User Manual eCRF Castor EDC SAVE FGR trial

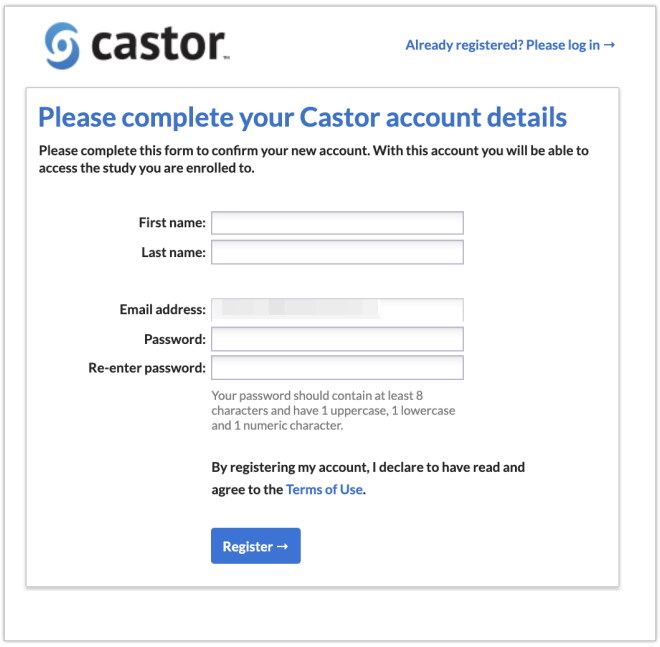
Castor EDC Data Entry User Guide

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:



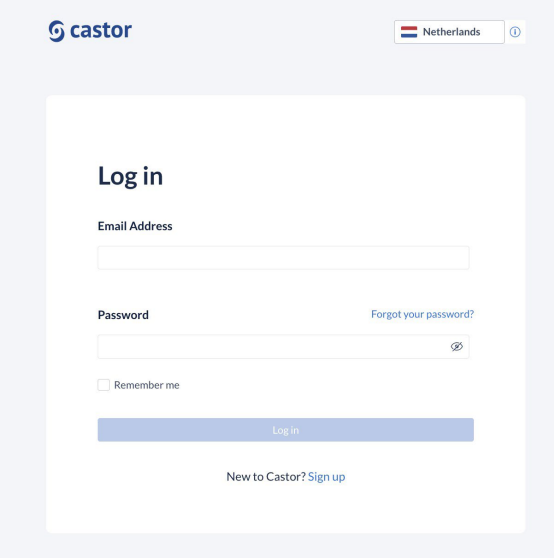
1. Fill in first and last name(s).
2. The email address will be pre-filled, choose a strong password, consisting of at least 8 characters, one uppercase letter, one lowercase letter and a number.
3. Click on 'Register'. Shortly after registering a user details, an email with an activation link will be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

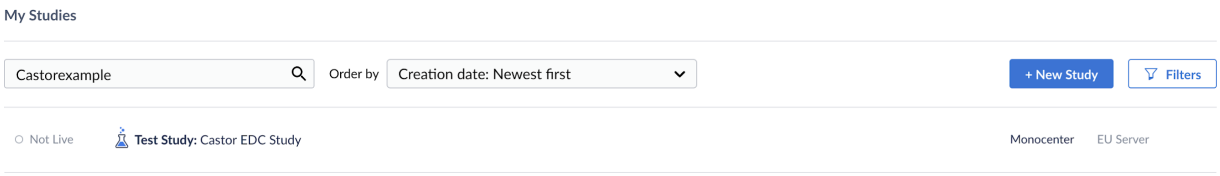
To access the study, log into Castor EDC via https://data.castoredc.com.

1. Enter your email address and password.
2. Click on 'Login'.

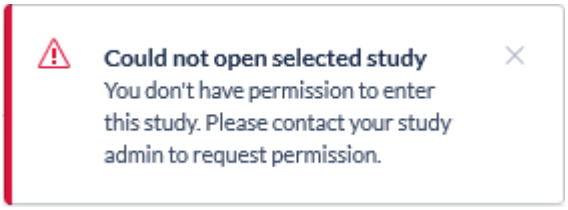


3. Open a study

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.



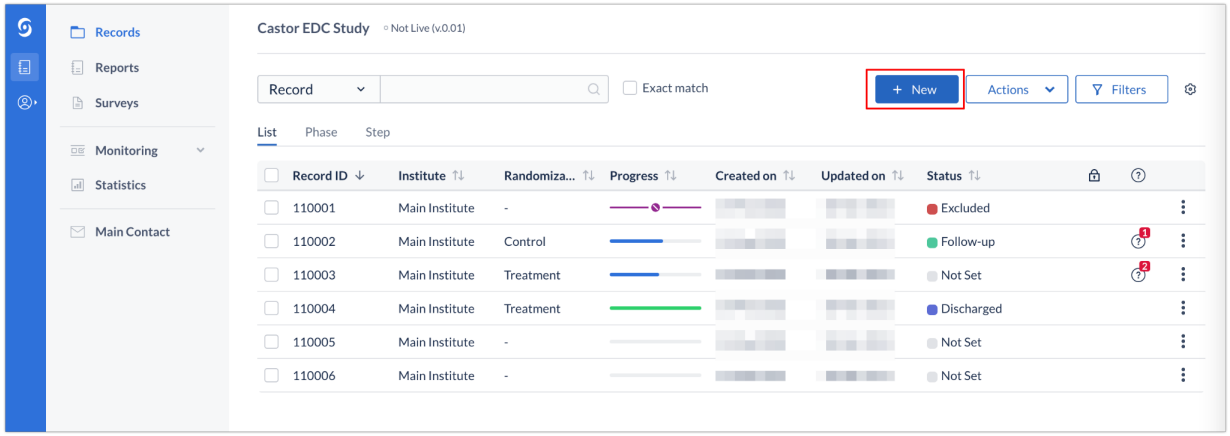
Trying to open a study that is not live will show the following warning:



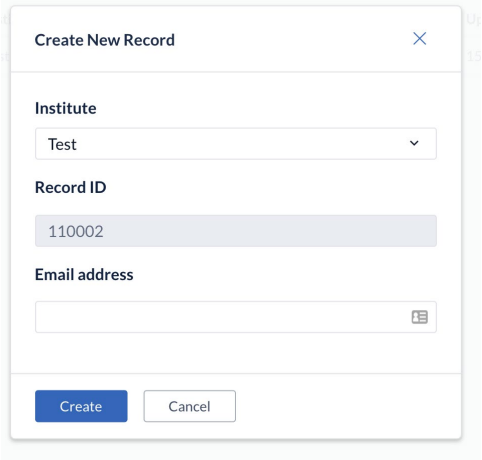
If the study is still in maintenance mode (the button is blank, and the status says 'Not Live') a user will only be able to open the study if a user has management rights.

4. Add/Open a record for a new patient

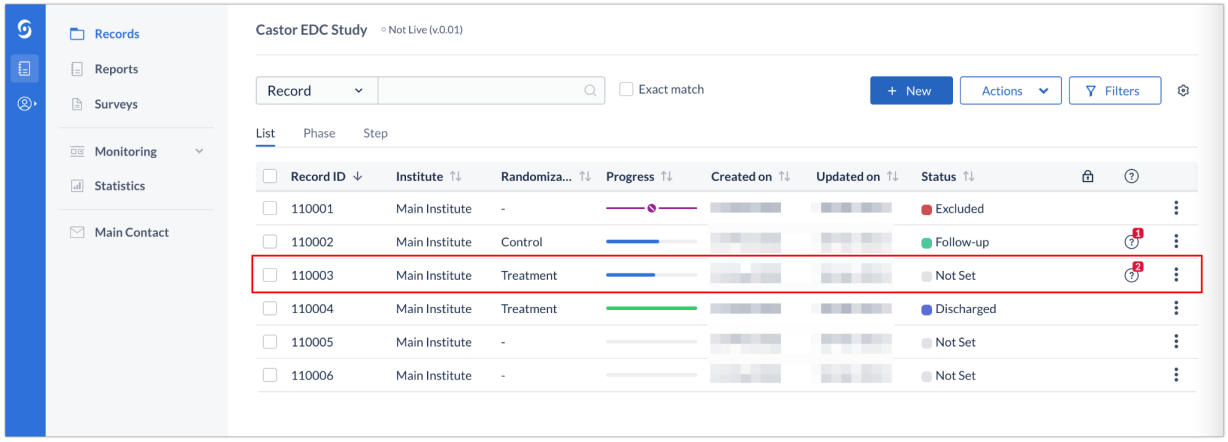
Once a user enters the study, a user will see a list of all records available based on their access level. To add a new patient to the database, a user will need to create a new record. Creating new records must be done from the Records tab, by clicking on the "+ New" button.



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

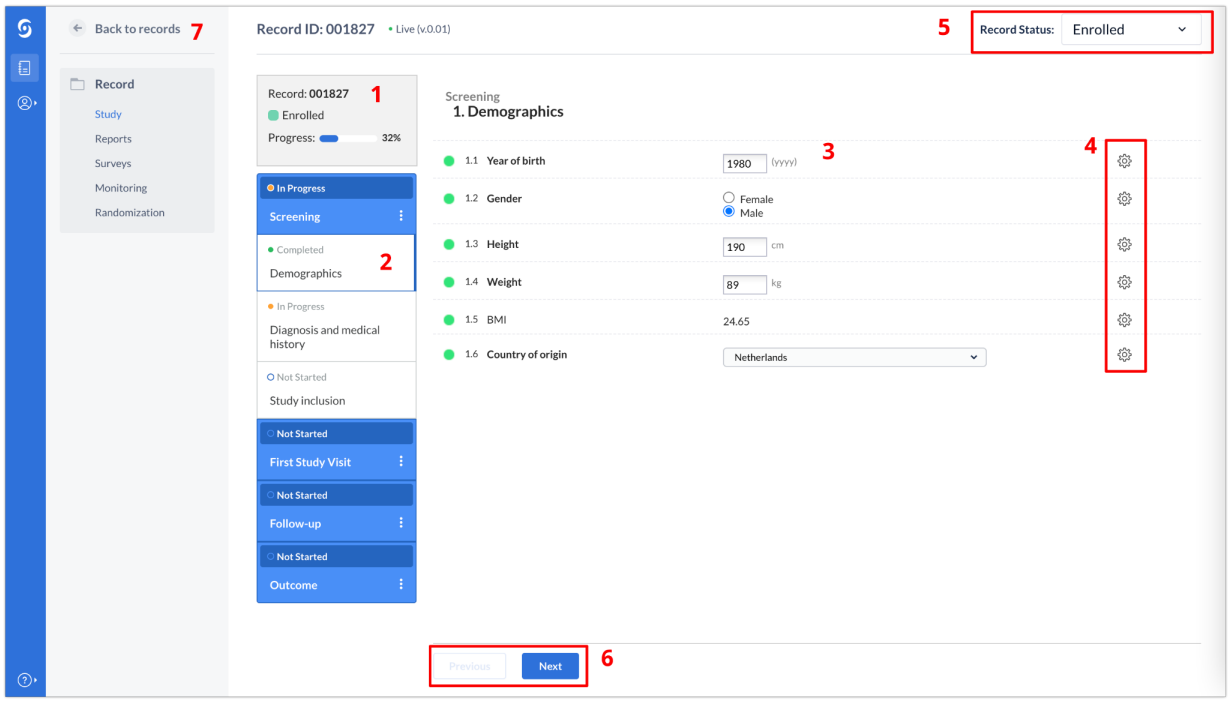


To open a previously created record, double click the row the record is on.



5. Doing data entry

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



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

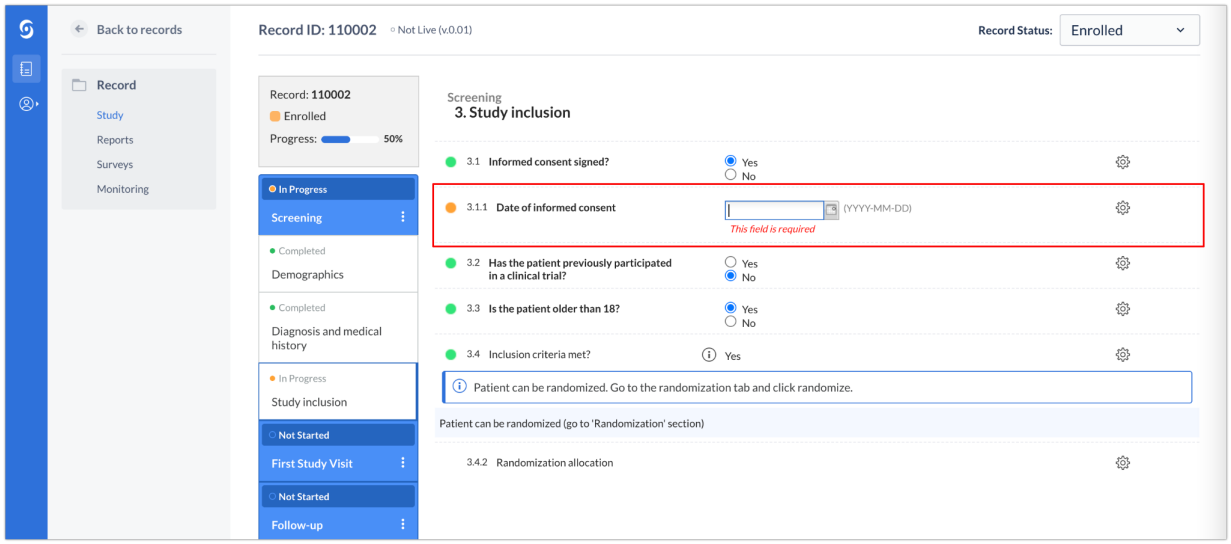
interest in this panel to start entering the required data. Once a user answers a question in the form, a user will see a small wheel turning to the left of the field and this means the data is being saved.

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.

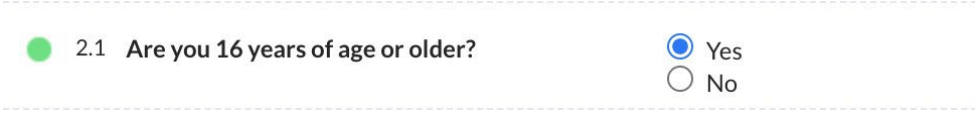
Some fields will appear only under certain conditions. In the example below, question 3.1.1 is shown only because question 3.1 is answered with 'Yes'.



5.1.1 Status icons

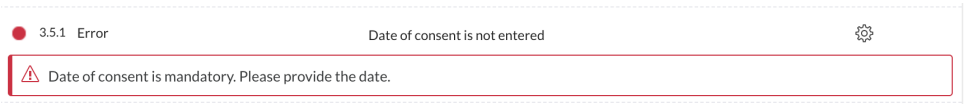
Shown to the left of each question is the status icon, which indicates whether the question has been answered (green) or not answered (orange). Where there is a problem with the provided answer, the icon will turn red and a red warning message will appear to provide more information about the problem.

- **Green** The input is valid and the data is saved. For example, field 2.1 after the data has been entered and saved:

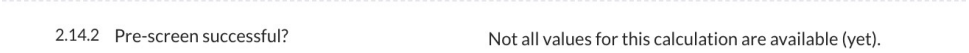


- **Orange** Data is required and no input has been entered yet. For example, field 2.3:

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

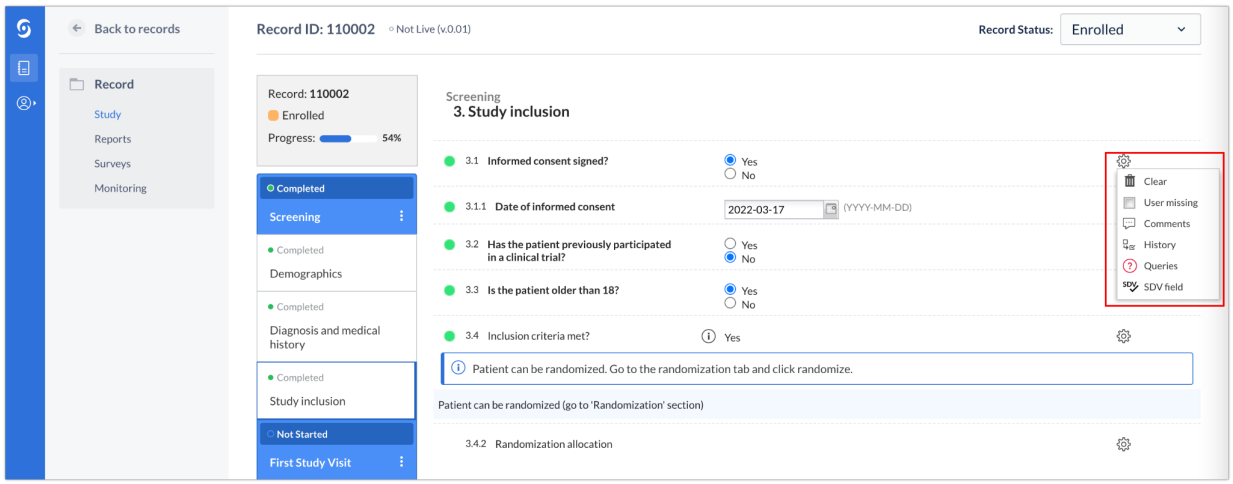


- **No icon** Data entry is not required and no input has been entered yet.

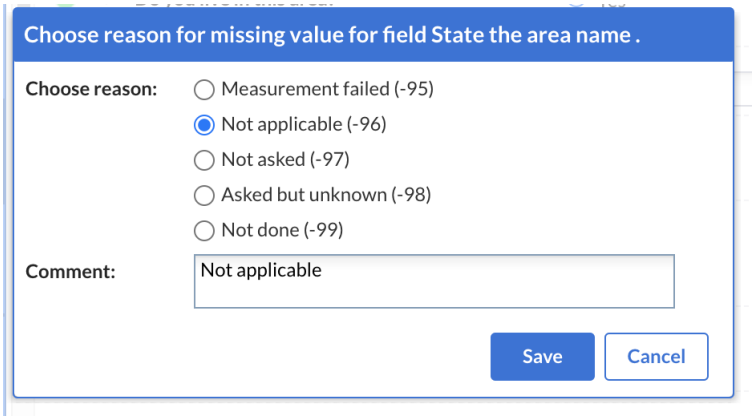


5.1.2 Additional options

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

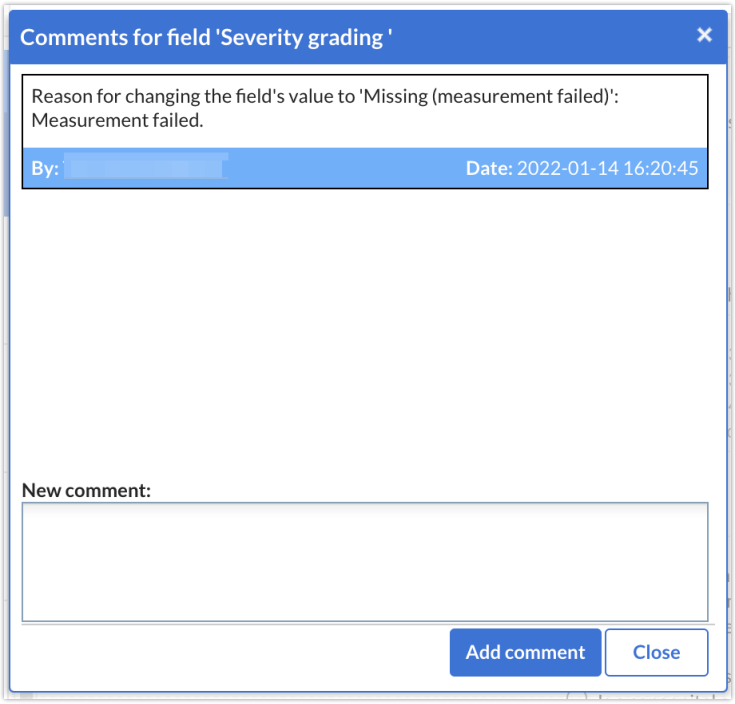


- To clear the value already entered for a field, press 'Clear'.
- If data is not available for a question, tick the 'User missing' box. A window will open to ask the user to provide the reason why the data is missing:



- 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'.

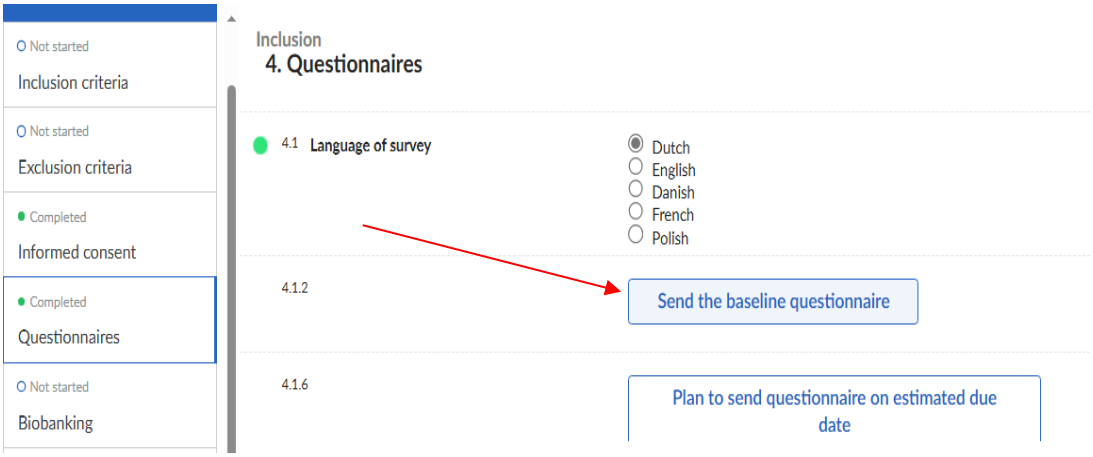
- If a user initially marked a field as missing but received information for this field at a later date, a user can click on the cogwheel again (even if the question is grayed out) and should unselect the option "User missing".
- If a user wants to add a comment to a field, press "Comments". Add a user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



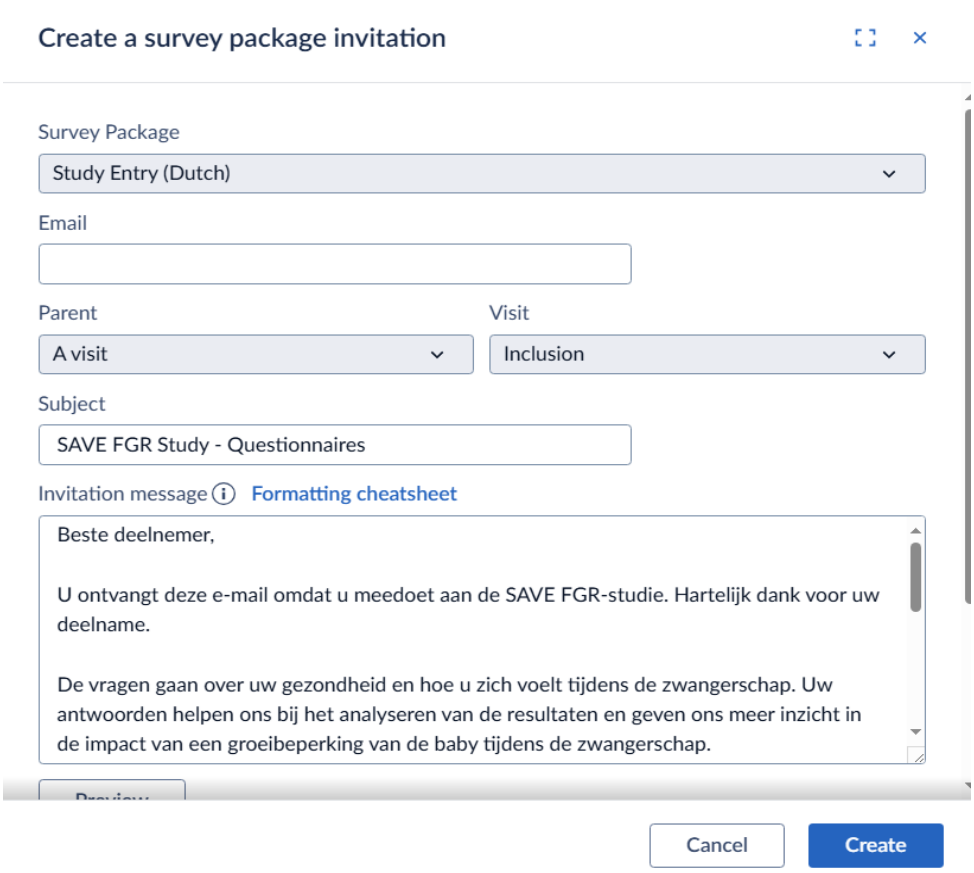
5.1.3 Send a survey

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

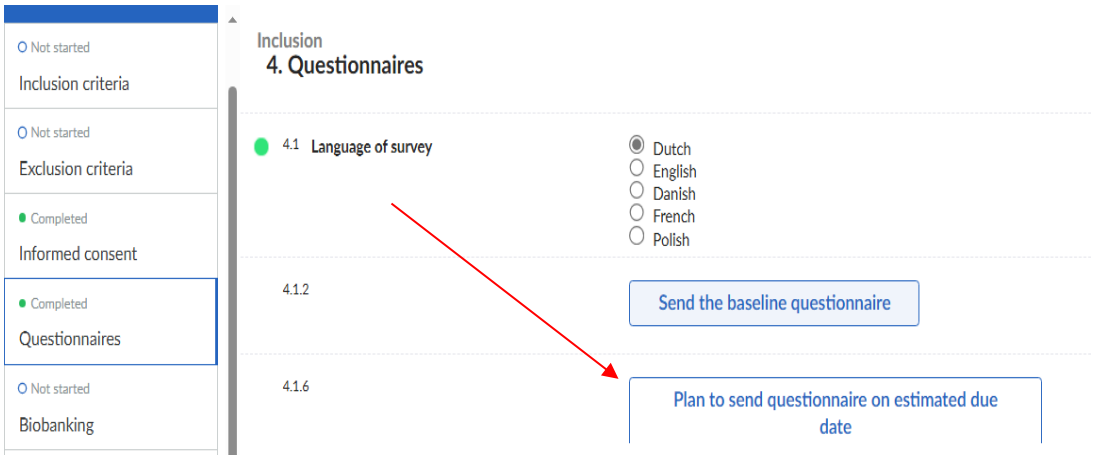
Go to the tab 'Questionnaires' and choose your language and click the 'send the baseline questionnaire'.



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.

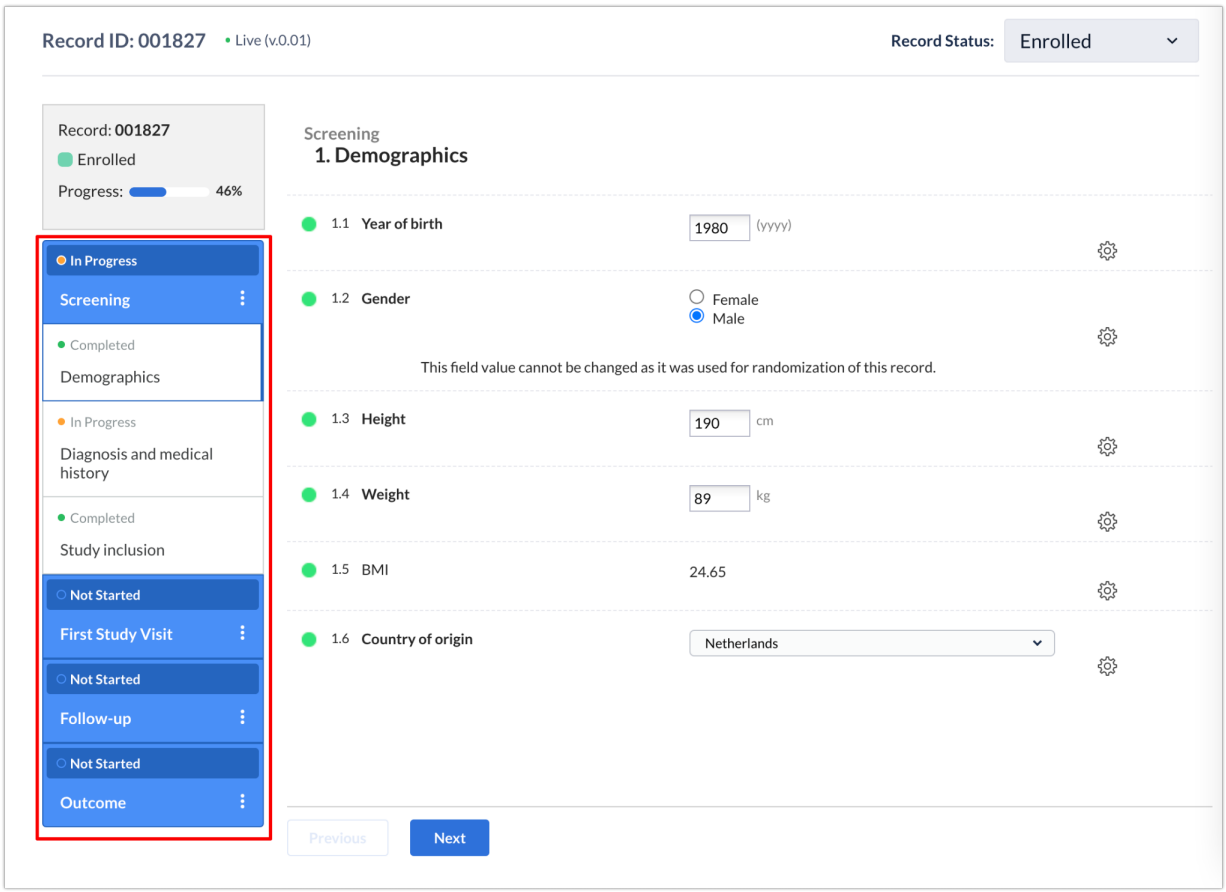

Create a survey package invitation
Survey Package
Study Entry (Dutch)
Email
Parent
A visit
Visit
Inclusion
Subject
SAVE FGR Study - Questionnaires
Invitation message
Formatting cheatsheet
Beste deelnemer,
U ontvangt deze e-mail omdat u meedoet aan de SAVE FGR-studie. Hartelijk dank voor uw deelname.
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.
Cancel
Create

The second survey package must be sent on the 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.



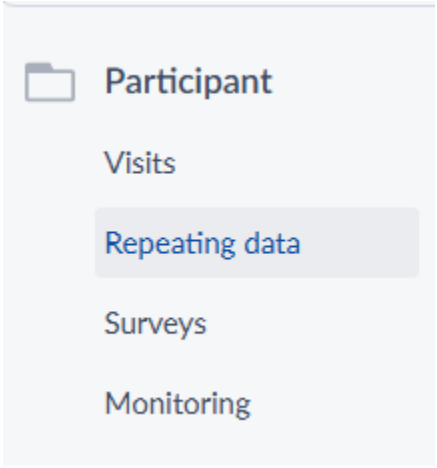
A step can have three different completion stages:

- *Gray* Not started
- *Orange* In Progress
- *Green* Completed

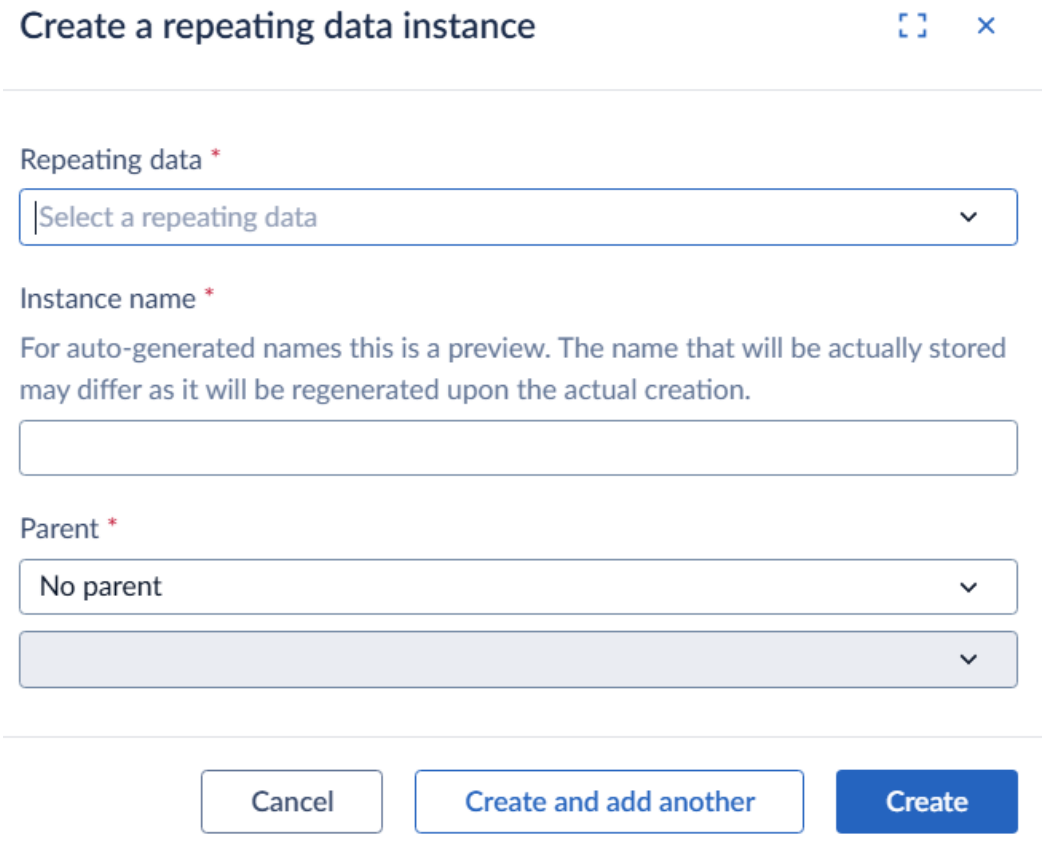
The overall record progress bar shown in the phase tab (blue) will also update automatically. Once all required fields have been completed, the icon will turn green.

7. Repeated Data

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



Click 'Create' to create a new entry and choose your repeating data and 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-learnings are useful introductions for those who enter study data.