IMPERIAL Research Governance and Integrity Team

Imperial College Healthcare NHS Trust

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IMP Management and Accountability

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Version 1.0	31 May 2007	Annual review
Version 2.0	20 Jun 2008	Annual review
Version 3.0	08 Feb 2010	Formation of Joint Research Office
Version 4.0	14 Jul 2011	Amendment following MHRA Inspection
Version 5.0	03 Dec 2012	Annual Review
Version 6.0	18 Feb 2015	Scheduled Review
Version 7.0	25 Oct 2017	Schedule Review. Addition of: IMP transfer between sites, CI to check SmPC regularly, Contracts responsible for technical agreement, Updated: IMP Label template
Version 8.0	19 Oct 2020	Scheduled Review. Templates removed & administrative changes to SOP. JRCO name change to RGIT.
Version 9.0	07 Jan 2021	Amendments due to leaving the European Union from 1st January 2021
Version 10.0	02 Aug 2024	Scheduled Review
Version 11.0	27 Apr 2026	Updates following legislative changes

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1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the management and accountability of Investigational Medicinal Products (IMPs) in clinical trials sponsored by Imperial College Academic Health Science Centre (AHSC).

2. INTRODUCTION

Section 3.15. of The International Conference on Harmonisation of Good Clinical Practice (ICH GCP) describes the information, manufacturing, and packaging, labelling, coding, supplying and handling of IMP (ICH E6 (R3) Guideline on good clinical practice (GCP) _Step 5).

Part 6 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument: 1031) details the regulations surrounding the manufacture and importation of IMPs. The regulations require that IMPs used in clinical trials (CTIMPs) are manufactured to Good Manufacturing Practice (GMP) standards and that GCP is adhered to.

This SOP will focus on IMP activities that Imperial College AHSC may undertake as sponsor of a clinical trial and as such, will not be an exhaustive operating procedure on all aspects concerning IMPs in clinical trials. For example, the Imperial AHSC is not currently involved in the manufacture or packaging of IMPs. This will be the responsibility of the pharmaceutical company (or other external company) involved in the clinical trial, either as funder or provider of the IMP and should be adequately detailed in all technical agreements. The pharmaceutical company (or other external company) is responsible for conducting final checks before release of IMP to the research site. This should be done by the Qualified Person (QP) to ensure that each batch has been manufactured to Good Manufacturing Practice (GMP) and all checks are in place before dispatch. This documentation would normally need to be submitted for the Clinical Trial (CT) authorisation to the Regulatory body.

The trial pharmacy is responsible for granting greenlight approval before releasing the IMP for dispensing to the trial. Pharmacy ‘greenlight’ can only be issued once all regulatory (MHRA in the UK), ethical and local trust approvals are in place to allow the dispense of the study IMP. The green light process will include review and approval of all QP and batch release documentation to ensure regulation has been followed. This will be an ongoing process for the duration of the trial and will occur for each separate batch supplied to the research site.

This SOP will not cover local pharmacy processes/procedures for dispensing of IMPs as this will be under the remit of the pharmacy department(s) in each host organisation (e.g. NHS Trust) involved in the trial. As part of the NHS controls assurance arrangements in England, a set of standards have been published on Medicines Management (safe and secure handling) against which NHS bodies report.

3. RESPONSIBILITIES

This SOP must be followed by the Chief Investigator, Principal Investigator, Trial Pharmacy Lead, monitors and other team members involved in the management of IMP.

It is the responsibility of the Head of Research Governance and Integrity Team to ensure that this SOP is updated by the review date or as necessary.

4. PROCEDURE

4.1. Management/supply of IMP

Management/supply of IMP is the CI's responsibility. They must ensure that the management of the IMP is to GCP and follows the requirements set out in the Medicines for Human Use (Clinical Trials) Regulations 2025. The CI may delegate this function to the suitability qualified pharmacy lead. The CI should ensure that responsibilities of the pharmacy department have been clearly defined in the study delegation log. An example delegation log can be found in Appendix 6.1.

The Chief Investigator (CI), with instructions from the relevant pharmaceutical company and in collaboration with the pharmacy department at the host organisation, should determine acceptable storage temperatures, storage conditions (e.g. protection from light), storage times, reconstitution fluids and procedures, and devices for product infusion, if any for all IMPs in the trial. The CI should inform all involved parties (e.g. monitors, investigators, pharmacists, storage managers) of these determinations. IMPs should ideally be stored in the pharmacy department, under the supervision of trained qualified pharmacists.

The CI should ensure that written procedures are provided to the local sites involved in the clinical trial including instructions for the handling and storage of IMP(s). The procedures should address adequate and safe receipt, handling, storage, dispensing, retrieval of unused product from subjects and return of unused IMP(s) to the CI (or alternative disposition if authorised by the sponsor and in compliance with the applicable regulatory requirement(s)).

For IMPs used within their Marketing Authorisation (MA), an up-to-date summary of product characteristics (SmPC) which is used as part of Reference Safety Information (RSI) must be included in the Trial Master File (TMF) and provided to the clinical trial pharmacist.

The CI is responsible for ensuring the SmPC is reviewed in a timely manner or at least annually and any change should be notified to the clinical trial pharmacist and an updated SmPC added to the TMF. Current SmPCs can be accessed at Electronic Medicines Compendium.

For unlicensed IMPs an Investigators Brochure (IB), full Investigational Medicinal Product Dossier (IMPD) or simplified IMPD, which is used as part of the RSI must be included in the TMF and provided to the clinical trial pharmacist from the manufacturer. The CI is responsible for ensuring the IB, full or simplified IMPD is reviewed in a timely manner or at least annually and any change should be notified to the clinical trial pharmacist and the updated document added to the TMF.

If there is a placebo, the sponsor will provide guidance as to whether a simplified IMPD or a full IMPD is required.

It is the responsibility of the CI to ensure that current SmPC, full or simplified IMPD/IB updates are checked regularly, and any significant safety/quality changes must be submitted as substantial amendment to the regulatory bodies.

Per regulation 45A of the Clinical Trials Regulations, all NIMPs (regardless of authorisation status) must be manufactured or assembled in accordance with the principles and guidelines for Good Manufacturing Practice that apply under the Medicines for Clinical Trials Regulations or the Human Medicines Regulations 2012. Evidence of this (e.g. a

manufacturer's authorisation for the site of manufacture) should be included in the application for clinical trial approval. The manufacture of non-medicinal products must be shown to comply with the safety standards applicable to that product. It may also be necessary to demonstrate compliance with relevant safety standards applicable to medicines suitable for use in humans. For examples of different types of NIMPs used in clinical trials, please see the following link (Clinical trials: Non-investigational medicinal products - GOV.UK)

The CI Clinical Trial pharmacy team in conjunction with the appropriate pharmaceutical company should:

a. Ensure timely delivery of IMP(s) to the local site(s)
b. Take steps to ensure that the IMP(s) are stable over the period of use in line with the pharmaceutical company QP clearance and stability testing.

The CI should not activate a local site and supply an investigator/institution with the IMP(s) until he/she obtains all required documentation (e.g. approval/favourable opinion from Research Ethics Committee (REC), the Medicines and Healthcare products Regulatory Agency (MHRA) and HRA, including local trust RD approvals/CCC clearance as necessary).

For a UK clinical trial involving Investigational Medicinal Products (IMPs) imported from approved countries (initially all EU and EEA countries), the sponsor must ensure that a UK Manufacturing and Import Authorisation (MIA(IMP)) holder has an assurance system in place. This system must verify that the IMPs are certified by a Qualified Person (QP) in the origin country before trial use. The QP oversees this process but does not need to recertify the IMPs. Routine verification tasks can be delegated within the MIA(IMP) quality system. The overseeing QP may be based in the UK or an approved country. For imports from non-approved countries, QP certification must be by a UK-resident QP.

From 1 January 2022, Sponsors holding a UK MIA(IMP) may perform or contract (outsource) QP certification, provided that:

- QP certification is performed by a UK Qualified Person named on a UK MIA(IMP), and
- Appropriate technical/quality agreements are in place.

A one-year transition period (1st January 2021 – 31st December 2021) was implemented by MHRA to allow compliance with these requirements IMPs arriving in Great Britain from Northern Ireland do not require additional importation or QP certification where:

- They have been QP-certified in the EU/EEA for use at Northern Ireland sites and then supplied onward to Great Britain, or.
- They are certified by a Northern Ireland MIA(IMP) holder.

IMPs from non-approved third countries (outside UK/EU/EEA):

- Require importation into Great Britain under a UK MIA(IMP), and
- Must undergo QP certification in the UK prior to release for use in a clinical trial.

4.2. Coordination with Pharmacy Department

Pharmacy staff should be involved early in the set-up of the clinical trial. Information regarding the trial should be discussed with the pharmacy department includes:

- Purpose of the trial
- Explanation of the responsibilities of the various parties involved
- Codes (e.g. for patient randomisation or unblinding)
- Numbers and recruitment parameters of patients as trial participants.

- Description of the final IMP (or parts of IMP if final IMP is to be assembled on pharmacy premises) and any relevant handling/Control of Substances Hazardous to Health (COSHH) data.
- Source of the products to be used.
- Labelling- inner and outer labelling as applicable.
- Name and contact details of CI, local investigators and others involved in organising, managing or administering the trial IMP (including trials unit if applicable).
- Oversight of trial documentation retained in pharmacy.

The CI in conjunction with the pharmacy department must:

a. Maintain records that document shipment, receipt, storage, safe handling, reconstitution/dispensing, patient returns, and destruction of the IMP(s) (see RGIT_SOP_005 for essential documentation).
b. Maintain a system for retrieving IMPs and documenting this retrieval (e.g. for deficient product recall, reclaim after trial completion, expired product reclaim).
c. Maintain a system for the handling of unused and expired IMP(s) and for the documentation of returned IMPs.
d. Maintain sufficient quantities of the unexpired and QP tested/stable IMP(s) to be used in the trials.
e. Reconfirm IMP specifications, should this become necessary, and maintain records of batch sample analyses, characteristics and storage conditions, e.g. temperature logs. To the extent stability permits, samples should be retained either until the analyses of the trial data are complete or as required by the applicable regulatory requirement(s), whichever represents the longer retention period.

It is recommended that a member of the pharmacy staff should have an assigned role as pharmaceutical coordinator in relation to each CTIMP. In most cases this will be a designated clinical trials pharmacist or technician.

The Pharmacy trial file will contain protocol and all IMP related documents including all subsequent amendments. Pharmacy/Pharmacies may follow their own trust SOPs of IMP management.

4.3. Coordination with contract

All IMP trials where IMP is manufactured by a third party or supplied by third party, there should be a technical agreement or equivalent in place. Head of research contracts should be involved early and discuss the project to initiate the set-up of the clinical trial. RGIT Clinical Trials Manager/s should also input/review the IMP technical agreement from a Sponsor's oversight perspective.

4.4. Drug Accountability

Drug accountability logs should be kept for all CTIMPs at pharmacy level. An example log can be found in appendix 6.2 and 6.3. These logs should detail at least:

- Trial Identifiers (e.g. Trial Name, IRAS number, EudraCT number (*if applicable*), PI Name, Institution and IMP name)
- Subject identification code
- Date dispensed
- Visit number – if applicable
- Dose
- Kit number - if applicable
- Quantity dispensed
- Batch number

- Expiry date
- Date returned (if applicable)
- Quantity returned
- Recorder's initials

All IMPs should be stored and dispensed by the hospital pharmacy at site and managed to the same standards as licensed medicines. IMPs must not be stored in offices, clinics or ward areas unless by prior written agreement with pharmacy.

Some pharmacies maintain their drug accountability databases and local practice should be utilised as much as possible so long as it meets legal requirement. Pharmacies can use their own log as long as they meet the minimum requirement mentioned above.

For clinical trials where the risk associated with the IMP is comparable to or only marginally higher than standard clinical care (e.g., low-intervention trials or those previously classified as Type A or certain Type B),a risk-proportionate approach to IMP management may be applied, in line with MHRA guidance.
Any adaptation to standard IMP management processes, including drug accountability procedures, must be:

- Based on a documented risk assessment,
- Justified in collaboration with the Sponsor, and
- Ensure that adequate traceability of the IMP is maintained at all times.

Where a drug accountability log is not used, alternative mechanisms must be in place to ensure traceability, reconciliation, and participant-level accountability.
Drug destruction arrangements should be discussed with the pharmaceutical company and the pharmacy department to determine how the process will be undertaken and agreed by the sponsor. An example drug destruction form is found in Appendix 6.4.

4.5. Labelling

This section discusses the labelling requirements for IMPs used in clinical trials which come under the requirements of the Medicines for Human Use (Clinical Trials) Regulations 2025 (Clinical trials for medicines: labelling - GOV.UK). For a flowchart which demonstrates the minimum labelling requirements for trials, please see the following link: Fig1._Labelling_requirements_for_IMPs_in_a_CT.pdf

Regarding implementation of the new labelling requirements, IMPs manufactured under the old regulations (before 28th April 2026) can continue to be used in the clinical trial for which they are for use using the previous trial IMP label. IMPs manufactured after 28th April 2026 must be labelled according to the amended Clinical Trials Regulations (please see the table below):

Area	Clinical trials where approval was submitted before 28Apr2026.	Clinical trials where approval was submitted on or after 28Apr2026.
Labelling of IMPs	New regulations for IMP labelling, however, IMPs manufactured before that date can continue to be used with the old labelling rules in the clinical trial for which they are for use.	New Regulations for IMP labelling required.

4.6. IMP Label Approvals

Labelling for all IMPs & NIMPs to be used in a clinical trial should be included with the initial application for clinical trial approval. These should be clear, legible and of a suitable size to aid participant compliance (with due regard for the participant population, e.g. those with sight issues). Further details on the CTA can be found in RGIT_SOP_008.

Submission of detailed labelling information is not needed where the IMP or NIMP is labelled in accordance with existing UK requirements for prescribed medicines dispensed by pharmacies set out in Part 13 of the Human Medicines Regulations 2012. In this case, confirmation that this labelling approach will be followed is sufficient.

When submitting an application for clinical trial approval, the applicant may request an exemption from, or variation to, any of the labelling requirements described below. This should be done by including the request, with justification, in the labelling documents included in the application. If this request is agreed by the licensing authority, the applicant will be informed of this at the same time as the outcome of the application for approval is communicated. Please note, any change to our standard label templates would need to be agreed by the sponsor and risk assessed prior to approval, either as part of sponsor or amendment review.

If an exemption from, or variation to, any of the labelling requirements described above is not requested at the time of approval, the sponsor may subsequently request this via a Route A substantial modification. If the sponsor wishes to make a change to the text of the labelling of the IMPs or NIMPs after approval and that change is considered to be a substantial modification, they must submit a Route A substantial modification.

Where a request to vary, or disapply, labelling requirements for an IMP or NIMP is made for a **notifiable trial**, this must be specified in the cover letter and may result in the licensing authority undertaking a full review of the notifiable trial before issuing a decision. The exception to this is where the request is to vary or disapply the labelling requirements for an authorised IMP that is to be exclusively administered in a hospital or health centre taking part in the trial. In this case, the trial may be submitted for automatic authorisation. The licensing authority will not give notice that the request to disapply or vary the labelling requirements has been accepted, but the request should still be treated as approved.

4.6.1 IMPs authorised within the UK

If an IMP to be used in a clinical trial has a UK marketing authorisation or Article 126a authorisation, is not modified and is used within the terms of that authorisation it must be labelled **either**:

- As per regulation 46(1) of the Clinical Trials Regulations (please see example label below and the following link for full details: Clinical trials for medicines: labelling - GOV.UK).
- In accordance with existing UK requirements for prescribed medicines dispensed by pharmacies set out in Part 13 of the Human Medicines Regulations 2012 with some additional information (please see the following link for full details: Clinical trials for medicines: labelling - GOV.UK).

Where IMP to be used in a trial is authorised in the UK and is exclusively administered in a hospital or health centre taking part in the clinical trial or is a radiopharmaceutical used for diagnostic purposes, it can have reduced labelling (please see the second example label below and the following link for full details: Clinical trials for medicines: labelling - GOV.UK).

Note: If an IMP has marketing authorisation in the UK but is used outside the terms of its authorisation, full labelling as per regulation 46(1) of the Clinical Trials Regulations must be used (as per non-authorised IMPs). This includes where an authorised product is repackaged (e.g. de-blistered, repacked and labelled) to support blinding or treatment compliance

Example IMP label below containing full labelling requirements as per regulation 46(1) of the Clinical Trials Regulations:

For Clinical Trial Use Only

Trial Name (**IRAS Number**): xxxxx (xxxxx)

Sponsor Name: Imperial College London/Imperial College NHS Trust RGIT *(Delete as Appropriate)*

Investigator: Dr xxxxx

Investigator Contact Number: xxxxx

Product Name, Form & Strength: xxxxx

Contents (*by weight, volume or number of doses*): xxxxx

Batch/Code Number: xxxxx

Directions for Use *(as specified by the prescriber): xxxxx*

(***Examples:*** *Instructions for administration, method or route of administration & special storage precautions).*

Participant Name or Code: xxx

Date of Supply: xxxxx

Visit Number: xxxxx

Expiry Date: xxxxx

Name & Address of Hospital/Primary Care Supplier: xxxxx

Keep Out of Reach & Sight of Children

Any additional cautionary label *(as recommended by the BNF)*

(Only applicable to UK Authorised IMPs (Please delete for Non-UK Authorised IMPs)

Example IMP label below containing reduced labelling requirements (should the IMP meet reduced labelling criteria):

For Clinical Trial Use Only

Trial Name (**IRAS Number**): xxxxx (xxxxx)

Product Name, Form & Strength: xxxxx

Contents (*by weight, volume or number of doses*): xxxxx

Batch/Code Number: xxxxx

Directions for Use *(as specified by the prescriber): xxxxx*

*(**Examples:** Instructions for administration, method or route of administration & special storage precautions).*

Participant Name or Code: xxx **Date of Supply**: xxxxx

Visit Number: xxxxx **Expiry Date**: xxxxx

Note: Labelling information is generally expected to be applied to the primary packaging. If the full information cannot be included on the primary packaging, it can instead be applied to the secondary packaging. In this case, the primary containers should also be labelled with certain trial information.

4.6.2 IMPs not authorised in the UK but authorised in the EU or an ICH region

By default, these IMPs must have full labelling as per regulation 46(1) of the Clinical Trials Regulations (please see example label above).

There are certain circumstances in which reduced labelling can be used. In these cases, the sponsor may submit a request to vary the labelling requirements as part of the application for clinical trial approval. These circumstances include:

- If IMP is unmodified, used according to the terms of its EU or ICH region authorisation and is exclusively administered in a hospital or health centre taking part in the trial,

sponsor may request IMP is labelled with the same information as an IMP with a UK authorisation used only in a hospital or health centre taking part in the trial.

- If IMP is unmodified, used according to the terms of its EU or ICH region authorisation and the pre-printed original pack labelling is in English, sponsor may request IMP is labelled in accordance with Part 13 of the Human Medicines Regulations 2012 and, on either the primary container or outer pack, includes “for clinical trial use only” with information to identify the clinical trial, sponsor and contact persons involved in the trial.

4.6.3 IMPs not authorised in the UK, EU, or an ICH region country

These IMPs must be labelled as per regulation 46(1) of the Clinical Trials Regulations (please see example label above).

The only exception to this requirement is if the IMP is to be exclusively administered in a hospital or health centre taking part in the clinical trial, then it may be applicable to use reduced labelling requirements (please see example label above).

4.6.4 Labelling of NIMPs in clinical trials

NIMPs used in a clinical trial are, in most cases, subject to the same labelling requirements as IMPs. As the majority of NIMPs will be authorised medicinal products, used unmodified, they should be labelled in accordance with existing UK requirements for prescribed medicines dispensed by pharmacies set out in Part 13 of the Human Medicines Regulations 2012 with some additional information on top (please see the following link for full details: Clinical trials for medicines: labelling - GOV.UK).

Unlike IMPs, NIMPs authorised in the UK, EU or an ICH region that are to be exclusively administered in a hospital or health centre taking part in the clinical trial, cannot be labelled in accordance with regulation 46(3) and 46(4). These NIMPs must instead be labelled either:

- In accordance with existing UK requirements for prescribed medicines as Part 13 of the Human Medicines Regulations 2012 (ideally, with the additional information above), if the pre-printed original pack labelling information is in English.
- In accordance with regulation 46(1) of the Clinical Trials Regulations (please see the full IMP Trial label above).

4.6.5 Decentralised manufactured IMPs

The labelling requirements above do not apply to any point of care decentralised manufactured IMP that is to be administered immediately and entirely after its manufacture. In these cases, no labelling is required, although the use of a pre-applied patient identifier on the primary packaging is advised.

In all other cases, decentralised manufactured IMPs should be labelled in the same way as conventionally manufactured IMPs. For further guidance, please see the following link: Decentralised manufacture hub - GOV.UK.

4.6.6 Labelling in blinded trials

In blinded trials, the labelling (including for small primary containers) should include the name of any comparator or placebo used alongside the IMP being tested. This is mandatory where the IMP is unauthorised in the UK.

Care should be taken that the labelling does not inadvertently reveal the treatment assignment for blinded clinical trials. In blinded trials, all supplies should be in consistent packaging with consistent labelling to maintain blinding. Consideration should be given as to what measures are necessary to protect the treatment allocation where authorised IMPs are used, including whether re-labelling or re-packaging away from the authorised livery, packaging and labelling is required. If the original product's MA holder is prepared to provide packs of the matching placebo, the company is also likely to agree to provide them in similar containers and with consistent labelling with the IMP. In other circumstances, consistency is likely to be best achieved through repackaging and full labelling.

In blinded trials, the coding system for the investigational product(s) should include a mechanism that permits rapid identification of the product(s) in case of a medical emergency but does not permit undetectable breaks of the blinding.

All trials, including double blinded trials, are dispensed by pharmacy using trial specific dispensing procedure.

4.6.7 IMP transfer between sites

Once an IMP has been delivered to a site, it should not subsequently be transferred to another site without first being returned to the clinical trial supply company for inspection and further QP release. The packs would then be available for delivery to another site. Documentation (quantity, locations, dates, method of transfer) on the IMP transferred should be maintained. However, in very exceptional cases (e.g. where the safety of the subject is jeopardised if supplies are not provided from another site), IMP can be transferred between sites with valid documentation.

Transfer of stock within a pharmacy department in a same trust hospital is not considered as site-to-site transfer.

Responsible parties for transfer of IMP between sites should be noted on the IMP technical agreement or equivalent.

4.7. Trial specific IMP SOPs

The CI, in conjunction with the pharmaceutical company and the pharmacy department at the host organisation, should ensure that the following trial specific SOPs are in place before starting the trial:

- Receipt and recording of safe delivery of IMPs
- Safe handling and storage of IMPs
- Code breaking of blinded IMPs
- Preparation and dispensing of IMPs
- Return and disposal of unused and expired IMPs
- Maintaining a pharmacy study file
- Relabelling of IMPs
- Temperature monitoring

5. REFERENCES

Clinical trials for medicines: labelling - GOV.UK

RGIT_SOP_005 - Essential Documentation and the Creation and Maintenance of Trial Master Files

RGIT_SOP_008 - Submitting a CTA Application to the MHRA

Regulation 37 of SI 2004/1031 as amended (2025/538)

ICH GCP (1996), Sections 5.12, 5.13, 5.14

Medicines for Human Use (Clinical Trials) Regulations 2004, SI: 1031, Part 6, as amended 2025.

Human Medicines Regulations 2012 (SI 2012/1916), as amended
MHRA Risk Adapted Approaches to the Management of Clinical trials of Investigational Medicinal Products:

6. APPENDICES

The following Appendices list the following Templates associated to this SOP which can be found on the SOP, Associated Documents & Templates page.

Appendix 1: Study Delegation Log – RGIT_TEMP_037
Appendix 2: Subject Dispensing and Return Accountability Log – RGIT_TEMP_038
Appendix 3: Drug Accountability Log – RGIT_TEMP_039
Appendix 4: IMP Destruction Log – RGIT_TEMP_040
Appendix 5: Labelling Requirements for CTIMPS – RGIT_TEMP_051