Global COVID-19 Clinical Platform

NOVEL CORONAVIRUS (COVID-19) - RAPID VERSION

DESIGN OF THIS CASE RECORD FORM (CRF)

This CRF has 3 modules:

Module 1 to be completed on the first day of admission to the health centre.

Module 2 to be completed on first day of admission to ICU or high dependency unit. Module 2 should also be completed daily for as many days as resources allow. Continue to follow-up patients who transfer between wards.

Module 3 to be completed 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 retrospectively if the patient is enrolled after the admission date.
- Participant Identification Numbers consist of a site code and a 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 00001. In the case of a single site recruiting participants on different wards, or where it is otherwise difficult to assign sequential numbers, you can assign numbers in blocks or incorporate alpha characters. E.g. Ward X will assign numbers from 00001 or A0001 onwards and Ward Y will assign numbers from 50001 or B0001 onwards. Enter the Participant Identification Number at the top of every page.
- Data are entered to the central electronic REDCap database at https://ncov.medsci.ox.ac.uk or to your site/network's independent database. Printed paper CRFs may be used and the data can be typed into the electronic database afterwards.
- Complete every section. Questions marked "If yes,…" should be left blank when they do not apply (i.e. when the answer is not yes).
- Selections with square boxes (☐) are single selection answers (choose one answer only).
- Selections with circular boxes (O) are multiple selection answers (choose all that apply).
- Mark 'Unknown' for any data that are not available or unknown.
- Avoid recording data outside of the dedicated areas.
- If using paper CRFs, we recommend writing clearly in ink, using BLOCK-CAPITAL LETTERS.
- Place an (X) in the boxes to mark the 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 can be stored by the institution responsible for them. All data should be transferred to the 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 can support the establishment of locally hosted databases.
- Please contact us at ncov@isaric.org. If we can help with databases, if you have comments and to let us know that you are using the forms.

World Health Organization ISARIC

PARTICIPANT ID I 1 I I 2 I I3 I I 4 I I 5 I -- I 6 I I 7 I I 8 I I 9 I

MODULE1: complete on admission/enrolment

Site name _Glasgow **Country** _UK

Date of enrolment [_0_][_9_]/[_0_][_7_]/[_2_][_0_][_2_][_0_]

CLINICAL INCLUSION CRITERIA

Proven or suspected infection with pathogen of Public Health Interest ×Yes ☐No

One or more	A history of self-reported feverishness or measured fever of ≥ 38oC	×Yes	☐No
of these	Cough	×Yes	☐No
during this	Dyspnoea (shortness of breath) OR Tachypnoea*	×Yes	☐No
illness	Clinical suspicion of ARI despite not meeting criteria above	☐Yes	×No

** respiratory rate ≥50 breaths/min for <1 year; ≥40 for 1-4 years; ≥30 for 5-12 years; ≥20 for ≥13 years*

DEMOGRAPHICS

Sex at Birth ×Male ☐Female ☐Not specified **Date of birth** [_1_][_0_]/[_0_][_7_]/[_1_][_9_][_8_][_0_] If date of birth is unknown, record: **Age** [0___][4__][0__]years OR [_][_]months

Healthcare Worker? ☐Yes ×No ☐Unknown **Laboratory Worker?** ☐Yes ×No ☐Unknown

Pregnant? ☐Yes ×No ☐Unknown ☐N/A **If yes: Gestational weeks assessment** [_][_] weeks

DATE OF ONSET AND ADMISSION VITAL SIGNS *(first available data at presentation/admission)*

Symptom onset (date of first/earliest symptom) [_1_][_5_]/[_0_][_3_]/[_2_][_0_][_2_][_0_]

Admission date at this facility [_1_][_7_]/[_0_][_3_]/[_2_][_0_][_2_][_0_]

Temperature [_3_][8__].[_9_]°C **Heart rate** [1_][0_][9_]beats/min

Respiratory rate [_1_][_1_]breaths/min

BP [_1_] [_2_] [_0_](systolic) [_0_][_8_][_0_](diastolic) mmHg **Severe dehydration** ☐Yes ×No ☐Unknown

Sternal capillary refill time >2seconds ×Yes ☐No ☐Unknown

Oxygen saturation: [0_][_9_][0_]% on ×room air ☐oxygen therapy ☐Unknown **A V P U** (circle one)

Glasgow Coma Score (GCS /15) [_0_][_9_] **Malnutrition** ☐Yes ×No ☐Unknown

Mid-upper arm circumference [3___][8___][5___]mm **Height:** [1___] [8___][0___]cm **Weight**: [0_][8_][0___]kg

CO-MORBIDITIES *(existing prior to admission) (Unk = Unknown)*

Chronic cardiac disease *(not hypertension)*	☐Yes	×No	☐Unk	Diabetes	☐Yes	×No	☐Unk
Hypertension	☐Yes	×No	☐Unk	Current smoking	☐Yes	×No	☐Unk
Chronic pulmonary disease	☐Yes	×No	☐Unk	Tuberculosis	☐Yes	×No	☐Unk
Asthma	☐Yes	×No	☐Unk	Asplenia	☐Yes	×No	☐Unk
Chronic kidney disease	☐Yes	×No	☐Unk	Malignant neoplasm	☐Yes	×No	☐Unk
Chronic liver disease	☐Yes	×No	☐Unk	Other	☐Yes	×No	☐Unk
Chronic neurological disorder	☐Yes	×No	☐Unk	If yes, specify: _			
HIV	☐Yes-on ART		☐Yes-not on ART	×No	☐Unknown		

PRE-ADMISSION & CHRONIC MEDICATION **Were any of the following taken within 14 days of admission?**

Angiotensin converting enzyme inhibitors (ACE inhibitors)?	☐Yes ×No ☐Unknown
Angiotensin II receptor blockers (ARBs)?	☐Yes ×No ☐Unknown
Non-steroidal anti-inflammatory (NSAID)?	☐Yes ×No ☐Unknown

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

History of fever	×Yes ☐No ☐Unk	Lower chest wall indrawing	☐Yes ×No ☐Unk
Cough	×Yes ☐No ☐Unk	Headache.	☐Yes ×No ☐Unk
with sputum production	☐Yes ×No ☐Unk	Altered consciousness/confusion	☐Yes ×No ☐Unk
with haemoptysis	☐Yes ×No ☐Unk	Seizures	☐Yes ×No ☐Unk
Sore throat	☐Yes ×No ☐Unk	Abdominal pain	☐Yes ×No ☐Unk
Runny nose (rhinorrhoea).	☐Yes ×No ☐Unk	Vomiting / Nausea	☐Yes ×No ☐Unk
Wheezing	☐Yes ×No ☐Unk	Diarrhoea	☐Yes ×No ☐Unk
Chest pain.	☐Yes ×No ☐Unk	Conjunctivitis	☐Yes ×No ☐Unk
Muscle aches (myalgia)	☐Yes ×No ☐Unk	Skin rash	☐Yes ×No ☐Unk
Joint pain (arthralgia).	☐Yes ×No ☐Unk	Skin ulcers	☐Yes ×No ☐Unk
Fatigue / Malaise	×Yes ☐No ☐Unk	Lymphadenopathy	☐Yes ×No ☐Unk
Shortness of breath.	×Yes ☐No ☐Unk	Bleeding (Haemorrhage).	☐Yes ×No ☐Unk
Inability to walk	☐Yes ☐No ×Unk	If bleeding: specify site(s):	

Other ☐Yes ☐No ×Unk If yes, specify: _____

MEDICATION ***Is the patient CURRENTLY receiving any of the following?***

Oral/orogastric fluids? ☐Yes ×No ☐ Unknown **Intravenous fluids?** ×Yes ☐No ☐Unknown

Antiviral? ☐Yes ×No ☐Unknown **If yes:** ○Ribavirin ○Lopinavir/Ritonavir ○Neuraminidase inhibitor ○Interferon alpha ○Interferon beta ○Other, specify: _____

Corticosteroid? ☐Yes ☐No ☐Unknown **If yes,** route: ○Oral ○Intravenous ○Inhaled

If yes, please provide agent and maximum daily dose: _____

Antibiotic? ☐Yes ☐No ☐Unknown **Antifungal agent?** ☐Yes ☐No ☐Unknown

Antimalarial agent? ☐Yes ☐No ☐Unknown **If yes,** specify:_____

Experimental agent? ☐Yes ☐No ☐Unknown **If yes,** specify:_____

Non-steroidal anti-inflammatory (NSAID) ☐Yes ☐No ☐Unknown

Angiotensin converting enzyme inhibitors (ACE inhibitors) ☐Yes ☐No ☐Unknown

Angiotensin II receptor blockers (ARBs) ☐Yes ☐No ☐Unknown

SUPPORTIVE CARE ***Is the patient CURRENTLY receiving any of the following?***

ICU or High Dependency Unit admission? ☐Yes ☐No ☐Unknown

Oxygen therapy? ☐Yes ☐No ☐ Unknown **If yes**, complete all below

O_2 flow: ☐1-5 L/min ☐6-10 L/min ☐11-15 L/min ☐>15 L/min ☐Unknown

Source of oxygen: ☐Piped ☐Cylinder ☐Concentrator ☐Unknown

Interface: ☐Nasal prongs ☐HF nasal cannula ☐Mask ☐Mask with reservoir ☐CPAP/NIV mask ☐Unknown

Non-invasive ventilation? *(e.g.BIPAP/CPAP)* ☐Yes ☐No ☐N/A

Invasive ventilation *(Any)***?** ☐Yes ☐No ☐ Unknown **Inotropes/vasopressors?** ☐Yes ☐No ☐Unknown

Extracorporeal (ECMO) support? ☐Yes ☐No ☐ Unknown **Prone position?** ☐Yes ☐No ☐ Unknown

LABORATORY RESULTS ON ADMISSION (**record units if different from those listed)*

Parameter	Value*	Not done	Parameter	Value*	Not done
Haemoglobin (g/L)		☐	Creatinine (µmol/L)		☐
WBC count (x10⁹/L)		☐	Sodium (mEq/L)		☐
Haematocrit (%)		☐	Potassium (mEq/L)		☐
Platelets (x10⁹/L)		☐	Procalcitonin (ng/mL)		☐
APTT/APTR		☐	CRP (mg/L)		☐
PT (seconds)		☐	LDH (U/L)		☐
INR		☐	Creatine kinase (U/L)		☐
ALT/SGPT (U/L)		☐	Troponin (ng/mL)		☐
Total bilirubin (µmol/L)		☐	ESR (mm/hr)		☐
AST/SGOT (U/L)		☐	D-dimer (mg/L)		☐
Urea (BUN) (mmol/L)		☐	Ferritin (ng/mL)		☐
Lactate (mmol/L)		☐	IL-6 (pg/mL)		☐

MODULE 2: follow-up (frequency of completion determined by available resources)

Date of follow up [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

VITAL SIGNS *(record most abnormal value between 00:00 to 24:00)*

Temperature [___][___].[___]°C **Heart rate** [___][___][___]beats per min **Respiratory rate** [___][___]breaths/min

BP [___] [___] [___](systolic) [___][___][___](diastolic) mmHg **Severe dehydration** ☐Yes ☐No ☐Unknown

Sternal capillary refill time >2seconds ☐Yes ☐No ☐Unknown **GCS/15** [___][___]

Oxygen saturation [_][ ][ ]% on ☐ room air ☐ oxygen therapy ☐Unknown **A V P U** (circle one)

DAILY CLINICAL FEATURES *(Unk = Unknown)*

Cough	☐Yes ☐No ☐Unk		Seizures	☐Yes ☐No ☐Unk	
and sputum production	☐Yes ☐No ☐Unk		Vomiting / Nausea	☐Yes ☐No ☐Unk	
Sore throat	☐Yes ☐No ☐Unk		Diarrhoea	☐Yes ☐No ☐Unk	
Chest pain	☐Yes ☐No ☐Unk		Conjunctivitis	☐Yes ☐No ☐Unk	
Shortness of breath	☐Yes ☐No ☐Unk		Myalgia	☐Yes ☐No ☐Unk	
Confusion	☐Yes ☐No ☐Unk		Other, specify: _	☐Yes ☐No ☐Unk	

LABORATORY RESULTS (**record units if different from those listed)*

Parameter	Value*	Not done	Parameter	Value*	Not done
Haemoglobin (g/L)		☐	Creatinine (µmol/L)		☐
WBC count (x10⁹/L)		☐	Sodium (mEq/L)		☐
Haematocrit (%)		☐	Potassium (mEq/L)		☐
Platelets (x10⁹/L)		☐	Procalcitonin (ng/mL)		☐
APTT/APTR		☐	CRP (mg/L)		☐
PT (seconds)		☐	LDH (U/L)		☐
INR		☐	Creatine kinase (U/L)		☐
ALT/SGPT (U/L)		☐	Troponin (ng/mL)		☐
Total bilirubin (µmol/L)		☐	ESR (mm/hr)		☐
AST/SGOT (U/L)		☐	D-dimer (mg/L)		☐
Urea (BUN) (mmol/L)		☐	Ferritin (ng/mL)		☐
Lactate (mmol/L)		☐	IL-6 (pg/mL)		☐

MEDICATION ***Is the patient CURRENTLY receiving any of the following?***

Oral/orogastric fluids? ☐Yes ☐No ☐ Unknown **Intravenous fluids?** ☐Yes ☐No ☐Unknown

Antiviral? ☐Yes ☐No ☐Unknown **If yes:** ○Ribavirin ○Lopinavir/Ritonavir ○Neuraminidase inhibitor ○Interferon alpha ○Interferon beta ○Other, specify: _____

Corticosteroid? ☐Yes ☐No ☐Unknown **If yes,** route: ○Oral ○Intravenous ○Inhaled

If yes, please provide agent and maximum daily dose: _____

Antibiotic? ☐Yes ☐No ☐Unknown **Antifungal agent?** ☐Yes ☐No ☐Unknown

Antimalarial agent? ☐Yes ☐No ☐Unknown **If yes,** specify: _____

Experimental agent? ☐Yes ☐No ☐Unknown **If yes,** specify:_____

Non-steroidal anti-inflammatory (NSAID) ☐Yes ☐No ☐Unknown

Angiotensin converting enzyme inhibitors (ACE inhibitors) ☐Yes ☐No ☐Unknown

Angiotensin II receptor blockers (ARBs) ☐Yes ☐No ☐Unknown

SUPPORTIVE CARE ***Is the patient CURRENTLY receiving any of the following?***

ICU or High Dependency Unit admission? ☐Yes ☐No ☐Unknown

Oxygen therapy? ☐Yes ☐No ☐Unknown **If yes,** complete all below:

O_2 flow volume: ☐1-5 L/min ☐6-10 L/min ☐11-15 L/min ☐>15 L/min ☐Unknown

Source of oxygen: ☐Piped ☐Cylinder ☐Concentrator ☐Unknown

Interface: ☐Nasal prongs ☐HF nasal cannula ☐Mask ☐Mask with reservoir ☐CPAP/NIV mask ☐Unknown

Non-invasive ventilation? *(e.g. BIPAP, CPAP)* ☐Yes ☐No ☐Unknown

Invasive ventilation *(Any)***?** ☐Yes ☐No ☐Unknown **Inotropes/vasopressors?** ☐Yes ☐No ☐Unknown

Extracorporeal (ECMO) support? ☐Yes ☐No ☐Unknown **Prone position?** ☐Yes ☐No ☐ Unknown

Renal replacement therapy (RRT) or dialysis? ☐Yes ☐No ☐Unknown

MODULE 3: complete at discharge/death

DIAGNOSTIC/PATHOGEN TESTING

Chest X-Ray /CT performed? ☐Yes ☐No ☐Unknown **If Yes: infiltrates present?** ☐Yes ☐No ☐Unknown

Was pathogen testing done during this illness episode? ☐Yes ☐No ☐Unknown **If yes**, complete all below:

Influenza virus: ☐Positive ☐Negative ☐Not done **If positive,** type _____

Coronavirus: ☐Positive ☐Negative ☐Not done **If positive:** ☐MERS-CoV ☐SARS-CoV-2 ☐Other _____

Other respiratory pathogen: ☐Positive ☐Negative ☐Not done **If positive,** specify _____

Viral haemorrhagic fever: ☐Positive ☐Negative ☐Not done **If positive,** specify virus _____ _____

Other pathogen of public health interest detected: If yes, specify:

Falciparum malaria: ☐Positive ☐Negative ☐Not done **Non-falciparum malaria:** ☐Positive ☐Negative ☐Not done

HIV: ☐Positive ☐Negative ☐Not done

COMPLICATIONS: At any time during hospitalisation did the patient experience:

Shock	☐Yes ☐No ☐Unknown	Bacteraemia	☐Yes ☐No ☐Unknown
Seizure	☐Yes ☐No ☐Unknown	Bleeding	☐Yes ☐No ☐Unknown
Meningitis/Encephalitis	☐Yes ☐No ☐Unknown	Endocarditis	☐Yes ☐No ☐Unknown
Anaemia	☐Yes ☐No ☐Unknown	Myocarditis/Pericarditis	☐Yes ☐No ☐Unknown
Cardiac arrhythmia	☐Yes ☐No ☐Unknown	Acute renal injury	☐Yes ☐No ☐Unknown
Cardiac arrest	☐Yes ☐No ☐Unknown	Pancreatitis	☐Yes ☐No ☐Unknown
Pneumonia	☐Yes ☐No ☐Unknown	Liver dysfunction	☐Yes ☐No ☐Unknown
Bronchiolitis	☐Yes ☐No ☐Unknown	Cardiomyopathy	☐Yes ☐No ☐Unknown
Acute Respiratory Distress Syndrome	☐Yes ☐No ☐Unknown	Other If Yes, specify	☐Yes ☐No ☐Unknown _____

MEDICATION: While hospitalised or at discharge, were any of the following administered?

Oral/orogastric fluids? ☐Yes ☐No ☐Unknown **Intravenous fluids?** ☐Yes ☐No ☐Unknown

Antiviral? ☐Yes ☐No ☐Unknown **If yes:** ○Ribavirin ○Lopinavir/Ritonavir ○Neuraminidase inhibitor ○Interferon alpha ○Interferon beta ○Other, specify: _____

Antibiotic? ☐Yes ☐No ☐Unknown **If yes,** specify: _____

Corticosteroid? ☐Yes ☐No ☐Unknown **If yes,** route: ○Oral ○Intravenous ○Inhaled

If yes, specify agent and maximum daily dose: _____

Antifungal agent? ☐Yes ☐No ☐Unknown **If yes,** specify: _____

Antimalarial agent? ☐Yes ☐No ☐Unknown **If yes,** specify:_____

Experimental agent? ☐Yes ☐No ☐Unknown **If yes,** specify:_____

Non-steroidal anti-inflammatory (NSAID) ☐Yes ☐No ☐Unknown **If yes,** specify: _____

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

ICU or High Dependency Unit admission? ☐Yes ☐No ☐ Unknown **If yes,** total duration:_____days

Date of ICU admission:[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐N/A

Date of ICU discharge:[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐in ICU at outcome ☐N/A

Oxygen therapy? ☐Yes ☐No ☐Unknown **If yes, complete all:** **Total duration**:_____days

O_2 flow volume: ○1-5 L/min ○6-10 L/min ○11-15 L/min ○>15 L/min

Source of oxygen: ○Piped ○Cylinder ○Concentrator

Interface: ○Nasal prongs ○HF nasal cannula ○Mask ○Mask with reservoir ○CPAP/NIV mask

Non-invasive ventilation? *(e.g. BIPAP, CPAP)* ☐Yes ☐No ☐ Unknown **If yes,** total duration:_____days

Invasive ventilation *(Any)***?** ☐Yes ☐No ☐Unknown **If yes,** total duration:_days

Extracorporeal (ECMO) support? ☐Yes ☐No ☐Unknown **If yes,** total duration:_____days

Prone position? ☐Yes ☐No ☐ Unknown **If yes,** total duration:_____days

Renal replacement therapy (RRT) or dialysis? ☐Yes ☐No ☐Unknown

Inotropes/vasopressors? ☐Yes ☐No ☐Unknown **If yes,** total duration:_____days

OUTCOME

Outcome: ☐Discharged alive ☐Hospitalized ☐Transfer to other facility ☐Death ☐Palliative discharge ☐Unknown

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

If Discharged alive: Ability to self-care at discharge versus before illness: ☐Same as before illness ☐Worse ☐Better ☐Unknown