

# Study Monitoring in Castor EDC

## Register an account

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

Alternatively, you can go directly to our website to create an account before being invited to a study. You will choose the site to create your account on based on the location of your study data<sup>1</sup>.

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

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

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

To register your Castor account:

Already registered? [Log in](#) →

First Name  Last Name

Email

Phone Number

Password  [Show](#)

Password should contain at least 8 characters with 1 uppercase, 1 lowercase and 1 numeric character.

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

[Create Account](#)

**castor**

Sign up and join 30,000+ researchers in 90+ countries

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

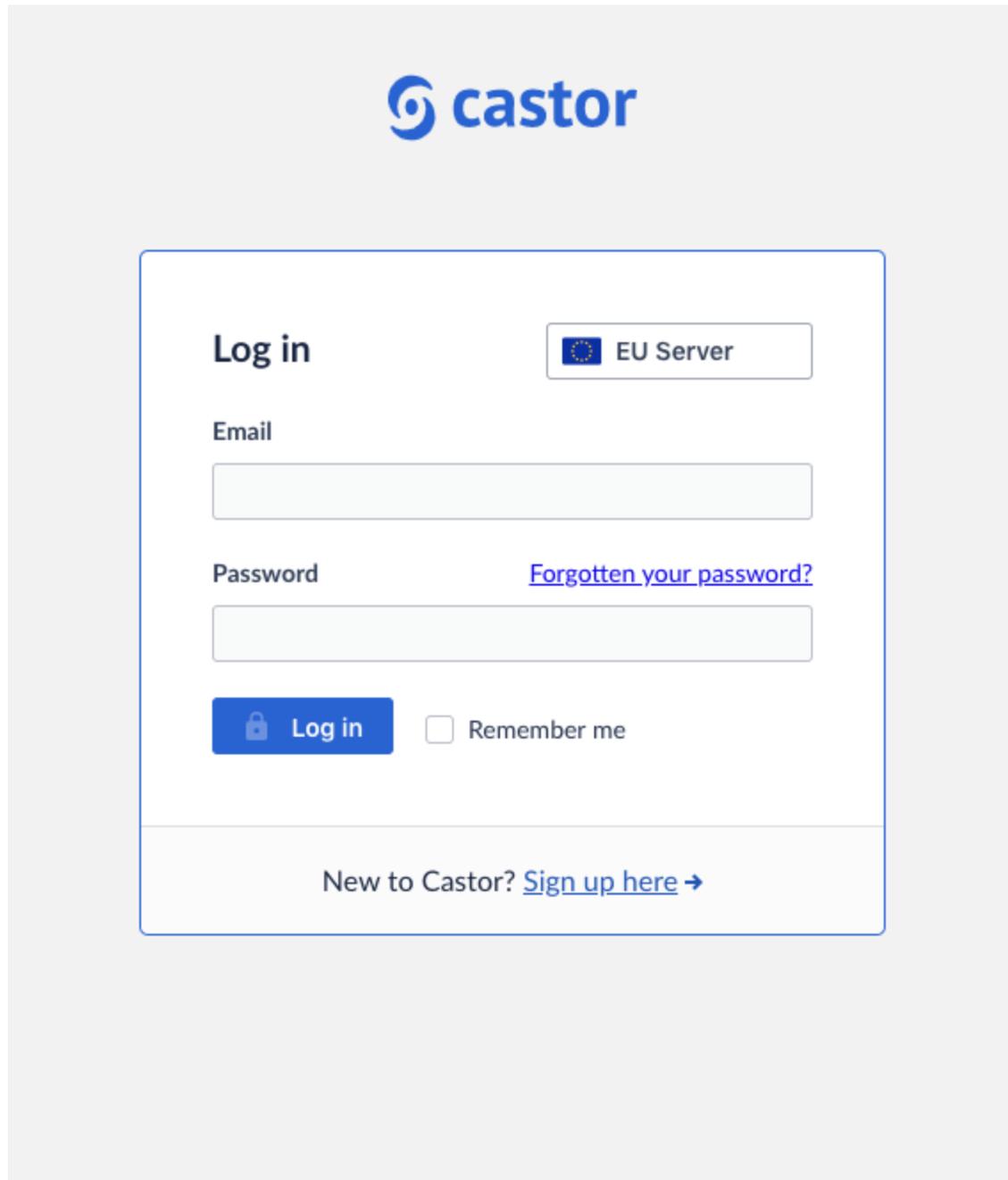
1. Fill in your first and last name(s).
2. Enter your email address and choose a strong password, consisting of at least 8 characters, one uppercase letter, one lowercase letter and a number.
3. Enter your phone number.

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

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

## 2. Log in



The image shows a login form for the Castor platform. At the top center is the Castor logo, which consists of a blue circular icon with a white swirl and the word "castor" in a blue, lowercase, sans-serif font. Below the logo is a white rectangular box with a blue border containing the login fields. The box is titled "Log in" in bold black text. To the right of the title is a button with the European Union flag icon and the text "EU Server". Below the title are two input fields: "Email" and "Password". The "Email" field is a simple white rectangle with a light gray border. The "Password" field is a white rectangle with a light gray border and a small eye icon on the right side. To the right of the "Password" field is a blue link that says "Forgotten your password?". Below the input fields is a blue button with a white lock icon and the text "Log in". To the right of the "Log in" button is a checkbox with the text "Remember me". At the bottom of the white box is a link that says "New to Castor? Sign up here →".

1. To access the study, log into Castor EDC via <https://data.castoredc.com>. If your study is on the US or UK server, you should go to <http://us.castoredc.com> or <http://uk.castoredc.com>, respectively.
2. Enter your email address and password.
3. Click on 'Login' to access the 'My studies' overview.

### 3. Access a study for monitoring

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

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

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

### 4. The Records tab

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

Castor EDC Study - Not Live (v0.01)

Record   Exact match + New Actions Filters 5

List 2 Phase Step 3 4

| Record ID | Institute      | Randomiza... | Progress  | Created on | Updated on | Status     |
|-----------|----------------|--------------|---|------------|------------|------------|
| 110001    | Main Institute | -            | <div style="width: 20%; background-color: purple;"></div> |            |            | Excluded   |
| 110002    | Main Institute | Control      | <div style="width: 40%; background-color: blue;"></div>   |            |            | Follow-up  |
| 110003    | Main Institute | Treatment    | <div style="width: 60%; background-color: blue;"></div>   |            |            | Not Set    |
| 110004    | Main Institute | Treatment    | <div style="width: 80%; background-color: green;"></div>  |            |            | Discharged |
| 110005    | Main Institute | -            | <div style="width: 0%; background-color: gray;"></div>    |            |            | Not Set    |
| 110006    | Main Institute | -            | <div style="width: 0%; background-color: gray;"></div>    |            |            | Not Set    |

1. In the 'Records' tab, a search box is available, in which you can search for a particular record ID. More information on the search is provided in section 4.1.
2. It is possible to change the view mode to show the progress of the records by phases or steps.
3. Progress: This column will show you the status of completion for each record. The same color scheme as for the steps applies (see section 6). The purple bar with a pencil icon indicates that an exclusion validation has been triggered for this record. You can double click on any record to directly access it.
4. Queries: displays the number of queries created for a record.
5. By default, all records are shown, however you can use the Filter by record status boxes to show records that are complete, incomplete or not started.

## 4.1 - Search for records

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

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

The screenshot shows the 'Records' tab in the Castor EDC Study interface. A search box is open, and the field 'Gender' is selected from a dropdown menu. The search term 'female' is entered in the search box. The search results table shows two records:

| Institute      | Randomiza... | Progress | Created on | Updated on | Status   |
|----------------|--------------|----------|------------|------------|----------|
| Main Institute | -            |          |            |            | Excluded |
| Main Institute | Treatment    |          |            |            | Not Set  |

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

## 4.2 Accessing a single record

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

The screenshot shows the 'Castor EDC Study' interface. On the left is a navigation menu with options: Records, Reports, Surveys, Monitoring, Statistics, and Main Contact. The main area displays a table of records with columns: Record ID, Institute, Randomiza..., Progress, Created on, Updated on, and Status. The record with ID 110003 is highlighted with a red box. Below the table are buttons for '+ New', 'Actions', and 'Filters'.

| Record ID | Institute      | Randomiza... | Progress | Created on | Updated on | Status     |
|-----------|----------------|--------------|----------|------------|------------|------------|
| 110001    | Main Institute | -            |          |            |            | Excluded   |
| 110002    | Main Institute | Control      |          |            |            | Follow-up  |
| 110003    | Main Institute | Treatment    |          |            |            | Not Set    |
| 110004    | Main Institute | Treatment    |          |            |            | Discharged |
| 110005    | Main Institute | -            |          |            |            | Not Set    |
| 110006    | Main Institute | -            |          |            |            | Not Set    |

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:

The screenshot shows the 'Record ID: 110003' details page. On the left is a sidebar with a 'Record' tab highlighted in a red box. The main area shows the 'Screening' section with '2. Diagnosis and medical history'. It includes several sub-sections with radio button options and checkboxes. At the bottom, there is a table for recording current medications and 'Previous' and 'Next' buttons.

| Created on | Name | Start date | Stop date | Dose | Units |
|------------|------|------------|-----------|------|-------|
|            |      |            |           |      |       |

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.

- Monitoring tab - contains an overview of relevant monitoring information, such as queries, verifications, and validations (see 'The Monitoring tab' section below).
- 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 displays the 'Study' tab for a specific record (ID: 110001). On the left, a sidebar provides navigation options, with 'Back to records' (5) and 'Record' (containing 'Study', 'Reports', 'Surveys', 'Monitoring', 'Randomization') highlighted. The main area shows the record's status as 'Not Set' (8) and a progress bar at 20%. Below this, a list of study forms is shown, with 'Screening' (1) and 'Demographics' (2) selected. The 'Demographics' form is expanded, showing fields for 'Year of birth' (1993, 3), 'Gender' (Female), 'Height' (171 cm), 'Weight' (65 kg), 'BMI' (22.23), and 'Country of origin' (Brazil). A vertical cogwheel menu (4) is visible on the right side of the form. At the bottom, 'Previous' (7) and 'Next' (6) navigation buttons are present.

- Record ID, record status and progress of completion.
- An overview of the study forms (phases and steps of the study). Phases consist of steps and each step contains a set of questions. You can click on the step of interest in this panel to review the entered data.
- Data is added via questions, known as 'fields' in Castor.
- The cogwheel menu beside each field can be clicked to view available options for the field. The options can include comments, audit trail and queries.
- To exit the record and return to the record list, click on the 'Back to record list' button.
- Once you have reviewed the form, you can navigate to the next step by clicking on 'Next'.
- You can return to the previous step by clicking on 'Previous'.

## 4.2.2 The Reports tab

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

Record ID: 110003 (v0.01) Not Live

Record Status: Not Set

Record: 110003  
Not Set  
Progress: 32%

All reports

1 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

3 Add a report

| Status | Report            | Name                  | Type              | Created on | Created by | Assigned to |
|--------|-------------------|-----------------------|-------------------|------------|------------|-------------|
| ○      | Adverse event     | Adverse event - 1...  | Adverse Event     |            |            | Follow-up   |
| ●      | Adverse event     | Adverse event - 1...  | Adverse Event     |            |            | Follow-up   |
| ●      | Unscheduled visit | Unscheduled visit ... | Unscheduled phase |            |            | Outcome     |

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

Report

Previous Next

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

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

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

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

## 4.3 Important indicators in data entry

### 4.3.1 Data validations

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

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

### 4.3.2 Signed, locked, and verified steps

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

The screenshot displays the Castor EDC interface for a record with ID 110002. The record status is 'Discharged'. The progress bar shows 100% completion. The left sidebar lists navigation options: Record, Study, Reports, Surveys, Monitoring, and Randomization. The main content area shows the 'Screening' section, specifically '1. Demographics'. A banner at the top indicates that this step was signed on, with an 'Unsign' button. Below this, another banner shows that the step was verified on for Source Data Verification (SDV), with a 'Remove' button. A third banner indicates that the record was locked on. The form fields include: 1.1 Year of birth (1990), 1.2 Gender (Female), 1.3 Height (180 cm), 1.4 Weight (80 kg), 1.5 BMI (24.69), and 1.6 Country of origin (Netherlands). A note states: 'This field value cannot be changed as it was used for randomization of this record.' The bottom of the form has 'Previous' and 'Next' buttons.

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:

Record ID: 110004 (v.0.01) Not Live

Record Status: Not Set

Record: 110004  
Not Set  
Progress: 20%

Screening  
1. Demographics

|    |                   |                |   |
|----|-------------------|----------------|---|
| 11 | Year of birth     | 1990 (yyyy)    |    |
| 12 | Gender            | Female<br>Male |    |
| 13 | Height            | 190 cm         |    |
| 14 | Weight            | 92 kg          |    |
| 15 | BMI               | 25.48          |    |
| 16 | Country of origin | Netherlands    |    |

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

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

## 5. Monitoring Queries

### 5.1 Adding queries

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

Record ID: 110004 (v.0.01) Not Live

Record Status: Not Set

Record: 110004  
Not Set  
Progress: 16%

Screening  
1. Demographics

|    |                   |                |   |
|----|-------------------|----------------|---|
| 11 | Year of birth     | 1990 (yyyy)    |    |
| 12 | Gender            | Female<br>Male |    |
| 13 | Height            | 190 cm         |    |
| 14 | Weight            | 92 kg          |    |
| 15 | BMI               | 25.48          |    |
| 16 | Country of origin |                |    |

- Clear
- User missing
- Comments
- History
- Queries**
- SDV field

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

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

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

## 5.2 Query resolution

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

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

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

|              |                                    |      |
|--------------|------------------------------------|------|
| ● 5.3 Weight | <input type="text" value="81"/> Kg | ⚙️ ? |
| ● 5.4 Length | <input type="text" value="1.82"/>  | ⚙️ ✓ |
| ● 5.5 BMI    | 24.45                              | ⚙️ ✓ |

## 5.3. Query overview

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

| Record ID | Institute      | Randomiza... | Progress  | Created on | Updated on | Status     | Queries |
|-----------|----------------|--------------|---|------------|------------|------------|---------|
| 110001    | Main Institute | -            | <div style="width: 50%; background-color: purple;"></div> |            |            | Excluded   | ?       |
| 110002    | Main Institute | Control      | <div style="width: 50%; background-color: blue;"></div>   |            |            | Follow-up  | ? 1     |
| 110003    | Main Institute | Treatment    | <div style="width: 50%; background-color: blue;"></div>   |            |            | Not Set    | ? 2     |
| 110004    | Main Institute | Treatment    | <div style="width: 50%; background-color: green;"></div>  |            |            | Discharged | ?       |
| 110005    | Main Institute | -            | <div style="width: 0%; background-color: gray;"></div>    |            |            | Not Set    |         |
| 110006    | Main Institute | -            | <div style="width: 0%; background-color: gray;"></div>    |            |            | Not Set    |         |

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

| Record ID | Institute      | Screening             | First Study Visit    | Follow-up            | Outcome              |
|-----------|----------------|-----------------------|----------------------|----------------------|----------------------|
| 110001    | Main Institute | Progress bar (purple) | Progress bar (blue)  | Progress bar (green) | Progress bar (green) |
| 110002    | Main Institute | Progress bar (green)  | Progress bar (blue)  | Progress bar (green) | Progress bar (green) |
| 110003    | Main Institute | Progress bar (green)  | Progress bar (blue)  | Progress bar (green) | Progress bar (green) |
| 110004    | Main Institute | Progress bar (green)  | Progress bar (green) | Progress bar (green) | Progress bar (green) |
| 110005    | Main Institute | Progress bar (green)  | Progress bar (green) | Progress bar (green) | Progress bar (green) |
| 110006    | Main Institute | Progress bar (green)  | Progress bar (green) | Progress bar (green) | Progress bar (green) |

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 | Location                               | Last Remark                 | Status |
|---------------|------------|--|-----------------------------|--------|
|               |            | Phase: First Study Visit Step: Phys... | Please add the missing date | New    |

1. The record's monitoring overview opens on the query tab.
2. Queries can be filtered by the query status.
3. Clicking on the eye icon, will take you to the field where the query was placed.

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

## 5.4 Automating queries

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

## 5.5 Query notifications

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

## 6. Data validations

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

There are three types of validations that can be active:

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

The screenshot shows a patient record for ID 110005. The record status is 'Not Set' and the progress is 54%. The form is in the 'Screening' section, specifically '3. Study inclusion'. The following questions are visible:

- 3.1 Informed consent signed? (Yes selected)
- 3.1.1 Date of informed consent (2022-03-17)
- 3.2 Has the patient previously participated in a clinical trial? (No selected)
- 3.3 Is the patient older than 18? (Yes selected)
- 3.4 Inclusion criteria met? (Yes selected)

A blue banner with an information icon and the text "Patient can be randomized. Go to the randomization tab and click randomize." is displayed below the questions. Below the banner, a smaller text says "Patient can be randomized (go to 'Randomization' section)".

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

The screenshot shows a patient record for ID 110004. The record status is 'Not Set' and the progress is 40%. The form is in the 'Screening' section, specifically '3. Study inclusion'. The following questions are visible:

- 3.1 Informed consent signed? (No selected)
- 3.2 Has the patient previously participated in a clinical trial? (No selected)
- 3.3 Is the patient older than 18? (No selected)
- 3.4 Inclusion criteria met? (Not all values for this calculation are available (yet).)

An orange banner with a warning icon and the text "Please check that the IC form is signed" is displayed above question 3.2.

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

The screenshot displays the 'Record ID: 110004' page in the Castor EDC system. The record status is 'Not Set' and the progress is at 46%. The 'Study inclusion' step is active, showing several validation questions:

- 3.1 Informed consent signed? (Yes/No)
- 3.1.1 Date of informed consent (2022-03-03)
- 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? (Not all values for this calculation are available (yet).)

Two exclusion validation messages are highlighted with red boxes: 'Previous trial participation is an exclusion criterion. You cannot proceed with data entry.' The 'Step: Study inclusion' is indicated in the top right of the validation area.

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:

The screenshot shows the 'Monitoring' tab in the Castor EDC system, specifically the 'Validations' subtab. The filters are set to 'Filter by type' (Exclusion, Warning, Message) and 'Data Entry Type' (Study, Report, Survey). The 'Filter by institute' dropdown is set to 'Castor, Test Institute'.

| Record | Institute | Date              | Field name       | Field value | Operator | Reference value | Type    | View |
|--------|-----------|-------------------|------------------|-------------|----------|-----------------|---------|------|
| 110001 | Castor    | 21 Aug 2019 15:00 | Age at inclusion | 17          | <        | 18              | Warning | 👁    |

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

## 7. Source Data Verification

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

Currently, verification per field is not supported.

### 7.1. Verify a study form

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

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

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

Record ID: 110005 ◦ Not Live (v.0.01) Record Status: Not Set

Record: 110005  
Not Set  
Progress: 54%

Screening  
1. Demographics

1.1 Year of birth 1990 (yyyy)

1.2 Gender  Female  Male

1.3 Height 170 cm  
67 kg  
23.18  
Netherlands

Completed  
Screening  
Demographics  
Diagnosis and medical history  
Study inclusion  
Not Started  
First Study Visit

Mark step as missing  
Lock this step  
Sign this step  
Custom verification  
SDV this step  
Print this step

SDV all required fields  
SDV all fields  
SDV step only (no fields)

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

Data verification

For what reason are you verifying this step:

Other

Does the verification need to be removed when data on this step is modified? ⓘ

Yes  
 No

OK Cancel

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

## 7.2 SDV indicators

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

Record ID: 110005 (Not Live (v0.01)) Record Status: Not Set

Record: 110005 Not Set Progress: 54%

Screening 1. Demographics

This step was verified on [redacted] by user [redacted] for Source Data Verification [Remove]

|                       |                         |     |
|-----------------------|-------------------------|-----|
| 1.1 Year of birth     | 1990 (yyyy)             | SDV |
| 1.2 Gender            | Female (radio selected) | SDV |
| 1.3 Height            | 170 cm                  | SDV |
| 1.4 Weight            | 67 kg                   | SDV |
| 1.5 BMI               | 23.18                   | SDV |
| 1.6 Country of origin | Netherlands             | SDV |

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

Record ID: 110005 (Not Live (v0.01)) Record Status: Not Set

Record: 110005 Not Set Progress: 54%

Screening 1. Demographics

This step was verified on [redacted] for Other [Remove]

This step was verified on [redacted] for Source Data Verification [Remove]

|                       |                         |         |
|-----------------------|-------------------------|---------|
| 1.1 Year of birth     | 1990 (yyyy)             | SDV VER |
| 1.2 Gender            | Female (radio selected) | SDV     |
| 1.3 Height            | 170 cm                  | SDV     |
| 1.4 Weight            | 67 kg                   | SDV     |
| 1.5 BMI               | 23.18                   | SDV     |
| 1.6 Country of origin | Netherlands             | SDV     |

## 7.3 Modifying data after SDV

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

Record ID: 110005 Not Live (v0.01) Record Status: Not Set

Record: 110005  
Not Set  
Progress: 54%

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 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:

Structure | Forms | Records | Reports | Surveys | **Monitoring** | Queries | Validations | Verifications

Familiarise Yourself With Castor Not Live (v0.31)

Queries

| Record ID | Institute      | Created on  | Created By    | Last updated by | Closed by     | Location         | First Remark | Last Remark | Status      | Query age | Time to resol | View |
|-----------|----------------|-------------|---------------|-----------------|---------------|------------------|--------------|-------------|-------------|-----------|---------------|------|
| 110001    | Main Institute | 20 Jul 2021 | Ernest Mbyeti | Ernest Mbyeti   |               | Phase Infor... > | test         | test        | New         | 0         | 0             |      |
| 110002    | Main Institute | 20 Jul 2021 | Ernest Mbyeti | Ernest Mbyeti   |               | Phase Infor... > | ok           | ok          | Resolved    | 0         | 0             |      |
| 110002    | Main Institute | 20 Jul 2021 | Ernest Mbyeti | Ernest Mbyeti   | Ernest Mbyeti | Phase Infor... > | test         | test        | Closed      | 0         | 0             |      |
| 110002    | Main Institute | 20 Jul 2021 | Ernest Mbyeti | Ernest Mbyeti   |               | Phase Infor... > | test         | test        | Unconfirmed | 0         | 0             |      |
| 110002    | Main Institute | 20 Jul 2021 | Ernest Mbyeti | Ernest Mbyeti   | Ernest Mbyeti | Phase Infor... > | test         | test        | Closed      | 0         | 0             |      |

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

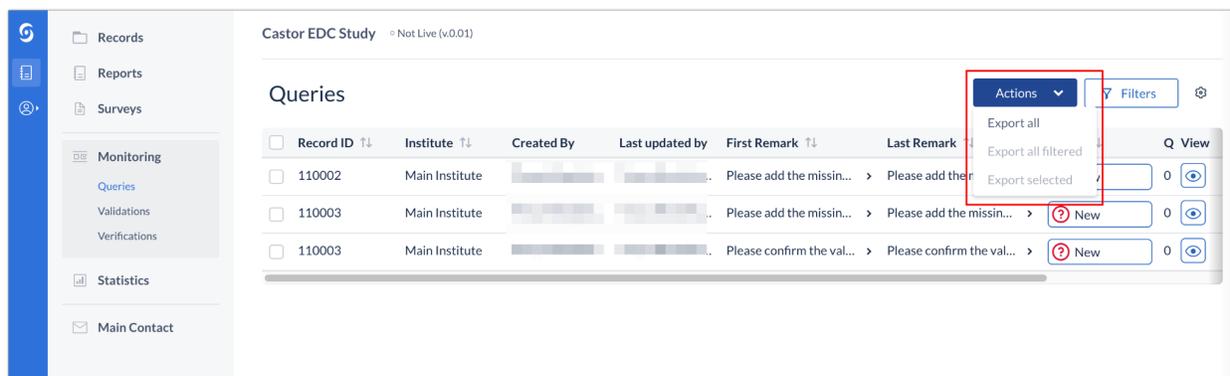
- **Query age:** how long ago was a query created
- **Time to resolve:** time that require to resolve a query
- **View:** click on the eye icon to view the query in a step where it was created

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

## 8.2. Exporting Queries

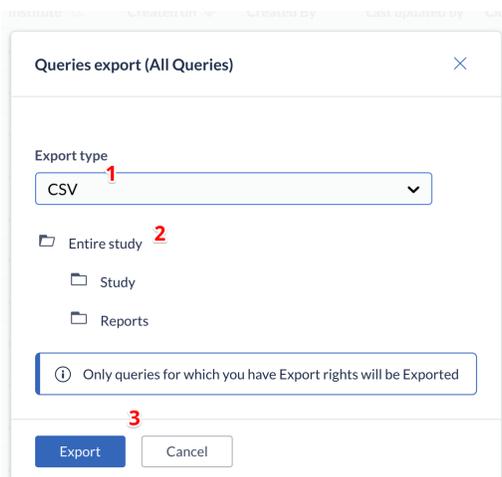
Users with Export rights can export the queries overview in bulk, either by exporting all available queries or only the ones that the user has selected or filtered. To export the queries from the Monitoring tab, Queries sub-tab, follow the steps below:

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



In Queries export dialog window, specify:

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



## 8.2 Validations subtab

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

| Record ... | Institute      | Date         | Field    | Field value | Opera... | Reference... | Type      | View |
|------------|----------------|--------------|----------|-------------|----------|--------------|-----------|------|
| 110027     | Main Institute | 15 Mar 20... | INCL_met | No          | ==       | No           | Exclusion |      |
| 110003     | Main Institute | 15 Mar 20... | INCL_met | No          | ==       | No           | Exclusion |      |

- Using the “Filters” button, you can filter the validations by validation type, data entry type, and institute.
- Each row contains the record ID, institute name, date, field name and field value associated with the validation.
- The operator represents how the field and reference values are compared, depending on the setup of the validation message. The reference value represents the value that is used to compare the value that was entered in a field, as defined during the validation setup. To open the record and jump to the step with the validation click on the eye icon in the column 'View'.

## 8.3 Verifications subtab

This subtab displays all dropped verifications in the study:

Castor EDC Study - Not Live (v0.01)

Dropped verifications Filters

| Record... | Institute      | Create... | Drop... | Phase     | Step                | Field        | Dropped by | View |
|-----------|----------------|-----------|---------|-----------|---------------------|--------------|------------|------|
| 110002    | Main Institute |           |         | Screening | Demographics        | dem_weight   |            |      |
| 110002    | Main Institute |           |         | Screening | Demographics        | dem_weight   |            |      |
| 110002    | Main Institute |           |         | Screening | Diagnosis and me... | his_diabetes |            |      |
| 110002    | Main Institute |           |         | Screening | Diagnosis and me... | his_diabetes |            |      |

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

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

## 10. Using the Audit Trail

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

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

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

Record: 110003  
Not Set  
Progress: 54%

Screening  
1. Demographics

1.1 Year of birth: 1988 (yyyy)

1.2 Gender: Female (Selected), Male  
This field value cannot be changed as it was used for randomization of this record.

1.3 Height: 167 cm

1.4 Weight: 65 kg

1.5 BMI: 23.31

1.6 Country of origin: Germany

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

## 11. Study statistics

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

Castor EDC Study Not Live (v.9.01)

Country filter:  Institute filter:

### Study Statistics overview

|                               |       |
|-------------------------------|-------|
| Number of inclusions          | 5     |
| Number of completed records   | 0     |
| Average completion percentage | 57.8% |

| Institute | Number of inclusions |
|-----------|----------------------|
| Castor    | 5                    |

|                            |   |
|----------------------------|---|
| Number of randomized cases | 1 |
|----------------------------|---|

| Randomization Group        | Number of inclusions |
|----------------------------|----------------------|
| Records not randomized yet | 4                    |
| Control                    | 1                    |

Randomizations per institute

| Institute | Records not randomized yet | Control |
|-----------|----------------------------|---------|
|           |                            |         |

### Cumulative number of inclusions over time

| Date    | Cumulative number of inclusions |
|---------|---------------------------------|
| 2019-05 | 1                               |
| 2019-08 | 5                               |

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

## 11. Further information

If you would like to watch our webinar for study monitoring, you can do so [here](#).

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