

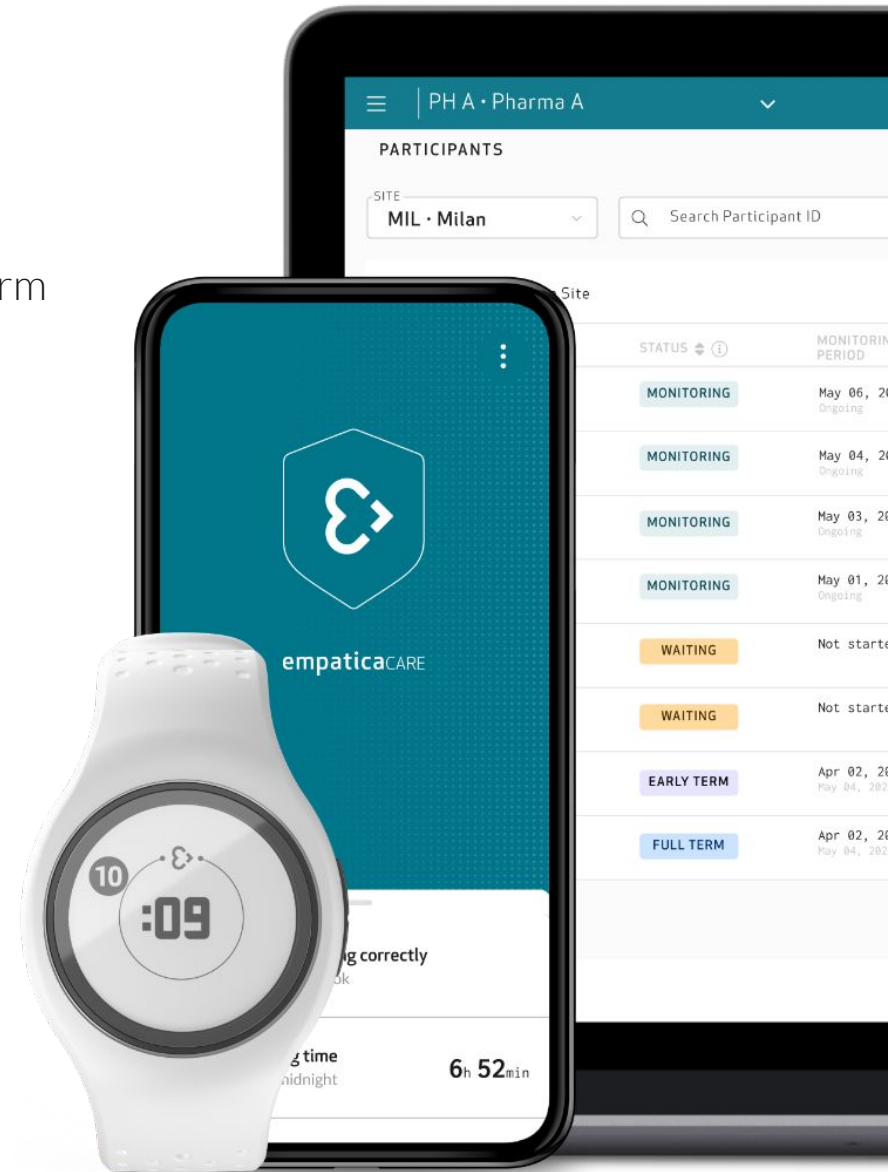


# Empatica Health Monitoring Platform

**TRAINING DECK**

# Contents

- › Understanding the platform
- › Getting started with the Empatica Health Monitoring Platform
- › Enrolling participants in your study
- › Managing the study and site
- › Monitoring the study and site
- › Access your Data
- › Multiple short-lab sessions
- › Getting support
- › Tips for participants



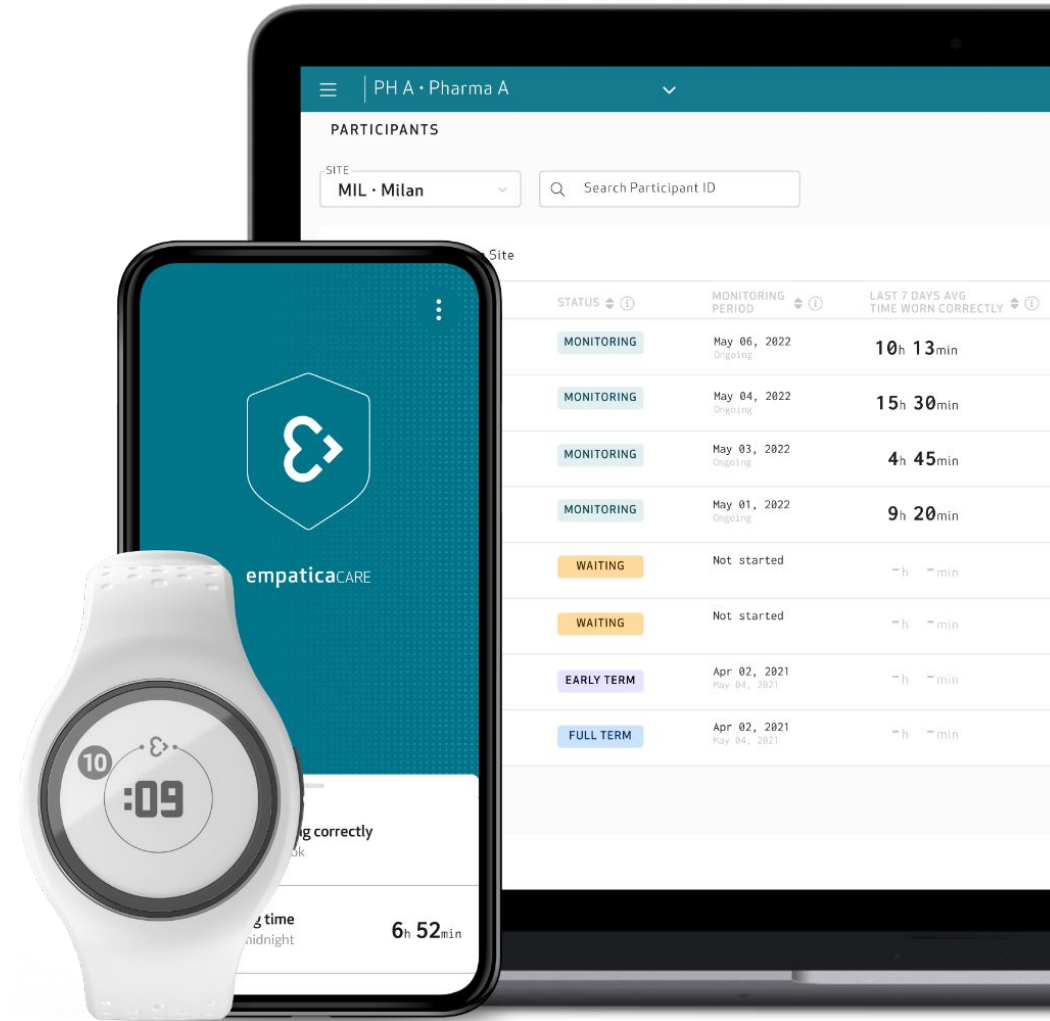


# Understanding the Platform

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# What is the platform?

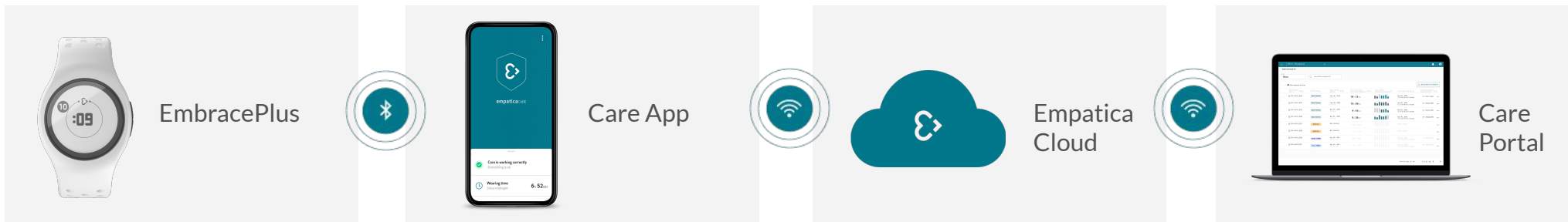
A modular, cloud-based remote health monitoring platform, comprised of Empatica's medical-grade wearables, software and digital biomarkers.





# How the platform works

The **EmbracePlus** medical wearable collects physiological parameters from the participant's wrist. The data is then transferred to the **Care Lab App** via Bluetooth®. **Collected physiological data** is moved from the Care Lab App through an internet connection to the **Empatica Cloud**, which securely stores data and makes it available via direct download or through online visualization on the **Care Portal**.



# What is the EmbracePlus?

EmbracePlus is a wearable health monitor that collects, processes, stores, and wirelessly transmits physiological parameters to a companion device (e.g., a smartphone).



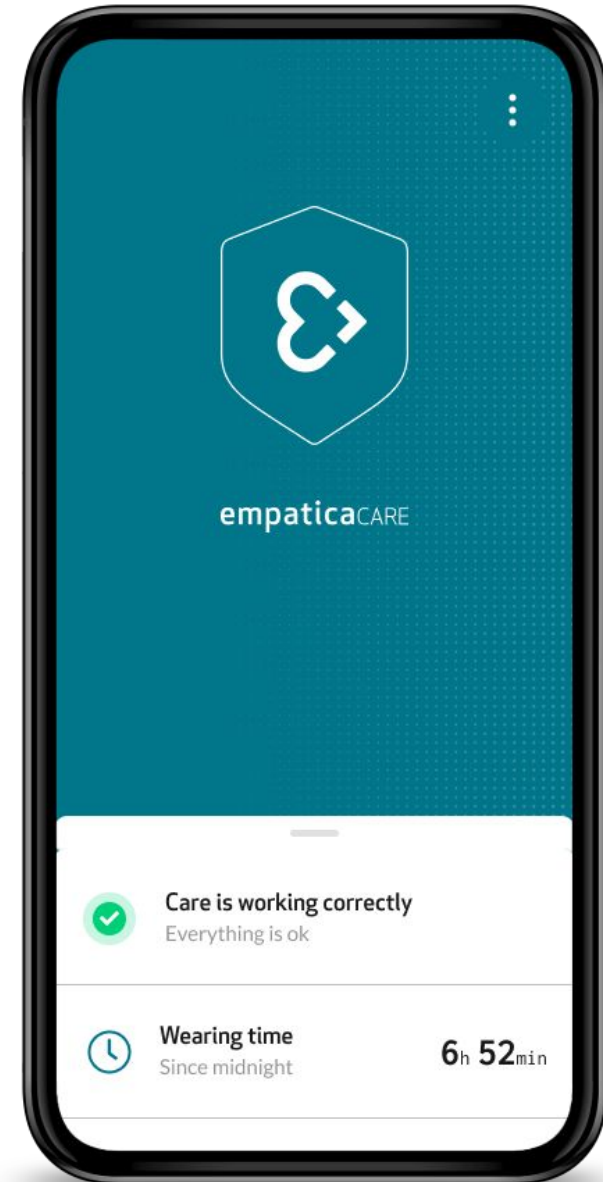
# What is the Care Lab App?

The Care Lab App is the companion app for EmbracePlus, which runs multiple algorithms to continuously analyze acquired data and extract specific digital biomarkers.

It collects data recorded by the EmbracePlus via Bluetooth® and uses the smartphone's internet connection (WiFi or cellular) to securely upload them to the Empatica Cloud.

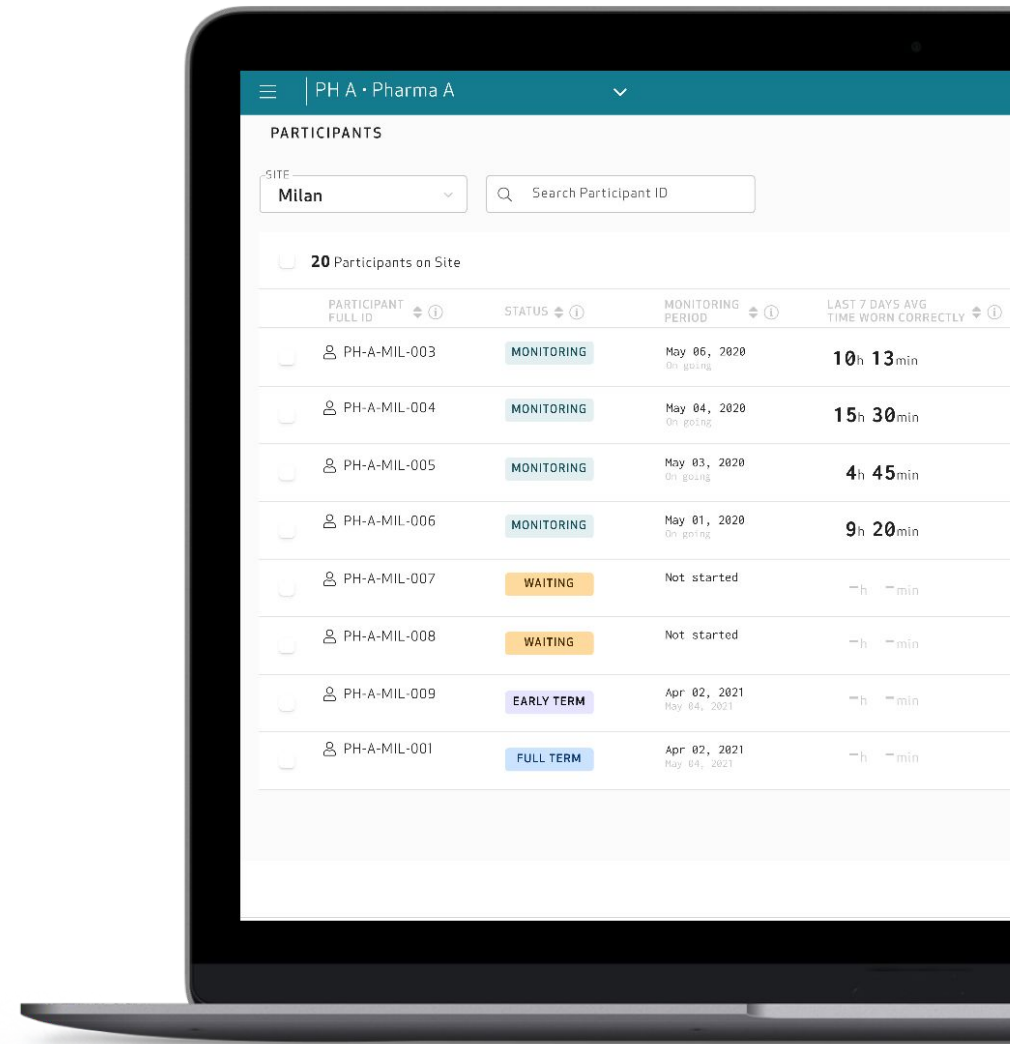
Check smartphone compatibility here:

<https://www.empatica.com/embraceplus-compatibility/>



# What is the Care Portal?

The Care Portal is a web portal which allows Study Team members to manage and monitor participants of studies using the EmbracePlus and the Care Lab App. In addition, the Care Portal provides visual summaries of the participants digital biomarkers, and the Data Access Keys give access to download all collected raw data and digital biomarkers from the AWS S3 Bucket.



The screenshot displays the 'PARTICIPANTS' section of the Care Portal for 'PH A · Pharma A' at the 'Milan' site. It shows a table with 10 participants, each with a unique ID, status, monitoring period, and average time worn correctly over the last 7 days. The interface includes a search bar and a summary of 20 participants on site.

PARTICIPANT FULL ID	STATUS	MONITORING PERIOD	LAST 7 DAYS AVG TIME WORN CORRECTLY
PH-A-MIL-003	MONITORING	May 06, 2020 <small>On going</small>	10h 13min
PH-A-MIL-004	MONITORING	May 04, 2020 <small>On going</small>	15h 30min
PH-A-MIL-005	MONITORING	May 03, 2020 <small>On going</small>	4h 45min
PH-A-MIL-006	MONITORING	May 01, 2020 <small>On going</small>	9h 20min
PH-A-MIL-007	WAITING	Not started	-h -min
PH-A-MIL-008	WAITING	Not started	-h -min
PH-A-MIL-009	EARLY TERM	Apr 02, 2021 <small>May 04, 2021</small>	-h -min
PH-A-MIL-001	FULL TERM	Apr 02, 2021 <small>May 04, 2021</small>	-h -min

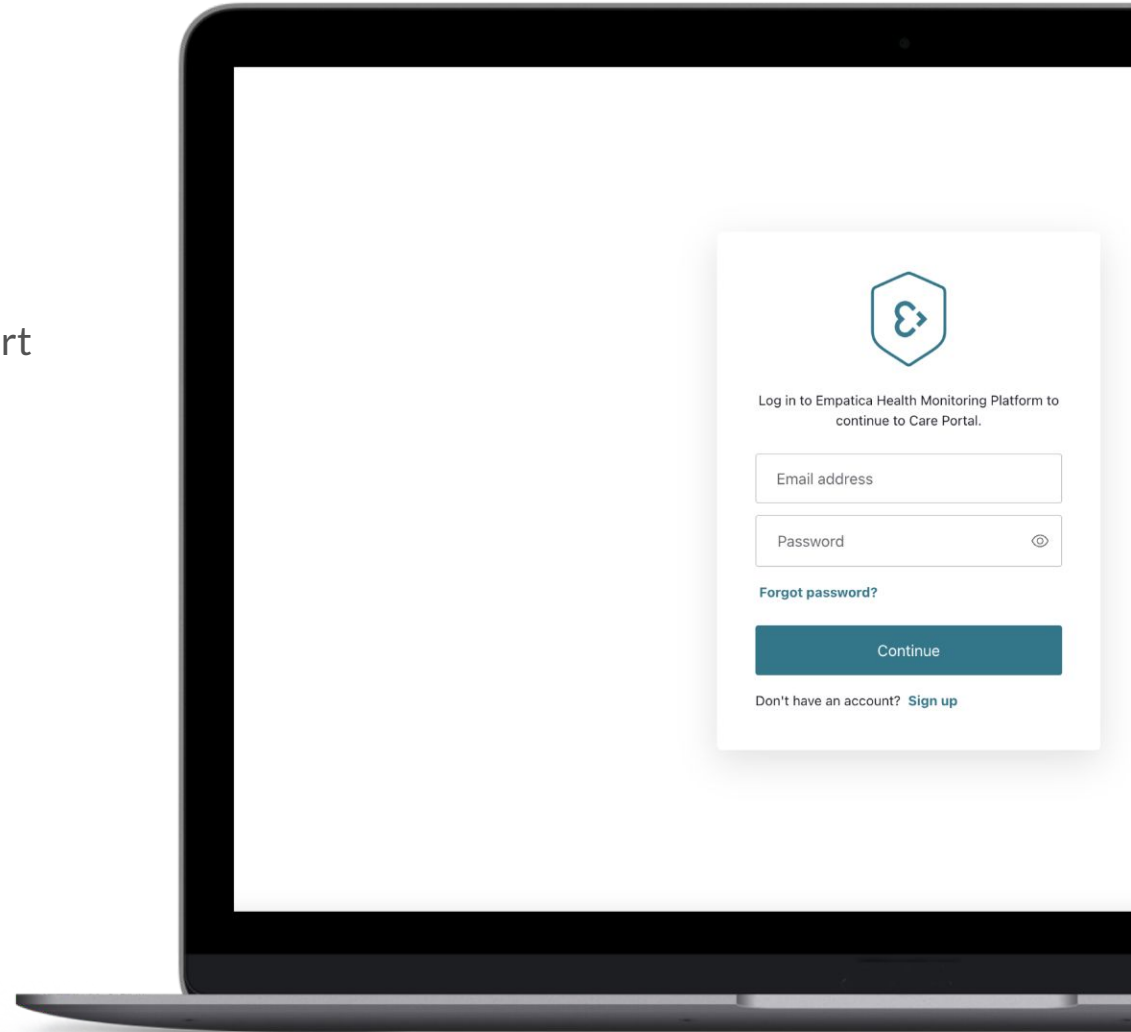


# Getting Started with the Empatica Health Monitoring Platform

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# Gaining access to the Care Portal

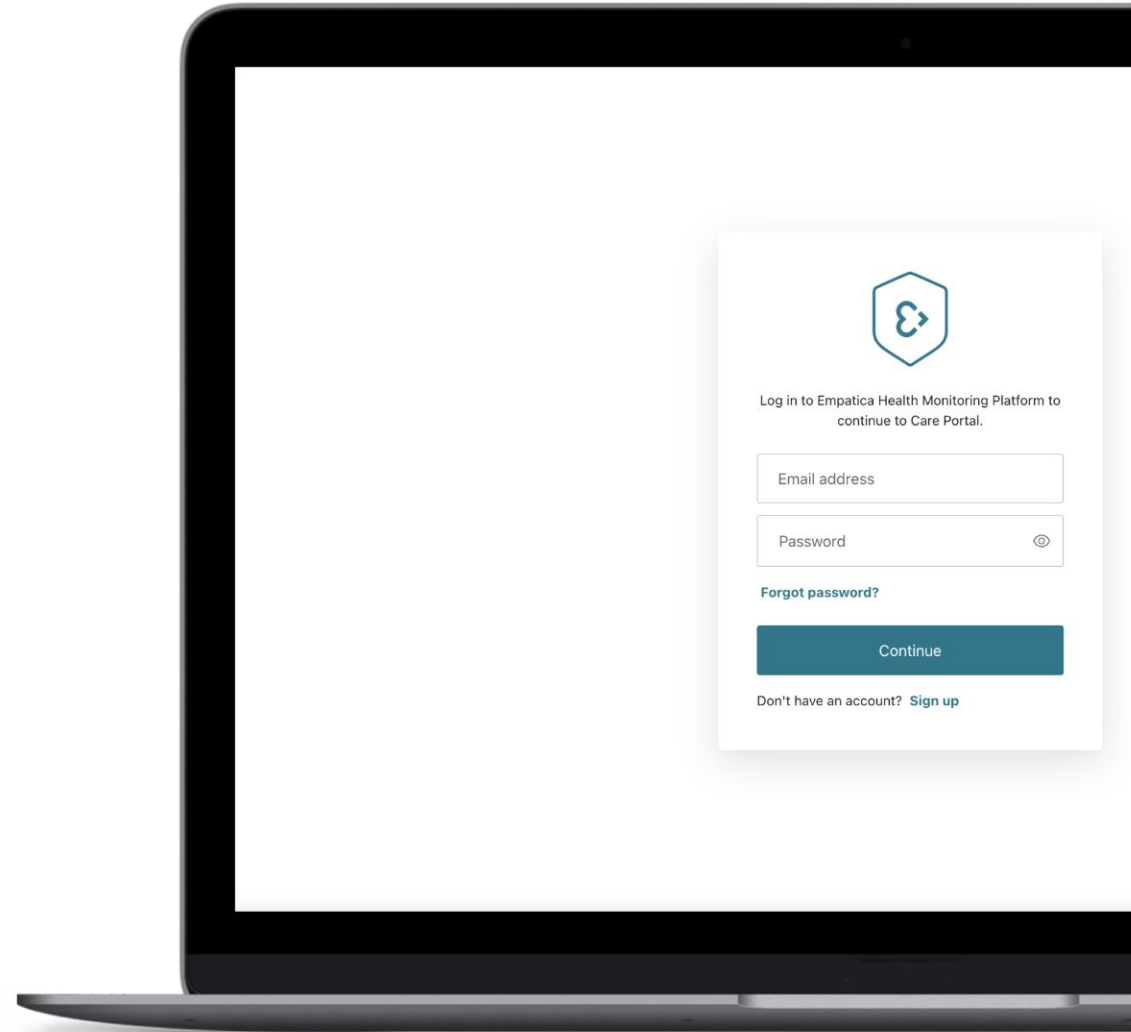
To register with the Empatica Health Monitoring Platform, go to [carelab.empatica.com/signup](https://carelab.empatica.com/signup) and insert your preferred email address and a secure password that matches with the security criteria.



# Access and Login

You will be able to access the Care Portal with your chosen email address and password by visiting

[carelab.empatica.com](https://carelab.empatica.com)



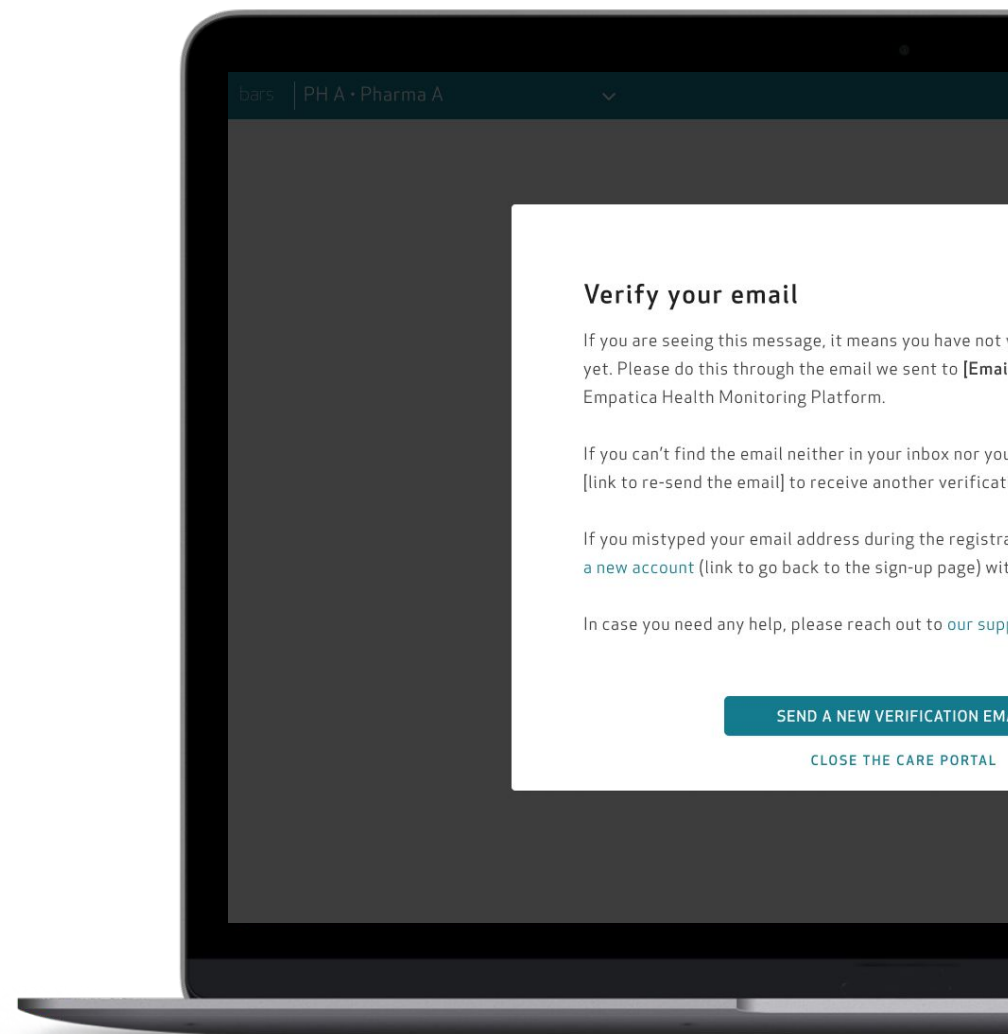
# Verify your email address

During your very first access to the Care Portal, you will be asked to verify your email address. Please note that without this step you will not be able to use the Empatica Health Monitoring Platform.

We will send a verification email to the email address you provided when registering your Care Lab Portal account. Once you receive this email, follow the instructions and press the button to verify your email. If you cannot locate the email in your inbox, press the button in the pop-up to receive a new one.

A pop-up in the portal will inform you that the process has been successfully completed.

If you need help, reach out to [our support team](#).



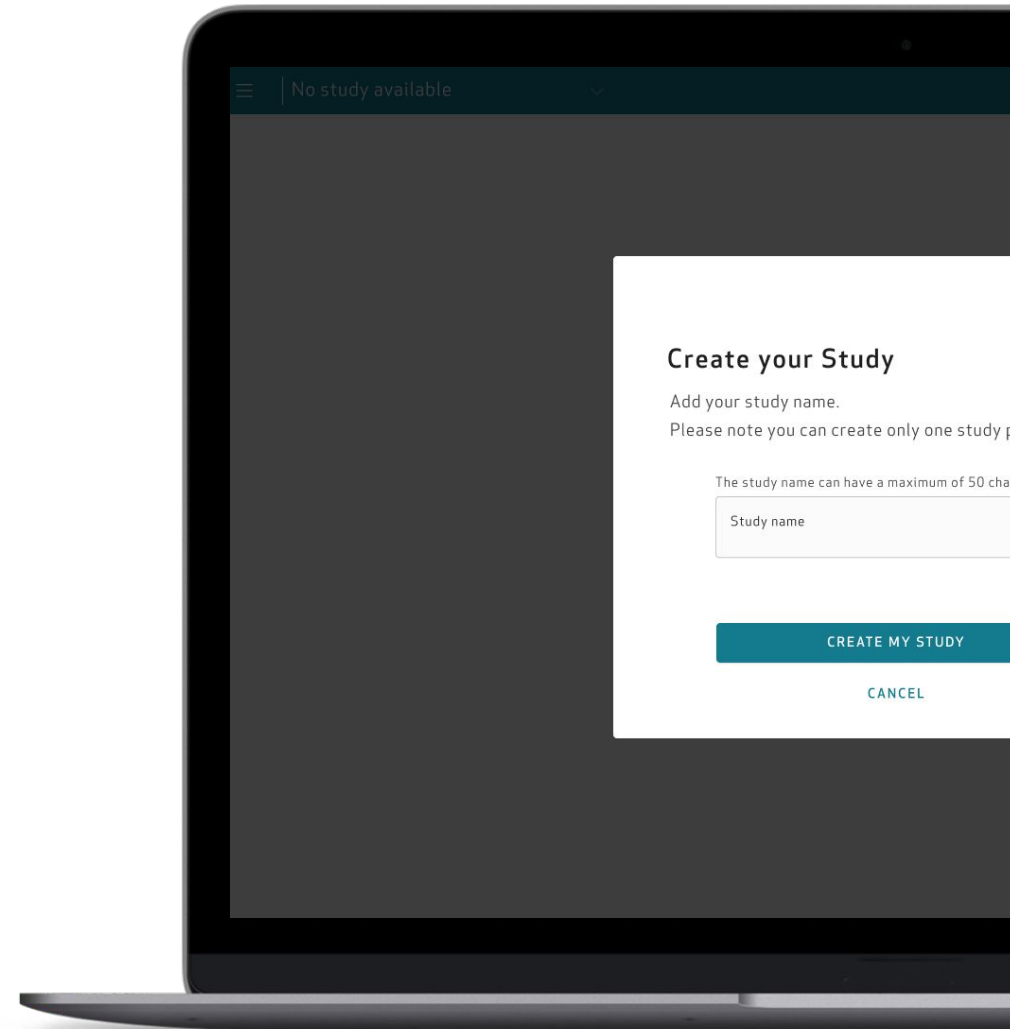


# Create your study

Once your email address is verified, you will be asked to insert your name, surname and **chosen study name**.

Please note you can create only one study per account.

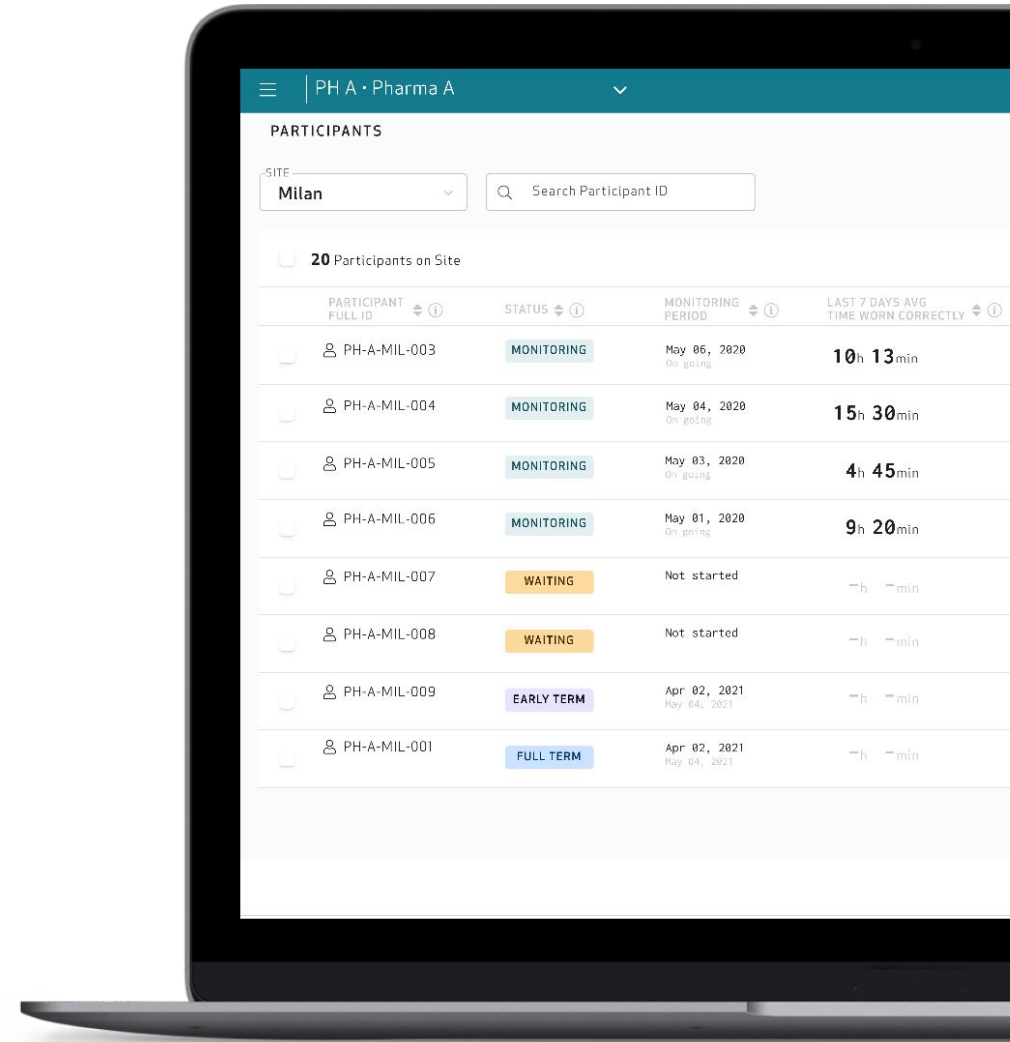
You will be able to change the name of your study at anytime, by clicking on the edit icon (✎) next to the study name in the top teal bar.



# Care Portal navigation

The Care Portal is composed of three essential navigation elements:

- **Profile** to view and change settings (e.g. password).
- A **side navigation menu** to select the activity to perform.
- A **search and filter bar** at the top of each page to narrow down the list (columns can also be sorted).



## Care Portal navigation

**1** Side navigation menu

**2** Profile

**3** Search and filter bar

**PH A · Pharma A**

**PARTICIPANTS**

SITE: **MI · Milan** Search Participant ID

20 Participants on Site [ADD PARTICIPANTS](#)

PARTICIPANT FULL ID	STATUS	DATA SYNC	MONITORING PERIOD	LAST 7 DAYS AVG TIME WORN CORRECTLY	LAST 7 DAYS WEARING DETECTION
PH-A-MIL-003	PAUSED	Fully synced May 06, 2023 12:15:43 AM (UTC +02:00)	May 06, 2020 Ongoing	10h 13min	
PH-A-MIL-004	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 04, 2020 Ongoing	15h 30min	
PH-A-MIL-005	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 03, 2020 Ongoing	4h 45min	
PH-A-MIL-006	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 01, 2020 Ongoing	9h 20min	
PH-A-MIL-007	WAITING	Never synced	Not started	-h -min	
PH-A-MIL-008	WAITING	Never synced	Not started	-h -min	
PH-A-MIL-009	EARLY TERM	Dec 01, 2022 12:15:43 AM (UTC +02:00)	Apr 02, 2021 May 04, 2021		
PH-A-MIL-001	FULL TERM	Dec 06, 2022 12:15:43 AM (UTC +02:00)	Apr 02, 2021 May 04, 2021		

Where are the 3 elements located in the Care Portal?

1. Side navigation menu
2. Profile
3. Search and filter bar

## Profile

**PROFILE**

**Your Information**  
View email, name and password of your profile. EDIT

Email\*  
youremail@company.com

First name\*  
Jane

Last name\*  
Doe

Password\*  
\*\*\*\*\*

**Setting**  
Please select a preferred language for your Dashboard, including date, time, and number formatting. EDIT

Language\*  
English

Temperature unit  
Celsius (°C)

Date format\*  
Language default (e.g. MM/DD/YYYY)

Time format\*  
Language default (e.g. 11:06)

To manage and modify your profile information and settings, follow these steps:

Click the “user icon” on the top-right of the teal header bar.  
Click ‘PROFILE’.

Click the ‘EDIT’ button under ‘Your Information’ to edit the first name and last name, and then click ‘SAVE’.

Click ‘Change Password’ to modify the account password, following the steps listed on-screen.

Click on ‘EDIT’ under ‘Setting’ to modify the Temperature unit, Date format, Time format, and then click ‘SAVE’.

## Side navigation menu

The screenshot displays the Empatica Health Monitoring Platform interface. On the left, a side navigation menu is visible, containing sections for MANAGEMENT, MONITORING, DATA, and DOCUMENTATION. The 'PARTICIPANTS' option under MANAGEMENT is highlighted. The main content area shows the 'PARTICIPANTS' page for site 'MI • Milan'. It includes a search bar for 'Search Participant ID' and a summary of '20 Participants on Site' with an 'ADD PARTICIPANTS' button. Below this is a table listing individual participants with columns for ID, status, data sync, monitoring period, and wearing detection metrics.

PARTICIPANT FULL ID	STATUS	DATA SYNC	MONITORING PERIOD	LAST 7 DAYS AVG TIME WORN CORRECTLY	LAST 7 DAYS WEARING DETECTION
PH-A-MIL-003	PAUSED	Fully synced May 06, 2023 12:15:43 AM (UTC +02:00)	May 06, 2020 Ongoing	10h 13min	[Bar chart]
PH-A-MIL-004	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 04, 2020 Ongoing	15h 30min	[Bar chart]
PH-A-MIL-005	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 03, 2020 Ongoing	4h 45min	[Bar chart]
PH-A-MIL-006	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 01, 2020 Ongoing	9h 20min	[Bar chart]
PH-A-MIL-007	WAITING	Never synced -	Not started	-h -min	[Bar chart]
PH-A-MIL-008	WAITING	Never synced -	Not started	-h -min	[Bar chart]
PH-A-MIL-009	EARLY TERM	Dec 01, 2022 12:15:43 AM (UTC +02:00)			
PH-A-MIL-001	FULL TERM	Dec 06, 2022 12:15:43 AM (UTC +02:00)			






empaticaCARE  
 ● All systems operational. View more.  
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To navigate between the functionalities available in the Care Portal: press the “Hamburger Menu Icon” and the side menu will open. Within the side menu, you can view and navigate through all the functionalities available for your study.

**IMPORTANT:** Availability of the activities depends on the plan

## Side navigation menu

The contents of the side navigation menu varies depending on the user's rights and permissions. Detailed below are the different possible sections and the information you can find in each section.

<p>MANAGEMENT</p> <hr/> <p> <b>PARTICIPANTS</b></p>	<p>A list view of all the participants and their relevant information. It is possible to perform the following actions: Add Participant, End Monitoring of Participants, and Reset Participant's Password.</p>
<p>MONITORING</p> <hr/> <p> <b>DIGITAL BIOMARKERS</b></p>	<p>View the latest digital biomarkers uploaded in the study by a participant, and take a close look at different time spans by using the date picker.</p>
<p>DATA</p> <hr/> <p> <b>DATA ACCESS KEY</b></p>	<p>Here you can generate, download, and revoke the Data Access Keys to access the data stored on AWS S3 Bucket.</p>
<p>DOCUMENTATION</p> <hr/> <p> <b>REGULATORY</b></p>	<p>Within this section, it is possible to view the regulatory information about the Care Portal and download the Care Portal User Manual.</p>
<p>GET HELP</p> <hr/> <p> <b>SUPPORT</b></p>	<p>Here, you will find useful documents, guides, and the link to submit requests to our Support Team.</p>

## Search and filter

**PARTICIPANTS**

SITE: **MI • Milan**

20 Participants on Site ADD PARTICIPANTS

PARTICIPANT FULL ID	STATUS	DATA SYNC	MONITORING PERIOD	LAST 7 DAYS AVG TIME WORN CORRECTLY	LAST 7 DAYS WEARING DETECTION
PH-A-MIL-003	PAUSED	Fully synced May 06, 2023 12:15:43 AM (UTC +02:00)	May 06, 2020 Ongoing	10h 13min	
PH-A-MIL-004	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 04, 2020 Ongoing	15h 30min	
PH-A-MIL-005	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 03, 2020 Ongoing	4h 45min	
PH-A-MIL-006	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 01, 2020 Ongoing	9h 20min	
PH-A-MIL-007	WAITING	Never synced	Not started	-h -min	
PH-A-MIL-008	WAITING	Never synced	Not started	-h -min	
PH-A-MIL-009	EARLY TERM	Dec 01, 2022 12:15:43 AM (UTC +02:00)	Apr 02, 2021 May 04, 2021		
PH-A-MIL-001	FULL TERM	Dec 06, 2022 12:15:43 AM (UTC +02:00)	Apr 02, 2021 May 04, 2021		

In the **list view**, you can navigate the data by site using the filter highlighted in the image above. You can also search participant full IDs and sort columns.

**IMPORTANT:** Availability of the feature depends on the plan



# Enrolling Participants in your Study

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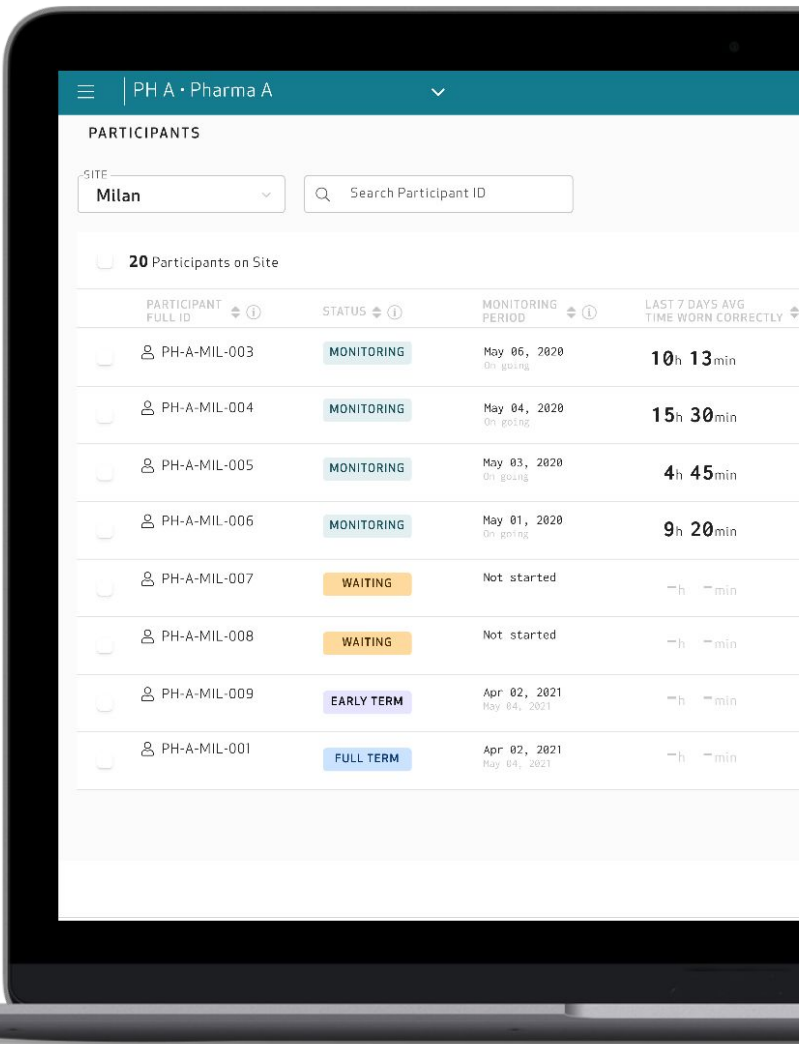


## *Add participants to a study and generate credentials*

To create participants within the Care Portal, you will need to add them to the study. This will generate their login credentials, which are needed to access the Care Lab App and pair EmbracePlus.

To add a participant to a site, follow the steps outlined on the next slides.

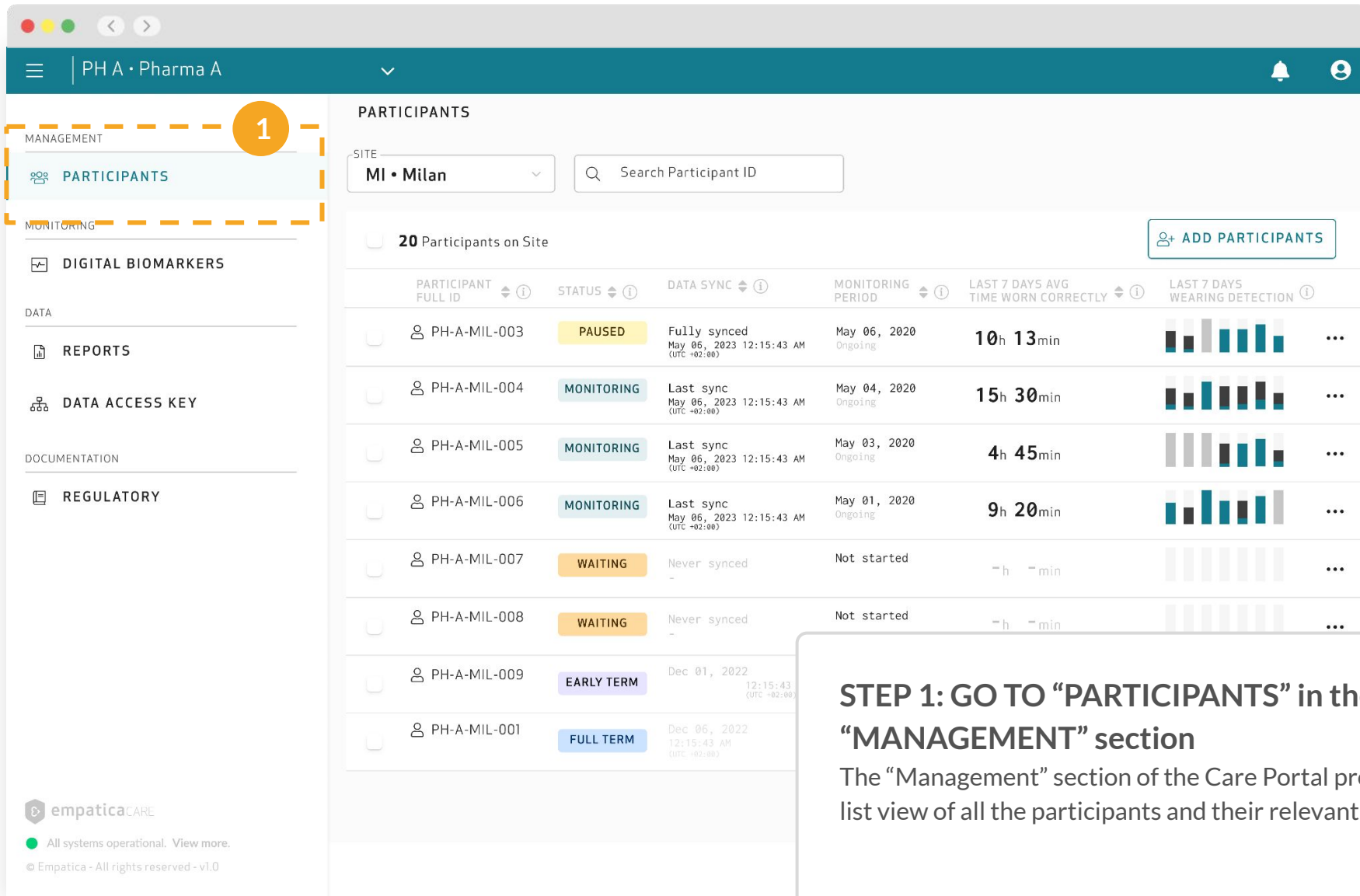
**IMPORTANT:** If the flow is not completed the action will be canceled. All the steps listed below should be performed to complete the action.



The screenshot displays the 'PARTICIPANTS' section of the Empatica Health Monitoring Platform. The site is set to 'Milan'. A search bar is available for finding participants by ID. Below the search bar, it indicates '20 Participants on Site'. A table lists the participants with their full IDs, status, monitoring period, and the average time worn correctly over the last 7 days.

PARTICIPANT FULL ID	STATUS	MONITORING PERIOD	LAST 7 DAYS AVG TIME WORN CORRECTLY
PH-A-MIL-003	MONITORING	May 06, 2020 <small>On going</small>	10h 13min
PH-A-MIL-004	MONITORING	May 04, 2020 <small>On going</small>	15h 30min
PH-A-MIL-005	MONITORING	May 03, 2020 <small>On going</small>	4h 45min
PH-A-MIL-006	MONITORING	May 01, 2020 <small>On going</small>	9h 20min
PH-A-MIL-007	WAITING	Not started	-h -min
PH-A-MIL-008	WAITING	Not started	-h -min
PH-A-MIL-009	EARLY TERM	Apr 02, 2021 May 04, 2021	-h -min
PH-A-MIL-001	FULL TERM	Apr 02, 2021 May 04, 2021	-h -min

## Add participants to a study and generate login credentials



**1**

MANAGEMENT

PARTICIPANTS

MONITORING

DIGITAL BIOMARKERS

DATA

REPORTS

DATA ACCESS KEY

DOCUMENTATION

REGULATORY

empaticaCARE

All systems operational. View more.

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**PARTICIPANTS**

SITE: MI • Milan

Search Participant ID

20 Participants on Site

ADD PARTICIPANTS

PARTICIPANT FULL ID	STATUS	DATA SYNC	MONITORING PERIOD	LAST 7 DAYS AVG TIME WORN CORRECTLY	LAST 7 DAYS WEARING DETECTION
PH-A-MIL-003	PAUSED	Fully synced May 06, 2023 12:15:43 AM (UTC +02:00)	May 06, 2020 Ongoing	10h 13min	
PH-A-MIL-004	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 04, 2020 Ongoing	15h 30min	
PH-A-MIL-005	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 03, 2020 Ongoing	4h 45min	
PH-A-MIL-006	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 01, 2020 Ongoing	9h 20min	
PH-A-MIL-007	WAITING	Never synced	Not started	-h -min	
PH-A-MIL-008	WAITING	Never synced	Not started	-h -min	
PH-A-MIL-009	EARLY TERM	Dec 01, 2022 12:15:43 (UTC +02:00)			
PH-A-MIL-001	FULL TERM	Dec 06, 2022 12:15:43 AM (UTC +02:00)			

### STEP 1: GO TO “PARTICIPANTS” in the “MANAGEMENT” section

The “Management” section of the Care Portal provides you with a list view of all the participants and their relevant information.

## Add participants to a study and generate login credentials

The screenshot shows the 'PARTICIPANTS' view for site 'MI • Milan'. At the top right, there is a button labeled 'ADD PARTICIPANTS' with a person icon, which is highlighted by a dashed orange box and a circle containing the number '2'. Below the button is a table of participants with columns for ID, status, data sync, monitoring period, and wearing detection. At the bottom right, a text box provides instructions for Step 2.

PARTICIPANT FULL ID	STATUS	DATA SYNC	MONITORING PERIOD	LAST 7 DAYS AVG TIME WORN CORRECTLY	LAST 7 DAYS WEARING DETECTION
PH-A-MIL-003	PAUSED	Fully synced May 06, 2023 12:15:43 AM (UTC +02:00)	May 06, 2020 Ongoing	10h 13min	[Bar chart showing wearing detection]
PH-A-MIL-004	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 04, 2020 Ongoing	15h 30min	[Bar chart showing wearing detection]
PH-A-MIL-005	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 03, 2020 Ongoing	4h 45min	[Bar chart showing wearing detection]
PH-A-MIL-006	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 01, 2020 Ongoing	9h 20min	[Bar chart showing wearing detection]
PH-A-MIL-007	WAITING	Never synced	Not started	-h -min	[Bar chart showing wearing detection]
PH-A-MIL-008	WAITING	Never synced	Not started	-h -min	[Bar chart showing wearing detection]
PH-A-MIL-009	EARLY TERM	Dec 01, 2022 12:15:43 AM (UTC +02:00)	Apr 02, 2021 May 04, 2021		
PH-A-MIL-001	FULL TERM	Dec 06, 2022 12:15:43 AM (UTC +02:00)	Apr 02, 2021 May 04, 2021		

**STEP 2: CLICK “ADD PARTICIPANTS”**  
Once inside the ‘PARTICIPANTS’ view of your site, click the ‘ADD PARTICIPANTS’ button.

Rows per page: 8 | 1-8 of 20

## Add participants to a study and generate login credentials

ADD PARTICIPANTS

### ADD PARTICIPANTS

You have selected to add participants to **PH A MIL • Pharma A Milan**.

The Participant Full ID is composed by OrgID-StudyID-SiteID-Participant ID. You can generate the Participant IDs (up to 10 characters) that will be added at the end of the already existing OrgID-StudyID-SiteID.

Select below how you want to add the participants to the above site to continue.

**AUTOMATIC ID**

If you want our system to automatically generate Participant IDs for you, press **AUTOMATIC IDS**. These IDs will consist in up to ten numerical digits.

**CUSTOMIZED ID**

If you want to add Participants with customized Participant IDs you should press **CUSTOMIZED IDS** and follow the next steps, that consist in manually writing the IDs or pasting them from an Excel file.

### STEP 3: CHOOSE TYPE OF CREDENTIALS

**Automatic ID:** Add participants to the site using IDs that are generated automatically by the system.

**Customized ID:** Add participants to the site using customized IDs.

CANCEL

## Add participants to a study and generate login credentials

ADD PARTICIPANTS > AUTOMATIC ID > PARTICIPANTS CREDENTIALS

### ADD PARTICIPANTS - AUTOMATIC IDS

You have selected to add new Participants to your Site with Automatic IDs. In order to continue, answer the questions below.

You have 436 Participant slots available.

1. How many Participants would you like to add?

2. What should the first ID be? (the other IDs added will be an ascending numerical sequence starting from this ID)

3. How many digits should the IDs have?

This is how the IDs will look like:

PH-A-MIL-0011   PH-A-MIL-0012   ...   HCK-MI-8

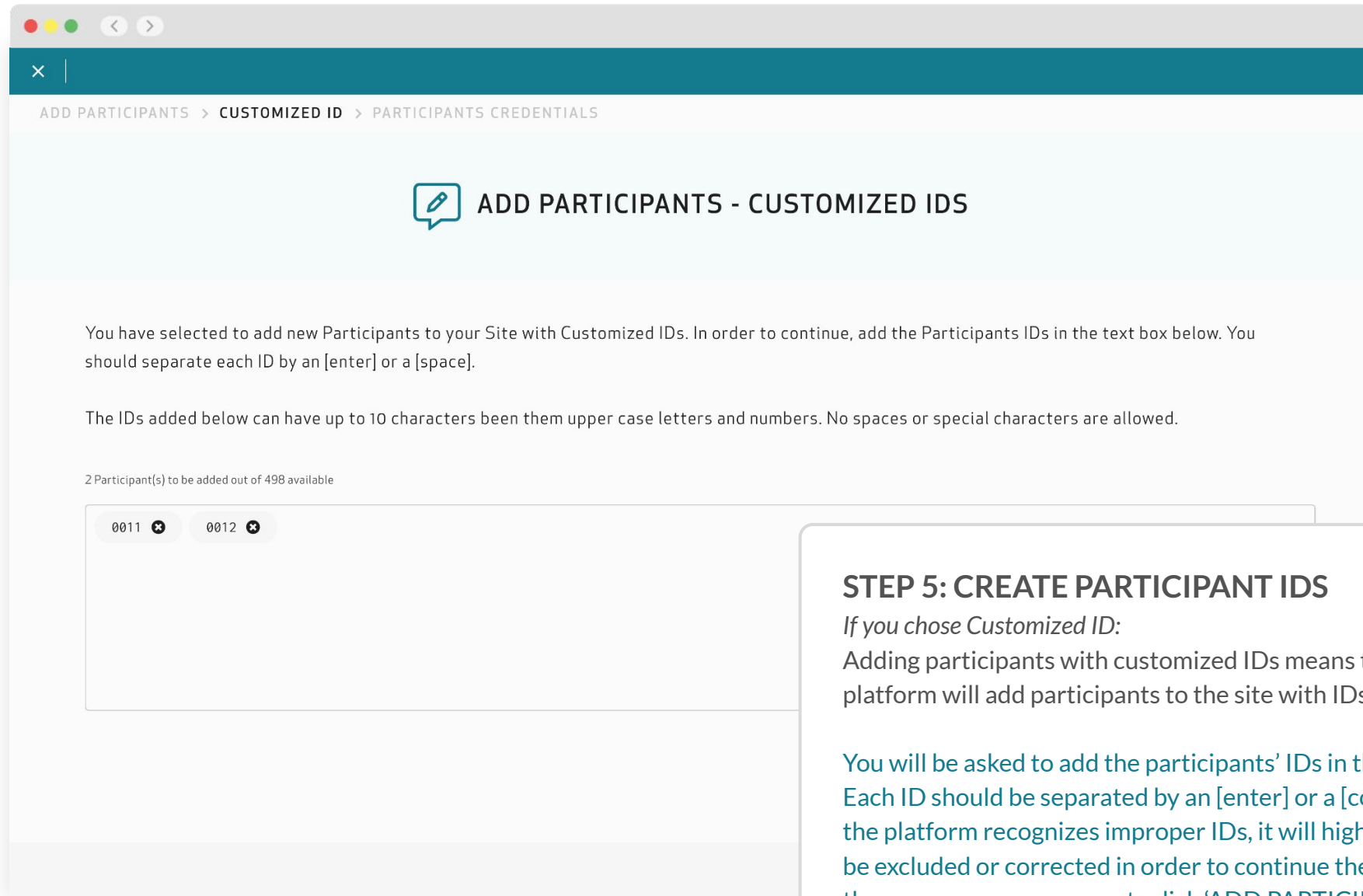
### STEP 4: CREATE PARTICIPANT ID

*If you chose Automatic ID:*

Adding participants with automatic IDs means that the platform will automatically generate the IDs of the participants within the site.

After defining the three questions asked, click 'ADD PARTICIPANTS' and the system will add the participants to the site.

## Add participants to a study and generate login credentials



ADD PARTICIPANTS > CUSTOMIZED ID > PARTICIPANTS CREDENTIALS

### ADD PARTICIPANTS - CUSTOMIZED IDS

You have selected to add new Participants to your Site with Customized IDs. In order to continue, add the Participants IDs in the text box below. You should separate each ID by an [enter] or a [space].

The IDs added below can have up to 10 characters been them upper case letters and numbers. No spaces or special characters are allowed.

2 Participant(s) to be added out of 498 available

0011 ✕ 0012 ✕

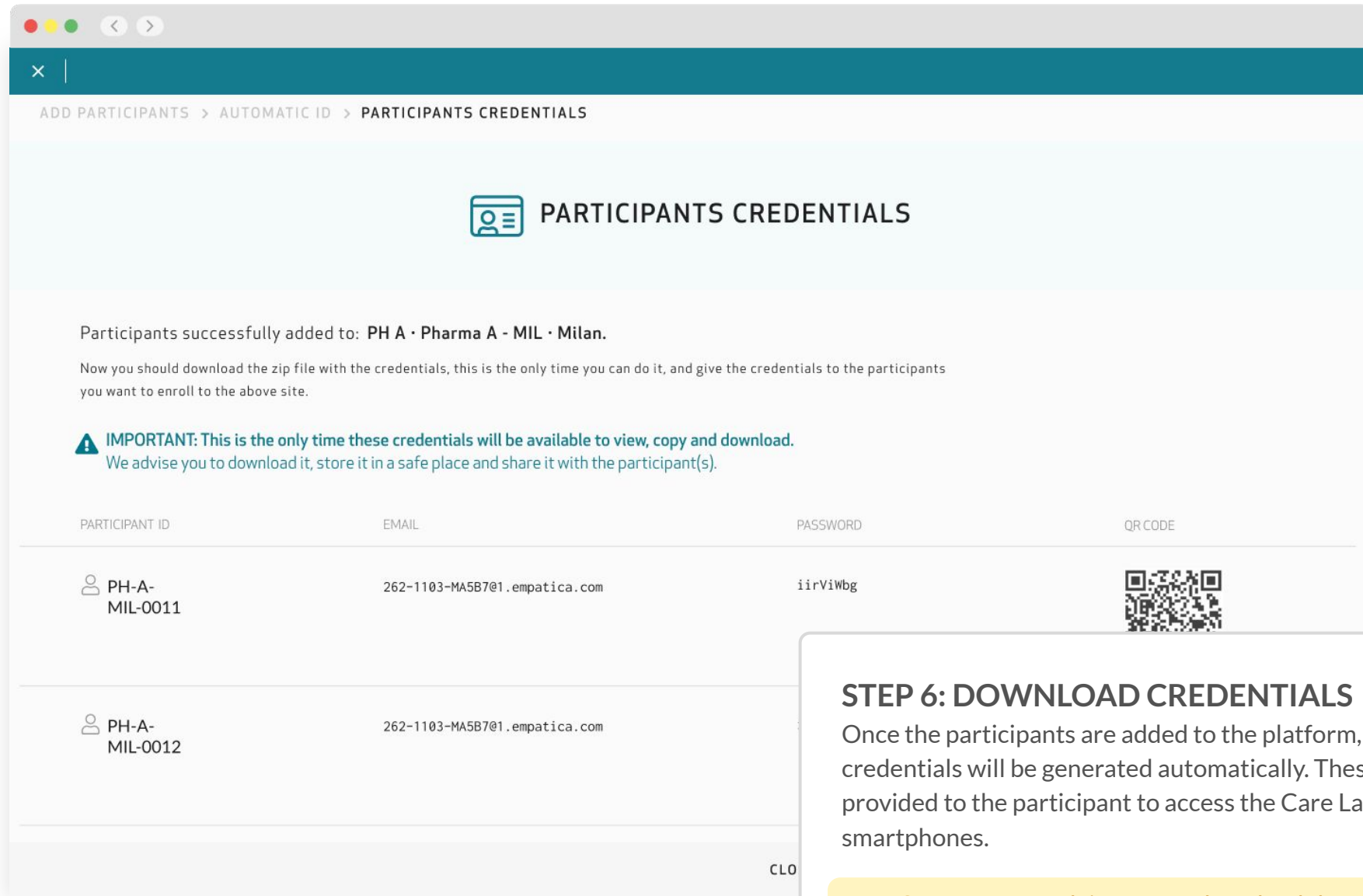
### STEP 5: CREATE PARTICIPANT IDS

*If you chose Customized ID:*

Adding participants with customized IDs means that the platform will add participants to the site with IDs chosen by you.

You will be asked to add the participants' IDs in the text box. Each ID should be separated by an [enter] or a [comma]. In case the platform recognizes improper IDs, it will highlight them to be excluded or corrected in order to continue the process. If there are no errors present, click 'ADD PARTICIPANTS' and continue.

## Add participants to a study and generate login credentials






ADD PARTICIPANTS > AUTOMATIC ID > PARTICIPANTS CREDENTIALS

### PARTICIPANTS CREDENTIALS

Participants successfully added to: **PH A · Pharma A - MIL · Milan.**

Now you should download the zip file with the credentials, this is the only time you can do it, and give the credentials to the participants you want to enroll to the above site.

**⚠ IMPORTANT: This is the only time these credentials will be available to view, copy and download.**  
We advise you to download it, store it in a safe place and share it with the participant(s).

PARTICIPANT ID	EMAIL	PASSWORD	QR CODE
 PH-A-MIL-0011	262-1103-MA5B7@1.empatica.com	iirViWbg	
 PH-A-MIL-0012	262-1103-MA5B7@1.empatica.com		

CLO

### STEP 6: DOWNLOAD CREDENTIALS

Once the participants are added to the platform, their login credentials will be generated automatically. These should be provided to the participant to access the Care Lab App on their smartphones.

**IMPORTANT:** We advise you to download the credentials, and store a copy in a safe place, so you do not have to generate new credentials in the future.

## Share login credentials with participant

### CONTENT OF THE DOWNLOADED ZIP FOLDER

The downloaded zip file will contain three different folders:

**Participant Credentials List:** a CSV file containing Participant Full IDs, emails, and passwords generated for each participant. This file is good for keeping a record of all the login credentials generated.

**QR Codes (PNG):** folder with all the generated QR Codes per participant.

**Participant Login Credentials (PNG):** folder that contains the participant login credential file. The PNG should be given to each participant, where they will find instructions on how to download and use the Care Lab App. This should be shared with the participant.

**IMPORTANT:** Each set of credentials is designed to be used by only one participant. Credentials should not be shared with multiple participants.

It is important for participants to keep their credentials in a safe place in case they ever need to reuse them to log in to the system again.

We also advise that the Study and Site coordinators keep a safe copy of participant credentials.

embrace<sup>PLUS</sup>

[ORG-STUDY NAME]  
[PARTICIPANT ID]

### Getting started

- 1. DOWNLOAD THE CARE LAB APP**  
IF USING A PROVISIONED DEVICE, SKIP TO STEP 2  
To download open the store on your smartphone (App Store if iOS, Play Store if Android) and search for 'Empatica Care Lab'. Tap on 'Get it' or 'Download' to start the download process.
- 2. OPEN THE CARE LAB APP**  
Open the App by tapping its icon on the device. If you are using a provisioned device and cannot locate the App, connect the device to the internet, and it should download automatically.
- 3. LOGIN WITH THESE CREDENTIALS**  
Use these credentials to access the Care Lab App. You can do so by either scanning the QR code or typing in the participant identifier and password provided. The App will guide you through the next steps.  
These credentials should only be used by you and cannot be shared with another participant



CREDENTIALS GENERATED:

LOGIN WITH QR CODE	PARTICIPANT IDENTIFIER
PASSWORD	

**TURN ON EMBRACEPLUS**  
Turn on EmbracePlus by pressing the upper button, EmbracePlus will greet you with a HI. If this doesn't happen, you may need to charge it.



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DCRE-3 REV1.0 20221020



## Log into the Care Lab App

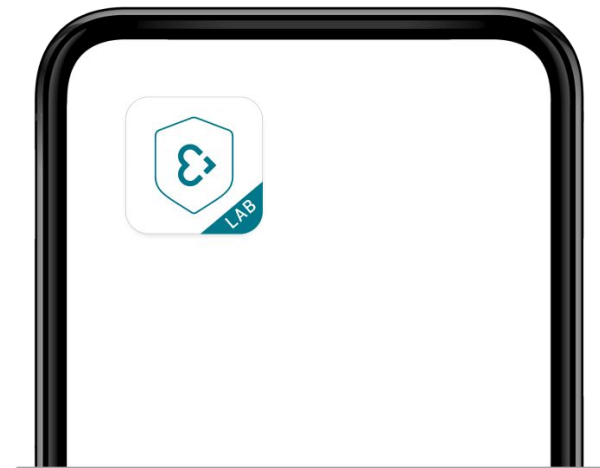
Instruct participants to download the Care Lab App on their compatible smartphones.

To download the Care Lab App, open the app store on the smartphone (App Store if iOS, Play Store if Android) and search for '**Empatica Care Lab**'. Click on 'Install' or 'Download'.

Remember that the smartphone must be compatible with the system, to check compatibility go to:

[empatica.com/embraceplus-compatibility](https://empatica.com/embraceplus-compatibility)

**IMPORTANT:** If you are using the Professional Plan, make sure that you search "Empatica Care Lab" in the app store and download the Empatica Care Lab App (white background, teal outline).

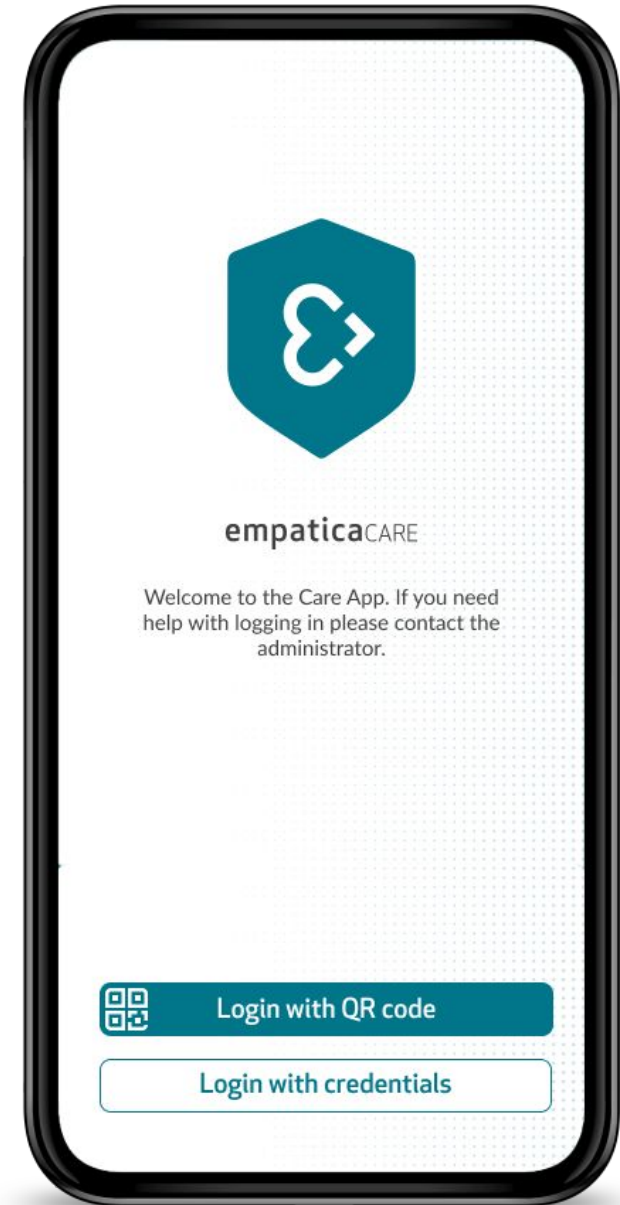


## Log into the Care Lab App

Instruct participants to open the Empatica Care Lab App by tapping the icon on the device.

Once inside the Care Lab App, the participant should use the provided login credential which was generated by the Study Team through the Care Portal. The participant can either scan the QR code, or type in the participant identifier and password provided. The Care Lab App will guide the participant through the next steps.

**IMPORTANT:** These login credentials should only be used by the assigned participant and cannot be shared with multiple participants.



## Pair the EmbracePlus with the Care Lab App

1. Make sure the companion device has Bluetooth® and the internet connection (WiFi or cellular network) is activated.

2. Make sure the EmbracePlus is turned on:  
Click the top button on the right side of the EmbracePlus.  
'HI' or the battery status should appear on the display.

*If nothing happens, i.e. EmbracePlus screen display remains dark:*

Charge EmbracePlus by plugging it into a standard 5V USB 2.0 power source. Slide EmbracePlus into the charger, making sure the buttons are on the outer side. The EmbracePlus will turn on and display 'HI', and then the battery percentage will appear.

**IMPORTANT:** If participants are using a provisioned phone the Care Lab App should already be installed on the phone.



### *Pair the EmbracePlus with the Care Lab App*

3. Keep the EmbracePlus close to the companion device (even if it is charging).
4. After logging into the Care Lab App, start the pairing flow and follow the steps provided.
5. When the process is completed, the EmbracePlus will display the time on a light background. (If it is placed in the charger, temporarily remove it to ensure that pairing was successful).



## Pair the EmbracePlus with the Care Lab App

*If you have multiple EmbracePlus devices nearby*

You will need to select the serial number (S/N) of the EmbracePlus you want to pair in the Care Lab App. You can find the EmbracePlus (S/N) on:

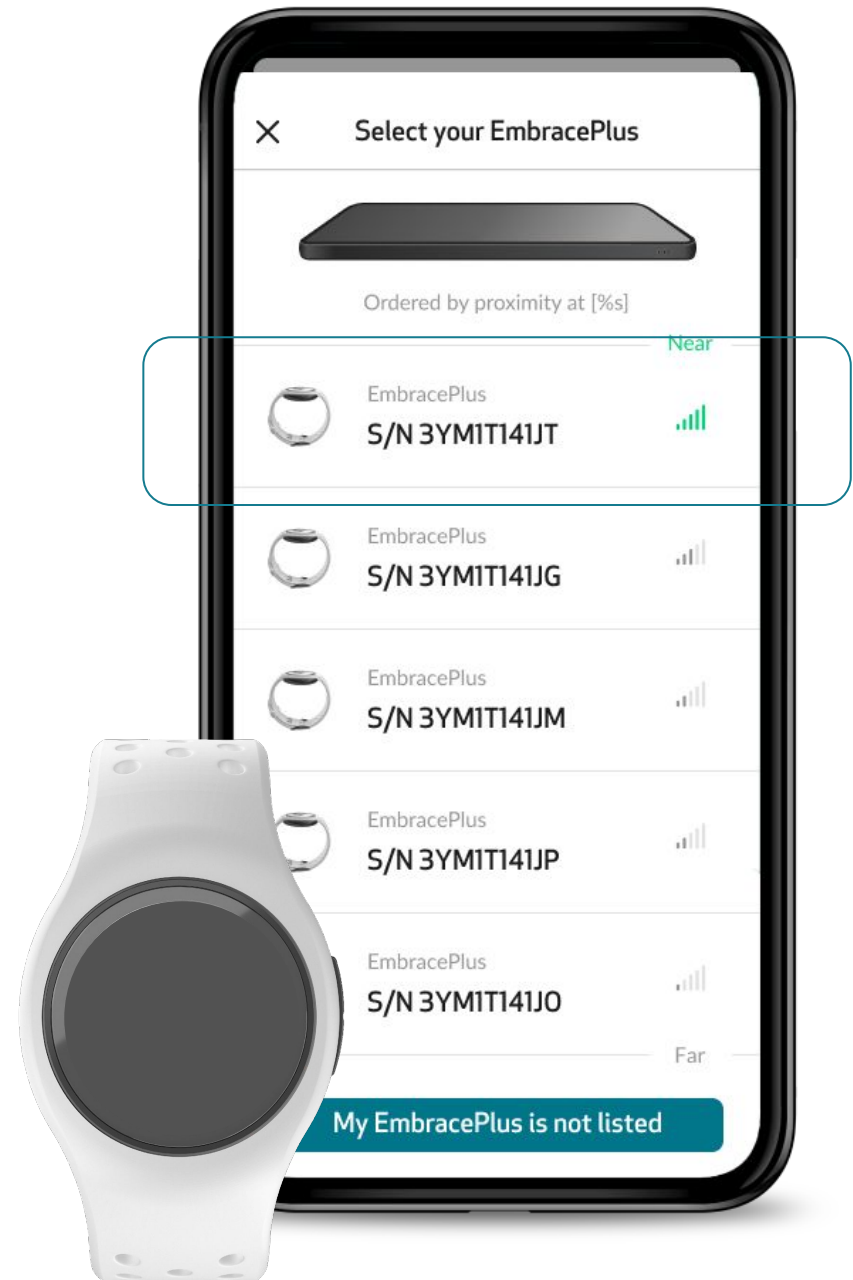


### The back of EmbracePlus

The EmbracePlus serial number can be found at the bottom of the EmbracePlus pod, near the sensors.

### The box side label

Check the EmbracePlus box side label, the serial number is printed at the center of the label.



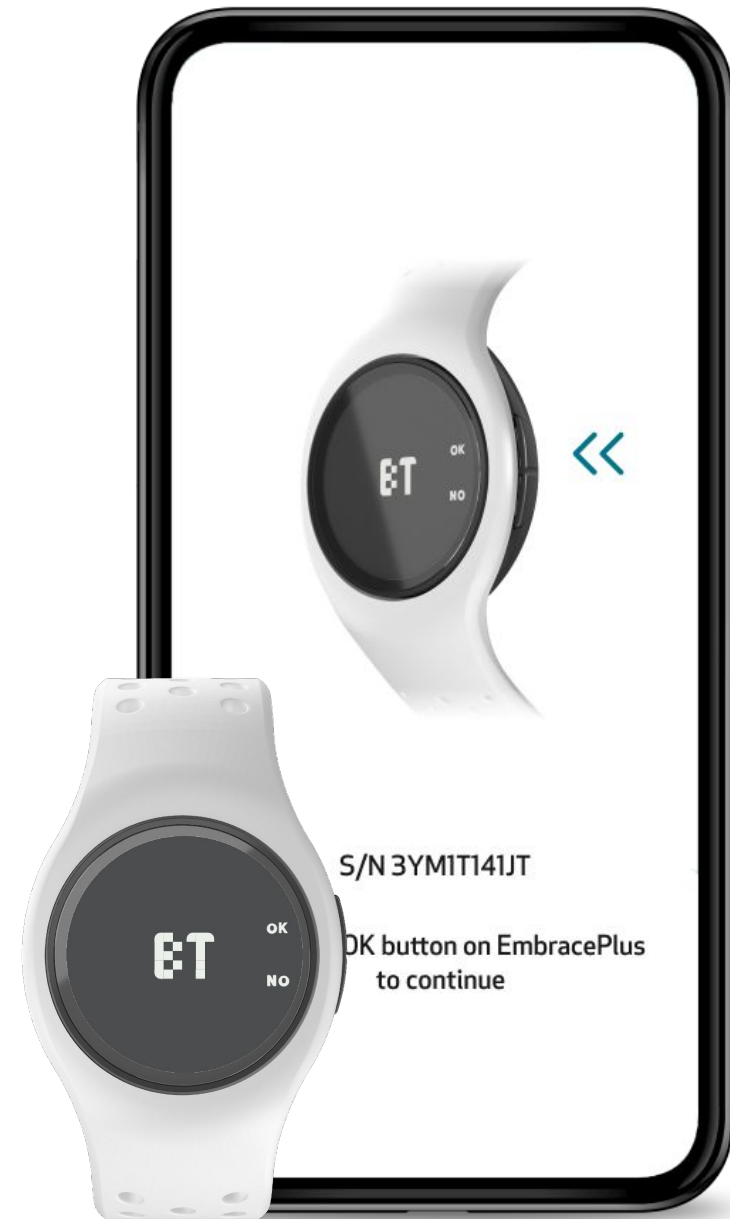
## Pair the EmbracePlus with the Care Lab App

### Encrypted Bluetooth® pairing

Once you have selected which EmbracePlus you want to pair, the display of the EmbracePlus will show a Bluetooth® (BT) confirmation icon.

To confirm the Bluetooth® pairing, press the top button of the EmbracePlus (OK). To reject the pairing, press the bottom button of the EmbracePlus (NO).

Confirm the pairing only if the serial number of the EmbracePlus, and the one shown in the Care Lab App, match.



**Final check: Before the participant starts collecting data using the EmbracePlus, make sure that**



## CARE LAB APP

Open the application and check that:

- The background is teal;
- The Status card reads 'Care is running smoothly';
- Wearing time is increasing;
- The Participant has the correct EmbracePlus. You can check this by looking at the serial number on the EmbracePlus, and comparing it to the serial number in the Settings menu of the Care Lab App



## EMBRACEPLUS

Check the EmbracePlus and verify that:

- The display is light;
- The Empatica heart icon is visible;
- The sensor is on (there is a green light from the bottom of the device)



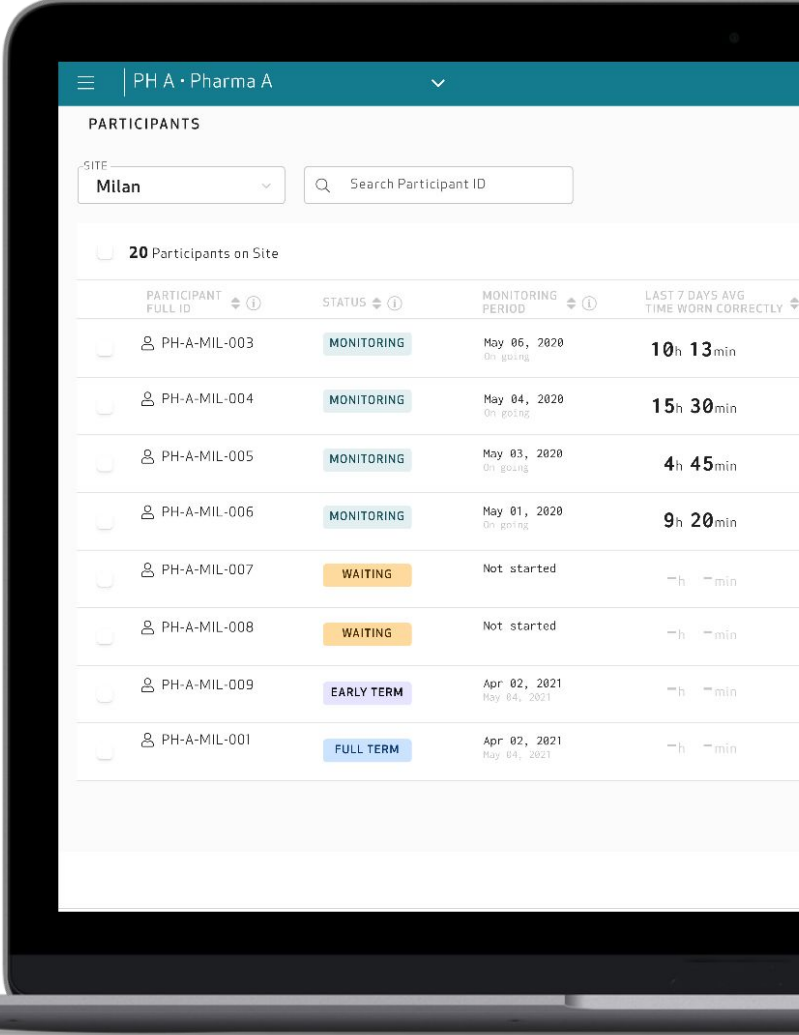
# Managing the Study and Site

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# How to manage the study and site

The Empatica Health Monitoring Platform was built to facilitate the management of studies and sites within the Care Portal. Within the **Management - Participants** section of the side navigation menu, you can find a list view of all of the participants.



The screenshot displays the 'PARTICIPANTS' section of the Empatica Health Monitoring Platform. The interface shows a list of participants for the 'Milan' site. The table includes columns for Participant Full ID, Status, Monitoring Period, and Last 7 Days Avg Time Worn Correctly. The participants are listed in descending order of their monitoring period.

PARTICIPANT FULL ID	STATUS	MONITORING PERIOD	LAST 7 DAYS AVG TIME WORN CORRECTLY
PH-A-MIL-003	MONITORING	May 06, 2020 <small>On going</small>	10h 13min
PH-A-MIL-004	MONITORING	May 04, 2020 <small>On going</small>	15h 30min
PH-A-MIL-005	MONITORING	May 03, 2020 <small>On going</small>	4h 45min
PH-A-MIL-006	MONITORING	May 01, 2020 <small>On going</small>	9h 20min
PH-A-MIL-007	WAITING	Not started	-h -min
PH-A-MIL-008	WAITING	Not started	-h -min
PH-A-MIL-009	EARLY TERM	Apr 02, 2021 <small>May 04, 2021</small>	-h -min
PH-A-MIL-001	FULL TERM	Apr 02, 2021 <small>May 04, 2021</small>	-h -min

## Checking participant compliance

PH A · Pharma A
🔔 👤

**PARTICIPANTS**

SITE: **MI • Milan**

📌 20 Participants on Site + ADD PARTICIPANTS

PARTICIPANT FULL ID	STATUS	DATA SYNC	MONITORING PERIOD	LAST 7 DAYS AVG TIME WORN CORRECTLY	LAST 7 DAYS WEARING DETECTION
PH-A-MIL-003	PAUSED	Fully synced May 06, 2023 12:15:43 AM (UTC +02:00)	May 06, 2020 Ongoing	10h 13min	
PH-A-MIL-004	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 04, 2020 Ongoing	15:00	
PH-A-MIL-005	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 03, 2020 Ongoing		
PH-A-MIL-006	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 01, 2020 Ongoing		
PH-A-MIL-007	WAITING	Never synced	Not started		
PH-A-MIL-008	WAITING	Never synced	Not started		
PH-A-MIL-009	EARLY TERM	Dec 01, 2022 12:15:43 AM (UTC +02:00)	Apr 02, 2021 May 04, 2021		
PH-A-MIL-001	FULL TERM	Dec 06, 2022 12:15:43 AM (UTC +02:00)	Apr 02, 2021 May 04, 2021		

### HOW TO CHECK COMPLIANCE?

Once participants begin uploading data, you can view their compliance.

In order to check participants compliance, you can observe the information from the highlighted columns and compare to the compliance protocol of your study:

**Last 7 Days AVG Time Worn Correctly:**  
Average time worn correctly by the participant in the last 7 (seven) days

**Last 7 Days Wearing Detection:**  
Graphical view of the wearing detection in the last 7 (seven) days

Worn correctly    Not worn correctly    Not connected

**Data Sync:**  
Timeframe when the participant has last synced data from the Care Lab App to the Empatica Cloud.

# Participant Status

Participants added in the Care Portal can have four different statuses:

<b>WAITING</b>	Participant login credentials have been generated, but have not yet been used to pair EmbracePlus with the Care App.
<b>MONITORING</b>	The Participant has paired EmbracePlus and has been uploading data (Last Data Sync).
<b>PAUSED</b>	The Participant Monitoring has logged out and therefore the data collection is paused
<b>EARLY TERM</b>	The Participant has been withdrawn from the Study before having completed it.
<b>FULL TERM</b>	The Participant has completed the Study.

## ***End monitoring of participants***

Once a participant is no longer part of a study, you can end their monitoring period within the **Management - Participant** section, by either marking the participant as Early-term or Full-term. The Care Portal will record their termination date.



### **END: EARLY TERM**

When a participant's monitoring time should be ended without completing the data collection period  
(e.g. participant withdrew, participant failed screening).



### **END: FULL TERM**

When a participant has fully completed the data collection period.

## End monitoring of participants

The screenshot displays the 'PARTICIPANTS' section of the Empatica Health Monitoring Platform. The interface includes a header with the site name 'PH A · Pharma A', a search bar for 'Search Participant ID', and a dropdown for 'SITE' set to 'MI · Milan'. Below the search bar, there are bulk action buttons: '1 Participants out of 20 selected', 'SELECT ALL PARTICIPANTS', and 'DESELECT'. Two buttons for ending monitoring are highlighted with a dashed orange box: 'END: EARLY TERM' and 'END: FULL TERM'. The main table lists participants with columns for 'PARTICIPANT FULL ID', 'STATUS', 'DATA SYNC', 'MONITORING PERIOD', 'LAST 7 DAYS AVG TIME WORN CORRECTLY', and 'LAST 7 DAYS WEARING DETECTION'. The first participant, PH-A-MIL-003, is selected and has a 'PAUSED' status. Other participants have statuses like 'MONITORING', 'WAITING', 'EARLY TERM', and 'FULL TERM'.

PARTICIPANT FULL ID	STATUS	DATA SYNC	MONITORING PERIOD	LAST 7 DAYS AVG TIME WORN CORRECTLY	LAST 7 DAYS WEARING DETECTION
<input checked="" type="checkbox"/> PH-A-MIL-003	PAUSED	Fully synced May 06, 2023 12:15:43 AM (UTC +02:00)	May 06, 2020 Ongoing	10h 13min	
<input type="checkbox"/> PH-A-MIL-004	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 04, 2020 Ongoing	15h 30min	
<input type="checkbox"/> PH-A-MIL-005	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 03, 2020 Ongoing	4h 45min	
<input type="checkbox"/> PH-A-MIL-006	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 01, 2020 Ongoing	9h 20min	
<input type="checkbox"/> PH-A-MIL-007	WAITING	Never synced	Not started	-h -min	
<input type="checkbox"/> PH-A-MIL-008	WAITING	Never synced	Not started	-h -min	
<input type="checkbox"/> PH-A-MIL-009	EARLY TERM	Dec 01, 2022 12:15:43 AM (UTC +02:00)	Apr 02, 2021 May 04, 2021		
<input type="checkbox"/> PH-A-MIL-001	FULL TERM	Dec 06, 2022 12:15:43 AM (UTC +02:00)	Apr 02, 2021 May 04, 2021		


### STEP 1: SELECT PARTICIPANT(S) TO END MONITORING

You can select multiple participants and end monitoring for all of them by using the bulk actions. Use the bulk options by clicking on the checkbox in the left corner of the participant row. Select the chosen participants and then click on the type of termination you want for all the participants you have selected.

## End monitoring of participants

×


**END: FULL TERM CONFIRM**



### END: FULL TERM

You have selected to **END: FULL TERM** of the participant(s) below. Review the data shown below and confirm you want to end these participant(s).

**! IMPORTANT: This is an irreversible process.**

PARTICIPANT ID ⓘ	MONITORING PERIOD ⓘ	LAST DATA SYNC ⓘ	ACTIONS
 PH-A-MIL-003	May 06, 2020 <small>Ongoing</small>	May 06, 2020 12:15:43 AM (UTC +02:00)	<a href="#" style="border: 1px solid #007a8c; padding: 5px 10px; text-decoration: none; color: #007a8c;">CANCEL</a>

The selected participant(s) will be withdrawn from this study and therefore data recording will stop. By confirming this flow, you acknowledge that:

- The participant(s) have completed the study;
- The participant(s) data currently available in the system is sufficient;
- The participant(s) Care App will permanently stop uploading data.

To confirm type bellow "FULL TERM"

FULL TERM

### STEP 2: CONFIRM END MONITORING

Confirm the action by following the instructions on the screen. It is possible to review the participant(s) and "CANCEL" the end monitoring directly on this page.

**IMPORTANT:** Before ending the monitoring of a participant, make sure that all data has been recently synced. Check that all data from the Care Lab App and EmbracePlus have been synced, and review the "Last Data Sync" column in the Care Portal.

## Reset participant's password

When a participant loses their password, and cannot retrieve the original credentials, the password should be reset by following these steps:

1. Select reset password action
2. Confirm reset participant password
3. Download credentials with new password
4. Send new login credentials

The screenshot shows the 'embracePLUS' 'Getting started' page. At the top right, there are placeholders for '[ORG-STUDY NAME]' and '[PARTICIPANT ID]'. The page contains a numbered list of instructions:

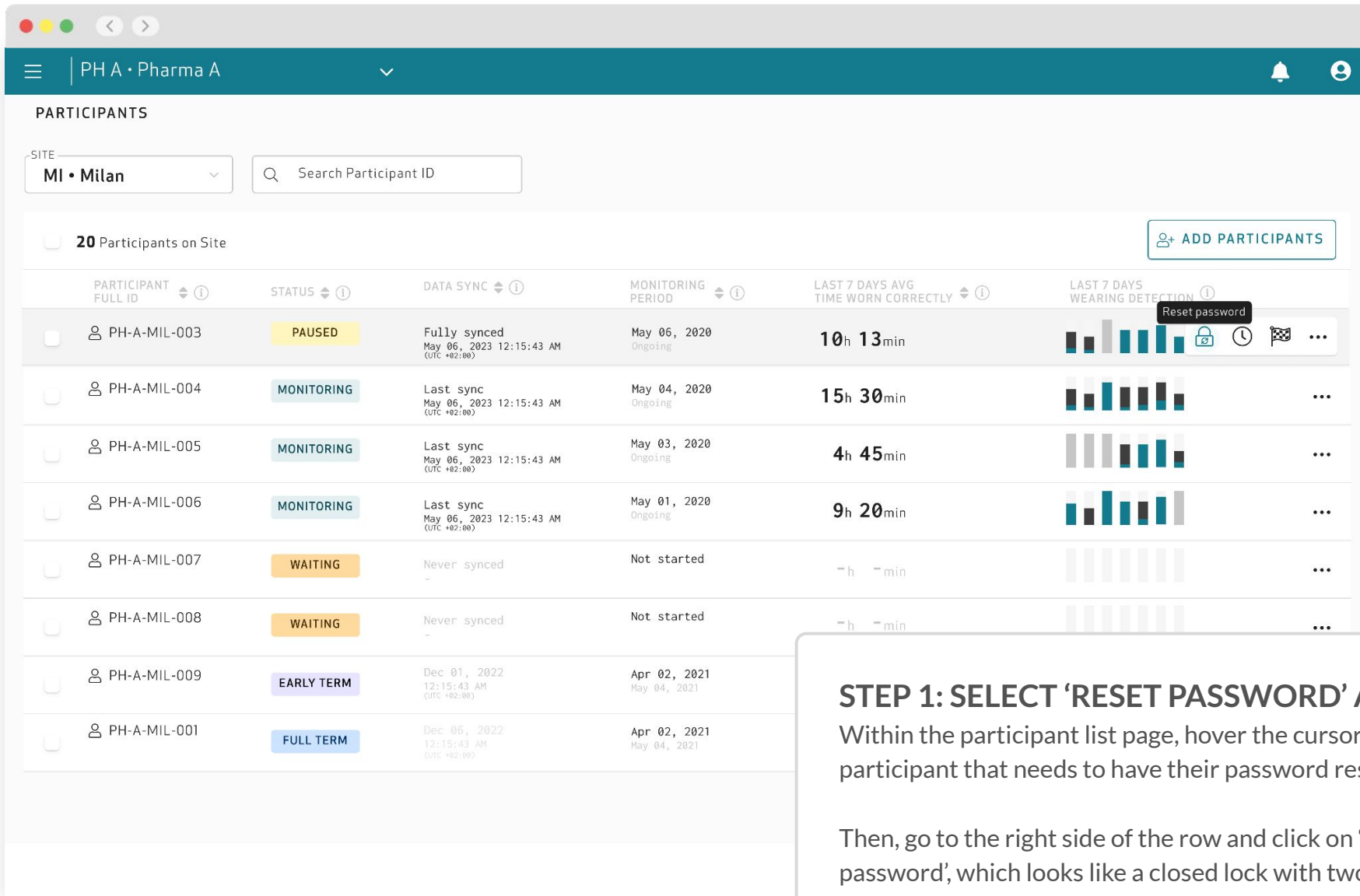
- 1. DOWNLOAD THE APP**  
IF USING A PROVISIONED DEVICE  
To download open the App Store or Google Play Store. If you are using a personal device, you can download the app from the Embrace Care website. The download link is provided below.
- 2. OPEN THE APP**  
Open the app on your device. The app will guide you through the setup process.
- 3. LOG IN**  
Use the credentials provided to you. If you are a participant, you will be guided through the process. These credentials are unique to you and cannot be shared.

Below the list, there is a section titled 'TURN ON EMBRACEPLUS' with an information icon. The text reads: 'Turn on EmbracePlus by pressing the upper button on the device. The device will greet you with a HI. If this doesn't happen, you may need to charge the device.' To the right of this text are images of the EmbracePlus device and its charging cable.

At the bottom left is the 'empatica' logo, and at the bottom right is the document ID 'DCRE-3 REV1.0 20221020'. A large teal circular icon with a white padlock and a refresh symbol is overlaid on the right side of the page.

**IMPORTANT:** Resetting a participant's password will stop their old password from working, and the participant will be logged out.

## Reset participant's password



The screenshot displays the 'PARTICIPANTS' section of the Empatica Health Monitoring Platform. The interface includes a header with the site name 'PH A · Pharma A', a search bar for 'Search Participant ID', and a dropdown for 'SITE' set to 'MI · Milan'. A summary shows '20 Participants on Site' and an 'ADD PARTICIPANTS' button. The main table lists participants with columns for ID, status, data sync, monitoring period, and last 7 days average time worn correctly. A tooltip 'Reset password' is shown over the 'PH-A-MIL-003' row, which is currently 'PAUSED'.

PARTICIPANT FULL ID	STATUS	DATA SYNC	MONITORING PERIOD	LAST 7 DAYS AVG TIME WORN CORRECTLY	LAST 7 DAYS WEARING DETECTION
PH-A-MIL-003	PAUSED	Fully synced May 06, 2023 12:15:43 AM (UTC +02:00)	May 06, 2020 Ongoing	10h 13min	[Bar chart with lock icon]
PH-A-MIL-004	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 04, 2020 Ongoing	15h 30min	[Bar chart]
PH-A-MIL-005	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 03, 2020 Ongoing	4h 45min	[Bar chart]
PH-A-MIL-006	MONITORING	Last sync May 06, 2023 12:15:43 AM (UTC +02:00)	May 01, 2020 Ongoing	9h 20min	[Bar chart]
PH-A-MIL-007	WAITING	Never synced	Not started	-h -min	[Bar chart]
PH-A-MIL-008	WAITING	Never synced	Not started	-h -min	[Bar chart]
PH-A-MIL-009	EARLY TERM	Dec 01, 2022 12:15:43 AM (UTC +02:00)	Apr 02, 2021 May 04, 2021		
PH-A-MIL-001	FULL TERM	Dec 06, 2022 12:15:43 AM (UTC +02:00)	Apr 02, 2021 May 04, 2021		

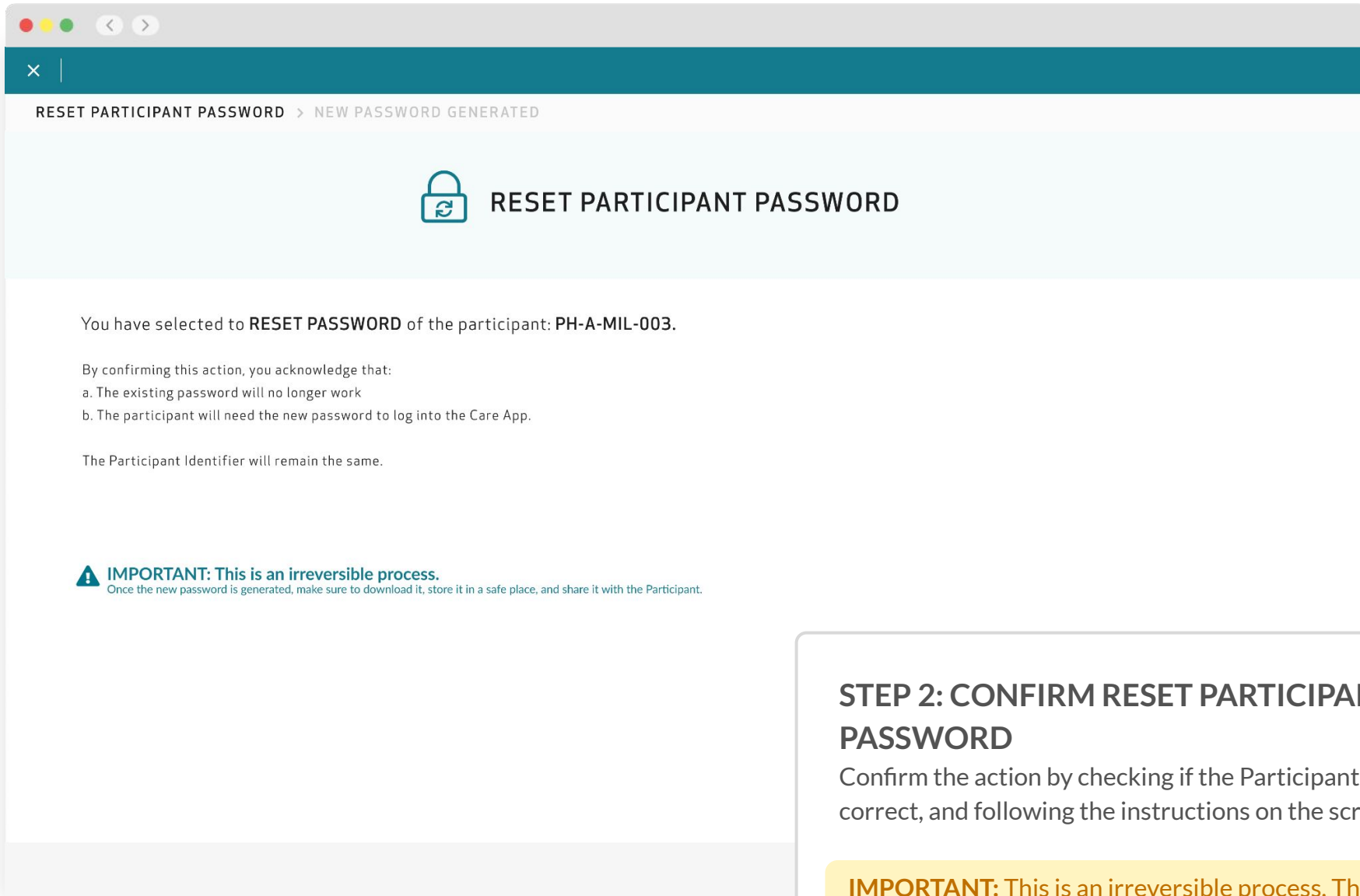
### STEP 1: SELECT 'RESET PASSWORD' ACTION

Within the participant list page, hover the cursor over the participant that needs to have their password reset.

Then, go to the right side of the row and click on 'Reset password', which looks like a closed lock with two spinning arrows.



## Reset participant's password



RESET PARTICIPANT PASSWORD > NEW PASSWORD GENERATED

### RESET PARTICIPANT PASSWORD

You have selected to **RESET PASSWORD** of the participant: **PH-A-MIL-003**.

By confirming this action, you acknowledge that:

- The existing password will no longer work
- The participant will need the new password to log into the Care App.

The Participant Identifier will remain the same.

**! IMPORTANT: This is an irreversible process.**  
Once the new password is generated, make sure to download it, store it in a safe place, and share it with the Participant.

### STEP 2: CONFIRM RESET PARTICIPANT PASSWORD

Confirm the action by checking if the Participant Full ID is correct, and following the instructions on the screen.

**IMPORTANT:** This is an irreversible process. The old credentials will not work and the participant will be logged out.

## Reset participant's password

RESET PARTICIPANT PASSWORD > NEW PASSWORD GENERATED

embracePLUS  
Getting started

- 1. DOWNLOAD THE CARE LAB APP**  
*IF USING A PROVISIONED DEVICE, SKIP TO STEP 2*  
 To download open the store on your smartphone (App Store if iOS, Play Store if Android) and search for 'Empatica Care Lab'. Tap on 'Get it' or 'Download' to start the download process.
- 2. OPEN THE CARE LAB APP**  
 Open the App by tapping its icon on the device. If you are using a provisioned device and cannot locate the App, connect the device to the internet, and it should download automatically.
- 3. LOGIN WITH THESE CREDENTIALS**  
 Use these credentials to access the App. You can do so by either scanning the QR code or typing in the participant identifier and password provided. The App will guide you through the next steps.  
*These credentials should only be used by you and cannot be shared with another participant*

**TURN ON EMBRACEPLUS**  
 Turn on EmbracePlus by pressing the upper button, EmbracePlus will greet you with a HL. If this doesn't happen, you may need to charge it.

**STEP 3: DOWNLOAD CREDENTIALS WITH NEW PASSWORD**  
 Once the reset password is completed, the new participant password will be generated.

**STEP 4: SEND NEW LOGIN CREDENTIALS**  
 The new login credentials should be sent to the participant.

**IMPORTANT:** We suggest you download the credentials, and store a copy in a safe place so you do not have to generate new credentials in the future.



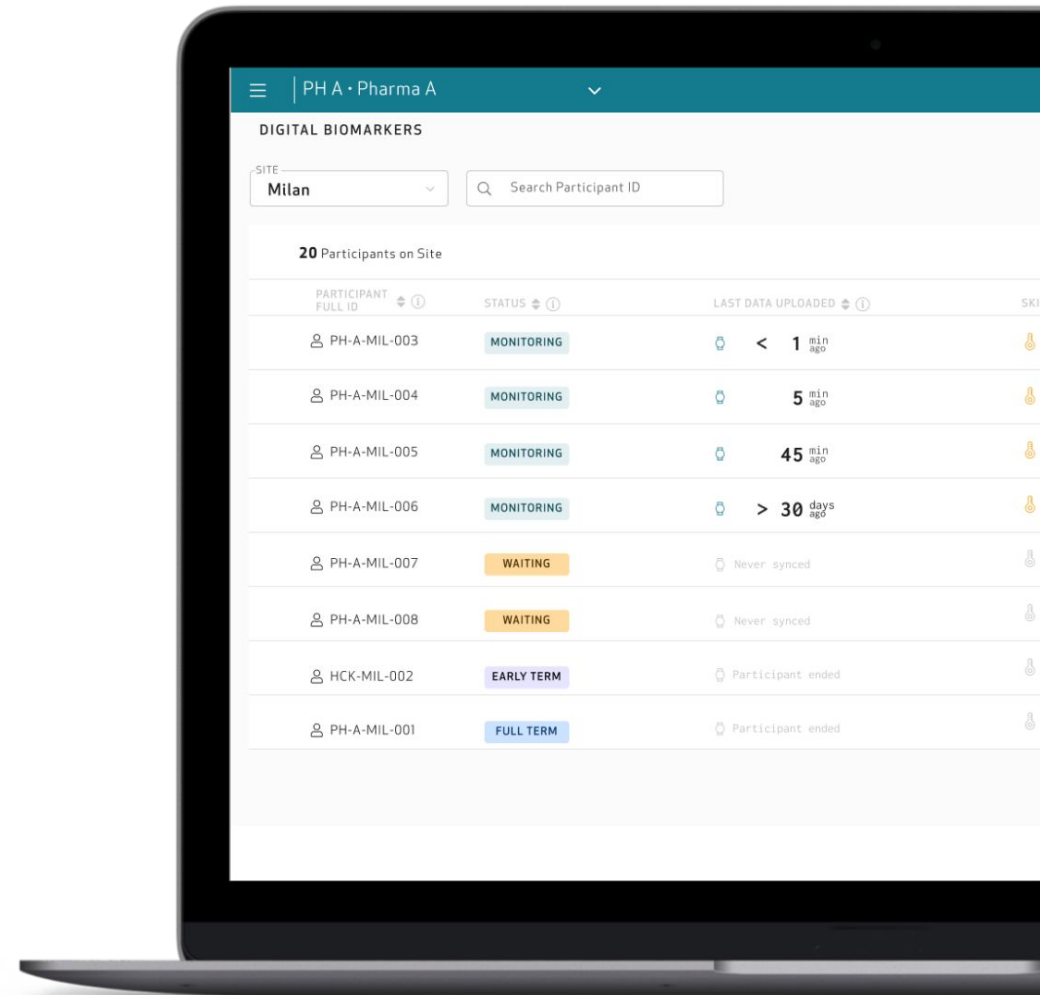
# Monitoring the Study and Site

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# How to monitor the study and site

To help monitor the study and site, the Empatica Health Monitoring Platform has two different functions that will be detailed in this section.

The first functionality is present within the Care Portal and is called **Monitor - Digital Biomarkers**.



## Monitoring - Digital Biomarkers

The screenshot displays the 'DIGITAL BIOMARKERS' section of the Empatica Health Monitoring Platform. The interface includes a sidebar with navigation options: MANAGEMENT, PARTICIPANTS, MONITORING, DIGITAL BIOMARKERS (selected), DATA, REPORTS, DOCUMENTATION, and REGULATORY. The main content area shows a list of participants for the 'Milan' site, with columns for PARTICIPANT FULL ID, STATUS, LAST DATA UPLOADED, SKIN TEMP., and PULSE RATE. The status of participants varies, including MONITORING, WAITING, EARLY TERM, and FULL TERM. A search bar for 'Search Participant ID' is available at the top of the list view.

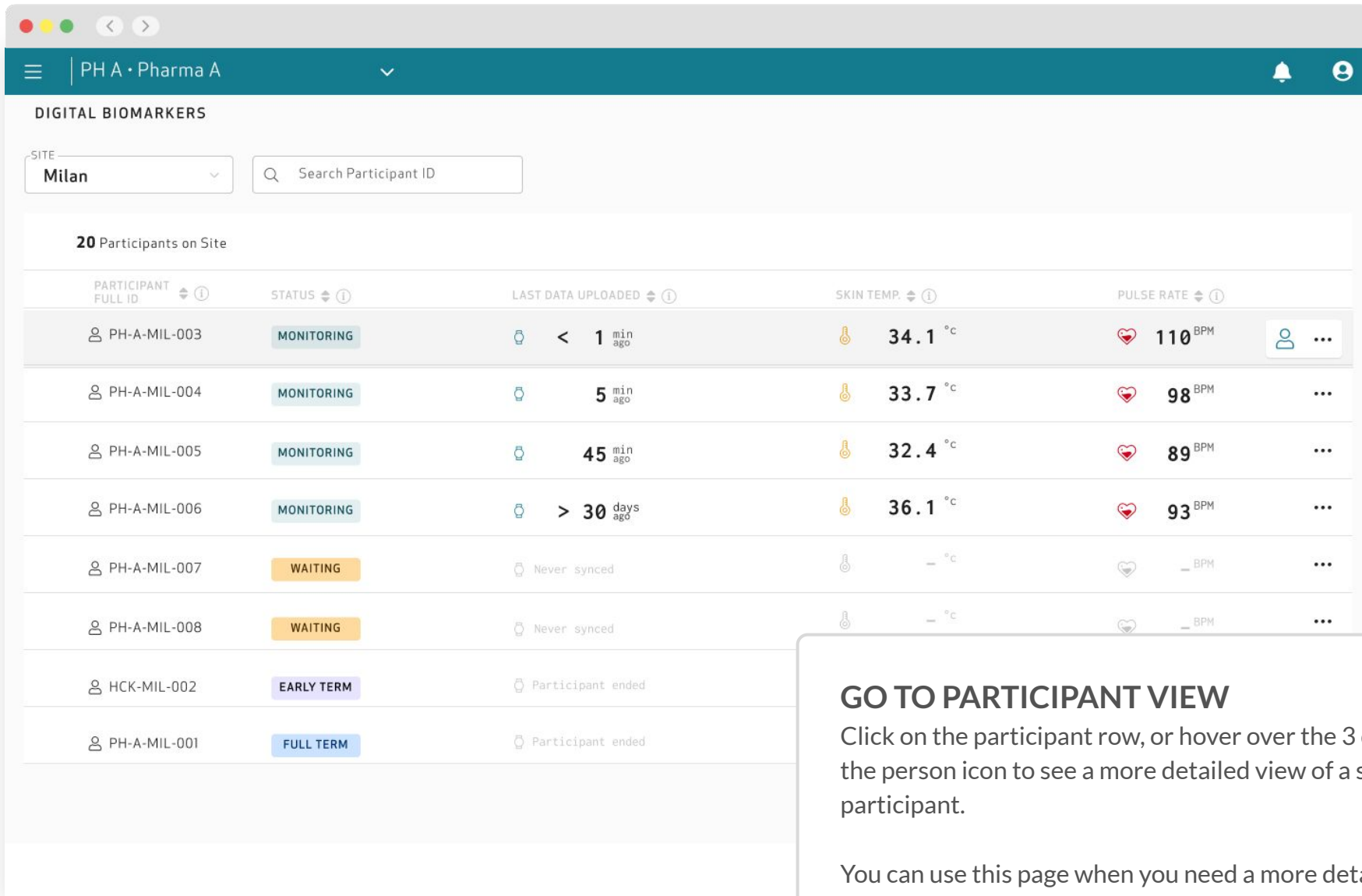
PARTICIPANT FULL ID	STATUS	LAST DATA UPLOADED	SKIN TEMP.	PULSE RATE
PH-A-MIL-003	MONITORING	< 1 min ago	34.1 °C	110 BPM
PH-A-MIL-004	MONITORING	5 min ago	33.7 °C	98 BPM
PH-A-MIL-005	MONITORING	45 min ago	32.4 °C	89 BPM
PH-A-MIL-006	MONITORING	> 30 days ago	36.1 °C	93 BPM
PH-A-MIL-007	WAITING	Never synced	- °C	- BPM
PH-A-MIL-008	WAITING	Never synced	- °C	- BPM
HCK-MIL-002	EARLY TERM	Part		
PH-A-MIL-001	FULL TERM	Part		

**LIST VIEW**

The Care Portal study team member will be able to check the Pulse Rate, Skin Temperature, and the Last Data Uploaded for each participant. The device also collects multiple other digital biomarkers that will be available at the end of the study.

This section provides a list view of all the participants grouped within one site. It is also possible to search for participant ID, and to move to the single participant view.

## Monitoring - Digital Biomarkers



The screenshot displays a web application interface for monitoring digital biomarkers. The header shows the site name 'PH A · Pharma A' and navigation icons. Below the header, the page is titled 'DIGITAL BIOMARKERS' and includes a dropdown menu for the site 'Milan' and a search bar for 'Search Participant ID'. A summary indicates '20 Participants on Site'. The main content is a table with columns for 'PARTICIPANT FULL ID', 'STATUS', 'LAST DATA UPLOADED', 'SKIN TEMP.', and 'PULSE RATE'. The table lists several participants with their respective statuses (Monitoring, Waiting, Early Term, Full Term) and data upload times. A callout box provides instructions on how to view a detailed participant view.

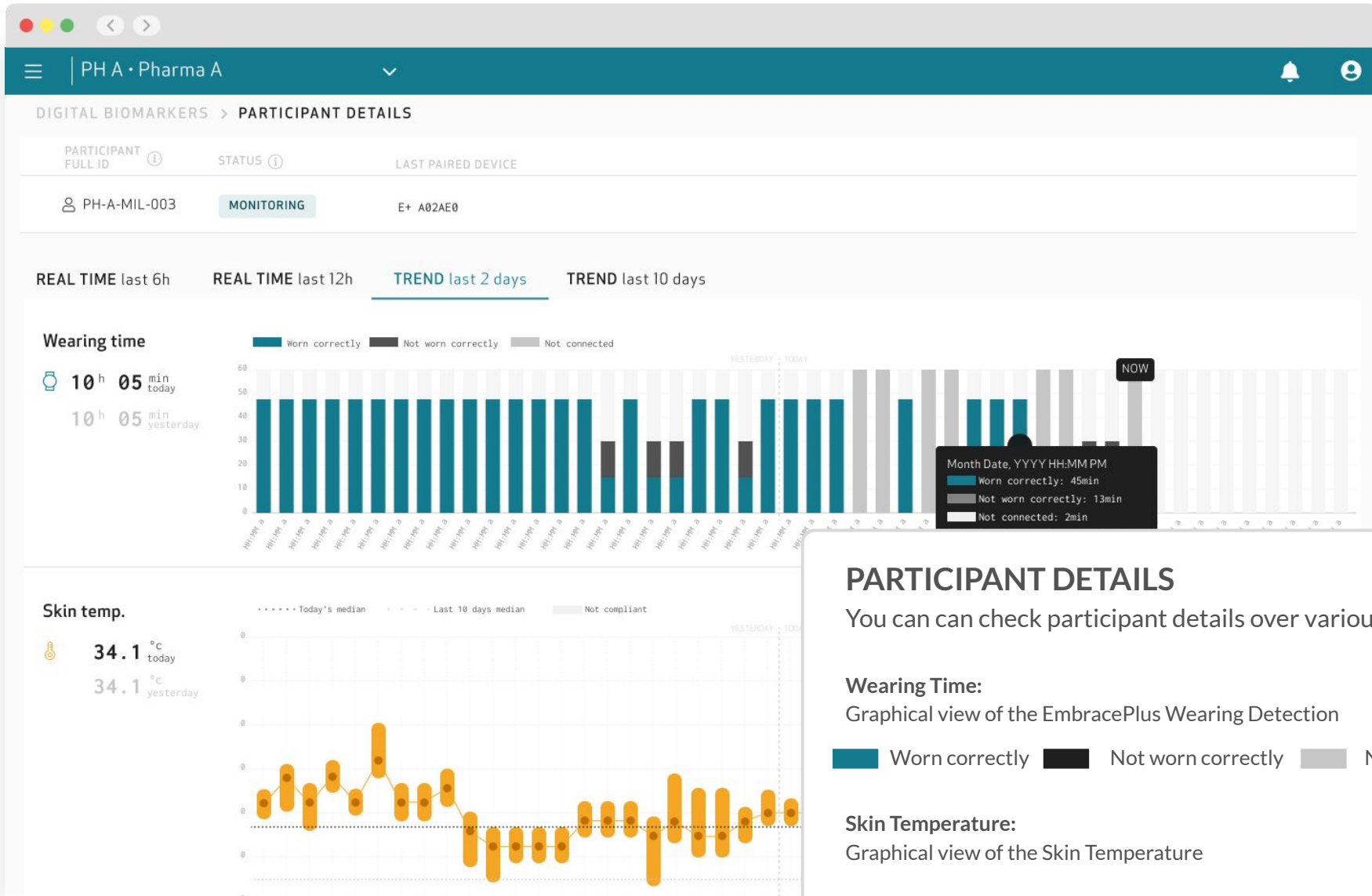
PARTICIPANT FULL ID	STATUS	LAST DATA UPLOADED	SKIN TEMP.	PULSE RATE
PH-A-MIL-003	MONITORING	< 1 min ago	34.1 °C	110 BPM
PH-A-MIL-004	MONITORING	5 min ago	33.7 °C	98 BPM
PH-A-MIL-005	MONITORING	45 min ago	32.4 °C	89 BPM
PH-A-MIL-006	MONITORING	> 30 days ago	36.1 °C	93 BPM
PH-A-MIL-007	WAITING	Never synced	- °C	- BPM
PH-A-MIL-008	WAITING	Never synced	- °C	- BPM
HCK-MIL-002	EARLY TERM	Participant ended		
PH-A-MIL-001	FULL TERM	Participant ended		

**GO TO PARTICIPANT VIEW**

Click on the participant row, or hover over the 3 dots, and click the person icon to see a more detailed view of a single participant.

You can use this page when you need a more detailed view of the participant's wearing time and digital biomarkers over different time spans.

## Monitoring - Digital Biomarkers



### PARTICIPANT DETAILS

You can check participant details over various time frames:

**Wearing Time:**  
Graphical view of the EmbracePlus Wearing Detection

Worn correctly
  Not worn correctly
  Not connected

**Skin Temperature:**  
Graphical view of the Skin Temperature

**Pulse Rate:**  
Graphical view of the Pulse Rate

# Monitoring - Digital Biomarkers

The screenshot displays the 'PARTICIPANT DETAILS' page for 'PH A • Pharma A'. It includes a table with participant information and two charts: 'Wearing time' and 'Skin temp.'. The 'Wearing time' chart is a stacked bar chart showing 'Worn correctly', 'Not worn correctly', and 'Not connected' over time. The 'Skin temp.' chart is a line graph showing temperature fluctuations. Both charts include callouts explaining that all times are shown in the participant's timezone (UTC -4).

PARTICIPANT FULL ID	STATUS	LAST PAIRED DEVICE
PH-A-MIL-003	MONITORING	E+ A02AE0

**Wearing time**

10 h 05 min today  
10 h 05 min yesterday

Month Date, YYYY HH:MMPM  
Worn correctly: 45min  
Not worn correctly: 13min  
Not connected: 2min

Participant Timezone: UTC -4 (-5h)  
All times in this page are shown in the Participant's timezone (UTC -4): -5h from your timezone (based on your device time).

All times in this page are shown in the Participant's timezone (UTC -4): -5h from your timezone (based on your device time).

**Skin temp.**

34.1 °C today  
34.1 °C yesterday

## DIFFERENT TIME ZONES

Some participants might be in different time zones. All graphs displayed in the participant detail view will be shown in the participant's timezone. If this timezone is different from the location of the Care User Account, the Care Portal will display a warning to remind you.



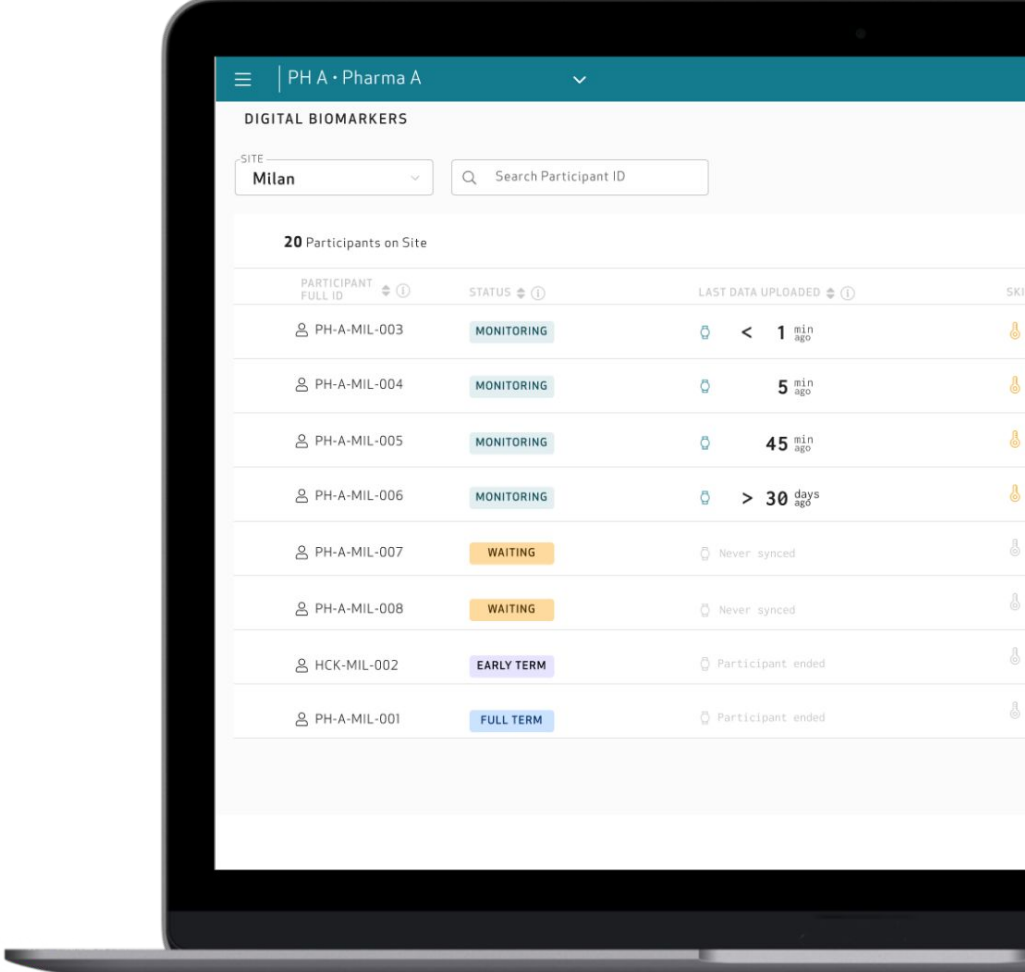


# Access your Data

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# Access your data

To gain access to all the data collected by the EmbracePlus, including the raw data and digital biomarkers, follow the steps outlined in the next slides.



The screenshot displays the 'DIGITAL BIOMARKERS' section of the Empatica Health Monitoring Platform. The interface is for 'PH A - Pharma A' and shows data for the 'Milan' site. A search bar for 'Search Participant ID' is visible. Below the search bar, it indicates '20 Participants on Site'. The main content is a table with columns for 'PARTICIPANT FULL ID', 'STATUS', 'LAST DATA UPLOADED', and 'SKI'. The table lists several participants with their respective statuses and last data upload times.

PARTICIPANT FULL ID	STATUS	LAST DATA UPLOADED	SKI
PH-A-MIL-003	MONITORING	< 1 min ago	
PH-A-MIL-004	MONITORING	5 min ago	
PH-A-MIL-005	MONITORING	45 min ago	
PH-A-MIL-006	MONITORING	> 30 days ago	
PH-A-MIL-007	WAITING	Never synced	
PH-A-MIL-008	WAITING	Never synced	
HCK-MIL-002	EARLY TERM	Participant ended	
PH-A-MIL-001	FULL TERM	Participant ended	

## Data Access Keys section

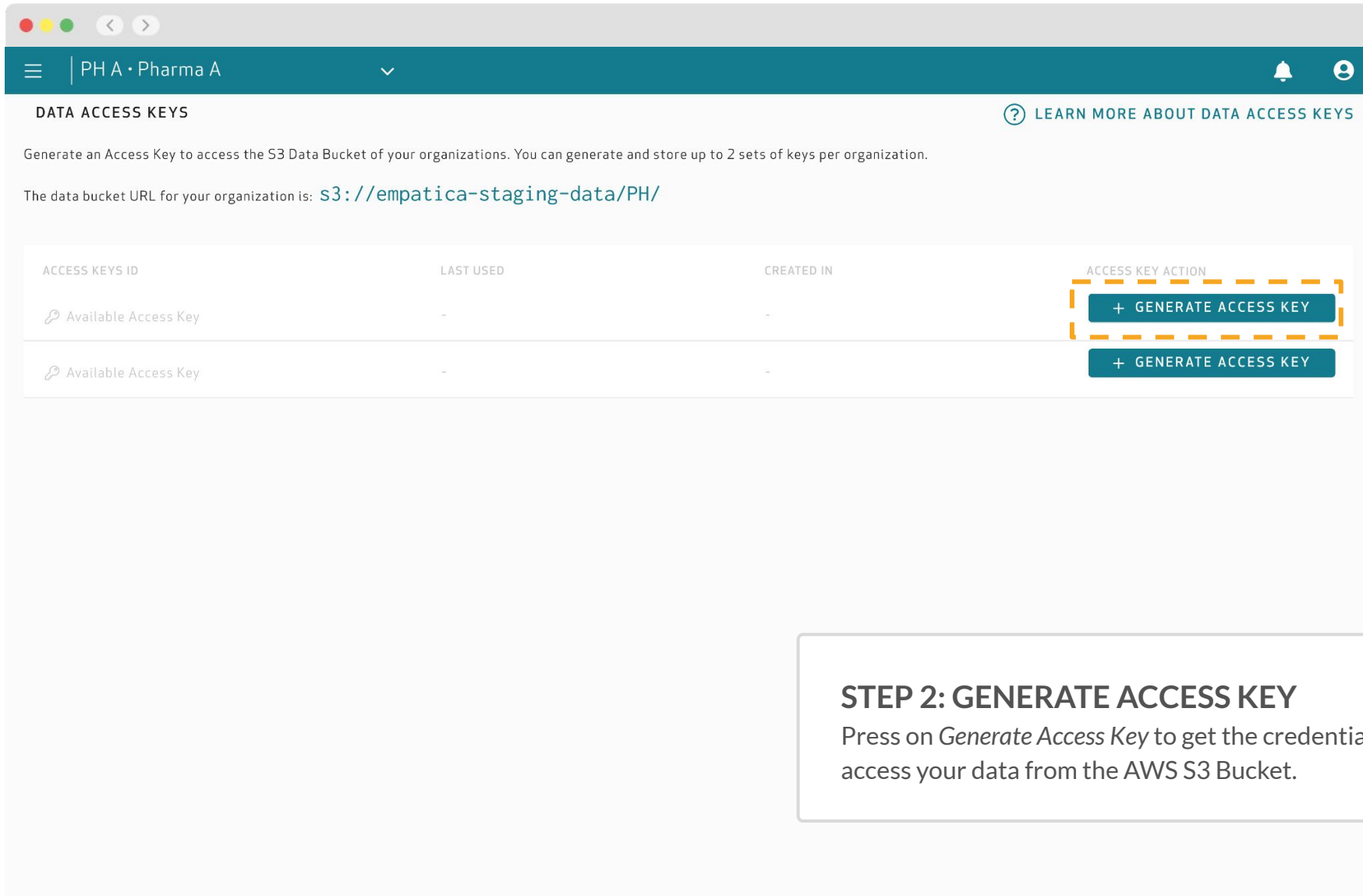
The screenshot displays the Empatica Health Monitoring Platform interface. The left sidebar contains a navigation menu with the following sections: MANAGEMENT (PARTICIPANTS), MONITORING (DIGITAL BIOMARKERS), DATA (REPORTS, DATA ACCESS KEYS), and DOCUMENTATION (REGULATORY). The 'DATA ACCESS KEYS' section is highlighted with a dashed orange box. The main content area shows the 'DIGITAL BIOMARKERS' section for 'PH A · Pharma A'. It includes a header with a help icon and the text 'LEARN MORE ABOUT DATA ACCESS KEYS'. Below the header, there is a paragraph explaining that users can generate up to 2 sets of keys per organization and a data bucket URL: `s3://empatica-staging-data/PH/`. A table lists two 'Available Access Key' entries, each with a '+ GENERATE ACCESS KEY' button.

ACCESS KEYS ID	LAST USED	CREATED IN	ACCESS KEY ACTION
Available Access Key	-	-	+ GENERATE ACCESS KEY
Available Access Key	-	-	+ GENERATE ACCESS KEY

**STEP 1: GO TO THE DATA ACCESS KEYS SECTION**  
Open the side navigation menu and click on Data Access Keys.

empaticaCARE  
● All systems operational. [View more.](#)  
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## Generate your data access keys



**DATA ACCESS KEYS** [? LEARN MORE ABOUT DATA ACCESS KEYS](#)

Generate an Access Key to access the S3 Data Bucket of your organizations. You can generate and store up to 2 sets of keys per organization.

The data bucket URL for your organization is: <s3://empatica-staging-data/PH/>


ACCESS KEYS ID	LAST USED	CREATED IN	ACCESS KEY ACTION
<a href="#">Available Access Key</a>	-	-	<a href="#">+ GENERATE ACCESS KEY</a>
<a href="#">Available Access Key</a>	-	-	<a href="#">+ GENERATE ACCESS KEY</a>

### STEP 2: GENERATE ACCESS KEY



Press on *Generate Access Key* to get the credentials needed to access your data from the AWS S3 Bucket.


## Monitoring - Digital Biomarkers

ACCESS KEY GENERATED

 **ACCESS KEY GENERATED**

Your Access Key has been generated. You can view and copy the "Access Key ID" and its "Secret Access Key" below.

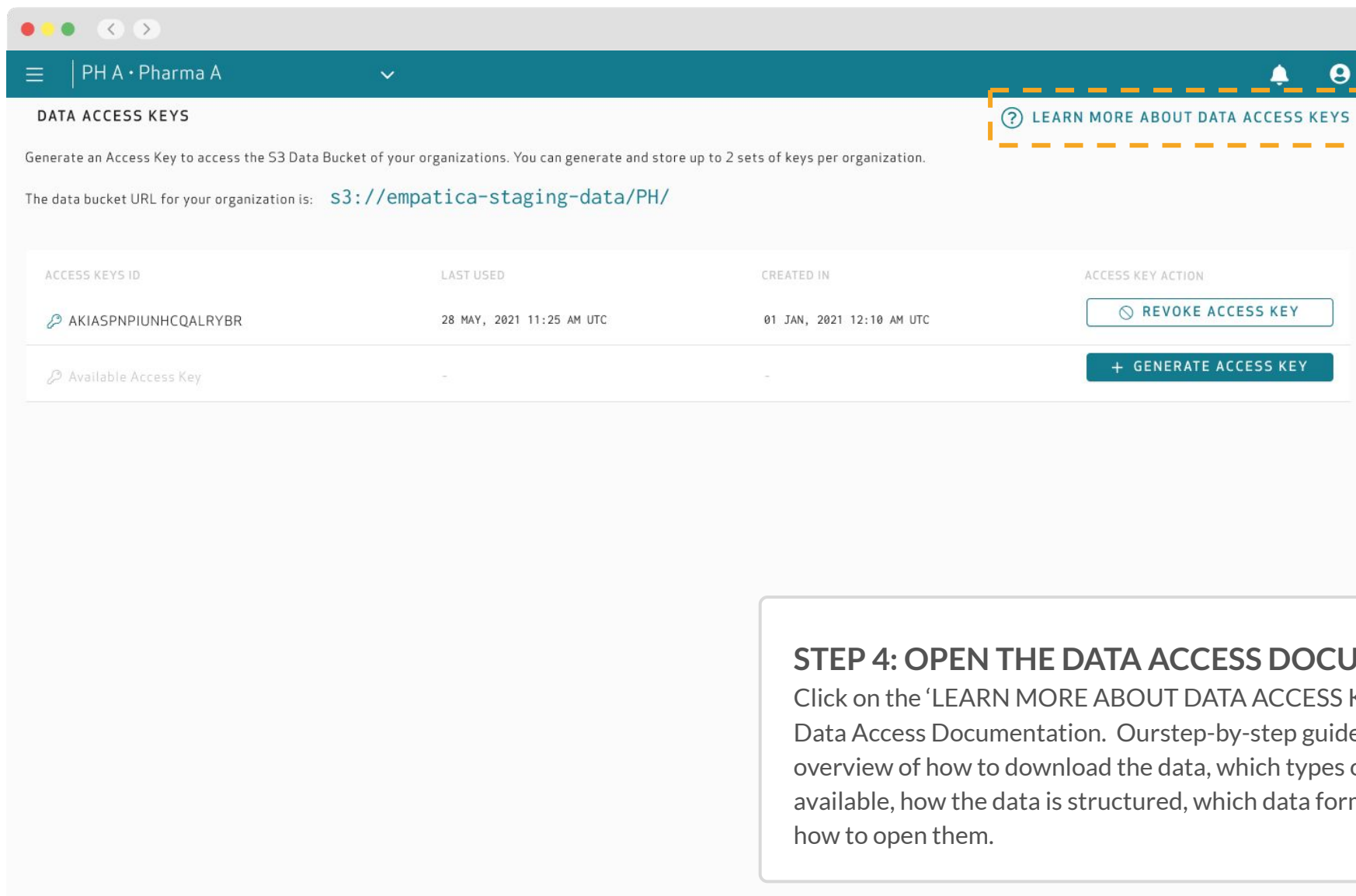
Data Bucket URL	s3://empatica-staging-data/C19/
Access Key ID	AKIASPNPIUNHCQALRYBR 
Last Used	never
Secret Access Key	*****  <a href="#">SHOW</a>

 **IMPORTANT!** For security reasons, this is the only time the key will be available to view, copy, or download. We recommend using a secure connection, and if you can store it in a secure location.

**STEP 3: DOWNLOAD CREDENTIALS**  
After having generated your Data Access Keys, download the credentials.

[CLOSE WITHOUT DOWNLOADING](#) [DOWNLOAD ACCESS KEY AND CLOSE](#)





## Monitoring - Digital Biomarkers



**DATA ACCESS KEYS**

Generate an Access Key to access the S3 Data Bucket of your organizations. You can generate and store up to 2 sets of keys per organization.

The data bucket URL for your organization is: `s3://empatica-staging-data/PH/`

ACCESS KEYS ID	LAST USED	CREATED IN	ACCESS KEY ACTION
 AKIASPNIUNHCQALRYBR	28 MAY, 2021 11:25 AM UTC	01 JAN, 2021 12:10 AM UTC	 REVOKE ACCESS KEY
 Available Access Key	-	-	 GENERATE ACCESS KEY

**STEP 4: OPEN THE DATA ACCESS DOCUMENTATION**  
Click on the 'LEARN MORE ABOUT DATA ACCESS KEYS' to open the Data Access Documentation. Our step-by-step guide gives an overview of how to download the data, which types of data are available, how the data is structured, which data formats are used, and how to open them.



# Multiple Short-Lab Sessions

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# How to enroll a new participant, with the same device?

The Empatica Health Monitoring Platform was designed to support **continuous, long term data collection studies**. The platform stores and organizes data individually for each participant under their unique credentials.

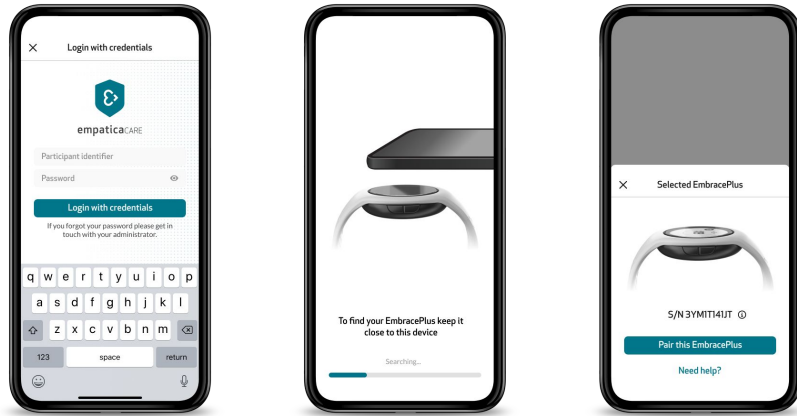
In these next slides, we aim to help you **collect data from multiple participants using the same device**.





## AVAILABLE FROM AUGUST 2023

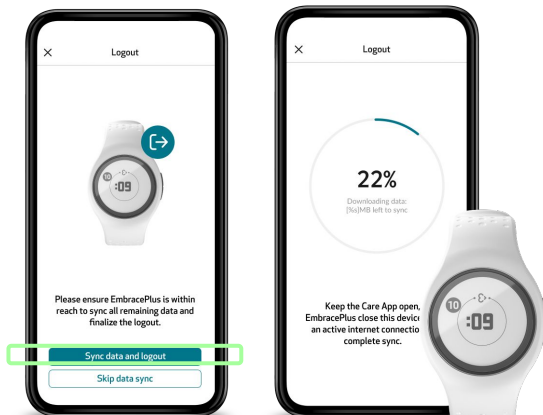
1. Create the credentials for the first participant, and pair the device to allow the data collection to begin



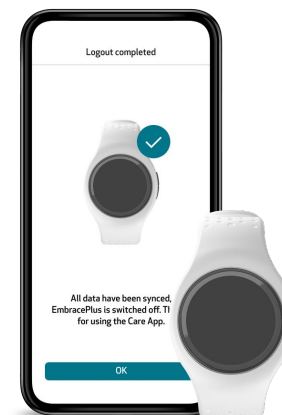
2. When the entire data collection is completed, open the Care Lab App, go to **Settings** and press **Logout**. Make sure that the EmbracePlus is connected to the Care App and the phone is connected to the internet before starting.



3. Click on **Sync data & Logout** and keep EmbracePlus close by while the process takes place.

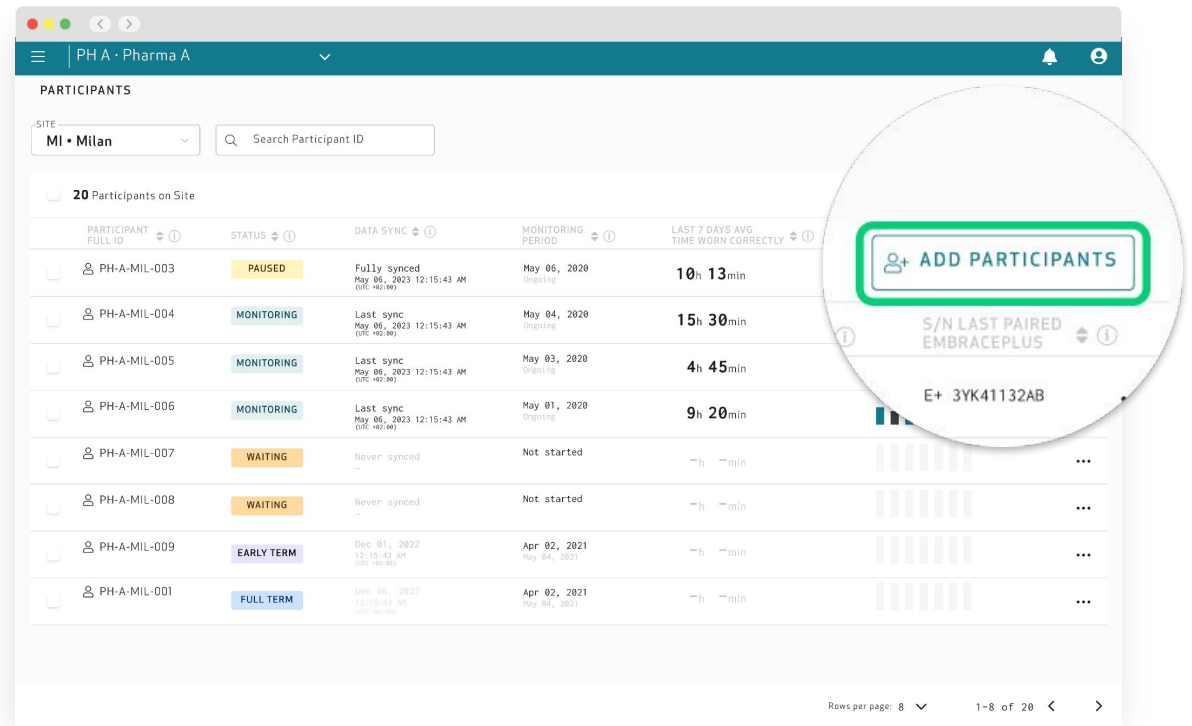


4. Once the process is complete EmbracePlus will switch off and is ready to be used again.

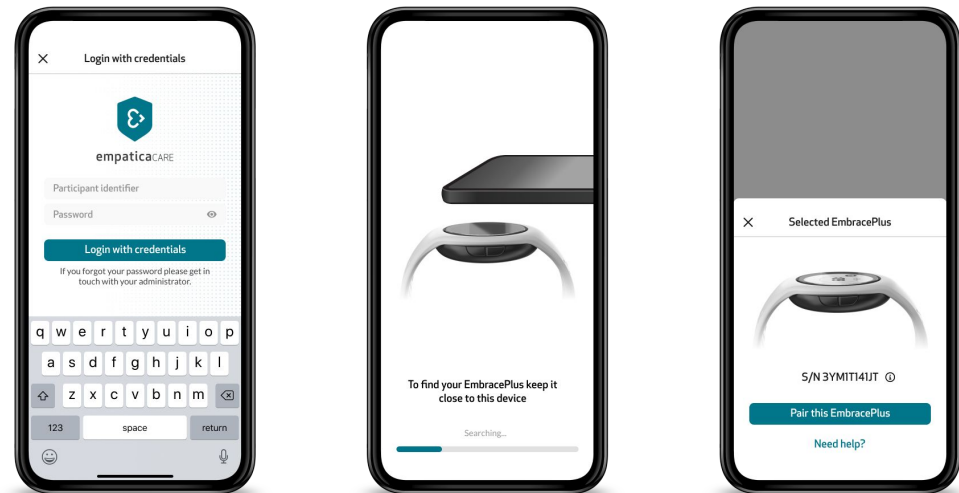


## AVAILABLE FROM AUGUST 2023

5. If you need to create a new session, you will need to create new credentials and associate them with a new participant ID



6. Switch on the device,, execute the pairing process, and start a new data collection





# Getting Support

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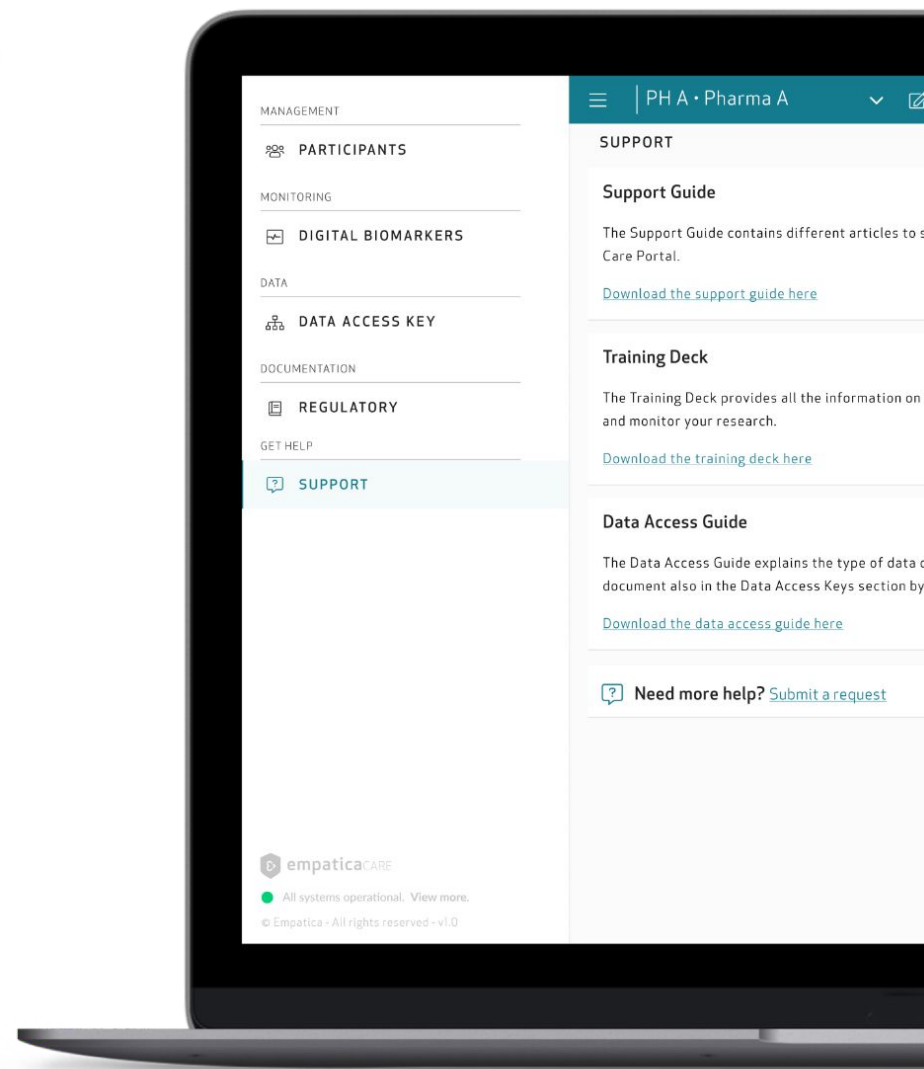
# Support

If you need help, you can select **Support** in the side navigation menu. In this section, you can find useful documents (such as this guide) and a link to submit a request to our Customer Support team.

On this page, you will find the following:

- The **Support Guide** contains several articles to support you in troubleshooting any issues you may encounter on the EmbracePlus, the Care Lab App, and the Care Portal.
- The **Training Deck** is the document you are reading right now. It is a guide that provides you with all the information you may need on how the Empatica Health Monitoring Platform works.
- The **Data Access Guide** is a step-by-step guide to assist you in understanding which types of data are available, how the data is structured, which data formats are used, and how to open them.

Should you have any further doubts or question, you can always reach out to our Customer Support team by clicking **Submit a request** or visiting the page [empatica.com/submitrequest](https://empatica.com/submitrequest).





# Tips for Participants

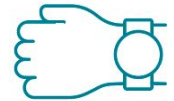
---

# Reminders for participants

Using your EmbracePlus is easy. Just keep these 4 steps in mind to make sure the participant has the best experience possible and data collection is robust.

## 1. Wear your EmbracePlus Correctly

Check the Status card inside the Care Lab App to make sure that the Wearing Time is increasing and the app background is teal. If not, try adjusting the fit.



## 2. Keep your phone Close

Keep Bluetooth® on at all times, and ensure your smartphone is close to you so that your EmbracePlus is able to transfer data. You can quickly confirm a Bluetooth® connection is established by looking for the Empatica heart icon on the EmbracePlus display.



## 3. Keep your phone Connected

Ensure your smartphone is connected to the Internet, either via Wi-Fi or a cellular connection.



## 4. Keep EmbracePlus Charged

Your EmbracePlus should be kept charged. It is recommended that you charge your EmbracePlus daily at a regular time. For example, while taking a shower.



## 5. Tag events with a Click

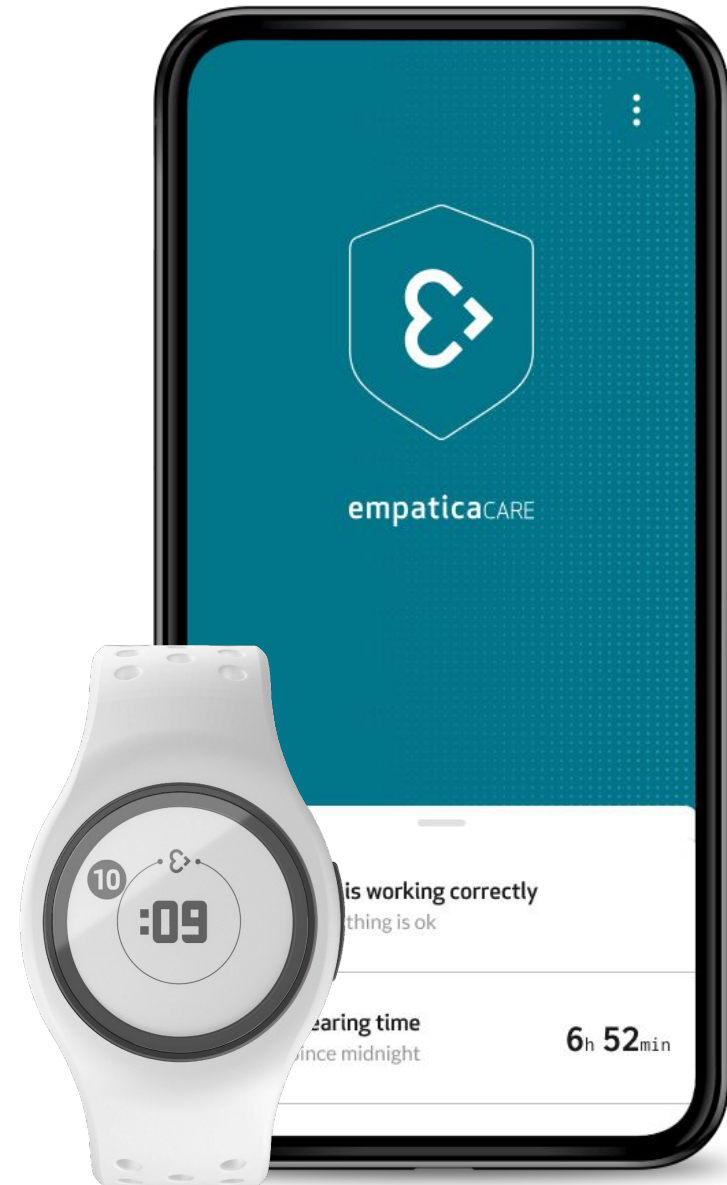
To mark an event, in line with the administrator's instructions, click one of the two side buttons of the EmbracePlus for one second. A light vibration and a temporary check mark on the display will confirm the action.



# Daily usage of the system

The participants using the Empatica Health Monitoring system will need to interact with the EmbracePlus along with the Care Lab App.

The following slides detail how both of these touchpoints work, and include tips on how to help participants have the best experience while collecting data for the study.



# Using EmbracePlus

EmbracePlus is the wearable health monitor that will collect data from the participants during the Study. To get the best results from the device, follow the tips in the next slides.

**IMPORTANT:** More information about the EmbracePlus is also available in the Empatica Health Monitoring Patient Instruction for Use.





## Wake up and pair EmbracePlus



### WAKE UP THE DEVICE

Turn on EmbracePlus by pressing the upper button. EmbracePlus will greet you with a 'HI'. If nothing happens, you may need to charge it.

### PAIR VIA BLUETOOTH®

If requested to confirm the pairing via Bluetooth® from a companion device, EmbracePlus will show the display 'BT'. Press 'OK' to accept the connection request, or 'NO' to reject it. Only accept pairing requests if you know which device the request is coming from.

## Wear EmbracePlus Correctly

Make sure the participant is wearing EmbracePlus correctly, since using it the wrong way affects the quality of the data collection. In order to wear it correctly, follow the steps below:

1. Wear it on your non-dominant hand (unless otherwise instructed)
2. Place the EmbracePlus one (1) finger's width from your wrist bone
3. Fasten the band and secure the EmbracePlus until you feel a light pressure
4. Ensure that the sensors are in contact with your skin
5. Check to make sure that you do not see green light coming from the sensor on the underside of the EmbracePlus while it is being worn, as this suggests it is too loose.



## How to read time

EmbracePlus has a 12-hour clock, with no distinction between AM and PM. The hour is shown in the outer circle, while the minutes are shown in the center of the display. The time indicated by EmbracePlus is based on the time of the paired companion app/system.



## How to do a system check



### RECORDING DATA

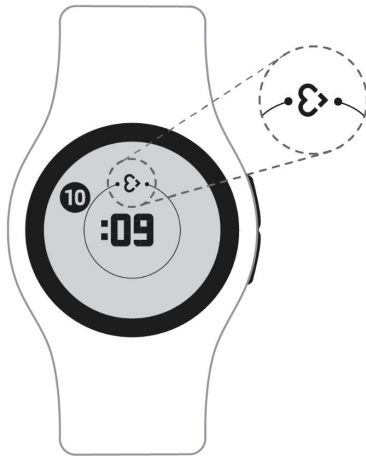
When the display background is light, EmbracePlus is recording.



### NOT RECORDING DATA

When the display background is dark, EmbracePlus is not recording.

## How to do a system check



### CONNECTED: SYNCHRONIZING DATA

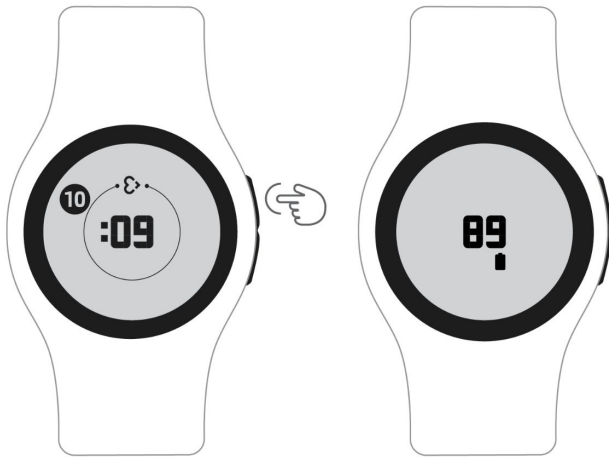
If the Empatica heart is visible on the display, there is an active Bluetooth® connection between EmbracePlus and the companion app.



### CONNECTED: NOT SYNCHRONIZING DATA

If the Empatica heart is not visible, there is no active Bluetooth® connection between EmbracePlus and the companion app/system. Reconnect via Bluetooth® to sync. Data will be stored on the internal memory and transferred as soon as a connection is re-established.

## How to check and charge the battery



### CHECK BATTERY PERCENTAGE

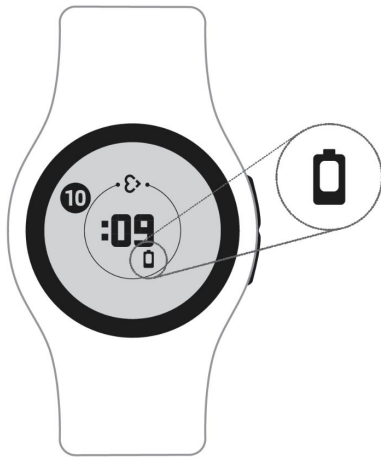
To check the battery percentage, briefly press on either one of the buttons on the right side of EmbracePlus. You will see the battery percentage appear next to a battery icon.



### PLACE IN CHARGER

Connect the cable charger to a standard 5V USB 2.0 power source and slide EmbracePlus into it until it snaps into place and the display starts showing the battery percentage. Make sure the display and side buttons are visible. A full charge should take about 1 hour and 30 minutes.

## How to check and charge the battery



### LOW BATTERY: CHARGE SOON

When the battery level begins to run low, the battery icon will be visible on the display. Charge at your earliest convenience.

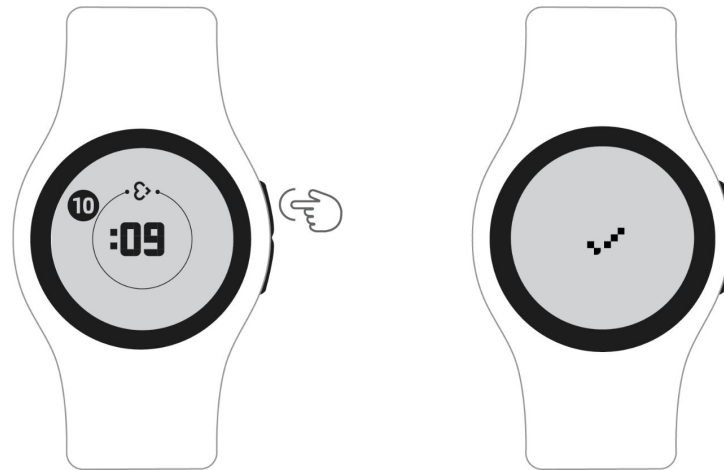


### LOW BATTERY: CHARGE NOW

When the battery level is critical, a 'low' message will appear on the display. You should place the EmbracePlus in the charger as soon as possible. You can click 'OK' with the top side button to confirm your acknowledgement of the battery status.

## How to tag events

The EmbracePlus allows the user to tag events according to the study protocol. To tag an event, press one of the side buttons for one second and a light vibration will occur while a check mark appears on the display, confirming the action. The display will then go back to showing the time.





## Troubleshooting



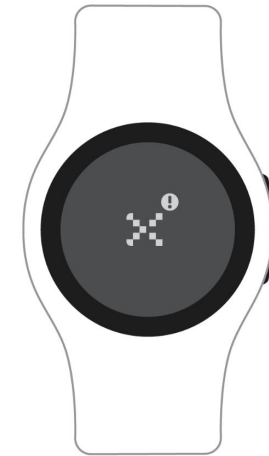
### NOT RECORDING: OUT OF BATTERY

When EmbracePlus is out of battery, the display background will turn dark and a small battery icon will be visible. Charge it to continue with data collection.



### NOT RECORDING: MEMORY FULL

The EmbracePlus memory is full, and data recording has stopped. Connect EmbracePlus to its companion app/system via Bluetooth® to start data synchronization.



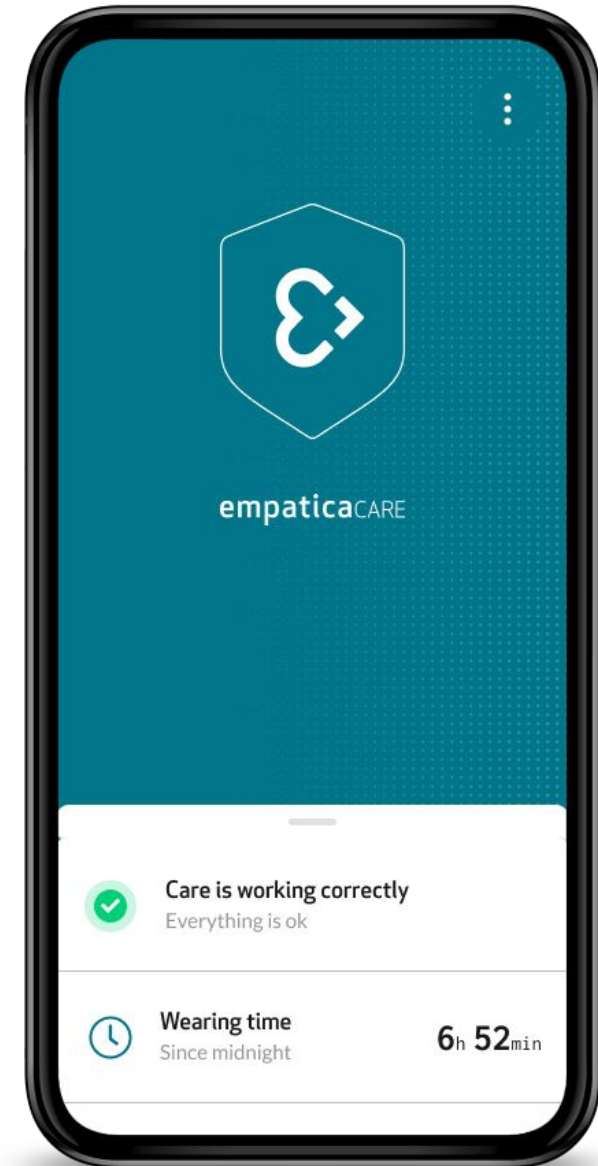
### NOT RECORDING: NO COMPANION APP/SYSTEM

Make sure the companion app/system has Bluetooth® activated and is within range of the EmbracePlus (10 meters/30 feet) to re-establish a connection.

# Using the Care Lab App

The Care Lab App was designed to help participants identify and quickly resolve anything that is interfering with data collection and might need their attention.

**IMPORTANT:** More information about the Care App is also available in the Empatica Health Monitoring Patient Instruction for Use.



## Care Lab App Status

The background of the main screen is intuitively color-coded so that participants can quickly understand the status of the system.



### TEAL

Care Lab and EmbracePlus are working correctly.



### YELLOW

Data is being collected, but something with the Care App and/or EmbracePlus needs your attention.



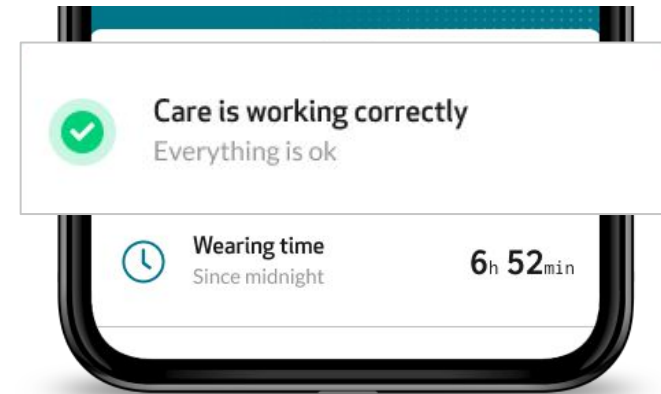
### RED

Data collection and/or transfer has stopped, you need to take action.

## Care Lab App Cards

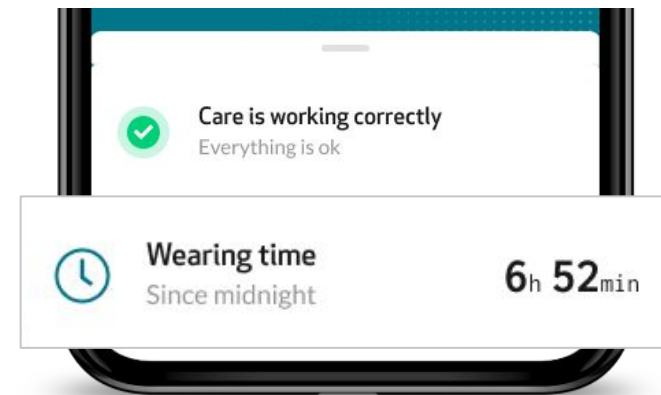
### Status card

The first card that you see in the Care Lab App displays the status. If Care is not working correctly, the Status card will guide the participant through steps to resolve the problem.

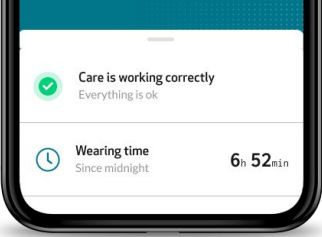
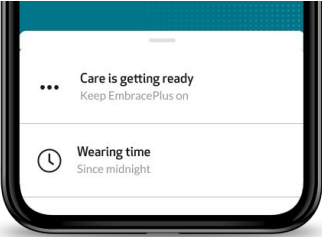
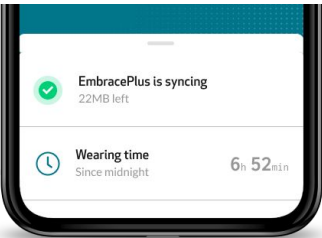


### Wearing time card

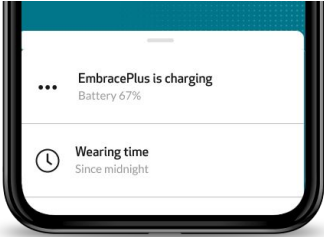
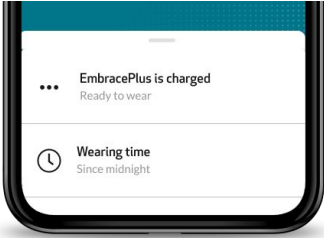
The Wearing time card displays how long the EmbracePlus has been worn since midnight on that day. It can be a useful tool in helping participants identify when they have not been wearing their device correctly.



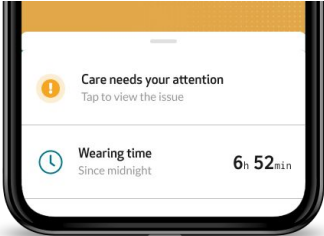
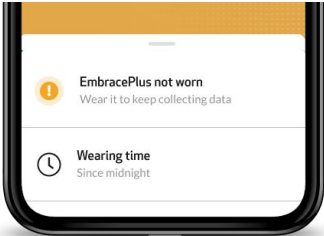
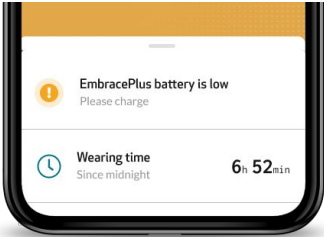
## Understanding the different Care statuses

Image	Message	Meaning/Issues	Action(s)
	<p>Care is working correctly</p>	<p>The Care Lab App and EmbracePlus are working correctly, and the system is running smoothly.</p>	<p>None - no action is needed.</p>
	<p>Care is getting ready</p>	<p>The Care Lab App and EmbracePlus are calibrating. This should only take a few minutes.</p>	<p>Keep the EmbracePlus on and the Care Lab App open.</p>
	<p>EmbracePlus is syncing</p>	<p>EmbracePlus is syncing data stored in its internal memory with the companion device.</p>	<p>Keep EmbracePlus close to the companion device.</p>

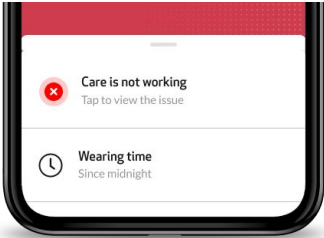
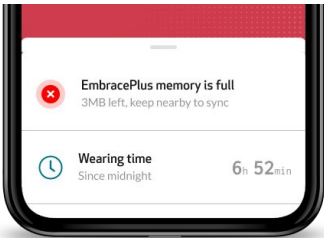
## Understanding the different Care statuses

Image	Message	Meaning/Issues	Action(s)
 <p>The image shows a smartphone notification card. At the top, it says 'EmbracePlus is charging' with a battery icon and 'Battery 67%'. Below that, it says 'Wearing time' with a clock icon and 'Since midnight'.</p>	<p>EmbracePlus is charging</p>	<p>The Care Lab App will notify you when the battery is fully charged.</p>	<p>None.</p>
 <p>The image shows a smartphone notification card. At the top, it says 'EmbracePlus is charged' with a battery icon and 'Ready to wear'. Below that, it says 'Wearing time' with a clock icon and 'Since midnight'.</p>	<p>EmbracePlus is charged</p>	<p>EmbracePlus battery is fully charged and ready to be used.</p>	<p>Remove EmbracePlus from the charger to continue collecting data.</p>

## Understanding the different Care statuses

Image	Message	Meaning/Issues	Action(s)
	<p>Care needs your attention</p>	<p>Data is being collected, but something needs to be addressed as soon as possible. Possible causes include:</p> <ol style="list-style-type: none"> <li>1) Missing internet connection (either cellular data or WiFi)</li> <li>2) A new version of the Care Lab App is available</li> </ol>	<p>Tap the Status card to see tips on how to address the underlying issue.</p> <ol style="list-style-type: none"> <li>1) Check the status of your mobile device's internet connectivity</li> <li>2) Install the latest version of the Care Lab App</li> </ol>
	<p>EmbracePlus not worn</p>	<p>The participant is not wearing EmbracePlus, or it is not positioned properly on your wrist.</p>	<p>Wear the device and adjust the fit to ensure it is worn snugly on the wrist.</p>
	<p>EmbracePlus battery is low</p>	<p>EmbracePlus will run out of battery soon.</p>	<p>Charge EmbracePlus as soon as possible.</p>

## Understanding the different Care statuses

Image	Message	Meaning/Issues	Action(s)
	<p>Care is not working</p>	<p>Care Lab App and EmbracePlus are not working. Possible causes:</p> <ol style="list-style-type: none"> <li>1) EmbracePlus might not be connected to the smartphone.</li> <li>2) The smartphone's Bluetooth® might be off.</li> <li>3) EmbracePlus is out of battery.</li> </ol>	<ol style="list-style-type: none"> <li>1) Make sure EmbracePlus is switched on.</li> <li>2) Make sure the smartphone's Bluetooth® is turned on.</li> <li>3) Make sure the EmbracePlus and companion device are within 30 feet of each other.</li> </ol>
	<p>The EmbracePlus' memory is full</p>	<p>The EmbracePlus' internal memory is full, and therefore it cannot collect and record data.</p>	<p>Keep EmbracePlus close to your companion device to free up memory and resume data collection.</p>



## Performing a status check

Tapping the Status card allows you to go into more detail and troubleshoot any issues.

**EmbracePlus:** check the status of the EmbracePlus that is connected to the Care Lab App

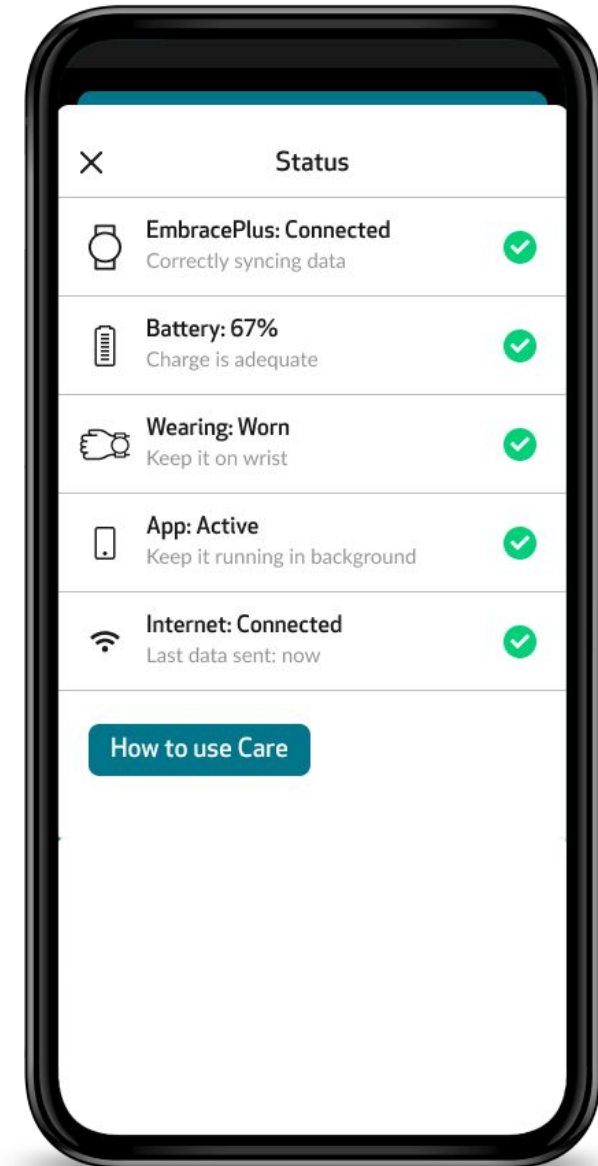
**Battery:** check the battery status of the EmbracePlus connected to the Care Lab App

**Wearing:** check if the EmbracePlus that is connected to the Care Lab App is being worn correctly

**App:** check the status of the Care Lab App

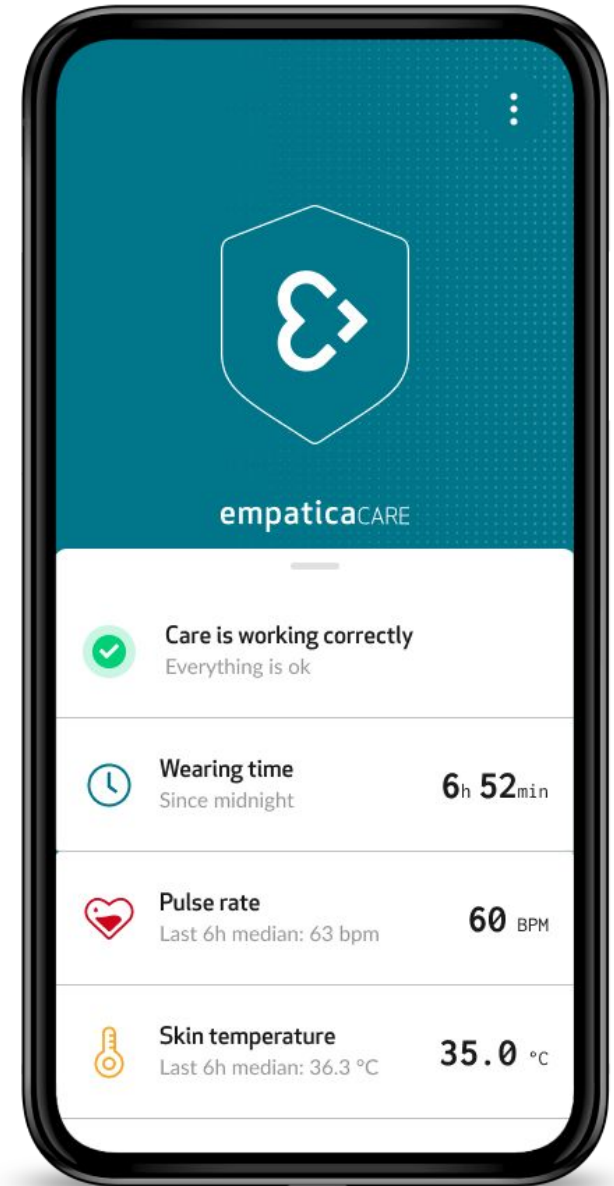
**Internet:** check the status of the Internet connection

**IMPORTANT:** More information about the Care Lab App status check is also available in the Empatica Health Monitoring Patient Instruction for Use.



## Digital biomarkers

The Digital biomarkers section contains the physiological parameters gathered from the EmbracePlus at a frequency of 1 minute. Meaning, the values you see were collected over the last 60 seconds.



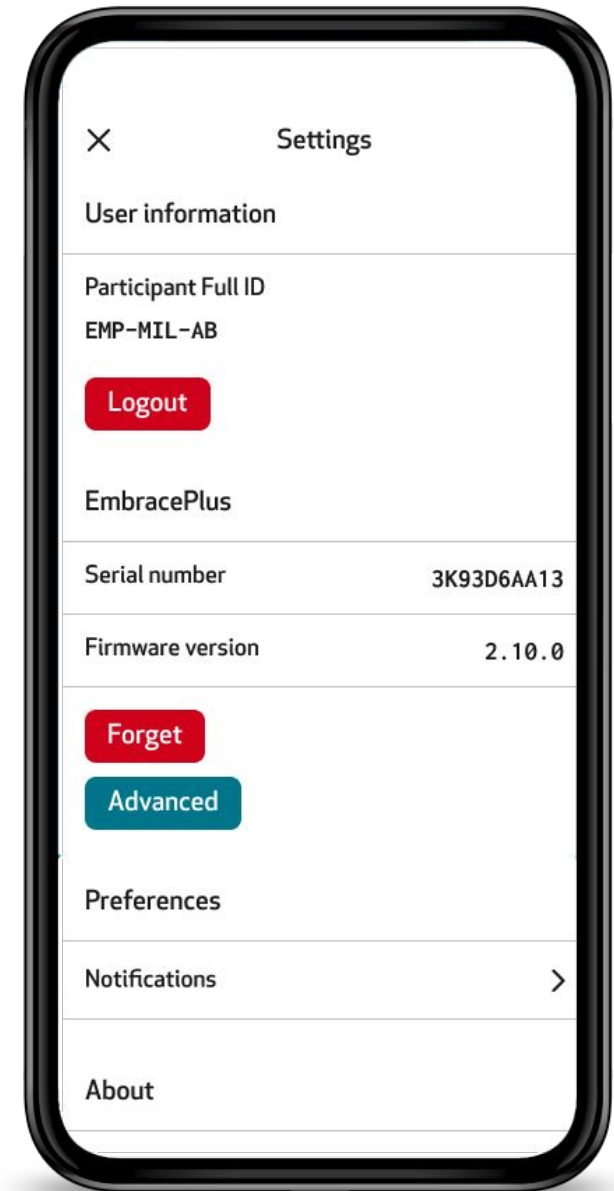
## Settings screen

In order to access the settings screen of the Care Lab App, tap the 3 dots on the top right of the main screen.

From here you will be able to visualize additional information about the EmbracePlus that is connected to the Care Lab App.

### User information

Participant Full ID: The unique identifier that was assigned to the participant. This ID, as well as the EmbracePlus serial number, can come in handy in case the participant needs to report any issues to the administrator.



## Settings screen

### EmbracePlus

**Serial number:** The serial number of the EmbracePlus that is paired with the companion device. It is also possible to find the serial number on the back of the EmbracePlus.

**Firmware version:** The version of the device firmware running on the EmbracePlus.

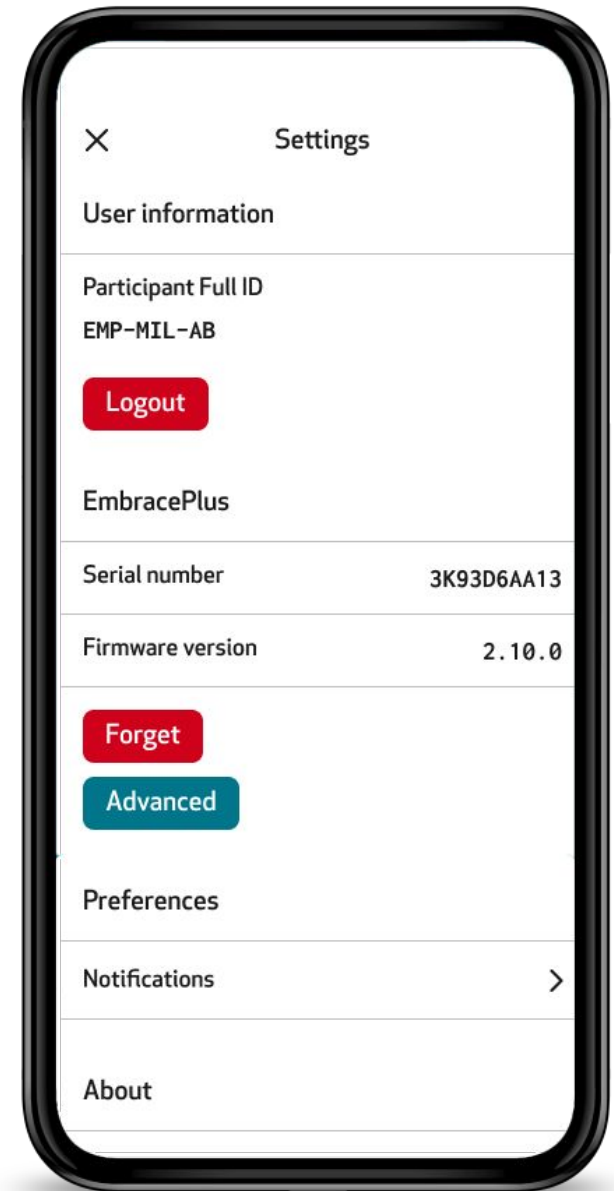
### Preferences

**Notifications:** Allows participants to control the notifications that are received on the Care Lab App. By default, all of the notifications are toggled ON, which is the recommended setting.

### About

**User manual:** Link to view the Care Lab App and EmbracePlus Manuals.

**Regulatory & compliance:** Regulatory and compliance information on the Care Lab App and its intended use.



## Settings screen

### Copyright and App version

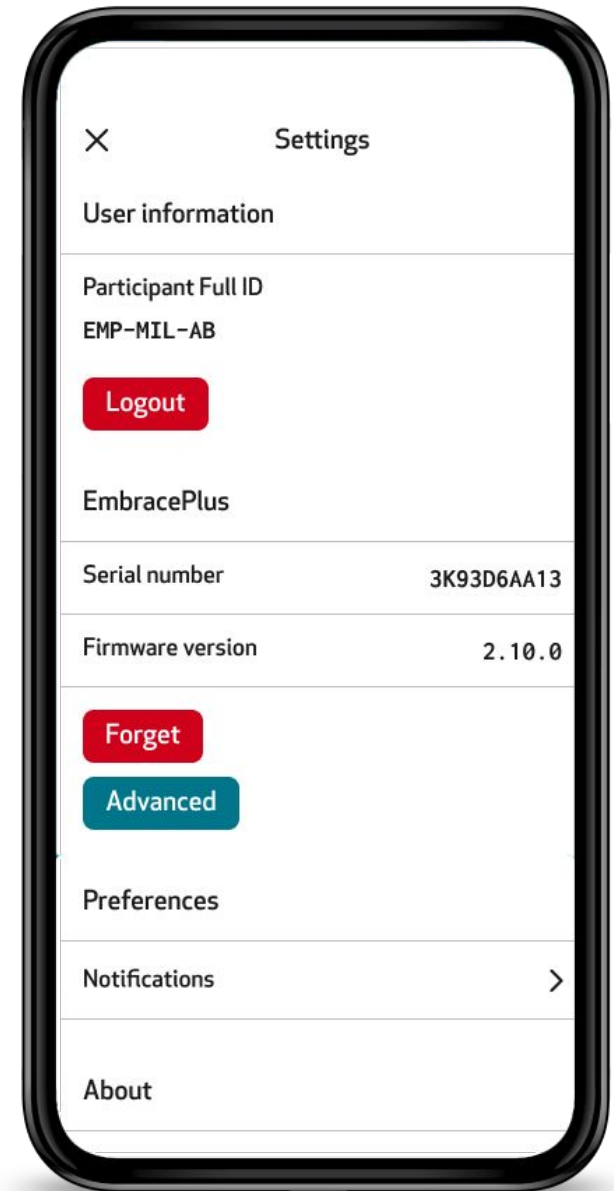
The version of the Care Lab App that you are currently using.

### Other tools (for troubleshooting purposes only)

It is also possible to “Forget Device” and ”Logout“ of the Care Lab App. Participants should only perform these actions when specifically requested by the Administrator.

**Forget:** Allows the participant to disassociate the paired EmbracePlus from the companion device. By forgetting the EmbracePlus on the companion device, it will disconnect, and might result in data loss. In order to reconnect to the device, the EmbracePlus will need to be re-paired following the setup steps.

**Logout:** Allows the participant to sign out of the Care Lab App. Please note that when logging out, the EmbracePlus will stop collecting data, and might result in data loss. To reconnect, log back in using the same credentials given by the administrator. In case the participant has lost the credentials, it is possible to generate new credentials within the Care Lab Portal (see Reset Participant Password)



## Settings screen

### Advanced

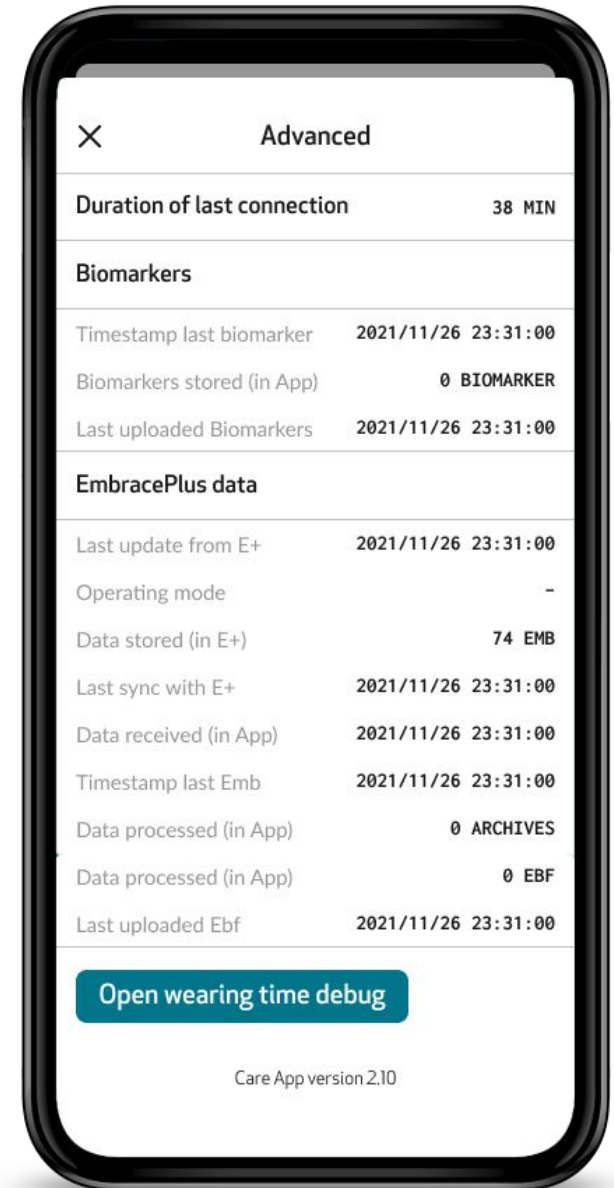
By clicking the 'Advanced' button, it is possible to see a more detailed/technical view of what is happening in the Care Lab App and on the EmbracePlus.

Here you will be able to check:

**Duration of last connection:** This is the duration of the last continuous connection between the EmbracePlus and the Care Lab App.

**Biomarkers:** details of the Digital Biomarker Data exchange between the EmbracePlus and the Care Lab App, as well as the upload from the Care Lab App to the Empatica Cloud.

**EmbracePlus:** This section lists all the details about the RAW data exchange and uploads between the EmbracePlus, the Care Lab App on the smartphone, and the Empatica Cloud.



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