Joint Research Management Office Standard Operating Procedure for:			
Pharmacy involvement in hosted studies			
SOP Number:	**42b**	Version Number:	**4.0**
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Purpose:

To standardise the process of Investigational Medicinal Product (IMP) management between the Clinical Trials (CT) Pharmacy and the Joint Research Management Office (JRMO) for Barts Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary) hosted studies.

To outline CT Pharmacy's involvement and responsibilities in ensuring that IMP provision for Barts Health and Queen Mary hosted studies are in line with Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP) regulations.

Scope:

This SOP covers Barts Health and Queen Mary hosted Clinical Trial of an Investigational Medicinal Product (CTIMPs) only.

IMP management of studies sponsored by either institution is covered in Pharmacy SOPCT050 (Role of Pharmacy in Clinical Trials and Management of IMP) and JRMO SOP 42a IMP management.

For purposes of this SOP, "CT pharmacy" is defined as the Lead Clinical Trial Pharmacy Personnel / Clinical Trial Pharmacy Coordinator.

Pharmacy Clinical Trial SOPs for specific activities should be consulted and adhered to in addition to this SOP.

Abbreviations:	
Barts Health	Barts Health NHS Trust
CI	Chief Investigator
CT	Clinical Trial
CTIMP	Clinical Trial of an Investigational Medicinal Product
EU	European Union
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
IMP	Investigational Medicinal Product
JRMO	Joint Research Management Office
PI	Principal Investigator
PSF	Pharmacy Site File
Queen Mary	Queen Mary University of London
SIV	Site Initiation Visit
SOP	Standard Operating Procedure
UTIN	Unique Trial Identification Number

Definitions:

- CT pharmacy: The Lead Clinical Trial Pharmacy Personnel / Clinical Trial Pharmacy Coordinator.

Relevant SOPs:

- JRMO SOP 42a Pharmacy involvement for sponsored CTIMP studies,
- Barts Health NHS Trust Pharmacy Clinical Trials SOPs

SOP Text:

Pharmacy activity at study set up

	Responsibility	Activity
1.	Principal Investigator (PI)/ Clinical Research Network staff/ JRMO Governance Officer	**Contact CT Pharmacy coordinator to make them aware of any potential CTIMP.**
2.	CT Pharmacy	**Review, cost and approve studies** This process should include identifying suitable CT pharmacy locations or where appropriate out of pharmacy storage area within the host institution
3.	CT pharmacy	**Identify suitable CT pharmacies** or where appropriate out of pharmacy storage area, and liaise with the PI, study team and Sponsor.

		Identify suitable CT pharmacy locations or where appropriate out of pharmacy storage area within the host institution, and work with the PI, Study team and Sponsor to ensure arrangements for IMP handing (e.g. storage and dispensing) are compliant with GCP and GMP regulations. Suitable pharmacy storage requirements include the need for appropriate stable temperature monitored premises, which includes, but may not be limited to storage at ambient temperature, refrigeration and standard or low temperature freezers. Pharmacy will review the storage requirements prior to approving a trial. The same level of review will be carried out by pharmacy where drugs are to be stored out of pharmacy – see section 5 below.
4.	PI/ Clinical Research Network staff/ JRMO Governance Officer	**Provide the CT Pharmacy with all relevant essential documents including Study Protocol, Pharmacy Manual, Investigators Brochure/Summary of Product Characteristics, approvals, etc. Inform the CT Pharmacy about Sight Initiation Visit (SIVs) (and ensure CT Pharmacy staff are invited), site activation, and first prescription. Notify CT Pharmacy of Unique Trial Identification Numbers (UTINs) for each new script created.** If a pharmacy manual has not already been created by the Chief Investigator (CI) and coordinating study team, liaise with the CT Pharmacy to establish what information they require and ensure they are provided with this. Please refer CT Pharmacy sponsor pack on http://www.jrmo.org.uk/performing-research/research-facilities/clinical-facilities/pharmacy-support/ for comprehensive list of documents required. Ensure CT Pharmacy coordinator is aware of the study and is invited to all Pre-Study Visits and SIVs. Ensure CT Pharmacy is informed of site activation by sponsor and inform the CT Pharmacy coordinator when the CT pharmacy can expect the first trial prescription. The pharmacy team must be sent a registration document / randomisation document (via email: ctpharmacy.bartshealth@nhs.net) by the study team with the participant's UTIN each time a new participant's script is created.
5.	CT pharmacy	**Consider out of pharmacy storage in local pharmacy approval.** If out-of-pharmacy storage is needed, follow CT pharmacy form FORCT031 (Non-Pharmacy Storage of IMP – Location Assessment Form) for set up, on-going review and audit. Use of out-of-pharmacy storage should be included in Local Pharmacy approval. CT pharmacy will maintain a list of all out-of-Pharmacy IMP storage areas. A list of out of pharmacy storage areas will be discussed in regular JRMO and pharmacy meetings.
6.	CT pharmacy	**Create and maintain a pharmacy site file (PSF) and fulfil agreed / contracted roles.** The PSF must be maintained according to local Pharmacy SOPS, GCP, and GMP requirements. The CT pharmacy will be aware and fulfil any specific roles outlined in agreements and / or contracts.
7.	CT Pharmacy	**Provide Pharmacy Final Approval**

		Should be completed by pharmacy to determine when this can be issued
Pharmacy activity during the study		
	Responsibility	**Activity**
8.	PI	**Provide CT Pharmacy with details of all amendments.** All documents and approvals must be forwarded to the CT Pharmacy via email- ctpharmacy.bartshealth@nhs.net. Ensure that all relevant correspondence with sponsor and JRMO is forwarded to the CT pharmacy in a timely manner.
9.	CT pharmacy	**Facilitate monitoring.** Liaise with Sponsors to arrange suitable time and space for monitoring visits to occur. All reasonable efforts should be made to accommodate monitoring visits and provide requested information. Respond to monitoring reports and queries in a timely manner.
10.	CT pharmacy	**Notify JRMO of audits and IMP related findings.** Ensure that the JRMO are made aware of any audits being conducted for hosted studies. Advise JRMO of any IMP related findings following the audit.
11.	CT pharmacy and study team	**Inform the JRMO in a timely manner of any issues, and / or potential breach that may affect study/ies.**
Pharmacy activity during study closure		
	Responsibility	**Activity**
14.	PI and Study team	**Notify the CT pharmacy at the end of pharmacy involvement and provide copies of the End of Trial notifications.** Inform the CT pharmacy in a timely manner when pharmacy involvement is at an end (e.g. last prescription, last returned medication etc.). Forward official end of trial notifications when received.
15.	CT pharmacy	**Conclude pharmacy involvement in a timely manner.** Work with the PI, study team, and sponsor to ensure pharmacy involvement is completed in a timely manner in line with CT pharmacy SOPCT050 (Role of Pharmacy in Clinical Trials and Management of IMP), GCP, and GMP regulations. Study files are archived as per Pharmacy SOP CTS14 (Trials Closedown and Archiving in Pharmacy).

Change control

This section outlines changes from version **3.0** to version **4.0**

Section changed	Summary and description of changes
Throughout	General Administrative changes

List of appendices

There are no appendices for this SOP.

List of Associated Documents

There are no associated documents for this SOP