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. If 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.

<table>
<thead>
<tr>
<th>Data Collection Instrument</th>
<th>Contact</th>
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<tbody>
<tr>
<td>Participant Identification Number Pin</td>
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<tr>
<td>Data Platform Terms of Submission</td>
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<td>Inclusion Criteria</td>
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<td>Demographics</td>
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<td>Onset and Admission</td>
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<tr>
<td>Admission Signs and Symptoms</td>
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<td>Pre Admission Medication</td>
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<tr>
<td>Comorbidities</td>
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<tr>
<td>Daily Form</td>
<td><a href="mailto:ncov@isaric.org">ncov@isaric.org</a></td>
</tr>
<tr>
<td>Treatment</td>
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<tr>
<td>Complications</td>
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<tr>
<td>Infectious Respiratory Disease Diagnosis</td>
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<td>Infectious Respiratory Disease Pathogen Testing</td>
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<tr>
<td>Medication</td>
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<tr>
<td>Outcome</td>
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<td>Core Additional Information</td>
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<tr>
<td>EOT ICU Admis</td>
<td><a href="mailto:g.libassi@uq.edu.au">g.libassi@uq.edu.au</a> OR <a href="mailto:ECMOCARD@health.qld.gov.au">ECMOCARD@health.qld.gov.au</a></td>
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<tr>
<td>EOT Start Mech Vent</td>
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<tr>
<td>EOT Start ECMO</td>
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<tr>
<td>EOT Final</td>
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<td>EOT Daily</td>
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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:

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.
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.

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)]

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Female patients: $45.5 + [0.91 \times (\text{centimeters of height} - 152.4)]$

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

\[(\text{patient’s tidal volume associated with the ‘worst’ ABG in mL}) / (\text{IBW in kg})\]

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.

   ![Image](image.png)

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 PaO2/FiO2 ratio. Please calculate the PaO2/FiO2 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 FiO2 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
**Patient Event**

- Hospital admission
- ICU Admission
- Commencement of Invasive Mechanical Ventilation
- 4 days after ICU Admission
- Commencement of ECMO
- ECMO Discontinuation
- Invasive Mechanical Ventilation Discontinuation
- Final Assessment

**Forms Completed**

- **Admission**
  - Patient PIN
  - Data ToS
  - Inclusion Criteria
  - Demographics
  - Onset and Admission
  - Admission signs and symptoms
  - Pre-admission medication
  - Co-morbidities

- **Daily Form**
  - EOT ICU Admis Form
  - EOT Start Mech Vent Form
  - EOT Daily
  - EOT Daily*
  - EOT Daily
  - EOT Daily
  - EOT Daily
  - EOT Daily
  - EOT Daily

- **Discharge / Outcome**
  - Treatment:
    - Complications
    - Infectious Respiratory Disease
    - Infectious Respiratory Disease Diagnosis
    - Medication
    - Outcomes

**Notes**

- Only complete EOT Daily form 4 days after ICU admission if the patient is / was mechanically ventilated.
- If patient events occur on the same day, e.g. ICU admission and mechanical ventilation commencement, please only complete the Daily Form and EOT Daily Form once for that day.

**Color Coding**

- Blue = ISARIC Form
- Peach = ECMOCARD Form
12. How to change 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.

Select the EOT ICU Admission form.

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.