



CoroPrevention EDC -Training Master Deck

v1.0

edc.coroprevention.eu



Agenda

- Login
- Training
- Navigation
- Reports
- Forgot Password
- •Reset 2FA





Login





Login - Account Activation

- An activation email is sent to you
- Click "Activate account" or use the activation code and navigate to the link

•! Expires after 48 hours







Login - Account Activation (2)

• Enter/review the username/e-mail address and activation code

Click "Activate"

Username or e-mail		
liesbeth.renneboog		
Activation code		
ck to login		





Login - Account Activation (3)

• Choose a password that meets the requirements

Click "Set Password"





Login - Two-Factor Authentication

- Download one of the following two-factor authentication apps on your mobile device from the App Store (for iOS) or the Google Play Store (for Android):
 - Google Authenticator, Authy, Duo Mobile, LastPass, Microsoft Authenticator

• This can be skipped if you already have one of these apps on your device



Login - Register Two-Factor Authentication

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



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.







Login - General

After initial login, follow these steps to login:

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

\sim	
×	EDC
Velcome	Back. Please login to your account:
Usernam	e or e-mail
Passwo	ord
orgot Pas	sword?
	vHEAD.1128928
	2021-10-12 19:13:07
Activate us	ser Login





Login - General (2)

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

Enter a 6-digit code from y	your Authentication App
Login	
Back to login	





Logout

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

Click Sign out

ŝ	CoroPrevention	≡		Working in: Country: Finland Site: Helsinki University Hospital	Log Renneboog Liesbeth (Inve	gged in as: estigator)	L •
ŵ	Home	Subjects		A	udit	Change	e Password y Settings
â	Subjects	Subjects 🚭	Add new 🛛 🗮 List		Subject Audit Trail 🗮 List	➔ Sign ou	ıt
¢	DCR	DCR					
<u>₽</u>	Export 🗸	Data Clarification Equest	List				

Log out when stepping away from your computer.





Training





Training - Initial

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

ŝ	CoroPrevention	Training				Working in: Country: Finland Site: Helsinki University Hospi	Logged tal Renneboog Liesbeth (Investig	in as: Jator)
ŵ	Home	▲ Warning! You need to download and sign all required training	js before you can acc	ess the platform				×
<u>8</u>	Subjects							
		Training ↓	Required	Status	Completion date a	nd time A	ction	
Û	DCR	Query Management		Not Done			DOCUMENT DOWNLOAD	
	Training	SAE Reporting	yes	Not Done			▲ DOCUMENT DOWNLOAD	
⊉	Export 🗸 🗸	User Guidelines for Investigator	yes	Not Done			DOCUMENT DOWNLOAD	
	EproLink						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







Training - Sign

• Click "Sign" to acknowledge that you have completed training on the topic



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





Training - Sign (2)

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

Sign User Guidelines for Investigator

By entering my username and password, I acknowledge that I have completed
training on the topics covered in this document.

Username		
l.renneboog		
Password		
	✓ SIGN	× CANCEL

i Success! Training signed successfully				×
Warning! You need to download and sign all required	l 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

ŝ	CoroPrevention	Training			Working in: Country: Finland Site: Helsinki University Ho	spital Renneboog Liesbeth (Investigator)
ŵ	Home	i Success! Training signed successfully				×
<u> </u>	Subjects					
		Training ↓	Required	Status	Completion date and time	Action
Û	DCR	Query Management	no	Not Done		▲ DOCUMENT DOWNLOAD
	Training	SAE Reporting	yes	Completed	16 Nov 2021 10:48:22	DOCUMENT DOWNLOAD
₽	Export 🗸	User Guidelines for Investigator	yes	Completed	16 Nov 2021 10:41:46	DOCUMENT DOWNLOAD
	EproLink					1 / 1 - 3 results - Per page 32 •





Navigation





Navigation - Location Select

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

Location

Countries	Sites
All my countries	All my countries and sites
Belgium	
+ Finland	
i Germany	
🔚 Greece	
I aly	
se North Macedonia	
- Poland	
Portuaal	
	✓ CONFIRM

• Or to more than one site:

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

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.





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

😪 CoroPreventi	on	=		Working in: Country: Finland Site: Helsinki Univ	ersity Hospital	Logged in as: Renneboog Liesbeth (Investigator)	L
命 Home		Subjects			Audit		
왔 Subjects		Subjects	O Add new I≣ List		Subjec	t Audit Trail 🛛 🔚 List	
Å DCR		DCR					
<u> </u>	~	Data Clarification Request	i≣ List				
Q Audit	~						
EproLink		Export					
		Downloads	≣ List				





Navigation - Access Details

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

- Study you are working in
- Toggle to hide/unhide the navigation bar
- Location button: Country flag & Site / "Multiple Sites" or "Multiple countries"
- Your name and user type
- Link to actions related to your account







Navigation - Go to Subject

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

ŝ	CoroPrevention	Subjects			v C S	Vorking in: country: Finland ite: Helsinki University	Hospital	Renneb	Logged ir oog Liesbeth (Investiga	as: tor)	L •
ŵ	Home								▼ Filters 0 -	O Add ne	9W
2	Subjects	Subject Id ↓	Study	Site ID	Last Visit Ti	tle Status	Monitor St	atus	Progress Status	Action	
^	DCP	coro-001001-001	CoroPrevention	Helsinki University Hospital	Enrolment V	/1	Ê		Randomised	O VIE	W
Ļ	DCK	coro-001001-002	CoroPrevention	Helsinki University Hospital	Enrolment V	/1	Ê		Randomised	• VIE	W
<u>∓</u>	Export ~	coro-001001-003	CoroPrevention	Helsinki University Hospital	Enrolment V	/1	Ê		Allocated		
â	Audit						-			O VIE	v
Ň	· · · · ·	coro-001001-004	CoroPrevention	Helsinki University Hospital	Enrolment V	'1	Ē		Allocated	VIE	W
	EproLink	coro-001001-005	CoroPrevention	Helsinki University Hospital	Informed Co	onsent 🕕	Ê		Screening	• VIE	W

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

CoroPrevention	Subjects / coro-001001-003 / View	Working in: Country: Finland Site: Helsinki University Hospital	Logged in as: Renneboog Liesbeth (Investigator)	(L) •	
Subject ID: coro-001001-003 Site: Helsinki University	Show monitoring status				
Hospital Progress: Randomised	Vital Signs			Audit trail	
 Subject Summary Informed Consent Informed Consent: Blood Sampling Sub-study for Future Research 	Body height 181 Body weight 78.3 kg			۵	
 Enrolment V1 Visit Date Inclusion / Exclusion Criteria Demographics 	Blood pressure Systolic 121 mmHg Diastolic 81 mmHg			۵	
 Medical History Vital Signs Cardiac Assessment Concomitant Medications 	Pulse Rate 61 bpm Back		Sign	Next	CoroPrevention PERSONALISED PREVENTION FOR CORONARY HEART DISEASE



Reports



Reports - General

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

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

Click the desired type of report or export



The reports and exports are categorized in three categories:

- Study Management
- Study Execution
- Reports

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







Reports - Generation

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

Export / Report Management				🛨 001001 - Helsinki University Hospital	L •
Filters				Saver	i filters +
Countries	Equal *				
Sites	Equal *				
Subjects	Equal *	× coro-001001-096 × coro-001001-185]		
Filter title				🖺 Save 🥥 Cle	ear 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

•	CoroPrevention	:	Export / Report Management			The data to be exported has been
ŵ	Home		Filters			successfully queued. Upon completion of the work, you will receive a notification by email
ĝ	Subjects		August 1			
۵	DCR		Countries	Equal *		
Ť			Sites	Equal *		
E	Documents		Subjects			
	Training		Subjects	Equal *	× coro-001001-096 × c	coro-001001-185
⊉	Export	^	Filter title			Save Oclear filters
	Study Execution					
	Report Management		Adverse Events	Page Status		Subject Enrolment
	Downloads		DCR Status	Protocol Deviations		
	Adjudication					
	EproLink		CSV - ADD REPORT TO QUEUE			
0	Audit	~				





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

Filters		Saved filters
eCRF *	Equal +	×
Countries	Equal	
Sites	Equal	
Subjects	Equal +	
Filter title		Save Ø Clear filters
Adverse Events	Long Term Samples	Protocol Deviations
Clinical Endpoints	Missing CoroPredict Score V1	Subject Discontinuation and Reason
CoroPredict Score	Monitoring Status Overview	Subject Enrolment
DCR Status	Monitoring Status Pages	Visits Eligible for Payment
Data Listing	Page Status	
CSV - ADD REPORT TO QUI	EUE	

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

命	Home	Subjects	
2	Subjects	Subjects	≣ List
Ų	DCR	DCR	
	Training	Data Clarification	≣ List
<u>T</u>	Export ^	Request	
	Study Management	Training	
	Report Management	Training	IIII List
	Downloads	Export	
0	Audit 🗸	Study Management	I Add export to queue
0_	Location Select	Report Management	I Add report to queue
		Downloads	≣ List





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 / Dov	Export / Downloads									
									T Filters 0	
Dataset	User	Total Rows	Export Status	File Type	Archive size	Started At 1	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 v	

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

% (CoroPreven	tion	=	Export / Downloads		Working in: Countries: Multipl Sites: Multiple (i)	e i		Smith John (Ad	Logged in as: dministrator)
										▼ Filters 0 ▼
Туре	Title	User	Total Rows	Progress	Export Status		File Type	Archive size	Completed At	Action
Report	SubjectData	Smith John			IN PROGRESS		CSV			II PAUSE CANCEL
Report	Data Listing	Smith John			NO DATA		PDF			DELETE



Forgot Password





Forgot Password

- If you forgot your password, click Forgot Password? on the login page
- Provide your username or email address and click Send Recovery Email

Recover your account by entering your username or e-mail

User ID or email

Back to login

Send Recovery Email



Velcome Back.	Please	login	to you	ir account:
		5	,	

Pas	sword		
Forgot I	Password	2	
		v -HEAD 2ac21b5	
		V. TTE/(D.2002100	





Forgot Password (2)

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



••••••		0
✓ A number	 A special symbol 	
✓ Uppercase	✓ Lowercase	
✓ 30 or less characters	✓ 8 or more characters	

Set Password

Back to login





Reset Two-Factor Authentication (TFA)





Reset TFA

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

Logge Renneboog Liesbeth (Invest	Logged in as: eboog Liesbeth (Investigator)							
Audit	Change	Password y Settings						
Subject Audit Trail	➔ Sign ou	t						

• Click Reset the TFA application



Two-Factor Authentication Settings

You have already enabled a one-time password authenticator

If you wish, you can 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



- Open Google Authenticator app on your new mobile device
- Scan the QR code with your new mobile device or enter the key and user **Two-Factor Authentication Settings** 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





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.



