COVID-19 CORE CASE REPORT FORM

ACUTE RESPIRATORY INFECTION CLINICAL CHARACTERISATION DATA TOOL

DESIGN OF THIS CASE REPORT FORM (CRF)
This CRF is set up in modules to be used for recording data on the ISARIC COVID-19 Core Database or for independent studies.

Module 1 and Module 2 complete on the first day of presentation/admission or on first day of COVID-19 assessment.
Module 2 also complete on first day of admission to ICU or high dependency unit, or if receiving critical care in any ward, and on any days that research specific samples are taken. In addition, complete daily if of interest for local, specific analysis. Continue to follow-up patients who transfer between wards.
Module 3 (Outcome) complete at discharge or death

GENERAL GUIDANCE

- The CRF is designed to collect data obtained through examination, interview and review of hospital notes. Data may be collected prospectively or retrospectively if the patient is enrolled after the admission date.
- For more detailed guidance on how to complete these forms, please refer to the CRF Completion Guideline.
- Participant Identification Numbers consist of a 3 or 5 digit site code and a 4 digit participant number.
  You can obtain a site code and register on the data management system by contacting ncov@isaric.org. Participant numbers should be assigned sequentially for each site beginning with 0001. In the case of a single site recruiting participants on different wards, or where it is otherwise difficult to assign sequential numbers, it is acceptable to assign numbers in blocks or incorporate alpha characters. E.g. Ward X will assign numbers from 0001 or A001 onwards and Ward Y will assign numbers from 5001 or B001 onwards. Enter the Participant Identification Number at the top of every page.
- Printed paper CRFs may be used for later transfer of the data onto the electronic database.
- For participants who return for re-admission to the same site, start a new form with a different Participant Identification Number. Please check “YES-admitted previously to this facility” in the RE-ADMISSION section. Enter as 2 separate entries in the electronic database.
- For participants who transfer between two sites that are both collecting data on this form, it is preferred to have the data entered by a single site as a single admission, under the same Participant Identification Number. When this is not possible, the first site should record “Transfer to other facility” as an OUTCOME, and the second site should start a new form with a new patient number and indicate “YES-transferred from other facility” RE-ADMISSION.
- Complete every line of every section, except where the instructions say to skip a section based on a response.
- Selections with circles (〇) are single selection answers (choose one answer only). Selections with square boxes (□) are multiple selection answers (choose as many answers as are applicable).
- Mark ‘Not done’ for any results of laboratory values that are not available, not applicable or unknown.
- Avoid recording data outside of the dedicated areas. Sections are available for recording additional information.
- If using paper CRFs, we recommend writing clearly in ink, using BLOCK-CAPITAL LETTERS.
- Place an (X) when you choose the corresponding answer. To make corrections, strike through (-------) the data you wish to delete and write the correct data above it. Please initial and date all corrections.
- Please keep all of the sheets for a single participant together e.g. with a staple or participant-unique folder.
- Please transfer all paper CRF data to the electronic database. All paper CRFs needs to be stored locally, do not send any forms to us. Data are accepted only via secure electronic database.
- Please enter data on the electronic data capture system at https://ncov.medsci.ox.ac.uk/. If your site would like to collect data independently, we are happy to support the establishment of locally hosted databases.
- Please contact us at ncov@isaric.org if you need help with databases, if you have comments and to let us know that you are using the forms.
**MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM**

### CLINICAL INCLUSION CRITERIA

Suspected or confirmed novel coronavirus (COVID-19) infection:  
- [ ] Yes  
- [ ] No

Is COVID-19 the reason for hospital admission?  
- [ ] Yes, COVID-19 is the reason for hospital admission  
- [ ] No, the patient is admitted to hospital for a reason other than COVID-19

### DEMOGRAPHICS

- **Clinical centre name:** ____________________________  
- **Country:** ____________________________  
- **Enrolment date /first COVID-19 assessment date:**   
  - [ ] Day [ ] Month [ ] Year  
  - [ ] Month [ ] Year

- **Ethnic group (check all that apply):**  
  - [ ] Arab  
  - [ ] Black  
  - [ ] East Asian  
  - [ ] South Asian  
  - [ ] West Asian  
  - [ ] Latin American  
  - [ ] White  
  - [ ] Aboriginal/First Nations  
  - [ ] Other: ____________________________  
  - [ ] Unknown

- **Employed as a Healthcare Worker?**  
  - [ ] Yes  
  - [ ] No  
  - [ ] Unknown  
  - **Employed in a microbiology laboratory?**  
  - [ ] Yes  
  - [ ] No  
  - [ ] Unknown

- **Sex at Birth:**  
  - [ ] Male  
  - [ ] Female  
  - [ ] Not specified/Unknown  
  - **Age:** [ ] [ ] [ ] years OR [ ] [ ] [ ] months

- **Pregnant?**  
  - [ ] Yes  
  - [ ] No  
  - [ ] Unknown  
  - **If YES: Gestational weeks assessment:**   
  - [ ] [ ] [ ] weeks

- **POST PARTUM (within 6 weeks of delivery)?**  
  - [ ] Yes  
  - [ ] No  
  - [ ] Unknown (if NO or Unknown skip this section)

- **Pregnancy Outcome:**  
  - [ ] Live birth  
  - [ ] Still birth  
  - **Delivery date:**   
  - [ ] Day [ ] Month [ ] Year  
  - [ ] Month [ ] Year

- **Baby tested for COVID-19/SARS-CoV-2 infection?**  
  - [ ] Yes  
  - [ ] No  
  - [ ] Unknown  
  - **If YES, result of test:**  
  - [ ] Positive  
  - [ ] Negative  
  - [ ] Unknown  
  - (If Positive, complete a separate CRF for baby)

- **INFANT – Less than 1 year old?**  
  - [ ] Yes  
  - [ ] No (If NO skip this section)

- **Birth weight:**   
  - [ ] [ ] [ ] kg or [ ] [ ] lbs  
  - [ ] Unknown

- **Gestational outcome:**  
  - [ ] Term birth (≥37wk GA)  
  - [ ] Preterm birth (<37wk GA)  
  - [ ] Unknown

- **Breastfed?**  
  - [ ] YES-currently breastfeeding  
  - [ ] YES-breastfeeding discontinued  
  - [ ] NO  
  - [ ] Unknown

- **Vaccinations appropriate for age/country?**  
  - [ ] Yes  
  - [ ] No  
  - [ ] Unknown

### PREVIOUS COVID-19 INFECTIONS

- **Has the patient had COVID-19 previously?**  
  - [ ] No  
  - [ ] Yes - once previously  
  - [ ] Yes - twice previously  
  - [ ] Yes - three times previously

  (there is more space on the eCRF to capture this)

- **First COVID-19 infection: When did their first COVID infection occur?** (MM/YY)   
  - [ ] Yes, confirmed by testing  
  - [ ] No, not confirmed by testing

- **Were they admitted to hospital for their first infection of COVID?**  
  - [ ] Yes  
  - [ ] No

- **Second COVID-19 infection: When did their second COVID infection occur?** (MM/YY)   
  - [ ] Yes, confirmed by testing  
  - [ ] No, not confirmed by testing

- **Were they admitted to hospital for their second infection of COVID?**  
  - [ ] Yes  
  - [ ] No

If data on this patient was previously recorded in this study, record the Participant Identification Number (PIN) previously used in the section below
MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

RE-ADMISSION AND PREVIOUS PIN

Was the patient admitted previously or transferred from any other facility during this illness episode? 
- YES-admitted previously to this facility
- YES–transferred from other facility
- NO
- Unknown

Number of previous admissions for this infection: _____

Has this patient’s data been previously collected under a different patient number? 
- YES
- NO
- Unknown

If YES, Participant Identification number (PIN): ________________

ONSET & ADMISSION

Onset date of first/earliest symptom: [Day] [Month] [Year]

Most recent presentation/admission date at this facility: [Day] [Month] [Year]

SIGNS AND SYMPTOMS AT HOSPITAL ADMISSION (first available data at presentation/admission – within 24 hours)

- Temperature: [__]°C or [__]°F
- HR: [__] beats/minute
- RR: [__] breaths/minute
- Systolic BP: [__] mmHg
- Diastolic BP: [__] mmHg
- Oxygen saturation: [__]% On: Room air
- Oxygen therapy
- Unknown
- Sternal capillary refill time >2sec. 
- YES
- NO
- Unknown
- Height: [__] cm
- Weight: [__] kg

SIGNS AND SYMPTOMS ON ADMISSION (Unk = Unknown)

- History of fever
- YES
- NO
- Unk

- Cough
- YES - non-productive
- YES - productive
- YES - with haemoptysis
- NO
- Unk

- Fatigue / Malaise
- Anorexia
- Altered consciousness/confusion
- Muscle aches (myalgia)
- Joint pain (arthralgia)
- Inability to walk
- Abdominal pain
- Diarrhoea
- Vomiting / Nausea
- Skin rash
- Bleeding (Haemorrhage)
- Other symptom(s):
- If YES, specify site(s):
- If YES, specify:

- Headache
- YES
- NO
- Unk

- Loss of smell (Anosmia)
- YES
- NO
- Unk

- Loss of taste (Ageusia)
- YES
- NO
- Unk

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**MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM**

### VACCINATIONS

**Covid-19 vaccination:**  
- YES  
- NO  
- Unk  

Date of first vaccine: [___]  
Type of first vaccine:  
- Pfizer/BioNTech  
- AstraZeneca Oxford (Covishield in India)  
- Moderna  
- Novavax  
- Janssens (Johnson & Johnson)  
- Sinopharm  
- Sputnik V  
- Covaxin  
- CanSinoBio  
- Unknown  

Date of second vaccine: [___]  
Type of second vaccine:  
- Pfizer/BioNTech  
- AstraZeneca/University of Oxford (Covishield in India)  
- Moderna  
- Novavax  
- Janssens (Johnson & Johnson)  
- Sinopharm  
- Sputnik V  
- Covaxin  
- CanSinoBio  
- Unknown  

Date of third vaccine: [___]  
Type of third vaccine:  
- Pfizer/BioNTech  
- AstraZeneca/University of Oxford (Covishield in India)  
- Moderna  
- Novavax  
- Janssens (Johnson & Johnson)  
- Sinopharm  
- Sputnik V  
- Covaxin  
- CanSinoBio  
- Unknown  

Influenza vaccination within the last 6 months:  
- YES  
- NO  

Date of influenza vaccine: [___]

### PRE-ADMISSION MEDICATION  (taken within 14 days prior to admission/presentation at healthcare facility)

**Steroids**  
- YES  
- NO  
- Unk  

If YES,  
- Oral  
- Inhaled  

**Other immunosuppressant agents**  
- YES  
- NO  
- Unk  

**Antibiotics**  
- YES  
- NO  
- Unk  

If YES, agent(s):  

**Antivirals**  
- YES  
- NO  
- Unk  

If YES, agent(s):  

**Other targeted COVID-19 Medications**  
- YES  
- NO  
- Unk  

If YES, agent(s):  

### CO-MORBIDITIES AND RISK FACTORS  (existing prior to admission and ongoing)

<table>
<thead>
<tr>
<th>Chronic cardiac disease (not hypertension)</th>
<th>YES</th>
<th>NO</th>
<th>Unk</th>
<th>Chronic hematologic disease</th>
<th>YES</th>
<th>NO</th>
<th>Unk</th>
</tr>
</thead>
</table>
| Hypertension                              | YES | NO | Unk  | AIDS / HIV:  
- YES-on ART  
- NO Unk  
If YES, most recent CD4 count:  
- < 200  
- 200-500  
- ≥ 500 cells/µL  

| Chronic pulmonary disease (not asthma)   | YES | NO | Unk  | Diabetes Mellitus:  
- YES-Type 1  
- NO Unk  
- YES-Type 2  
- NO Unk  
If YES, HbA1C results (within last 6 months):  
- Units: mmol/mol  
- mmol/L  
- %  

| Asthma (physician diagnosed)              | YES | NO | Unk  | Rheumatologic disorder:  
- YES  
- NO Unk  

| Chronic kidney disease                    | YES | NO | Unk  | Dementia:  
- YES  
- NO Unk  

| Obesity (as defined by clinical staff)   | YES | NO | Unk  | Tuberculosis:  
- YES  
- NO Unk  

| Moderate or severe liver disease         | YES | NO | Unk  | Malnutrition:  
- YES  
- NO Unk  

| Mild liver disease                       | YES | NO | Unk  | Smoking:  
- YES  
- NO Unk  

| Asplenia                                 | YES | NO | Unk  | Other relevant risk factor(s):  
- YES  
- NO Unk  

| Chronic neurological disorder            | YES | NO | Unk  | If YES, specify:  
- YES  
- NO Unk  

| Malignant neoplasm                       | YES | NO | Unk  |
## MODULE 2: CASE REPORT FORM ON ADMISSION, CRITICAL CARE, RESEARCH SAMPLING

Complete on the day of admission or first COVID-19 investigation, and on the first day of ICU admission (if different from day of admission). In addition, complete for days when biochemical results are available.

### SIGNS AND SYMPTOMS

*Record the worst value between 00:00 to 24:00 on day of assessment (worst=furthest from normal range)*

<table>
<thead>
<tr>
<th>DATE OF ASSESSMENT (DD/MM/YYYY):</th>
<th>[ ] [ ] [ ] [ ] / [ ] [ ] [ ] / [ ] [ ] [ ] / [ ] [ ] [ ] [ ]</th>
</tr>
</thead>
</table>

**Highest temperature:** [ ] [ ] [ ] [ ] °C or °F
**HR:** [ ] [ ] [ ] [ ] beats/minute
**RR:** [ ] [ ] [ ] [ ] breaths/minute

**Systolic BP:** [ ] [ ] [ ] [ ] mmHg
**Diastolic BP:** [ ] [ ] [ ] [ ] mmHg

**Oxygen saturation SaO₂:** [ ] [ ] [ ] [%]

**Any supplemental oxygen:** YES NO Unknown if yes,

**FiO₂ (0.21-1.0):** [ ] [ ] [ ] [ ] or [ ] [ ] [ ] % or [ ] [ ] [ ] L/min (Highest L/min)

**PaO₂ (at time nearest to the FiO₂ recorded at top of page):** [ ] [ ] [ ] [ ] kPa or [ ] [ ] [ ] mmHg

**PaO₂ sample type:** Arterial Capillary Venous Unknown

**From same blood gas record as PaO₂:**

<table>
<thead>
<tr>
<th>PCO₂</th>
<th>O kPa or [ ] [ ] [ ] mmHg</th>
<th>pH</th>
<th>HCO₃⁻</th>
<th>Base excess</th>
<th>mmol/L</th>
</tr>
</thead>
</table>

**Sternal capillary refill time:** >2 seconds YES NO Unknown

**AVPU:** Alert [ ] Verbal[ ] Pain [ ] Unresponsive [ ] Glasgow Coma Score (GCS / 15) [ ] [ ]

**Richmond Agitation-Sedation Scale (RASS):** [ ]

**Mean Arterial Blood Pressure:** [ ] [ ] [ ] [ ] mmHg

**Urine flow rate:** [ ] [ ] [ ] [ ] mL/24 hours

**Is the patient currently receiving, or has received (between 00:00 to 24:00 on day of assessment):**

- **Current admission to ICU/ITU/IMC/HDU?** YES NO Unknown
- **High-flow nasal cannula oxygen therapy?** YES NO Unknown
- **Non-invasive ventilation (Any)?** YES NO Unknown
- **Invasive ventilation?** YES NO Unknown
- **Prone positioning?** YES NO Unknown If yes, during invasive ventilation whilst self-ventilating Unknown
- **Inhaled Nitric Oxide?** YES NO Unknown
- **Tracheostomy inserted?** YES NO Unknown
- **Extra corporeal life support (ECLS/ ECMO)?** YES NO Unknown
- **Renal replacement therapy (RRT) or dialysis?** YES NO Unknown
- **Any vasopressor/inotropic support?** YES NO Unknown (if NO, select NO for the next 3 questions)
  - **Dopamine <5 μg/kg/min OR Dobutamine OR milrinone OR levosimendan:** YES NO
  - **Dopamine 5-15 μg/kg/min OR Epinephrine/Norepinephrine < 0.1 μg/kg/min OR vasopressin OR phenylephrine:** YES NO
  - **Dopamine >15 μg/kg/min OR Epinephrine/Norepinephrine > 0.1 μg/kg/min:** YES NO
- **Neuromuscular blocking agents?** YES NO Unknown
- **Other intervention(s) or procedure(s)?** YES NO Unknown If YES, Specify: ____________________________

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MODULE 2: CASE REPORT FORM ON ADMISSION, CRITICAL CARE, RESEARCH SAMPLING
Complete on the day of admission or first COVID-19 investigation, and on the first day of ICU admission (if different from day of admission). In addition, complete for days when biochemical results are available.

LABORATORY RESULTS (on admission, on any admission to ICU, then daily) – complete every line

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value*</th>
<th>Not done</th>
<th>Parameter</th>
<th>Value*</th>
<th>Not done</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemoglobin (g/L)</td>
<td></td>
<td></td>
<td>Urea (BUN) (mmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WBC count (x10⁹/L)</td>
<td></td>
<td></td>
<td>Lactate (mmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lymphocyte count (10⁹/L)</td>
<td></td>
<td></td>
<td>Creatinine (µmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neutrophil count (10⁹/L)</td>
<td></td>
<td></td>
<td>Sodium (mmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haematocrit (%)</td>
<td></td>
<td></td>
<td>Potassium (mmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Platelets (x10⁹/L)</td>
<td></td>
<td></td>
<td>Procalcitonin (ng/mL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>APTT (seconds)</td>
<td></td>
<td></td>
<td>CPR (mg/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>APTR</td>
<td></td>
<td></td>
<td>LDH (U/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PT (seconds)</td>
<td></td>
<td></td>
<td>Creatine kinase (U/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INR</td>
<td></td>
<td></td>
<td>Troponin I (ng/mL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALT/SGPT (U/L)</td>
<td></td>
<td></td>
<td>D-dimer (mg/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total bilirubin (µmol/L)</td>
<td></td>
<td></td>
<td>Ferritin (ng/mL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AST/SGOT (U/L)</td>
<td></td>
<td></td>
<td>IL-6 (pg/mL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucose (mmol/L)</td>
<td></td>
<td></td>
<td>Fibrinogen (mg/dl)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TREATMENT: At ANY time during hospitalisation, did the patient receive/undergo:

<table>
<thead>
<tr>
<th>Treatment</th>
<th>YES</th>
<th>NO</th>
<th>Unknown</th>
<th>If YES, total duration: _______ days</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Oxygen therapy?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum O₂ flow volume:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;2 L/min</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-5 L/min</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-10 L/min</td>
<td></td>
<td></td>
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<tr>
<td>11-15 L/min</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;15 L/min</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-invasive ventilation? (Any)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Invasive ventilation? (Any)</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>High flow nasal oxygen</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Prone Positioning?</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Inhaled Nitric Oxide?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tracheostomy inserted?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extracorporeal support (ECMO)?</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Renal replacement therapy (RRT) or dialysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inotropes/vasopressors?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICU or High Dependency Unit admission?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If YES, date of ICU admission: [D][D]/[M][M]/[Y][Y] Unknown

If YES, date of ICU discharge: [D][D]/[M][M]/[Y][Y] Unknown

MODULE 3: OUTCOME CASE REPORT FORM

PARTICIPANT IDENTIFICATION #: [___][___][___][___][___]---[___][___][___][___]

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### Module 3: Outcome Case Report Form

**COMPLICATIONS:** At any time during hospitalisation did the patient experience: *(Unk = Unknown)*

<table>
<thead>
<tr>
<th>Condition</th>
<th>YES</th>
<th>NO</th>
<th>Unk</th>
<th>YES</th>
<th>NO</th>
<th>Unk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral pneumonia/pneumonitis</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
</tr>
<tr>
<td>Bacterial pneumonia</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
</tr>
<tr>
<td>Acute Respiratory Distress Syndrome</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
</tr>
<tr>
<td>Pleural effusion</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
</tr>
<tr>
<td>Cryptogenic organizing pneumonia (COP)</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
</tr>
<tr>
<td>Bronchiolitis</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
</tr>
<tr>
<td>Cardiac ischaemia</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
</tr>
<tr>
<td>Cardiac arrhythmia</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
</tr>
<tr>
<td>Myocarditis / Pericarditis</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
</tr>
<tr>
<td>Endocarditis</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
</tr>
<tr>
<td>Cardiomyopathy</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
</tr>
<tr>
<td>Seizure</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
</tr>
<tr>
<td>Stroke / Cerebrovascular accident</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
<td>O</td>
<td>O</td>
<td>Unk</td>
</tr>
</tbody>
</table>

**Diagnosis**

**Section 1: Respiratory Virus PCR Testing**

- SARS-CoV-2 (COVID-19): **O** Positive  **O** Negative  **O** Not done  **O** Unknown
- Was other pathogen testing done during this illness episode? **O** YES *(complete section)*  **O** NO  **O** Unknown
- Influenza: **O** Positive  **O** Negative  **O** Not done  **O** Unknown
  - If Positive: **O** A-not typed  **O** A/H3N2  **O** A/H1N1pm09  **O** A/H7N9  **O** A/H5N1  **O** Other: ___________________  **O** Unknown
- Respiratory Syncytial Virus (RSV): **O** Positive  **O** Negative  **O** Not done  **O** Unknown
- Adenovirus: **O** Positive  **O** Negative  **O** Not done  **O** Unknown

**Section 2: Bacterial Testing**

- Bacteria: **O** Positive  **O** Negative  **O** Not done  **O** Unknown
  - If Positive, specify: ___________________  **O** Unknown
- Other pathogen/s detected: **O** YES  **O** NO  **O** Unknown
  - If YES, specify all: ___________________  **O** Unknown

**Section 3: Radiology**

- Clinical pneumonia diagnosed? **O** YES  **O** NO  **O** Unknown
- Chest X-Ray performed? **O** YES  **O** NO  **O** Unknown
- CT performed? **O** YES  **O** NO  **O** Unknown

---

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MODULE 3: OUTCOME CASE REPORT FORM

DIAGNOSTICS continued

Section 4: PATHOGEN TESTING DETAILS

<table>
<thead>
<tr>
<th>Collection Date (DD/MM/YYYY)</th>
<th>Biospecimen Type</th>
<th>Laboratory Test Method</th>
<th>Result</th>
<th>Pathogen Tested/Detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>D. D. / M. M. / 20 Y Y</td>
<td>Nasal/NP swab</td>
<td>PCR</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Throat swab</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Combined nasal/NP+throat swab</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sputum BAL ETA Urine Blood</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other, Specify:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>Nasal/NP swab</td>
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</tr>
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<td></td>
</tr>
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<td></td>
</tr>
<tr>
<td></td>
<td>Other, Specify:</td>
<td></td>
<td></td>
<td></td>
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<td>Sputum BAL ETA Urine Blood</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other, Specify:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

MEDICATION: While hospitalised or at discharge, were any of the following administered? (Unk=Unknown)

ANTIVIRAL OR COVID-19 TARGETED AGENT? ☐ YES ☐ NO ☐ Unknown If YES, specify (all):

☐ Ribavirin Date commenced [D] [D] / [M] [M] / [L_2] [L_0] [Y_1] [Y_1] Unk Duration: _______ days Unk

☐ Lopinavir/Ritonavir Date commenced [D] [D] / [L_2] [M_1] [M_1] [M_1] / [L_2] [L_0] [Y_1] [Y_1] Unk Duration: _______ days Unk

☐ Remdesivir (Veklury) Date commenced [D] [D] / [L_1] [Y_1] / [M_1] [M_1] [L_2] [L_0] [Y_1] [Y_1] Unk Duration: _______ days Unk

☐ Interferon alpha Date commenced [D] [D] / [L_1] [Y_1] / [M_1] [M_1] [L_2] [L_0] [Y_1] [Y_1] Unk Duration: _______ days Unk

☐ Interferon beta Date commenced [D] [D] / [L_1] [Y_1] / [M_1] [M_1] [L_2] [L_0] [Y_1] [Y_1] Unk Duration: _______ days Unk

☐ Chloroquine/hydroxychloroquine:

Date commenced [D] [D] / [M_1] [M_1] [L_2] [L_0] [Y_1] [Y_1] Unk... Duration: _______ days Unk

☐ Interleukin-6 (IL-6) inhibitor IF YES which: ☐ Tocilizumab ☐ Sarilumab ☐ Other IL-6 inhibitor _______ days Unk

Date commenced [D] [D] / [L_1] [Y_1] / [M_1] [M_1] [L_2] [L_0] [Y_1] [Y_1] Unk... Duration: _______ days Unk

☐ Convalescent plasma Date commenced [D] [D] / [L_1] [Y_1] / [M_1] [M_1] [L_2] [L_0] [Y_1] [Y_1] Unk Duration: _______ days Unk

☐ Anti-influenza anti-viral IF YES which: ☐ Oseltamivir (Tamiflu®) ☐ Zanamivir Unk

Date commenced [D] [D] / [L_1] [Y_1] / [M_1] [M_1] [L_2] [L_0] [Y_1] [Y_1] Unk... Duration: _______ days Unk

☐ Other Date commenced [D] [D] / [L_1] [Y_1] / [M_1] [M_1] [L_2] [L_0] [Y_1] [Y_1] Unk... Duration: _______ days Unk
## MODULE 3: OUTCOME CASE REPORT FORM

### MEDICATION (continued):

**ANTIBIOTIC?**  
- YES  
- NO  
- Unknown  

If yes, specify all:

- **Agent 1:** __________________________ Date commenced [D][D]/[M][M]/[2]/[0]/[Y][Y] Duration: ____ days  
- **Agent 2:** __________________________ Date commenced [D][D]/[M][M]/[2]/[0]/[Y][Y] Duration: ____ days  
- **Agent 3:** __________________________ Date commenced [D][D]/[M][M]/[2]/[0]/[Y][Y] Duration: ____ days

**CORTICOSTEROID?**  
- YES  
- NO  
- Unknown

If YES:  
- Dexamethasone?  
  - YES  
  - NO  
  - Unknown

If YES, check all that apply:

- □ 6mg once per day (od)?  
  - YES  
  - NO  
  - Unknown  
  If YES, Route:  
    - □ Oral  
    - □ Intravenous  
    - Unknown

If YES, dates commenced [D][D]/[M][M]/[2]/[0]/[Y][Y] Duration: ____ days  

- □ other dose or frequency?  
  - YES  
  - NO  
  - Unknown  
  If YES, dates commenced [D][D]/[M][M]/[2]/[0]/[Y][Y] Duration: ____ days  

If YES:  
- Other corticosteroid?  
  - YES  
  - NO  
  - Unknown

If YES:  
- Which steroid:  
  - Prednisolone  
  - Hydrocortisone  
  - Methylprednisolone  
  - Other

  Route:  
  - □ Oral  
  - □ Intravenous  
  - Unknown

**ANTICOAGULATION?**  
- YES  
- NO  
- Unknown  

If YES:  
- Agent: ________________

  Route:  
  - □ Subcutaneous  
  - □ Intravenous (IV)  
  - Unknown

  Indication:  
  - □ therapeutic (treatment of DVT/PE)  
  - □ enhanced prophylaxis for COVID-19  
  - □ routine inpatient prophylaxis  
  - Unknown

**ANTIFUNGAL AGENT?**  
- YES  
- NO  
- Unknown

**OTHER treatments administered for COVID-19 including experimental or compassionate use?**  
- YES  
- NO  
- Unknown

If YES, specify agent and timing of administration:

- **Agent 1:** __________________________
  
  Date commenced [D][D]/[M][M]/[2]/[0]/[Y][Y]  
  - Unk  
  Duration: ____ days  
  - Unk

- **Agent 2:** __________________________
  
  Date commenced [D][D]/[M][M]/[2]/[0]/[Y][Y]  
  - Unk  
  Duration: ____ days  
  - Unk

- **Agent 3:** __________________________
  
  Date commenced [D][D]/[M][M]/[2]/[0]/[Y][Y]  
  - Unk  
  Duration: ____ days  
  - Unk
### MODULE 3: OUTCOME CASE REPORT FORM

#### OUTCOME

<table>
<thead>
<tr>
<th>Was patient diagnosed with Covid-19?</th>
<th>YES</th>
<th>NO</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, was the diagnosis based on:</td>
<td>Laboratory confirmation</td>
<td>clinical assessment</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is the patient infected with a variant of concern (VOC)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unknown</td>
</tr>
<tr>
<td>Yes: Omicron, B.1.1.529, identified Nov 2021</td>
</tr>
<tr>
<td>Yes: Beta - B.1.351, identified in South Africa May 2020</td>
</tr>
<tr>
<td>Yes: Epsilon - B.1.427/B.1.429, identified in USA Mar 2021</td>
</tr>
<tr>
<td>Yes: Eta - B.1.525, identified in Multiple Countries Dec 2020</td>
</tr>
<tr>
<td>Yes: Iota - B.1.526, identified in USA Nov 2020</td>
</tr>
<tr>
<td>Yes: Lambda - C.37, identified in Peru Dec 2020</td>
</tr>
<tr>
<td>Yes: A variant not listed above</td>
</tr>
</tbody>
</table>

*Please check the REDCAP database for variants not listed above. New variants will be added to the database as they are identified.*

<table>
<thead>
<tr>
<th>If the Omicron variant was identified, what method was used to identify it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genomic sequencing</td>
</tr>
</tbody>
</table>

#### Outcome: 

<table>
<thead>
<tr>
<th>Discharged alive</th>
<th>Hospitalised</th>
<th>Transfer to other facility</th>
<th>Death</th>
<th>Palliative discharge</th>
<th>Unknown</th>
</tr>
</thead>
</table>

| Outcome date: | [D] [D] / [M] [M] / [Y] [Y] | Unknown |

<table>
<thead>
<tr>
<th>If alive at outcome date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ability to self-care at discharge versus before illness:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Post-discharge treatment: Oxygen therapy?</th>
<th>YES</th>
<th>NO</th>
<th>Unknown</th>
</tr>
</thead>
</table>

| Ongoing health care needs relating to this admission for COVID-19: | YES | NO | Unknown |

| Ongoing health care needs NOT related to COVID episode: | YES | NO | Unknown |

| Medically fit for discharge (COVID-19 resolved) but remains in hospital for other reason (e.g. awaiting suitable care in community, resident in long term health care or mental health facility): | YES | NO | Unknown |