

Castor

Castor EDC Monitoring User Guide

Version 2022.2

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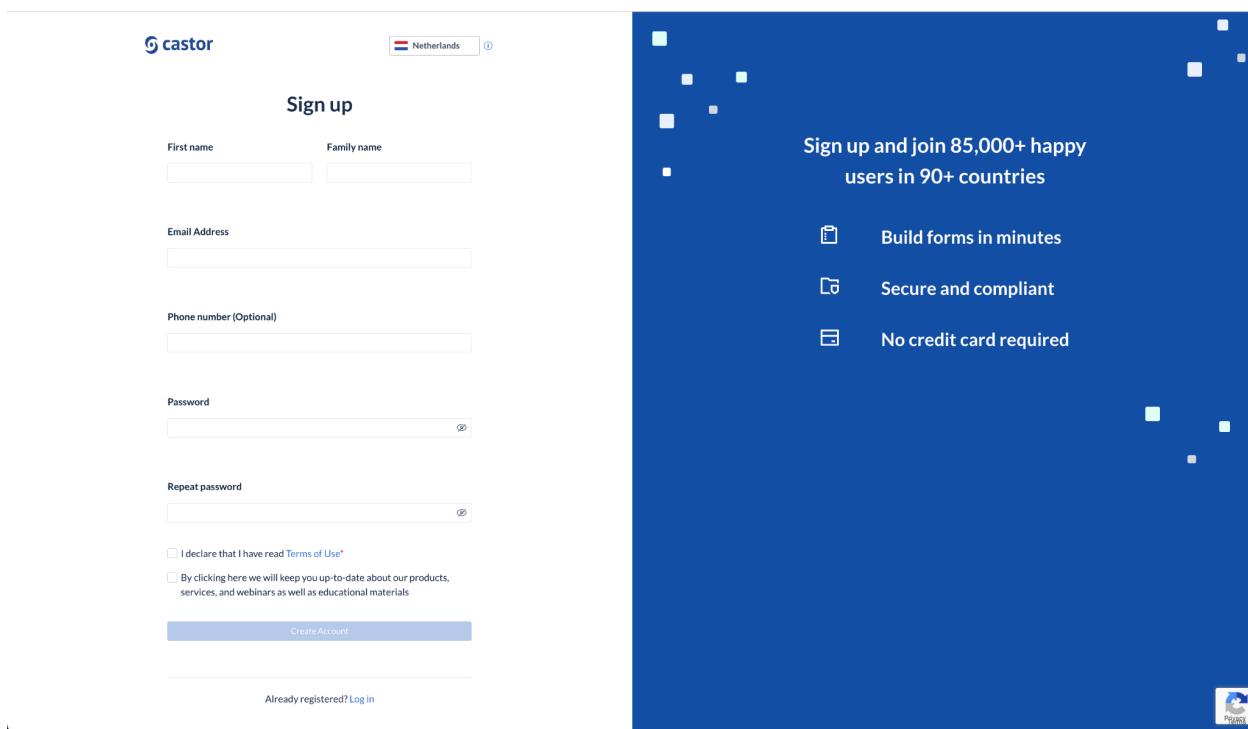
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1. Register an account

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:



The image shows two side-by-side screenshots. On the left is the 'Sign up' page for the Netherlands, featuring fields for First name, Family name, Email Address, Phone number (Optional), Password, and Repeat password. It includes terms of use checkboxes and a 'Create Account' button. On the right is a promotional image for Castor, highlighting '85,000+ happy users in 90+ countries' and listing benefits: 'Build forms in minutes', 'Secure and compliant', and 'No credit card required'.

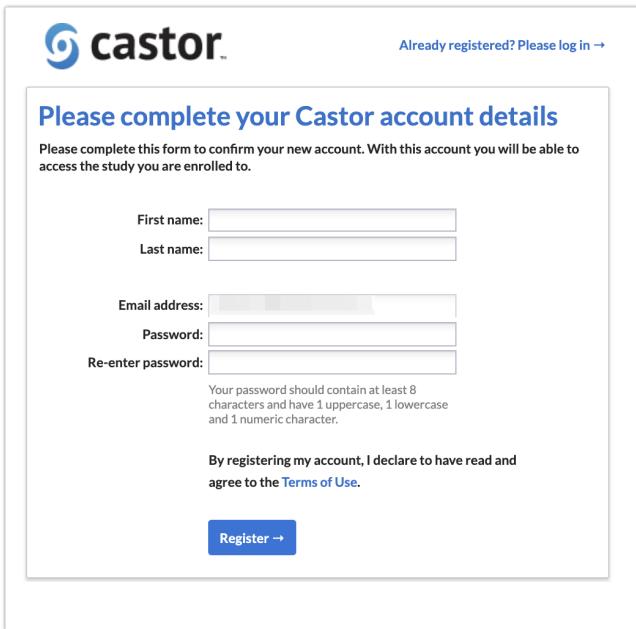
- EU Account: <https://data.castoredc.com/register>
- UK Account: <https://uk.castoredc.com/register>
- US Account: <https://us.castoredc.com/register>
- AU Account: <https://au.castoredc.com/register>

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:



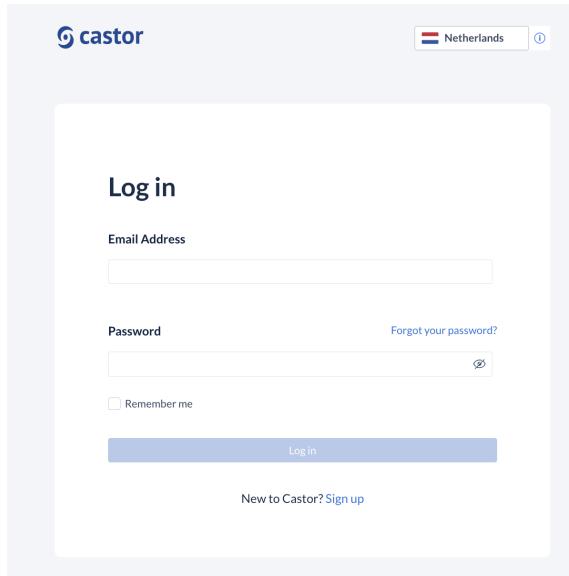
The screenshot shows a registration form for Castor. At the top, there is a logo and a link to log in for existing users. The main title is 'Please complete your Castor account details', with a sub-instruction: 'Please complete this form to confirm your new account. With this account you will be able to access the study you are enrolled to.' The form contains fields for 'First name' and 'Last name', both with placeholder text. Below these are fields for 'Email address' and 'Password', with the latter having a placeholder. A 'Re-enter password' field is also present. A note below the password fields specifies password requirements: 'Your password should contain at least 8 characters and have 1 uppercase, 1 lowercase and 1 numeric character.' At the bottom of the form, there is a declaration: 'By registering my account, I declare to have read and agree to the [Terms of Use](#).' A blue 'Register →' button is at the bottom right.

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 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

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'.



Log in

Email Address

Forgot your password?

>Password

Remember me

Log in

New to Castor? [Sign up](#)

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.

My Studies

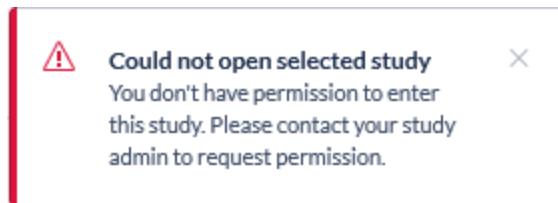


Castorexample Order by Creation date: Newest first

Not Live  Test Study: Castor EDC Study

Monocenter EU Server

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.



My Studies

Castorexample Order by Creation date: Newest first

 **Test Study: Castor EDC Study**

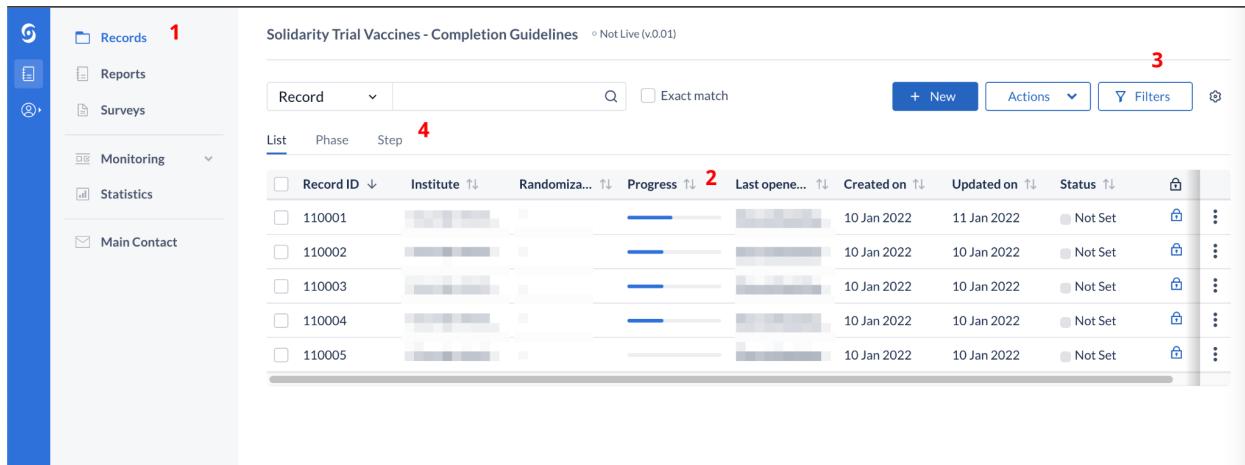
Monocenter EU Server

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

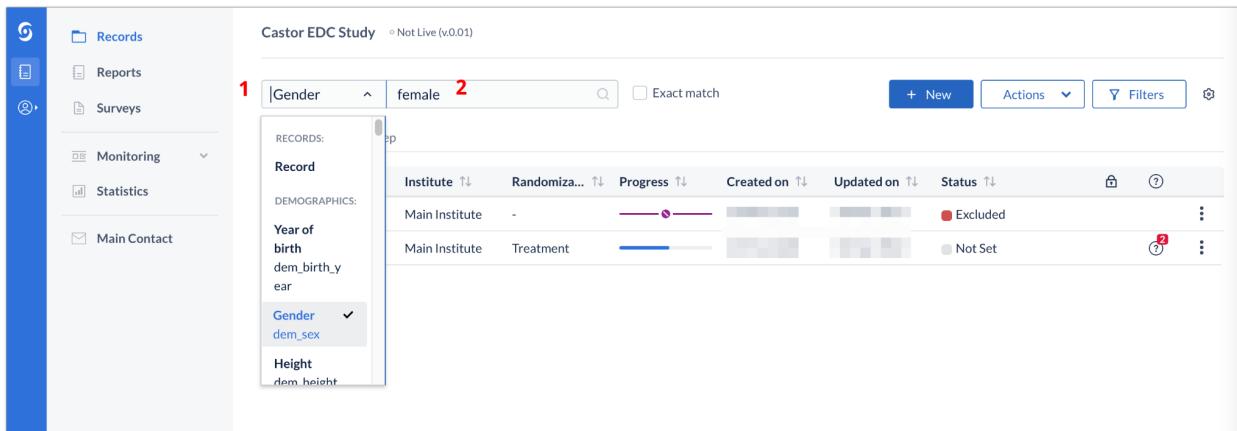
In the Records tab, a list is displayed showing all records for the institutes to which you have 'View' rights (see Section 6).



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.

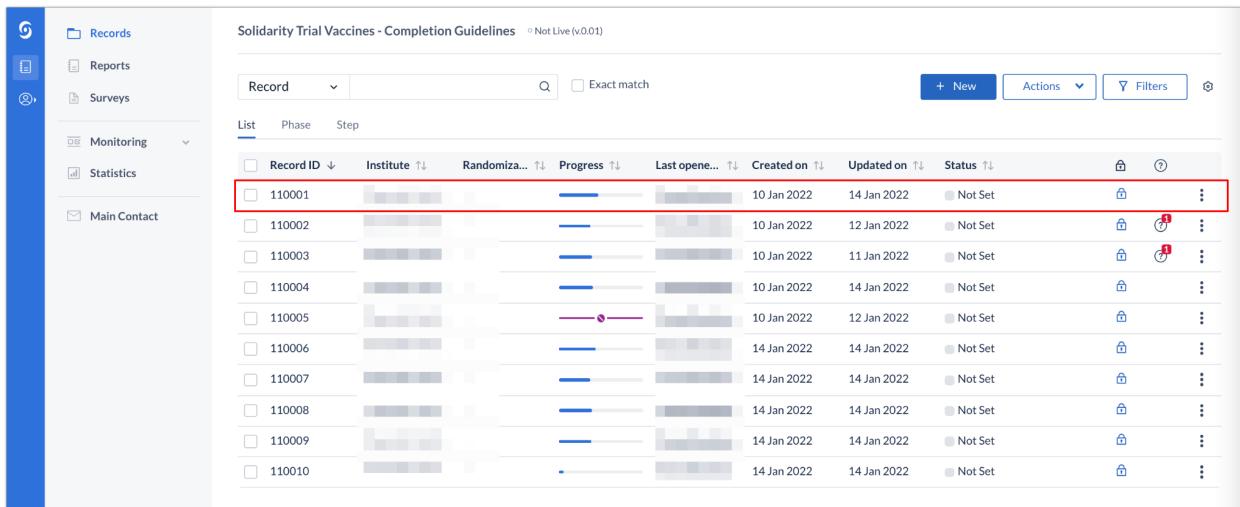


The screenshot shows the Castor EDC Study interface. On the left, a sidebar includes 'Records', 'Reports', 'Surveys', 'Monitoring', 'Statistics', and 'Main Contact'. The main area is titled 'Castor EDC Study' and shows a search bar with 'Gender' selected and 'female' entered. A red box highlights the search term 'female'. Below the search bar is a table with columns: Institute, Randomiza..., Progress, Created on, Updated on, Status. Two rows are visible: 'Main Institute' with 'Excluded' status and 'Main Institute' with 'Not Set' status. A sidebar on the left lists 'Year of birth', 'dem_birth_y', 'Gender', 'dem_sex', and 'Height', 'dem_height'.

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.

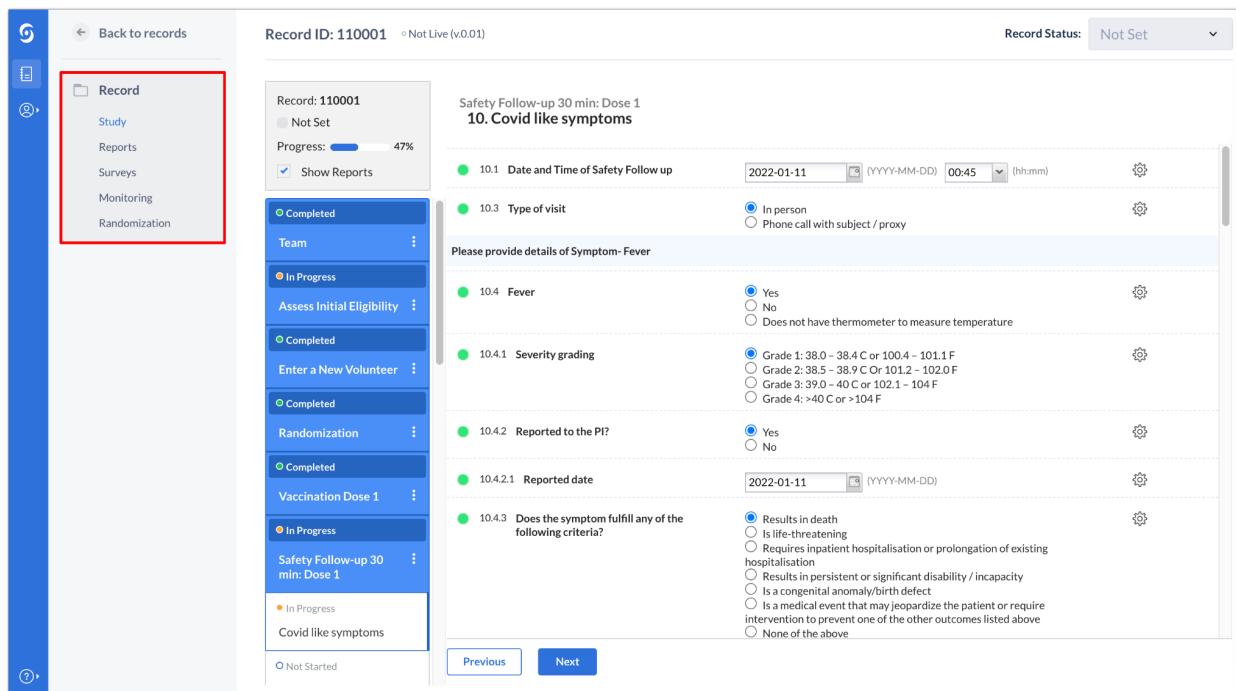
4.2. Accessing a Single record

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



The screenshot shows the Solidarity Trial Vaccines - Completion Guidelines interface. The sidebar includes 'Records', 'Reports', 'Surveys', 'Monitoring', 'Statistics', and 'Main Contact'. The main area is titled 'Solidarity Trial Vaccines - Completion Guidelines' and shows a search bar with 'Record' selected and '110001' entered. A red box highlights the record ID '110001'. Below the search bar is a table with columns: Record ID, Institute, Randomiza..., Progress, Last opene..., Created on, Updated on, Status. Ten rows of data are listed, each with a checkbox and a red box around the 'Record ID' column.

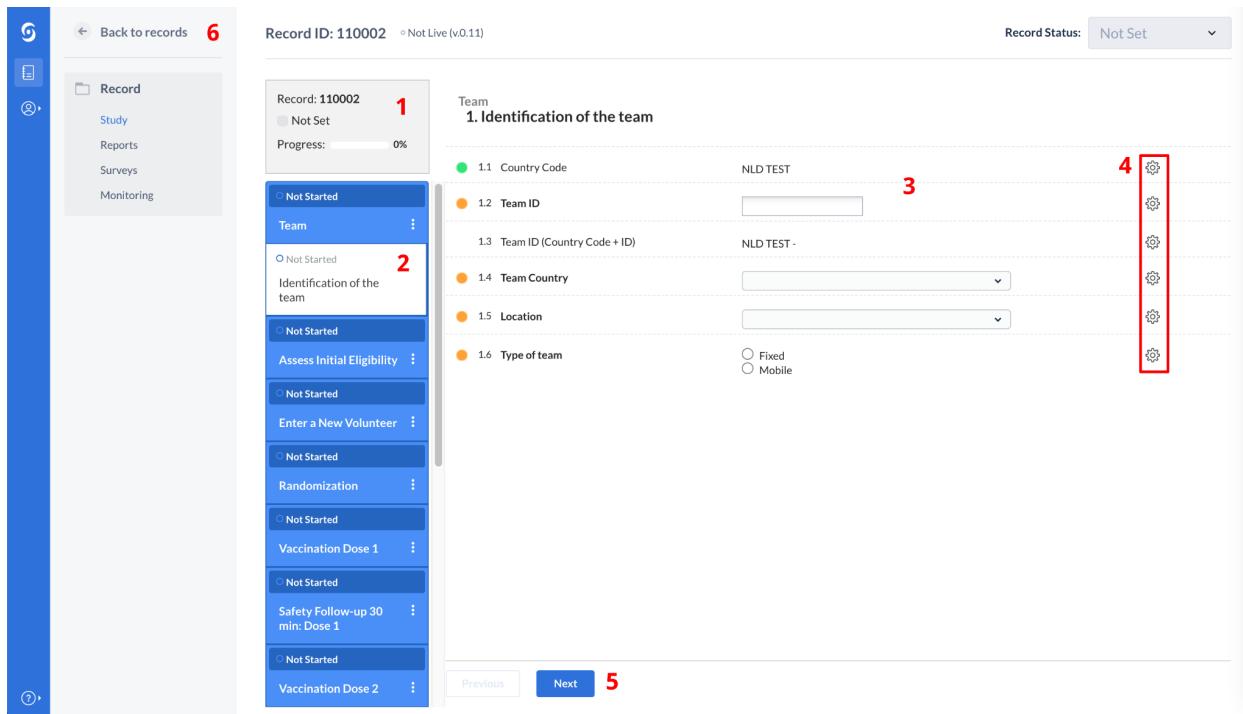
There are a total of 5 available tabs within a record, but which tabs you see depends on the study setup and your specific user rights:



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.



The screenshot shows the 'Study' tab in a record interface. The left sidebar shows a navigation menu with 'Record' (selected), 'Study' (highlighted in blue), 'Reports', 'Surveys', and 'Monitoring'. The main area displays the 'Record ID: 110002' and its status as 'Not Live (v.0.11)'. The 'Record Status' is set to 'Not Set'. The 'Team' section is selected, showing the '1. Identification of the team' form. The form contains questions 1.1 through 1.6, with question 1.2 currently active. The right side of the form has a red box around the 'NLD TEST' field and a vertical red box on the right edge. Navigation buttons 'Previous' and 'Next' are at the bottom, with '5' highlighted in red.

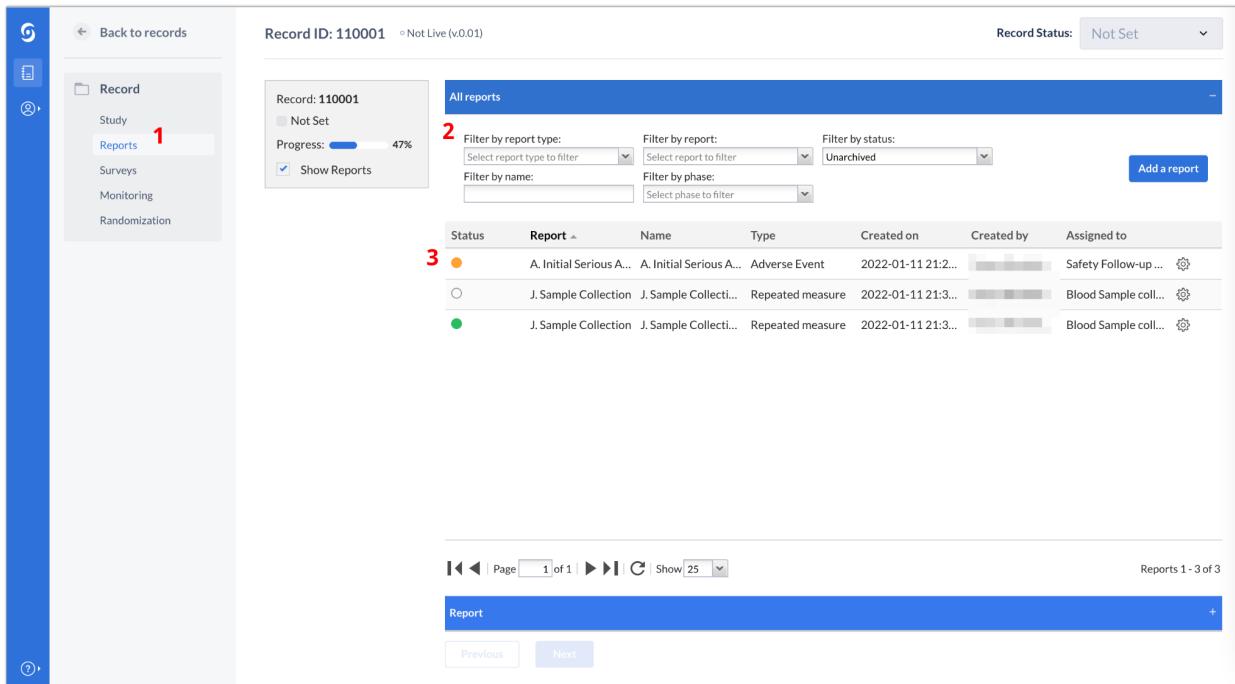
It consists of the following elements:

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.



Record ID: 110001 Not Live (v0.01) Record Status: Not Set

Record: 110001 Not Set Progress: 47% Show Reports

All reports

Filter by report type: Select report type to filter Filter by report: Select report to filter Filter by status: Unarchived

Filter by name: Filter by phase: Select phase to filter Add a report

Status	Report	Name	Type	Created on	Created by	Assigned to
3	A. Initial Serious A...	A. Initial Serious A...	Adverse Event	2022-01-11 21:2...	[redacted]	Safety Follow-up...
	J. Sample Collection	J. Sample Collecti...	Repeated measure	2022-01-11 21:3...	[redacted]	Blood Sample coll...
	J. Sample Collection	J. Sample Collecti...	Repeated measure	2022-01-11 21:3...	[redacted]	Blood Sample coll...

1 of 1 | Page Show 25 Reports 1 - 3 of 3

Report

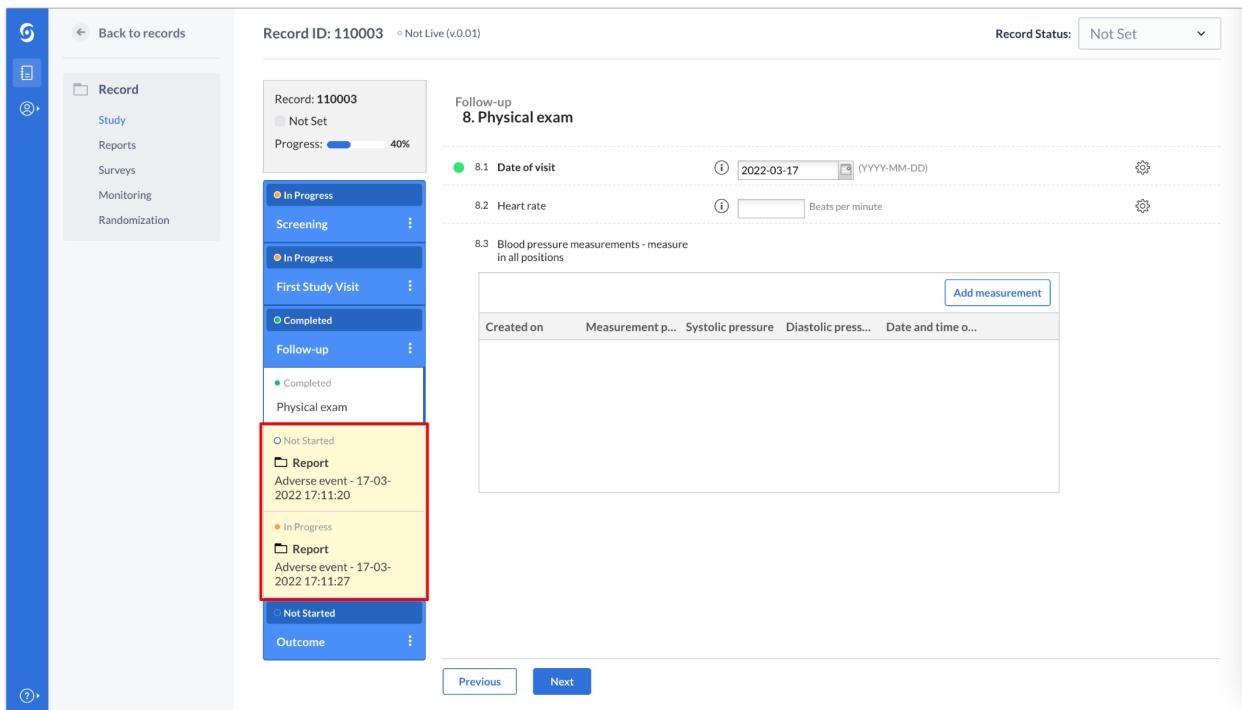
Previous Next

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:



The screenshot shows the study overview for Record ID: 110003, which is Not Live (v0.01). The left sidebar includes 'Back to records', a navigation menu with 'Record' (selected), 'Study', 'Reports', 'Surveys', 'Monitoring', 'Randomization', and a search bar. The main content area shows the 'Follow-up' section for '8. Physical exam'. A report for '8.1 Date of visit' is listed with a green dot (Complete) and a date of 2022-03-17. Below it, '8.2 Heart rate' is listed with a white dot (Not Started) and a placeholder for 'Beats per minute'. A third item, '8.3 Blood pressure measurements - measure in all positions', is listed with a white dot and a placeholder for 'Systolic pressure' and 'Diastolic pressure'. A 'Measurement' table is present with columns for 'Created on', 'Measurement p...', 'Systolic pressure', 'Diastolic press...', and 'Date and time o...'. At the bottom, there are 'Previous' and 'Next' buttons. The 'Report' section in the sidebar is highlighted with a red box, showing items for 'Not Started' (Adverse event - 17-03-2022 17:11:20) and 'In Progress' (Adverse event - 17-03-2022 17:11:27). The 'Report' section is also highlighted with a red box.

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:

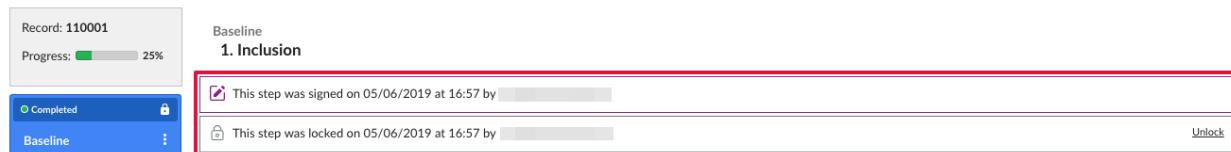


The screenshot shows a data entry interface. At the top, there is a field labeled "3.1.1 Date of informed consent" with the value "2022-05-14" and a date format indicator "(YYYY-MM-DD)". To the right of the field is a gear icon. Below the field, a red-bordered box contains a warning message: "⚠ Date of signature cannot be in the future".

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 screenshot shows a study or report form. On the left, there is a sidebar with the text "Record: 110001" and "Progress: 25%". The main content area is titled "Baseline 1. Inclusion". Below the title, there are two red-bordered boxes containing messages: "This step was signed on 05/06/2019 at 16:57 by" and "This step was locked on 05/06/2019 at 16:57 by". To the right of the second message is a "Unlock" button.

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:

11.8 Was a Covid test performed?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	  
----------------------------------	---	---

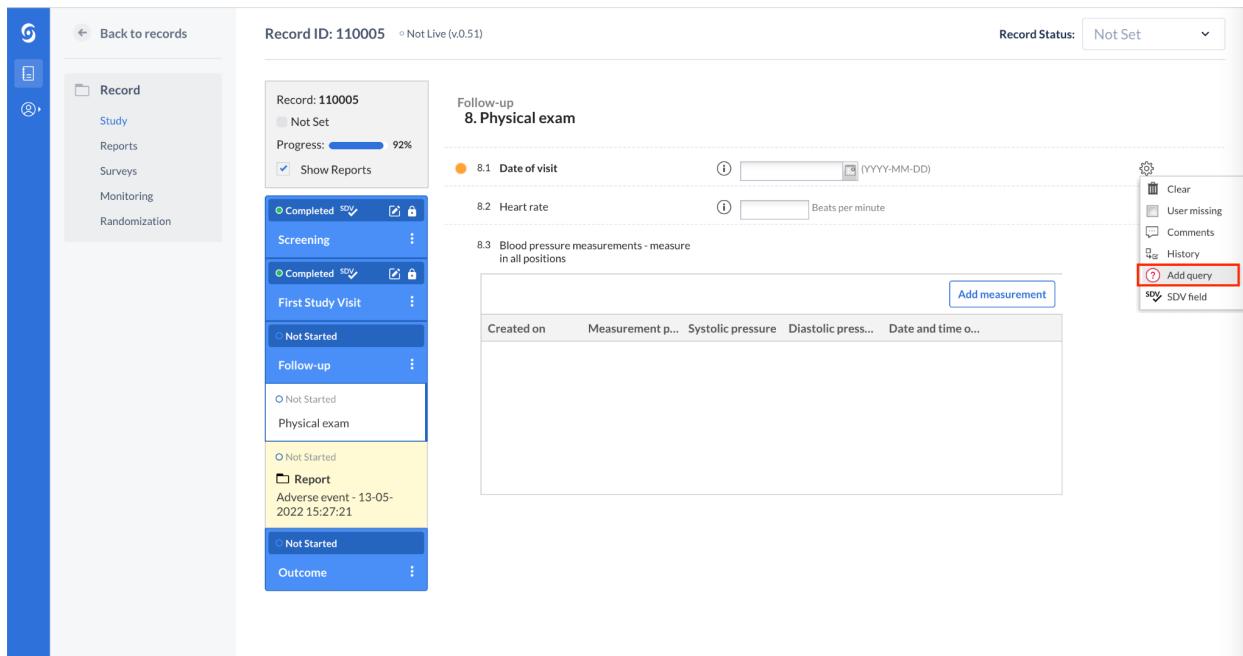
Comments are mandatory when making changes to a signed or verified form or, if the GCP module is turned on in Study settings, changing a field's value. All fields with such changes will have an associated comment. These cannot be modified or deleted.

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

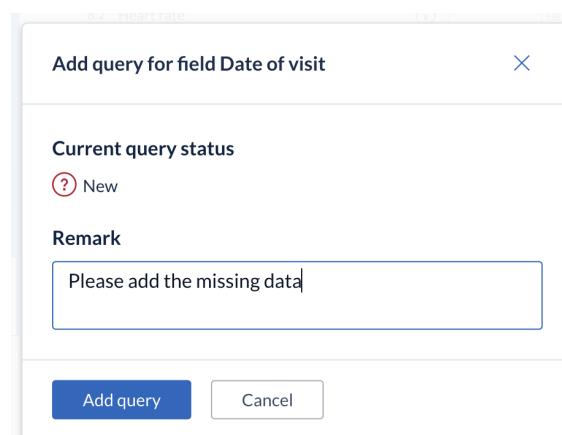
5. Monitoring queries

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.



Add query for field Date of visit

Current query status

New

Remark

Please add the missing data

Add query Cancel

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.



A screenshot of a data entry form. The field is labeled '8.1 Date of visit'. It contains a date input field with the placeholder '(YYYY-MM-DD)' and a small orange bullet icon to its left. To the right of the input field is a small red circle with the number '1', indicating a new query. There are also icons for settings and help.

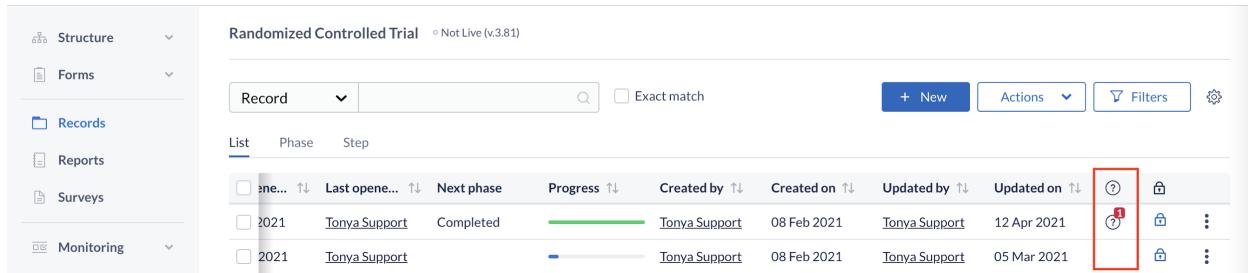
5.2 Query resolution

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:

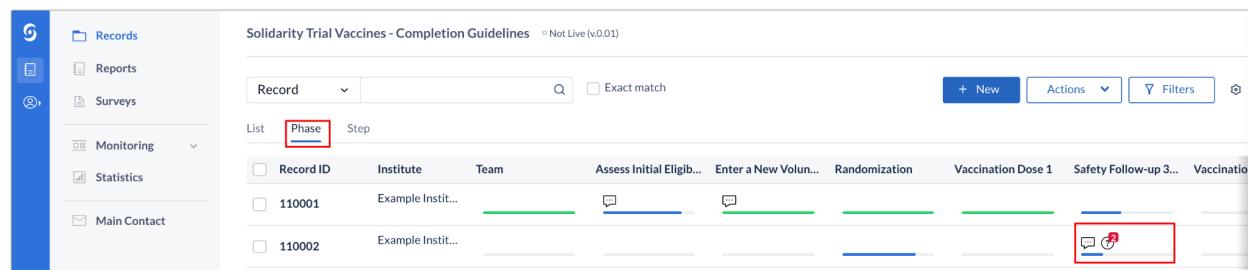
- **New:** This query has not been reviewed.
- **Open:** This query was viewed but a change of status or comment was not made.
- **Unconfirmed:** The user does not agree with the monitor.
- **Confirmed:** The user agrees with the monitor and will try to resolve the issue.
- **Resolved:** The user has 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

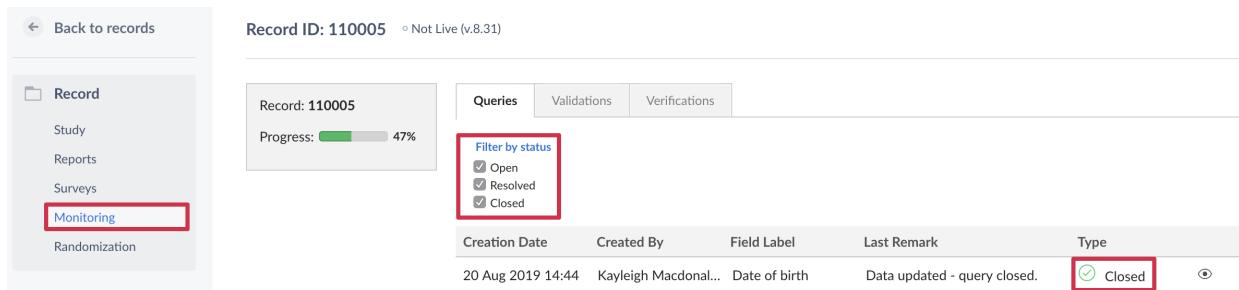
Existing queries are indicated with their respective icon in the 'Records' list, in the 'Queries' column:



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:

 3.4 Inclusion criteria met?	 Yes	
 Patient can be randomized. Go to the randomization tab and click randomize.		

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

 3.1 Informed consent signed?	<input type="radio"/> Yes	
 Please check that the IC form is signed		

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

Screening
3. Study inclusion

🚫 Inclusion criteria are not met! Step: Study inclusion

3.1 Informed consent signed? Yes No ⚙

⚠ Please check that the IC form is signed

3.2 Has the patient previously participated in a clinical trial? Yes No ⚙

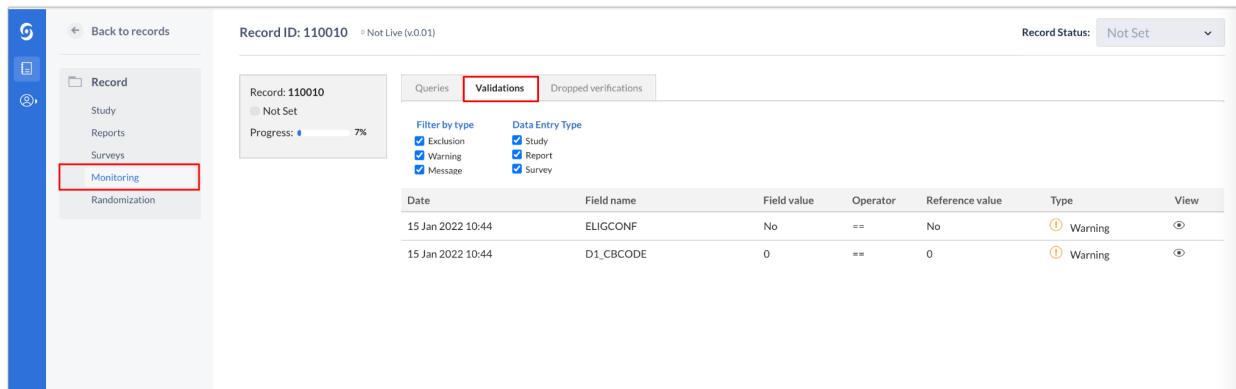
3.3 Is the patient older than 18? Yes No ⚙

3.4 Inclusion criteria met? No ℹ ⚙

🚫 Inclusion criteria are not met!

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:



Date	Field name	Field value	Operator	Reference value	Type	View
15 Jan 2022 10:44	ELIGCONF	No	==	No	⚠ Warning	 ⓘ
15 Jan 2022 10:44	D1_CBCODE	0	==	0	⚠ Warning	 ⓘ

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.

Record ID: 110005 • Not Live (v.0.51)

Record Status: Not Set

Follow-up
8. Physical exam

8.1 Date of visit: 2022-02-10 (YYYY-MM-DD)

8.2 Heartrate: 71 Beats per minute

8.3 Blood pressure measurements - measure in all positions

Add measurement

Created on	Measurement p...	Systolic pressure	Diastolic press...	Date and time o...
2022-05-13	Lying down	120	80	05-05-2022 07....

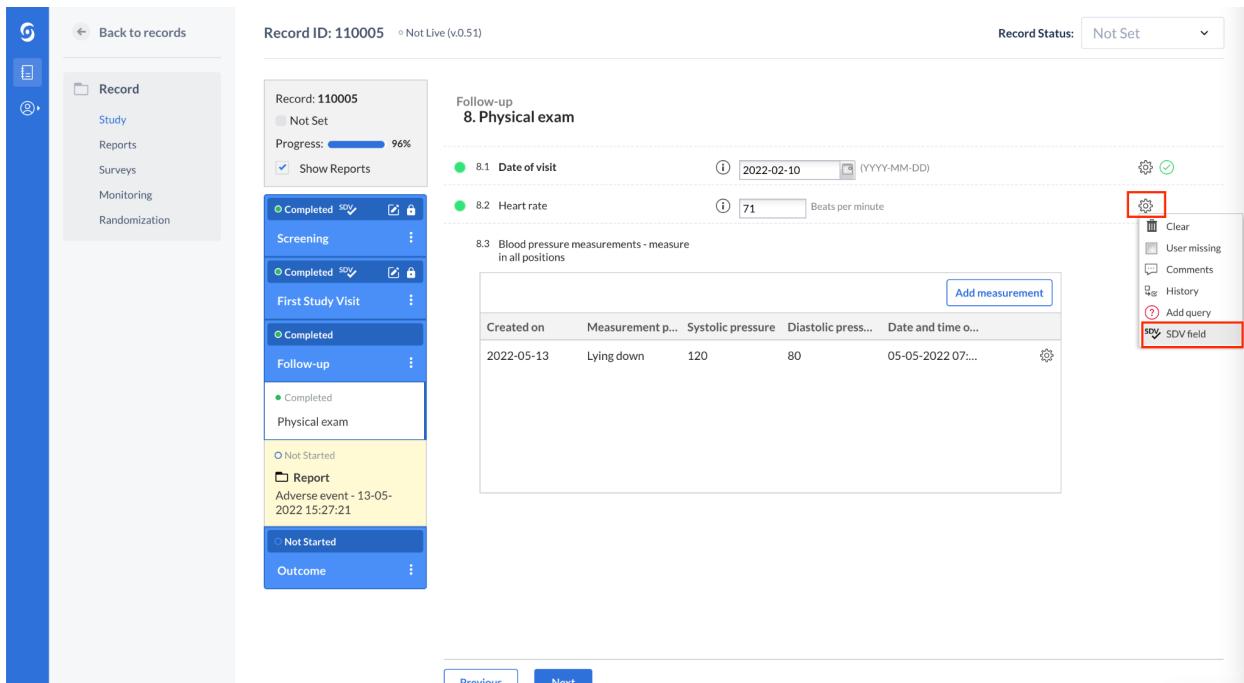
Mark step as missing
Lock this step
Sign this step
Custom verification
SDV this step
SDV all required fields
SDV all fields
SDV step only (no fields)

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'



Record ID: 110005 Not Live (v.0.51)

Record Status: Not Set

Follow-up 8. Physical exam

8.1 Date of visit: 2022-02-10 (YYYY-MM-DD)

8.2 Heart rate: 71 Beats per minute

8.3 Blood pressure measurements - measure in all positions

Add measurement

Created on	Measurement p...	Systolic pressure	Diastolic press...	Date and time o...
2022-05-13	Lying down	120	80	05-05-2022 07:...

Previous Next

Record: 110005
Not Set
Progress: 96%
Show Reports

Completed SDV
Not Started Report
Not Started Report
Not Started Report

Physical exam

Follow-up

Physical exam

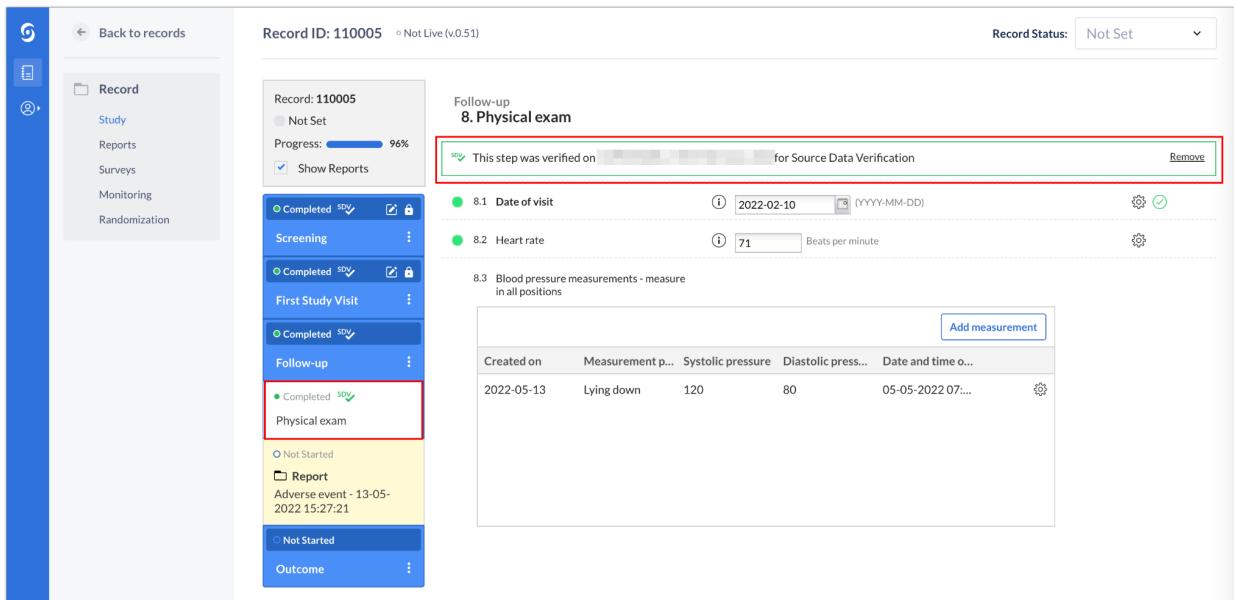
Not Started Report
Adverse event - 13-05-2022 15:27:21

Not Started Report
Outcome

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.

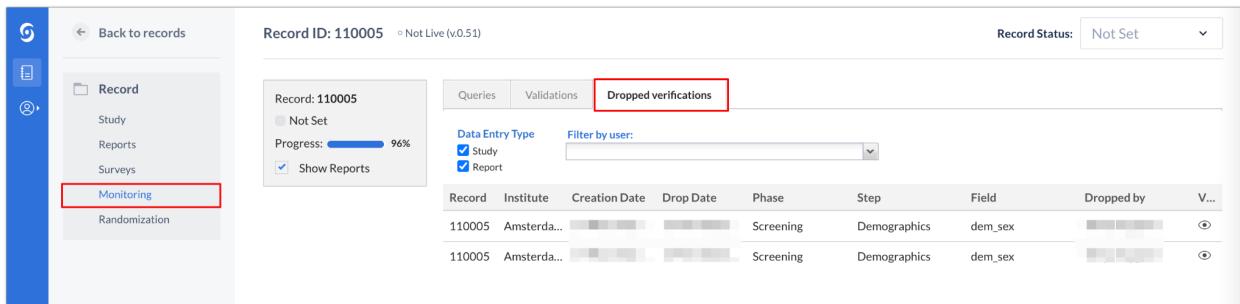
When dropping SDV:

- 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:



Record ID: 110005 (Not Live (v.0.51))

Record Status: Not Set

Record: 110005

Not Set

Progress: 96%

Study

Reports

Surveys

Monitoring

Randomization

Queries

Validations

Dropped verifications

Data Entry Type: Study, Report

Filter by user:

Record	Institute	Creation Date	Drop Date	Phase	Step	Field	Dropped by	V...
110005	Amsterda...			Screening		Demographics	dem_sex	
110005	Amsterda...			Screening		Demographics	dem_sex	

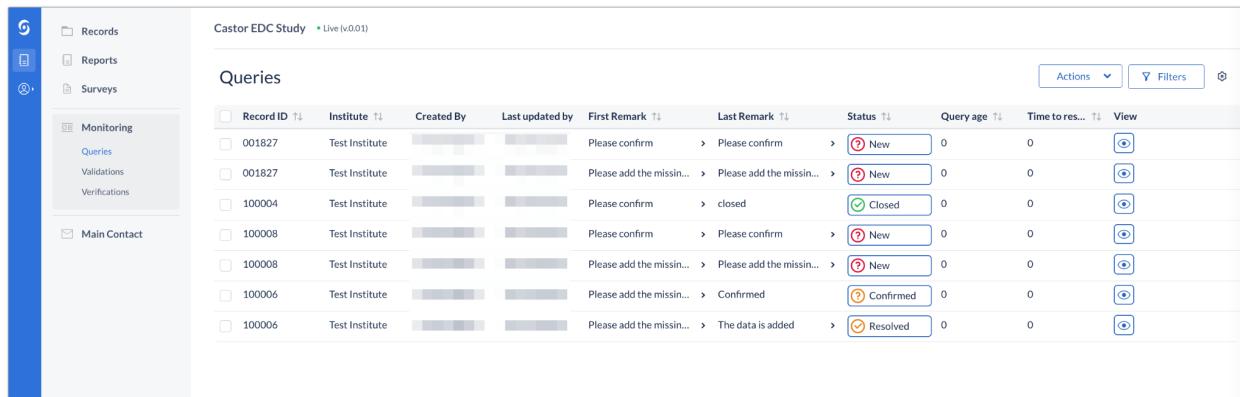
All dropped verifications for *all* records are available in the general Monitoring tab (see Monitoring tab section below).

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	Institute	Created By	Last updated by	First Remark	Last Remark	Status	Query age	Time to res...	View
001827	Test Institute	[REDACTED]	[REDACTED]	Please confirm	> Please confirm	? New	0	0	
001827	Test Institute	[REDACTED]	[REDACTED]	Please add the missin...	> Please add the missin...	? New	0	0	
100004	Test Institute	[REDACTED]	[REDACTED]	Please confirm	> closed	✓ Closed	0	0	
100008	Test Institute	[REDACTED]	[REDACTED]	Please confirm	> Please confirm	? New	0	0	
100008	Test Institute	[REDACTED]	[REDACTED]	Please add the missin...	> Please add the missin...	? New	0	0	
100006	Test Institute	[REDACTED]	[REDACTED]	Please add the missin...	> Confirmed	? Confirmed	0	0	
100006	Test Institute	[REDACTED]	[REDACTED]	Please add the missin...	> The data is added	✓ Resolved	0	0	

- **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

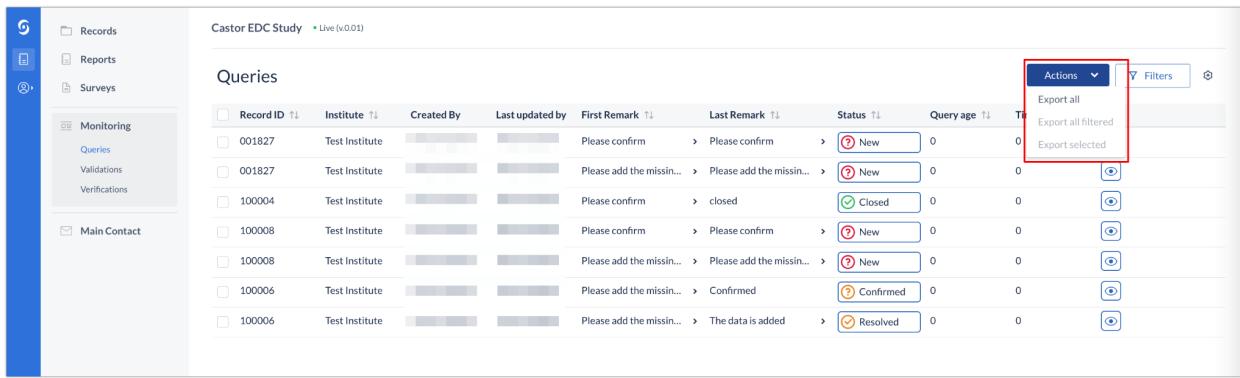
- **Time to resolve:** time that require to resolve a query
- **View:** click on the eye icon to view the query in a step where it was created

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.

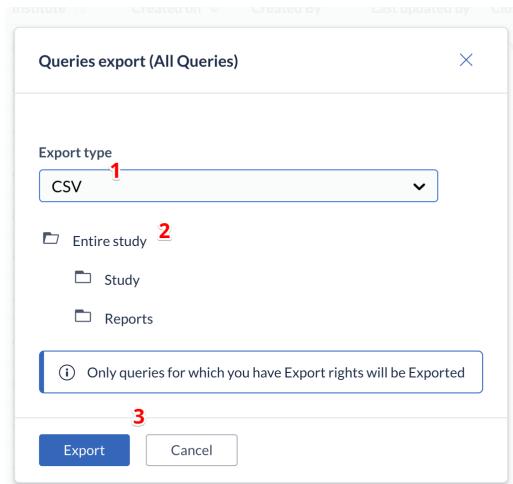


The screenshot shows the 'Castor EDC Study' interface with the 'Monitoring' tab selected. Under 'Monitoring', the 'Queries' sub-tab is active. The main area displays a table of queries with columns: Record ID, Institute, Created By, Last updated by, First Remark, Last Remark, Status, Query age, and Time since opened. The 'Actions' dropdown menu is open, showing three options: 'Export all', 'Export all filtered', and 'Export selected'. The 'Export selected' option is highlighted with a red box.

Record ID	Institute	Created By	Last updated by	First Remark	Last Remark	Status	Query age	Time since opened
001827	Test Institute	[redacted]	[redacted]	Please confirm	> Please confirm	New	0	0
001827	Test Institute	[redacted]	[redacted]	Please add the missin...	> Please add the missin...	New	0	0
100004	Test Institute	[redacted]	[redacted]	Please confir...	> closed	Closed	0	0
100008	Test Institute	[redacted]	[redacted]	Please confir...	> Please confir...	New	0	0
100008	Test Institute	[redacted]	[redacted]	Please add the missin...	> Please add the missin...	New	0	0
100006	Test Institute	[redacted]	[redacted]	Please add the missin...	> Confirmed	Confirmed	0	0
100006	Test Institute	[redacted]	[redacted]	Please add the missin...	> The data is added	Resolved	0	0

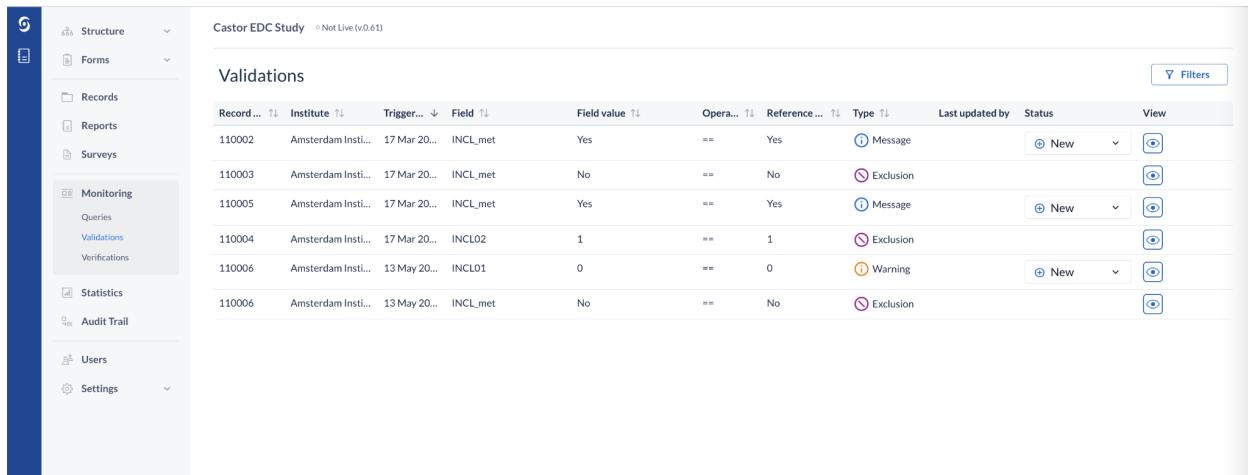
2. In Queries export dialog window, specify:
 - **Export type:** choose to export into CSV or Excel (1)
 - **Export tree:** choose if you would like to export queries for entire study, specific study phases or steps in your study or for reports, a specific report or a report step (2)

- **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.



Record ID	Institute	Triggered	Field	Field value	Operator	Reference	Type	Last updated by	Status	View
110002	Amsterdam Insti...	17 Mar 20...	INCL_met	Yes	==	Yes	Message	⊕ New		
110003	Amsterdam Insti...	17 Mar 20...	INCL_met	No	==	No	Exclusion	⊕ New		
110005	Amsterdam Insti...	17 Mar 20...	INCL_met	Yes	==	Yes	Message	⊕ New		
110004	Amsterdam Insti...	17 Mar 20...	INCL02	1	==	1	Exclusion	⊕ New		
110006	Amsterdam Insti...	13 May 20...	INCL01	0	==	0	Warning	⊕ New		
110006	Amsterdam Insti...	13 May 20...	INCL_met	No	==	No	Exclusion	⊕ New		

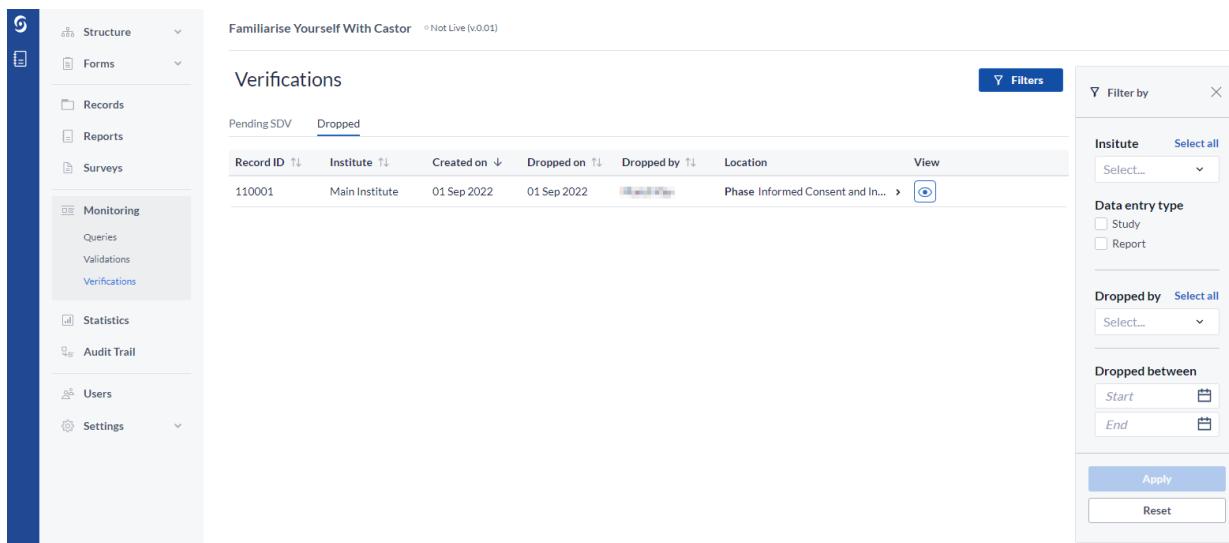
1. A user can filter validations by type (Exclusion, Warning, Message), by institute to show records with validations which belong to a particular institute, by data entry type and period when the validations were triggered using the 'Filters' button.
2. An overview of all records is given with the details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

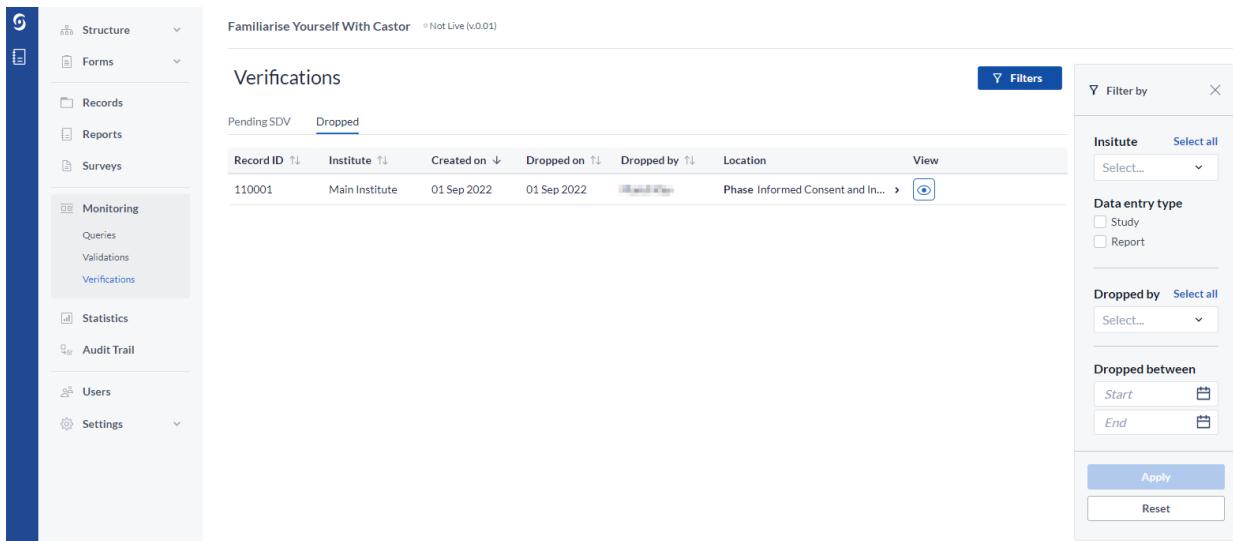
Dropped Verifications



Record ID	Institute	Created on	Dropped on	Dropped by	Location	View
110001	Main Institute	01 Sep 2022	01 Sep 2022	[redacted]	Phase Informed Consent and In...	> [eye icon]

- 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), by institute, and date range.
- 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'.

Pending Verification



The screenshot shows the Castor interface with the 'Verifications' page selected. The left sidebar has a 'Monitoring' section with 'Verifications' highlighted. The main area shows a table with the following data:

Record ID	Institute	Created on	Dropped on	Dropped by	Location	View
110001	Main Institute	01 Sep 2022	01 Sep 2022	Study	Phase: Informed Consent and In...	

On the right, there is a 'Filters' sidebar with the following settings:

- Filter by:**
 - Institute:** Select all
 - Data entry type:** Study, Report
 - Dropped by:** Select all
 - Dropped between:** Start (calendar icon), End (calendar icon)
- Buttons:** Apply, Reset

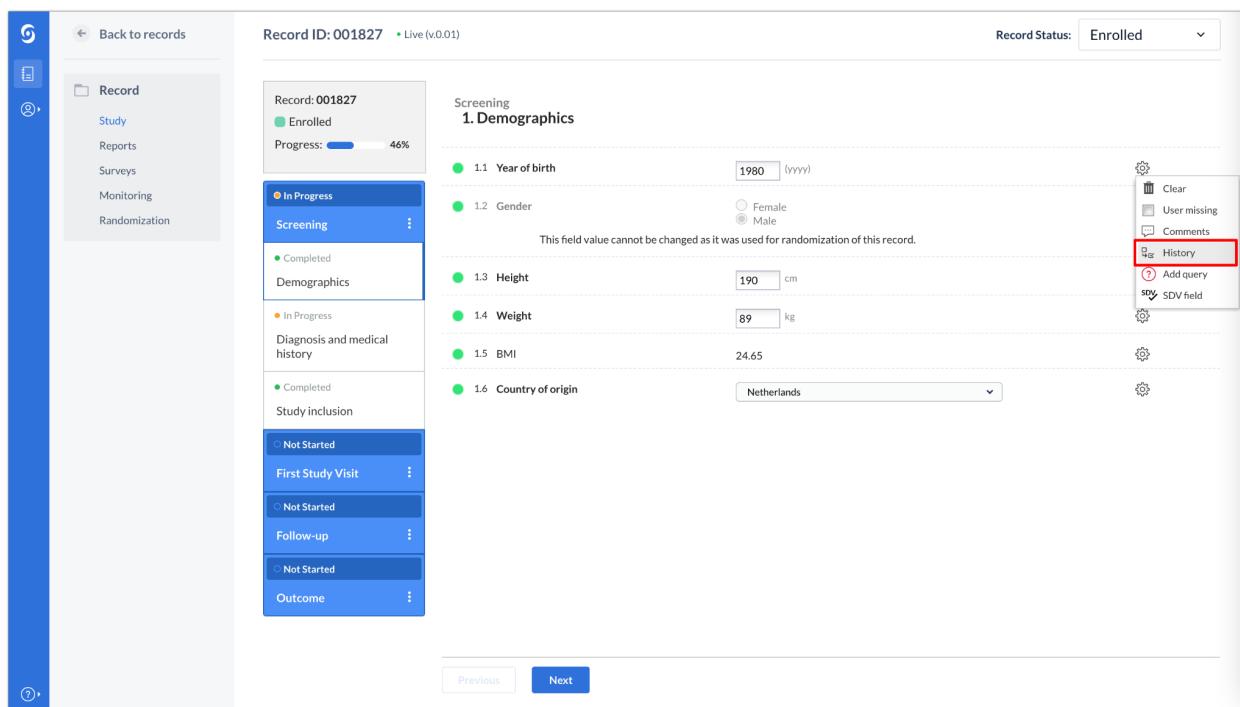
- Using the 'Filters' button, you can choose to show pending verifications for the study or for reports only. You can also choose to filter by institute, data entry type (Study and/or Reports), location and date range.
- Each row shows the record ID, the institute name, last update date, the phase and step where the field is located and the name of the field where the verification was entered
- 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 all active verifications, only those included are fields that are required and have been completed. 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

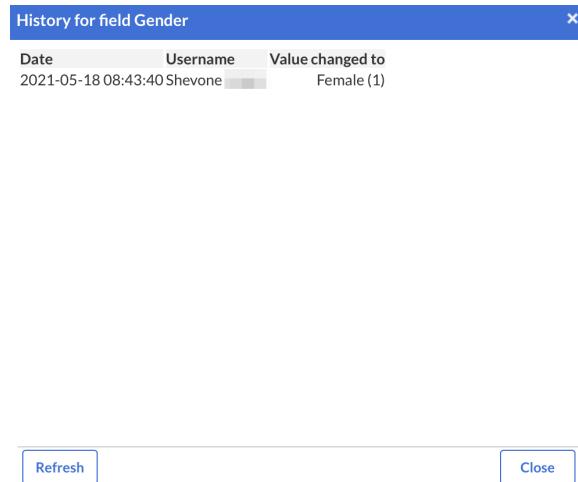
The study audit trail allows for a review of all access and changes made to study settings and data. It is possible to apply a filter to the displayed information based upon the event type, the user and the affected variable (where applicable). Access to the full audit trail is normally available only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



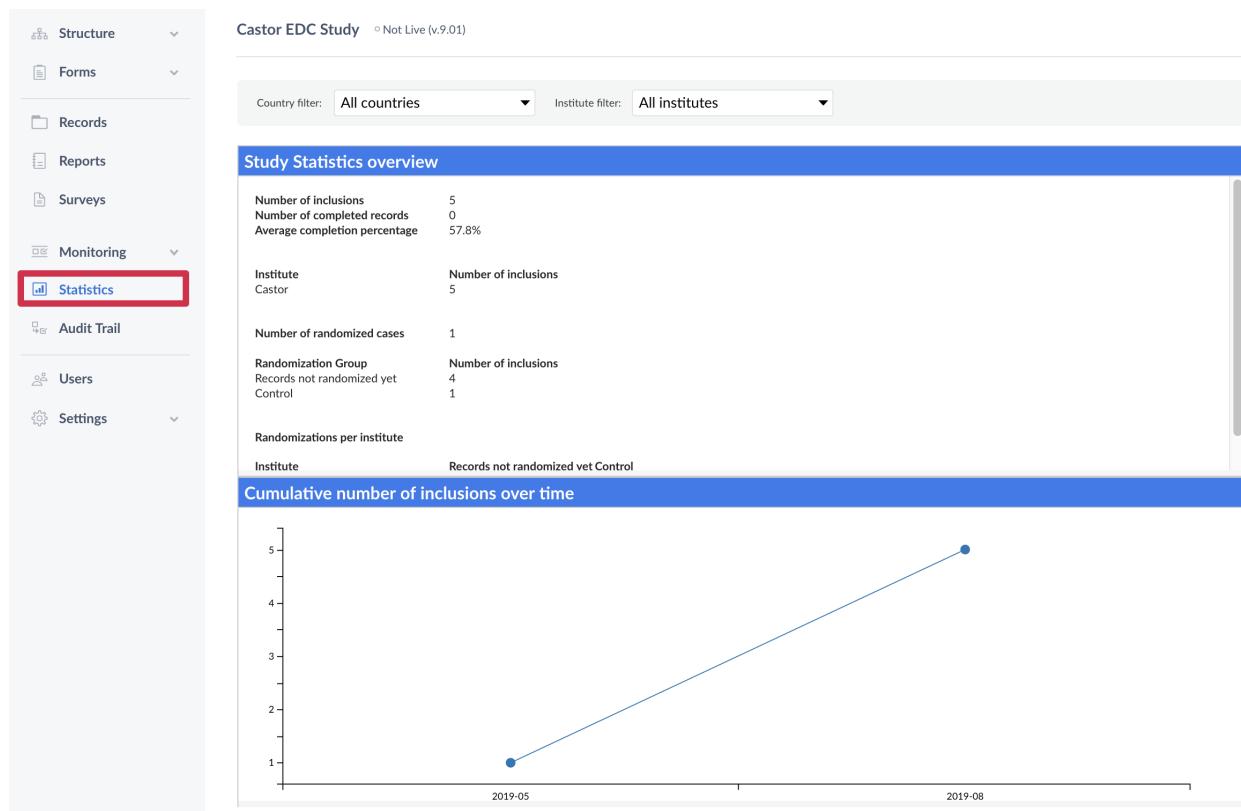
The screenshot shows a study record for Record ID: 001827, which is live (v.0.01) and Enrolled. The progress is 46%. The left sidebar shows the navigation menu with 'Record' selected. The main content area displays the 'Screening' section, specifically '1. Demographics'. The fields shown are 1.1 Year of birth (1980), 1.2 Gender (Male), 1.3 Height (190 cm), 1.4 Weight (89 kg), 1.5 BMI (24.65), and 1.6 Country of origin (Netherlands). A tooltip indicates that the value for 'Year of birth' cannot be changed as it was used for randomization of this record. On the right, a context menu is open, with the 'History' option highlighted with a red box. The menu also includes 'Clear', 'User missing', 'Comments', 'Add query', and 'SDV 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>