Appendix 2: Pharmacy Delegation of Duties

Example - Pharmacy Delegation of Duties for Individual Trials

"✓" = Completes the task

"(✓)" = Supports completion of the task

Note:

1. The IMP Manufacturer for the Trial XXXX study refers to XXXXX Pharmacy Manufacturing Unit (Manufacturer).
2. All documentation will be produced under close supervision of the CI and the Sponsor. 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	Host Pharmacy
1.0 Pre-study	1.1	Assign a pharmacy representative; including input into the protocol, prepare pharmacy manual and ensure IMP supply					
	1.2	Accept role of Sponsor's / Lead pharmacist					

ASPECT	ITEM	RESPONSIBILITY	NHS Trust R&D	Sponsor Lead Pharmacist Role	CTU	IMP Manufacturer	Host Pharmacy
	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 CTU 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					
	1.7	Perform a vendor assessment and selection of the IMP supplier(s)					
	1.8	Act as main point of contact with IMP manufacture during trial set-up					
	1.9	Input to site feasibility questionnaire (to ensure facilities, staffing and clinical consideration are covered at host site)					
	1.10	Completion of site feasibility questionnaire					

ASPECT	ITEM	RESPONSIBILITY	NHS Trust R&D	Sponsor Lead Pharmacist Role	CTU	IMP Manufacturer	Host Pharmacy
	1.11	Ensure that all clinical trial medicines have been manufactured in a licensed production unit 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 checked 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 EU countries, Pharmacy shall ensure QP certificates and EU GMP compliance statements are in place in accordance with GMP Annex 13.					

ASPECT	ITEM	RESPONSIBILITY	NHS Trust R&D	Sponsor Lead Pharmacist Role	CTU	IMP Manufacturer	Host Pharmacy
	1.13	Ensure appropriate IMP supply is agreed with IMP manufacturer or their third party (i.e. production runs, schedule of distribution / dispensation) • IMP supply processes, including QP release and support, distribution • Stability data for IMP • Supply chain • Returns and destruction • Product defect support • 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 for continued supply • IMP delivery and storage conditions (e.g. acceptable tolerance limits for temperature, humidity, exposure to light) • Use of specialist couriers to transport IMP deliveries • Discuss any specific requirement for trial dispensing					

ASPECT	ITEM	RESPONSIBILITY	NHS Trust R&D	Sponsor Lead Pharmacist Role	CTU	IMP Manufacturer	Host Pharmacy
	1.14	Review and approve all appropriate Clinical Trials Agreements (where applicable)					
	1.15	Ensure appropriate Clinical Trials Agreements 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)					
	1.18	Review and approval of the dispensing and checking procedure					
	1.19	Generate a site specific dispensing and checking procedure (if standard practise at site)					
	1.20	Review and approval of the 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)					

ASPECT	ITEM	RESPONSIBILITY	NHS Trust R&D	Sponsor Lead Pharmacist Role	CTU	IMP Manufacturer	Host Pharmacy
	1.22	Provide a named representative for inclusion in the clinical study protocol					
	1.23	Review and approval of the relevant sections of the clinical study protocol					
	1.24	Input to the IMP section of the Patient Information Sheet					
	1.25	Review and approval of the IMP section of the Patient Information Sheet					
	1.26	Review of IMP / pharmacy sections of IRAS					
	1.27	Draft clinical study pharmacy manual which should include: • IMP handling and administration requirements • 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					
	1.28	Input and review of clinical study pharmacy manual					
	1.29	Approval and sign-off of clinical study pharmacy manual					

ASPECT	ITEM	RESPONSIBILITY	NHS Trust R&D	Sponsor Lead Pharmacist Role	CTU	IMP Manufacturer	Host Pharmacy
	1.30	Generate pharmacy trial file					
	1.31	Review and approval pharmacy trial file					
	1.32	Identify trial labelling requirements (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					

ASPECT	ITEM	RESPONSIBILITY	NHS Trust R&D	Sponsor Lead Pharmacist Role	CTU	IMP Manufacturer	Host Pharmacy
	1.40	Generate master IMP accountability log (main and patient specific)					
	1.41	Review and approval 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					
	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					
	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)					

ASPECT	ITEM	RESPONSIBILITY	NHS Trust R&D	Sponsor Lead Pharmacist Role	CTU	IMP Manufacturer	Host Pharmacy
	1.51	Review and approval of site specific temperature excursion log					
	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					
	1.56	Input to and approval of SIV pharmacy slides					
	1.57	Input into the randomisation procedure					
	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					
	1.60	Ensure all conditions related to IMP outlined in the MHRA CTA notice of acceptance letter have been met					

ASPECT	ITEM	RESPONSIBILITY	NHS Trust R&D	Sponsor Lead Pharmacist Role	CTU	IMP Manufacturer	Host Pharmacy
	1.61	Provide a pharmacy representative for membership of the TMG (if funders require)					
2.0 During study	2.1	IMP supply and destruction maintenance					
	2.2	Notify Sponsor immediately of any issues regarding trial status change, IMP supply and management					
	2.3	Reconciliation of emerging IMP related issues					
	2.4	Remediate IMP related issues (where longstanding or significant issues arise)					
	2.5	Ensure that it informs any drug alerts and drug recalls from the Manufacturer or MHRA immediately to the Sponsor, Chief Investigator and/or study team					
	2.6	Advise and support any protocol, temperature and storage excursion reports					
	2.7	Assist with monitoring and data queries related to IMP/ drugs					
	2.8	Oversight committee attendance					

ASPECT	ITEM	RESPONSIBILITY	NHS Trust R&D	Sponsor Lead Pharmacist Role	CTU	IMP Manufacturer	Host Pharmacy
3.0 During an amendment	3.1	Review proposed protocol amendment and assess for impact on IMP management					
	3.2	Review and input into changes to IMP activities (e.g. extension to expiry dates)					
	3.3	Advise on re-labelling activities					
4.0 Host Pharmacy	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					
	4.3	IMP receipt – including acknowledgment of shipment and ensuring QP release statement held in pharmacy for each batch of IMP delivered					
	4.4	Aware of code breaking / unblinding procedure					
	4.5	Ensure temperate monitoring system / procedure is in place					
	4.6	Ensure accountability procedures are in place for dispensing of study IMP					

ASPECT	ITEM	RESPONSIBILITY	NHS Trust R&D	Sponsor Lead Pharmacist Role	CTU	IMP Manufacturer	Host Pharmacy
	4.7	Ensure procedure is in place for recording of destruction / returned of IMP					
	4.8	Ensure all staff undergoes appropriate study training (SIV slides, etc.)					
	4.9	Keep an up-to-date delegation and training log in the site pharmacy trial file					
	4.10	Storage and records of returned, destructed or expired IMP (including quarantine of IMP where appropriate)					
	4.11	Ensure procedures are in place to allow monitoring, audits or inspection of host pharmacy as necessary					
	4.12	Reconciliation and destruction or return of IMP at study closure					
	4.13	Perform a final check of pharmacy trial file prior to archiving					