



**CoroPrevention**

PERSONALISED PREVENTION FOR  
CORONARY HEART DISEASE



# CoroPrevention EDC - Training Project Manager

v1.0

# Agenda

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



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# Agenda (2)

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



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# Login

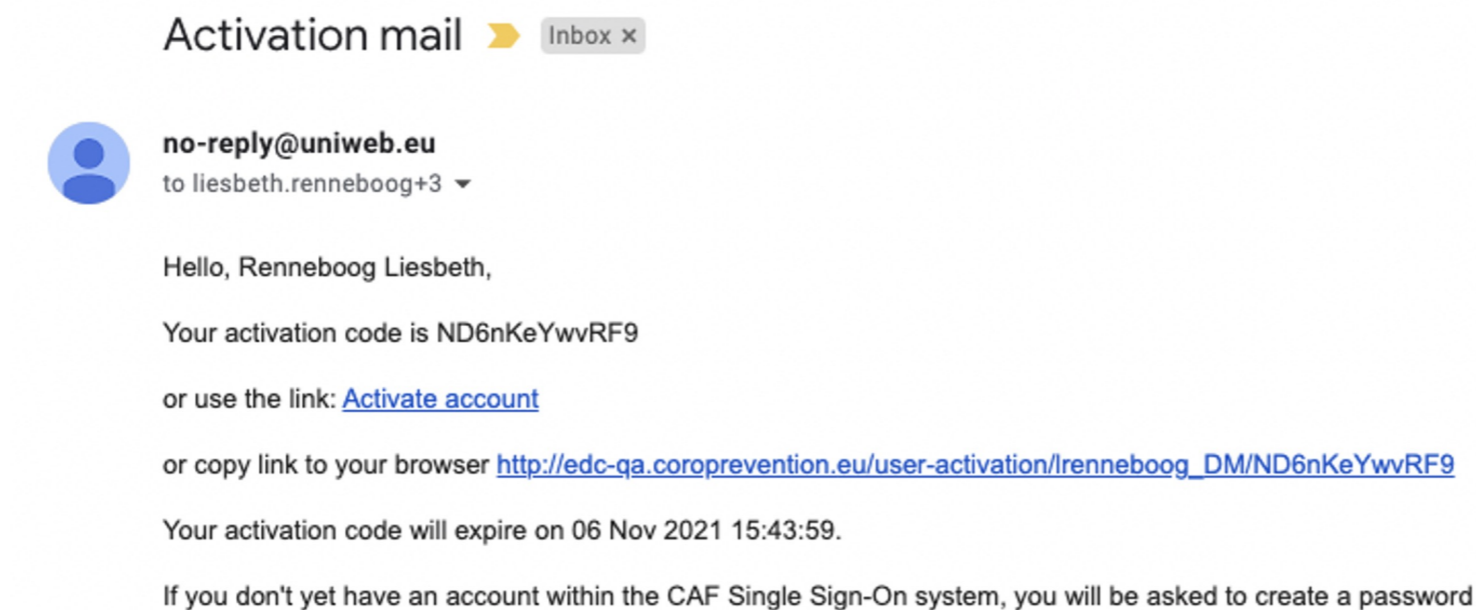


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# Login - Account Activation

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



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# Login - Account Activation (2)

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

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

Username or e-mail liesbeth.renneboog
Activation code .....

[Back to login](#)

**Activate**



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# Login - Account Activation (3)

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

✓ 30 or less characters

✓ Uppercase

✓ A number

✓ 8 or more characters

✓ Lowercase

✓ A special symbol

Set Password

[Back to login](#)

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



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# Login - Register Two-Factor Authentication

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

## Two-Factor Authentication Settings

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

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



Pin code\*

Register with 2-Factor App

Can't scan the code?

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

Account

Key: 1

MJ5NRHNSJC4{

HG305H

Time based: Yes



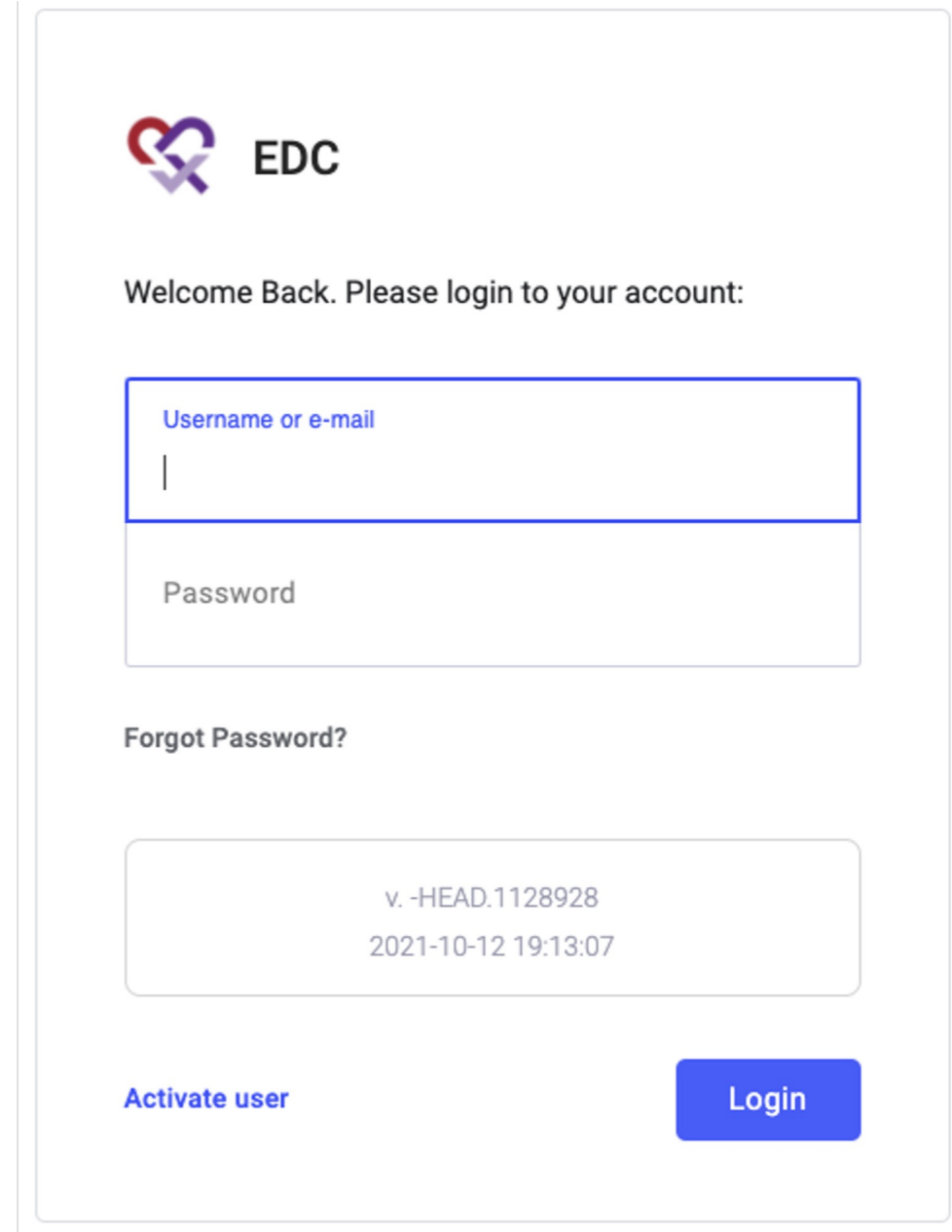
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# Login - General

After initial login, follow these steps to login:

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



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



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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](mailto:yourusername@coroprevention.eu)
- Click Login

Enter a 6-digit code from your Authentication App

Login

[Back to login](#)

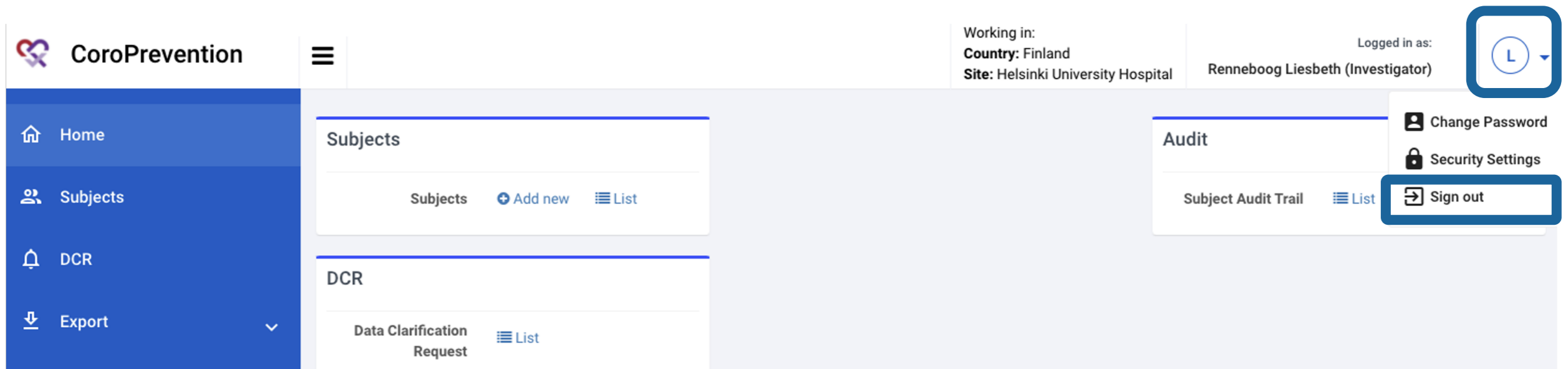


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# Logout

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



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

Log out when stepping away from your computer.



# Training



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# Training - Initial

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

CoroPrevention Training

Working in: Country: Finland Site: Helsinki University Hospital

Logged in as: Renneboog Liesbeth (Investigator)

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

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

1 / 1 - 3 results - Per page 32

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



# Training - Download

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

CoroPrevention

☰
Training

Working in:  
Country: Finland  
Site: Helsinki University Hospital

Logged in as:  
Renneboog Liesbeth (Investigator)

L
▼

⚠ **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		<a href="#">DOCUMENT DOWNLOAD</a>
SAE Reporting	yes	Not Done		<a href="#">DOCUMENT DOWNLOAD</a>
User Guidelines for Investigator	yes	Not Done		<a href="#">DOCUMENT DOWNLOAD</a>

1 / 1 - 3 results - Per page 32 ▼

- 🏠 Home
- 👤 Subjects
- 🔔 DCR
- 📁 Training
- 📄 Export
- 📁 EproLink



# Training - Sign

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

The screenshot shows the CoroPrevention interface. At the top left is the CoroPrevention logo. A navigation menu on the left includes Home, Subjects, DCR, Training (highlighted), Export, and EproLink. The main header area shows 'Working in: Country: Finland, Site: Helsinki University Hospital' and 'Logged in as: Renneboog Liesbeth (Investigator)'. A yellow warning banner at the top states: 'Warning! You need to download and sign all required trainings before you can access the platform'. Below this is a table with the following data:

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

At the bottom right of the table area, 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**

✓ 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		<a href="#">DOCUMENT DOWNLOAD</a>
SAE Reporting	yes	Not Done		<a href="#">DOCUMENT DOWNLOAD</a>
User Guidelines for Investigator	yes	Completed	16 Nov 2021 10:41:46	<a href="#">DOCUMENT DOWNLOAD</a>

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



# Training - Access

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

CoroPrevention

☰
Training

Working in:

**Country:** Finland

**Site:** Helsinki University Hospital

Logged in as:

Renneboog Liesbeth (Investigator)

L
▼

**Success!**  
Training signed successfully
✕

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

1 / 1 - 3 results - Per page 32 ▼



# Navigation



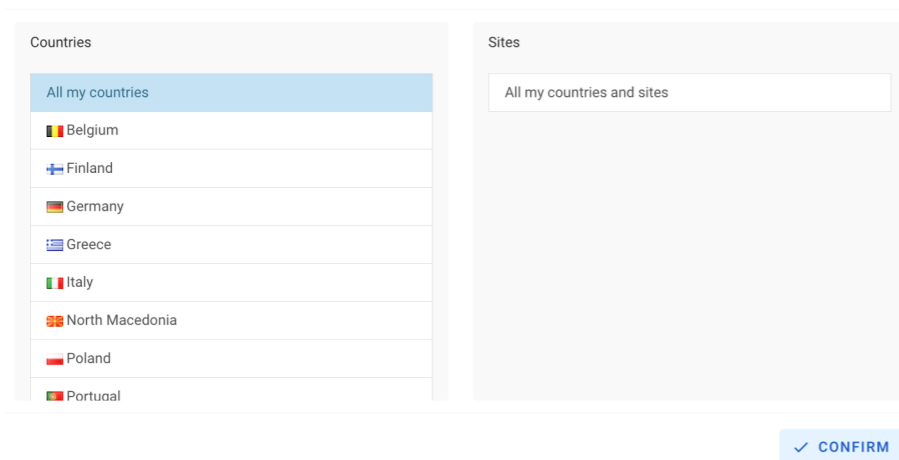
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# Navigation - Location Select

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

Location



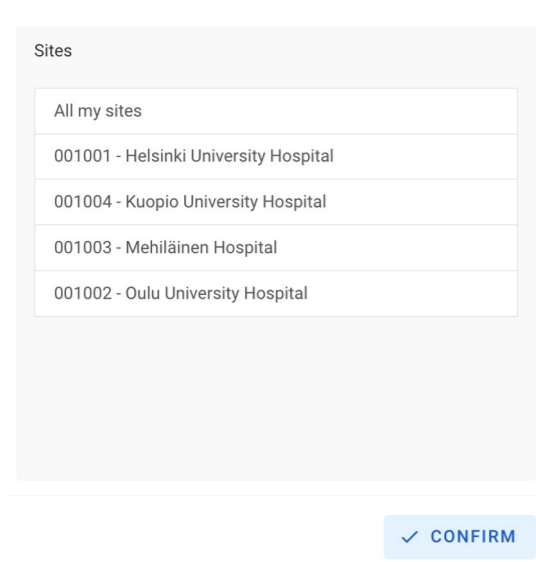
Countries	Sites
All my countries	All my countries and sites
Belgium	
Finland	
Germany	
Greece	
Italy	
North Macedonia	
Poland	
Portugal	

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

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

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

- Or to more than one site:

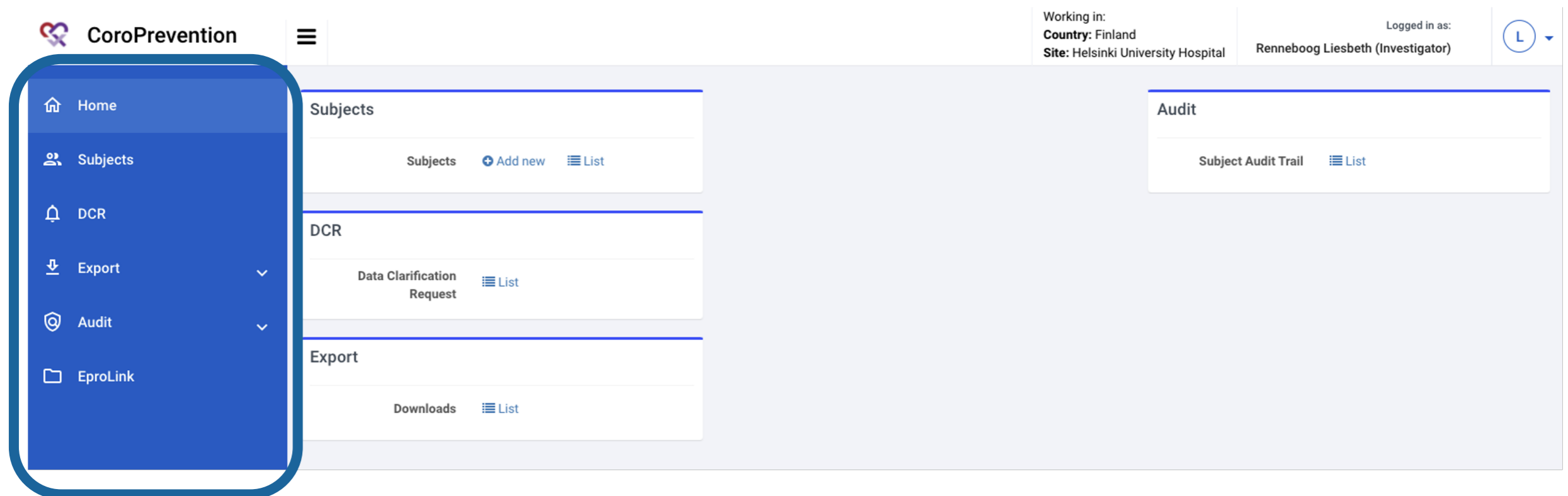


Sites
All my sites
001001 - Helsinki University Hospital
001004 - Kuopio University Hospital
001003 - Mehiläinen Hospital
001002 - Oulu University Hospital



# Navigation - Bar

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



The screenshot displays the CoroPrevention web application interface. On the left, a blue navigation bar is highlighted with a rounded rectangle, containing the following menu items: Home (with a house icon), Subjects (with a person icon), DCR (with a bell icon), Export (with a download icon and a dropdown arrow), Audit (with a shield icon and a dropdown arrow), and EproLink (with a folder icon). The main content area is divided into three horizontal panels: 'Subjects' with a 'Subjects' link, '+ Add new' button, and 'List' link; 'DCR' with a 'Data Clarification Request' link and 'List' link; and 'Export' with a 'Downloads' link and 'List' link. On the right side, there is an 'Audit' panel with a 'Subject Audit Trail' link and 'List' link. The top right corner shows user information: 'Working in: Country: Finland Site: Helsinki University Hospital' and 'Logged in as: Renneboog Liesbeth (Investigator)' next to a user profile icon.



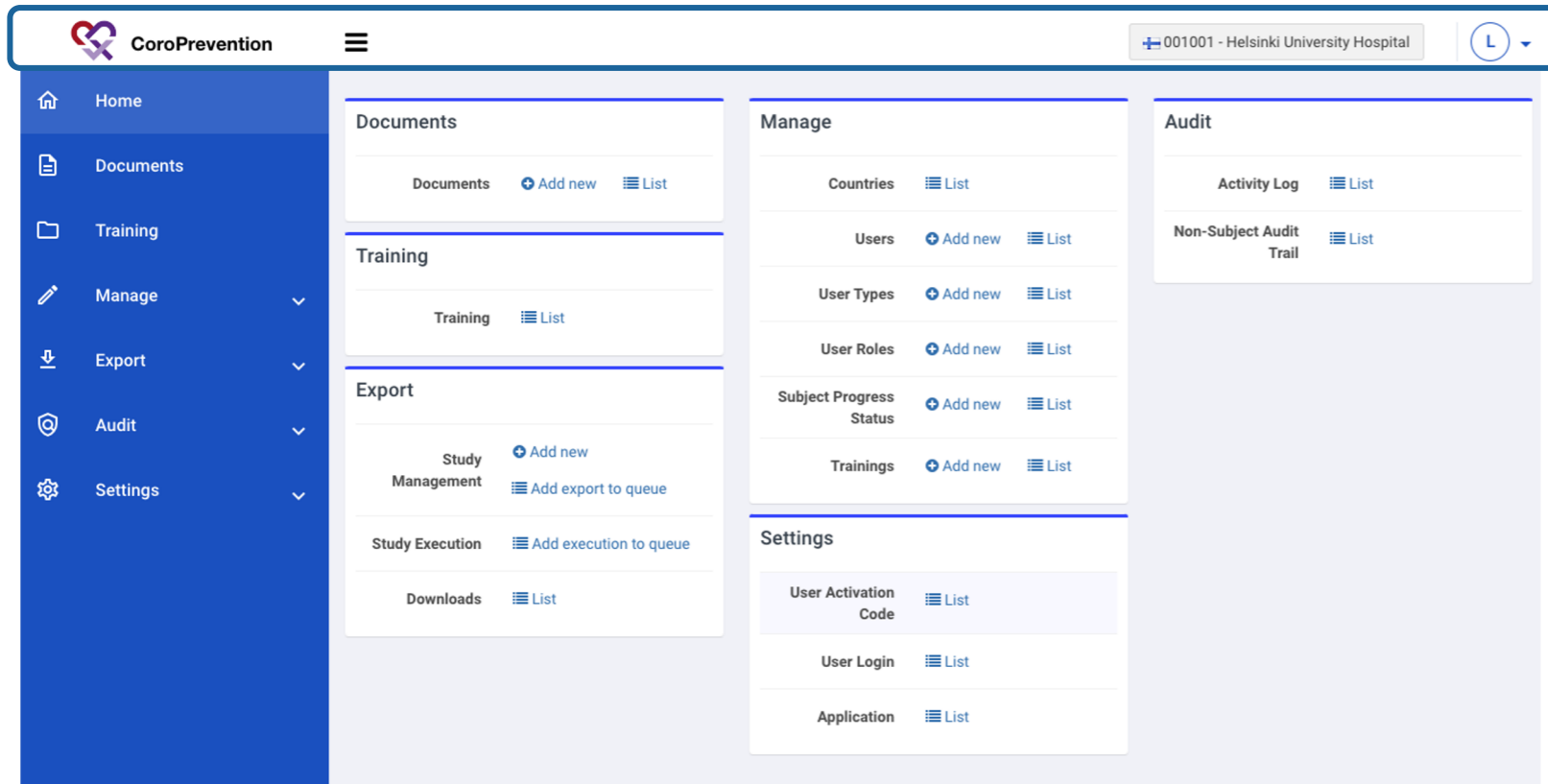
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# Navigation - Access Details

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



The screenshot displays the CoroPrevention EDC interface. The top navigation bar includes the CoroPrevention logo, a hamburger menu icon, the site identifier "001001 - Helsinki University Hospital", and a user profile icon. The main content area is divided into several sections: Documents, Training, Export, Manage, and Audit. The Manage section contains sub-sections for Countries, Users, User Types, User Roles, Subject Progress Status, and Trainings. The Audit section contains Activity Log and Non-Subject Audit Trail. The Settings section contains User Activation Code, User Login, and Application. Each sub-section typically includes an "Add new" button and a "List" button.



# 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 main content area shows a table of subjects with 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 shows the UniWeb interface for a subject in the CoroPrevention study. The top navigation bar includes the study name 'CoroPrevention', a breadcrumb trail 'Subjects / coro-001001-003 / View', and user information: 'Working in: Country: Finland, Site: Helsinki University Hospital' and 'Logged in as: Renneboog Liesbeth (Investigator)'. The subject details on the left include 'Subject ID: coro-001001-003', 'Site: Helsinki University Hospital', and 'Progress: Randomised'. A sidebar on the left 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 main content area displays 'Vital Signs' with a 'Show monitoring status' toggle and an 'Audit trail' button. The data includes: Body height (181 cm), Body weight (78.3 kg), Blood pressure (Systolic: 121 mmHg, Diastolic: 81 mmHg), and Pulse Rate (61 bpm). At the bottom, there are 'Back', 'Sign', and 'Next' buttons, with 'Next' highlighted by a blue box.





# Enter and Edit Data



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# Enter/Edit Data - Flow

Use the subject flow to navigate to a form:

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

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

### Subject Summary

Status filter

Monitoring filter

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

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

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



# Enter/Edit Data - Subject Summary

Or use the subject summary to navigate to a form:

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

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

### Subject Summary

**Status filter**

**Monitoring filter**

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

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







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

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



# 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

Show monitoring status

Visit Date DCR ① Audit trail

Visit Date !

dd	mon	yyyy	
è	Nov	2021	



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



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# Enter/Edit Data - Open DCR

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

Show monitoring status

Visit Date DCR ① Audit trail

! Visit Date ! ⚙️

dd mon yyyy  
è Nov 2021 📅



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# Enter/Edit Data - Edit

Update the entered data accordingly if applicable:

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

Please enter the reason for changing this data ✕

Data Entry Error

Data changed because:

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



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# Enter/Edit Data - Edit (2)


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

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

Show monitoring status

Visit Date Audit trail

Visit Date ⚙️

dd	mon	yyyy	
7	Nov	2021	

Back Sign Next



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# 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

# 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

**Systolic**

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

#7 • 09 Nov 2021 10:07:39

You

**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

# 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

<input checked="" type="checkbox"/> 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"/>	

<input checked="" type="checkbox"/> 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 type="radio"/>	<span style="border: 1px solid #0070C0; border-radius: 5px; padding: 2px 5px;">Audit Trail</span>
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

🔍

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

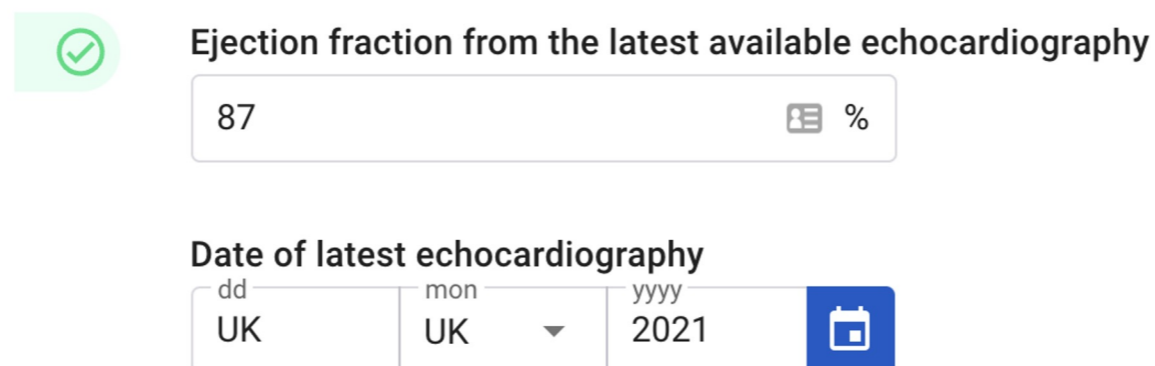
# Enter/Edit Data - Required Data


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

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



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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 <span>▾</span> - < >					



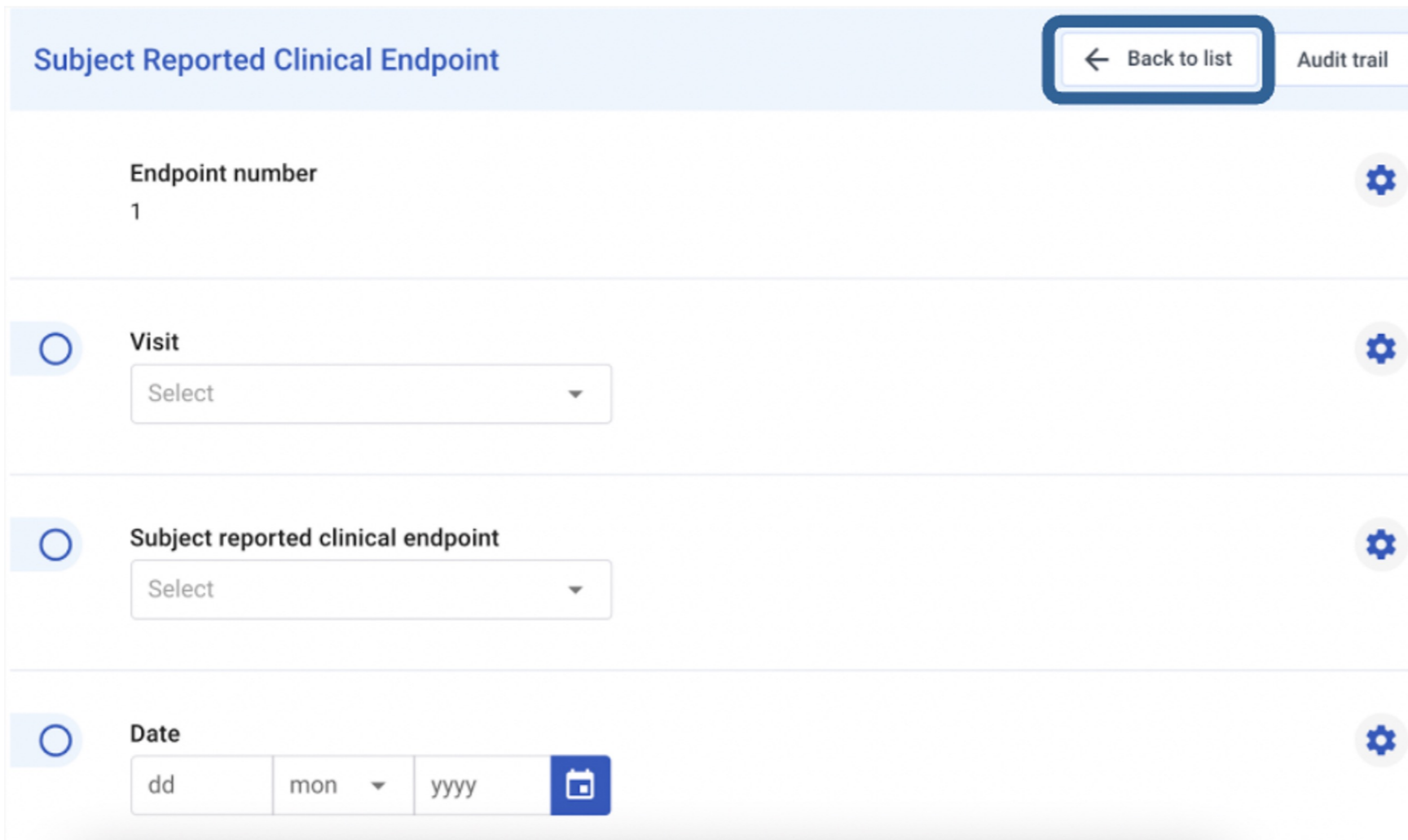
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# Enter/Edit Data - Log Forms (2)

- 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



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# 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	<span>✓</span> <span>📄</span>	<span>✎</span> <span>🗑</span>

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



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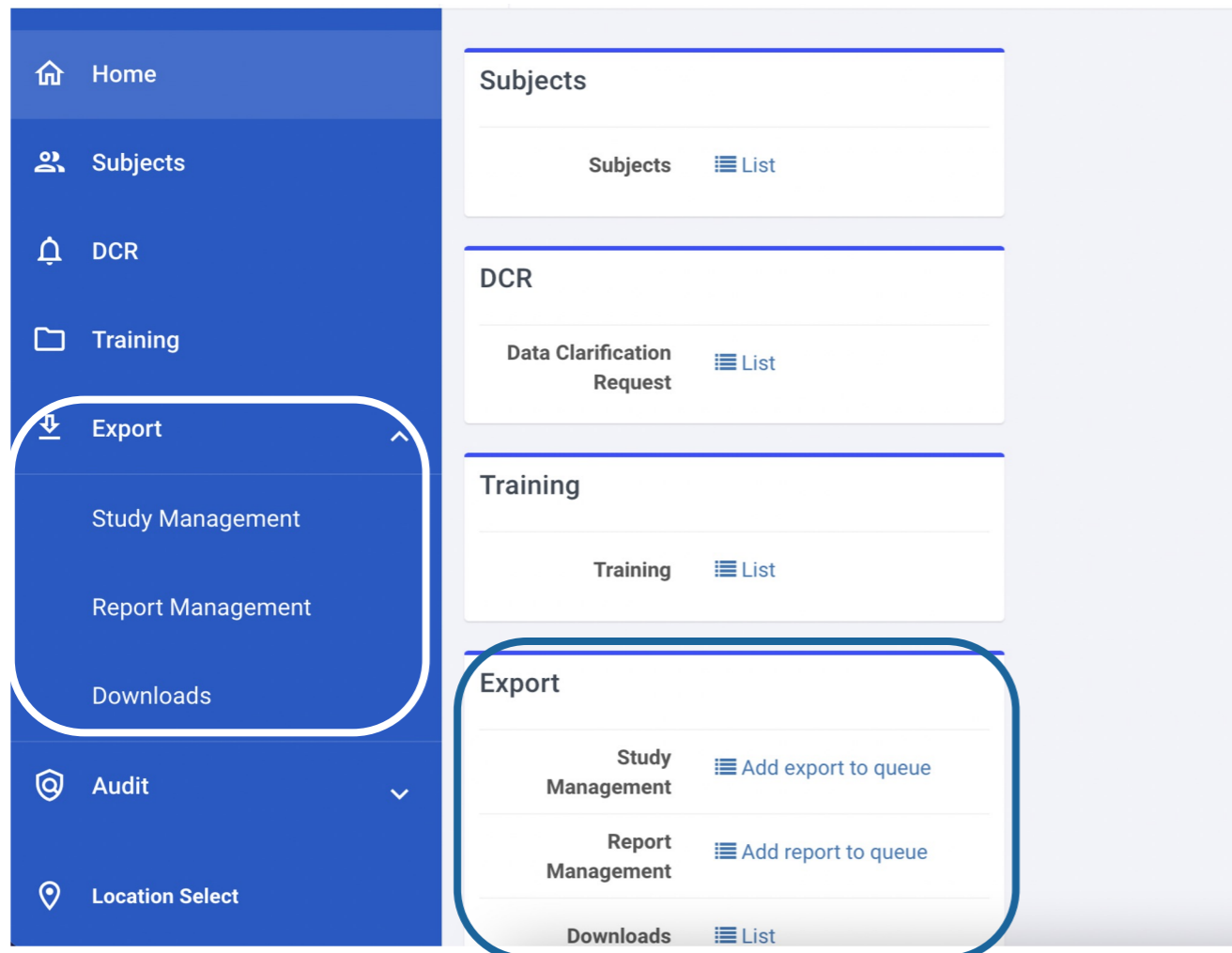
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# Reports - General

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 screenshot displays the UniWeb interface. On the left is a blue navigation bar with icons and labels for Home, Subjects, DCR, Training, Export, Audit, and Location Select. The 'Export' menu is expanded, showing options for Study Management, Report Management, and Downloads. The main content area on the right is divided into sections: 'Subjects' with a 'List' button; 'DCR' with a 'Data Clarification Request' and 'List' button; 'Training' with a 'List' button; and 'Export' with options to 'Add export to queue' for Study Management, 'Add report to queue' for Report Management, and a 'List' button for Downloads. A white rounded rectangle highlights the 'Export' menu in the navigation bar, and a blue rounded rectangle highlights the 'Export' section in the main content area.

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.

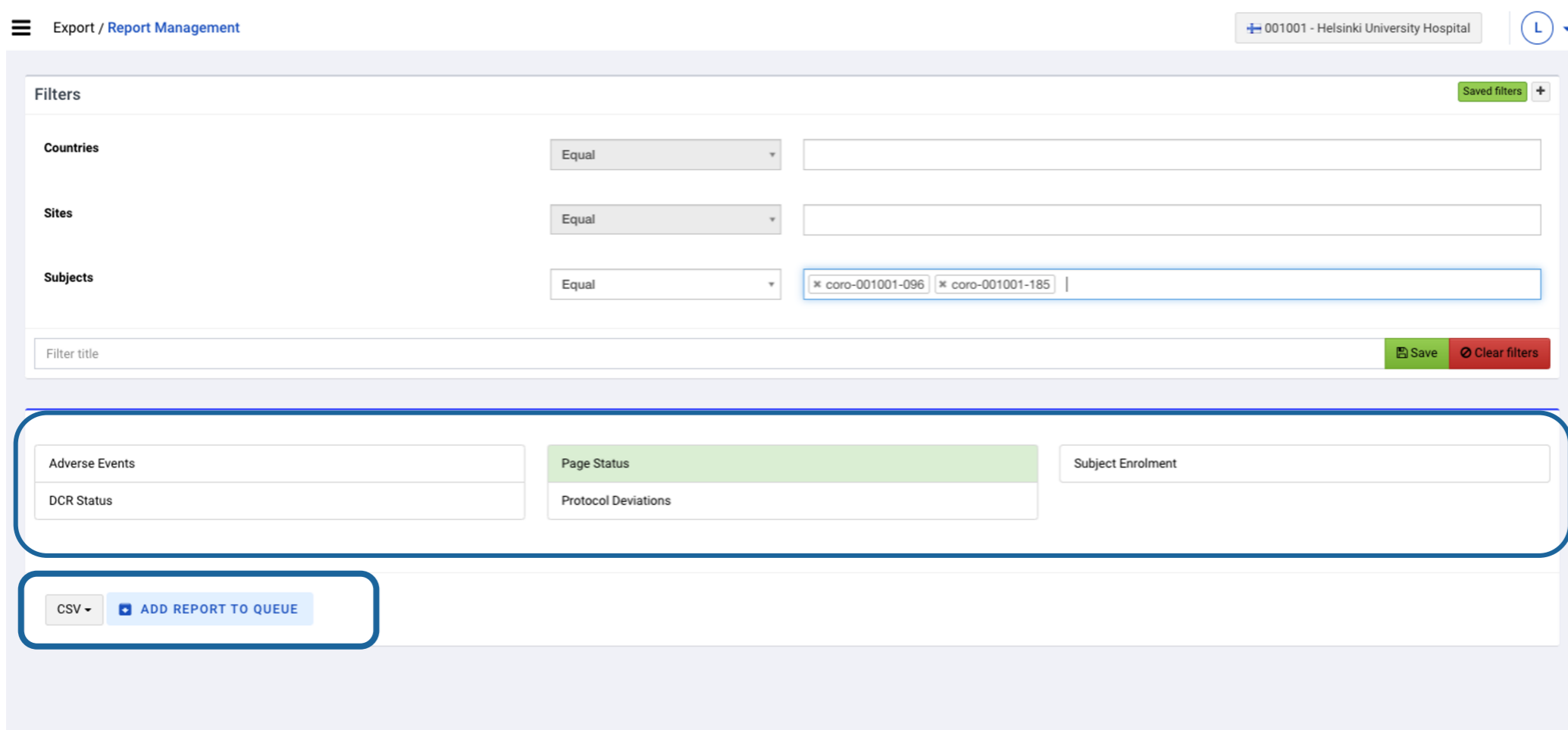


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# Reports - Generation

- 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



Export / Report Management

001001 - Helsinki University Hospital

L

Filters Saved filters +

Countries Equal

Sites Equal

Subjects Equal \* coro-001001-096 \* coro-001001-185

Filter title Save Clear filters

Adverse Events

DCR Status

Page Status

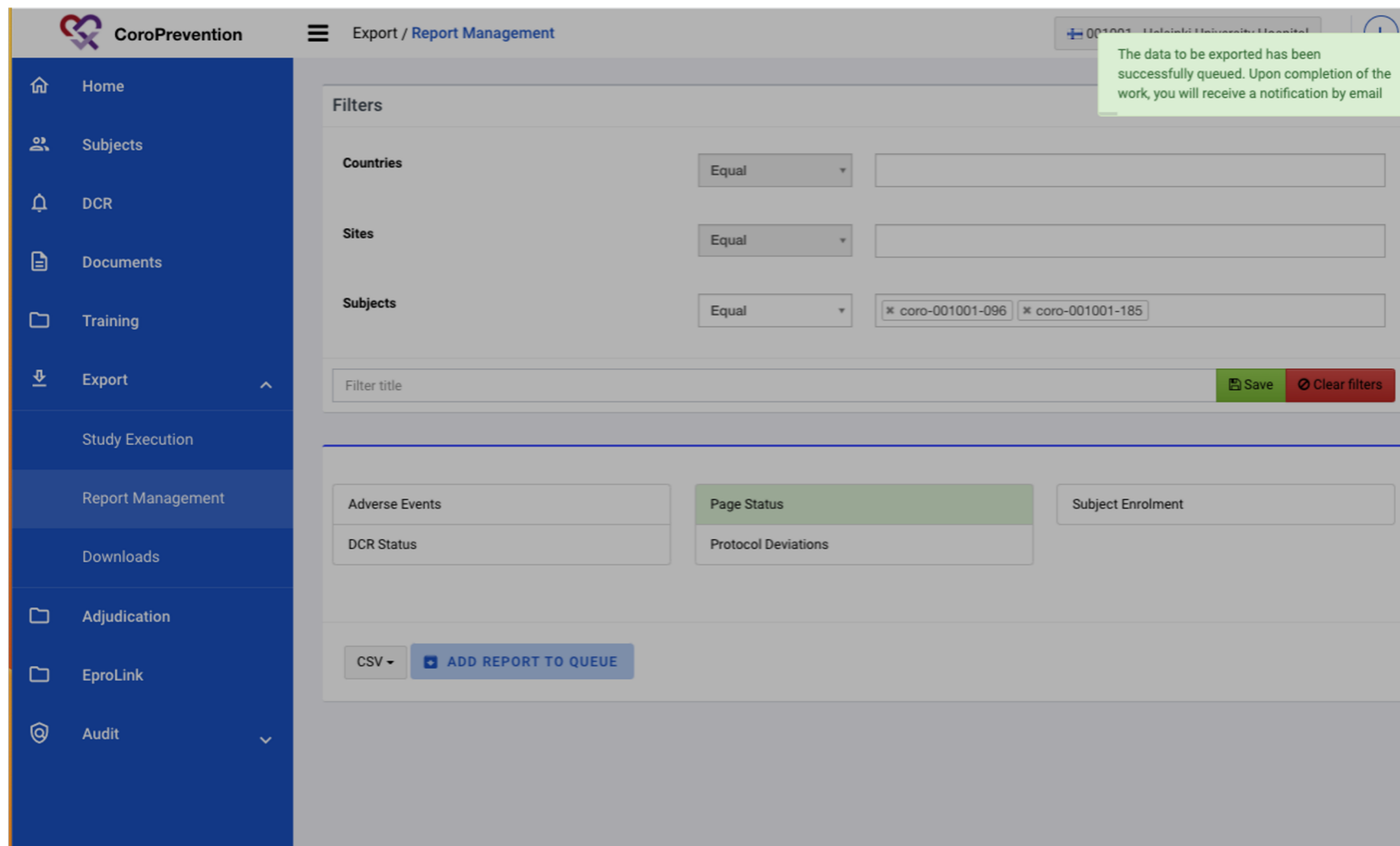
Protocol Deviations

Subject Enrolment

CSV ADD REPORT TO QUEUE

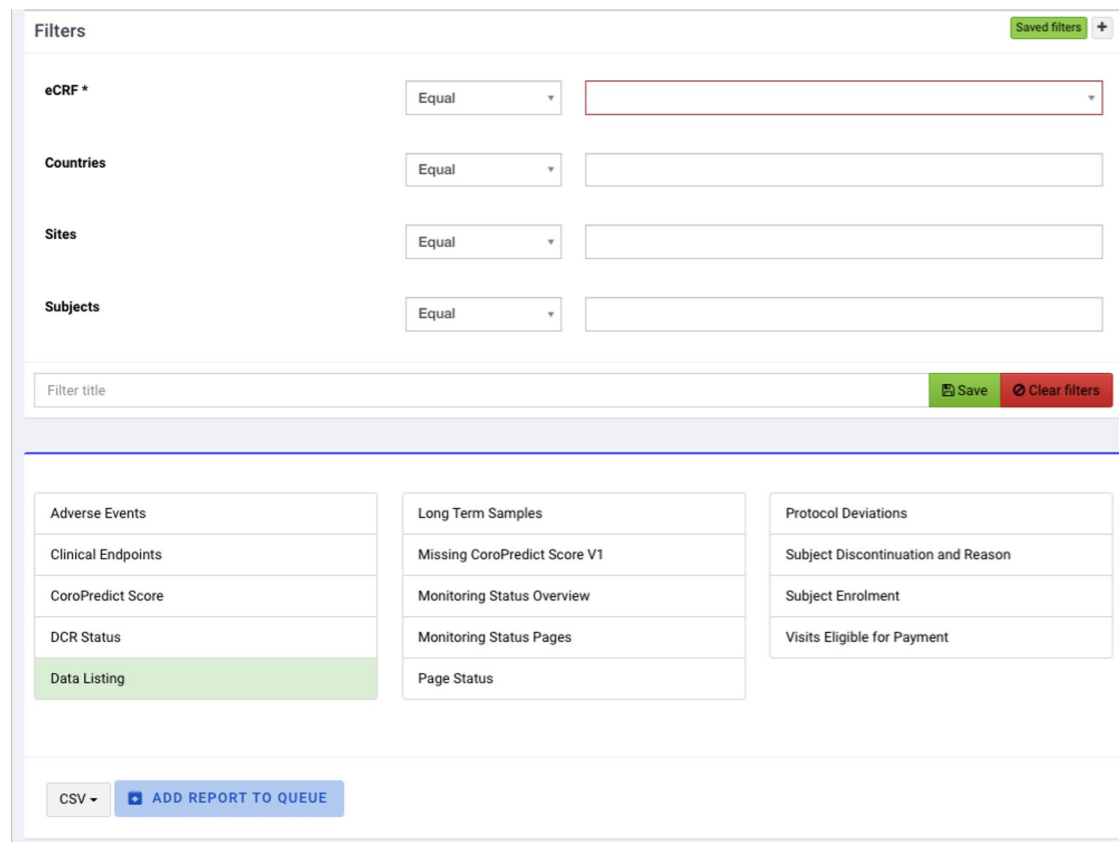
# Reports - Generation (2)

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



# Reports - Filters

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



The screenshot shows the 'Filters' section of the UniWeb interface. It features a 'Saved filters' button with a plus sign. Below this, there are four filter rows, each with a label, a dropdown menu set to 'Equal', and an input field. The labels are 'eCRF \*', 'Countries', 'Sites', and 'Subjects'. Below the filter rows is a 'Filter title' input field, a 'Save' button, and a 'Clear filters' button. At the bottom of 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 very bottom, there is a 'CSV' dropdown and an 'ADD REPORT TO QUEUE' button.

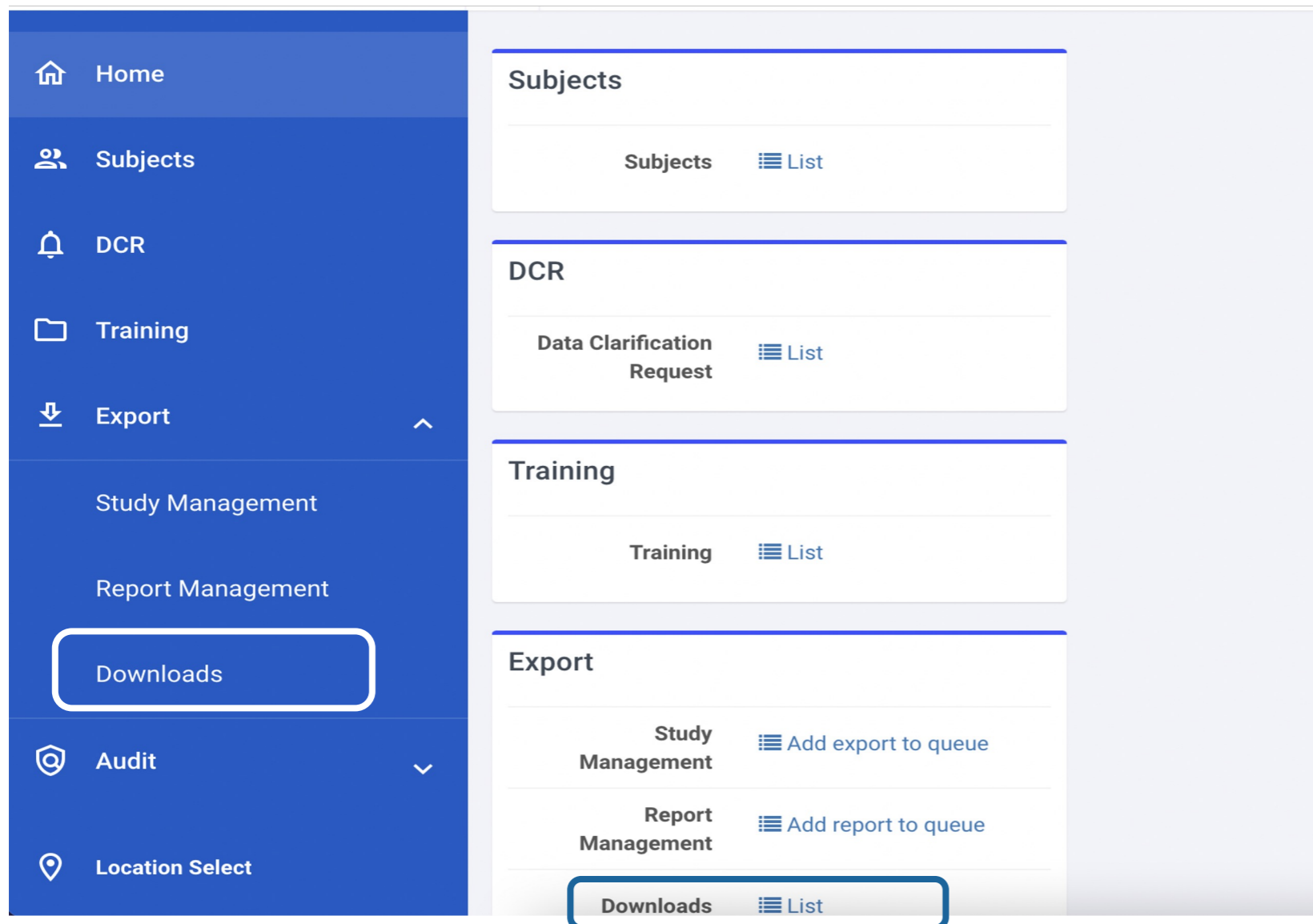
You can save your filter combinations for future use by providing a title for the filter and clicking “Save”





# Reports - Download

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



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



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# 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		<a href="#">DELETE</a>
Subject Enrolment	investigator	2	FINISHED	CSV	327 Bytes	02 Nov 2022 09:56:41	02 Nov 2022 09:56:42	<a href="#">DOWNLOAD ARCHIVE</a> <a href="#">DELETE</a>
Page Status	investigator	4422	FINISHED	CSV	17.41 KB	27 Sep 2022 13:33:32	27 Sep 2022 13:33:35	<a href="#">DOWNLOAD ARCHIVE</a> <a href="#">DELETE</a>
Adverse Events	investigator	2	FINISHED	CSV	487 Bytes	12 Sep 2022 13:43:37	12 Sep 2022 13:43:38	<a href="#">DOWNLOAD ARCHIVE</a> <a href="#">DELETE</a>
DCRs	investigator	989	FINISHED	CSV	18.36 KB	12 Sep 2022 12:10:43	12 Sep 2022 12:10:45	<a href="#">DOWNLOAD ARCHIVE</a> <a href="#">DELETE</a>
DCR Status	investigator	384	FINISHED	CSV	2.58 KB	12 Sep 2022 10:52:00	12 Sep 2022 10:52:01	<a href="#">DOWNLOAD ARCHIVE</a> <a href="#">DELETE</a>

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

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

# Forgot Password



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# 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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# 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](https://edc-qa.coroprevention.eu/user-activation/!renneboog_inv/VGRtwCCeC4Kp/set-password)

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



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# Reset Two-Factor Authentication (TFA)

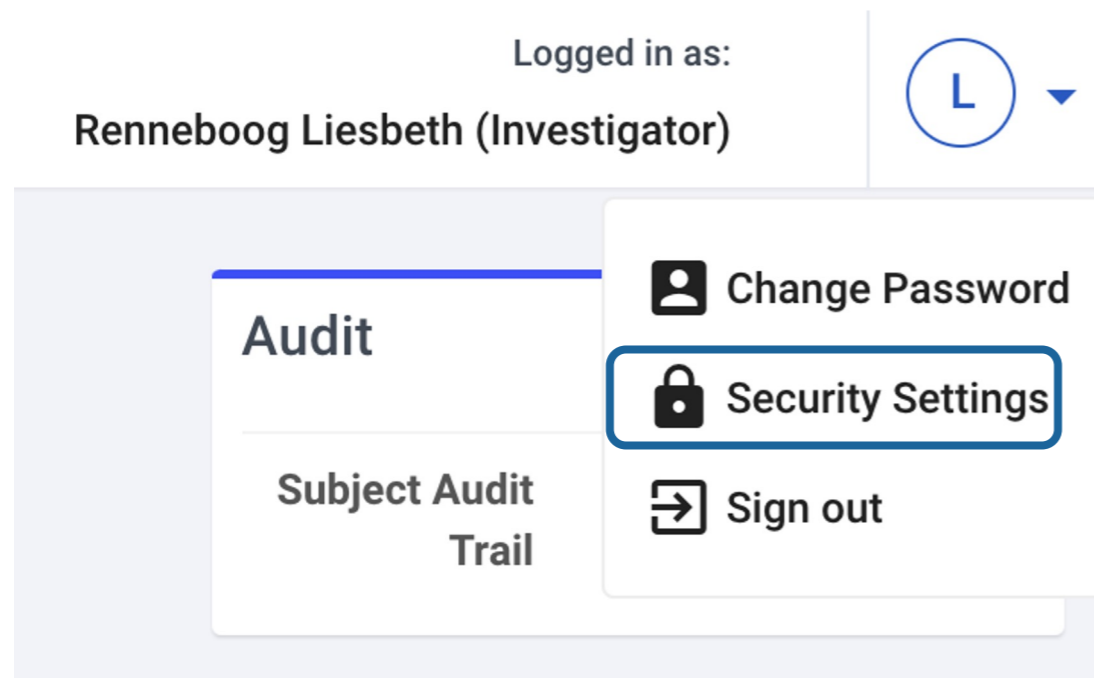


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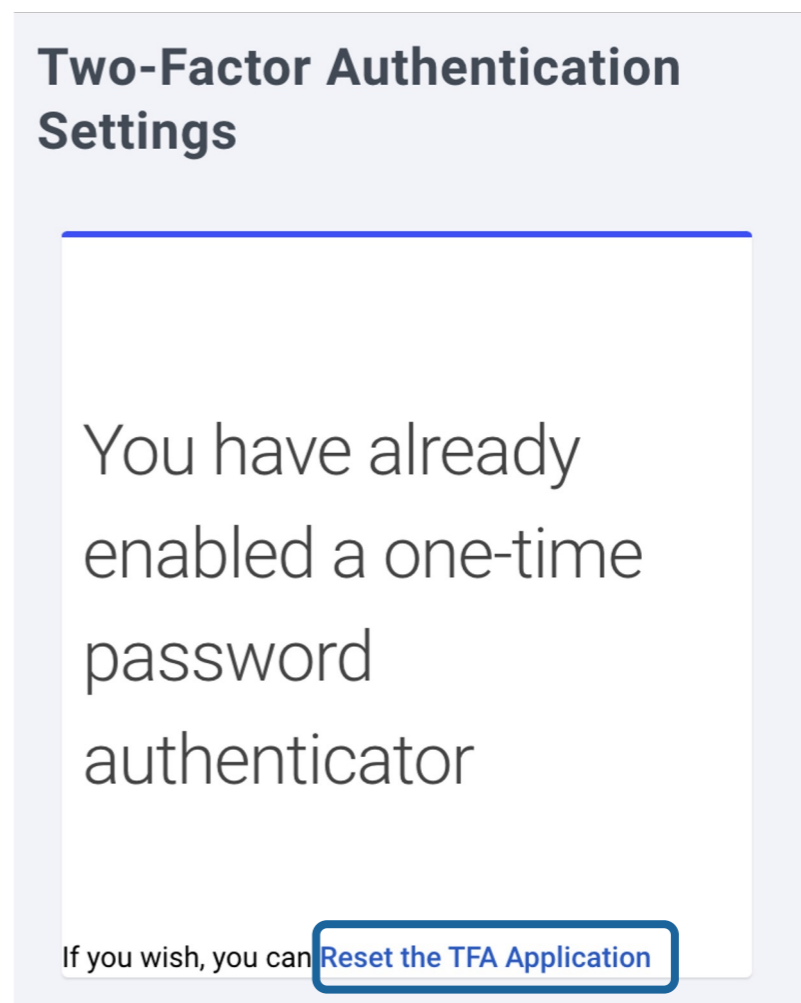
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# Reset TFA

- 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](mailto: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

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	<span>✓</span> <span>📄</span>	<span>✎</span> <span>🗑️</span>
2	CYBCK	Cystatin C	44	mg/L	H	11	33	<span>✓</span> <span>📄</span>	<span>✎</span> <span>🗑️</span>
3	CERT2	Ceramide Score	11					<span>!</span> <span>📄</span>	<span>✎</span> <span>🗑️</span>
4	TROIHS	hs-Troponin I	11	pg/mL			4	<span>!</span> <span>📄</span>	<span>✎</span> <span>🗑️</span>
5	ALTBC	ALT, 37°C	22	U/L				<span>!</span> <span>📄</span>	<span>✎</span> <span>🗑️</span>

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

ADD BLOOD SAMPLE RECORD

**Blood Sample**

Nr  
5

Test code

Test name

Value

Unit

Normal Ranges Flag

Lower Normal Limit

Upper Normal Limit

# Blood Sampling: Sub-study for Future Research

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

Blood Sampling: Sub-study for Future Research Audit trail

---

Was a sample taken? ⚙️

Yes  No

---

Date sample taken ⚙️

dd mon yyyy  
03 Nov 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?

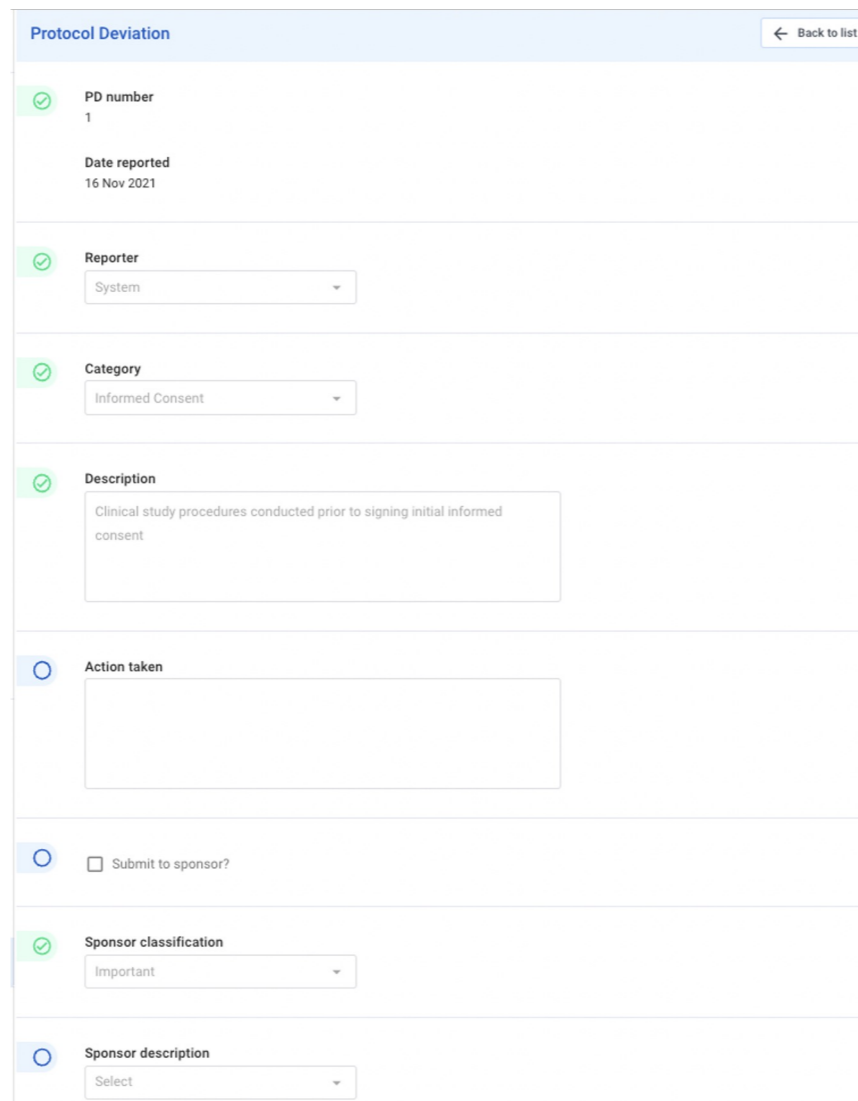
Ticking Submit to sponsor? triggers an email notification to the sponsor.

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.



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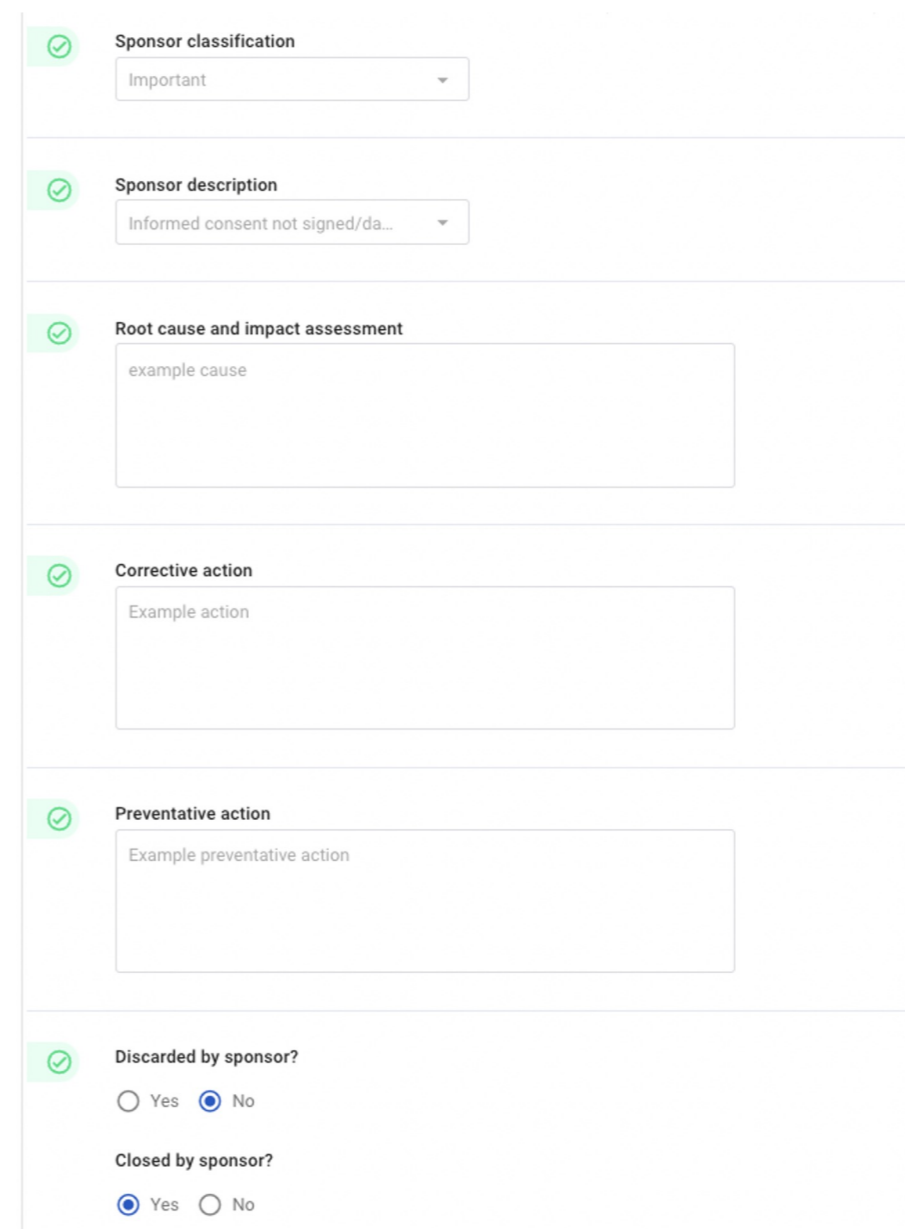
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# Protocol Deviations - Sponsor Evaluation

- 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



The screenshot displays a form for Protocol Deviation (PD) evaluation. It features several sections, each with a green checkmark icon indicating completion:

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