# Castor

## Castor EDC Data Entry User Guide

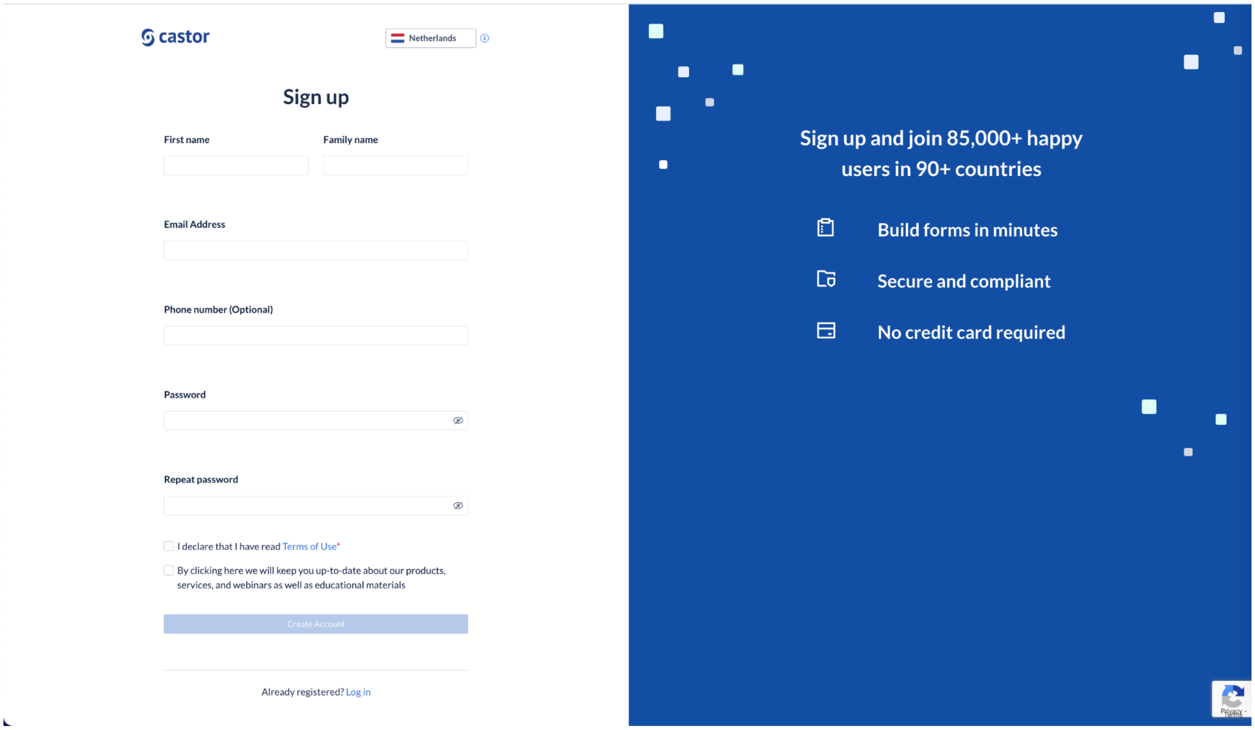
Version 2021.6

## 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:



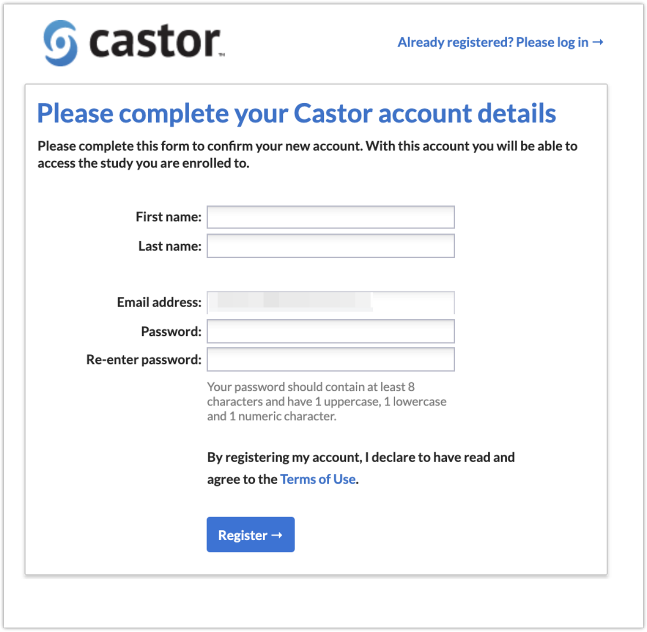

- EU Account: https://data.castoredc.com/register
- UK Account: https://uk.castoredc.com/register
- US Account: https://us.castoredc.com/register
- AU Account: https://au.castoredc.com/register

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

## 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:

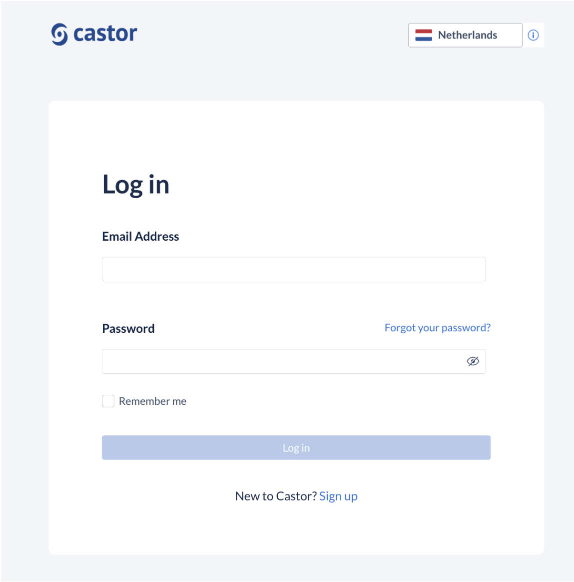



1. Fill in first and last name(s).
2. The email address will be pre-filled, choose a strong password, consisting of at least 8 characters, one uppercase letter, one lowercase letter and a number.
3. Click on 'Register'. Shortly after registering a user details, an email with an activation link will be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

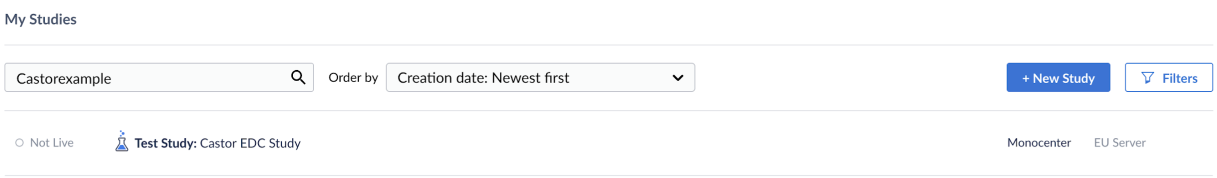
To access the study, log into Castor EDC via https://data.castoredc.com. If your study is on the US, AU or UK server, you can also directly go to https://au.castoredc.com/register, http://us.castoredc.com or http://uk.castoredc.com, respectively.

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’.

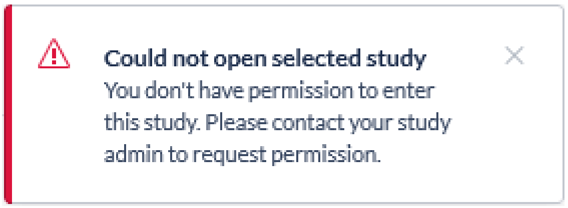


# 3. Open a study

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.



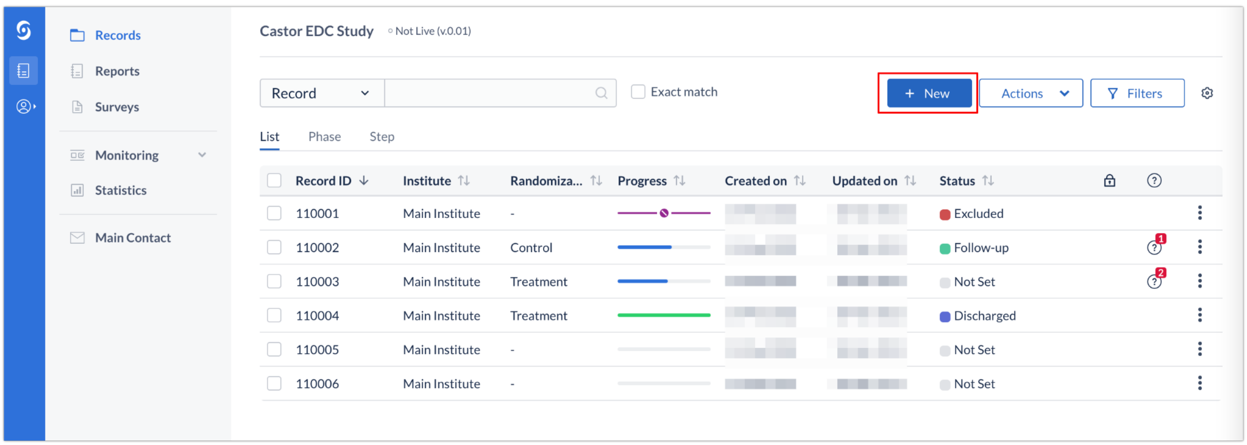

Trying to open a study that is not live will show the following warning:



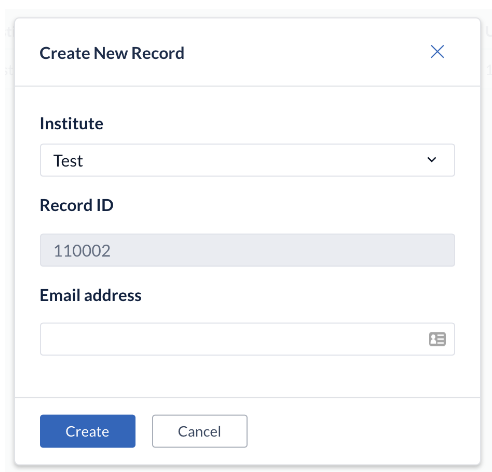

If the study is still in maintenance mode (the button is blank, and the status says ‘Not Live’) a user will only be able to open the study if a user has management rights.

# 4. Add/Open a record for data entry

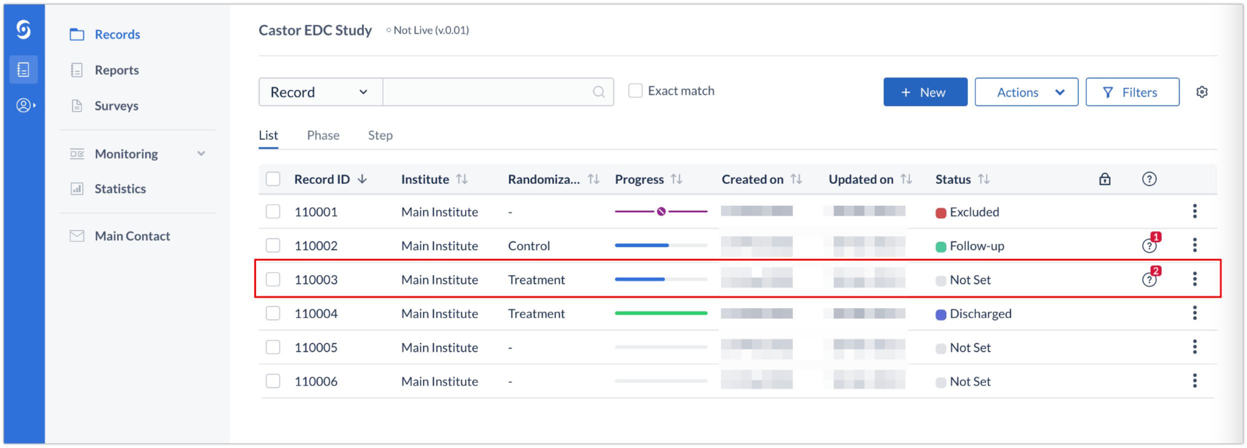
Once a user enters the study, a user will see a list of all records available based on their access level . To add a new patient to the database, a user will need to create a new record. Creating new records must be done from the Records tab), by clicking on the “+ New" button.




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

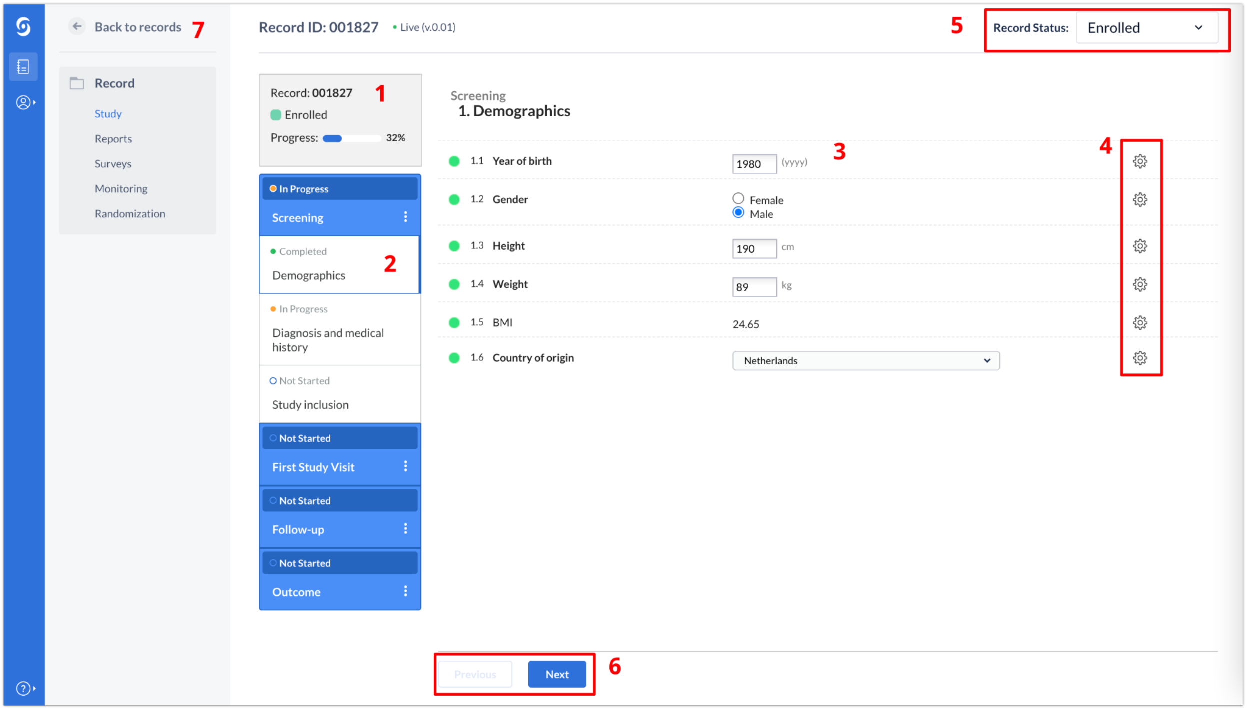


To open a previously created record, double click the row the record is on.



# 5. Doing data entry

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




It consists of the following elements:

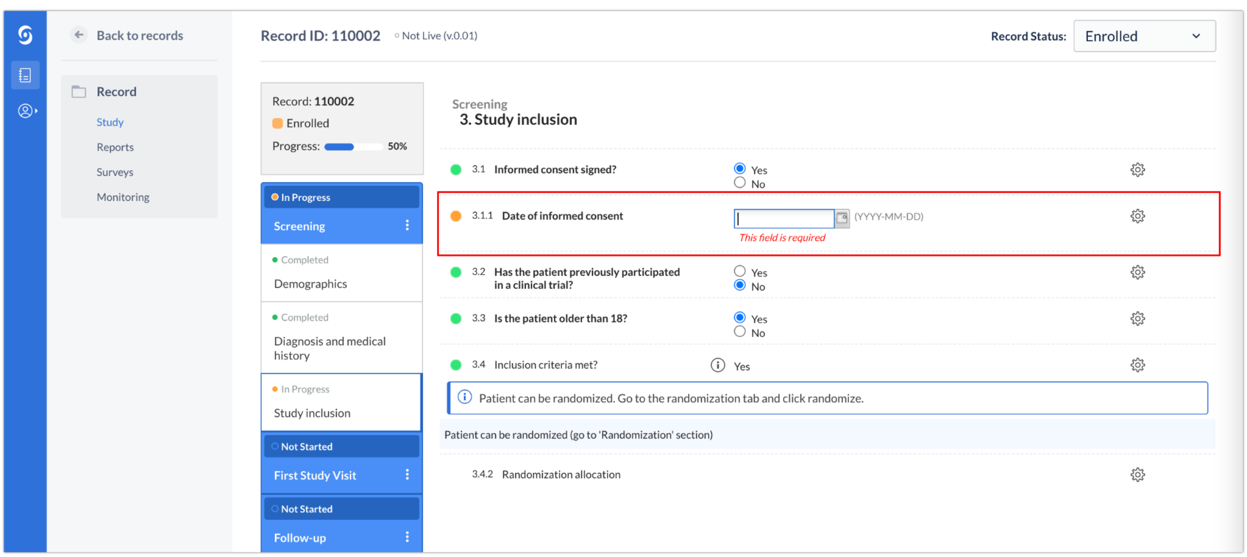
1. Record ID, progress of completion, and Record status.
2. An overview of the study forms (phases and steps of the study). Phases consist of steps and each step contains a set of questions. A user can click on the step of interest in this panel to start entering the required data. Once a user answers 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 forms (steps).
4. Each field is accompanied by a cogwheel menu, containing options for each record. 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 record 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 step 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 record and return to the record list, click on the 'Back to records' 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.

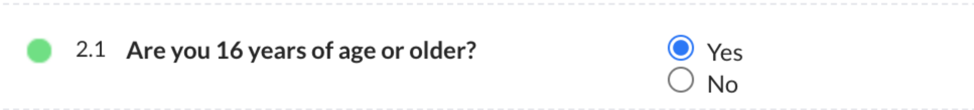
Some fields will appear only under certain conditions. In the example below, question 3.1.1 is shown only because question 3.1 is answered with 'Yes'.



### 5.1.1 Status icons

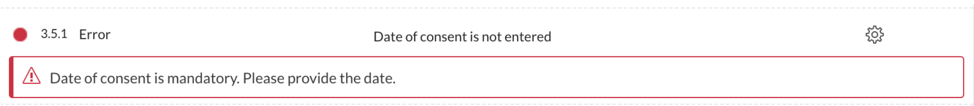
Shown to the left of each question is the status icon, which indicates whether the question has been answered (green) or not answered (orange). Where there is a problem with the provided answer, the icon will turn red and a red warning message will appear to provide more information about the problem.

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

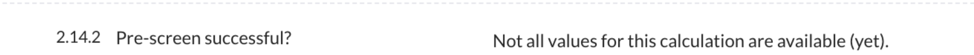



*Orange* Data is required and no input has been entered yet. For example, field 2.3:


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

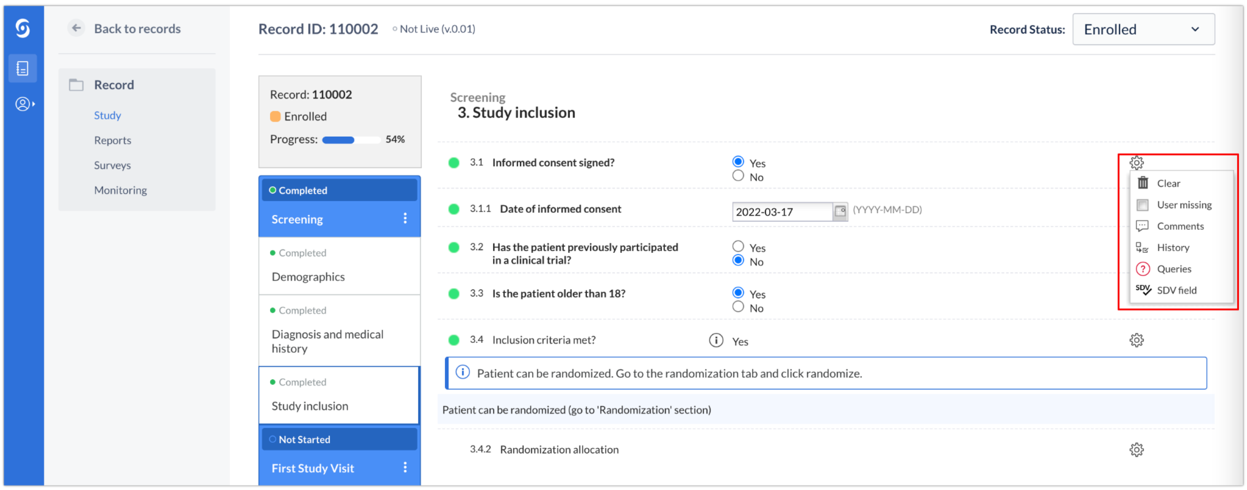



*No icon* Data entry is not required and no input has been entered yet.

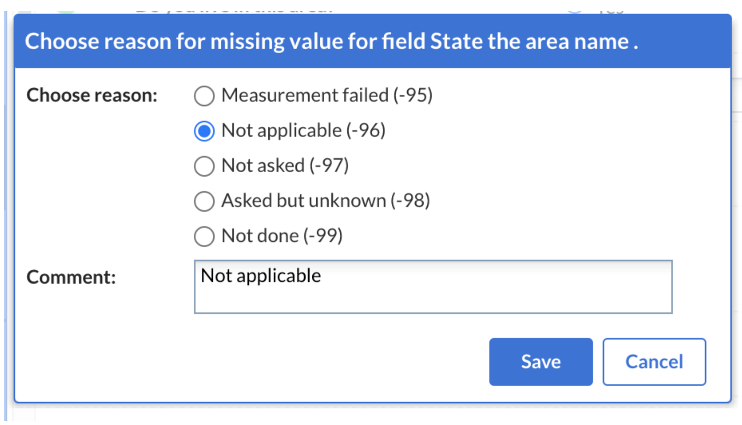


## 5.1.2 Additional options

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

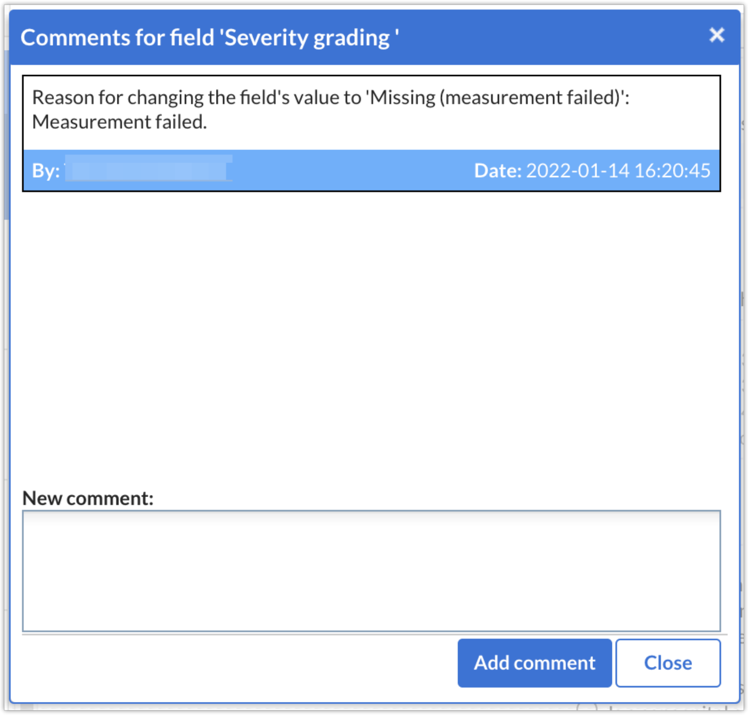



- To clear the value already entered for a field, press ‘Clear’.
- If data is not available for a question, tick the ‘User missing’ box. A window will open to ask the user to provide the reason why the data is missing:



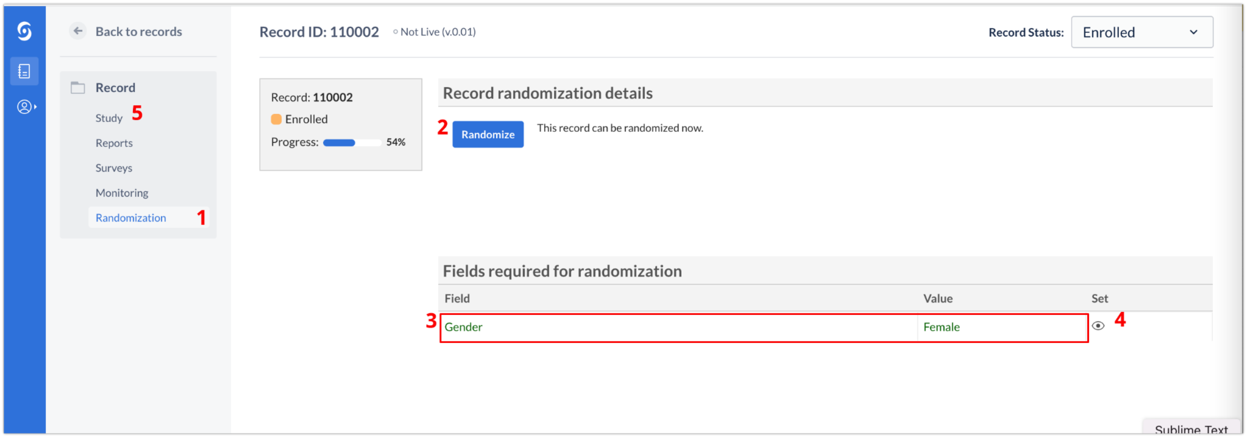

- Select the appropriate option and if necessary, add a comment. Click Save to store the option and return to the question list. The field marked as ‘User Missing’ will be grayed out in the list and marked as ‘Completed’.

- 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":



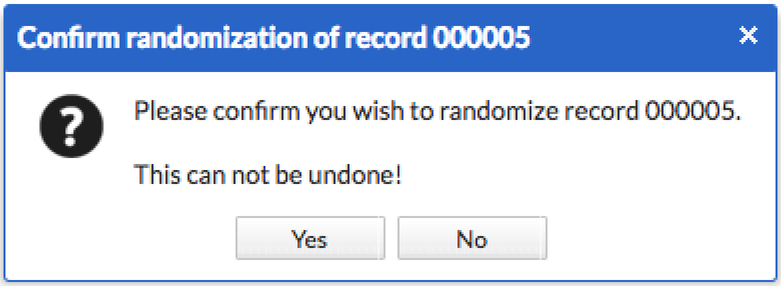
## 5.1.3 Randomize a record

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

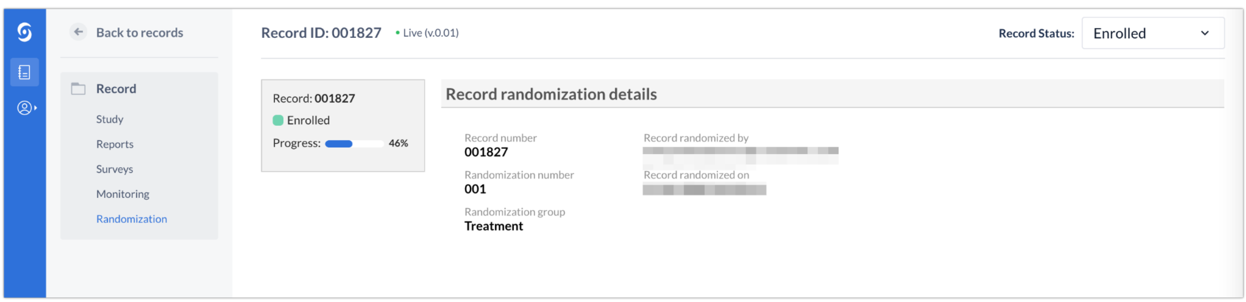



1. From the record overview, select the 'Randomization' sub-tab.
2. Click the 'Randomize' button to randomize the record.
3. Fields required for randomization are summarized in the lower right of the tab.
4. If the required fields for randomization have not been completed, click the eye icon ( ) to be taken to the required field in the CRF.
5. Click on the 'Study' tab to return to the study forms after the record has been randomized.

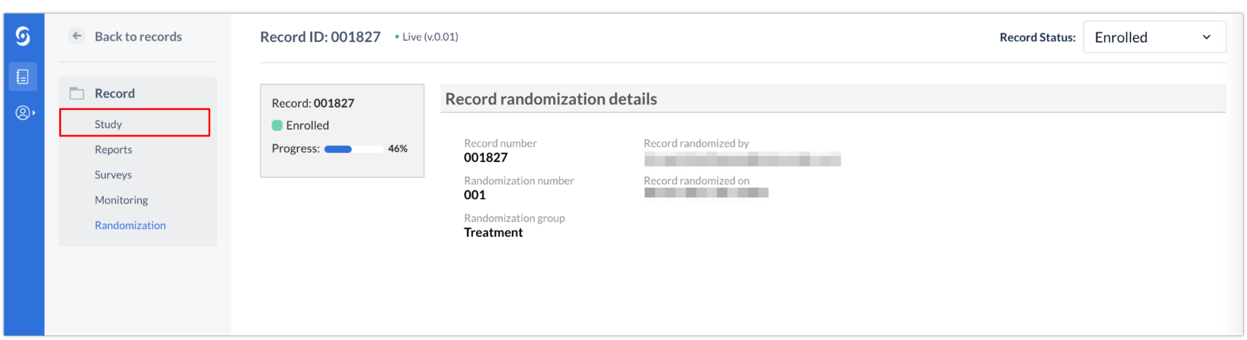
A window will appear and ask to confirm the randomization, advising that randomization cannot be undone once confirmed.



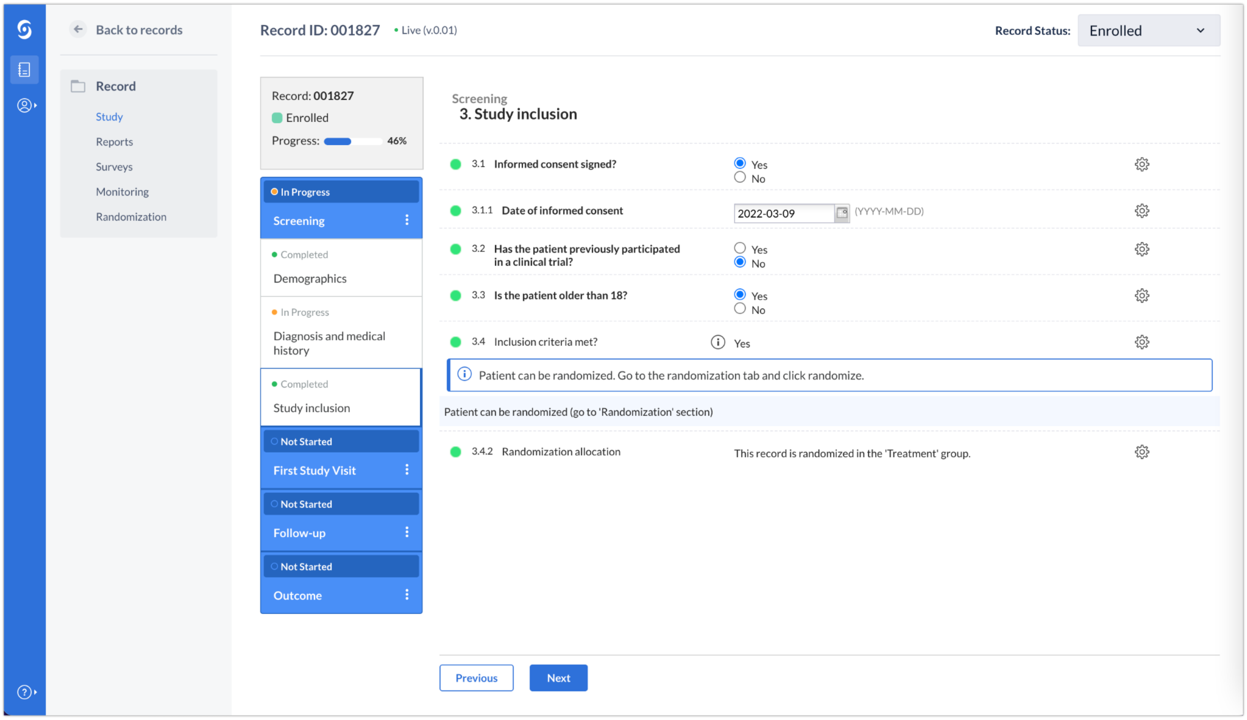

The randomization tab will now display the randomization group and the randomization number and other relevant information. This tab is only visible for users with randomization rights.



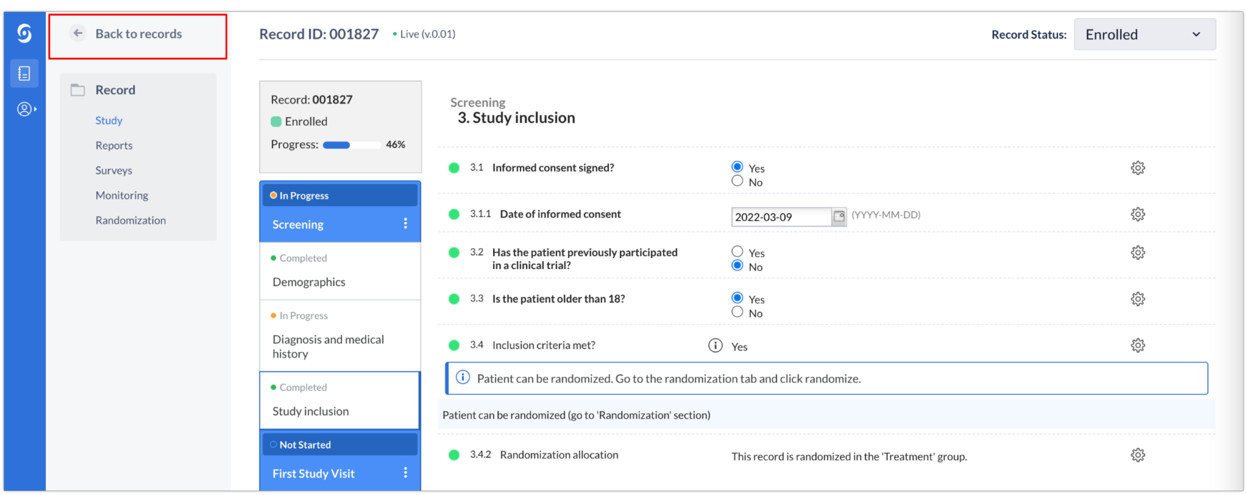

After randomizing a record, to continue the data entry, click on the 'Study' button:



This will open the data entry overview for this record:



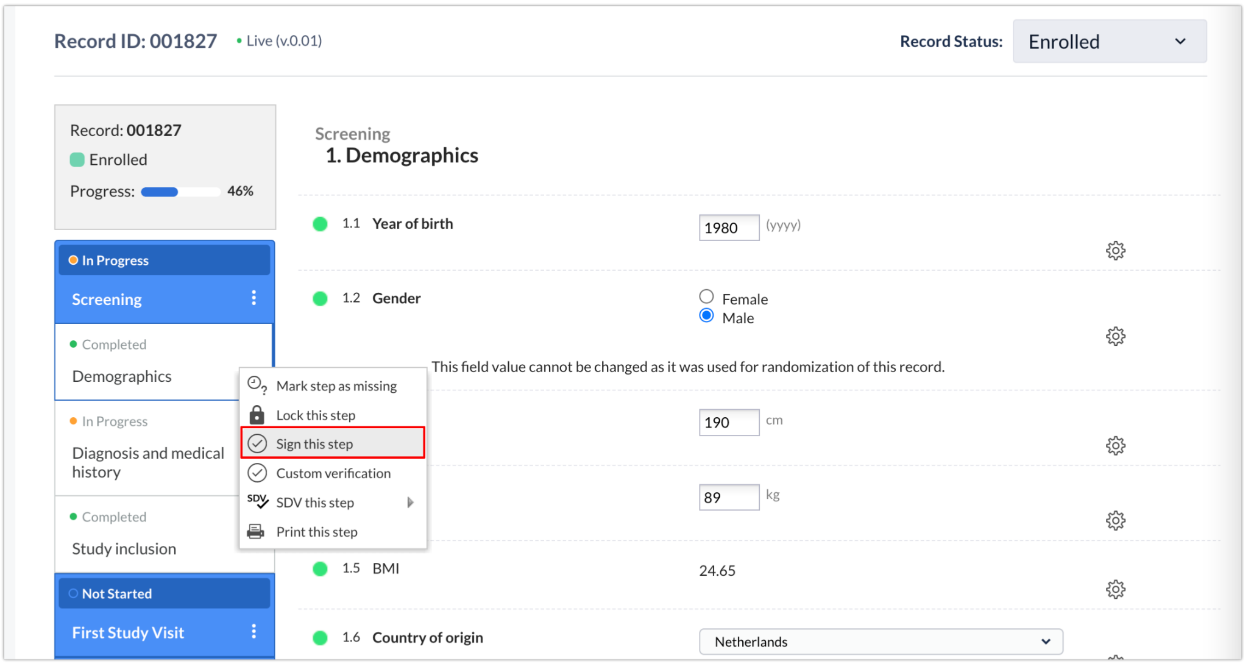

To get back to the global Records tab with an overview of all Records, click the ‘Back to records’ button:




This will open the global ‘Records’ tab with all records.

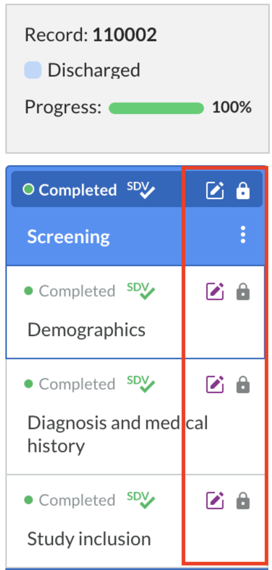
## 5.1.4 Signing and locking a step

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

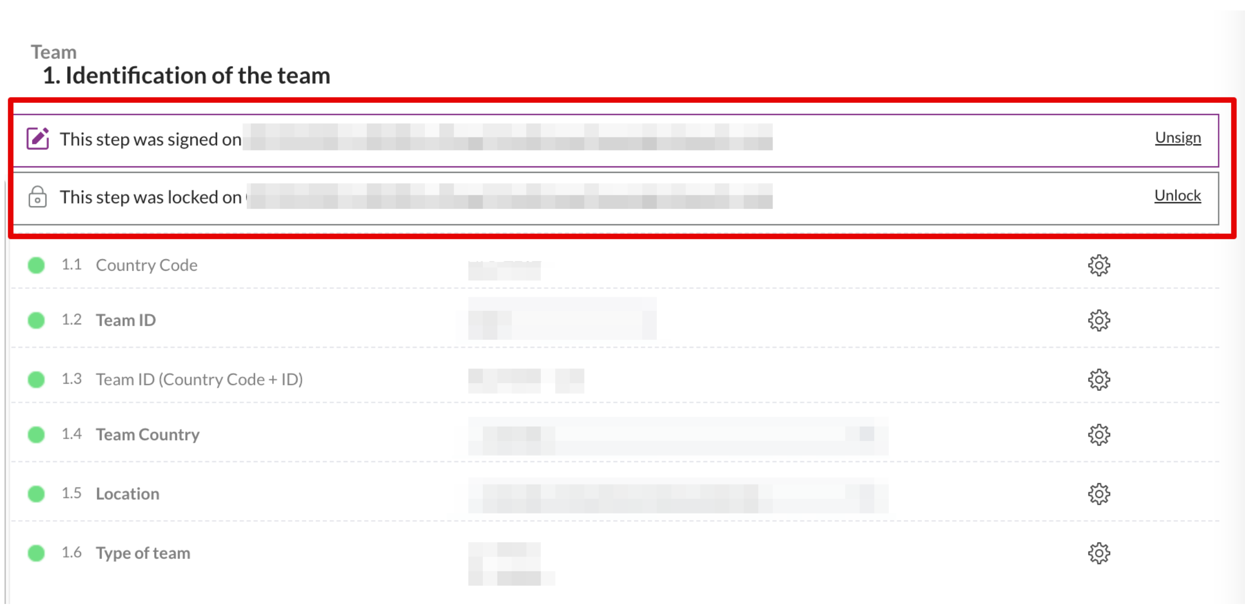



1. Hover over the right side of a step or phase with the cursor. Click on the three dots that appear.
2. Click on 'Sign this phase' for phases or 'Sign this step' for steps.
3. The user will be prompted to enter his/her email address and password to confirm their identity.
4. Click 'Sign' to confirm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

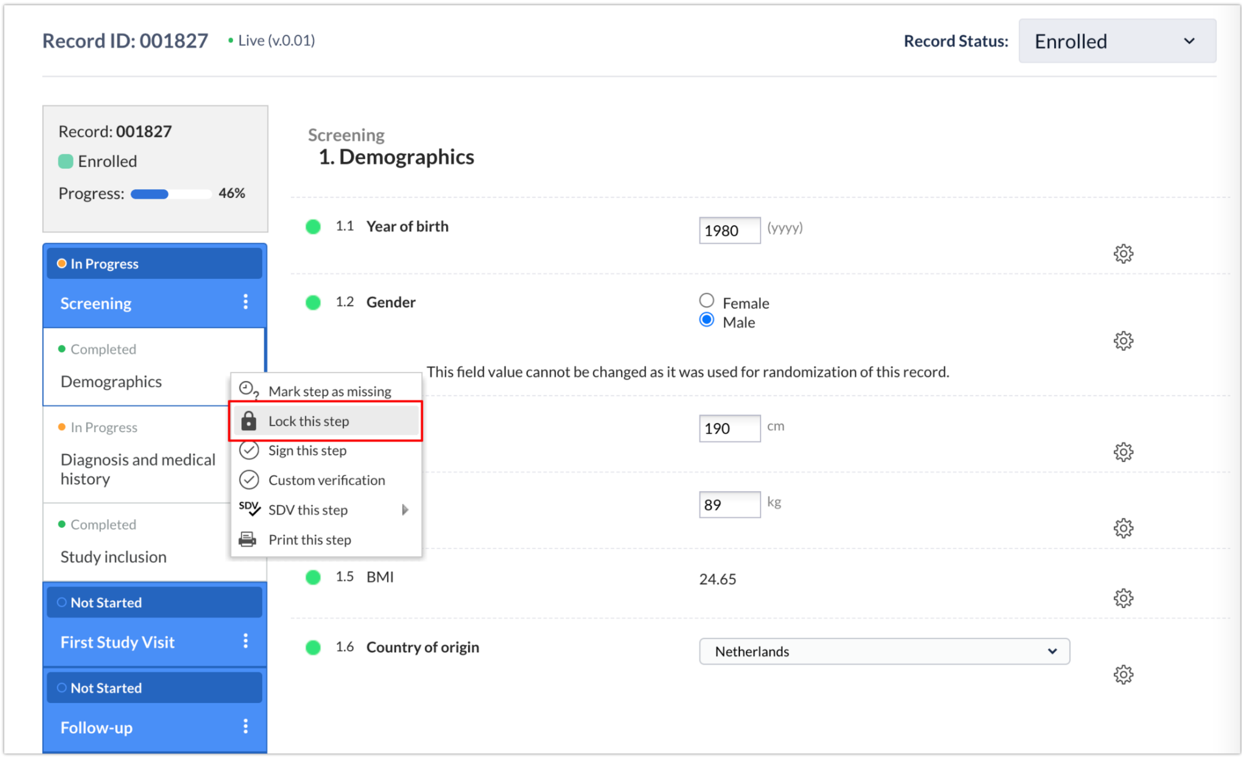
The phase or step will be updated with icons to reflect that it has been signed and/or locked:




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



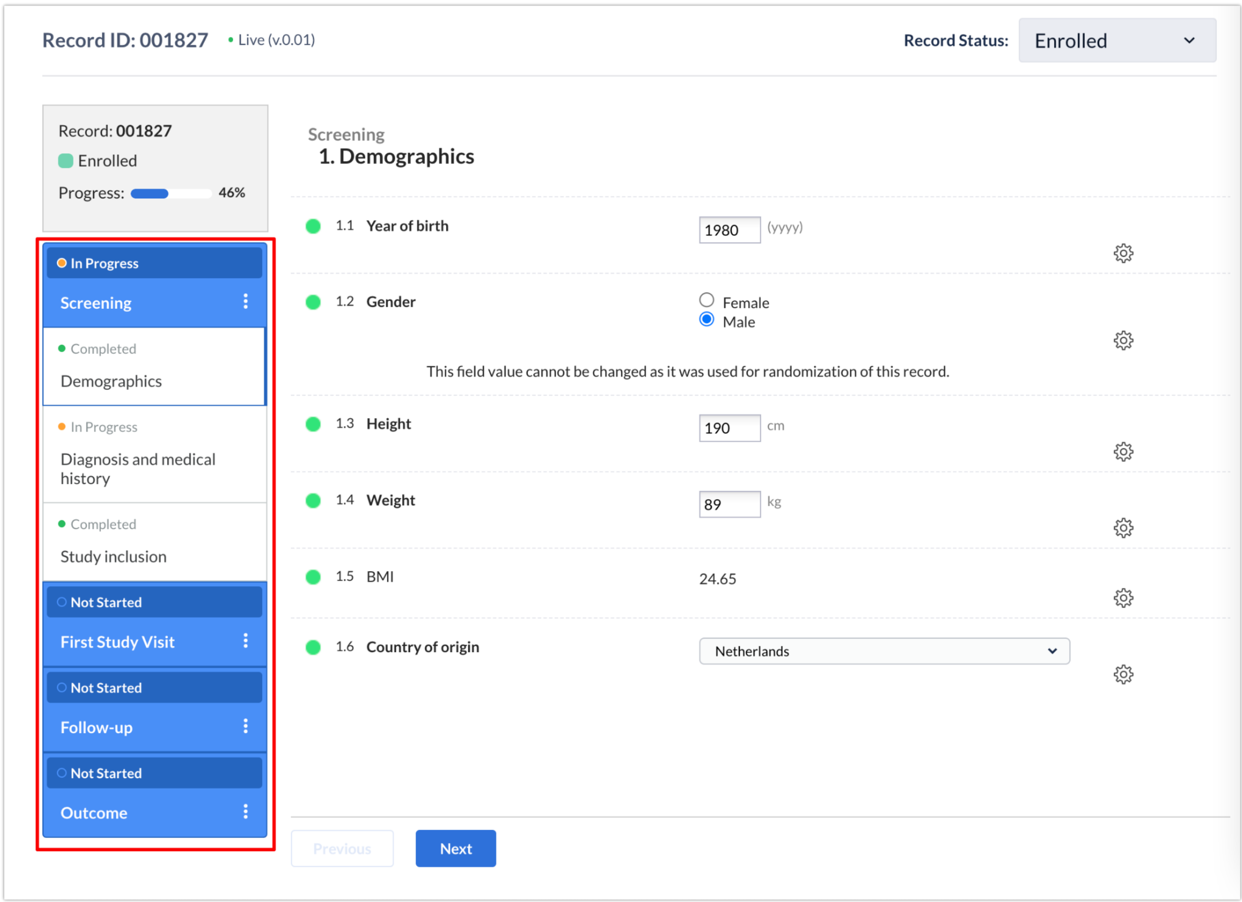
If a user has lock rights, a user can also choose to lock a phase or a step to prevent further data entry directly from the record navigation.




1. Navigate to the right side of a step or phase with a user mouse. Click on the three dots that appear.
2. Click on '(Un)Lock this phase' for phases or '(Un)Lock this step' for steps.

## 6. Record progress

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



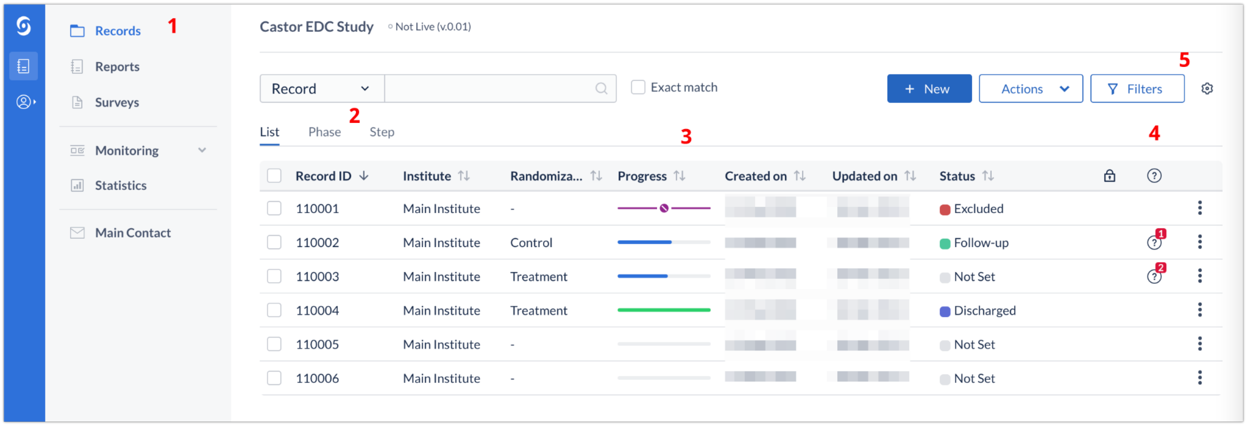

A step can have three different completion stages:

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

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

# 7. The Records tab

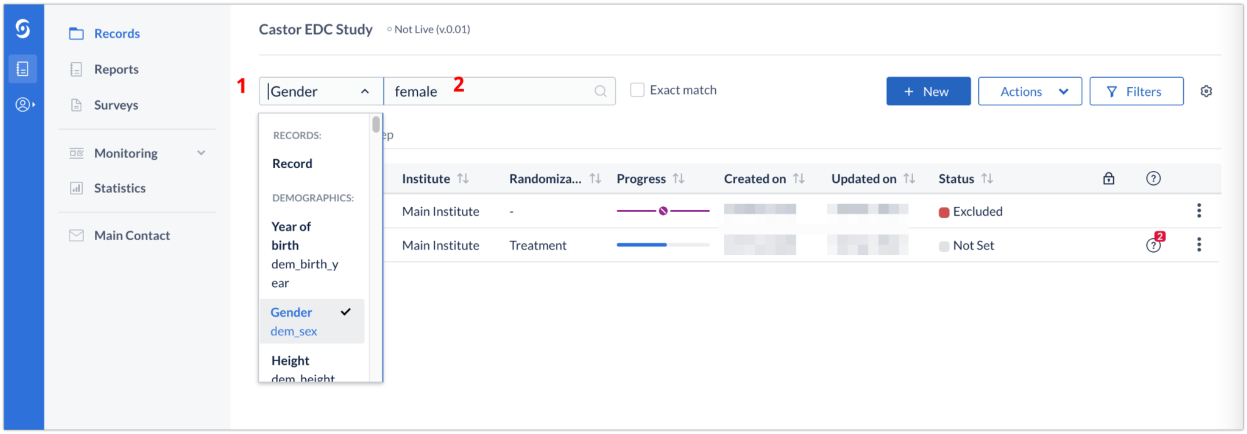
In the Records tab, a list is displayed showing all records a user has created (see Section 6). The user may also see records that have been created by other users at the institute.




1. In the 'Records' tab, a search box is available, in which you can search for a particular record 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 records by phases or steps (see section 7.2).
3. Progress: This column will show you the status of completion for each record. The same color scheme as for the steps applies (see section 6). The purple bar with a pencil icon indicates that an exclusion validation has been triggered for this record. You can double click on any record to directly access it.
4. Queries: displays the number of queries created for a record.
5. By default, all records are shown, however you can use the 'Filters' button to filter the records based on different parameters.

## 7.1. Search for data

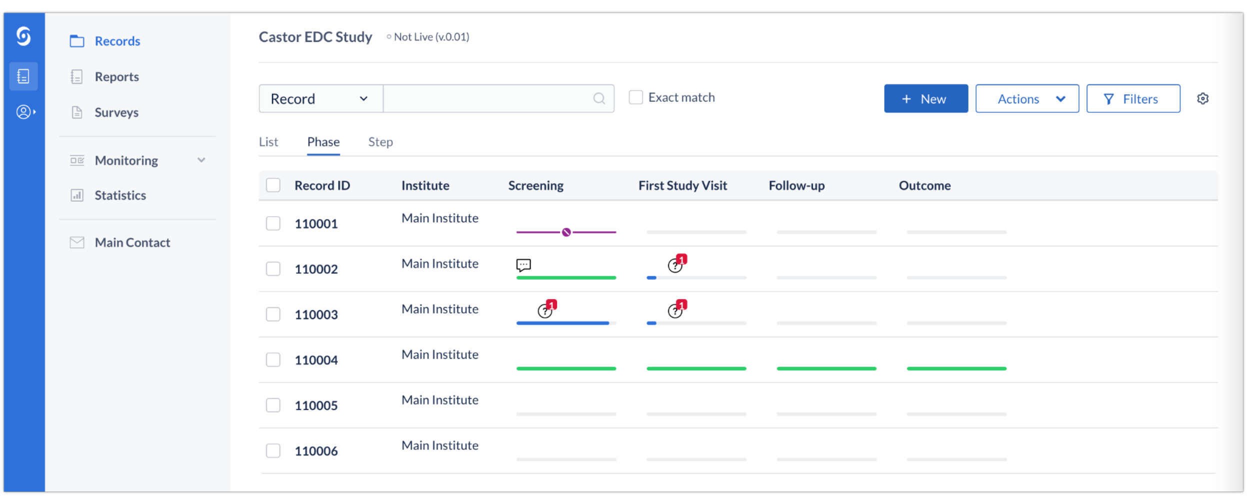
A user can use the search bar to find records that contain certain data, for example if a user wants to find the patients with a certain age at onset.




1. Click on the arrow in the right search box and find the field (question) of interest. In this example 'Please enter the barcode number' field is selected.
2. Enter the value of interest in the left search box (in this example ABC-abc-123) and all matching records will be displayed.

## 7.2. Phase/Step view

By default, the 'Records' tab displays all records in the "List" view. You can change the view mode to either Phase view or Step view.



This will show you the status of completion of each phase or step for each record by clicking on “Phase” or “Step”. The same color scheme as for the steps applies (see section 6). You can double click on any phase or  step to directly access it.

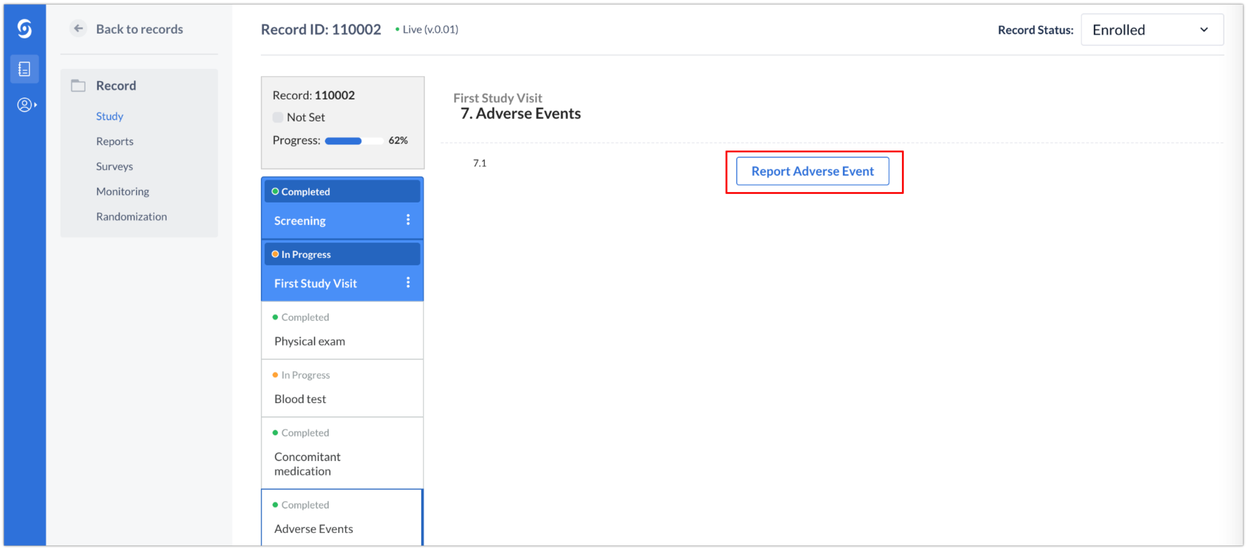
# 8. Creating Reports

Reports can be used to register adverse events (AE) and also to record any other data which is not part of the main study protocol, for instance any unexpected hospital visits or emergency surgical procedure.

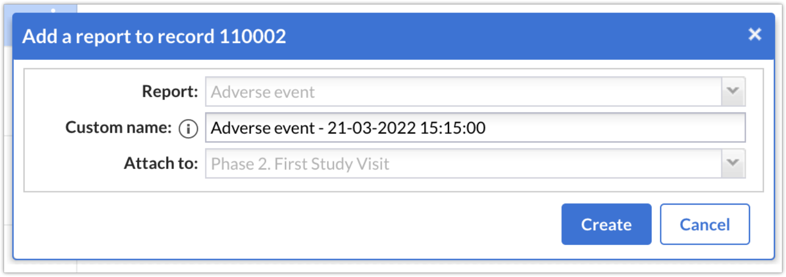
## 8.1. Adding a report

There are two ways to add a report form to a record: 1) via an Add Report button directly in a step, or 2) via the Reports tab.

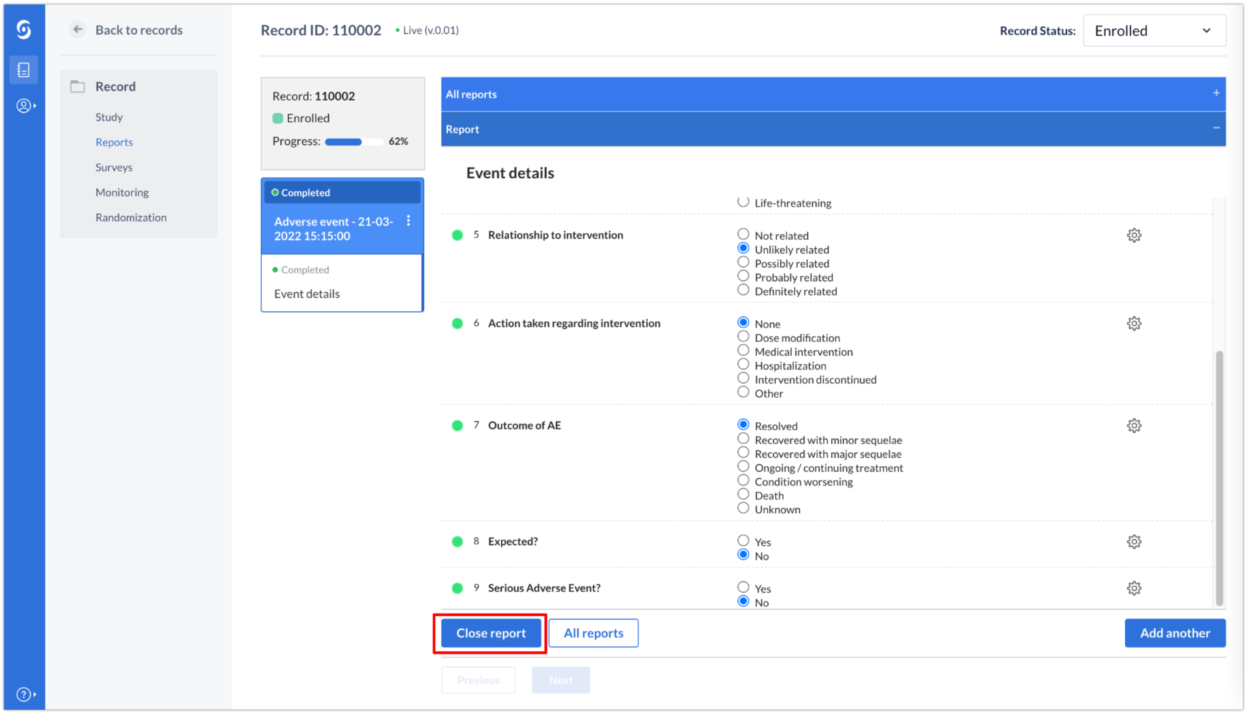
To add a report via the button, navigate to the step and click on the 'Add report button' in the relevant step. Please note that the report button might have a different name in your study:



The following dialog window will appear:

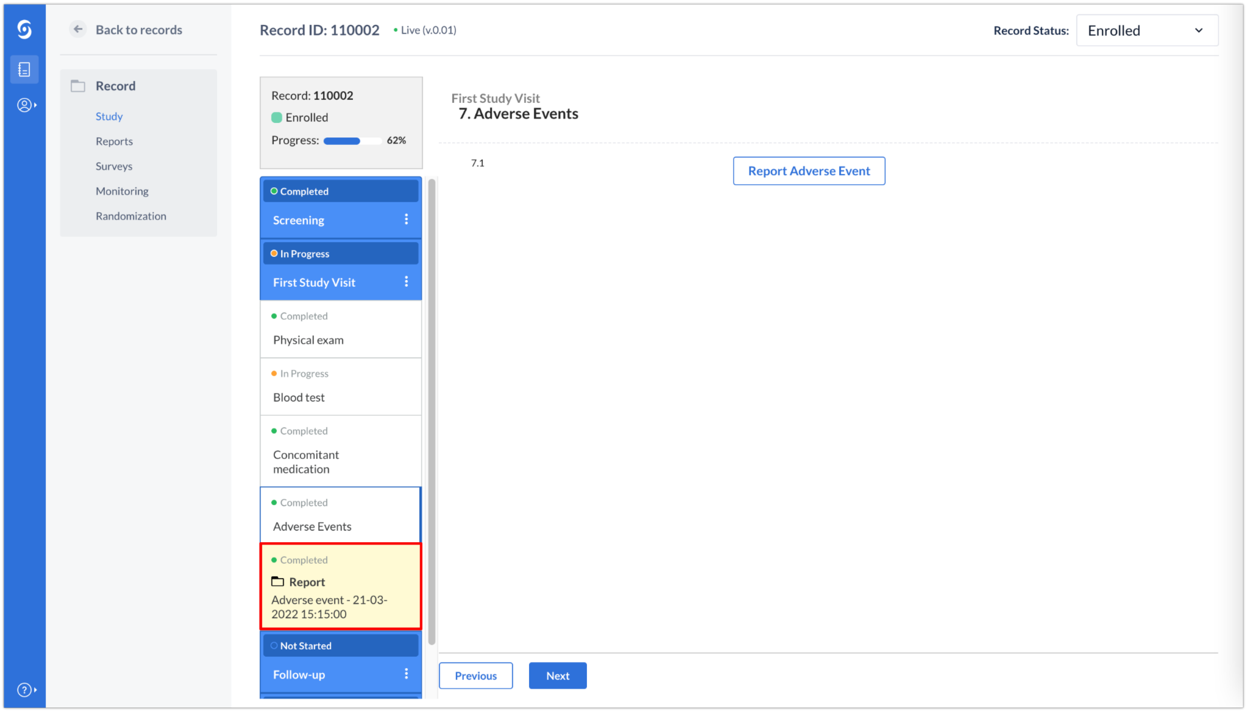



1. Report: this field contains the report type which is pre-filled
2. Custom name: Enter a custom name for the report, this is how the report will be displayed in the study and exports. In some cases, the custom name won't be editable, as the study admin can disable the option to adjust the report name.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



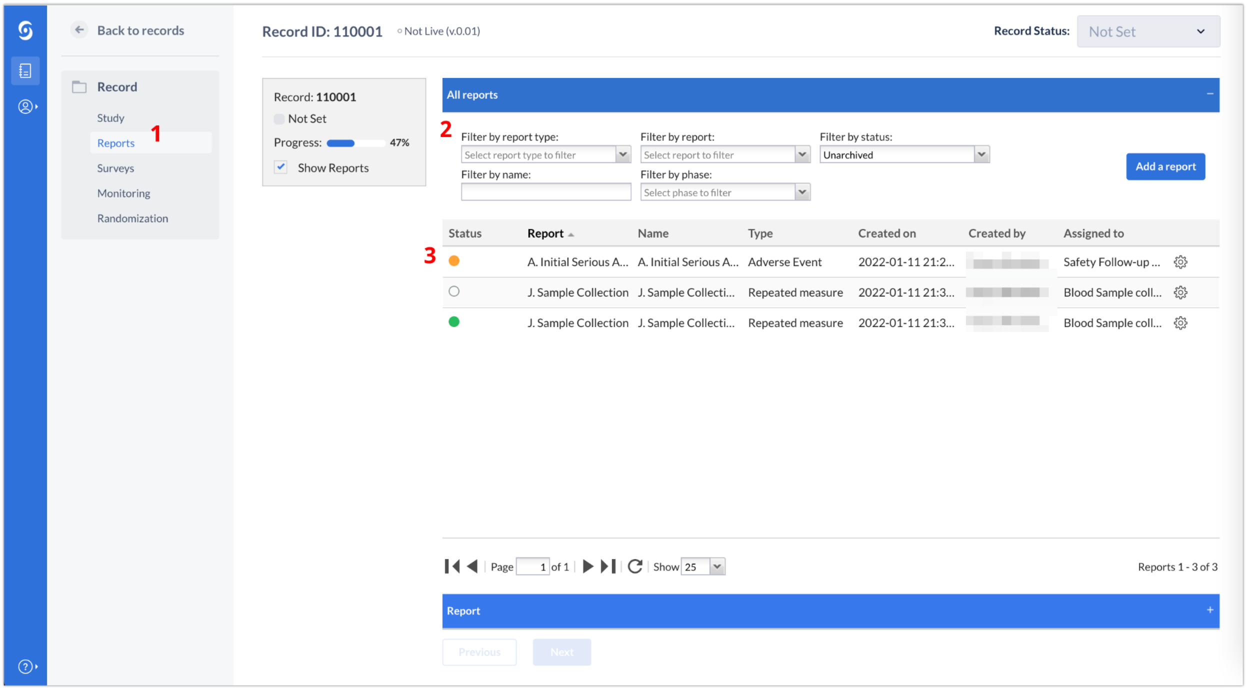
6. Once the data for a report is complete, click on the 'Close report' to return to the main study form.

The added report will be linked to the phase where this report was created:



## 8.2. Viewing the report

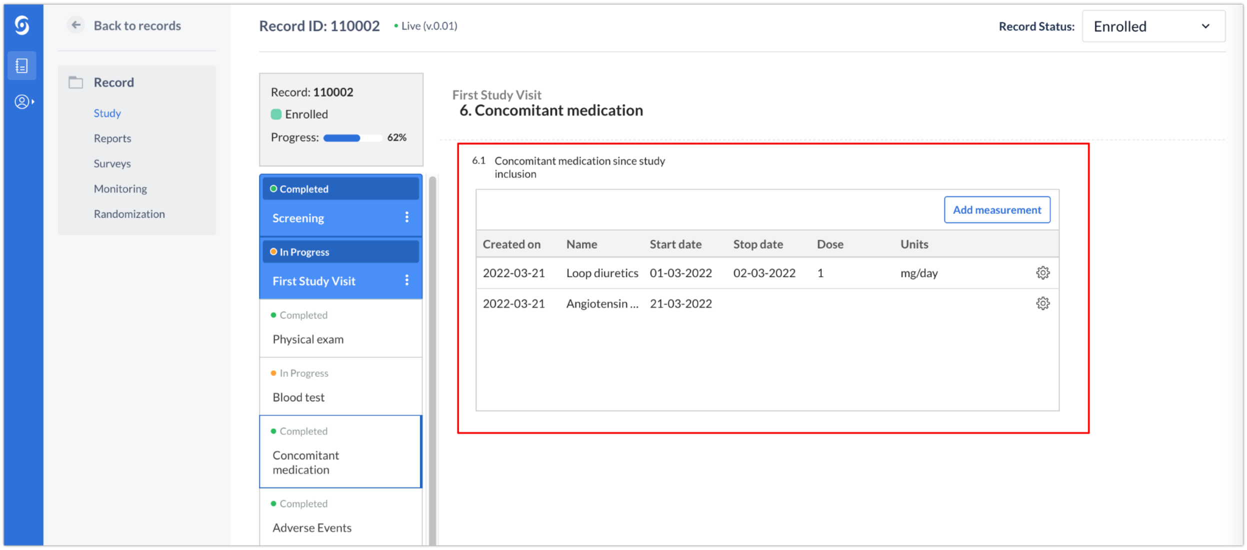
It is possible to view the reports which are attached to the record by using the 'Reports' tab:




1. Opening the record and navigating to the 'Reports' tab will display the reports overview.
2. A user can filter by report type, report type, report name, or by the phase to which a report is linked.
3. The list of reports linked to the selected record. A status indicator allows a user to see the completion status of the report.

# 9. Repeated Measures

In main data entry view, the repeated measure field looks like this:

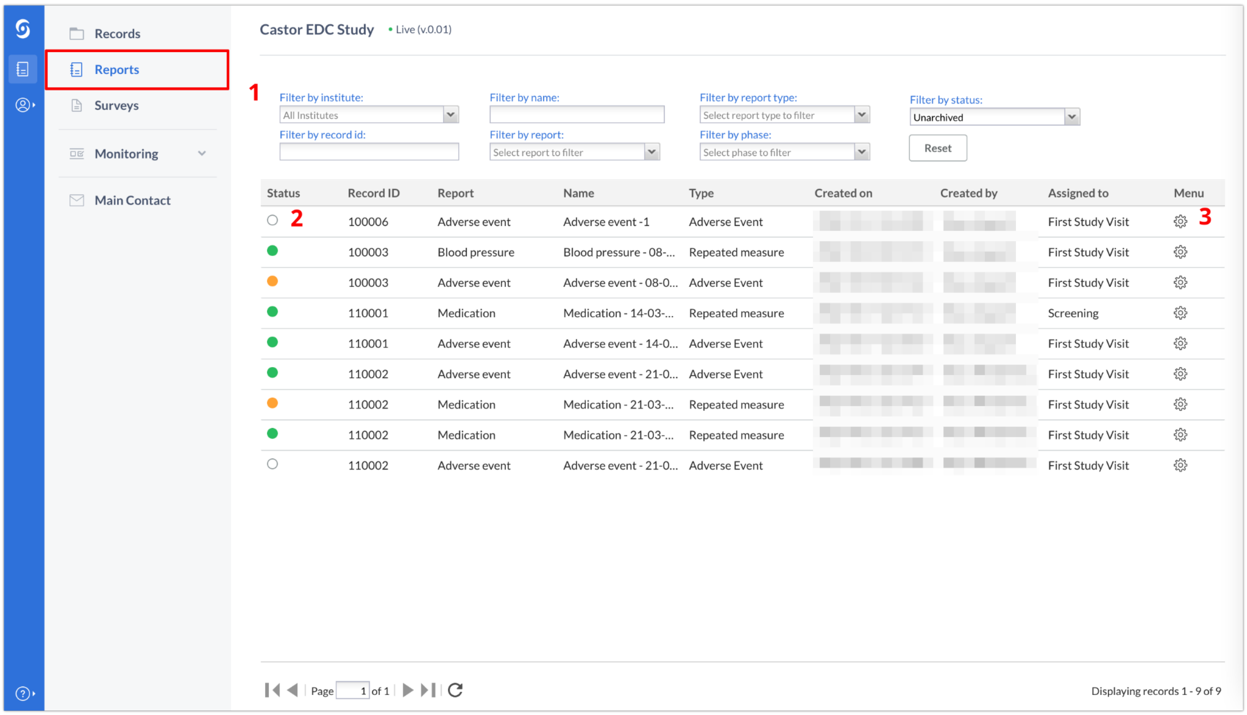



1. By selecting 'Add measurement', measurements are easily added to the form and will be shown in the form of a grid, representing each measurement as a new row and each field that is part of the repeated measure as a separate column.

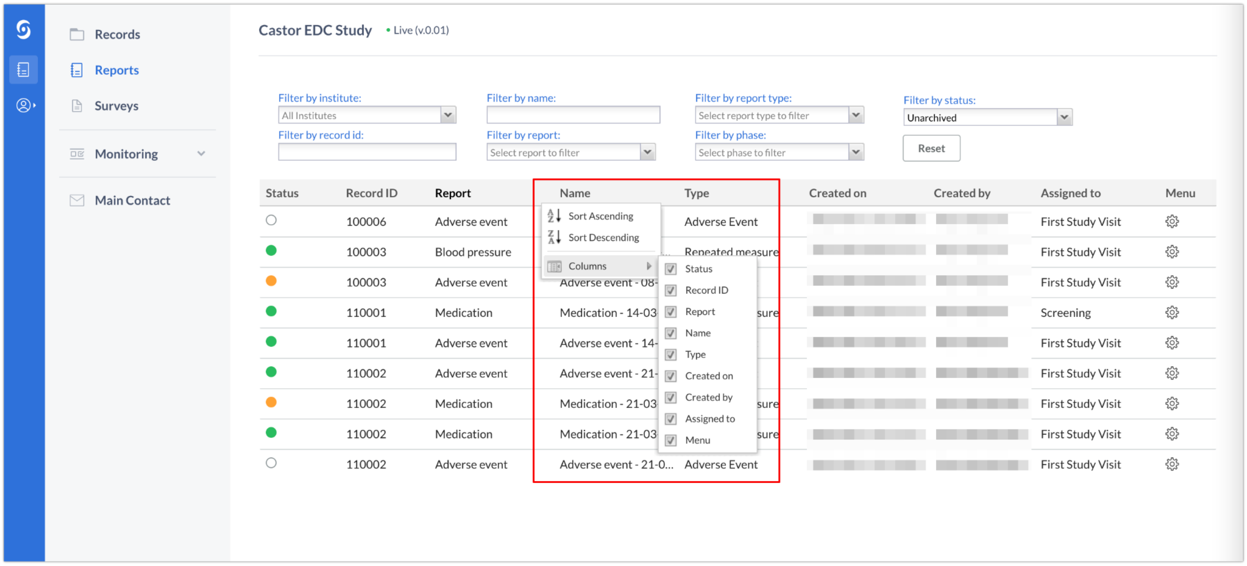
2. Each measurement will be saved as a new report and will appear in the 'Reports' tab and will be attached to the phase (or report) where the repeated measure field is located.

# 10. The global Reports tab

In the 'Reports' tab, an overview of all the reports within the study is shown. A user can only see reports from records that belong to an institute for which they have "View" rights:

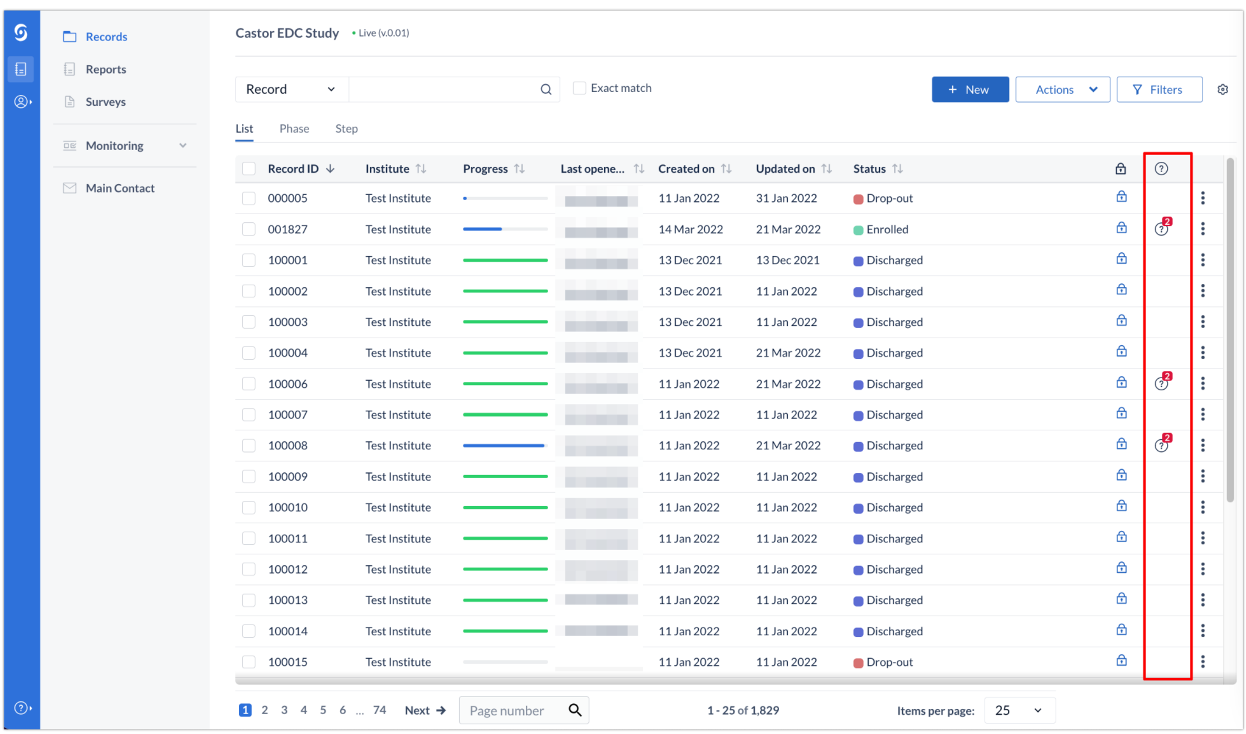



1. A user can make use of the filters in the top panel. For example, a user can filter on institute, on record ID, or on report type. a user can also click on the column labels to sort the reports in a relevant order.
2. An overview of all reports is shown, with the completion level and other details such as name, date and creator. For example, a user can sort by the date of creation of the report by clicking on the 'Created on'.
3. A user can archive or print a report using the cogwheel menu.
4. The column label turns bold. If a user clicks once, the order is ascending, if a user clicks once again, the order will be descending. A user can also click on the arrowhead next to a column to display an additional menu for report 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. By default, all columns are visible.

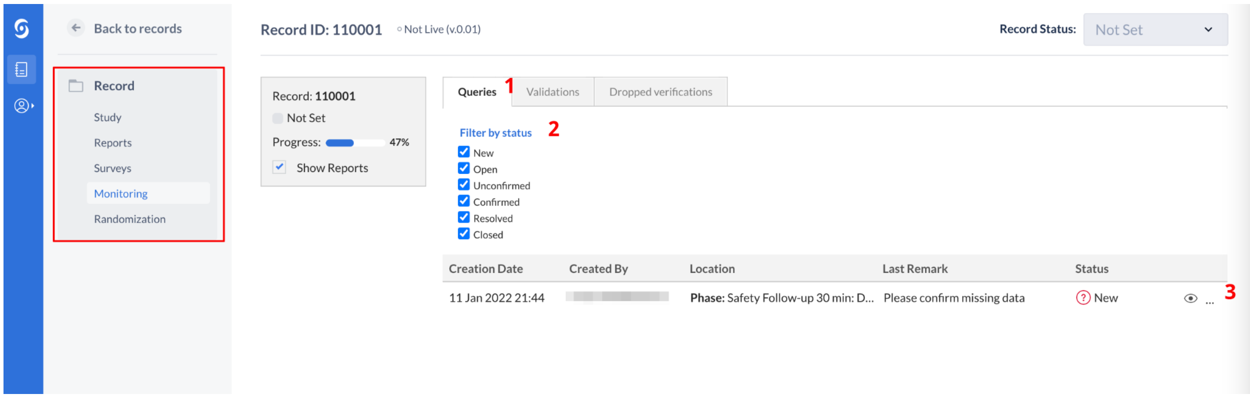



# 11. Responding to queries

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



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




1. The record's monitoring overview opens on the query tab.
2. Queries can be filtered by the query status.
3. Clicking on the eye icon, will take a user to the field where the query was placed.

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.

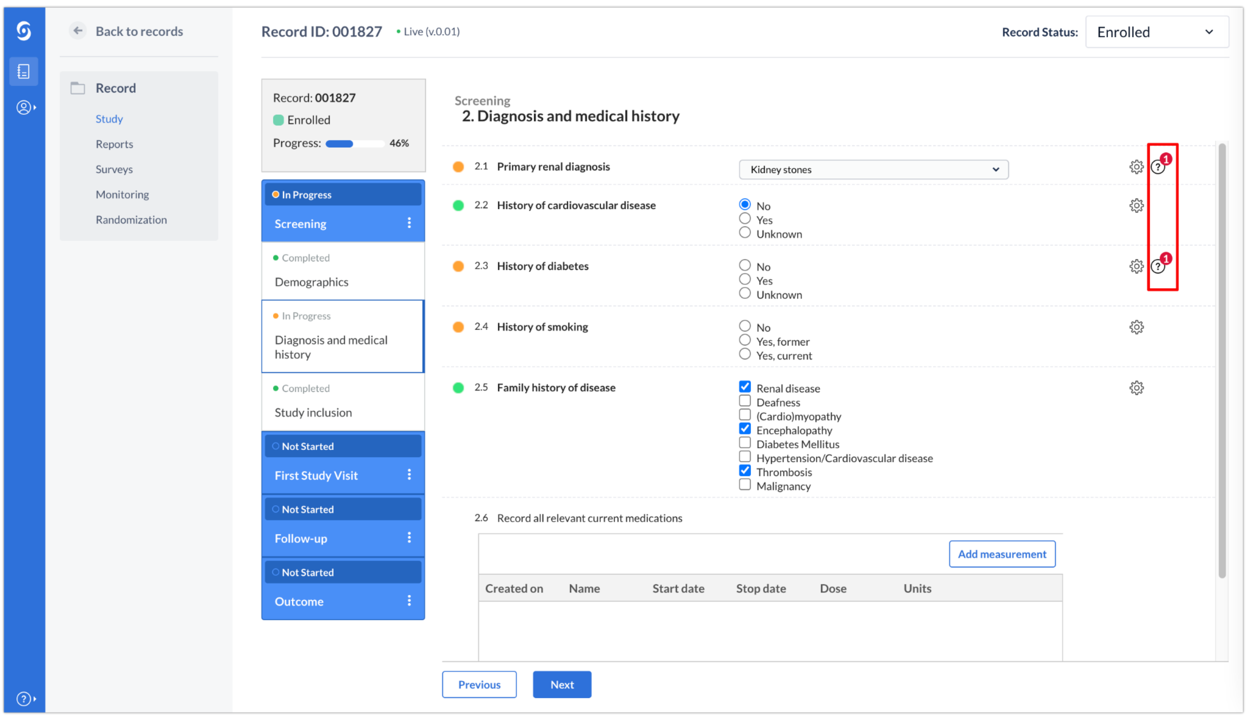
**Unconfirmed**: The user does not agree with the monitor.

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

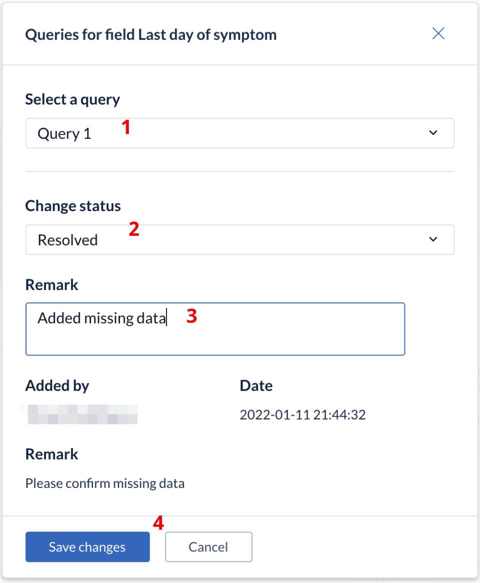
**Resolved**:The user has changed the value and indicates the issue is resolved, for example the user has reacted to a query and left a comment.

**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 record, 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.



A dialog window will appear:



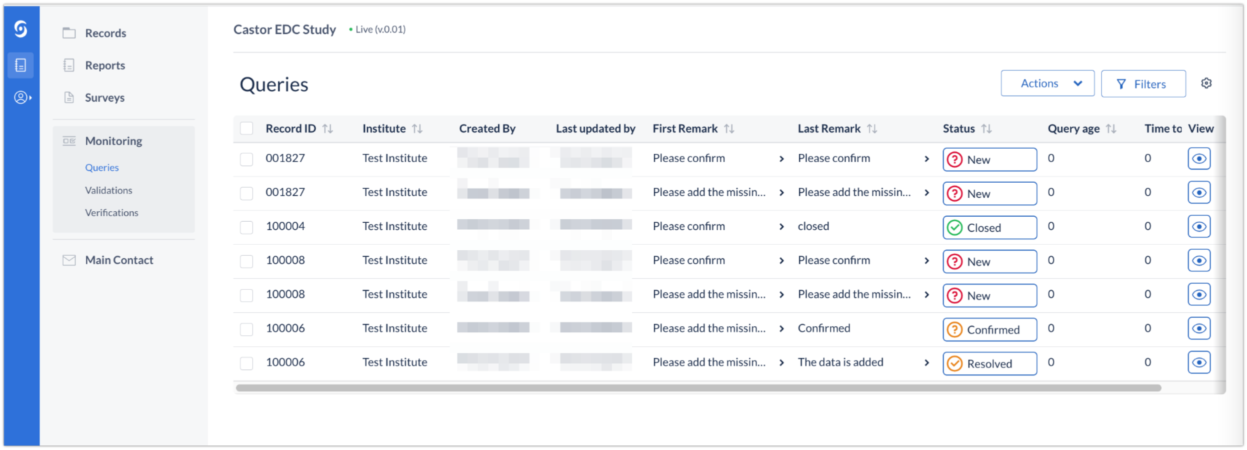

1. In case of multiple queries, a user can select a query to which a user needs to respond.
2. A user can change the status of a query by choosing from the list in the dropdown box.
3. The Remark field allows a user to enter comments on the query.
4. Once a user selects 'Save changes' the status and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

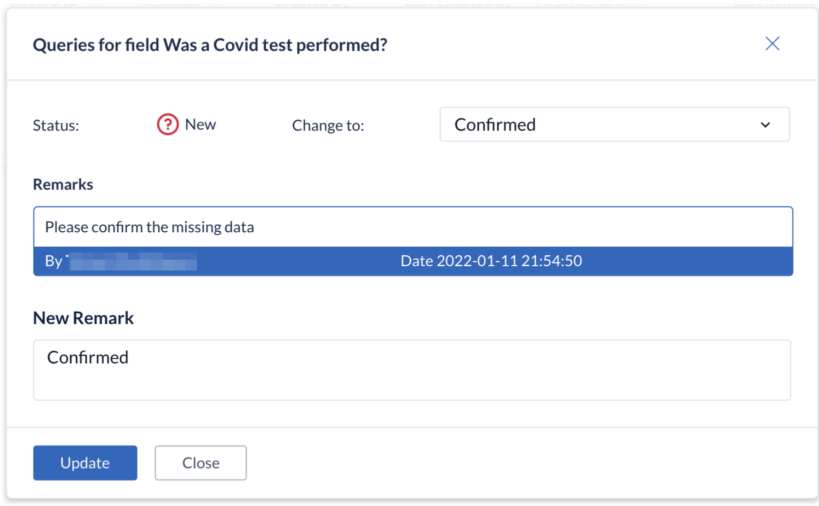
## 12.1. Queries

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



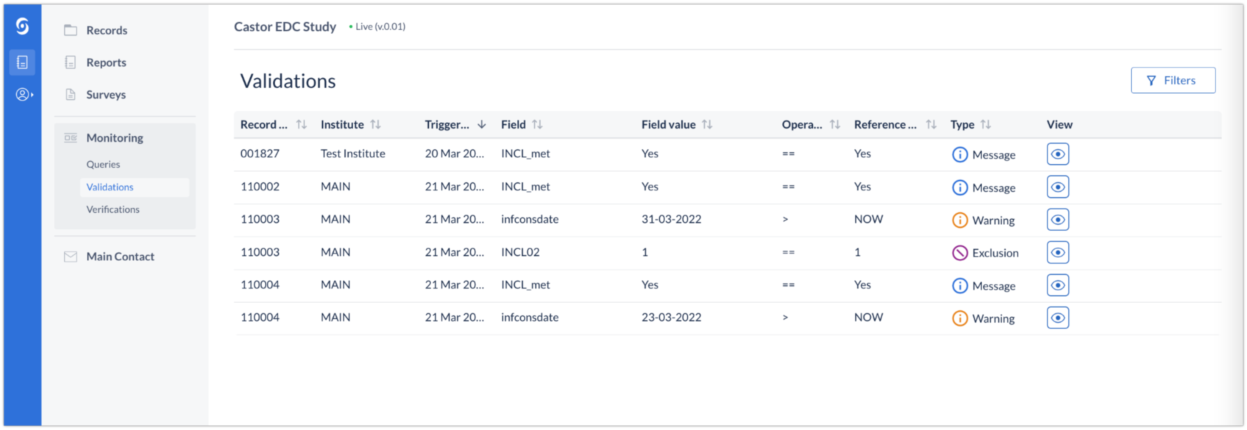

1. The user can click on the 'Filters' button to filter by institute, location, status (open, resolved, closed or all Monitoring queries), and other parameters.
2. An overview of all queries in the study (unless a user filtered the results) are displayed here.
3. Click on the eye icon to open a  step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

By clicking on the status, the queries can be sorted based on the associated record 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, reports or surveys of the type Exclusion, Warning, and Message.

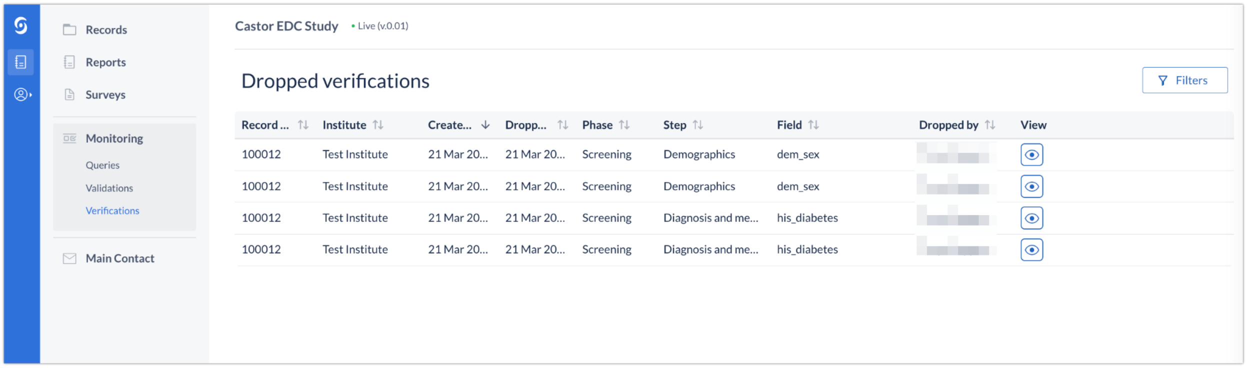



1. A user can filter validations by type (Exclusion, Warning, Message), by institute to show records with validations which belong to a particular institute, by data entry type and period when the validations were triggered using the 'Filters' button.
2. An overview of all records is given with the details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

To open the record and jump to the step with the validation, click on the eye icon in the column 'View'.

## 12.3. Verifications

This sub-tab displays all *dropped* verifications in the study or in reports:




Using the 'Filters' button, a user can choose to show dropped verifications only for study or reports, and filter by user, by institute, and period when the verifications were dropped.

To open the record and directly view the step where the verification was dropped, click on the eye icon in the column 'View'.

To see *all active* verifications, go to the 'Records' tab and use the "progress by step" view mode. Verified steps can be identified by a green checkmark.

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

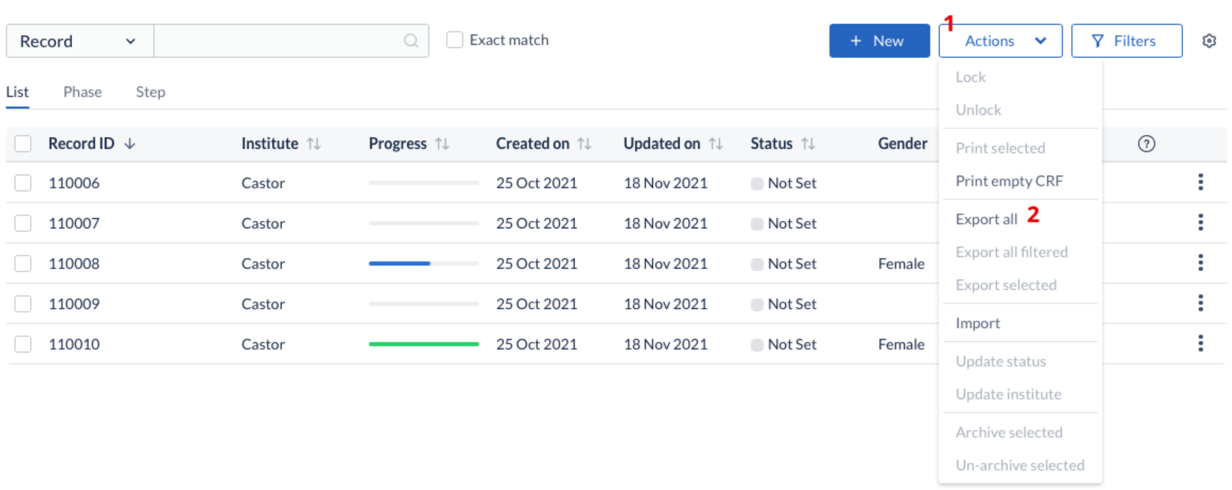
# 13. Exporting data

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

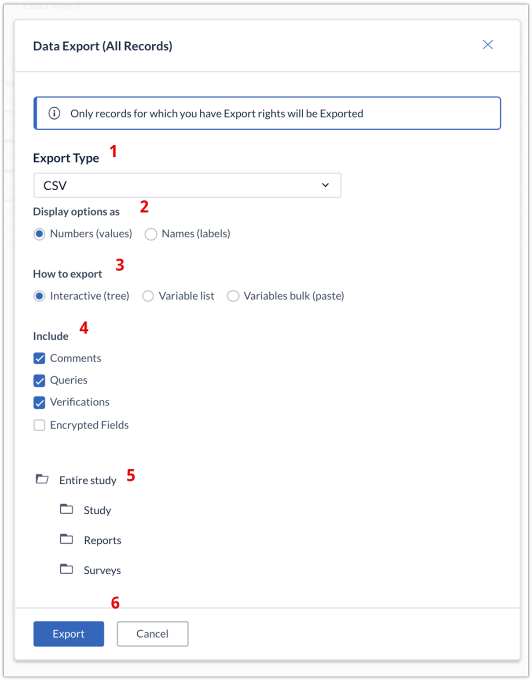
Apart from the study data, the export file will contain a list of all the variables created in the study and a list of all the option groups with the option group names and values.

## 13.1. How to export data

1. Navigate to the 'Records' tab and click the 'Actions' icon.
2. Choose 'Export all' to export all record data. If you are exporting only data from selected or filtered records, first select or filter the records 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 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/report) and the report 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, reports and surveys. This is shown in the Entire study export structure immediately being selected in the tree-view. In this interactive tree-view you can select smaller subsets (on the step-level). Using this tree-view you can export only a subset of your data, for example only study, reports, surveys or steps of your study, any report or any particular survey.
6. Click Export to export your data.

## 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 report has its own Excel sheet or file. For example, SAE reports and blood pressure reports 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 reports, every survey has its own file.
- Variable lists of study forms, reports, 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 report, each survey, a list of variables and option groups.
2. A set of separate CSV files, one for study data and one for each report and survey, a list of variables and option groups, example below.