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 (O) 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: O YES O NO

Is COVID-19 the reason for hospital admission?

O Yes, COVID-19 is the reason for hospital admission

O 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: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Ethnic group *(check all that apply)*: ☐ Arab ☐ Black ☐ East Asian ☐ South Asian ☐ West Asian ☐ Latin American ☐ White ☐ Aboriginal/First Nations ☐ Other: _____ O Unknown

Employed as a Healthcare Worker? O YES O NO O Unknown **Employed in a microbiology laboratory?** O YES O NO O Unknown

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

Pregnant? O YES O NO O Unknown **If YES: Gestational weeks assessment:** [___][___] weeks

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

ONSET & ADMISSION

Onset date of first/earliest symptom: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Most recent presentation/admission date at this facility: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

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

Temperature: [____][____][____].[____] O °C *or* O °F

HR: [____][____][____]beats/minute **RR:** [____][____]breaths/minute

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

Oxygen saturation: [___][___][___]% **On:** O Room air O Oxygen therapy O Unknown

Sternal capillary refill time >2sec. O YES O NO O Unknown **Height:** [___][___][___]cm **Weight:** [___][___][___]kg

SIGNS AND SYMPTOMS ON ADMISSION *(Unk = Unknown)*

History of fever	O YES O NO O Unk	Fatigue / Malaise	O YES O NO O Unk
Cough O YES - non-productive O YES - productive O YES - with haemoptysis O NO O Unk		Anorexia	O YES O NO O Unk
		Altered consciousness/confusion	O YES O NO O Unk
Sore throat	O YES O NO O Unk	Muscle aches (myalgia)	O YES O NO O Unk
Runny nose (rhinorrhoea)	O YES O NO O Unk	Joint pain (arthralgia)	O YES O NO O Unk

Wheezing	O YES O NO O Unk	Inability to walk	O YES O NO O Unk
Shortness of breath	O YES O NO O Unk	Abdominal pain	O YES O NO O Unk
Lower chest wall indrawing	O YES O NO O Unk	Diarrhoea	O YES O NO O Unk
Chest pain	O YES O NO O Unk	Vomiting / Nausea	O YES O NO O Unk
Conjunctivitis	O YES O NO O Unk	Skin rash	O YES O NO O Unk
Lymphadenopathy	O YES O NO O Unk	Bleeding (Haemorrhage)	O YES O NO O Unk
Headache	O YES O NO O Unk	If YES, specify site(s):_____	
Loss of smell (Anosmia)	O YES O NO O Unk	Other symptom(s)	O YES O NO O Unk
Loss of taste (Ageusia)	O YES O NO O Unk	If YES, specify:_____	
Seizures	O YES O NO O Unk		

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

PRE-ADMISSION MEDICATION *(taken within 14 days prior to admission/presentation at healthcare facility)*	
Steroids	O YES O NO O Unk If YES, O Oral O Inhaled O Unk
Other immunosuppressant agents (not oral steroids)	O YES O NO O Unk
Antibiotics	O YES O NO O Unk If YES, agent(s):_____
Antivirals	O YES O NO O Unk If YES, agent(s):_____
Other targeted COVID-19 Medications	O YES O NO O Unk If YES, agent(s):_____

CO-MORBIDITIES AND RISK FACTORS *(existing prior to admission and ongoing)*			
Chronic cardiac disease *(not hypertension)*	O YES O NO O Unk	Chronic hematologic disease	O YES O NO O Unk
Hypertension	O YES O NO O Unk	AIDS / HIV O YES-on ART O YES-not on ART O NO O Unk If YES, most recent CD4 count: O < 200 O 200-< 500 O ≥ 500 cells/uL O Unk	
Chronic pulmonary disease *(not asthma)*	O YES O NO O Unk	Diabetes Mellitus O YES-Type 1 O YES -Type 2 O YES -Gestational O NO O Unk If YES, HbA1C results (within last 6 months) :_____ Units: O mmol/mol O mmol/L O %	
Asthma *(physician diagnosed)*	O YES O NO O Unk	Rheumatologic disorder	O YES O NO O Unk
Chronic kidney disease	O YES O NO O Unk	Dementia	O YES O NO O Unk
Obesity *(as defined by clinical staff)*	O YES O NO O Unk	Tuberculosis	O YES O NO O Unk
Moderate or severe liver disease	O YES O NO O Unk	Malnutrition	O YES O NO O Unk
Mild liver disease	O YES O NO O Unk	Smoking O YES O Never smoked O Former smoker O Unk	
Asplenia	O YES O NO O Unk	Other relevant risk factor(s)	O YES O NO O Unk
Chronic neurological disorder	O YES O NO O Unk	If YES, specify:	
Malignant neoplasm	O YES O NO O 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)*

DATE OF ASSESSMENT *(DD/MM/YYYY)*: [_D_][_D_]/[_M_][_M_]/[__2_][__0_][_Y_][_Y_]

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

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

Oxygen saturation SaO_2 [___][___][___]%

Any supplemental oxygen: OYES ONO OUnknown If yes,

FiO_2 *(0.21-1.0)* [___].[___][___] or [___][___] % or [___][___]L/min (Highest L/min)

PaO_2 *(at time nearest to the FiO_2 recorded at top of page)* [___][___][___]OkPa *or* OmmHg ONot done

PaO_2 sample type: OArterial OCapillary OVenous OUnknown

From same blood gas record as PaO_2:

PCO_2 _____OkPa *or* OmmHg **| pH** _____ **| HCO_3-** _____mEq/L **| Base excess** _____ mmol/L

Sternal capillary refill time >2seconds **OYES** **ONO** **OUnknown**

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

Richmond Agitation-Sedation Scale (RASS) [___]

Mean Arterial Blood Pressure [___][___][___]mmHg OUnknown

Urine flow rate [___][___][___][___][___]mL/24 hours O Check if estimated OUnknown

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? OYES ONO OUnknown

High-flow nasal cannula oxygen therapy? OYES ONO OUnknown

Non-invasive ventilation *(Any)*? OYES ONO OUnknown **If YES:** OBIPAP OCPAP OOther OUnknown

Invasive ventilation? OYES ONO OUnknown

Prone positioning? OYES ONO OUnknown If yes, Oduring invasive ventilation Owhilst self-ventilating OUnknown

Inhaled Nitric Oxide? OYES ONO OUnknown

Tracheostomy inserted? OYES ONO OUnknown

Extra corporeal life support (ECLS/ ECMO)? OYES ONO OUnknown **If YES:** OVV OAV OCentral OUnknown

Renal replacement therapy (RRT) or dialysis? OYES ONO OUnknown

Any vasopressor/inotropic support? OYES ONO OUnknown *(if NO, select NO for the next 3 questions)*

Dopamine <5µg/kg/min OR Dobutamine OR milrinone OR levosimendan: OYES ONO

Dopamine 5-15µg/kg/min OR Epinephrine/Norepinephrine < 0.1µg/kg/min OR vasopressin OR phenylephrine: OYES ONO

Dopamine >15µg/k/min OR Epinephrine/Norepinephrine > 0.1µg/kg/min: OYES ONO

Neuromuscular blocking agents? OYES ONO OUnknown

Other intervention(s) or procedure(s)? OYES ONO OUnknown If YES, Specify: _____

_____

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

DATE OF ASSESSMENT *(DD/MM/YYYY):* [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

LABORATORY RESULTS (**record units if different from those listed)*
Record the worst value between 00:00 to 24:00 on day of assessment (if Not Available write 'N/A')

Parameter	Value*	Not done	Parameter	Value*	Not done
Haemoglobin (g/L)		O	Urea (BUN) (mmol/L)		O
WBC count (x10^9/L)		O	Lactate (mmol/L)		O
Lymphocyte count (10^9/L)		O	Creatinine (µmol/L)		O
Neutrophil count (10^9/L)		O	Sodium (mmol/L)		O
Haematocrit (%)		O	Potassium (mmol/L)		O
Platelets (x10^9/L)		O	Procalcitonin (ng/mL)		O
APTT (seconds))		O	CRP (mg/L)		O
APTR		O	LDH (U/L)		O
PT (seconds)		O	Creatine kinase (U/L)		O
INR		O	Troponin I (ng/mL)		O
ALT/SGPT (U/L)		O	D-dimer (mg/L)		O
Total bilirubin (µmol/L)		O	Ferritin (ng/mL)		O
AST/SGOT (U/L)		O	IL-6 (pg/mL)		O
Glucose (mmol/L)		O	Fibrinogen (mg/dl)		O

MODULE 3: OUTCOME CASE REPORT FORM

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

Any Oxygen therapy? OYES ONO OUnknown **If YES, total duration:** _____days OUnknown

Maximum O_2 flow volume: O <2 L/min O2-5 L/min O6-10 L/min O11-15 L/min O>15 L/min

Non-invasive ventilation? *(Any)* OYES ONO OUnknown **If YES, total duration:** _____days OUnknown

Invasive ventilation? *(Any)* OYES ONO OUnknown **If YES, total duration:** _____days OUnknown

High flow nasal oxygen OYES ONO OUnknown **If YES, total duration:** _____days OUnknown

Prone Positioning? OYES ONO OUnknown

Inhaled Nitric Oxide? OYES ONO OUnknown

Tracheostomy inserted? OYES ONO OUnknown

Extracorporeal support (ECMO)? OYES ONO OUnknown **If YES, total duration:** _____days OUnknown

Renal replacement therapy (RRT) or dialysis? OYES ONO OUnknown

Inotropes/vasopressors? OYES ONO OUnknown

ICU or High Dependency Unit admission? OYES ONO OUnknown **If YES, total duration:** _____days OUnknown

If YES, date of ICU admission: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] OUnknown

date of ICU discharge: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] OUnknown

MODULE 3: OUTCOME CASE REPORT FORM

COMPLICATIONS: At any time during hospitalisation did the patient experience: *(Unk = Unknown)*			
Viral pneumonia/pneumonitis	O YES O NO O Unk	Meningitis / Encephalitis	O YES O NO O Unk
Bacterial pneumonia	O YES O NO O Unk	Bacteremia	O YES O NO O Unk
Acute Respiratory Distress Syndrome	O YES O NO O Unk	Coagulation disorder / DIC	O YES O NO O Unk
Pneumothorax	O YES O NO O Unk	Pulmonary Embolism	O YES O NO O Unk
Pleural effusion	O YES O NO O Unk	Deep Vein Thrombosis	O YES O NO O Unk
Cryptogenic organizing pneumonia (COP)	O YES O NO O Unk	Other thromboembolism (not PE or DVT)	O YES O NO O Unk
Bronchiolitis	O YES O NO O Unk	Anemia	O YES O NO O Unk
Cardiac arrest	O YES O NO O Unk	Rhabdomyolysis / Myositis	O YES O NO O Unk
Myocardial infarction	O YES O NO O Unk	Acute renal injury/ Acute renal failure	O YES O NO O Unk
Cardiac ischaemia	O YES O NO O Unk	Gastrointestinal haemorrhage	O YES O NO O Unk
Cardiac arrhythmia	O YES O NO O Unk	Pancreatitis	O YES O NO O Unk
Myocarditis / Pericarditis	O YES O NO O Unk	Liver dysfunction	O YES O NO O Unk
Endocarditis	O YES O NO O Unk	Hyperglycemia	O YES O NO O Unk
Cardiomyopathy	O YES O NO O Unk	Hypoglycemia	O YES O NO O Unk
Congestive heart failure	O YES O NO O Unk	Other	O YES O NO O Unk
Seizure	O YES O NO O Unk	If YES, specify:_____	
Stroke / Cerebrovascular accident	O YES O NO O Unk		

DIAGNOSTICS

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/H1N1pdm09 O A/H7N9 O A/H5N1 O B O Other:_____ .. O Unk

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 **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 **If Yes: Were infiltrates present?** O YES O NO O Unknown

CT performed? O YES O NO O Unknown **If Yes: Were infiltrates present?** O YES O NO O Unknown

MODULE 3: OUTCOME CASE REPORT FORM

DIAGNOSTICS *continued*

Section 4: PATHOGEN TESTING DETAILS

Collection Date (DD/MM/YYYY)	Biospecimen Type	Laboratory test Method	Result	Pathogen Tested/Detected
_D_ _D_ / _M_ _M_ /20_Y_ _Y_	○Nasal/NP swab ○Throat swab ○Combined nasal/NP+throat swab ○Sputum ○BAL ○ETA ○Urine ○Feces/rectal swab ○Blood ○Other, *Specify:* ___________________	○PCR ○Culture ○Other, *Specify:* _____________	○Positive ○Negative ○Unknown	________________
_D_ _D_ / _M_ _M_ /20_Y_ _Y_	○Nasal/NP swab ○Throat swab ○Combined nasal/NP+throat swab ○Sputum ○BAL ○ETA ○Urine ○Feces/rectal swab ○Blood ○Other, *Specify:* ___________________	○PCR ○Culture ○Other, *Specify:* _____________	○Positive ○Negative ○Unknown	________________
_D_ _D_ / _M_ _M_ /20_Y_ _Y_	○Nasal/NP swab ○Throat swab ○Combined nasal/NP+throat swab ○Sputum ○BAL ○ETA ○Urine ○Feces/rectal swab ○Blood ○Other, *Specify:* ___________________	○PCR ○Culture ○Other, *Specify:* _____________	○Positive ○Negative ○Unknown	________________
_D_ _D_ / _M_ _M_ /20_Y_ _Y_	○Nasal/NP swab ○Throat swab ○Combined nasal/NP+throat swab ○Sputum ○BAL ○ETA ○Urine ○Faeces/rectal swab ○Blood ○Other, *Specify:* ___________________	○PCR ○Culture ○Other, *Specify:* _____________	○Positive ○Negative ○Unknown	________________

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_]/[_2_][_0_][_Y_][_Y_] ○Unk **Duration:** ________ days ○Unk

☐ **Lopinavir/Ritonavir** **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ○Unk **Duration:** ________ days ○Unk

☐ **Remdesivir (Veklury)** **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ○Unk **Duration:** ________ days ○Unk

☐ **Interferon alpha** **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ○Unk **Duration:** ________ days ○Unk

☐ **Interferon beta** **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ○Unk **Duration:** ________ days ○Unk

☐ **Chloroquine/hydroxychloroquine:**

Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ○Unk... **Duration:** ________days ○Unk

☐ **Interleukin-6 (IL-6) inhibitor** **IF YES which:** ☐ Tocilizumab ☐ Sarilumab ☐ Other IL-6 inhibitor________________________ ○Unk

Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ○Unk... **Duration:** ________days ○Unk

☐ **Convalescent plasma** **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ○Unk **Duration:** ________days ○Unk

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

Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ○Unk... **Duration:** ________days ○Unk

☐ **Other**______________________ **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ○Unk

duration: ________days ○Unk

MODULE 3: OUTCOME CASE REPORT FORM

MEDICATION (continued):

ANTIBIOTIC? O YES O NO O Unknown **If yes, specify all:**

Agent 1:_____ **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **Duration**: ____ days O Unk

Agent 2:_____ **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **Duration**: ____ days O Unk

Agent 3:_____ **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **Duration**: ____ days O Unk

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CORTICOSTEROID? O YES O NO O Unknown

If YES: **Dexamethasone?** O YES O NO O Unknown

If YES, check all that apply:

☐ **6mg once per day (od)?** O YES O NO O Unknown If YES, Route: ☐ Oral ☐ Intravenous O Unk

If YES, **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **Duration**: _____ days O Unk

☐ **other dose or frequency?** O YES O NO O Unknown If YES, Route: ☐ Oral ☐ Intravenous O Unk

If YES, **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **Duration**: _____ days O Unk

If YES: **Other corticosteroid?** O YES O NO O Unknown

If YES: **Which steroid:** ☐ Prednisolone ☐ Hydrocortisone ☐ Methylprednisolone ☐ Other

Route: ☐ Oral ☐ Intravenous O Unk

ANTICOAGULATION? O YES O NO O Unk

If YES: Agent: _____

Route: ☐ Subcutaneous ☐ Intravenous (IV) O Unk

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

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ANTIFUNGAL AGENT? O YES O NO O Unk

OTHER treatments administered for COVID-19 including experimental or compassionate use? O YES O NO O Unk

If YES, specify agent and timing of administration:

Agent 1: _____

Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unk **Duration**: _____ days O Unk

Agent 2: _____

Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unk **Duration**: _____ days O Unk

Agent 3: _____

Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unk **Duration**: _____ days O Unk

MODULE 3: OUTCOME CASE REPORT FORM

OUTCOME

Outcome: ○Discharged alive ○Hospitalised ○Transfer to other facility ○Death ○Palliative discharge ○Unknown

Outcome date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ○Unknown

If alive at outcome date:

Ability to self-care at discharge versus before illness: ○Same as before illness ○Worse ○Better ○Unknown

Post-discharge treatment: Oxygen therapy? ○YES ○NO ○Unknown

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

POST PARTUM (within 6 weeks of delivery)? O YES O NO O Unknown *(if NO or Unknown skip this section)*

Pregnancy Outcome: O Live birth O Still birth **Delivery date:** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Baby tested for COVID-19/SARS-CoV-2 infection? O YES O NO O Unknown

If YES, result of test: O Positive O Negative O Unknown (If Positive, complete a separate CRF for baby)

INFANT – Less than 1 year old? O YES O NO *(If NO skip this section)*

Birth weight: [___][___].[___] O kg or O lbs O Unknown

Gestational outcome: O Term birth (≥37wk GA) O Preterm birth (<37wk GA) O Unknown

Breastfed? O YES-currently breastfeeding O YES-breastfeeding discontinued O NO O Unknown

Vaccinations appropriate for age/country? O YES O NO O Unknown

PREVIOUS COVID-19 INFECTIONS

Has the patient had COVID-19 previously?

O No O Yes - once previously O Yes - twice previously O 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/YYY) _____

Was their first COVID infection confirmed by testing: O Yes, confirmed by testing O No, not confirmed by testing

Were they admitted to hospital for their first infection of COVID? O Yes O No

Second COVID-19 infection: When did their second COVID infection occur? (MM/YYY) _____

Was their second COVID infection confirmed by testing: O Yes, confirmed by testing O No, not confirmed by testing

Were they admitted to hospital for their second infection of COVID? O Yes O No

If data on this patient was previously recorded in this study, record the Participant Identification Number (PIN) previously used in the section below

RE-ADMISSION AND PREVIOUS PIN

Was the patient admitted previously or transferred from any other facility during this illness episode?

O YES-admitted previously to this facility O YES–transferred from other facility O NO O Unknown

Number of previous admissions for this infection: _____

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

If YES, Participant Identification number (PIN): _____

VACCINATIONS

Covid-19 vaccination: O YES O NO O Unk

Date of first vaccine **:**[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Date: O actual O estimated

Type of first vaccine: O Pfizer/BioNTech |O AstraZeneca Oxford (Covishield in India) |O Moderna |O Novavax
O Janssens (Johnson & Johnson) |O Sinopharm |O Sinovac |O Sputnik V |O Covaxin |O CanSinoBIO
O Unknown |O other, please specify _____

Date of second vaccine **:**[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Date: O actual O estimated

Type of second vaccine: O Pfizer/BioNTech |O AstraZeneca/University of Oxford (Covishield in India) |O Moderna |O Novavax
O Janssens (Johnson & Johnson) |O Sinopharm |O Sinovac |O Sputnik V |O Covaxin |O CanSinoBIO
O Unknown |O other, please specify _____

Date of third vaccine **:**[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Date: O actual O estimated

Type of third vaccine: O Pfizer/BioNTech |O AstraZeneca/University of Oxford (Covishield in India) |O Moderna |O Novavax
O Janssens (Johnson & Johnson) |O Sinopharm |O Sinovac |O Sputnik V |O Covaxin |O CanSinoBIO
O Unknown |O other, please specify _____

Influenza vaccination within the last 6 months: O YES O NO O Unknown

Date of influenza vaccine :[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Date: O actual O estimated

Was patient diagnosed with Covid-19? O YES O NO O Unknown

If yes, was the diagnosis based on: O laboratory confirmation O clinical assessment

Is the patient infected with a variant of concern (VOC)?

- O Unknown
- O No: Variant is known and no VOC identified
- O Yes: Delta - B.1.617.2, identified Oct 2020
- O Yes: Omicron, B.1.1.529, identified Nov 2021
- O Yes: Alpha - B.1.1.7, identified in UK Sept 2020
- O Yes: Beta - B.1.351, identified in South Africa May 2020
- O Yes: Gamma - P.1, identified in Brazil Nov 2020
- O Yes: Epsilon - B.1.427/B.1.429, identified in USA Mar 2021
- O Yes: Zeta - P.2, identified in Brazil Apr 2020
- O Yes: Eta - B.1.525, identified in Multiple Countries Dec 2020
- O Yes: Theta - P.3, identified in Philippines Jan 2021
- O Yes: Iota - B.1.526, identified in USA Nov 2020
- O Yes: Kappa - B.1.617.1, identified in India Oct 2020
- O Yes: Lambda - C.37, identified in Peru Dec 2020
- O Yes: Mu - B.1.621, identified in Colombia Jan 2021
- O Yes: A variant not listed above

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

If the Omicron variant was identified, what method was used to identify it?

O Genomic sequencing O S-gene target failure (SGTF) testing O PCR genotyping O Unknown or untested