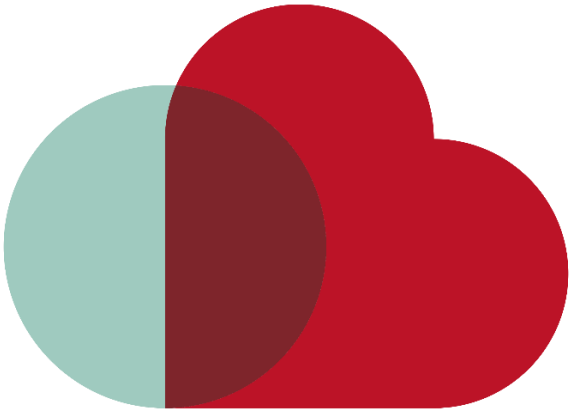

retention
SMART HEART FAILURE MANAGEMENT

Horizon 2020 Project RETENTION

"HEART FAILURE PATIENT MANAGEMENT AND INTERVENTIONS USING CONTINUOUS PATIENT MONITORING OUTSIDE HOSPITALS AND REAL WORLD DATA"

Research and Innovation Action
H2020-SC1-BHC-2018-2020
GA 965343

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		CL = Classified

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Deliverable description (from DoA)

A report documenting the integrated platform's (a) functionalities and (b) any amendments made to its architecture and design, (c) the outcomes of testing the platform and (d) installation, deployment and usage guidelines for the platform.

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1. Executive Summary

This document is a report on the first version of the RETENTION platform, an integrated healthcare platform designed to monitor and provide potential interventions for chronic Heart Failure (HF) patients. RETENTION platform uses a range of data including medical clinical physiological and behavioural data to detect patterns of disease progression and offer personalized interventions taking advantage of big data analytics and machine learning techniques.

The report provides a detailed view of the “user” (as defined in D.3.2 Architecture), by describing the roles of the users, system set up, use cases and scenarios, Platform Infrastructure Deployment and User focused Descriptions and Flows. This deliverable is the amalgamation of all other related deliverables that define the requirements, architecture, data model, analytics, and decision-making mechanisms of the RETENTION system solution.

As a reminder, the RETENTION platform is divided into three layers: the Global Insights Cloud (GIC), the Clinical Site Backend (CSB), and the Patient Edge (PE). The PE layer involves the Mobile App and the Local Home Gateway that collect and pre-process data from home-based sensors and medical devices. The CSB layer contains components responsible for monitoring patients' health and wellbeing at clinical centres. The GIC layer is responsible for data analysis and decision-making.

2. About this Document

2.1. Role of deliverable

This report escorts the first version of the integrated RETENTION platform, involving the first release of its components developed in WP3, WP4, WP5 and WP6, as integrated, tested and deployed in the production environment. Its purpose is to demonstrate the functionalities of the 1st version of the integrated platform, from the user perspective. This deliverable marks an important milestone (MS5) for the project as the version of the platform demonstrated herein has been put into production and will be used for supporting the RETENTION clinical study. D7.1 focuses on a concise but complete presentation of the platform UIs without reference to technical details and processes. These are offered in its sister deliverable, D7.2 which documents the platform from a technical perspective, including any amendments made to its initially proposed architecture and design, as well as presenting the Consortium's efforts to bring the platform to the readiness level that would allow it to support RETENTION's clinical study, including platform testing and user documentation.

2.2. Relationship to other RETENTION deliverables

This report is the escort to the first version of the platform, and it is the amalgamation and if need be, amendment of the following deliverables:

- D3.1 Requirements Document (the system requirement as defined by the primary users and the technical team).
- D3.2 Architecture document (the definition of the total system architecture).
- D4.1 RETENTION Data Model, which generates the design & specification of the RETENTION Data Model.
- D4.2 RETENTION Data Management enabling mechanisms version 1, which describe RETENTION data repositories, data transfer and handling mechanisms.
- D5.1 RETENTION Analytics & Decision-making enabling mechanisms version 1.
- D6.1 RETENTION Interfacing, Device Federation and Visualization components version 1.
- D6.2 RETENTION Security & Privacy by design enabling mechanisms version 1.

2.3. Structure of the document

The current deliverable provides the integration status of the RETENTION components. The purpose of this version is to provide an overview of the roles of the users, system set up, use cases and scenarios, Platform Infrastructure Deployment and User focused Descriptions and Flows.

Section 1 presents an executive summary of this deliverable.

Section 2 presents the overview of this deliverable, the relationship to other RETENTION deliverables.

Section 3 presents platform modules/services to be integrated and reference to the system's architecture.

Section 4 presents the RETENTION Platform User categories.

Section 5 presents the RETENTION Mobile Application through technician's and user's perspective.

Section 6 presents the Home Gateway Application through technician's and user's perspective.

Section 7 presents the Clinical Site backend Dashboard through clinician's and technician's perspective.

Section 8 presents the Global Insights Cloud Dashboard through Data Analyst and other user perspective.

Section 9 presents a summary of the deliverable and the future improvements of the platform.

Section 10 presents a summary of the work done.

3. Summary of platform modules and services which are integrated

The RETENTION platform is a holistic tool for patient management and remote patient monitoring, aided by Artificial Intelligence that will continuously monitor real-world data (clinical and environmental data) and offering support for clinical side interventions and predicting Heart Failure risk.

The RETENTION platform should provide the following characteristics:

- Fluent data flow for patient-doctor communication
- User friendly environment
- Improved patient therapeutic adherence to medication and lifestyle
- Enhanced patient´s clinical stability and prevent decompensations

As described in D3.2, the architecture consists of 3 layers:

- Global Insights Cloud (GIC),
- Clinical Site Backend (CSB) and
- Patient Edge (PE).

The diagram from Figure 1 presents an overview of the RETENTION Architecture.

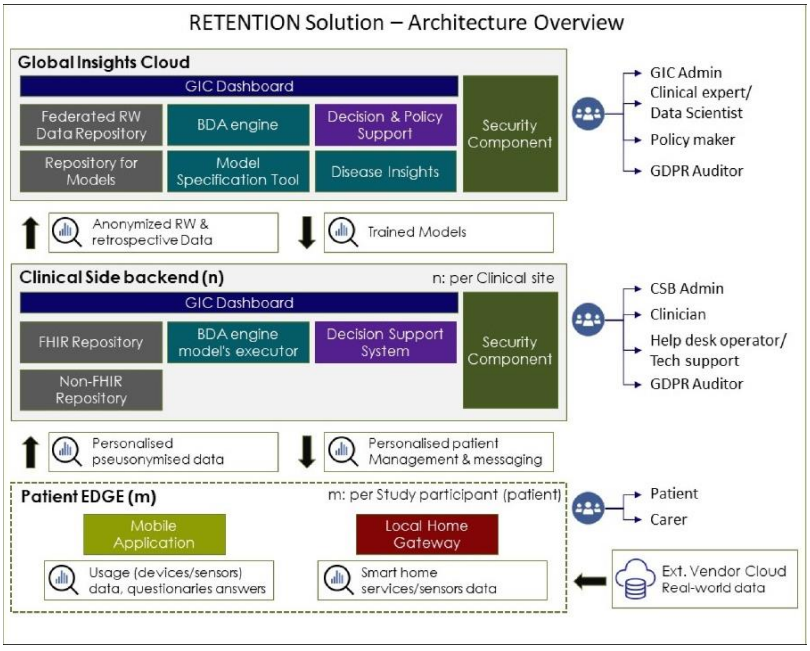

Figure 1: Architecture Overview of the RETENTION project

The RETENTION solution comprises of three main components: the GIC layer, the CSB layer, and the Patient Edge (PE) layer.

The GIC layer includes sub-components such as the GIC Dashboard, Federated RW Data Repository, Repository for Models, BDA Engine, Model Specification Tool, Disease Insights, Decision & Policy Support, Security Component, and GIC Rest API, as described in D.3.2 Architecture.

The CSB layer includes sub-components such as the CSB Dashboard, FHIR & Non-FHIR Repository, BDA Engine Models Executor, Decision Support System, Security Component, and CSB Rest API, as described in D.3.2 Architecture.

The PE layer includes the Mobile App and Local Home Gateway. Additionally, there is a security component that ensures privacy and data protection for all operations.

The GIC and CSB Dashboards support data input and usage of services while communication with other components has been implemented through REST interfaces. REST services also provide communication between the BDA engine, Data Repository, and different repositories located in GIC or CSB. Each CSB interacts with the Local Home Gateway and Mobile Application through REST interfaces. The Local Home Gateway collects data from home-based sensors, while the Mobile Application handles medical and non-medical device information. This information is pre-processed and sent to the Clinical Site Backend in compliance with GDPR regulations through REST services. Interactions between these components, as well as authentication for the Dashboards, are secured by the Security Component, which also holds end-user account information.

More details about the platform architecture are provided in D3.2 and D7.2.

3.1 Platform Infrastructure Deployment

The integrated platform of RETENTION employs a hybrid hosting model, to support project and future extensions of the platform. The RETENTION platform is designed to be integrated into the hospital systems and to be compliant to FHIR. However, during the pilot phase of the RETENTION project, connection with the hospital information systems is not going to be implemented because of security policies that cannot be overcome within the project timeframe. The integration can be performed after the validation of the solution and acceptance of the Hospitals involved. Specific terms and conditions of use among partners will be achieved within the Exploitation relevant Task. As described in the relevant sections of this document, two of the main components that have been deployed on the infrastructure are CSB and GIC. GIC is hosted on a private cloud infrastructure, located at ICCS's server room. CSB instances are planned to be hosted by the pilot sites. In case this is not feasible for any pilot site, they can be hosted at ICCS, in a separate environment, to comply with the architecture of the platform.

The devices to be used with the RETENTION mobile app are the following:

Figure 2: Samsung A03s (version 2021)

Figure 3: Omron M4 Intelli IT pressure meter

Figure 4: Omron HN 300T2 Intelli IT weight scale

Figure 5: Omron P300 Intelli IT pulse oximeter

Figure 6: Garmin Venue SQ

The devices to be used with the Home Gateway are the following:

Figure 7: Xiaomi MI temperature & humidity monitor

Figure 8: Raspberry PI 4 Model B/ 4GB

Figure 9: 32GB Micro SD Card with NOOBS for RPI

Figure 10: Raspberry Pi 4 Official power unit 3A (15,3W) USB-C

Figure 11: Ethernet cable

Figure 12: Official Raspberry Pi 4 Model B Black Case

Figure 13: Official Raspberry Pi 4 Case Fan for Official Case

The hosting features, the required services, the usage protocol are described in detail in D7.2.

4. Retention Platform User Categories

The RETENTION Platform is designed to accommodate the needs of a variety of stakeholders. Below we examine the corresponding user's categories.

4.1. Hospital-side user categories

There are two categories of users at each hospital: clinicians (also referred to as "clinical case managers") and technicians (also referred to as "helpdesk users"). Both have access to the CSB where clinical data pertaining to the hospital's patients who signed up to the RETENTION clinical trial are being managed, via the CSB Dashboard. The CSB Dashboard is primarily designed for clinicians, but also provides functionality to allow technicians to set-up and ensure the correct operation of patient monitoring devices. More details can be found in Section 7.

4.2. Patient-side user categories

RETENTION patients have an active role in the platform. The patient takes home both the local home gateway and the mobile with the Retention application that allows communication with all the devices. For the Local home gateway the only action required by the patient is a simple power and internet connection, as instructed by the hospital technicians (see section 6), while for the usage of the mobile application, a daily user interaction is necessary in order to establish communication with the devices and carry out the daily measurements (see section 5). When the patient cannot carry out those tasks, it is foreseen that their carer steps in and helps out. So, the two patient-side user categories are: the patients and their carers.

4.3. Other user categories

Part of the RETENTION value proposition stems from the GIC and its ability to collect data from hospitals' CSBs (with standard personal identifiers removed). The GIC Dashboard will act as a graphical interface for users to access its features and functionality.

At the current stage of development, the GIC caters to the needs of data analysts who want to gain insights from data from all RETENTION hospitals. As the collected base of data grows, data analysts will be able to create data analysis and Machine Learning (ML) flows that will be available to the CSBs, so it was important to provide the relevant tools as early as possible. Thus, they are included in the present version.

The RETENTION Global Insights Cloud is also meant to provide non-technical users (e.g., policy makers) with insights from the cumulative collection of data from all RETENTION CSBs. However, as these insights will only be reliably obtained after the RETENTION study has run for enough time and Artificial Intelligence (AI) based analyses have been developed and utilised, the relevant functionalities will be included in forthcoming releases of the GIC.

5. The RETENTION Mobile App

5.1 Technician's Perspective

The RETENTION mobile application is a native ANDROID software, that is easily installed in any Modern ANDROID phone via the Google store. The version of the operating system should be 12 and over. The first sign-in should be done as an administrator to configure the application. Tap the retention icon seven times to reach the admin login page. The response from the app will show the remaining entry times. The Administrator should use the Patient ID, URL, Language and Admin Password to sign into the appropriate hospital Database or test environment (shown below).

Figure 14: Initial screen of mobile application

By Tapping the "Submit" button the app will return the user to the login screen and will allow her/him to log in either as a carer or as a patient. The user should tap "Patient" or "Carer" and use his/her biometrics in order to log in. Subsequently, the user should accept the privacy policy by tapping "OK".

The connection of the devices to the application is essential in order to collect and store the measurements. The devices that will be used are a smartwatch, an oximeter, a pressure gauge, a scale, and a thermometer.

Smartwatch

The user should select the Watch icon. The application will search for adjacent pairable devices automatically. From the list of available devices, the user should choose the desired device and fill the necessary demographic information. By tapping “Save” all the information is saved.

In order to synchronize the smartwatch with the application, the user should tap “Measures” icon and select “watch”. The Watch will automatically synchronize with the application. If the application seems to be unresponsive, the user should tap the “refresh” icon. The user should repeat this process every morning.

After synchronization, the user can tap on the “Measures” and “Charts” icon subsequently and 3 graphs of the steps, sleep and heart rate are presented. By selecting on “Activity” icon the user can observe a report of his daily steps, distance and calories.

Oximeter

The user should select the “Oxygen Level” icon and a pop-up will appear. Then the user should follow the instructions on it to pair with the device and following tap the “I did it” button. A second pop-up will appear, giving the option of syncing with the device.

After taking the measurement, the user should tap the “Sync” button. As soon as synchronization is complete, a third pop-up will show the results.

Pressure gauge

The user should select the “Blood Pressure” icon. The user should follow the instructions on it to pair with the device and then tap the “I did it” button. A second pop-up will appear, giving the option of syncing with the device.

After taking the measurement, the user should tap the “Sync” button. As soon as synchronization is complete, a third pop-up will show the results.

Scale

The user should select the “Weight” icon. The user should follow the instructions on it to pair with the device and then tap the “I did it” button. A second pop-up will appear, giving the option of syncing with the device.

After taking the measurement, the user should tap the “Sync” button. As soon as synchronization is complete, a third pop-up will show the results.

Caution: The Admin should FIRST add the patient to the CSB, before continuing to the next steps!

Caution: The initialization of the phone and the google account, as well as the installation of the application, should be completed before continuing on to the next steps!

To set up the application the following procedure must be followed:

i. The Hospital IT administrator should tap the RETENTION icon seven times to access the admin login page.

ii. Add the patient to the application.
iii. Select the correct URL for the Hospital in question or test or staging systems available (from a drop-down menu).
iv. Add a global password (the password is only for the use of Hospital IT administrators and is not to be shared with the patient/carer).
v. Select the language of the application.
vi. Add the device ID to the CSB.
vii. The “test” button should be pressed, to verify the connectivity to the CSB and Databases. In case of an error in the above procedure, a failure indication appears on the screen. Users should proceed by following the instructions.
viii. All data will be saved automatically.
ix. Exit the Admin screen.

The system is now set up.

5.2 Patient/Carer Perspective

The initial set up of the Mobile app is performed once at the hospital, by the technician. The patient (or his/her carer) will receive the mobile phone with the RETENTION app already configured and ready to use, on a daily basis, in accordance with the RETENTION protocol. It is expected that the patient should use the mobile application in a daily basis.

The following flow describes the daily patient workflow.

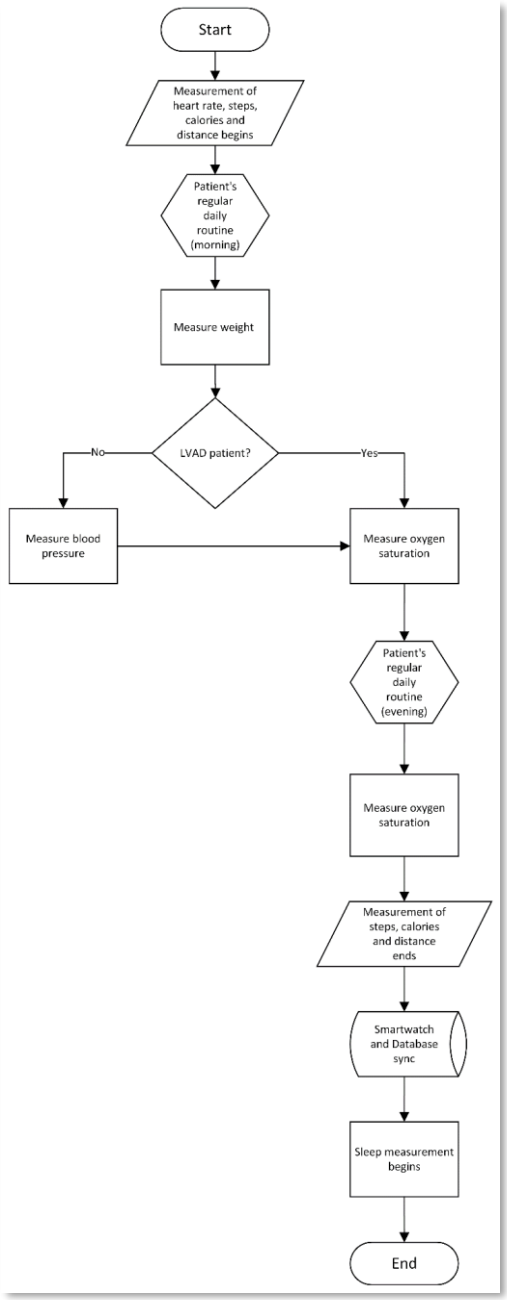

Figure 15: Daily patient workflow

The user starts with his morning routine. Initially she/he administers all appropriate measurements (like her/his body weight, pressure, oxygen saturation, etc) and for users with LVAD, they need to pass the LVAD system parameters. The user should also follow an evening routine and adhere to the medication given by the clinical team. Finally, the patient should follow the afternoon monitoring routine as described in the medical protocol. During the day, steps, distance and calories consumed by the user will be recorded. At the same time, the heart rate is recorded. During sleep, deep and light sleep as well as sleep interruptions are recorded.

One procedure that should be done on a daily basis is the reporting of medication. The user should note the medications taken during the day.

On a weekly basis the user must complete a questionnaire, which asks the user a set of simple questions regarding his/her condition. This questionnaire must be completed on a weekly basis. However, the user may complete it more frequently in cases where he/she considers it necessary.

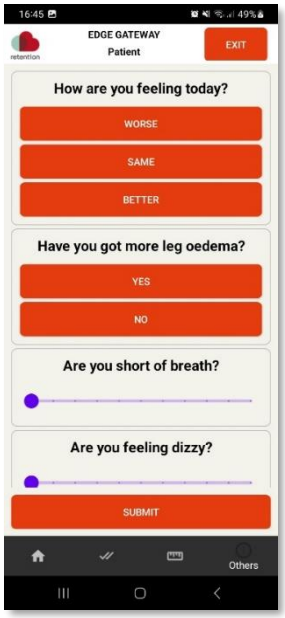

Figure 16: Questionnaire

All Symptoms and VAD parameters should also be reported to the Medical staff during the scheduled appointment, at least every 4, 8, 12 and 18 months, or by the consult of the doctor.

Smartwatch

The user should select the Watch icon.

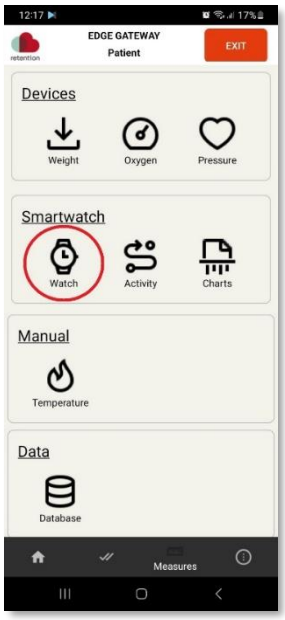

Figure 17: Smartwatch widget

The program will look for adjacent pairable devices automatically. From the list of available devices, the user should choose the desired device and fill the necessary demographic information. By tapping “Save” all the information is saved.

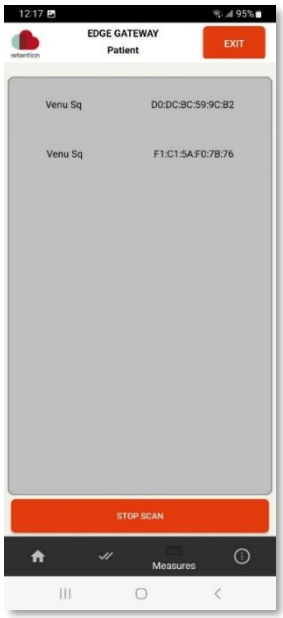

Figure 18: Smartwatch selection screen

In order to synchronize the smartwatch with the application, the user should tap the “Measures” icon and select “Watch”. The Watch will automatically synchronize with the application. If the application seems to be unresponsive, the user should tap the “refresh” icon. The user should complete this process every morning.

After synchronization, the user can tap on the “Measures” and “Charts” icon subsequently and 3 graphs of the steps, sleep and heart rate are presented. By selecting on “Activity” icon the user can observe a report of his daily steps, distance and calories.

Figure 19: Screenshot of sleep and heart rate chart and sleep result

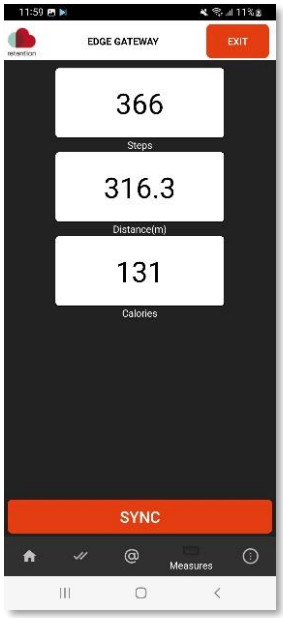

Figure 20: Steps, distance and calories information

Oximeter

The user should select the “Oxygen Level” icon.

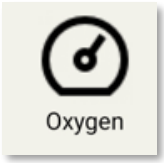

Figure 21: Oximeter widget

A pop-up will appear. The user should follow the instructions on it to pair with the device and then tap the “I did it” button.

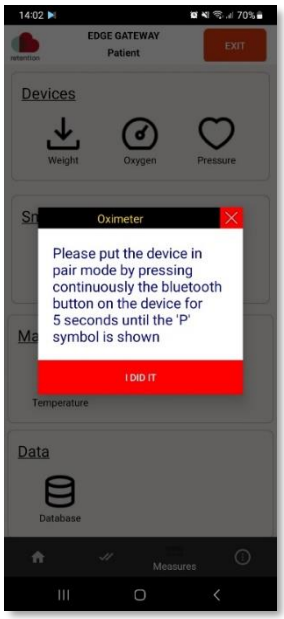

Figure 22: Screenshot of pairing

A second pop-up will appear, giving the option of syncing with the device. After taking the measurement, the user should tap the “Sync” button. As soon as synchronization is complete, a third pop-up will show the results.

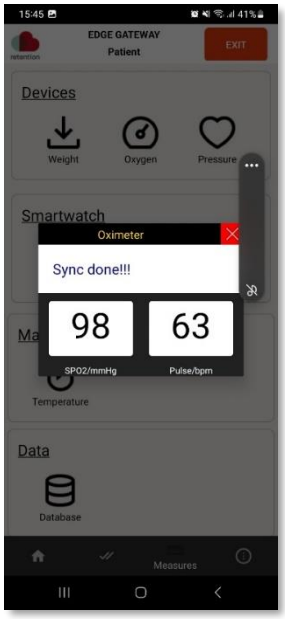

Figure 23: Screenshot of successful synchronization.

Pressure gauge

The user should select the “Blood Pressure” icon.

Figure 24: Pressure gauge widget

The user should follow the instructions on it to pair with the device and then tap the “I did it” button.

Figure 25: Screenshot of pairing

A second pop-up will appear, giving the option of syncing with the device.

After taking the measurement, the user should tap the “Sync” button.

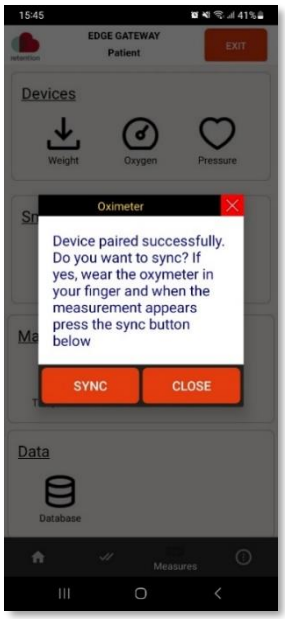

Figure 26: Screenshot of synchronization

As soon as synchronization is complete, a third pop-up will show the results.

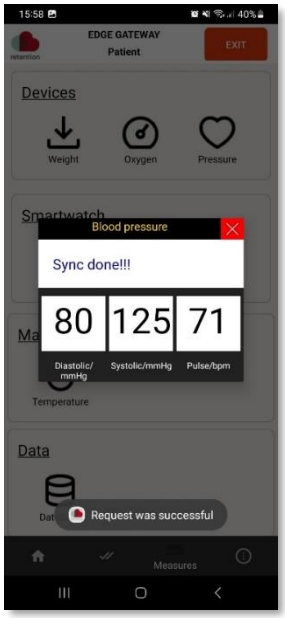

Figure 27: Screenshot of successful synchronization

Scale

The user should select the “Weight” icon.

Figure 28: Scale widget

The user should follow the instructions on it to pair with the device and then tap the “I did it” button.

Figure 29: Screenshot of pairing

A second pop-up will appear, giving the option of syncing with the device.

After taking the measurement, the user should tap the “Sync” button.

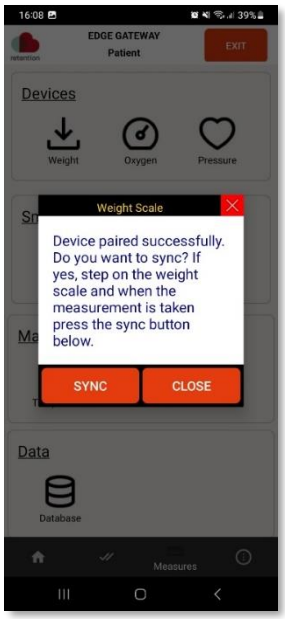

Figure 30: Screenshot of synchronization

As soon as synchronization is complete, a third pop-up will show the results.

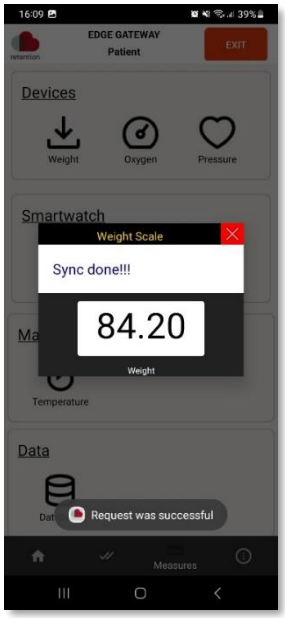

Figure 31: Screenshot of successful synchronization

Thermometer

The process for recording the temperature is a little different. The user should tap “Measures” and “Temperature” icon and manually input the measurement value.

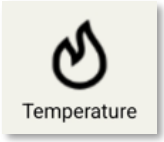

Figure 32: Thermometer widget

By tapping “Submit”, the measurement is recorded in the system.

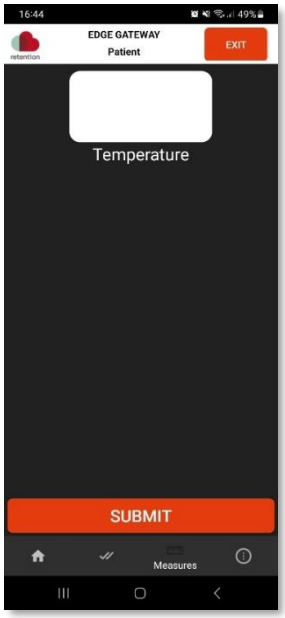

Figure 33: Screenshot of temperature entry measurement

6. Home Gateway Application

The following flow chart, presents the steps needed for the Home Gateway:

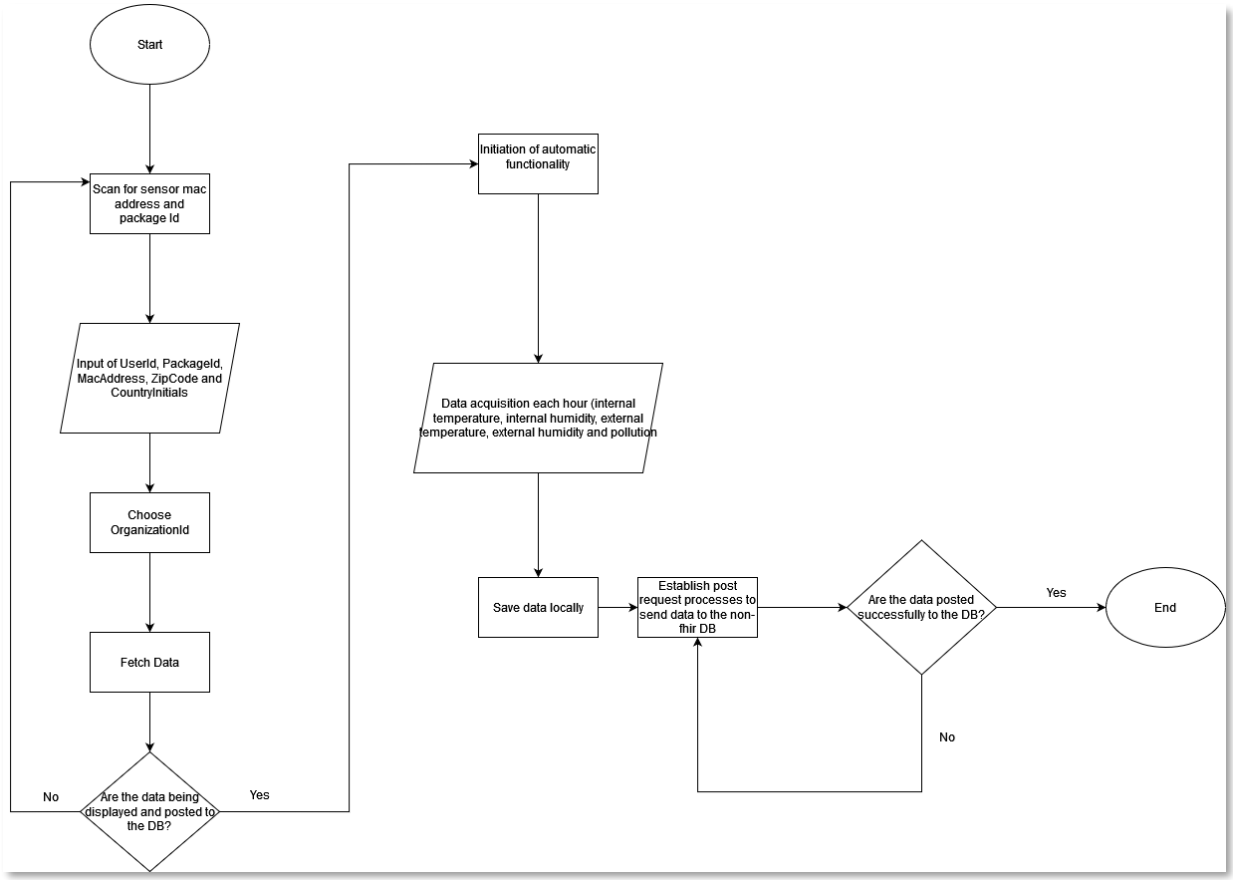

Figure 34: Home Gateway flowchart

6.1 Hospital Technician Perspective

The initial setup of the Local Home Gateway is carried out by the corresponding technician of each hospital. A thorough technician manual is provided (Local_Home_Gateway_Installation_V0.3.2.pdf) to each hospital technician, that describes every aspect of the installation in fine detail. A summary of the process is described below.

For the initialisation of the Local Home Gateway to be successful, apart from the Raspberry Pi and the temperature and humidity sensor, the technician needs to have also a personal computer with at least 35 GB of free disk space, a USB to SD card reader (or SD card reader port) in order to work with the SD card of the Raspberry Pi, an HDMI monitor, an Internet router, a micro-HDMI to HDMI cable, an ethernet cable, and a (3V) battery for the sensor.

A download link of the clone image of the Raspberry Pi OS is provided in the technician manual. The technician needs to download this file, unzip it and flash it to the Raspberry Pi SD card. Subsequently, the

technician needs to insert a battery to a temperature and humidity sensor, insert the SD card in the Raspberry Pi, connect it to the power, connect it to the Internet router via a Lan cable and finally connect it to a monitor through a micro-HDMI to HDMI cable, as seen in the following figures.

Figure 35: Battery placement into the temperature and humidity sensor

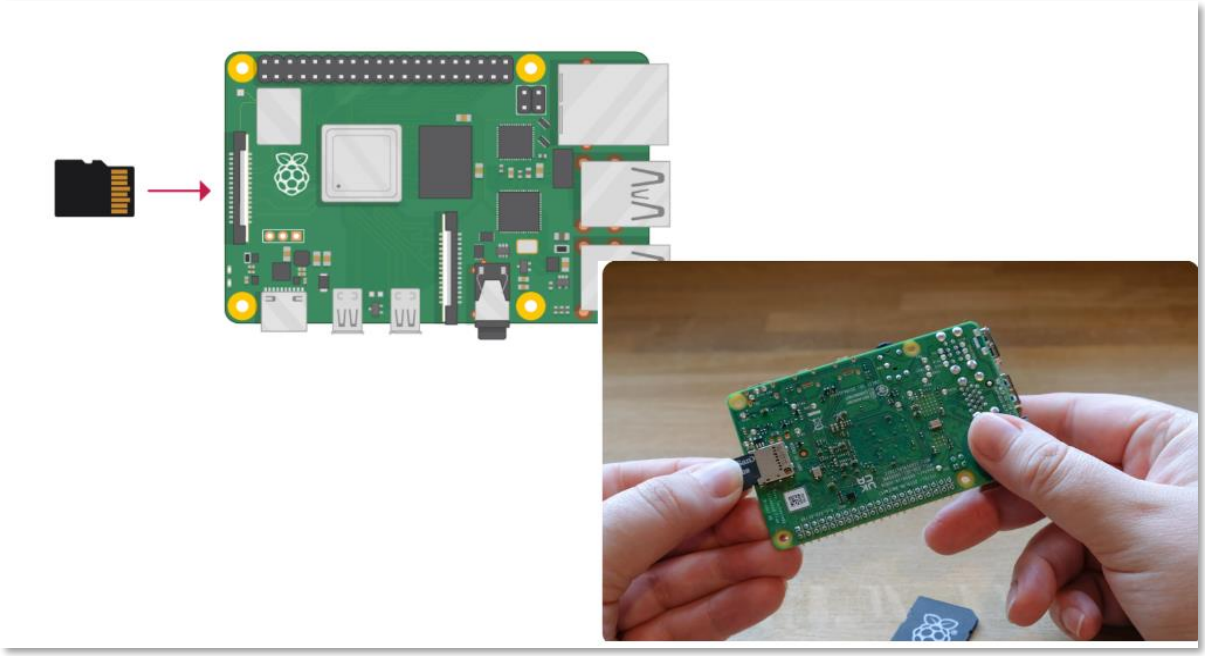

Figure 36: SD card placement into the Raspberry Pi

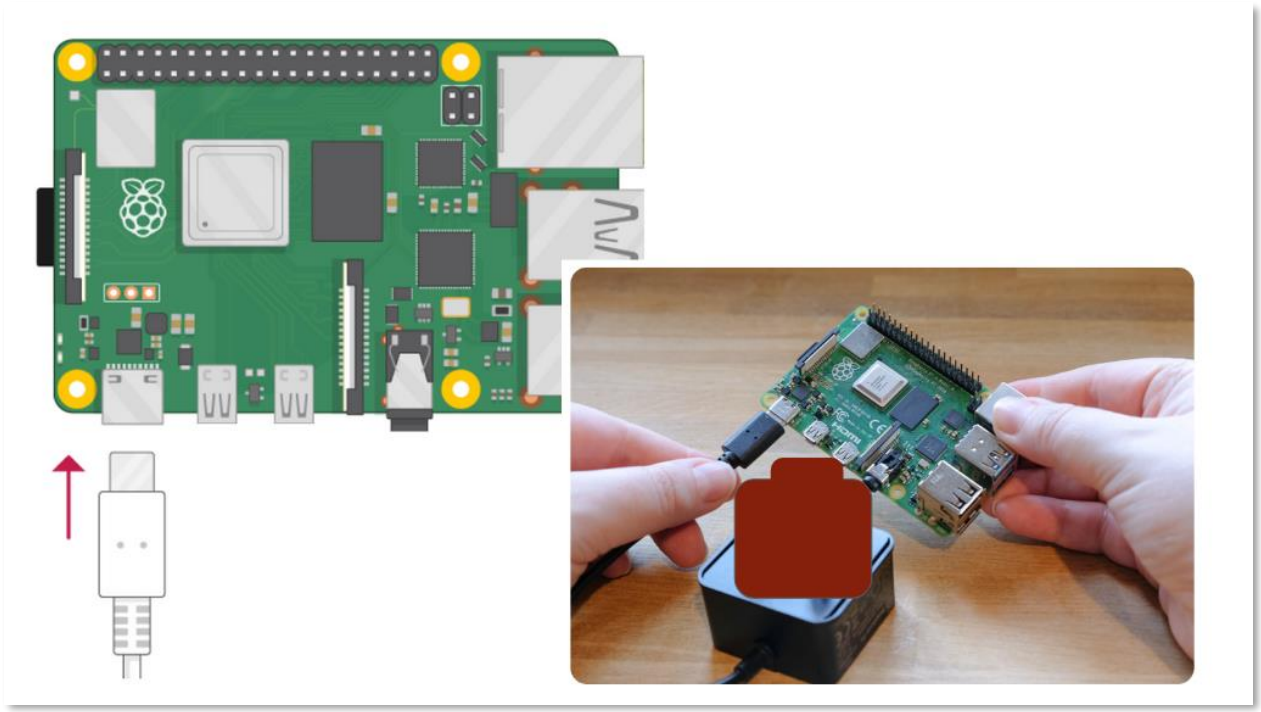

Figure 37: Power cable connection with the Raspberry Pi

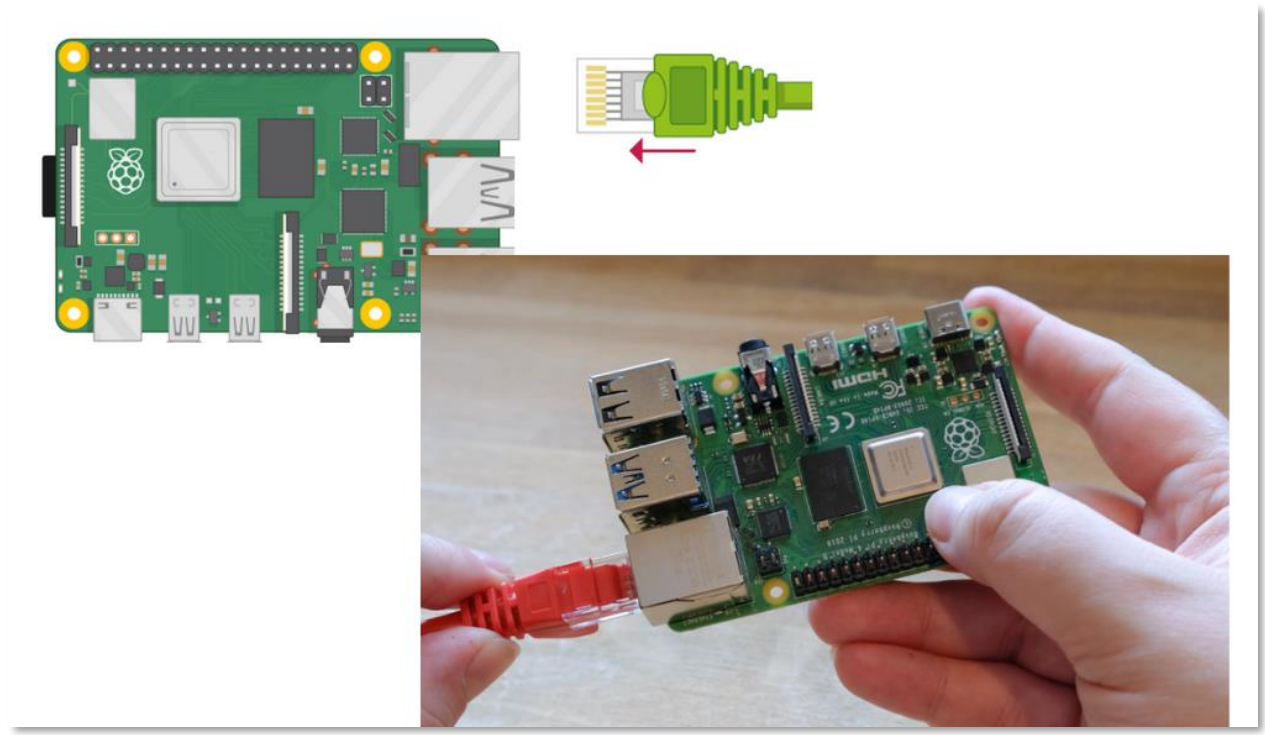

Figure 38: Ethernet cable connection to the Raspberry Pi

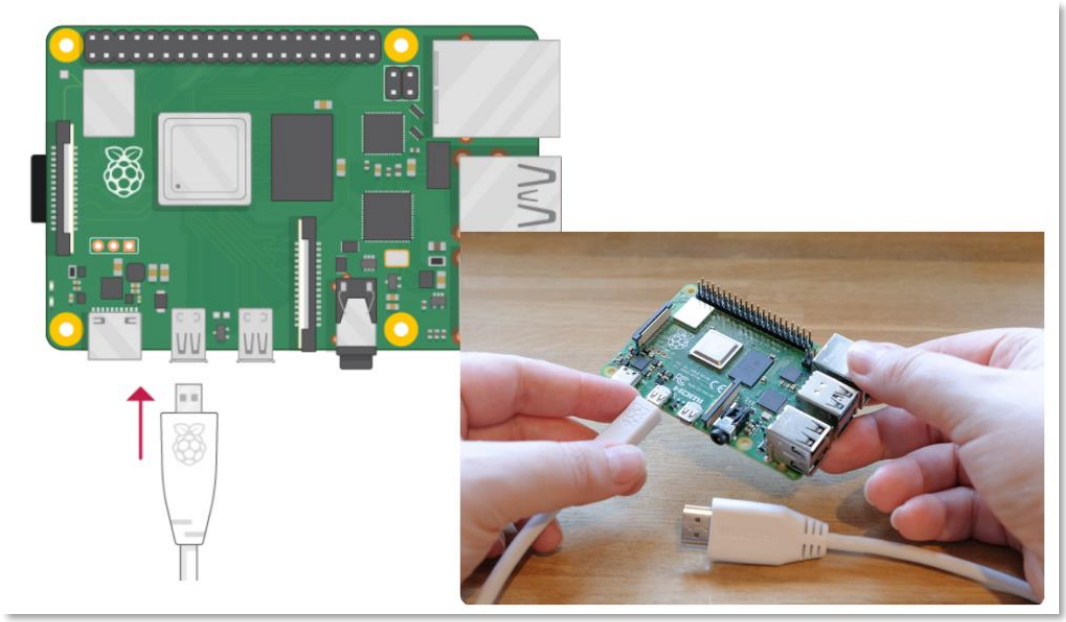

Figure 39: Micro HDMI to HDMI cable connection to the Raspberry Pi

Internet connection via ethernet cable is required in order to avoid problems with the wireless communication between Raspberry Pi and the sensor.

Also, the technician needs to make sure that only one temperature and humidity sensor is functional (with a battery placed inside), each time a Raspberry Pi setup takes place. If more Xiaomi temperature and humidity sensors are in range, the technician needs to make sure to remove their batteries before moving on with the installation. That is because the sensor will be matched to work (send data) with the current Raspberry Pi that is being configured and if more sensors are in range a misconfiguration may occur.

The technician needs to bring the sensor near the Raspberry Pi in order to make sure that the transmission of data will be successful.

After the Raspberry Pi is turned on, the first step is the installation of a remote software, as described in the technician manual, that allows remote access for the technician to support the pilot process and offers the ability to connect to the Raspberry Pi without a monitor plugged in. A detailed process of the installation of the proposed remote software and their configuration is described in detail in the technician manual.

Then, the technician needs to make use of a tool suitably developed for the facilitation of the installation of the Local Home Gateway, in order to begin the main process of inputting the necessary configuration parameters to establish the automatic Raspberry Pi functionality for the corresponding patient.

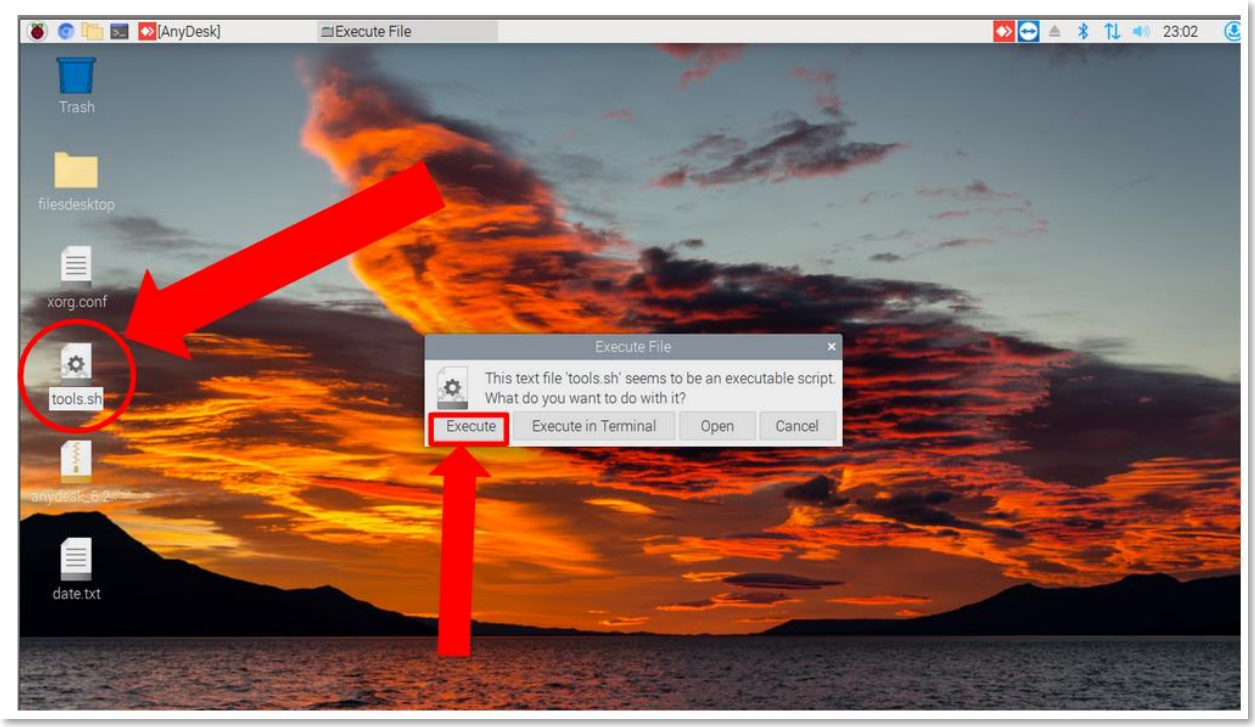

Figure 40: Access to the installation tool

The tool's main screen can be seen in the following image, where the installation process is broken down in multiple steps for the technician's convenience.

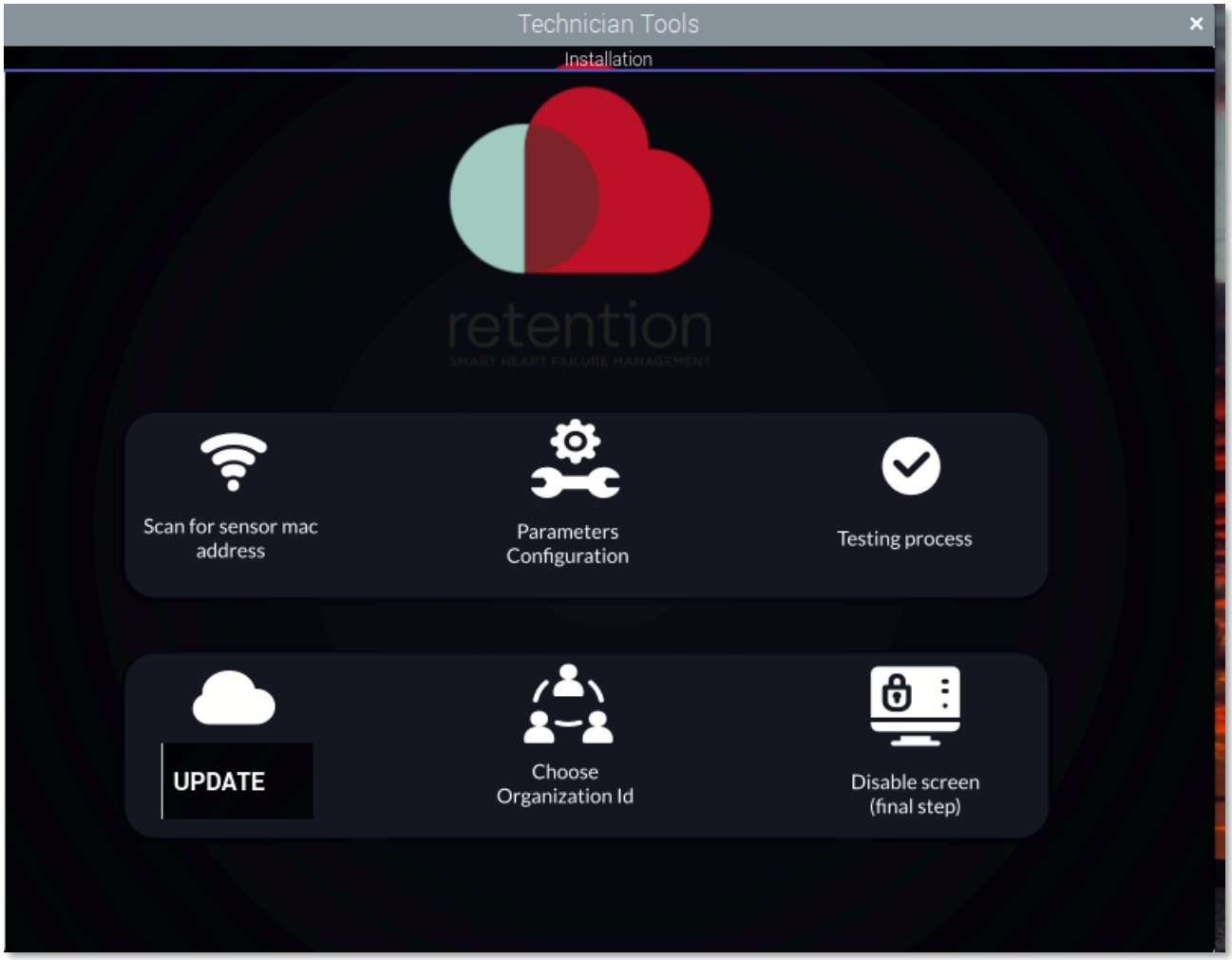

Figure 41: Main menu of the installation tool

The first step that should be followed according to the manual (see deliverable 7.2, Appendix A), is the update of the software, that is carried out by clicking the "UPDATE" button. The update takes place and when it is done, a message appears on the screen in order to confirm that the latest version of the software is utilised.

Then, the technician needs to click the "Scan for sensor MAC address" button, in order for the Raspberry Pi to provide both the temperature and humidity sensor's MAC address and the Raspberry Pi's MAC address (package Id). A quick nearby device scan takes place and after a few seconds, both MAC addresses appear on the screen.

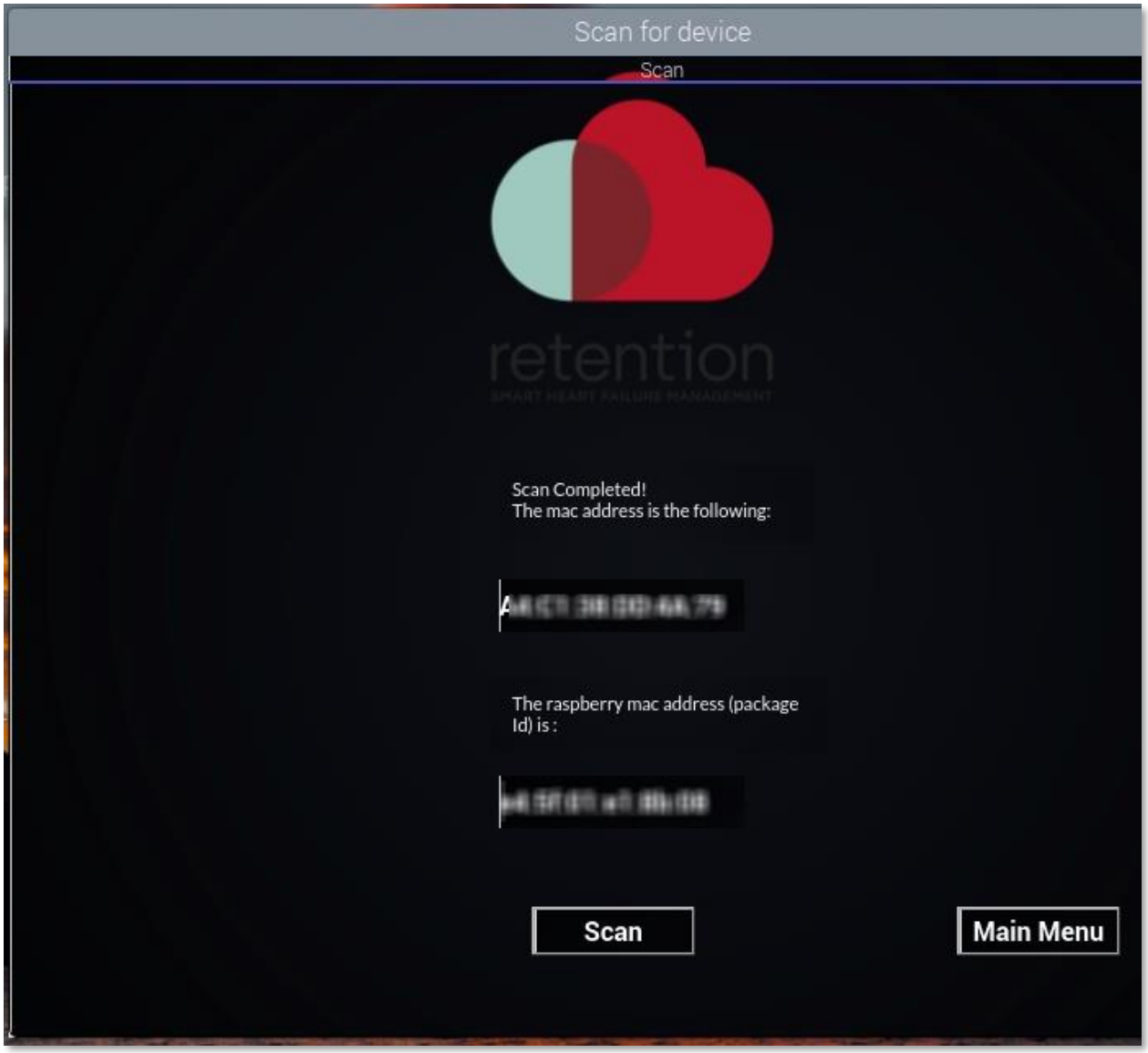

Figure 42: Scanning for MAC Addresses Tab

Following, the configuration process needs to take place (“Parameters Configuration” button) where the necessary parameters (“UserId”, “MacAddress”, “PackageId”, “ZipCode” or “Municipality”, “CountryInitials”) will be inserted by the technician. The two MAC addresses are automatically inserted, while all the others need to be manually inserted.

Figure 43: Parameters configuration tab

An important step that needs to be taken into consideration before the parameter configuration is the creation of the patient in the dashboard. This step provides the user Id of the patient, that the technician is required to know beforehand in order to fill it in the corresponding field while setting up the Raspberry Pi.

Also, the technician is required to access the dashboard and input the Raspberry Pi's MAC address (Package Id), for the corresponding patient (User Id) in the appropriate field in order to match user Id with package Id. In order to do that the technician needs to access the "Devices" tab on "Basic Patient Info" tab and insert in the "UUID/MAC address" field the Raspberry Pi's MAC address.

The following step in the installation process, is the selection of the corresponding organisation id that is done by choosing the necessary hospital.

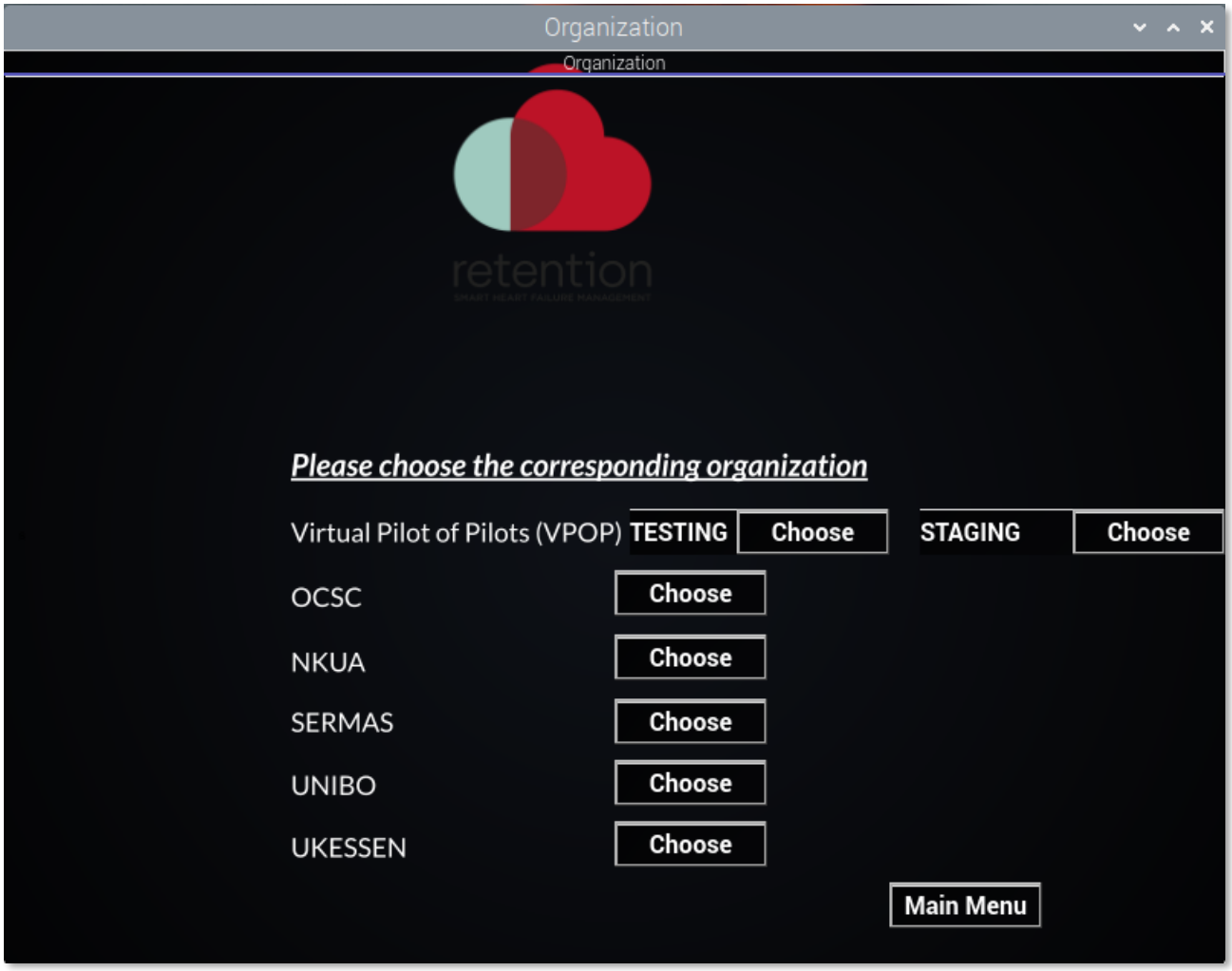

Figure 44: Organisation selection tab

Having made the above necessary configurations, the Local Home Gateway is ready for a testing process in order to verify that every parameter has been inserted correctly and that no problems will be occurring regarding the Raspberry Pi's, temperature and humidity sensor and weather API's functionality. This testing process is presented in the following figure.

Figure 45: Testing Process of the Local Home Gateway

The above figure describes a successful initialization of the Local Home Gateway by the technician, as we can see that the process managed to fetch all the necessary data both from the temperature and humidity sensor ("Temperature", "Humidity" and "Battery" values), as well as from the open weather API ("Ext. Temperature", "Ext. Humidity" and "Pollution". The message "Posted To DB", makes it clear that these obtained values of interest have been posted successfully to the non-FHIR database and are also visible to the dashboard by the clinician.

The technician's manual offers insights on the installation process, addressing many details and possible errors that may come up and what steps to follow in order to resolve them.

Finally, the last step that the technician needs to follow before handing over the Local Home Gateway to the corresponding patient, is to choose the option "Disable Screen", which allows the Raspberry Pi to function without a screen, configures it to work automatically with the above inserted parameters and providing at the same time remote access to the technician in case of possible troubleshooting.

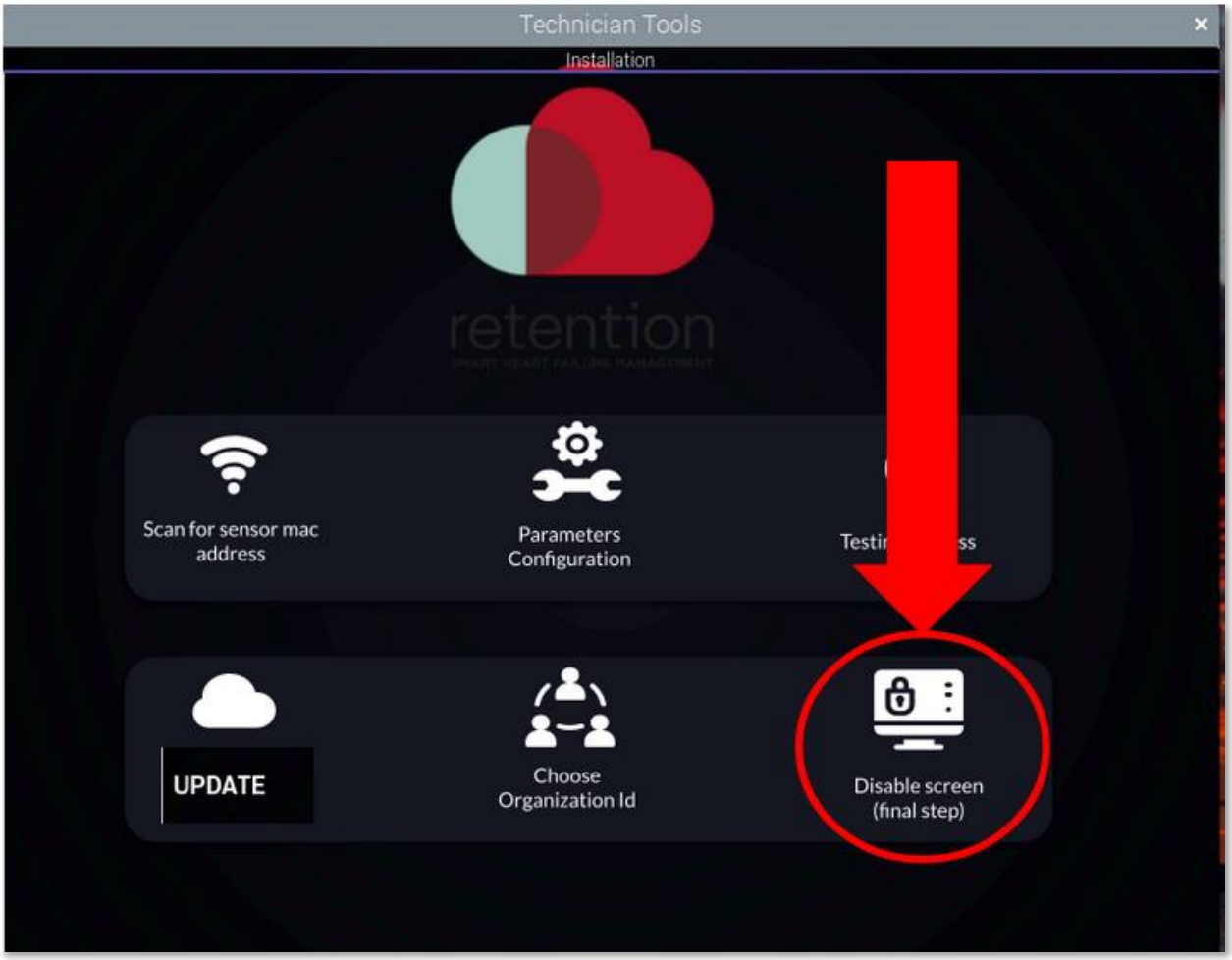

Figure 46: The last step of the installation is to disable the Raspberry Pi's screen

A summary of the system's set up is provided below.

Before beginning the installation, the hospital technician needs to have in place all the necessary equipment as described in the technician manual and chapter 7.1, as well as having created the patient in the dashboard (user Id required), for whom the Local Home Gateway will be configured. Finally, the technician needs to create pairs (Raspberry Pis along with their respective sensors), keeping active at the time of each installation, only the pairs that are configured to avoid misconfigurations.

The steps of the installation of the Local Home Gateway are summarised below:

I. Download the clone image for the Raspberry Pi from the provided download link.
II. Unzip the MyImageV03.img.gz file.
III. Flash the image (MyImage.img) to the micro-SD card of the Raspberry Pi. A laptop with a micro-SD card reader port or an external SD card reader to USB is required.
IV. Insert the SD card into the Raspberry Pi.
V. Connect the Raspberry Pi 4 to the power, to the internet through an ethernet cable and to a monitor through a micro-HDMI to HDMI cable.
VI. Insert a battery into the Xiaomi temperature and humidity sensor.
VII. Install a remote software for remote troubleshooting and access without the need for a monitor.
VIII. Run the tool script that is developed for the needs of the installation.
IX. Update to the latest software.
X. Choose the option “Scan for sensor MAC address” and then click the button “Scan” and wait for the MAC addresses to appear.
XI. Choose the option “Parameters Configuration” and fill in all the fields.
XII. Choose the option “Choose Organization Id” and make a choice between the available pilot sites
XIII. Choose the option “Testing Process” and click the button “Fetch”, to try out the configuration.
XIV. If all the above steps are successful, choose the option “Disable screen”.

If all the above steps are successful, the system is now set up and ready to be provided for use at the patient's homes.

6.2 Patient/Carer Perspective

The patient simply takes home the Home Gateway (Raspberry Pi), already configured by the hospital’s technician, along with the temperature and humidity sensor, connects it to the home Internet router via a LAN cable and plugs it in. If they cannot do it themselves, their carer or a friend or family member can do this for them. The temperature/humidity sensor device should be placed close enough to the Home Gateway device, ideally at a place where the temperature and humidity is representative of the temperature and humidity of the patient’s living quarters.

Apart from the above steps, the patient doesn’t have to do anything else, since the Local Home Gateway works automatically as already described. The only case of patient intervention is in case of a low battery of the sensor, where the user will be notified from the corresponding clinician (or technician), that will be monitoring the patient’s data through the dashboard, to change the battery of the sensor.

A very short user manual is also prepared for the patients, describing how to connect the Raspberry Pi correctly at their homes. Following are figures describing the connection of power and ethernet cables by the end users, that are the only steps that they need to take in order to establish the Local Home Gateway’s connection.

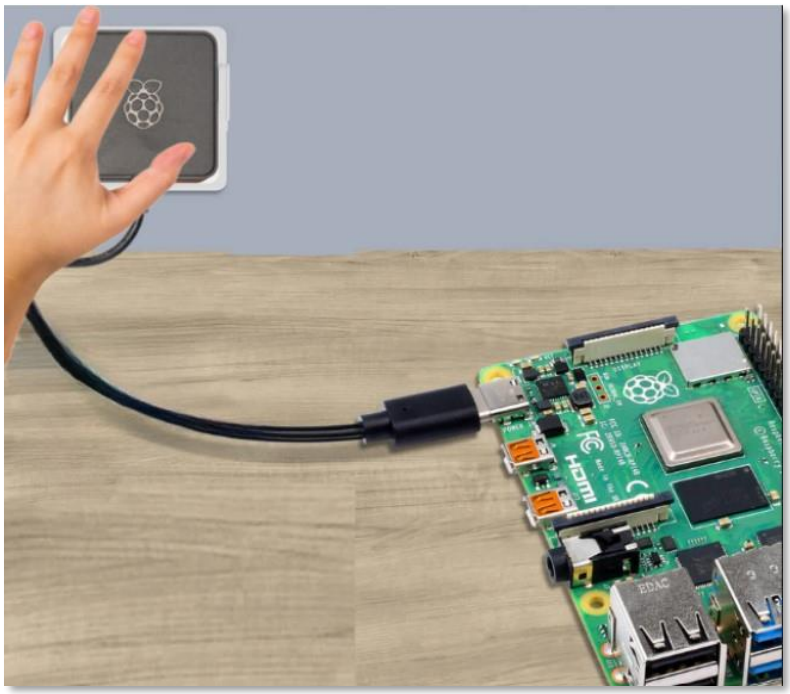

Figure 47: Power cable connection to the Raspberry Pi

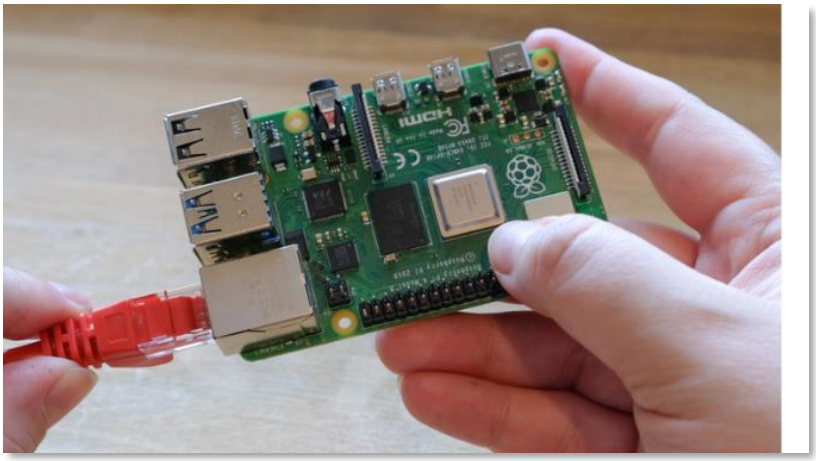

Figure 48: Ethernet cable connection to the Raspberry Pi

After the above connections, the patients need to bring the temperature and humidity sensor near the Raspberry Pi and the setup is complete. The following image shows the final hardware setup of the Local Home Gateway

7. Clinical Site Backend Dashboard

Deliverable 6.1 offers thorough analysis of the Clinical Site Backend Graphical User Interface. The version of the CSB Dashboard with which the RETENTION Clinical Trial commenced includes some functionality enhancements but also hides AI-based functionality that has already been developed (and presented in D6.1) that has not been deemed ready to include in the production version.

AI results is one aspect that differentiates the CSB Dashboard from a traditional e-CRF system; the others are the RETENTION alert mechanism and the display and visualisations of enhanced patient monitoring data obtained from/using devices given to patients participating in the RETENTION Clinical Trial. Because it is these highly desirable functionalities that the RETENTION Clinical Trial aims to assess, they are available only to clinicians, when they are viewing the records of patients randomised into the intervention group.

7.1 Security Component

To support the secure management and transferring of personal data without compromising privacy of the data-subjects, the RETENTION platform introduces secure ways to handle, distribute, and show information, to the correct set of 'eyes' (i.e., CSB and GIC end-users with appropriate access rights based on Role-based Access Control – RBAC), without compromising usability or speed. Furthermore, the security component supports the API management of CSB and GIC through a combination of two open-source tools to ensure provisioning, securing, and maintaining REST APIs. The RETENTION endpoints have been triggered by both end-users (machine-to-human) and devices (machine-to-machine) with the following workflow.

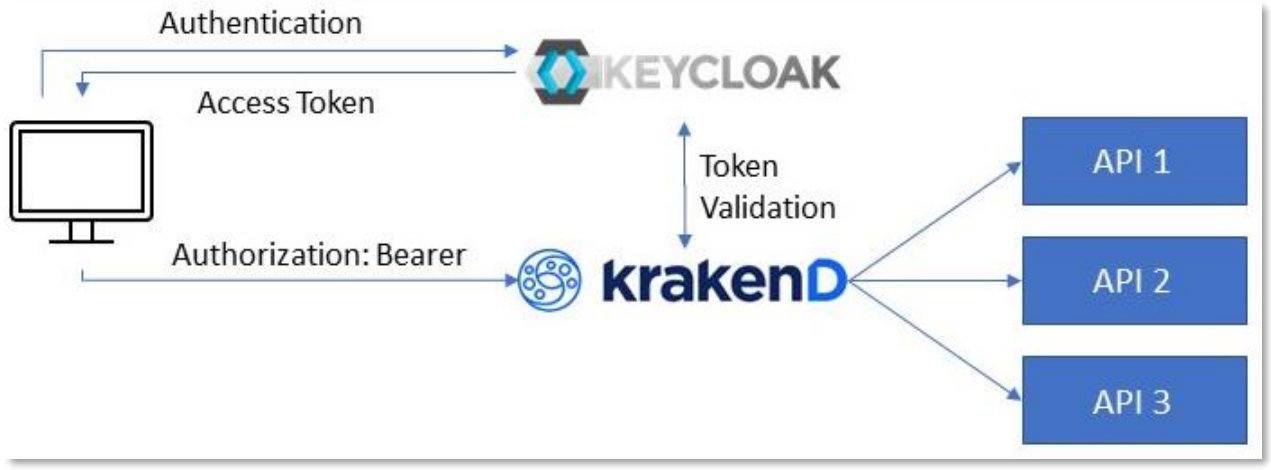

Figure 49: The Access token is been issued by Keycloak then KrakenD allows the triggering of an end-point if role policy permits.

The following actions are supported:

- End-Users use their applications to log in to Keycloak which provide an access token for the session.
- Machine-to-machine communication also uses a token from Keycloak (using a client_id and a client_secret).
- With the token generated by Keycloak, the client passes it to KrakenD in each request inside an HTTP header or cookie
- KrakenD authorises or not the usage of the specific endpoint according to the rules.

- As KrakenD can validate the Keycloak signature by itself, it does not need to call the Keycloak server to validate the token every time. Instead, KrakenD queries Keycloak every 15 minutes (configurable) to ensure the key has not rotated.

CSB and GIC end-user's management is supported by Keycloak, which provides a single sign on solution for web apps and RESTful web services. Security features that developers normally have to write for themselves are provided out of the box and are easily tailorable to the individual requirements of a specific project.

For each CSB instance a login page allow access to previously registered by the CSB Administrator end-user. The authentication flow uses OpenId-Connect as provided by Keycloak. To grand access to a production CSB instance or GIC, the following procedure should be followed:

- Each Pilot (hospital) to compile a list of individuals and associated supported-by-the-platform role(s) (full name, role, and email);
- Access is approved by Responsible for Granting Access (RGA) per CSB instance;
- Approved access list (and any future updates) forwarded by RGA to the CSB Administrator;
- Whenever a new registration happens, the Administrator compares the registration info of the registrant against those of this list (of the related organization) and acts accordingly.

The end-user management service allows the management of CSB Dashboard and GIC Dashboard end-user accounts. Access is not granted automatically, but via a moderation mechanism the CSB or the GIC Administrator creates an account and selected upon a predefined end-user role to gain access according to it. Administrator may assign a different role that the one originally requested (during the creation process), and as such different privileges and access to the services supported. In addition, an account can be temporary cancelled or suspended.

Following this, to login in a CSB instance or a GIC, an end-user will use the credentials provided by the CSB Administrator (or the GIC Administrator respectively). Upon first login will be required to modify the password. Via a login form, end-user will enter his/her credentials in order to access the CSB or GIC services.

By default, Keycloak is installed with an admin user, and a "master" realm. A realm is the logical collection of a set of users, credentials, roles, and groups. A single user belongs and logs into a realm. For example, the "admin" account, which is present by default, belongs to the "master" realm. To keep the Keycloak administrator and the RETENTION application's administrator separate, a new realm has been created, titled "retention". This realm holds all end-user accounts, credentials, and roles.

To create the new realm, the system administrator:

1. Logs in at the Keycloak administration dashboard.
2. From the menu (on the left) hovers over the "Master" dropdown and clicks on "Add realm" (Figure 51).
3. Inputs the new realm name and clicks "Create" (Figure 52).

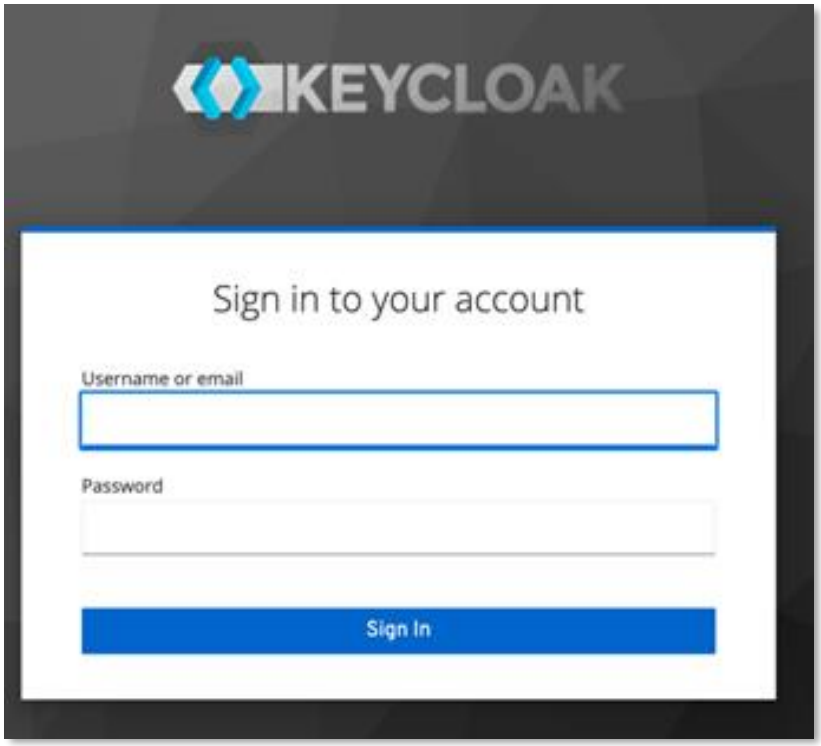

Figure 50: Keycloak login

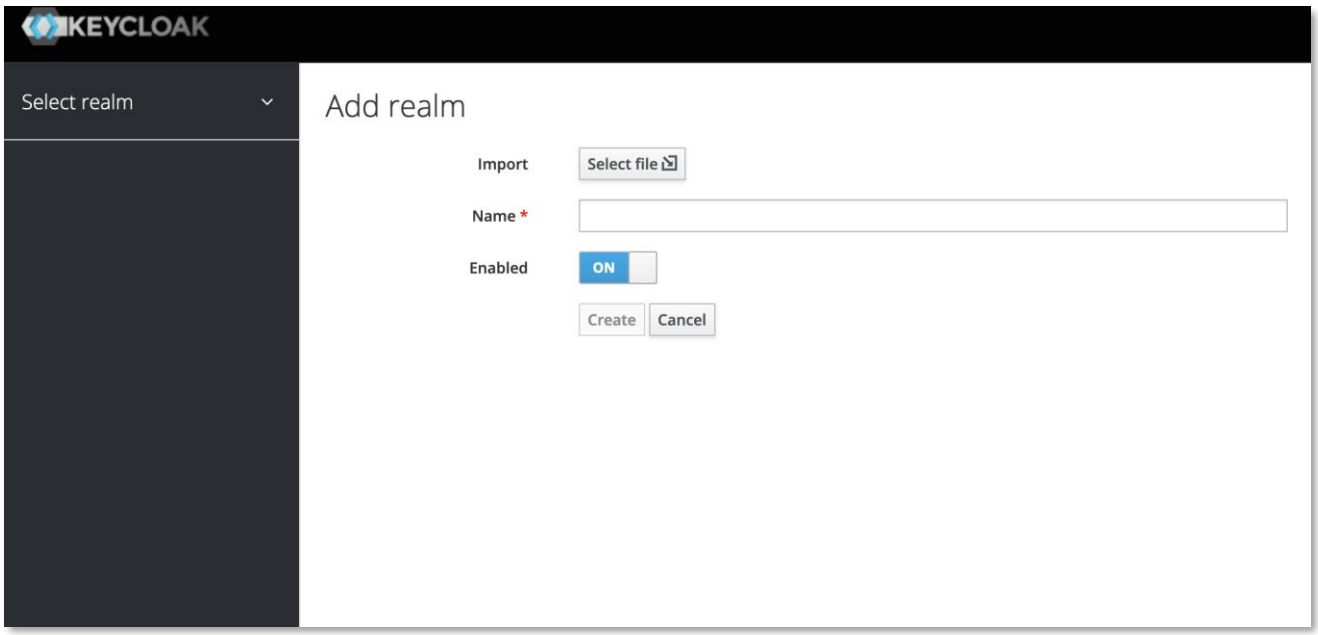

Figure 51: Realm creation

Following the realm creation, users can be created by selecting “Users” on the sidebar, then clicking on “Add user” (Figure 52).

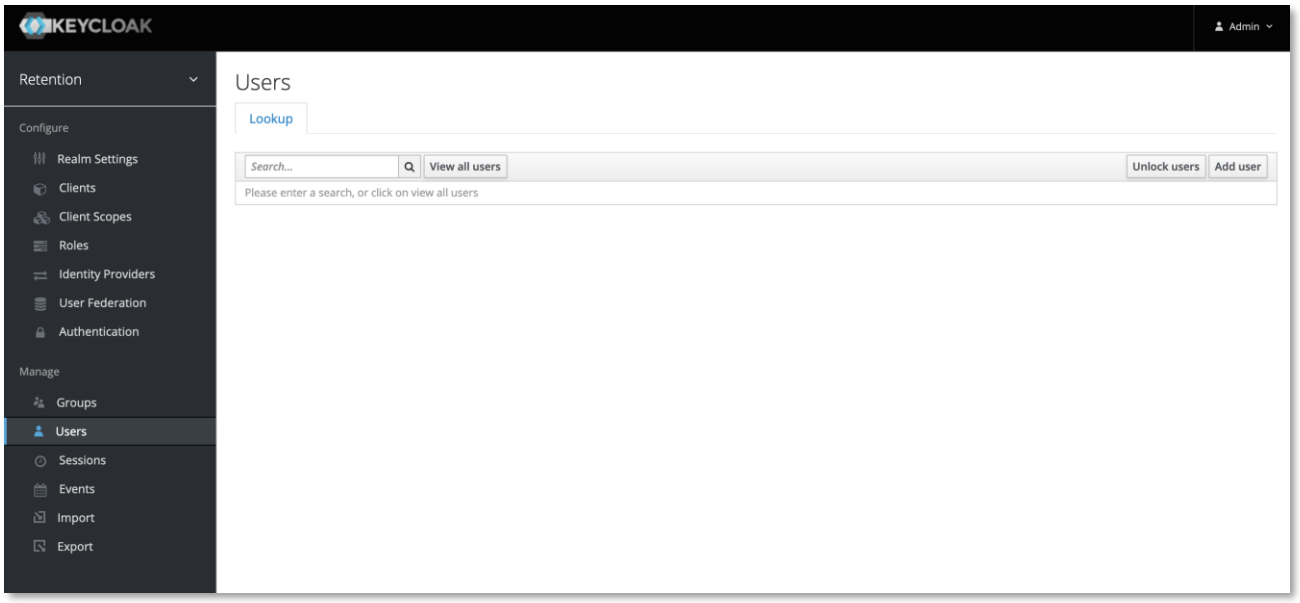

Figure 52: User creation

For a user to login however, one needs to create the appropriate clients. Clients are entities that can request Keycloak to authenticate a user; as such, the mobile application or the web dashboard are clients and need to be created. To create such clients:

1. The Keycloak administrator clicks on “Clients” in the sidebar.
2. Clicks on “Create”.
3. Inputs a client id (e.g., “dashboard” or “mobile”), and clicks on “Save”.
4. Additional settings may be configured. For example, Access Token lifespan, or Access Type.

Now, the exact realm and client combination can be used to integrate Keycloak’s provided login page to any GUI. Alternatively, a direct API call can be used to retrieve the token at “/auth/realms/{realm-name}/protocol/OpenId-connect/token” where {realm-name} is the name of the Keycloak realm. The payload of the request depends on the grant_type.

To create a role the system administrator should follow the following steps:

1. Logs in at the Keycloak administration dashboard;
2. From the menu (on the left) select “Roles” and then “Add Role”;
3. Inserts the role’s name and optionally a description;
4. Repeats steps 2 and 3 until all roles are created (Figure 54).

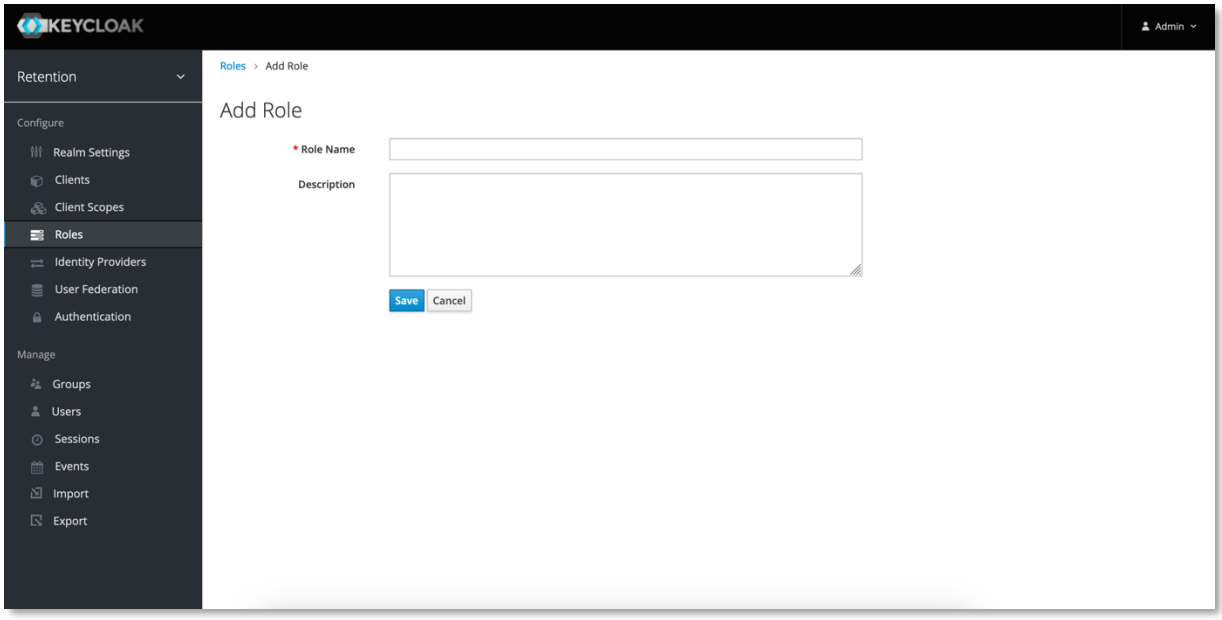

Figure 53: Step 2/3: Role addition

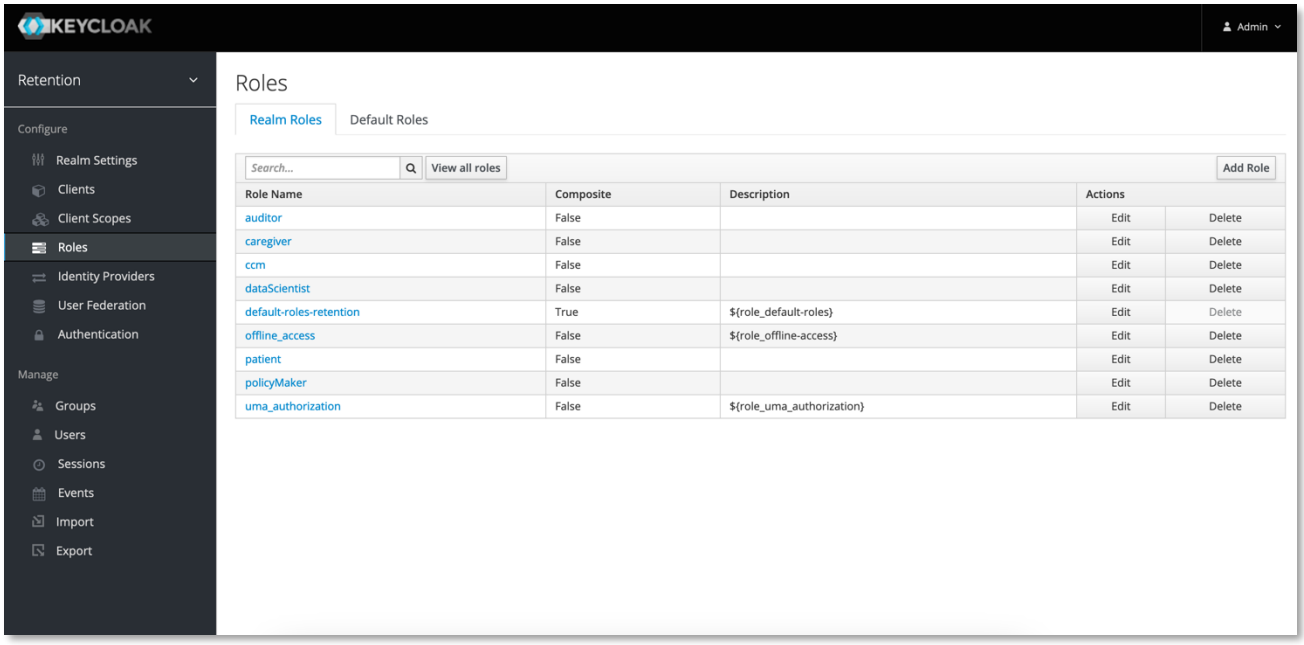

Figure 54: Step 3/3: Roles added

More details about the security component can be found in deliverable D6.2.

7.2 Clinician's Perspective

For clinicians the CSB Dashboard is a system that provides electronic Case Record File (eCRF) for all patients (both intervention and control group patients) enrolled in the RETENTION Clinical Trial *plus additional* functionality for patients that are randomised into the intervention group, namely visualisations and AI results that utilise enhanced RETENTION monitoring data.

The main functionalities of CSB Dashboard for clinician's concern:

a) Patient record creation

b) Patient record, initial data entry and

c) Patient Monitoring (with some functionalities only available for Intervention Group patients)

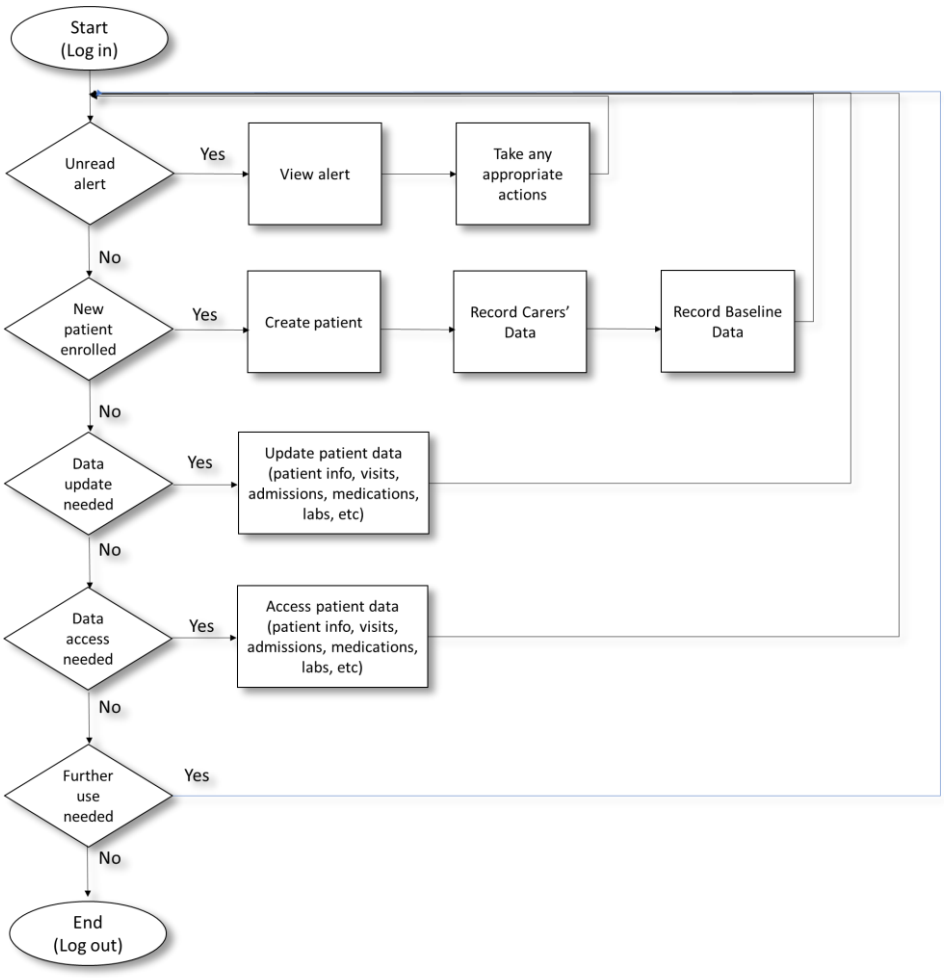

Figure 55: Flowchart of clinical site backend dashboard

Authentication & Authorization

Clinicians enter the CSB Dashboard by providing their username and password. The system validates their credentials and if they are authenticated and authorise as clinicians (clinical case managers), they are offered the corresponding functionality and access rights.

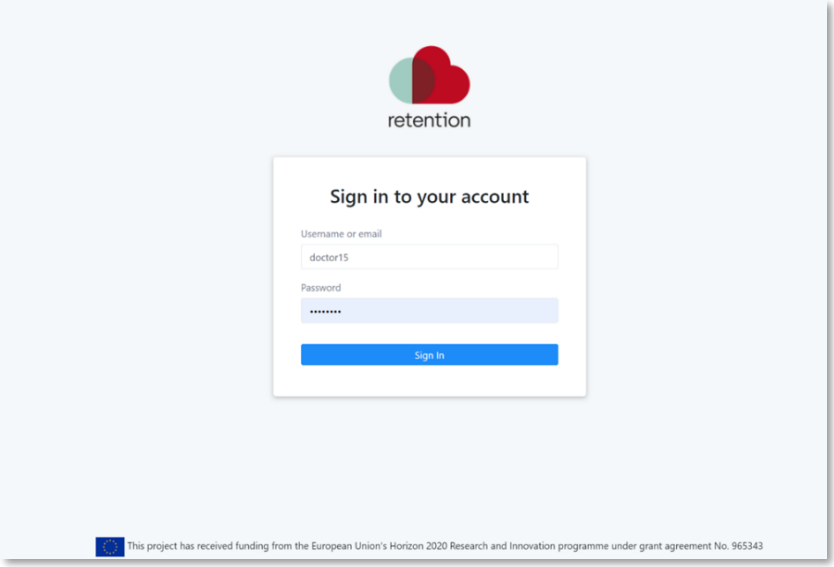

Figure 56: Screenshot of authentication & authorization

Patient Creation

From the menu 'Patients Monitoring' the user can access the complete list of the patients of the specific CSB.

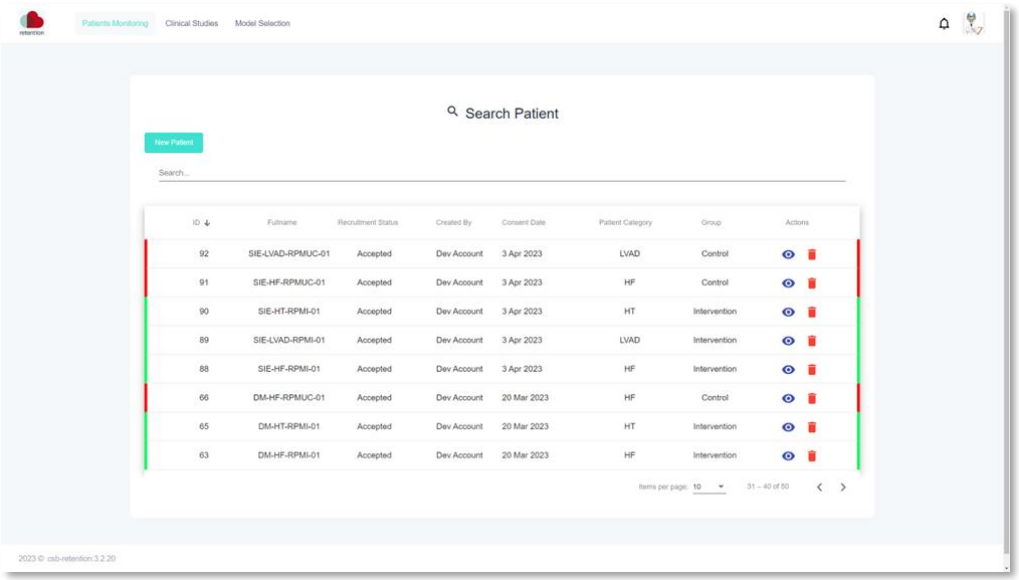

Figure 57: Screenshot of patient creation

The 'New Patient' button leads to the following screen where all minimum required data should be entered.

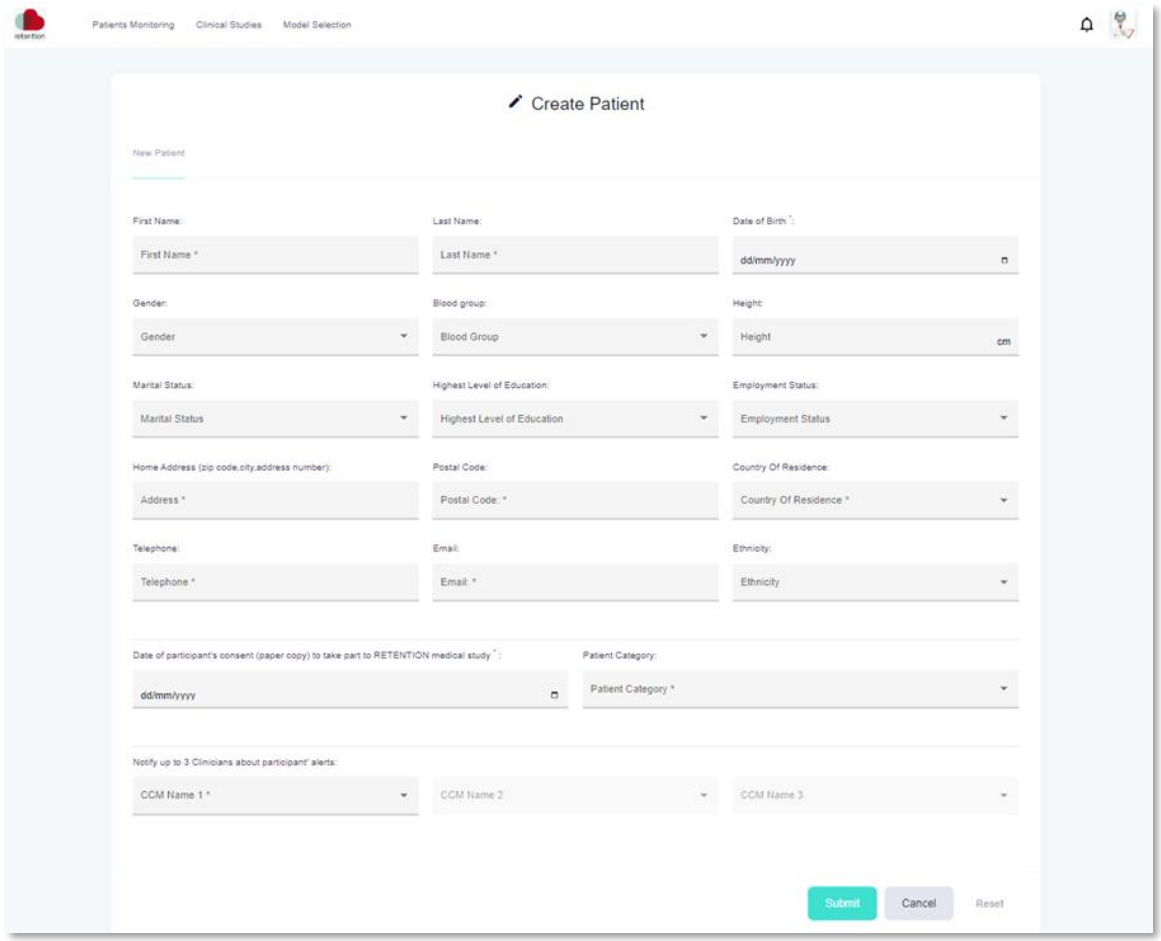

Figure 58: Patient creation screen

Patient Basic Info

After the creation of the patient, the clinician can update the profile of the specific patient and store and track additional info, organized in 3 tabs: 'Basic Patient Info', 'Patient Monitoring' and 'Notifications'. The user can update the patient record accordingly. Also, the user can search for a specific patient by using various criteria such as full name, ID, date, status, clinician who created the user record etc.

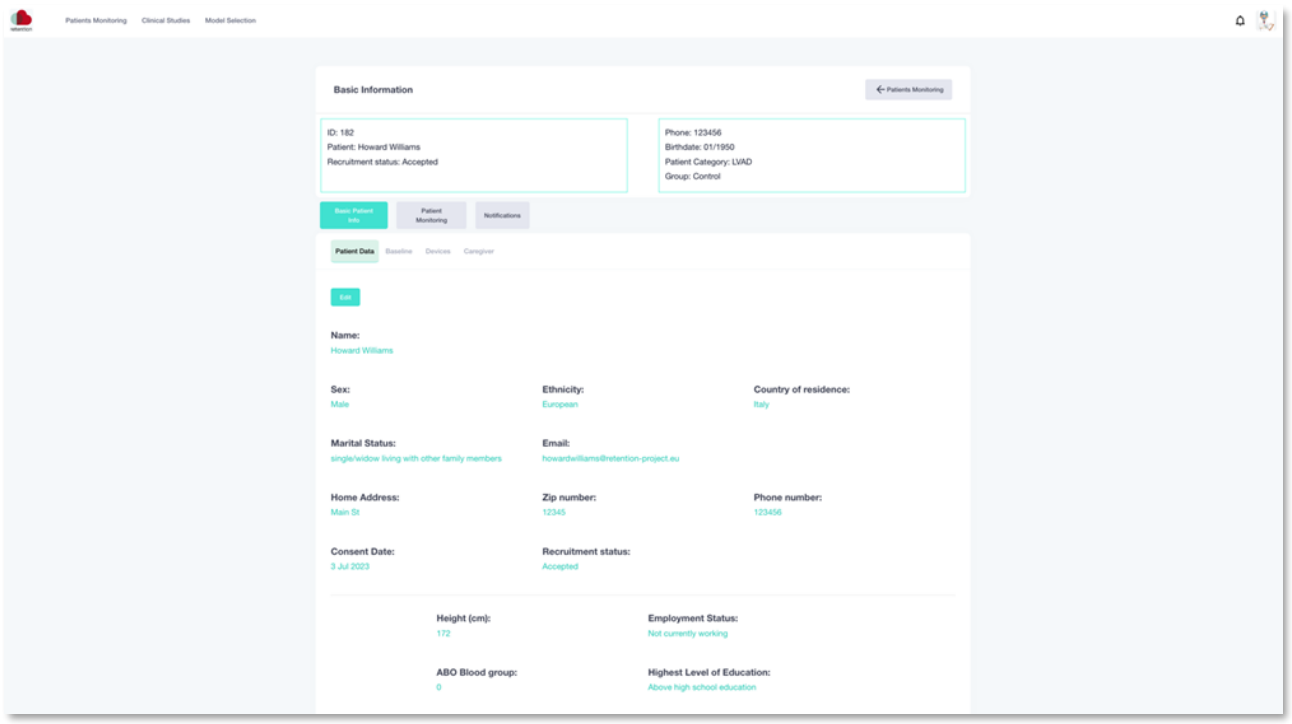

Figure 59: Patient's basic info fields

Patient Monitoring and Notifications

The CSB supports the monitoring of the visits and interaction between the clinician and the patient. Through the very first visit, the clinician creates the baseline of the patient and can update all the available fields indicated by the clinical protocol. These differ according to the patient cohort/category (HF, LVAD, HT).

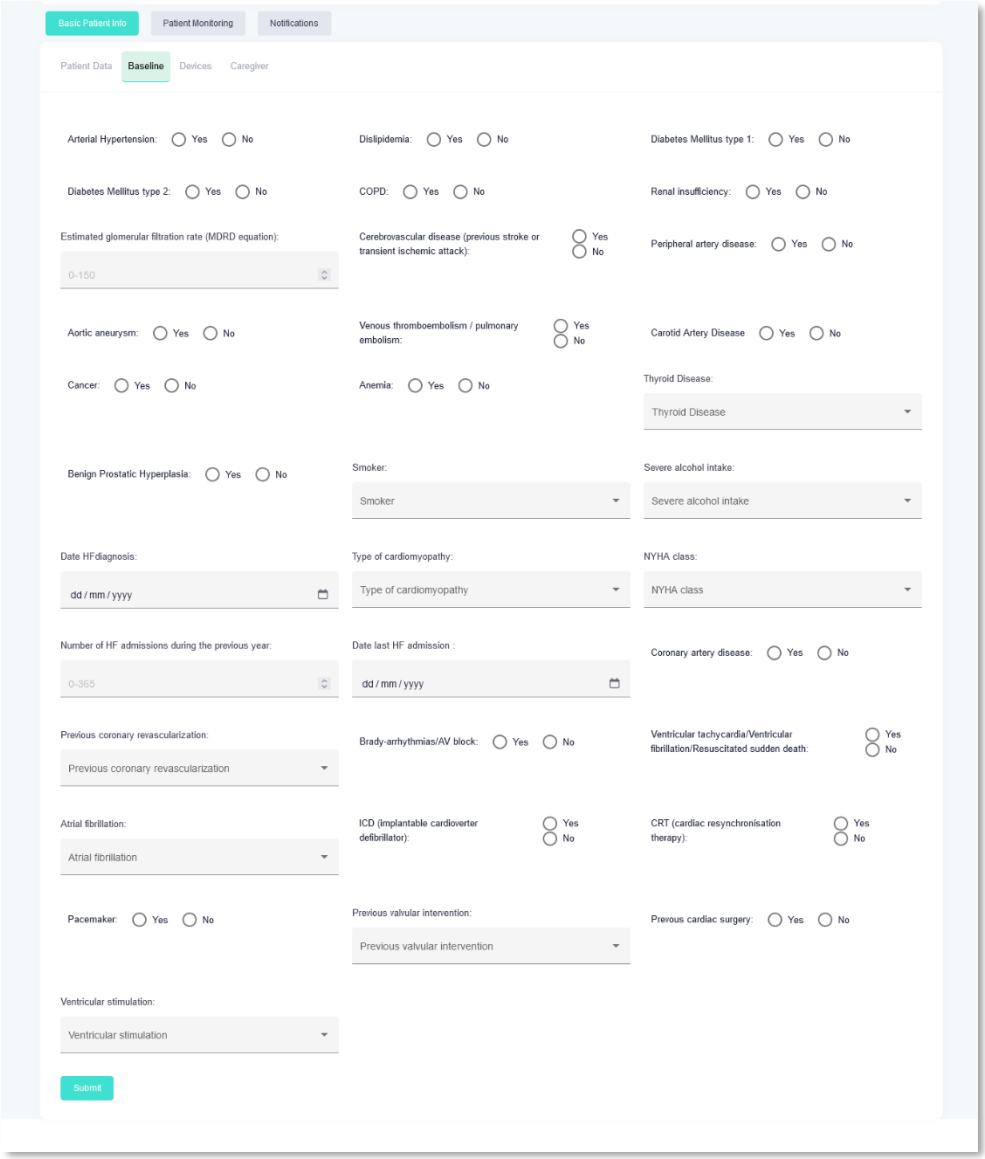

Figure 60: Patient's baseline

As described further in the user guide (see D7.2), the other important basic patient information to be recorded at the start of a patient's participation includes: (a) the patient devices (by the hospital's technician) and (b) the patient's caregivers' details (by the clinicians enrolling and following up the patient in the trial). Subsequently, the main tab to be used by clinicians will be the Patient Monitoring tab.

Patient Monitoring

The 'Patient Monitoring' tab (see below) is the main tab to be used by clinicians when following up a patient in the context of the RETENTION clinical trial. Its functionality is adjusted according to the group the patient belongs to. Core patient monitoring functionality is available for all patients: visits, hospital admissions, events, medications, as well as clinical, ECG, lab, echocardiography, 6MWT, and cardiopulmonary data, and scores for validated questionnaires (collected at the hospital) are to be entered into the CSB databased via the Dashboard. This functionality is described further in the user guide (see D7.2).

For intervention group patients, clinicians additionally have access to data provided by the patients at their home. The Overview sub-tab (see below), only available for intervention-group patients, provides visualisations for the measurements obtained using RETENTION devices. In addition to that, they have access to questionnaires filled in using the RETENTION mobile app and, for LVAD patients, LVAD device measurements entered by the patient or a carer.

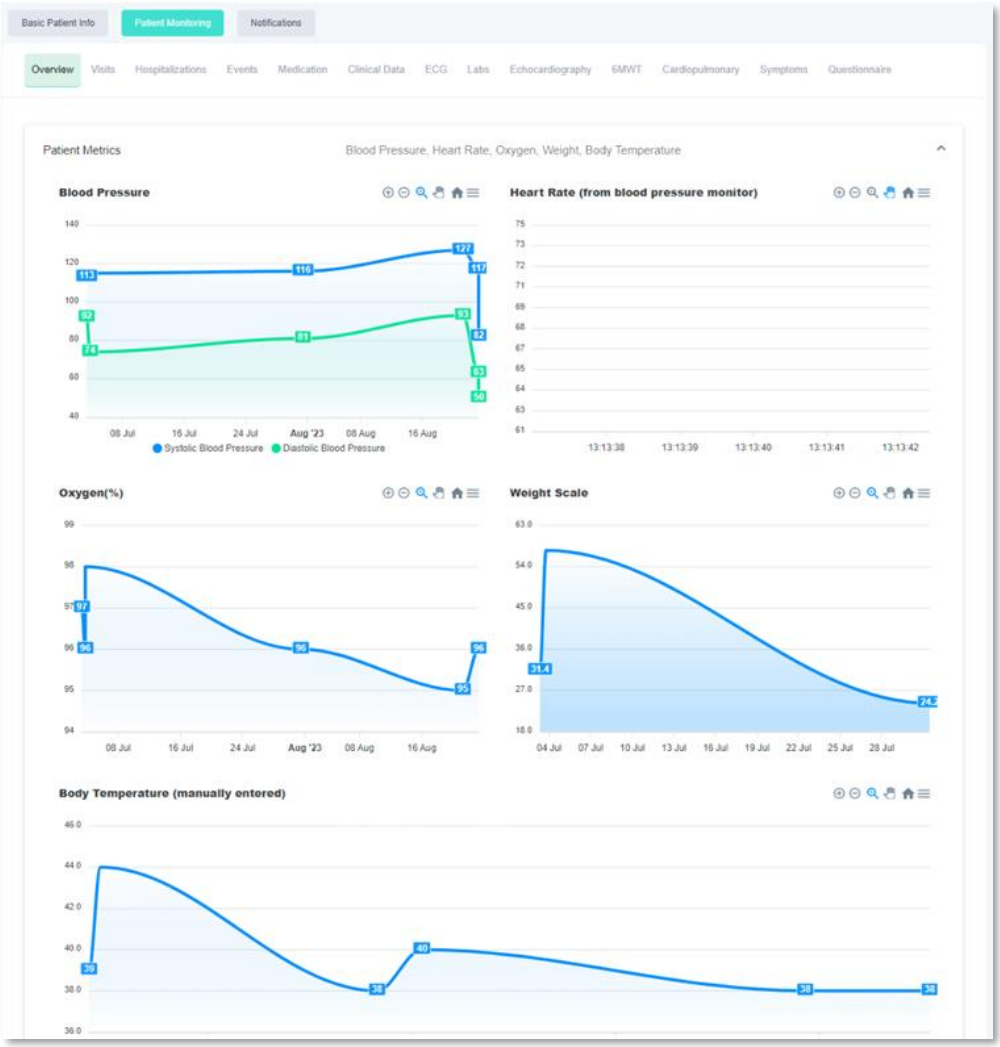

Figure 61: RETENTION-enhanced patient monitoring: Overview Visualisations

Another feature only available for intervention-group patients is the listing of alarms by the RETENTION DSS. It is possible to see the notifications concerning the particular patient by selecting the Notifications tab.

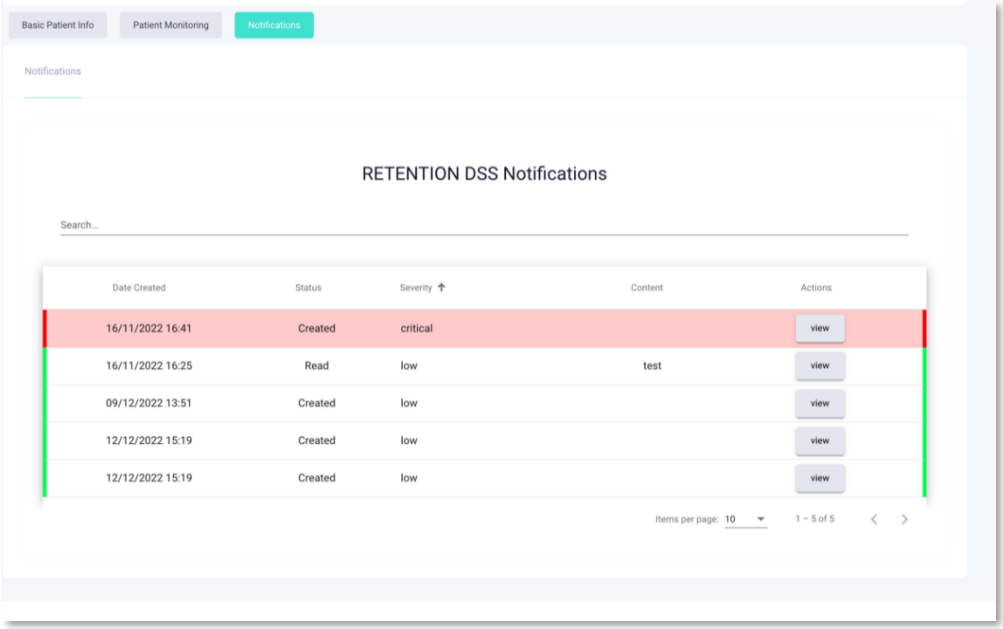

Figure 62: Patient's notification screen

The clinician can sort the available notifications (by date, status, criticality etc.), can have a short overview of all notifications and select to view one or more notifications. After viewing a notification, the status of the notification is changed to 'read'.

This is the per-patient view of alerts. New (unread) notifications for all patients followed by the clinician are added in the clinician's unread notifications list. This is accessed by clicking on the notification icon on the top right-hand corner of the page.

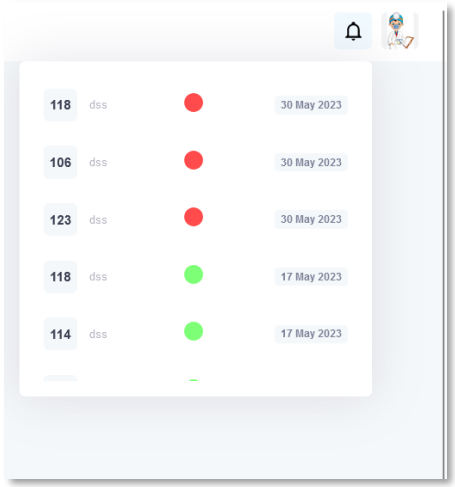

Figure 63: CSB Notification Centre

By clicking a specific notification from the block, the user navigates to the profile of the patient.

To summarise, for intervention group patients the RETENTION CSB Dashboard provides: (a) functionality to doctors to obtain information from RETENTION'S enhanced patient monitoring facilities and (b) the RETENTION alerting mechanism.

Dataflows

To better present the flow of actions that a clinician will perform, and to grasp the implementation effort for this GUI form, we will present several sequence diagrams for specific type of actions that take place within CSB.

In Figure 64, the actions that one doctor must perform in order to introduce patient's information into the RETENTION system are presented. This step is crucial because using this data, the data scientist will train models that will be delivered back to the clinician.

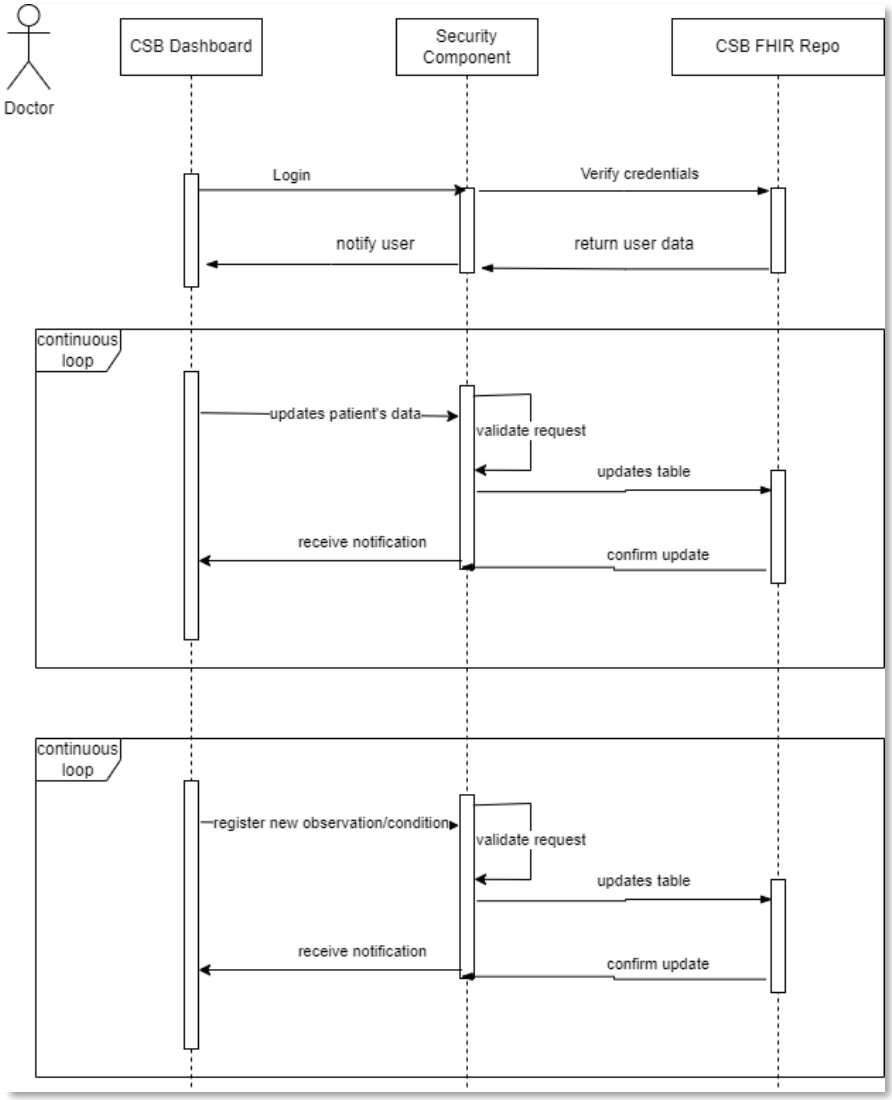

Figure 64: Clinician actions regarding patient data

In Figure 65, presumably after the data scientist has created the models, we show what are the steps that the doctor must perform in order to get insights about his or her patient evolution, insights supported by AI algorithms.

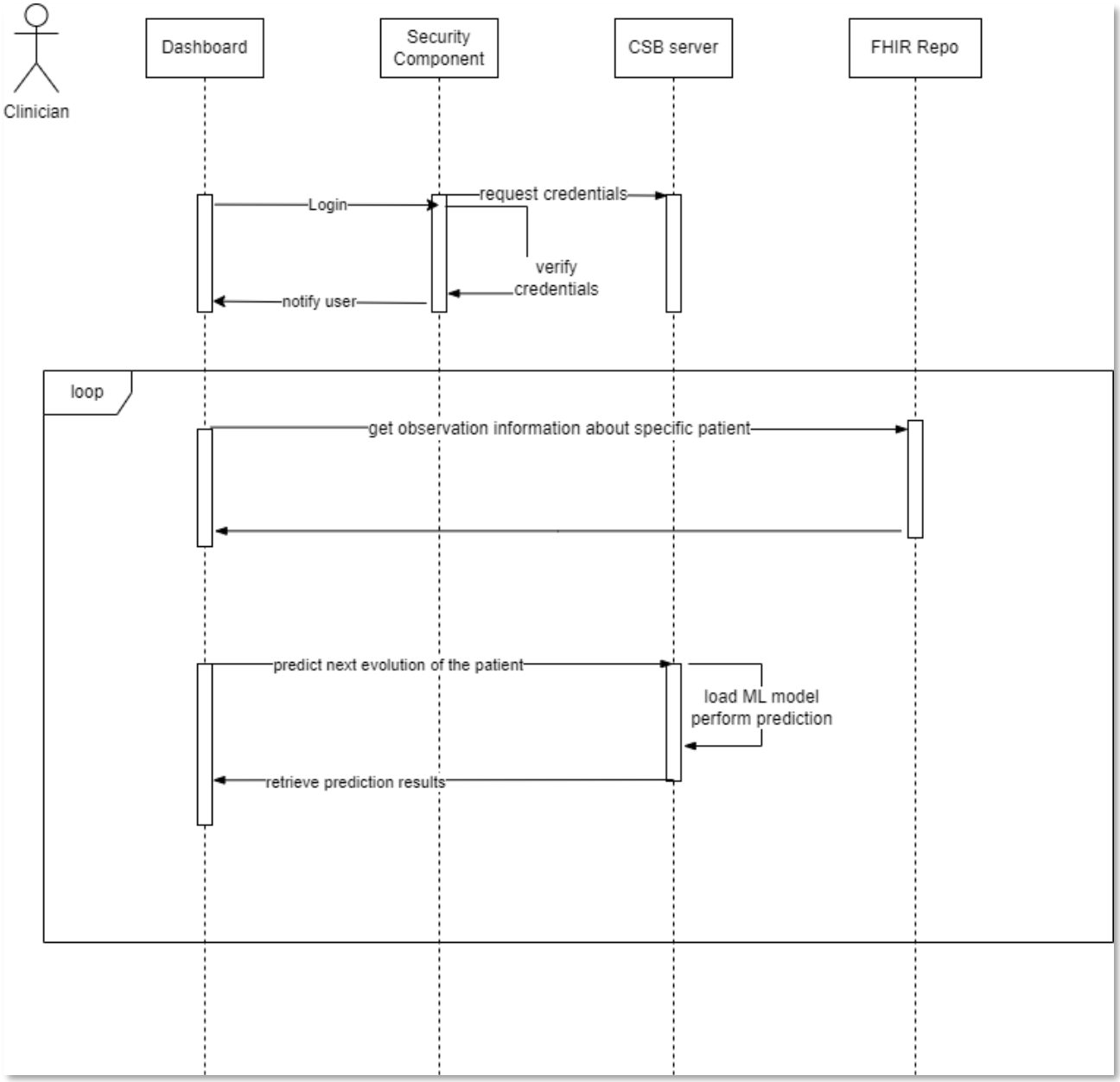

Figure 65: Clinician Prediction Flow

7.3 Technician's Perspective

One or more IT support staff members at the hospital, take on the 'technician' role in each hospital.

Their first line of duty is to prepare the RETENTION patient devices for use by the patient and/or their carer(s). They also remotely monitor patient devices to ensure they remain in working order and send data to the CSB.

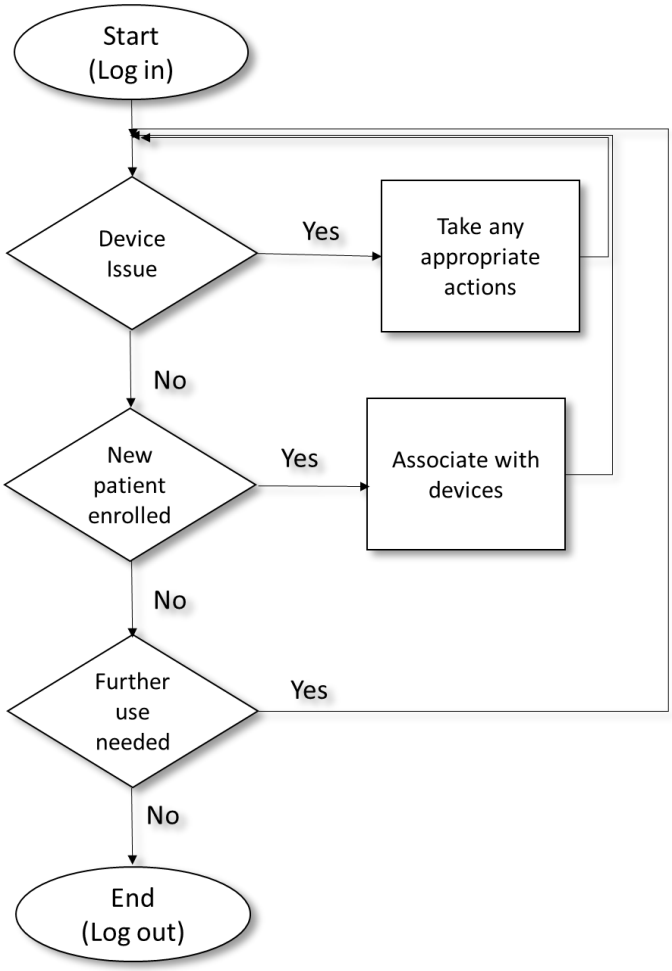

Figure 66: Flowchart of technician's perspective

Authentication & Authorization

Technicians enter the CSB Dashboard by providing their username and password. The system validates their credentials and if they are authenticated and authorise as technicians (clinical case managers), they are offered the corresponding functionality and access rights.

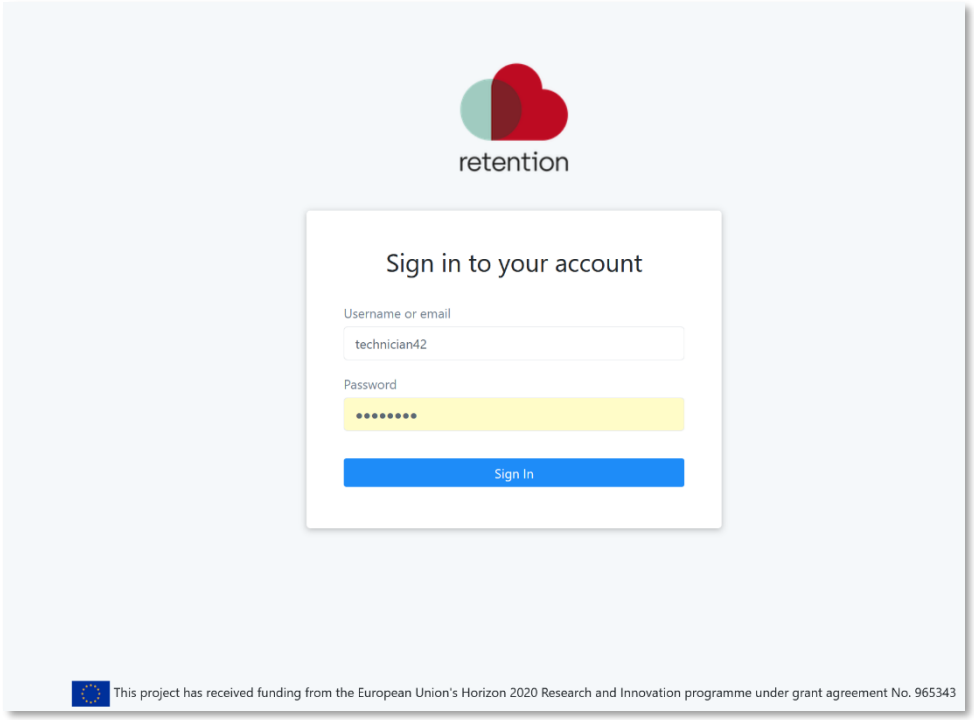

Figure 67: Authentication & Authorization

Patient-Device Association

Technicians cannot add patient records and have very limited functionality available to them via the CSB Dashboard. They have access to the hospital's RETENTION-enrolled list of patients, but cannot modify their data nor view clinical data.

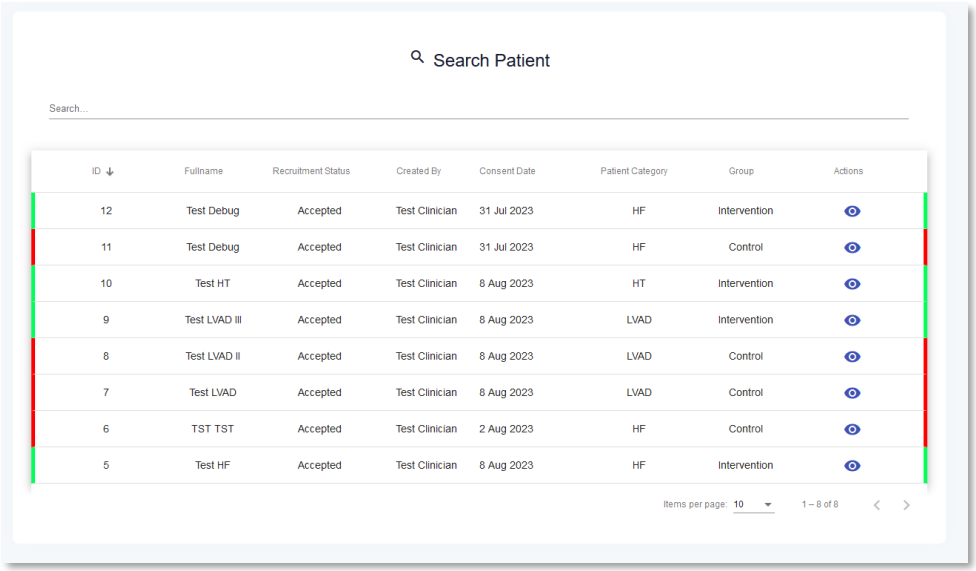

Figure 68: Patient-Device Association

When navigating to a specific user, the technicians only have access to functionality for registering and keeping up to date information about the mobile phone and the Raspberry-Pi-based home gateway which together through RETENTION software enable the RETENTION enhanced patient monitoring the RETENTION clinical trial aims to evaluate. More details are provided in the relevant user guide (see D7.2).

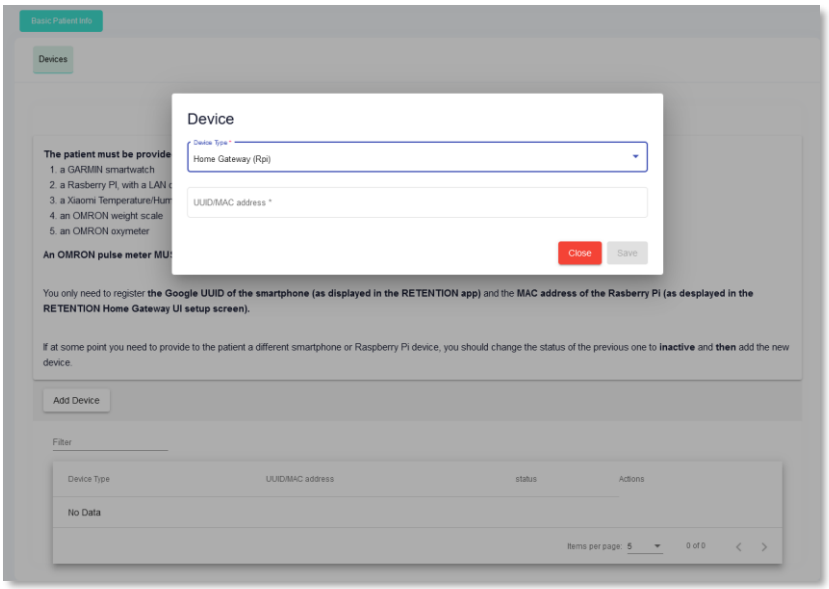

Figure 69: Registering Patient Devices

Device Monitoring

Hospital technicians also have an overview of all the devices handed out to patients and can detect if any devices have remained inactive for a long time.

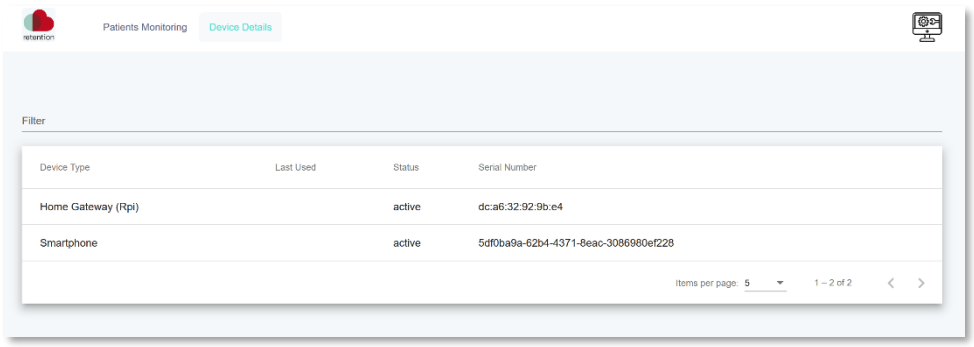

Figure 70: Screenshot of Device Monitoring

8. Global Insights Cloud Dashboard

8.1 Data Analyst Perspective

Managing Public health policy decision-making models

The managing of the public health policy decision-making models is done within the provided Jupyter Notebooks. The data scientist is able to elaborate various scenarios, writing code that will process the FHIR data in order to create the desired models. Only a registered and approved user can access the available tools. The login and registration process are similar to the process followed in CSB.

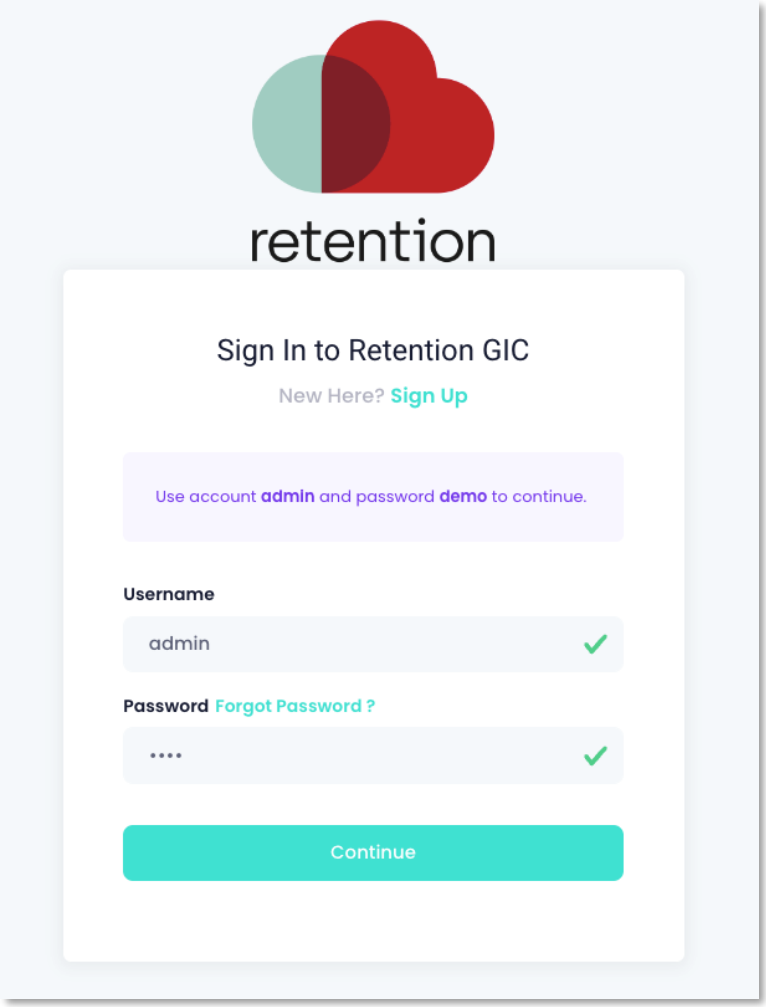

Figure 71: User registration form in GIC

After a successful login, the data scientist can access the available options regarding the ML Flow and the Jupyter Notebooks

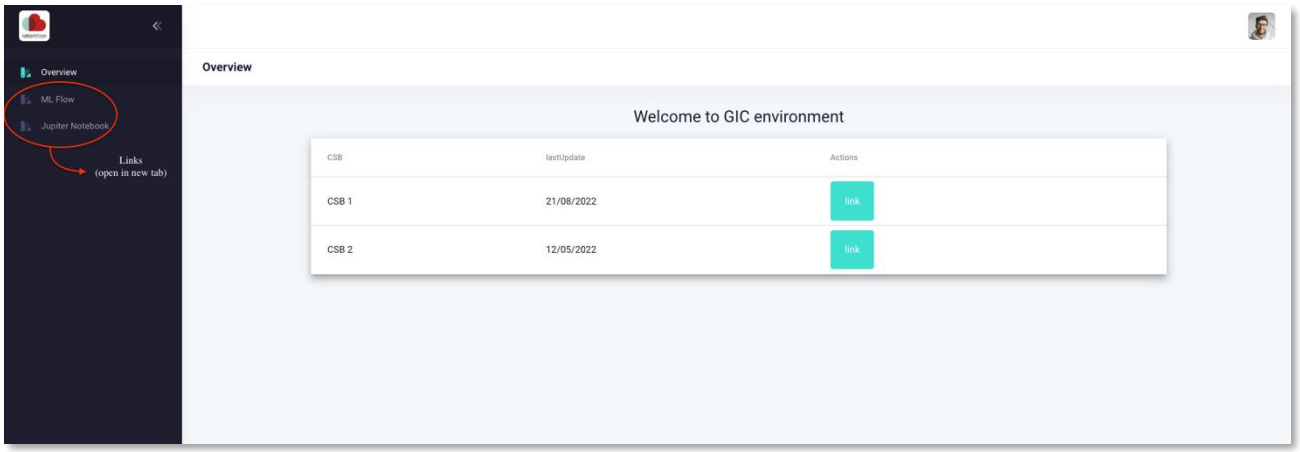

Figure 72: GIC data scientist's tools

Dataflows

By means of sequence diagrams, we will depict the flow that the Data Scientist will follow in order to create and store a model along with additional meta-data, which will be described in what follows.

In Figure 73, we present the model management flow in our current vision. This version of the deliverable will be updated, so it's very likely that the diagrams will be updated if new suggestions or recommendations appear.

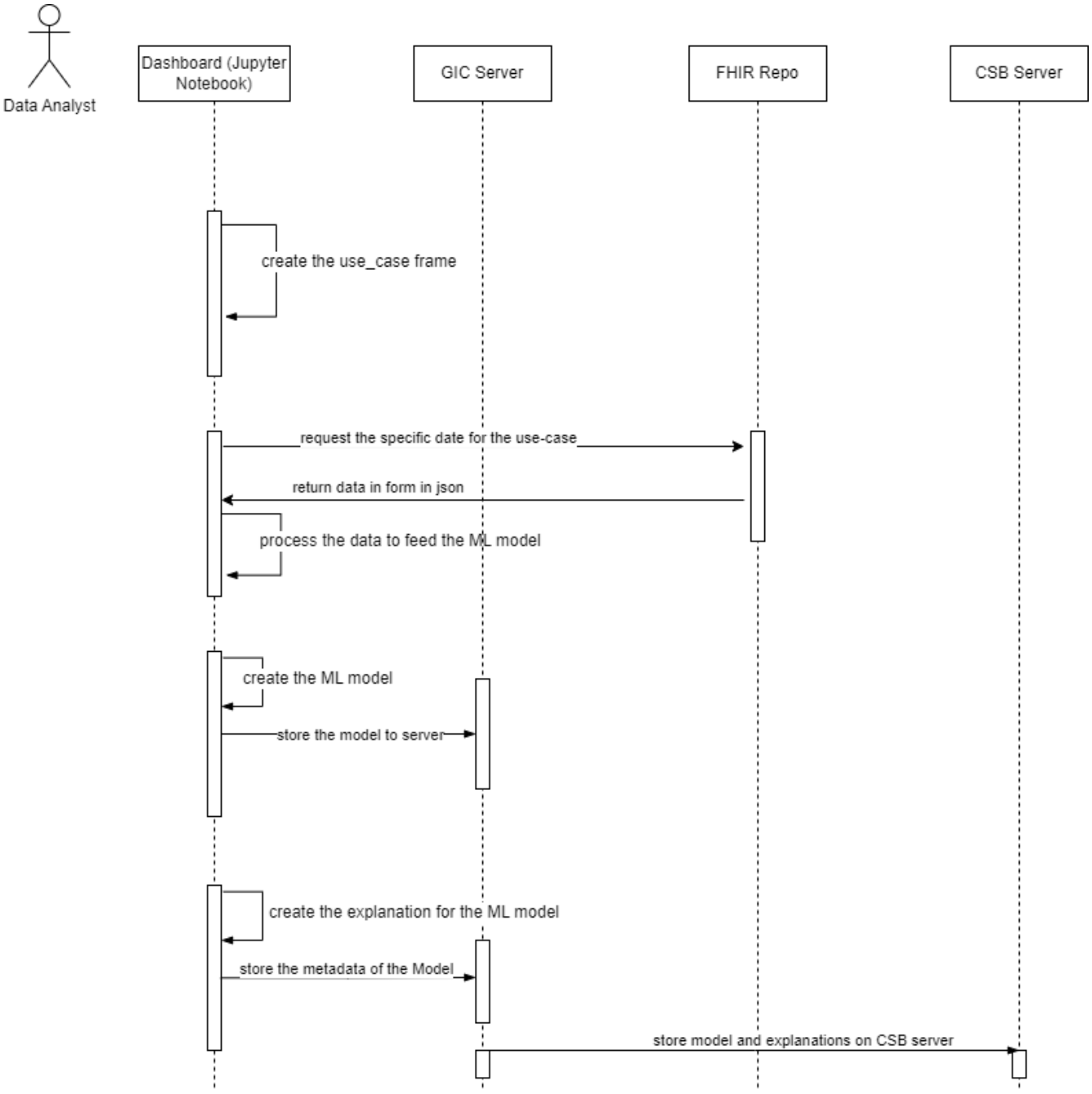

Figure 73: Model management flow

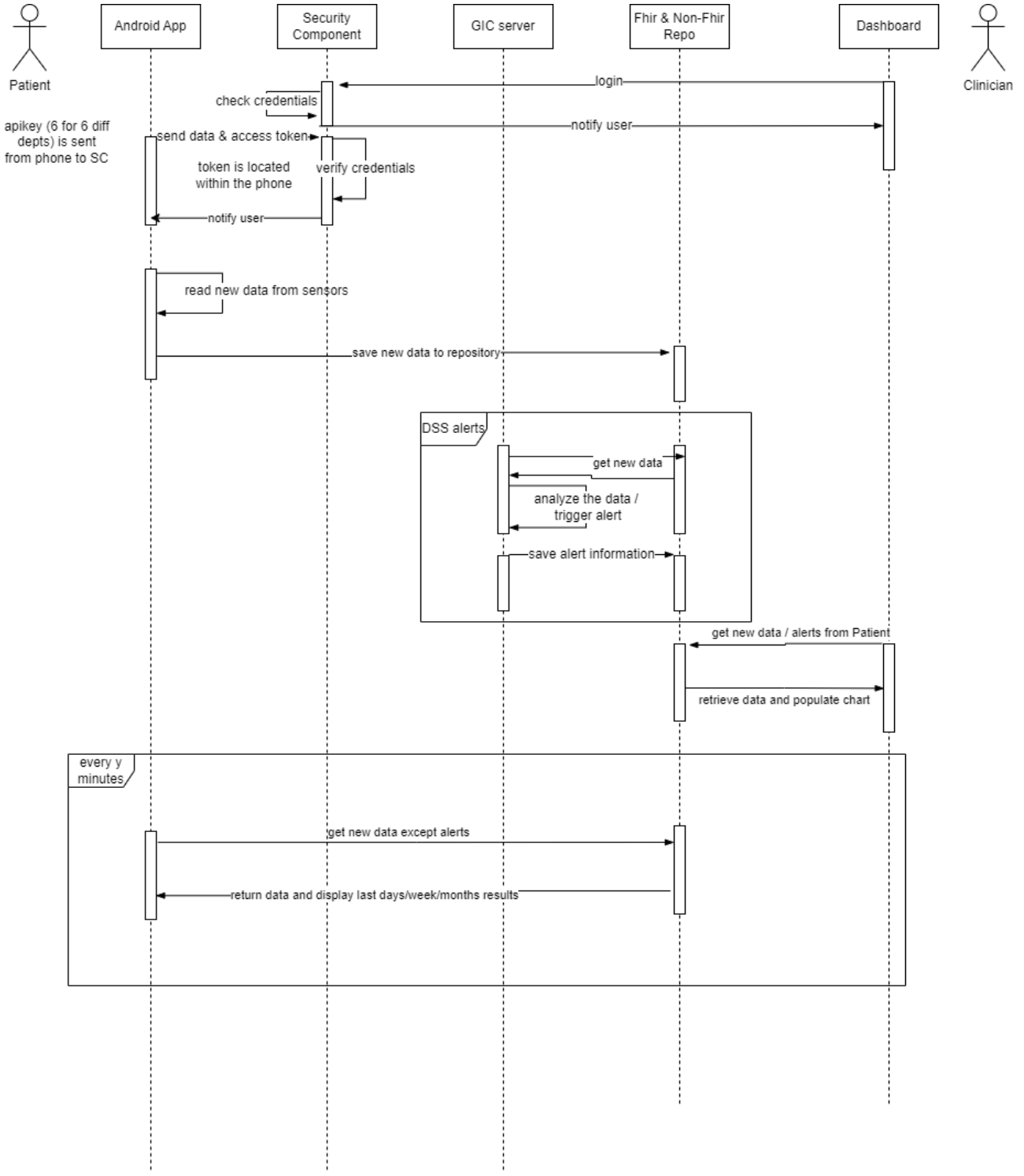

Figure 74: Data flow from device to the RETENTION repos

Figure 74 presents a sequence diagram that depicts our current vision of data flow from patient's android devices to the FHIR repositories, so to serve as additional input for models.

Configuration details

Using MLFlow, as presented in D5.1 the data scientist is able to store the model once the training has been completed as presented in Figure 75 and Figure 76.

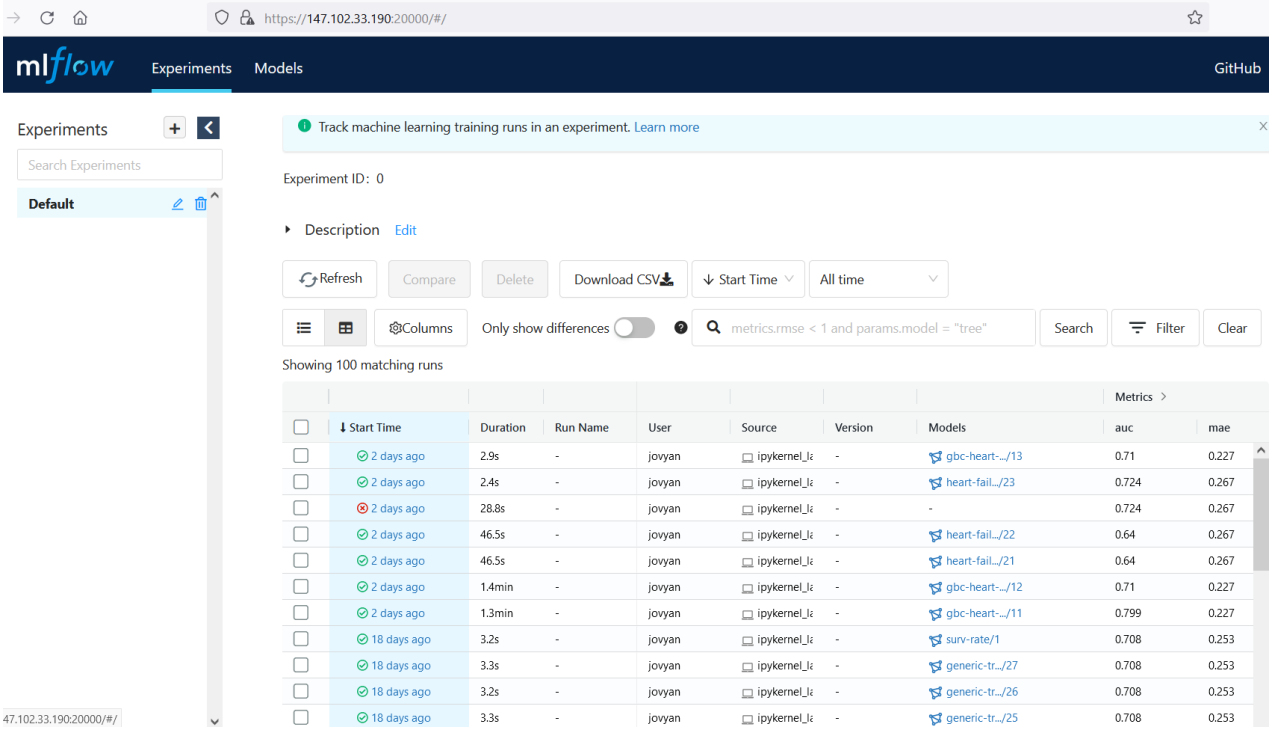

Figure 75: ML Flow Experiments

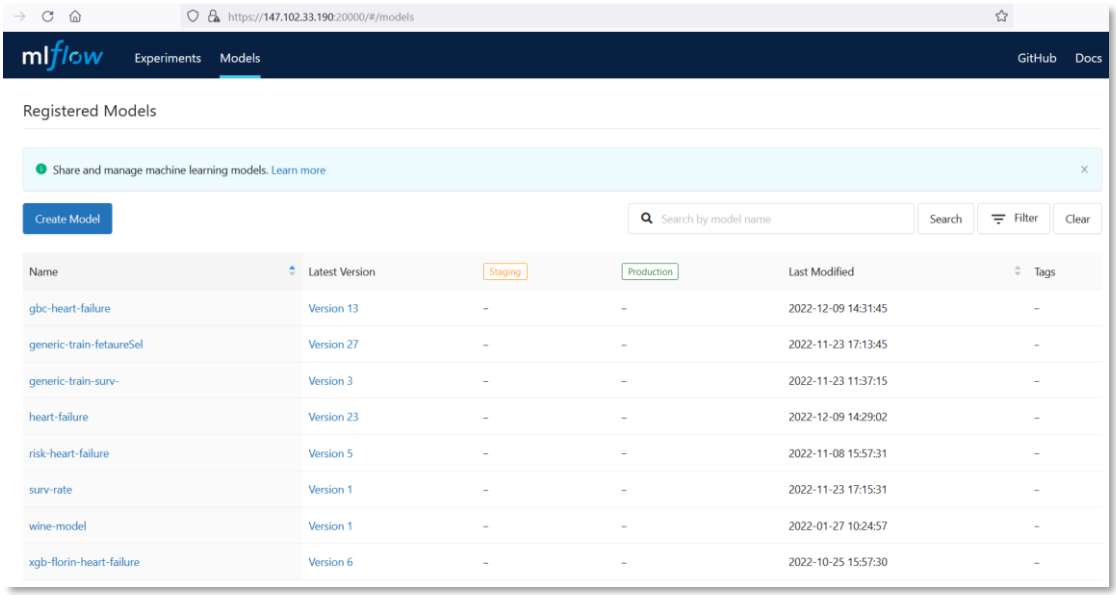

Figure 76: List of models, ML Flow Models

With help of this GUI, the data scientist can see when the model was created, how long the training took, what are the models metrics (like accuracy, auc or rmse).

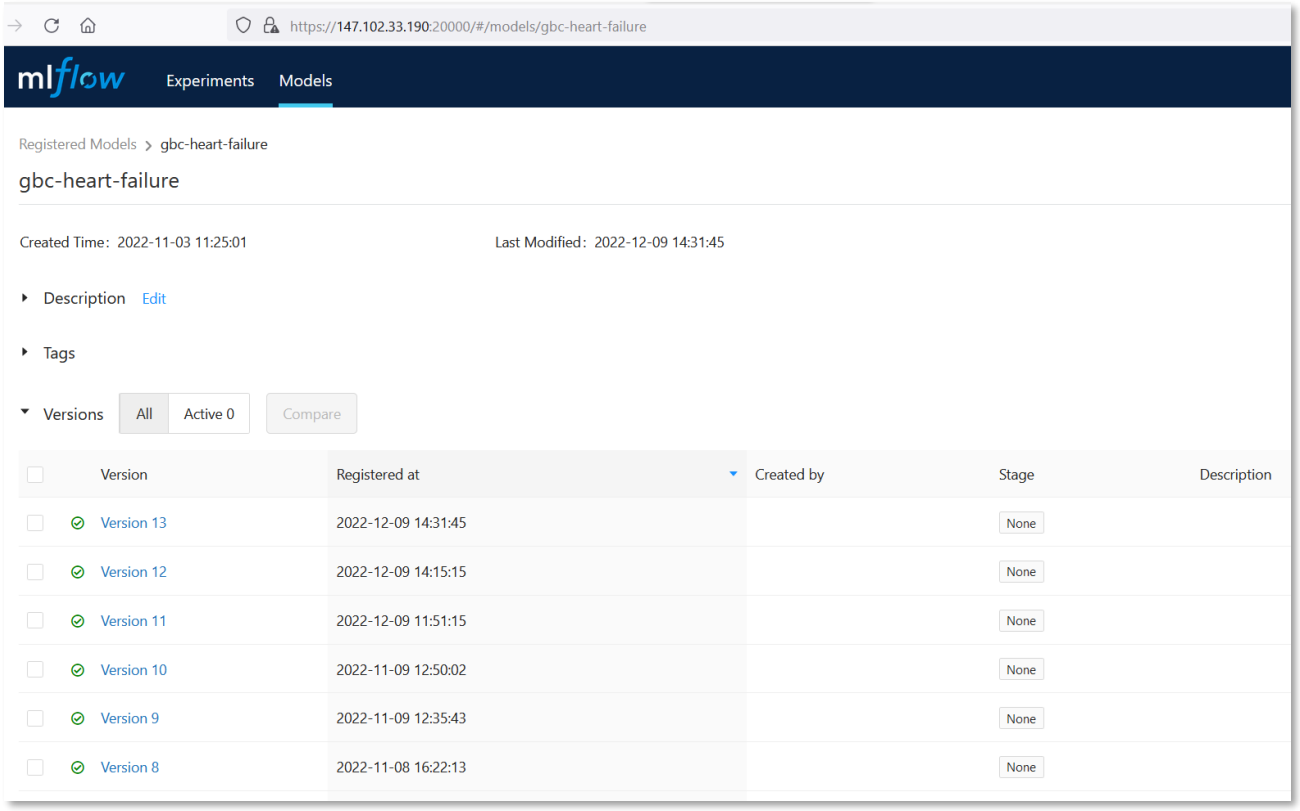

Figure 77: Model versioning details for 'Survival Rate' prediction study

In Figure 77, and Figure 78 we have a view of all model versions that were tested to assure the correct creation of one model that covers the "Survival Rate" scenario.

In Figure 79 the model's metrics are presented in detail.

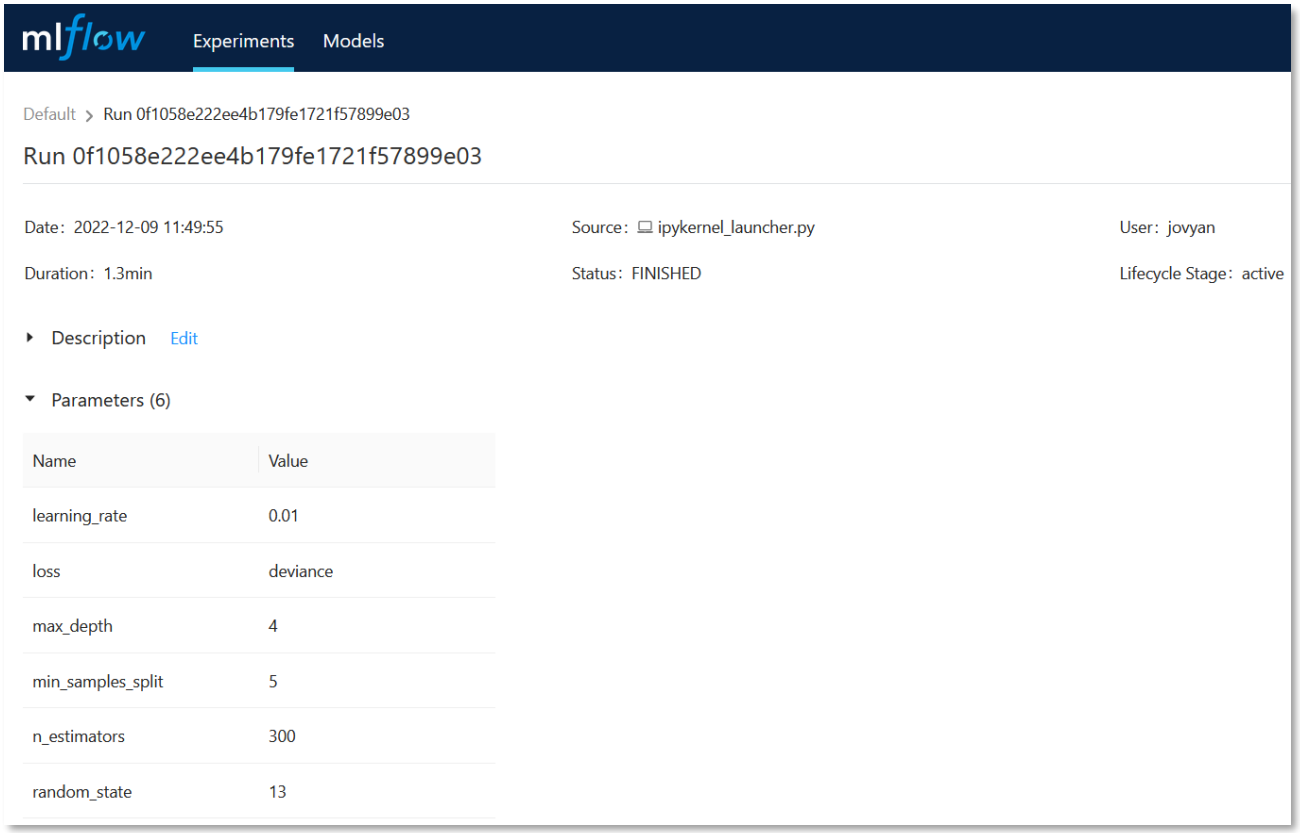

Figure 78: Model performance, KPI

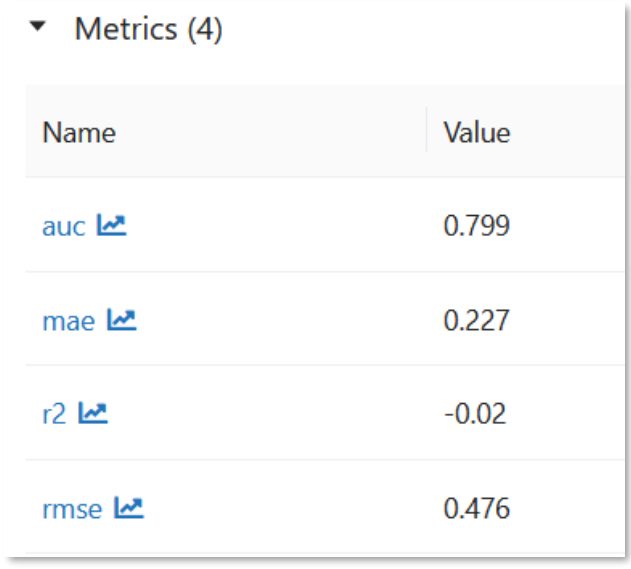

Figure 79: Model's metrics

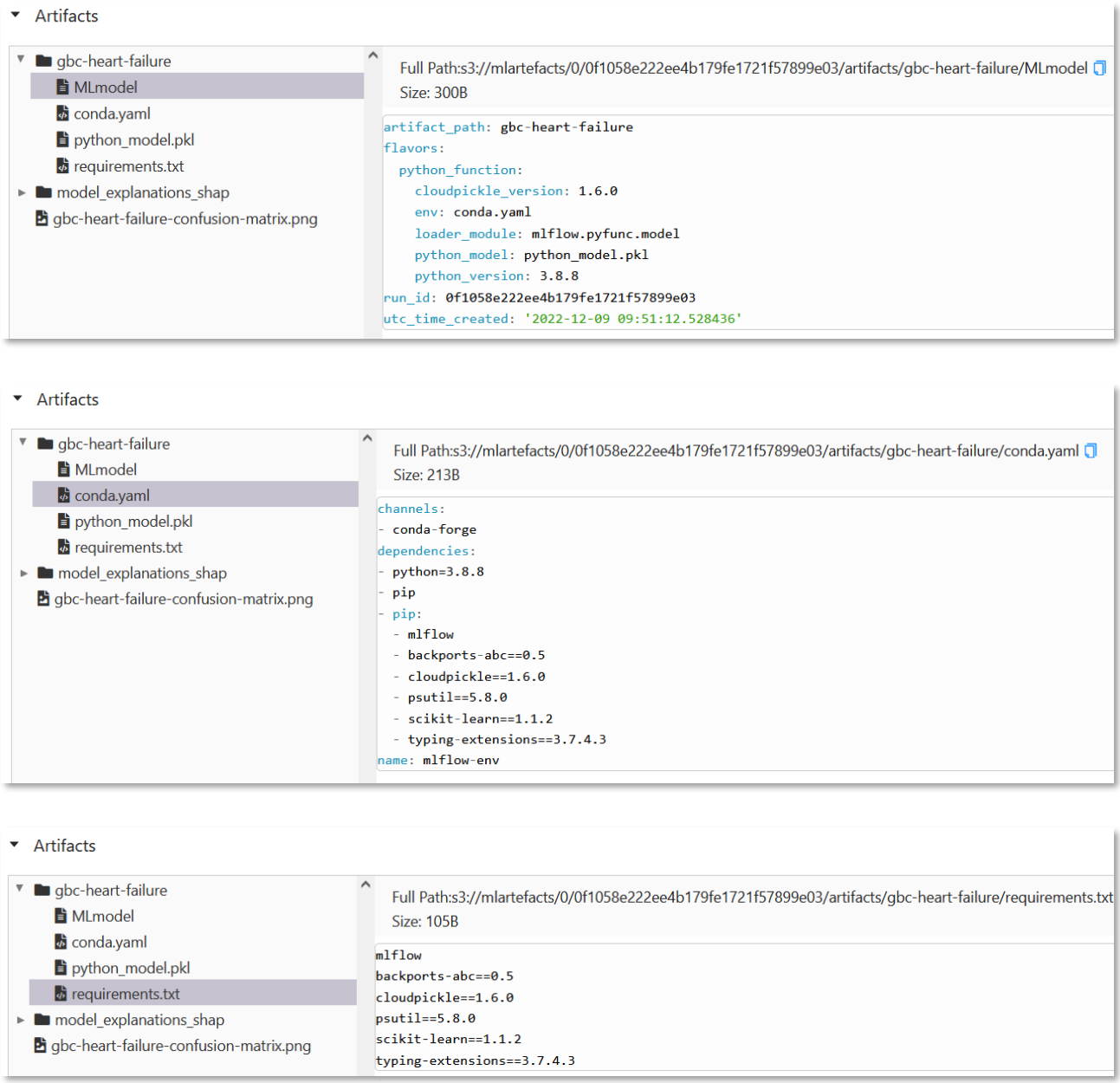

Figure 80: Model artifacts

Here we can see the details of one model artifacts (Figure 80). Along with the "pkl" file, which is actually the serialized model, there are several other types of information like the requirements, the environment in which the model was trained, Python version etc.

Besides this type of information, we store attached to the model additional "meta-information" of the model. This is currently represented by the confusion matrix depicted in Figure 81 and the feature importance in model creation obtained using SHAP. The results from SHAP algorithm are presented in Figure 82.

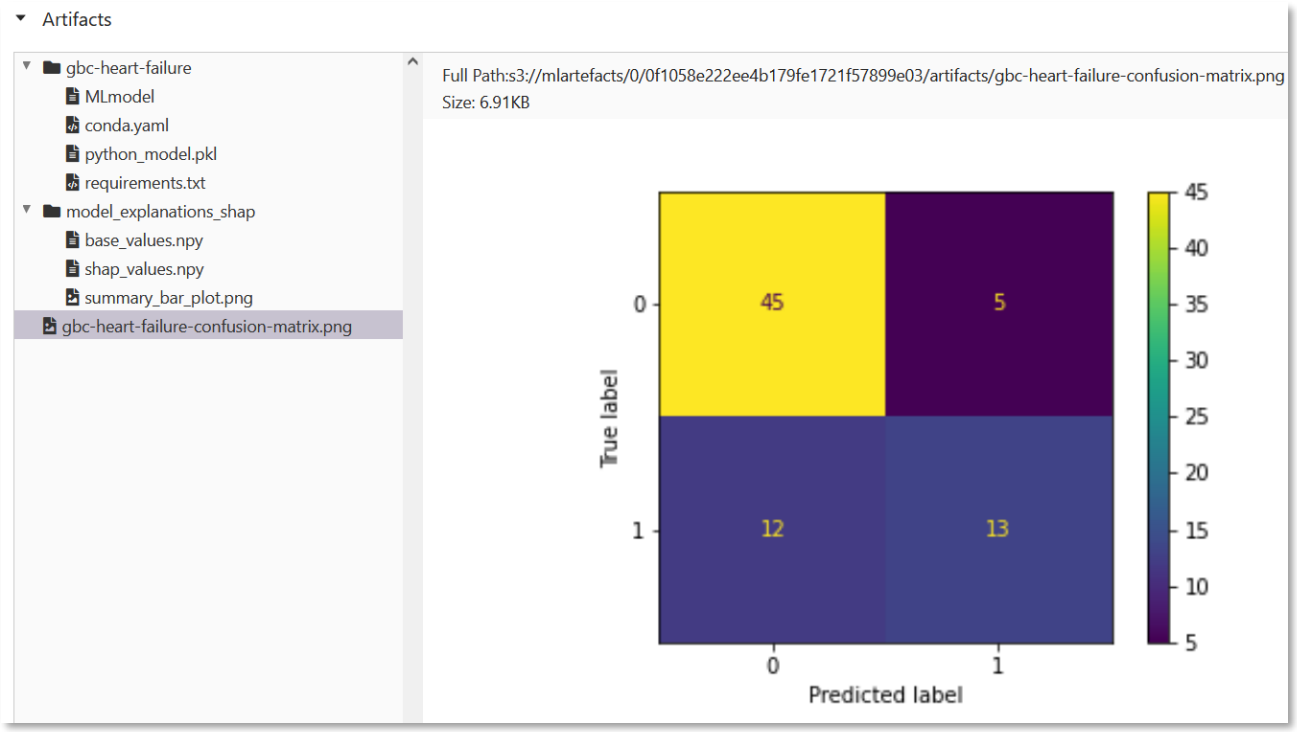

Figure 81: Confusion Matrix

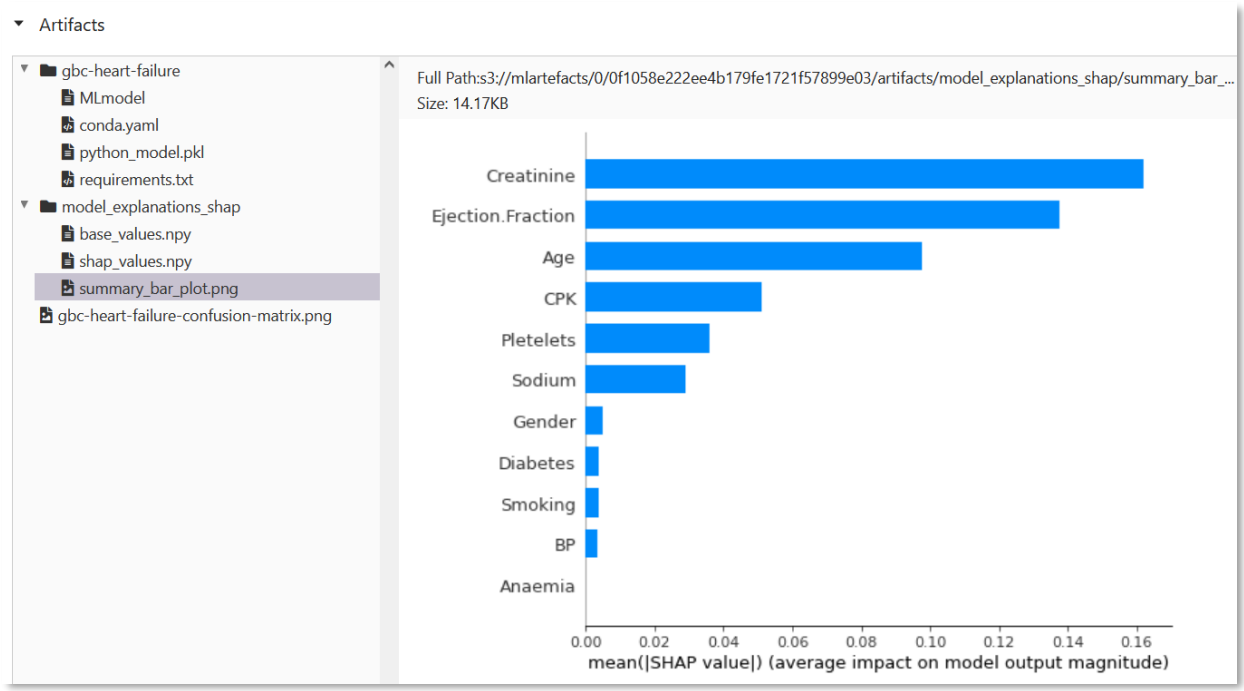

Figure 82: SHAP results

8.2 Other User Categories' Perspective

As explained in Section 3, the current version of the Global Insights Cloud is focused only on data analysis tasks. In addition to the existing AI model management for data scientist users, the next version of the platform will offer updated model management functionalities and sharing, will provide policy analytics assisting policy makers, configuration and administrative panels for administrative users and additional views for the Continuous Security and Privacy Assurance tool.

9. Use cases and scenarios

Use cases can benefit developers by revealing how the system should behave while also helping identify any errors that could arise in the process. The following table contains information about different use cases. More information is included in the deliverable D3.1 in chapter 5.

Table 1: Use cases and scenarios

Category	Use case code	Name	Status	Comments
Clinician's use cases	RTCL01	Creation of patient and data visualization	Implemented	Creation of patient from the clinical team, Input of baseline data on the CSB, and routinely follow the patient's well-being. The use case is fully implemented.
	RTCL02	Patient-doctor interactions	Implemented	The clinical team follows the patient with interactions called "clinical visits". The doctor is able to give a final action of the visit. The clinical team can run the AI mechanism and get a suggested outcome. First version of this use case is fully implemented.
	RTCL03	Alarms	Implemented	Alarms from the DSS to the doctor. The first version of the used case is implemented.
	RTCL04	Event record	Implemented	Every encounter or event with the patient is recorded with patient, so the clinical team has a holistic vie of the patient. This use case is fully

				implemented.
Patient's use cases	RTP01	Daily data entry	Implemented	Patients enter the measurements of everyday data. The use case is fully implemented.
	RTP02	Special variables	Implemented	Patients collect some data that are not daily monitored such as questionnaires. The use case is fully implemented.
	RTP03	Special events	Implemented	Clinicians are notified of worsening of symptoms. The use case is fully implemented.
	RTP04	Automatic messages	Partial Implemented	Messages to the patient and clinical team. The clinical partners revised the initial flow of operations and decided that the messages should be sent to the clinical team and the clinical team will address the patient. Partial implementation of the use case, after clinical team intervention.
Carer's use cases	RTCA01	Daily data entry	Implemented	The carer enters the measurements of every day data. The use case is fully implemented.
	RTCA02	Automatic messages	Partial Implemented	Messages to the patient and clinical

				team. The clinical partners revised the initial flow of operations and decided that the messages should be sent to the clinical team and the clinical team will address the patient. Partial implementation of the use case, after clinical team intervention.
Risk assessment generated by AI	RTBD01	Risk assessment generated by AI	Implemented	New parameters related too HF/LVAD/Transplantation outcomes are identified The use case is fully implemented.
Technical staff usecases	RTS01	Dashboard End-user moderated registration	Implemented	An end-user registers to gain access to the RETENTION Dashboard. The use case is fully implemented.
	RTS02	Dashboard End-user login	Implemented	A valid RETENTION Platform end-user signs in the system to use available (to his/her role and Organisation scope) service The use case is fully implemented.
	RTS03	Manage end-user account information	Implemented	End-user manages his/her personal information and login credentials The use case is fully implemented.

	RTS04	Associating a device ID to a patient	Implemented	Technical staff can pair a smartphone and other devices/sensors with a patient via a device ID and patient's RETENTION identification The use case is fully implemented.
	RTS05	Configuring a device and App	Implemented	Technical staff can manage the status of the previously paired smartphone and other devices/sensors Installing/configuring the App The use case is fully implemented.
	RTS06	Managing Public health policy decision-making models	Implemented	Technical staff can manage public health policy decision-making models and the execution of data analytics tasks which constitute them The use case is fully implemented.
	RTS07	Performing GDPR compliance check	Partial Implemented	Right to access auditor control. The system security, administration, anonymization and crypto functions are all active and operating. A dashboard log access should be implemented. The use case is partially implemented.

10. Conclusions

This deliverable provides a detailed view of the “user”, by describing the roles of the users, system set up, use cases and scenarios, Platform Infrastructure Deployment and User focused Descriptions and Flows.

More details about future work can be found in 7.2. However, below are some improvements that will potentially be implemented in v2 of the platform.

i. Update check functionality. The application will check for updates automatically and block usage if the latest version isn’t installed, while also prompting the user to update it.
ii. The chat functionality will be implemented after more discussions are held regarding the issues with it and a suitable solution has been determined.
iii. A function that will forward DSS messages to the patient (currently they’re only transmitted to physicians), imploring them to take their measurements (oxygen, pressure etc) if they haven’t done so already during a particular day.
iv. The abovementioned function can also be expanded to include medication alerts; in the case the patient has not marked their prescribed medication as “taken” during a particular day.