



CoroPrevention
PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE



CoroPrevention EDC - Training Site Nurse and Investigator

v1.0

Agenda

- Login
- Training
- Navigation
- Add Subject
- Enter and Edit Data
- Apply Signature on eCRFs



Agenda (2)

- Reports
- Forgot Password
- Reset 2FA
- CoroPrevention: Laboratory Data
- CoroPrevention: Randomise / Allocate Treatment
- CoroPrevention: SAE / SADE Form
- CoroPrevention: Import Data from Tool Suite



Agenda (3)

- CoroPrevention: Import Data from Tool Suite
- CoroPrevention: Generate ePRO Link
- CoroPrevention: Protocol Deviations
- CoroPrevention: Endpoint Collection



Login

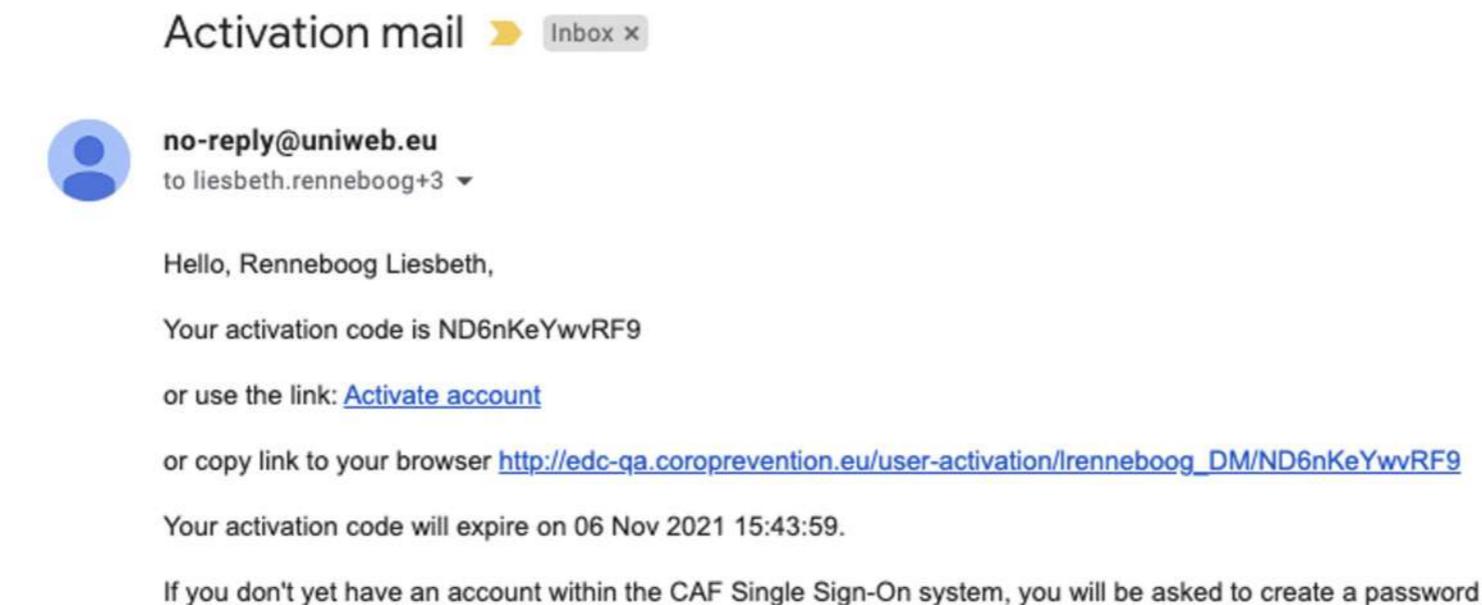


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Login - Account Activation

- An activation email is sent to you
- Click “Activate account” or use the activation code and navigate to the link
- ! Expires after 48 hours



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Login - Account Activation (2)

- Enter/review the username/e-mail address and activation code
- Click “Activate”

Activate your account by entering your username or e-mail and the activation code

Username or e-mail liesbeth.renneboog
Activation code

[Back to login](#)

Activate



Login - Account Activation (3)

- Choose a password that meets the requirements
- Click “Set Password”

✓ 30 or less characters
✓ 8 or more characters
✓ Uppercase
✓ Lowercase
✓ A number
✓ A special symbol



Note:

Your password should not be shared.

[Back to login](#)



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Login - Two-Factor Authentication

- Download one of the following two-factor authentication apps on your mobile device from the App Store (for iOS) or the Google Play Store (for Android):
 - Google Authenticator, Authy, Duo Mobile, LastPass, Microsoft Authenticator
- This can be skipped if you already have one of these apps on your device



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Login - Register Two-Factor Authentication

- Open the authenticator app on your mobile device
- Scan the QR code via the app or enter the key and user account manually
- Enter the 6-digit code shown by the authenticator app
- Click the register button to complete your account activation

Two-Factor Authentication Settings

Use a one-time password authenticator on your mobile device or computer to enable two-factor authentication (2FA).

We recommend cloud-based mobile authenticator apps such as Authy, Duo Mobile, and LastPass. They can restore access if you lose your hardware device.



Pin code*

Register with 2-Factor App

Can't scan the code?

To add the entry manually, provide the following details to the application on your phone.

Account

Key: 1

MJ5NRHNSJC4

HG305H

Time based: Yes



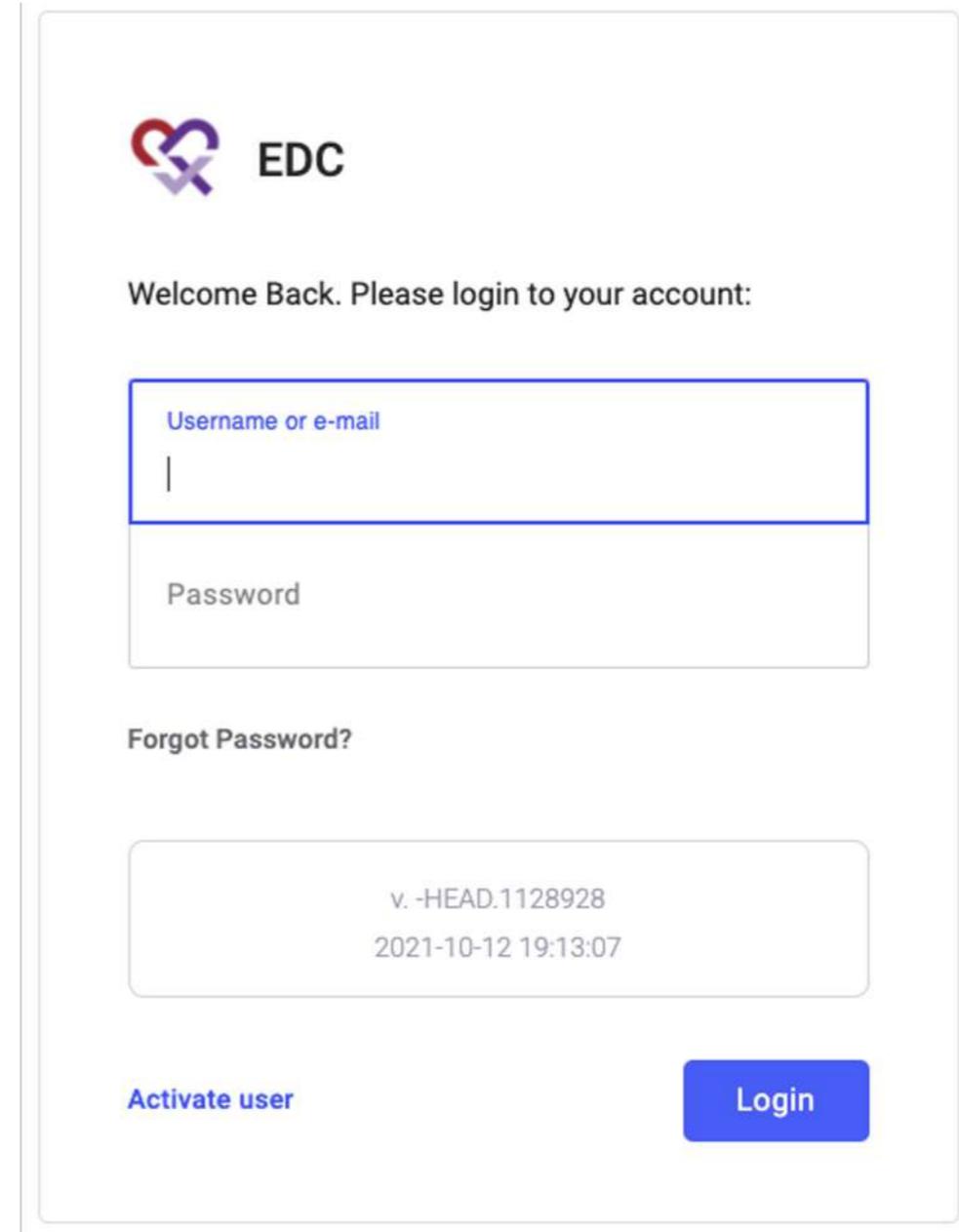
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Login - General

After initial login, follow these steps to login:

- Browse to <https://edc.coroprevention.eu/>
- Enter your username or e-mail address and password
- Click Login



The screenshot shows the EDC login interface. At the top left is the EDC logo, which consists of a stylized heart shape formed by two overlapping lines in red and purple, followed by the text "EDC". Below the logo, the text "Welcome Back. Please login to your account:" is displayed. There are two input fields: the first is labeled "Username or e-mail" and contains a vertical cursor; the second is labeled "Password". Below the input fields, there is a link "Forgot Password?". At the bottom of the form, there is a box containing the text "v. -HEAD.1128928" and "2021-10-12 19:13:07". At the bottom left, there is a link "Activate user", and at the bottom right, there is a blue button labeled "Login".



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Login - General (2)

- Open the Google Authenticator app on your mobile device
- Enter the 6-digit code displayed for yourusername@coroprevention.eu
- Click Login

Enter a 6-digit code from your Authentication App

Login

[Back to login](#)

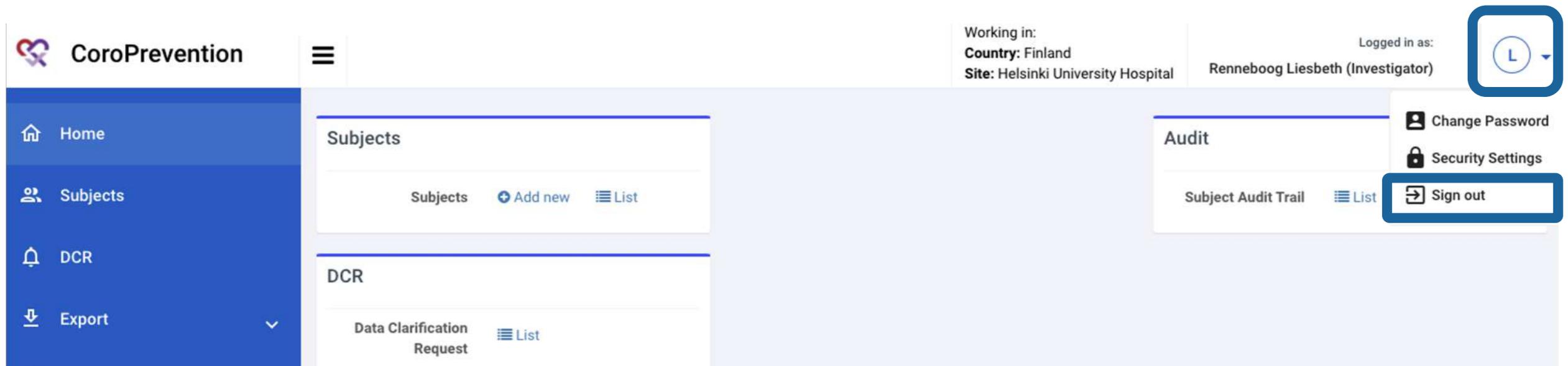


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Logout

- To logout, click the icon in the upper right corner
- Click Sign out



The screenshot shows the CoroPrevention web application interface. On the left is a blue navigation sidebar with the CoroPrevention logo and menu items: Home, Subjects, DCR, and Export. The main content area is divided into two sections: 'Subjects' and 'DCR'. The 'Subjects' section has a 'Subjects' link, an 'Add new' button, and a 'List' button. The 'DCR' section has a 'Data Clarification Request' link and a 'List' button. In the top right corner, there is a user information box showing 'Working in: Country: Finland, Site: Helsinki University Hospital' and 'Logged in as: Renneboog Liesbeth (Investigator)'. A circular profile icon with a clock symbol is highlighted with a blue box. A dropdown menu is open from this icon, showing options: 'Change Password', 'Security Settings', and 'Sign out'. The 'Sign out' option is highlighted with a blue box.

Log out when stepping away from your computer.



Training



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Training - Initial

- Training is required for all staff who requires access to EDC or the Tool Suite
- After login you will be directed to the Training module if you have pending required trainings
- You will not be able to access any other modules in EDC

CoroPrevention Training

Working in: Country: Finland Site: Helsinki University Hospital

Logged in as: Renneboog Liesbeth (Investigator)

Warning!
You need to download and sign all required trainings before you can access the platform

Training ↓	Required	Status	Completion date and time	Action
Query Management	no	Not Done		DOCUMENT DOWNLOAD
SAE Reporting	yes	Not Done		DOCUMENT DOWNLOAD
User Guidelines for Investigator	yes	Not Done		DOCUMENT DOWNLOAD

1 / 1 - 3 results - Per page 32

The “Required” column indicates which training(s) are required for you based on your assigned user type.

Training - Download

- Click “Document Download” to access the training
- Perform your training of the document

CoroPrevention ☰ Training Working in: Country: Finland Site: Helsinki University Hospital Logged in as: Renneboog Liesbeth (Investigator)

Warning!
You need to download and sign all required trainings before you can access the platform

Training ↓	Required	Status	Completion date and time	Action
Query Management	no	Not Done		DOCUMENT DOWNLOAD
SAE Reporting	yes	Not Done		DOCUMENT DOWNLOAD
User Guidelines for Investigator	yes	Not Done		DOCUMENT DOWNLOAD

1 / 1 - 3 results - Per page 32



Training - Sign

- Click “Sign” to acknowledge that you have completed training on the topic

The screenshot shows the CoroPrevention interface. At the top right, it indicates the user is working in Finland at Helsinki University Hospital and is logged in as Renneboog Liesbeth (Investigator). A yellow warning banner at the top states: "Warning! You need to download and sign all required trainings before you can access the platform". Below this is a table with the following data:

Training ↓	Required	Status	Completion date and time	Action
Query Management	no	Not Done		DOCUMENT DOWNLOAD
SAE Reporting	yes	Not Done		DOCUMENT DOWNLOAD
User Guidelines for Investigator	yes	Downloaded		DOCUMENT DOWNLOAD SIGN

The "SIGN" button for the "User Guidelines for Investigator" row is highlighted with a red box. At the bottom right of the table, it shows "1 / 1 - 3 results - Per page 32".

A warning message is shown as long as you have not completed the required trainings assigned to you



Training - Sign (2)

- Enter your credentials and click Sign to confirm
- The training now receives status Completed
- You can still download this document at any point

Sign User Guidelines for Investigator ✕

By entering my username and password, I acknowledge that I have completed training on the topics covered in this document.

Username

Password

Success!
Training signed successfully ✕

Warning!
You need to download and sign all required trainings before you can access the platform ✕

Training ↓	Required	Status	Completion date and time	Action
Query Management	no	Not Done		DOCUMENT DOWNLOAD
SAE Reporting	yes	Not Done		DOCUMENT DOWNLOAD
User Guidelines for Investigator	yes	Completed	16 Nov 2021 10:41:46	DOCUMENT DOWNLOAD

1 / 1 - 3 results - Per page

A success message is shown when a training is signed successfully

A warning message is shown as long as you have not completed the required trainings assigned to you



Training - Access

- Complete all **required** trainings to gain access to the rest of the platform
- Optional trainings can be accessed and completed, but are not required to be completed to gain access
- Navigate to your assigned trainings at any time by clicking Training

CoroPrevention

☰
Training

Working in:

Country: Finland

Site: Helsinki University Hospital

Logged in as:

Renneboog Liesbeth (Investigator)

L
▼

Success!
Training signed successfully
✕

Training ↓	Required	Status	Completion date and time	Action
Query Management	no	Not Done		DOCUMENT DOWNLOAD
SAE Reporting	yes	Completed	16 Nov 2021 10:48:22	DOCUMENT DOWNLOAD
User Guidelines for Investigator	yes	Completed	16 Nov 2021 10:41:46	DOCUMENT DOWNLOAD

1 / 1 - 3 results - Per page 32 ▼



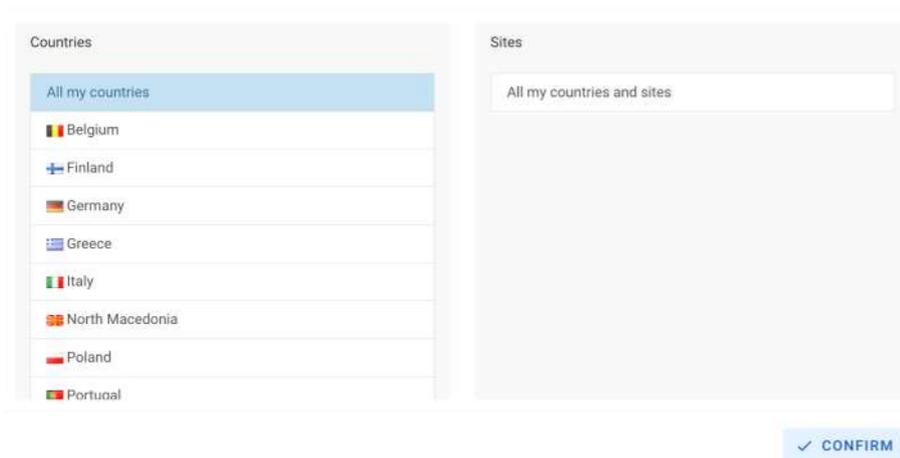
Navigation



Navigation - Location Select

- After successful login, you will be requested to choose your location if you have access to more than one country:

Location



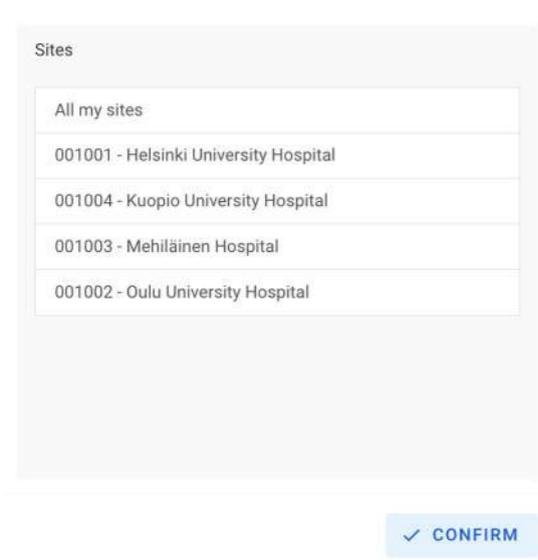
Countries	Sites
All my countries	All my countries and sites
Belgium	
Finland	
Germany	
Greece	
Italy	
North Macedonia	
Poland	
Portugal	

Select *All my countries* and then *All my countries and sites* to have access to the entire trial.

Select a *specific country* and *All my sites* within the country to have access to the entire country.

Select a *specific country* and a *specific site* within the country to have access to that specific site.

- Or to more than one site:

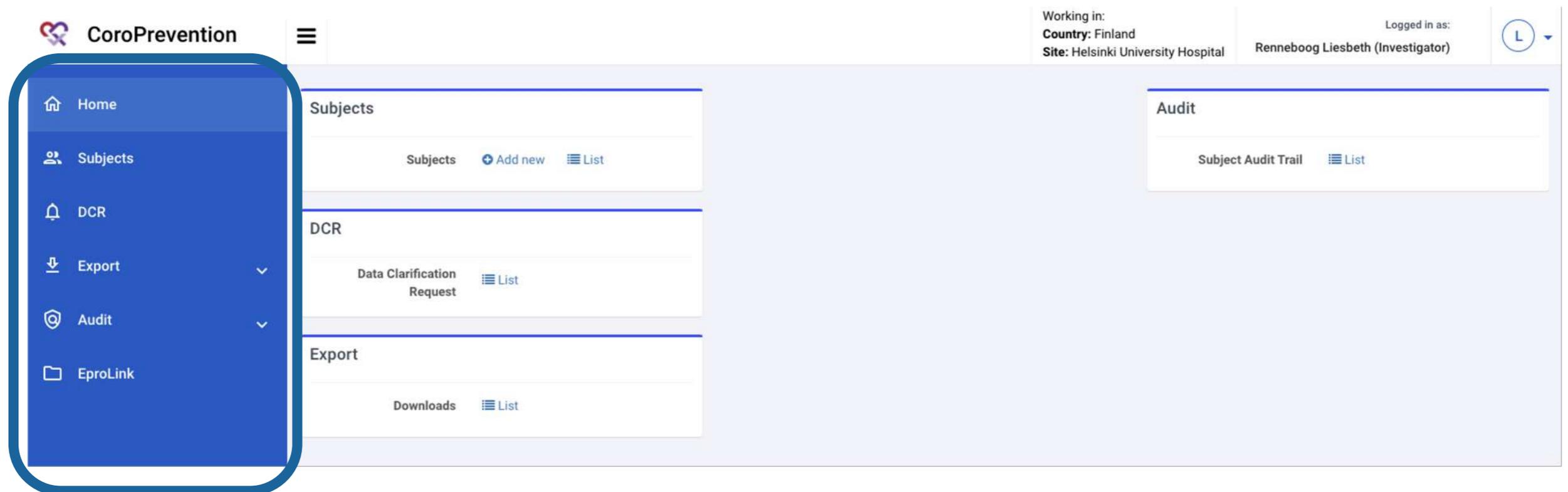


Sites
All my sites
001001 - Helsinki University Hospital
001004 - Kuopio University Hospital
001003 - Mehiläinen Hospital
001002 - Oulu University Hospital



Navigation - Bar

- Navigation bar contains links to the modules for which you have access
- “Home” takes you to the dashboard, listing actions applicable for your user type



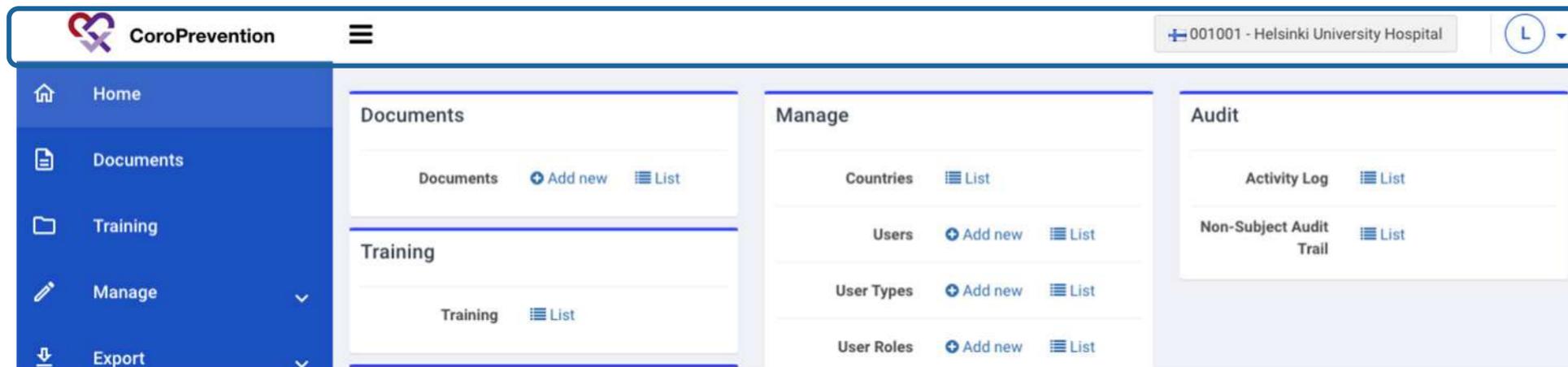
The screenshot displays the CoroPrevention web application interface. The navigation bar is highlighted with a blue rounded rectangle and contains the following items: Home, Subjects, DCR, Export, Audit, and EproLink. The main content area is divided into three sections: Subjects, DCR, and Export. The Subjects section includes a 'Subjects' link, an 'Add new' button, and a 'List' button. The DCR section includes a 'Data Clarification Request' link and a 'List' button. The Export section includes a 'Downloads' link and a 'List' button. The top right corner shows the user's current context: Working in: Country: Finland, Site: Helsinki University Hospital, Logged in as: Renneboog Liesbeth (Investigator), and a user profile icon.



Navigation - Access Details

The upper bar - visible on each page within EDC - displays the following:

- Study you are working in
- Toggle to hide/unhide the navigation bar
- Location button: Country flag & Site / “Multiple Sites” or “Multiple countries”
- Your name and user type
- Link to actions related to your account



Navigation - Go to Subject

Navigate to a subject by clicking “Subjects” and clicking “View” for the applicable subject:

CoroPrevention

Subjects

Working in:
Country: Finland
Site: Helsinki University Hospital

Logged in as:
Renneboog Liesbeth (Investigator)

Filters 0 Add new

Subject Id ↓	Study	Site ID	Last Visit Title	Status	Monitor Status	Progress Status	Action
coro-001001-001	CoroPrevention	Helsinki University Hospital	Enrolment V1			Randomised	VIEW
coro-001001-002	CoroPrevention	Helsinki University Hospital	Enrolment V1			Randomised	VIEW
coro-001001-003	CoroPrevention	Helsinki University Hospital	Enrolment V1			Allocated	VIEW
coro-001001-004	CoroPrevention	Helsinki University Hospital	Enrolment V1			Allocated	VIEW
coro-001001-005	CoroPrevention	Helsinki University Hospital	Informed Consent			Screening	VIEW

By default, this list is filtered based on the location you are working in.

Additionally it is possible to filter the list of subjects on Subject ID, Last Visit, Data Status, Monitor Status, Progress Status.



Navigation - eCRF

- Within a subject, you can navigate to a specific eCRF by clicking the eCRF title in the subject's flow
- If the eCRF is part of a visit, you need to click the visit title first.
- You can also use the “Next” and “Back” buttons to navigate to the next / previous eCRF

CoroPrevention

Subjects / coro-001001-003 / View

Working in:
Country: Finland
Site: Helsinki University Hospital

Logged in as:
Renneboog Liesbeth (Investigator)

Subject ID: coro-001001-003
Site: Helsinki University Hospital
Progress: Randomised

Show monitoring status

Vital Signs Audit trail

Body height
181 cm

Body weight
78.3 kg

Blood pressure
Systolic 121 mmHg Diastolic 81 mmHg

Pulse Rate
61 bpm

Back Sign Next



Add Subject

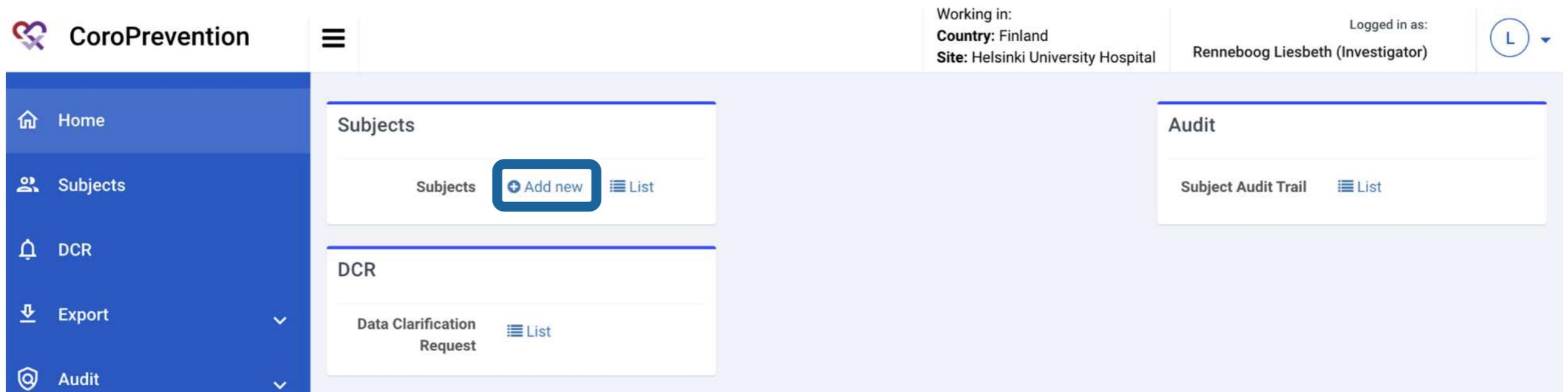


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Add Subject

- Click “Add new” on the dashboard in section “Subjects”



The screenshot shows the CoroPrevention dashboard interface. On the left is a blue navigation sidebar with icons and labels for Home, Subjects, DCR, Export, and Audit. The main content area is divided into three sections: 'Subjects', 'DCR', and 'Audit'. In the 'Subjects' section, there is a 'Subjects' label, a '+ Add new' button (highlighted with a red box), and a 'List' icon. The 'DCR' section contains a 'Data Clarification Request' label and a 'List' icon. The 'Audit' section contains a 'Subject Audit Trail' label and a 'List' icon. At the top right, there is a header area with 'Working in: Country: Finland, Site: Helsinki University Hospital' and 'Logged in as: Renneboog Liesbeth (Investigator)'.

- Adding a subject is only possible when you:
- have selected one site in Location Select
 - have the Study Nurse or Investigator user type



Add Subject (2)

Alternatively

- Go to “Subjects”
- Click “Add new”

The screenshot shows the CoroPrevention web application interface. The top navigation bar includes the CoroPrevention logo, a hamburger menu, the current page 'Subjects', and user information: 'Working in: Country: Finland, Site: Helsinki University Hospital' and 'Logged in as: Renneboog Liesbeth (Investigator)'. A left sidebar contains navigation options: Home, Subjects, DCR, Export, and Audit. The main content area displays a table of subjects with columns for Subject Id, Study, Site ID, Last Visit Title, Status, Monitor Status, Progress Status, and Action. A '+ Add new' button is highlighted with a red box in the top right of the table area.

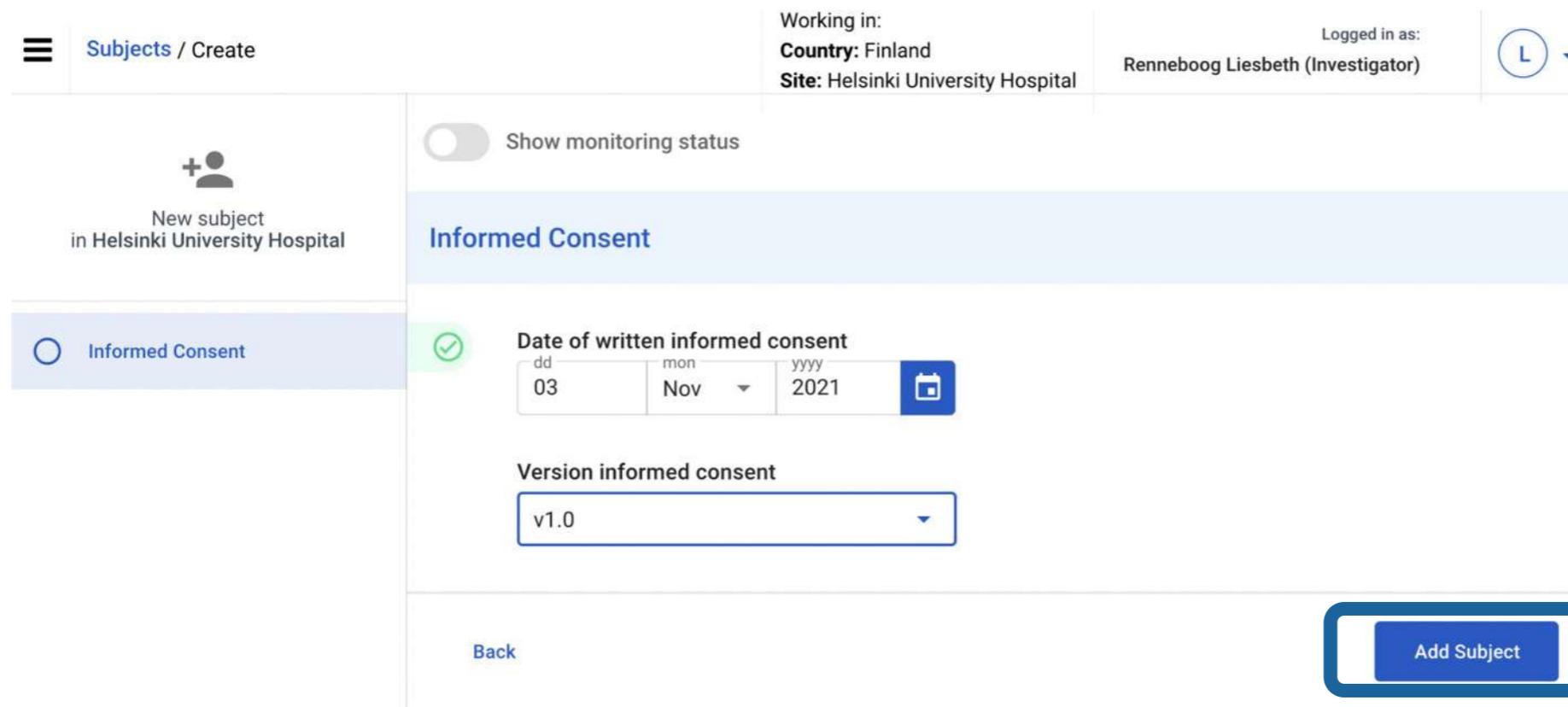
Subject Id	Study	Site ID	Last Visit Title	Status	Monitor Status	Progress Status	Action
coro-001001-008	CoroPrevention	Helsinki University Hospital	Enrolment V1			Randomised	VIEW
coro-001001-006	CoroPrevention	Helsinki University Hospital	Enrolment V1			Randomised	VIEW
coro-001001-007	CoroPrevention	Helsinki University Hospital	Enrolment V1			Randomised	VIEW
coro-001001-001	CoroPrevention	Helsinki University Hospital	Enrolment V1			Randomised	VIEW



Add Subject (3)

- Complete the requested data
- Click “Add Subject” to proceed

! “Add Subject” will only be enabled if the provided data is valid



The screenshot shows the UniWeb interface for adding a new subject. The top navigation bar includes a menu icon, 'Subjects / Create', and user information: 'Working in: Country: Finland Site: Helsinki University Hospital' and 'Logged in as: Renneboog Liesbeth (Investigator)'. The main content area is titled 'New subject in Helsinki University Hospital' and features a sidebar with 'Informed Consent' selected. The 'Informed Consent' section includes a 'Show monitoring status' toggle, a green checkmark, and a date picker for 'Date of written informed consent' set to 03 Nov 2021. Below this is a dropdown for 'Version informed consent' set to 'v1.0'. At the bottom, there is a 'Back' link and a prominent blue 'Add Subject' button.



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Add Subject (4)

- Subject is created, received a subject ID and initial progress status

Subject ID: **coro-001001-011**
 Site: Helsinki University Hospital
 Progress: Screening

Subject Summary

Export PDF

Export Audit Trail

Status filter

Monitoring filter

Legend

	Status
Informed Consent	<input checked="" type="radio"/> <input type="checkbox"/>
Informed Consent: Blood Sampling Sub-study for Future Research	<input type="radio"/> <input type="checkbox"/>
End Of Trial	<input type="radio"/> <input type="checkbox"/>
Informed Consent Amendments	<input type="radio"/> <input type="checkbox"/>
Concomitant Medications Log	<input type="radio"/> <input type="checkbox"/>
Primary and Secondary Endpoints	<input type="radio"/> <input type="checkbox"/>
Protocol Deviations	<input type="radio"/> <input type="checkbox"/>

	Enrolment V1
Visit Date	<input type="radio"/> <input type="checkbox"/>
Inclusion / Exclusion Criteria	<input type="radio"/> <input type="checkbox"/>
Demographics	<input type="radio"/> <input type="checkbox"/>



Subject Summary

- Subject summary is shown
- Subject's flow is shown containing the initial set of visits and forms

Subject ID: coro-001001-011
 Site: Helsinki University Hospital
 Progress: Screening

Subject Summary Export PDF Export Audit Trail

Status filter ○ ◐ ◑ ⚠ 🔗 🚫

Monitoring filter 📄 ⚠ 📝 ✅ 📄

[Legend](#)

👤 Subject Summary

◐ Informed Consent

○ Informed Consent: Blood Sampling Sub-study for Future Research

○ Enrolment V1 ▾

○ End Of Trial

○ Informed Consent Amendments

○ Logs ▾

	Status
Informed Consent	◐ 📄
Informed Consent: Blood Sampling Sub-study for Future Research	○ 📄
End Of Trial	○ 📄
Informed Consent Amendments	○ 📄
Concomitant Medications Log	○ 📄
Primary and Secondary Endpoints	○ 📄
Protocol Deviations	○ 📄

	Enrolment V1
Visit Date	○ 📄
Inclusion / Exclusion Criteria	○ 📄
Demographics	○ 📄



Enter and Edit Data



Enter/Edit Data - Flow

Use the subject flow to navigate to a form:

- Some forms are not part of a visit (e.g. Informed Consent)
- Click a visit to view its forms

Subject ID: coro-001001-005
 Site: Helsinki University Hospital
 Progress: Screening

Subject Summary

Status filter: ○ 🌙 ✅ ⚠️ 🕒 🚫 Monitoring filter: 📄 ⚠️ 📝 ✅ 📄

	Status
Informed Consent	🌙 📄
Informed Consent: Blood Sampling Sub-study for Future Research	○ 📄
End Of Trial	○ 📄
Informed Consent Amendments	○ 📄
Concomitant Medications Log	○ 📄
Primary and Secondary Endpoints	○ 📄
Protocol Deviations	○ 📄

	Enrolment V1
Visit Date	○ 📄
Inclusion / Exclusion Criteria	○ 📄
Demographics	○ 📄

- 👤 Subject Summary
- 🌙 Informed Consent
- Informed Consent: Blood Sampling Sub-study for Future Research
- Enrolment V1 ⤴
- Visit Date
- Inclusion / Exclusion Criteria
- Demographics
- Medical History



Enter/Edit Data - Subject Summary

Or use the subject summary to navigate to a form:

- Optionally click a status filter to only view forms for a given data entry status
- Click the status icon for the form to access it

Subject ID: coro-001001-002
Site: Helsinki University Hospital
Progress: Randomised

Subject Summary

Status filter:

Monitoring filter:

	Status
Informed Consent: Blood Sampling Sub-study for Future Research	<input type="radio"/> <input type="checkbox"/>
End Of Trial	<input type="radio"/> <input type="checkbox"/>
Informed Consent Amendments	<input type="radio"/> <input type="checkbox"/>
Adverse Events Log	<input type="radio"/> <input type="checkbox"/>
Concomitant Medications Log	<input type="radio"/> <input type="checkbox"/>
Subject Reported Clinical Endpoints Log	<input type="radio"/> <input type="checkbox"/>
Primary and Secondary Endpoints	<input type="radio"/> <input type="checkbox"/>
Protocol Deviations	<input type="radio"/> <input type="checkbox"/>

	Enrolment V1	Visit 6	Visit 7
Visit Date	<input type="radio"/> <input type="checkbox"/>	<input type="radio"/> <input type="checkbox"/>	<input type="radio"/> <input type="checkbox"/>
Demographics	<input type="radio"/> <input type="checkbox"/>		
Medical History	<input type="radio"/> <input type="checkbox"/>		
Vital Signs	<input type="radio"/> <input type="checkbox"/>		
Cardiac Assessment	<input type="radio"/> <input type="checkbox"/>		
Concomitant Medications	<input type="radio"/> <input type="checkbox"/>		
Questionnaires	<input type="radio"/> <input type="checkbox"/>		
Smoking Behaviour	<input type="radio"/> <input type="checkbox"/>		
Blood Sampling - Basic Laboratory Assessments and CoroPredict Score	<input checked="" type="radio"/> <input type="checkbox"/>		

In the example given, the subject summary is filtered on entry status “Empty” and “Incomplete”.

The summary now shows all forms where data is still expected.



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Enter/Edit Data - Status Icons

Status Icons indicate the data entry status of a subject/visit/form/block:

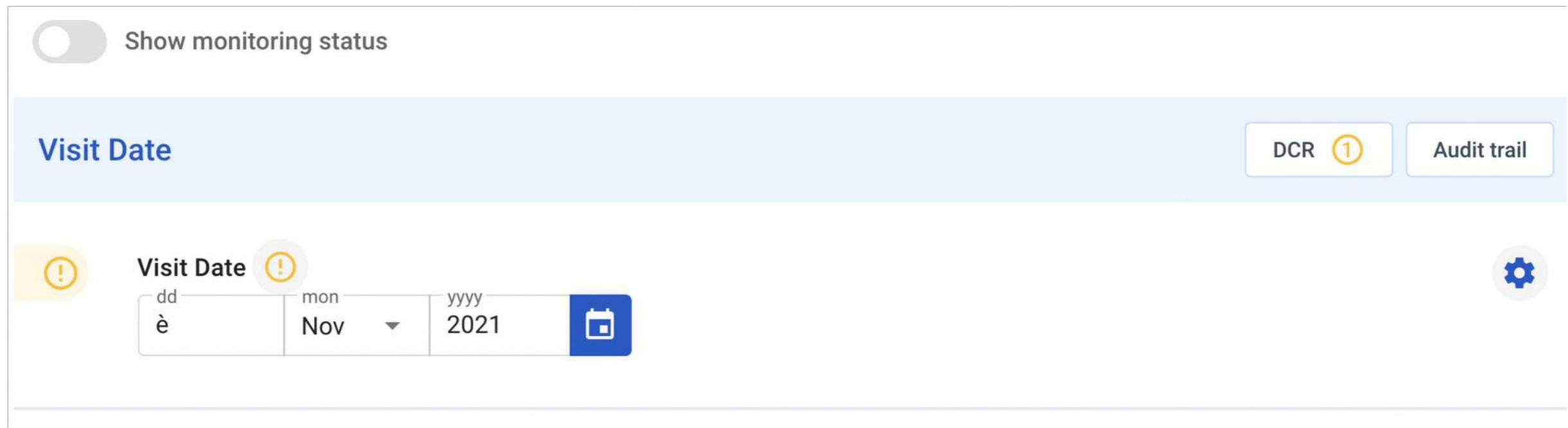
 Empty	No data is present.
 Incomplete	Data is present, but data entry is not complete.
 Invalid	Invalid data is present: at least one DCR (query) is raised.
 Valid	All data is present and valid.
 Answered DCR	At least one DCR (query) has been answered.
 Signed	Data has been signed.



Enter/Edit Data - Data Saving

Data entered is automatically validated and saved in-real time:

- No Save button
- Instant feedback in form of automatic DCRs (queries) on the entered data
- Dynamic fields or forms depending on the entered data appear immediately



The screenshot shows a user interface for data entry. At the top left, there is a toggle switch labeled "Show monitoring status" which is currently turned off. Below this, a light blue header bar contains the text "Visit Date" on the left and two buttons on the right: "DCR" with a yellow circle containing the number "1", and "Audit trail". The main form area has a yellow warning icon on the left. The "Visit Date" label is followed by a yellow warning icon. The date input is split into three fields: "dd" with the character "è", "mon" with a dropdown menu showing "Nov", and "yyyy" with the value "2021". A blue calendar icon is positioned to the right of the date fields. A gear icon for settings is located in the bottom right corner of the form area.

In this example, a DCR is raised as the day contains a non-numeric character



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Enter/Edit Data - Open DCR

- Hover over the DCR icon next to the field label to view the DCR message
- Or open the DCR by clicking the DCR icon or the DCR button

Show monitoring status

Visit Date DCR ① Audit trail

⚠ Visit Date ⚠ ⚙

dd mon yyyy
è Nov 2021 



Enter/Edit Data - Edit

Update the entered data accordingly if applicable:

- Change the entered data
- Provide a reason for change
- Click Save to confirm or cancel to return to the form without making the update

Please enter the reason for changing this data ✕

Data Entry Error

Data changed because:

Choose 'Data changed because' to provide a custom reason for making the data update



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Enter/Edit Data - Edit (2)

The updated data is saved and validated in-real time:

- Automatic DCRs are closed automatically if they are no longer applicable

Show monitoring status

Visit Date Audit trail

Visit Date ⚙️

dd	mon	yyyy	
7	Nov ▼	2021	

Back Sign Next



Enter/Edit Data - Answer DCR

Provide an answer to a DCR if applicable:

- Open the DCR by clicking the icon on the left or the button on top
- Select or provide a custom answer and click Save

Vital Signs - coro-001001-001 ✕

Data Clarification Requests

Systolic #7 • 09 Nov 2021 10:07:39 R

 Difference between systolic blood pressure [199] mmHg and diastolic blood pressure [45] mmHg is out of the expected range [5-140] mmHg. You Please verify.

Data is correct

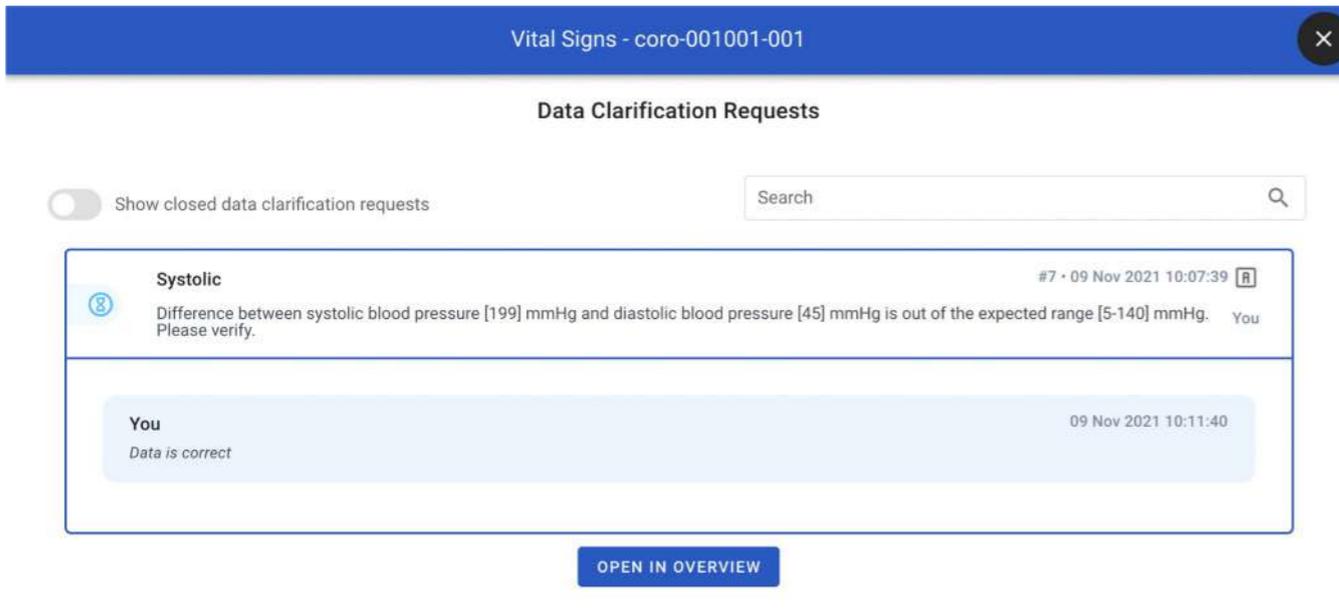
Data is correct for the following reason:

Data is incorrect

Enter/Edit Data - Answer DCR (2)

The Data Manager / CRA can subsequently:

- Close the DCR if the provided answer is satisfactory
- Reopen the DCR to require an additional response from the site (additional clarification or data update)



Vital Signs - coro-001001-001

Data Clarification Requests

Show closed data clarification requests

Search

Systemic #7 • 09 Nov 2021 10:07:39
Difference between systolic blood pressure [199] mmHg and diastolic blood pressure [45] mmHg is out of the expected range [5-140] mmHg. Please verify.

You 09 Nov 2021 10:11:40
Data is correct

OPEN IN OVERVIEW



Blood pressure

Systolic 199 mmHg

Diastolic 45 mmHg

Pulse Rate

103 bpm

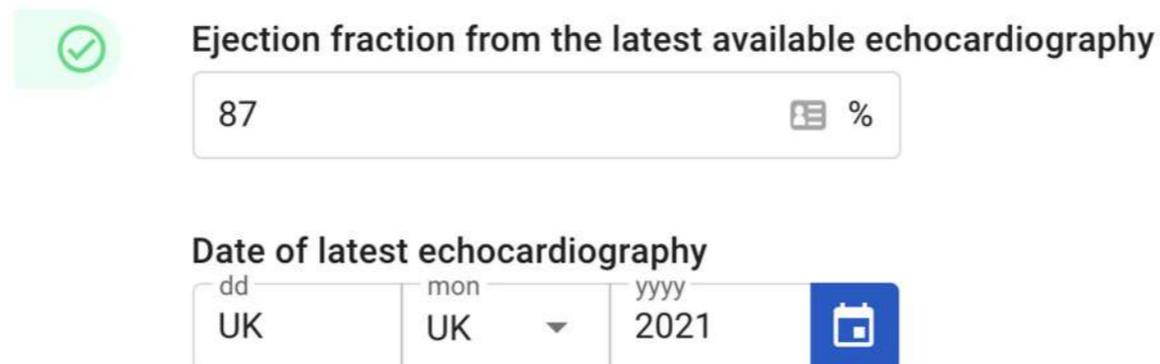
Enter/Edit Data - Required Data

Almost all data fields in the CoroPrevention trial are **required** (= must be completed) and **mandatory** (= cannot be completed as UK, NA or ND).

Notable exceptions:

- Day and month for “Date of latest echocardiography”
- Day for Date on Subject Reported Clinical Endpoints Log

In case this information is **unknown**, this can be entered as “UK” or “NA” or “ND” and will be considered valid and complete by the system.



 Ejection fraction from the latest available echocardiography

87 %

Date of latest echocardiography

dd	mon	yyyy
UK	UK	2021



Enter/Edit Data - Confirm Empty Values

Notable exception (2):

- check box fields with only one option

e.g. 'Tick in case the date of written informed consent needs to be corrected'

Should only be completed (ticked) in case applicable.

If not applicable, click the cog wheel and select '**Confirm empty values**' to validate this field:

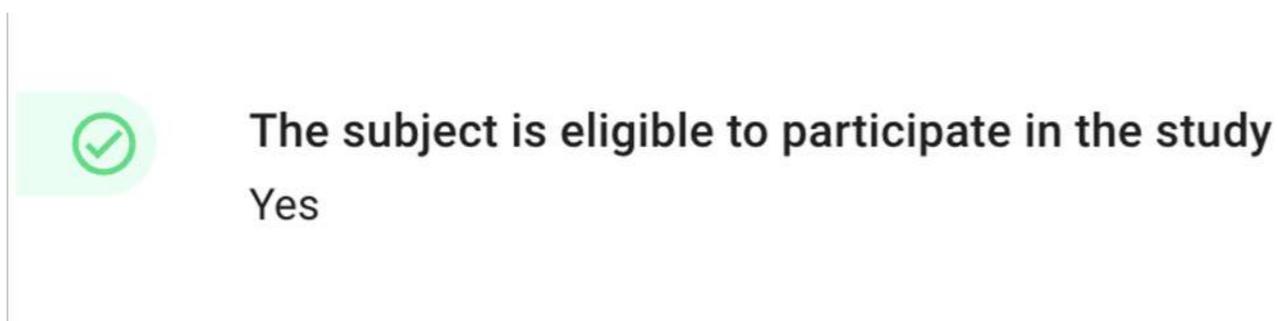
Use "Confirm empty values" to confirm any other data that is not available.

Enter/Edit Data - Calculated Fields

It is not possible to enter/edit data for calculated fields:

- System will calculate the value
- All parameters need to be entered, the system will not calculate the value if data is missing

E.g.: eligibility of a subject will only be calculated once all inclusion and exclusion criteria questions have been filled in



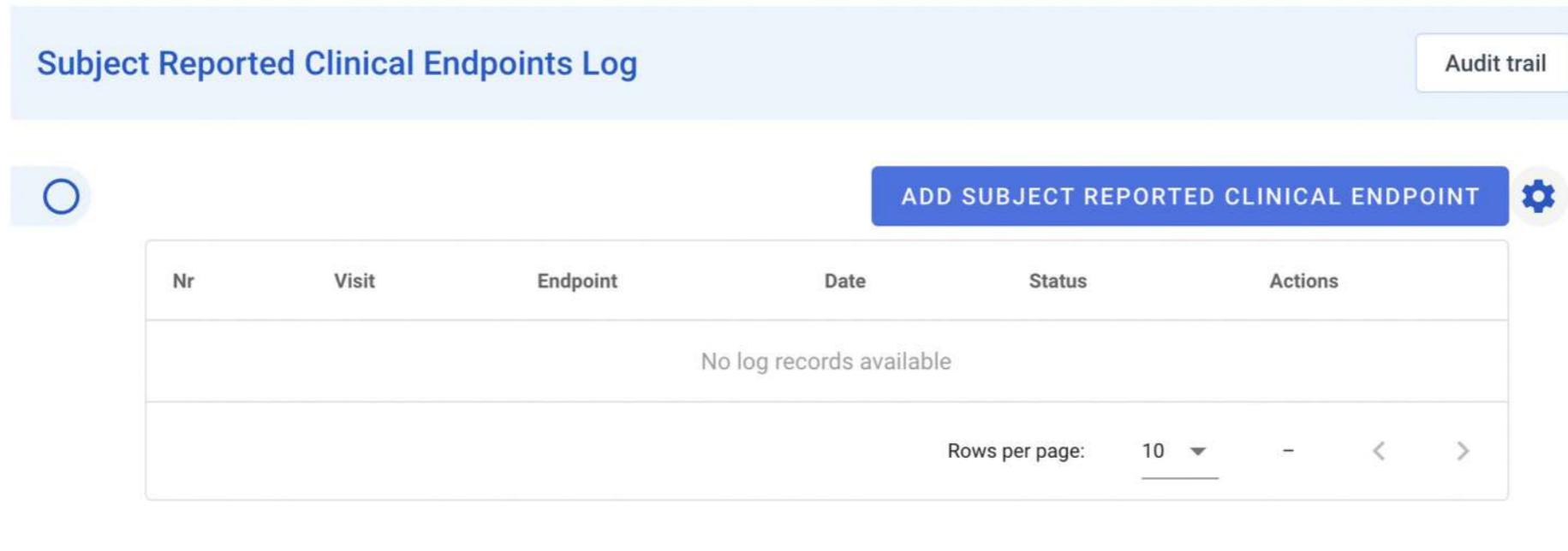
CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Enter/Edit Data - Log Forms

Log forms are forms that are repeating in nature

- To add a new record, click the “Add” button
- There is no limit on the number of records that can be added



Subject Reported Clinical Endpoints Log Audit trail

○ ADD SUBJECT REPORTED CLINICAL ENDPOINT ⚙️

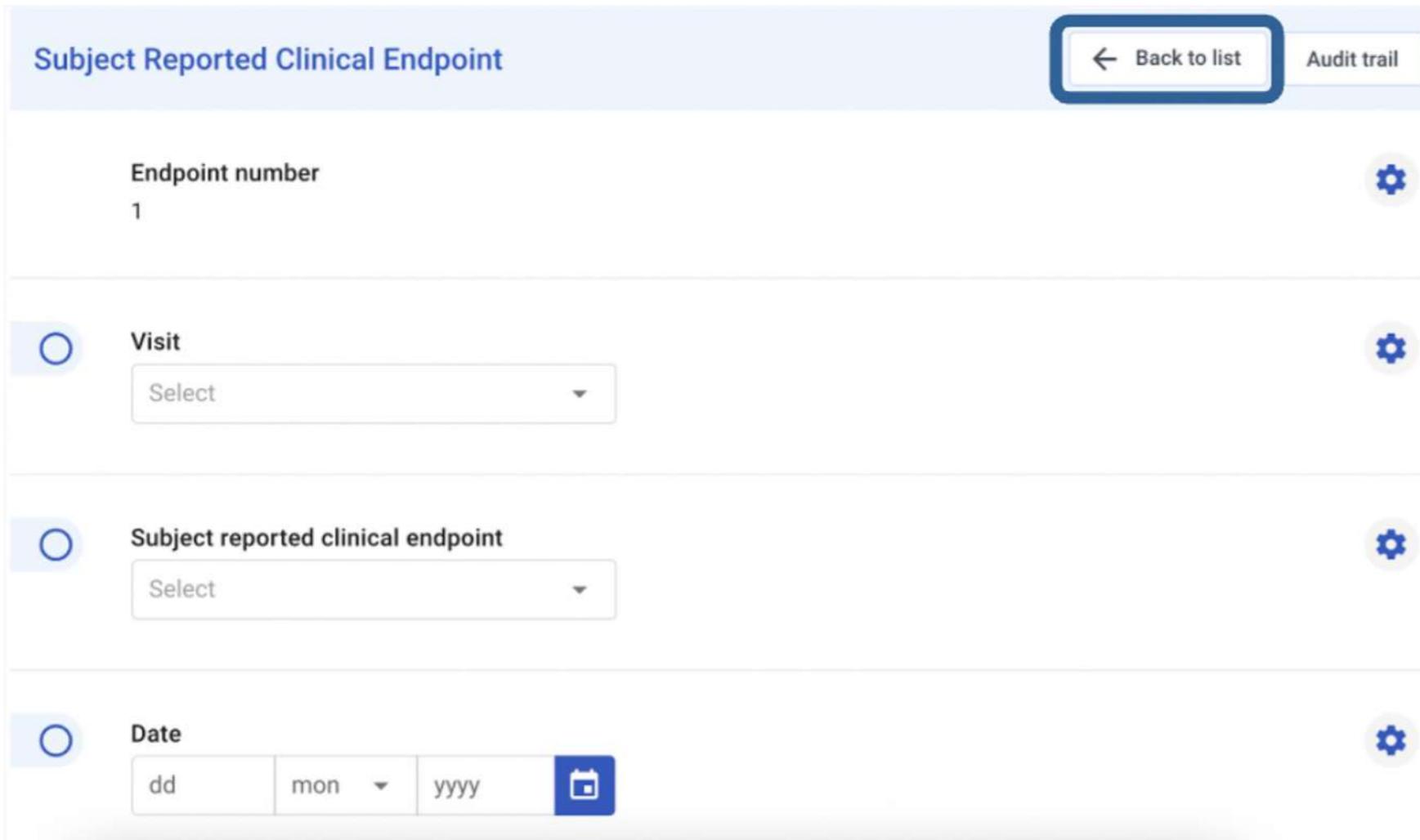
Nr	Visit	Endpoint	Date	Status	Actions
No log records available					

Rows per page: 10 ▾ - < >



Enter/Edit Data - Log Forms (2)

- The record will open in portrait mode allowing you to enter the data
- The system will automatically determine a log number for the record
- After data entry, click “Back to list” to return to the list of records for the form
- Use the “Back” or “Next” buttons to navigate to the previous or next record



Enter/Edit Data - Log Forms (3)

- Click the pencil icon to edit the record, the record will open in portrait mode
- Click the trash can icon to delete the record

Subject Reported Clinical Endpoints Log Audit trail

✔ ADD SUBJECT REPORTED CLINICAL ENDPOINT 

Nr	Visit	Endpoint	Date	Status	Actions
1	Visit 2	Unstable angina	09 Nov 2021	✔ 	 

Rows per page: 10 ▼ 1-1 of 1 < >

Enter/Edit Data - Log Forms (4)

- Click the arrow to reactivate the deleted record

Subject Reported Clinical Endpoints Log

Audit trail

✓ ADD SUBJECT REPORTED CLINICAL ENDPOINT ⚙️

Nr	Visit	Endpoint	Date	Status	Actions
1	Visit 2	Unstable angina	09 Nov 2021		

Rows per page: 10 ▼ 1-1 of 1 < >

Editing data on a record, deleting and reactivating a record will require a reason for change to be provided



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Apply Signature on eCRFs



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Apply Signature on eCRFs - General

- Investigators can provide their signature on valid  eCRFs
- Valid = data entry complete and no open/answered DCRs
- Click the Sign button to initiate sign-off

Vital Signs DCR Audit trail

 **Body height** 

187.4 cm

Body weight

83.1 kg

 **Blood pressure** 

Systolic 199 mmHg Diastolic 45 mmHg

Pulse Rate

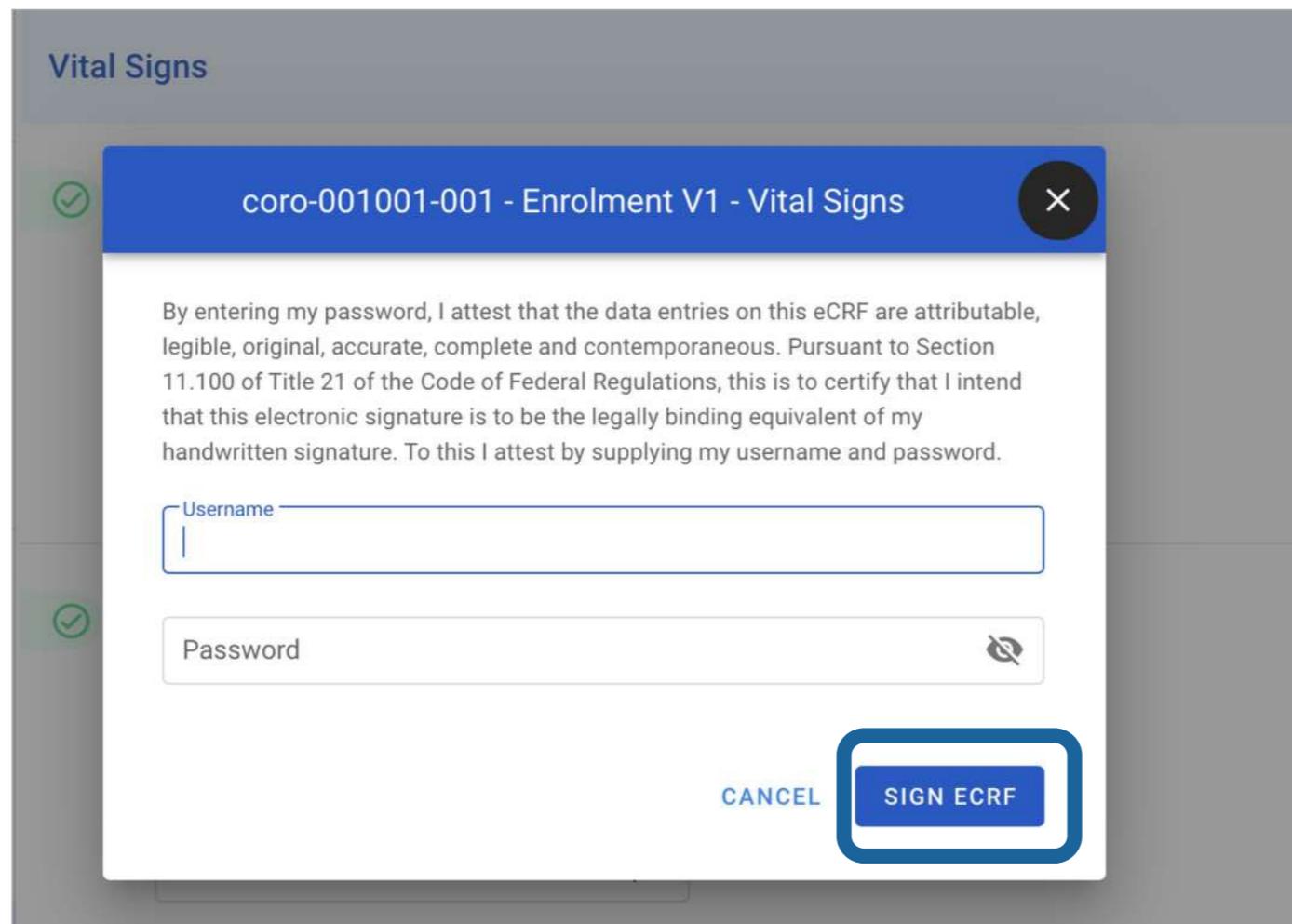
103 bpm

Back **Sign** Next



Apply Signature on eCRFs - Credentials

- Provide your username and password
- Click Sign eCRF to proceed or cancel to return to the eCRF



Vital Signs

coro-001001-001 - Enrolment V1 - Vital Signs

By entering my password, I attest that the data entries on this eCRF are attributable, legible, original, accurate, complete and contemporaneous. Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature. To this I attest by supplying my username and password.

Username

Password

CANCEL SIGN ECRF



Apply Signature on eCRFs - Signed eCRF

- Signature is applied on each field on the eCRF
- And on the eCRF itself: a watermark is added to the bottom of the form

Vital Signs DCR Audit trail

 **Body height** 

187.4 cm

Body weight

83.1 kg

 **Blood pressure** 

Systolic 199 mmHg Diastolic 45 mmHg

Pulse Rate

103 bpm

 **eCRF Signed**
User Investigator (investigator) 09 Nov 2021 11:16:43 (UTC)



Apply Signature on eCRFs - Invalidation

A data update on a signed form will:

- Invalidate the signature on eCRF level, the watermark will disappear
- Invalidate the signature on the updated field(s)

The screenshot shows a 'Vital Signs' form with two sections. The top section, 'Body height' and 'Body weight', is marked with a red 'X' icon, indicating it is invalid. The bottom section, 'Blood pressure' and 'Pulse Rate', is marked with a green checkmark icon, indicating it is valid. The 'Blood pressure' section shows 'Systolic' at 101 mmHg and 'Diastolic' at 45 mmHg. The 'Pulse Rate' is 103 bpm. At the top right of the form are buttons for 'DCR' and 'Audit trail'. At the bottom are 'Back', 'Sign', and 'Next' buttons.

Field	Value	Unit	Status
Body height	187.4	cm	Invalid
Body weight	83.1	kg	Invalid
Blood pressure (Systolic)	101	mmHg	Valid
Blood pressure (Diastolic)	45	mmHg	Valid
Pulse Rate	103	bpm	Valid

! Adding DCRs / changes to monitoring status of a field or page will not invalidate the signature

In this example, the data was updated for Systolic blood pressure.



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CORONARY HEART DISEASE

Apply Signature on eCRFs - Batch Signing

The Sign button on Subject Summary allows to apply your signature to all valid eCRFs at once. This can be done on multiple occasions.

CoroPrevention | Subjects / coro-001001-001 / View | Working in: Country: Finland, Site: Helsinki University Hospital | Logged in as: Renneboog Liesbeth (Investigator)

Subject Summary | Subject ID: coro-001001-001 | Site: Helsinki University Hospital | Progress: Randomised

Buttons: **Sign** (highlighted), Export PDF, Export Audit Trail

Status filter: [Icons] | Monitoring filter: [Icons] | Legend

	Status
Informed Consent	✓ [Icon]
Informed Consent: Blood Sampling Sub-study for Future Research	✓ [Icon]
End Of Trial	○ [Icon]
Informed Consent Amendments	○ [Icon]
Adverse Events Log	○ [Icon]
Concomitant Medications Log	✓ [Icon]
Subject Reported Clinical Endpoints Log	✓ [Icon]
Call Log	○ [Icon]
Primary and Secondary Endpoints	✓ [Icon]
Protocol Deviations	! [Icon]

	Enrolment V1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7
Visit Date	✓ [Icon]	✓ [Icon]	○ [Icon]				
Inclusion / Exclusion Criteria	✓ [Icon]						
Demographics	! [Icon]						
Medical History	✓ [Icon]						

Apply Signature on eCRFs - Batch Signed

After providing valid credentials, the system will apply the signature to all valid eCRFs

CoroPrevention

Subjects / coro-001001-001 / View

Working in:
Country: Finland
Site: Helsinki University Hospital

Logged in as:
 Renneboog Liesbeth (Investigator)

Subject ID: **coro-001001-001**
 Site: Helsinki University Hospital
 Progress: Randomised

Subject Summary
Export PDF
Export Audit Trail

Status filterMonitoring filterLegend

- 👤 Subject Summary
- 🚫 Informed Consent
- 🚫 Informed Consent: Blood Sampling Sub-study for Future Research
- ⚠️ Enrolment V1
- 🚫 Visit Date
- 🚫 Inclusion / Exclusion Criteria
- ⚠️ Demographics
- 🚫 Medical History
- ⚠️ Vital Signs
- 📄 Cardiac Assessment

	Status
Informed Consent	🚫 📄
Informed Consent: Blood Sampling Sub-study for Future Research	🚫 📄
End Of Trial	📄
Informed Consent Amendments	📄
Adverse Events Log	📄
Concomitant Medications Log	🚫 📄
Subject Reported Clinical Endpoints Log	🚫 📄
Call Log	📄
Primary and Secondary Endpoints	🚫 📄
Protocol Deviations	📄

	Enrolment V1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7
Visit Date	🚫 📄	🚫 📄	📄				
Inclusion / Exclusion Criteria	🚫 📄						
Demographics	⚠️ 📄						
Medical History	🚫 📄						

Reports



CoroPrevention

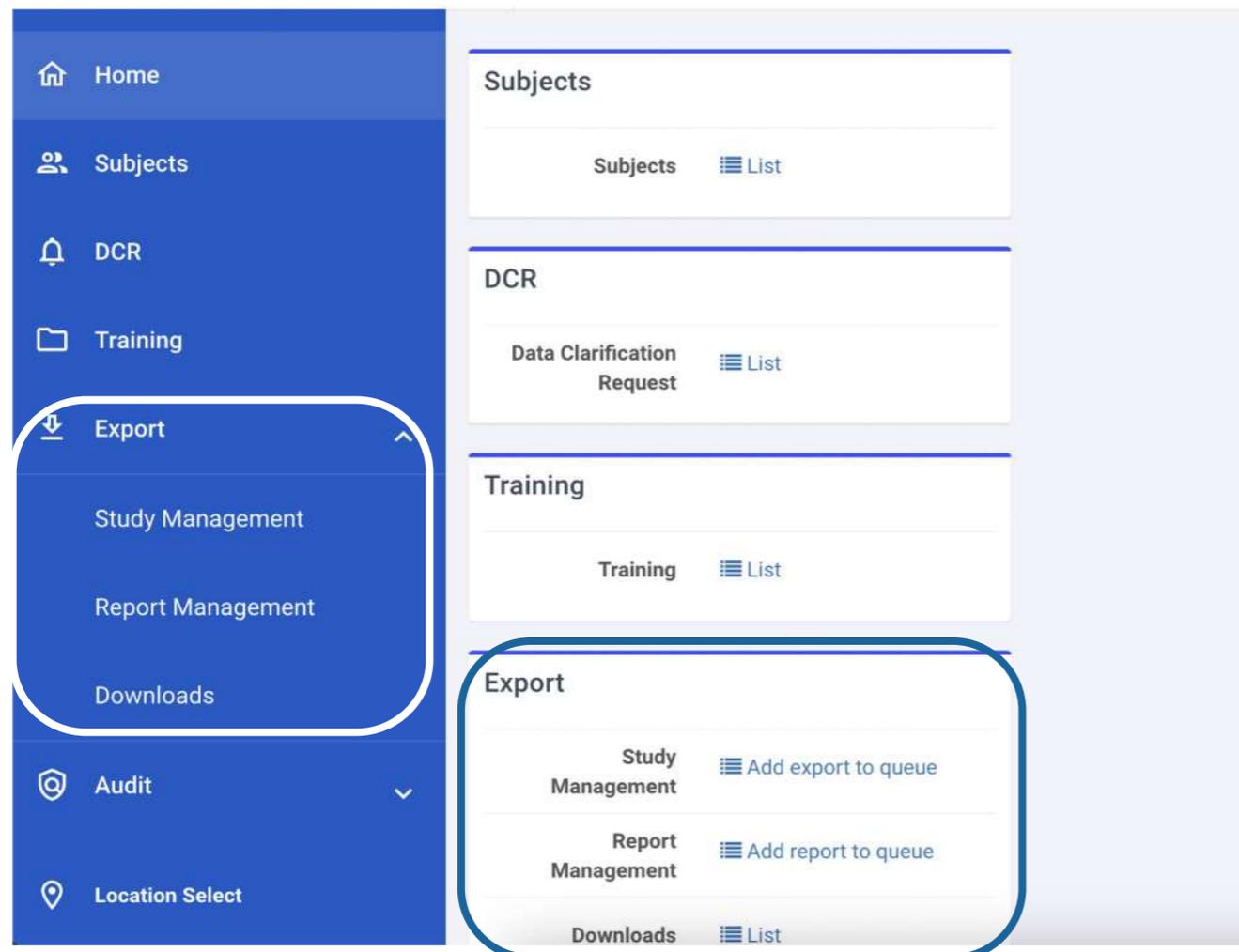
PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Reports - General

All reports and/or exports available to you can be found:

- By clicking Export in the navigation bar
- Or through the dashboard

Click the desired type of report or export



The reports and exports are categorized in three categories:

- Study Management
- Study Execution
- Reports

Which reports and exports are available to you are depending on your user type.

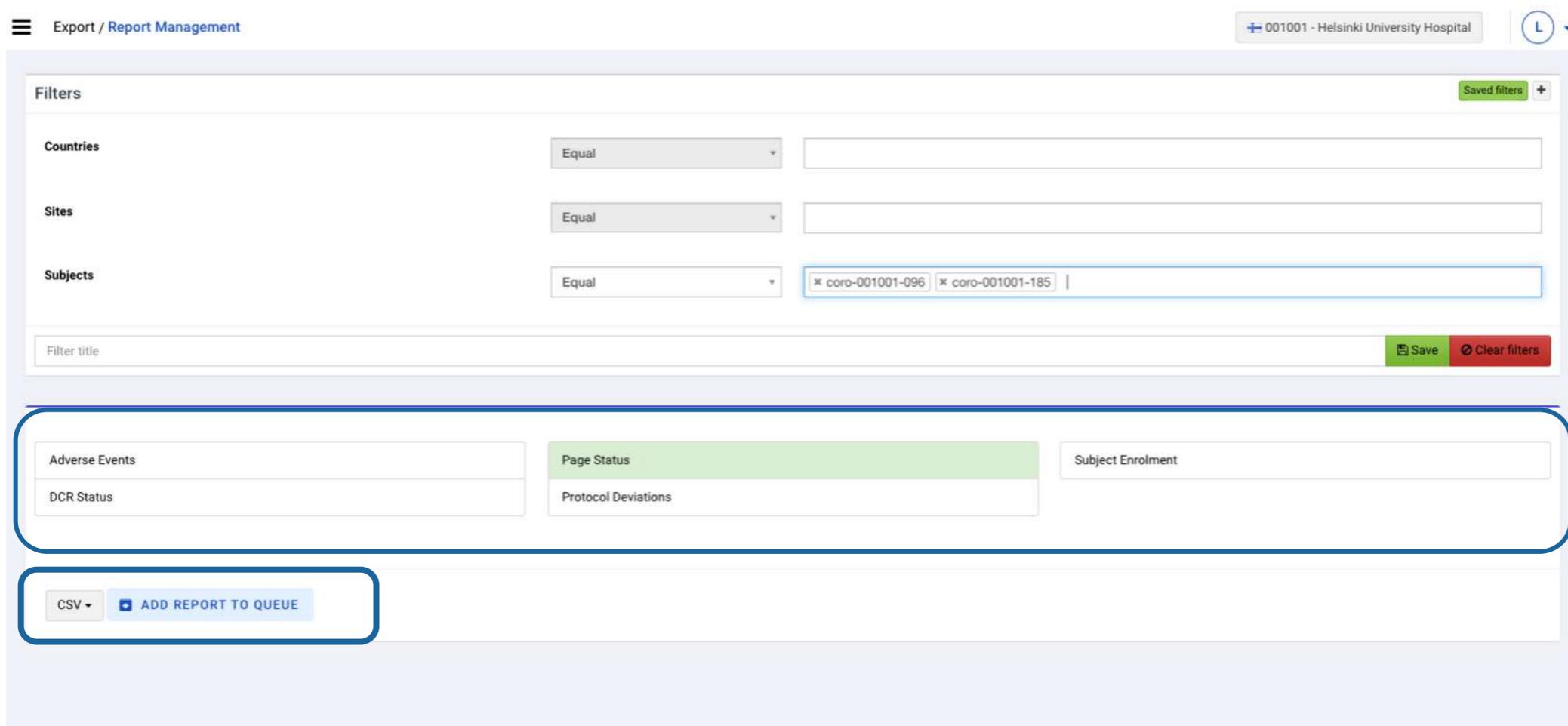


CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Reports - Generation

- Select the desired export / report
- Specify the filters if applicable
- Select the desired format from the dropdown of available formats
- Click Add Export / Report To Queue to start the creation of the export / report



Export / Report Management

001001 - Helsinki University Hospital

Filters Saved filters +

Countries Equal

Sites Equal

Subjects Equal ✕ coro-001001-096 ✕ coro-001001-185

Filter title Save Clear filters

Adverse Events

DCR Status

Page Status

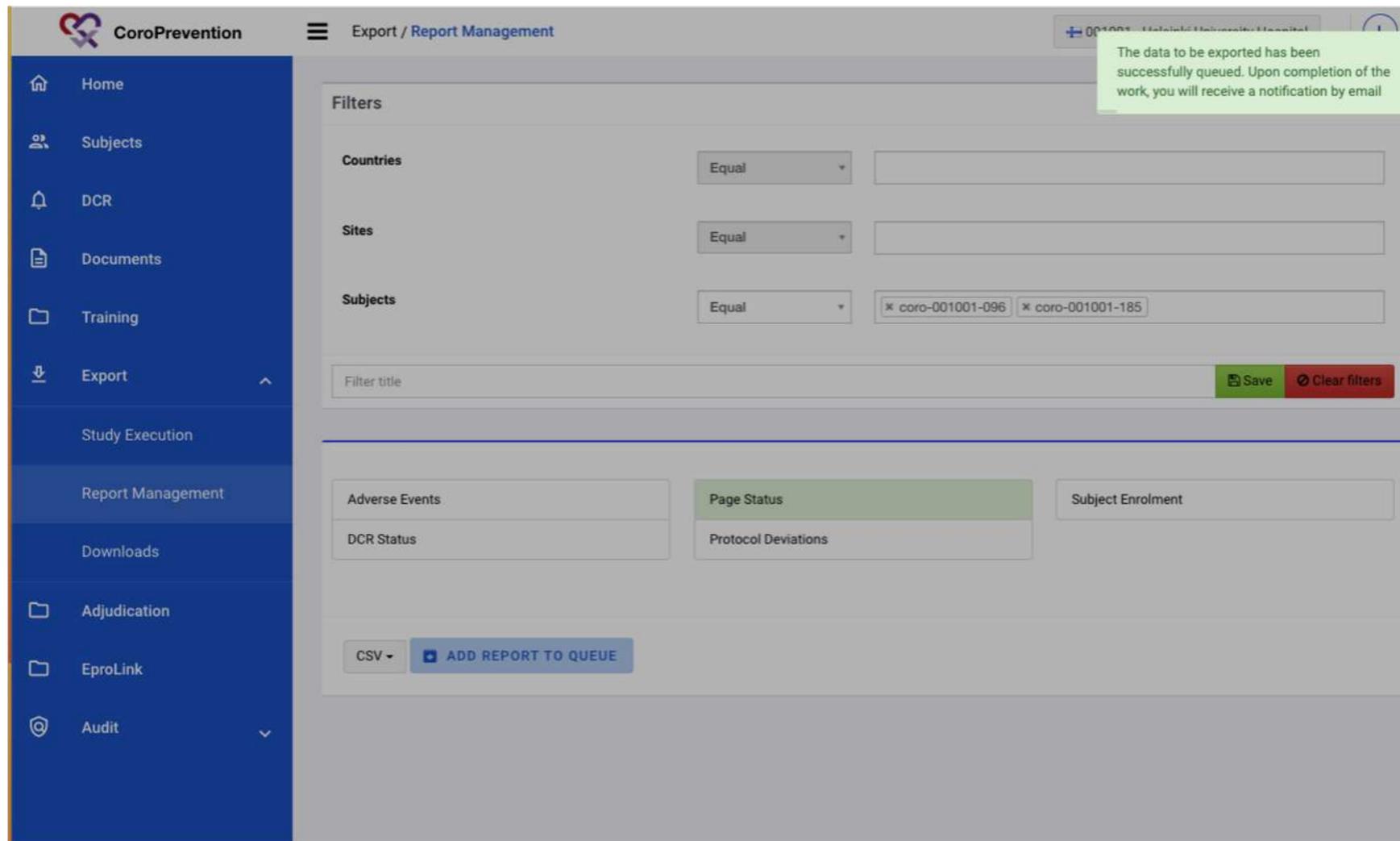
Protocol Deviations

Subject Enrolment

CSV ADD REPORT TO QUEUE

Reports - Generation (2)

- A success message pop-up is shown
- You will receive an email when the export / report has finished and is available for you to download

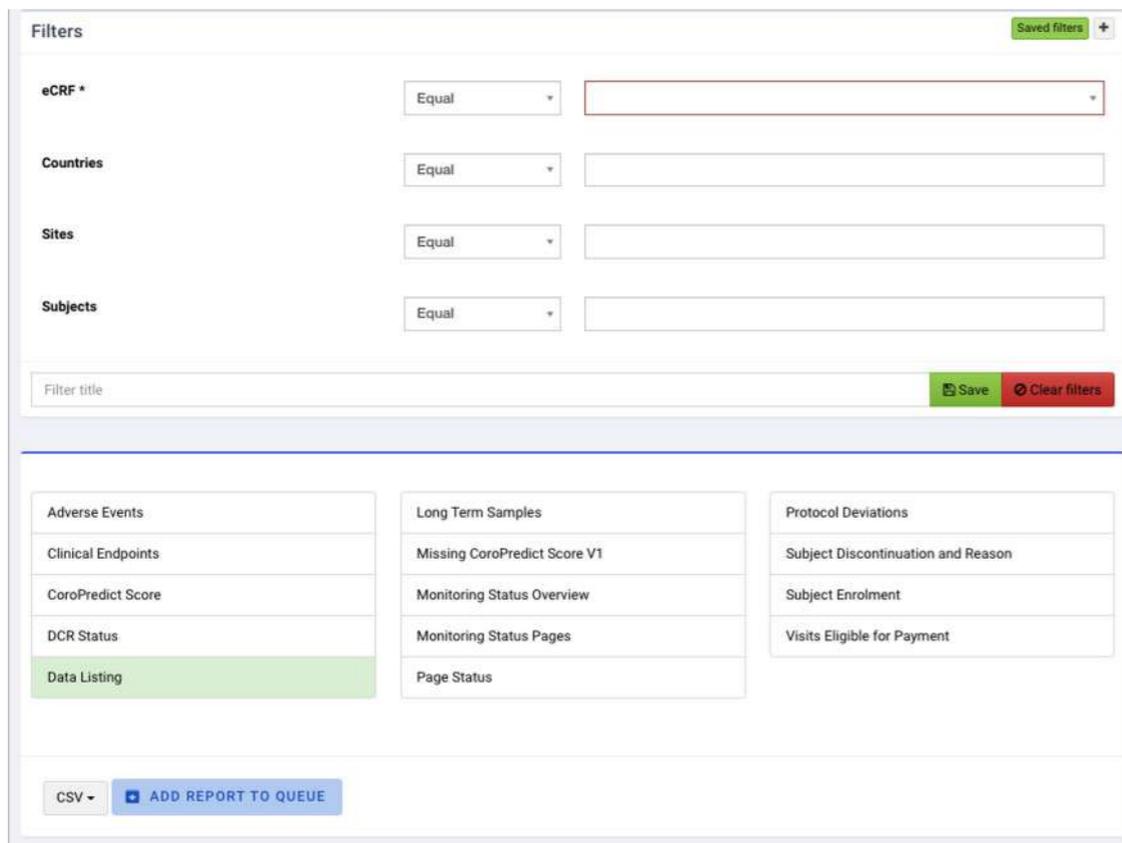


The screenshot displays the 'Export / Report Management' interface in the CoroPrevention system. A success message pop-up is visible at the top right, indicating that the data to be exported has been successfully queued and a notification will be sent via email upon completion. The interface includes a sidebar with navigation options and a main content area with filters for Countries, Sites, and Subjects. The Subjects filter is set to 'Equal' and includes two selected subject IDs: 'coro-001001-096' and 'coro-001001-185'. Below the filters, there are buttons for 'Save' and 'Clear filters'. At the bottom of the main content area, there is a 'CSV' dropdown and an 'ADD REPORT TO QUEUE' button.



Reports - Filters

- Before generating the report it is possible to use filters, this will limit the data of your export / report
- For most reports and exports, the filters are optional
- For some reports a filter is required: e.g. the Data Listing report requires an eCRF to be selected
- The system will warn you in case a filter needs to be specified



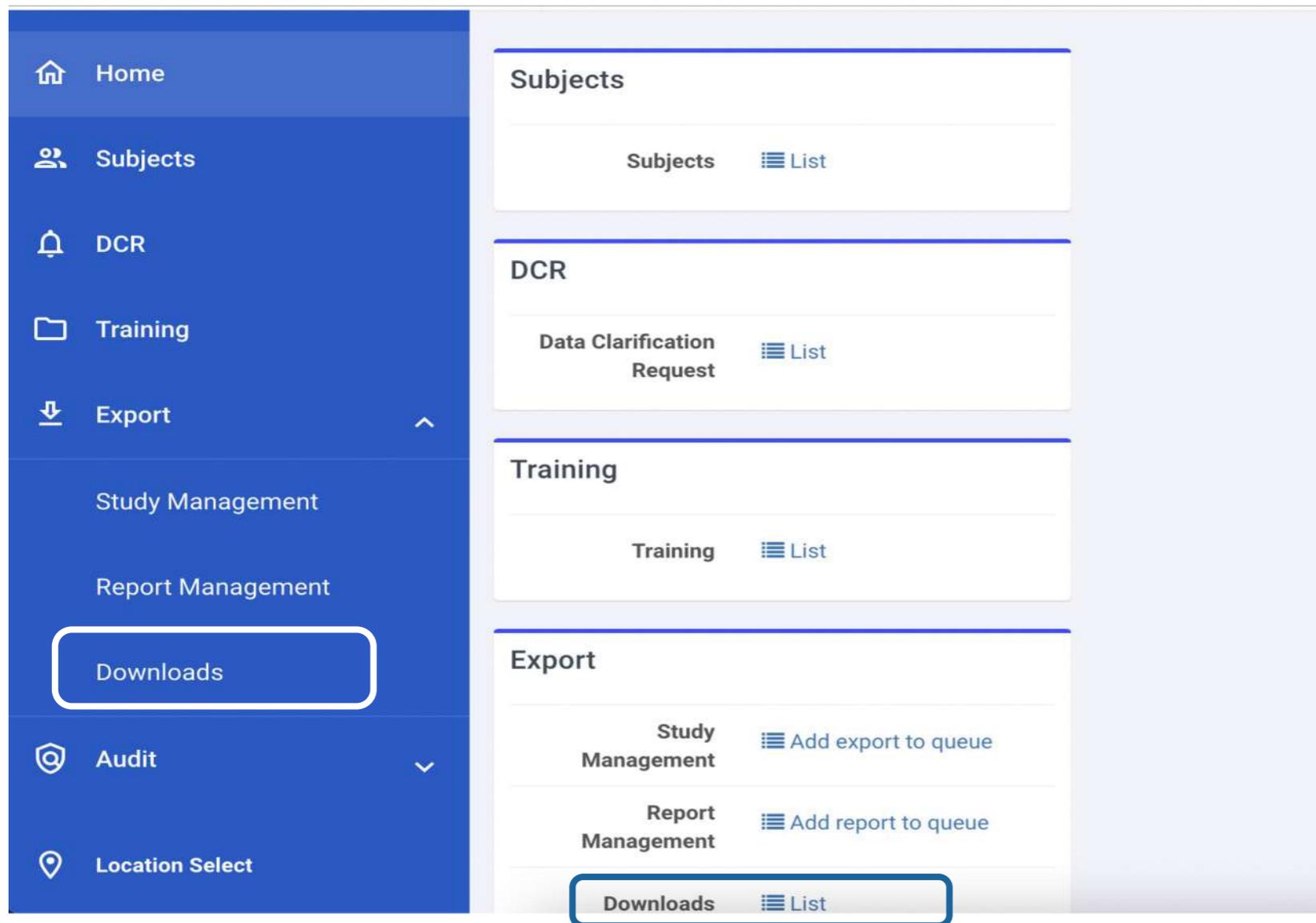
The screenshot shows the 'Filters' section of the UniWeb interface. It features a 'Saved filters' button with a plus sign. Below this, there are four filter rows, each with a label, a dropdown menu set to 'Equal', and an input field. The labels are 'eCRF *', 'Countries', 'Sites', and 'Subjects'. At the bottom of the filter section, there is a 'Filter title' input field, a green 'Save' button, and a red 'Clear filters' button. Below the filter section, there is a grid of report categories: Adverse Events, Clinical Endpoints, CoroPredict Score, DCR Status, Data Listing (highlighted in green), Long Term Samples, Missing CoroPredict Score V1, Monitoring Status Overview, Monitoring Status Pages, Page Status, Protocol Deviations, Subject Discontinuation and Reason, Subject Enrolment, and Visits Eligible for Payment. At the bottom left, there is a 'CSV' dropdown and an 'ADD REPORT TO QUEUE' button.

You can save your filter combinations for future use by providing a title for the filter and clicking “Save”



Reports - Download

- Requested reports / exports are listed in the Downloads section
- Navigate through the blue bar or via the dashboard to Downloads

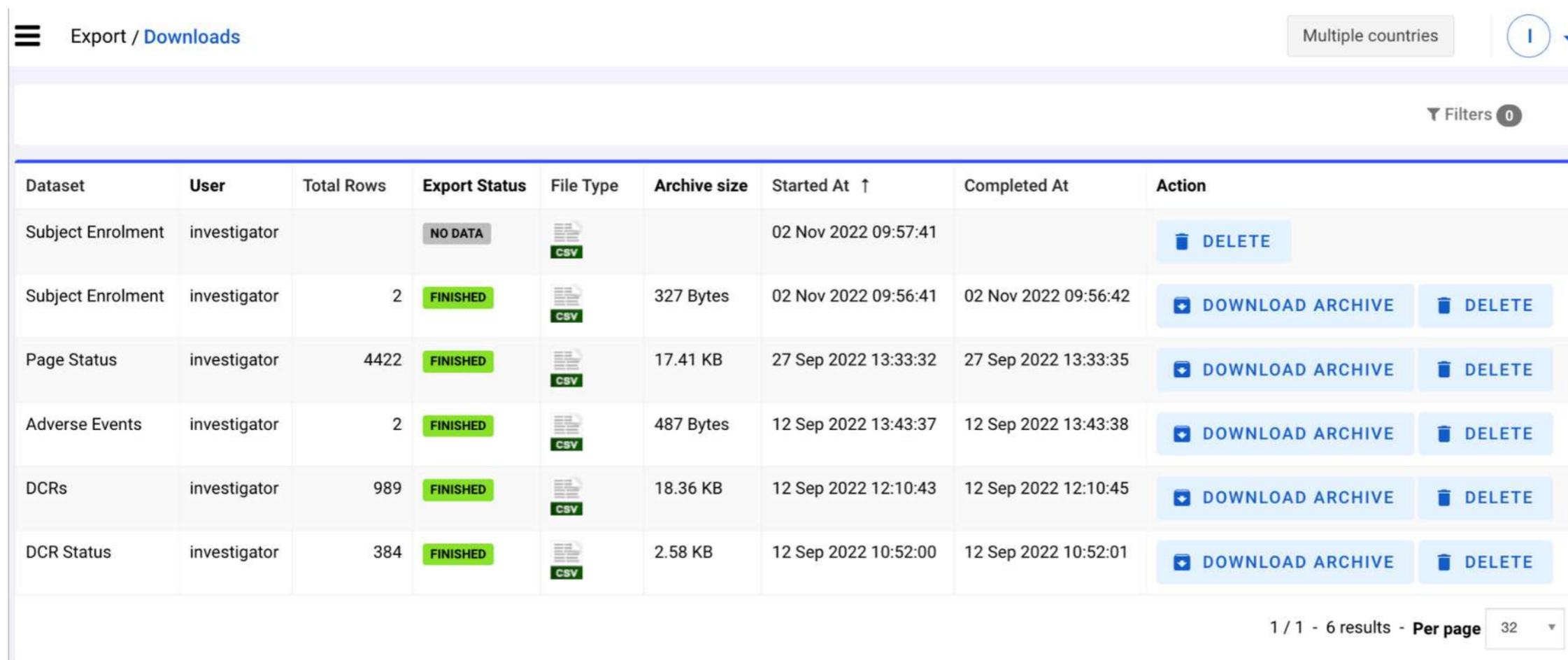


The screenshot displays the UniWeb interface. On the left is a blue navigation sidebar with the following items: Home, Subjects, DCR, Training, Export (with an upward arrow), Study Management, Report Management, Downloads (highlighted with a white border and rounded corners), Audit (with a downward arrow), and Location Select. The main content area on the right is divided into four sections: Subjects, DCR, Training, and Export. Each section contains a list icon and a 'List' link. The 'Downloads' link in the sidebar and the 'Downloads List' link at the bottom of the Export section are also highlighted with white borders and rounded corners.



Reports - Download (2)

- Download the desired report / export by clicking the 'Download Archive' button
- A .zip file containing the report / export is saved on your device
- Use the 'Delete' button to delete requests you no longer need



Export / Downloads Multiple countries 1

Filters 0

Dataset	User	Total Rows	Export Status	File Type	Archive size	Started At ↑	Completed At	Action
Subject Enrolment	investigator		NO DATA	 CSV		02 Nov 2022 09:57:41		DELETE
Subject Enrolment	investigator	2	FINISHED	 CSV	327 Bytes	02 Nov 2022 09:56:41	02 Nov 2022 09:56:42	DOWNLOAD ARCHIVE DELETE
Page Status	investigator	4422	FINISHED	 CSV	17.41 KB	27 Sep 2022 13:33:32	27 Sep 2022 13:33:35	DOWNLOAD ARCHIVE DELETE
Adverse Events	investigator	2	FINISHED	 CSV	487 Bytes	12 Sep 2022 13:43:37	12 Sep 2022 13:43:38	DOWNLOAD ARCHIVE DELETE
DCRs	investigator	989	FINISHED	 CSV	18.36 KB	12 Sep 2022 12:10:43	12 Sep 2022 12:10:45	DOWNLOAD ARCHIVE DELETE
DCR Status	investigator	384	FINISHED	 CSV	2.58 KB	12 Sep 2022 10:52:00	12 Sep 2022 10:52:01	DOWNLOAD ARCHIVE DELETE

1 / 1 - 6 results - Per page 32

If the request returned no data, the export status will show 'No Data'. It is not possible to download this empty file.

Reports - Download (3)

- Any requests still being processed by the system will also show up in the list
- You can track the progress in the Progress column
- If applicable, you can pause or cancel the request in this stage

CoroPrevention Export / Downloads Working in: Countries: Multiple Sites: Multiple Logged in as: Smith John (Administrator) Filters 0

Type	Title	User	Total Rows	Progress	Export Status	File Type	Archive size	Completed At	Action
Report	SubjectData	Smith John			IN PROGRESS	CSV			PAUSE CANCEL
Report	Data Listing	Smith John			NO DATA	PDF			DELETE

Forgot Password



CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Forgot Password

- If you forgot your password, click **Forgot Password?** on the login page
- Provide your username or email address and click **Send Recovery Email**

Recover your account by entering your username or e-mail

[Back to login](#)

Send Recovery Email



Welcome Back. Please login to your account:

[Forgot Password?](#)

v. -HEAD.2ac21b5
2021-11-16 13:29:06

[Activate user](#)

Login



CoroPrevention
PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

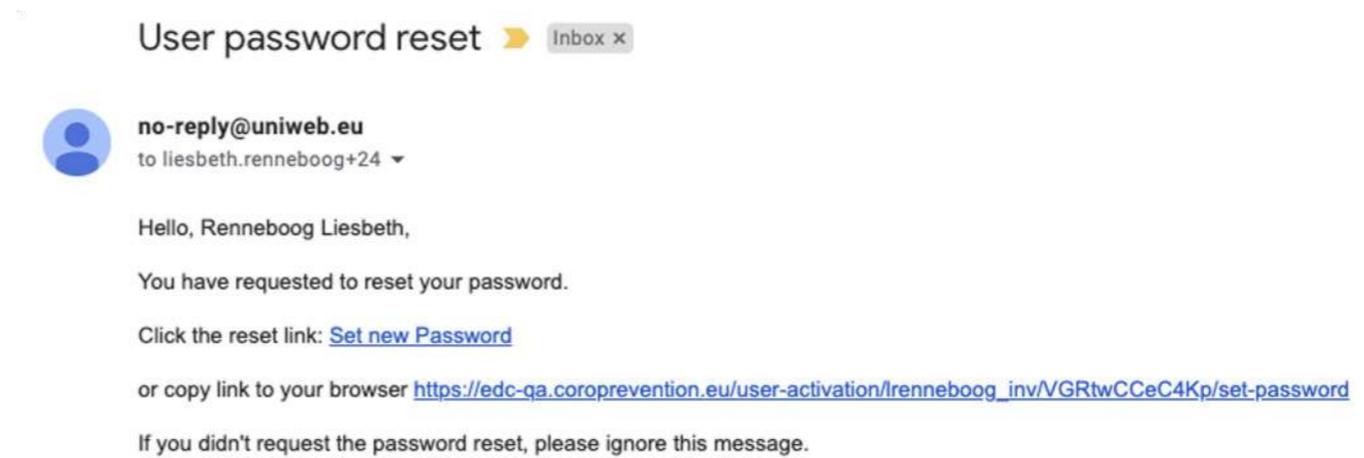
Forgot Password (2)

- An email is sent to your email address
- Click Set new Password
- Enter a new password
- Click Set Password

- ✓ 30 or less characters
- ✓ 8 or more characters
- ✓ Uppercase
- ✓ Lowercase
- ✓ A number
- ✓ A special symbol

Set Password

[Back to login](#)

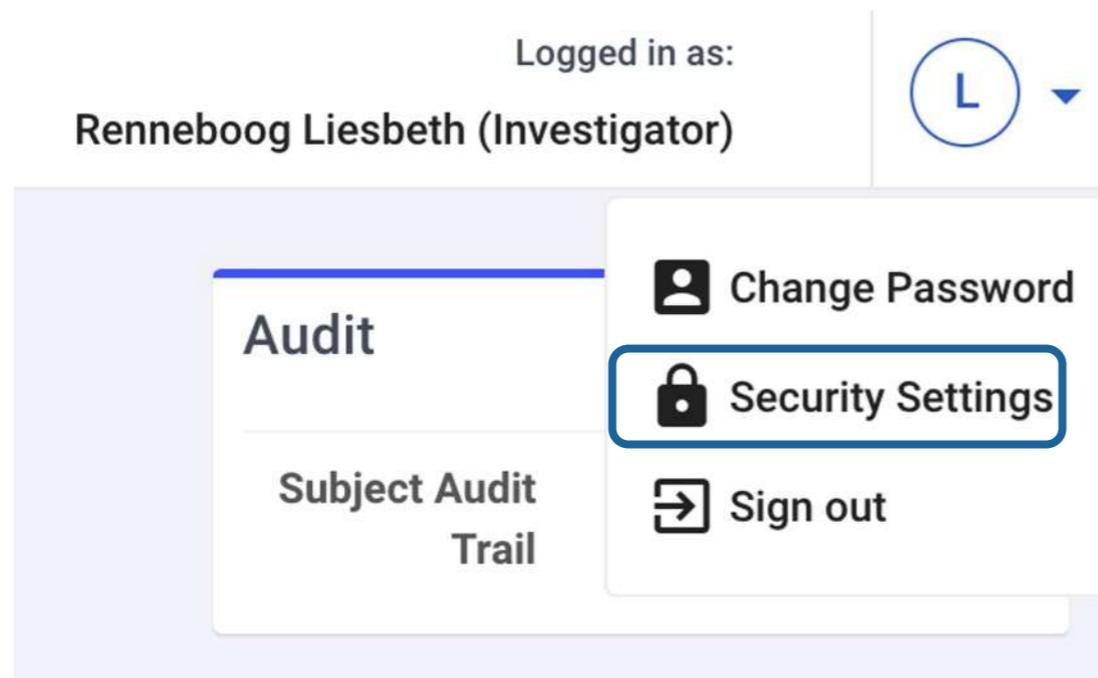


Reset Two-Factor Authentication (TFA)

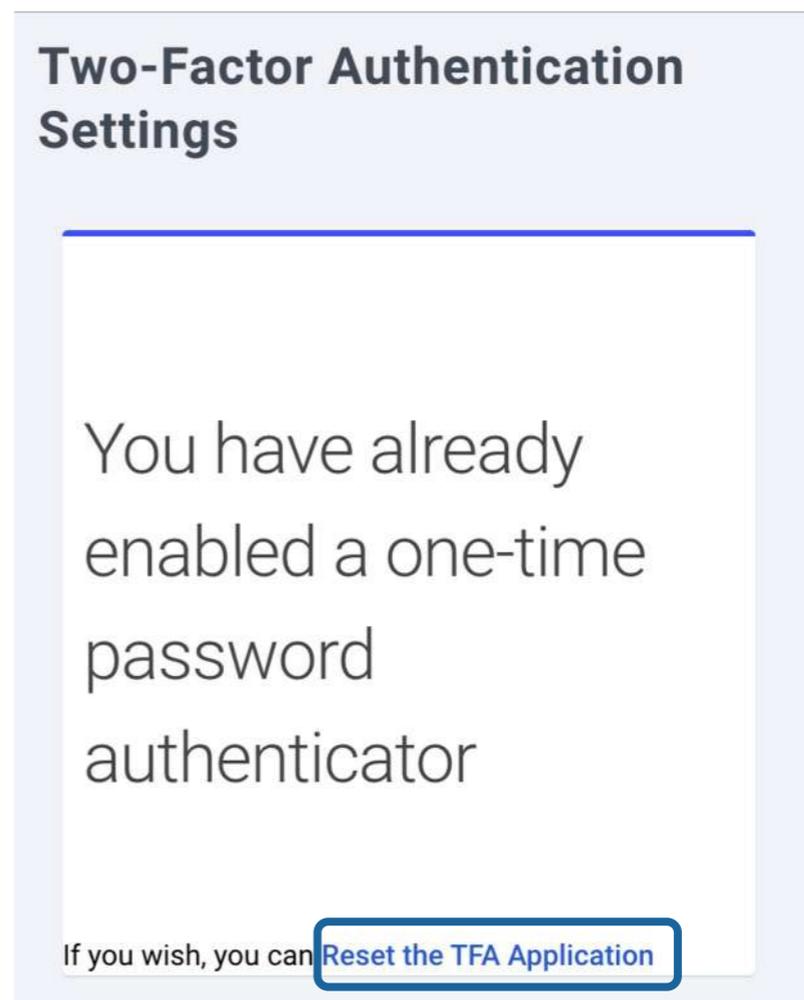


Reset TFA

- After logging in using your current (mobile) device to provide the TFA code, click Security Settings in the user menu (upper right corner)



- Click Reset the TFA application



Reset TFA (2)

- Using your current (mobile) device, provide the 6-digit TFA code

You have already enabled a one-time password authenticator

In case you want to register a new device, you can reset the previous 2FA setup.

If you still have the old device, enter the 6 digit code from your authentication App.

If you do not have access to your previous device, you can enter one of the back-up codes.

If neither are possible, please contact system administrators for assistance.

Pin code or Back-up code*

Reset the 2-Factor account

If you do not have access to your current device, please contact support@uniweb.eu to receive a back-up code

Reset TFA - Register New Device

- Open Google Authenticator app on your new mobile device
- Scan the QR code with your new mobile device or enter the key and user account manually
- Enter the 6-digit code shown by the authenticator app
- Click the register button to complete the TFA registration for your new device

Two-Factor Authentication Settings

Use a one-time password authenticator on your mobile device or computer to enable two-factor authentication (2FA).

We recommend cloud-based mobile authenticator apps such as Authy, Duo Mobile, and LastPass. They can restore access if you lose your hardware device.



Pin code*

Register with 2-Factor App

Can't scan the code?

To add the entry manually, provide the following details to the application on your phone.

Account

Key: 1

MJ5NRHNSJC4{

HG305H

Time based: Yes



CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Laboratory Data



Laboratory Data - General

- The trial contains two types of laboratory data forms
 - Blood Sampling - Basic Laboratory Assessments and CoroPredict Score
 - Blood Sampling: Sub-study for Future Research
 - Only if Informed Consent for Blood Sampling Sub-study for Future Research is given
- Compliance Assessments results are not collected in EDC



CoroPrevention

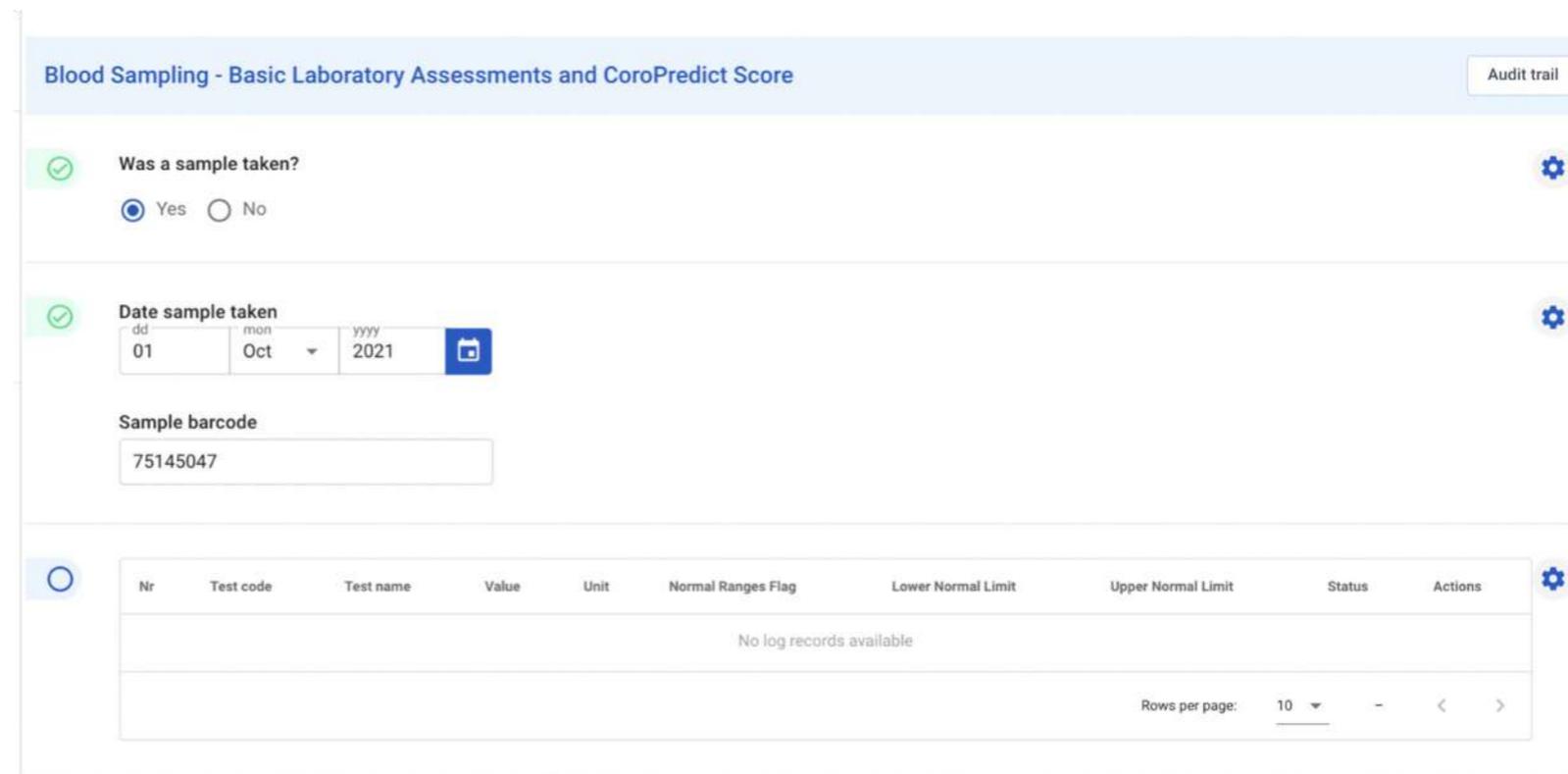
PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Blood Sampling - Basic Laboratory Assessments and CoroPredict Score

- Blood Sampling results are provided by the central lab and uploaded automatically to the eCRF within the subject's visit
- At least the following data should be entered into EDC to enable this:
 - Subject needs to be created
 - Year of birth and Sex on Demographics form
 - Visit Date (visits except Enrolment V1)
 - Was a sample taken?
 - Sample barcode

The laboratory assessments details for a subject-visit can only be uploaded if the above data has been completed in EDC.

The lab results will appear automatically once they've been made available.



Blood Sampling - Basic Laboratory Assessments and CoroPredict Score Audit trail

Was a sample taken? ⚙️
 Yes No

Date sample taken ⚙️
dd mon yyyy
01 Oct 2021 

Sample barcode
75145047

Nr	Test code	Test name	Value	Unit	Normal Ranges Flag	Lower Normal Limit	Upper Normal Limit	Status	Actions
No log records available									

Rows per page: 10 - < >

Blood Sampling - Basic Laboratory Assessments and CoroPredict Score - Biobank Subjects

- Only applicable for Finnish sites - Biobank subjects in Enrolment V1
- Indicate in the subject's eCRF that the subject is a biobank subject
- An “Add Blood Sample Record” button appears, click the button to add a laboratory assessment
- Complete the available details for the assessment
- Test name and Unit appear automatically when a Test code is selected
- Repeat for each available assessment

Nr	Test code	Test name	Value	Unit	Normal Ranges Flag	Lower Normal Limit	Upper Normal Limit	Status	Actions
1	BNPRO2	NT proBNP	444	pg/ml	H	88	111		
2	CYBCK	Cystatin C	44	mg/L	H	11	33		
3	CERT2	Ceramide Score	11						
4	TROIHS	hs-Troponin I	11	pg/mL			4		
5	ALTBC	ALT, 37°C	22	U/L					

Rows per page: 10 1-5 of 5 < >

ADD BLOOD SAMPLE RECORD

Blood Sample

Nr
5

Test code
ALTBC

Test name
ALT, 37°C

Value

Unit
U/L

Normal Ranges Flag

Lower Normal Limit

Upper Normal Limit

Blood Sampling: Sub-study for Future Research

- Only if Informed Consent for Blood Sampling Sub-study for Future Research is given
- Complete whether the sample was taken and if so, the date
- Sample barcodes will be derived from the Blood Sampling - Basic Laboratory Assessments and CoroPredict Score form within the same visit

Blood Sampling: Sub-study for Future Research Audit trail

Was a sample taken? ⚙️

Yes No

Date sample taken ⚙️

dd mon yyyy

Sample barcode (Plasma) ⚙️

1239987

Sample barcode (Serum)

123998701

Sample barcode (EDTA-blood)

123998710

[Back](#)

The Visit Date needs to be completed to trigger this form for the visit.

The Visit Date needs to be after or equal to the date of informed consent for the sub-study.



CoroPrevention
PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Randomise / Allocate Treatment



CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Eligibility

- Randomisation or treatment allocation can only be done for **eligible** subjects
- The system will calculate whether a subject is eligible when **all inclusion criteria** fields and **all exclusion criteria** fields have been completed on the Inclusion / Exclusion Criteria form:

Subject ID: coro-001001-006
Site: Helsinki University Hospital
Progress: Enrolled

Show monitoring status

Inclusion / Exclusion Criteria Audit trail

Inclusion Criteria	Yes	No
<input checked="" type="checkbox"/> Informed consent form signed by the study subject.	<input checked="" type="radio"/>	<input type="radio"/>
Male or female aged 30 to 80 years on the day of enrolment.	<input checked="" type="radio"/>	<input type="radio"/>
≥ 50% stenosis in one or more major coronary arteries on angiography or computerised tomography (CT) performed within the preceding year (from enrolment visit) or myocardial infarction (type I, II) during the preceding year.	<input checked="" type="radio"/>	<input type="radio"/>

Exclusion Criteria	Yes	No
Hospitalisation for acute coronary syndrome, myocardial infarction, stroke, coronary revascularisation or acute heart failure within the preceding month (30 days). These subjects can be enrolled after a one-month stabilisation period, which begins from the time of the event.	<input type="radio"/>	<input checked="" type="radio"/>
Subjects with NYHA class III-IV heart failure i.e. marked limitation in activity due to symptoms, comfortable only at rest.	<input type="radio"/>	<input checked="" type="radio"/>
Uncontrolled arrhythmias such as ventricular tachycardias.	<input type="radio"/>	<input checked="" type="radio"/>
Subjects undergoing dialysis due to severe renal disease.	<input type="radio"/>	<input checked="" type="radio"/>
Diseases that severely disable exercising (per investigator's judgement), such as rheumatoid arthritis, neurological or orthopaedic diseases.	<input type="radio"/>	<input checked="" type="radio"/>
Known aplastic or haemolytic anaemia or other severe anaemia.	<input type="radio"/>	<input checked="" type="radio"/>
Concomitant non-coronary disease, such as malignancy that limits life expectancy to less than three years.	<input type="radio"/>	<input checked="" type="radio"/>
Concurrent participation in another interventional study.	<input type="radio"/>	<input checked="" type="radio"/>
Subjects not able and/or willing to attend all scheduled visits and comply with all study procedures and use a smartphone application.	<input type="radio"/>	<input checked="" type="radio"/>

The subject is eligible to participate in the study
Yes

CoroPredict Score and Risk Category

- Based on the laboratory data, the system will calculate the CoroPredict Score for a subject
- In visit Enrolment V1: the system will determine the subject's risk category based on the calculated CoroPredict Score

- Risk category = low and medium risk

⇒ Allocate Treatment
(Usual Care)

- Risk category = high risk
⇒ Randomise Treatment
(Usual Care or PPP
- Personalised Prevention Programme)

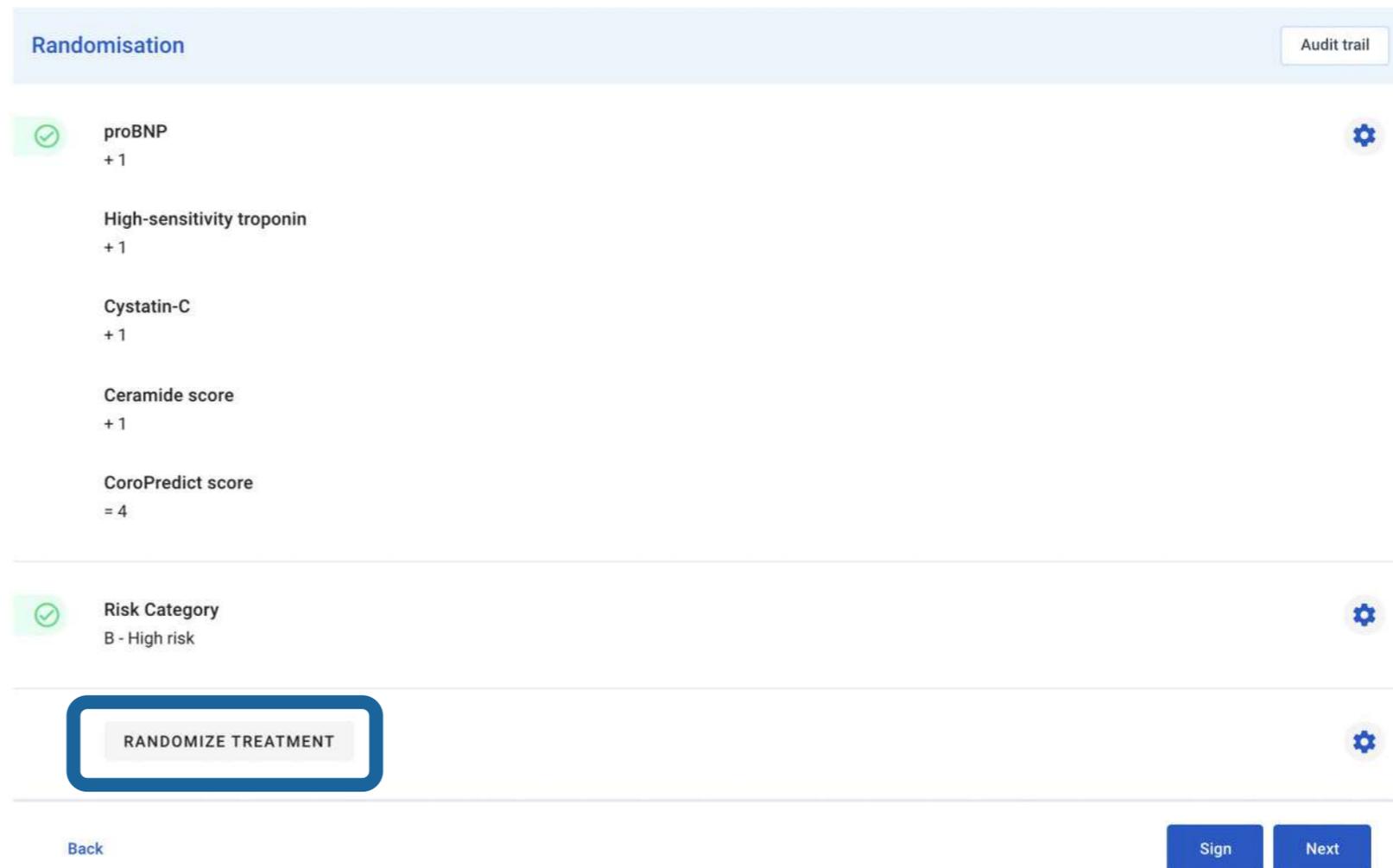
The screenshot displays the CoroPrevention web interface for a subject. The top navigation bar includes the site name 'CoroPrevention', a breadcrumb 'Subjects / coro-001001-006 / View', and user information: 'Working in: Country: Finland, Site: Helsinki University Hospital' and 'Logged in as: Renneboog Liesbeth (Investigator)'. The main content area is titled 'Randomisation' and shows a list of laboratory results with their scores and a 'Risk Category' of 'B - High risk'. A 'RANDOMIZE TREATMENT' button is visible at the bottom of the results section.

Parameter	Score
proBNP	+1
High-sensitivity troponin	+1
Cystatin-C	+1
Ceramide score	+1
CoroPredict score	= 4
Risk Category	B - High risk

Randomise Treatment

- Study Nurses and Investigators can randomise a subject if:
 - The subject is eligible
 - The system has determined the risk category as “high risk” based on the CoroPredict Score

- Navigate to Randomisation form in Enrolment V1
- Click Randomise Treatment



Randomisation Audit trail

- ✓ proBNP +1
- High-sensitivity troponin +1
- Cystatin-C +1
- Ceramide score +1
- CoroPredict score = 4

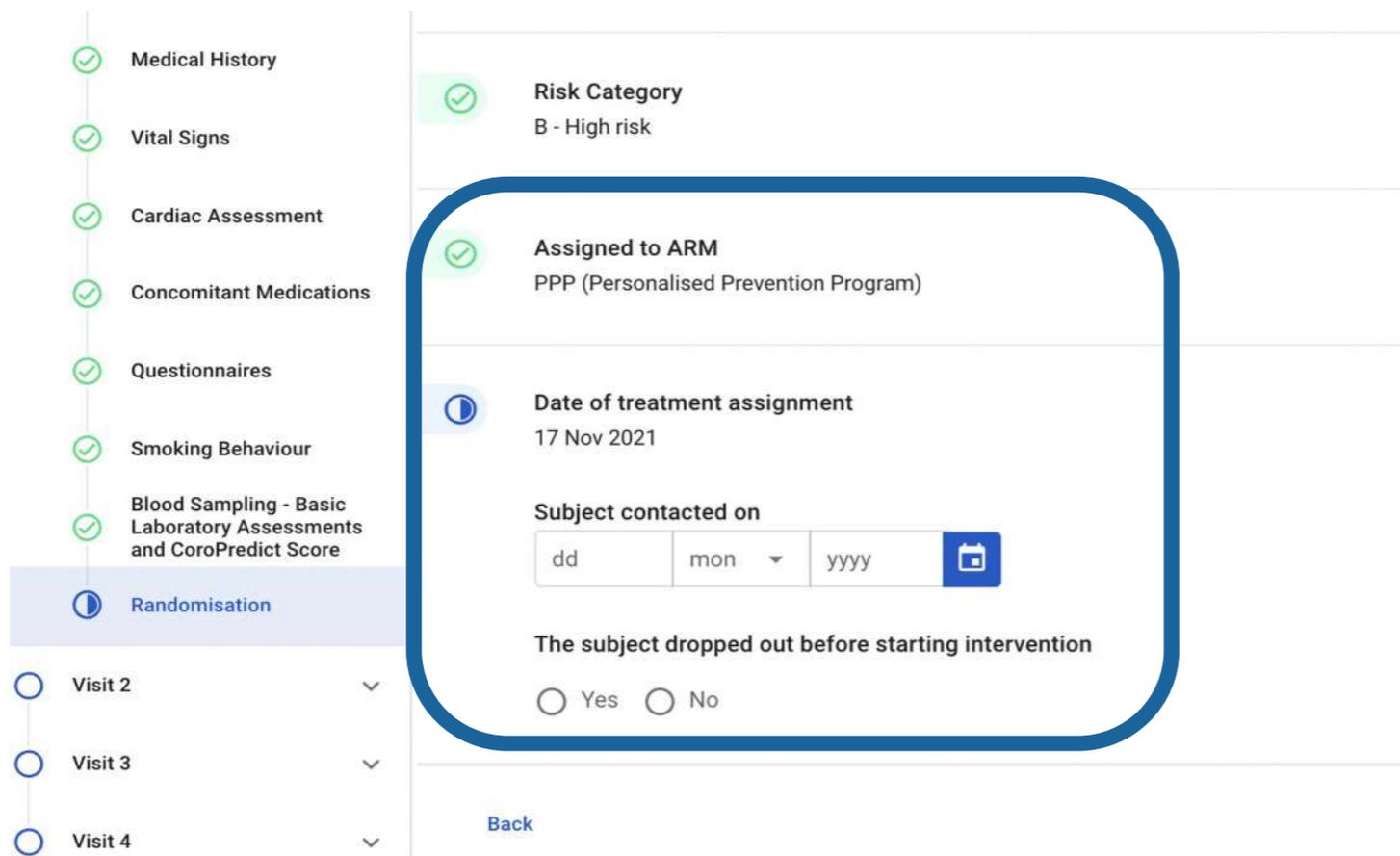
- ✓ Risk Category B - High risk

RANDOMIZE TREATMENT

Back Sign Next

Randomise Treatment (2)

- The system will randomly assign the subject to one of the arms - the arm is displayed in field “Assigned to ARM”:
 - Usual Care (UC)
 - PPP (Personalised Prevention Programme)
- Fields “Date of treatment assignment”, “Subject contacted on” and “The subject dropped out before starting intervention” appear



Medical History

Vital Signs

Cardiac Assessment

Concomitant Medications

Questionnaires

Smoking Behaviour

Blood Sampling - Basic Laboratory Assessments and CoroPredict Score

Randomisation

Visit 2

Visit 3

Visit 4

Risk Category
B - High risk

Assigned to ARM
PPP (Personalised Prevention Program)

Date of treatment assignment
17 Nov 2021

Subject contacted on
dd mon yyyy

The subject dropped out before starting intervention
 Yes No

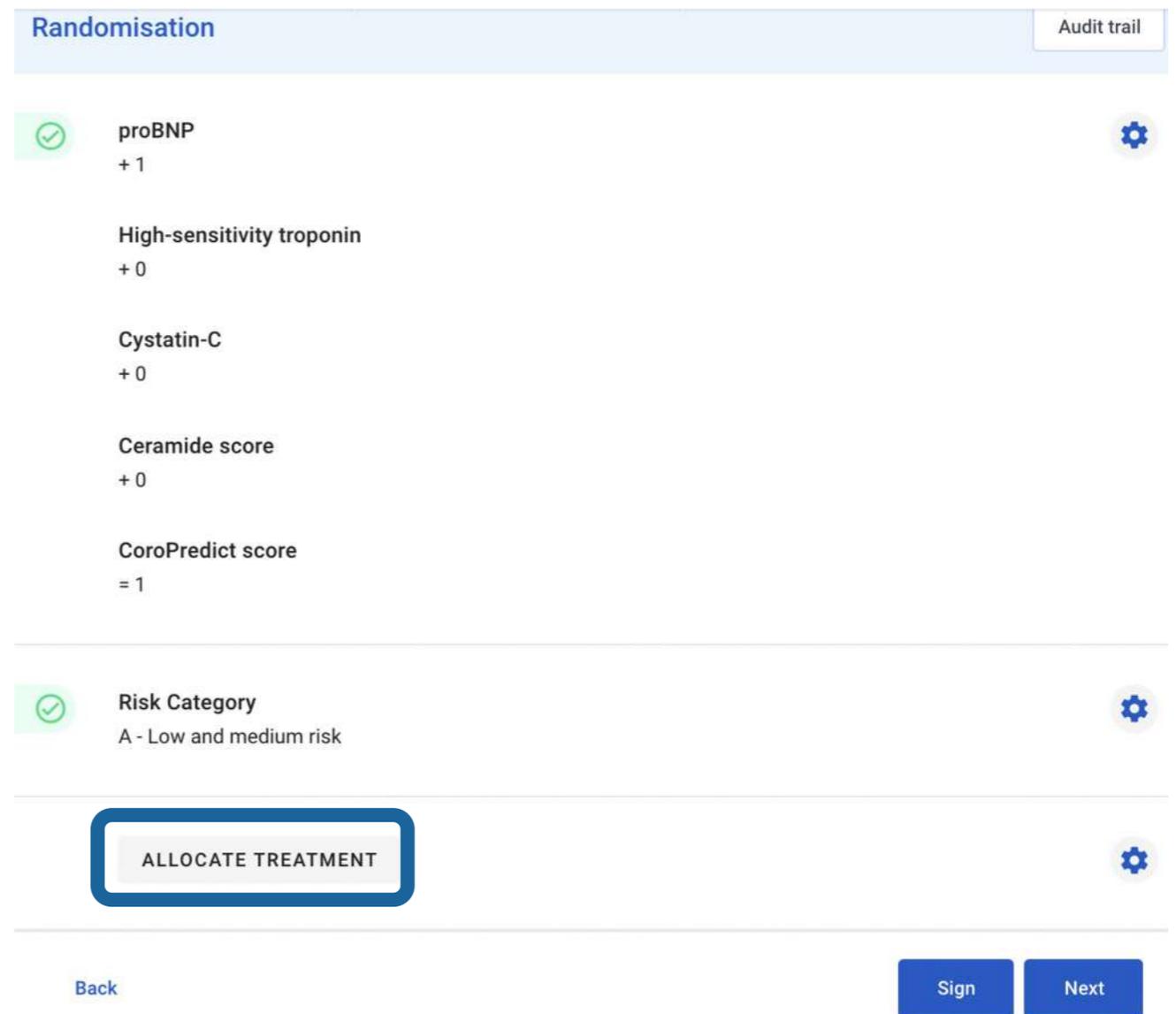
Back

“Subject contacted on” and “The subject dropped out before starting intervention” should be completed by the site after informing the subject on the treatment.



Allocate Treatment

- Study Nurses and Investigators can allocate treatment to a subject if:
 - The subject is eligible
 - The system has determined the risk category as “low or medium risk” based on the CoroPredict Score
- Navigate to Randomisation form in Enrolment V1
- Click Allocate Treatment



Randomisation Audit trail

✓ proBNP +1 ⚙️

High-sensitivity troponin +0

Cystatin-C +0

Ceramide score +0

CoroPredict score = 1

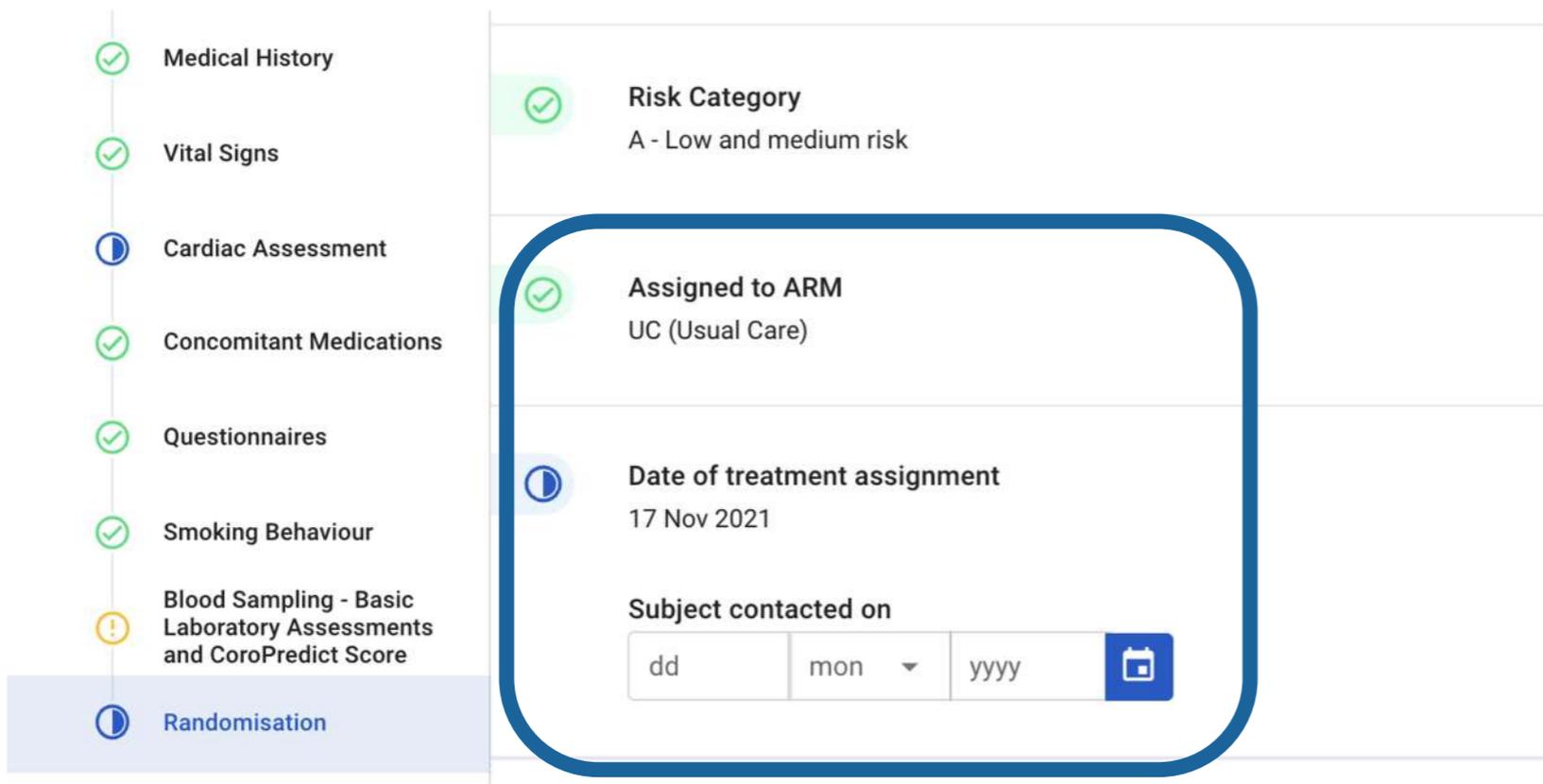
✓ Risk Category A - Low and medium risk ⚙️

ALLOCATE TREATMENT ⚙️

Back Sign Next

Allocate Treatment (2)

- The system will assign the subject to the treatment arm UC (Usual Care)
- Fields “Date of treatment assignment” and “Subject contacted on” appear



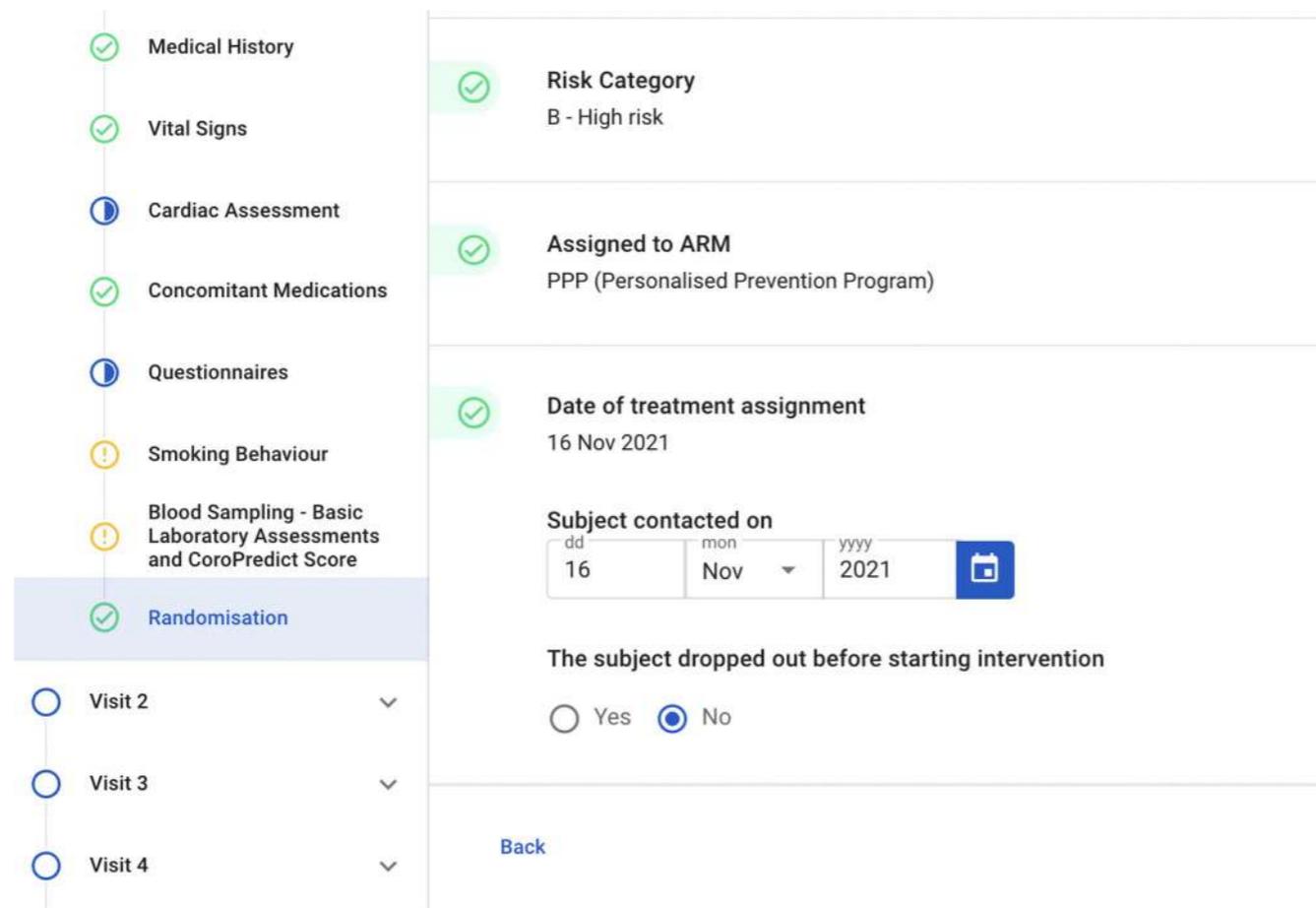
The screenshot displays a web interface for patient management. On the left is a vertical checklist with the following items: Medical History (checked), Vital Signs (checked), Cardiac Assessment (not checked), Concomitant Medications (checked), Questionnaires (checked), Smoking Behaviour (checked), Blood Sampling - Basic Laboratory Assessments and CoroPredict Score (warning icon), and Randomisation (not checked). The main content area shows a form with the following fields: Risk Category (checked, A - Low and medium risk), Assigned to ARM (checked, UC (Usual Care)), Date of treatment assignment (not checked, 17 Nov 2021), and Subject contacted on (not checked, with a date picker showing dd, mon, yyyy). A blue rounded rectangle highlights the 'Assigned to ARM' and 'Date of treatment assignment' fields.

“Subject contacted on” should be completed by the site after informing the subject on the treatment.



Randomise / Allocate Treatment

- After successful randomisation / treatment allocation, the action button disappears
- Randomisation / treatment allocation are irreversible
- The assigned arm will remain unchanged, even if the risk group would be recalculated



Medical History

Vital Signs

Cardiac Assessment

Concomitant Medications

Questionnaires

Smoking Behaviour

Blood Sampling - Basic Laboratory Assessments and CoroPredict Score

Randomisation

Visit 2

Visit 3

Visit 4

Risk Category
B - High risk

Assigned to ARM
PPP (Personalised Prevention Program)

Date of treatment assignment
16 Nov 2021

Subject contacted on
dd: 16, mon: Nov, yyyy: 2021

The subject dropped out before starting intervention
 Yes No

[Back](#)



Randomise / Allocate Treatment - Errors

- In case the action was unsuccessful, the system will display an error message

Error	Details
Randomise / Allocate Treatment button is not available	Ensure the eligibility and laboratory data is available for the subject in the Enrolment V1 visit. The button will only appear for eligible subjects for which the system could calculate the risk group.
“The subject has not been randomised as the randomisation cap for the trial has been reached”	The maximum number of randomised subjects within the trial has been reached or the maximum number of subjects randomised to a specific arm has been reached. Randomisation is no longer allowed.
“The subject has not been randomised as the randomisation cap for the country has been reached”	The maximum number of randomised subjects within the country has been reached or the maximum number of subjects randomised to a specific arm has been reached. Randomisation is no longer allowed.
“The subject has not been randomised as the randomisation list is not available in the system”	The randomisation list is not available in the system for the site.
“The subject has not been randomised as all randomisation records are already in use”	The randomisation list for the site is full.



SAE / SADE Form



CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

SAE

- Adverse Events can be reported on the Adverse Events Log form
- Indicate whether the AE is considered serious
- In case Yes, a banner appears
- Click the SAE/SADE form hyperlink to access the form

CoroPrevention | Subjects / coro-001001-003 / View

Working in: Country: Finland Site: Helsinki University Hospital | Logged in as: Renneboog Liesbeth (Investigator)

Yes No

Date of resolution
 dd: 18 | mon: Nov | yyyy: 2021

Relationship to PPP intervention
 Related
 Possibly related
 Unrelated

Serious Adverse Event
 Yes No

Please fill out the SAE/SADE form!

Outcome
 Recovered
 Continuing with intervention
 Continuing without intervention
 Death



SADE

- Device deficiencies can be reported on the Device Deficiencies form
- Indicate whether any deficiency with SADE potential was experienced
- In case Yes, a banner appears
- Click the SAE/SADE form hyperlink to access the form

Device Deficiencies Audit trail

Did the subject experience any device deficiencies since last visit? i ⚙️

Yes No

Please specify the device deficiency

example

Did the subject experience any device deficiencies with SADE potential? ⚙️

Yes No

⚠️ Please fill out the SAE/SADE form

[Back](#) [Sign](#) [Next](#)



SAE / SADE Form - Completing

- Can be completed electronically
- Or can be printed out and completed on paper

sae-sade-form 1 / 4 100%


CoroPrevention
PERSONALISED PREVENTION FOR CORONARY HEART DISEASE

Protocol ID: CPP-2020-1	Protocol version:	Country:	Site:
Sponsor: Tampere University Medicine and Health Technology Arvo Ylpön katu 6 FIN-33520 Tampere		Subject ID:	Arm: <input type="radio"/> PPP <input type="radio"/> UC Subject gender: <input type="radio"/> Male <input type="radio"/> Female
		Subject age at date of onset:	AE number (from AE log). If DD leave empty:

Type of Report

Choose relevant option: Initial Report Follow Up Report Final Report

Initial Report: The first time you are reporting this event this may be a signed or unsigned report. At this time point either, not all details are available, the form is unsigned, or the event is marked as ongoing. Follow up or Final report should be provided in 30 days.

Follow Up Report: Follow up information to an initial report is provided in this report. The event may still be marked as ongoing or resolved. If ongoing, further reports must be submitted until the resolution of the event.

Final Report: When all follow up information is available for this Serious Adverse Event and the outcome for the event has been completed.

Date of Report: / / (dd/mm/yyyy)

Date of Onset: / / (dd/mm/yyyy)

Date of Report: Date you are completing this report (Initial, Follow-up or Final).

Date of Onset: Date of onset of the event reported. If a full date is not known either on the first or subsequent reports then UK/Month/Year should be completed.

! The form contains multiple pages



SAE / SADE Form - Sending

- After completing the form, provide a signature
- Send the form to the specified email address

Reporting Person

Supply full details as indicated of person reporting the event. Please ensure the contact email address is complete.

Principal Investigator / Delegated Medically Qualified Person	
Name:	Role:
Tel:	Email:
Signature:	

Principal Investigator / Delegated Medically Qualified Person:

Please note the person signing this form must be either the Principal Investigator or a medically qualified individual (sub investigator) as agreed by the Sponsor to undertake this role. The person must be named and delegated the duty on the delegation of authority log.

Sending the Form

PLEASE SEND THIS FORM TO: CoroPrevention@tuni.fi

In case a receive acknowledge is not sent back in two days, please re-send.



Import Data from Tool Suite



CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Import Data from Tool Suite

- For subjects randomised to the PPP arm only
- Import Data button is available for following forms from Visit 2 onwards:
 - Vital Signs
 - Clinical Assessment
 - Smoking Behaviour
 - 6 Minute Walking Test
- It is possible to enter the data manually as well

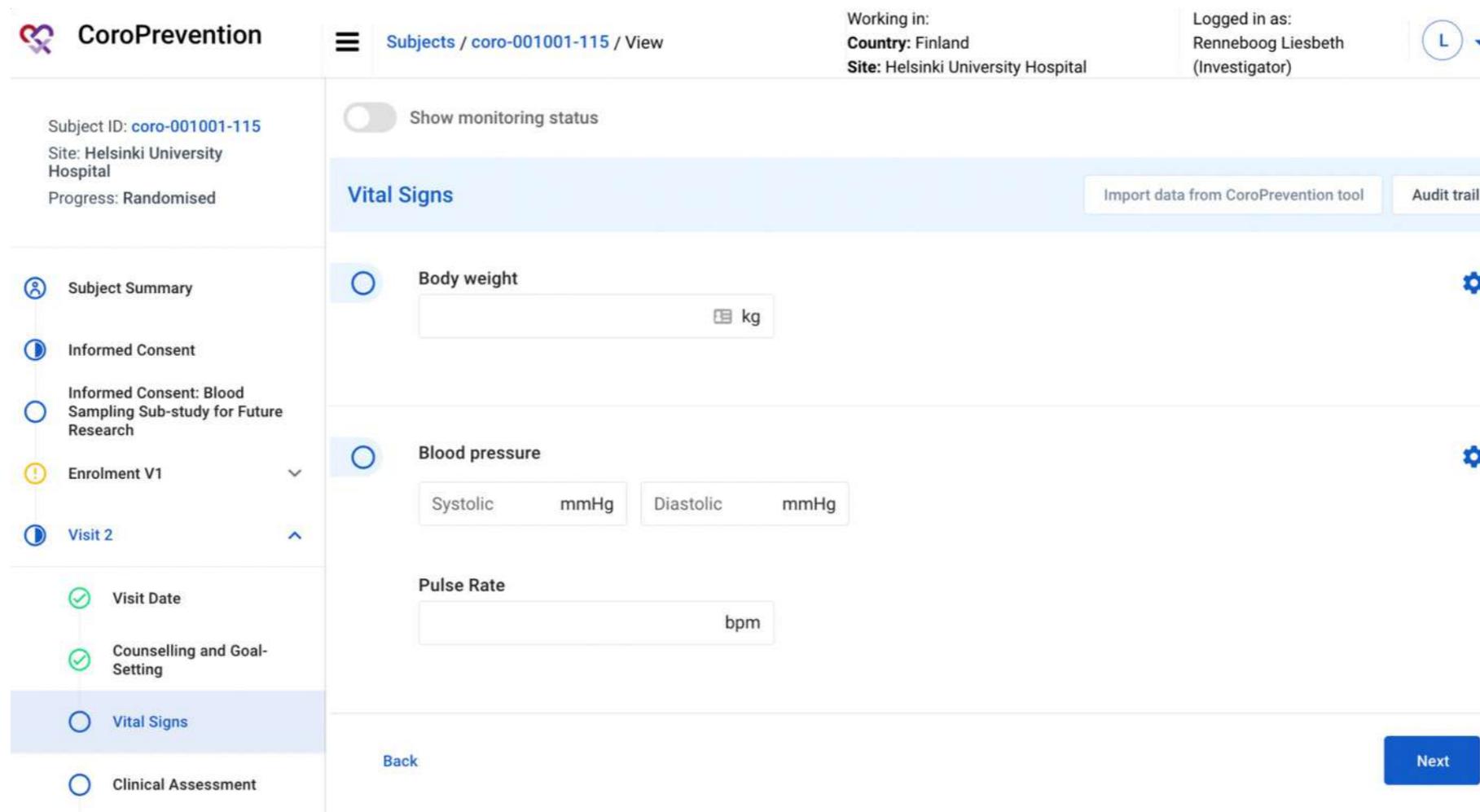


CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Import Data from Tool Suite (2)

- To import data from the Tool Suite, click “Import data from CoroPrevention tool”



The screenshot shows the CoroPrevention web application interface. At the top, the user is logged in as Renneboog Liesbeth (Investigator) at Helsinki University Hospital. The main content area is titled 'Vital Signs' and contains several input fields: 'Body weight' (kg), 'Blood pressure' (Systolic and Diastolic mmHg), and 'Pulse Rate' (bpm). A button labeled 'Import data from CoroPrevention tool' is located in the top right of the Vital Signs section. The sidebar on the left shows a navigation menu with options like 'Subject Summary', 'Informed Consent', 'Enrolment V1', 'Visit 2', 'Vital Signs', and 'Clinical Assessment'. The 'Vital Signs' option is currently selected and highlighted.

Import Data from Tool Suite (3)

- A pop-up window will appear that will show:
 - Question - the field on the eCRF
 - Current value - the current value of the question on the eCRF in EDC
 - New value - the value that can be imported from the CoroPrevention tool
- Review the data and click “Import” to import the new values into the eCRF
- Or click “Cancel” to return to the eCRF without importing the data

Import data for Vital Signs - coro-001001-115 ×		
Question	Current value	New value
Systolic		133
Diastolic		111
Body weight		88.5
Pulse Rate		101

CANCEL IMPORT

Import Data from Tool Suite (4)

- After clicking “Import”, the system will automatically populate the listed fields with the new values:

Subjects / coro-001001-115 / View

Working in:
Country: Finland
Site: Helsinki University Hospital

Logged in as:
Renneboog Liesbeth
(Investigator)

Show monitoring status

Vital Signs

Import data from CoroPrevention tool

Audit trail

Body weight

88.5 kg

Blood pressure

Systolic: 133 mmHg

Diastolic: 111 mmHg

Pulse Rate

101 bpm

Back

Sign Next



Import Data from Tool Suite - Data Updates

- The most efficient way to make updates to already imported data is by:
 - Making the necessary updates to the data in the Tool Suite
 - Then navigating to the subject in eCRF and to the applicable eCRF
 - And clicking “Import data from CoroPrevention tool” and then “Import”
- The pop-up window will show the updated value(s) in the “New value” column:



Question	Current value	New value
Systolic	133	133
Diastolic	111	111
Body weight	88.5	85.5
Pulse Rate	101	99

CANCEL IMPORT

Import Data from Tool Suite - No Data

- In case the data was not yet provided in the Tool Suite, the pop-up window will be empty
- You won't be able to import the data:
 - Either complete the data in the eCRF manually or
 - Add the data in the Tool Suite and then import the data for the subject's eCRF in EDC

Import data for Clinical Assessment - coro-001001-087



Question	Current value	New value
----------	---------------	-----------

No data available

CANCEL

IMPORT

Generate ePRO Link



Generate ePRO Link

Generate a QR code or hyperlink to provide to the subject to complete their questionnaires on their mobile device or on the tablet by:

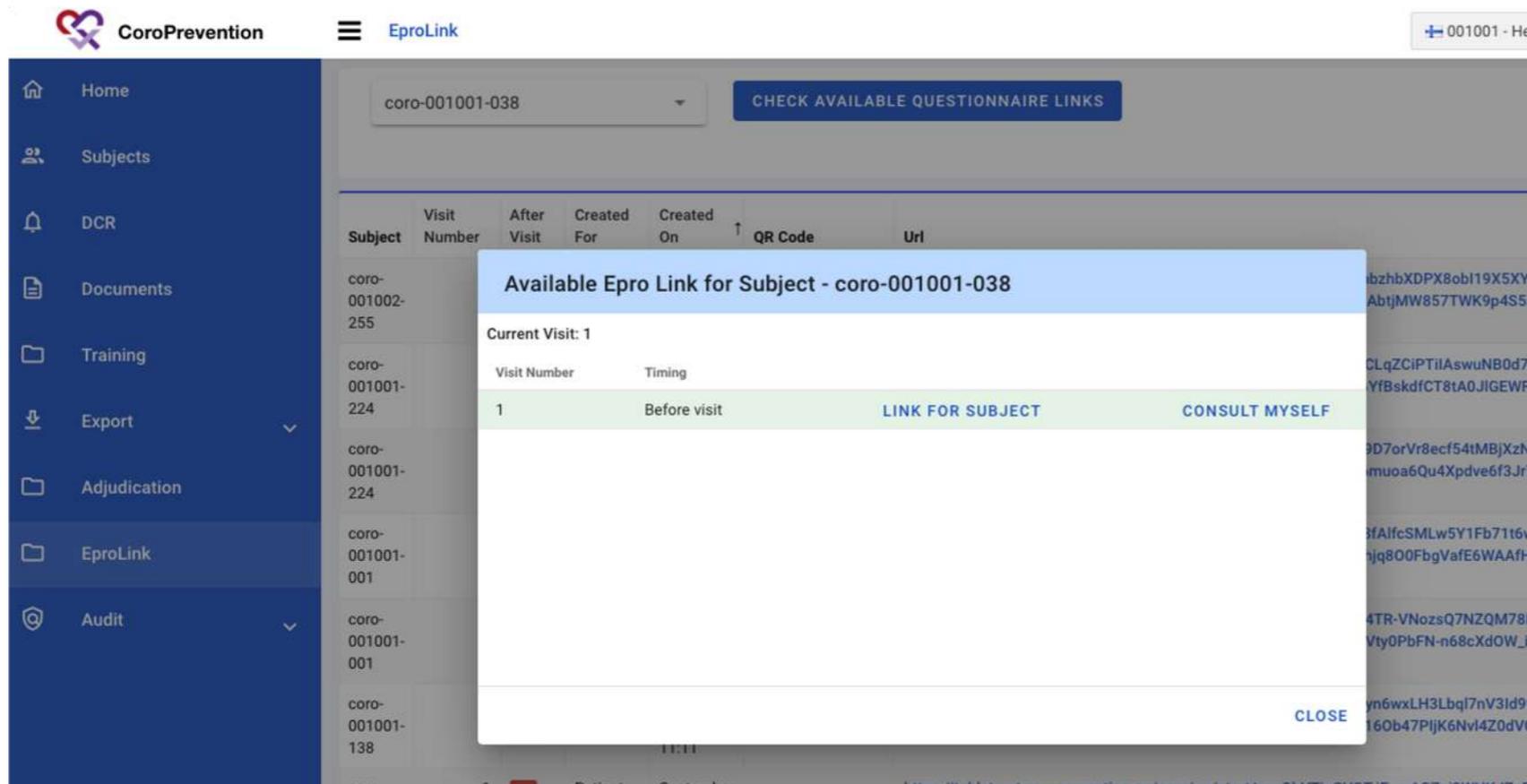
- Navigating to the “Epro Link” tab in the navigation bar
- Selecting a subject from the dropdown menu
- Clicking “Check available questionnaire links”

The screenshot shows the 'EproLink' interface in the CoroPrevention system. A navigation sidebar on the left includes Home, Subjects, DCR, Documents, Training, Export, Adjudication, EproLink (selected), and Audit. The main content area features a dropdown menu with 'coro-001001-038' selected and a 'CHECK AVAILABLE QUESTIONNAIRE LINKS' button. Below this is a table with the following data:

Subject	Visit Number	After Visit	Created For	Created On	QR Code	Url
coro-001002-255	1	no	Patient	October 14, 2022 08:38	Show QR Code	https://tablet-uat.coroprevention.eu/session/start/_uiPz1k4Jx8HmbzhbXDPX8ob119X5XyBBB2T01GWtHKiiXBRjqd8pK-5xt0JLIFW5su939T2xgUafW1iPtMtCabtjMW857TWK9p4S5
coro-001001-224	1	no	Study Nurse	September 16, 2022 05:50	Show QR Code	https://tablet-uat.coroprevention.eu/session/start/j9TVdENgCgG1CLqZCIPtIiAswuNB0d7huK9EGExpUWE8W6FofuCYTsyLU9K_FITcwKCz8bg_1ZfPym8SiQGYfBskdfCT8tA0JIGEWf
coro-001001-224	1	no	Patient	September 13, 2022 11:28	Show QR Code	https://tablet-uat.coroprevention.eu/session/start/T7NTuv-Q3eCK9D7orVr8ecf54tMBjXzfm1U04uNL7CA4LQzNi9i6TXrYnwibrT2KWkuPWw1vSlcNcLEBIAY6muoa6Qu4Xpdve6f3Jr
coro-001001-001	1	no	Patient	September 12, 2022 13:36	Show QR Code	https://tablet-uat.coroprevention.eu/session/start/cesHIFhGcmz83fAlfcSMLw5Y1Fb71t6jKnXsvsFUL0fUBt_oqzKx5rBEK53t2gCAV4_xOR0z5PMTup0HYXbhjq800FbgVafE6WAAf
coro-001001-001	1	no	Patient	September 12, 2022 12:16	Show QR Code	https://tablet-uat.coroprevention.eu/session/start/J7XrtsTSgU2_u4TR-VNozsQ7NZQM78Q2Tpt0p6eWfXCTkBRMGU8ir_GJDWmEtY2ZXQeqFTggZ4k5nNlpAVty0PbFN-n68cXdOW_

Generate ePRO Link (2)

- The system will display the available ePRO links for the subject in a pop-up window:
 - Link for the subject to complete their ePRO's
 - Link for the study nurse/investigator to consult the subject's ePRO's



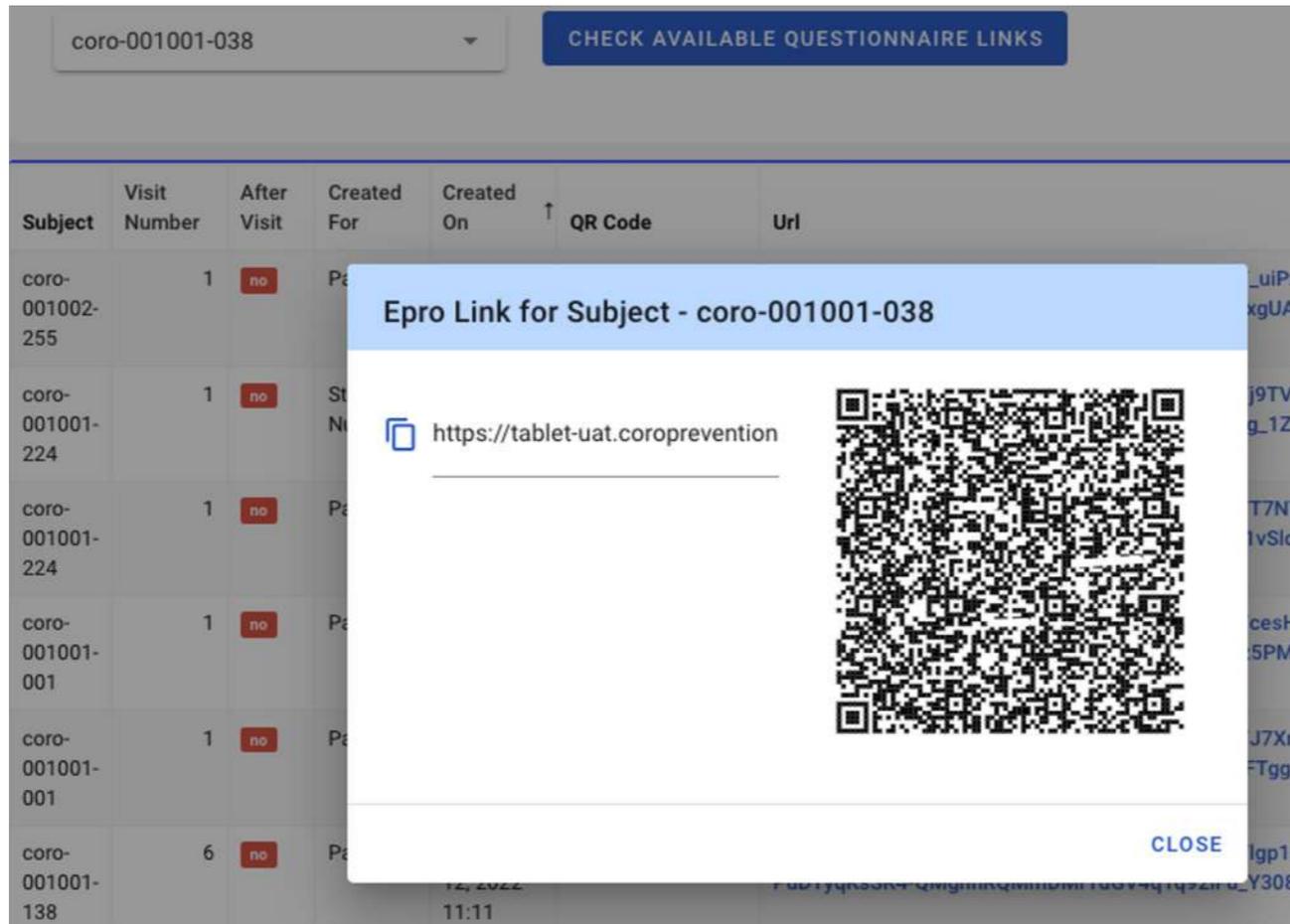
The screenshot shows the CoroPrevention EproLink interface. A sidebar on the left contains navigation options: Home, Subjects, DCR, Documents, Training, Export, Adjudication, EproLink, and Audit. The main area displays a table of subjects with columns for Subject, Visit Number, After Visit, Created For, Created On, QR Code, and Url. A pop-up window titled "Available Epro Link for Subject - coro-001001-038" is overlaid on the table. The pop-up shows "Current Visit: 1" and a table with columns for Visit Number and Timing. The first row shows "1" for Visit Number and "Before visit" for Timing. Below this, there are two buttons: "LINK FOR SUBJECT" and "CONSULT MYSELF". A "CLOSE" button is located at the bottom right of the pop-up.

Subject	Visit Number	After Visit	Created For	Created On	QR Code	Url
coro-001002-255						bzhhbXDPX8obI19X5XYV AbtjMW857TWK9p4S5s
coro-001001-224						CLqZCIPtIiAswuNB0d7n YfBskdfCT8tA0JIGEWfC
coro-001001-224						9D7orVr8ecf54tMBjXzNH muoa6Qu4Xpdve6f3Jr7f
coro-001001-001						fAlfcSMLw5Y1Fb71t6w hjq800FbgVafE6WAAfHc
coro-001001-001						4TR-VN0zsQ7NZQM78K Vty0PbFN-n68cXdOW_IQ
coro-001001-138						yn6wxLH3LbqI7nV3Id9tv 160b47PijK6Nvi4Z0dVG



Generate ePRO Link (3)

- A pop-up window appears containing the URL and showing the QR code
- The subject can scan the QR code with their mobile device
- The URL can be copied by clicking the  icon to e.g. send via email



The screenshot shows a web application interface with a table of subjects and a pop-up window. The table has columns for Subject, Visit Number, After Visit, Created For, Created On, QR Code, and Url. A pop-up window titled "Epro Link for Subject - coro-001001-038" displays a URL and a QR code. A "CLOSE" button is visible in the bottom right corner of the pop-up.

Subject	Visit Number	After Visit	Created For	Created On	QR Code	Url
coro-001001-038						
coro-001002-255	1	no	Pa			
coro-001001-224	1	no	St			
coro-001001-224	1	no	Pa			
coro-001001-001	1	no	Pa			
coro-001001-001	1	no	Pa			
coro-001001-138	6	no	Pa			



CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

List of ePRO Links

- Every time an ePRO link is generated, the request is added to the list
- You can use the filters to search for specific requests
- Click “Show QR code” to see the QR code
- The URL is displayed in column “Url”

EproLink 001001 - Helsinki University Hospital

Subject CHECK AVAILABLE QUESTIONNAIRE LINKS Filters 1

Subject Filter Reset

[Advanced filters](#)

Subject	Visit Number	After Visit	Created For	Created On	QR Code	Url
coro-001001-038	1	no	Patient	November 2, 2022 08:35	Show QR Code	https://tablet-uat.coroprevention.eu/session/start/5AV5EjBqm7Ak5BKT0EYBMBaHv70nRcuZmCfwi4-dRSY1YP27G6pvl8yGZFMaIdT-M_eX6oN5Dg5g80QGh7SV0c4w-AP8ID06UITWUVks-Rrb3VgktqqEQ7VYaBpVv2fCxtDJPY2iMyawnRBnke9XK7WStFA1jyQ0A0RnWf2oMezt
coro-001001-038	1	no	Patient	June 15, 2022 07:32	Show QR Code	https://tablet-uat.coroprevention.eu/session/start/mtyrSJRvmmzDJmSqqc9dKhXTxc0edj6xOERFarTYJUUMM7I0ctgJU047v_UVVhYmW5FVxRXN16rl2c1XuX629X0QM7cnf5xwQ6C6Yu9UzC0p6E9b94S4UUJe_EVmrjfdDS4dvqHboQrXr08wTq_i8aVi8BmPeCNWTG7E6-ruN-pk
coro-001001-038	1	no	Study Nurse	June 4, 2022 03:07	Show QR Code	https://tablet-uat.coroprevention.eu/session/start/miRvblONLwIX8SSd08x76-B0SgBr2OdlxiJax0tHrSRmuY08alzDyS7EjynGJ5wplNoCBku4gR_12xPAsS97BoOIKN8M5fOXx6vcrz5_lzJvNd0Q40wTvsoowN0jYxBv2bck7ozTh_cjdEYjBBMLYo1TdSXbzzwUo6iGXAMqI2e3GP49BVKnR3zmdnV1YVFBmau4/fi



Protocol Deviations



CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Protocol Deviations - Log

Any protocol deviations (PDs) on subject are to be collected on the Protocol Deviations Log.

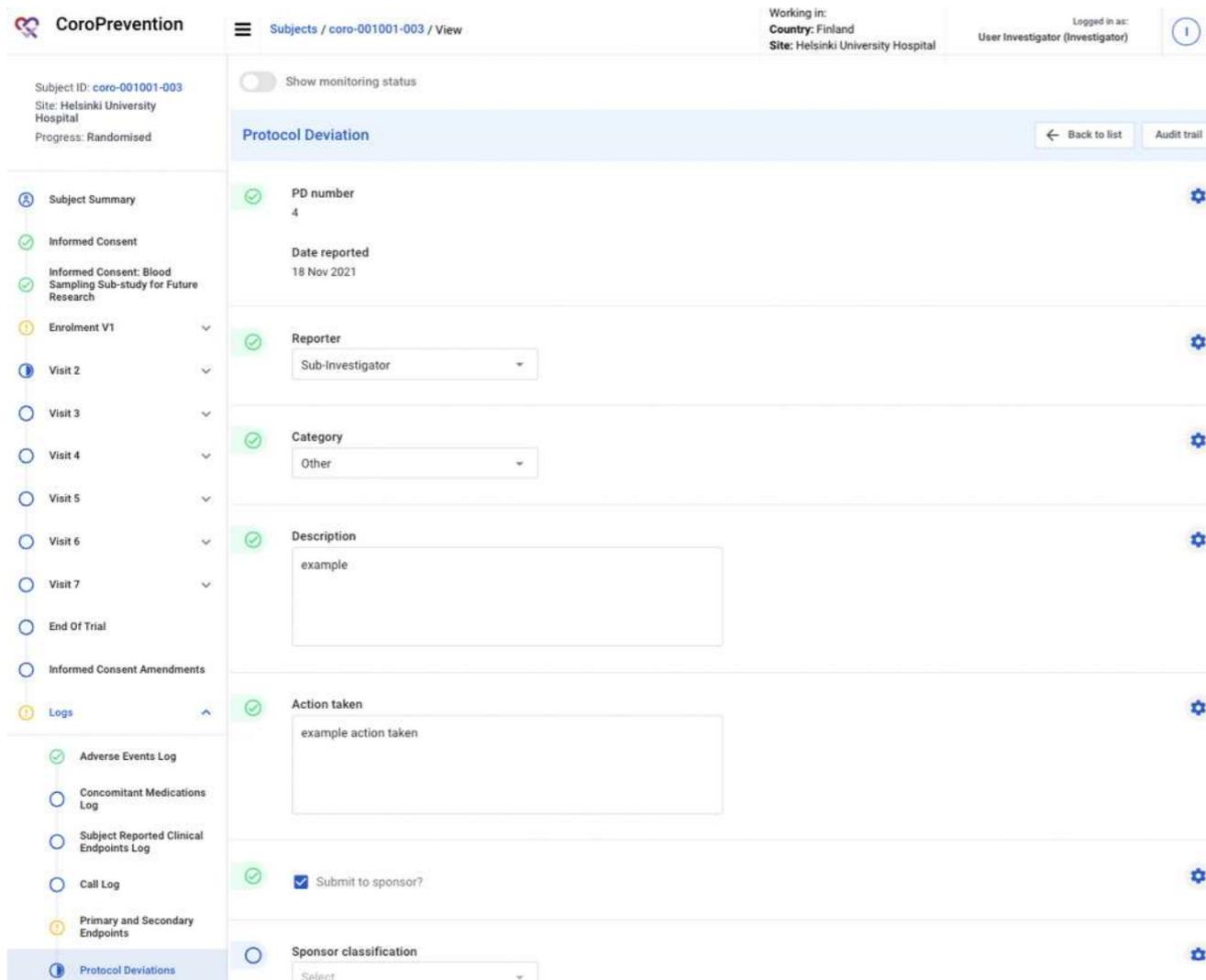
PDs can be manually created or automatically generated based on predefined conditions. Automatic PDs have “System” as reporter.

Protocol Deviations												Audit trail
Nr	Date Reported	Reporter	Category	Description	Action taken	Created by	Date last modified by site	Sponsor classification	Discarded by sponsor?	Closed by sponsor?	Status	Actions
1	16 Nov 2021	System	Informed Consent	Clinical study procedures conducted prior to signing initial informed consent		System	16 Nov 2021	Important	Yes	Yes		
2	16 Nov 2021	System	Inclusion/Exclusion	Non-eligible subject enrolled		System	16 Nov 2021	Important	No	No		
3	18 Nov 2021	Sub-Investigator	Discontinuation	example	EoT form completed	investigator	18 Nov 2021	Non-Important	No	Yes		
4	18 Nov 2021	Sub-Investigator	Other	example	example action taken	investigator	18 Nov 2021	Important				

Rows per page: 10 1-4 of 4

Protocol Deviations - Create

- Click Add Protocol Deviation to create a new PD for a subject
- The PD number and Date reported will be set by the system
- Complete fields Reporter, Category, Description, Action Taken
- If the PD is ready to be submitted, tick Submit to sponsor?



CoroPrevention

Subjects / coro-001001-003 / View

Working in:
Country: Finland
Site: Helsinki University Hospital

Logged in as:
User Investigator (Investigator)

Subject ID: coro-001001-003
Site: Helsinki University Hospital
Progress: Randomised

Show monitoring status

Protocol Deviation

← Back to list Audit trail

PD number: 4

Date reported: 18 Nov 2021

Reporter: Sub-Investigator

Category: Other

Description: example

Action taken: example action taken

Submit to sponsor?

Sponsor classification: Select

Ticking Submit to sponsor? triggers an email notification to the sponsor.

The sponsor will complete the other fields of this PD record.

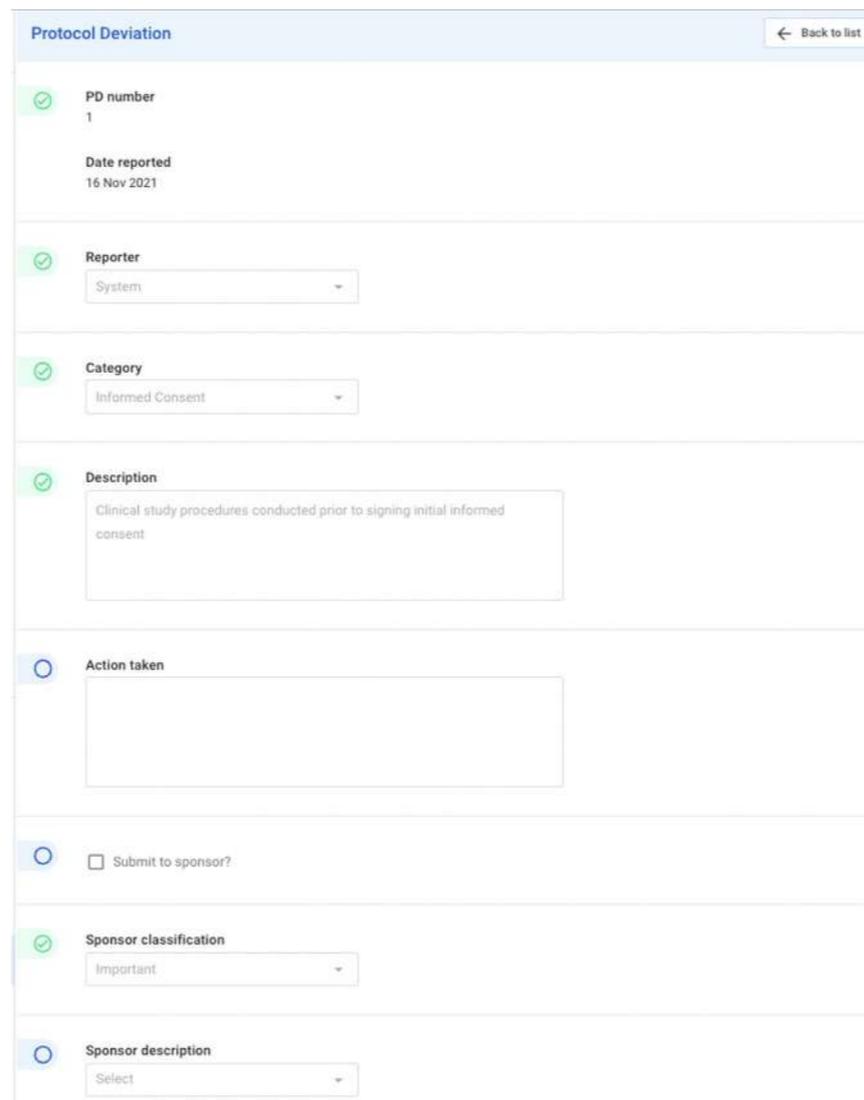


CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Protocol Deviations - Automatic PDs

- Created by the system based on predefined data conditions
- Fields PD number, Date reported, Reporter, Category, Description and Sponsor Classification are automatically set
- Complete Action taken and if the PD is ready to be submitted, tick Submit to sponsor?



Ticking Submit to sponsor? triggers an email notification to the sponsor.

The sponsor will complete the other fields of this PD record.



CoroPrevention

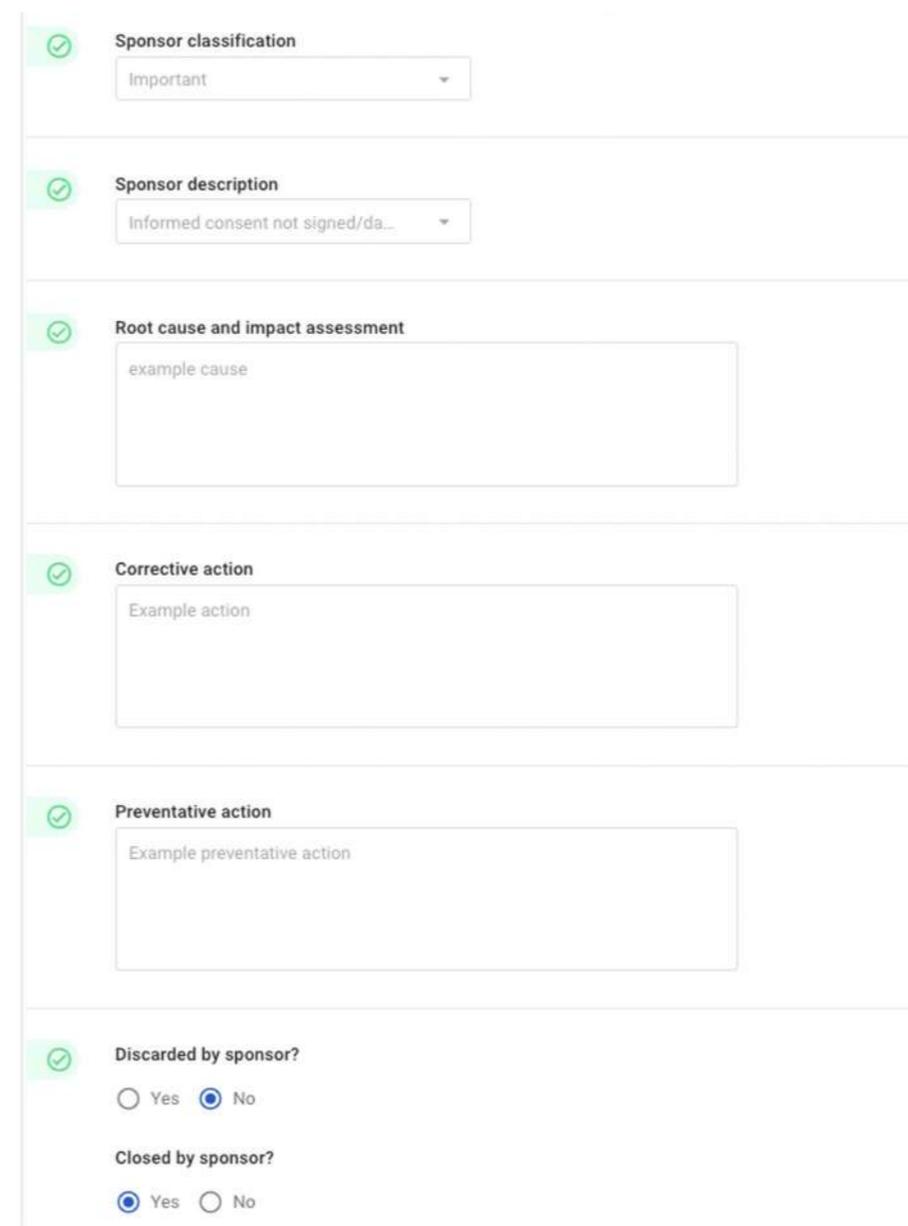
PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Protocol Deviations - Sponsor Evaluation

- A PD that is submitted will be evaluated by the sponsor
- The evaluation is final when fields Discarded by sponsor? and Closed by sponsor? have been completed
- A closed PD can no longer be edited

If Sponsor classification = Important, additional sponsor fields will be displayed:

- Sponsor description
- Root cause and impact assessment
- Corrective action
- Preventative action



The screenshot shows a form with the following sections:

- Sponsor classification:** A dropdown menu with "Important" selected.
- Sponsor description:** A dropdown menu with "Informed consent not signed/da..." selected.
- Root cause and impact assessment:** A text input field containing "example cause".
- Corrective action:** A text input field containing "Example action".
- Preventative action:** A text input field containing "Example preventative action".
- Discarded by sponsor?:** Radio buttons for "Yes" and "No", with "No" selected.
- Closed by sponsor?:** Radio buttons for "Yes" and "No", with "Yes" selected.

Endpoint Collection



Endpoint Collection - General

The trial has two ways of collecting endpoint-related data:

- Subject Reported Clinical Endpoints:
 - Subject-reported MIs, HF events, unstable angina, stroke and coronary revascularisations (PCI and/or CABG)
 - Collected in Visit 6 and Visit 7 for high-risk UC subjects
 - Collected in Visit 2, 3, 4, 5, 6 and 7 for high-risk PPP subjects

- Primary and Secondary Endpoints:
 - Collected from national and local hospital registries up to 36 mo for all enrolled subjects
 - When not possible to collect from registries, collected directly from the subject or subject's relatives or health records
 - MIs, HF events, unstable angina, stroke, coronary revascularisations (PCI and/or CABG), CV death, all-cause mortality, incidence of DM2, CKD, PAD or hypertension (if new incidents since trial visits)

Endpoint Collection - Subject Reported Clinical Endpoints

In each applicable visit, indicate whether the Subject Reported Clinical Endpoints were collected as per protocol:

Show monitoring status

Subject Reported Clinical Endpoints Audit trail

Subject reported clinical endpoints since last visit? ⚙️

Yes No

[Back](#) [Next](#)



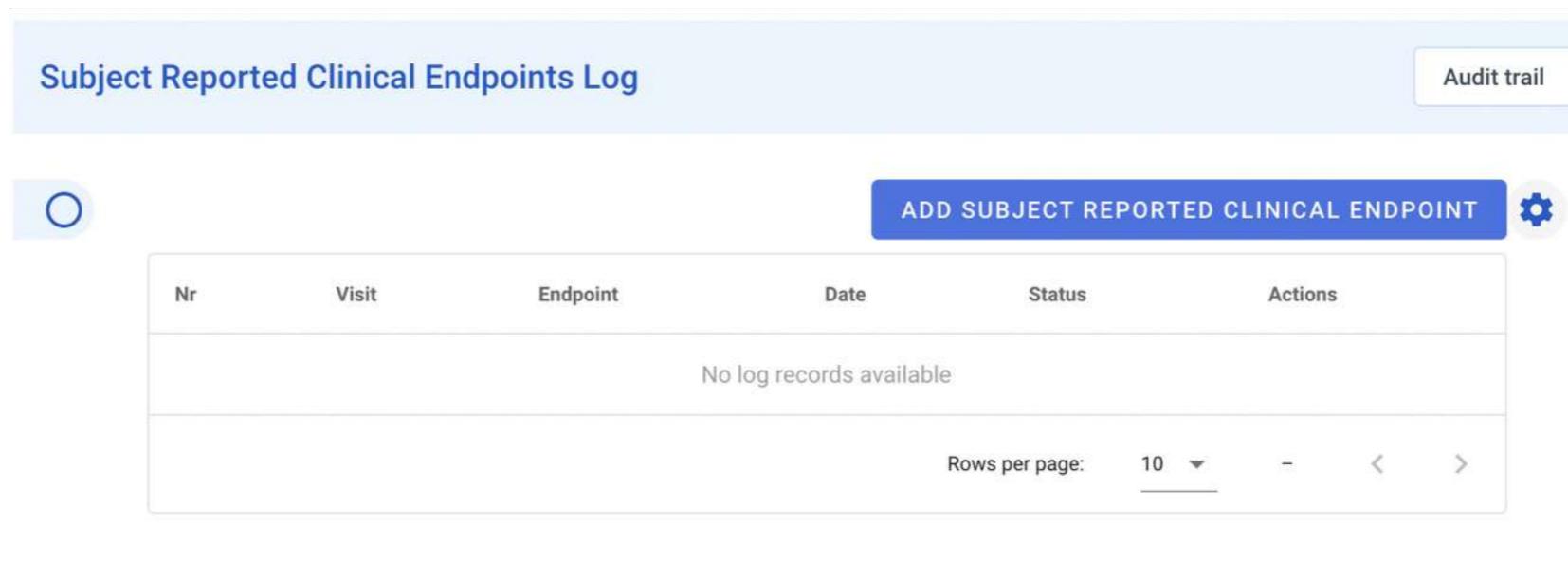
CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Endpoint Collection - Subject Reported Clinical Endpoints (2)

If subject reported clinical endpoints were collected in a visit:

- Browse to the “Subject Reported Clinical Endpoints Log” form in the “Logs” section
- Click “Add Subject Reported Clinical Endpoint” to enter the necessary information



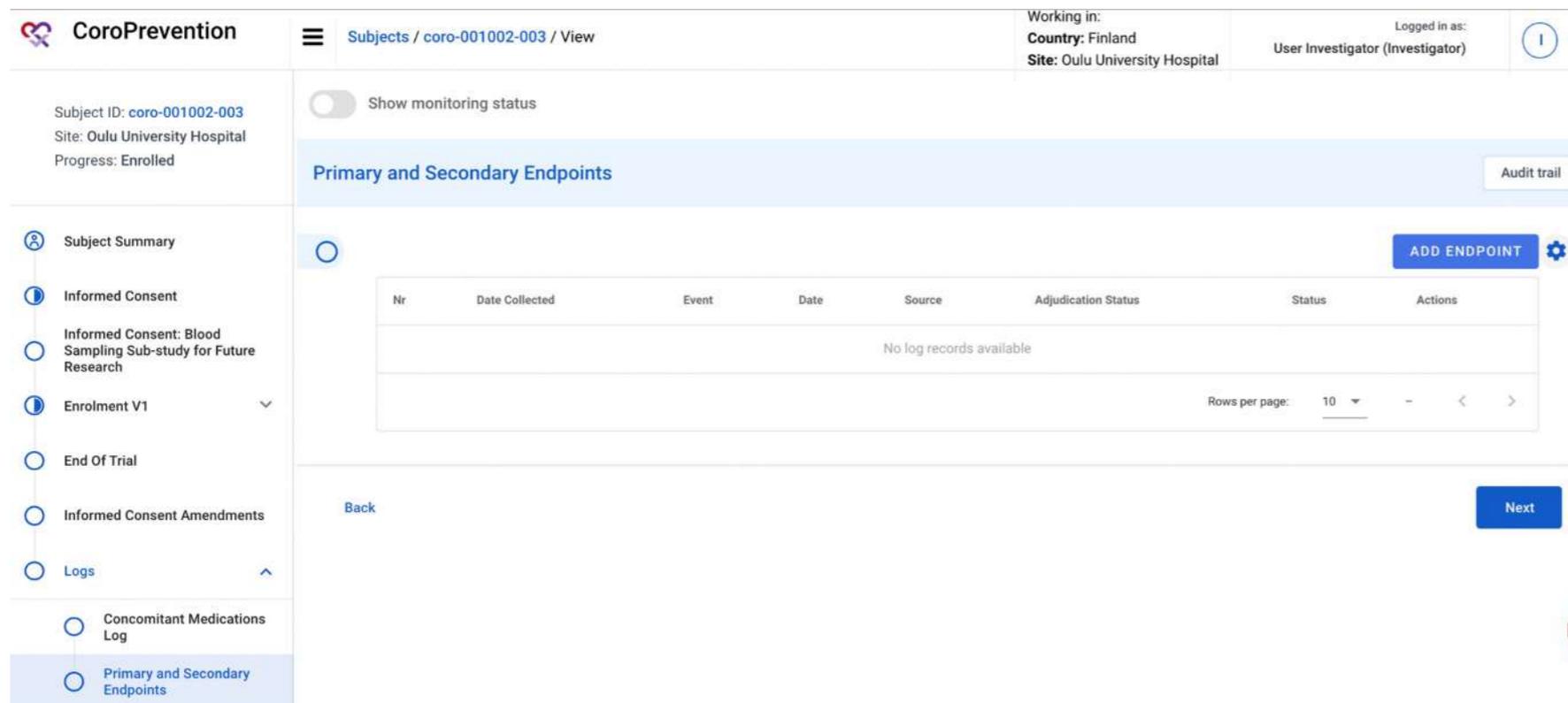
The screenshot shows the 'Subject Reported Clinical Endpoints Log' interface. At the top, there is a header bar with the title 'Subject Reported Clinical Endpoints Log' and an 'Audit trail' button. Below the header, there is a blue button labeled 'ADD SUBJECT REPORTED CLINICAL ENDPOINT' with a gear icon. A table with the following columns is displayed: 'Nr', 'Visit', 'Endpoint', 'Date', 'Status', and 'Actions'. The table is currently empty, with the text 'No log records available' centered in the body. At the bottom of the table, there is a pagination control showing 'Rows per page: 10' and navigation arrows.



Endpoint Collection - Primary and Secondary Endpoints

Primary and secondary endpoint data should be entered on the Primary and Secondary Endpoints form:

- Browse to the “Primary and Secondary Endpoints” form in the “Logs” section
- Click “Add Endpoint” to enter the necessary information



The screenshot displays the CoroPrevention web application interface. The top navigation bar includes the CoroPrevention logo, a menu icon, and the breadcrumb "Subjects / coro-001002-003 / View". It also shows the user's working location: "Country: Finland" and "Site: Oulu University Hospital", along with the logged-in user: "User Investigator (Investigator)".

The main content area is titled "Primary and Secondary Endpoints" and features a toggle for "Show monitoring status" (currently off) and an "Audit trail" button. Below this is a table with columns: "Nr", "Date Collected", "Event", "Date", "Source", "Adjudication Status", "Status", and "Actions". The table is currently empty, displaying "No log records available". A blue "ADD ENDPOINT" button with a gear icon is positioned above the table. At the bottom of the table area, there are "Back" and "Next" buttons.

The left sidebar contains a navigation menu with the following items: "Subject Summary", "Informed Consent", "Informed Consent: Blood Sampling Sub-study for Future Research", "Enrolment V1", "End Of Trial", "Informed Consent Amendments", "Logs", "Concomitant Medications Log", and "Primary and Secondary Endpoints" (which is highlighted).

