

ISARIC

ACUTE RESPIRATORY INFECTION CLINICAL CHARACTERISATION DATA TOOL

CRF Completion Guide

DESIGN OF THIS CASE REPORT FORM (CRF)

This CRF is set up in modules to be used for recording data on the ISARIC_nCov Core Database or for independent studies.

Module 1 and Module 2 complete on the first day of admission or on first day of <u>COVID-19 assessment</u>. **Module 2** also complete on first day of admission to ICU or high dependency unit. In addition, complete daily for as many days as resources allow up to a maximum of 14 days. 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.
- Participant Identification Numbers consist of a 5 digit site code and a 4 digit participant number. You can obtain a site code and registering on the data management system by contacting <u>ncov@isaric.org</u>.
 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 incorporating 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.
- In the case of a participant transferring between sites, it is preferred to maintain the same Participant Identification Number (PIN) across the sites. 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 PIN and indicate 'YEStransferred' in the RE-ADMISSION section. If the PIN from the previous site is eventually obtained this can be entered under 'If YES 'Participant Identification Number:'
- For participants who are re-admitted with COVID-19 to the same site, **start a new form with a different Participant Identification Number (PIN)** and enter the previous PIN in response to the question 'Previous participant ID'.
- 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 <u>ncov@isaric.org</u> if you need help with databases, if you have comments and to let us know that you are using the forms.

COVID-19 CORE CASE REPORT FORM





ACUTE RESPIRATORY INFECTION CLINICAL CHARACTERISATION DATA TOOL

CRF Completion Guide

FURTHER GUIDANCE AND DEFINITIONS

Comorbidities

Comorbidities present before the onset of COVID-19 and are still present. Do not include those that developed following the onset of COVID-19 symptoms. More detailed guidance is provided.

Hospital admission

For patients who were admitted to hospital with COVID-19 or symptoms consistent with possible COVID-19 infection, please enter details for the date of hospital admission. For patients with a clear alternative diagnosis leading to admission who subsequently acquired COVID-19, original admission date should be provided, but all subsequent references to admission should be taken as referring to day COVID-19 was first clinically suspected (or within the first 24 hours after first day of suspected or confirmed COVID-19 infection).

Where a patient was admitted via multiple hospital departments, count admission from the time they came to the first department during the visit that led to their admission (e.g. arrival at the Emergency Department).

Oxygen therapy

Include any form of supplemental oxygen received using any methods.

Invasive ventilation

Please include any mechanical ventilation delivered following intubation or via a tracheostomy. Do not include patients who are breathing independently via a tracheostomy.

Non-invasive ventilation

Please include any positive-pressure treatment given via a tight-fitted mask. This can be continuous positive pressure (CPAP) or bi-level positive pressure (BIPAP).

Renal replacement therapy or dialysis

Please include any form of continuous renal replacement therapy or intermittent haemodialysis.

Worst result

References to 'worst result' refer to those furthest from the normal physiological range or laboratory normal range.

Results that were rejected by the clinical team (e.g. pulse oximetry on poorly perfused extremities, haemolysed blood samples, contaminated microbiology results) should not be reported.

The following measures should be considered as a single observation and entered together:

Blood gas results: Please report the measures from the blood gas with the lowest pH (most acidotic).

Blood pressure: Please report the systolic and diastolic blood pressure from the observation with the lowest mean arterial pressure (if mean arterial pressure has not been calculated, report the measurement with lowest systolic blood pressure).

Respiratory rate: If both abnormal low and high rate observed, record the abnormally high rate.



MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM CLINICAL INCLUSION CRITERIA

Suspected or confirmed novel coronavirus (COVID-19) infection:

Select yes if patient has either clinically suspected or laboratory-confirmed SARS-CoV-2 /COVID-19 infection.

DEMOGRAPHICS

Enrolment date: Date of enrolment into the study or for in-patients is the date that COVID-19 was first assessed as suspected or confirmed by a clinician.

Ethnic group:

Please enter all that apply of the following choices which best describe the patient's ethnicity or major ethnic group at birth. Please exclude nationality as nations often include many different ethnic groups (For example, Singaporean is the nationality but the ethnic grouping within Singapore could be East Asian, South Asian etc.) Cross (X) all that apply. If 'Other' write the full name of the ethnic group of the patient. Please do not enter a letter or number corresponding to a local/national ethnicity coding system.

If the patient's ethnicity is not known, please place a cross (X) in the 'Unknown' box.

Post-partum: Defined as within six weeks of delivery.

If the baby is positive for COVID-19 please complete a separate form for the baby as well.

ONSET & ADMISSION

Onset date of first/earliest symptom:

Please provide the date of patient reported onset of the first symptom that you clinically believe was related to this episode of COVID-19 infection.

Most recent presentation/admission date at this facility:

Where a patient was admitted via multiple hospital departments, count admission from the time they came to the first department during the visit that led to their admission (e.g. arrival at the Emergency Department). For patients with a clear alternative diagnosis leading to admission who subsequently acquired COVID-19 report the date of admission as the day they were admitted to the healthcare facility.

RE-ADMISSION

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

For participants who return for re-admission to the same site, start a new form with the same Participant Identification Number. Please check "YES-admitted previously to this facility". Enter each re-admission as a separate entry 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" in RE- ADMISSION.

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-

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

CLINICAL INCLUSION CRITERIA

Suspected or confirmed novel coronavirus (COVID-19) infection: OYES ONO

DEMOGRAPHICS

Clinical centre name:

Enrolment date /first COVID-19 assessment date: [D][D]/[M][M]/[2][0][Y][Y]

Employed as a Healthcare Worker? OYES ONO OUnknown Employed in a microbiology laboratory? OYES ONO OUnknown

Country:

Sex at Birth: OMale OFemale ONot specified/Unknown Age [__][__]years OR [__][__]months

Pregnant? OYES ONO OUnknown If YES: Gestational weeks assessment: [___][___] weeks

POST PARTUM (within 6 weeks of delivery)? OYES ONO OUnknown (if NO or Unknown skip this section)

 Pregnancy Outcome: OLive birth
 OStill birth
 Delivery date: [D][D]/[M][M]/[2][0][Y][Y]

Baby tested for COVID-19/SARS-CoV-2 infection? OYES ONO OUnknown

If YES, result of test: OPositive ONegative OUnknown (If Positive, complete a separate CRF for baby)

INFANT – Less than 1 year old? OYES ONO (If NO skip this section)

Birth weight: [___].[__]Okg or Olbs OUnknown

Gestational outcome: O Term birth (≥37wk GA) OPreterm birth (<37wk GA) OUnknown

Breastfed? OYES-currently breastfeeding OYES-breastfeeding discontinued ONO OUnknown

Vaccinations appropriate for age/country? OYES ONO OUnknown

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_]

RE-ADMISSION

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

OYES-admitted previously to this facility OYES-transferred from other facility ONO OUnknown

Has this patient's data been previously collected under a different patient number? OYES ONO OUnknown

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 OYES ONO OUnknown

Previous participant ID: OUnknown

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

Please provide reason for readmission:



ADMISSION section. Enter as a separate entry in the electronic database.



SIGNS AND SYMPTOMS AT HOSPITAL ADMISSION

Please provide details of clinical observations made as close to presentation/admission, or within 24 hours of admission. For observations not made immediately at admission, please record the first available data (patient reported and/or from medical records) within 24 hours of admission. For patients with a clear alternative diagnosis leading to admission who subsequently acquired COVID-19, complete these observations for the 24 hours after onset of symptoms of suspected or confirmed COVID-19 infection.

Temperature

Please enter the peripheral body temperature (rectal if < 3 months) in the space provided and indicate the unit of measurement, either degrees Celsius (°C) or Fahrenheit (°F).

Heart rate (HR)

Enter the heart rate measured in beats per minute. This may be measured manually or by electronic monitoring.

Respiratory rate (RR)

Enter the respiratory rate in breaths per minute. Manual rather than electronic measurement is preferred where possible (this is achieved by counting the number of breaths for one minute, counting how many times the chest rises within this time period). Record the highest respiratory rate documented on admission.

Systolic BP

Please enter the systolic blood pressure measured in millimetres of mercury (mmHg), in the relevant sections. For example, if the blood pressure is 120/85 mmHg, enter 120 in the section marked 'systolic BP'. Use any recognised method for measuring blood pressure.

Diastolic BP

Please enter the diastolic blood pressure measured in millimetres of mercury (mmHg), in the relevant sections. For example, if the blood pressure is 120/85 mmHg, enter 85 in the section marked 'diastolic BP'. Use any recognised method for measuring blood pressure.

Oxygen saturation

For all patients, irrespective of ventilation or supplemental oxygen requirement, please enter the percentage oxygen saturation (the percentage of haemoglobin binding sites in the bloodstream occupied by oxygen) at the time of admission. This may be measured by pulse oximetry or by arterial blood gas analysis.

Sternal capillary refill time > 2 seconds?

Sternal capillary refill time is measured by pressing on the sternum for five seconds with a finger or thumb until the underlying skin turns white and then noting the time in seconds needed for the colour to return once the pressure is released.

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

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: ORoom air OOxygen therapy OUnknown
Sternal capillary refill time >2sec. OYES ONO OUNknown Height: [][][][][][][][][][][][][][][][][][][]

SIGNS AND SYMPTOMS ON AD	MISSION (Unk = Unkno	own)	
History of fever	OYES ONO OUnk	Fatigue / Malaise	OYES ONO OUnk
Cough OYES - non-productive	OYES - productive	Anorexia	OYES ONO OUnk
OYES - with haemoptysis	ONO OUnk	Altered consciousness/confusion	OYES ONO OUnk
Sore throat	OYES ONO OUnk	Muscle aches (myalgia)	OYES ONO OUnk
Runny nose (rhinorrhoea)	OYES ONO OUnk	Joint pain (arthralgia)	OYES ONO OUnk
Wheezing	OYES ONO OUnk	Inability to walk	OYES ONO OUnk
Shortness of breath	OYES ONO OUnk	Abdominal pain	OYES ONO OUnk
Lower chest wall indrawing	OYES ONO OUnk	Diarrhoea	OYES ONO OUnk
Chest pain	OYES ONO OUnk	Vomiting / Nausea	OYES ONO OUnk
Conjunctivitis	OYES ONO OUnk	Skin rash	OYES ONO OUnk
Lymphadenopathy	OYES ONO OUnk	Bleeding (Haemorrhage)	OYES ONO OUnk
Headache	OYES ONO OUnk	If YES, specify site(s):	
Loss of smell (Anosmia)	OYES ONO OUnk	Other symptom(s)	OYES ONO OUnk
Loss of taste (Ageusia)	OYES ONO OUnk	If YES, specify:	
Seizures	OYES ONO OUnk		

VACCINATIONS

Covid-19 vaccination OYES ONO OUnk Estimated date of most recent dose: [D][D]/[M]/[2][0]Y

If YES, number of doses received: ____

If YES, specify type of the most recent vaccine: _____

If more than one dose has been given, specify all types of vaccine previously received:

Influenza vaccination within the last 6 months: OYES ONO OUnknown

PRE-ADMISSION MEDICATION (taken w	ithin 14 days prior to admission/presentation at healthcare facility)
Steroids	OYES ONO OUnk If YES, OOral OInhaled OUnk
Other immunosuppressant agents (not oral steroids)	OYES ONO OUnk
Antibiotics	OYES ONO OUnk If YES, agent(s):
Antivirals	OYES ONO OUnk If YES, agent(s):
Other targeted COVID-19 Medications	OYES ONO OUnk If YES, agent(s):





SIGNS AND SYMPTOMS ON ADMISSION

Please provide details of clinical observations made as close to presentation/admission, or within 24 hours of admission. For observations not made immediately at admission, please record the first available data (patient reported and/or from medical records) within 24 hours of admission. For patients with a clear alternative diagnosis leading to admission who subsequently acquired COVID-19, complete these observations for the 24 hours after onset of symptoms of suspected or confirmed COVID-19 infection.

VACCINATIONS

If the exact date of the most recent dose of COVID-19 vaccine isn't available, please provide an estimate of the day the vaccine was given. Partial dates (e.g. Jan-2021) cannot be entered in the database.

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

Steroids: Examples include prednisolone, betamethasone, dexamethasone, hydrocortisone, methylprednisolone, deflazacort and fludrocortisone (oral), budesonide, flucatisone (inhaled).

Other immunosuppressant agents (not oral steroids): Examples include tofacitinib, cyclosporine, tacrolimus, sirolimus, everolimus, azathioprine, leflunomide, mycophenolate and biologics such as abatacept, adalimumab, anakinra, certolizumab, etanercept, adalimumab, infliximab and rituximab

Antibiotics: 'Antibiotic' refers to any agent(s) that selectively target bacteria. Please list generic names. Topical preparations should not be recorded.

Antivirals: Examples include ribavirin, lopinavir, ritonavir, remdesivir, oseltamivir, zanamivir, acyclovir, ganciclovir, and interferons. Please list generic names. Topical preparations should not be recorded. Other targeted COVID-19 Medications: Includes for example: chloroquine, hydroxychloroquine, Interferon antibodies, convalescent plasma or any other COVID-19 therapeutics not included in the categories listed above. Please list generic names.

General Note: For free text entry of medications, please ensure correct spelling. For reference you may use: www.drugs.com

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

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: ORoom air OOxygen therapy OUnknown
Sternal capillary refill time >2sec. OYES ONO OUnknown Height: [][]cm Weight: [][]kg

SIGNS AND SYMPTOMS ON ADMISSION (Unk = Unknown)										
History of fever	OYES ONO OUnk	Fatigue / Malaise	OYES ONO OUnk							
Cough OYES - non-productive	OYES - productive	Anorexia	OYES ONO OUnk							
OYES - with haemoptysis	ONO OUnk	Altered consciousness/confusion	OYES ONO OUnk							
Sore throat	OYES ONO OUnk	Muscle aches (myalgia)	OYES ONO OUnk							
Runny nose (rhinorrhoea)	OYES ONO OUnk	Joint pain (arthralgia)	OYES ONO OUnk							
Wheezing	OYES ONO OUnk	Inability to walk	OYES ONO OUnk							
Shortness of breath	OYES ONO OUnk	Abdominal pain	OYES ONO OUnk							
Lower chest wall indrawing	OYES ONO OUnk	Diarrhoea	OYES ONO OUnk							
Chest pain	OYES ONO OUnk	Vomiting / Nausea	OYES ONO OUnk							
Conjunctivitis	OYES ONO OUnk	Skin rash	OYES ONO OUnk							
Lymphadenopathy	OYES ONO OUnk	Bleeding (Haemorrhage)	OYES ONO OUnk							
Headache	OYES ONO OUnk	If YES, specify site(s):								
Loss of smell (Anosmia)	OYES ONO OUnk	Other symptom(s)	OYES ONO OUnk							
Loss of taste (Ageusia)	OYES ONO OUnk	If YES, specify:								
Seizures	OYES ONO OUnk									

VACCINATIONS

Covid-19 vaccination OYES ONO OUnk Estimated date of most recent dose: [D][D]/[M]/[2][0]Y

If YES, number of doses received:

If YES, specify type of the most recent vaccine:

If more than one dose has been given, specify all types of vaccine previously received:

Influenza vaccination within the last 6 months: OYES ONO OUnknown

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PRE-ADMISSION MEDICATION (taken w	ithin 14 days prior to admission/presentation at healthcare facility)
Steroids	OYES ONO OUnk If YES, OOral OInhaled OUnk
Other immunosuppressant agents (not oral steroids)	OYES ONO OUnk
Antibiotics	OYES ONO OUnk If YES, agent(s):
Antivirals	OYES ONO OUnk If YES, agent(s):
Other targeted COVID-19 Medications	OYES ONO OUnk If YES, agent(s):





CO-MORBIDITIES AND RISK FACTORS

Please record if any of these comorbidities existed prior to admission.

In general, do not include past comorbidities that are no longer ongoing. Additional details are given below. Where example conditions are given, these are not intended to be exhaustive and other conditions of equivalent severity should be included.

Chronic cardiac disease (not hypertension)

Please include any of coronary artery disease, heart failure, congenital heart disease, cardiomyopathy, rheumatic heart disease.

Hypertension

Elevated arterial blood pressure diagnosed clinically, >140mmHg systolic or >90mmHg diastolic.

Chronic pulmonary disease (not asthma)

Please include any of chronic obstructive pulmonary disease (chronic bronchitis, chronic obstructive pulmonary disease (COPD), emphysema), cystic fibrosis, bronchiectasis, interstitial lung disease, preexisting requirement for long term oxygen therapy. Do not include asthma.

Asthma (physician diagnosed)

Clinician-diagnosed asthma

Chronic Kidney Disease

Please include any of clinician-diagnosed chronic kidney disease, chronic estimated glomerular filtration rate < 60 mL/min/1.73m², history of kidney transplantation

Obesity (as defined by clinical staff)

This refers to patients for whom an attending clinician has assessed them to be obese - ideally but not necessarily with an objective measurement of obesity, such as calculation of the body mass index (BMI of 30 or more) or measurement of abdominal girth.

Moderate or severe liver disease

This is defined as cirrhosis with portal hypertension, with or without bleeding or a history of variceal bleeding.

Mild liver disease

This is defined as cirrhosis without portal hypertension or chronic hepatitis

Asplenia

Please include any of splenectomy, non-functional spleen, and congenital asplenia.

Chronic neurological disorder

Please include any of cerebral palsy, multiple sclerosis, motor neurone disease, muscular dystrophy, myasthenia gravis, Parkinson's disease, stroke, severe learning difficulty

Malignant neoplasm

Current solid organ or haematological malignancy. Please do not include malignancies that have been declared 'cured' \geq 5 years ago with no evidence of ongoing disease. Do not include non-melanoma skin cancers. Do not include benign growths or dysplasia.

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

CO-MORBIDITIES AND RISK FACTORS (existing prior to admission and ongoing)										
Chronic cardiac disease (not hypertension)	OYES	ONO	OUnk	Chronic hematologic disease	OYES ONO OUnk					
				AIDS / HIV OYES-on ART OYES-no	t on ART ONO OUnk					
Hypertension	OYES	ONO	OUnk	If YES, most recent CD4 count:						
				O < 200 O 200-< 500 O ≥ 500 c	ells/uL OUnk					
				Diabetes Mellitus OYES-Type 1	OYES -Type 2					
	O VEO	0 110		OYES -Gestational	ONO OUnk					
ronic pulmonary disease (not asthma)	OYES	ONO	OUnk	If YES, HbA1C results (within last 6 m	onths) :					
				Units: Ommol/mol Ommol/L	O %					
Asthma (physician diagnosed)	OYES	ONO	OUnk	Rheumatologic disorder	OYES ONO OUnk					
Chronic kidney disease	OYES	ΟΝΟ	OUnk	Dementia	OYES ONO OUnk					
Obesity (as defined by clinical staff)	OYES	ΟΝΟ	OUnk	Tuberculosis	OYES ONO OUnk					
Moderate or severe liver disease	OYES	ONO	OUnk	Malnutrition	OYES ONO OUnk					
Mild liver disease	OYES	ΟΝΟ	OUnk	Smoking OYES ONever smoked O	Former smoker O Unk					
Asplenia	OYES	ONO	OUnk	Other relevant risk factor(s)	OYES ONO OUnk					
Chronic neurological disorder	OYES	ONO	OUnk	If YES, specify:						
Malignant neoplasm	OYES	ΟΝΟ	OUnk							

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_](__2_][_0_][Y_][Y_]

Highest temperature: [][][].[] O °C <i>or</i> O °F	HR: [][][]beats/minute	RR: [][][]breaths/minute

Systolic BP: [__][__]mmHg Diastolic BP: [__][_]mmHg

Oxygen saturation SaO₂ [___][___]%

Any supplemental oxygen: OYES ONO OUnknown 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) [___][__]OkPa or OmmHg ONot done

PaO2 sample type: OArterial OCapillary OVenous OUnknown

From same blood gas record as PaO₂:

PCO2OkPa or OmmH		н нсо	D₃mEq/I	LI	Base excess	mmol/L
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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





Chronic hematologic disease

Any long-term disorder of the red or white blood cells, platelets or coagulation system requiring regular or intermittent treatment. Do not include leukaemia, lymphoma or myeloma, which should be entered under malignancy. Do not include iron-deficiency anaemia which is explained by diet or chronic blood loss.

AIDS/HIV

History of laboratory-confirmed HIV infection. Indicate whether or not the patient is on ART (antiretroviral therapy). Please provide the most recent CD4 count, if available.

Diabetes Mellitus

Type 1 or Type 2 diabetes mellitus requiring oral or subcutaneous treatment. Please indicate whether Type 1 or Type 2.If HbA1c results are available from the last 6 months only, please provide the most recent value.

Rheumatologic disorder

This is defined as an inflammatory and degenerative diseases of connective tissue structures. It includes chronic arthropathies and arthritis, connective tissue disorders and vasculitides.

Dementia

This is defined as clinical diagnosis of dementia

Tuberculosis

Patients currently receiving treatment for tuberculosis. Do not include latent tuberculosis.

Malnutrition

Any clinically identified deficiency in intake, either of total energy or of specific nutrients that led to a dietetic intervention or referral prior to the onset of COVID-19 symptoms. Do not include people who needed supplementary nutrition solely due to reduced intake during their current illness episode.

Smoking

Smoking at least one cigarette, cigar, pipe or equivalent per day before the onset of the current illness. Do not include smoke-free tobacco products such as chewed tobacco or electronic nicotine delivery devices.

Other relevant risk factor List any significant risk factors or comorbidities that existed prior to admission, are ongoing, that are not already listed.

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

CO-MORBIDITIES AND RISK FACTORS	(existing prid	or to admissi	on and ongoing)							
Chronic cardiac disease (not hypertension)	OYES O	NO OUnk	Chronic hematologic disease OYES ONO (
Hypertension	OYES O	NO O Unk	AIDS / HIV OYES-on ART OYES-not on ART ONO If YES, most recent CD4 count: O< 200 O200-< 500 O≥ 500 cells/uL OUni							
Chronic pulmonary disease (not asthma)	OYES O	NO O Unk	Diabetes Mellitus OYES-Type 1 OYES -Type 2 OYES -Gestational ONO If YES, HbA1C results (within last 6 months) : Units: Ommol/mol Ommol/L O%	OUnk						
Asthma (physician diagnosed)	OYES O	NO OUnk	Rheumatologic disorder OYES ONO	OUnk						
Chronic kidney disease	OYES O	NO OUnk	Dementia OYES ONO	OUnk						
Obesity (as defined by clinical staff)	OYES O	NO OUnk	Tuberculosis OYES ONO	OUnk						
Moderate or severe liver disease	OYES O	NO OUnk	Malnutrition OYES ONO	OUnk						
Mild liver disease	OYES O	NO OUnk	Smoking OYES ONever smoked OFormer smoker	OUnk						
Asplenia	OYES O	NO OUnk	Other relevant risk factor(s) OYES ONO	OUnk						
Chronic neurological disorder	OYES O	NO OUnk	If YES, specify:							
Malignant neoplasm	OYES O	NO OUnk								

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°CorO°F HR: [][]]beats/minute RR: [][]]breaths/minute

Systolic BP: [__][__]mmHg Diastolic BP: [__][__]mmHg

Oxygen saturation SaO₂ [___][___]%

Any supplemental oxygen: OYES ONO OUnknown 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) [___][___]OkPa or OmmHg ONot done

PaO2 sample type: OArterial OCapillary OVenous OUnknown

From same blood gas record as PaO₂:

PCO2OkPa or OmmH	g	p۲	HCO3	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





MODULE 2 CASE REPORT FORM ON ADMISSION, CRITICAL CARE, RESEARCH SAMPLING

SIGNS AND SYMPTOMS

Highest Temperature

Please enter the highest peripheral body temperature (rectal if < 3 months) recorded during the course of the day in the space provided and indicate the unit of measurement, either degrees Celsius (°C) or Fahrenheit (°F).

Heart rate (HR)

Enter the heart rate measured in beats per minute. This may be measured manually or by electronic monitoring.

Respiratory rate (RR)

Enter the respiratory rate in breaths per minute. Manual rather than electronic measurement is preferred where possible (this is achieved by counting the number of breaths for one minute, counting how many times the chest rises within this time period). If both abnormal low and high rate observed, record the abnormally high rate.

Systolic BP

Please report the systolic and diastolic blood pressure from the observation with the lowest mean arterial pressure (if mean arterial pressure has not been calculated, report the measurement with lowest systolic blood pressure).

Please enter the systolic blood pressure measured in millimetres of mercury (mmHg), in the relevant sections. For example, if the blood pressure is 120/85 mmHg, enter 120 in the section marked 'systolic BP'. Use any recognised method for measuring blood pressure.

Diastolic BP

Please enter the diastolic blood pressure measured in millimetres of mercury (mmHg), in the relevant sections. For example, if the blood pressure is 120/85 mmHg, enter 85 in the section marked 'diastolic BP'. Use any recognised method for measuring blood pressure.

Oxygen saturation SaO₂

For all patients, irrespective of ventilation or supplemental oxygen requirement, please enter the percentage oxygen saturation. This may be measured by pulse oximetry or by arterial blood gas analysis.

Any supplemental oxygen: FiO₂ (0.21-1.0)

This is a key indicator to complete for all patients. If the patient received any form of supplemental oxygen through a mask or nasal cannula that delivers a known concentration of oxygen or is being ventilated, please provide the fraction of inspired oxygen (FiO₂) delivered. For patients receiving oxygen through any means, such as a face mask or nasal cannula, that does not deliver a known oxygen concentration provide the maximum flow rate received on day of completion in L/min.

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

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

CO-MORBIDITIES AND RISK FACTORS	(existing	prior to	aamissio	n and ongoing)					
Chronic cardiac disease (not hypertension)	OYES	ONO	OUnk	Chronic hematologic disease OYES ONO					
				AIDS / HIV OYES-on ART OYES-not on A	rt O NO	OUnk			
Hypertension	OYES	ONO	OUnk	If YES, most recent CD4 count:					
				O<200 O200-< 500 O≥ 500 cells/u	L OUn	k			
				Diabetes Mellitus OYES-Type 1 OY	S -Type 2				
	•	•	OUnk	OYES -Gestational ON	C	OUnk			
Chronic pulmonary disease (not asthma)	OYES	ONO		If YES, HbA1C results (within last 6 month):	_			
				Units: Ommol/mol Ommol/L O%					
Asthma (physician diagnosed)	OYES	ONO	OUnk	Rheumatologic disorder OY	S ONO	OUnk			
Chronic kidney disease	OYES	ONO	OUnk	Dementia OY	S ONO	OUnk			
Obesity (as defined by clinical staff)	OYES	ONO	OUnk	Tuberculosis OY	S ONO	OUnk			
Moderate or severe liver disease	OYES	ONO	OUnk	Malnutrition OY	S ONO	OUnk			
Mild liver disease	OYES	ONO	OUnk	Smoking OYES ONever smoked OForm	er smoker	OUnk			
Asplenia	OYES	ONO	OUnk	Other relevant risk factor(s) OY	S ONO	OUnk			
Chronic neurological disorder	OYES	ONO	OUnk	If YES, specify:					
Malignant neoplasm	OYES	ONO	OUnk						

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_](__2_][_0_][_Y_][_Y_]

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

Systolic BP: [__][__]mmHg Diastolic BP: [__][_]mmHg

Oxygen saturation SaO₂ [___][___]%

Any supplemental oxygen: OYES ONO OUnknown 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) [___][__]OkPa or OmmHg ONot done

PaO₂ sample type: OArterial OCapillary OVenous OUnknown

From same blood gas record as PaO₂:

PCO2_____OkPa or OmmHg | pH_____ | HCO3-____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



SIGNS AND SYMPTOMS, continued

PaO₂ (at time nearest to the FiO₂ recorded at top of page)

 PaO_2 (partial pressure of oxygen in blood) as determined by arterial/ capillary blood gas analysis. This PaO_2 must correspond with the oxygen therapy documented in the FiO_2 field. Please fill in the lowest value in either mmHg or kPa depending on the output of your blood gas analyser. If the PaO_2 is not known, place NA in the data field.

From the same blood gas record as PaO₂:

 $PaCO_2$ is the partial pressure of carbon dioxide measured in the sample. pH is the measure of the activity of the (solvated) hydrogen ion (H+) measured in the sample. HCO_3 - refers to the bicarbonate measured in the blood gas sample. Base excess refers to standardised base excess (SBE). If standardised base excess is not reported, enter the base excess value presented, this can be either a positive or negative value.

Sternal capillary refill time > 2 seconds?

Sternal capillary refill time is measured by pressing on the sternum for five seconds with a finger or thumb until the underlying skin turns white and then noting the time in seconds needed for the colour to return once the pressure is released.

AVPU

Alert – responding to voice – responding to pain – unresponsive: please state the least responsive condition of the patient during the calendar day (not counting normal sleep). On day of admission record the value as close to admission as possible before treatments have been administered. For daily records, if the patient is being sedated on the day of assessment record the value before the sedation.

Glasgow Coma Score (GCS / 15)

Please state the lowest GCS recorded. For intubated patients and patients with a non-fenestrated tracheostomy, give 1 point for the voice component and calculate the total as usual. Suffixes such as t for tracheostomy cannot be entered on to the database. If the patient is sedated on the day of assessment these parameters should correspond to the values observed before sedation. For daily recording, if the patient is fully sedated for the duration of the day of assessment (from 00:00 to 24:00) record non testable. Glasgow Coma Score: https://www.glasgowcomascale.org/downloads/GCS-Assessment-Aid-English.pdf?v=3

Richmond Agitation-Sedation Scale (RASS)

RASS – If done, enter the lowest calculated value (between -5 and 4) on the date of assessment.

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

Chronic cardiac disease (not hypertension)	OYES	ONO	OUnk	Chronic hematologic disease	OYES	ONO	OUnk
				AIDS / HIV OYES-on ART OYES-no	t on ART	ONO	OUnk
Hypertension	OYES	ονο	OUnk	If YES, most recent CD4 count:			
				O<200 O200-< 500 O≥ 500 O	cells/uL	OUnk	1
				Diabetes Mellitus OYES-Type 1	OYES -	Type 2	
Chronic pulmonon disease (not asthma)	OVER	010	Ollak	OYES -Gestational	ONO		OUnk
Chronic pulmonary disease (not asthma)	OYES ONO	UNO	OUnk	If YES, HbA1C results (within last 6 m	onths) :_		_
				Units: Ommol/mol Ommol/L	0%		
Asthma (physician diagnosed)	OYES	ONO	OUnk	Rheumatologic disorder	OYES	ONO	OUnk
Chronic kidney disease	OYES	ONO	OUnk	Dementia	OYES	ONO	OUnk
Obesity (as defined by clinical staff)	OYES	ONO	OUnk	Tuberculosis	OYES	ONO	OUnk
Moderate or severe liver disease	OYES	ONO	OUnk	Malnutrition	OYES	ONO	OUnk
Mild liver disease	OYES	ONO	OUnk	Smoking OYES ONeversmoked O	Former s	moker	OUnk
Asplenia	OYES	ONO	OUnk	Other relevant risk factor(s)	OYES	ONO	OUnk
Chronic neurological disorder	OYES	ONO	OUnk	If YES, specify:			
Malignant neoplasm	OYES	ONO	OUnk	Ī			

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_]_YY_
Highest temperature: [][].[] O°Cor O°F HR: [][]beats/minute RR: [][]breaths/mir
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
PaO2 sample type: OArterial OCapillary OVenous OUnknown
From same blood gas record as PaO2:
PCO2OkPa or OmmHg pH HCO3mEq/L Base excess mmo
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 O Unknown



Current admission to ICU/ITU/IMC/HDU?

If the patient has been admitted to an intensive care, intensive therapy, intermediate care or high dependency unit please tick 'yes'. If the patient is on a general care ward then select 'no' or 'Unknown'.

See Outcome Case Report Form (below) for guidelines on recording treatment data

LABORATORY RESULTS

Please record all laboratory results available on day of admission, or the day that COVID-19 was first clinically suspected in patients already admitted to hospital, and on day of admission to ICU/HDU.

For daily records: record the date of assessment as the day the blood sample/s were taken.. If the unit of measurement is not shown on the paper form it will likely appear in the dropdown list in the eCRF. If you cannot find the correct unit on the eCRF please use a unit converter, such as: http://unitslab.com/ or equivalent or email ncov@isaric.org to let us know.

'Worst value' refers to values furthest from the normal physiological range or laboratory normal range. Results that were rejected by the clinical team (e.g. haemolysed blood samples, contaminated microbiology results) should not be reported.

Haemoglobin (Hb or Hgb) refers to haemoglobin concentration measurement in blood.

WBC count is the total white blood cell count in blood.

Haematocrit (Ht or HCT), also known as packed cell volume (PCV) or erythrocyte volume fraction (EVF), is the volume percentage (%) of red blood cells in blood.

- **APTT** is the activated partial thromboplastin time. Record the highest value.
- **APTR** is the activated partial thromboplastin ratio. Record the highest value.
- PT is the prothrombin time. Record the highest value.
- INR is the international normalised ratio. Record the highest value.

ALT/SGPT: ALT is alanine transaminase (also called serum glutamic pyruvate transaminase, SGPT). Record the highest value.

Total Bilirubin refers to total bilirubin measured in the blood. Record the highest value.

AST/SGOT is aspartate transaminase (also called serum glutamic oxaloacetic transaminase, SGOT). Record the highest value.

Glucose refers to blood glucose test. Random glucose measurement is preferred to a fasted measurement.

Blood urea nitrogen is also known as 'urea', measured in a blood sample. Record the highest value.

Lactate refers to blood lactate. Record the highest value.

Creatinine refers to serum creatinine. Record the highest value.

Procalcitonin or PCT refers to blood procalcitonin. Record the highest value.

CRP is C-reactive protein and refers to the blood (serum or plasma) CRP level. Record the highest value.

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, depending on available resources, complete every day for a maximum of 14 days, or for days when biochemical results are available.

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	n			
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 O	ONC			
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 O	ONC			
Neuromuscular blocking agents? OYES ONO OUnknown				
Other intervention(s) or procedure(s)? OYES ONO OUnknown If YES, Specify:				

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)		0	Urea (BUN) (mmol/L)		0
WBC count (x10 ⁹ /L)		0	Lactate (mmol/L)		0
Lymphocyte count (10 ⁹ /L)		0	Creatinine (µmol/L)		0
Neutrophil count (10 ⁹ /L)		0	Sodium (mmol/L)		0
Haematocrit (%)		0	Potassium (mmol/L)		0
Platelets (x10 ⁹ /L)		0	Procalcitonin (ng/mL)		0
APTT (seconds))		0	CRP (mg/L)		0
APTR		0	LDH (U/L)		0
PT (seconds)		0	Creatine kinase (U/L)		0
INR		0	Troponin I (ng/mL)		0
ALT/SGPT (U/L)		0	D-dimer (mg/L)		0
Total bilirubin (µmol/L)		0	Ferritin (ng/mL)		0
AST/SGOT (U/L)		0	IL-6 (pg/mL)		0
Glucose (mmol/L)		0	Fibrinogen (mg/dl)		0



LDH is lactate dehydrogenase. Record the highest value.

Creatine kinase (CK, or creatine phosphokinase, CPK) refers to total creatine kinase measured in the blood. Record the highest value. Troponin I Record the highest value D-dimer Record the highest value Ferritin Record the highest value IL-6 is Interleukin 6. Record the highest value

COVID-19 CORE CASE REPORT FORM Completion Guide



MODULE 3: OUTCOME CASE REPORT FORM

TREATMENT

For all questions of duration, please count the number of calendar days that the patient received the treatment. For treatments that were stopped and restarted, count those days on which the treatment was given but don't count any calendar days on which it was not given at all.

Oxygen therapy

Complete this field for all patients. If the patient received any form of supplementary oxygen, via nose cannula, mask or non-invasive or invasive ventilation tick 'yes' and indicate the total days they received any form of oxygen (O_2) therapy.

If any supplemental oxygen (at any concentration) was given by any means of delivery <u>at any point</u> during the patient's hospital stay, place a cross in the box marked 'yes'. This includes any supplementary oxygen (O_2) delivered via non-invasive facemasks/nasal cannula/mask or via invasive mechanical ventilation. Please also indicate the maximum O_2 flow volume. If it is not possible to access record of the absolute highest O_2 volume delivered during the admission indicate the highest known.

Non-invasive ventilation (Any)

If the patient received non-invasive ventilation (NIV), defined as the provision of ventilatory support through the patient's upper airway using a mask or similar device, at any time during their hospital stay, place tick 'yes' and enter the total duration in days if known.

Invasive ventilation (Any)

Invasive ventilation means that patient has undergone tracheal intubation, for the purpose of invasive mechanical ventilation. Invasive ventilation is a method to mechanically assist or replace spontaneous breathing in patients by use of a powered device that forces oxygenated air into the lungs. The mode of intubation may be orotracheal, nasotracheal, or via a cricothyrotomy or tracheotomy.

Prone Positioning

Prone ventilation refers to ventilation with the patient lying in the prone position. If the patient received prone ventilation at any time during their hospital stay, please tick 'yes' and indicate the total duration in days.

Renal replacement therapy (RRT) or dialysis

Renal replacement therapy includes haemodialysis, peritoneal dialysis (PD), intermittent haemodialysis (IHD), on-line intermittent haemofiltration (IHF), on-line haemodiafiltration (IHDF), continuous haemofiltration (CHF) and continuous haemodiafiltration (CHDF), continuous venovenous haemofiltration (CVVH), continuous venovenous haemodialysis (CVVHD), continuous venovenous haemodiafiltration (CVVHDF), slow continuous ultrafiltration (SCUF), continuous arteriovenous haemofiltration (CAVHD), sustained low-efficiency dialysis (SLED) and continuous renal replacement therapy (CRRT)

Inotropes/vasopressors?

A vasopressor is a pharmaceutical agent that causes vasoconstriction. Agents include norepinephrine, epinephrine, vasopressin, terlipressin and phenylephrine. An inotrope is a pharmaceutical agent that alters the force of myocardial contractility. Commonly used 'positive' inotropes include dobutamine, dopamine, milrinone and adrenaline (epinephrine). If the patient received a vasopressor or inotrope for at least one hour during their hospital stay, place tick 'yes'

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 O2 flow volume: O	<2 L/min O 2-5	L/min O6-10 L/min (O 11-15 L/min O >15 L/min				
Non-invasive ventilation? (Any)	OYES ONO C	Unknown	If YES, total duration:	days O Unknown			
Invasive ventilation? (Any)		Unknown	If YES, total duration:	days O Unknown			
High flow nasal oxygen	OYES ONO O	Unknown	If YES, total duration:	days OUnknown			
Prone Positioning?	OYES ONO C	Unknown					
Inhaled Nitric Oxide?	OYES ONO C	Unknown					
Tracheostomy inserted?	OYES ONO C	Unknown					
Extracorporeal support (ECMO)?	OYES ONO C	OUnknown	If YES, total duration:	days O Unknown			
Renal replacement therapy (RRT)	or dialysis? O	YES ONO OUnknown					
Inotropes/vasopressors?	OYES ONO O	Unknown					
ICU or High Dependency Unit adm	ission? 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	J discharge:	[_D_][_D_]/[_M_]	[_M_]/[_2_][_0_][_Y_][_Y_]	OUnknown			

COMPLICATIONS: At any time during hospitalisation did the patient experience: (Unk = Unknown)						
Viral pneumonia/pneumonitis	OYES ONO OUnk	Meningitis / Encephalitis	OYES ONO OUnk			
Bacterial pneumonia	OYES ONO OUnk	Bacteremia	OYES ONO OUnk			
Acute Respiratory Distress Syndrome	OYES ONO OUnk	Coagulation disorder / DIC	OYES ONO OUnk			
Pneumothorax	OYES ONO OUnk	Pulmonary Embolism	OYES ONO OUnk			
Pleural effusion	OYES ONO OUnk	Deep Vein Thrombosis	OYES ONO OUnk			
Cryptogenic organizing pneumonia (COP)	OYES ONO OUnk	Other thromboembolism (not PE or DVT)	OYES ONO OUnk			
Bronchiolitis	OYES ONO OUnk	Anemia	OYES ONO OUnk			
Cardiac arrest	OYES ONO OUnk	Rhabdomyolysis / Myositis	OYES ONO OUnk			
Myocardial infarction	OYES ONO OUnk	Acute renal injury/ Acute renal failure	OYES ONO OUnk			
Cardiac ischaemia	OYES ONO OUnk	Gastrointestinal haemorrhage	OYES ONO OUnk			
Cardiac arrhythmia	OYES ONO OUnk	Pancreatitis	OYES ONO OUnk			
Myocarditis / Pericarditis	OYES ONO OUnk	Liver dysfunction	OYES ONO OUnk			
Endocarditis	OYES ONO OUnk	Hyperglycemia	OYES ONO OUnk			
Cardiomyopathy	OYES ONO OUnk	Hypoglycemia	OYES ONO OUnk			
Congestive heart failure	OYES ONO OUnk	Other	OYES ONO OUnk			
Seizure	OYES ONO OUnk	If YES, specify:				
Stroke / Cerebrovascular accident	OYES ONO OUnk					



and the total duration in days if known.



COMPLICATIONS

Please select all that were clinically identified at any time during the hospital admission. Do not include known comorbidities (e.g. previous atrial fibrillation should not be included but new onset during this admission should). Record physician diagnosed complications.

Viral pneumonitis/pneumonia

Clinically or radiologically diagnosed viral pneumonitis/pneumonia.

Bacterial pneumonia

Clinically or radiologically diagnosed bacterial pneumonia (including community, hospital and ventilator acquired) managed with antimicrobials. Bacteriological confirmation not required.

Acute Respiratory Distress Syndrome (ARDS)

Defined according to Berlin criteria as:

- Occurring within 1 week of a known clinical insult or worsening respiratory symptoms
- Bilateral radiological opacities not fully explained by effusions, lobar/lung collapse, or nodules
- Respiratory failure not fully explained by cardiac failure or fluid overload

Pneumothorax

Is defined as the abnormal presence of air in the pleural cavity (between the lungs and the chest wall), causing collapse of the lung. It may be diagnosed clinically, usually with radiological confirmation.

Pleural effusion

Is defined as increased amounts of fluid within the pleural cavity. It may be diagnosed clinically, with or without radiological or interventional confirmation.

Cryptogenic organizing pneumonia (COP)

Idiopathic diffuse interstitial lung disease, diagnosed radiologically (multiple consolidative or ground glass opacities) or histologically (granulation tissue and chronic inflammatory infiltrate in alveoli). Formerly known as bronchiolitis obliterans organizing pneumonia (BOOP)

Bronchiolitis

This is a clinical diagnosis.

Cardiac arrest

Sudden cessation of cardiac activity with no normal breathing and no signs of circulation.

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 O2 flow volume: O	<2 L/min 02-5	L/min O6-10 L/min (O 11-15 L/min O >15 L/min			
Non-invasive ventilation? (Any)	OYES ONO C	Unknown	If YES, total duration:	days O Unknown		
Invasive ventilation? (Any)	OYES ONO C	Unknown	If YES, total duration:	days O Unknown		
High flow nasal oxygen	OYES ONO O	Unknown	If YES, total duration:	days OUnknown		
Prone Positioning?	OYES ONO C	Unknown				
Inhaled Nitric Oxide?	OYES ONO C	OUnknown				
Tracheostomy inserted?	OYES ONO C	Unknown				
Extracorporeal support (ECMO)?	OYES ONO C	OUnknown	If YES, total duration:	days O Unknown		
Renal replacement therapy (RRT)	or dialysis? O	YES ONO OUnknown				
Inotropes/vasopressors?	OYES ONO O	Unknown				
ICU or High Dependency Unit adm	nission? OYES (ONO OUnknown	If YES, total duration:	days O Unknown		
If YES, date of IC	U admission:	[_D_][_D_]/[_M_]	[_M_]/[_2_][_0_][_Y_][_Y_]	OUnknown		
date of ICU	U discharge:	[][]/[]	[M]/[_2][_0][_Y_][_Y_]	OUnknown		

COMPLICATIONS: At any time during hospitalisation did the patient experience: (Unk = Unknown)						
Viral pneumonia/pneumonitis	OYES ONO	OUnk	Meningitis / Encephalitis	OYES	ONO	OUnk
Bacterial pneumonia	OYES ONO	OUnk	Bacteremia	OYES	ONO	OUnk
Acute Respiratory Distress Syndrome	OYES ONO	OUnk	Coagulation disorder / DIC	OYES	ONO	OUnk
Pneumothorax	OYES ONO	OUnk	Pulmonary Embolism	OYES	ONO	OUnk
Pleural effusion	OYES ONO	O Unk	Deep Vein Thrombosis	OYES	ONO	OUnk
Cryptogenic organizing pneumonia (COP)	OYES ONO	OUnk	Other thromboembolism (not PE or DVT)	OYES	ONO	OUnk
Bronchiolitis	OYES ONO	OUnk	Anemia	OYES	ONO	OUnk
Cardiac arrest	OYES ONO	OUnk	Rhabdomyolysis / Myositis	OYES	ONO	OUnk
Myocardial infarction	OYES ONO	OUnk	Acute renal injury/ Acute renal failure	OYES	ONO	OUnk
Cardiac ischaemia	OYES ONO	OUnk	Gastrointestinal haemorrhage	OYES	ONO	OUnk
Cardiac arrhythmia	OYES ONO	OUnk	Pancreatitis	OYES	ONO	OUnk
Myocarditis / Pericarditis	OYES ONO	OUnk	Liver dysfunction	OYES	ONO	OUnk
Endocarditis	OYES ONO	OUnk	Hyperglycemia	OYES	ONO	OUnk
Cardiomyopathy	OYES ONO	OUnk	Hypoglycemia	OYES	ONO	OUnk
Congestive heart failure	OYES ONO	OUnk	Other	OYES	ONO	OUnk
Seizure	OYES ONO	OUnk	If YES, specify:			
Stroke / Cerebrovascular accident	OYES ONO	OUnk				





COMPLICATIONS, continued

Myocardial infarction

Myocardial ischaemia (MI) leading to injury/necrosis, diagnosed by clinical findings, altered electrocardiography and elevated cardiac enzymes.

Cardiac ischaemia

Is defined as diminished blood and oxygen supply to the heart muscle, also known as myocardial ischemia, It is confirmed by an electrocardiogram (showing ischaemic changes, e.g. ST depression or elevation) and/or cardiac enzyme elevation.

Cardiac arrhythmia

If a cardiac arrhythmia is identified and there is no previous record of it, select 'yes'.

Myocarditis / Pericarditis

Myocarditis / pericarditis refers to an inflammation of the heart or pericardium (outer lining of the heart). Diagnosis can be clinical, biochemical (cardiac enzymes) or radiological

Endocarditis

Endocarditis is an inflammation of the endocardium (inner lining of the heart). Diagnosis is according to modified Duke criteria, using evidence from microbiological results, echocardiogram and clinical signs.

Cardiomyopathy

Structural and functional disorders of myocardium commonly diagnosed by echocardiography. Can be primary (genetic) or secondary (e.g. following myocardial infarction).

. Physician diagnosis,

Congestive heart failure

Is defined as failure of the heart to pump a sufficient amount of blood to meet the needs of the body tissues, resulting in tissue congestion and oedema.

Seizure

Select 'yes' for any seizure regardless of cause (e.g. febrile or due to epilepsy)

Stroke / Cerebrovascular accident

Stroke may be a clinical diagnosis, with or without supportive radiological findings.

Meningitis / Encephalitis

Inflammation of the meninges or the brain parenchyma. Select yes if diagnosed clinically, radiologically or microbiologically.

Bacteremia

Growth of bacteria on a blood culture. Select 'no' if the only bacteria grown were believed to be skin contaminants (e.g. coagulase negative Staphylococci or diphtheroids).

Coagulation disorder / DIC

Abnormal coagulation identified by abnormal prothrombin time or activated partial thromboplastin time. Disseminated intravascular coagulation (DIC; consumption coagulopathy; defibrination syndrome) is defined by thrombocytopenia, prolonged prothrombin time, low fibrinogen, elevated D-dimer and thrombotic microangiopathy.

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 O2 flow volume: O	<2 L/min 02-5 L/min 06-10 L/min	O 11-15 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 O Unknown				
High flow nasal oxygen	OYES ONO OUnknown	If YES, total duration:	days O Unknown				
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 O Unknown				
Renal replacement therapy (RRT)	or dialysis? OYES ONO OUnknown	n					
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] OUnknown							

date of ICU discharge:

[D][D]/[M][M]/[2][0][Y][Y] OUnknown

COMPLICATIONS: At any time during hospitalisation did the patient experience: (Unk = Unknown) OYES ONO OUnk OYES ONO OUnk Meningitis / Encephalitis Viral pneumonia/pneumonitis OYES ONO OUnk OYES ONO OUnk Bacterial pneumonia Bacteremia Acute Respiratory Distress Syndrome OYES ONO OUnk Coagulation disorder / DIC OYES ONO OUnk OYES ONO OUnk Pneumothorax OYES ONO OUnk **Pulmonary Embolism** Pleural effusion OYES ONO OUnk OYES ONO OUnk Deep Vein Thrombosis Cryptogenic organizing pneumonia (COP) OYES ONO OUnk Other thromboembolism (not PE or DVT) OYES ONO OUnk Bronchiolitis OYES ONO OUnk OYES ONO OUnk Anemia Cardiac arrest OYES ONO OUnk Rhabdomyolysis / Myositis OYES ONO OUnk Myocardial infarction OYES ONO OUnk Acute renal injury/ Acute renal failure OYES ONO OUnk Cardiac ischaemia OYES ONO OUnk Gastrointestinal haemorrhage OYES ONO OUnk OYES ONO OUnk OYES ONO OUnk Cardiac arrhythmia Pancreatitis Myocarditis / Pericarditis OYES ONO OUnk Liver dysfunction OYES ONO OUnk Endocarditis OYES ONO OUnk Hyperglycemia OYES ONO OUnk Cardiomyopathy OYES ONO OUnk Hypoglycemia OYES ONO OUnk Congestive heart failure OYES ONO OUnk Other OYES ONO OUnk Seizure OYES ONO OUnk If YES, specify: OYES ONO OUnk Stroke / Cerebrovascular accident



Pulmonary embolism

Obstruction of pulmonary artery by thrombus, air or fat. Physician diagnosis based on clinical signs, computed tomographic pulmonary angiography and/or ventilation/perfusion scanning.

Deep Vein Thrombosis

Blood clots in deep veins of leg, pelvis or arm. Physician diagnosis based on clinical signs, and/or duplex ultrasonography, d-dimer blood test, contrast venography or magnetic resonance imaging (MRI),

Other thromboembolism (not Pulmonary Embolism or Deep Vein Thrombosis)

Please record any other type of physician diagnosed thromboembolism

Anemia

Select 'yes' if haemoglobin levels were lower than age- and sex-specific thresholds listed below

	Haemoglobin threshold		
Age or gender group	(g/L)	(mmol/l)	
Age 6 months to 5 years	110	6.8	
Age 5–12 years	115	7.1	
Age 12–15 years	120	7.4	
Age > 15 years, non-pregnant women	120	7.4	
Pregnant women	110	6.8	
Age >15 years, men	130	8.1	

Rhabdomyolysis / Myositis

Rhabdomyolysis is a syndrome characterised by muscle necrosis and the release of myoglobin into the blood. Muscle biopsy, electromyography, radiological imaging and the presence of myoglobinuria are not required for the diagnosis.

Myositis may be a clinical diagnosis with supporting evidence from laboratory tests e.g. elevated serum creatine kinase; histological confirmation is not required to make the diagnosis. Myositis can occur without progression to rhabdomyolysis.

Acute renal injury/Acute renal failure

Acute renal injury is defined as any of:

- Increase in serum creatinine by \geq 0.3 mg/dL (\geq 26.5 µmol/L) within 48 hours
- Increase in serum creatinine to ≥1.5 times baseline, which is known or presumed to have occurred within the prior 7 days
- Urine volume <0.5 mL/kg/hour for 6 hours

Gastrointestinal haemorrhage

Refers to bleeding originating from any part of the gastrointestinal tract (from the oropharynx to the rectum).

Pancreatitis



Inflammation of the pancreas, diagnosed from clinical, biochemical, radiological or histological evidence.



COMPLICATIONS, continued

Liver dysfunction

A finding that indicates abnormal liver function, may refer to any of the following:

- Clinical jaundice
- Hyperbilirubinaemia (blood bilirubin level twice the upper limit of the normal range)
- An increase in alanine transaminase or aspartate transaminase that is twice the upper limit of the normal range

Hyperglycaemia

For adults, is defined as an abnormally high level of glucose in the blood, blood glucose level that is consistently above 126mg/dL or 7 mmol/L. For children, is defined as a blood glucose level consistently above 8.3 mmol/L.

Hypoglycaemia

For adults, is defined as an abnormally low level of glucose in the blood, a blood glucose level that is consistently below 70mg/dL or 4 mmol/L. For children, is defined as a blood glucose level below 3 mmol/L.

Other

Please specify other complications in the space provided.

MODULE 3: OUTCOME CASE REPORT FORM

TREATMENT: At ANY time during hospitalisation, did the patient receive/undergo:							
Any Oxygen therapy? OYES ON	O OUnknown If YES, total durat	tion:days OUnknown					
Maximum O2 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 O Unknown				
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 O Unknown				
Renal replacement therapy (RRT)	or dialysis? OYES ONO OUnknow	vn					
Inotropes/vasopressors?	OYES ONO OUnknown						
ICU or High Dependency Unit adn	nission? OYES ONO OUnknown	If YES, total duration:	days OUnknown				
If YES, date of IC	U admission: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	OUnknown				
date of IC	U discharge: [_D_][_D_]/[_M_	_][_M_]/[_2_][_0_][_Y_][_Y_]	OUnknown				

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

COMPLICATIONS: At any time during i	OWPLICATIONS: At any time during hospitalisation did the patient experience: (<i>Unk = Unknown</i>)					
Viral pneumonia/pneumonitis	OYES ONO OUnk	Meningitis / Encephalitis	OYES ONO OUnk			
Bacterial pneumonia	OYES ONO OUnk	Bacteremia	OYES ONO OUnk			
Acute Respiratory Distress Syndrome	OYES ONO OUnk	Coagulation disorder / DIC	OYES ONO OUnk			
Pneumothorax	OYES ONO OUnk	Pulmonary Embolism	OYES ONO OUnk			
Pleural effusion	OYES ONO OUnk	Deep Vein Thrombosis	OYES ONO OUnk			
Cryptogenic organizing pneumonia (COP)	OYES ONO OUnk	Other thromboembolism (not PE or DVT)	OYES ONO OUnk			
Bronchiolitis	OYES ONO OUnk	Anemia	OYES ONO OUnk			
Cardiac arrest	OYES ONO OUnk	Rhabdomyolysis / Myositis	OYES ONO OUnk			
Myocardial infarction	OYES ONO OUnk	Acute renal injury/ Acute renal failure	OYES ONO OUnk			
Cardiac ischaemia	OYES ONO OUnk	Gastrointestinal haemorrhage	OYES ONO OUnk			
Cardiac arrhythmia	OYES ONO OUnk	Pancreatitis	OYES ONO OUnk			
Myocarditis / Pericarditis	OYES ONO OUnk	Liver dysfunction	OYES ONO OUnk			
Endocarditis	OYES ONO OUnk	Hyperglycemia	OYES ONO OUnk			
Cardiomyopathy	OYES ONO OUnk	Hypoglycemia	OYES ONO OUnk			
Congestive heart failure	OYES ONO OUnk	Other	OYES ONO OUnk			
Seizure	OYES ONO OUnk	If YES, specify:				
Stroke / Cerebrovascular accident	OYES ONO OUnk					





World Health Organization

Radiology

Chest X-Ray/ CT performed?

Record if X-ray and/or CT were performed, even if no infiltrates were present.

Pathogen Testing Details

Details of pathogen testing per biospecimen type

ISARIC

If the patient had samples taken for pathogen detection testing during their hospital stay, please complete a row for every type of sample collected (e.g. nasal/NP swab, sputum, etc.).

Where both positive and negative results for a particular sample type exist (from samples taken at different time points during the patient's hospital stay) please record the earliest positive result.

If results are indeterminate' or considered by the clinical team to represent contamination/colonisation, record on the form as Negative

If only multiple negative results exist for a particular sample type (from samples taken at different time points during the patient's hospital stay), please document the earliest negative result.

MODULE 3: OUTCOME CASE REPORT FORM

DIAGNOSTICS				
Section 1: RESPIRATORY VIRUS PCR TESTING				
SARS-CoV-2 (COVID-19): OPositive ONegative ONot done OUnknown				
Was other pathogen testing done during this illness episode? OYES (complete section) ONO OUnknown				
Influenza : OPositive ONegative ONot done OUnknown				
If Positive: OA-not typed OA/H3N2 OA/H1N1pdm09 OA/H7N9 OA/H5N1 OB OOther:OUnk				
Respiratory Syncytial Virus (RSV): OPositive ONegative ONot done OUnknown				
Adenovirus: OPositive ONegative ONot done OUnknown				
Section 2: BACTERIAL TESTING				
Bacteria: OPositive ONegative ONot done If Positive, specify: OUnknown				
Other pathogen/s detected: OYES ONO OUnknown If YES, specify all:OUnknown				
Section 3: RADIOLOGY				
Clinical pneumonia diagnosed? OYES ONO OUnknown				
Chest X-Ray performed? OYES ONO OUnknown If Yes: Were infiltrates present? OYES ONO OUnknown				
CT performed? OYES ONO OUnknown If Yes: Were infiltrates present? OYES ONO OUnknown				

Section 4: PATHOGEN TESTING DETAILS

Collection Date (DD/MM/YYYY)	Biospecimen Type	Laboratory test Method	Result	Pathogen Tested/Detected
_D_D/_MM/20_Y_Y_	ONasal/NP swab OThroat swab OCombined nasal/NP+throat swab OSputum OBAL OETA OUrine OFeces/rectal swab OBlood OOther, Specify:	OPCR OCulture OOther, <i>Specify:</i>	OPositive ONegative OUnknown	
_D_D_/_MM_/20_YY	ONasal/NP swab OThroat swab OCombined nasal/NP+throat swab OSputum OBAL OETA OUrine OFeces/rectal swab OBlood OChter, Specify:	OPCR OCulture OOther, <i>Specify:</i>	OPositive ONegative OUnknown	
DD/_MM_/20_YY_	ONasal/NP swab OThroat swab OCombined nasal/NP+throat swab OSputum OBAL OETA OUrine OFeces/rectal swab OBlood OOther, Specify:	OPCR OCulture OOther, <i>Specify:</i>	OPositive ONegative OUnknown	
_D_D_/_MM_/20_Y_Y_	ONasal/NP swab OThroat swab OCombined nasal/NP+throat swab OSputum OBAL OETA OUrine OFaeces/rectal swab OBlood OOther, Specify:	OPCR OCulture OOther, <i>Specify:</i>	OPositive ONegative OUnknown	



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

Antiviral or COVID-19 targeted agent

Record all antivirals or COVID-19 targeted agents administered from date of admission or during the hospitalisation. Record the total number of days the treatment was given.

Additional space is available under 'Other treatments...' at the end of this section if required

Antibiotic

'Antibiotic' refers to any agent(s) are substances naturally produced by microorganisms or their derivatives that selectively target microorganisms. These substances are used in the treatment of bacterial and other microbial infections. Topical preparations are not included.

Corticosteroid

'Corticosteroids' (commonly referred to as 'steroids') refers to all types of therapeutic corticosteroid, made in the adrenal cortex (the outer part of the adrenal gland). They are also made in the laboratory. Examples include: prednisolone, prednisone, methyl-prednisolone, dexamethasone, hydrocortisone, fluticasone, betamethasone (note that other examples exist). Topical preparations are not included, but inhaled preparations are included. The indication for administering corticosteroids does not need to be directly related to the treatment of COVID-19.

Anticoagulants

These include heparin, enoxaparin, apixaban, dabigatran, rivaroxaban, edoxaban, warfarin. For heparin treatment, please specify if unfractionated or low molecular weight heparin was administered.

Antifungal Agent

'Antifungal agent' refers to any agent(s) prescribed specifically to treat systemic or topical infections caused by fungi. Examples include fluconazole, amphotericin, caspofungin, anidulafungin, posaconazole, itraconazole (note that other examples exist). Topical preparations should not be recorded.

Other treatment administered for COVID-19

Record any other medications, experimental or re-purposed, administered to modify the course of COVID-19 during the admission (including as part of a clinical trial). This could include convalescent plasma, immuno-modulatory agents and anti-viral agents not already recorded above.

MODULE 3: OUTCOME CASE REPORT FORM
MEDICATION: While hospitalised or at discharge, were any of the following administered? (Unk=Unknown)
ANTIVIRAL OR COVID-19 TARGETED AGENT? OYES ONO OUnknown If YES, specify (all) :
□ Ribavirin Date commenced[_D_]_D_]/[_M_]/[_2_][_0_][_Y_][_Y_] OUnk Duration:days OUnk
□ Lopinavir/Ritonavir Date commenced [_D_]_D_]/[_M_][_M_]/[_2_][_0_][_Y_]_V OUnk Duration: days OUnk
Remdesivir (Veklury) Date commenced [D][D]/[M][M]/[2][0][Y][Y] OUnk Duration: days OUnk
□ Interferon alpha Date commenced [_D_]_D_]/[_M_]/[_2_][_0_][_Y_][_Y_] OUnk Duration:days OUnk
□ Interferon beta Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] OUnk Duration: days OUnk
Chloroquine/hydroxychloroquine:
Date commenced [D] [D] / [M] [M] / [2] [0] [Y] OUnk Duration: days OUnk
□ Interleukin-6 (IL-6) inhibitor IF YES which: □ Tocilizumab □ Sarilumab □ Other IL-6 inhibitorOUnk
Date commenced [D] [D] / [M] [M] / [2] [0] [Y] [Y] OUnk Duration:days OUnk
Convalescent plasma Date commenced [_D][D]/[M]/[2][0][Y][Y] OUnk Duration:days OUnk
□ Anti-influenza anti-viral IF YES which: □Oseltamivir (Tamiflu®) □ Zanamivir OUnk
Date commenced _D_/[_M_]/[_2_][_0_](_Y_] OUnk Duration:days OUnk
□ OtherDate commenced [D][D]/[M][M]/[2][0][Y][Y] OUnk Duration:days OUnk
ANTIBIOTIC? OYES ONO OUnknown If yes, specify all:
Agent 1: Date commenced [_D][_D]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: days OUnk
Agent 2: Date commenced [_D_[D_]/[M_][M_]/[2_[0_[Y_][Y_] Duration: days OUnk
Agent 3: Date commenced [_D_[/_M_]/_2_[0_[/_]_Y] Duration: days OUnk
CORTICOSTEROID? OYES ONO OUnknown
If YES: Dexamethasone? OYES ONO OUnknown
If YES, check all that apply:
□ 6mg once per day (od)? OYES ONO OUnknown If YES, Route: □ Oral □ Intravenous OUnk
If YES, Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: days OUnk
□ other dose or frequency? OYES ONO OUnknown If YES, Route: □ Oral □ Intravenous OUnk
If YES, Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: days OUnk
If YES: Other corticosteroid? OYES ONO OUnknown
If YES: Which steroid: 🗆 Prednisolone 📄 Hydrocortisone 📄 Methylprednisolone 📄 Other

Route:
Oral
Intravenous OUnk



OUTCOME

Was patient diagnosed with Covid-19?

Please confirm method of diagnosis, confirming diagnosis by clinical assessment only if no positive laboratory result was obtained.

Discharged alive can mean discharge to their usual place of residence before their illness, to the home of a relative or friend, or to a social care facility, because their illness is no longer severe enough to warrant treatment in a medical facility.

Hospitalized means they are still in hospital but have recovered from COVID-19 infection and the form has been completed as the patient is in a part of the hospital for care of other conditions and where the form will not be completed at a later date.

Transfer to other facility means they have been transferred to another facility that provides medical care. This could be a specialist centre for more intensive treatment or a step-down for rehabilitation. It does not include facilities that solely provide social care (these patients should be listed as discharged alive).

Death means the patient died in the hospital.

Palliative discharge means the patient has been discharged with the expectation that they will not recover from this or other co-existing illness. This could be to a specialist hospice facility, or to their usual home address with anticipatory end of life medications.

Outcome date Please state the date for the outcome listed above.

If Discharged Alive: (answer these questions only if outcome is 'Discharged Alive'

Ability to self-care at discharge versus before illness: the patient is able to care for themselves at discharge (in terms of activities of daily living) at the same level as before they developed illness then tick 'same as before illness'. If their ability to self-care has decreased or increased, then tick the appropriate circle ('worse' or 'better').

Post-discharge treatment

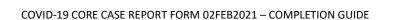
Oxygen therapy includes, NIV or home ventilation (respiratory support/treatment).

MODULE 3: OUTCOME CASE REPORT FORM

MEDICATION (continued):		
ANTICOAGULATION? OYES ONO OUnk		
If YES: Agent:		
Route: Subcutaneous Intravenous (IV) OUnk		
Indication: therapeutic (treatment of DVT/PE) enhanced prophylaxis for		
ANTIFUNGAL AGENT? OYES ONO OUnk		
OTHER treatments administered for COVID-19 including experimental or co		
If YES, specify agent and timing of administration:		
Agent 1:		
Date commenced [](]/(_M_](_M_]/(_2_](_0_](_Y_)(_Y_) OUnk	Duration: days	OUnk
Agent 2:		
Date commenced [](]/(_M_](_M_]/(_2_](_0_](_Y_)(_Y_) OUnk	Duration: days	OUnk
Agent 3:		
Date commenced [][_]/[]/[_4]/[_2_][_0_][_Y_][_Y_] OUnk	Duration: days	OUnk

OUTCOME Was patient diagnosed with Covid-19? OYES ONO OUnknown If yes, was the diagnosis based on: Olaboratory confirmation O clinical assessment Outcome: ODischarged alive OHospitalised OTransfer to other facility ODeath OPalliative discharge OUnknown Outcome date: [D][D]/[M][M]/[2][0][Y][Y] OUnknown If alive at outcome date: Ability to self-care at discharge versus before illness: OSame as before illness OWorse OBetter OUnknown Post-discharge treatment: Oxygen therapy? OYES ONO OUnknown Ongoing health care needs relating to this admission for COVID-19: OYES ONO OUnknown Ongoing health care needs NOT related to COVID episode: OYES ONO OUnknown 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): OYES ONO OUnknown











APPENDIX C: DATA COLLECTION FORM ECMOCARD

EOT ICU Admis

UPON ICU ADMISSION – Please complete the below data as of the date and time of the patient's admission to the ICU			
	Is this patient's data being collected	Please select which daily data format this patient's record will use.	
	using the Full or Basic daily data	'FULL' daily data	
	forms?	Complete the EOT Daily form every day of mechanical ventilation (ie. from mechanical ventilation commencement (intubation) to discontinuation of mechanical ventilation (extubation)).	
		'BASIC' daily data	
		 Complete the EOT Daily form: Four (4) days after ICU admission (only if the patient is mechanically ventilated at that time) Upon commencement of mechanical ventilation Upon ECMO commencement Upon ECMO discontinuation Upon mechanical ventilation discontinuation. 	
	Date of ICU admission	Only enter date in DD/MM/YYYY format from 14/12/2019.	
1.1	Height	Height on admission to ICU in centimetres. If this data has already been entered into the 'Signs and Symptoms' section of the ISARIC CRF, please DO NOT re-enter the data here. Leave this '1.1 Height' box blank.	
1.2	Body Weight	Weight on admission to ICU in kilograms. If this data has already been entered into the 'Signs and Symptoms" section of the ISARIC CRF, please DO NOT re-enter the data here. Leave this '1.2 Body Weight' box blank.	
1.3a	Arterial Hypertension	Please select Yes or No. Arterial hypertension is defined by the chronic use of therapy for the indication of blood pressure-lowering, prior to hospital admission. If this data has already been entered into the 'Co-Morbidities & Risk Factors' section of the ISARIC CRF, please DO NOT re-enter the data	
1.3b	Chronic anti-hypertensive therapy	here. Leave this '1.3 Hypertension' box blank. If 'Yes' to 1.3, please select up to three (3) types of anti- hypertensive medications the patient was receiving prior to hospital admission.	









		If 'No' to 1.3, please select 'Not applicable'.
		If 'ACE inhibitors' and 'Angiotensin II receptor antagonist' data has already been entered in the 'Pre-Admission Medication' section of the ISARIC CRF, please DO NOT re-enter the data here. Leave these boxes blank.
1.4	Pre-hospital Admission creatinine Available	Select yes or no
1.4a	Pre-hospital Admission Creatinine	Document value in mg/dL or umol/Lif available
1.5	Gastrointestinal and Pancreatic Comorbidities	 Select yes or no. Gastrointestinal and pancreatic comorbidities are restricted to: Example A: Ulcerative colitis Example B: Pancreatic cancer Comment on REDCap database if applicable.
1.6	Hepatic and Biliary Comorbidities	 Select yes or no. Hepatic and biliary comorbidities are restricted to: Example A: Cirrhosis Example B: Primary biliary cholangitis Comment on REDCap database if applicable.
1.7	Haematologic and spleen comorbidities	 Select yes or no. Haematologic and spleen comorbidities are restricted to: Example A: Leukaemia Example B: Asplenia Comment on REDCap database if applicable.
1.8	Immunological and transplant comorbidities	 Select yes or no. Immunological and transplant comorbidities are restricted to: Example A: systemic lupus erythematosus Example B: Previous heart transplant Comment on REDCap database if applicable.
1.9	Endocrinological Comorbidities	Select yes or no. Endocrinological comorbidities are restricted to: • Example A: Diabetes









		Example B: Hypothyroidism
		Comment on REDCap database if applicable.
1.10	Genito-Urinary Comorbidities	Select yes or no.
		Genito-urinary comorbidities are restricted to:
		Example A: Chronic kidney failureExample B: Interstitial cystitis
		Comment on REDCap database if applicable.
1.11	Chronic Alcohol Abuse	Select yes or no.
		'Chronic' is defined as continual excessive alcohol consumption as defined as frequent binge drinking (more than 4 drinks per day for woman or 5 drinks per day for men) in the 6 months prior to this ICU presentation.
		Comment on REDCap database if applicable.
1.12	Intravenous Drugs Abuse	Select yes or no.
		Use of intravenous drug abuse in the 6 months prior to this ICU presentation.
		Comment on REDCap database if applicable.
1.13	Immuno-Competent	Select yes or no. Yes = immunocompetent; No = immune- incompetent.
		'Immuno-incompetent' examples:
		Example A: Use of immunosuppressant drugsExample B: Acquired immunodeficiency syndrome
		Comment on REDCap database if applicable.
1.14	APACHE II Score	At the time of the patient's admission to ICU.
		Only enter score numbers from 0-71.
		An APACHE II calculator can be found at <u>https://www.mdcalc.com/apache-ii-score</u>
		If the APACHE II Score is unable to be calculated, please select 'Not Available'.
1.15	SOFA Score	At the time of the patient's admission to ICU.
		Only enter score numbers from 0-24.
		A SOFA score calculator can be found at









		https://www.mdcalc.com/sequential-organ-failure-assessment- sofa-score		
		If the SOFA Score is unable to be calculated, please select 'Not Available'.		
	BLOOD GAS ANALYSIS (Qs 1.16 – 1.21) – Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to ICU admission. 'Worst' blood gas is defined as the blood gas with the lowest PaO2/FiO2 ratio.			
1.16	Arterial pH in the last 6 hours	Record pH to the nearest three decimal places.		
		Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to ICU admission. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.		
		Only values between 6.500-7.600.		
		If arterial pH was not measured in the 6 hours before the patient's admission to the ICU, please select 'Not available'.		
1.17	Arterial partial pressure of oxygen (PaO_2) in the last 6 hours	Record PaO_2 in mmHg or kPa. Round to the nearest one decimal place.		
		Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to ICU admission. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.		
		Only enter values from 10-500 mmHg or 1.3 – 66.7 kPa.		
		If PaO_2 was not measured in the 6 hours before the patient's admission to the ICU, please select 'Not available'.		
1.18	Arterial partial pressure of carbon dioxide (PaCO ₂) in the last 6 hours	Record PaCO ₂ in mmHg or kPa. Round to the nearest one decimal place.		
		Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to ICU admission. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.		
		Only enter values from 10-100 mmHg or 1.3-13.3 kPa.		
		If PaCO ₂ was not measured in the 6 hours before the patient's admission to the ICU, please select 'Not available'.		
1.19	Arterial HCO ₃ in the last 6 hours	Record bicarbonate measurement in mmol/L or mEq/L.		
		Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to ICU admission. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.		









		Only enter values from 1-50.
		If HCO_3 was not measured in the 6 hours before the patient's admission to the ICU, please select 'Not available'.
1.20	Arterial base excess in the last 6	Record base excess measurement in mmol/L.
	hours	Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to ICU admission. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Only enter values from -50 – +50.
		If base excess was not measured in the 6 hours before the patient's admission to the ICU, please select 'Not available'.
1.21	Lactate in the last 6 hours	Record arterial lactate in mmol/L.
		Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to ICU admission. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Only enter values from 0-200.
		If arterial lactate was not measured in the 6 hours before the patient's admission to the ICU, please select 'Not available'.
1.22	Troponin in the last 12 hours	Please enter the highest troponin levels in the last 12 hours in either ng/mL or ng/L.
		Please enter up to two (2) different types of troponin levels.
		If troponin was not measured, please select 'Not available'.
1.23	Cardiac BNP in the last 12 hours	Please enter the highest cardiac BNP in the last 12 hours in picograms/mL.
		If cardiac BNP was not measured, please select 'Not available'.
1.24	Upon ICU admission, did the patient present with cutaneous manifestations?	If it is not known whether or not the patient presented with cutaneous manifestations, please select 'Not available'.
	If yes to 1.24, type of cutaneous manifestations	Please specify what type of cutaneous manifestations the patient presents with.
		Please select up to three (3) options.
	If yes to 1.24, please specify the involved regions.	Please specify what regions are involved in the cutaneous manifestations.
		Please select up to three (3) options.



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EOT Mech Vent

UPON COMMENCEMENT OF MECHANICAL VENTILATION - 'Mechanical ventilation' includes invasive mechanical ventilation via an endotracheal tube or tracheostomy only. Importantly, this module will be active only when you click 'YES' in the field '1.17 Invasive ventilation' of the SPRINT-SARI form.

2.1	Date of Start of Mechanical	Date format is dd-mm-yyyy
	Ventilation	'Mechanical ventilation' includes invasive mechanical
		ventilation via an endotracheal tube or tracheostomy
		only.
2.2	Site of Intubation	Select where intubation took place;
		Outside hospital
		Intensive Care Unit
		Emergency Department
		Hospital Ward
		Different Hospital then patient was transferred
		Other
2.3	Type of Intubation	Select type of intubation;
		Elective (patient is conscious but deteriorating and requires planned intubation).
		Emergent (under emergency circumstances, airway under immediate threat)
2.4	Cardiac Arrest	Please enter Yes or No.
		Answer 'Yes' if the patient had a cardiac arrest 2 hours
		before or after endotracheal intubation, answer 'No' if
		the patient did not have a cardiac arrest within this
		timeframe.
2.5	Ventilatory Support Before	Select ventilatory support immediately before
	Intubation	intubation, if not known please select not available.
		High-Flow Oxygen ventilation:















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THE UNIVERSITY OF QUEENSLAND



		Nasal Prongs Oxygen Therapy
analysis		ocument the values associated with the 'worst' blood gas of mechanical ventilation. 'Worst' blood gas is defined as
2.6	Arterial pH in the 6 hours before start of MV.	Record pH to the nearest three decimal places. Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to commencement of mechanical ventilation. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio. Only values between 6.500-7.600. If arterial pH was not measured in the 6 hours prior to
2.7	Arterial partial pressure of oxygen	commencement of mechanical ventilation, please select 'Not available'. Record PaO ₂ in mmHg or kPa. Round to the nearest one
	(PaO ₂) (mmHg) in the 6 hours before the start of MV.	decimal place. Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to commencement of mechanical ventilation. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Only enter values from 20-500 mmHg or 2.7-66.7 kPa. If PaO ₂ was not measured in the 6 hours before commencement of mechanical ventilation, please select 'Not available'.



Criticalcare









2.8	Arterial partial pressure of carbon dioxide	Record PaCO ₂ in mmHg or kPa. Round to the nearest whole number.
		Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to commencement of mechanical ventilation. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Only in numbers from 10-100 mmHg or 1.3-13.3kPa.
		If PaCO ₂ was not measured in the 6 hours before commencement of mechanical ventilation, please select 'Not available'.
2.9	Arterial HCO3 in the 6 hours before	Record bicarbonate measurement in mmol/L or mEq/L.
	the start of MV.	Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to commencement of mechanical ventilation. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Only enter values from 1-50.
		If HCO ₃ was not measured in the 6 hours before commencement of mechanical ventilation, please select 'Not available'.
2.10	Arterial base excess in the 6 hours	Record base excess measurement in mmol/L.
	before start of MV.	Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to commencement of mechanical ventilation. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Only enter values from $-50 - +50$.
		If base excess was not measured in the 6 hours before commencement of mechanical ventilation, please select 'Not available'.
2.11	Arterial lactate in the 6 hours before	Record arterial lactate in mmol/L.
	the start of MV.	Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to commencement of mechanical ventilation. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.









		Only enter values from 0-200. If arterial lactate was not measured in the 6 hours before commencement of mechanical ventilation, please select 'Not available'.
2.12	Use of continuous renal replacement therapy before start of MV.	Document if patient is receiving continuous renal replacement therapy in the 6 hours before commencement of mechanical ventilation.
		Select yes or no.
2.13	Use of vasoactive drugs before start of MV	Document if patient is receiving vasoactive drugs therapy in the 6 hours prior to MV.
		Select yes or no.
		Examples of vasoactive drugs:
		 Dopamine Noradrenaline Dobutamine Milrinone Adrenaline
2.14	Use of cardiac assist devices before start of MV	Document if patient has a cardiac assist device in the 6 hours prior to MV commencement.
		Select yes or no.
		Examples of cardiac assist devices:
		left ventricular assist device (LVAD)
		 Intra-aortic balloon pump (IABP) Pulsatile ventricular assist device (pVAD)
2.15.1	Type 1 Antibiotic	Select antibiotic therapy in the 6 hours prior to MV:
		 Amikacin Amoxicillin Amoxicillin + Clavulanate Ampicillin Ampicillin + Sulbactam Atovaquone Azithromycin Aztreonam











	Bacampicillin Bacitra sin
	Bacitracin
	Capreomycin
	Carbenicillin indanyl sodium
	Cefaclor
	Cefadroxil
	Cefamandole
	Cefazolin
	Cefdinir
	Cefditoren
	Cefepime
	Cefixime
	Cefmetazole
	Cefonicid
	Cefoperazone
	Cefotaxime
	Cefotetan
	Cefoxitin
	Cefpodoxime Proxetil
	Cefprozil
	Ceftazidime
	Ceftazidime/Avibactam
	Ceftibuten
	Ceftizoxime
	Ceftobiprole
	Ceftolozane/Tazobactam
	Ceftriaxone
	Cefuroxime
	Cephalexin
	Cephalothin
	Cephapirin
	Cephradine
	Chloramphenicol
	Cinoxacin
	Ciprofloxacin
	Clarithromycin
	Clindamycin
	Cloxacillin
	Colistimethate







	Cycloserine
	Daptomycin
	Demeclocycline
	Dicloxacillin
	Dirithromycin
	Doripenem
	Linezolid
	Lomefloxacin
	Loracarbef
	Mafenide
	Meropenem
	Methenamine hippurate
	Methicillin
	Metronidazole
	Mezlocillin
	Minocycline
	Moxifloxacin
	Mupirocin
	Nafcillin
	Nalidixic Acid
	Neomycin
	Netilmicin
	Nitrofurantoin
	Nitrofurazone
	Norfloxacin
	Novobiocin
	Ofloxacin
	Oxacillin
	Oxytetracycline
	Penicillin
	Piperacillin
	Piperacillin + Tazobactam
	Podofilox
	Polymyxin B
	Quinupristin + Dalfopristin
	Retapamulin
	Rifapentine
	Rifaximin
	Saturated Solution of Potassium Iodide (SSKI)









		□ Sparfloxacin
		Spectinomycin
		□ Streptomycin
		□ Sulfadiazine
		Sulfamethoxazole
		□ Sulfisoxazole
		Sulphur, precipitated in petrolatum
		□ TCA (trichloroacetic acid), BCA (bichloroacetic acid).
		Teicoplanin
		Telavancin
		Telithromycin
		Terbinafine
		Tetracycline
		Ticarcillin
		Ticarcillin + Clavulanic Acid
		□ Tigecycline
		Tobramycin
		Trimethoprim
		Trimethoprim + Sulfamethoxazole
		Trovafloxacin
		□ Vancomycin
2.15.2	Type 2 Antibiotic	Same as above
2.15.3	Type 3 Antibiotic	Same as above
2.15.4	Type 4 Antibiotic	Same as above
2.15.5	Type 5 Antibiotic	Same as above.
		If the patient received more than 5 different antibiotics
		in the 6 hours before mechanical ventilation
		commencement, please only list the first 5 the patient
		received in order of prescription.











EOT START ECMO

	JPON COMMENCEMENT OF ECMO. Importantly, this module will be active only when you click 'YES' in the			
	ield "1.18 ECLS?' of the SPRINT-SARI form.			
3.1	Date of start of ECMO	Date format is dd-mm-yyyy ECMO start is defined as commencement of the ECMO blood pump.		
3.2	Is this patient enrolled in the EXCEL study?	The EXCEL study is the "The EXCEL Study: A comprehensive national registry on the treatment and outcomes of patients requiring ECMO" (NCT03793257).		
3.3	If yes to 3.2, what is the patient's EXCEL study number?	Please enter the patients unique EXCEL study identification number.		
3.4	Is this patient enrolled in the ELSO Registry?	Please answer 'Yes' or 'No'		
3.5	If yes to 3.4, what is the patient's ELSO Registry number?	Please enter the patient's unique ELSO Registry identification number.		
3.6	Location of ECMO Cannulation	 Select the location of where patient was cannulated. Options are: Same Hospital Other Hospital, then patient was retrieved and transferred Comment on REDCap database if applicable. 		
3.7	Type and manufacturer of centrifugal blood pump driven circuit	Please enter text describing the name and manufacturer of the ECMO circuit.		
3.8	Type and manufacturer of Low-Resistance Oxygenator	Please enter text describing the name and manufacturer of the ECMO oxygenator.		
3.9	Type Of ECMO	 Select which type of ECMO patient is receiving. Options are: Venous-venous Venous-arterial 		
3.10	Drainage cannula insertion site	Select the cannulation site for access/drainage peripheral access.		









3.10a 3.10b	Drainage cannula size Drainage cannula size	 Options are: Left femoral vein Left internal jugular vein Right femoral vein Right internal jugular vein Please select 'Yes' (size available) or 'No' (size unavailable). Please enter the size of the drainage
		cannula in Fr. Please only enter numbers between 5 and 30.
3.11	Return cannula insertion site	Select the cannulation site for return peripheral access. Options are: • Left femoral vein • Left internal jugular vein • Right femoral vein • Right internal jugular vein • Left femoral artery • Right femoral artery
3.11a	Return cannula size	Please select 'Yes' (size available) or 'No' (size unavailable).
3.11b	Return cannula size	Please enter the size of the return cannula in Fr. Please only enter numbers between 5 and 30.
	ENT PRIOR TO COMMENCEMENT OF ECMO – Please e ommencement.	enter the below data from within 6 hours of
3.12	Cardiac arrest before start of ECMO	Please select either Yes or No. Answer 'Yes' if the patient had a cardiac arrest 2 hours before or after ECMO commencement, answer 'No' if the patient did not have a cardiac arrest within this timeframe.











3.13	Use of prone position before start of ECMO	Please select Yes or No.
		Select Yes is the patient was proned in the 6 hours before commencement of ECMO.
		Select No if the patient was not proned prior to commencement of ECMO, or if the patient was proned outside the 6 hour window prior to ECMO commencement.
3.14	Use of Neuromuscular Blockade before start of ECMO	Did the patient receive neuromuscular blockers in the 6 hours prior to starting ECMO?
		Select Yes or No
		Examples of neuromuscular blockers:
		Atracurium
		Cisatracurium
		Nimbex
		NorcuronPancuronium
		ParticuloniumPavulon
		Rocuronium
		Tracrium
		• Vecuronium
		• Zemuron
3.15	Use of recruitment manoeuvres before start of	Please select either Yes or No.
	ECMO	Manoeuvres must have been used within 6 hours prior to commencing ECMO for Yes to be selected.
		Recruitment manoeuvres are defined as changes in ventilatory settings to increase delivered volume or airway pressure to reopen collapsed lung regions
3.16	Use of Inhaled Nitric Oxide before start of ECMO	Please select either Yes or No.
		The patient must have received inhaled Nitric Oxide (iNO) in the 6 hours before ECMO was started for Yes to be selected. If outside this timeframe or if the patient did not receive iNO at any point before











		commencement of ECMO, please select No.
3.17	Use of bicarbonate before start of ECMO	Please select either Yes or No. Select Yes if the patient received bicarbonate within the 6 hours before ECMO commencement. Select No if the patient did not receive bicarbonate before ECMO commencement or received it outside 6 hours before ECMO commencement.
3.18	Ventilatory Mode before start of ECMO	Please enter the mode of ventilation the patient was receiving immediately preceding the commencement of ECMO. If not known, please select 'Not available'.
blood ga	hours before the commencement of ECMO. 'Worst' m is with the lowest PaO2/FiO2 ratio. Please report vention plood gas.	
3.19	Inspiratory fraction of oxygen in the 6 hours before	Place onter the highest ovugen
	start of ECMO	Please enter the highest oxygen requirement as a percentage, not a decimal number. Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to commencement of ECMO. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio. For example, please enter 80%, not 0.8. Please enter numbers between 21 and 100.











		spontaneous breaths).
		Please enter a number between 2-60.
3.21	Tidal Volume	Please enter the highest tidal volume in the 6 hours prior to ECMO commencement.
		Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to commencement of ECMO. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Please enter as ml/kg of ideal body weight.
		Ideal Body Weight formula:
		Male patients: 50 + (0.91 x [height in cm – 152.4])
		Female patients: 45.5 + (0.91 x {height in cm – 152.4])
		Please enter a number between 1.0 and 14.0.
		If unable to be calculated, please select Not available.
3.22	Positive end expiratory pressure in the 6	Document the highest set PEEP.
	hours before the start of ECMO.	Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to commencement of ECMO. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Record in cmH2O.
		Please enter numbers between 0 and 25.
3.23	Peak airway pressure in the 6 hours before the start of ECMO.	Document the highest Peak Airway Pressure in cmH ₂ O.
		Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to commencement of ECMO. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.











		Please enter values between 0 and 85.
3.24	Airway plateau pressure in the 6 hours before the	Record in cmH2O
	start of ECMO.	Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to commencement of ECMO. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		If unable to be calculated, please select Not available.
3.25	Arterial pH in the 6 hours before start of ECMO.	Record pH to the nearest three decimal places.
		Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to commencement of ECMO. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Only values between 6.500-7.600.
		If arterial pH was not measured in the 6 hours before ECMO commencement, please select 'Not available'.
3.26	Arterial partial pressure of oxygen (PaO ₂) (mmHg) in the 6 hours before the start of ECMO.	Record PaO_2 in mmHg or kPa. Round to the nearest one decimal place.
		Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to commencement of ECMO. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Only enter values from 20-500 mmHg or 2.7-66.7kPa.
		If PaO ₂ was not measured in the 6 hours before commencement of ECMO, please select 'Not available'.
3.27	Arterial partial pressure of carbon dioxide (PaCO ₂) in the 6 hours before the start of ECMO.	Record PaCO ₂ in mmHg or kPa. Round to the nearest whole number.
		Please document the values associated with the 'worst' blood gas analysis in the 6











		hours prior to commencement of ECMO. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio. Only in numbers from 10-100 mmHg or 1.3-13.3 kPa. If PaCO ₂ was not measured in the 6 hours
		before commencement of ECMO, please select 'Not available'.
3.28	Arterial HCO3 in the 6 hours before the start of ECMO.	Record bicarbonate measurement in mmol/L or mEq/L.
		Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to commencement of ECMO. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Only enter values from 1-50.
		If HCO ₃ was not measured in the 6 hours prior to commencement of ECMO, please select 'Not available'.
3.29	Arterial base excess in the 6 hours before start of ECMO.	Record base excess measurement in mmol/L.
		Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to commencement of ECMO. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Only enter values from -50 – +50.
		If base excess was not measured in the 6 prior to commencement of ECMO, please select 'Not available'.
3.30	Arterial lactate in the 6 hours before the start of	Record arterial lactate in mmol/L.
	ECMO.	Please document the values associated with the 'worst' blood gas analysis in the 6 hours prior to commencement of ECMO. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.









		Only enter values from 0-200.
		If arterial lactate was not measured in the 6 hours before start of ECMO, please select 'Not available'.
3.31	Use of the continuous renal replacement therapy before the start of ECMO.	Please select Yes or No. Select Yes if the patient received CRRT in the 6 hours prior to ECMO commencement. Select No otherwise.
3.32	Use of vasoactive drugs before the start of ECMO.	Select Yes or No. Select Yes if the patient received any of the below drugs within 6 hours of ECMO commencement. Vasoactive drugs include: Adrenaline Adrenaline Noradrenaline Dopamine Dobutamine Isoprenaline Dopexamine Milrinone Amrinone Levosimendan Phenylephrine Metaraminol Vasopressin Digoxin
3.33	Use of cardiac assist device before start of ECMO.	Document if patient has a cardiac assist device in the 6 hours prior to ECMO commencement. Select yes or no. Examples of cardiac assist devices: • left ventricular assist device (LVAD) • Intra-aortic balloon pump (IABP)









		 Pulsatile ventricular assist device (pVAD)
3.34 &	Use of antibiotics before the start of ECMO	Please select Yes or No.
3.34 & 3.35	Use of antibiotics before the start of ECMO	
		Ceftibuten
		 Ceftizoxime Ceftobiprole
		Ceftobiprole
l		Ceftolozane/Tazobactam











[Ceftriaxone
[Cefuroxime
]	Cephalexin
[Cephalothin
[Cephapirin
[Cephradine
[Chloramphenicol
[Cinoxacin
[Ciprofloxacin
[Clarithromycin
[Clindamycin
[Cloxacillin
[Colistimethate
[Cycloserine
[Daptomycin
	Demeclocycline
	Dicloxacillin
	Dirithromycin
	Doripenem
	Linezolid
	Lomefloxacin
	Loracarbef
	Mafenide
[Meropenem
[Methenamine hippurate
[Methicillin
]	Metronidazole
[Mezlocillin
[Minocycline
]	Moxifloxacin
]	Mupirocin
[Nafcillin
[Nalidixic Acid
[Neomycin
	Netilmicin
[Nitrofurantoin
[Nitrofurazone
[Norfloxacin
	Novobiocin









			Ofloxacin
			Oxacillin
			Oxytetracycline
			Penicillin
			Piperacillin
			Piperacillin + Tazobactam
			Podofilox
			Polymyxin B
			Quinupristin + Dalfopristin
			Retapamulin
			Rifapentine
			Rifaximin
			Saturated Solution of Potassium
			lodide (SSKI)
			Sparfloxacin
			Spectinomycin
			Streptomycin
			Sulfadiazine
			Sulfamethoxazole
			Sulfisoxazole
			Sulphur, precipitated in petrolatum
			TCA (trichloroacetic acid), BCA
			(bichloroacetic acid).
			Teicoplanin
			Telavancin
			Telithromycin
			Terbinafine
			Tetracycline
			Ticarcillin
			Ticarcillin + Clavulanic Acid
			Tigecycline
			Tobramycin
			Trimethoprim
			Trimethoprim + Sulfamethoxazole
			Trovafloxacin
			Vancomycin
3.36	Chest x-ray within 24 hours pre or post- ECMO		ease select 'Yes' or 'No'.
	cannulation		
			r example, if the patient was cannulated
		at	8pm (20:00hrs) on the 03/05/2020,











		please select 'Yes' if the patient had a chest x-ray between 8pm on the 02/05/2020 and 8pm on the 04/05/2020. Select 'No' if the patient did not have a chest x-ray taken within the above time period.
3.36a	If 'Yes' to 3.36, number of chest x-ray quadrants with infiltrates	Please select the number of quadrants identified on the chest x-ray as having infiltrates.











EOT Daily

4. DAILY CASE RECORD FORM

'FULL' daily data

Complete the daily form every day of mechanical ventilation (ie. from mechanical ventilation commencement (intubation) to discontinuation of mechanical ventilation (extubation)). **Please commence this data the day after the patient is intubated.**

'BASIC' daily data

Complete this daily form:

- 1. Four (4) days after ICU admission (only if the patient is mechanically ventilated at that time)
- 2. Upon commencement of mechanical ventilation
- 3. Upon ECMO commencement
- 4. Upon ECMO discontinuation
- 5. Upon mechanical ventilation discontinuation.

Please collect all daily data retrospectively, at least 24h after the day of assessment, since the worst parameters of the 24-h period of assessment need to be identified.

Importantly, parameters related to mechanical ventilation or ECMO will be active only when you click 'YES' in the field '1.17 Invasive ventilation?' or when you click 'YES' in the field '1.18 ECLS?', respectively, of the SPRINT-SARI form.

4.1	Date of observation	Document the date of the observation
4.2	Patient Position	'Full' daily data collection: Patient position applied most predominantly in the last 24 hours
		'Basic' daily data collection: Patient position applied most predominantly since the last EOT Daily form
		If this is the 'Four days after ICU admission' timepoint, please collect the position applied most predominantly in the last 24 hours.
		Is the patient position supine or prone predominantly?
		If patient is in mild tilt positioning on their back, tick supine
4.3	Highest ECMO Flow rate in the last 24 hours	Document the flow rate. Record in L/min.
4.4	Highest ECMO gas flow rate in the last 24 hours	Document the highest gas flow rate.
		Record in L/min
4.5	ECMO Circuit change	Did the patient have their ECMO circuit changed?
		'full' daily data collection: Circuit change in the last 24 hours











		'basic' daily data collection: circuit change since last EOT Daily from If this is the "Four days after ICU admission" timepoint, please answer with reference to the 24 hours Select Yes or No
4.6	Use of neuromuscular blockade	Did the patient receive neuromuscular blockers?
		'full' daily data collection: Neuromuscular blockade in the last 24 hours
		'basic' daily data collection: Neuromuscular blockade since last EOT Daily form
		If this is the 'Four days after ICU admission' timepoint, please answer with reference to the 24 hoursSelect Yes or No
		Examples of neuromuscular blockers: Atracurium Cisatracurium Nimbex Norcuron Pancuronium Pavulon Rocuronium Tracrium Vecuronium Zemuron
4.7	Use of recruitment manoeuvres	Recruitment manoeuvres are defined as changes in ventilatory settings to increase delivered volume or airway pressure to reopen collapsed lung regions. 'Full' daily data collection: Recruitment
		manoeuvres in the last 24 hours 'Basic' daily data collection: Recruitment manoeuvres since the last EOT Daily form If this is the 'Four days after ICU admission'











		timepoint, please answer with reference to the last 24 hours.
		Please select either Yes or No.
4.8	Use of inhaled nitric oxide	The patient must have received inhaled Nitric Oxide (iNO) in the last 24 hours for Yes to be selected. If outside this timeframe or if the patient did not receive iNO at any point during the 24 hours, please select No.
		'Full' daily data collection: Inhaled nitric oxide in the last 24 hours
		'Basic' daily data collection: Inhaled nitric oxide since the last EOT Daily form
		If this is the 'Four days after ICU admission' timepoint, please answer with reference to the last 24 hours.
		Please select either Yes or No.
4.9	Most frequent ventilatory mode in the last 24 hours	Document the most predominant ventilatory
		mode in the last 24 hours.
in the la	NICAL VENTILATION & BLOOD GAS ANALYSIS (Qs 4.10 ast 24 hours. 'Worst' means all values associated with iO2 ratio. Please report ventilatory settings associated Inspiratory fraction of oxygen in the last 24 hours) – 4.21) – Please document the 'worst' value the arterial blood gas with the lowest
in the la PaO2/F	ast 24 hours. 'Worst' means all values associated with iO2 ratio. Please report ventilatory settings associated	0 – 4.21) – Please document the 'worst' value the arterial blood gas with the lowest d with the worst arterial blood gas.
in the la PaO2/F	ast 24 hours. 'Worst' means all values associated with iO2 ratio. Please report ventilatory settings associated	 0 - 4.21) - Please document the 'worst' value the arterial blood gas with the lowest d with the worst arterial blood gas. Please document the values associated with the 'worst' blood gas analysis in the last 24 hours. 'Worst' is defined as the











		Please document the values associated with the 'worst' blood gas analysis in the last 24 hours. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Enter total respiratory rate (set rate plus spontaneous breaths).
		Please enter a number between 2-60.
4.12	Tidal Volume in the last 24 hours	Please document the values associated with the 'worst' blood gas analysis in the last 24 hours. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Please enter as ml/kg of ideal body weight.
		Ideal Body Weight formula:
		Male patients: 50 + (0.91 x [height in cm – 152.4])
		Female patients: 45.5 + (0.91 x {height in cm – 152.4])
		Please enter a number between 1.0 and 14.0.
		If unable to be calculated, please select Not available.
4.13	Positive end expiratory pressure in the last 24 hours.	Please document the values associated with the 'worst' blood gas analysis in the last 24 hours. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Record in cmH ₂ O.
		Please enter numbers between 0 and 25.
4.14	Airway plateau pressure in the last 24 hours	Please document the values associated with the 'worst' blood gas analysis in the last 24 hours. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Please enter numbers between 0 and 50.
4.15	Arterial pH in the last 24 hours.	Record pH to the nearest three decimal places.
		Please document the values associated with the 'worst' blood gas analysis in the last 24 hours. 'Worst' is defined as the











		blood gas with the lowest PaO2/FiO2 ratio.
		Only values between 6.500-7.600.
		If arterial pH was not measured in the last 24 hours, please select 'Not available'.
4.16	Arterial partial pressure of oxygen (PaO_2) (mmHg) in the last 24 hours.	Record PaO_2 in mmHg or kPa. Round to the nearest one decimal place.
		Please document the values associated with the 'worst' blood gas analysis in the last 24 hours. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Only enter values from 20-500 mmHg or 2.7-66.7 kPa.
		If PaO_2 was not measured in the last 24 hours, please select 'Not available'.
4.17	Arterial partial pressure of carbon dioxide (PaCO ₂) in the last 24 hours.	Record PaCO ₂ in mmHg or kPa. Round to the nearest whole number.
		Please document the values associated with the 'worst' blood gas analysis in the last 24 hours. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Only in numbers from 10-100 mmHg or 1.3 – 13.3 kPa
		If $PaCO_2$ was not measured in the last 24 hours, please select 'Not available'.
4.18	Arterial HCO3 in the last 24 hours.	Record bicarbonate measurement in mmol/L or mEq/L.
		Please document the values associated with the 'worst' blood gas analysis in the last 24 hours. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Only enter values from 1-50.
		If HCO₃ was not measured in the last 24 hours, please select 'Not available'.
4.19	Arterial base excess in the last 24 hours.	Record base excess measurement in mmol/L.
		Please document the values associated with the 'worst' blood gas analysis in the last 24 hours. 'Worst' is defined as the









		blood gas with the lowest PaO2/FiO2 ratio.
		Only enter values from -50 -+50.
		If base excess was not measured in the last 24 hours, please select 'Not available'.
4.20	Arterial lactate in the last 24 hours.	Record arterial lactate in mmol/L.
		Please document the values associated with the 'worst' blood gas analysis in the last 24 hours. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Only enter values from 0-200.
		If arterial lactate was not measured in the last 24 hours, please select 'Not available'.
		If this data has already been entered in the 'Daily Case Report Form – Laboratory Results' section of the ISARIC CRF, please DO NOT re-enter the data here. Please
		leave '4.20 Lactate' blank.
4.21	Creatinine in the last 24 hours	Document the worst creatinine in the last 24 hours. Please document the values associated with the 'worst' blood gas analysis in the last 24 hours. 'Worst' is defined as the blood gas with the lowest PaO2/FiO2 ratio.
		Record as mg/dL
		If creatinine has not been measured in the last 24 hours, please select Not available. If this data has already been entered in the 'Daily Case Report Form – Laboratory Results' section of the ISARIC CRF, please DO NOT re-enter the data here. Please
		leave '4.21 Creatinine' blank.
4.22	Use of continuous renal replacement therapy (CRRT)	Is the patient or has the patient received CRRT i <i>'Full' daily data collection: CRRT in the last</i> <i>24 hours</i>
		'Basic' daily data collection: CRRT since the last EOT Daily form
		<i>If this is the 'Four days after ICU admission' timepoint, please answer with reference to</i>











		the last 24 hours
		Select Yes or No.
4.23-	Use of vasoactive drugs	Select Yes or No.
4.29		Select Yes if the patient received any of the below drugs within the last 24 hours. Vasoactive drugs include:
		 Adrenaline Noradrenaline Dopamine Dobutamine Isoprenaline Dopexamine Milrinone Amrinone Levosimendan Phenylephrine Metaraminol Vasopressin
		Please enter the highest dose of each vasoactive medication received in the last 24 hours in mcg/kg/min. If the patient is on more than three different vasoactive medications, please list the three which have the highest doses.
4.30	Use of cardiac assist devices	
		'Full' daily data collection: Cardiac assist device use in the last 24 hours
		'Basic' daily data collection: Cardiac assist device use since the last EOT Daily form
		If this is the 'Four days after ICU admission' timepoint, please answer with reference to the last 24 hours.Select Yes or No
		Examples of cardiac assist devices:
		 left ventricular assist device (LVAD) Intra-aortic balloon pump (IABP)









		 Pulsatile ventricular assist device (pVAD)
4.31	Use of antibiotics	'Full' daily data collection: Antibiotics administered in the last 24 hours
		'Basic' daily data collection: Antibiotics administered since the last EOT Daily form
		If this is the 'Four days after ICU admission' timepoint, please answer with reference to the last 24 hours.
		Select Yes or No.
		If yes, please list up to five antibiotics the patient is currently receiving.
		If the patient received more than 5 different antibiotics in the last 24 hours, please only list the first 5 the patient received in order of prescription.
4.32	Worst haemoglobin	Please enter the most deranged haemoglobin in the last 24 hours in g/dL.
		If haemoglobin not assessed in the last 24 hours, please select 'Not available'.
		If this data has already been entered in the 'Daily Case Report Form – Laboratory Results' section of the ISARIC CRF, please DO NOT re-enter the data here. Please leave '4.32 Haemoglobin' blank.
4.33	Worst white blood cells in the last 24 hours	Please enter the most deranged white blood cell levels in the last 24 hours in.
		If white blood cells not assessed in the last 24 hours, please select 'Not available'.
		If this data has already been entered in the 'Daily Case Report Form – Laboratory Results' section of the ISARIC CRF, please DO NOT re-enter the data here. Please leave '4.33 White Blood Cells' blank.
4.34	White blood cells unit	Please indicate the units of measure for the white blood cells.











4.35	Worst AST/SCGOT in last 24 hours	Please specify the most deranged AST/SCGOT value in the past 24 hours.
		If not measured in the last 24 hours, please select 'Not available'.
		If this data has already been entered in the 'Daily Case Report Form – Laboratory Results' section of the ISARIC CRF, please DO NOT re-enter the data here. Please leave '4.34 AST' blank.
4.36	Worst ALT/SGPT in last 24 hours	Please specify the most deranged ALT/SGPT value in the past 24 hours.
		If not measured in the last 24 hours, please select 'Not available'.
		If this data has already been entered in the 'Daily Case Report Form – Laboratory Results' section of the ISARIC CRF, please DO NOT re-enter the data here. Please leave '4.36 ALT' blank.
4.37	Anticoagulants	'Full' daily data collection: Anticoagulants administered in the last 24 hours
		'Basic' daily data collection: Anticoagulants administered since the last EOT Daily form
		If this is the 'Four days after ICU admission' timepoint, please answer with reference to the last 24 hours.
		Select either Yes or No.
4.38	Type of anticoagulants	If yes to 4.37, please specify what type of anticoagulant has been used.
		Please select only one type. If the patient is receiving more than one type, please list the most predominant.
4.39	Transfused packed red blood cell concentrate	Has the patient received a transfusion of packed RBC?
		'Full' daily data collection: PRBCs administered in the last 24 hours
		'Basic' daily data collection: PRBCs administered since the last EOT Daily form











		If this is the 'Four days after ICU admission' timepoint, please answer with reference to the last 24 hours Select Yes or No.
4.40	Transfused platelets concentrate	Has the patient received a transfusion of platelet concentrate?
		'Full' daily data collection: Platelets administered in the last 24 hours
		'Basic' daily data collection: Platelets administered since the last EOT Daily form
		If this is the 'Four days after ICU admission' timepoint, please answer with reference to the last 24 hours
		Select Yes or No.
4.41	Transfused fresh frozen plasma	Has the patient received a transfusion of FFP?
		'Full' daily data collection: FFP administered in the last 24 hours
		'Basic' daily data collection: FFP administered since the last EOT Daily form
		If this is the 'Four days after ICU admission' timepoint, please answer with reference to the last 24 hours
		Select Yes or No.
4.42	Transfused cryoprecipitates	Has the patient received a transfusion of cryoprecipitate?
		'Full' daily data collection: Cryoprecipitate administered in the last 24 hours
		'Basic' daily data collection: Cryoprecipitate administered since the last EOT Daily form
		If this is the 'Four days after ICU admission' timepoint, please answer with reference to the last 24 hours
		Select Yes or No.
4.43 -	Infection complication	Please specify the source of the infectious











4.54		complication and causative pathogen if known.
		If more than one pathogen is identified, please select the most predominant pathogen.
		Please list up to three infections. If more than three infections are currently active, please list the three most predominant.
4.55- 4.58	Haemorrhagic complication	Please specify the source of the haemorrhagic complication.
		Please list up to two sources. If more than two sources are currently active, please list the two most predominant.
4.59	Other complication	List any other non-haemorrhagic complications.
4.60	Troponin in the last 24 hours	Please enter the highest troponin levels in the last 24 hours in either ng/mL or ng/L.
		Please enter up to two (2) different types of troponin levels.
		If troponin was not measured, please select 'Not available'.
		If Troponin I data has already been entered in the 'Daily Case Report Form – Laboratory Results' section of the ISARIC CRF, please DO NOT re-enter the data here. Please leave '4.59 Troponin I' blank.
4.61	Cardiac BNP in the last 24 hours	Please enter the highest cardiac BNP in the last 24 hours in picograms/mL.
		If cardiac BNP was not measured, please select 'Not available'.











EOT Final

Outco	mes	
5.1	Date of ECMO discontinuation	Please enter the date ECMO was
		discontinued
		Format DD/MM/YYYY
5.2	Date of invasive mechanical ventilation	Please enter the date invasive
	discontinuation	mechanical ventilation was
		discontinued.
		Invasive mechanical ventilation includes
		ventilation via an endotracheal tube or
		tracheostomy.
		Format DD/MM/YYYY
5.3	Date of ICU discharge	Please enter the date the patient was
		discharged from ICU.
		If the patient died whilst in ICU, their
		date of ICU discharge will be the same
		as their date of death.
		Format DD/MM/YYYY
5.4	Date of hospital discharge	Please enter the date the patient was
		discharged from hospital.
		If the patient died whilst in hospital,
		their date of hospital discharge will be
		the same as their date of death.
		Format DD/MM/YYYY
5.5	Date of death	Format DD/MM/YYYY
		If the patient did not die whilst in ICU or
		hospital, please select Not applicable.
5.6	Site of death	Please select the patient's location at
		their time of death.
5.7	Main cause of death	Please select the main cause of the
		patient's death.
5.8	Alive at 28 days post ICU admission?	Please select Yes or No
5.9	Final assessment notes	Please enter any further relevant
		information.
5.10	At any time post ICU admission and until ICU	Please select Yes or No.
	discharge, did the patient present new cutaneous	If this data is not available, please select
	manifestations?	Not available.
		Please select Yes only if the patient
		presented new cutaneous manifestation
		post ICU admission, or cutaneous
		manifestations different from those











		present upon ICU admission.
5.10a	If yes to 5.10, type of cutaneous manifestations	Please select up to three (3) options.
		If Other, please specify.
5.10b	If yes to 5.10, specify the involved regions	Please select up to three (3) options.
5.11	At any time post ICU admission and until ICU	Please select either 'Yes' or 'No'.
	discharge, did the patient have a stroke?	
5.11a	If yes to 5.11, type of stroke	Please select up to two (2) options.
		If the type of stroke was unknown,
		please select 'Unknown'.
5.11b	If yes to 5.11, side of stroke	Please select the side of the stroke.
		Please select only one option.
		If the side was unknown, please select
		'Unknown'.



