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

v9.9 11NOV2020

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.

Data can be collected as Tier Zero activity without consent including retrospectively and from deceased cases.

IMPORTANT CHANGES FOR SECOND WAVE OF COVID-19

Tier Zero will only include proved (positive test) COVID-19/ SARS-COV-2 cases and ANY admission following proved COVID-19/ SARS-COV-2 in the past 21 days regardless of setting of test (community or hospital tests).

Tiers 1 and 2 for now will only apply to patients with *re-infection, co-infection (flu/RSV) or inflammation (MIS-A/MIS-C).* Ideally, data and samples will be collected with consent using Tier 2 of the protocol schedule.

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

Tier Zero	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 **INTERIM OUTCOME CRF** at day 28, discharge or death (whichever occurs first), and **FINAL OUTCOME** when known. N.B. For patients receiving **Remdesivir** (RDV), please complete an extra **DAILY CRF** for **first day** that the 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.** **OR** For sites where caseload or facilities limit research capacity to deliver planned Tier 1 or Tier 2 activity.
Tier 1 & 2	Tier 1- For sites where facilities limit research capacity to deliver Tier 2 activity or where consent is only for single timepoint biological sampling. Tier 2- For sites with available resources to deliver Tier 2 activity per the protocol schedule and then with consent for multiple timepoint biological sampling. For these tiers 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 **INTERIM OUTCOME CRF** at day 28, discharge or death (whichever occurs first), and **FINAL OUTCOME** when known. N.B. For patients receiving **Remdesivir** (RDV)**,** 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.**

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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.
- **Please generate a new subject ID for each re-admission**
- 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

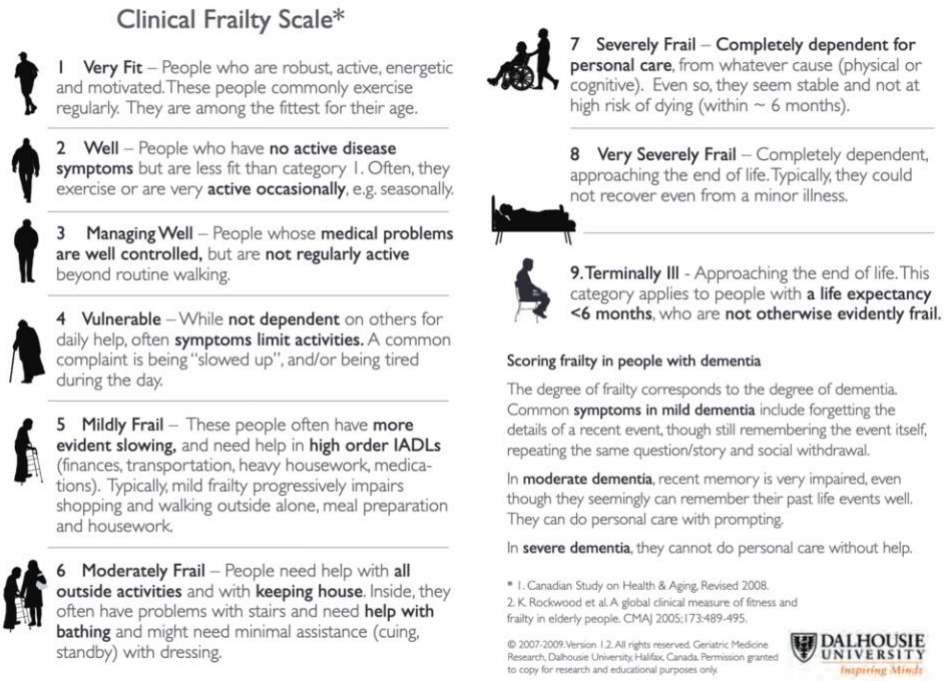
1. Day of Admission = Day of Admission regardless, e.g. even if admitted 2 months ago for a broken hip.
2. For Community Acquired COVID-19 i.e. admitted with symptoms consistent with COVID-19, day 1 = first 24 hours of admission.
3. For those who are already admitted for any other reason and who subsequently 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 date of consent.

Patients with *confirmed Covid-19* with any of the following syndromes should be recruited to tiers 1 or 2:

- **Re-infection**. The patient had Covid-19 more than 21 days ago:
  1. See criteria for identifying suspected re-infection on page 4.
  2. If you think a patient has suspected re-infection, please call 0300 365 4423to discuss.
- **Co-infection**. The patient has **confirmed co-infection** with:
  1. Influenza A or B virus; or,
  2. Respiratory syncytial virus (RSV).
- **Clinical suspicion of Multisystem Inflammatory Syndrome in Adults (MIS-A) or Children (MIS-C)**

CASE REPORT FORMS **FRONT PAGE 3 of 4**

- 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*

GENERAL GUIDANCE

Definitions:

INFLAMMATION - Children and adolescents

WHO preliminary criteria Multisystem inflammatory syndrome in children and adolescents temporally related to COVID-19

Children and adolescents 0–19 years of age with fever ≥ 3 days

AND any two of the following:

1. Rash or bilateral non-purulent conjunctivitis or muco-cutaneous inflammation signs (oral, hands or feet).
2. Hypotension or shock.
3. Features of myocardial dysfunction, pericarditis, valvulitis, or coronary abnormalities (including ECHO findings or elevated Troponin/NT-proBNP),
4. Evidence of coagulopathy (by PT, PTT, elevated d-Dimers).
5. Acute gastrointestinal problems (diarrhoea, vomiting, or abdominal pain).

AND

Elevated markers of inflammation such as ESR, C-reactive protein, or procalcitonin.

AND

No other obvious microbial cause of inflammation, including bacterial sepsis, staphylococcal or streptococcal shock syndromes.

AND

Evidence of COVID-19 **(**RT-PCR, antigen test or serology positive), or likely contact with patients with COVID-19

INFLAMMATION - Adults

We deliberately do not give criteria to avoid selection bias. Adults with an inflammatory should to be identified at clinical discretion.

If you think a patient meets these criteria or wish to discuss, please call 0300 365 4423.

RE-INFECTION

To be considered a suspected Covid-19 re-infection the patient should meet one prior Covid-19 criterion and one timing criterion. If you think a patient meets these criteria or wish to discuss, please call 0300 365 4423.

Prior Covid-19 criteria

- A positive test for virus (PCR or antigen) or antibodies, in the community or in a hospital. Evidence of this can be from the patient's own recollection, or from medical records.
- Patient-reported symptoms strongly suggestive of Covid-19, including cough, fever and altered taste/smell

Timing criteria

- If the patient was previously hospitalised with Covid-19, they must be more than 21 days from discharge from acute hospital (not including rehabilitation hospital).
- If the patient was not hospitalised but had symptoms of Covid-19, they must be more than 21 days from last symptoms.
- If the patient did not have symptoms, they must be more than 21 days from their last positive Covid-19 test.

PARTICIPANT ID I___I I___I I___I I___I I___I -- I___I I___I I___I I___I

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ADMISSION FORM

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

CLINICAL INCLUSION CRITERIA

Proven 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

Adult or child who meets Case Definition for Multisystem Inflammatory Syndrome (MIS-C/MIS-A) : ☐ 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

VACCINATION STATUS

Has the patient received a Covid-19 vaccine (open label licenced product) ☐YES ☐NO ☐N/K
date if known: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

has the patient been involved in a vaccine COVID trial? ☐YES ☐NO ☐N/K
date if known (first trial vaccination): [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] (*please complete study participation CRF page 3 of outcome CRF)*

Has patient received a 2020/21 seasonal influenza vaccine ☐YES ☐NO ☐N/K
date if known: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

ONSET AND ADMISSION

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? *(Please only add re-admission episodes for COVID patients remaining positive or new positive COVID test- Please assign new subject ID)* ☐YES ☐NO ☐N/K

Previous participant ID: I__I I__I I__I I__I I__I -- I__I I__I I__I I__I ☐ NK

Please provide reason for readmission: _____ ☐N/K

Is this a suspected re-infection with COVID-19? Defined as proven (PCR or antibody test) or highly probable (clinical case definition met) more than 21 days prior to this new laboratory proven covid-19 infection ☐YES ☐NO ☐N/K
If yes, please complete REINFECTION FORM and seek consent for biological sampling, ideally at Tier 2)

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 prior 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 to the facility.*
(This section should refer to data from the date of admission to this facility)

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**

SIGNS AND SYMPTOMS- *This section should refer to the start of the COVID episode*

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**	☐YES ☐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**	
Chronic hematologic disease	☐YES ☐NO ☐N/K	☐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 severe 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
Anti-infectives for this illness episode prior to admission? ☐YES ☐NO ☐N/K If yes, specify:_____	Angiotensin II receptor blockers (ARBs)? ☐YES ☐NO ☐N/K Non-steroidal anti-inflammatory (NSAID)? ☐YES ☐NO ☐N/K

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):*

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REINFECTION FORM

SUSPECTED RE-INFECTION WITH COVID-19: DETAILS OF PREVIOUS INFECTION	
Did the patient have a positive PCR (virus) test for SARS-CoV-2? If yes, enter date of positive test: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐YES ☐NO ☐N/K
Did the patient have a positive antigen (virus) test for SARS-CoV-2? If yes, enter date of positive test: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐YES ☐NO ☐N/K
Did the patient have a positive serology (antibody) test for SARS-CoV-2? If yes, enter date of positive test: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐YES ☐NO ☐N/K
Symptom onset date of first/earliest symptom for previous infection: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] OR ☐ Asymptomatic	

SIGNS AND SYMPTOMS for PREVIOUS COVID-19 episode			
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
TREATMENT: During the previous episode, was the patient:			
Admitted to hospital:	☐YES ☐NO ☐N/K	Treated with:	
Treated with oxygen:	☐YES ☐NO ☐N/K	Dexamethasone	☐YES ☐NO ☐N/K
Admitted to HDU/ICU:	☐YES ☐NO ☐N/K	Any other steroid	☐YES ☐NO ☐N/K
Receive invasive ventilation:	☐YES ☐NO ☐N/K	Tocilizumab	☐YES ☐NO ☐N/K
Receive extracorporeal membrane oxygenation (ECMO)	☐YES ☐NO ☐N/K	Remdesivir	☐YES ☐NO ☐N/K
		Convalescent plasma	☐YES ☐NO ☐N/K
		Lopinavir/Ritonavir	☐YES ☐NO ☐N/K
		Interferon	☐YES ☐NO ☐N/K
		Chloroquine/Hydroxychloroquine	☐YES ☐NO ☐N/K

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DAILY FORM complete per Tier of activity AND if research samples are collected Page 1 of 1

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)** **RR: [___][___]breaths per minute (highest)**

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/hrDone** ☐**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** **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** date of HbA1c [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Chest X-Ray /CT performed? ☐YES ☐NO ☐N/K IF Yes: Were infiltrates present? ☐YES ☐NO ☐N/K

ISARIC CCP-UK RESEARCH SAMPLES

Was a biological sample taken for research on this day?	☐**YES** ☐**NO**
If yes, please record the KIT number:	**KIT NUMBER** [_C_] [_C_] [_P_] [_ _] [_ _][_ _][_ _][_ _]

ISARIC WHO Clinical Characterisation Protocol for Severe Emerging Infections UK

OUTCOME FORM

PATHOGEN TESTING

Was pathogen testing done during this illness episode? ☐YES ☐NO ☐N/K
(*NB Should be a YES as this is key eligibility criteria)
***please record the detail of any COVID-19 / SARS2-CoV-2 which may have been done in the community**

Section 1: Pathogen Diagnosis Summary ***(Respiratory virus PCR or antigen tests -NOT serology/antibody tests)***

	Tested and POSITIVE (please tick)	Tested and NEGATIVE (Please tick)	NOT TESTED (please tick)
COVID-19 / SARS-CoV-2	Yes☐	☐	☐
Influenza virus *NB: Please do not enter Haemophilus influenza or parainfluenza virus here – enter them under "other" below*	Yes ☐ Please confirm type: ☐ A/H3N2 ☐ A/H1N1pdm09 ☐ A/H7N9 ☐ A not typed other A ☐_____ ☐ B not typed ☐ Other type (specify):_____	☐	☐
Respiratory syncytial virus (RSV)	Yes ☐	☐	☐
Adenovirus	Yes ☐	☐	☐
Other	Yes ☐ please specify : _____		

Section 2: Pathogen Testing Details
(Please record the details of all tests carried out during this illness episode below -including the details of the tests indicated above).

	Select one:	Organism	Date sample obtained
Nasal and/ or throat swab	☐ Obtained: positive ☐ Obtained: negative ☐ Not obtained	…… …… …… ……	…… …… …… ……
Blood culture	☐ Obtained: positive ☐ Obtained: negative ☐ Not obtained	…… …… …… ……	…… …… …… ……
Sputum	☐ Obtained: positive ☐ Obtained: negative ☐ Not obtained	…… …… …… ……	…… …… …… ……
Deep respiratory sample (BAL/ETA)	☐ Obtained: positive ☐ Obtained: negative ☐ Not obtained	…… …… …… ……	…… …… …… ……

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

OInterferon beta **O**Chloroquine / Hydroxychloroquine **O**Oseltamivir (Tamiflu®) **O**Zanamivir

OOther antiviral _____

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 ☐ Other IL6 inhibitor_____

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

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

Corticosteroid? ☐YES ☐NO ☐N/K

If yes, please confirm type: ☐ Dexamethasone ☐ Methylprednisolone ☐ Prednisolone ☐ Other, please specify _____

Route: ☐ Oral ☐ Intravenous ☐ Inhaled, maximum daily dose: _____

If given Dexamethasone, was this given as 6mg once per day (od) ? ☐YES ☐NO ☐N/K

If Other Dexamethasone dose, please confirm _____mg

If Other Dexamethasone other frequency please confirm: OBD OTDS OQDS OOther _____

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**

If NO, ☐Not Indicated ☐Not appropriate*

(*Advanced care plan/discussion documented in notes regarding not for escalation of care beyond ward)

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

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

INTERIM OUTCOME: DAY 28 (i.e. 28 days from 'day 1' as per 'rules defining days')

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

☐ **Ongoing health care needs NOT related to COVID episode**

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**

Interim 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

FINAL OUTCOME (If status has changed since day 28)

Outcome:

☐ **Discharged alive expected to survive** ☐ **Palliative discharge** ☐ **Death** ☐ **Transfer to other facility** ☐ **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: _____