D7.1

Experimentation scenarios and validation plan

ABSTRACT

This deliverable describes the activity of the three pilots of InteropEHRate project to validate the InteropEHRate scenarios and platform components. It also describes the clinical research study designed to collect and process information related to the pilots, submitted to the reference ethical committee of the healthcare organization involved to grant permission on the execution of the experimentation scenario with real patients.

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ACRONYMS

Acronym	Term and definition
A7	A7 Software
API	Application Programming Interface
BYTE	BYTE Computer Anonymi Viomichanikiemporiki Etaireia
CHU	Centre Hospitalier Universitaire De Liège
CTR	Clinical Trials Regulation
D2D	Device to Device
DICOM	Digital Imaging and Communication in Medicine
DMP	Data Management Plan
EC	EC European Commission
EFN	Fédération Européenne Des Associations Infirmières Aisbl
eHDSI	eHealth Digital Service Infrastructure
EHR	Electronic Health Record
EHTEL	European Health Telematics Association
EMR	EMR Electronic Medical Records
ENG	Engineering - Ingegneria Informatica SPA
EU	European Union
FAIR	FAIR Findable, Accessible, Interoperable and Reusable
FRAU	Fraunhofer (Fraunhofer-Gesellschaft zur Förderung der angewandten Forschung E.V.)
FTGM	Fondazione Toscana Gabriele Monasterio Per La Ricerca Medica E Di Sanita Pubblica
GDPR	General Data Protection Regulation
HCP	Healthcare Professional
HL7	HL7
HL7-CDA	HL7 Clinical Document Architecture

HL7-FHIR	Health Level 7 - Fast Healthcare Interoperability Resources
IEHR	InteropEHRate project
INFOQUAL	Information Quality
INTERQUAL	Interface Quality
IPS	International Patient Summary
IT	Information Technology
OS	Operating System (for workstations, servers, etc.). e.g. OS Windows
PI	Principal Investigator
PSSUQ	Post-Study System Usability Questionnaire
R2D	Remote-to-Device
RO	Research Organization
SCP (SCP-ECG)	ECG Protocol (Standard communications protocol for computer assisted electrocardiography)
SCUBA	Spitalul Clinic De Urgenta Bagdasar-Arseni
S-EHR	Smart HER
SIMAVI	Software Imagination & Vision SRL
SNOMED-CT	Systematized Nomenclature of Medicine Clinical Terminology
SUS	System Usability Scale
SYSUSE	System Usefulness
UBITECH	UBITECH Limited
UML	Universal Modelling Language
UNITN	Universita Degli Studi Di Trento
UPRC	University Of Piraeus Research Center

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1 INTRODUCTION

1.1 Scope of the document

This document describes the experimentation scenario applied in the three pilots of the InteropEHRate project. It describes how the different types of final users and other stakeholders will interact with the applications and other artefacts produced by the reference implementations of the InteropEHRate Architecture, defined by Deliverable D2.6 — InteropEHRate Architecture V2 [7] .

The generic user scenarios, on which those pilots' descriptions are based, are defined in the InteropEHRate deliverable D2.3 — User Requirements for cross-border HR integration V3 [2] .

The clinical pilot scenarios described in this deliverable customize the generic user scenarios to include any details that are specific to each clinical and organizational context of the InteropEHRate pilot sites and related experimentation activities. The pilot scenarios have to be sufficiently detailed to allow the software analysts to determine the requirements for specific configurations (e.g., specific local dictionaries to support) and specific software plugins or library and which component, i.e., reusable pieces of software, can be used for a particular experimentation. Specific configurations will be described at the end of the experimental phase, in the deliverables reporting on the executions of the Pilots, namely: D7.3 "Citizen centered healthcare pilot report", for medical visit abroad pilot report; D7.4 "Emergency pilot report" for Emergency access pilot report; in D7.5 "Citizen centered medical research pilot report" for Health research study pilot report.

Additionally, this document describes the specific health dataset that will be used during the pilots and that will be compatible with the FHIR profile described in the InteropEHRate deliverable D2.8 - FHIR profile for EHR interoperability - V2 [3] .

Finally, the participation of patients in the pilots shall be approved by the reference Ethical Committee of the involved hospitals (FTGM, HYG, CHU, SCUBA), according to local regulation.

The three experimentation scenarios and the project partners participating are:

- Scenario 1 Medical Visit scenario: responsible partner CHU (BE); Partners: HYG (GR), FTGM (IT).
- Scenario 2 Emergency scenario: responsible partner SCUBA (RO); Partners: FTGM (IT), CHU (BE).
- Scenario 3 Research scenario: responsible partner FTGM (IT); Partners: CHU (BE).

If not specified otherwise, in the following text the term "scenario" will always refer only to the "pilot scenarios". The scenarios described in deliverable D2.3[2] will be referred to as "General Scenario".

1.2 Intended audience

The document is intended for users, policymakers, IT solution architects and developers interested in having an overview of how the InteropEHRate platform requirements were implemented in a real-world environment 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 “Validation Plan” describes the principles applied in the definition of experimentation scenarios to support the validation plan, and the principles applied to collect responses from the patients, physicians, nurses, and researchers involved in the execution of the pilots’ activities.
- Section 3 “PILOT P1 - Medical visit abroad” describes the activities executed in the pilot to test the platform and demonstrator’s functionalities in a real visit, according to general principles of patient care. In the final sections are described the set of questionnaires used for platform performance and functionalities evaluation.
- Section 4 “PILOT P2 - Emergency access” describes the activities executed in the pilot to test the platform and demonstrator’s functionalities in a real encounter (admission), according to general principles of patient care. In the final sections are described the set of questionnaires used for platform performance and functionalities evaluation.
- Section 5 “PILOT P3 - Health research study” describes the activities executed in the pilot to test the platform and demonstrator’s functionalities in a real clinical research protocol, according to general principles of health research studies. In the final sections are described the set of questionnaires used for platform performance and functionalities evaluation.
- Section 6 “Clinical Research Protocol” reports a summary of the clinical study submitted to the reference Ethical Committee. In the final sections are described the clinical questionnaire of the study and the informed consent for the principal investigator (FTGM).
- Section 7 “Conclusions and next steps” outlines the conclusions of the current document, and activities that will be performed to implement the experimental phase in the next months.

1.4 Updates with respect to previous version

Not Applicable.

2 VALIDATION PLAN

The main result of InteropEHRate will be an open specification, a set of new interoperability protocols for secure and cross-border exchange of health data, allowing the citizens to interact with healthcare organizations and research institutions, while at the same time being in full control of the usage and the routes of their health data (see InteropEHRate deliverable D4.3 - Specification of remote and D2D protocol and APIs for HR exchange - V3 [1]).

The open specification is accompanied by a reference implementation, called InteropEHRate Framework, composed of discrete and interoperable software components, each one implementing a different part of the open specification. The InteropEHRate Framework also contains a set of complementary applications and interfaces, supporting the usage of the interoperability protocols. Its purpose is to check that the open specification is implementable and to provide a tangible paradigm of how this can be accomplished.

The reference implementation will be validated in a real healthcare and research setting, and the goal of the InteropEHRate validation will be a technical assessment of the solution and not a clinical validation. This will be done by implementing the scenarios defined in deliverable D2.3 [2] **,** referred in the present deliverable, and involving the end-users in each pilot site, to assess satisfaction level of functional requirements, as well as to understand the potential social and technical impact of the solution on the existing healthcare processes.

The validation is the process that will collect information for the final evaluation of the platform and tools, thus the validation will focus on three different types of end-users:

(1) a “primary end-user”, i.e. the patient;

(2) a “secondary end-user”, i.e. the healthcare provider responsible for the healthcare of the above-mentioned patient;

(3) a “tertiary end-user”, i.e. researcher involved in the analysis of data collected during the healthcare provision and specific data requested for the research protocol.

The validation will be executed in three pilots, each one focusing on one or more designed protocols, deployed in 4 different sites and 4 nations, corresponding to the Hospital partners of this project: FTGM, CHU, SCUBA, HYG.

For two pilot sites, Italy (FTGM) and Belgium (CHU), the collection of components provided by the InteropEHRate Framework will be connected with data of the Hospitals’ EHR, and a deployment architecture for each pilot site will be defined considering the local regulation and Hospital’s policy, that may allow a direct connection to the production EHR or to a sandboxed safe copy of it. The deployment architecture will be described in the deliverable related to the execution of pilots’ activities: D7.3 - Citizen centered healthcare pilot report, for medical visit abroad pilot report; D7.4 - Emergency pilot report, for Emergency access pilot report; D7.5 - Citizen centered medical research pilot report, for Health research study pilot report.

At each pilot site, the InteropEHRate solution will be tested with a small-scale dataset, consistent with healthcare provision for cardiac chronic patients, and validated in a real healthcare setting with real patients.

The first experimental pilot, Pilot 1 — Medical Visit, will be validated in a real medical visit scenario using the D2D protocol, and will also involve the R2D Access protocol to have an initial population of S-EHR. A group of 3 citizens/patients per site will be equipped with the S-EHR Application for Smartphones and will be requested to interact with different specialists (not only the caring medical doctor) using the S-EHR for exchanging health data with them (e.g.: hospital specialist, nurses, etc.) in a real visit. Will be evaluated at the beginning of each pilot site, the level of patient safety related to SARS2 COVID-19 pandemic regulations for the participant patients to travel to another pilot site.

The second experimental pilot, Pilot 2 — Emergency Access, will be validated in a real hospital setting leveraging the usage of the emergency access to patient S-EHR using the R2D Emergency protocol, involving also the usage of R2D Backup and R2D access. A group of 3 citizens/patients per site will be equipped with the S-EHR Application for Smartphones and will be requested to activate the S-EHR cloud. Later on, they will be asked to switch the phone off and then be the subject of an hospital encounter, allowing attending healthcare professionals to access their health data using the emergency tag for the identification of the patient through the S-EHR cloud component. Will be evaluated at the beginning of each pilot site, the level of patient safety related to SARS2 COVID-19 pandemic regulations for the participant patients to travel to another pilot site.

The third experimental pilot, Pilot 3 — Health Research Study, will be validated in a real clinical research protocol defined by two research organizations and addressing data donation support capability of the InteropEHRate platform by using the RDS protocol. It will also use the R2D Access protocol to have an initial population of the S-EHR. A group of 30 citizens/patients in two sites will be equipped with the S-EHR Application for Smartphones and will be requested to download their health data from the research Hospital sites that are supporting the experimentation scenario and participate in the research protocol proposed in the scenario, providing the information requested by the protocol.

Next paragraphs provide details on each action performed to implement the three scenarios by the different actors, both Humans and IT-class.

2.1 Ethical Committee

To execute the experimental scenarios with real patients, the referenced Ethical Committees of each pilot site will be activated in order to get an approval on the planned experimentation, and the involved citizens/patients will be requested to sign an informed consent form prior to any activity.

The first step to collect this permission was to define and prepare a documentation package for a clinical study protocol; the study defined for InteropEHRate was called INTERVAL (INTERopehrate VALidation – INTERVAL Study). The above-mentioned package is composed of different documents, according to the local/national regulation on which the reference committee is working, but some documents are usually requested by every committee to evaluate the study. For a centre participating in the study, the package is composed of:

1. the protocol description;
2. the protocol synopsis;
3. the informed consent for the patient;
4. the letter to the General Practitioner of the patient;
5. the Case Report Form;

6. the study questionnaire (adverse reactions, evaluation questionnaires);
7. the Data Protection Impact Assessment Document (DPIA) for the research center in application of the clinical study;

The most important document of the package is the protocol description, containing the general description of the study, with primary and secondary objectives. In this document it is described the clinical background and the actions for the experimental protocol; it is also described the target population of the study, formalized with inclusion and exclusion criteria to be applied in some selected subjects. Another important point to describe is patient risk/benefit ratio and risks associated with the study and statements on ethical aspects and data protection management. The documentation package contains also the informed consent for the patients and information document for the patients' GP. The summary of the clinical study is reported in chapter 6 of this document.

The DPIA document was personalized by the hospital partners (FTGM, CHU, SCUBA and HYG) with site-specific constraints according to the local amendments of the GDPR in relation to the country of the pilot site.

Since the pilots will take place in different countries, a multicentric study is designed with a Principal Investigator identified with FTGM (IT) acting as a coordinator of the research and the other sites acting as a research centre participant in the research. The principal investigator submits the documentation package as the first centre, and the other pilot centres follow according to their local regulation. The approval for the principal investigator is mandatory, so the other participant centres submit the documentation package following the permission given to the principal investigator.

The study will be carried out following the "Ethical principles for medical research in humans" included in the latest version of the Declaration of Helsinki (Edinburgh Amendment, October 2000) and in accordance with the protocol which will be submitted to the regional Ethics Committee and with the standardized work procedures (SOPs) that ensure compliance with Good Clinical Practice (GCP) standards, as described in the Harmonized Tripartite Standards of the ICH for Good Clinical Practice (1996).

Some ethical aspects considered by the team supporting the pilot of the Hospital partners FTGM, CHU, SCUBA and HYG are the following:

- The patients included in this study are NOT subjected to experimental consideration, as the comprehensive clinical-medical support program that is in fact already implemented in the usual clinical practice of the participating center, and therefore will not pose any additional risk.
- The collection and processing of personal and health data of the subjects participating in this study will be limited to the data necessary for the correct development of the study and described in the research protocol that will be approved by the Ethics Committee according to the applicable regulations. For the clinical study protocol there will be no direct identification elements recorded for patients, and a pseudo-ID will be used to identify the patient, also allowing to avoid duplicates from the sources. This confidential information, the pseudo-ID assigned to the patient, will be the exclusive property of the clinical institution, it will not be disclosed to others without the prior written consent of the coordinating researcher and the rest of the principal investigators and may not be used except for the conduct of this study, excluding life-threatening events. During the conduct of the study, the medical researcher and the persons who must handle the information derived from it, will act with the strictest confidentiality.

The principal investigator FTGM submitted the package of the INTERVAL study to the reference Ethical Committee and received the permission to execute the study in June 2021.

Data collected during the execution of the experimental scenarios will be managed according to the Data Management Plan, described in the InteropEHRate deliverable D1.8 — Data Management Plan V2 [8] .

2.2 Platform test-flight

Before involving real patients, an initial validation test will be performed, using smartphones and related healthcare data, which will simulate the travelling of a patient to the different sites in order to check if the different protocols work as planned.

For pilots 1 and 2, HCPs of the different sites, involved in the experimentation of the real scenario will use the D2D, R2D emergency, R2D backup and R2D Remote protocol, entering and exchanging data of synthetic, i.e. non-existing, patients to check if the systems correctly transmit and translate the data. This will be done by stressing the system with exchange and translation of complex synthetic health data among the different healthcare structures involved in the experimentation (Italy, Romania, Greece and Belgium). The HCPs will have to evaluate the accuracy and completeness of the information exchanged for each level of interoperability: security, syntactic and semantic. This evaluation will be done by controlling the application of the security mechanism at user level (identification of the user), and, for the accuracy and completeness, through the comparison of the synthetic source data with the ones available on the S-EHR application and HCP application.

For pilot 3 will be defined 3 different research protocols on which to test submission to the research network, and using the patients subjects of the previous tests: will be tested the interaction between patients and the researchers to exchange with them the requested data. In particular, systems behaviour will be tested in terms of informed consent requests, GDPR compliance, data selection and anonymization/pseudonymization, data transfer and feedback received by the citizens/patients.

At the end of this validation, the platform and set of tools will be ready for use.

This final validation will be done in a cooperative way with the reference ICT providers of each pilot site (i.e. ENG, BYTE, A7, SIMAVI, UPRC and UNITN) supplying constant interaction with and support to involved actors, with the final goal to collect feedback, bugs, problems that will be solved in the end for the final technical assessment of the solution.

2.3 Users' evaluation and assessment

For the assessment of the results produced during the execution of the three Experimentation scenarios in the pilots' sites, are considered the following principles:

- Usability;
- Usefulness (also in healthcare processes);
- Information Quality;
- Interface quality.

Such principles can be detailed in the following topics of the platform functionalities:

- human-machine ergonomics, considered in the usability and interface quality evaluation;
- resilience to human errors, considered in the information quality;

- data availability, considered in usability and system usefulness;
- data readiness, considered in usability and system usefulness;
- user expectation upon defined functionalities, considered in system usefulness;
- level of awareness and confidence of device/tools usage, considered in the system usability and usefulness;
- perceived level of trustability, considered in system usability and usefulness.

For each type of scenario, the above-mentioned principles will correspond to different actions performed by different final users and related functionalities to be evaluated. Since the functionalities requested by the user requirements are used in a different way or in a different context, depending on the profile/role of final user (patient, HCP, researcher) and the type of scenario, a differentiated set of scales will be adopted for each profile/role to evaluate correctly the implemented functionalities related to each scenario.

At the end of the activities executed on each pilot, a questionnaire will be submitted for completion to each patient enrolled in the three pilots. An equivalent assessment will be compiled by the Healthcare professionals involved in the first two pilots and by the researchers of the third pilot.

The evaluation of results reported in questionnaires will provide an overall score for the platform.

2.4 Questionnaires

Among the several criteria listed above, usability is both a relevant and critical evaluation aspect. The usability of an artefact is defined by the context in which that artefact is used and, since we are considering different contexts, the measures of usability must depend on how the usability is defined and related to the context.

It is possible to consider some general classes of usability measure; the standard ISO 9241-11 [9] suggests that measures of usability should cover:

- effectiveness (the ability of users to complete tasks using the system, and the quality of the output of those tasks);
- efficiency (the level of resource consumed in performing tasks);
- satisfaction (users' subjective reactions to using the system).

In response to these requirements, in 1986 a simple usability scale was developed. The System Usability Scale (SUS) [4] is a simple, ten-item scale giving a global view of subjective assessments of usability. SUS is a kind of Likert scale [5] , and this kind of scale is used in many other contexts in healthcare, from pain measurement to drugs efficiency. It is often assumed that a Likert scale is simply based on forced-choice questions, where a statement is made, and the respondent indicates the degree of agreement or disagreement with the statement on a 5 (or 7) points scale.

The technique used for selecting items for a Likert scale was to identify examples of things using a range of answer options that go from strongly agree to strongly disagree. In addition, items were selected so that the common response to half of them was strong agreement, and to the other half, strong disagreement. This was done in order to prevent response biases caused by respondents not having to think about each statement; by alternating positive and negative items, the respondent has to read each statement and make an effort to think whether they agree or disagree with it.

The SUS is a 10-item questionnaire with 5 response options on the following topics:

1. I think that I would like to use this system frequently.
2. I found the system unnecessarily complex.
3. I thought the system was easy to use.
4. I think that I would need the support of a technical person to be able to use this system.
5. I found the various functions in this system were well integrated.
6. I thought there was too much inconsistency in this system.
7. I would imagine that most people would learn to use this system very quickly.
8. I found the system very cumbersome to use.
9. I felt very confident using the system.
10. I needed to learn a lot of things before I could get going with this system.

The SUS uses the following response format:

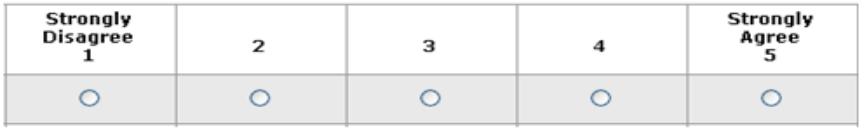

Figure 1 - Example of response from the user

The final score for SUS is produced applying the following rules:

- For odd-numbered items: subtract one from the user response.
- For even-numbered items: subtract the user responses from 5.
- This scales all values from 0 to 4 (with four being the most positive response).
- Add up the converted responses for each user and multiply that total by 2.5. This converts the range of possible values from 0 to 100 instead of from 0 to 40.

SUS scale evaluation is evaluated as sufficient with results greater than 68, considering this number the average score emerging from the application of the scale. Good results are scoring more than 80 in the final calculation.

Concerning the set of tools provided by the InteropEHRate platform, and tested by the final users in the pilots, there are also aspects related to Information Quality and Interface Quality to be evaluated, not precisely addressed in the SUS questionnaire. To evaluate these aspects was developed another Likert scale, similar to the SUS scale, the Post-Study System Usability Questionnaire – PSSUQ[6] .

The questionnaire is using the following items:

1. Overall, I am satisfied with how easy it is to use this system.

2. It was simple to use this system.

3. I was able to complete the tasks and scenarios quickly using this system.

4. I felt comfortable using this system.

5. It was easy to learn to use this system.

6. I believe I could become productive quickly using this system.

7. The system gave error messages that clearly told me how to fix problems.

8. Whenever I made a mistake using the system, I could recover easily and quickly.

9. The information (such as online help, on-screen messages, and other documentation) provided with this system was clear.

10. It was easy to find the information I needed.

11. The information was effective in helping me complete the tasks and scenarios.

12. The organization of information on the system screens was clear.

13. The interface of this system was pleasant.

14. I liked using the interface of this system.

15. This system has all the functions and capabilities I expect it to have.

16. Overall, I am satisfied with this system

To address the topics:

- Questions 1 to 16: Overall
- Questions 1 to 6: System Usefulness (SYSUSE)
- Questions 7 to 12: Information Quality (INFOQUAL)
- Questions 13 to 16: Interface Quality (INTERQUAL)

In particular the usefulness can be detailed in the context of patients' illness, and in Pilot 3 - Health research study – another questionnaire will be defined in addition of the above-mentioned questionnaire to collect a specific response from patients.

In the sections dedicated to Pilots, for each Pilot will be described the questionnaires used for the final assessment.

2.5 Validation plan and planned activities

The validation plan of each pilot consists in the execution of the related experimentation scenario, defined starting from the actions described in the general scenario in deliverable D2.3 [2] . The scenarios 1, 2, and 3 are supported also by precondition and actions from the Scenario 0 "Initial S-EHR feed".

The experimentation scenario is expressed as a list of action to be executed and, considering the human-centric approach, the list is divided in two types:

A list of preliminary actions for the scenario (Scenario pre-conditions), composed by actions executed once for each site and for each patient (and HCP).

A list of actions for the live scenario, that is repeated for each patient (and HCPs), corresponding to general scenario actions description

For each pilot are specified two tables, classified as “preliminary” and “live”. The tables describe on the column “Action” the list of actions performed by the different types of actors, reported on the column “Actor”. Each action reported can be related to the general scenario in the column “Ref. general scenario”, to highlight the correspondence between this one and the real-life application for the pilot site. The same reference can be reported in different actions and it corresponds to a finer level of detail of the referenced general scenario to be executed in the pilot. The reference is composed by the referred scenario (e.g.: S0 for Scenario 0, S1 for Scenario 1, etc.) and the referred step (e.g.: A, B, C, 1, 2, 3, etc.) corresponding to deliverable D2.3 [2] , thus “S0.2” corresponds to the action 2 of Scenario 0.

Each action is customized, where necessary, according to the specific needs of the Pilots’ site, related to national/local regulation, and in compliance with business processes and rules of the pilot site. For each hospital involved in the Pilot, general actions constraints are reported in the respective table column, to support the execution and validation of the pilot experimental scenario. Where the action can be executed as described in the “Action” column, in the corresponding column of the pilot site will be reported the comment “no personalization expected”.

From those lists are excluded some preliminary or live actions that are expressing functional or non-functional requirements. which are: not a subject of the test, or not relevant for the human actors of the scenario (e.g.: corresponding to internal technological requirements of the platform), or cannot be implemented by the pilot site within the project scope.

However, the excluded actions don’t affect the capability to run the experimental scenarios for the pilots site supporting the expected healthcare process neither to compromise the validity of the project piloting.

Data collected during the execution of the experimental scenarios will be manged according to the Data Management Plan, described in the InteropEHRate deliverable D1.8 - Data Management Plan V2 [8] .

Before starting each pilot, the InteropEHRate data integration platform will be installed on the pilot site, configured and tested according to its local language, dictionaries and integration capability, also to support the conversion and translation of structured and unstructured information.

2.6 Involved actors

The following sections refer to different kinds/roles of final users (called “actors”, following the UML terminology) and IT systems, interacting between them across the two different classes.

The Human actors, also including represented organizations (research, healthcare providers, etc.), are structured in a generalization hierarchy, where for example a Data User is a more general kind of actor than a Patient. The specification of experimentation scenarios mainly refers to the actors Researcher, HCP, and Patient.

In the following table are described the human-class actors.

Actors	Description	General actor
Data user	Any person that may perform a processing (creation, reading,	-

	updating, etc.) on health data.	
Citizen	Any person in a specific country whose health data is managed by an application included in the InteropEHRate architecture.	Data user
Patient	A citizen with a disease or a health issue. Any person that receives healthcare from HCPs. Current requirements consider patients that are also citizens.	Citizen
HCP	A healthcare professional that produces and/or accesses to health data of a Patient. Can be a member of a multidisciplinary team composed of several healthcare professionals working together to execute healthcare processes (e.g.: Medical Doctors, Nurses, Midwives, physiotherapists, …)	Data user
Doctor	Medical Doctor - a kind of HCP who is concerned with promoting, maintaining, or restoring health through the study, diagnosis, prognosis, and treatment of disease, injury, and other physical and mental impairments.	Data user
Nurse	A profession within the health care professionals focused on the care of individuals, families, and communities, so they may attain, maintain, or recover optimal health and quality of life.	HCP
GP	General Practitioner – A first-line Doctor	Doctor
Data scientist	Any person able to understand specific kinds of health data and express them according to specific standards adopted in the health domain.	Data user
IT Administrator	Technical IT personnel responsible for system administration.	Data user
ORG	Healthcare organization: any organization that provides healthcare services to citizens.	Data user
Hospital	Healthcare Institution Organization. A healthcare organization for in- and out-patient services provisioning.	Healthcare organization
RO	Research Organization — Hospital, University, Research Centre, Institute, etc., recognized by EU/national regulations as an actor responsible and/or performer of clinical or health related research.	Data user
Researcher	Any person that desires to exploit the citizens' health data for research purposes.	Data user
Coordinating Research Centre	A medical research centre that initiates a particular research study and is in charge of defining it and carrying it out.	RO
PI	Principal Investigator of a research study — a researcher internal to the Coordinating Research Centre, who is in charge of leading the study.	Researcher
Reference / local Research Centre (of a citizen)	A research centre participating in a given study that is a reference point for a specific citizen. The citizen sends health data to it for the duration of the study, and the reference research centre is responsible for monitoring the citizen during the study.	RO

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

In some activities are specified also IT-class actors, i.e. electronic or software systems. Their action is operated or triggered by some actions performed or requested by Human actors.

In the following table are described the IT-class actors.

Actors	Description
S-EHR, S-EHR App	Mobile application, installed on patient's phone for storage, control, anonymization, and exchange of health data, without the obligation to store data in the cloud.
S-EHR device	A device (laptop, computer) that is able, using the D2D protocol, to read and transfer the content of S-EHR or part of the content of S-EHR.
S-EHR Cloud	Secure cloud service, able to store on the cloud the data collected by S-EHRs, adopting the standard protocols defined by the project.
HCP App	Any app used by HCPs to securely exchange health data with any S-EHR. An HCP App may be the front end of an EHR, may be a distinct application integrated with an EHR, or it a may be a completely independent application.
HCP Terminal	Any computer or smart device where the HCP App is installed and running.
EHR	Electronic Health Record: IT system(s) used to support processes related to patient care (diagnosis, complications, administrative, treatment, clinical, management, legal, etc.). It contains a collection of health data of citizens, including prevention data, supporting care and wellbeing roadmaps, linking different sectors within the health and social care ecosystems.
EHR app	Electronic Health Record Application - The application installed on every HCP terminal that gives access to the EHR of all known patients.
HR	Health Record, any data related to a person's health.
Smart Device	iOS or Android device. Patient's or HCP's phone/tablet/handheld device.
IDP	Identity Provider Organization.
ID	Identification of person document, smart card, token, OTP, etc., used to identify a person (patient or HCP).
eIDAS	eIDAS - electronic IDentification, Authentication and trust Services - is an EU regulation on electronic identification and trust services for electronic transactions in the European Single Market. It was established in EU Regulation 910/2014 of 23 July 2014 on electronic identification and repeals 1999/93/EC from 13 December 1999.
RSW	Réseau santé wallon - An index of clinical documents for every Walloon citizen. The index can be queried externally to have a list of matching documents. Then, individual documents can be retrieved from the source.
ItsME	ItsMe is the currently certified eIDAS Qualified Trust Service Provider in Belgium
SPID	SPID is the certified eIDAS Qualified Authentication Service Provider in Italy
C7	EHR of FTGM.

Table 2 - IT-class Actors involved in the definition of experimentation scenarios

2.7 Reference InteropEHRate architecture

A simplified view of the architecture (described in deliverable D2.6 [7]) is included in this document because in the pilots' activities description will be referred elements of the architecture and to the interactions among them.

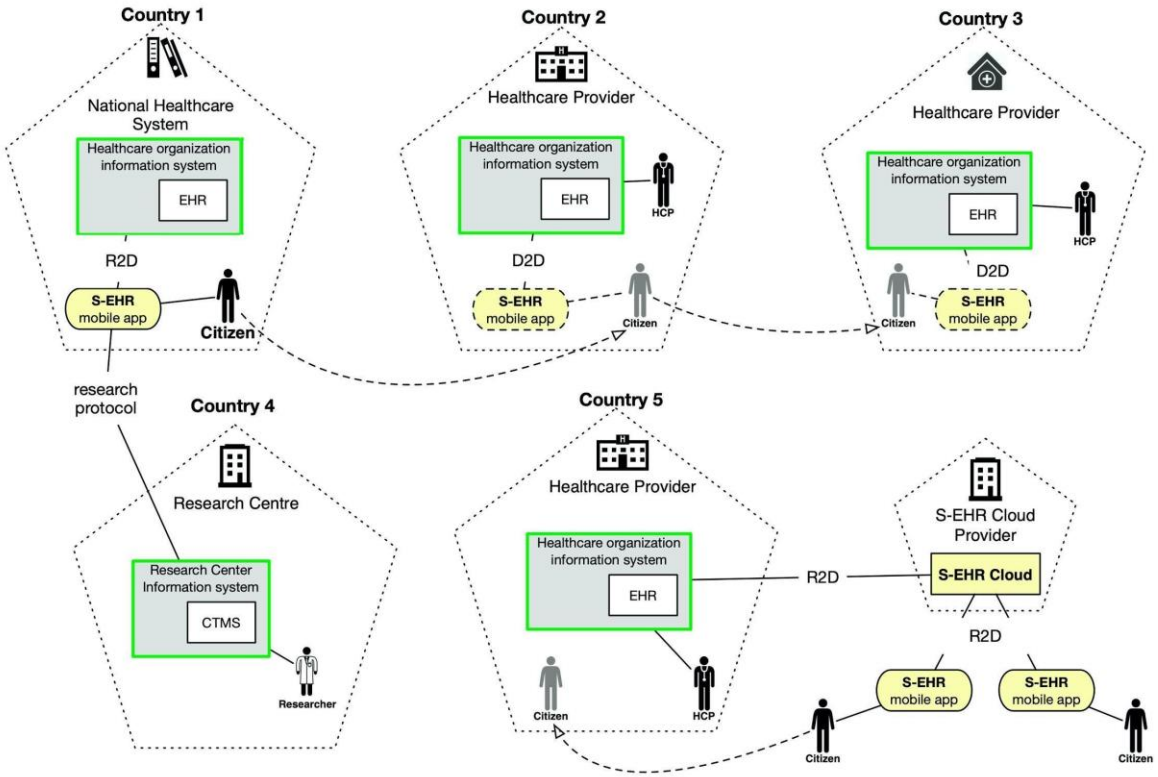

Figure 2 - Reference general architecture for InteropEHRate

3 PILOT P1 - MEDICAL VISIT ABROAD

The main purpose of this pilot 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 the internet nor cloud storage.

3.1 Experimentation scenario

The scenario referenced in this pilot is S1- Medical Visit (see deliverable D2.3 [2]).

A common device owned by a patient is represented by a smartphone (or tablet/smartphone, or phablet), on iOS or Android platform, so the 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. This app is called S-EHR (Smart-EHR) Mobile App, or simply S-EHR.

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

In the pilot sites exchanged information, collected on HCP App, will not be maintained by the HCP and/or his/her healthcare organization, and will be deleted at the end of the project.

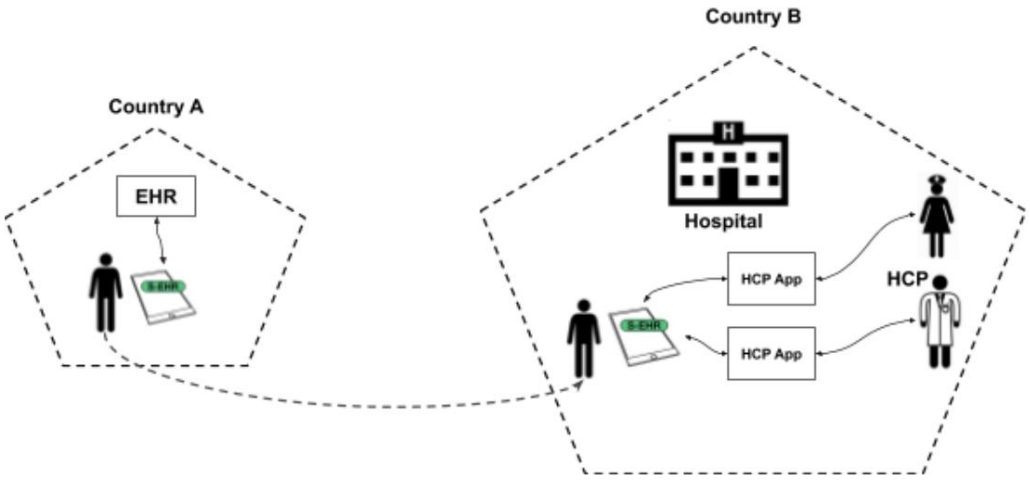

Figure 3 - Reference scenario S1 - Medical visit abroad

For this scenario, the platform will be tested in the following countries:

- Belgium: UNIVERSITY HOSPITAL CENTER OF LIEGE (CHU) enrolling 3 patients.
- Greece: ATHENS DIAGNOSTIC AND TREATMENT CENTERS (HYG) enrolling 3 patients.
- Italy: GABRIELE MONASTERIO TUSCANY FOUNDATION (FTGM) enrolling 3 patients.

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3.2 Validation plan

The following actions are performed to implement the preconditions described in the general scenario S1 and represent preliminary actions for the execution of the experimental scenario 1 for each patient. When the action is preliminary and needs to be executed just once for each pilot's site, will be specified in the action's description. The description of the tables are reported in section 2.5 Validation plan and planned activities of this document.

#	Actor	Ref. general scenario	Preliminary Action	CHU	HYG	FTGM
A	Patient	S0.A	The Patient installs S-EHR app on his/her smartphone with Android OS. A minimum of 4 GB available for mass storage is requested for the Pilot activities.	no personalization expected	no personalization expected	no personalization expected
B	Patient	S0.B	The Patient gives 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.	no personalization expected	no personalization expected	no personalization expected
C	S-EHR	S1.B	If the Patient is owning a digital identity eIDAS compatible, 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.	no personalization expected	Not applicable	no personalization expected
C.1	Patient	S0.2	the Citizen logs into the emulated eIDAS provider and obtains a certificate of identification from his/her CEF-ID trusted certification authority	ItsMe in Belgium is certified as an eIDAS Qualified Trust Service Provider	no personalization expected	SPID in Italy is certified as an eIDAS Qualified Trust Service Provider
D	Patient	S1.D	Download previous health data from Hospital	no personalization expected	will be manually entered by the patient on the S-EHR	no personalization expected

					the following sections: • current medication, • allergies, • chronic disease	
D.1	Patient, S-EHR App	S0.1	The patient accesses the list of Hospitals connected to the S-EHR and selects his reference Hospital;	CHU is selected for patients enrolled by CHU	This function is not used	FTGM is selected for patients enrolled by FTGM
D.2	Patient, S-EHR App	S0.3	A list of encounters of the chosen Hospital is presented. An item related to the latest IPS downloadable is added at the beginning of the encounter list.	no personalization expected	This function is not used	IPS will not be available for FTGM.
D.3	Patient, S-EHR App	S0.4	The patient selects one encounter or IPS to be downloaded	the IPS of the CHU Hospital will be selected	This function is not used	the last visit/admission will be selected
D.4	Patient, S-EHR App	S0.4	Health data related to the selected encounter are transmitted to S-EHR	IPS will be used for the following sections: • current medication, • allergies, • chronic disease	This function is not used	will be provided the following sections: • current medication, • allergies, • chronic disease
E	HCP HCP App	S1.G	Each HCP involved in this scenario works in a setting/room where he/she uses an HCP workstation 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. Accounts will be created by the IT administrator with username	Each patient is examined in a visiting room by one or more HCPs. 3 HCP workstations will be used with OS	3 HCP workstations will be used, with OS windows. 4 HCP and 1 IT administrator will be registered on the platform as	3 HCP workstations will be used, with OS windows. 4 HCP and 1 IT administrator will be registered on the platform as

			and password assigned to the involved personnel of hospital partners. The IT administrator account will be created by the provider of the software demonstrator HCP App *This preliminary action is executed once for each site*.	Windows. 4 HCP and 1 IT administrator will be registered on the platform as users.	users.	users.
F	ORG	S1.H	Each healthcare organization has a digital identity that may be represented within the HCP App and is trusted by the S-EHR. *This preliminary action is executed once for each site.*	The digital identity will be generated by the HCP App platform provider and will be locally valid for the site.	The digital identity will be generated by the HCP App platform provider and will be locally valid for the site..	The digital identity will be generated by the HCP App platform provider and will be locally valid for the site.
G	Patient HCP	S1.I	Any 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. *This preliminary action is executed once for each site*.	Access with an IT Administrator account on HCP App and check the logs reported.	Access with an IT Administrator account on HCP App and check the logs reported.	Access with an IT Administrator account on HCP App and check the logs reported.

Table 3 - List of preliminary actions for Pilot 1

The following actions are performed in the execution of the experimental scenario 1 for each visit of the involved patients.

#	Actor	Ref. general scenario	Live Action	CHU	HYG	FTGM
0	Patient	S1.D	The day before the visit the patient enters manually on the S-EHR App: • body weight • blood pressure	no personalization expected	no personalization expected	no personalization expected
1	Patient HCP1	S1.1	The patient is admitted.	HCP1 = welcome desk staff member	HCP1 = nurse	HCP1 = nurse

1.0	Patient HCP1	S1.1	HCP1 asks the Patient to: • open the S-EHR App • open data sharing functionality	no personalization expected	no personalization expected	no personalization expected
1.1	HCP1	S1.1	HCP1 selects the Outpatient settings on HCP App, and opens a new connection with the S- EHR of the patient. A QR code is displayed on the screen.	no personalization expected	no personalization expected	no personalization expected
1.2	Patient	S1.1	The patient starts local sharing on the S-EHR, enabling Bluetooth connection, and scans the QR code of the HCP's screen.	no personalization expected	no personalization expected	no personalization expected
2	Patient	S1.2	As soon as the connection is successfully completed, the patient may see on the screen of his/her Smartphone the data describing the Health Organization (name, address, etc.) and the identity of the HCP1 logged into HCP App.	no personalization expected	no personalization expected	no personalization expected
3	Patient	S1.3	The patient recognizes that the description corresponds to the organization where he/she is at that moment, so he/she continues in the connection.	no personalization expected	no personalization expected	no personalization expected
4	HCP1	S1.4	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).	no personalization expected	no personalization expected	no personalization expected
5	Patient	S1.10	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.	no personalization expected	no personalization expected	no personalization expected
6	Patient	S1.11	Through 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	no personalization expected	no personalization expected	no personalization expected

			5.1).			
6.a	HCP1, HCP2, HCP3	S1.11	the other HCP having an account registered for the Healthcare Organization in HCP App and involved in that specific patient care/treatment are authorized to access S-EHR data trough HCP App.	HCP1 has only access to identification data. HCP2 and HCP3 can read/write medical content.	Write grants is related to authors	no personalization expected
7	HCP App	S1.12	The consent is transmitted to the HCP App and recorded by it for future traceability. The consent is readable on the log system of HCP App.	no personalization expected	no personalization expected	no personalization expected
8	HCP1 HCP App	S1.13	A dataset of patient's data is 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).	no personalization expected	no personalization expected	no personalization expected
8.0	HCP App	S1.15	Downloaded patient's data are imported into HCP App and translated into HCPs natural language (target language). HCPs target language is the one officially related to the Healthcare provider. Structured data will be translated in the target language. Unstructured data will be translated in the target language. Documents (pdf, images, signals) will not be translated.	French	Greek	Italian
8.1	HCP2	S1.13	Admission is now completed, and the patient moves on to the consultation room. From this on, the patient interacts with HCP2 on a different workstation.	HCP2 = nurse	HCP2 = nurse	HCP2 = nurse
8.2	HCP2	S1.14	HCP2 logs on HCP App.	no personalization expected	no personalization expected	no personalization expected
8.3	HCP2	S1.14	HCP2 has to re-pair the S-EHR with the HCP App.	no personalization expected	no personalization expected	no personalization expected

9	HCP2	S1.14	patient's data, downloaded on action 13, is visualized, by the HCP2 using the HCP App.	no personalization expected	no personalization expected	no personalization expected
10	HCP2 HCP App	S1.15	Are visualized on HCP App: body weight and blood pressure measurements, entered by the patient.	no personalization expected	no personalization expected	no personalization expected
11	HCP2	S1.16	HCP2 measures vital signs, body weight, BP, pulse, respiratory rate, SPO2, Temp.	HCP2 enter anamnesis on HCP App	no personalization expected	no personalization expected
12	HCP2	S1.17	HCP2 can optionally request for a chest X-ray and/or an echocardiogram at local imaging facilities, to be executed immediately	No X-ray nor Echo will be performed. (see step 21)	Optionally Executed exams results will be manually uploaded in HCP App as a file (PDF file and DICOM file)	Optionally Executed exams results will be manually uploaded in HCP App as a file (PDF file and DICOM file)
13	HCP2	S1.17	If requested: HCP2 accompanies the patient to execute the requested chest X-Ray and/or echocardiogram and then in a waiting room where he/she can wait to have a specialist evaluation	If requested: HCP2 performs an electrocardiogram (ECG). Executed exams results will be manually uploaded in HCP App as a file (PDF file)	no personalization expected	no personalization expected
14	HCP3 HCP App	S1.18	Another HCP, HCP3, is assigned to evaluate the patient in a different room. HCP3 logs on HCP App, with assigned credentials. HCP3 has to pair (again) the S-EHR with the HCP App, reapplying the same actions defined in 1.0 to 11. S-EHR is connected with HCP3 workstation and HCP App.	HCP3 = cardiologist	HCP3 = cardiologist	HCP3 = cardiologist

14.1	HCP App	S1.18	Data produced by the HCP1 and HCP2 during the evaluation are collected in the HCP App and available for HCP3.	no personalization expected	no personalization expected	no personalization expected
15	HCP3 HCP App	S1.20	HCP3 starts to visit the patient: evaluate the patient's history from the S-EHR app	no personalization expected	no personalization expected	no personalization expected
16	HCP3 HCP App	S1.21	HCP3 updates on the HCP App the patient's clinical history, reporting new symptoms.	If requested: HCP3 performs echocardiogram to measure vital signs. Executed exams results will be manually uploaded in HCP App as a file (DICOM file) by HCP3.	no personalization expected	no personalization expected
17	HCP3 HCP App	S1.22	HCP3 evaluates previous vital signs and measures, and compares them with current values.	no personalization expected	no personalization expected	no personalization expected
18	HCP3	S1.24	The HCP3 retrieves information from S-EHR on prescribed drugs. HCP3 decides to initiate a new drug / update current prescription. HCP adds a new prescription in the HCP App.	no personalization expected	no personalization expected	no personalization expected
19	HCP3	S1.25	The HCP3 finalizes the visit by compiling an evaluation report on the HCP app. The report contains: ● visit's reason, ● updated patient's history, ● diagnostic conclusions, ● evaluation report and treatment plan, ● reports and images of diagnostic examinations (X-Ray, Echocardiogram, etc.),	will be reported just the executed examination, i.e. EKG, X-Ray, Echocardiogram, etc.	will be reported just the executed examination, i.e. EKG, X-Ray, Echocardiogram, etc.	will be reported just the executed examination, i.e. EKG, X-Ray, Echocardiogram, etc.

			• drugs prescriptions and administration plan			
20	HCP3	S1.27	The HCP3 uploads data from the HCP app to S-EHR using the D2D connection already established from the HCP3 workstation, and close the visit.	no personalization expected	no personalization expected	no personalization expected
POST.1	HCP App	S1.POST1	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 up to the end of the pilot activity.	no personalization expected	no personalization expected	no personalization expected
POST.2	Patient	S1.POST2	The citizen uses S-EHR to look at the medication management, reading prescribed drugs and dosage.	no personalization expected	no personalization expected	no personalization expected

Table 4 - List of actions for Pilot 1

3.3 Dataset

In the following section is reported a sample dataset of values that will be contained in S-EHR for the evaluation of the patients.

General Data:

- Name, Surname
- gender
- Date of Birth, place of birth (town, country)

Current status:

- Allergies and intolerance
- Main Chronic Conditions
    - Ischemic heart disease
    - Heart failure
    - Hypertension
    - Pulmonary disease
- Current Medications

History:

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

Vital parameters:

- Body weight (Kg), date of measurement
- blood pressure (mmHg), date of measurement
- heart rate (bpm), date of measurement

EKG:

- PDF report
- DICOM waveform (optional)
- rhythm (e.g.: sinus rhythm, atrial fibrillation, paced, etc.)
- heart rate (bpm)
- QRS intervals (msec) (optional)
- QTc intervals (msec)(optional)

Echocardiogram:

- DICOM movie
- pdf report
- LVEF (%)
- left ventricular end systolic/diastolic volume (mL) (optional)

- septum thickness

Chest X-ray:

- PDF report (optional)
- textual report;
- DICOM images

Latest bio-humoral values:

- haemoglobin (g/dl)
- white blood count
- creatinine (mg/dl)
- eGFR (ml/min/1.73m2)
- AST
- ALT

3.4 Involved Participants

In this Pilot will be involved 9 Patients and 12 Healthcare professionals in 3 different pilot sites Hospitals.

In each Hospital a set of 4 HCPs will be selected and trained on the usage of the platform, and they will be registered as users of the platform for the HCP App tool to access patient's data and enter health information.

For each Hospital involved, each patient candidate will be contacted by the investigator of the Hospital at the beginning of the Pilot, asking for the participation to this experimental scenario as a part of the usual healthcare process. If the patient candidate accepts, an informed consent will be submitted to him/her for data collection and for the submission of the anonymous final evaluation questionnaire.

3.5 Evaluation questionnaire

The final questionnaire will be submitted to involved patients and Healthcare Professionals.

For the patients will be used the SUS questionnaire related to the usage of the S-EHR application on the smartphone and interaction with other actors in the scenario.

In the following figure is reported the patient's questionnaire:

System Usability Scale

For each of the following statements, please mark one box that best describes your reactions to S-EHR App.

		Strongly disagree				Strongly agree
1.	I think that I would like to use S-EHR App frequently.	1	2	3	4	5
2.	I found S-EHR App unnecessarily complex.	1	2	3	4	5
3.	I thought S-EHR App was easy to use.	1	2	3	4	5
4.	I think that I would need the support of a technical person to be able to use S-EHR App.	1	2	3	4	5
5.	I found the various functions in S-EHR App were well integrated.	1	2	3	4	5
6.	I thought there was too much inconsistency in S-EHR App.	1	2	3	4	5
7.	I would imagine that most people would learn to use S-EHR App very quickly.	1	2	3	4	5
8.	I found S-EHR App very cumbersome (awkward) to use.	1	2	3	4	5
9.	I felt very confident using S-EHR App.	1	2	3	4	5
10.	I needed to learn a lot of things before I could get going with S-EHR App.	1	2	3	4	5

Comments (optional):

Figure 4 - Pilot 1 patient's questionnaire

For the HCPs will be used, the PSSUQ questionnaire related to the usage of the HCP application on the workstation and interaction with other actors in the pilot.

The figure below details the HCP's questionnaire:

	Strongly Agree						Strongly Disagree	
PSSUQ	1	2	3	4	5	6	7	N.A.
1. Overall, I am satisfied with how easy it is to use this system.								
2. It was simple to use this system.								
3. I was able to complete the tasks and scenarios quickly using this system.								
4. I felt comfortable using this system.								
5. It was easy to learn to use this system.								
6. I believe I could become productive quickly using this system.								
7. The system gave error messages that clearly told me how to fix problems.								
8. Whenever I made a mistake using the system, I could recover easily and quickly.								
9. The information (such as online help, on-screen messages, and other documentation) provided with this system was clear.								

	Strongly Agree						Strongly Disagree	
	1	2	3	4	5	6	7	N.A.
10. It was easy to find the information I needed.								
11. The information was effective in helping me complete the tasks and scenarios.								
12. The organization of information on the system screens was clear.								
13. The interface of this system was pleasant.								
14. I liked using the interface of this system.								
15. This system has all the functions and capabilities I expect it to have.								
16. Overall, I am satisfied with this system.								

Questions 1 to 16: Overall
Questions 1 to 6: System Usefulness (SYSUSE)
Questions 7 to 12: Information Quality (INFOQUAL)
Questions 13 to 16: Interface Quality (INTERQUAL)

Figure 5 - Pilot 1 HCP's questionnaire

4 PILOT P2 — EMERGENCY ACCESS

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

4.1 Experimentation scenario

The scenario referenced in this pilot is S2- Emergency Access (see deliverable D2.3 [2]).

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.

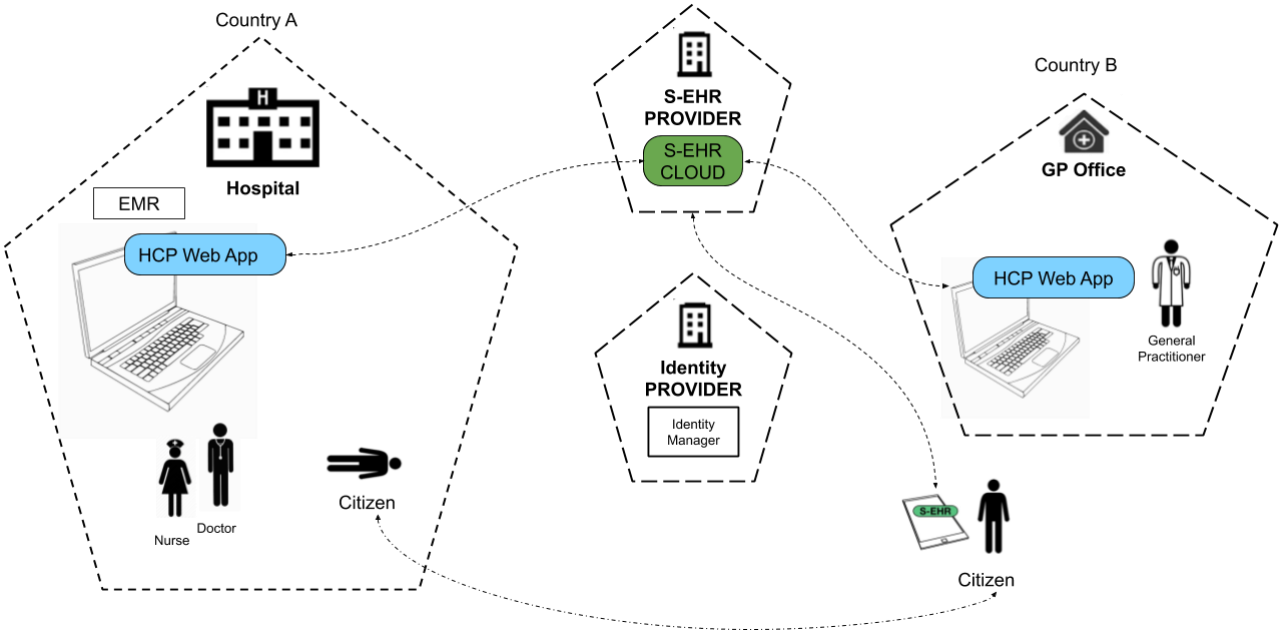

Figure 6 - Reference Scenario S2 - Emergency access

For this scenario, the platform will be tested in the following countries:

- Romania: BAGDASAR-ARSEN EMERGENCY CLINICAL HOSPITAL (SCUBA): 3 patients.
- Italy: GABRIELE MONASTERIO TUSCANY FOUNDATION (FTGM): 3 patients.
- Belgium: UNIVERSITY HOSPITAL CENTER OF LIEGE (CHU): 3 patients.

4.2 Validation plan

The following actions are performed to implement the preconditions described in the general scenario S2 and represent preliminary actions for the execution of the experimental scenario 2 for each patient. When the action is preliminary and needs to be executed just once for each pilot's site, will be specified in the action's description. The description of the tables is reported in paragraph 2.5-Validation plan and planned activities of this document.

#	Actor	Ref. general scenario	Preliminary Action	SCUBA	CHU	FTGM
A	Patient	S2.A	The Patient owns an S-EHR, installed on his/her smartphone, and pertinent consent is granted.	no personalization expected	no personalization expected	no personalization expected
B	Patient	S2.B	The Patient gave his/her consent (informed consent) to the S-EHR to store and manage his/her personal health data on the S-EHR demographic data and a photo of the patient's face is stored to identify the patient.	no personalization expected	no personalization expected	no personalization expected
C	Patient	S2.C	Download previous health data from Hospital	Will be manually entered on the S-EHR the following sections: ● current medication, ●allergies, ●chronic disease	no personalization expected	no personalization expected
C.1	Patient, S-EHR App	S0.1	The patient accesses the list of Hospitals connected to the S-EHR and selects his reference Hospital;	This function is not implemented	CHU is selected for patients enrolled by CHU	FTGM is selected for patients enrolled by FTGM
C.2	Patient, S-EHR App	S0.3	A list of encounters of the chosen Hospital is presented. An item related to the latest IPS downloadable is added at the beginning of the encounter list.	This function is not implemented	IPS of CHU will be available	List of encounters is extracted from C7 EHR
C.3	Patient, S-EHR App	S0.4	the patient selects one encounter or the IPS to be downloaded	This function is not implemented	The IPS of CHU will be selected	The last visit/admission will be selected

C.4	Patient, S-EHR App	S0.4	Health data related to the selected encounter are transmitted to S-EHR	This function is not implemented	Will be provided the following sections: ● current medication, ● allergies, ●chronic disease	Will be provided the following sections: ● current medication, ● allergies, ● chronic disease
D	Patient	S2.D	The Patient has activated and given his/her consent to the functionality that automatically replicates the content of his/her S-EHR on the S-EHR Cloud and (vice versa) copies on the S-EHR any new data uploaded by authorized actors on the S-EHR Cloud. The alignment happens automatically each time that the smartphone of the Patient is connected to the internet. Also, identity data, including a photo of the face of the patient, are uploaded in the S-EHR cloud, to identify the patient	Allow 1 day to transfer the information on the S-EHR cloud	Allow 1 day to transfer the information on the S-EHR cloud	Allow 1 day to transfer the information on the S-EHR cloud
E	S-EHR Cloud	S2.E	The content of the Patient's S-EHR is currently aligned with the content of the S-EHR Cloud.	no personalization expected	no personalization expected	no personalization expected
F	S-EHR Cloud	S2.F	The kind of data included in the emergency data set is the same defined by the International Patient Summary.	● medication, ● allergies, ● latest blood tests	● medication, ● allergies, ● latest blood tests	● medication, ● allergies, ● latest blood tests
G	Patient, S-EHR App	S2.H	The patient has an emergency identity token.	no personalization expected	no personalization expected	no personalization expected
H.1	Patient	S2.H	S-EHR generates a unique emergency code (also called "emergency identity token") and a corresponding QR-code that has been associated with that patient. The patient prints the QR-Code on paper and brings the code	no personalization expected	no personalization expected	no personalization expected

			with her or him in her or his wallet.			
H.2	HCP	S2.H	The token is used in emergency by HCPs to access to the data contained in S-EHR Cloud	The token has to be printed by the Hospital	The token has to be printed by the Hospital	The token has to be printed by the Hospital
I	Patient	S2.I	The patient gave his/her consent in S-EHR to the emergency identification by means of an emergency identity token and to share her or his health data stored on the S-EHR Cloud with HCPs in an emergency.	no personalization expected	no personalization expected	no personalization expected
J	S-EHR Cloud	S2.J	Each HCP involved in this scenario has a digital identity issued by a legal national or local authority or healthcare provider recognised by the Hospital and sent to the S-EHR Cloud infrastructure, and associated in a trusted way to his/her qualification.	The Hospital, 4 HCP and 1 IT administrator will be registered on the platform as users.	The Hospital, 4 HCP and 1 IT administrator will be registered on the platform as users.	The Hospital, 4 HCP and 1 IT administrator will be registered on the platform as users.
			Accounts will be created by the IT administrator with username and password assigned to the involved personnel of hospital partners. The IT Administrator account will be created by the provider of the software demonstrator HCP App.			
			This preliminary action is executed once for each site.			
K	HCP, HCP App	S2.K	Each HCP involved in this scenario works in a setting/room where he/she uses an HCP workstation (tablet, smartphone, PC, Mac) running the HCP App. Different rooms imply different HCP workstations. The workstation is provided with a network connection with the S-EHR cloud and a suitable device to read the emergency token.	3 HCP workstations will use OS Windows.	3 HCP workstations will use OS Windows.	3 HCP workstations will use OS Windows.
			This preliminary action is executed once for each site.			
L	HCP App	S2.M	Every action performed on the S-EHR Cloud by an author/actor is registered (logged) by both the S-EHR Cloud and the HCP App and associated permanently with the unique identification of the involved patient and HCP author/actor. This includes obvious “special actions” like accessing an Emergency Dataset.	Access with an IT Administrator account on HCP App and check the logs reported.	Access with an IT Administrator account on HCP App and check the logs reported.	Access with an IT Administrator account on HCP App and check the logs reported.
			This preliminary action is executed once for each site.			

Table 5 - List of preliminary actions for Pilot 2

The following actions are performed in the execution of the experimental scenario 2 for each patient.

#	Actor	Ref. general scenario	Live Action	SCUBA	CHU	FTGM
1	Patient	S2.1	The patient is referred to a local department for an evaluation.	no personalization expected	no personalization expected	no personalization expected
2	Patient	S2.2	Once the patient has arrived at the department, an admitting HCP1 requests the emergency identity token.	HCP1= physician	HCP1= nurse	HCP1= nurse
	HCP1		The smartphone of the patient is not available.			
3	Patient	S2.3	The HCP1 reads with a QR-code scanner the code contained in the emergency identity token and uses it on the HCP App.	no personalization expected	no personalization expected	no personalization expected
	HCP1					
4	HCP1	S2.4	HCP1, log in the HCP App, and using QR code requests access to the associated health data for emergency reasons.	no personalization expected	no personalization expected	no personalization expected
5	HCP1	S2.5	Initially, the HCP App authorizes the HCP1 to look only at the identification data of the patient associated with the emergency identity token.	no personalization expected	no personalization expected	no personalization expected
6	HCP1	S2.6	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.	no personalization expected	no personalization expected	no personalization expected
7	HCP1	S2.7	The HCP1 confirms the identification of the patient on the HCP App.	no personalization expected	no personalization expected	no personalization expected
8	HCP1	S2.8	The HCP App authorizes the HCP1 (as well as other HCPs involved in the patient's treatment) to access the (emergency) health data of the patient contained in S-EHR Cloud.	no personalization expected	no personalization expected	no personalization expected
9	HCP App	S2.9	The Patient's health data is imported from the S-EHR cloud to the HCP App.	no personalization expected	no personalization expected	no personalization expected
9.1	HCP1	S2.9	Data is visualized (and imported) by the HCP App used by HCPs currently authorized to treat patient's data (i.e. involved in the patient's treatment process).	language = Romanian	language = French	language = Italian
			imported data are translated into HCPs natural language (target language). HCPs target language is the one officially related to the			

			Healthcare provider. Structured data will be translated in the target language. Unstructured data will be translated in the target language. Documents (pdf, images, signals) will not be translated.			
10	HCP2	S2.10	HCP2 logs into the HCP App on another workstation and selects the patient encounter. The admitting HCP2 performs a physical examination on the patient.	HCP2= physician	HCP2= physician	HCP2= physician
11	HCP2	S2.11	HCP2 consults the patient's history on the HCP App, imported from the S-EHR cloud. On HCP App the imported information from S-EHR Cloud contains the author or source.	no personalization expected	no personalization expected	no personalization expected
13	HCP2	S2.13	HCP2 performs an exam on the patient. Results are displayed on the HCP App.	Executed exams results will be manually uploaded in HCP App as a file (PDF or DICOM file)	Executed exams results will be manually uploaded in HCP App as a file (PDF file)	Executed exams results will be manually uploaded in HCP App as a file (PDF or DICOM file)
14	HCP3	S2.14	Optional: HCP3 logs into the HCP App on another workstation, and selects the patient. HCP3 performs an evaluation of the patient entering results on HCP App.	HCP3=nurse	HCP3=nurse	HCP3=nurse
16	Patient	S2.16	The Patient will continue with normal hospital courses.	no personalization expected	no personalization expected	no personalization expected
19	HCP4	S2.18	At the end of the hospital course, HCP4 writes the discharge summary for the patient on HCP App. At patient discharge, the S-EHR Cloud is updated with the Discharge Report compiled on the HCP App and containing: ● cause/reason of admission, ● discharge diagnostic assessment,	HCP4= physician	HCP4= physician	HCP4= physician

			• instrumental examinations reports (EKG and other tests), • future visits and recommendations, • therapy and prescriptions.			
20	HCP App	S1.POST1	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 up to the end of the pilot activity.	no personalization expected	no personalization expected	no personalization expected
POST. 2	HCP App	S2.POST2	When the S-EHR App of the patient is connected again with the internet, the new data produced by the hospital is downloaded from S-EHR Cloud to the patient's phone.	no personalization expected	no personalization expected	no personalization expected

Table 6 - List of actions for Pilot 2

4.3 Dataset

In this section is reported a sample dataset of values that will be contained in S-EHR for the evaluation of the patients.

General Data:

- Name, Surname, gender
- Date of Birth, place
- Allergies
- Main Chronic Conditions
    - Ischaemic heart disease
    - Heart failure
    - Pulmonary disease
    - Abnormal kidney function
    - Abnormal liver function
    - Previous major surgery
    - Active malignancy
- Current Medications

4.4 Involved Participants

In this Pilot will be involved 9 Patients and 12 Healthcare professionals in 3 different pilot sites Hospitals.

In each Hospital a set of 4 HCPs will be selected and trained on the usage of the platform, and they will be registered as users of the platform for the HCP App tool to access patient's data and enter health information.

For each Hospital involved, each patient candidate will be contacted by the investigator of the Hospital at the beginning of the Pilot, offering the participation to this experimental scenario as a part of the usual healthcare process, and an informed consent will be submitted to them for data collection and final questionnaire submission.

4.5 Evaluation questionnaire

The final questionnaire will be submitted to involved patients and Healthcare Professionals.

For the patients will be used the SUS questionnaire related to the usage of the S-EHR application on the smartphone and interaction with other actors in the scenario.

The SUS questionnaire is reported in paragraph 3.5-Evaluation questionnaire of this document.

For the HCPs will be used the PSSUQ questionnaire related to the usage of the HCP application on the workstation and interaction with other actors in the scenario.

The PSSUQ questionnaire is reported in paragraph 3.5-Evaluation questionnaire of this document.

5 PILOT P3 - HEALTH RESEARCH STUDY

The main purpose of this pilot is to show how clinical data owned by a patient, and collected during healthcare processes involving the patient as a subject, can be shared for research purposes.

5.1 Experimentation scenario

The scenario referenced in this pilot is S3- Health Research Study (see deliverable D2.3 [2] **)**.

Citizens and researchers decide to participate in the InteropEHRate Open Research Network. The InteropEHRate Open Research Network is constituted by agreeing patients and by a group of research organizations (Hospitals, Universities, Research Centres, Institutes, etc.) that exploit a common IT infrastructure implementing the communication protocol for Health Data Sharing for Research defined by the InteropEHRate project.

This Open Research Network allows the participating researchers to enrol citizens in their research studies (described by specific research protocols) and collect health data for the studies directly from the enrolled citizens. Researchers belonging to the InteropEHRate Open Research Network share a common vocabulary, defined by the InteropEHRate profiles, used to refer to any health data required by the research studies performed on the InteropEHRate Open Research Network, and they are able to describe the selection/exclusion criteria, the requested data and related collection policies, the exit criteria of the clinical research protocol referring to those vocabularies and rules of expression.

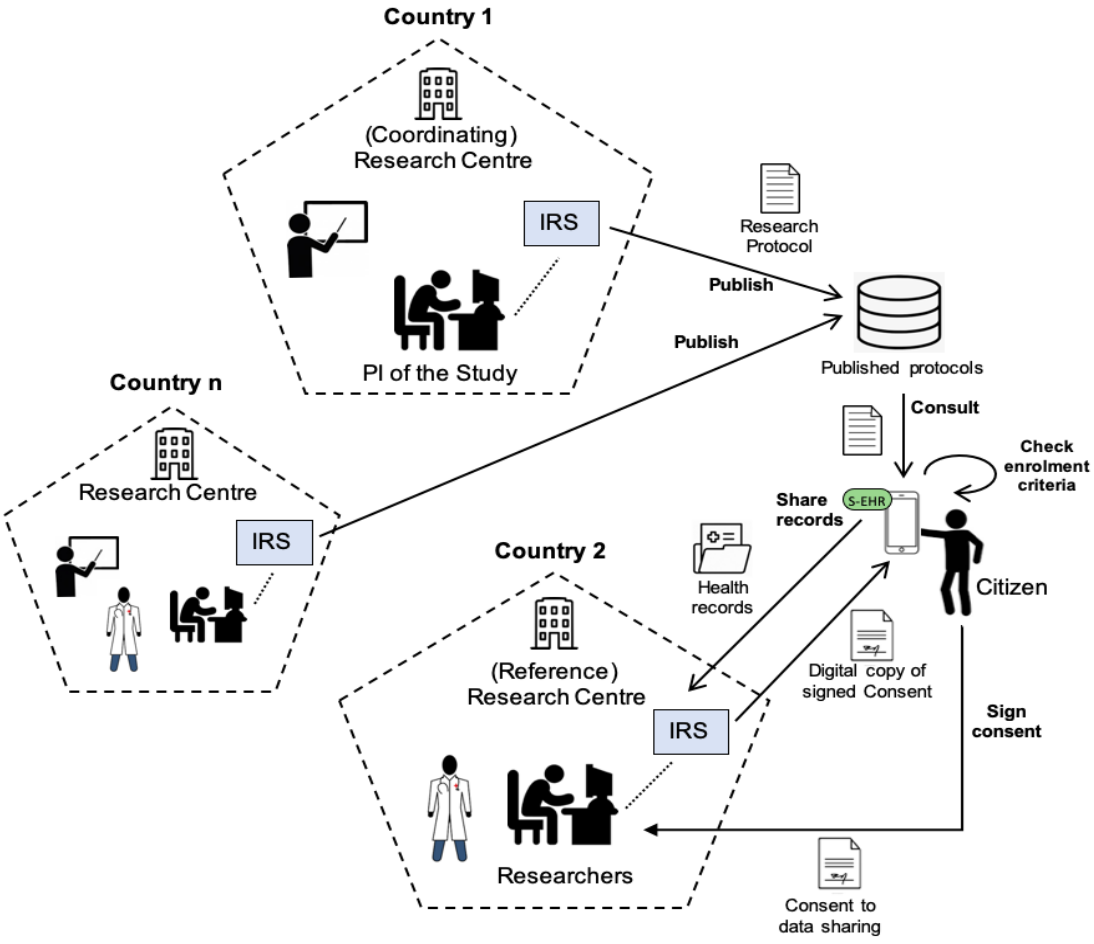

Figure 7 - Reference Scenario S3 - Health research study

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

For this scenario, the platform will be tested in the following countries:

- Italy: GABRIELE MONASTERIO FOUNDATION (FTGM): 20 patients.
- Belgium: UNIVERSITY HOSPITAL OF LIEGE (CHU): 20 patients.

5.2 Validation plan

The following actions are performed to implement the preconditions described in the general scenario S3 and represent preliminary actions for the execution of the experimental scenario 3 for each patient. When the action is preliminary and needs to be executed just once for each pilot's site, will be specified in the action's description. The description of the tables is reported is paragraph2.5 Validation plan and planned activities of this document.

#	Actor	Ref. general scenario	Preliminary Action	FTGM	CHU
A	patient	S0.A	The Patient installs S-EHR app on his/her smartphone with Android OS. A minimum of 4 Gb available for mass storage is requested for the Pilot activities.	no personalization expected	no personalization expected
B	patient	S3.B	Patients gave their consent (informed consent) to store data into their S-EHR app.	no personalization expected	no personalization expected
C	patient	S3.B	Download previous health data from Hospital	no personalization expected	no personalization expected
C.1	Patient, S-EHR App	S0.1	The patient accesses the list of Hospitals connected to the S-EHR and selects his reference Hospital;	FTGM is selected for patients enrolled by FTGM	CHU is selected for patients enrolled by CHU
C.2	Patient, S-EHR App	S0.3	List of encounters of the chosen Hospital is presented. An item related to the latest IPS downloadable is added at the beginning of the encounter list.	no personalization expected	no personalization expected
C.3	Patient, S-EHR App	S0.4	The patient selects one encounter to be downloaded	The last visit/admission will be selected	The IPS will be selected. The last visit will be selected.
C.4	Patient,	S0.4	Health data related to the selected encounter	will be provided the following sections:	will be provided the following sections:

	S-EHR App		are transmitted to S-EHR. Unstructured data provided by EHR are processed to extract: 1. For prescriptions: list of ATC drug code 2. For chronic disease: list of ICD code of the disease	● current medication, ● allergies, ● chronic disease ● lab exams will be provided the anonymized following sections: ● EKG report and signal ○ PDF file of the report ○ DICOM waveform file ● Echocardiogram report and video ○ PDF file of the report ○ DICOM file ● EF, septum	● current medication, ● allergies, ● chronic disease ● lab exams will be provided the anonymized following sections: ● EKG report and signal ○ PDF file of the report ○ DICOM waveform file ● Echocardiogram report and video ○ PDF file of the report ○ DICOM file ● EF, septum
D.	RO	S3.D	Research Organizations (ROs) belong to the InteropEHRate Research Network. *This preliminary action is executed once for each site.*	no personalization expected	no personalization expected
E.	Patient	S3.K	Patient can select a reference region/area, i.e. a preferred region/area as location of the research centre that he/she can contact in case of participation in a research study, when a study is multi-centric.	no personalization expected	no personalization expected
F.	Patient	S3.L	Patients can withdraw from their participation in the InteropEHRate Open Research Network at any moment.	no personalization expected	no personalization expected

Table 7 - List of preliminary actions for Pilot 3

The following actions are performed for the execution of the experimental scenario 3 for each involved patient. If the action needs to be executed just once for each pilot's site or just for one pilots' site, this will be specified in the action's description.

#	Actor	Ref. general scenario	Live Action	FTGM	CHU
1	Patient	S3.1	Patient give consent to be part of the InteropEHRate Open Research Network. They consent to their S-EHR app to match the health data stored by the app with the enrolment criteria of new research studies and be notified, in case of positive match, of the possibility to apply as participants to the study.	no personalization expected	no personalization expected
2	RO	S3.2	A Research Organization, Coordinating Research Centre, formalizes the research protocol called "INTERopehrate VALidation – INTERVAL Study". UNITN will contribute to the creation of the file to be uploaded in the IHT platform. *This action is executed once and only for FTGM pilot site.*	no personalization expected	no personalization expected
2.1	RO	S3.2	The protocol enrolls patients with selection criteria of INTERVAL study (see D10.1 [10]) *This action is executed once and only for FTGM pilot site.*	no personalization expected	no personalization expected
2.2	RO	S3.2	The protocol requires a set of pseudonymized health data: - Age, gender - Allergies - Medications - Year of diagnosis - blood pressure measurement SYS/DIA (mmHg/mmHg) - Latest creatinine (mg/dL)	Patient consent will be uploaded in English. Patient's Questionnaire will be used in Italian language.	Patient consent will be uploaded in English. Patient's Questionnaire will be used in French language

			- Current Medications - EKG report and signal - Echocardiogram report and video - Latest left ventricular ejection fraction (%) - Latest interventricular septum thickness (mm) - symptoms Evaluation questionnaire - Platform Evaluation questionnaire The study contains also: - Patient informed consent document - information letter for the patient's GP *This action is executed once and only for FTGM pilot site.*		
2.3	RO	S3.2	The protocol specifies a set of participating Reference Research Centres belonging to specific regions: FTGM in Italy and CHU de Liege in Belgium. *This action is executed once and only for FTGM pilot site.*	no personalization expected	no personalization expected
3	RO IRS	S3.3	Using the InteropEHRate Research Service, the Coordinating Research Centre publishes the research protocol on the InteropEHRate Open Research Network. The protocol references requested data and constraints (selection and exit criteria) with InteropEHRate profiles terminologies. *This action is executed once and only for FTGM site.*	no personalization expected	no personalization expected
4	S-EHR	S3.4	The research protocol is transmitted to the S-EHR of the patients.	no personalization expected	no personalization expected
5	S-EHR	S3.5	The S-EHR apps of the patients that have given consent to be invited to new research studies,	no personalization expected	no personalization expected

			automatically and silently match the enrolment criteria of the protocol with the content of the S-EHR app, without transmitting any data, in order to determine if the patient may be enrolled in the research.		
6	S-EHR app	S3.6	If the evaluation of research criteria is positive, the S-EHR app displays to the owner patient a notification communicating that the patient may participate in the study and that he/she is to adhere to the research.	no personalization expected	no personalization expected
7	Patient	S3.7	The patient accesses on the S-EHR app a list showing the studies she may participate in and selects the invitation called “Side effects from hypertensive medication study”.	no personalization expected	no personalization expected
8	S-EHR app	S3.8	The S-EHR app shows to the patient the details of the research protocol, including details about:	no personalization expected	no personalization expected
8.1	S-EHR app	S3.8	the Coordinating Research Centre	FTGM	FTGM
8.2	S-EHR app	S3.8	the Local Research Centre (belonging to the Reference Region she previously selected),	FTGM	CHU
8.3	S-EHR app	S3.8	reference contacts for further details,	FTGM PI	CHU investigator
8.4	S-EHR app	S3.8	the requested health data (type of data and covering period),	no personalization expected	no personalization expected
8.5	S-EHR app	S3.8	the purpose of the research,	no personalization expected	no personalization expected
8.6	S-EHR app	S3.8	the data retention period,	no personalization expected	no personalization expected

8.7	S-EHR app	S3.8	the level of anonymization of the requested data.	Pseudonymization requested	Pseudonymization requested
9	Patient	S3.10	The patient accepts to participate in the research.	no personalization expected	no personalization expected
9.1	Patient	S3.10	The patient digitally signs on the S-EHR App the consent to participate in the research study;	In case the patient cannot sign the consent on the S-EHR App or if required by the research protocol, he/she goes to the selected Reference Research Centre and signs the consent to participate in the research study.	In case the patient cannot sign the consent on the S-EHR App or if required by the research protocol, he/she goes to the selected Reference Research Centre and signs the consent to participate in the research study.
9.2	Patient , S-EHR app	S3.10	The S-EHR App shows to the patient the Reference Research Centres included in the protocol and belonging to the region she previously selected;	FTGM	CHU
9.3	Patient , S-EHR app	S3.10	The patient selects a Reference Research Centre;	FTGM is selected	CHU is selected
9.4	Patient , S-EHR app	S3.10	The S-EHR app receives and stores on the mobile device an electronic copy of the consent digitally signed by the Reference Research Centre.	no personalization expected	no personalization expected
9.5	Patient , S-EHR app	S3.10	A pseudonym identifier is requested by the S-EHR App to the RO IHT services, in order to be used for health data pseudo-anonymization only in the research “INTERVAL”	no personalization expected	no personalization expected
10	RO	S3.11	A Reference Research Centre may obtain in any moment a statistic showing the number of citizens that consented to participate in the research protocol.	no personalization expected	no personalization expected

11	S-EHR app	S3.12	At the start of the research, as indicated within the specification of the research protocol, the S-EHR app sends the pseudonymized health data to the Reference Research Centre, according to the clinical protocol design:	no personalization expected	no personalization expected
12	Patient, S-EHR app	S3.15	The patient can withdraw the participation at any time.	no personalization expected	no personalization expected
12.1	RO	S3.15	In case of withdrawal, the event is notified to the Reference Research Centre of the patient.	no personalization expected	no personalization expected
13	S-EHR app, RO	S3.16	Every data upcoming to the Reference Research Centre, updated in S-EHR and related to the research, are conveyed to the researcher Database for the period described by the research protocol	FTGM receive information will be provided the pseudonymized following sections: ● Age, gender ● Allergies (LOINC codes) ● Medications (ATC codes and DDD) ● Year of diagnosis ● Last blood pressure measurement SYS/DIA (mmHg/mmHg) ● Last creatinine (mg/dL) ● Last EKG report and signal ○ PDF file of the report ○ DICOM waveform file ● Last Echocardiogram report and video ● Text report, PDF file of the report ○ DICOM file	CHU receive information will be provided the pseudonymized following sections: ● Age, gender ● Allergies (LOINC codes) ● Medications (ATC codes and DDD) ● Year of diagnosis ● Last blood pressure measurement SYS/DIA (mmHg/mmHg) ● Last creatinine (mg/dL) ● Last EKG report and signal ○ PDF file of the report ● Last Echocardiogram report and video ○ Text report, PDF file of the report ○ DICOM file ○ left ventricular

				○ left ventricular ejection fraction (%) ○ interventricular septum thickness (mm)	ejection fraction (%) ○ interventricular septum thickness (mm)
14.1	Patient, S-EHR app	S3.13	The patient is asked to fill a questionnaire on self-reported side effects from anti-hypertensive medications the questionnaire is compiled and sent to the reference RO	FTGM receive the questionnaire	CHU receives the questionnaire
14.2	Patient, S-EHR app	S3.13	At the end of the study the patient is asked to fill in the evaluation questionnaire	FTGM receive the questionnaire	CHU receives the questionnaire
POST-1	RO	S3.POST	At the end of the research, data imported from S-EHR are stored safely in the research facilities of the ROs and retained for the period specified by the research protocol or by the local/national regulation, then they are deleted (disposed)[1].	Patients' consents are stored for a period of 10 years. Patients' health data is stored in the pilots' research facility for a period of 7 years.	Patients' consents are stored for a period of 10 years. Patients' health data is stored in the pilots' research facility for a period of 7 years.

Table 8 - List of actions for Pilot 3

[1] See deliverable D1.8 – Data Management Plan [8] for details.

5.3 Dataset

In this section, is reported a sample dataset of values that will be contained in S-EHR for the patients.

All data shall be anonymized and associated with the assigned pseudonym ID.

Requested Data:

1) Pseudonymization ID
2) Name, Surname
3) Gender
4) Date of Birth [place]

5) Year of hypertension diagnosis
6) blood pressure measurement SYS/DIA (mmHg/mmHg)
7) Latest creatinine (mg/dL)
8) Current Medications
9) EKG report and signal
    a) PDF file of the report
    b) DICOM waveform file
10) Echocardiogram report and video
    a) PDF file of the report
    b) DICOM file
    c) left ventricular ejection fraction (%)
    d) interventricular septum thickness (mm)

11) Name of the DRUG
12) Type of symptom(s)
    a) Cutaneous symptoms (please describe)
    b) Nausea
    c) Constipation
    d) Palpitation
    e) Cough
    f) Swollen feet or legs
    g) Cold hands or feet
    h) Cramps
    i) Persistent dry cough
    j) Frequent urination
    k) Decreased sexual desire
    l) Other (please specify):
13) How long the adverse event last?
    a) < 1 day
    b) 1 day to 1 week
    c) 1 week to 1 month
    d) 1 month
14) Did you withdraw the drug?

15) Did the adverse reaction require specific treatment?

5.4 Involved Participants

In this Pilot will be involved 30 Patients and 4 researchers in 2 different pilot sites. Involved researchers are also reference Healthcare Professionals of the enrolled patients.

In each site a set of 2 researchers will be selected and trained on the usage of the platform, and they will be registered as users of the platform for the HTI tool to access patient's data.

For each Hospital involved, each patient candidate will be contacted by the investigator of the Hospital at the beginning of the Pilot, offering the participation to this experimental scenario, and an informed consent will be submitted to them for data collection and processing and final questionnaire submission.

5.5 Evaluation questionnaire

The final questionnaire will be submitted to involved patients and researchers.

For the patients will be used the SUS questionnaire already used in the Pilot 1 and 2 and another questionnaire related to the usage of the S-EHR application on the smartphone and interaction with other actors in the scenario, with few more items on their social/living status and clinical care feedback.

The SUS questionnaire is reported in paragraph 3.5-Evaluation questionnaire of this document.

In the following figure is reported the patient's questionnaire in addition:

Preliminary Questions
Age: __
Sex: _____

Educational level:
No studies ☐
Some School ☐
Graduate ☐
Postgraduate ☐

Urban zone (rural/urban): _____

Profession (if retired, previously exercised): _____

_____

Do you routinely use apps of your smartphone/tablet in your daily life (excluded messages and phone calls)?
Yes No

Do you have wifi/xDSL/3g/4g connection in your home?
Yes No

What satisfaction level do you have about the clinical staff explanation for use and maintenance of the system?

☐Very dissatisfied ☐Dissatisfied ☐Satisfied ☐Very Satisfied

What satisfaction level do you have about the received clinical care?

☐Very dissatisfied ☐Dissatisfied ☐Satisfied ☐Very Satisfied

Has the INTEROPEHRATE System helped you to understand better your disease?

☐Strongly disagree ☐Disagree ☐Agree ☐Strongly Agree

Has the INTEROPEHRATE System allowed you to have more autonomy to access to hospitals or care Centres?

☐Strongly disagree ☐Disagree ☐Agree ☐Strongly Agree ☐

Do you consider that INTEROPEHRATE system has a major role in communicating with foreign healthcare provider?

☐Strongly disagree ☐Disagree ☐Agree ☐Strongly Agree ☐

The INTEROPEHRATE System has had a positive impact in the way that you live with your disease.

☐Strongly disagree ☐Disagree ☐Agree ☐Strongly Agree ☐

Do you consider that your family/caregivers have been benefited from the INTEROPEHRATE system by a lower possibility of psychological or physical burden that can cause the disease?

☐Strongly disagree ☐Disagree ☐Agree ☐Strongly Agree

Please, mark from 1 to 4 your satisfaction level about the INTEROPEHRATE system.

1 2 3 4
I_____I_____I_____I

Where value 1 is considered as *"Very* dissatisfied*"* and 4 as *"Very satisfied"*.

Would you recommend other people to use the INTEROPEHRATE System?

1 2 3 4
I_____I_____I_____I

Where value 1 is considered as *"Never"* and 4 as *"Certain"*.

Figure 8 - Pilot 3 patient's questionnaire #2

For the researchers, also HCP, will be used the PSSUQ questionnaire related to the usage of the HCP application and IHT tools, considering also the interaction with other actors in the scenario.

The PSSUQ questionnaire is reported in paragraph 3.5-Evaluation questionnaire of this document.

6 CLINICAL RESEARCH PROTOCOL SUMMARY – THE INTERVAL STUDY

To support the execution of Pilot 3, for data processing and data collection, it was designed a research protocol describing a primary and secondary objective and description of data that are requested to support the final processing to achieve the objectives.

The clinical protocol submitted to the ethical committee was called "INTERVAL" (INTERopehrate VALidation – INTERVAL Study), and in the following sections is reported a summary of the paragraphs extracted from the study protocol document. Those sections describe just the information needed by the Ethical committee to evaluate the feasibility of the study, the respect of data minimization principles to support the objectives and the level of knowledge and accountability of the participating centres on the field subject of study.

6.1 Background & study aims

6.1.1 Background

Citizens moving across Europe have very limited control on their own health data, spread out in different silos. Legal constraints may prevent controllers of these silos from exchanging the managed data, even in an anonymized way, without the intervention of higher authorities. As a consequence, health data cannot be fully exploited for healthcare and research. The InteropEHRate project has been funded by the European Union to improve continuity of care and exchange of health records across Europe by proactive involvement of empowered citizens. According to the vision of InteropEHRate, in the next few years more and more people will use Smart Electronic Health Records (S-EHRs) to manage their health data. S-EHRs are defined by InteropEHRate as mobile apps that store, in a secure way on a personal smart device (e.g. a smartphone), any health data of a single user, including clinical data produced by healthcare providers (e.g. hospitals). Specifically, InteropEHRate project has been designed to empower the citizen and unlock health data from local silos, using a bottom-up approach for EHR interoperability.

1. mediated by the citizen: through the adoption of a D2D (device to device) standard, that, by exploiting edge computing and short-range wireless technologies, will allow the citizens to import their own health data on personal smart devices, and exchange them, in a confidential way, independently from the availability of internet, with healthcare professionals and researchers, without the intervention of other authorities.

2. authorized by the citizen: through peer-to-peer protocols for cross-border interoperability among EHRs and research apps, using decentralized authorization mechanisms based on citizens' consent, to guarantee data accountability and provenance traceability, in compliance to patients' rights and GDPR.

3. open and incremental: based on open specifications, connecting for-profit and non-profit data providers with different levels of interoperability, starting from a low level for secure exchange of unconverted data, to a high-level combining knowledge extraction and adaptive data integration, to translate data to a common HL7 FHIR profile and into the natural language of the consumer.

At present, a smart electronic health record mobile application (S-EHR app) has been implemented, and populated by data coming also from 2 scenarios experimented by 4 Hospitals and Health Research Centres from different European countries: Hygeia Hospital (Greece), Fondazione Toscana Gabriele Monasterio per la Ricerca Medica e di Sanità Pubblica (Italy), Centre Hospitalier Universitaire de Liège (Belgium), Bagdasar Arseni Emergency Hospital from Bucharest (Romania):

- Scenario 1: citizen and health care providers exchange clinical data on an ambulatory setting through their devices, using only a "local" link (D2D connection), not involving the use of internet and cloud storage.
- Scenario 2: access and contribution to Patients' health data by healthcare providers when a S-EHR is not available or when the Patient cannot use it, e.g. in an emergency situation.

In the InteropEHRate vision, the relationship between citizens and medical research is likely to change. Citizens will be able to share their anonymised health records directly with specific research organizations for specific research purposes, leaving to the S-EHR the processing and communication of data. On the other hand, the researchers will be able to easily invite S-EHR users to participate in selected clinical studies.

6.2 Objectives

Primary objective

The primary objective is technical, i.e. to assess the ease of use and feasibility of the InteropEHRate platform in terms of collection of clinical data (including history, bio humoral & imaging) for research purposes (user's questionnaire)

Secondary objectives

#1 Clinical (for validation purposes): to assess the prevalence of reported side effects and their association to specific disease and drug characteristics;

#2 Technical: to assess the accuracy of the pseudonymized data available for research purposes.

6.3 Study design and protocol

6.3.1 Study design

INTERVAL will be a prospective, multicentre, observational study.

6.3.2 Experimental protocol

Primary objective

Patients who have installed and populated a S-EHR within the InteropEHRate project will be asked, *via* mobile app notification, to share some of their clinical data for the aims of the INTERVAL study.

Among S-EHR app users, only those fulfilling pre-specified inclusion criteria will be contacted *via* mobile app and asked to sign the informed consent for participating in the study. Once the informed consent is obtained, the following data will be retrieved from patients' S-EHR app:

- age and gender;
- year of hypertension diagnosis;
- latest blood pressure measurement;
- latest creatinine value;
- latest echocardiogram, including left ventricular ejection fraction and interventricular septum thickness;

- latest ECG;
- concomitant medication.

In the moment they're enrolled, patients will be asked to fill a questionnaire focused on the perceived side effects of antihypertensive medications.

The feasibility and ease of use of data transfer from patients' S-EHR app to the study investigators will be assessed by means of the two different questionnaires to be filled by both patients and by the investigators.

Secondary objectives

#1: The relative amount of patients with data available on arterial blood pressure and anti-hypertensive medications and possible side-effects (patient questionnaire) will be calculated. The prevalence of reported side-effects will be assessed and the association between each side-effect and disease/patients characteristics will be investigated.

#2: Anonymized data collected by the investigators will be decrypted and compared to source data from patients S-EHR app. A pre-specified threshold of >99.5% for data consistency will be considered as indicative of adequate accuracy.

6.4 Study population and data sources

The description of criteria applied to the subjects of this study is described in the deliverable D10.1 [10] since this information is marked as confidential.

6.5 End-points

Primary end point: Achievement of 80% maximum score for the questionnaire related to the users' profile will be considered as indicative of adequate ergonomics.

Secondary end points: A pre-specified threshold of >99.5% for data consistency will be considered as indicative of adequate accuracy.

6.6 Statistical analysis

Variables with normal distribution will be presented as mean and standard deviation; variables with skewed distribution will be presented as median and interquartile range. Logistic regression analysis will be performed to assess correlations between side effects and patient/disease characteristics.

6.7 Expected value of the results

The project aims to test the technical validity of the InteropEHRate platform applied to a research protocol. The investigators envisage the use of cross-border platforms to enable researchers to perform observational and interventional studies using S-EHR tools as a data source. This may allow patients recruitment of a large, potentially global scale, mainly dedicated to epidemiological and phase IV studies. Should be validated, this approach may also be useful to improve resilience of the clinical trial machinery to major events limiting patient's mobility and/or interpersonal interactions.

6.8 Ethical aspects and privacy assessment

The study will be conducted according to the EMA *Guidelines for Good Clinical Practice* (23/07/2015) and to the principles of the *Helsinki Declaration*.

Informed consent will be obtained from all patients. Each patient will decide autonomously to participate (or not to participate) in the study. Participation in the study will not influence standard medical management. At any moment, patients will be able to withdraw their consent to the study; in such a case, investigators will be able to use only the information collected up to the moment of consent withdrawal.

No discrimination will be applied as for gender, race, political, religious or sexual orientation. Investigators will use data in a pseudonymized fashion. Data will be obtained through a dedicated form and collected in a central database, protected by individual credential.

6.9 Exit criteria

Study participants may withdraw their consent, therefore leaving the study at any point during the study at any time for any reason without any prejudice to their medical care, and without incurring any other negative repercussions.

6.10 Risk/benefit ratio

The present study is of observational nature and no invasive procedure is planned. Individual patient risk is therefore considered negligible.

6.11 Study centres

The Centre leading the study will be the Fondazione Toscana Gabriele Monasterio, Pisa (Italy).

6.12 Antihypertensive adverse reaction assessment Questionnaire

Section 3: Questionnaire on side effects

Patient ID: **ITA_907_** _____

(the patients selects the drug from the list of current/past antihypertensive drugs)

Repeat for each current/past antihypertensive drugs associated to adverse effects:

Name of the DRUG	
1. Type of symptom(s)	a. Cutaneous symptoms (please describe)
	b. Nausea
	c. Constipation
	d. Palpitation
	e. Cough
	f. Swollen feet or legs
	g. Cold hands or feet
	h. Cramps
	j. Persistent dry cough
	j. Frequent urination
	k. Decreased sexual desire
	l. Other (please specify):
2. How long the adverse event last?	< 1 day
	1 day to 1 week
	1 week to 1 month
	> 1 month
3. Did you withdraw the drug?	Yes NO
4. Did the adverse reaction require specific treatment?	Yes NO

7 CONCLUSIONS AND NEXT STEPS

In this document are described the definitions of actions depicting the three experimentation scenarios applied in the pilots' sites of Italy, Belgium, Romania and Greece. Pilot activities for each site will be based on the application of what is defined in the current document. Local needs and national regulation were considered in the list of actions, and variations to consider and respect these are applied for each step where required.

The general deployment and configuration of IT components and software systems are activities that will be coordinated and performed in a dedicated task dedicated to the set-up of the environment needed for the execution of the Pilots (and described in deliverable D7.2 - Pilots). In that task will be also tested the integrated system prior to the beginning of pilots' activities, in a test flight approach.

Results of the activities performed in each scenario, about the deployed architecture, and considerations will be reported in the deliverables on the execution of the Pilots: D7.3 - Citizen centered healthcare pilot report, for medical visit abroad pilot report; D7.4 - Emergency pilot report, for Emergency access pilot report; and D7.5 - Citizen centered medical research pilot report, for Health research study pilot report.

In the final report D7.6 -InteropEHRate final evaluation, will be reported final conclusions and assessments, including overall evaluation of efforts spent to implement and support the InteropEHRate platform and services in the current Hospitals' facility.

8 REFERENCES

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