

1. Go to “CRF data”

The screenshot shows the EDC | Electronic Data Capture software interface. At the top, there is a blue header bar with the text "EDC | Electronic Data Capture". Below the header, there is a navigation bar with links for "Home", "CRF" (which is currently selected and highlighted in red), and "Support". On the left side, there is a sidebar titled "Studies overview" with a "Filter" section. The "Filter" section includes dropdown menus for "Study name", "Number", "Study description", "Participants", "Last activity", and "Status". A dropdown menu for "CRF data" is open, showing options like "Search", "Overview", "Working sets", "Imports", "Exports", and "Audit trail". The main content area displays a table with columns for "Study name", "Number", "Study description", "Participants", "Last activity", "Status", and "Sites". There are four items checked in the "Participants" column. The "Status" column shows "Under Construction". The "Sites" column lists various medical institutions with zero participants: Academisch Medisch Centrum (0 participants), Canisius Wilhelmina Ziekenhuis (0 participants), Catharina Ziekenhuis (0 participants), Centre Hospitalier Chrétien-MontLégia (0 participants), CHU Marie Curie (0 participants), CHU Sart-Tilman (0 participants), CHU Tivoli (0 participants), Clinique Saint-Pierre Ottignies (0 participants), Erasmus UMC (0 participants), Hospital Universitaire de Bruxelles (0 participants), Leiden UMC (0 participants), Maasstad Ziekenhuis (0 participants), Medisch Spectrum Twente (0 participants), Radboud UMC (0 participants), Rijnstate Ziekenhuis (0 participants), St. Antonius Ziekenhuis (0 participants), UMC Groningen (0 participants), Universitair Ziekenhuis Brussel (0 participants), and VieCuri Medisch Centrum (0 participants). At the bottom of the page, there are navigation icons for back, forward, and search, along with a "Page size" dropdown set to 10.

Study name	Number	Study description	Participants	Last activity	Status	Sites
TELSTAR2			0	12-3-2025 15:37	Under Construction	<ul style="list-style-type: none">• Academisch Medisch Centrum (0 participants)• Canisius Wilhelmina Ziekenhuis (0 participants)• Catharina Ziekenhuis (0 participants)• Centre Hospitalier Chrétien-MontLégia (0 participants)• CHU Marie Curie (0 participants)• CHU Sart-Tilman (0 participants)• CHU Tivoli (0 participants)• Clinique Saint-Pierre Ottignies (0 participants)• Erasmus UMC (0 participants)• Hospital Universitaire de Bruxelles (0 participants)• Leiden UMC (0 participants)• Maasstad Ziekenhuis (0 participants)• Medisch Spectrum Twente (0 participants)• Radboud UMC (0 participants)• Rijnstate Ziekenhuis (0 participants)• St. Antonius Ziekenhuis (0 participants)• UMC Groningen (0 participants)• Universitair Ziekenhuis Brussel (0 participants)• VieCuri Medisch Centrum (0 participants)

2. Click on “Add participant”

The screenshot shows the EDC interface. At the top, there's a dark blue header bar with the text "EDC | Electronic Data Capture". Below it, a white navigation bar contains links for "Home", "CRF", and "Support". The main area is titled "Data entry". It features a dropdown menu "Sort by entry date" and a section for "Rijnstate Ziekenhuis - RZA" which includes a red-bordered button labeled "Add participant".

3. Click on “Save & open”

The screenshot shows the "Add participant" form. At the top, it says "Add participant" and has a "General" tab selected. Below that, under "Participant details", there's a field for "Participant number" with the placeholder "Automatically generated". At the bottom, there are two buttons: "Save & new" and "Save & open", with "Save & open" also having a red border around it.

4. Click on participant number

Data entry

Sort by entry date

▼ Rijnstate Ziekenhuis - RZA

▶ RZA-00001 RZA-00001

Add participant

5. Click on Randomization

Data entry

Sort by entry date

▼ Rijnstate Ziekenhuis - RZA

▶ RZA-00001 RZA-00001

▶ Randomization Randomization

▶ Informed consent

▶ Baseline

▶ Treatment

▶ Follow up - 72 hours

▶ ICU discharge

▶ Follow up - 3 months

▶ Follow up 6 months

▶ Follow up 12 months

▶ SAE & SUSAR

▶ Additional examinations

▶ End of study

Add participant

6. Click on “Inclusion and randomization”

Data entry

Sort by entry date

▼ Rijnstate Ziekenhuis - RZA

▶ RZA-00001 RZA-00001

▶ Randomization

▶ Inclusion and randomization Inclusion and randomization

▶ Informed consent

▶ Baseline

▶ Treatment

▶ Follow up - 72 hours

▶ ICU discharge

▶ Follow up - 3 months

▶ Follow up 6 months

▶ Follow up 12 months

▶ SAE & SUSAR

▶ Additional examinations

▶ End of study

Add participant

7. Fill out inclusion / exclusion criteria & randomization module

Checklist in- and exclusion criteria		
Inclusion criteria		
Coma (Glasgow Coma Scale score ≤ 8) after out of hospital cardiac arrest and resuscitation	<input checked="" type="radio"/> Yes	<input type="radio"/> No
Age ≥ 18 years	<input checked="" type="radio"/> Yes	<input type="radio"/> No
Continuous EEG with at least eight electrodes started < 24h after return of spontaneous circulation (ROSC)	<input checked="" type="radio"/> Yes	<input type="radio"/> No
ESE or possible ESE according to the Salzburg and ACNS criteria*	<input checked="" type="radio"/> Yes, definite status epilepticus <input type="radio"/> Yes, possible status epilepticus (ictal-interictal continuum) <input type="radio"/> No	
* Explanation diagnosis criteria	NB: - Pattern needs to be present for at least 10 min to fulfil the criteria. - Explanatory ACNS pocket chart can be found here: ACNSNomenclature2021_ReferenceChart_2020_0725ForPublicComment.pdf	
Possibility to start treatment < 3 hours after detection ESE	<input checked="" type="radio"/> Yes	<input type="radio"/> No
Exclusion criteria		
Known history of another medical condition with limited life expectancy (< 6 months)	<input checked="" type="radio"/> Yes	<input type="radio"/> No
Any progressive brain illness, such as a brain tumor or neurodegenerative disease	<input checked="" type="radio"/> Yes	<input type="radio"/> No
Pre-admission Glasgow Outcome Scale score ≤ 3	<input checked="" type="radio"/> Yes	<input type="radio"/> No
EEG background activity prior to the emergence of ESE is indicative of extensive irreversible anoxic brain injury**	<input checked="" type="radio"/> Yes	<input type="radio"/> No
** Explanation EEG background	**Some EEG background patterns strongly associated with extensive anoxic brain injury and unfavorable outcome and implicate exclusion of study: 1. Suppression - burst with identical bursts 2. Suppression - GPDs 3. Persistent suppression for more than 24h prior to ESE onset	
Reason other than the neurological condition to withdraw treatment	<input checked="" type="radio"/> Yes	<input type="radio"/> No
Follow-up impossible due to logistic reasons, for example not living in the Netherlands or Belgium.	<input checked="" type="radio"/> Yes	<input type="radio"/> No
Insufficient understanding of the Dutch or French language.	<input checked="" type="radio"/> Yes	<input type="radio"/> No
Randomization module		
EEG background activity prior to the emergence of ESE*	<input checked="" type="radio"/> Benign	<input type="radio"/> Intermediate
* Explanation EEG background	Benign: normal voltage, continuous or nearly continuous background Intermediate: all backgrounds not meeting "highly malignant" or "benign" criteria.	
Name physician who performs inclusion and randomization	<input type="text"/>	
Date and time of randomization	<input type="text"/>	<input type="button" value="Calendar"/>
	<input type="text"/>	<input type="button" value="Clock"/>

Please note: "EEG background activity" should be filled in order to randomize

8. Click on “Save as complete”

Please note: button may be visible under “Actions” drop down menu

RZA-00001 - Randomization - Inclusion and randomization Status: Empty

Checklist in- and exclusion criteria

Inclusion criteria

Coma (Glasgow Coma Scale score ≤ 8) after out of hospital cardiac arrest and resuscitation	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Age ≥ 18 years	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Continuous EEG with at least eight electrodes started < 24h after return of spontaneous circulation (ROSC)	<input checked="" type="radio"/> Yes <input type="radio"/> No	
ESE or possible ESE according to the Salzburg and ACNS criteria*	<input checked="" type="radio"/> Yes, definite status epilepticus <input type="radio"/> Yes, possible status epilepticus (ictal-interictal continuum) <input type="radio"/> No	
Possibility to start treatment < 3 hours after detection ESE	<input checked="" type="radio"/> Yes <input type="radio"/> No	

* Explanation diagnosis criteria

Definite ESE

- PDs or SW discharges > 2.5 Hz (> 25 discharges in 10s)
- Rhythmic or periodic discharge ≤ 2.5 Hz or any RDA with spatiotemporal evolution
- Rhythmic or periodic discharge ≤ 2.5 Hz or any RDA with time-locked clinical manifestation

Possible ESE

- PDs or SW > 1.0 Hz but ≤ 2.5 Hz (> 10 but ≤ 25 discharges in 10s)
- PDs or SW ≥ 0.5 Hz but ≤ 1 Hz (≥ 5 but ≤ 10 discharges in 10s), with either « + » modifier or fluctuation
- Non-generalized RDA > 1 Hz (≥ 10 waves in 10s), with either a « + » modifier or fluctuation

Pattern needs to be present for at least 10 minutes to fulfill criteria.

Exclusion criteria

9. Click on participant number

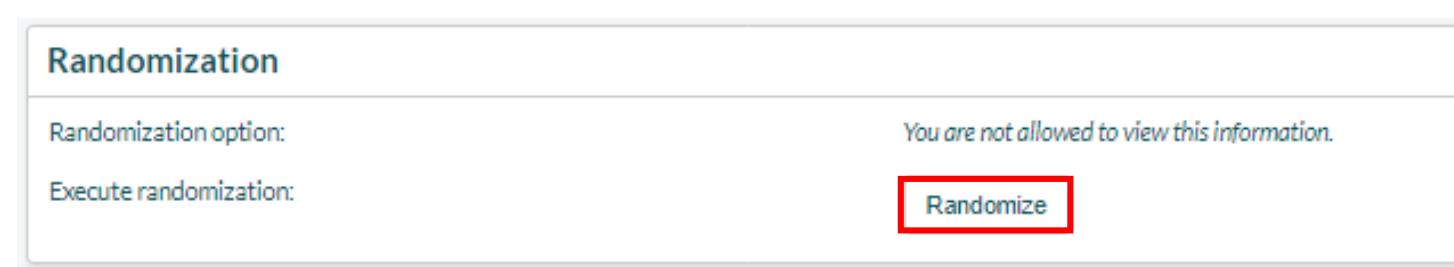


The screenshot shows a participant list interface. At the top, there is a dropdown menu with the option 'Rijnstate Ziekenhuis - RZA'. Below it, a participant record for 'RZA00001' is highlighted with a red box. A small yellow checkmark icon is next to the participant ID. To the right of the participant ID, there is a 'Randomization' link and a 'Inclusion and randomization' button, which is also highlighted with a red box. Below these, there is a list of study events: Baseline, Treatment, Follow up - 72 hours, ICU discharge, Follow up - 3 months, Follow up 6 months, Follow up 12 months, SAE & SUSAR, Additional examinations, and End of study. At the bottom of the list, there is a blue 'Add participant' button.

- ▼ Rijnstate Ziekenhuis - RZA
- ▶ **RZA00001**
- ▼ **Randomization**
- Inclusion and randomization**
- ▶ **Baseline**
- ▶ **Treatment**
- ▶ **Follow up - 72 hours**
- ▶ **ICU discharge**
- ▶ **Follow up - 3 months**
- ▶ **Follow up 6 months**
- ▶ **Follow up 12 months**
- ▶ **SAE & SUSAR**
- ▶ **Additional examinations**
- ▶ **End of study**

Add participant

10. Click on “Randomize”



The screenshot shows a 'Randomization' form. The title is 'Randomization'. Below the title, there is a note: 'Randomization option: You are not allowed to view this information.' Underneath this, there is a 'Execute randomization:' field and a 'Randomize' button, which is highlighted with a red box.

Randomization

Randomization option: *You are not allowed to view this information.*

Execute randomization:

Randomize