Site Feasibility Questionnaire

Study Title: PANTHER
Sponsor: Imperial College London ; **Study Protocol Number: 175151**

Chief Investigator: Professor Danny McAuley

We kindly request you to return this completed form by email to pantheruk@imperial.ac.uk at Imperial College Clinical Trials Unit (ICTU) within 1 week of receipt or please notify us if you require more time or assistance.

Date: _____ Name and role of person completing the form: _____

Site Information			
Principal Investigator (PI):			
Site Name:			
Institution/Trust Name:			
Department:			
Address (Line 1):		**Address (Line 2):**	
Town/City:		**State/County/Province:**	
Country:		**Postcode:**	
Phone:		**Email:**	
Essential Site Study Team & Contact Details			
	Name:	**Phone:**	**Email:**
Sub-Investigator(s):			

Research Nurse(s)/Coordinator:			
Pharmacist:			
Contracts Manager:			
R&D Contact:			

The following should be completed by and/or discussed with the Principal Investigator(s) and proposed site study team, as applicable (specify any further details in the comments section):	**Comments**
SECTION 1: Participant Characteristics	
Overall Inclusion **1.** How many potential participants meet the following: - Critically ill Adults (≥18 years of age) admitted to ICU due to Acute Respiratory Distress Syndrome (ARDS) *ARDS as defined by:* *(i) a known acute clinical insult or new or worsening respiratory dysfunction, and* *(ii) receiving respiratory support via invasive mechanical ventilation or non-invasive ventilation including continuous positive airway pressure, or high-flow nasal oxygen ≥30L/min and* *(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* • *respiratory failure not fully explained by cardiac failure, fluid overload, pulmonary embolism, acute airways disease, or interstitial lung disease and,* • *PaO2/FiO2 ratio <40 kPa from arterial blood gases, or SpO2/FiO2 <315 from pulse oximetry where SpO2 <97* *The time of onset of ARDS is when the last criterion in (iii) is met.*	Number of Participants: annually/monthly ☐ This is an actual number ☐ This is an estimate

2. How many participants could you potentially enrol in the study **per month?**	Number of Participants:
SECTION 2: Participant Identification & Selection	
1. Please indicate how the proposed study team would recruit potential participants for this study.	
2. Which clinic lists/therapeutic areas will you screen eligible patients from (*e.g., inpatient/outpatient clinics*)	
3. Each intervention will have its own control which will be usual care. Usual care will be directed by international treatment guidelines, such as the European Society of Intensive Care Medicine ARDS guidelines. Agreement to comply with these guidelines will be a condition for a site to participate in the trial to ensure standardised best practice usual care. Do you agree to comply with these guidelines?	☐ Yes ☐ No
4. Does your site have access to electronic patient records?	☐ Yes ☐ No
5. What do you envisage might be the key challenges for your site to successfully screen and recruit to this trial? *i.e. any issues with sourcing the drug stock (simvastatin/baricitinib)*	

6. Are there any other competing studies currently involving this patient population*? If yes, please provide details.*	☐ Yes, *please specify* ☐ No
7. How long does R&D study set up take on average at your site?	Months
SECTION 3: Study Site Staff	
1. Does the PI/Study Team have previous experience in Academic/ /Interventional; IMP/clinical trials?	☐ Yes, *please specify number of previous studies as PI* ☐ No
2. Within the study team, will there be a Research Nurse/Coordinator with adequate time allocated to the study?	☐ Yes, *please provide details*: ☐ No
3. Does the PI and site study team have sufficient time to: a. Conduct the study? b. Be available for monitoring visits? c. Attend study meetings?	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No
4. Does each member of the study team have documented GCP training within the last 2 years (and understand Regulatory and local Ethics Committee requirements)? (If your site mandates GCP training on a 3-year basis, please indicate this)	☐ Yes ☐ No ☐ GCP training conducted every 3 years (rather than 2)
5. Is the PI aware of his/her specific responsibilities to comply with the protocol, ICH GCP and all applicable laws and regulations? (e.g. oversight of team, consent, source documents/data, accurate data entry)	☐ Yes ☐ No

SECTION 4: Facilities/Equipment	
Space & Storage Facilities:	
1. Is there adequate examination/procedure room space to conduct assessments as specified in the protocol?	☐ Yes ☐ No
2. Do you have sufficient space to store the device? 585 (H) x 535 (D) x 570 (W) mm	☐ Yes ☐ No
3. How many beds does your ICU Unit have?	
4. Do the study staff have adequate space and IT systems for data entry/management?	☐ Yes ☐ No
5. PANTHER will utilise an electronic TMF and ISF, does your site foresee any issues with this or has any comments to add?	☐ Yes ☐ No Comments:-
6. Do you have access to a -20°C or a -70°C /-80°C freezer?	☐ No ☐ -20°C ☐ -70°C/-80°C
7. Do you have permission/capacity to download large complex files in relation to the device on your PC?	☐ Yes ☐ No
Clinical Areas:	
8. Are the specific types of clinical equipment that are needed for this study available and adequately maintained, such as a centrifuge for spinning samples?	☐ Yes ☐ No
Pharmacy:	
9. Is pharmacy experienced with clinical trials of IMPs?	☐ Yes ☐ No

10. Does pharmacy and ICU have adequate storage facilities for IMP?	☐ Yes ☐ No
Laboratory:	
11. Who collects clinical specimens and how are they handled prior to transfer to a laboratory facility?	
12. This trial may include sample collection and processing of the following samples:- blood, tracheal aspirate, nasal swab, and bronchoalveolar lavage, these will be collected, and processed for either initial short term storage and/or transport to a storage facility in Belfast. If the option for sample collection is available, would the site be using a **local laboratory** for **research specimen preparation and storage**? If yes, is the laboratory qualified/certified to perform procedures for the study? *If yes, please provide evidence.* Are the following available for review:	☐ Yes ☐ No Lab Certification? ☐ Yes ☐ No Lab Normal Ranges? ☐ Yes ☐ No
13. Does your site have access to a Randox Evidence MultiSTAT Analyser?	☐ Yes ☐ No
SECTION 5: Monitoring	
1. Are the PI and Study Team willing to allow a Monitor to visit the site to review consent documents and adherence to the protocol?	☐ Yes ☐ No, *please specify*
2. Would the site be happy to participate in remote monitoring if the option were available?	☐ Yes ☐ No, *any additional information*
3. Does the PI and Study Team agree to remote monitoring calls with the monitor to discuss progress, issues and adherence to the protocol?	☐ Yes ☐ No, *please specify* ☐ Not applicable

4. Will the Monitor have adequate workspace to conduct an on-site visit?	☐ Yes ☐ No, *please specify*
5. Will the monitor have direct access to the medical records (paper and electronic) so that adequate review of source documentation can be completed during the visit?	☐ Yes ☐ No, *please specify*

May we contact you further regarding participation in this study?	☐ Yes ☐ No