

<b>Site Name</b>	
<b>Patient ID</b>	

## **PANTHER Eligibility form**

Complete this form as part of the screening process for the PANTHER trial – to be completed by a clinician on the delegation log and filed in the medical records and eISF once complete.

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

<b>Platform Inclusion Criteria</b>	<b>Please circle which apply</b>	
Critically ill patients in hospital with at least one of the following: - a) Acute respiratory distress syndrome (ARDS)* b) A pandemic associated syndrome (this will be triggered if a new pandemic is declared) *ARDS as defined by:-	Yes	No
(i) a known acute clinical insult or new or worsening respiratory dysfunction, and	Yes	No
(ii) receiving respiratory support via invasive mechanical ventilation or non-invasive ventilation including continuous positive airway pressure, or high-flow nasal oxygen $\geq 30\text{L/min}$ and	Yes	No
(iii) Within the same 24-hour time period: • bilateral opacities on chest imaging not fully explained by effusions, lobar/lung collapse/atelectasis, or nodules, and	Yes	No
• respiratory failure not fully explained by cardiac failure, fluid overload, pulmonary embolism, acute airways disease, or interstitial lung disease and	Yes	No
• $\text{PaO}_2/\text{FiO}_2$ ratio $< 40$ kPa from arterial blood gases, or $\text{SpO}_2/\text{FiO}_2$ $< 315$ from pulse oximetry where $\text{SpO}_2 < 97$ .	Yes	No

<b>Platform Exclusion Criteria</b>	<b>Please circle which apply</b>	
$> 48$ hours from diagnosis of ARDS	Yes	No
Planned withdrawal of life-sustaining treatment within the next 24 hours	Yes	No
Previous enrolment in the PANTHER trial in the last 12 months	Yes	No
Declined consent	Yes	No

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

To complete eligibility for the Interventions please complete page 2 and 3 of this form.

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## PANTHER – Eligibility for Simvastatin

Complete this form as part of the screening process for the simvastatin intervention only. Answering **yes** to any of the questions below will exclude the patient from this intervention.

Exclusion Criteria	Please circle which apply	
Age < 18 years	Yes	No
Patient is known to be pregnant (pregnancy test must have been completed for all female patients)	Yes	No
Creatine kinase >10 times the upper limit of the normal range (please enter value below):  <b>CK = Please enter value</b> _____	Yes	No*
Liver transaminases >8 times the upper limit of the normal range (please enter values below)  <b>ALT = Please enter value</b> _____ <b>AST = Please enter value</b> _____	Yes	No*
Currently receiving ongoing treatment with any of the following: itraconazole, ketoconazole, HIV protease inhibitors, nefazodone, cyclosporine, amiodarone, verapamil, or diltiazem	Yes	No
Severe renal impairment (eGFR < 30mL/min and not receiving renal replacement therapy).	Yes	No
Current or recent treatment (within 2 weeks) with statins	Yes	No
Physician decision that a statin is required for proven indication	Yes	No
Contraindication to enteral drug administration, e.g., patients with mechanical bowel obstruction. Patients with high gastric aspirates due to an ileus are not excluded.	Yes	No
Known hypersensitivity to simvastatin	Yes	No
Breast Feeding	Yes	No
Any other medical condition or treatment that, at the clinical discretion of the investigator, is considered not in the participants best interest to start treatment with the IMP based on the approved version of the IMP SmPC.	Yes	No

**Is the subject eligible to participate in the Simvastatin Intervention?**      **YES / NO**

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

has been screened for the PANTHER study and is suitable to be enrolled.



Form completed by (MUST BE A CLINICIAN)

\_\_\_\_\_ on \_\_\_\_/\_\_\_\_/\_\_\_\_ (date)

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## **PANTHER – Eligibility for Baricitinib**

Complete this form as part of the screening process for the Baricitinib intervention only. Answering **yes** to any of the questions below will exclude the patient from this intervention.

Exclusion Criteria	Please circle which apply	
Age < 18 years	Yes	No
Patient is known to be pregnant (pregnancy test must have been completed for all female patients)	Yes	No
Absolute neutrophil count less than $0.5 \times 10^9/L$ (please enter value below):	Yes	No*
<b>*NEUT = Please enter value</b> _____		
Liver transaminases >8 times the upper limit of the normal range (please enter values below)	Yes	No*
<b>*ALT = Please enter value</b> _____		
<b>*AST = Please enter value</b> _____		
Currently receiving ongoing immunosuppressants (high-dose corticosteroids, T-cell-targeted or B-cell targeted therapies, interferon, or JAK inhibitors)	Yes	No
Severe renal impairment (eGFR < 15mL/min or receiving renal replacement therapy).	Yes	No
Known active tuberculosis infection or, if known, latent TB treated for less than 4 weeks with appropriate anti-tuberculosis therapy per local guidelines	Yes	No
Known hypersensitivity to baricitinib	Yes	No
Breast feeding	Yes	No
Known herpes zoster virus, hepatitis B virus, hepatitis C virus or human immunodeficiency virus (HIV)	Yes	No
Any other medical condition or treatment that, at the clinical discretion of the investigator, is considered not in the participants best interest to start treatment with the IMP based on the approved version of the IMP SmPC.	Yes	No

**Is the subject eligible to participate in the Baricitinib Intervention?**      **YES / NO**

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



has been screened for the PANTHER study and is suitable to be enrolled.

Site Name	
Patient ID	

Form completed by (MUST BE A CLINICIAN) \_\_\_\_\_ on  
\_\_\_\_/\_\_\_\_/\_\_\_\_ (date)