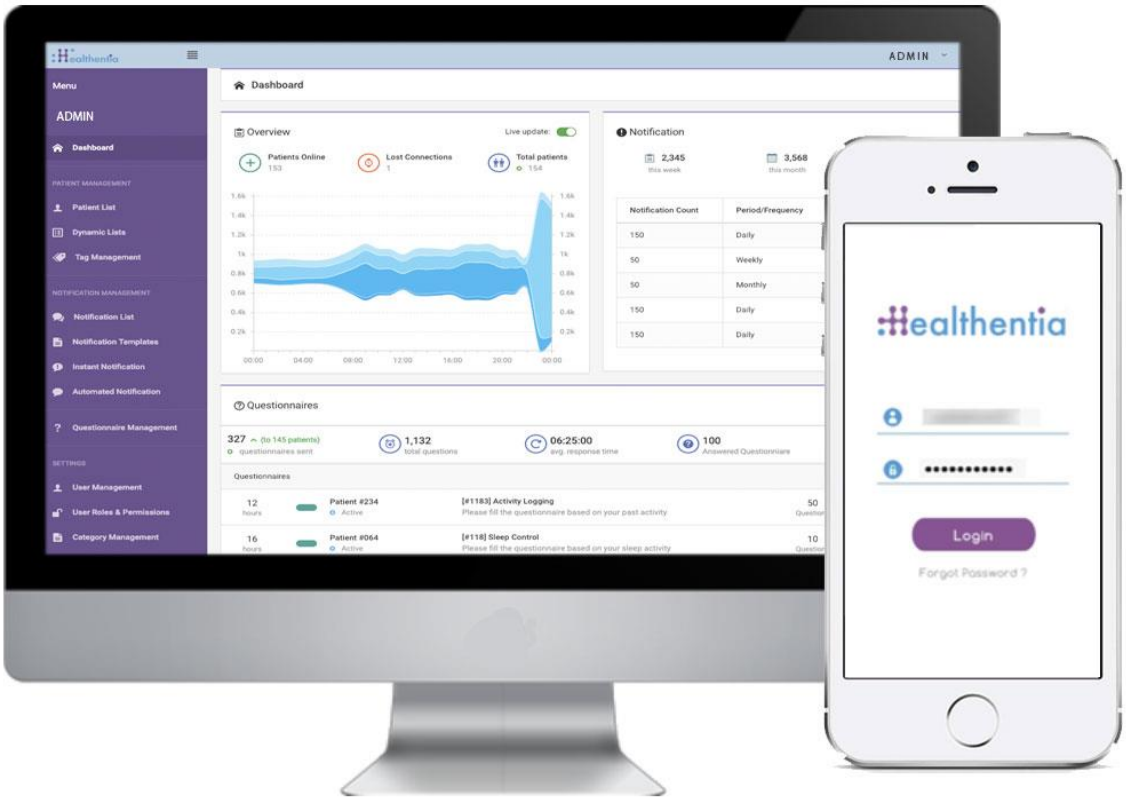

INSTRUCTIONS FOR USE

HEALTHCARE PROFESSIONALS

IFU Version v2.6

INNOVATION SPRINT SRL
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1200 Brussels, Belgium

Document History

Document Version	Nature of change	Date
2.6	Updated Operating system / browser requirements (Minimum Requirements)	01.06.2025

ABOUT

The Healthentia Portal is a collection of various modules. Several modules are considered as medical devices and are covered by the CE mark according to the European Regulation 2017/745:

CE 1912

- Subjects-based dashboard: The HEALTHENTIA system offers several subject-level dashboards. There are three broad categories of information to be presented through visualizations related to each subject: subject overview, their reports and their measurements.
- Alerts: The Alerts functionality is using a user interface to set rules and thresholds regarding values collected from various sources like questionnaire answers or IoT devices as an absolute number for a period of time or relative to previous vectors in a period of time. These will then create alerts to clinicians or tag patients.
- Virtual coaching: It is the functionality that allows the user (subject/patient) to interact with an embodied conversational coach for informative and motivational purposes. Users of the HEALTHENTIA Mobile app can interact with the virtual coach through natural language in a controlled manner (I.e., no free text/speech input). The dialogues that are supported by the virtual coach are scripted interactions, which are authored by our clinical experts. Users can navigate through the dialogues by choosing at each step of the conversation between a number of provided reply options. In this way, it is feasible to provide an engaging natural language user interface to the virtual coach, while keeping strict control over which information is provided to the user, or which advice is given.
- Other supportive modules of portal: Study services (questionnaire editor, composite questionnaire, study configurator, multisite study), subject list, study-level dashboard.
- Other supportive modules of backed: scheduler, security & regulatory, management, data handling, API & SDK.

Information
For more information, please visit: https://healthentia.com
For any privacy related questions or requests, you can contact: dpo@healthentia.com
For general questions, you can contact: info@healthentia.com

Report of serious incident
Any serious incident that has occurred in relation to the Healthentia Medical Device App, you can contact the manufacturer (Innovation Sprint Srl) in: support@healthentia.com and the authority having jurisdiction in your locale.

Technical support
Healthentia support service is offered at best-effort level.
For any technical support queries, you can contact: support@healthentia.com
Our support team will reply to you within 1 working day.

Paper version of IFU

If you would like a paper version of the instructions for use, please contact the manufacturer at the following e-mail address: info@healthentia.com. It will be delivered within 7 calendar days after receiving the request.

INTENDED PURPOSE

Healthentia is a software intended for: a) the collection and transmission of physiological data including heart rate, blood pressure, oxygen saturation, and weight directly to care providers via automated electronic means in combination with validated IoT devices; b) the visualization (subjects-based dashboards) and the mathematical treatment of data (trends analysis, alerts) related to the monitored chronic disease subject's physiological parameters; c) the transmission of patient's outcomes and outcome scores related to patient's health status, health-affecting factors, health-related quality of life, disease knowledge and adherence to treatment through validated questionnaires; d) the user (subject/patient) interaction with a conversational virtual coach for informative and motivational purposes, in order to support subject telemonitoring, decision making and virtual coaching.

CLINICAL BENEFITS

The use of Healthentia allows to:

- Provide objective inputs for healthcare professionals to support diagnosis.
- Highlight evolution of physiological parameters by trends analysis of the patient's inputs
- Allow healthcare professionals to provide the same quality of care and safety as the standard of care.

CLINICAL INDICATIONS

Telemonitoring of chronic disease patients (such as heart failure, cancer, COPD, etc.)

CONTRA-INDICATIONS

- Healthentia is not intended for the monitoring of patients in critical situations (operating room, emergency, intensive care).
- Any physical or cognitive condition that, in clinical judgment, would prevent the patient from using Healthentia, e.g. dementia.
- The device should not be used during pregnancy.
- Healthentia has not been tested with paediatric population. Therefore, Healthentia is intended for adult use only (>18 years old) and does not cover use by children.

PATIENTS TARGET GROUP

Chronic disease patients taking part of clinical investigation or a medical treatment

INTENDED USERS

Telemonitored patients and their healthcare professionals

USE ENVIRONMENT AND DURATION

Healthentia can be used as Remote Patient Monitoring solution for patients that are released from hospital and have to follow a certain treatment. Duration depends on the study or intervention or patient's will.

WARNINGS

- The device is not intended to replace the care of a health care professional, including prescription, diagnosis or treatment.
- Consult periodically the Alerts dashboard as it may influence the follow-up of your patients.

PATIENT INFORMATION

Please inform your patient about the following information:

- Healthentia is not monitored in real time by healthcare personnel; it is intended for non-emergency communication only. In case of an emergency, contact your care unit or the emergency number by phone.
- In some special cases, the self-care advice and instructions provided by Healthentia may not be applicable to your situation. If you have questions about your care, symptoms and management, contact the health care team.
- If you have questions about your care, symptoms and management, contact your healthcare team.
- The device is not intended to replace the care of a healthcare professional, including prescription, diagnosis or treatment.
- Telemonitoring does not replace regular check-ups with your doctor. Consult your doctor in case of severe and persistent symptoms.
- In combination with Healthentia, use only measuring devices for which the technical performances (accuracy, precision) have been verified by your healthcare provider as it may affect the outcome of your monitoring.
- Verify the consistency of your clinical data and the good transfer of them to your healthcare provider as the quality of the diagnosis and treatment is partially based on this information.

DISCLAIMER

- The user is responsible of the final assessment of the diagnosis and treatment decided for the patient.
- The device providing information to support diagnostic and therapeutic decision, but the overall clinical context should be taken into consideration before taking any decision.

MINIMUM REQUIREMENTS

Supported hardware

Any personal computer that is using the supported Operating System (OS) and browser – see below- is a supported hardware device.

Operating system/browser requirements

Healthentia Portal requires a stable Internet connection and a compatible device (laptop, desktop, etc). The operating systems supported are:

- Microsoft Windows: version 7 and above
- MacOS: version 10.15 and above
- Linux: LTS distributions released after 2016
- Debian distributions released after 2017
- Fedora distributions released after 2017

This device will need an up-to-date internet browser in order to consult the web application. It is suggested using one of the following browsers that were each tested:

- Google Chrome: version 93 and above
- Mozilla Firefox: version 88 and above
- Safari: version 11 and above
- Microsoft Edge: version 88 and above

Specific issues that come in at Innovation Sprint from the users (post-market surveillance) are analyzed and when a systematic error on one browser is detected, this is added to the backlog and prioritized for the correct version.

INTEGRATION WITH OTHER DEVICES

The accuracy requirements for IoT devices that are connected to Healthentia are listed below.

measurement	Min. accuracy	Medical module
Blood pressure	≤10mmHg (at least 85% probability)	Yes
SpO2	A_{rms} ±2-3% of arterial blood gas values	Yes
Heart (RHR, max, …)	±10% of the input rate or ±5 bpm	Yes
Weight	±0.5-1.0 kg	Yes
Physical activity (steps, …)	n/a	No
Sleep	n/a	No

Healthentia App is compatible with other devices to collect lifestyle information and vital signs. The supported devices intended for use together with Healthentia are:

- Garmin trackers and watches via the Garmin API (Android & iOS)**: Fenix 5 pro, Fenix 6 pro, Forerunner 945, Vivoactive 4, Vivosmart 4, Venu 2S,
- Fitbit trackers and watches via the Fitbit API (Android & iOS)**: Versa, Inspire 2
- iHealth devices via Bluetooth (Android & iOS): Connected Blood Pressure Monitor iHealth Track (KN-550BT)*, Smart body composition scale iHealth Fit (HS2S)**, Smart Pulse Oximeter - iHealth Air (POM3)*
- Polar belt via the Polar API (Android & iOS): H9**

* Device has acceptable accuracy for the intended purpose of Healthentia

** Device does not have acceptable accuracy for the intended purpose of Healthentia and can only be used for measurements that do not require accuracy (e.g. step counter, sleep).

These devices constitute a safe combination and currently there is no device specific information on any known restrictions to combinations. It is the responsibility of the healthcare provider to select the connected devices, among the validated ones listed above, that are appropriate for the intended purpose in terms of measurement accuracy, repeatability and range as it may affect the diagnosis of the patient. Healthentia displays values in international metrics (m, kg, s) regardless of the preference of the patient in his/her IoT device.

SECURITY & PERFORMANCE

Security

Innovation Sprint is committed to protecting the security of data subject's information and takes reasonable precautions to protect it, including protection against unauthorised access, necessary to run the software as intended. In this context, Innovation Sprint regularly evaluates and reviews technologies, facilities, procedures and potential risks to maintain the security and privacy of users' data, paying particular attention to role-based access and logging

of health data access. Moreover, any potential changes to software applications, provided services and/or hardware systems are properly justified, evaluated and registered based on international best practices and standards.

- Avoid using public wi-fi networks to connect to Healthentia when you are about to add and/or manage health data and/or your profile details.
- Do not use jailbroken devices.
- Passwords should be at least eight (8) characters long, contain characters from three of the following four groups: Lowercase letters, Uppercase letters, Numbers (0-9), Special characters.
- Never store your passwords on your devices.
- Change your passwords at least every six months.
- Install an anti-malware program on your devices and update it regularly.
- Make sure that each e-mail you register in Healthentia corresponds to you.
- Ignore and delete messages of doubtful origin and do not follow links that include and refer to websites.
- Do not reveal by phone, e-mail, Internet form, or social media, confidential information such as your username, password.
- Always use the most up-to-date versions of your device operating system and Healthentia App.

Performance

- Provide objective inputs for healthcare professionals to support diagnosis and patient management;
- Highlight evolution of physiological parameters by trends analysis of the patient's inputs;
- Increase patient's adherence to treatment.

TABLE OF CONTENTS

1 GETTING STARTED

HEALTHENTIA can be used both by individuals and by sponsors of clinical trials. Individuals can report and monitor their outcomes (e.g. symptoms) and activity and receive automatic-generated questionnaires for wellbeing. Aggregated data provided after users' consent, can be processed for conducting non-profit research studies. Clinical trial sponsors can operate HEALTHENTIA to collect ePROM/ePREMs under the appropriate regulatory framework (e.g. Good Clinical Practice) to carry out study protocols, often by the use of a PaaS instance of the platform. Individuals, depending on their consent information, may receive invitation to participate in research studies.

This manual is targeting Organization Admins, Study Admin, Investigators and other authorized personnel of the Study Portal.

1.1 LOGIN/ REGISTER AS A PORTAL USER

To login user should go to the login page, which is available in https://saas.healthentia.com for the SaaS version, or a specified URL for the PaaS version.

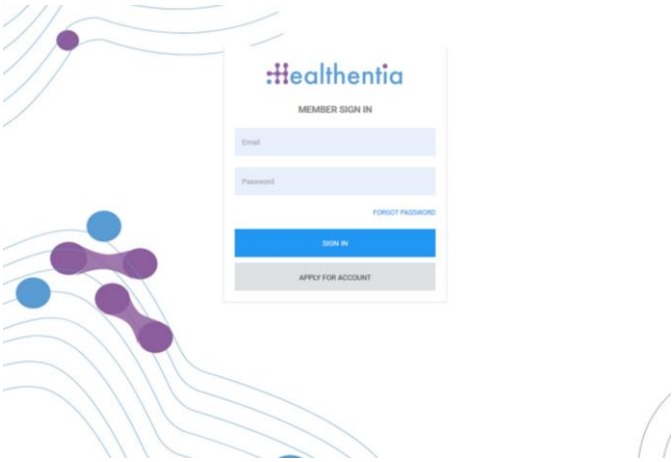

Figure 1: Login page

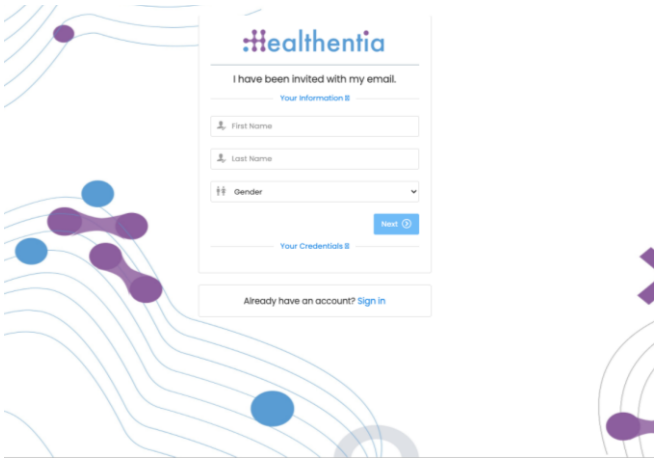

Figure 2 - Registration page

Users receive an invitation from an Organization Admin to register their account and enter in the portal in the allocated study with an allocated role.

1.2 FORGOT PASSWORD AS A PORTAL USER

If you can access to your account, use the forgot password button in the login page.

Figure 3: Recovery password and email reset

Users receive an email for set up a new password and login to their account.

2 STUDY MANAGEMENT

2.1 STUDY OVERVIEW

After log in you are directed to the Study Overview Page – My Studies, which has a list of your available studies and some overall statistics. You can access your Studies, edit them or create a new one.

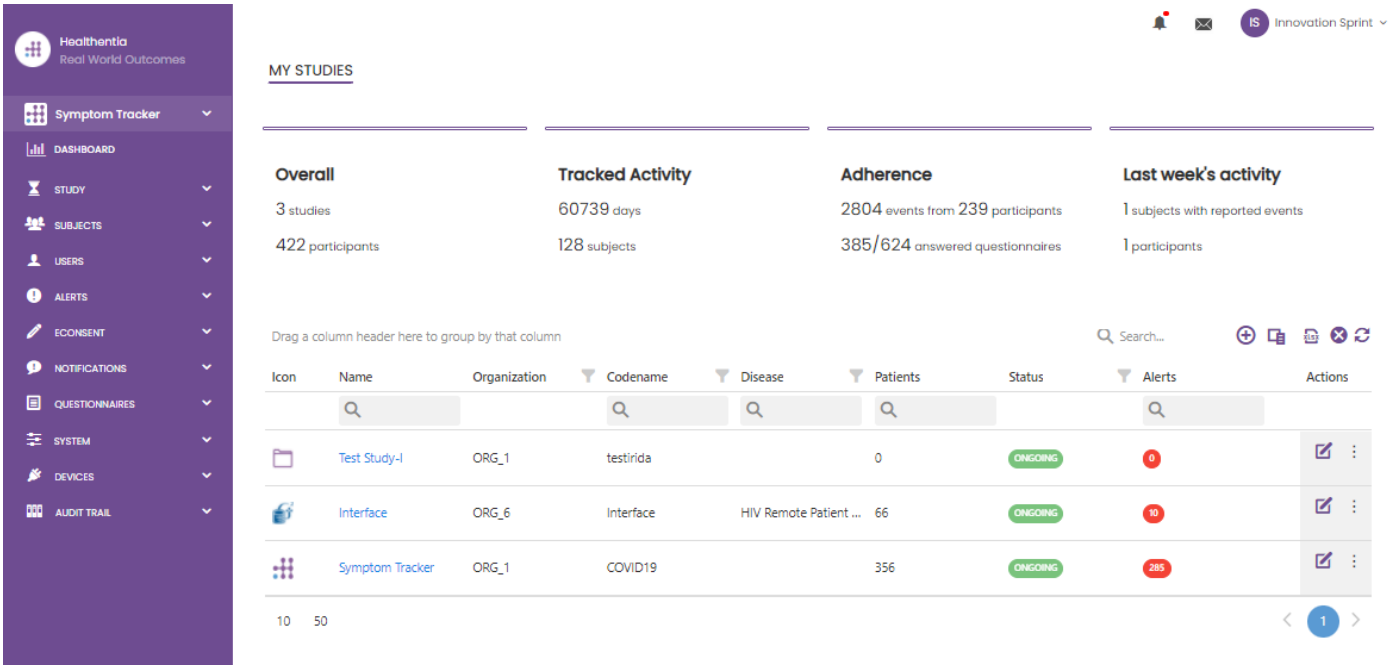

Figure 4 - Study Overview

2.2 SETTING UP A NEW STUDY

From this first page, you have the option to create a new study. Depending on the type of study, investigator provides different information. In Figure 5 one can see the available configurations for the study per se but also the mobile App. There is a selection of available widgets to select for the new study and configure the data sources but also several fields to fill in like Name, Code, logo, Languages, therapeutic area, duration and consents.

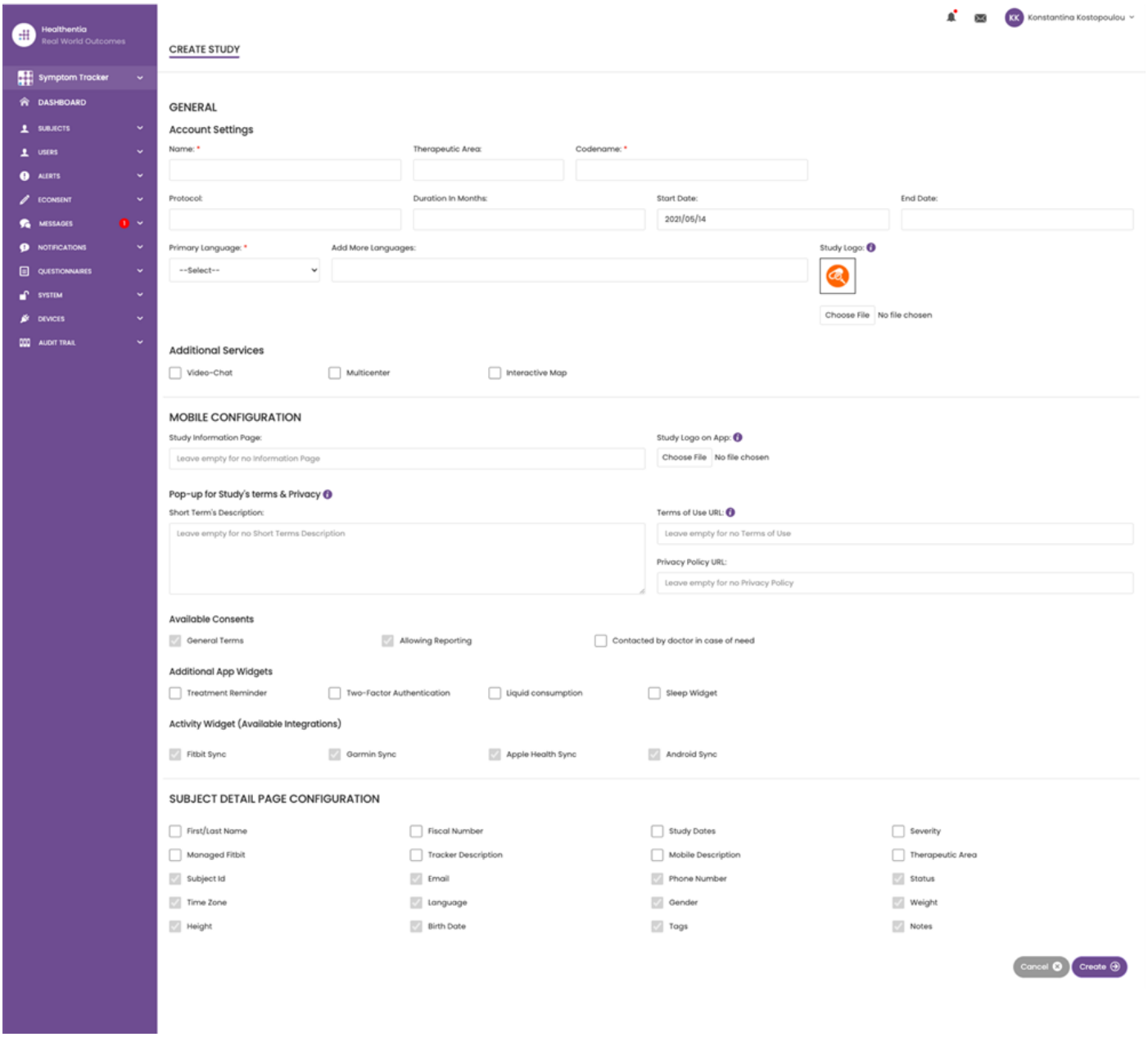

Figure 5 - Create New Study

3 DASHBOARD

The user dashboard contains information of the selected study in tabs, e.g. Interactive map, Study Overview, Measured Activities Overview and Outcomes Overview. This is a customizable set of dashboard tabs; they depend on the Outcomes that each trial collects. The map is connected to a Location question, Measured activity requires a connection the mobile sensors (or fitbit, Garmin, etc) and the reported outcomes tab has a self-service mechanisms for questions asked in the questionnaire to be seen in two types of graphs

3.1 INTERACTIVE MAP

At the configuration of the study, the Study Admin can select to enable the interactive map if there are questions regarding location. Portal users can select parameters through several filters and have an overview of subject outcomes at a geographical level, as presented in Figure 6.

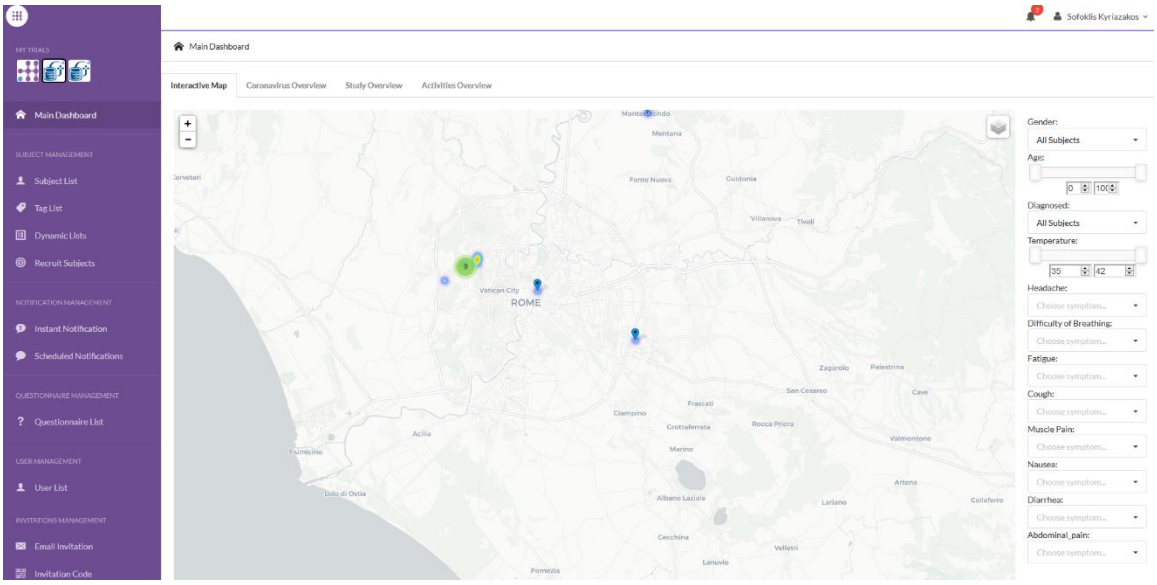

Figure 6: Interactive Map

3.2 BI DASHBOARD

Further to the Interactive map, there are other tabs in the Dashboard that can be configured with study Overview statics, like registrations and protocol adherence – Figure 7.

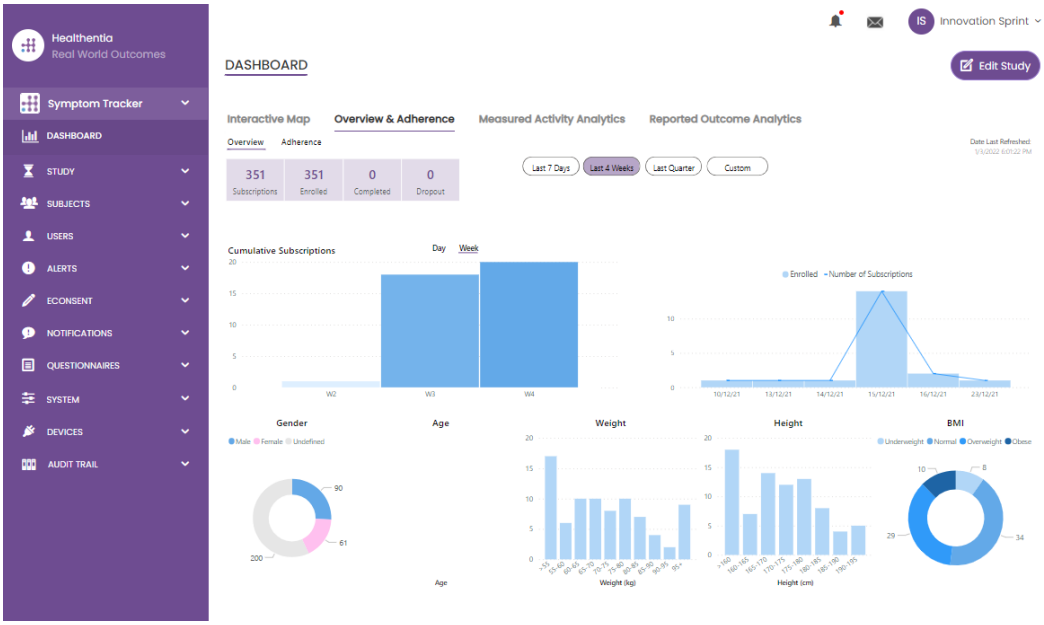

Figure 7: Study registration and compliance overview

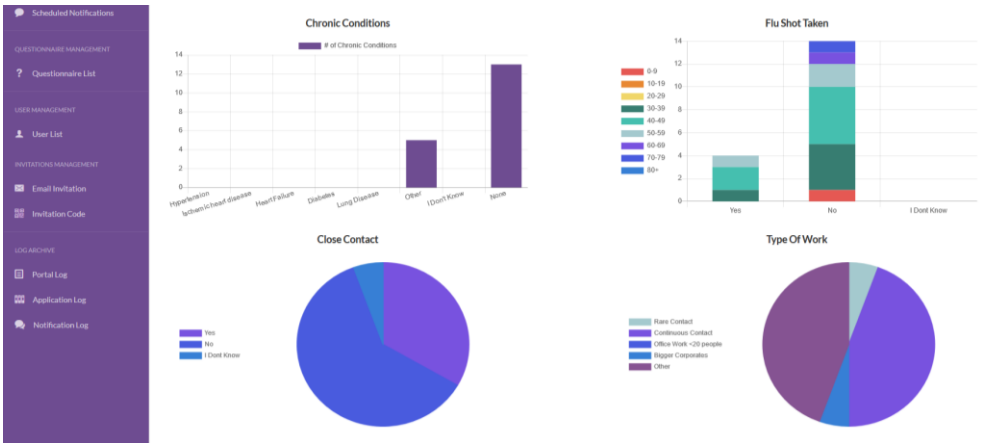

Figure 8: Study Measured Activities statistics overview

4 SUBJECTS

4.1 ADD A SUBJECT

Subjects are either imported via an integration with an EDC into Healthentia as inactive subjects that are activated once they have logged in to Healthentia, they can be manually added by the button on the Subject List or invited through the system from the Subject Invitations. The email used for the invitation will be recognized by the system to allow them, at registration on the App to enter to the specific Study. **Not using the same email will not enroll the Subject in the correct Study.**

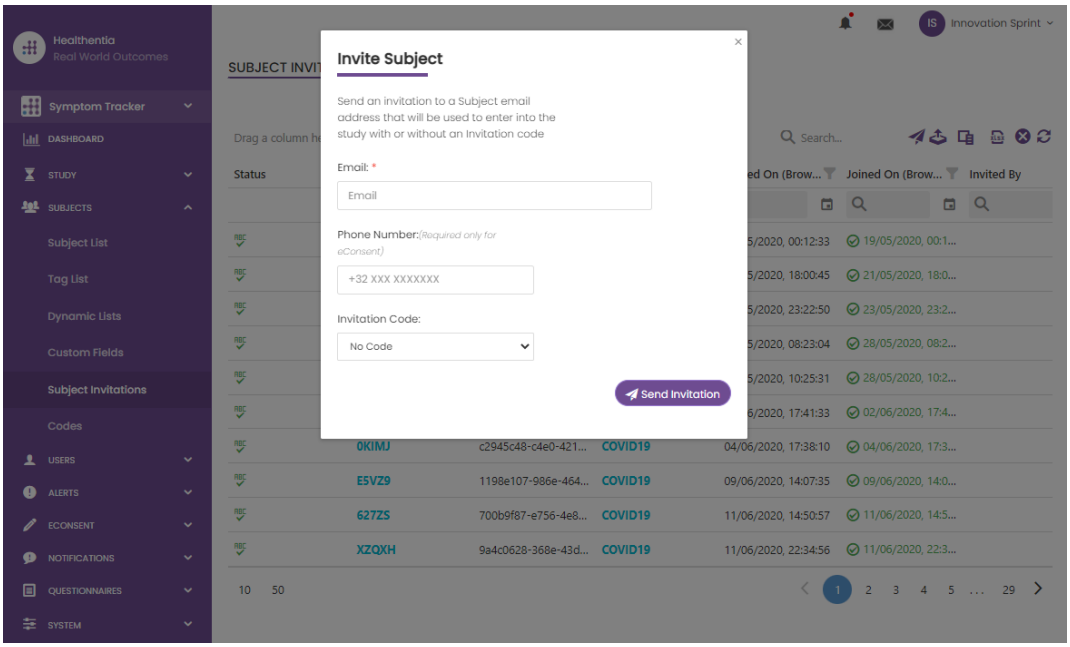

Figure 9 - Invite Subjects

Similarly, to the Email invitation above, the investigator can invite patients by providing them a code. Subjects can enter this code at the registration, even if they have not received an email. Once they register, they are automatically connected to that specific study only. They can be massively generated to use one per subject and or one can be used for all the subjects for the Study as seen in Figure 10: Create Invitation Codes

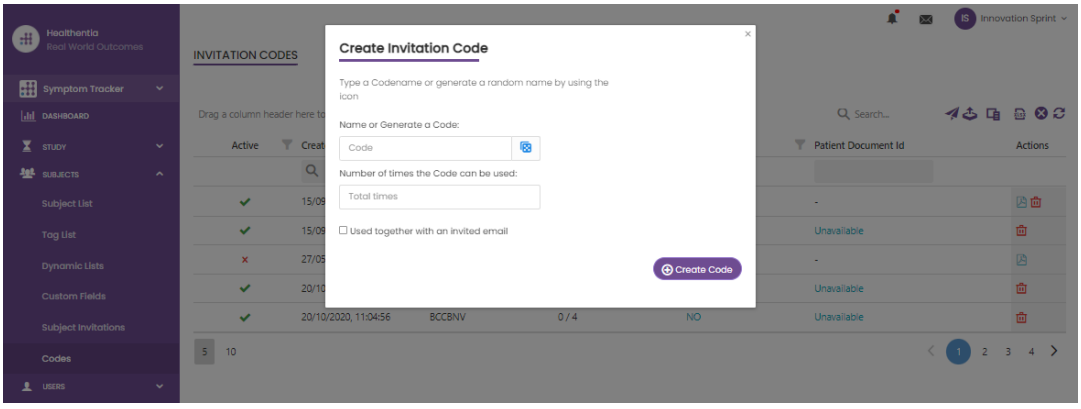

Figure 10: Create Invitation Codes

Each Subject has a record of profile details and several other tabs of different information coming from the ePRO or the Activity tracker

4.2 SUBJECT RECORD

In the Subject record, the portal user that has permissions to view or edit the patient details and view ePRO related data and measured activity can have access to the different tabs of information coming from different sources. They can even have the ability to complete questionnaires for them.

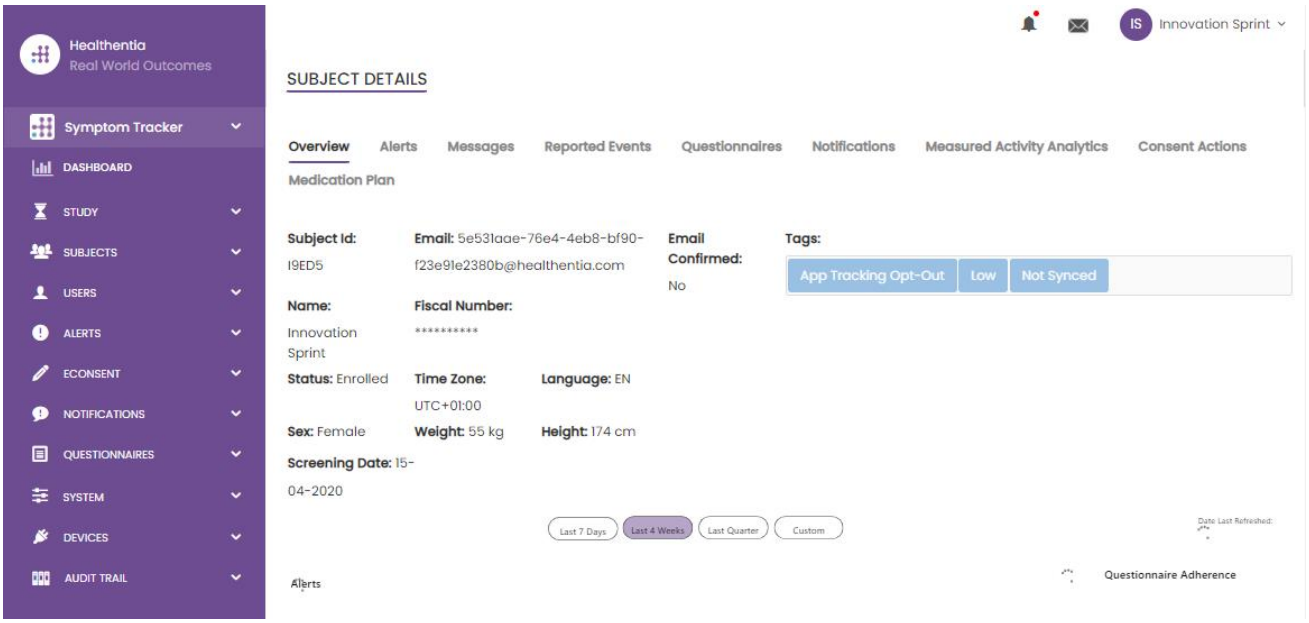

Figure 11 - Subject Details

4.3 SUBJECT LIST

The subject's list gathers in a table all patients assigned in the specific study. The list table gives an overview of important elements like dates, Questionnaire adherence, tags, activity status and more.

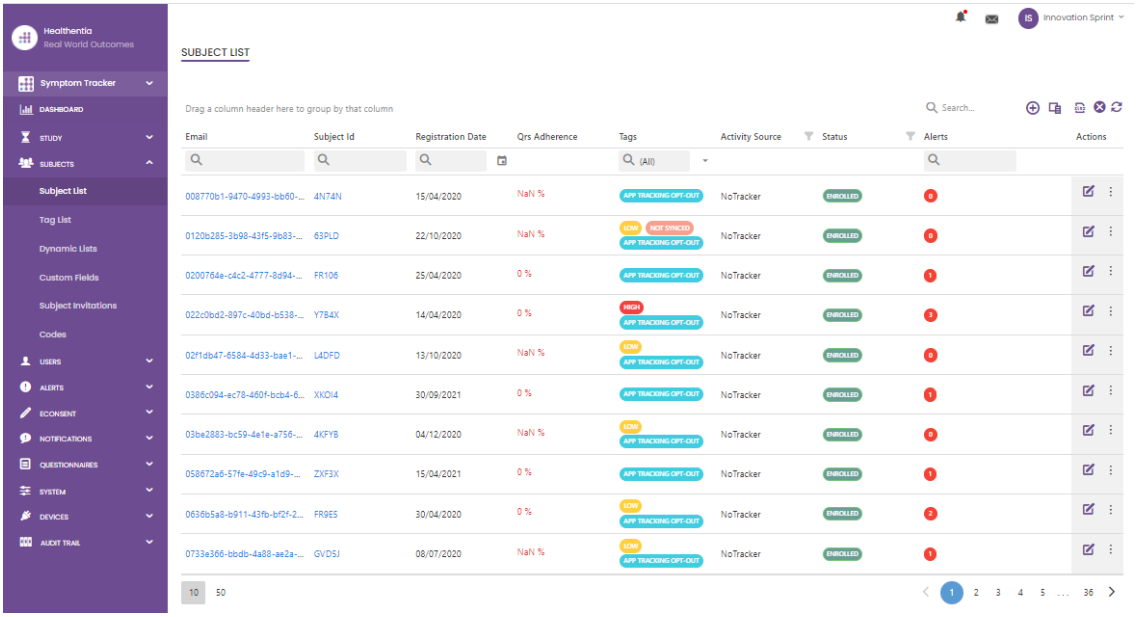

Figure 12 Subject list

4.4 TAGS & DYNAMIC ALERTS (not a medical module)

In the section of Tags, we list all the tags available in the study as seen in Figure 13 to be used for grouping the patients in their entry in the system or depending on their answers in the questionnaires. These tags can be than attached to an Alert seen in Figure 14 - Dynamic Alerts List. All Alerts are featured in a table as seen in Figure 14. As in all sections of the portal all data are exportable to an excel file.

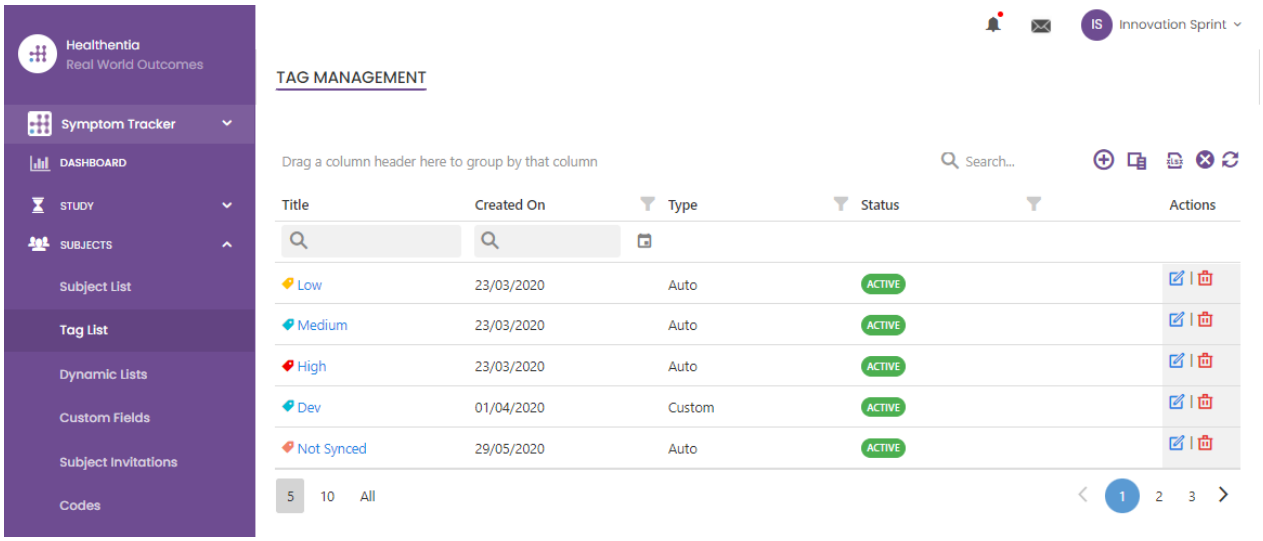

Figure 13 Tags List

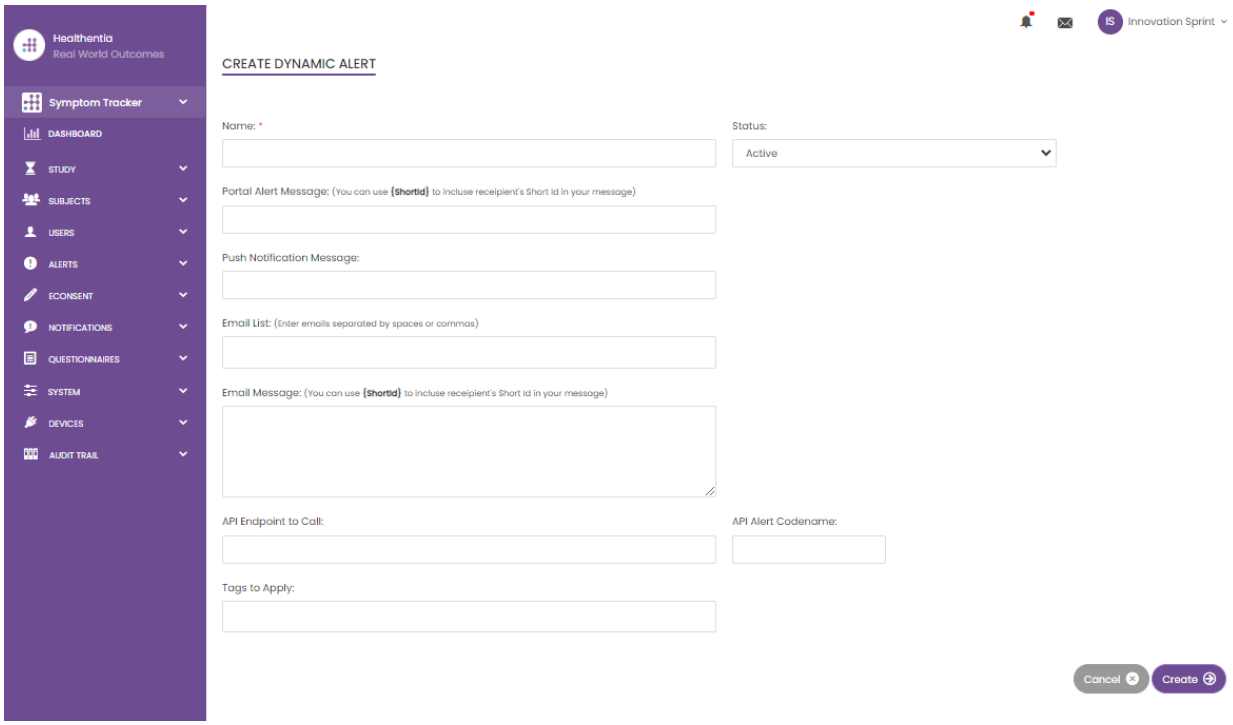

Figure 14 - Dynamic Alerts List

4.5 ALERTS DASHBOARD

The Alerts are shown in a separate Dashboard where the portal user has an overview of what tags are allocated and whether a patients requires an immediate action or has low adherence in his reporting of questionnaires.

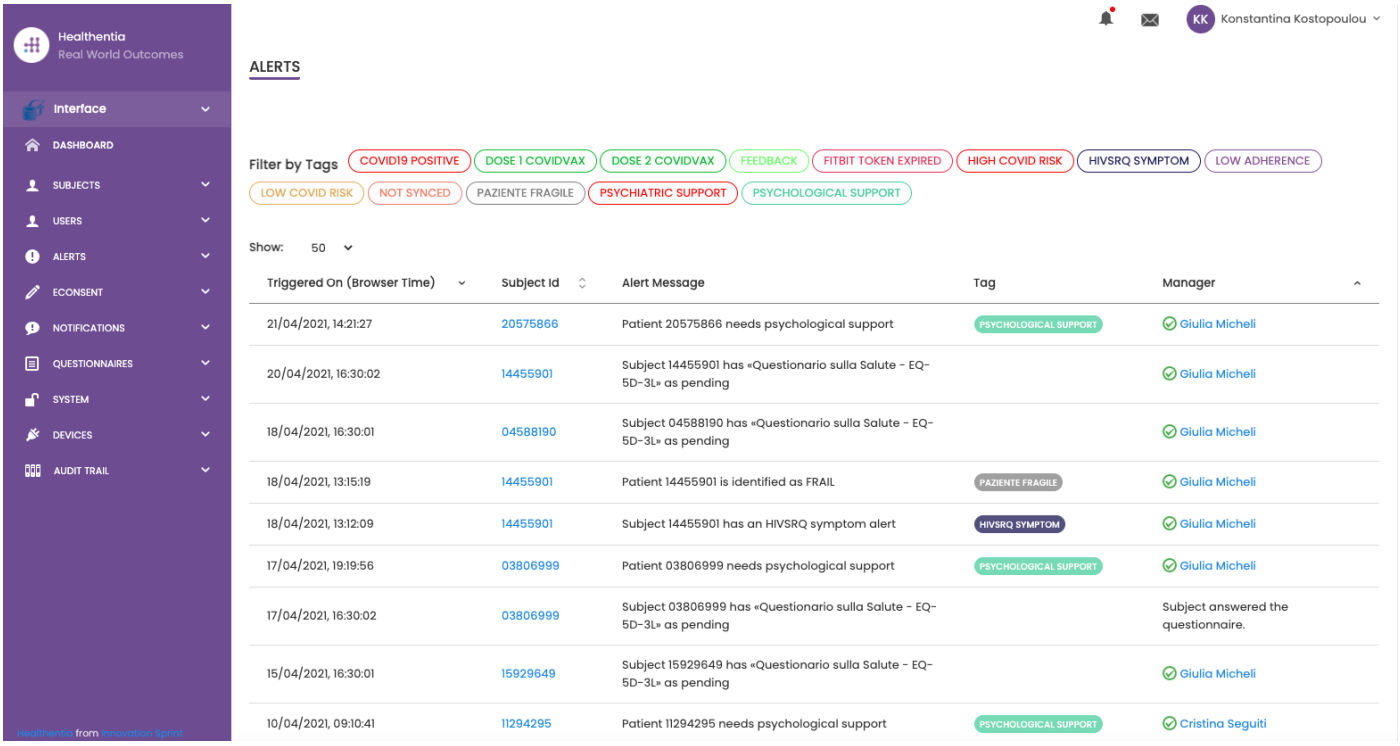

Figure 15 - Alerts Dashboard

4.6 DYNAMIC LISTS

The Dynamic lists are used to group patients in a dynamic way. We create grouping requirements and patients are added automatically in a list when they meet the criteria. The attributes of patients that can be used as criteria for filtering the patient list are status, screening, termination or treatment switch date and even using tags that are explained below. As in all sections of the portal all data are exportable to an excel file, as presented in Figure 16.

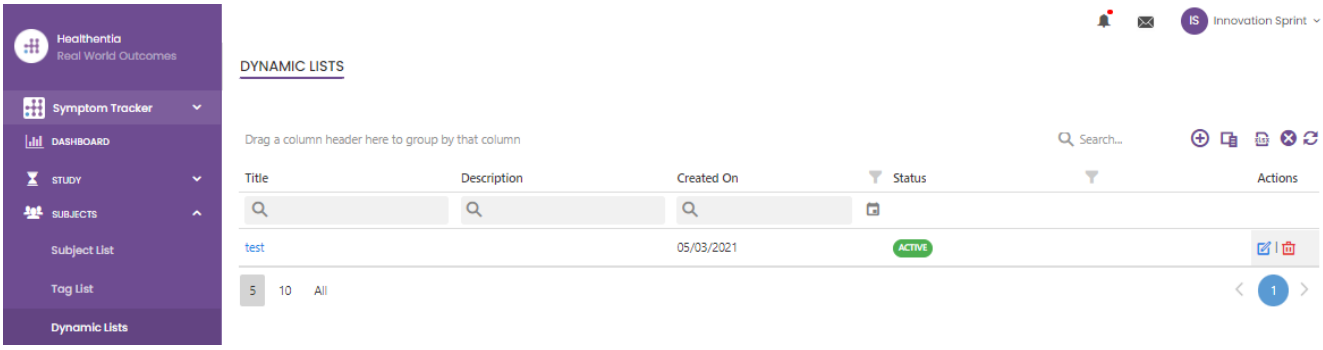

Figure 16 Dynamic List table

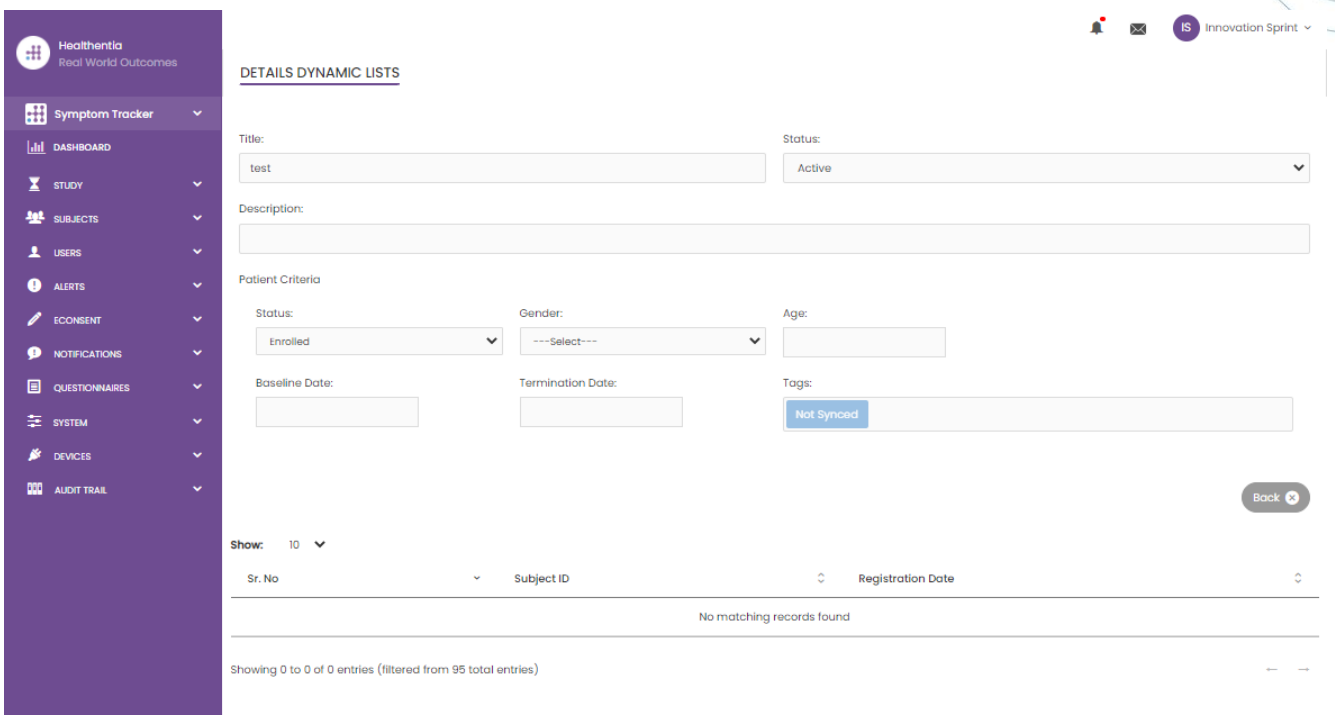

Figure 17 - Dynamic list details

5 NOTIFICATIONS

5.1 NOTIFICATION LOG

In the section of Notifications, we can see all communication sent by the system to patients, we can create instant notifications or scheduled. All notifications are listed by date in the Notification List and you have an overlook of the content of these notifications and if their type. As in all sections of the portal all data are exportable to an excel file, as presented in Figure 18.

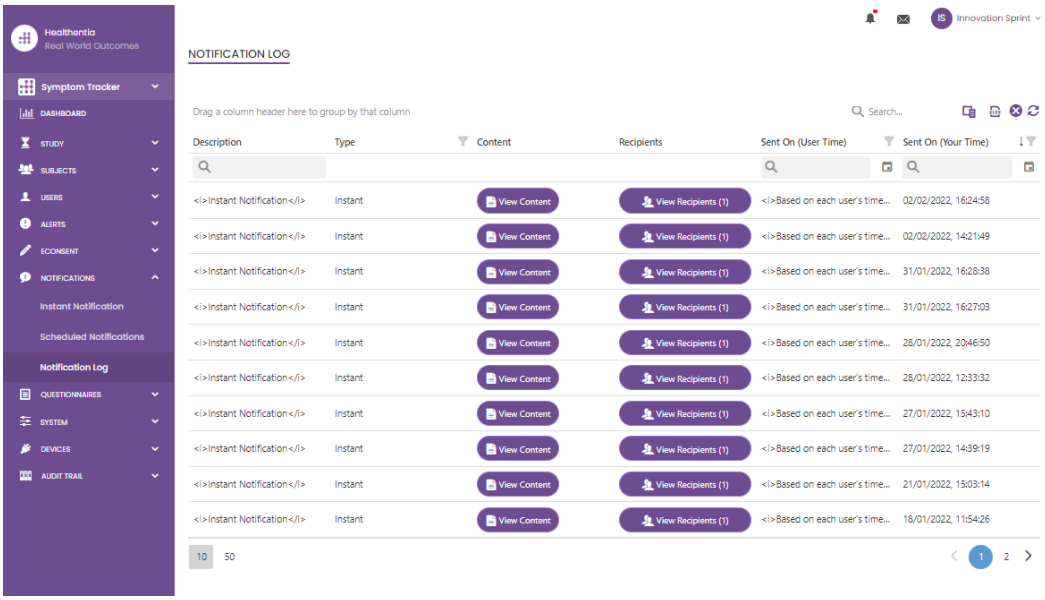

Figure 18 - Notification Log

5.2 INSTANT NOTIFICATIONS

Instant Notifications are the ad hoc messages that the investigator can send to a patient that hold a simple message or accompany a questionnaire. You can select individual recipients for the notification from the full subject list or filter by using tags or Dynamic Lists as seen in Figure 19.

Figure 19 - Instant Notification

5.3 SCHEDULED NOTIFICATIONS

Scheduled notifications are the ones that are created in the beginning of the study and are used to schedule the questionnaires to be sent to a group of recipients based on a filtering by tags or dynamic lists or to the whole list.

The scheduling of a notification can be done based on a regular Date with a Daily, weekly or Monthly interval sent once at a specific time or recurring. The system also allows the coordinator to send notifications based on the protocol's specific dates and X days before or after these days. You can see the Notifications List at Figure 20 and the New Scheduling Notification at Figure 21 - New Scheduled Notification.

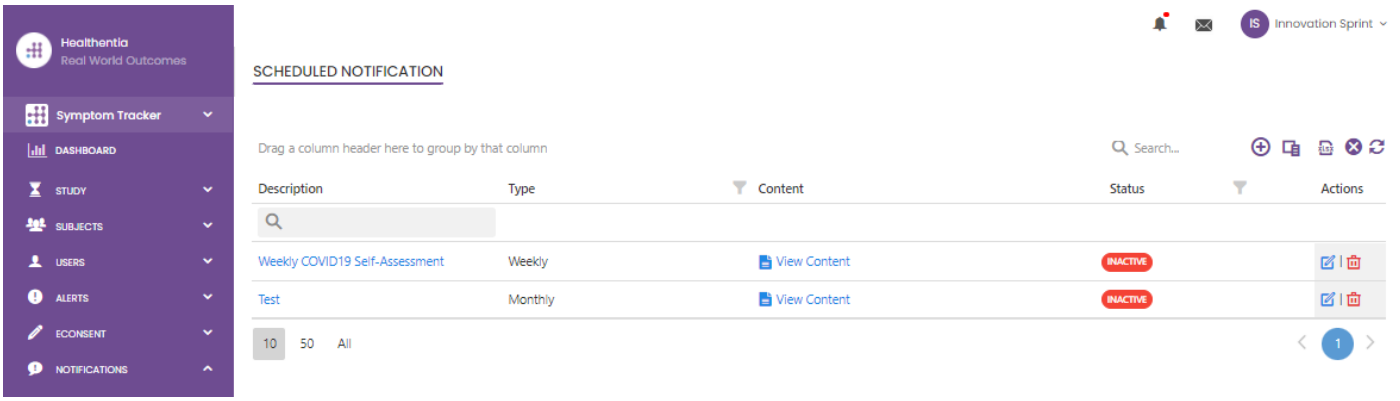

Figure 20 - Scheduled Notifications

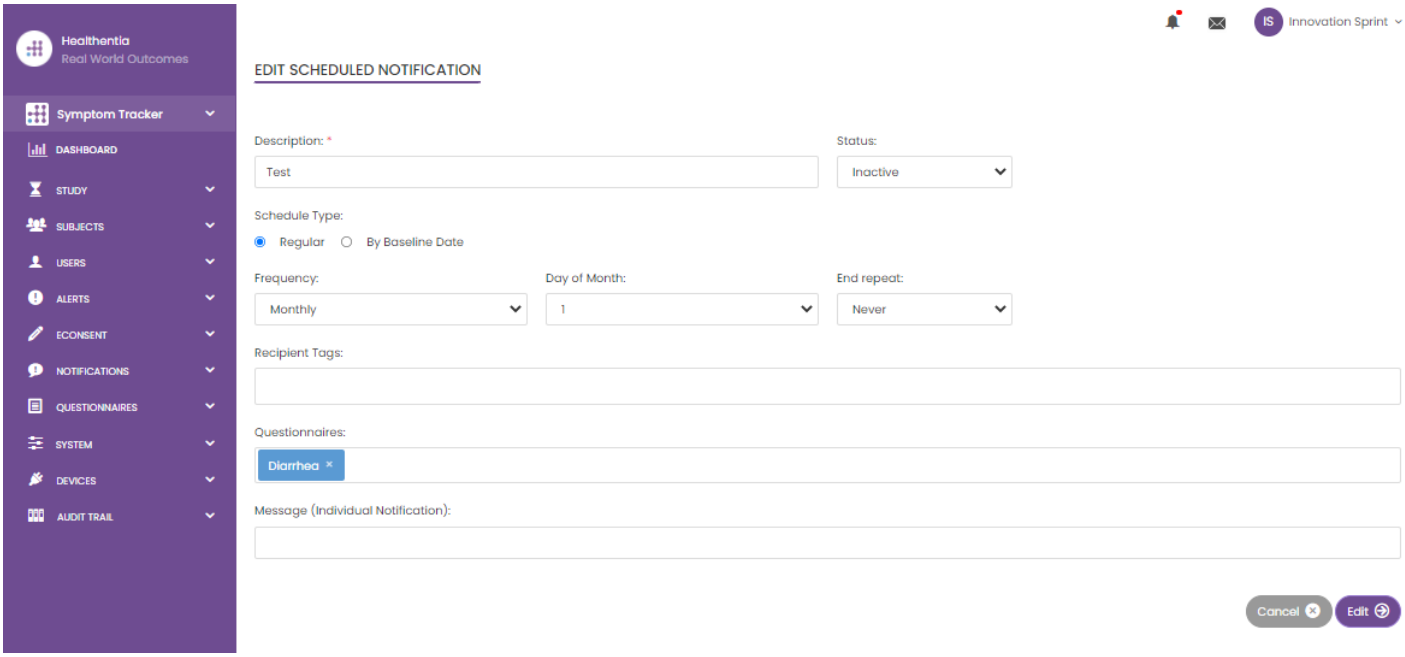

Figure 21 - New Scheduled Notification

6 MESSAGES- TELECONSULTATION

6.1 MESSAGE INBOX

End-users of the mobile app if the feature is enabled they can send a Message to the Investigator/study assistant and start a conversation. If needed the investigator can start a teleconsultation video link that will be valid for 15 minutes. See inbox in Figure 22 and the conversation in

Figure 23.

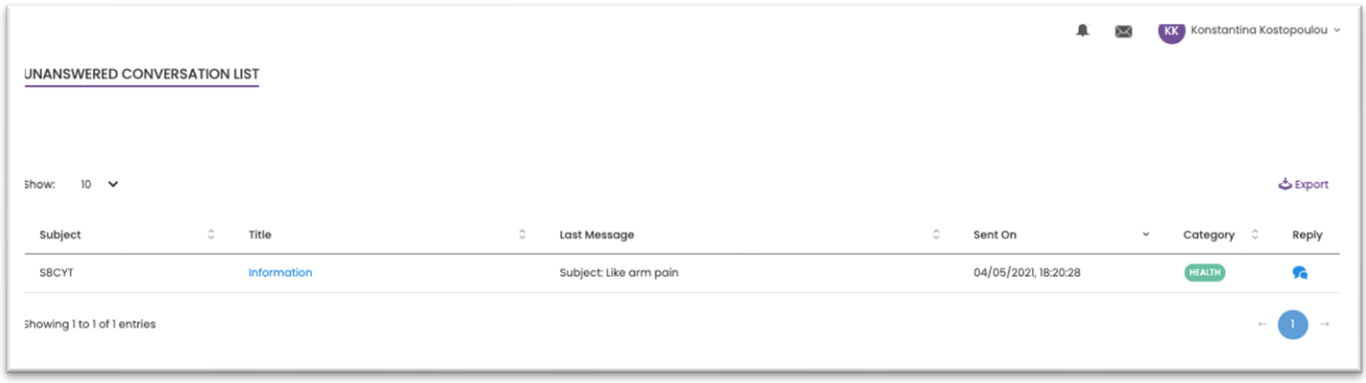

Figure 22 - Message Inbox

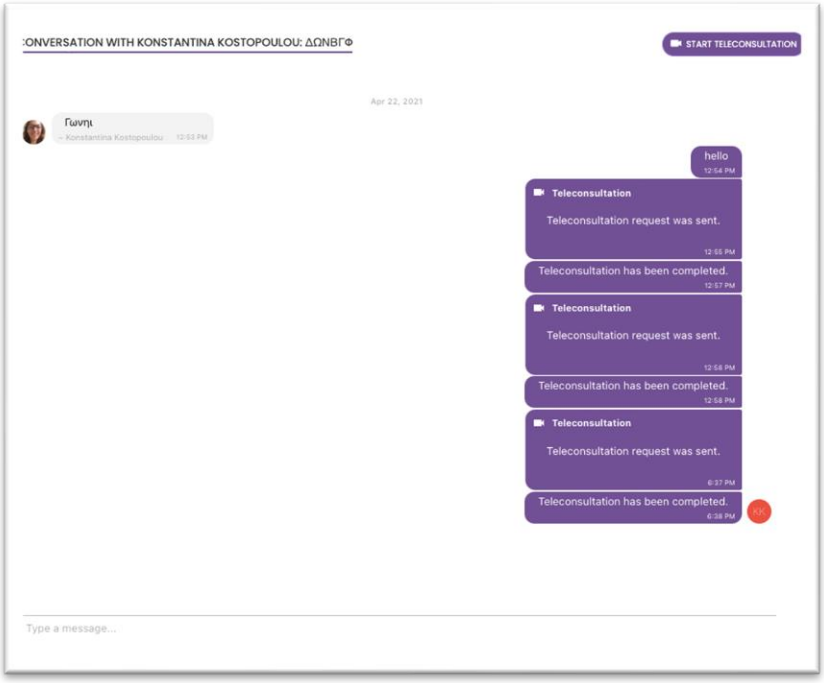

Figure 23 - Message conversation

6.2 TELECONSULTATION

If needed, the investigator can start a teleconsultation video link that will be valid for 15 minutes, as shown in the Figure below.

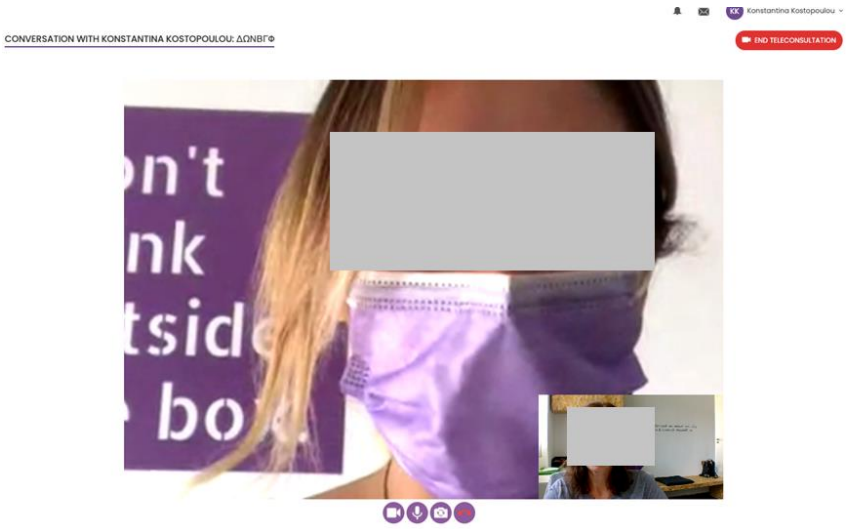

Figure 24 – Teleconsultation

7 ECONSENT

7.1 ECONSENT

If the trial has an active eConsent, the eConsent is triggered by the Healthentia app after the user has registered and agreed with the Terms of the Healthentia application. Each eConsent form must have a unique Version and a unique Title in the context of this study or site (in case of multicenter trials). When creating or editing an eConsent form, users with the appropriate permission shall be able to: (1) add a plain text field to write the "Terms" of the eConsent Form; (2) add a plain text field to write the "Introduction" of the eConsent form; (3) upload a url from a video streaming provider to the eConsent form; and (4) define a Status. An eConsent setup has three status: "draft", "active" and "inactive". While in "draft" mode, the eConsent is editable. Once the investigator changes its status to "active", the eConsent is locked and no longer editable. The "inactive" status is given to eConsent forms that are no longer active but that have been signed at least by one study participant. See Figure 25 and Figure 26.

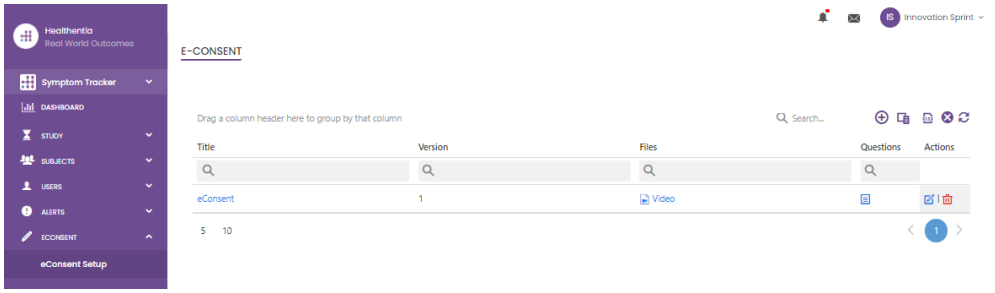

Figure 25 - eConsent list

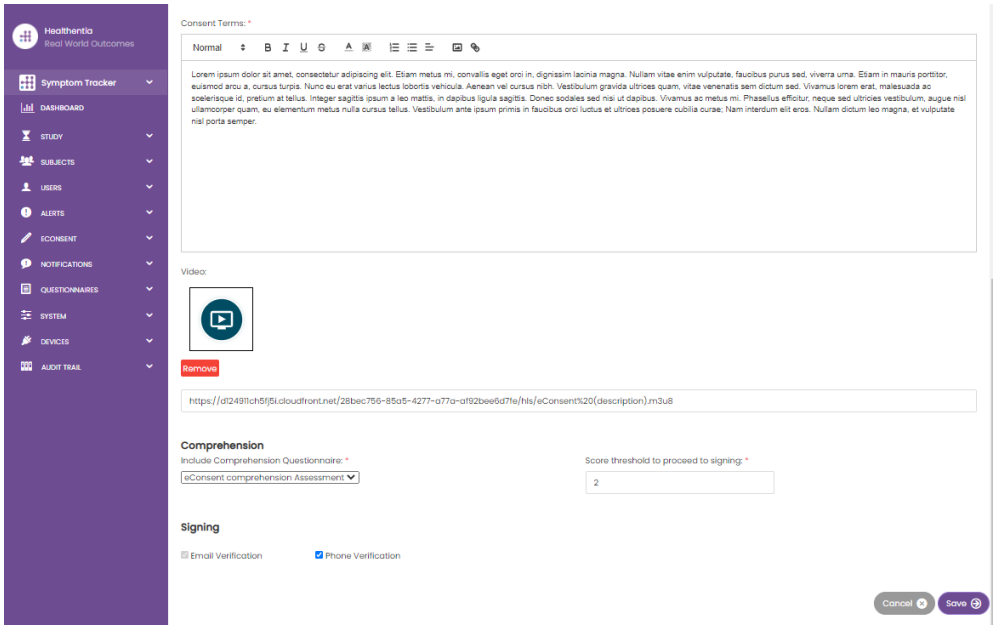

Figure 26 - eConsent configuration

The process of signing an eConsent form can only be completed after a mobile app user has verified his identity providing a code received via email or mobile phone. Once the participant has signed the eConsent, a pdf document is created with the name, date and signature of the participant on top of the Terms plain text. The pdf document created after the participant signed the eConsent is saved in the Healthentia Patient documents with type "consent". Once the participant has signed the eConsent, the tag of the eConsent in the subject list changes from "not started" to "requires signature".

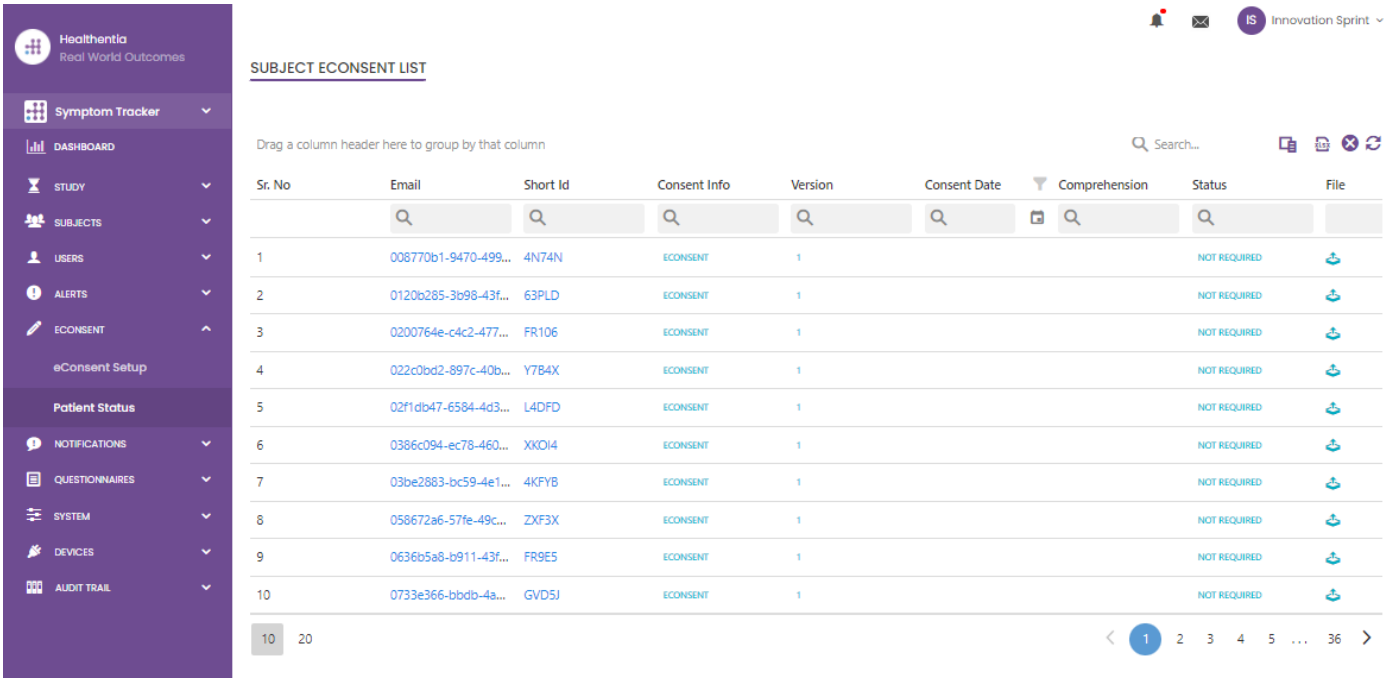

Figure 27 – Subject eConsent list

8 QUESTIONNAIRES

8.1 QUESTIONNAIRE LIST

The portal allows the study coordinators to create a questionnaire with different question types but also allows the questionnaire to be uploaded from a specified excel file. These questionnaires are then sent to the patient through a notification. In the Questionnaire management one can see the list of available questionnaires in the study and the number of questions that each has as well as their status and date created.

A list of qualified questionnaires is made available. A qualified questionnaire, specifically a Patient-Reported Outcome Measure (PROM), in the context of a clinical research system, refers to a standardized, validated instrument used to assess health outcomes directly from patients. Such qualified questionnaires include standardized set of questions and be validated through rigorous scientific processes to ensure reliability, validity, and responsiveness to change. Qualified questionnaires are identified by a tag in the Questionnaire Management tool. This subset of questionnaires is part of the medical modules of Healthentia and are subject to the CE mark. This is also described on the website and a list is available in the portal of the healthcare professionals.

As in all sections of the portal all questionnaires can be exportable to an excel file.

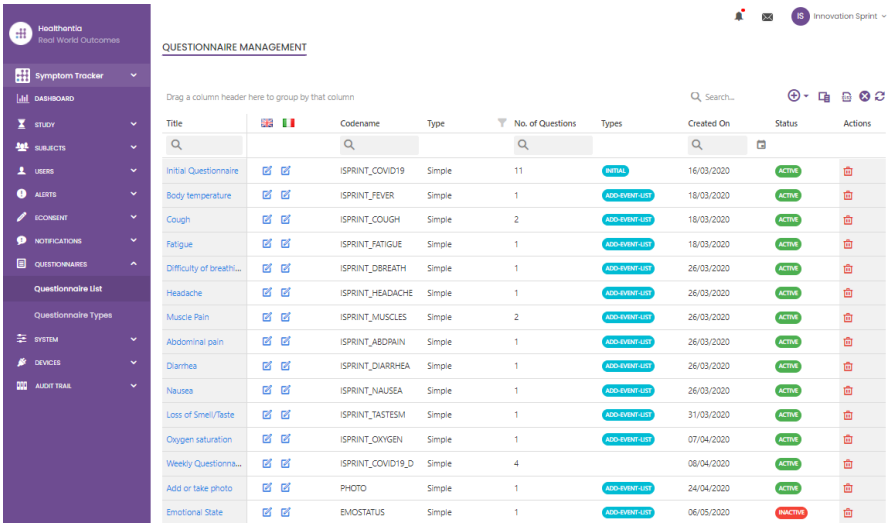

Figure 28 Questionnaire Management

When creating a new one you define the title and questionnaire type (select from a list created by the admin) and upload a characteristic image for it if you want it to be shown on the app and start adding the questions one by one. In the question options you can choose from a variety of UI controls like if the question is a single, multiple, entry text or slider bar as presented in Figure 29.

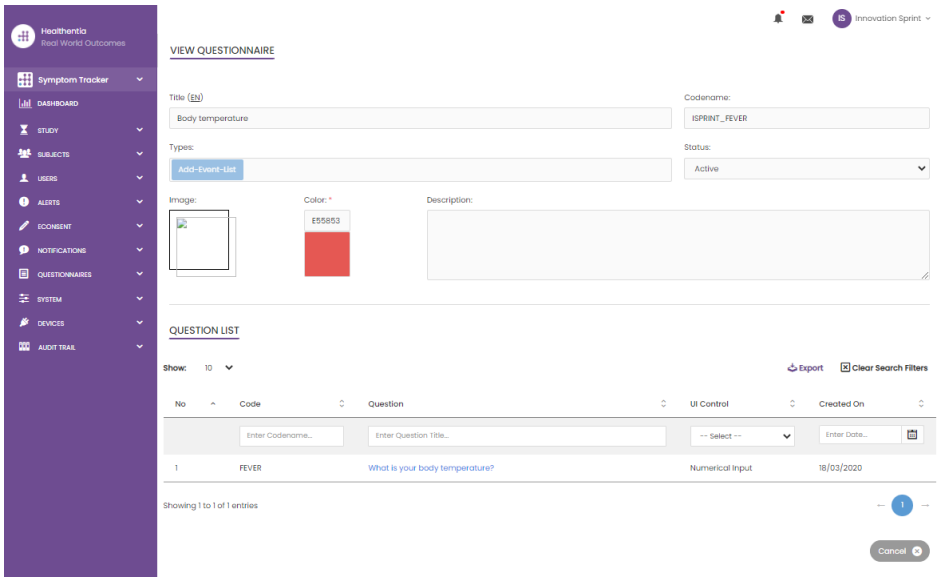

Figure 29 - Simple Questionnaire Details

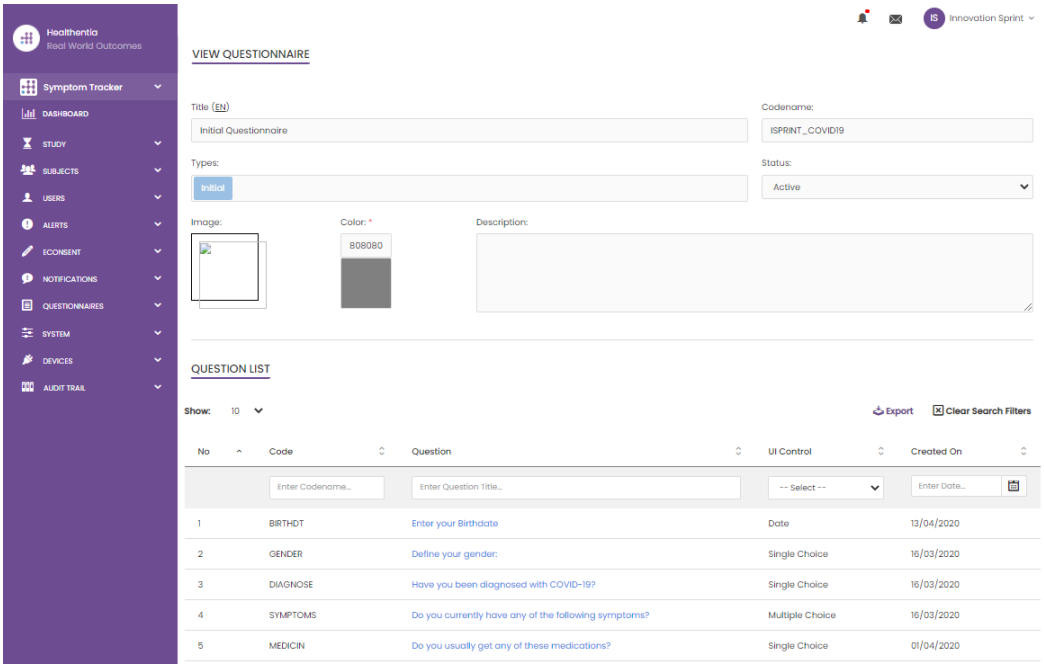

Figure 30 - Composite Questionnaire

9 USERS

9.1 ROLES & PERMISSIONS

This section is used by the admin to create the main roles and their permissions in the portal sections. Permissions can be configured for viewing, editing and delete, as depicted in Figure 31.

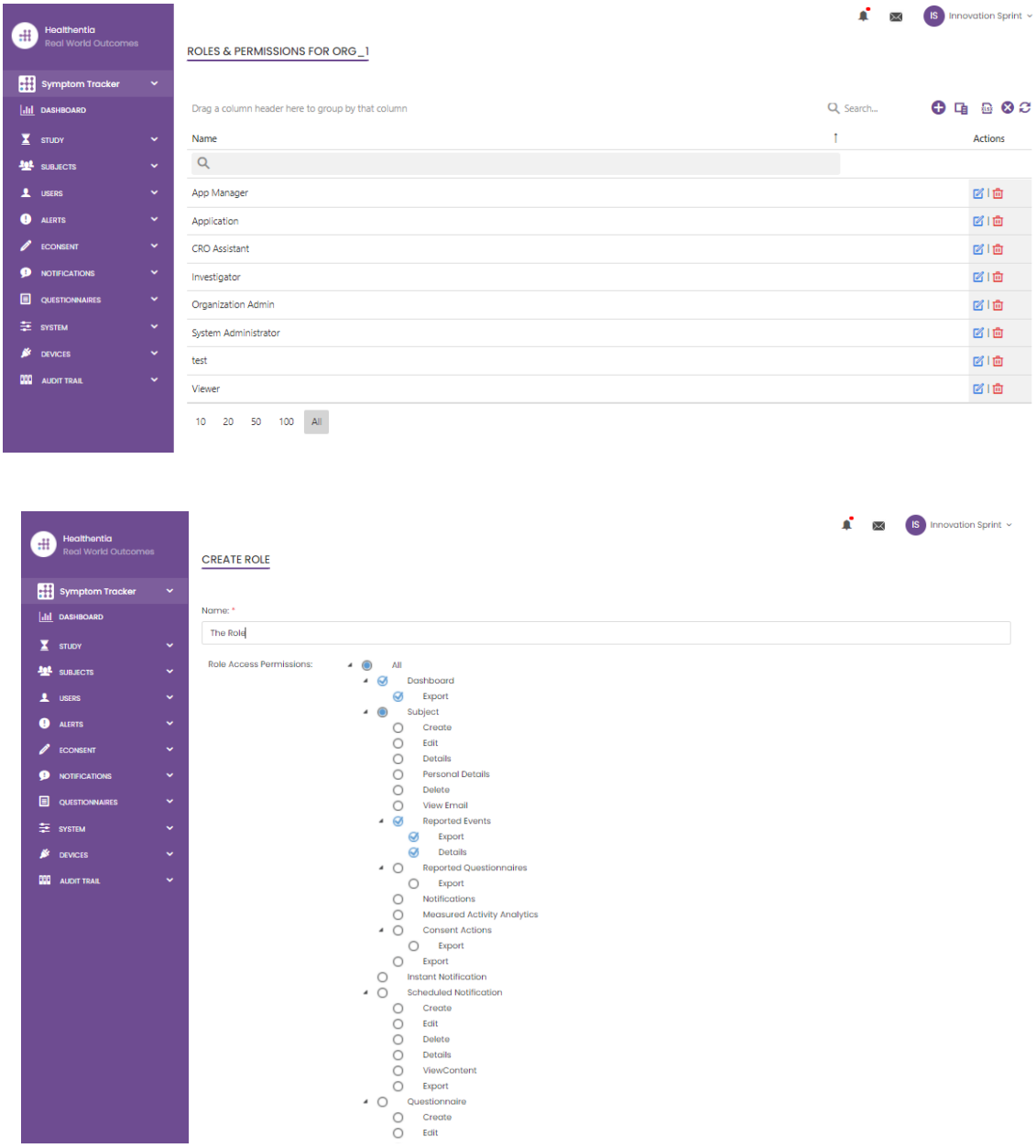

Figure 31 Role Management and Add new Role

9.2 USER LIST

In the users list you can find all the portal users that are assigned in the study. The study admin can create or invite new users or assign existing ones to a specific study with a permission role. The user provides the email of an investigator that triggers an auto generated email to that email. Upon receipt, investigators need to confirm the email and follow a registration. This list can be then exported to an excel, as depicted in Figure 32.

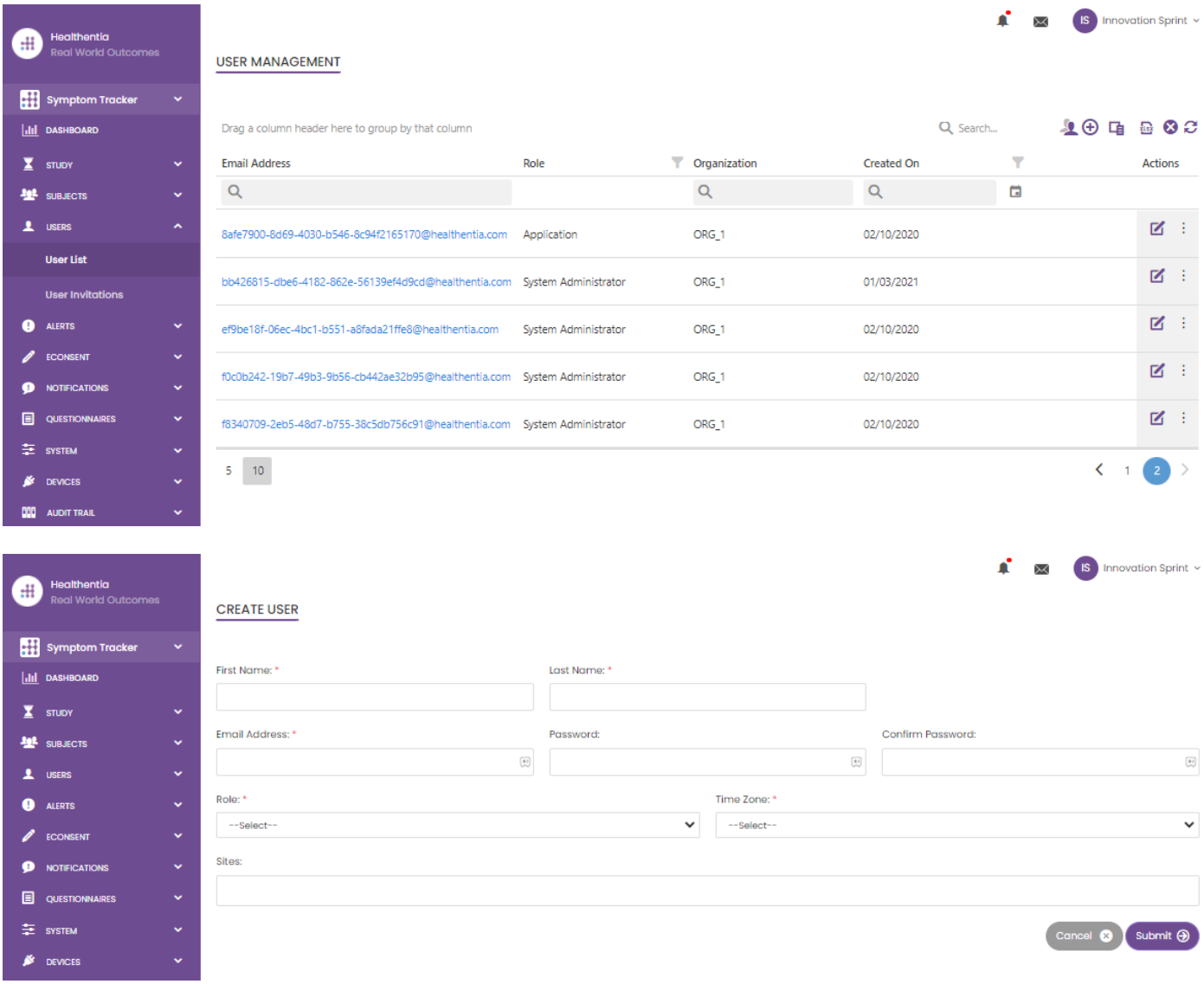

Figure 32 User Management and User Creation

10 AUDIT TRAIL

10.1 PORTAL LOG

In the section of Log Management all actions that users do from viewing to editing or deleting. The log list of actions can be filtered by date from the top of the page, while each column on the table allows the search for a specific result. You can also short by alphabetic or numeric order per column. When viewing the log details you can get more information on the reported action. As in all sections of the portal all data are exportable to an excel file.

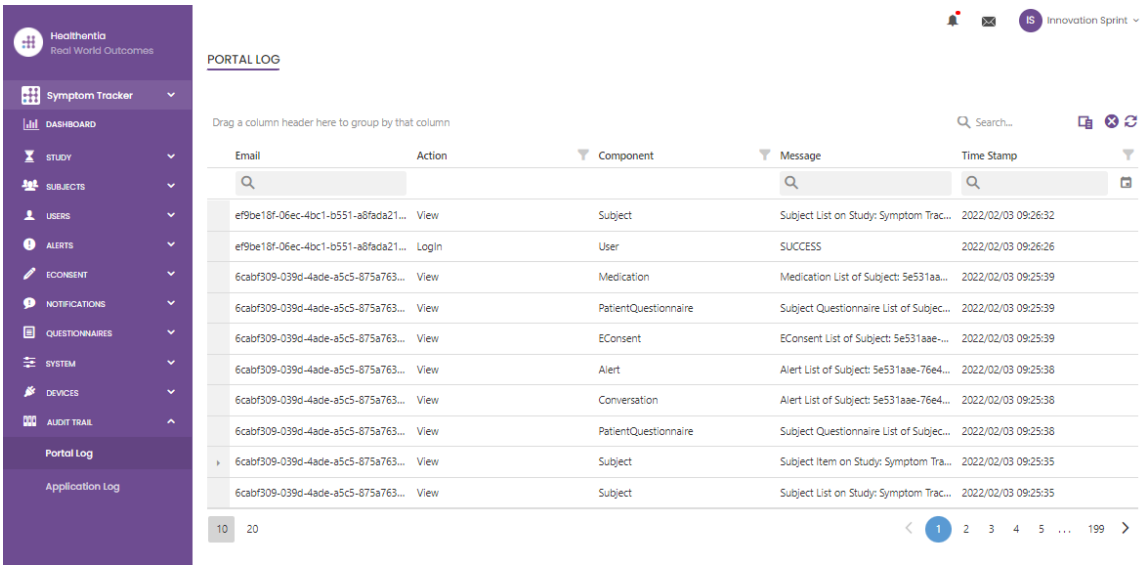

Figure 33 Log Management & Details

10.2 APPLICATION LOG

The application log, provides information about the actions of the subjects, e.g. their participation in questionnaires, as shown in Figure

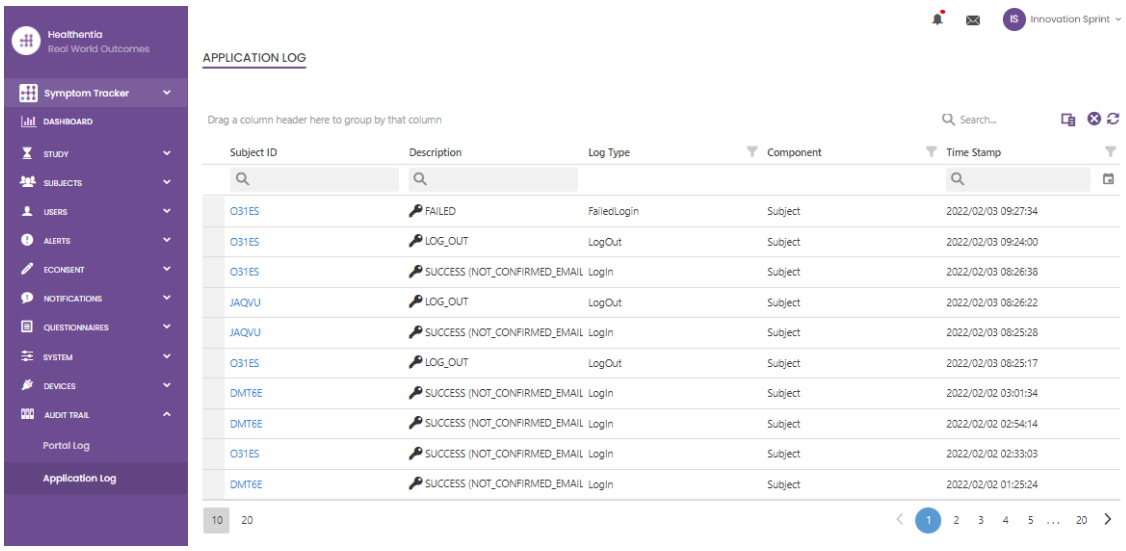

Figure 34 Application Log Detail