Specialist Pharmacy Service

NPCTAG National Pharmacy Clinical Trials Advisory Group

Appendix 1

Division of Responsibilities

Example - Pharmacy Delegation of Duties for Individual Trials

Note:

1. The IMP Manufacturer for the Trial XXXX study refers to XXXXX Pharmacy Manufacturing Unit (Manufacturer).
2. The CI will review all final documents, including revised versions, and have oversight of all activities.

Abbreviations: CI – Chief Investigator, LP – Lead Pharmacy, TM – Trial Manager

Aspect	Item	Responsibility	NHS Trust R&D	Sponsor Lead Pharmacist Role	CTU	IMP Manufacturer and/or importer	Host Pharmacy
1.0 Pre-study	1.1	Assign a Sponsor pharmacy representative; including input into the protocol, prepare pharmacy manual and ensure IMP supply conforms to regulatory requirements.					
	1.2	Accept role of Sponsor Lead pharmacist					
	1.3	Input to Sponsor study risk assessments (including consideration of whether IMP poses any risk to patients or pharmacy staff)					
	1.4	Input to Sponsor risk assessment regarding IMP management					
	1.5	Provide pharmacy costing for sponsor/lead pharmacist for inclusion in grant application (if applicable)					
	1.6	Coordinate and provide estimated host site costs for inclusion in grant application (including excess treatment costs and how these will be managed)					
	1.7	Risk assess the level of vendor assessment required and perform the appropriate vendor assessment and selection of the IMP supplier(s) in accordance with Sponsor processes.					

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	1.8	Act as main point of contact with IMP manufacturer(s) and any packaging and distribution vendors during trial set-up and conduct of the trial.					
	1.9	Input to site feasibility questionnaire (to ensure facilities, staffing and clinical consideration are covered at host site)					
	1.10	Completion of participating site feasibility questionnaire					
	1.11	Ensure that all clinical trial medicines have been manufactured in accordance with Good Manufacturing Practice (GMP), are of suitable quality and fit for purpose					
	1.12	Ensure that the source of all trial IMPs are appropriate and all IMP documentation are received from IMP manufacturer (including, but not limited to, manufacturing or importing authorisation, stability data of IMP, QP certificates, and IB or SmPC) For CTIMPs sourced from outside the UK, Sponsor Pharmacy representative shall ensure all release documentation is compliant with UK legislation and regulation.					

Aspect	Item	Responsibility	NHS Trust R&D	Sponsor Lead Pharmacist Role	CTU	IMP Manufacturer and/or importer	Host Pharmacy
	1.13	Ensure appropriate IMP supply is appropriately contracted with IMP manufacturer or their third party (i.e. production runs, schedule of distribution / supply) • IMP supply processes, including QP release and support, distribution (ensure compliance with all EU exit guidance) • Stability data for IMP • Supply chain • Returns and destruction • Product defect support & complaint process • Form and strength of the IMP (e.g. capsule, ampoule etc.) • Quantity, size and frequency of deliveries (to permit consideration of sites' facilities and conditions to handle the intended shipments) • Expiry date of the current batch and new batch shelf life; to be able to effectively plan any manufacturing campaigns • The mechanism(s) for continued supply • IMP delivery and storage conditions (e.g. acceptable tolerance limits for temperature, humidity, exposure to light) • Support for managing temperature excursions • Use of specialist couriers to transport IMP deliveries • Discuss any specific requirement for trial supply					
	1.14	Review and approve all appropriate contracts Clinical Trials Agreements in relation to the IMP Management for the trial (where applicable)					
	1.15	Ensure appropriate clinical trials contracts are in place (IMP supply and technical agreements)					
	1.16	Finalise arrangement for IMP delivery, receipt and storage					
	1.17	Generate a master trial specific dispensing and checking procedure (IMP management procedure for Sponsor processes)					

Aspect	Item	Responsibility	NHS Trust R&D	Sponsor Lead Pharmacist Role	CTU	IMP Manufacturer and/or importer	Host Pharmacy
	1.18	Review and approve the master trial specific dispensing and checking procedure (IMP management procedure for Sponsor processes)					
	1.19	Generate a participating site specific dispensing and checking procedure (if standard practise at site to use their own)					
	1.20	Review and approval of the participating site specific dispensing and checking procedure					
	1.21	Input and review of clinical study protocol (including ensure dose is appropriate to trial population, all contra-indications, drug/disease interaction and side effects are listed)					
	1.22	Provide a named Sponsor Pharmacy representative and contact for inclusion in the clinical study protocol					
	1.23	Review and approval of the relevant sections of the clinical study protocol					
	1.24	Input & review of the IMP information included in any patient facing documentation (including but not limited to the Patient Information Sheet, medication diaries, alert cards)					
	1.25	Review and approval of the any documentation related to point 1.24					
	1.26	Review of IMP / pharmacy sections of IRAS/Combined Review application					
	1.27	Draft clinical study pharmacy manual which should include: • IMP handling and administration requirements • Ordering procedures • Temperature excursion / quarantine handling procedure • Pharmacy deviation reporting procedure • Procedure for the notification of any errors (temperature, deviation or dispensing) are notified to the Sponsor					

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	1.28	Input and review of clinical study pharmacy manual					
	1.29	Approval and sign-off of clinical study pharmacy manual					
	1.30	Generate site pharmacy trial file					
	1.31	Review and approval of site pharmacy trial file					
	1.32	Identify trial labelling requirements for each country the IMP will be used (i.e. meets the requirements covered by the Medicines for Human Use (Clinical Trials) Regulations 2004 and EU Directive 91/356; used within or outside of its MA)					
	1.33	Generate a trial specific labelling					
	1.34	Review of trial specific labelling					
	1.35	Approval of trial specific labelling					
	1.36	Generate a master trial prescription					
	1.37	Review and approval of trial prescription					
	1.38	Generate a site specific trial prescription (if standard practise at site)					
	1.39	Review and approval of site specific trial prescription (if standard practise at site to use their own)					
	1.40	Generate site master IMP accountability log (main and patient specific)					
	1.41	Review and approval of site IMP accountability log					
	1.42	Generate a site specific IMP accountability log (if standard practise at site					
	1.43	Review and approval of site specific IMP accountability log (if standard practise at site to use their own)					

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	1.44	Generate temperature log (if appropriate)					
	1.45	Review and approval temperature log					
	1.46	Generate a site specific temperature log (if standard practise at site)					
	1.47	Review and approval of site specific temperature log (if standard practise at site to use their own)					
	1.48	Generate temperature excursion log					
	1.49	Review and approval temperature excursion log					
	1.50	Generate a site specific temperature excursion log (if standard practise at site)					
	1.51	Review and approval of site specific temperature excursion log (if standard practise at site to use their own)					
	1.52	Generate pharmacy deviation log					
	1.53	Review and approval pharmacy deviation log					
	1.54	Generate a site specific pharmacy deviation log (if standard practise at site)					
	1.55	Review and approval of site specific pharmacy deviation log (if standard practise at site to use their own)					
	1.56	Input to and approval of SIV pharmacy slides					
	1.57	Input into the randomisation procedure/IRT system					
	1.58	Ensure an unblinding procedure is in place including decision of whether procedure is necessary, who can perform unblinding and what personal needs to remain unblinded					
	1.59	Review and approval of unblinding procedure					

Aspect	Item	Responsibility	NHS Trust R&D	Sponsor Lead Pharmacist Role	CTU	IMP Manufacturer and/or importer	Host Pharmacy
	1.60	Test of unblinding procedure					
	1.61	Document testing of unblinding procedure					
	1.62	Ensure all conditions related to IMP outlined in the MHRA CTA notice of acceptance letter have been met					
	1.63	Provide a pharmacy representative for membership of the TMG and SRC and any other committees as required by Sponsor (where deemed appropriate)					
	1.64	Provide technical Green light for IMP to Sponsor					
	1.65	Input to Sponsor Regulatory green light for trial					
	1.66	Input to Sponsor green light for each participating site.					
2.0 During study	2.1	IMP supply and destruction maintenance					
	2.2	Notify Sponsor immediately of any issues regarding IMP status change that could affect the conduct of the trial e.g. IMP supply and management					
	2.3	Remediate IMP related issues (where longstanding or significant issues arise)					
	2.4	Review all drug alerts and advise Sponsor on impact to the trial with particular attention to those that contain the IMP being used. Any that contain drug recalls for the IMP(s) from the Manufacturer or MHRA must immediately escalated within the Sponsor for communication and action of the CI and/or study teams as appropriate.					
	2.5	Support any drug recall activities on behalf of the sponsor					
	2.6	Advise and support any protocol, temperature and storage excursion reports from sites					

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	2.7	Assist with monitoring and data queries related to IMP/ drugs					
	2.8	Sponsor oversight committee attendance					
	2.9	Review proposed protocol amendment and assess for impact on IMP management					
3.0 IMP revisions	3.1	Review and input into changes to IMP activities (e.g. extension to expiry dates)					
	3.2	Advise on re-labelling activities					
4.0 Host Pharmacy (in some organisations this may form part of the contract with the host site)	4.1	Provide pharmacy trial file to site at initiation/activation					
	4.2	Ensure any updated documents are provided to site following amendment approval by REC/MHRA/HRA					
	4.3	IMP receipt – including acknowledgment of shipment and ensuring QP release statement held in pharmacy for each batch of IMP delivered if required by site.					
	4.4	Aware of code breaking / unblinding procedure					
	4.5	Ensure temperature monitoring system / procedure is in place					
	4.6	Calibration of temperature monitoring system; provision of certificates to Sponsor on request					
	4.7	Ensure accountability procedures are in place for dispensing of study IMP					
	4.8	Ensure procedure is in place for recording of destruction / returned of IMP					
	4.9	Ensure all staff undergoes appropriate study training (SIV slides, etc.)					

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	4.10	Keep an up-to-date delegation and training log in the site pharmacy trial file					
	4.11	Storage and records of returned, destructed or expired IMP (including quarantine of IMP where appropriate)					
	4.12	Ensure procedures are in place to allow monitoring, audits or inspection of host pharmacy as necessary					
	4.13	Reconciliation and destruction or return of IMP at study closure					
	4.14	Perform a final check of pharmacy trial file prior to archiving					