Pharmacy Technical Review Form for CTIMPs

Please note that Pharmacy Assurance will be provided based on the study documents listed in Section 2. Amendments will not be reviewed through Pharmacy Assurance.

Sponsors and participating sites: guidance is available on the IRAS website about how to provide feedback if you have a query or concern regarding the information provided in this form. See https://www.myresearchproject.org.uk/help/hlppharmacyassurance.aspx

Part 1: Study identification. To be completed by lead nation administrative support (All nations)

Section 1: Study Identification	
Pharmacy Specialisms	Adult Oncology ☐ Paediatric Oncology ☐ Adult Non-oncology ☒ Paediatric Non-oncology ☐ Radiopharmacy ☐ ATIMPs ☐
Full Protocol Title	Precision medicine adaptive network platform trial in hypoxemic acute respiratory failure
Study Acronym (if applicable)	PANTHER
Sponsor Protocol Reference	V2.0 11 June 2025
NRS ID Number (Scotland only)	n/a
EudraCT Number	n/a
IRAS Number	1008743
Sponsor Organisation	Imperial College London

Section 2: Documents reviewed as part of this submission		
Document	**Version Number**	**Date**
PANTHER Master Protocol	V2.0	11 Jun 2025
PANTHER UK Region Specific Appendix	V1.0	03 Mar 2025
PANTHER Intervention appendix _Simvastatin	V2.0	11 Jun 2025
PANTHER Intervention appendix _Baricitinib	V2.0	11 Jun 2025
PANTHER Subphenotype appendix ARDS	V1.0	06 Feb 2025
Summary of Product Characteristics (SmPC) for both IMPs – Simvastatin	n/a	31 Jul 2023
Summary of Product Characteristics (SmPC) for both IMPs – Baricitinib	n/a	25 Sep 2023
Pharmacy Manual	V1.0	17 Feb 2025

Section 3: Details of Sites	
Number of sites in UK at initial submission	30
Total recruitment planned in UK at initial submission	1563 (PANTHER is a Platform trial and so the sample size is not fixed)
Does the study involve Primary Care?	No

Part 2: Technical pharmacy review. To be completed by HRA Pharmacy Reviewer(s) (All nations)

Section 4: Study Summary	
a) Description of study treatment regimen Brief summary to be used as a reference, include full information on doses, routes of administration, timing of administration, length of infusion (if applicable), blinding and placebos	This trial is an allocation concealed, randomised, open-label Bayesian adaptive multi-arm platform trial. The trial will stratify participants by biological markers into different subphenotypes. Therapeutic interventions will be compared with usual care within each subphenotype. The trial will start with two interventions (Baricitinib and Simvastatin) and usual care. Additonal interventions can be added by replacing the initial interventions when criteria of efficacy has been reached. Each intervention will be details in separate intervention specific appendices alongside the master protocol. The trial will recruit patients in hospital, who are critically ill with different clinical syndromes. Initially the target population will be patients with Acute Respiratory Distress Syndrome. Baricitinib/usual care Intervention If randomised to Baricitinib it will administered at a dose of 4mg once daily by enteral route for up to 10 days. If then patient is discharged from ICU before day 10 treatment will be discontinued. First dose should be given ideally within 4 hours of randomisation, subsequent doses each morning starting on the following calendar day. Dose adjustments in renal impairment eGFR 30 to <60 mL/min = 2mg once daily dose eGFR 15 to <30 mL/min = 1mg once daily dose eGFR <15 mL/min (or receiving RRT) = withhold dose Simvastatin/ usual care intervention If randomised to Simvastatin it will be administered at a dose of 80mg once daily by enteral route for up to 28 days. Simvastatin will only be adminstered to participants while they are in-patients in ICU. First dose should be given ideally withinn 4 hours of randomisation, subsequent doses each morning starting on the following calendar day.

	There is no simvastatin dose adjustment for renal failure/ renal replacement. However it must be stopped if renal failure is caused or contributed to by Rhabdomyolysis. It must also be stopped if creatine kinase is elevated more than 10 times the upper limit of normal or if alanine transaminase or aspartate transaminase are elevated more than 8 times ULN. If a patient receives more than a single dose of amiodarone then simvastatin dose should be reduced to 20mg daily. Patients unable to swallow whole tablets or have an enteral feeding tube in situ or gastric (PEG or PEJ) guidance for administration is in the pharmacy manual for both interventions.

Section 5: Pharmacy Resources	
a) Type of Study	Dispensary ☒ Aseptic ☐ Radiopharmacy ☐
Set up, management and close-down costs	
a) Set Up/Close Down type	Type A ☒ Type B ☐ Type C ☐ Type D ☐
Additional resource information	
a) Dispensing schedule Include number of dispensing and frequency	Day 1 only - use hospital stock
b) Duration of treatment E.g. 13 days/6 cycles/2 years/until disease progression	Baricitinib Intervention - up to 10 days Simvastatin Intervention - up to 28 days
c) Does the protocol dictate dispensing out of hours?	Yes ☐ No ☒

Section 6: Treatment allocation/Randomisation/Blinding	
a) Is Pharmacy blinded?	Yes ☐ No ☐ N/A ☒ open label
b) If local pharmacies will be involved in repackaging and/or relabelling open-label medication to blind, give details	n/a
c) Will Pharmacy be involved in treatment allocation?	Yes ☐ No ☐ N/A ☒
d) How will Pharmacy be notified of treatment allocation details?	N/A
e) Can randomisation be done in advance of patient visit?	No

f) Does dispensing need to be verified on IXRS by Pharmacy, and if so does it need to be done in real time?	Yes ☐ No ☐ N/A ☒
g) Can Pharmacy dispense from the IXRS system in advance of patient visits? If yes, specify the timescale for this.	Yes ☐ No ☐ N/A ☒

Section 7: Emergency Unblinding	
a) What is the process for emergency unblinding?	n/a open label
b) Will Pharmacy be involved in emergency unblinding?	Yes ☐ No ☐ N/A ☒

Section 8: General Funding	
a) Are there likely to be excess treatment costs or other local funding implications?	Yes, UK region specific appendix indicates that commercial hospital stock will be used as identified as type A trial. Baricitinib BNF price £805.56 for 28 of 2mg and 4mg is a high cost drug.
b) Where product(s) are not supplied free of charge, are they supplied at a discounted rate for the duration of the trial?	Yes ☐ No ☒
c) Is information given on compassionate use/ongoing supply after the trial finishes? Include arrangement details and whether there is written confirmation of the exit strategy.	Yes ☐ No ☐ N/A ☒
d) Other/Comments	The treatment of Baricitinib within the trial is to be covered by patient fees and excess treatment costs to be claimed via usual NHS trust channels. If some trusts require the use of Blueteq forms and the sponsor will work with these Trusts to help lift any restrictions.

Section 9: Further Information on Study	
a) Method(s) permitted for calculating BSA (body surface area)	N/A ☒ Du Bois ☐ Mosteller ☐ Local practice ☐ Other (please specify) ☐
b) Method permitted for calculating dose based on weight	N/A ☒ IBW ☐ ABW ☐

c) Are methods permitted for calculating BSA/weight detailed in the protocol?	N/A ☒ Yes ☐ No ☐
d) Method(s) permitted for calculating GFR (glomerular filtration rate)	N/A ☐ Cockcroft-Gault ☐ Local practice ☒ Other (please specify) ☐ Any method of calculating glomerular filtration rate used clinically by sites will be allowed.
e) Blood test validity periods/Frequency specified	Baseline (24 hours pre randomisation), research samples also taken on Day 3 and Day 7

Section 10.1: Product Information	
Description and Product Type	
a) Description of Product Include name, strength, concentration, volume, form e.g. Drug A 100mg in 5ml Injection (10ml vial)	Baricitinib 2mg film coated tablets Baricitinib 4mg film coated tablets
b) Is the product an IMP (investigational medicinal product) or AMP (auxiliary medicinal product)?	IMP ☒ AMP ☐
c) Are all the drug names correct (i.e. rINN)?	Yes ☒ No ☐
d) Route of administration (include detail of timing in relation to food and how to take etc.)	Oral
e) Licence status	Licensed outside this indication
f) Properties of product requiring special attention	N/A ☐ Cytotoxic ☐ Monoclonal Antibody ☐ Cytotoxic Monoclonal Antibody ☐ Cytostatic ☐ Biological ☐ ATMP ☐ Radiopharmaceutical ☐ Other (please specify) ☒ Staff should wear a mask and gloves when dispensing Baricitinib. Do not prepare or disperse Baricitinib tablets if pregnant.
g) Is it a controlled drug? If yes, include details of Sponsor's arrangements for safe and secure handling of drug	Yes ☐ No ☒ N/A ☐
h) If it is a controlled drug, which schedule is it in?	N/A ☒ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
i) Will additional licenses be required?	Yes ☐ No ☐ N/A ☒
Dose banding and capping	
a) Is dose banding permitted? If nationally dose banded drug, is the use of national dose banding table permitted?	Yes ☐ No ☒ N/A ☐
b) What dose capping/rounding protocols are permitted?	n/a
Product Source	
a) Source of product	Dispensed from commercial stocks

b) If the product is to be sourced from commercial stocks, will it be reimbursed?	Yes ☒ No ☐ N/A ☐ Sites will be paid a per patient fee which will cover work on the trial and additional cost for IMPs.
c) If the product is to be sourced from commercial stocks, can any brand be used?	Yes ☐ No ☐ N/A ☒
d) Is the use of pre-filled infusion bags and/or syringes procured through a third-party manufacturer permitted?	Yes ☐ No ☐ N/A ☒
Packaging and Storage	
a) Packaging of IMP E.g. Primary: in HDPE bottles with child resistant cap; Secondary: 1 carton (kit) contains 2 bottles. Dimensions: Kit dimensions – 12x20x10cm	Aluminium perforated unit dose blisters in cartons of of various sizes depending on hospital stock.
b) Storage conditions of the product E.g. 2-8°C. Include details of temperature monitoring requirements and temperature deviation procedures	Baricitinib will be stored as per SmPC requirements, typically in tablet form and usually at room temperature. No reporting of temperature excursions to the Sponsor are required if hospital stock is used. IMP must only be accessed by appropriate staff on the delegation log or the clinical personnel who will be administering the IMP.
c) Storage space requirements for initial supplies i.e. details on size of initial shipment	Hospital own stock
Product Preparation	
a) Provide detailed information on methods of reconstitution/dilution/preparation Include information on diluents, time to dissolve/reconstitute, container compatibility, equipment (filters etc.) and safety handling requirements, detail on any drug/drug compatibility	Preparation may be required if patient is on a reduced dose and if the 1 mg tablets are not available, a 2 mg tablet can be split using a tablet splitter that has a razor blade to administer half a 2 mg tablet once daily. Alternatively, 2 mg of baricitinib can be given every second day. In addition the pharmacy manual contains information on preparation of a dose for administration via a gastrostomy tube, nasogastric tube or PEG or PEJ tubes.
b) Does the Sponsor require product preparation in an aseptically controlled environment, or can it be prepared using aseptic manipulation in a general area?	n/a
c) Stability and storage requirements of reconstituted/diluted/prepared product of those requiring aseptic manipulation E.g. Diluted solution to be stored at room temperature for no more than 12 hours after preparation	n/a

d) Are all drug formulations appropriate to the patient population (e.g. liquids for paediatrics)?	Yes ☒ No ☐ Preferred method of administration is tablets swallowed whole, however the pharmacy manual provides detailed instruction for administration for patients with swallowing difficulties or that have gastric tubes.
IMP/AMP Labelling	
a) Are the drug labels available for review?	Yes ☐ No ☐ N/A ☒ The MHRA IMP risk classification for the trial is Type A risk adapted CTIMP as any potential risk is no higher than that of standard medical care. As new interventions are added to the trial, this will be reviewed. Commercial IMP taken from hospital stock already stored in the hospital will not require a study specific label.
b) For IMP(s), are these compliant with Annexe 13?	Yes ☐ No ☐ n/a
c) Is there any other information that should be on the labels?	n/a
d) Are sites allowed to use their own labels in their local format?	Yes ☐ No ☐ n/a
e) Are sites required or permitted to add their own dispensing labels?	Yes ☐ No ☐ n/a
f) Is there consistency between drug names in the protocol and on the label?	Yes ☐ No ☐ n/a
Management of IMP/AMP	
a) Will the Sponsor provide prescription forms or is it permitted for sites to use their own? If it is permitted for a site to use their own, will the Sponsor need to approve the prescription forms?	If the Baricitinib is provided via hospital stock, they study does not mandate the study drug prescription template. It should be prescribed as per the sites standard practice. Sites will be encouraged to include the trial name on the patient prescription for traceability
b) Accountability requirements Check if site's own accountability logs may be used	Where IMP is taken from routine hospital stock, accountability will be risk adapted, and there will be no requirement for trial specific accountability.
c) How will receipt and re-ordering of IMP/AMP be done?	Other (please specify) Hospital own stock
d) How is the IMP transported from supplier to site? E.g. use of TempTale® device, requirement to return shipping box on receipt. Include any specific requirements for transportation of IMP from pharmacy to clinic on site	Hospital own stock
e) When will the initial shipment of IMP be sent? E.g. at site activation, at first patient screening, at first patient randomisation	Hospital own stock
f) What is the lead time for delivery of IMP to site once the order is placed?	Hospital own stock

g) Level of control required on trial stock E.g. dispensing of specific pack numbers, reporting stock balance	Sites should follow local processes for ensuring that stock is available for the trial. It is the responsibility of the site team (pharmacy and ICU teams) to ensure there are adequate stock levels of the IMP available at the time of randomisation (which may be outside normal office hours).
h) Management of returned IMP Would pharmacy be responsible for a compliance count?	If provided by hospital stock, please follow local procedures for the return and destruction of hospital stock.
i) Disposal arrangements	Local disposal

Section 10.2: Product Information	
Description and Product Type	
a) Description of Product Include name, strength, concentration, volume, form e.g. Drug A 100mg in 5ml Injection (10ml vial)	Simvastatin 20mg tablets Simvastatin 40mg tablets Simvastatin 80mg tablets
b) Is the product an IMP (investigational medicinal product) or AMP (auxiliary medicinal product)?	IMP ☒ AMP ☐
c) Are all the drug names correct (i.e. rINN)?	Yes ☒ No ☐
d) Route of administration (include detail of timing in relation to food and how to take etc.)	Oral
e) Licence status	Licensed outside this indication
f) Properties of product requiring special attention	N/A ☐ Cytotoxic ☐ Monoclonal Antibody ☐ Cytotoxic Monoclonal Antibody ☐ Cytostatic ☐ Biological ☐ ATMP ☐ Radiopharmaceutical ☐ Other (please specify) ☐ For those preparing to administer simvastatin, ensure the tablet is not crushed or dispersed if you are pregnant.
g) Is it a controlled drug? If yes, include details of Sponsor's arrangements for safe and secure handling of drug	Yes ☐ No ☒ N/A ☐
h) If it is a controlled drug, which schedule is it in?	N/A ☒ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
i) Will additional licenses be required?	Yes ☐ No ☐ N/A ☒
Dose banding and capping	
a) Is dose banding permitted? If nationally dose banded drug, is the use of national dose banding table permitted?	Yes ☐ No ☐ N/A ☒
b) What dose capping/rounding protocols are permitted?	n/a
Product Source	

a) Source of product	Dispensed from commercial stocks
b) If the product is to be sourced from commercial stocks, will it be reimbursed?	Yes ☒ No ☐ N/A ☐ Sites will be paid a per patient fee which will cover work on the trial and additional cost for IMPs.
c) If the product is to be sourced from commercial stocks, can any brand be used?	Yes ☒ No ☐ N/A ☐ obtained via hospital stock from each participating site where possible
d) Is the use of pre-filled infusion bags and/or syringes procured through a third-party manufacturer permitted?	Yes ☐ No ☐ N/A ☒
Packaging and Storage	
a) Packaging of IMP E.g. Primary: in HDPE bottles with child resistant cap; Secondary: 1 carton (kit) contains 2 bottles. Dimensions: Kit dimensions – 12x20x10cm	Dependent on hospital stocks
b) Storage conditions of the product E.g. 2-8°C. Include details of temperature monitoring requirements and temperature deviation procedures	Simvastatin should be stored as per SmPC. If provided from hospital stock, temperature monitoring should be as per local site practice. Local practice should also be followed for dealing with temperature excursions. No reporting of temperature excursions to the sponsor is required.
c) Storage space requirements for initial supplies i.e. details on size of initial shipment	Hospital own stock
Product Preparation	
a) Provide detailed information on methods of reconstitution/dilution/preparation Include information on diluents, time to dissolve/reconstitute, container compatibility, equipment (filters etc.) and safety handling requirements, detail on any drug/drug compatibility	The pharmacy manual contains information on preparation of a dose for administration if the patient has swallowing difficulties but does not have a gastric tube in situ and preparation for adminsitration via a orogastric, nasogastric tube or PEG or PEJ tubes.
b) Does the Sponsor require product preparation in an aseptically controlled environment, or can it be prepared using aseptic manipulation in a general area?	n/a
c) Stability and storage requirements of reconstituted/diluted/prepared product of those requiring aseptic manipulation E.g. Diluted solution to be stored at room temperature for no more than 12 hours after preparation	n/a
d) Are all drug formulations appropriate to the patient population (e.g. liquids for paediatrics)?	Yes ☒ No ☐ Preferred method of administration is tablets swallowed whole, however the pharmacy manual provides detailed instruction for administration for patients with swallowing difficulties or that have gastric tubes.

IMP/AMP Labelling	
a) Are the drug labels available for review?	Yes ☐ No ☐ N/A ☒
b) For IMP(s), are these compliant with Annexe 13?	Yes ☐ No ☐ n/a
c) Is there any other information that should be on the labels?	The MHRA IMP risk classification for the trial is Type A risk adapted CTIMP as any potential risk is no higher than that of standard medical care. As new interventions are added to the trial, this will be reviewed. Commercial IMP taken from hospital stock already stored in the hospital will not require a study specific label.
d) Are sites allowed to use their own labels in their local format?	Yes ☐ No ☐ n/a
e) Are sites required or permitted to add their own dispensing labels?	Yes ☐ No ☐ n/a
f) Is there consistency between drug names in the protocol and on the label?	Yes ☐ No ☐ n/a
Management of IMP/AMP	
a) Will the Sponsor provide prescription forms or is it permitted for sites to use their own? If it is permitted for a site to use their own, will the Sponsor need to approve the prescription forms?	For hospital stock Simvastatin, the study does not mandate a study drug prescription template. It should be prescribed as per the sites normal practice. Sites will be encouraged to include the trial name on the patient prescription for traceability.
b) Accountability requirements Check if site's own accountability logs may be used	Where IMP is taken from routine hospital stock, accountability will be risk adapted, and there will be no requirement for trial specific accountability.
c) How will receipt and re-ordering of IMP/AMP be done?	Other (please specify) Hospital own stock
d) How is the IMP transported from supplier to site? E.g. use of TempTale® device, requirement to return shipping box on receipt. Include any specific requirements for transportation of IMP from pharmacy to clinic on site	Hospital own stock
e) When will the initial shipment of IMP be sent? E.g. at site activation, at first patient screening, at first patient randomisation	Hospital own stock
f) What is the lead time for delivery of IMP to site once the order is placed?	Hospital own stock
g) Level of control required on trial stock E.g. dispensing of specific pack numbers, reporting stock balance	Sites should follow local processes for ensuring that stock is available for the trial. It is the responsibility of the site team (pharmacy and ICU teams) to ensure there are adequate stock levels of the IMP available at the time of randomisation (which may be outside normal office hours).

h) Management of returned IMP Would pharmacy be responsible for a compliance count?	If provided by hospital stock, please follow local procedures for the return and destruction of hospital stock.
i) Disposal arrangements	Local disposal

Section 11: Additional Information
For example, information on supportive care (pre or post medication requirements), specific consumables, potential issue e.g. gene therapy isolators, or any further requirements (drug interactions/contraindications, concomitant meds) which may affect pharmacy. Please include details if the study is a stratified CTIMP or additional arms are expected.
This is an adaptive trial design, platform study, where the arms (interventions) may change over time. The MHRA IMP risk classification for the trial is Type A risk adapted CTIMP as any potential risk is no higher than that of standard medical care. As new interventions are added to the trial, this will be reviewed. Commercial IMP taken from hospital stock already stored in the hospital will not require a study specific label or accountability.

Part 3: Nation specific review. To be completed by Pharmacy Reviewer(s) (Devolved Administrations only, if applicable)

Section 12: Clinical Information	
a) Is appropriate guidance given of support/rescue medication e.g. antiemetics/pre-medications?	Yes ☐ No ☐ N/A ☐
b) Is information given on side-effects?	Yes ☐ No ☐ N/A ☐
c) Is information given on treatment of side-effects?	Yes ☐ No ☐ N/A ☐
d) Are cautions/contra-indications listed?	Yes ☐ No ☐ N/A ☐
e) Is information given on concomitant medication permitted/prohibited?	Yes ☐ No ☐ N/A ☐
f) Is appropriate information given on dose modifications/delays and interruptions?	Yes ☐ No ☐ N/A ☐
g) Is the drug information contained in the Participant Information Sheet complete and appropriate?	Yes ☐ No ☐ N/A ☐
h) Other/Comments	

Section 13: GP Letter	
a) Does the GP letter contain information regarding permitted/disallowed concomitant medications?	Yes ☐ No ☐ N/A ☐
b) Does the GP letter contain information regarding potential interactions and known side-effects as detailed in the study protocol?	Yes ☐ No ☐ N/A ☐
c) Is the GP required to see the patient in direct respect of their participation in the study? If yes – add detail.	Yes ☐ No ☐ N/A ☐
d) Is the GP required to prescribe any IMP or supportive medication as a result of patient participation in the study? If yes, add detail.	Yes ☐ No ☐ N/A ☐
e) Is the letter explicit on any GP activity required as a result of the patient's participation in the study? If yes – add detail	Yes ☐ No ☐ N/A ☐

Section 14: Commercial Costing Template/Fees Agreed	
a) State version of commercial template used.	Version
Set up, management and close-down costs	
a) Set Up/Close Down for each additional site	Yes ☐ No ☐ N/A ☐
b) IMP management fee	Yes ☐ No ☐ N/A ☐
Per Patient Costs Per Drug	
a) Number of drugs:	Standard Dispensing Aseptic Dispensing
b) Dispensing time for standard agent or IMP/AMP (excluding use of IVR/IWR)	Yes ☐ No ☐ N/A ☐
c) Aseptic dispensing agent time	Yes ☐ No ☐ N/A ☐
d) Controlled drug – additional dispensing time	Yes ☐ No ☐ N/A ☐
e) Use of IVR/IWR system for dispensing by Pharmacy (additional time)	Yes ☐ No ☐ N/A ☐
f) Pharmacy arrangement of IMP delivery or posting preparation time	Yes ☐ No ☐ N/A ☐
g) Patient drug accountability time/medicine reconciliation	Yes ☐ No ☐ N/A ☐
Variable Costs (only charged if applicable)	
a) Storage space over 0.5m² approx. (=one shelf 0.3m deep x 1.5m long) per month	Yes ☐ No ☐ N/A ☐
b) Waste disposal as hazardous waste per 50L container	Yes ☐ No ☐ N/A ☐
c) Waste disposal storage pending collection or disposal of all unused/unwanted/expired medicines originally supplied by Sponsor per month or part thereof (Chargeable only if not collected within 1 month of the first request to collect)	Yes ☐ No ☐ N/A ☐
Additional costs (to be met by Sponsor as required)	
a) Re-labelling and releasing of IMP batch (e.g. shelf life extension)	Yes ☐ No ☐ N/A ☐
b) CRA-requested dedicated Pharmacy staff time to support monitoring visits. Chargeable as additional to standard/routine service provision of basic access, hospitality, documentation provision and query response	Yes ☐ No ☐ N/A ☐

c) Revision of relevant SOPs or IMP documentation as a result of a substantial protocol amendment	Yes ☐ No ☐ N/A ☐
d) Non-standard reporting of or additional company requested stock or temperature checks	Yes ☐ No ☐ N/A ☐
Miscellaneous Costs	
a) IMP specific consumables (total cost)	Yes ☐ No ☐ N/A ☐
b) Equipment purchase for specific IMP requirements in storage space or conditions (total cost)	Yes ☐ No ☐ N/A ☐
Drug Costs	
a) Name of drug/product	
b) Drug reimbursement to be covered in contract	Yes ☐ No ☐ N/A ☐
Potential Fees that would be specific to individual sites and their agreement to commit to extra workload	
a) Courier/posting costs for IMPs (third party costs as required e.g. per patient)	Yes ☐ No ☐ N/A ☐
b) Out-of-hours working (Usual staff hourly rate + 100%)	Yes ☐ No ☐ N/A ☐
c) Extending working hours (Usual staff hourly rate + 50%)	Yes ☐ No ☐ N/A ☐
d) Other/Comments	

Section 15: Non-commercial Costing	
a) Are fees available for any activities relating to the placebo drug in the project?	Yes ☐ No ☐ N/A ☐
b) Other/Comments	

Section 16: General	
a) Any comments on study design?	
b) Are the archiving arrangements specified?	Yes ☐ No ☐ N/A ☐
c) Other/Comments	

Section 17: Identified Sites		
List all Potential Sites	**Local Pharmacy Contact**	**Contact Made**

		Yes ☐ No ☐ N/A ☐
		Yes ☐ No ☐ N/A ☐
		Yes ☐ No ☐ N/A ☐
		Yes ☐ No ☐ N/A ☐
		Yes ☐ No ☐ N/A ☐

Part 4: Review outcome. To be completed by HRA Pharmacy Reviewer(s) (All nations)

Section 18: Review form completion				
Completed By (Lead Reviewer)	**Employing Organisation/Health Board**	**HRA registered reviewer number**	**Date**	**Outcome**
Holly Burton	UHS	HRA6012PA	09/07/2025	1 ☐ 2 ☒ Baricitinib is high cost drug, sponsor have said they expect the treatment of Baricitinib within the trial to be covered by patient fees and excess treatment costs. Locally sites will need to manage ordering of high cost drug and reimbursment.

Outcome

1 **Co-ordinated Review Completed** All risks managed & mitigated. Proceed to final local review

2 **Co-ordinated Review Completed** Some risks require local mitigation. Proceed to local review with clarification required

Completed By (Additional Reviewer)	**Employing Organisation/Health Board**	**HRA registered reviewer number**	**Date**