

CoroPrevention EDC - Training CRA

v1.0

Agenda

- Login
- Training
- Navigation
- Enter and Edit Data
- Reports



CoroPrevention
PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Agenda (2)

- Monitor Data
- Manage DCRs
- Forgot Password
- Reset 2FA
- CoroPrevention: Laboratory Data
- CoroPrevention: Protocol Deviations



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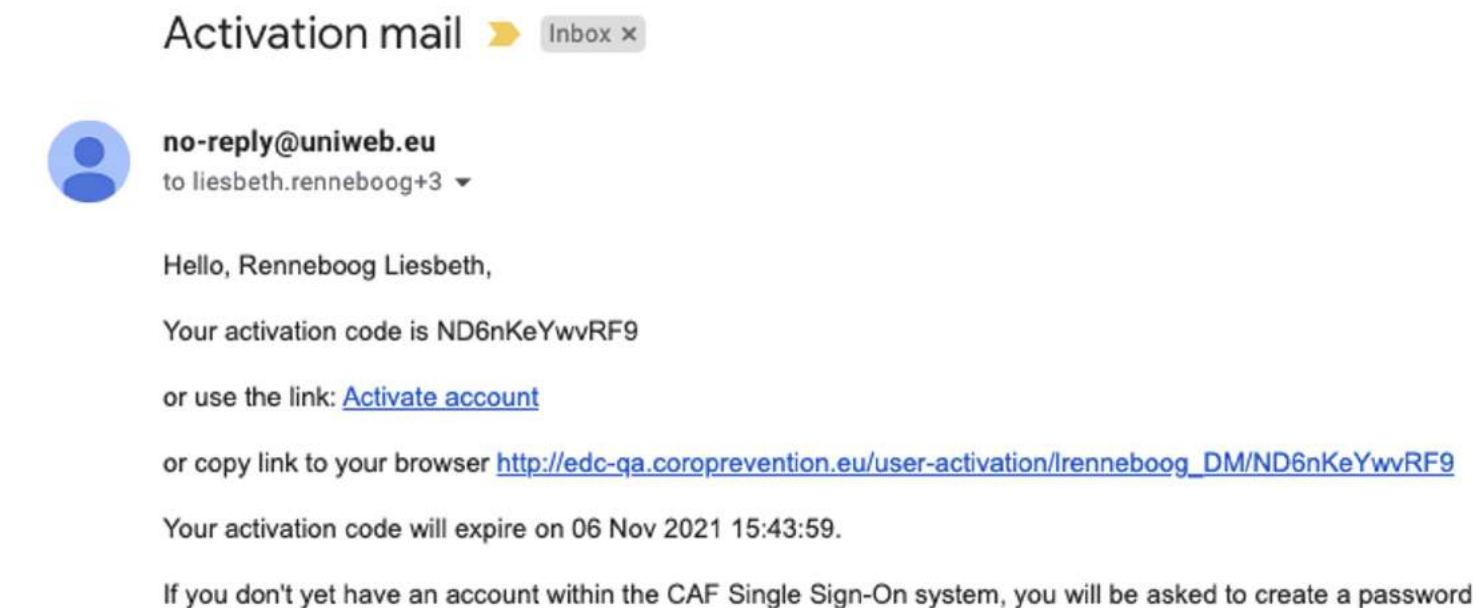
Login



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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



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

..... 

Set Password

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

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



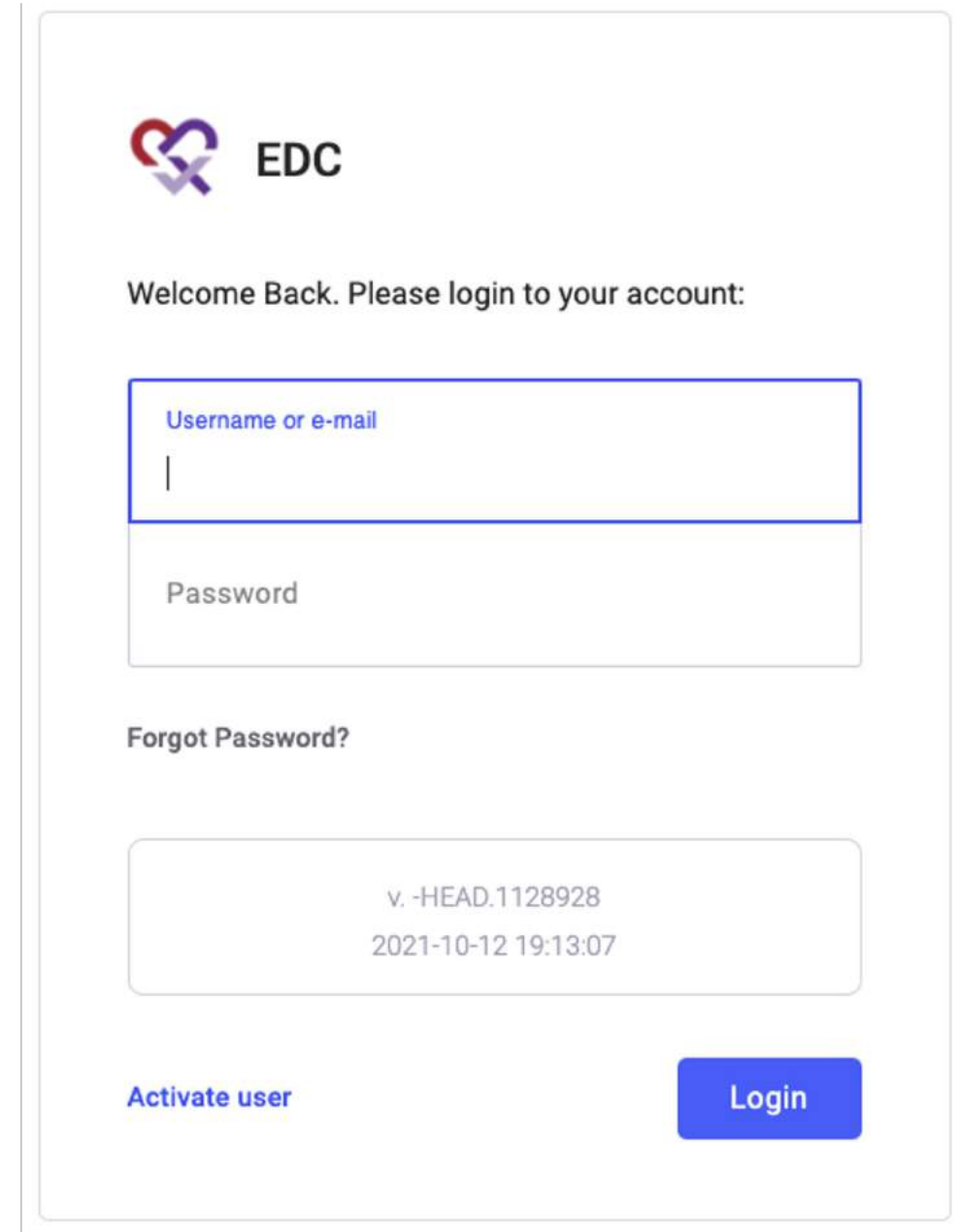
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Login - General

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 interlocking loops, one red and one purple. To the right of the logo is the text "EDC". Below the logo and text is the message "Welcome Back. Please login to your account:". Underneath this message are two input fields: the first is labeled "Username or e-mail" and the second is labeled "Password". Below the input fields is a link that says "Forgot Password?". At the bottom of the form area, there is a box containing the text "v. -HEAD.1128928" and "2021-10-12 19:13:07". At the very bottom of the page, there are two buttons: "Activate user" on the left and "Login" on the right. The "Login" button is blue with white text, while "Activate user" is a link in blue text.



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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

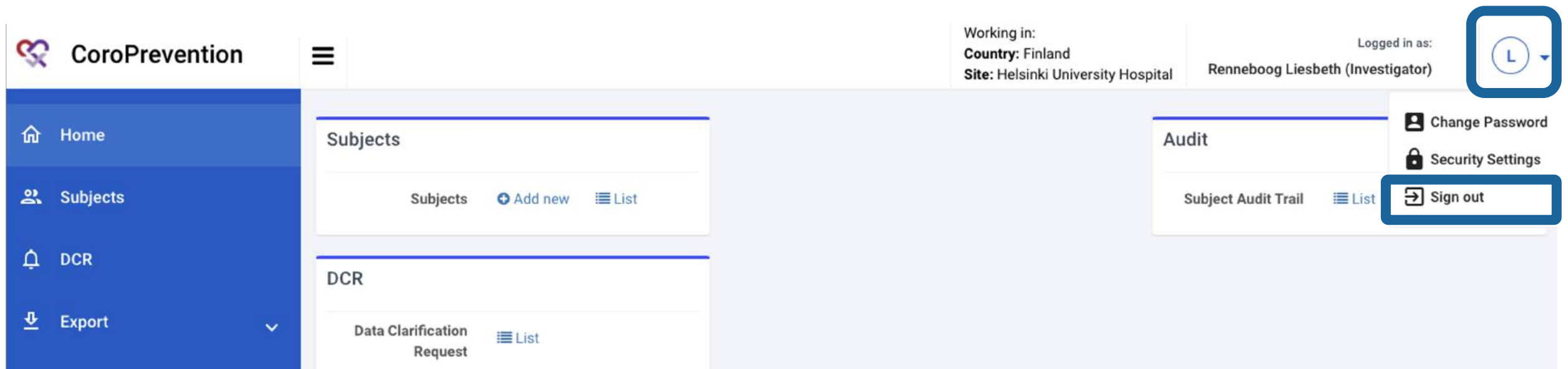
[Back to login](#)



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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 sidebar with navigation links: Home, Subjects, DCR, and Export. The main content area is divided into sections for Subjects and DCR. In the top right corner, there is a user profile section showing 'Working in: Country: Finland Site: Helsinki University Hospital' and 'Logged in as: Renneboog Liesbeth (Investigator)'. A dropdown menu is open next to the user profile, showing options: Change Password, Security Settings, and Sign out. The 'Sign out' button is highlighted with a red box.

Log out when stepping away from your computer.



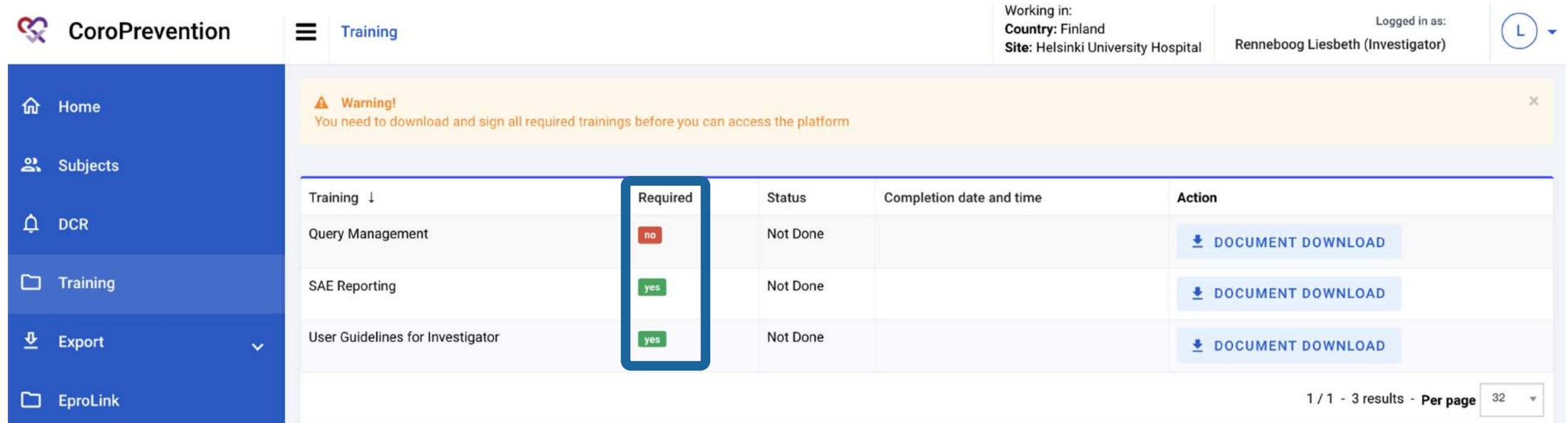
Training



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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



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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.



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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) L

[Home](#) [Subjects](#) [DCR](#) [Training](#) [Export](#) [EproLink](#)

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

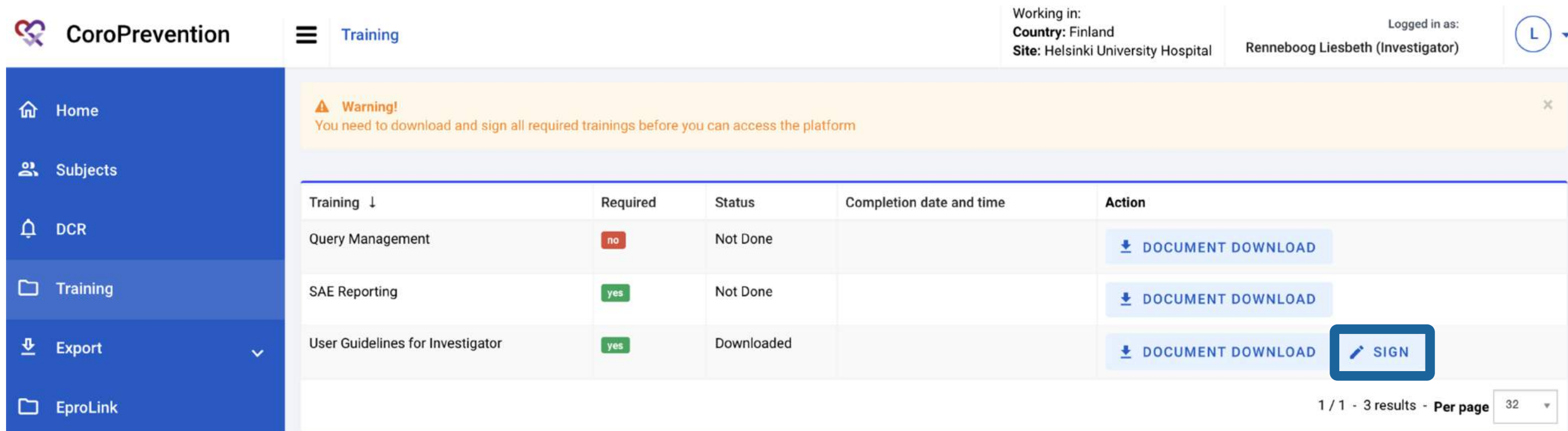
Training ↓	Required	Status	Completion date and time	Action
Query Management	no	Not Done		DOCUMENT DOWNLOAD
SAE Reporting	yes	Not Done		DOCUMENT DOWNLOAD
User Guidelines for Investigator	yes	Not Done		DOCUMENT DOWNLOAD

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 web interface. The top navigation bar includes the CoroPrevention logo, a hamburger menu, and the 'Training' tab. On the right, it displays 'Working in: Country: Finland, Site: Helsinki University Hospital' and 'Logged in as: Renneboog Liesbeth (Investigator)'. A blue sidebar on the left contains links for Home, Subjects, DCR, Training (selected), Export, and EproLink. A yellow warning banner at the top of the main content area states: 'Warning! You need to download and sign all required trainings before you can access the platform'. Below this is a table with training records:

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

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 32

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




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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)





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



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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

All my countries

Belgium

Finland

Germany

Greece

Italy

North Macedonia

Poland

Portugal

Sites

All my countries and sites

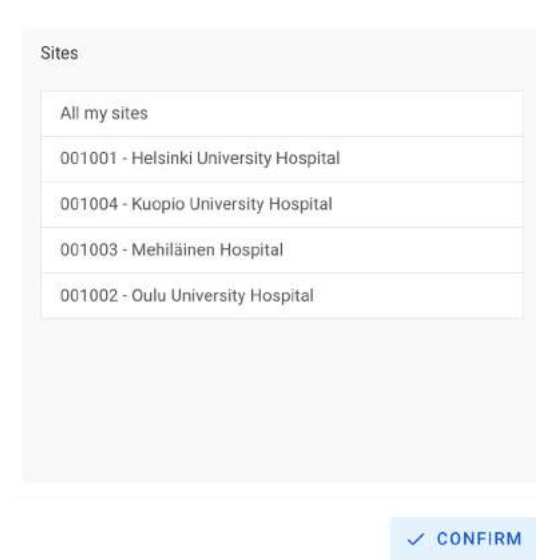
✓ CONFIRM

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

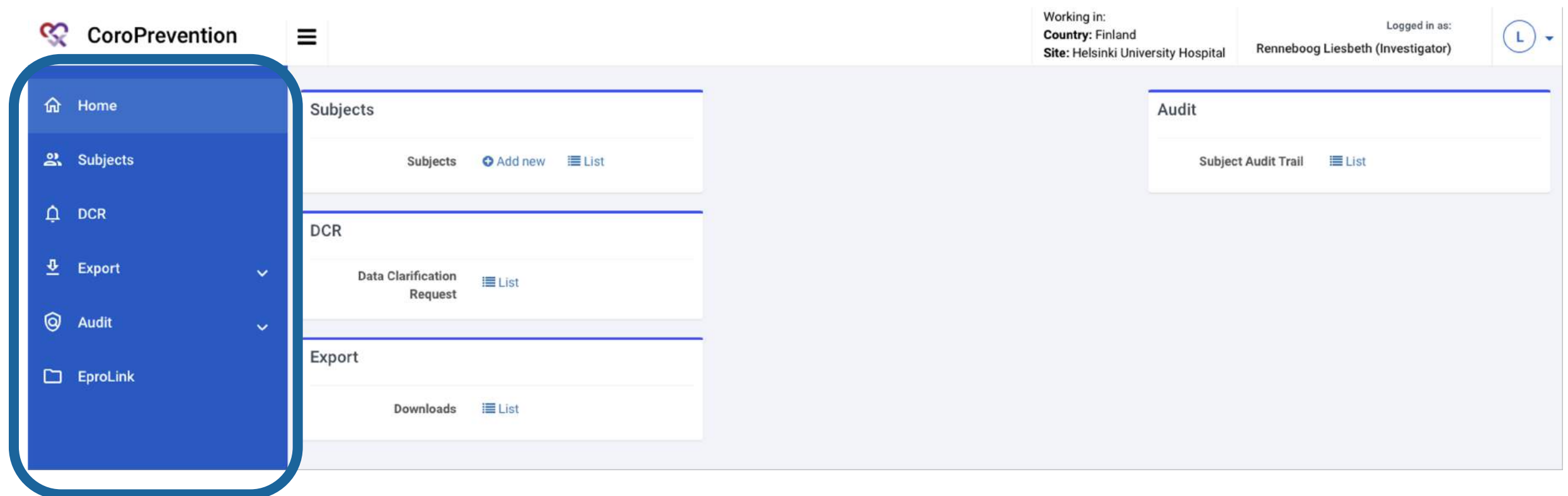
✓ CONFIRM



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Navigation - Bar

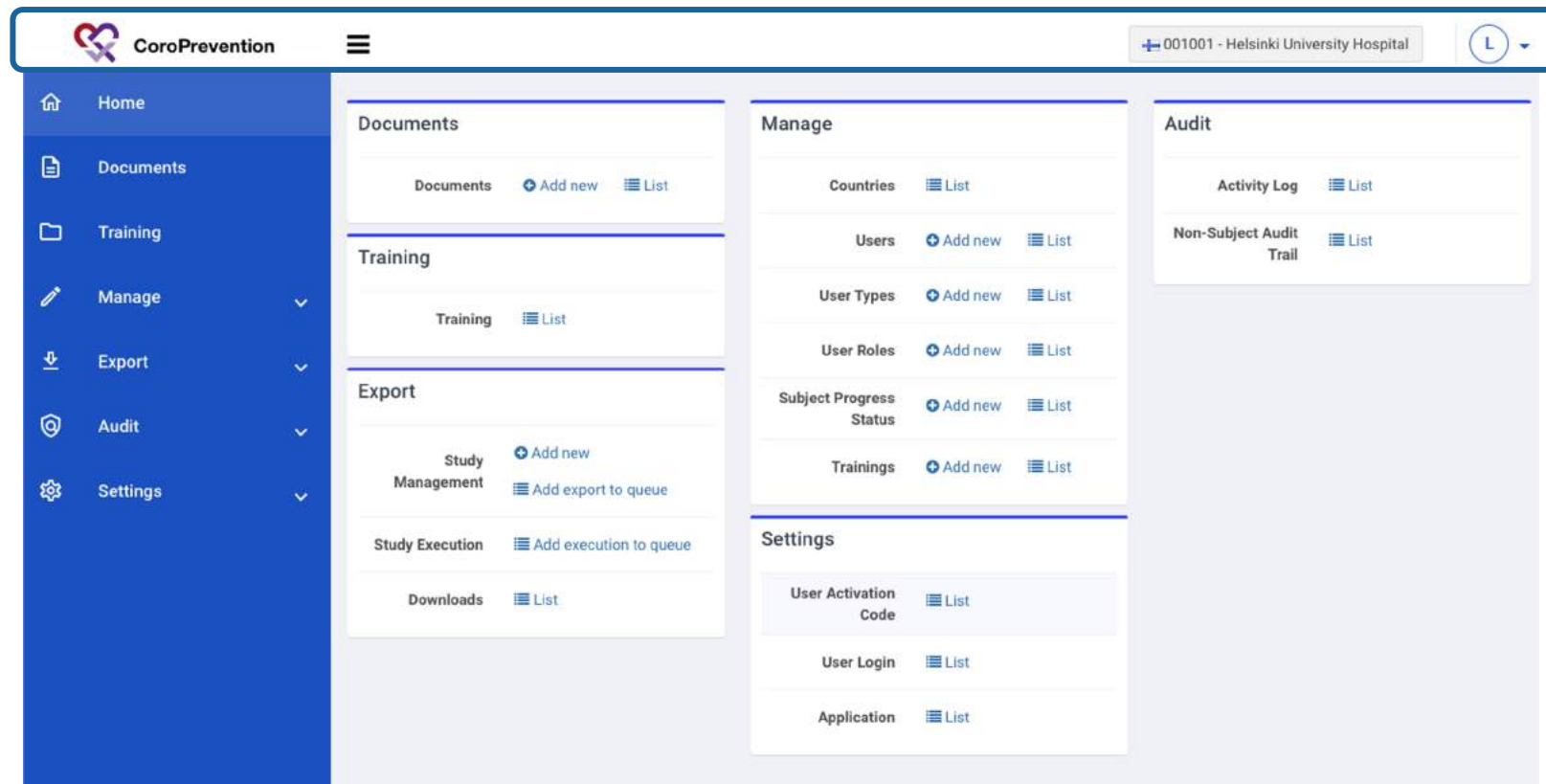
- Navigation bar contains links to the modules for which you have access
- “Home” takes you to the dashboard, listing actions applicable for your user type



Navigation - Access Details

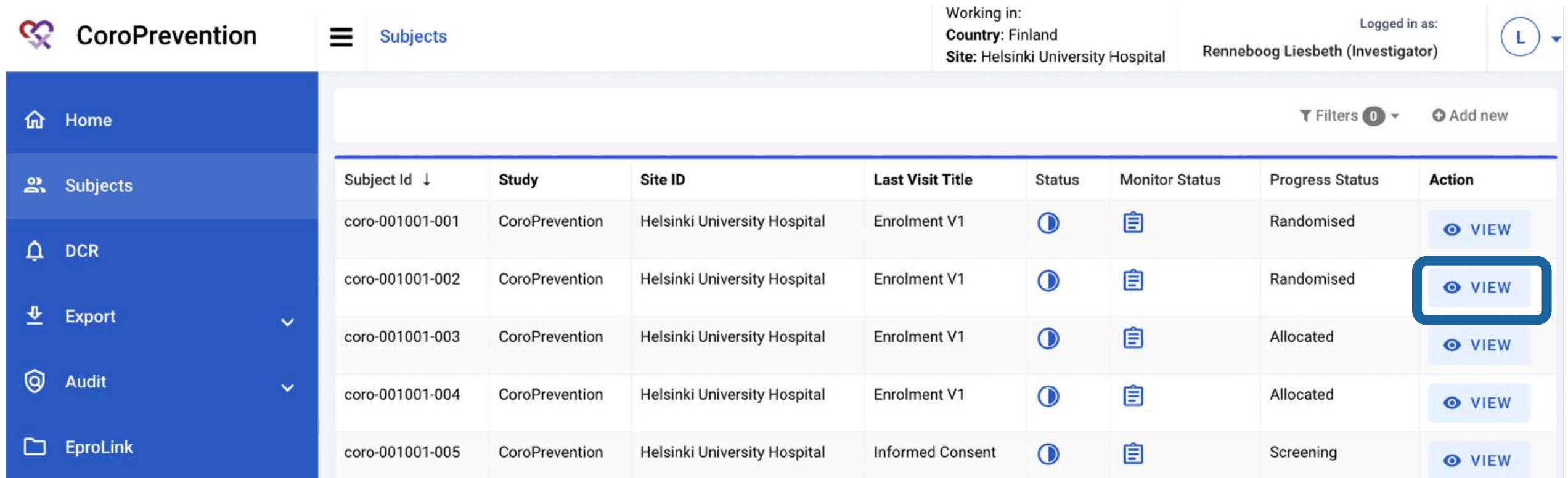
The upper bar - visible on each page within EDC - displays the following:

- 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:



The screenshot shows the CoroPrevention web application interface. The top navigation bar includes the CoroPrevention logo, a hamburger menu, and the 'Subjects' tab. The top right corner displays the user's working location (Country: Finland, Site: Helsinki University Hospital) and the logged-in user (Renneboog Liesbeth (Investigator)). The left sidebar contains navigation links for Home, Subjects, DCR, Export, Audit, and EproLink. The main content area displays a table of subjects, filtered by location. The table has columns for Subject ID, Study, Site ID, Last Visit Title, Status, Monitor Status, Progress Status, and Action. The 'VIEW' button for the second subject (coro-001001-002) is highlighted with a red box.

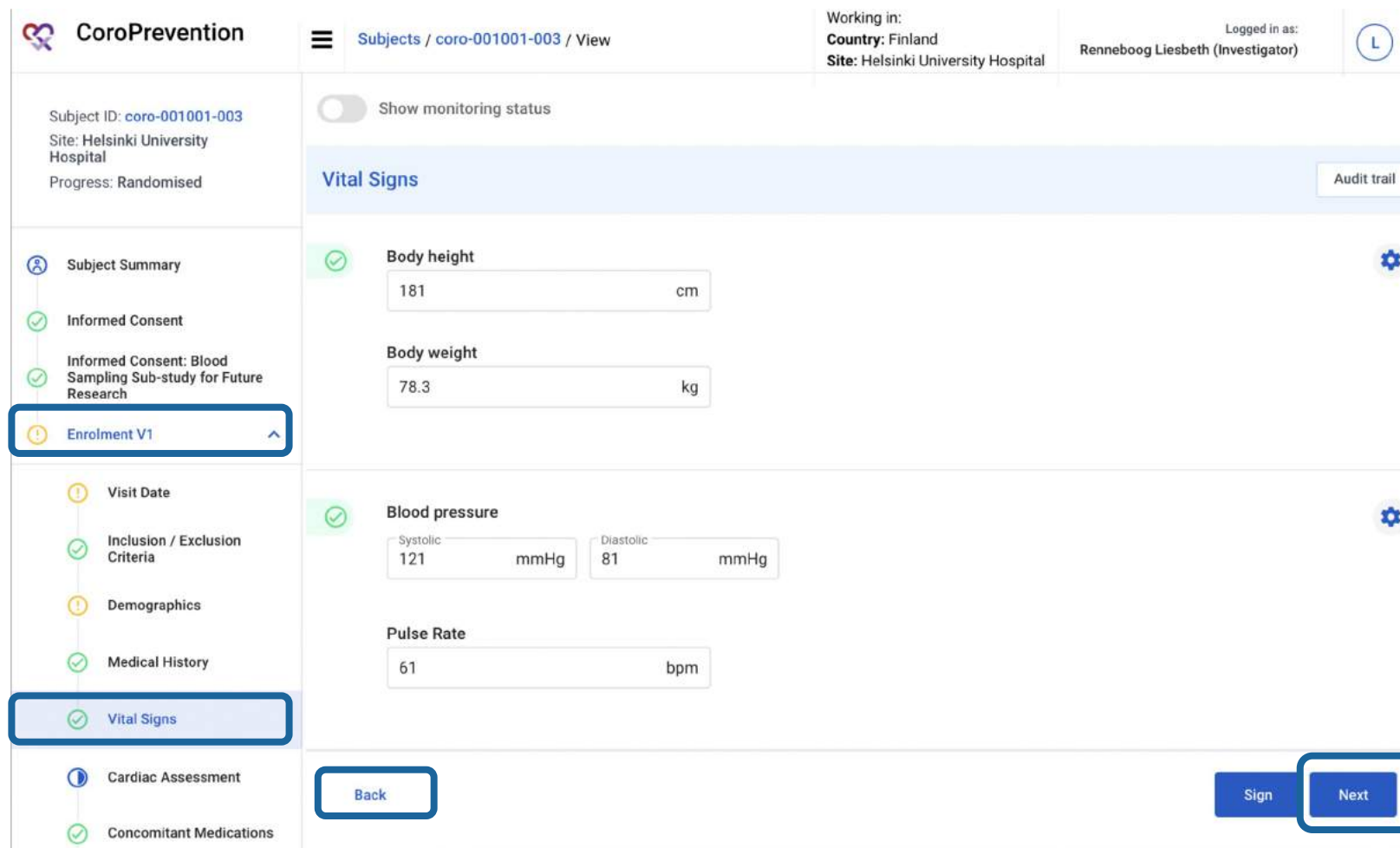
Subject Id ↓	Study	Site ID	Last Visit Title	Status	Monitor Status	Progress Status	Action
coro-001001-001	CoroPrevention	Helsinki University Hospital	Enrolment V1			Randomised	VIEW
coro-001001-002	CoroPrevention	Helsinki University Hospital	Enrolment V1			Randomised	VIEW
coro-001001-003	CoroPrevention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



The screenshot displays the CoroPrevention eCRF interface. At the top, the header includes the CoroPrevention logo, a navigation menu, and user information: "Working in: Country: Finland, Site: Helsinki University Hospital" and "Logged in as: Renneboog Liesbeth (Investigator)". The main content area is divided into a left sidebar and a central panel. The sidebar lists various eCRF sections: Subject Summary, Informed Consent, Informed Consent: Blood Sampling Sub-study for Future Research, Enrolment V1 (highlighted with a blue box), Visit Date, Inclusion / Exclusion Criteria, Demographics, Medical History, Vital Signs (highlighted with a blue box), Cardiac Assessment, and Concomitant Medications. The central panel shows the "Vital Signs" section, which includes fields for Body height (181 cm), Body weight (78.3 kg), Blood pressure (Systolic: 121 mmHg, Diastolic: 81 mmHg), and Pulse Rate (61 bpm). Each field has a green checkmark indicating it is completed. At the bottom of the central panel, there are "Back", "Sign", and "Next" buttons. The "Next" button is highlighted with a blue box.



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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: 

Subject Flow:

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

	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	 



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Or use the subject summary to navigate to a form:

- Subject ID: coro-001001-002

Site: Helsinki University Hospital

Progress: Randomised

Subject Summary

Status filter

☐
☒
☐
☐
☐
☐

Monitoring filter

☐
☐
☐
☐
☐

Subject Summary

Informed Consent

Informed Consent: Blood Sampling Sub-study for Future Research

Enrolment V1

Visit 6

Visit 7

End Of Trial

Informed Consent Amendments

Logs







	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"/>		

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

Enter/Edit Data - Status Icons

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

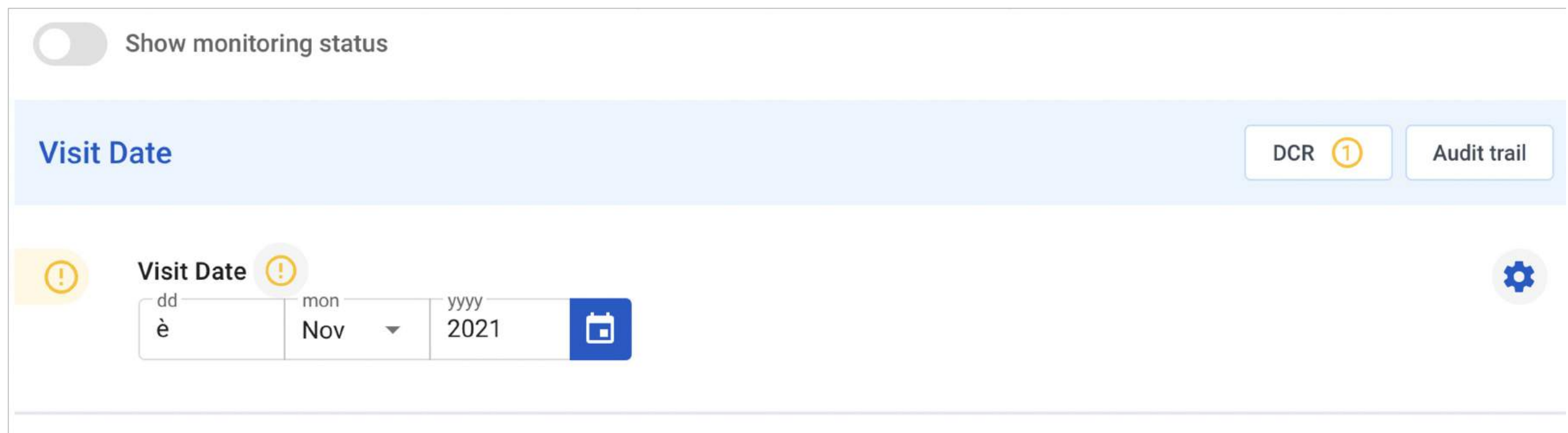
 Empty	No data is present.
 Incomplete	Data is present, but data entry is not complete.
 Invalid	Invalid data is present: at least one DCR (query) is raised.
 Valid	All data is present and valid.
 Answered DCR	At least one DCR (query) has been answered.
 Signed	Data has been signed.



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 displays a web form 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 shows a "Visit Date" label with a yellow warning icon. Below the label is a date input field with three parts: "dd" (containing "è"), "mon" (containing "Nov" with a dropdown arrow), and "yyyy" (containing "2021"). To the right of the date field is a blue calendar icon. A yellow warning icon is also present to the left of the date field. In the bottom right corner of the form area, there is a gear icon for settings.

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
è

mon
Nov ▼

yyyy
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:

SAVE

CANCEL CHANGE

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

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

7


mon


Nov

▼

yyyy

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

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

Save

Cancel

OPEN IN OVERVIEW

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

Systolic

#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. You Please verify.

You

Data is correct

09 Nov 2021 10:11:40

OPEN IN OVERVIEW

Blood pressure

Systolic

199

mmHg

Diastolic

45

mmHg

Pulse Rate

103

bpm

34

Enter/Edit Data - Audit Trail


All data entry is logged in the audit trail

- Click the “Audit trail” button to view the audit trail for the entire form
- Click the cog wheel and then “Audit Trail” to view the audit trail for the block of fields


☐ Show monitoring status

Inclusion / Exclusion Criteria Audit trail

☒ **Inclusion Criteria**

	Yes	No	
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"/>	Audit Trail
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"/>	

Enter/Edit Data - Audit Trail (2)

The data audit trail is toggled by default ('Data changes')

- For initial data entry, the justification shows "New Data"
- For data edits, the justification shows "Data Entry Error" if this was the provided reason or it will show the custom reason provided by the user

Visit Date - coro-001001-007

Data Clarification Requests

Audit Trail

Data changes

Status updates

Search

ID	Type	Variable	Rec.	Old Value	New Value	Justification	Modified By	Date and Time (UTC) ↑
10608	Answer updated	DVISD		è	7	Data Entry Error	Irenneboog_inv	08 Nov 2021 13:01:16
10605	Answer updated	DVISM			11	New Data	Irenneboog_inv	08 Nov 2021 12:58:51
10603	Answer updated	DVISY			2021	New Data	Irenneboog_inv	08 Nov 2021 12:58:51
10601	Answer updated	DVISD			è	New Data	Irenneboog_inv	08 Nov 2021 12:58:51

Rows per page:

10

1-4 of 4

<

>

OPEN IN OVERVIEW


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

 %

Date of latest echocardiography

dd	mon	yyyy	
UK	UK ▼	2021	

Enter/Edit Data - Confirm Empty Values

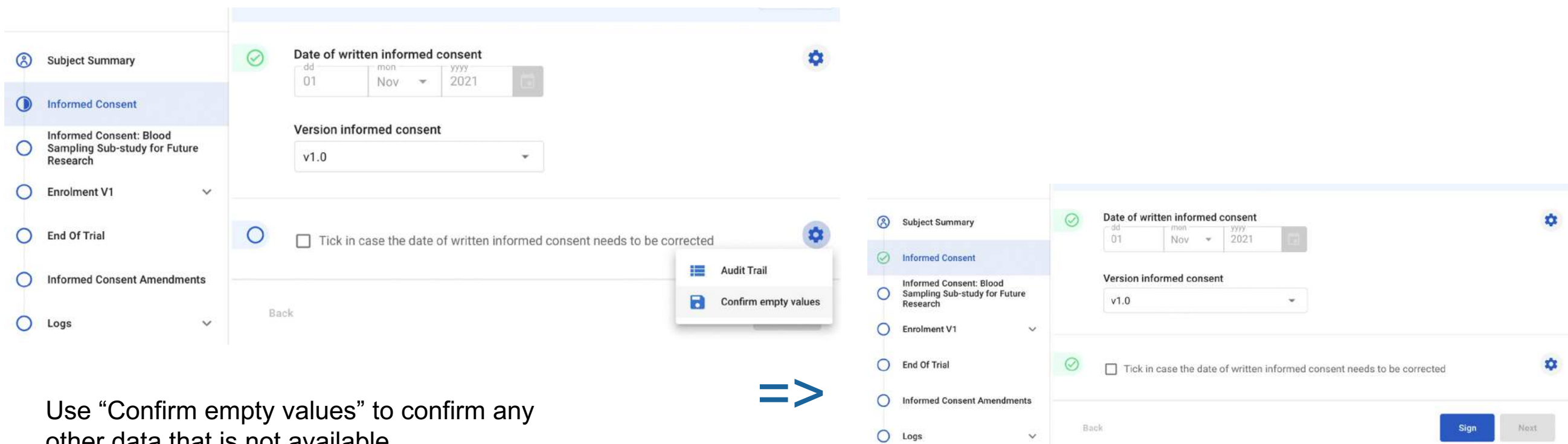
Notable exception (2):

- 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



The subject is eligible to participate in the study

Yes



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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

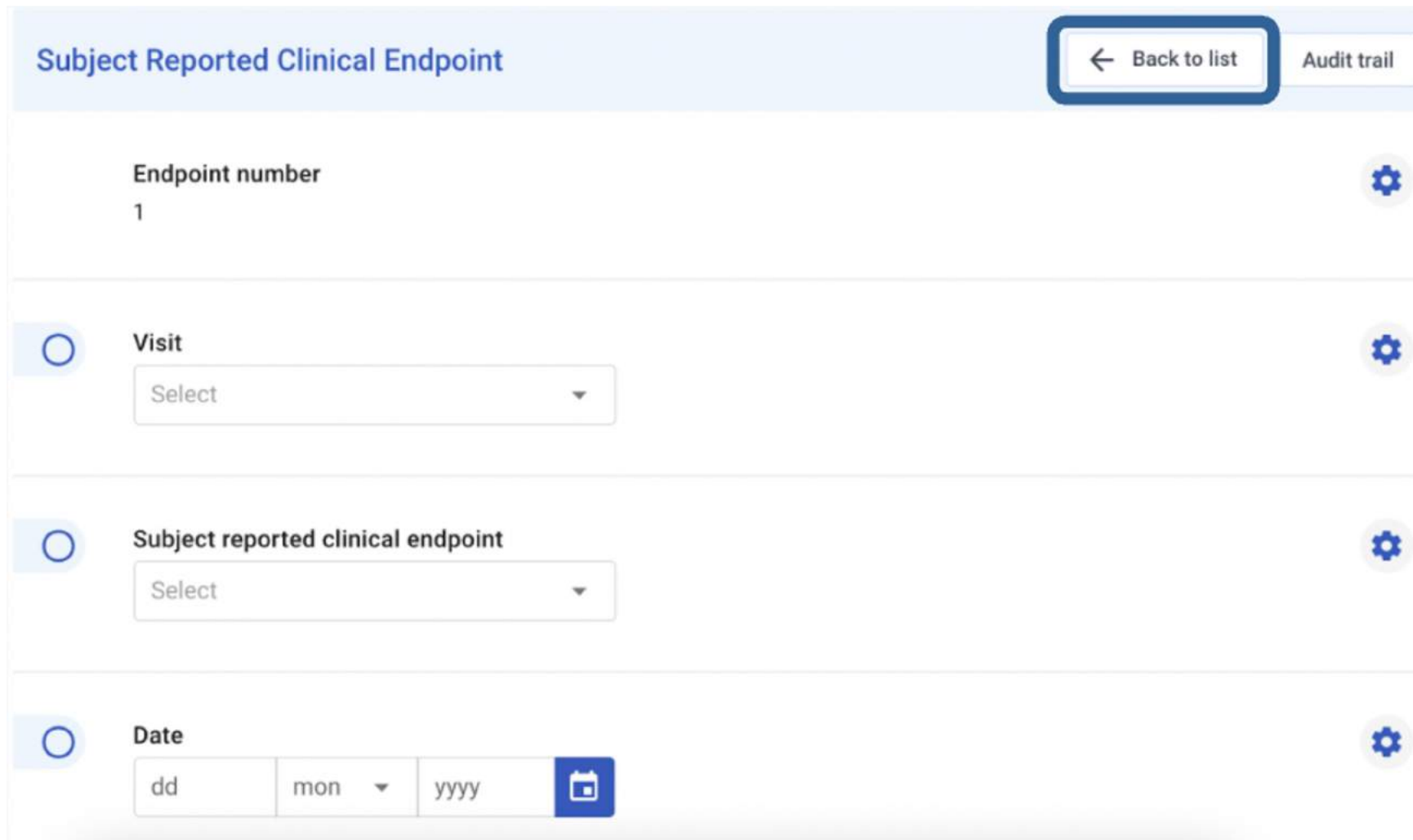
ADD SUBJECT REPORTED CLINICAL ENDPOINT

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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Reports

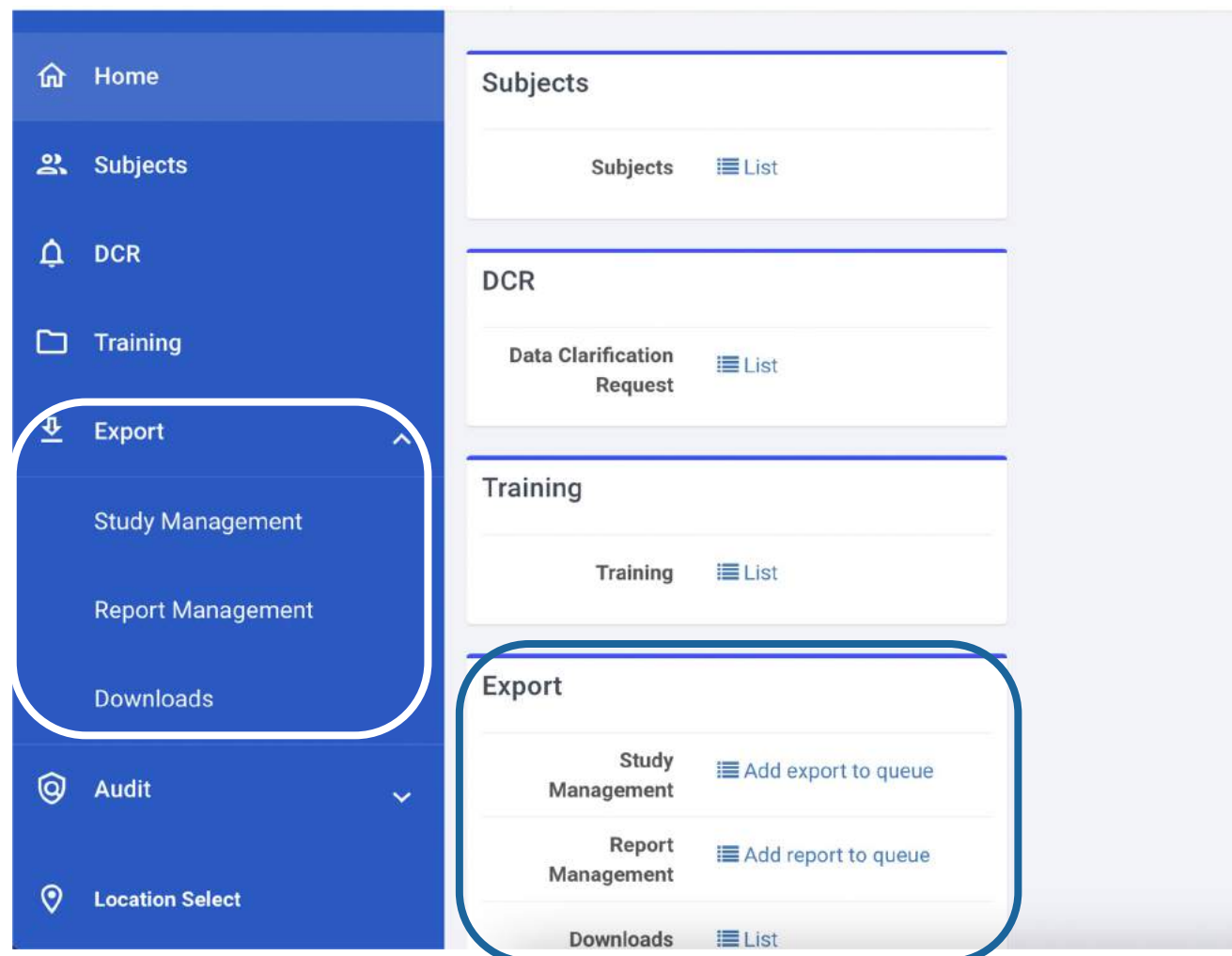


Reports - General

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

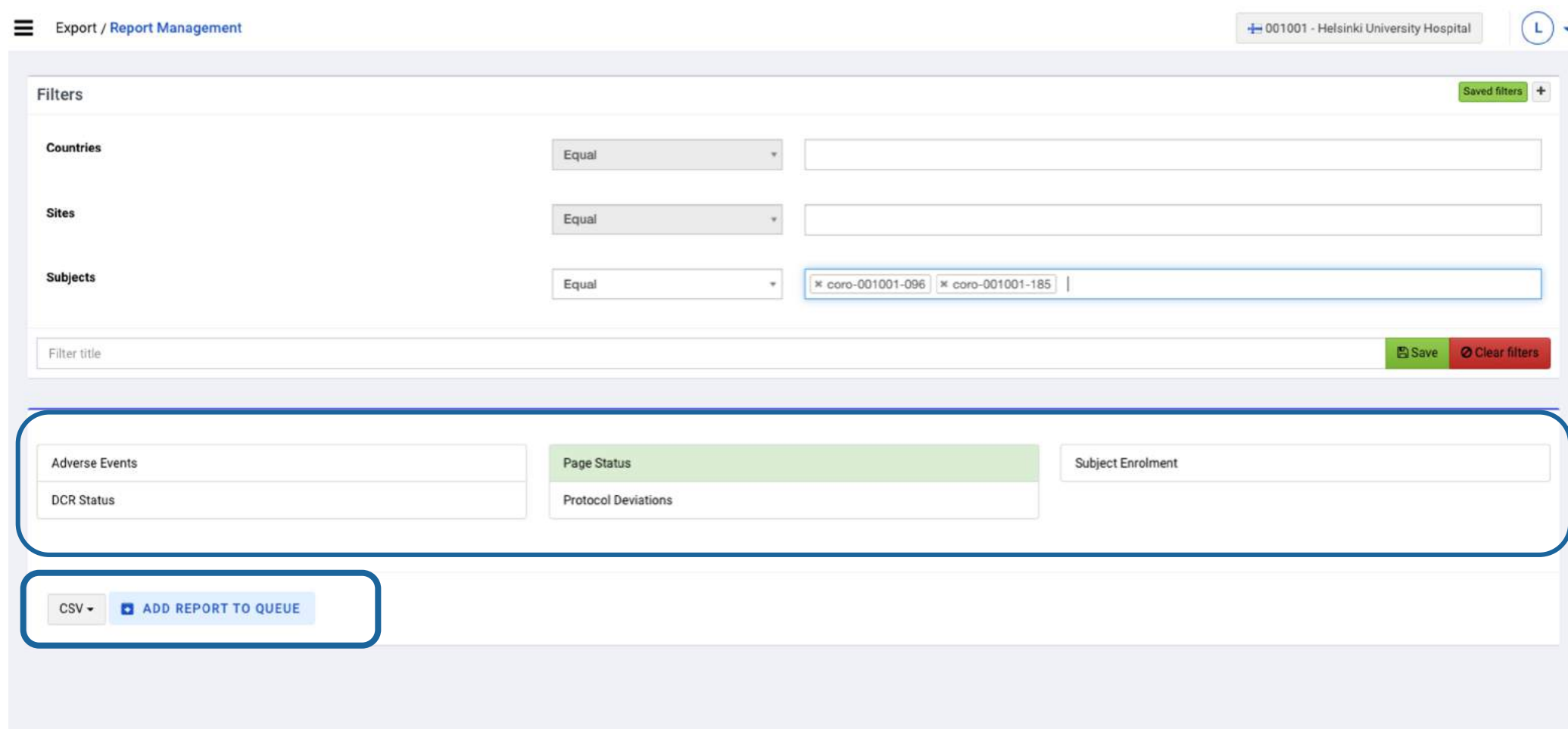
Which reports and exports are available to you are depending on your user type.



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Reports - Generation

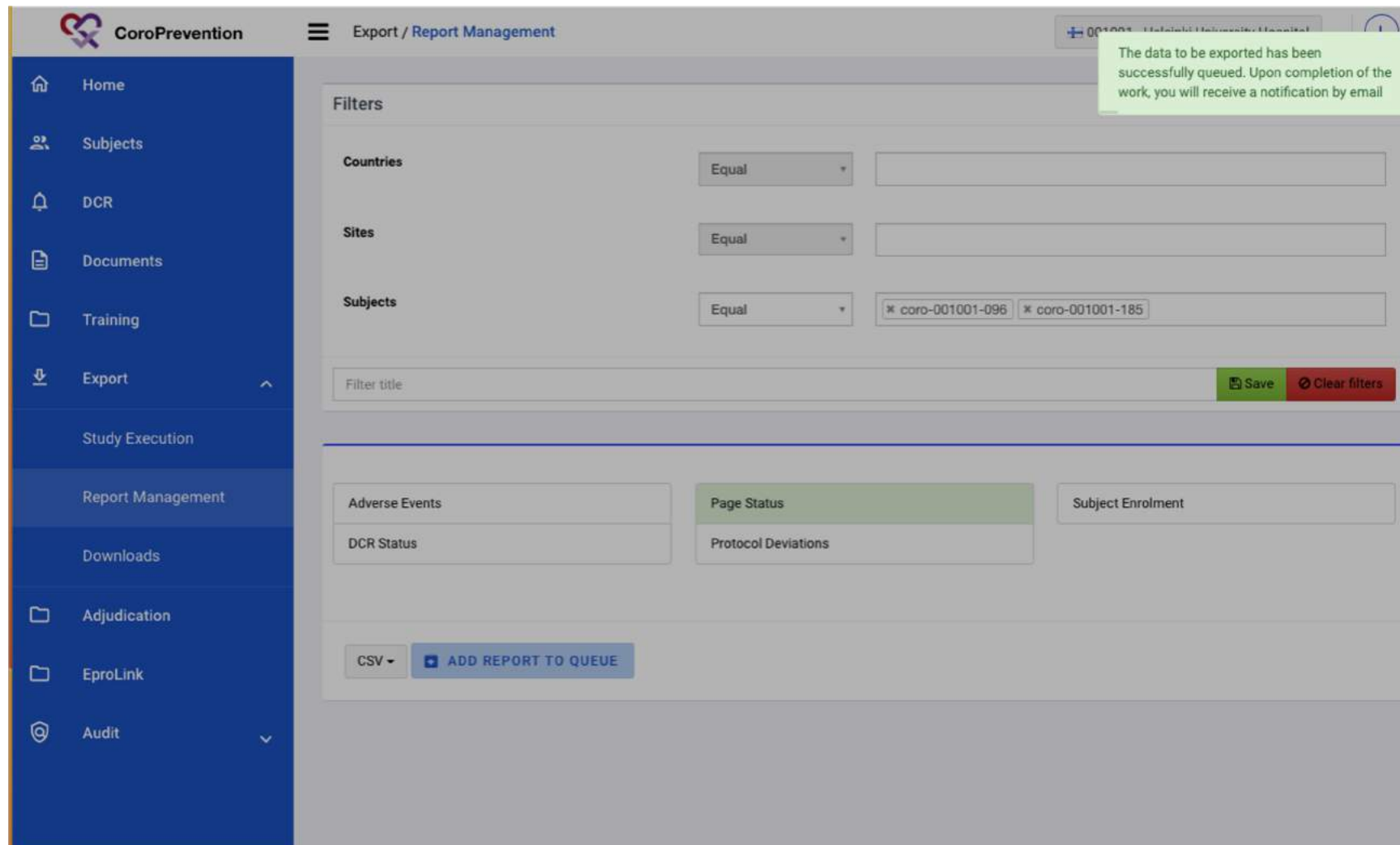
- Select the desired export / report
- Specify the filters if applicable
- Select the desired format from the dropdown of available formats
- Click Add Export / Report To Queue to start the creation of the export / report



The screenshot displays the 'Export / Report Management' interface. At the top, there is a header with a menu icon, the text 'Export / Report Management', a user identifier '001001 - Helsinki University Hospital', and a profile icon 'L'. Below the header, the 'Filters' section contains three rows: 'Countries', 'Sites', and 'Subjects'. Each row has a dropdown menu set to 'Equal' and a text input field. The 'Subjects' field contains two selected items: 'coro-001001-096' and 'coro-001001-185'. To the right of the filters is a 'Saved filters' button with a plus icon. Below the filters is a 'Filter title' input field and two buttons: 'Save' and 'Clear filters'. The main content area is divided into three columns: 'Adverse Events' (containing 'DCR Status'), 'Page Status' (containing 'Protocol Deviations'), and 'Subject Enrolment'. At the bottom, there is a 'CSV' dropdown and a blue button labeled '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

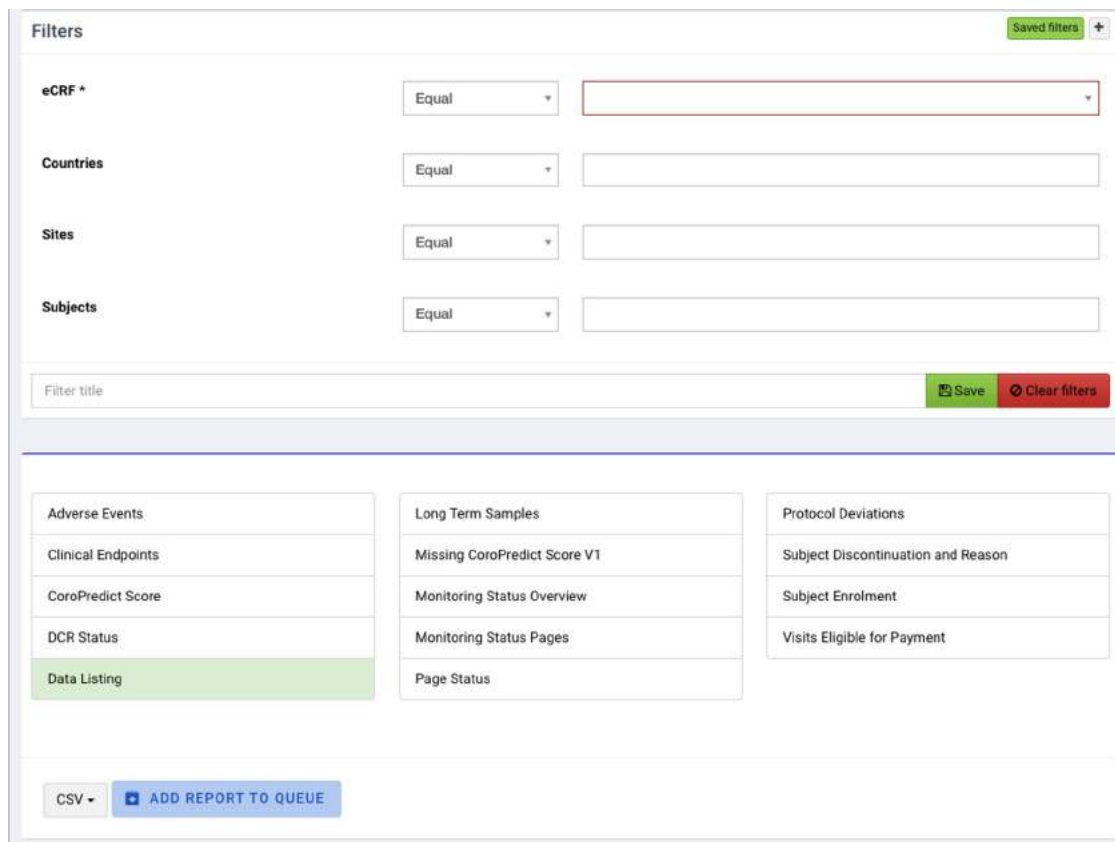


The screenshot shows the 'Export / Report Management' interface of the CoroPrevention system. On the left is a dark blue sidebar with navigation links: Home, Subjects, DCR, Documents, Training, Export (highlighted), Study Execution, Report Management, Downloads, Adjudication, EproLink, and Audit. The main content area has a header with the CoroPrevention logo and a hamburger menu. Below the header, there's a 'Filters' section with three rows: 'Countries' with an 'Equal' dropdown and an empty text box; 'Sites' with an 'Equal' dropdown and an empty text box; and 'Subjects' with an 'Equal' dropdown and a text box containing two subject IDs: '* coro-001001-096' and '* coro-001001-185'. Below the filters is a 'Filter title' input field and two buttons: 'Save' (green) and 'Clear filters' (red). Underneath, there are four report categories: 'Adverse Events', 'DCR Status', 'Page Status' (highlighted in green), and 'Subject Enrolment'. At the bottom, there's a 'CSV' dropdown and a blue button labeled 'ADD REPORT TO QUEUE'. A green success message pop-up is visible in the top right corner, stating: 'The data to be exported has been successfully queued. Upon completion of the work, you will receive a notification by email'.



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 includes a 'Saved filters' button with a plus icon. Below this, there are four filter rows: 'eCRF *', 'Countries', 'Sites', and 'Subjects'. Each row has a dropdown menu set to 'Equal' and a text input field. 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 of the interface, there is a 'CSV' dropdown and a blue 'ADD REPORT TO QUEUE' button.

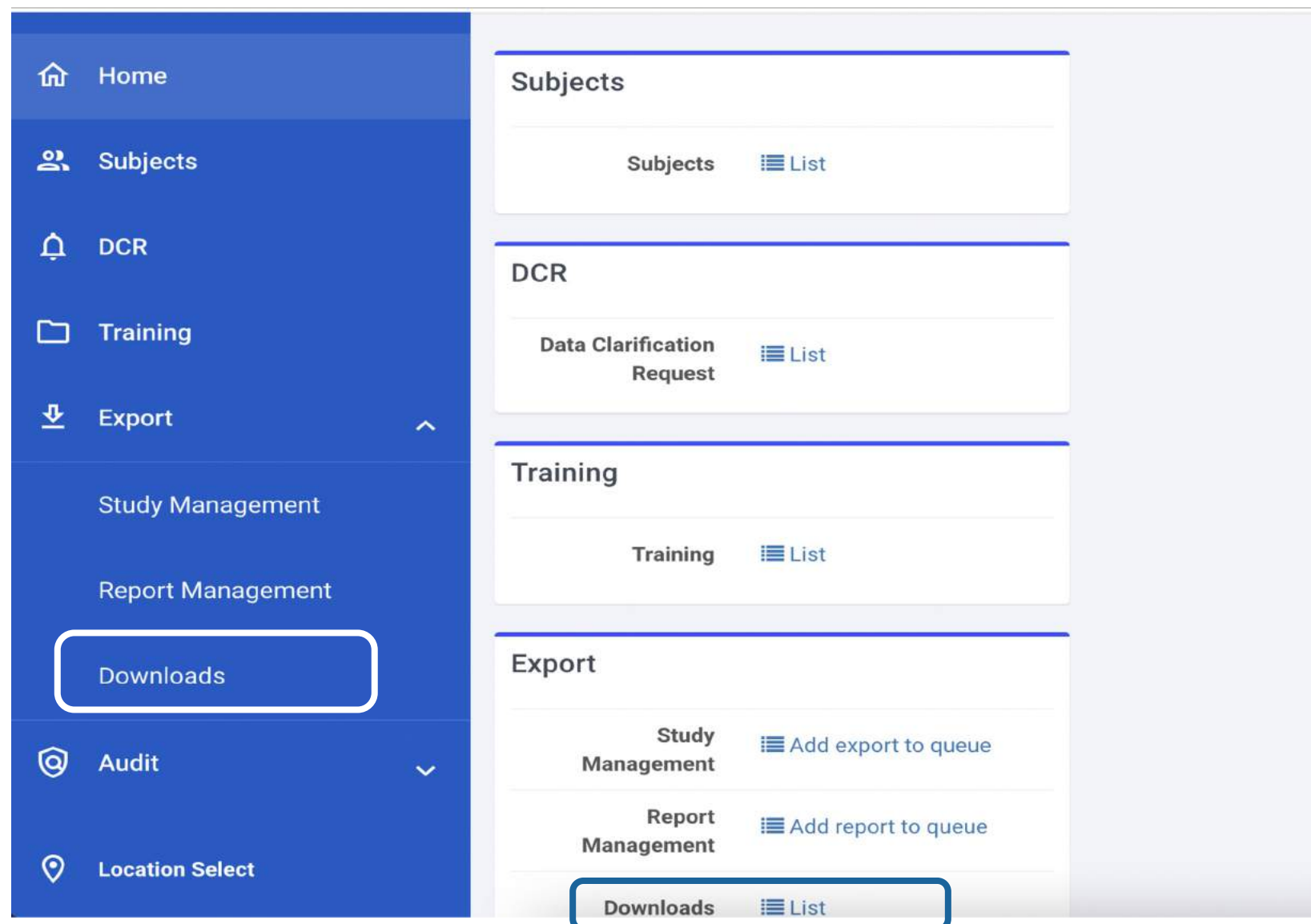
You can save your filter combinations for future use by providing a title for the filter and clicking “Save”



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Reports - Download

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



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

Monitor Data



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Monitor 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-001001-003
Site: Helsinki University Hospital
Progress: Enrolled

Subject Summary

Status filter: ☐ ☐ ☒ ☐ ☐ ☐ Monitoring filter: ☐ ☐ ☐ ☒ ☒

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	<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 checked="" 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"/>



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Monitor 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 or monitoring status
- Click the status icon for the form to access it

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

Subject Summary

Status filter:  Monitoring filter: 

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

	Enrolment V1
Inclusion / Exclusion Criteria	 
Blood Sampling - Basic Laboratory Assessments and CoroPredict Score	 
Randomisation	 

Left sidebar navigation:

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

In the example given, the subject summary is filtered on monitoring status “Requiring monitoring”.

It's possible to combine the Status and Monitoring filters.



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Monitor Data - Monitor Toggle

By default, users with monitoring permissions will see Monitoring status in the subject's flow


- Click the toggle button on any form to switch to data entry view

Subject ID: **coro-001001-003**

Site: Helsinki University Hospital


Progress: Randomised

☒ Show monitoring status

 Requiring monitoring

Inclusion / Exclusion Criteria


Monitor Audit trail




Inclusion Criteria

Yes

No






Informed consent form signed by the study subject.

☒


☐



Male or female aged 30 to 80 years on the day of enrolment.

☒


☐



≥ 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.

☒


☐




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.

☐


☒



Subjects with NYHA class III-IV heart failure i.e. marked limitation in activity due to symptoms, comfortable only at rest.

☐


☐



Uncontrolled arrhythmias such as ventricular tachycardias.

☐

☐









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55

Monitor Data - Entry Status Icons





Entry 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.



Monitor Data - Monitoring Status Icons

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

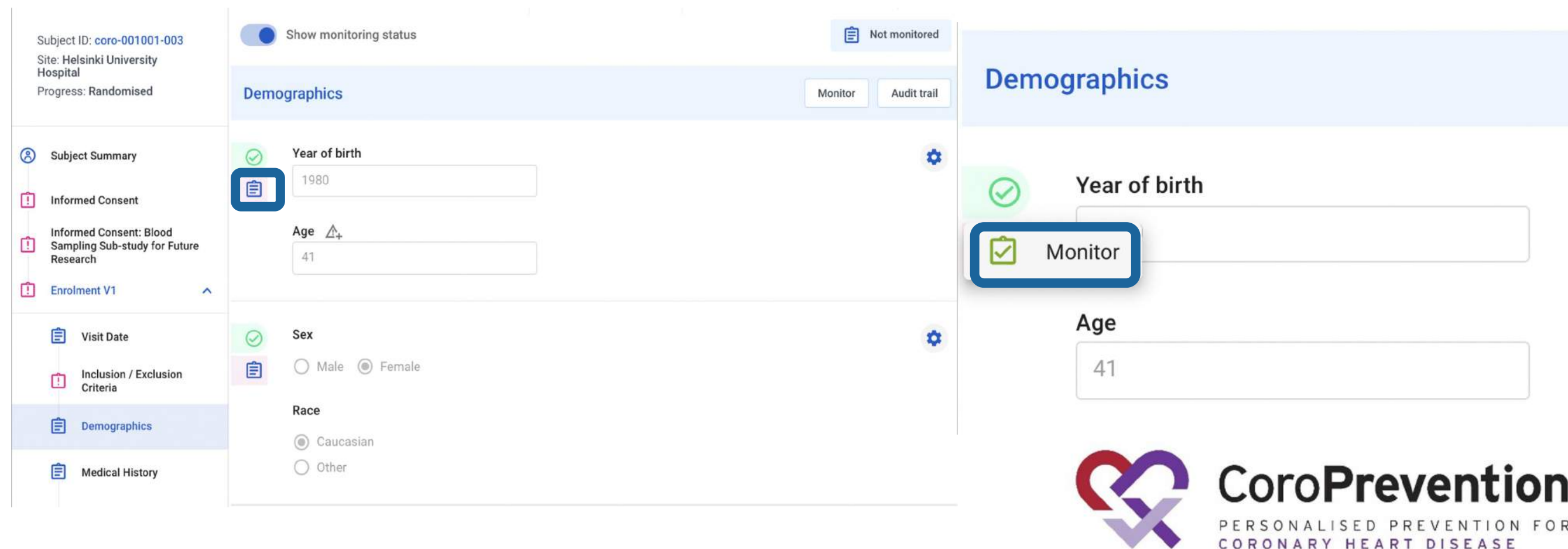
	Not monitored
	Requiring monitoring
	Modified after monitoring (the data was updated after monitoring)
	Monitored
	Closed (data manager closed the eCRF for monitoring)



Monitor Data - Monitor Block

To perform data verification (monitoring), the Show monitoring status toggle needs to be on

- Click the monitoring status icon of the block you want to monitor
- Click Monitor





The screenshot displays the UniWeb interface for a subject with ID **coro-001001-003**, Site: Helsinki University Hospital, and Progress: Randomised. The left sidebar shows a navigation menu with items: Subject Summary, Informed Consent, Informed Consent: Blood Sampling Sub-study for Future Research, Enrolment V1, Visit Date, Inclusion / Exclusion Criteria, **Demographics** (highlighted), and Medical History. The main content area shows the 'Demographics' block with a 'Show monitoring status' toggle set to 'On' and a 'Not monitored' status icon. The 'Demographics' block contains fields for Year of birth (1980), Age (41), Sex (Male/Female), and Race (Caucasian/Other). A 'Monitor' button is highlighted with a blue box, and a 'Monitor' tooltip is visible over the button. The bottom right corner features the CoroPrevention logo and text: 'CoroPrevention PERSONALISED PREVENTION FOR CORONARY HEART DISEASE'.

Monitor Data - Monitor Block (2)



The status of the block changes to “Monitored”

Demographics
Monitor
Audit trail

Year of birth
1980

Age
41

Sex

☐ Male
☒ Female

Race

☒ Caucasian
☐ Other



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Monitor Data - Monitor eCRF

- To monitor all fields on an eCRF at once, click the Monitor button

☒ Show monitoring status

Requiring monitoring

Informed Consent

Monitor Audit trail

☒ Date of written informed consent

☐ 01 Nov 2021

Version informed consent

v1.0

☒ Tick in case the date of written informed consent needs to be corrected

Back Add Manual DCR Next

☒ Show monitoring status

Monitored

Informed Consent

Undo Monitoring Audit trail

☒ Date of written informed consent

☒ 01 Nov 2021

Version informed consent

v1.0

☐ Tick in case the date of written informed consent needs to be corrected

Back Add Manual DCR Next

Monitor Data - General

- Monitoring is possible for all blocks/eCRFs with one of following statuses:
 - Not monitored
 - Requiring monitoring
 - Modified after monitoring
- As a monitor you are expected to monitor the blocks/eCRFs with status Requiring monitoring



Monitor Data - Preconditions

- A block can only be monitored if no data is missing:

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

Subject Summary
Informed Consent
Informed Consent: Blood Sampling Sub-study for Future Research
Enrolment V1

Visit Date
Inclusion / Exclusion Criteria
Demographics
Medical History

Show monitoring status

Not monitored

Cardiac Assessment

Monitor Audit trail

Ischaemic heart disease status at enrolment visit

Unstable angina
Non-ST elevation MI
ST elevation MI
Stable angina
None

Type of treatment

Monitor

Monitoring of the block is only possible when the data in the block is completed or confirmed as empty.

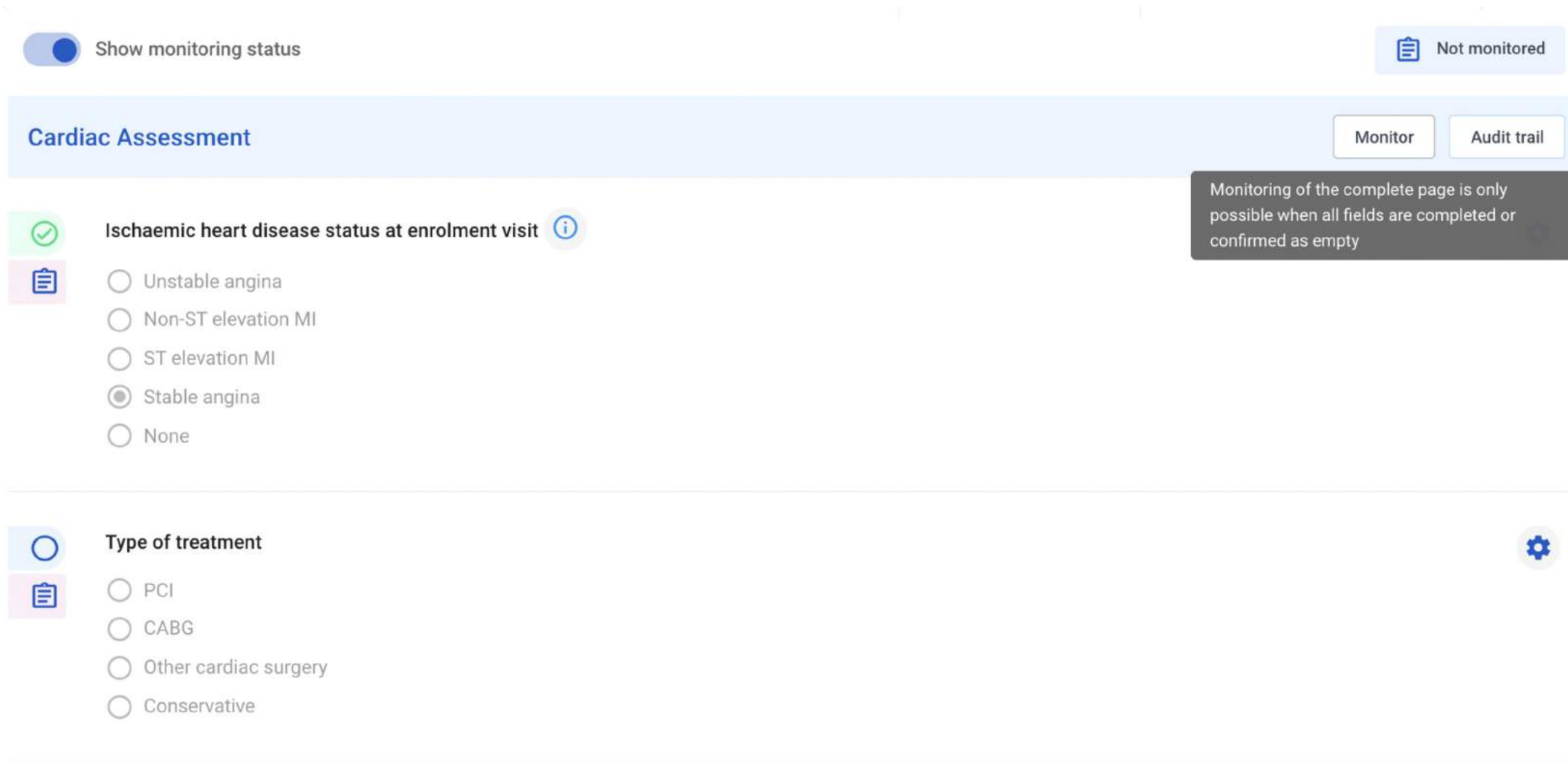
Blocks that have been confirmed as empty can also be monitored



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Monitor Data - Preconditions (2)

- An entire eCRF can only be monitored if no data is missing in any of its blocks:



The screenshot shows the UniWeb eCRF monitoring interface for the 'Cardiac Assessment' block. At the top, there is a toggle switch for 'Show monitoring status' which is turned on. To the right, there is a 'Not monitored' status indicator with a clipboard icon. Below the block title, there are 'Monitor' and 'Audit trail' buttons. The 'Ischaemic heart disease status at enrolment visit' section is marked with a green checkmark and contains five radio button options: 'Unstable angina', 'Non-ST elevation MI', 'ST elevation MI', 'Stable angina' (which is selected), and 'None'. The 'Type of treatment' section is marked with a blue circle and contains four radio button options: 'PCI', 'CABG', 'Other cardiac surgery', and 'Conservative'. A grey tooltip box on the right side of the form states: 'Monitoring of the complete page is only possible when all fields are completed or confirmed as empty'. A gear icon is visible in the bottom right corner of the form area.

Blocks that have been confirmed as empty can also be monitored



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Monitor Data - Updates After Monitoring

- Site can make modifications to monitored data
- The block, eCRF and subject receive status “Modified after monitoring” 

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

☒ Show monitoring status Modified by site

Inclusion / Exclusion Criteria Monitor Audit trail

	Yes	No	
Inclusion Criteria			
 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 type="radio"/>	<input checked="" type="radio"/>	
Exclusion Criteria			
 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"/>	








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When these modifications are monitored again, status will change to “Monitored”

Monitor Data - Closed for Monitoring


- Data Manager can close eCRFs for monitoring e.g. if no data is expected
- Monitoring is not possible in this case 

Subject ID: **coro-001001-003**
Site: **Helsinki University Hospital**
Progress: **Screening Failure**



 Subject Summary
 Informed Consent
 Informed Consent: Blood Sampling Sub-study for Future Research
 Enrolment V1
 Visit 2



 Visit Date

☒ Show monitoring status

 Closed for monitoring

Visit Date Audit trail

 Visit Date 

[Back](#) [Add Manual DCR](#) [Next](#)



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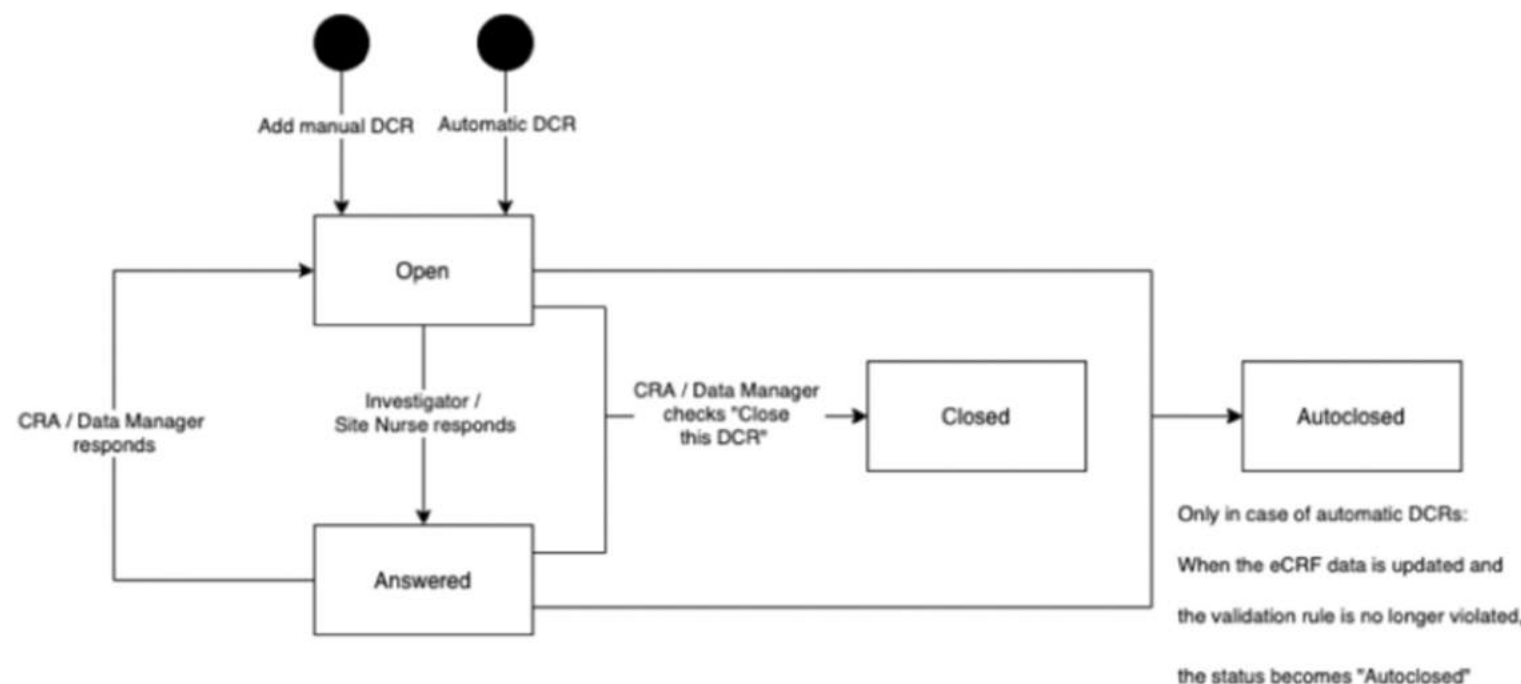
Manage DCRs



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Manage DCRs - DCR Workflow

- CRA, Lead CRA and Data Manager can manually create a DCR (query) on a data field or eCRF
- CRA and Lead CRA can only provide a response to or close a DCR that was raised by a CRA or Lead CRA
- Data Manager can only provide a response to or close a DCR that was raised by a Data Manager
- Auto-DCRs can only be closed by the system (when conditions are satisfied) or manually by a Data Manager



Manage DCRs - Create DCR on block


CRA, Lead CRA and Data Manager can manually create a DCR (query) on a data field:

- Hover over the field,  appears
- Click  to add a DCR


Demographics


Monitor

Audit trail




Year of birth







Age




Sex



☐ Male ☒ Female



Race



☒ Caucasian ☐ Other

Back

Add Manual DCR

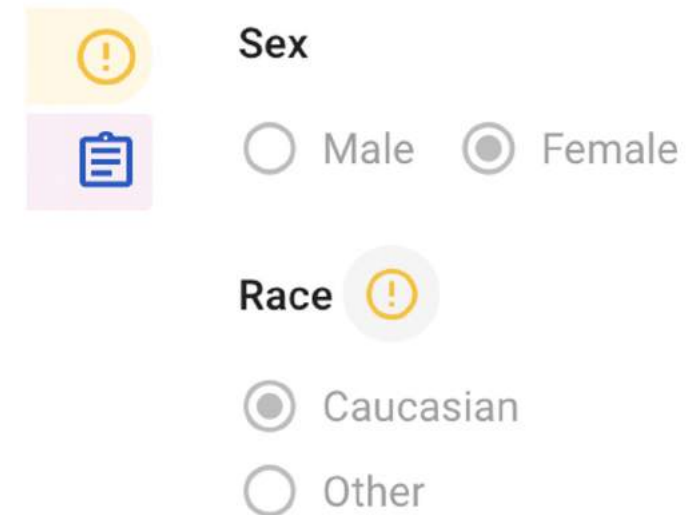
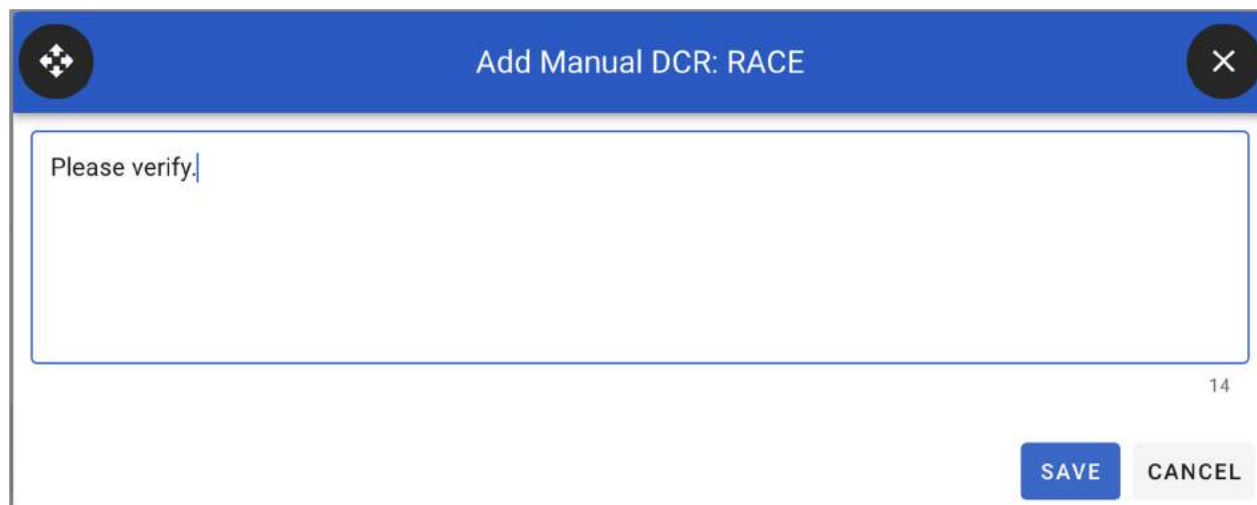
Next



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Manage DCRs - Create DCR on block (2)

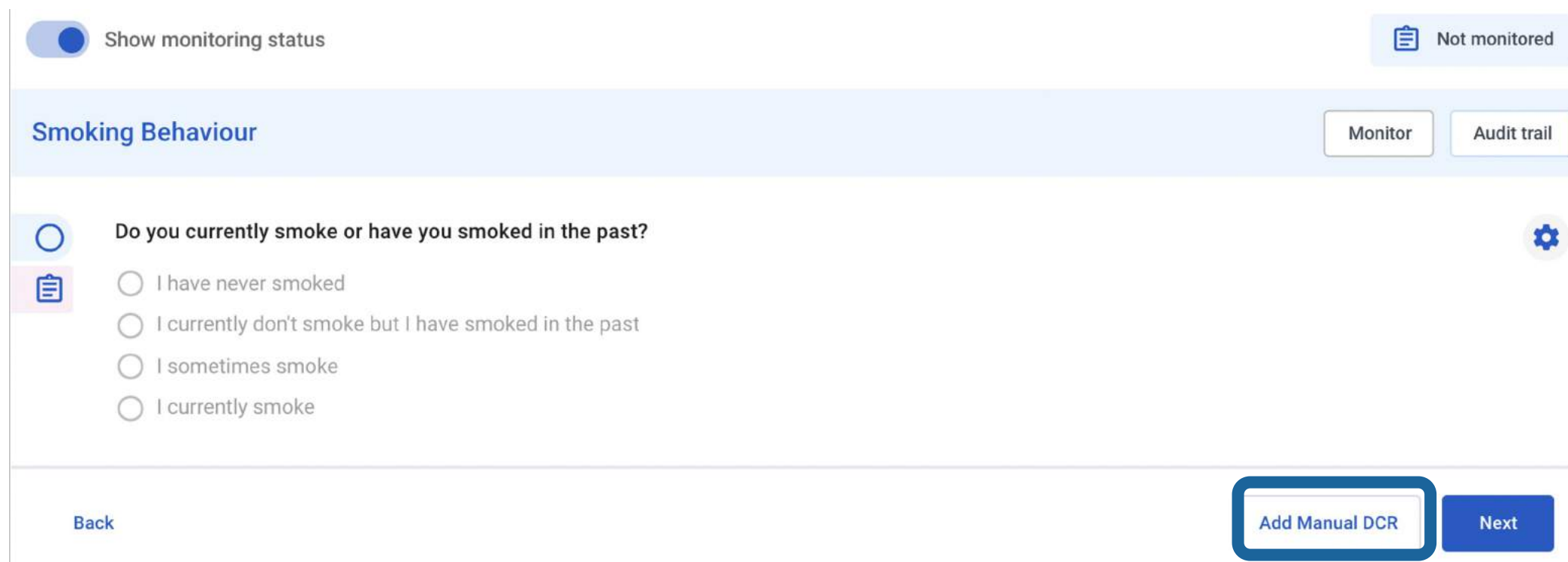
- Enter the data clarification request and click Save to confirm or Cancel to return to the form



Manage DCRs - Create DCR on eCRF

CRA, Lead CRA and Data Manager can manually create a DCR (query) on an entire eCRF:

- Click the “Add Manual DCR” button

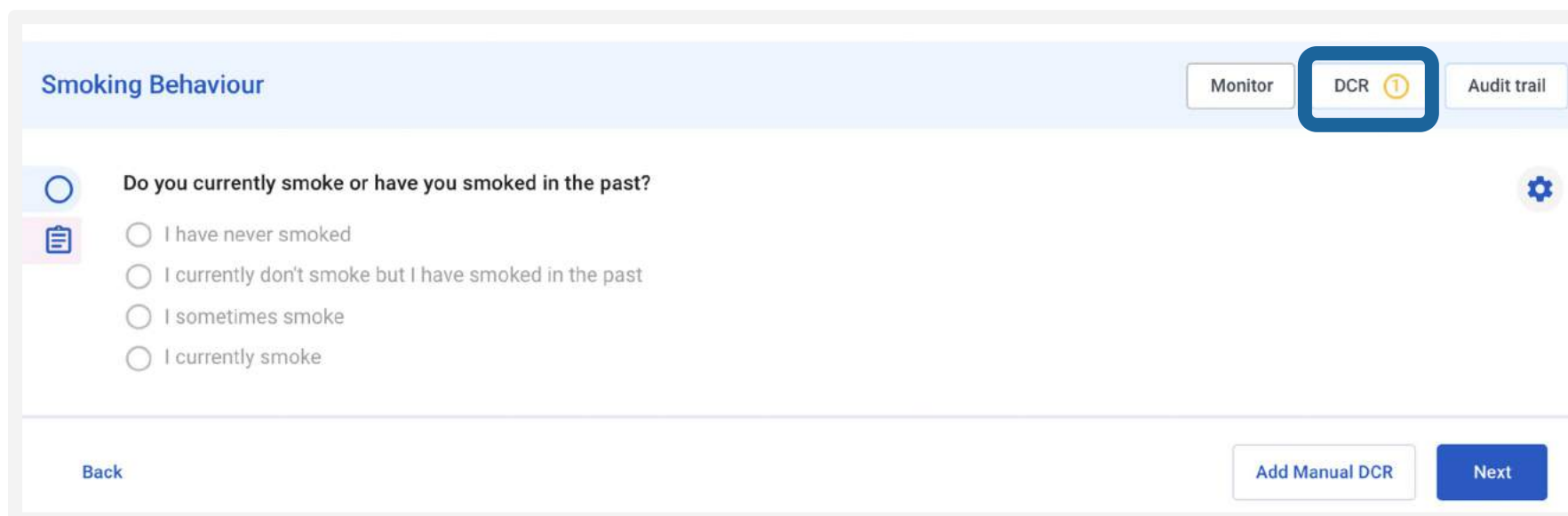
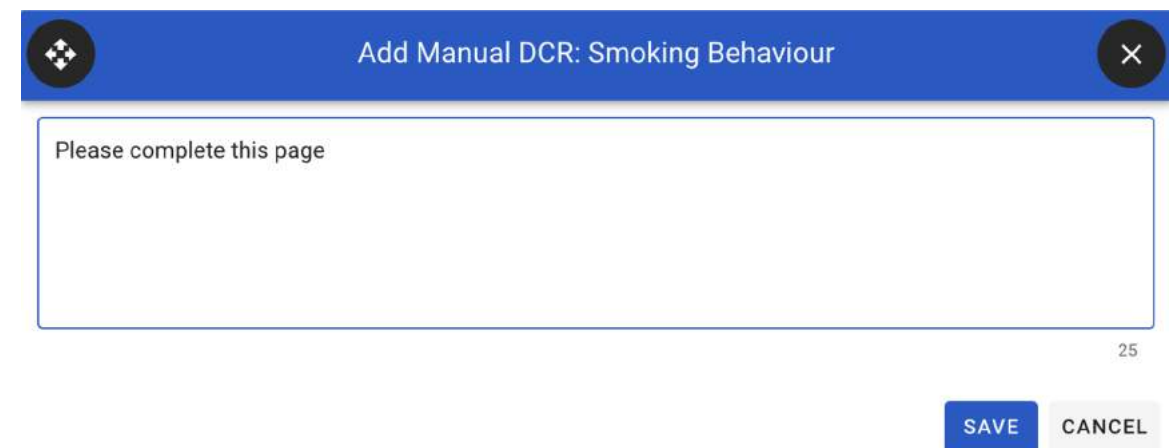


The screenshot shows the UniWeb interface for managing DCRs. At the top, there is a toggle switch for 'Show monitoring status' which is currently turned on. To the right, there is a 'Not monitored' status indicator. Below this, the 'Smoking Behaviour' section is highlighted in light blue. In the top right corner of this section, there are two buttons: 'Monitor' and 'Audit trail'. The main content area contains a question: 'Do you currently smoke or have you smoked in the past?'. Below the question are four radio button options: 'I have never smoked', 'I currently don't smoke but I have smoked in the past', 'I sometimes smoke', and 'I currently smoke'. A settings gear icon is located to the right of the question. At the bottom of the form, there is a 'Back' button on the left and two buttons on the right: 'Add Manual DCR' (which is highlighted with a red box) and 'Next'.



Manage DCRs - Create DCR on eCRF (2)


- Enter the data clarification request and click Save to confirm or Cancel to return to the form
- eCRF DCRs are shown by clicking the DCR button
- These do not appear on a field itself



Manage DCRs - Answered DCR


The site (Study Nurse, Investigator) can provide an answer to a DCR:

- Indicated by the Answered DCR icon 
- Click the icon to open the DCR and view the response



Sex

☐ Male
 ☒ Female

Race 

☐ Caucasian
 ☒ Other

Specify


Asian

Demographics - coro-001001-003

Data Clarification Requests

☐ Show closed data clarification requests

Search



Race

Please verify.

#16 • 16 Nov 2021 15:14:47

You

Renneboog Liesbeth

Corrected the data now.

16 Nov 2021 15:58:12

Add a response

☐ Close this DCR

Save

Cancel

OPEN IN OVERVIEW



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Manage DCRs - Re-open a DCR

To re-open the DCR to the site, provide a response and click Save

Demographics - coro-001001-003

Data Clarification Requests

☐ Show closed data clarification requests

Search

Race

Please verify.

#16 • 16 Nov 2021 15:14:47

You

Renneboog Liesbeth

Corrected the data now.

16 Nov 2021 15:58:12

Add a response

Please verify the provided race, thank you

☐ Close this DCR

Save

Cancel

OPEN IN OVERVIEW

!

Sex

☐ Male

☒ Female

!

Race

☐ Caucasian

☒ Other


Specify


Asian



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It is possible to provide a response when closing a DCR, this is not required.





Sex

☐ Male ☒ Female

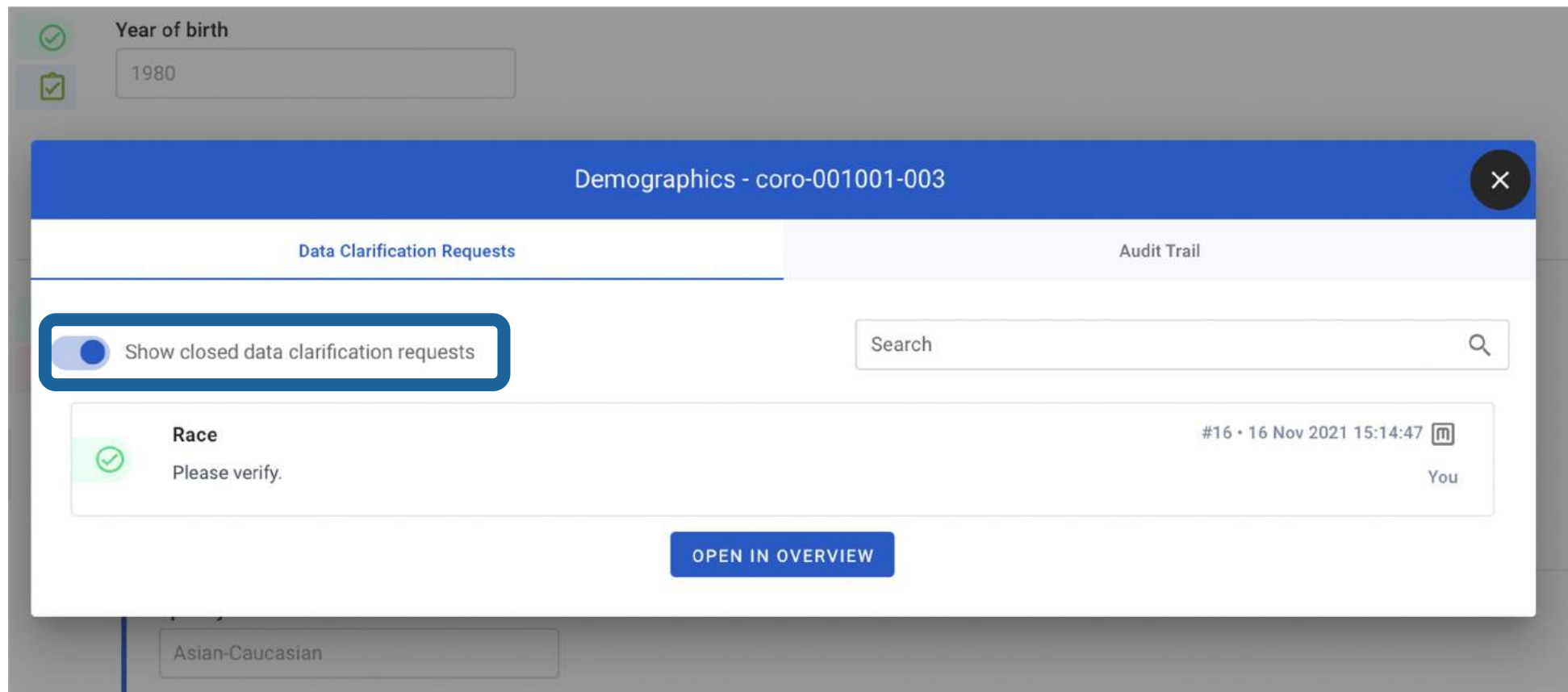
Race

☐ Caucasian ☒ Other

Specify

Manage DCRs - View DCRs

- Click the DCR button on top of the page or the data entry status icon of a block to open the DCRs for the page/block
- Toggle Show closed data clarification requests to include closed DCRs



The screenshot shows a web interface for managing Data Clarification Requests (DCRs) for a specific demographic record. The interface is titled "Demographics - coro-001001-003" and has a close button (X) in the top right corner. Below the title bar, there are two tabs: "Data Clarification Requests" (selected) and "Audit Trail". In the "Data Clarification Requests" tab, there is a toggle switch labeled "Show closed data clarification requests" which is currently turned on. To the right of the toggle is a search bar with the placeholder text "Search". Below the search bar, there is a list of DCRs. The first entry is for "Race" with a status of "Please verify." and a timestamp of "#16 • 16 Nov 2021 15:14:47". The user "You" is listed as the creator of this request. At the bottom of the list, there is a blue button labeled "OPEN IN OVERVIEW". The background of the interface shows a form for "Year of birth" with the value "1980" and a "Race" field with the value "Asian-Caucasian".



Manage DCRs - DCRs Overview

- To see all DCRs for the location you're working in, click DCR in the navigation bar
- Use the filters to search for specific DCRs

Home

Subjects

DCR

Training

Export

Audit

Location Select

Filters 0

Subject	Visit Title	Ecrf Title	Study	Site	Variable	Dcr Type	Message	Created By	Created At	Status	Closed By	Closed At	Action
coro-001001-003	Enrolment V1	Smoking Behaviour	CoroPrevention	Helsinki University Hospital		manual	Please complete this page	Renneboog Liesbeth	16 Nov 2021	open			
coro-001001-003	Enrolment V1	Demographics	CoroPrevention	Helsinki University Hospital		manual	example query	Renneboog Liesbeth	16 Nov 2021	open			
coro-001001-003	Enrolment V1	Demographics	CoroPrevention	Helsinki University Hospital	RACE	manual	Please verify.	Renneboog Liesbeth	16 Nov 2021	closed	Renneboog Liesbeth	16 Nov 2021	
coro-001001-003		Primary and Secondary Endpoints Record	CoroPrevention	Helsinki University Hospital	DEPD	automatic	Date of the endpoint [2021-10-25]...	User Investigator	16 Nov 2021	open			
coro-001001-003		Primary and Secondary Endpoints Record	CoroPrevention	Helsinki University Hospital	DEPD	automatic	Date of the endpoint [02 Nov 2021]...	User Investigator	16 Nov 2021	autoclosed		16 Nov 2021	
coro-001001-003	Enrolment V1	Visit Date	CoroPrevention	Helsinki University Hospital	DVISD	automatic	Visit date [06 Oct 2021] is before...	User Investigator	16 Nov 2021	open			
coro-001001-003	Enrolment V1	Blood Sample	CoroPrevention	Helsinki University Hospital	BSORNRL0	automatic	Lower Normal Limit is required....	User Investigator	15 Nov 2021	open			
coro-001001-003	Enrolment V1	Blood Sample	CoroPrevention	Helsinki University Hospital	BSORRESU	automatic	Unit is required. Please fill...	User Investigator	15 Nov 2021	autoclosed		15 Nov 2021	

1 / 1 - 8 results - Per page 32

Manage DCRs - DCRs Overview (2)

- This includes system-generated DCRs and manual DCRs
- Closed and autoclosed DCRs are also listed here

[Home](#)
[Subjects](#)
[DCR](#)
[Training](#)
[Export](#)
[Audit](#)
[Location Select](#)

Filters 0

Subject	Visit Title	Ecrf Title	Study	Site	Variable	Dcr Type	Message	Created By	Created At	Status	Closed By	Closed At	Action
coro-001001-003	Enrolment V1	Smoking Behaviour	CoroPrevention	Helsinki University Hospital		manual	Please complete this page	Renneboog Liesbeth	16 Nov 2021	open			
coro-001001-003	Enrolment V1	Demographics	CoroPrevention	Helsinki University Hospital		manual	example query	Renneboog Liesbeth	16 Nov 2021	open			
coro-001001-003	Enrolment V1	Demographics	CoroPrevention	Helsinki University Hospital	RACE	manual	Please verify.	Renneboog Liesbeth	16 Nov 2021	closed	Renneboog Liesbeth	16 Nov 2021	
coro-001001-003		Primary and Secondary Endpoints Record	CoroPrevention	Helsinki University Hospital	DEPD	automatic	Date of the endpoint [2021-10-25]...	User Investigator	16 Nov 2021	open			
coro-001001-003		Primary and Secondary Endpoints Record	CoroPrevention	Helsinki University Hospital	DEPD	automatic	Date of the endpoint [02 Nov 2021]...	User Investigator	16 Nov 2021	autoclosed		16 Nov 2021	
coro-001001-003	Enrolment V1	Visit Date	CoroPrevention	Helsinki University Hospital	DVISD	automatic	Visit date [06 Oct 2021] is before...	User Investigator	16 Nov 2021	open			
coro-001001-003	Enrolment V1	Blood Sample	CoroPrevention	Helsinki University Hospital	BSORNRL0	automatic	Lower Normal Limit is required....	User Investigator	15 Nov 2021	open			
coro-001001-003	Enrolment V1	Blood Sample	CoroPrevention	Helsinki University Hospital	BSORRESU	automatic	Unit is required. Please fill...	User Investigator	15 Nov 2021	autoclosed		15 Nov 2021	

1 / 1 - 8 results - Per page 32

- Download this list through Export > Study Management Data Export > DCRs

Forgot Password



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](#)

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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](#)

User password reset  Inbox x



no-reply@uniweb.eu
to liesbeth.renneboog+24 ▾

Hello, Renneboog Liesbeth,

You have requested to reset your password.

Click the reset link: [Set new Password](#)

or copy link to your browser https://edc-qa.coroprevention.eu/user-activation/renneboog_inv/VGRtwCCeC4Kp/set-password

If you didn't request the password reset, please ignore this message.



CoroPrevention

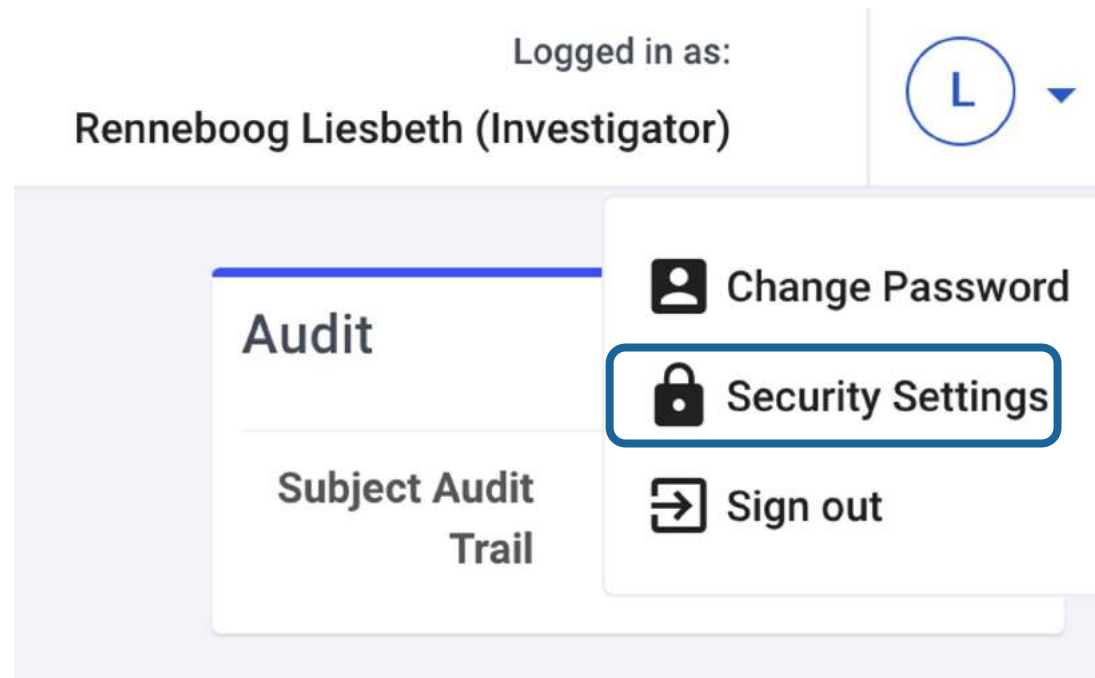
PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Reset Two-Factor Authentication (TFA)

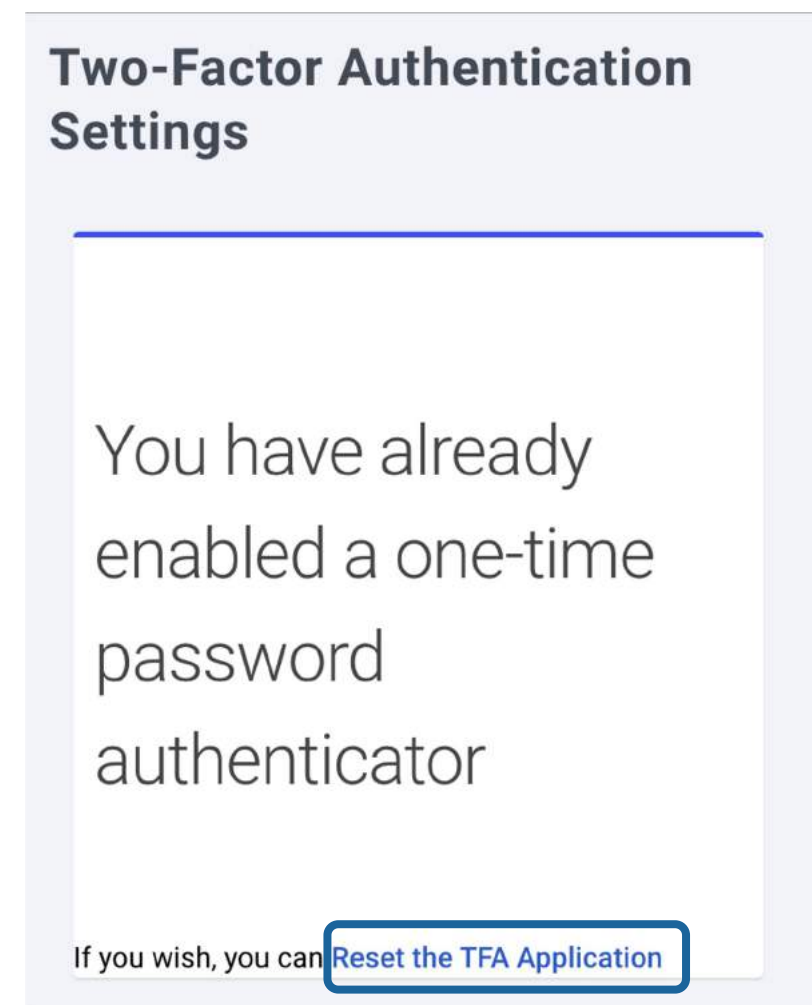


Reset TFA

- 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



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Laboratory Data



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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



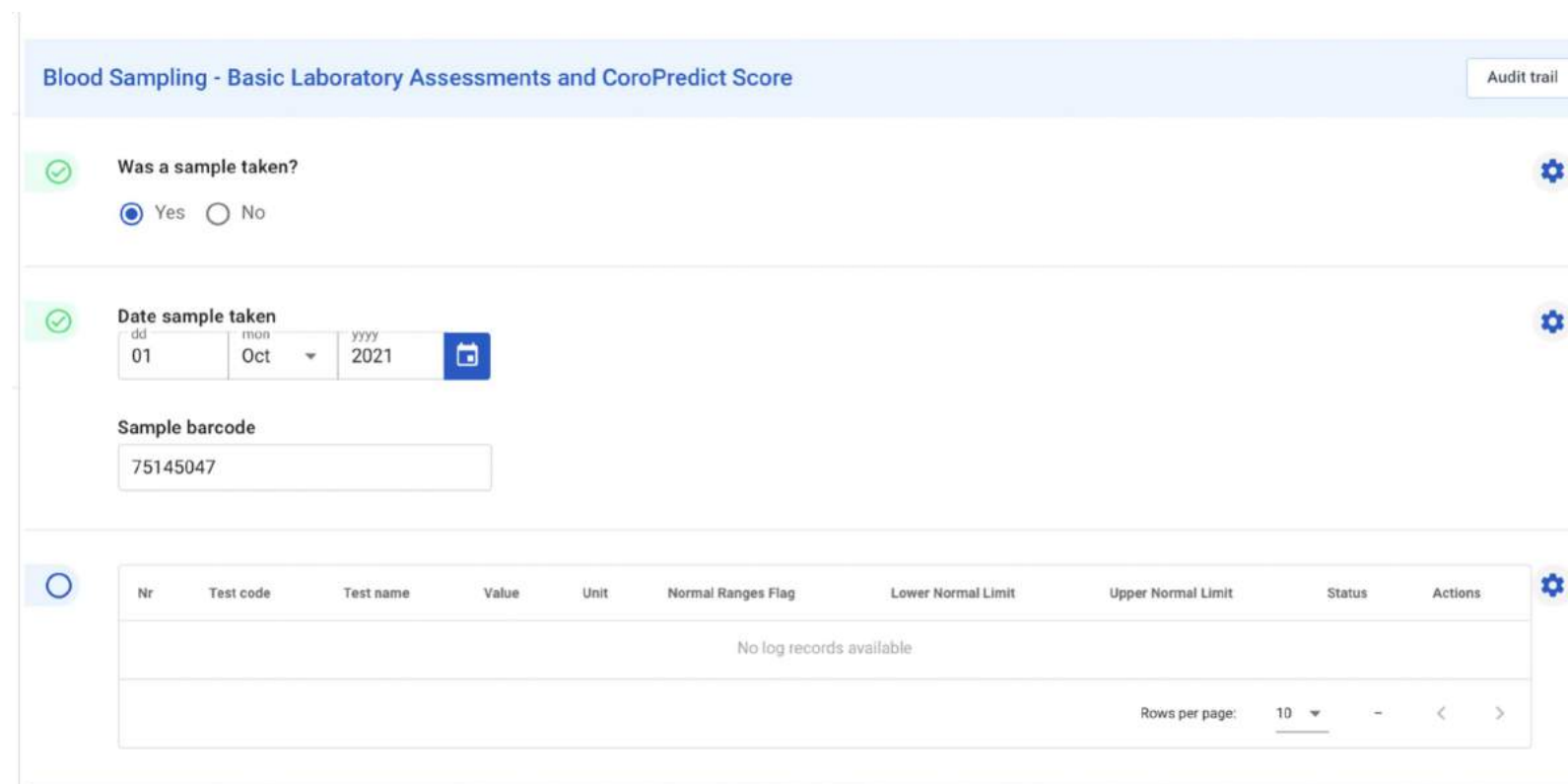
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Blood Sampling - Basic Laboratory Assessments and CoroPredict Score

- 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

ADD BLOOD SAMPLE RECORD									
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 < >									

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

03

mon

Nov

yyyy

2021

📅

⚙

✓

Sample barcode (Plasma)

1239987

⚙

Sample barcode (Serum)

123998701

Sample barcode (EDTA-blood)

123998710

Back

Sign

Next

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.



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Protocol Deviations















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Protocol Deviations - Log

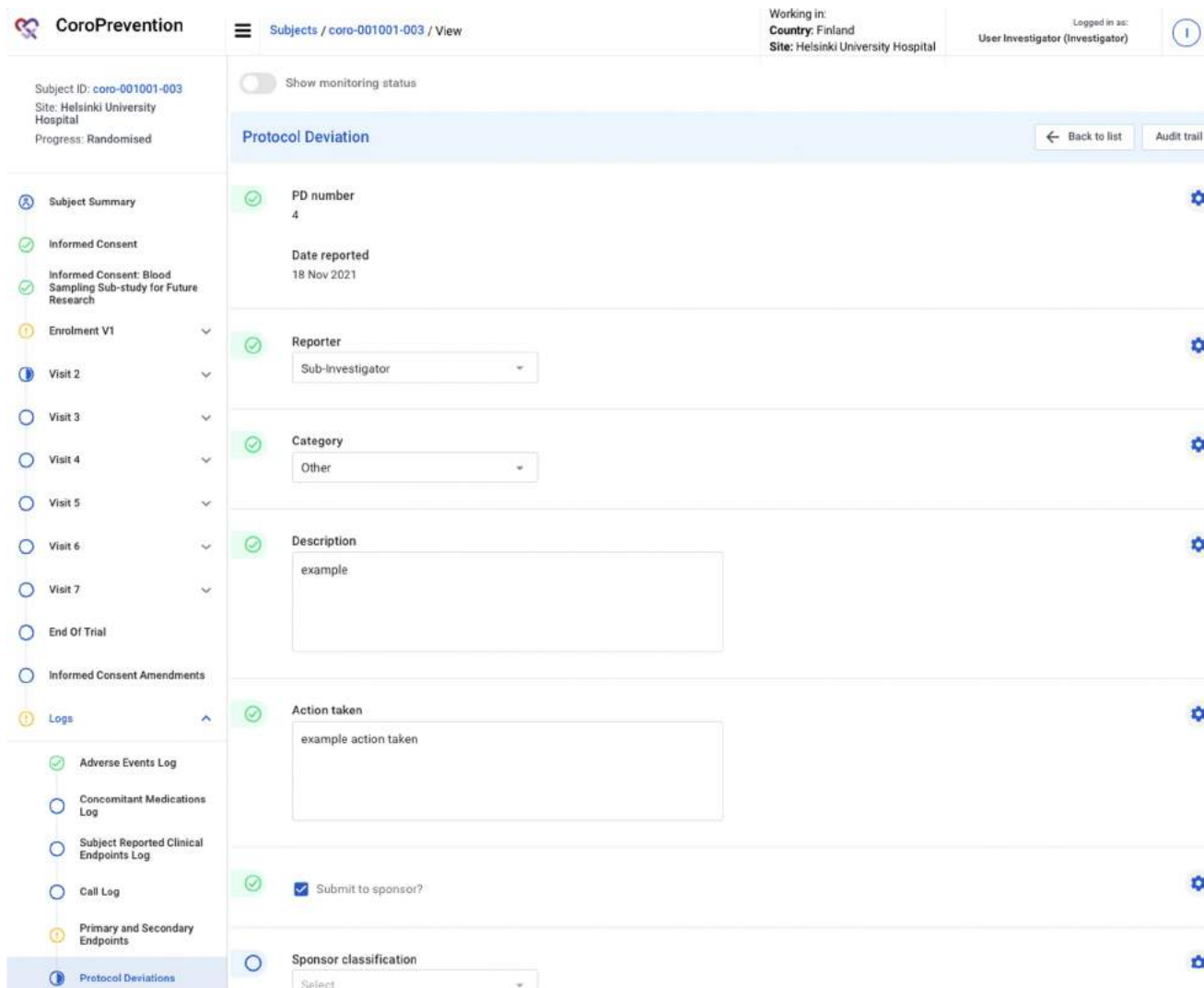
Any protocol deviations (PDs) on subject are to be collected on the Protocol Deviations Log.

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?



The screenshot displays the CoroPrevention web application interface. The top navigation bar includes the CoroPrevention logo, a menu icon, and the subject ID 'coro-001001-003 / View'. The right side of the header shows the user's role as 'User Investigator (Investigator)' and the location as 'Helsinki University Hospital'. The left sidebar contains a list of navigation items, with 'Protocol Deviations' selected at the bottom. The main content area is titled 'Protocol Deviation' and includes a 'Back to list' button and an 'Audit trail' link. The form fields are as follows:

- 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.

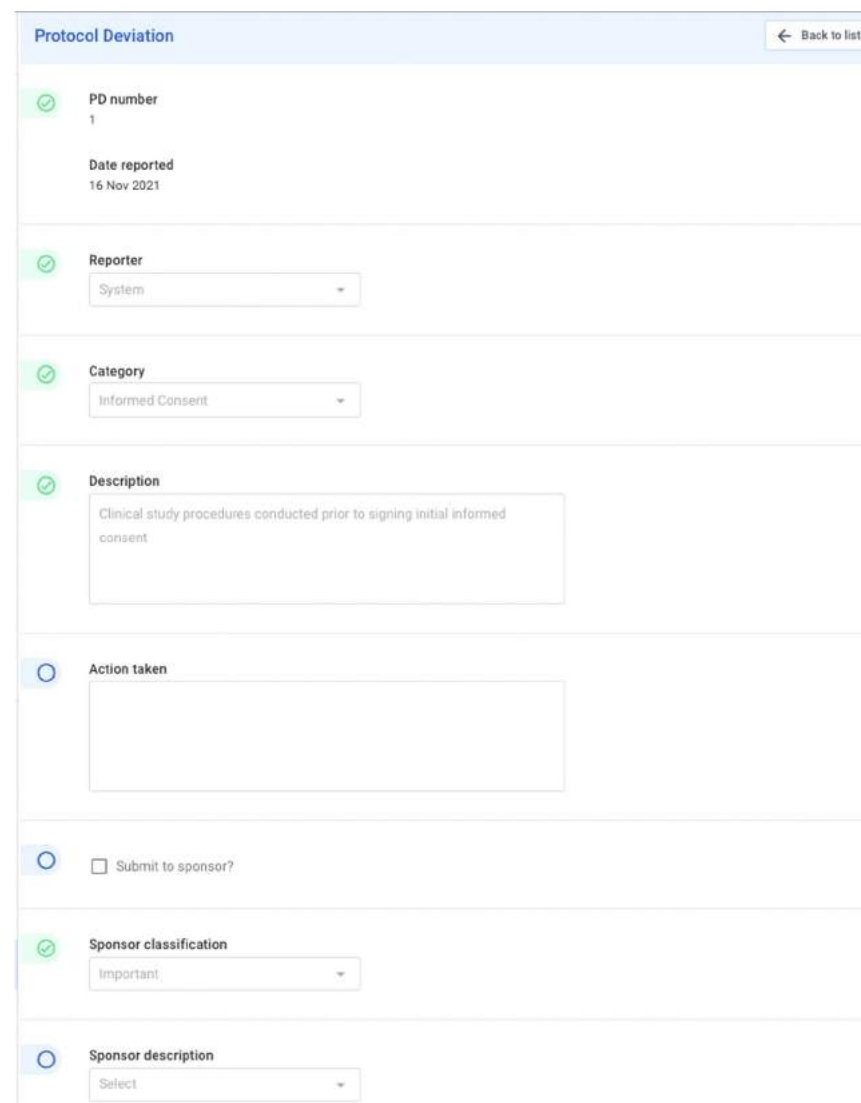
The sponsor will complete the other fields of this PD record.



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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?



The screenshot shows a 'Protocol Deviation' form with the following fields and values:

- PD number:** 1
- Date reported:** 16 Nov 2021
- Reporter:** System
- Category:** Informed Consent
- Description:** Clinical study procedures conducted prior to signing initial informed consent
- Action taken:** (Empty text box)
- Submit to sponsor?:** (Unchecked checkbox)
- Sponsor classification:** Important
- Sponsor description:** Select

A 'Back to list' button is located at the top right of the form.

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

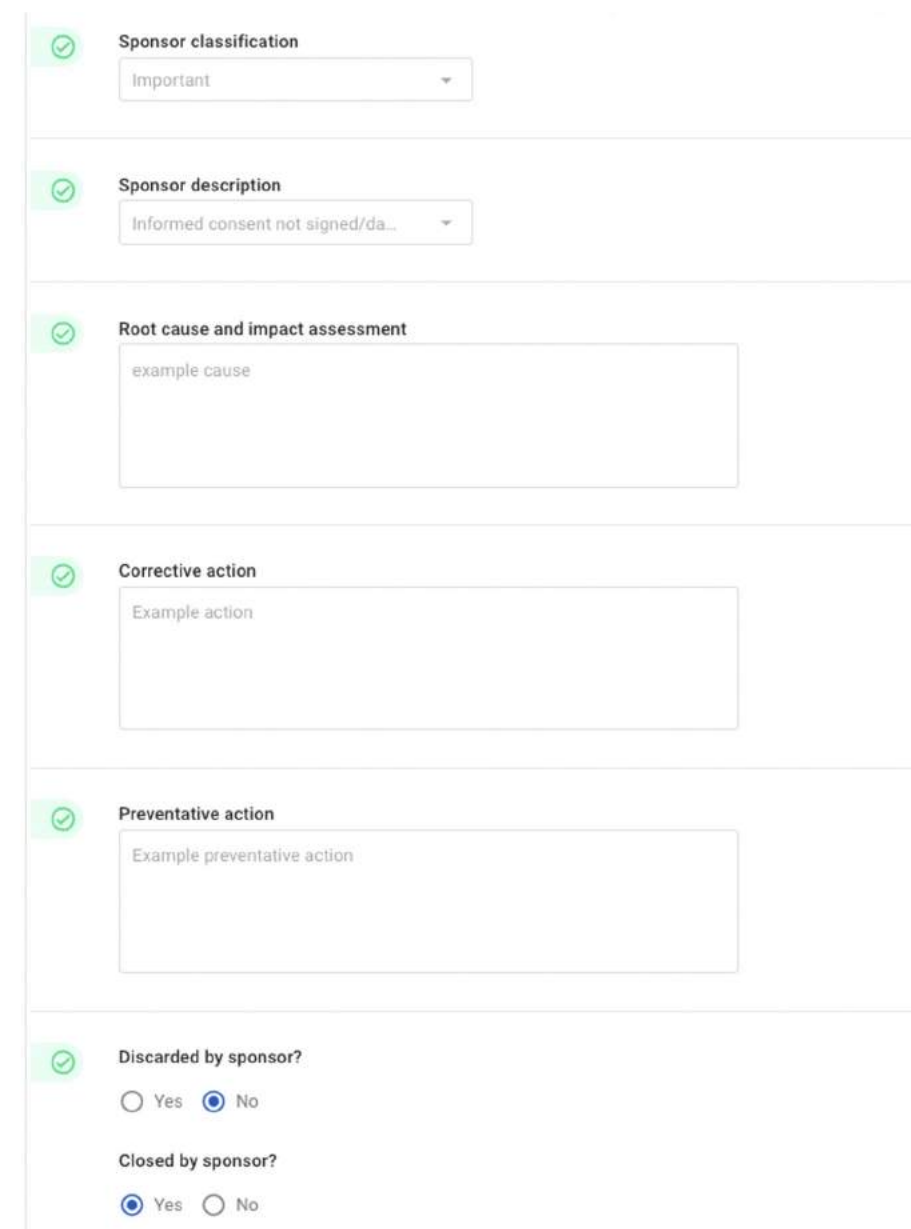
The sponsor will complete the other fields of this PD record.

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 displays a web form for 'Sponsor Evaluation'. It consists of several sections, each with a green checkmark icon in a light green box on the left. The sections are: 1. 'Sponsor classification' with a dropdown menu showing 'Important'. 2. 'Sponsor description' with a dropdown menu showing 'Informed consent not signed/da...'. 3. 'Root cause and impact assessment' with a text input field containing 'example cause'. 4. 'Corrective action' with a text input field containing 'Example action'. 5. 'Preventative action' with a text input field containing 'Example preventative action'. 6. 'Discarded by sponsor?' with radio buttons for 'Yes' and 'No', where 'No' is selected. 7. 'Closed by sponsor?' with radio buttons for 'Yes' and 'No', where 'Yes' is selected.