D6.1

Software requirements and architecture specification of a S-EHR - V1

ABSTRACT

Fundamental technical result of InteropEHRate will be composed of two aspects. The first one will be a set of open specifications, implementable by any vendor or institution. The second technical result will be a reference implementation composed of reusable software components, which will implement the specifications and will be interoperable with any other implementation of the same specifications. This document focuses on the requirements and the reference implementation of one of the components; the Smart-EHR mobile app (S-EHR-A).

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ACRONYMS

Acronym	Description
API	Application Program Interface
CEF	Connecting Europe Facility
D2D	Device to Device
eCOA	Electronic Clinical Outcome Assessment
HER	Electronic Health Record
eID	Electronic identification
GDPR	General Data Protection Regulation
HCP	Healthcare Professional
HQ	Headquarter
HR	Health Record
IT	Information Technology
QR code	Quick Response code
R2D	Remote to Device
S-EHR	Smart HER
S-EHR-A	S-EHR Mobile Application
S-EHR-A-RI	S-EHR-A Reference Implementation

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1. INTRODUCTION

1.1. Scope of the document

This document has the objective of providing the software requirements specification of the **S-EHR Mobile App RI (S-EHR-A-RI)** that is the reference implementation of S-EHR Mobile App (S-EHR-A), able to import/share data from/with EHR and with research centres, using short-range wireless D2D (device to device) communication or remote communication protocols.

This document presents the design of the S-EHR-A based on the user requirements defined for the first year of the InteropEHRate project. It will also describe the future features implemented by the S-EHR-A-RI.

1.2. Intended audience

The document is intended to all people interested to have an overview on the design, workflow and ideas of improvement of S-EHR app and core application.

1.3. Structure of the document

This document will be structured into seven sections:

1. **Introduction**: description of the purpose and objectives of this document, the intended audience that can be interested to read it, and the structure of the document.
2. **Software requirements of S-EHR-A**: definition of the purpose and objectives of the S-EHR-A and the S-EHR-A-RI.
3. **Andaman7 as the core app for the S-EHR-A reference implementation**: description of the application used as a base to create the S-EHR-A-RI, and the user requirements that are already covered by this application.
4. **Definition of the user requirements not yet implemented for the S-EHR-A**: definition of the user requirements not covered by the core application, and explanation of how it will be through wireframe model. This section also contains explanations on the interactions between each feature.
5. **Design of S-EHR-A-RI**: visual mock-ups for each wireframe described in the previous section.
6. **Improvement of the S-EHR-A-RI**: ideas to improve the user experience and the design of the S-EHR-A.
7. **Conclusions and next steps**: conclusion of this document.

1.4. Updates with respect to previous version (if any)

Not applicable

2. SOFTWARE REQUIREMENTS OF A S-EHR-A

2.1. The S-EHR-A overview

An S-EHR-A is an application installed on a personal mobile device, that is able to store the personal health data of a user in a secure (encrypted) way according to the constraints specified by the conformance levels [D3.1] and that supports the InteropEHRate protocols [D4.1][D4.8].

The S-EHR-A is able to receive health data from any healthcare organization that adopts the standard protocols specified by the InteropEHRate project. More specifically the S-EHR mobile app uses the so called Remote to Device (R2D) protocol to exchange health data at distance (with the usage of internet) with healthcare organizations while the Device to device (D2D) protocol allows to exchange health data with healthcare organizations during face to face encounters (without the usage of internet, but adopting short range communication technologies like bluetooth).

The reference implementation of the S-EHR mobile app (S-EHR-A-RI) will be used for experimenting the approach during the validation phases. Starting from the user requirements specified in collaboration with final users and focus groups, a first version of mock-ups of S-EHR-A-RI are presented.
Details on the architecture of the S-EHR-A-RI can be found in the design deliverable [D2.4].

2.2. Process to define software requirements

In order to develop new software and create a new product, such as an S-EHR mobile application in this case, the whole process of designing the solution has to be performed in the first place.

To begin with, a person or a group of people need to decide what is the general purpose of the project and what kind of solution they seek to achieve this purpose. The main goals of this project were initially described in Horizon 2020 call on the topic “Prototyping a European interoperable Electronic Health Record (EHR) exchange”: “Large amounts of valuable health data are generated and collected during and between citizens' medical examinations across Europe. However, opportunities to reuse these data for research and better healthcare are often missed because health data continue to be confined in data silos, often not matching semantic standards, quality needs and safe data exchange techniques. [...]”. To read the full topic description, please refer to European Commission’s website at the URL referenced at the end of this document [European Commission 2017].

A solution to this challenge has been described in the proposal submitted to the European Commission by the InteropEHRate consortium. To briefly summarize it, the solution consists of several applications, used by several actors (citizens, also sometimes referred to as patients, healthcare professionals and researchers), that are interoperable. The main specificity of the solution however, is that it is centred on the citizen. The citizen is the centrepiece of all data exchanges. He’s acting as the hub of his own data, and is offered the possibility to exchange his data with other actors or organisations, such as hospitals, research centres, etc. In this document, we are going to focus on the application used by the citizen, referred to as the S-EHR-A (Smart-Electronic Health Record Application).

Once this general purpose and solution have been agreed on, the requirements need to be further defined, in a more granular way. As anyone can imagine, an S-EHR application can be packed with a tremendous amount of different features. To get started and help focusing the work, we started from three different use case scenarios; "Edge to edge temporary sharing", "Sharing of personal health data for research" and "Emergency consultation of S-EHR cloud". Then, each of these scenarios are broken down into different steps; the user requirements. This work required the participation of many stakeholders. Especially that in this project, the consortium opted for a "co-design" approach, involving the final users in the design of the different versions of the solution. If you're interested in reading into more details the description of the user requirements for each scenario, you can read the document dedicated to this topic [D2.1].

It is only after all those discussions and decisions that we can achieve the next steps: translating the user requirements into software requirements. The user requirements are expressed as "user stories[1]", for example: "a European citizen should be able to download the S-EHR app on his smartphone". The software requirements will consist of describing all the technical specifications required achieving that goal, for example the steps needed to create the application and make it available for download on the Play Store and/or the App Store (platforms to download applications for Android and iOS respectively).

Most of the time, the process of translating user requirements into software requirements requires back and forth discussions with the final users or the other partners involved in the development of the solution. It can be because technical constraints make it difficult to stick to the initial user requirement, or because the user story was not sufficiently detailed, etc. In this document, we will present software requirements as they are at month 6 of this project. As you understood, the software requirements of the S-EHR-A will evolve with the subsequent versions of the solution.

2.3.User requirements for version 1 of the S-EHR-A-RI

At the end of the first requirements gathering cycle, the following requirements were identified (here after only the requirements that will be implemented within the first year).

User requirement title	User requirement description
S-EHR download from Android store	S-EHR is downloadable from the Android store (aka the Play Store). The citizen downloads the S-EHR-A from Play Store and installs it on its Android device.
S-EHR download from iOS store	S-EHR is downloadable from the iOS store (aka the App Store). The citizen downloads the S-EHR-A from the App Store and installs it on its iOS device.
S-EHR runs on Android smartphone	The S-EHR is a mobile app that can run on Android version X
S-EHR runs on iOS smartphone	The S-EHR is a mobile app that can run on iOS version X
Consent to S-EHR data management	At installation the S-EHR app obtains from to the Citizen his/her consent (informed consent) to store and manage his/her personal health data on the smart device.

[1] User stories are part of an agile approach that helps shift the focus from writing about requirements to talking about them. All agile user stories include a written sentence or two. User stories are short, simple descriptions of a feature told from the perspective of the person who desires the new capability, usually a user or customer of the system.

Enabling of Citizen identification from S-EHR	The S-EHR app asks to the Citizen and stores on the device a qualified certificate that identifies the Citizen. The certificate is released by a CEF eID trusted certification authority.
R2D import of (portion of) Patient Summary from national EHR on S-EHR	Citizen health data (portion of Patient Summary) can be imported from the citizen's national EHR on Citizen S-EHR.
R2D import of (portion of) prescriptions from national EHR on S-EHR	Citizen health data (portion of prescriptions) can be imported from the citizen's national EHR on citizen S-EHR.
D2D device pairing	The citizen connects/pairs his/her smart device to the HCP computer/device.
D2D visualization of the healthcare organization by the citizen	The citizen sees on the S-EHR app the data describing the identity of the healthcare organization.
D2D Access consent to healthcare organization by Citizen	The citizen gives the consent to the healthcare organization to get his/her identifying data
D2D consent by the citizen to healthcare organization for temporary S-EHR access	The citizen may give his/her temporary consent, to all HCP belonging to a specific healthcare organization and involved in a specific care/treatment, to download data from the S-EHR app and upload the updated/acquired data back to the S-EHR app. The temporary consent of the citizen for data exchange automatically expires at the end of the day.

Table 1 - User requirements for the first version of the S-EHR-A-RI

2.4.Software requirements for version 1 of the S-EHR-A-RI

Each user requirement identified in the previous paragraph needs to be translated into software requirements in order to be implemented in the S-EHR-A-RI.

Before actually starting the implementation, the global architecture for the project and the different technical components had to be defined. It is important so that the S-EHR-A-RI can be nicely integrated with other components developed, and all the components can actually interact with one another. For more details on the global architecture, refer to the document on the subject [D2.4].

After setting up the development environment to start the coding of the S-EHR-A-RI, the consortium decided to work in an "agile" way[2]. What it implies is that user requirements are not translated into software requirements all in one shot. Instead, user requirements are considered one at a time. This allows to work in a more incremental way, more adapted to software development, and has the advantage to provide the first concrete results more quickly. It is also very efficient to respond more rapidly to potential unpredicted difficulties. This is why, in the rest of this document, some of the requirements won't be described in much detail, even though their implementation is foreseen for the first S-EHR-A-RI version, due end of 2019.

[2] The Agile Method is a particular approach to project management that is utilized in software development. This method assists teams in responding to the unpredictability of constructing software. It uses incremental, iterative work sequences that are commonly known as sprints. Definition from Team Linchpin (https://linchpinseo.com/the-agile-method/).

3. ANDAMAN7 AS THE CORE APP FOR THE S-EHR-A REFERENCE IMPLEMENTATION

For the S-EHR-A reference implementation, the InteropEHRate consortium decided not to start from scratch. Instead, it will start from an existing S-EHR application called Andaman7. Therefore, some user requirements identified in the InteropEHRate project were already implemented. Also, Andaman7 goes beyond the InteropEHRate specifications on many features, as it is currently the result of approximately 30 man years of development. On the other end, some user requirements needed for the three use case scenarios the project focuses on are not yet implemented in Andaman7.

This section will present the Andaman7 mobile application and briefly describes what it already offers. Further in the document, some of the new requirements that will be implemented in the existing app will be described.

3.1. Andaman7 presentation

Andaman7 is a combination of

- mobile apps for patients (and individual care providers like doctors, nurses, physiotherapists,...) and
- A HIP - Health Intermediation Platform.

The HIP is a peer-to-peer platform storing information at the edge (in mobile devices). That makes Andaman7 very secure and privacy compliant (GDPR).

The intermediation platform can be used by care actors for home care, remote patient monitoring, etc. while the pharmaceutical industry can use it for clinical trials, especially real world evidence and eCOA - always with the patient's consent.

In short, Andaman7 is a broker to patients' platform enabling disease management and outcome assessment.

The company also has a social goal. The article 25 of the declaration of human rights sums it up nicely: everyone has a right to good health and well-being for himself and his family. Andaman7 does that in practice by providing all persons with a free, advanced personal health record system that enables patient empowerment. The company does this because Andaman7 started from a personal / family history (see http://bit.ly/a7vkblogen).

Andaman7 is an advanced system (more than 30 man years of investment) and includes some technical innovations: http://bit.ly/a7TechInno .

The company is based in Belgium Europe (HQ) and in Redwood City, CA.

The team is very experienced (several large scale health IT projects - info available upon request).

3.2. Core application

Andaman7 is a free app designed by patients for patients. Integrate your complete health history. Decide what you share and with whom. Manage your health with the ones you trust.

Patients and healthcare providers can now access, collect and share their personal and patient's health records. You can collect and store your electronic health records, vitals, allergies, medications, vaccinations, hospital admissions, lab results, emergency contacts, health history, medical imaging and more. The app connects with other Apple Health enabled apps and smart devices such as iWatch, weighing scale, glucose meter, blood pressure monitor, medical devices and others.

You can securely share part or all of your records with family members and other healthcare providers. No data is stored in the cloud. Data is stored locally and exchanged directly, from person to person, no one other than you and the people you trust will have access to your data.

All healthcare providers can connect and share health records with patients, outpatient facilities, other hospitals, organizations active in clinical studies or research with explicit consent from patients to participate in patient reported outcome or experience initiatives.

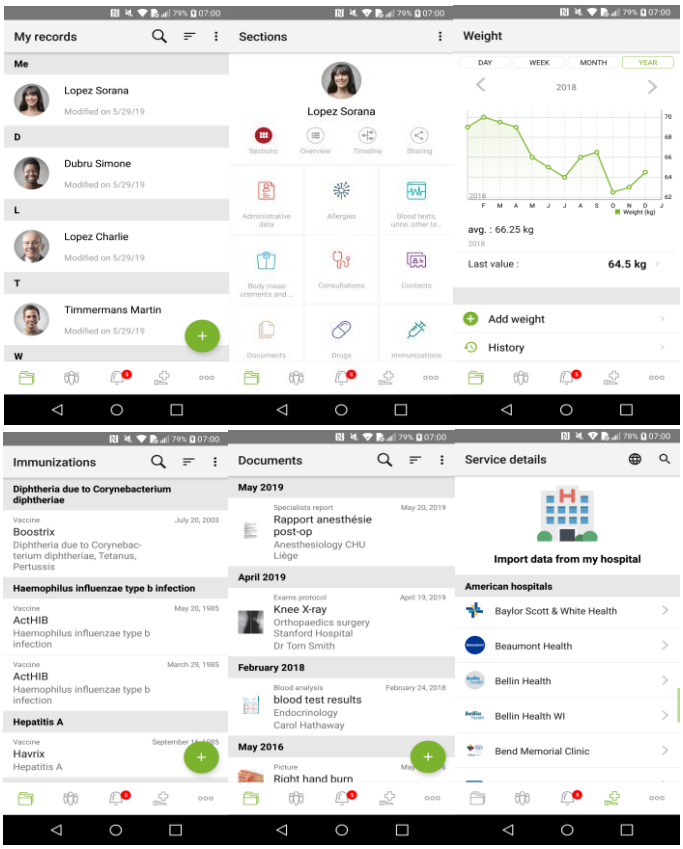

Figure 1 - Screenshots of the core application

3.3.User requirement already implemented by the core application

3.3.1. S-EHR download from Android / iOS store

First of all, citizens need to acquire the application. Two solutions for this, the Play store for Android users, and the App store for iOS users. Once one of these 2 stores is opened, users can simply search for « Andaman7 » and will be able to click a button to download the application.

Users will start using their application with an authentication part. Based on their email address, the core application server will determine if it's a new account or an existing one. In the first case, the user will be redirected to the registration part of the application. In the second one, the user will complete the login with his password. Now the user can start using the application.

Even if a user already has an account, he will not automatically retrieve his data. Because data are not stored on the cloud, everything is stored on the device. There are two ways to retrieve his data:

- **Use a backup**: The application provides the possibility to the user to create a backup of his data, and to use it to transfer data from his old to his new device.
- **Share his data with a trusted user**: with this option, the application will automatically call a share back of shared data to this trusted user.

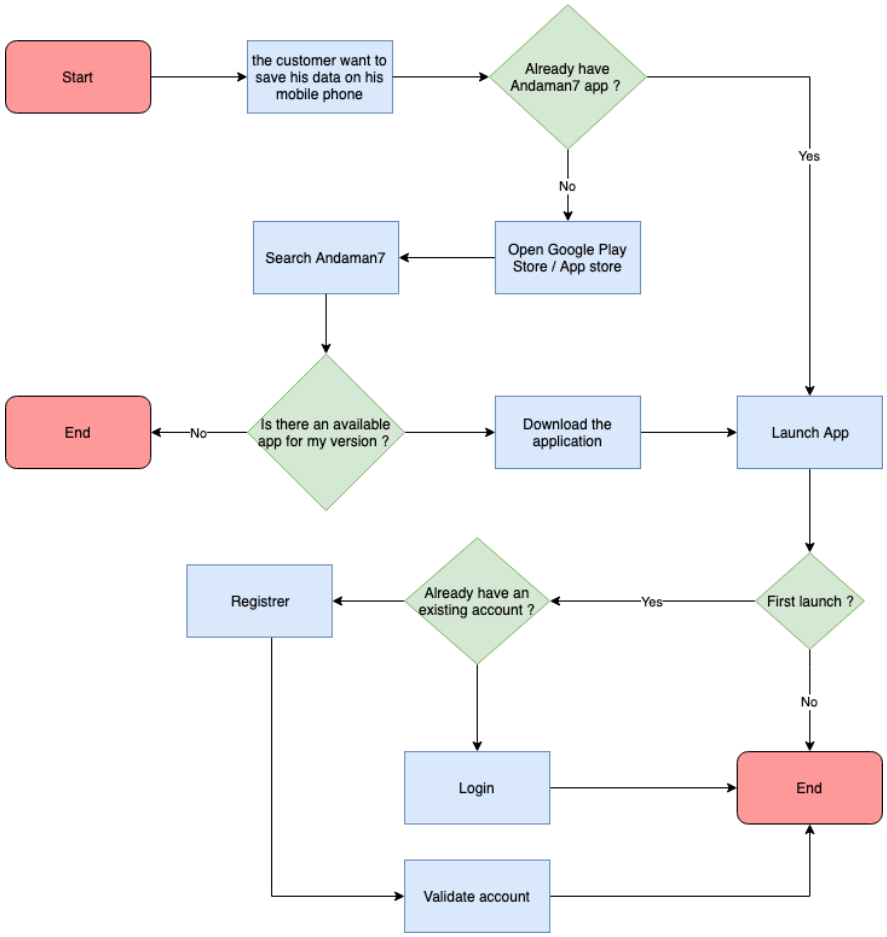

Figure 2 - User flow diagram: Download and launch in the core application

3.3.2. S-EHR runs on Android / iOS smartphone

The S-EHR-A must be able to run on both Android and iOS smartphones, each application on both operating systems must define the minimum version managed by the application.

For Android, the version is fixed through the properties “minimum sdk version” defined in the properties files of each Android application. At this moment, the version goes from 1 to 29 and represents each commercial version of the Android software. For the S-EHR-A-RI, the version will be the one already fixed by the core Android application (16) which corresponds to the Android commercial version “Android 4.1 Jelly Bean JRO03D”.

For iOS, the version is fixed through the properties “iOS deployment target” defined in the project properties of each iOS application. At this moment, the version goes from 1 to 12. For the S-EHR-A-RI, the version will be the one already fixed by the core iOS application (9). The version 9 is the last one supported by Apple. Each year, Apple stops to support the oldest version, and releases a new one.

3.3.3. Consent to S-EHR data management

When the citizen registers to the application (as shown in figure 2), he must check a widget to give his/her consent to the core application for storage and management of his data. After the consent is given, and the account is validated, the core application provides some functionalities useful for the S-EHR-A:

- **Add/ Update data**: The main functionality of the chosen core application is to store health data on the mobile phone. Data types are sort in different sections, for example: the data type «Weight» is available in the «Body and measurement» section.
  To add new data, the user must go to the right section and select the type of data he wants to add. Then he will have the choice to add a new data or update an older one.
  In this application, data is never erased. The app keeps in memory every change about a data. Users have the possibility to see the history of their modifications in a view provided for this purpose.

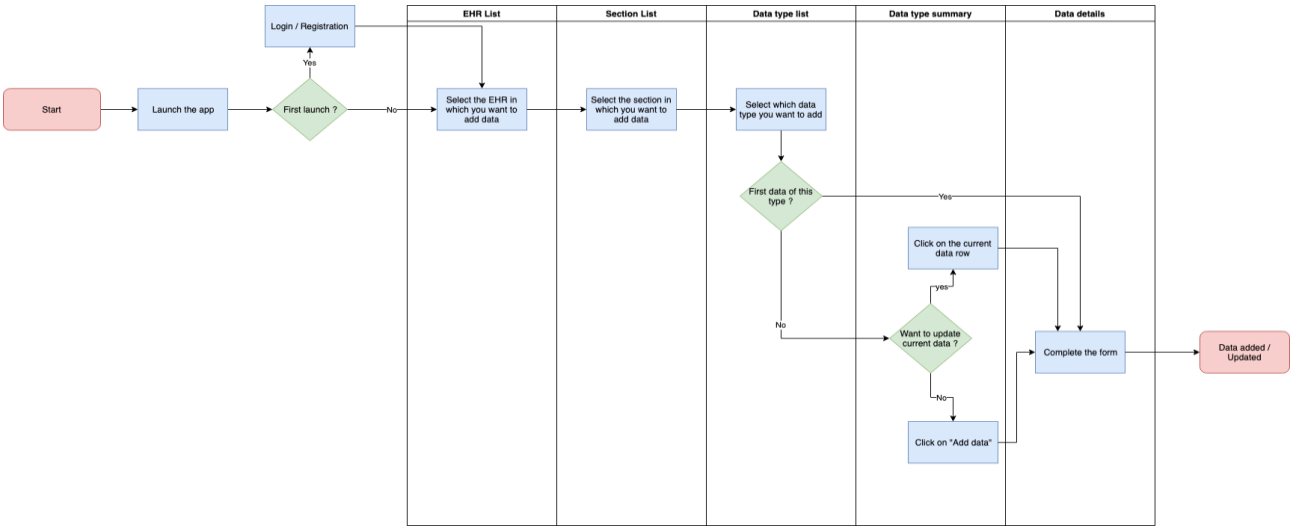

Figure 3 - User flow diagram: Add / Update a data

- **Share data**: Users have the possibility to share their EHR folder to other users. This functionality gives the user two possibilities:

    - The first one his to share his health data with his health care provider (he needs to have the application too). The HCP can complete the user's EHR with new data and share it back to the user. So the user doesn't need to update his data himself.

    - The second one is to share his EHR with a trusted user. If the user loses or changes his mobile, he would have the possibility to easily retrieve his data.

  Once the user has chosen a trusted user to share his data with, he can decide which data type he wants to share through a selection list.

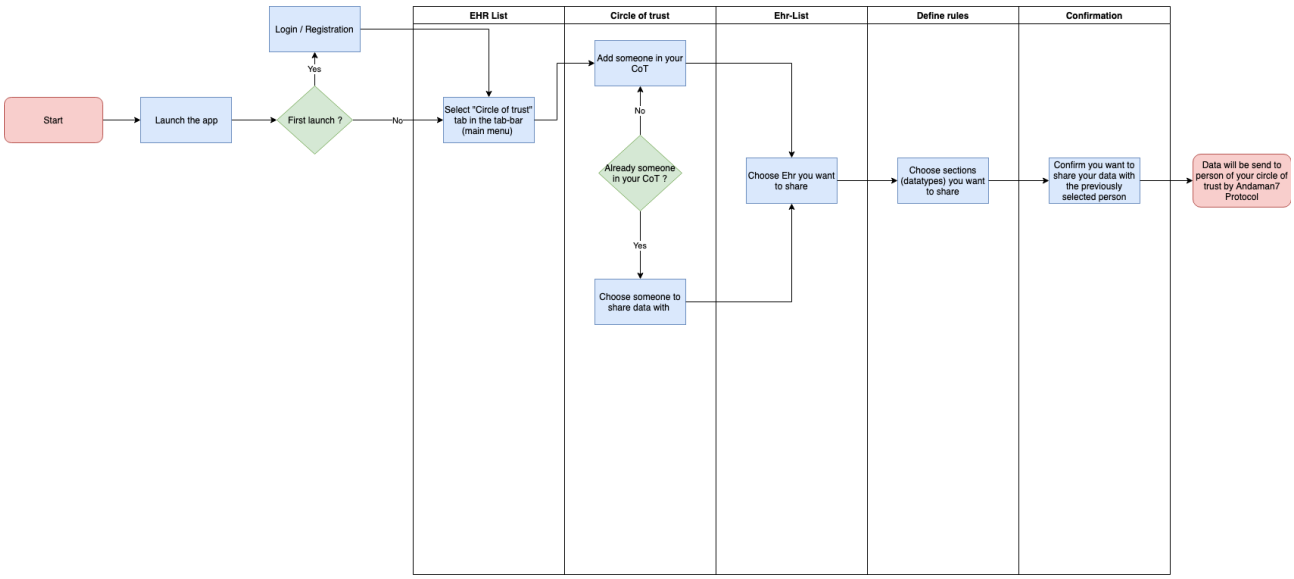

Figure 4 - User flow diagram: Share data

3.3.4. R2D import of Patient Summary from national EHR on S-EHR

The core application already provides the possibilities for the user to register to different kind of services. The main types are:

- Clinical Study: part of the application is dedicated to clinical studies. Once the user is registered to a study (the enrolment is carried out by an external party, through the Andaman7 web application), he has access to the related service. After accepting the service, the user will have access to the concerning study section and its surveys.

- Hospital Service: the core application is already linked to numerous hospitals. It allows Andaman7 to give users access to their health data which was for the moment only stored in their hospital.

The R2D (Remote to Device) protocol implementation will be added to the existing feature as a hospital service.

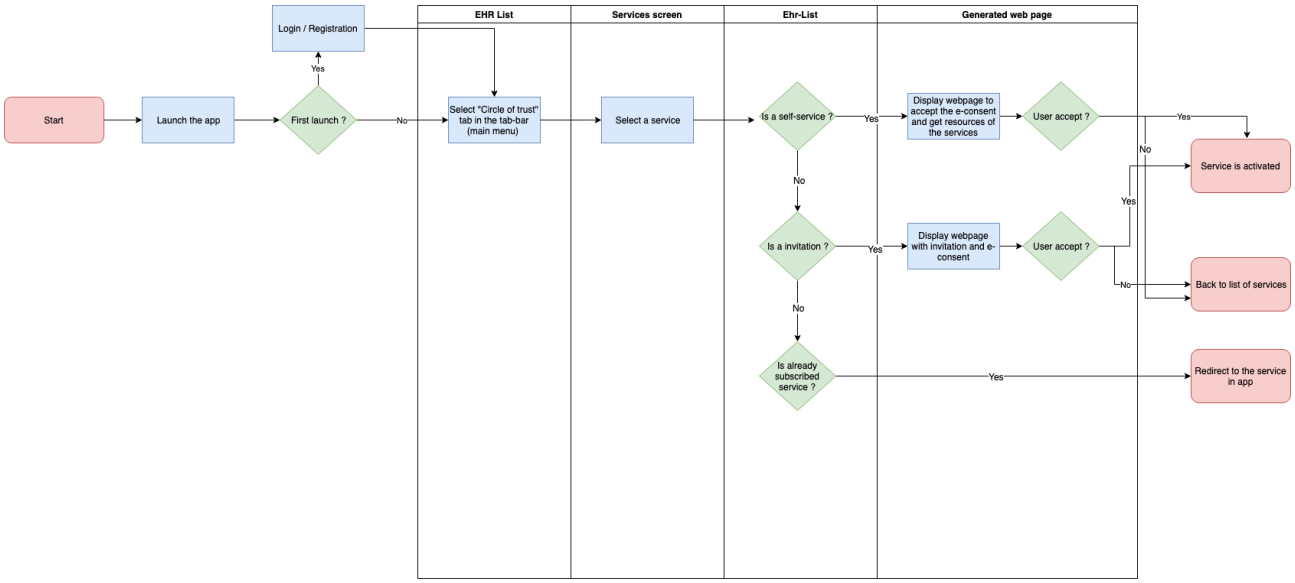

Figure 5 - User flow diagram: register to service

3.3.5. R2D import of (portion of) prescriptions from national EHR on S-EHR

As with the previous requirement, it will also be added to the existing feature explained in the section 3.3.4.

4. DEFINITION OF THE USER REQUIREMENTS NOT YET IMPLEMENTED FOR THE S-EHR-A

4.1. User flow of S-EHR-A D2D protocol

Here is one of the main user flows provided by the S-EHR application, each step is made to establish a connexion between the citizen and the HCP. The technology selected to make the connection is « Bluetooth ». This will allow an easy connection, but over a short distance.

The Bluetooth connection is established when a valid QR code is scanned by the user. However we consider that the connexion is fully established when the user has accepted the temporary consent request received from the HCP app. Otherwise, if the user refuses or cancels one of these steps, the connexion is closed.

Once all steps are done and connexion is fully established, the HCP app can use, modify and add data. At the end, each modification is shared back to the user into his S-EHR application.

If the connexion is interrupted (example: if the user moves too far away from the connexion source), the user will be automatically reconnected when he/she approaches again.

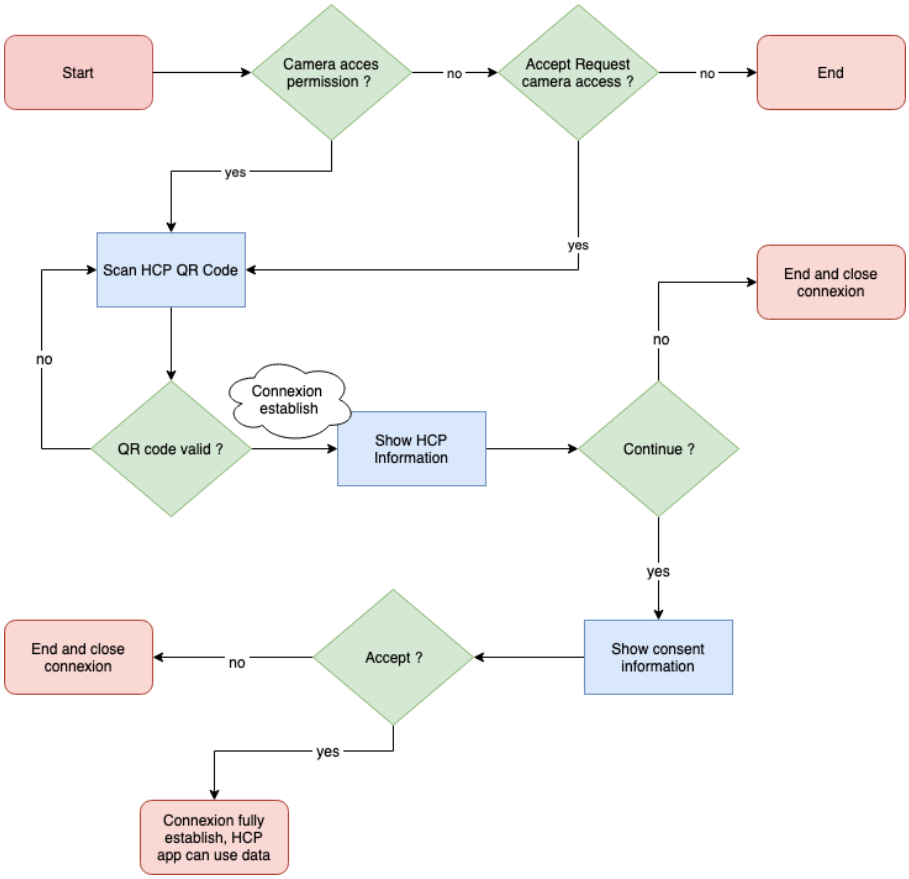

Figure 6 - User flow diagram: S-EHR-A D2D protocol

4.2. Wireframe of S-EHR-A-RI based on user requirements

In this section, we will define the structure of each screen that will be shown to user.

4.2.1. D2D device pairing

The purpose of this requirement is to start the connection between the citizen and the HCP application. This will be done through the scan of a QR code that will contain all data necessary to establish the connexion between the two actors.

To satisfy this need, a simple screen is provided, that will contain a scanner that can read the HCP QR code information. It will be shown as a dialog. To be able to use the scanner, the user must give permission to the application to use the camera. So the first time this screen is launched, it will start by a permission request.

Once a valid QR code is scanned, a message pop-up will be shown to the user to inform him/her that the connexion to the HCP is started.

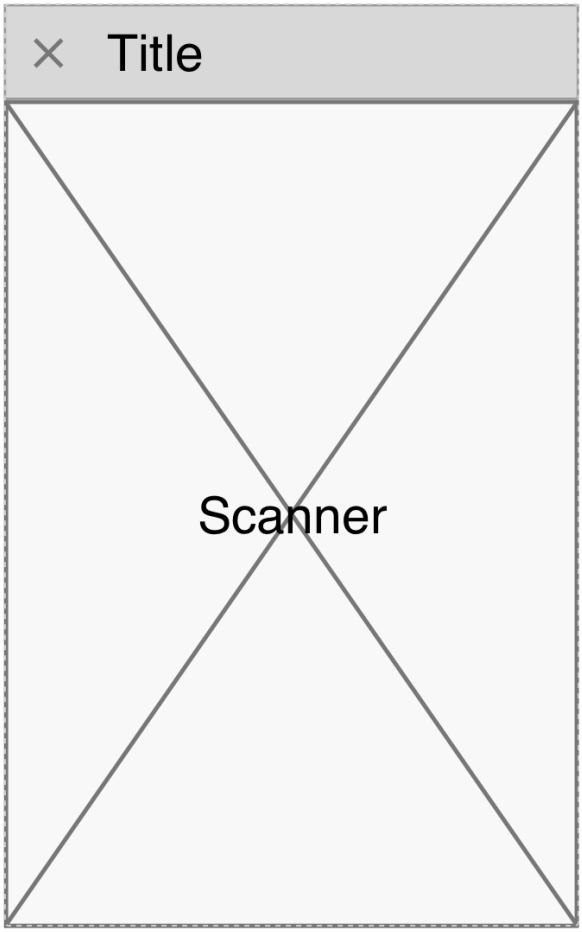

Figure 7 - Wireframe: D2D device pairing

4.2.2. D2D visualization of the healthcare organization by the citizen

Here is the screen about the HCP information. It will regroup essential information that will allow the user to easily identify who they are connecting to.

The user will have access to the name, address and phone of the HCP organisation. Except for the name, the other information will be clickable to allow user to directly call, or find the HCP (maybe not very useful for this version of the S-EHR library, but it will be more useful for the next versions).

Figure 8 - Wireframe: D2D visualization of the healthcare organization by the citizen

4.2.3. D2D access consent to healthcare organization by Citizen

In the same screen as the HCP information (Figure 8), the user will give his consent for sharing his personal data through a checkbox widget. The consent text will contain a clickable link that will redirect the citizen to the privacy notices and information about data exchange.

The « continue » button will be locked until the user gives his consent for sharing his/her personal data with the HCP application. Without this consent, the HCP app cannot identify which user he will connect to, and so the connexion isn't possible.

4.2.4. D2D consent by the citizen to the healthcare organization for temporary S-EHR access

The last step of connexion for the user is to give his/her consent for sharing his/her health data to the HCP application. This will allow the HCP app to read the user's data, modify it and add new data to the user EHR.

After this step, the connexion will be fully established. The user will come back to the core application.

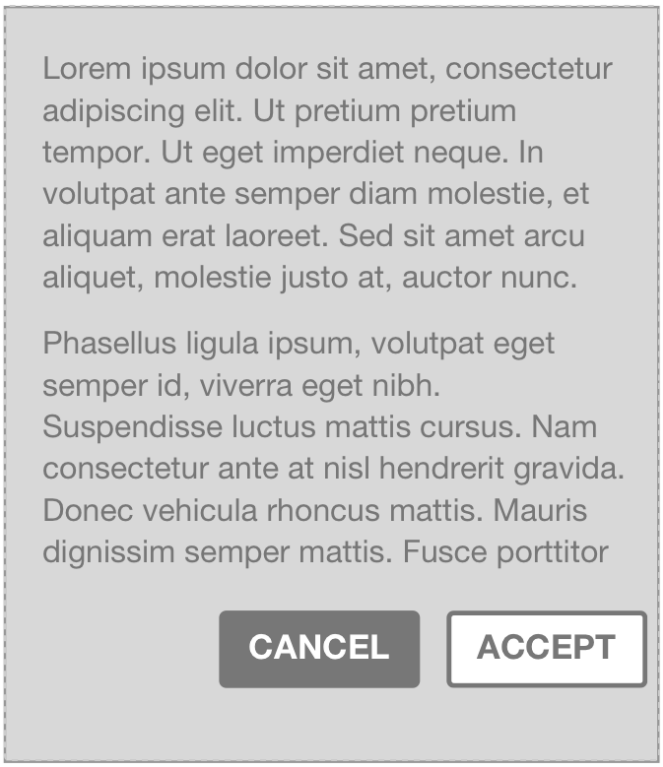

Figure 9 - Wireframe: D2D consent by the citizen to the healthcare organization for temporary S-EHR access

4.3. Integration of new functionalities to the core application to make the S-EHR-A

The S-EHR-A is divided into two parts, the first one is the core application, it already contains all the necessary features to manage and store the citizen data. In the case of the InteropEHRate project, this part is managed by the existing Andaman7 application.

The second part contains all the necessary features to connect the mobile application with other actors or organizations, such as hospitals, research centres, etc. It implements the two mobile side protocols of this project: the mobile D2D protocol that allows to connect directly with the web EHR app via Bluetooth and the mobile R2D protocol that allows to connect to different actors through the internet. This part will be provided as a library to integrate into the core application.

This library provides to the core application two views, one to have access to a scanner, and the second one to have access to the HCP information. The first one is used to scan the QR code, and return a healthcare

provider. The second one is to show information about the health care provider that is given in parameters. Next step will be called automatically.

Once the connection is established, health data are shared with the HCP application from the core application through the library. Once the web application has finished receiving the data, each change is shared back to the base application in the opposite way. The basic application can display a message to inform the citizen that the connection is complete, and what changes has been received.

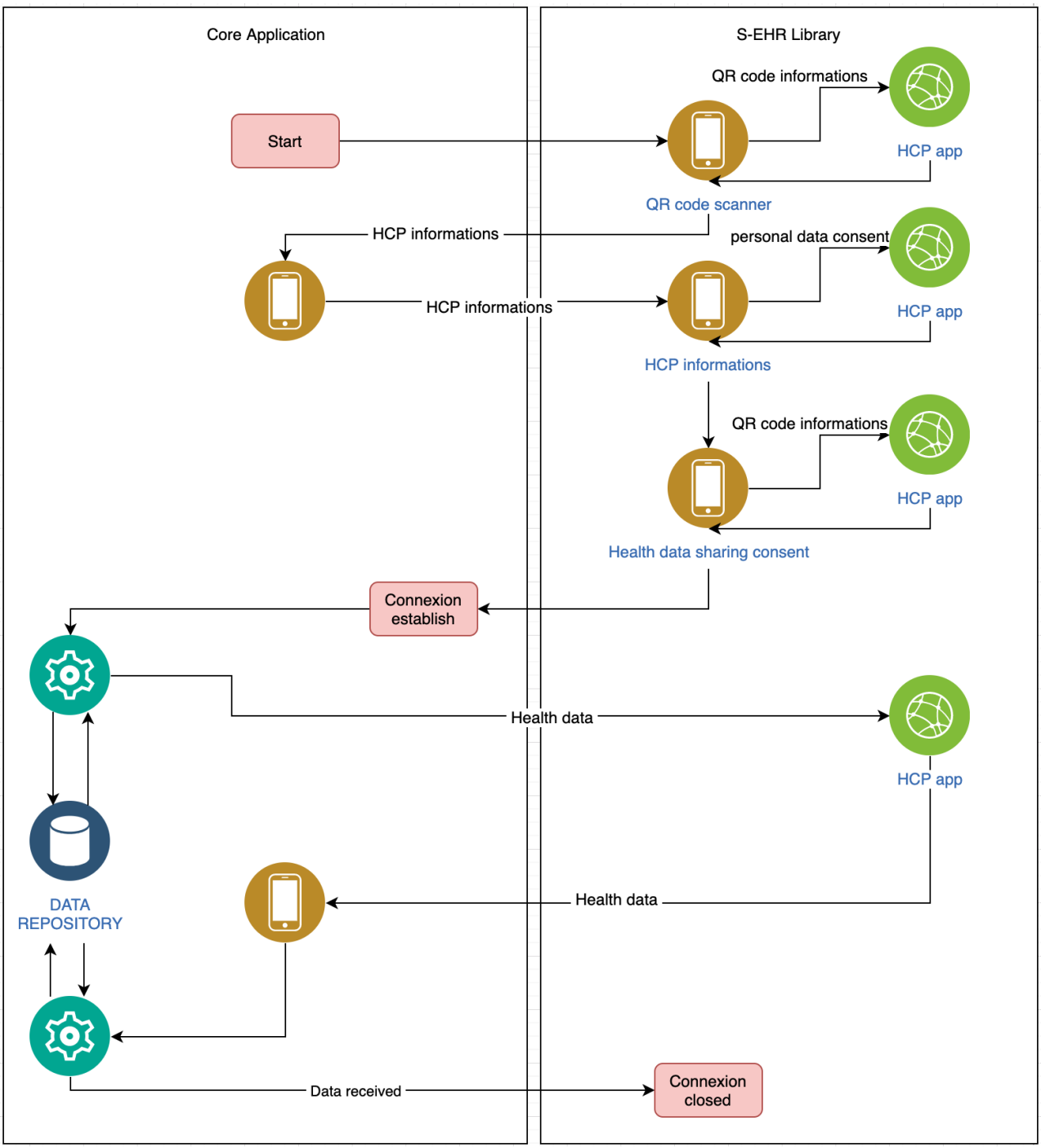

Figure 10 - Diagram: Integration of new functionalities to the core application to make the S-EHR-A

5. DESIGN OF THE S-EHR-A-RI

5.1. Visual Mock-up of S-EHR-A-RI based on user requirement

Based on the wireframe, here is the visual for the implementation of each screen.

5.1.1. D2D device pairing

The screen will be shown in a bottom sheet view. Practically, bottom sheet is a component that slides up from the bottom of the screen to reveal more content.

For the scanner, the one provided by the Mobile Vision API from google is used. The framework provides a lot of camera functionalities, including a barcode detector.

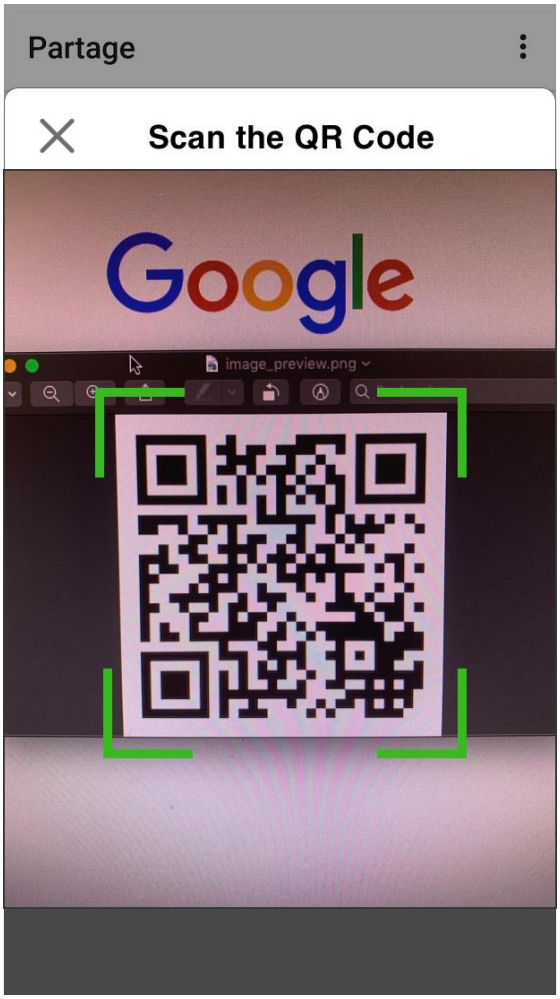

Figure 11 - Mock-up: D2D device pairing

5.1.2. D2D visualization of the healthcare organization by the citizen

The HCP information will be shown as a dialog. Some icons have been added to help the citizen to easily detect each information. The information about the phone and address will be clickable.

The user cannot continue the process without accepting the personal consent.

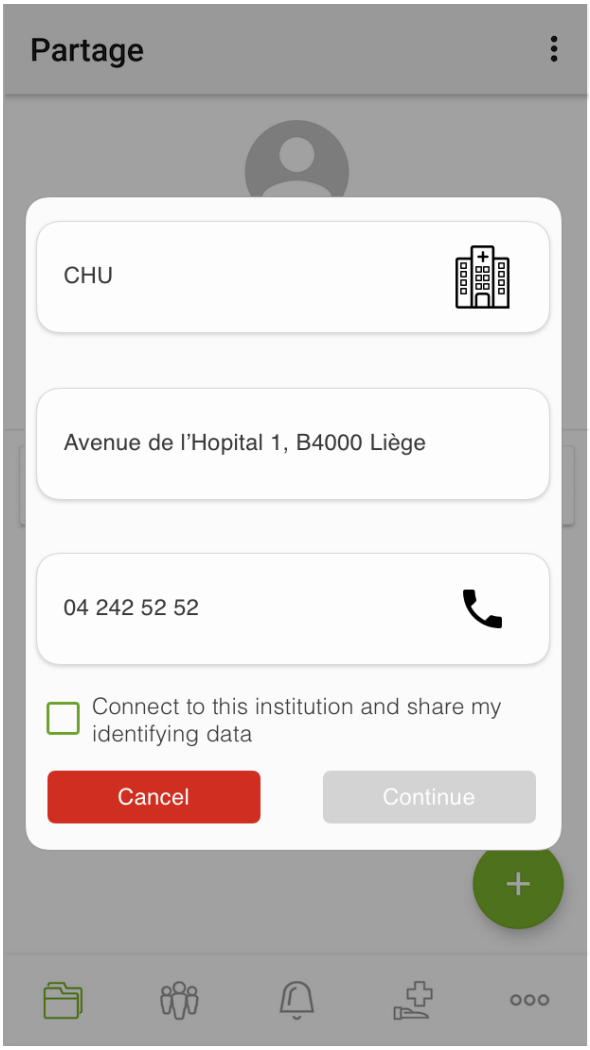

Figure 12 - Mock-up: D2D visualization of the healthcare organization by the citizen

5.1.3. D2D consent by the citizen to healthcare organization for temporary S-EHR access

The consent for health data sharing will be shown in a dialog.

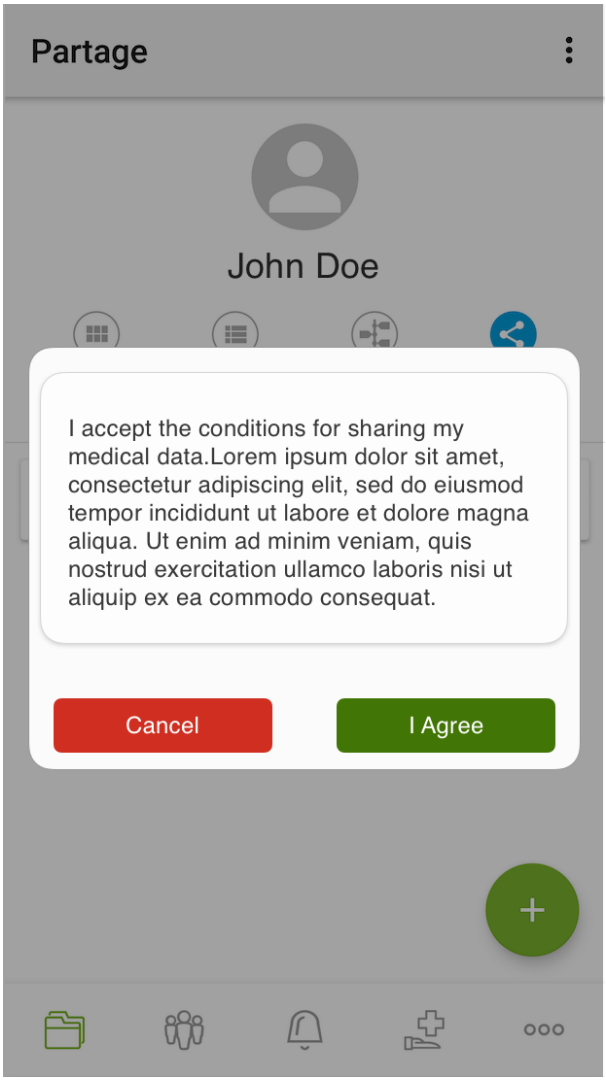

Figure 13 - Mock-up: D2D consent by the citizen to healthcare organization for temporary S-EHR access

6. IMPROVEMENT OF THE S-EHR-A-RI

This section explains some improvement that could be done on the requirements presented in the previous sections, in the next versions of the S-EHR application.

6.1. Customize the type of data to share in the S-EHR-A-RI

We could imagine to give to the citizen the possibility to choose which data he wants to transfer to the HCP. The goal is for the citizen to maintain total control over his data, and thus increase his confidence in the application and process.

There is also the possibility to show to the citizen the data that he is about to share with the HCP, without giving him the choice of whether or not to select the data he wants to share. We are removing some control for the citizen, but we will be more transparent and clear about the data that will be shared with the HCP.

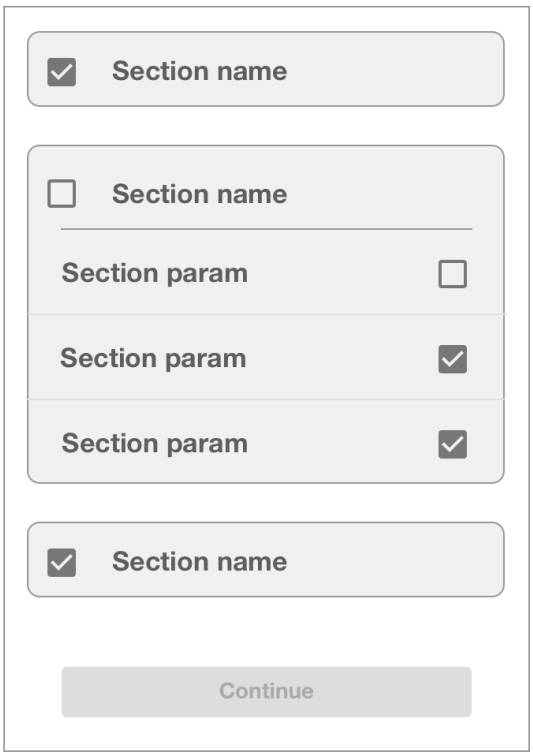

Figure 14 - Wireframe: Customized data type to share

6.2. Allow to close the connection from the S-EHR-A side

A feature that can be useful will be to keep the patient informed of the connection state.

Following this idea, we can imagine a kind of banner that informs the user on the connection state and who he's connected with.

If the user wishes it, a simple touch on the banner could stop the connection (with a confirmation dialog).

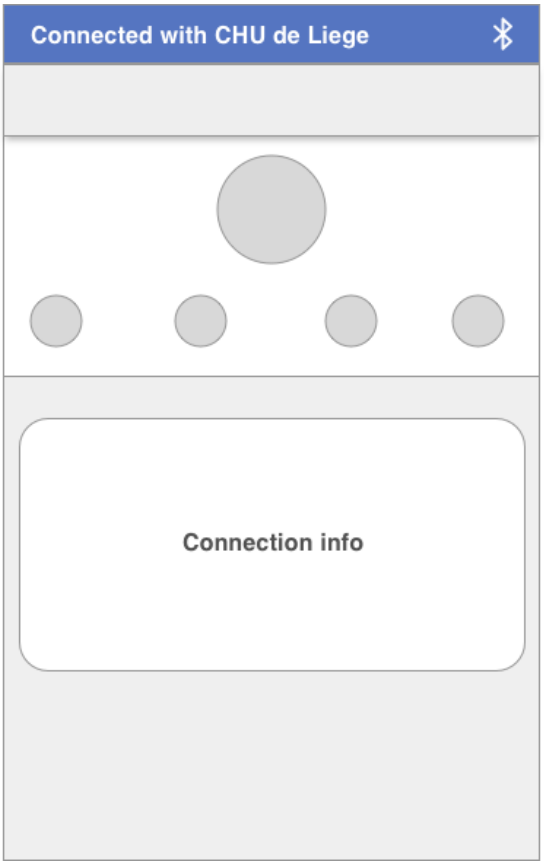

Figure 15 - Wireframe: Close connection from the S-EHR-A

7. CONCLUSIONS AND NEXT STEPS

This document describes the first draft of the design and the reference implementation of the S-EHR-A realized in the context of the InteropEHRate framework. This document is a first version and reflects the current understanding of the project by the consortium. There will be two other versions of this document, one in March 2020, and one in March 2021. These two future versions will contain relevant updates of the current version of the S-EHR-A-RI. It will also contain the design and the reference implementation of user requirements that will have taken place until then.

REFERENCES

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