

Castor

Castor EDC Monitoring User Guide

Version 2022.1

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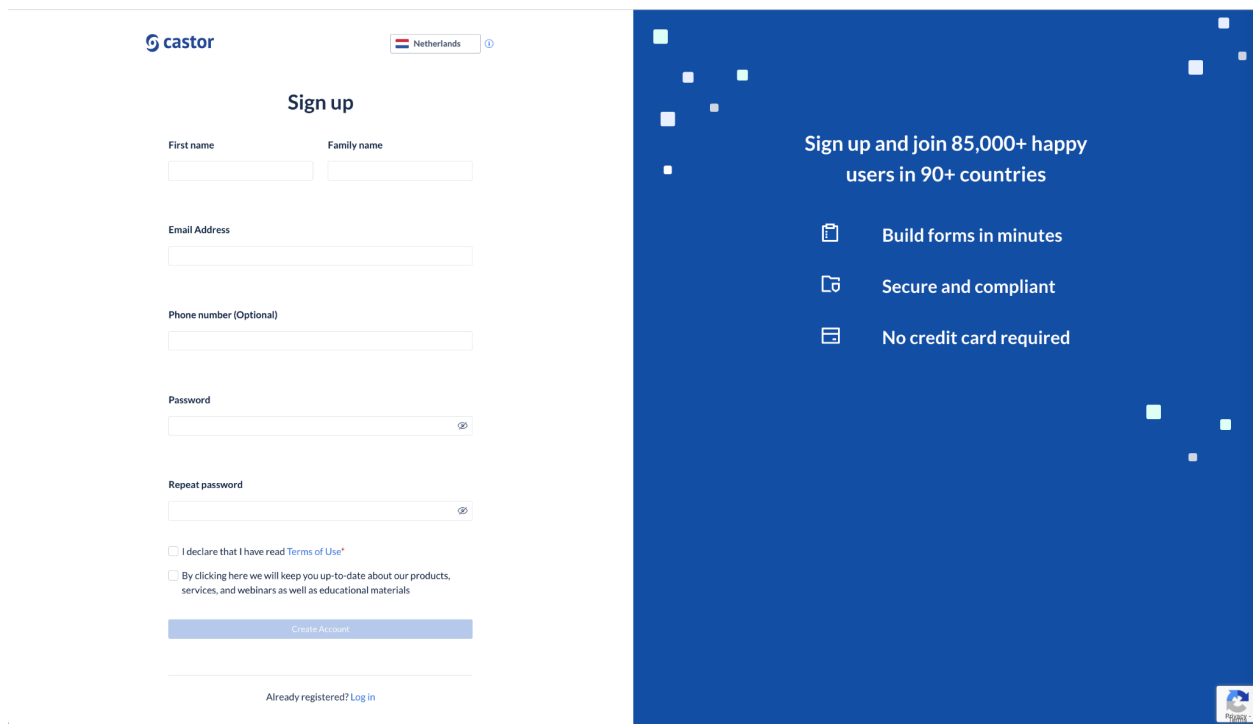
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1. Register an account

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:



Sign up

First name Family name

Email Address

Phone number (Optional)

Password

Repeat password




☐ I declare that I have read [Terms of Use](#)*

☐ By clicking here we will keep you up-to-date about our products, services, and webinars as well as educational materials

[Create Account](#)

[Already registered? Log in](#)

Sign up and join 85,000+ happy users in 90+ countries

-  Build forms in minutes
-  Secure and compliant
-  No credit card required

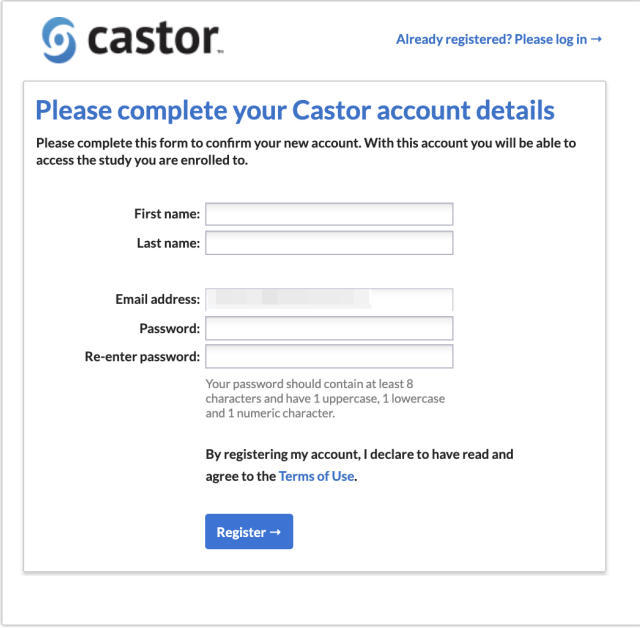
- EU Account: <https://data.castoredc.com/register>
- UK Account: <https://uk.castoredc.com/register>
- US Account: <https://us.castoredc.com/register>
- AU Account: <https://au.castoredc.com/register>

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:



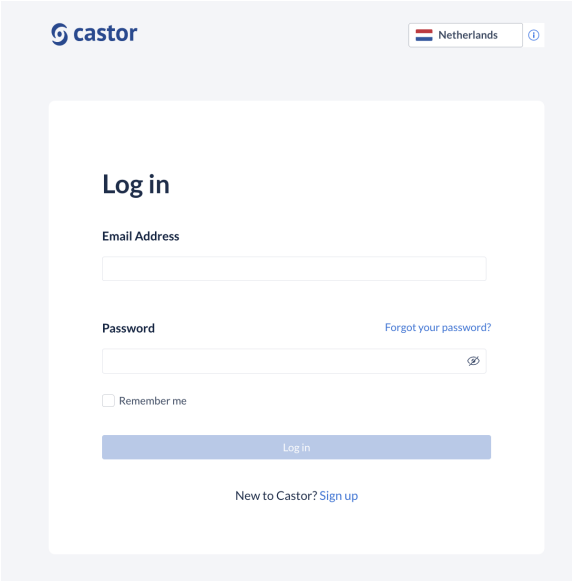
The image shows a web form for registering a Castor account. At the top left is the Castor logo. At the top right is a link: "Already registered? Please log in →". The main heading is "Please complete your Castor account details". Below this is a subtext: "Please complete this form to confirm your new account. With this account you will be able to access the study you are enrolled to." The form contains several input fields: "First name:", "Last name:", "Email address:", "Password:", and "Re-enter password:". Below the password fields is a note: "Your password should contain at least 8 characters and have 1 uppercase, 1 lowercase and 1 numeric character." Below this note is a declaration: "By registering my account, I declare to have read and agree to the [Terms of Use](#)." At the bottom is a blue button labeled "Register →".

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'.




The image shows the Castor EDC login interface. At the top left is the Castor logo. At the top right, there is a dropdown menu showing 'Netherlands' with a flag icon and an information icon. The main content area is titled 'Log in'. It contains two input fields: 'Email Address' and 'Password'. To the right of the password field is a link that says 'Forgot your password?'. Below the password field is a checkbox labeled 'Remember me'. At the bottom of the form is a blue 'Log in' button. Below the button is a link that says '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




Order by

Creation date: Newest first 

+ New Study

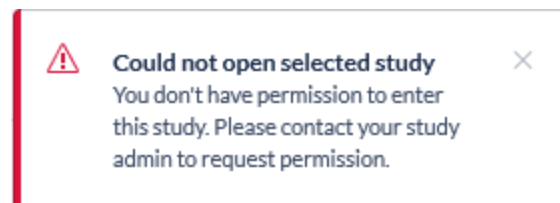
 Filters

☐ 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

Order by

☐ Not Live
☒  **Test Study: Castor EDC Study**

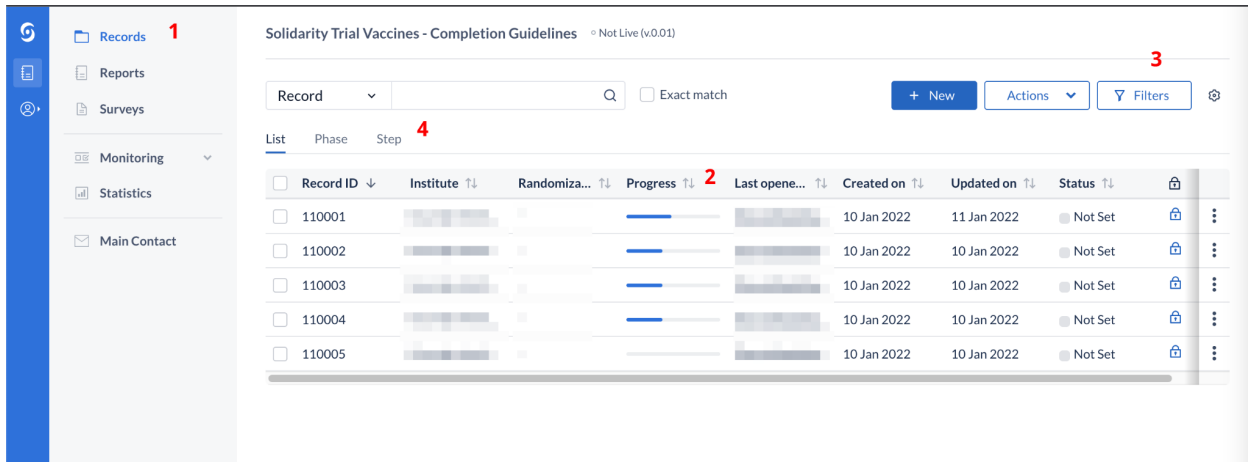
Monocenter EU Server

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

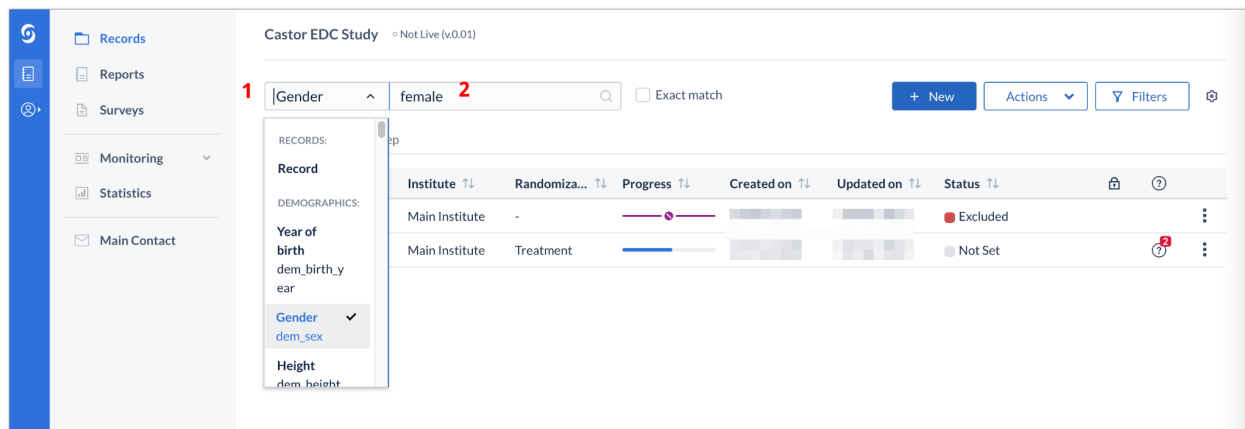
In the Records tab, a list is displayed showing all records for the institutes to which you have 'View' rights (see Section 6).



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

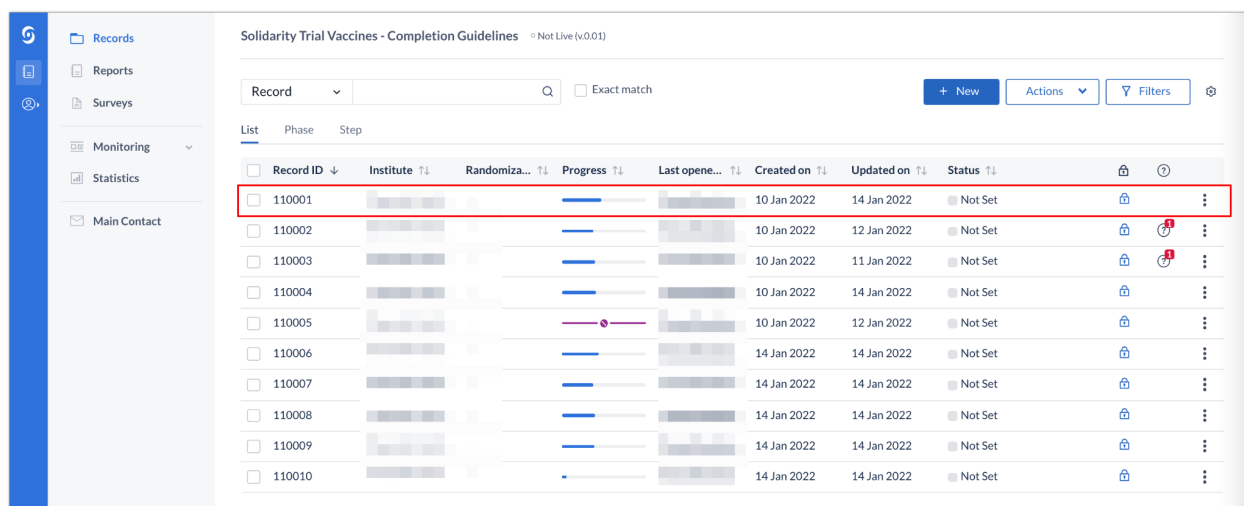
You can use the search bar to find records that contain certain data, for example if you want to find the patients with a certain age at onset.



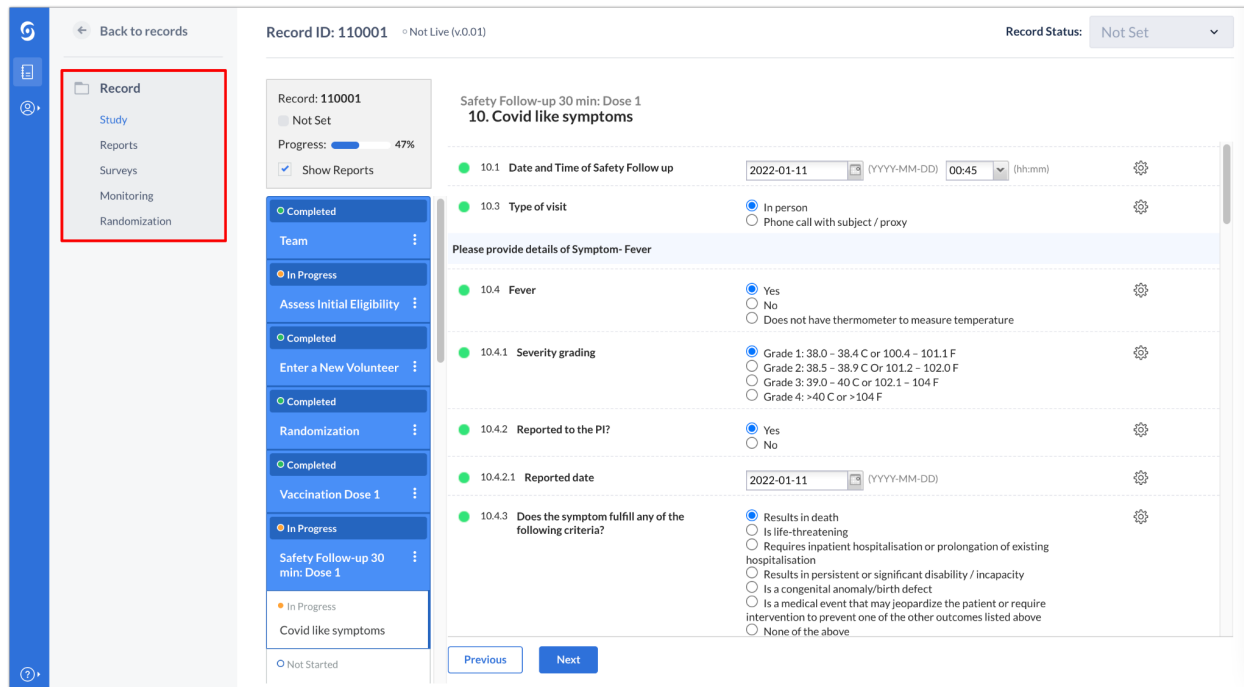
1. Click on the arrow in the right search box and find the field (question) of interest. In this example 'Gender' is selected.
2. Enter the value of interest in the left search box (in this example 'female') and all matching records will be displayed.

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:



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

Record: 110001
Not Set
Progress: 47%
☒ Show Reports

Study
Reports
Surveys
Monitoring
Randomization

Completed
Team
In Progress
Assess Initial Eligibility
Completed
Enter a New Volunteer
Completed
Randomization
Completed
Vaccination Dose 1
In Progress
Safety Follow-up 30 min: Dose 1
In Progress
Covid like symptoms
Not Started

Safety Follow-up 30 min: Dose 1
10. Covid like symptoms

10.1 Date and Time of Safety Follow up 2022-01-11 (YYYY-MM-DD) 00:45 (hh:mm)

10.3 Type of visit
☒ In person
☐ Phone call with subject / proxy

Please provide details of Symptom- Fever

10.4 Fever
☒ Yes
☐ No
☐ Does not have thermometer to measure temperature

10.4.1 Severity grading
☒ Grade 1: 38.0 - 38.4 C or 100.4 - 101.1 F
☐ Grade 2: 38.5 - 38.9 C or 101.2 - 102.0 F
☐ Grade 3: 39.0 - 40 C or 102.1 - 104 F
☐ Grade 4: >40 C or >104 F

10.4.2 Reported to the PI?
☒ Yes
☐ No

10.4.2.1 Reported date 2022-01-11 (YYYY-MM-DD)

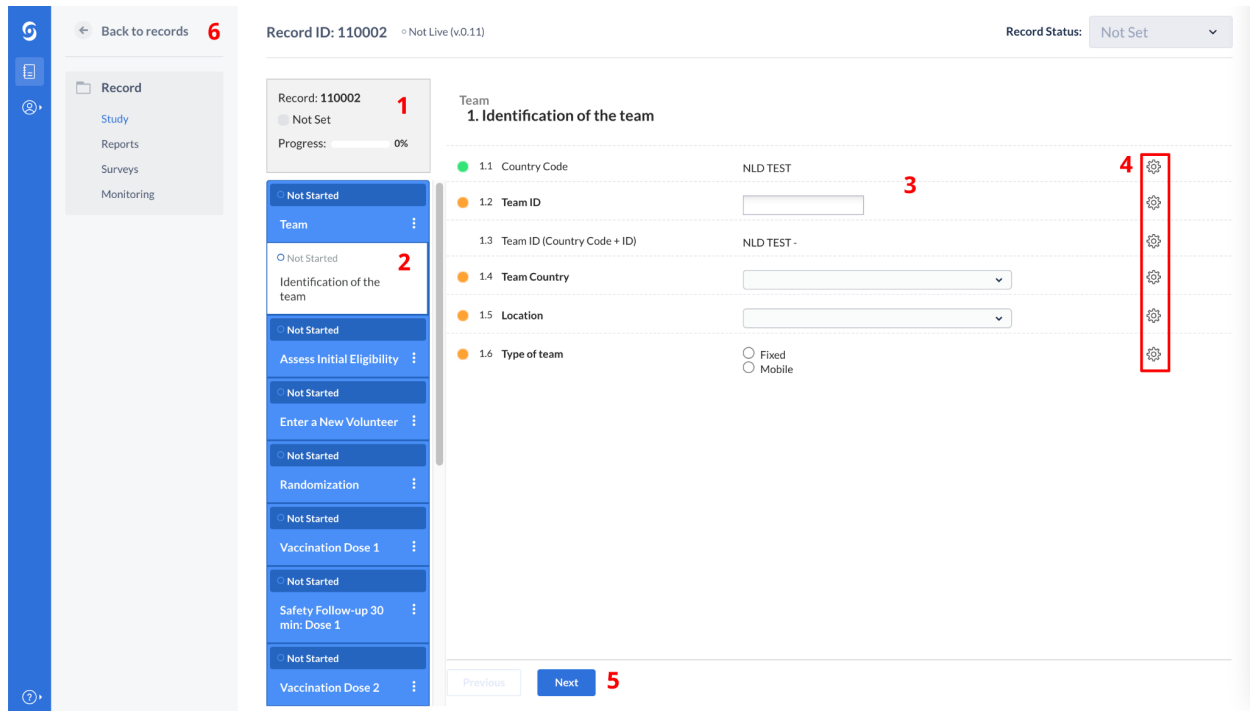
10.4.3 Does the symptom fulfill any of the following criteria?
☒ Results in death
☐ Is life-threatening
☐ Requires inpatient hospitalisation or prolongation of existing hospitalisation
☐ Results in persistent or significant disability / incapacity
☐ Is a congenital anomaly/birth defect
☐ Is a medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above
☐ None of the above

Previous Next

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 Castor Study tab interface for Record ID: 110002. The interface is divided into several sections:

- Top Bar:** Includes a "Back to records" button (6), the Record ID "110002" (1), a version indicator "v0.11", and a "Record Status" dropdown menu set to "Not Set".
- Left Sidebar:** Contains navigation options: "Record", "Study" (highlighted), "Reports", "Surveys", and "Monitoring".
- Main Content Area:**
 - Record Summary:** Shows "Record: 110002" (1), "Not Set" status, and "Progress: 0%".
 - Study Forms List:** A vertical list of study forms, each with a status indicator (e.g., "Not Started", "Not Started") and a title. The first form, "1. Identification of the team" (2), is selected and expanded.
 - Form Fields:** The expanded form shows fields for:
 - 1.1 Country Code: NLD TEST (3)
 - 1.2 Team ID: [Text Input]
 - 1.3 Team ID (Country Code + ID): NLD TEST -
 - 1.4 Team Country: [Dropdown]
 - 1.5 Location: [Dropdown]
 - 1.6 Type of team: Radio buttons for "Fixed" and "Mobile".
 - Navigation:** At the bottom of the form, there are "Previous" and "Next" (5) buttons.

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).

- 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.
- 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.
- 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.

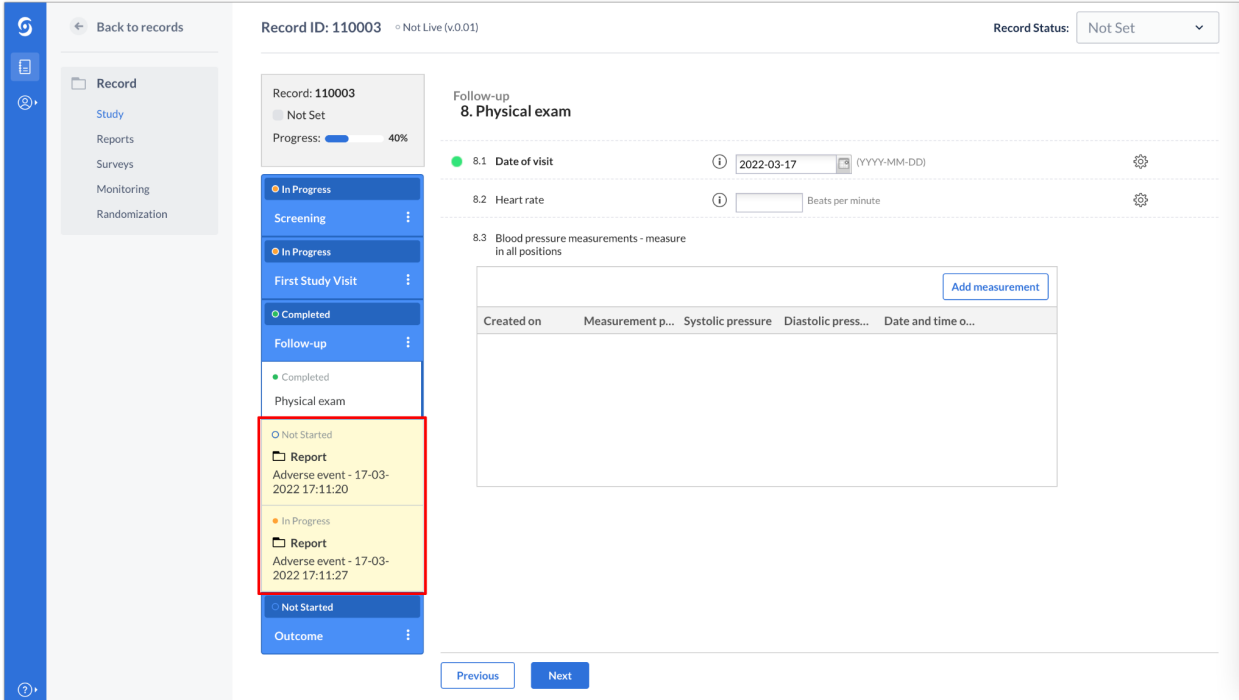
The screenshot displays the 'Reports' tab for a specific record (ID: 110001). The interface includes a sidebar on the left with a 'Reports' tab highlighted (1). The main content area shows a record summary card (2) with a progress bar at 47% and a 'Show Reports' checkbox. Below this is a table of reports (3) with columns for Status, Report, Name, Type, Created on, Created by, and Assigned to. The table lists three reports: 'A. Initial Serious A...' (Adverse Event), 'J. Sample Collection' (Repeated measure), and 'J. Sample Collection' (Repeated measure). The table also includes filter options for report type, report name, phase, and status, along with an 'Add a report' button. At the bottom, there are pagination controls showing 'Page 1 of 1' and 'Show 25' reports.

- 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.
- 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).

- 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:



Record ID: 110003 Not Live (v0.01) Record Status: Not Set

Record: 110003
Not Set
Progress: 40%

Follow-up
8. Physical exam

8.1 Date of visit 2022-03-17 (YYYY-MM-DD)

8.2 Heart rate 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...

Follow-up

- Physical exam**
- Report**
Adverse event - 17-03-2022 17:11:20
- Report**
Adverse event - 17-03-2022 17:11:27
- Outcome**

[Previous](#) [Next](#)

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:

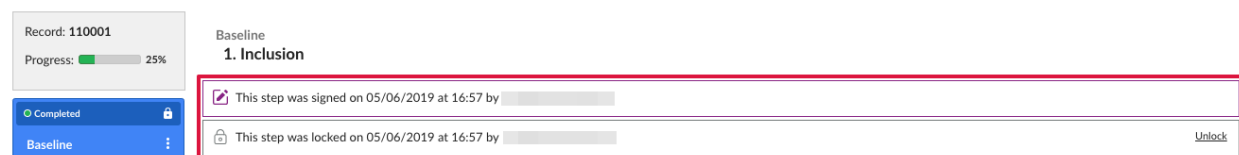


The screenshot shows a data entry field for '3.1.1 Date of informed consent' with the value '2022-05-14' and a format '(YYYY-MM-DD)'. Below the field, a red-bordered box contains a warning icon and the message: 'Date of signature cannot be in the future'.

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 form with a sidebar on the left containing 'Record: 110001', 'Progress: 25%', and a 'Completed' button. The main area shows 'Baseline 1. Inclusion'. Two banners are displayed at the top of the form: 'This step was signed on 05/06/2019 at 16:57 by [redacted]' and 'This step was locked on 05/06/2019 at 16:57 by [redacted]'. An 'Unlock' link is visible at the end of the second banner.

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?

☒ Yes

☐ No

☐ Unknown



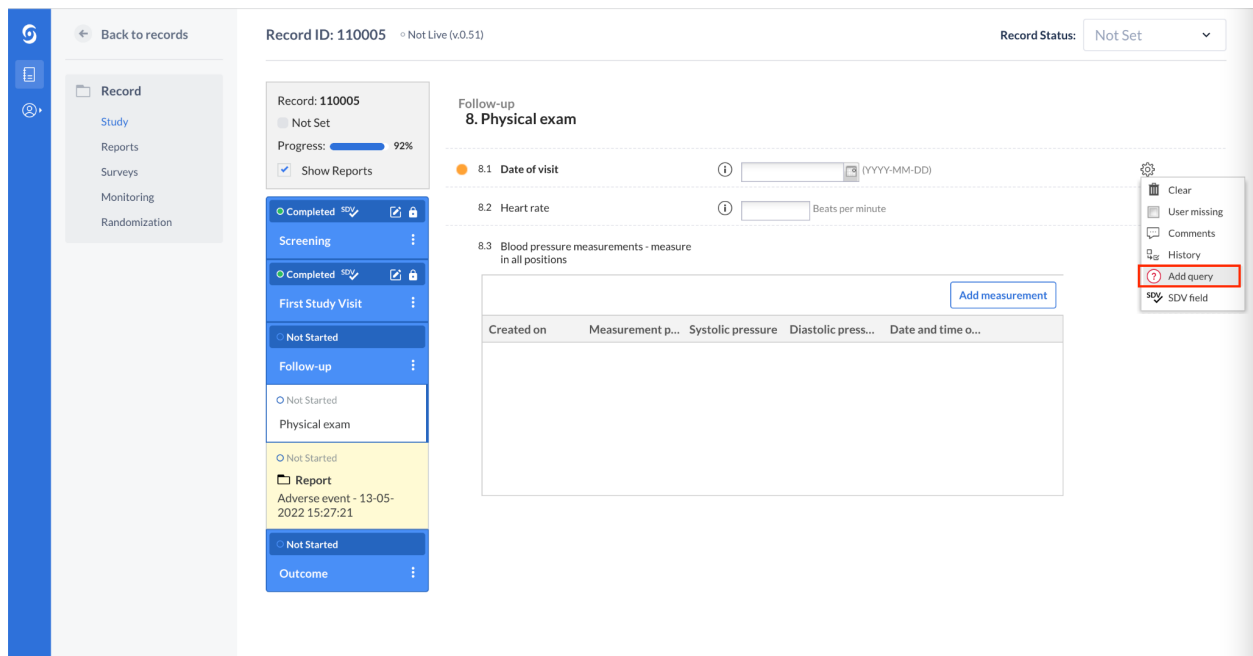
Comments are mandatory when making changes to a signed or verified form or, if the GCP module is turned on in Study settings, changing a field's value. All fields with such changes will have an associated comment. These cannot be modified or deleted.

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

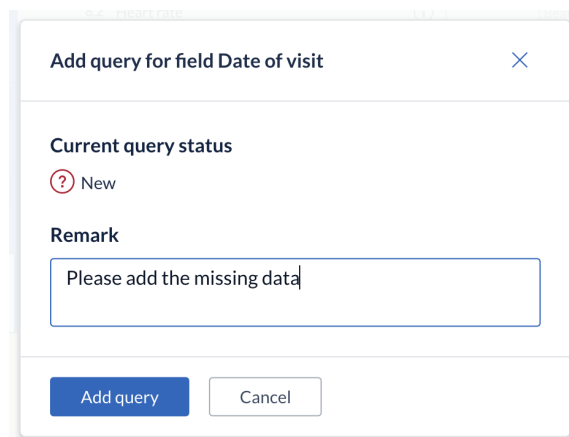
5.1 Adding queries

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':



The screenshot shows the Castor study interface for Record ID: 110005. The record status is 'Not Set' and the progress is 92%. The 'Physical exam' section is active, showing fields for 'Date of visit', 'Heart rate', and 'Blood pressure measurements'. A dropdown menu is open next to the 'Date of visit' field, displaying options: 'Clear', 'User missing', 'Comments', 'History', 'Add query' (highlighted in red), and 'SDV field'.

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



The screenshot shows a pop-up window titled 'Add query for field Date of visit'. The window contains the following information:

- Current query status:** New
- Remark:** Please add the missing data
- Buttons:** 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.

● 8.1 Date of visit

i
(YYYY-MM-DD)

⚙️ ?¹

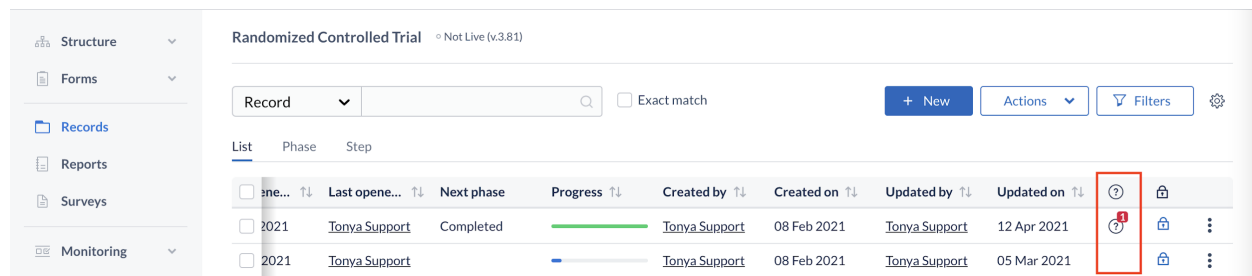
5.2 Query resolution

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).

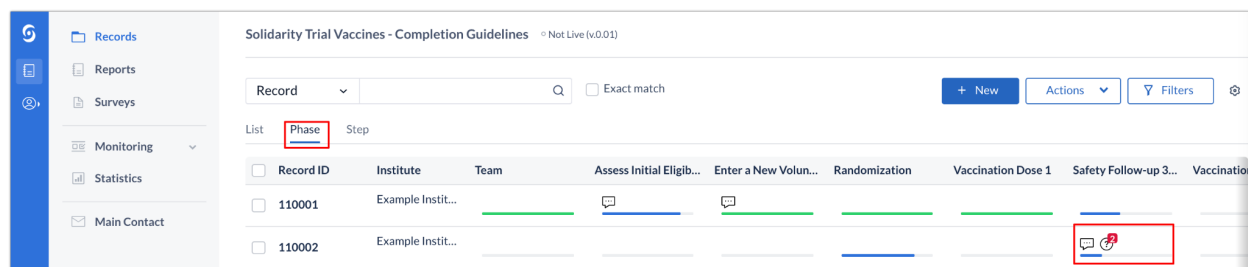
5.3. Query overview

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



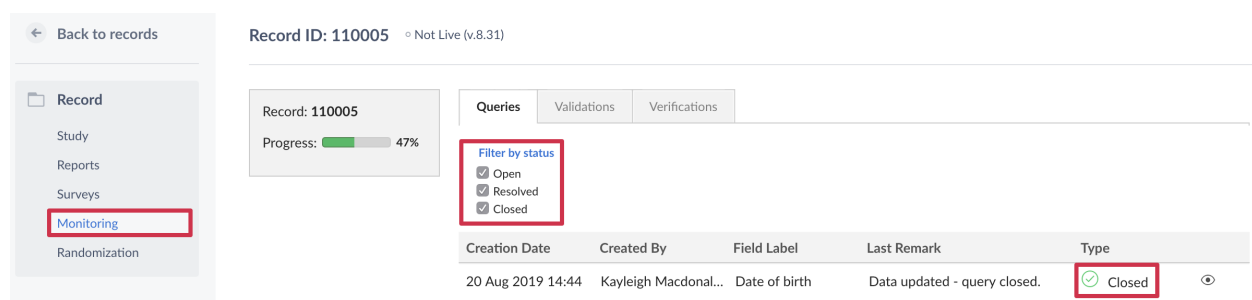
Record	Phase	Step	Progress	Created by	Created on	Updated by	Updated on	Queries
2021	Tonya Support	Completed	<div><div></div></div>	Tonya Support	08 Feb 2021	Tonya Support	12 Apr 2021	?
2021	Tonya Support		<div><div></div></div>	Tonya Support	08 Feb 2021	Tonya Support	05 Mar 2021	?

The queries are also indicated in the 'Phase' and 'Step' view mode in the 'Records' tab:



Record ID	Institute	Team	Assess Initial Eligib...	Enter a New Volun...	Randomization	Vaccination Dose 1	Safety Follow-up 3...	Vaccination
110001	Example Instit...		<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
110002	Example Instit...		<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>

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



Creation Date	Created By	Field Label	Last Remark	Type
20 Aug 2019 14:44	Kayleigh Macdonal...	Date of birth	Data updated - query closed.	Closed

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?
Yes
No

⚠ 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

⚙️

⊘ 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:

[Back to records](#)

Record ID: 110010

Not Live (v0.01)

Record Status: Not Set

Record

Study

Reports

Surveys

Monitoring

Randomization

Record: 110010

Not Set

Progress: 7%

Queries

Validations

Dropped verifications

Filter by type

☒ Exclusion
☒ Warning
☒ Message

Data Entry Type

☒ Study
☒ Report
☒ Survey

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).

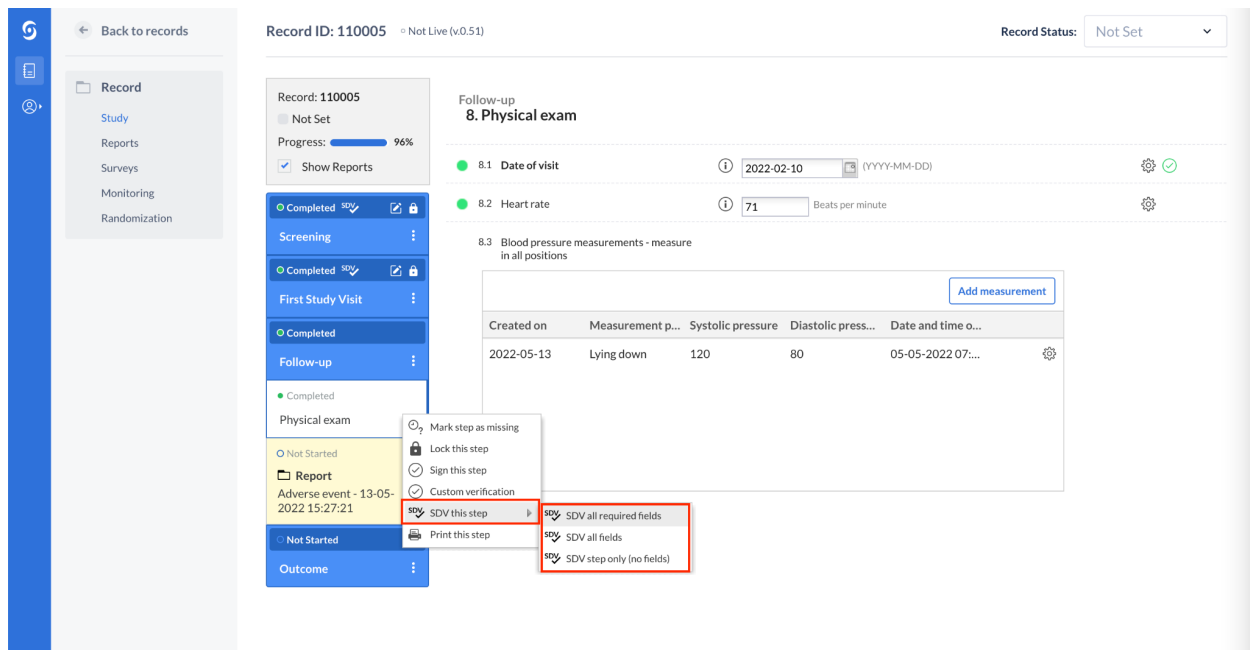
7. Source Data Verification

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.



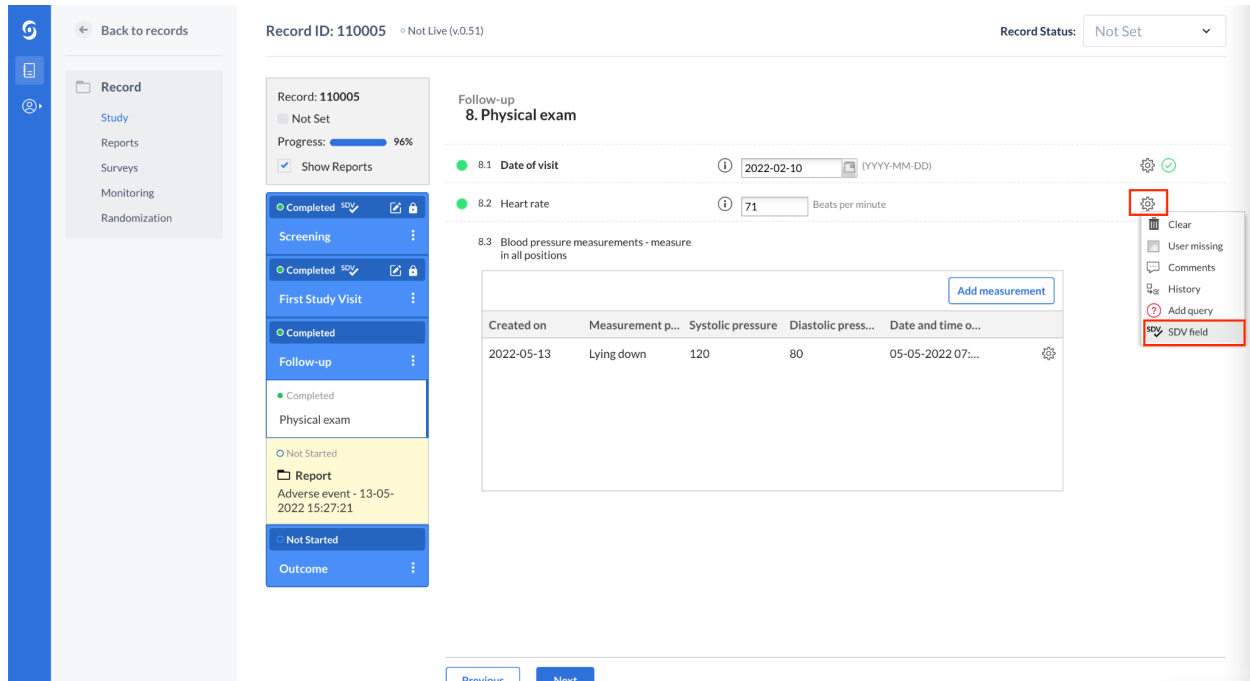
The screenshot shows the Castor EDC interface for Record ID: 110005. The left sidebar contains a navigation menu with options: Record, Study, Reports, Surveys, Monitoring, and Randomization. The main content area displays the record details, including the progress bar (96%) and a list of steps. The 'Physical exam' step is highlighted, and a context menu is open, showing options: Mark step as missing, Lock this step, Sign this step, Custom verification, SDV this step, and Print this step. The 'SDV this step' option is selected, and a sub-menu is open, showing options: SDV all required fields, SDV all fields, and SDV step only (no fields). The 'SDV all required fields' option is highlighted.

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'



The screenshot displays the Castor EDC interface for Record ID: 110005. The left sidebar shows a navigation menu with options like Record, Study, Reports, Surveys, Monitoring, and Randomization. The main content area shows the record details, including a progress bar at 96% and a list of study visits. The 'Follow-up' section is expanded, showing '8. Physical exam' with fields for '8.1 Date of visit' and '8.2 Heart rate'. A table for '8.3 Blood pressure measurements - measure in all positions' is also visible. A red box highlights the cogwheel icon next to the '8.2 Heart rate' field, and another red box highlights the 'SDV field' option in the dropdown menu that appears when the cogwheel is clicked.

Record ID: 110005 Not Live (v0.51) Record Status: Not Set

Record: 110005
Not Set
Progress: 96%
Show Reports

Completed SDV

Screening

Completed SDV

First Study Visit

Completed

Follow-up

Completed

Physical exam

Not Started

Report
Adverse event - 13-05-2022 15:27:21

Not Started

Outcome

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

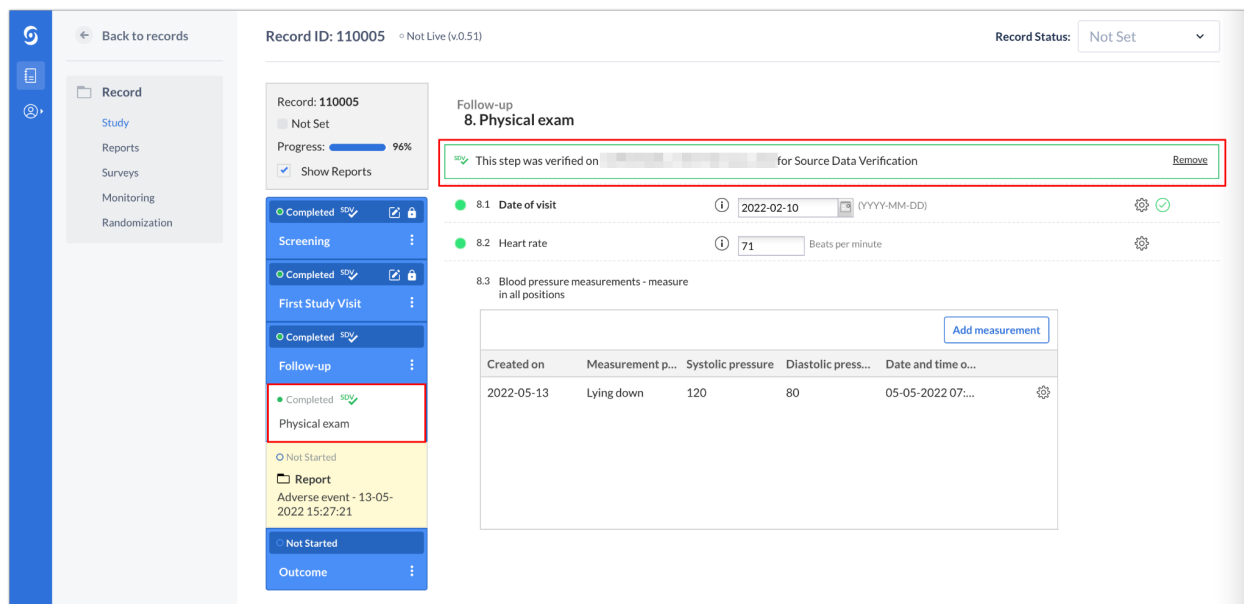
Created on	Measurement p...	Systolic pressure	Diastolic press...	Date and time o...	
2022-05-13	Lying down	120	80	05-05-2022 07:...	

Previous Next

Clear
User missing
Comments
History
Add query
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.



The screenshot displays the Castor interface for Record ID: 110005. The left sidebar shows a navigation menu with options like Study, Reports, Surveys, Monitoring, and Randomization. The main content area shows the record details, including a progress bar at 96% and a list of steps. The 'Physical exam' step is highlighted with a red box, indicating it is completed and has an SDV icon. A green banner at the top of the 'Physical exam' section states 'This step was verified on [date] for Source Data Verification' with a 'Remove' button. Below this, the '8.1 Date of visit' and '8.2 Heart rate' fields are shown with their respective values and SDV icons. The '8.3 Blood pressure measurements' section includes a table with columns for 'Created on', 'Measurement p...', 'Systolic pressure', 'Diastolic press...', and 'Date and time o...'. The table contains one row of data: '2022-05-13', 'Lying down', '120', '80', and '05-05-2022 07:...'. An 'Add measurement' button is located at the top right of the table.

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.

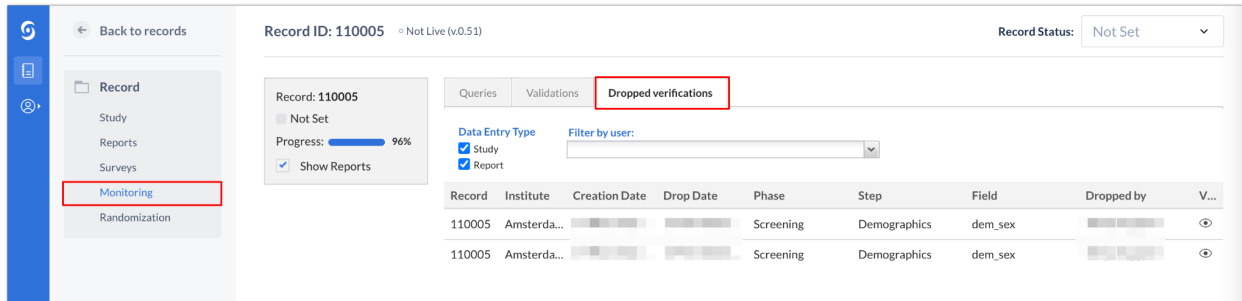
When dropping SDV:

- 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:



The screenshot displays the Castor web application interface. On the left, a sidebar contains a 'Monitoring' tab highlighted with a red box. The main content area shows 'Record ID: 110005' with a status of 'Not Live (v0.51)'. Below this, there are tabs for 'Queries', 'Validations', and 'Dropped verifications', with the latter being selected and highlighted with a red box. The 'Dropped verifications' tab displays a table with columns: Record, Institute, Creation Date, Drop Date, Phase, Step, Field, and Dropped by. Two rows of data are visible, both for Record ID 110005, showing 'Amsterdam' as the institute, 'Screening' as the phase, and 'Demographics' as the step. The 'Field' column shows 'dem_sex' for both entries. The 'Dropped by' column shows a user icon for both entries.

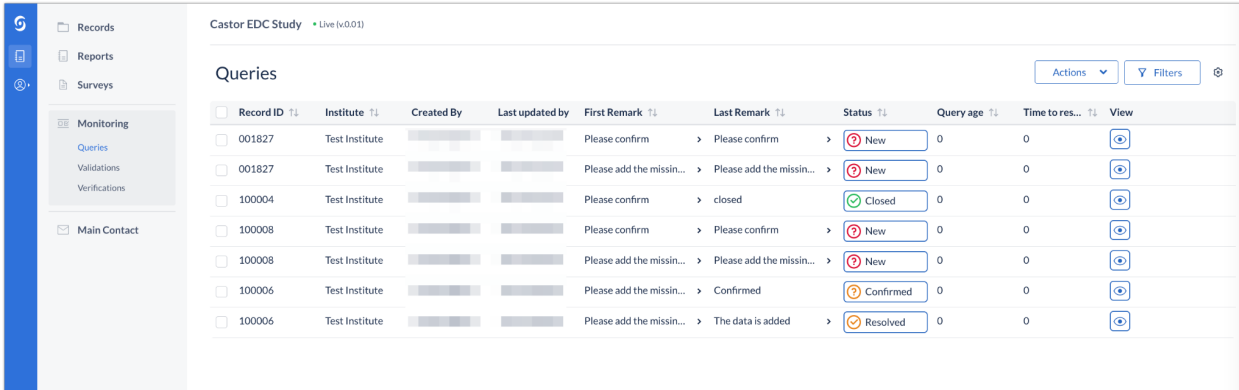
All dropped verifications for *all* records are available in the general Monitoring tab (see Monitoring tab section below).

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			Please confirm	Please confirm	New	0	0	
001827	Test Institute			Please add the missin...	Please add the missin...	New	0	0	
100004	Test Institute			Please confirm	closed	Closed	0	0	
100008	Test Institute			Please confirm	Please confirm	New	0	0	
100008	Test Institute			Please add the missin...	Please add the missin...	New	0	0	
100006	Test Institute			Please add the missin...	Confirmed	Confirmed	0	0	
100006	Test Institute			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

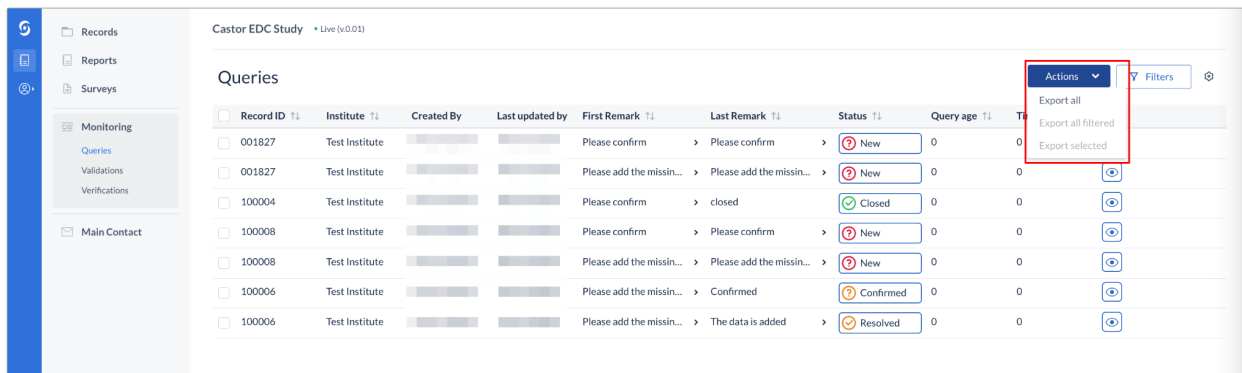
- **Time to resolve:** time that require to resolve a query
- **View:** click on the eye icon to view the query in a step where it was created

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.

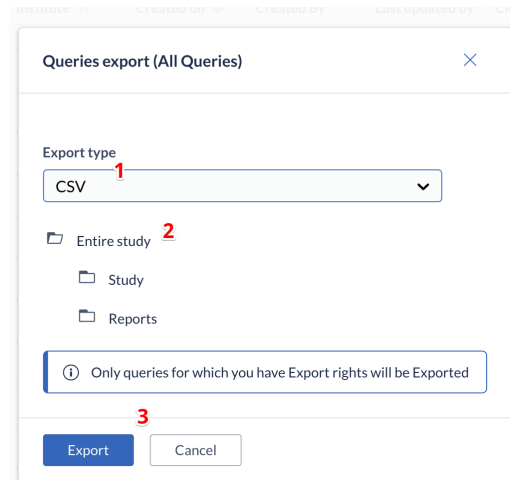


The screenshot shows the 'Castor EDC Study' interface with the 'Queries' sub-tab selected. The 'Queries' table is displayed with columns: Record ID, Institute, Created By, Last updated by, First Remark, Last Remark, Status, Query age, and Time to resolve. The 'Status' column shows various query states like 'New', 'Closed', 'Confirmed', and 'Resolved'. The 'Actions' dropdown menu is open, showing options: 'Export all', 'Export all filtered', and 'Export selected'.

Record ID	Institute	Created By	Last updated by	First Remark	Last Remark	Status	Query age	Time to resolve
001827	Test Institute			Please confirm	Please confirm	New	0	0
001827	Test Institute			Please add the missin...	Please add the missin...	New	0	0
100004	Test Institute			Please confirm	closed	Closed	0	0
100008	Test Institute			Please confirm	Please confirm	New	0	0
100008	Test Institute			Please add the missin...	Please add the missin...	New	0	0
100006	Test Institute			Please add the missin...	Confirmed	Confirmed	0	0
100006	Test Institute			Please add the missin...	The data is added	Resolved	0	0

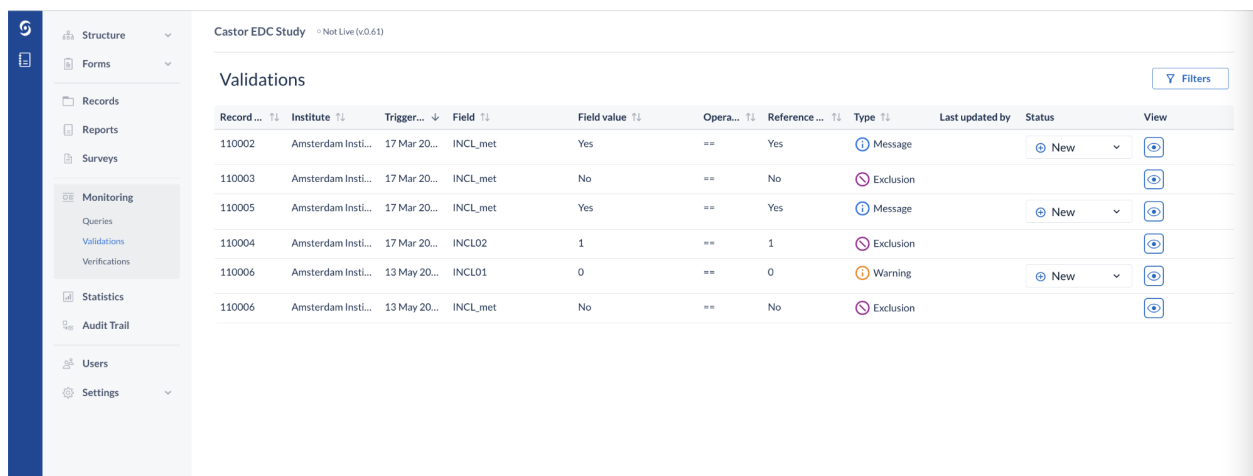
2. In Queries export dialog window, specify:
 - **Export type:** choose to export into CSV or Excel (1)
 - **Export tree:** choose if you would like to export queries for entire study, specific study phases or steps in your study or for reports, a specific report or a report step (2)

- **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.



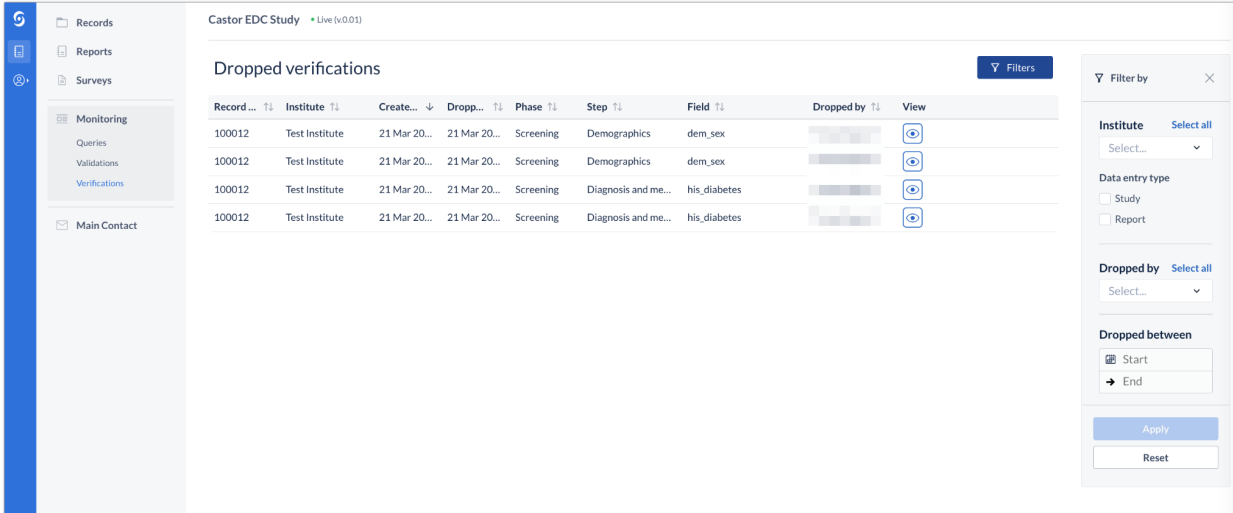
Record ID	Institute	Trigger date	Field	Field value	Operator	Reference value	Type	Last updated by	Status	View
110002	Amsterdam Insti...	17 Mar 20...	INCL_met	Yes	==	Yes	Message		New	
110003	Amsterdam Insti...	17 Mar 20...	INCL_met	No	==	No	Exclusion			
110005	Amsterdam Insti...	17 Mar 20...	INCL_met	Yes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

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:



Record ID	Institute	Create...	Drop...	Phase	Step	Field	Dropped by	View
100012	Test Institute	21 Mar 20...	21 Mar 20...	Screening	Demographics	dem_sex	[Redacted]	[Eye icon]
100012	Test Institute	21 Mar 20...	21 Mar 20...	Screening	Demographics	dem_sex	[Redacted]	[Eye icon]
100012	Test Institute	21 Mar 20...	21 Mar 20...	Screening	Diagnosis and me...	his_diabetes	[Redacted]	[Eye icon]
100012	Test Institute	21 Mar 20...	21 Mar 20...	Screening	Diagnosis and me...	his_diabetes	[Redacted]	[Eye icon]

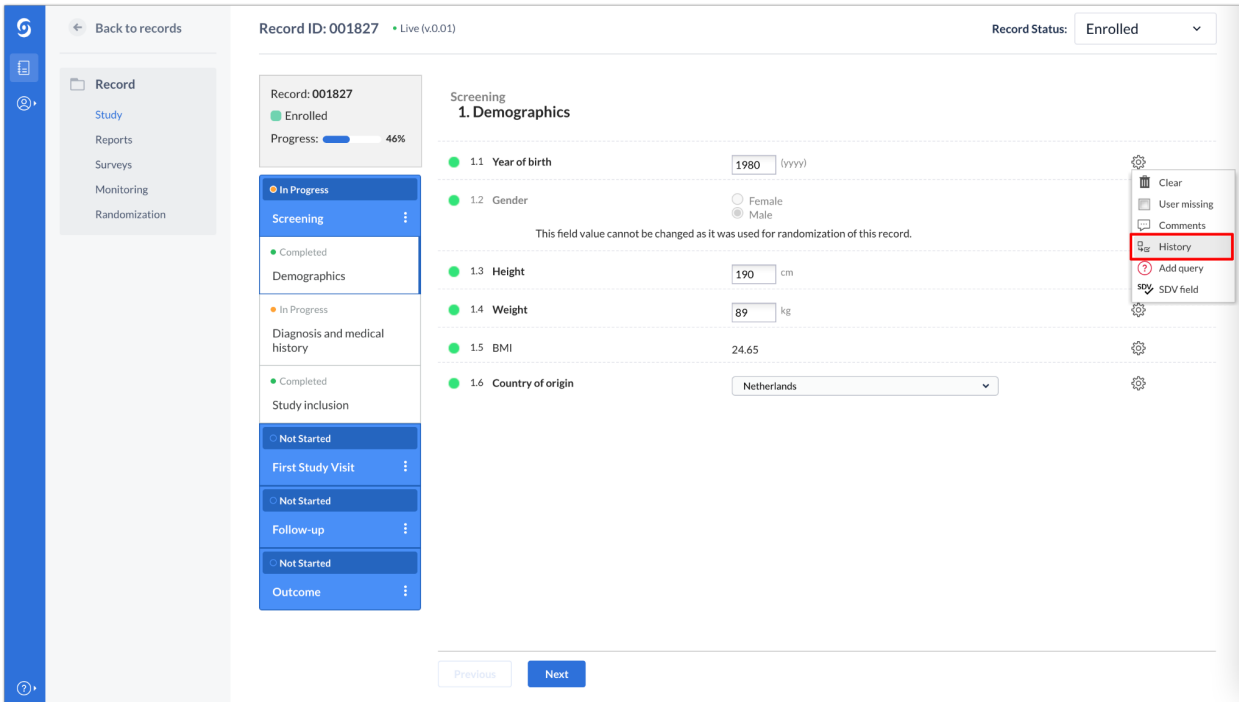
- Using the 'Filters' button, you can choose to show dropped verifications for the study or for reports only. You can also choose to filter by user (who dropped the verification) and by institute.
- Each row shows the record ID, the institute name, creation date, drop date, the phase and step where the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



The screenshot displays the Castor data entry interface for Record ID: 001827, which is in the 'Enrolled' status. The interface is divided into a left sidebar, a central record overview, and a main data entry area.

Left Sidebar: Contains navigation links for 'Record', 'Study', 'Reports', 'Surveys', 'Monitoring', and 'Randomization'. The 'Record' section is expanded, showing a list of record stages: 'In Progress' (Screening), 'Completed' (Demographics), 'In Progress' (Diagnosis and medical history), 'Completed' (Study inclusion), 'Not Started' (First Study Visit), 'Not Started' (Follow-up), and 'Not Started' (Outcome).

Central Record Overview: Shows the record's progress (46%) and a list of screening items. Item 1.1 'Year of birth' is highlighted with a green dot. Item 1.2 'Gender' is also highlighted with a green dot. Item 1.3 'Height' is highlighted with a green dot. Item 1.4 'Weight' is highlighted with a green dot. Item 1.5 'BMI' is highlighted with a green dot. Item 1.6 'Country of origin' is highlighted with a green dot.

Main Data Entry Area: Displays the 'Screening 1. Demographics' section. It includes a table of demographic data:

Item	Value	Unit	Field Type
1.1 Year of birth	1980	(yyyy)	Text
1.2 Gender	Female		Radio
1.3 Height	190	cm	Text
1.4 Weight	89	kg	Text
1.5 BMI	24.65		Text
1.6 Country of origin	Netherlands		Dropdown

Below the table, there are 'Previous' and 'Next' buttons. A red box highlights the 'History' button in the top right corner of the interface, indicating the location to click to view the audit trail for a specific 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:

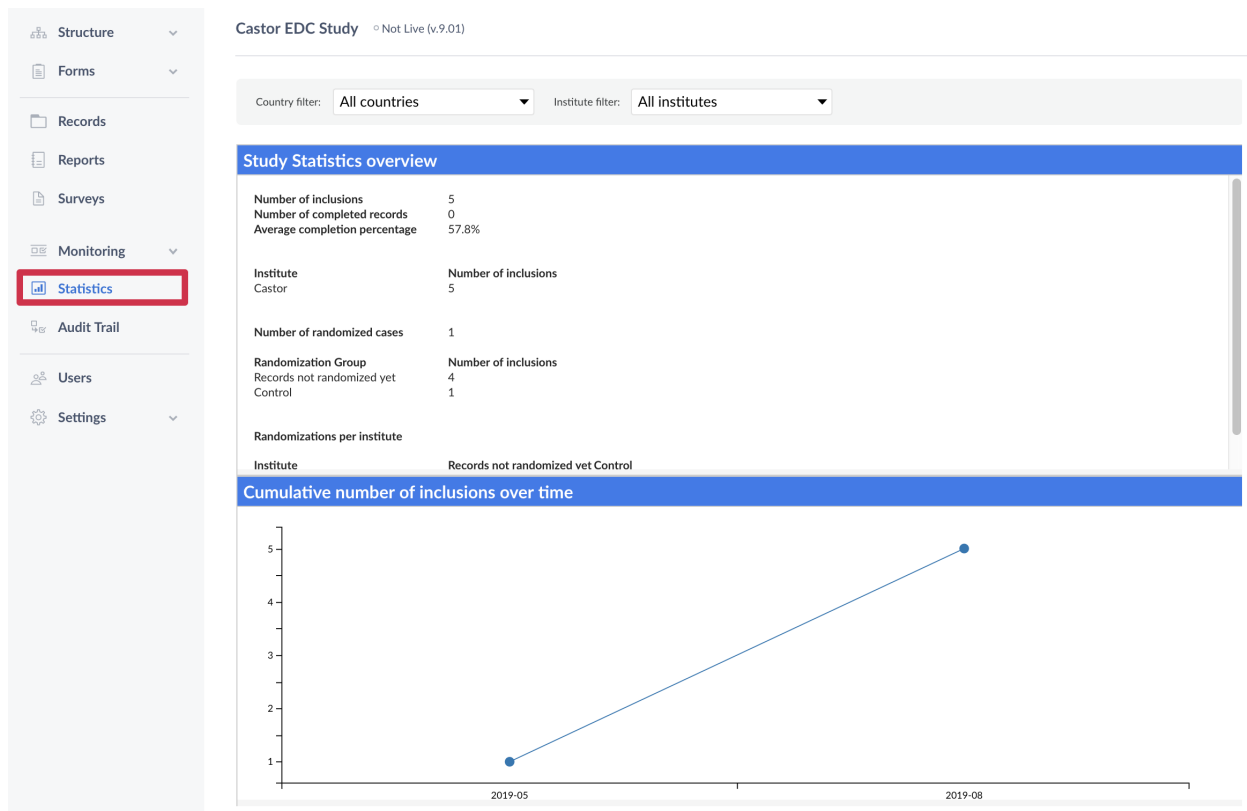
History for field Gender		
Date	Username	Value changed to
2021-05-18 08:43:40	Shevone	Female (1)

Refresh

Close

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>