Castor

Castor CDMS Data Entry User Guide

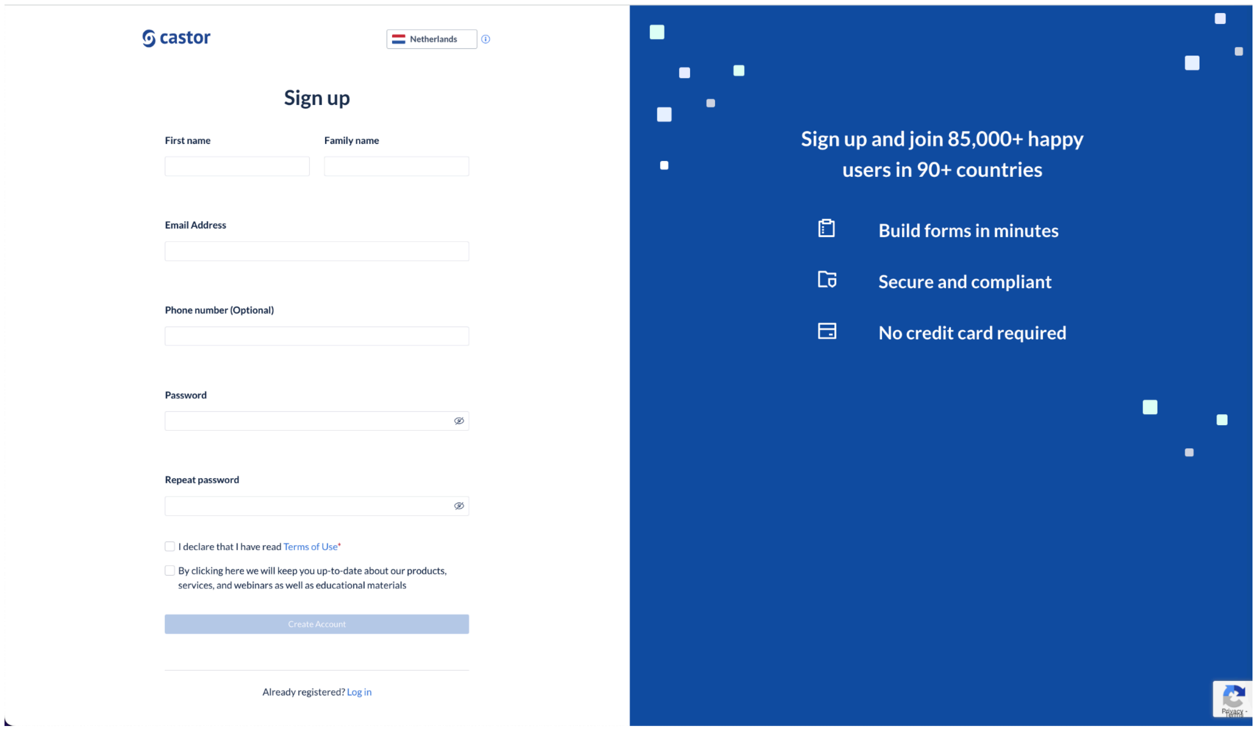
Version 2025.2.0.0

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:

- 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'

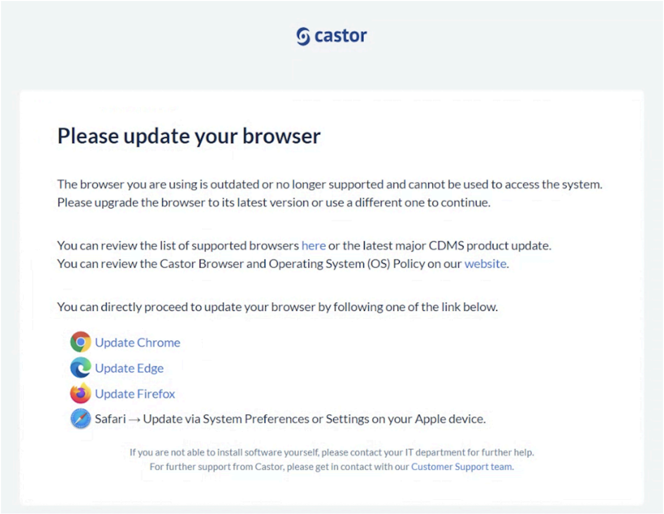
You will receive an email to verify your account. After clicking the link in the email address, you will be prompted to confirm the server where your account will be created.

1.2. System Access. Browser & Operating Support Policy

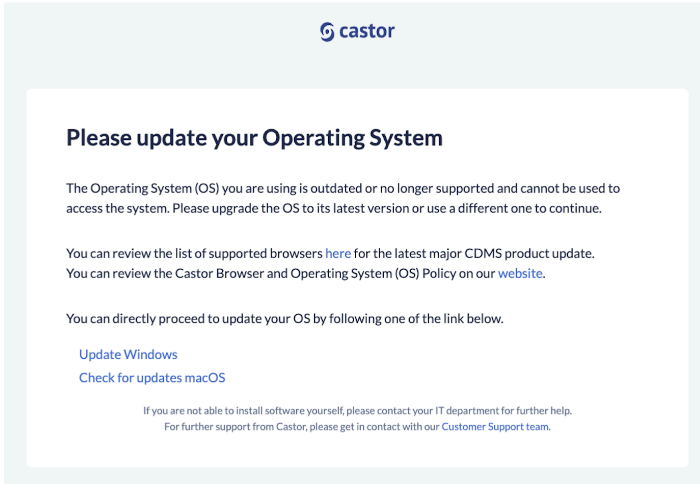
Study teams (clinicians, researchers etc.) accessing CDMS with an unsupported browser or operating system (OS) will now be blocked from logging in and shown a clear error message. This ensures a reliable experience by enforcing access only through allowlisted environments. This change is applicable to all CDMS users that are required to log into the system.

Two new messages have been introduced as part of Castor's Browser and Operating System Policy enforcement for study teams. If both the OS and browser are unsupported, the OS message takes priority.

Unsupported Browser Message:



Unsupported OS Message:



Note: The above messages apply only to clinician-facing CDMS interfaces

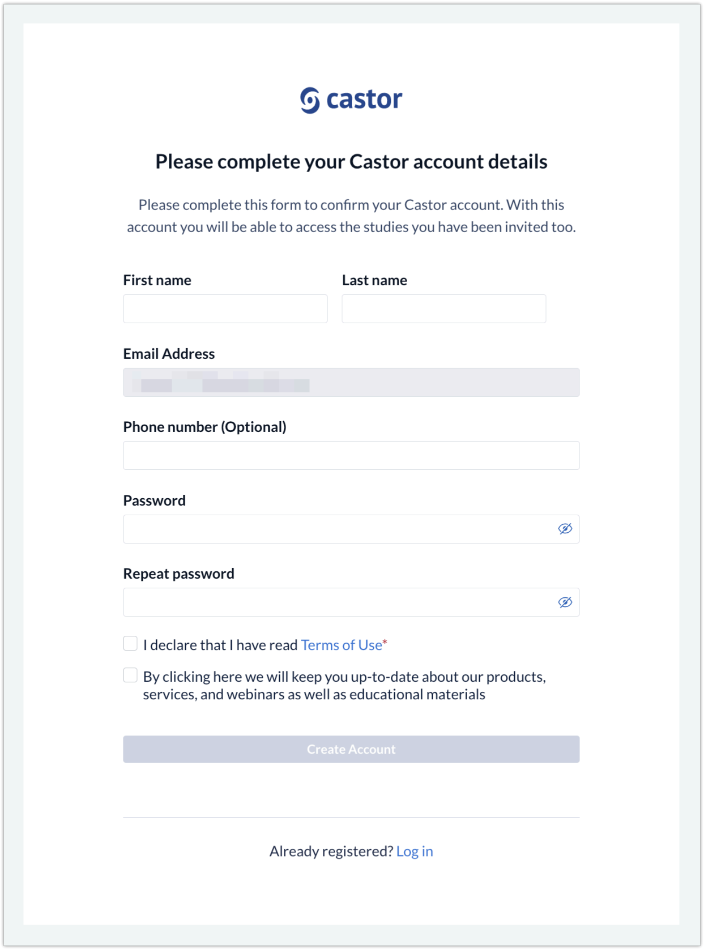
Supported and validated versions for v2025.2.0.0

Clinicians:

- Chrome 125 or newer
- Microsoft Edge 124 or newer
- Firefox 127 or newer
- Safari 17 or newer (macOS)
- Safari on iOS 17 or newer

1.3. 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:



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

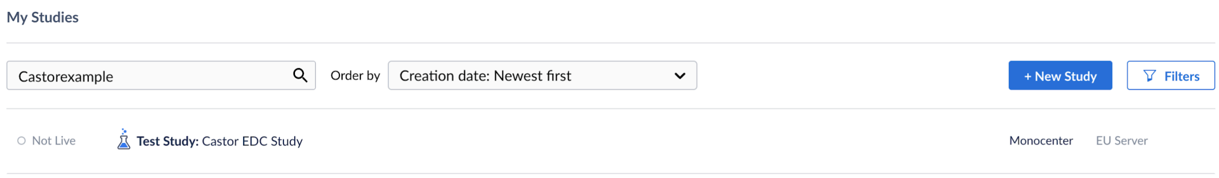
To access the study, log into Castor CDMS via https://data.castoredc.com. If your study is on the US, AU or UK server, you can also directly go to https://au.castoredc.com/register, http://us.castoredc.com or http://uk.castoredc.com, respectively.

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.

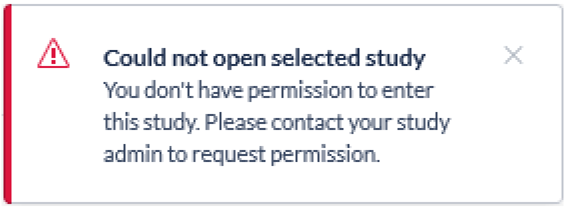
3. Click on 'Login'.

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.



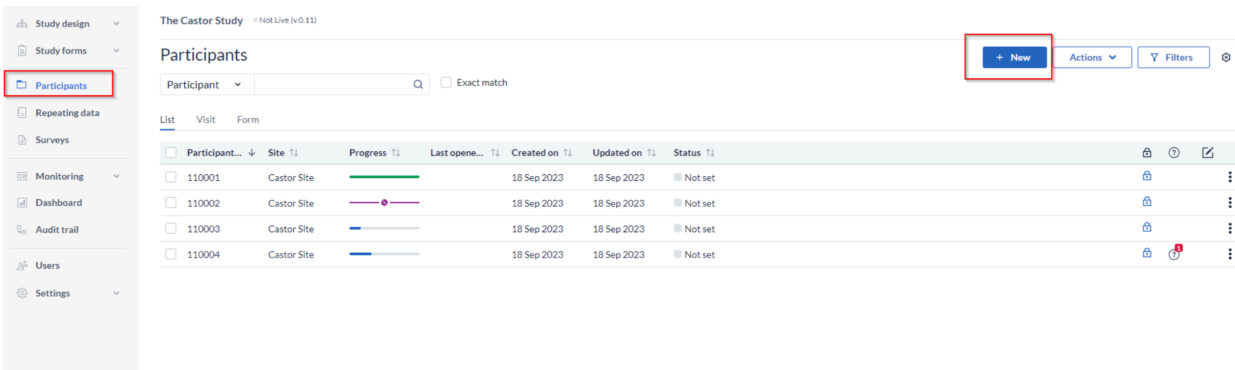
Trying to open a study that is not live will show the following warning:



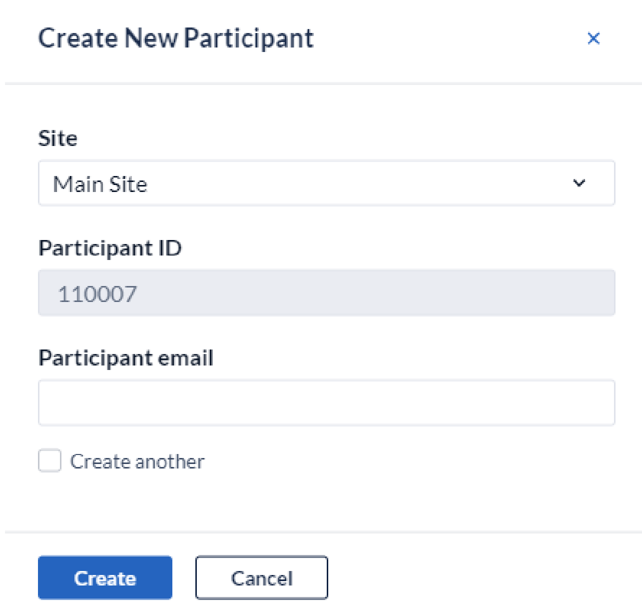
If the study is still in maintenance mode (the button is blank, and the status says 'Not Live') a user will only be able to open the study if a user has management permissions.

4. Add/Open a participant for data entry

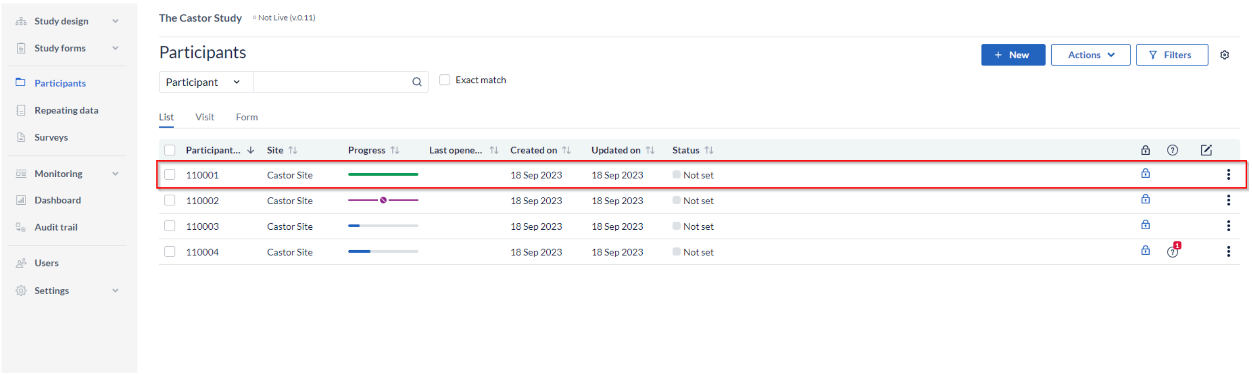
Once a user enters the study, a user will see a list of all participants available based on their access level . To add a new participant to the database, a user will need to create a new participant participant. Creating new participant participants must be done from the Participant tab, by clicking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



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

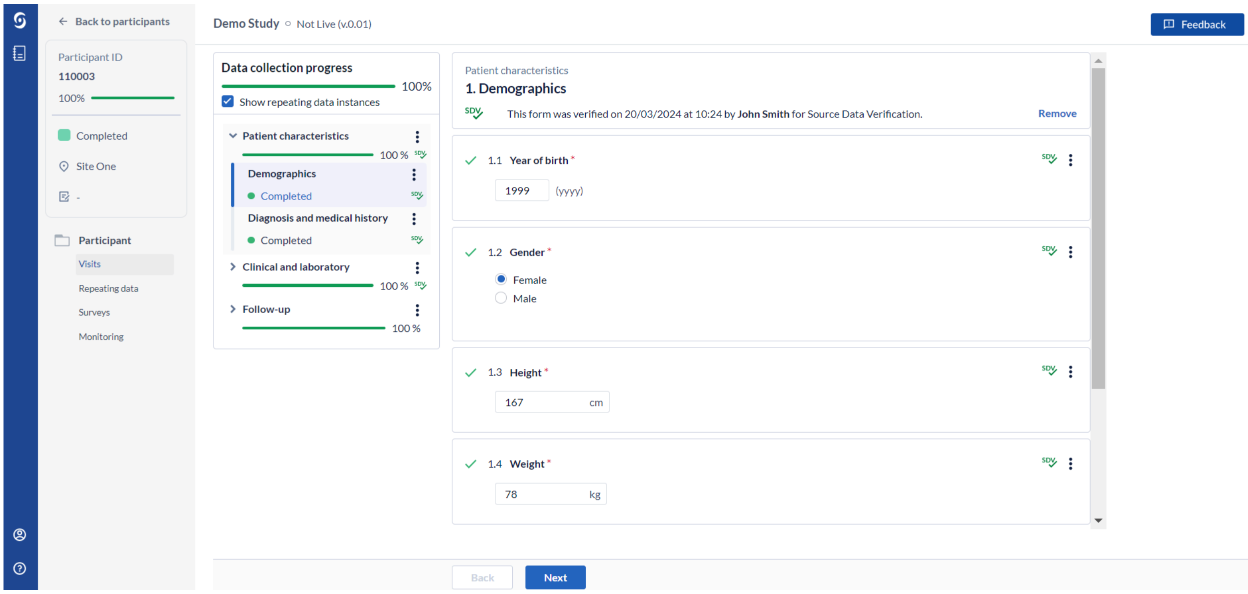


To open a previously created participant, double click the row the participant is located on.



5. Doing data entry

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



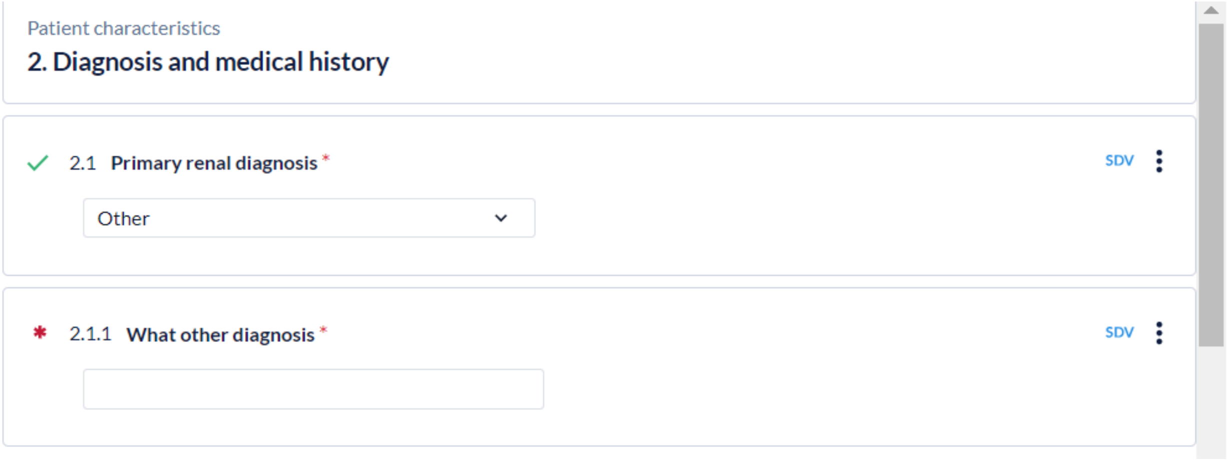
It consists of the following elements:

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 three dots 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. A 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.
7. To exit the participant and return to the participant list, click on the 'Back to participants' button.

5.1. Elements in each question

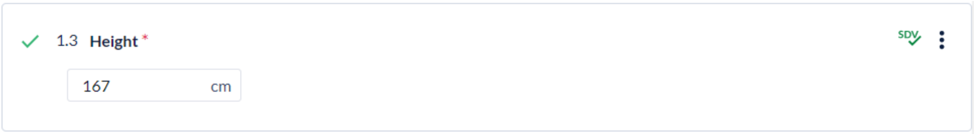
Depending on the type of question, a user will need to select one or more of the provided options, enter a number or date, upload a file etc.

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'.

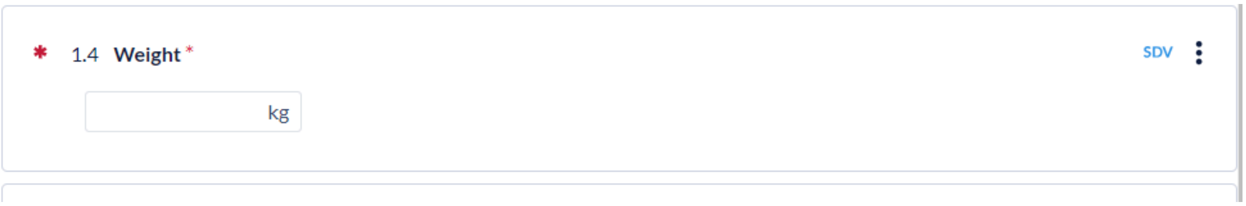


5.1.1 Status icons

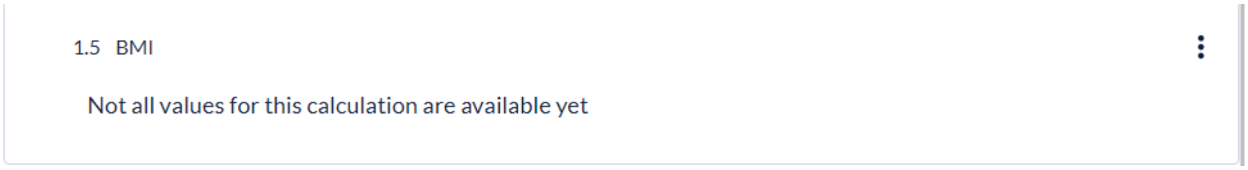
Shown to the left of each question is the status icon, which indicates whether the question:
- has been answered (green thick):



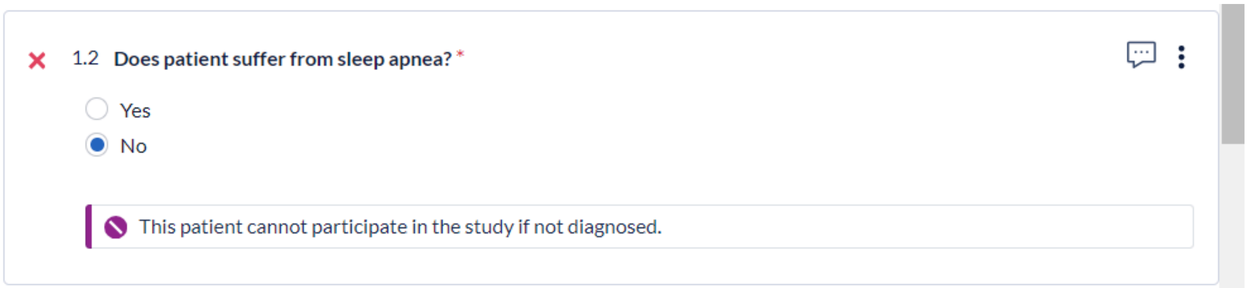
- data entry is required and no input has been entered yet (red asterisk):



- data entry is not required - field shows the value based on calculation (no icon)

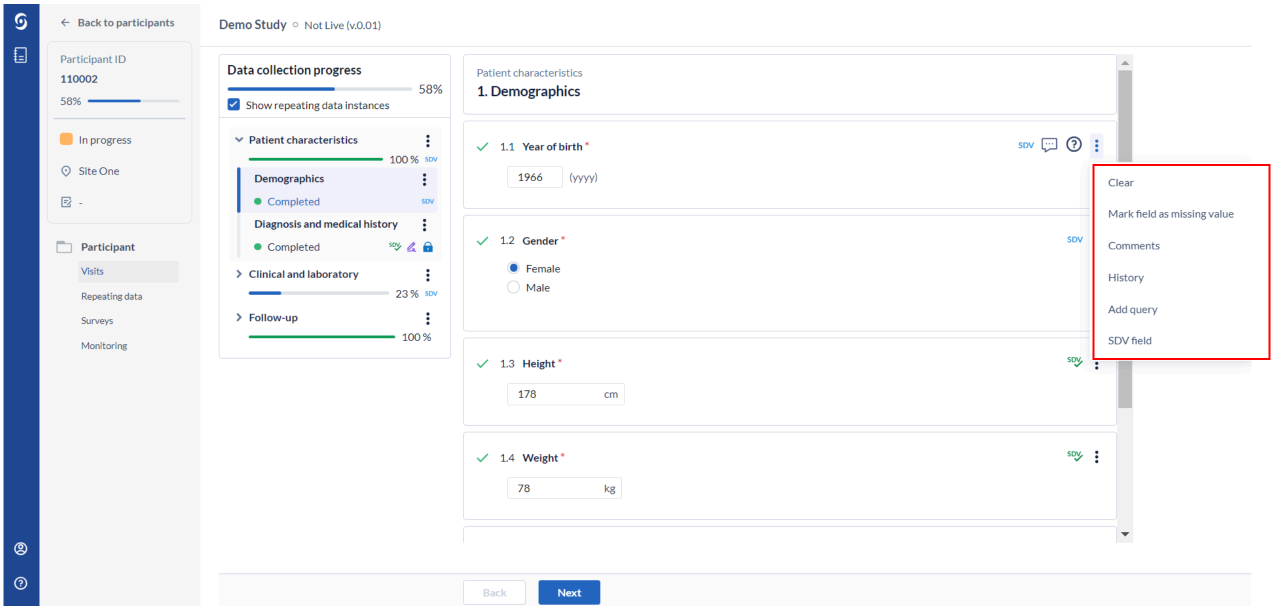


- the input is invalid or does not comply with the inclusion criteria for the study. This is accompanied by a red warning message (red cross)

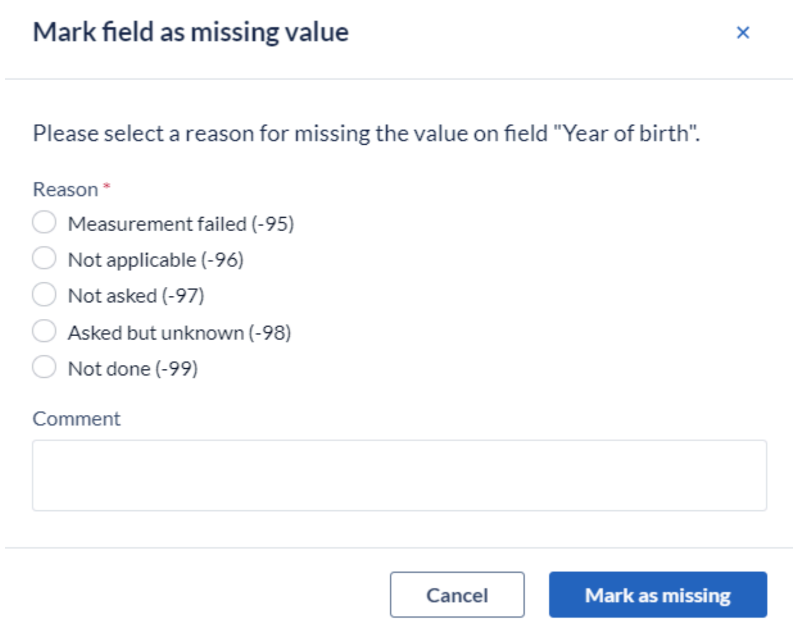


5.1.2 Additional options

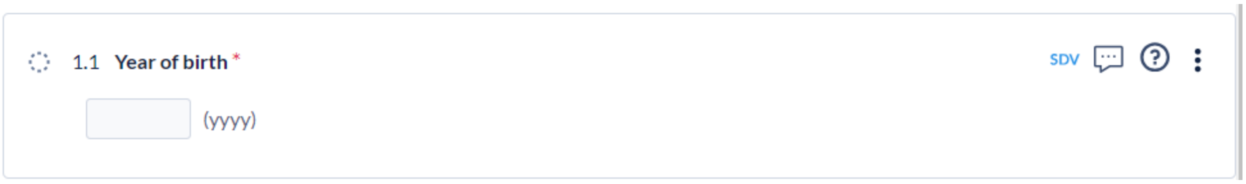
To the right of each question there is a the three dots with additional options:



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



- Select the appropriate option and if necessary, add a comment. Click ‘Mark as missing’ 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’.



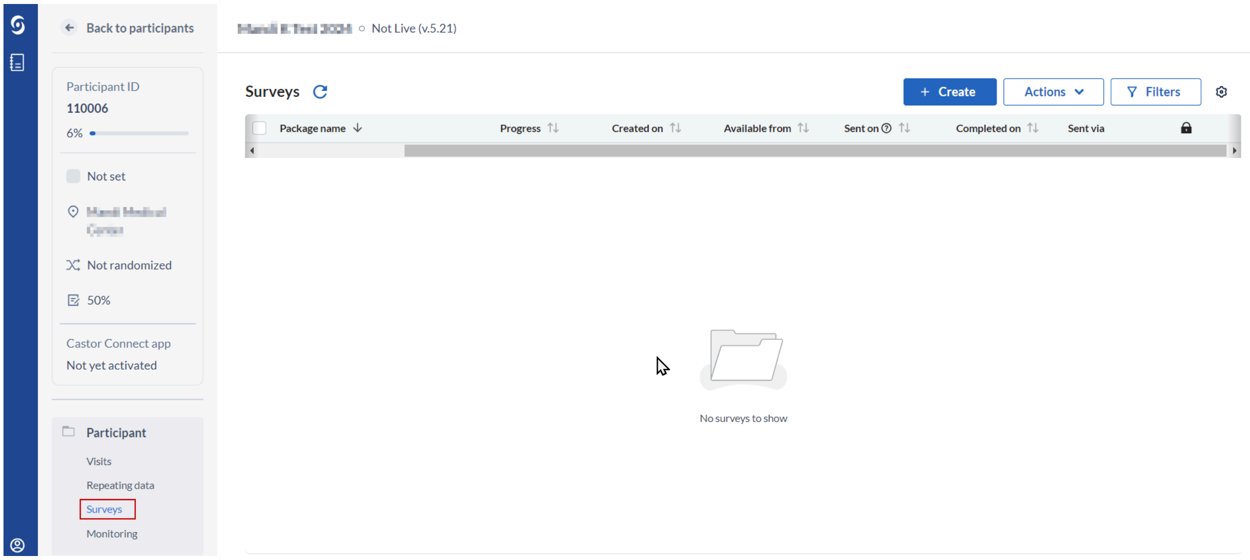
- If a user initially marked a field as missing but received information for this field at a later date, a user can click on the three dots again (even if the question is grayed out) and should unselect the option “Unmark field as missing value”.
- If a user wants to add a comment to a field, press “Comments”.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

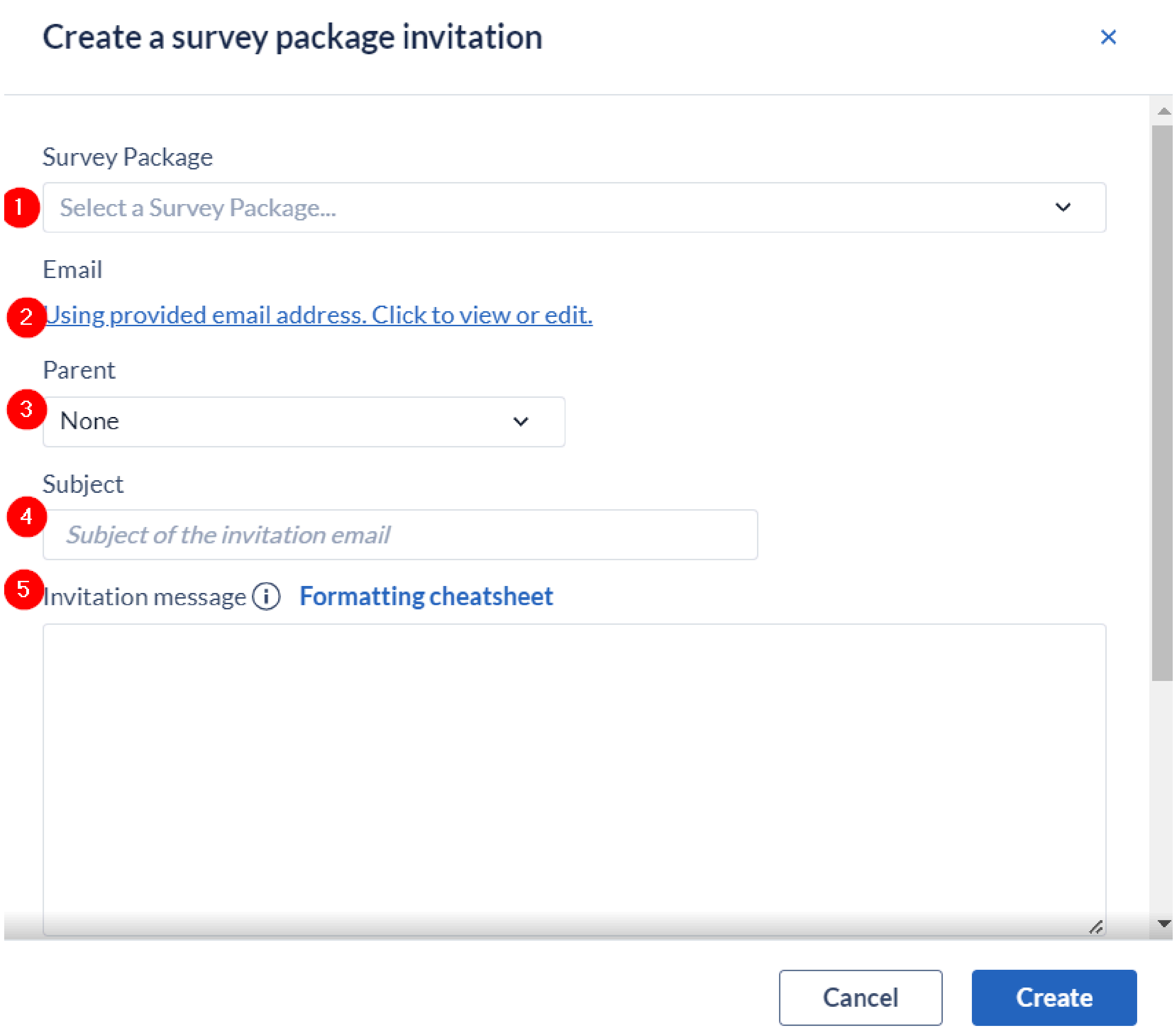
5.2 Send an individual survey invitation

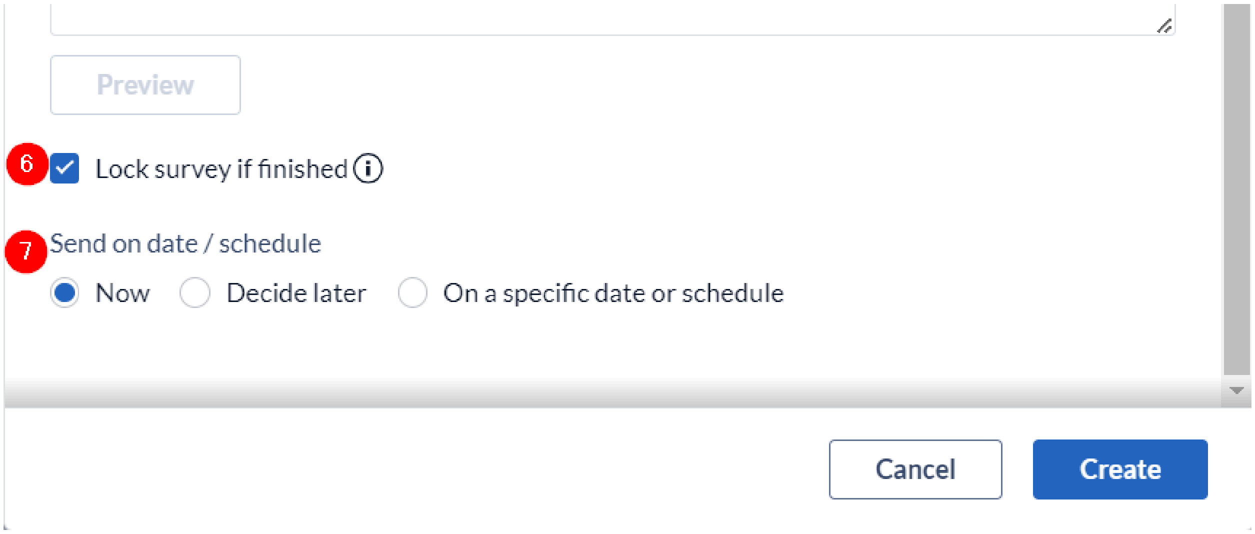
In Castor, surveys are sent out by creating survey invitations. In order to send a survey you must first have created a survey form and a survey package. Surveys are always sent in the form of survey packages, even if the package consists of only one survey.

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

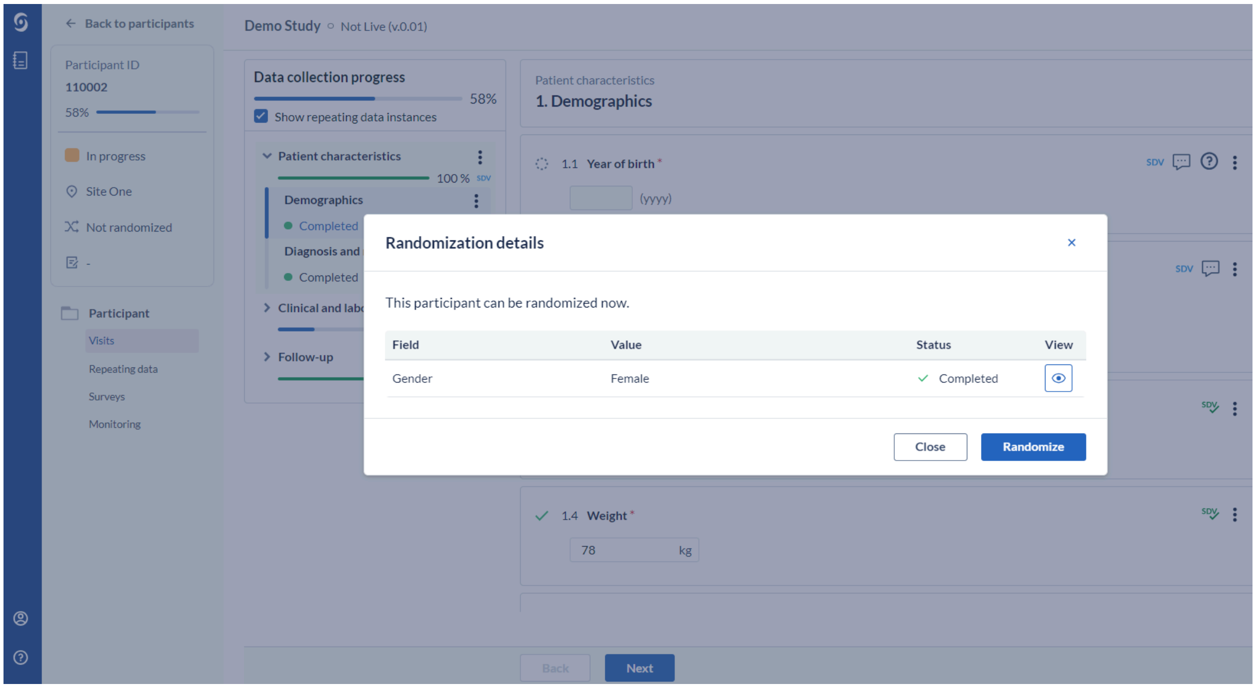


1. Select the survey package you want to send.
2. Add the email of the participant if this hasn't been previously added to the participant. If the email was already added to the participant itself, it will be automatically extracted and this section will be pre-filled with the email address. To view the address, you will need to authenticate yourself again with your password and this viewing will be logged in the audit trail. If an email address is not associated with a participant, a pop-up window will appear asking if you would like to associate the participant with this e-mail address which will be used as a primary e-mail address for the survey invitations.
3. Select a visit/repeating data of your study, if you want to attach the survey to a certain visit or repeating data. This is optional.
4. The subject of the email that the participant will receive.
5. The text of the email that the participant will receive will be drawn from your survey package settings. You can modify these here, if you wish.
6. Check this box if you want the survey to be locked after finishing. This is convenient if you want to prevent further changes being made when the subject finishes the survey.
7. Select when you want to send the survey. You have three options:
    a. **Now** - the email invitation will be sent immediately after saving
    b. **Decide later** - the invitation will be created but will not be sent. You will be able to define the date of sending later.
    c. **On a specific date or schedule** - you can select a specific date when you want the survey to be sent or you can define a schedule in case you want to send the same package repetitively. You can learn more about survey schedules here (Schedule surveys in CDMS).
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

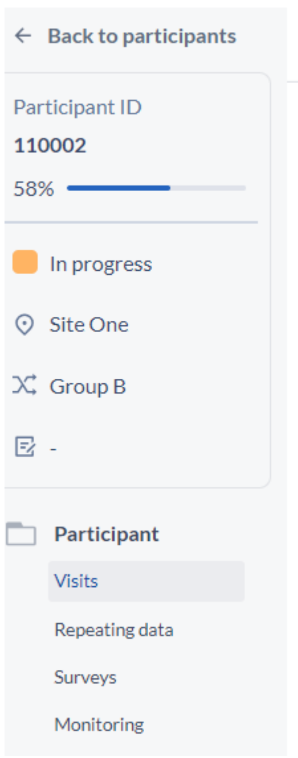
If a user needs to perform randomization in the study, the user can follow these forms to randomize a participant.



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, has 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’

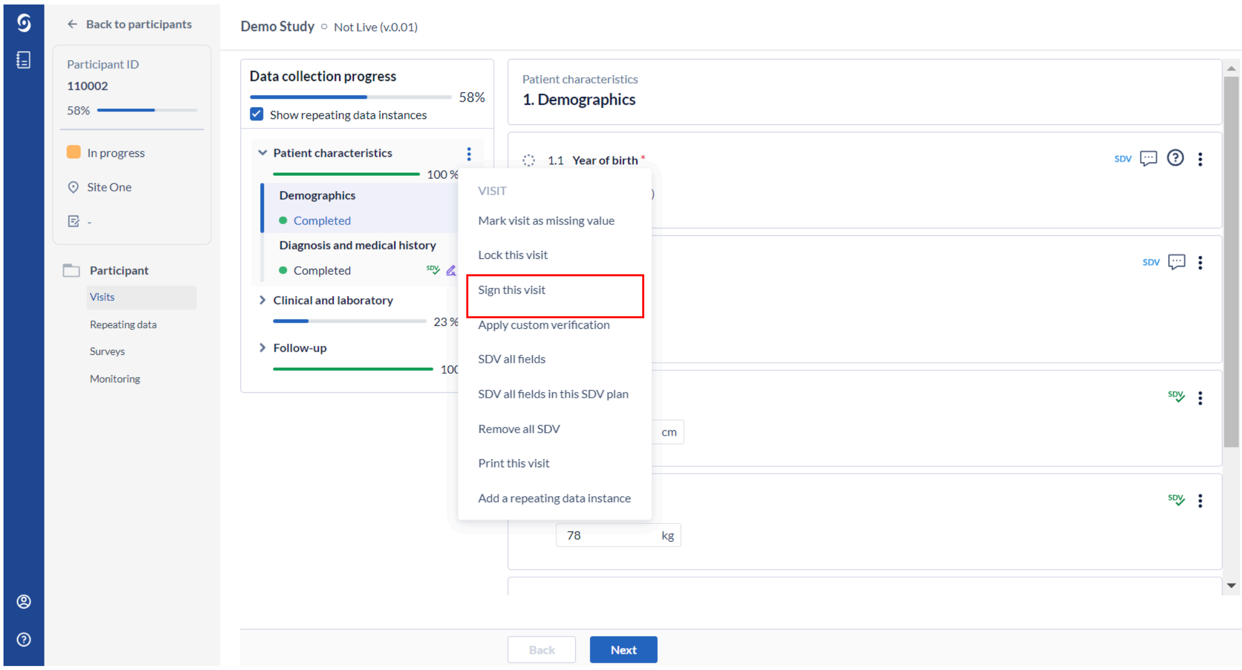


To see additional randomization details click on the randomization group from the participant panel.

To get back to the global Participants tab with an overview of all Participants, click the ‘Back to participants’. This will open the global ‘Participants’ tab with all participants.

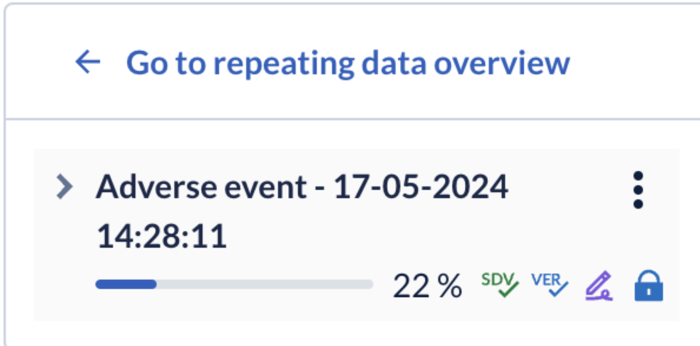
5.4 Signing and locking a form

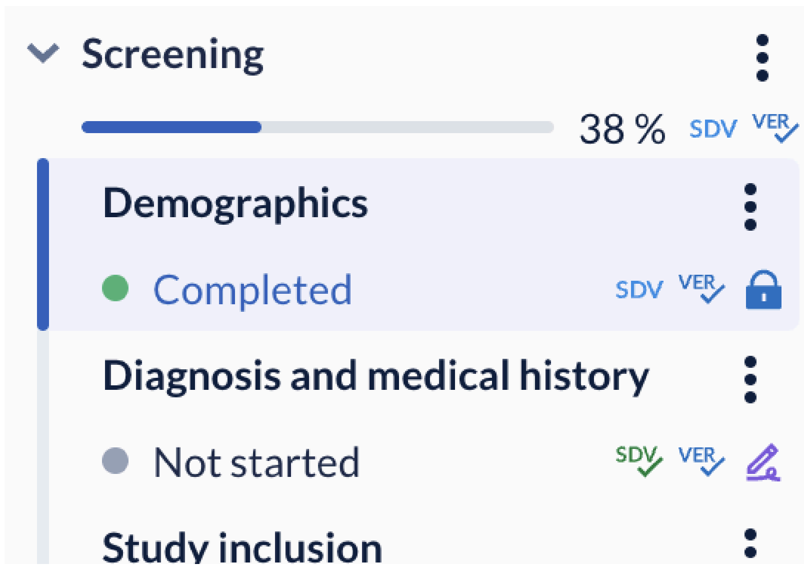
A user can electronically sign and/or lock individual visits and forms in Castor EDC. Users will need the appropriate rights in order to do so.



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 visit’ for visits.
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:





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:

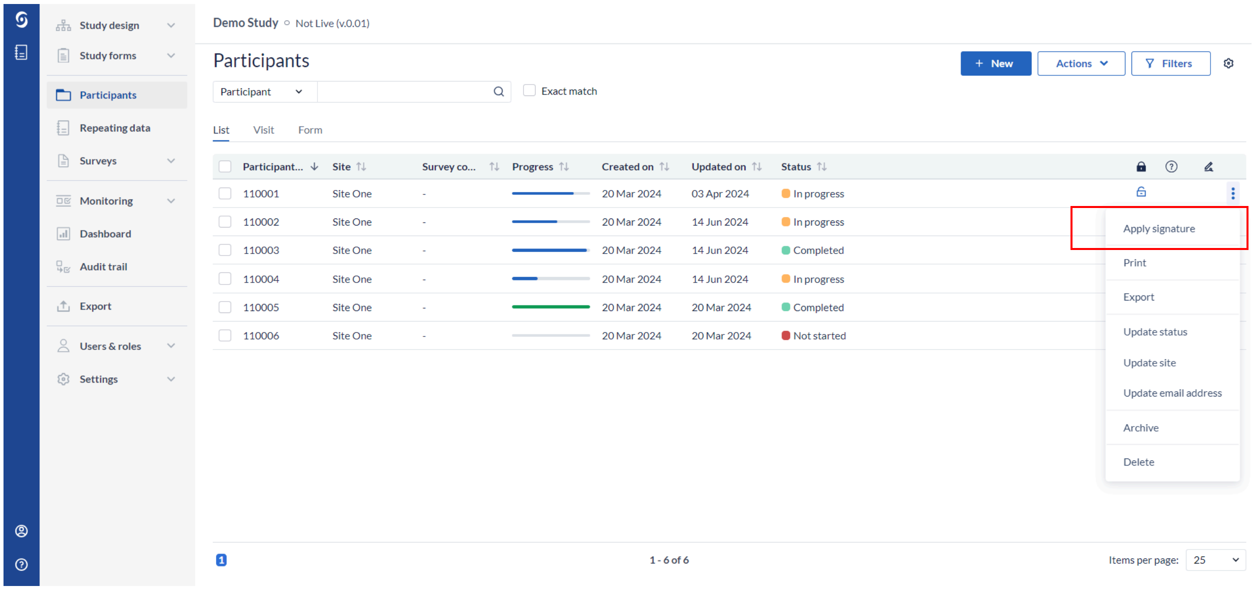
If a user does not have view rights for all the forms, they are notified about the signature being applied only to forms for which viewing rights have been granted.

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:

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

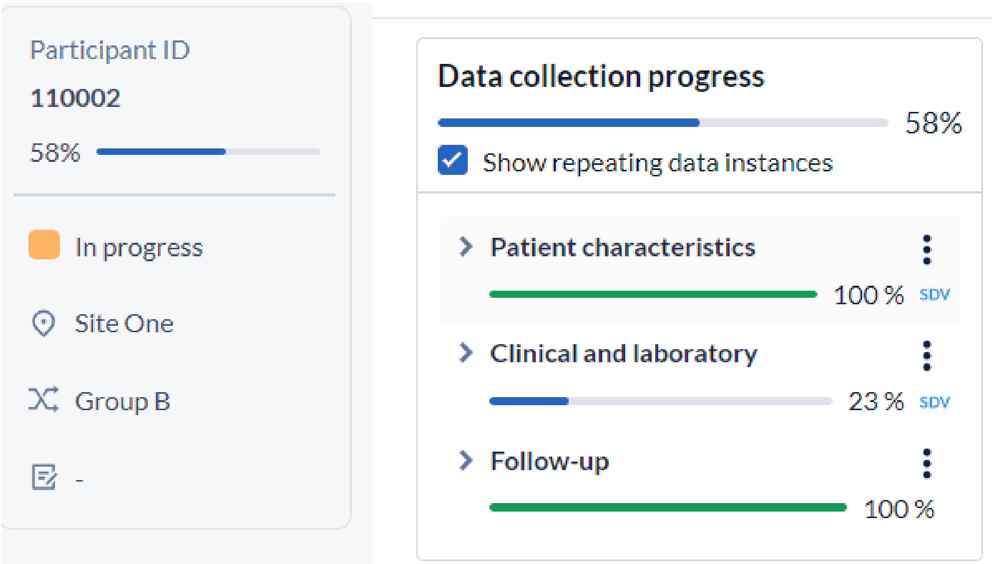
Castor CDMS offers the ability to seamlessly sign all forms of a selected participant at once, directly from the 'Participants overview' page.



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.



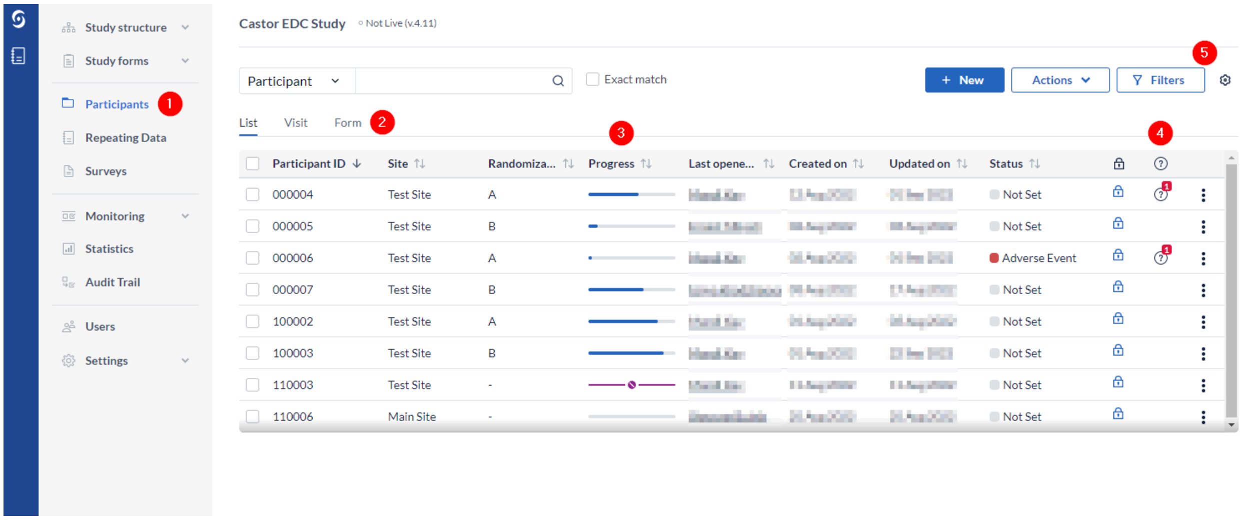
A form can have three different completion stages:

Gray	Not started
Blue	In Progress
Green	Completed

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

7. Participant status

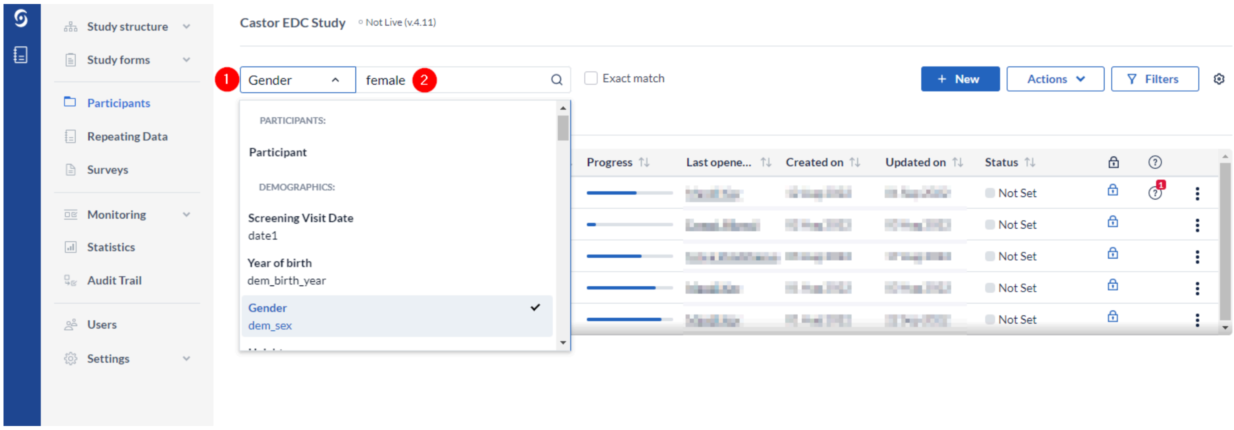
In the 'Participants' tab, a list is displayed showing all participants a user has created (see Section 6). The user will also see participants that have been created by other users at the site.



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

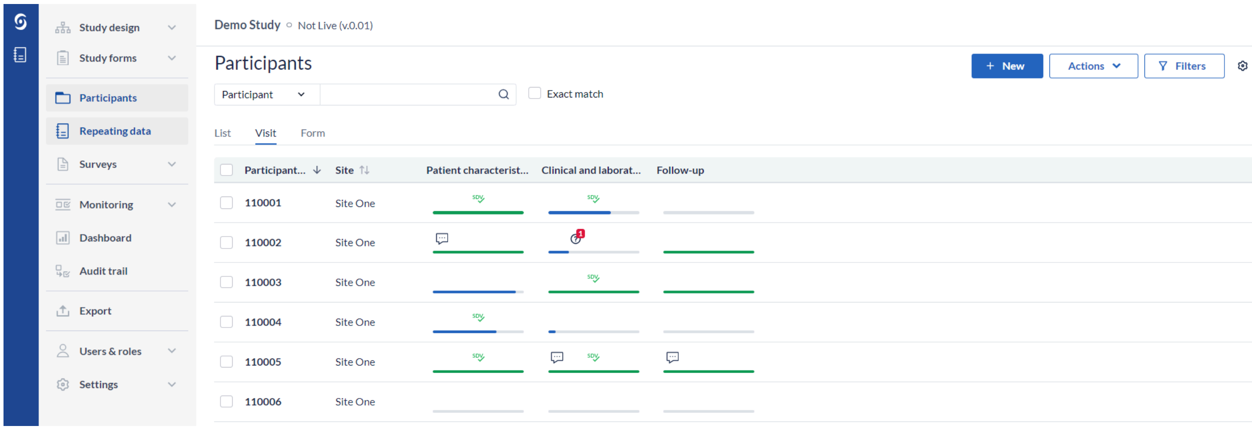
A user can use the search bar to find participants that contain certain data, for example if a user wants to find the patients with a certain age at onset.



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.



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.

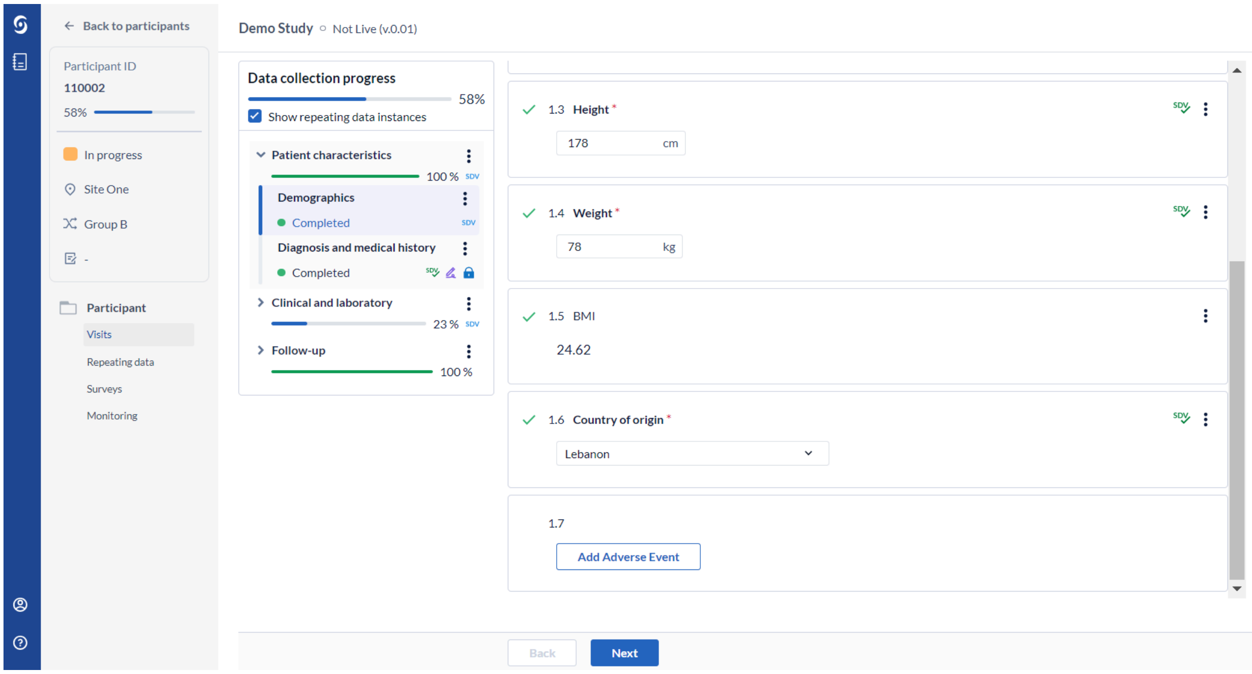
8. Creating Repeating Data

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.

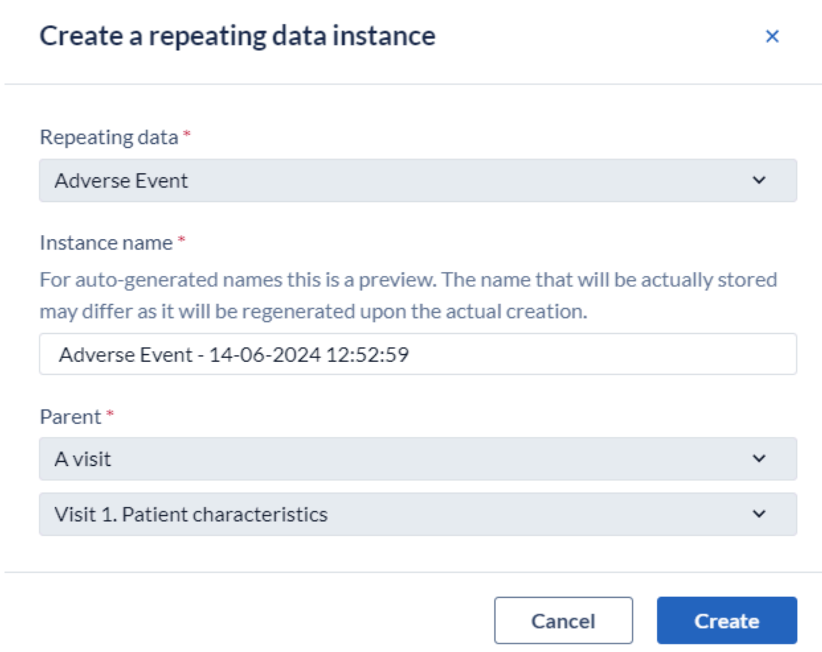
8.1. Adding a repeating data instance

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 Adverse Event' button in the relevant form. Please note that the repeating data button might have a different name in your study:

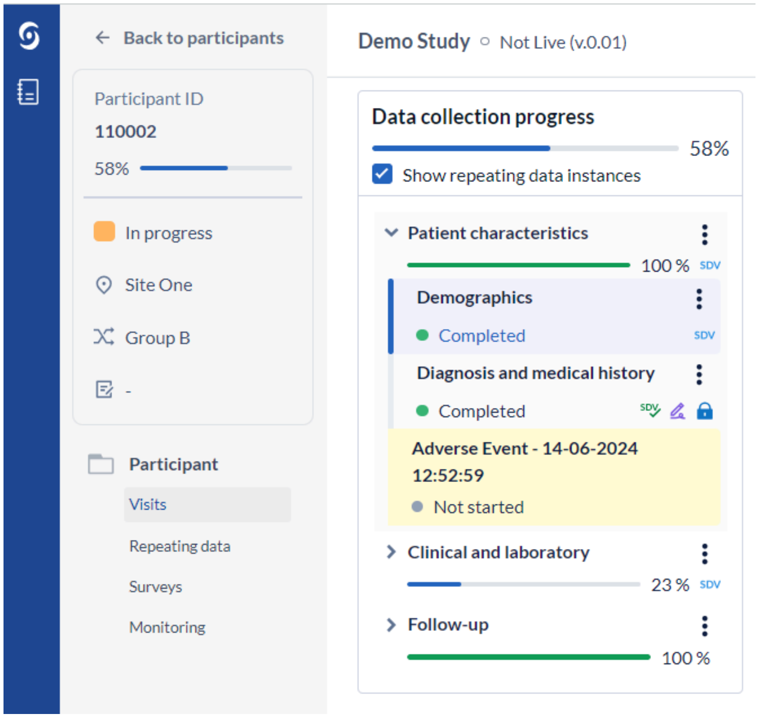


The following dialog window will appear:



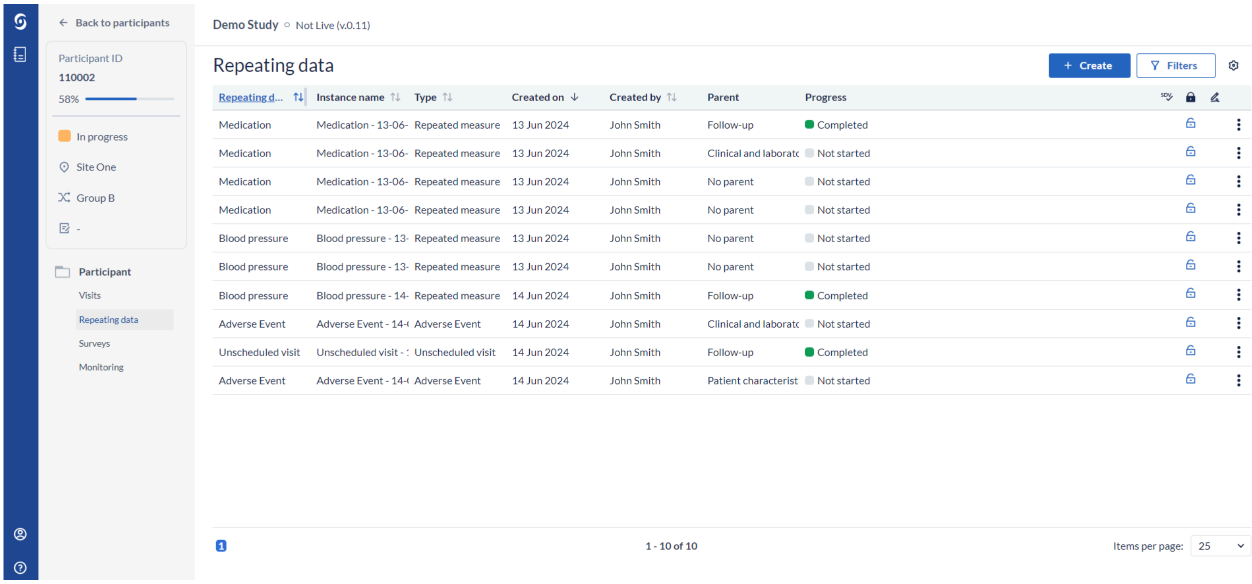
1. Repeating Data: this field contains the repeating data type which is pre-filled
2. Instance name: Enter a custom name for the repeating data, this is how the repeating data will be displayed in the study and exports. In some cases, the custom name won't be editable, as the study admin can disable the option to adjust the repeating data name.
3. Parent: this is a visit to which a repeating data will be linked by default. When creating a repeating data using the button from the form, 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.
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:



8.2. Viewing repeating data

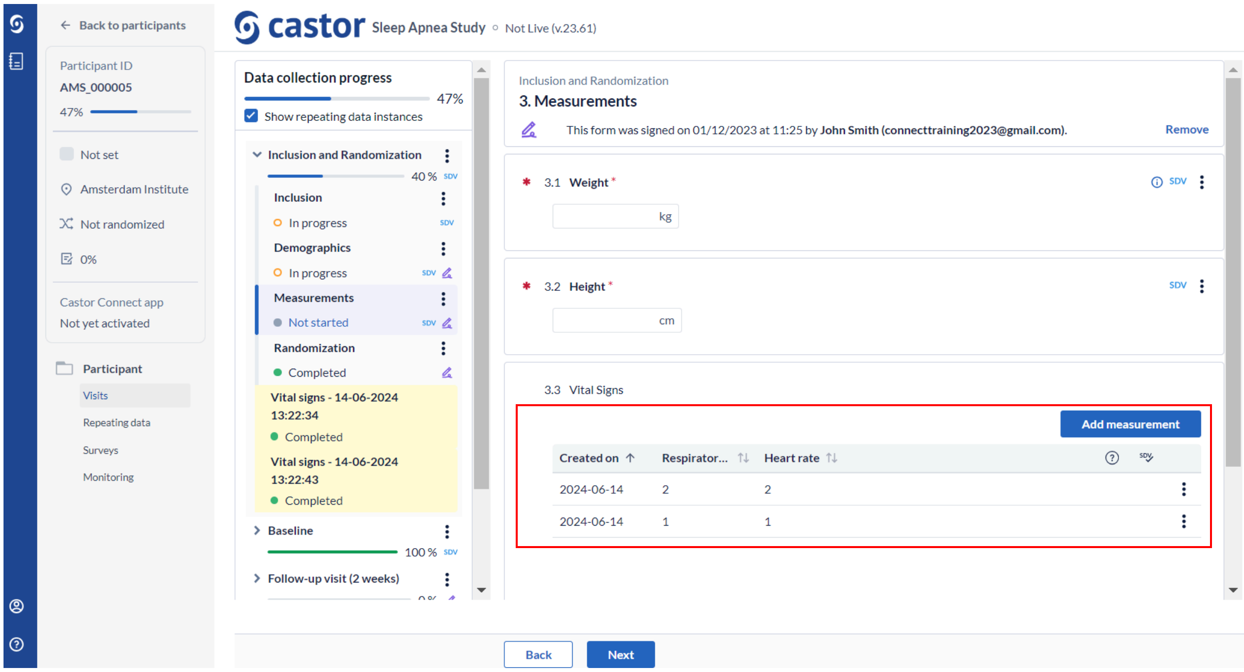
It is possible to view the repeating data instances which are attached to the participant by using the ‘Repeating data’ tab. From here you can also create a new Repeating data instance, using the ‘Create’ button.



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:

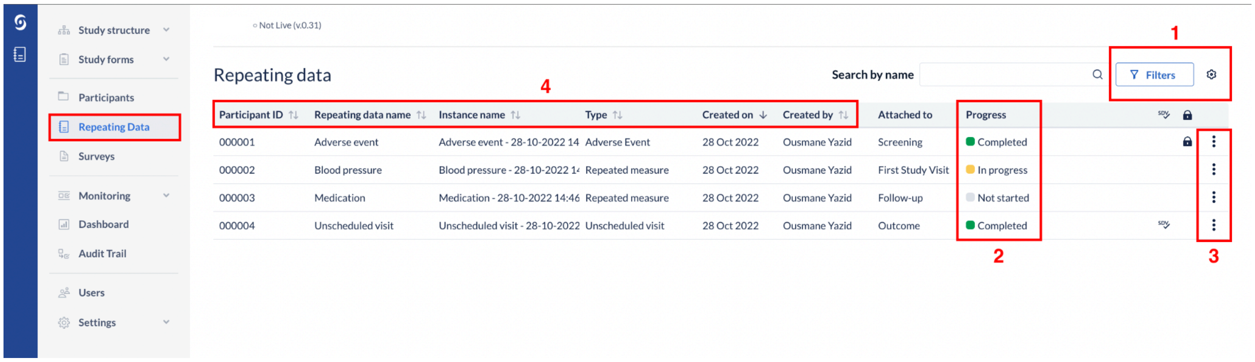


1. By pressing a button 'Add measurement', measurements are easily added to the form and will be shown in the form of a grid, representing each measurement as a new row and each field that is part of the repeated measure as a separate column.

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

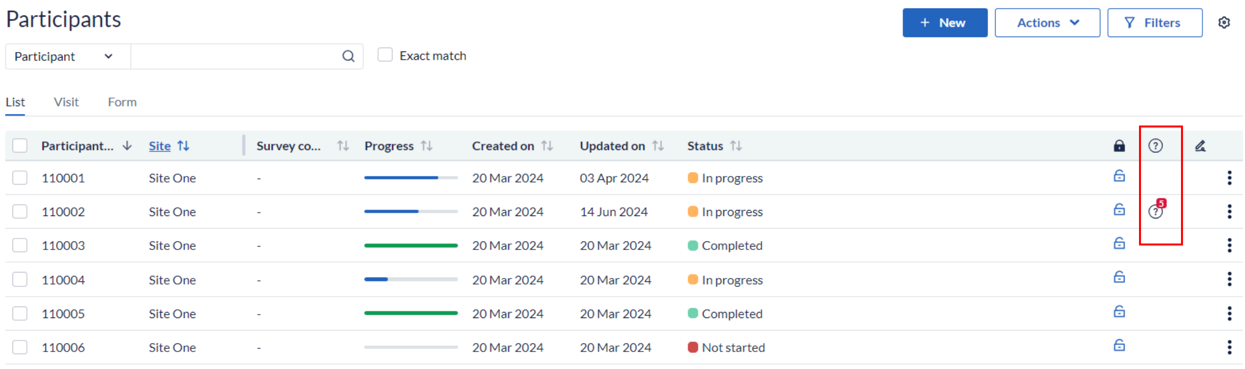
In the 'Repeating Data' tab, an overview of all the repeating data instances within the study are shown. Using the 'Search by name' option, you can search for repeating data instances by entering the instance name (for example, 'Adverse event -1'). A user can only see repeating data instances from participants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



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'.

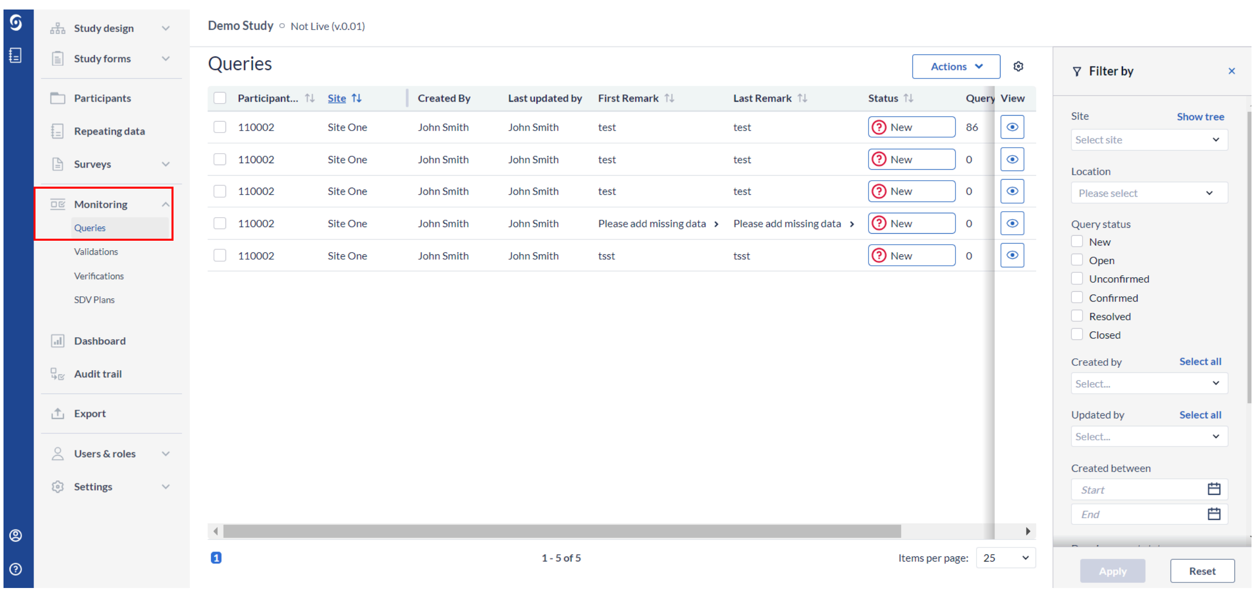
11. Responding to queries

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



11.1. Participant Monitoring tab

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



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.

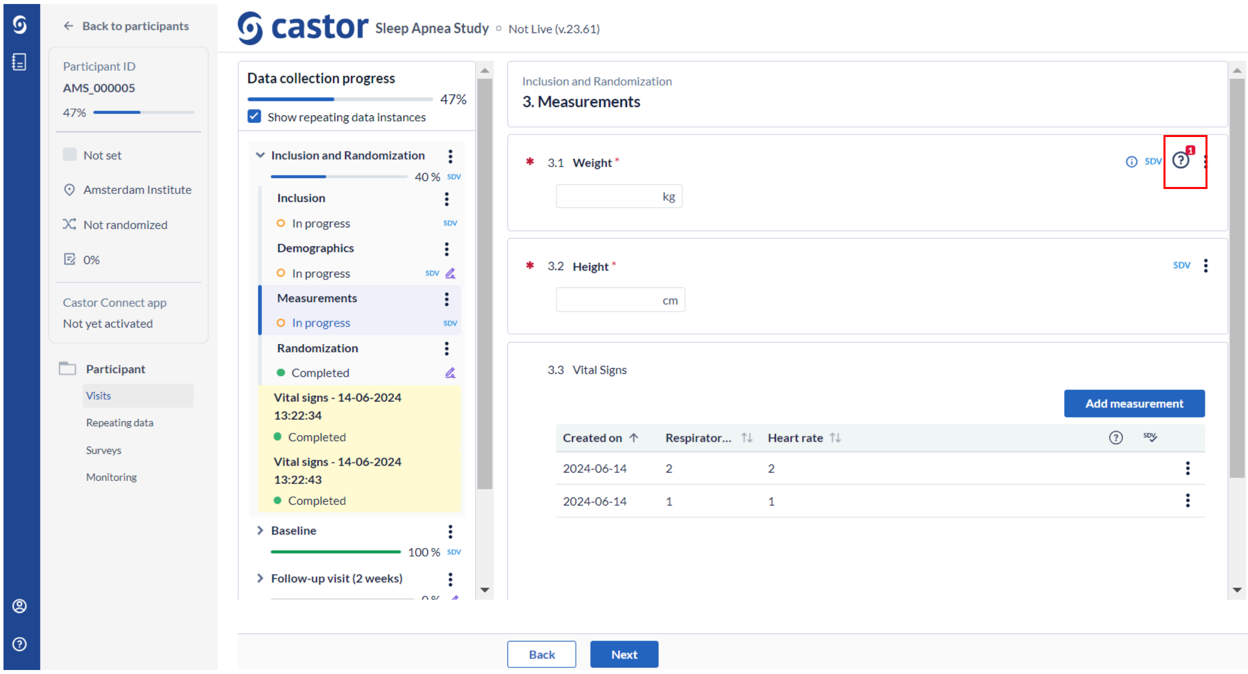
New: This query has not been reviewed.
Open: This query was viewed but a change of status or comment was not made.
Unconfirmed: The user does not agree with the monitor.

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

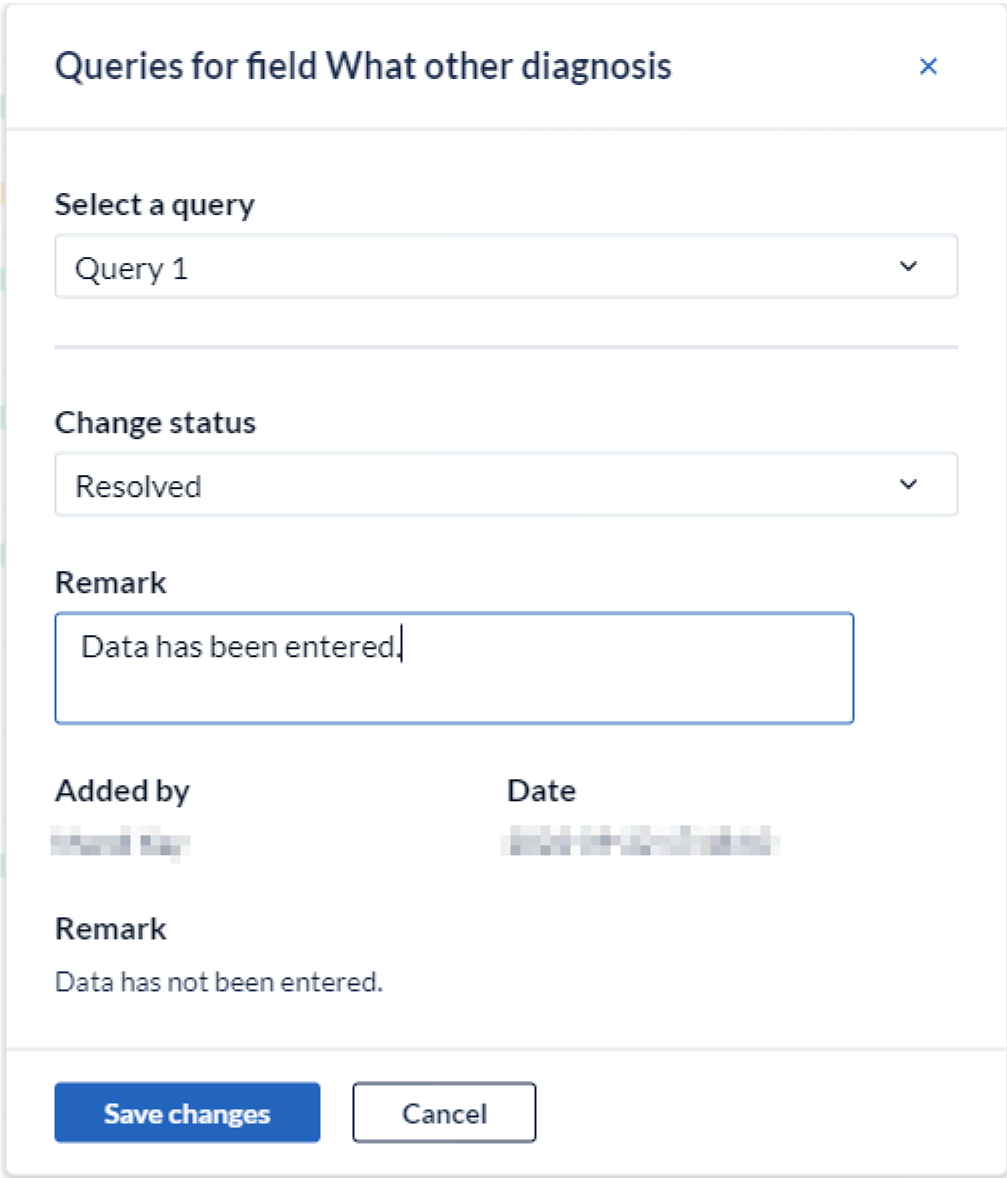
Resolved:The user has changed the value and indicates the issue is resolved, for example the user has reacted to a query and left a comment.

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
castor Sleep Apnea Study
Not Live (v.23.61)
Participant ID
AMS_000005
47%
Not set
Amsterdam Institute
Not randomized
0%
Castor Connect app
Not yet activated
Participant
Visits
Repeating data
Surveys
Monitoring
Data collection progress
47%
Show repeating data instances
Inclusion and Randomization
40 %
Inclusion
In progress
Demographics
In progress
Measurements
In progress
Randomization
Completed
Vital signs - 14-06-2024 13:22:34
Completed
Vital signs - 14-06-2024 13:22:43
Completed
Baseline
100 %
Follow-up visit (2 weeks)
Inclusion and Randomization
3. Measurements
3.1 Weight *
kg
3.2 Height *
cm
3.3 Vital Signs
Add measurement
Created on
Respirator...
Heart rate
2024-06-14
2
2
2024-06-14
1
1
Back
Next

A dialog window will appear:



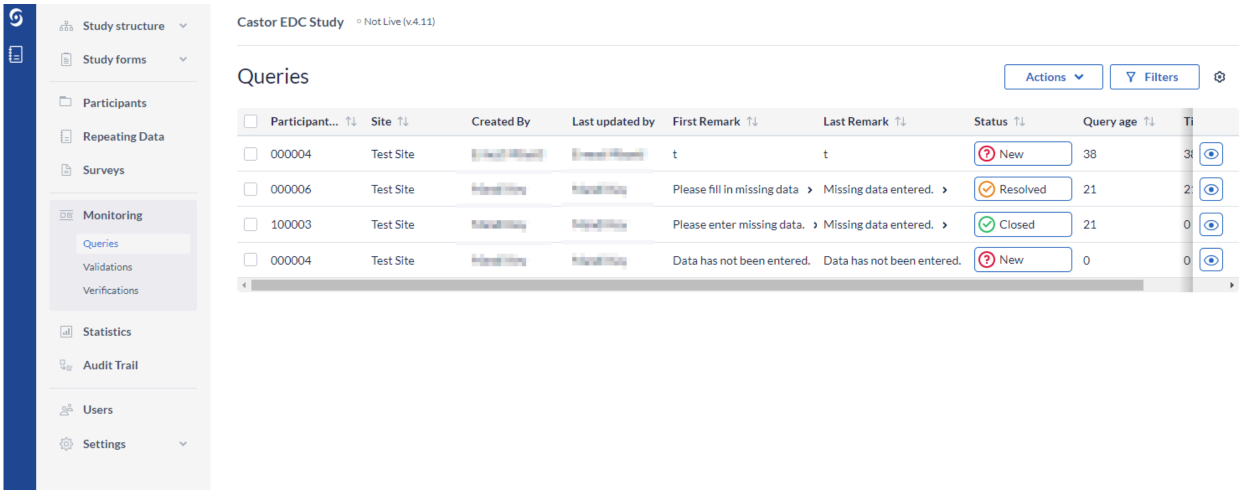
1. In case of multiple queries, a user can select a query to which a user needs to respond.
2. A user can change the status of a query by choosing from the list in the dropdown box.
3. The Remark field allows a user to enter comments on the query.
4. Once a user selects ‘Save changes’ the status and 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.

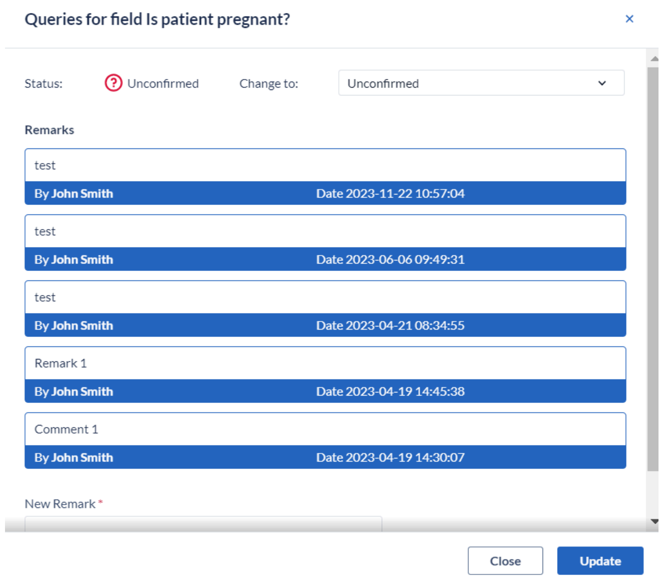
12.1. Queries

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



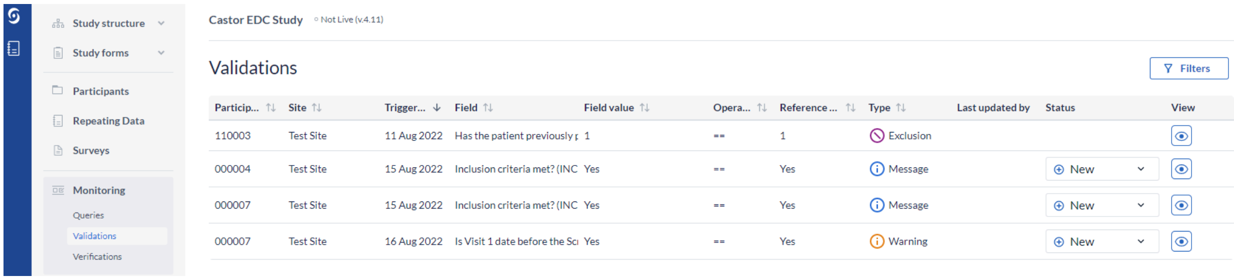
1. The user can click on the ‘Filters’ button to filter by site, location, status (open, resolved, closed or all [Monitoring queries](#)), and other parameters.
2. An overview of all queries in the study (unless a user filtered the results) are displayed here.
3. Click on the eye icon to open a form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



12.2. Validations

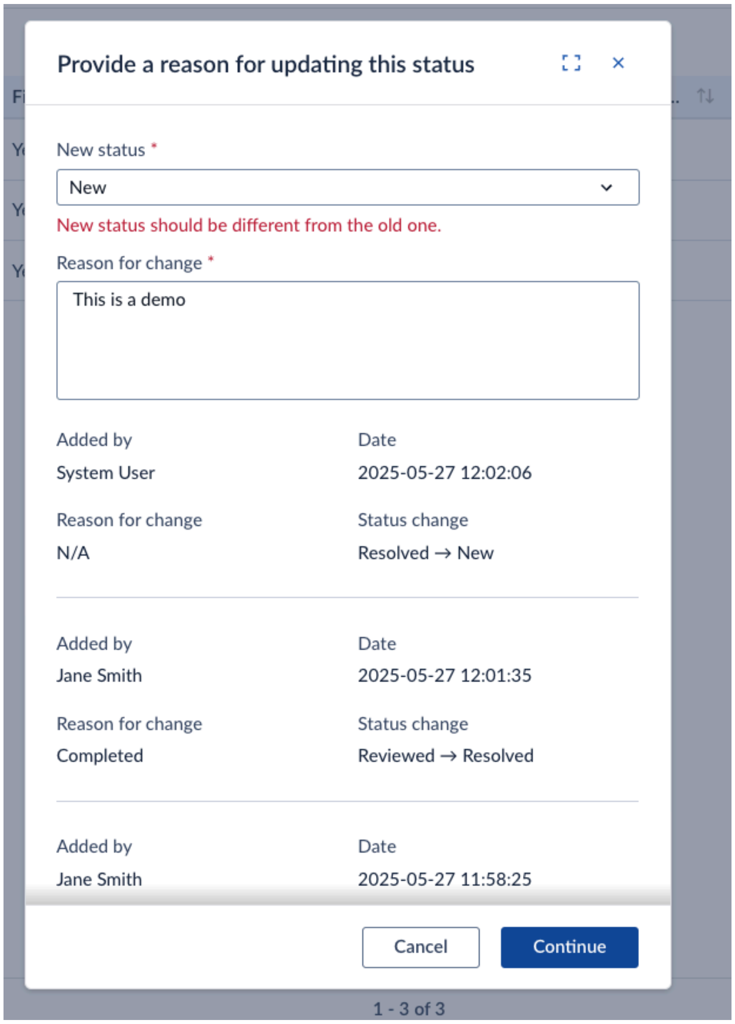
The 'Validations' sub-tab displays all active validation fields in study, repeating data instances, or surveys of the type Exclusion, Warning, and Message.



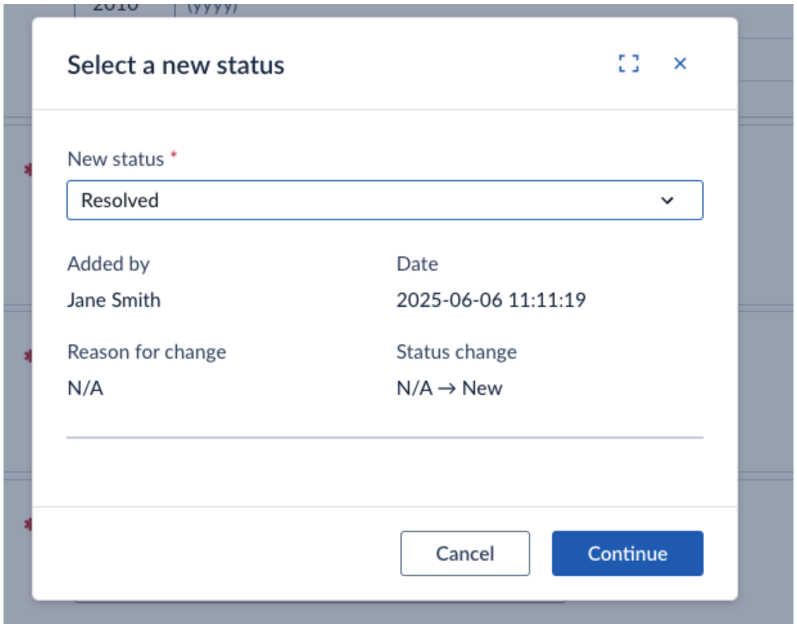
1. A user can filter validations by type (Exclusion, Warning, Message), by site to show participants with validations which belong to a particular site, by data entry type and period when the validations were triggered using the 'Filters' button.
2. An overview of all participants is given with the details 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. Validations Management

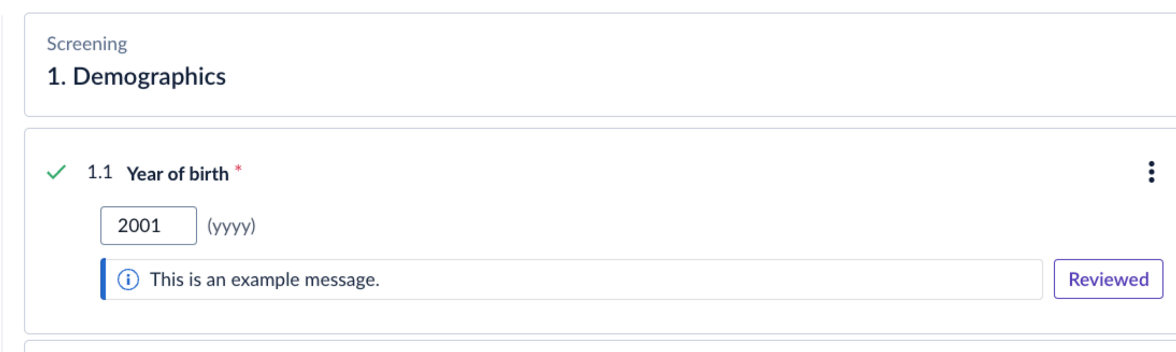
If a "Confirm validation updates" setting is enabled for the study, it will require a reason for manual validation status edits and will add a static system generated reason for any automatic changes of the validations status (i.e. when a validation is auto-closed after a value update event).
To strengthen audit traceability and compliance, users updating validation statuses in studies with the “Confirm validation updates” setting enabled will be prompted to enter a mandatory reason for change.
This reason is logged in the Audit Trail.



For system-triggered status changes, the static note "Automatically updated by the system" is recorded automatically. For studies where the “Confirm validation updates” setting is disabled, the status updates can be completed without inputting a reason.



Users can update the status of Information and Warning Validations directly within the CRF views in modern Data Entry, eliminating the need to switch to the Validations overview. If the user does not have 'Validations' permissions, the status button will be read-only. If Monitoring is disabled, then this will not show in Data Entry.



Status changes are permission-based, logged in the Audit Trail, and reflected instantly across all views with confirmation toasts. If Monitoring is not enabled for the study, validation statuses remain read-only. This update streamlines workflows for data managers and monitors by reducing clicks and context switching.

Audit trail

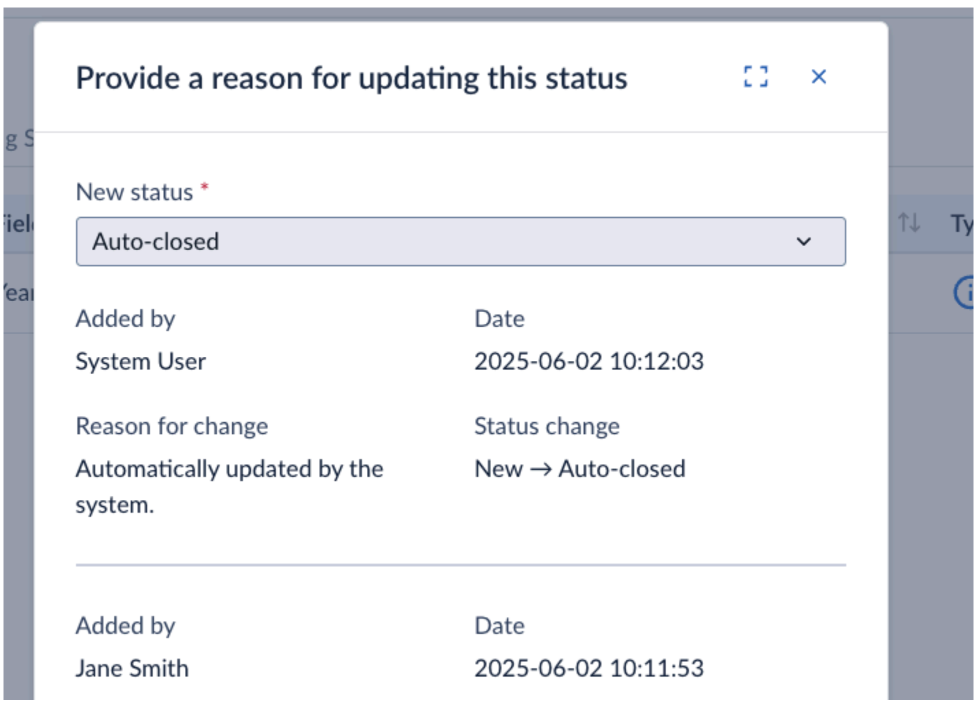
Filters 1

Date	Performed by	User role	Participant ID	Event type	Old value	New value
27 May 2025 12:10:29	System User (emai	—	110003	Validation status updated	reviewed	auto-closed
27 May 2025 12:10:17	Jane Smith (alexan	—	110003	Validation status updated	new	reviewed

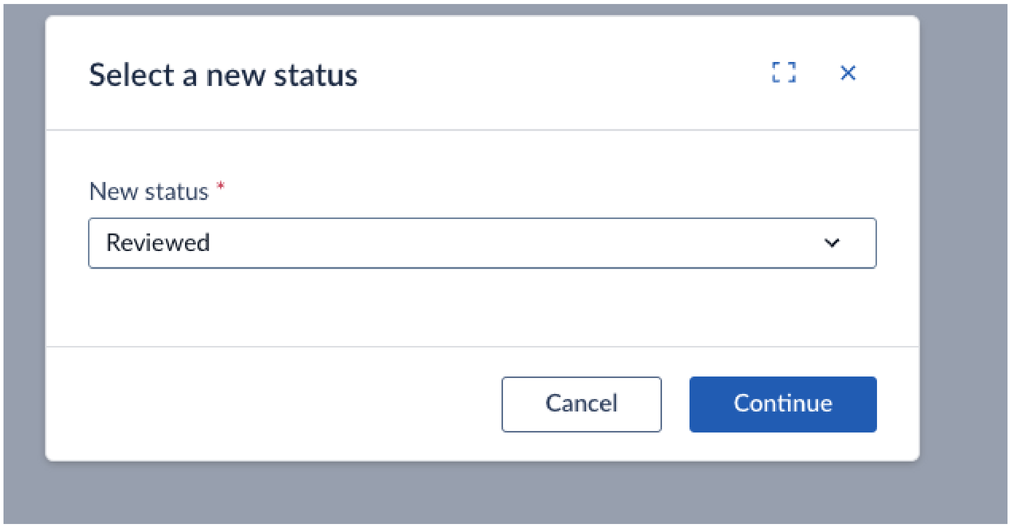
Applicable only for studies which are using the updated Validations logic (CDMS v2024.4.0.0):

Validation status updates include a full change history within the status update modal. Users can view the status change history including who made each change, when it was made, and the reason for it, if the “Confirm validation updates” setting is enabled. For studies without the setting enabled, reasons are omitted or marked as “N/A.”

Entries are listed from newest to oldest, providing transparency and auditability directly within the workflow.



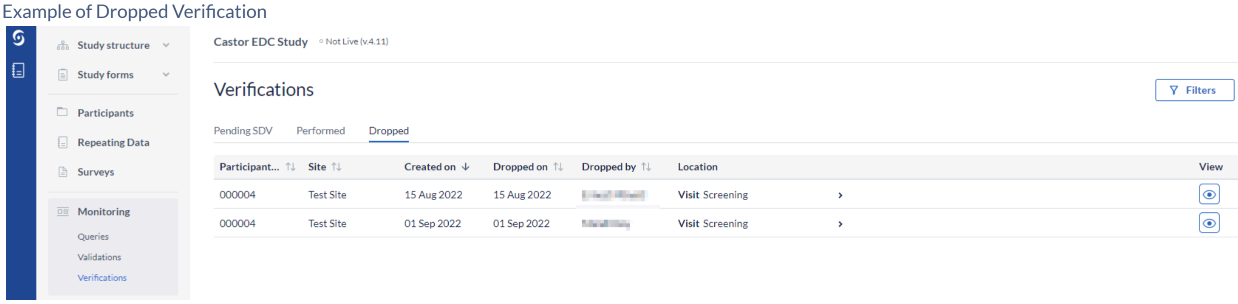
For studies that have not adopted the new Validations logic, the validations status change flow remains as before. Only some visual changes apply.



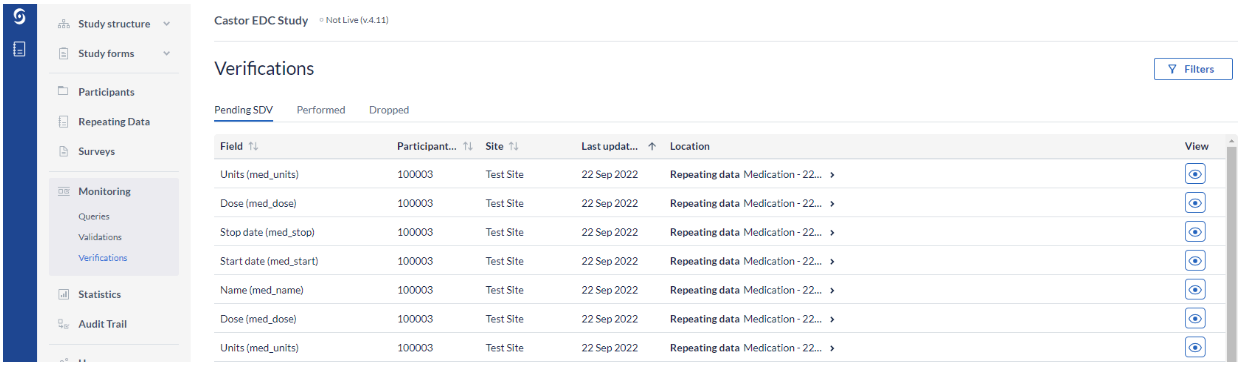
12.4. Verifications

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

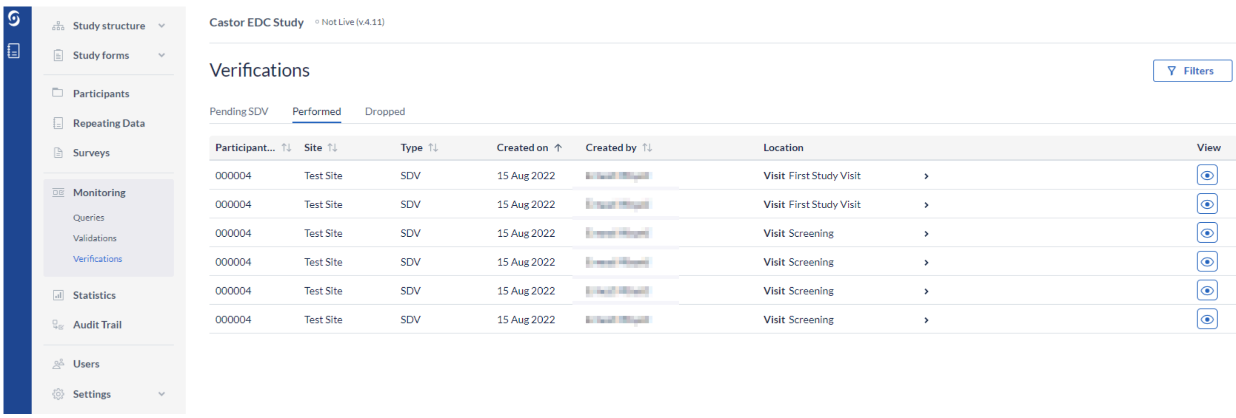
Example of Dropped Verification



Example of Pending Verification



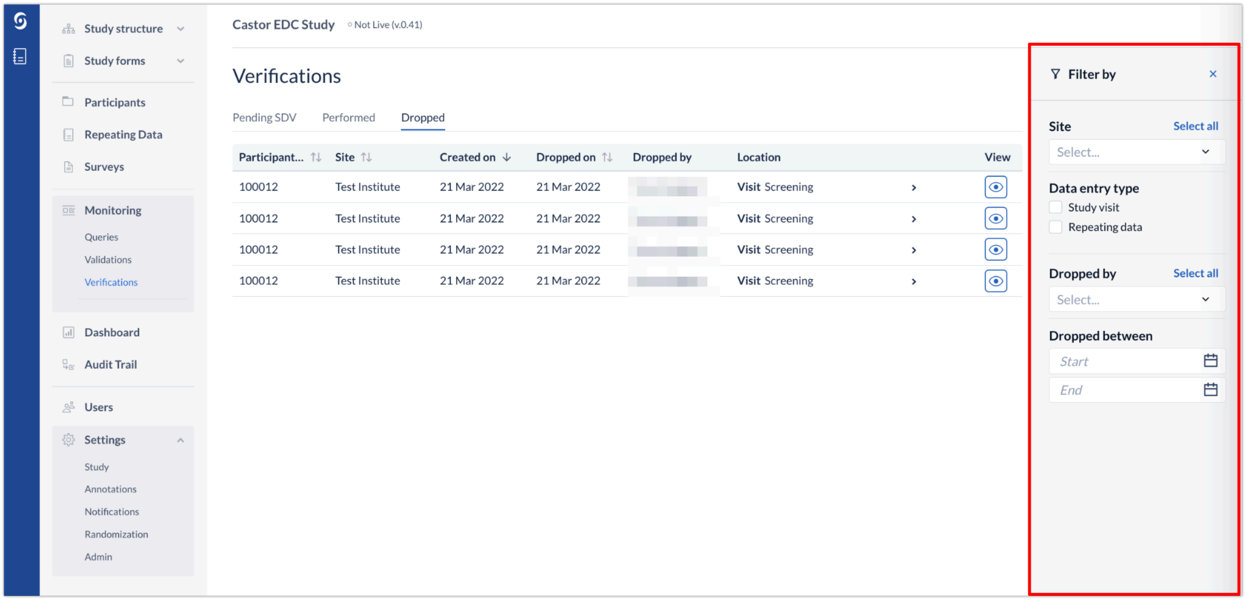
Example of Performed Verification



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.



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

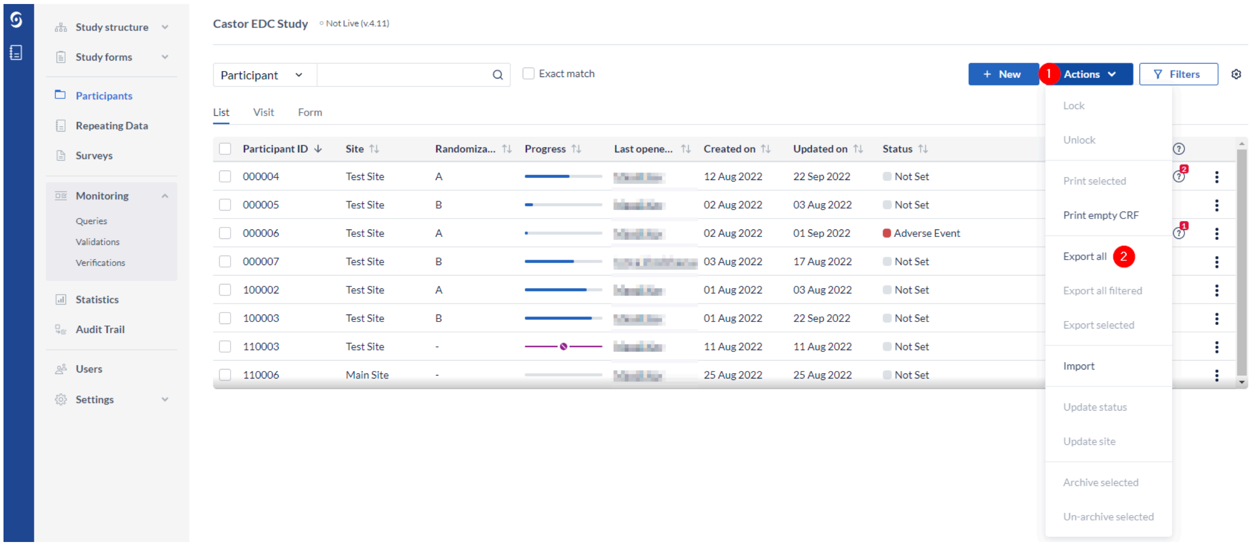
Data can be exported in SPSS, SAS, Excel, and CSV formats.

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.

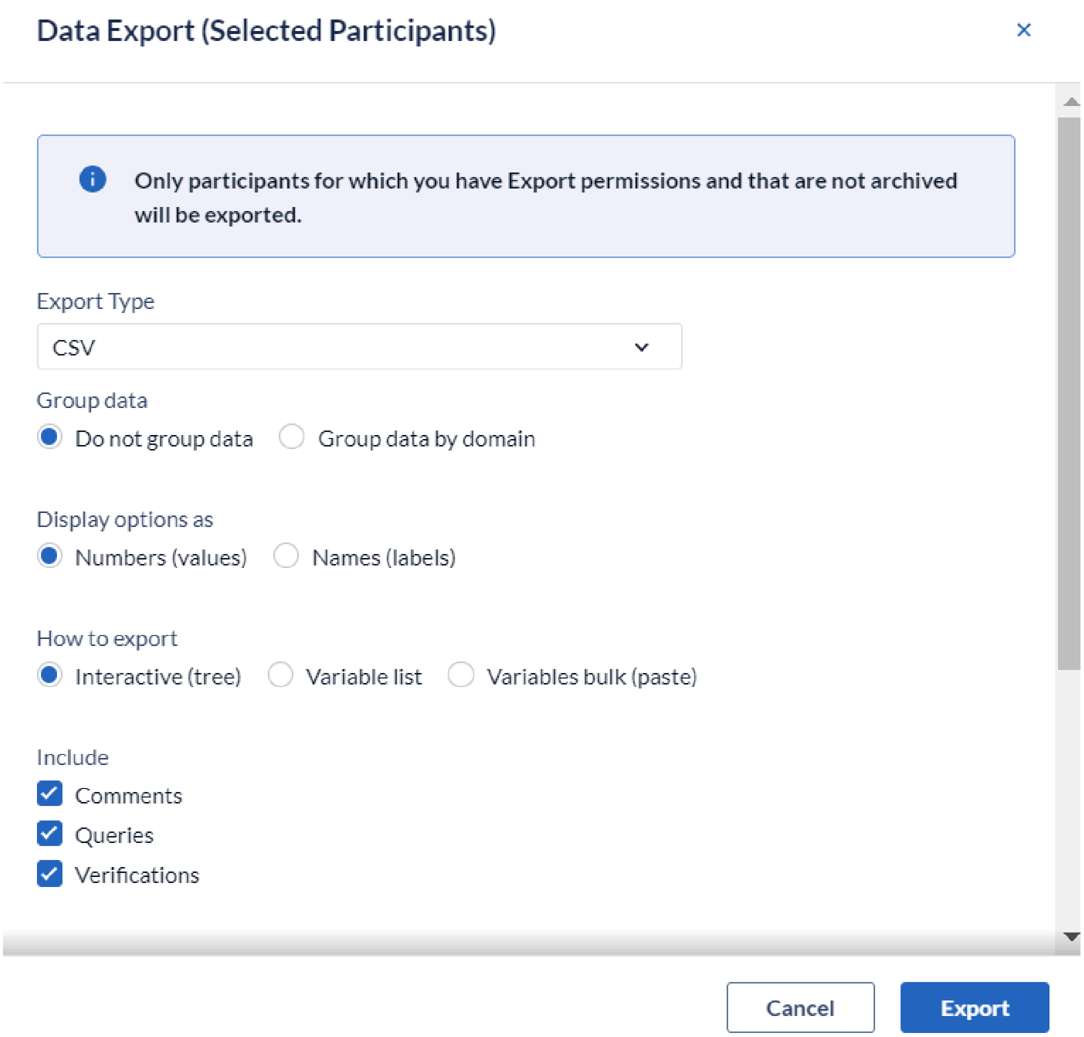
13.1. How to export data

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:



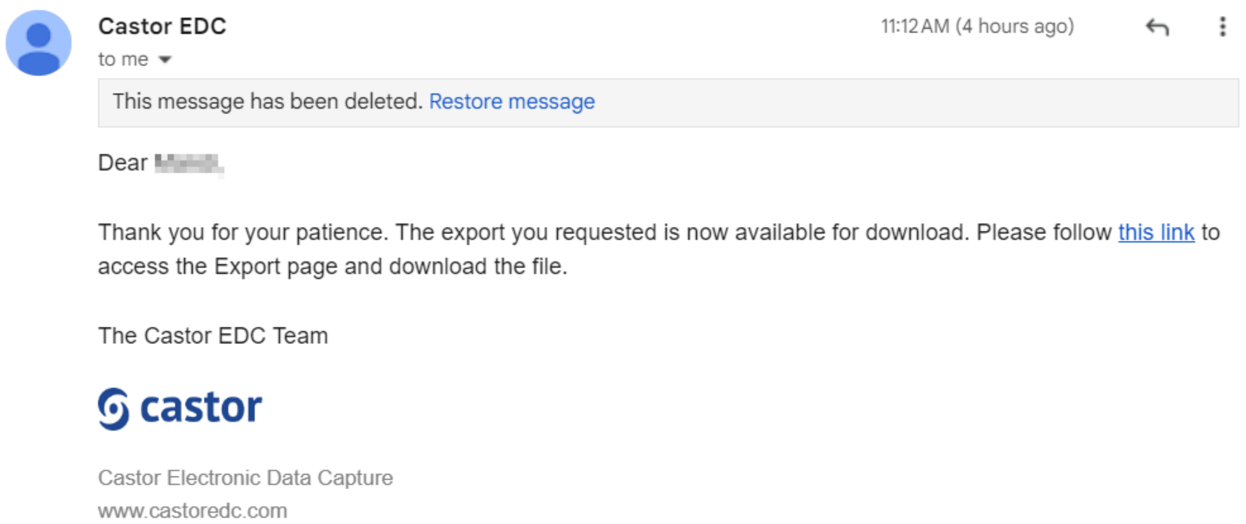
3. A 'Data Export' dialog window will appear:



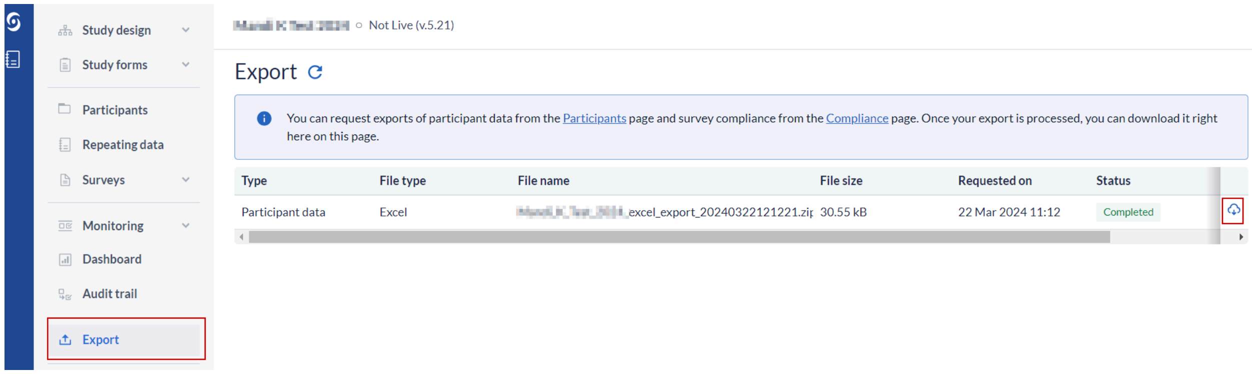
1. Select the file format you want to export your data in. You can choose between CSV, Excel, SPSS and SAS (SAS XPT or SAS 7BDAT) or CDISC-ODM formats. You also have the option to download all uploaded files in the 'Upload file field' in your study by selecting 'Uploaded files (to zip-file)'.
2. In case you select a CSV or SAS file type, an option is presented to ‘Do not group data’ (default) or ‘Group data by domain’.
3. 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.
4. Select between exporting the certain parts of the study, variable list or specific variables (only CSV and Excel formats).
5. 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.

6. 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.
7. Click Export to export your data.
8. 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 datasets 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.

When data is grouped by domain, the exported file format follows the following structure, with one line per Visit/Repeating Data instance/Survey instance:

- Participant Id
- Participant Status
- Site Abbreviation
- Randomization Id
- Randomization Group
- Randomized On
- Participant Creation Date
- Visit name
- Visit number (as set on the Study Structure page)
- Type (Visit, Repeating data, Survey)
- Name (of the Visit, Repeating data, Survey)

vs

Participant Id	Participant Status	Site Abbreviation	Randomization Id	Randomization Group	Randomized On	Participant Creation Date	Visit name	Visit number	Type	Name	bmi	height	hr	weight
120001	Not Set	GGWC				2024-03-19 11:06:17	Screening	1	Visit	Screening	23.5	167		65.4
120001	Not Set	GGWC				2024-03-19 11:06:17	Second Study Visit	2	Visit	Second Study Visit	21.9	167	75.3	61.1
120001	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Visit	Follow-up			65.6	
120001	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #1			68.7	63.1
120001	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #2			85.9	78.4
120001	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #3			59.5	76.6
120002	Not Set	GGWC				2024-03-19 11:06:17	Screening	1	Visit	Screening	30.52	166.7		84.8
120002	Not Set	GGWC				2024-03-19 11:06:17	Second Study Visit	2	Visit	Second Study Visit	28.7	166.7	81.6	79.7
120002	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Visit	Follow-up			77	
120002	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #1			76.2	79
120003	Not Set	GGWC				2024-03-19 11:06:17	Screening	1	Visit	Screening	21.56	176.4		67.1
120003	Not Set	GGWC				2024-03-19 11:06:17	Second Study Visit	2	Visit	Second Study Visit	21.9	176.4	85.8	68.3
120003	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Visit	Follow-up			76.3	
120003	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #1			67.9	62.1
120004	Not Set	GGWC				2024-03-19 11:06:17	Screening	1	Visit	Screening	20.5	162.3		54
120004	Not Set	GGWC				2024-03-19 11:06:17	Second Study Visit	2	Visit	Second Study Visit	20.2	162.3	78.3	53.1
120004	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Visit	Follow-up			86.8	
120004	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #1			58.8	68.8
120005	Not Set	GGWC				2024-03-19 11:06:17	Screening	1	Visit	Screening	24	157.6		59.6
120005	Not Set	GGWC				2024-03-19 11:06:17	Second Study Visit	2	Visit	Second Study Visit	24.0	157.6	81.9	59.7
120005	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Visit	Follow-up			91.3	
120005	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #1			65.7	79.4
120005	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #2			85.1	61.9
120006	Not Set	GGWC				2024-03-19 11:06:17	Screening	1	Visit	Screening	22.07	183		73.9
120006	Not Set	GGWC				2024-03-19 11:06:17	Second Study Visit	2	Visit	Second Study Visit	21.4	183	71.7	71.7
120006	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Visit	Follow-up			69	
120006	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #1			78.9	55.8
120006	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #2			65.3	57.4
120007	Not Set	GGWC				2024-03-19 11:06:17	Screening	1	Visit	Screening	21.93	188.6		78
120007	Not Set	GGWC				2024-03-19 11:06:17	Second Study Visit	2	Visit	Second Study Visit	11.7	188.6	65.1	41.7
120007	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Visit	Follow-up			70.1	
120007	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #1			62.2	69.5
120008	Not Set	GGWC				2024-03-19 11:06:17	Screening	1	Visit	Screening	24.11	172.1		71.4
120008	Not Set	GGWC				2024-03-19 11:06:17	Second Study Visit	2	Visit	Second Study Visit	23.6	172.1	71.2	69.8
120008	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Visit	Follow-up			75.9	
120008	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #1			63.9	70.8
120008	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #2			79.3	86.3
120009	Not Set	GGWC				2024-03-19 11:06:17	Screening	1	Visit	Screening	18.14	171.9		53.6
120009	Not Set	GGWC				2024-03-19 11:06:17	Second Study Visit	2	Visit	Second Study Visit	18.1	171.9	60.8	53.5
120009	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Visit	Follow-up			84.1	
120009	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #1			88.9	71.4
120009	Not Set	GGWC				2024-03-19 11:06:17	Follow-up	3	Repeating data	Unscheduled Visit #2			68.5	81.2

- All dates (field values & metadata) are exported in YYYY-MM-DD hh:mm (date and time), or YYYY-MM-DD (date) format.
- Checkboxes are exported in the [domain variable name]_[option name] format, with a value of 1 representing a checked option, and 0 representing an unchecked option.
- Number and date fields are exported in the [domain variable name]_number and [domain variable name]_date format.
- Grid fields are exported in the [domain variable name]_[row name]_[column name] format.
- Row and column names are cut off at 15 characters.
- Data marked as missing is handled the same way as our other exports.
- Form blinding permissions are taken into account while exporting data. In case the user is blinded, the related cells are empty in the export.
- View randomization permissions are taken into account while exporting data. Only randomization information from sites where a user has View randomization permissions for, are included in the export.
- In case variable names are generated, they are limited at 64 characters.
- A field variable list is added per domain ([domain abbreviation]_variablelist.[filetype]).

- If the user does not have decrypt permissions for the site the participant is assigned to, the encrypted value will be exported as *encrypted*.

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