CoroPrevention EDC -
Training Data Manager

v1.0

Agenda

- Login

- Training

- Navigation

- Enter and Edit Data

- Reports

Agenda (2)

- Manage DCRs

- Forgot Password

- Reset 2FA

- CoroPrevention: Laboratory Data

- CoroPrevention: Protocol Deviations

CoroPrevention
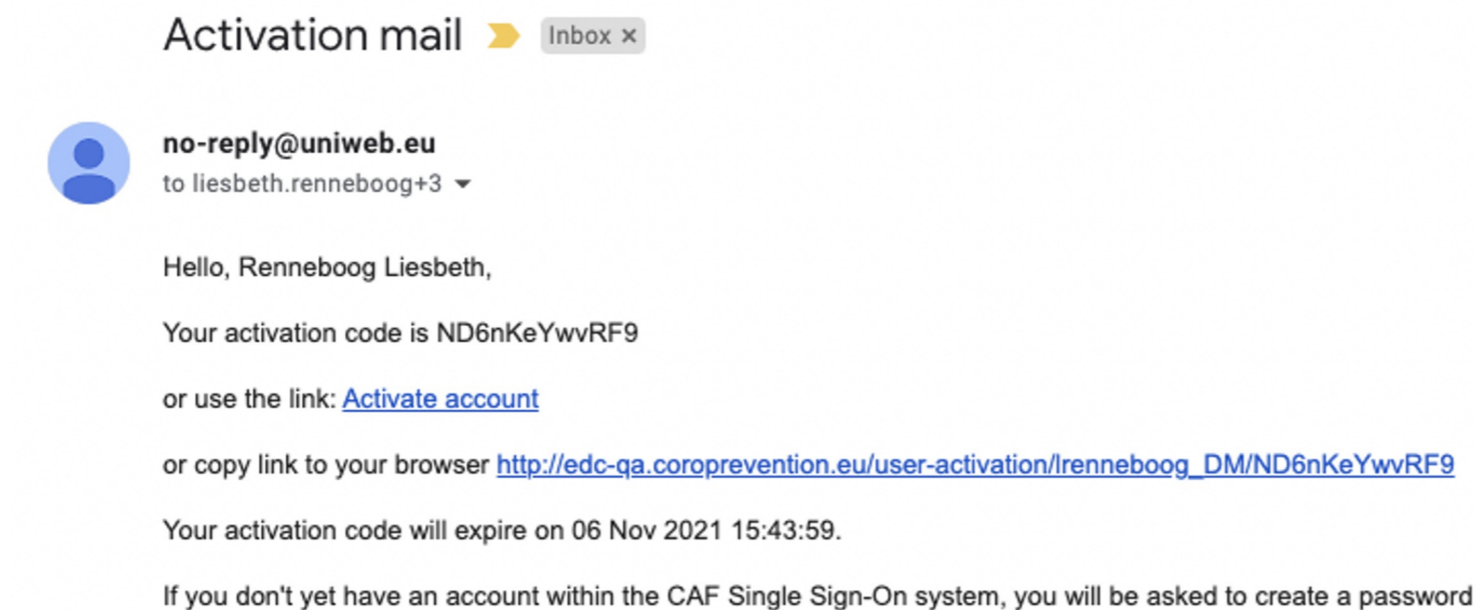PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

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

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

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CORONARY HEART DISEASE

Login - Account Activation (3)

- Choose a password that meets the requirements

- Click "Set Password"

Note:
Your password should not be shared.

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(HG3O5H

Time based: Yes
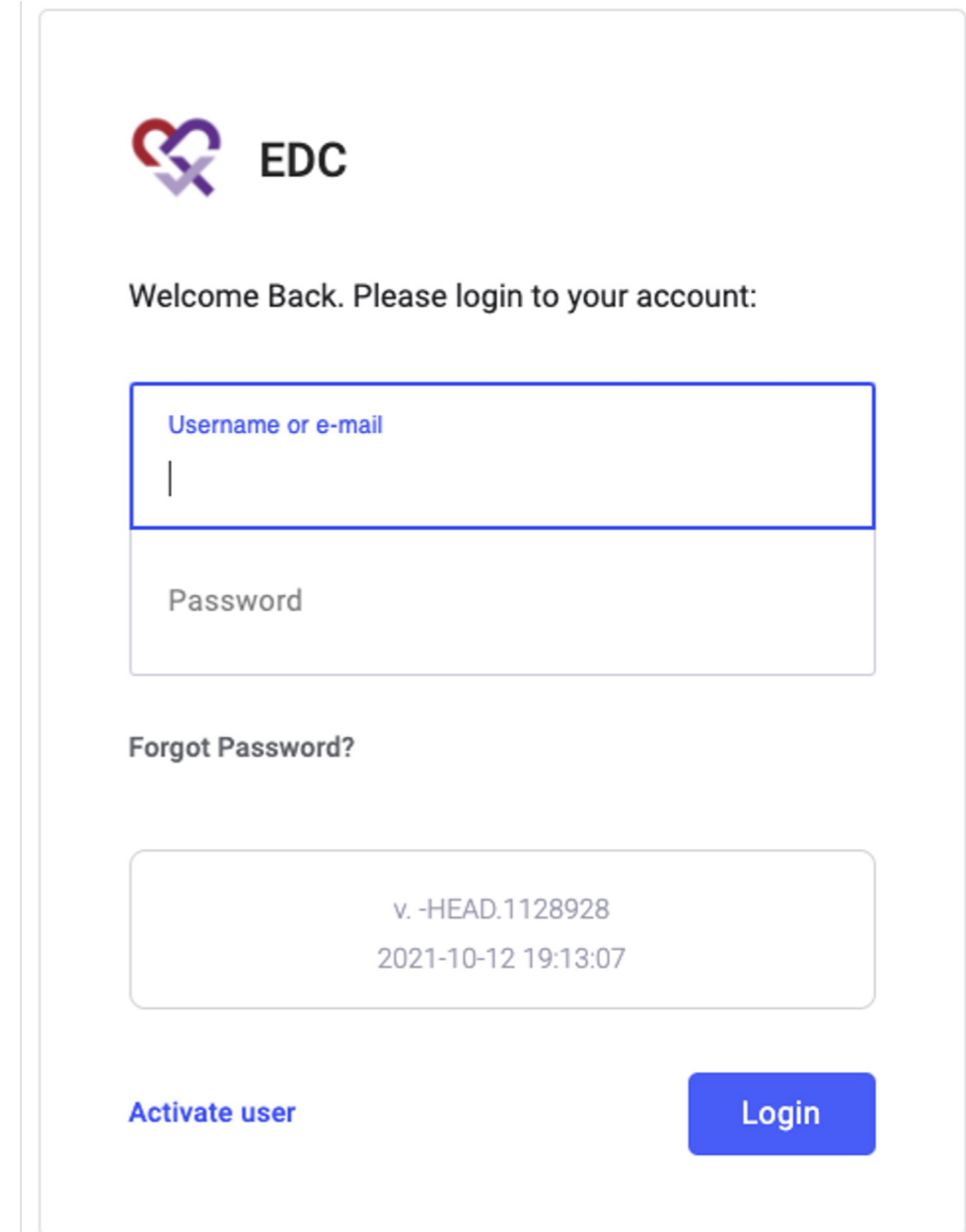
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Login - General

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

EDC

Welcome Back. Please login to your account:

Username or e-mail

Password

Forgot Password?

v. -HEAD.1128928
2021-10-12 19:13:07

Activate user   **Login**

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Login - General (2)

- Open the Google Authenticator app on your mobile device

- Enter the 6-digit code displayed for yourusername@coroprevention.eu

- Click Login

Enter a 6-digit code from your Authentication App

Login

Back to login

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![UniWeb]
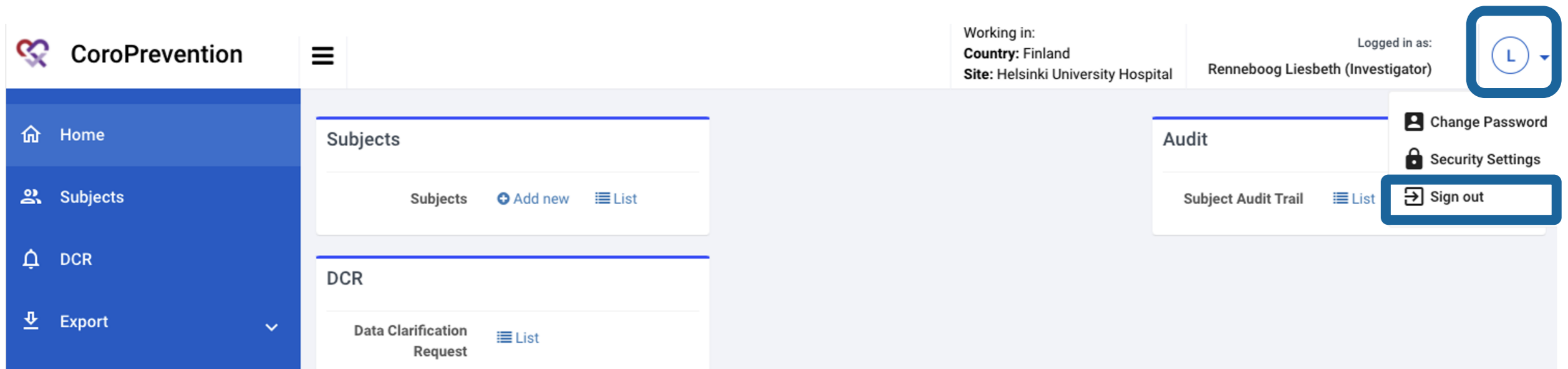
Logout

● To logout, click the icon in the upper right corner

● Click Sign out

Log out when stepping away from your computer.

![CoroPrevention — PERSONALISED PREVENTION FOR CORONARY HEART DISEASE]

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.

Training - Download

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

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

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

l.renneboog

Password

••••••••••••••

✓ SIGN   ✕ CANCEL

ⓘ **Success!**
Training signed successfully   ×

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

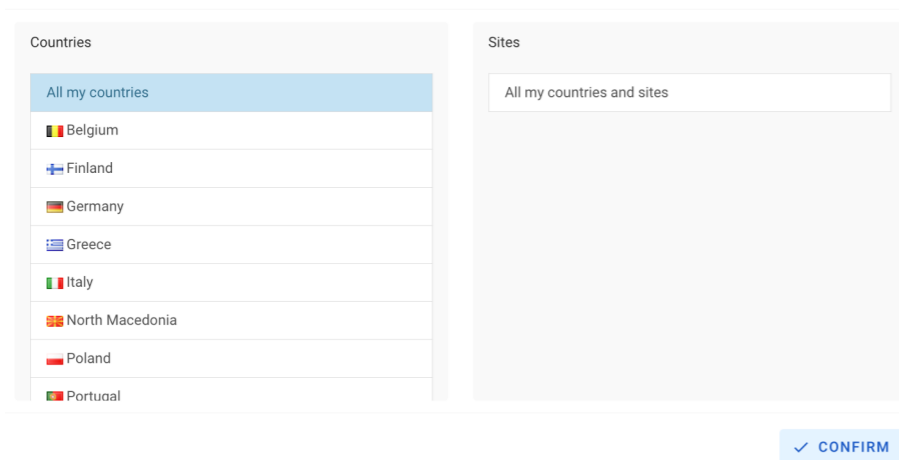| Training ↓	Required	Status	Completion date and time	Action
Query Management	no	Not Done		⬇ DOCUMENT DOWNLOAD
SAE Reporting	yes	Not Done		⬇ DOCUMENT DOWNLOAD
User Guidelines for Investigator	yes	Completed	16 Nov 2021 10:41:46	⬇ DOCUMENT DOWNLOAD

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

17

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

Navigation

Navigation - Location Select

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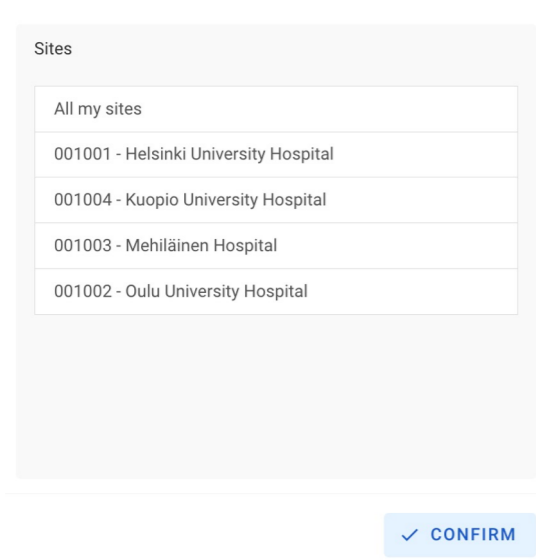
Location

Countries		Sites
All my countries		All my countries and sites
🇧🇪 Belgium		
➕ Finland		
🇩🇪 Germany		
🇬🇷 Greece		
🇮🇹 Italy		
🇲🇰 North Macedonia		
🇵🇱 Poland		
🇵🇹 Portugal		

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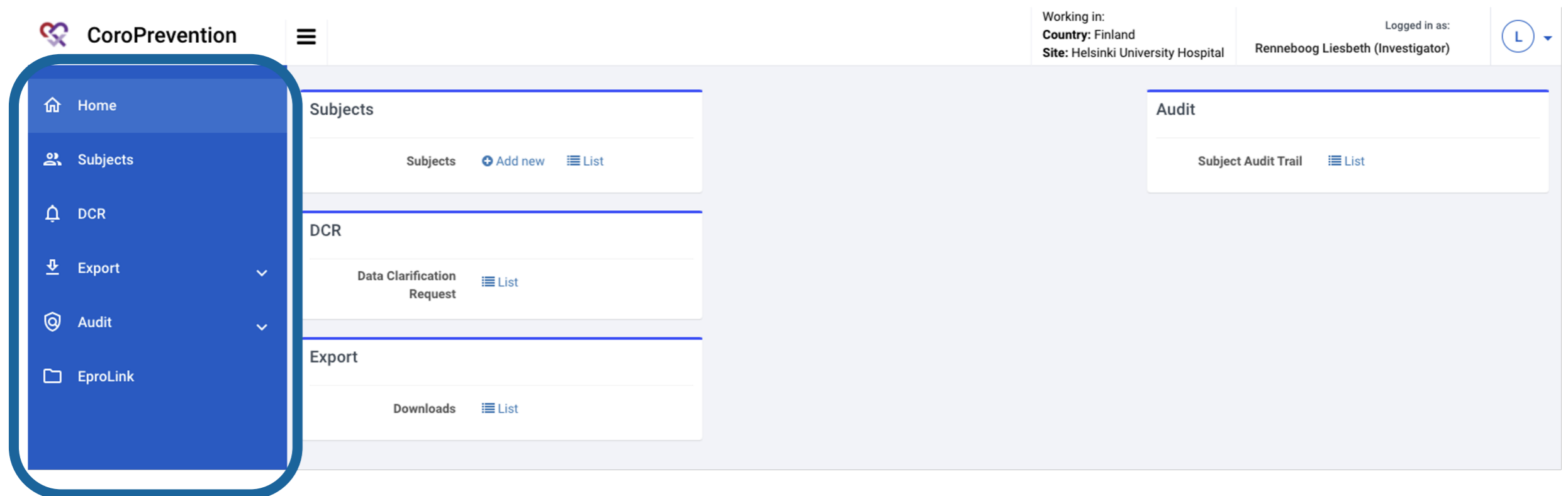
Sites
All my sites
001001 - Helsinki University Hospital
001004 - Kuopio University Hospital
001003 - Mehiläinen Hospital
001002 - Oulu University Hospital

✓ CONFIRM

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:

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

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

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:

Icon		Description
○	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

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

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

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)

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.

Ejection fraction from the latest available echocardiography

87   %

Date of latest echocardiography

dd	mon	yyyy
UK	UK	2021

Enter/Edit Data - Confirm Empty Values

Notable exception (2):

- check box fields with only one option

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

Should only be completed (ticked) in case applicable.

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

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

Enter/Edit Data - Calculated Fields

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

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

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

The subject is eligible to participate in the study
Yes

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 ▾   –   ⟨   ⟩
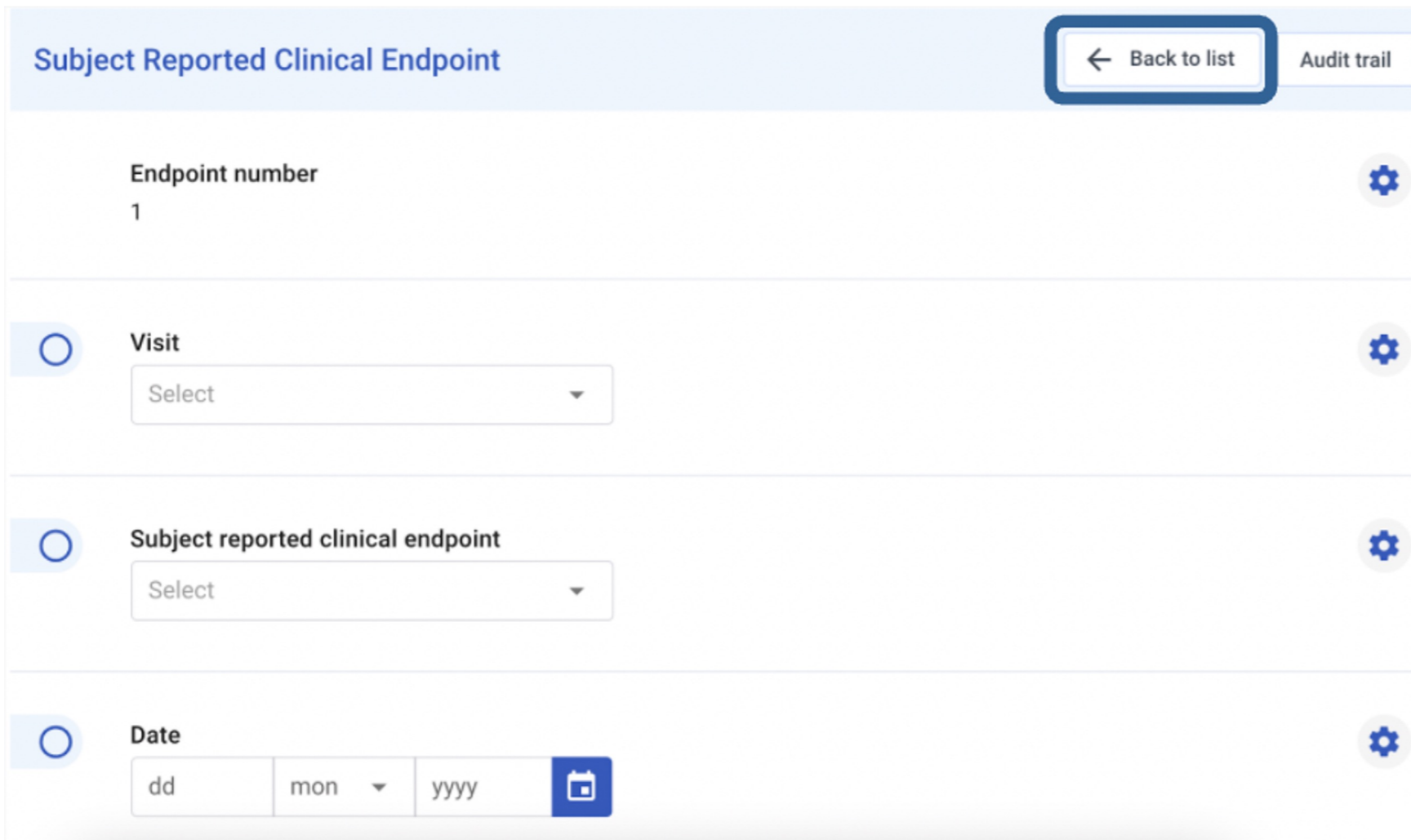
Enter/Edit Data - Log Forms (2)

- 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

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
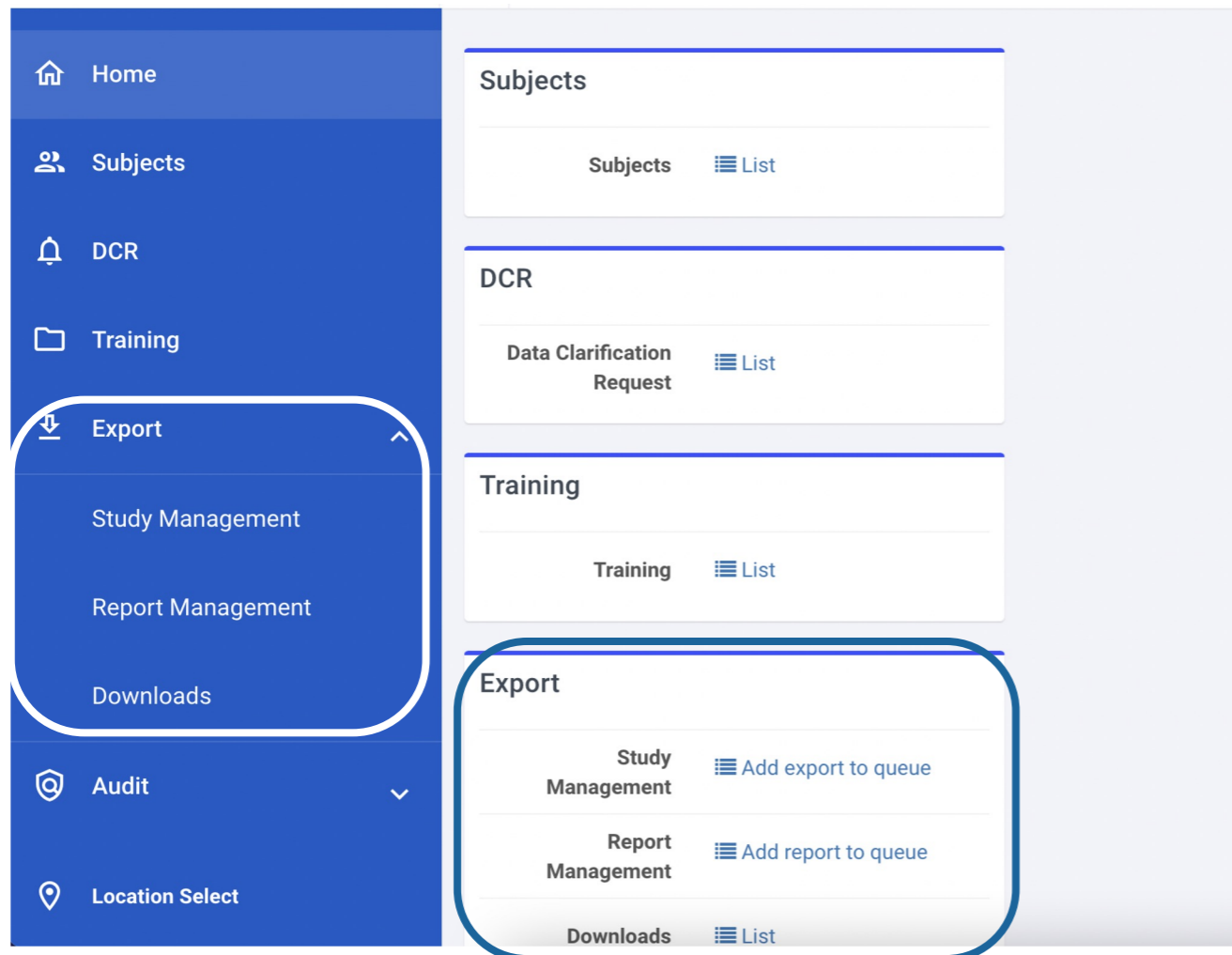
The reports and exports are categorized in three categories:
- Study Management
- Study Execution
- Reports

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

Reports - Generation

- Select the desired export / report
- Specify the filters if applicable
- Select the desired format from the dropdown of available formats
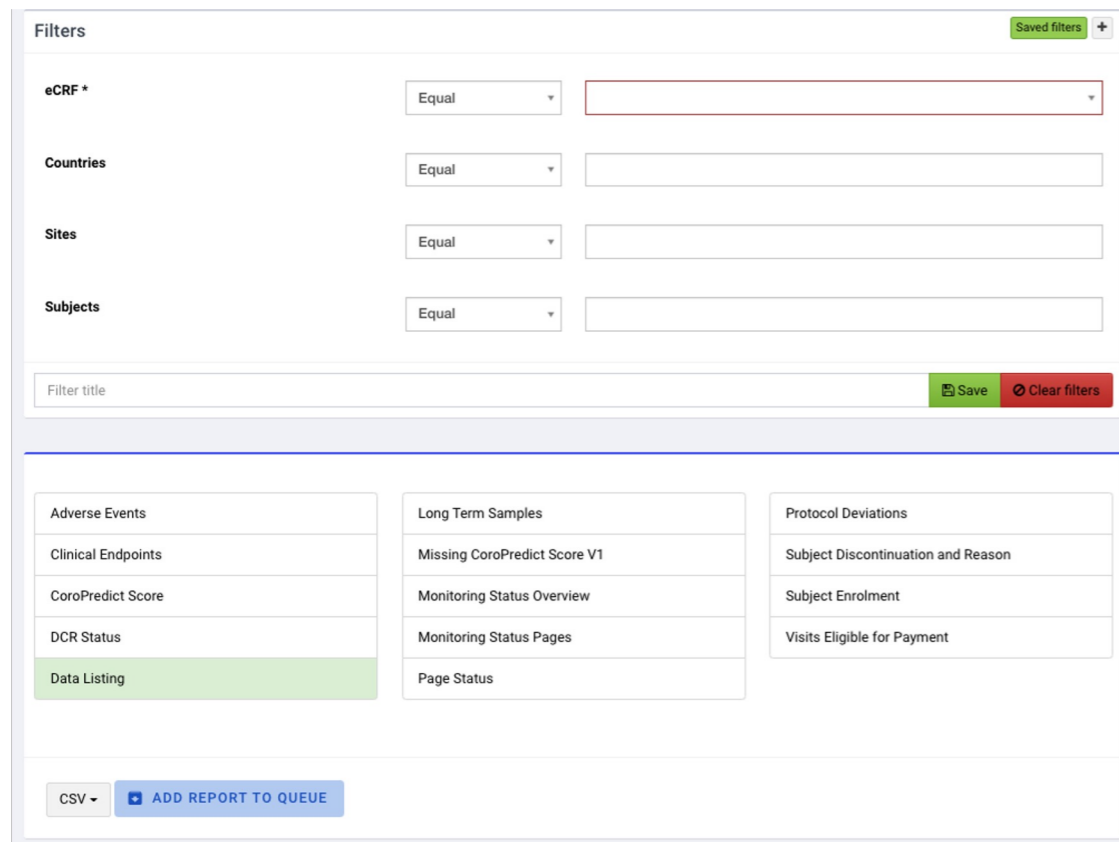- Click Add Export / Report To Queue to start the creation of the export / report
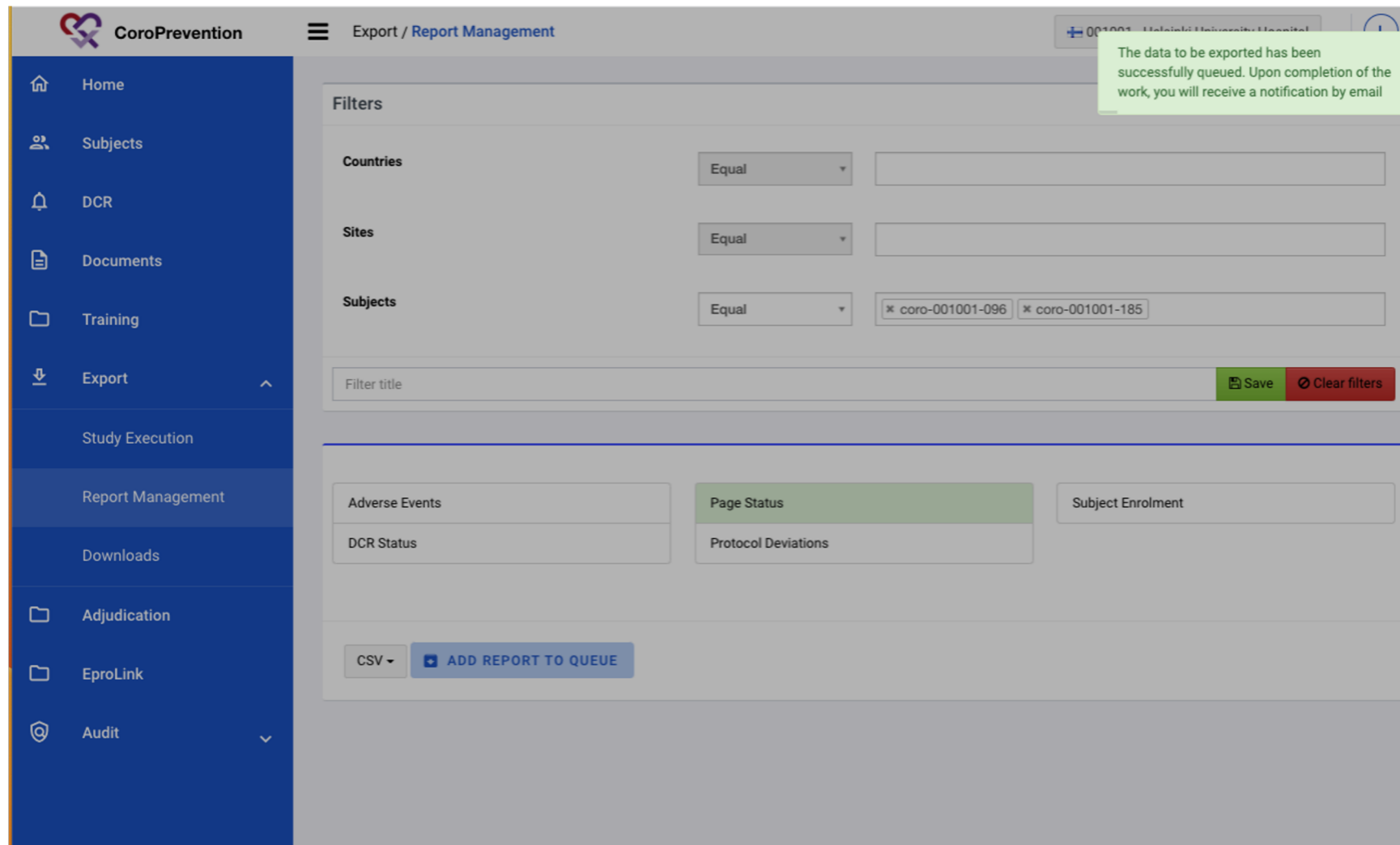
Reports - Generation (2)

- 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

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
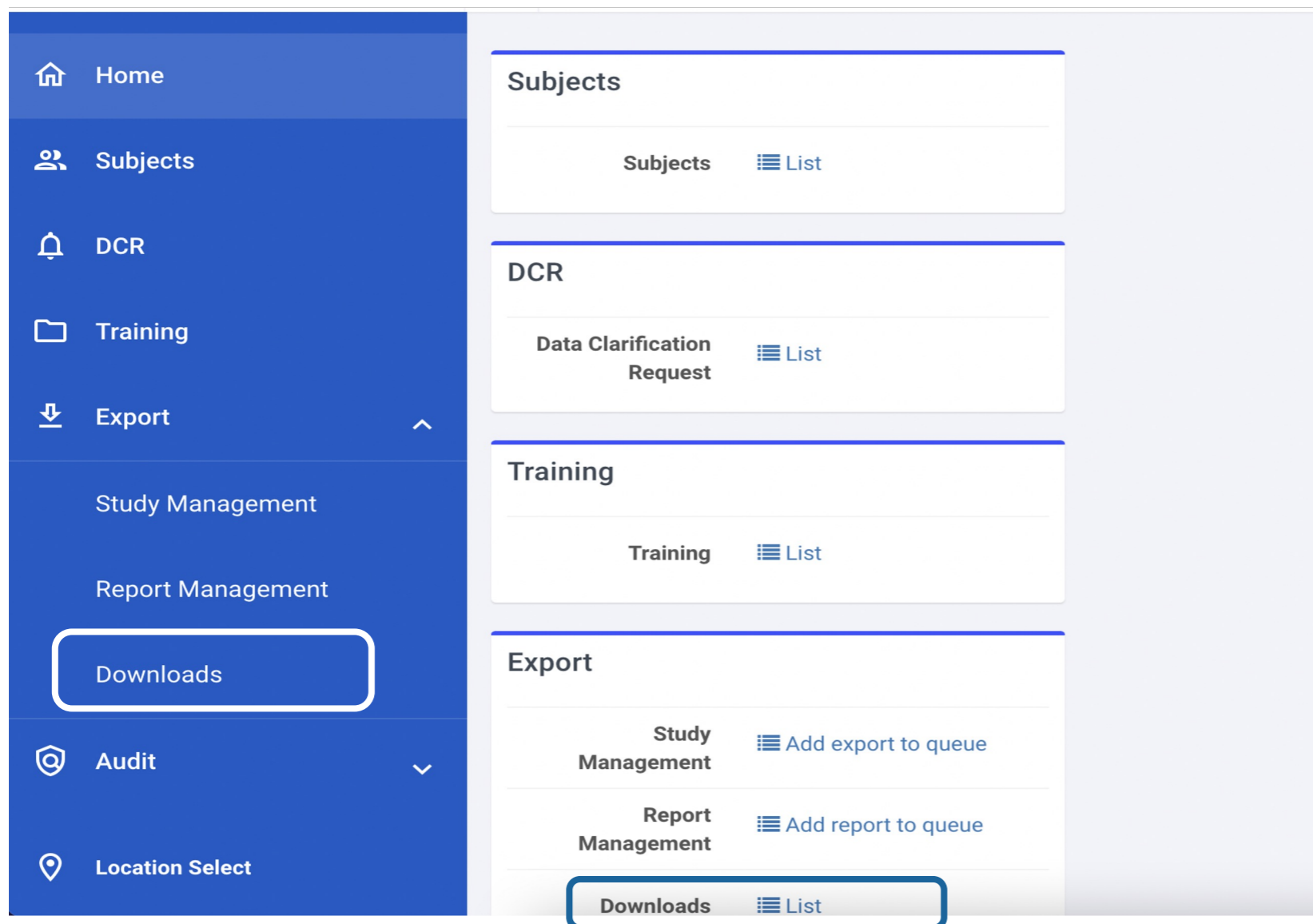- The system will warn you in case a filter needs to be specified

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

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

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

Export / Downloads — Multiple countries — Filters 0

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

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
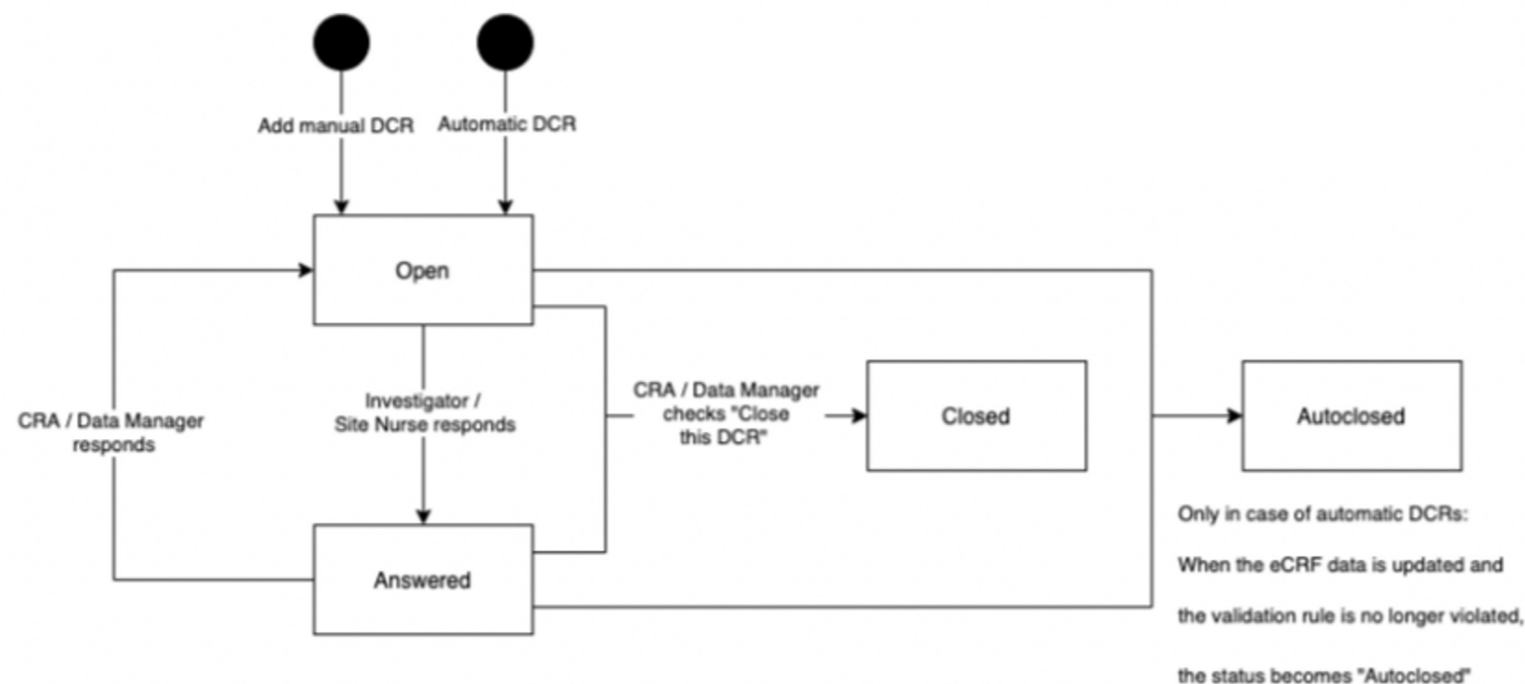
Manage DCRs - Create DCR on block

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
1980

Age
41

Sex
○ Male ◉ Female

Race ⚠₊
◉ Caucasian
○ Other

Back   Add Manual DCR   Next

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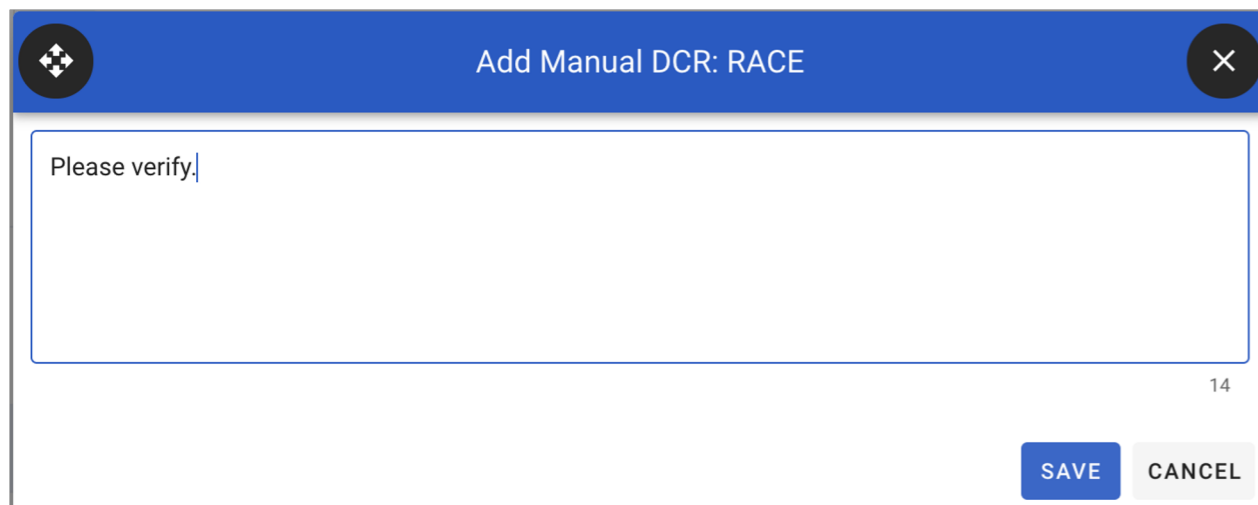
Manage DCRs - Create DCR on block (2)

- 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

Manage DCRs - Create DCR on eCRF (2)

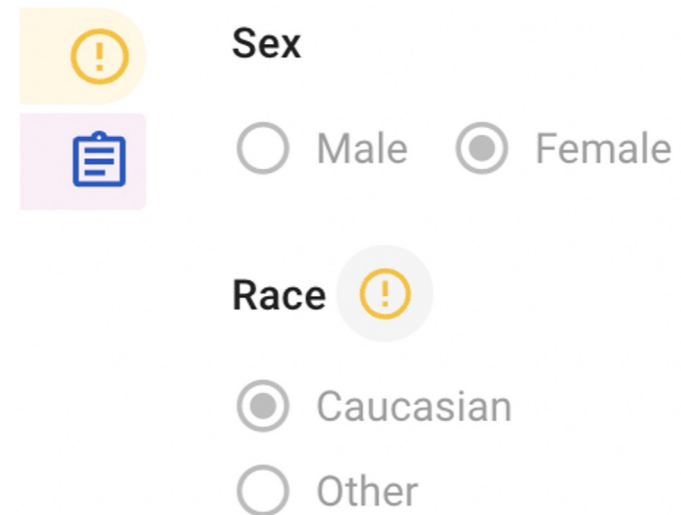- Enter the data clarification request and click Save to confirm or Cancel to return to the form
- eCRF DCRs are shown by clicking the DCR button
- These do not appear on a field itself

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

Manage DCRs - Re-open a DCR

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

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.

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

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

Manage DCRs - DCRs Overview (2)

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

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

Forgot Password

Forgot Password

EDC

- If you forgot your password, click Forgot Password? on the login page

- Provide your username or email address and click Send Recovery Email

Welcome Back. Please login to your account:

Username or e-mail

Password

Forgot Password?

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

Activate user   Login

Recover your account by entering your username or e-mail

User ID or email

Back to login   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

User password reset ➤ Inbox ×

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/lrenneboog_inv/VGRtwCCeC4Kp/set-password

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

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

●●●●●●●●●●●●●●   👁

Set Password

Back to login

Reset Two-Factor Authentication (TFA)

Reset TFA

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

Logged in as:

Renneboog Liesbeth (Investigator)

L ▼

Audit

👤 Change Password

🔒 Security Settings

Subject Audit Trail

➔ Sign out

Two-Factor Authentication Settings

You have already enabled a one-time password authenticator

If you wish, you can Reset the TFA Application
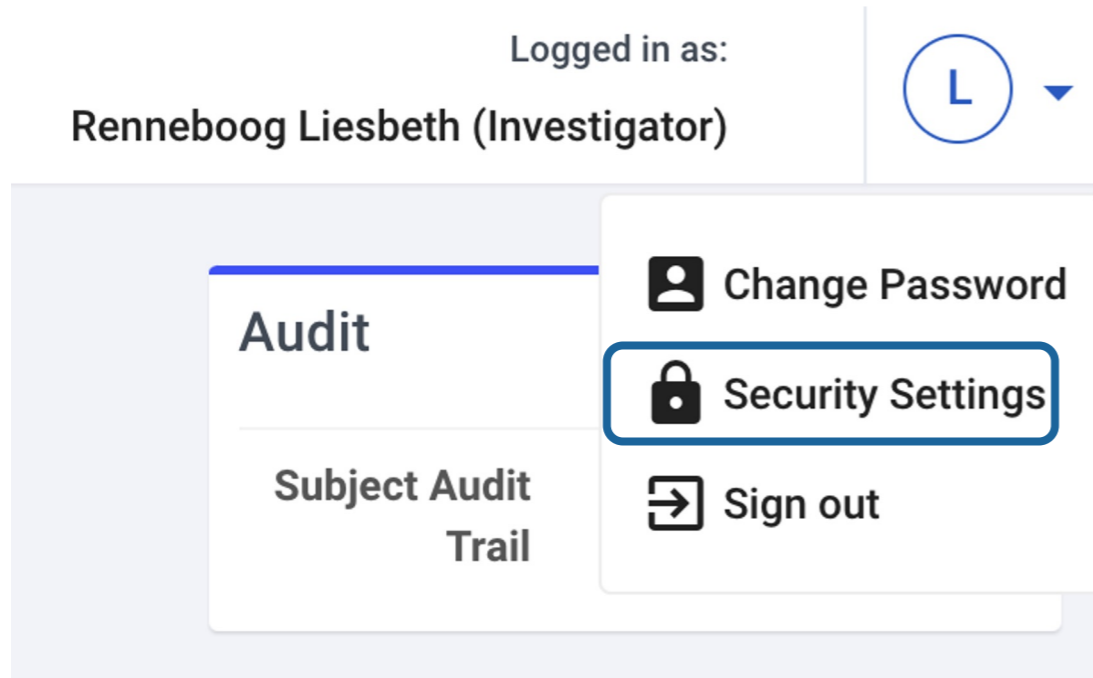
- Click Reset the TFA application
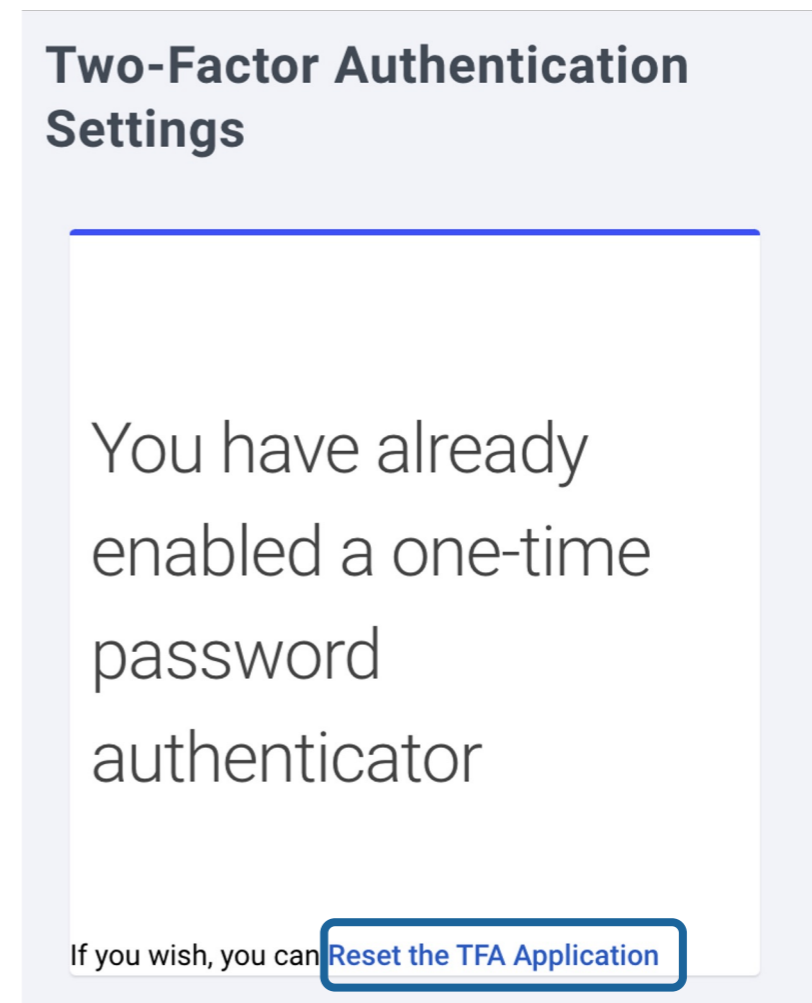
Reset TFA (2)

- 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: ꞌ   MJ5NRHNSJC4(HG3O5H

Time based: Yes

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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

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

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					

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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.

CoroPrevention
PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Randomise / Allocate Treatment

Eligibility

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

CoroPredict Score and Risk Category

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

- Risk category = low and medium risk
  ⇒ Allocate Treatment
  (Usual Care)

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

CoroPrevention

Subjects / coro-001001-006 / View

Working in:
Country: Finland
Site: Helsinki University Hospital

Logged in as:
Renneboog Liesbeth (Investigator)

Site: Helsinki University Hospital
Progress: Enrolled

Randomisation

Audit trail

- 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
  - Concomitant Medications

proBNP
+ 1

High-sensitivity troponin
+ 1

Cystatin-C
+ 1

Ceramide score
+ 1

CoroPredict score
= 4
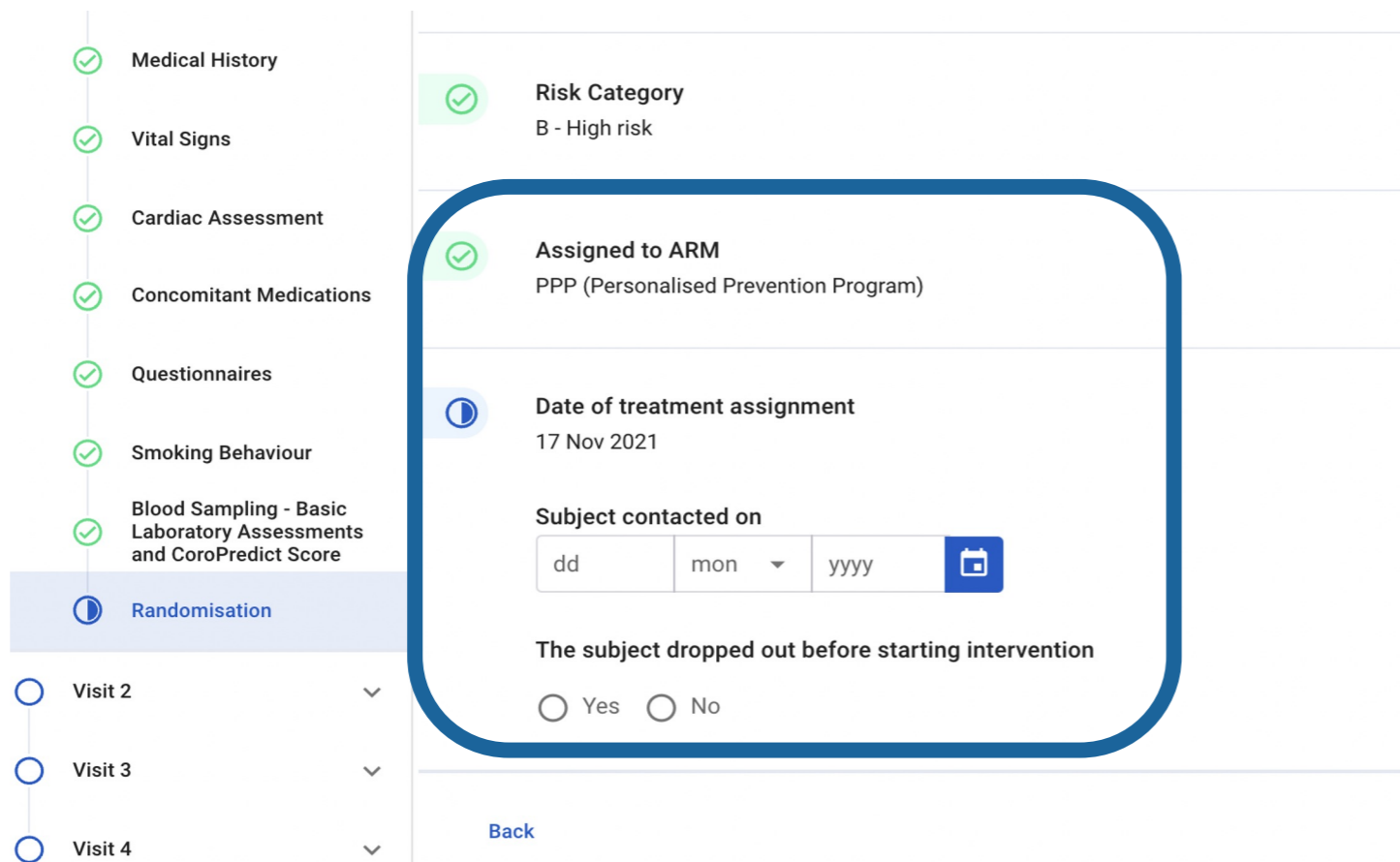
Risk Category
B - High risk

RANDOMIZE TREATMENT

Randomise Treatment

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

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

Randomise Treatment (2)

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

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

Allocate Treatment

- Study Nurses and Investigators can allocate treatment to a subject if:
    - The subject is eligible
    - The system has determined the risk category as "low or medium risk" based on the CoroPredict Score

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

Allocate Treatment (2)

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

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

Randomise / Allocate Treatment

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

Randomise / Allocate Treatment - Errors

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

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

SAE / SADE Form

SAE

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

SADE

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

SAE / SADE Form - Completing

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

! The form contains multiple pages

SAE / SADE Form - Sending

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

Reporting Person

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

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

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

Sending the Form

PLEASE SEND THIS FORM TO: CoroPrevention@tuni.fi
In case a receive acknowledge is not sent back in two days, please re-send.

SAE/SADE v1.0_28Jun2021

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CoroPrevention
PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Import Data from Tool Suite

Import Data from Tool Suite

- For subjects randomised to the PPP arm only

- Import Data button is available for following forms from Visit 2 onwards:
  - Vital Signs
  - Clinical Assessment
  - Smoking Behaviour
  - 6 Minute Walking Test

- It is possible to enter the data manually as well

Import Data from Tool Suite (2)

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

Import Data from Tool Suite (3)

- A pop-up window will appear that will show:
  - Question - the field on the eCRF
  - Current value - the current value of the question on the eCRF in EDC
  - New value - the value that can be imported from the CoroPrevention tool

- Review the data and click "Import" to import the new values into the eCRF
- Or click "Cancel" to return to the eCRF without importing the data

Import data for Vital Signs - coro-001001-115 ✕

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

CANCEL **IMPORT**

Import Data from Tool Suite (4)

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

Import Data from Tool Suite - Data Updates

- The most efficient way to make updates to already imported data is by:
  - Making the necessary updates to the data in the Tool Suite
  - Then navigating to the subject in eCRF and to the applicable eCRF
  - And clicking "Import data from CoroPrevention tool" and then "Import"

- The pop-up window will show the updated value(s) in the "New value" column:

Import data for Vital Signs - coro-001001-115		✕
Question	**Current value**	**New value**
Systolic	133	133
Diastolic	111	111
Body weight	88.5	85.5
Pulse Rate	101	99

CANCEL   **IMPORT**

Import Data from Tool Suite - No Data

- In case the data was not yet provided in the Tool Suite, the pop-up window will be empty

- You won't be able to import the data:
  - Either complete the data in the eCRF manually or
  - Add the data in the Tool Suite and then import the data for the subject's eCRF in EDC

Import data for Clinical Assessment - coro-001001-087		✕
Question	**Current value**	**New value**
	No data available	

CANCEL   IMPORT

Generate ePRO Link

Generate ePRO Link

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

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

Generate ePRO Link (2)

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

Generate ePRO Link (3)

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

List of ePRO Links

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

Protocol Deviations

Protocol Deviations - Log

Any protocol deviations (PDs) on subject are to be collected on the Protocol Deviations Log.
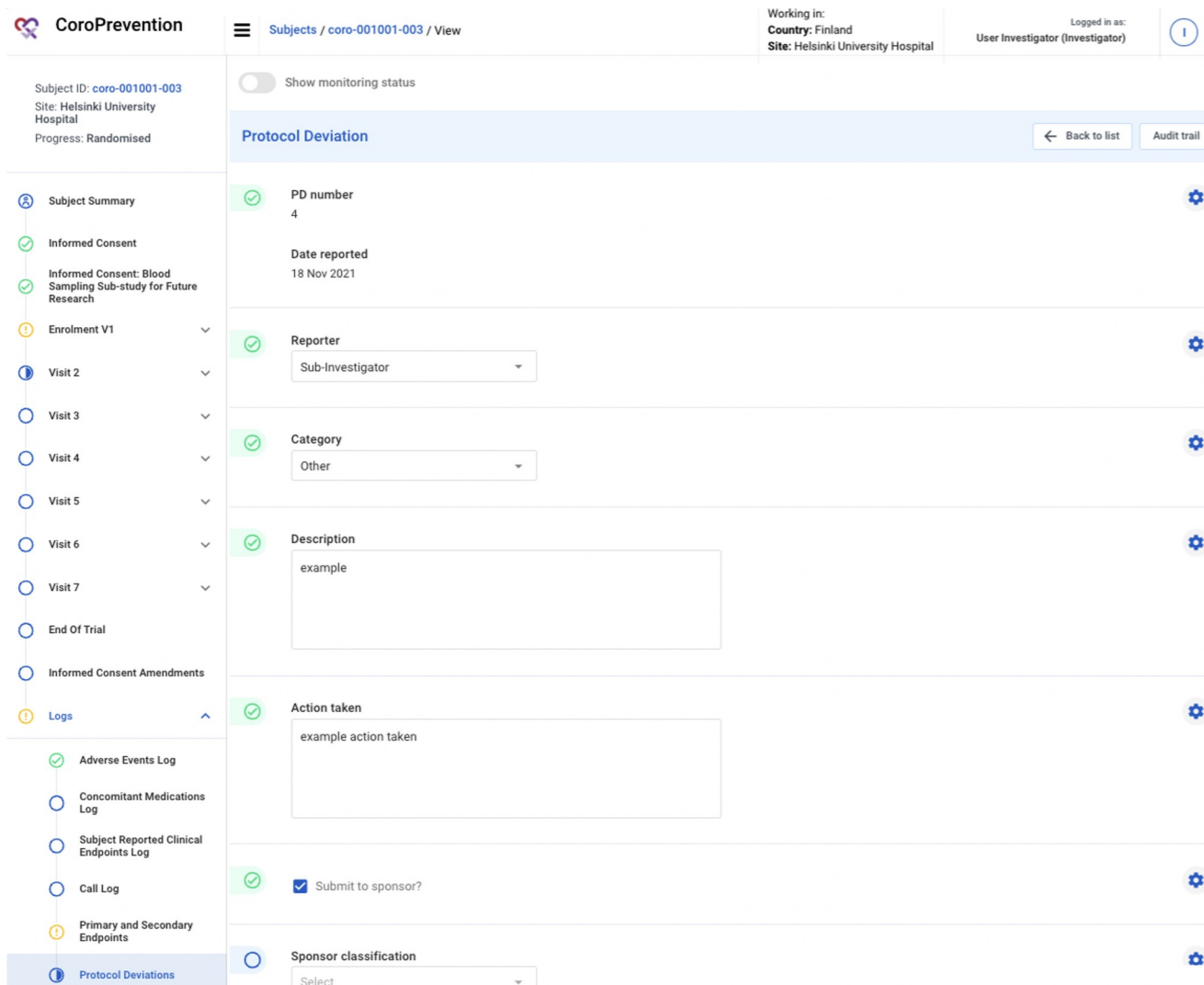
PDs can be manually created or automatically generated based on predefined conditions. Automatic PDs have "System" as reporter.

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				✏

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?

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

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

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.

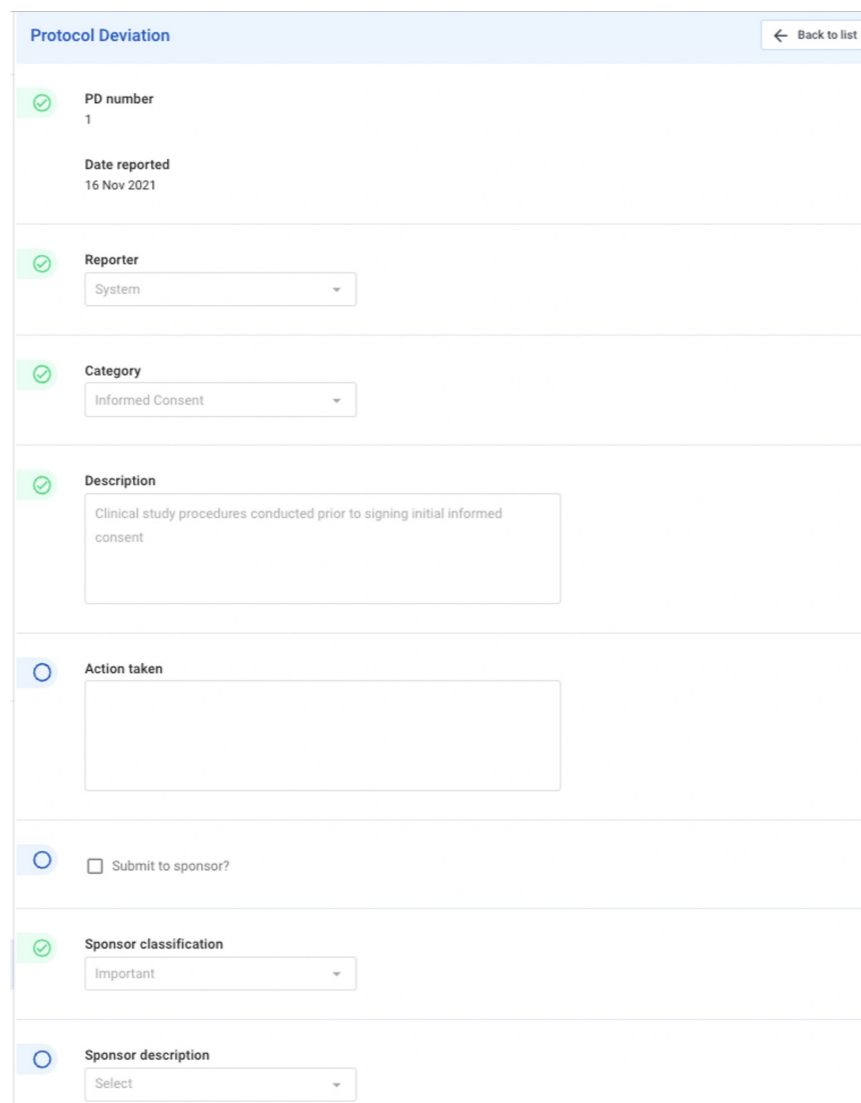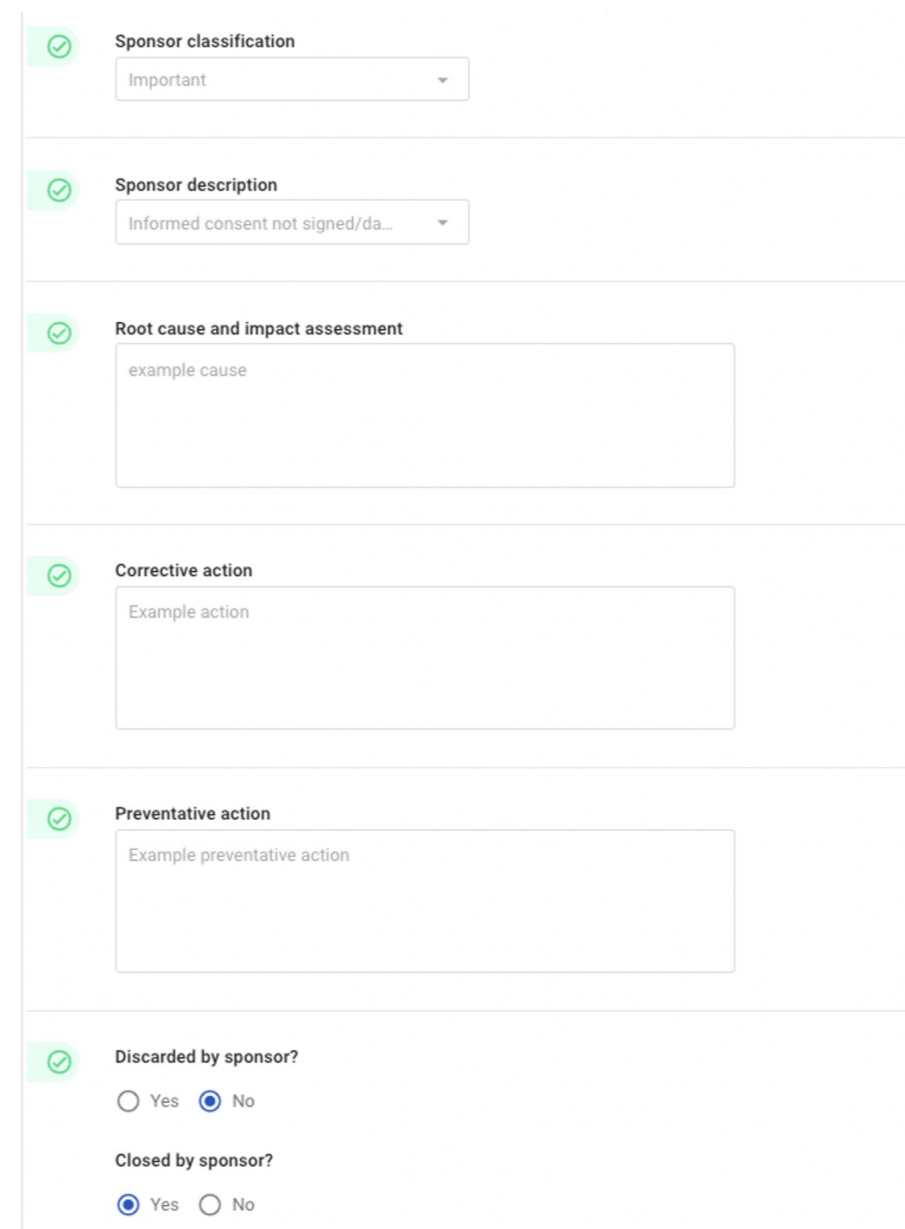The sponsor will complete the other fields of this PD record.

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

Sponsor classification

Important

Sponsor description

Informed consent not signed/da...

Root cause and impact assessment

example cause

Corrective action

Example action

Preventative action

Example preventative action

Discarded by sponsor?

◯ Yes ⦿ No

Closed by sponsor?

⦿ Yes ◯ No