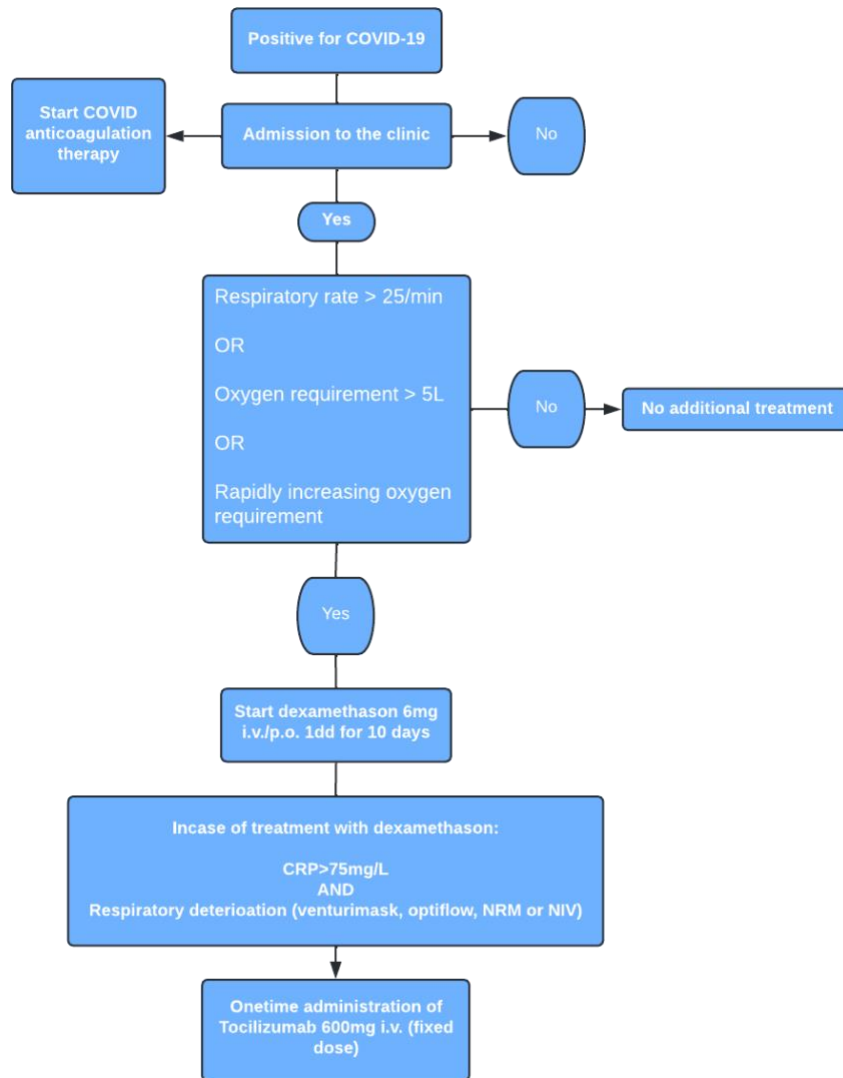


Annex 1 – MST COVID-19 treatment protocol





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@isarc.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, you can 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 S001 or B001 onwards. Enter the Participant Identification Number at the top of every page.
- Data are entered to the central electronic REDCap database at <https://ncov.medschool.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 (☐) 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.medschool.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@isarc.org. If we can help with databases, if you have comments and to let us know that you are using the forms.



PARTICIPANT ID |__| |__| |__| |__| |__| |__| - |__| |__| |__| |__|

MODULE1: complete on admission/enrolment

Site name _____ Country _____

Date of enrolment 1 D 11 M 2 0 Y Y Y

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 $\geq 38^{\circ}\text{C}$ ☐ Yes ☐ No

of these	Cough	☐ Yes ☐ No
----------	-------	--

during this	Dyspnoea (shortness of breath) OR Tachypnoea*	☐ Yes ☐ No
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* respiratory rate ≥ 50 breaths/min for ≤ 1 year; ≥ 40 for 1–4 years; ≥ 30 for 5–12 years; ≥ 20 for ≥ 13 years

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

Sex at Birth ☐ Male ☐ Female ☐ Not specified Date of birth [D][D][M][M][Y][Y][Y][Y]

If date of birth is unknown, record: Age [] [] [] 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

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/YYY) _____

Was their first COVID infection confirmed by testing:

☐ Yes, confirmed by testing

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

Second COVID-19 infection:
When did the second COVID infection occur? (MM/DD/YY)

When did their second COVID infection occur? (MM/YYYY) _____

Was their second COVID infection confirmed by testing: _____

☐ 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)

RE ADMISSION AND PREVIOUS BIAS

RE-ADMISSION AND PREVIOUS PIN

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

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):

SIGNS AND SYMPTOMS ON ADMISSION (Link = Unknown)						
History of fever	☐ Yes	☐ No	☐ Unknown	Lower chest wall indrawing	☐ Yes	☐ No ☐ Unknown
Cough	☐ Yes	☐ No	☐ Unknown	Headache	☐ Yes	☐ No ☐ Unknown
with sputum production	☐ Yes	☐ No	☐ Unknown	Altered consciousness/confusion	☐ Yes	☐ No ☐ Unknown
with haemoptysis	☐ Yes	☐ No	☐ Unknown	Seizures	☐ Yes	☐ No ☐ Unknown
Sore throat	☐ Yes	☐ No	☐ Unknown	Abdominal pain	☐ Yes	☐ No ☐ Unknown
Runny nose (rhinorrhoea)	☐ Yes	☐ No	☐ Unknown	Vomiting / Nausea	☐ Yes	☐ No ☐ Unknown
Wheezing	☐ Yes	☐ No	☐ Unknown	Diarrhoea	☐ Yes	☐ No ☐ Unknown
Chest pain	☐ Yes	☐ No	☐ Unknown	Conjunctivitis	☐ Yes	☐ No ☐ Unknown
Muscle aches (myalgia)	☐ Yes	☐ No	☐ Unknown	Skin rash	☐ Yes	☐ No ☐ Unknown
Joint pain (arthralgia)	☐ Yes	☐ No	☐ Unknown	Skin ulcers	☐ Yes	☐ No ☐ Unknown
Fatigue / Malaise	☐ Yes	☐ No	☐ Unknown	Lymphadenopathy	☐ Yes	☐ No ☐ Unknown
Shortness of breath	☐ Yes	☐ No	☐ Unknown	Bleeding (Haemorrhage)	☐ Yes	☐ No ☐ Unknown
Inability to walk	☐ Yes	☐ No	☐ Unknown	If bleeding, specify site(s):		
Other (Yes/No/Unknown) Click if uses 'specify'						

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

Oral/organic 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 ☐ Yes, complete all below

O₂ flow: ☐ 1-5 L/min ☐ 6-10 L/min ☐ 11-15 L/min ☐ 15 L/min ☐ Unknown

Source of oxygen: ☐ Pipel ☐ 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 ☐ CNIA

Invasive ventilation (Armo)? ☐ 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 (x10 ⁹ /L)		☐	Sodium (mEq/L)		☐
Haematocrit (%)		☐	Potassium (mEq/L)		☐
Platelets (x10 ⁹ /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)		☐

[illegible]

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

Oral/ogastric 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:**

O₂ flow volume: 0.1-1.5 L/min ☐ 0.6-1.0 L/min ☐ 11-1.5 L/min ☐ >1.5 L/min ☐ Unknown

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

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

Non-invasive ventilation (if yes: BiPAP, APAP) ☐ Yes ☐ No ☐ Unknown

Invasive ventilation? ☐ Yes ☐ No ☐ Unknown **Inotropes/vasopressors?** ☐ Yes ☐ No ☐ Unknown

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

Renal replacement therapy/RTT 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 tested/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:** CMERS-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: ☐ 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:

IMPLICATIONS: At any time during the hospitalization, the patient experienced:			
Seizure	Yes	Unknown	No
Shore	Yes	Unknown	No
Meningitis/Encephalitis	Yes	Unknown	No
Anaemia	Yes	Unknown	No
Cardiac arrhythmia	Yes	Unknown	No
Cerebral palsy	Yes	Unknown	No
Pneumonia	Yes	Unknown	No
Bronchitis	Yes	Unknown	No
Acute Respiratory Syndrome	Yes	Unknown	No
		If Yes, specify	

Symptoms		If Yes, specify	
MEDICATION: While hospitalised or at discharge, were any of the following administered?			

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

Antiviral? ☐ Yes ☐ No ☐ Unknown **If yes:** ☐ Ribavirin ☐ Lopinavir/Ritonavir ☐ Neuraminidase inhibitor

Antifungal? ☐ Yes ☐ No ☐ Unknown **Antifungal alpha** ☐ Olfenteron beta ☐ Other: _____

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

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

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 hospitalization, did the patient receive/undergo:

SUPPORTIVE CARE: At any time during hospitalization, did the patient receive/undergo:

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

Date of ICU admission: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12

Date of ICU discharge: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ In ICU at outcome ☐ N/A

Oxygen therapy: ☐ Yes ☐ No ☐ Unknown **If yes, total duration:** _____ days

☐ O₂ flow rate: **O1-5 L/min** **O6-10 L/min** **O11-15 L/min** **O>15 L/min**

Source of oxygen: ☐ Pipet ☐ Cylinder ☐ Concentrator

Interface: ☐ Nasal prongs ☐ BIPAP 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? ☐ 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/vasoconstrictors? ☐ Yes ☐ No ☐ Unknown **If yes, total duration:** _____ days

MODULE 3: complete at discharge/death

OUTCOME

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

- ☐ Unknown
- ☐ No: Variant is known and no VOC identified
- ☐ Yes: Delta - B.1.617.2, identified Oct 2020
- ☐ Yes: Omicron, B.1.1.529, identified Nov 2021
- ☐ Yes: Alpha - B.1.1.7, identified in UK Sept 2020
- ☐ Yes: Beta - B.1.351, identified in South Africa May 2020
- ☐ Yes: Gamma - P.1, identified in Brazil Nov 2020
- ☐ Yes: Epsilon - B.1.427/8, 1.429, identified in USA Mar 2021
- ☐ Yes: Zeta - P.2, identified in Brazil Apr 2020
- ☐ Yes: Eta - B.1.525, identified in Multiple Countries Dec 2020
- ☐ Yes: Theta - P.3, identified in Philippines Jan 2021
- ☐ Yes: Iota - B.1.526, identified in USA Nov 2020
- ☐ Yes: Kappa - B.1.617.1, identified in India Oct 2020
- ☐ Yes: Lambda - C.37, identified in Peru Dec 2020
- ☐ Yes: Mu - B.1.621, identified in Colombia Jan 2021
- ☐ 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 omicron variant was identified, what method was used to identify it?

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

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

Outcome date: ☐ D ☐ I ☐ P ☒ M ☐ I ☐ M ☐ V ☐ 2 ☐ 0 ☐ Y ☐ Y ☐ Y ☐ Unknown

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