

STU-SOP-TM-012 – Standard Operating Procedure on Management of Medicinal Products used in Research

Version No:	3	Effective Date:	24-Apr-2026
Description of changes:	Moved to SOP Template v5. SOP reviewed in light of clinical trial regulations 2025 and GCP updates. Specific references to QPulse as the QMS have been removed. We now only refer to a QMS system.		

Abbreviations	
CI	Chief Investigator
CTA	Clinical Trial Authorisation
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTP	Clinical Trial Pharmacist
GMP	Good Manufacturing Process
IB	Investigator Brochure
LCTP	Lead Clinical Trial Pharmacist
MAH	Marketing Authorisation Holder
MHRA	Medicines and Healthcare products Regulatory Agency
MP	Medicinal Product
PI	Principal Investigator
QP	Qualified Person
SmPC	Summary of Product Characteristics
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
SU	Swansea University

1. Purpose and Definitions

This Standard Operating Procedure (SOP) describes the management process of Medicinal Products (MPs) in non-commercial Clinical Trials of Investigational Medicinal Products (CTIMPs) and other research projects conducted at single or multiple trial locations.

This SOP does not describe the processes for manufacture or packaging of MP or the release of an Investigational Medicinal Product (IMP) by a Qualified Person (QP), nor the responsibilities of pharmacy departments in dispensing MP for research projects.

Definitions	
Medicinal Product (MP)	<p>Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or, any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.</p> <p>It should be noted that medicinal products can be human, animal, vegetable or chemical in origin. A substance may come under both parts of the definition; however, it need only fall under either part of the definition to be classified as a MP</p>

Investigational Medicinal Product (IMP)	<p>A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation 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. Such research projects are classified as Clinical Trials of Investigational Medicinal Products (CTIMPs).</p>
--	---

2. Background

All research projects involving a MP require considerations to be made for the manufacture, management, distribution and accountability of MP. Where such projects are CTIMPs under the Clinical Trial Regulations 2004 and 2025, there is a legal requirement to receive a clinical trial authorisation (CTA) from the regulatory body in all countries to cover the management of the trial and use of an IMP. The CTA terms ensure the IMP is of sufficient quality and is manufactured and labelled to ensure the safety of the participants and quality of the data.

In addition to the legal requirements there are a number of points for Sponsor and CI to consider during design and set-up of a research project involving MP:

- Confirmation of regulatory, ethical and local R&D approvals are received
- All MP manufacture/assembly/importation activities must be conducted to Good Manufacturing Practice (GMP) by the MP supplier/Marketing Authorisation Holder (MAH) and confirmation of release performed by a Qualified Person (QP)
- An appropriate contract must be in place between the sponsor and any vendor to provide MP and document respective responsibilities, including the quality standards that will be adhered to.
- For blinded trials, unless the products are being provided in a final blinded format by the MP supplier/MAH, a process must be agreed for any required manufacturing and assembly activities.
- An assessment of all vendors must be performed and where applicable, documented as in SOP STU-CT008 (Selection and Oversight of Vendors). It is possible that the review conducted in a tender process may suffice. Sponsor will decide this.
- An assessment made to establish the level of MP labelling required as per Annexe 13 (https://www.gmp-compliance.org/files/guidemgr/guideline_adopted_1_en_act_part1_v3.pdf).

3. Roles and Responsibilities

The **Sponsor** has overall responsibility for MP management and may take direct responsibility for arranging MP distribution. The sponsor may delegate duties to the Chief Investigator or a vendor.

The **Chief Investigator (CI)** is responsible for liaising with a Clinical Trial Pharmacist (CTP) or equivalent throughout the research project. This action may be delegated to the Trial Manager.

The **Principal Investigator (PI)** is responsible for the IMP management at their trial location, although this is often delegated to pharmacy departments.

A **Lead Clinical Trial Pharmacist (LCTP)** or equivalent must be appointed and is responsible for advising on MP storage and handling requirements during the design and oversight of the research project.

A **Clinical Trial Pharmacist (CTP)** or equivalent oversees the receipt and management of MP used in a research project at a trial location.

The **Trial Manager (TM)** or delegate has responsibility for advising when MP should be released to trial locations and to oversee the management, distribution and accountability by trial locations.

External use of SOP: this SOP and Associated Documents (AD) may be used for research projects not adopted by STU where Swansea University (SU) staff and associated NHS organisations require guidance. In such instances, oversight responsibility for any associated tasks will not be the responsibility of STU.

4. Procedure

4.1 Project design and protocol development

During drafting of the grant proposal and the risk assessment the CI will convene a Trial Management Group (TMG) and involve a LCTP or equivalent to advise on the use of the MP.

The CI and LCTP shall discuss MP supply, the need for an external vendor, or if MP can be sourced from hospital stock whilst taking into consideration storage requirements for MP and returns.

The CI will establish pharmacy and MP costs and, if required, will obtain an illustrative quote for inclusion with the grant proposal, including arrangements and costs for drug packaging, distribution and randomisation if involved.

The LCTP will review a protocol involving a MP to ensure that all relevant product information and an emergency unblinding mechanism (if required) is included. Unblinding will be documented in an Emergency Unblinding Form (STU-AD-FRM-012).

The LCTP should review the content of the Participant Information Sheet (PIS) to assess the information supplied to the participant, and the required product information (e.g. Summary of Product Characteristics (SmPC), Investigator Brochure (IB), Simplified Investigational Medicinal Product Dossier (sIMPD), label requirement and text, stability data) for relevance prior to submission for appropriate approvals. STU-AD-TMP-043 provides examples of labels.

The CI, and other parties (as appropriate) will input into the selection of, and contractual arrangements with MP suppliers/manufacturers/distributors, as required.

4.2 MP Ordering, Shipment, Storage and Accountability

The Sponsor or delegate must confirm that all required regulatory approvals and where required, the QP release of MP are in place. This must occur prior to authorising the dispensing of any MP for the research project, as detailed in the Trial Green Light Form (STU-AD-FRM-022) and SOP (STU-SOP-TS-007). Where MP management is delegated, the oversight required will depend on the MP's characteristics. This should be reflected in the risk assessment.

For ordering externally sourced MP an MP Order Form (see example STU-AD-FRM-031) should be used. An equivalent sponsor or external vendor order form may be used as appropriate.

For all orders of MP, consideration should be given to MP expiry date and expected recruitment rate in order to identify when multiple manufacturing campaigns and/or orders are required and to minimise wastage.

Advice from a manufacturer or QP should be sought regarding the transportation and temperature monitoring (if required) of MP during transit to a central and/or local pharmacy.

All research projects involving MP require a Pharmacy Site File (PSF) to be issued by the TM (see STU-SOP-TM-003).

In consultation with the LCTP, all project specific templates related to MP shall be developed, including a Site Medicinal Product Accountability Log (STU-AD-TMP-041), Research Project Prescription (STU-AD-TMP-042), emergency Site Unblinding Request Form (STU-AD-FRM-012) and Medicinal Product Request Form (STU-AD-FRM-032).

When a marketed product is used and no trial specific labelling is required, as per Annexe 13 of the Clinical Trials Directive, a justification for the decision will be documented in the trial risk assessment and included in the regulatory application.

MP pharmacy storage areas, including those out with pharmacy, must be locally approved with appropriate processes in place before MP can be sent. If storage of returns out with pharmacy will be undertaken this shall be documented in the protocol and/or the PSF detailing the procedure for recording compliance and return to site pharmacy at appropriate intervals during the project.

For some trials, MP may be shipped directly to participants and administered by the research team, caregivers, healthcare professionals or the participant themselves. The details of this must be in the protocol.

4.3 Conduct of research

There are at least two options for the release of MP to the nominated Pharmacy of a trial location:

a) Trial location's nominated Pharmacy to receive batch shipment of multiple participant MP packs to hold for release

MP will be released in bulk to trial locations on approval by sponsor of a Site Green Light Form (STU-AD-FRM-022) in accordance with an agreement of how much stock will be shipped per delivery. Locations expecting higher numbers of participants should be issued more stock than those expecting low numbers.

Following Sponsor confirmation that all required approvals have been received, MP shall be dispensed on receipt of a signed Research Project Prescription (STU-AD-TMP-042) or transferred to a locally approved storage area, on receipt of a signed Medicinal Product Request Form (STU-AD-FRM-032). Labelling of MP, when required, shall be conducted by pharmacy in accordance with local pharmacy SOPs.

b) Trial location's nominated Pharmacy to receive individual participant-specific MP packs triggered by a randomisation

The agreement to release participant-specific MP to the Pharmacy will require a completed Site Green Light Form (STU-AD-FRM-022). However, the manufacturer will not release MP until a participant has been randomised.

The accountability (including compliance) of MP is the responsibility of all delegated research team members. Project specific requirements will be detailed in the protocol. All dispensing/return of MP shall be recorded in medical records, Case Report Forms (CRF) and a Site Medicinal Product Accountability Log (STU-AD-TMP-041)

Temperature logging and temperature deviations of MP stored within pharmacy will be managed by pharmacy in accordance with local SOPs. The trial office and Sponsor must be informed of any temperature excursions as soon as pharmacy become aware. The CI/TM shall liaise with a LCTP or manufacturer to advise on a required correction and any corrective and preventive action (CAPA).

Expiry management and relabelling, where required, shall usually be conducted by the local pharmacy in accordance with pharmacy SOPs.

For randomised research projects, arrangements shall be in place for emergency unblinding, detailed in the protocol and documented via a Site Unblinding Request Form (STU-AD-FRM-012). In exceptional circumstances, the trial location CTP may need to be involved in out of hours unblinding. The trial location CTP shall be consulted on all unblinding procedures.

MP recall, where required, shall be conducted by the local pharmacy and trial office in accordance with the protocol and pharmacy SOPs.

A LCTP will be consulted during drafting of any modification that affects management of the MP or involves the addition of an investigational site which will require supply of MP. Site CTPs will be given copies of all documents relating to relevant modifications to the research project for information and for filing in the Pharmacy file.

In exceptional circumstances, MP transfer to another investigational site, where needed, shall be conducted by the LCTP and TM in accordance with the Sponsor's SOPs.

All MP and/or packaging returned to trial location e.g., routine returns, withdrawals, recalls etc. must be documented in a Local Medicinal Product Accountability Log (STU-AD-TMP-041). Once recorded, all MP shall be returned to the local pharmacy for accountability and destruction. This will be done in accordance with local pharmacy SOPs, unless otherwise notified in the protocol.

4.4 Close-out

Once recruitment and any follow up is completed, the TM or delegate will inform the trial location CTP that the project is complete, and that the pharmacy file can be archived. The pharmacy file will be reconciled, and all documentation completed and accounted for. Any unblinding documentation shall remain in the pharmacy file unless requested by the CI for inclusion in the TMF.

The trial location CTP will reconcile all remaining MP. Any remaining MP that had been stored outside pharmacy must have been returned for destruction along with a copy of the completed Local Medicinal Product Accountability Log (STU-AD-TMP-041). The trial location CTP will

ensure that pharmacy accountability logs are reconciled, completed and signed off. MP shall be destroyed as per pharmacy SOPs. A local destruction form shall be completed and signed off by the trial location CTP.

The pharmacy file should be archived with the TMF.

5. References

- Health Research Authority website (HRA) - <http://www.hra.nhs.uk/>
- Medicine and Healthcare products Regulatory Agency website (MHRA) - <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information>
- UK policy framework for health and social care research (2017) - <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>
- UK Medicine for Human Use (Clinical Trials) Regulations 2025 - <https://www.legislation.gov.uk/ukxi/2025/538/contents>
- International Conference of Harmonisation (ICH) Good Clinical Practice (GCP) E6 R3 Guideline - https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf

It is assumed that by referencing the principal regulations that all subsequent amendments are included in this citation.

6. Associated Documents

Number	Title	Location
STU-AD-FRM-012	Emergency Site Unblinding Form	QMS
STU-AD-TMP-043	Example IMP Label Form	QMS
STU-AD-FRM-022	Regulatory Green Light Form	QMS
STU-AD-FRM-031	Medicinal Product Order Form	QMS
STU-AD-TMP-041	Local Medicinal Product Accountability Log	QMS
STU-AD-TMP-042	Research Project Prescription	QMS
STU-AD-FRM-032	Medicinal Product Request Form	QMS