## PLATFORM

### 1.0 HOSPITAL & ICU ADMISSION SOURCE

**Hospital admission source:**
- [ ] Home / community
- [ ] Assisted living not in own home
- [ ] Nursing home / chronic care / palliative care

**Hospital admission date & time:**
- [ ] DD
- [ ] MM
- [ ] YY
- [ ] HH
- [ ] MM

- **24 hour clock**
- **e.g. 01/JUN/2018**
- **e.g. 8:05pm = 20:05hours**

**Patient location at baseline:**
- [ ] Physical ICU
- [ ] Ward
- [ ] Re-purposed ICU
- [ ] ED

**ICU admission source:**
- [ ] Emergency department – same hospital
- [ ] Emergency department – other hospital
- [ ] ICU/HDU – same hospital
- [ ] ICU/HDU – other hospital
- [ ] Ward – same hospital
- [ ] Ward – other hospital

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### 2.0 DEMOGRAPHICS

**Height:**
- [ ] cm
- [ ] inches

**Weight:**
- [ ] kg
- [ ] lbs

**Pregnant at hospital admission:**
- [ ] Yes
- [ ] No
- [ ] Not applicable

**Gestation in weeks:**
- [ ] weeks

**Postpartum at hospital admission:**
- [ ] Yes
- [ ] No

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### 3.0 ENVIRONMENTAL RISK FACTORS

**Current tobacco smoker:**
- [ ] Yes
- [ ] No
- [ ] Not recorded

**History of hazardous alcohol consumption:**
- [ ] Yes
- [ ] No
- [ ] Not recorded

**Patient is a healthcare worker:**
- [ ] Yes
- [ ] No

---

### 4.0 PAST MEDICAL HISTORY

**Chronic respiratory or pharyngeal neuromuscular weakness:**
- [ ] Yes
- [ ] No

**Diabetes:**
- [ ] Not diagnosed with diabetes
- [ ] Type 1 diabetes
- [ ] Type 2 diabetes
- [ ] Current gestational diabetes

**Chronic kidney disease:**
- [ ] Normal renal function
- [ ] Abnormal renal function not normally receiving dialysis
- [ ] Normally receiving dialysis
- [ ] Not recorded
Respiratory co-morbidities: (check all that apply)
- Asthma
- Bronchiectasis
- Chronic obstructive pulmonary disease
- Interstitial lung disease
- Primary lung cancer
- Other
- None

If a respiratory co-morbidity was selected (excluding NONE), answer the next question

Severe respiratory co-morbidity: Y Yes N No

Immunosuppressive treatment: Y Yes N No

Immunosuppressive disease: (check all that apply)
- AIDS
- Acute leukaemia
- Lymphoma
- Metastatic cancer

Other APACHE II co-morbidities: (check all that apply)
- Chronic cardiovascular disease
- Cirrhosis

Clinical frailty score: (check one)
1. Very fit
2. Well
3. Managing well
4. Vulnerable
5. Mildly frail
6. Moderately frail
7. Severely frail
8. Very severely frail
9. Terminally ill

COVID-19 vaccination prior to this acute illness: (check one)
Y Yes N No U Unknown

5.0 APACHE II

(24 hours prior to randomisation)

APACHE II acute physiology score: (0–60) APS

6.0 INTERVENTIONS & PHYSIOLOGY AT BASELINE

(This hospital admission, closest prior to randomisation)

Creatinine: µmol/L mg/dL N Not recorded
Platelet count: Cells x 10⁹/L Cells/mm³ N Not recorded
Bilirubin: µmol/L mg/dL N Not recorded
Lactate: mmol/L mg/dL N Not recorded
FiO₂ at time of ABG: e.g. room air = 0.21
Corresponding PaO₂: mmHg kPa N Not recorded
Corresponding PEEP: cmH₂O Patient receiving APRV N Not recorded
Glasgow Coma Scale Score:
## 7.0 PHYSIOLOGY AT BASELINE (PANDEMIC ONLY)

**(Closest prior to randomisation, within 8 hours of randomisation or two hours after randomisation)**

### Extended Cardiovascular SOFA score:
- 0
- 1
- 2
- 3
- 4
- 4+

### Renal replacement therapy:
- Yes
- No

### Extracorporeal gas exchange:
- Yes
- No

#### Received:
- Extracorporeal membrane oxygenation (ECMO)
- Extracorporeal carbon dioxide removal (ECCO2R)

### Treatment limitation:
- Yes
- No

*Only collect for patients enrolled in the moderate state (not receiving organ support at the time of randomisation)*

### 8.0 CORTICOSTEROID DOMAIN

Was etomidate administered between hospital admission and randomisation:
- Yes
- No

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**UK REMAP-CAP Case Report Form 2, V10 dated 20210510**

**www.remapcap.org**
**END OF BASELINE CRF**

**PLATFORM PATIENT SUMMARY PAGE**

(United Kingdom sites only, not a part of the Baseline eCRF)

**UNITED KINGDOM SITES ONLY (on Spiral database)**

ICNARC Case Mix Programme Admission Number:   

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**UK REMAP-CAP Case Report Form 2, V10 dated 20210510**
VENTILATION DOMAIN

1.0 ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS)

(Closest and prior to randomisation to the ventilation domain)

Was chest imaging performed within the last 24 hours: (check one)

- Yes
- No

If YES:

Select all lung quadrants with infiltrates:

- R1
- L1
- R2
- L2

No infiltrates present

2.0 BASELINE ARTERIAL BLOOD GAS

(ABG collected closest to and within 6 hours prior to randomisation to the ventilation domain)

PaO2: [ ] mmHg [ ] kPa [ ] Not recorded

FiO2 at time of ABG: [ ] % e.g. room air = 0.21

pH: [ ] Not recorded

PaCO2: [ ] mmHg [ ] kPa [ ] Not recorded

HCO3: [ ] mEq/L or mmol/L [ ] Not recorded

SaO2: [ ] % [ ] Not recorded

Lactate: [ ] mmol/L [ ] mg/dL [ ] Not recorded

Base excess: +/- [ ] mEq/L [ ] Not recorded

At time of corresponding ABG:

SpO2: [ ] % [ ] Not recorded

EtCO2: [ ] mmHg [ ] kPa [ ] Not recorded
### 3.0 THERAPIES

(At time of randomisation)

- Is the patient receiving continuous or intermittent neuromuscular blockade:  Yes  No
- Is the patient receiving continuous vasopressor and/or inotrope infusion:  Yes  No
- Renal replacement therapy:  Yes  No
- Extracorporeal gas exchange:  Yes  No
  - ECMO:  Yes  No
  - ECCO₂R:  Yes  No
- Recruitment manoeuvre:  Yes  No
- Nitric oxide:  Yes  No
- Prone positioning:  Yes  No
- Inhaled prostacyclin:  Yes  No

### 4.0 BASELINE VENTILATION

(Closest and prior to randomisation to the ventilation domain)

- Mode of ventilation:
  - Airway pressure release ventilation (APRV)
  - Assist control, pressure regulated volume control
  - NAVA
  - Continuous positive airway pressure
  - Proportional assist ventilation
- Set respiratory rate:  bpm
- Recorded total respiratory rate:  bpm
- Are the mandatory breaths that the patient is receiving pressure-cycled or volume-cycled:
  - Pressure-cycled
  - Volume-cycled
  - *Required if set respiratory rate is not 0
- Expired tidal volume:  mL
- Recorded peak inspiratory pressure:  cmH₂O
- Set pressure support:  cmH₂O
- Recorded plateau pressure:  cmH₂O
- Set PEEP:  cmH₂O
- I:E Ratio:  :  

*Not recorded

The patient is receiving APRV
### 5.0 OXYGENATION TARGET

(Closest and prior to randomisation to the ventilation domain)

<table>
<thead>
<tr>
<th>Did the patient have a specified target for oxygenation or carbon dioxide: (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Yes, SpO₂</td>
</tr>
</tbody>
</table>

**IF YES, SPO₂**

- **Upper SpO₂ target range value:**
  - □ %
  - □ No upper limit documented

- **Lower SpO₂ target range value:**
  - □ %
  - □ No lower limit documented

**IF YES, PAO₂**

- **Upper PaO₂ target range value:**
  - □ mmHg □ kPa
  - □ No upper limit documented

- **Lower PaO₂ target range value:**
  - □ mmHg □ kPa
  - □ No lower limit documented

**IF YES, PACO₂**

- **Upper PaCO₂ target range value:**
  - □ mmHg □ kPa
  - □ No upper limit documented

- **Lower PaCO₂ target range value:**
  - □ mmHg □ kPa
  - □ No lower limit documented
### 1.0 CAUSATIVE ORGANISM

Upper or lower respiratory tract PCR test result:

- **Influenza A**: + Positive result, - Negative result, N Not tested
- **Influenza B**: + Positive result, - Negative result, N Not tested
- **Legionella spp**: + Positive result, - Negative result, N Not tested

On specimens collected during this acute respiratory illness, up until 72 hours after completion of the eligibility assessment
- **SARS-CoV-2**: + Positive result, - Negative result, N Not tested

Other upper or lower respiratory tract PCR detected organisms:

- Chlamydia pneumoniae
- Coronavirus
- Mycoplasma pneumoniae
- Respiratory Syncytial Virus
- Not tested / None of the above positive

Tuberculosis detected on PCR or culture:

- Yes
- No

Urinary antigen test performed:

- Yes
- No

Which organisms were detected:

- Legionella pneumophila serogroup 1
- Streptococcus pneumoniae
- None of the above

Aspergillus isolated from the lower respiratory tract

- Yes
- No

Invasive pulmonary aspergillosis diagnosed and treated with one or more systemic antifungal agents

- Yes
- No

Diagnosed by the treating clinician at any time during hospital admission
### Positive Blood Culture

**On specimens collected within 72 hours of this hospital admission, unless otherwise indicated**

#### Positive Blood Culture Result:

- [ ] Yes
- [ ] No
- [ ] Not tested

#### Which organisms were detected:

*Check all that apply*

- [ ] Acinetobacter spp
- [ ] Burkholderia pseudomallei
- [ ] Escherichia coli
- [ ] Haemophilus influenzae
- [ ] Klebsiella spp
- [ ] Moraxella catarrhalis
- [ ] Pseudomonas aeruginosa
- [ ] Staphylococcus aureus
- [ ] Streptococcus pneumoniae
- [ ] Streptococcus pyogenes
- [ ] Streptococcus agalactiae
- [ ] Coagulase negative staphylococci
- [ ] Corynebacterium, Bacillus spp, Micrococcus, Propionibacterium
- [ ] Other, specify

#### If Acinetobacter spp

- Reported as resistant to ceftazidime and/or piperacillin-tazobactam:
  - [ ] Yes
  - [ ] No

#### If Escherichia coli

- Reported as resistant to ceftriaxone and/or ceftazidime:
  - [ ] Yes
  - [ ] No

- Reported as resistant to meropenem and/or imipenem:
  - [ ] Yes
  - [ ] No

#### If Klebsiella spp

- Reported as resistant to ceftriaxone and/or ceftazidime:
  - [ ] Yes
  - [ ] No

- Reported as resistant to meropenem and/or imipenem:
  - [ ] Yes
  - [ ] No

#### If Pseudomonas aeruginosa

- Reported as resistant to ceftazidime and/or piperacillin-tazobactam:
  - [ ] Yes
  - [ ] No

- Reported as resistant to meropenem and/or imipenem:
  - [ ] Yes
  - [ ] No

#### If Staphylococcus aureus

- Reported as methicillin-resistant staphylococcus aureus:
  - [ ] Yes
  - [ ] No

#### If Streptococcus pneumoniae

- Reported as resistant to erythromycin and/or azithromycin:
  - [ ] Yes
  - [ ] No

- Reported as resistant to penicillin:
  - [ ] Yes
  - [ ] No

- Reported as resistant to moxifloxacin, norfloxacin and/or levofloxacin:
  - [ ] Yes
  - [ ] No
### 3.0 PLEURAL ASPIRATE

**Microbiological tests performed on pleural fluid:**
On specimens collected within 7 days of hospital admission (e.g., culture, PCR)

#### Positive pleural aspirate culture result:
On specimens collected within 7 days of hospital admission

**Which organisms were detected:**
(check all that apply)

- [ ] **Acinetobacter spp**
- [ ] **Burkholderia pseudomallei**
- [ ] **Escherichia coli**
- [ ] **Haemophilus influenzae**
- [ ] **Klebsiella spp**
- [ ] **Moraxella catarrhalis**
- [ ] **Pseudomonas aeruginosa**

**Other, specify** __________________________________________________________________________________

---

**IF ACINETOBACTER SPP**
- [ ] Reported as resistant to ceftazidime and/or piperacillin-tazobactam: ____________________________________________________________________________
- [ ] Reported as resistant to meropenem and/or imipenem: ____________________________________________________________________________________

**IF E COLI**
- [ ] Reported as resistant to ceftriaxone and/or ceftazidime: ______________________________________________________________________________
- [ ] Reported as resistant to meropenem and/or imipenem: __________________________________________________________________________________

**IF KLEBSIELLA SPP**
- [ ] Reported as resistant to ceftriaxone and/or ceftazidime: ______________________________________________________________________________
- [ ] Reported as resistant to meropenem and/or imipenem: __________________________________________________________________________________

**IF PSEUDOMONAS AERUGINOSA**
- [ ] Reported as resistant to ceftazidime and/or piperacillin-tazobactam: ______________________________________________________________________
- [ ] Reported as resistant to meropenem and/or imipenem: __________________________________________________________________________________

**IF STAPHYLOCOCCUS AUREUS**
- [ ] Reported as methicillin-resistant staphylococcus aureus: ______________________________________________________________________________

**IF STREPTOCOCCUS PNEUMONIAE**
- [ ] Reported as resistant to erythromycin and/or azithromycin: __________________________________________________________________________
- [ ] Reported as resistant to penicillin: _______________________________________________________________________________________________
- [ ] Reported as resistant to moxifloxacin, norfloxacin and/or levofloxacin: __________________________________________________________________

---

**PCR performed on pleural fluid:**
On specimens collected within 7 days of hospital admission

**IF YES**
- [ ] Positive for *Streptococcus pneumoniae*: __________________________________________________________________________________________

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Skip to Positive lower respiratory tract specimen culture

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Positive lower respiratory tract specimen culture: On specimens collected within 72 hours of hospital admission

Which organisms were detected: (check all that apply)

- Acinetobacter spp
- Burkholderia pseudomallei
- Escherichia coli
- Haemophilus influenzae
- Klebsiella spp
- Moraxella catarrhalis
- Pseudomonas aeruginosa
- Staphylococcus aureus
- Streptococcus pneumoniae
- Streptococcus pyogenes
- Streptococcus agalactiae
- None of the above

IF ACINETOBACTER SPP
- Reported as resistant to ceftazidime and/or piperacillin-tazobactam: Y Yes N No
- Reported as resistant to meropenem and/or imipenem: Y Yes N No

IF E COLI
- Reported as resistant to ceftiraxone and/or ceftazidime: Y Yes N No
- Reported as resistant to meropenem and/or imipenem: Y Yes N No

IF KLEBSIELLA SPP
- Reported as resistant to ceftiraxone and/or ceftazidime: Y Yes N No
- Reported as resistant to meropenem and/or imipenem: Y Yes N No

IF PSEUDOMONAS AERUGINOSA
- Reported as resistant to ceftazidime and/or piperacillin-tazobactam: Y Yes N No
- Reported as resistant to meropenem and/or imipenem: Y Yes N No

IF STAPHYLOCOCCUS AUREUS
- Reported as methicillin-resistant staphylococcus aureus: Y Yes N No

IF STREPTOCOCCUS PNEUMONIAE
- Reported as resistant to erythromycin and/or azithromycin: Y Yes N No
- Reported as resistant to penicillin: Y Yes N No
- Reported as resistant to moxifloxacin, norfloxacin and/or levofloxacin: Y Yes N No

4.0 IMMUNOCOMPROMISED PATIENTS

(This question will appear on the eCRF if applicable)

Positive lower respiratory tract or lung tissue specimen: On specimens collected within 7 days of hospital admission

Which organisms were detected: (check all that apply)

- Aspergillus
- Cryptococcus species
- Mucormycosis species
- Nocardia species
- Non-TB mycobacteria
- Pneumocystis
- Tuberculosis
- Varicella zoster virus
- None of the above

Y Yes N No
**PLATFORM**

**1.0 STUDY DAY**

Collect daily data for the duration of the ICU admission (censored at study day 28). If the patient is allocated to fixed course steroid, collect corticosteroid administration up until D9 while on ward.

#### Study day

- [ ] Study days (01-28)

#### Date

- D D M M Y Y Y
- e.g. 18/JUL/2018

#### Patient in ICU during this day

- [Y] Yes
- [N] No

#### Patient location on study day

- [ ] Physical ICU
- [ ] Re-purposed ICU

**2.0 DAILY TREATMENTS**

**Airway:**

- [ ] Maintaining own
- [ ] Endotracheal tube
- [ ] Tracheostomy

*IF MAINTAINING OWN*

- [ ] High flow nasal prong oxygen therapy:
  - [Y] Yes
  - [N] No

- [ ] Non invasive ventilation:
  - [Y] Yes
  - [N] No

*IF ETT or TT*

- [ ] Hours of invasive mechanical ventilation:
  - [ ] hours (0-24)

- [ ] FiO₂ associated with lowest P/F ratio:
  - [ ] e.g. 0.21

- [ ] Corresponding PaO₂:
  - [ ] mmHg

- [ ] Corresponding PEEP:
  - [ ] cmH₂O

**Extended Cardiovascular SOFA score:**

- [ ] 0
- [ ] 1
- [ ] 2
- [ ] 3
- [ ] 4
- [ ] 4+

**Renal replacement therapy:**

- [Y] Yes
- [N] No

**Extracorporeal gas exchange:**

- [Y] Yes
- [N] No

*IF YES*

- [ ] Received:
  - [ ] Extracorporeal membrane oxygenation (ECMO)
  - [ ] Extracorporeal carbon dioxide removal (ECCO₂R)
### 3.0 CORTICOSTEROID ADMINISTRATION

<table>
<thead>
<tr>
<th>Hydrocortisone (IV)</th>
<th>Dexamethasone</th>
<th>Prednisone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocortisone (oral)</td>
<td>Methylprednisolone</td>
<td>Triamcinolone</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>Prednisolone</td>
<td></td>
</tr>
</tbody>
</table>

**Was a corticosteroid administered on this study day:**
- [ ] Yes
- [ ] No

- **Name of corticosteroid**
- **Total daily dose:** [ ] mg

**Was this dose administered for the patient’s initial episode of CAP or its complications:**
- [ ] Yes
- [ ] No

**What was the corticosteroid administered for:**

---

UK REMAP-CAP Case Report Form 4, V10 dated 20210510
**VENTILATION DOMAIN**

**1.0 DAILY ABG 1**

This section is required on study days 1, 2, 3, 5, 7, 10, 14, 21, and 28 following randomisation to this domain while the patient is invasively mechanically ventilated. On study days 1, 2, and 3 following randomisation to this domain two entries are required, one for the first 12 hours of the study day, and one for the second. Where the study day is < 16 hours only one entry is required. If the patient has had one or more ABGs during the specified period, record the FiO₂ associated with the lowest P:F ratio while the patient is receiving IMV.

**Was an ABG taken during this time:**

\[Yes \quad N\] No

*If NO, complete only FiO₂, SpO₂, and EtCO₂.*

*If YES, complete all questions in this section.*

- **FiO₂:**
  - [ ] [ ] e.g. 0.21

- **PaO₂:** [ ] [ ] mmHg [ ] [ ] kPa
  - [N] Not recorded

- **PaCO₂:** [ ] [ ] mmHg [ ] [ ] kPa
  - [N] Not recorded

- **pH:** [ ] [ ]
  - [N] Not recorded

- **HCO₃⁻:** [ ] [ ] mEq/L or mmol/L
  - [N] Not recorded

- **SaO₂:** [ ] [ ] %
  - [N] Not recorded

- **Lactate:** [ ] [ ] mmol/L [ ] [ ] mg/dL
  - [N] Not recorded

- **Base excess:** +/- [ ] mEq/L
  - [N] Not available

*Collect value closest to FiO₂ entered above:*

- **SpO₂:** [ ] [ ] %
  - [N] Not recorded

- **EtCO₂:** [ ] [ ] mmHg [ ] [ ] kPa
  - [N] Not recorded

**2.0 VENTILATION PARAMETERS 1**

- **Mode of ventilation:**
  - Airway pressure release ventilation (APRV)
  - Assist control, pressure regulated volume control
  - NAVA
  - Continuous positive airway pressure
  - Proportional assist ventilation

- **Set respiratory rate:** [ ] bpm
- **Recorded total respiratory rate:** [ ] bpm

- **Are the mandatory breaths that the patient is receiving pressure-cycled or volume-cycled:**
  - Pressure-cycled
  - Volume-cycled

- **Expired tidal volume:** [ ] mL

- **Recorded peak inspiratory pressure:** (not required if receiving APRV)
  - [ ] cmH₂O

- **Set pressure support:** [ ] cmH₂O

*Required if set respiratory rate is not 0*
### 3.0 DAILY ABG 2

Was an ABG taken during this time:  
- Yes  
- No

If NO, complete only FiO₂, SpO₂, and EtCO₂  
If YES, complete all questions in this section

- FiO₂:  
- PaO₂: mmHg  
- PaCO₂: mmHg  
- pH:  
- HCO₃⁻: mEq/L or mmol/L  
- SaO₂: %  
- Lactate: mmol/L  
- Base excess: +/- mEq/L

Collect value closest to FiO₂ entered above:

- SpO₂: %  
- EtCO₂: mmHg

### 4.0 VENTILATION PARAMETERS 2

Mode of ventilation:  
- Airway pressure release ventilation (APRV)  
- Assist control, pressure regulated volume control  
- NAVA  
- Continuous positive airway pressure  
- Proportional assist ventilation  
- Pressure support ventilation  
- Mandatory minute ventilation PSV  
- Mandatory minute ventilation (volume control, pressure control, pressure support)  
- Ventilation synchronized intermittent mandatory ventilation (pressure control, volume control)

Set respiratory rate:  
- Recorded total respiratory rate: bpm
### Ventilation Daily

**Participant Study Number**

**Mechanical Ventilation Study Day**

**Patient Initials**

---

**Are the mandatory breaths that the patient is receiving pressure-cycled or volume-cycled:**

(check one)

- [ ] Pressure-cycled
- [ ] Volume-cycled

*Required if set respiratory rate is not 0*

---

**Expired tidal volume:**

- [ ] ml

---

**Recorded peak inspiratory pressure:**

(Not required if receiving APRV)

- [ ] cmH₂O

---

**Set pressure support:**

- [ ] cmH₂O

---

**Recorded plateau pressure:**

*Not recorded*

---

**Set PEEP:**

- [ ] cmH₂O

---

**I:E Ratio:**

*Not recorded*

---

**Complete only if the mode of invasive ventilation is APRV**

- [ ] T_low: . seconds
- [ ] T_high: . seconds
- [ ] P_low: . cmH₂O
- [ ] P_high: . cmH₂O

*Not recorded*

---

### 5.0 Daily Therapies

**Did the patient receive any of the following therapies on this study day:**

(check all that apply)

- [ ] Continuous neuromuscular blockade
- [ ] Recruitment maneuver
- [ ] Nitric oxide
- [ ] Prone positioning
- [ ] Inhaled prostacyclin
- [ ] Other hypoxemic rescue therapy
- [ ] None of the above

**Specify:**

(IF OTHER HYPOXEMIC RESCUE THERAPY:

---

**Did the patient undergo a formal or informal unassisted breathing trial:**

- [ ] Informal unassisted breathing
- [ ] Formal unassisted breathing
- [ ] None

(IF OTHER THAN NONE

---

**Did the patient pass any unassisted breathing trial:**

- [ ] Yes
- [ ] No
## General Guidance
- Enter all medications administered between arrival at the randomising hospital and the end of study day 14.
- Enter all statins administered between arrival at the randomising hospital and the end of study day 28.
- Include medications administered prior to randomisation (e.g. medications administered in ED or on a ward) even if not continued in ICU.
- If the patient is randomised on a ward and later admitted to ICU collect 14 days of administration while in ICU (only include this for regions randomising to moderate).
- Where a STAT dose of the same medication is received prior to the administration of a regular course, record as one entry.
- Administration of corticosteroids within the Corticosteroid Domain should be entered on the daily form.

**Enter a new course if:**
- the same agent was switched from IV to enteral administration (and vice versa)
- the medication has been ceased/interrupted for more than 36 hours

**Do not enter a new course if:**
- the initial prescribed frequency was changed
- the initial prescribed dose was changed

### 1.0 ANTIBIOTIC COURSE ADMINISTRATION

<table>
<thead>
<tr>
<th>Antibiotic name:</th>
<th>Date &amp; time first dose administered:</th>
<th>Prescribed dose:</th>
<th>Prescribed route of administration:</th>
<th>Initial prescribed frequency:</th>
<th>Date last dose administered:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Textbox)</td>
<td>DD/MM/MY</td>
<td>24 hour clock</td>
<td>g</td>
<td>Continuous infusion</td>
<td>6 hourly</td>
</tr>
<tr>
<td></td>
<td>DD/MM/MY</td>
<td>24 hour clock</td>
<td>g</td>
<td>Continuous infusion</td>
<td>6 hourly</td>
</tr>
<tr>
<td></td>
<td>DD/MM/MY</td>
<td>24 hour clock</td>
<td>g</td>
<td>Continuous infusion</td>
<td>6 hourly</td>
</tr>
</tbody>
</table>
### 2.0 ANTIVIRAL ADMINISTRATION

**Record only selected antiviral medications**

**Generic antiviral names only**

<table>
<thead>
<tr>
<th>Antiviral name</th>
<th>Date &amp; time first dose administered</th>
<th>Prescribed dose</th>
<th>Prescribed route of administration</th>
<th>Initial prescribed frequency</th>
<th>Date last dose administered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osimertinib</td>
<td>D D M M M / Y Y Y Y e.g. 01/JUN/2018</td>
<td>D D M M M / Y Y Y Y</td>
<td>Intravenous</td>
<td>Daily</td>
<td>D D M M M / Y Y Y Y e.g. 18/JUL/2018</td>
</tr>
<tr>
<td>Hydroxychloroquine</td>
<td></td>
<td>mg</td>
<td>Enteral</td>
<td>12 hourly</td>
<td></td>
</tr>
<tr>
<td>Lopinavir/ritonavir (Kaletra)</td>
<td></td>
<td>g</td>
<td></td>
<td>6 hourly</td>
<td></td>
</tr>
<tr>
<td>Laninamivir octanoate</td>
<td></td>
<td>mcg</td>
<td></td>
<td>STAT</td>
<td></td>
</tr>
<tr>
<td>Amantadine</td>
<td>Baloxavir</td>
<td></td>
<td></td>
<td>Intermittent depending on levels</td>
<td></td>
</tr>
<tr>
<td>Peramivir</td>
<td>Ribavirin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zanamivir</td>
<td>Rimantadine</td>
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<td>Remdesivir</td>
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<td>Unifonovir (arbidol)</td>
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<tr>
<td>Darunavir/cobicistat</td>
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<tr>
<td>Favipiravir</td>
<td>Nafamostat</td>
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<tr>
<td>Chloroquine</td>
<td>Camostat</td>
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<tr>
<td>Ivermectin</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

### Notes

- **24 hour clock**
  - e.g. 8:05pm = 20:05 hours

- **Censored**
  - At study day 14 (inclusive)
  - At hospital discharge
### PLATFORM

#### 3.0  ADMINISTRATION OF LOPINAVIR/RITONAVIR

This CRF page is only required if Lopinavir/Ritonavir was administered during first 14 days. If no lopinavir/ritonavir was administered via this route on this study day, enter 0 (zero).

<table>
<thead>
<tr>
<th>Study Date:</th>
<th>Study Day:</th>
<th>Lopinavir/ritonavir administered:</th>
<th>Total dose (swallowed/dissolved/suspension):</th>
<th>Total dose (crushed tablet):</th>
</tr>
</thead>
<tbody>
<tr>
<td>DD/MM/YY</td>
<td>1</td>
<td>Y Yes</td>
<td></td>
<td>mg</td>
</tr>
<tr>
<td>DD/MM/YY</td>
<td>2</td>
<td>Y Yes</td>
<td></td>
<td>mg</td>
</tr>
<tr>
<td>DD/MM/YY</td>
<td>3</td>
<td>Y Yes</td>
<td></td>
<td>mg</td>
</tr>
<tr>
<td>DD/MM/YY</td>
<td>4</td>
<td>Y Yes</td>
<td></td>
<td>mg</td>
</tr>
<tr>
<td>DD/MM/YY</td>
<td>5</td>
<td>Y Yes</td>
<td></td>
<td>mg</td>
</tr>
<tr>
<td>DD/MM/YY</td>
<td>6</td>
<td>Y Yes</td>
<td></td>
<td>mg</td>
</tr>
<tr>
<td>DD/MM/YY</td>
<td>7</td>
<td>Y Yes</td>
<td></td>
<td>mg</td>
</tr>
<tr>
<td>DD/MM/YY</td>
<td>8</td>
<td>Y Yes</td>
<td></td>
<td>mg</td>
</tr>
<tr>
<td>DD/MM/YY</td>
<td>9</td>
<td>Y Yes</td>
<td></td>
<td>mg</td>
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<tr>
<td>DD/MM/YY</td>
<td>10</td>
<td>Y Yes</td>
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<td>mg</td>
</tr>
<tr>
<td>DD/MM/YY</td>
<td>11</td>
<td>Y Yes</td>
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<td>mg</td>
</tr>
<tr>
<td>DD/MM/YY</td>
<td>12</td>
<td>Y Yes</td>
<td></td>
<td>mg</td>
</tr>
<tr>
<td>DD/MM/YY</td>
<td>13</td>
<td>Y Yes</td>
<td></td>
<td>mg</td>
</tr>
<tr>
<td>DD/MM/YY</td>
<td>14</td>
<td>Y Yes</td>
<td></td>
<td>mg</td>
</tr>
</tbody>
</table>
### 4.0 IMMUNE MODULATION ADMINISTRATION

**Agent name:**

- Interferon-ß 1a
- Interferon-ß 1b
- Interferon-α
- Interferon-γ
- IL1-Ra (Anakinra (IL1-Ra))
- Tocilizumab
- Sarilumab
- Baricitinib
- Imatinib
- Monoclonal antibody

**Date & time first dose administered:**

- **D D M M M Y Y Y Y**
  - *e.g. 01/JUN/2018 01/06/2018*  
  - **H H : M M**  
  - *24 hour clock 24-hour clock*  
  - *e.g. 8:05pm = 20:05hours*  

**Prescribed dose:**

- **D D M M M Y Y Y Y**
  - **mg**
  - **g**

**Prescribed route of administration:**

- **Check one**
  - Intravenous
  - Enteral
  - Inhaled
  - Subcutaneous or intra-muscular

**Initial prescribed frequency:**

- **Check one**
  - Continuous infusion
  - Daily
  - 12 hourly
  - 8 hourly
  - 6 hourly
  - 4 hourly
  - STAT
  - Intermittent depending on levels

**Date last dose administered:**

- **D D M M M Y Y Y Y**
  - *e.g. 18/JUL/2018*
### 5.0 IMMUNOMODULATORY AND ANTIBODY ADMINISTRATION

(New course censored at study day 14 (inclusive))

<table>
<thead>
<tr>
<th>Agent name: (Check one)</th>
<th>Date &amp; time infusion commenced:</th>
<th>Date &amp; time infusion ceased: (Censored at hospital discharge)</th>
<th>Volume transfused:</th>
<th>Donation number: (Textbox)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>D D / M M M Y Y Y, e.g. 01/JUN/2018 H H : M M 24 hour clock</td>
<td>D D / M M M Y Y Y, e.g. 18/JUL/2018 H H : M M 24 hour clock</td>
<td>ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td>D D / M M M Y Y Y, e.g. 01/JUN/2018 H H : M M 24 hour clock</td>
<td>D D / M M M Y Y Y, e.g. 18/JUL/2018 H H : M M 24 hour clock</td>
<td>ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td>D D / M M M Y Y Y, e.g. 01/JUN/2018 H H : M M 24 hour clock</td>
<td>D D / M M M Y Y Y, e.g. 18/JUL/2018 H H : M M 24 hour clock</td>
<td>ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td>D D / M M M Y Y Y, e.g. 01/JUN/2018 H H : M M 24 hour clock</td>
<td>D D / M M M Y Y Y, e.g. 18/JUL/2018 H H : M M 24 hour clock</td>
<td>ml</td>
<td></td>
</tr>
</tbody>
</table>

- **Agent name:**
  - Intravenous immunoglobulin (non-pandemic specific)
  - Pandemic hyperimmune globulin
  - Pandemic convalescent plasma

- **Volume transfused:**
  - ml

- **Donation number:** (Textbox)
## Medication Administration

### 6.0 Anticoagulant / Antiplatelet Agent Administered as Stat or Intermittent Dosing

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Date &amp; Time First Dose Administered</th>
<th>Prescribed Dose</th>
<th>Prescribed Route of Administration</th>
<th>Initial Prescribed Frequency</th>
<th>Date Last Dose Administered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unfractionated Heparin</td>
<td>D D / M M M Y Y Y Y e.g. 01/JUN/2018</td>
<td>mg</td>
<td>Intravenous</td>
<td>Daily</td>
<td>D D / M M M Y Y Y Y e.g. 18/JUL/2018</td>
</tr>
<tr>
<td>Enoxaparin</td>
<td>D D / M M M Y Y Y Y e.g. 01/JUN/2018</td>
<td>mcg</td>
<td>Subcutaneous</td>
<td>12 hourly</td>
<td></td>
</tr>
<tr>
<td>Dalteparin</td>
<td>H H : M M 24 hour clock e.g. 8:05pm = 20:05 hours</td>
<td></td>
<td>Enteral</td>
<td>8 hourly</td>
<td></td>
</tr>
<tr>
<td>Tinzaparin</td>
<td></td>
<td></td>
<td></td>
<td>6 hourly</td>
<td></td>
</tr>
<tr>
<td>Nadroparin</td>
<td></td>
<td></td>
<td></td>
<td>4 hourly</td>
<td></td>
</tr>
<tr>
<td>Fraxiparine</td>
<td></td>
<td></td>
<td></td>
<td>STAT</td>
<td></td>
</tr>
<tr>
<td>Apixaban</td>
<td></td>
<td></td>
<td></td>
<td>Intermittent depending on levels</td>
<td></td>
</tr>
<tr>
<td>Rivaroxaban</td>
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<td></td>
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<tr>
<td>Edoxaban</td>
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</tr>
<tr>
<td>Dabigatran</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Bilivalirudin</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Argatroban</td>
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<tr>
<td>Fondaparinux</td>
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<tr>
<td>Warfarin</td>
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<tr>
<td>Acetylsalicylic acid (Aspirin)</td>
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<tr>
<td>Clopidogrel</td>
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<tr>
<td>Ticagrelor</td>
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<td>Prasugrel</td>
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<tr>
<td>Dipyridamole</td>
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<tr>
<td>Dipyridamole/aspirin</td>
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<tr>
<td>Ticlopidine</td>
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<tr>
<td>Eptifibatide</td>
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<tr>
<td>Triofiban</td>
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<td></td>
</tr>
<tr>
<td>Abciximab</td>
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</tr>
</tbody>
</table>

**Note:** Record only selected anticoagulant medications. Generic anticoagulant names only. (New course censored at study day 14 (inclusive)).
<table>
<thead>
<tr>
<th>Medication name:</th>
<th>Date &amp; time infusion commenced:</th>
<th>Prescribed initial infusion rate:</th>
<th>Prescribed route of administration:</th>
<th>Initial prescribed frequency:</th>
<th>Date infusion ceased:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unfractionated heparin</td>
<td>D M Y Y Y Y 01/JUN/2018 08:05pm = 20:05hours</td>
<td>mg/hr</td>
<td>Intravenous</td>
<td>Continuous infusion</td>
<td>D M Y Y Y Y 18/JUL/2018</td>
</tr>
<tr>
<td>Bilivalirudin</td>
<td></td>
<td></td>
<td>Into haemofilter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Argatroban</td>
<td></td>
<td></td>
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<tr>
<td>Eptifibatide</td>
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<tr>
<td>Triofiban</td>
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<tr>
<td>Abciximab</td>
<td></td>
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</tr>
<tr>
<td>Unfractionated heparin</td>
<td>D M Y Y Y Y 01/JUN/2018 08:05pm = 20:05hours</td>
<td>mg/hr</td>
<td>Intravenous</td>
<td>Continuous infusion</td>
<td>D M Y Y Y Y 18/JUL/2018</td>
</tr>
<tr>
<td>Bilivalirudin</td>
<td></td>
<td></td>
<td>Into haemofilter</td>
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<tr>
<td>Argatroban</td>
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<tr>
<td>Eptifibatide</td>
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<tr>
<td>Triofiban</td>
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<tr>
<td>Abciximab</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Unfractionated heparin</td>
<td>D M Y Y Y Y 01/JUN/2018 08:05pm = 20:05hours</td>
<td>mg/hr</td>
<td>Intravenous</td>
<td>Continuous infusion</td>
<td>D M Y Y Y Y 18/JUL/2018</td>
</tr>
<tr>
<td>Bilivalirudin</td>
<td></td>
<td></td>
<td>Into haemofilter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Argatroban</td>
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<tr>
<td>Eptifibatide</td>
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<tr>
<td>Triofiban</td>
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<tr>
<td>Abciximab</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unfractionated heparin</td>
<td>D M Y Y Y Y 01/JUN/2018 08:05pm = 20:05hours</td>
<td>mg/hr</td>
<td>Intravenous</td>
<td>Continuous infusion</td>
<td>D M Y Y Y Y 18/JUL/2018</td>
</tr>
<tr>
<td>Bilivalirudin</td>
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<td>Into haemofilter</td>
<td></td>
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<tr>
<td>Argatroban</td>
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<td>Triofiban</td>
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</tr>
<tr>
<td>Abciximab</td>
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</tbody>
</table>
### PLATFORM

**7.0 VITAMIN C**

(New course censored at study day 14 (inclusive))

<table>
<thead>
<tr>
<th>Medication name:</th>
<th>Date &amp; time first dose administered:</th>
<th>Prescribed dose:</th>
<th>Prescribed route of administration:</th>
<th>Initial prescribed frequency:</th>
<th>Date last dose administered:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DD/MM/YYYY HH:MM 24 hour clock</td>
<td>mg</td>
<td>Intravenous</td>
<td>Continuous infusion</td>
<td>DD/MM/YYYY 18/07/2018</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>e.g. 01/JUN/2018 8:05pm = 20:05 hours</td>
<td></td>
<td>Daily</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<td>12 hourly</td>
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<td>8 hourly</td>
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<td></td>
<td></td>
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<td>6 hourly</td>
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<td>4 hourly</td>
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<td></td>
<td>STAT</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Intermittent depending on levels</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medication name:</th>
<th>Date &amp; time first dose administered:</th>
<th>Prescribed dose:</th>
<th>Prescribed route of administration:</th>
<th>Initial prescribed frequency:</th>
<th>Date last dose administered:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DD/MM/YYYY HH:MM 24 hour clock</td>
<td>mg</td>
<td>Intravenous</td>
<td>Continuous infusion</td>
<td>DD/MM/YYYY 18/07/2018</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>e.g. 01/JUN/2018 8:05pm = 20:05 hours</td>
<td></td>
<td>Daily</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>12 hourly</td>
<td></td>
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<td></td>
<td></td>
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<td>8 hourly</td>
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<td>6 hourly</td>
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<td></td>
<td>4 hourly</td>
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<td>STAT</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Intermittent depending on levels</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 8.0 STATIN ADMINISTRATION

**Record only selected medications**

**Generic statin names only**

<table>
<thead>
<tr>
<th>Medication name</th>
<th>Date &amp; time first dose administered:</th>
<th>Prescribed dose:</th>
<th>Prescribed route of administration:</th>
<th>Prescribed daily frequency:</th>
<th>Date last dose administered:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simvastatin</td>
<td>[DD/MM/YYYY]</td>
<td>[mg]</td>
<td>Enteral</td>
<td>Daily</td>
<td>[DD/MM/YYYY]</td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>[DD/MM/YYYY]</td>
<td>[mg]</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Rosuvastatin</td>
<td>[DD/MM/YYYY]</td>
<td>[mg]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pravastatin</td>
<td>[DD/MM/YYYY]</td>
<td>[mg]</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Lovastatin</td>
<td>[DD/MM/YYYY]</td>
<td>[mg]</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Example dates and times are provided:* 

- [DD/MM/YYYY]
- [HH:MM]
- [24 hour clock]
- [e.g. 01/JUN/2018]
- [e.g. 8:05pm = 20:05 hours]
## CORTICOSTEROID ADMINISTRATION

(New course censored at study day 14 (inclusive)). Pandemic only.

<table>
<thead>
<tr>
<th>Medication name: Record only selected medications Generic steroid names only</th>
<th>Date &amp; time first dose administered:</th>
<th>Prescribed dose:</th>
<th>Prescribed route of administration: (Check one)</th>
<th>Prescribed daily frequency: (Check one)</th>
<th>Date last dose administered: (Censored at hospital discharge)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Hydrocortisone</td>
<td>DD-MM-YYYY e.g. 01/JUN/2018</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H H : M M 24 hour clock e.g. 8:05pm = 20:05hours</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Betamethasone</td>
<td>DD-MM-YYYY e.g. 01/JUN/2018</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>□ Dexamethasone</td>
<td>DD-MM-YYYY e.g. 01/JUN/2018</td>
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<td>□ Methylprednisolone</td>
<td>DD-MM-YYYY e.g. 01/JUN/2018</td>
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<td>□ Prednisolone</td>
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<td>□ Prednisone</td>
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<td>□ Triamcinolone</td>
<td>DD-MM-YYYY e.g. 01/JUN/2018</td>
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<td>H H : M M 24 hour clock e.g. 8:05pm = 20:05hours</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Medication name: Record only selected medications Generic steroid names only</th>
<th>Date &amp; time first dose administered:</th>
<th>Prescribed dose:</th>
<th>Prescribed route of administration: (Check one)</th>
<th>Prescribed daily frequency: (Check one)</th>
<th>Date last dose administered: (Censored at hospital discharge)</th>
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<tr>
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<td>□ Hydrocortisone</td>
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<td>□ Betamethasone</td>
<td>DD-MM-YYYY e.g. 01/JUN/2018</td>
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<td>H H : M M 24 hour clock e.g. 8:05pm = 20:05hours</td>
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</tbody>
</table>
### 10.0 RENIN-ANGIOTENSIN SYSTEM MODULATOR ADMINISTRATION

(Required for patients randomised to ACE2 RAS domain)

<table>
<thead>
<tr>
<th>Medication name:</th>
<th>Date &amp; time course commenced:</th>
<th>Date course ceased:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>24 hour clock e.g. 01/JUN/2018</td>
<td>(Censored at hospital discharge) e.g. 18/JUL/2018</td>
</tr>
</tbody>
</table>

- **Losartan**
- **Valsartan**
- **Candesartan**
- **Irbesartan**
- **Telmisartan**
- **Olmesartan**
- **Ramipril**

**Generic names only**

- Li**sinopril**
- Perindopril
- Enalapril
- Trandolapril
- Captopril
- DMX-200

**Medication name:**
Record only selected RAS medications

**Date & time course commenced:**

- **Losartan**
- **Valsartan**
- **Candesartan**
- **Irbesartan**
- **Telmisartan**
- **Olmesartan**
- **Ramipril**

**Date course ceased:**

- **Losartan**
- **Valsartan**
- **Candesartan**
- **Irbesartan**
- **Telmisartan**
- **Olmesartan**
- **Ramipril**
### PLATFORM

#### 11.0 RENIN-ANGIOTENSIN SYSTEM MODULATOR – DAILY ADMINISTRATION

(Required for patients randomised to ACE2 RAS domain)

Choose one RAS modulator agent per sheet and record daily data collection for each study day (up to study day 28 max) between the start and end of the course.

<table>
<thead>
<tr>
<th>Study Date:</th>
<th>Study Day:</th>
<th>Total dose administered: Total dose administered on each study day</th>
<th>Was the medication withheld at any time on this study day:</th>
<th>Reason for withholding medication: (check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>D D MMM YYYY</td>
<td></td>
<td>mg</td>
<td>Yes □ No □</td>
<td>Hyperkalemia □ Significantly elevated blood pressure □ Hyperkalemia □ Clinical significance □ Angioedema □</td>
</tr>
<tr>
<td>D D MMM YYYY</td>
<td></td>
<td>mg</td>
<td>Yes □ No □</td>
<td>Hyperkalemia □ Significant renal insufficiency □ Deteriorating renal function □ Significant exposure to nephrotoxic agents □</td>
</tr>
<tr>
<td>D D MMM YYYY</td>
<td></td>
<td>mg</td>
<td>Yes □ No □</td>
<td>Hyperkalemia □ Significant renal insufficiency □ Deteriorating renal function □ Significant exposure to nephrotoxic agents □</td>
</tr>
</tbody>
</table>

**Specify:**

- Hyperkalemia
- Significant renal insufficiency
- Deteriorating renal function
- Significant exposure to nephrotoxic agents

Other □

Specify: ____________________________  

---

**RAS modulator agents:**

- Losartan
- Irbesartan
- Ramipril
- Enalapril
- Valsartan
- Telmisartan
- Lisinopril
- Trandolapril
- Candesartan
- Olmesartan
- Perindopril
- Captopril
- DMX-200
- DMX-20
- DMX-100

**Choose one RAS modulator agent per sheet and record daily data collection for each study day (up to study day 28 max) between the start and end of the course.**
# PLATFORSM

## 1.0 ICU DISCHARGE

### (First ICU discharge)

<table>
<thead>
<tr>
<th>ICU discharge date &amp; time:</th>
<th>D</th>
<th>M</th>
<th>M</th>
<th>Y</th>
<th>Y</th>
<th>Y</th>
<th>Y</th>
<th>H</th>
<th>H</th>
<th>24 hour clock: M</th>
<th>M</th>
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<td>Status: (check one)</td>
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<td>e.g. 01/JUN/2018</td>
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</tr>
<tr>
<td>*Date and time of last organ support in ICU:</td>
<td>D</td>
<td>M</td>
<td>M</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>H</td>
<td>H</td>
<td>24 hour clock: M</td>
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<td>e.g. 01/JUN/2018</td>
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</tbody>
</table>

## 2.0 ICU READMISSION

### (ICU readmissions)

<table>
<thead>
<tr>
<th>ICU readmission:</th>
<th>Yes</th>
<th>No</th>
<th>Skip to section 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICU readmission date &amp; time:</td>
<td>D</td>
<td>M</td>
<td>M</td>
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<tr>
<td></td>
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<tr>
<td>ICU discharge date &amp; time:</td>
<td>D</td>
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<td>M</td>
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<tr>
<td>Did the patient receive organ support during this ICU admission</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>*Date and time of first organ support in ICU this readmission:</td>
<td>D</td>
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<td>M</td>
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<tr>
<td>*Date and time of last organ support in ICU this readmission:</td>
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<td>M</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>2nd ICU readmission:</th>
<th>Yes</th>
<th>No</th>
<th>Skip to section 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICU readmission date &amp; time:</td>
<td>D</td>
<td>M</td>
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<tr>
<td>ICU discharge date &amp; time:</td>
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<tr>
<td>Did the patient receive organ support during this ICU admission</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>*Date and time of first organ support in ICU this readmission:</td>
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<tr>
<td>*Date and time of last organ support in ICU this readmission:</td>
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</tbody>
</table>

* = Only required for Pandemic Infection Suspected or Confirmed Patients

## 3.0 HOSPITAL DISCHARGE

### (Censored at hospital discharge)

<table>
<thead>
<tr>
<th>Dialysis at hospital discharge:</th>
<th>Yes</th>
<th>No</th>
<th>Skip to Hospital discharge date &amp; time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last creatinine:</td>
<td>µmol/L</td>
<td>mg/dL</td>
<td>Not recorded</td>
</tr>
<tr>
<td>Hospital discharge date &amp; time:</td>
<td>D</td>
<td>M</td>
<td>M</td>
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</tbody>
</table>

* = Only required for Pandemic Infection Suspected or Confirmed Patients

UK REMAP-CAP Case Report Form 6, V10 dated 20210510

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www.remapcap.org
Discharge

Ultimate hospital discharge date: DD/MM/YYYY

Still in hospital on study day 90

Status at ultimate hospital:
- Alive (A)
- Deceased (D)
- Unable to ascertain (U)

*Was patient admitted to ICU during this hospital admission:
- Yes (Y)
- No (N)

If Yes:
- ICU admission date & time: DD/MM/YYYY HH:MM (24 hour clock)
- ICU discharge date & time: DD/MM/YYYY HH:MM (24 hour clock)
- Did the patient receive organ support during this ICU admission:
  - Yes (Y)
  - No (N)

Readmission:
- Yes (Y)
- No (N)

*Date and time of first organ support in ICU this readmission:
- DD/MM/YYYY HH:MM (24 hour clock)

*Date and time of last organ support in ICU this readmission:
- DD/MM/YYYY HH:MM (24 hour clock)

* = Only required for Pandemic Infection Suspected or Confirmed Patients
### 4.0 CO-ENROLMENT

Co-enrolled in another study:  

**YES**

- ATTACC study ID:  
  - Not enrolled in ATTACC

- ASCOT study ID:  
  - Not enrolled in ASCOT

- LOVIT study ID:  
  - Not enrolled in LOVIT

**NO**

Other co-enrolment study name:  

- Other co-enrolment study name:
- Other co-enrolment study name:
- Other co-enrolment study name:

Skip to 5.0 Platform endpoints

### 5.0 PLATFORM ENDPOINTS

*(Censored at hospital discharge)*

**Only required for Pandemic Infection Suspected or Confirmed Patients who are alive and in hospital at study day 14**

Select the highest level of organ support on Day 14 after **first** randomisation:  
(check one)

- Hospitalised, no supplemental oxygen
- Non-invasive ventilation or high-flow oxygen
- Invasive mechanical ventilation plus additional organ support (inotrope/vasopressor infusion, renal replacement therapy)
- Deceased

Select the highest level of organ support on Day 14 after **last** randomisation:  
(check one)

- Hospitalised, no supplemental oxygen
- Non-invasive ventilation or high-flow oxygen
- Invasive mechanical ventilation plus additional organ support (inotrope/vasopressor infusion, renal replacement therapy)
- Deceased

- Hospitalised, low-flow oxygen by mask or nasal prongs
- Invasive mechanical ventilation
- ECMO
- Unknown

- Hospitalised, low-flow oxygen by mask or nasal prongs
- Invasive mechanical ventilation
- ECMO
- Unknown
**ANTIBIOTIC DOMAIN**

**6.0 MULTI-RESISTANT ORGANISMS**

(Censored at hospital discharge)

- **Clostridium difficile toxin detected on a faecal specimen:**
  - **Yes**
  - **No**
  - **Skip to MRSA isolated or detected**
  - **Date first positive specimen collected:**
  - **Y**
  - **Y**
  - **Y**
  - **Y**
  - **e.g. 01/JUN/2018**

- **Methicillin-resistant Staphylococcus aureus isolated or detected:**
  - **Yes**
  - **No**
  - **Skip to VRE isolated or detected**
  - **Date first positive specimen collected:**
  - **Y**
  - **Y**
  - **Y**
  - **Y**
  - **e.g. 01/JUN/2018**

- **Vancomycin-resistant Enterococcus isolated or detected:**
  - **Yes**
  - **No**
  - **Skip to ESBL isolated or detected**
  - **Date first positive specimen collected:**
  - **Y**
  - **Y**
  - **Y**
  - **Y**
  - **e.g. 01/JUN/2018**

- **Extended- Spectrum Beta-Lactamases producing Escherichia coli and/or Klebsiella spp isolated or detected:**
  - **Yes**
  - **No**
  - **Skip to CRE/CPE isolated or detected**
  - **Date first positive specimen collected:**
  - **Y**
  - **Y**
  - **Y**
  - **Y**
  - **e.g. 01/JUN/2018**

- **Carbapenem-resistant gram-negative organism isolated or detected:**
  - **Yes**
  - **No**
  - **Skip to MRSA isolated or detected**
  - **Date first positive specimen collected:**
  - **Y**
  - **Y**
  - **Y**
  - **Y**
  - **e.g. 01/JUN/2018**

**MACROLIDE DURATION DOMAIN**

**7.0 DOMAIN SECONDARY OUTCOMES**

(Censored at hospital discharge)

- **Documented serious ventricular arrhythmia:**
  - **Yes**
  - **No**
  - **Date & time of serious ventricular arrhythmia:**
  - **Y**
  - **Y**
  - **Y**
  - **Y**
  - **24 hour clock**
  - **e.g. 01/JUN/2018**
  - **e.g. 8:05pm = 20:05 hours**

- **Patient died while not on continuous cardiac monitoring:**
  - **Yes**
  - **No**
  - **Death was unexpected and sudden:**
  - **Yes**
  - **No**

**CORTICOSTEROID DOMAIN**

**8.0 ETOMIDATE ADMINISTRATION**

(Censored at the end of Day 8)

- **Etidamate administered between randomisation in the Corticosteroid domain and the end of study day 8:**
  - **Yes**
  - **No**
ANTICOAGULATION / ANTIPLATELET

9.0 DOMAIN-SPECIFIC ENDPOINTS

(Censored at hospital discharge)

If a patient is randomised into the Therapeutic Anticoagulation and Immunoglobulin domains at two different timepoints additional peak troponin tests, major bleeding episodes and RBC transfusion episodes can be added in the supplementary form and the eCRF.

Peak troponin-test method: between first randomisation and hospital discharge

Test: (check one)
- High sensitivity Troponin T
- High sensitivity Troponin I
- Troponin T
- Troponin I

Result:
- ng/L or pg/mL
- Not recorded

Upper reference limit (99th percentile):
- ng/L or pg/mL
- Not recorded

Major bleeding: Y Yes N No

Date & time of major bleeding event:
- between first randomisation and 15 days after last randomisation

Only required for patients randomised to V3 anticoagulation domain (and antiplatelet going forward)

Which one or more of these criteria were met: (check all that apply)
- Fatal bleeding
- Symptomatic or clinically manifest bleeding in a critical area or organ
- Blood loss causing a fall in haemoglobin ≥ 2 g/dL
- Blood loss leading to transfusion of ≥ 2 units of red cells or whole blood

Major bleeding description of event(s):

Number of units of red blood cells transfused:
- between first randomisation and end of study day 15

Clinically diagnosed acute myocardial infarction:
- Y Yes N No

Date & time of myocardial infarction:
- between first randomisation and hospital discharge

Confirmed deep vein thrombosis:
- Y Yes N No

Date & time of deep vein thrombosis:
- between first randomisation and hospital discharge
Confirmed pulmonary emboli:

- **Yes**
- **No**

Date & time of pulmonary emboli: between first randomisation and hospital discharge

Confirmed ischaemic stroke:

- **Yes**
- **No**

Date & time of ischaemic stroke: between first randomisation and hospital discharge

Other confirmed thrombotic event:

- **Mesenteric ischaemia**
- **Critical ischaemia of limb(s)**
- **Other**
- **None**

Date & time of thrombotic event: between first randomisation and hospital discharge

Only required for patients randomised to V3 anticoagulation domain (and antiplatelet going forward)

Therapeutic dose anticoagulation commenced for a new clinical indication: between randomisation and hospital discharge

- **Yes**
- **No**

Commencement date:

Indication: (check all that apply)

- Venous thromboembolism
- Arterial thromboembolism
- Atrial Fibrillation
- ECMO
- COVID-19 without venous or arterial thromboembolism
- RRT
- Other

Specify: ........................................................................................................
ACE2 RAS DOMAIN

10.0 DOMAIN-SPECIFIC ENDPOINTS

(Censored at hospital discharge)

Did the patient receive renal replacement therapy: Yes No
between randomisation to ACE2 domain and hospital discharge

Did the patient develop angioedema: Yes No
between randomisation to ACE2 domain and end of study day 12

Was treatment for angioedema instituted: Yes No
If ‘No intervention’ is selected, other options don’t apply
- No intervention
- Ceased ACEi administration
- Initiation of new treatment for angioedema

Peak creatinine in first 7 days after randomisation:
between randomisation and 168h after randomisation to ACE2 domain

- [μmol/L]
- [mg/dL]
- Not recorded

Between randomisation and 336h after randomisation to ACE2 domain:

Peak creatinine in first 14 days after randomisation:

- [μmol/L]
- [mg/dL]
- Not recorded

Peak ALT in first 14 days after randomisation:

- [IU/L]
- Not recorded

Peak AST in first 14 days after randomisation:

- [IU/L]
- Not recorded

Peak bilirubin in first 14 days after randomisation:

- [μmol/L]
- [mg/dL]
- Not recorded

Clinically relevant hypotension while admitted to a ward: Yes No
between randomisation and 336h after randomisation to ACE2 domain while not in ICU

VENTILATION DOMAIN

10.0 DOMAIN-SPECIFIC ENDPOINTS

(Censored at hospital discharge)

Date and time of first successful unassisted breathing:

- [D D M M Y Y Y Y]
e.g. 01/JUN/2018
- [H H]
e.g. 8:05pm = 20:05

- Not applicable

Was one or more intercostal catheter inserted for barotrauma: Yes No
between randomisation to ventilation domain and end of invasive mechanical ventilation
## PLATFORM

### 1.0 AGREEMENT EVENT

(At any time in accordance with your regions ethical requirements)

Who was approached to provide agreement:

- [ ] Professional legal representative
- [ ] Personal legal representative
- [ ] Patient  
  → Skip to Section 2.0 Patient agreement event

**Date & time approached:**

<table>
<thead>
<tr>
<th>Day</th>
<th>Month</th>
<th>Year</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Date & time of agreement decision:**

<table>
<thead>
<tr>
<th>Day</th>
<th>Month</th>
<th>Year</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Agreement decision:**

- [ ] A Agreement
- [ ] D Declined
- [ ] N No outcome
- [ ] N Not applicable

### Antibiotic Domain Outcome:

- (check one)

### Macrolide Duration Domain Outcome:

- (check one)

### Corticosteroid Domain Outcome:

- (check one)

### Antiviral Domain Outcome:

- (check one)

### COVID-19 Antiviral Domain Outcome:

- (check one)

### COVID-19 Immune Mod Domain Outcome:

- (check one)

### Immunoglobulin Domain Outcome:

- (check one)

### Anticoagulation Domain Outcome:

- (check one)

### Vitamin C Domain Outcome:

- (check one)

### Simvastatin Domain Outcome:

- (check one)

### Antiplatelet Domain Outcome:

- (check one)

### ACE2 RAS Domain Outcome:

- (check one)

### Ventilation Domain Outcome:

- (check one)

### Permission to use data from the patient’s medical record:

- (check one)

**IF DECLINED ANY OF THE ABOVE**

- Reason for non-agreement:

  ........................................................................................................
  [ ] N Not applicable
## 1.0 AGREEMENT EVENT

(At any time in accordance with your region's ethical requirements)

<table>
<thead>
<tr>
<th>Did the personal legal representative provide agreement: (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y Yes</td>
</tr>
</tbody>
</table>

### Date & time approached:

- **D** Day
- **M** Month
- **Y** Year

**Example:**

- *01/JUN/2018*
- *8:05pm = 20:05 hours*

### Date & time of agreement decision:

- **D** Day
- **M** Month
- **Y** Year

**Example:**

- *01/JUN/2018*
- *8:05pm = 20:05 hours*

### Agreement decision:

<table>
<thead>
<tr>
<th>Antibiotic Domain Outcome: (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Agreement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Macrolide Duration Domain Outcome: (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Agreement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Corticosteroid Domain Outcome: (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Agreement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Antiviral Domain Outcome: (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Agreement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COVID-19 Antiviral Domain Outcome: (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Agreement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COVID-19 Immune Mod Domain Outcome: (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Agreement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Immunoglobulin Domain Outcome: (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Agreement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anticoagulation Domain Outcome: (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Agreement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vitamin C Domain Outcome: (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Agreement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Simvastatin Domain Outcome: (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Agreement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Antiplatelet Domain Outcome: (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Agreement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ACE2 RAS Domain Outcome: (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Agreement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ventilation Domain Outcome: (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Agreement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Permission to use data from the patient’s medical record: (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Agreement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Permission to contact the patient to complete the follow-up questionnaires: (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Agreement</td>
</tr>
</tbody>
</table>

**IF DECLINED ANY OF THE ABOVE**

- Reason for non-agreement: ____________________________________________  N Not applicable
# PLATFORM

## 2.0 PATIENT AGREEMENT EVENT

(At any time in accordance with your regions ethical requirements)

<table>
<thead>
<tr>
<th>Was the patient capable of providing agreement during this hospital admission:</th>
<th>Y Yes</th>
<th>N No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the patient approached to provide agreement:</td>
<td>Y Yes</td>
<td>N No</td>
</tr>
<tr>
<td>IF NO Reason not approached:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IF YES Date &amp; time approached:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date &amp; time of agreement decision:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agreement decision:</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Antibiotic Domain Outcome:</strong></td>
<td>A Agreement</td>
<td>D Declined</td>
</tr>
<tr>
<td><strong>(check one)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Macrolide Duration Domain Outcome:</strong></td>
<td>A Agreement</td>
<td>D Declined</td>
</tr>
<tr>
<td><strong>(check one)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Corticosteroid Domain Outcome:</strong></td>
<td>A Agreement</td>
<td>D Declined</td>
</tr>
<tr>
<td><strong>(check one)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Antiviral Domain Outcome:</strong></td>
<td>A Agreement</td>
<td>D Declined</td>
</tr>
<tr>
<td><strong>(check one)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>COVID-19 Antiviral Domain Outcome:</strong></td>
<td>A Agreement</td>
<td>D Declined</td>
</tr>
<tr>
<td><strong>(check one)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>COVID-19 Immune Mod Domain Outcome:</strong></td>
<td>A Agreement</td>
<td>D Declined</td>
</tr>
<tr>
<td><strong>(check one)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Immunoglobulin Domain Outcome:</strong></td>
<td>A Agreement</td>
<td>D Declined</td>
</tr>
<tr>
<td><strong>(check one)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Anticoagulation Domain Outcome:</strong></td>
<td>A Agreement</td>
<td>D Declined</td>
</tr>
<tr>
<td><strong>(check one)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Vitamin C Domain Outcome:</strong></td>
<td>A Agreement</td>
<td>D Declined</td>
</tr>
<tr>
<td><strong>(check one)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Simvastatin Domain Outcome:</strong></td>
<td>A Agreement</td>
<td>D Declined</td>
</tr>
<tr>
<td><strong>(check one)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Antiplatelet Domain Outcome:</strong></td>
<td>A Agreement</td>
<td>D Declined</td>
</tr>
<tr>
<td><strong>(check one)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ACE2 RAS Domain Outcome:</strong></td>
<td>A Agreement</td>
<td>D Declined</td>
</tr>
<tr>
<td><strong>(check one)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ventilation Domain Outcome:</strong></td>
<td>A Agreement</td>
<td>D Declined</td>
</tr>
<tr>
<td><strong>(check one)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Permission to use data from the patient’s medical record:</strong></td>
<td>A Agreement</td>
<td>D Declined</td>
</tr>
<tr>
<td><strong>(check one)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Permission to contact the patient to complete the follow-up questionnaires:</strong></td>
<td>A Agreement</td>
<td>D Declined</td>
</tr>
<tr>
<td><strong>(check one)</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IF DECLINED ANY OF THE ABOVE

Reason for non-agreement: 

---

© UK REMAP-CAP Case Report Form 7, V10 dated 20210510
# Consented Study From

## PLATFORM

### 3.0 AGREEMENT REVOKED

(At any time in accordance with your regions ethical requirements)

<table>
<thead>
<tr>
<th>Date agreement revoked:</th>
<th>D D / M M / Y Y Y Y e.g. 01/JUN/2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agreement revoked by:</td>
<td></td>
</tr>
<tr>
<td>Professional legal representative</td>
<td>R Revoked</td>
</tr>
<tr>
<td>Personal legal representative</td>
<td>R Revoked</td>
</tr>
<tr>
<td>Patient</td>
<td>R Revoked</td>
</tr>
</tbody>
</table>

**Revoke decision:**

- **Antibiotic Domain Outcome:**
  - (check one)
  - R Revoked | N No change

- **Macrolide Duration Domain Outcome:**
  - (check one)
  - R Revoked | N No change

- **Corticosteroid Domain Outcome:**
  - (check one)
  - R Revoked | N No change

- **Antiviral Domain Outcome:**
  - (check one)
  - R Revoked | N No change

- **COVID-19 Antiviral Domain Outcome:**
  - (check one)
  - R Revoked | N No change

- **COVID-19 Immune Mod Domain Outcome:**
  - (check one)
  - R Revoked | N No change

- **Immunoglobulin Domain Outcome:**
  - (check one)
  - R Revoked | N No change

- **Anticoagulation Domain Outcome:**
  - (check one)
  - R Revoked | N No change

- **Vitamin C Domain Outcome:**
  - (check one)
  - R Revoked | N No change

- **Simvastatin Domain Outcome:**
  - (check one)
  - R Revoked | N No change

- **Antiplatelet Domain Outcome:**
  - (check one)
  - R Revoked | N No change

- **ACE2 RAS Domain Outcome:**
  - (check one)
  - R Revoked | N No change

- **Ventilation Domain Outcome:**
  - (check one)
  - R Revoked | N No change

- **Permission to use data from the patient’s medical record:**
  - (check one)
  - R Revoked | N No change

- **Permission to contact the patient to complete the follow-up questionnaires:**
  - (check one)
  - R Revoked | N No change

**Reason agreement revoked:**

........................................................................................................................................ N Not applicable

---

**END OF CONSENT CRF**
PLATEFORM (PANDEMIC ONLY)

1.0 PATIENT STATUS

(Only complete for patients randomised to one of the COVID-19 Domains. Can only be completed from the end of study day 22 onwards)

Assessment date: [D D / M M / Y Y Y Y] e.g. 18/JUL/2018

ICU status:

☐ Still in ICU  ☐ Discharged from ICU  ☐ Never admitted to ICU

If discharged from ICU enter details in Form 6 – Discharge.

Was the patient discharged and readmitted to ICU prior to the end of study day 22:

☐ Yes  ☐ No

Please enter date and time of any admission to and discharge from ICU into Form 6 – Discharge.

Hospital status:

☐ Still in hospital  ☐ Discharged from hospital

If discharged from hospital enter details in Form 6 – Discharge.

END OF D21 CRF
**PLATFORM**

### 1.0 VITAL STATUS

**Assessment date:** 
D D / M M / Y Y Y Y e.g. 18/JUL/2018

**Status:**
- **A** Alive
- **D** Deceased
- **U** Unable to ascertain

**IF DECEASED**

**Date of death:** 
D D / M M / Y Y Y Y e.g. 18/JUL/2018

**IF UNABLE TO ASERTAIN**

**Date last known alive:** 
D D / M M / Y Y Y Y e.g. 18/JUL/2018

### SOURCE DOCUMENT

**Source:**
- **M** Medical Record
- **P** Phone call
- **O** Other

**Follow-up completed by:**  
________________________________________

**Signature:**  
________________________________________
### PLATFORM

#### 1.0 VITAL STATUS

**Assessment date:**

\[DD/MM/YY\] e.g. 18/JUL/2018

**Status:**

- **A** Alive
- **D** Deceased
- **U** Unable to ascertain

**Location on study day 180:**

- Home
- Nursing home or long-term care facility
- Rehabilitation hospital
- Acute care hospital
- Hospital ICU
- Other, specify

**Date of death:**

\[DD/MM/YY\] e.g. 18/JUL/2018

**Date last known alive:**

\[DD/MM/YY\] e.g. 18/JUL/2018

**Additional information:**

________________________________________________________________________

________________________________________________________________________

#### 2.0 SOURCE DOCUMENT

**Source:**

- **M** Medical Record
- **P** Phone call
- **O** Other

**Follow-up completed by:**

________________________________________________________________________

**Signature:**

________________________________________________________________________
## PLATFORM FOLLOW-UP QUESTIONNAIRES

### 2.0 D180 SURVEYS

**Were any of the survey tools completed:**
- Yes
- No  
  >>> Skip to date completed

**Reason unable to proceed:**
- Unable to contact patient or suitable proxy
- Language or competence barrier
- Declined to answer subsequent questions
- Other, specify ____________________________

**Date completed:**
- D M M Y Y Y Y
  >>> e.g. 18/JUL/2018

- Same date as Assessment date

**Person interviewed:**
- Patient
- Proxy

**IF PROXY Do they live with the patient:**
- Yes
- No

### 3.0 EQ5D-5L

**Was the EQ5D-5L completed:**
- Yes
- No

---

**Please select ONE option that best describes the patients health TODAY**

**Mobility:**
- (check one)
  - I have no problems with walking around
  - I have slight problems with walking around
  - I have moderate problems with walking around
  - I have severe problems with walking around
  - I am unable to walk around

**Personal care:**
- (check one)
  - I have no problems with washing or dressing myself
  - I have slight problems with washing or dressing myself
  - I have moderate problems with washing or dressing myself
  - I have severe problems with washing or dressing myself
  - I am unable to wash or dress myself

**Usual activities**
- (check one)
  - I have no problems doing my usual activities
  - I have slight problems doing my usual activities
  - I have moderate problems doing my usual activities
  - I have severe problems doing my usual activities
  - I am unable to do my usual activities
Please select ONE option that best describes the patient's health TODAY

<table>
<thead>
<tr>
<th>Pain/discomfort (check one)</th>
<th>Health today scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ I have no pain or discomfort</td>
<td>The best health you can imagine</td>
</tr>
<tr>
<td>☐ I have slight pain or discomfort</td>
<td>100</td>
</tr>
<tr>
<td>☐ I have moderate pain or discomfort</td>
<td>95</td>
</tr>
<tr>
<td>☐ I have severe pain or discomfort</td>
<td>90</td>
</tr>
<tr>
<td>☐ I am extreme pain or discomfort</td>
<td>85</td>
</tr>
</tbody>
</table>

| Anxiety/depression: (check one) | | |
|---------------------------------|-----------------|
| ☐ I am not anxious or depressed | The worst health you can imagine |
| ☐ I am slightly anxious or depressed | 80 |
| ☐ I am moderately anxious or depressed | 75 |
| ☐ I am severely anxious or depressed | 70 |
| ☐ I am extremely anxious or depressed | 65 |

We would like to know how good or bad your health is TODAY:
- On a scale from 0 to 100
- 100 means the BEST health you can imagine
- 0 means the WORST health you can imagine
- Mark an X on the scale to indicate how your health is TODAY
- Now, please write the number you marked on the scale in the box below

YOUR HEALTH TODAY: [ ] [ ] [ ]
### 4.0 WHODAS 2.0

**Was the WHODAS Completed:**
- Yes
- No

**How many years in all did you spend studying in school, college or university:**

- [ ] years

**What is your current marital status:**
- [ ] Never married
- [ ] Separated
- [ ] Divorced
- [ ] Currently married
- [ ] Widowed
- [ ] Cohabiting

**Which describes your main work status best:**
- [ ] Paid work
- [ ] Student
- [ ] Keeping house/homemaker
- [ ] Unemployed (health reason)
- [ ] Unemployed (other reason)
- [ ] Self-employed
- [ ] Non-paid work
- [ ] Retired
- [ ] Other, specify ________________

**In the past 30 days, how much difficulty did you have doing the following activities:**

<table>
<thead>
<tr>
<th>Activity</th>
<th>NONE</th>
<th>MILD</th>
<th>MODERATE</th>
<th>SEVERE</th>
<th>EXTREME OR CANNOT DO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standing for long periods such as 30 minutes?</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Taking care of your household responsibilities?</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Learning a new task, for example learning how to get to a new place?</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>How much of a problem did you have joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>How much have you been emotionally affected by your health problems?</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

**In the past 30 days, how much difficulty did you have in:**

<table>
<thead>
<tr>
<th>Activity</th>
<th>NONE</th>
<th>MILD</th>
<th>MODERATE</th>
<th>SEVERE</th>
<th>EXTREME OR CANNOT DO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentrating on doing something for ten minutes?</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Walking a long distance such as a kilometre?</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Or equivalent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Washing your whole body?</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Getting dressed?</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Dealing with people you do not know?</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Maintaining a friendship?</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Your day-to-day work/school?</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>
Overall, in the past 30 days, how many days were these difficulties present?  

In the past 30 days, for how many days were you totally unable to carry out your usual activities or work because of any health condition?  

In the past 30 days, not counting the days that you were totally unable, for how many days did you cut back or reduce your usual activities or work because of any health condition?

5.0 BASELINE  

Before your ICU admission which describes your main work status best? 

- Paid work  
- Self-employed  
- Non-paid work  
- Student  
- Keeping house/homemaker  
- Retired  
- Unemployed (health reason)  
- Unemployed (other reason)  
- Other, please specify ________________________________

In the month before your ICU admission were you receiving any treatment for anxiety or depression?  

6.0 ETHICS  

When you were admitted to the Intensive Care Unit, you were signed up to take part in REMAP-CAP  
The following questions will help us understand your views on the way we signed you up to the REMAP-CAP study  

As you were unable to make a decision yourself about taking part, a relative or someone similar made that decision for you  

If you had been able to give consent yourself before we signed you up to the study, would you have agreed to participate in the trial?  

- Yes  
- No  
- Unsure  
- Prefer not to answer  
- Not applicable

Prior to the hospital admission had you ever discussed your participation in research with the person who made the decision for you to participate in the trial?  

- Yes  
- No  
- Unsure  
- Prefer not to answer  
- Not applicable

Imagine this study had happened during a public health emergency, such as a severe flu outbreak  

How acceptable would it be to you if a doctor not involved in the study gave consent for you to be included in the trial instead of a family member?  

- Acceptable  
- Not acceptable  
- Unsure  
- Prefer not to answer
# PLATFORM

## 1.0 ADVERSE EVENT

<table>
<thead>
<tr>
<th>Event: (Textbox)</th>
<th>Participation: (Enter all that apply)</th>
<th>AE onset date: (code)</th>
<th>Action taken (code)</th>
<th>Outcome (code)</th>
<th>Relationship to treatment (code)</th>
<th>AE resolution date: (If AE persisting or the outcome is unknown leave blank)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>MM/MM/YY/YY/YY</td>
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</tbody>
</table>

## CODES

- **Participation:**
  - P = Immunoglobulin Domain
  - A = Antibiotic Domain
  - M = Macroide Duration Domain
  - C = Corticosteroid Domain
  - I = Antiviral Domain
  - X = COVID-19 Antiviral Domain
  - Y = COVID-19 Immune Mod Domain

- **Action taken:**
  - 1 = None
  - 2 = Treatment modified or temporarily discontinued
  - 3 = Treatment permanently discontinued

- **Outcome:**
  - 1 = Unknown / Lost to follow-up
  - 2 = Unresolved
  - 3 = Resolved
  - 4 = Resolved with sequelae

- **Relationship to treatment:**
  - 1 = Not related
  - 2 = Unlikely
  - 3 = Possible
  - 4 = Probably
  - 5 = Definitely
# Form 12
---
## Serious Adverse Event

### PLATFORM

#### 1.0 SERIOUS ADVERSE EVENT DETAILS

(Censored at hospital discharge)

<table>
<thead>
<tr>
<th>Report type:</th>
<th>Initial report</th>
<th>Follow-up report</th>
<th>Final report</th>
</tr>
</thead>
</table>

**Diagnosis:**

- [ ] Congenital anomaly
- [ ] Permanently disabled
- [ ] Death
- [ ] Prolongation of (current) hospitalisation or re-hospitalisation
- [ ] Life threatening
- [ ] Medically important

**SAE type:**

(check one)

- [ ] [ ]

**SAE description:**

(check all that apply)

### Suspected intervention:

(check all that apply)

- [G] General participation
- [A] Antibiotic
- [M] Macrolide
- [C] Corticosteroid
- [T] Antiviral
- [S] COVID-19 Antiviral
- [Y] COVID-19 Immune modulation therapy
- [D] Immunoglobulin
- [H] Anticoagulation
- [L] Vitamin C
- [R] Simvastatin
- [B] Antiplatelet
- [V] ACE2 RAS
- [R] Ventilation

**Is this event a SUSAR:**

- [ ] Yes
- [ ] No

Only required if the patient is allocated to the ARB + DMX-200 intervention in the ACE2 RAS Domain

### (If Antibiotic Domain)

#### Suspected relationship:

(check one)

- [ ] Not related to intervention/participation
- [ ] Unlikely to be related to intervention/participation
- [ ] Possibly related to intervention/participation
- [ ] Probably related to intervention/participation
- [ ] Definitely related to intervention/participation

### (If Macrolide Duration Domain)

#### Suspected relationship:

(check one)

- [ ] Not related to intervention/participation
- [ ] Unlikely to be related to intervention/participation
- [ ] Possibly related to intervention/participation
- [ ] Probably related to intervention/participation
- [ ] Definitely related to intervention/participation

### (If Corticosteroid Domain)

#### Suspected relationship:

(check one)

- [ ] Not related to intervention/participation
- [ ] Unlikely to be related to intervention/participation
- [ ] Possibly related to intervention/participation
- [ ] Probably related to intervention/participation
- [ ] Definitely related to intervention/participation
1.0 SERIOUS ADVERSE EVENT DETAILS

(IF ANTIVIRAL DOMAIN)

Suspected relationship:
(check one)

☐ Not related to intervention/participation
☐ Unlikely to be related to intervention/participation
☐ Possibly related to intervention/participation
☐ Probably related to intervention/participation
☐ Definitely related to intervention/participation

(IF COVID-19 ANTIVIRAL DOMAIN)

Suspected relationship:
(check one)

☐ Not related to intervention/participation
☐ Unlikely to be related to intervention/participation
☐ Possibly related to intervention/participation
☐ Probably related to intervention/participation
☐ Definitely related to intervention/participation

(IF COVID-19 IMMUNE MODULATION THERAPY DOMAIN)

Suspected relationship:
(check one)

☐ Not related to intervention/participation
☐ Unlikely to be related to intervention/participation
☐ Possibly related to intervention/participation
☐ Probably related to intervention/participation
☐ Definitely related to intervention/participation

(IF IMMUNOGLOBULIN DOMAIN)

Suspected relationship:
(check one)

☐ Not related to intervention/participation
☐ Unlikely to be related to intervention/participation
☐ Possibly related to intervention/participation
☐ Probably related to intervention/participation
☐ Definitely related to intervention/participation

(IF ANTICOAGULATION DOMAIN)

Suspected relationship:
(check one)

☐ Not related to intervention/participation
☐ Unlikely to be related to intervention/participation
☐ Possibly related to intervention/participation
☐ Probably related to intervention/participation
☐ Definitely related to intervention/participation

(IF VITAMIN C DOMAIN)

Suspected relationship:
(check one)

☐ Not related to intervention/participation
☐ Unlikely to be related to intervention/participation
☐ Possibly related to intervention/participation
☐ Probably related to intervention/participation
☐ Definitely related to intervention/participation

(Censored at hospital discharge)
1.0 SERIOUS ADVERSE EVENT DETAILS

**PLATFORM**

**IF SIMVASTATIN DOMAIN**

- Suspected relationship: (check one)
  - Unlikely to be related to intervention/participation
  - Possibly related to intervention/participation
  - Probably related to intervention/participation
  - Definitely related to intervention/participation

**IF ANTIPLATELET DOMAIN**

- Suspected relationship: (check one)
  - Unlikely to be related to intervention/participation
  - Possibly related to intervention/participation
  - Probably related to intervention/participation
  - Definitely related to intervention/participation

**IF ACE2 RAS DOMAIN**

- Suspected relationship: (check one)
  - Unlikely to be related to intervention/participation
  - Possibly related to intervention/participation
  - Probably related to intervention/participation
  - Definitely related to intervention/participation

**IF VENTILATION DOMAIN**

- Suspected relationship: (check one)
  - Unlikely to be related to intervention/participation
  - Possibly related to intervention/participation
  - Probably related to intervention/participation
  - Definitely related to intervention/participation

Onset date: D D / M M / Y Y Y Y e.g. 18/JUL/2018
2.0 ACTION TAKEN

**IF TEMPORARILY OR PERMANENTLY DISCONTINUED VITAMIN C**

- **Date & time intervention started:**
  - D D M M M Y Y Y Y
  - e.g. 18/JUL/2018
  - **H H:** M M
  - 24 hour clock
  - e.g. 8:05pm = 20:05 hours

- **Date & time intervention stopped:**
  - D D M M M Y Y Y Y
  - e.g. 18/JUL/2018
  - **H H:** M M
  - 24 hour clock
  - e.g. 8:05pm = 20:05 hours

**IF TEMPORARILY OR PERMANENTLY DISCONTINUED SIMVASTATIN**

- **Date & time intervention started:**
  - D D M M M Y Y Y Y
  - e.g. 18/JUL/2018
  - **H H:** M M
  - 24 hour clock
  - e.g. 8:05pm = 20:05 hours

- **Date & time intervention stopped:**
  - D D M M M Y Y Y Y
  - e.g. 18/JUL/2018
  - **H H:** M M
  - 24 hour clock
  - e.g. 8:05pm = 20:05 hours

**IF TEMPORARILY OR PERMANENTLY DISCONTINUED ANTIPLATELET**

- **Date & time intervention started:**
  - D D M M M Y Y Y Y
  - e.g. 18/JUL/2018
  - **H H:** M M
  - 24 hour clock
  - e.g. 8:05pm = 20:05 hours

- **Date & time intervention stopped:**
  - D D M M M Y Y Y Y
  - e.g. 18/JUL/2018
  - **H H:** M M
  - 24 hour clock
  - e.g. 8:05pm = 20:05 hours

**IF TEMPORARILY OR PERMANENTLY DISCONTINUED ACE2 RAS**

- **Date & time intervention started:**
  - D D M M M Y Y Y Y
  - e.g. 18/JUL/2018
  - **H H:** M M
  - 24 hour clock
  - e.g. 8:05pm = 20:05 hours

- **Date & time intervention stopped:**
  - D D M M M Y Y Y Y
  - e.g. 18/JUL/2018
  - **H H:** M M
  - 24 hour clock
  - e.g. 8:05pm = 20:05 hours

**IF TEMPORARILY OR PERMANENTLY DISCONTINUED VENTILATION**

- **Date & time intervention started:**
  - D D M M M Y Y Y Y
  - e.g. 18/JUL/2018
  - **H H:** M M
  - 24 hour clock
  - e.g. 8:05pm = 20:05 hours

- **Date & time intervention stopped:**
  - D D M M M Y Y Y Y
  - e.g. 18/JUL/2018
  - **H H:** M M
  - 24 hour clock
  - e.g. 8:05pm = 20:05 hours

Treatment: 

<table>
<thead>
<tr>
<th>Date &amp; time intervention started</th>
<th>Date &amp; time intervention stopped</th>
</tr>
</thead>
<tbody>
<tr>
<td>D D M M Y Y Y Y</td>
<td>D D M M Y Y Y Y</td>
</tr>
<tr>
<td>e.g. 18/JUL/2018</td>
<td>e.g. 18/JUL/2018</td>
</tr>
<tr>
<td><strong>H H:</strong> M M</td>
<td><strong>H H:</strong> M M</td>
</tr>
<tr>
<td>24 hour clock</td>
<td>24 hour clock</td>
</tr>
</tbody>
</table>

**e.g. 8:05pm = 20:05 hours**
### 3.0 OUTCOME

*Note: Follow-up SAE until resolved*

<table>
<thead>
<tr>
<th>Outcome: (check one)</th>
<th>Unknown/lost to follow-up</th>
<th>Resolved with sequelae</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unresolved</td>
<td>Death</td>
</tr>
<tr>
<td></td>
<td>Resolved</td>
<td></td>
</tr>
</tbody>
</table>

**IF RESOLVED**

- Resolution date: 
  - D D / M M / Y Y Y Y e.g. 18/Jul/2018

**IF RESOLVED WITH SEQUELAE**

- Resolution date: 
  - D D / M M / Y Y Y Y e.g. 18/Jul/2018

**IF DEATH**

- Date of death: 
  - D D / M M / Y Y Y Y e.g. 18/Jul/2018

- Cause: 

- Location: 
  - ICU
  - Ward
  - Other acute hospital
  - Rehabilitation hospital
  - Nursing home or Long-term care facility
  - Home

- Autopsy: 
  - Yes
  - No

  **IF YES**

- Report emailed: 
  - Yes
  - No
**PLATFORM**

### 1.0 PROTOCOL DEVIATION

*(Censored at ICU discharge)*

**Deviation date:**

**Platform eligibility deviation:**

- [ ] Patient was not an adult in your jurisdiction
- [ ] Patient is a resident of a nursing home or long-term care facility
- [ ] Patient was an inpatient in a healthcare facility within the last 30 days
- [ ] Patient was hospitalised for 48 hours or longer prior to ICU admission
- [ ] Community-acquired pneumonia was not the primary diagnosis at randomisation
- [ ] Influenza was incorrectly entered as suspected or confirmed at time of randomisation
- [ ] Patient was not receiving the required organ support at randomisation
- [ ] Death was deemed to be imminent and inevitable
- [ ] Patient was randomised in REMAP-CAP in the previous 90 days
- [ ] Other, specify ________________________________

**Reason:**

______________________________________________________________

______________________________________________________________

**What were the consequences or actions taken:**

______________________________________________________________

______________________________________________________________

**ANTIBIOTIC DOMAIN**

### 2.0 PROTOCOL DOMAIN-SPECIFIC DEVIATION

*(Censored at ICU discharge)*

**Deviation date:**

**Deviation type:**

- [ ] Randomised but ineligible
- [ ] Allocated study antibiotic not administered as per protocol
- [ ] Received prohibited empiric antibiotic therapy
- [ ] Other, specify ________________________________

**IF RANDOMISED BUT INELIGIBLE**

- [ ] Patient received IV antibiotics for more than 48 hours prior to randomisation
- [ ] Patient was in ICU for more than 24 hours prior to randomisation
- [ ] Patient had a known contraindication at the time of randomisation
- [ ] Standard empiric antibiotic therapy was known to be inappropriate at time of randomisation
- [ ] Other, specify ________________________________

**IF ALLOCATED STUDY ANTIBIOTIC NOT ADMINISTERED AS PER PROTOCOL**

- [ ] Allocated study antibiotic not available
- [ ] Allocated study antibiotic not prescribed
- [ ] Other, specify ________________________________
**MACROLIDE DURATION DOMAIN**

**3.0 PROTOCOL DOMAIN-SPECIFIC DEVIATION** (Censored at ICU discharge)

**Deviation date:**

**Deviation type:**
- Randomised but ineligible
- Incorrect duration of macrolide therapy
- Received prohibited macrolide therapy
- Other, specify

**IF RANDOMISED BUT INELIGIBLE**
- Specify:
  - Patient had a known contraindication at the time of randomisation
  - Patient was not allocated to a beta-lactam in the Antibiotic Domain
  - Other, specify

**IF INCORRECT DURATION OF MACROLIDE THERAPY**
- Specify:
  - Allocated to standard duration and received less than 3 days
  - Allocated to standard duration and received a macrolide on study day 6
  - Allocated to extended duration and received less than 14 days (censored at ICU discharge)
  - Allocated to extended duration and received more than 14 days
  - Other, specify

**IF RECEIVED PROHIBITED MACROLIDE THERAPY**
- Specify:
  - Protocol macrolide not available
  - Other, specify

**Reason:**

**What were the consequences or actions taken:**
## Protocol Deviation

### CORTICOSTEROID DOMAIN

**4.0 PROTOCOL DOMAIN-SPECIFIC DEVIATION**

(Censored at ICU discharge)

<table>
<thead>
<tr>
<th>Deviation date:</th>
<th>D D M M Y Y Y</th>
<th>e.g. 18/JUL/2018</th>
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<tbody>
<tr>
<td>Deviation type: (check one)</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>R</td>
<td>Randomised but ineligible</td>
</tr>
<tr>
<td></td>
<td>A</td>
<td>Intervention not administered as per protocol</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>Another corticosteroid was administered</td>
</tr>
<tr>
<td></td>
<td>O</td>
<td>Other, specify</td>
</tr>
</tbody>
</table>

**IF RANDOMISED BUT INELIGIBLE**

Specify: (check one)

| | |
| | Systemic corticosteroids required for a known indication other than CAP at time of randomisation |
| | Patient had a known contraindication at the time of randomisation |
| | Other, specify |

**IF INTERVENTION NOT ADMINISTERED AS PER PROTOCOL**

Specify: (check one)

| | |
| | Hydrocortisone not available |
| | Incorrect dose administered |
| | Incorrect frequency administered |
| | Remaining course of hydrocortisone not prescribed at ICU discharge |
| | Received hydrocortisone when they should not have |
| | Did not receive hydrocortisone when they should have |
| | Other, specify |

**Reason:**

| | |
| | |
| | |

**What were the consequences or actions taken:**

| | |
| | |
| | |

Participant Study Number

Patient Initials
## ANTIVIRAL DOMAIN

### 4.0 PROTOCOL DOMAIN-SPECIFIC DEVIATION

**Deviation date:**
```
DD/MM/YY
```

**Deviation type:**
- [R] Randomised but ineligible
- [A] Oseltamivir not administered as per protocol
- [C] Administration of another antiviral active against influenza
- [O] Other, specify

**IF RANDOMISED BUT INELIGIBLE**

Specify:
- [ ] Patient received two or more doses of Oseltamivir prior to randomisation
- [ ] There was an intention to prescribe an antiviral active against influenza other than Oseltamivir at the time of randomisation
- [ ] Patient had a known contraindication at the time of randomisation
- [ ] Other, specify

**IF OSELTAMIVIR NOT ADMINISTERED AS PER PROTOCOL**

Specify:
- [ ] Interruption of more than 36 hours within the course (for 5-day and 10-day intervention)
- [ ] Oseltamivir not available
- [ ] Incorrect duration of therapy administered (premature cessation or continuation beyond the specified time)
- [ ] Remaining course of Oseltamivir not prescribed at ICU discharge
- [ ] Other, specify

**IF ADMINISTRATION OF ANOTHER ANTIVIRAL ACTIVE AGAINST INFLUENZA**

Specify:
- [ ] Received Oseltamivir and another antiviral active against influenza
- [ ] Did not receive Oseltamivir and received a different antiviral active against influenza
- [ ] Other, specify

**Reason:**
```

```

**What were the consequences or actions taken:**
```

```
## COVID-19 ANTIVIRAL DOMAIN

### 5.0 PROTOCOL DOMAIN-SPECIFIC DEVIATION

(Censored at ICU discharge)

#### Deviation date:

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<tr>
<td>e.g. 18/Jul/2018</td>
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</table>

#### Deviation type:

- **R** Randomised but ineligible
- **A** Intervention not administered as per protocol
- **C** Received prohibited antiviral active against SARS-CoV-2
- **O** Other, specify  

If **RANDOMISED BUT INELIGIBLE**

Specify:  
- Microbiological testing for SARS-CoV-2 infection of upper or lower respiratory tract secretions not completed during hospital admission
- Patient was participant in a trial of antivirals intended to be active against COVID-19 where continuation of the study assignment was required
- At randomisation the patient had laboratory confirmed MERS-CoV infection
- Patient had a known contraindication at the time of randomisation
- Other, specify  

If **INTERVENTION NOT ADMINISTERED AS PER PROTOCOL**

Specify:  
- No administration of an allocated antiviral
- Incorrect dose administered
- Other, specify  

If **RECEIVED PROHIBITED ANTIVIRAL ACTIVE AGAINST SARS-COV-2**

Specify:  
- Patient was administered another antiviral not licensed for the treatment of COVID-19
- Other, specify  

Reason:

-  
-  
-  

What were the consequences or actions taken:

-  
-  
-  

## COVID-19 IMMUNE MODULATION THERAPY DOMAIN

### 6.0 PROTOCOL DOMAIN-SPECIFIC DEVIATION

**Deviation date:**

- **DD/MM/YY**
  - e.g. 18/JUL/2018

**Deviation type:**

- (check one)
  - R Randomised but ineligible
  - A Intervention not administered as per protocol
  - C Received prohibited immune modulation agent for COVID-19
  - O Other, specify

### IF RANDOMISED BUT INELIGIBLE

**Specify:**

- (check one)

  - Microbiological testing for SARS-CoV-2 infection of upper or lower respiratory tract secretions not completed during hospital admission
  - Patient was a participant in a trial of immune modulating drugs for COVID-19 where continuation of study assignment was required
  - Patient was receiving one of the agents included as interventions in this domain as a pre-hospitalisation usual medication
  - Patient had received one of the agents included as interventions in this domain during this hospitalisation
  - Patient had a known condition or was receiving treatment resulting in ongoing immune suppression at the time of randomisation
  - Patient had a known contraindication at the time of randomisation
  - Other, specify

### IF INTERVENTION NOT ADMINISTERED AS PER PROTOCOL

**Specify:**

- (check one)

  - No administration of an immune modulating agent intended to be active against SARS-CoV-2
  - Incorrect dose administered
  - Two or more sequential doses of Interferon beta-1a were missed
  - Two or more sequential doses of anakinra were missed
  - Two or more sequential doses of tocilizumab were missed
  - Two or more sequential doses of sarilumab were missed
  - Other, specify

### IF RECEIVED PROHIBITED IMMUNE MODULATION AGENT FOR COVID-19

**Specify:**

- (check one)

  - Patient was administered a non-assigned immune modulating agent for COVID-19
  - Other, specify

**Reason:**

- Specify

**What were the consequences or actions taken:**

- Specify
COVID-19 IMMUNOGLOBULIN DOMAIN

7.0 PROTOCOL DOMAIN-SPECIFIC DEVIATION

(Censored at ICU discharge)

Deviation date: D D M M M M Y Y Y (e.g. 18/JUL/2018)

Deviation type:
- R Randomised but ineligible
- A Intervention not administered as per protocol
- C Received prohibited antibody therapy
- O Other, specify

IF RANDOMISED BUT INELIGIBLE

 Specify: (check one)
- Patient did not have confirmed COVID-19 infection
- Patient had already received treatment with antibody therapy with the potential to be active against COVID-19 prior to randomisation
- Patient was a participant in a trial of antibody therapy intended to be active against COVID-19 where continuation of study assignment was required
- Patient had a known contraindication at the time of randomisation
- Other, specify

IF INTERVENTION NOT ADMINISTERED AS PER PROTOCOL

 Specify: (check one)
- No administration of convalescent plasma
- Incorrect dose administered
- Three or more units of convalescent plasma administered
- Two units of convalescent plasma administered within less than 12 hours of each other
- Incorrect convalescent plasma administered
- Allocated convalescent plasma not administered within 48 hours of randomisation
- Other, specify

IF RECEIVED PROHIBITED THERAPY

 Specify: (check one)
- Administered non-assigned convalescent plasma for COVID-19
- Other, specify

Reason: ________________________________________________________
---------------------------------------------------------------------
---------------------------------------------------------------------
---------------------------------------------------------------------

What were the consequences or actions taken:

---------------------------------------------------------------------
---------------------------------------------------------------------
---------------------------------------------------------------------
### COVID-19 ANTICOAGULATION DOMAIN

#### 8.0 PROTOCOL DOMAIN-SPECIFIC DEVIATION

(Censored at ICU discharge)

**Deviation date:**

- **DD/MM/YY** e.g. 18/Jul/2018

**Deviation type:**

- **R** Randomised but ineligible
- **A** Intervention not administered as per protocol
- **C** Received prohibited therapeutic anticoagulation
- **O** Other, specify _______________________________________________________________________

**IF RANDOMISED BUT INELIGIBLE**

Specify:

- **☐** Microbiological testing for SARS-CoV-2 infection of upper or lower respiratory tract secretions not completed during hospital admission
- **☐** Therapeutic anticoagulation already present at the time of randomisation
- **☐** Patient was a participant in a trial of therapeutic anticoagulation for COVID-19 where continuation of study assignment was required
- **☐** Patient had a known contraindication at the time of randomisation
- **☐** Other, specify _______________________________________________________________________

**IF INTERVENTION NOT ADMINISTERED AS PER PROTOCOL**

Specify:

- **☐** No administration of therapeutic anticoagulation
- **☐** Therapeutic anticoagulation ceased for more than 24 hours
- **☐** Local standard pharmacological thromboprophylaxis not administered
- **☐** Low dose or intermediate dose pharmacological thromboprophylaxis not administered
- **☐** Other, specify _______________________________________________________________________

**IF RECEIVED PROHIBITED THERAPY**

Specify:

- **☐** Administered non-assigned therapeutic anticoagulation
- **☐** New agent commenced that is active against platelet formation
- **☐** Other, specify _______________________________________________________________________

**Reason:**

__________________________________________________________________________________________

__________________________________________________________________________________________

__________________________________________________________________________________________

**What were the consequences or actions taken:**

__________________________________________________________________________________________

__________________________________________________________________________________________

__________________________________________________________________________________________
### VITAMIN C DOMAIN

#### 9.0 PROTOCOL DOMAIN-SPECIFIC DEVIATION

**Reason:** 

- Incorrect dose administered
- Missed two or more consecutive doses of vitamin C
- Missed more than a total of four doses of vitamin C
- Other, specify

---

### Deviation date:

- DD/MM/YY e.g. 18/JUL/2018

### Deviation type:

- R Randomised but ineligible
- A Intervention not administered as per protocol
- C Received prohibited therapy
- O Other, specify

**If RANDOMISED BUT INELIGIBLE**

- Specify:
  - Patient had received any IV vitamin C prior to randomisation during this hospitalisation
  - Patient was a participant in a trial of vitamin C where continuation of study assignment was required
  - Patient had a known contraindication at the time of randomisation
  - Other, specify

**If INTERVENTION NOT ADMINISTERED AS PER PROTOCOL**

- Specify:
  - No administration of vitamin C
  - Incorrect dose administered
  - Missed two or more consecutive doses of vitamin C
  - Missed more than a total of four doses of vitamin C
  - Other, specify

**If RECEIVED PROHIBITED THERAPY**

- Specify:
  - Administered non-assigned vitamin C
  - Other, specify
### COVID-19 SIMVASTATIN DOMAIN

#### 10.0 PROTOCOL DOMAIN-SPECIFIC DEVIATION

(Censored at ICU discharge)

**Deviation date:**

- **DD/MM/YY**
- **e.g. 18/Jul/2018**

**Deviation type: (check one)**

- **R** Randomised but ineligible
- **A** Intervention not administered as per protocol
- **C** Received prohibited therapy
- **O** Other, specify

**IF RANDOMISED BUT INELIGIBLE**

- **Specify: (check one)**
  - Known severe liver disease
  - Hypersensitivity to simvastatin
  - Creatinine more the 200 μmol/L (2.26 mg/dL) and not receiving renal replacement therapy
  - At the time of eligibility assessment was being treated with a medicine that could not be co-administered with simvastatin
  - At the time of eligibility assessment was being treated with a statin
  - Known to be pregnant or breastfeeding at the time of eligibility assessment
  - Other, specify

**IF INTERVENTION NOT ADMINISTERED AS PER PROTOCOL**

- **Specify: (check one)**
  - No administration of allocated simvastatin
  - Incorrect dose administered
  - Missed two or more consecutive doses of simvastatin
  - Other, specify

**IF RECEIVED PROHIBITED THERAPY**

- **Specify: (check one)**
  - Patient was administered a non-assigned statin for treatment of confirmed or suspected COVID-19
  - Patient allocated to simvastatin intervention and received lopinavir/ritonavir
  - Other, specify

**Reason:**

- Specify

**What were the consequences or actions taken:**

- Specify
# COVID-19 ANTIPLATELET DOMAIN

## 11.0 PROTOCOL DOMAIN-SPECIFIC DEVIATION

### Deviation date:

<table>
<thead>
<tr>
<th>D</th>
<th>M</th>
<th>M</th>
<th>Y</th>
<th>Y</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>D</td>
<td>M</td>
<td>M</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
</tbody>
</table>

**e.g. 18/JUL/2018**

### Deviation type:

- **R** Randomised but ineligible
- **A** Intervention not administered as per protocol
- **C** Received prohibited antiplatelet therapy
- **O** Other, specify 

#### IF RANDOMISED BUT INELIGIBLE

Specify:

- [ ] Microbiological testing for SARS-CoV-2 infection of upper or lower respiratory tract secretions not completed during hospital admission
- [ ] Antiplatelet or NSAID therapy already commenced at the time of randomisation
- [ ] Patient was a participant in a trial of antiplatelet therapy for COVID-19 where continuation of study assignment was required
- [ ] Patient had a known contraindication at the time of randomisation (including clinical or laboratory bleeding risk, Creatinine Clearance < 30 ml/min, or receiving renal replacement therapy or ECMO)
- [ ] Other, specify 

#### IF INTERVENTION NOT ADMINISTERED AS PER PROTOCOL

Specify:

- [ ] No administration of antiplatelet therapy
- [ ] Incorrect dose administered
- [ ] Incorrect duration of antiplatelet therapy administered
- [ ] Other, specify 

#### IF RECEIVED PROHIBITED THERAPY

Specify:

- [ ] Administered non-assigned antiplatelet therapy
- [ ] Received concomitant lopinavir/ritonavir with ticagrelor or clopidogrel
- [ ] Other, specify 

### Reason:

___________________________________________________________

___________________________________________________________

___________________________________________________________

### What were the consequences or actions taken:

___________________________________________________________

___________________________________________________________

___________________________________________________________
## COVID-19 ACE2 RAS DOMAIN

### 12.0 PROTOCOL DOMAIN-SPECIFIC DEVIATION

**Deviation date:**
- **DD/MM/YY/MM/YYYY:** 18/JUL/2018

**Deviation type:**
- **R** Randomised but ineligible
- **A** Intervention not administered as per protocol
- **C** Received prohibited renin-angiotensin modulation therapy
- **O** Other, specify

#### IF RANDOMISED BUT INELIGIBLE
- **Specify:**
  - **(check one)**
    - Patient was a participant in a trial of ACE2 RAS agent for COVID-19 where continuation of study assignment was required
    - Patient was receiving one of the ACE2 RAS agents included as interventions in this domain as a pre-hospitalisation usual medication
    - Known hypersensitivity to ACEi or ARB, including angioedema
    - Renal impairment with creatinine clearance < 30 ml/min or receiving renal replacement therapy
    - Known severe liver disease at the time of randomisation
    - Known severe renal artery stenosis at the time of randomisation
    - Patient had a known contraindication at the time of randomisation
    - Other, specify

#### IF INTERVENTION NOT ADMINISTERED AS PER PROTOCOL
- **Specify:**
  - **(check one)**
    - Patient had an alanine aminotransferase or aspartate aminotransferase more than 5 times the upper limit of normal and received ARB + DMX-200
    - Patient had known viral hepatitis and received ARB + DMX-200
    - Patient had hypersensitivity to repagliflozin and received ARB + DMX-200
    - Other, specify

#### IF RECEIVED PROHIBITED THERAPY
- **Specify:**
  - **(check one)**
    - Administered non-assigned renin-angiotensin modulation therapy
    - Other, specify

**Reason:**
- Specify:
  - **(check one)**

**What were the consequences or actions taken:**
- Specify:
  - **(check one)**

---

**Note:**
- (Censored at ICU discharge)
**COVID-19 VENTILATION DOMAIN**

### 13.0 PROTOCOL DOMAIN-SPECIFIC DEVIATION

(Censored at ICU discharge)

<table>
<thead>
<tr>
<th>Deviation date:</th>
<th>18/JUL/2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deviation type:</td>
<td>R</td>
</tr>
<tr>
<td>(check one)</td>
<td>DDMYYYY</td>
</tr>
</tbody>
</table>

**IF RANDOMISED BUT INELIGIBLE**

- Specify: (check one)
  - [ ] Patient was not receiving invasive mechanical ventilation at time of randomisation
  - [ ] At time of randomisation patient was known to have a P:F ratio of greater than 200 mmHg
  - [ ] Patient was not expected to receive invasive mechanical ventilation until the day after randomisation
  - [ ] Patient had been receiving invasive mechanical ventilation for more than 48 hours at time of randomisation to the Mechanical Ventilation Domain
  - [ ] Patient receives long-term invasive ventilation
  - [ ] Other, specify

**IF INTERVENTION NOT ADMINISTERED AS PER PROTOCOL**

- Specify: (check one)
  - [ ] Protocolised ventilation strategy discontinued and clinician-preferred strategy implemented
  - [ ] Patient allocated to receive protocolised ventilation strategy received tidal volume of less than 4 ml/kg
  - [ ] Patient allocated to receive protocolised ventilation strategy received > 6 ml/kg tidal volume with an arterial pH of > 7.15 (unless tidal volume was increased to maintain pH > 7.15)
  - [ ] Patient allocated to receive protocolised ventilation strategy received plateau pressure of 30 mgH2O with an arterial pH of > 7.15 (unless plateau pressure was increased to maintain pH > 7.15)
  - [ ] Use of pressure-controlled mode of ventilation (pressure control, APRV) in a patient allocated to receive protocolised ventilation strategy
  - [ ] Patient allocated to receive protocolised ventilation strategy received a PEEP/FiO2 combination not specified by the site selected PEEP table, with a plateau pressure of < 30 cmH2O
  - [ ] Other, specify

**IF RECEIVED PROHIBITED THERAPY**

- Specify: (check one)
  - [ ] Administered non-assigned ventilation therapy
  - [ ] Other, specify

Reason:

- [ ]
- [ ]
- [ ]

What were the consequences or actions taken:

- [ ]
- [ ]
- [ ]
### PLATFORM

#### 1.0 ICU ADMISSION SOURCE

- **Patient location at baseline:**
  - [ ] Physical ICU
  - [ ] Ward
  - [ ] Re-purposed ICU
  - [ ] ED

- **ICU admission source:**
  - [ ] Emergency department – same hospital
  - [ ] ICU/HDU – same hospital
  - [ ] Ward – same hospital
  - [ ] Emergency department – other hospital
  - [ ] ICU/HDU – other hospital
  - [ ] Ward – other hospital

#### 2.0 APACHE II

- **APACHE II acute physiology score:** [ ] (0-60) APS

#### 3.0 INTERVENTIONS & PHYSIOLOGY AT BASELINE

- **Creatinine:** [ ] µmol/L  [ ] mg/dL  
  - N Not recorded

- **Platelet count:** [ ] Cells x 10⁹/L  [ ] Cells/mm³  
  - N Not recorded

- **Bilirubin:** [ ] µmol/L  [ ] mg/dL  
  - N Not recorded

- **Lactate:** [ ] mmol/L  [ ] mg/dL  
  - N Not recorded

- **FiO₂ at time of ABG:** [ ] e.g. room air = 0.21

- **Corresponding PaO₂:** [ ] mmHg  [ ] kPa  
  - N Not recorded

- **Corresponding PEEP:** [ ] cmH₂O
  - Patient receiving APRV  
  - N Not recorded

- **Glasgow Coma Scale Score:** [ ]

- **Extended Cardiovascular SOFA score:**
  - (check one)
    - [ ] 0
    - [ ] 1
    - [ ] 2
    - [ ] 3
    - [ ] 4
    - [ ] 4+

- **Renal replacement therapy:**
  - [ ] Yes
  - [ ] No

- **Extracorporeal gas exchange:**
  - (check all that apply)
    - [ ] Yes
    - [ ] No
    - [ ] Extracorporeal membrane oxygenation (ECMO)
    - [ ] Extracorporeal carbon dioxide removal (ECCO₂R)
**4.0 PHYSIOLOGY AT BASELINE (PAANDEMIC ONLY)**

(Closest prior to randomisation, within 8 hours of randomisation or two hours after randomisation)

<table>
<thead>
<tr>
<th>Test (check one)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ferritin: µg/L or ng/mL</td>
<td>D-dimer: µg/L or ng/mL</td>
<td>C-Reactive Protein: mg/L or µg/mL</td>
</tr>
<tr>
<td>Neutrophil count: Cells x 10^9 /L</td>
<td>Lymphocyte count: Cells x 10^9 /L</td>
<td>Troponin: ng/L or pg/mL</td>
</tr>
<tr>
<td>Troponin (check one)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High sensitivity Troponin T</td>
<td>Troponin I</td>
<td></td>
</tr>
<tr>
<td>High sensitivity Troponin I</td>
<td>Troponin I</td>
<td></td>
</tr>
<tr>
<td>Upper reference limit (99th percentile)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INR or Prothrombin ratio (PR): INR: preferred; PR: accepted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibrinogen: g/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature: °C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart rate: bpm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic blood pressure: mmHg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory rate: bpm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bicarbonate: mEq/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Albumin: g/dL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Not recorded
1.0 STUDY DAY

Collect daily data for the duration of the ICU admission (censored at study day 28). If the patient is allocated to fixed course steroid, collect corticosteroid administration up until D9 while on ward.

- **Study day**: [ ] Study days (01-28)
- **Date**: [D D M M M Y Y Y Y] e.g. 18/JUL/2018
- **Patient in ICU during this day**: [ ] Yes [ ] No
- **Patient location on study day**: [ ] Physical ICU [ ] Re-purposed ICU

2.0 DAILY TREATMENTS

- **Airway**:
  - (check one)
  - IF MAINTAINING OWN
    - High flow nasal prong oxygen therapy: [ ] Yes [ ] No
    - Non invasive ventilation: [ ] Yes [ ] No
  - IF ETT or TT
    - Hours of invasive mechanical ventilation: [ ] hours (0-24)
    - FiO2 associated with lowest P/F ratio: [ , ] e.g. 0.21
    - Corresponding PaO2: [ ] mmHg [ ] kPa
    - Corresponding PEEP: [ ] cmH2O [ ] Patient receiving APRV
  - Extended Cardiovascular SOFA score: [ ] 0 [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 4*
  - Renal replacement therapy: [ ] Yes [ ] No
  - Extracorporeal gas exchange:
    - IF YES
      - Received: (check all that apply)
        - Extracorporeal membrane oxygenation (ECMO)
        - Extracorporeal carbon dioxide removal (ECCO2R)
CORTICOSTEROID DOMAIN

3.0 CORTICOSTEROID ADMINISTRATION

Was a corticosteroid administered on this study day:

IF YES ➔ Name of corticosteroid:

- Hydrocortisone (IV)
- Hydrocortisone (oral)
- Methylprednisolone
- Prednisolone
- Prednisone
- Triamcinolone

Total daily dose: ______ mg

Was this dose administered for the patient’s initial episode of CAP or its complications:

IF NO ➔

Was another corticosteroid administered:

IF YES ➔ Name of corticosteroid:

- Hydrocortisone (IV)
- Hydrocortisone (oral)
- Methylprednisolone
- Prednisolone
- Prednisone
- Triamcinolone

Total daily dose: ______ mg

Was this dose administered for the patient’s initial episode of CAP or its complications:

IF NO ➔

4.0 HYDROCORTISONE ADMINISTRATION

Study day: [ ] (01-28)

Was another corticosteroid administered:

IF YES ➔ Name of corticosteroid:

- Hydrocortisone (IV)
- Hydrocortisone (oral)
- Methylprednisolone
- Prednisolone
- Prednisone
- Triamcinolone

Total daily dose: ______ mg

Was this dose administered for the patient’s initial episode of CAP or its complications:

IF NO ➔

Was another corticosteroid administered:

IF YES ➔ Name of corticosteroid:

- Hydrocortisone (IV)
- Hydrocortisone (oral)
- Methylprednisolone
- Prednisolone
- Prednisone
- Triamcinolone

Total daily dose: ______ mg

Was this dose administered for the patient’s initial episode of CAP or its complications:

IF NO ➔

What was the corticosteroid administered for:
Study day: [ ] (01-28)

Was another corticosteroid administered: [ ] Yes [ ] No

IF YES

Name of corticosteroid: ◻ Hydrocortisone (IV) ◻ Dexamethasone ◻ Prednisone
◻ Hydrocortisone (oral) ◻ Methylprednisolone ◻ Triamcinolone
◻ Betamethasone ◻ Prednisolone

Total daily dose: [ ] [ ] [ ] mg

Was this dose administered for the patient’s initial episode of CAP or its complications: [ ] Yes [ ] No

IF NO

What was the corticosteroid administered for: .............................................................................................................

Study day: [ ] (01-28)

Was another corticosteroid administered: [ ] Yes [ ] No

IF YES

Name of corticosteroid: ◻ Hydrocortisone (IV) ◻ Dexamethasone ◻ Prednisone
◻ Hydrocortisone (oral) ◻ Methylprednisolone ◻ Triamcinolone
◻ Betamethasone ◻ Prednisolone

Total daily dose: [ ] [ ] [ ] mg

Was this dose administered for the patient’s initial episode of CAP or its complications: [ ] Yes [ ] No

IF NO

What was the corticosteroid administered for: .............................................................................................................

Study day: [ ] (01-28)

Was another corticosteroid administered: [ ] Yes [ ] No

IF YES

Name of corticosteroid: ◻ Hydrocortisone (IV) ◻ Dexamethasone ◻ Prednisone
◻ Hydrocortisone (oral) ◻ Methylprednisolone ◻ Triamcinolone
◻ Betamethasone ◻ Prednisolone

Total daily dose: [ ] [ ] [ ] mg

Was this dose administered for the patient’s initial episode of CAP or its complications: [ ] Yes [ ] No

IF NO

What was the corticosteroid administered for: .............................................................................................................
2.0 ICU READMISSION

(Supplementary to FORM 6 Discharge)

3rd ICU readmission:

1. Yes  N No → Skip to section 3

  a. ICU readmission date & time:
     * Date: e.g. 01/JUN/2018
     * Time: e.g. 08:05pm

  b. ICU discharge date & time:
     * Date: e.g. 01/JUN/2018
     * Time: e.g. 08:05pm

  c. Did the patient receive organ support during this ICU admission?
     * Yes  N No

     * Date and time of first organ support in ICU this readmission:
       * Date: e.g. 01/JUN/2018
       * Time: e.g. 08:05pm

     * Date and time of last organ support in ICU this readmission:
       * Date: e.g. 01/JUN/2018
       * Time: e.g. 08:05pm

4th ICU readmission:

1. Yes  N No → Skip to section 3

  a. ICU readmission date & time:
     * Date: e.g. 01/JUN/2018
     * Time: e.g. 08:05pm

  b. ICU discharge date & time:
     * Date: e.g. 01/JUN/2018
     * Time: e.g. 08:05pm

  c. Did the patient receive organ support during this ICU admission?
     * Yes  N No

     * Date and time of first organ support in ICU this readmission:
       * Date: e.g. 01/JUN/2018
       * Time: e.g. 08:05pm

     * Date and time of last organ support in ICU this readmission:
       * Date: e.g. 01/JUN/2018
       * Time: e.g. 08:05pm

* = Only required for Pandemic Infection Suspected or Confirmed Patients
If a patient is randomised into the Anticoagulation and Immunoglobulin domains at two different timepoints multiple peak troponin tests, major bleeding episodes and RBC transfusion episodes can be added to the eCRF.

2nd Peak troponin-test method:

- **Test:** (check one)
  - High sensitivity Troponin T
  - High sensitivity Troponin I
  - Troponin T
  - Troponin I

- **Result:**
  - ng/L or pg/mL
  - ng/mL

- **Upper reference limit (99th percentile):**
  - ng/L or pg/mL
  - ng/mL

2nd Major bleeding:

- **Yes**
- **No**

**Major bleeding event date & time:**

- **D M Y**
- **H H**
- **24 hour clock**

**Only required for patients randomised to V3 anticoagulation domain (and antiplatelet going forward)**

Which one or more of these criteria were met: (check all that apply)

- Fatal bleeding
- Symptomatic or clinically manifest bleeding in a critical area or organ
- Blood loss causing a fall in haemoglobin ≥ 2g/dL
- Blood loss leading to transfusion of ≥ 2 units of red cells or whole blood

**Major bleeding description of event(s):**

- ……………………………………………………………………………………………………………………
- ……………………………………………………………………………………………………………………
- ……………………………………………………………………………………………………………………
- ……………………………………………………………………………………………………………………

2nd Number of units of red blood cells transfused:

- ……………………………………………………………………………………………………………………