

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 (●) 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

DEMOGRAPHICS

Clinical centre name: _____ Country: _____

Enrolment date /first COVID-19 assessment date: [][][][][][]/[][][][][][]/[][][][][][]

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: [][][][][][]/[][][][][][]/[][][][][][]

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

ONSET & ADMISSION

Onset date of first/earliest symptom: [][][][][][]/[][][][][][]/[][][][][][]

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

RE-ADMISSION

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

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

If YES, Participant Identification number (PIN): _____

Is the patient being re-admitted with or due to COVID-19? (Please only add re-admission episodes for COVID related complications or patients remaining positive). Assign new subject ID YES NO Unknown

Previous participant ID: _____ Unknown

Number of re-admissions: _____ (record as a new patient for each re-admission)

Please provide reason for readmission: _____

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

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	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk	Fatigue / Malaise	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk
Cough <input type="radio"/> YES - non-productive <input type="radio"/> YES - productive <input type="radio"/> YES - with haemoptysis <input type="radio"/> NO <input type="radio"/> Unk	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk	Anorexia	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk
		Altered consciousness/confusion	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk
Sore throat	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk	Muscle aches (myalgia)	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk
Runny nose (rhinorrhoea)	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk	Joint pain (arthralgia)	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk
Wheezing	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk	Inability to walk	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk
Shortness of breath	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk	Abdominal pain	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk
Lower chest wall indrawing	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk	Diarrhoea	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk
Chest pain	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk	Vomiting / Nausea	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk
Conjunctivitis	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk	Skin rash	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk
Lymphadenopathy	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk	Bleeding (Haemorrhage)	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk
Headache	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk	If YES, specify site(s): _____	
Loss of smell (Anosmia)	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk	Other symptom(s)	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk
Loss of taste (Ageusia)	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk	If YES, specify: _____	
Seizures	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unk		

VACCINATIONS

Covid-19 vaccination: YES NO Unk

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

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

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

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

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

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

Influenza vaccination within the last 6 months: YES NO Unknown

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

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

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

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

LABORATORY RESULTS (on admission, on any admission to ICU, then daily) – complete every line					
DATE OF ASSESSMENT (DD/MM/YYYY): [_] [_] [_] [_] / [_] [_] [_] [_] / [_] [_] [_] [_]					
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)		<input type="radio"/>	Urea (BUN) (mmol/L)		<input type="radio"/>
WBC count (x10 ⁹ /L)		<input type="radio"/>	Lactate (mmol/L)		<input type="radio"/>
Lymphocyte count (10 ⁹ /L)		<input type="radio"/>	Creatinine (µmol/L)		<input type="radio"/>
Neutrophil count (10 ⁹ /L)		<input type="radio"/>	Sodium (mmol/L)		<input type="radio"/>
Haematocrit (%)		<input type="radio"/>	Potassium (mmol/L)		<input type="radio"/>
Platelets (x10 ⁹ /L)		<input type="radio"/>	Procalcitonin (ng/mL)		<input type="radio"/>
APTT (seconds)		<input type="radio"/>	CRP (mg/L)		<input type="radio"/>
APTR		<input type="radio"/>	LDH (U/L)		<input type="radio"/>
PT (seconds)		<input type="radio"/>	Creatine kinase (U/L)		<input type="radio"/>
INR		<input type="radio"/>	Troponin I (ng/mL)		<input type="radio"/>
ALT/SGPT (U/L)		<input type="radio"/>	D-dimer (mg/L)		<input type="radio"/>
Total bilirubin (µmol/L)		<input type="radio"/>	Ferritin (ng/mL)		<input type="radio"/>
AST/SGOT (U/L)		<input type="radio"/>	IL-6 (pg/mL)		<input type="radio"/>
Glucose (mmol/L)		<input type="radio"/>	Fibrinogen (mg/dl)		<input type="radio"/>

MODULE 3: OUTCOME CASE REPORT FORM

TREATMENT: At ANY time during hospitalisation, did the patient receive/undergo:	
Any Oxygen therapy? <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	If YES, total duration: _____ days <input type="radio"/> Unknown
Maximum O ₂ flow volume: <input type="radio"/> <2 L/min <input type="radio"/> 2-5 L/min <input type="radio"/> 6-10 L/min <input type="radio"/> 11-15 L/min <input type="radio"/> >15 L/min	
Non-invasive ventilation? (Any) <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	If YES, total duration: _____ days <input type="radio"/> Unknown
Invasive ventilation? (Any) <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	If YES, total duration: _____ days <input type="radio"/> Unknown
High flow nasal oxygen <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	If YES, total duration: _____ days <input type="radio"/> Unknown
Prone Positioning? <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	
Inhaled Nitric Oxide? <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	
Tracheostomy inserted? <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	
Extracorporeal support (ECMO)? <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	If YES, total duration: _____ days <input type="radio"/> Unknown
Renal replacement therapy (RRT) or dialysis? <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	
Inotropes/vasopressors? <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	
ICU or High Dependency Unit admission? <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	If YES, total duration: _____ days <input type="radio"/> Unknown
If YES, date of ICU admission: [_] [_] [_] [_] / [_] [_] [_] [_] / [_] [_] [_] [_]	<input type="radio"/> Unknown
date of ICU discharge: [_] [_] [_] [_] / [_] [_] [_] [_] / [_] [_] [_] [_]	<input type="radio"/> Unknown

MODULE 3: OUTCOME CASE REPORT FORM

MEDICATION (continued):

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

Agent 1: _____ Date commenced [] [] [] [] / [] [] [] [] / [2] [0] [] [] Duration: _____ days Unk

Agent 2: _____ Date commenced [] [] [] [] / [] [] [] [] / [2] [0] [] [] Duration: _____ days Unk

Agent 3: _____ Date commenced [] [] [] [] / [] [] [] [] / [2] [0] [] [] Duration: _____ days Unk

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 Unk

If YES, Date commenced [] [] [] [] / [] [] [] [] / [2] [0] [] [] Duration: _____ days Unk

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

If YES, Date commenced [] [] [] [] / [] [] [] [] / [2] [0] [] [] Duration: _____ days Unk

If YES: Other corticosteroid? YES NO Unknown

If YES: Which steroid: Prednisolone Hydrocortisone Methylprednisolone Other

Route: Oral Intravenous Unk

ANTICOAGULATION? YES NO Unk

If YES: Agent: _____

Route: Subcutaneous Intravenous (IV) Unk

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

ANTIFUNGAL AGENT? YES NO Unk

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

If YES, specify agent and timing of administration:

Agent 1: _____

Date commenced [] [] [] [] / [] [] [] [] / [2] [0] [] [] Unk Duration: _____ days Unk

Agent 2: _____

Date commenced [] [] [] [] / [] [] [] [] / [2] [0] [] [] Unk Duration: _____ days Unk

Agent 3: _____

Date commenced [] [] [] [] / [] [] [] [] / [2] [0] [] [] Unk Duration: _____ days Unk

MODULE 3: OUTCOME CASE REPORT FORM**OUTCOME****Was patient diagnosed with Covid-19?** YES NO UnknownIf yes, was the diagnosis based on: Laboratory confirmation clinical assessment**Has a variant of concern (VOC) or variant of interest (VOI) been identified in this patient?**

- Unknown
- Yes, a variant not listed below
- Alpha - B.1.1.7, identified in UK Sept 2020
- Beta - B.1.351, identified in South Africa May 2020
- Gamma - P.1, identified in Brazil Nov 2020
- Delta - B.1.617.2, identified in India Oct 2020
- Epsilon - B.1.427/B.1.429, identified in USA Mar 2021
- Zeta - P.2, identified in Brazil Apr 2020
- Eta - B.1.525, identified in Multiple Countries Dec 2020
- Theta - P.3, identified in Philippines Jan 2021
- Iota - B.1.526, identified in USA Nov 2020
- Kappa - B.1.617.1, identified in India Oct 2020
- Lambda - C.37, identified in Peru Dec 2020

*Please check the REDCAP database for variants not listed above. New variants will be added to the database as they are identified.***Outcome:** Discharged alive Hospitalised Transfer to other facility Death Palliative discharge Unknown**Outcome date:** [_] [_] / [_] [_] / [2] [0] [_] [_] 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