Study Monitoring in Castor EDC

Register an account

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

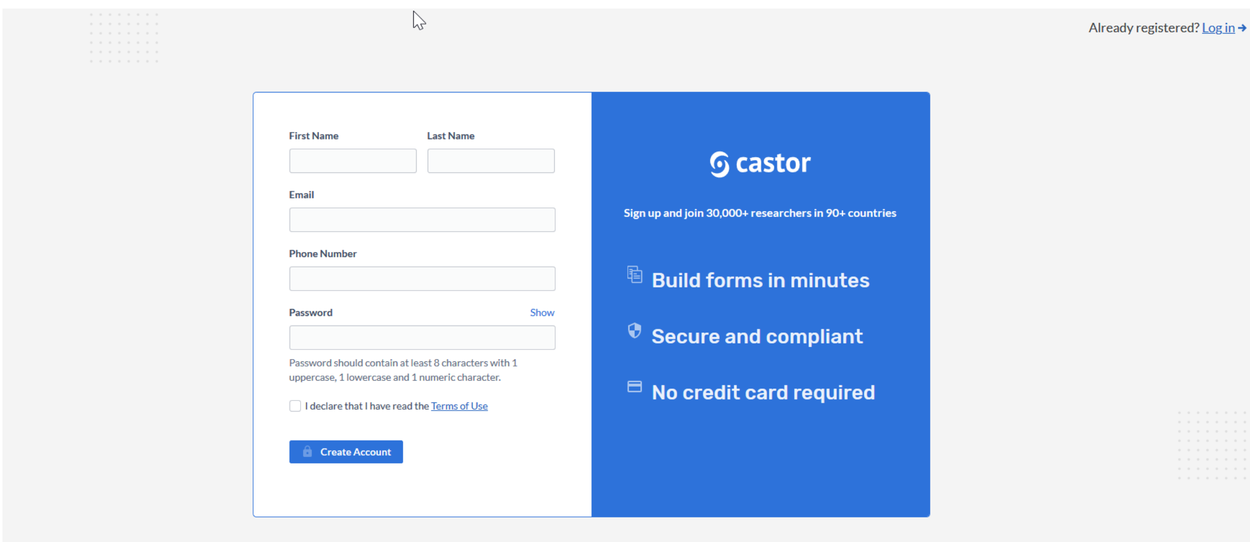
Alternatively, you can go directly to our website to create an account before being invited to a study. You will chose the site to create your account on based on the location of your study data[1].

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

UK Account: https://uk.castoredc.com/register

US Account: https://us.castoredc.com/register

To register your Castor account:

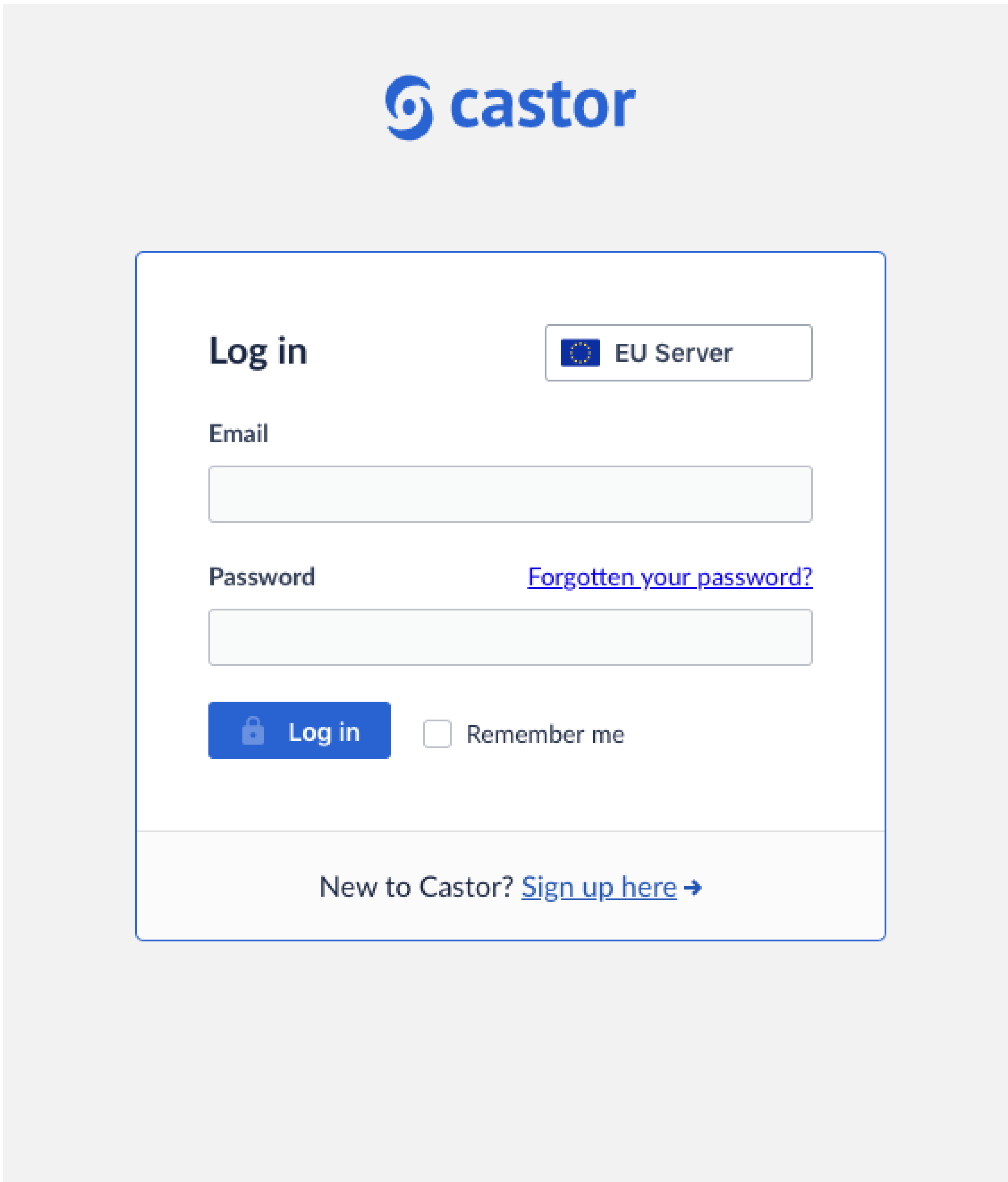


1. Fill in your first and last name(s).
2. Enter your email address and choose a strong password, consisting of at least 8 characters, one uppercase letter, one lowercase letter and a number.
3. Enter your phone number.

[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 or UK server, you should go to http://us.castoredc.com or http://uk.castoredc.com, respectively.
2. Enter your email address and password.
3. Click on 'Login' to access the 'My studies' overview.

3. Access a study for monitoring

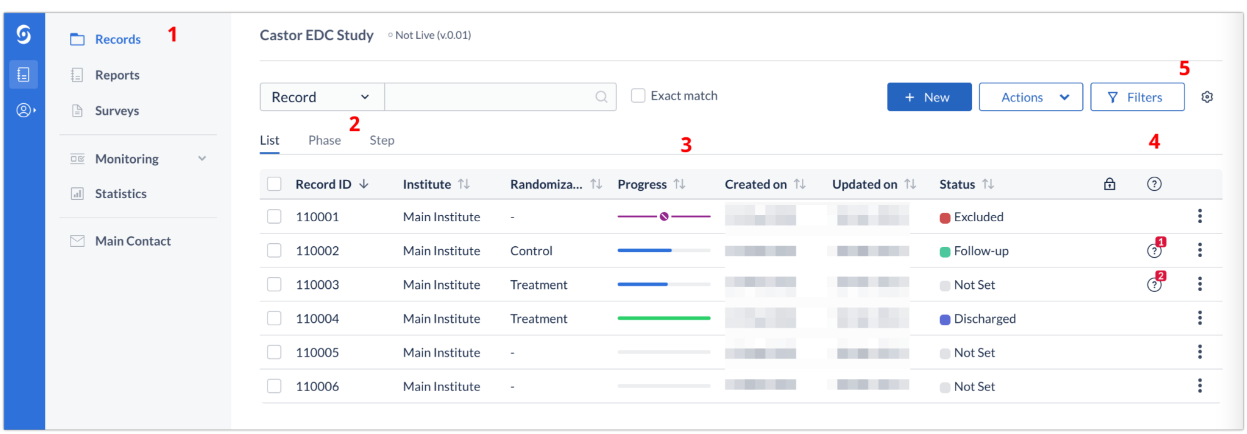
Once you have logged into Castor EDC, you will see the My Studies page where all of the studies (databases) you have access to are shown. Only live studies can be accessed by monitors. If a study is live (indicated by a green button above the name), you can click on the study name to enter the study and do your monitoring activities.

The study will open on the Records tab. As a monitor, you will most likely see the following tabs:

1. **Records**: Contains an overview of all records in the study, where you can access the records for data review.
2. **Reports**: Contains an overview of all reports created within the study.
3. **Surveys**: In this tab, there is an overview of all the survey invitations that have been created, sent and filled.
4. **Monitoring**: Queries, validations, and verifications are shown in this tab.

4. The Records tab

Once you enter the study, you will see a list of all patient records available for review. You will also see relevant record information, such as which institute the record belongs to, when it was last opened and its completion (progress) status.

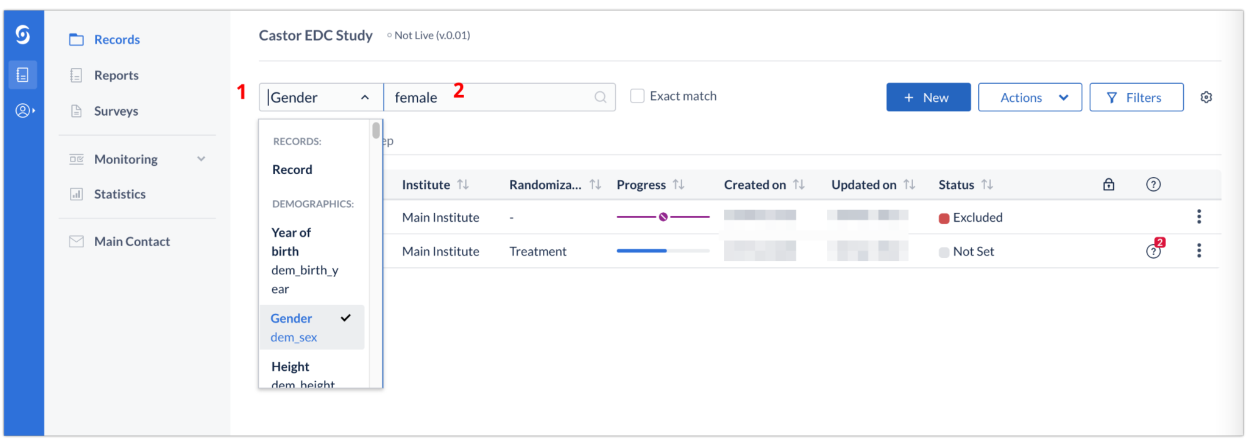


1. In the 'Records' tab, a search box is available, in which you can search for a particular record ID. More information on the search is provided in section 4.1.
2. It is possible to change the view mode to show the progress of the records by phases or steps.
3. Progress: This column will show you the 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.

4.1 - Search for records

You can use the search bar in the Records tab to search records by their ID. This works on the basis of 'begins with', so it is sufficient to enter the first few digits of the ID.

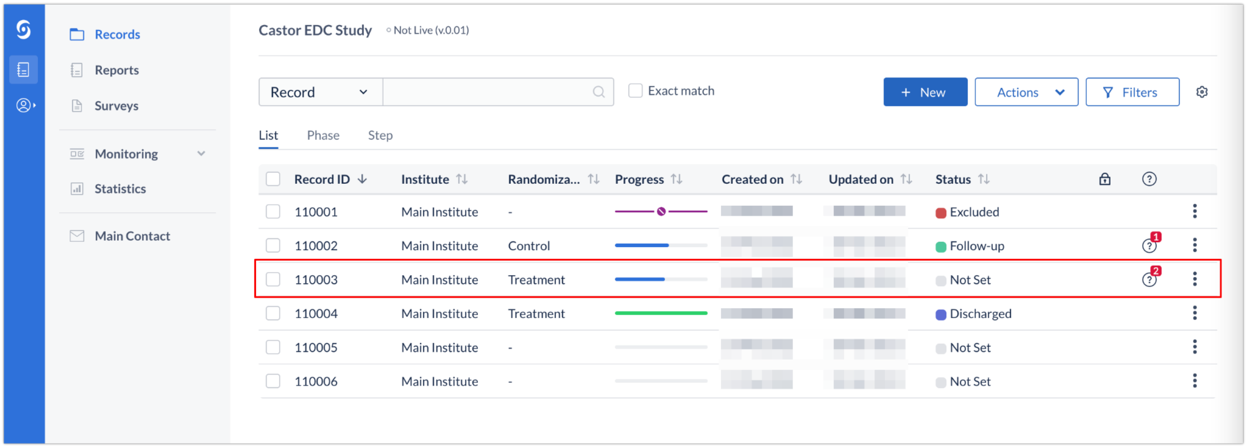
You can also search for records that contain certain data values, for example when you want to find all male patients:



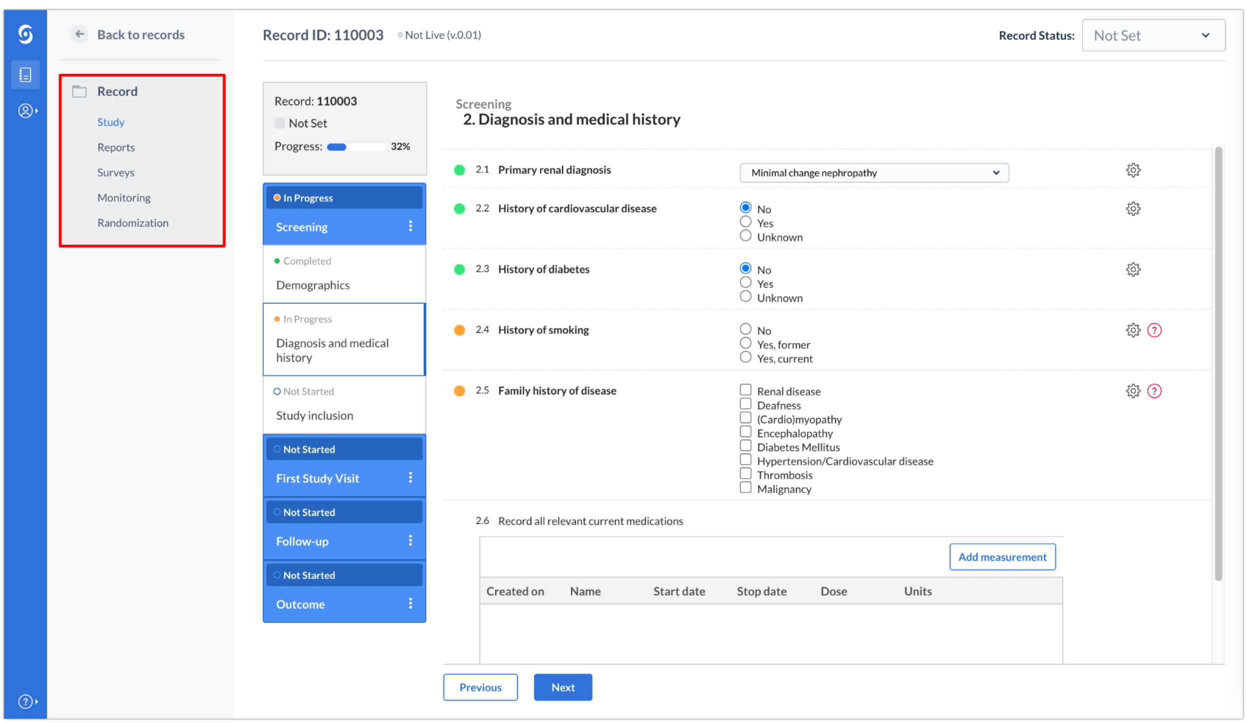
1. Click on the arrow in the left search box and find the field (question) of interest. In this example 'Gender' is selected.
2. Enter the value of interest in the right search box (in this example 'Female') and all matching records will be displayed. You can also search on option value (e.g. 1) instead of option label. Some values that you search for, such as date, require you to enter an exact match

4.2 Accessing a single record

To open a record double click the line the record is on:



There are a total of 5 available tabs within a record, but which tabs you see depends on the study setup and your specific user rights:

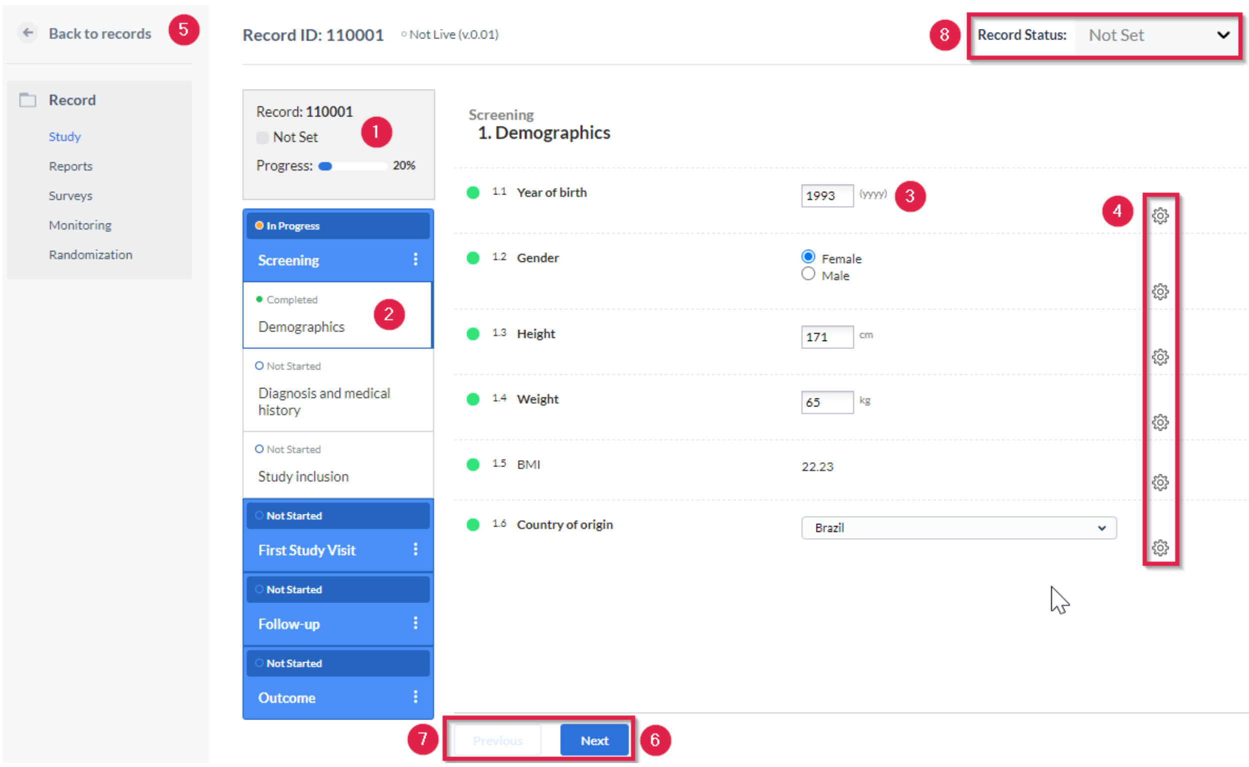


1. Study tab - You access this tab by default when you open the record; this is where you will see the study forms and can navigate between them.
2. Reports tab - Contains all reports that were created for the record, such as Adverse Event reports (see 'The Reports tab' section below).
3. Surveys tab - Contains all surveys that were created or sent to a participant.

4. Monitoring tab - contains an overview of relevant monitoring information, such as queries, verifications, and validations (see 'The Monitoring tab' section below).
5. Randomization tab - contains information on when and by whom the record was randomized and, in unblinded studies, the randomization allocation.

4.2.1 The Study tab

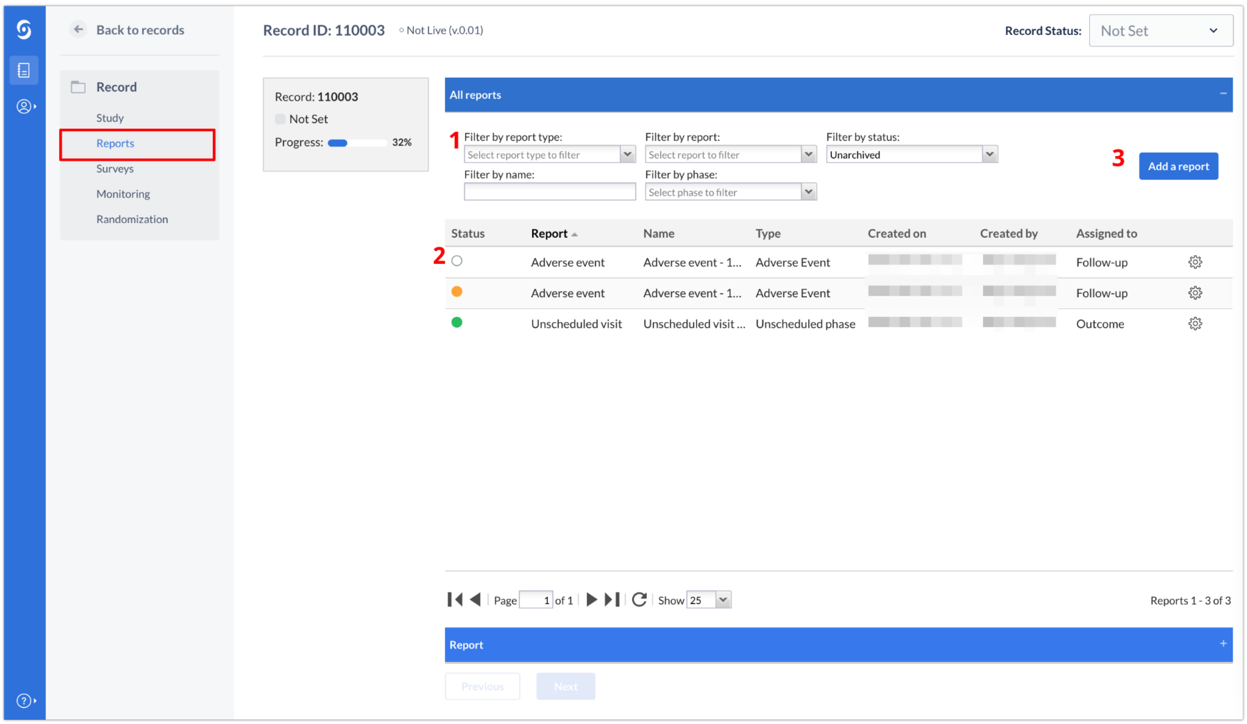
The Study tab in a record outlines all the study forms and allows you to navigate between the different pages.



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 review the entered data.
3. Data is added via questions, known as 'fields' in Castor.
4. The cogwheel menu beside each field can be clicked to view available options for the field. The options can include comments, audit trail and queries.
5. To exit the record and return to the record list, click on the 'Back to record list' button.
6. Once you have reviewed the form, you can navigate to the next step by clicking on 'Next'.
7. You can return to the previous step by clicking on 'Previous'.

4.2.2 The Reports tab

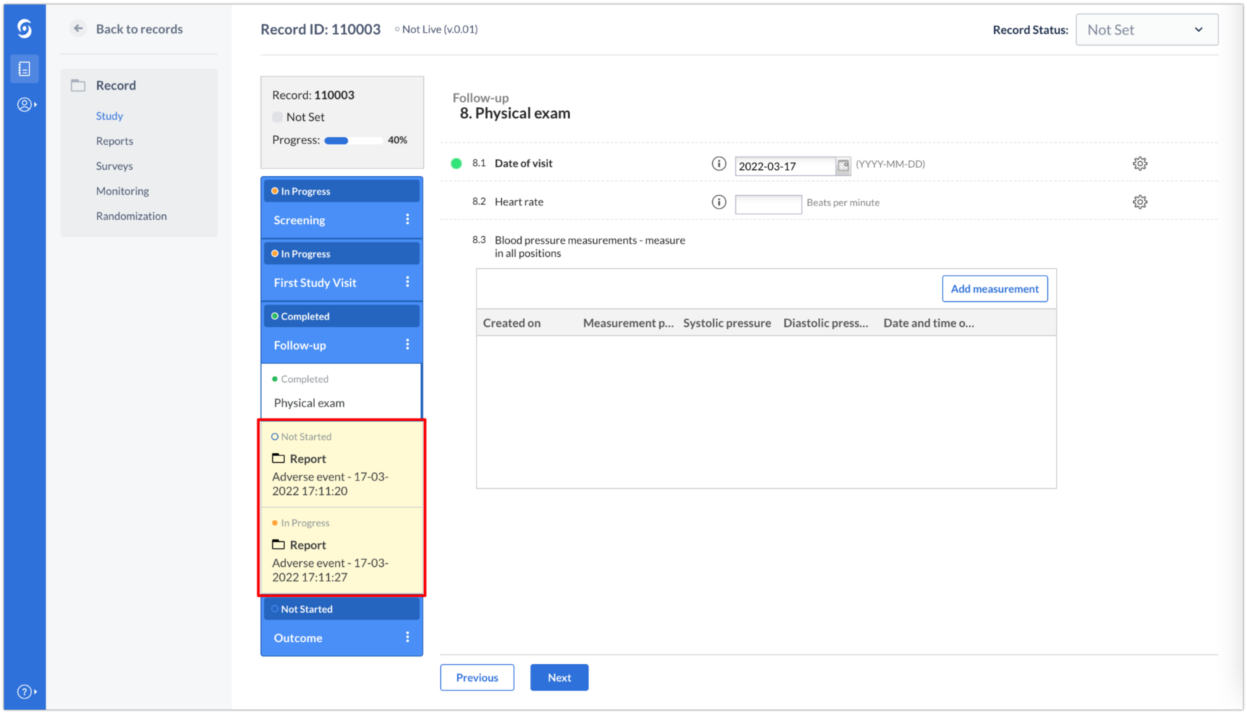
Report forms are used for unscheduled events, such as Adverse Event reports. The Reports tab in a record will show you all existing reports for that record. The 'general' Reports tab in the study overview will list all reports for all records.



1. To search for a report, you can use the many filter options in the top, such as report type (e.g. unscheduled visit) and parent phase (the phase to which a report is attached to).
2. Double-click the report of interest to open it. The dot/icon beside the report is used to indicate progress: green indicates the report is complete, orange indicates that the report is still in progress, and white indicates a report that has been created but not started.
3. You may also see the 'Add a report' button, which is used for adding new reports to the record.

The same data entry and monitoring rules apply for reports, as for the study forms: The reports have a status indicator which shows their completion and reports can be queried, signed, and verified.

If a report was attached to a phase, it will also be shown in the study overview:

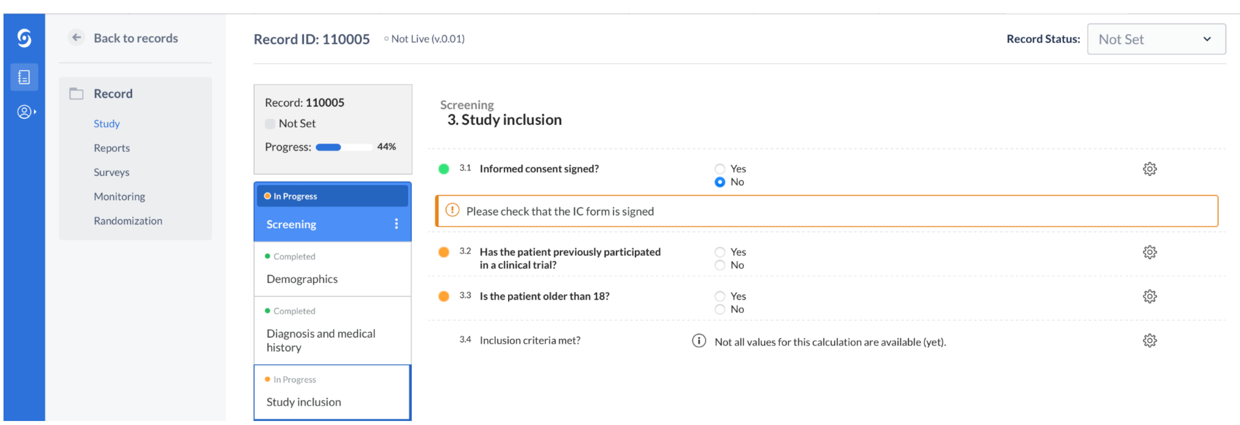


If you do not want to see the reports, you can untick the box 'Show reports' in the top left under the record progress.

4.3 Important indicators in data entry

4.3.1 Data validations

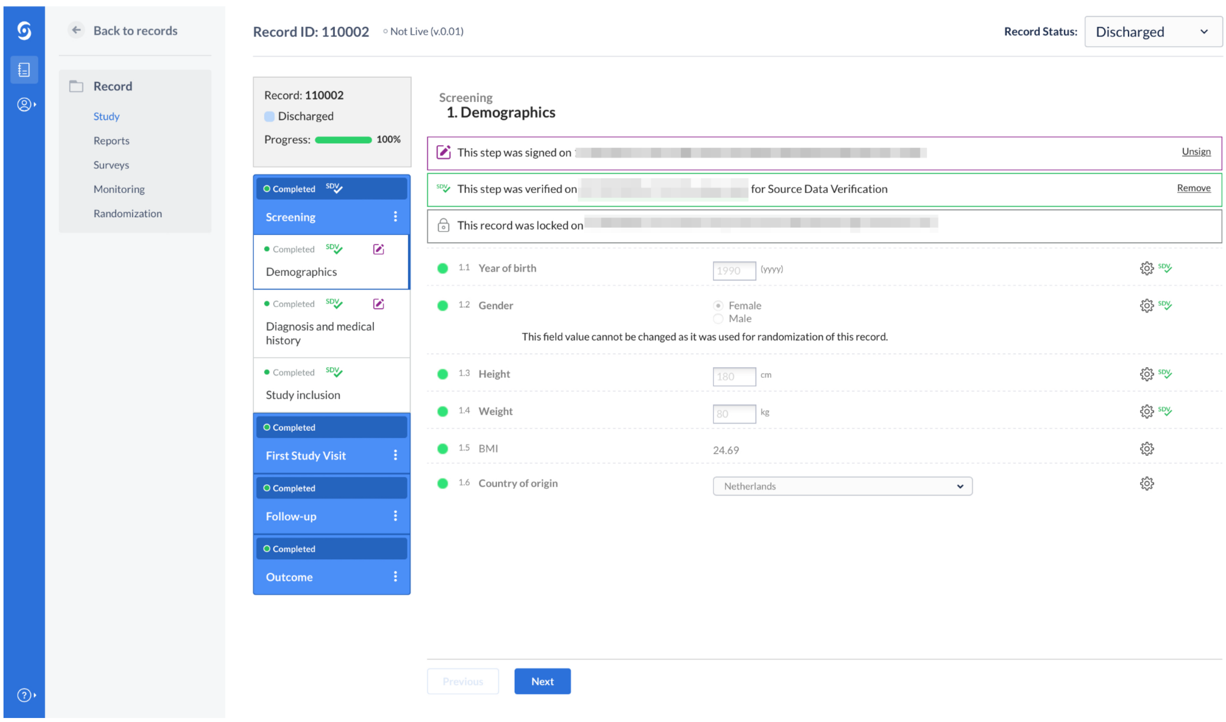
Data validations (edit checks) are programmed by the study admin at the beginning of the study. If the entered data in the study or reports meets a certain condition, a message will appear indicating this next to the affected field:



Data validation types include errors, messages, warnings, and exclusions. With the exception of errors, existing data validations will be saved on the Monitoring tab under validations.

4.3.2 Signed, locked, and verified steps

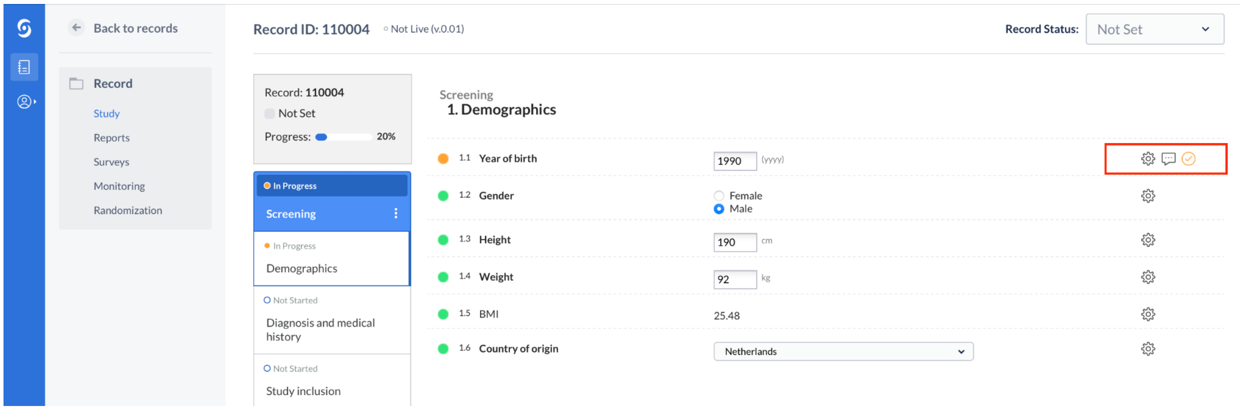
While navigating through the study or report forms, if a form was signed or locked, there will be banners indicating it at the top:



The signature, lock and SDV icons will also be displayed next to the step name in the step navigator to the left. (See also: SDV section below).

4.3.3 Field comments and queries

You might also notice a text bubble in certain fields, this indicates an added comment:



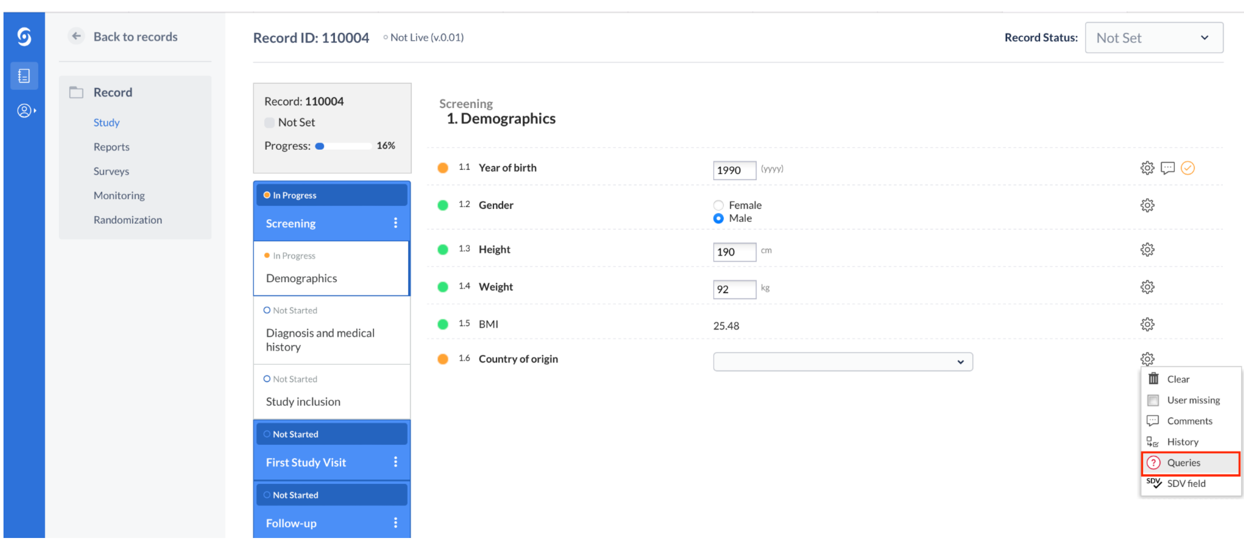
Comments are mandatory when making changes to a signed or verified form or, if the GCP module is turned on in Study settings, changing a field's value. All fields with such changes will have an associated comment. These cannot be modified or deleted.

When a query is present in a field, the query sign will be shown next to the field (see Monitoring Queries section below).

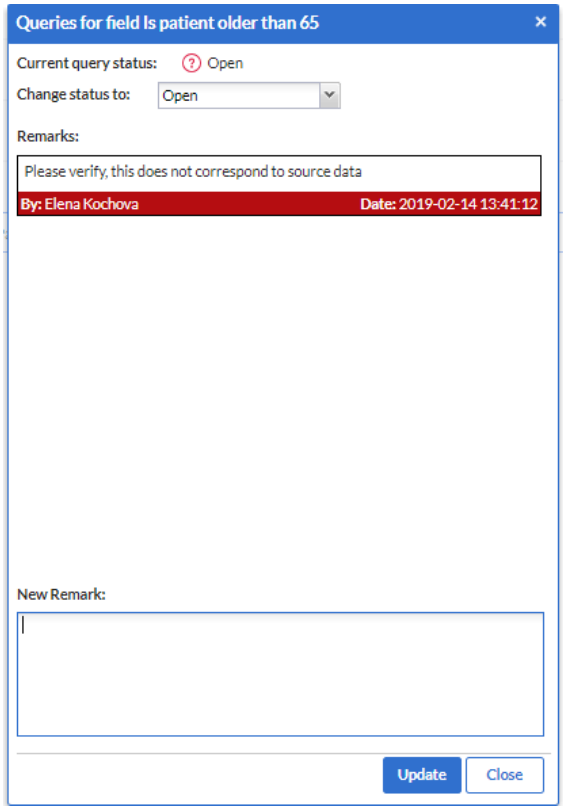
5. Monitoring Queries

5.1 Adding queries

To create a query for a field, while in the relevant form, click on the cogwheel icon to the right of the question. From the presented options, choose 'Queries':

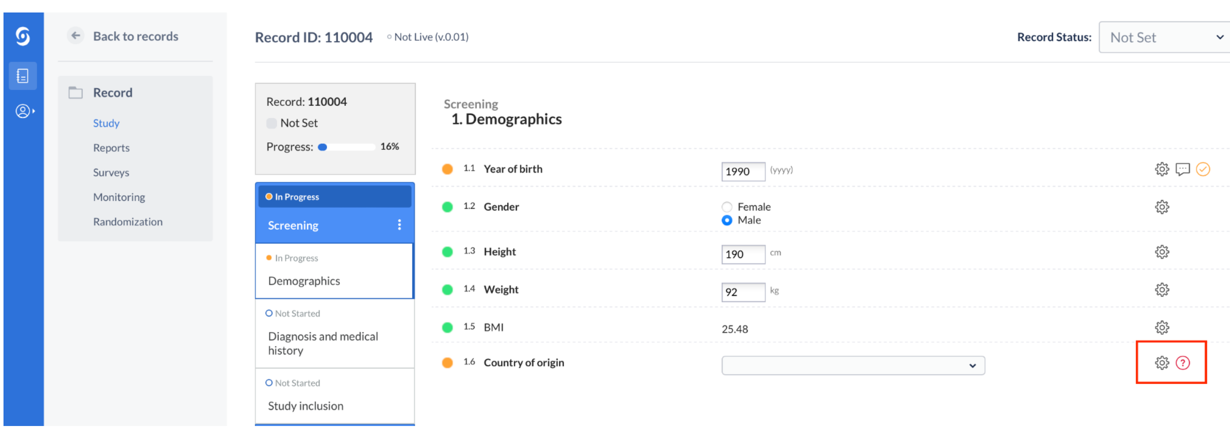


This will open a new dialog, where you can add your remark and click on 'Update' to save the query. The query dialog displays the following:



- The current query status.
- The 'Change status to' dropdown - here you can change the status to Closed when necessary.
- Remarks - This is where all remarks entered by you or by data entry users are listed.

Once you have added a query, you will see that the field status has been updated to incomplete, as indicated by the orange bullet. The query icon (question mark) will appear next to the field.



5.2 Query resolution

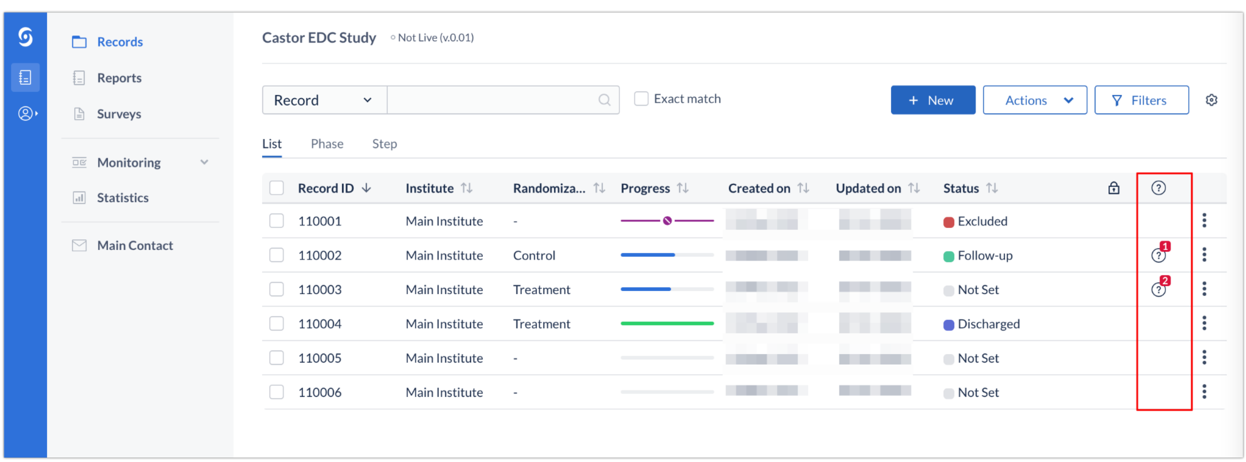
When an existing query is verified or resolved by a data entry user, they can add their remark by changing the status of the query to one of the following options:

- Unconfirmed: The user does not agree with the monitor.
- Confirmed: The user agrees with the monitor and will resolve the issue.
- Resolved: The user has changed the value and indicates the issue is resolved.

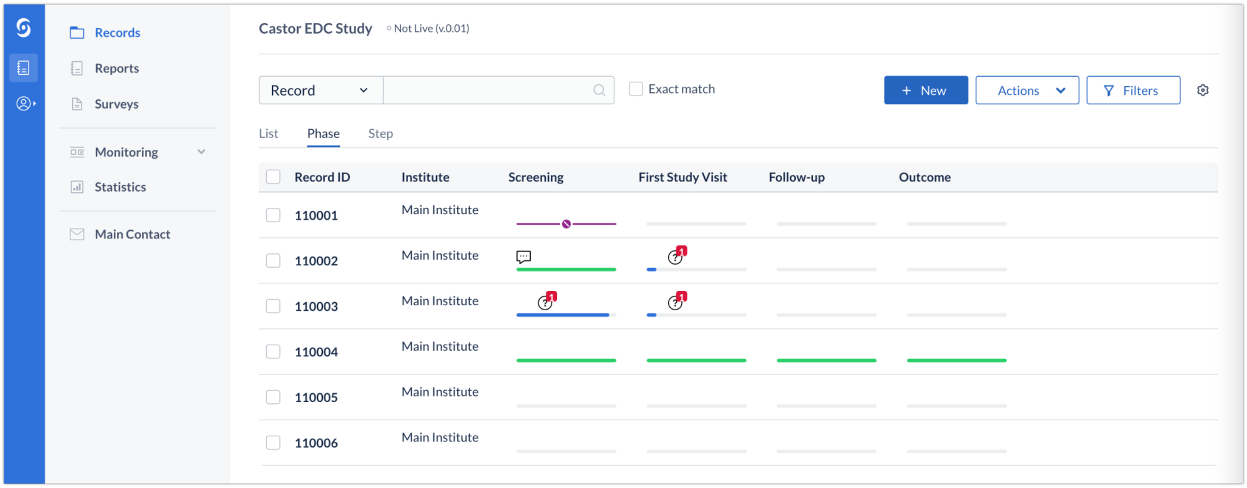
There are three types of query icons: Open (includes confirmed and unconfirmed queries), Resolved, and Closed. Only when the query is closed will this field be marked as complete again (green bullet). Only the monitor can close a query.

5.3. Query overview

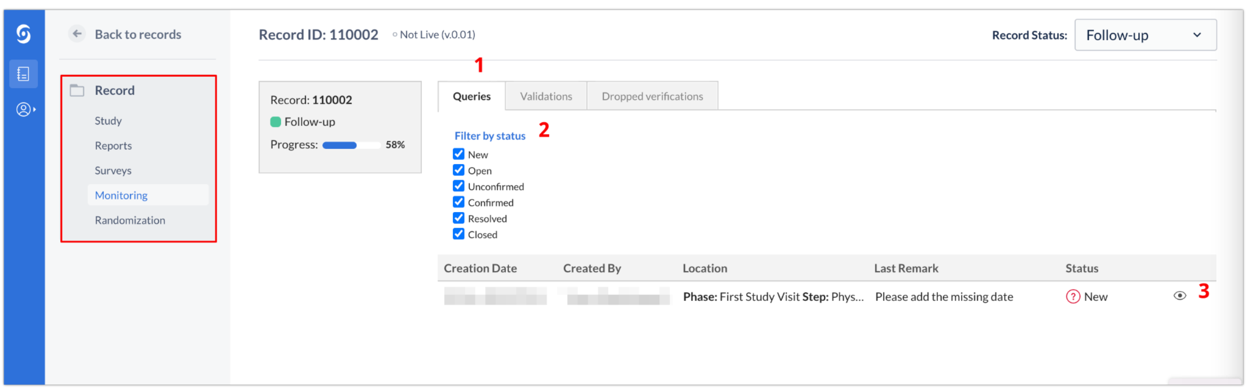
Existing queries are indicated with their respective icon in the Records list, in the 'Queries' column:



This is also indicated in the ‘Progress by steps/phases’ view mode in the Records tab:



All queries for a record and their status are listed and can be reviewed from the record’s Monitoring tab, Queries subtab:



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.

All queries for *all* records are available in the general Monitoring tab (see Monitoring tab section below).

5.4 Automating queries

Automated queries can be programmed by the study admin. When this is the case, the queries are automatically generated when the defined conditions are met.

5.5 Query notifications

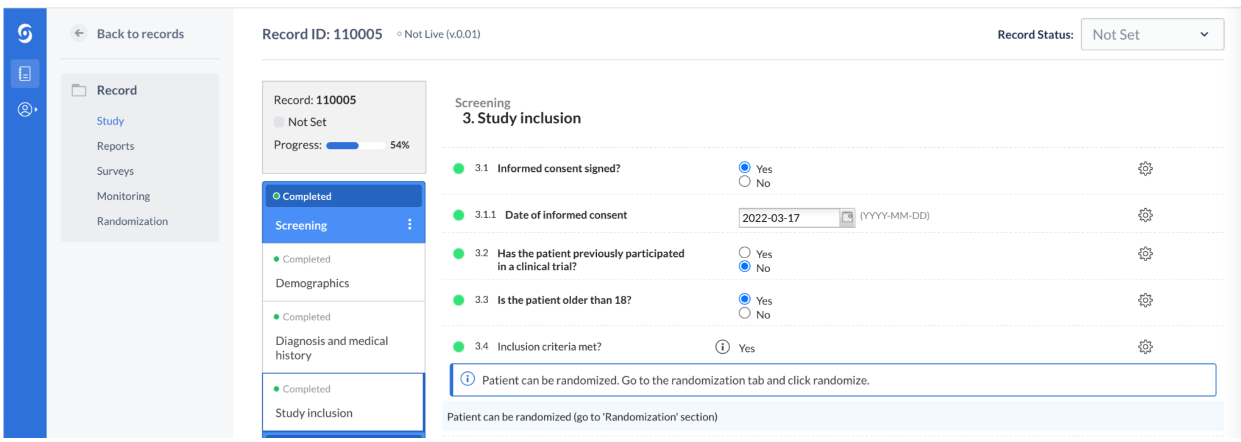
Upon query creation, a notification can be sent to a selected user in the study. All query creation notifications will be sent to that user. This notification needs to be set up by the study admin in the Settings tab.

6. Data validations

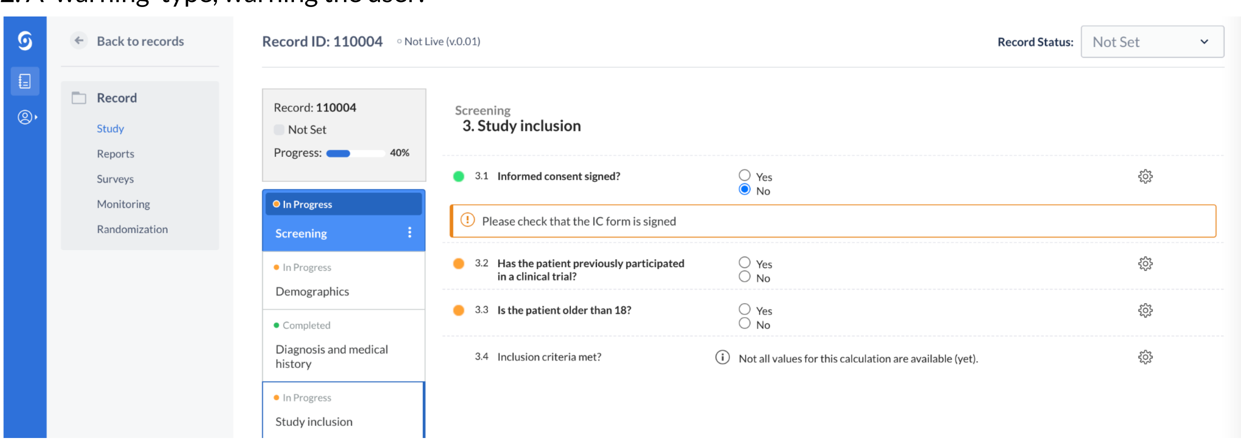
Validations are pre-programmed edit checks that show messages to the data entry users. While navigating through the study forms, you can check if such validations have been activated. These appear as banners attached to a field for which they were programmed.

There are three types of validations that can be active:

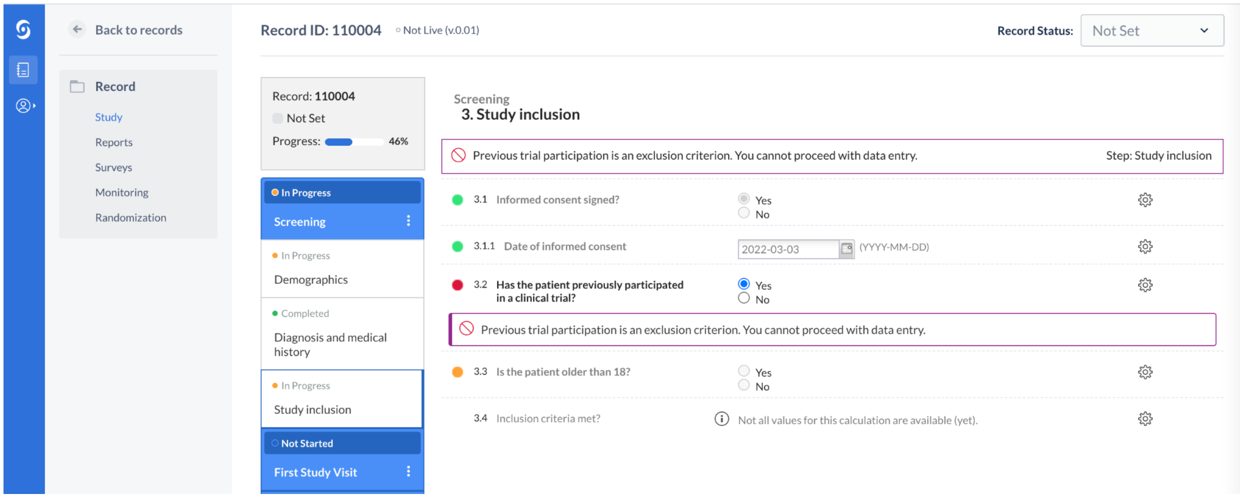
1. A 'message' type, conveying information to the user:



2. A 'warning' type, warning the user:

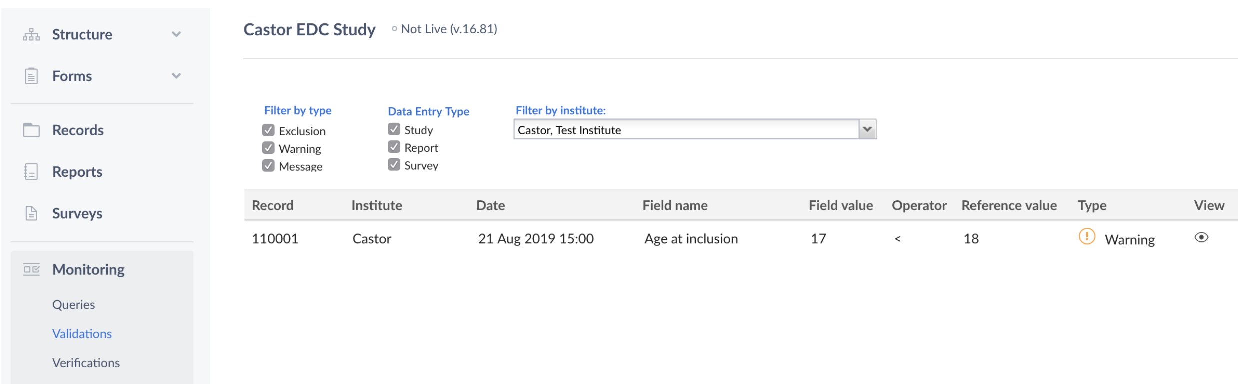


3. An 'exclusion' type, when the entered data does not meet inclusion/exclusion criteria:



When the exclusion validation is active, further data entry or navigation between steps is not possible.

All active validations for a record are shown in the record's Monitoring tab, Validations subtab:



All active validations for *all* records are available in the general Monitoring tab (see Monitoring tab section below).

7. Source Data Verification

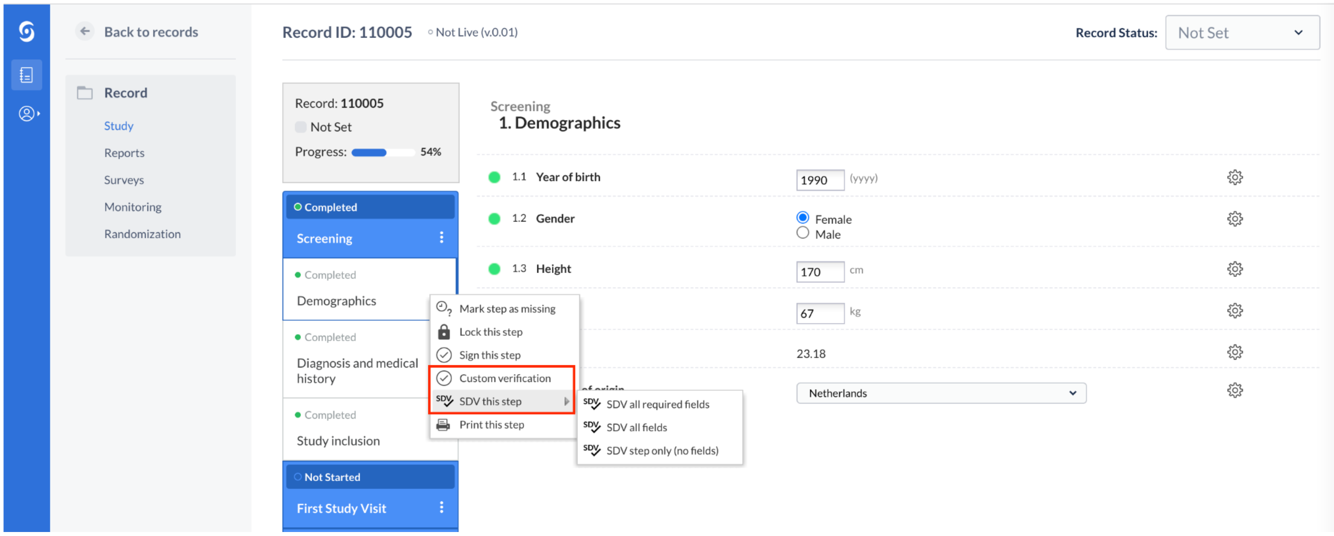
Study monitors performing source data verification (SDV) are able to mark steps and phases as verified. Currently, verification per field is not supported.

7.1. Verify a study form

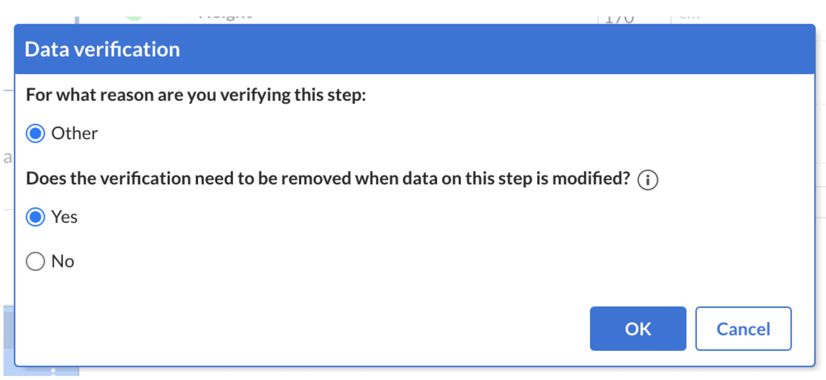
You can mark a step or phase as verified. To do so:

1. Open the record where you want to perform SDV or any other data verification that is relevant for your study.

2. In the left panel, click on the phase or step that you want to verify. Click on the three dots next to it and select to apply Source Data Verification or Custom verification:



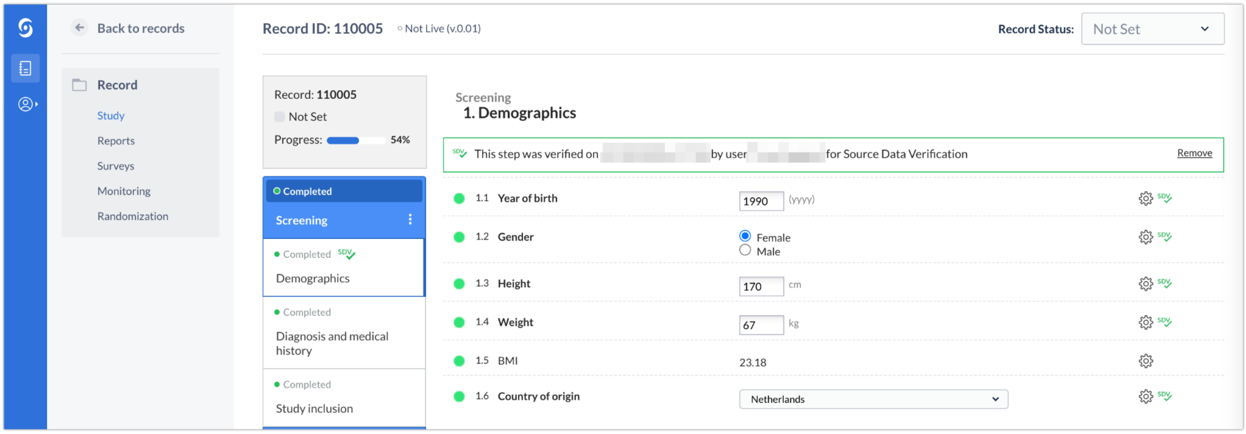
For custom defined verifications, you can select whether the verification will be dropped (invalidated) if data is modified in that step/phase. For source data verification, this is by default the case:



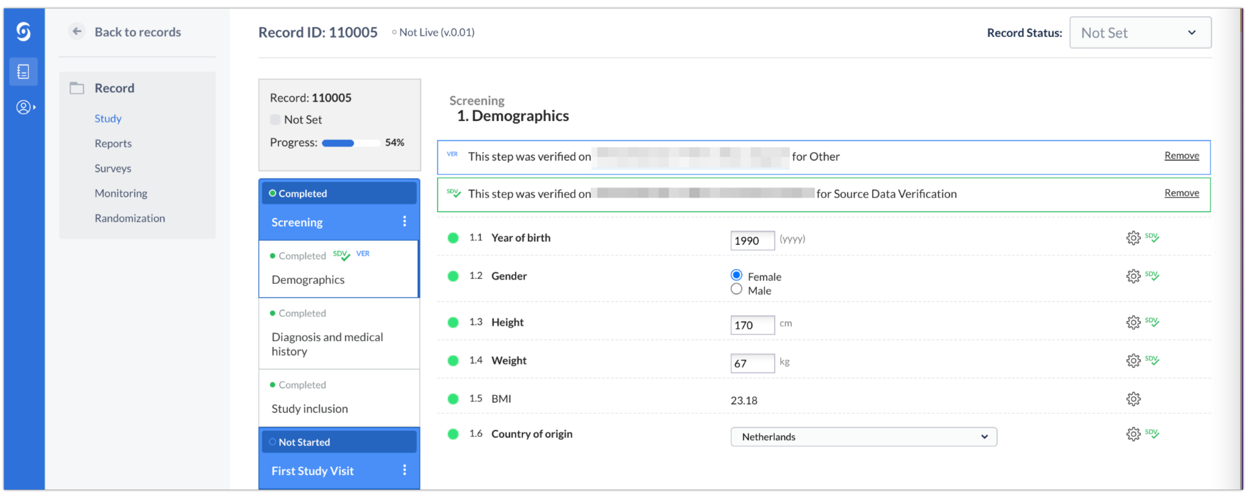
3. Click 'OK' to save the verification or 'Cancel' to return to the data entry view.

7.2 SDV indicators

In a record, each verified step will be marked with a green banner indicating the date and time of verification as well as the name of the user who performed verification. If two users need to verify the same form, the banner will appear twice. In the banner, there is the option to 'remove' the verification - this can be done only by the user who performed the verification.

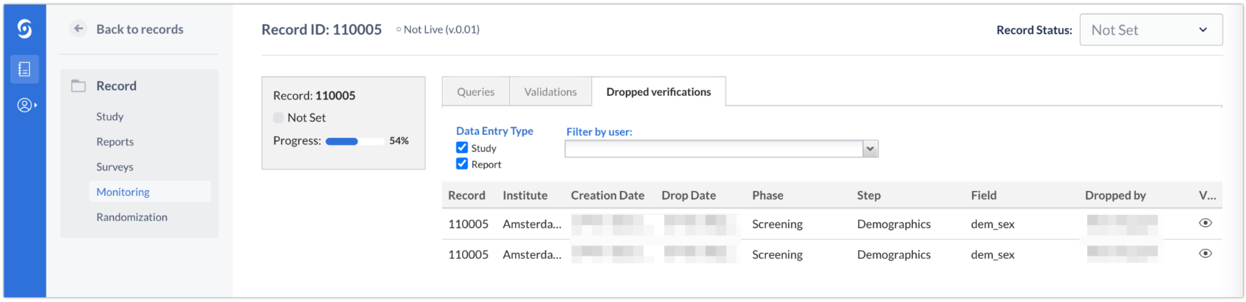


Reports that are marked as verified have the SDV icon when attached to a phase. In the event that a custom verification type was performed, the VER icon is attached:



7.3 Modifying data after SDV

After a form is verified, if a user attempts to change data, they will receive a warning and any data modification will cause the form verification to be dropped. It is also possible for the study admin to set up email notifications whenever form verifications are dropped, to ensure that the appropriate contacts are notified of changes made to verified data. All dropped verifications for a record are listed in the record's Monitoring tab, Verifications subtab:



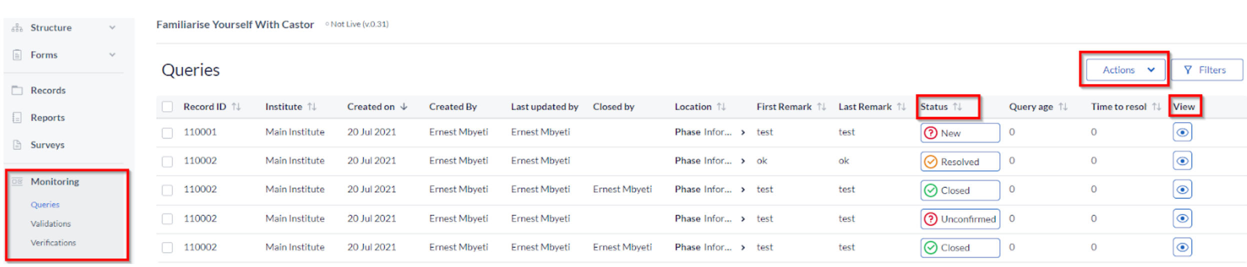
All dropped verifications for *all* records are available in the general Monitoring tab (see Monitoring tab section below).

8 The Monitoring tab

Within the general study overview, you can also access the 'general' monitoring tab, that gives an overview of all the queries, data validations and dropped verifications for all records in a study. The Monitoring tab within a record will include the same sub-tabs, but these will contain only the information relevant for the selected record.

8.1 Queries subtab

In the Queries subtab you will find an overview of all queries in a study and details associated with them:



- **Record ID**: ID of a record where a query has been created
- **Institute**: institute to which the record is linked
- **Created on**: date and time when a query is created
- **Created by**: user who created a query
- **Last updated by**: last user who updated a query
- **Closed by**: user who closed a query
- **Location**: location of the field where a query was raised. Clicking on the arrow icon > allows you to expand the location and see the Phase, step and field labels where the query was created.
- **First Remark**: initial comment which was added when creating a query
- **Status**: status of a query. Clicking on the query status will open the query window where you can update the query.

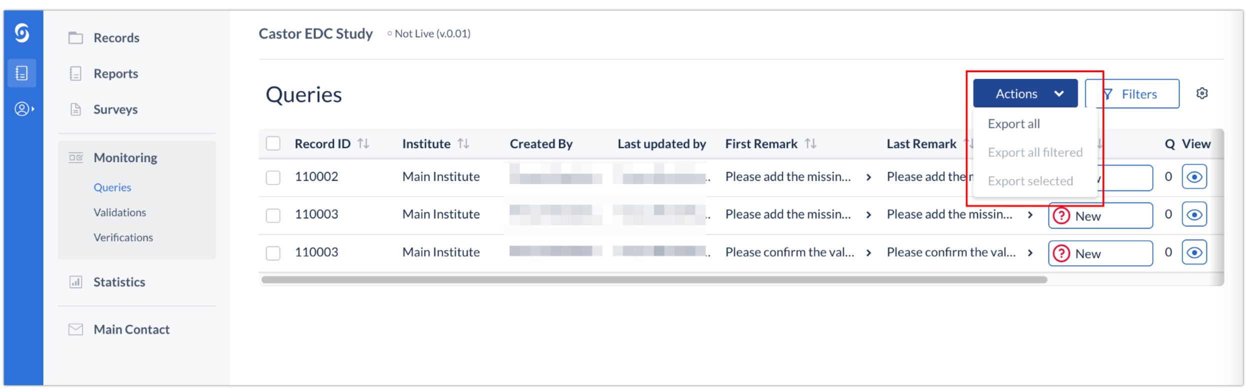
- **Query age**: how long ago was a query created
- **Time to resolve**: time that require to resolve a query
- **View**: click on the eye icon to view the query in a step where it was created

Using the “Filters” button, you can filter by status (open, resolved, closed), or filter by institute to only show queries for records which belong to a particular institute. You can sort the queries based on the record ID or creation date by clicking on the column name. By clicking the status icon of the query, you can view all associated remarks and you can also add a remark and change the status of the query, if necessary.

8.2. Exporting Queries

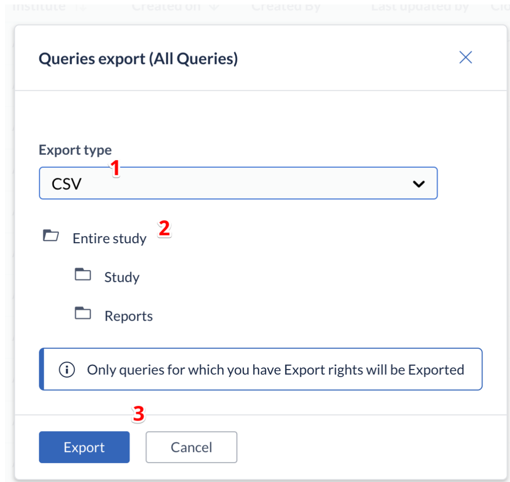
Users with Export rights can export the queries overview in bulk, either by exporting all available queries or only the ones that the user has selected or filtered. To export the queries from the Monitoring tab, Queries sub-tab, follow the steps below:

1. Click on the Actions button and choose to Export either all queries, export all filtered or all selected:



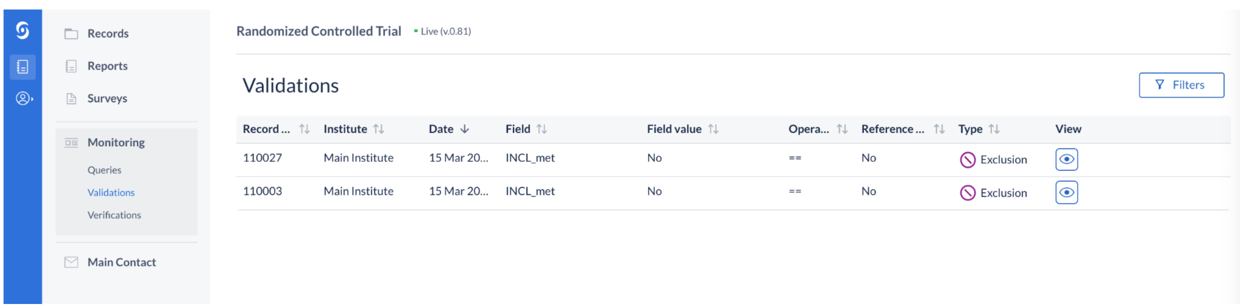
In Queries export dialog window, specify:

- **Export type**: choose to export into CSV or Excel (1)
- **Export tree**: choose if you would like to export queries for entire study, specific study phases or steps in your study or for reports, a specific report or a report step (2)
- **Export**: click on Export button to generate export of the queries (3)



8.2 Validations subtab

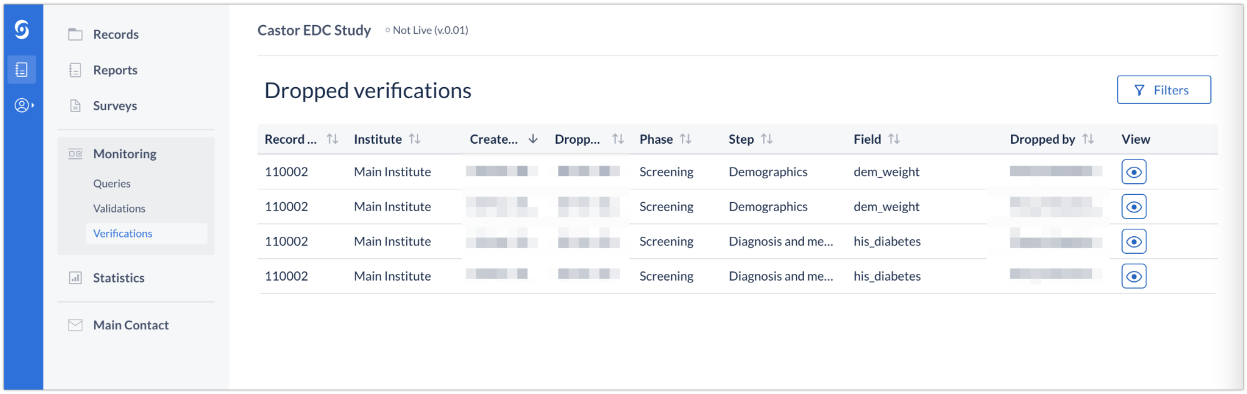
The Validations subtab displays all active validation fields in the study, reports or surveys.



- Using the "Filters" button, you can filter the validations by validation type, data entry type, and institute.
- Each row contains the record ID, institute name, date, field name and field value associated with the validation.
- The operator represents how the field and reference values are compared, depending on the setup of the validation message. The reference value represents the value that is used to compare 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'.

8.3 Verifications subtab

This subtab displays all dropped verifications in the study:



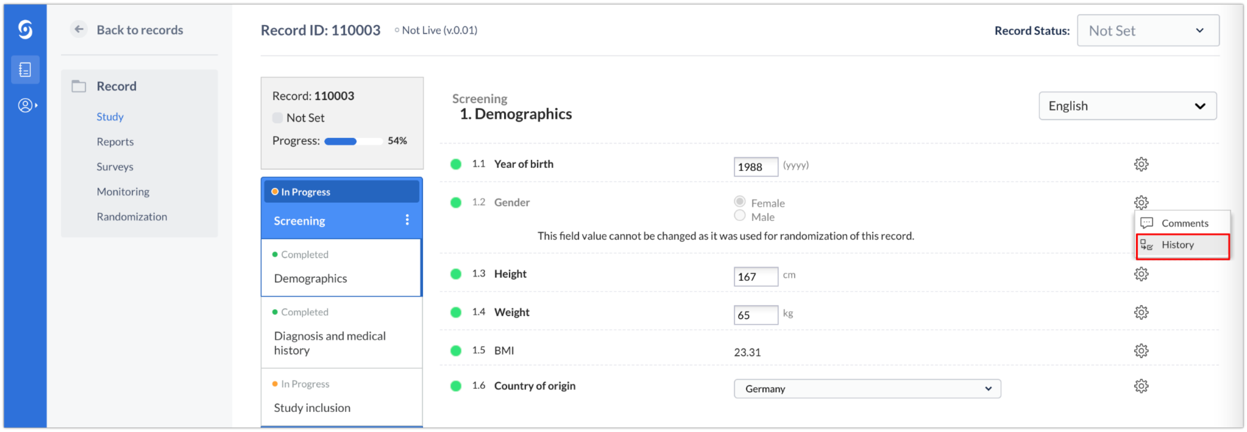
- Using the “Filters” button, you can choose to show dropped verifications for the study or for reports only. You can also choose to filter by user (who dropped the verification) and by institute.
- Each row shows the record ID, the institute name, creation date, drop date, the phase and step where the field is located and the name of the field that was changed to remove the verification.
- To open the record and jump to the step where the verification was dropped, click on the eye icon in the column 'View'.

Please note that this tab does not display active verifications, but only invalidated ones. To see all active verifications, go to the Records tab and use the "Phase" or “Step” view mode. Verified steps will contain a green checkmark. (See Records tab section below)

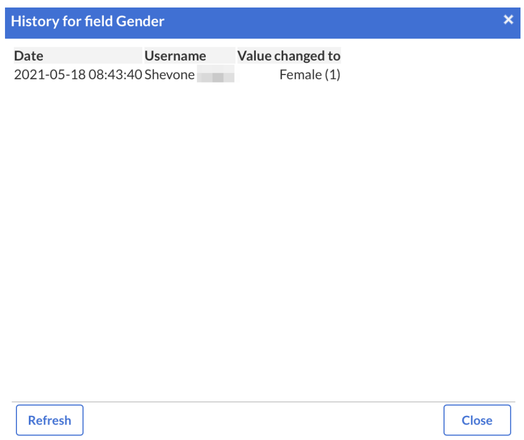
10. Using the Audit Trail

The study audit trail allows for a review of all access and changes made to study settings and data. It is possible to apply a filter to the displayed information based upon the event type, the user and the affected variable (where applicable). Access to the full audit trail is normally available only to study admins with all management rights.

As a monitor, in data entry you can view the audit trail for all record results. To view the audit trail of a single field, click on the cogwheel next to the field:

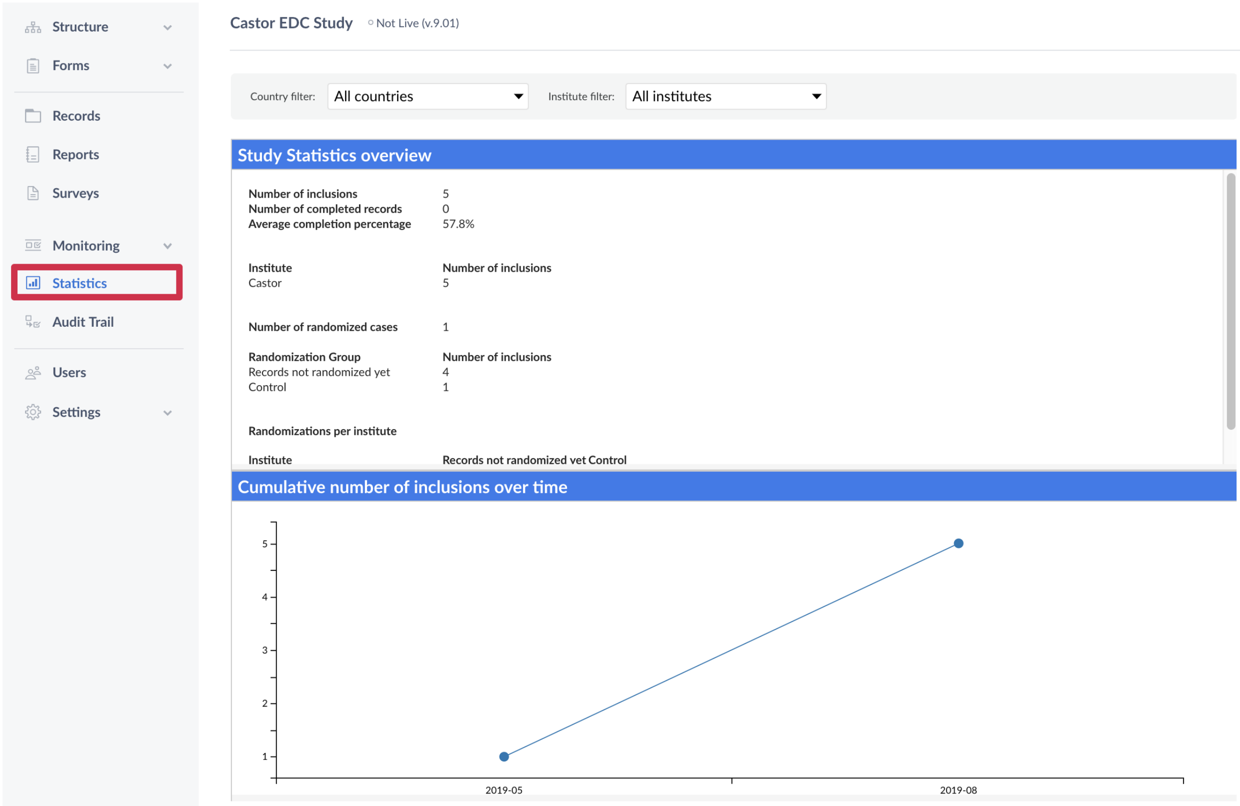


A popup will appear detailing the changes to the field. The date, the user who changed the field, and the new value are all displayed:



11. Study statistics

The study statistics overview shows inclusions and randomization information. Users that have "Manage Records" rights can view the Statistics tab:



In this tab you can see the inclusions for each institute and the number of randomized records. The randomization allocation will only be visible if you have 'View randomization' rights. In the lower graph on this page, the cumulative number of inclusions over time is shown.

11. Further information

If you would like to watch our webinar for study monitoring, you can do so here.

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