**REMAP-CAP Eligibility Checklist and Statement**

Please complete this form as part of the screening process for the REMAP-CAP trial, Core Protocol v3.1 dated 9th Nov 2022.

To be signed by a **clinician or doctor** who has undergone the **REMAP-CAP eligibility assessor training** and is listed on the **delegation log** (but does not necessarily require GCP training).

Here, clinician is defined as any role who has **prescribing rights** i.e. nurses, practitioners.

Once completed/signed, this form should be filed in the patient’s medical records.

**Platform Inclusion:**

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| **Inclusion Criteria** | **Please circle which apply** |
| Adult or paediatric patient (28 days or older) hospitalized with an acute illness due to a lower respiratory tract infection | Yes | No |

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| --- | --- |
| **Exclusion Criteria** | **Please circle which apply** |
| More than 14 days has elapsed since admission to hospital | Yes | No |
| If receiving organ failure support in an ICU, more than 48 hours has elapsed since admission to ICU | Yes | No |
| Death is deemed to be imminent and inevitable during the next 24 hours AND one or more of the patients, substitute decision maker or attending physician are not committed to full active treatment | Yes | No |
| Previous participation in this REMAP within the last 90 days | Yes | No |
| Expected to be discharged from this hospital admission within the next 24 hours | Yes | No |

**Is the subject eligible to participate in the Platform of the study? YES / NO**

**NOTE: Illness severity states**

**Moderate:** On ward or ICU, but NOT receiving organ failure support

**Severe:** In ICU and receiving organ failure support

**Wards and ICU domains**

**Influenza strata: Antiviral domain
[Please delete domain if not applicable to the site]**

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| **Inclusion Criteria** | **Please circle which apply** |
| Influenza infection has been confirmed by microbiological testing | Yes | No |

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| **Exclusion Criteria** | **Please circle which apply** |
| Patient has already received two or more doses of Oseltamivir or other neuraminidase inhibitors | Yes | No |
| Patient has already received one or more doses of Baloxavir | Yes | No |
| Patient is already receiving, or a clinical decision has been made to commence, an antiviral active against influenza other than Oseltamivir or Baloxavir, or both | Yes | No |
| The treating clinician believes that participation in the domain would not be in the best interests of the patient | Yes | No |
| **If in Moderate State** | **Please circle which apply** |
| More than 96 hours has elapsed since hospital admission | Yes | No |
| **If in Severe State** | **Please circle which apply** |
| More than 48 hours has elapsed since ICU admission, unless the patient has already been assigned a treatment in another domain in the Moderate State, in which case exclusion will occur if more than 48 hours has elapsed since commencement of sustained organ failure support in an ICU | Yes | No |
| **Intervention Specific Exclusions** | **Please circle which apply** |
| Known hypersensitivity to Oseltamivir or Baloxavir. | Yes | No |
| Known or suspected pregnancy will result in exclusion from interventions that include Baloxavir | Yes | No |

**Is the subject eligible to participate in the Antiviral domain of the study? YES / NO**

**Influenza or CAP stratas: Corticosteroid domain
[Please delete domain if not applicable to the site]**

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| **Inclusion Criteria – if in Moderate State** | **Please circle which apply** |
| If in the Moderate State, receiving some form of supplemental oxygen (simple facemask, low- or high-flow oxygen, or non-invasive ventilation) | Yes | No |

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| **Exclusion Criteria** | **Please circle which apply** |
| Known hypersensitivity to any corticosteroid | Yes | No |
| Intention to prescribe systemic corticosteroids for a reason that is unrelated to the current episode of CAP (or direct complications of CAP), such as chronic corticosteroid use before admission, acute severe asthma, or suspected or proven Pneumocystis jirovecii or COVID19 pneumonia | Yes | No |
| The treating clinician believes that participation in the domain would not be in the best interests of the patient | Yes | No |
| **If in Severe State** | **Please circle which apply** |
| More than 24 hours have elapsed since ICU admission; if the patient has already been assigned a treatment in another domain in the Moderate State, exclusion will occur if more than 24 hours has elapsed since commencement of sustained organ failure support in an ICU | Yes | No |
| **If in Moderate State,** platform exclusion timeframe applies (to be excluded if more than 14 days have elapsed while admitted to hospital) |

**Is the subject eligible to participate in the Corticosteroid domain of the study? YES / NO**

**COVID strata: Immunoglobulin domain
[Please delete domain if not applicable to the site]**

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| **Inclusion Criteria** | **Please circle which apply** |
| Patients are eligible for this domain if SARS-CoV-2 infection is confirmed by microbiological testing | Yes | No |
| Patient has an underlying immunodeficiency or has received recent immunosuppressant therapy, corresponding to the APACHE II definitions (Knaus et al., 1985), extended to take into account equivalent forms of immunosuppressant therapy that post-date the APACHE II definitions | Yes | No |

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| **Exclusion Criteria** | **Please circle which apply** |
| Patient has already received treatment with any non-trial prescribed polyclonal antibody therapy (hyperimmune immunoglobulin, or convalescent plasma) intended to be active against COVID-19 during this acute illness | Yes | No |
| The treating clinician believes that participation in the domain would not be in the best interests of the patient | Yes | No |
| Known hypersensitivity/allergy to an agent specified as an intervention in this domain will exclude a patient from receiving that agent | Yes | No |
| Known previous history of transfusion-related acute lung injury will exclude a patient from receiving high titre plasma | Yes | No |
| Known objection to receiving plasma products will exclude a patient from receiving any plasma components | Yes | No |

**Is the subject eligible to participate in the Immunoglobulin domain of the study? YES / NO**

**ICU only domains**

**Influenza strata: Immune Modulation domain
[Please delete domain if not applicable to the site]**

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| **Inclusion Criteria** | **Please circle which apply** |
| Aged 2 years or older | Yes | No |
| Admitted to ICU and in severe illness state | No | No |
| Influenza infection has been confirmed by microbiological testing | Yes | No |
| In the opinion of the treating clinician, the primary contributor to the patient’s severe illness is a respiratory tract infection (e.g. not unwell with trauma and happen to have influenza) | Yes | No |

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| **Exclusion Criteria** | **Please circle which apply** |
| SARS-COV-2 infection has been confirmed by microbiological testing | Yes | No |
| Known condition or treatment resulting in ongoing immune suppression including neutropenia prior to this hospitalisation | Yes | No |
| A neutrophil count <1.0 x 10^9 / L | Yes | No |
| Neutr count: |
| Confirmed or strongly suspected active mycobacterial infection or invasive fungal infection | Yes | No |
| Patient has already received any dose of one or more of Tocilizumab (or another IL-6 receptor antagonist) or Baricitinib (or another JAK inhibitor) during this hospitalisation or is in long-term therapy with any of these agents prior to this hospital admission | Yes | No |
| The treating clinician believes that participation in the domain would not be in the best interests of the patient | Yes | No |
| **Intervention Exclusion Criteria** | **Please circle which apply** |
| Known hypersensitivity to an agent specified as an intervention in this domain will exclude a patient from receiving that agent | Yes | No |
| Known or suspected pregnancy is an exclusion for Baricitinib (whether known or suspected pregnancy results in exclusion from the tocilizumab intervention depends on local approvals) | Yes | No |
| An ALT or an AST that is >5x the upper limit of normal is an exclusion for Tocilizumab | Yes | No |
| ALT:AST: |
| A platelet count < 50 x 10^9 / L is an exclusion for Tocilizumab. | Yes | No |
| Plt count:  |
| A baseline eGFR (15 mL/min/1.73m^2 and/or receipt of renal replacement therapy (including long-term renal replacement therapy) at baseline is an exclusion from Baricitinib. | Yes | No |
| eGFR:Receiving RRT (tick) [ ]  |

**Is the subject eligible to participate in the Immune Modulation domain of the study? YES / NO**

 **CAP strata: Antibiotic domain
[Please delete domain if not applicable to the site]**

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| **Inclusion Criteria** | **Please circle which apply** |
| Admitted to ICU with severe CAP | Yes | No |

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| **Exclusion Criteria** | **Please circle which apply** |
| Received more than 48 hours of intravenous antibiotic treatment for this index illness | Yes | No |
| More than 24 hours has elapsed since ICU admission | Yes | No |
| Known hypersensitivity to all of the study drugs in the site randomization schedule | Yes | No |
| A specific antibiotic choice is indicated, for example: | **Please circle which apply** |
| Suspected or proven concomitant infection such as meningitis | Yes | No |
| Suspected or proven infection with resistant bacteria where agents being trialled would not be expected to be active. This includes cystic fibrosis, bronchiectasis or other chronic suppurative lung disease where infection with Pseudomonas may be suspected but does not include patients with suspected methicillin-resistant staphylococcus aureus (MRSA) infection | Yes | No |
| Febrile neutropenia or significant immunosuppression (including organ or bone marrow transplantation, human immunodeficiency virus (HIV) Infection with CD4 cell count 4 preceding weeks) | Yes | No |
| Suspected melioidosis | Yes | No |
| Specific microbiological information available to guide specific antibacterial therapy | Yes | No |
| The treating clinician believes that participation in the domain would not be in the best interests of the patient | Yes | No |
| **Intervention Specific Exclusions** | **Please circle which apply** |
| Known non-serious hypersensitivity to penicillins will result in exclusion from receiving interventions that include Piperacillin and Amoxicillin | Yes | No |
| Known non-serious hypersensitivity to cephalosporins will result in exclusion from receiving interventions that include Ceftriaxone and Ceftaroline | Yes | No |
| Known serious hypersensitivity to beta-lactams, including penicillins or cephalosporins, will result in exclusion from interventions that include Piperacillin, Amoxicillin, Ceftriaxone, and Ceftaroline. | Yes | No |
| Known hypersensitivity to Moxifloxacin or Levofloxacin will result in exclusion from Moxifloxacin or Levofloxacin intervention. | Yes | No |
| Known serious hypersensitivity to the macrolide will result in exclusion from interventions that include Piperacillin, Amoxicillin, Ceftriaxone, and Ceftaroline. | Yes | No |
| Known or suspected pregnancy will result in exclusion from Moxifloxacin or Levofloxacin and Ceftaroline interventions. It is normal clinical practice that women admitted who are in an age group in which pregnancy is possible will have a pregnancy test conducted. The results of such tests will be used to determine interpretation of this exclusion criteria. | Yes | No |

**Is the subject eligible to participate in the Antibiotic domain of the study? YES / NO**

 **CAP strata: Macrolide domain
[Please delete domain if not applicable to the site]**

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| **Inclusion Criteria** | **Please circle which apply** |
| Patients are eligible for this domain only if they have been allocated a beta-lactam plus macrolide intervention within the Antibiotic domain | Yes | No |

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| **Exclusion Criteria** | **Please circle which apply** |
| Agreement to participate in this domain has been declined or has not been requested before the end of study day 5 | Yes | No |
| There is microbiological confirmation, or the clinician strongly suspects Legionella or any other form of atypical pneumonia. | Yes | No |
| Macrolide antibiotics have already been discontinued for more than 36 hours | Yes | No |
| The treating clinician believes that participation in the domain would not be in the best interests of the patient | Yes | No |

**Is the subject eligible to participate in the Macrolide domain of the study? YES / NO**

**Eligibility confirmation**

I confirm that patient (name) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

has been screened for the REMAP-CAP trial and is suitable to be enrolled to the platform and the following domains **[Please delete domains below that are not applicable to the site]:**

* Influenza: Antiviral domain **YES / NO**
* Influenza/CAP: Corticosteroid domain **YES / NO**
* COVID: Immunoglobulin domain **YES / NO**
* Influenza: Immune Modulation domain **YES / NO**
* CAP: Antibiotic domain **YES / NO**
* CAP: Macrolide domain **YES / NO**

The results of all screening assessments required by the current protocol were reviewed by the PI or clinician delegated to do so.

**PI / delegated clinician signature:** ­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PI / delegated clinician name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(Please print)*

**Date**: \_\_\_\_\_\_/\_\_\_\_\_\_\_/\_\_\_\_\_\_\_ (DD/MMM/YYYY)