

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:

Sign Up

Netherlands

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](#)

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

Create Account

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

Build forms in minutes

Secure and compliant

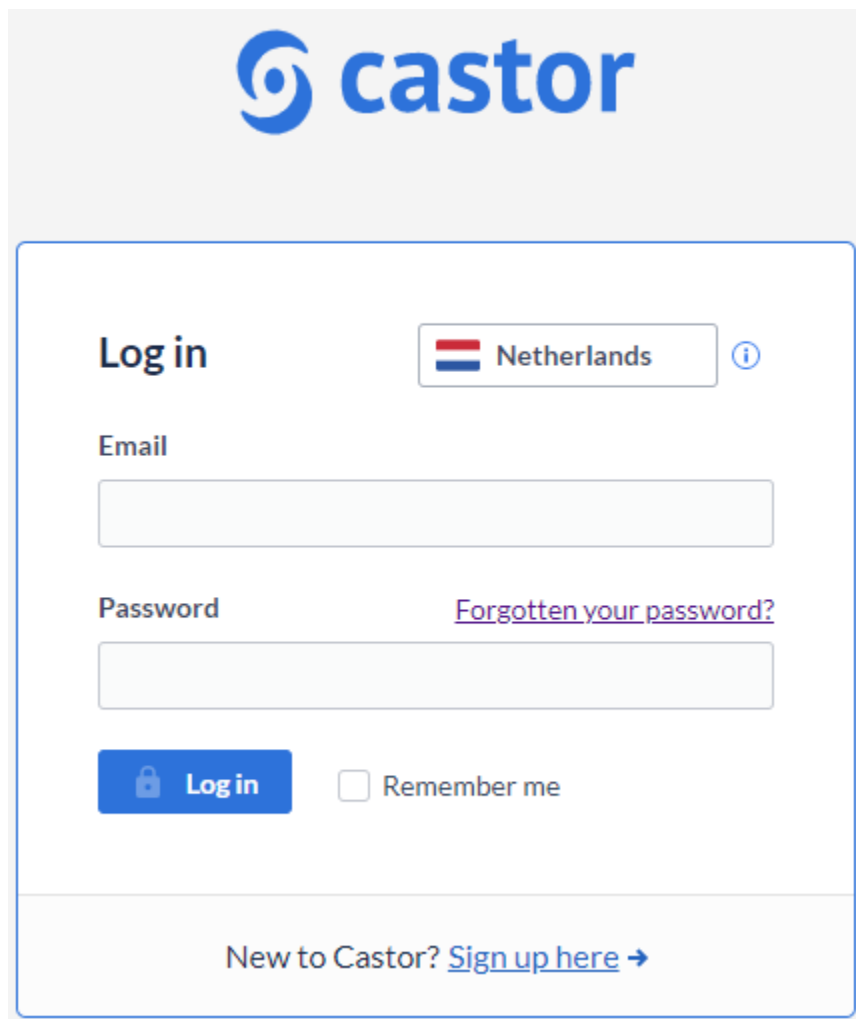
No credit card required

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

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

The image shows the Castor EDC login interface. At the top is the Castor logo, which consists of a blue circular icon with a stylized 'C' followed by the word 'castor' in a bold, blue, sans-serif font. Below the logo is a white rectangular box with a blue border. Inside this box, the word 'Log in' is displayed in a bold, black, sans-serif font. To the right of 'Log in' is a dropdown menu showing the flag of the Netherlands and the text 'Netherlands', with a small blue information icon to its right. Below the 'Log in' text are two input fields: one for 'Email' and one for 'Password'. To the right of the 'Password' field is a 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 this 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 →'.

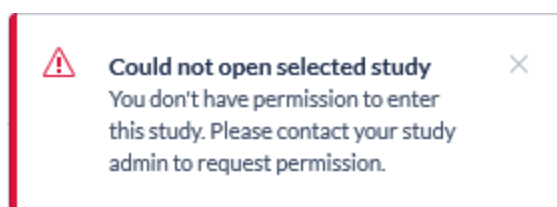
1. To access the study, log into Castor EDC via <https://data.castoredc.com>. If your study is on the US, AU or UK server, you can also directly go to <https://au.castoredc.com/register>, <http://us.castoredc.com> or <http://uk.castoredc.com>, respectively.
2. Choose the server that is used for your 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.



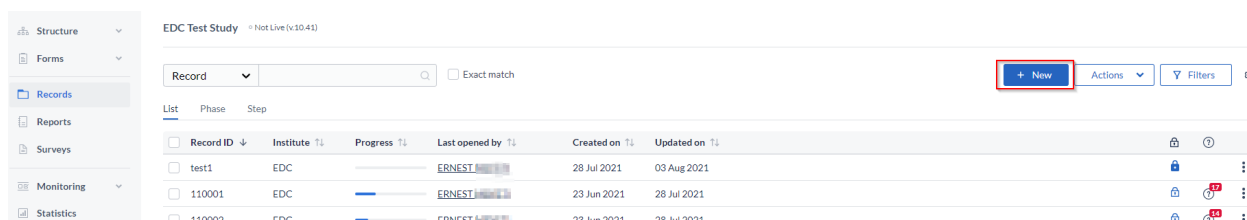
Trying to open a study that is not live will show the following warning:



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.



Then, select your institute and click 'Create'. The record will be created and opened so you can begin data entry.

Create New Record

×

Institute

EDC

Record ID

110008

Create

Cancel

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

Structure

Forms

Records

Reports

Surveys

Monitoring

Statistics

Audit Trail

Users

Settings

EDC Test Study

Not Live (v10.41)

Record

Exact match

+ New

Actions

Filters

List	Phase	Step							
Record ID	Institute	Progress	Last opened by	Created on	Updated on				
test1	EDC		ERNEST.MBYETI	28 Jul 2021	03 Aug 2021				
110001	EDC		ERNEST.MBYETI	23 Jun 2021	28 Jul 2021				
110002	EDC		ERNEST.MBYETI	23 Jun 2021	28 Jul 2021				
110004	EDC		ERNEST.MBYETI	19 Jul 2021	27 Jul 2021				
110005	EDC		ERNEST.MBYETI	28 Jul 2021	28 Jul 2021				
110006	EDC		ERNEST.MBYETI	28 Jul 2021	28 Jul 2021				
110007	EDC		ERNEST.MBYETI	28 Jul 2021	28 Jul 2021				
test1	EDC		ERNEST.MBYETI	28 Jul 2021	28 Jul 2021				
test2	EDC		ERNEST.MBYETI	28 Jul 2021	28 Jul 2021				
110007-1	EDC		ERNEST.MBYETI	28 Jul 2021	28 Jul 2021				
test1-1	EDC		ERNEST.MBYETI	28 Jul 2021	28 Jul 2021				

5. Doing data entry

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

Record ID: 110001 Not Live (v.7.91)

Record: 110001 **1**
Progress: 53%

Baseline

1. Inclusion

1.1 Does patient have example disease? ☒ Yes ☐ No **3**

1.2 Is the patient older than 65? ☒ Yes ☐ No

1.3 Has patient signed informed consent? ☒ Yes ☐ No

1.4 Can patient participate in the study? Yes

4

7 Previous Next **6**

It consists of the following elements:

1. Record ID 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 1.5.1 is shown only because question 1.5 is answered with 'Yes'.

Record ID: 120001 Not Live (v1.41)

Record: 120001 Progress: 50%

Baseline 1. Demographics

1.1	Age at Informed Consent	37	Green
1.2	Gender	male	Green
1.3	Race	White or Caucasian	Green
1.4	Date of Diagnosis	03-05-2020	Green
1.5	Does the patient smoke?	yes	Green
1.5.1	How many cigarettes per day does the patient smoke?		Orange
1.6	Does the patient drink alcohol?		Orange


This field is required

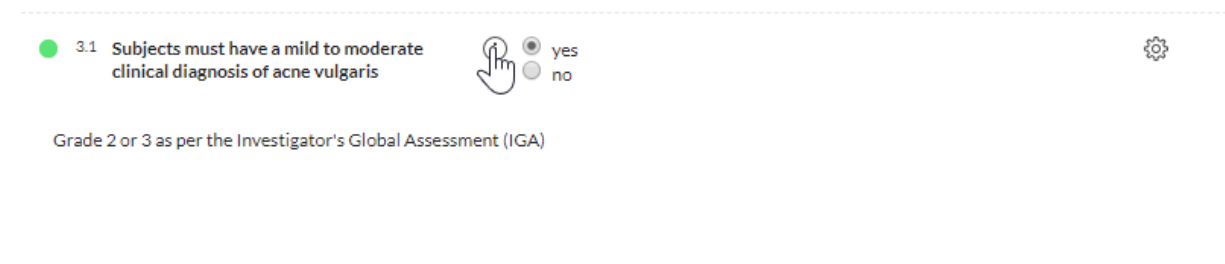
5.1.1 - Status icons

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:



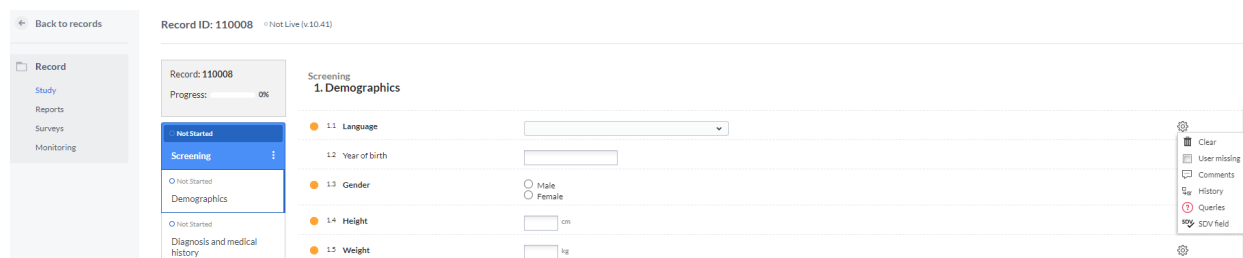
3.1 Subjects must have a mild to moderate clinical diagnosis of acne vulgaris

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: 110008 Not Live (x10.41)

Record: 110008 Progress: 0%

Screening 1. Demographics

1.1 Language

1.2 Year of birth

1.3 Gender

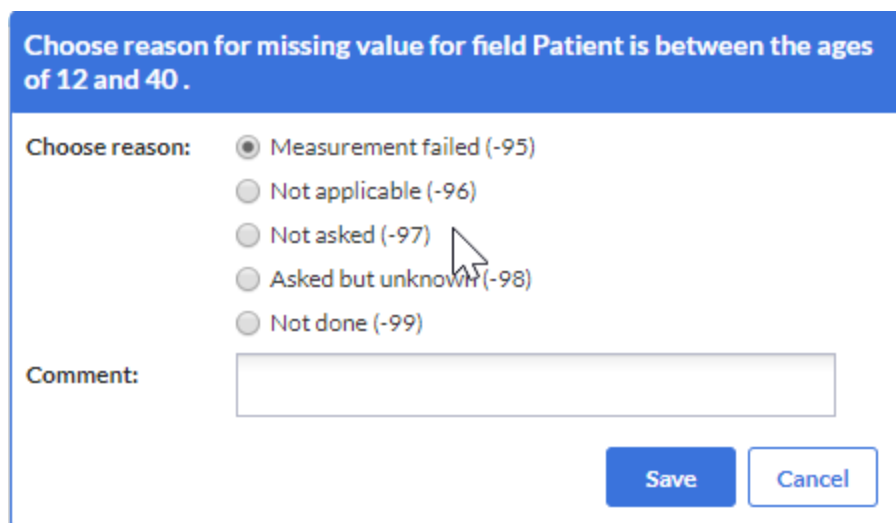
1.4 Height

1.5 Weight

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”:

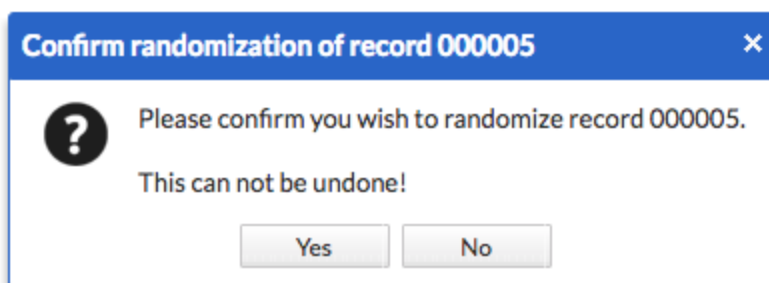
5.1.4 - Randomize a record

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 summarised 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.

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.

[← Back to records](#)

- Record
- Study
- Reports
- Surveys
- Monitoring
- Randomization

Record ID: 120004 Not Live (v.4.71)

Record: 120004

Progress: 42%

Record randomization details

Record number 120004	Record randomized by [redacted]
Randomization number 002	Record randomized on 2020-03-04 15:16:02
Randomization group Control	

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.

Record ID: 110002 • Live (v0.81)

Record: 110002
Progress: 100%
☒ Show Reports

First Study Visit
6. Concomitant medication

6.1 Concomitant medication since study inclusion

Screening 1

Completed SDV ✓
Demographics
Completed SDV ✓
Diagnosis and medical history
Completed SDV ✓
Study inclusion
Completed
First Study Visit
Completed
Follow-up
Completed
Outcome

Mark phase as missing
Lock this phase
Sign this phase 2
Custom verification
Print this phase
Add a report to this phase

Add measurement

Name	Start date	Stop date	Dose	Units
------	------------	-----------	------	-------

1. Go to 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

Sign **Cancel**

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

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.

[← Back to records](#)

Record

Study

Reports

Surveys

Monitoring

Randomization

Record ID: 110001

Not Live (v.6.41)

Record: 110001

Progress: 56%

In Progress

Screening

Completed

Completed

Not Started

Demographics

Diagnosis and Medical history

Screening

1. Demograp

This step was l

Information

1.1 Year of bi

Unlock this step

Sign this step

Custom verification

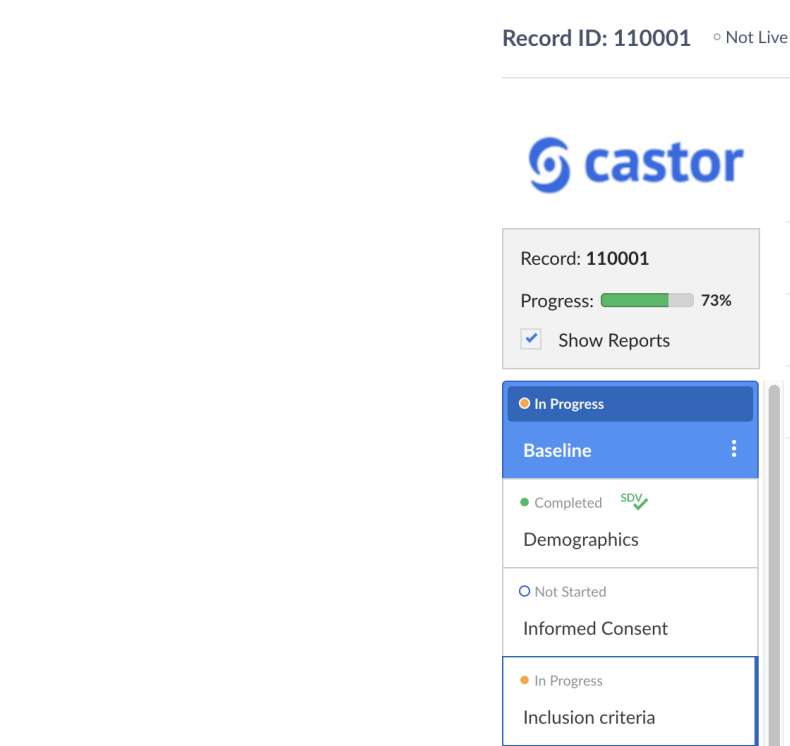
SDV this step

Print this step

Go to the right side of a step or phase with your mouse. Click on the three dots that appear. 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 steps which will update as you fill in the data.



A step 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. 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.

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

7.1 - Search for data

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.

Phase view provides an overview of the completion status for each phase.

Step view provides an overview of the completion status for each step.

Randomized Controlled Trial • Live (v0.81)

Record ☐ Exact match + New Actions Filters ⚙

List Phase Step

Record	Institute	Demographics	Diagnosis and med...	Study inclusion	Physical exam	Blood test	Concomitant med
<input type="checkbox"/> 110002	Main Institute	<div><div></div></div>					
<input type="checkbox"/> 110003	Main Institute			<div><div></div></div>			
<input type="checkbox"/> 110004	Main Institute						
<input type="checkbox"/> 110005	Main Institute						
<input type="checkbox"/> 110006	Main Institute						

This will show you the status of completion of each 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 step to directly access it.

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.

Gender ¹ female ² ☐ Exact match + New Actions Filters ⚙

RECORDS:

Record

DEMOGRAPHICS:

Gender ☒ ☐

dem_sex

Height ☐

dem_height

Weight ☐

dem_weight

BMI ☐

	Created by ↑↓	Created on ↑↓	Updated by ↑↓	Updated on ↑↓	Gender	Country	
<div></div>	Tonya Support	12 Feb 2020	Tonya Support	18 Feb 2021	0	Albania	⋮
<div></div>	Tonya Support	15 Dec 2020	Tonya Support	15 Dec 2020	0	Afghanistan	⋮
<div></div>	Tonya Support	15 Dec 2020	Tonya Support	18 Feb 2021	0		⋮
<div></div>	Tonya Support	15 Dec 2020	Tonya Support	15 Dec 2020	0		⋮

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: 120002 ◉ Not Live (v6.21)

Record: 120002
Progress: 100%

All reports

1 Filter by report type: Select report type to filter Filter by report: Select report to filter Filter by status: Unarchived Add a report

Filter by name: Filter by phase: Select phase to filter

Status	Report	Name	Type	Created on	Created by	Assigned to
2 ○	Adverse Events	Adverse Events...	Event	2020-03-04 19...	Mary Curran	Screening
●	Concomitant ...	Concomitant ...	Medication	2020-03-04 19...	Mary Curran	Screening
●	Protocol Devia...	Protocol Devia...	Other	2020-03-04 19...	Mary Curran	No parent
●	Vital Signs	Vital Signs - 04-...	Repeated meas...	2020-03-04 19...	Mary Curran	Baseline
●	Vital Signs	Vital Signs - 04-...	Repeated meas...	2020-03-04 19...	Mary Curran	Baseline

Report

Previous Next

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 1

Custom name: Adverse event - 25-05-2021 19:06:02 2

Attach to: Phase 1. Screening 3

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.
3. 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 Castor EDC data entry interface for Record ID: 120002. On the left is a sidebar with a 'Record' section containing links for Study, Reports, Surveys, Monitoring, and Randomization. The main content area shows the record's progress (100%) and a list of phases: Completed Screening, Completed Baseline, Completed Vital Signs (highlighted), and Completed End of Study. The 'Vital Signs' phase is expanded, showing a question '5.1 Were vital signs taken today?' with 'yes' selected. Below this is a table for '5.1.1 Vital Signs' with columns: Created on, Visit Date, Height, Weight, Blood Press..., and Blood Press... The table contains two rows of data. An 'Add measurement' button is in the top right of the table. At the bottom are 'Previous' and 'Next' navigation buttons.

Created on	Visit Date	Height	Weight	Blood Press...	Blood Press...
2020-03-04	04-03-2020	77	62	119	82
2020-03-04	01-03-2020	1.78	63	120	80

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.

← Back to records

Record ID: 120002 ◉ Not Live (v.6.21)

Record: 120002
Progress: 100%

All reports

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

[Add a report](#)

Status	Report	Name	Type	Created on	Created by	Assigned to
○	Adverse Events	Adverse Events...	Event	2020-03-04 19...	Mary Curran	Screening
●	Concomitant ...	Concomitant ...	Medication	2020-03-04 19...	Mary Curran	Screening
●	Protocol Devia...	Protocol Devia...	Other	2020-03-04 19...	Mary Curran	No parent
●	Vital Signs	Vital Signs - 04...	Repeated meas...	2020-03-04 19...	Mary Curran	Baseline
●	Vital Signs	Vital Signs - 04...	Repeated meas...	2020-03-04 19...	Mary Curran	Baseline

Report

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9. Responding to queries

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

← Back to records

Record ID: 120002 ◉ Not Live (v.11.91)

Record: 120002
Progress: 60%

Monitoring

Queries **Validations** **Verifications**

Filter by status

☒ New
☒ Open
☒ Unconfirmed
☒ Confirmed
☒ Resolved
☒ Closed

Creation Date	Created By	Field Label	Last Remark	Type
13 Mar 2020 18:...	Niecy Dun...	Were vital signs taken today?	Why were vital signs not taken?	Opened

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.

[← Back to records](#)

Record

Study

Reports

Surveys

Monitoring

Record ID: 120002 Not Live (v.11.91)

Record: 120002

Progress: 60%

☒ Show Reports

In Progress

Screening

In Progress

Baseline

In Progress

Vital Signs

Not Started

End of Study

Baseline

5. Vital Signs

5.1 Were vital signs taken today?

☒ yes
 ☐ no

5.1.1 Vital Signs

Add measurement

Created on	Visit Date	Height	Weight	Blood Press...	Blood Press...	
2020-03-13	13-03-2020	77	72	140	80	
2020-03-04	01-03-2020	77	62	119	82	
2020-03-04	01-03-2020	1.78	63	120	80	

Previous

Next

To respond to a query, click on the query icon

Queries for field Were vital signs taken today? [X]

Current query status: ? Open

Change status to: Open [v] 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 [Update] [Close]

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>