

Castor

Castor CDMS Data Entry User Guide

Version 2024.1

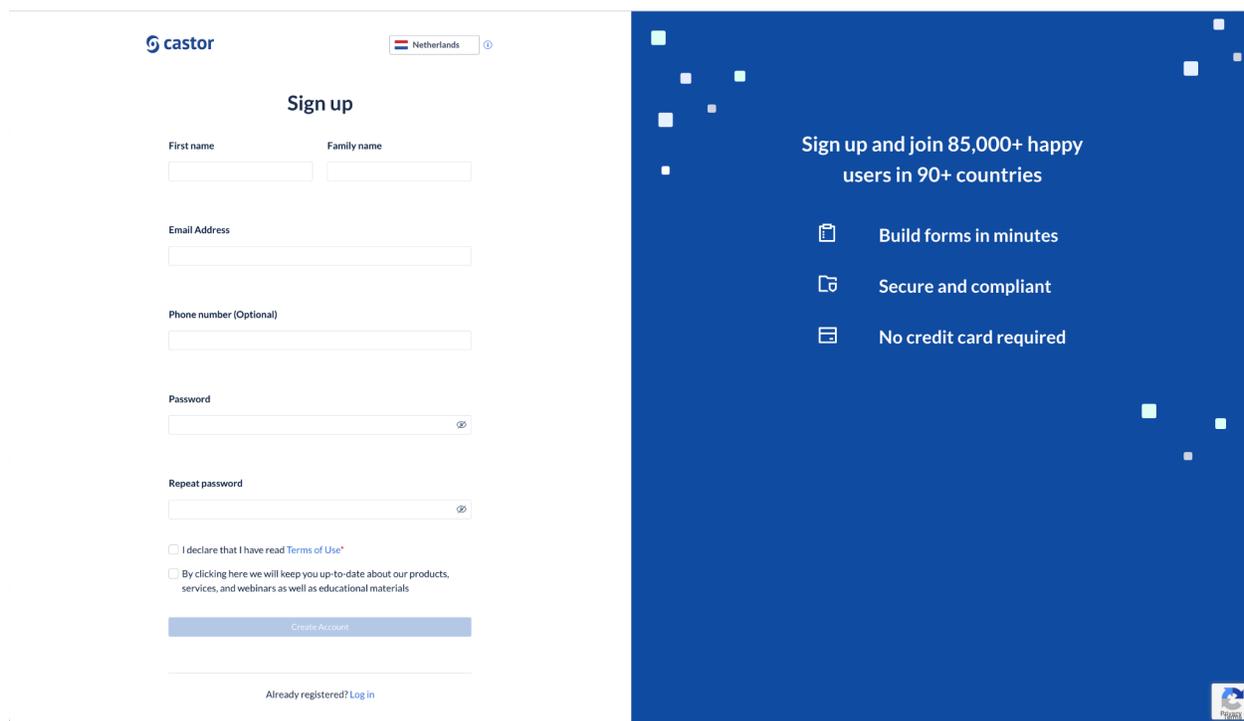
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1. Register an account

There are two ways to register an account: a) via the registration page b) by being added to a study by a study administrator.

1.1. Registration page

You can go directly to our website to create an account before being invited to a study. You will choose the site to create your account based on the location of your study data. Navigate to one of the URLs below to access the registration page:



The image shows a screenshot of the Castor registration page. On the left, there is a white form titled "Sign up" with the following fields: "First name" and "Family name" (two input boxes), "Email Address" (one input box), "Phone number (Optional)" (one input box), "Password" (one input box with an eye icon), and "Repeat password" (one input box with an eye icon). Below the fields are two checkboxes: "I declare that I have read Terms of Use*" and "By clicking here we will keep you up-to-date about our products, services, and webinars as well as educational materials". A blue "Create Account" button is at the bottom of the form. Below the button is a link: "Already registered? Log in". On the right, there is a blue promotional banner with the text "Sign up and join 85,000+ happy users in 90+ countries" and three bullet points: "Build forms in minutes", "Secure and compliant", and "No credit card required". The banner also features a small Castor logo in the bottom right corner.

- EU Account: <https://data.castoredc.com/register>
- UK Account: <https://uk.castoredc.com/register>
- US Account: <https://us.castoredc.com/register>
- AU Account: <https://au.castoredc.com/register>

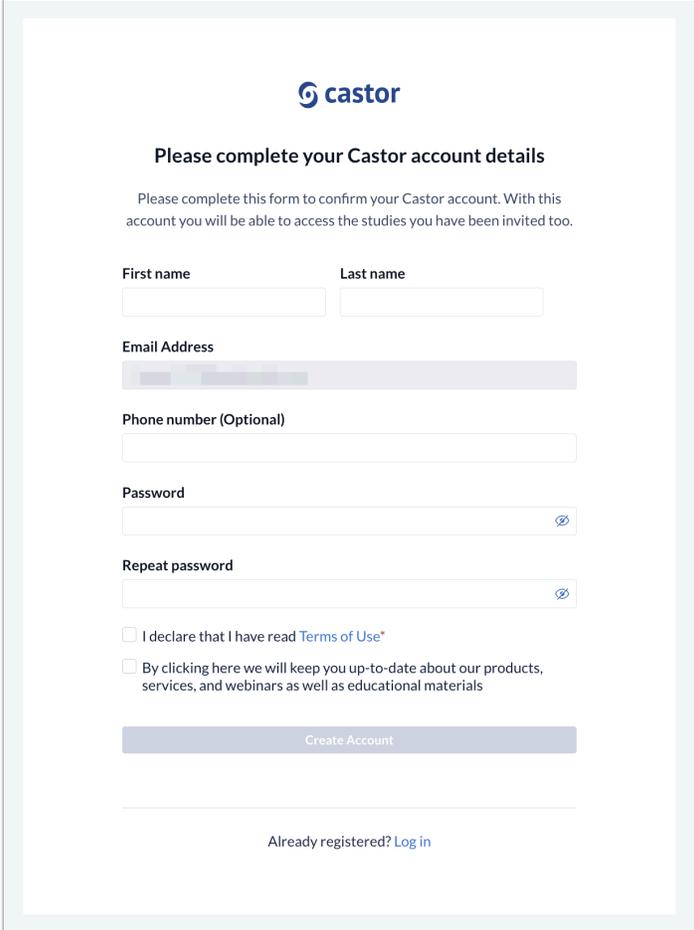
To register your Castor account:

1. Fill in your first and last name(s).
2. Enter your email address and choose a strong password, consisting of at least 8 characters, one uppercase letter, one lowercase letter and a number.
3. Enter your phone number
4. Accept the 'Terms of Use' and opt-in the email communications (optional)
5. Press the button 'Create Account'

You will receive an email to verify your account. After clicking the link in the email address, you will be prompted to confirm the server where your account will be created.

1.2. User is added to a study

If a study administrator has added you to a study, you will receive an invitation by email for the study for which you need to do data entry. Click on the activation link in the email and it will redirect you to the registration page. To register Castor account:



castor

Please complete your Castor account details

Please complete this form to confirm your Castor account. With this account you will be able to access the studies you have been invited too.

First name Last name

Email Address

Phone number (Optional)

Password

Repeat password

I declare that I have read [Terms of Use](#)*

By clicking here we will keep you up-to-date about our products, services, and webinars as well as educational materials

[Create Account](#)

Already registered? [Log in](#)

1. Fill in first and last name(s).
2. The email address will be pre-filled, choose a strong password, consisting of at least 8 characters, one uppercase letter, one lowercase letter and a number.
3. Click on 'Register'. Shortly after registering a user details, an email with an activation link will be sent to the email address a user has provided. Click on this link to confirm that the supplied email address belongs to a user and verify a user account.

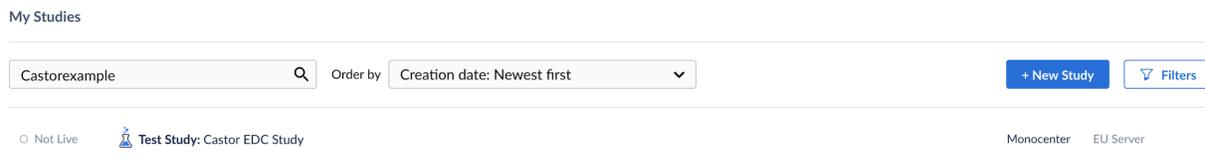
2. Log In

To access the study, log into Castor CDMS via <https://data.castoredc.com>. If your study is on the US, AU or UK server, you can also directly go to <https://au.castoredc.com/register>, <http://us.castoredc.com> or <http://uk.castoredc.com>, respectively.

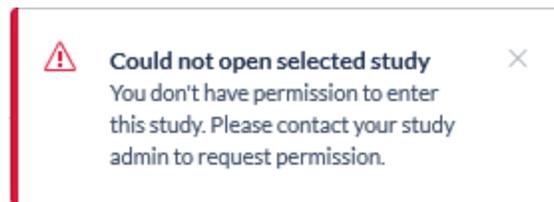
1. Choose the server that is used for your study in order to be able to access the study.
2. Enter your email address and password.
3. Click on 'Login'.

3. Open a study

Once you have logged into Castor EDC, you will see the 'My Studies' overview where all of the user studies (databases) are shown. If a study is live (indicated by a green button and 'Live' to the left of the study name), a user can click on the study name to enter the study and start data entry.



Trying to open a study that is not live will show the following warning:



If the study is still in maintenance mode (the button is blank, and the status says 'Not Live') a user will only be able to open the study if a user has management permissions.

4. Add/Open a participant for data entry

Once a user enters the study, a user will see a list of all participants available based on their access level. To add a new participant to the database, a user will need to create a new participant participant. Creating new participant participants must be done from the Participant tab, by clicking on the “+ New” button.

The screenshot shows the 'Participants' section of the Castor Study interface. On the left is a navigation menu with options like 'Study design', 'Study forms', 'Participants', 'Repeating data', 'Surveys', 'Monitoring', 'Dashboard', 'Audit trail', 'Users', and 'Settings'. The 'Participants' option is highlighted with a red box. The main area shows a table of participants with columns for 'Participant ID', 'Site', 'Progress', 'Last opened', 'Created on', 'Updated on', and 'Status'. A '+ New' button is highlighted with a red box in the top right corner of the main area.

Participant ID	Site	Progress	Last opened	Created on	Updated on	Status
110001	Castor Site	<div style="width: 100%; height: 5px; background-color: green;"></div>		18 Sep 2023	18 Sep 2023	Not set
110002	Castor Site	<div style="width: 50%; height: 5px; background-color: purple;"></div>		18 Sep 2023	18 Sep 2023	Not set
110003	Castor Site	<div style="width: 20%; height: 5px; background-color: blue;"></div>		18 Sep 2023	18 Sep 2023	Not set
110004	Castor Site	<div style="width: 10%; height: 5px; background-color: blue;"></div>		18 Sep 2023	18 Sep 2023	Not set

Then, select a user site and click 'Next'. The participant will be created and opened so a user can begin data entry.

Create New Participant ×

Site

Main Site
▼

Participant ID

110007

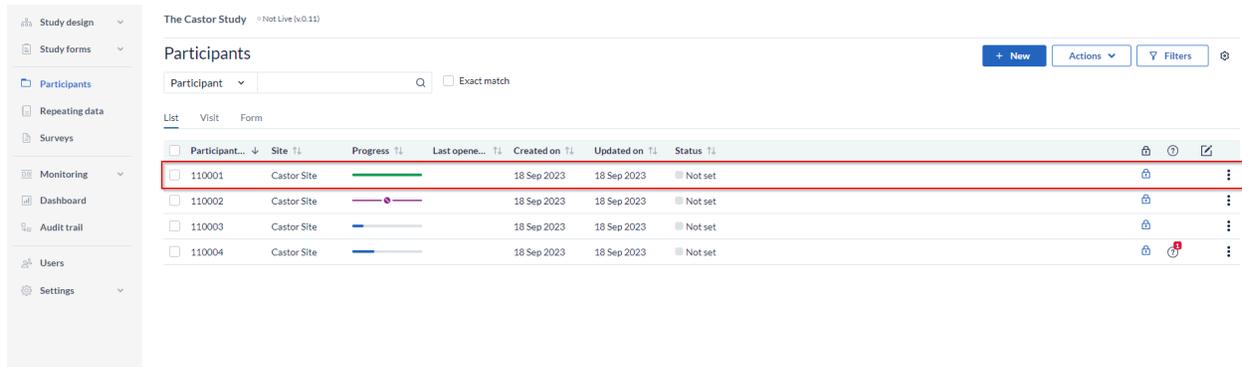
Participant email

Create another

Create

Cancel

To open a previously created participant, double click the row the participant is located on.

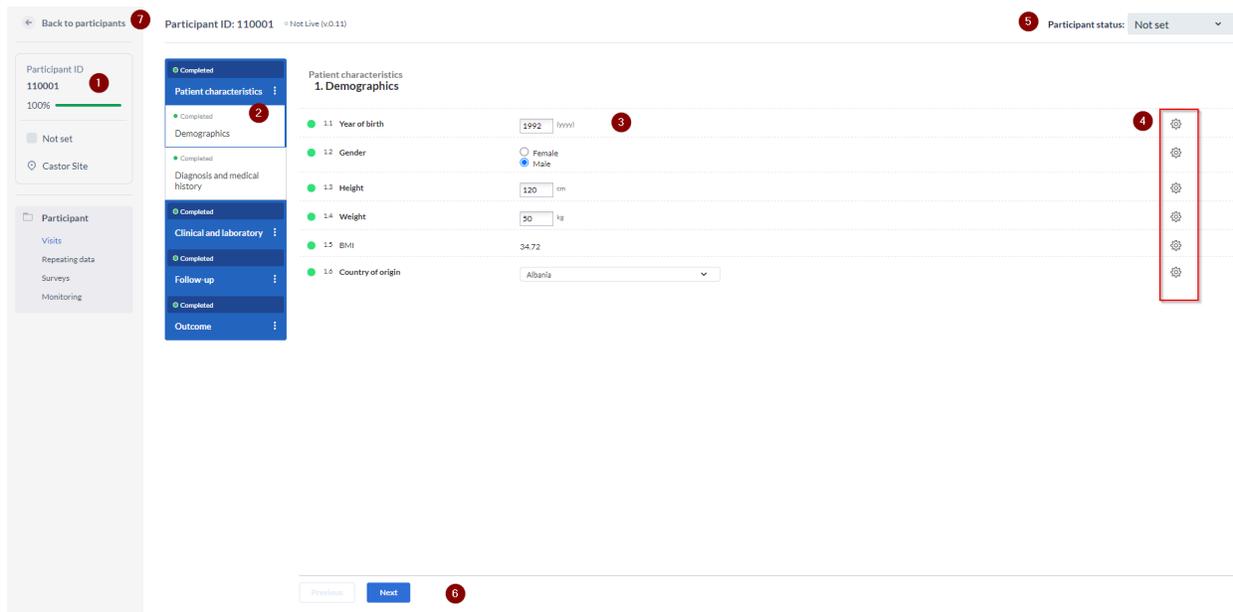


The screenshot shows the 'Participants' section of 'The Castor Study' (v0.11). A sidebar on the left contains navigation options: Study design, Study forms, Participants, Repeating data, Surveys, Monitoring, Dashboard, Audit trail, Users, and Settings. The main area displays a table of participants with columns for ID, Site, Progress, Last opened, Created on, Updated on, and Status. The first row (ID 110001) is highlighted with a red border. Below the table are buttons for '+ New', 'Actions', and 'Filters'.

Participant...	Site	Progress	Last opened	Created on	Updated on	Status			
110001	Castor Site	<div style="width: 100%;"></div>		18 Sep 2023	18 Sep 2023	Not set			
110002	Castor Site	<div style="width: 50%;"></div>		18 Sep 2023	18 Sep 2023	Not set			
110003	Castor Site	<div style="width: 20%;"></div>		18 Sep 2023	18 Sep 2023	Not set			
110004	Castor Site	<div style="width: 10%;"></div>		18 Sep 2023	18 Sep 2023	Not set			

5. Doing data entry

When a user opens a participant, the user will be taken to the main data entry view:



The screenshot displays the main data entry view for a participant with ID 110001. The interface includes a sidebar on the left with navigation options like 'Back to participants', 'Participant ID', 'Not set', and 'Castor Site'. The main content area shows a list of study forms, with 'Demographics' selected. The 'Demographics' form contains several fields: 'Year of birth' (1992), 'Gender' (Male), 'Height' (120 cm), 'Weight' (50 kg), 'BMI' (34.72), and 'Country of origin' (Albania). A cogwheel menu is visible next to the 'Year of birth' field. The participant status is 'Not set'. At the bottom, there are 'Previous' and 'Next' buttons.

It consists of the following elements:

1. Participant ID, progress of completion, and participant status.
2. An overview of the study forms (visits and forms of the study). Visits consist of forms and each form contains a set of questions. A user can click on the visit of interest in this panel to start entering the required data. Once a user answers a question in the form, a user will see a small wheel turning to the left of the field and this means the data is being saved.
3. Data is entered into questions, or fields within the study form (forms).
4. Each field is accompanied by a cogwheel menu, containing options for each participant. In this menu, a user can clear the data from a field, add a comment or mark the field as 'missing' data.
5. Dropdown field displaying participant status. Click on the field to select a different status.
6. Once a user has completed the first form, a user can navigate to the next form by clicking on 'Next'. To navigate to the previous form, click on the 'Previous' button. If the user is on the first or the last form, the buttons 'Previous' and 'Next' will be grayed out.

- To exit the participant and return to the participant list, click on the 'Back to participants' button.

5.1. Elements in each question

Depending on the type of question, a user will need to select one or more of the provided options, enter a number or date, upload a file etc.

Some fields will appear only under certain conditions. In the example below, question 2.1.1 is shown only because question 2.1 is answered with 'Other'.

5.1.1 Status icons

Shown to the left of each question is the status icon, which indicates whether the question has been answered (green) or not answered (orange). Where there is a problem with the provided answer, the icon will turn red and a red warning message will appear to provide more information about the problem.

- Green** The input is valid and the data is saved. For example, field 2.1 after the data has been entered and saved:

● 2.1 Are you 16 years of age or older?
 Yes
 No

- **Orange** Data is required and no input has been entered yet. For example, field 2.3:

● 2.3 Are you planning to reside in this area for the next 6 months? Yes No

- **Red** The input is invalid or does not comply with the inclusion criteria for the study. This is accompanied by a red warning message.

● 3.5.1 Error Date of consent is not entered 

 Date of consent is mandatory. Please provide the date.

- No icon** Data entry is not required and no input has been entered yet.

2.14.2 Pre-screen successful?

Not all values for this calculation are available (yet).

5.1.2 Additional options

To the right of each question there is a cogwheel with additional options:

The screenshot shows the Castor participant interface for participant ID 000004. The main content area displays a form titled '2. Diagnosis and medical history' with several questions. A red box highlights a cogwheel menu on the right side of the form, which contains the following options: 'Clear', 'User missing', 'Comments', 'History', 'Add query', and 'SDV field'.

- To clear the value already entered for a field, press 'Clear'.
- If data is not available for a question, tick the 'User missing' box. A window will open to ask the user to provide the reason why the data is missing:

The dialog box is titled "Choose reason for missing value for field State the area name." It contains the following options:

Choose reason:

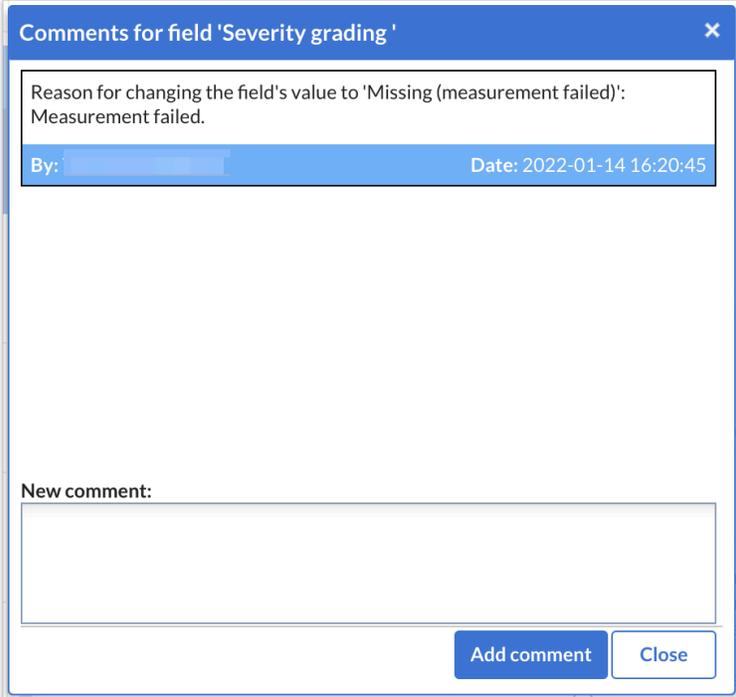
- Measurement failed (-95)
- Not applicable (-96)
- Not asked (-97)
- Asked but unknown (-98)
- Not done (-99)

Comment:

Buttons: **Save** **Cancel**

- Select the appropriate option and if necessary, add a comment. Click Save to store the option and return to the question list. The field marked as 'User Missing' will be grayed out in the list and marked as 'Completed'.

- If a user initially marked a field as missing but received information for this field at a later date, a user can click on the cogwheel again (even if the question is grayed out) and should unselect the option “User missing”.
- If a user wants to add a comment to a field, press “Comments”. Add a user text and press “Add comment”:



Comments for field 'Severity grading' ✕

Reason for changing the field's value to 'Missing (measurement failed)':
Measurement failed.

By: [blurred] Date: 2022-01-14 16:20:45

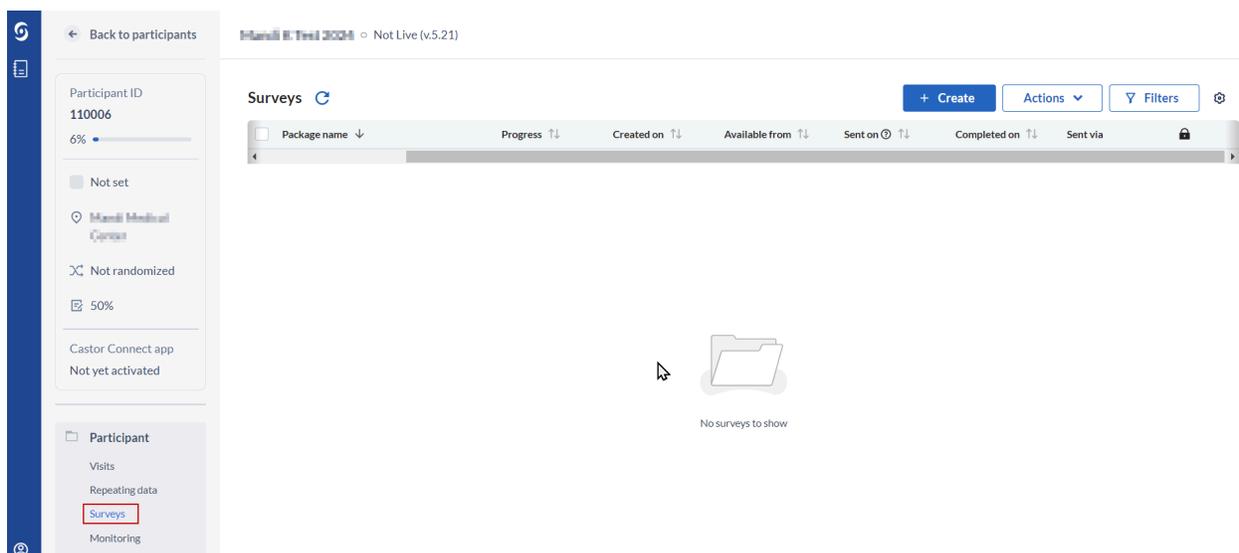
New comment:

Note: If GCP is enabled and reason for change has been entered, this information will be listed in the audit trail within the ‘participant results’ event.

5.2 Send an individual survey invitation

In Castor, surveys are sent out by creating survey invitations. In order to send a survey you must first have created a survey form and a survey package. Surveys are always sent in the form of survey packages, even if the package consists of only one survey.

To send a survey to a single participant, first enter the participant for that participant by navigating to the 'Participants' tab and double-clicking on the participant of interest (or clicking the eye icon). Within the participant, navigate to the Surveys tab and click on 'Create'.



A dialog window will appear - in here, you are required to select the survey package you want to send and other details of the invitation:

Create a survey package invitation



Survey Package

1 Select a Survey Package... 

Email

2 [Using provided email address. Click to view or edit.](#)

Parent

3 None 

Subject

4 *Subject of the invitation email*

5 Invitation message  [Formatting cheatsheet](#)

Cancel

Create

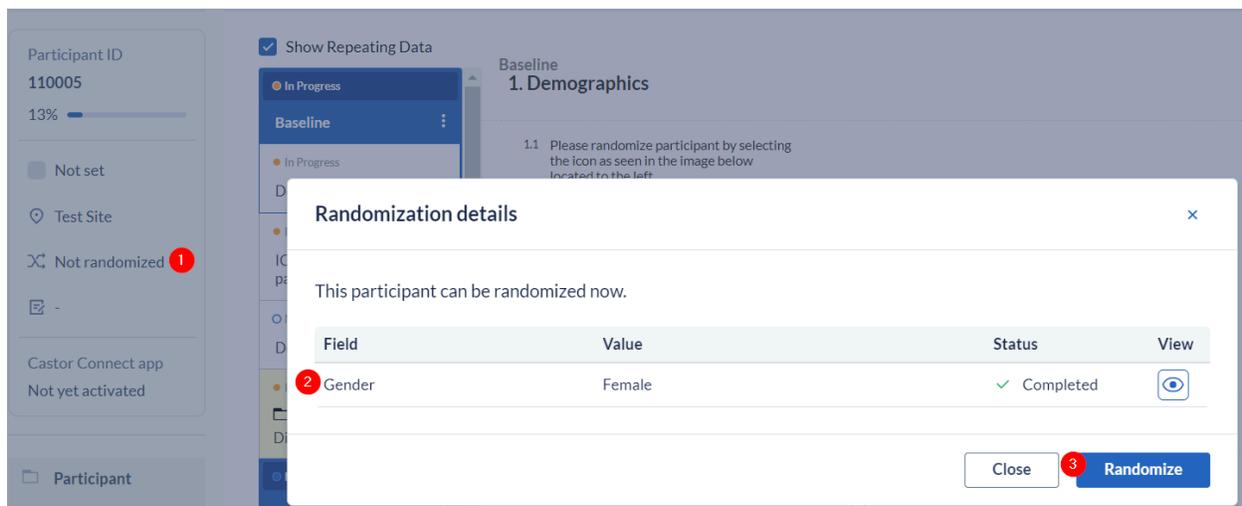
send the same package repetitively. You can learn more about survey schedules [here](#).

8. Click 'Save' to create the survey invitation, or click 'Cancel' to exit this dialog and discard the changes.

Please note that to enhance the security of the CDMS, we have introduced the reCAPTCHA functionality to all actions that include sending emails with custom text. Should any suspicious activities of the CDMS user be identified a reCAPTCHA challenge will be invoked.

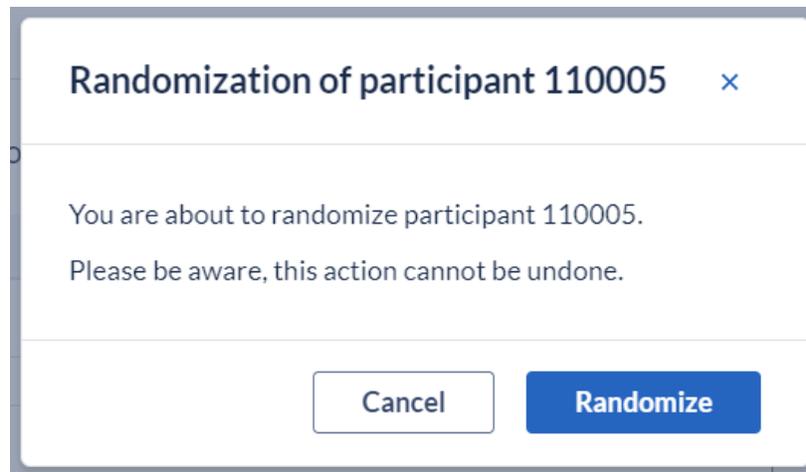
5.3 Randomize a participant

If a user needs to perform randomization in the study, the user can follow these forms to randomize a participant.

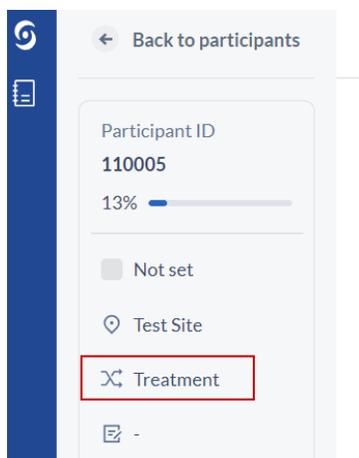


1. From the participant overview, select the 'Not Randomization' sub-tab.
2. A pop-up will be presented and will show if the stratification field, if applicable, as been completed. If not completed, selecting the eye icon under view will direct the user to the field to complete.
3. Select Randomize

A window will appear and ask to confirm the randomization, advising that randomization cannot be undone once confirmed.



Once randomized the participant panel will be updated to show the randomization. If the user is blinded from seeing randomization details this location will be listed as 'Hidden'



To see additional randomization details click on the randomization group from the participant panel.

Randomization details ×

Participant ID	110005
Randomization number	002
Randomization group	Treatment
Randomized by	[redacted]
Randomized on	22-03-2024 16:18:45

Close

To get back to the global Participants tab with an overview of all Participants, click the 'Back to participants' button:

← Back to participants

Participant ID: 110005
13%

Not set

Test Site

Treatment

Castor Connect app
Not yet activated

Participant

- Visits
- Repeating data
- Surveys
- Monitoring

Show Repeating Data

Baseline

- In Progress
- Demographics
- In Progress
- ICF, inclusie en patientkarakteristieken
- Not Started
- Depend test
- In Progress
- Repeating Data
- Dit is een test Report - 1
- Not Started
- Follow-up
- Not Started
- Test 3

Baseline

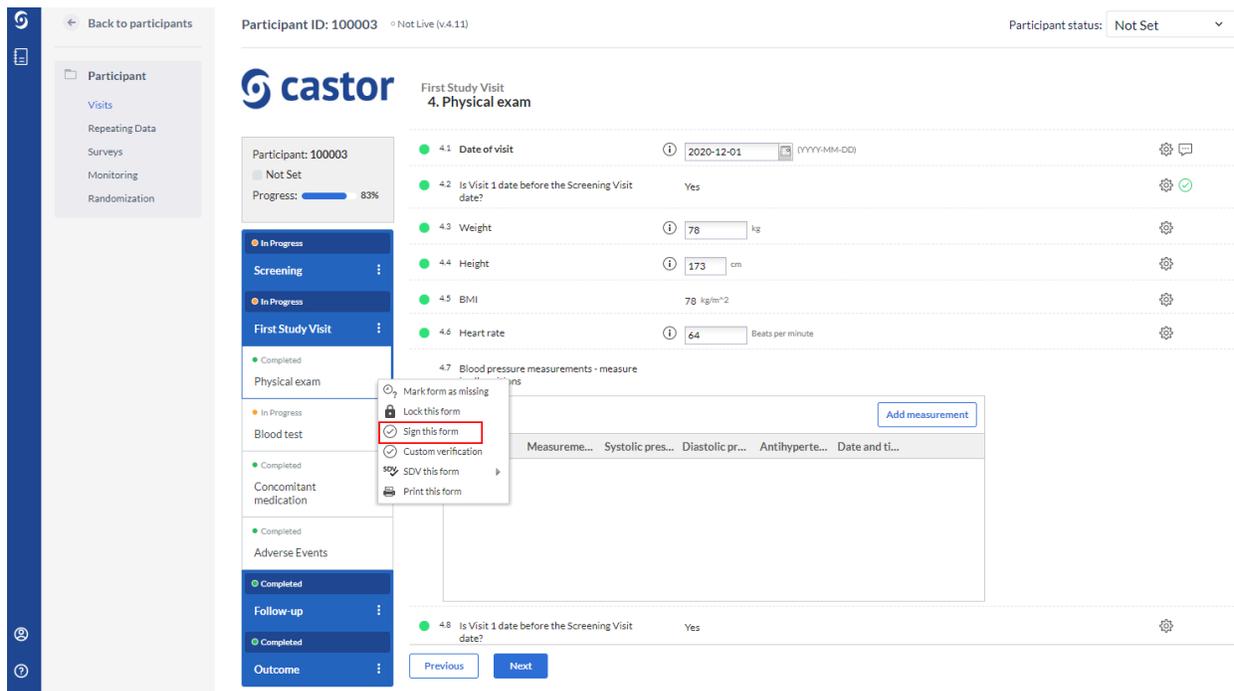
1. Demogr

- 1.1 Please r the icor located
- 1.2 Hide Vi
- 1.3 Depend
- 1.4 Gender

This will open the global 'Participants' tab with all participants.

5.4 Signing and locking a form

A user can electronically sign and/or lock individual visits and forms in Castor EDC. Users will need the appropriate rights in order to do so.



The screenshot displays the Castor EDC interface for a participant with ID 100003. The participant's status is 'Not Set'. The main content area shows a list of visits and forms, including 'First Study Visit', 'Physical exam', 'Blood test', 'Concomitant medication', 'Adverse Events', 'Follow-up', and 'Outcome'. A context menu is open over the 'Physical exam' form, showing options like 'Mark form as missing', 'Lock this form', 'Sign this form', 'Custom verification', 'SDV this form', and 'Print this form'. The 'Sign this form' option is highlighted with a red box. The 'Physical exam' form is currently in progress, with fields for 'Date of visit', 'Is Visit 1 date before the Screening Visit date?', 'Weight', 'Height', 'BMI', and 'Heart rate'. The 'Blood pressure measurements - measure' form is also visible, with fields for 'Systolic pres...', 'Diastolic pr...', 'Antihyperte...', and 'Date and ti...'. The 'Sign this form' option is highlighted with a red box.

1. Hover over the right side of a form or visit with the cursor. Click on the three dots that appear.
2. Click on 'Sign this visit' for visits or 'Sign this form' for forms.
3. The user will be prompted to enter his/her email address and password to confirm their identity.
4. Click 'Sign' to confirm and to sign the visit or form. If a user wishes to also lock this visit, the user will tick the 'Lock visit and child forms' checkbox.
5. The user will receive a confirmation that the audit trail has been updated. Upon signing the next visit/form, only the password will be required.

The visit or form will be updated with icons to reflect that it has been signed and/or locked:

Participant: 100003

Not Set

Progress: 83%

● In Progress	
Screening	⋮
● In Progress	✍️ 🔒
First Study Visit	⋮
● Completed	✍️ 🔒
Physical exam	
● In Progress	✍️ 🔒
Blood test	
● Completed	✍️ 🔒
Concomitant medication	
● Completed	✍️ 🔒
Adverse Events	

A banner will also be displayed at the top of the data entry screen, warning the user that the current form has been signed and/or locked including the date, time and user who applied signature or locked a visit or a form:

Team

1. Identification of the team

	This step was signed on [redacted]	Unsign
	This step was locked on [redacted]	Unlock

	1.1 Country Code	[redacted]	
	1.2 Team ID	[redacted]	
	1.3 Team ID (Country Code + ID)	[redacted]	
	1.4 Team Country	[redacted]	
	1.5 Location	[redacted]	
	1.6 Type of team	[redacted]	

If a user does not have view rights for all the forms, they are notified about the signature being applied only to forms for which viewing rights have been granted.

If a user has lock rights, a user can also choose to lock a visit or a form to prevent further data entry directly from the participant navigation.

Participant: 100003

Not Set

Progress: 83%

- In Progress
- Screening
- In Progress
- Demographics
- In Progress
- Diagnosis and medical history
- In Progress
- Study inclusion
- In Progress
- First Study Visit
- Completed
- Follow-up

	1.1 Screening Visit Date	2022-07-01 (YYYY-MM-DD)	
Please complete the inclusion criteria for this subject.			
	1.2 Year of birth	1986 (yyyy)	
	1.3 Gender	<input checked="" type="radio"/> Female <input type="radio"/> Male	
Not be changed as it was used for randomization of this record.			
		173 cm	
		78 kg	
		26.06	
	1.7 Country of origin	Netherlands	
	1.8 Screening Complete?	<input type="radio"/> Yes <input type="radio"/> No	

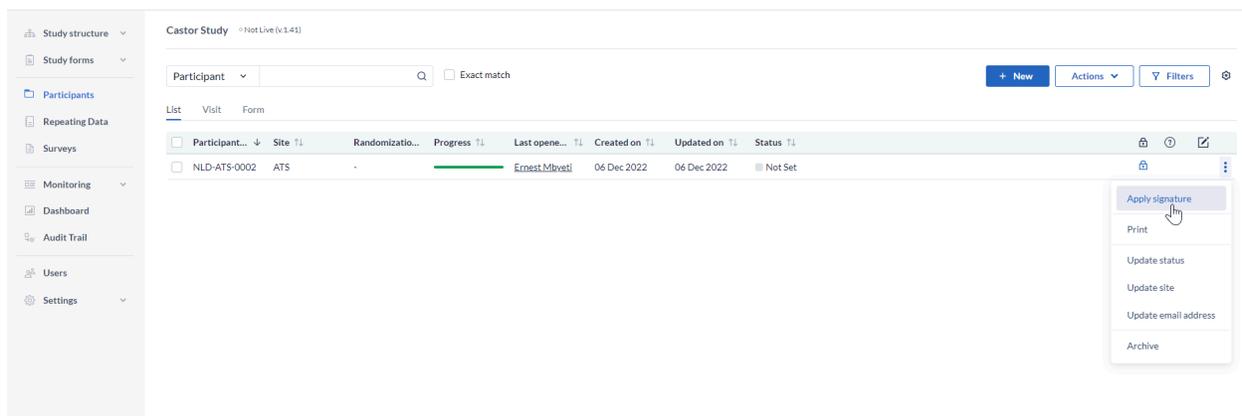
- Mark visit as missing
- Lock this visit
- Sign this visit
- Custom verification
- SDV visit & forms only (no fields)
- Print this visit
- Add a repeating data instance to this visit

1. Navigate to the right side of a form or visit and click on the three dots that appear.

2. Click on '(Un)Lock this visit' for visits or '(Un)Lock this form' for forms.

5.5 Signing the Participant

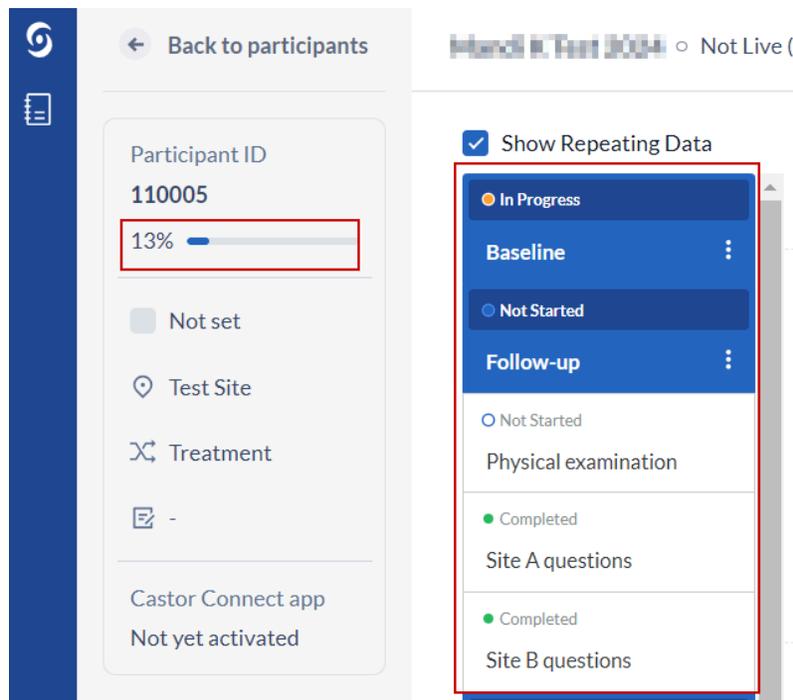
Castor CDMS offers the ability to seamlessly sign all forms of a selected participant at once, directly from the 'Participants overview' page.



You will be prompted to enter your credentials in order to sign the participant. Additionally you can also select to lock the participant upon signing, by ticking the 'Lock participant' box.

6. Participant progress

In the left panel in the data entry, a user can view the progress of the forms which will update as a user fills in the data.



A form can have three different completion stages:

- *Gray* Not started
- *Orange* In Progress
- *Green* Completed

The overall participant progress bar shown in the visit tab (blue) will also update automatically. Once all required fields have been completed, the icon will turn green.

7. Participant status

In the 'Participants' tab, a list is displayed showing all participants a user has created (see Section 6). The user will also see participants that have been created by other users at the site.

Castor EDC Study (v4.11)

Participant Exact match + New Actions Filters

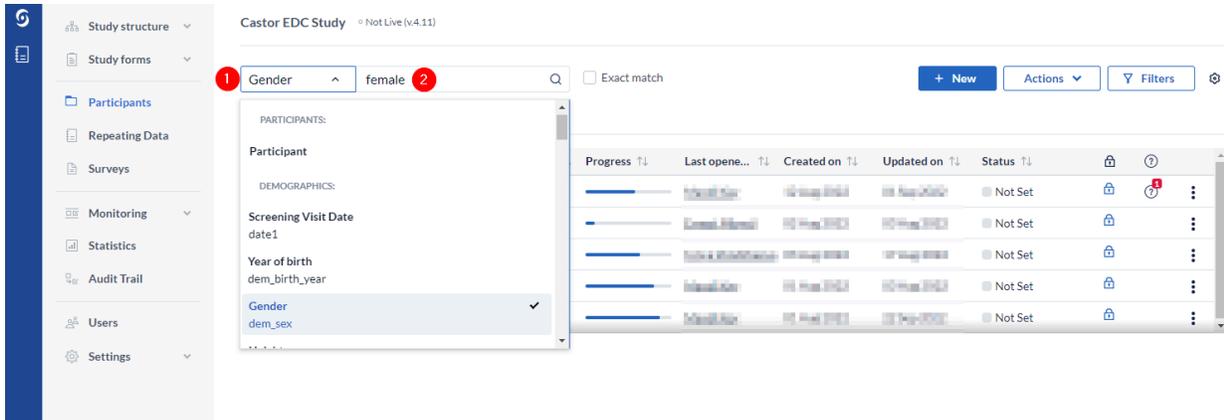
List Visit Form

Participant ID	Site	Randomiza...	Progress	Last opene...	Created on	Updated on	Status	Queries
000004	Test Site	A	<div style="width: 100%; height: 10px; background-color: #007bff;"></div>	Manual Kit	03-Aug-2020	03-Aug-2020	Not Set	1
000005	Test Site	B	<div style="width: 100%; height: 10px; background-color: #007bff;"></div>	Manual Kit	08-Aug-2020	08-Aug-2020	Not Set	0
000006	Test Site	A	<div style="width: 100%; height: 10px; background-color: #007bff;"></div>	Manual Kit	03-Aug-2020	03-Aug-2020	Adverse Event	1
000007	Test Site	B	<div style="width: 100%; height: 10px; background-color: #007bff;"></div>	Manual Kit	04-Aug-2020	17-Aug-2020	Not Set	0
100002	Test Site	A	<div style="width: 100%; height: 10px; background-color: #007bff;"></div>	Manual Kit	04-Aug-2020	04-Aug-2020	Not Set	0
100003	Test Site	B	<div style="width: 100%; height: 10px; background-color: #007bff;"></div>	Manual Kit	04-Aug-2020	03-Aug-2020	Not Set	0
110003	Test Site	-	<div style="width: 100%; height: 10px; background-color: #6f42c1; border: 1px solid #000;"></div>	Manual Kit	11-Aug-2020	11-Aug-2020	Not Set	0
110006	Main Site	-	<div style="width: 100%; height: 10px; background-color: #007bff;"></div>	Manual Kit	04-Aug-2020	04-Aug-2020	Not Set	0

1. In the 'Participants' tab, a search box is available, in which you can search for a particular participant ID. More information on the search is provided in section 7.1.
2. It is possible to change the view mode to show the progress of the participants by visits or forms (see section 7.2).
3. Progress: This column will show you the status of completion for each participant. The same color scheme as for the forms applies (see section 6). The purple bar with a pencil icon indicates that an exclusion validation has been triggered for this participant. You can double click on any participant to directly access it.
4. Queries: displays the number of queries created for a participant.
5. By default, all participants are shown, however you can use the 'Filters' button to filter the participants based on different parameters.

7.1. Search for data

A user can use the search bar to find participants that contain certain data, for example if a user wants to find the patients with a certain age at onset.

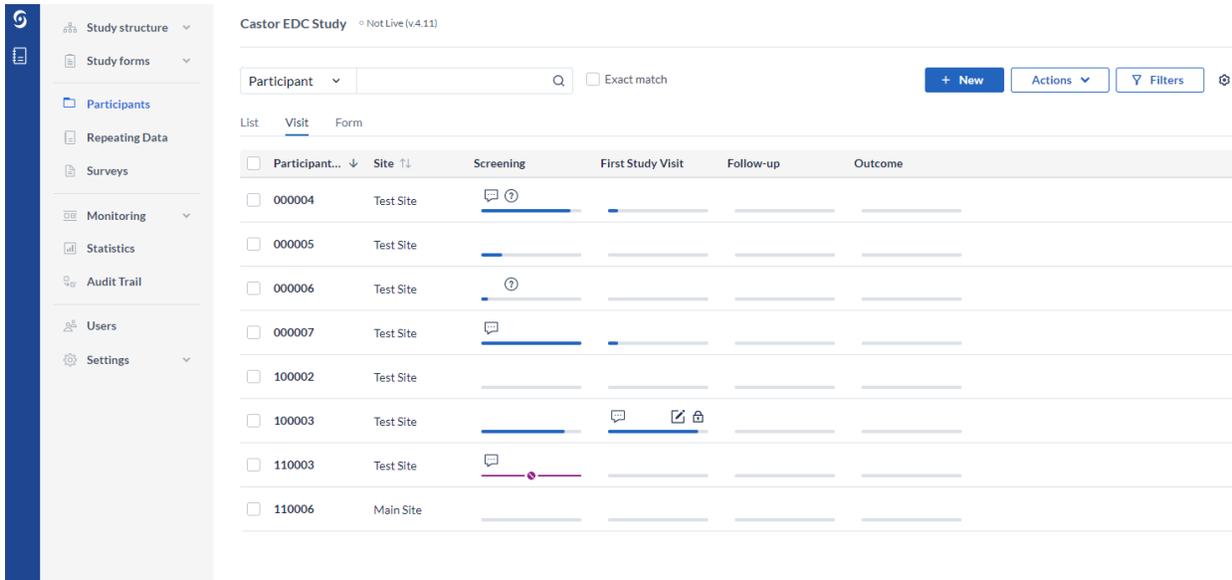


The screenshot shows the Castor EDC Study interface. On the left is a navigation menu with options like Study structure, Study forms, Participants, Repeating Data, Surveys, Monitoring, Statistics, Audit Trail, Users, and Settings. The main area displays a search bar with 'Gender' selected (indicated by a red circle '1') and 'female' entered (indicated by a red circle '2'). Below the search bar is a dropdown menu showing 'Gender' and 'dem_sex' as options. To the right, a table of participants is visible with columns for Progress, Last opened, Created on, Updated on, and Status. The table shows several rows of participant data, with the first row having a status of 'Not Set'.

1. Click on the arrow in the right search box and find the field (question) of interest. In this example 'Gender' field is selected.
2. Enter the value of interest in the left search box (in this example female) and all matching participants will be displayed.

7.2. Visit/Form view

By default, the 'Participants' tab displays all participants in the "List" view. You can change the view mode to either Visit view or Form view.



Participant...	Site	Screening	First Study Visit	Follow-up	Outcome
000004	Test Site	Progress bar with icons	Progress bar	Progress bar	Progress bar
000005	Test Site	Progress bar	Progress bar	Progress bar	Progress bar
000006	Test Site	Progress bar with icon	Progress bar	Progress bar	Progress bar
000007	Test Site	Progress bar with icon	Progress bar	Progress bar	Progress bar
100002	Test Site	Progress bar	Progress bar	Progress bar	Progress bar
100003	Test Site	Progress bar	Progress bar with icons	Progress bar	Progress bar
110003	Test Site	Progress bar with icon	Progress bar	Progress bar	Progress bar
110006	Main Site	Progress bar	Progress bar	Progress bar	Progress bar

This will show you the status of completion of each visit or form for each participant by clicking on "Visit" or "Form". The same color scheme as for the forms applies (see section 6). You can double click on any visit or form to directly access it.

When in the "Visit" or "Form" view on the participants tab you can also sort the "Participant" and "Site" columns in ascending or descending order.

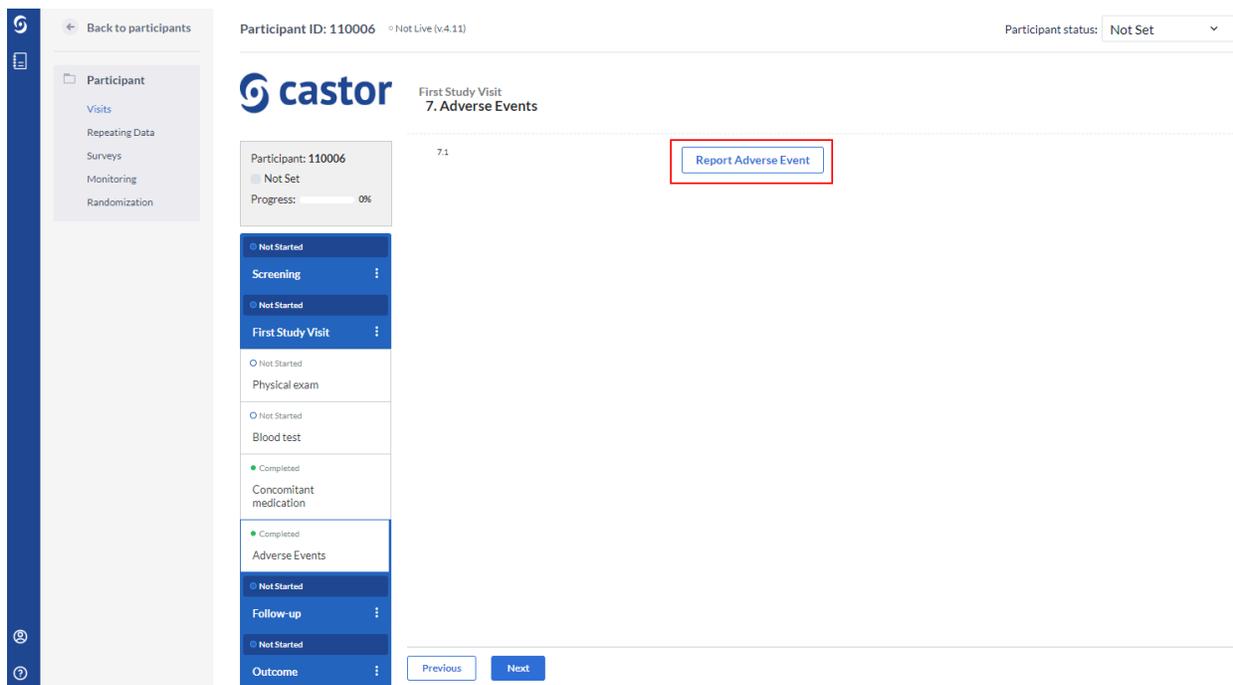
8. Creating Repeating Data

Repeating data can be used to register items such as adverse events (AE), vital signs, and/or any other data which is not part of the main study protocol, for instance any unexpected hospital visits or emergency surgical procedure.

8.1. Adding a repeating data instance

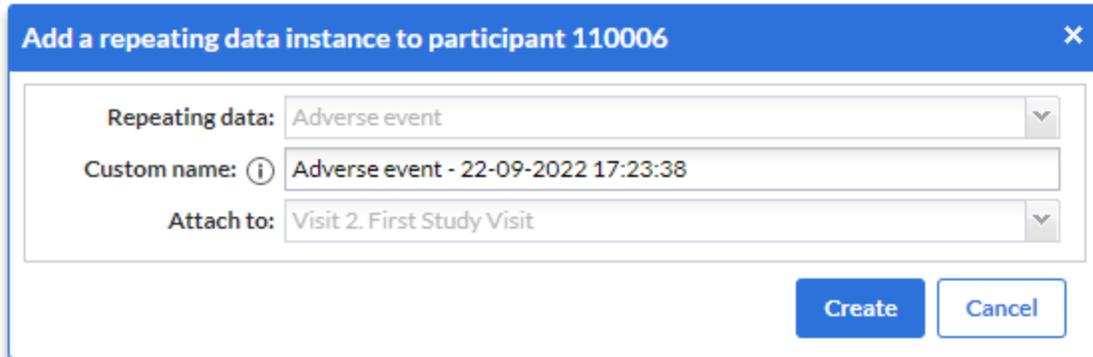
There are two ways to add a repeating data instance to a participant: 1) via an Add Repeating data button directly in a form, or 2) via the Repeating data tab.

To add a repeating data via the repeating data button, navigate to the form and click on the 'Add repeating data button' in the relevant form. Please note that the repeating data button might have a different name in your study:



The screenshot displays the Castor web interface for a participant with ID 110006. The interface includes a sidebar with navigation options like 'Participant', 'Visits', 'Repeating Data', 'Surveys', 'Monitoring', and 'Randomization'. The main content area shows the participant's status as 'Not Set' and a progress bar at 0%. A list of study visits is shown, with '7. Adverse Events' highlighted in blue. A red box highlights a 'Report Adverse Event' button. At the bottom, there are 'Previous' and 'Next' navigation buttons.

The following dialog window will appear:



1. Repeating Data: this field contains the repeating data type which is pre-filled
2. Custom name: Enter a custom name for the repeating data, this is how the repeating data will be displayed in the study and exports. In some cases, the custom name won't be editable, as the study admin can disable the option to adjust the repeating data name.
3. Attach to: this is a visit to which a repeating data will be linked by default. When creating a repeating data using the 'Add Repeating Data' button, this field will be pre-filled.
4. Click the 'Create' button to add the new repeating data.
5. Proceed with the data entry for the repeating data.

Participant ID: 110006 Not Live (v4.11) Participant status: Not Set

Back to participants

Participant

- Visits
- Repeating Data
- Surveys
- Monitoring
- Randomization

Participant: 110006

Not Set

Progress: 0%

● In Progress

Adverse event - 22-09-2022 17:23:38

● In Progress

Event details

Event details

● 4 Severity

- Mild
- Moderate
- Severe
- Life-threatening

● 5 Relationship to intervention

- Not related
- Unlikely related
- Possibly related
- Probably related
- Definitely related

● 6 Action taken regarding intervention

- None
- Dose modification
- Medical intervention
- Hospitalization
- Intervention discontinued
- Other

● 7 Outcome of AE

- Resolved
- Recovered with major sequelae
- Recovered with minor sequelae
- Ongoing / continuing treatment
- Condition worsening
- Death
- Unknown

● 8 Expected?

- Yes
- No

Close repeating data
All repeating data
Add another

Previous
Next

6. Once the data for a repeating data is complete, click on the 'Close repeating data' to return to the main study form.

The added repeating data will be linked to the visit where this repeating data was created and will be visible in the form navigator if the option to display repeating data is enabled in the Settings tab:

The screenshot shows the Castor web application interface for a participant with ID 110006. The participant's status is 'Not Set'. The current visit is '7. Adverse Events'. The interface includes a sidebar with navigation options: Participant, Visits, Repeating Data, Surveys, Monitoring, and Randomization. The main content area displays a progress bar for the participant, a 'Report Adverse Event' button, and a list of activities. The activities listed are: Not Started (Screening), Not Started (First Study Visit), Not Started (Physical exam), Not Started (Blood test), Completed (Concomitant medication), Completed (Adverse Events), and In Progress (Repeating Data). The 'Repeating Data' activity is highlighted with a red box and shows an 'Adverse event - 22-09-2022 17:23:38'. At the bottom of the activity list, there are 'Previous' and 'Next' buttons.

8.2. Viewing repeating data

It is possible to view the repeating data instances which are attached to the participant by using the 'Repeating data' tab:

Participant ID: 000005 Not Live (v.4.11) Participant status: Not Set

castor All repeating data

Participant: 000005
 Not Set
 Progress: 11%

Filter by Repeating Data type: Filter by Repeating Data: Filter by status:

Filter by name: Filter by visit:

Status	Repeating Data	Name	Type	Created on	Created by	Assigned to
●	Medication	Medication - 03-08-2...	Repeated measure	2022-08-03 15:49:27	Marcela Reis	First Study Visit
●	Medication	Medication - 03-08-2...	Repeated measure	2022-08-03 15:50:55	Marcela Reis	First Study Visit
○	Medication	Medication - 03-08-2...	Repeated measure	2022-08-03 15:51:19	Marcela Reis	First Study Visit

Page 1 of 1 | Show 25 | Repeating Data 1 - 3 of 3

Repeating Data

Previous Next

1. Opening the participant and navigating to the 'Repeating Data' tab will display the repeating data overview.
2. A user can filter by repeating data type, repeating data type, repeating data name, or by the visit to which a repeating data instance is linked.
3. The list of repeating data instances linked to the selected participant. A status indicator allows a user to see the completion status of the repeating data instance.

9. Repeated Measures

In main data entry view, the repeated measure field looks like a grid, see below:

The screenshot shows the Castor data entry interface for a participant with ID 100003. The main content area displays a '2.4 Record all relevant current medications' field. This field contains a table with the following data:

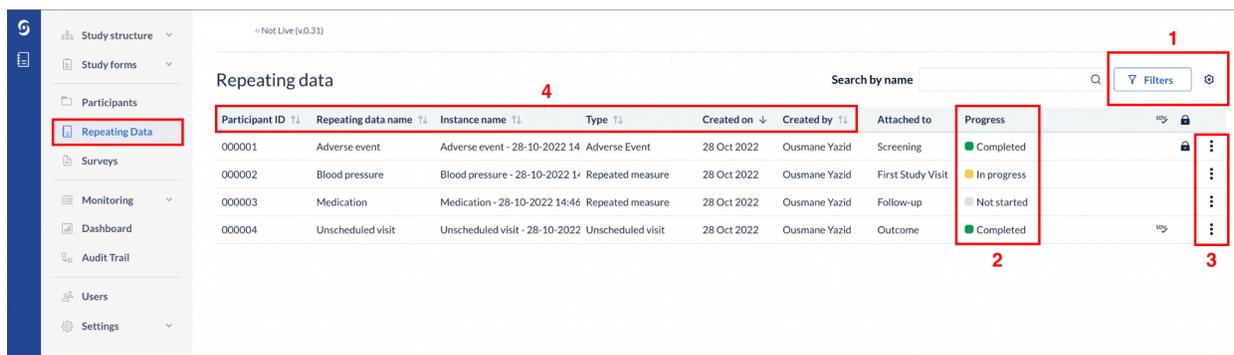
Created on	Name	Start date	Stop date	Dose	Units	
2022-09-22	Thiazide diu...	01-09-2022	30-09-2022	10	mg/day	
2022-09-22	ACE inhibito...	01-09-2021	30-09-2022	25	mg/day	

An 'Add measurement' button is located at the top right of the table. The interface also shows a sidebar with navigation options and a top navigation bar with 'Back to participants' and 'Participant ID: 100003'.

1. By pressing a button 'Add measurement', measurements are easily added to the form and will be shown in the form of a grid, representing each measurement as a new row and each field that is part of the repeated measure as a separate column.
2. Each measurement will be saved as a new repeating data and will appear in the 'Repeating Data' tab and will be attached to the visit (or repeating data) where the repeated measure field is located.

10. The global Repeating Data tab

In the 'Repeating Data' tab, an overview of all the repeating data instances within the study are shown. Using the 'Search by name' option, you can search for repeating data instances by entering the instance name (for example, 'Adverse event -1'). A user can only see repeating data instances from participants that belong to a site for which they have "View" rights:



Participant ID	Repeating data name	Instance name	Type	Created on	Created by	Attached to	Progress
000001	Adverse event	Adverse event - 28-10-2022 14	Adverse Event	28 Oct 2022	Ousmane Yazid	Screening	Completed
000002	Blood pressure	Blood pressure - 28-10-2022 14	Repeated measure	28 Oct 2022	Ousmane Yazid	First Study Visit	In progress
000003	Medication	Medication - 28-10-2022 14:46	Repeated measure	28 Oct 2022	Ousmane Yazid	Follow-up	Not started
000004	Unscheduled visit	Unscheduled visit - 28-10-2022	Unscheduled visit	28 Oct 2022	Ousmane Yazid	Outcome	Completed

1. A user can make use of the filters in the top panel. For example, a user can filter on site, type, status, repeating data, and on visit to which a repeating data instance is linked to. A user can also click on the cogwheel next to a column to display an additional menu for repeating data columns. Here, a user can select whether to sort on ascending or descending and a user can also deselect the columns that the user doesn't want to see in a user overview.
2. An overview of all repeating data instances progress is shown, with the completion level and other details (Not started, In Progress, Completed).
3. Context menu which allows to archive, unarchive, delete or print a Repeating data instance depending on the user rights and the current study status.
4. The column label becomes underlined when the user clicks once to apply ascending or descending order. Upon selecting the column header the first time the order will appear as ascending, if a user clicks once again, the order will be descending. For example, a user can sort by the date of creation of the repeating data instance by clicking on the 'Created on'.

11. Responding to queries

If a monitor has placed a query on a participant, this query icon appears on the participant list in the Queries column.

Castor EDC Study - Not Live (v.4.11)

Participant ID: 000004, 000005, 000006, 000007, 100002, 100003, 110003, 110006

Participant ID	Site	Randomiza...	Progress	Last opene...	Created on	Updated on	Status	Queries
000004	Test Site	A	Progress bar	Completed	13 Aug 2022	24 Nov 2022	Not Set	Query icon
000005	Test Site	B	Progress bar	Completed	09 Aug 2022	09 Aug 2022	Not Set	
000006	Test Site	A	Progress bar	Completed	04 Aug 2022	04 Aug 2022	Adverse Event	Query icon
000007	Test Site	B	Progress bar	Completed	09 Aug 2022	17 Aug 2022	Not Set	
100002	Test Site	A	Progress bar	Completed	08 Aug 2022	08 Aug 2022	Not Set	
100003	Test Site	B	Progress bar	Completed	04 Aug 2022	22 Nov 2022	Not Set	
110003	Test Site	-	Progress bar	Completed	13 Aug 2022	13 Aug 2022	Not Set	
110006	Main Site	-	Progress bar	Completed	04 Aug 2022	04 Aug 2022	Not Set	

11.1. Participant Monitoring tab

Users with only data-entry rights can see all queries for a participant on the participant's 'Monitoring' tab.

Participant ID: 000005 - Not Live (v.5.11)

Participant status: Not Set

Monitoring

Queries | Validations | Dropped Verifications

Site	Created on	Created By	Last updated by	Closed by	Location	First Remark	Last Remark	Status	Query age	Time to resol...	View
Test Institute	23 Nov 2022				Visit Inclusion and rando...	The field is empty, please add dat...	The field is empty, please add dat...	New	0	0	View
Test Institute	23 Nov 2022				Visit Inclusion and rando...	The field is empty, please add dat...	The field is empty, please add dat...	New	0	0	View
Test Institute	23 Nov 2022				Visit Inclusion and rando...	The field is empty, please add dat...	The field is empty, please add dat...	New	0	0	View

1. The participant's monitoring overview opens on the 'Queries' tab.
2. Queries can be filtered by the query status, location, created/updated by, days in current status, and days since opened using the 'Filters' button.
3. Clicking on the eye icon in the 'View' column, will take a user to the field where the query was placed.

11.2. Queries in the data entry view

In the data entry view, queries are shown as a circle and the status is indicated by the sign within it as well as the color.

New: This query has not been reviewed.

Open: This query was viewed but a change of status or comment was not made.

Unconfirmed: The user does not agree with the monitor.



Confirmed: The user agrees with the monitor and will try to resolve the issue.



Resolved: The user has changed the value and indicates the issue is resolved, for example the user has reacted to a query and left a comment.



Closed: The monitor indicates the issue is resolved and marks the query as closed. Only users with query rights can close a query.



Once the user has accessed the participant, a user will see the status icon next to the queried field. To respond to a query, a user needs to click on the query icon next to a field.

← Back to participants

Participant

- Visits
- Repeating Data
- Surveys
- Monitoring
- Randomization

In Progress

- Screening
- Demographics
- Diagnosis and medical history
- Study inclusion
- First Study Visit
- Follow-up
- Outcome

Participant ID: 000004 Not Live (v4.11)

Participant status: Not Set



Screening

2. Diagnosis and medical history

Participant: 000004
Not Set
Progress: 58%
 Show Repeating Data

2.1 Primary renal diagnosis	Other	
2.1.1 What other diagnosis		
2.2 History of cardiovascular disease	<input checked="" type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown	
2.3 History of diabetes	<input type="radio"/> No <input checked="" type="radio"/> Yes <input type="radio"/> Unknown	
2.4 History of smoking	<input type="radio"/> No <input checked="" type="radio"/> Yes, former <input type="radio"/> Yes, current	
2.4.1 Year smoking started	<input type="text"/> (yyyy)	
2.4.2 Number of packs per day	<input type="text"/> packs per day	
2.5 Family history of disease	<input checked="" type="checkbox"/> Renal disease <input type="checkbox"/> Deafness <input type="checkbox"/> (Cardi)myopathy <input type="checkbox"/> Encephalopathy <input type="checkbox"/> Diabetes Mellitus <input type="checkbox"/> Hypertension/Cardiovascular disease <input type="checkbox"/> Thrombosis <input type="checkbox"/> Malignancy	
2.6 Record all relevant current medications	<input type="text"/>	<input type="button" value="Add measurement"/>

A dialog window will appear:

Queries for field What other diagnosis
✕

Select a query

Query 1
▼

Change status

Resolved
▼

Remark

Data has been entered

Added by

Richard Ray

Date

2022-04-22 10:00:00

Remark

Data has not been entered.

Save changes

Cancel

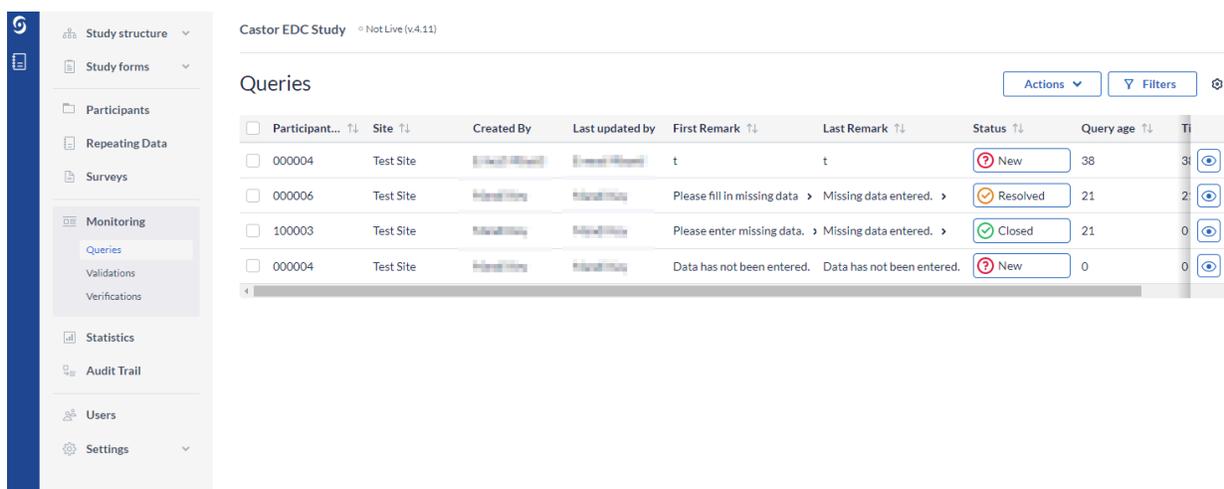
1. In case of multiple queries, a user can select a query to which a user needs to respond.
2. A user can change the status of a query by choosing from the list in the dropdown box.
3. The Remark field allows a user to enter comments on the query.
4. Once a user selects 'Save changes' the status and comment will be saved.
5. All saved remarks are added to the list.

12. The global Monitoring tab

The 'Monitoring' tab gives an overview of all the queries, data validations and dropped verifications in a study. Only users with edit rights can view the 'Monitoring' tab, which contains overviews of queries, data validations and verifications.

12.1. Queries

The 'Monitoring' tab contains three subtabs. Open the 'Queries' tab to access the queries overview:



Participant...	Site	Created By	Last updated by	First Remark	Last Remark	Status	Query age	TI
000004	Test Site	[User]	[User]	t	t	New	38	3
000006	Test Site	[User]	[User]	Please fill in missing data	Missing data entered.	Resolved	21	2
100003	Test Site	[User]	[User]	Please enter missing data.	Missing data entered.	Closed	21	0
000004	Test Site	[User]	[User]	Data has not been entered.	Data has not been entered.	New	0	0

1. The user can click on the 'Filters' button to filter by site, location, status (open, resolved, closed or all [Monitoring queries](#)), and other parameters.
2. An overview of all queries in the study (unless a user filtered the results) are displayed here.
3. Click on the eye icon to open a form and view the field which contains the query.

By clicking on the status, the queries can be sorted based on the associated participant ID or by creation date. Clicking the status icon next to a query opens a window, in which all comments related to the query can be reviewed. It is also possible to add a remark and change the status of the query, if necessary.

Queries for field Was a Covid test performed? ✕

Status: 🔔 New Change to: ▼

Remarks

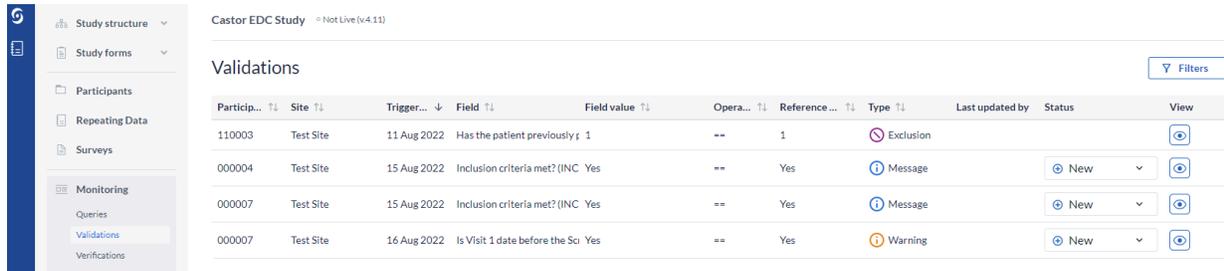
Please confirm the missing data

By ██████████ Date 2022-01-11 21:54:50

New Remark

12.2. Validations

The 'Validations' sub-tab displays all active validation fields in study, repeating data instances, or surveys of the type Exclusion, Warning, and Message.



Particip...	Site	Trigger...	Field	Field value	Opera...	Reference ...	Type	Last updated by	Status	View
110003	Test Site	11 Aug 2022	Has the patient previously	1	--	1	Exclusion			
000004	Test Site	15 Aug 2022	Inclusion criteria met?(INC	Yes	--	Yes	Message		New	
000007	Test Site	15 Aug 2022	Inclusion criteria met?(INC	Yes	--	Yes	Message		New	
000007	Test Site	16 Aug 2022	Is Visit 1 date before the So	Yes	--	Yes	Warning		New	

1. A user can filter validations by type (Exclusion, Warning, Message), by site to show participants with validations which belong to a particular site, by data entry type and period when the validations were triggered using the 'Filters' button.
2. An overview of all participants is given with the details of the validation.
3. The operator represents how the field value and the reference value are compared, depending on the setup of the validation message. There are several operators: greater than, greater than or equal to, equal to, smaller than, smaller than or equal to, not. The 'Reference value' represents the value that is used in comparison to the value that was entered in a field, as defined during the validation setup.
4. It is possible to manage the field's validation using the status feature in the Monitoring tab. You are able to select the following status: New, Reviewed and Completed for the following validation message types: Message, Warning. In this way, it is possible to see the remaining active validations that still need to be evaluated and resolved. Once marked as 'resolved', the validation is not shown any longer in the Validations overviews AND in Data entry. But as soon as a user changes the status from 'resolved' to 'reviewed' or 'new', the validation is shown again in data entry.
5. To open the participant and jump to the form with the validation, click on the eye icon in the column 'View'.

12.3. Verifications

This sub-tab displays all *pending*, *performed*, and *dropped* verifications in the study or in repeating data instances:

Example of Dropped Verification

Castor EDC Study Not Live (v4.11)

Verifications

Pending SDV | **Performed** | Dropped

Participant...	Site	Created on	Dropped on	Dropped by	Location	View
000004	Test Site	15 Aug 2022	15 Aug 2022	[User]	Visit Screening	[View]
000004	Test Site	01 Sep 2022	01 Sep 2022	[User]	Visit Screening	[View]

Example of Pending Verification

Castor EDC Study Not Live (v4.11)

Verifications

Pending SDV | **Performed** | Dropped

Field	Participant...	Site	Last updated...	Location	View
Units (med_units)	100003	Test Site	22 Sep 2022	Repeating data Medication - 22...	[View]
Dose (med_dose)	100003	Test Site	22 Sep 2022	Repeating data Medication - 22...	[View]
Stop date (med_stop)	100003	Test Site	22 Sep 2022	Repeating data Medication - 22...	[View]
Start date (med_start)	100003	Test Site	22 Sep 2022	Repeating data Medication - 22...	[View]
Name (med_name)	100003	Test Site	22 Sep 2022	Repeating data Medication - 22...	[View]
Dose (med_dose)	100003	Test Site	22 Sep 2022	Repeating data Medication - 22...	[View]
Units (med_units)	100003	Test Site	22 Sep 2022	Repeating data Medication - 22...	[View]

Example of Performed Verification

Castor EDC Study Not Live (v4.11)

Verifications

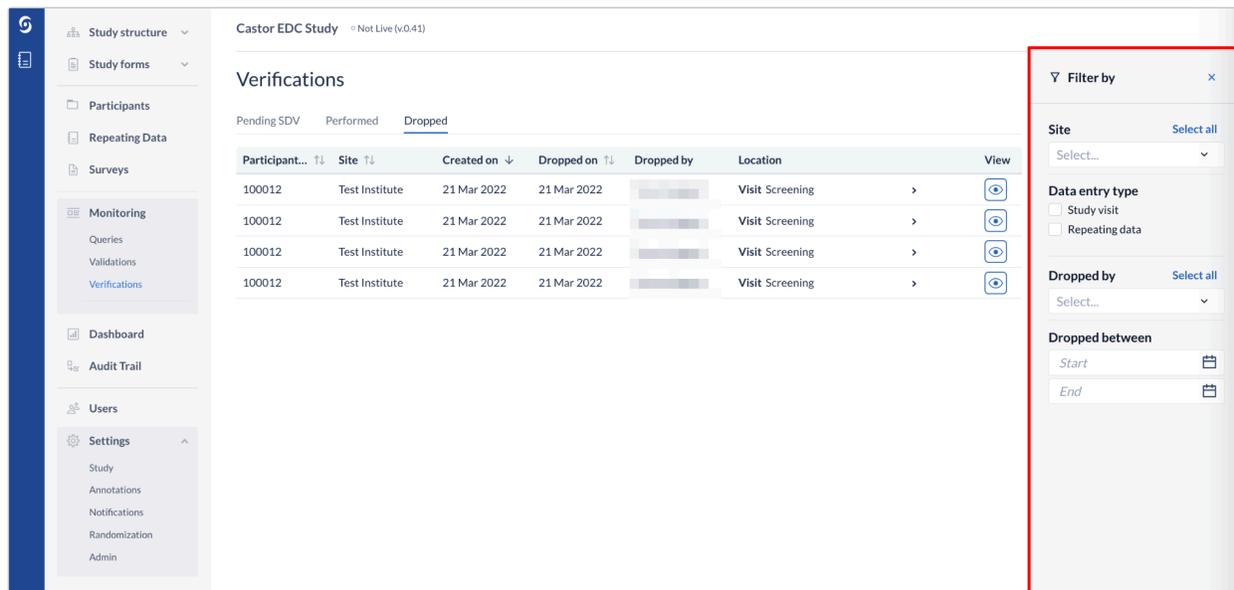
Pending SDV | **Performed** | Dropped

Participant...	Site	Type	Created on	Created by	Location	View
000004	Test Site	SDV	15 Aug 2022	[User]	Visit First Study Visit	[View]
000004	Test Site	SDV	15 Aug 2022	[User]	Visit First Study Visit	[View]
000004	Test Site	SDV	15 Aug 2022	[User]	Visit Screening	[View]
000004	Test Site	SDV	15 Aug 2022	[User]	Visit Screening	[View]
000004	Test Site	SDV	15 Aug 2022	[User]	Visit Screening	[View]
000004	Test Site	SDV	15 Aug 2022	[User]	Visit Screening	[View]

For pending verifications only verifications added to required fields will be shown.

Using the 'Filters' button on the dropped tab, a user can choose to show dropped verifications only for study or repeating data instances. A user will also be able to filter by a selected user who dropped the verification, by site, and period when the verifications were dropped.

Using the 'Filters' button on the Pending SDV tab, a user can show pending verifications only for study or repeating data instances, by location (e.g. Visits, form, or repeating data), and last update date range.



The screenshot shows the 'Verifications' section in the Castor EDC Study interface. The 'Dropped' tab is selected, displaying a table with the following data:

Participant...	Site	Created on	Dropped on	Dropped by	Location	View
100012	Test Institute	21 Mar 2022	21 Mar 2022	[Redacted]	Visit Screening	[Eye icon]
100012	Test Institute	21 Mar 2022	21 Mar 2022	[Redacted]	Visit Screening	[Eye icon]
100012	Test Institute	21 Mar 2022	21 Mar 2022	[Redacted]	Visit Screening	[Eye icon]
100012	Test Institute	21 Mar 2022	21 Mar 2022	[Redacted]	Visit Screening	[Eye icon]

The 'Filter by' sidebar on the right includes the following options:

- Site:** Select all, Select...
- Data entry type:** Study visit, Repeating data
- Dropped by:** Select all, Select...
- Dropped between:** Start, End

Using the 'Filters' button on the Performed tab, a user can filter by site, data entry type (Study Visit or Repeating data), type, created by, and created between dates.

To open the participant and directly view the form where the verification is located, click on the eye icon in the column 'View'.

To see *all active* verifications, go to the '[Participants](#)' tab and use the "progress by form" view mode. Verified forms can be identified by a green checkmark.

The 'Monitoring' tab will also appear in the participant view and will include the same sub-tabs, but these will contain only the information (queries, validations, and verifications) associated with the selected participant.

13. Exporting data

Data can be exported in SPSS, SAS, Excel, and CSV formats.

Apart from the study data, the export file will contain a list of all the variables created in the study and a list of all the option groups with the option group names and values.

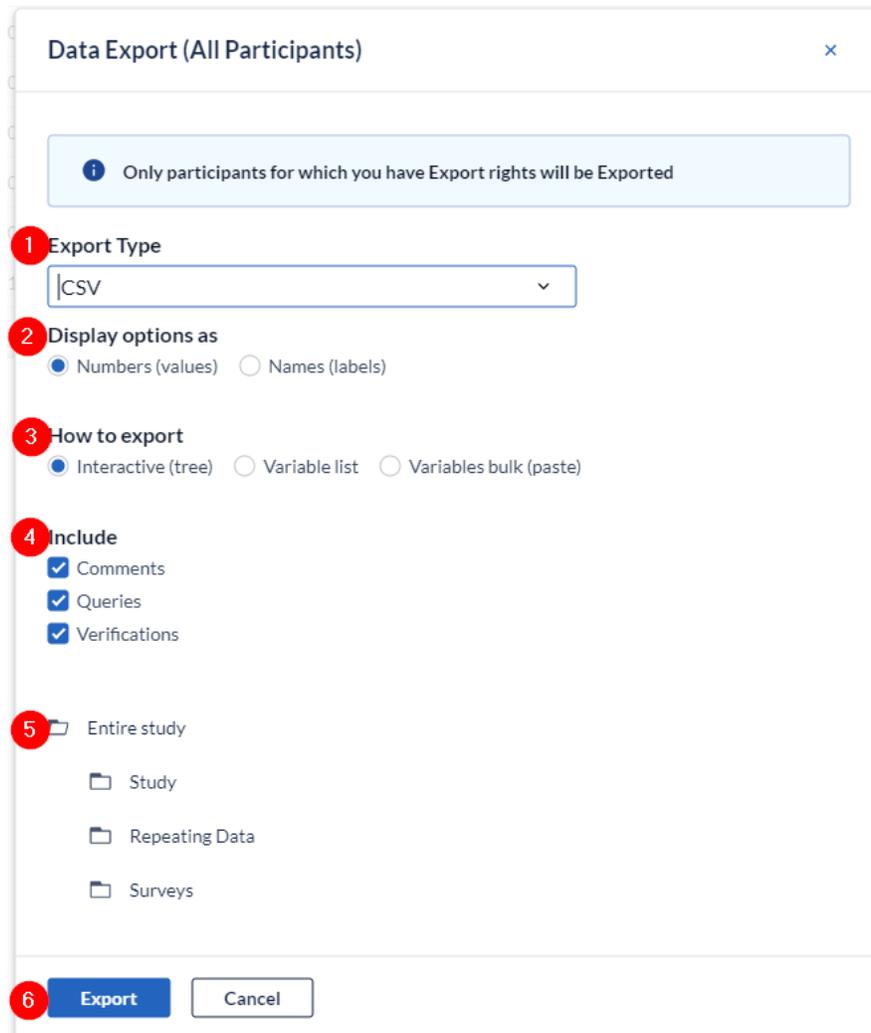
13.1. How to export data

1. Navigate to the 'Participants' tab and click the 'Actions' icon.
2. Choose 'Export all' to export all participant data. If you are exporting only data from selected or filtered participants, first select or filter the participants you wish to export and then click the 'Actions' icon, then choose 'Export all filtered' or 'Export selected' from the list:

The screenshot shows the 'Castor EDC Study' interface. On the left is a navigation sidebar with options like 'Study structure', 'Study forms', 'Participants', 'Repeating Data', 'Surveys', 'Monitoring', 'Statistics', 'Audit Trail', 'Users', and 'Settings'. The main area displays a table of participants with columns for Participant ID, Site, Randomization, Progress, Last opened, Created on, Updated on, and Status. A search bar and 'Exact match' checkbox are at the top. A '+ New' button and an 'Actions' dropdown menu (with a red '1' next to it) are on the right. The 'Actions' menu is open, showing options like 'Lock', 'Unlock', 'Print selected', 'Print empty CRF', 'Export all' (with a red '2' next to it), 'Export all filtered', 'Export selected', 'Import', 'Update status', 'Update site', 'Archive selected', and 'Un-archive selected'.

Participant ID	Site	Randomiza...	Progress	Last opene...	Created on	Updated on	Status
000004	Test Site	A	<div style="width: 100%;"></div>	Infected Site	12 Aug 2022	22 Sep 2022	Not Set
000005	Test Site	B	<div style="width: 100%;"></div>	Infected Site	02 Aug 2022	03 Aug 2022	Not Set
000006	Test Site	A	<div style="width: 100%;"></div>	Infected Site	02 Aug 2022	01 Sep 2022	Adverse Event
000007	Test Site	B	<div style="width: 100%;"></div>	Infected Site	03 Aug 2022	17 Aug 2022	Not Set
100002	Test Site	A	<div style="width: 100%;"></div>	Infected Site	01 Aug 2022	03 Aug 2022	Not Set
100003	Test Site	B	<div style="width: 100%;"></div>	Infected Site	01 Aug 2022	22 Sep 2022	Not Set
110003	Test Site	-	<div style="width: 100%;"></div>	Infected Site	11 Aug 2022	11 Aug 2022	Not Set
110006	Main Site	-	<div style="width: 100%;"></div>	Infected Site	25 Aug 2022	25 Aug 2022	Not Set

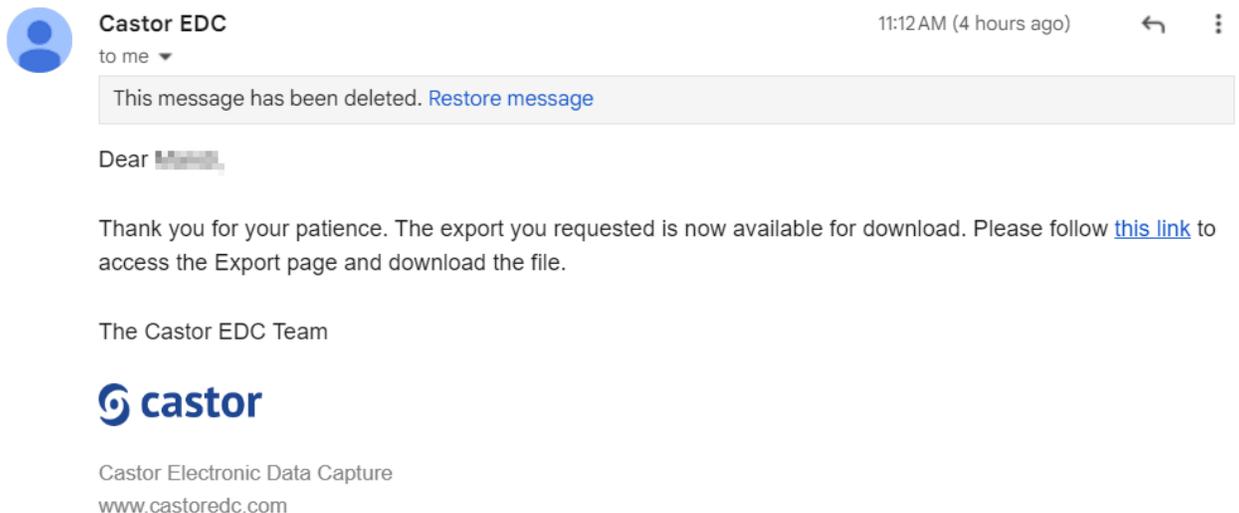
3. A 'Data Export' dialog window will appear:



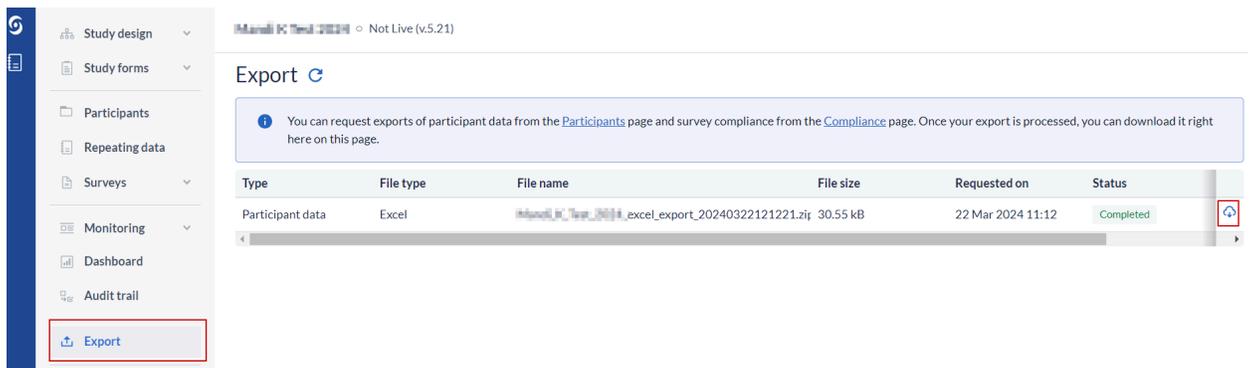
1. Select the file format you want to export your data in. You can choose between CSV, Excel, SPSS and SAS (SAS XPT or SAS 7BDAT) or CDISC-ODM formats. You also have the option to download all uploaded files in the 'Upload file field' in your study by selecting 'Uploaded files (to zip-file)'.
2. In case you select CSV or Excel as export type, pick the way options are displayed in the export. Numbers will export the option values, while Names will export the options labels.
3. Select between exporting the certain parts of the study, variable list or specific variables (only CSV and Excel formats).
4. Choose whether you want to export all comments. These will be exported to a separate sheet in Excel, or in a separate CSV file. The export for comments contains

the following information: current value of the field, which type of form the field is located on (study/repeating data) and the repeating data name if applicable. Choose whether you want to export all queries. These will be exported to a separate sheet in Excel, or in a separate CSV file. Choose whether you want to export data verifications. These will be exported to a separate sheet in Excel, or in a separate CSV file.

5. In CSV and Excel formats it is possible to decide which part of the study you want to export. By default, the export will contain all the data from your study, repeating data and surveys. In the interactive tree-view you can select smaller subsets (on the form-level) by selecting the file icon next to each option (Study, Repeating data, and surveys). Using this tree-view you can export only a subset of your data, for example only study, repeating data, surveys or forms of your study.
6. Click Export to export your data.
7. Once the file has been exported successfully the user will receive a completion email. You can select the link located within this email and be directed to the exported file to download.



You can also navigate to the 'Export' tab and see a listing of all available exports to download.



13.2. Exported files

The export includes multiple data sets. In an Excel export, these data sets are in different Excel sheets. In CSV and SPSS exports, the data sets are in separate files.

- Study data in one file called 'STUDYNAME_export_DATE.csv' or 'STUDYNAME_date.dat'
- Report data in separate files. Every repeating data has its own Excel sheet or file. For example, SAE repeating data and blood pressure repeating data will be in 2 sheets or files, which are called 'STUDYNAME_SAE_date' and 'STUDYNAME_blood_pressure_date', respectively.
- Survey data in separate files. Like repeating data, every survey has its own file.
- Variable lists of study forms, repeating data, and surveys - a list of all fields.
- Comments, incl. the current field value
- Queries

The export file will be saved as a zip-file, containing either:

1. An Excel file with separate sheets for the study data, each repeating data instance, each survey, a list of variables and option groups.
2. A set of separate CSV files, one for study data and one for each repeating data and survey, a list of variables and option groups.

14. Further Information

If you would like to view our Castor CDMS video tutorials, you can do so [here](#).

For more information regarding data entry, please check Castor CDMS's knowledge base: <https://helpdesk.castoredc.com>. If you have any questions or concerns, please contact us at support@castoredc.com