ISARIC WHO Clinical Characterisation Protocol for Severe Emerging Infections UK (CCP-UK) CASE REPORT FORMS

v9.6 06JULY2020

DESIGN OF THE CCP-UK CASE REPORT FORM (CRF)

This CRF is divided into a "**ADMISSION**" form (4 pages), a "**DAILY**" form (2 pages) for daily clinical and laboratory and data, an "**OUTCOME**" form (4 pages) and a **"WITHDRAWAL"** form (1 page).

HOW TO USE THIS CRF

The CRF is designed to complement the **Tier** of activity that a site has capacity and capability to work to. This is likely to vary over the course of an outbreak. The decision on which **Tier** to use is up to the Local Principal Investigator. All high-quality data is valuable for analysis.

Ideally, data and samples will be collected with consent using Tier 2 of the protocol schedule, as outlined below. This will be of greatest public health research value in the early stages of an outbreak.
Data can be collected as Tier Zero activity regardless of consent including retrospectively and from deceased cases.

Consent must be obtained for any biological sampling at Tier 1 and Tier 2 activity.

Tier Zero	For sites where caseload or facilities limit research capacity to deliver Tier 1 or Tier 2 activity. **OR** For collection of data without consent from any case; current, past and deceased. Please complete the **ADMISSION CRF** and **DAILY CRF** for the first day of hospital admission (day 1), the **DAILY CRF** again for the first day of any ICU admission, then the **OUTCOME CRF** at day 28, discharge or death (whichever occurs first). N.B. For patients receiving **Remdesivir** (RDV) **and IL6 inhibitors,** please complete an extra **DAILY CRF** for **first day** that such a drug is dosed and for day 14 after drug initiation (if patient remains admitted). **Collection of this data is requested by the CMOs in all nations.**
Tier 1	For sites where facilities limit research capacity to deliver Tier 2 activity or where consent is only for single timepoint biological sampling. Please complete the **ADMISSION CRF** and **DAILY CRF** for the first day of hospital admission (day 1), the **DAILY CRF** for the third (d3), sixth (d6) and ninth (d9) days, the **DAILY CRF** again for the first day of any ICU admission, and then the **OUTCOME CRF** at day 28, discharge or death (whichever occurs first). N.B. For patients receiving **Remdesivir** (RDV) **and IL6 inhibitors,** please complete an extra **DAILY CRF** for **first day** that such a drug is dosed and for day 14 after drug initiation (if patient remains admitted). **Collection of this data is requested by the CMOs in all nations.**
Tier 2	For sites with available resources to deliver Tier 2 activity per the protocol schedule. With consent for multiple timepoint biological sampling. Please complete the **ADMISSION CRF** and **DAILY CRF** for the first day of hospital admission (day 1), the **DAILY CRF** for the third (d3), sixth (d6) and ninth (d9) days, the **DAILY CRF** again for the first day of any ICU admission, and then the **OUTCOME CRF** at day 28, discharge or death whichever occurs first. If biological sampling for research purposes occurs outside of the CRF occurs. N.B. For patients receiving **Remdesivir** (RDV) **and IL6 inhibitors,** please complete an extra **DAILY CRF** for **first day** that such a drug is dosed and for day 14 after drug initiation (if patient remains admitted). **Collection of this data is requested by the CMOs in all nations.**

CASE REPORT FORMS

GENERAL GUIDANCE

- The CRF is designed to collect data obtained through examination, interview and review of hospital notes. Data may be collected retrospectively if the patient is enrolled after the admission date or deceased after admission.
- Participant Identification Numbers consist of a 5-digit CPMS / ODS site code and a 4-digit participant number. You should obtain a site code by contacting your local R&D office or CCP@liverpool.ac.uk. 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. E.g. Ward X will assign numbers from 0001 onwards and Ward Y will assign numbers from 5001 onwards. Enter the Participant Identification Number at the top of every page.
- CRF data should be entered to the central database at https://ncov.medsci.ox.ac.uk
- REDCap registration access is obtained by contacting CCP.REDCap@liverpool.ac.uk
- Please contact us at CCP.REDCap@liverpool.ac.uk for help with database problems.

RULES DEFINING DAYS

1. Day of Admission = Day of Admission regardless, e.g. even if admitted 2 months ago for a broken hip.
2. For Community Acquired COVID-19 i.e. admitted with symptoms consistent with COVID-19, day 1 = first 24 hours of admission.
3. For those who are already admitted for any other reason and who subsequently test positive, day 1 = day the positive COVID-19 test **was collected**.
4. Rules 2 and 3 are important but we recognise that start of biological sampling for Tier 1 and 2 may be deferred or delayed for several reasons, e.g. due to a delay in the COVID-19 result being reported. If this happens, please take the d1 sample set as soon as possible and then d3 and d9 according to schedule, or as close as possible.
5. For Tier Zero date of enrolment is date on which the act of data collection started (no consent). For Tier 1 & 2 date of enrolment is enrolment = date of consent.

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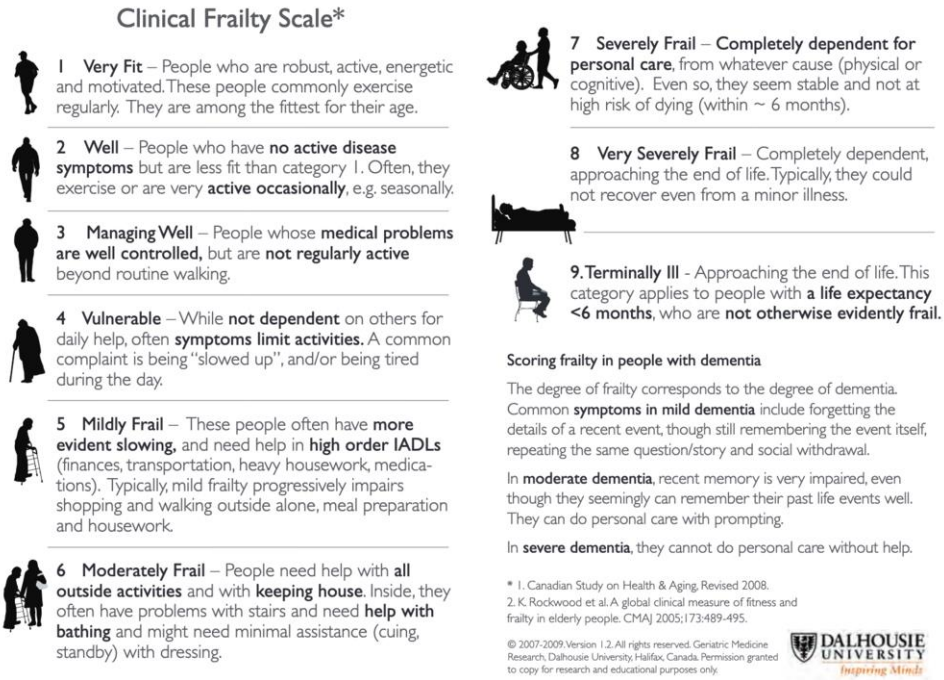
- Complete every line of every section, except for where the instructions say to skip a section based on certain responses.
- Selections with square boxes (☐) are single selection answers (choose one answer only). Selections with circles (**O**) are multiple selection answers (choose as many answers as are applicable).
- Some fields are considered **URGENT AND ESSENTIAL**. These are marked **BOLD AND UNDERLINED IN ALL CIRCUMSTANCES PLEASE PRIORITISE THESE DATA POINTS FOR URGENT UPLOAD.**
- Mark 'N/K' for any results of laboratory values that are not known or not available.
- Avoid recording data outside of the dedicated areas. Sections are available for recording additional information.
- We recommend writing clearly in black 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.
- In the case of a participant transferring between study sites, such as to a Nightingale Hospital, or other surge facility, it is preferred to maintain the same Participant Identification Number across the sites. When this is not possible a new Participant Identification Number should be assigned, the transferred participant will be linked by their identifiable data.
- Please keep all of the sheets for a single participant together e.g. with a staple or participant-unique folder.
- These three FRONT PAGES do not need to be retained.
- **DO NOT SEND CRFs to anyone by email or post.**
- See the training guide on how to send consent to **CCP@liverpool.ac.uk** using [SECURE] encryption
- The Dalhousie University Clinical Frailty Score is provided below for your reference.



Clinical Frailty Scale*

1 **Very Fit** – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.

2 **Well** – People who have **no active disease symptoms** but are less fit than category 1. Often, they exercise or are very **active occasionally**, e.g. seasonally.

3 **Managing Well** – People whose **medical problems are well controlled,** but are **not regularly active** beyond routine walking.

4 **Vulnerable** – While **not dependent** on others for daily help, often **symptoms limit activities.** A common complaint is being "slowed up", and/or being tired during the day.

5 **Mildly Frail** – These people often have **more evident slowing,** and need help in **high order IADLs** (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.

6 **Moderately Frail** – People need help with **all outside activities** and with **keeping house**. Inside, they often have problems with stairs and need **help with bathing** and might need minimal assistance (cuing, standby) with dressing.

7 **Severely Frail** – **Completely dependent for personal care**, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).

8 **Very Severely Frail** – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.

9. **Terminally Ill** - Approaching the end of life. This category applies to people with **a life expectancy <6 months**, who are **not otherwise evidently frail.**

Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common **symptoms in mild dementia** include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In **moderate dementia**, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In **severe dementia**, they cannot do personal care without help.

* 1. Canadian Study on Health & Aging, Revised 2008.
2. K. Rockwood et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005;173:489-495.

DALHOUSIE UNIVERSITY *Inspiring Minds*

ISARIC WHO Clinical Characterisation Protocol for Severe Emerging Infections UK
ADMISSION FORM

Date of enrolment [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **Site Location**_____

For Tier Zero date of enrolment is date on which the act of data collection started.
For Tier 1 & 2 enrolment = date of consent

CLINICAL INCLUSION CRITERIA

Proven or high likelihood of infection with pathogen of Public Health Interest: ☐ YES ☐ NO

N.B. For acute covid-19, please only collect data from proven (laboratory test-positive) people.

OR

Experience of the following symptoms during this illness episode: (one or more required for inclusion)

History of self-reported feverishness or measured fever of ≥ 38°C: ☐ YES ☐ NO

Cough: ☐ YES ☐ NO

Dyspnoea (shortness of breath) OR Tachypnoea*: ☐ YES ☐ NO

Clinical suspicion of Acute Respiratory Infection despite not meeting criteria above: ☐ YES ☐ NO

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

N.B. For acute covid-19, please only collect data from proven (laboratory test-positive) people.

OR

Adult or child who meets Case Definition for Inflammatory Multi-system Syndrome: ☐ YES ☐ NO

N.B. This group should be recruited regardless of covid-19 test as this syndrome can occur after mild disease in the community which has gone untested.

DEMOGRAPHICS

Sex at Birth: ☐ Male ☐ Female ☐ Not specified Date of birth [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_][_Y_][_Y_]

If date of birth is Not Known (N/K) record Age: [___][___][___]years **OR** [___][___]months

Postcode: [___][___][___][___] [___][___][___]

England & Wales NHS number , Scotland CHI: [___][___][___] [___][___][___] [___][___][___][___]
NB Northern Ireland Health & Care Number is not being collected at this time

Ethnic group *(check all that apply)*:

OArab OBlack OEast Asian OSouth Asian OWest Asian OLatin American OWhite OAboriginal/First Nations

OOther: _____ ☐N/K

Employed as a Healthcare Worker? ☐YES ☐NO ☐N/K

Pregnant? ☐ YES ☐ NO ☐ N/K If YES: Gestational weeks assessment: [___][___] weeks

POST PARTUM (within six weeks of delivery)? ☐YES ☐NO or ☐N/K *(skip this section - go to INFANT)*

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

Has infant(s) been tested for Mother's infection? ☐YES ☐NO ☐N/K If YES: ☐Positive ☐Negative

IF POSITIVE PLEASE COMPLETE A SEPARATE CASE REPORT FORM FOR THE INFANT(s)

INFANT – Less than 1 year old? ☐YES ☐NO *(skip this section)* Birth weight: [___].[___]kg ☐N/K

Gestational: ☐ Term birth (≥37wk GA) ☐Preterm birth (<37wk GA) if <37wk Estimated gestation _____weeks ☐N/K

Breastfed? ☐YES ☐NO ☐N/K If YES: ☐Currently breastfed ☐Breastfeeding discontinued ☐N/K

ONSET AND ADMISSION

Symptom onset date of first/earliest symptom: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **OR** ☐ **Asymptomatic**

Admission date at this facility: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Is the patient being readmitted with Covid-19? ☐**YES** ☐**NO** ☐**N/K**

Please provide reason for readmission: _____ ☐**N/K**

Is this a NIGHTINGALE or other SURGE FACILITY ☐YES ☐NO ☐N/K

Transfer from other facility? ☐YES-other facility is a study site ☐YES-other facility is not a study site ☐NO ☐N/K

If YES: Name of transfer facility:_____ ☐N/K

If YES: Admission date at previous facility *(DD/MM/YYYY)*: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐N/K

If YES-Study Site: Participant ID # at previous facility: I__I I__I I__I I__I I__I -- I__I I__I I__I I__I

OR ☐**Same as above**

VITAL SIGNS AT HOSPITAL ADMISSION *(first available data at presentation/Admission – within 24 hours)*

Temperature: [_][_].[_]°C **HR:** [_][_][_]**beats per minute** **RR:** [_][_]**breaths per minute**

Systolic BP: [_] [_] [_]**mmHg Diastolic BP:** [_][_][_]**mmHg** **Severe dehydration:** ☐**YES** ☐**NO** ☐**N/K**

Sternal capillary refill time >2seconds ☐**YES** ☐**NO** ☐**N/K**

Oxygen saturation: [_][_][_]% **On:** ☐**Room air** ☐**Any Oxygen therapy** ☐**N/K**

Admission signs and symptoms *(observed/reported at admission and associated with this episode of acute illness)*

History of fever	☐YES ☐NO ☐N/K	**Lower chest wall indrawing**	☐YES ☐NO ☐N/K
Cough	☐YES ☐NO ☐N/K	**Headache**	☐YES ☐NO ☐N/K
with sputum production	☐YES ☐NO ☐N/K	**Altered consciousness/confusion**	☐YES ☐NO ☐N/K
bloody sputum/haemoptysis	☐YES ☐NO ☐N/K	**Seizures**	☐YES ☐NO ☐N/K
Sore throat	☐YES ☐NO ☐N/K	**Abdominal pain**	☐YES ☐NO ☐N/K
Runny nose (Rhinorrhoea)	☐YES ☐NO ☐N/K	**Vomiting / Nausea**	☐YES ☐NO ☐N/K
Ear pain	☐YES ☐NO ☐N/K	**Diarrhoea**	☐YES ☐NO ☐N/K
Wheezing	☐YES ☐NO ☐N/K	**Conjunctivitis**	☐YES ☐NO ☐N/K
Chest pain	☐YES ☐NO ☐N/K	**Skin rash**	☐YES ☐NO ☐N/K
Muscle aches (Myalgia)	☐YES ☐NO ☐N/K	**Skin ulcers**	☐YES ☐NO ☐N/K
Joint pain (Arthralgia)	☐YES ☐NO ☐N/K	**Lymphadenopathy**	☐YES ☐NO ☐N/K
Fatigue / Malaise	☐YES ☐NO ☐N/K	**Bleeding (Haemorrhage)**	☐YES ☐NO ☐N/K
Shortness of breath (Dyspnoea)	☐YES ☐NO ☐N/K	**If Bleeding: specify site(s):**	_____
Disturbance or loss of taste (Ageusia)	☐YES ☐NO ☐N/K	**Disturbance or loss of smell (Anosmia)**	☐YES ☐NO ☐N/K
		None	☐YES ☐NO ☐N/K

CO-MORBIDITIES *(existing prior to admission)*					
Chronic cardiac disease, including congenital heart disease. *(not hypertension)*	☐YES	☐NO	☐N/K	**Obesity *(as defined by clinical staff)***	☐YES ☐NO ☐N/K
Hypertension *(physician diagnosed)*	☐YES	☐NO	☐N/K	**Diabetes and Type**	☐NO ☐1 ☐2 ☐N/K
Chronic pulmonary disease *(not asthma)*	☐YES	☐NO	☐N/K	**Diabetes (any) with complications**	☐YES ☐NO ☐N/K
Asthma *(physician diagnosed)*	☐YES	☐NO	☐N/K	**Diabetes (any) without complications**	☐YES ☐NO ☐N/K
Chronic kidney disease	☐YES	☐NO	☐N/K	**Rheumatologic disorder**	☐YES ☐NO ☐N/K
Moderate / severe liver disease	☐YES	☐NO	☐N/K	**Dementia**	☐YES ☐NO ☐N/K
Mild liver disease	☐YES	☐NO	☐N/K	**Malnutrition**	☐YES ☐NO ☐N/K
Chronic neurological disorder	☐YES	☐NO	☐N/K	**Smoking** ☐YES ☐Never smoked ☐Former smoker	☐N/K
Malignant neoplasm	☐YES	☐NO	☐N/K	**Other relevant risk factor** ☐YES ☐NO ☐N/K	
Chronic hematologic disease	☐YES	☐NO	☐N/K		
AIDS / HIV	☐YES	☐NO	☐N/K	**If yes, specify**_____	

Is the patient thought to be a member of a CLINICALLY EXTREMELY VULNERABLE GROUP

Solid organ transplant recipients: ☐YES ☐NO ☐N/K

People with specific cancers: ☐YES ☐NO ☐N/K

- people with cancer who are undergoing active chemotherapy
- people with lung cancer who are undergoing radical radiotherapy
- people with cancers of the blood or bone marrow such as leukaemia, lymphoma or myeloma who are at any stage of treatment
- people having immunotherapy or other continuing antibody treatments for cancer
- people having other targeted cancer treatments which can affect the immune system, such as protein kinase inhibitors or PARP inhibitors
- people who have had bone marrow or stem cell transplants in the last 6 months, or who are still taking immunosuppression drugs

People with <u>severe</u> respiratory conditions including all cystic fibrosis, severe asthma requiring daily oral steroid or injectable maintenance therapy and severe chronic obstructive pulmonary requiring oxygen (COPD): ☐YES ☐NO ☐N/K

People with rare diseases and inborn errors of metabolism that significantly increase the risk of infections (such as Severe combined immunodeficiency (SCID), homozygous sickle cell): ☐YES ☐NO ☐N/K

People on immunosuppression therapies sufficient to significantly increase risk of infection: ☐YES ☐NO ☐N/K

Women who are pregnant with significant heart disease, congenital or acquired: ☐YES ☐NO ☐N/K

PRE-ADMISSION MEDICATION Were any of the following taken within 14 days of admission?	
Immunosuppressant e.g. oral (not inhaled) corticosteroids (not low dose hydrocortisone) ☐YES ☐NO ☐N/K	**Angiotensin converting enzyme inhibitors (ACEI)?** ☐YES ☐NO ☐N/K **Angiotensin II receptor blockers (ARBs)?** ☐YES ☐NO ☐N/K **Non-steroidal anti-inflammatory (NSAID)?** ☐YES ☐NO ☐N/K
Anti-infectives for this illness episode prior to admission? ☐YES ☐NO ☐N/K **If yes, specify:**_____	

CLINICAL FRAILTY SCORE **With reference to the Dalhousie University Clinical Frailty Score (see guidance page 3 of complete CRF)**	
Clinical Frailty Score	[___] value 1 to 9 or ☐N/K

CURRENT MEDICATION ON ADMISSION **Record medication the patient is currently taking or has taken within the past 14 days**
Medication name *(generic name preferred):*

PARTICIPANT ID |___| |___| |___| |___| |___| -- |___| |___| |___| |___|

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DAILY TREATMENT *(complete every line)*:

DATE OF ASSESSMENT *(DD/MM/YYYY):* [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]
Record the worst value between 00:00 to 24:00 on day of assessment *(if Not Available write 'N/K')*:

Is the patient in a high-level care area i.e. admitted to ICU/ITU/IMC/HDU ☐YES ☐NO ☐N/K

Highest Temperature: [_][__].[__] ☐°C

Any Supplemental Oxygen ☐YES ☐NO ☐N/K FiO_2 *(0.21-1.0)* [___].[___][___] or [___][___] % or [___][___] L/min (highest)

Oxygen saturation ☐YES ☐NO ☐N/K SpO_2 [___][___][___]% (lowest)

AVPU Alert[___] Verbal[___] Pain [___] Unresponsive[___] or ☐N/K Glasgow Coma Score (GCS / 15) [___][___] or ☐N/K

Is the patient currently receiving, or has received (from 00:00 to 24:00) on day of assessment:
Non-invasive respiratory support *(e.g. NIV, BIPAP, CPAP)*? ☐YES ☐NO ☐N/K Invasive ventilation? ☐YES ☐NO ☐N/K
High-flow nasal canula? ☐YES ☐NO ☐N/K ECLS/ECMO? ☐YES ☐NO ☐N/K

DAILY LABORATORY RESULTS

Record the values of laboratory results taken between 00:00 to 24:00 on day of assessment *(if Not Available write 'N/K, if multiple record the values for the blood draw taken closest to midday')*:

Done ☐YES ☐NO ☐N/K Haemoglobin _____ ☐g/L *or* ☐g/dL
Done ☐YES ☐NO ☐N/K WBC count _____ ☐x10^9/L *or* ☐x10^3/µL
Done ☐YES ☐NO ☐N/K Lymphocyte count _____ _____ ☐cells/ µL *or* ☐x10^9/L *or* ☐x10^3/µL
Done ☐YES ☐NO ☐N/K Neutrophil count _____ _____ ☐ cells/ µL *or* ☐x10^9/L *or* ☐x10^3/µL
Done ☐YES ☐NO ☐N/K Platelets _____ ☐x10^9/L *or* ☐x10^3/µL Done ☐YES ☐NO ☐N/K APTT/APTR _____
Done ☐YES ☐NO ☐N/K PT _____ seconds *or* Done ☐YES ☐NO ☐N/K INR_____
Done ☐YES ☐NO ☐N/K ESR _____ mm/hr

Done ☐YES ☐NO ☐N/K Ferritin _____ ☐µg/L *or* ☐ ng/mL
Done ☐YES ☐NO ☐N/K ALT/SGPT _____ U/L
Done ☐YES ☐NO ☐N/K Total Bilirubin _____☐µmol/L *or* ☐mg/dL
Done ☐YES ☐NO ☐N/K AST/SGOT _____ U/L
Done ☐YES ☐NO ☐N/K Glucose _____ ☐mmol/L *or* ☐mg/dL
Done ☐YES ☐NO ☐N/K Blood Urea Nitrogen (urea) _____ ☐mmol/L *or* ☐mg/dL
Done ☐YES ☐NO ☐N/K Lactate _____☐mmol/L *or* ☐mg/dL
Done ☐YES ☐NO ☐N/K LDH [___][___][___].[___]_U/L
Done ☐YES ☐NO ☐N/K Creatinine Kinase (CPK) [___][___][___].[___]_U/L
Done ☐YES ☐NO ☐N/K Creatinine _____ ☐µmol/L *or* ☐mg/dL
Done ☐YES ☐NO ☐N/K Sodium _____ ☐mmol/L *or* ☐mEq/L
Done ☐YES ☐NO ☐N/K Potassium _____ ☐mmol/L *or* ☐mEq/L
Done ☐YES ☐NO ☐N/K Procalcitonin [___][___].[___][___]ng/mL
Done ☐YES ☐NO ☐N/K CRP [___][___][___].[___] mg/L
Done ☐YES ☐NO ☐N/K eGFR _____ mL/min/1.73 m^2 **O**CKD-EPI **O**MDRD **O**CG
Most recent HbA1c_____ ☐ N/K
Chest X-Ray /CT performed? ☐YES ☐NO ☐N/K IF Yes: Were infiltrates present? ☐YES ☐NO ☐N/K

DAILY FORM complete per Tier of activity AND if research samples are collected Page 2 of 2

RESEARCH SAMPLES	
Where biological samples have been taken for research please record the KIT number here.	**KIT NUMBER** [_C_] [_C_] [_P_] [_ _] [_ _][_ _][_ _][_ _]

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OUTCOME FORM

PATHOGEN TESTING

Was pathogen testing done during this illness episode? ☐YES ☐NO ☐N/K

WERE THE FOLLOWING TESTS POSITIVE? (PLEASE ENSURE FULL DETAILS OF TESTS ARE IN THE TABLE BELOW)

Influenza : ☐ **YES** ☐ **NO** **If YES:** ☐ **A/H3N2** ☐ **A/H1N1pdm09** ☐ **A/H7N9** ☐ **A/H5N1**

☐ **A not typed,** **other A** ☐ ____________ ☐ **B not typed** ☐ **Other type (specify):** ____________

NB: Please do not enter Haemophilus influenza or parainfluenza above here – enter them under "other" below

Coronavirus: ☐ **YES** ☐ **NO** **If YES:** ☐ **COVID-19/SARS-CoV-2 2019**

☐ **Other CoV (specify):** ____________________

RSV: ☐ **YES** ☐ **NO**

Adenovirus: ☐ **YES** ☐ **NO**

Bacteria: : ☐ **YES** : **specify :** __________________________ **list all below** ☐ **No**

Other : ☐ YES ☐ NO

If yes Other, specify____

On the form below please enter pathogen names in full without abbreviations

Collection Date *(DD/MM/YYYY)*	Bio specimen Type	Laboratory Test Method	Result	Pathogen Detected
__ __/__ __/20__ __	☐Nasal/NP swab ☐Throat swab ☐Combined nasal/NP+throat swab ☐Sputum ☐BAL ☐ETA ☐Urine ☐Feces/rectal swab ☐Blood ☐Other, *Specify:* __________________	☐PCR ☐Culture ☐Other, *Specify:* ____________	☐Positive ☐Negative ☐N/K	____________
__ __/__ __/20__ __	☐Nasal/NP swab ☐Throat swab ☐Combined nasal/NP+throat swab ☐Sputum ☐BAL ☐ETA ☐Urine ☐Feces/rectal swab ☐Blood ☐Other, *Specify:* __________________	☐PCR ☐Culture ☐Other, *Specify:* ____________	☐Positive ☐Negative ☐N/K	____________
__ __/__ __/20__ __	☐Nasal/NP swab ☐Throat swab ☐Combined nasal/NP+throat swab ☐Sputum ☐BAL ☐ETA ☐Urine ☐Feces/rectal swab ☐Blood ☐Other, *Specify:* __________________	☐PCR ☐Culture ☐Other, *Specify:* ____________	☐Positive ☐Negative ☐N/K	____________

OUTCOME FORM

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

Antiviral agent? ☐YES ☐NO ☐ N/K **If YES, tick all the apply: O**Ribavirin **O**Lopinavir/Ritonavir **O**Interferon alpha **O**Interferon beta **O**Chloroquine / Hydroxychloroquine

ORemdesivir **If YES**: first dose: [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_] and last dose [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_]

O IL6 inhibitor IF YES which ☐ Tocilizumab ☐ Anakinra ☐ Other IL6 inhibitor_____

IL6 inhibitor first dose: [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_] and last dose [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_]

ONeuraminidase inhibitor **if YES: Which _____** **O**Other antiviral _____

Antibiotic? ☐YES ☐NO ☐N/K **If YES: specify type(s): _____ _____ _____**

Corticosteroid? ☐YES ☐NO ☐N/K **If YES, Route: ☐ Oral ☐ Intravenous ☐ Inhaled**

If YES, please provide type / name and maximum daily dose: _____

Dexamethasone 6mg once per day (od) ? ☐YES ☐NO ☐N/K **If YES, Route: ☐ Oral ☐ Intravenous**

Dexamethasone other dose _____mg

Dexamethasone other frequency OBD **O**TDS **O**QDS **O**Other _____

Route: ☐ Oral ☐ Intravenous

Antifungal agent? ☐YES ☐NO ☐N/K If YES: which _____

Off-label / Compassionate Use medications? ☐YES ☐NO ☐N/K **If YES:** which _____

Interleukin inhibitors ☐YES ☐NO ☐N/K **If YES:** which _____

Convalescent plasma ☐YES ☐NO ☐N/K

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

ICU or High Dependency Unit admission? ☐YES ☐NO ☐N/K If YES, total duration: _____days O still in ICU/HDU

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

ICU/HDU discharge date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐N/K

Any Oxygen therapy? ☐YES ☐NO ☐N/K High-flow nasal canula? ☐YES ☐NO ☐N/K

Non-invasive ventilation? *(e.g. BIPAP, CPAP)* ☐YES ☐NO ☐N/K

Invasive ventilation *(Any intubation)*? ☐YES ☐NO ☐N/K If YES, total duration: _____days O still on

Prone Ventilation? ☐YES ☐NO ☐N/K

Inhaled Nitric Oxide? ☐YES ☐NO ☐N/K

Tracheostomy inserted? ☐YES ☐NO ☐N/K

Extracorporeal (ECMO) support? ☐YES ☐NO ☐N/K If YES, total duration: _____days O still on

Renal replacement therapy (RRT) or dialysis? ☐YES ☐NO ☐N/K If YES, total duration: _____days **O still on**

Inotropes/vasopressors? ☐YES ☐NO ☐N/K If YES, total duration: _____days **O still on**

Blood Group (please check past as well as current medical record): **o**A **o**B **o**AB **o**O **o**N/K

OUTCOME FORM

COMPLICATIONS: At any time during hospitalisation did the patient experience:			
Viral pneumonia	☐YES ☐NO ☐N/K	Cardiac arrhythmia	☐YES ☐NO ☐N/K
Bacterial pneumonia	☐YES ☐NO ☐N/K	Cardiac ischemia	☐YES ☐NO ☐N/K
Acute Respiratory Distress Syndrome	☐YES ☐NO ☐N/K	Cardiac arrest	☐YES ☐NO ☐N/K
Cryptogenic organizing pneumonia (COP)	☐YES ☐NO ☐N/K	Bacteraemia	☐YES ☐NO ☐N/K
Pneumothorax	☐YES ☐NO ☐N/K	Coagulation disorder / Disseminated Intravascular Coagulation	☐YES ☐NO ☐N/K
Pleural effusion	☐YES ☐NO ☐N/K	Anaemia	☐YES ☐NO ☐N/K
Bronchiolitis	☐YES ☐NO ☐N/K	Rhabdomyolysis / Myositis	☐YES ☐NO ☐N/K
Meningitis / Encephalitis	☐YES ☐NO ☐N/K	Acute renal injury/acute renal failure	☐YES ☐NO ☐N/K
Seizure	☐YES ☐NO ☐N/K	Gastrointestinal haemorrhage	☐YES ☐NO ☐N/K
Stroke / Cerebrovascular accident	☐YES ☐NO ☐N/K	Pancreatitis	☐YES ☐NO ☐N/K
Other neurological complication	☐YES ☐NO ☐N/K	Liver dysfunction	☐YES ☐NO ☐N/K
Congestive heart failure	☐YES ☐NO ☐N/K	Hyperglycaemia	☐YES ☐NO ☐N/K
Endocarditis	☐YES ☐NO ☐N/K	Hypoglycaemia	☐YES ☐NO ☐N/K
Myocarditis/Pericarditis	☐YES ☐NO ☐N/K	Other, if yes specify below	☐YES ☐NO ☐N/K
Cardiomyopathy	☐YES ☐NO ☐N/K	Other	

STUDY PARTICIPATION

Is / Has the participant being/ been recruited to a trial or multi-centre study during the period of their current illness (including initiation in the community and hospital)? ☐ YES ☐ NO

IF YES , specify
Name of study_____
Study Participant ID _____

Add another study? ☐ YES ☐ NO
IF YES , specify
Name of study_____
Study Participant ID _____

Add another study? ☐ YES ☐ NO
IF YES , specify
Name of study_____
Study Participant ID _____

OUTCOME

Outcome: ☐ **Discharged alive expected to survive**

☐ **Hospitalisation = Remains in Hospital ≥ Day 28 after symptom onset**

- if so ☐ **Ongoing health care needs relating to this admission for COVID-19**

OR

☐ **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)**

☐ **Transfer to other facility** ☐ **Palliative discharge** ☐ **Death** ☐ **N/K**

Outcome date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐ **N/K**

If Discharged alive:

Ability to self-care at discharge versus before illness: ☐ Same as before illness ☐ Worse ☐ Better ☐ N/K

If Discharged alive: Post-discharge treatment:

Oxygen therapy? ☐ YES ☐ NO ☐ N/K

If Transferred: Facility name: _____ ☐ N/K

If Transferred: Is the transfer facility a study site? ☐ YES ☐ NO ☐ N/K

If a Study Site: Participant ID # at new facility: ☐ Same as above

☐ Different: [___][___][___][___][___]- [___][___][___][___] ☐N/K

ISARIC WHO Clinical Characterisation Protocol for Severe Emerging Infections UK

WITHDRAWAL FORM

WITHDRAWAL

Date of withdrawal: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐ N/K

Type of withdrawal: ☐ Withdrawal from samples only ☐ Other Please specify: _____

Reason for withdrawal: _____