LinCTU
Lincoln Clinical Trials Unit

UNIVERSITY OF LINCOLN

STANDARD OPERATING PROCEDURE

Trials Supplies
LinCTU SOP 14

Version Final 1.0 Date 19 July 2022

Effective Date: 01 November 2022

Next review: 02 years

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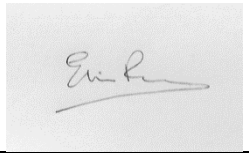
Version History	Reason for change
1.0	First LinCTU version

NOTE: All SOPs are subject to regular review.

Please ensure that the version of this SOP is the most up-to-date.

OUT OF DATE DOCUMENTS MUST NOT BE USED AND HARD COPIES SHOULD BE DESTROYED

The following have read, reviewed and advised on the SOP

Reviewer name	**Role**	**Date**	**Signature**
LinCTU Steering Committee		24/20/2022	
Dr Elise Rowan	LinCTU Data Manager	25/07/2022	
Pilar Pousada Solino	Reviewer	26/07/2022	P
Prof Graham Law	Reviewer	26/07/2022	

1 PURPOSE

This SOP applies to planning, forecasting and arrangement of Trial supplies in all types of Clinical trials or studies sponsored or co-sponsored by University of Lincoln, UK and developed, supported, and managed by Lincoln Trials Unit (LinCTU). This includes Clinical Trials of Investigational Medical Products (CTIMPs), medical devices and equipment.

2 SCOPE

This SOP is applicable to the pharmacy representative or the delegated personnel. This person, who may be external or internal to LinCTU, should take overall responsibility for trial supplies and completion on behalf of the sponsor. If needed the trial supplies can also be formally delegated to a LinCTU trial manager / coordinator provided that the pharmacy representative takes overall responsibility for final approval and sign off.

3 BACKGROUND

3.1 This SOP will ensure the forecasting and management of trial supplies for a CTIMPs, medical devices and equipment so that it is maintained according to the study/trial protocols and that the aims of the studies/trials are met as a result.

3.2 Pharmacy Representative/ delegated personnel will be responsible for procurement of Trial Supplies and will also identify potential suppliers required according to the study/trial protocol. They will also manage and oversee trial supplies stock.

3.3 The SOP will describe the steps required for trial supply management set-up and to arrange and oversight trial supply Stock.

3.4 All members of a trial/research study team who are involved with trials supplies should be familiar with this SOP.

3.5 A Non-Investigational Medicinal Product (NIMP) is a medicinal product which is not classified as an IMP in a trial but may be taken by subjects during the trial.

3.6 A medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose.

3.7 A Clinical Trial Supplies include Investigational Medical Products (IMPs), Non- Investigational Medical Products (NIMPs), medical devices and equipment.

4 CROSS REFERENCES

CG-QMS CGQM Clinical Governance - Quality Manual Final v2.0

CG-QMS SOP CG06 Regulatory Applications Final v1.0

LinCTU SOP 10 Trial Closure Final v2.0

LinCTU SOP 11 Trial Initiation Final v2.0

LinCTU SOP 12 Trial Master Site File Final v2.0

5 PROCEDURE

The definition of IMP is as follows: “a pharmaceutical form of an active substance and placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorization but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an

unauthorised indication, or when used to gain further information about the authorised form." (Directive 2001/20/EC defines in Article 2 (d)).

Non-IMPs (NIMPs), defined as "medicinal products such as concomitant or rescue/escape medication for preventive, diagnostic or therapeutic reasons and/or to ensure that adequate medical care is provided for the subject. They may also be used in accordance with the protocol to induce a physiological response." (Article 3(3) of Directive 2001/83/EC).

5.1 ROLES AND RESPONSIBILITIES

LinCTU (Lincoln Clinical Trials Unit) in collaboration with University of Lincoln (UoL) will liaise with Pharmacy Representative/delegated personnel for the Trial Supplies for each LinCTU trial/study. They will have the responsibility to ensure proper trial supplies by coordinating with respective Trial Suppliers via hospital stock or third- party vendor.

5.2 PLANNING AND FORECASTING

The planning and forecasting of Trial supplies is set up during the study start-up phase and is maintained throughout the course of the trial. Sponsor is responsible to ensure the trial supplies are managed according to relevant policies and requirements. Trial set-ups includes manufacturing of trial supplies to final importation and distribution, as appropriate. A pharmacy representative/delegated personnel should collaborate with Lincoln Trials Unit (LinCTU) to ensure proper technical oversight of trial procedures.

5.3 TRIAL SUPPLY MANAGEMENT PLAN

Trials supplies management plan is required for study of drugs or medical devices in accordance with protocol and applicable regulatory requirements. This process includes oversight of the planning, packaging, forecasting, labelling, sourcing, distribution, and trial supplies for studies sponsored or co-sponsored by University of Lincoln, UK.

Trials supplies should be managed prior to trial initiation to ensure plans are in place to carry out Trial Supply Management activities during the trial. A Trial Supply Management Plan must be established prior to starting the trial by Pharmacy representative to ensure the proper monitoring and quality is maintained.

5.4 TRIAL SUPPLY PLANNING AND FORECASTING

The Pharmacy representative/delegated personnel in collaboration with LinCTU (Lincoln Clinical Trials Unit) should ensure the planning and forecasting of trial supply is adequate for study at the beginning of trial initiation.

The trials forecasting should be analysed at various stages of trial's lifecycle. The assessment of overall trial supply should be forecasted ahead of the trial launch. The stability data of each trial supplies utilized in the trial should be documented in the eTMF (electronic Trial Master File) by Trial Manager/ Coordinator.

5.5 SUPPLY AGREEMENTS

A Supply agreement should be maintained between Sponsor, Trial Suppliers and LinCTU in accordance with Good Manufacturing Practice and Good Distribution Practice.

Each party will require a copy of the fully signed Trials Supply agreement to keep for their records. LinCTU (Lincoln Clinical Trials Unit) will store finalized signed contracts in the eTMF (electronic Trial Master File) to ensure good documentation practice.

6 FLOW CHART

None required