Sponsor Investigational Medicinal Product (IMP) / Intervention Management

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1 Introduction

1.1 The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).

1.2 The Medicines for Human Use (Clinical Trials) Regulations SI 2004/1031 (as amended) describe Sponsor responsibilities in relation to the manufacture, assembly, importation and labelling of investigational products.

1.3 This SOP does not cover the requirements for dispensing Investigational Medicinal Products (IMPs) as this may be the responsibility of pharmacy departments at Investigator sites. Under these circumstances, processes will be detailed in local SOPs with any specific arrangements detailed in the clinical trial protocol where required.

2 Purpose

2.1 The purpose of this SOP is to describe IMP management activities that NHSL and/or UoE may undertake as Sponsors of a Clinical Trial of an Investigational Product (CTIMP). For the purpose of this SOP, IMP may also refer to a substance for example human blood cells, food products, medical devices or imaging agents in the context of a non-CTIMP.

2.2 This SOP will not capture trial specific issues pertaining to the manufacture, assembly, packaging, blinding, labelling, supply and storage of IMPs. This will be discussed and documented at the ACCORD combined risk assessment (ACCORD SOP GS002) and captured in the study protocol and appropriate study specific agreements.

3 Scope

3.1 This SOP applies to the Principal Investigator (PI), or designee, responsible for the management of IMP at their location.

3.2 This SOP applies to individuals delegated IMP management tasks by NHSL and/or UoE as Sponsors of a clinical trial.

3.3 This SOP also applies to ACCORD Quality Assurance (QA) and Monitoring staff as well as UoE Research Governance personnel, who have oversight of IMPs in clinical trials sponsored by NHSL and/or UoE.

3.4 This SOP applies to CTIMPs and any clinical research for which a Combined Risk Assessment is deemed appropriate (e.g. first-in-man, invasive, experimental or complex research).

4 Responsibilities

4.1 The Sponsor has ultimate responsibility for the conduct of a clinical trial, including IMP management.

4.2 The Sponsor Reviewer is responsible for;

- Providing written authorisation to start the trial, ensuring all necessary agreements are in place.
- Review of label templates for IMP and NIMP (where applicable)
- Reviewing and approving the use of documents for location-location IMP transfers and providing written authorisation for any transfers.

4.3 The ACCORD Clinical Trials Monitor, or designee, is responsible for Sponsor oversight activities in relation to IMP management for studies sponsored by NHSL and UoE including;

- Providing written authorisation for the release of IMP to sites for single centre studies.
- Providing Sponsor Authorisation to Open (SATO).
- Contacting the manufacturer of the IMP, where appropriate, in light of an IMP storage temperature deviation.
- Review of trial specific pharmacy manual before first Site Initiation Visit (SIV) for compliance with manufacturer's Summary Product Characteristics (SPC)/Investigator's Brochure (IB) and protocol IMP and/ or NIMP instructions.
- Determining the extent of IMP accountability checks that will be required for a trial and reviewing trial specific accountability logs and prescriptions prior to SATO, where applicable.

4.4 The PI will be responsible for the IMP management at their location and maintaining source records to evidence the management activities. IMP management includes IMP receipt, accountability, handling, dispensing, administration and return/destruction of IMP. Tasks associated with IMP management are often delegated to pharmacy departments. Where tasks relating to IMP management are delegated to pharmacy, or another individual according to local requirements, they must be under the oversight of the Investigator or part of the same institution. The PI, or designee, is also responsible for ensuring the integrity of IMP during transfers between hospitals within the same Board/Trust and filing the associated documentation.

4.5 The Trial Manager, or designee, will be responsible for developing trial specific master accountability and/or prescription templates if required at combined risk assessment (GS002) and providing the release of IMP to sites for multi-centre studies. In addition, the Trial Manager, or designee will be responsible for ensuring a continued supply of IMP for locations and coordinating and documenting IMP location-location transfers, where applicable.

5 Procedure

5.1 Authorisation to Start the Trial

5.1.1 The Sponsor Reviewer will ensure that all necessary agreements are in place prior to authorisation to start the trial.

5.1.2 The Sponsor Reviewer will ensure that where required, a QP certifies that the IMP has been manufactured to Annex 13 of Volume 4 of The Rules Governing Medicinal Products: Guideline to Good Manufacturing Practices (GMP) (January 2010) standards and in accordance with the Clinical Trials Authorisation (CTA) and Product Specification File.

5.1.3 Following 'Technical Release' from the QP (section 5.1.2), the Sponsor Reviewer will provide written authorisation to start the clinical trial ('Regulatory Checks Complete') to the Chief Investigator (CI), once a Research Ethics Committee (REC) favourable opinion and a CTA has been granted in the applicable territory(ies). Written authorisation to start the trial will be documented on the Facilitation Checklist as per

ACCORD SOP FA001 (Facilitating a Regulated or Complex Research Project) and written confirmation will be provided to the trial team in the form of an e-mail.

5.1.4 For single location studies, the Clinical Trials Monitor will provide authorisation to release IMP to the location ('Regulatory Green Light') as per ACCORD SOP CM001 (Site Initiation and Sponsor Authorisation). For multi-location studies, the Trial Manager will provide the 'Regulatory Green Light' to locations as delegated in the study specific Co-Sponsorship Agreement.

5.1.5 Once IMP is available at the location, the Clinical Trials Monitor will provide SATO as per ACCORD SOP CM001 (Site Initiation and Sponsor Authorisation).

5.1.6 Where the IMP is an off-the-shelf product, Technical Release and Regulatory Green Light are not required. Required checks are still performed by the Clinical Trials Monitor and will be documented through SATO (CM001 Site Initiation and Sponsor Authorisation).

6 Site Pharmacy Procedures

6.1 Pharmacy Manual

6.1.1 Where a pharmacy manual/IMP handling instruction is required, the document will be sent to the clinical trial monitor for review. The review will take place in accordance with GS010-T04 (Pharmacy/IMP handling checklist). As an example, the pharmacy manual may detail:

- Summary of trial design
- Description of IMP or agent
- Manufacturer of drug
- Drug label
- Pharmacy set up process
- IMP Storage conditions including temperature excursion procedure
- Ordering Process
- Prescription, dispensing, returns and destruction process
- Unblinding information and any information required to maintain blind (where required)
- Pharmacy file and monitoring requirements

6.1.2 GS010-T04 sign off is required before CM001-T03 (regulatory green light) is issued (if required) or CM001-T02 (SATO) is issued if regulatory green light is not required.

6.1.3 If, due to trial design, it is anticipated that pharmacies will need to dispense IMP which will expire during the treatment course the associated risks must be considered and documented in the Combined Risk Assessment (GS002) and mitigated where possible. These mitigations must be reflected in the pharmacy manual where appropriate.

6.1.4 If, due to logistical reasons, it is essential to dispense IMP which will expire during the treatment course as a temporary measure to ensure continued participant supply, the plan to ensure IMP will be returned or stock finished by participants prior to the expiry date must be agreed with the Sponsor in advance of dispensing. The pharmacy manual must be updated to reflect the agreed plan where appropriate.

6.2 Labelling of IMP

6.2.1 Requirements for labelling IMPs and Non-Investigational medicinal products (NIMPs) will be discussed and documented at combined risk assessment (GS002). The following categories of labelling are possible:

Full labelling according to regulation 46(1) of Clinical Trial Regulation (CTR): For IMPs/NIMPs that are not authorised in the UK, EU or an ICH region country or where an IMP/NIMP with a marketing authorisation is modified as part of the trial (e.g. de-blistered or repackaged) or used outside the terms of its marketing authorisation, full labelling is required. The label will contain the following information (where applicable):

1. The words 'for clinical trial use only'
2. A warning that the product must be stored out of reach and sight of children
3. Information to identify the Sponsor and contact persons involved in the clinical trial (e.g. the names and telephone numbers of the local PI and Sponsor)
4. Information to allow identification of the clinical trial (e.g. trial acronym, protocol number, IRAS number)
5. Information linking the product to the participant (e.g. participant number)
6. Information allowing for identification of the medicinal product including the common name of the active substance (or medical product code), the strength and pharmaceutical form, contents by weight/volume/number of doses and batch number
7. Information related to the use of the medicinal product including instructions for use (may be by reference to an instruction leaflet) or administration, method or route of administration, expiry date and any special storage precautions.

Labelling according to part 13 of Human Medicines Regulation 2012: IMPs/NIMPs that have a marketing authorisation in the UK, are not modified as part of the clinical trial and are used within the terms of the marketing authorisation can apply abbreviated labelling in accordance with the existing UK requirements for prescribed medicines (see part 13 of the Human Medicines Regulation 2012). Where possible, the label should also include on the primary container or outer pack the words 'for clinical trial use only', and full labelling requirements 3 (information to identify the sponsor and contact persons involved in the clinical trial) and 4 (information allowing the identification of the clinical trial) (see 6.2.1 above for details). In this case a label template is not required for regulatory submission to the MHRA, confirmation that this labelling approach will be followed will be included in the submission.

Labelling according to regulation 46(4) of CTR: Where the IMP is authorised in the UK and is exclusively administered in the hospital or health centre which forms the trial location or is a radiopharmaceutical used for diagnostic purposes labelling requirements 2 (the warning that the product must be stored out of reach and sight of children) and 3 (the information to identify the sponsor and contact persons involved in the clinical trial) can be omitted from the full labelling requirements outlined in 6.2.1 above (note this cannot be applied to NIMPs).

See the MHRA decision tree for further guidance on labelling content.

6.2.2 Any labelling is expected to be applied to the primary packaging of the IMP. Where the primary packaging takes the form of a blister pack or other small container which cannot reasonably fit the required full labelling text this can be applied to the secondary packaging only and a reduced label applied to the primary packaging. Where this is the case any small primary containers will be labelled with the following full labelling requirements: 3 (information to identify the Sponsor), 4 (information to identify the trial), 5 (information to link the product to the participant), 6 (Information allowing identification of the medicinal product) and route of administration only (this may be excluded for oral solid dosage forms) (see 6.2.1 for details). Labelling requirements for primary and secondary packaging will be agreed and documented at combined risk assessment (GS002).

6.2.3 Where the trial is blinded, the label will include the name of any comparator or placebo used alongside the IMP being tested.

6.2.4 Where justifiable the CI, or designee, can request an exemption from, or variation to any of the labelling requirements for IMPs/NIMPs outlined above. Details of the request and the justification will be included in the cover letter or label documents for

MHRA submission or, where requested after initial MHRA approval, as a route A substantial modification.

6.2.5 Where required, template labels for IMPs/NIMPs (including primary and secondary packaging where applicable) will be developed by the CI, or designee, and provided to the Sponsor Representative for review. Review of the label template(s) will be documented in the Facilitation checklist (FA001-T03)

6.2.6 Any changes to the information contained on the label templates will be sent to the Sponsor Representative as a modification for review according to GS011.

6.3 IMP Storage

6.3.1 The PI, or designee, will ensure the IMP is stored under the conditions detailed in the trial protocol and/or trial pharmacy manual and/or SPC/IB.

6.3.2 If there is a requirement to monitor the storage temperature, the PI or designee, will ensure a temperature log is maintained with temperatures recorded by a calibrated temperature-recording device. Where possible, this device should be linked to an alarm system should temperatures fall out of range.

6.3.3 Where a temperature deviation is recorded, the PI or designee, will quarantine the affected IMP under the appropriate storage conditions, and inform the Clinical Trials Monitor.

6.3.4 Where necessary, the Clinical Trials Monitor, or designee, will contact the manufacturer of the IMP to determine whether there is stability data to support storage of the IMP out with the conditions specified in the clinical trial protocol or SPC.

6.3.5 The Clinical Trial Monitor will determine, in consultation with the study specific QP, PI and the Sponsor Reviewer (where necessary), whether the quarantined IMP can be released for use or must be destroyed.

6.3.6 Temperature deviations will be documented in accordance with ACCORD SOP CR010 (Management of Protocol and GCP Deviations and Violations).

6.3.7 If IMP is stored on the ward, out with Pharmacy, this should be stored separately from clinical stock. The PI, or designee, will ensure a local risk assessment is carried out for the assessment and approval of the storage area, shipping arrangements and the dispensing and record keeping processes. This risk assessment will be reviewed by

the Clinical Trials Monitor. Requirement for this will be documented at combined risk assessment (GS002).

6.4 IMP Accountability and Prescription

6.4.1 The Clinical Trial Monitor will determine the extent of IMP management documentation required (based on risk) on a trial specific basis. Where risk adaption is possible for IMP storage, accountability, prescription or destruction documentation this will be documented in the combined risk assessment (GS002-T01). The monitoring checks required for IMP management will be detailed in the trial specific Monitoring and/or Source Data Verification Plans prepared by the Clinical Trials Monitor in accordance with ACCORD SOP CM004 (Developing a Monitoring and SDV Plan).

6.4.2 The PI, or designee, will maintain IMP management records for their location, where necessary.

6.4.3 Where required after combined risk assessment, a master trial specific accountability and/or prescription template will be generated by the Trial Manager, or designee. The Clinical Trials Monitor will review any master accountability record and prescription template prior to first study SATO using GS010-T02 (Accountability Log Review Checklist) and GS010-T03 (Prescription Review Checklist). As an example, the accountability log may detail;

- Participant ID number
- IMP pack number
- Date dispensed
- Dose
- Quantity dispensed
- Batch number and expiry date
- Quantity in stock (if applicable)
- Date returned (if applicable)
- Quantity returned
- Destruction date (if applicable)
- Recorder's initials

As an example, the prescription may detail:

- Participant details (names, address, date of birth, hospital identifier, known allergies)
- Participant ID number
- Name of IMP prescribed (including form & strength)
- Dose of IMP prescribed

- Quantity of IMP to dispense/IMP pack number(s) to dispense
- Date prescribed
- Prescriber details and signature (name, contact)
- Dispensed by/checked by initials and date
- Any other study specific requirements (e.g. participant weight if dosing is weight based)

6.4.4 Consideration must be given to maintaining the blind (where required) when developing the accountability and prescription template, especially where aspects of the trial, e.g. pharmacy, are unblinded. Information which may have the potential to unblind, e.g. batch number, must be carefully managed to ensure the blind is maintained.

6.4.5 Where a master accountability and/or prescription template exists, this will be circulated to all locations during set-up to support documentation of IMP management.

6.4.6 Where a location chose to use a local accountability and/or prescription template to create source records for IMP management, including local electronic systems, the local PI, or designee, will confirm that all information contained on the master prescription and/or accountability template is included in the local template. If certain fields are omitted due to local practice these must be identified and a justification provided for their omission. This confirmation will be documented as part of the location set-up process (e.g. in the SIV report or associated correspondence) and prior to SATO at that location. The fitness for use of any site level electronic systems will be assessed at feasibility according to GS013 (Site feasibility).

6.4.7 If risks are identified in a clinical trial design which require the monitor to review location specific accountability and/or prescription templates as a mitigation this will be documented at combined risk assessment (GS002) and a monitoring management strategy put in place.

6.4.8 The PI, or designee, will ensure that any unused or expired IMP will be managed in accordance with the study protocol and/or pharmacy manual and that destruction of IMP will only be conducted with the Sponsors approval.

6.5 Transfer of IMP

6.5.1 The Co-Sponsors may permit transfer of IMP from one trial location to another under exceptional circumstances. For example, where the safety of the participant is jeopardised if supplies are not provided from another site in accordance with Annex

13 of Volume 4 of The Rules Governing Medicinal Products: Guideline to GMP (January 2010)

6.5.2 In situations where the transfer of IMP is required, the PI, or designee, or the Trial Manager must seek advice and approval from the Sponsor Reviewer in advance of the transfer.

6.5.3 The Sponsor Reviewer will ensure that the process for the transfer is agreed with the study specific QP and documented in the Rationale and procedures for location-to-location transfer of IMPs (GS010-T01).

6.5.4 The Trial Manager, or designee, will follow steps detailed in the Rationale and procedures for location-to-location transfer of IMPs (GS010-T01) when managing a location to location transfer.

6.5.5 The Trial Manager, or designee, must ensure that written approval for IMP transfer is obtained from the Sponsor Reviewer prior to each transfer.

6.5.6 The PI, or designee, will retain the necessary transfer paperwork in the Investigator Site File (ISF).

6.5.7 The Sponsor Reviewer will retain the necessary transfer paperwork in the Sponsor File. They will also advise the Trial Manager/PI or designee, if the product is to be quarantined if there are any missing documents

6.5.8 Transfer of IMP between hospitals in the same Health Board/Trust does not meet the criteria for location-to-location transfer requirements. There will be a formalised local procedure in place at site to conduct such transfers. Consideration will be given to the following (as directed by the relevant Clinical Trials Pharmacist):

- Temperature monitoring during transfer.
- Process/documentation (e.g., accountability logs).
- Record of transfers kept at local pharmacies.

Documentation required, as per the local procedure, will be retained and filed in the Investigator Site File (ISF).

7 References and Related Documents

- GS010-T01 Rationale and Procedures for Location-to-Location Transfer of IMPs
- GS010-T02 Accountability Log Review Checklist
- GS010-T03 Prescription Review Checklist
- GS010-T04 Pharmacy Manual/IMP Handling Instructions Review Checklist
- SOP GS00 Combined Risk Assessment
- SOP FA001 Facilitating a Regulated or Complex Research Project
- SOP CR010 Management of Protocol and GCP Deviations and Violations
- SOP CM001 Site Initiation and Sponsor Authorisation
- SOP CM004 Developing a Monitoring and SDV Plan.
- SOP GS011 Sponsor Approval of Modifications
- Part 13 of the Human Medicines Regulation 2012
- Medicines for Human Use (Clinical Trials) Regulations 2004 ("the Clinical Trials Regulations"), as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025
- Regulation 46(1) of the Clinical Trials Regulations

8 Document History

Version Number	Effective Date	Reason for Change
1.0	11 JUN 2018	New SOP
2.0	10 DEC 2019	Addition of GS010-T02 (Accountability Log Review Checklist) and GS010-T03 (Prescription Review Checklist). At section 5.1.3: 'Regulatory Release' has been renamed 'Regulatory Checks Complete'. Clarification added that the scope of this SOP includes studies subject to risk assessment (i.e. non-CTIMPs). Section 4.2 responsibility updated from Clinical Research Facilitator to Sponsor Reviewer. Update to SOP title. Change of author.
3.0	30 JUN 2020	Addition of GS010-T04 (Pharmacy manual/IMP handling instruction review) under new section 6.
4.0	14 FEB 2023	Added at section 5.1.2 and 6.5.1 'annex 13 Jan 2010' as EU has updated to 31 Jan 2022 but until UK has own regulations MHRA will inspect to Jan 2010. Addition of section 6.5.8 to outline considerations for transfer of IMP between hospital sites within the same Board/Trust. PI responsibilities expanded at 4.4 to ensure integrity of IMP during these transfers.

5.0	20 MAY 2025	Addition of sections 6.1.3 and 6.1.4 relating to IMP expiry. Minor updates to grammar and clarifications throughout. SOP transferred to new ACCORD template. GS010-T01, T02, T03 and T04 also transferred to new template (all updated to v2.0).
6.0	28 APR 2026	Updated to align with new Clinical Trial Regulations and ICH-GCP (R3), which includes extensive re-write/additional information added to section 6.2 (Labelling of IMP) and section 6.4 (IMP accountability and prescription). GS010-T01, T02, T03 and T04 all updated to v3.0.

9 Approvals

Sign	Date
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Gavin Robertson (16-Apr-2026 14:51:38 GMT+1) APPROVED: Gavin Robertson, QA Coordinator, NHSL, ACCORD	16-Apr-2026
L. Mackenzie AUTHORISED: Lorn Mackenzie, QA Manager, NHSL, ACCORD	16-Apr-2026

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