CoroPrevention
PERSONALISED PREVENTION FOR CORONARY HEART DISEASE

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CoroPrevention EDC - Training CRA

v1.0

Agenda

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

Agenda (2)

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

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Login

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

Activation mail Inbox ×

no-reply@uniweb.eu
to liesbeth.renneboog+3

Hello, Renneboog Liesbeth,

Your activation code is ND6nKeYwvRF9

or use the link: Activate account

or copy link to your browser http://edc-qa.coroprevention.eu/user-activation/lrenneboog_DM/ND6nKeYwvRF9

Your activation code will expire on 06 Nov 2021 15:43:59.

If you don't yet have an account within the CAF Single Sign-On system, you will be asked to create a password

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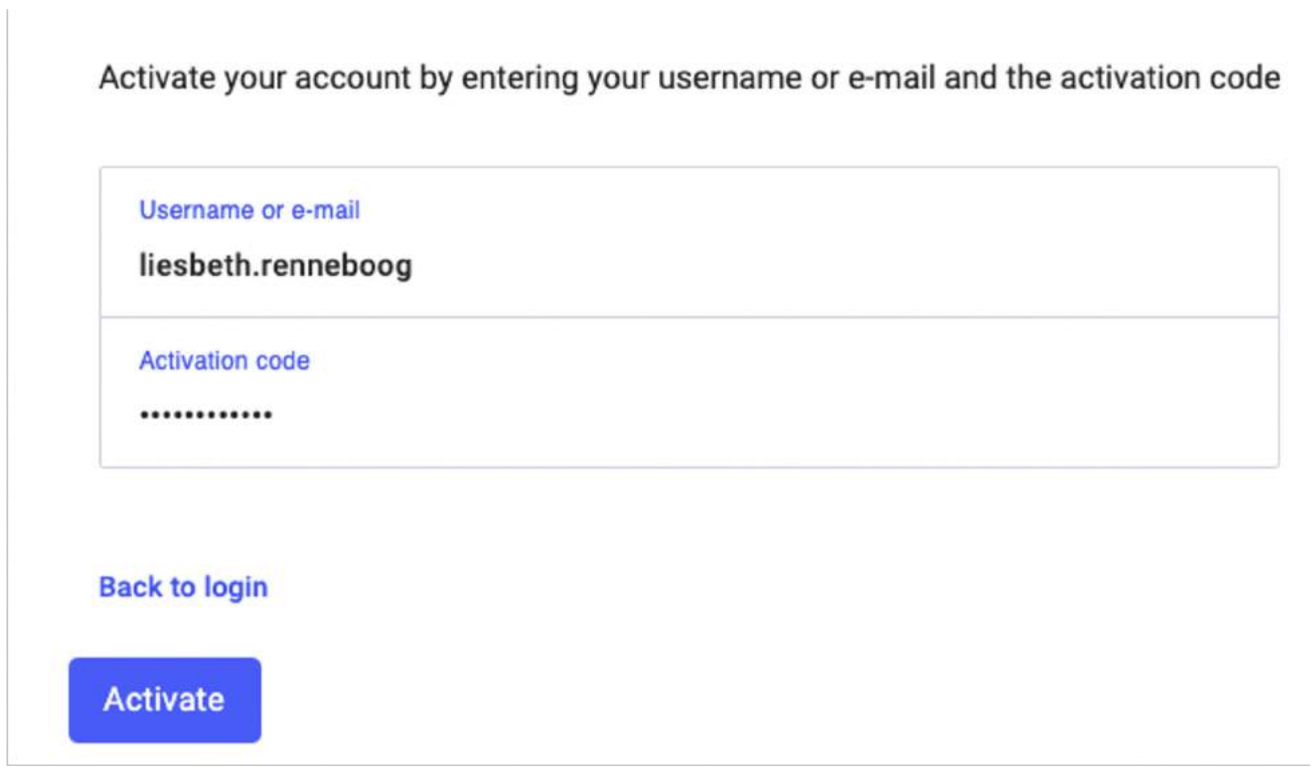
Login - Account Activation (2)

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



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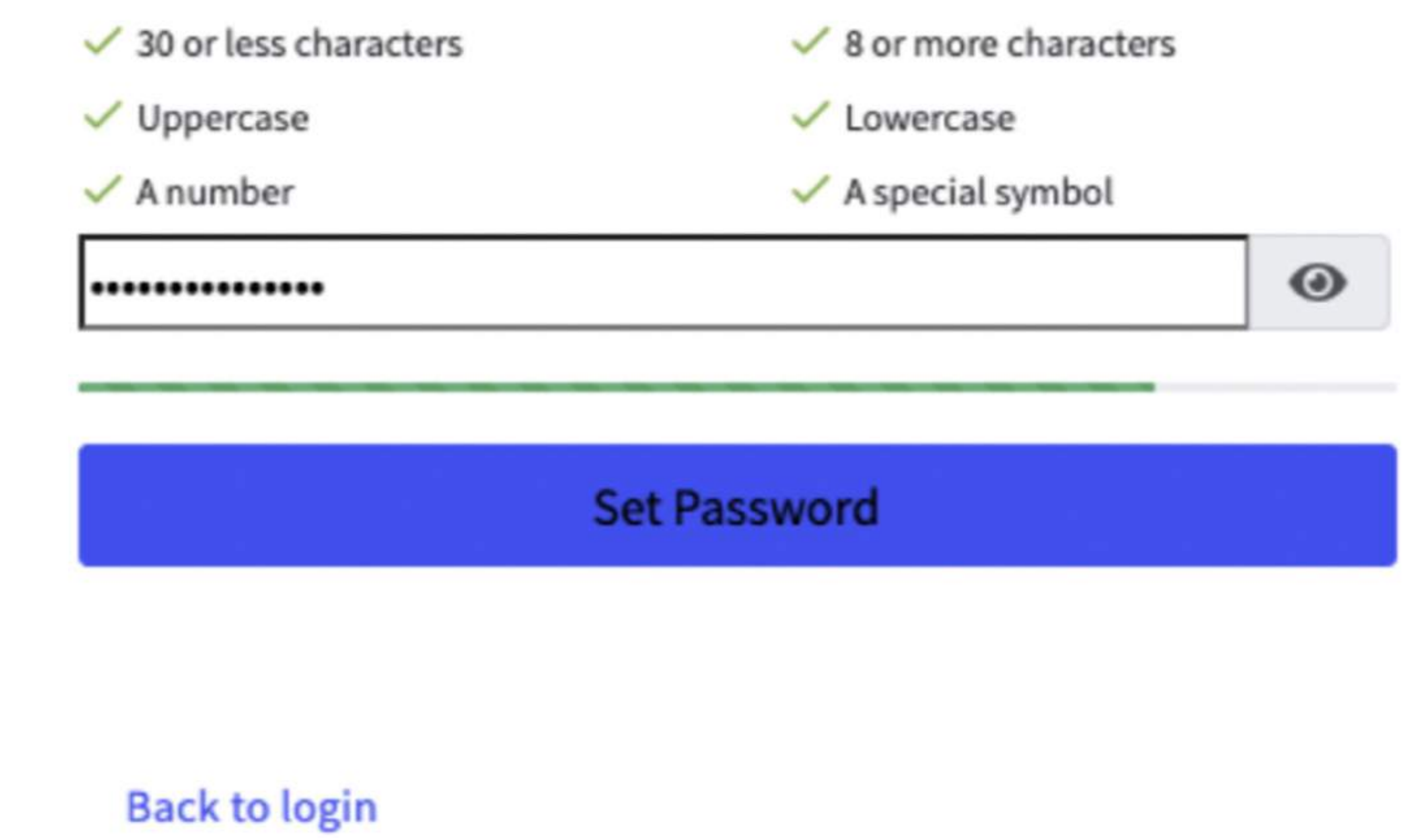
Login - Account Activation (3)

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



Note:
Your password should not be shared.

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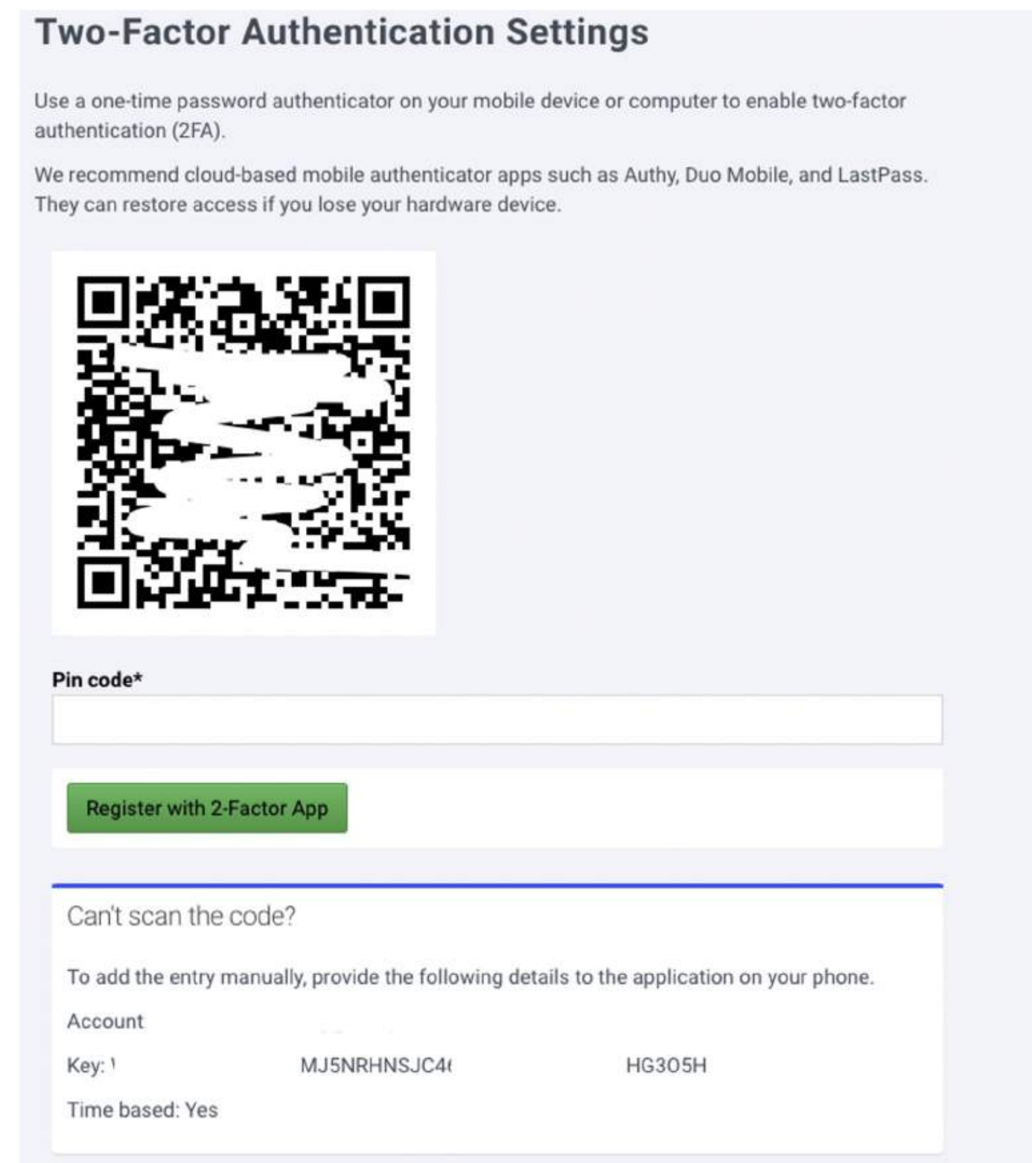
Login - Two-Factor Authentication

- 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



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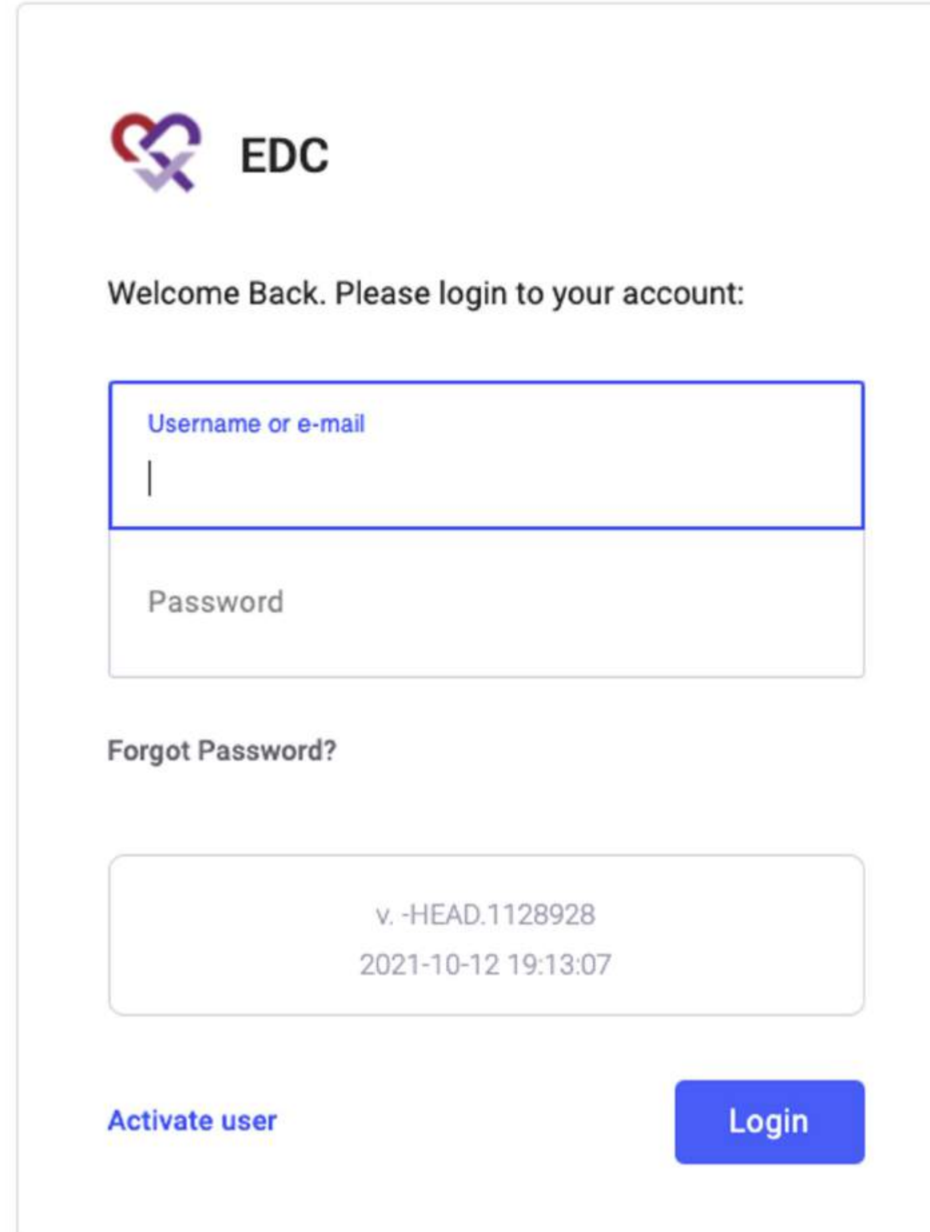
Login - General

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



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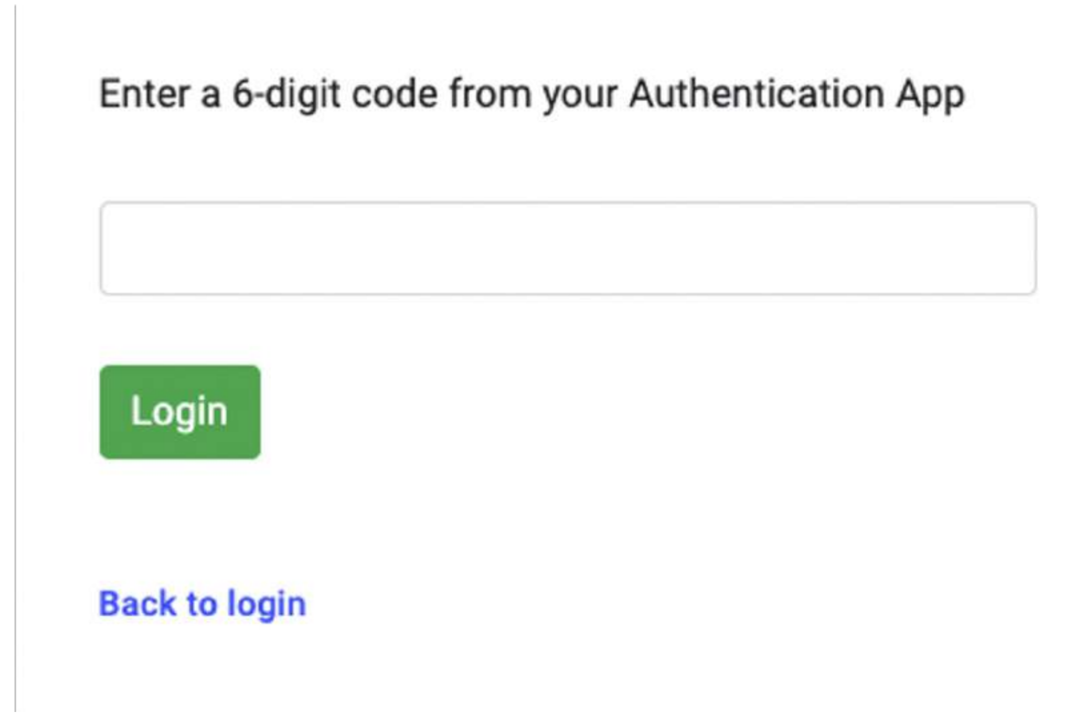
Login - General (2)

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



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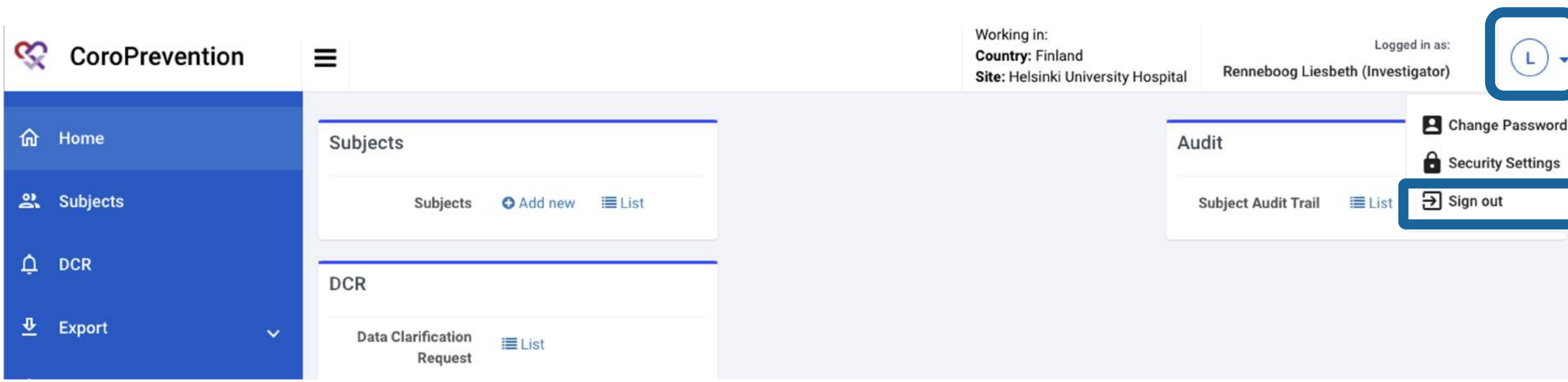
Logout

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

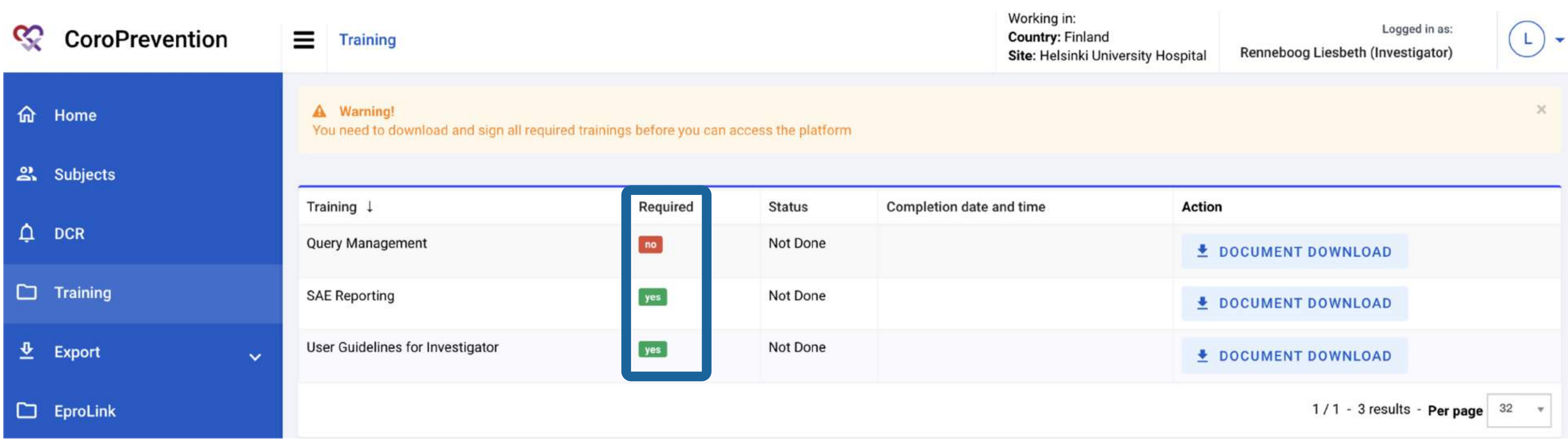


Log out when stepping away from your computer.

Training

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



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

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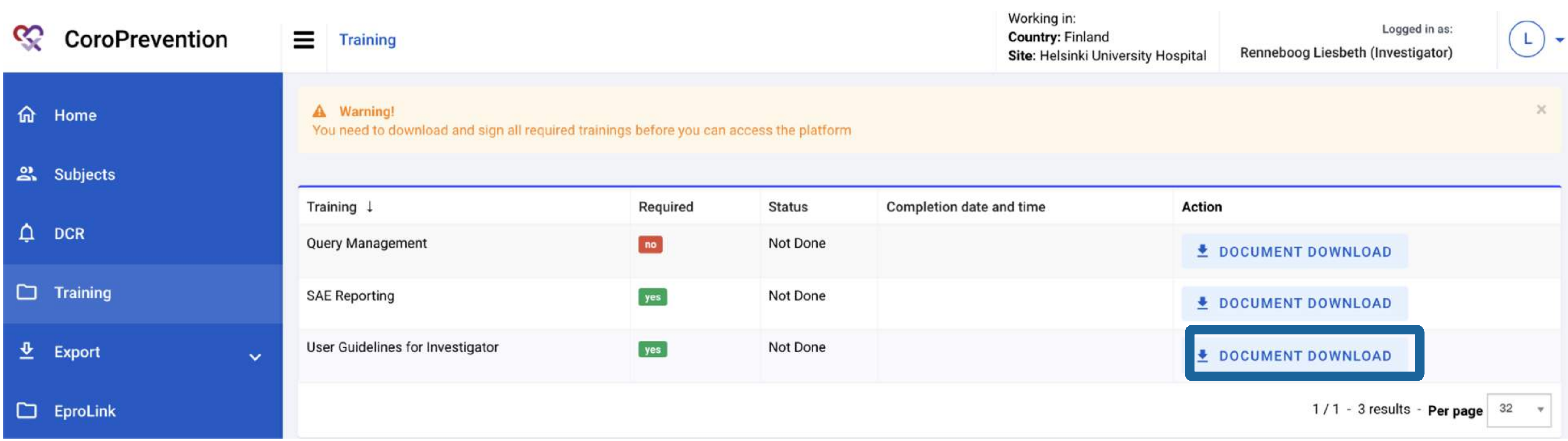
Training - Download

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



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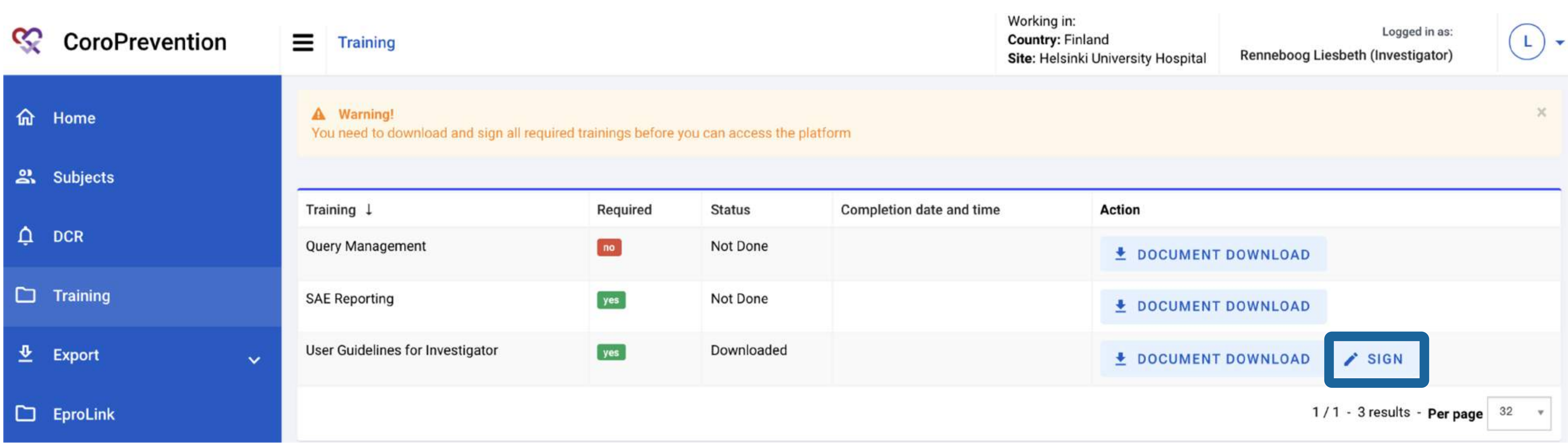
Training - Sign

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



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

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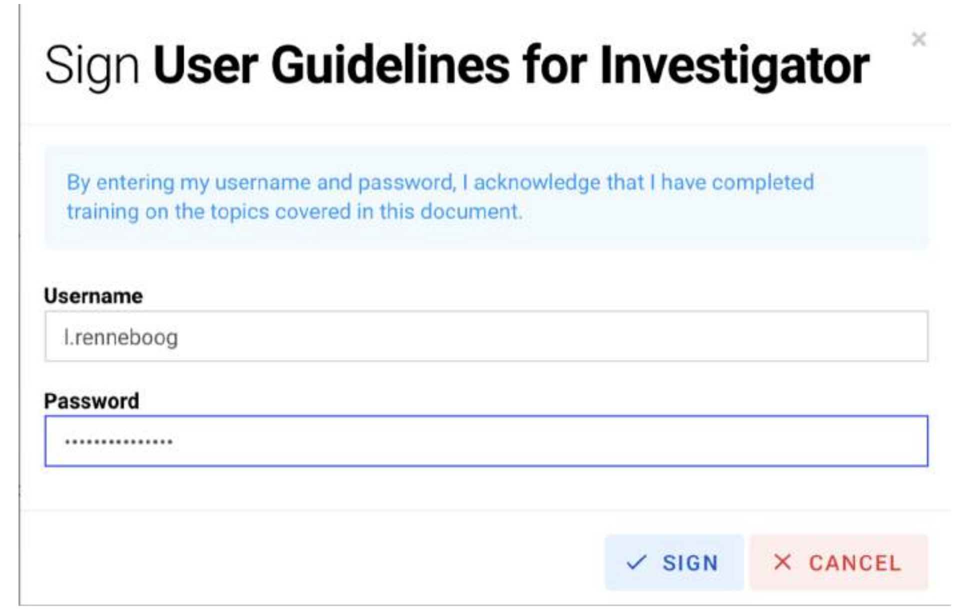
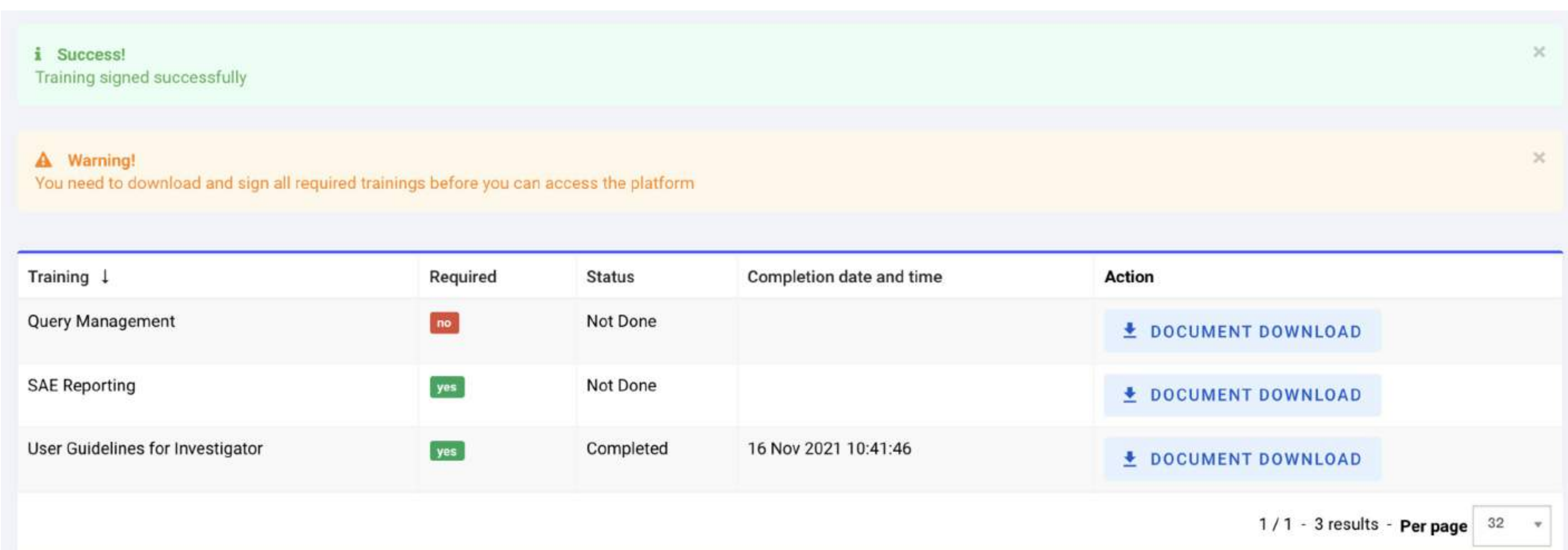
Training - Sign (2)

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





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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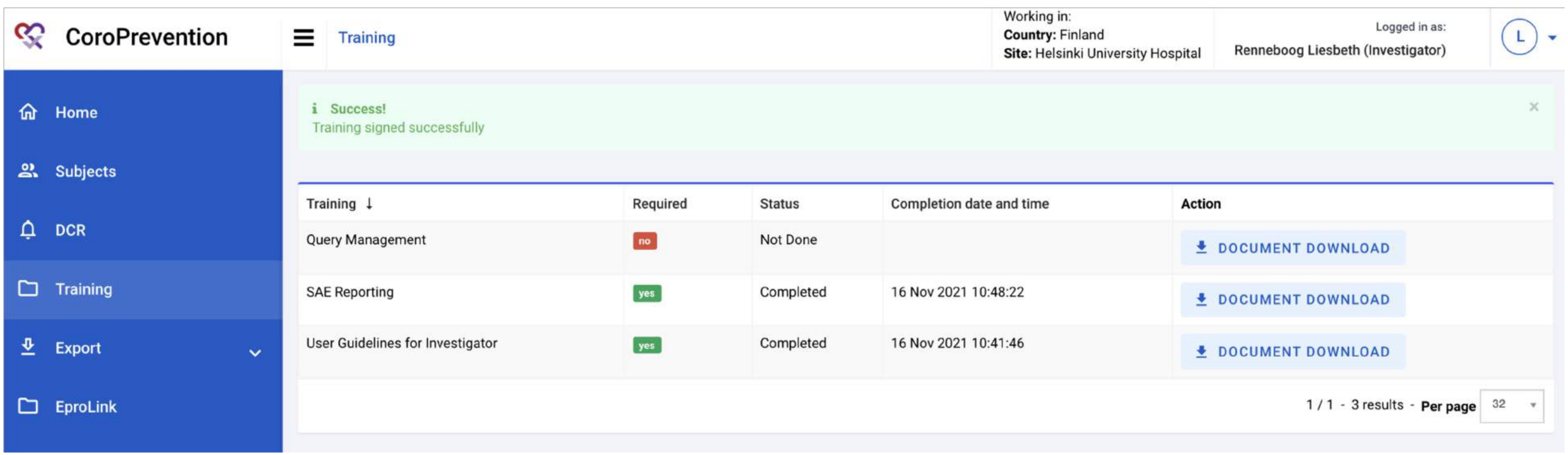
Training - Access

- 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



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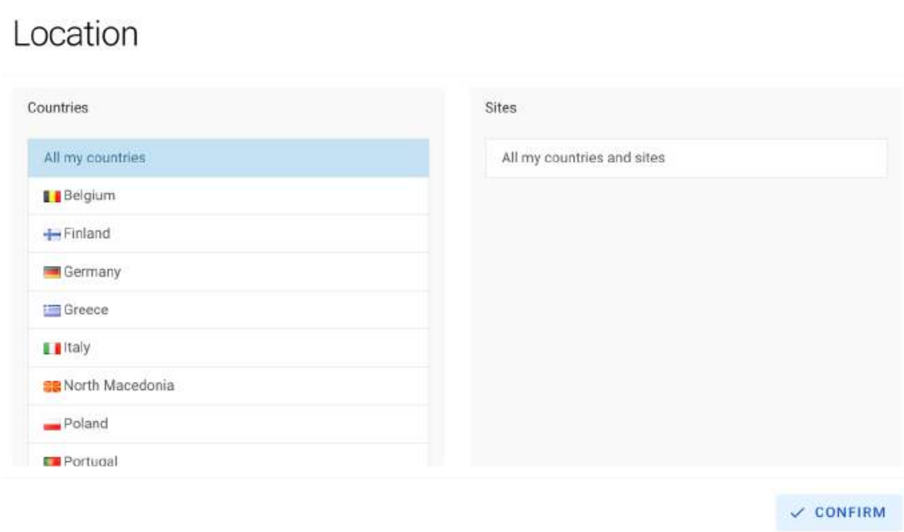
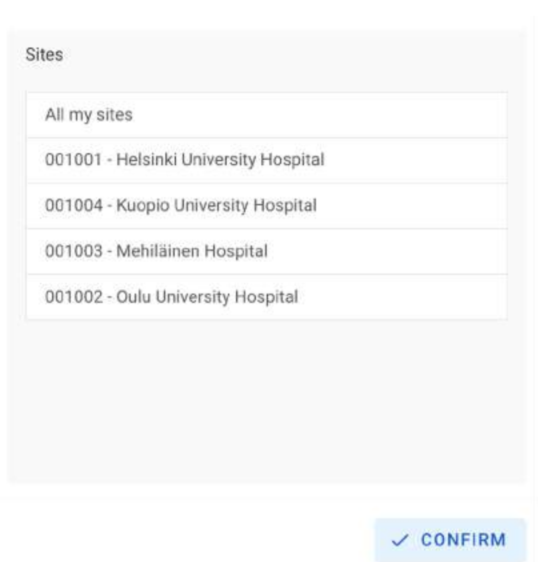
Navigation

Navigation - Location Select

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



- Or to more than one site:



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.

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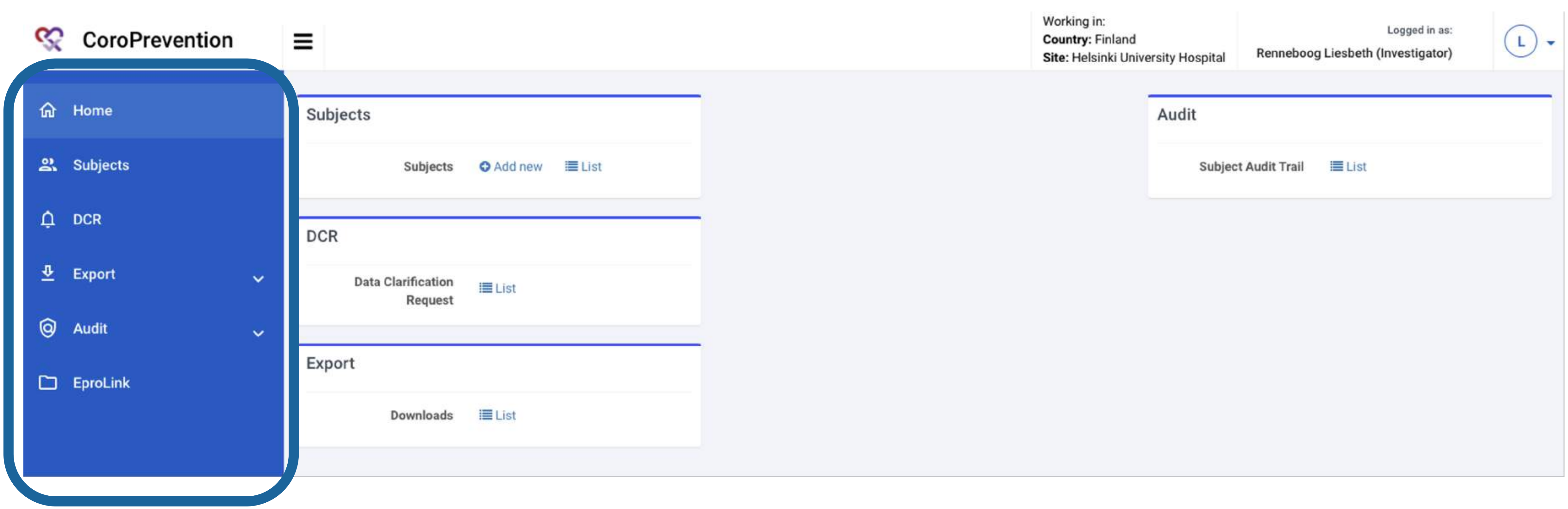
Navigation - Bar

- 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



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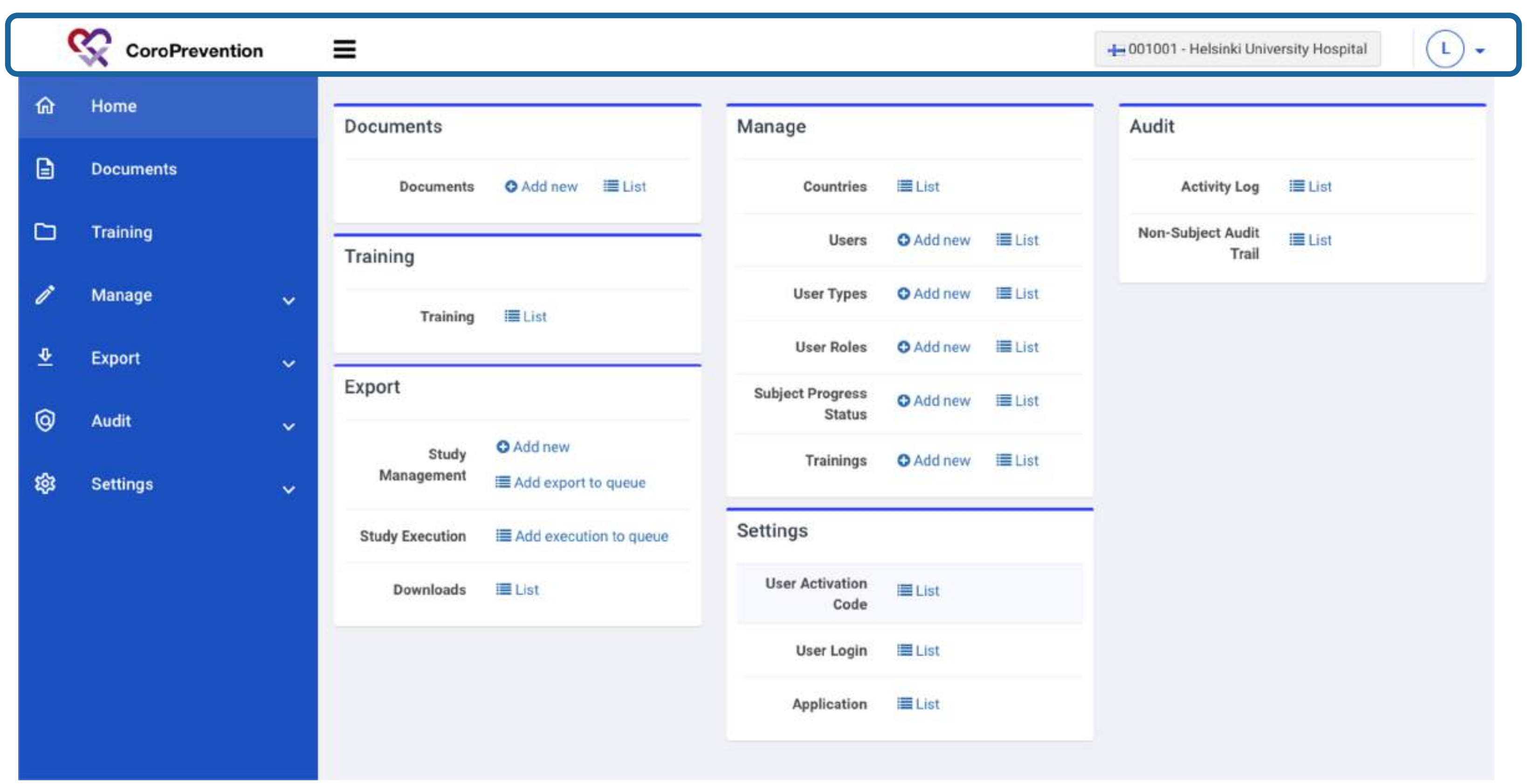
Navigation - Access Details

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



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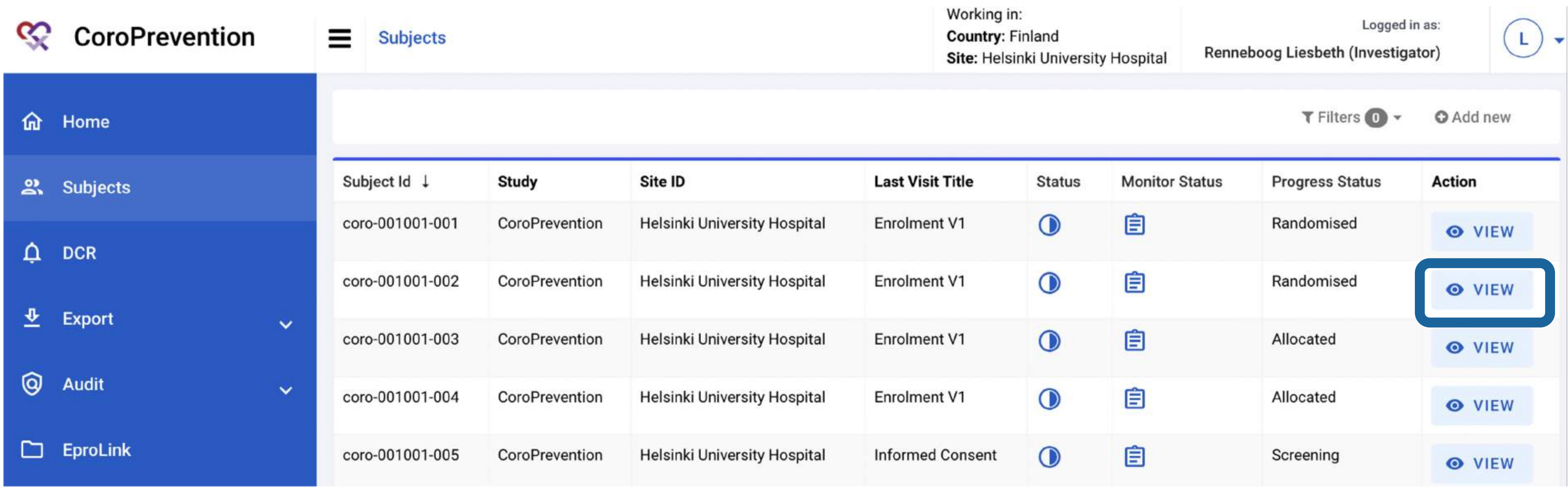
Navigation - Go to Subject

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



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.

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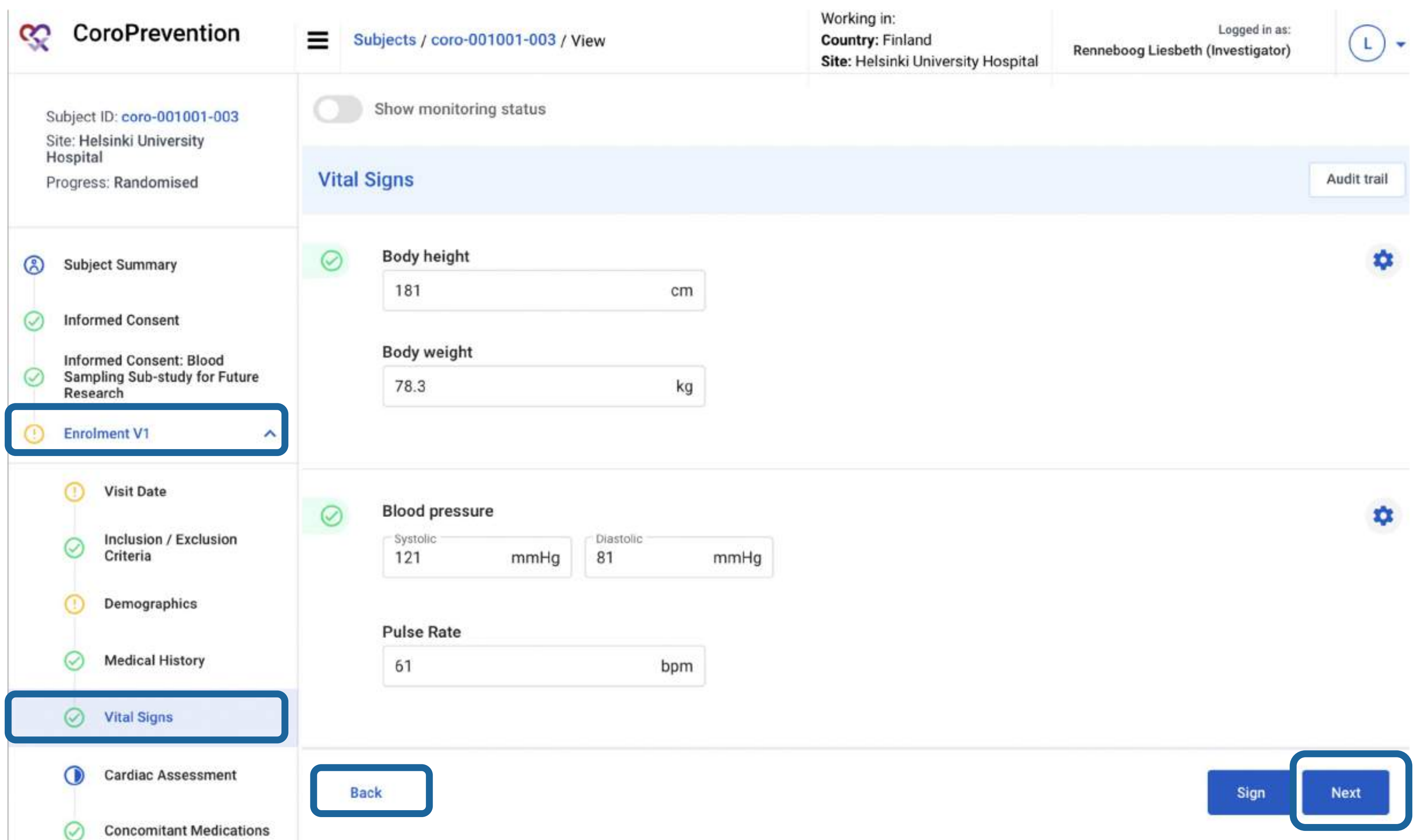
Navigation - eCRF

- 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



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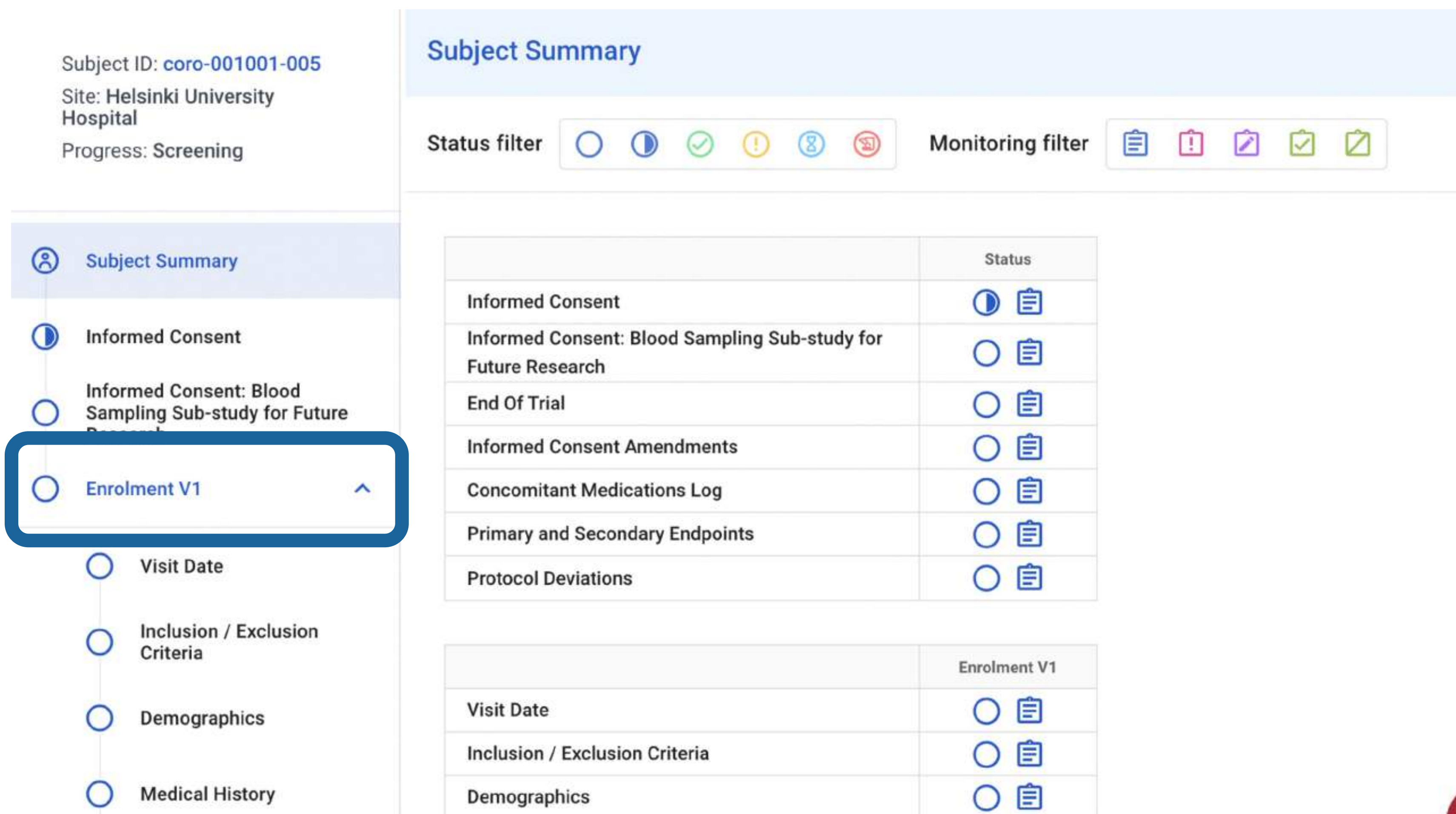
Enter and Edit Data

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



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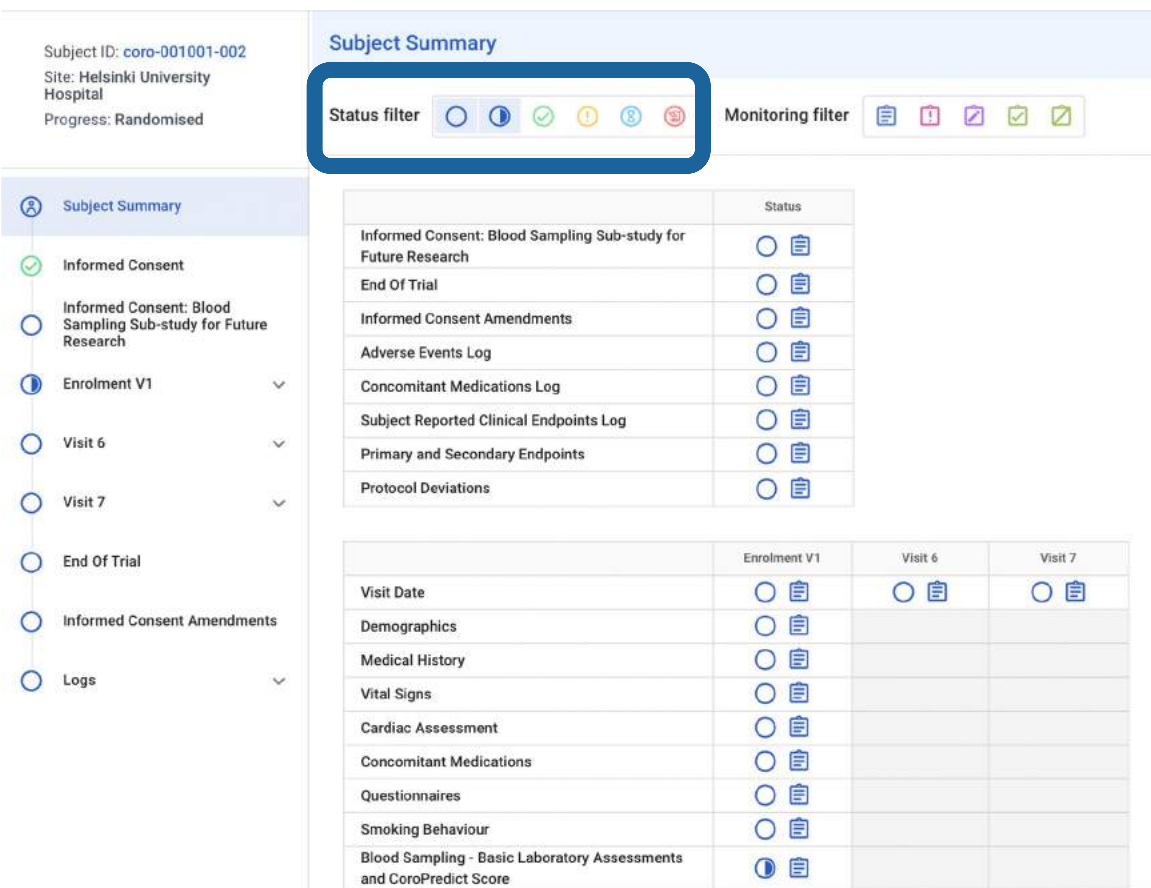
Enter/Edit Data - Subject Summary

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



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.

Enter/Edit Data - Status Icons

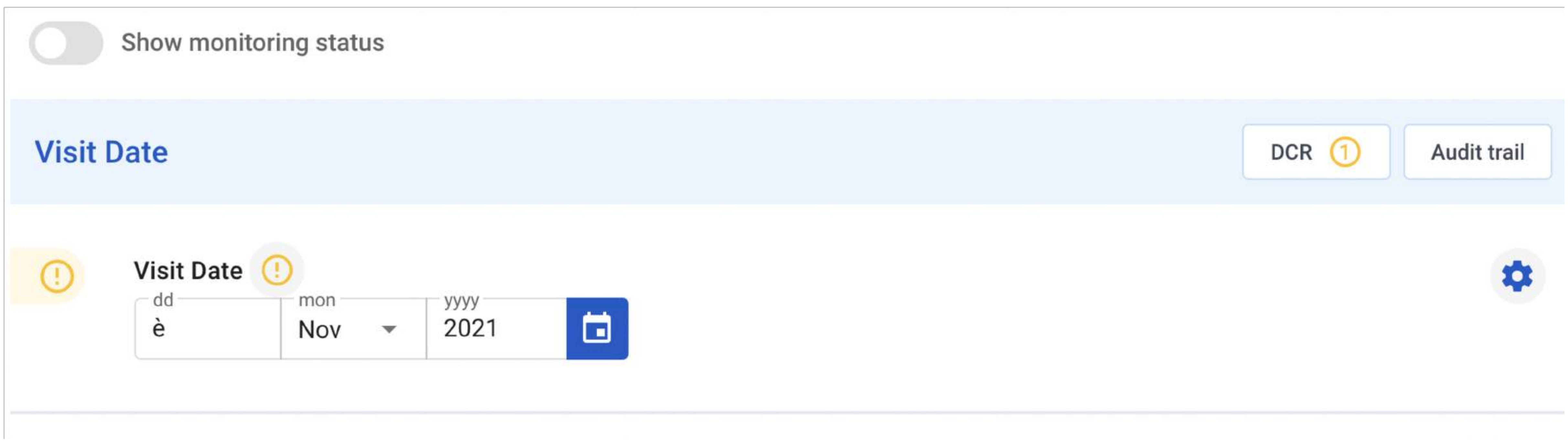
Status Icons indicate the data entry status of a subject/visit/form/block:

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



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

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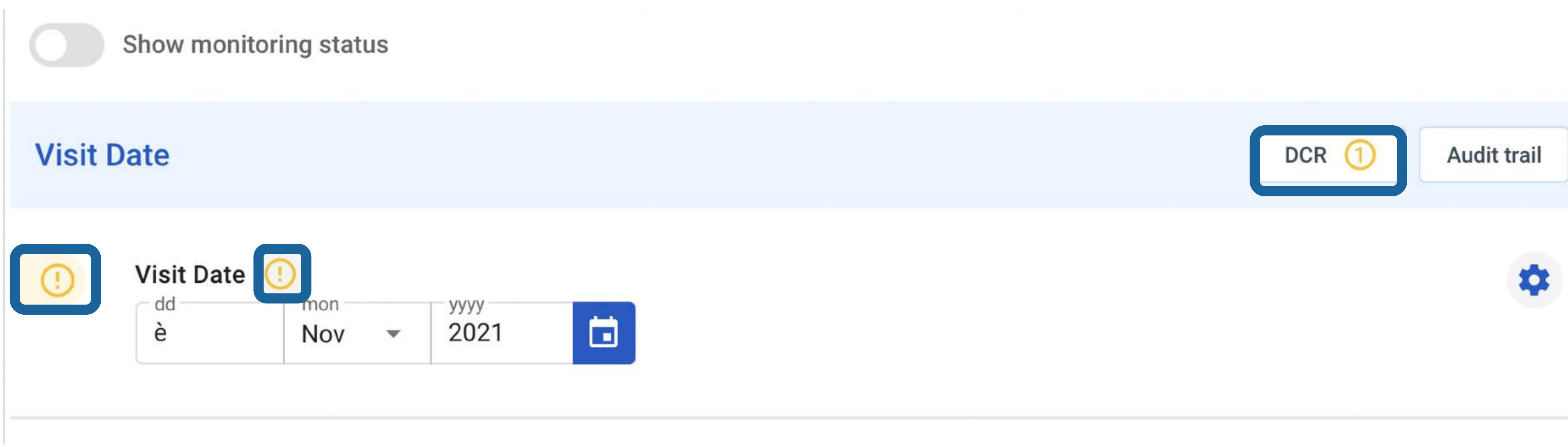
Enter/Edit Data - Open DCR

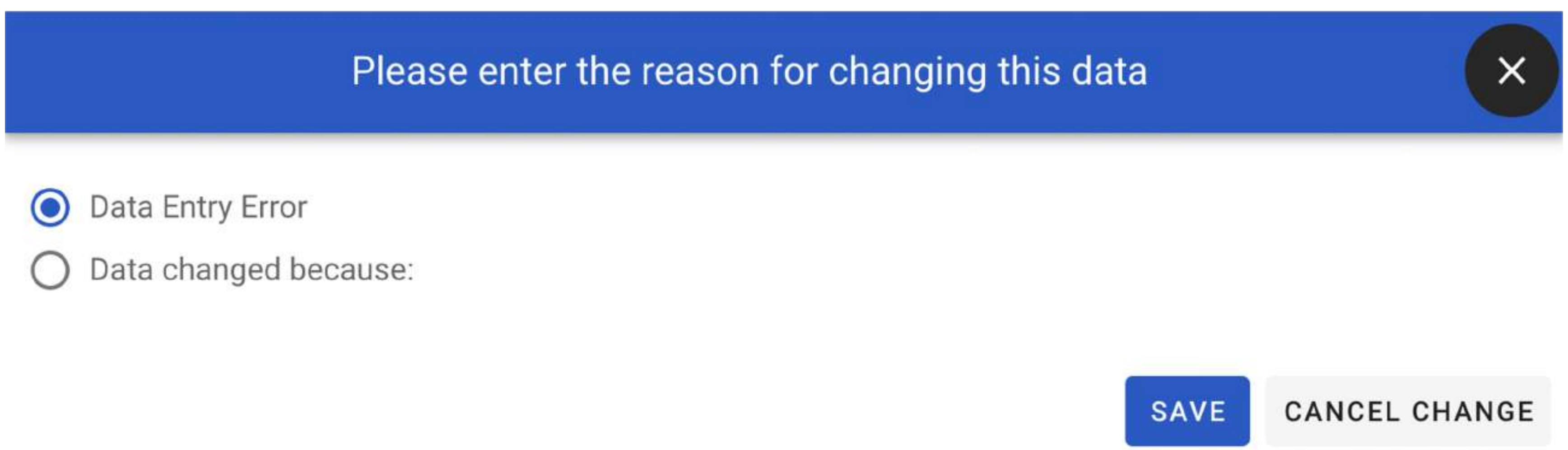
- Hover over the DCR icon next to the field label to view the DCR message
- Or open the DCR by clicking the DCR icon or the DCR button



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



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

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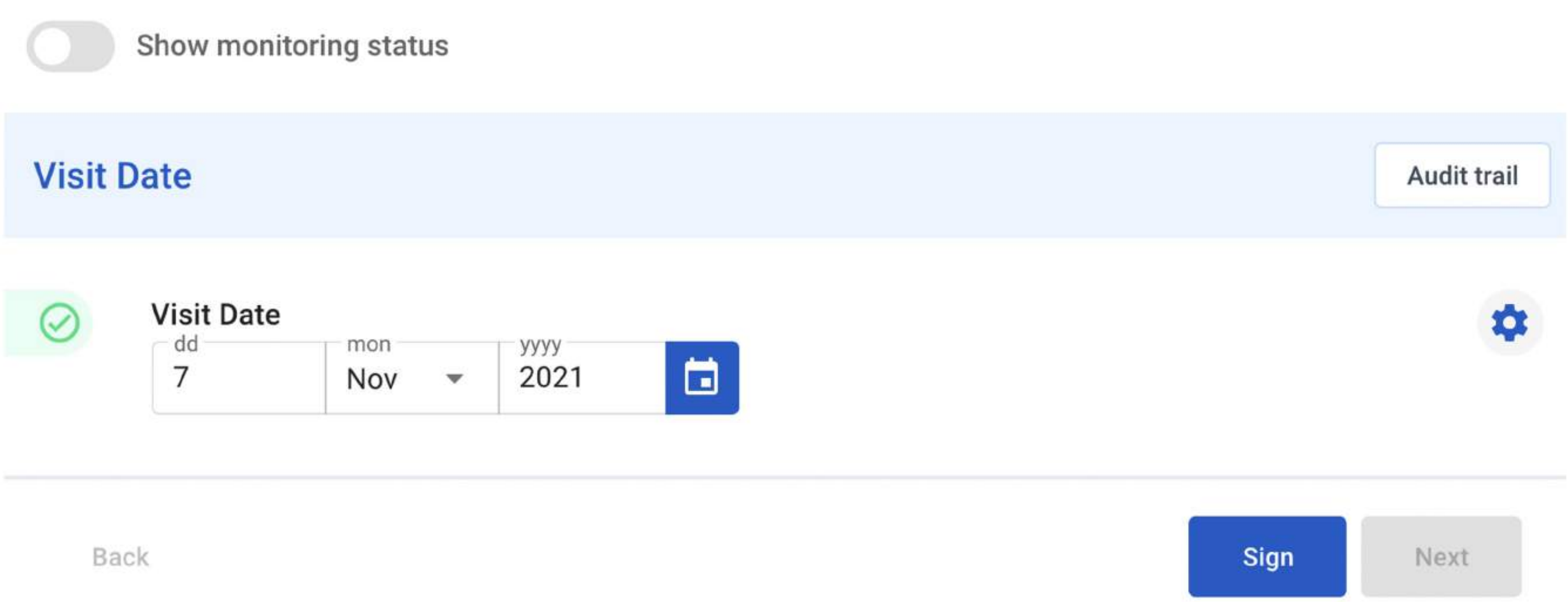
Enter/Edit Data - Edit (2)

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

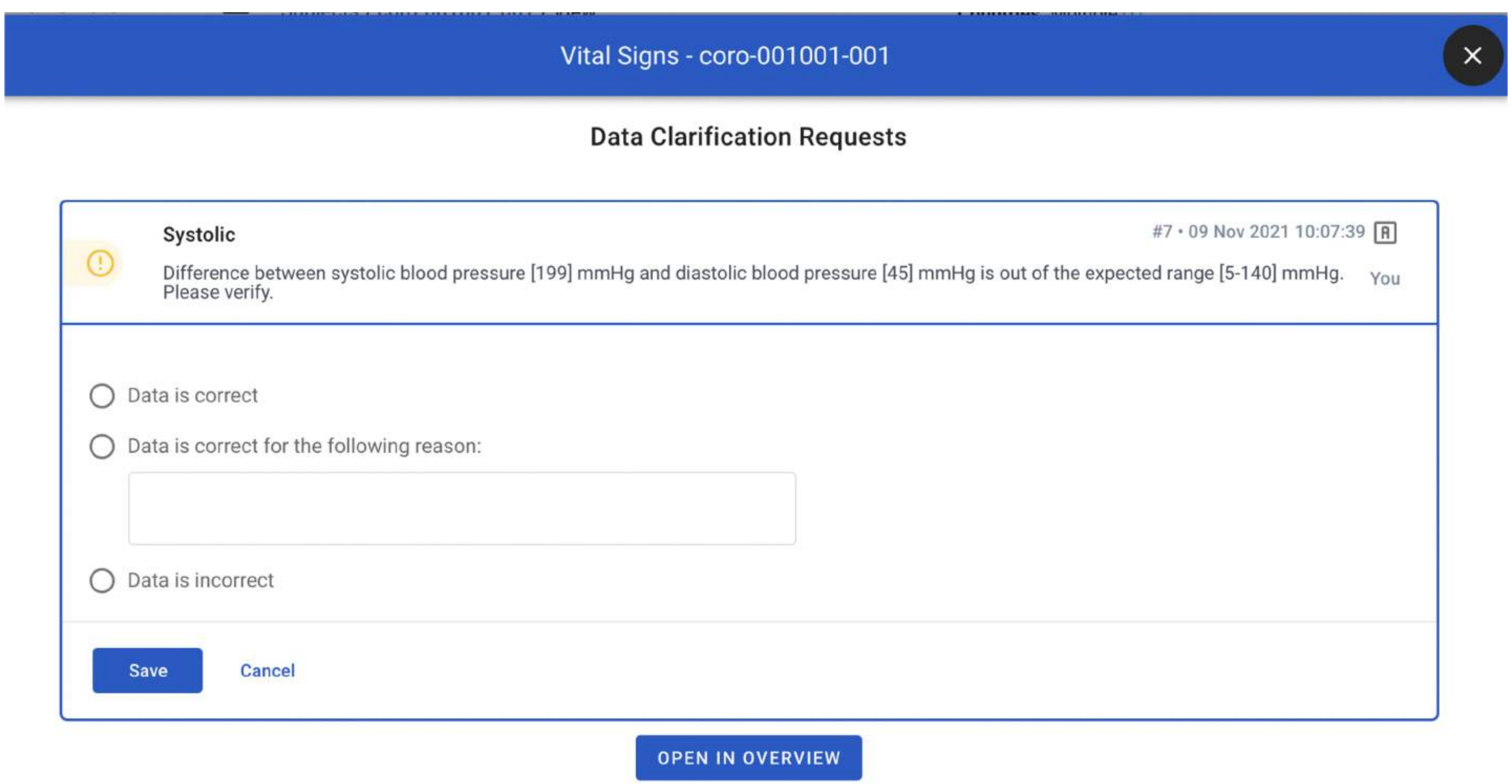
- Automatic DCRs are closed automatically if they are no longer applicable



Enter/Edit Data - Answer DCR

Provide an answer to a DCR if applicable:

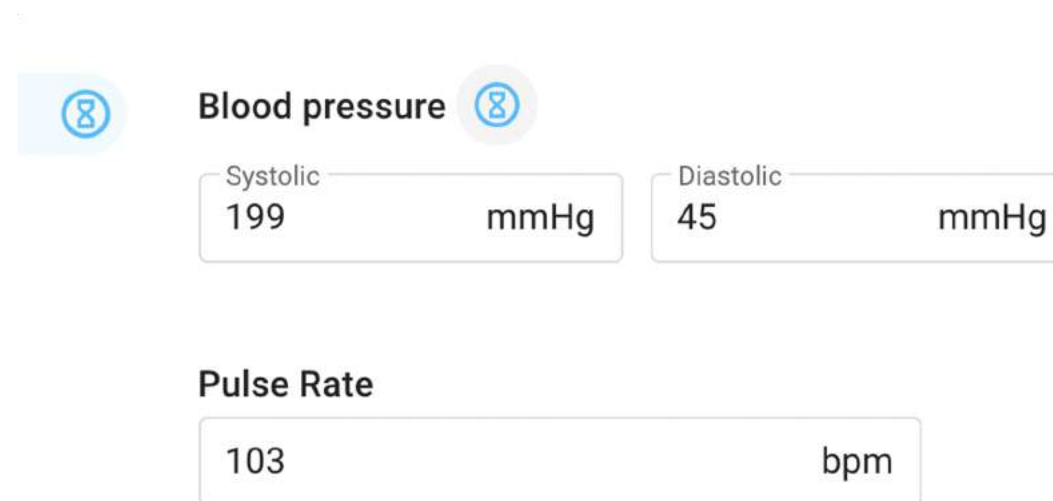
- Open the DCR by clicking the icon on the left or the button on top
- Select or provide a custom answer and click Save



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)



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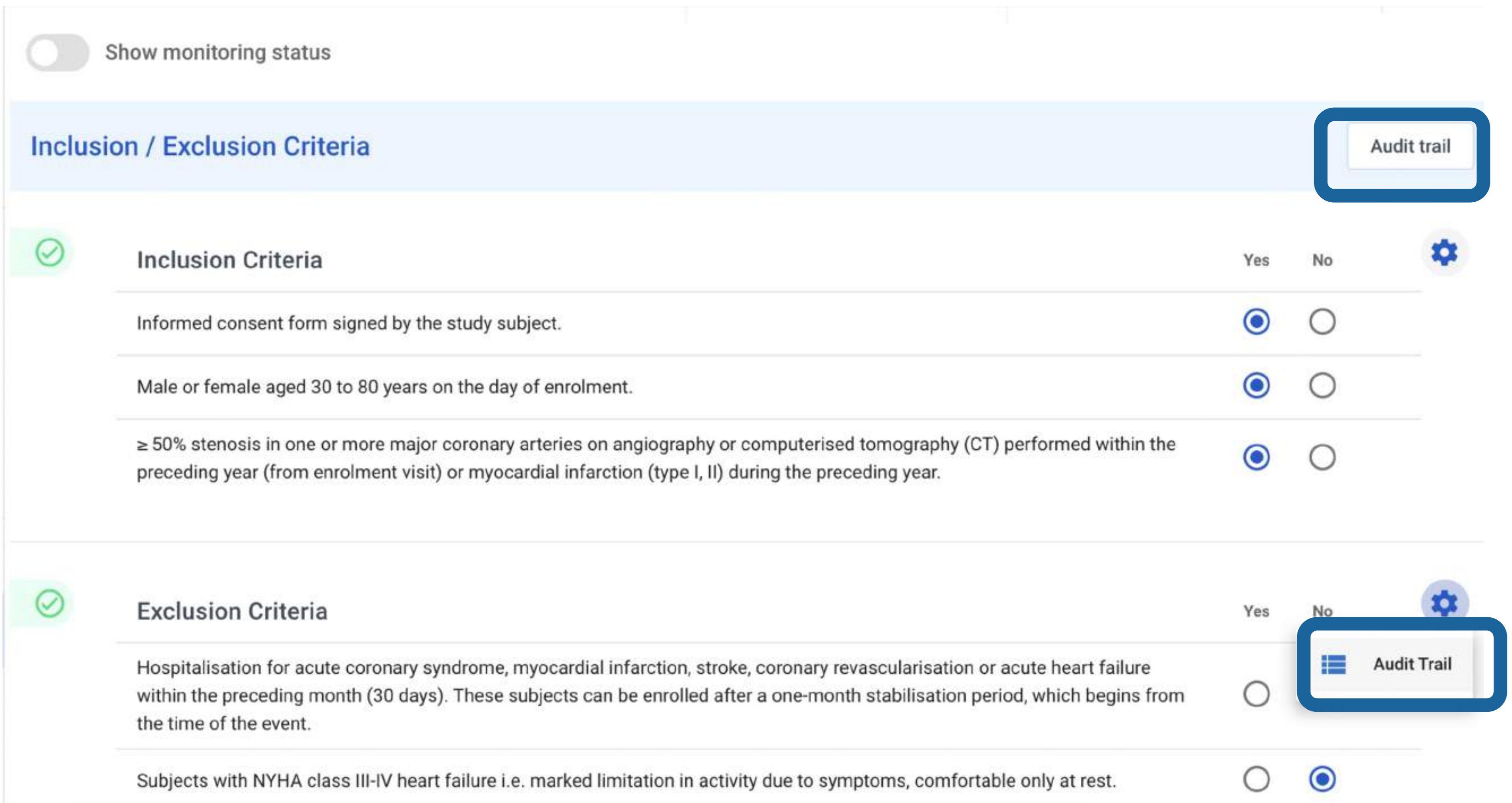
Enter/Edit Data - Audit Trail

All data entry is logged in the audit trail

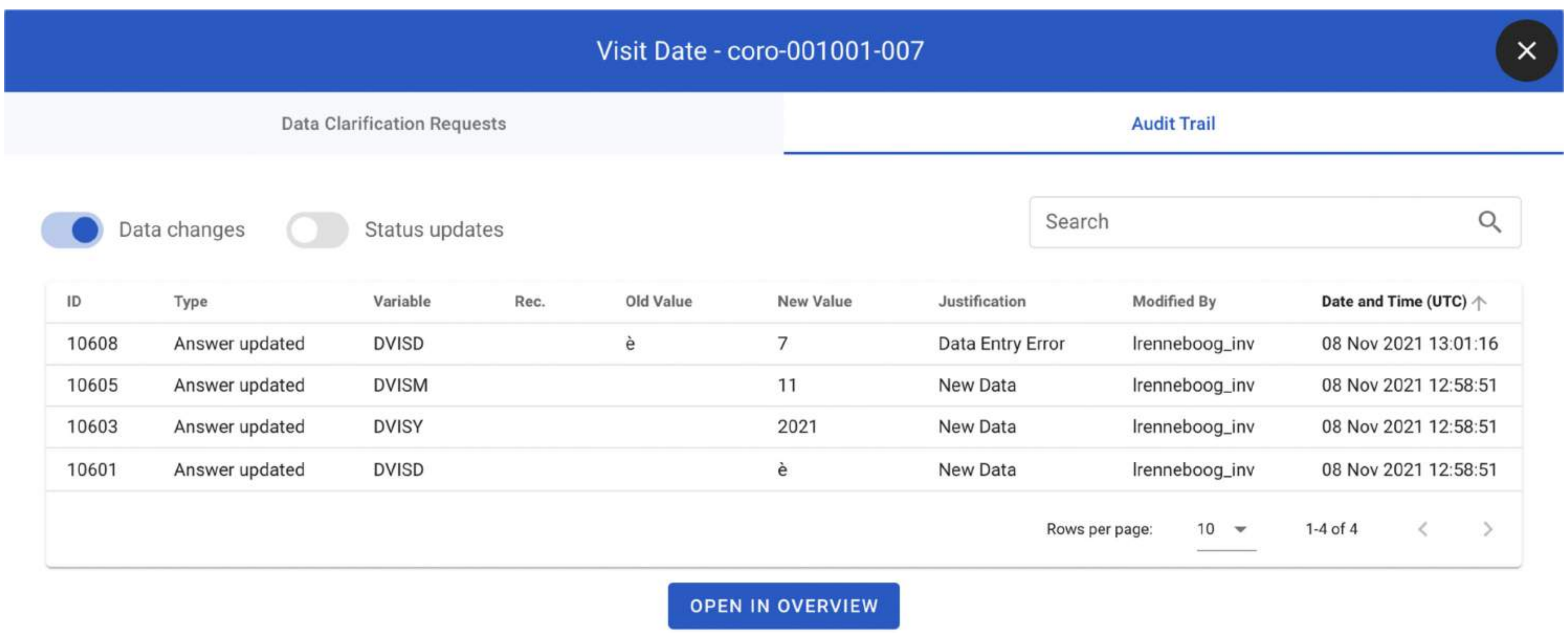
- Click the “Audit trail” button to view the audit trail for the entire form
- Click the cog wheel and then “Audit Trail” to view the audit trail for the block of fields



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



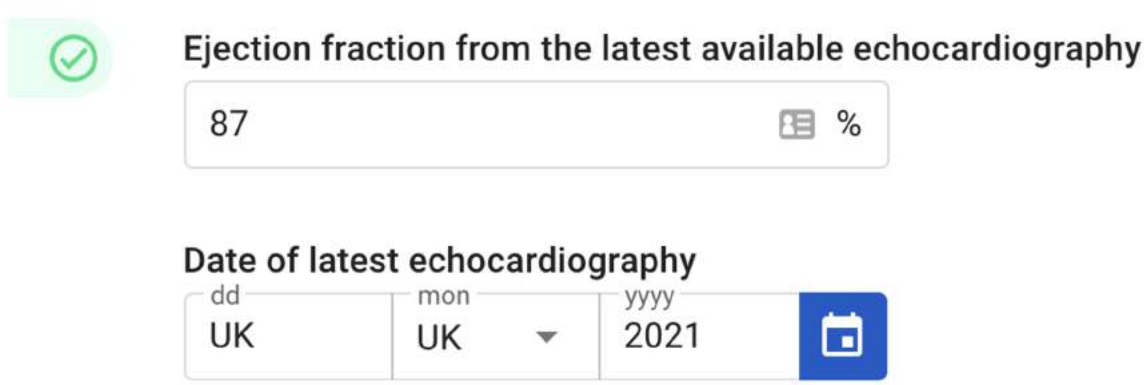
Enter/Edit Data - Required Data

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.

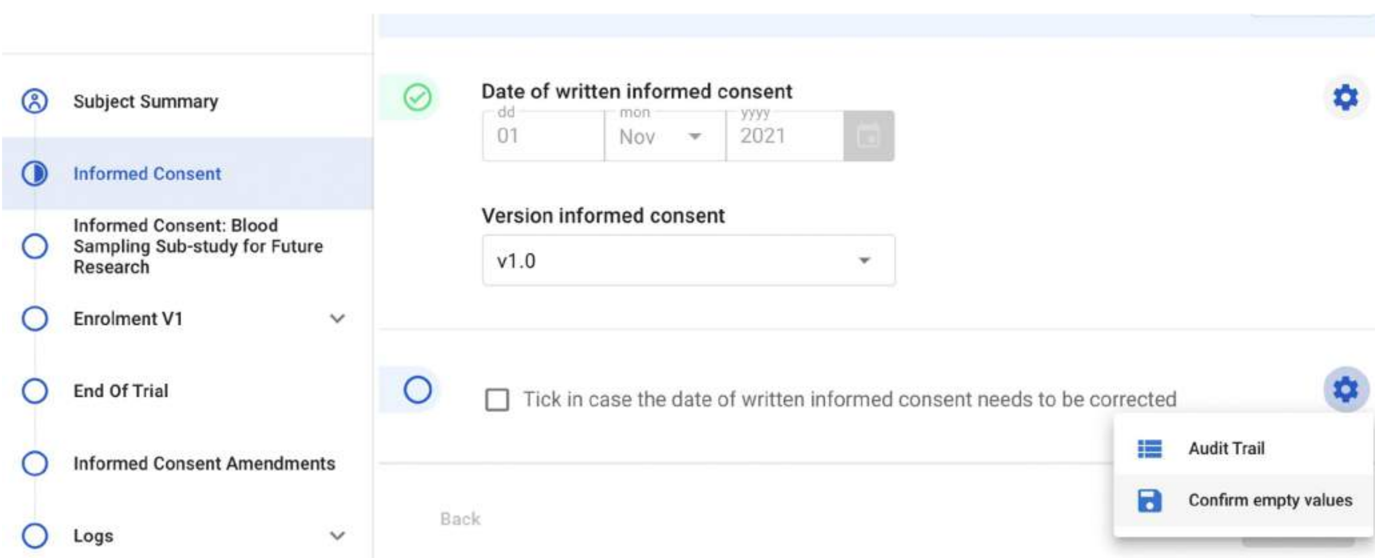


Enter/Edit Data - Confirm Empty Values

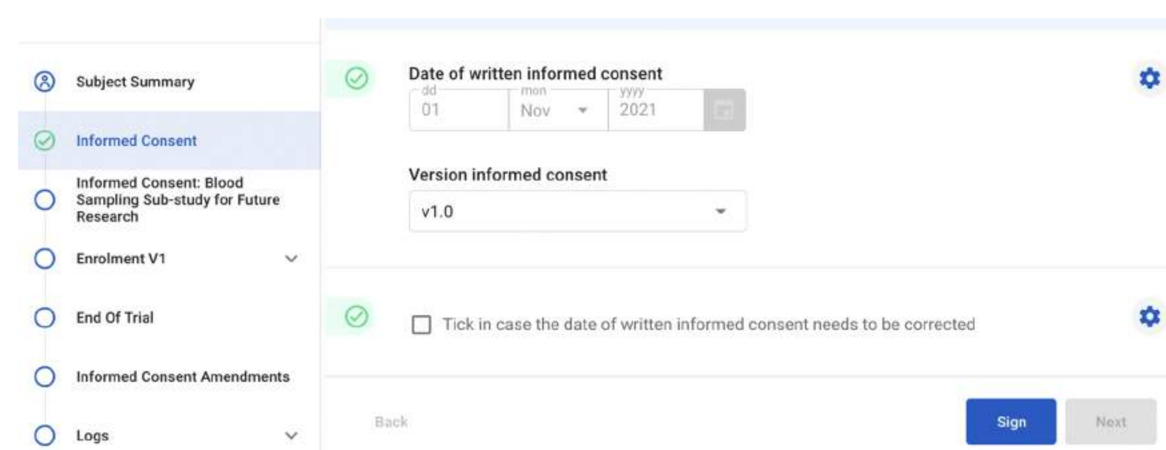
Notable exception (2):
- check box fields with only one option
e.g. ‘Tick in case the date of written informed consent needs to be corrected’

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.

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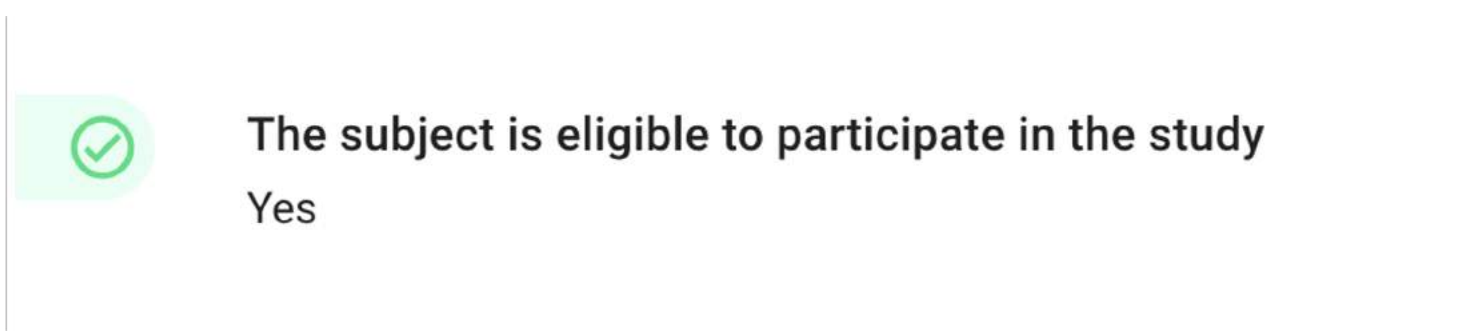
Enter/Edit Data - Calculated Fields

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



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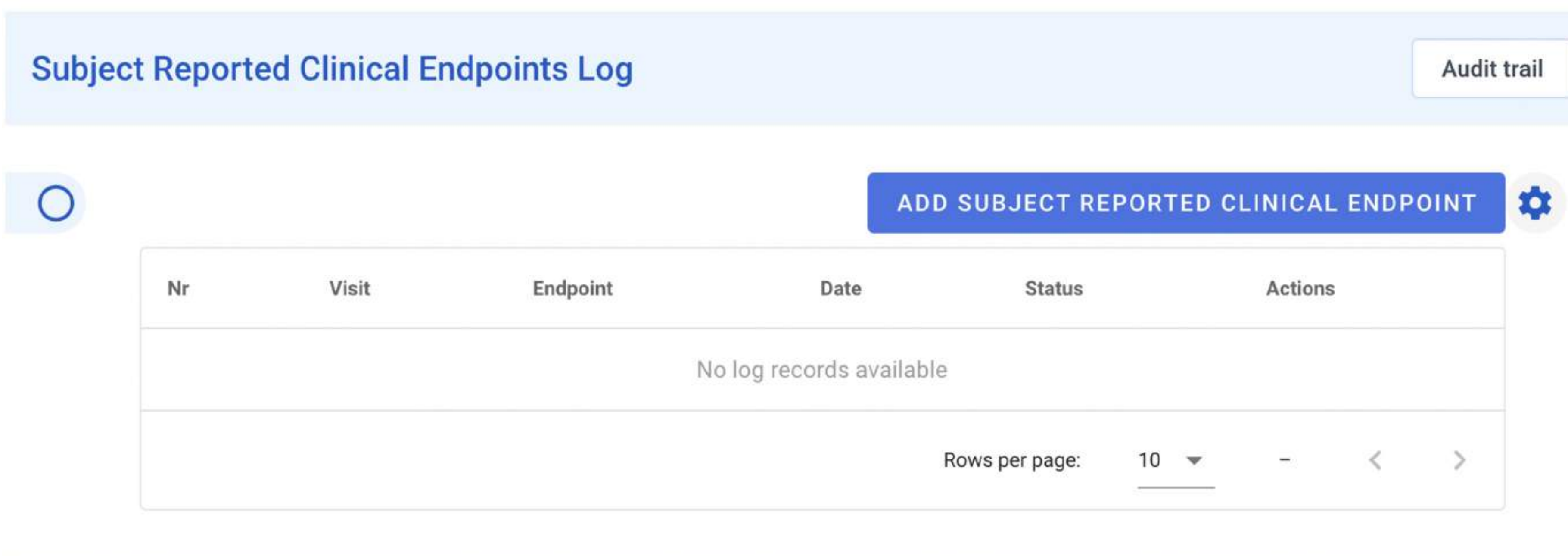
Enter/Edit Data - Log Forms

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



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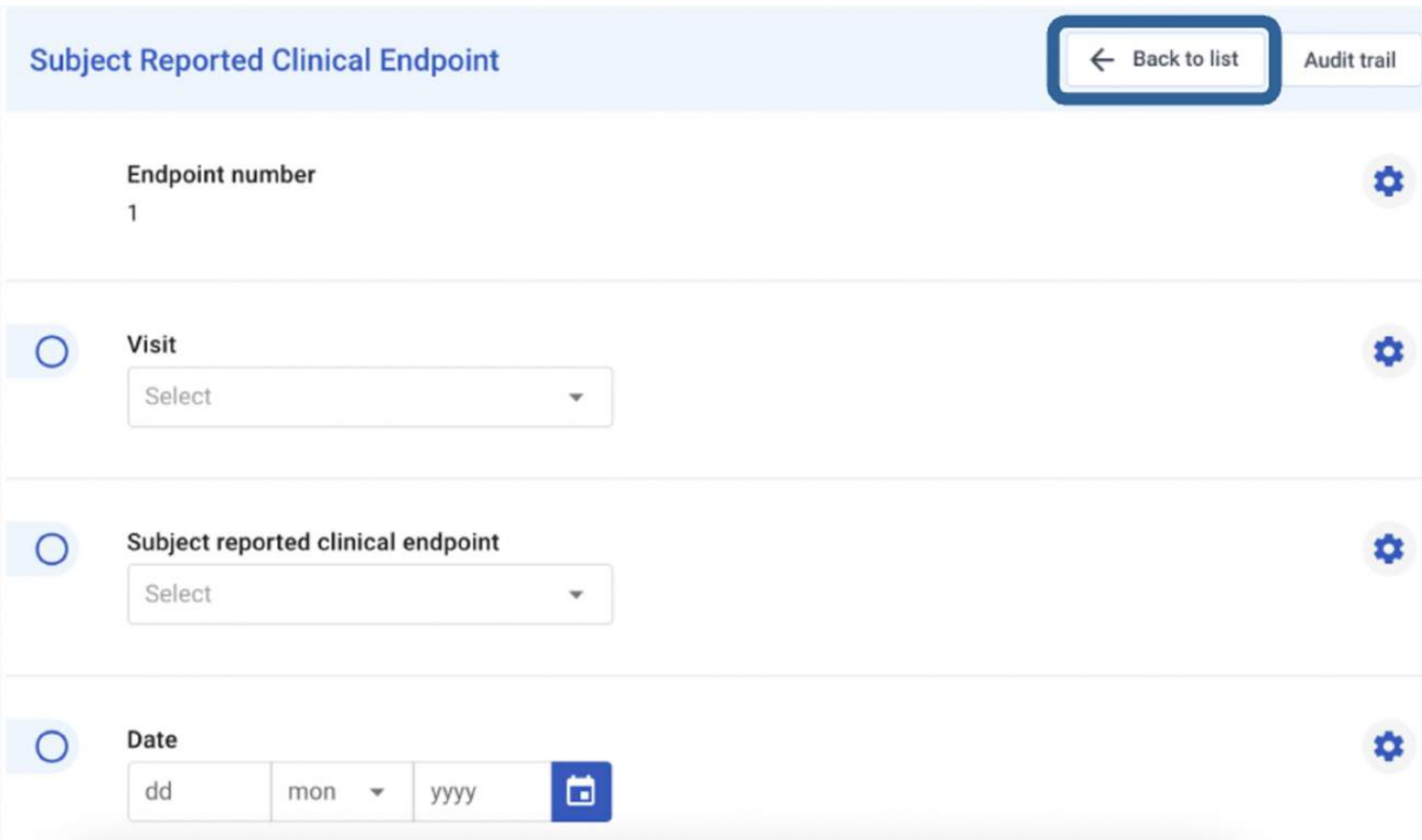
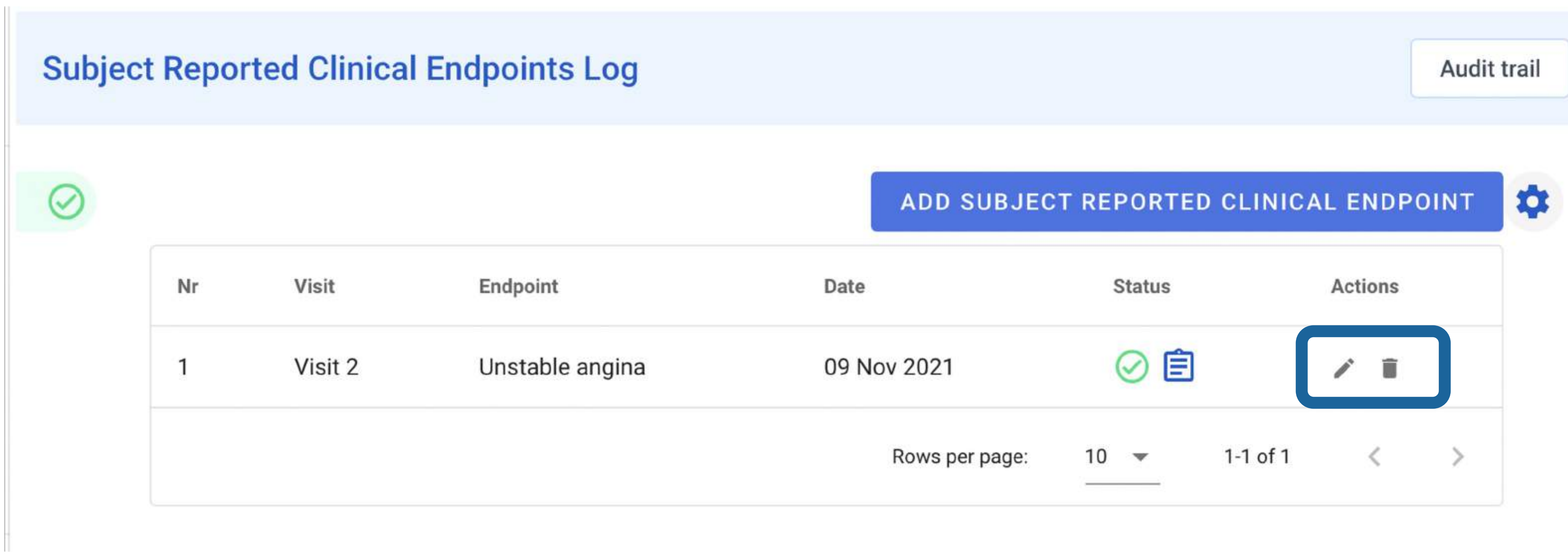
Enter/Edit Data - Log Forms (2)

- 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



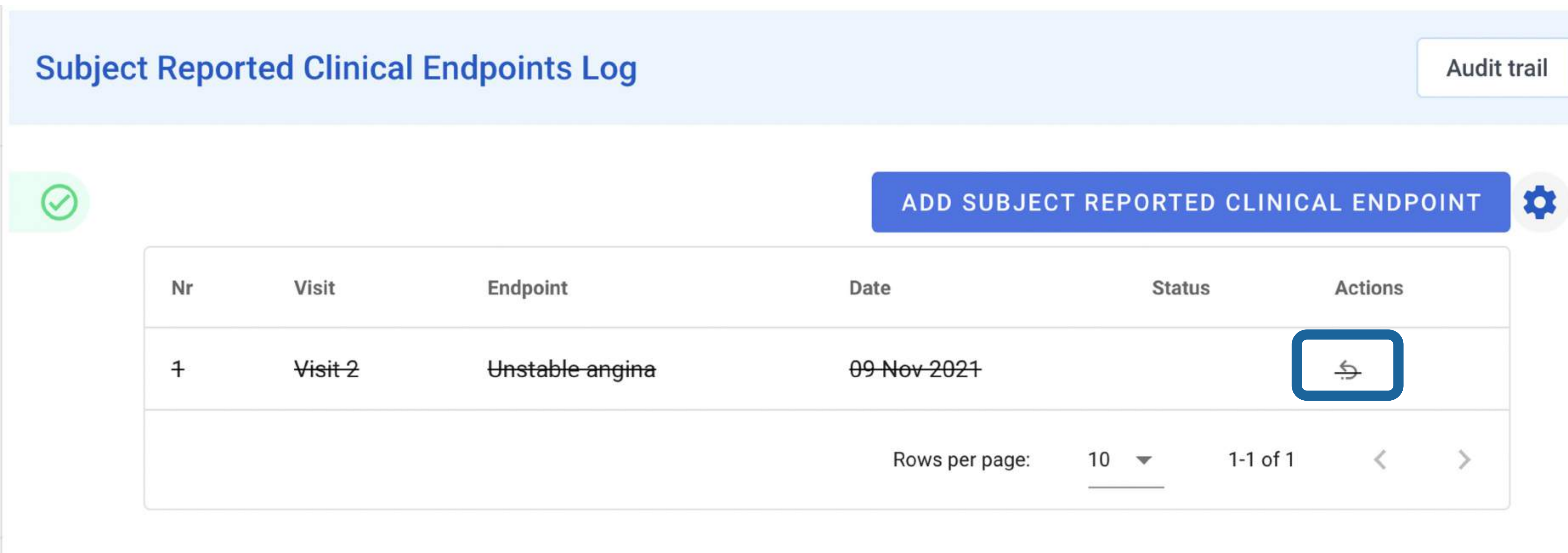
Enter/Edit Data - Log Forms (3)

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



Enter/Edit Data - Log Forms (4)

- Click the arrow to reactivate the deleted record



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

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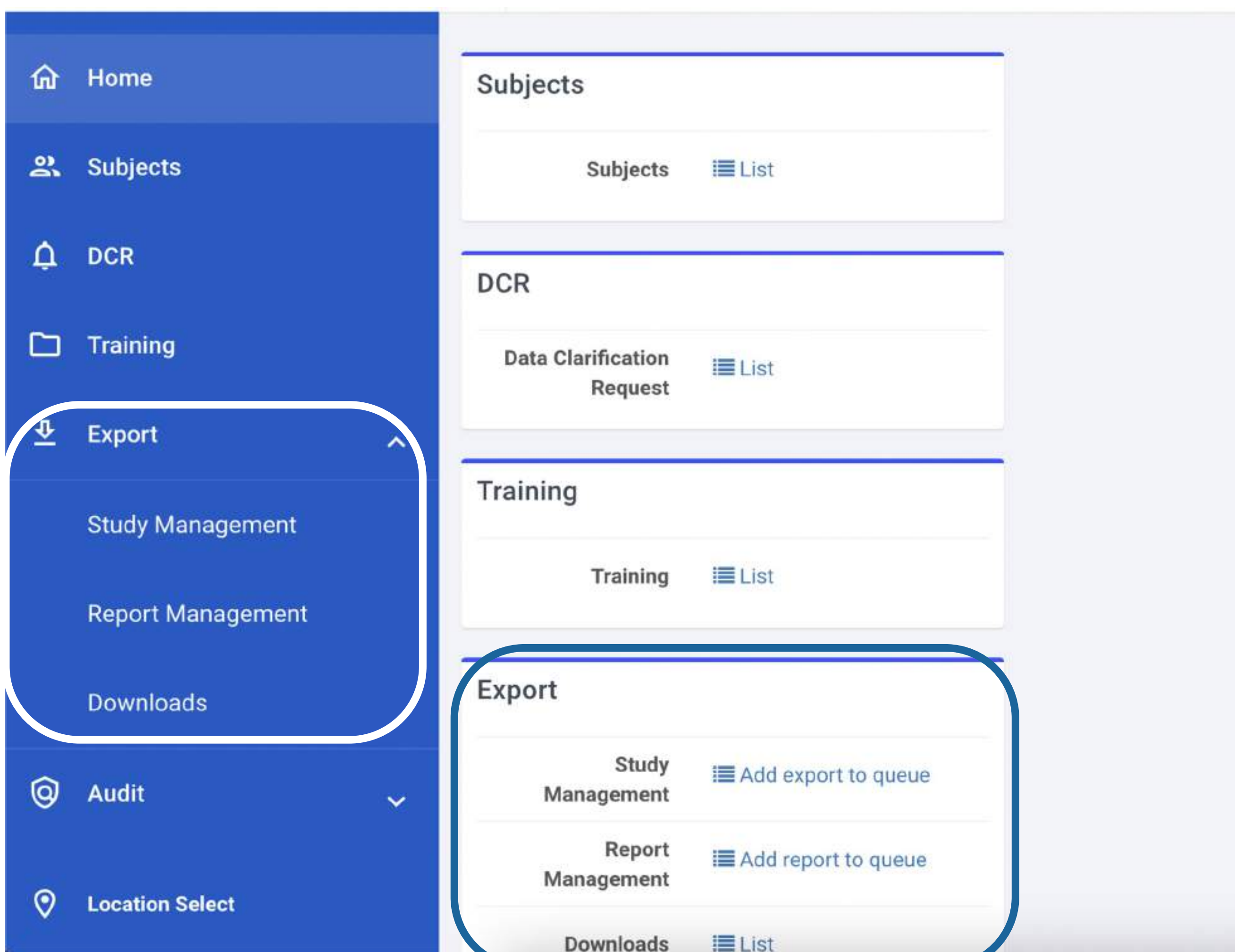
Reports

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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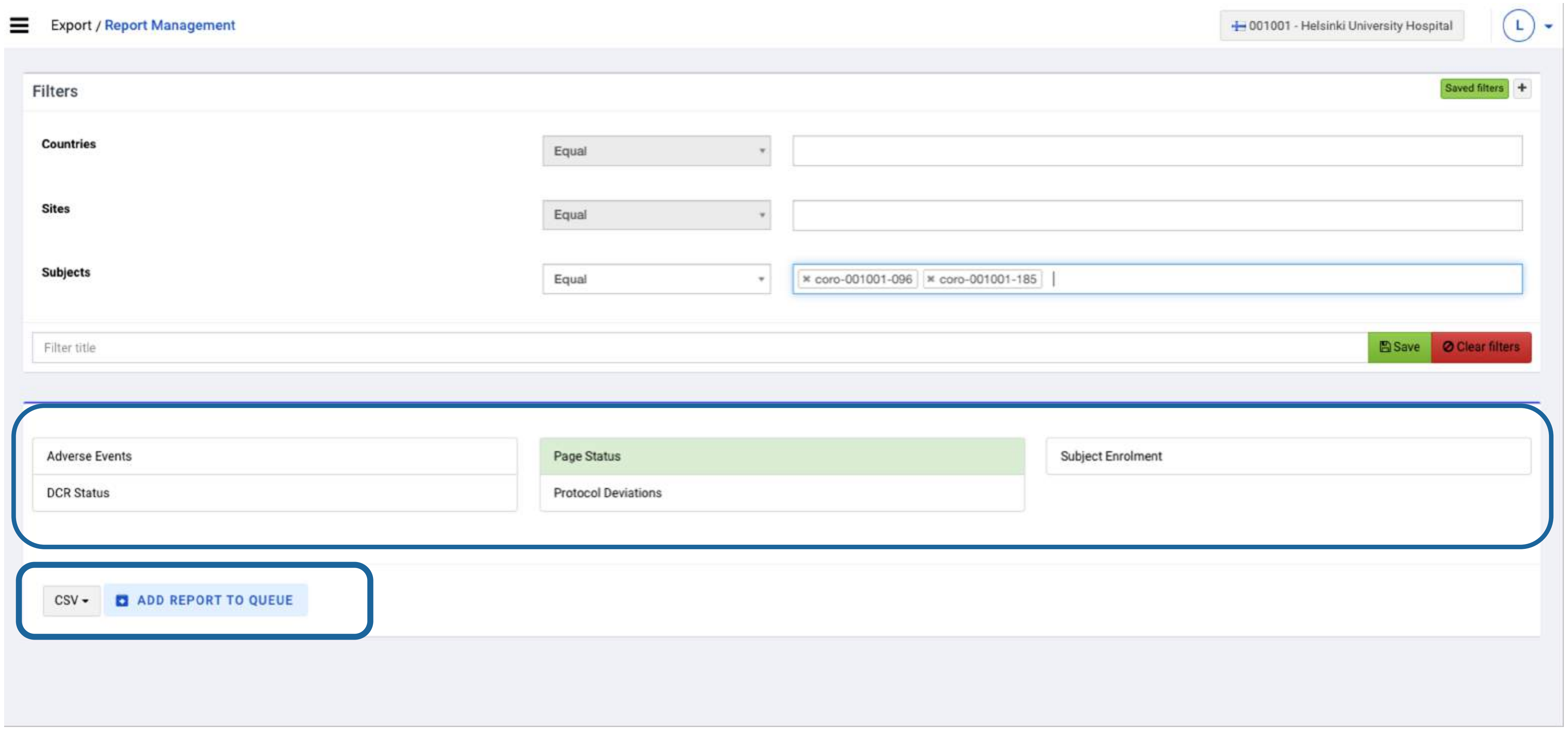
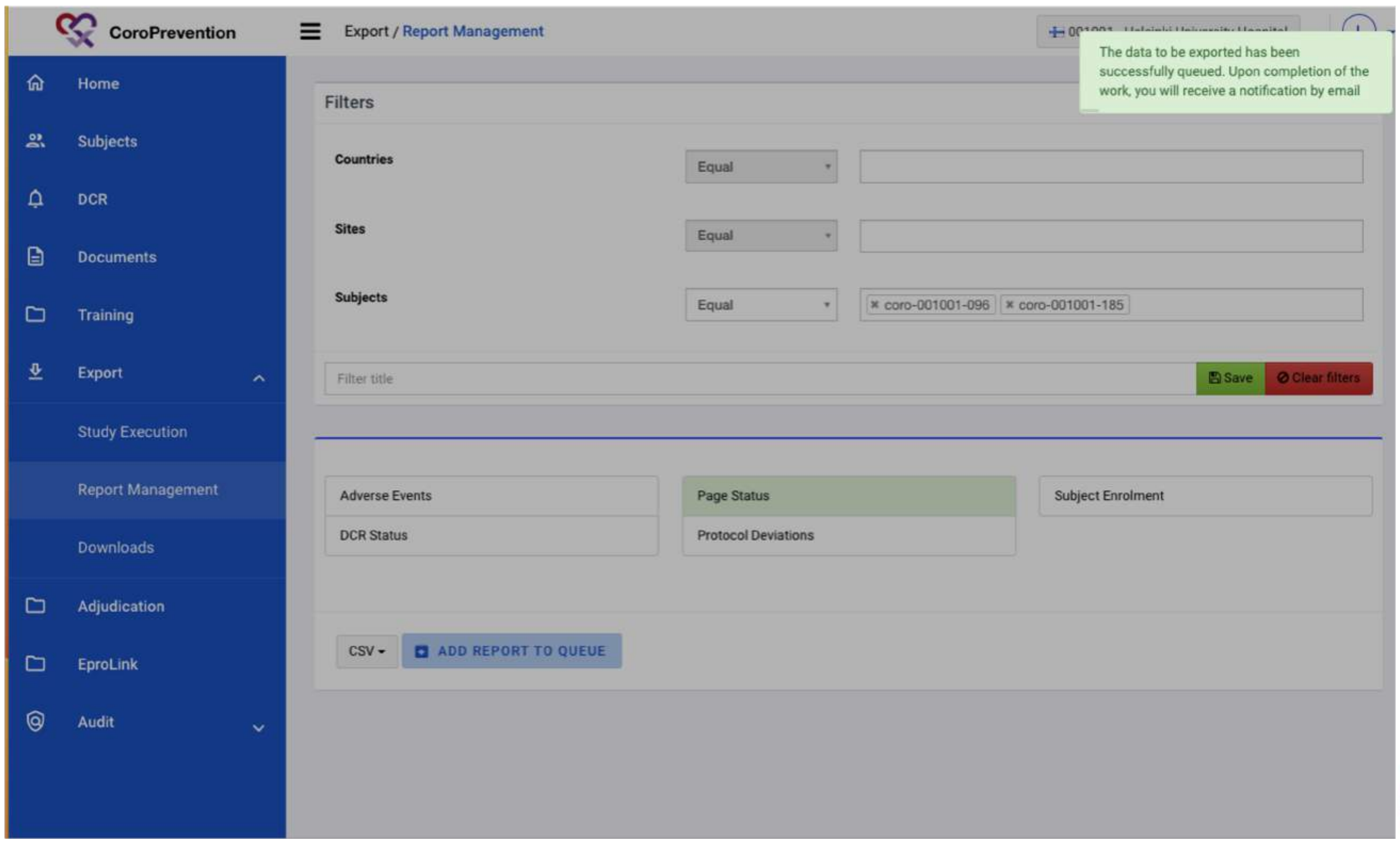
Reports - Generation

- 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



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



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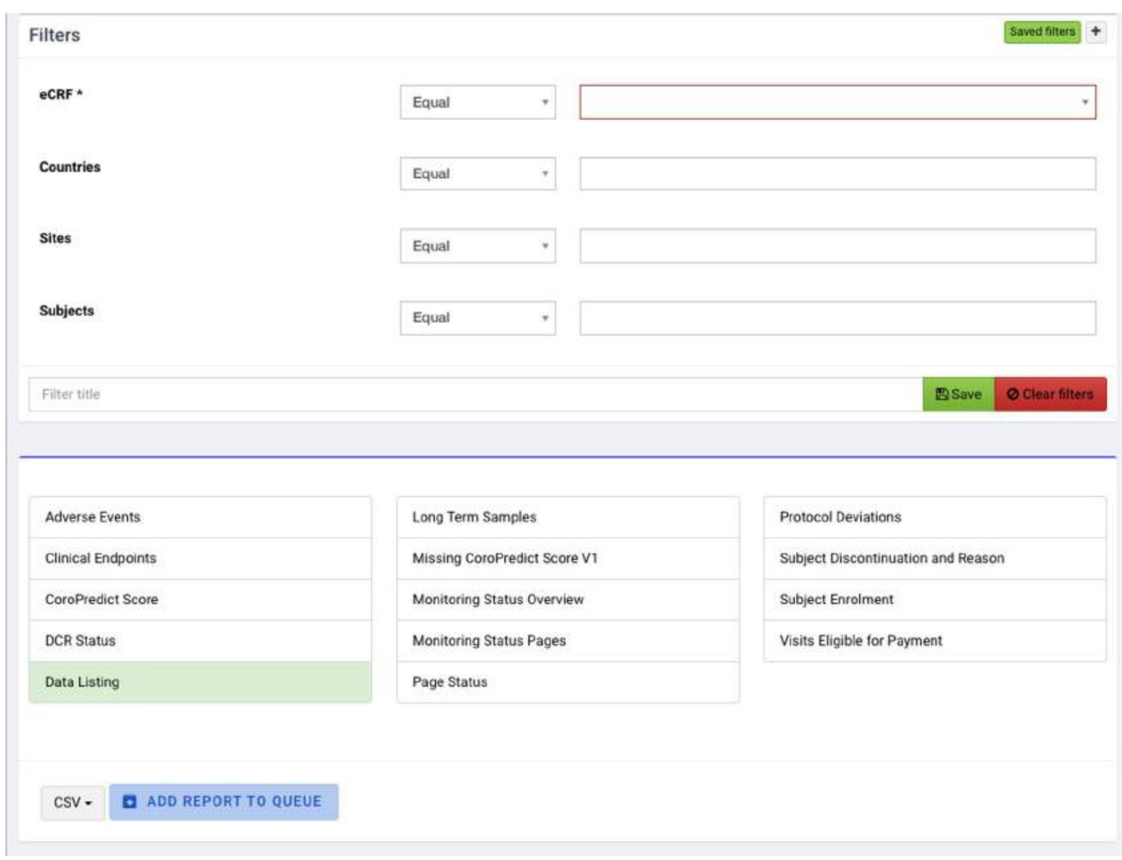
Reports - Filters

- 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



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

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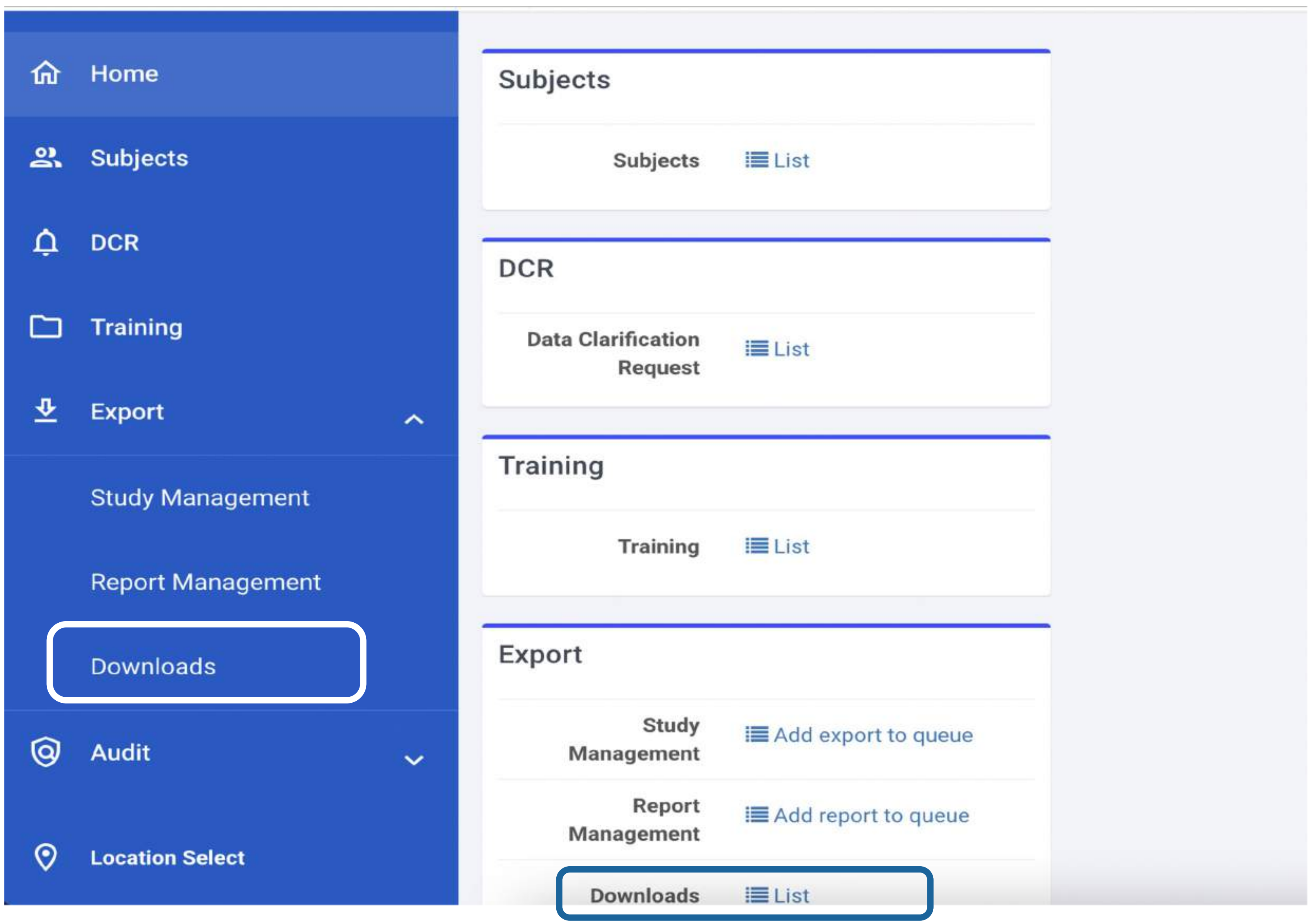
Reports - Download

- 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

Filters 0

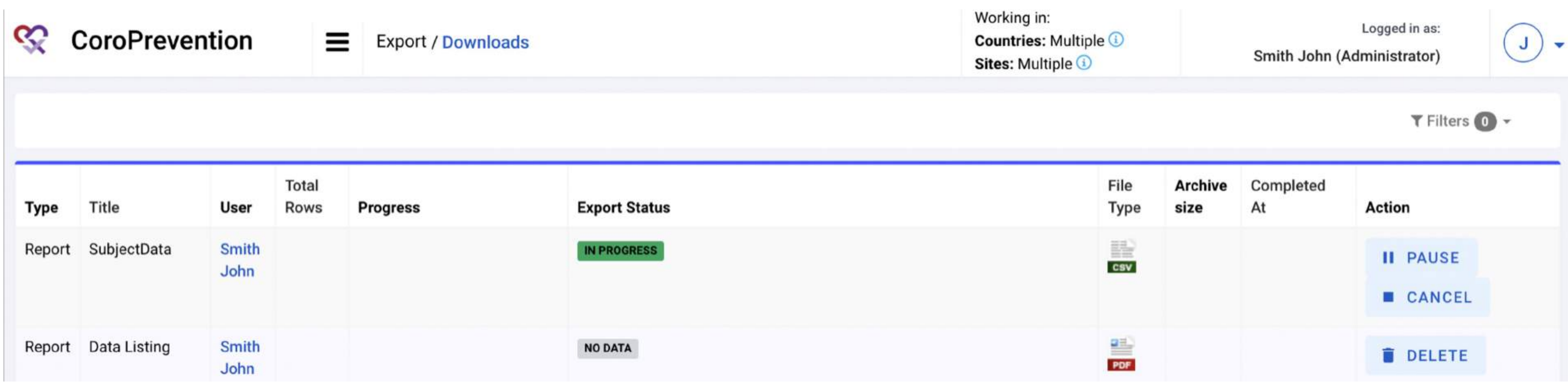
Dataset	User	Total Rows	Export Status	File Type	Archive size	Started At ↑	Completed At	Action
Subject Enrolment	investigator		NO DATA	CSV		02 Nov 2022 09:57:41		DELETE
Subject Enrolment	investigator	2	FINISHED	CSV	327 Bytes	02 Nov 2022 09:56:41	02 Nov 2022 09:56:42	DOWNLOAD ARCHIVE DELETE
Page Status	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

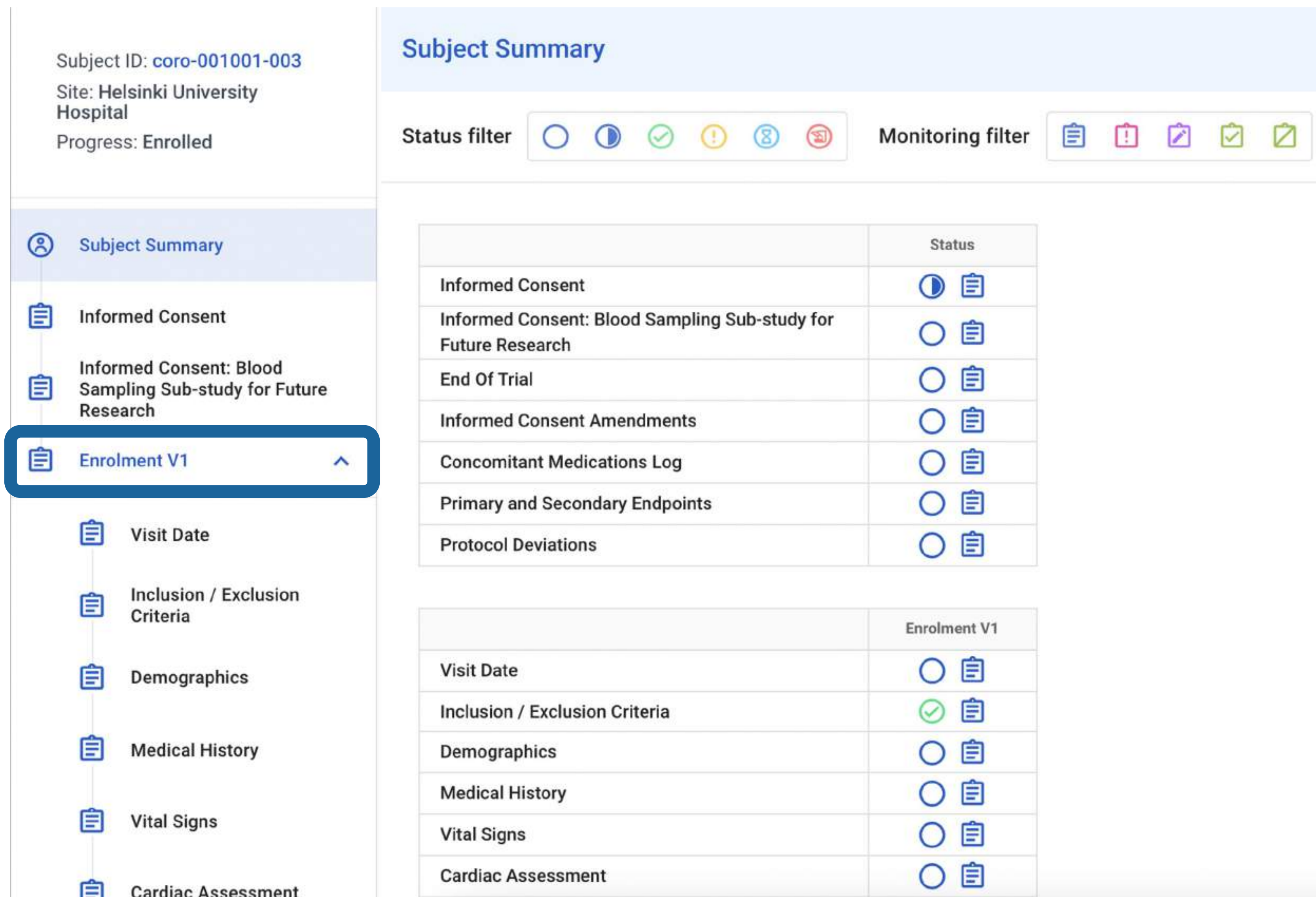


Monitor Data

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



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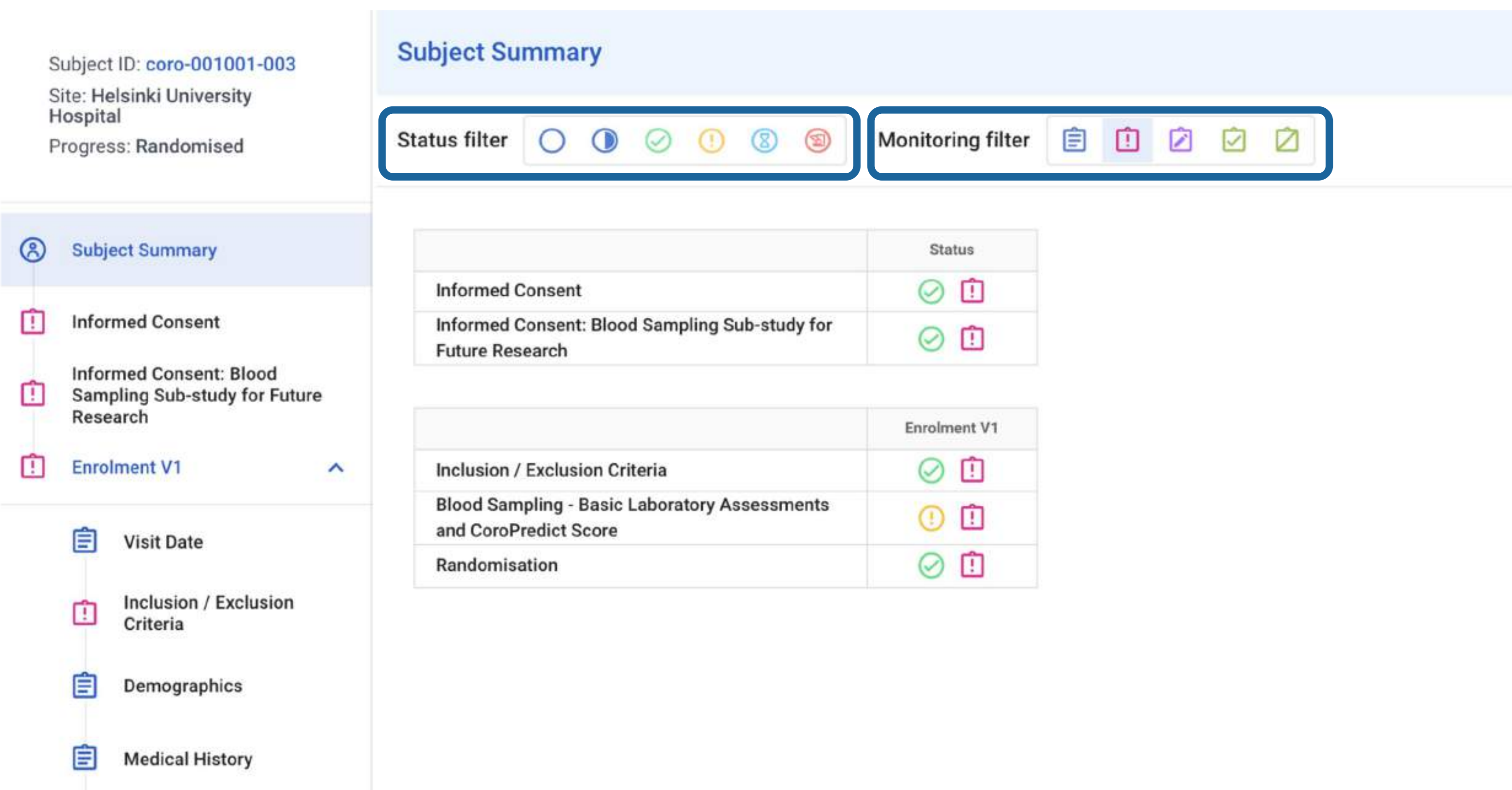
Monitor Data - Subject Summary

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



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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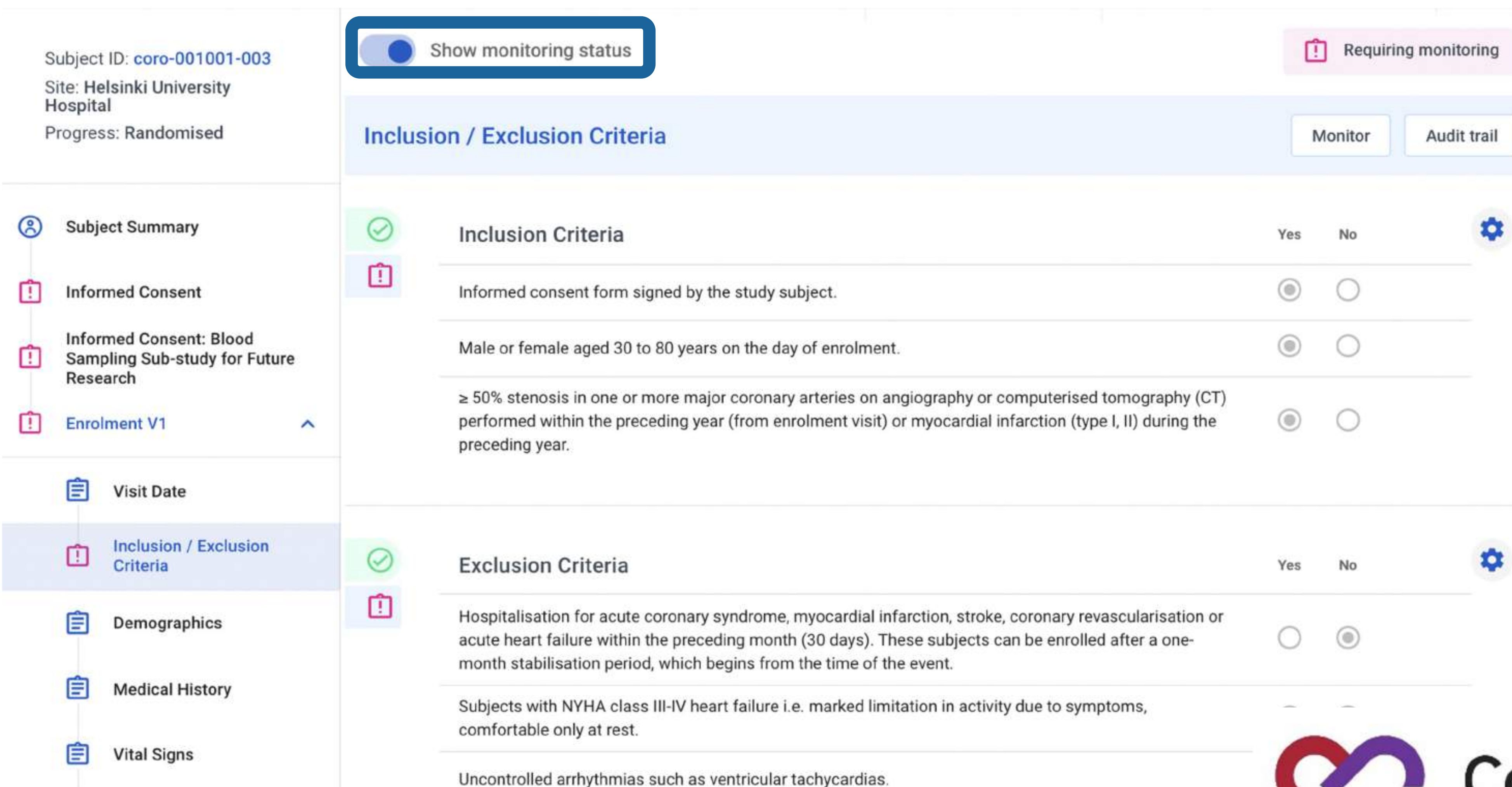
Monitor Data - Monitor Toggle

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



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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

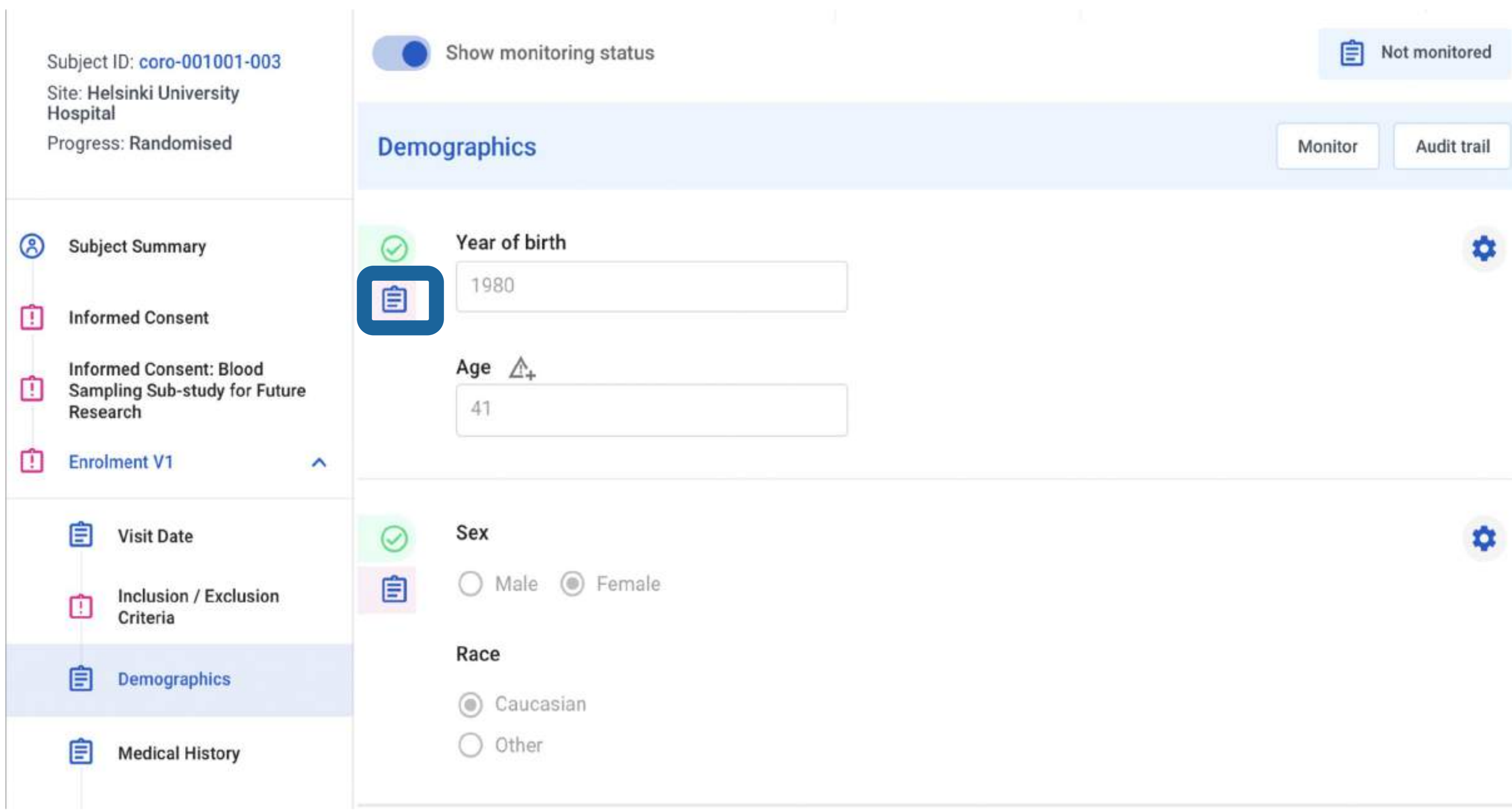
Monitoring Status Icons indicate the data entry status of a subject/visit/form/block:

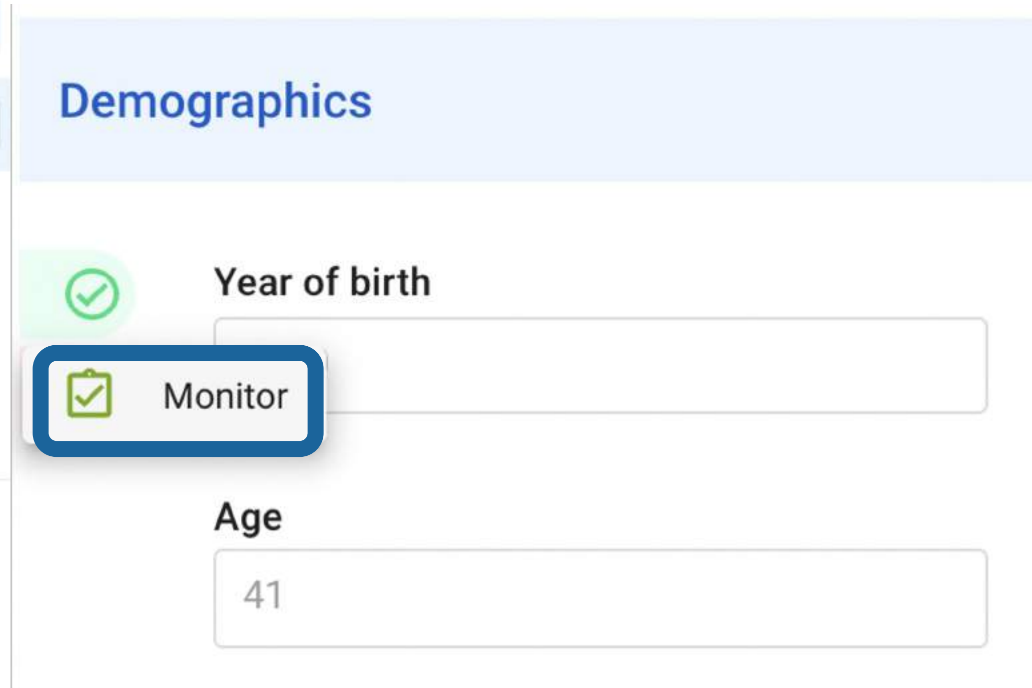
	Not monitored
	Requiring monitoring
	Modified after monitoring (the data was updated after monitoring)
	Monitored
	Closed (data manager closed the eCRF for monitoring)

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





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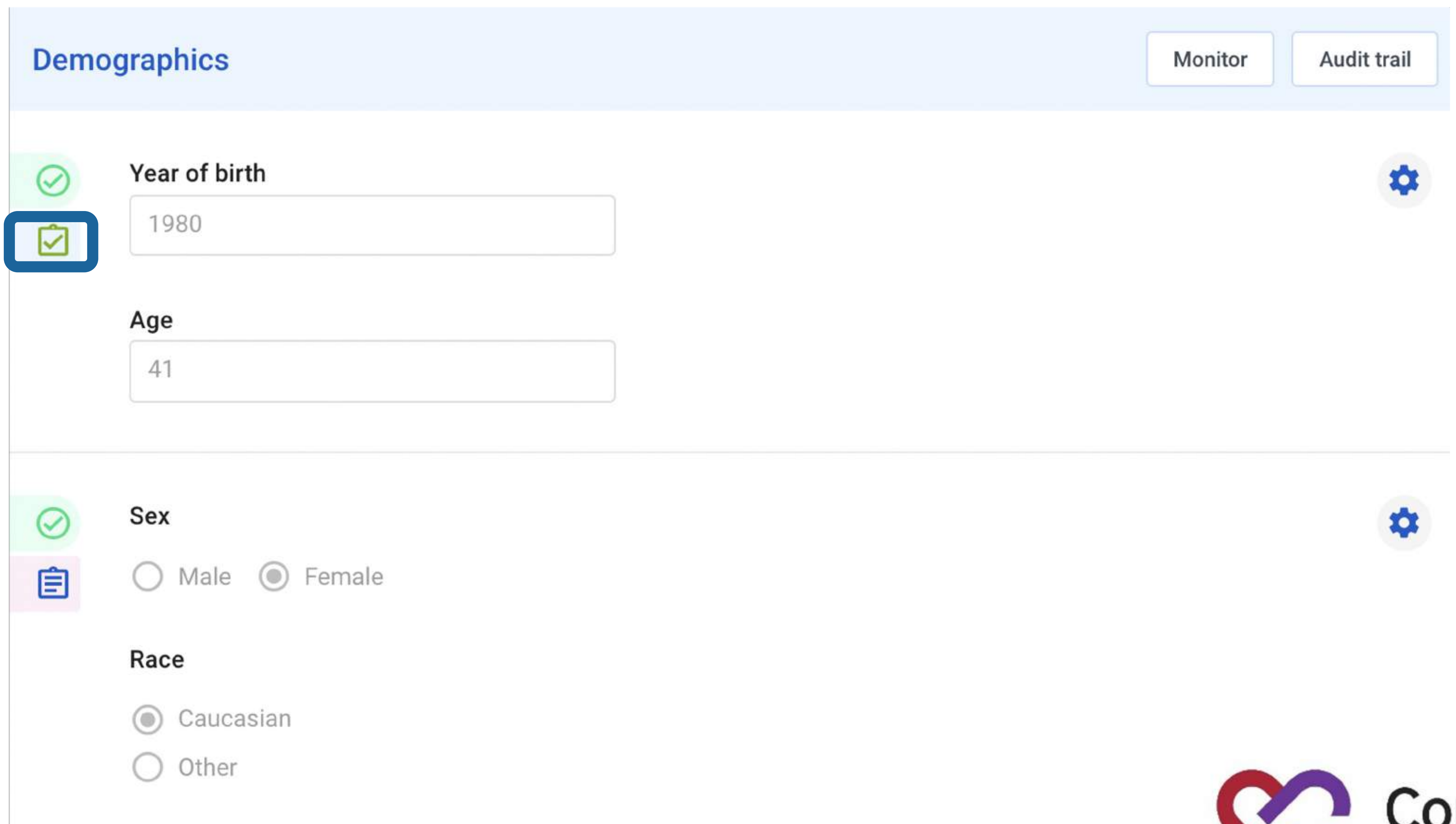
Monitor Data - Monitor Block (2)

The status of the block changes to “Monitored”



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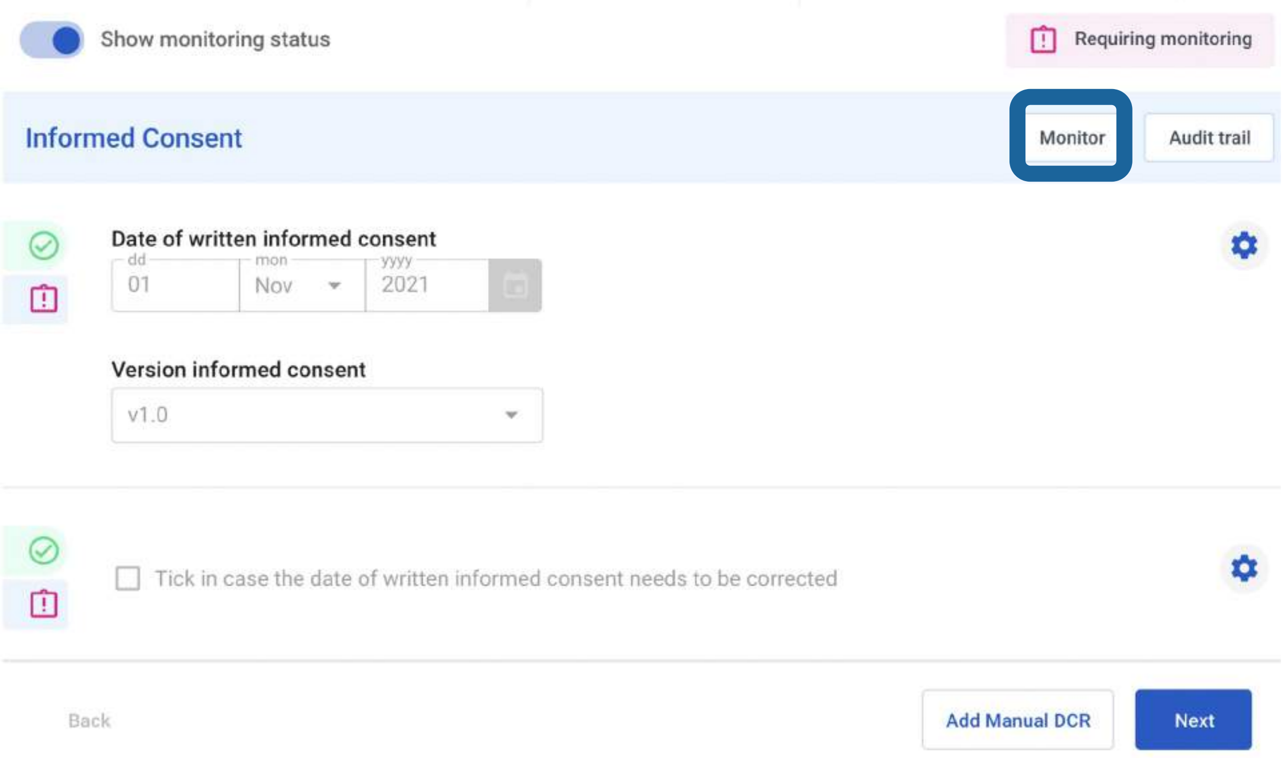
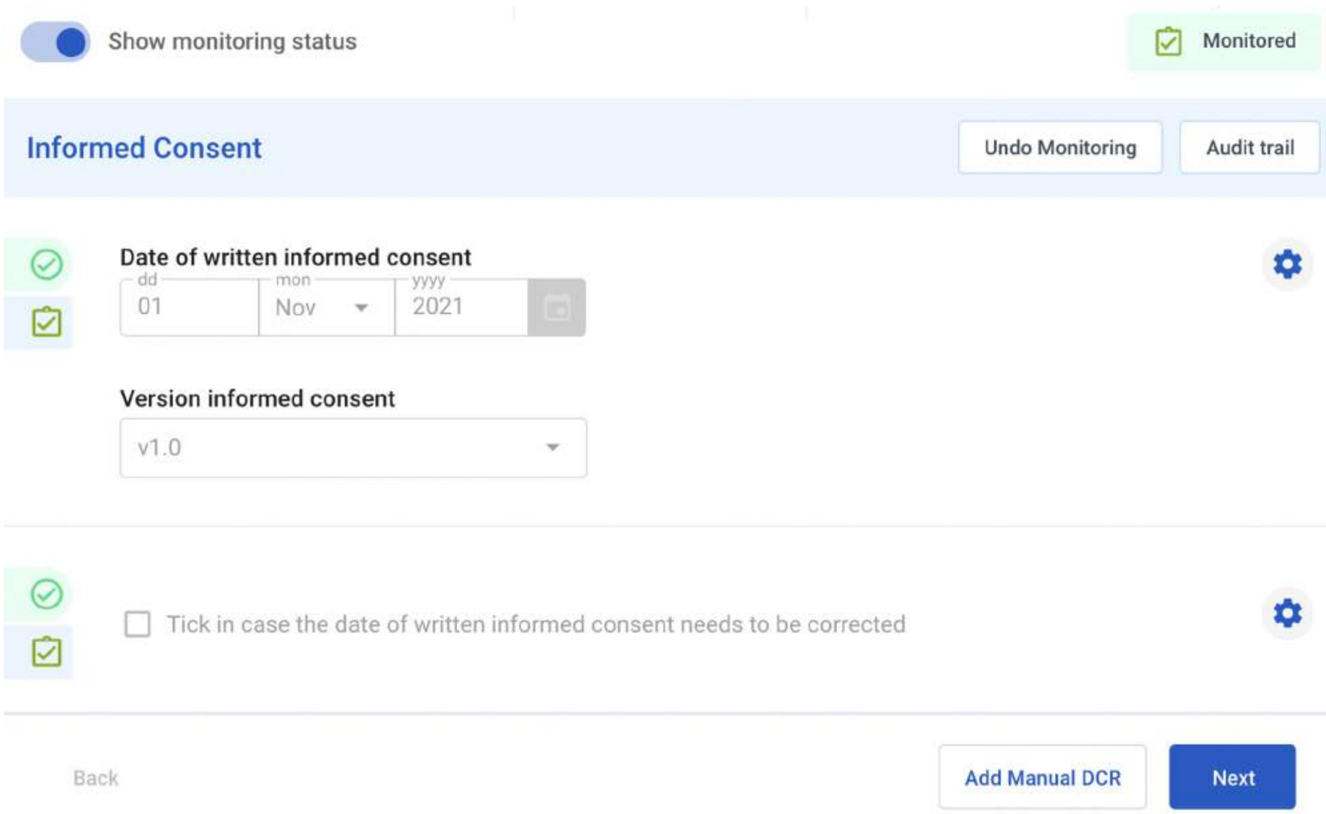
Monitor Data - Monitor eCRF

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





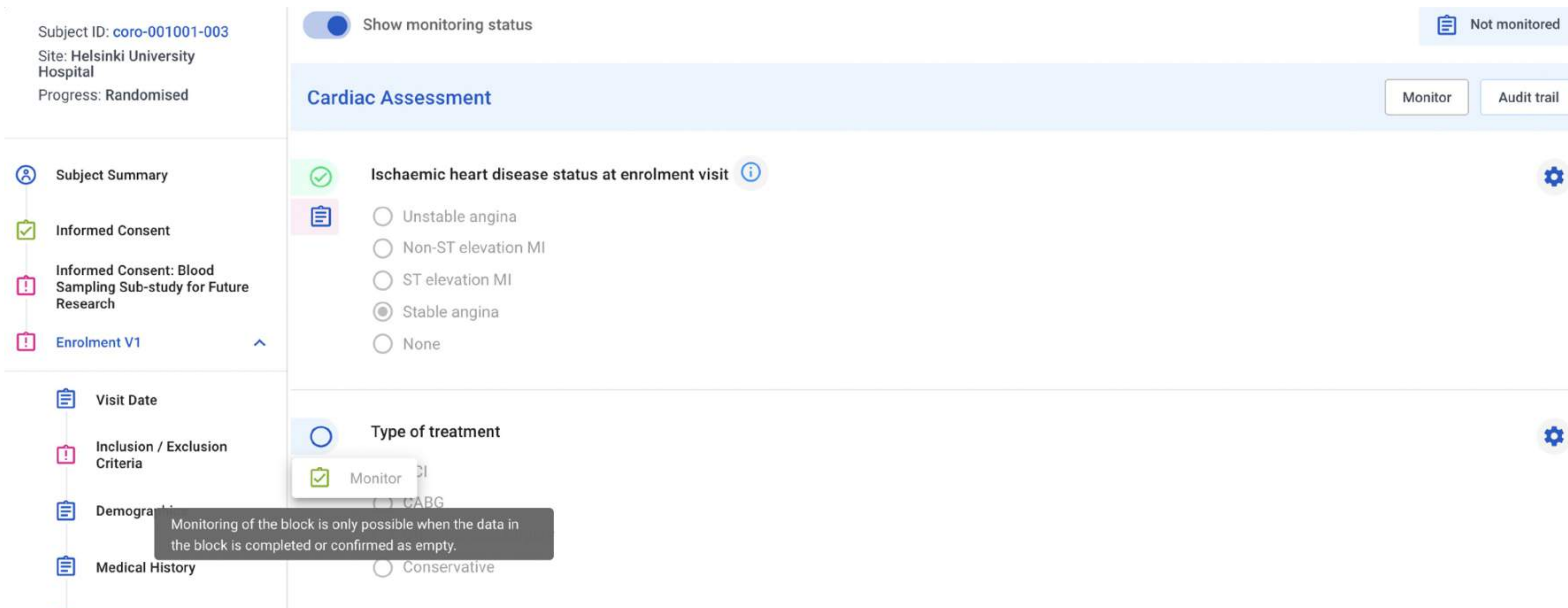
Monitor Data - General

- 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:



Blocks that have been confirmed as empty can also be monitored

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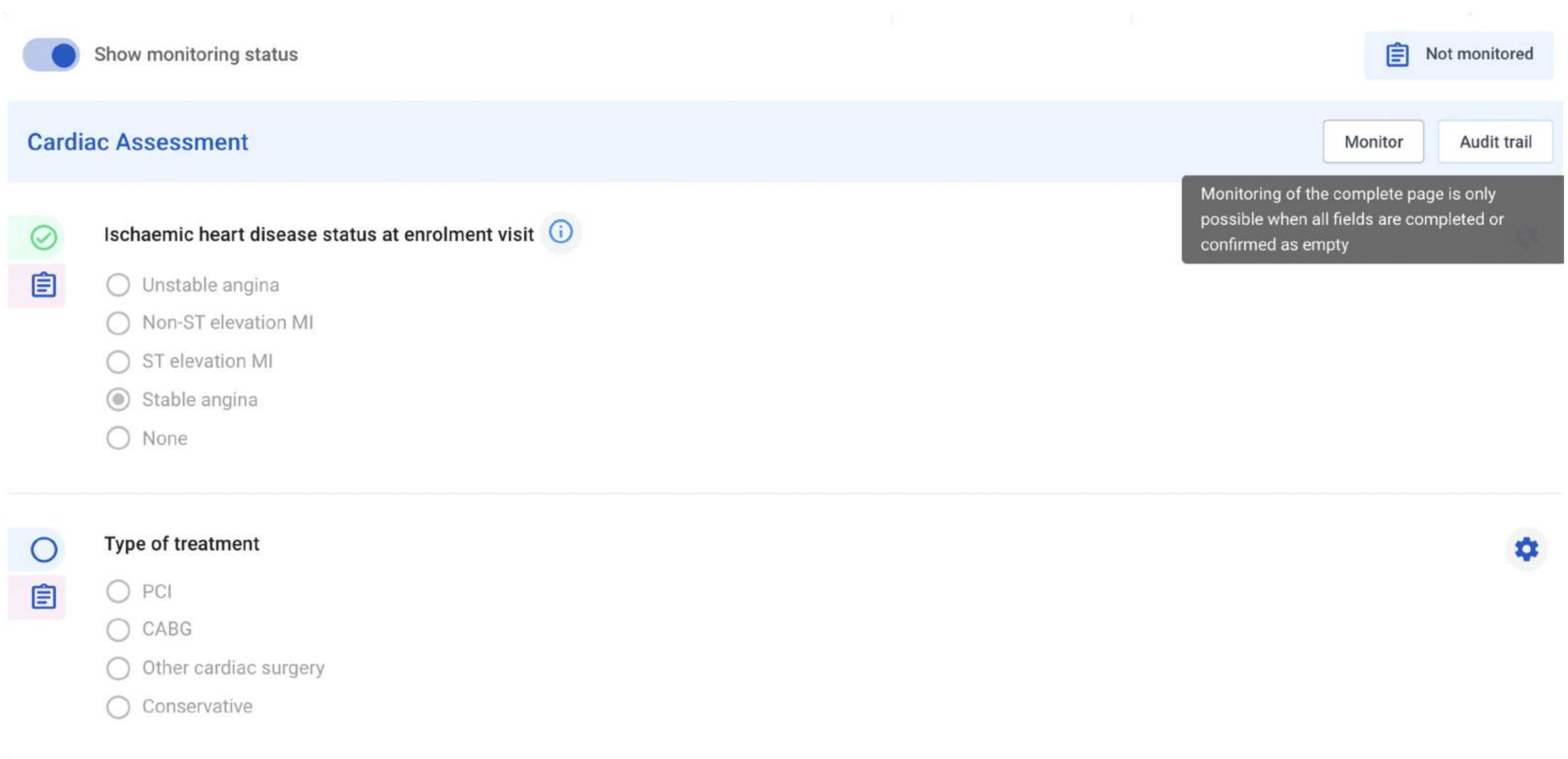
Monitor Data - Preconditions (2)

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



Blocks that have been confirmed as empty can also be monitored

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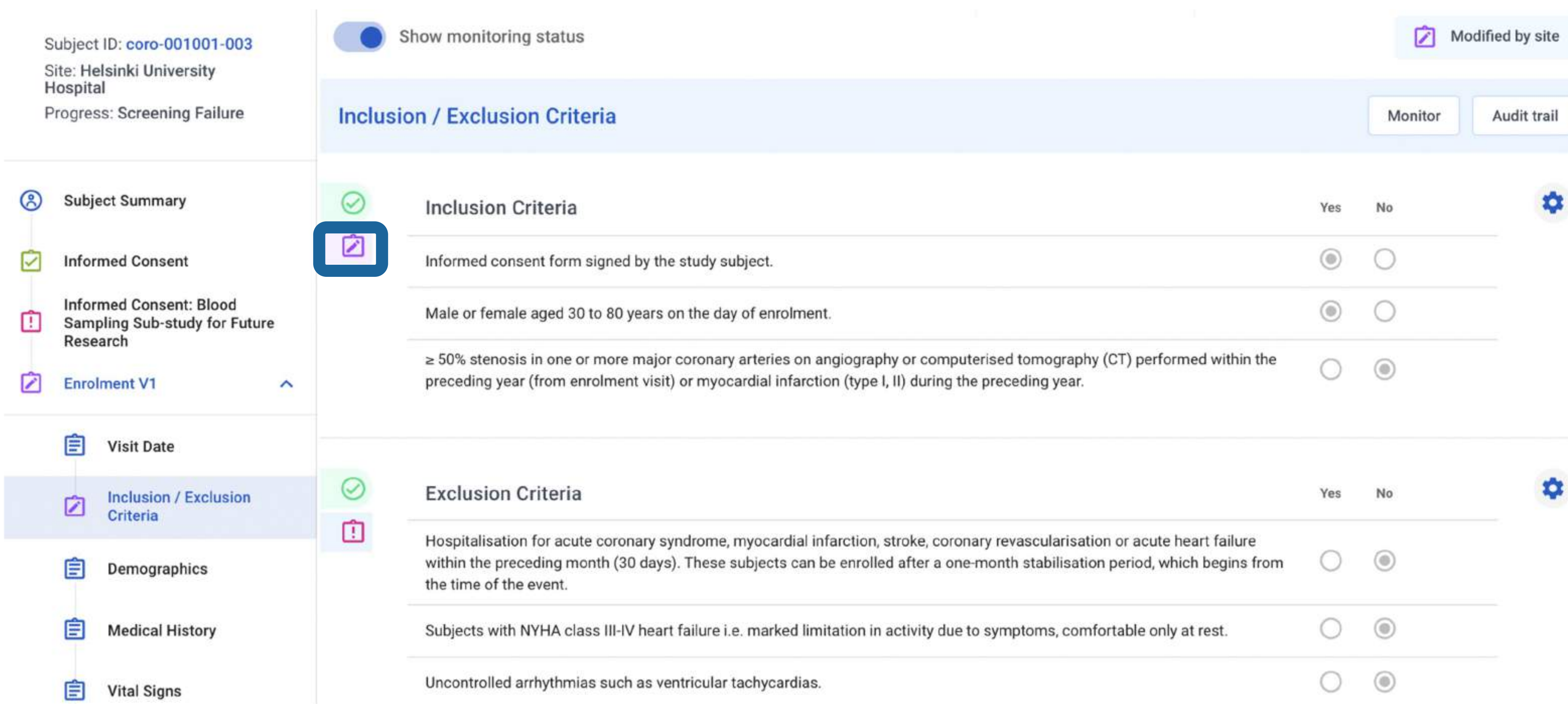
Monitor Data - Updates After Monitoring

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



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

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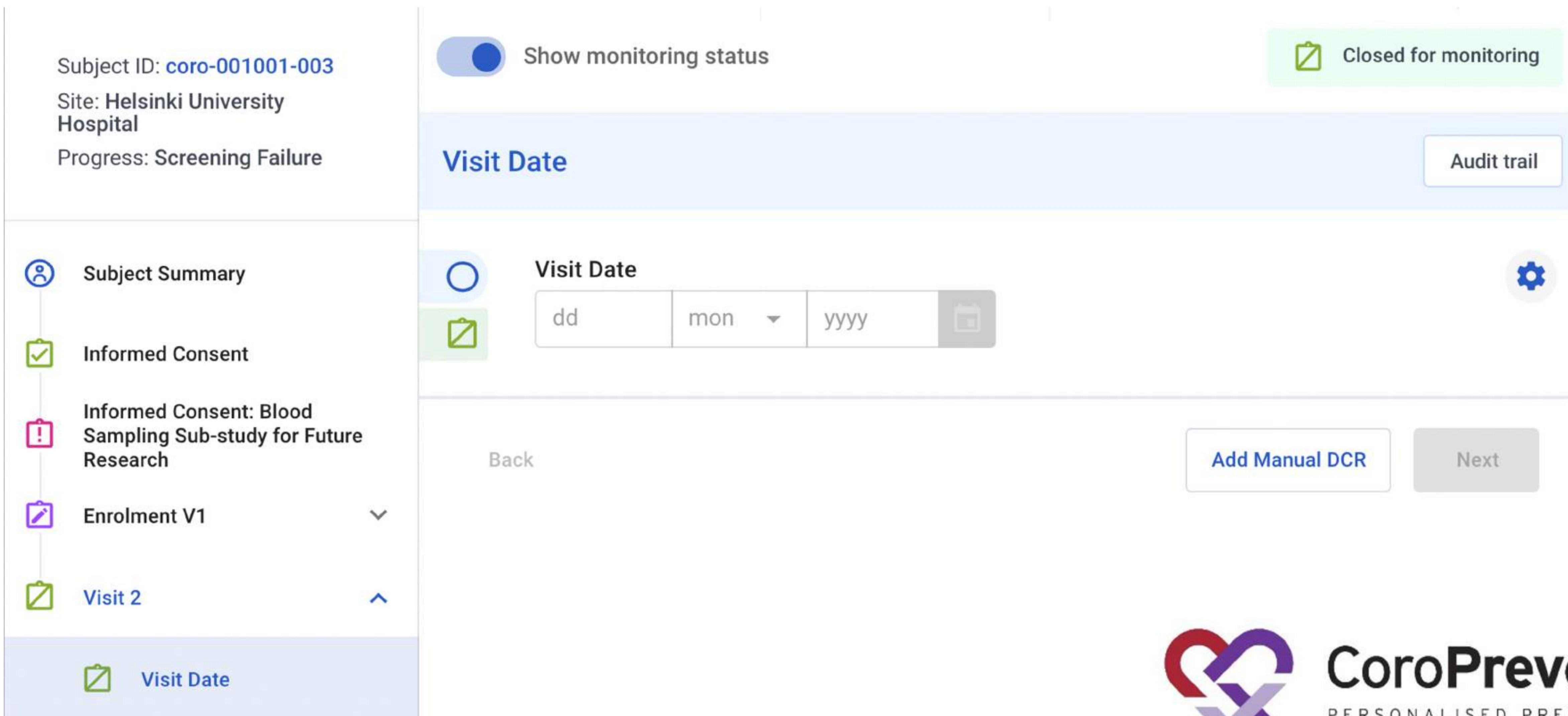
Monitor Data - Closed for Monitoring

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



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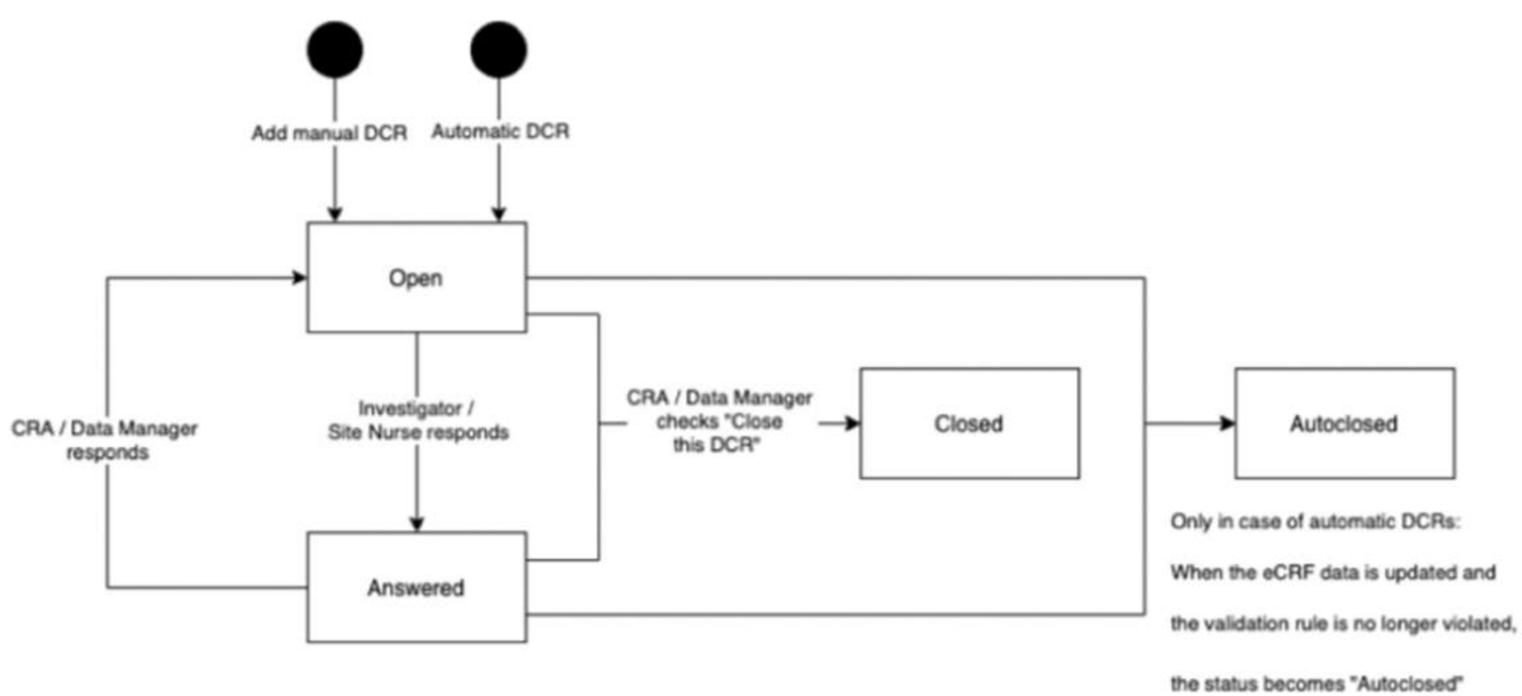
Manage DCRs

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



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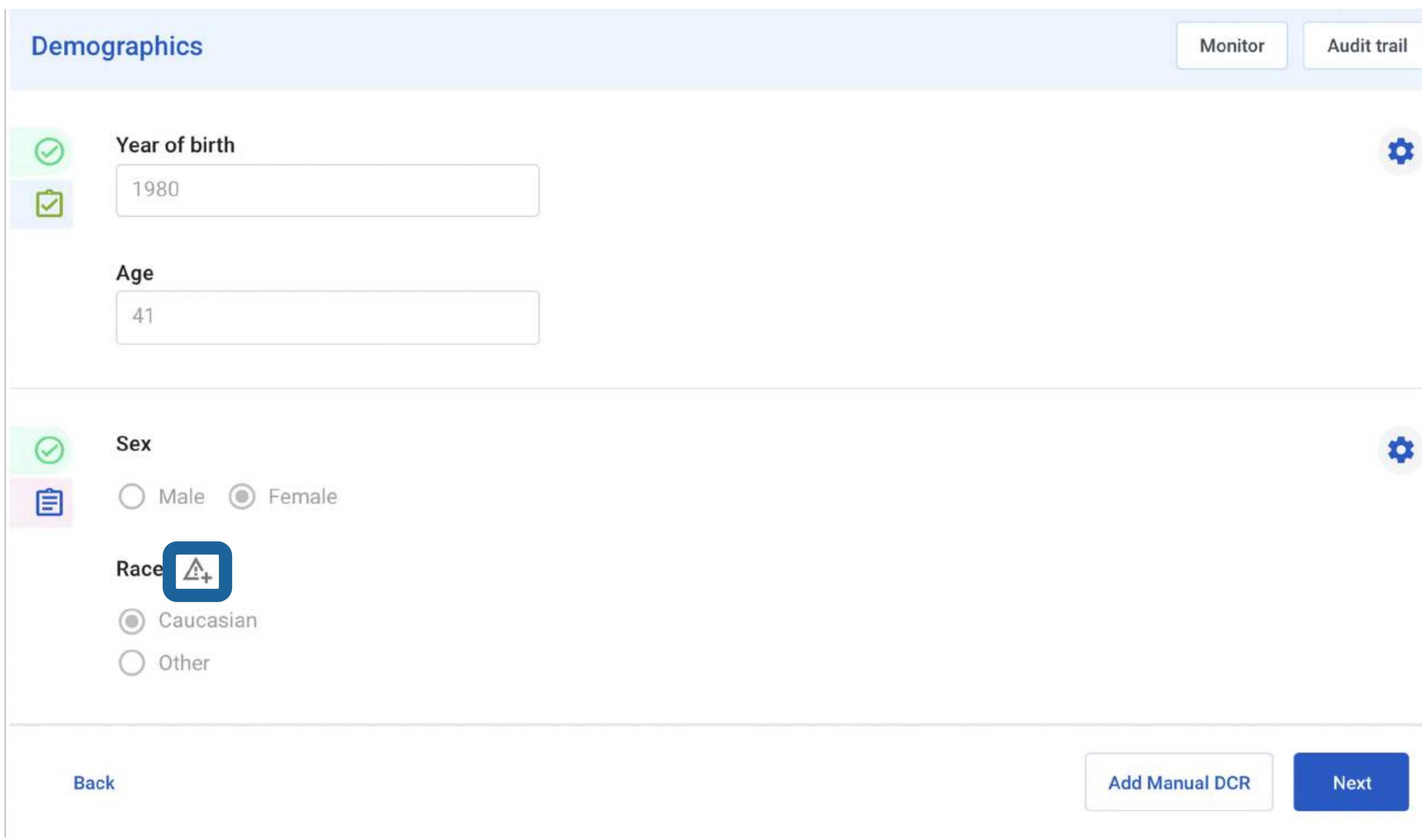
Manage DCRs - Create DCR on block

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



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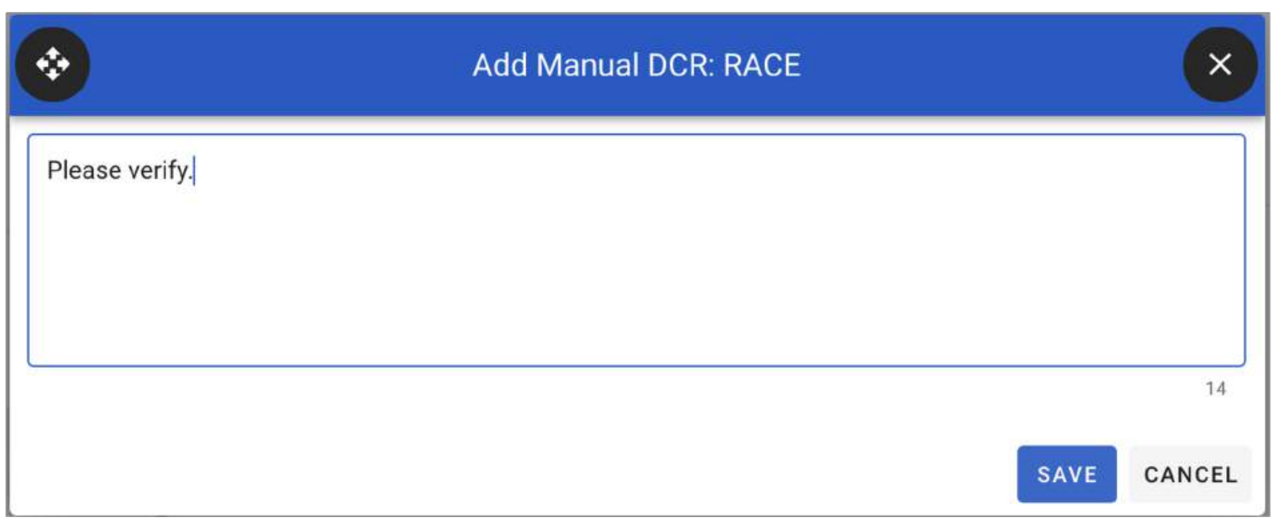
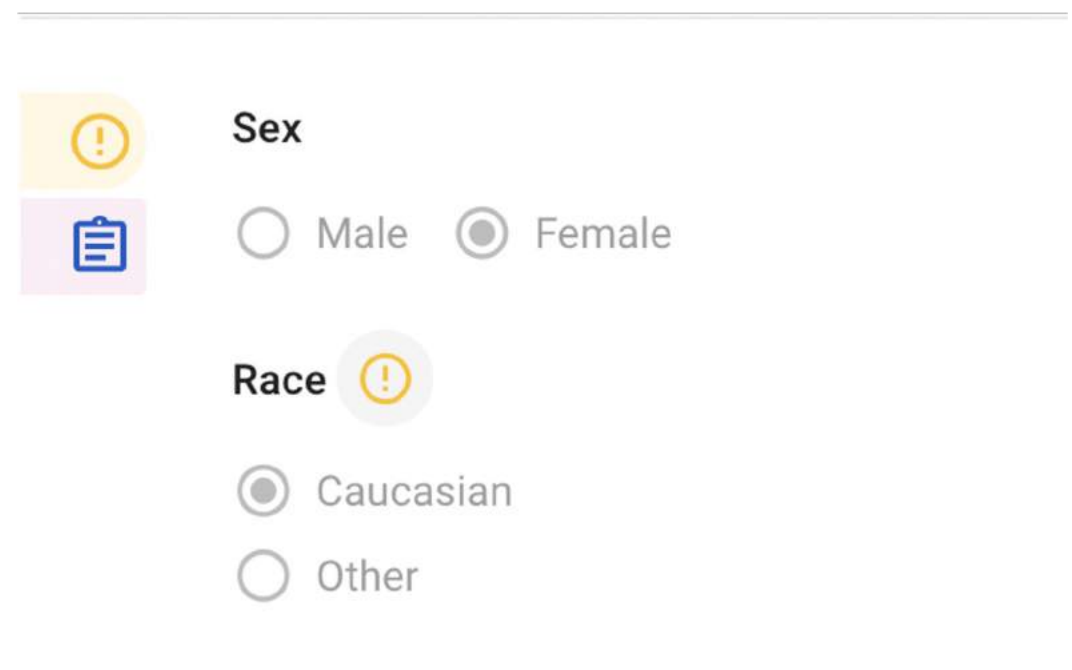
Manage DCRs - Create DCR on block (2)

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





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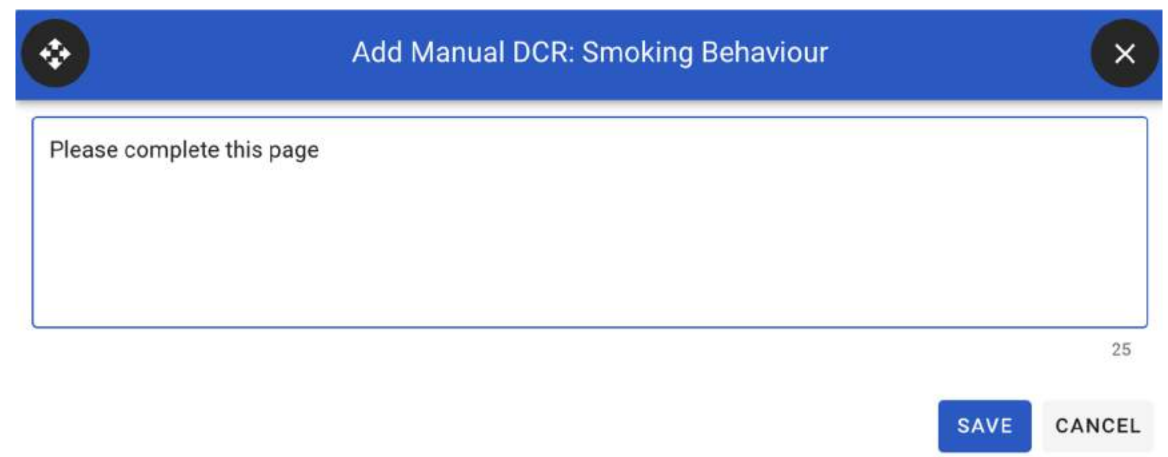
Manage DCRs - Create DCR on eCRF

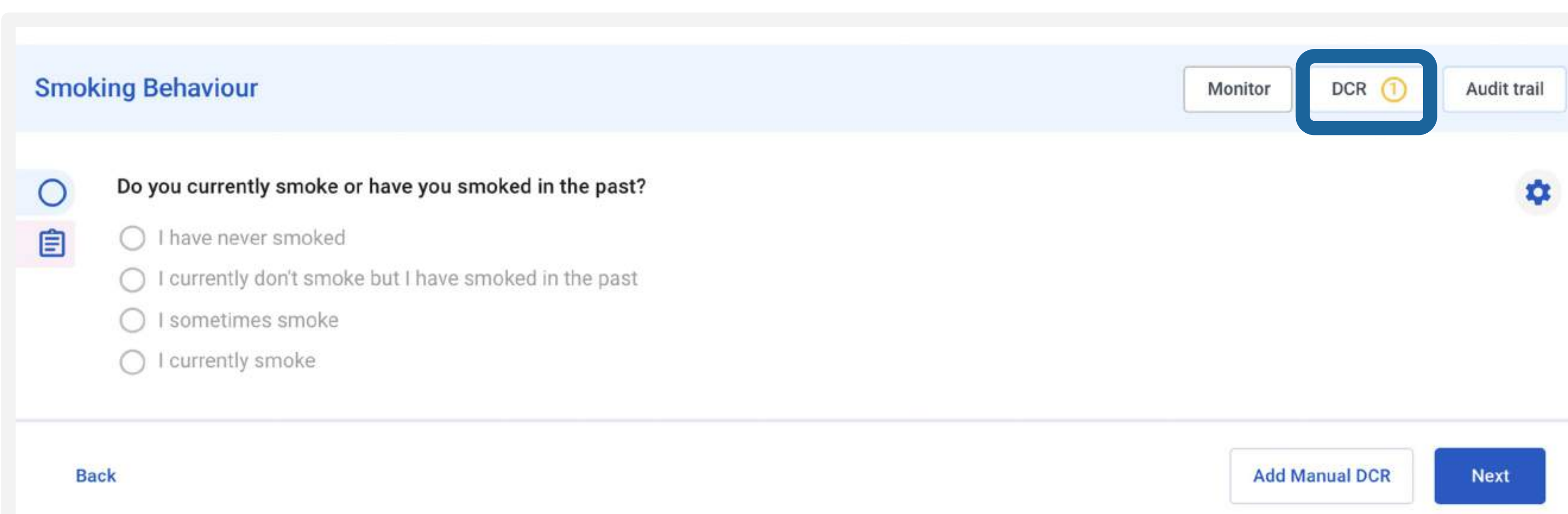
CRA, Lead CRA and Data Manager can manually create a DCR (query) on an entire eCRF:

- Click the “Add Manual DCR” button

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





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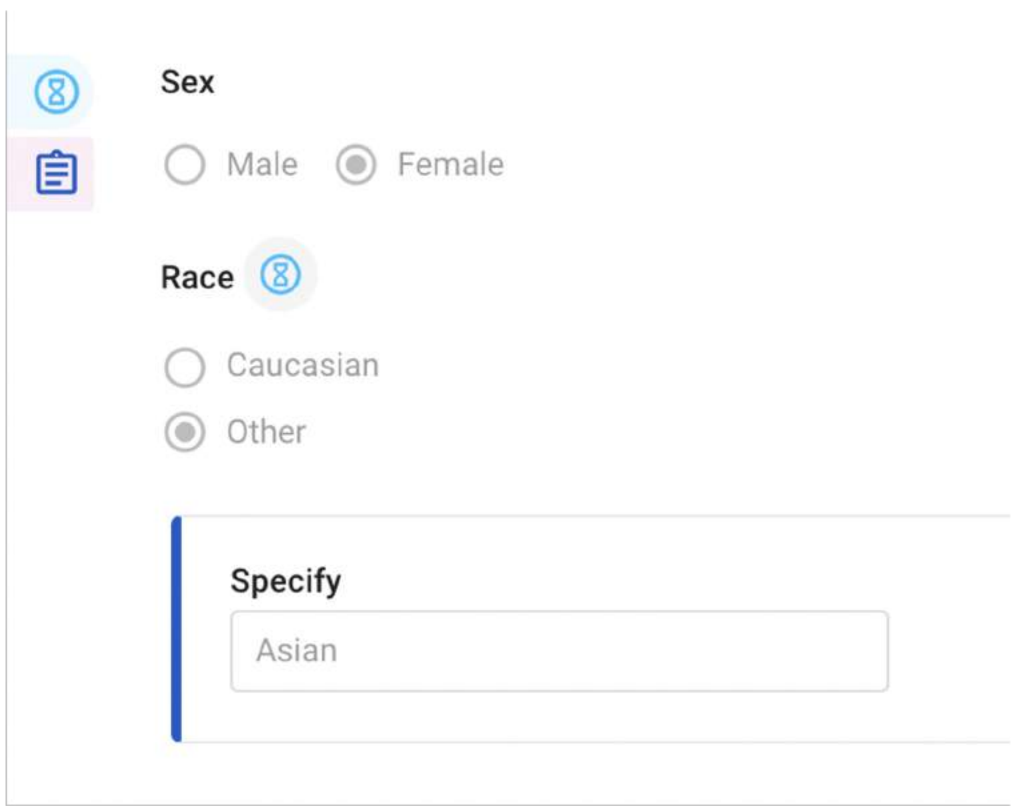
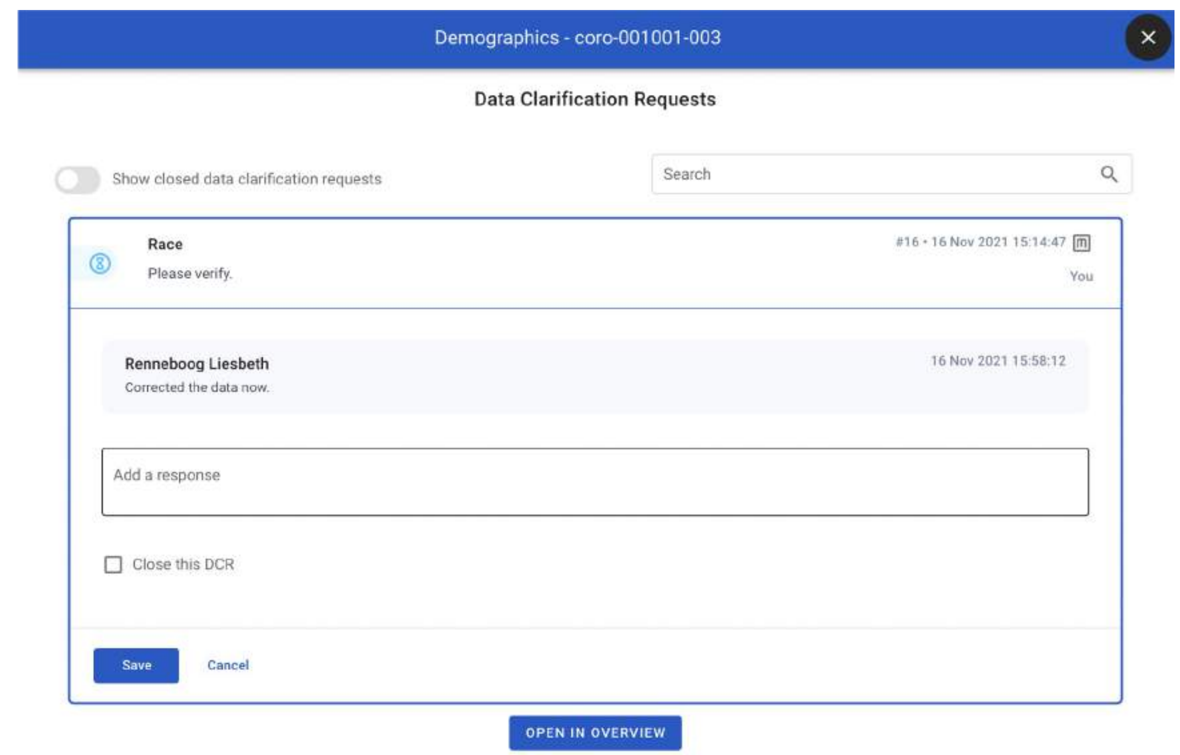
Manage DCRs - Answered DCR

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





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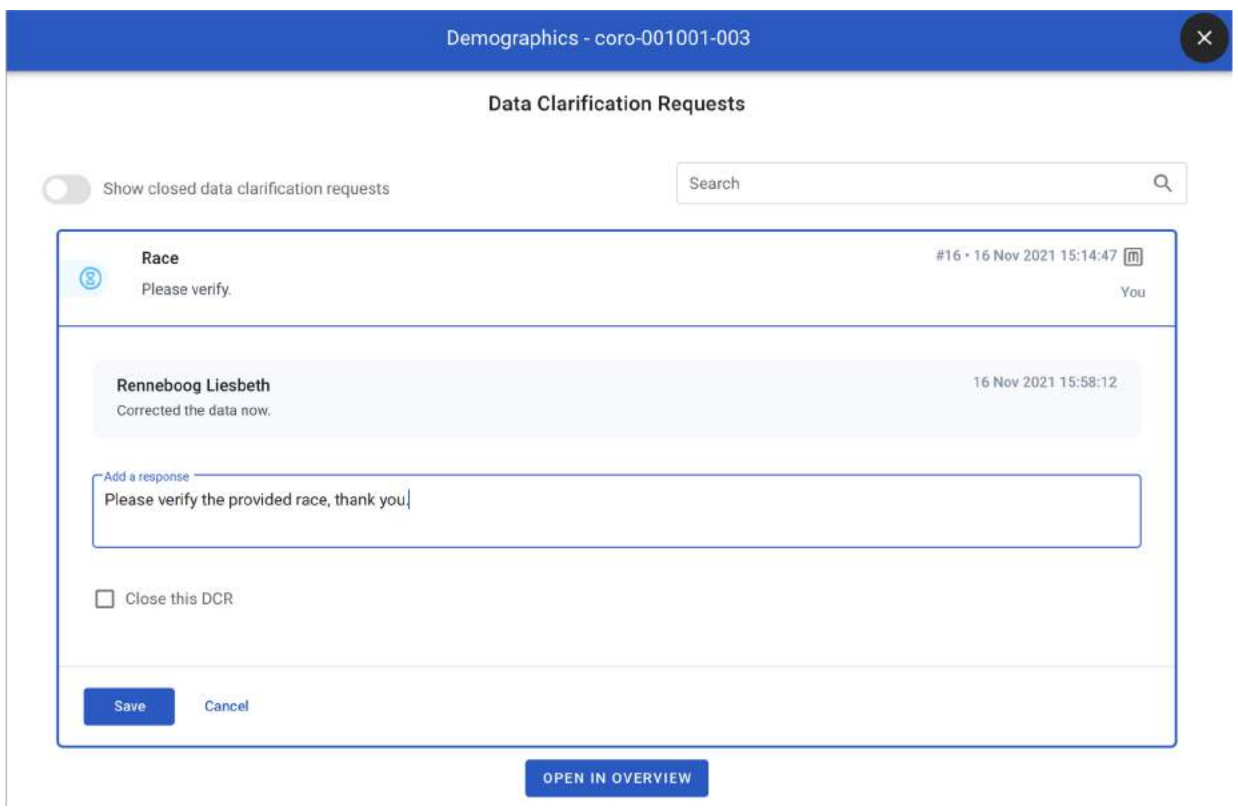
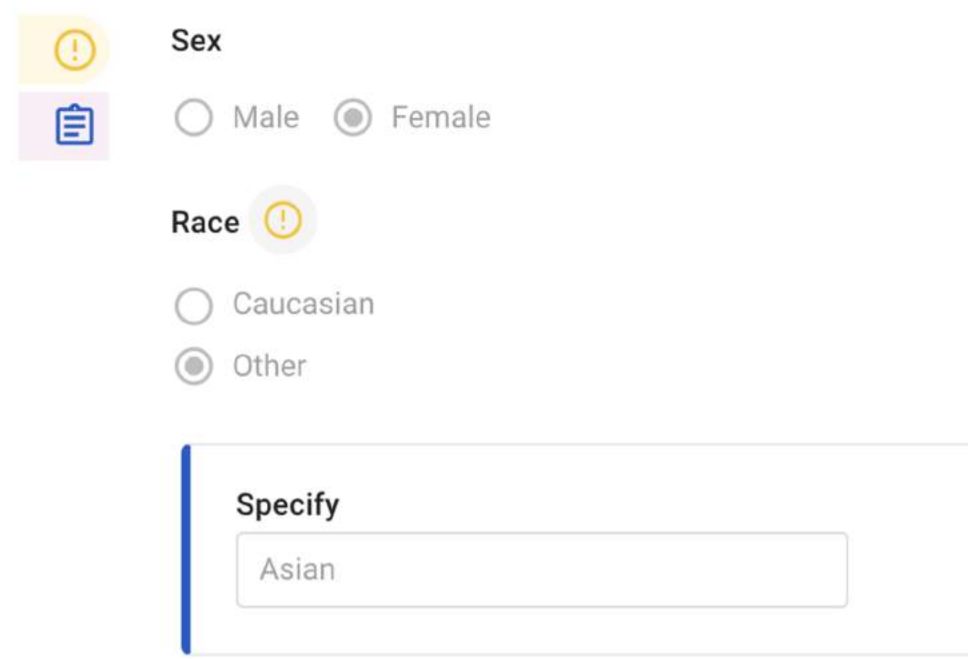
Manage DCRs - Re-open a DCR

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





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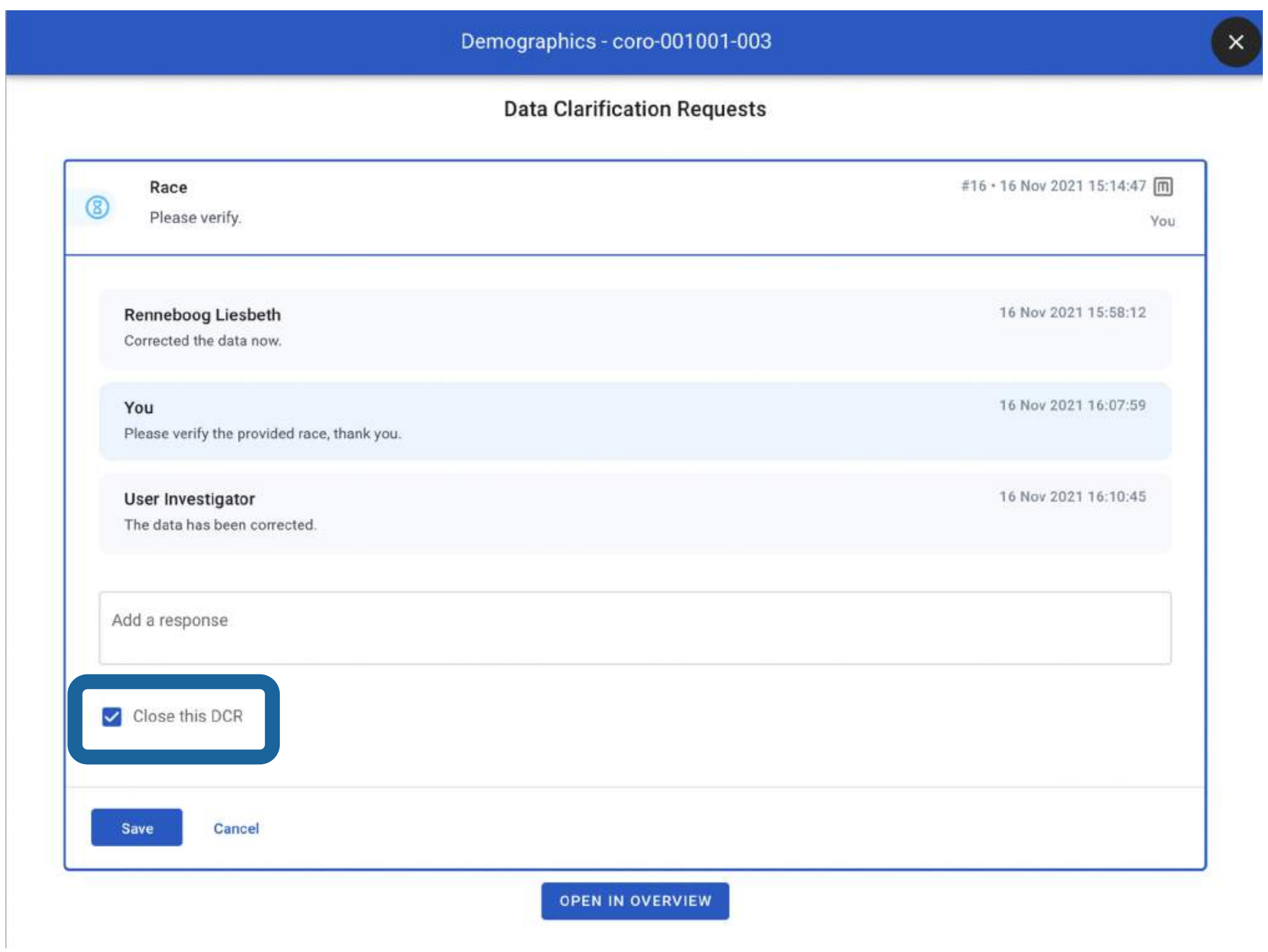
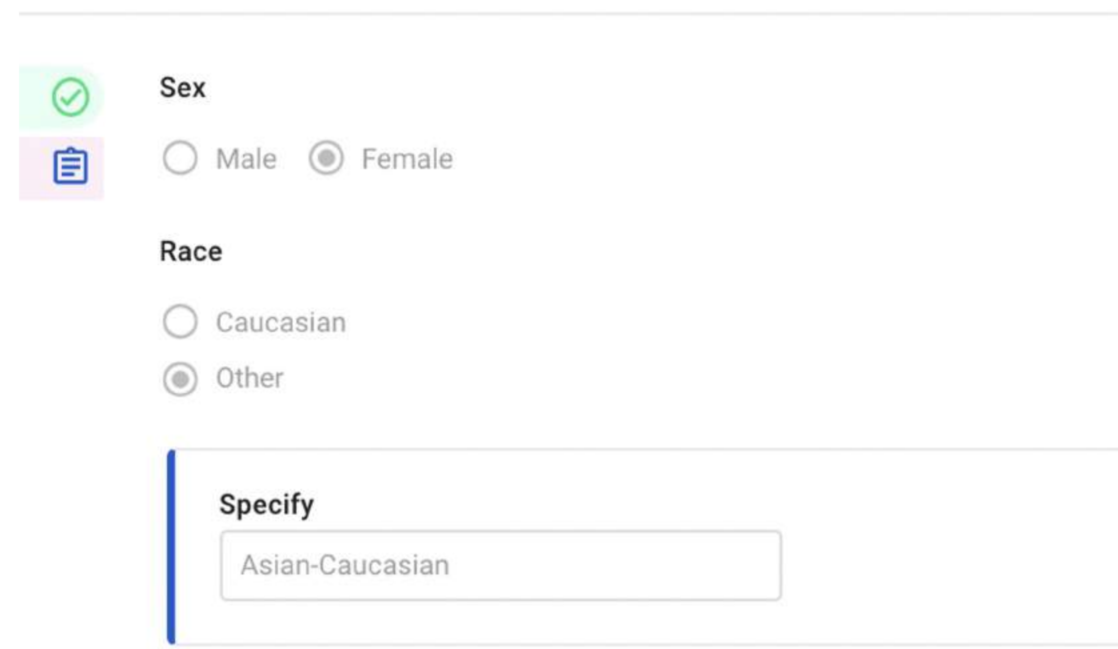
Manage DCRs - Close a DCR

If the DCR is resolved, tick Close this DCR and click Save.

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





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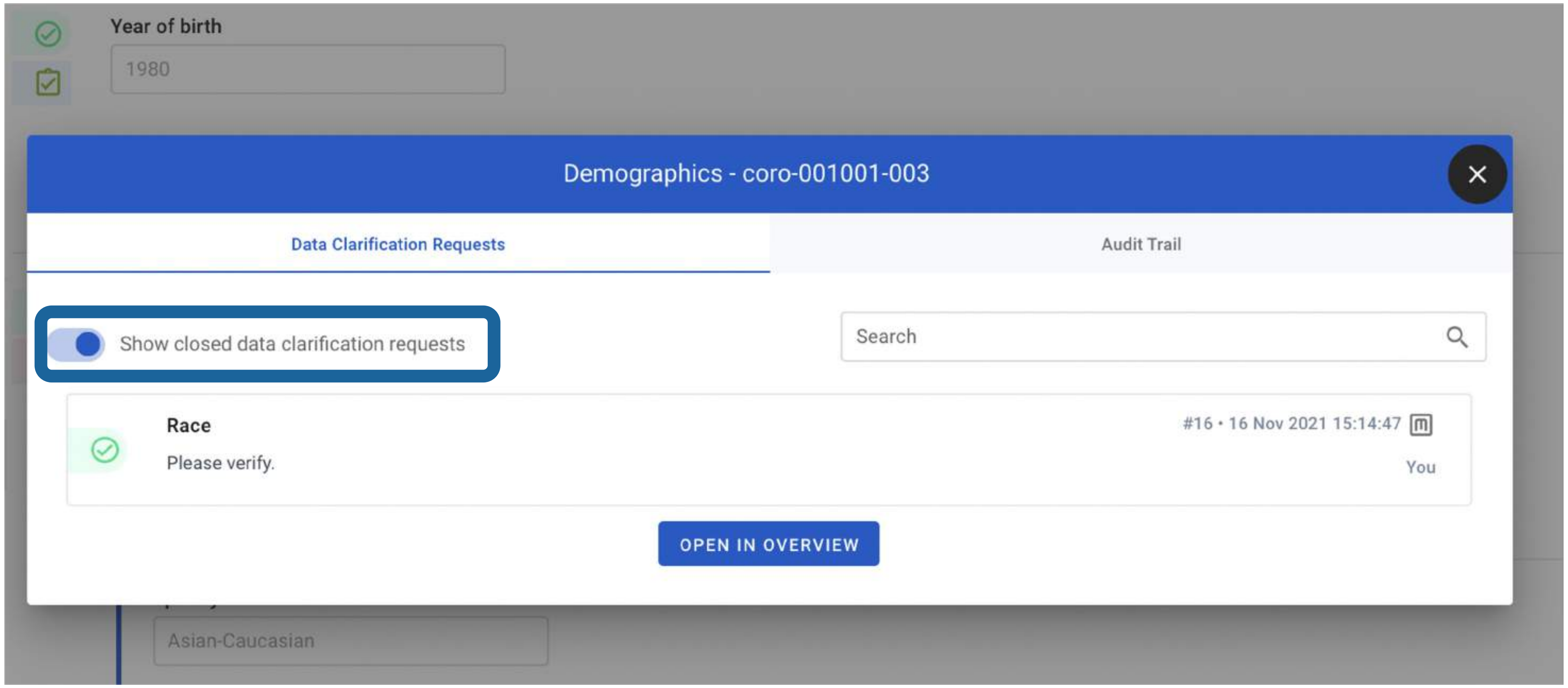
PERSONALISED PREVENTION FOR CORONARY HEART DISEASE

Manage DCRs - View DCRs

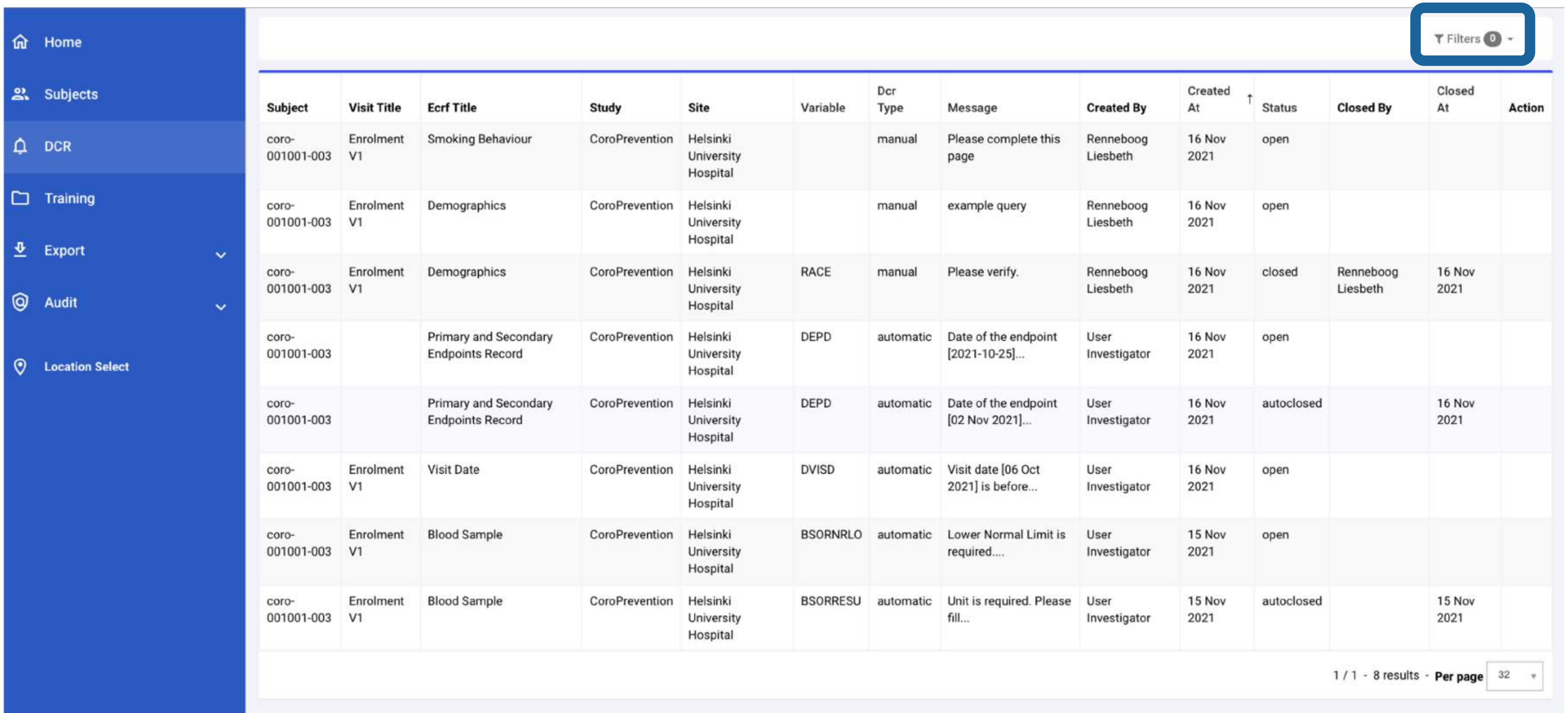
- Click the DCR button on top of the page or the data entry status icon of a block to open the DCRs for the page/block
- Toggle Show closed data clarification requests to include closed DCRs



CoroPrevention
PERSONALISED PREVENTION FOR CORONARY HEART DISEASE

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

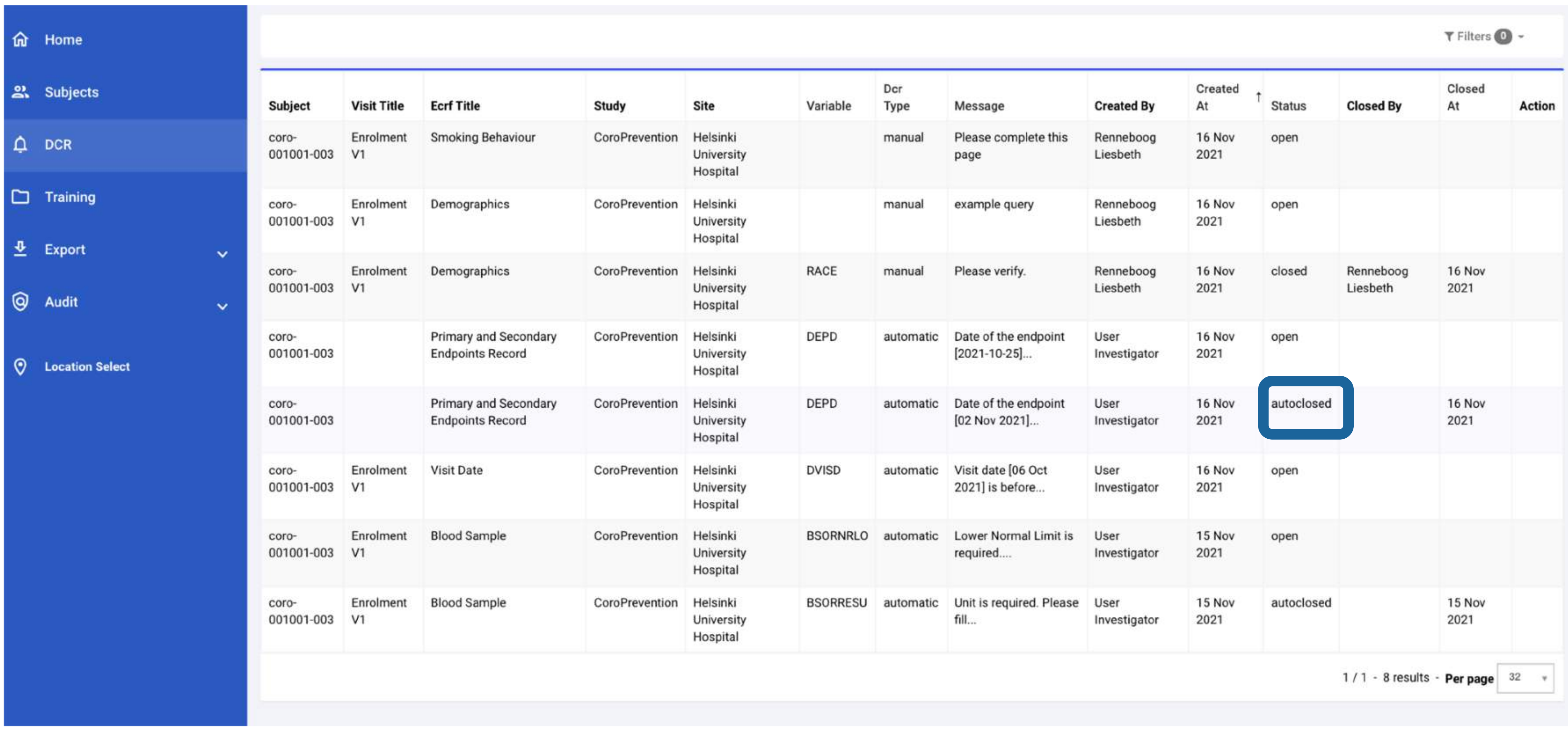


Subject	Visit Title	Ecrf Title	Study	Site	Variable	Dcr Type	Message	Created By	Created At	Status	Closed By	Closed At	Action
coro-001001-003	Enrolment V1	Smoking Behaviour	CoroPrevention	Helsinki University Hospital		manual	Please complete this page	Renneboog Liesbeth	16 Nov 2021	open			
coro-001001-003	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	BSORNRLO	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



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	BSORNRLO	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	

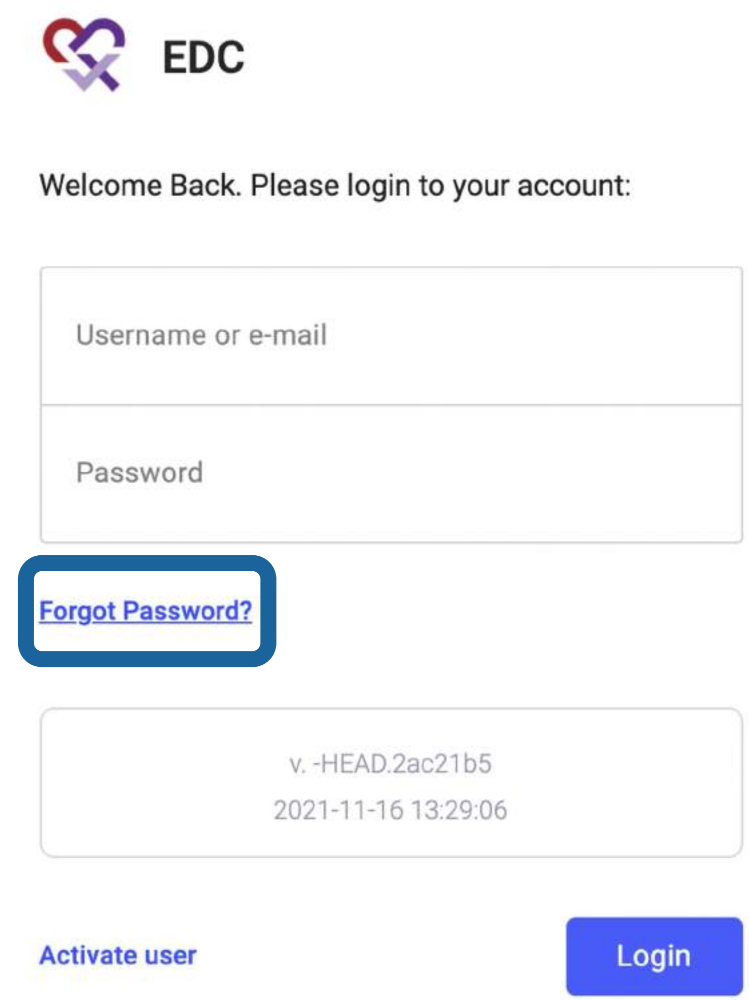
1 / 1 - 8 results - Per page 32

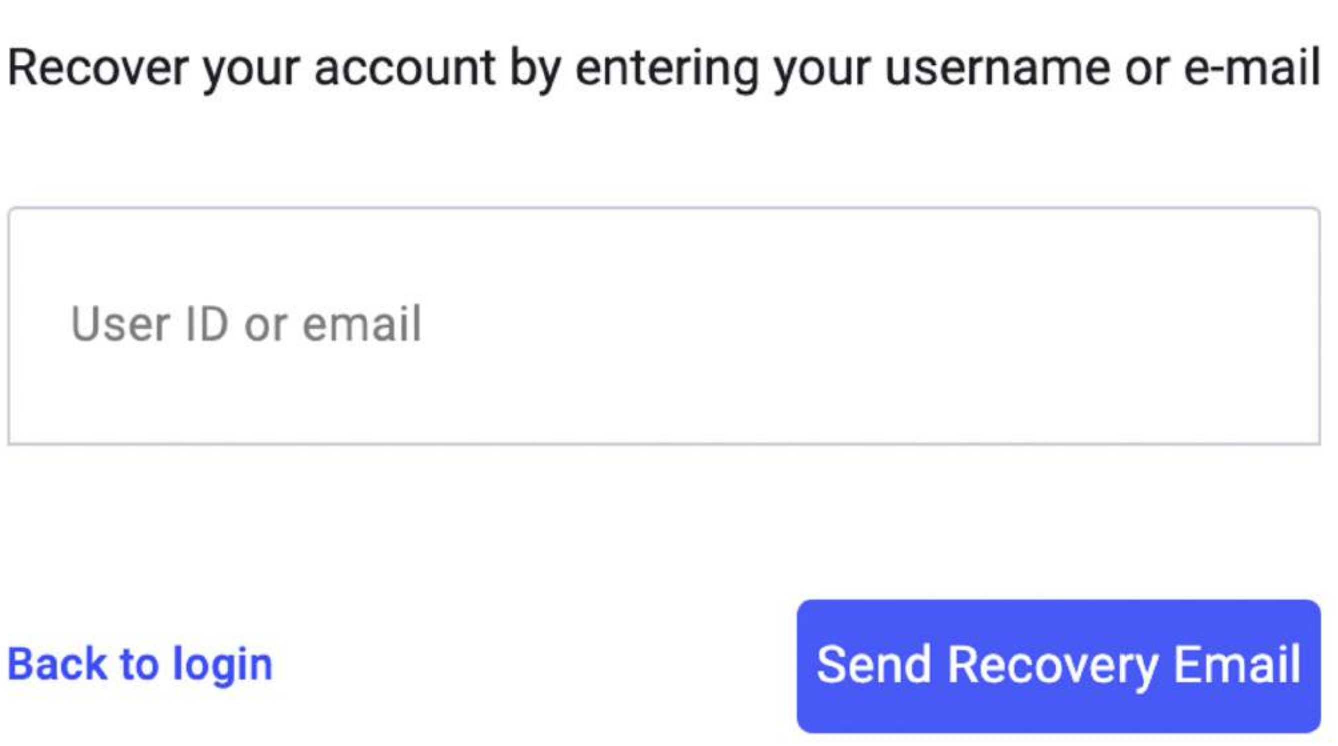
- Download this list through Export > Study Management Data Export > DCRs

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





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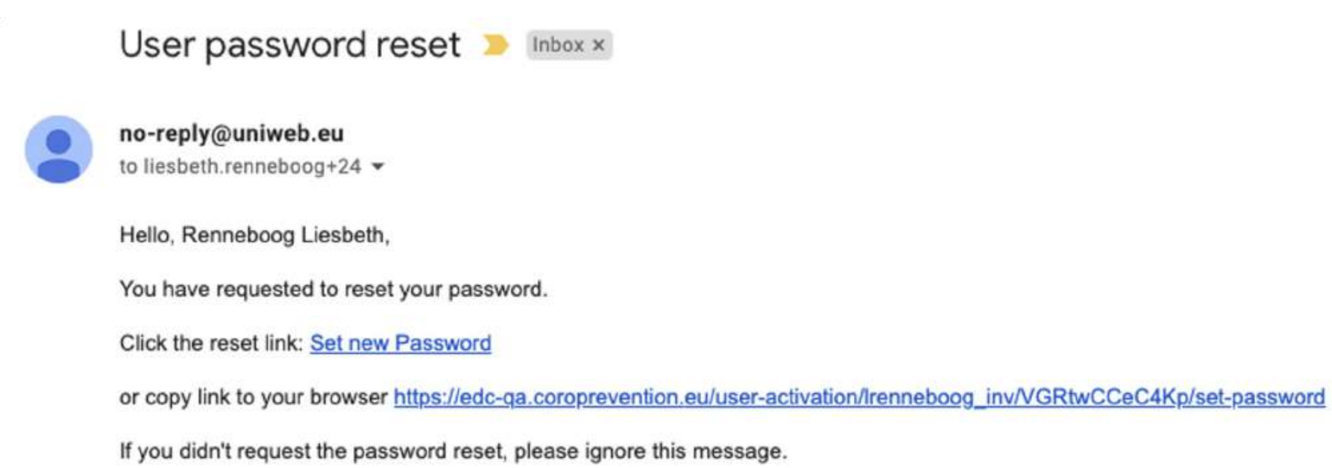
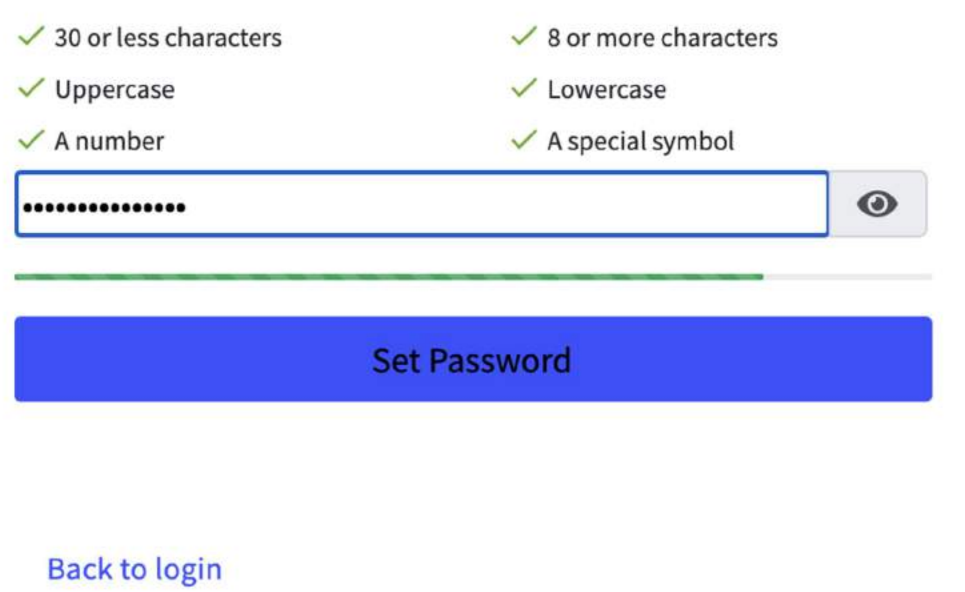
Forgot Password (2)

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



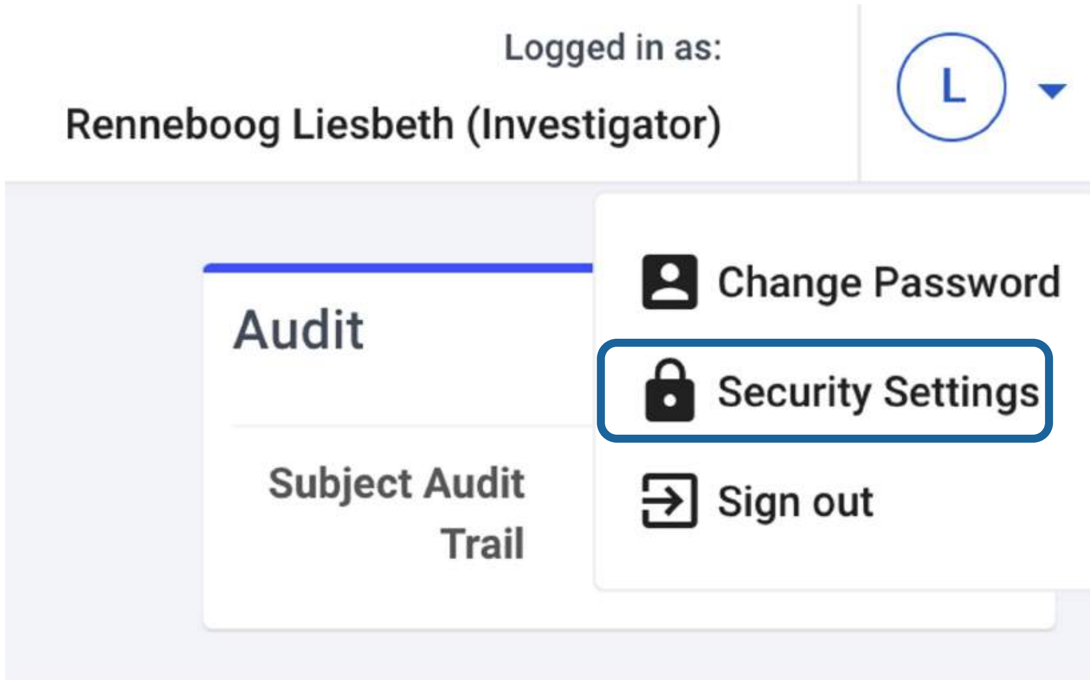


CoroPrevention
PERSONALISED PREVENTION FOR CORONARY HEART DISEASE

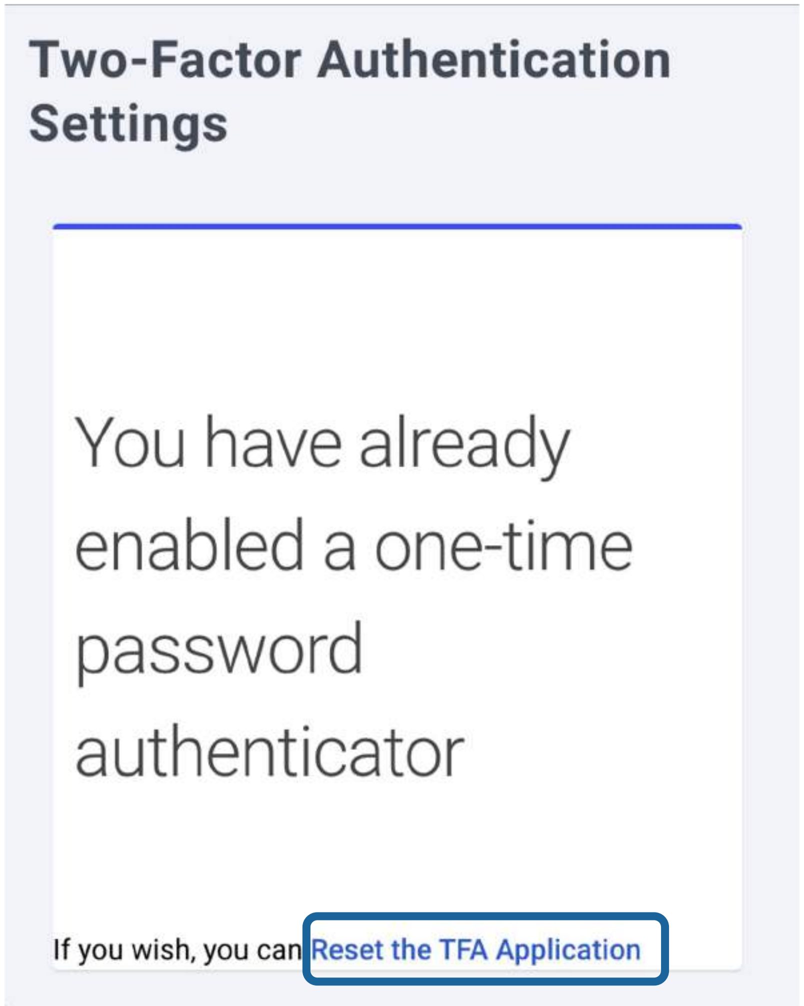
Reset Two-Factor Authentication (TFA)

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)

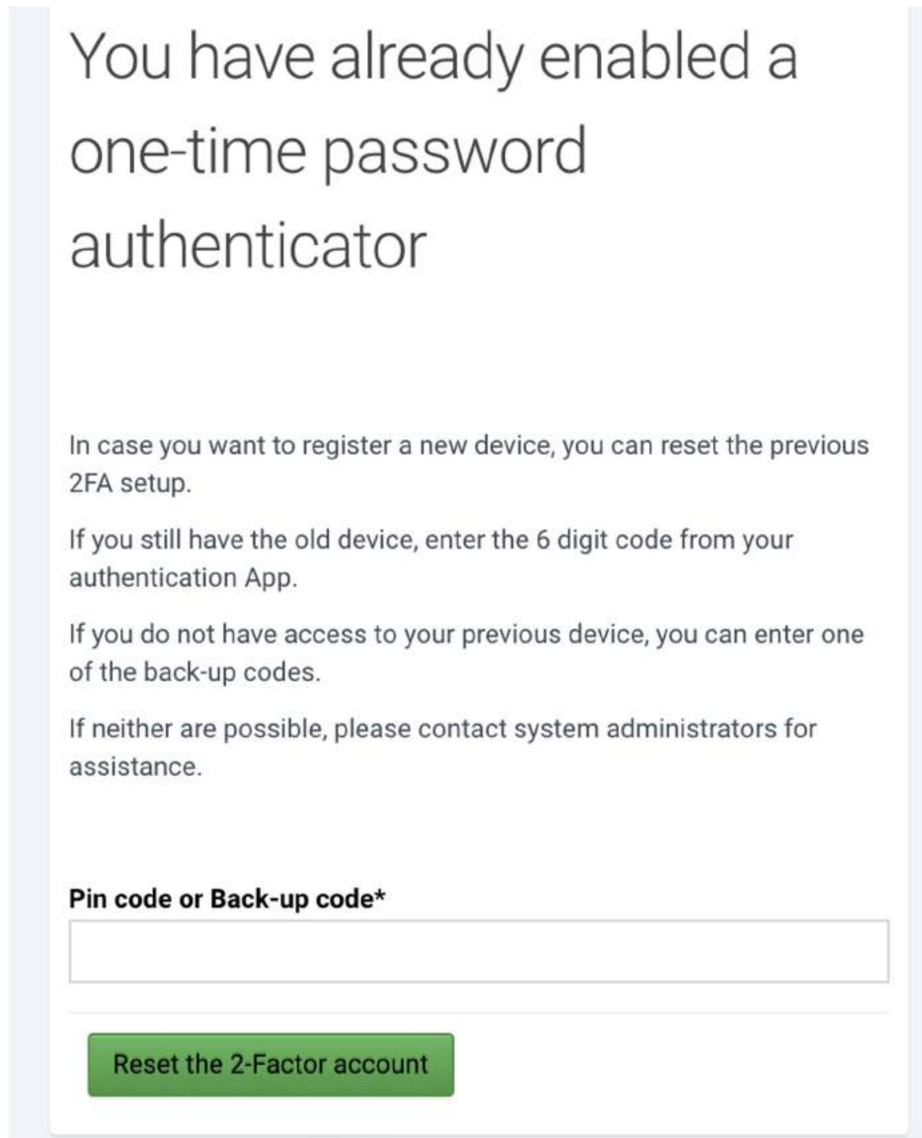


- Click Reset the TFA application



Reset TFA (2)

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



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

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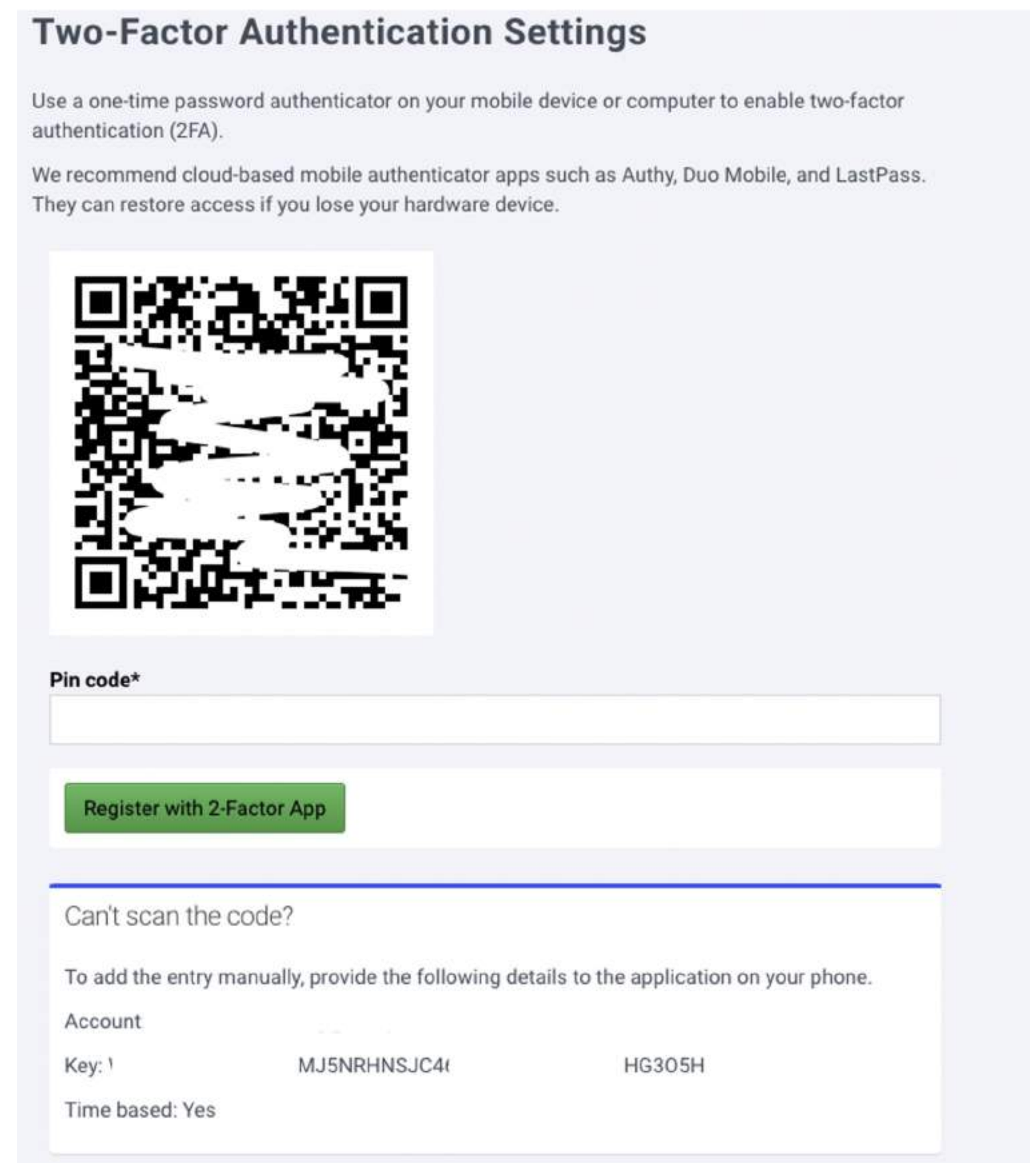
Reset TFA - Register New Device

- 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



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PERSONALISED PREVENTION FOR CORONARY HEART DISEASE

Laboratory Data

Laboratory Data - General

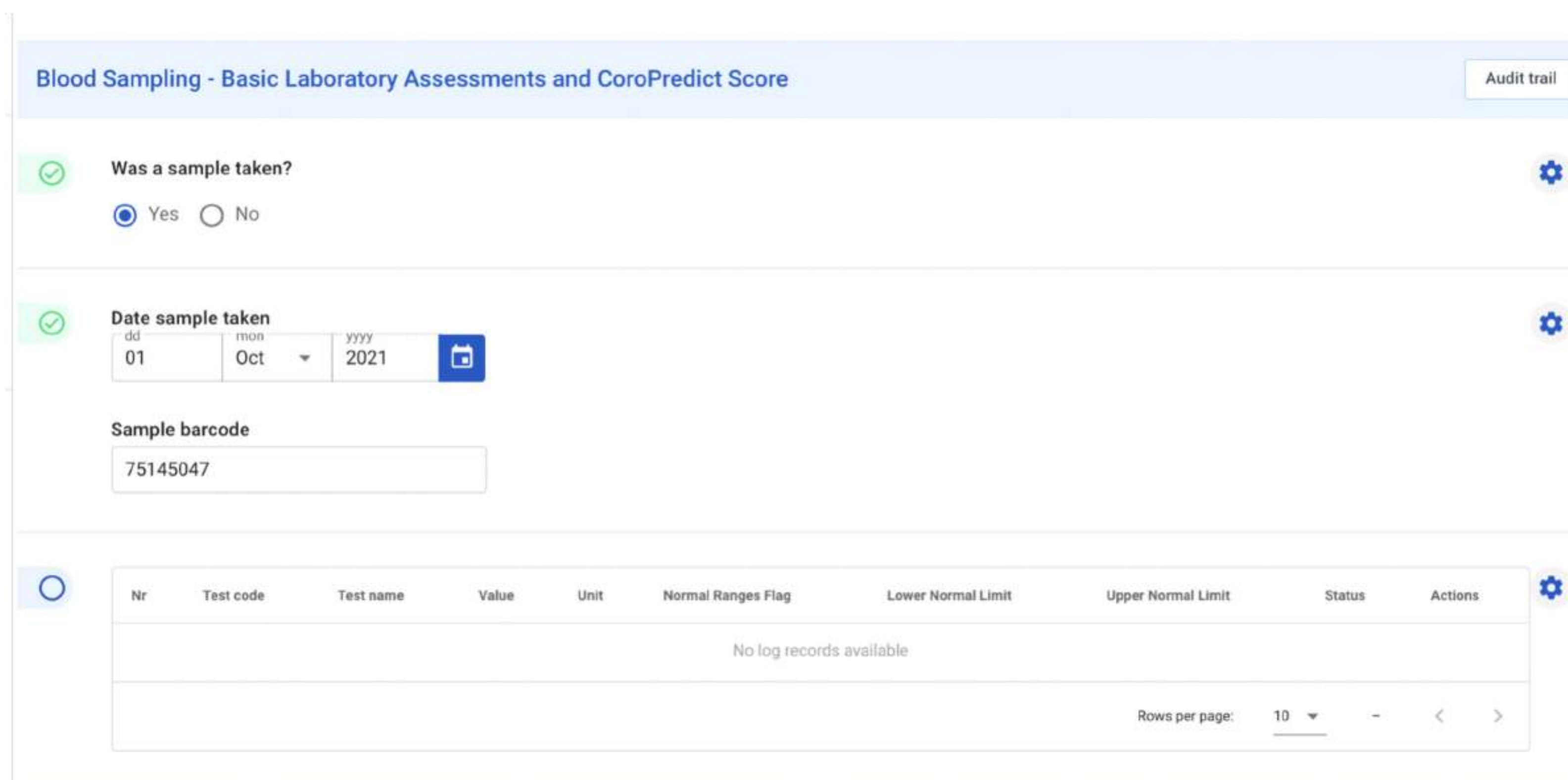
- The trial contains two types of laboratory data forms
    - Blood Sampling - Basic Laboratory Assessments and CoroPredict Score
    - Blood Sampling: Sub-study for Future Research
        - Only if Informed Consent for Blood Sampling Sub-study for Future Research is given
- Compliance Assessments results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

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

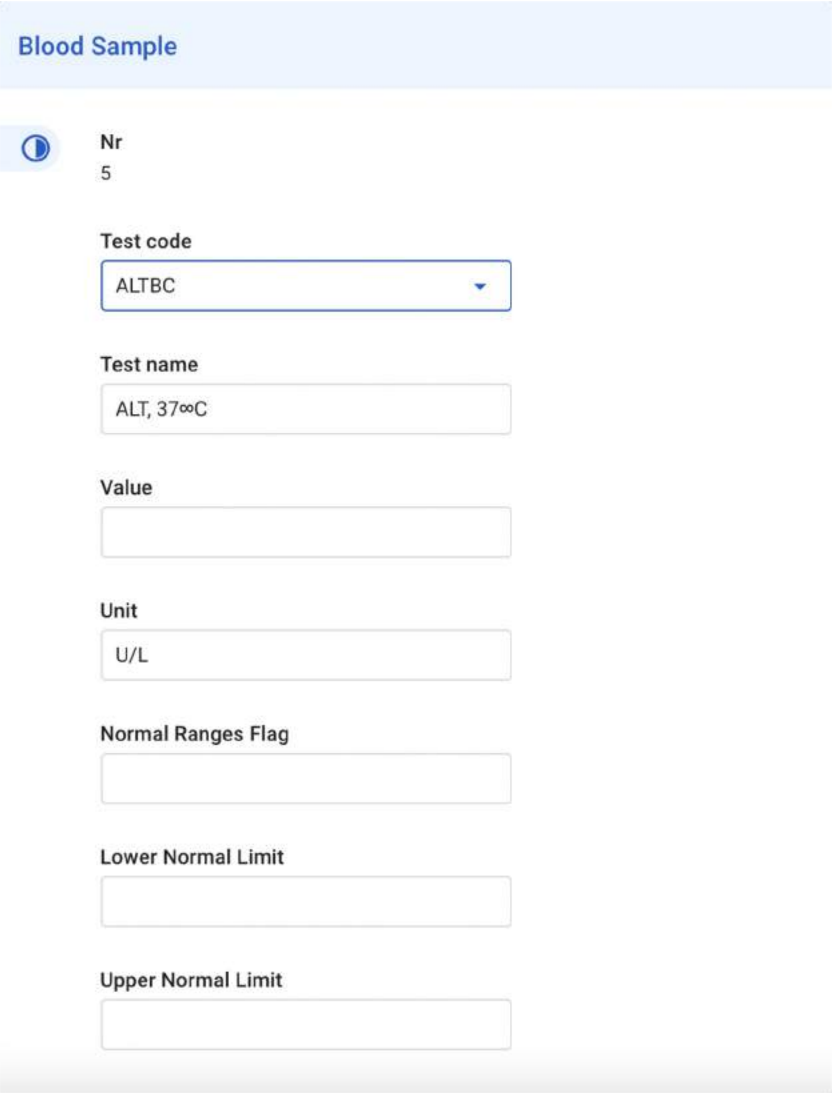
The laboratory assessments details for a subject-visit can only be uploaded if the above data has been completed in EDC.

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



Blood Sampling - Basic Laboratory Assessments and CoroPredict Score - 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



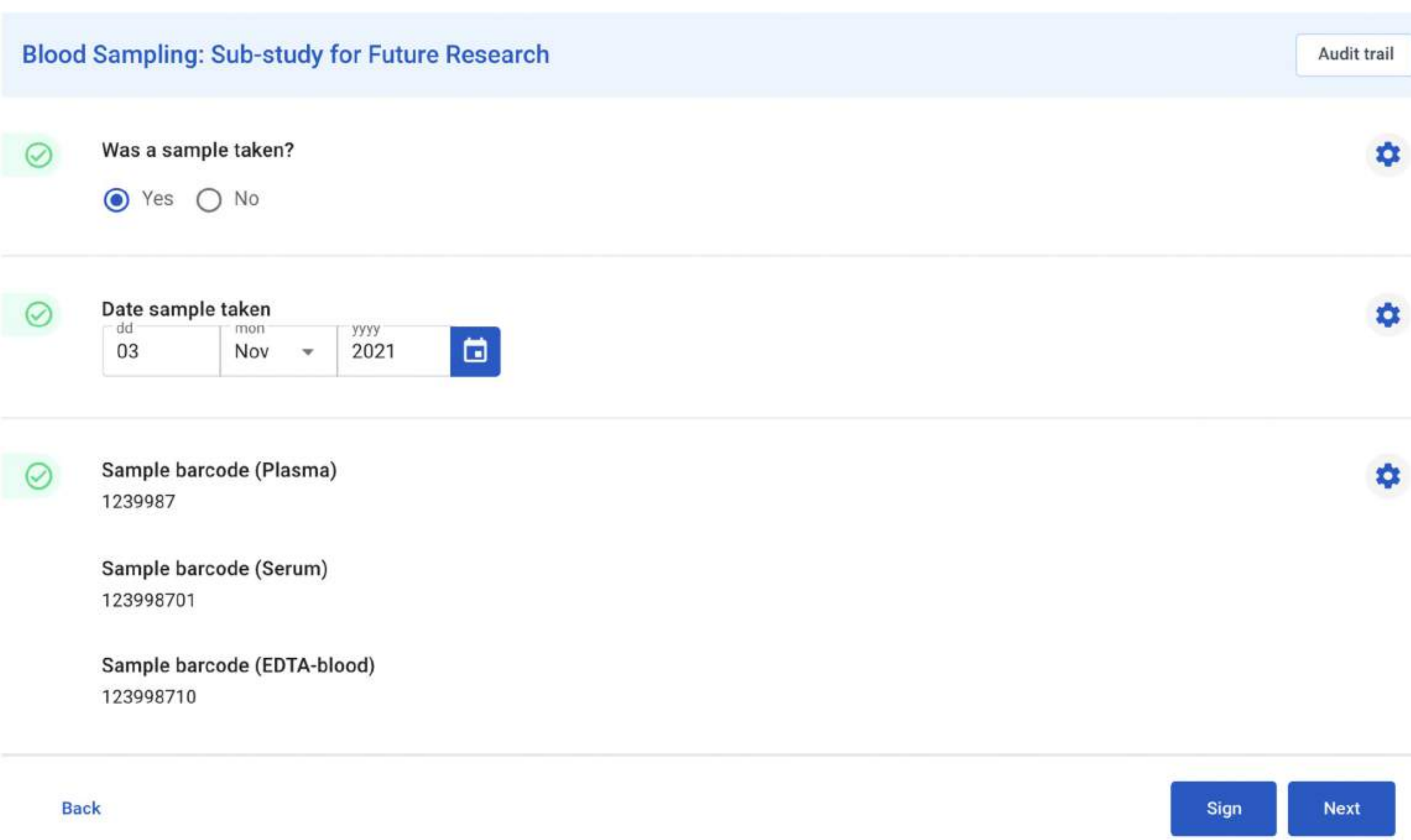
ADD BLOOD SAMPLE RECORD

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	CYBCCK	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 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



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

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				

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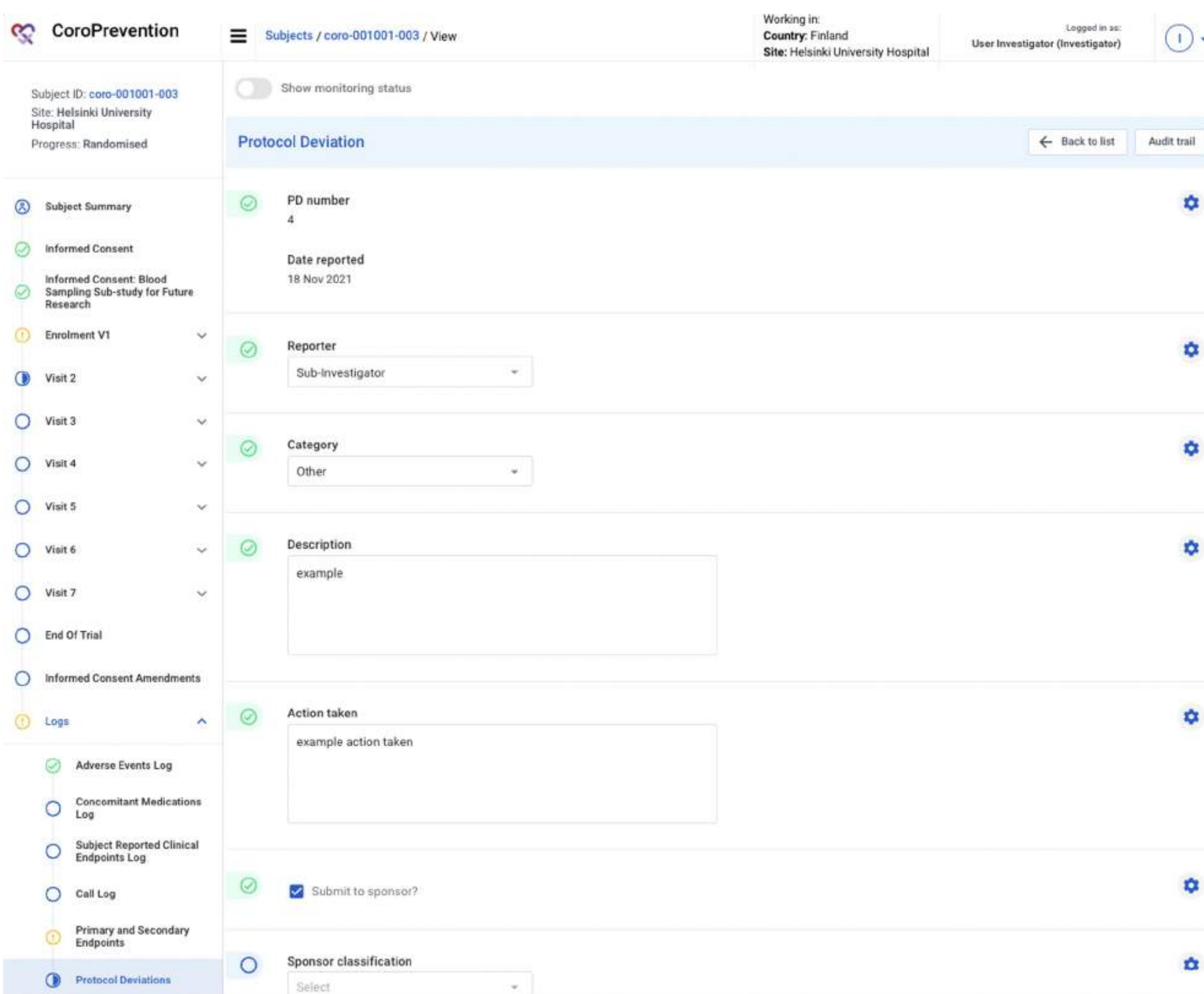
Protocol Deviations - Create

- 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?



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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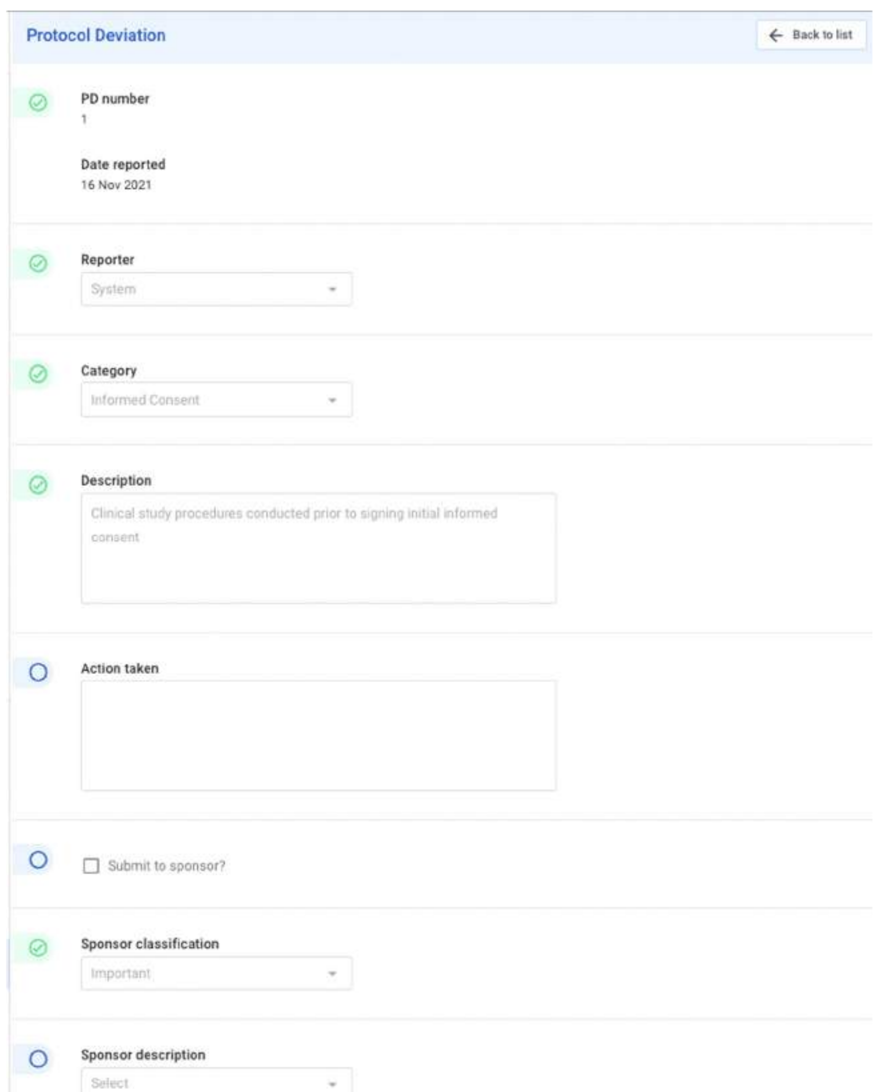
Protocol Deviations - Automatic PDs

- 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.

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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