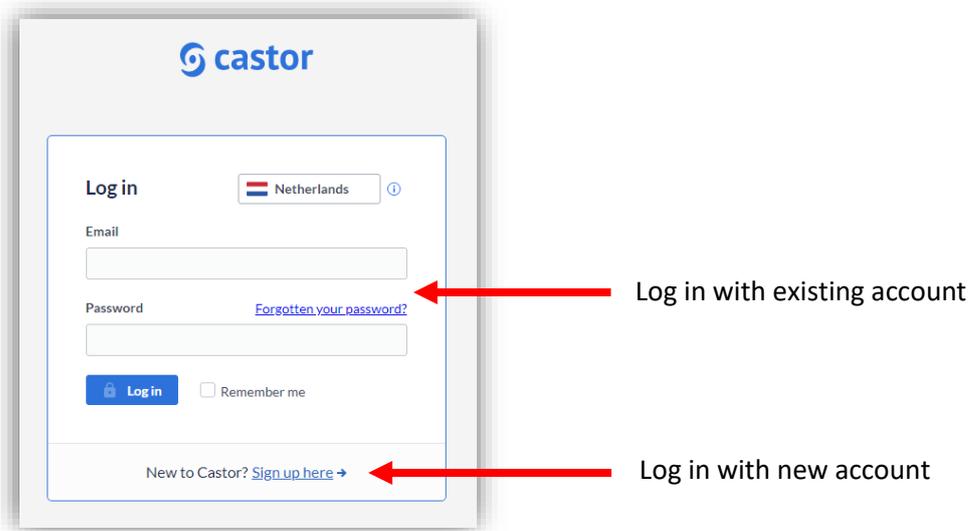


Standard Operating Procedure data entry Castor DOXA-Trial

AIM: this SOP is a guide for eCRF data entry in CASTOR, including instructions on the login procedure, prescreening and randomized database, for a patient in the DOXA-Trial.

LOGIN PROCEDURE

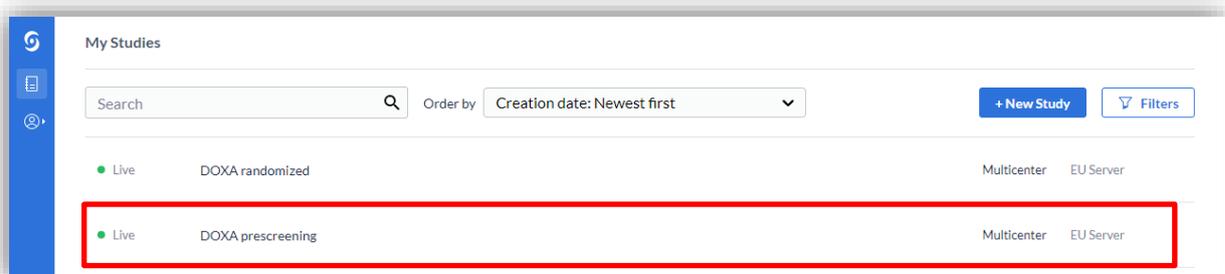
1. An invitation per email with the link to the DOXA-Trial database will be sent by the principle investigator or research nurse for each site.



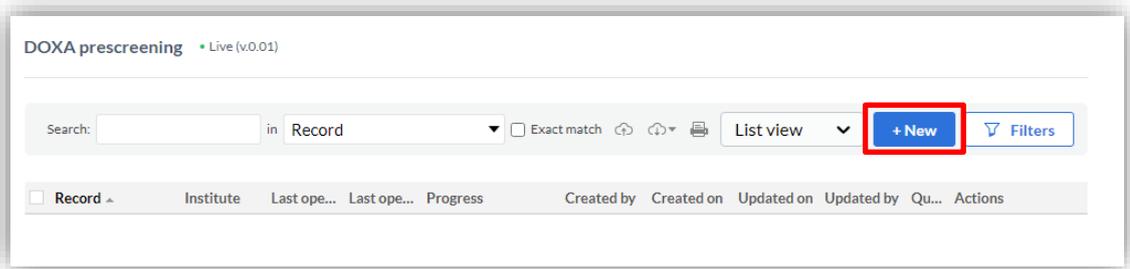
Two databases appear: the DOXA prescreening (all eligible patients) and DOXA randomized (only randomized patients).

PRESCREENING DATABASE (*all eligible patients*)

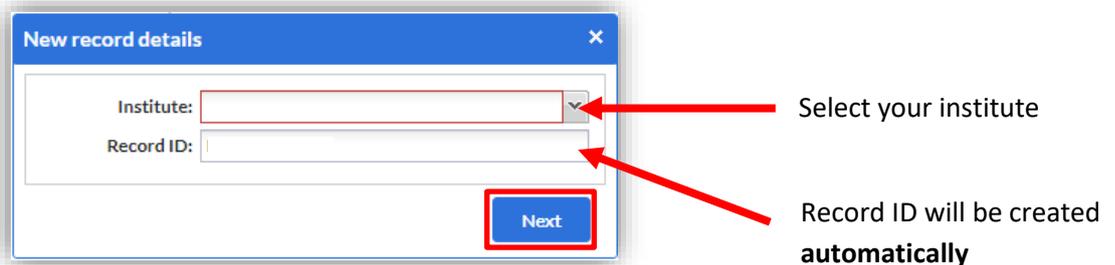
2. Click on 'DOXA prescreening' to open the prescreening database.



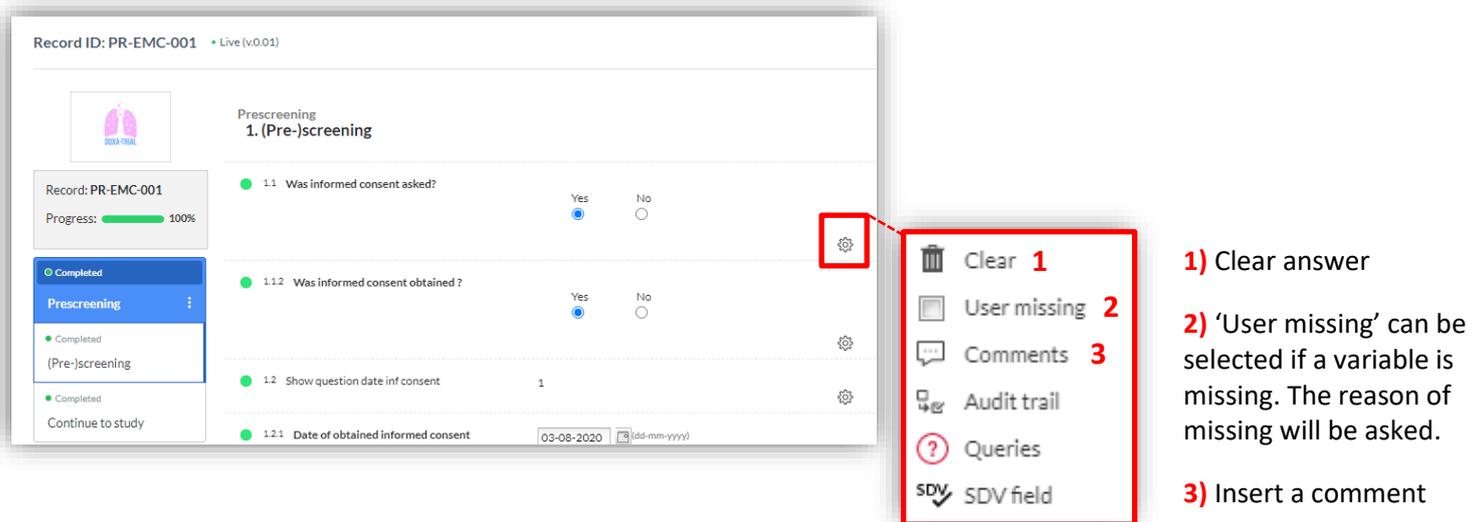
3. Click on '+ New' to create a new record.



4. A pop-up will appear in which you can select your 'Institute', and a record ID will be created automatically. Click 'Next' to continue to the record.



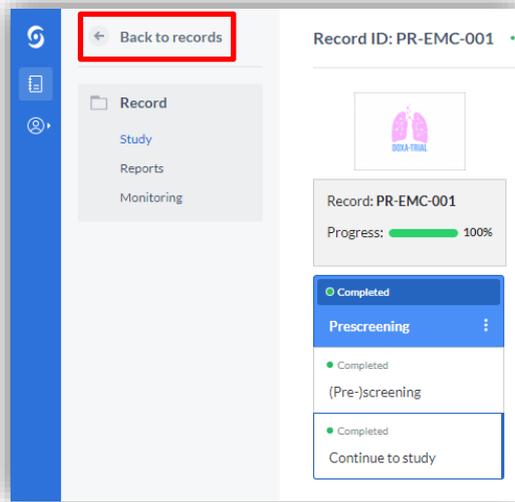
5. The 'Prescreening' page will open and the information can be filled in. To the right of each question an icon to open the settings (clear answer, missing data, add comment) can be selected.



6. If informed consent is obtained and a patient is randomized, the subject number as obtained at randomization in ALEA is asked (format xx-xxx).

11.2.3 Provide subject number as obtained at randomization (ALEA) (format: 00-000)

7. Select **'Back to records'** to close the patient record.



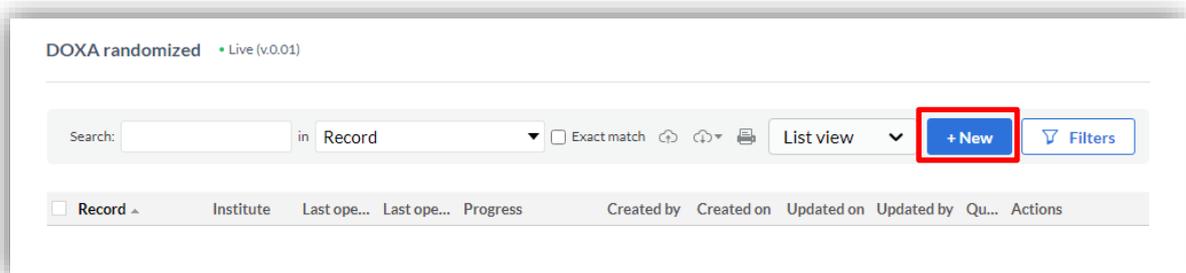
Continue to the randomized database after completion of the prescreening database.

RANDOMIZED DATABASE (randomized patients)

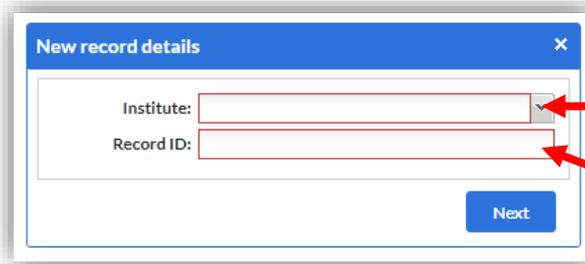
8. Click on **'DOXA randomized'** to open the randomized database.



9. Click on **'+ New'** to create a new record.



10. A pop-up will appear in which you can select your 'Institute' and fill in the 'Record ID'. The Record ID is de **subject number obtained from randomization in ALEA (xx-xxx)**. Click 'Next' to continue to the record.

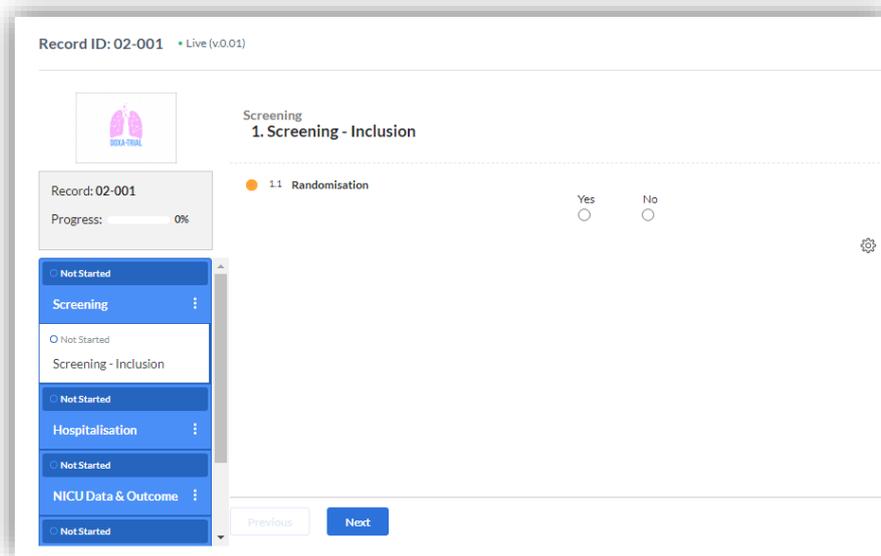


The screenshot shows a 'New record details' pop-up window. It contains two input fields: 'Institute:' and 'Record ID:'. A dropdown arrow is visible on the right side of the 'Institute' field. A blue 'Next' button is located at the bottom right of the form.

Select your institute

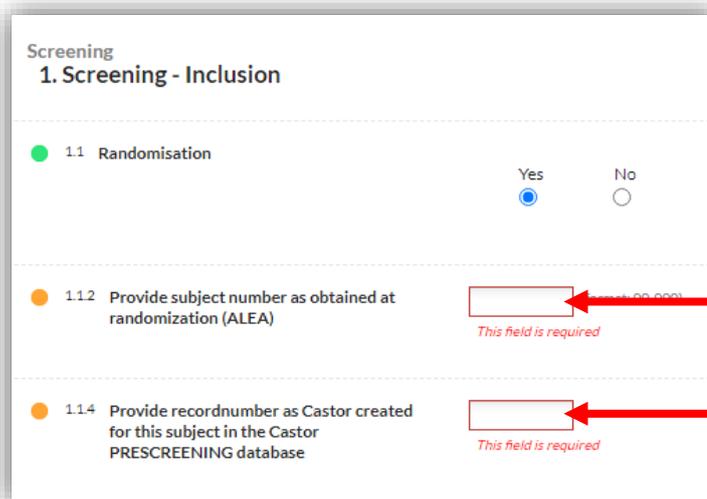
Record ID is the subject number from ALEA (format xx-xxx)

11. The 'Screening – Inclusion' page will open and the information can be filled in. To the right of each question the settings menu can be opened as described in point 6.



The screenshot shows the 'Screening - Inclusion' page in the CASTOR system. The page title is 'Record ID: 02-001 • Live (v0.01)'. Below the title is a progress bar showing 0% completion. The main content area is titled 'Screening 1. Screening - Inclusion' and contains a question '1.1 Randomisation' with 'Yes' and 'No' radio buttons. A settings gear icon is visible to the right of the question. A sidebar on the left shows a list of sections: 'Not Started', 'Screening', 'Screening - Inclusion', 'Hospitalisation', 'NICU Data & Outcome', and 'Not Started'. 'Previous' and 'Next' buttons are at the bottom.

12. The subject number obtained from **randomization in ALEA (xx-xxx)** and the recordnumber created by Castor in the **prescreening database (PR-site-xxx)** will be asked.

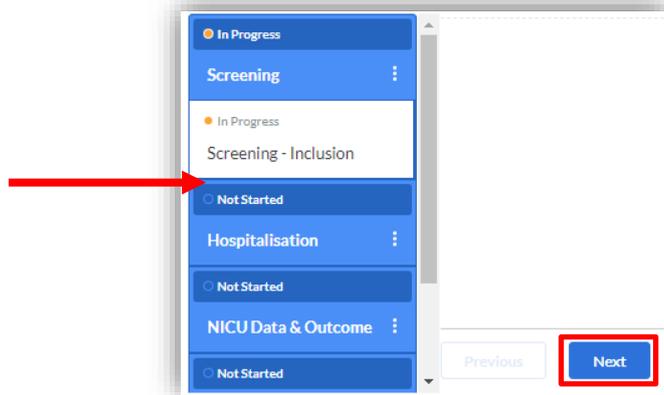


The screenshot shows a close-up of the 'Screening - Inclusion' page. Question 1.12 asks for the 'subject number as obtained at randomization (ALEA)' and question 1.14 asks for the 'recordnumber as Castor created for this subject in the Castor PRESCREENING database'. Both questions have empty input fields and a red error message 'This field is required' below them. Question 1.11 'Randomisation' is also visible above, with the 'Yes' radio button selected.

Subject number obtained from randomization in ALEA (format xx-xxx)

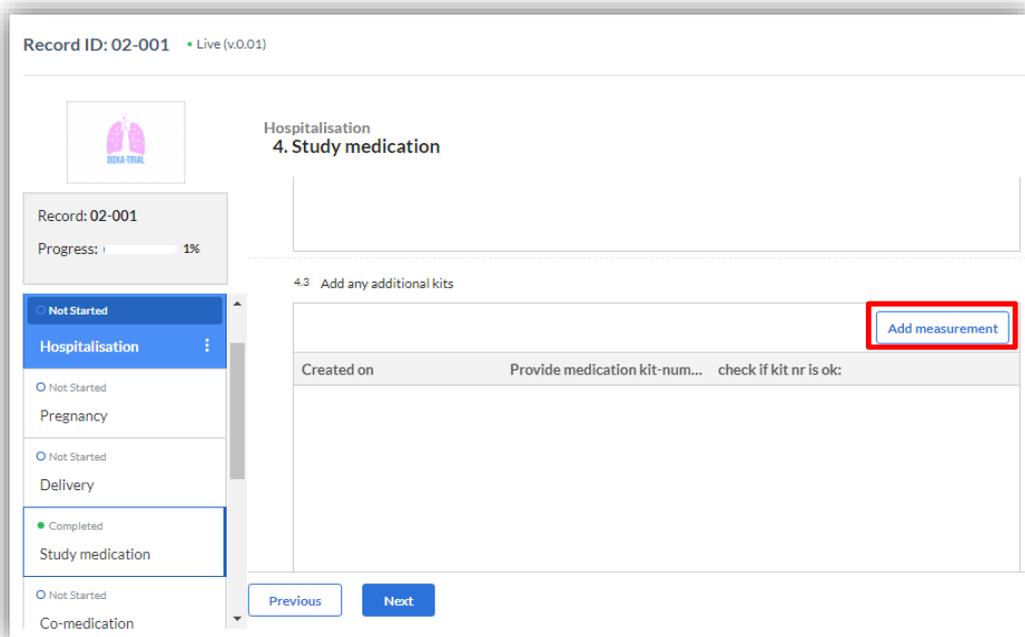
Record number created by Castor in de prescreening database (format PR-site-xxx)

13. Data entry can be continued by clicking **'Next'** or selecting one of the subheadings on the left.

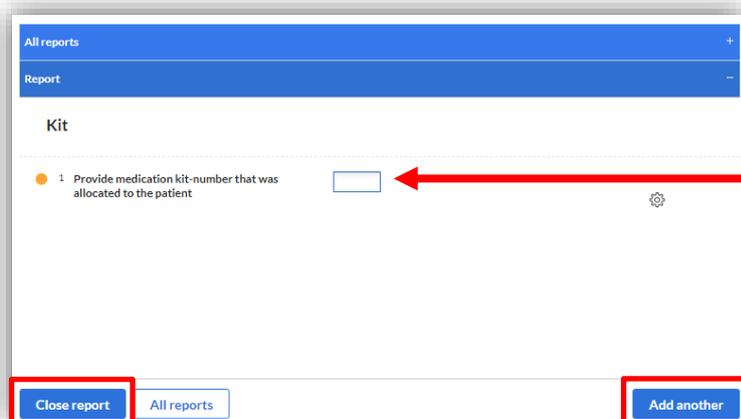


14. The study medication is allocated to a randomized patient using kit numbers. Kit number are dispensed in ALEA (for instructions see randomization procedure). Depended on the duration of therapy one or more kit numbers are allocated to a patient. The kit numbers can be registered in the subheading **'Hospitalisation'** under **'Study medication'**.

Click on **'Add measurement'** to add a kit number to the record.



Click **'Close report'** if the allocated kit number(s) are registered. Click **'Add another'** to add another kit number.



Add kit number
(format xxxxx)