



CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE



CoroPrevention EDC - Training Data Manager

v1.0

Agenda

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



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Agenda (2)

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



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Login

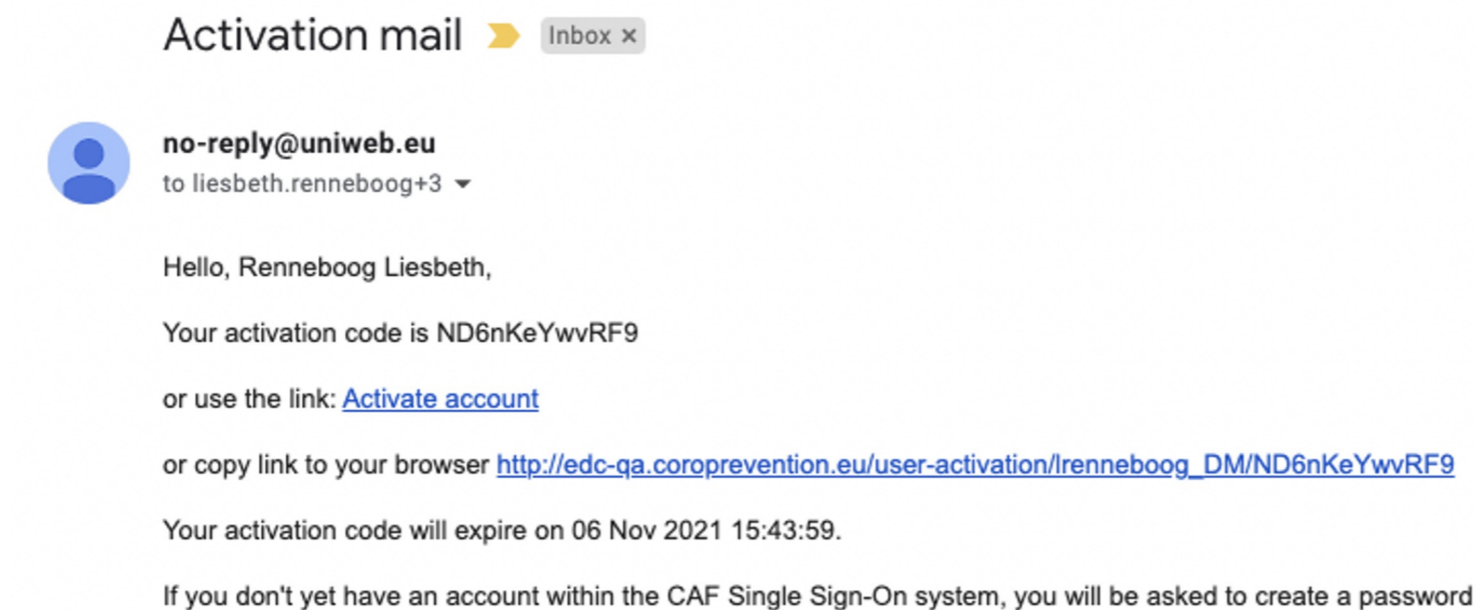


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Login - Account Activation

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



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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



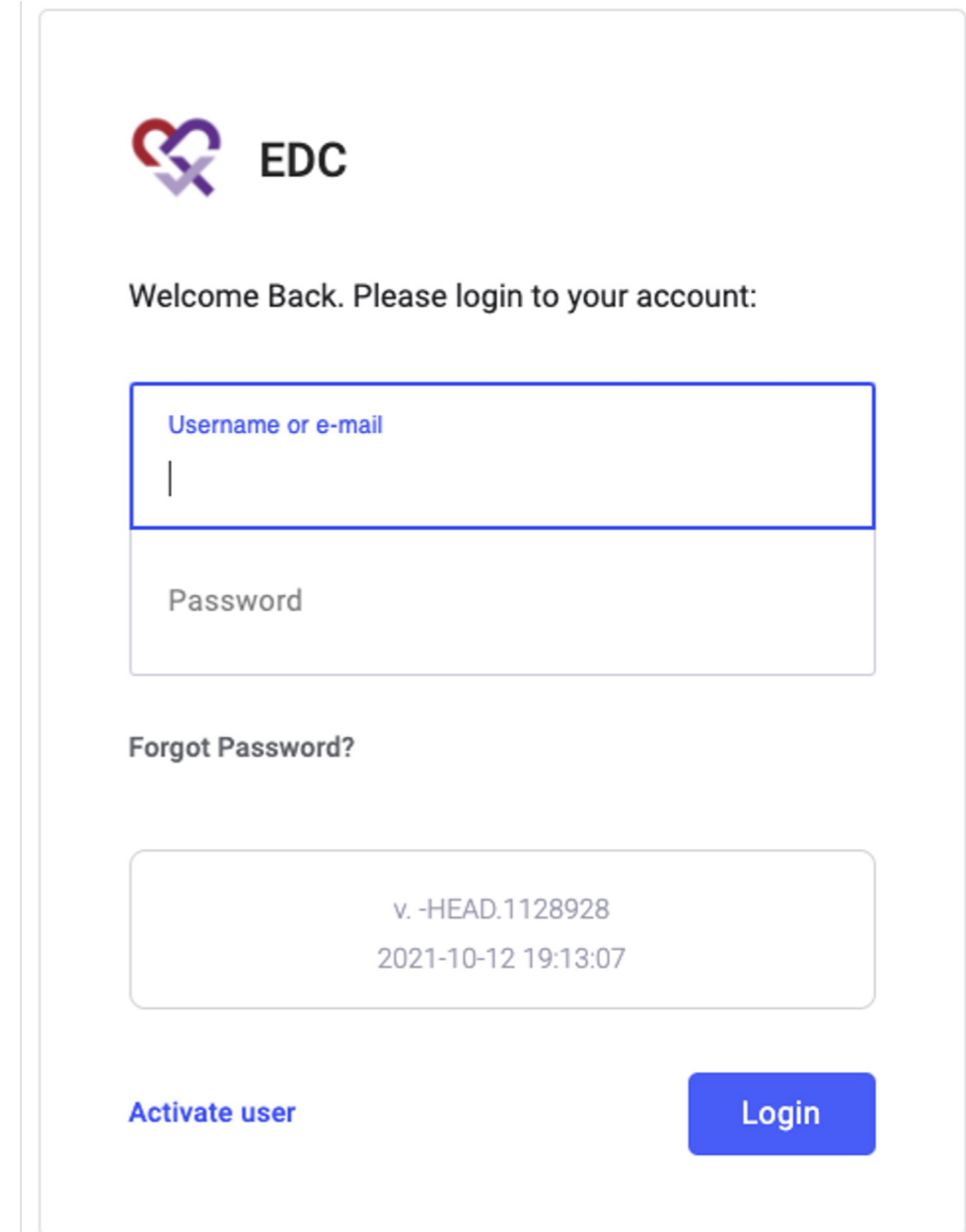
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Login - General

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, the text "Welcome Back. Please login to your account:" is displayed. There are two input fields: the first is labeled "Username or e-mail" and contains a vertical cursor; the second is labeled "Password". Below the input fields, there is a link "Forgot Password?". A box below that contains the text "v. -HEAD.1128928" and "2021-10-12 19:13:07". At the bottom left is a link "Activate user" and at the bottom right is a blue button labeled "Login".



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Login - General (2)

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

Enter a 6-digit code from your Authentication App

Login

[Back to login](#)

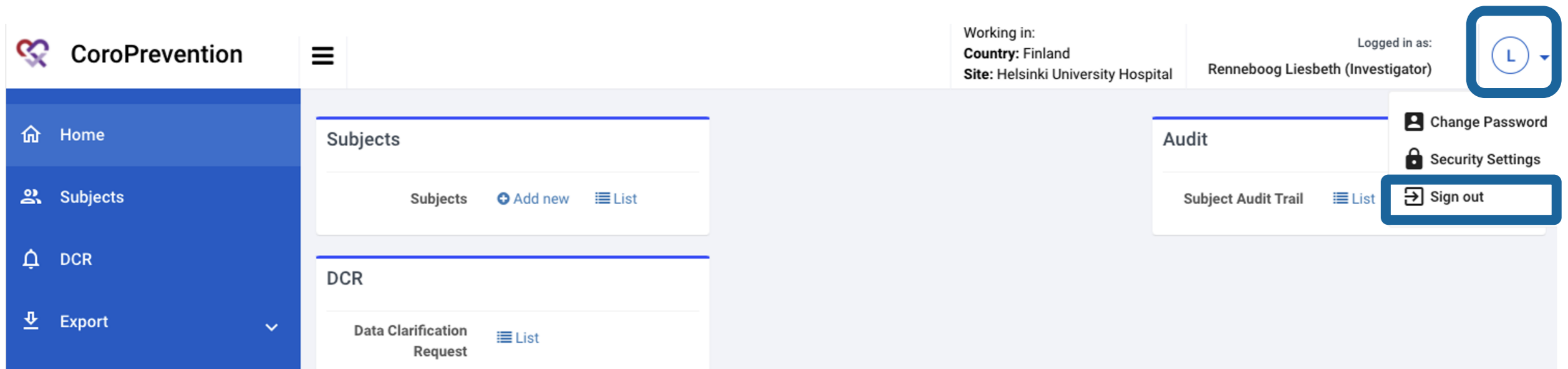


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Logout

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



The screenshot shows the CoroPrevention web application interface. On the left is a blue navigation sidebar with the 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 red box.

Log out when stepping away from your computer.



Training



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Training - Initial

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

CoroPrevention Training

Working in: Country: Finland Site: Helsinki University Hospital

Logged in as: Renneboog Liesbeth (Investigator)

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

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

1 / 1 - 3 results - Per page 32

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



Training - Download

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

CoroPrevention

☰
Training

Working in:
Country: Finland
Site: Helsinki University Hospital

Logged in as:
Renneboog Liesbeth (Investigator)

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

| Training ↓ | Required | Status | Completion date and time | Action |
|----------------------------------|----------|----------|--------------------------|---|
| Query Management | no | Not Done | | ↓ DOCUMENT DOWNLOAD |
| SAE Reporting | yes | Not Done | | ↓ DOCUMENT DOWNLOAD |
| User Guidelines for Investigator | yes | Not Done | | <div style="border: 2px solid #0070c0; padding: 2px;"> ↓ DOCUMENT DOWNLOAD </div> |

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

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

The "SIGN" button for the "User Guidelines for Investigator" row is highlighted with a red box. At the bottom right of the table 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

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

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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☰
Training

Working in:

Country: Finland

Site: Helsinki University Hospital

Logged in as:

Renneboog Liesbeth (Investigator)

L
▼

Success!
Training signed successfully
✕

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

1 / 1 - 3 results - Per page 32 ▼



Navigation



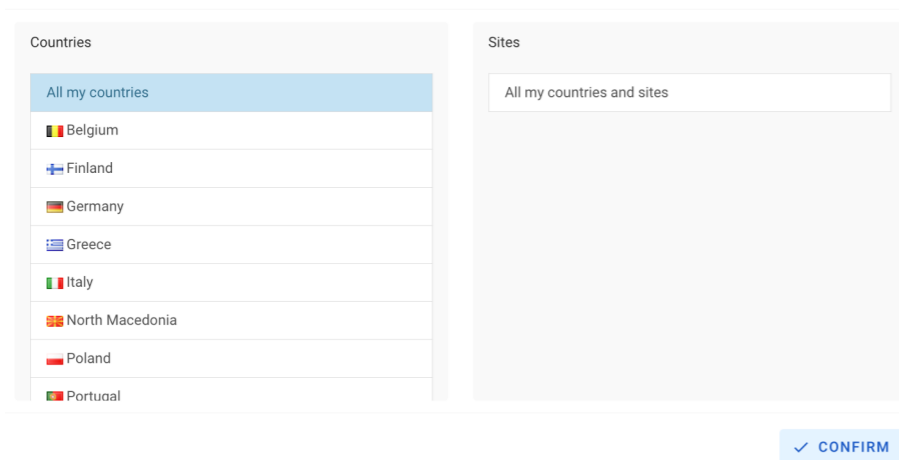
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Navigation - Location Select

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

Location



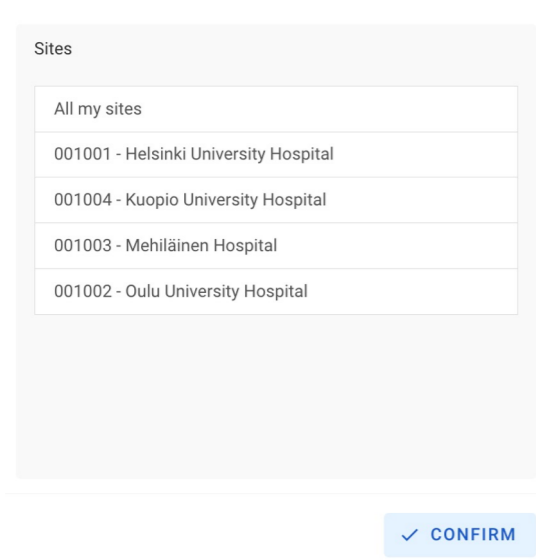
| Countries | Sites |
|------------------|----------------------------|
| All my countries | All my countries and sites |
| Belgium | |
| Finland | |
| Germany | |
| Greece | |
| Italy | |
| North Macedonia | |
| Poland | |
| Portugal | |

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:

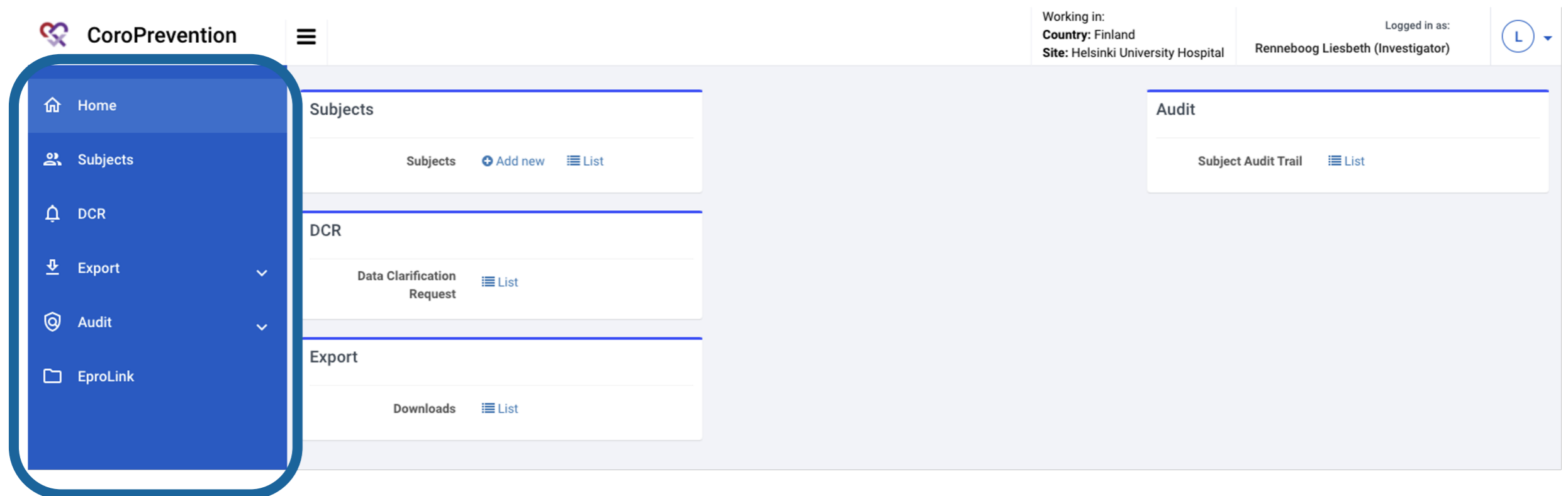


| Sites |
|---------------------------------------|
| All my sites |
| 001001 - Helsinki University Hospital |
| 001004 - Kuopio University Hospital |
| 001003 - Mehiläinen Hospital |
| 001002 - Oulu University Hospital |



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



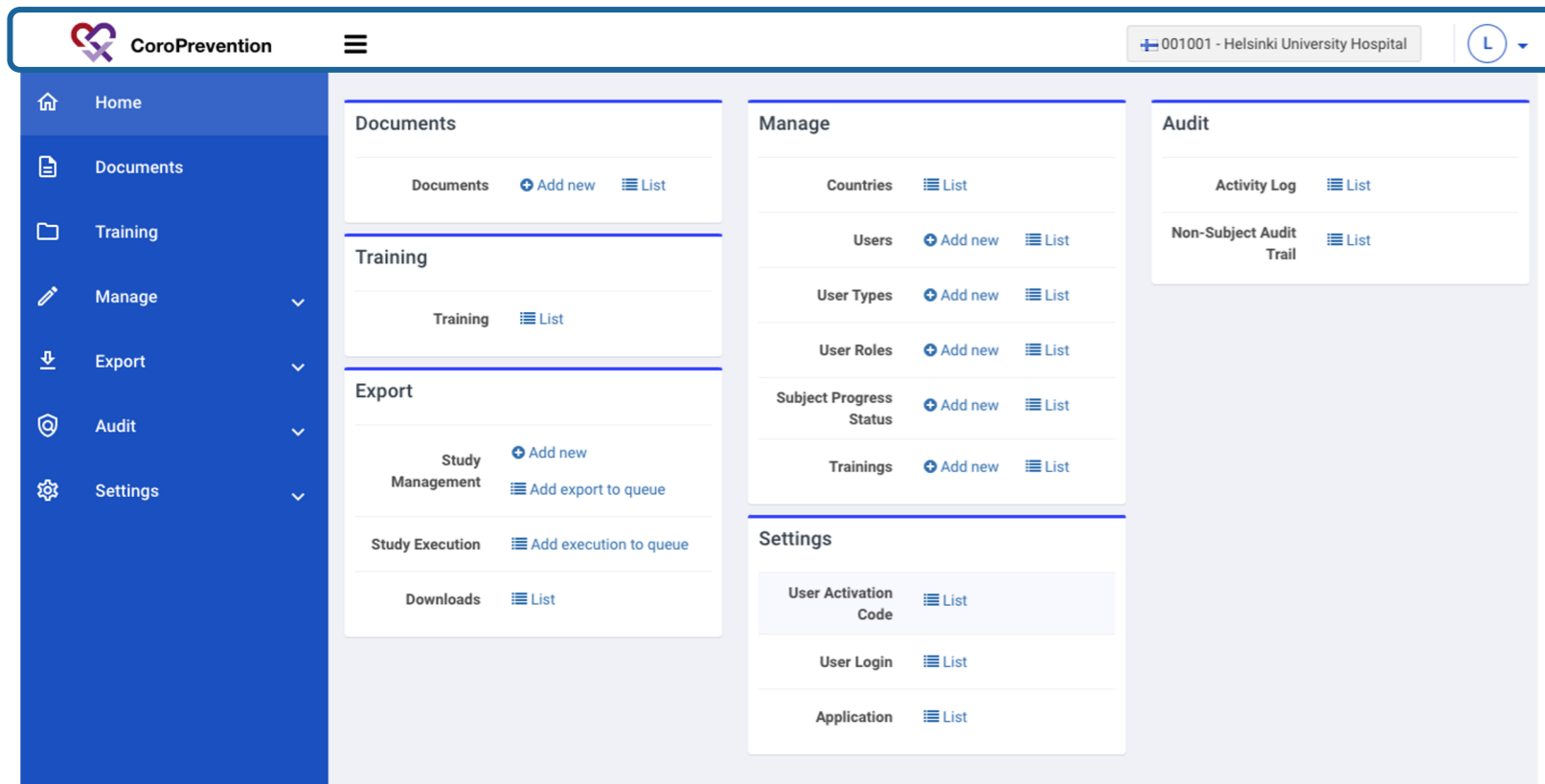
The screenshot displays the CoroPrevention web application interface. On the left, a blue navigation bar is highlighted with a rounded rectangle. It contains the following menu items: Home (with a house icon), Subjects (with a person icon), DCR (with a bell icon), Export (with a download icon and a dropdown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



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:** Includes a "Documents" section with "Add new" and "List" options.
- Training:** Includes a "Training" section with a "List" option.
- Export:** Includes "Study Management" with "Add new" and "Add export to queue" options, and "Study Execution" with "Add execution to queue" and "Downloads" with a "List" option.
- Manage:** Includes sections for "Countries", "Users", "User Types", "User Roles", "Subject Progress Status", and "Trainings", each with "Add new" and "List" options.
- Settings:** Includes "User Activation Code", "User Login", and "Application", each with a "List" option.
- Audit:** Includes "Activity Log" and "Non-Subject Audit Trail", each with a "List" option.



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. At the top left is the CoroPrevention logo. A navigation menu on the left includes Home, Subjects, DCR, Export, Audit, and EproLink. The main content area displays a table of subjects. The table has columns for Subject ID, Study, Site ID, Last Visit Title, Status, Monitor Status, Progress Status, and Action. The 'VIEW' button for the second subject (coro-001001-002) is highlighted with a red box. The top right of the interface shows the user's current location (Finland, Helsinki University Hospital) and the logged-in user (Renneboog Liesbeth).

| 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 'Subjects / coro-001001-003 / View', and user information: 'Working in: Country: Finland, Site: Helsinki University Hospital' and 'Logged in as: Renneboog Liesbeth (Investigator)'. The main content area is divided into a left sidebar and a main panel. The sidebar lists various eCRF sections: Subject Summary, Informed Consent, Informed Consent: Blood Sampling Sub-study for Future Research, Enrolment V1 (highlighted with a blue box), Visit Date, Inclusion / Exclusion Criteria, Demographics, Medical History, Vital Signs (highlighted with a blue box), Cardiac Assessment, and Concomitant Medications. The main panel displays the 'Vital Signs' section, which is also highlighted with a blue box. It includes a 'Show monitoring status' toggle, an 'Audit trail' button, and input fields for 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 of the main panel, 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 | ○ 📄 |
| End Of Trial | ○ 📄 |
| Informed Consent Amendments | ○ 📄 |
| Adverse Events Log | ○ 📄 |
| Concomitant Medications Log | ○ 📄 |
| Subject Reported Clinical Endpoints Log | ○ 📄 |
| Primary and Secondary Endpoints | ○ 📄 |
| Protocol Deviations | ○ 📄 |

| | Enrolment V1 | Visit 6 | Visit 7 |
|---|--------------|---------|---------|
| Visit Date | ○ 📄 | ○ 📄 | ○ 📄 |
| Demographics | ○ 📄 | | |
| Medical History | ○ 📄 | | |
| Vital Signs | ○ 📄 | | |
| Cardiac Assessment | ○ 📄 | | |
| Concomitant Medications | ○ 📄 | | |
| Questionnaires | ○ 📄 | | |
| Smoking Behaviour | ○ 📄 | | |
| Blood Sampling - Basic Laboratory Assessments and CoroPredict Score | ⓘ 📄 | | |







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

| | | Yes | No | |
|---|---|----------------------------------|----------------------------------|--|
| ✔ | Inclusion Criteria | | | ⚙️ |
| | Informed consent form signed by the study subject. | <input checked="" type="radio"/> | <input type="radio"/> | |
| | Male or female aged 30 to 80 years on the day of enrolment. | <input checked="" type="radio"/> | <input type="radio"/> | |
| | ≥ 50% stenosis in one or more major coronary arteries on angiography or computerised tomography (CT) performed within the preceding year (from enrolment visit) or myocardial infarction (type I, II) during the preceding year. | <input checked="" type="radio"/> | <input type="radio"/> | |
| ✔ | Exclusion Criteria | | | ⚙️ |
| | Hospitalisation for acute coronary syndrome, myocardial infarction, stroke, coronary revascularisation or acute heart failure within the preceding month (30 days). These subjects can be enrolled after a one-month stabilisation period, which begins from the time of the event. | <input type="radio"/> | <input type="radio"/> | <div style="border: 1px solid blue; border-radius: 5px; padding: 2px 5px; display: inline-block;"> ☰ Audit Trail </div> |
| | 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

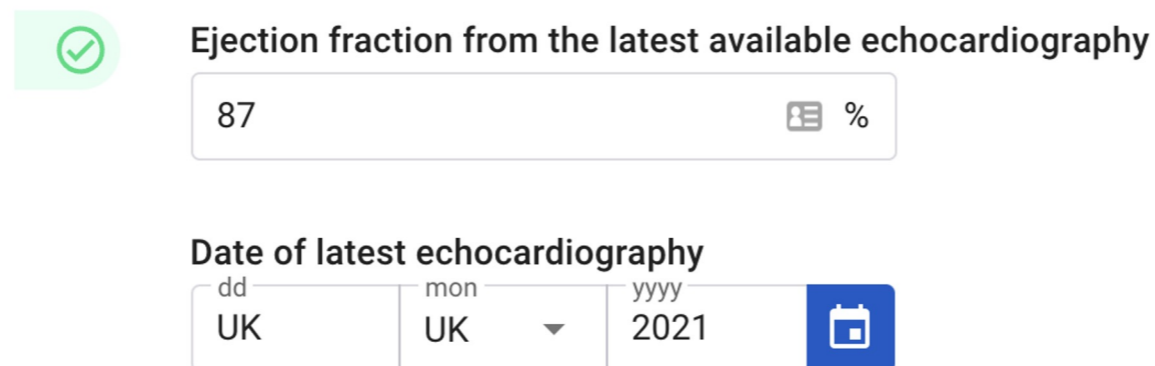
Enter/Edit Data - Required Data


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 ▼ - < > | | | | | |

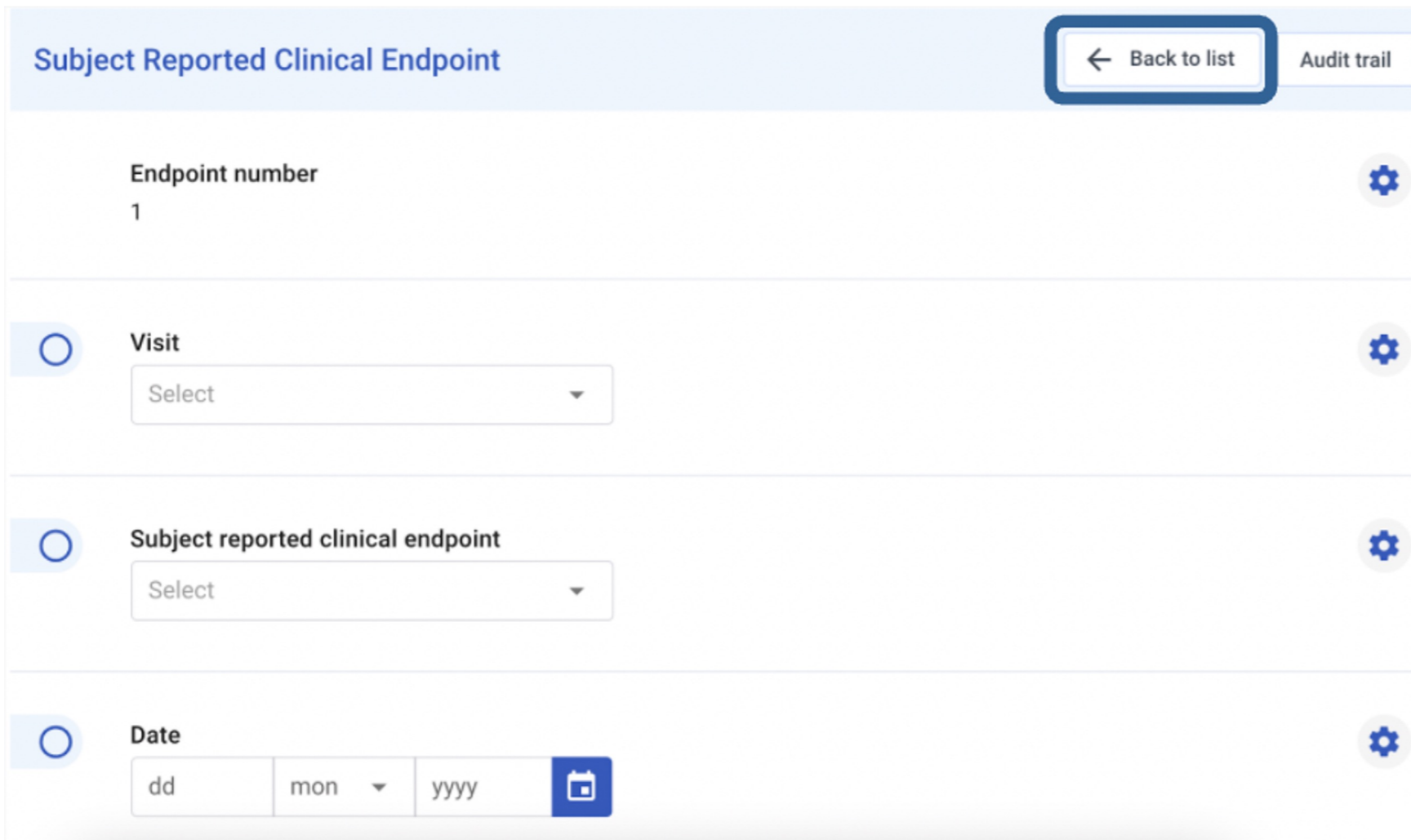


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Enter/Edit Data - Log Forms (2)

- 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 | ✓ 📄 | ✎ 🗑 |

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



CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Reports



CoroPrevention

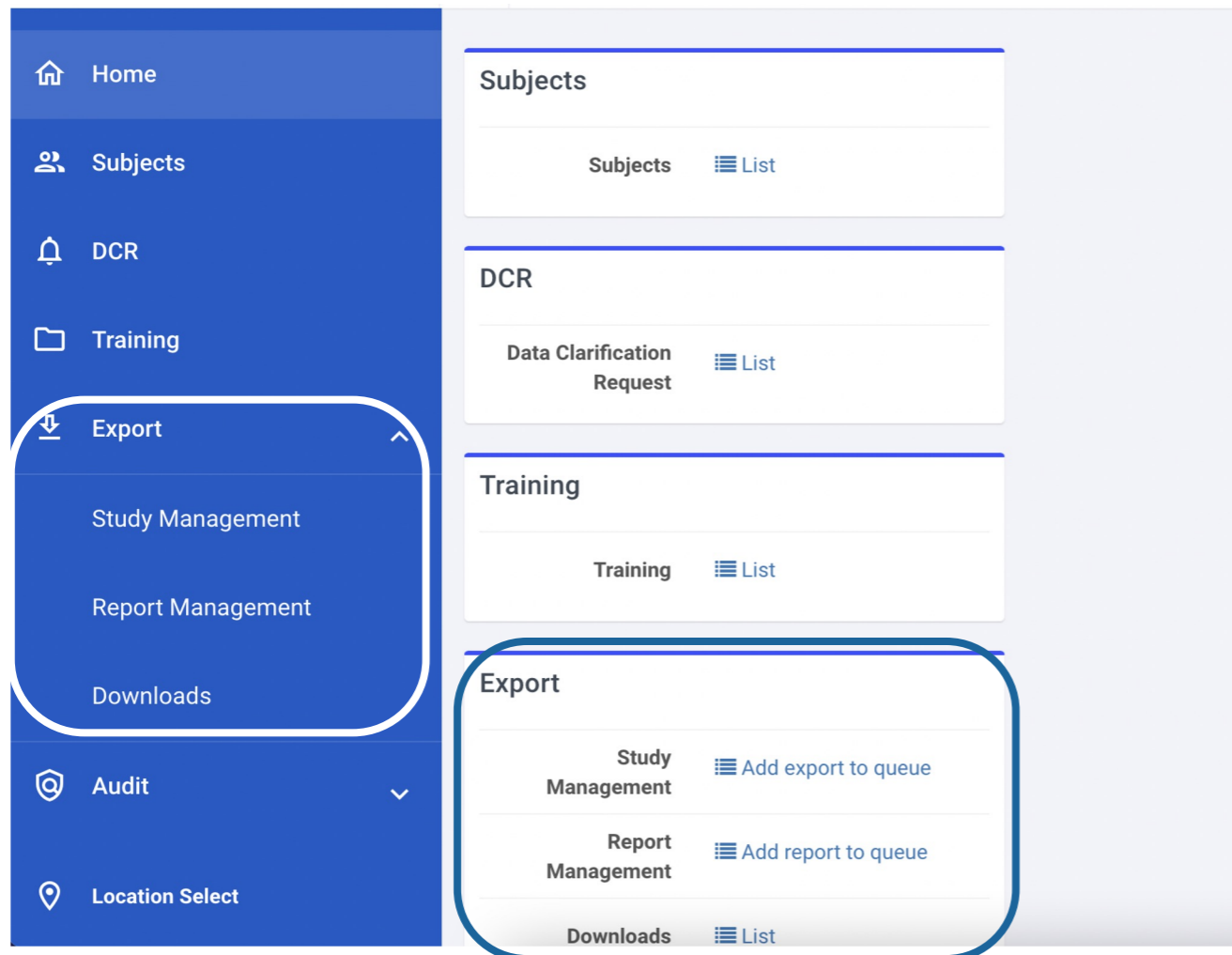
PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Reports - General

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

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

Click the desired type of report or export



The reports and exports are categorized in three categories:

- Study Management
- Study Execution
- Reports

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



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

Filter title Save Clear filters

Adverse Events

Page Status

Subject Enrolment

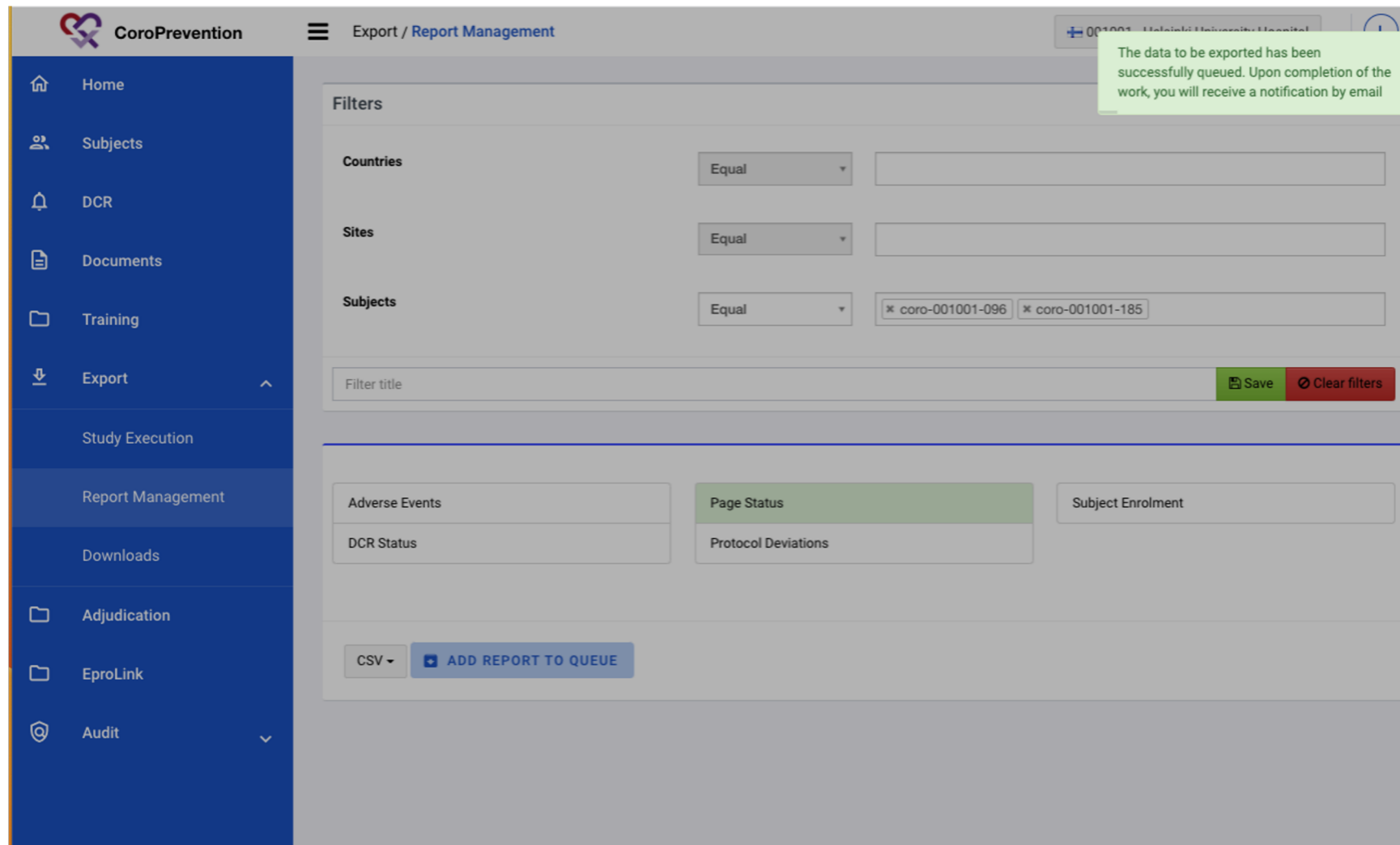
DCR Status

Protocol Deviations

CSV ADD REPORT TO QUEUE

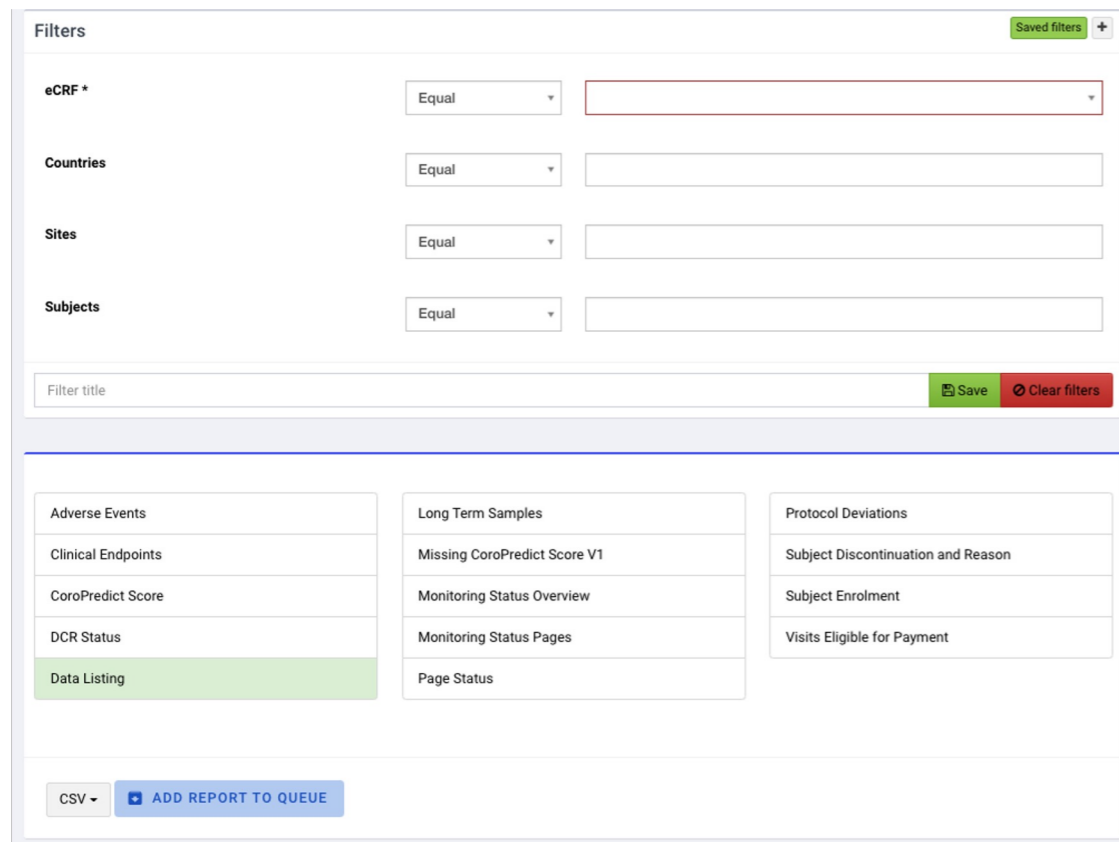
Reports - Generation (2)

- 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



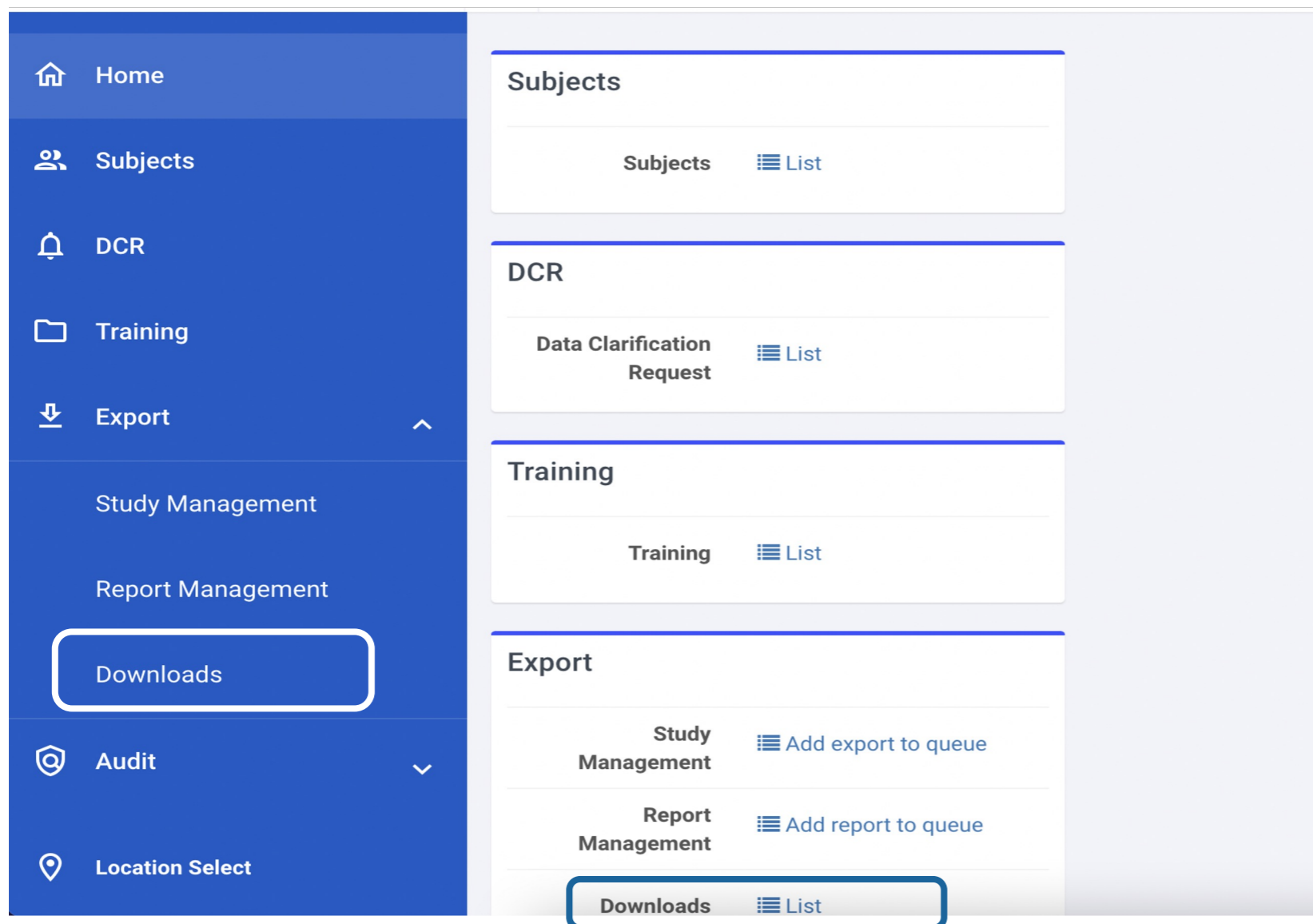
The screenshot shows the 'Filters' section of the UniWeb interface. It features a 'Saved filters' button with a plus sign. Below this, there are four filter rows, each with a label, a dropdown menu set to 'Equal', and an input field. The labels are 'eCRF *', 'Countries', 'Sites', and 'Subjects'. Below 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 shows the UniWeb interface with a blue navigation sidebar on the left and a main content area on the right. The sidebar contains the following items: Home, Subjects, DCR, Training, Export, Study Management, Report Management, Downloads (highlighted with a white border), Audit, and Location Select. The main content area displays four sections: Subjects, DCR, Training, and Export. Each section has a 'List' button. 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.



Reports - Download (2)

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

Export / Downloads Multiple countries 1

Filters 0

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

1 / 1 - 6 results - Per page 32

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

Reports - Download (3)

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

| 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 |

Manage DCRs

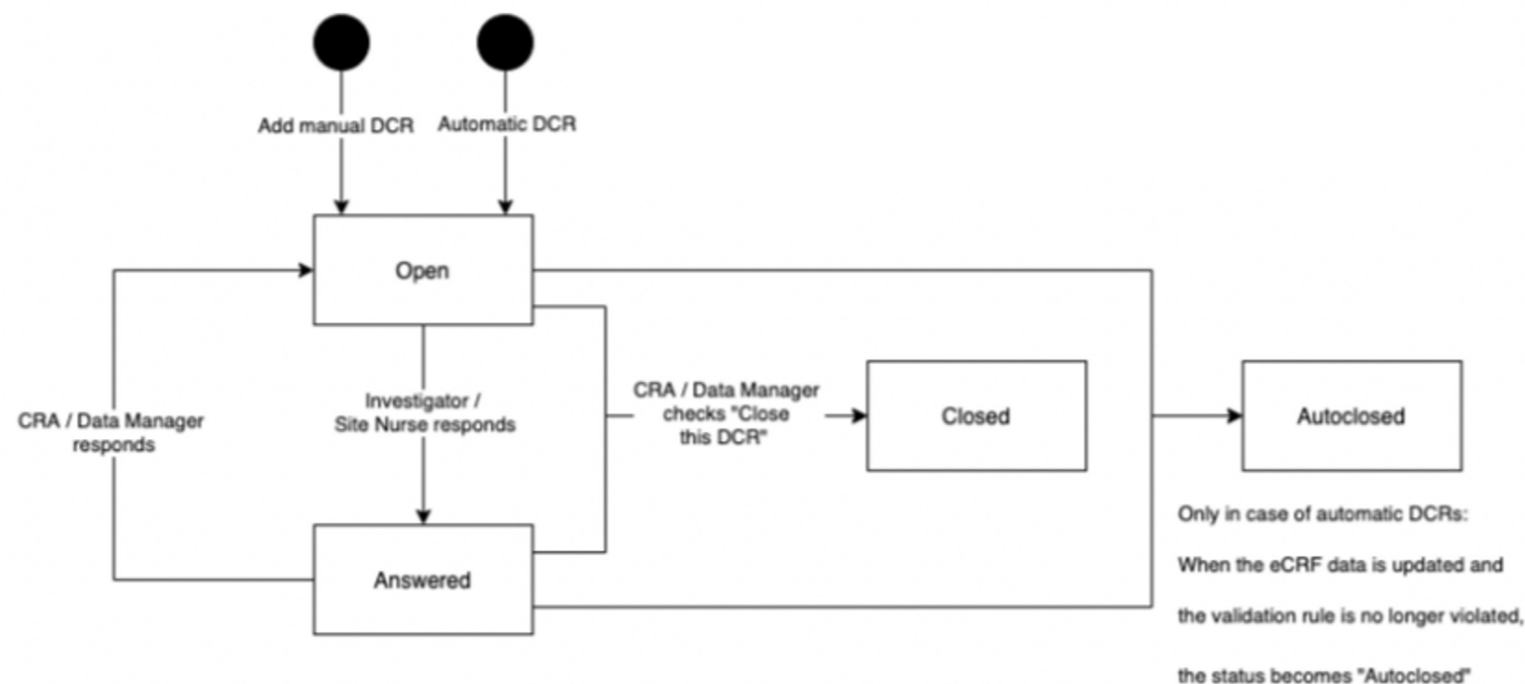


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Manage DCRs - DCR Workflow

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




Manage DCRs - Create DCR on block

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

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


Demographics Monitor Audit trail

Year of birth 


1980

Age

41

Sex 

Male Female

Race 

Caucasian

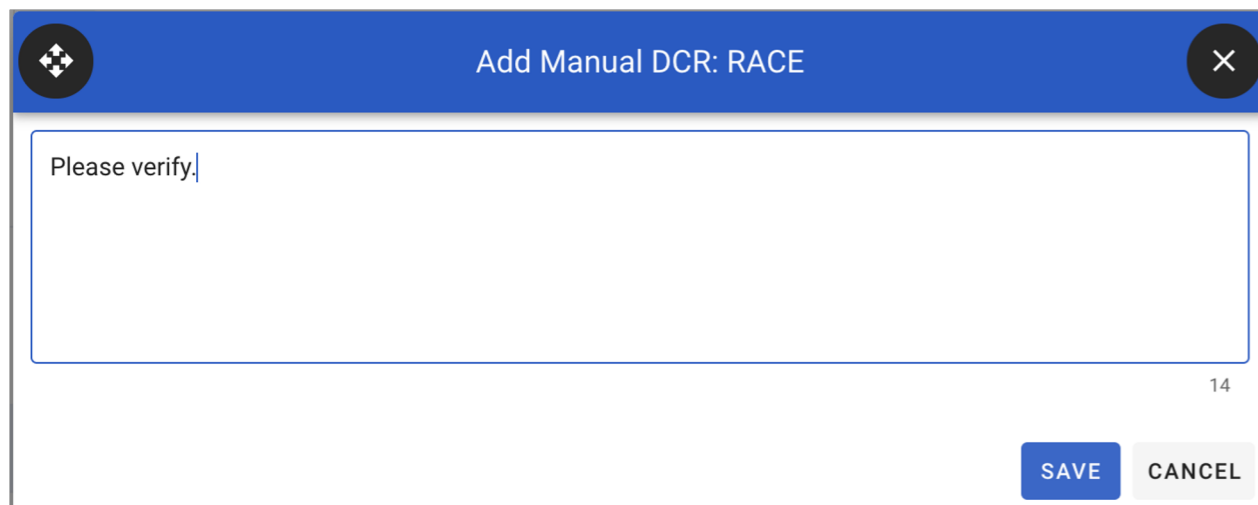
Other

[Back](#) Add Manual DCR Next



Manage DCRs - Create DCR on block (2)

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

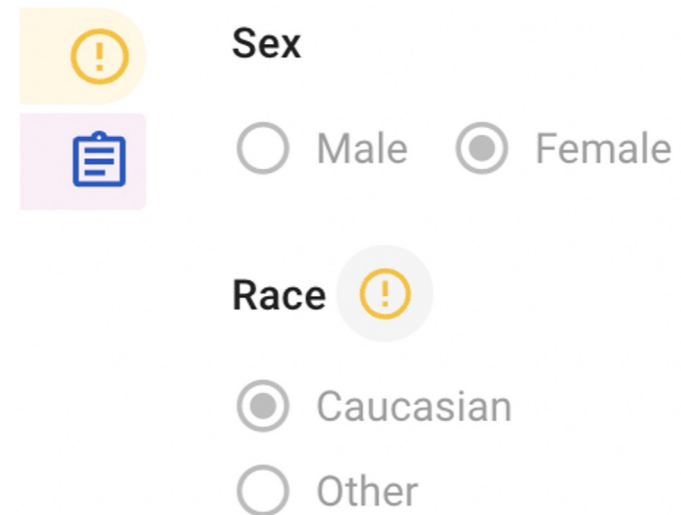


Add Manual DCR: RACE

Please verify|

14

SAVE CANCEL



Sex

Male Female

Race

Caucasian Other



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

Show monitoring status 📄 Not monitored

Smoking Behaviour Monitor Audit trail

Do you currently smoke or have you smoked in the past ⚙️

📄

- I have never smoked
- I currently don't smoke but I have smoked in the past
- I sometimes smoke
- I currently smoke

Back Add Manual DCR Next



Manage DCRs - Create DCR on eCRF (2)

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

✕
Add Manual DCR: Smoking Behaviour
✕

Please complete this page

25

SAVE
CANCEL

Smoking Behaviour

Monitor
DCR ①
Audit trail

Do you currently smoke or have you smoked in the past?

⚙️

I have never smoked

I currently don't smoke but I have smoked in the past

I sometimes smoke

I currently smoke

Back

Add Manual DCR
Next



Manage DCRs - Answered DCR

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

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

Sex

Male Female

Race

Caucasian Other

Specify

Asian

Demographics - coro-001001-003
✕

Data Clarification Requests

Show closed data clarification requests

Search 🔍

Race

Please verify.

#16 • 16 Nov 2021 15:14:47

You

Renneboog Liesbeth

Corrected the data now. 16 Nov 2021 15:58:12

Add a response

Close this DCR

Save
Cancel

OPEN IN OVERVIEW

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 CORONARY HEART DISEASE

58

Manage DCRs - Re-open a DCR

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

Demographics - coro-001001-003
✕

Data Clarification Requests

Show closed data clarification requests

Search 🔍

Race #16 • 16 Nov 2021 15:14:47 m

Please verify. You

Renneboog Liesbeth 16 Nov 2021 15:58:12

Corrected the data now.

Add a response

Please verify the provided race, thank you!

Close this DCR

Save
Cancel

OPEN IN OVERVIEW

!

Sex

Male Female

📄

Race !

Caucasian

Other

Specify

Asian



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.

Demographics - coro-001001-003
✕

Data Clarification Requests

Race
#16 · 16 Nov 2021 15:14:47

Please verify.

You

Renneboog Liesbeth
16 Nov 2021 15:58:12

Corrected the data now.

You
16 Nov 2021 16:07:59

Please verify the provided race, thank you.

User Investigator
16 Nov 2021 16:10:45

The data has been corrected.

Add a response

Close this DCR

Save

Cancel

OPEN IN OVERVIEW

✓

Sex

☰

Male
 Female

Race

Caucasian
 Other

Specify

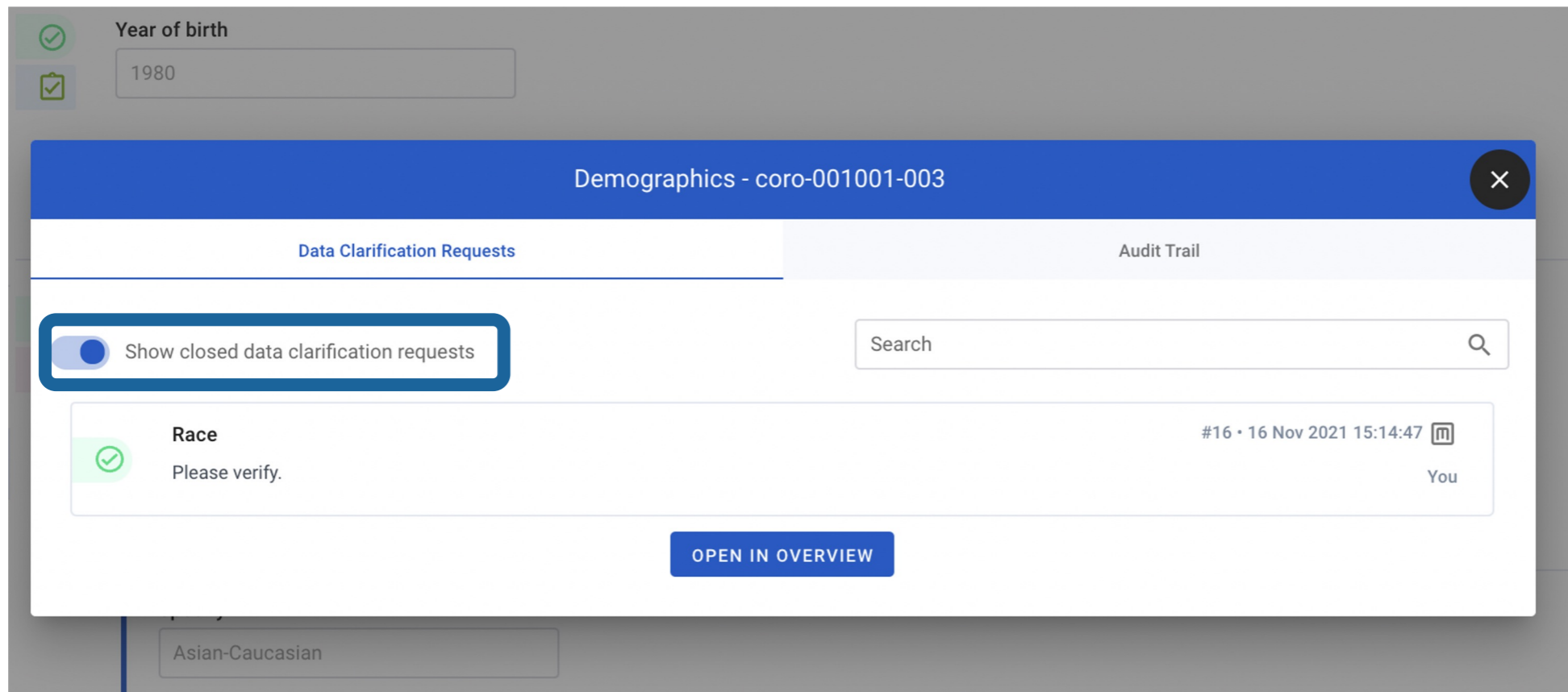
Asian-Caucasian

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CORONARY HEART DISEASE

60

Manage DCRs - View DCRs

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



The screenshot displays a web interface for managing Data Clarification Requests (DCRs). At the top, there is a header for 'Demographics - coro-001001-003'. Below this, there are two tabs: 'Data Clarification Requests' (active) and 'Audit Trail'. A toggle switch labeled 'Show closed data clarification requests' is highlighted with a blue box and is currently turned on. To the right of the toggle is a search bar. Below the search bar, a DCR entry is shown for the field 'Race' with the message 'Please verify.' and a green checkmark icon. The entry includes a timestamp '#16 • 16 Nov 2021 15:14:47' and a user icon labeled 'You'. At the bottom of the entry, there is a blue button labeled 'OPEN IN OVERVIEW'. In the background, a form for 'Year of birth' with the value '1980' and a form for 'Race' with the value 'Asian-Caucasian' are visible.



Manage DCRs - DCRs Overview

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

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

Filters 0

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

1 / 1 - 8 results - Per page 32

Manage DCRs - DCRs Overview (2)

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

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

1 / 1 - 8 results - Per page 32

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

Forgot Password



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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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PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Forgot Password (2)

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

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

Set Password

[Back to login](#)

User password reset Inbox x



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

Hello, Renneboog Liesbeth,

You have requested to reset your password.

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

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

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



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Reset Two-Factor Authentication (TFA)

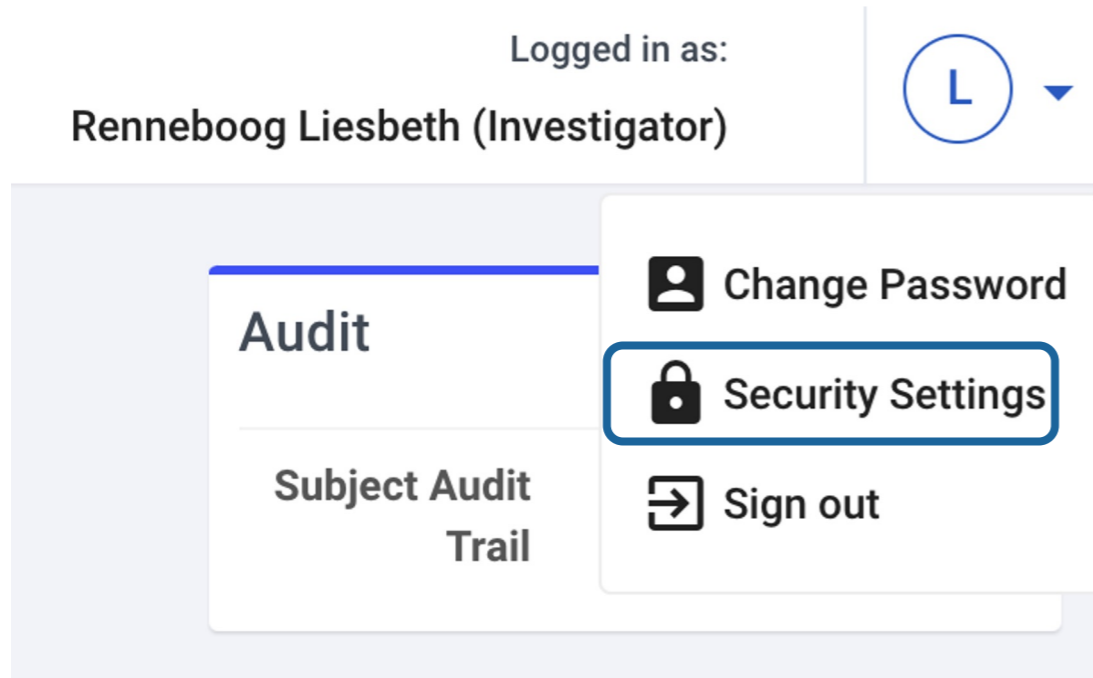


CoroPrevention

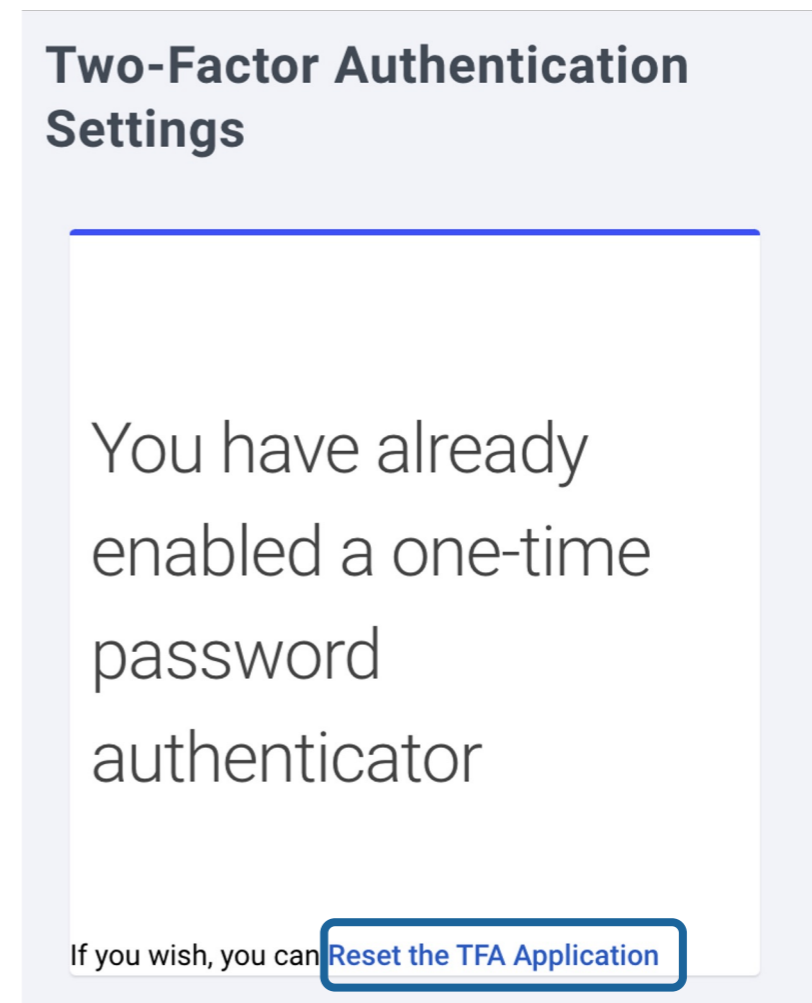
PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Reset TFA

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



- Click Reset the TFA application



Reset TFA (2)

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

You have already enabled a one-time password authenticator

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

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

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

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

Pin code or Back-up code*

Reset the 2-Factor account

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

Reset TFA - Register New Device

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

Two-Factor Authentication Settings

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

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



Pin code*

Register with 2-Factor App

Can't scan the code?

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

Account

Key: 1

MJ5NRHNSJC4{

HG305H

Time based: Yes



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CORONARY HEART DISEASE

Laboratory Data



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CORONARY HEART DISEASE

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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CORONARY HEART DISEASE

Blood Sampling - Basic Laboratory Assessments and CoroPredict Score

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

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

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

Blood Sampling - Basic Laboratory Assessments and CoroPredict Score Audit trail

Was a sample taken? ⚙️
 Yes No

Date sample taken ⚙️
dd mon yyyy
01 Oct 2021

Sample barcode
75145047

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

Rows per page: 10 - < >

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

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

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

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

ADD BLOOD SAMPLE RECORD ⚙️

Blood Sample

ⓘ Nr
5

Test code

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.



CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Randomise / Allocate Treatment



CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Eligibility

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

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

- 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
- Questionnaires
- Smoking Behaviour
- Blood Sampling - Basic Laboratory Assessments and CoroPredict Score
- Randomisation
- End Of Trial
- Informed Consent Amendments

Show monitoring status

Inclusion / Exclusion Criteria
Audit trail

| | Yes | No | |
|---|----------------------------------|----------------------------------|----|
| <input checked="" type="checkbox"/> Inclusion Criteria | | | ⚙️ |
| Informed consent form signed by the study subject. | <input checked="" type="radio"/> | <input type="radio"/> | |
| Male or female aged 30 to 80 years on the day of enrolment. | <input checked="" type="radio"/> | <input type="radio"/> | |
| ≥ 50% stenosis in one or more major coronary arteries on angiography or computerised tomography (CT) performed within the preceding year (from enrolment visit) or myocardial infarction (type I, II) during the preceding year. | <input checked="" type="radio"/> | <input type="radio"/> | |
| <input checked="" type="checkbox"/> Exclusion Criteria | | | ⚙️ |
| Hospitalisation for acute coronary syndrome, myocardial infarction, stroke, coronary revascularisation or acute heart failure within the preceding month (30 days). These subjects can be enrolled after a one-month stabilisation period, which begins from the time of the event. | <input type="radio"/> | <input checked="" type="radio"/> | |
| Subjects with NYHA class III-IV heart failure i.e. marked limitation in activity due to symptoms, comfortable only at rest. | <input type="radio"/> | <input checked="" type="radio"/> | |
| Uncontrolled arrhythmias such as ventricular tachycardias. | <input type="radio"/> | <input checked="" type="radio"/> | |
| Subjects undergoing dialysis due to severe renal disease. | <input type="radio"/> | <input checked="" type="radio"/> | |
| Diseases that severely disable exercising (per investigator's judgement), such as rheumatoid arthritis, neurological or orthopaedic diseases. | <input type="radio"/> | <input checked="" type="radio"/> | |
| Known aplastic or haemolytic anaemia or other severe anaemia. | <input type="radio"/> | <input checked="" type="radio"/> | |
| Concomitant non-coronary disease, such as malignancy that limits life expectancy to less than three years. | <input type="radio"/> | <input checked="" type="radio"/> | |
| Concurrent participation in another interventional study. | <input type="radio"/> | <input checked="" type="radio"/> | |
| Subjects not able and/or willing to attend all scheduled visits and comply with all study procedures and use a smartphone application. | <input type="radio"/> | <input checked="" type="radio"/> | |
| <input checked="" type="checkbox"/> The subject is eligible to participate in the study | | | ⚙️ |
| Yes | | | |

CoroPredict Score and Risk Category

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

- Risk category = low and medium risk

⇒ Allocate Treatment
(Usual Care)

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

The screenshot displays the CoroPrevention web interface for a subject. The top navigation bar includes the site name 'CoroPrevention', a breadcrumb trail 'Subjects / coro-001001-006 / View', and user information: 'Working in: Country: Finland Site: Helsinki University Hospital' and 'Logged in as: Renneboog Liesbeth (Investigator)'. The main content area is titled 'Randomisation' and features an 'Audit trail' button. A list of laboratory results is shown, each with a green checkmark icon and a gear icon for settings:

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

At the bottom of the results section, there is a button labeled 'RANDOMIZE TREATMENT'.

The left sidebar contains a navigation menu with the following items:

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

Randomise Treatment

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

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

Randomisation Audit trail

proBNP
+ 1 ⚙️

High-sensitivity troponin
+ 1

Cystatin-C
+ 1

Ceramide score
+ 1

CoroPredict score
= 4

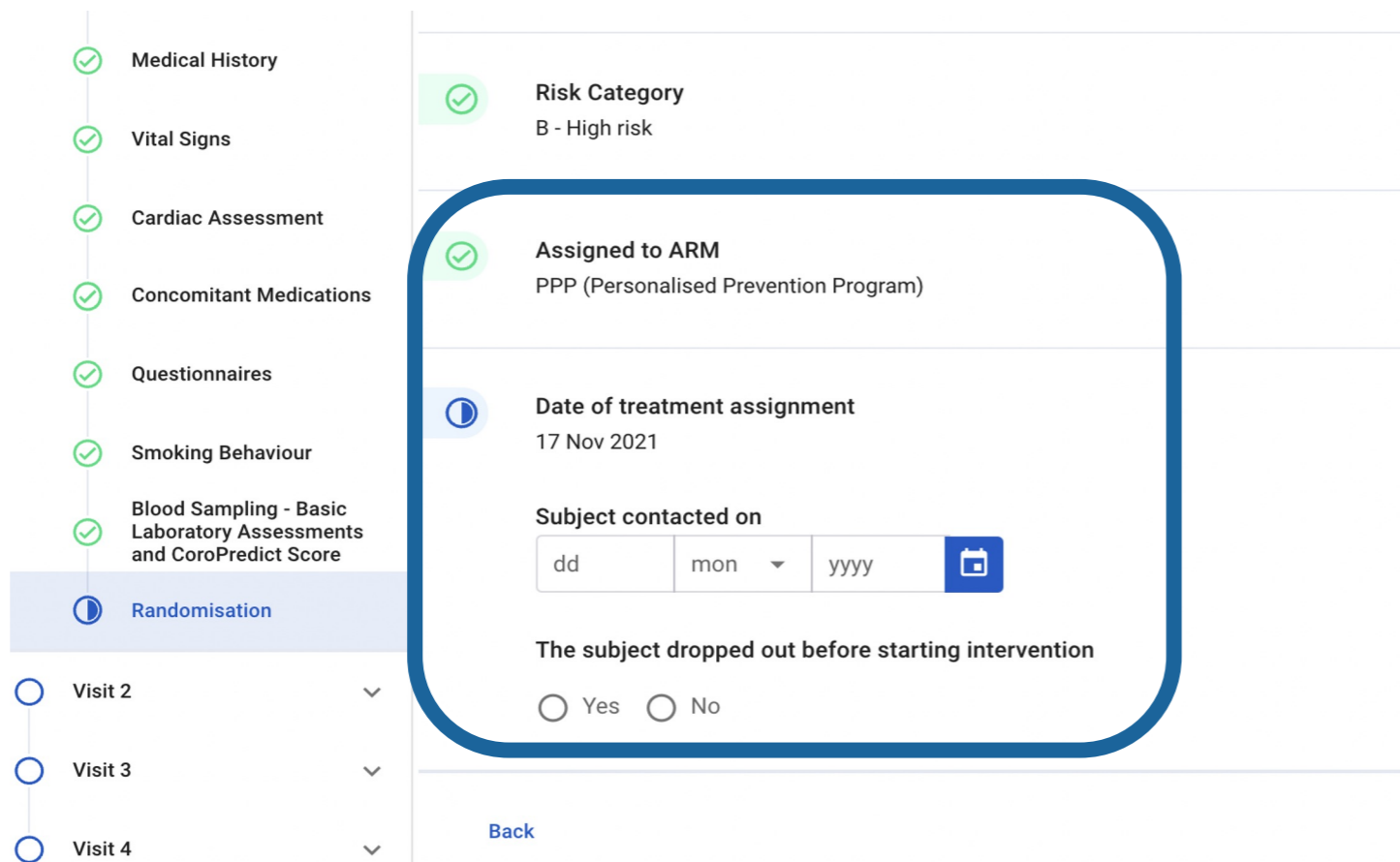
Risk Category
B - High risk ⚙️

⚙️

[Back](#)

Randomise Treatment (2)

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



Medical History

Vital Signs

Cardiac Assessment

Concomitant Medications

Questionnaires

Smoking Behaviour

Blood Sampling - Basic Laboratory Assessments and CoroPredict Score

Randomisation

Visit 2

Visit 3

Visit 4

Risk Category
B - High risk

Assigned to ARM
PPP (Personalised Prevention Program)

Date of treatment assignment
17 Nov 2021

Subject contacted on
dd mon yyyy

The subject dropped out before starting intervention
 Yes No

Back

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



CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Allocate Treatment

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

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

Randomisation Audit trail

proBNP
+ 1 ⚙️

High-sensitivity troponin
+ 0

Cystatin-C
+ 0

Ceramide score
+ 0

CoroPredict score
= 1

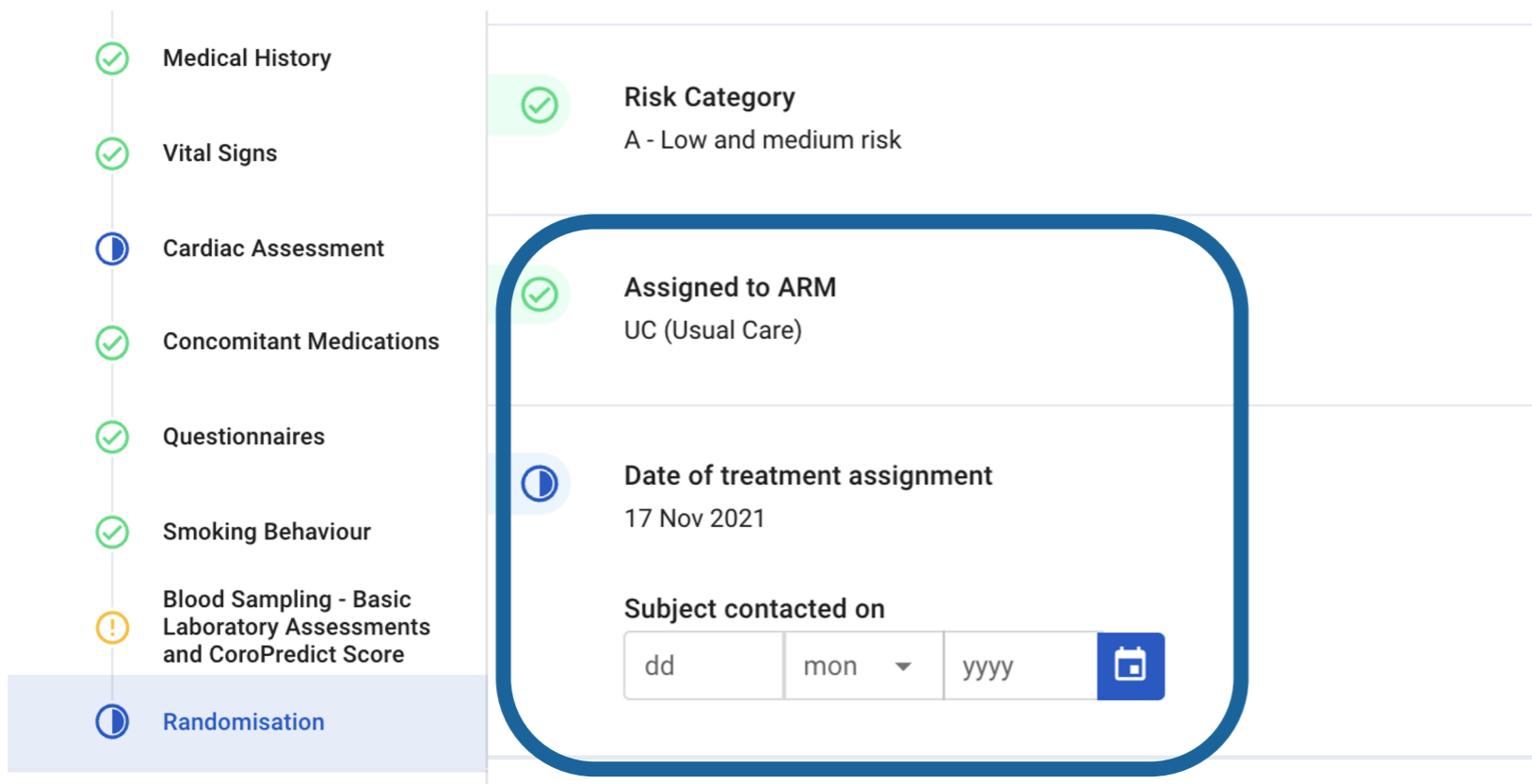
Risk Category
A - Low and medium risk ⚙️

ALLOCATE TREATMENT ⚙️

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

Allocate Treatment (2)

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



The screenshot shows a vertical checklist on the left with the following items: Medical History (checked), Vital Signs (checked), Cardiac Assessment (not checked), Concomitant Medications (checked), Questionnaires (checked), Smoking Behaviour (checked), Blood Sampling - Basic Laboratory Assessments and CoroPredict Score (warning icon), and Randomisation (not checked). The main form on the right contains the following fields:

- Risk Category:** A - Low and medium risk (checked)
- Assigned to ARM:** UC (Usual Care) (checked)
- Date of treatment assignment:** 17 Nov 2021 (not checked)
- Subject contacted on:** A date picker with fields for 'dd', 'mon', and 'yyyy', and a calendar icon.

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



Randomise / Allocate Treatment

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

- Medical History
- Vital Signs
- Cardiac Assessment
- Concomitant Medications
- Questionnaires
- Smoking Behaviour
- Blood Sampling - Basic Laboratory Assessments and CoroPredict Score
- Randomisation
- Visit 2
- Visit 3
- Visit 4

Risk Category
B - High risk

Assigned to ARM
PPP (Personalised Prevention Program)

Date of treatment assignment
16 Nov 2021

Subject contacted on

| | | | |
|----|-----|------|---|
| dd | mon | yyyy | 📅 |
| 16 | Nov | 2021 | |

The subject dropped out before starting intervention
 Yes No

[Back](#)



Randomise / Allocate Treatment - Errors

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

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



SAE / SADE Form



CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

SAE

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

The screenshot displays the UniWeb interface for the 'CoroPrevention' study. The main content area shows the 'Adverse Events Log' form for subject 'coro-001001-003'. The form includes the following sections:

- Working in:** Country: Finland, Site: Helsinki University Hospital
- Logged in as:** Renneboog Liesbeth (Investigator)
- Relationship to PPP intervention:** Radio buttons for 'Related', 'Possibly related' (selected), and 'Unrelated'.
- Serious Adverse Event:** Radio buttons for 'Yes' (selected) and 'No'.
- Outcome:** Radio buttons for 'Recovered' (selected), 'Continuing with intervention', 'Continuing without intervention', and 'Death'.

A warning banner is present, stating: "Please fill out the SAE/SADE form!". The left sidebar contains navigation options such as 'Visit 3' through 'Visit 7', 'End Of Trial', 'Informed Consent Amendments', 'Logs', 'Adverse Events Log', 'Concomitant Medications Log', 'Subject Reported Clinical Endpoints Log', and 'Call Log'.



SADE

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

Device Deficiencies Audit trail

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

Yes No

Please specify the device deficiency

example

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

Yes No

⚠️ Please fill out the SAE/SADE form

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



SAE / SADE Form - Completing

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

sae-sade-form | 1 / 4 | 100%

CoroPrevention
PERSONALISED PREVENTION FOR CORONARY HEART DISEASE

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

Type of Report

Choose relevant option: Initial Report Follow Up Report Final Report

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

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

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

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

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

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

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

! The form contains multiple pages



SAE / SADE Form - Sending

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

Reporting Person

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

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

Principal Investigator / Delegated Medically Qualified Person:

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

Sending the Form

PLEASE SEND THIS FORM TO: CoroPrevention@tuni.fi

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



Import Data from Tool Suite



CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Import Data from Tool Suite

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



CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Import Data from Tool Suite (2)

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

CoroPrevention

Subjects / coro-001001-115 / View

Working in:
Country: Finland
Site: Helsinki University Hospital

Logged in as:
Renneboog Liesbeth
(Investigator)

Subject ID: coro-001001-115
Site: Helsinki University Hospital
Progress: Randomised

Show monitoring status

Vital Signs

Import data from CoroPrevention tool

Audit trail

Body weight

kg

Blood pressure

Systolic mmHg Diastolic mmHg

Pulse Rate

bpm

Back

Next



Import Data from Tool Suite (3)

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

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

CANCEL IMPORT

Import Data from Tool Suite (4)

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

Subjects / [coro-001001-115](#) / View

Working in:
Country: Finland
Site: Helsinki University Hospital

Logged in as:
 Renneboog Liesbeth
 (Investigator)

L

Show monitoring status

Vital Signs

Import data from CoroPrevention tool

Audit trail

✔

Body weight

kg

⚙️

✔

Blood pressure

Systolic

mmHg

Diastolic

mmHg

⚙️

Pulse Rate

bpm

Back

Sign

Next



Import Data from Tool Suite - Data Updates

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



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

CANCEL IMPORT

Import Data from Tool Suite - No Data

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

Import data for Clinical Assessment - coro-001001-087



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

No data available

CANCEL

IMPORT

Generate ePRO Link



CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Generate ePRO Link

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

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

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

| Subject | Visit Number | After Visit | Created For | Created On | QR Code | Url |
|-----------------|--------------|-------------|-------------|--------------------------|--------------|---|
| coro-001002-255 | 1 | no | Patient | October 14, 2022 08:38 | Show QR Code | https://tablet-uat.coroprevention.eu/session/start/_uiPz1k4Jx8HmbzhbXDPX8ob119X5X\BBB2T01GWtHKiiXBRjqd8pK-5xt0JLIFW5su939T2xgUafW1iPtMtCABtjMW857TWK9p4S5 |
| coro-001001-224 | 1 | no | Study Nurse | September 16, 2022 05:50 | Show QR Code | https://tablet-uat.coroprevention.eu/session/start/j9TVdENgCgG1CLqZCIPtIiAswuNB0d7huK9EGExpUWE8W6FofuCYTsyLU9K_FITcwKCz8bg_1ZfPym8SiQGYfBskdfCT8tA0JIGEWf |
| coro-001001-224 | 1 | no | Patient | September 13, 2022 11:28 | Show QR Code | https://tablet-uat.coroprevention.eu/session/start/T7NTuv-Q3eCK9D7orVr8ecf54tMBjXzfm1U04uNL7CA4LQzNl9I6TXrYnwIbrT2KWkuPWw1vSlcNcLEBIAY6muoa6Qu4Xpdve6f3Jr |
| coro-001001-001 | 1 | no | Patient | September 12, 2022 13:36 | Show QR Code | https://tablet-uat.coroprevention.eu/session/start/cesHIFhGcmz83fAlfcSMLw5Y1Fb71t6jKnXsvsFUL0fUBt_oqzKx5rBEK53t2gCAV4_xOR0z5PMTup0HYXbhjq800FbgVafE6WAAff |
| coro-001001-001 | 1 | no | Patient | September 12, 2022 12:16 | Show QR Code | https://tablet-uat.coroprevention.eu/session/start/J7XrtsTSgU2_u4TR-VNozsQ7NZQM78Q2Tpt0p6eWfXCTkBRMGU8lr_GJDWmEtY2ZXQeqFTggZ4k5nNlpAVty0PbFN-n68cXdOW_ |

Generate ePRO Link (2)


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

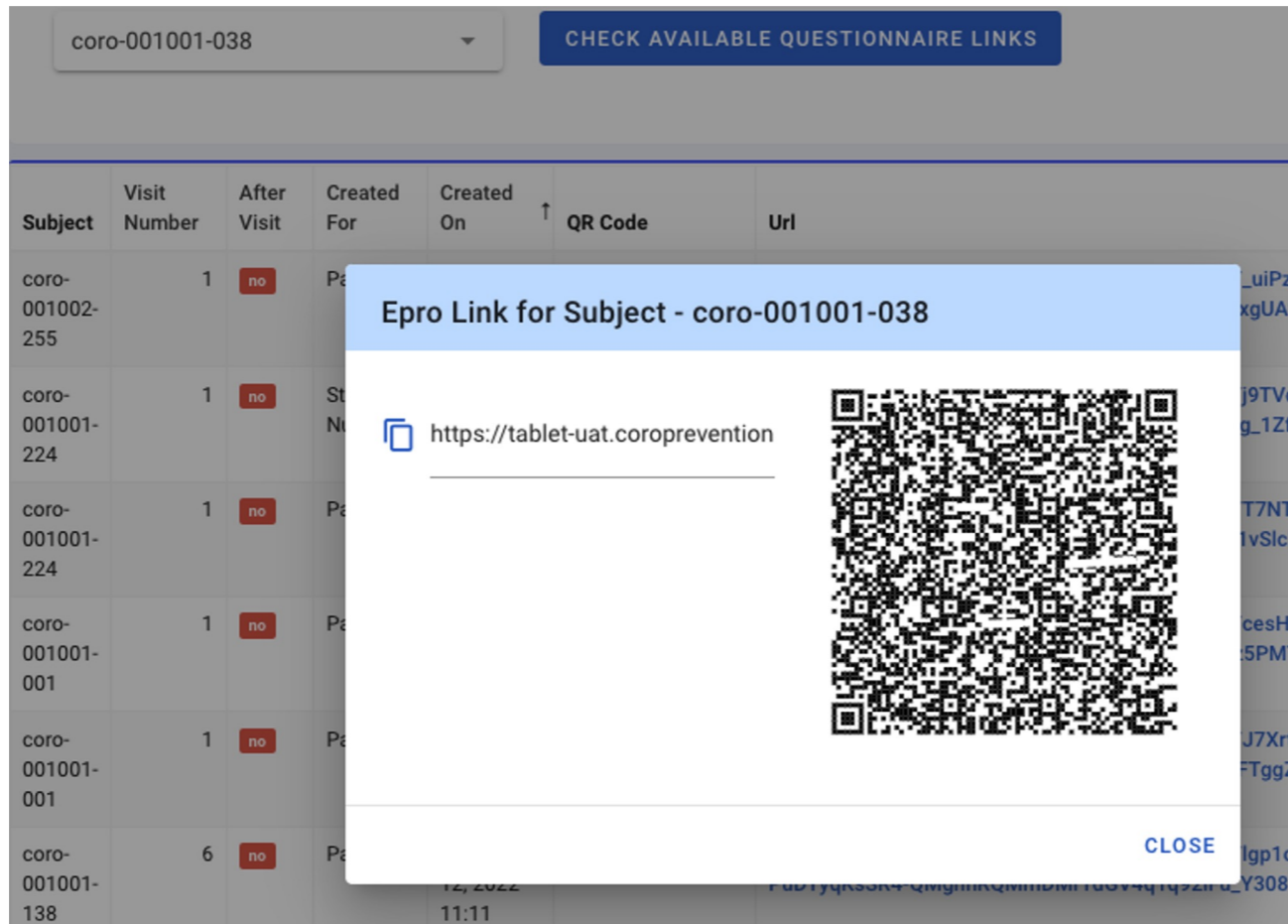
The screenshot shows the CoroPrevention EproLink interface. A sidebar on the left contains navigation options: Home, Subjects, DCR, Documents, Training, Export, Adjudication, EproLink, and Audit. The main content area displays a table of subjects with columns for Subject, Visit Number, After Visit, Created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

| Subject | Visit Number | After Visit | Created For | Created On | QR Code | Url |
|-----------------|--------------|-------------|-------------|------------|---------|---|
| coro-001002-255 | | | | | | bzbhXDPX8obI19X5XYV AbtjMW857TWK9p4S5s |
| coro-001001-224 | | | | | | CLqZCiPTiIAswuNB0d7n YfBskdfCT8tA0JIGEWf |
| coro-001001-224 | | | | | | 9D7orVr8ecf54tMBjXzNH muoa6Qu4Xpdve6f3Jr7 |
| coro-001001-001 | | | | | | 3fAlfcSMLw5Y1Fb71t6w hjq800FbgVafE6WAAfHc |
| coro-001001-001 | | | | | | 4TR-VNozsQ7NZQM78K Vty0PbFN-n68cXd0W_IQ |
| coro-001001-138 | | | | | | yn6wxLH3LbqI7nV3Id9tv 160b47PijK6Nvi4Z0dVG |



Generate ePRO Link (3)

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



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

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



CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

List of ePRO Links

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

EproLink 001001 - Helsinki University Hospital

Subject CHECK AVAILABLE QUESTIONNAIRE LINKS Filters 1

Subject Filter Reset

[Advanced filters](#)

| Subject | Visit Number | After Visit | Created For | Created On | QR Code | Url |
|-----------------|--------------|-------------|-------------|------------------------|--------------|---|
| coro-001001-038 | 1 | no | Patient | November 2, 2022 08:35 | Show QR Code | https://tablet-uat.coroprevention.eu/session/start/5AV5EjBqm7Ak5BKT0EYBMBaHv70nRcuZmCfwi4-dRSY1YP27G6pvl8yGZFManIdT-M_eX6oN5Dg5g80QGh7SV0c4w-AP8ID06UITWUVks-Rrb3VgktqqEQ7VYaBpVv2fCxtDJPY2iMyawnRBnke9XK7WStFA1jyQ0A0RnWf2oMezr... |
| coro-001001-038 | 1 | no | Patient | June 15, 2022 07:32 | Show QR Code | https://tablet-uat.coroprevention.eu/session/start/mtyrSJRvmmzDJmSqqc9dKhXTxc0edj6xOERFarTYJUUMM7I0ctgJU047v_UVVhYmW5FVxRXN16rl2c1XuX629X0QM7cnf5xwQ6C6YU9UZC0p6E9b94S4UUJe_EVmrjfdDS4dvqHboQrXr08wTq_i8aVi8BmPeCNWTG7E6-ruN-pk... |
| coro-001001-038 | 1 | no | Study Nurse | June 4, 2022 03:07 | Show QR Code | https://tablet-uat.coroprevention.eu/session/start/miRvbiONLwIX8SSd08x76-B0SgBr2OdlxiJax0tHrSRmuY08alzDyS7EjynGJ5wplNoCBku4gR_12xPAAsS97BoOIKNn8M5fOXx6vcrz5_LzJvNd0Q40wTvsoowN0jYxBv2bck7ozTh_cjdEYjBBMLYo1TdSXbzzwUo6iGXAMqI2e3GP49BVKnR3zmdnV1YVFBmau4/fi |



Protocol Deviations



CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Protocol Deviations - Log

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

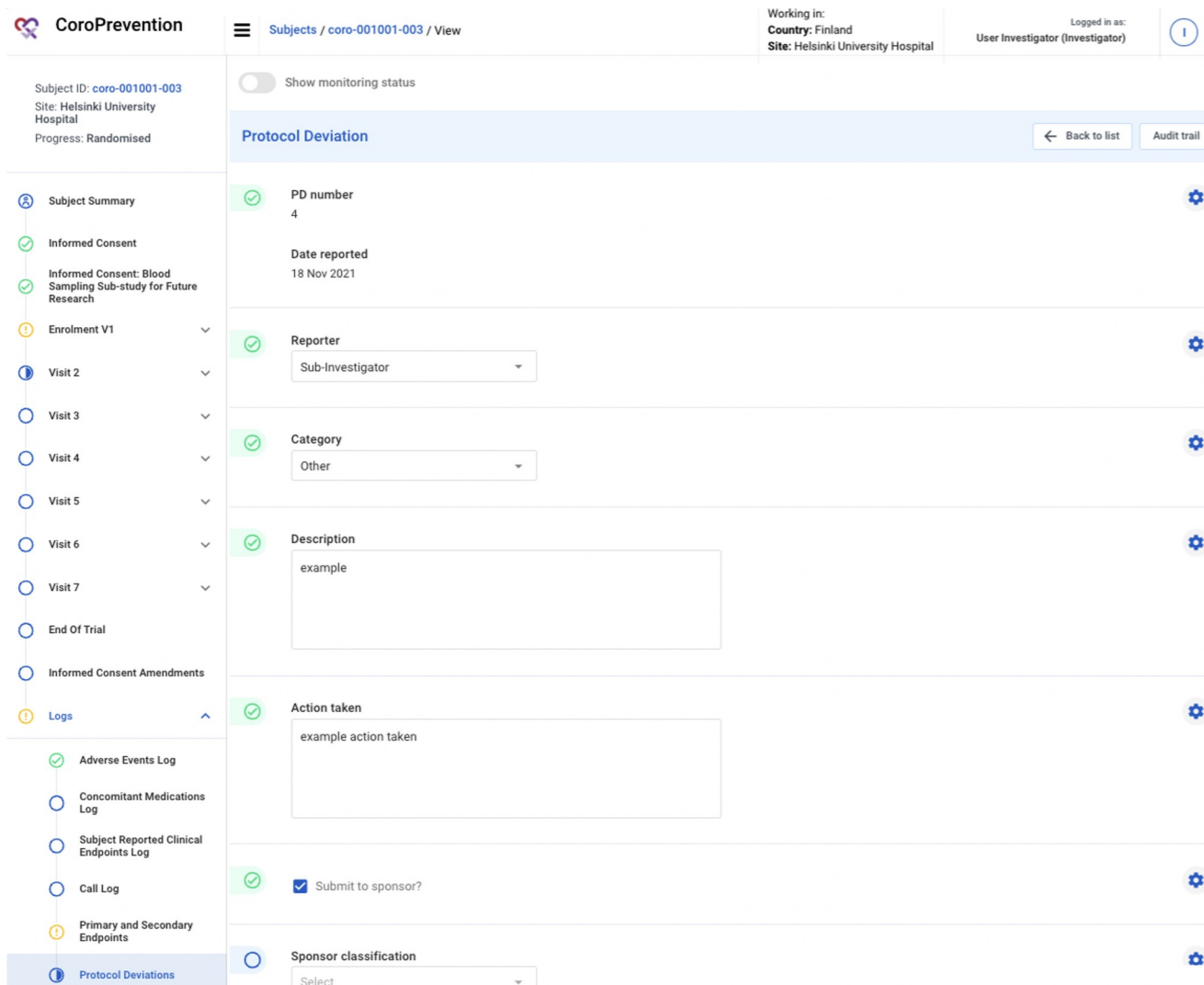
PDs can be manually created or automatically generated based on predefined conditions. Automatic PDs have “System” as reporter.

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

Rows per page: 10 1-4 of 4

Protocol Deviations - Create

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



CoroPrevention

Subjects / coro-001001-003 / View

Working in:
Country: Finland
Site: Helsinki University Hospital

Logged in as:
User Investigator (Investigator)

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

Show monitoring status

Protocol Deviation

Back to list Audit trail

PD number
4

Date reported
18 Nov 2021

Reporter
Sub-Investigator

Category
Other

Description
example

Action taken
example action taken

Submit to sponsor?

Sponsor classification
Select

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

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

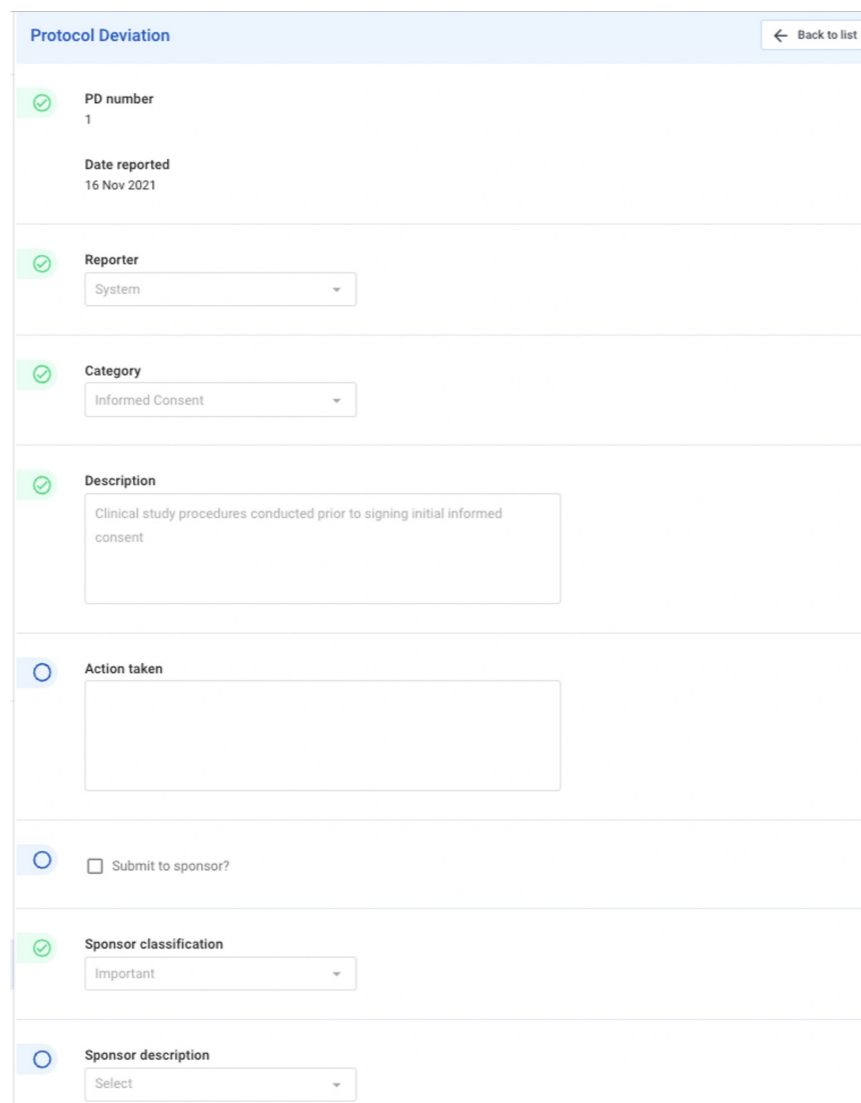


CoroPrevention

PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Protocol Deviations - Automatic PDs

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



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

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



CoroPrevention

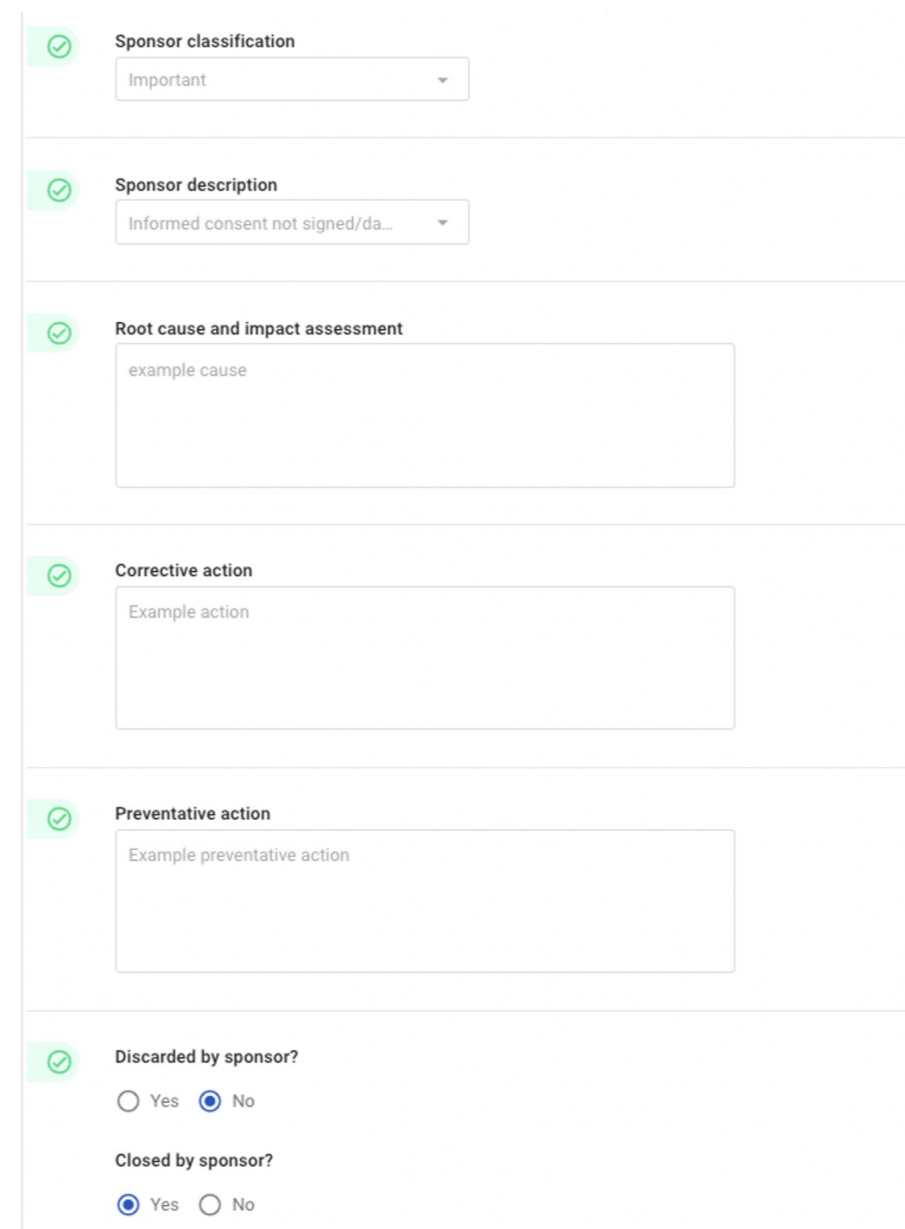
PERSONALISED PREVENTION FOR
CORONARY HEART DISEASE

Protocol Deviations - Sponsor Evaluation

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

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

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



The screenshot shows a form with the following sections:

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