

GENERATOR trial

Randomization instructions

Before it is possible to randomize the patient, you need to arrange several things in Castor. Timing wise, we strongly advise to perform items 1) and 2) before the day of surgery and item 3) just before the surgery.

- 1) Create a new patient record in Castor (for instructions see document *GENERATOR Data Entry Instructions (e)CRF 1.0, 31-01-2024*)
- 2) Fill out the preoperative form in Castor. It is preferable to complete it, **but at a minimum, enter the inclusion and exclusion criteria; otherwise, the randomization button will not appear in the randomization form**. Also, provide the patient's height and weight for BMI calculation, which is utilized for stratified randomization.
- 3) Randomize the patient.

Follow these steps

Step 1. Go to [Castor - Top-Rated eClinical Data Management Platform \(castoredc.com\)](https://castoredc.com) and log in using your personal intraoperative account.

Step 2. Add a new record.

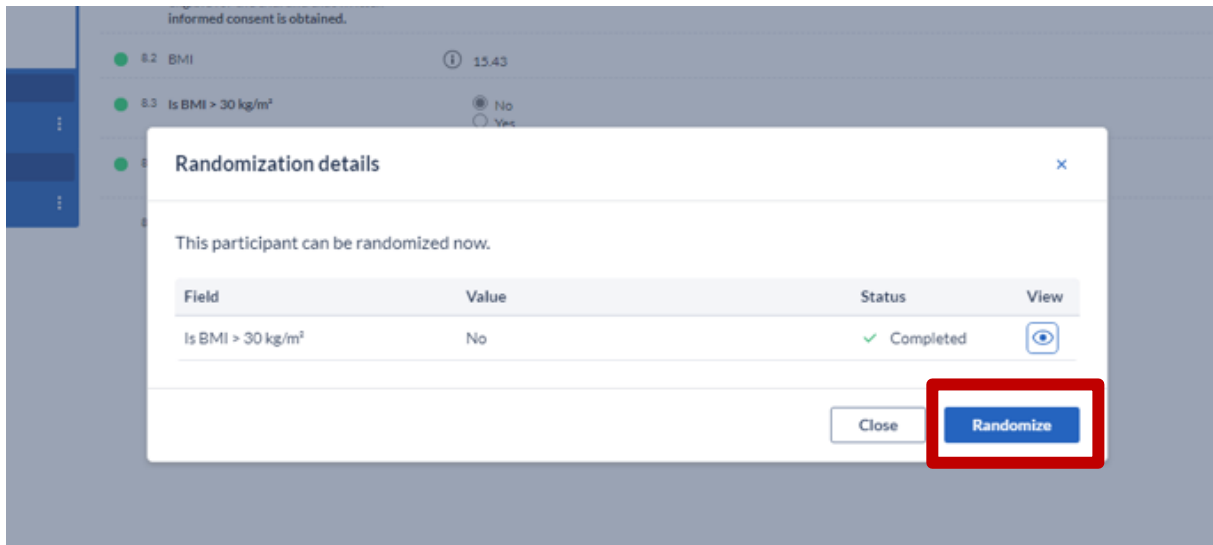
Step 3. Go to the Preoperative visit and fill in the questions about the inclusion, exclusion criteria and patient details.

Step 4. Proceed to the randomization form. If the in- and exclusion criteria are entered appropriately, you will see the message '*Patient can be randomized, please proceed to the randomization tab in the Participant menu on the left.*' in field 8.4. You will also need to fill in whether the BMI of the patient is more or less than 30kg/m².

Step 5. Go to the randomization tab '*Not randomized*' on the left and press '*Randomize*'.

The screenshot displays the Castor interface for a participant with ID 7. On the left, a sidebar menu shows the participant's status as 'Not randomized' (highlighted with a red box). The main area shows the '8. Randomization' form with the following fields:

Field ID	Question	Response
8.1	It appears that all inclusion criteria have been met and exclusion criteria are not applicable. Confirm that the patient is eligible for the trial and that written informed consent is obtained.	Yes
8.2	BMI	15.43
8.3	Is BMI > 30 kg/m ²	No
8.4	Randomization	Patient can be randomized, please proceed to the randomization tab in the Participant menu on the left.
8.5	Randomization allocation	This participant was not randomized yet.



Step 6. The randomization group will appear on the screen.

Congratulations! You have randomized a patient for the GENERATOR trial.