Data Entry in Castor

1. Register an account

You will receive an invitation by email for the study for which you need to do data entry. Please click the link in the email, it will redirect you to the registration page.

Alternatively, you can go directly to our website to create an account before being invited to a study. You will chose the site to create your account on based on the location of your study data[1].

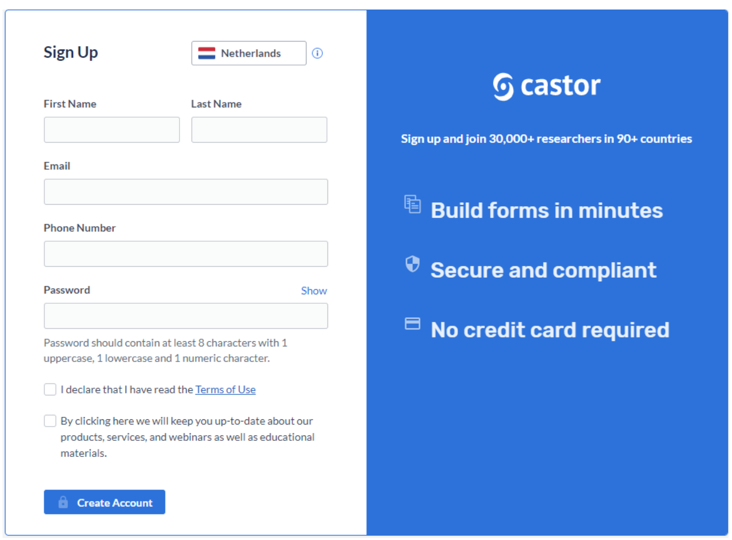
EU Account: https://data.castoredc.com/register

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:

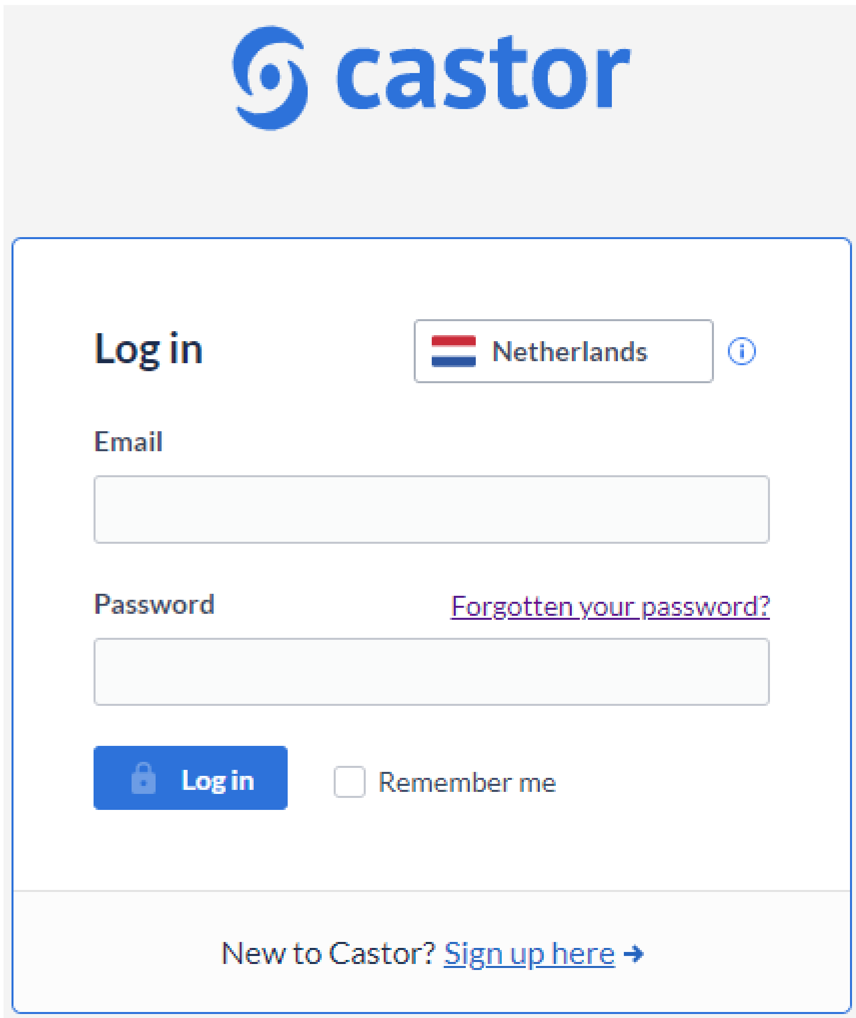


1. Fill in your first and last name(s).
2. Enter your email address and choose a strong password, consisting of at least 8 characters, one uppercase letter, one lowercase letter and a number.
3. Enter your phone number

[1] The server you choose is not related to your own location; it is where your study data is stored. For example, if you work from the US, but your study admin from the Netherlands has chosen to store the study on the EU server, you should also choose the EU server when you login.

4. Click on "Create Account". Shortly after registering your details, an email with an activation link will be sent to the email address you have provided. Click on this link to confirm that the supplied email address belongs to you and verify your account.

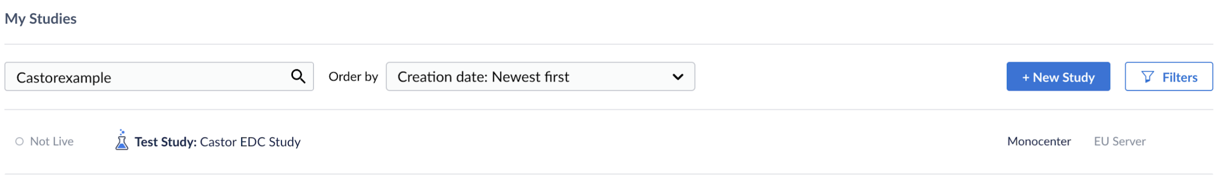
2. Log in



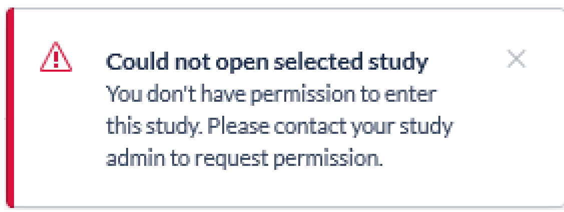
1. To access the study, log into Castor EDC via https://data.castoredc.com. If your study is on the US, AU or UK server, you can also directly go to https://au.castoredc.com/register, http://us.castoredc.com or http://uk.castoredc.com, respectively.
2. Choose the server that is used for your study in order to be able to access the study.
3. Enter your email address and password.
4. Click on 'Login'.

3. Open a study

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



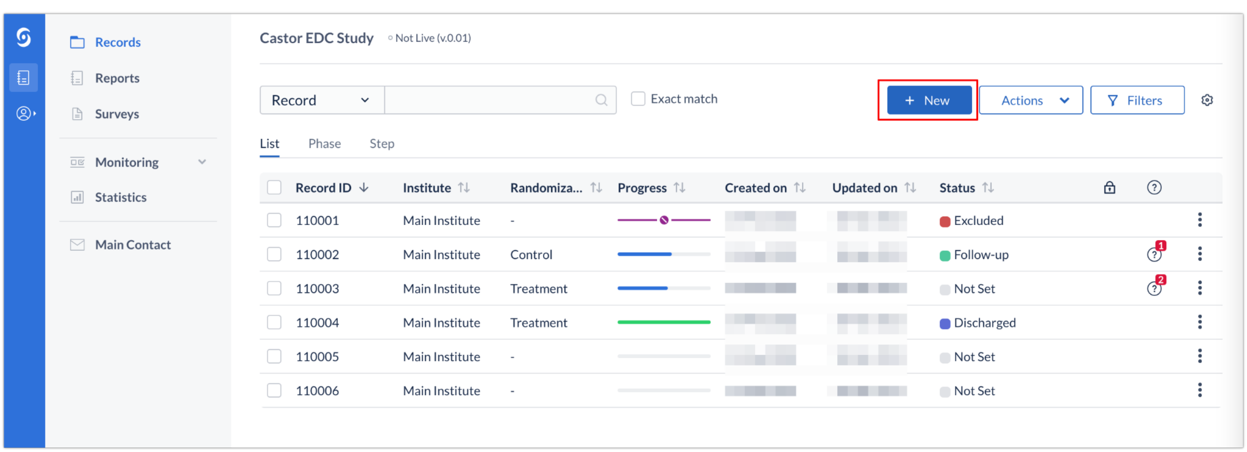
Trying to open a study that is not live will show the following warning:



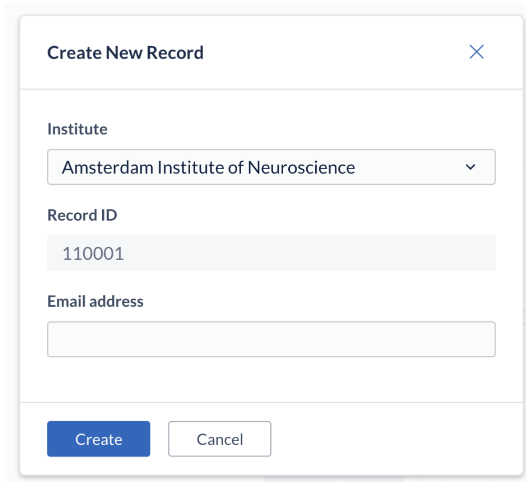
If the study is still in maintenance mode (the button is blank, and the status says 'Not Live') you will only be able to open the study if you have management rights.

4. Open a record for data entry

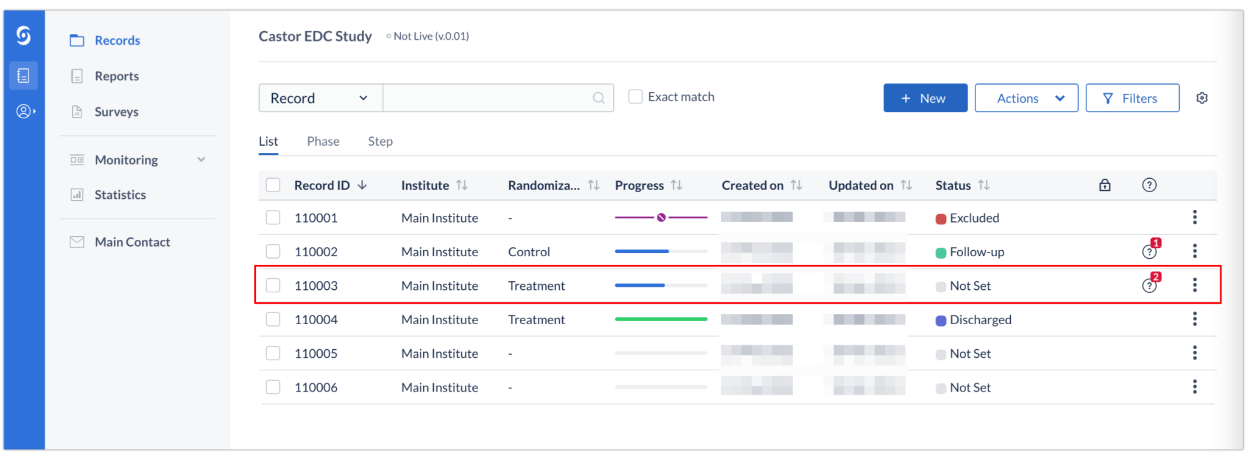
Once you enter the study, you will see a list of all records available for your access level. To add a new patient to the database, you will need to create a new record. Creating new records must be done from the Records tab by clicking on the "+ New" button.



The 'Create New Record' dialogue box will open and you will select the Institute you wish to add the record to. The record ID will be auto generated.. Add record's email address in the 'Email address' field if applicable.. The record will be created and opened so you can begin data entry.

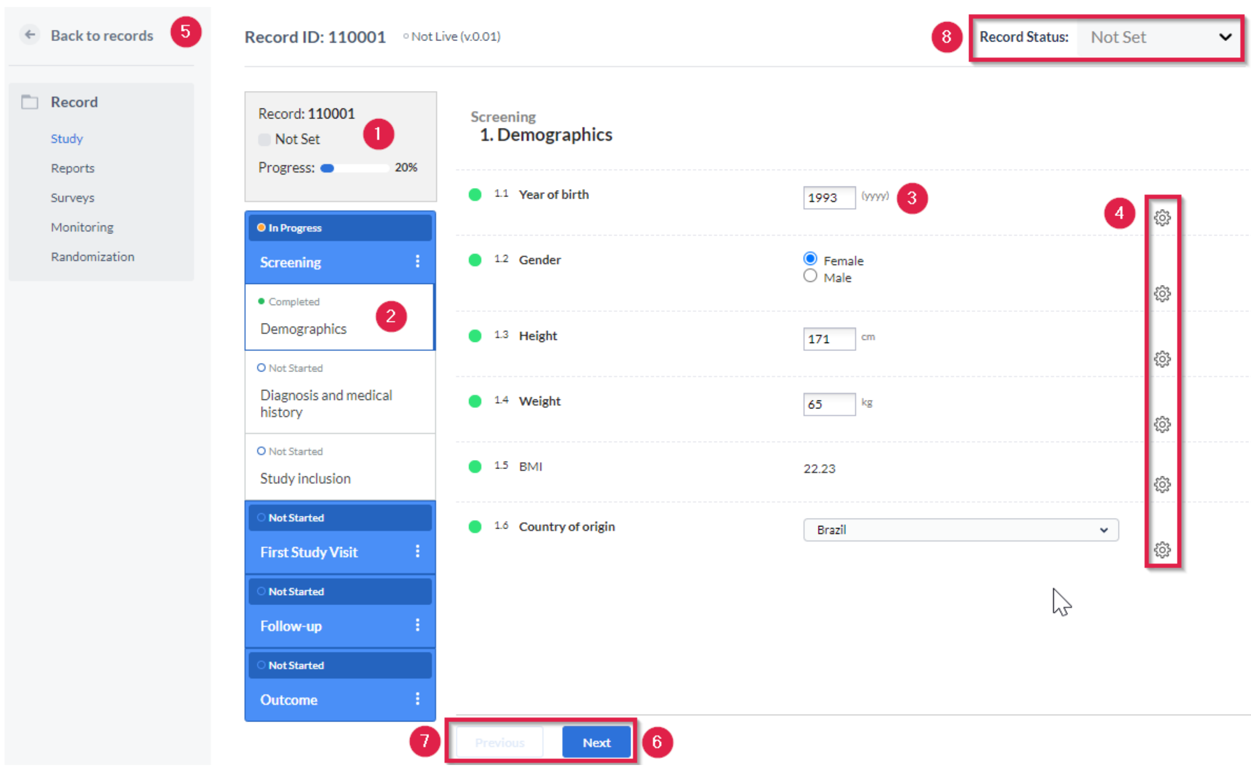


To open a previously created record double click the row the record is on:



5. Doing data entry

When you open a record, you will be taken to the main data entry view:



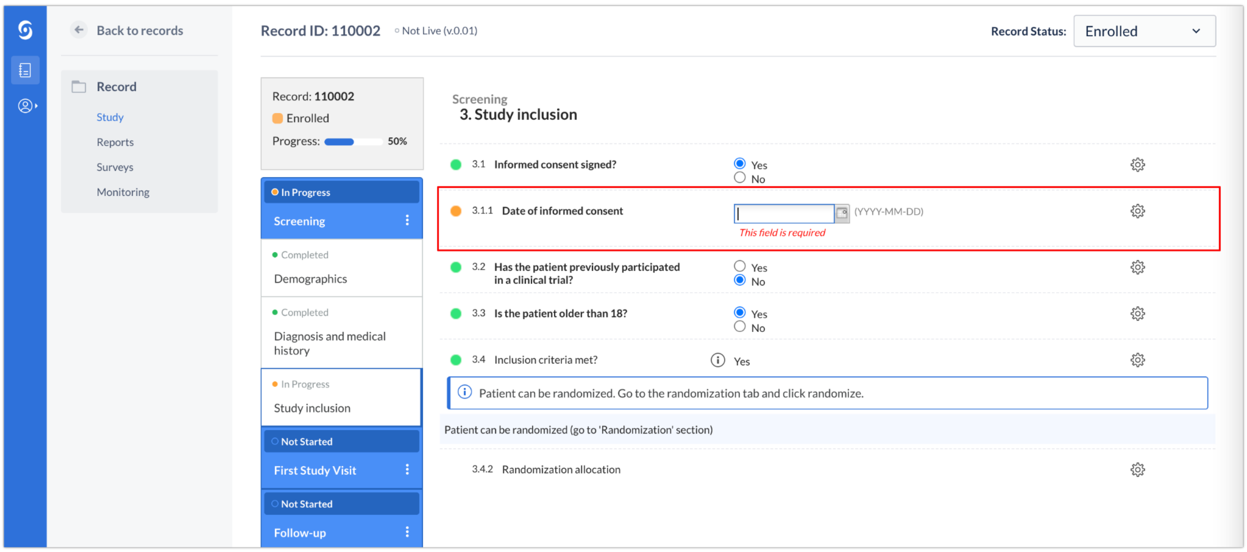
It consists of the following elements:

1. Record ID, Record status and progress of completion.
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. You can click on the step of interest in this panel to start entering the required data. Once you answer a question in the form, you 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, you can clear the data from a field, add a comment or mark the field as ‘missing’ data.
5. To exit the record and return to the record list, click on the ‘Back to records’ button.
6. Once you have completed the first form, you can navigate to the next step by clicking on ‘Next’.
7. You can return to the previous step by clicking on ‘Previous’.

5.1 - Elements in each question

Depending on the type of question, you 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'.



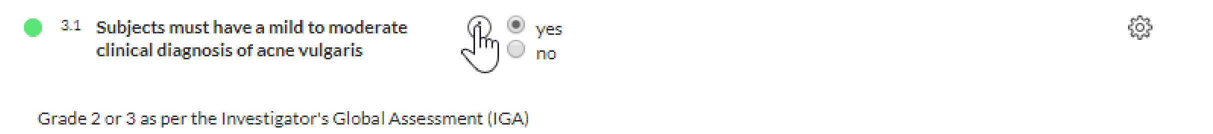
5.1.1 - Status icons

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.
●	*Orange*	Data is required and no input has been entered yet.
●	*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 values have been saved.

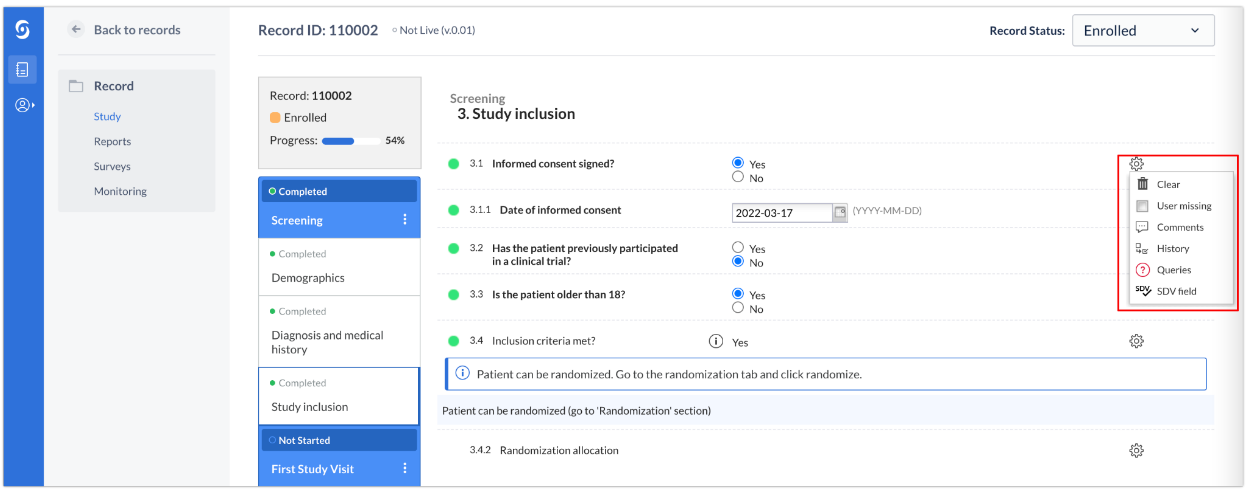
5.1.2 - Additional information

If additional information has been provided with a question, the ⓘ icon will be displayed beside the input. Clicking on the icon will allow you to view the information:



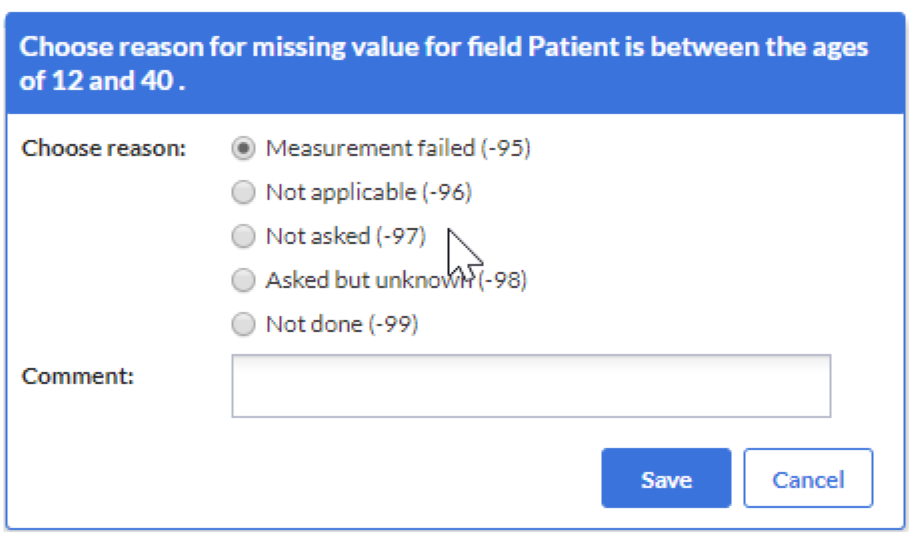
5.1.3 - Additional options

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



To clear the value already entered for a field, press "Clear".

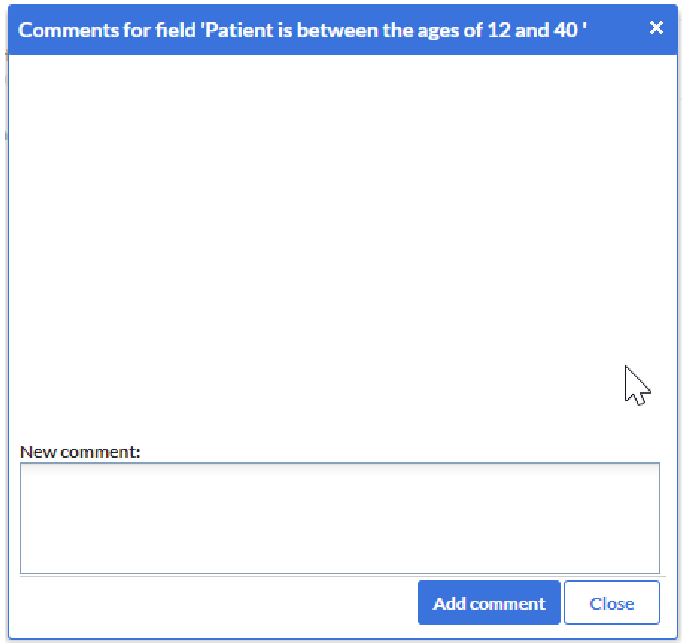
If data is not available for a question, tick the "User missing" box. A window will open to ask the user to provide the reason why the data is missing:



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'.

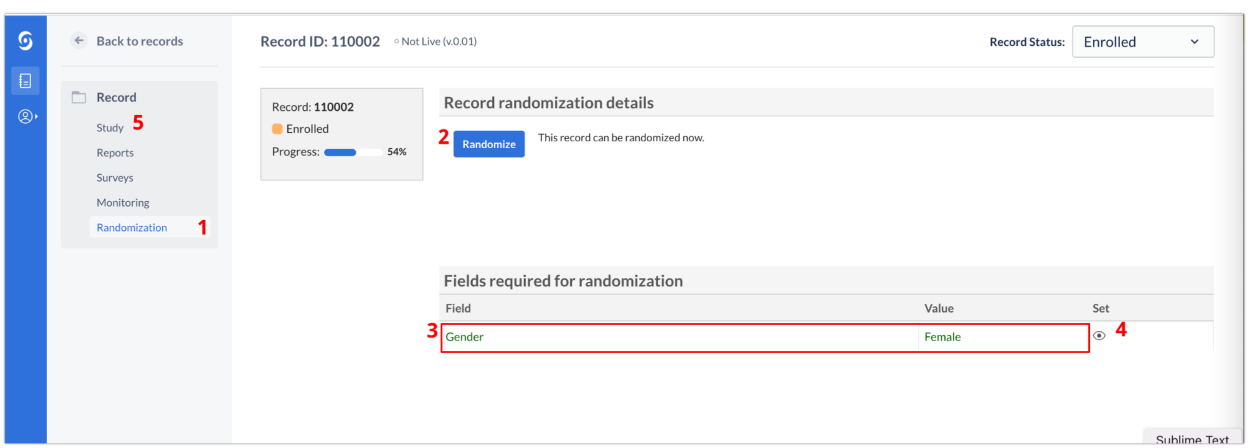
If you initially marked a field as missing but receive information for this field at a later date, you can click on the cogwheel again (even if the question is grayed out) and should unselect the option "User missing".

If you want to add a comment to a field, press "Comments". Add your text and press "Add comment":



5.1.4 - Randomize a record

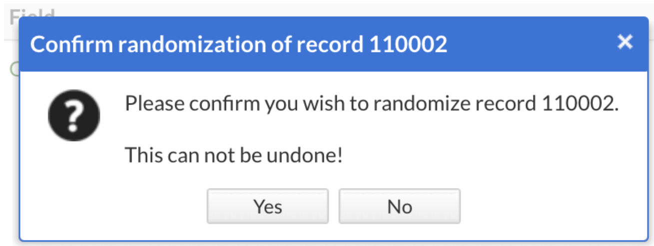
If you need to perform randomization in the study, you can follow these steps to randomize a record.



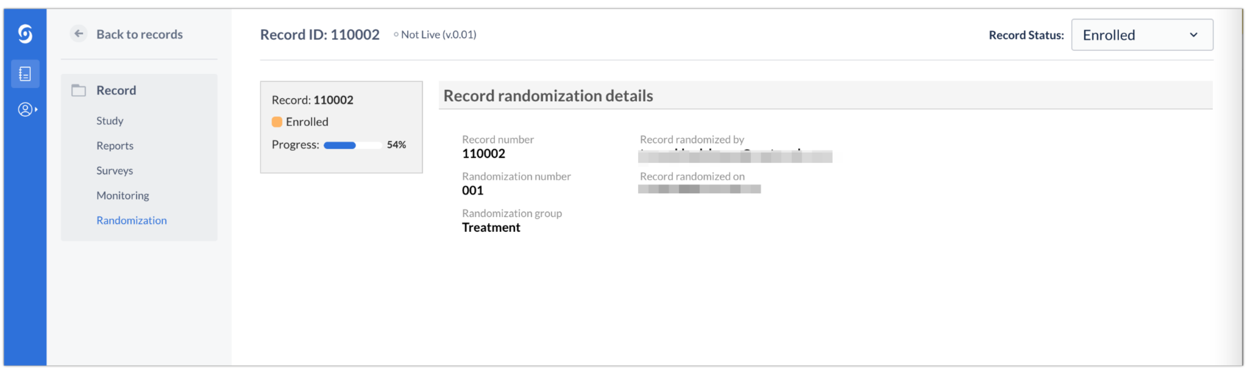
1. From the record overview, select the 'Randomization' sub-tab.
2. Click the "Randomize' button to randomize the record.
3. Fields required for randomization are summarized in the lower right of the tab.

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 get back to the study forms

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

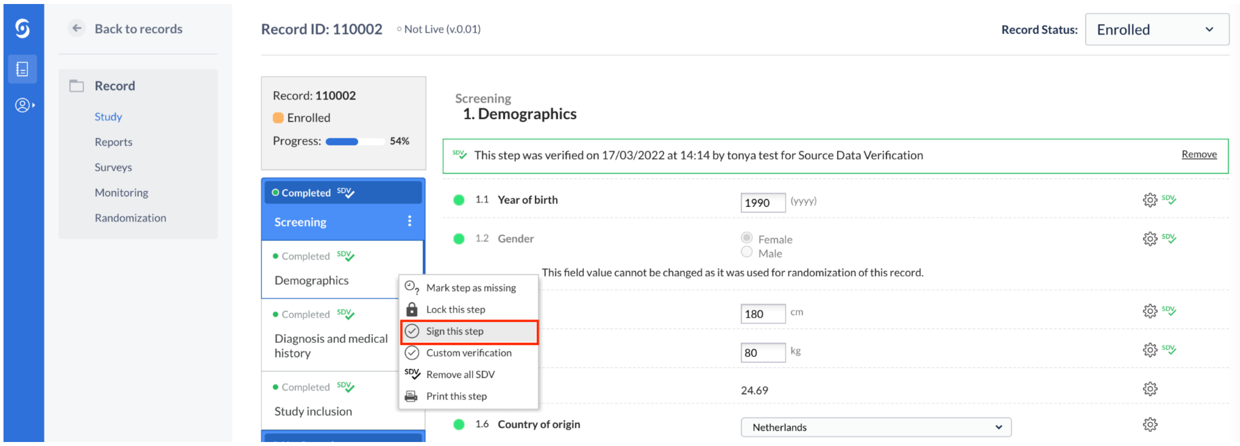


The randomization tab will now display the randomization group and the randomization number and other relevant information. This tab is only visible for users with randomization rights.



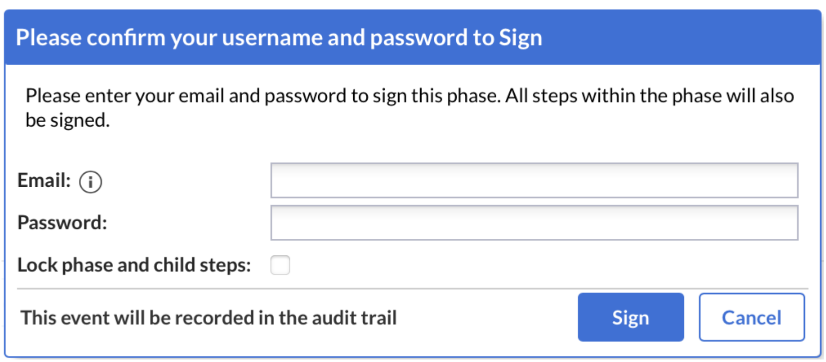
5.1.5 - Signing and locking a step

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

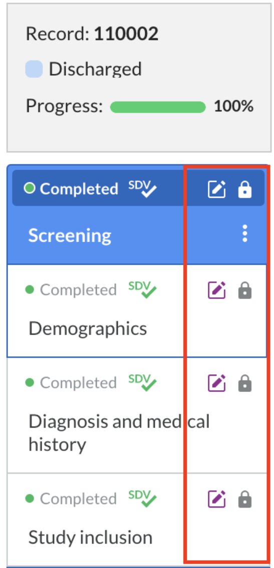


1. Hover over the right side of a step or phase with your mouse. Click on the three dots that appear.
2. Click on "Sign this phase" for phases or "Sign this step" for steps.

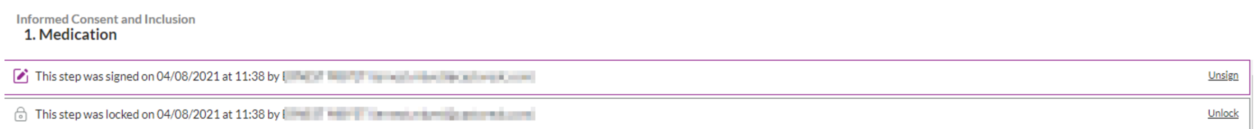
You will be prompted to enter your email and password to confirm your identity. Click "Sign" to confirm and to sign the phase or step. If you wish to also lock this phase, you will tick the “Also lock this phase” checkbox. You will receive a confirmation that the audit trail has been updated.



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



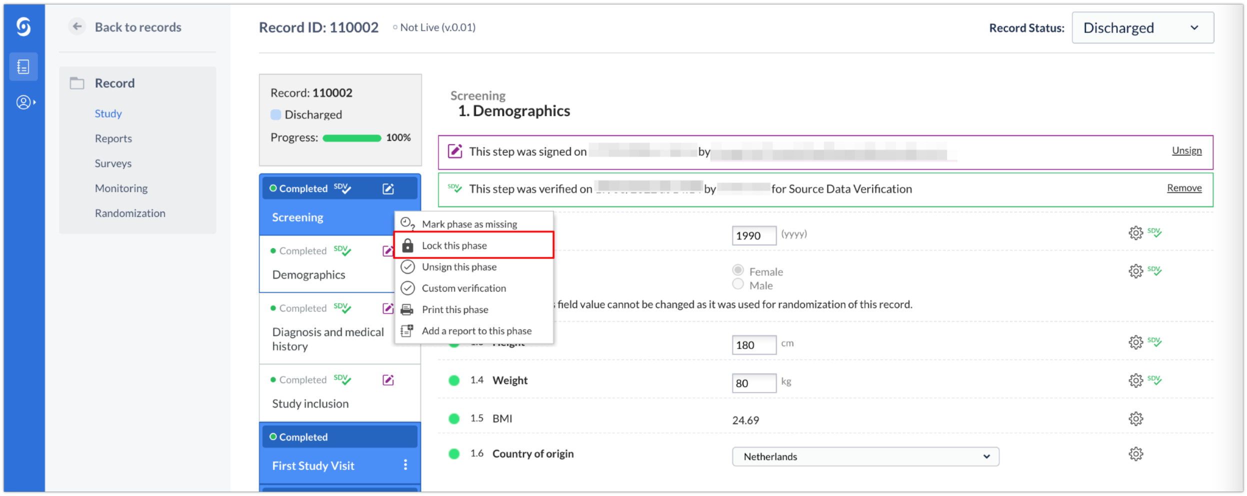
A warning will also be displayed at the top of the data entry screen, warning the user that the current step has been signed and/or locked:



You can also unlock and unsign the step by clicking on the “Unlock” and “Unsign” buttons.

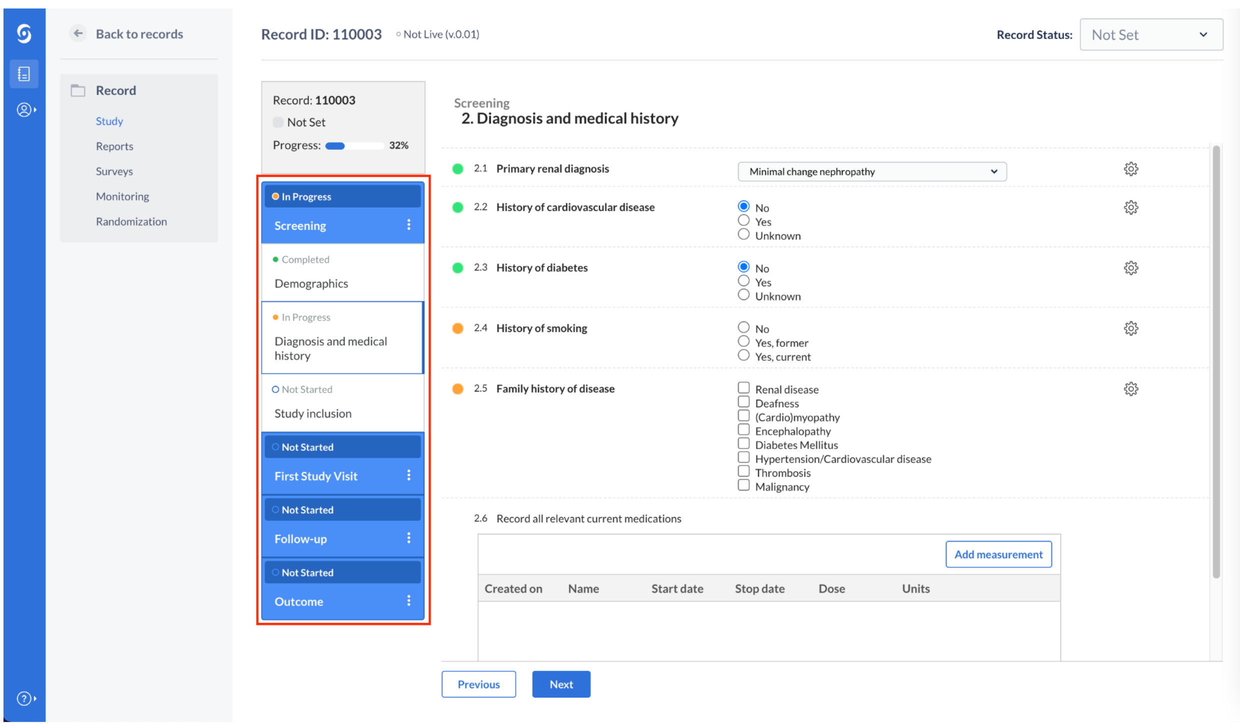
If you have lock rights, you can also choose to lock a phase or a step to prevent further data entry directly from the record navigation.

- Click on the three dots menu next to a step or a phase.
- Click on "(Un)Lock this phase" for phases or "(Un)Lock this step" for steps.



6. Record progress

In the left panel in data entry, you can view the progress of the phases and steps which will update as you fill in the data.



Phases and steps can have three different completion stages:

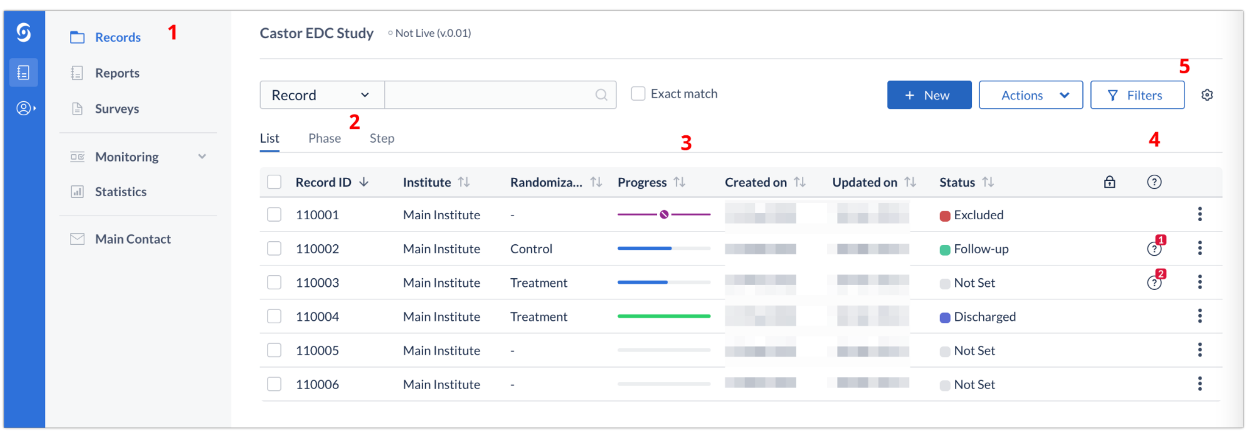
- *Gray* Not started
- *Orange* In Progress
- *Green* Completed

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 you have created (see Section 6). You may also see records that have been created by other users at your institute.

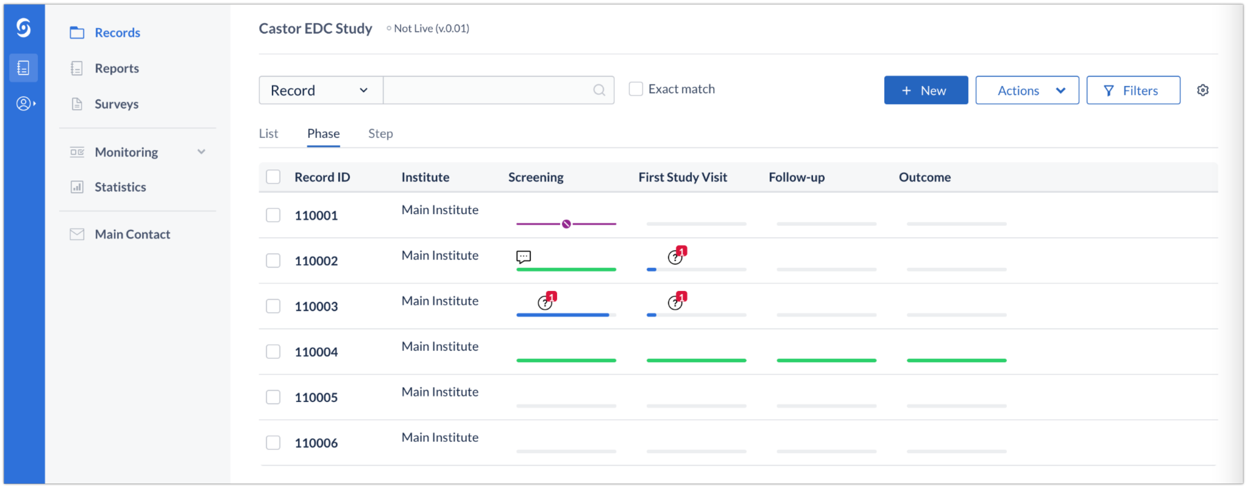
1. In the ‘Records’ tab, a search box is available, in which you can search for a particular record ID. More information on the search is provided in section 7.2.
2. It is possible to change the view mode to show the progress of the records by phases or steps (see section 7.1).
3. Progress: This column 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 Filter by record status boxes to show records that are complete, incomplete or not started.



7.1 – Phase/Step View

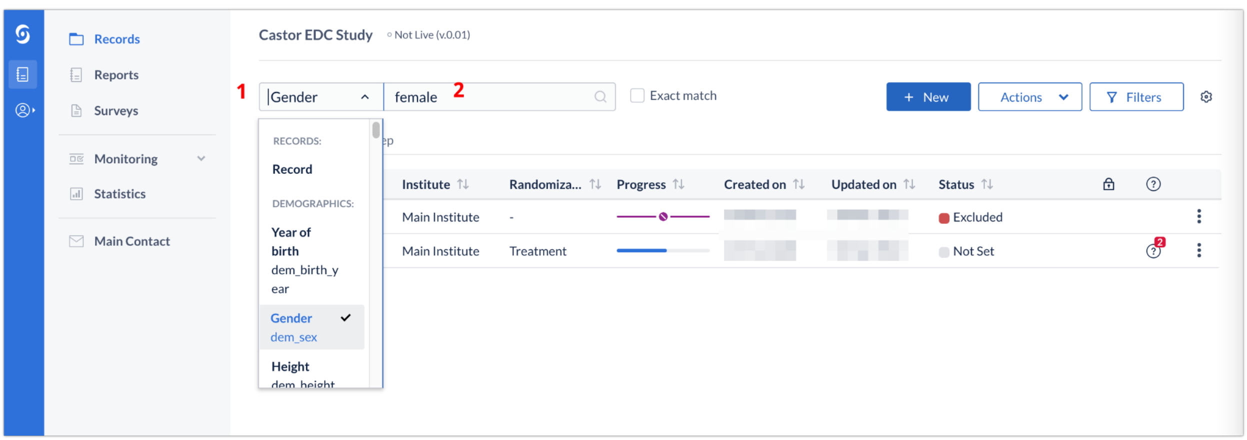
By default, the ‘Records’ tab displays all records in the “List” view. You can change the view mode to either Phase view or Step view.

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 phas eor step to directly access it.



7.2 - Search for data

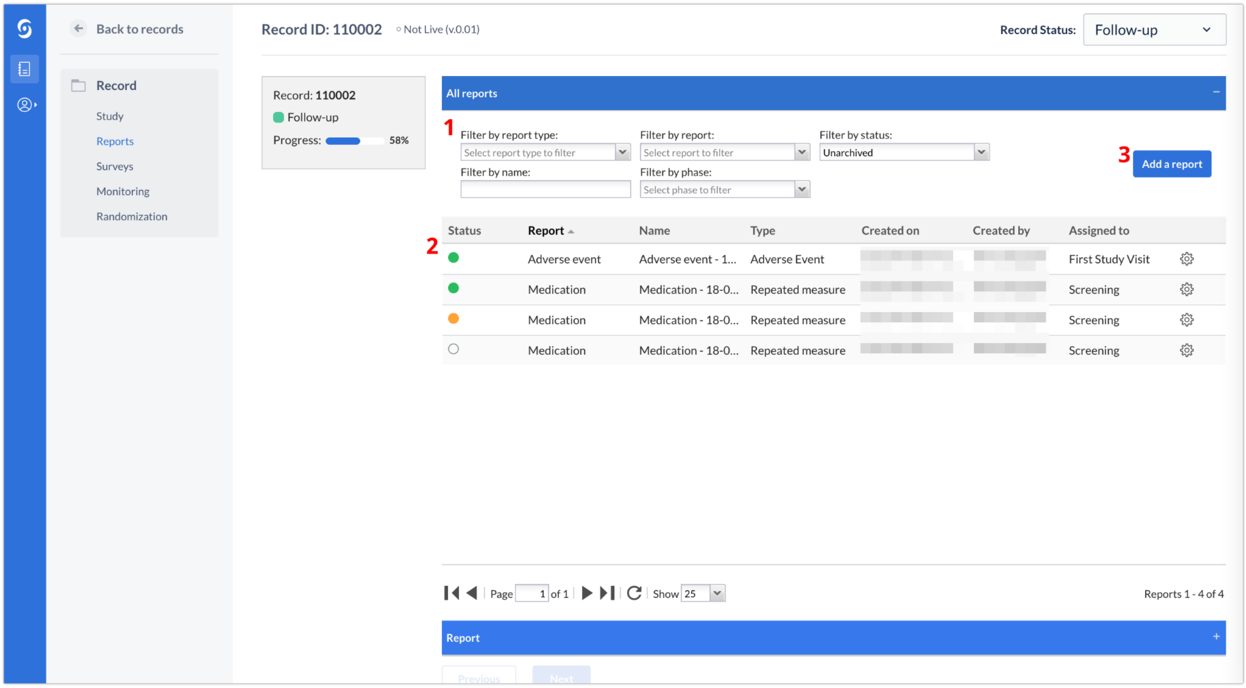
You can use the search bar to find records that contain certain data, for example if you want to find the patients with a certain age at onset.



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

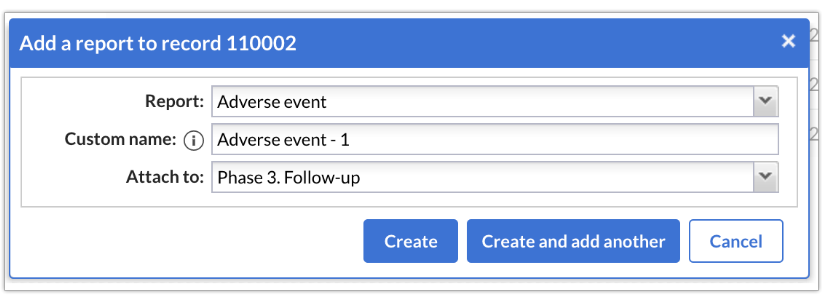
8. Creating reports

In the data entry view, you can view any reports attached to the record or create a new report. Opening the record and navigating to the Reports tab will display the reports overview:



1. You can filter by report type, report type, report name, or by the phase to which a report is linked.
2. The list of reports linked to the selected record. A status indicator allows you to see the completion status of the report.
3. Click the 'Add a report' button to create a new report.

After clicking 'Add a report', the following dialog window will appear:



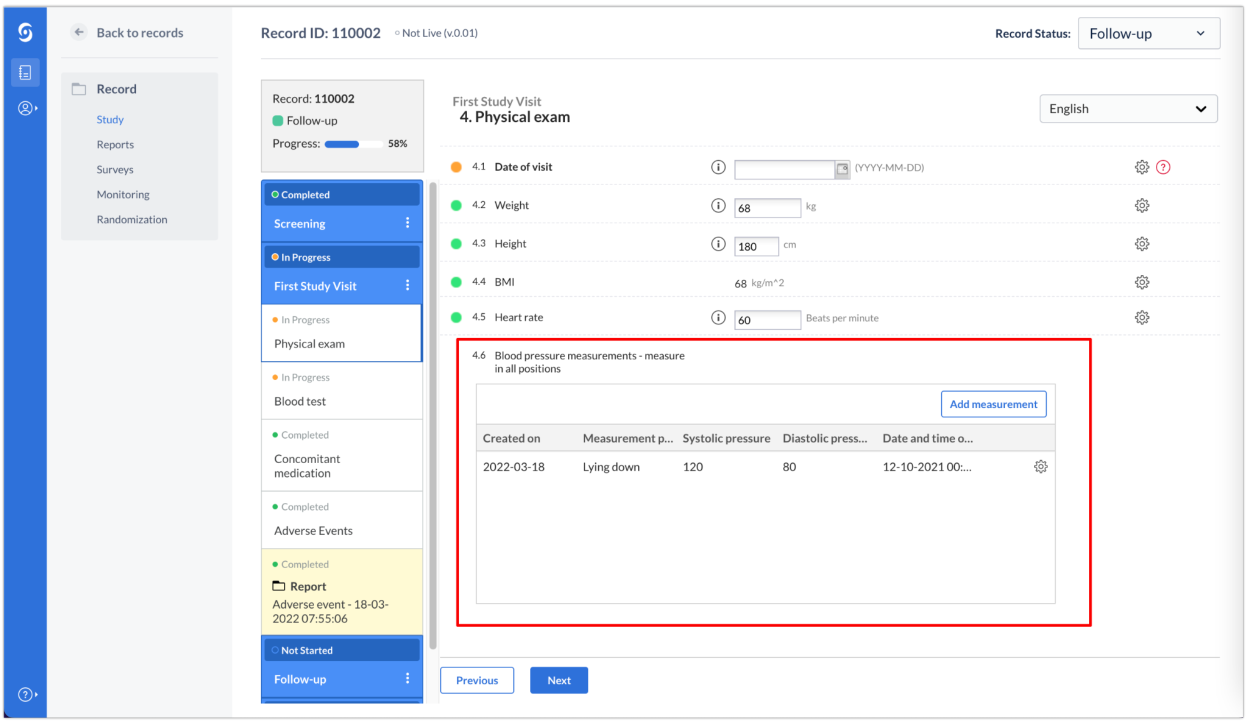
1. Select from the dropdown menu which report type you wish to create.
2. Depending on the settings, the option to enter a custom name for the report might be enabled or disabled. The report custom name is how the report will be displayed in the study and exports.

3. You have the option to attach the report to a phase or to another report. Attaching the report to a phase will display the report in the Phase/Step navigator on the left sidebar in the data entry view. Note: the report can also be attached to unscheduled phases.

Click the 'Create' button to add the new report and return to data entry. Alternatively, you can click 'Create and add another' to save the new report and immediately create another new report.

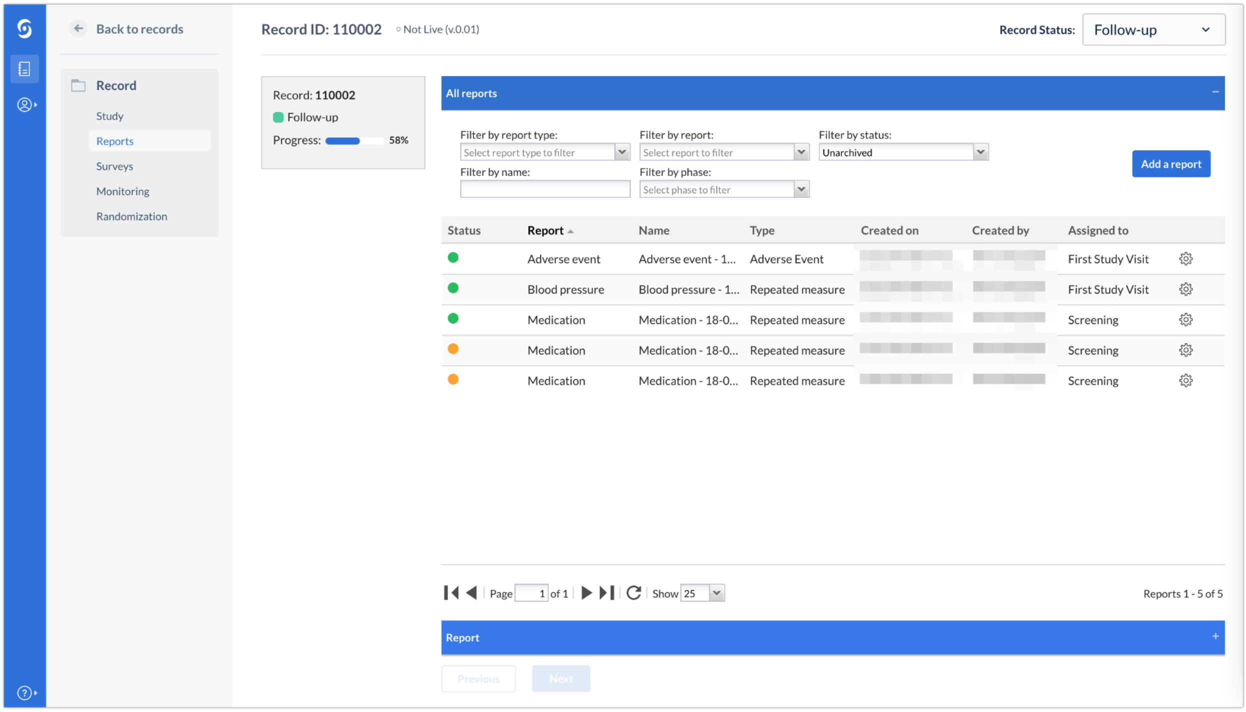
9. Repeated Measures

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



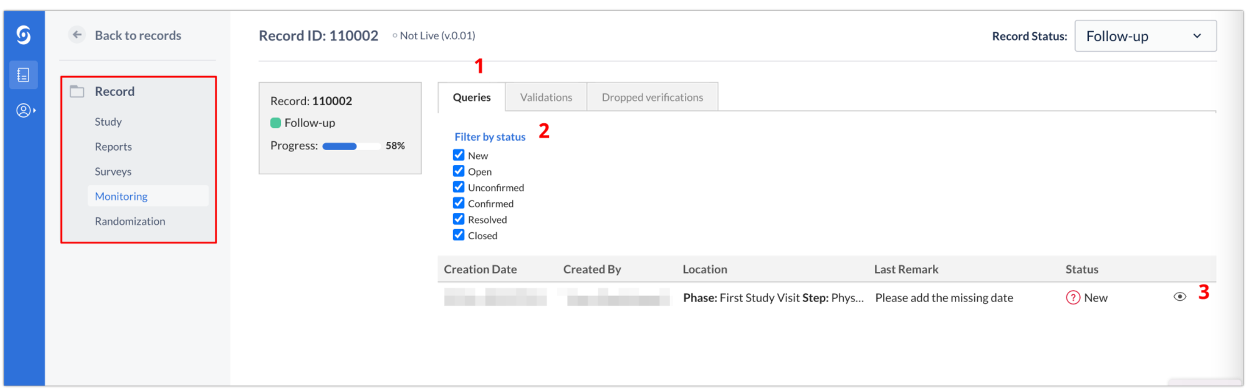
By selecting 'Add measurement', measurements are easily added to the form and will be shown in the form of a grid, representing each measurement as a new row and each field that is part of the repeated measure as a separate column.

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.



9. Responding to queries

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 you 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.

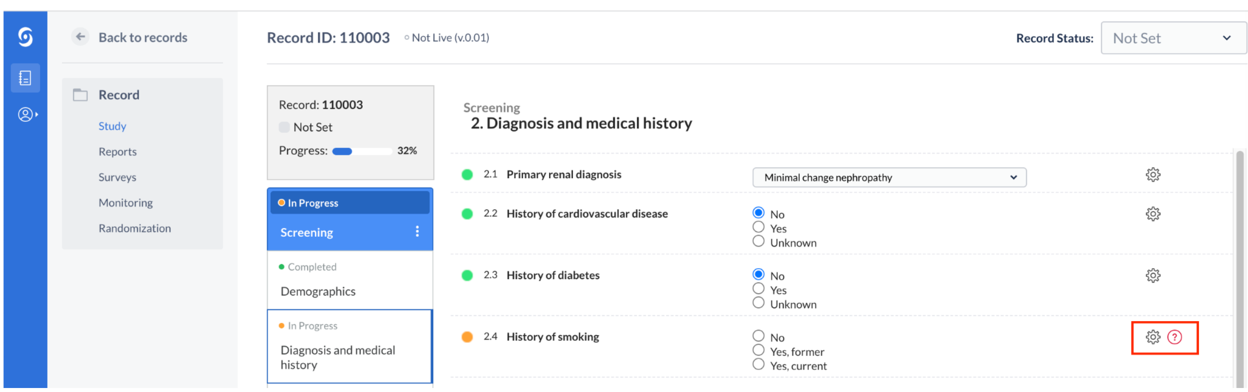
Unconfirmed: The user does not agree with the monitor.

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

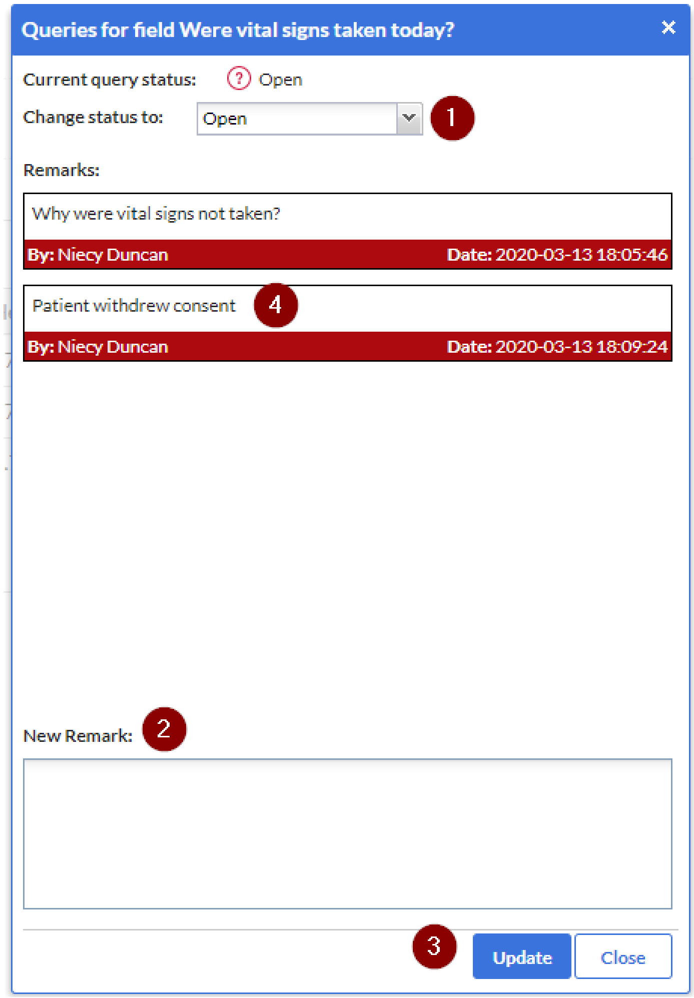
Resolved:The user has changed the value and indicates the issue is resolved, for example the user has reacted to a query and left a comment.

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

Once you are in the record, you will see the status icon next to the queried field.



To respond to a query, click on the query icon



1. You can change the status of a query by choosing from the list in the dropdown box.
2. The New Remark field allows you to enter your comments on the query.
3. Once you select 'Update' the status and comment will be saved.
4. All saved remarks are added to the list.

10. Further information

If you would like to watch a video tutorial for performing data entry, you can do so here. We also invite you to take our online Data Entry course at Castor Academy.

For more information regarding data entry, please check Castor EDC's knowledge base: https://helpdesk.castoredc.com