Acute Kidney Injury-Epidemiology in ICU Patients 2

CRF Completion Guidelines

Study title: AKI-EPI 2

Sponsor: Ghent University Hospital, Belgium

Version	Date	Reason for revision
1	02.06.2025	Original version
2	11.06.2025	Update after questions from centres

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1 STUDY AND SPONSOR INFORMATION

Study title	Acute Kidney Injury – Epidemiology in ICU patients 2
Acronym	AKI-EPI 2
Sponsor	Ghent University Hospital, Belgium
Coordinating Investigator	Dr Eric Hoste, Ghent

Study chairs

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2 ABBREVIATIONS

CRF	Case Report Form
eCRF	electronic Case Report Form
EDC	Electronic Data Capture
FAQ	Frequently Asked Questions
HIRUZ	Health, Innovation and Research Institute of the Ghent University Hospital
ISF	Investigator Site File
PI	Principal Investigator
REDCap	Research Electronic Data Capture (i.e. Electronic Data Capture software provided and maintained by Vanderbilt University)
TMF	Trial Master File

3 DOCUMENT SCOPE

The aim of this document is to provide guidance on the usage of the Electronic Data Capture (EDC) system, for CRF completion in general as well as for the AKI-EPI 2 study specifically.

4 DOCUMENT FILING AND ARCHIVING

The document will be stored in the Investigator Site File (ISF) at each participating site.
The Sponsor will save this document in the Trial Master File (TMF).

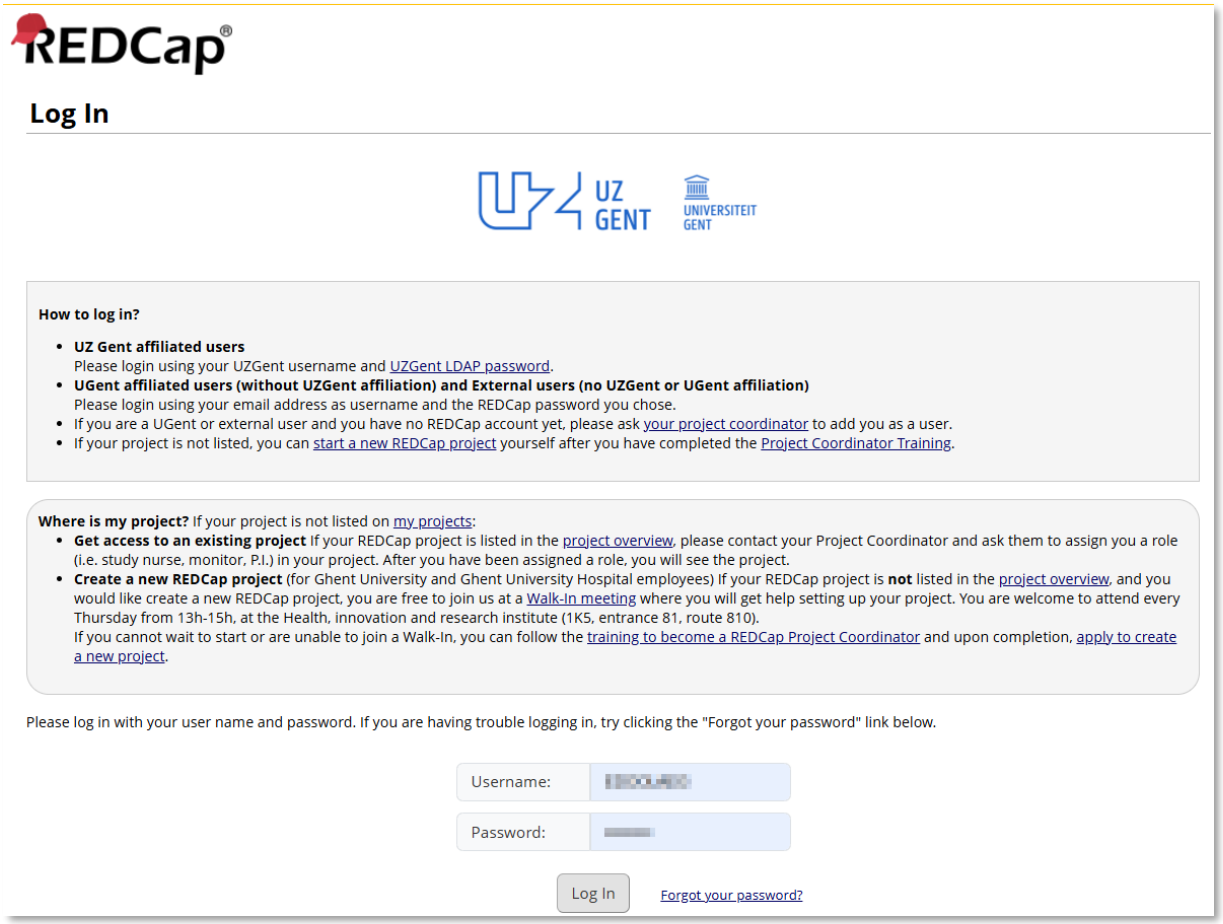
5 ELECTRONIC DATA CAPTURE IN REDCap

Electronic Data Capture (EDC) in this trial is done through the Research Electronic Data Capture system (REDCap), provided by Vanderbilt University and installed and maintained by the Health, Innovation and Research Institute UZ Gent (HIRUZ).

REDCap is available via the following link https://openredcap.uzgent.be
Each study staff member will have his own unique username and password.

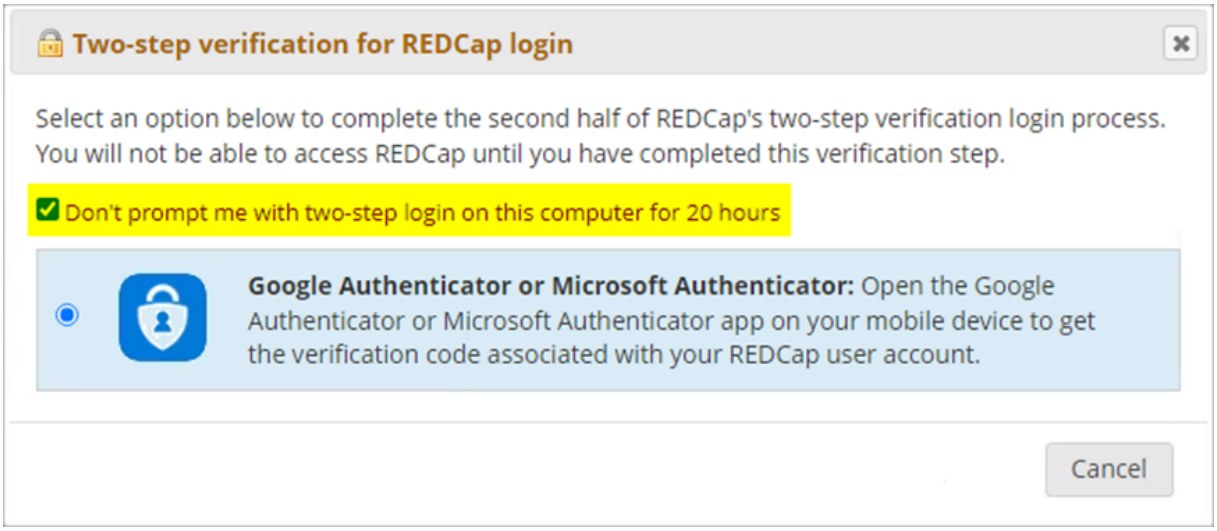
5.1 Getting access to REDCap & the AKI-EPI 2 study

1. Visit https://openredcap.uzgent.be.



- UZ Gent employees
  - Users log in using their UZ Gent username and password.
- Study staff members at other sites
  - External user accounts are created with a table-based login based on the user's email address. The Data Manager will contact the HIRUZ REDCap team to request the creation of new users.
  - The Data Manager will assign the new users to the correct role and institution.

2. On the next screen, check the box "Don't prompt me with two-step login on this computer for 20 hours", to avoid being asked for 2FA information at every login for the next 20 hours. Then, select the "Google Authenticator or Microsoft Authenticator" option.



4. **If you have not yet set up 2FA** for https://openredcap.uzgent.be for your account:

- If you have not yet downloaded an Authenticator app, download & install the Authenticator app of your preference on your mobile device.

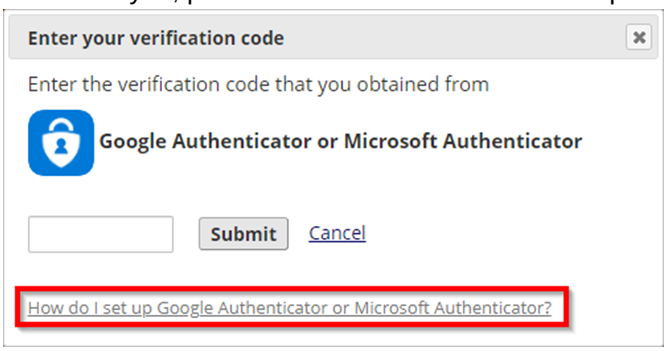
Android

Microsoft Authenticator	Google Play Store	
Google Authenticator	Google Play Store	

Apple

Microsoft Authenticator	Apple App Store	
Google Authenticator	Apple App Store	

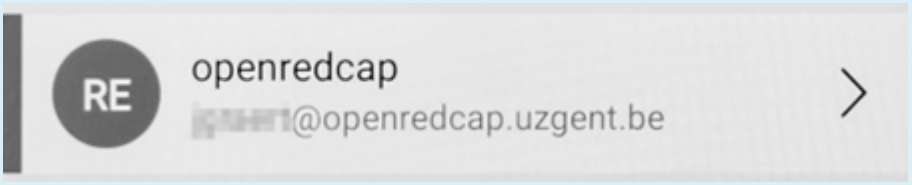
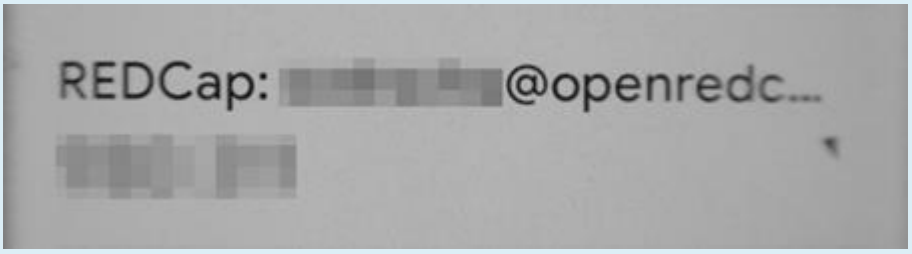
- Click the “How do I set up Google Authenticator or Microsoft Authenticator?” link in the popup and follow the on-screen instructions.
- Attention: these instructions will only be shown once. If the instructions are no longer available to you, please contact the UZ Gent REDCap admin team at redcap@uzgent.be.



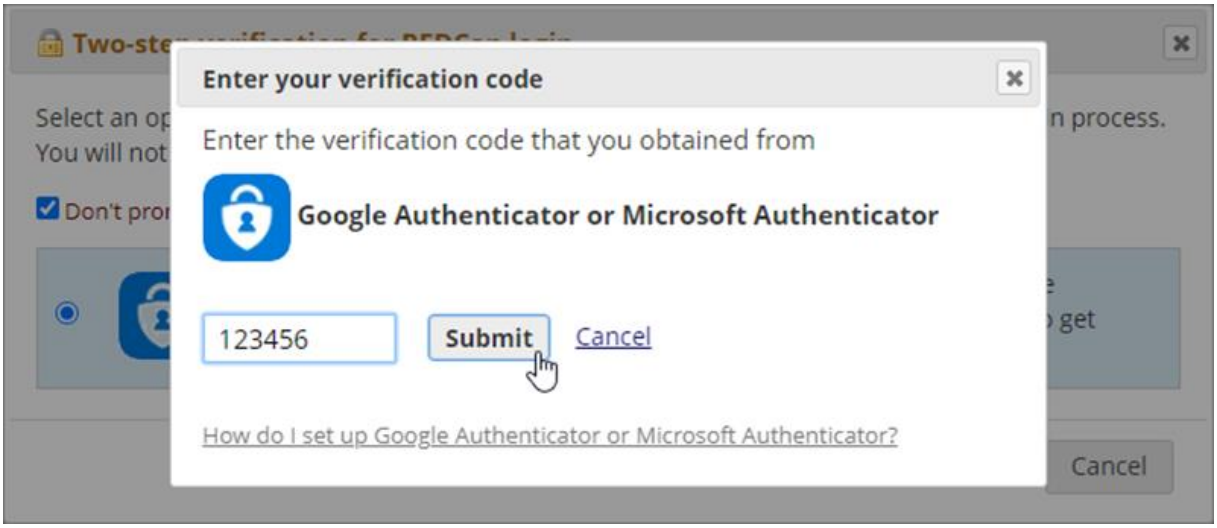
- App-specific instructions on how to add an entry into the Microsoft/Google Authenticator app can be found below:
  - Microsoft Authenticator
    - Click the plus (+) sign.
    - In the ‘Add account’ page, choose ‘Other account’.
    - Scan the QR code displayed on the account site sign in page.
  - Google Authenticator
    - Click the plus (+) sign.
    - Select ‘Scan a QR code’.
    - Scan the QR code displayed on the account site sign in page.

5. **If you have successfully set up 2FA** on https://openredcap.uzgent.be for your account, the verification code can be obtained as follows:

- Open the Authenticator app on your mobile device.
- Locate the entry for openredcap:

Microsoft Authenticator	
Google Authenticator	

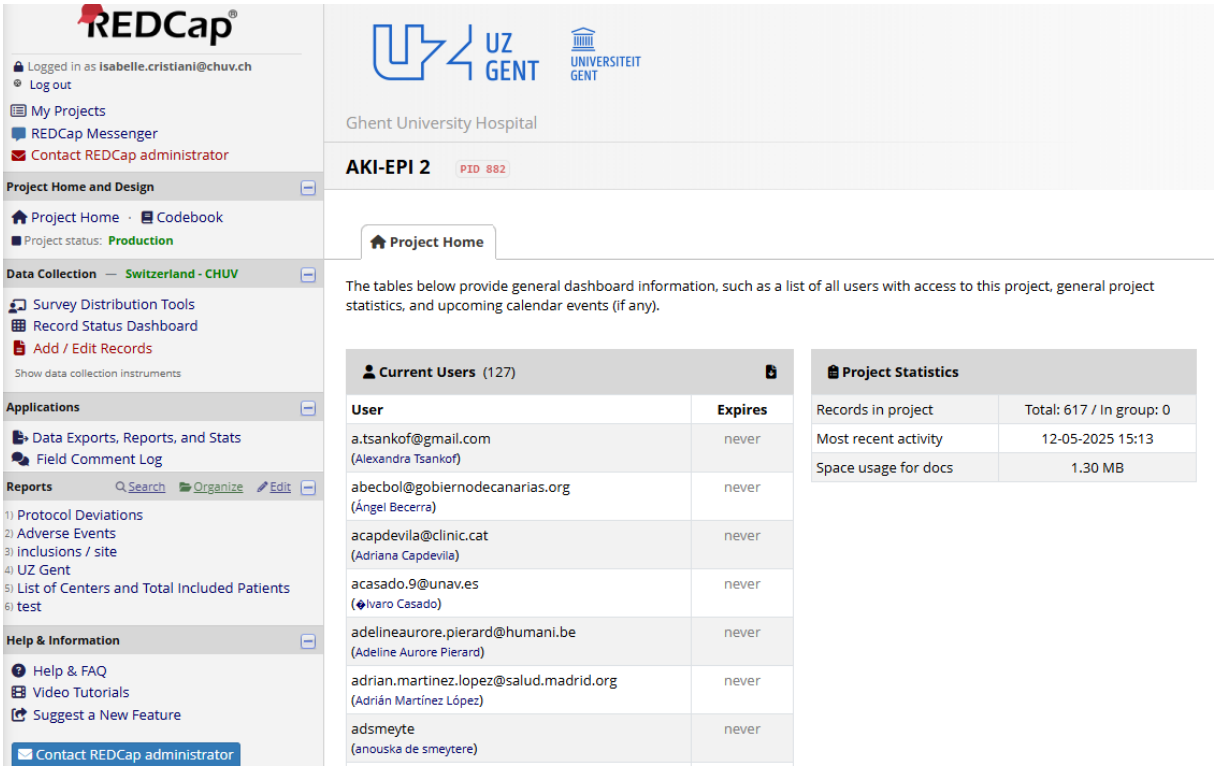
- Copy the appropriate code from the Authenticator app into the field and click 'Submit'



6. **That's it!** You are now logged in using 2FA for the duration of the working day.
7. You will be taken to the 'My Projects' webpage, which contains an overview of all projects you currently have access to.
8. Select the AKI-EPI 2 project. You will be taken to the 'Project Home Page'

6 GUIDANCE ON THE STRUCTURE OF REDCAP

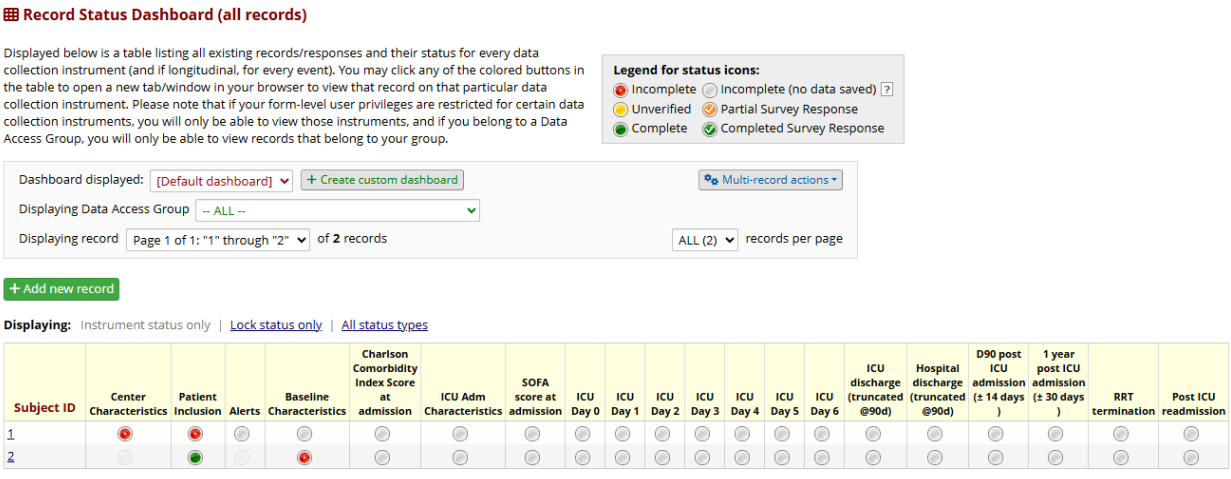
6.1 Project Home Page



The menu on the left-hand site of the 'Project Home Page' provides quick links to different sections (you may not have access to all of them). The sections that will be useful to you are described below.

6.2 Record Status Dashboard

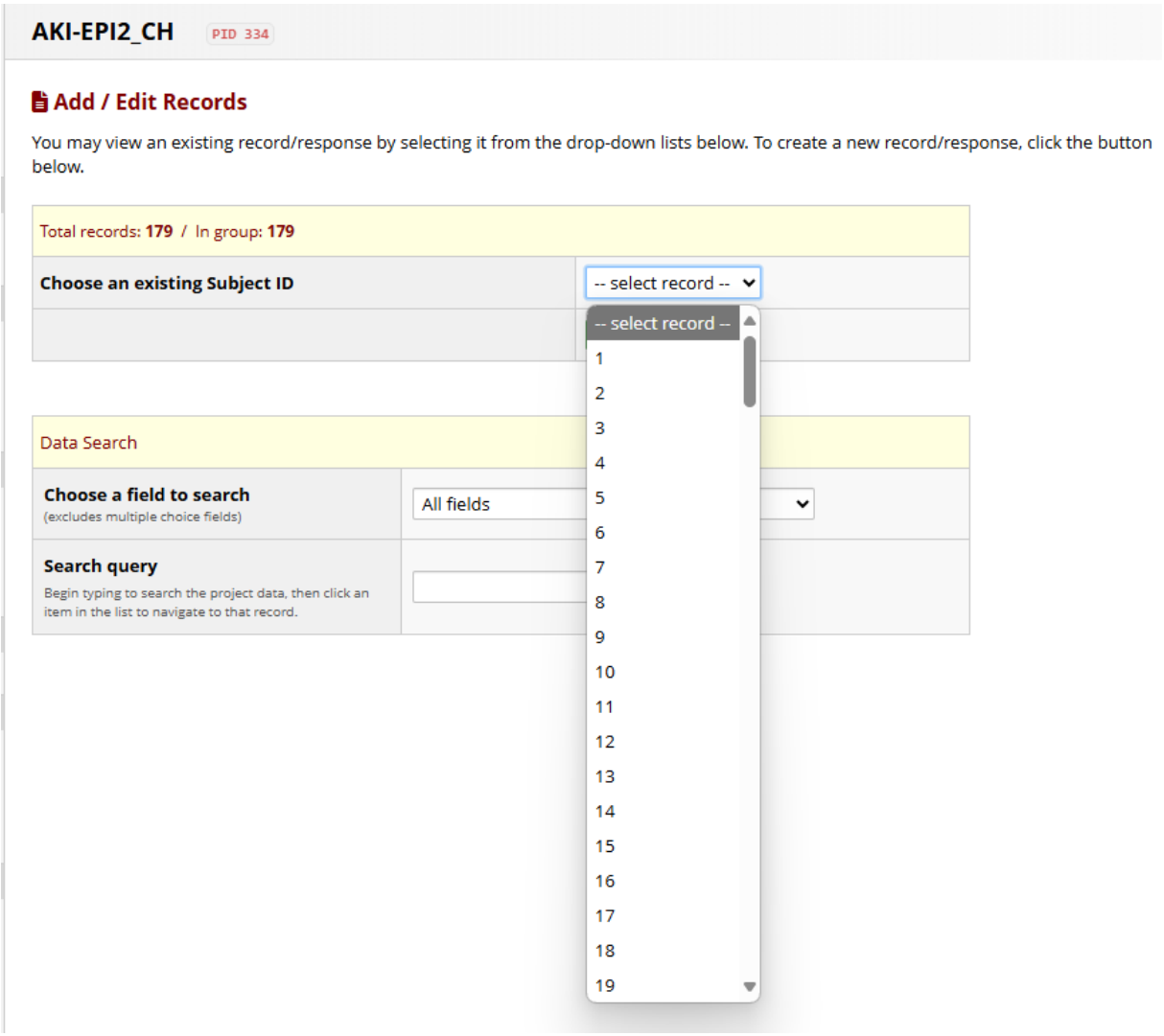
The 'Record Status Dashboard' page displays a table, listing all existing subjects and their status for every CRF and timepoint. You may click any of the colored buttons to open a new tab/window in your browser and view this particular form for this specific record. Alternatively, you can go to the subject's 'Record Home Page' by clicking the Subject ID.



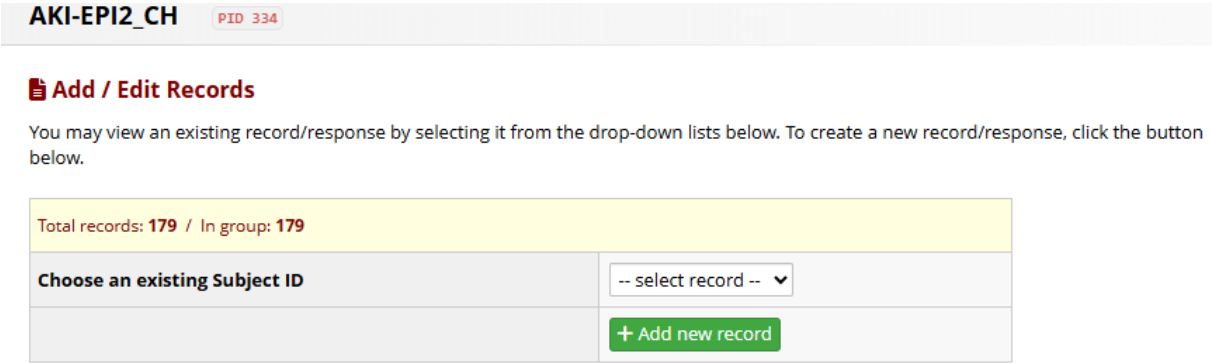
The colors of the buttons are based on the Form Status that is collected at the bottom of every CRF (see section 6.4.5).

6.3 Add / Edit Records

'Add/Edit Records' provides a different way to find existing subjects (besides through the 'Record Status Dashboard'). You may view an existing record by selecting it from the drop-down list:



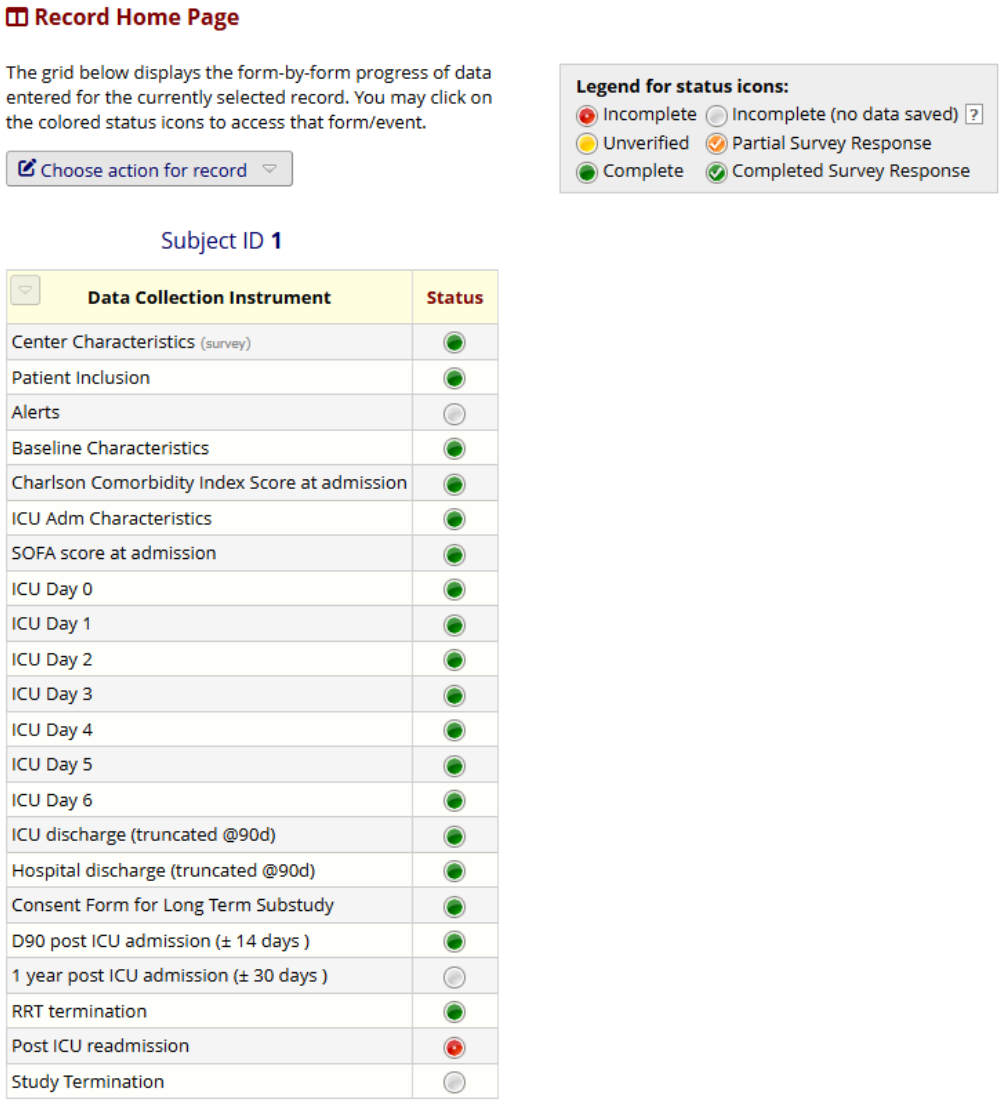
To create a new record, click the green 'Add new record' button:



Alternatively, if the Subject ID is unknown, it is possible to find a subject by searching through a field for which you know the value for that particular subject (e.g. subject's birth year).

6.4 Record Home Page

After selecting a subject (by clicking the Subject ID on the 'Record Status Dashboard', selecting an existing subject on the 'Add / Edit Records' page, or adding a new record on the 'Add / Edit Records' page), you are taken to the 'Record Home Page'. The grid displays the form-by-form progress of data entry for the selected record. You may click on the colored buttons to access a specific CRF for a specific timepoint. The colors of the buttons are based on the Form Status that is at the bottom of every form (see section 6.4.5).

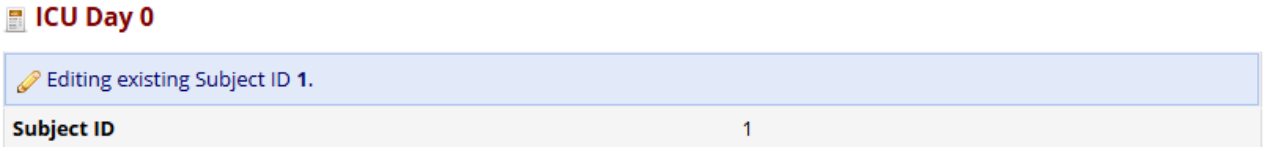


6.5 CRF structure

6.5.1 Form header

Every form has a header, which contains the following information:

- The name of the form
- The name of the participating site the subject is part of (called 'Data Access Group' in REDCap)
- The Subject ID (either displayed as '*Adding new'* or '*Editing existing Subject ID x-y'*)

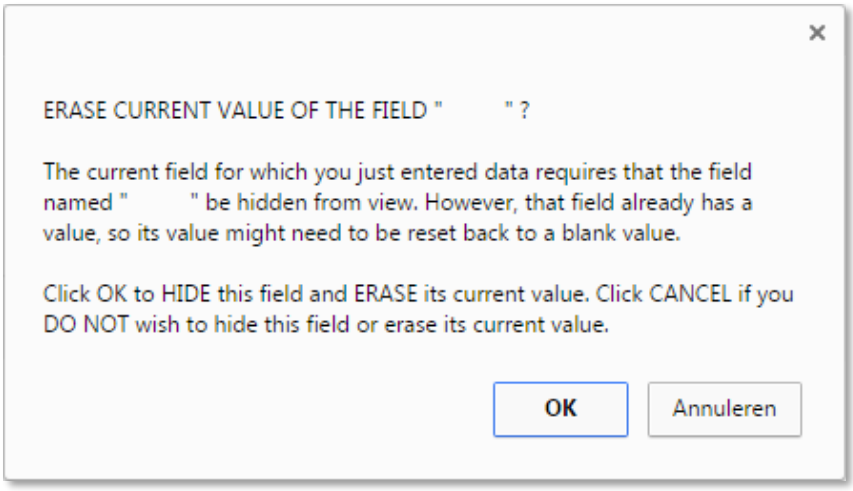


6.5.2 Sections

Every CRF is divided into smaller sections of related questions.

Each CRF is set up in such a way that only relevant sections are shown. Irrelevant sections will be hidden depending on answers to other questions. In case an irrelevant section is shown, or a relevant section is not shown, please check your previous answers.

In case an answer is modified, causing other fields with previously completed data to be hidden, your web browser will show one pop-up per field requesting to erase the values from these fields. Clicking 'OK' will erase the field's value. Clicking 'Cancel' will not erase the value. Please erase data that is no longer applicable.



6.5.3 Required fields

Fields that must be completed on a particular CRF are marked with * must provide value. If a required field on a form is not completed, a warning will be displayed upon saving the CRF. This message can be ignored, but leaving a required field empty will eventually result in a query from the Data Manager.

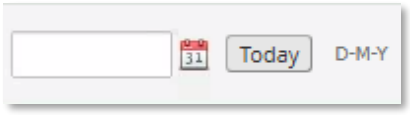
6.5.4 Data field types

A CRF can contain a number of different field types. Please find an overview below.

Text fields:
Text fields can be completed with any type of text.

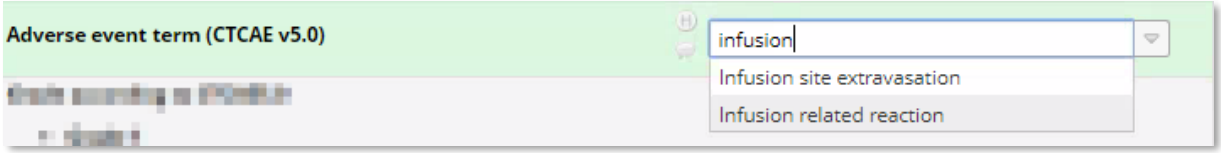
Numerical fields:
Numerical fields look the same as text fields but should be completed with an integer or a number (depending on the question). Furthermore, a minimum and maximum allowed value may be assigned to them. In case a value does not match the defined validation rule(s), a warning is displayed. This warning can be ignored, but an out-of-range value will eventually result in a query from the Data Manager.

Date fields:



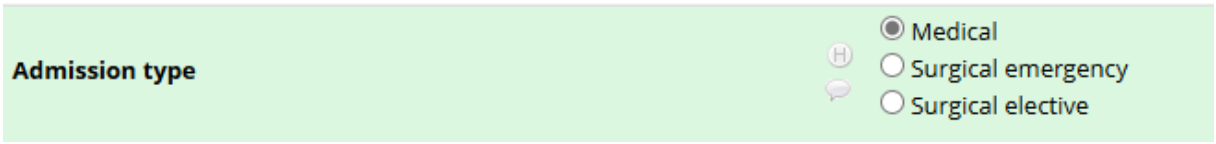
A date can be completed by typing in the field, by choosing a date from the date picker (calendar icon) or by clicking the button 'Today'. The required date format (e.g. D-M-Y) is visible next to the 'Today' button.

Drop-down list (single answer):



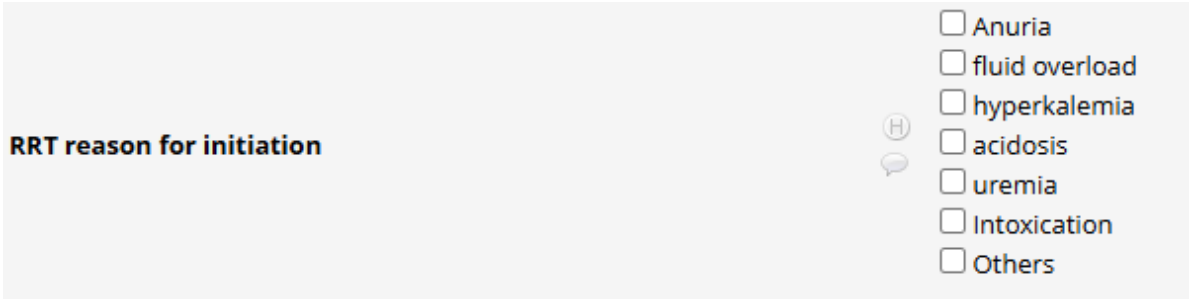
Drop-down lists allow you to select a single answer from a list of pre-specified options. When the option 'enable auto-complete for this drop-down' is ticked in the setting of the field, you can start typing your answer in the field to narrow down the list of possibilities to choose from.

Radio buttons (single answer):



Radio button fields immediately show all possible values, allowing you to select the one applicable option.

Checkboxes (multiple answers):

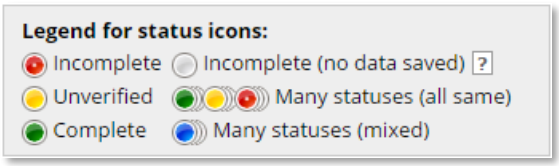


Checkboxes allow you to select multiple options from a list of possibilities.

6.5.5 Form status

At the bottom of each form, a form status can be assigned.

This can be used to reflect the status of data entry.



6.5.6 Data history

Click the icon (H) next to a data field in order to show the data history of that field. The data history is displayed in a table containing all changes made to the field (date/time of change, user & data changes made).

Date/Time of Change	User	Data Changes Made
18-09-2024 08:52:55	[redacted]	Type Ad (SAA > 1.7 mmho) (3)
18-09-2024 08:53:00	[redacted]	Type C (5)
18-09-2024 08:53:06 (most recent data change)	[redacted]	Type A (1)

6.5.7 Data resolution workflow

Clicking the speech balloon next to a data field will open the related 'Data Resolution Workflow' pop-up. This pop-up displays the 'Data Resolution Workflow' for the specified record, field and timepoint and records a documented process of resolving a data issue.
Depending on the user role, different user privileges may apply that relate to opening, responding to and closing data queries.
All data queries can also be viewed on the 'Resolve Issues' page in this project.

Fields can have several data resolution workflow icons next to them:

 No currently outstanding query

 There is an open query, which is yet unresponded

 There is an open query, which has been responded

 The query is already closed/resolved

7 STUDY-SPECIFIC GUIDANCE

7.1 Guidelines for completing a form

7.1.1 Date and time format

Dates should be entered in dd-mm-yyyy format or chosen from the calendar e.g. 14-02-2025.
Time should be entered in 24-hour clock format (hh:mm) e.g. 14:30.

7.1.2 Units

If the standard unit used at your site is not available in the predefined list of units, please contact the Data Manager to check if an additional unit can be added.

7.1.3 Comments

A comments field is present at the bottom of each CRF. This field should be used only to provide additional information that cannot be reported in a field on the form and that might help clarify the subject's situation, to reduce the query load and/or increase the query efficiency (e.g. confirmation of an out-of-range value reported in the form).

7.1.4 Data entry error

In case a form or event is created that is not needed, please remove all data from the specific form and add the following comment: 'Form/event created in error, can be removed.'. The Data Manager will then remove the unwanted form/event.

7.2 Clarification regarding timepoints

ICU Day 0
Day 0 refers to the day of ICU admission and lasts until your data management system's cut-off time. For example, if data is collected until 6 a.m., any events occurring before this time (e.g., at 5 a.m.) are considered part of Day 0, while events at 7 a.m. fall under Day 1.

For instance, if a patient is admitted at 8 p.m. on Day 0 and your data management system ends at 6 a.m., urine output would be collected for 10 hours on Day 0. However, if your system resets at midnight, then urine would have been collected on Day 0 for only 4 hours.

7.3 Clarification regarding forms

If a patient does not meet inclusion criteria, please do not create a CRF.

7.3.1 Center characteristics

Type of area: Urban/Rural/Remote

Urban: when the hospital is located in urban environment / city and the patients referred to the hospital are also predominantly from an urban environment
Rural: when the hospital recruits patients from rural environment
Remote: > 6 hours from tertiary center

Level of care: Primary/secondary/tertiary
Primary Care: indicates the first contact the person has with a health system. Treatments are a standard set of treatments
Secondary Care: indicates a level of care involving specialist care
Tertiary Care: indicates a higher level of specialist care, i.e. as provided in university centers

Is your ICU open or closed
In a closed ICU, the patient management and treatment prescriptions are by ICU staff only. It is possible that in a closed ICU a non-ICU specialist suggests treatments or medication. However, it is the ICU staff that actually prescribes these.
In an open ICU, also non-ICU staff can prescribe treatment or medication

Typical nurse to patient ratio
Indicate here the number of patients treated by 1 nurse. If this number varies e.g. different during night shifts and day shifts, please indicate the lowest number of patients cared for by 1 nurse in your unit.

Typical senior physician to patient ratio (day shift)
Indicate here the number of patients treated by 1 senior physician. If this number varies e.g. different during weekends, please indicate the lowest number of patients cared for by 1 senior physician in your unit.

Who prescribes RRT? Nephrology/ICU/both
Please indicate who prescribes RRT.

7.3.2 Patient inclusion

Exclusion criteria “Readmission to the ICU during the same hospitalization episode”:
A patient can only be enrolled once in the study.
If a patient has been admitted in the ICU for 24h or less, this is not considered an ICU admission, and the patient could not be included in the AKI-EPI 2 study. Therefore, if this patient is readmitted in the ICU, this patient may be included.

Inclusion criteria “Informed consent according to the ethical committee”:
Even if no consent is needed in your juridiction, please tick the box.

7.3.3 Baseline characteristics

Race/Ethnicity
Please indicate the race/ethnicity as assessed by the investigator.

Hypertension
Please indicate if the patient has a medical history of hypertension or is chronically treated with antihypertensive drugs.

Diabetes
Please indicate if the patient has a medical history of diabetes, treated by insulin or oral antidiabetics.

Height and weight

1. Consider pre-op or pre-admission weight. If not available,
2. Consider lowest weight measured during ICU stay. If not available,
3. Estimated weight by ICU staff. If not available,
4. Missing

Baseline serum creatinine
Serum creatinine concentration (sCr) considered representative for kidney function before admission to the ICU**.**

To help determine representative values, we propose to consider values according to the 5 Tiers (in decreasing preference):

1. sCr within 3 Mo assessed in the outpatient clinic if not available consider
2. sCr within 3 Mo while in hospital (not ICU) if not available consider
3. sCr within 3-12 Mo assessed in the outpatient clinic if not available consider
4. sCr within 3-12 Mo while in hospital (not ICU) if not available consider
5. The lowest of either admission creatinine, or the CKD-EPI 2021 back-calculated creatinine (see table; see tool)

If >1 value within tier: take median value. Do not consider creatinine concentration recordings at time of AKI, or in episodes with "false low" concentration e.g. after volume resuscitation, or at time of severe muscle wasting e.g. after prolonged bed rest or critical illness.

Age (years)	Scr Females (mg/dl)	Scr Females (µmol/L/)	Scr Males (mg/dL)	Scr Males (µmol/L/)	eGFR
18	1.10	97	1.40	123	75
19	1.09	96	1.39	123	75
20	1.09	96	1.38	122	75
21	1.08	95	1.37	121	75
22	1.07	95	1.37	121	75
23	1.07	94	1.36	120	75
24	1.06	94	1.35	120	75
25	1.06	93	1.35	119	75
26	1.05	93	1.34	118	75
27	1.05	92	1.33	118	75
28	1.04	92	1.33	117	75
29	1.04	92	1.32	117	75
30	1.03	91	1.31	116	75
31	1.03	91	1.31	115	75
32	1.02	90	1.30	115	75
33	1.01	90	1.29	114	75
34	1.01	89	1.29	114	75
35	1.00	89	1.28	113	75
36	1.00	88	1.27	112	75
37	0.99	88	1.27	112	75
38	0.99	87	1.26	111	75
39	0.98	87	1.25	111	75
40	0.98	86	1.25	110	75
41	0.97	86	1.24	110	75
42	0.97	86	1.23	109	75
43	0.96	85	1.23	108	75
44	0.96	85	1.22	108	75
45	0.95	84	1.21	107	75
46	0.95	84	1.21	107	75
47	0.94	83	1.20	106	75
48	0.94	83	1.20	106	75
49	0.93	83	1.19	105	75
50	0.93	82	1.18	104	75
51	0.92	82	1.18	104	75
52	0.92	81	1.17	103	75
53	0.91	81	1.16	103	75
54	0.91	80	1.16	102	75
55	0.91	80	1.15	102	75
56	0.90	80	1.15	101	75
57	0.90	79	1.14	101	75
58	0.89	79	1.13	100	75
59	0.89	78	1.13	100	75
60	0.88	78	1.12	99	75

61	0.88	78	1.12	99	75
62	0.87	77	1.11	98	75
63	0.87	77	1.11	98	75
64	0.86	76	1.10	97	75
65	0.86	76	1.09	97	75
66	0.86	76	1.09	96	75
67	0.85	75	1.08	96	75
68	0.85	75	1.08	95	75
69	0.84	74	1.07	95	75
70	0.84	74	1.07	94	75
71	0.83	74	1.06	94	75
72	0.83	73	1.06	93	75
73	0.82	73	1.05	93	75
74	0.82	72	1.04	92	75
75	0.82	72	1.04	92	75
76	0.81	72	1.03	91	75
77	0.81	71	1.03	91	75
78	0.80	71	1.02	90	75
79	0.80	71	1.02	90	75
80	0.80	70	1.01	89	75
81	0.79	70	1.01	89	75
82	0.79	70	1.00	89	75
83	0.78	69	1.00	88	75
84	0.78	69	0.99	88	75
85	0.78	69	0.99	87	75
86	0.77	68	0.98	87	75
87	0.77	68	0.98	86	75
88	0.76	67	0.97	86	75
89	0.76	67	0.97	85	75
90	0.76	67	0.96	85	75
91	0.75	66	0.96	85	75
92	0.75	66	0.95	84	75
93	0.74	66	0.95	84	75
94	0.74	65	0.94	83	75
95	0.74	65	0.94	83	75
96	0.73	65	0.93	82	75
97	0.73	64	0.93	82	75
98	0.72	64	0.92	82	75
99	0.72	64	0.92	81	75
100	0.72	63	0.91	81	75

Do you suspect that there is chronic kidney disease (CKD)?

You should tick “Yes” when there is *known or suspected* CKD (eGFR<60).

7.3.4 ICU Adm characteristics

Admission type: Medical
Primary reason for admission is medical, i.e. non-surgical.

Admission type: Surgical emergency
Emergent surgical procedures are for acute pathology and are planned less than 24-h before surgery.

Admission type: Surgical elective
Elective surgical procedures are planned more than 24-h before surgery.

7.3.5 ICU discharge (truncated @90d)

In case the patient stays in the ICU for a long time, we limited the observation period to 90 days: 'truncated @90d'. In other words, if the patient stays in the ICU/hospital for 91 days or more, we ask for the outcome data as they appear at day 90 of ICU/hospital stay.

How many days was the patient admitted to the ICU? (Length of ICU stay): consider full calendar days (eg if the patient was admitted in ICU on 04 June 2025 at 6pm and discharged on 06 June 2025 at 8am, enter 3 days).

Total number of days on vasopressors (any dose): consider epinephrine, norepinephrine, vasopressin and phenylephrine. Consider full calendar days (eg if the patient was on vasopressors only for 2 hours on Day 1, enter 1 day).

Total number of days on inotropes (any dose): consider dobutamine, dopamine, Milrinone and Levosimendan. Consider full calendar days (eg if the patient was on inotropes only for 2 hours on Day 1, enter 1 day).

7.3.6 Hospital discharge (truncated @90d)

1. Hospital Discharge:

This is hospital in general, not only the hospital of index admission.
In case of transfer to another hospital, enter discharge date of the other hospital.

In case your ethics approval allows you to collect data solely at your hospital, enter discharge date at your hospital.

2. How many days was the patient admitted to the hospital? (Length of hospital stay):

This should include the whole stay in hospital: so starting at hospital admission, and ending at hospital discharge. In case of 2 hospitals, without discharge to home in between, this starts in hospital 1, and ends in hospital 2.

In case your ethics approval allows you to collect data solely at your hospital, only consider length of stay at first hospital.

3. Did RRT and Blood Purification take place :
- Blood Purification (hemoadsorption with any device, for instance CytoSorb or Jafron HA380 utilization of an Oxiris filter, Polymixin B or others)
- Hemodialysis
- Plasmapheresis

7.3.7 D90 post ICU admission (± 14 days) / 1 year post ICU admission (± 30 days)

These are the forms when patients are contacted at 90 d and 1 y after inclusion, for recording of survival, quality of life (EQ-5D questionnaire), use of RRT and creatinine if available.

For patients that cannot be reached at D90, attempts to contact them at D365 should be made and data at D90 can be collected retrospectively (except for EQ-5D).

For creatinine value at D90, please only consider analyses made within the D90 ± 14 days window.

For creatinine value at D365, please only consider analyses made within the D365 ± 30 days window.

The EQ-5D questionnaires are provided in an electronic form by Ghent/Lausanne.

If your centre does not participate in this follow-up, you see both D90 and D365 forms but you won't be able to access them.

7.3.8 RRT termination

Reason for RRT termination
- Recovered
- Palliative care
- Not weaned but alive
- Not weaned and died

➔ Not weaned means still receiving **dialysis**.

7.3.9 Post-ICU readmission (truncated@90d)

This form is only for centers participating in the follow-up.

1. **Was the patient readmitted after the index admission?**
This is hospital readmission into any hospital after discharge from the hospital of first admission.
This does not include transfer to another hospital.
This is truncated at D90.

2. If Post ICU readmission is Yes, serum creatinine value is asked.
This is the value taken the day of (first) readmission.