criticalcare RESEARCH GROUP | The University Of Queensland AUSTRALIA | ELSO | SPRINT SARI 2019 n-CoV | ISARIC

COVID-19 Critical Care Consortium Incorporating ECMOCARD

This document is updated weekly to reflect current data collection questions raised by ECMOCARD sites

Frequently Asked Questions – Data Queries and Entry

1. We are unsure of one of the database questions. **Who do we contact?**

Please initially direct all ECMOCARD clinical data queries to your site Principal Investigator. Is still unresolved, please contact Chief Investigator Gianluigi Li Bassi (g.libassi@uq.edu.au), or Study Coordination Team ECMOCARD@health.qld.gov.au.

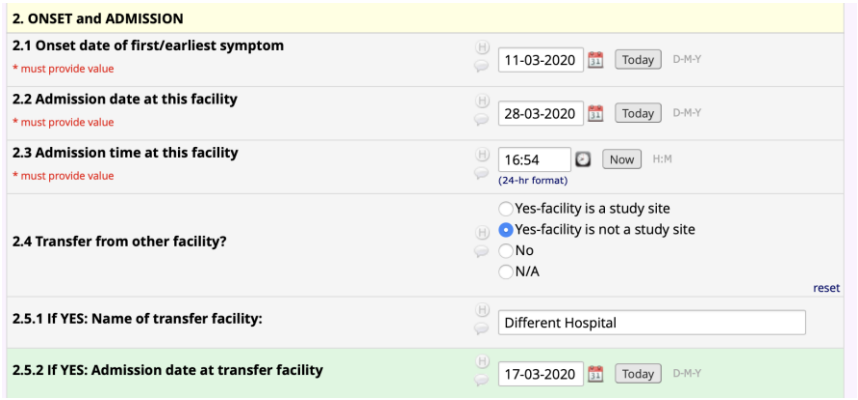
A 'drop-in' teleconference to raise and address ECMOCARD data queries will also be available every Tuesday at 4:15pm-5:15pm AEST and every Thursday at 7:30am-8:30am AEST. The teleconference can be accessed via the links https://uqz.zoom.us/j/98419097289 (Tuesday) and https://uqz.zoom.us/j/94398152451 (Thursday).

Please address all ISARIC nCoV form queries to ncov@isaric.org. Below is a table to highlight the most appropriate contact depending on what form the query is contained in.

Data Collection Instrument	**Contact**
Participant Identification Number Pin	ncov@isaric.org
Data Platform Terms of Submission	
Inclusion Criteria	
Demographics	
Onset and Admission	
Admission Signs and Symptoms	
Pre Admission Medication	
Comorbidities	
Daily Form	
Treatment	
Complications	
Infectious Respiratory Disease Diagnosis	
Infectious Respiratory Disease Pathogen Testing	
Medication	
Outcome	
Core Additional Information	
EOT ICU Admis	g.libassi@uq.edu.au OR ECMOCARD@health.qld.gov.au
EOT Start Mech Vent	
EOT Start ECMO	
EOT Final	
EOT Daily	

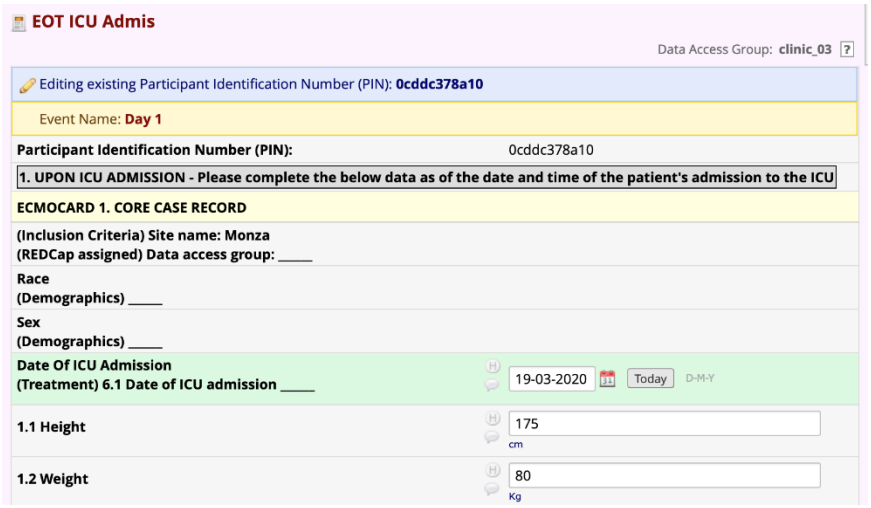
2. A patient was admitted for initial treatment to an outside hospital ICU which *does not* participate in ECMOCARD. The patient has then been transferred to your ICU for further treatment. **Which ICU admission date do you use?**

In case of patients transferred from another facility, it is crucial to record appropriate date of onset of symptoms, admission date to the first hospital ('*Transfer Facility*'), admission date to the second hospital ('*This Facility*', which is the facility collaborating with the study), as reported in the example below:



2. ONSET and ADMISSION	
2.1 Onset date of first/earliest symptom * must provide value	11-03-2020 Today D-M-Y
2.2 Admission date at this facility * must provide value	28-03-2020 Today D-M-Y
2.3 Admission time at this facility * must provide value	16:54 Now H:M (24-hr format)
2.4 Transfer from other facility?	Yes-facility is a study site Yes-facility is not a study site No N/A reset
2.5.1 If YES: Name of transfer facility:	Different Hospital
2.5.2 If YES: Admission date at transfer facility	17-03-2020 Today D-M-Y

As for the admission to the ICU, we are interested in comprehensively appraising the clinical status of patients upon their first admission to the ICU. Hence, always report dates and blood gas test results from the first ICU admission, assuming that results from the previous admission can be evaluated, as reported in the example below.



EOT ICU Admis

Data Access Group: **clinic_03**

Editing existing Participant Identification Number (PIN): **0cddc378a10**

Event Name: **Day 1**

Participant Identification Number (PIN):	0cddc378a10
1. UPON ICU ADMISSION - Please complete the below data as of the date and time of the patient's admission to the ICU	
ECMOCARD 1. CORE CASE RECORD	
(Inclusion Criteria) Site name: Monza **(REDCap assigned) Data access group: ____**	
Race **(Demographics) ____**	
Sex **(Demographics) ____**	
Date Of ICU Admission **(Treatment) 6.1 Date of ICU admission ____**	19-03-2020 Today D-M-Y
1.1 Height	175 cm
1.2 Weight	80 Kg

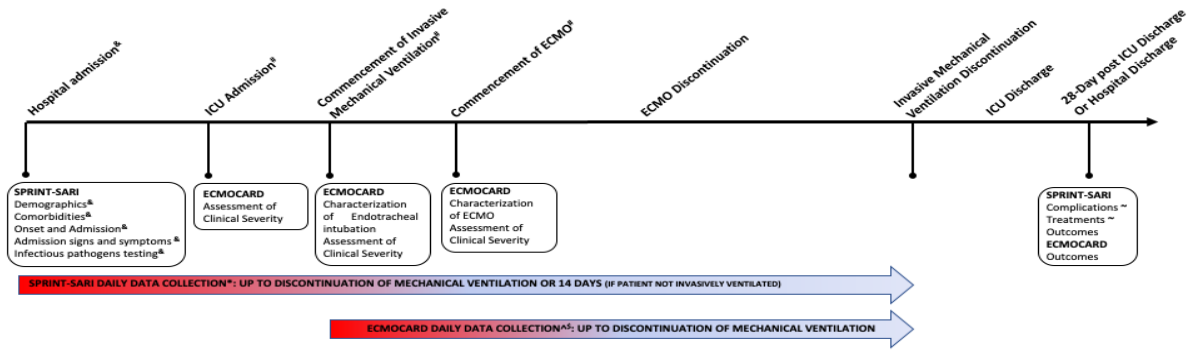
3. A patient was admitted for initial treatment to an outside hospital ICU which *does* participate in ECMOCARD. The patient has then been transferred to your ICU for further treatment. How do we keep collecting REDCap data for this patient?

If a patient was enrolled in ECMOCARD at another facility, please attempt to contact the facility from which the patient came and ascertain their patient ID (including site code and patient number). Please then enter this number when creating the patient's REDCap record at your site, and continue entering the patient's data from there.

4. How long do I need to complete **daily patient data** ('EOT Daily')for?

Daily assessment for ECMOCARD commences 24 hours after the patient is put on invasive mechanical ventilation, and continues until the patient is removed from mechanical ventilation or patient death, whichever occurs first.

The figure below depicts key events and data collection.



& If the patients was transferred from another hospital, please refer to medical charts from previous hospitalization
* Sprint-Sari daily data collection starts upon hospital admission and comprises arterial blood gases, neurological and haemodynamic parameters and laboratory results, including infectious pathogens testing. *Data collectors will record data retrospectively to review data from previous 24h and identify the worst values*
^ ECMOCARD daily data collection starts upon endotracheal intubation and comprises mechanical ventilator and ECMO settings, adjunctive ventilatory support, blood gases, laboratory results, transfusions, infectious and haemorrhagic complications. *Data collectors will record data retrospectively to review data from previous 24h and identify worst values*
$ The majority of ECMOCARD parameters are matched with SPRINT-SARI parameters by date of assessment. Always report the date of data collection
# These events may all occur prior to ICU admission. If the patients was transferred from another department/hospital, please refer to medical charts from previous hospitalization
~ The majority of these parameters are categorical (yes/no) and can be completed as soon as the event occurs during ICU stay

5. There are two daily forms ('Daily Data' & 'EOT Daily') in the database. **Do I need to complete both?**

Yes. Please complete the ISARIC daily form (Daily Data) for 14 days post hospital admission or discontinuation of mechanical ventilation (whichever comes first), and the ECMOCARD daily form (EOT Daily) from 24 hours after commencement of mechanical ventilation until discontinuation of mechanical ventilation or death.

Please note: If your centre does not have the resources to collect data for all days, please focus your efforts to complete full daily forms for the first few days of daily data.

6. Tidal volume (Qs 3.19 & 4.12) is measured in mL/kg of ideal body weight (IBW). **How do I calculate IBW?**

ECMOCARD uses the ARDS-Net formula to calculate IBW as below:

Male patients: 50 + [0.91 * (centimeters of height – 152.4)]

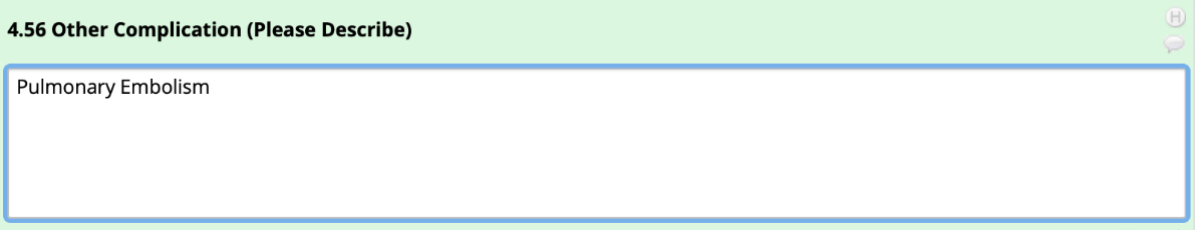
Female patients: 45.5 + [0.91 * (centimeters of height – 152.4)]

The final values for tidal volume to be entered into REDCap is as below:

(patient's tidal volume associated with the 'worst' ABG in mL) / (IBW in kg)

6. Which **'Other Complications'** (Q 4.56) should I report on the ECMOCARD Daily Data forms?

Please record (in English, if possible), and complication the patient experienced on that study day as demonstrated below.



7. What constitutes the **'worst' blood gas** (Qs 1.15-1.20, 2.6-2.11, 3.17-3.28, 4.10-4.21)?

In ECMOCARD, 'worst' blood gas is defined as the arterial blood gas with the lowest PaO_2/FiO_2 ratio. Please calculate the PaO_2/FiO_2 ratio by dividing the PaO2 in mmHg by the FiO2 as a decimal.

For example:

The patient's PaO2 was 88 mmHg and the patient's corresponding FiO_2 was 0.4 (40%).

The equation would be 88/0.4 = 220

8. The way the **blood gas data** is collected on the ISARIC 'Daily Form' and the 'EOT Daily' form are different. Is this a mistake?

No, the ISARIC/SPRINT SARI study do collect blood gas data differently. Please follow the instructions on each of the Data Collection Instruments/ CRF for correct completion.

9. When collecting **infection data** (Qs 4.43-4.51), how do we know when an infection has been resolved? Do we need to record infections once only, or daily until they are resolved?

Please record active infections only upon diagnosis of the infection. Often, in order to diagnose an infection, microbiology cultures will be needed and results will be available after 2 days or longer. If results come back positive and infection is diagnosed, the date when the microbiology sample was obtained is the date of commencement of the infection.

10. A patient was admitted to your ICU with COVID-19 and enrolled in ECMOCARD. The patient was discharged some time later, but then re-admitted to the ICU and re-intubated. Do we re-commence collecting daily data on this patient?

If the patient is re-admitted to your ICU with respiratory failure directly related to their COVID infection, then technically they would be eligible for re-enrolment to the study if resources at your site allow.

If the patient was re-admitted and intubated for a reason other than COVID-19, then they are no longer eligible as per the inclusion/exclusion criteria and should not have more data collected on them. Just complete the patient's outcome data as per their first ICU admission.

11. What is the frequency of data collection for the Basic CRF?

The Basic CRF only requires data collection on key events:

Admission to ICU

Day 4 of admission to ICU

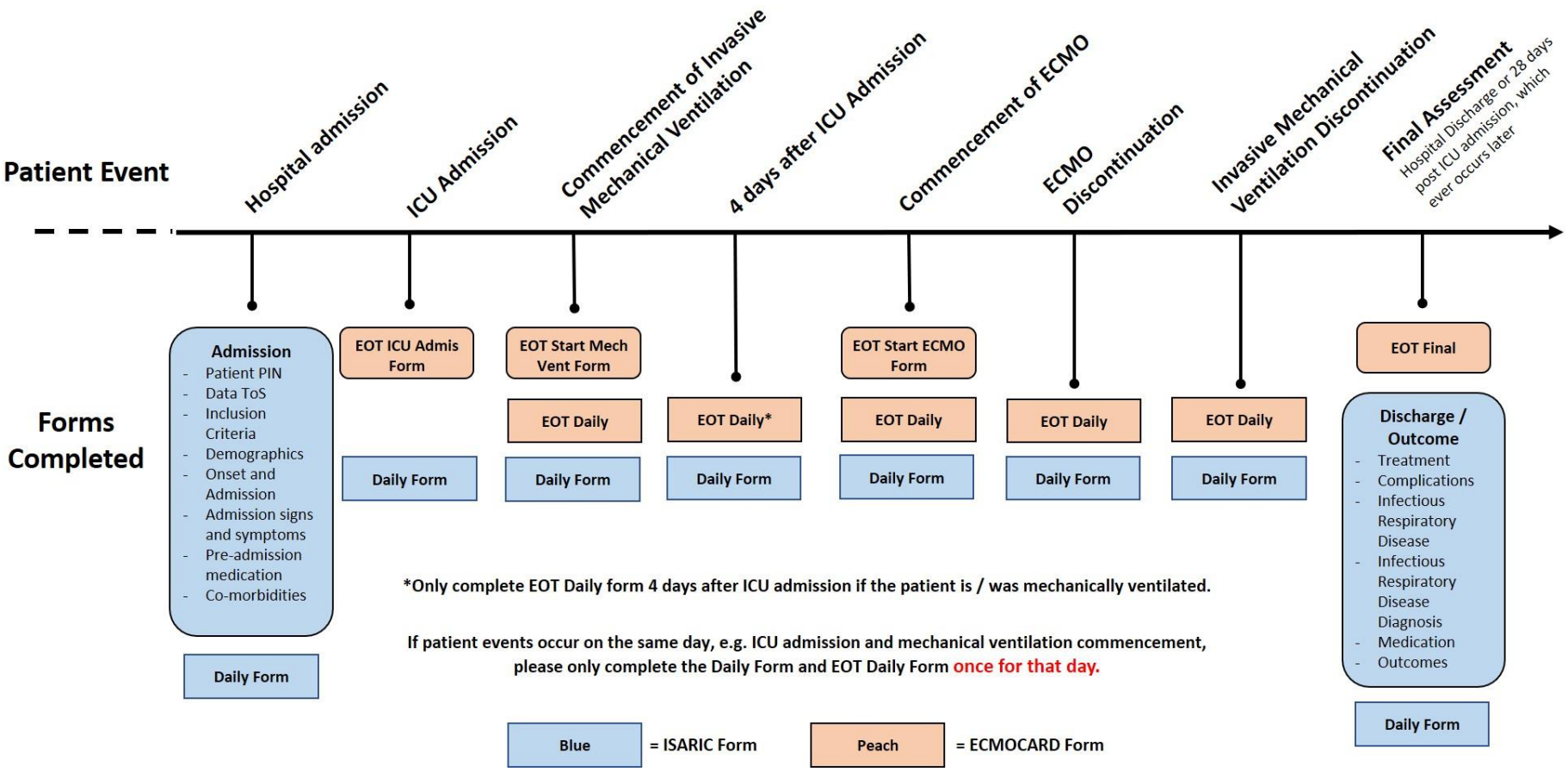
Commencement of Mechanical Ventilation

Commencement of ECMO

Cessation of Mechanical Ventilation

Cessation of ECMO

Discharge from ICU



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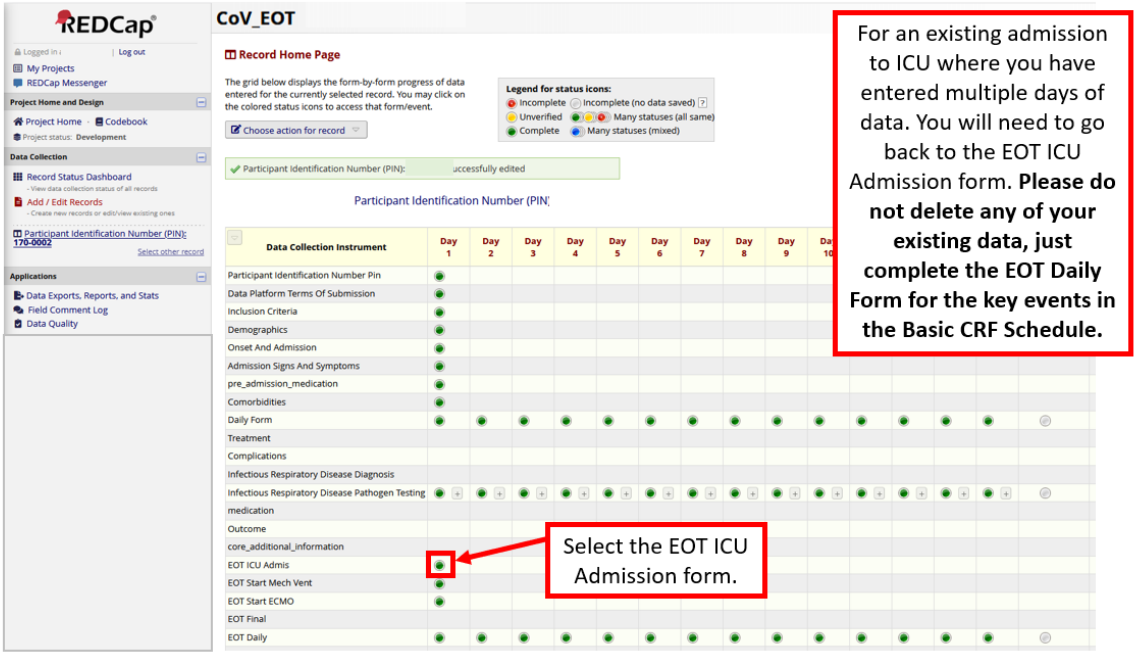
12. How a current admission from the full CRF to the basic CRF?

For an existing admission to ICU where you have entered multiple days of data. You will need to go back to the EOT ICU Admission form. Please do not delete any of your existing data, just complete the EOT Daily Form for the key events in the Basic CRF Schedule.

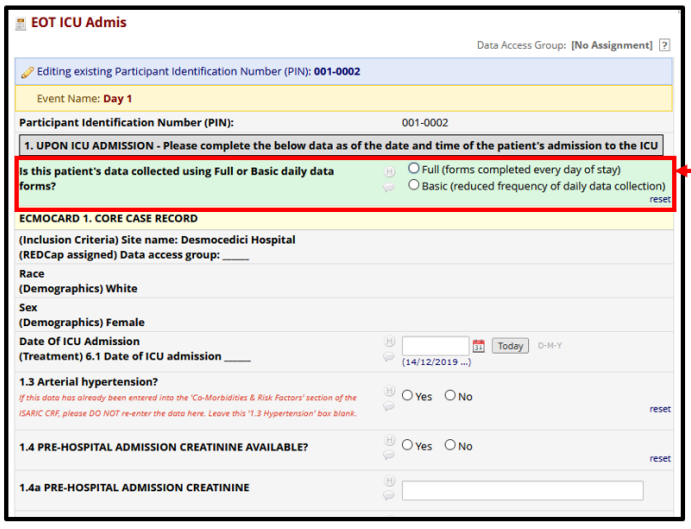
Accessing Basic CRF (Current Admission)



For an existing admission to ICU where you have entered multiple days of data. You will need to go back to the EOT ICU Admission form. **Please do not delete any of your existing data, just complete the EOT Daily Form for the key events in the Basic CRF Schedule.**

Accessing Basic CRF

Please do not delete any of your existing data, just complete the EOT Daily Form for the key events in the Basic CRF Schedule.

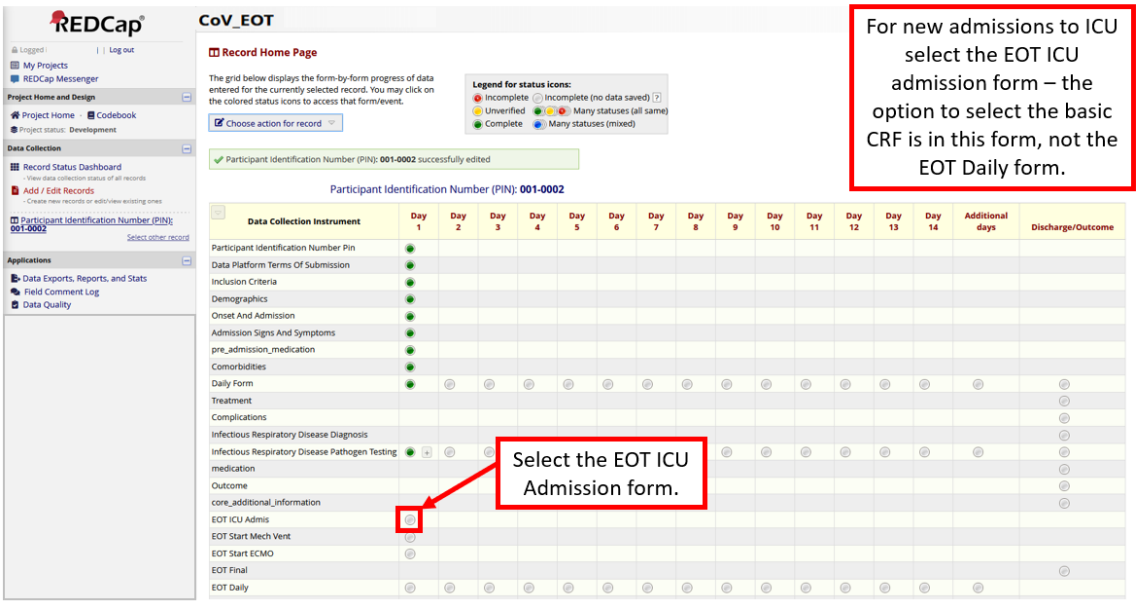
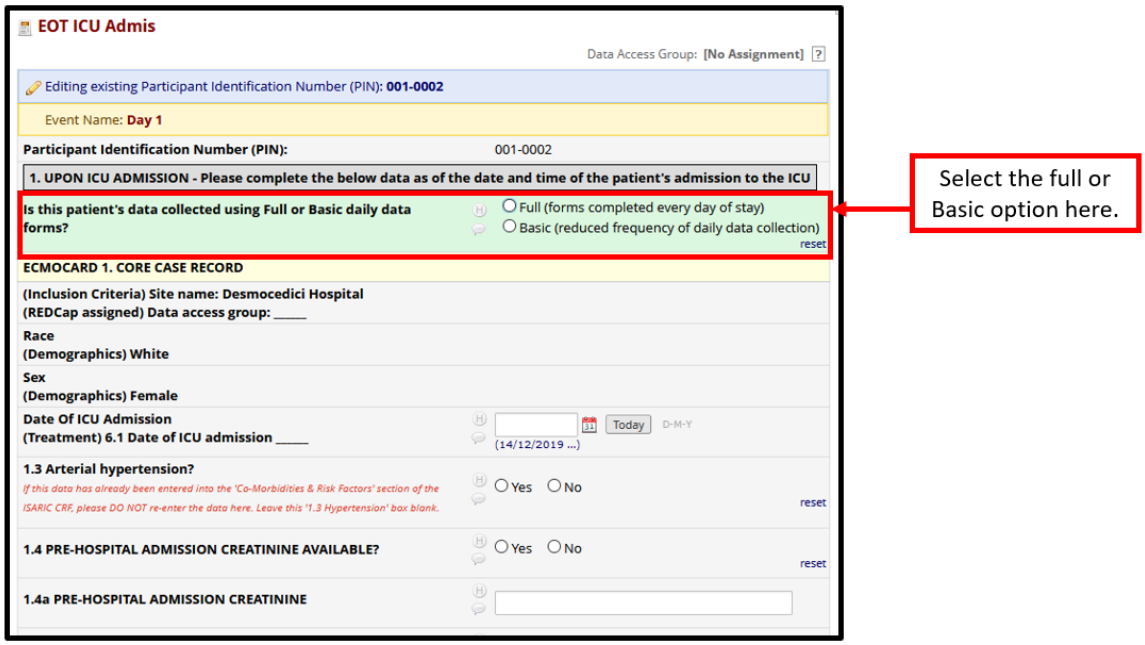


Select the Basic option here.

13. Where do I find the basic CRF?

The basic CRF is encompassed with in the main CRF. You select the basic CRF option in the EOT ICU Admission form.

Accessing Basic CRF (New Admission)



Accessing Basic CRF