UNIVERSITY OF WARWICK

STANDARD OPERATING PROCEDURE 27

Management of Investigational Medicinal Products (IMPs) for Clinical Trials

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Version 3.0	8 March 2024	Biennial review: Updates to web links. New process flowchart for IMP supply. Addition of information relating to quarantining of IMP stock.
Version 2.0	17 November 2021	Biennial review: Change to new format. Amended title to Management of IMP. New sections on IMP returns and destruction, IMP stability and shelf-life extension and co-enrolment added.
Version 1.5	24 July 2019	Biennial review: Addition of further information on the regulatory release procedure. Other minor text updates
Version 1.4	27 July 2016	Biennial review: Reference to use of MHRA's Grey Guide and new section on non-IMPs added. Clarification of when supplies should be sent to sites and of labelling requirements.
Version 1.3	9 June 2014	Biennial review: Title amended to include 'Storage,' plus inclusion of IMP storage requirements.
Version 1.2	26 March 2012	Format change to comply with SOP 1.
Version 1.1	26 March 2010	Addition of details regarding transfer of IMP(s) between sites (section 3.3.5).
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1 Purpose and Scope

To describe the management process for the supply, storage, and destruction of Investigational Medicinal Products (IMPs) and how IMPs must be labelled according to the requirements of the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (SI 2025/538).

It is applicable to all University of Warwick staff involved in Clinical Trials of Investigational Medicinal Products (CTIMPs) and to staff working on externally sponsored trials where use of UoW SOPs has been agreed.

2 Acronyms

BNF	British National Formulary
CI	Chief Investigator
CT	Clinical Trial
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTA	Clinical Trial Authorisation
ICH	International Conference on Harmonisation
IMP	Investigational Medicinal Product
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
MIA	Marketing & Importers Authorisation
MHRA	Medicines and Healthcare products Regulatory Agency
NIMP	Non-Investigational Medicinal Product
PI	Principal Investigator
PSF	Pharmacy Site File
QA	Quality Assurance
QP	Qualified Person
R&IS	Research & Impact Services
SOP	Standard Operating Procedure
TMF	Trial Master File
WCTU	Warwick Clinical Trials Unit

3 Definitions

IMP	A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
NIMP	Product used or to be used in a clinical trial, as described in the protocol, but not as an IMP.
CTIMP	Investigation in human participants intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an IP, and/or to identify adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.

QP	An individual trained by a recognised professional body who will certify each batch of IMP has been manufactured in accordance with GMP and meets the conditions of the CTA and the product specification file, prior to dispatch to research sites.

4 Background

All clinical trials involving IMPs must comply with ICH GCP and the Medicines for Human Use (Clinical Trials) Regulations. The Regulations require that IMPs are manufactured and imported in accordance with GMP standards.

A risk-proportionate approach, supported by MHRA guidance, should be applied to trial design and IMP management, recognising that risks to participant safety and trial integrity vary between studies.

5 Responsibilities

CI (or delegate)	• Overall responsibility for the management, delivery, storage, use and accountability of IMP(s). • Ensure appropriate delegation of activities and provide adequate oversight.
Sponsor	• Adherence to ICH GCP E6R3. May facilitate IMP management.
PI	• Ensure IMPs are only used in compliance with the approved protocol/trial-specific manual. • Provide an explanation on the correct use of the IMP to each trial participant, and check at intervals appropriate for the trial, that each participant is following the instructions properly. • Liaise with trial pharmacist to maintain accurate records of the product's delivery to site, use by participants and the return or destruction of the product. • Final reconciliation of all IMP related documentation to ensure that all participants were given the doses specified by the protocol
Pharmacist	• Protocol review to assess practicalities. • Maintain accountability logs for receipt, storage, dispensing, return and/or destruction of IMP(s). • Temperature monitoring whilst in storage (as applicable). • Involvement in unblinding procedures (where applicable). • Oversight of local stock management and reordering (where applicable).
QP	• Certify each manufactured drug intended for human use prior to its use in a clinical trial. The QP ensures compliance of each batch of IMP manufactured, or imported, with current requirements.

6 When

The IMP supply and labelling requirements should be determined at the earliest possible stage of the trial design process as costs need to be included in the grant application.

The trial risk assessment and monitoring plan should detail all aspects of IMP management and should be reviewed regularly throughout the course of the trial.

7 How

A risk appropriate approach to IMP management should be implemented to reflect the IMP's characteristics, the risk to the participant and/or trial integrity of the research carried out, and to the risk related to the reliability of trial results.

The CI or delegate should determine the supply, labelling requirements, recipients, storage conditions and dispensing procedures for all IMPs in the trial. It is good practice to involve a pharmacist and/or the IMP supplier, and to document decisions and actions required.

The investigator and/or pharmacist or other appropriate individual should maintain records of the IMPs delivery to the trial delivery location, local stock levels, the use by each participant, and the return to the sponsor or alternative disposition of unused product(s). The protocol should detail where documentation should be retained.

All involved should be properly informed about their responsibilities. This will usually take place during the initiation visits/training with the pharmacy department and should include (as applicable):

- Purpose of the trial
- Explanation of responsibilities
- Codes e.g., for participant randomisation or unblinding
- Description of the IMP and any handling, storage or safety issues
- Source of the products to be used
- Labelling requirements
- Name and contact details of key staff involved in the management or administration of the trial
- Documentation for retention in the pharmacy site file
- Destruction of unused IMP

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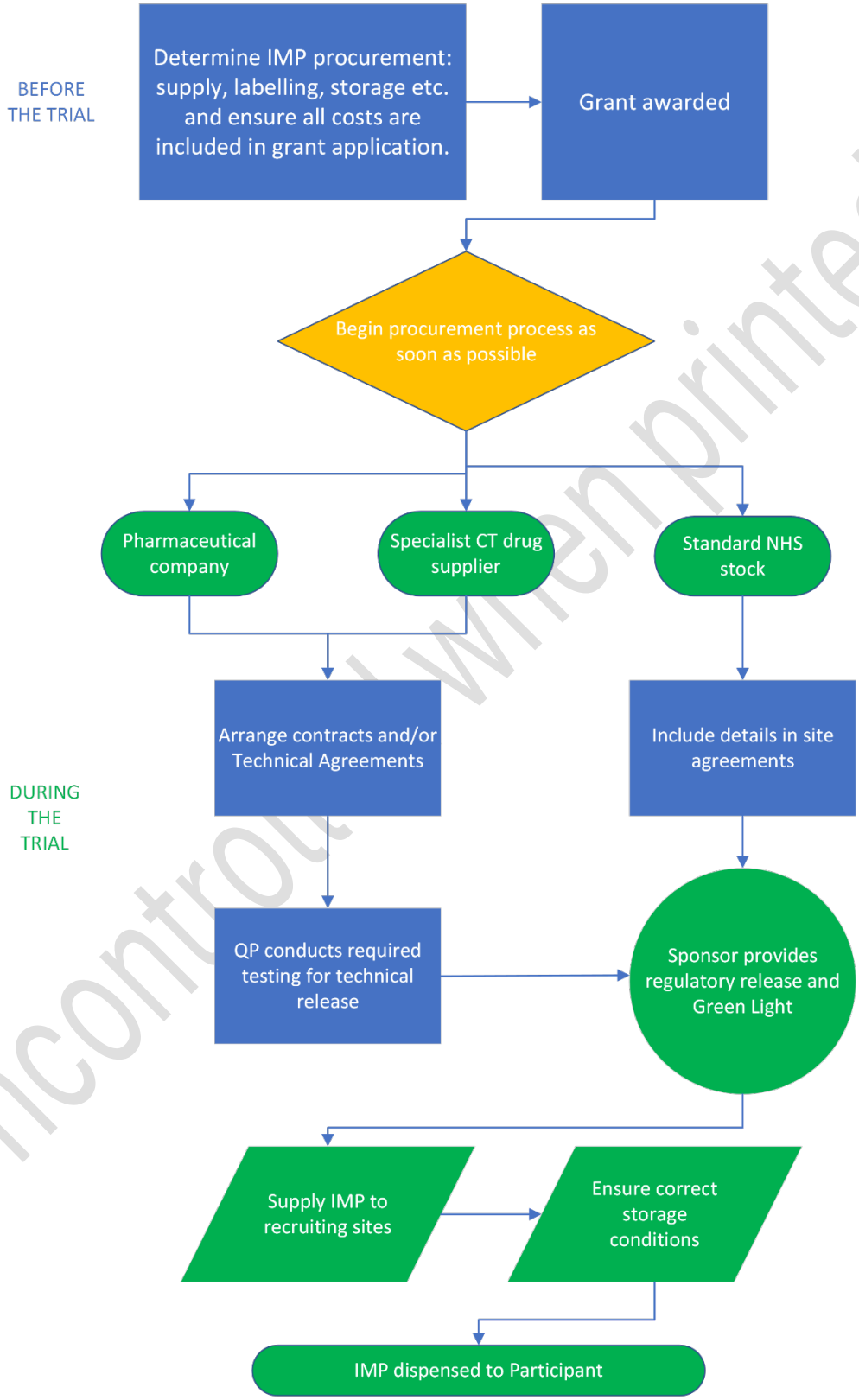
7.1 IMP supply



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IMP(s) may be obtained directly from a pharmaceutical company, a specialist clinical trial supplier or from standard NHS stock depending on the trial design. Organisations involved in either manufacturing or importing must hold a manufacturing authorisation. In the UK this is a specific manufacturer's/importation authorisation for investigational medicinal products known as the MIA(IMP).

Manufacturing, packaging, and labelling of IMPs for a study may be the responsibility of an IMP supply company with a MIA(IMP) and their responsibilities should be detailed in any contractual agreements.

IMP manufacture and importation must be performed in accordance with the EU 'Rules governing medicinal products in the European Union' (EudraLex Volume 4 – Annex 13). The sponsor retains ultimate responsibility for a trial and must ensure that all aspects required to comply with the clinical trials regulations are in place prior to authorising the start of the trial. Responsibility for the quality of the IMP is generally delegated to an appropriate QP.

For University of Warwick sponsored or co-sponsored studies, responsibility for IMP management should be documented on the Division of Responsibilities Form. A technical agreement may be required between the sponsor and the delegate to document respective responsibilities for manufacture, storage, shipping, batch certification and testing of the IMPs etc.

Where a clinical trial IMP supply company has been contracted to undertake the manufacturing of the IMP, they will usually be responsible for conducting final batch certification checks before its release. Checks should be completed by the organisation's QP to ensure that each batch has been manufactured to GMP standards and all checks and documentation are in place (technical release), followed by the sponsor or delegate completing the regulatory release or regulatory green light, prior to authorising the commencement of a trial.

Key activities should be documented by completing the 'Permissions Required to Commence a Randomised Controlled Trial' or 'Green Light Form.' (Template T18 on WCTU SOP templates page).

Regulatory release checks to ensure compliance with regulations may include:

- Contracts with investigators and any service providers
- If the trial's CTA is subject to conditions, that those conditions are met
- Any local or national approvals
- De-coding arrangements are in place (if applicable)

The sponsor (or delegate) is responsible for ensuring both steps are completed, recorded and the documentation produced is retained in the TMF. These steps are also required for the release of all subsequent batches.

Trial delivery locations should not be supplied with IMP until the trial 'Green Light' and site specific 'Site Activation Checklist' forms have been completed and signed off by appropriate staff. (Site activation checklist C09).

A sample of each batch of the IMP (and placebo, if used) should be retained for later testing to verify that (a) it is the correct IMP and (b) the randomisation list has recorded the allocations correctly. This is usually the responsibility of the IMP manufacturer or their contracted laboratory, but the study coordinating team should check that this is being undertaken and documentation is produced as required.

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7.2 Labelling

The MHRA must approve the label content before the trial starts. Information can be given in tabular format and does not require submission of the label proof.

MHRA label requirements are available here: **Labelling for IMPs used in Clinical Trials** covering:

- IMPs that are not authorised in the UK, EU or an ICH region country
- IMPs that are authorised in the UK
- IMPs that are not authorised in the UK but are authorised in the EU or an ICH region
- Labelling for small primary containers
- Labelling IMPs in trials where blinding occurs
- Decentralised manufactured IMPs
- Post-Qualified Person certification labelling
- Determining the minimum labelling requirements for IMPs used in a clinical trial
- Labelling for non-investigational medicinal products used in clinical trials
  Submitting labelling for investigational medicinal products and non-investigational medicinal products for approval by the licensing authority
- Varying or disapplying labelling requirements
- Modifying the approved labelling while a clinical trial is ongoing

7.3 Drug accountability

**If required by trial protocol, otherwise instruct sites to destroy unused IMP according to their local policies.*

Each site must maintain records to document shipment, receipt, handling, return and disposal/destruction of used and unused IMP(s). Records should be maintained to adequately document that participants were provided protocol-specified doses and to reconcile all IMP(s) received from the sponsor.

For IMPs used within an MIA which are supplied via the site pharmacy's local stock, shipment, receipt and return details are not applicable.

IMP accountability logs (T06) should be kept for each trial as described in the protocol to detail:

- Name of site and PI
- Participant identification code
- Date dispensed
- Batch/serial numbers
- Dose
- Quantity dispensed
- Date returned or destroyed*
- Expiration dates
- Quantity returned
- Recorders' initials and date

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**As applicable*

If local practices are in place for drug accountability these may be used. However, the trial sponsor should have oversight of this and only approve local procedures if they adequately record all required information.

7.3.1 Returns

If or when a participant returns used or partially used containers accountability of the returns may be performed by the appropriate staff and recorded on the CRF as detailed in the protocol.

IMP returned to pharmacy should be segregated from unused trial stock to avoid inadvertent use. Returns must not be re-allocated to another participant, as the integrity of the product cannot be ensured.

If the IMP is taken off-site by the participant and they decline to return for accountability and destruction, this information should be recorded on the accountability log.

7.4 IMP storage and quarantine requirements

IMP(s) should be stored as specified by the sponsor and in accordance with applicable regulatory requirements. It is the sponsor's responsibility to determine acceptable storage temperatures, storage conditions. The sponsor should inform all parties involved of these determinations and ensure written procedures are in place to inform the investigators of the handling and storage requirements and the documentation thereof.

A calibrated thermometer must be used by the investigator site to monitor temperature-controlled stock in accordance with MHRA regulations. A copy of the calibration certificate must be provided to WCTU prior to activating a site to start recruitment (C09) and must be retained in the TMF. The investigator site must also retain a copy of the calibration certificate in the investigator and pharmacy site files for monitoring purposes. The investigator site is responsible for re-calibrating thermometer devices in accordance with local policy.

IMP(s) should be stored and dispensed by pharmacy, with access to stock restricted to authorised personnel only. IMP(s) may be stored in alternative locations as determined by the sponsor or delegate and documented in the protocol.

If a batch of IMP is to be stored in a department outside of pharmacy e.g., Intensive Care Unit for ease of access by clinical team, the sponsor or delegate should ensure adequate oversight of the IMP is in place prior to issuing sponsor green light to commence recruitment. This can include documenting access to the stock is restricted to authorised personnel only, stock is kept segregated from general medical stock, stock is clearly labelled and identifiable to the trial and clear accountability management is in place. Storage areas should be assessed to ensure that they are not liable to large daily temperature fluctuations.

Whenever there is any concern as to the suitability of the IMP for use in humans (e.g., the product was exposed to a temperature excursion, the manufacturer instigates a recall, the IMP has been received by pharmacy prior to Trust approval and pharmacy green light), it must be quarantined until further advice has been given from the manufacturer and the sponsor overseeing the trial. The products should be stored separately in an area clearly labelled as 'quarantine' and discussions held with the sponsor and manufacturer to agree actions. IMP held in quarantine should not be dispensed to participants.

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7.5 IMP Stability and shelf-life extension

The shelf life should be established based on the available stability data for the product. If an extension of the product's shelf life is anticipated, this can be addressed at the application stage by including a proposal that defines the criteria under which the sponsor will extend the shelf life during an ongoing clinical trial. Provided that this proposal was submitted either with the initial application or as part of a previous substantial modification to the IMP dossier, and has not been queried by the competent authority, no further substantial modification would be required.

If the proposal to extend shelf-life based on new stability data is proposed during the trial, defining the criteria based on which the sponsor will extend the shelf-life during an ongoing clinical trial has not been approved with the initial filing of the IMP Dossier, then a substantial modification would be required.

If a substantial modification is required, the Product Specification File would require a controlled change such that manufacturing sites and the QPs can take appropriate action (update labelling instructions, certification criteria etc.). IMPs already manufactured, must be relabeled. This relabeling will need to be conducted, checked, and documented as per Annex 13 requirements.

7.6 Transfer of IMP between research sites

Once an IMP has been delivered to a site it should not be transferred to another site unless there are exceptional circumstances (e.g., where the safety of a participant is jeopardised if supplies are not provided from another site or if a non-recruiting site was closed and medication was in short supply). Where transfer does occur, it should be covered by a formal procedure, with clearly documented records of what has been transferred (including quantities, batch numbers, dates, method of transfer etc.). The advice of a QP should be sought to ensure the product is suitable for transfer. Evidence should be held to show that the storage conditions of the product were maintained during shipment. The product should be returned to the manufacturer/clinical trial drug supply company for re-labelling, if necessary, and certified by the QP prior to further transfers. Records should be retained in the TMF, and full traceability ensured.

As there are costs involved in any drug pack transfer, this should only be done if there were no other options to ensure supplies are available at a particular site.

The transfer of IMP(s) by an NHS Trust with a central pharmacy to another site within that same NHS Trust, or when a pharmacy of an NHS Trust dispenses an IMP at one of its sites and transfers it to another of its sites where trial participants are managed is not classified as a site-to-site transfer. However, where either of these activities occurs, there should be a clear formalised procedure in place to ensure the quality of the product (including temperature) is maintained during transit, with documentation of what has been transferred and received, when and by whom.

7.7 Destruction

Authorisation for the destruction of trial IMP supply may be required from the sponsor, their delegate, or manufacturer depending on the circumstances, and the person responsible for providing any such authorisation should be documented in the protocol or technical agreement with the drug supply company (as appropriate). Sites should also inform the sponsor of any actions taken if specific sponsor authorisation was not required.

Once a trial has ended, the accountability records reconciled, and all IMP/placebo have been accounted for, remaining IMP can be destroyed. If possible, it is good practice to destroy the IMP only after the

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clinical trial report has been written, which allows for the IMP to be re-reviewed if any discrepancies are identified.

If IMP needs to be destroyed during a trial (e.g. due to temperature excursions or batch expiry), local procedures may be followed and documented. If a batch of IMP is recalled for any reason e.g., after a drug alert from the MHRA defective medicines report centre, the pharmacy department within the recruiting site should follow their local procedures and ensure the PI and trial team are aware of the situation.

For blinded trials considerations should be made regarding maintaining the integrity of the blind against the regulatory requirements and that any decisions must be justified and documented. It is recommended that advice is sought from the QP working on the trial to determine appropriate actions.

8 Co-enrolment into other CTIMPs

This is the process of recruiting participants into more than one study either concurrently or sequentially.

The following should be considered before co-enrolment is agreed: study design and statistical considerations; legal and ethical considerations; biological and scientific rationale; participant considerations and logistical and organisational issues.

Plans for co-enrolment should be considered at an early stage of the trial and should be included in the protocol.

The safety of study participants, interventions involved, participant burden and the potential impact on the study endpoints must be considered.

It is recommended that a washout period should be defined if there is an intention to allow co-enrolment between studies involving interventions.

9 Non-Investigational Medicinal Product (NIMP)

These products do not fall within the definition of IMP and may be supplied by the trial sponsor or the investigator in accordance with the approved protocol. The quality of the product should be assured and the advice and involvement of a QP is recommended. See Section 7.2 for labelling requirements.

For guidance on NIMPs, see Clinical trials for medicines: non-investigational medicinal products - GOV.UK

10 Associated Templates and Documents

T06	IMP Accountability Log
T14	Pharmacy Site File Index
T16	CTIMP protocol writing template
T18	Green Light RCT Activation form
C09	Site Activation Checklist

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