



User Manual eCRF Castor EDC SAVE FGR trial

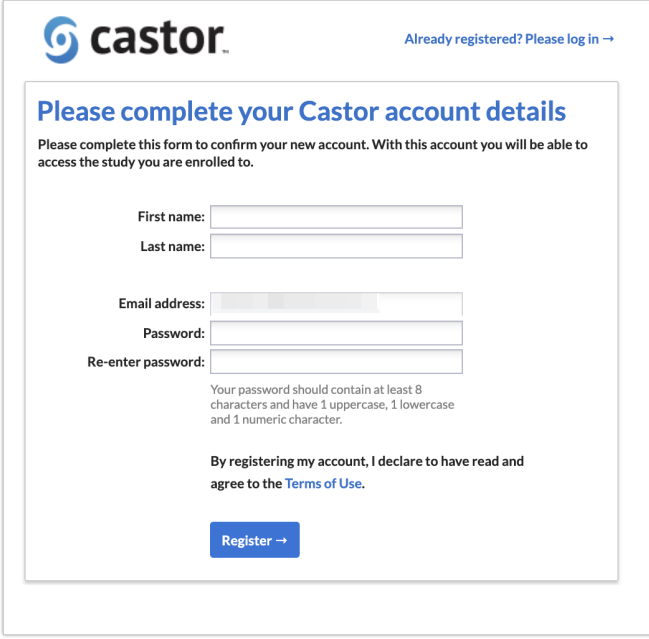
Castor EDC Data Entry User Guide

Version JUN2025

1. Get started

User is added to a study – register an account

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, and 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 sub-heading: "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 five 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." At the bottom of the form is a checkbox area with the text "By registering my account, I declare to have read and agree to the [Terms of Use](#)." and a blue "Register →" button.

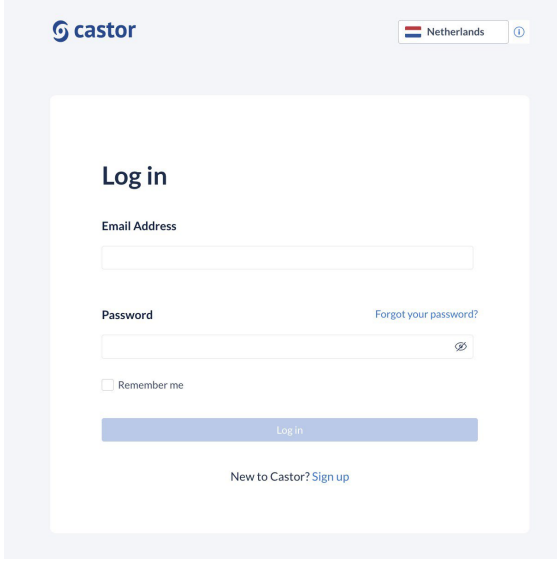
1. Fill in first and last name(s).
2. The email address will be pre-filled, choose a strong password, consisting of at least 8 characters, one uppercase letter, one lowercase letter and a number.
3. Click on 'Register'. Shortly after registering a user details, an email with an activation link will be sent to the email address a user has provided. Click on this

link to confirm that the supplied email address belongs to a user and verify a user account.

2. Log In

To access the study, log into Castor EDC via <https://data.castoredc.com>.

1. Enter your email address and password.
2. 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 language selector showing the Netherlands flag and a help icon. The main content area is titled 'Log in'. It contains two input fields: 'Email Address' and 'Password'. The 'Password' field has a 'Forgot your password?' link to its right and a toggle icon to its left. Below the password field is a 'Remember me' checkbox. A blue 'Log in' button is positioned below the checkbox. At the bottom of the form, there 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), a user can click on the study name to enter the study and start data entry.

My Studies

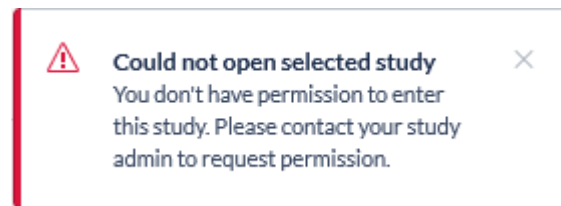
Order by

Creation date: Newest first ▼

☐ Not Live ☒  Test Study: Castor EDC Study

Monocenter EU Server

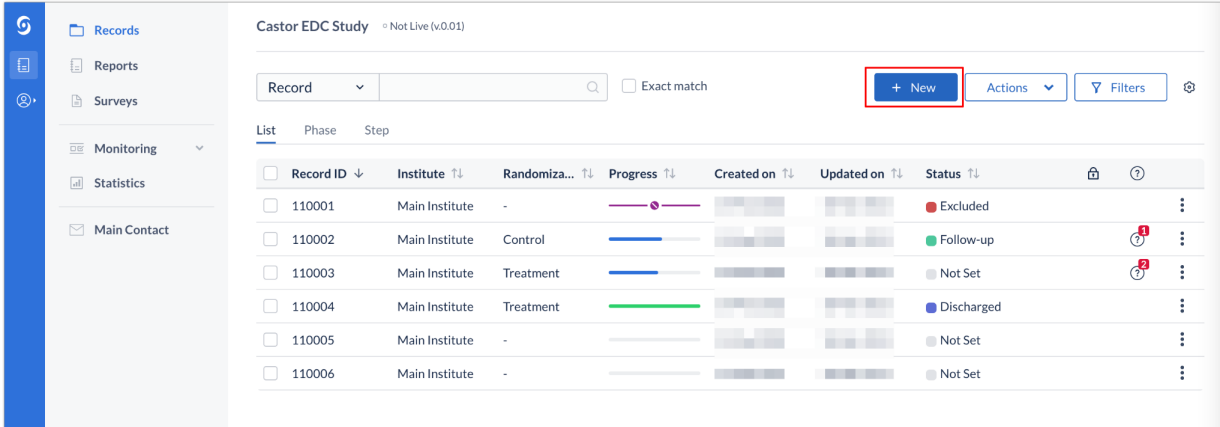
Trying to open a study that is not live will show the following warning:



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

4. Add/Open a record for a new patient

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



Castor EDC Study - Not Live (v0.01)

Record ☐ Exact match + New Actions

List	Phase	Step						
<input type="checkbox"/> Record ID ↓	<input type="checkbox"/> Institute ↑↓	<input type="checkbox"/> Randomiza... ↑↓	<input type="checkbox"/> Progress ↑↓	<input type="checkbox"/> Created on ↑↓	<input type="checkbox"/> Updated on ↑↓	<input type="checkbox"/> Status ↑↓	<input type="checkbox"/> Lock	<input type="checkbox"/> Help
<input type="checkbox"/> 110001	Main Institute	-	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	Excluded	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 110002	Main Institute	Control	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	Follow-up	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 110003	Main Institute	Treatment	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	Not Set	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 110004	Main Institute	Treatment	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	Discharged	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 110005	Main Institute	-	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	Not Set	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 110006	Main Institute	-	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	Not Set	<input type="checkbox"/>	<input type="checkbox"/>

Then, select a user institute and click 'Next'. The record will be created and opened so a user can begin data entry.

Create New Record

Institute

Test

Record ID

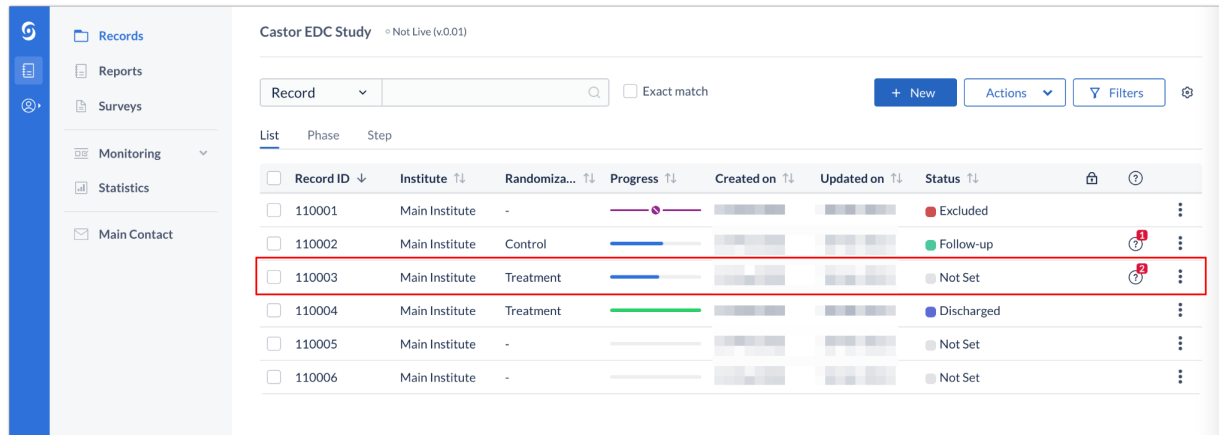
110002

Email address

Create

Cancel

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



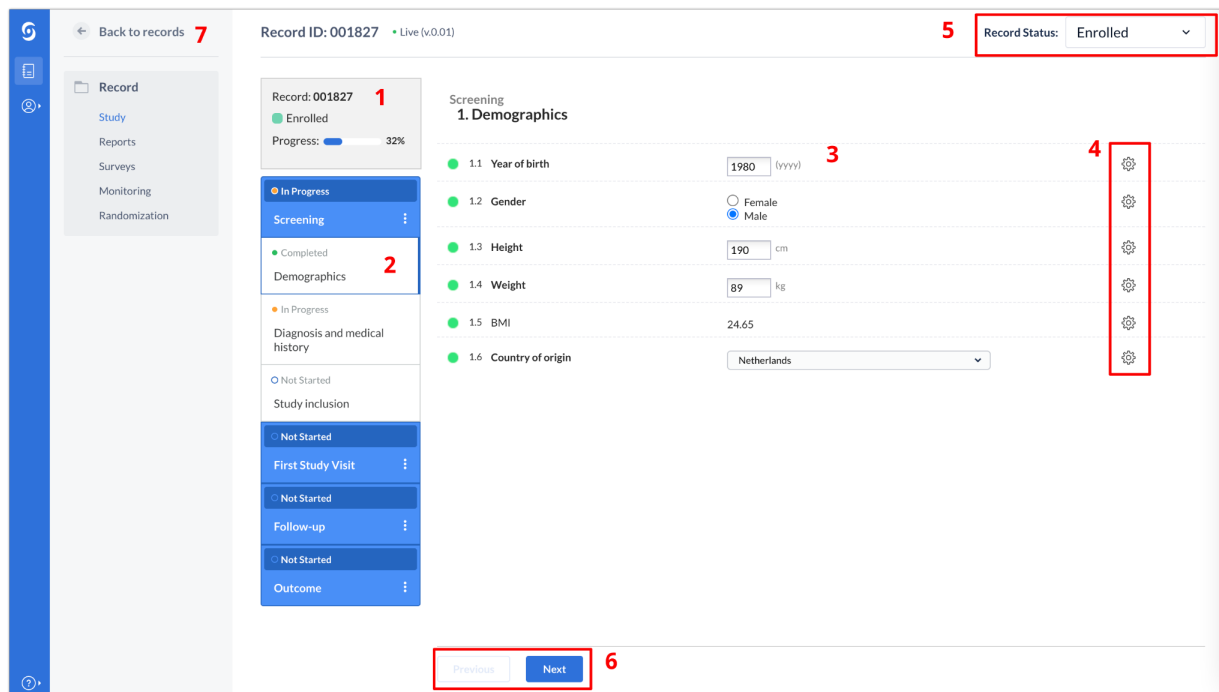
Castor EDC Study - Not Live (v0.01)

Record ID 110003 is highlighted.

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 a user opens a record, the user will be taken to the main data entry view:



Record ID: 001827 - Live (v0.01)

Record Status: Enrolled

Screening 1. Demographics

- 1.1 Year of birth: 1980 (yyyy)
- 1.2 Gender: Female, Male
- 1.3 Height: 190 cm
- 1.4 Weight: 89 kg
- 1.5 BMI: 24.65
- 1.6 Country of origin: Netherlands

Previous Next

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. A user can click on the step of

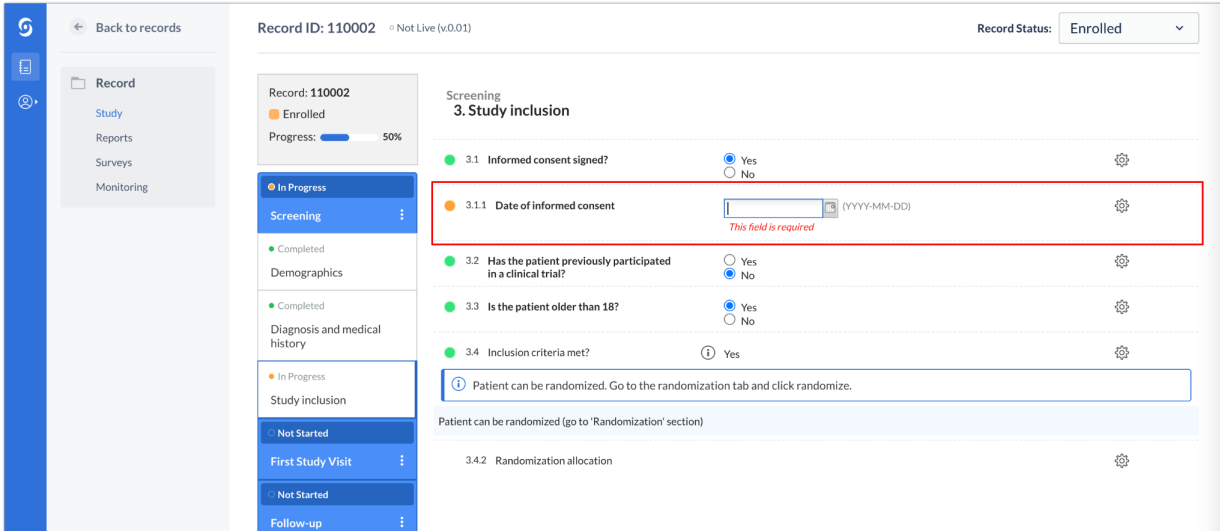
interest in this panel to start entering the required data. Once a user answers a question in the form, a user will see a small wheel turning to the left of the field and this means the data is being saved.

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, a user can clear the data from a field, add a comment or mark the field as 'missing' data.
5. Dropdown field displaying record status. Click on the field to select a different status.
6. Once a user has completed the first form, a user can navigate to the next step by clicking on 'Next'. To navigate to the previous form, click on the 'Previous' button. If the user is on the first or the last form, the buttons 'Previous' and 'Next' will be grayed out.
7. To exit the record and return to the record list, click on the 'Back to records' button.

5.1. Elements in each question

Depending on the type of question, a user 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'.



Record ID: 110002 • Not Live (v0.01) Record Status: Enrolled

Record: 110002
Enrolled
Progress: 50%

Screening
3. Study inclusion

3.1 Informed consent signed? ☒ Yes ☐ No

3.1.1 Date of informed consent (YYYY-MM-DD) *This field is required*

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

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. For example, field 2.1 after the data has been entered and saved:

● 2.1 Are you 16 years of age or older?

☒ Yes
 ☐ No

- Orange** Data is required and no input has been entered yet. For example, field 2.3:

● 2.3 Are you planning to reside in this area for the next 6 months?

☐ Yes
 ☐ No

- Red** The input is invalid or does not comply with the inclusion criteria for the study. This is accompanied by a red warning message.

● 3.5.1 Error Date of consent is not entered
 ⚙️

⚠️ Date of consent is mandatory. Please provide the date.

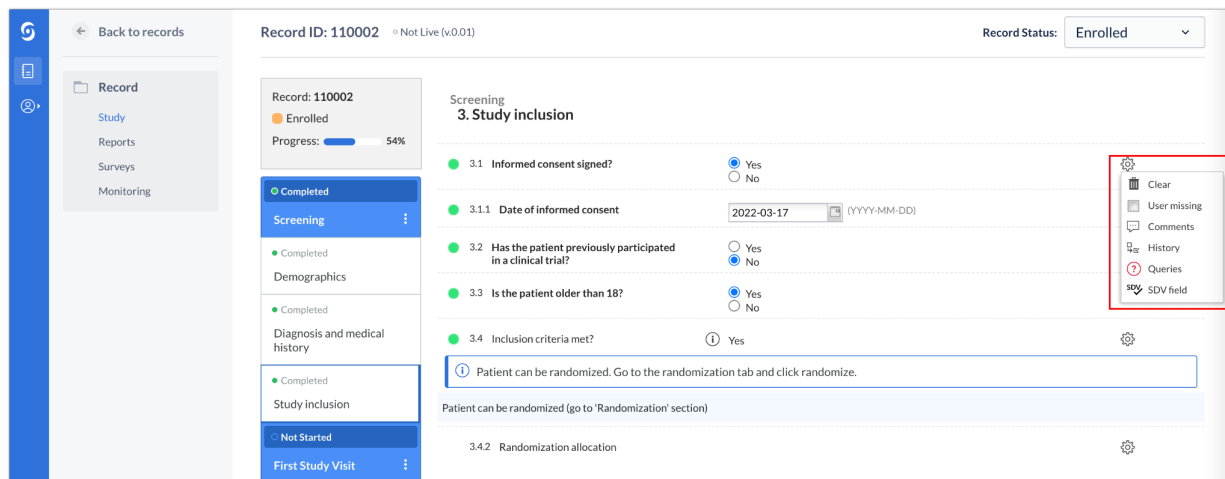
- No icon** Data entry is not required and no input has been entered yet.

2.14.2 Pre-screen successful?

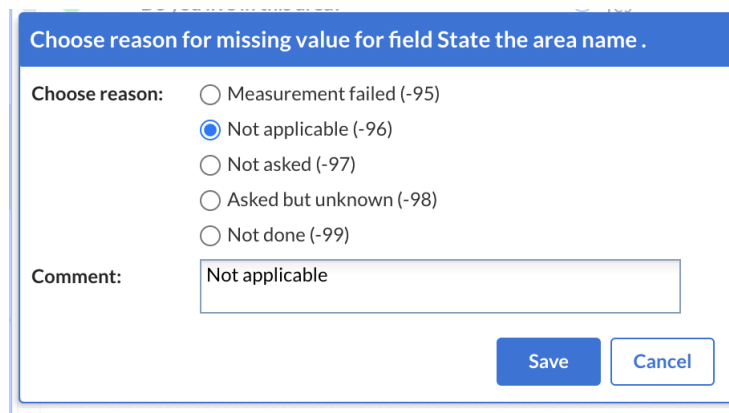
Not all values for this calculation are available (yet).

5.1.2 Additional options

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

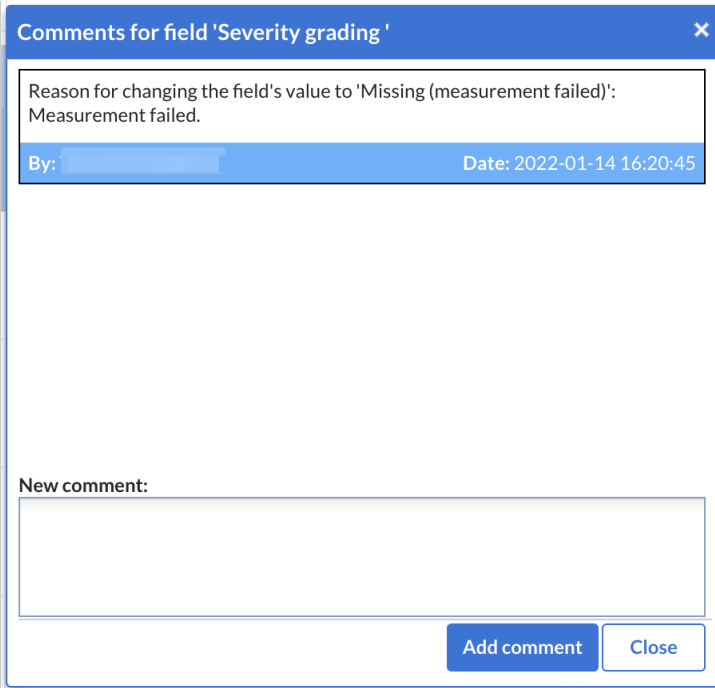


- To clear the value already entered for a field, press 'Clear'.
- If data is not available for a question, tick the 'User missing' box. A window will open to ask the user to provide the reason why the data is missing:



- 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 a user initially marked a field as missing but received information for this field at a later date, a user can click on the cogwheel again (even if the question is grayed out) and should unselect the option “User missing”.
- If a user wants to add a comment to a field, press “Comments”. Add a user text and press “Add comment”:

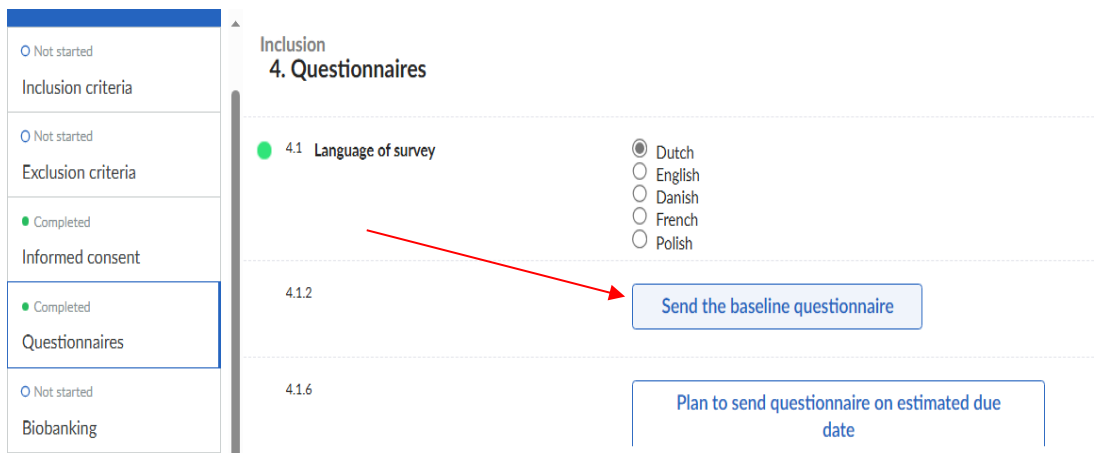


The screenshot shows a dialog box titled "Comments for field 'Severity grading'". Inside the dialog, there is a text area containing the text: "Reason for changing the field's value to 'Missing (measurement failed)': Measurement failed." Below this text area, there is a row with two fields: "By:" followed by a blurred user name, and "Date: 2022-01-14 16:20:45". At the bottom of the dialog, there is a large text input field labeled "New comment:". To the right of this input field are two buttons: "Add comment" and "Close".

5.1.3 Send a survey

When you have included a new patient you will have to send the survey package 'Study Entry'.

Go to the tab 'Questionnaires' and choose your language and click the 'send the baseline questionnaire'.



The screenshot shows the Castor interface with a sidebar on the left containing a list of tabs: 'Not started', 'Inclusion criteria', 'Exclusion criteria', 'Completed', 'Informed consent', 'Questionnaires' (highlighted with a blue border), and 'Biobanking'. The main content area is titled 'Inclusion 4. Questionnaires'. It displays a list of items: '4.1 Language of survey' (with a green dot), '4.1.2', and '4.1.6'. To the right of '4.1 Language of survey' are radio buttons for language selection: Dutch (selected), English, Danish, French, and Polish. A red arrow points from the '4.1 Language of survey' item to a blue button labeled 'Send the baseline questionnaire'. Below the '4.1.6' item, there is a box containing the text 'Plan to send questionnaire on estimated due date'.

Add the email of the participant if this hasn't been previously added to the record. If the email was already added in the record itself, it will be automatically extracted and this section will be pre-filled with the email address. To view the address, you will need to authenticate yourself again with your password and this viewing will be logged in the audit trail. If an email address is not associated with a record, a pop-up window will appear asking if you would like to associate an entire record with this e-mail address which will be used as a primary e-mail address for the survey invitations.

Create a survey package invitation



Survey Package

Study Entry (Dutch) ▾

Email

Parent

A visit ▾

Visit

Inclusion ▾

Subject

SAVE FGR Study - Questionnaires

Invitation message ⓘ [Formatting cheatsheet](#)

Beste deelnemer,

U ontvangt deze e-mail omdat u meedoet aan de SAVE FGR-studie. Hartelijk dank voor uw deelname.

De vragen gaan over uw gezondheid en hoe u zich voelt tijdens de zwangerschap. Uw antwoorden helpen ons bij het analyseren van de resultaten en geven ons meer inzicht in de impact van een groeibeperking van de baby tijdens de zwangerschap.

[Preview](#)[Cancel](#)[Create](#)

The second survey package must be sent on the due date...!

Not started

Inclusion criteria

Not started

Exclusion criteria

Completed

Informed consent

Completed

Questionnaires

Not started

Biobanking

Inclusion

4. Questionnaires

4.1 Language of survey

☒ Dutch
 ☐ English
 ☐ Danish
 ☐ French
 ☐ Polish

4.1.2

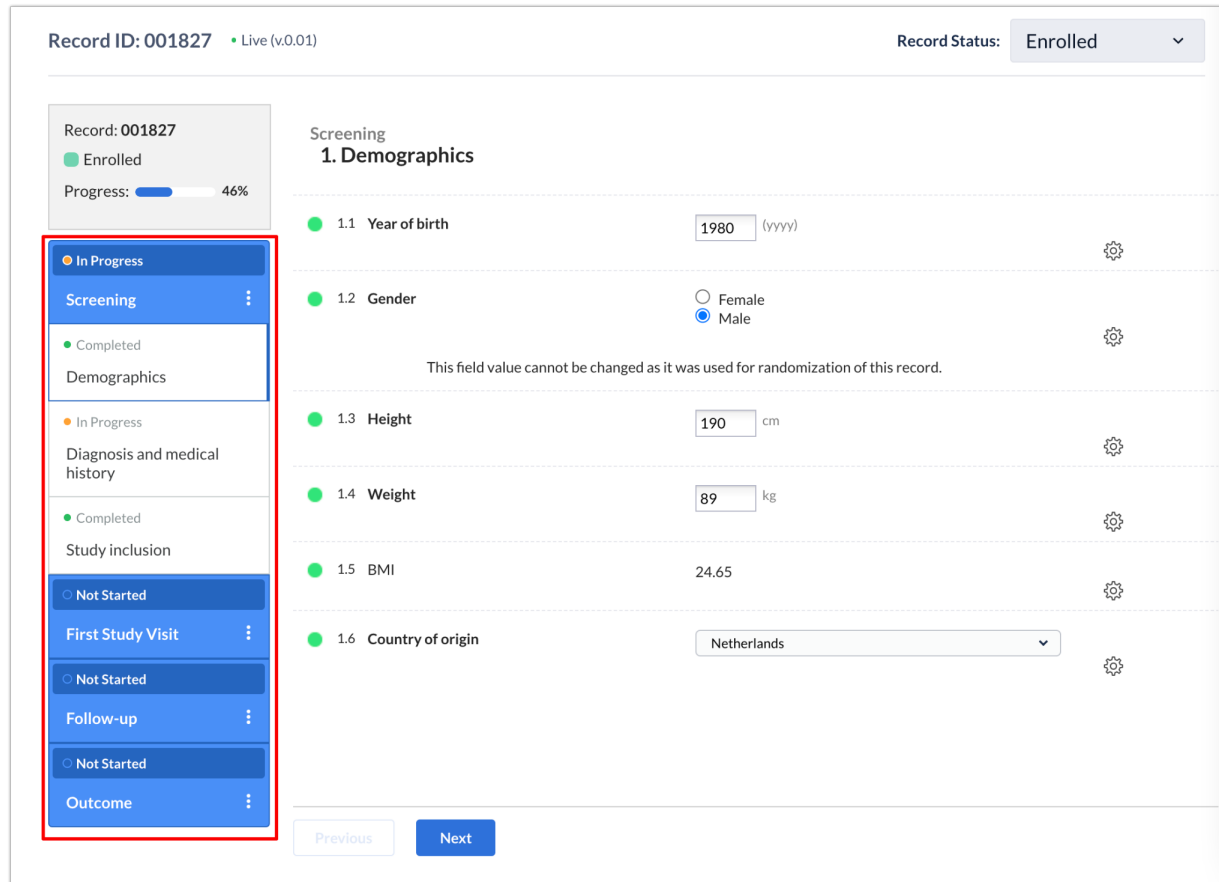
Send the baseline questionnaire

4.1.6

Plan to send questionnaire on estimated due date

6. Record progress

In the left panel in the data entry, a user can view the progress of the steps which will update as a user fills in the data.



The screenshot displays the Castor data entry interface for Record ID: 001827, which is Live (v.0.01) and has a status of Enrolled. The interface is divided into a left sidebar and a main content area.

Left Sidebar: A vertical list of steps with their completion status:

- Record: 001827** (Enrolled, Progress: 46%)
- Screening** (In Progress, highlighted with a red box)
- Demographics** (Completed)
- Diagnosis and medical history** (In Progress)
- Study inclusion** (Completed)
- First Study Visit** (Not Started)
- Follow-up** (Not Started)
- Outcome** (Not Started)

Main Content Area: Titled "Screening 1. Demographics", it contains a list of fields with their values and completion status (indicated by colored dots):

- 1.1 Year of birth:** 1980 (yyyy) - Completed (Green dot)
- 1.2 Gender:** Male (radio button selected) - Completed (Green dot). A note below states: "This field value cannot be changed as it was used for randomization of this record."
- 1.3 Height:** 190 cm - Completed (Green dot)
- 1.4 Weight:** 89 kg - Completed (Green dot)
- 1.5 BMI:** 24.65 - Completed (Green dot)
- 1.6 Country of origin:** Netherlands - Completed (Green dot)

At the bottom of the main content area, there are "Previous" and "Next" buttons.


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. Repeated Data

If you need to enter data that occurs multiple times (e.g. ultrasounds, measurements, or procedures), use the repeated forms section.


Participant

Visits

Repeating data

Surveys

Monitoring

Click 'Create' to create a new entry and choose your repeating data and create:

Create a repeating data instance



Repeating data *



Instance name *

For auto-generated names this is a preview. The name that will be actually stored may differ as it will be regenerated upon the actual creation.

Parent *

Cancel

Create and add another

Create

Repeat this process for each new instance of the repeated event.

Make sure to double-check the data before saving. Each repeated form will be saved separately and can be edited later if needed.

8. Serious Adverse Events

SAEs must be reported within 24 hours after the event was noticed to the principal investigator via: savefgr@amsterdamumc.nl

Form available at: www.fetalgrowthrestriction.com

The following protocol-specific SAEs should be reported only in CRF:

- Fetal death
- Neonatal death
- Maternal hospital admission for giving birth, fetal monitoring, antenatal blood loss, (threatened) preterm labor or maternal hypertensive disorders

The Castor EDC Academy provides online training for Data Entry which can be found on the website <https://academy.castoredc.com/>. These online (free) e-learning are useful introductions for those who enter study data.