



BD4QoL

Big Data models and intelligent tools for Quality-of-Life monitoring and participatory empowerment of head and neck cancer survivors

User manual

Third release – 19/10/2021*

**This manual will be updated until the system is completely integrated and refined*



TABLE OF CONTENTS

1	BD4QoL System.....	3
1.1	System set up.....	3
1.1.1	Physicians scenario set up - Point of Care tool and REDCap for data collection.....	3
1.1.2	Participants scenario set up - Mobile app and questionnaires data collection	6
1.2	System demo	16
1.2.1	Physicians’ scenario - Point of Care tool and REDCap for data collection.....	16
1.2.2	Participants scenario - Mobile app and questionnaires data collection	29
1.2.3	Integrated scenarios.....	44
1.3	Test scenarios	45
1.4	Test Reporting	47

1 BD4QOL SYSTEM

BD4QoL system is composed of two main scenarios: one for physicians and one for participants.

Physicians' scenario is composed by the Point of Care (PoC) application, a decision support system and workflow management system for clinicians dedicated to head and neck cancer follow-up, visualization and management. This application gathers data from head and neck cancer survivors using custom-made mobile applications, patient input values in web questionnaires and the REDCap platform, a secure web application for building and managing online surveys and databases.

Participant's scenario is composed of two mobile applications: first a foreground application named 'foreground BD4QoL' for automatic data collection. The second, an android based mobile application named 'BD4QoL' that collects external data obtained from Google Fit (available in the App Store) as well as phone usage related data. The mobile app also includes the friendly Bidi chatbot, an interactive AI-based assistant that provides helpful information and assess subjective emotions. Apart from the data collection, the app provides dashboards and personal reports for the participant.

1.1 System set up

1.1.1 Physicians' scenario set up - Point of Care tool and REDCap

- **PoC set up:** The credentials for the PoC users are provided by UPM, being the default password the same as the given username. Afterwards, the clinicians will receive an email from bd4qol.keycloak@gmail.com to verify their account and set a new password. The PoC tool can be accessed through the link <https://pocool.web.app/> at any web browser. The detailed steps for the setup are described below.

1. Automatic email to update your account (Figure 1)

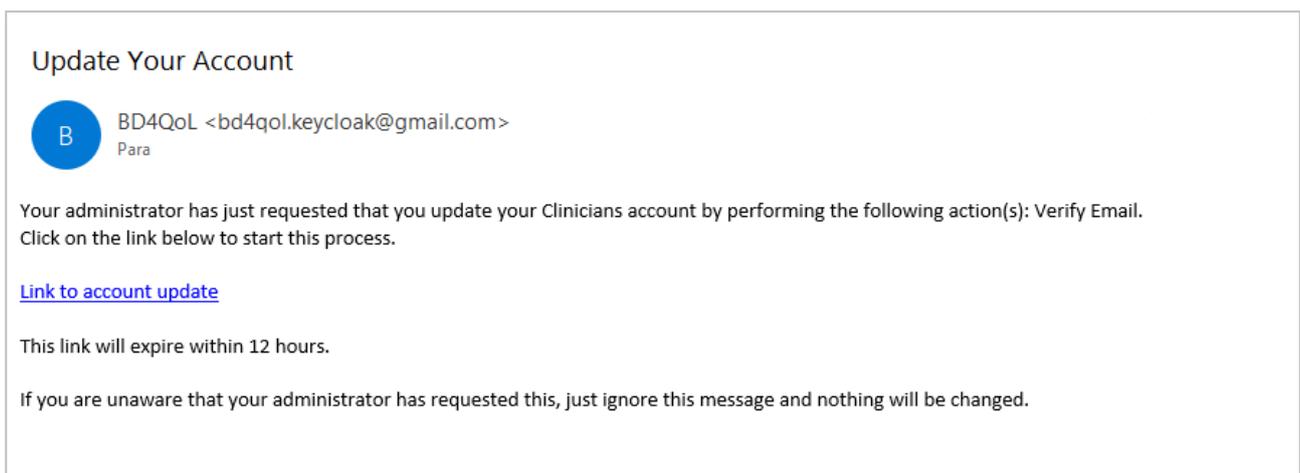


Figure 1. Email to set the password for the PoC tool

2. Click on the 'Link to account update' in the email to set your password. Once it is done, a confirmation message will appear (Figure 2).

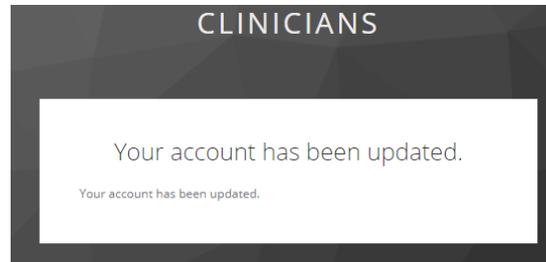


Figure 2. Confirmation of PoC password setup

3. Log in the PoC tool through this link <https://pocool.web.app/> with your credentials (username and password from step 2). If you do not remember, try the 'Forgot Password' option to set a new one.

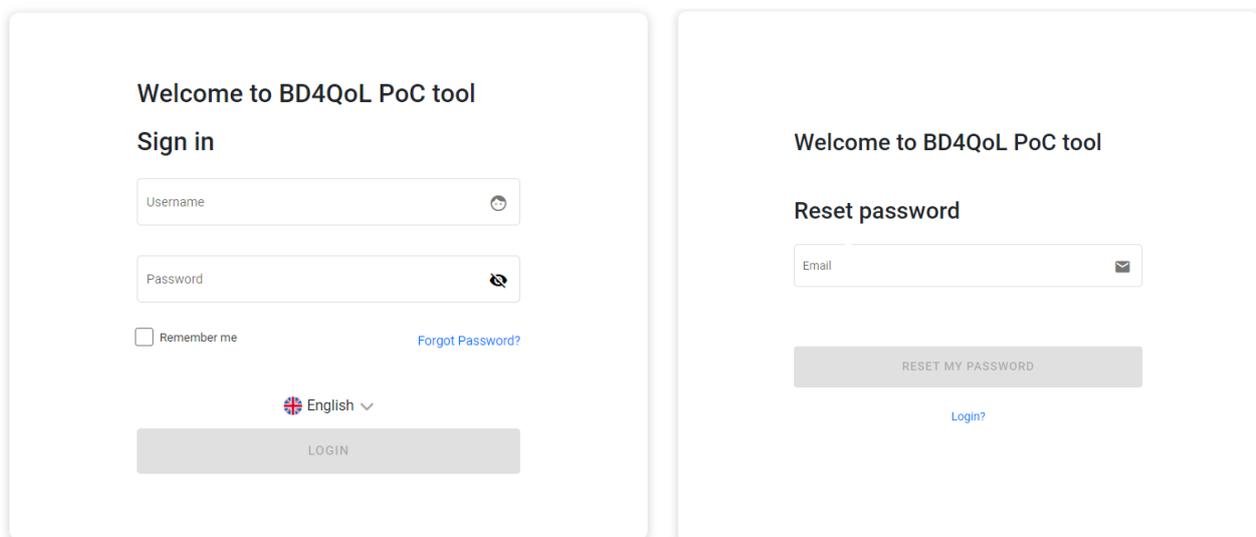


Figure 3. PoC tool login screen.

- **RedCap set up:** REDCap user credentials are also provided by UPM. The clinicians will receive an email from no-reply@cervima.upm.es to verify their REDCap account and a second email when they gain access to the BD4QoL-eCRF project. The REDCap platform can be accessed through the following link <https://redcap.cesvima.upm.es/> at any web browser. The detailed steps for the setup are described below.

1. Automatic email example to verify your REDCap account (Figure 4)

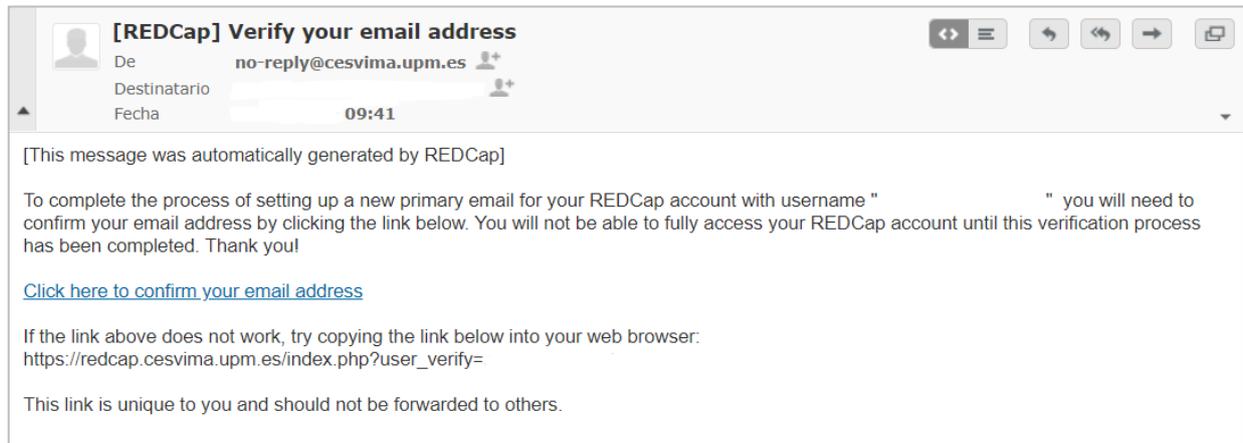


Figure 4. Email to set the password for the REDCap tool

2. Click on the 'Click here to confirm your email address' link to set your password. Once it is done, a confirmation will appear (Figure 5). Optionally, you can also set a recovery question.

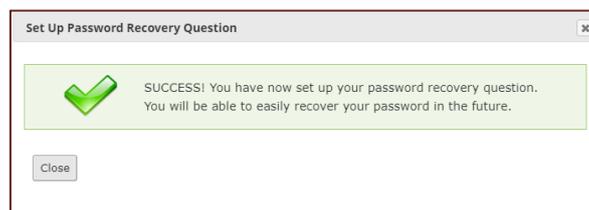


Figure 5. Set the REDCap password

3. You will receive a second email once you are included in the BD4QoL project (Figure 6).

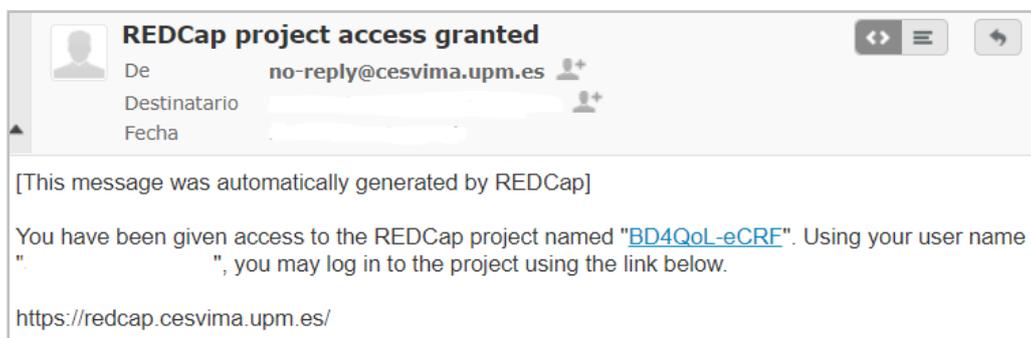


Figure 6. BD4QoL R

4. Login in REDCap with your credentials (username and password the one set up in step 2) as shown in Figure 7. If you do not remember, try the ‘Forgot your password’ option to set a new one.

Support CeSViMa.' There are two input fields: 'Username:' and 'Password:'. The 'Password:' field is masked with dots. Below the input fields is a 'Log In' button and a link for 'Forgot your password?'." data-bbox="121 190 889 394"/>

Figure 7. REDCap platform login screen.

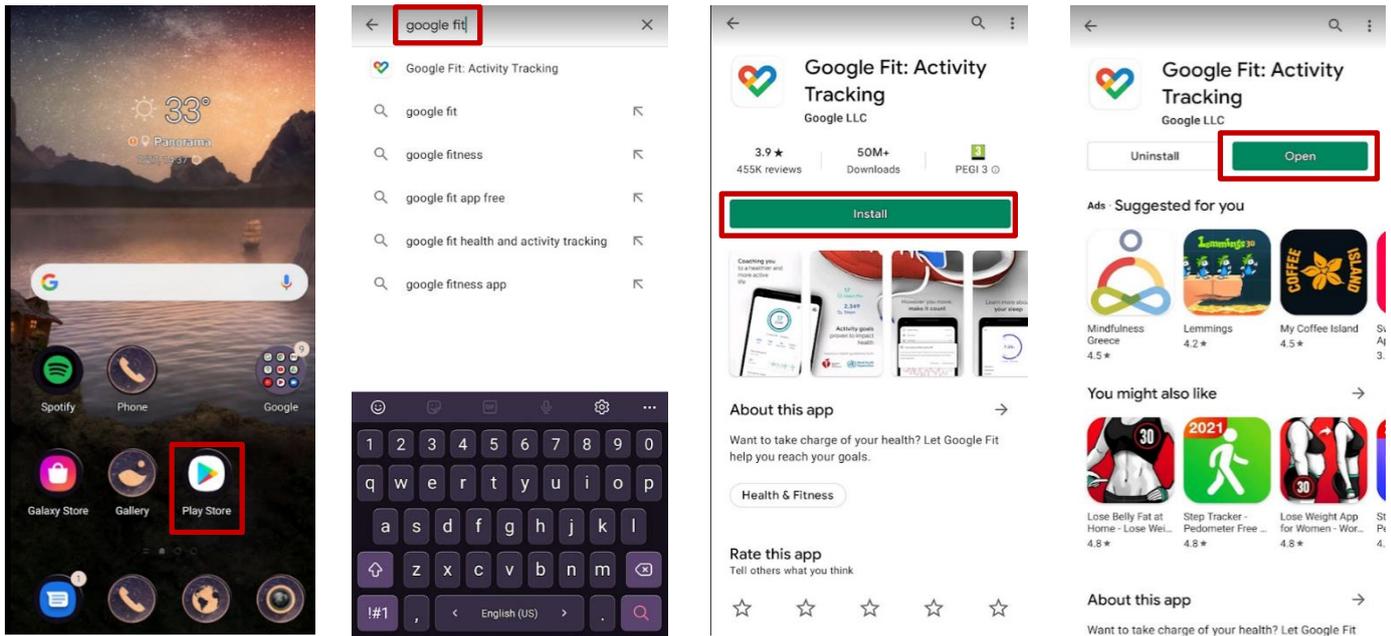
Once the setup for the PoC tool and REDCap platform is finished, the clinicians can start using both applications using the functionalities described in Section 1.2.

1.1.2 Participant’s scenario set up - Mobile app and questionnaires

- **Mobile app:** The data collection of the mobile app is based on three applications:
 - a) Google Fit app for collecting daily steps.
 - b) The foreground BD4QoL app for collecting data measurements as GPS, accelerometer, WiFi connections and screen time.
 - c) The main BD4QoL app for collecting smartphone device data and synchronization of data from Google Fit.

The instructions for the installation and permissions are described as follows:

1. Download Google Fit from Play Store



Locate the Play Store con in your smartphone.

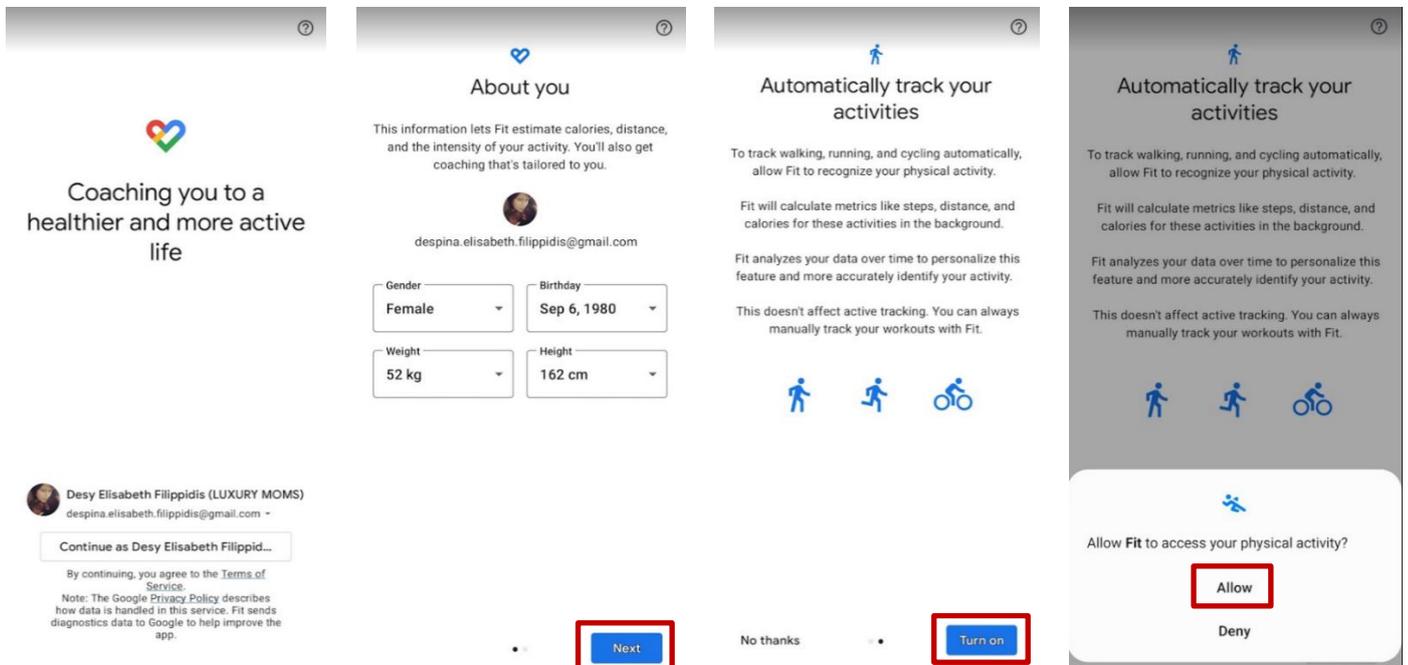
In the Play Store type 'google fit' in the search bar.

Press Install button to start Google Fit installation.

Once installed, press 'Open' to open Google Fit.

Figure 4. Installing Google Fit from the Play Store

2. Open and Login into Google Fit – follow the instructions below



Open the Google Fit app and login with your preferred Google account.

Setup your profile in Google Fit and press Next.

Press Turn on to allow Google Fit to automatically track your activities.

Press Allow to allow Google Fit to track your physical activity.

3. Enter the link and go to the spreadsheet “download mobile apps”. The app downloads will be soon available in the webpage of BD4QoL.

	A	B
1	Foreground	https://bd4qolfit.eu/BD4QoL_ForegroundService
2	Main app	https://bd4qolfit.eu/bd4qol_beta_v1.0.6.apk
3		
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Excel file with the updated applications:

<https://docs.google.com/spreadsheets/d/1cPcFmz5kMfb8f-ic49Rt0q8o1-slbanPcd09IOSwOxs/edit#gid=146445189>

You need to download both apks:

1. Foreground application

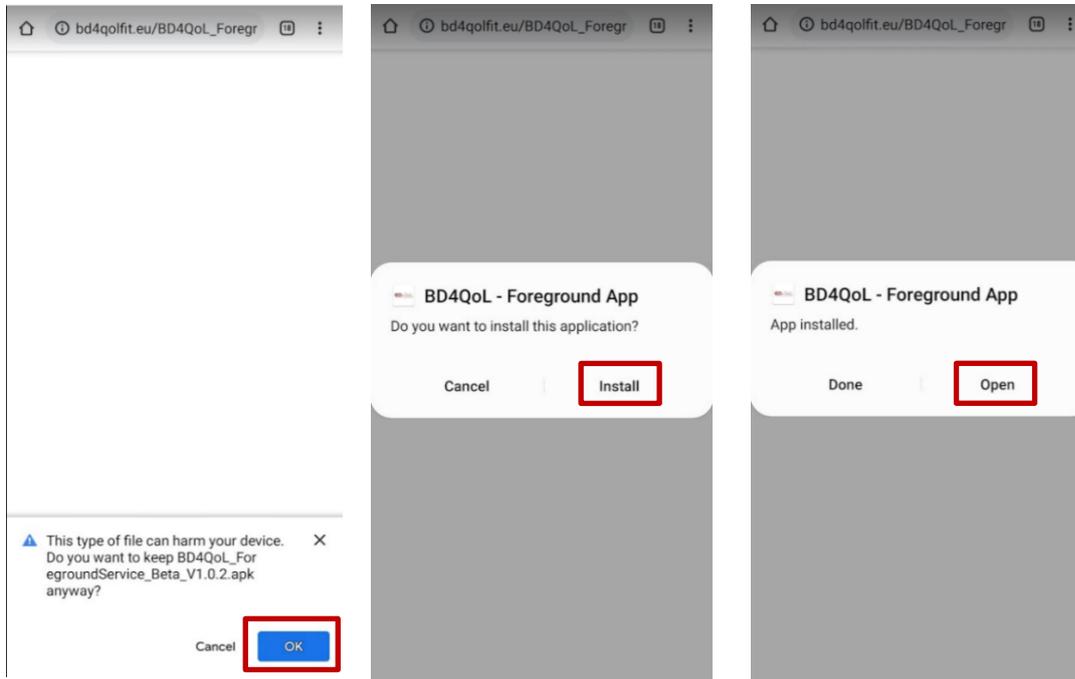
https://bd4qolfit.eu/BD4QoL_ForegroundService_V1.5.1.apk

2. Main BD4QoL application

https://bd4qolfit.eu/bd4qol_1.0.4.apk

Figure 5. Locating the mobile apps to download

4. Download first the foreground mobile app and then install it



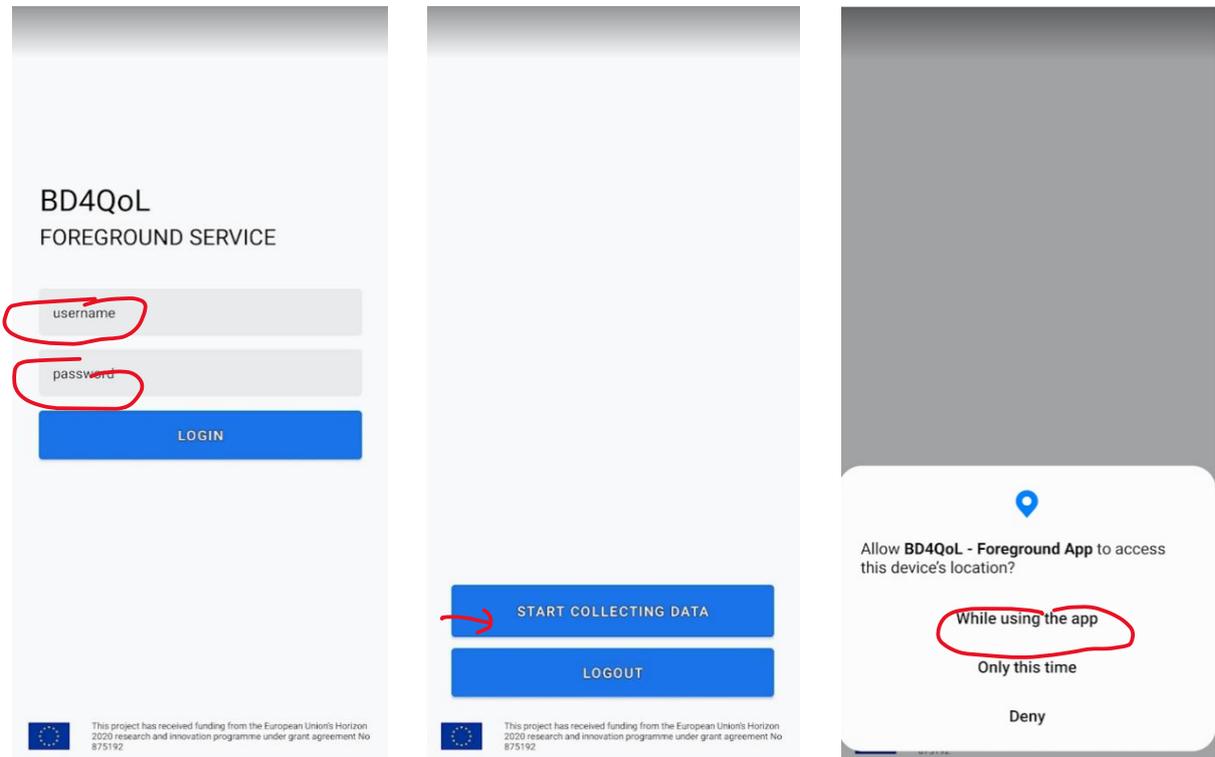
Press **OK** to download the foreground app.

Press **Install** to start the installation process.

Once installation finishes press **Open** to open the app

Figure 6. Installation and login setup into for the foreground mobile app

5. Login into the foreground mobile app – follow the instructions below for setting up permissions

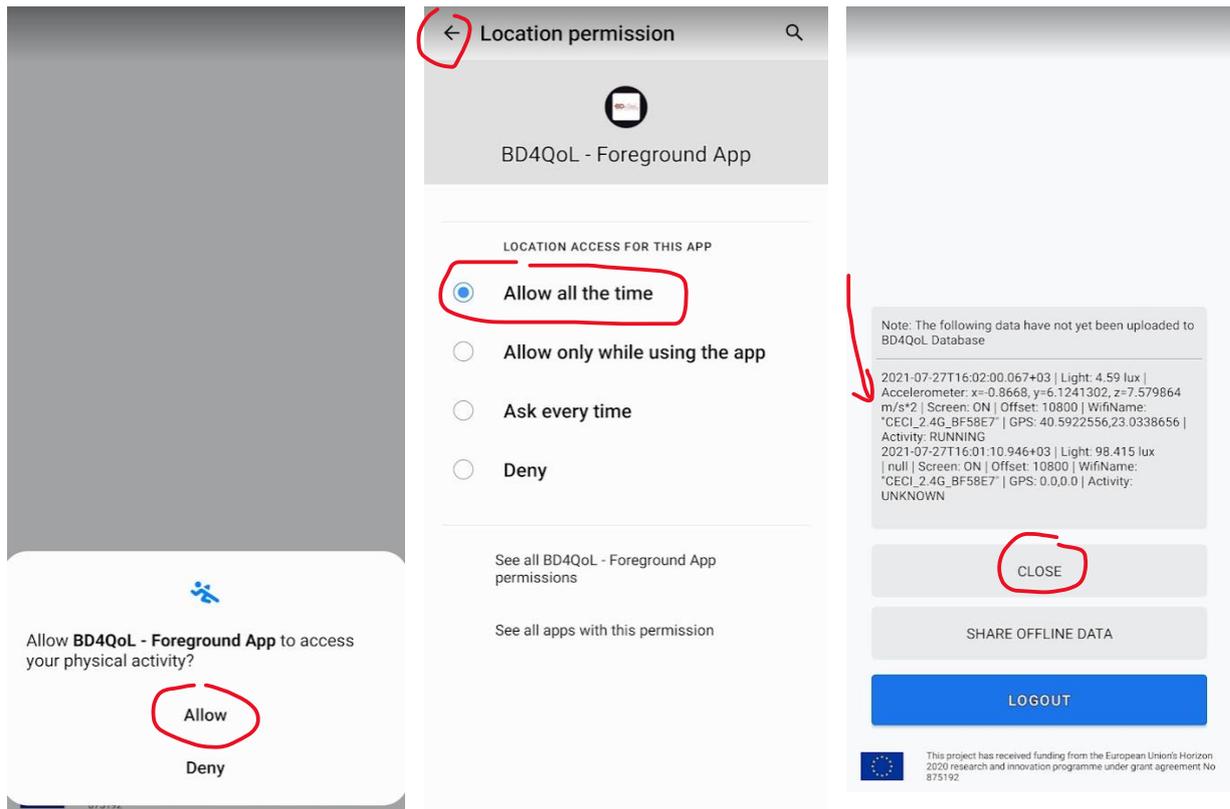


When opening the foreground app for the first time you see this screen. Please type in the username and password areas your credential as a clinical trial participant. Then press Login.

After successfully logging in, then press START COLLECTING DATA

To allow GPS data collection press initially While using the app

Figure 7. First time login into the foreground app and setup



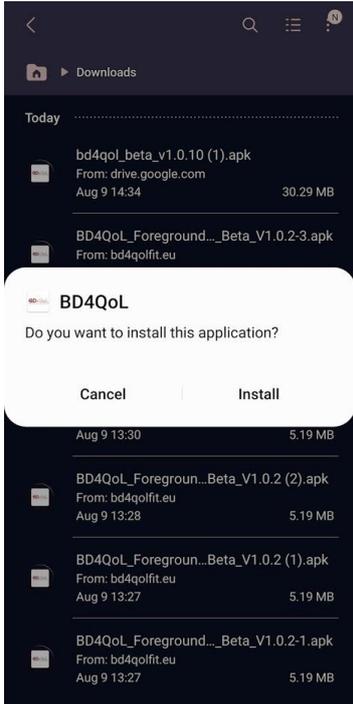
To allow physical activity data collection press **Allow**

In this screen, make sure you select **Allow all the time**. By default the second choice is shown *Allow only while using the app*. Change this to *Allow all the time* and then press the left top arrow.

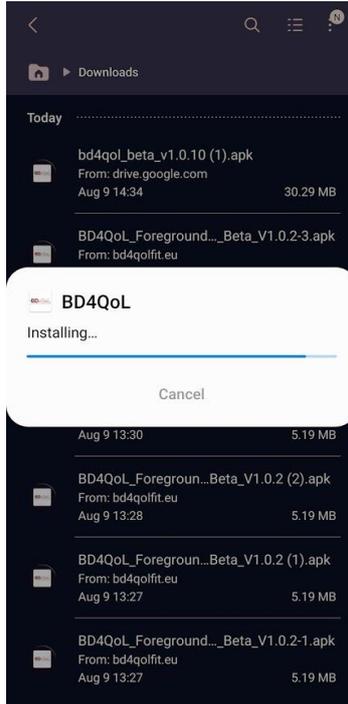
In the next screen you will start collecting data. This will be synced to the main database 3 hours later. The data includes: timestamp (UTC based), the offset (ex. +03 hours for Greece), Light level in Lux, the Accelerometer measurements (x,y,z), the Status of the screen (On or OFF), the UTC offset in seconds, the WiFi connected (if any), the GPS (Lat, Long) and the personal physical activity (initial it starts from Unknown until a person moves and changes physical “state”). You can press **Close**.

Figure 8. Setting up permissions for first time login with the foreground mobile app

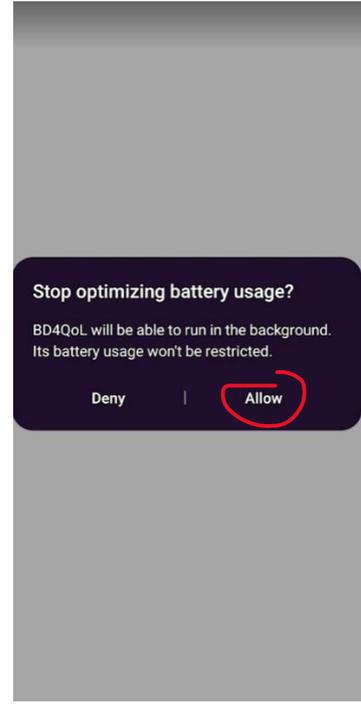
6. Download and Install the main mobile app – follow the instructions below



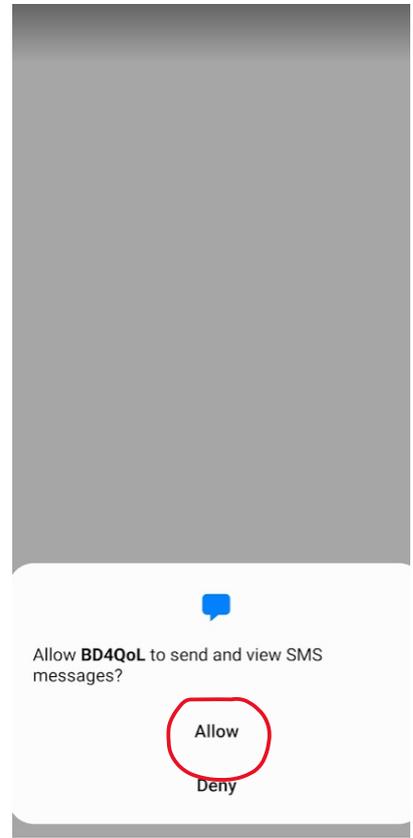
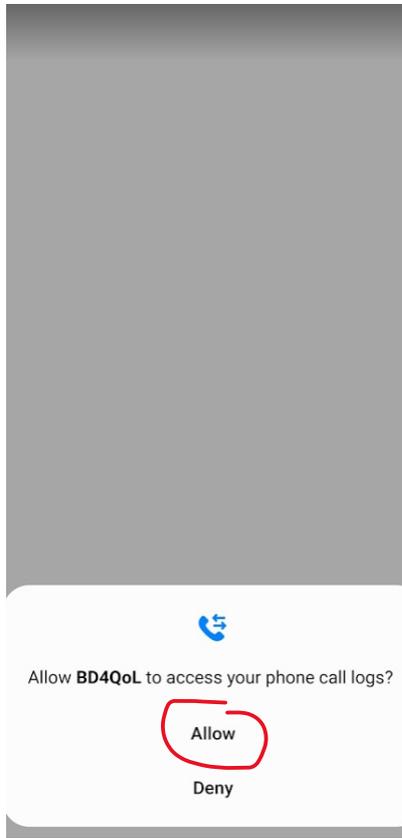
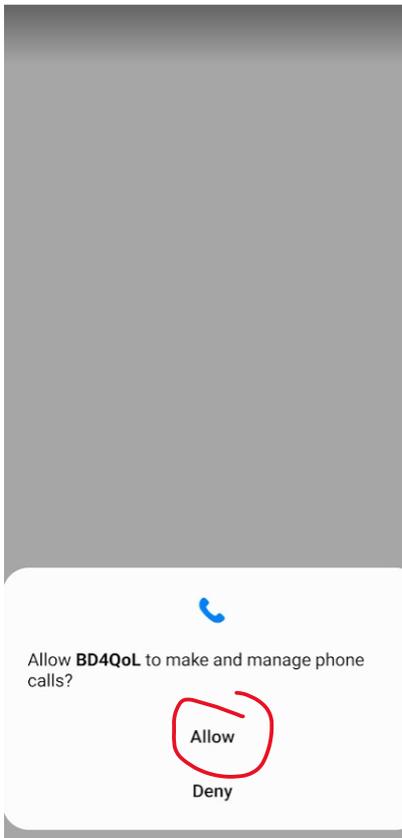
Install the app



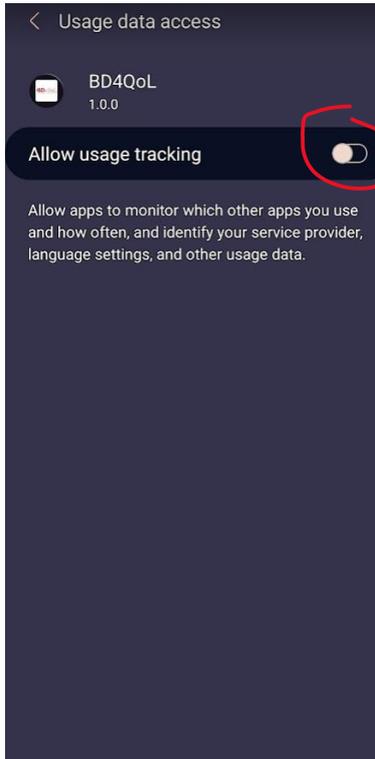
Once the installation comes to an end, then press Open



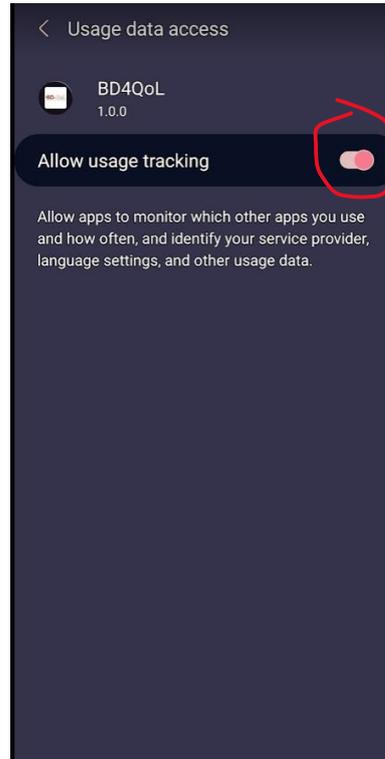
To allow operation of the app in the background, press Allow



Press **Allow** so that data about the calls done can be collected



Press **Allow** so that data about the calls done can be collected

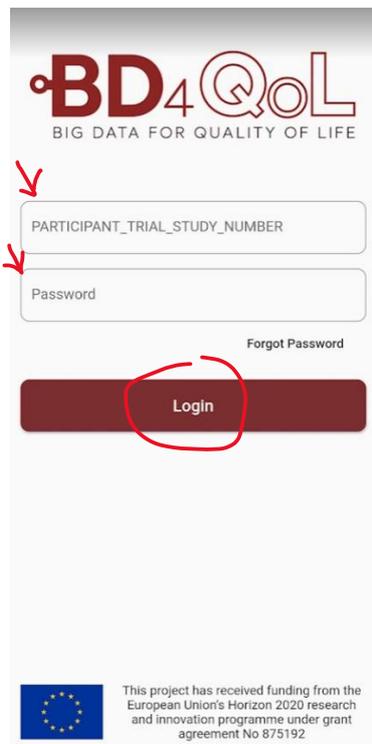


Press **Allow** so that data about SMSs can be collected

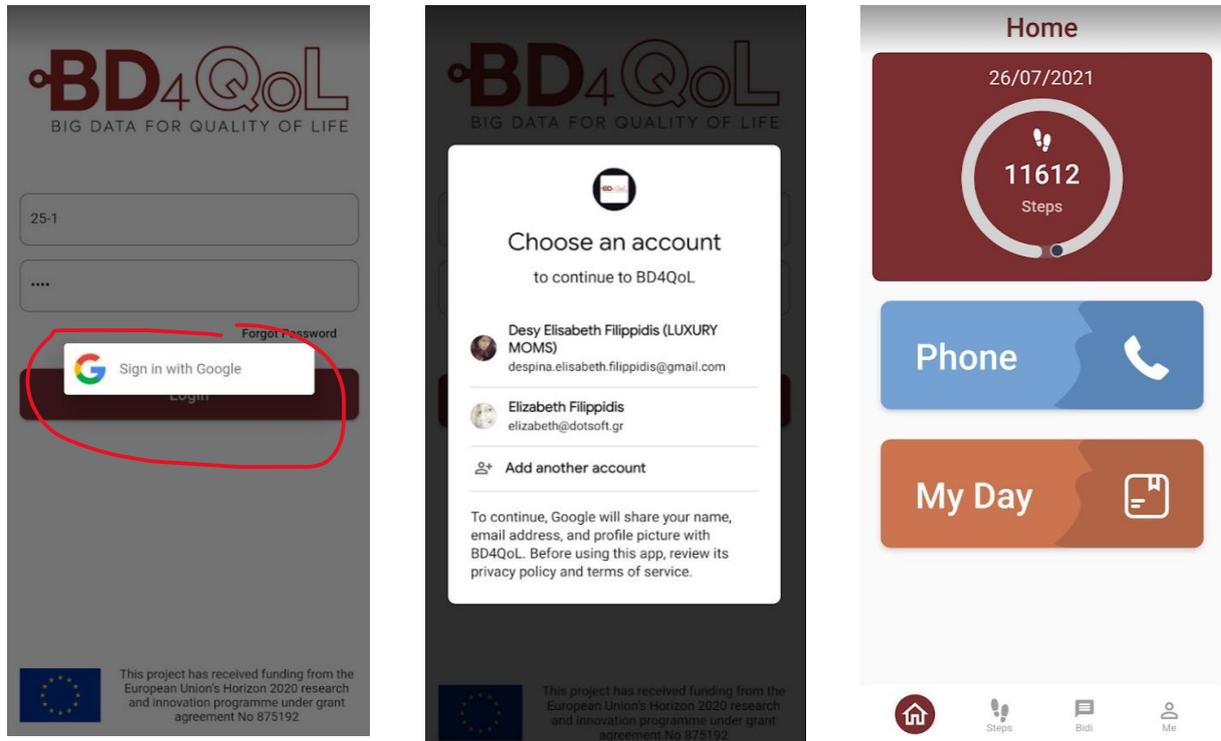
The next screen prompts the user to allow usage tracking, so that data from phone applications can be tracked. By default this is Off. The user needs to turn it on.

Figure 9. Installation and first time setup of main mobile app

7. Login into the main mobile app – follow the instructions below



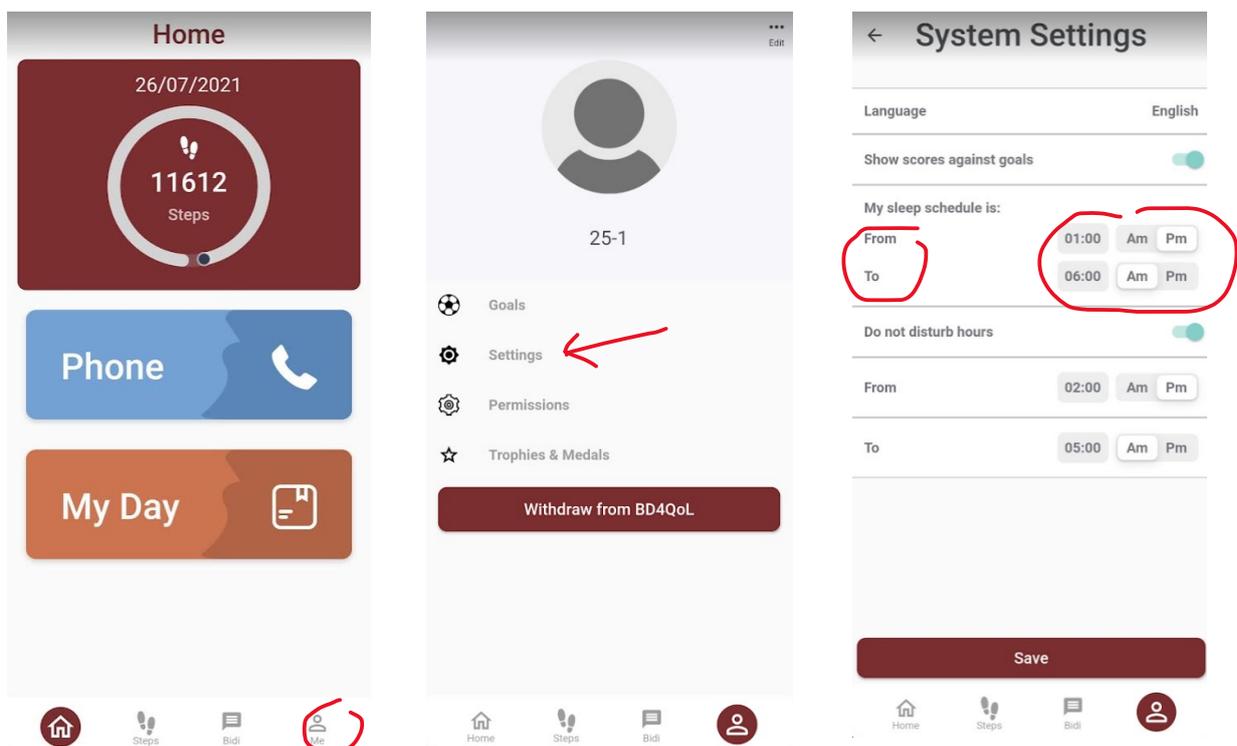
The main BD4QoL app should now open automatically (if not, locate it and open it). You then need to login. Please type your **PARTICIPANT_TRIAL_STUDY_NUMBER** (username) and your **password** and then press **Login**

Figure 10. First time login to the main mobile app**8. Connect your mobile BD4QoL account with Google Fit**

Press **Sign in with Google**

Select the Google account that is already connected with Google Fit

Then you automatically see the Home screen of the mobile app

Figure 11. First time connection with google fit account**9. Go to Settings and set your usual Sleep Schedule [obligatory for first time]**

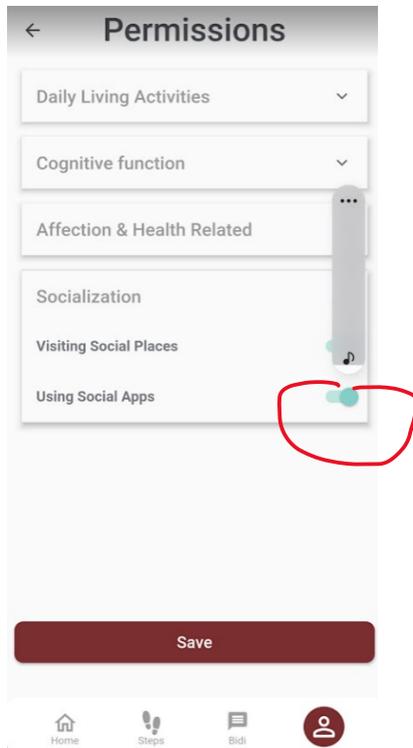
From Home screen select **Me**

Select **Settings**

Select the sleep schedule **From**
and **To** hours.

Figure 12. First time configuration of Settings

10. Go to Permissions and set your Socialization permissions [obligatory for first time]



The Using Social Apps is by default Off. If you wish to allow tracking of the time you spend at social apps, you should press it to turn it on.

Figure 13. First time configuration of Permissions

- **Questionnaires app:** In order to access the questionnaires, you need to login here <https://questionnaires.bd4qolfit.eu/login> .

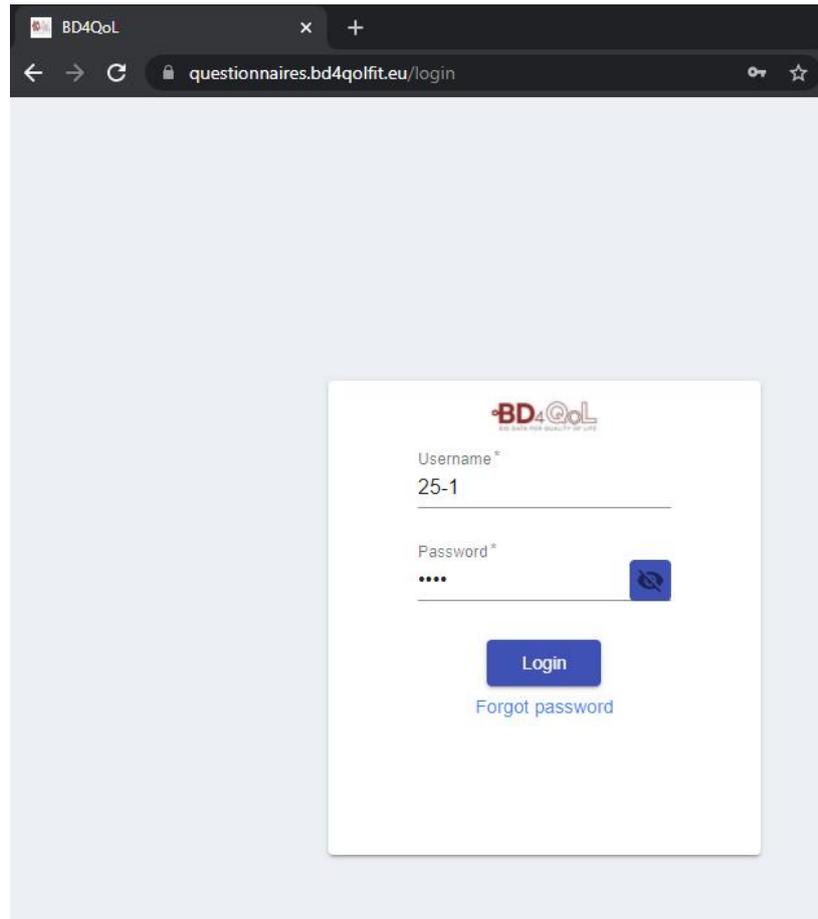


Figure 14. Questionnaires app login

1.2 System demo

1.2.1 Physicians' scenario - Point of Care tool and REDCap

The PoC tool includes several functionalities to manage the BD4QoL data. Once the users log into the PoC through the weblink <https://pocool.web.app> (see Section 1.1), clinicians access an overview of the Patient Information module. There is a sidebar navigation menu in every screen of the PoC tool that provides access to the five main modules (Figure 19, red square): Patient List, Trial Dashboard, Exploratory Dashboard, Visit Management and Alert Management, and the utility navigation menu (Figure 19, blue square) on the top-right corner allows essential functionalities as full-screen switch, notifications such as symptom alerts, and logout.

A) Navigate through the Patient Information

The main patient list (Figure 19) is ordered by patients' id number and shows their enrolment date, latest updates, the study arm they belong to, their status on the study (either *Active* or *Withdrawn*) and the eCRF data. The PoC users can enrol a new patient through the 'Data Collection (REDCap)' button and access patient's information by clicking on a particular id.

Study ID	Update	Randomization Date	End Date	Study Arm	Enrollment	View CRF Data
25-1	21-09-2021	24-06-2021	—	Intervention	Active	
25-2	24-06-2021	24-06-2021	—	Intervention	Active	
25-3	08-09-2021	24-06-2021	—	Intervention	Active	
25-4	10-08-2021	24-06-2021	—	Intervention	Active	
25-5	13-08-2021	24-06-2021	—	Intervention	Active	
25-6	13-08-2021	01-07-2021	—	Intervention	Active	
25-7	01-07-2021	01-07-2021	—	Intervention	Active	
25-9	19-07-2021	19-07-2021	—	Intervention	Active	
25-10	15-07-2021	15-07-2021	—	Intervention	Active	
25-11	20-07-2021	20-07-2021	—	Intervention	Active	

Figure 19. Patient list main dashboard.

After clicking on a patient id, a screen with basic demographic data and the study trial conditions appears (Figure 20). There also is a drop down list with the results of the five quality of life questionnaires that patients have to fill when enrolling the study.

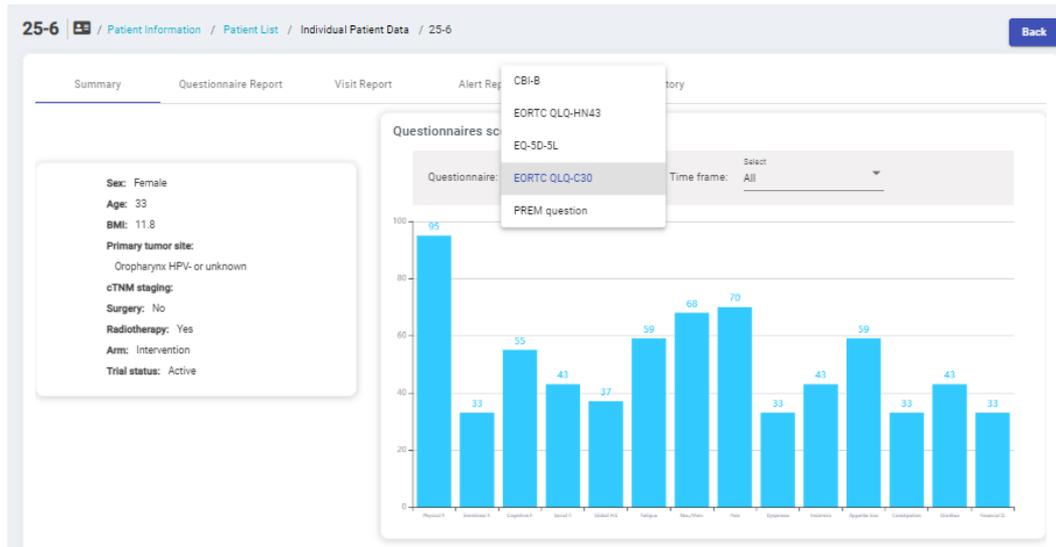


Figure 20. Patient summary basic data and questionnaires

Within the same screen, scrolling down, the user can visualize the phone-based data collected in terms of steps, non-sleep events rates, phone usage and affective traits. This data can be visualized by week, month, or year. There is also a ‘help’ icon for every chart with a short description. Figure 21 shows an example of these graphs.

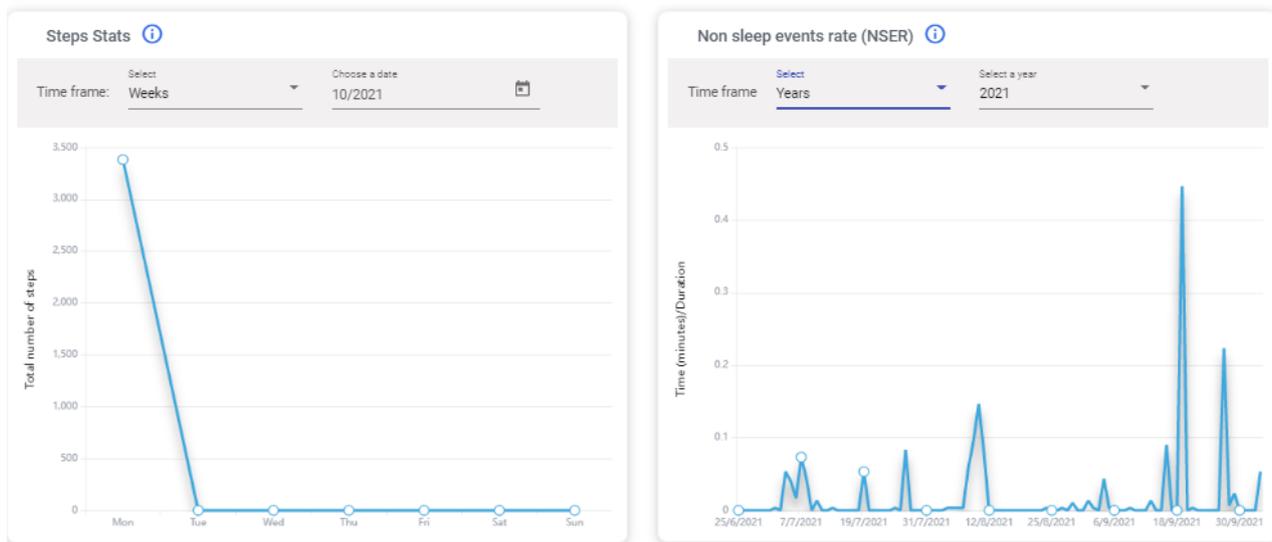


Figure 21. Patient summary phone gathered data displayed.

Navigating through the menu of the Patient Information module, the user can also access the questionnaire report, visit report, alert report, and communication history. At the Questionnaire Report (Figure 22) the user can check the data from previous questionnaires and inspect if there are any pending or outdated missing questionnaires.



Summary Questionnaire Report Visit Report Alert Report Communication History

Patient questionnaires Filter by questionnaire: Select All Patients' QoL questionnaires: <https://questionnaires.bd4qoL.eu>

Date	Questionnaire	Type	Status	Last follow up	Actions
02-08-2021	OLQ-HN43	QoL	Missing	+0 months	—
02-08-2021	EQ-5D-SL	QoL	Missing	+0 months	—
02-08-2021	OLQ-C30	QoL	Missing	+0 months	—
02-08-2021	PREM-question	PREM	Missing	+0 months	—
02-08-2021	CBiB	PROM	Missing	+0 months	—
02-02-2022	OLQ-C30	QoL	Complete	+6 months	👁️
02-02-2022	OLQ-HN43	QoL	Complete	+6 months	👁️
02-02-2022	CBiB	PROM	Complete	+6 months	👁️
02-02-2022	EQ-5D-SL	QoL	Complete	+6 months	👁️
02-02-2022	PREM-question	PREM	Complete	+6 months	👁️

Items per page: 10

Figure 22. Questionnaires report screen.

At the Visit Report (Figure 23) the user can check the data from previous visits (orange icon) or fill in the form for a pending visit by accessing the REDCap platform through the edit option (grey icon). To schedule a new unplanned visit the user may click on the ‘New Unplanned Visit’ button and specify a date. Pending visit dates can be modified at any time.

Summary Questionnaire Report Visit Report Alert Report Communication History

Patient visits New Unplanned Visit

Reason	Date	Status	Timing	Actions
Planned	13-02-2022	Pending	+12 months	✎️
Planned	13-08-2021	Complete	+6 months	👁️
Planned	02-08-2021	Complete	+0 months	👁️

Items per page: 10 1 - 3 of 3

Figure 23. Visit report screen menu.

At the Alerts Report screen (Figure 24) the user can check alerts generated from the BD4QoL mobile application. The list shows the date when the alert was generated, the frequency of appearance which influences the priority assigned, and the type of the alert, which can be related to social activity, physical activity or non-sleeping hours. The symptom level may be low priority (green), mid priority (yellow), high priority (red) or no symptom related (blue).

Summary Questionnaire Report Visit Report Alert Report Communication History

Patient alerts

Date	Frequency	Type	Origin	Symptoms	Status	Physicians Comments	Symptom Level	Actions
05-10-2021	2 time	Sleeping	Behaviour decay	Sleep decay: Patient ignored notification.	Complete	—	●	Managed by the chatbot
05-10-2021	1 time	Social	Behaviour decay	Social decay: Patient ignored notification.	Complete	—	●	Managed by the chatbot
04-10-2021	3 time	Social	Behaviour decay	Social decay: Patient ignored notification.	Pending	—	●	Go to manage alert

Figure 24. Alert Report screen menu.

The last column indicates how the alert was managed, otherwise the message link ‘Go to manage alert’ appears. Here the PoC users can manage any pending alert for this specific patient (by email, call, sending a writing message or creating an unscheduled visit) and add pertinent comments in the ‘intervention modal’ screen that appears after clicking the link (see Figure 25).

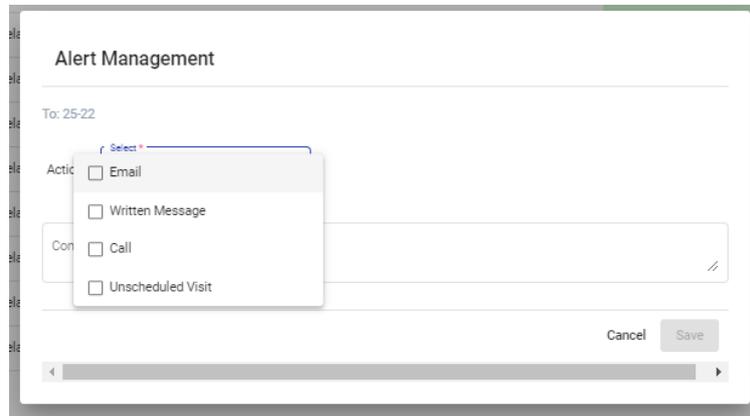


Figure 25 Intervention modal pop up screen.

After selecting a management option, the status of the alert will automatically change to ‘Complete’ and the last column ‘Action’ will specify the intervention selected.

Finally, at the Communication History (Figure 26) there is a recap of visits and alerts. They are categorized by the Communication Channel which can be on a clinical visit or through generated alert, the date it was notified, the type of the alert and the actions performed as previously described.

Summary	Questionnaire Report	Visit Report	Alert Report	Communication History
Communication History <input type="text" value="Search by any field"/>				
Communication Channel	Date	Type	Action	
Visit	02-08-2021	Planned	—	
Visit	13-08-2021	Planned	—	
Alert	15-09-2021	Sleeping	Managed by the chatbot	
Alert	12-09-2021	Sleeping	Managed by the chatbot	

Figure 26 Communication History screen menu.

B) Create a new patient ID

First, click on the ‘Data Collection (REDCap)’ button at the Patient Information module. The clinician will be redirected to the REDCap platform at the Record Status Dashboard (Figure 27), then click on the ‘Add new record’ button to access the Record Home Page.

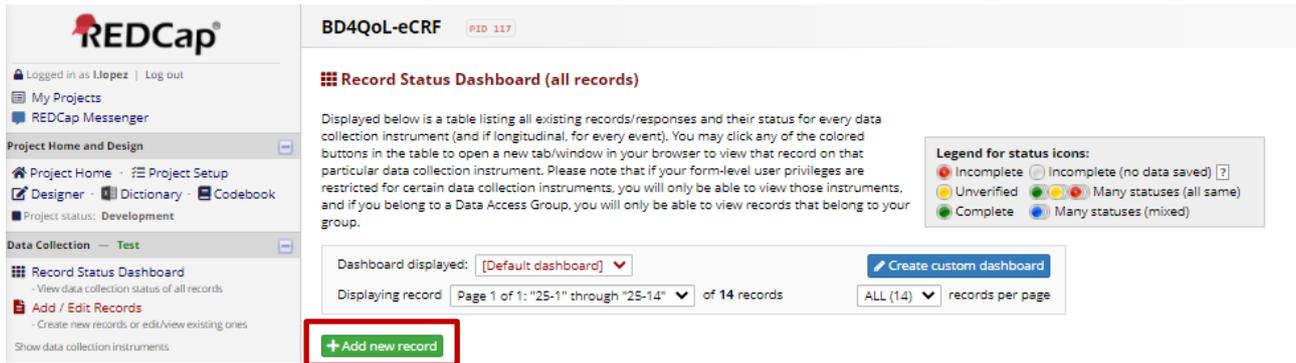


Figure 27. Second step to create a new patient ID: Click on 'Add new record' in the REDCap tool.

There is a table with a list of the available REDCap forms and the patient ID that will be associated to the new participant (Figure 22). Fill in the *Eligibility Form* to add basic information, and the *Randomization* to include that patient into a study group, either as Control or Intervention. Once completed, the new patient will appear at the PoC tool pending for the confirmation of enrolment.

NEW REDCap ID 25-26		REDCap ID 25-26	
Data Collection Instrument	Status	Data Collection Instrument	Status
Eligibility Form	<input type="radio"/>	Eligibility Form	<input checked="" type="radio"/>
Randomization	<input type="radio"/>	Randomization	<input checked="" type="radio"/>
Clinical characteristics at study entry	<input type="radio"/>	Clinical characteristics at study entry	<input type="radio"/>
Follow-up Consultation	<input type="radio"/>	Follow-up Consultation	<input type="radio"/>
Contact In Between Or After Study Scheduled Visits	<input type="radio"/>	Contact In Between Or After Study Scheduled Visits	<input type="radio"/>
New non-cancer-related medical event	<input type="radio"/>	New non-cancer-related medical event	<input type="radio"/>
Study Stop And Consent Withdrawal	<input type="radio"/>	Study Stop And Consent Withdrawal	<input type="radio"/>

Figure 22. Fill in the Eligibility and Randomization forms to create a new patient.

C) Enrol a new patient

Going back to the Point of Care tool, at the Patient Information list, patients pending for enrolment will appear with a blue plus sign on the enrolment column. Click on the plus button (Figure 23) to confirm the enrolment by entering the patient's email. Then the patient will appear as Active.

The screenshot shows the 'Patient List' interface with a table of patients. The table has columns for Study ID, Update, Randomization Date, End Date, Study Arm, Enrollment, and View CRF Data. The row for Study ID 25-26 is highlighted, and a blue plus icon in the Enrollment column is circled in red. Below the table, a modal titled 'Add patient' is open, showing the Study ID as 25-26 and the email address as test@gmail.com. The modal has 'Cancel' and 'Save' buttons.

Study ID	Update	Randomization Date	End Date	Study Arm	Enrollment	View CRF Data
25-23	20-09-2021	20-09-2021	—	Intervention	Active	
25-24	18-10-2021	30-09-2021	18-10-2021	Intervention	Withdrawn	
25-25	14-10-2021	30-09-2021	—	Intervention	Active	
25-26	19-10-2021	19-10-2021	—	Intervention		—

Figure 23. Enrolment of a new patient

D) View eCRF data

In the column View CRF data, click on the orange-eye icon to view the CRF data for a single patient (Figure 24). Select a form (i.e., Eligibility Form) to show the drop-down list with the corresponding eCRF information. Scroll down in the CRF data visualization panel to check other available forms (Figure 25).

The screenshot shows the 'Patient List' interface with a table of patients. The table has columns for Study ID, Update, Randomization date, End Date, Study Arm, Enrollment, and View CRF data. The row for Study ID 19-3 is highlighted, and the orange eye icon in the View CRF data column is circled in red. The interface includes a sidebar with navigation options and a top navigation bar.

Study ID	Update	Randomization date	End Date	Study Arm	Enrollment	View CRF data
19-3	26-07-2021	19-07-2021	—	Intervention	Active	
19-4	19-07-2021	19-07-2021	—	Intervention	Active	
19-5	19-07-2021	19-07-2021	—	Control		—
19-6	19-07-2021	19-07-2021	—	Control		—
19-1	19-07-2021	19-07-2021	—	Control		—
19-2	19-07-2021	19-07-2021	—	Control	Active	

Figure 24. View CRF data by clicking on the orange eye icon.

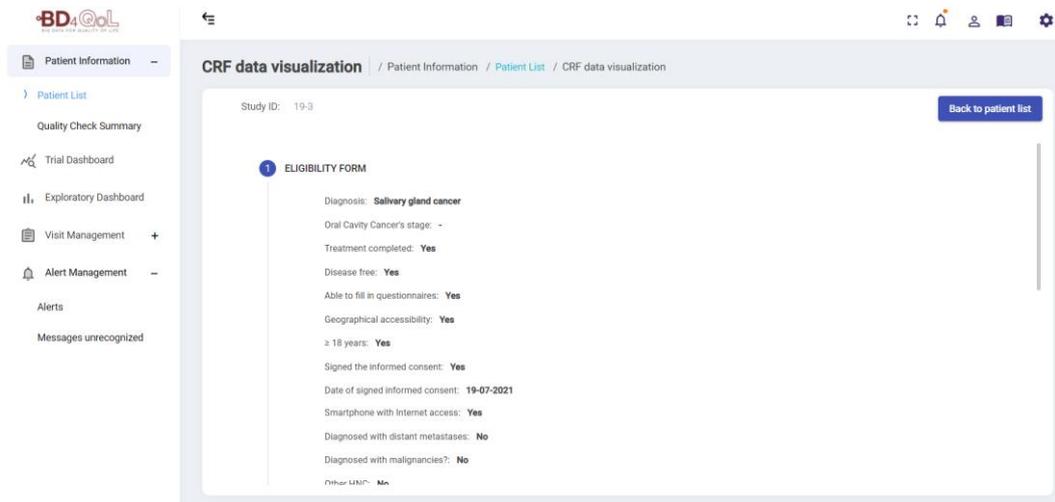
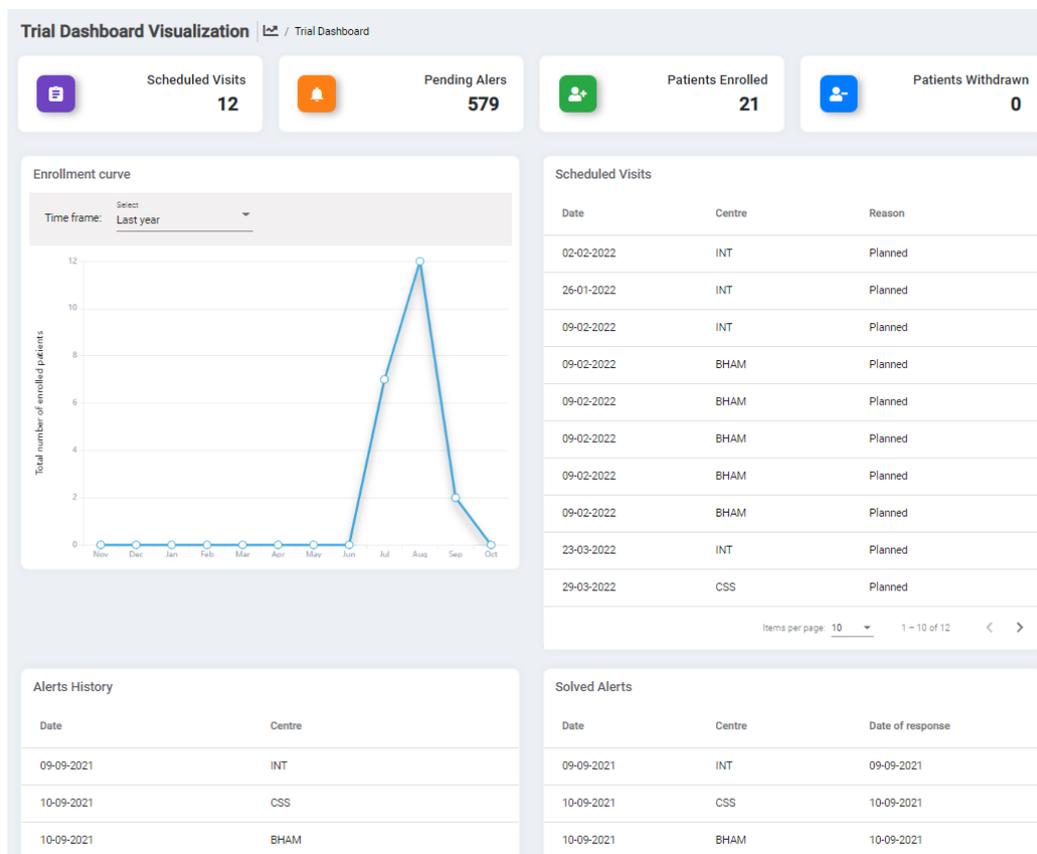


Figure 25. Example of CRF data visualization.

E) Navigate through the Trial Dashboard

The information presented on the Trial Dashboard includes information related to the clinical record pathway and the enrolment curve. All the data available for the study trial regarding scheduled visits and alerts is summarized here (Figure 26) and can be filtered by center. When scrolling down, the PoC user will find demographic data such as mean age and gender of the participants, tumour site and stage statistics, status of risk factors (smoking, alcohol consumption and comorbidities).



Basic Patient Information				
Characteristics	N	%	Median	SD
Age			49.2	4.32
Sex				
Male	11	73.33		
Female	4	26.67		
Tumour site				
Oral cavity	23	69.70		
Oropharynx HPV+	1	3.03		
Oropharynx HPV- or unknown	1	3.03		
Hypopharynx	1	3.03		
Larynx	2	6.06		

Figure 26. Trial Dashboard main menu.

F) Navigate through the Exploratory Dashboard

The Exploratory Dashboard provides an overview of all the data collected regarding questionnaires, physical activity, phone usage and affective traits (Figure 27). This data is the same data provided in the patient information but presented in an aggregated way and can also be filtered by last week, last month or year.

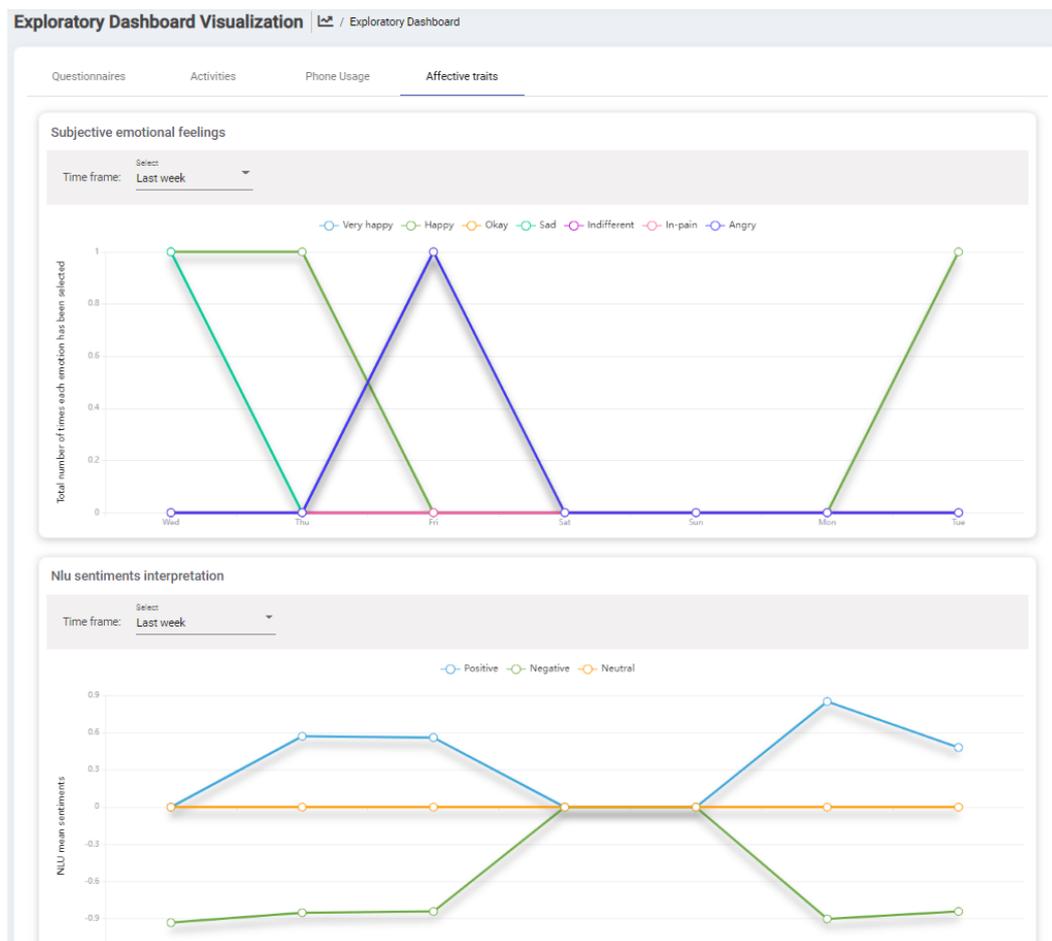


Figure 27. Exploratory Dashboard visualization of affective traits.

G) Navigate through the Visits Management

The Visits Management dashboard provides a visualization of the clinical appointments scheduled for each patient, this includes both planned and unplanned visits. The appointments list is provided in a table that contains the main information of each visit such as the reason (i.e., planned or unplanned), the date, and the timing since the enrolment. The table can be filtered by any of these fields to facilitate the visualization of all the visits. Within the “All visits” view, an additional column presents the status of de visit indicating if it is complete or pending (see Figure 28).

The image displays two screenshots of the Visits Management dashboard. The top screenshot shows the 'Pending Visits' view, which includes a search bar and a 'New Unplanned Visit' button. Below is a table of pending visits with columns for Study ID, Reason, Date, Timing, and Actions.

Study ID	Reason	Date	Timing	Actions
25-7	Planned	16-04-2022	+12 months	
25-25	Planned	06-04-2022	+6 months	
25-23	Planned	20-03-2022	+6 months	
25-18	Planned	17-03-2022	+ months	
25-19	Planned	17-03-2022	+6 months	
25-22	Planned	08-03-2022	+6 months	

The bottom screenshot shows the 'All Visits' view, which includes a search bar and a 'New Unplanned Visit' button. Below is a table of all patient visits with columns for Study ID, Reason, Date, Status, Timing, and Actions.

Study ID	Reason	Date	Status	Timing	Actions
25-23	Unplanned	15-09-2021	Pending	+0 months	
25-22	Planned	08-09-2021	Complete	+0 months	
25-3	Unplanned	08-09-2021	Complete	+5 months	
25-21	Planned	07-09-2021	Complete	+0 months	
25-3	Unplanned	24-08-2021	Pending	+1 months	
25-6	Planned	13-08-2021	Complete	+6 months	
25-4	Unplanned	09-08-2021	Pending	+1 months	

Figure 28. Visit Management main screens.

The column *Actions* show the CRF visualization button if the visit is complete. For pending visits, there are two buttons: a calendar button that allows the change of date of that visit, and an option to edit the information of the visit, provided in both visualizations for the pending visits. When the “edit” icon is selected for any pending visit, a pop up message will appear to access the REDCap platform (Figure 29) to edit or add the information of the CRF for the follow-up consultation (in the case of planned visits) or the Contact In Between Or After Study Scheduled Visits form (in the case of unplanned visits).

REDCap ID	Eligibility Form	Randomization	Clinical characteristics at study entry	Follow-up Consultation	Contact In Between Or After Study Scheduled Visits	New non-cancer-related medical event	Study Stop And Consent Withdrawal
25-1	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
25-2	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
25-3	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
25-4	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
25-5	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Figure 29. Access to the REDCap form for Follow-up Consultation form.

After clicking on a form dot-option, the corresponding form screen will appear (Figure 30). Fill in the form and click on save and continue at the end of the page. The *Status* of the visit will be automatically changed in the PoC tool and the eCRF data will now be available in the *Action* column.

Follow-up Consultation

Editing existing REDCap ID 25-25

REDCap ID 25-25

55. Is it planned follow-up? Yes No
* must provide value
It refers to a planned/unplanned follow-up according to the BD4QoL study protocol. reset

Type of consultation Face-to-face visit Telemedicine
* must provide value reset

56. Date of follow-up consultation
* must provide value
Date of follow-up visit (outpatient visit or teleconsultation).

Figure 30. Message to access the REDCap form for withdrawal.

In the case of the Withdrawal management, an alert appears in the bell icon of the top-right panel whenever a patient requests to withdraw and needs to talk to a physician, or if a patient has been logged out for at least two weeks. The message is ‘The patient wishes to withdraw from the study’ and can be accessed either by clicking on the alert or going to the Withdrawal Report at the Visits Management module.

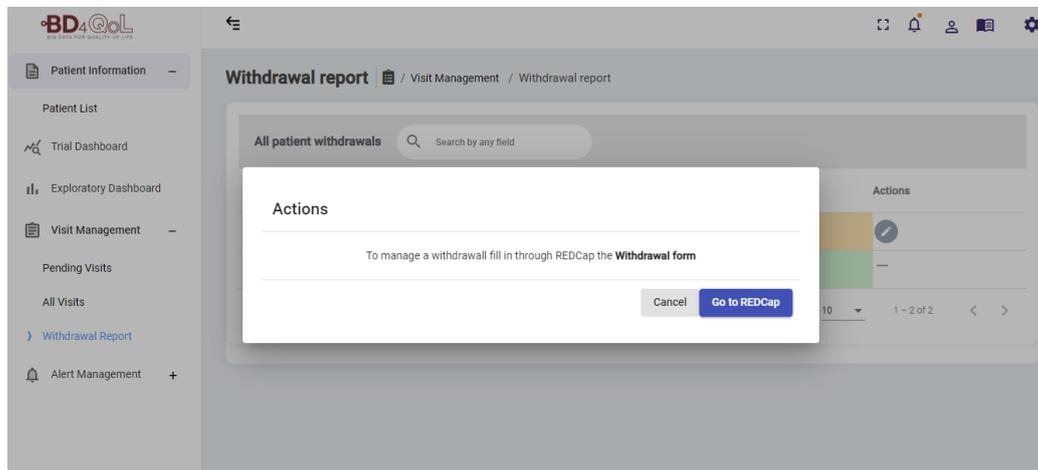


Figure 31. Message to access the REDCap form for withdrawal.

Afterwards, the physician should contact the patient and schedule a visit. This visit is required to understand the motives of the patient that wants to withdraw and to fill in the appropriate REDCap form where it is specified how to proceed with the data registered so far. When the Withdrawal report appears as pending the PoC user can click on the ‘edit’ button to access this REDCap form (Figure 31), then the status will change to ‘Confirmed’ in red. Alternatively, if the patients log into the mobile application, the status will automatically change to ‘Re-logged’ in green (Figure 32) and the REDCap form is no needed.

The screenshot shows the 'Withdrawal report' page in the BD4QoL system. The table displays the following data:

Study ID	Description	Date	Status	Actions
25-24	Patient waiting to be contacted	06-10-2021	Pending	
25-22	The patient has re-logged into the app	07-10-2021	Re-logged	—

Below the table, there is a pagination control showing 'Items per page: 10' and '1 - 2 of 2'.

Figure 32. Patient relogged status in the Withdrawal report

H) Navigate through the Alerts Management

The alerts management provides a summary of all the alerts generated for every patient ID. This functionality can be accessed either through by the navigation drawer or by clicking on the notification bell icon located in the header of all the screens of the PoC tool (Figure 31) and then clicking on *Go to alert management*. When a new alert is generated the bell icon changes, showing a small orange dot, and the list of alerts generated since the last access can be displayed.

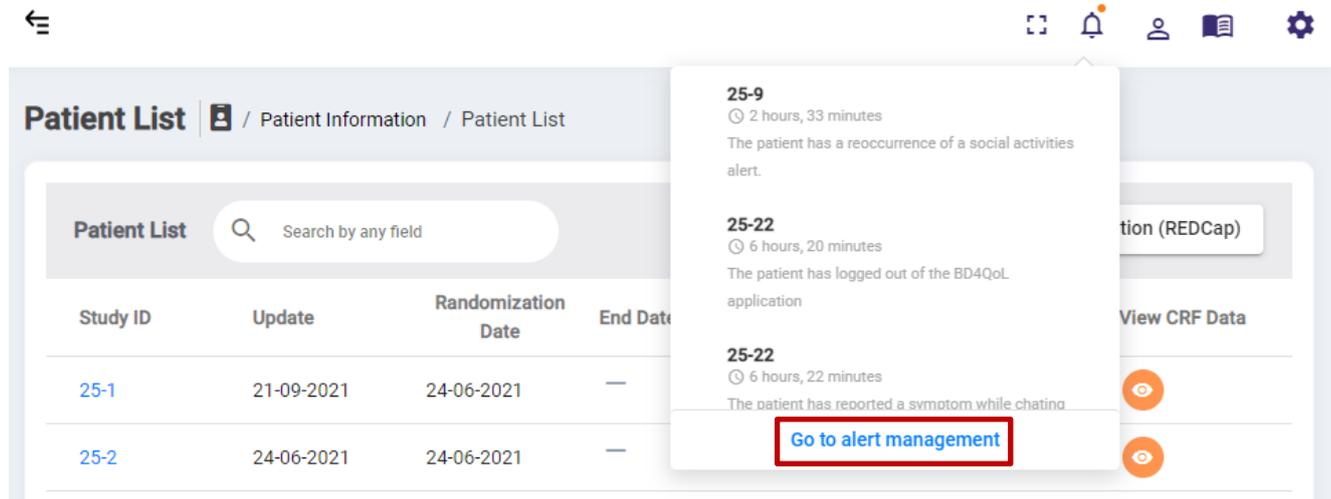


Figure 31. Alerts Management main screen.

The visualization of the Alerts Management (Figure 32) follows the same rationale as the Visits Management, being the alerts categorized as *Pending*, when new alerts generated that have not been managed yet, or *Solved*, when a physician has already handle this alert. By clicking either on the patient ID or the message ‘Go to patient alerts’ the PoC user will access the Alerts Report tab of the Individual Patient Data, as seen previously.

Study ID	Pending Alerts	Solved_alerts	Go to patient alerts
25-2	15	39	Go to patient alerts
25-3	51	301	Go to patient alerts
25-10	27	2	Go to patient alerts
25-6	18	25	Go to patient alerts
25-1	29	49	Go to patient alerts
25-5	31	49	Go to patient alerts
25-7	21	12	Go to patient alerts
25-22	95	18	Go to patient alerts
25-4	0	3	Go to patient alerts

Items per page: 10 | 1 - 9 of 9

Figure 32. Alerts Management main screen.

The Alert Management also includes the Messages Unrecognized by the chatbot (Figure 33). This table shows the patient ID who generated the message on a chatbot conversation, the date the message was registered, the type of message and the text itself. On the last column the clinician can mark as read those messages already reviewed.

Study ID	Date	Type	Message	Viewed
25-7	08-09-2021	FAQ	I'd like to buy a horse. Would you recommend horse riding for someone in my condition?	
25-7	13-09-2021	Other	Yo	Mark as read

Figure 33. Alerts Management unrecognized messages.

I) Notifications

- If the patient has not completed the five initial questionnaires within two weeks since the medical visit, a notification will appear in the PoC tool.

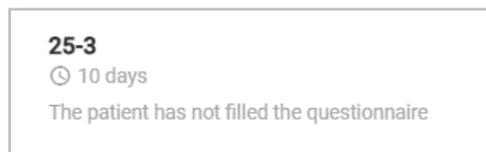


Figure 34. Questionnaire's notification

- If the patient logs out for more than 14 days or requests to withdraw from the clinical study, a notification will appear in the PoC tool.

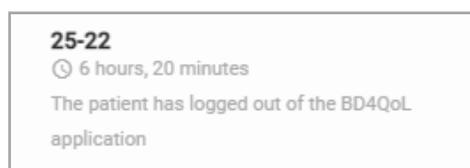


Figure 36. Logout and withdrawal notification

- If an alert occurs either because of a behavioral negative change or because of a symptom reported that may require physician intervention, a notification is sent to the PoC tool.

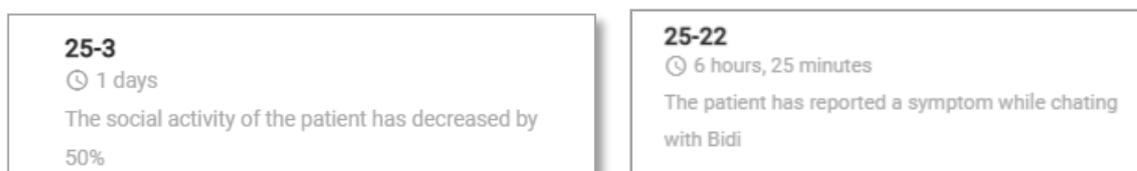


Figure 35. Alert notification

1.2.2 Participants scenario - Mobile app and questionnaires data collection

1. Usage of the main mobile application

- a. Locate the BD4QoL app at your smartphone device

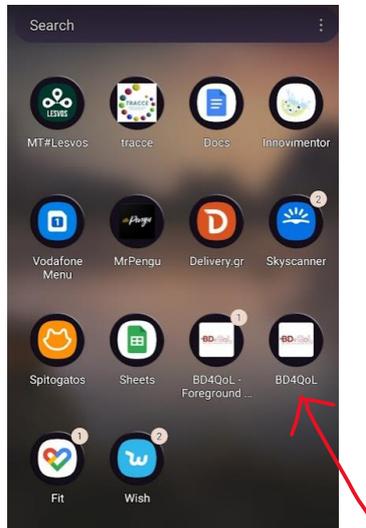
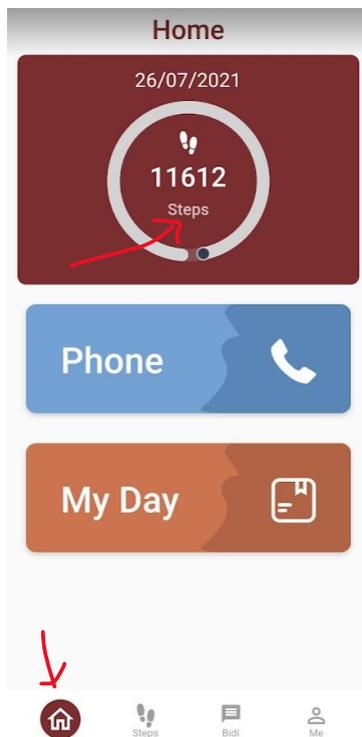


Figure 15. Locate the main BD4QoL app and open it

- b. Navigate into Personal Reports



Press **Home** and then inside the **Steps** circle

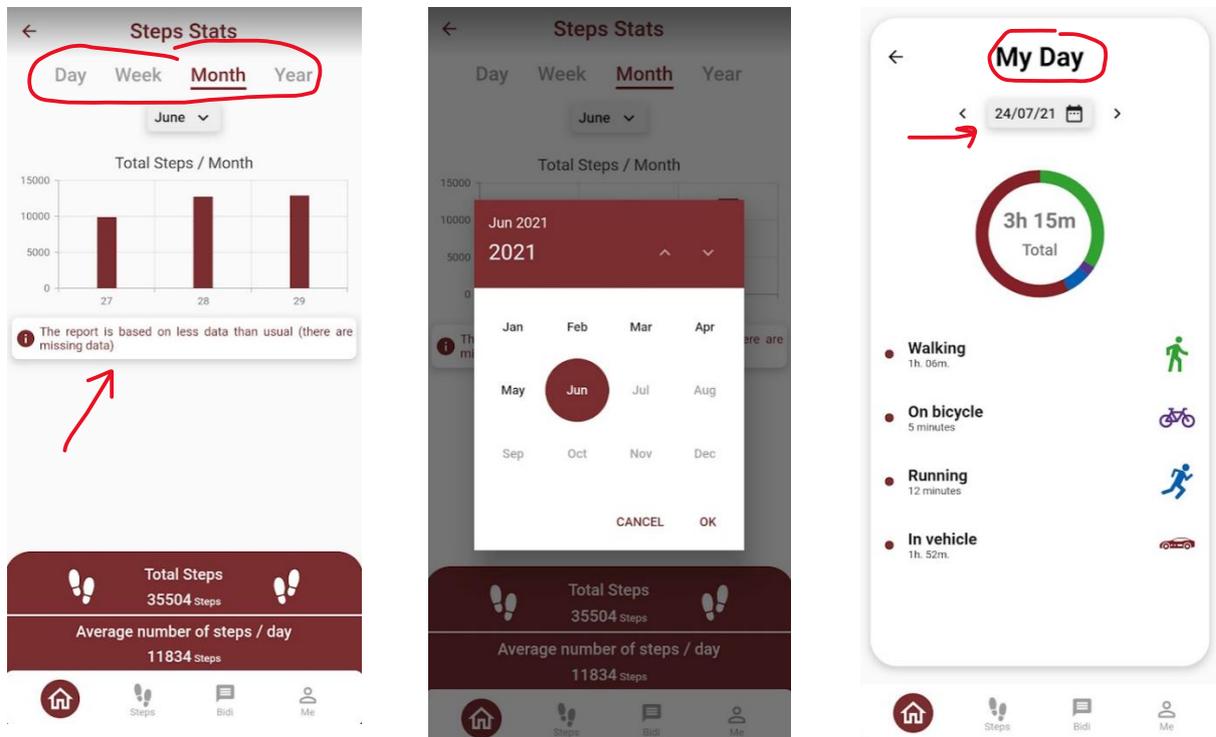


See the daily steps done (from yesterday and then backwards to the past) by pressing **Day**. You can navigate to a past day with the left (or when possible) the next arrow. If you wish to look into a



This is the screen calendar through which you can select a specific day to check physical activity (Steps)

specific day, you can press the Calendar

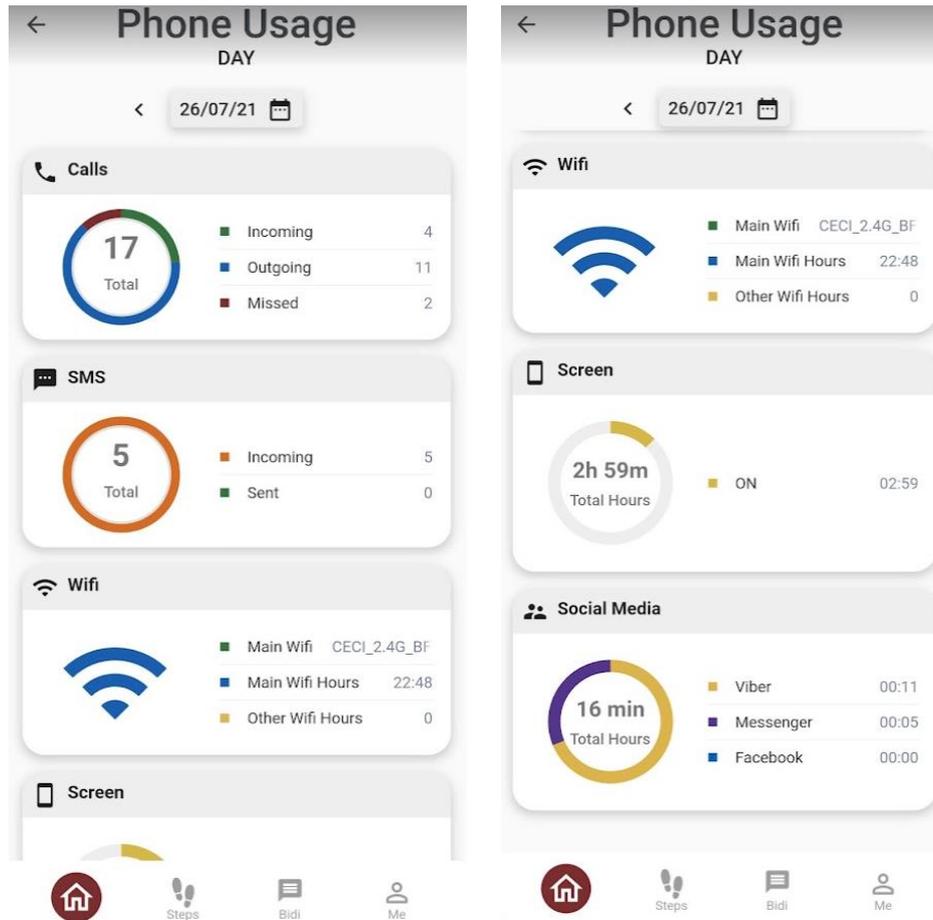


You can also navigate into different time periods for looking into your physical activity, like Week, Month or Year, for weekly, monthly or annual physical activity achievements. If there are missing done for more than 30% of daily time, then this message appears.

You can navigate into different time periods by the arrows or select the calendar view

You can see your daily physical and movement activities and how long you have spent on these by going to Home and then press My Day. The activities you can check upon are: Still, Walking, On bicycle, Running or In_Vehicle. The total time you spent moving or performing physical activity is shown in the top circle. A different color notation is used to denote the different types of activities performed. You can navigate into different days by the arrows or using the calendar button.

Figure 16. Check Physical activity (Steps) daily reports



You can check your phone usage by pressing **Home** and then **Phone**. In this view you see information about: a) Calls (total number of incoming, outgoing and missed calls) – the circle on the left describes the total number of calls, b) the number of SMS that have been received as well as those sent – the circle denotes the total number of SMS, c) The name of the main Wifi connected, the total number of wifi connection to the main wifi, and the time connected to other wifi routers.

Through the Phone statistics, you can also see information about: d) the time that one is ON the screen, and e) the time spent (in minutes on the right side of the screen) per different social application, along with the total time spent on these.

Figure 17. Check personal daily phone usage reports

c. Change Goals for Steps physical activity and review achievement

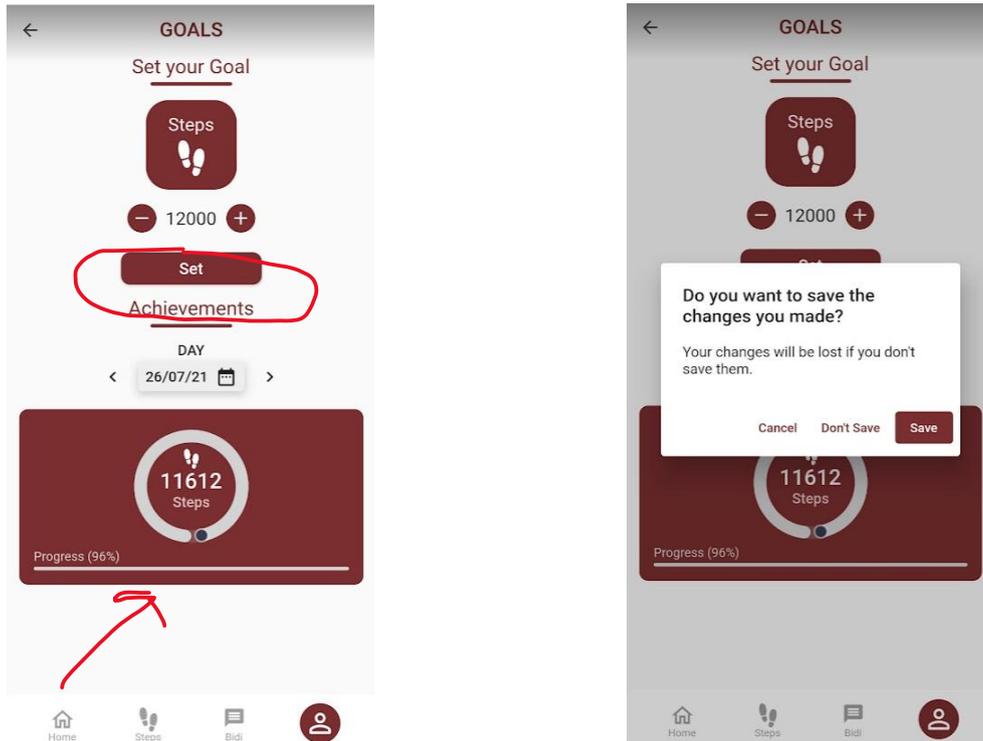


Figure 18. Setting daily goals for Steps and reviewing achievement (in the progress bar)

d. Other Settings and Permissions

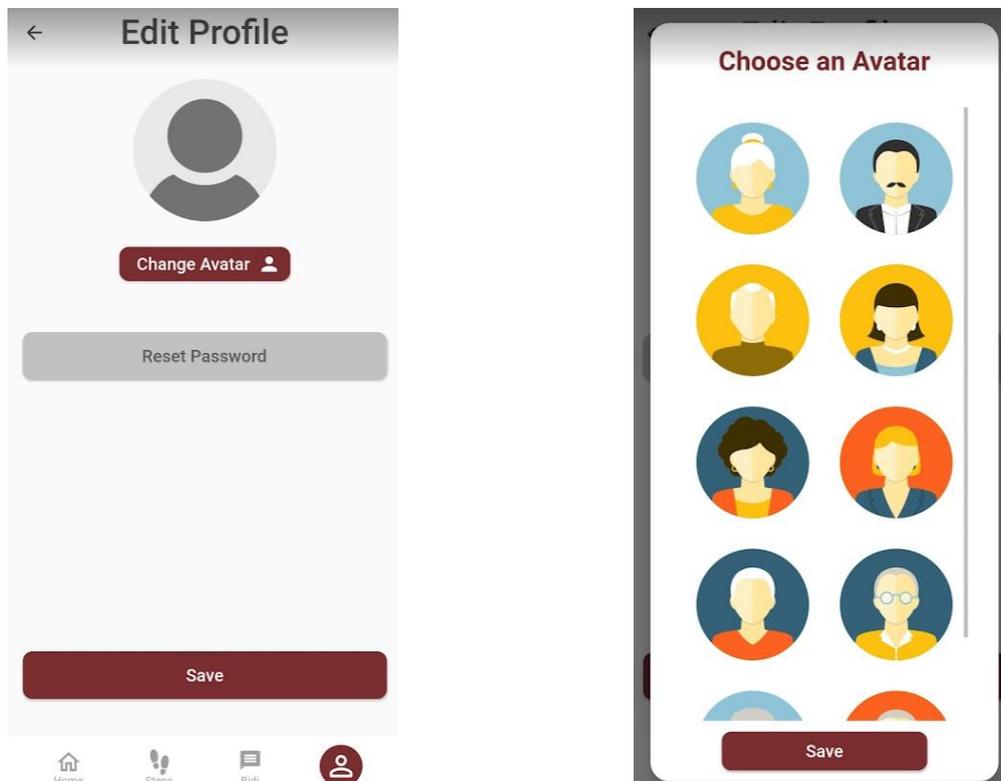


Figure 19. Changing the avatar profile picture

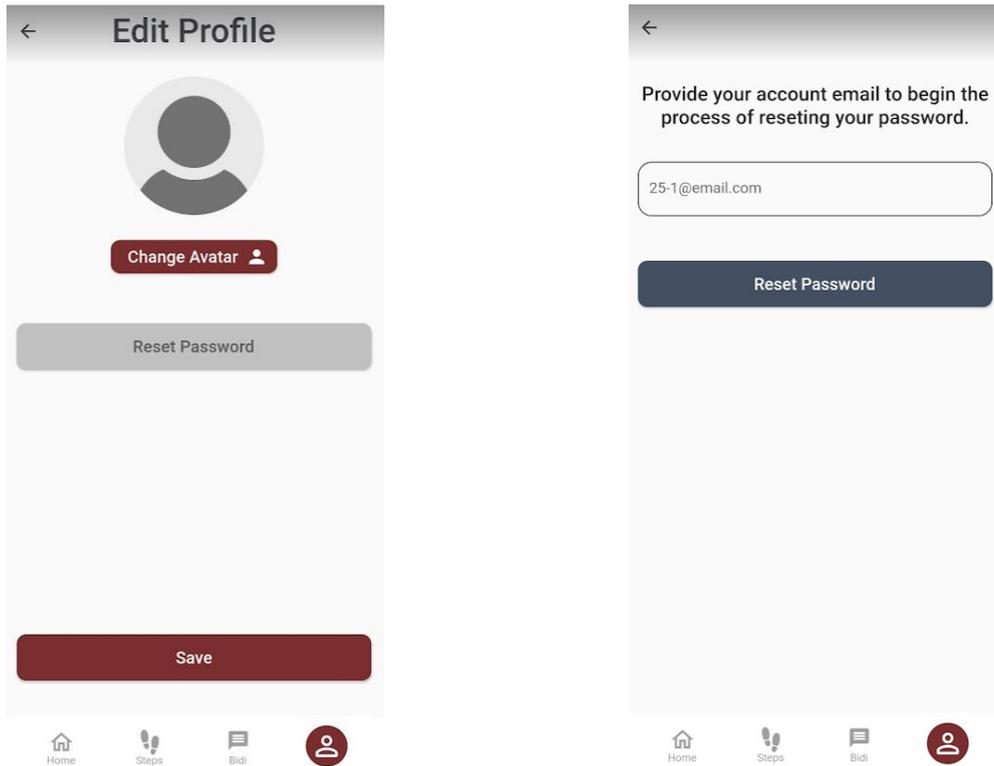


Figure 20. Password reset

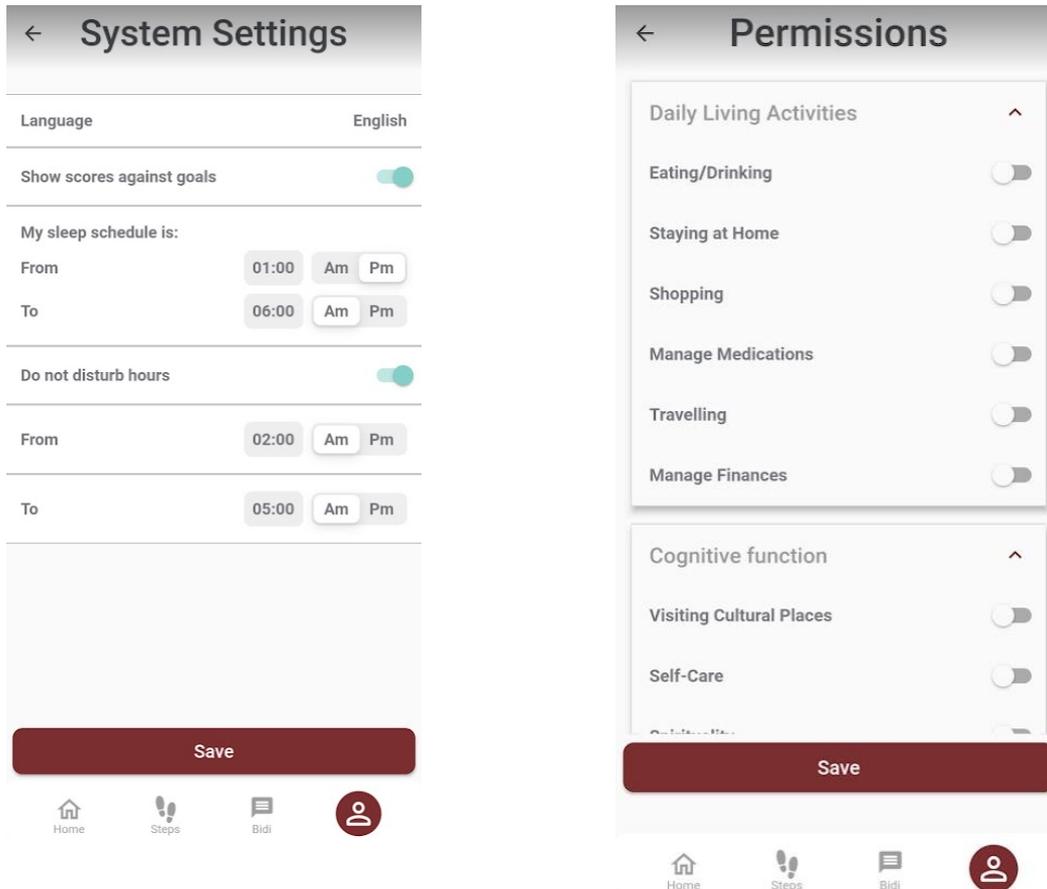
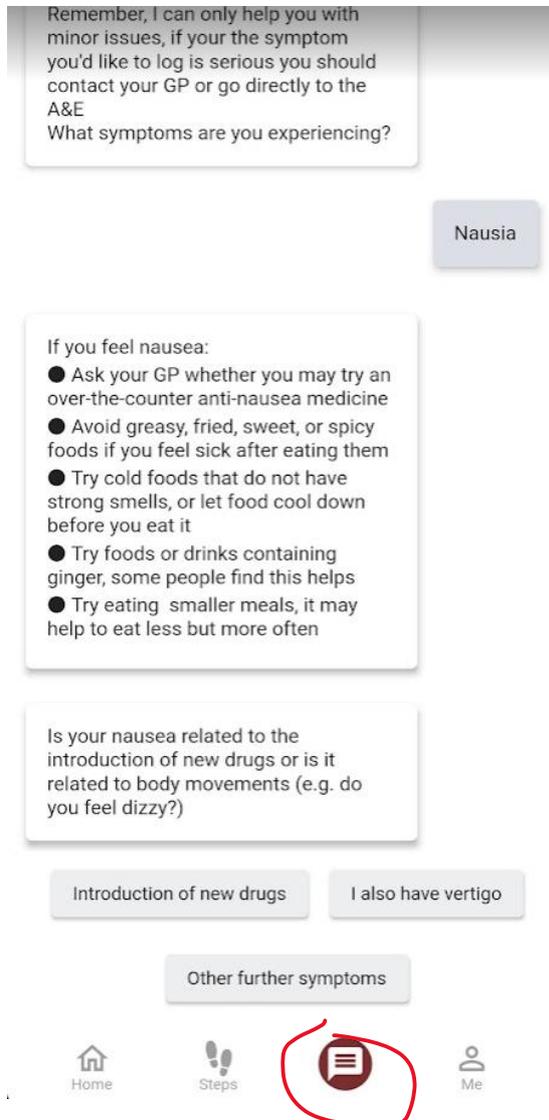


Figure 21. Other Settings and Permissions changed

e. Medals and Trophies [feature not yet operational in current release]

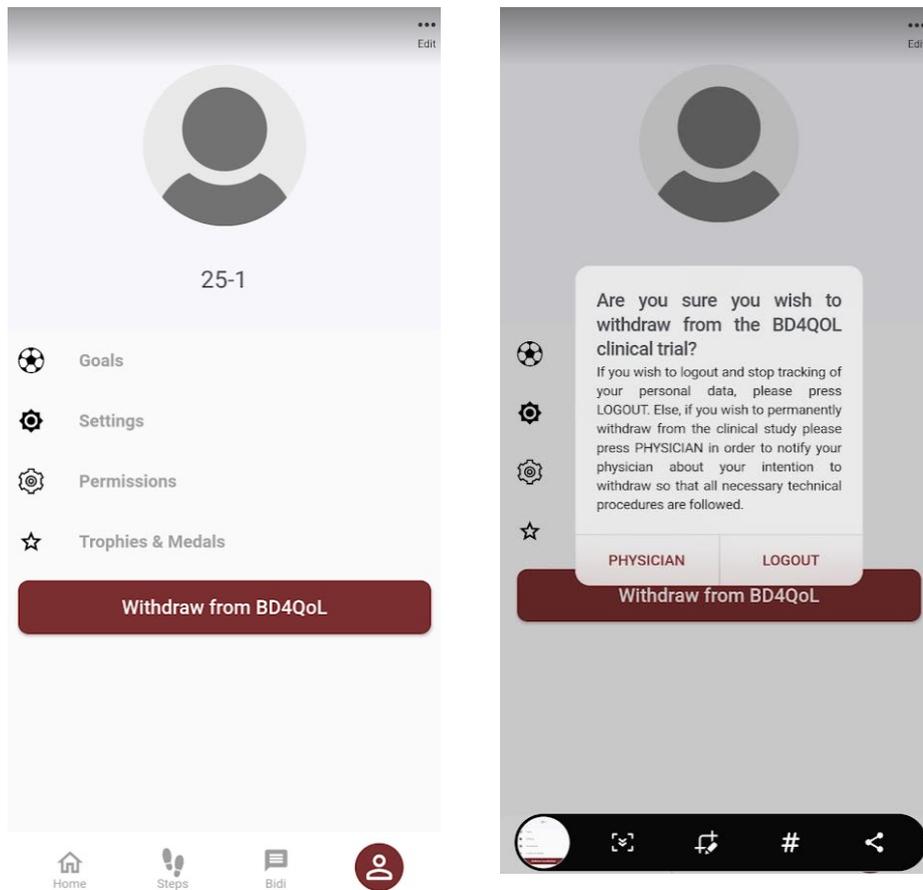
f. Talk with “Bidi”



You can always press the button on the Bottom to talk to the chatbot, Bidi.

Figure 22. Dialog conversations with the Bidi chatbot

g. Logout or Withdraw and Login again



To withdraw or logout from the main mobile app, you can press **Me** and then press **Withdraw from BD4QoL**

If you logout then data collection stops for a short period. If you press withdraw, then your physician knows about your intention about withdrawing from the clinical trial and will contact you.

Figure 23. Logout or Withdraw

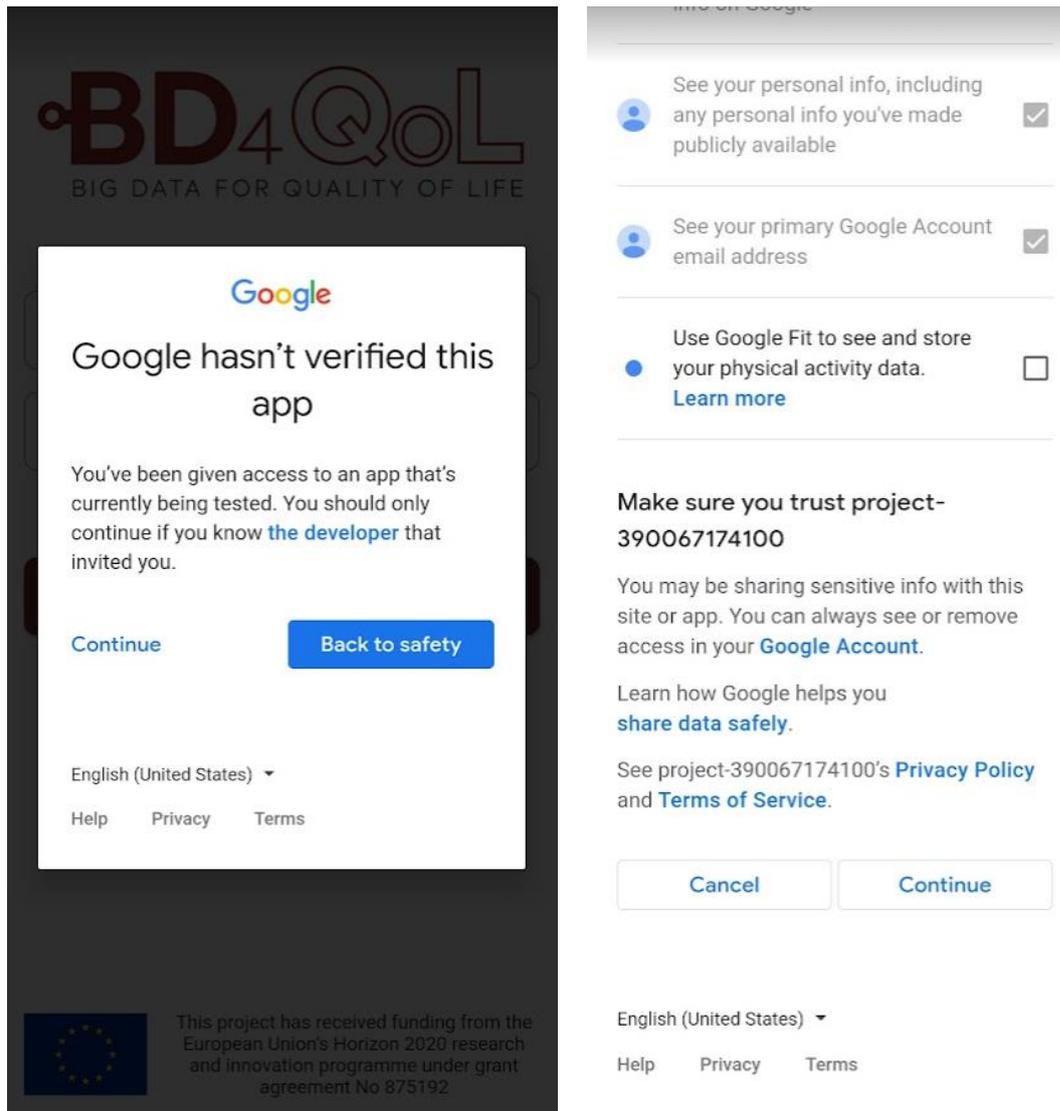


Figure 24. Re-login again (Google Fit permissions needed)

2. Usage of the main questionnaire forms (<https://questionnaires.bd4qolfit.eu/login>)
 - a. Login / Forgot password [*feature for resetting password will be created by next web app release*]

The image shows a login form for the BD4QoL system. At the top center is the logo for BD4QoL, which includes the text "BD4QoL" in a stylized font and "BIG DATA FOR QUALITY OF LIFE" underneath. Below the logo, there are two input fields. The first is labeled "Username*" and contains the text "25-1". The second is labeled "Password*" and is currently empty, with a blue eye icon to its right for toggling visibility. Below the password field is a blue button labeled "Login". Underneath the "Login" button is a blue text link that says "Forgot password".

Figure 25. Login / Forgot password – password reset

b. Completing the questionnaires

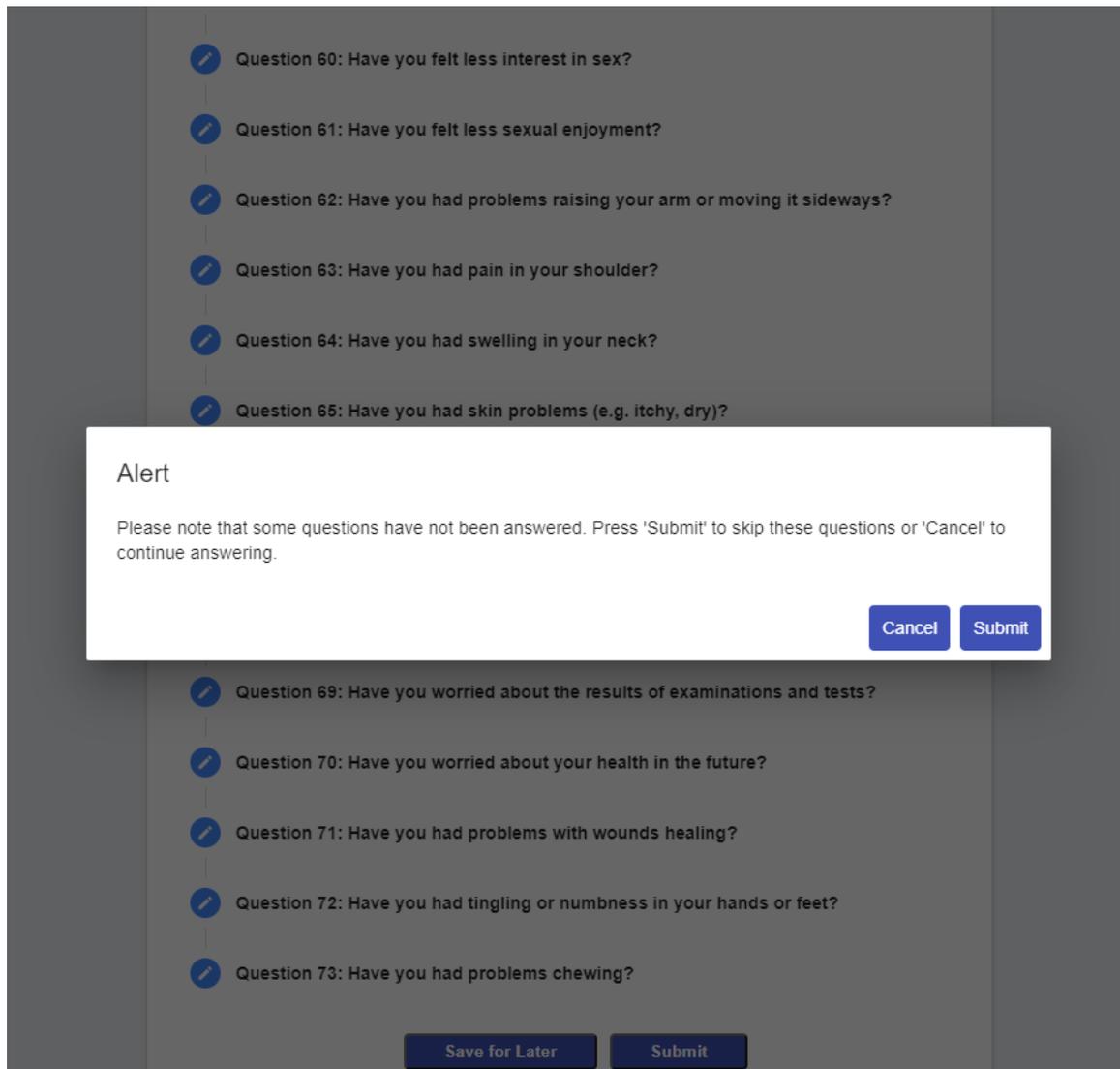
The image shows the start screen of the BD4QoL Questionnaire. At the top, there is a dark blue header bar. On the left side of the header, it says "BD4QoL Questionnaire". On the right side, it says "Logged in as:25-1" and there is a red button with a white arrow icon and the text "Sign out". In the center of the page, there is a white rectangular box containing a blue button with the text "Start Questionnaire". At the bottom of the page, there is a footer area. On the left is the BD4QoL logo. To its right is the European Union flag logo. Further right is the text: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875192".

Figure 26. Starting the completion of a new questionnaire



Figure 27. Quality of Life questionnaire (30 questions)

Figure 28. Head and Neck questionnaire (43 questions)



The image shows a screenshot of a questionnaire interface. A central white alert dialog box is overlaid on a grey background. The dialog box has the title "Alert" and the text: "Please note that some questions have not been answered. Press 'Submit' to skip these questions or 'Cancel' to continue answering." At the bottom right of the dialog box are two buttons: "Cancel" and "Submit".

Question 60: Have you felt less interest in sex?

Question 61: Have you felt less sexual enjoyment?

Question 62: Have you had problems raising your arm or moving it sideways?

Question 63: Have you had pain in your shoulder?

Question 64: Have you had swelling in your neck?

Question 65: Have you had skin problems (e.g. itchy, dry)?

Question 69: Have you worried about the results of examinations and tests?

Question 70: Have you worried about your health in the future?

Question 71: Have you had problems with wounds healing?

Question 72: Have you had tingling or numbness in your hands or feet?

Question 73: Have you had problems chewing?

Save for Later Submit

Figure 29. Alert shown when submitting a questionnaire with unanswered questions



← **BD4QoL Questionnaire** Logged in as:25-1 [Sign out](#)

✓ Quality of Life — ✓ Head & Neck Cancer — **3** Health Questionnaire — 4 Cancer Behavior Inventory — 5 Care received

Under each question, please select the ONE that best describes your health TODAY.

Question 74: MOBILITY

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

[Next question](#)

Question 75: SELF-CARE

Question 76: USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

Question 77: PAIN/DISCOMFORT

Question 78: ANXIETY/DEPRESSION

Figure 30. Health Questionnaire (5 multiple choice questions)

Under each question, please select the ONE that best describes your health TODAY.

Question 74: MOBILITY

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

Next question

Question 75: SELF-CARE

Question 76: USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

Question 77: PAIN/DISCOMFORT

Question 78: ANXIETY/DEPRESSION

We would like to know how good or bad your health is TODAY. This scale is numbered from 0 to 100. 100 means the best health you can imagine. 0 means the worst health you can imagine. Please, write down the number that indicates how your health is TODAY.

Your health today

90

Save for Later **Submit**

Figure 31. Health Questionnaire (1 scale question)

Under each question, please select the ONE that best describes your health TODAY.



Question 74: MOBILITY

Please answer question 74



Question 75: SELF-CARE

Please answer question 75



Question 76: USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)



Question 77: PAIN/DISCOMFORT

- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

Previous question

Next question



Question 78: ANXIETY/DEPRESSION

Please answer question 78

We would like to know how good or bad your health is TODAY. This scale is numbered from 0 to 100. 100 means the best health you can imagine. 0 means the worst health you can imagine. Please, write down the number that indicates how your health is TODAY.

Your health today

90

Save for Later

Submit

Figure 32. Red color Notation to identify un-answered questions



← **BD4QoL Questionnaire** Logged in as:25-1 [Sign out](#)

✓ Quality of Life — ✓ Head & Neck Cancer — ✓ Health Questionnaire — **4** Cancer Behavior Inventory — 5 Care received

Please complete this questionnaire to help us to know how confident you are that you can do the following things. Be sure your ratings are about your confidence even if you have not done it in the past. So, your ratings are about your confidence that you can do these things now or in the near future.

Please select the number between 1 and 9 that best applies to you, where 1 means “Not at all confident” and 9 means “Totally confident”. Numbers in the middle mean that you are somewhat confident that you can do that behavior.

Please rate all items. If you are not sure about an item please rate it as best you can.

Question 1: Maintaining independence

- Very poor
- Poor
- Quite poor
- Below Average
- Average
- Above average
- Quite good

Figure 33. CBI Questionnaire (12 questions)

← BD4QoL Questionnaire Logged in as:25-1 [Sign out](#)

✓ Quality of Life — ✓ Head & Neck Cancer — ✓ Health Questionnaire — ✓ Cancer Behavior Inventory — 5 Care received

It is important to know your level of satisfaction with the care you receive. Please answer by selecting the option that best applies to you.

Are you satisfied with the care you have received during the follow-up?

Absolutely Disagree
 Moderately Disagree
 Neither agree nor Disagree
 Moderately agree
 Absolutely agree

[Submit](#)

Figure 34. Care received questionnaire (1 question)

c. Saving for later [*Feature not yet operational*]

d. Submitting the BD4QoL Questionnaire

Thank you for completing this form [OK](#)

der grant agreement No 8751

Figure 35. Submitting the BD4QoL questionnaire

1.2.3 Integrated scenarios

[*to be included in the next release of the tools and manual*]



1.3 Test scenarios

The user participants under the Beta Pilot Tests will need to follow the usage scenarios below in order to test the alerts generation mechanism at PoC, as well as stress test the overall application.

1. Test mobile data collection and synchronization:
 - a. Daily check whether data in main mobile application appear for the date of enrolment until one day “before today”
 - i. Steps stats (validate with data from Google Fit)
 - ii. “My Day” activities (validate with your own experience of your personal actions)
 - iii. Check the number of calls done and SMS sent/received from phone to validate whether phone statistics are correct
 - b. Check whether conversations with Bidi evolve reasonably
2. Test user authentication – password reset
 - a. The participant can change his/her password either at:
 - i. a) questionnaires forms, i.e. the PREM/PROM questionnaires as in the web forms here <https://questionnaires.bd4qolfit.eu/login> , and
 - ii. b) the mobile app. The participant should try and change / reset the password in one app and check whether the new credentials are updated in the new app.
 - b. All user credentials should be synced, one with the other.

The test scenarios to generate alerts are as follows:

3. Testing of physical data alerts
 - a. The participant can leave the smartphone device still for most of the time, to test whether a significant deterioration for physical activity occurs and thus Alerts are generated at PoC and chatbot.
 - b. If significant deterioration for physical activity occurs, then alerts should be generated at PoC and if needed the chatbot should generate empowerment dialogs relating to the participant’s health problems. These events will be validated when they occur.
 - i. In the beta test scenarios, physical deterioration alerts will be initiated by the PoC and displayed in the form of a phone notification by the chatbot whenever there is a 50% decrease in step count in the last 2 days in relation to the average of steps in the last 6 days. The final application will change this time frame to 2 weeks and 6 weeks respectively.
 - c. If there is a health problem, the chatbot will question the participant to determine what the symptom is and initiate further actions like contacting the PoC and giving a recommendation tip.
4. Testing of phone usage alerts
 - a. The participant can test whether one week s/he can talk and use the phone for socialization and applications usage, and then a week later to not use this particular phone device, in order to test whether alerts are generated. Again, as with the previous alerts, in case of the phone use, the average will be calculated based on a 50% decrease in phone use in the last 2 days in relation to the average of steps in the last 6 days.



- b. If there is significant phone usage deterioration, then the system is expected to send alerts at PoC and if needed, empowerment dialogs will be generated from the Chatbot app.
 - c. If there is a health problem, the chatbot will question the participant to determine what the symptom is and initiate further actions like contacting the PoC and giving a recommendation tip.
5. Testing for sleep behaviour
 - a. The user can set a usual sleep behaviour, ex. 11pm-7am and let the platform collect all necessary data. In order to test the alerts generation, the participant can change the sleep behaviour into a timeframe that is daylight, so that the NSER variable (the non-sleep time over the usual sleep period) is significant higher, thus expecting alerts (based on two days over six-day averages).
 - b. If there is a health problem, the chatbot will question the participant to determine what the symptom is and initiate further actions like contacting the PoC and giving a recommendation tip.
6. Testing for weekly motivation [*This feature is under refinement and will be delivered in the next beta releases*]
 - a. The participant's weekly step activity has been below their goal on average
 - i. The participant is asked for their intention to walk more and *score low* on intention to walk more
 1. The chatbot questions why there has been a low intention to walk and provides helpful tips on physical activity
 - ii. The participant is asked for their intention to walk more and *score high* on intention to walk more
 1. The chatbot questions if there has been some difficulty with the participant's ability to do more physical activity
 - b. The participant has been achieving their weekly step goals on average
 - i. The chatbot asks for main difficulties for physical activities in the week ahead and provides the participant with some tips for how to handle those difficulties
7. Alerts related to proper functioning of the phone application [*This feature is under refinement and will be delivered in the next beta releases*]
 - a. Sensor and device operational data show MESSY quality of life behavioural models
 - i. Triggered manually or by the mobile app and displayed on the participant's phone in a form of a notification and a message from the chatbot
 - b. Sensor and device operational data show MINIMUM amount of data AND patient is at HOME
 - i. Triggered manually or by the mobile app and displayed on the participant's phone in a form of a notification and a message from the chatbot
 - c. Sensor and device operational data show MISSING data for daily time intervals
 - i. Triggered manually or by the mobile app and displayed on the participant's phone in a form of a notification and a message from the chatbot



- d. Sensor and device operational data show MISSING data for more than XYZ days
 - i. Triggered manually or by the mobile app and displayed on the participant's phone in a form of a notification and a message from the chatbot

Once the above occurs, then the PoC and if needed the Chatbot should generate alerts and relevant dialogs accordingly within the chatbot UI and starts the check-in activity to gather more insight on the patient's current activities, affective traits, emotional wellbeing and overall sentiment of their responses.

1.4 Test Reporting

- To report any error:
https://docs.google.com/spreadsheets/d/11GZv392XvTwWjdIYvmNCQYbl-zCKsHnYDWxaoFzf3sA?authuser=rgarcia%40st.tfo.upm.es&usp=drive_fs
- To validate data collection from the mobile application:
https://docs.google.com/spreadsheets/d/1vTFopHPAAFXhn15uhA_zP9rJNcnv9pyj/edit#gid=1742203640 Please check the spreadsheet related to your account as study participant (intervention arm) and then fill in three times a week the checklists shown.