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. The patient has already configured on his/her S-EHR a set of default permissions for any HCP that he authorizes to access his/her data.
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. [Sub-Scenario] the patient/GP/HCP selected a subset of data for emergency purposes (Emergency Dataset), and the patients give consent to access the Emergency Dataset to emergency HCP.
K. 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.
L. [Sub-Scenario] The patient gave his/her consent to the emergency identification by means of an emergency identity token.
M. [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.
N. 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.
O. 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.
P. 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.
Q. The hospital has full access to internet connection and to S-EHR cloud infrastructure
R. 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.
S. All the information is related to its producer/author
T. The HCP cannot repudiate the produced information.
U. The Patient cannot repudiate the produced information.
V. The data contained in the S-EHR are safe and represents a legal consistency on which it relies for diagnosis/treatment/prognosis/prevention
W. The HCP can verify the origin and validity of the information shared by the citizen.
X. 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 read with a QR-code scanner) the code contained in the emergency identity token on the HCP App.
4) HCP1 using the same HCP App, request 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).
9) The Patient's health data are imported in a few seconds (5 to 10) from the S-EHR cloud to the HCP App.
    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.
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 Discharge Report containing the cause of admission, discharge diagnostic assessment, prescriptions, visits and recommendations, therapy and prescriptions.

4.2.3. Post-conditions

[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.

4.2.4. Dataset

This dataset content is only for HCP interpretation and use, so will not be explained the meaning of each term and acronym.

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 Electrocardiogram (image)
- Latest bio-humoral exams

5. Surgical history

6. Current medications

4.3. Scenario S3 - Research protocol

The main concept contained in this scenario is the sharing of clinical data owned by a patient and collected during healthcare processes involving the patient as a subject, for research purposes. In this scenario an authorized researcher, also identified as a component of a group of researchers, represents the final user of such data.

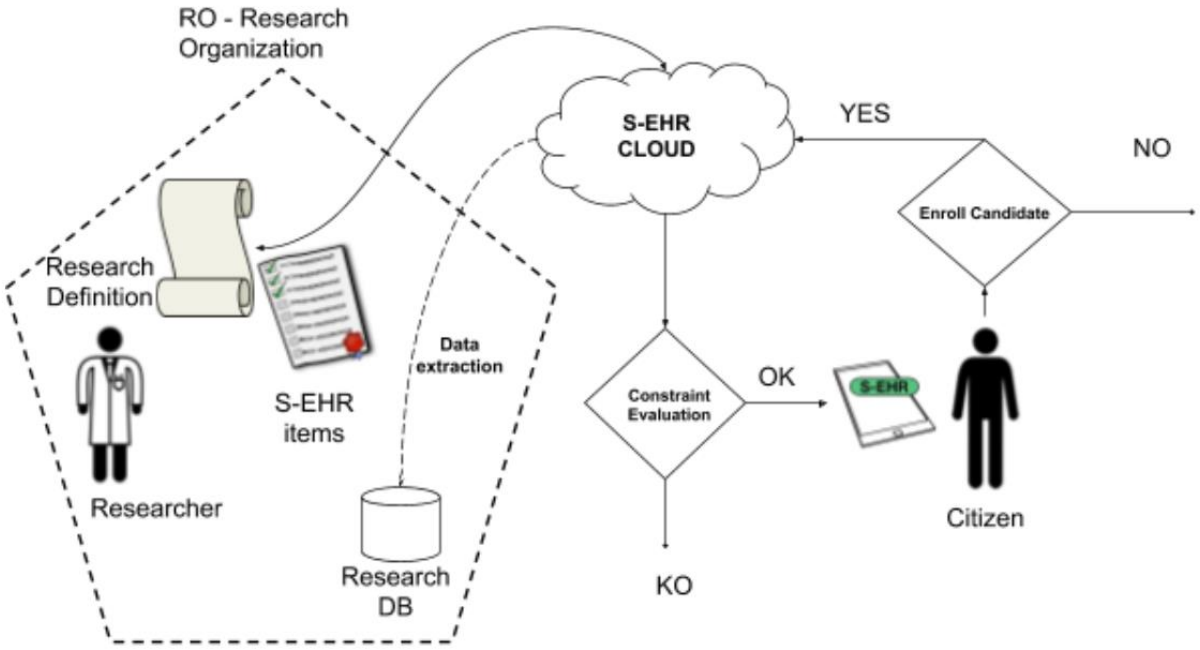

Figure 6. Research Scenario

To identify researchers a service is present, consistent among different affinity domains, authorized to certify researcher and correspondence with a research Organization/Institute.

4.3.1. Pre-conditions

In order to describe health data 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.

4.3.1.1 Clinical preconditions and assumptions

Generic Abstract description: A patient has a collection of clinical data related to his/her status and clinical condition. A Research Organization defines a research protocol with an associated clinical dataset.

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

Patient's data stored on the S-EHR app and S-EHR cloud platform have a strict correlation to the patient's owner and data authorship.

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

A researcher defines an investigation protocol using data selected from S-EHR-RDD, constraining special filters to select the population of patients that can be enrolled in the study.

4.3.1.2 IT and Data Protection preconditions and assumptions

A. The Citizen gave his consent (informed consent) to store data into his S-EHR cloud, and he asked to keep it up to date for every use.
B. The researchers have full access to internet connection and to S-EHR cloud infrastructure.
C. The Citizen has his most recent and updated health data stored in the "S-EHR cloud".
D. The Research Organization (Hospital/University/research centre/Institute) has its own regulations in terms of researcher's access.
E. Researchers own an electronic ID/account released by an authority, national or local for S-EHR infrastructure, certifying their identity and qualification.
F. EVERY action performed on IT system is registered (logged) and associated permanently with the unique identification of the author/actor and workstation/device.
G. Health data sets shared for research purposes can be accessed/queried only by the authorized researchers.

4.3.2. Scenario Description

1) A Research Organization (RO) defined a research protocol involving female patients with age > 65 years, with hypertension and treated with ACE inhibitors.
2) The protocol requires the prospective collection of a set of anonymized health data, which includes treatment plans, for 2 years after patient enrolment and a retrospective evaluation of his data up to 5 years before enrolment.
3) The defined Research, with the need to enrol these kind of patients (hypertensive females aged > 65 years, receiving ACE inhibitors) are published within S-EHR research network, in order to match those criteria against S-EHR contents of each patient.
4) Matching is performed and evaluated by S-EHR cloud, in a silent way, without data transmission to involved researchers.
5) Based on evaluation of research criteria, the S-EHR app displays an item within a list of research protocols, asking to adhere to the research for Mrs. Eve, and
    a) nothing is added for Mr. Adam.
6) She selects the research from a list of studies published in S-EHR, where the selection criteria are evaluated on Mrs. Eve clinical/social data,
7) and she is informed about the details of requested health data, the purpose of the research, the data retention periods and about the level of anonymization.
8) Tapping on the item will be displayed the information document of the research, containing reference contacts of OR and principal investigator, to be contacted for further details.
9) The request for the research protocol is to share her data in an anonymized configuration.

10) The patient decides to donate the health data of her previous 5 years and for the next 2 years, restricting their use only to that specific research protocol.
11) The researchers of the organization have access to all donated health data in a format suitable for their analysis tools, downloading the data in a research database maintained by the RO.
12) Since the research lasts for 2 years, all data updated in S-EHR and related to the research are conveyed to the researcher.

4.3.3. Post-conditions

A. The patient can withdraw her participation at any time, and, if requested, researchers will have to delete data transmitted to them.
B. The citizen can, at any time, withdraw his/her participation in the study. Since then, data belonging to the citizen will no longer be consulted and/or be object of analysis.
C. At the end of the research, data imported from S-EHR are stored safely in providers EHR for a 10-15-25 year, then are deleted (disposed).

4.3.4. Dataset

This dataset content is only for clinical Researchers interpretation and use, so will not be explained the meaning of each term and acronym.

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:

   - Latest bio-humoral exams

5. Surgical history

6. Current medications

5. USER REQUIREMENTS

As described in the section "Approach for requirement analysis", user requirements are identified by the analysis of the scenarios. More specifically, one or more requirements may be associated to 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.

During the first year, the analysis of requirements has been focused on "Scenario S1 - Device to Device HR exchange".

The following table shows what are the requirements associated with each portion of the scenario, while the successive subsections describe the referred requirements, grouped by the type of application they specify.

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 Mobile App", HCP-A means "HCP App", KMT means "Knowledge Management Tool", DMT means "Data Mapping Tool", S-H-A means that the requirement applies to both S-EHR Mobile App and HCP App.

Scenario step	Implied requirements
[Sub-scenario] The Patient owns an 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
[Sub-Scenario] The S-EHR app uses a certificate owned by the Citizen to support the identification of the Citizen	S-EHR-A-6
[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 and at moments explicitly authorised by the Citizen	S-EHR-A-5
[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-13, S-EHR-A-14
[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.	S-EHR-A-9
[Sub-Scenario] HCP uses the software "HCP App", able to access an S-EHR app by using a Device to Device connection.	
[Sub-Scenario] Each single HCP involved in this scenario owns an electronic certificate/ID released by an authority, national or local for S-EHR infrastructure, certifying his/her identity and qualification.(Person ID may be referred to a local	HCP-A-7

Scenario step	Implied requirements
LDAP or IHE-PWP, consistent and secure for S-EHR use)	
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
[Sub-Scenario] Each health care organization involved in this scenario is classified within S-EHR organizations, and is identified with an electronic certificate/ID.	HCP-A-8
Every action performed on the S-EHR system by an author/actor is registered (logged) by both the S-EHR and the HCP App	S-EHR-A-19, HCP-A-21
and associated permanently with the unique identification of the involved patient and HCP author/actor.	S-EHR-A-20, HCP-A-22
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.	S-EHR-A-9
The domain expert in the health care organization has described the semantic codes used locally from the organization (national and local codes) using the Knowledge Management Tool.	KMT-23
The domain expert of the healthcare organization has defined the mapping between the local codes and the international codes	DMT-24
While abroad, a patient decides to refer to a local physician, for a visit related to his/her health situation. The HCP1 asks the patient if he/she owns an S-EHR. As the patient answers yes, the HCP1 asks him/her to approach his/her Smart Device to the HCP1 terminal for the identification by means of the D2D protocol.	S-EHR-A-27
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
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
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	HCP-A-30

Scenario step	Implied requirements
birth, gender, country of residence (corresponding to the identity document) and social security number (or equivalent identifying data).	
The HCP1 asks the Citizen for his/her identity document and compares it with the information shown on the HCP App.	HCP-A-31
As the data are correct, the HCP1 confirms, using the HCP app, the identity of the patient. If data are not corresponding, Scenario stops here.	HCP-A-31
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
The admission data are stored by the HCP app for future traceability.	HCP-A-33, HCP-A-34
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
The patient 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
By means of the S-EHR the patient gives his/her consent (*)implicitly giving the default view/transmission permissions he 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
The consent is transmitted to the HCP App and recorded by it for future traceability.	HCP-A-38, HCP-A-39
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-	HCP-A-41, S-EHR-A-36, HCP-A-67

Scenario step	Implied requirements
20 Mb).	
The patient has the possibility to "customise" the permissions during a specific data exchange.	S-EHR-A-37
Downloaded patient's data may be visualized, using the HCP App, by an HCP1 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
Downloaded patient's data are translated into HCPs natural language. HCPs natural language is the one officially related to the Healthcare provider.	HCP-A-49, HCP-A-50, KMT-25, KMT-26, HCP-A-51, HCP-A-52
Optionally, the HCP may manually select a different preferred language	HCP-A-48
HCP1 measures vital signs, body weight, BP, pulse, respiratory rate, SPO2, Temp, AVPU and alertness.	HCP-A-53
During the evaluation S-EHR are connected to HCP App, and the newly collected data are transmitted back to the patient's S-EHR app. The HCP1 accompanies the patient in a waiting room where he/she can wait to have a specialist evaluation.	HCP-A-55, HCP-A-67
Another HCP, HCP2, is assigned to evaluate the patient in a different room. Data produced by the HCP2 during the evaluation are collected in the HCP App of HCP2. during the evaluation of HCP2, S-EHR are connected to HCP App.	S-EHR-A-27, HCP-A-55
Once the patient is in the visiting room, the consulting HCP2 asks the patient the reasons for his need for the visit.	HCP-A-58
HCP2 starts to visit the patient: download the patient's history from the S-EHR app	HCP-A-61, HCP-A-66, HCP-A-67
(translated into the HCPs language)	HCP-A-51, HCP-A-52
and import it into the HCP app.	HCP-A-42, HCP-A-66
HCP2 updates on the HCP app the patient's clinical history reporting new symptoms	HCP-A-58

Scenario step	Implied requirements
HCP2 downloads from S-EHR vital signs and measures from the previous month, compare them with current values and recognize a relevant gain in body weight.	HCP-A-66, HCP-A-47, HCP-A-71
HCP2 asks for a chest X-ray at local imaging facilities. HCP2 downloads from the S-EHR app images of a previous exam, performed in Belgium the year before, HCP2 compares them with the current exam and recognizes signs of increased interstitial congestion.	HCP-A-64, HCP-A-45
The HCP2 retrieves information from S-EHR on prescribed drugs. HCP2 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
The HCP2 finalizes the visit by compiling an evaluation report on the HCP app.	HCP-A-60
The HCP2 provides a drug prescription for furosemide 25 mg on the HCP app.	HCP-A-59
The HCP2 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: ● image and report of chest X-rays ● evaluation report ● drug prescription for furosemide 25 mg	S-EHR-A-27, HCP-A-67, HCP-A-54, HCP-A-56, HCP-A-57
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 4 - Requirements associated to "Scenario S1 - Device to Device HR exchange"

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**: an alternative identifier for the requirement that also summarizes its meaning.
- **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 behavior/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 system in correspondence of specific events (including user interactions).
  - NF: Non-Functional requirement, constraining some property or quality of the system or of the implementation of several functional requirements
- **Target**: indicates the candidate target version of the reference implementation (RI) where the requirement could be implemented. The possible values are:
  - NEVER: means the project decided not to implement the requirement, although of interest.
  - v1: first version of the RI, due on Dec 2019
  - v2: second version of the RI, due on Dec 2020
  - v3: third version of the RI, due on Dec 2021

The following list of requirements will be subject to possible changes during the development phases. Most of them may be split into more fine grained software requirements documented in other reports related to specific kinds of applications. 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.

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 fully realize the "Scenario S1 - Device to Device HR exchange". These requirements are further described in terms of more fine grained software requirements in the deliverable [D6.1].

ID	Title	Main actor	Requirement description	F/NF	Target
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 his/her Android device.	NF	v1
S-EHR-A-2	S-EHR download from iOS store	Citizen	S-EHR is downloadable from the iOS store. The Citizen downloads the S-EHR from the IoS store and installs it on his/her iOS 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 the Android version X	NF	v1
S-EHR-A-4	S-EHR runs on iOS smartphone	Citizen	The S-EHR is a mobile app that can run on the iOS version X	NF	v1

ID	Title	Main actor	Requirement description	F/NF	Target
S-EHR-A-5	Consent to S-EHR data management	Citizen	At installation the S-EHR app 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-6	Enabling of Citizen identification from S-HER	Citizen	The S-EHR app 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	v1
S-EHR-A-9	Data hiding management on S-HER	Citizen	The S-EHR app allows the Citizen to hide some data to HCPs	F	NEVER
S-EHR-A-13	R2D import of (portion of) Patient Summary from national EHR on S-HER	Citizen	Citizen health data (portion of Patient Summary) can be imported from the Citizens' National EHR on Citizen S-EHR.	F	v1
S-EHR-A-14	R2D import of (portion of) Prescription import from national EHR on S-HER	Citizen	Citizen health data (portion of Prescriptions) can be imported from the Citizens' National EHR on Citizen S-EHR.	F	v1
S-EHR-A-15	R2D import of (portion of) Laboratory results from national EHR on S-HER	Citizen	Citizen health data (portion of Laboratory results) can be imported from the Citizens' National EHR on Citizen S-EHR.	F	v2
S-EHR-A-16	R2D import of (portion of) diagnostic images and reports from national EHR on S-EHR	Citizen	Citizen health data (portion of reports and diagnostic images) can be imported from all remote National EHRs on Citizen S-EHR.	F	v2
S-EHR-A-17	R2D import of (portion of) Hospital discharge reports from national EHR on S-HER	Citizen	Citizen health data (portion of hospital discharge reports) can be imported from the Citizens' national EHR on Citizen S-EHR.	F	v3

ID	Title	Main actor	Requirement description	F/NF	Target
S-EHR-A-18	R2D import of (portion of) health data from all national EHRs on S-HER	Citizen	(A portion of) Citizen health data can be imported from all remote national EHRs on Citizen's S-EHR.	F	V3
S-EHR-A-19	Auditing for Citizen on S-HER	-	Any operation on health data (creation, reading, updating, deleting, sharing, authorization) performed by any user is tracked by the S-EHR app	NF	v3
S-EHR-A-20	Consultation of auditing for Citizen on S-HER	Citizen	Any audited operation performed on health data (creation, reading, updating, deleting, sharing, authorization) is consultable from the Citizen that is the owner of the data	F	v2
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-28	D2D Visualization of Healthcare organization to the Citizen	Citizen	The Citizen see on the S-EHR app the data describing the identity of the Health Organization	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 get his/her identifying data	F	v1
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 app and upload the updated/acquired data back to the S-EHR app. The temporary consent of the Citizen for data exchange automatically expires at the end of the day.	F	v1

ID	Title	Main actor	Requirement description	F/NF	Target
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	NEVER
S-EHR-A-37	Customisation of permissions during a specific data exchange	Citizen	It gives 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 hides the weight in his default permissions, we ask the patient if he wants to share the weight with HCP "x" anyway.	F	v2
S-H-A-69	Data provenance tracking	Data user	The data origin of any health data is verified, tracked and visible to any authorized user.	NF	v2
S-H-A-70	Integrity of healthcare information	Data user	Users are guaranteed that the managed health data (stored or transferred) hadn't been modified maliciously or accidentally.	F	v2

Table 5 - Requirements for the S-EHR mobile App

5.2. HCP App

The following table describes the requirements that the application used by the HCPs (HCP App) must fulfil in order to fully realize the "Scenario S1 - Device to Device HR exchange". These requirements are further described in terms of more fine grained software requirements in the report [D5.1].

ID	Title	Main actor	Requirement description	F/NF	Target
HCP-A-7	Enabling of HCP identification from HCP app	HCP	The S-EHR app 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	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 the HCP app	F	v1

ID	Title	Main actor	Requirement description	F/NF	Target
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	NEVER
HCP-A-12	HCP app Android support	-	HCP app is provided as an Android application	NF	NEVER
HCP-A-21	Auditing for healthcare organization	-	Any operation on health data (creation, reading, updating, deleting, sharing, authorization) is tracked from the HCP App	NF	v2
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	v2
HCP-A-30	D2D Visualization of Citizen identity to HCP	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-31	D2D Identification and Authentication of the citizen from HCP	HCP	Proposal: The citizen's identification data (certificate?) is used to create or match the citizen's digital identity in the HCP App. The HCP selects and confirms the matching digital identity. The match can be persistent in the HCP App in order to avoid manual confirmation for future use. The citizen's digital identity will be used for further transactions, e.g. D2D data exchange.	F	v1

ID	Title	Main actor	Requirement description	F/NF	Target
HCP-A-32	D2D Request of consent from HCP for download and storage of data from S-EHR and upload new data to S-EHR	HCP	The HCP can ask, contextually to the 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 app. 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.	F	v1
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	v2
HCP-A-34	Consultation of admission data on HCP App	HCP	The HCP can view the admission data on the HCP App	F	v2
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 app and upload the updated/acquired data back to the S-EHR app	F	v2
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 app and upload the updated/acquired data back to the S-EHR app	F	NEVER
HCP-A-40	Setup on HCP App of initial health data to be downloaded 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 app	F	v1

ID	Title	Main actor	Requirement description	F/NF	Target
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 app. If some of this data is hidden by the patient, they are not downloaded.	F	v1
HCP-A-42	Patient Summary consultation on HCP App	HCP	An HCP can view the Patient Summary (a portion of it) shared with him/her by a Citizen using the HCP App.	F	v1
HCP-A-43	Prescription consultation on HCP App	HCP	An HCP can view the Prescription (a portion of it) shared with him/her by a Citizen using the HCP App	F	v1
HCP-A-44	Laboratory results consultation on HCP App	HCP	An HCP can view the laboratory results (a portion of it) shared with him/her by a Citizen using the HCP App	F	v2
HCP-A-45	diagnostic images and reports consultation on HCP App	HCP	A Doctor can view the diagnostic 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	An HCP can view the hospital discharge (a portion of it) reports shared with him/her by a Citizen using the HCP App	F	v2
HCP-A-47	Vital signs and other measures consultation on HCP app	HCP	An HCP can view vital signs and other measurements using the HCP App	F	v1
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	v1
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	v1

ID	Title	Main actor	Requirement description	F/NF	Target
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 of information on HCP App 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	v3
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	v1
HCP-A-54	D2D upload by HCP App 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	v2
HCP-A-55	D2D upload by HCP App for the initial assessment of S-EHR	HCP	An HCP may upload an initial assessment to the S-EHR of the subject Citizen using the D2D protocol (Vital Signs)	F	v1
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 to the S-EHR using D2D protocol	F	v3
HCP-A-57	D2D upload by HCP of Prescription	HCP	An HCP may upload a Prescription and report to the S-EHR using the D2D protocol	F	v1

ID	Title	Main actor	Requirement description	F/NF	Target
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	v2
HCP-A-59	Prescription authoring on HCP App	HCP	An HCP may author and store a Prescription on the HCP app	F	v1
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	v2
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 app	F	v1
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 app	F	v1
HCP-A-63	D2D download on HCP App from S-EHR of a portion of Laboratory results	HCP	A portion of the Laboratory results are automatically downloaded at connection time of the HCP app with the S-EHR app	F	v2
HCP-A-64	D2D download on HCP App from S-EHR of a portion of reports and diagnostic images	HCP	A portion of reports and diagnostic images (X-Rays) are automatically downloaded at connection time of the HCP app with the S-EHR app	F	v3
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 app	F	v2

ID	Title	Main actor	Requirement description	F/NF	Target
HCP-A-66	D2D download on HCP App from S-EHR of vital signs and other measures	HCP	The vital signs and other measures taken during previous visits are downloaded from the S-EHR at the request of the HCP app	F	v1
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	v2
HCP-A-68	Consent to store Citizen's data	HCP	Citizen data can be stored by authorized HCP app and only until the Citizen's consent expires.	NF	v2
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	NEVER
S-H-A-69	Data provenance tracking	Data user	The data origin of any health data is verified, tracked and visible to any authorized user.	NF	v2
S-H-A-70	Integrity of healthcare information	Data user	Users are guaranteed that the managed health data (stored or transferred) hadn't been modified maliciously or accidentally.	NF	v2

Table 6 - Requirements for the HCP App

6. KNOWLEDGE MANAGEMENT TOOL

The "Scenario S1 - Device to Device HR exchange" assumes 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 scenario. These requirements will be further described in terms of more fine grained software requirements in the next report [D5.7].

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	v1

Table 7 - Requirements for the Knowledge Management Tool

6.1. Data Mapping Tool

If health data must be exchanged with 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 [D5.9]. Data Scientist will use a Data Mapping Tool to configure the correct conversion. The following table describes the (only) requirement of the application used by the Data Management Tool. The requirement will be described in terms of more fine grained software requirements in the next report [D5.7].

ID	Title	Main actor	Requirement description	F/NF	Target
DMT-24	Mapping between local and international codes by Domain Expert	Data scientist	The domain expert using the Data Mapping Tool defines the mappings between local and international codes	F	v1

Table 8 - Requirements for the Data Mapping Tool

7. 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).

IEHR 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 Hospitals 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 5 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 9 - 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 aim 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 IEHR platform, giving an immediate example and using that as a guide to developing comments and suggestions.

To guide discussion with focus group, it is used a questionnaire with a list of arguments to be exploited within discussion.

7.1.Patients Focus Groups

Patients Focus Groups was the most challenging focus group for this project. It consisted in persons who travel abroad, for business of 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 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 and CHU) 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.

7.1.1. 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 user for 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.

For each of the hospitals selected focus group members were:

- SCUBA: 5 patients from the Cardiology Department.
- HYG: 7 patients.
- FTGM: 5 cardiological patients.
- CHU: 8 patients.

7.1.2. 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.

Question	Multiple answers allowed	Answer 1	Answer 2	Answer 3	Answer 4	Answer 5
Have you ever needed a medical visit while abroad? To relax the abroad concept to say also in different cities or regions not necessarily countries.	-	1 to 5: 1= strongly disagree, 5= totally agree				
If you have answered yes to the previous question, did you share some health data with health care professionals, and how?	-	1 to 5: 1= strongly disagree, 5= totally agree	How:			
Have you ever thought that in the future you will need to share your health data abroad?		1 to 5: 1= strongly disagree, 5= totally agree				
Do you use any software application to store or access your health data?	-	I use my national EHR portal	I use an application or mobile app provided by my healthcare operator	I use a mobile application downloaded by an app store	I do not use any applications for health data management	
If you had the opportunity, would you be afraid to share your medical data through a software application?		1 to 5: 1= strongly disagree, 5= totally agree (1=not afraid: 5=extremely afraid)				
Would you like to have your health data always available (in your pocket)?	-	YES very much	YES, but it is not a priority for me	Not a real need	No. I think it is better that my health	

Question	Multiple answers allowed	Answer 1	Answer 2	Answer 3	Answer 4	Answer 5
					data are managed by doctors	
My preferred feature of the software application you use to access or manage my health data: I can store clinical data by myself	Y	1 to 5: 1= strongly disagree, 5= totally agree				
My preferred feature of the software application you use to access or manage my health data: I can access the clinical data provided by my healthcare operator/s	Y	1 to 5: 1= strongly disagree, 5= totally agree				
My preferred feature of the software application you use to access or manage my health data: I can bring my health data with me	Y	1 to 5: 1= strongly disagree, 5= totally agree				
My preferred feature of the software application you use to access or manage my health data: I can show/share my health data with my close relatives/entourage very quickly	Y	1 to 5: 1= strongly disagree, 5= totally agree				
The feature I do not like of the software application I use to access or manage your health data is: The complexity and the absence/lack of security	Y	1 to 5: 1= strongly disagree, 5= totally agree			-	
The feature I do not like about the software application I use		1 to 5: 1= strongly				

Question	Multiple answers allowed	Answer 1	Answer 2	Answer 3	Answer 4	Answer 5
to access or manage your health data is: absence/lack of ergonomic		disagree, 5= totally agree				
The feature I do not like about the software application I use to access or manage your health data is: absence/lack of functionalities		1 to 5: 1= strongly disagree, 5= totally agree				
Are you willing to store your healthcare data on the S-EHR cloud?	Y	Yes, but only for emergency data	Yes, for any personal health data	Yes, if they are deployed within a secure server and nobody can see my data without my authorization	NO	
If you have answered yes to the previous question, which of the following solutions would you prefer?	-	A public cloud hosted by your national healthcare system	A private cloud (e.g. Dropbox, Google Drive, OneDrive, iCloud)	Any type of cloud ensuring data security/ privacy	Any type of cloud	
What kind of information (health data) do you need to exchange with healthcare professionals when far from your regular health provider?	-	Only Emergency data	Any health data they need related to current clinical	All health data	None	OTHERS ...

Question	Multiple answers allowed	Answer 1	Answer 2	Answer 3	Answer 4	Answer 5
			encounter			
if you are able to share your health data with any health care professional, it is important FOR YOU to have full control over exchanged data, i.e. to be able to hide some health data to specific Hospitals	-	1 to 5: 1= strongly disagree, 5= totally agree (1= not control; 5= full control)				
Are you willing to allow foreign (or from different Hospital/Regions/etc.) healthcare professionals to access to your health data?	Y	Only in emergency, when I am abroad	Only during specific clinic episodes when I am abroad	NEVER	ALWAYS	
What kind of health information is requested for your treatments? (think about documentation requested by Nurses and Doctors for visits, hospital admissions, procedures)	Y	Images (x-ray, Ultrasounds, etc.) and signals (ECG, EEG, etc.)	Clinical reports of Visits, evaluations, Hospital admissions, procedures	Specific healthcare data representing my status (e.g. allergy, weight, BMI, glycaemia, ecg, etc.)	Prescriptions	None
Which kind of health information is most difficult for you to share with a foreign healthcare professional?	Y	Images (x-ray, Ultrasounds, etc.) and signals (ECG, EEG, etc.)	Clinical reports of Visits, evaluations, Hospital admissions, procedures	Specific healthcare data representing my status (e.g. allergy,	Prescriptions	None

Question	Multiple answers allowed	Answer 1	Answer 2	Answer 3	Answer 4	Answer 5
				weight, BMI, glycaemia, ecg, etc.)		
Which kind of health information is more difficult for you to understand when provided by a foreign healthcare professional?	Y	Images (x-ray, Ultrasounds, etc.) and signals (ECG, EEG, etc.)	Clinical reports of Visits, evaluations, Hospital admissions, procedures	Specific healthcare data representing my status (e.g. allergy, weight, BMI, glycaemia, ecg, etc.)	Prescriptions	ALL
It is important to know who has accessed your data, where and when.	-	1 to 5: 1= strongly disagree, 5= totally agree				
After a visit/exam, how long are you willing to wait to receive your results from Hospital/Doctor to your phone?	-	few seconds	few minutes	few hours		
Are there any privacy/security issues you are particularly concerned with when using a mobile application to store your health data?	Y	Yes, I'm worried that someone not concerned about my data can see them	Yes, I may lose my phone hence my data	Yes, using my phone somebody (accidentally or on purpose) may alter my health	NO	OTHER, SPECIFY

Question	Multiple answers allowed	Answer 1	Answer 2	Answer 3	Answer 4	Answer 5
				data		
Are there any privacy/security issues you are particularly concerned about when sharing your health data with a foreign healthcare professional?	Y	Yes, somebody working at the health operator may see my personal data	Yes, I am afraid of data theft due to insufficient data security system	NO	OTHER, SPECIFY	
Do you think that this kind of tool will support my disease management.		1 to 5: 1= strongly disagree, 5= totally agree				
S-EHR would allow me to better follow the treatment prescribed		1 to 5: 1= strongly disagree, 5= totally agree				
I think that I will need technical assistance available to solve problems associated with the use of S-EHR.		1 to 5: 1= strongly disagree, 5= totally agree				
I don't have to remember to bring with me every kind of clinical report when I go for a follow-up visit, because I have everything on my phone.		1 to 5: 1= strongly disagree, 5= totally agree				
I think it would be easy for me to learn how to use S-EHR		1 to 5: 1= strongly disagree, 5= totally agree				

Question	Multiple answers allowed	Answer 1	Answer 2	Answer 3	Answer 4	Answer 5
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)?	Y	Yes, only if data are used for that research	Yes, only if my data are not used to identify me	Yes, only if I am informed on the results of the study	NO	Yes, only if the organization can convince me that my data will never be sold.
Are you willing to give your health data for free to a Public-Body organization?		1 to 5: 1= strongly disagree, 5= totally agree				
Are you willing to give your health data for free to a private organization?		1 to 5: 1= strongly disagree, 5= totally agree				
Would you like to donate your health data to a research centre for future research also if you do not know the specific usage?		YES, my data may be useful in the future	YES, BUT only to know if I am a candidate to a research	NO, I want to send data only for the specific research for which I can apply		
Are you willing to allow research organizations to access to your health data?	Y	Only for specific study that involves my condition or disease	Only for some kind of generic population studies (not related to my specific	Only if I cannot be identified	NO	YES, I am willing to give my data to any research organization without

Question	Multiple answers allowed	Answer 1	Answer 2	Answer 3	Answer 4	Answer 5
			condition)			constraint
Would you like to know the partners of research protocols Organizations/multicentric research/industry	Y	1 to 5: 1= strongly disagree, 5= totally agree				
Are you willing to allow research organizations authorized on the SEHR platform to contact you?	-	1 to 5: 1= strongly disagree, 5= totally agree				
Are you willing to allow research organizations authorized in SEHR platform to contact you and better understand if you can be a candidate for a research?		1 to 5: 1= strongly disagree, 5= totally agree				
Are there any privacy/security issues you are particularly concerned with in sharing your health data with a research institution?	Y	Yes, they could use my data for another research without my permission	Yes, they could use my data for ads or donation requests	Yes, Data Breach (see GDPR)	Yes, they could be sold	Yes, if data were given were poorly pseudonymized/anonymized they can identify me back again
Are you willing to add specific data to your SEHR, requested by a research organization, only to participate in a research?		1 to 5: 1= strongly disagree, 5= totally agree				

Table 10 - Patient Questionnaire

7.1.3. 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.)

7.1.4. 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.

Even though many patients have never consulted abroad or at an unusual hospital, all of them have been considered that in the future they may ask for healthcare advice while far from home.

Among the few who had consulted far from home, no one had any paper or electronic support of their healthcare records. Therefore, they had to explain their healthcare past orally.

All participants thought that in the future they would need to use their health data while abroad. Participants were mainly interested in sharing their current prescription.

The Wallonia Region in Belgium has set up the Walloon Health Network (WHR), a secure platform storing healthcare data that can be used by doctors and patients. Many interviewees consult their EHR stored in the WHR and seem to be very satisfied with the service of this platform.

The Tuscany Region has a Regional EHR system, as part of the national EHR federation, but no patient is actually using that system to exchange information when abroad.

We have to acknowledge that some patients of Hygeia Group have some experience with Electronic Health Records that the general population in Greece may not have, since there is no National EHR portal for patients.

The participants liked the idea of having their health dated stored on their mobile device. Main concerns were regarding the security of data and the ease of using the application.

In general, patients have shown some distrust to share their healthcare data via software. The theft of data that hospitals suffer from is at the basis of this fear. Nonetheless, most of the interviewed patients appreciate the idea to be able to consult their data at any time through a software.

On the contrary, patients differ completely in their opinion on the proposition to enter by themselves health data. The same applies to data sharing possibilities with relatives. Indeed, half of the interviewed patients agree for both propositions while the other half completely disagrees. Interestingly, neither of these 2 questions gives mixed answers.

Far from it, there is a full agreement for an application that is extremely easy to manage. Patients want to avoid loss of time in solving how the application works. Most of them even affirm that a simple complication will discourage them from using the application.

Besides application management, patients are concerned about data security. The word “cloud” is for most of them synonymous with data leakage. In addition, concerns about the economic profit that some people and even entities could make with their data have been several times pronounced. This is in line with their wish to use a server managed by public authorities they consider as a protective entity of data security in compliance with ethics and the rules of law.

Most of the patients claim they do not have anything to hide and agree that HCP will provide better care based on their complete health record. Nevertheless, the possibility to use an application with a data sharing decision tool seems very attractive to some patients. Indeed, these patients are concerned about the prejudging that some HCPs could have upon them.

Images and signals are the most difficult information to understand and therefore to share. Yet, this does not seem to be an obstacle to adhere to the solution since patients believe that the most important data to share during a consultation are healthcare reports and specific health data representing their health status.

Obtaining the results after a few hours will not discourage patients to adhere to the application since most of them do not have the need to get them very quickly (seconds -minutes).

Although patients approve that better management of their health can be reached with the application, they have some concerns about the possibility to have technical assistance. They are wondering if hospitals could assist them with technical issues. In addition, several of the interviewed patients pointed out that elderly (> 65 y) do not have a smart-phone and those who have one use it only for phoning or sending text messages.

Regarding research, the participants would share their healthcare data only for specific research, for free for public institutions, but were reluctant when private institutions could be involved.

Again, through this scenario, fear of misuse of their health data is stressed by all the patients.

In Annex 1 it is reported analytical results of questionnaires.

7.2.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 (FTGM, SCUBA, HYG and CHU) 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.

7.2.1. 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 user for 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.

At the end of the recruitment process, selected focus group members were:

- SCUBA: 3 physicians and 3 nurses from the Cardiology Department.
- HYG: 5 nurses and 4 physicians.
- FTGM: 3 nurse and 4 physicians.
- CHU: 3 nurses and 10 physicians.
- ISA: 100 physicians.

7.2.2. 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	Multiple answers allowed	Answer 1	Answer 2	Answer 3	Answer 4	Answer 5
For foreign patients, would you like to access to their health data coming from EHR of other countries?	-	YES, to all clinical history of the patients	YES, but only for relevant clinical information. I don't have time to evaluate a lifespan EHR.	YES, especially for invasive or complex examinations (Xray, CT, surgery biopsy, etc.)	NO, at all, it does not make sense	
Would you let patients to share with you their relevant health data just moving their mobile	-	YES	NO	OTHER:		

Question	Multiple answers allowed	Answer 1	Answer 2	Answer 3	Answer 4	Answer 5
phone to your healthcare setting workstation or mobile device?						
How long do you expect it to spend for the transmission of information from the patient's cell phone?	-	1-5 sec	up to 1 minute	up to 10 minutes		
How long do you expect it to spend for the transmission of information from the cloud?	-	1-5 sec	up to 20 sec	up to 1 minute		
Are you used to share electronic information with your patients?	-	YES	NO	OTHER:		
If the answer to the question above is yes, what kind of information are you currently sharing and using which system?	-	WhatsApp	Telegram	Text Messages	email	OTHER:...
Are you used to share electronic health-related information with other hospitals?	-	YES	NO	OTHER:		
If you answered yes to the question above, what kind of information are you currently sharing, on what occasion and using which tool?	-					
Are you happy with the current way of collaboration with other EU/National/regional Hospitals?	-	1 to 5: 1= strongly disagree, 5= totally agree				
Do you have any national or regional platform that supports EHR data exchange?	-	1 to 5: 1= strongly disagree, 5= totally agree				
Do you have any suggestions on how to improve this collaboration based on your experience and expectations?	-					
Do you think it is a good idea to	-	1 to 5: 1= strongly				

Question	Multiple answers allowed	Answer 1	Answer 2	Answer 3	Answer 4	Answer 5
allow patients to share with you their Electronic Medical Records or any other certified health information stored in their mobile phones or cloud?		disagree, 5= totally agree				
Are there any security/privacy and ethical issues you see in adopting such solutions?	-	YES, please elaborate	NO, please elaborate:			
if a patient arrives at the emergency room in a state of confusion or unconsciousness, and you need to provide first aid, do you think it is useful to access his/her historical health data?		1 to 5: 1= strongly disagree, 5= totally agree				
if yes, which are the most relevant	Y	Allergies	Chronic Diseases	acute diseases	current medication	past medication
if yes, which are the reference times for historical data?	Y	few hours ago	few days ago	last year	forever	
Do you think it is a good idea to allow patients to share personal health data, entered from paper documents?	-	1 to 5: 1= strongly disagree, 5= totally agree				
does it make sense to you to aggregate data from HCP as well as wellbeing ones (not produced by medical devices, such as smartwatches, home scale, etc.)?		1 to 5: 1= strongly disagree, 5= totally agree				
Do you think that patients should be able to add personal health information?		1 to 5: 1= strongly disagree, 5= totally agree				
Would be interesting to add GP/specialist reference to contact?		1 to 5: 1= strongly disagree, 5= totally agree				

Question	Multiple answers allowed	Answer 1	Answer 2	Answer 3	Answer 4	Answer 5
How much this new development will support daily work?		1 to 5: 1= strongly disagree, 5= totally agree				
Do you expect that this kind of system will be useful for your job?		1 to 5: 1= strongly disagree, 5= totally agree				
Do you think that this kind of tool will be useful to the patient to empower the management of his/her condition?		1 to 5: 1= strongly disagree, 5= totally agree				
IEHR PLATFORM would allow me to make decisions about diagnosis and treatment of my patients based on better evidence		1 to 5: 1= strongly disagree, 5= totally agree				
I think that in my Healthcare Facility I will have technical assistance available to solve problems associated with IEHR		1 to 5: 1= strongly disagree, 5= totally agree				
IEHR PLATFORM could increase my effectiveness of diagnostic and treatment of my patients		1 to 5: 1= strongly disagree, 5= totally agree				
I think I will use IEHR PLATFORM for the diagnostic and treatment of my patients when available on my centre		1 to 5: 1= strongly disagree, 5= totally agree				
I think that navigation within IEHR PLATFORM would be easy.		1 to 5: 1= strongly disagree, 5= totally agree				
I already have the needed technical (PC, Workstation, mobile devices) and human resources (IT support) to use IEHR PLATFORM		1 to 5: 1= strongly disagree, 5= totally agree				
I think that my interaction with IEHR PLATFORM will require		1 to 5: 1= strongly disagree, 5= totally				

Question	Multiple answers allowed	Answer 1	Answer 2	Answer 3	Answer 4	Answer 5
much effort for my share		agree				
I think IEHR PLATFORM will be compatible with other systems that I use		1 to 5: 1= strongly disagree, 5= totally agree				

Table 11 - HCP Questionnaire

7.2.3. 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.

7.2.4. Response Analysis and Interpretation

Response interpretation is difficult to classify in a general perspective, due to heterogeneous experience and IT ecosystem deployed in hospital where the Healthcare professional works.

Some hospitals are provided with a complete Clinical Information System, and answers are implicitly affected by functionality already implemented for them, such as integration among different clinical subsystems (LIS, RIS-PACS, etc.), while other hospitals where lower levels of digitalisation and/or integration among systems are implemented, HCP were strongly asking for a wider spectrum of functionalities and system integrations.

The same principle is observed for Regional and National level EHR systems, but in this case a major absence of this kind of system is reported along the nations of participants.

In general, the participants embraced the idea of an S-EHR platform that could help them in their daily clinical practice. The main concern was about the possible overwhelming with information.

Several physicians accept that the transfer of patient data takes up to 10 min in scenario 1. They argue that this is a small price to pay for obtaining a big quantity of healthcare data which moreover will avoid to repeat exams. These same physicians accept the biggest delay (up to 1 min) for the data transfer during emergency (scenario 2).

HCPs are aware that in an emergency they will not have time to go through the whole patient's healthcare history, nevertheless once the emergency is controlled, they will rely on the whole healthcare history to take future health decisions.

Basically, the HCPs wanted to know about the chronic diseases and only the most recent data (check-ups, investigations etc. from last year). Also, they would prefer to have the imaging studies available (at least the report) and test results. HCPs would wait for up to 1 minute for the data transfer.

Some hospitals have their own EHR system but have no national platform that supports EHR data exchange or interoperability with other hospitals. Some national Electronic Health System is in a primitive stage and consists mainly of prescriptions and the diagnoses inserted by the prescribing physician.

One of the main concerns of the HCP group seems to be technical support to use the IEHR platform.

Most HCPs express dissatisfaction with the collaboration with other hospitals either at the national/regional level or at the European one.

HCPs propose an international standardized and open electronic platform avoiding above all local solutions. They would like to see a European Health Network where an identified HCP could consult data after justification. Moreover, the proposed platform should ensure data traceability and contain a uniform healthcare record with an international disease codification.

Regarding the answer to the question on security / privacy and ethical issues, those who do not see any implication of these issues in adopting the solutions proposed by IEHR explain this opinion based on the principle of confidentiality and professionalism of the HCP; However, they deem a written agreement between the patient and the HCP necessary for this purpose, in accordance with current legislation, and on condition that the SW used is safe.

In the context of data leaks, HCPs want to be sure that exchanges between hospitals are under the responsibility of the hospitals and not HCPs, but is widely demonstrated that main cyber-threats are represented by human errors and human behaviours, so the desired request cannot be satisfied, the single person must be aware of every action performed and eventually data leaked by his/her responsibility.

Most HCPs are positive about the proposed solution and are intending to use it since they strongly believe that it will enhance differential diagnosis. Nevertheless, there has been a reluctance to allow patients to enter data by themselves. They suggested adoption of a colour code differentiating data registered by patients/family caregivers from other ones authored by hospitals and professional healthcare providers.

Most HCPs think that the proposed solution will help patients, especially the younger, to better manage their disease. However, some patients, usually the elderly, are not interested in getting more autonomy. They prefer HCPs showing a paternalistic attitude with whom they can rely on.

In Annex 1 the analytical results of questionnaires are reported.

7.3.Researchers Focus Groups

Researcher Focus Groups was 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 (FTGM, SCUBA, HYG and CHU) 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.

7.3.1. Participant Recruitment

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 user for 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.

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 physicians.
- HYG: 7 researchers.
- FTGM: 5 researchers.
- CHU: 5 researchers.

7.3.2. 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.

Question	Multiple answers allowed	Answer 1	Answer 2	Answer 3	Answer 4	Answer 5
I like the idea to allow citizens to candidate their participation to your study using their mobile	-	1 to 5: 1= strongly disagree, 5= totally agree		OTHER:		

Question	Multiple answers allowed	Answer 1	Answer 2	Answer 3	Answer 4	Answer 5
devices						
I like to receive the health data for your study directly from citizens via their mobile devices	-	1 to 5: 1= strongly disagree, 5= totally agree				
I developed a research study involving patients with age < 14yy		YES	NO			
Which is the average dimension of cohorts involved in your studies?	-	up to 100	up to 1000	up to 10000	more than 10000	
Which kind of information you would like to receive directly from the Citizen	Y	Prospective Clinical data	Retrospective clinical data			
Are anonymized data enough for your research?	-	No, I need fully de-anonymized data	No, I need de-identified data	YES		
Which kind of data aggregation could be exploitable for your research?	Y	Aggregation of data of single citizens	Aggregation of data of multiple citizens	No one	OTHER:	
In which kind of format you would like to receive the research data	Y	CSV	Excel	XML	DB Table	OTHER: .....
Which kind of tools you currently use to elaborate research data?	Y	SPSS	RapidMiner	GNU R	JMP	Stata

Table 12 - Researchers Questionnaire

7.3.3. 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.)

7.3.4. Response Analysis and Interpretation

Most researchers like very much the idea of getting their data directly from patients. However, they fear that elderly patients do not adhere to this solution.

Researchers working with big data (i.e. geneticists) only need anonymized data.

On the other hand, after completing their studies, other researchers will need to have access to patient data in order to understand some results, so pseudonymized data is necessary.

Interviewees liked the possibility of allowing individual patients to apply for a research study, who saw a way of increasing, in a simple manner, the number of participants in the study. While others do not always consider it useful as they often perform studies with follow-up research and consider it important to perform studies on a local population, suitable for performing instrumental control examinations at regular intervals.

Receiving data through mobile devices has aroused some interest, especially if these data are certified by hospitals, and do not use manually entered data.

A researcher has had the opportunity to carry out research on patients under the age of 14, this generally depends on the type of daily clinical activity he performs, and everyone believes that the collection should be allowed even by children, provided that all the inherent privacy regulations are respected.

The data collected by the researchers must be both prospective and retrospective; each type of data collected is indispensable, especially with a view to broad-spectrum research or with a view to applying big data analysis and deep learning techniques.

The preferred exchange format is the Excel format, both in the Microsoft and Open Office versions. In addition to being the best known by researchers, it is easily usable through a large number of proprietary and open source statistical programs, and is compatible with the most common data cleaning programs (like Openrefine, Trifacta or Textwrangler).

The software used for statistical processing, by the interviewed research personnel, turns out to be Statview 5 and SPSS. The fist is obsolete but still valid program that is widely used due to its simple usage and nice graphic interface, the second is well known and expensive statistical software.

In Annex 1 are reported analytical results of questionnaires

8. CONCLUSIONS AND NEXT STEPS

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

Similarly to other reports of the InteropEHRate project, this document presents just a first draft of the intended content, reflecting the current understanding by the project consortium. Two other updated versions of this report are planned, one on March 2020 and another one on March 2021.

The following versions could introduce other elements to the list of functionalities that could be derived from the activities of the Focus group, and therefore useful for experimental use, and some adaptations related to the presentation of the experimental protocol to the reference ethical committee.

9. REFERENCES

[D3.1] InteropEHRate Consortium. D3.1: Specification of S-EHR mobile privacy and security conformance levels, due on March 2020. (www.interopehrate.eu/resources)

[D5.1] InteropEHRate Consortium. Software requirements specification of an integrated EHR web app for HCP, June 2019. (www.interopehrate.eu/resources)

[D5.7] InteropEHRate Consortium. Design of the data integration platform, due on September 2019. (www.interopehrate.eu/resources)

[D6.1] InteropEHRate Consortium. Software requirements & architecture specification of an S-EHR, June 2019. (www.interopehrate.eu/resources)

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

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

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

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

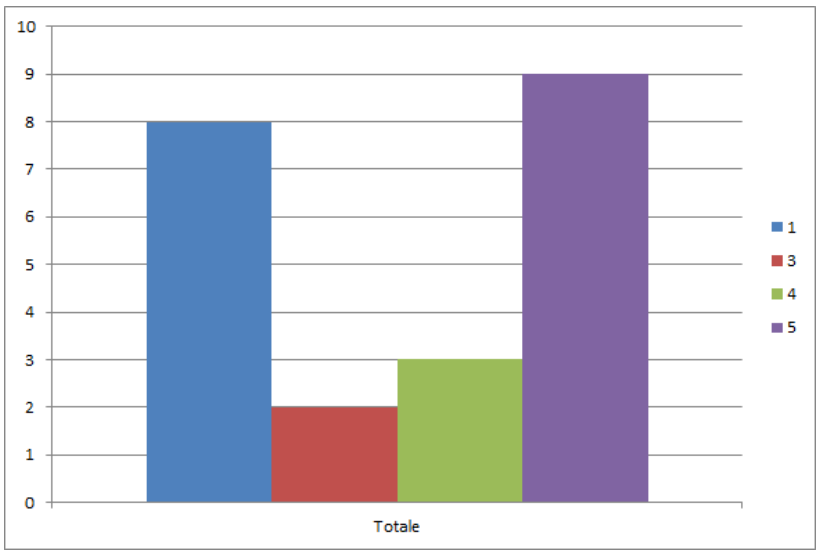
10. ANNEX 1

10.1. Patient Focus groups Response

In the following analytical results of questionnaires.

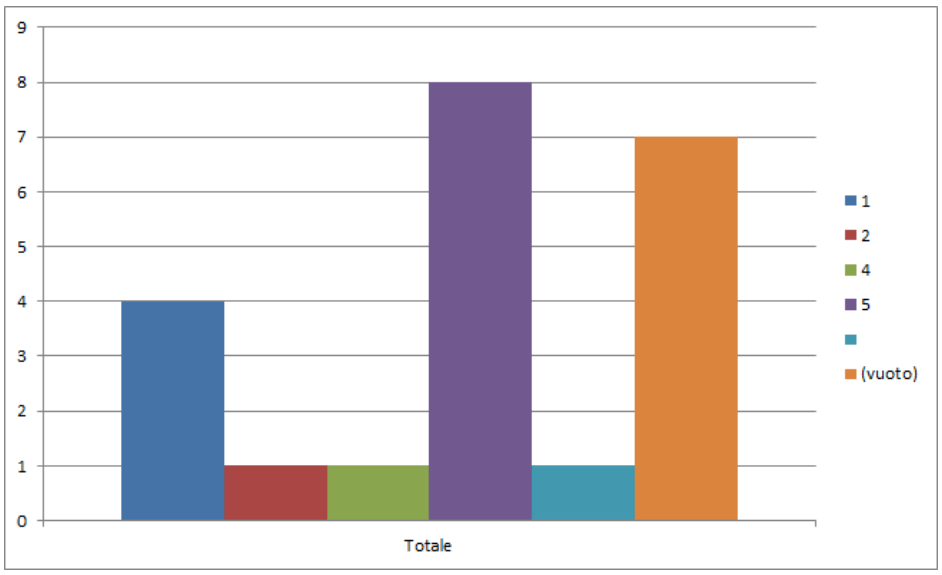
- *Have you ever needed a medical visit while abroad (different cities or regions)?*

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



- *If you have answered yes to previous question, did you share some health data with Health care professionals?*

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



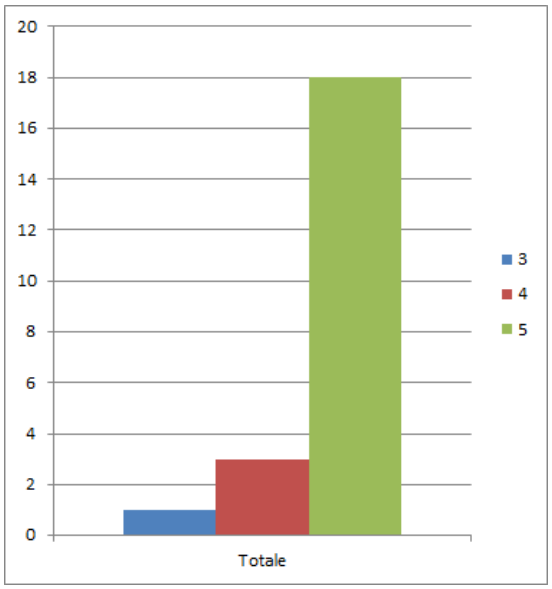
- *(if Yes) and How?*

Answers collected, not structured:

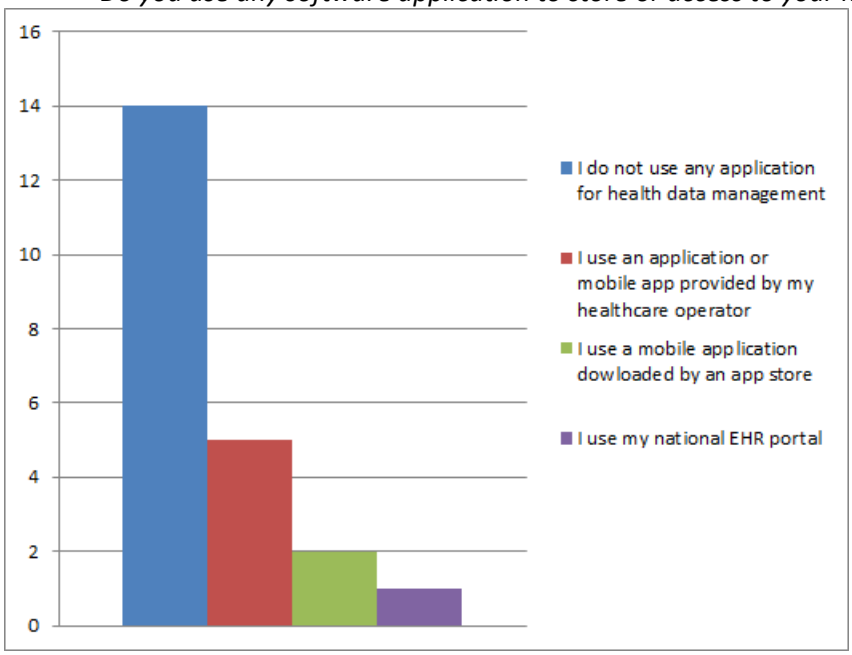
- voice, unable to transmit other information
- voice, unable to transmit other information
- voice, paper docs
- voice translation by his/her son (wasn't a physician/nurse)

- *Have you ever thought that in the future you will need to share your health data abroad?*

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

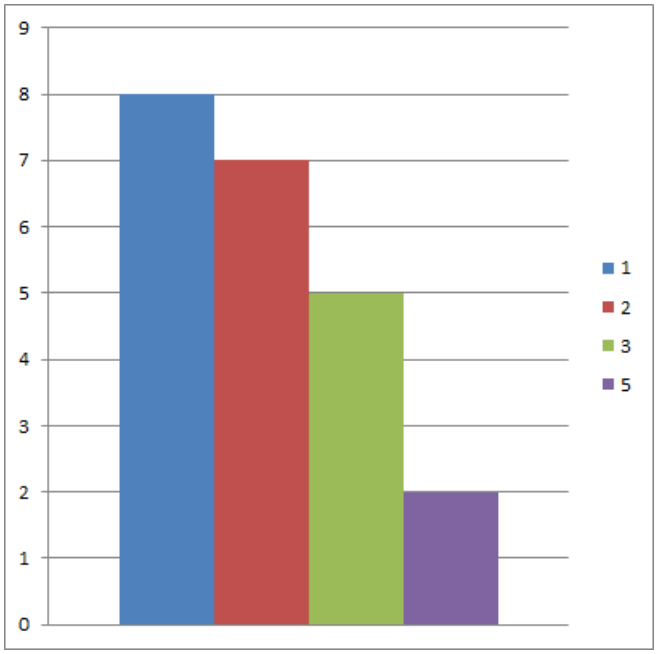


- *Do you use any software application to store or access to your health data?*

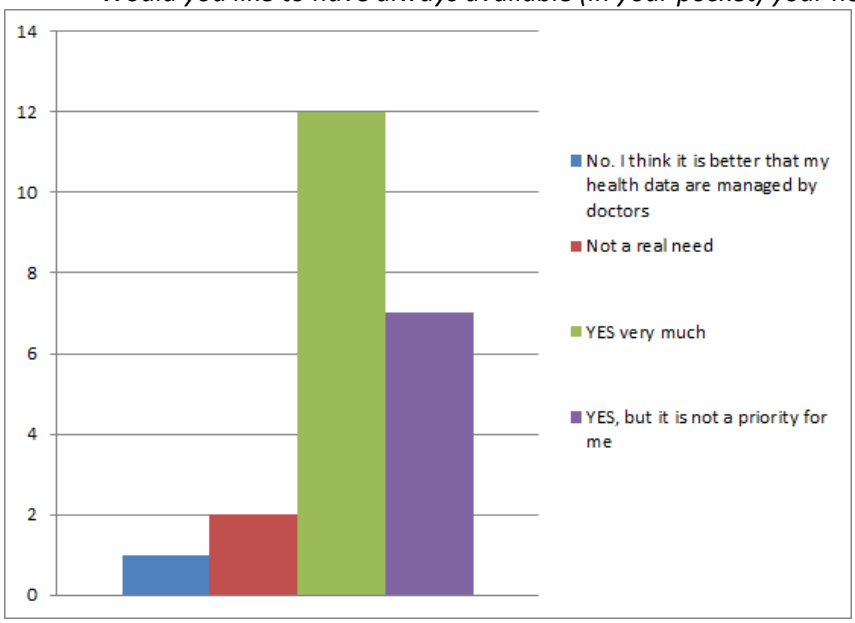


- *If you had the opportunity, would you be afraid to share your medical data through a software application?*

Answer= 1 to 5: 1= strongly disagree, 5= totally agree (1=not afraid: 5=extremely afraid)

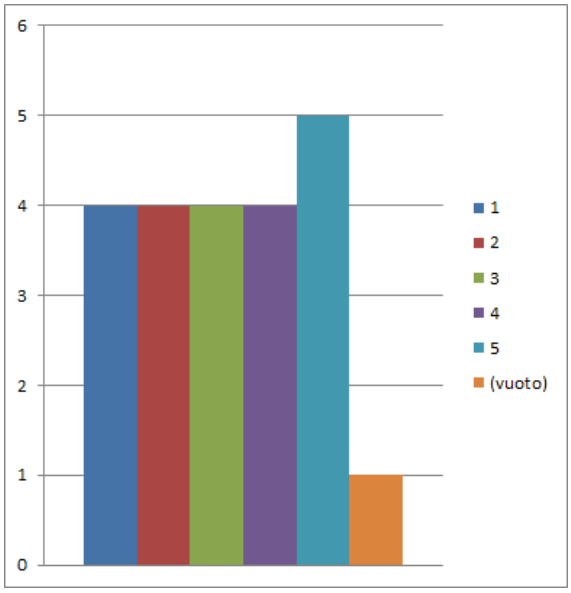


- *Would you like to have always available (in your pocket) your health data?*



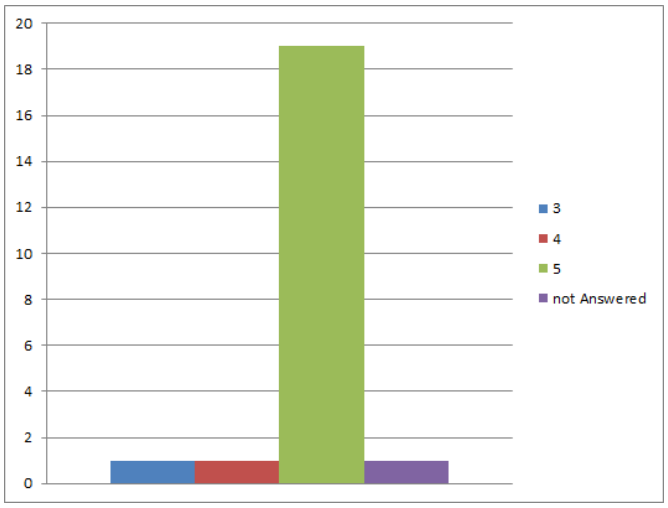
- *My preferred feature of the software application you use to access or manage my health data: I can store clinical data by myself*

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



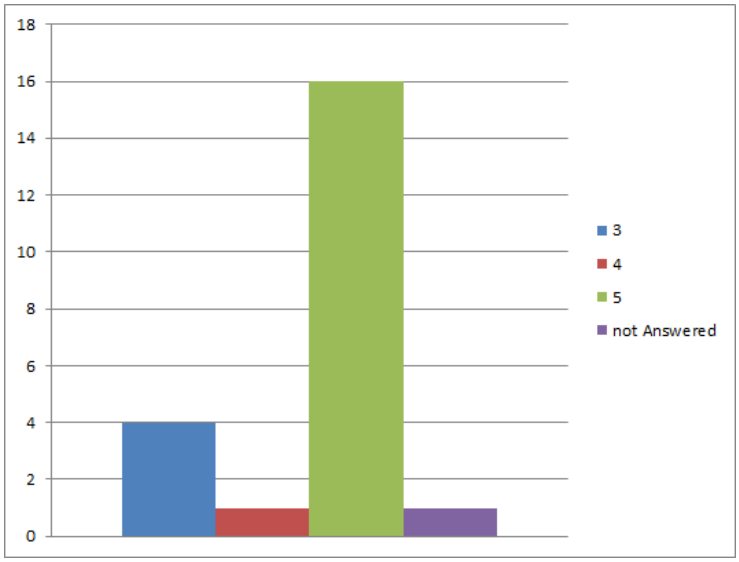
- *My preferred feature of the software application you use to access or manage my health data: I can access to clinical data provided by my healthcare operator/s*

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



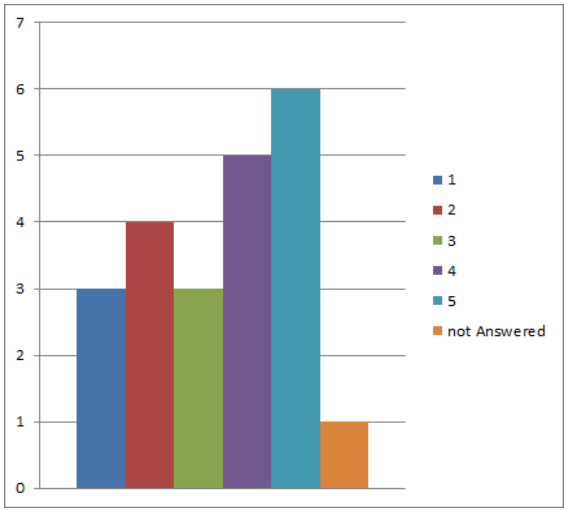
- *My preferred feature of the software application you use to access or manage my health data: I can bring my health data with me.*

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



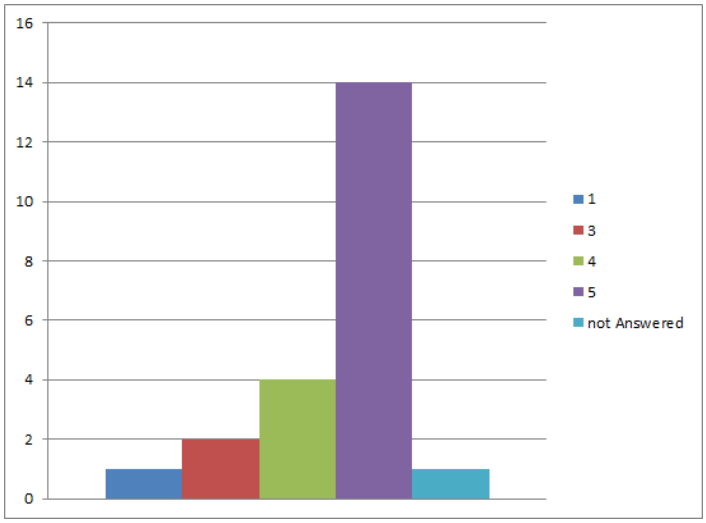
- *My preferred feature of the software application you use to access or manage my health data: I can show/share my health data with my close relatives/entourage very quickly ù*

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



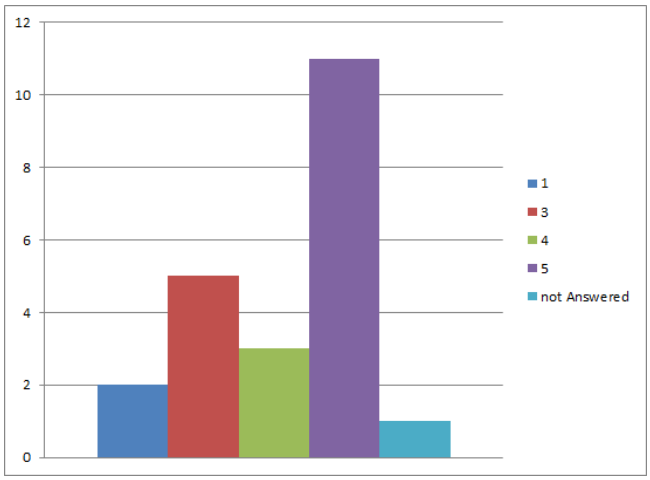
- *The feature I do not like of the software application I use to access or manage your health data is: The complexity and the absence/lack of security*

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



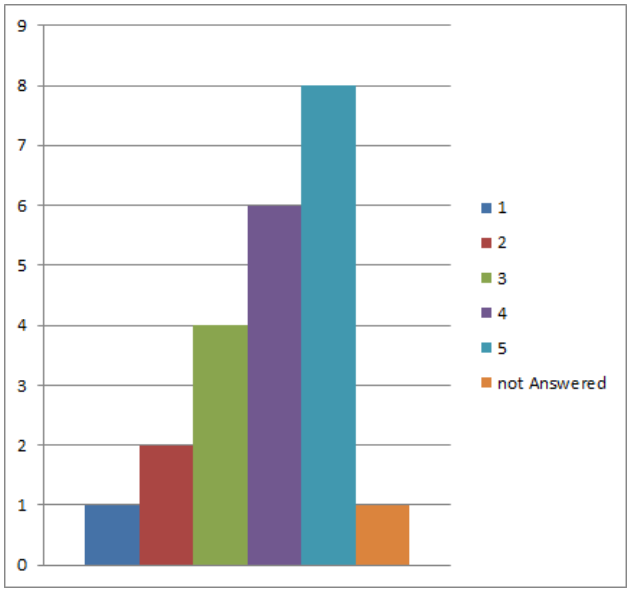
- *The feature I do not like of the software application I use to access or manage your health data is: absence/lack of ergonomic*

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



- *The feature I do not like of the software application I use to access or manage your health data is: absence/lack of functionalities*

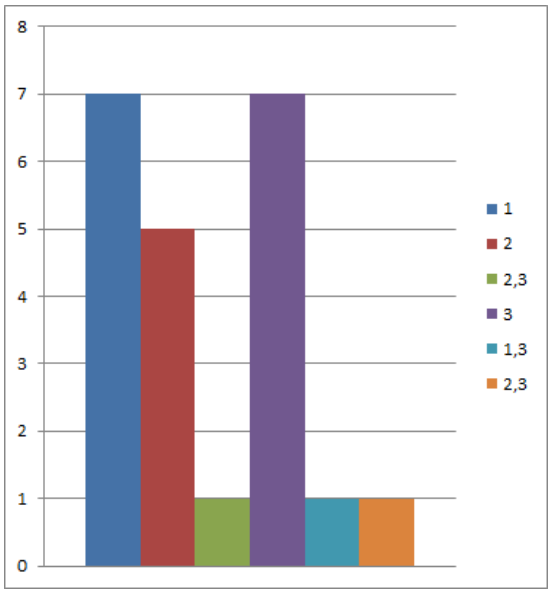
Answer= 1 to 5: 1= strongly disagree, 5= totally agree



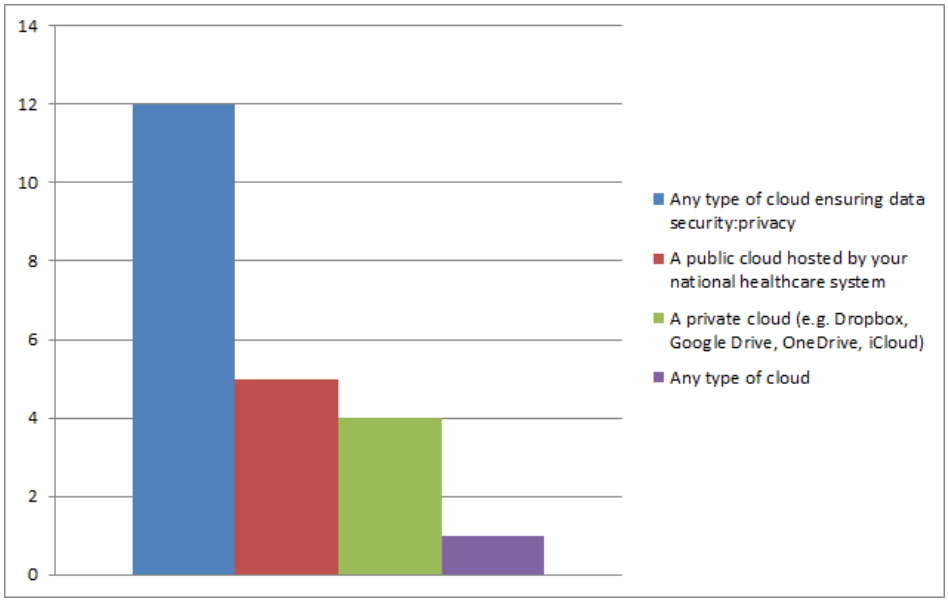
- *Are you willing to store your healthcare data on the S-EHR cloud?*

Answers:

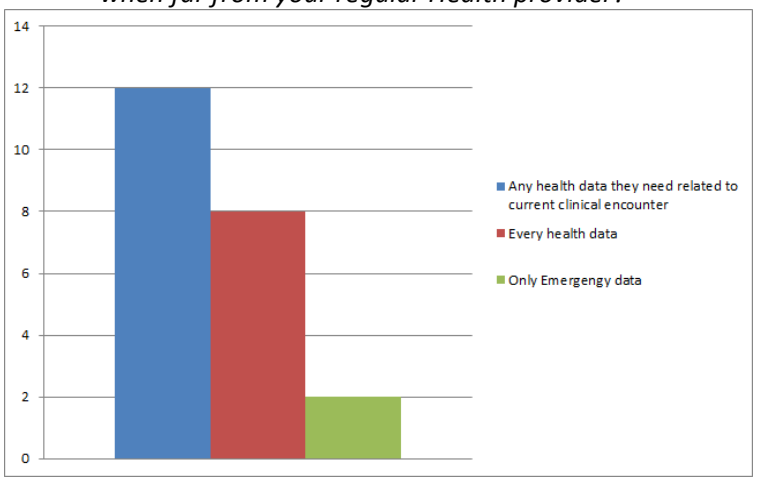
1. *Yes, but only for emergency data*
2. *Yes, for any personal health data*
3. *Yes, if they are deployed within a secure server and nobody can see my data without my authorization*
4. *NO*



- *If you have answered yes to the previous question, which of the following solution would you prefer?*

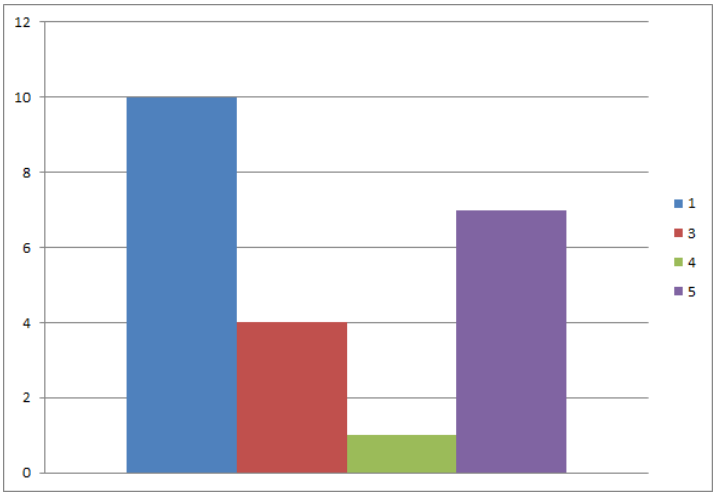


- *What kind of information (health data) do you need to exchange with healthcare professionals when far from your regular Health provider?*

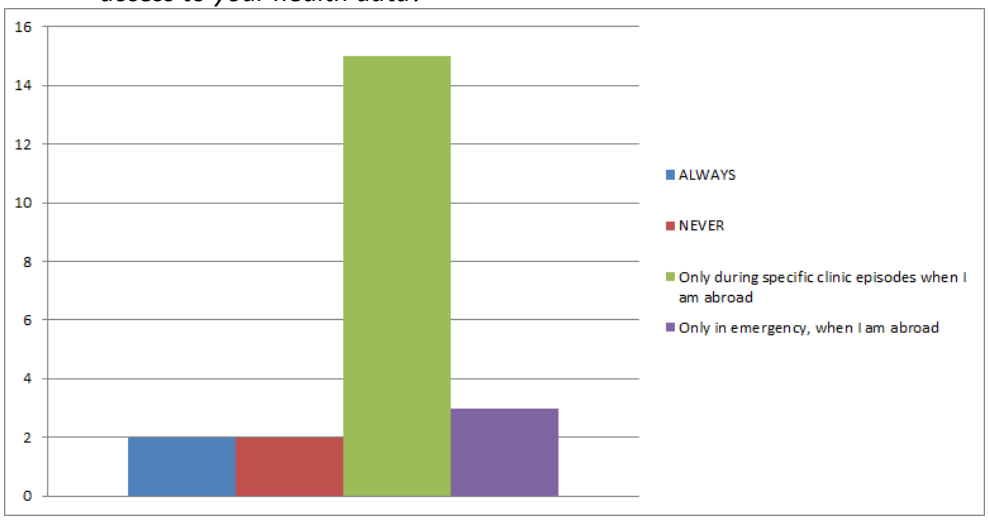


- *if you are able to share your health data with any health care professional, is important FOR YOU to have full control on exchanged data, i.e. to be able to hide some health data to specific Hospitals*

Answer= 1 to 5: 1= strongly disagree, 5= totally agree (1= not control; 5= full control)



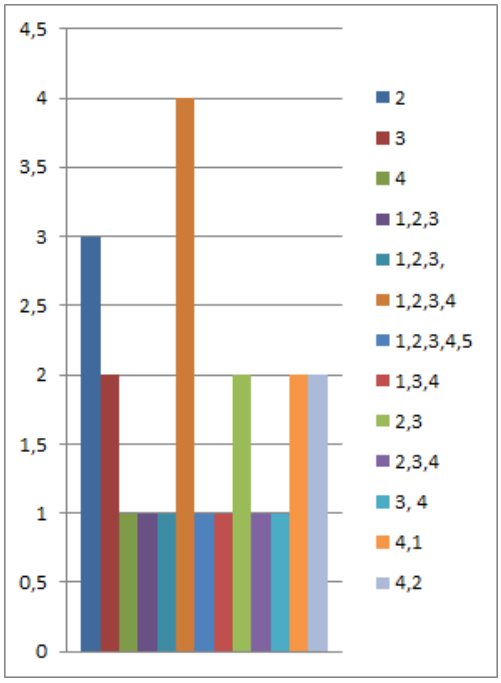
- *Are you willing to allow foreign (or from different Hospital/Regions/etc.) healthcare professionals to access to your health data?*



- *Which kind of health information are requested for your treatments? (think about documentation requested by Nurses and Doctors for visits, Hospital admissions, procedures)*

Answers:

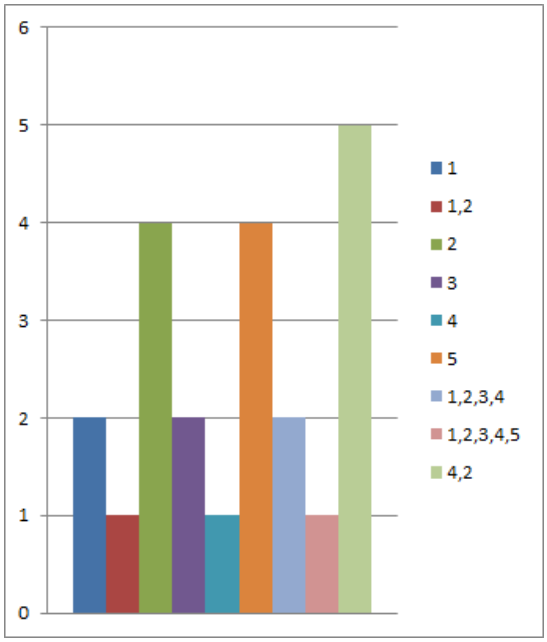
1. *Images (x-ray, Ultrasounds, etc.) and signals (ECG, EEG, etc)*
2. *Clinical reports of Visits, evaluations, Hospital admissions, procedures*
3. *Specific healthcare data representing my status (e.g. allergy, weight, BMI, glycaemia, ECG, etc.)*
4. *Prescriptions*
5. *None*



- *Which kind of health information is most difficult for you to share with a foreign healthcare professional?*

Answers:

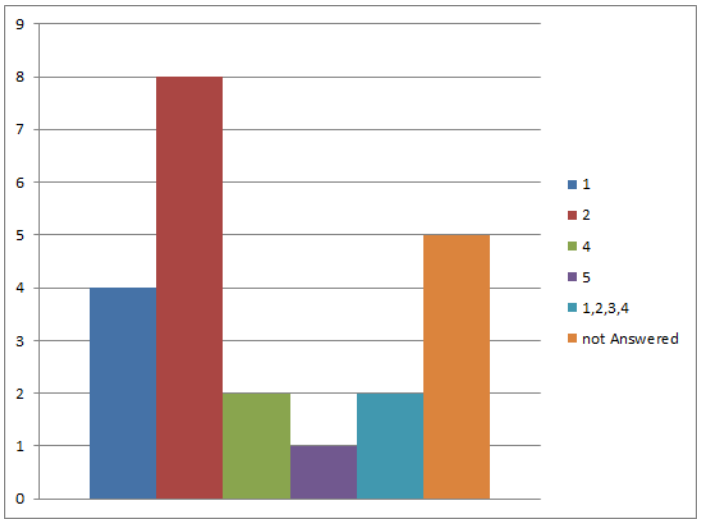
1. *Images (x-ray, Ultrasounds, etc.) and signals (ECG, EEG, etc.)*
2. *Clinical reports of Visits, evaluations, Hospital admissions, procedures*
3. *Specific healthcare data representing my status (e.g. allergy, weight, BMI, glycaemia, ECG, etc.)*
4. *Prescriptions*
5. *None*



- *Which kind of health information is more difficult for you to understand when provided by a foreign healthcare professional?*

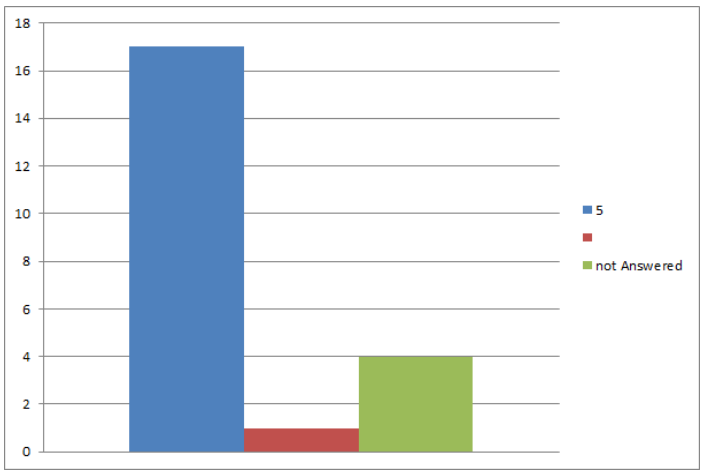
Answers:

1. *Images (x-ray, Ultrasounds, etc.) and signals (ECG, EEG, etc.)*
2. *Clinical reports of Visits, evaluations, Hospital admissions, procedures*
3. *Specific healthcare data representing my status (e.g. allergy, weight, BMI, glycaemia, ECG, etc.)*
4. *Prescriptions*
5. *None*

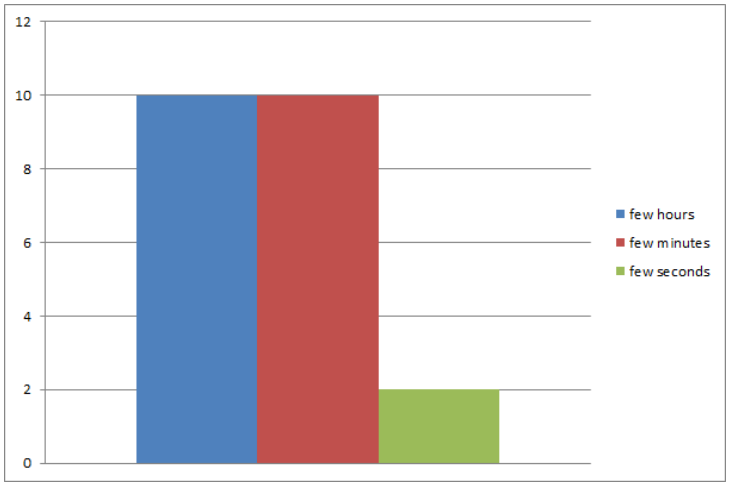


- *Is important to know who has access to your data, where and when.*

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



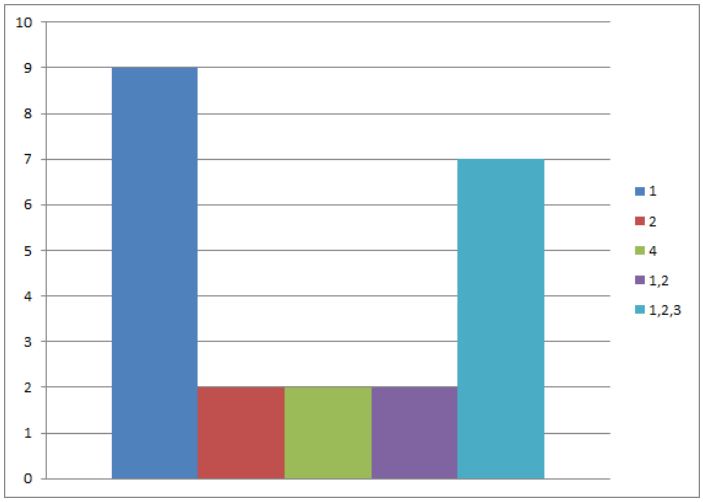
- *After a visit/exam, how long are you willing to wait for receiving your results from Hospital/Doctor to your phone?*



- *Is there any privacy/security issue you are particularly concerned with in using a mobile application to store your health data?*

Answers:

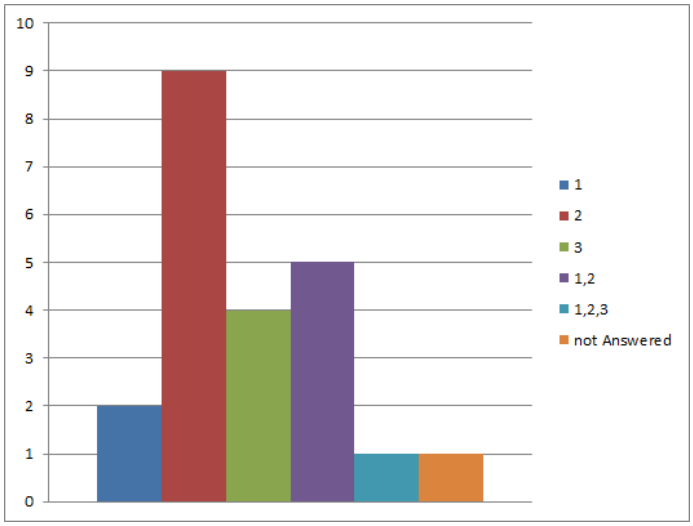
1. *Yes, I'm worried that someone not concerned about my data can see them*
2. *Yes, I may lose my phone hence my data*
3. *Yes, using my phone somebody (accidentally or on purpose) may alter my health data*
4. *NO*



- *Is there any privacy/security issue you are particularly concerned in sharing your health data with a foreign healthcare professional?*

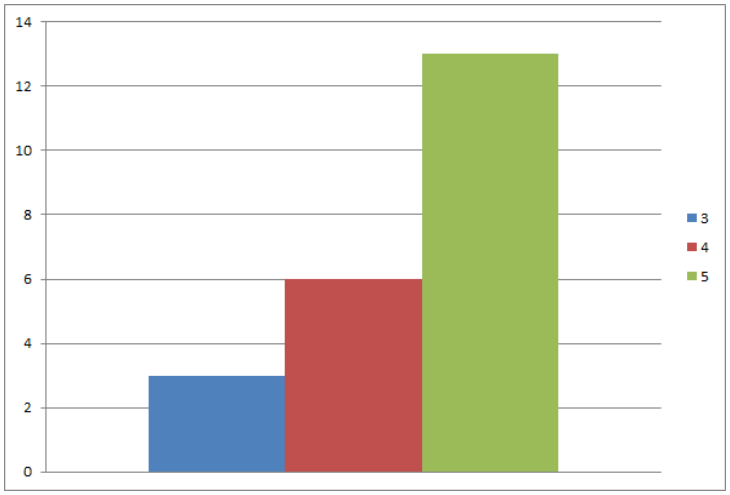
Answer=

1. *Yes, somebody working at the health operator may see my personal data*
2. *Yes, I am afraid of data theft due to insufficient data security system*
3. *NO*



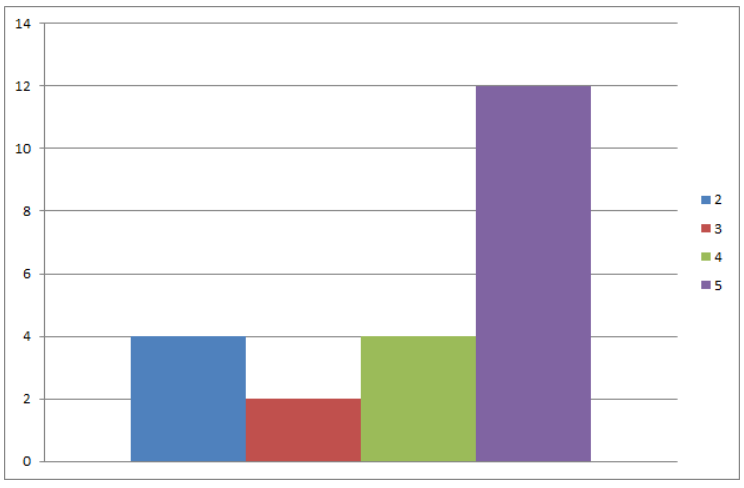
- *Do you think that this kind of tool will support my disease management?*

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



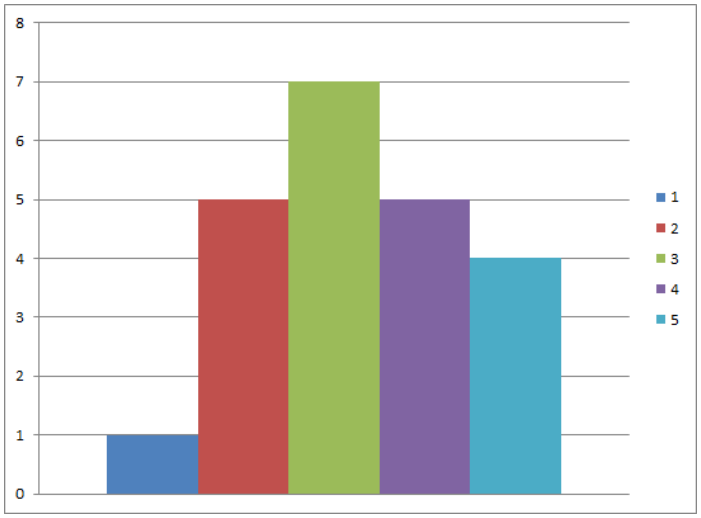
- *S-EHR would allow me to follow better the treatment prescribed*

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



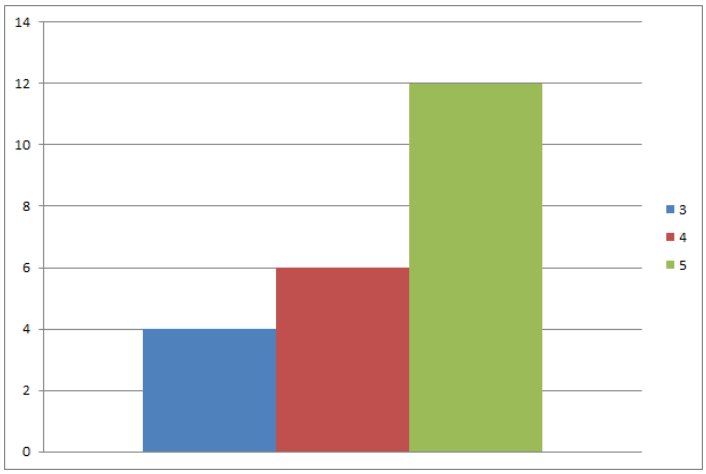
- *I think that I will need technical assistance available to solve problems associated to the use of S-EHR.*

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



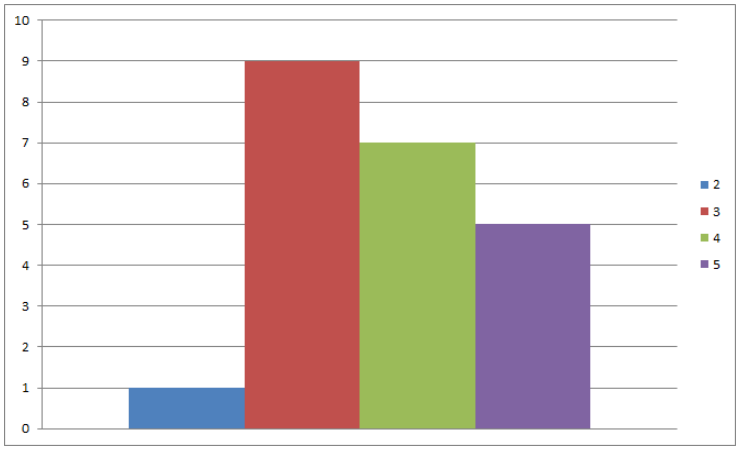
- *I don't have to remember to bring with me every kind of clinical report when I go to follow-up visit, because I have everything on my phone*

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



- *I think it would be easy to me learning how to use S-EHR*

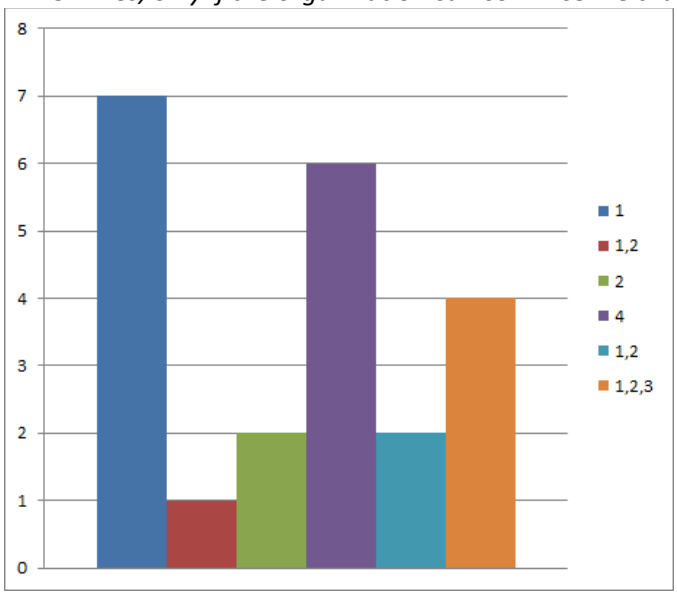
Answer= 1 to 5: 1= strongly disagree, 5= totally agree



- *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)?*

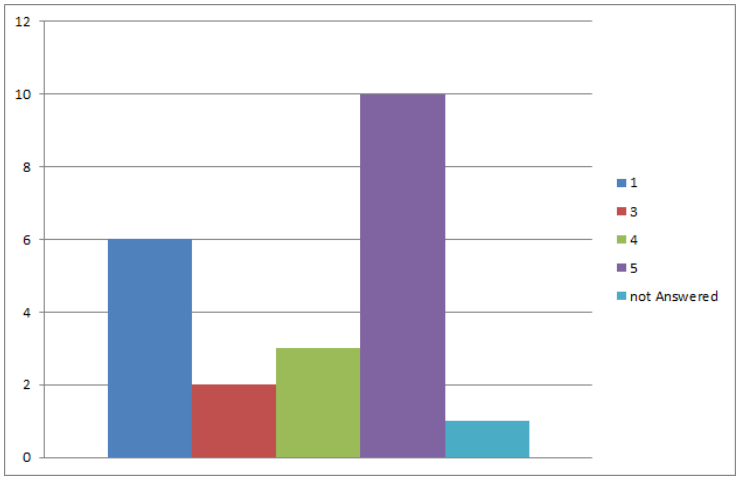
Answers:

1. *Yes, only if data are used for that research*
2. *Yes, only if my data are not used to identify me*
3. *Yes, only if I am informed on the results of the study*
4. *NO*
5. *Yes, only if the organization can convince me that my data will never be sold.*



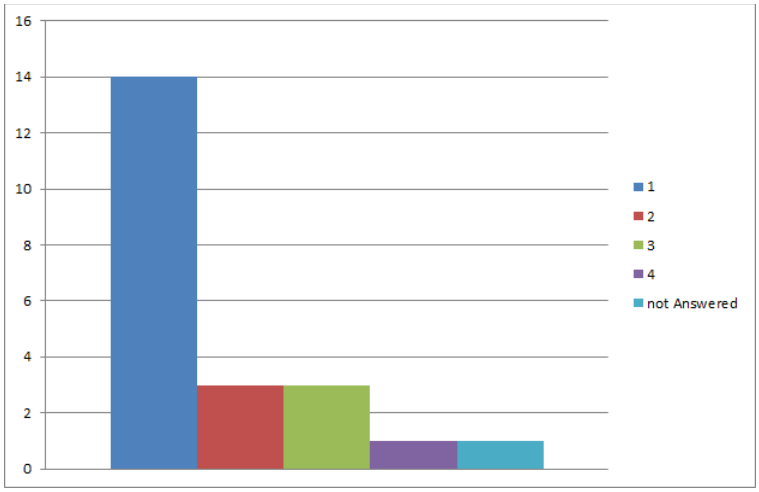
- *Are you willing to give your health data for free to a Public-Body organization?*

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

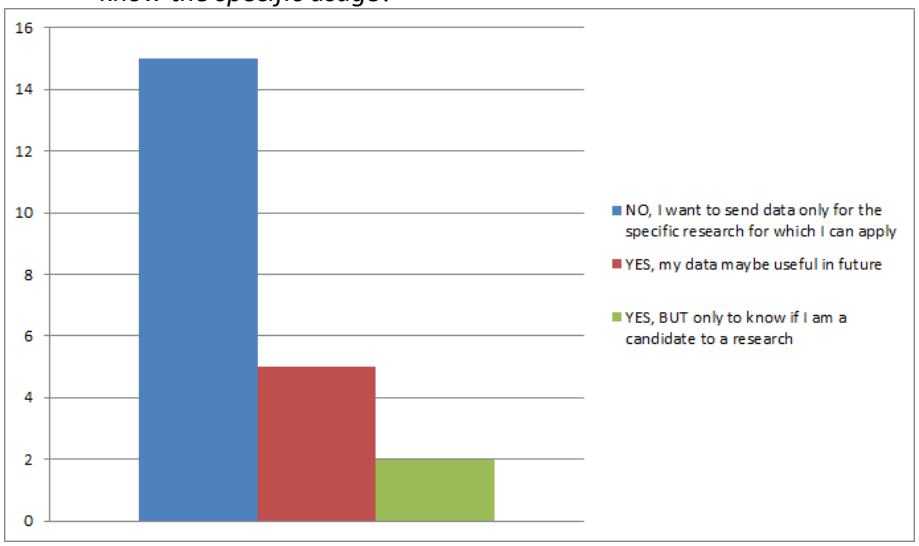


- *Are you willing to give your health data for free to a private organization?*

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



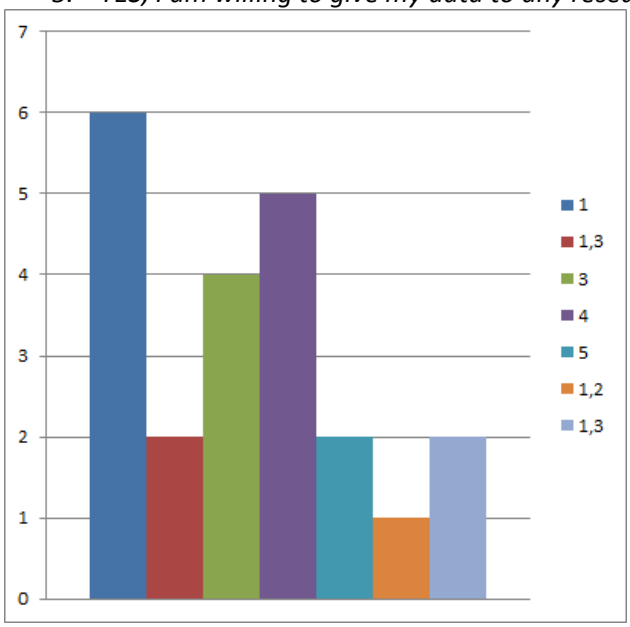
- *Would you like to donate your health data to a research centre for future research also if you do not know the specific usage?*



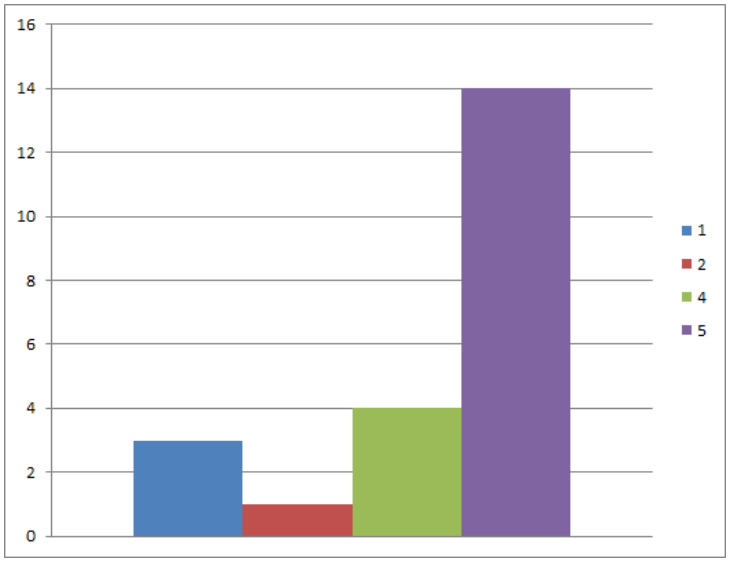
- *Are you willing to allow research organizations to access to your health data?*

Answers:

1. *Only for specific study that involves my condition or disease*
2. *Only for some kind of generic population studies (not related to my specific condition)*
3. *Only if I cannot be identified*
4. *NO*
5. *YES, I am willing to give my data to any research organization without constraint*

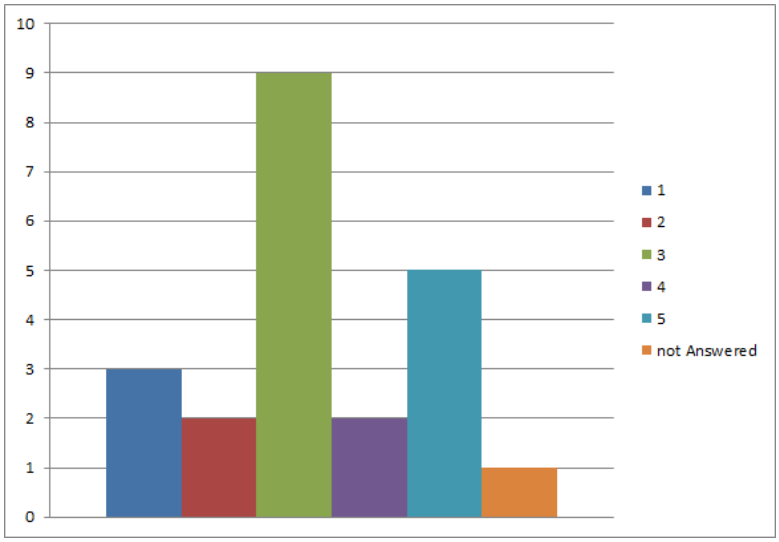


Would you like to know the partners of research protocols Organizations/multicentric research/industry
Answer= 1 to 5: 1= strongly disagree, 5= totally agree



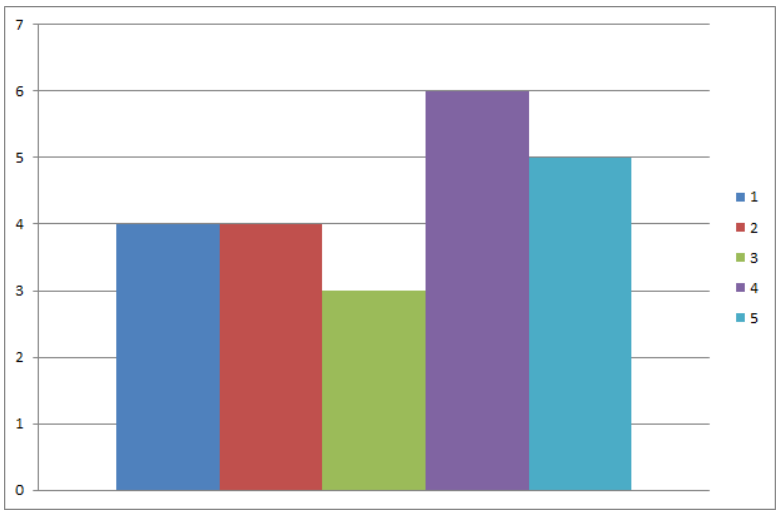
Are you willing to allow research organizations authorized in SEHR platform to contact you?

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



Are you willing to allow research organizations authorized in SEHR platform to contact you and better understand if you can be a candidate for a research?

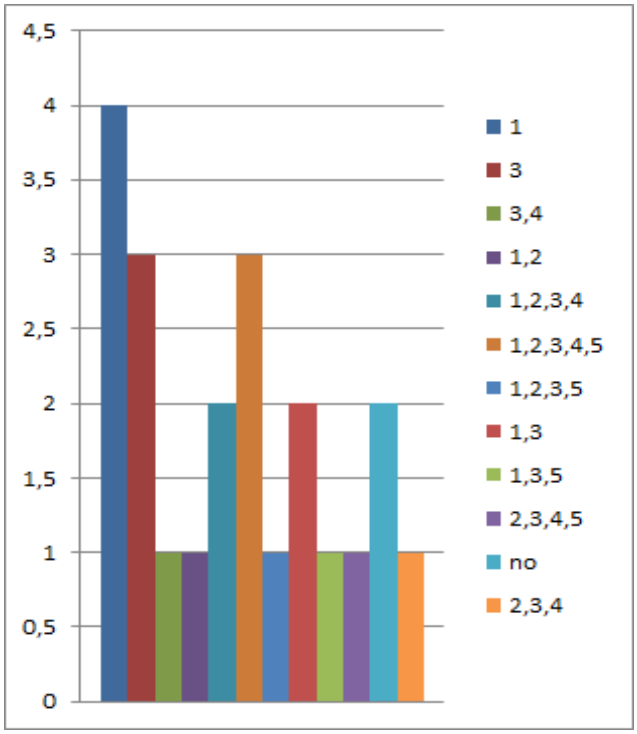
Answer= 1 to 5: 1= strongly disagree, 5= totally agree



Is there any privacy/security issue you are particularly concerned with in sharing your health data with a research institution?

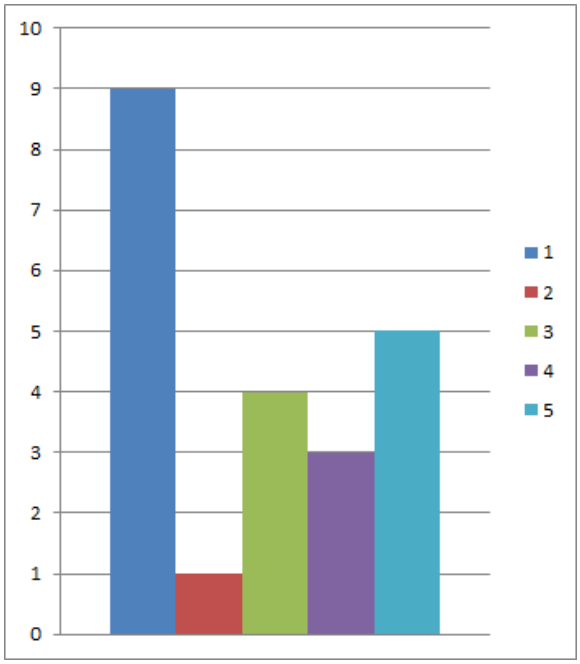
Answers:

1. *Yes, they could use my data for another research without my permission*
2. *Yes, they could use my data for ads or donation requests*
3. *Yes, Data Breach (see GDPR)*
4. *Yes, they could be sold*
5. *Yes, if data were given were poorly pseudonymized/anonymized they can identify me back again*



Are you willing to add specific data in you SEHR, requested by a research organization, only to participate in a research?

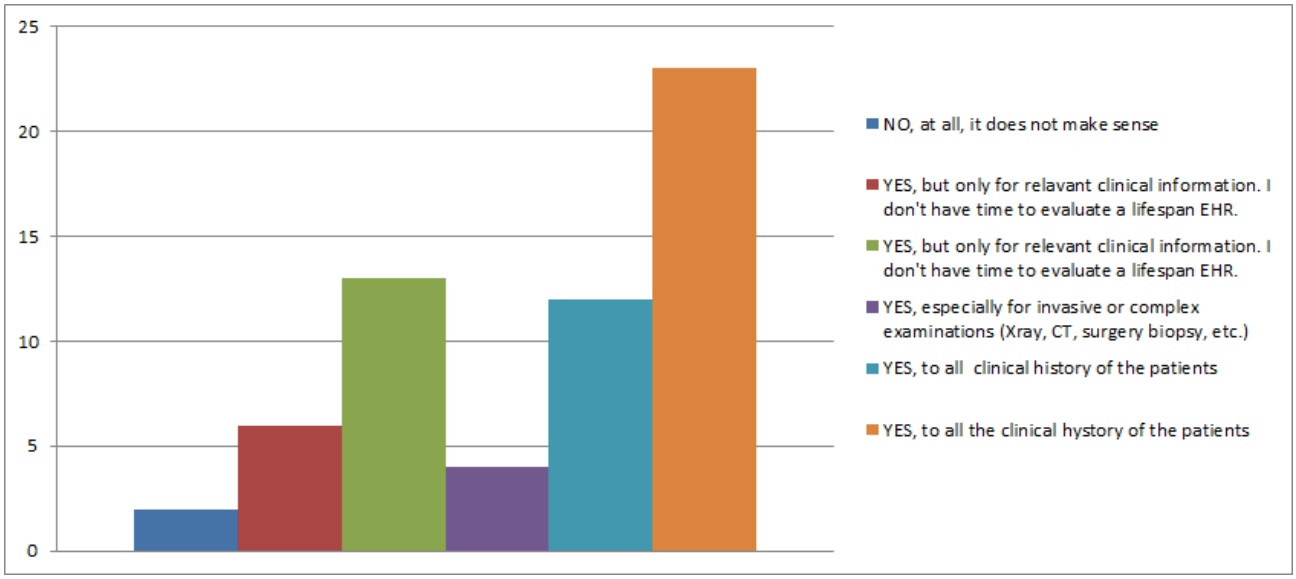
Answer= 1 to 5: 1= strongly disagree, 5= totally agree



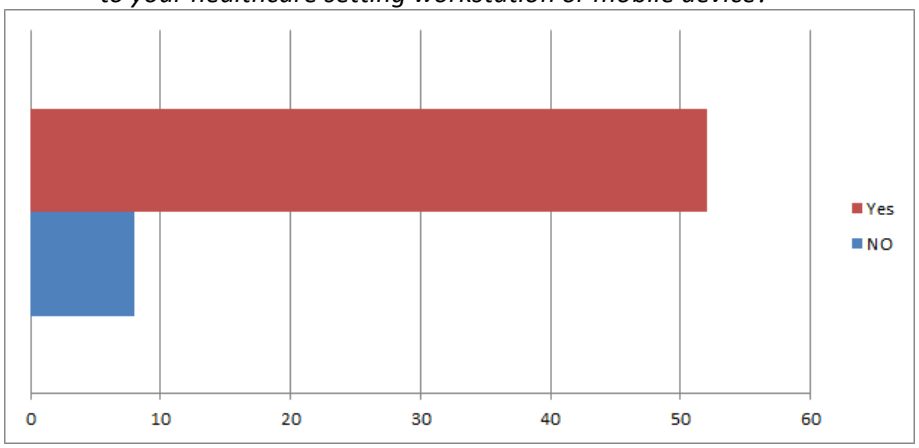
10.2. HCP Focus groups Response

In the following analytical results of questionnaires.

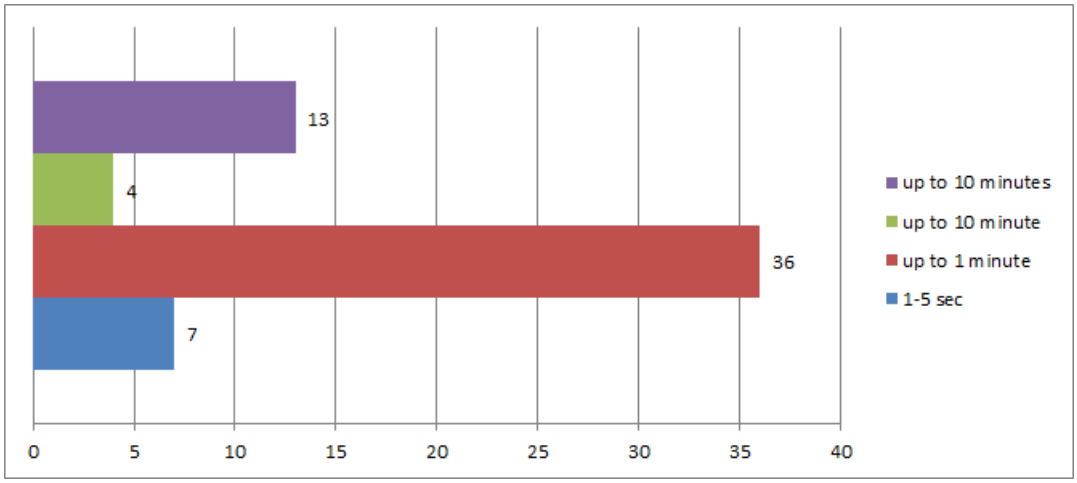
- *For foreign patients, would you like to access to their health data coming from EHR of other countries?*



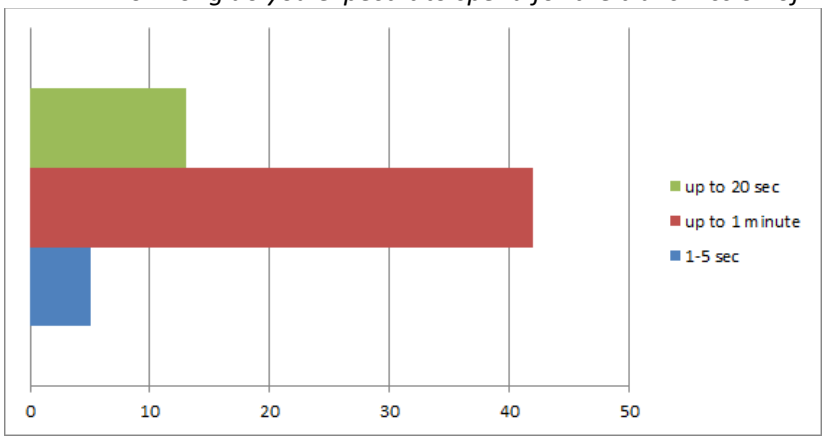
- *Would you let patients to share with you their relevant health data just moving their mobile phone to your healthcare setting workstation or mobile device?*



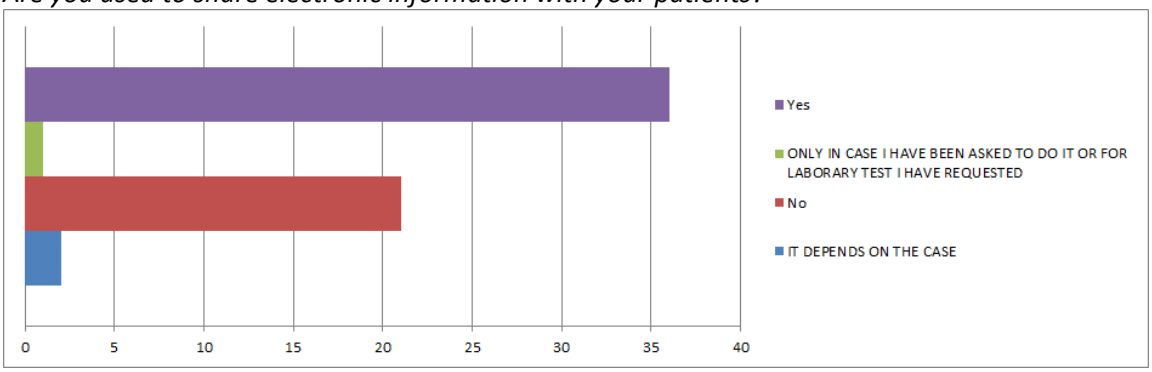
- *"How long do you expect it to spend for the transmission of information from the patient's cell phone?"*



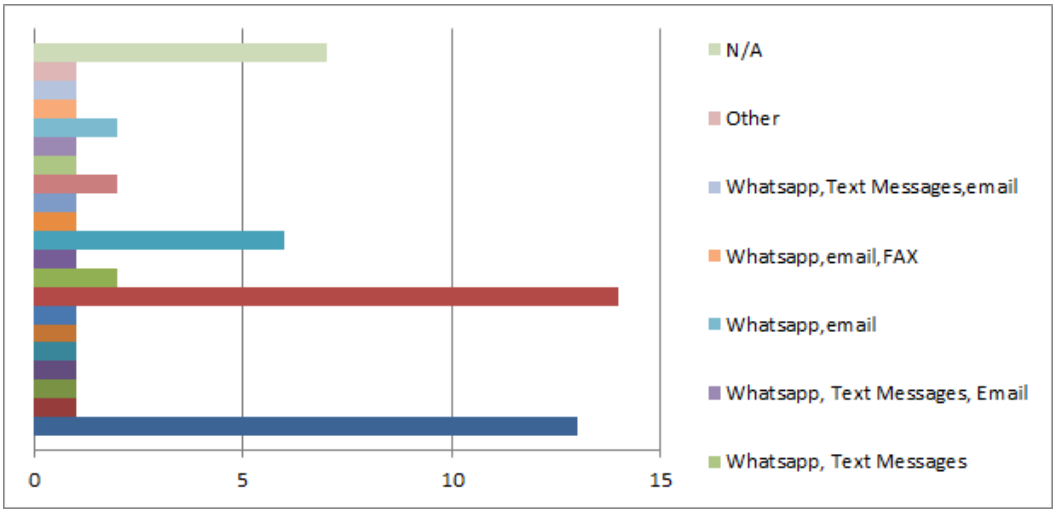
- *"How long do you expect it to spend for the transmission of information from the cloud?"*



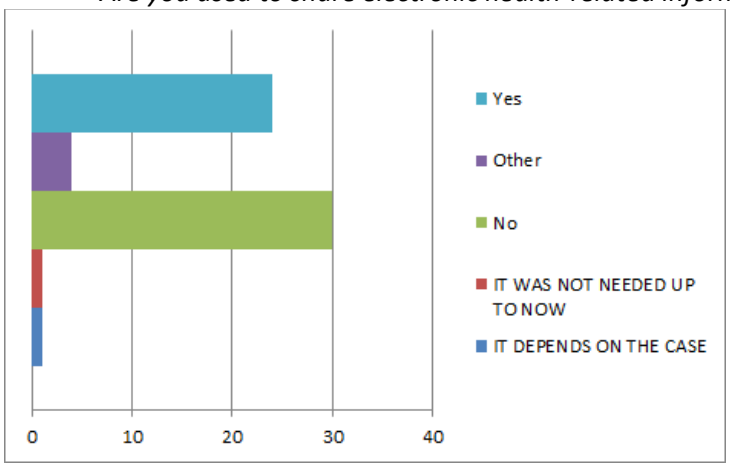
- *Are you used to share electronic information with your patients?*



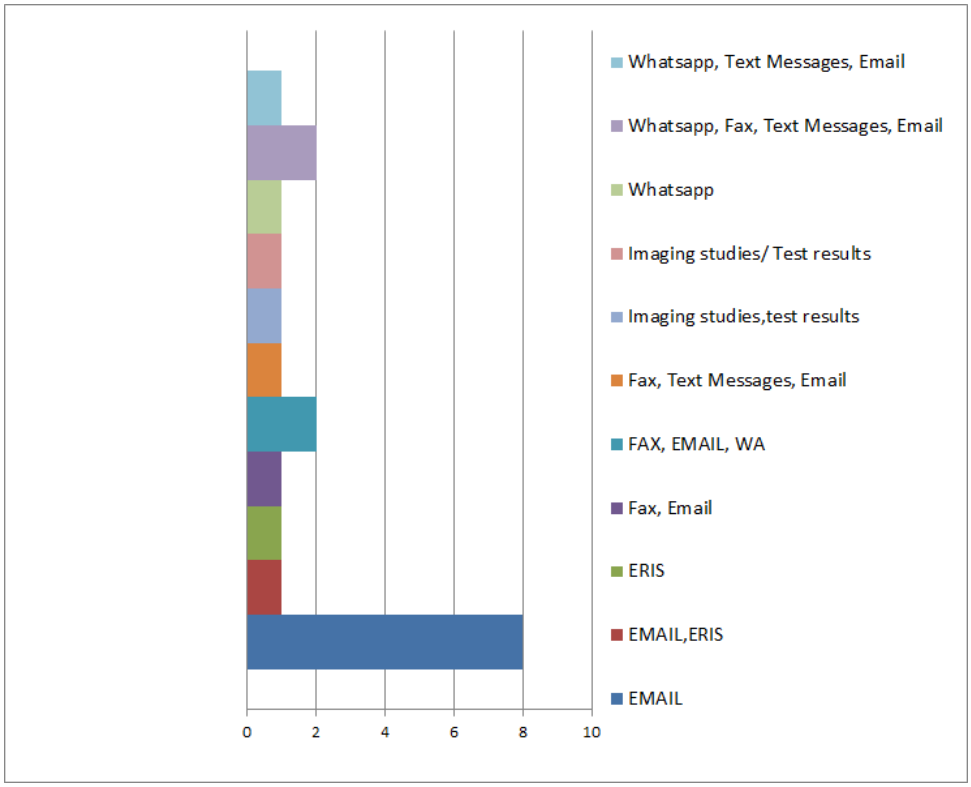
  - *If the answer to the question above is yes, what kind of information are you currently sharing and using which system?*



- *Are you used to share electronic health-related information with other hospitals?*

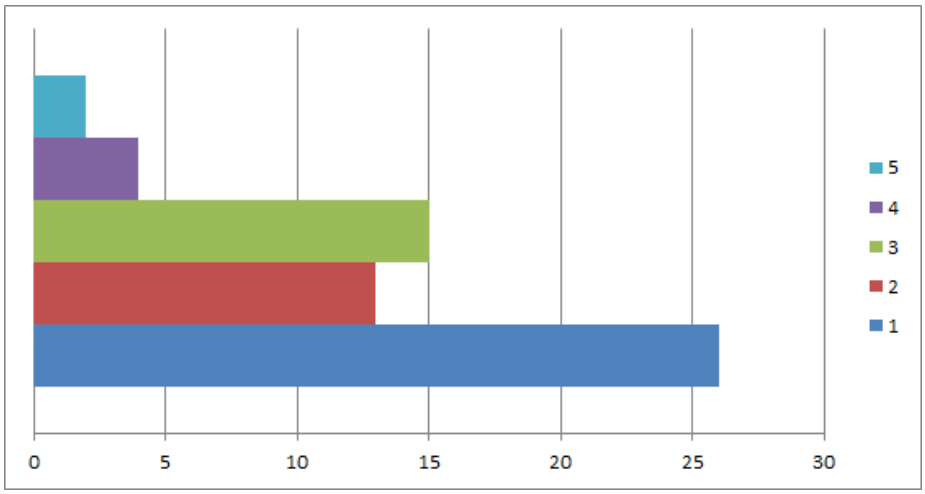


  - *If you answered yes to the question above, what kind of information are you currently sharing, in what occasion and using which tool?*



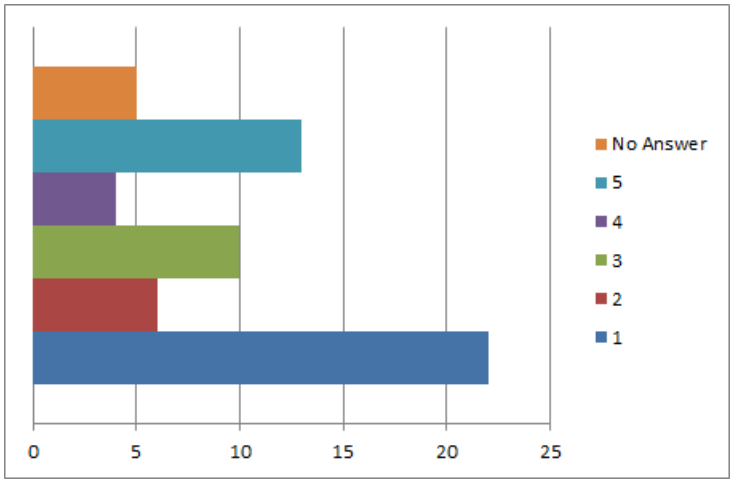
- *Are you happy with the current way of collaboration with other EU/National/regional Hospitals?*

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



- *Do you have any national or regional platform that supports EHR data exchange?*

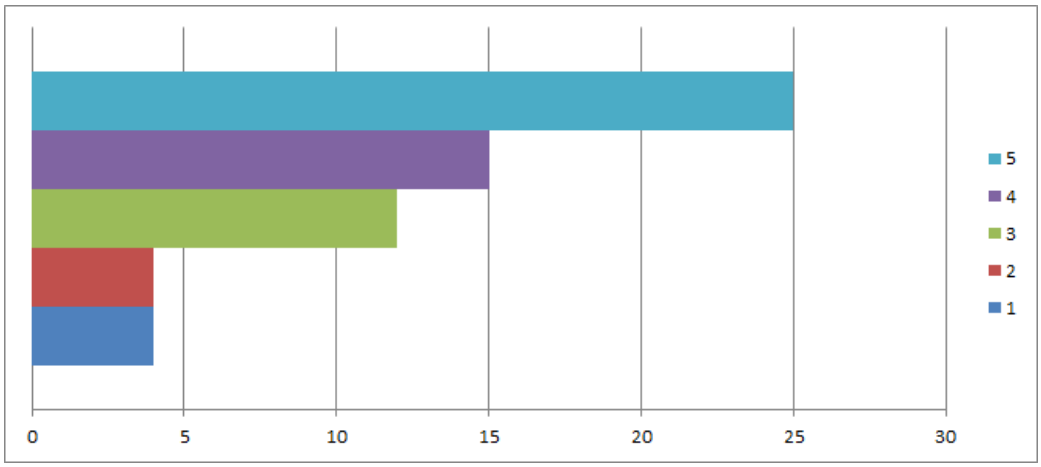
Answer= 1 to 5: 1= strongly disagree, 5= totally agree



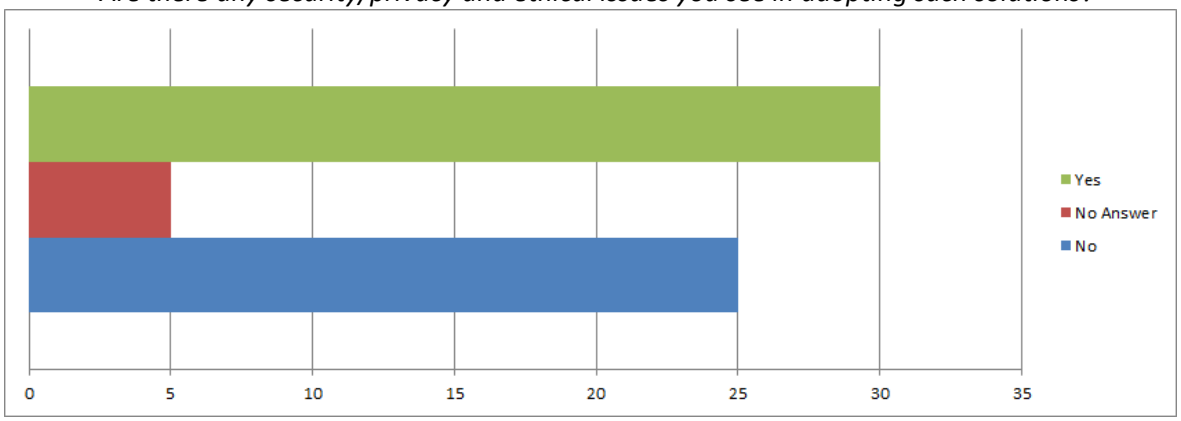
- *Do you have any suggestions on how to improve this collaboration based on your experience and expectations?*
  Answers, removing duplicate text:
  - *access to the electronic health record of the patient following his/her permission*
  - *at first stage, it is required collaboration on regional and national level of electronic systems of hospitals and health centres of the whole country , so that the paneuropean collaboration to be achievable. towards this end, it could work the obligatory establishment of a specific SW or more than one SW compatibles between each other*
  - *ehr sharing*
  - *creation of a local/regional pacs*
  - *digital archiving of historic health data and enabling interoperability to the data of the healthcare providers*
  - *have a unique platform for every hospital*
  - *I would prefer the suggestions to be linked to each specialty since there are peculiarities*
  - *integrated database on national level or even on paneuropean level if this is feasible using an interconnecting hospital SW (i.e. asklipios). all hospitals SW have to be interconnected*
  - *it is required real time on line connection to the database*
  - *it is required special and trained personnel working exclusively for the specific collaboration. the doctors have to work only on the diagnosis, the patient visits / laboratory tests*
  - *the electronic archival of the health data that refer to the patient, from all the laboratories, the medlabs and the hospitals, of the private and the public domain, has to be obligatory. what is most essential is the simplest, the quickest and the easiest data entry. for instance the data that refer to the vaccines could be entered just by scanning a label, barcode of the vaccine from the doctor*
  - *through the development of a digital health platform that will keep the personal data for every patient*
  - *using a form matching needs for everybody at no charge*
  - *using the same electronic health data format for all*
  - *your proposals cover my expectations*
  - *current platform*
  - *set up new HW & SW*

- *Do you think it is a good idea to allow patients to share with you their Electronic Medical Records or any other certified health information stored in their mobile phones or cloud?*

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



- *Are there any security/privacy and ethical issues you see in adopting such solutions?*



  - *elaborate*

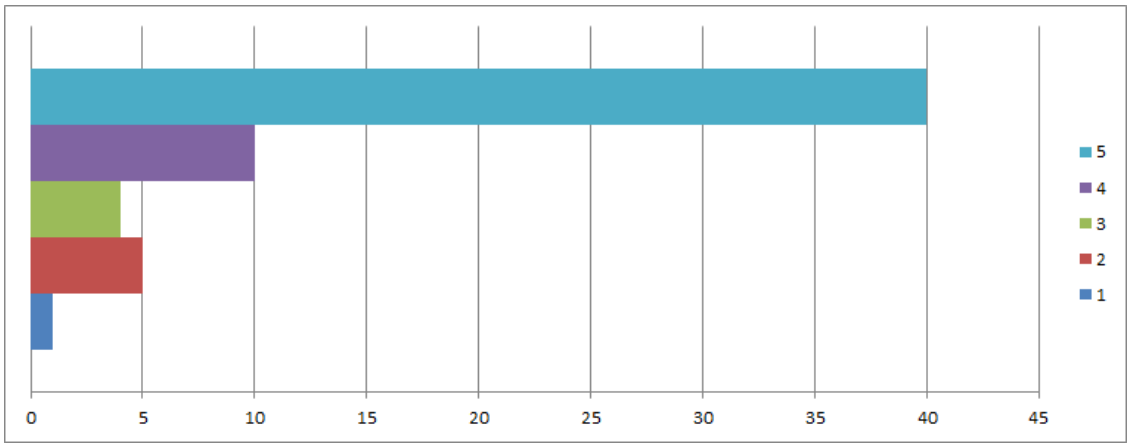
Answers, removing duplicate text:

- it is essential the exist an mou between the doctor and the patient, binding each other, that will be agreed European wide, otherwise the patient might at any time raise security, privacy issues and/or ethics without serious cause. the mou has to include family members of the patient as they might raise relevant issues in certain cases.
- it might be the case that the patient does not want all his/her health history to be kept on the cloud due to security issues. the patient might want to have the opportunity to choose how to administer on her/himself the historical health data
- medical confidentiality and gdpr have to be assured for enabling data access permission. those who have access need to be accredited for the level of the information viewing and writing. for example, somebody could have access only to view some data but no permission to edit them
- no, because there are ways of privacy assurance through the SW programme
- professionalism and ethics of the data recipient do not create issues other than facilitating the solution to the health problems
- the health data provision from the patient to the health provider has many advantages under the condition that ethics are being respected concerning the data archival, usage, and exchange between the health data providers and the private doctors

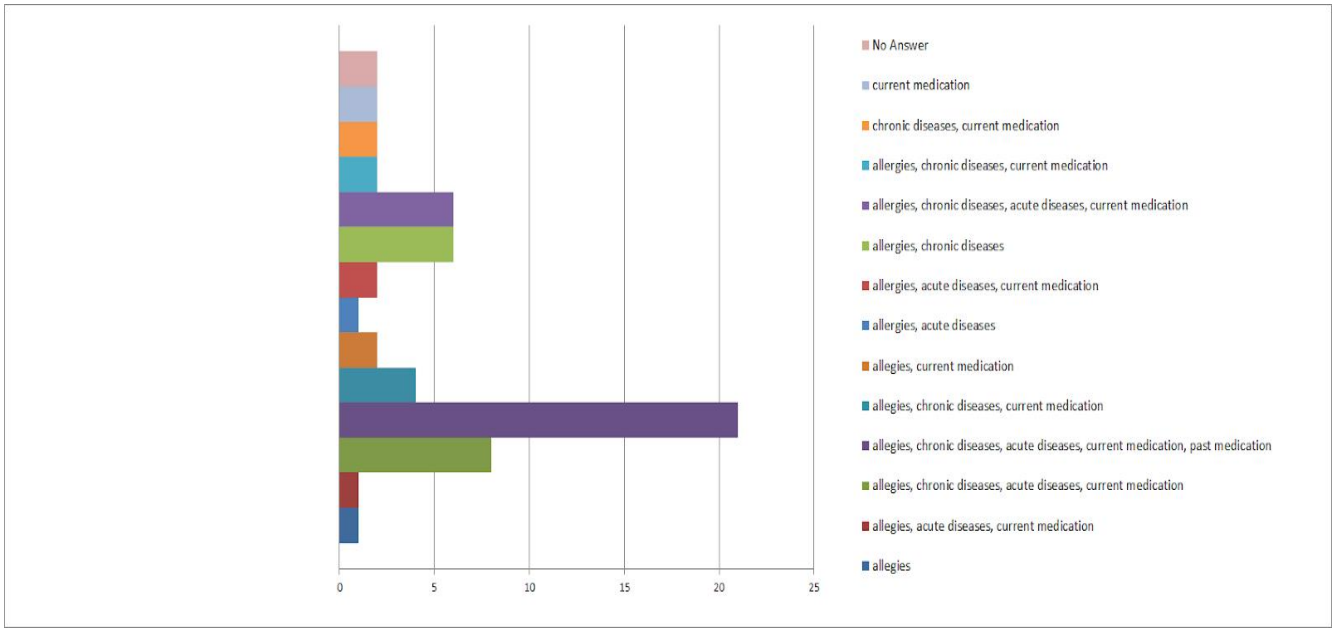
- the permission to the data has to be restricted to the patients and the health personnel. security assurance and encryption are required.
- the transfer of the data has to be guaranteed using the proper s/w security on the pc
- always
- clear guidance and protection protocols are required on local but also on broader level. control on who is permitted to view which information has to be set up. Furthermore, strict rules have to be set up in order to prevent the easy access of the companies of the health business domain and the assurance companies.
- in case of fraud the doctor is legally exposed
- it is enough the doctor to be a well cultivated person
- no because there is always the medical confidentiality and the doctor is always working for the benefit of the patient
- no issue is to be raised if the patient agrees.
- no problem when the data exchange is acceptable by the doctor and the patient
- no, I do not think that the health data are safe
- no, if this has to do with the health of the patient
- no, under the condition that the patient agrees in writing, that he/she has been informed and the doctor has been legally covered for that purpose. in this way the patient is being supported, while this process saves time and mistakes are also avoided.
- probably
- the current legislation is enough
- the patient has to trust the doctor and tell him/her whatever is required to help him/her issue the diagnose
- yes, because I believe in medical confidentiality

- *if a patient arrives at the emergency room in a state of confusion or unconsciousness, and you need to provide first aid, do you think it is useful to access his/her historical health data?*

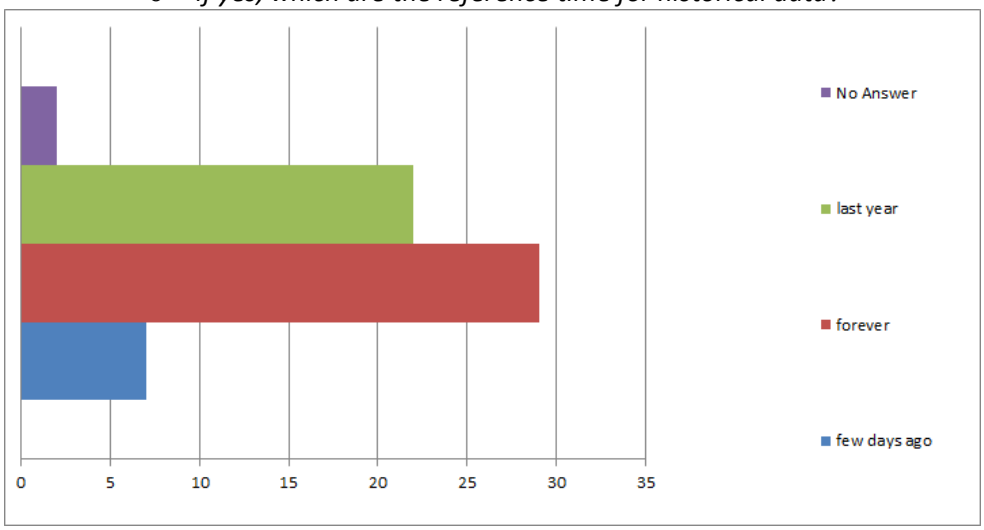
Answer= 1 to 5: 1= strongly disagree, 5= totally agree



  - *if yes, which are the most relevant*

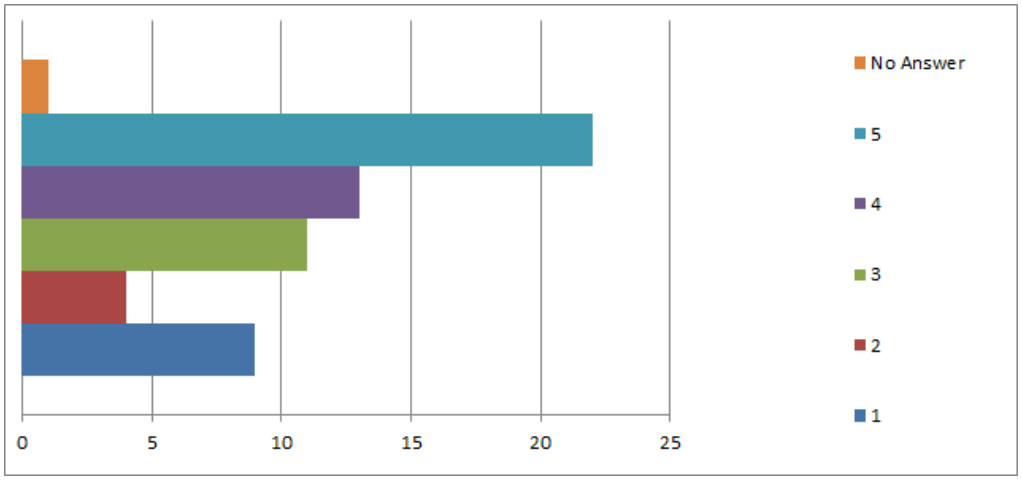


- *if yes, which are the reference time for historical data?*



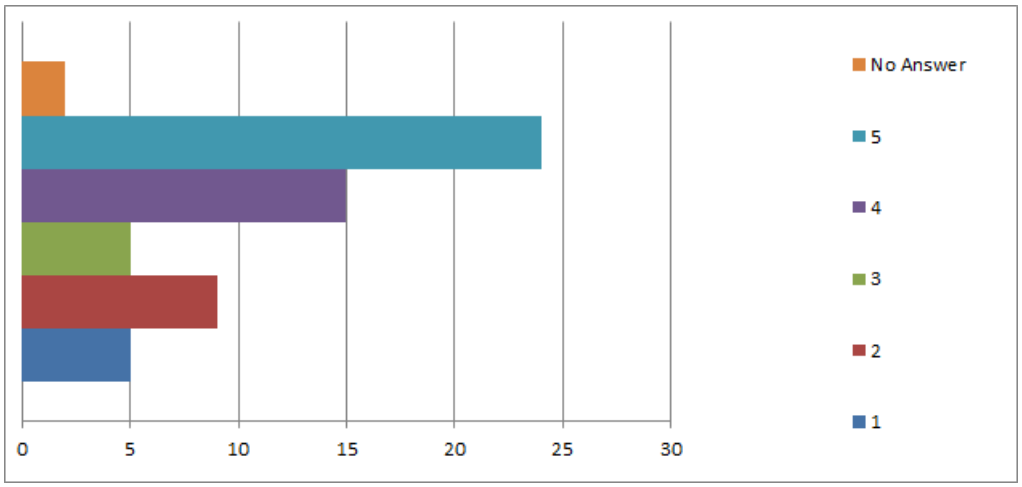
- *Do you think is a good idea to allow patients to share personal health data, entered from paper documents?*

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



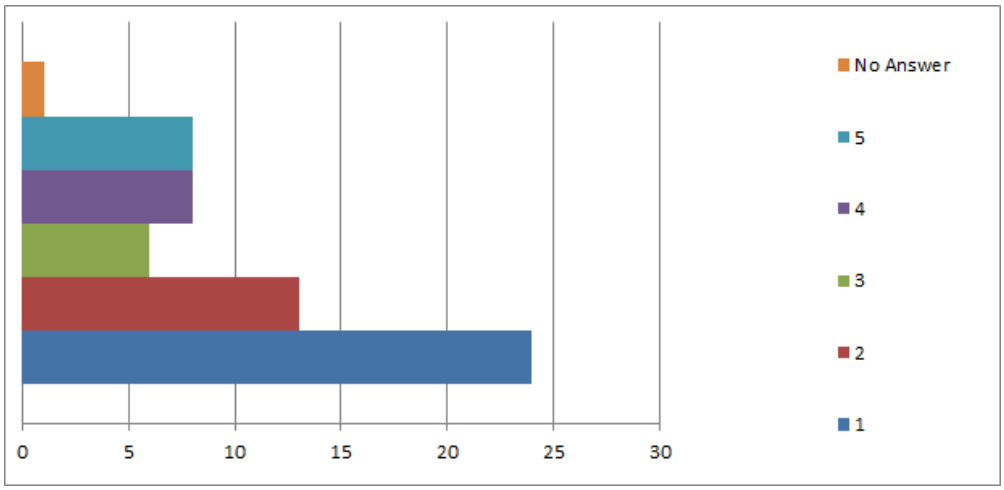
- *does it make sense to you to aggregate data from HCP as well as wellbeing ones (not produced by medical devices, such as smartwatches, home scale, etc.)?*

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



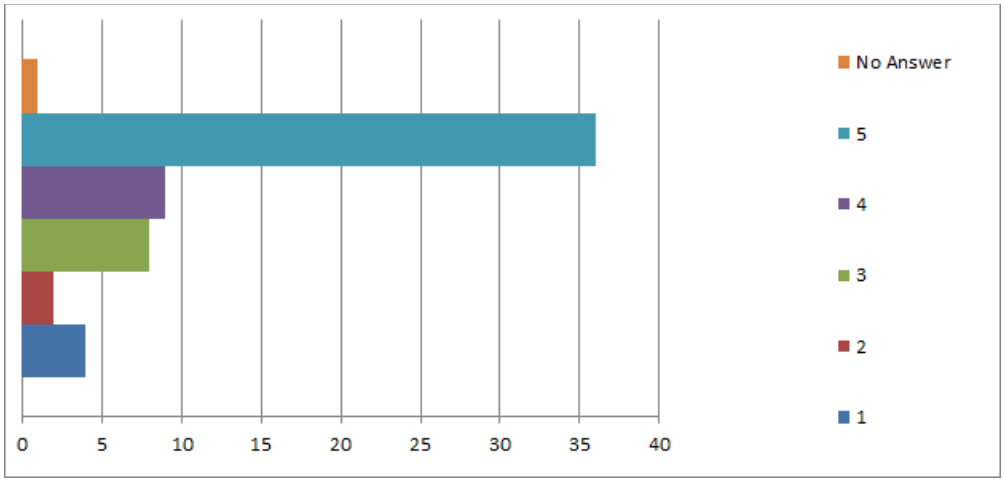
- *Do you think that patients should be able to add personal health information?*

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



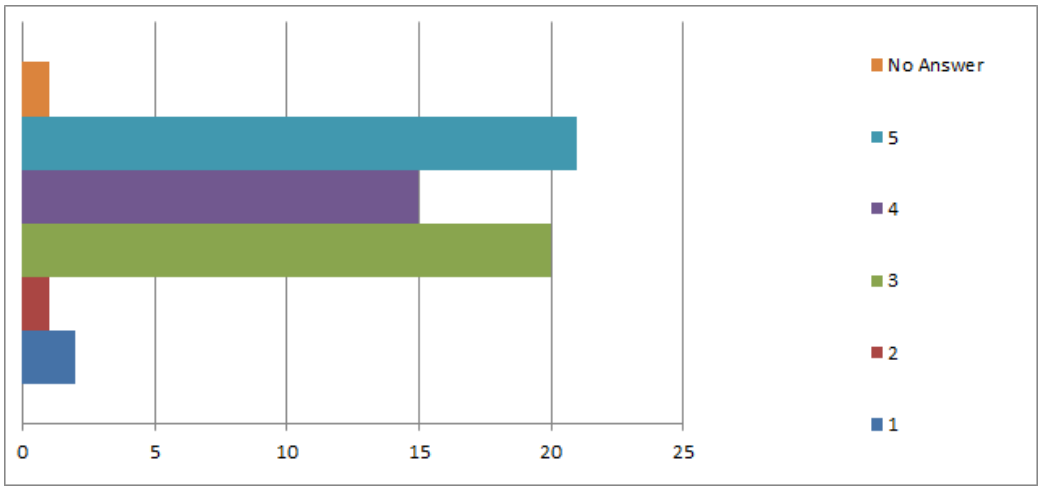
- *Would be interesting to add GP/specialist reference to contact?*

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



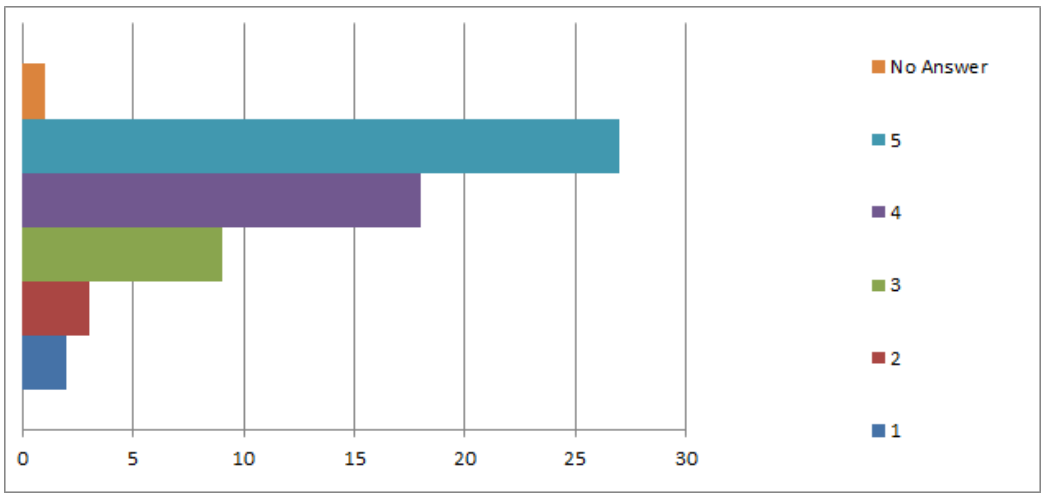
- *How much this new development will support daily work?*

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



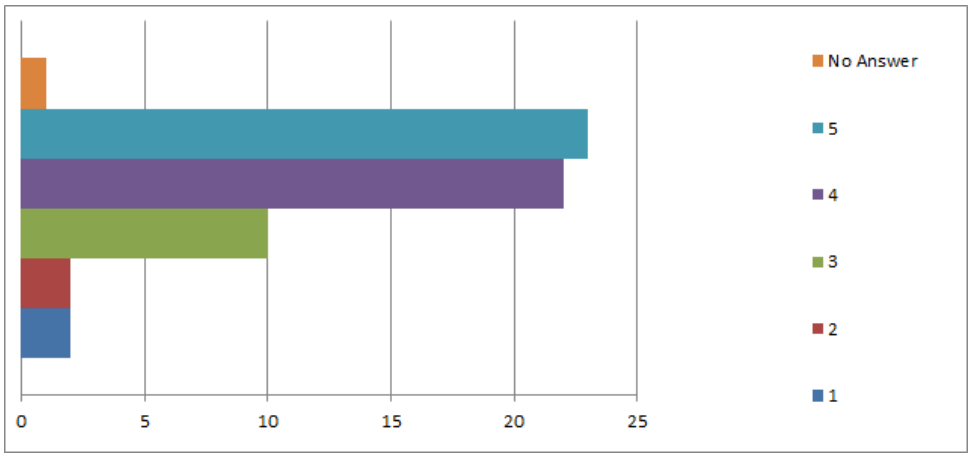
- *Do you expect that this kind of system will be useful for your job?*

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



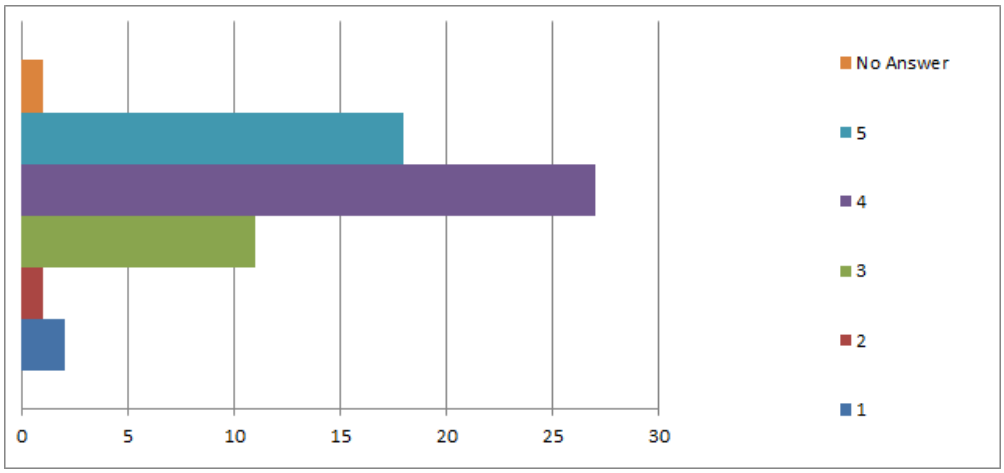
- *Do you think that this kind of tool will be useful to the patient to empower the management of his/her condition?*

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



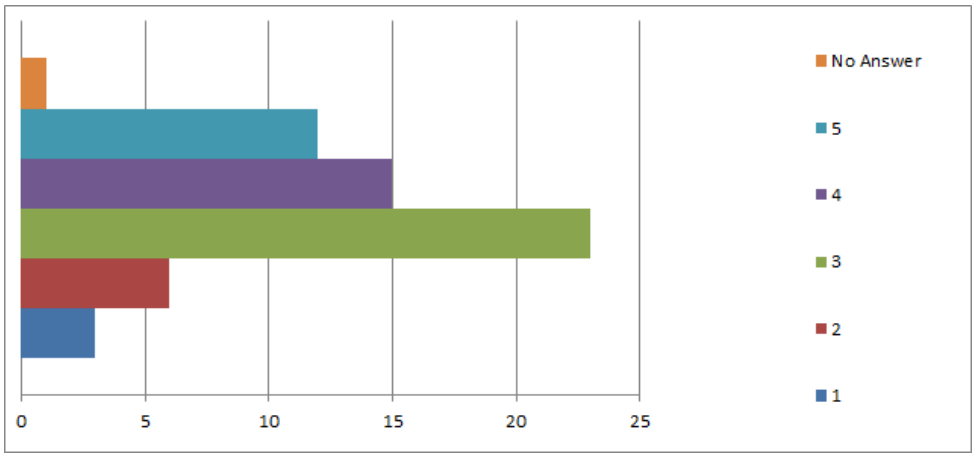
- *IEHR PLATFORM would allow me to make decisions about diagnosis and treatment of my patients based on better evidence*

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



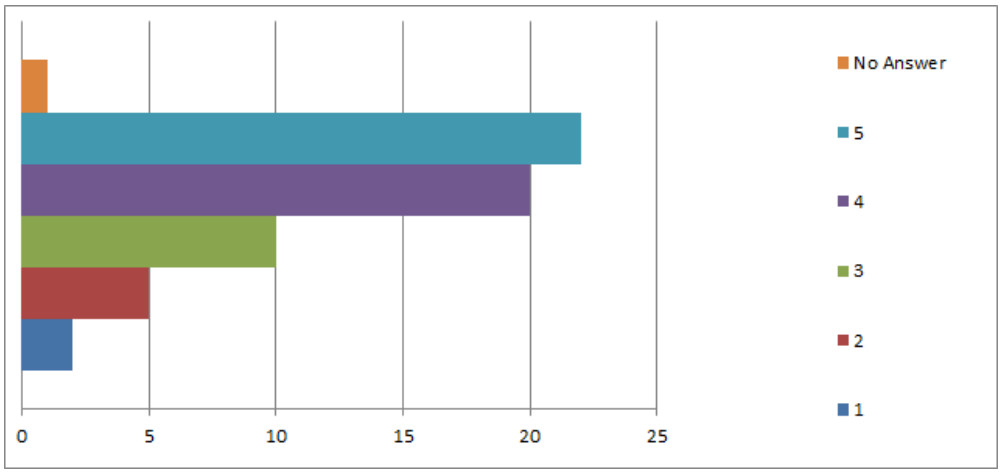
- *I think that In my Healthcare Facility I will have technical assistance available to solve problems associated to IEHR*

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



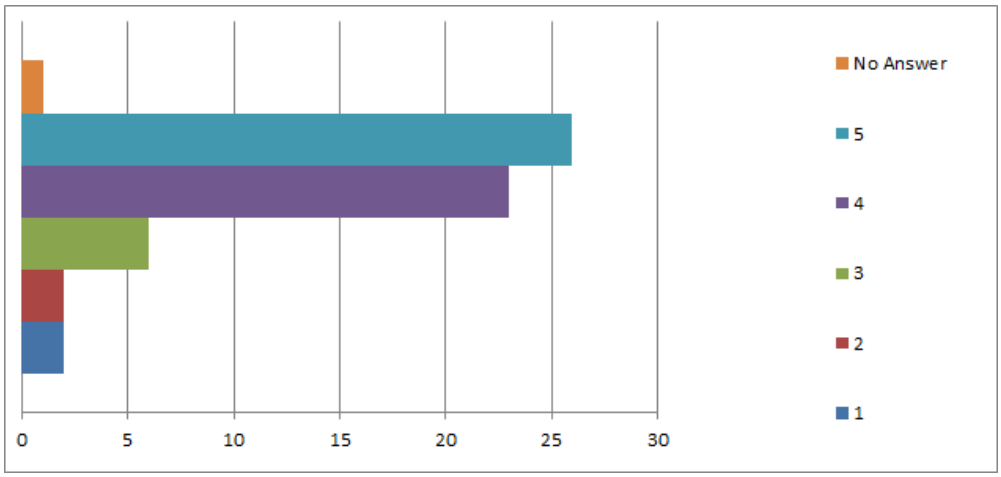
- *IEHR PLATFORM could increase my effectiveness of diagnostic and treatment of my patients*

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



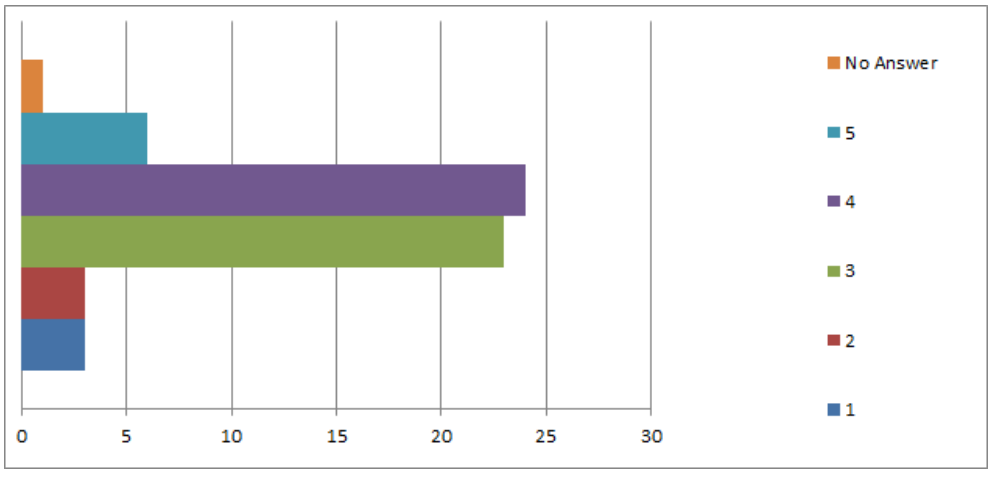
- *I think I will use IEHR PLATFORM for the diagnostic and treatment of my patients when available on my centre*

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



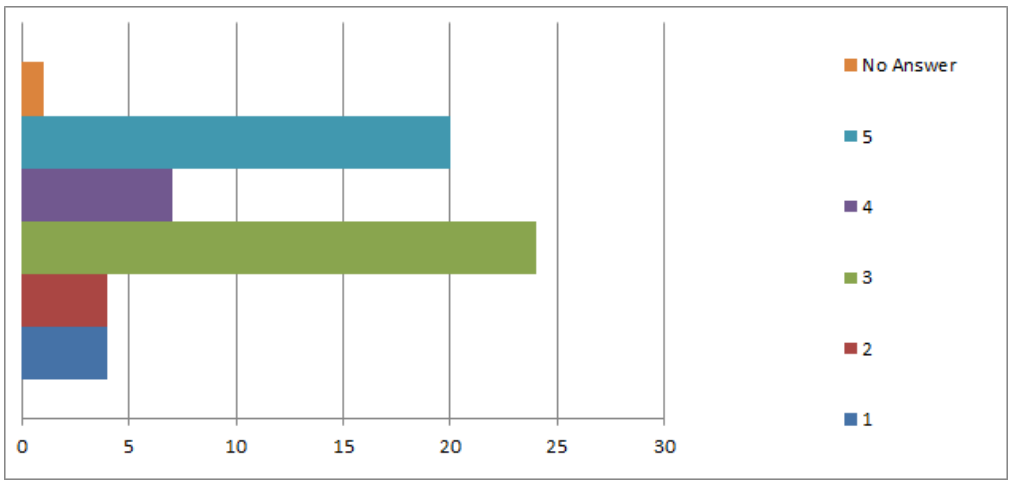
- *I think that navigation within IEHR PLATFORM would be easy.*

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



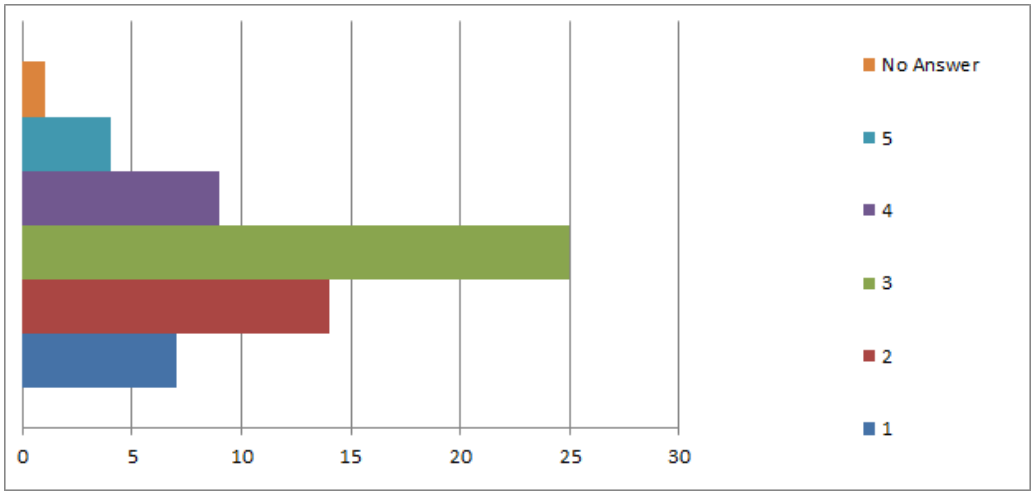
- *I already have the needed technical (PC, Workstation, mobile devices) and human resources (IT support) to use IEHR PLATFORM*

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



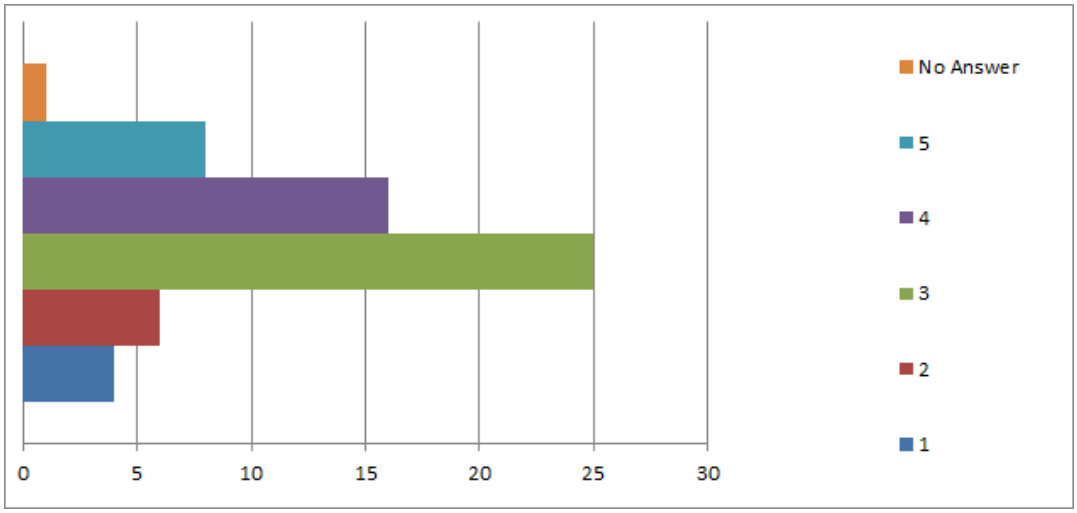
- *I think that my interaction with IEHR PLATFORM will require much effort for my share*

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

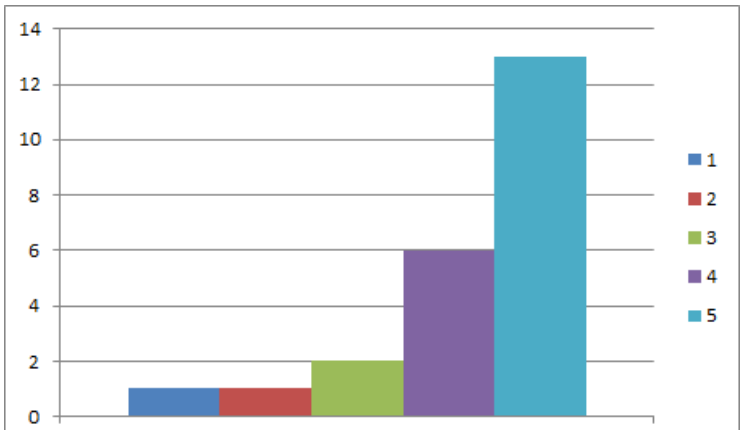


10.3. Researchers Focus groups Response

In the following analytical results of questionnaires.

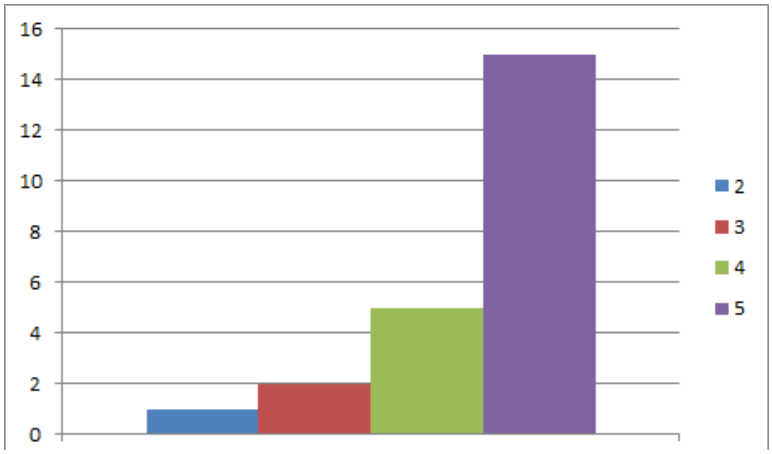
- *I like the idea to allow citizens to candidate their participation to your study using their mobile devices.*

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

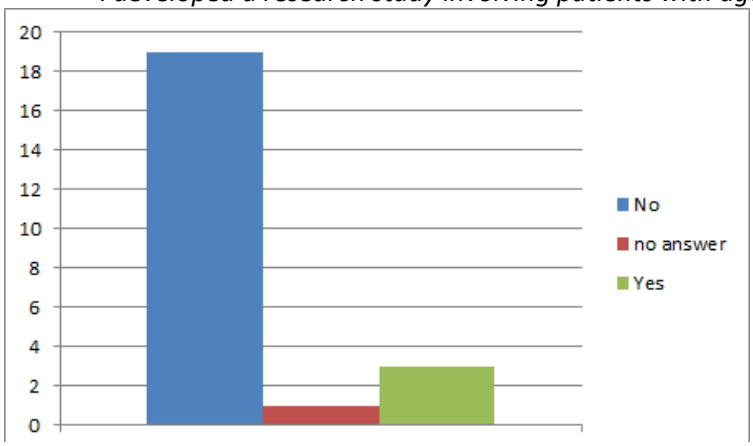


- *I like to receive the health data for your study directly from citizens via their mobile devices*

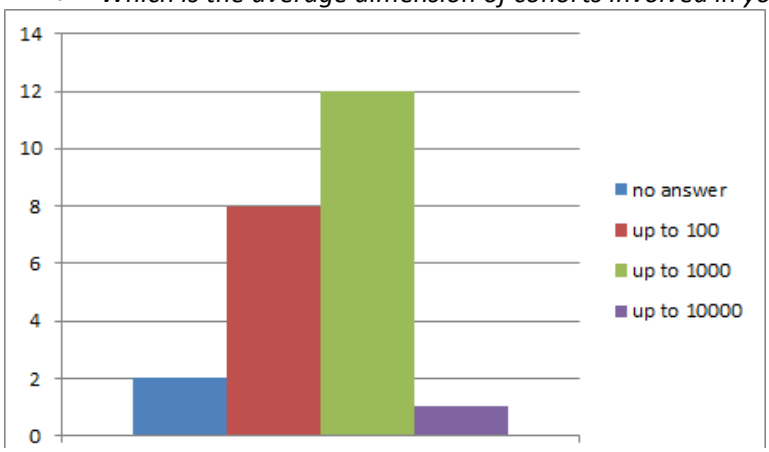
Answer: 1 to 5: 1= strongly disagree, 5= totally agree



- *I developed a research study involving patients with age < 14yy*



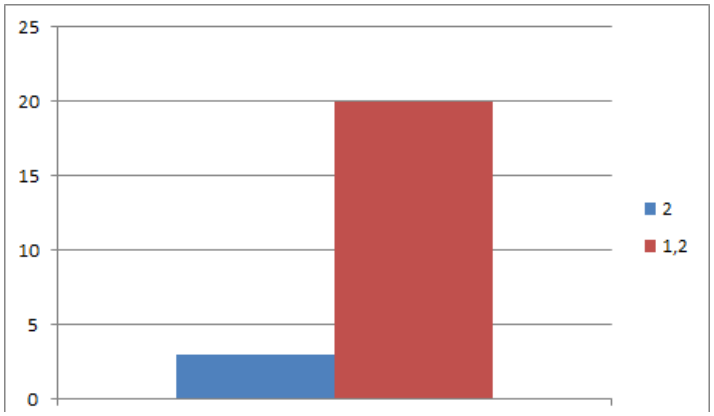
- *Which is the average dimension of cohorts involved in your studies?*



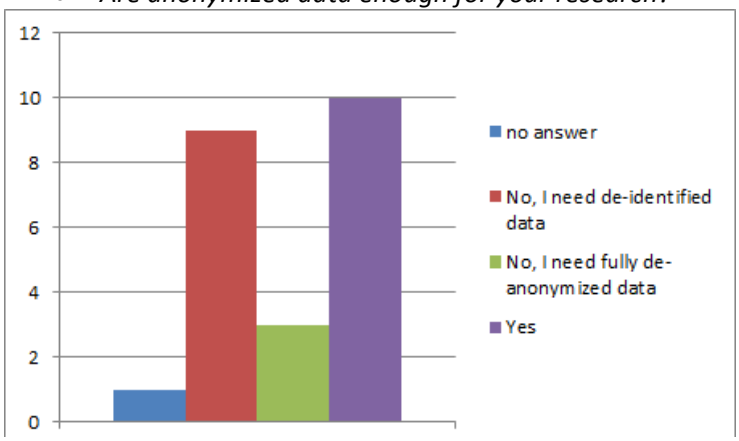
- *Which kind of information you would like to receive directly from the Citizen*

Answers:

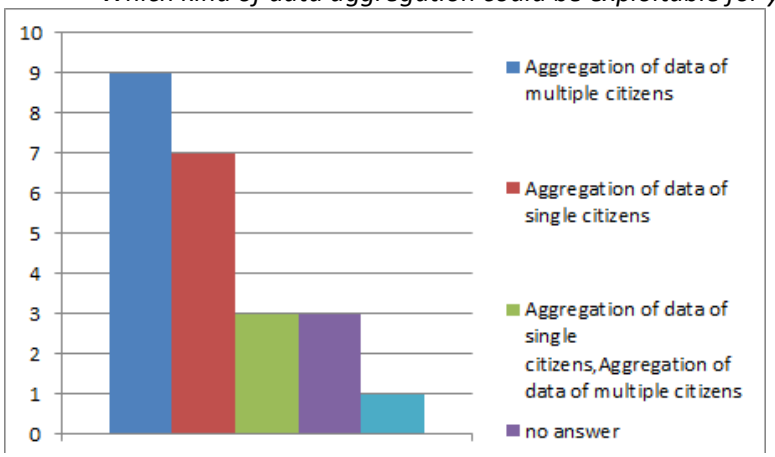
1. *Prospective Clinical data*
2. *Retrospective clinical data*



- *Are anonymized data enough for your research?*



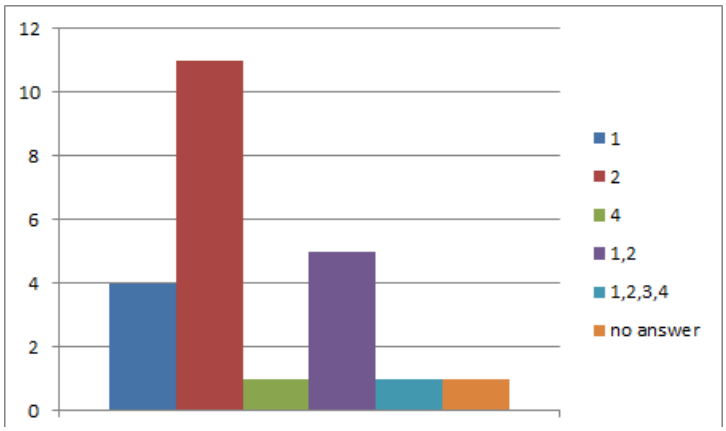
- *Which kind of data aggregation could be exploitable for your research?*



- *In which kind of format you would like to receive the research data*

Answers:

1. *CSV*
2. *Excel*
3. *XML*
4. *DB Table*
5. *OTHER*



- *Which kind of tools you currently use for elaborate research data?*

Answers:

1. *SPSS*
2. *RapidMiner*
3. *GNU R*
4. *JMP*
5. *STATVIEW*