Pharmacy Technical Review Form for CTIMPs

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

Section 1: Reviewer Identification			
Pharmacy Reviewer		**Employing Organisation/Health Board**	
Additional Pharmacy Reviewer		**Employing Organisation/Health Board**	

Section 2: Study Identification	
Pharmacy Specialisms	Adult Oncology ☐ Paediatric Oncology ☐ Adult Non-oncology ☐ Paediatric Non-oncology ☐ Radiopharmacy ☐ ATIMPs ☐
Full Protocol Title	
Study Acronym (if applicable)	
Sponsor Protocol Reference	
NRS ID Number (Scotland only)	
EudraCT Number	
IRAS Number	
Sponsor Organisation	

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Section 3: Documents reviewed as part of this submission		
Document	**Version Number**	**Date**

Section 4: Details of Sites	
Number of sites in UK at initial submission	
Total recruitment planned in UK at initial submission	
Does the study involve Primary Care?	

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

Section 5: 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	

Section 6: 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 ☐
Additional resource information	
a) Dispensing schedule Include number of dispensing and frequency	
b) Duration of treatment E.g. 13 days/6 cycles/2 years/until disease progression	
c) Does the protocol dictate dispensing out of hours?	Yes ☐ No ☐

Section 7: Treatment allocation/Randomisation/Blinding	
a) Is Pharmacy blinded?	Yes ☐ No ☐ N/A ☐
b) If local pharmacies will be involved in repackaging and/or relabelling open-label medication to blind, give	

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details	
c) Will Pharmacy be involved in treatment allocation?	Yes ☐ No ☐ N/A ☐
d) How will Pharmacy be notified of treatment allocation details?	Select:
e) Can randomisation be done in advance of patient visit?	
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 8: Emergency Unblinding	
a) What is the process for emergency unblinding?	
b) Will Pharmacy be involved in emergency unblinding?	Yes ☐ No ☐ N/A ☐

Section 9: General Funding	
a) Are there likely to be excess treatment costs or other local funding implications?	
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?	Yes ☐ No ☐ N/A ☐

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Include arrangement details and whether there is written confirmation of the exit strategy.	
d) Other/Comments	

Section 10: 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) ☐
e) Blood test validity periods/Frequency specified	

Section 11.1: 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)	
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.)	Select:
e) Licence status	Select:

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f) Properties of product requiring special attention	N/A ☐ Cytotoxic ☐ Monoclonal Antibody ☐ Cytotoxic Monoclonal Antibody ☐ Cytostatic ☐ Biological ☐ ATMP ☐ Radiopharmaceutical ☐ Other (please specify) ☐
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?	
Product Source	
a) Source of product	Select:
b) If the product is to be sourced from commercial stocks, will it be reimbursed?	Yes ☐ No ☐ N/A ☐
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 –	

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12x20x10cm	
b) Storage conditions of the product E.g. 2-8°C. Include details of temperature monitoring requirements and temperature deviation procedures	
c) Storage space requirements for initial supplies i.e. details on size of initial shipment	
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	
b) Does the Sponsor require product preparation in an aseptically controlled environment, or can it be prepared using aseptic manipulation in a general area?	
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	
d) Are all drug formulations appropriate to the patient population (e.g. liquids for paediatrics)?	Yes ☐ No ☐
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 ☐
c) Is there any other information that should be on the labels?	

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d) Are sites allowed to use their own labels in their local format?	Yes ☐ No ☐
e) Are sites required or permitted to add their own dispensing labels?	Yes ☐ No ☐
f) Is there consistency between drug names in the protocol and on the label?	Yes ☐ No ☐
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?	
b) Accountability requirements Check if site's own accountability logs may be used	
c) How will receipt and re-ordering of IMP/AMP be done?	Select:
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	
e) When will the initial shipment of IMP be sent? E.g. at site activation, at first patient screening, at first patient randomisation	
f) What is the lead time for delivery of IMP to site once the order is placed?	
g) Level of control required on trial stock E.g. dispensing of specific pack numbers, reporting stock balance	
h) Management of returned IMP Would pharmacy be responsible for a compliance count?	

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i) Disposal arrangements	Select:

Section 12: 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.

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

Section 13: 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 14: 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	Yes ☐ No ☐ N/A ☐

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their participation in the study? If yes – add detail.	
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 15: 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 ☐

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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	

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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 16: 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 17: General	
a) Any comments on study design?	
b) Are the archiving arrangements specified?	Yes ☐ No ☐ N/A ☐
c) Other/Comments	

Section 18: Identified Sites		
List all Potential Sites	**Local Pharmacy Contact**	**Contact Made**
		Yes ☐ No ☐ N/A ☐
		Yes ☐ No ☐ N/A ☐

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

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

Section 19: Review form completion				
Completed By	**Role**	**HRA registered reviewer number**	**Date**	**Outcome**
				1 ☐ 2 ☐

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