

Data Entry in Castor

1. Register an account

You will receive an invitation by email for the study for which you need to do data entry. 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 data¹.

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>

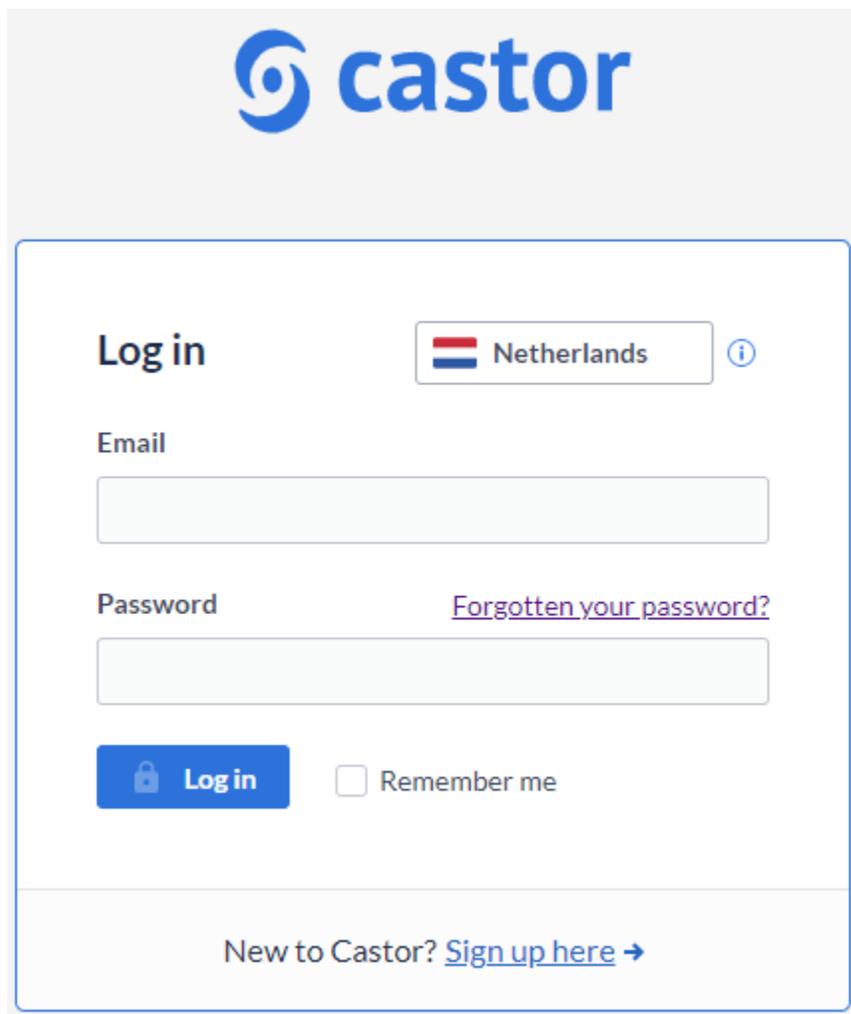
To register your Castor account:

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 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



Log in Netherlands ⓘ

Email

Password [Forgotten your password?](#)

Remember me

New to Castor? [Sign up here](#) →

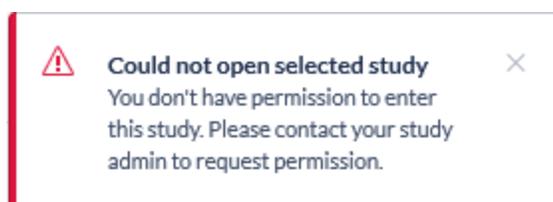
1. To access the study, log into Castor EDC via <https://data.castoredc.com>. If your study is on the US, AU or UK server, you can also directly go to <https://au.castoredc.com/register>, <http://us.castoredc.com> or <http://uk.castoredc.com>, respectively.
2. Choose the server that is used for your study in order to be able to access the study.
3. Enter your email address and password.
4. Click on 'Login'.

3. Open a study

Once you have logged into Castor EDC, you will see the Study overview where all of your 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 and start data entry.



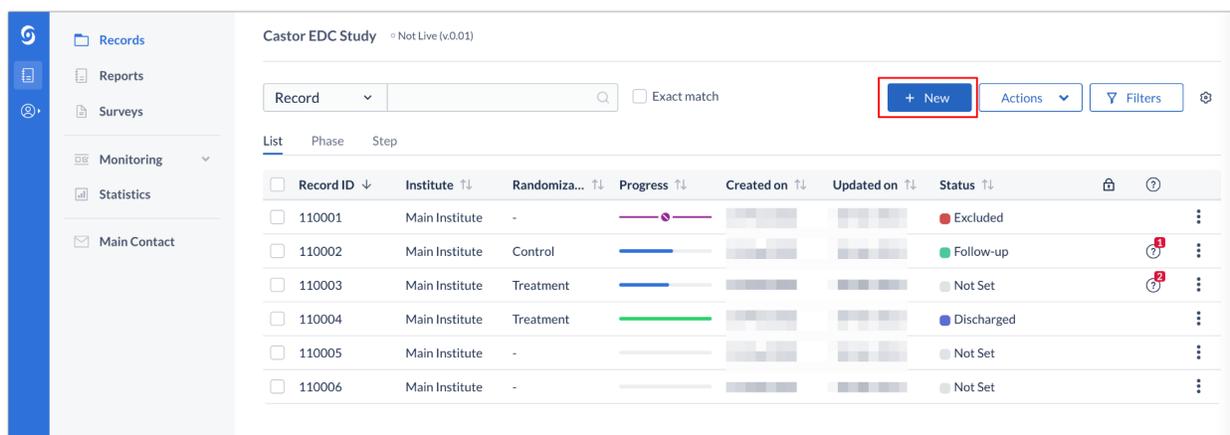
Trying to open a study that is not live will show the following warning:



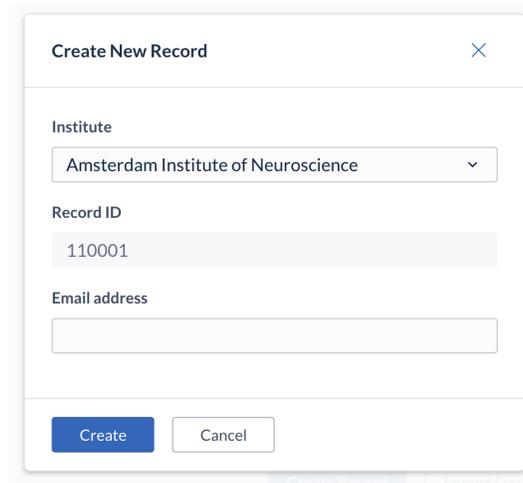
If the study is still in maintenance mode (the button is blank, and the status says 'Not Live') you will only be able to open the study if you have management rights.

4. Open a record for data entry

Once you enter the study, you will see a list of all records available for your access level. To add a new patient to the database, you will need to create a new record. Creating new records must be done from the Records tab by clicking on the "+ New" button.



The 'Create New Record' dialogue box will open and you will select the Institute you wish to add the record to. The record ID will be auto generated.. Add record's email address in the 'Email address' field if applicable.. The record will be created and opened so you can begin data entry.



Create New Record [X]

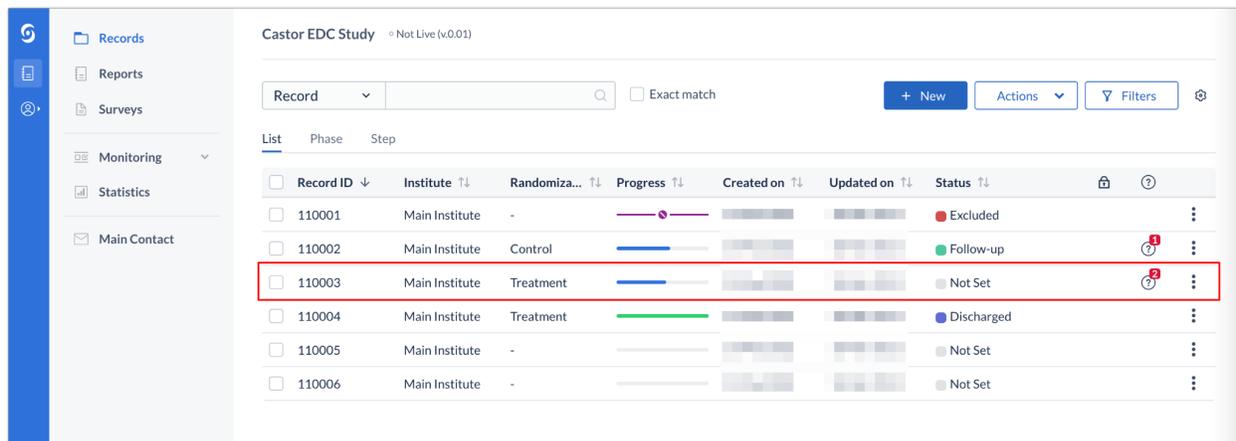
Institute
Amsterdam Institute of Neuroscience [v]

Record ID
110001

Email address
[]

Create **Cancel**

To open a previously created record double click the row the record is on:



Castor EDC Study - Not Live (v0.01)

Record [v] [] Exact match [+ New] [Actions v] [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	[]

5. Doing data entry

When you open a record, you will be taken to the main data entry view:

The screenshot displays the main data entry view for Record ID: 110001. The interface includes a sidebar on the left with navigation options (Record, Study, Reports, Surveys, Monitoring, Randomization). The main area shows the record status (Not Set) and a progress bar (20%). The 'Screening 1. Demographics' form contains the following fields:

Field ID	Field Name	Value	Unit
1.1	Year of birth	1993	(yyyy)
1.2	Gender	Female	
1.3	Height	171	cm
1.4	Weight	65	kg
1.5	BMI	22.23	
1.6	Country of origin	Brazil	

At the bottom, there are 'Previous' and 'Next' buttons for navigation.

It consists of the following elements:

1. Record ID, Record status and progress of completion.
2. An overview of the study forms (phases and steps of the study). Phases consist of steps and each step contains a set of questions. You can click on the step of interest in this panel to start entering the required data. Once you answer 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. To exit the record and return to the record list, click on the 'Back to records' button.
6. Once you have completed the first form, you can navigate to the next step by clicking on 'Next'.
7. You can return to the previous step by clicking on 'Previous'.

5.1 - Elements in each question

Depending on the type of question, you will need to select one or more of the provided options, enter a number or date, upload a file etc.

Some fields will appear only under certain conditions. In the example below, question 3.1.1 is shown only because question 3.1 is answered with 'Yes'.

5.1.1 - Status icons

Shown to the left of each question is the status icon, which indicates whether the question has been answered (green) or not answered (orange). Where there is a problem with the provided answer, the icon will turn red and a red warning message will appear to provide more information about the problem.

- **Green** The input is valid and the data is saved.
- **Orange** Data is required and no input has been entered yet.
- **Red** The input is invalid or does not comply with the inclusion criteria for the study. This is accompanied by a red warning message.
- No icon** Data entry is not required and no values have been saved.

5.1.2 - Additional information

If additional information has been provided with a question, the  icon will be displayed beside the input. Clicking on the icon will allow you to view the information:

- 3.1 Subjects must have a mild to moderate clinical diagnosis of acne vulgaris

yes
 no



Grade 2 or 3 as per the Investigator's Global Assessment (IGA)

5.1.3 - Additional options

To the right of each question there is a cogwheel with additional options:

Record ID: 110002 (Not Live (v.0.01)) Record Status: Enrolled

Record: 110002
Enrolled
Progress: 54%

Screening
3. Study inclusion

3.1 Informed consent signed? Yes No

3.1.1 Date of informed consent 2022-03-17 (YYYY-MM-DD)

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? Yes

① Patient can be randomized. Go to the randomization tab and click randomize.
Patient can be randomized (go to 'Randomization' section)

3.4.2 Randomization allocation

Clear
User missing
Comments
History
Queries
SDV field

To clear the value already entered for a field, press "Clear".

If data is not available for a question, tick the "User missing" box. A window will open to ask the user to provide the reason why the data is missing:

Choose reason for missing value for field Patient is between the ages of 12 and 40 .

Choose reason:

Measurement failed (-95)
 Not applicable (-96)
 Not asked (-97)
 Asked but unknown (-98)
 Not done (-99)

Comment:

Save **Cancel**

Select the appropriate option and if necessary, add a comment. Click 'Save' to store the option and return to the question list. The field marked as 'User Missing' will be grayed out in the list and marked as 'Completed'.

If you initially marked a field as missing but receive information for this field at a later date, you can click on the cogwheel again (even if the question is grayed out) and should unselect the option “User missing”.

If you want to add a comment to a field, press “Comments”. Add your text and press “Add comment”:

5.1.4 - Randomize a record

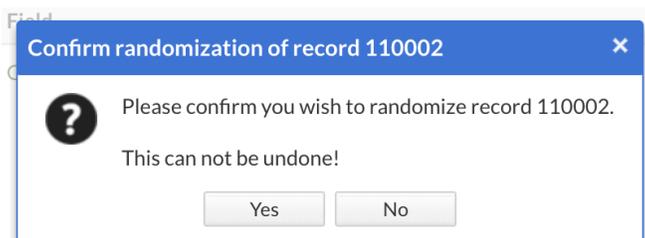
If you need to perform randomization in the study, you can follow these steps to randomize a record.

Field	Value	Set
Gender	Female	⊙

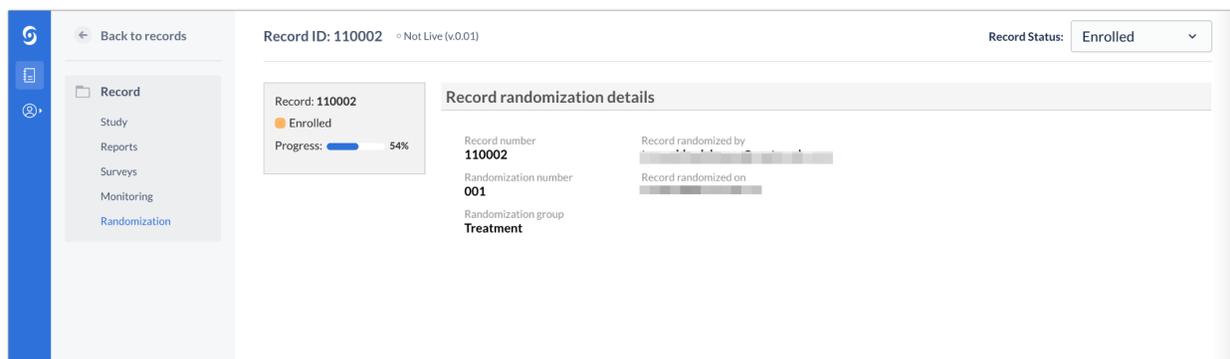
1. From the record overview, select the ‘Randomization’ sub-tab.
2. Click the “Randomize’ button to randomize the record.
3. Fields required for randomization are summarized in the lower right of the tab.

4. If the required fields for randomization have not been completed, click the eye icon () to be taken to the required field in the CRF.
5. Click on the 'Study' tab to get back to the study forms

A window will appear and ask you to confirm the randomization, advising that randomization cannot be undone once confirmed.



The randomization tab will now display the randomization group and the randomization number and other relevant information. This tab is only visible for users with randomization rights.



5.1.5 - Signing and locking a step

You can electronically sign and/or lock individual phases and steps in Castor EDC. Users will need the appropriate rights in order to do so.

The screenshot shows the Castor EDC interface for Record ID: 110002 (Not Live v.0.01). The record status is 'Enrolled'. The progress bar indicates 54% completion. The 'Screening' phase is active, and the '1. Demographics' step is selected. A dropdown menu is open over the '1.2 Gender' step, with 'Sign this step' highlighted in red. Other options in the menu include 'Mark step as missing', 'Lock this step', 'Custom verification', 'Remove all SDV', and 'Print this step'. The demographic fields are: Year of birth (1990), Gender (Female), Height (180 cm), Weight (80 kg), and Country of origin (Netherlands). A verification message at the top states: 'This step was verified on 17/03/2022 at 14:14 by tonya test for Source Data Verification'.

1. Hover over the right side of a step or phase with your mouse. Click on the three dots that appear.
2. Click on "Sign this phase" for phases or "Sign this step" for steps.

You will be prompted to enter your email and password to confirm your identity. Click "Sign" to confirm and to sign the phase or step. If you wish to also lock this phase, you will tick the "Also lock this phase" checkbox. You will receive a confirmation that the audit trail has been updated.

Please confirm your username and password to Sign

Please enter your email and password to sign this phase. All steps within the phase will also be signed.

Email:

Password:

Lock phase and child steps:

This event will be recorded in the audit trail

The phase or step will be updated with icons to reflect that it has been signed and/or locked:

Record: 110002
 Discharged
 Progress: 100%

Completed ^{SDV} ✓	
Screening	
Completed ^{SDV} ✓	
Demographics	
Completed ^{SDV} ✓	
Diagnosis and medical history	
Completed ^{SDV} ✓	
Study inclusion	

A warning will also be displayed at the top of the data entry screen, warning the user that the current step has been signed and/or locked:

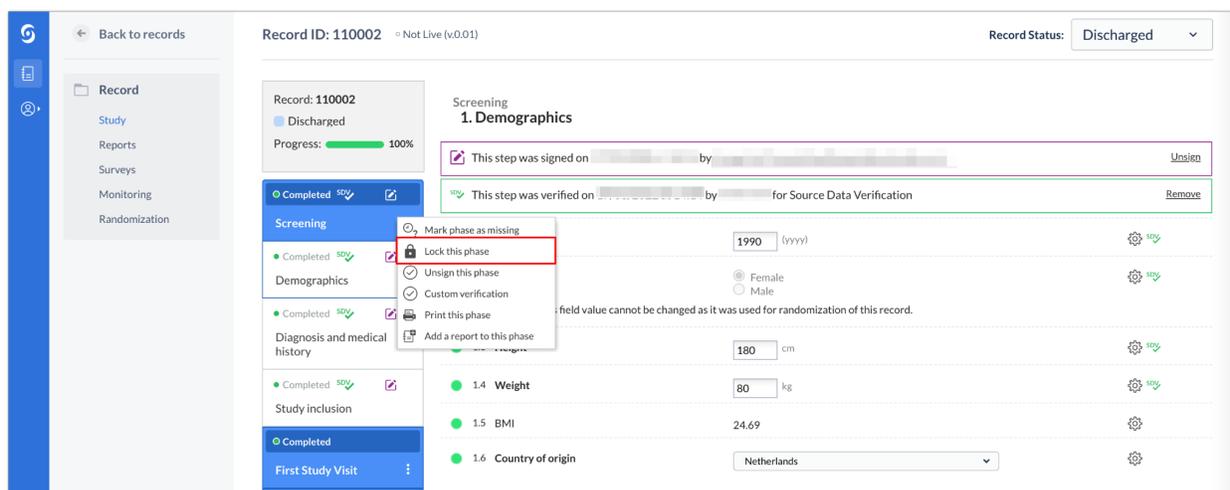
Informed Consent and Inclusion
 1. Medication

This step was signed on 04/08/2021 at 11:38 by [User Name]	Unsign
This step was locked on 04/08/2021 at 11:38 by [User Name]	Unlock

You can also unlock and unsign the step by clicking on the “Unlock” and “Unsign” buttons.

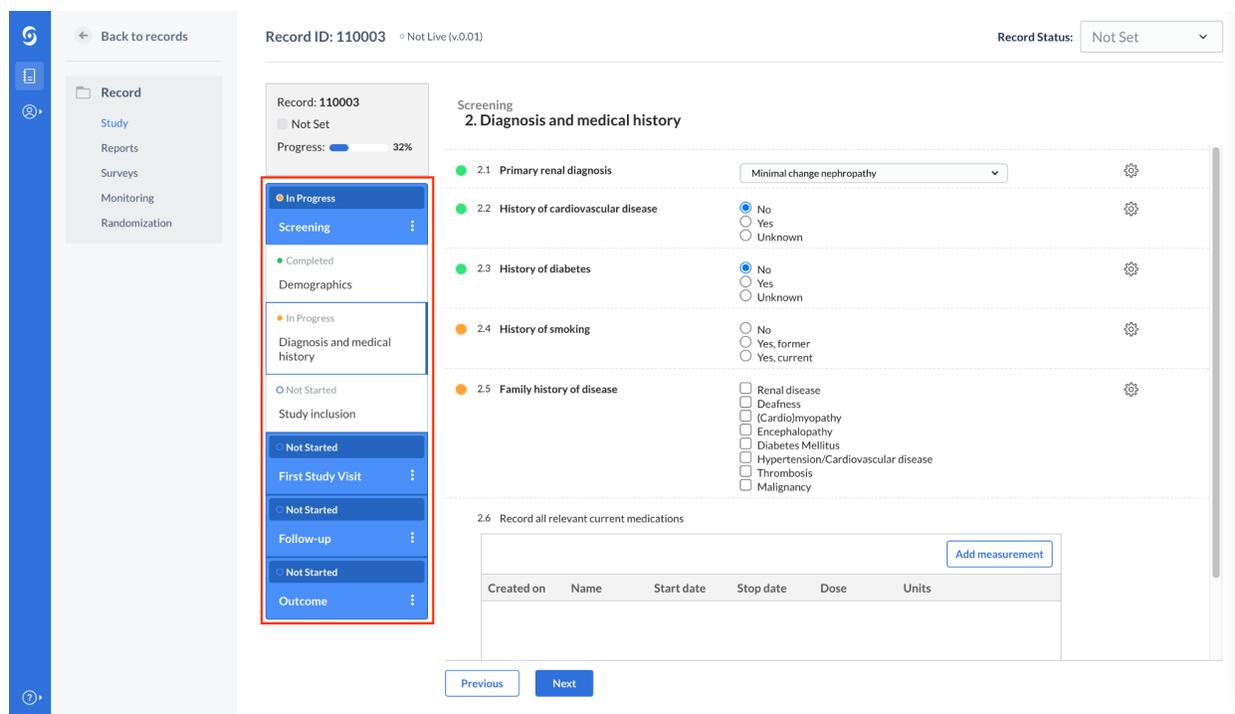
If you have lock rights, you can also choose to lock a phase or a step to prevent further data entry directly from the record navigation.

- Click on the three dots menu next to a step or a phase.
- Click on "(Un)Lock this phase" for phases or "(Un)Lock this step" for steps.



6. Record progress

In the left panel in data entry, you can view the progress of the phases and steps which will update as you fill in the data.



Phases and steps can have three different completion stages:

- Gray Not started
- Orange In Progress
- Green Completed

The overall record progress bar shown in the phase tab (blue) will also update automatically. Once all required fields have been completed, the icon will turn green.

7. The Records tab

In the Records tab, a list is displayed showing all records you have created (see Section 6). You may also see records that have been created by other users at your institute.

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 7.2.
2. It is possible to change the view mode to show the progress of the records by phases or steps (see section 7.1).
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.

Castor EDC Study - Not Live (v0.01)

Record Exact match + New Actions Filters

List Phase Step

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

7.1 - Phase/Step View

By default, the 'Records' tab displays all records in the "List" view. You can change the view mode to either Phase view or Step view.

This will show you the status of completion of each phase or step for each record by clicking on "Phase" or "Step". The same color scheme as for the steps applies (see section 6). You can double click on any phase or step to directly access it.

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

7.2 - Search for data

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.

Institute	Randomiza...	Progress	Created on	Updated on	Status
Main Institute	-	Progress bar (red)			Excluded
Main Institute	Treatment	Progress bar (blue)			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.

8. Creating reports

In the data entry view, you can view any reports attached to the record or create a new report. Opening the record and navigating to the Reports tab will display the reports overview:

Record ID: 110002 Not Live (v.0.01) Record Status: Follow-up

Record: 110002
Follow-up
Progress: 58%

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			First Study Visit
●	Medication	Medication - 18-0...	Repeated measure			Screening
●	Medication	Medication - 18-0...	Repeated measure			Screening
○	Medication	Medication - 18-0...	Repeated measure			Screening

2

Page 1 of 1 Show 25 Reports 1 - 4 of 4

Report

1. You can filter by report type, report type, report name, or by the phase to which a report is linked.
2. The list of reports linked to the selected record. A status indicator allows you to see the completion status of the report.
3. Click the 'Add a report' button to create a new report.

After clicking 'Add a report', the following dialog window will appear:

Add a report to record 110002

Report: Adverse event

Custom name: Adverse event - 1

Attach to: Phase 3. Follow-up

Create Create and add another Cancel

1. Select from the dropdown menu which report type you wish to create.
2. Depending on the settings, the option to enter a custom name for the report might be enabled or disabled. The report custom name is how the report will be displayed in the study and exports.

- You have the option to attach the report to a phase or to another report. Attaching the report to a phase will display the report in the Phase/Step navigator on the left sidebar in the data entry view.

Note: the report can also be attached to unscheduled phases.

Click the 'Create' button to add the new report and return to data entry. Alternatively, you can click 'Create and add another' to save the new report and immediately create another new report.

9. Repeated Measures

In data entry, the repeated measure field looks like this:

The screenshot displays the data entry interface for Record ID: 110002 (Not Live v.0.01) with a status of Follow-up. The interface is divided into a left sidebar, a top navigation bar, and a main content area. The sidebar shows a list of study components: Record, Study, Reports, Surveys, Monitoring, and Randomization. The main content area is titled 'First Study Visit 4. Physical exam' and includes a progress bar at 58%. Below the progress bar, there are several data entry fields for physical exam parameters: 4.1 Date of visit, 4.2 Weight (68 kg), 4.3 Height (180 cm), 4.4 BMI (68 kg/m²), and 4.5 Heart rate (60 Beats per minute). A red box highlights a section titled '4.6 Blood pressure measurements - measure in all positions'. This section contains an 'Add measurement' button and a table with the following data:

Created on	Measurement p...	Systolic pressure	Diastolic press...	Date and time o...
2022-03-18	Lying down	120	80	12-10-2021 00:...

At the bottom of the interface, there are 'Previous' and 'Next' navigation buttons.

By selecting 'Add measurement', measurements are easily added to the form and will be shown in the form of a grid, representing each measurement as a new row and each field that is part of the repeated measure as a separate column.

Each measurement will be saved as a new report and will appear in the 'Reports' tab and will be attached to the phase (or report) where the repeated measure field is located.

9. Responding to queries

Users with only data-entry rights can see all queries for a record on the record's 'Monitoring' tab.

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.

Queries are shown as a circle and the status is indicated by the sign within it as well as the color.

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.

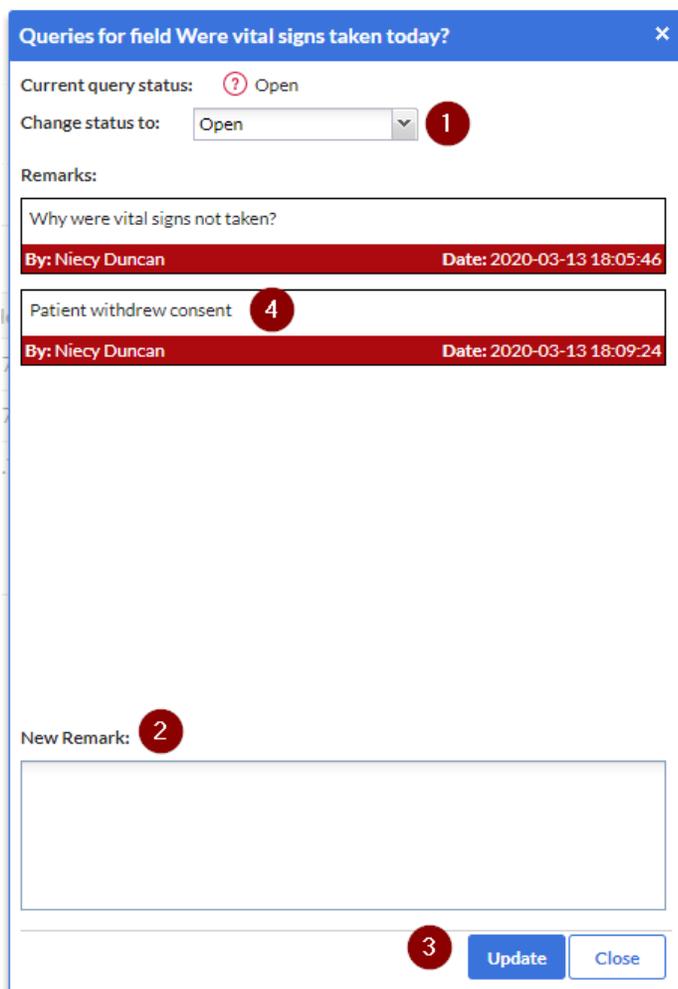


Once you are in the record, you will see the status icon next to the queried field.

The screenshot displays the Castor EDC interface for Record ID: 110003. The record status is 'Not Set'. The interface shows a sidebar with navigation options: Record, Study, Reports, Surveys, Monitoring, and Randomization. The main content area is titled 'Screening 2. Diagnosis and medical history' and contains a list of screening items:

Item ID	Item Name	Value	Status Icon
2.1	Primary renal diagnosis	Minimal change nephropathy	Settings icon
2.2	History of cardiovascular disease	No (selected)	Settings icon
2.3	History of diabetes	No (selected)	Settings icon
2.4	History of smoking	No	Settings icon with a red question mark

To respond to a query, click on the query icon



Queries for field **Were vital signs taken today?** ×

Current query status: ? Open

Change status to: 1

Remarks:

Why were vital signs not taken?

By: Niecy Duncan Date: 2020-03-13 18:05:46

Patient withdrew consent 4

By: Niecy Duncan Date: 2020-03-13 18:09:24

New Remark: 2

3

1. You can change the status of a query by choosing from the list in the dropdown box.
2. The New Remark field allows you to enter your comments on the query.
3. Once you select 'Update' the status and comment will be saved.
4. All saved remarks are added to the list.

10. Further information

If you would like to watch a video tutorial for performing data entry, you can do so [here](#). We also invite you to take our online Data Entry course at [Castor Academy](#).

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