

The University of Manchester

Appendix 3: Sponsor Lead Pharmacist Role Guideline

Introduction

Based on the Royal Pharmaceutical Society (RPS) Professional Guidance on Pharmacy Services for Clinical Trials Version 1, October 2013:

The role of the pharmacist in relation to clinical research is:

- a) To safeguard subjects, health care professionals and the Healthcare Provider Organisation (HPO) by ensuring that IMPs are appropriate for use and are procured, handled, stored and used safely and correctly.
- b) To ensure that IMPs are managed and dispensed to patients in accordance with the duly approved current protocol.
- c) To ensure that all pharmacy clinical trials procedures comply with relevant guidelines and regulations.

All pharmacy related activities, including Sponsor, and host pharmacy/pharmacist activities will usually be listed in the Pharmacy Delegation of Duties. This will be agreed with the Sponsor (but can vary depending on the specific requirements of a CTIMP) as seen in Appendix 2. The CI will be responsible for costing, securing funding and, where necessary, the agreed identification of the Sponsor Lead Pharmacist.

In the paragraphs below some of these activities are explained in more detail for guidance, these might vary according to the requirements of individual trials.

1. Lead Pharmacist Vendor Assessment

The Sponsor has the duty for ensuring responsibilities relating to IMP activities are delegated to individuals who are appropriately trained and qualified. This will be assessed in the Lead Pharmacist Vendor Assessment checklist. This will be performed by the Sponsor Lead Pharmacist. When noncompliance is identified, a corrective action and preventative action (CAPA) plan will be agreed with the Sponsor and implemented prior the activities involved taking place.

2. Funding Application

When possible the Sponsor Lead Pharmacist should be involved in the funding application to make sure all IMP management activities are adequately costed. Activities related to manufacturing and distribution, host pharmacy set up, close out and IMP management of the trial should be included.

Excess treatment costs and access to the IMP at the end of the trial will have to be evaluated at this stage.

3. Protocol Review (IB or SmPC)

The Sponsor Lead pharmacist must review the IMP related sections of the protocol, for safety and integrity of the research purpose, this should be done by cross-checking with the safety reference document available (IB or SmPC) and the investigational medicinal product dossier when available. Protocol sections related to IMP management include but are not restricted to: inclusion/exclusion criteria, IMP section, concomitant medication, side effects, pharmacovigilance, blinding procedure, IMP supplies, and IMP related quality management

4. IMP Risk Assessment

The Sponsor Lead Pharmacist should complete an IMP risk assessment (see Appendix A): This IMP risk assessment will feed back into the general risk assessment performed by the sponsor and in turn, to the monitoring plan when appropriate.

When more than one IMP is studied a separate IMP risk assessment can be used for each product.

This IMP risk assessment should be amended if a substantial amendment is approved that has the potential to change the previously identified risks.

5. Patient Information Sheet (PIS)

Prior to the submission of the ethics application, the Sponsor Lead Pharmacist should review the PIS for accuracy of the information provided to the participants. IMP, treatment, concomitant medications, SE and post-trial IMP access should be reviewed, cross checking with the protocol.

6. Clinical Trials Application

The Sponsor Lead Pharmacist should check or help when required with the provision of the IMP section of the clinical trials application including related documents ie. IB, IMPD, sIMPD, etc.

7. Pharmacy Manual

A pharmacy manual is required for multicentre trials. For single centre trials, a pharmacy manual will be written at the Sponsor Lead Pharmacist's discretion.

The Sponsor Lead Pharmacist should design, create or review the pharmacy manual when required. The IMP management and governance information contained must be in line with the protocol, safety reference, GMP, GDP and GCP.

As a minimum the pharmacy manual should contain information regarding:

- IMP information
- Supplies
- Storage
- Randomisation
- Blinding and unblinding procedure
- Prescribing
- Labelling and Dispensing
- Administration and precautions
- Temperature excursions
- Accountability
- IMP complaints
- IMP destruction
- Drug recallNIMPs
- Monitoring
- Archiving

8. IMP Supplies:

- a. **Vendor Assessment:** IMP manufacturing, labelling and distribution. A vendor assessment should be done to the IMP manufacturing and distributing sites following The University of Manchester vendor assessment SOP 21, when a full audit is required the sponsor supplies vendor assessment should be used.
- b. **Technical Agreement/Quality Agreement:** A technical agreement/Quality agreement must be put in place between the sponsor and the vendor to document respective responsibilities, and must include the quality standards that will be adhered to (e.g. GMP, GDP). In some cases this may be also present as a separate section in the general contract agreement with the sponsor.
 - The Sponsor Lead Pharmacist, must check the technical agreement(s) in place for the IMP supplies; this includes manufacturing and distribution of IMP. This should be done in accordance to Good Manufacturing Practice. The checklist detailed in Appendix B should be completed to assure the content covers all the points highlighted when relevant to the trial.

9. Conduct of the trial

Host pharmacies: For multicentre trials the Sponsor Lead Pharmacist will review the feasibility form sent to the host pharmacies, see Appendix C for guideline of questions relevant to IMP management for the feasibility form. When relevant, the Trial Lead Pharmacist should request and review the following SOPs from the local site pharmacies:

- Temperature monitoring system, out of hours procedures for temperature deviations, annual calibration certificates.
- Blinding and unblinding procedures, out of hour procedures when applicable.
- Recall SOP
- Destruction SOP or waste policy for the site.

When inadequacies, that might put at risk the safety of the participants or the validity of the research, are encountered, the sponsor should be informed and an action plan should be put in place- with the sponsor and completed by the host site prior to giving green light to the site.

10. Monitoring and auditing host pharmacies

The Sponsor will agree with the research team or CTU, when relevant, the level of monitoring required for the trial, this will include IMP management activities, and this will be reflected in the monitoring plan. The general risk assessment and IMP risk assessment will inform the monitoring plan.

11. Documentation

The Trial Lead Pharmacist will be advised to keep all correspondence and documentation related to the trial to be collated to the TMF at the end of the trial.



The University of Manchester

Appendix A: The University of Manchester IMP Risk Assessment Form (RAF) for XXX (name of trial)

Note Appendix A is a guideline	, the list of risk contained in this form	is not exhaustive, this can be	modified depending of the	specific risks of each trial and	d medicinal product being i	nvestigated ir
the study						

The RAF should be reviewed, and amended if necessary, whenever substantial amendments are made to the protocol or other key trial documentation with potential impact on efficacy or safety to the participant or the outcomes of the research.

Study Title (in full):							
Version							
IMP							
IMP class and mode of	action						
Date of Completion							
Completed by							
Review and Revision	record						
	1		<u> </u>			Outcome of review	T
RAF review			Version of RAF			(revision required /no	
date	Reason for re		reviewed		Protocol version & date	revision required)	Summary of revisions
	change requested by substantial amenda number); etc.						
for clinical monitoring of Measures and controls w consideration should be s	f such risks sho where the risk o summarised as	uld be descril f the interven part of the ju	bed below. Ition is considered	to be con			rials) details regarding specific risks to body systems and proposed methods elled out in detail. However basic assumptions about routine monitoring and
IMP/Intervention	Body system		Potential Toxiciti	ies		Mitigation s	trategies described in the protocol
Outline any other process	ses that have be	een put in plac	ce to mitigate risk:	s to partic	cipant safety		

		Is there a particular risk?	Mitigation Strategies / Adaptations to minimise the	
		Considerations/Concerns Identified	hazard: Address all concerns identified	Additional monitoring methods
	RISK/HAZARD	Provide details of trial-specific	Provide details of any risk-adaptations to conventional	required: discuss impact on trial monitoring
		considerations/risk concerns	GCP management strategies employed	requirements
1	SAFETY			
	Complex dose			
	schedule/ administration			
1.1	regime. Potential			
	risk for dosing			
	errors Dose, contra-			
	indications/cautions			
	in SmPC or IB correlate to protocol			
4.2	(e.g.			
1.2	inclusion/exclusion/			
	withdrawal criteria)			
	Known/anticipated			
1.3	side effects addressed within the			
	protocol			
	May concomitant			
	medications increase the risk? Are drug-			
1.4	drug or drug- food			
1.4	interactions detailed			
	in protocol and PIS?			
	Use of IMP in renal and liver impairment			
1.5	detailed in protocol?			
	Is patient			
4.6	monitoring			
1.6	required during			
	IMP administration?			
	Is patient monitoring			
	required after IMP			
	treatment? Is			
1.7	additional safety monitoring required?			
	Is process for dose			
	escalation, dose			
1.8	reduction, and			
	cessation of IMP			
	detailed in protocol?			
	Does length of treatment with			
4.0	IMP in trial exceed			
1.9	that for current			
	clinical practice?			
	Is an Investigator Brochure required? Is			
1.1.0	this the current			
	version?			
	Is IMP subject to any			
1.11	safety alerts or			
	require any special measures?			
	Have MHRA drug			
	analysis prints (DAPs) for			
1.12	IMP been			
	reviewed by the research team/CI?			
	Is the CI and the			
1.13	research team experienced with			
	IMP?			
	Has the safety data			
	sheet been			
1.14	reviewed and COSHH concerns			
	addressed?			
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manufactured and				
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country- QP			country- QP	
declaration. Detail			declaration. Detail	
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Appendix B: CHECKLIST and RESPONSIBILITIES FOR TECHNICAL AGREEMENTS

Tick who is responsible (UoM as Sponsor or IMP manufacturer/distributer as contractor):

Item/Activity	Sponsor	Contractor	Date	Comments
General Arrangements for Manuf		Contractor	Dute	Comments
Protocol provision	detaining			
If IMP manufacture takes place				
overseas, do they have an EU				
site to QP certify?				
Manufacturing License for				
Clinical Trials (MIA)				
QP in the MIA License for the				
services provided for the specific				
trial				
Report and advise on results of				
audits and inspections				
Operations in accordance with				
GMP (Annex 13)				
Setting up of Product				Containing all documentation pertaining to the
Specification File. Containing all				manufacture, assembly and distribution of the IMP/Placebo for approval by the contract giver.
approved documents.				ivit /1 facebo for approval by the contract giver.
Approval of SOP and batch manufacturing records.				
_				Including lead-time from order to deliver
Ordering process agreed Confidentiality arrangements				merading read-time from order to deliver
Starting Materials for Manufactu	ring			
Details of starting materials	· · · '8			Drug, excipients and packaging components
agreed and filed in the PSF				puringing components
Copy of the PSF signed by both				
parties as part as technical				
agreement				
Freedom from TSE statement for				
any liable materials used in				
manufacture or packaging				
Manufacture of Active and Placel	oo Products			
Agreement formulation and				
physical parameters for any				
placebo product				
Agreement the analytical testing				Microbiological testing will form part of the normal
of products to be undertaken				release criteria (agreed protocols will be filed in the PSF).
Packaging				1 S1).
Provision of details of packaging				Size, labelling instructions batch size and patient
The second of th				information leaflets.
Approval of Label				Signed copy filled in SPF
Details of Blinding and				
Randomisation				
Agreement on the control,				
security and disclosure				
arrangements for the blinding				
and randomisation details				
Quality Control				
Sampling and quality control				Establish extra number required
inspection Congrating quality specifications				
Generating quality specifications for all raw materials and finished	i			
l product				
product Storage conditions and deviation				Establish time-frame to report
Storage conditions and deviation				Establish time-frame to report
Storage conditions and deviation reporting				Establish time-frame to report
Storage conditions and deviation reporting Unplanned deviations reporting				Establish time-frame to report
Storage conditions and deviation reporting				Establish time-frame to report
Storage conditions and deviation reporting Unplanned deviations reporting and action plan				Establish time-frame to report
Storage conditions and deviation reporting Unplanned deviations reporting and action plan Details of analytical testing				Establish time-frame to report
Storage conditions and deviation reporting Unplanned deviations reporting and action plan Details of analytical testing agreed with QP				Establish time-frame to report
Storage conditions and deviation reporting Unplanned deviations reporting and action plan Details of analytical testing agreed with QP Retained Samples				Establish time-frame to report
Storage conditions and deviation reporting Unplanned deviations reporting and action plan Details of analytical testing agreed with QP Retained Samples Retain samples of final product				Establish time-frame to report
Storage conditions and deviation reporting Unplanned deviations reporting and action plan Details of analytical testing agreed with QP Retained Samples Retain samples of final product for agreed period Product Release and QP certificat QP approval that the product				Establish time-frame to report
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Storage conditions and deviation reporting Unplanned deviations reporting and action plan Details of analytical testing agreed with QP Retained Samples Retain samples of final product for agreed period Product Release and QP certificat QP approval that the product has been manufactured/assembled in compliance with GMP and the				Establish time-frame to report
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Storage conditions and deviation reporting Unplanned deviations reporting and action plan Details of analytical testing agreed with QP Retained Samples Retain samples of final product for agreed period Product Release and QP certificat QP approval that the product has been manufactured/assembled in compliance with GMP and the PSF The QP will provide a signed certificate of conformity with each batch of product				Establish time-frame to report

temperature as specified in the	
PSF	
Supply of Finished Product	
The product will be supply as	When the process is complete and QP approval has
directed in writing	been issued
Disposal of Surplus or Reject Product	
Disposal of any reject materials	
Complaints and Defect Reports	
Complaints will be investigated	In case of a potentially serious complaint the initial
within a reasonable time scale	response will be within 24h
upon written request and a	
written report will be provided	
Any quality defect in the product	
will be reported at any time	
Pharmacovigilance	
Advise of any suspected adverse	
events reported at any time	
Product Recall	
Responsibility for initiating a	Information and assistance
product recall	
Archiving	
Agreement on end-of-trial	
document archiving	
arrangements	
Supply of Product for Compassionate Use	
Assurance that the product will	
be available for compassionate	
use, if necessary	
Financial service provided	
agreed with company	
Agreement in place prior CTIMP	
commencing	



Appendix C. Pharmacy Site Feasibility Form

Site Name: Protocol:

The purpose of this document is to collect essential information on your site IMP management procedures. The information reported will be provided to The University of Manchester prior to the site activation visit.

STUDY LOGISTICS (To be completed by the Trial Manager)

Specify if IMP is Blinded: Yes/No

Randomisation and Product allocation system:

Initial IMP is supplied at: Local Site Activation/ Randomisation of first participant

Is IMP automatically supplied or do the site manage further supplies?:

Study Equipment is Supplied:

Estimated Pre activation visit date:

Other Important Information Site to be aware of:

IMPs F	ormulation		Acceptable Temperate Range
Key Pharmacy Contacts			
Pharmacist Name:		Pharma	ncy Technician Name
Email:		Email:	
Please specify Pharmacy Team's availab	ility for		Date(s):
	-	Specif	

Item	Pharmacy Team's Processes & Procedures	Checked by Trial Manager/CTU/ Sponsor [Date & Initials]
1.	Please provide a contact name & address for IMP deliveries	•
Pharmacy Response		
2.	Who will check if stock is received in the correct conditions & is suitable for use?	
Pharmacy Response		
3.	Will IMP be stored outside of the pharmacy unit (eg satellite sites, on ward, private dialysis unit, pharmacy stores)?	
Pharmacy Response		
4.	Will the IMP require any significant transportation that could put the IMP at risk of a temperature excursion?	
Pharmacy Response		
5.	Please describe the method used (manual / electronic) to monitor IMP temperature whilst in storage & how temperature excursions are identified?	
Pharmacy Response		
6.	If manual temperature monitoring is used how frequently is this checked and how is this managed during weekends?	
Pharmacy Response		
7.	ALL temperature excursions outside of the acceptable temperature range (see study logistics above) to be reported to the trial manager/CTU. Who will be responsible for notifying the trial manager/CTU?	
Pharmacy Response		
8.	What procedures are in place to ensure the calibration and maintenance of the pharmacy equipment (refrigerator, thermometer & alarm) are performed according to the manufacturing guidelines?	
Pharmacy Response		
9.	What procedures are in place within pharmacy in the event of a power failure?	
Pharmacy Response		
10.	Is there a back-up refrigerator/freezer in case of an emergency? Where are they located?	
Pharmacy Response		
11.	How will IMP treatment requests be provided to the person dispensing the drug for each patient? (E.g how will they know which batch No. or Med No. to dispense?)	
Pharmacy Response		
12.	If dose is based on weight, is there a robust process in place for updating weight in the prescribing system?	
Pharmacy Response		
13. Pharmacy Response	Will authorised prescriptions be filed in pharmacy for review by the monitor/trial manager/CTU?	
14.	How will you ensure IMP remains within the correct storage conditions from dispensing to administration?	
Pharmacy Response	(E.g. will reconstituted medication have an expiration date/time?)	
15.	If aseptic units are being used, when is the next shut-down for routine deep cleaning and how long does the shutdown take? Do you foresee any impact this will have on the conduct of this study?	
Pharmacy Response	Shakaowa take. Do you foresee any impact this will have on the conduct of this study:	
16.	What procedures are in place to arrange for unused/used/expired / damaged IMP to be destroyed on site or off site? Please attach SOPs	
Pharmacy Response		
17.	Do you prefer to use your own drug accountability log or the Sponsor's Accountability Logs? If you intend to use your own, please provide a copy for review.	
Pharmacy Response		
18.	What procedures are in place to ensure new pharmacy staff receives appropriate training for their role and how to manage the IMP for the study?	

Pharmacy Response		
19.	Will pharmacy produce study specific documents / work instructions? If yes, please list documents below as	
	the monitor will need to review them.	
Pharmacy Response		
20.	Please provide the email address for IMP Notifications for your pharmacy team	
Pharmacy Response		
21.	Please specify if your pharmacy has any internal requirements to be in place before a Pre Activation visit	
	date can be confirmed?	
Pharmacy Response		
22	Please provide any additional information including relevant SOPs ie. Recall SOP, electronic prescribing CT	
	SOP if used	
Pharmacy Response		
23	Please provide CV and GCP for all members of the trials pharmacy team	
	riease provide ev and der for all members of the trials pharmacy team	
Pharmacy Response		

Site Pharmacy Staff to complete	
Completed by:	Date:
Print Name:	
Job Title:	

 ${\it Please \ return \ completed \ copy \ to \ the \ Study \ Manager \ for \ review}$