Castor

Castor EDC Monitoring User Guide

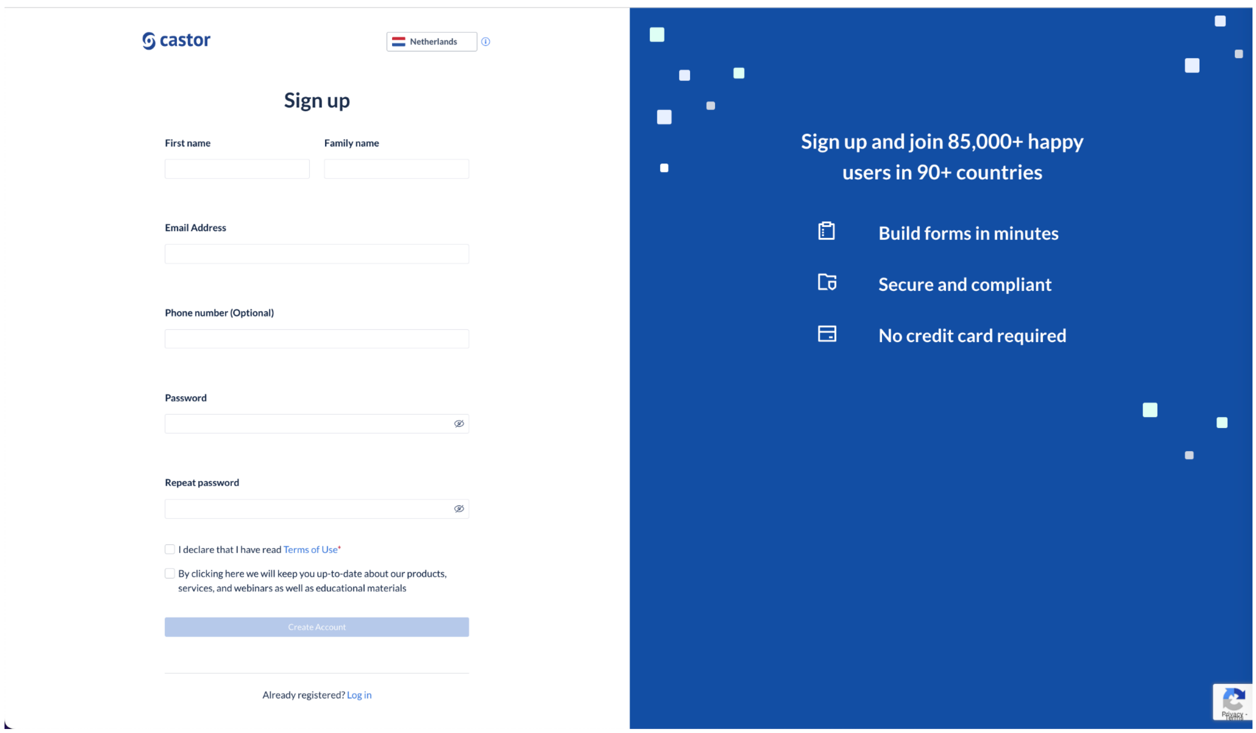
Version 2022.1

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:



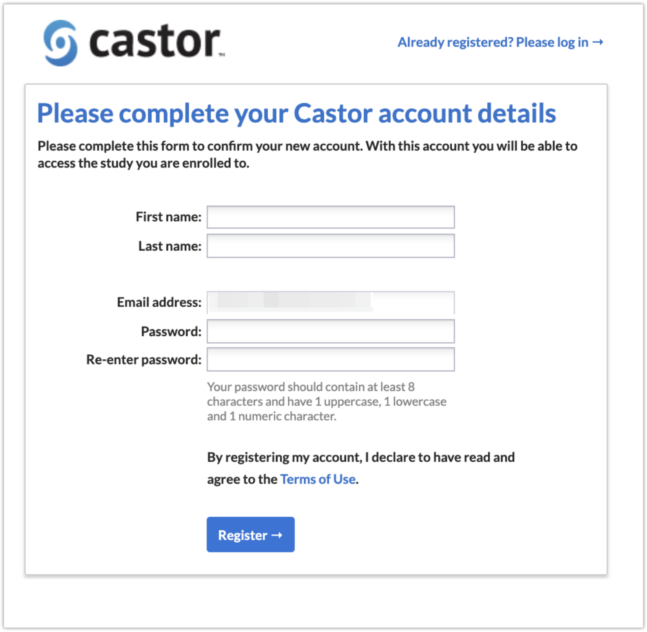
- EU Account: https://data.castoredc.com/register
- UK Account: https://uk.castoredc.com/register
- US Account: https://us.castoredc.com/register
- AU Account: https://au.castoredc.com/register

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:

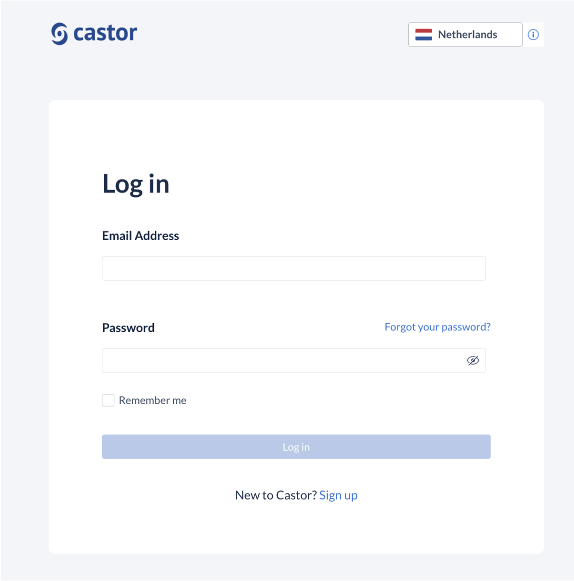


1. Fill in first and last name(s).
2. The email address will be pre-filled, choose a strong password, consisting of at least 8 characters, one uppercase letter, one lowercase letter and a number.
3. Click on 'Register'. Shortly after registering you details, an email with an activation link will be sent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

2. Log In

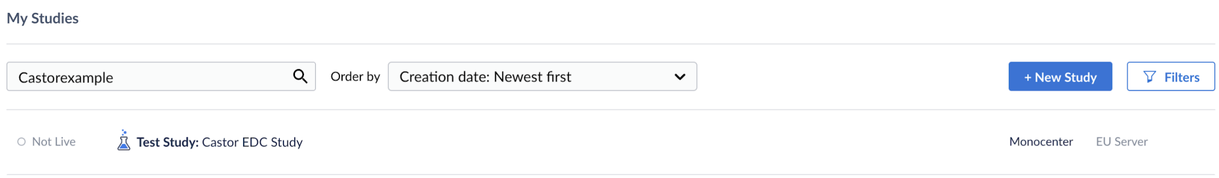
To access the study, log into Castor EDC via https://data.castoredc.com (NL server). If your study is on the US, AU or UK server, you can also directly go to https://au.castoredc.com/register, http://us.castoredc.com or http://uk.castoredc.com, respectively.

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'.

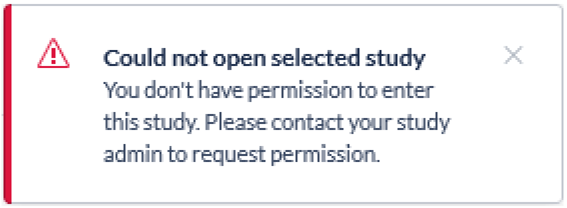


3. Open a study

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), you can click on the study name to enter the study.



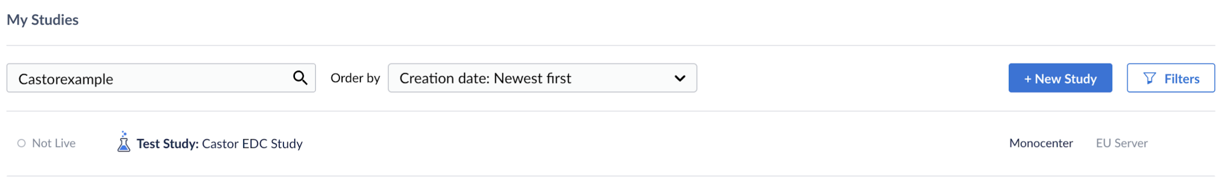
Trying to open a study that is not live will show the following warning:



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 has management rights.

3. Access 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 next to the study title), you can click on the study name to enter the study and perform your monitoring activities.

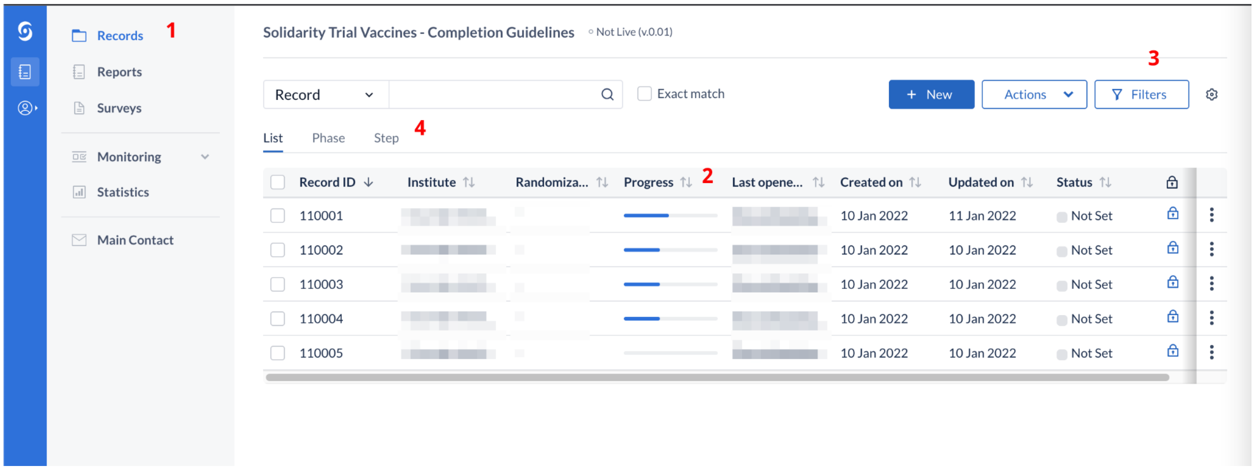


The study will open on the Records tab. As a monitor, you will most likely see the following tabs:

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

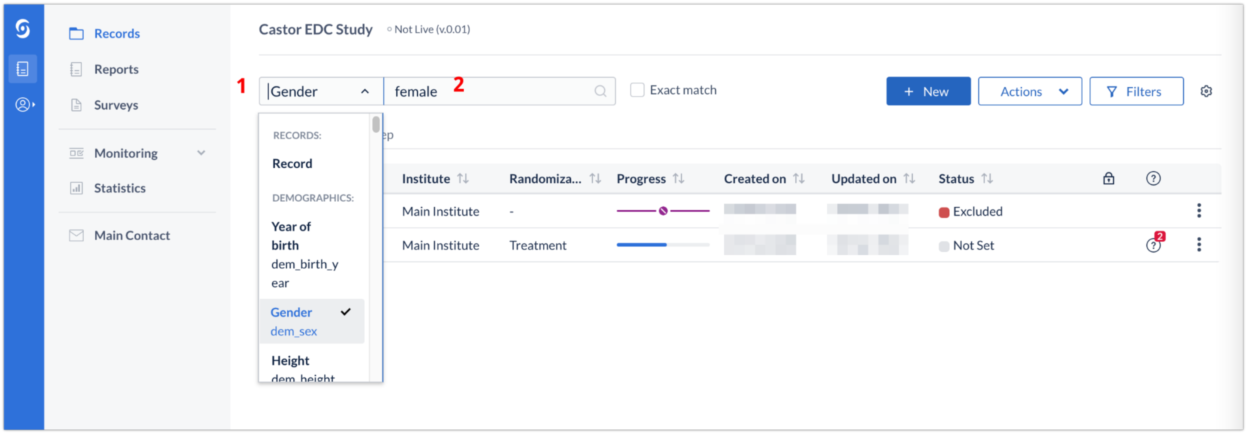
In the Records tab, a list is displayed showing all records for the institutes to which you have 'View' rights (see Section 6).



1. In the 'Records' tab, a search box is available, in which it is possible to search for a particular record ID. More information on the search is provided in section 4.1.
2. The 'Progress' column will show the status of completion for each record.
3. By default, all records are shown, however you can use the 'Filter' button to filter based on various parameters.
4. It is possible to change the view mode to show the progress of the records by phases or steps. This will display the status of completion of each step for each record. Double click on any phase or step to directly access it.

4.1. Search for Records

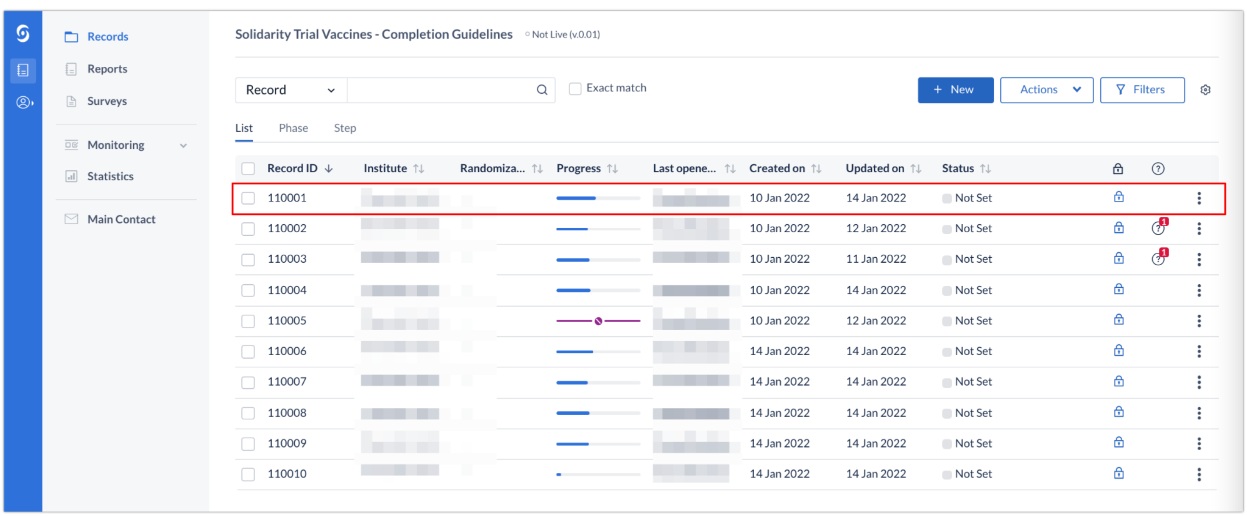
You can use the search bar to find records that contain certain data, for example if you want to find the patients with a certain age at onset.



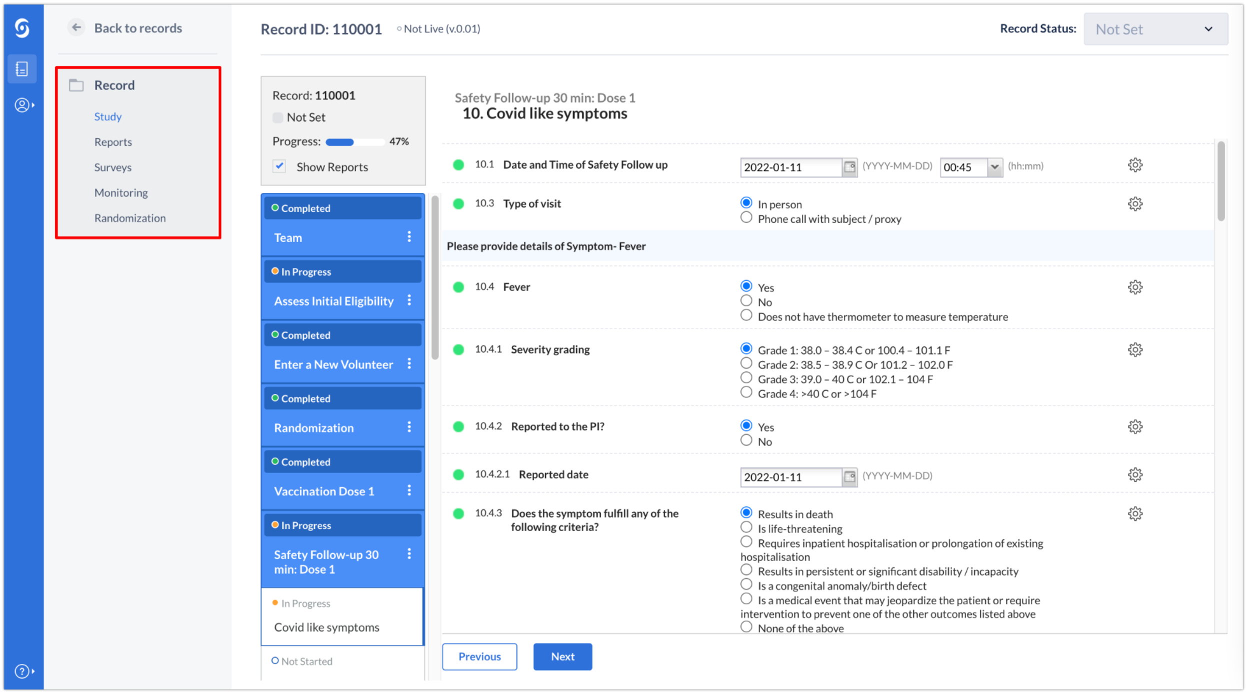
1. Click on the arrow in the right search box and find the field (question) of interest. In this example ‘Gender’ is selected.
2. Enter the value of interest in the left search box (in this example ‘female’) and all matching records will be displayed.

4.2. Accessing a Single record

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



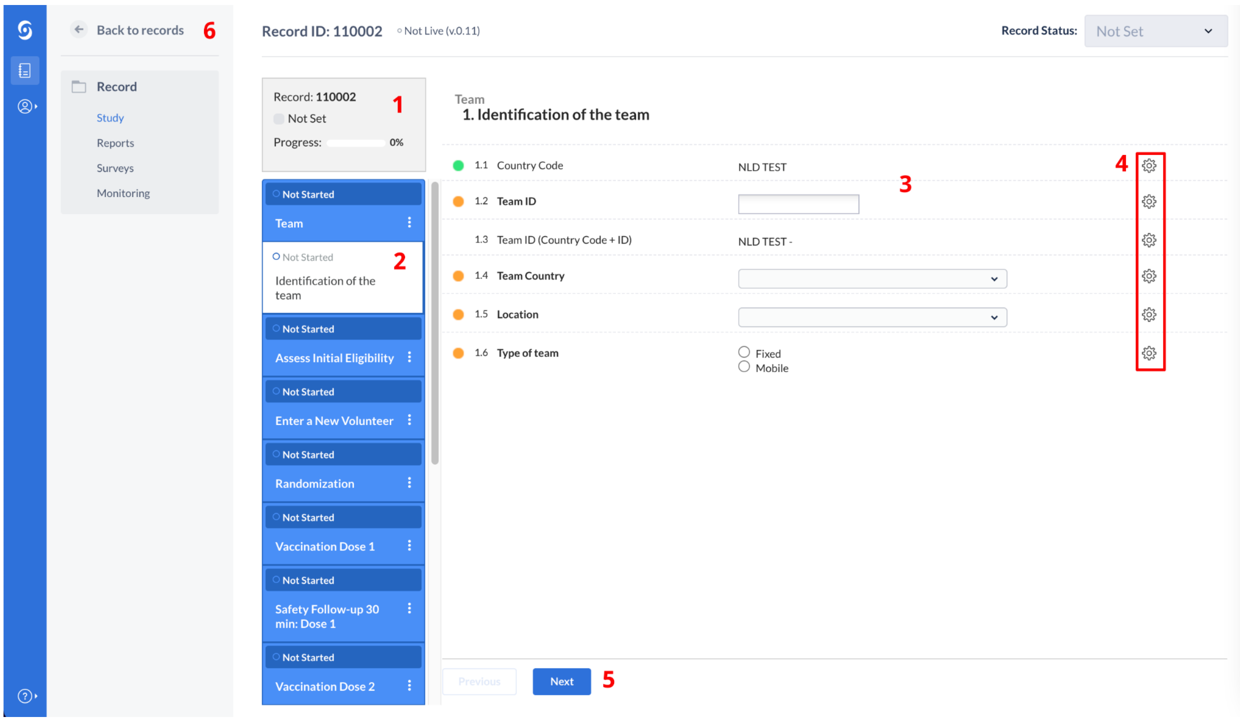
There are a total of 5 available tabs within a record, but which tabs you see depends on the study setup and your specific user rights:



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.



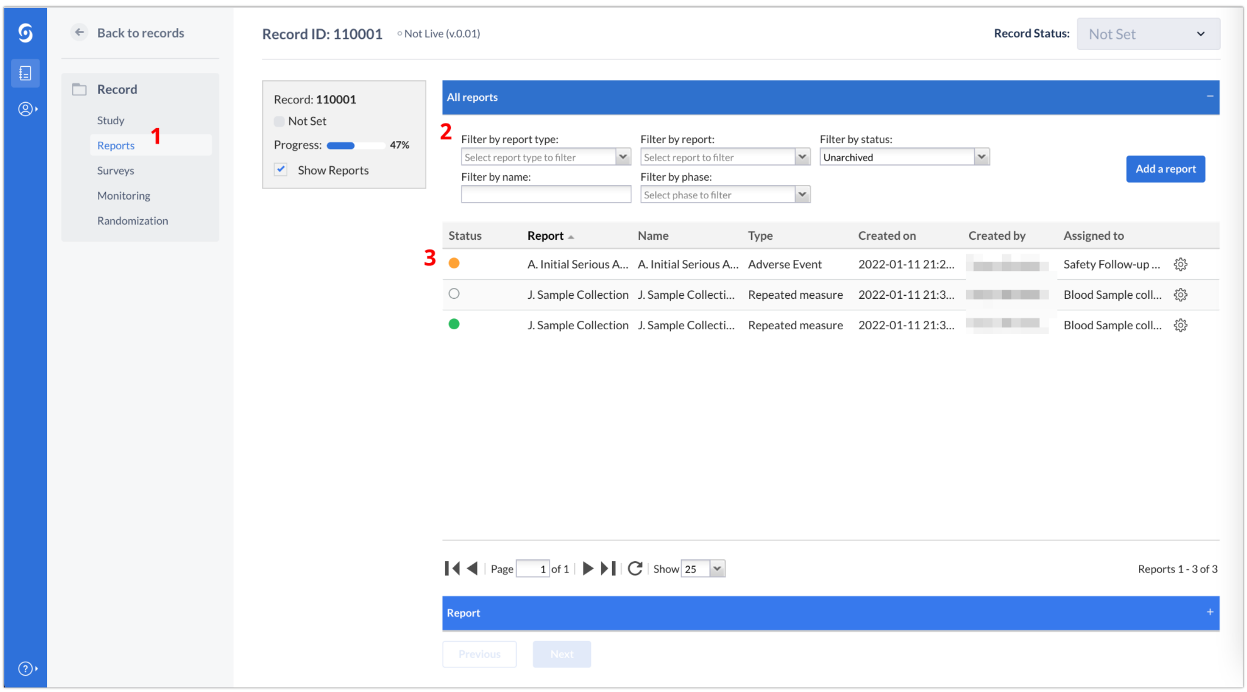
It consists of the following elements:

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. You can click on the step of interest in this panel to start entering the required data. Once you answers 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. It is possible to navigate to the previous/next step by clicking on 'Next' or 'Previous'. If you reach the first or the last form, these buttons will be grayed out.
6. To exit the record and return to the record list, click on the 'Back to records' button.

4.2.2 The Reports tab

Report forms are used for unscheduled events, such as Adverse Event reports.

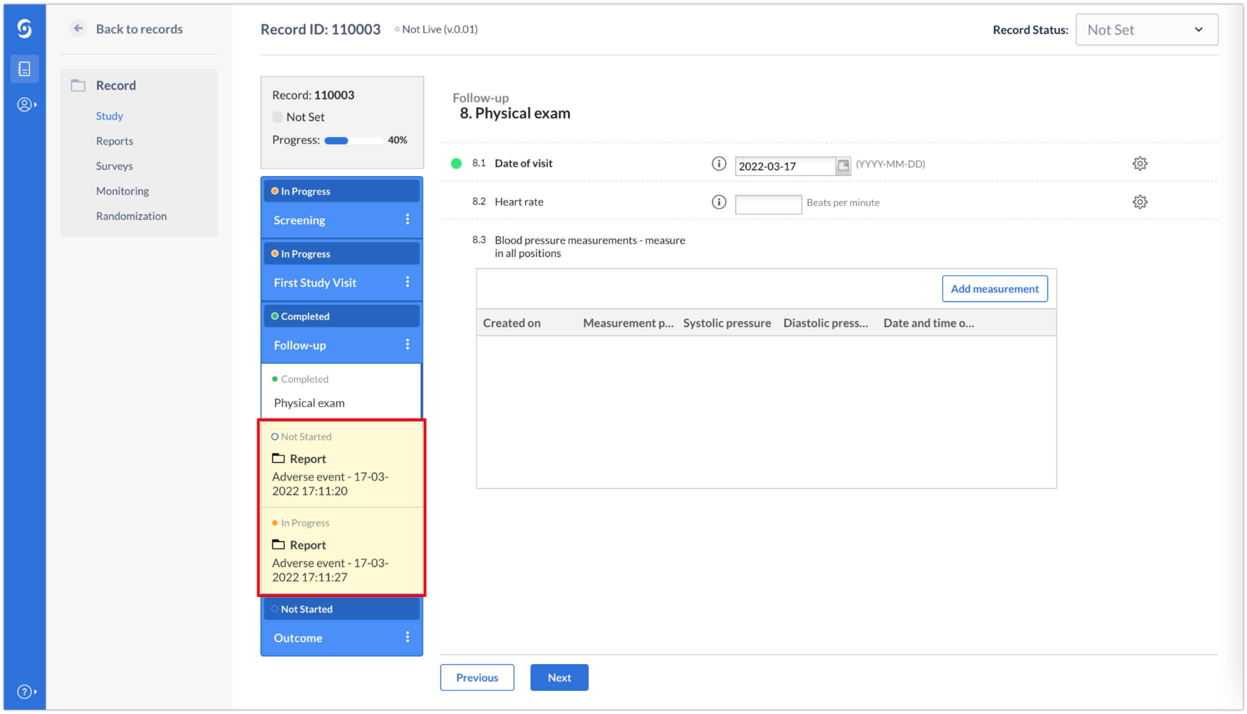


1. The 'Reports' tab in a record will show you all existing reports for that record. The global Reports tab in the study overview will list all reports for all records.
2. To search for a report, you can use the many filter options in the top, such as report type (e.g. unscheduled visit) and parent phase (the phase to which a report is attached to).

3. 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. You may also see the 'Add a report' button, which is used for adding new reports to the record. Additionally, reports are added directly via a step.

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:



4.3 Important indicators in data entry

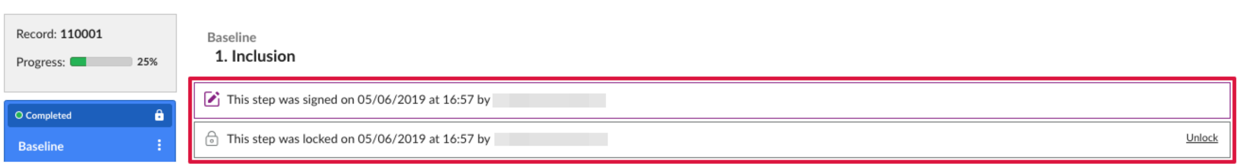
4.3.1 Data validations

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 visible in 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:

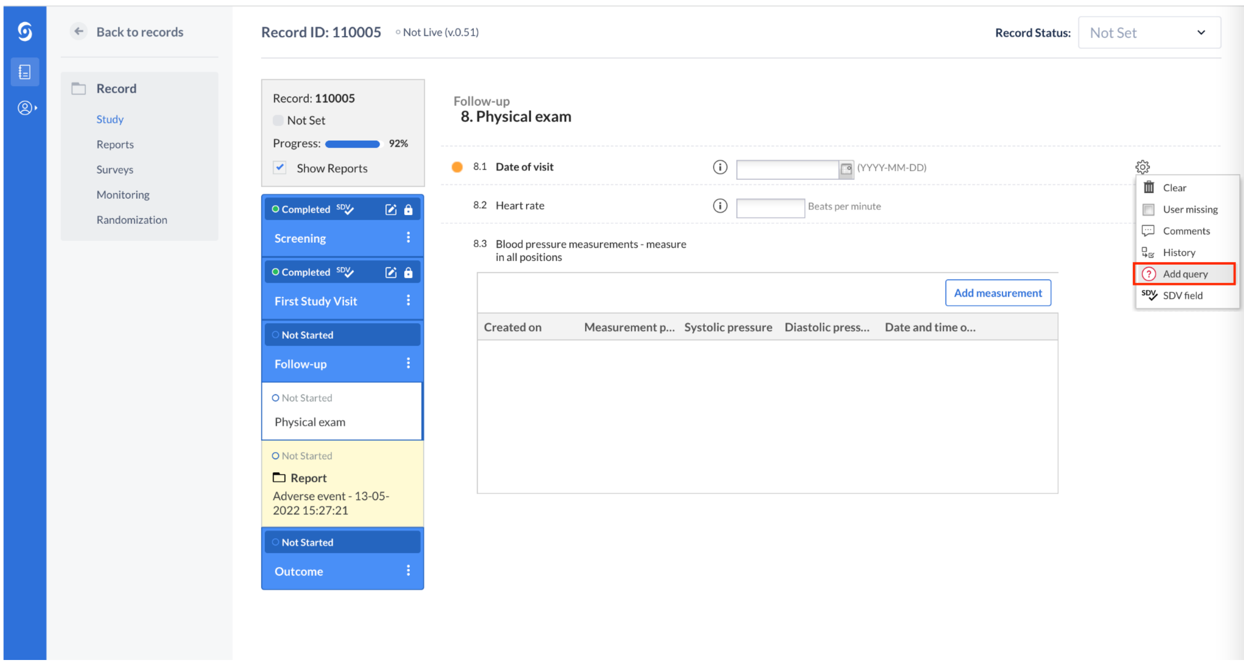
Comments are mandatory when making changes to a signed or verified form or, if the GCP module is turned on in Study settings, changing a field's value. All fields with such changes will have an associated comment. These cannot be modified or deleted.

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

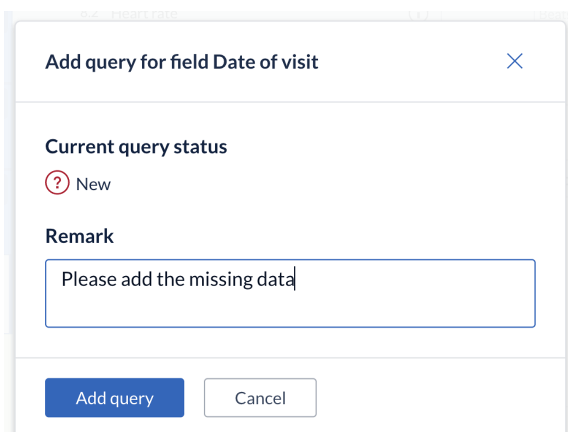
5. Monitoring queries

5.1 Adding queries

1. 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 ‘Add query’:



2. A pop-up window will appear where you can enter your remark. Click on the ‘Add query’ button to save the query.



3. You can also add multiple queries to the same field allowing them to be simultaneously managed by monitors on single data points (fields). Every time a new query is added, it gets an incremental number (eg. Query 1, Query 2, Query n+1) so that users can differentiate while responding to them and/or updating their status.
4. Once you have added a query, you will see that for fields with data, status has been updated to incomplete, as indicated by the orange bullet. The query icon (question mark) will appear next to the field.

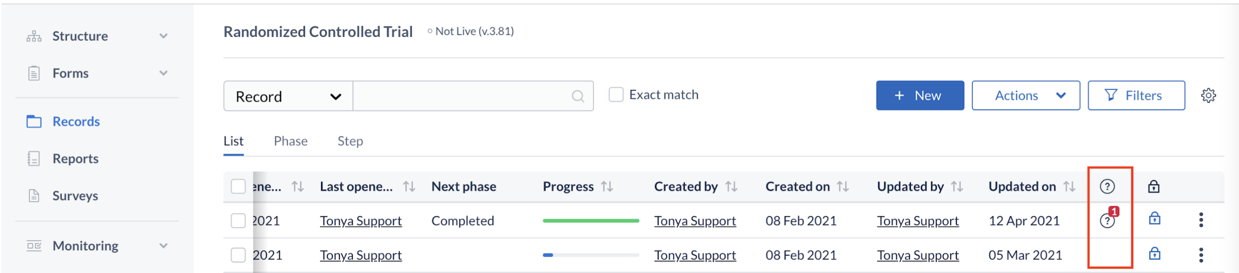
5.2 Query resolution

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:

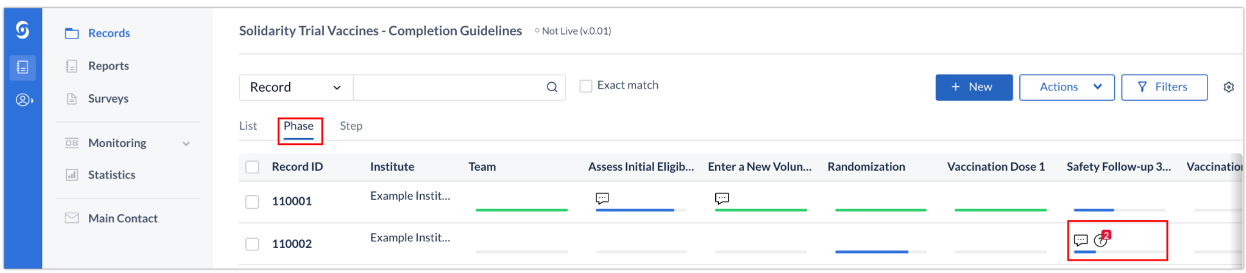
- **New**: This query has not been reviewed.
- **Open**: This query was viewed but a change of status or comment was not made.
- **Unconfirmed**: The user does not agree with the monitor.
- **Confirmed**: The user agrees with the monitor and will try to resolve the issue.
- **Resolved**: The user has 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. Only when the query is closed will this field be marked as complete again (green bullet).

5.3. Query overview

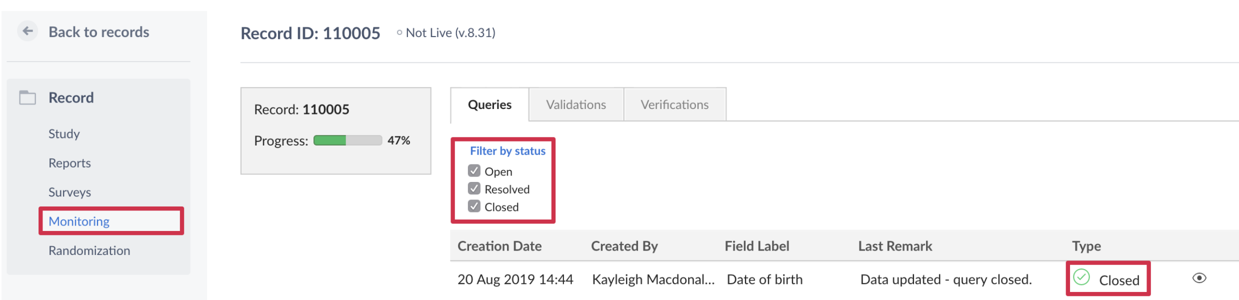
Existing queries are indicated with their respective icon in the 'Records' list, in the 'Queries' column:



The queries are also indicated in the 'Phase' and 'Step' 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:



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

5.4 Query notifications

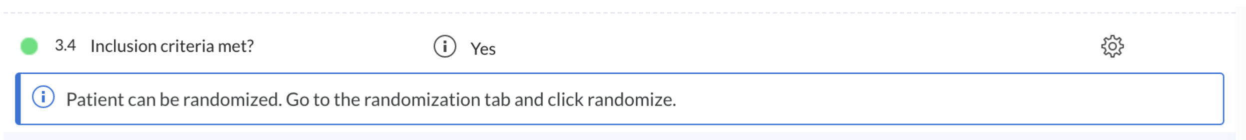
Upon query creation, a notification can be sent to a selected user in the study. All query creation notifications will be sent to that user. This notification needs to be set up by the study admin in the Settings tab.

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.

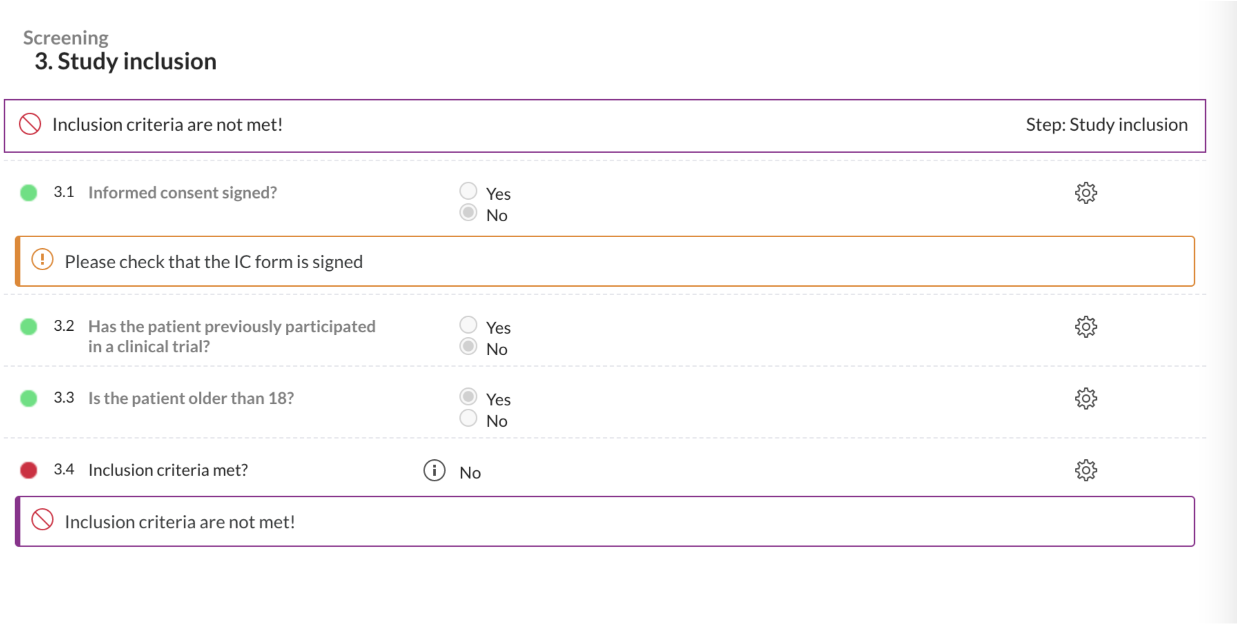
There are three types of validations that can be active:

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



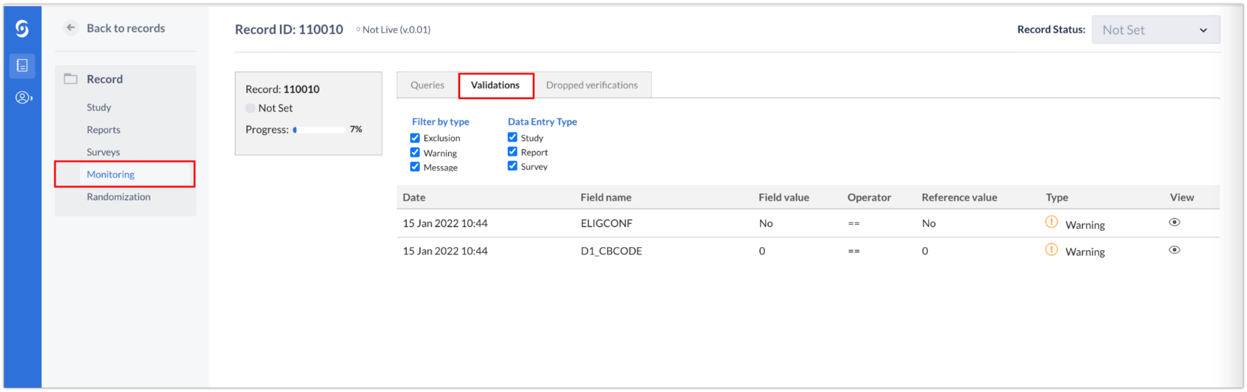
2. A 'warning' type, warning the user:

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 global Monitoring tab (see Monitoring tab section below).

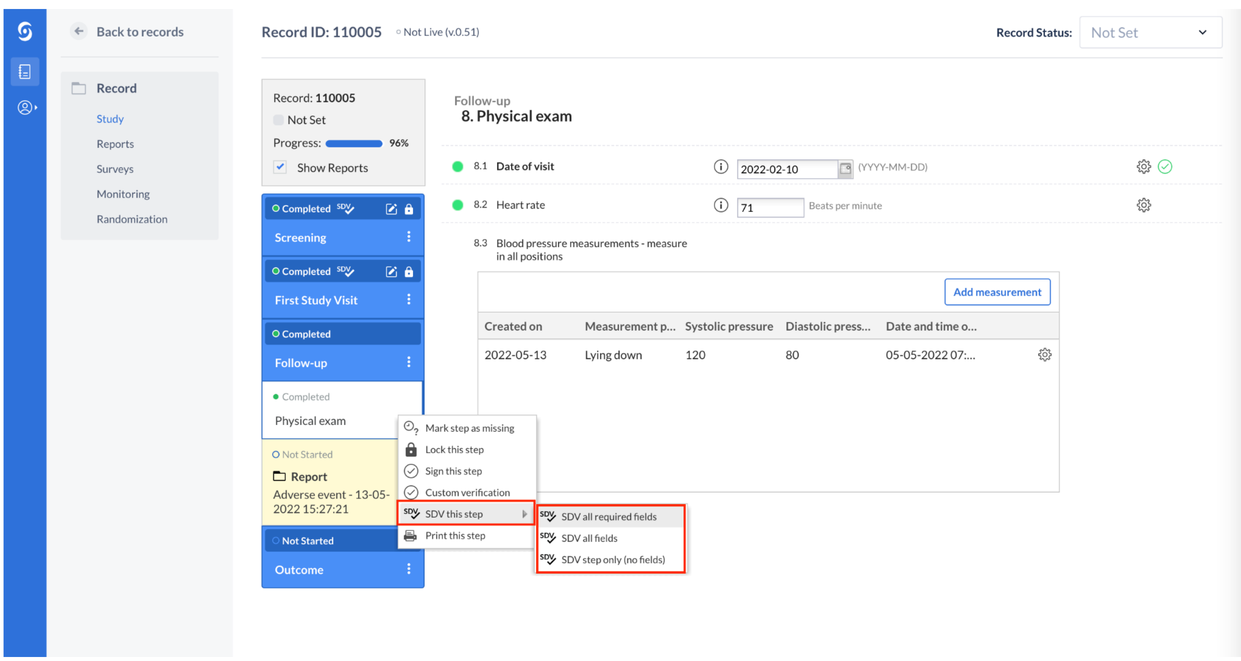
7. Source Data Verification

Study monitors performing source data verification (SDV) are able to mark fields, steps and phases as verified.

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 'SDV this step' and choose which verification you would like to apply.

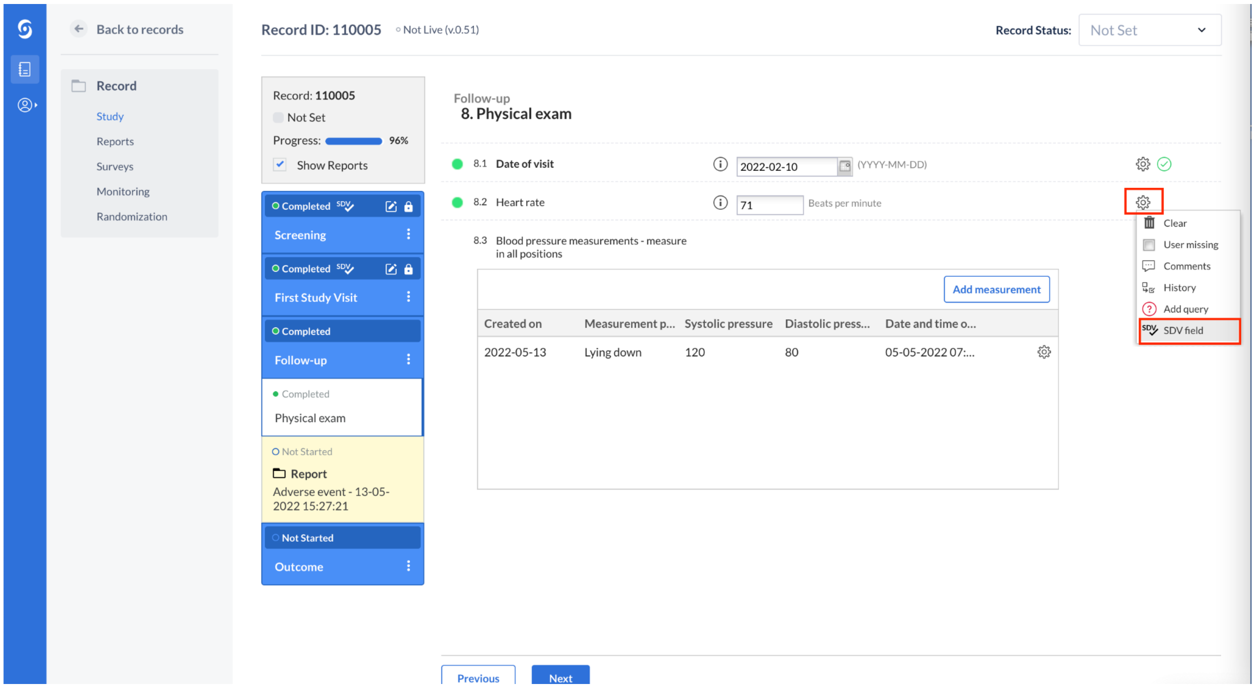


3. Click 'Continue' to save the verification or 'Cancel' to return to the data entry view.

7.2. Mark a field as verified

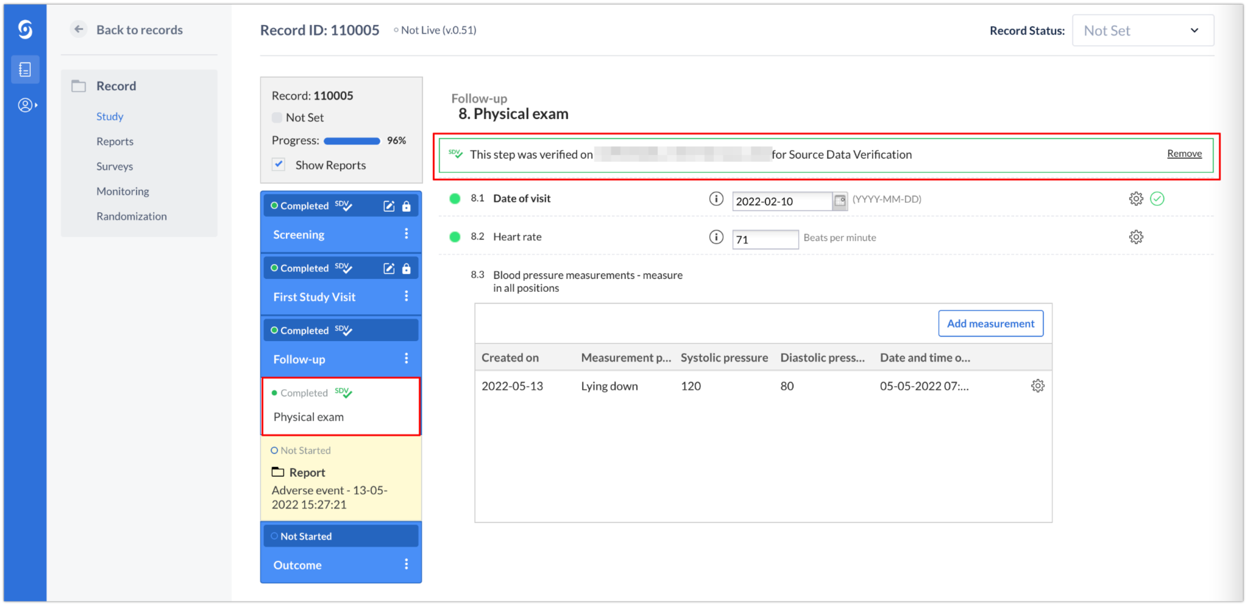
It is also possible to apply SDV to a field. To do so:

1. Click on the cogwheel next to a field where SDV should be applied
2. Choose the option ‘SDV field’



7.3 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. 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.

The following logic applies to banners and SDV icons:

- The Step SDV banner is shown when the user chooses any of the options to SDV a step and when all required fields in a step have been individually SDV'ed.
- The Step SDV icon is shown on the phase/step navigation bar when the user chooses any of the options to SDV a step or when all required fields in a step have been individually SDV'd.
- When the Step SDV banner is shown, the corresponding step is shown as SDV'd on the Step View of Records tab

When adding SDV:

- a step is considered SDV'ed when all the required fields have been individually marked as SDV'ed or if the step has been SDV'ed directly by the user;
- a Phase is considered SDV'ed when all its steps have been marked as SDV'ed;
- a Report instance is considered SDV'ed when all its steps have been marked as SDV'ed.

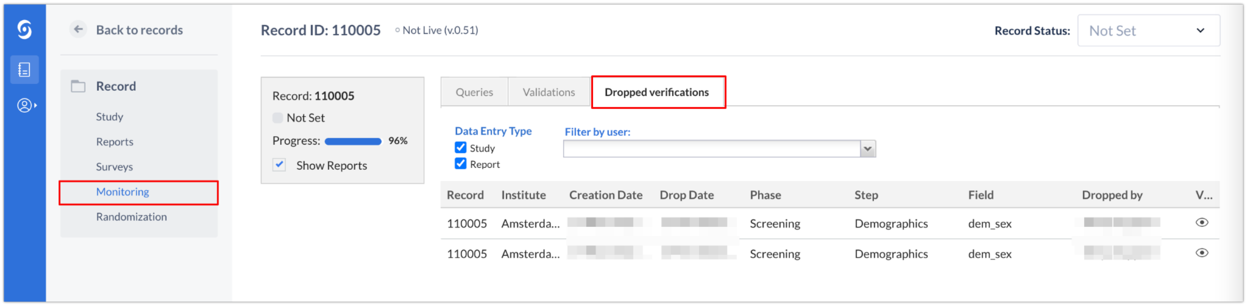
When dropping SDV:

- the Step SDV is removed when the SDV of any of the required fields within that step is removed;
- the Phase SDV is removed when the SDV of any of its child Steps is removed;
- the Report instance SDV is removed when the SDV of any of its child Steps is removed.

7.4 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:



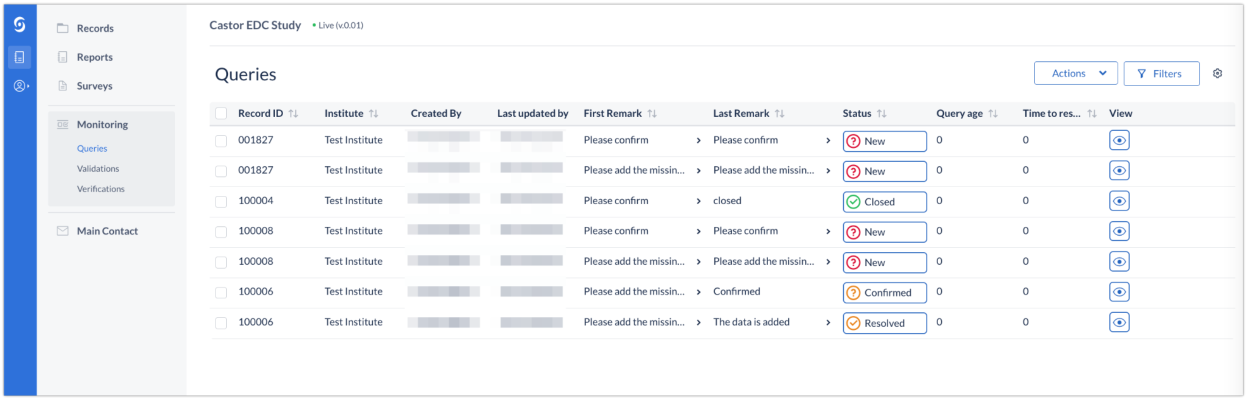
All dropped verifications for *all* records are available in the general Monitoring tab (see Monitoring tab section below).

8. The global 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 by**: user who created a query
- **Last updated by**: last user who updated a query
- **First Remark**: initial comment which was added when creating a query
- **Last Remark**: last comment that was added on the 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

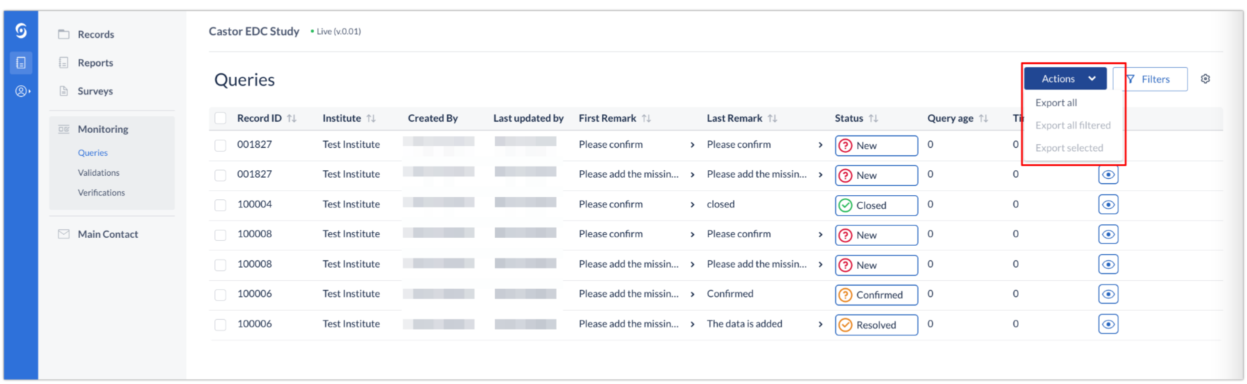
- **Time to resolve**: time that require to resolve a query
- **View**: click on the eye icon to view the query in a step where it was created

Using the ‘Filters’ button, you can filter by institute, location, query status, created by, updated by, created between, days in current status and days since opened.

8.2. Exporting Queries

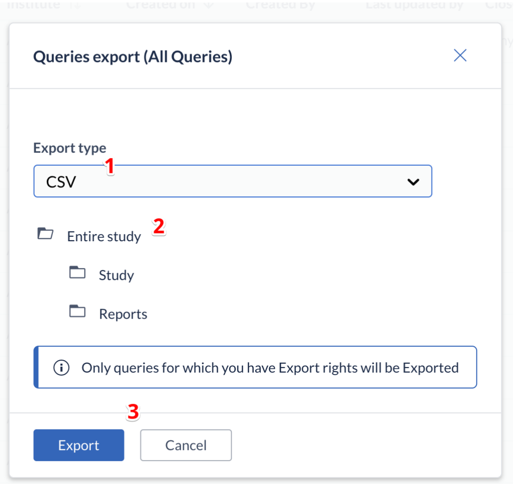
Users with ‘Export’ rights can export the queries overview in bulk, either by exporting all available queries or only the ones that the user has selected or filtered. To export the queries from the Monitoring tab, Queries sub-tab, follow the steps below:

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



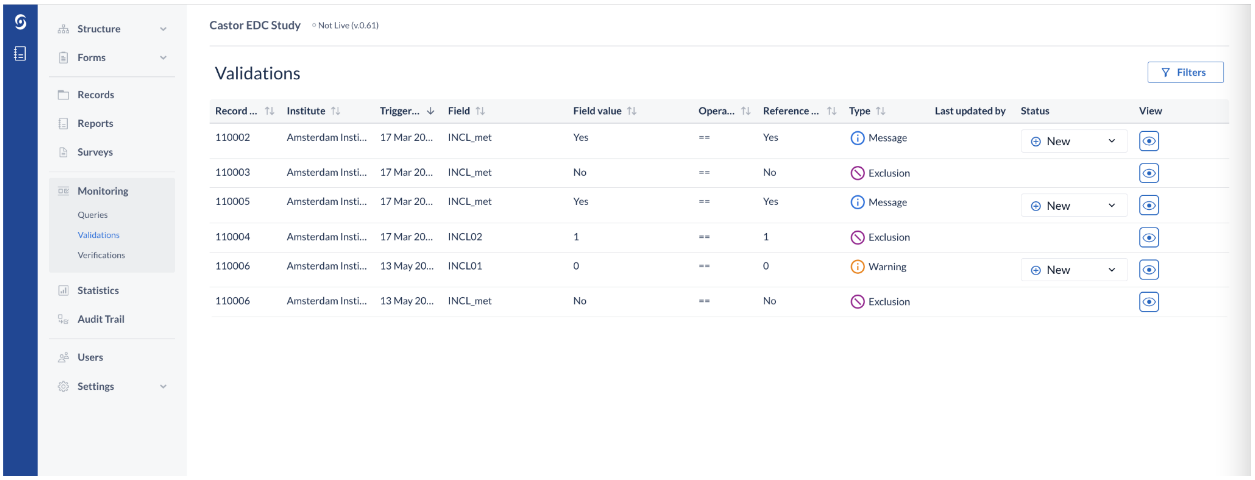
2. In Queries export dialog window, specify:
    - **Export type**: choose to export into CSV or Excel (1)
    - **Export tree**: choose if you would like to export queries for entire study, specific study phases or steps in your study or for reports, a specific report or a report step (2)

- **Export**: click on Export button to generate export of the queries (3)



8.3. Validations subtab

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

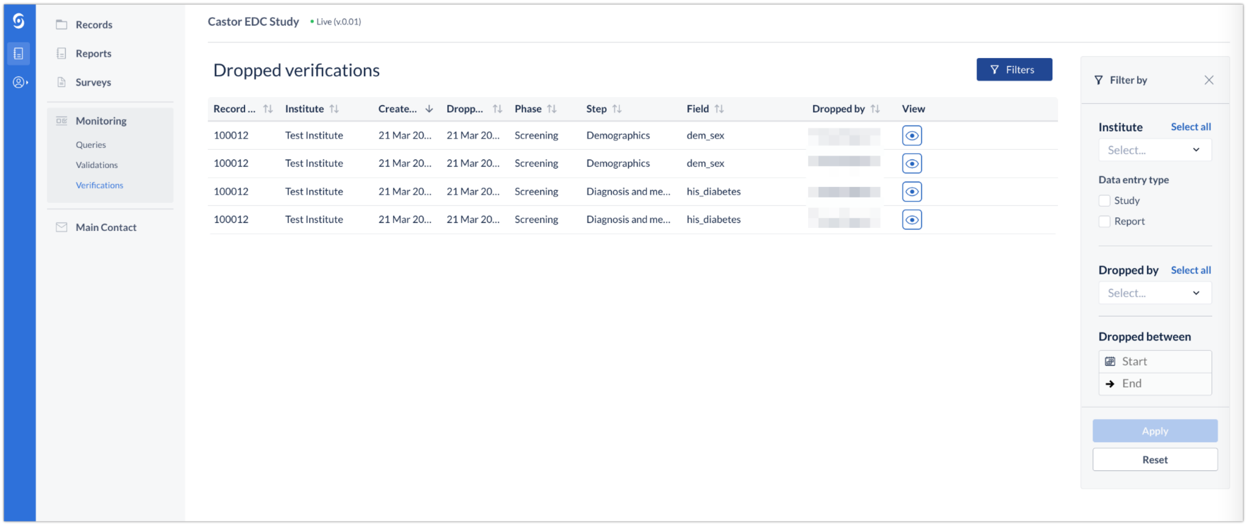


1. A user can filter validations by type (Exclusion, Warning, Message), by institute to show records with validations which belong to a particular institute, by data entry type and period when the validations were triggered using the 'Filters' button.
2. An overview of all records is given with the details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

8.4. Verifications subtab

This subtab displays all dropped verifications in the study:



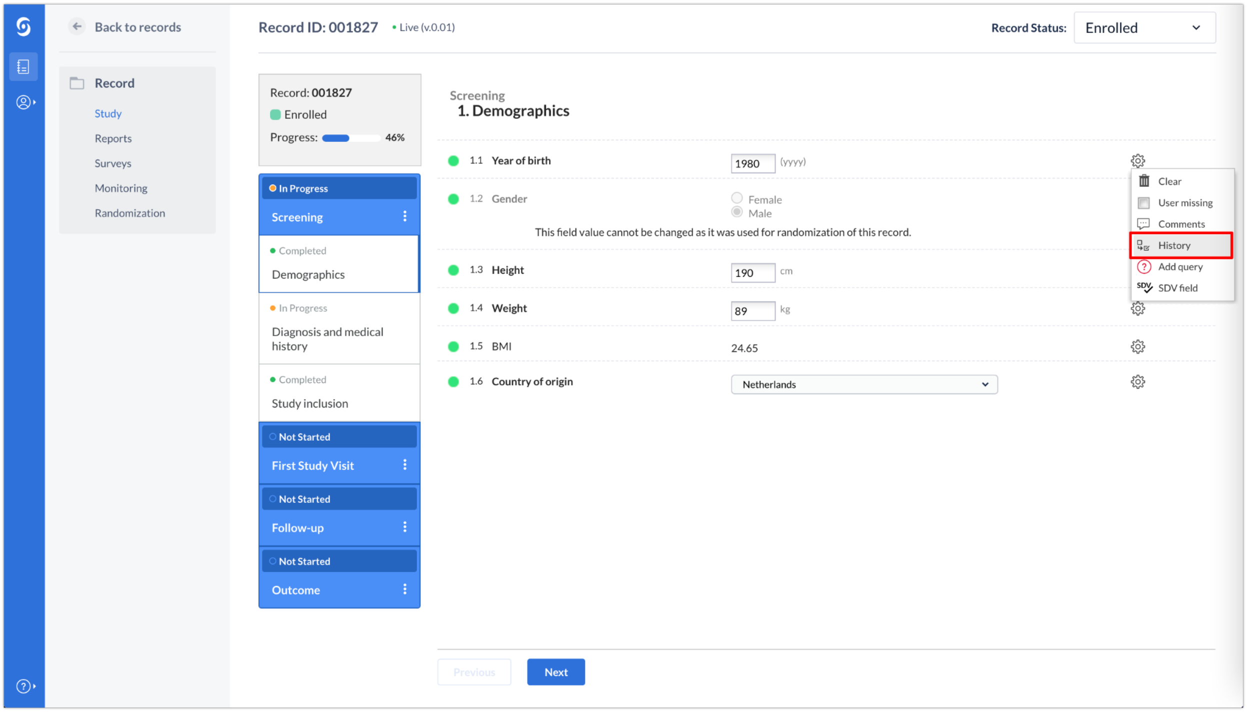
- Using the 'Filters' button, you can choose to show dropped verifications for the study or for reports only. You can also choose to filter by user (who dropped the verification) and by institute.
- Each row shows the record ID, the institute name, creation date, drop date, the phase and step where the 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)

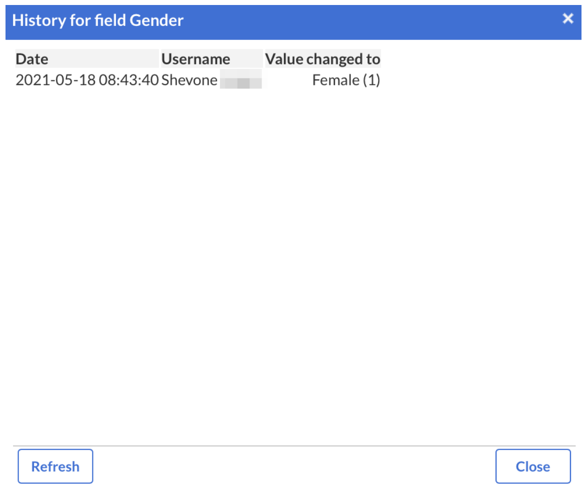
9. Using the Audit Trail

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:

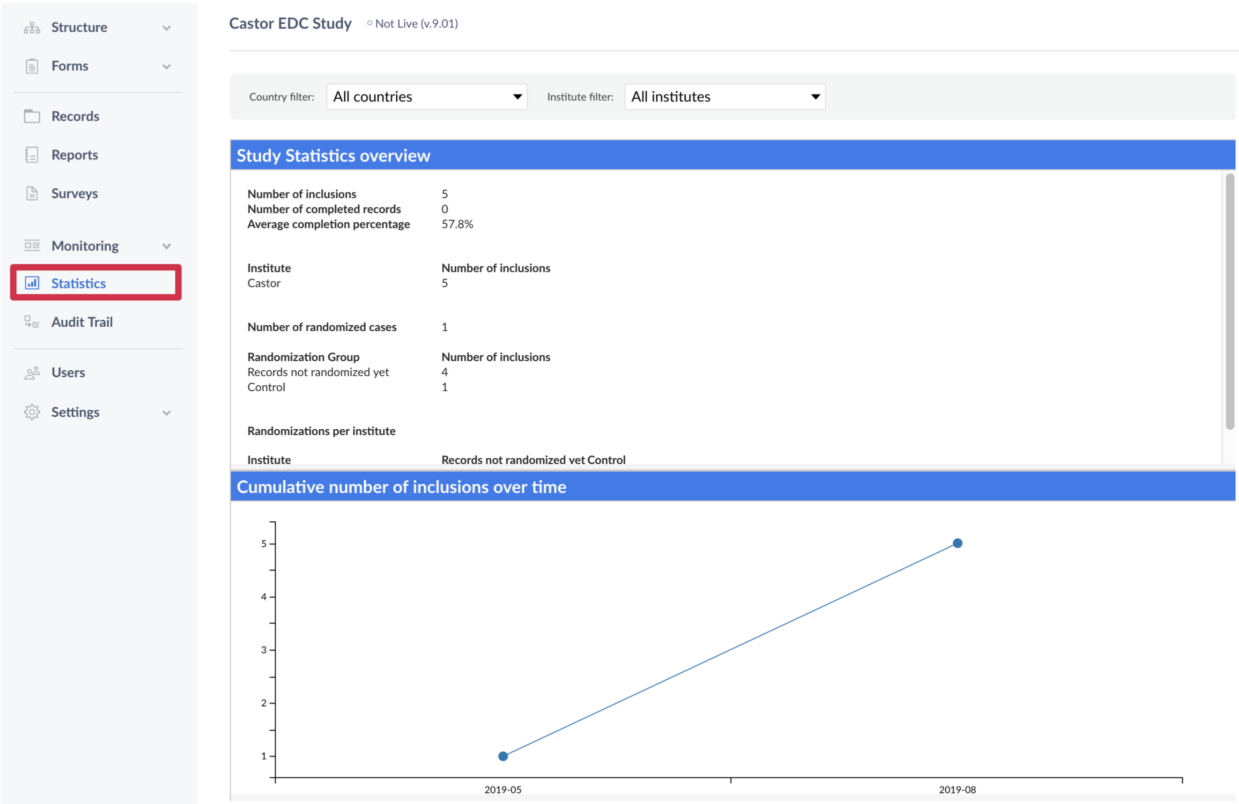


A popup will appear detailing the changes to the field. The date, the user who changed the field, and the new value are all displayed:



10. The Statistics tab

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

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