

Stock Management of IMP in Pharmacy

**IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT
THE CORRECT VERSION IS BEING USED**

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: <https://www.research.yorkhospitals.nhs.uk/sops-and-guidance/> and/or Q-Pulse

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Author:	Rachel Spooner
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Approved by:	Name/Position:	Poppy Cottrell-Howe, Pharmacy Clinical Trials Manager
	Date:	29 th January 2024
	Name/Position:	Sarah Sheath, SOP Controller
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This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reviewers	Details of significant changes
1.0	27 th February 2012		
2.0	22 nd July 2013		Amended to accommodate Scarborough Hospital as a site using this SOP, added references to the MHRA Good Clinical Practice Guide and Pharm/S76.
3.0	2 nd March 2015		Removal of Trial status inventory "How to obtain " IMP
4.0	18 th October 2017		
5.0	19 th December 2017		Merged procedure for both York and Scarborough sites for the maintenance of stock levels on the pharmacy stock control system (JAC)
6.0	3 rd September 2020		Change of author. Change of link to R&D website. Removed non-relevant procedures. Added extra information.
7.0	21 st February 2024	Rachel Spooner	Change of author. Addition of procedure for the prompting of cleaning IMP storage locations as part of the monthly stock check. Addition of more related Pharmacy SOPs/Forms.

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1 Introduction, Background and Purpose

The role of Pharmacy in relation to clinical research is:

- To safeguard subjects, healthcare professionals and the Trust by ensuring that IMPs (Investigational Medicinal Products) are appropriate for use and are procured, handled, stored and used safely.
- To ensure that IMPs are managed and dispensed to patients in accordance with the protocol.
- To ensure that all Pharmacy clinical trials procedures comply with relevant guidelines and regulations.

The purpose of this standard operating procedure is to describe the procedure of monitoring and ordering IMPs involved in clinical trials hosted or sponsored by York and Scarborough Teaching Hospitals NHS Foundation Trust.

The monitoring of stock of IMP is carried out to ensure that there are always sufficient supplies for dispensing to trial patients, as well as ensuring IMP is fit for use, in accordance with the mandated procedures for patient treatment contained within each study protocol.

The ordering of IMP is necessary to maintain adequate stock levels; however the process of ordering may differ depending upon the supplier. For the purpose of this SOP, IMP can be classed as three different types depending upon their source:

- Licensed or unlicensed products provided directly by the trial Sponsor.
- Normal hospital stock (but classified as an IMP for the trial)
- An IMP provided by a third party, e.g. bought in from a manufacturing unit, holding a Manufacturing Authorisation for Investigational Medicinal Product or MA (IMP), for use in a trial sponsored by York and Scarborough Teaching Hospitals NHS Foundation Trust.

2 Who Should Use This SOP

This SOP should be used by all members of the pharmacy clinical trials team within York and Scarborough Teaching Hospitals NHS Foundation Trust.

3 When this SOP Should be Used

This SOP should be used when performing the following activities:

- Routinely monitoring stock levels of IMP
- Routinely monitoring stock levels of Hospital Stock required for studies
- Ordering IMP from a trial Sponsor
- Performing expiry date checks on IMP and clinical trials stock
- Performing checks and maintenance of all storage locations of IMP/NIMP within Pharmacy clinical trials.

The monitoring and ordering of IMP stock, where IMP is stored outside of Pharmacy, is not covered by this SOP. The procedures for this will be detailed in

a study-specific SOP in these circumstances, describing the particular IMP arrangements for the relevant trial.

4 Procedure(s)

The following procedures should be followed:

4.1 Routines for monitoring stock levels and expiry date checking of IMP:

Stock levels of all IMPs and hospital stock should be monitored on a monthly basis. This is to ensure there are always sufficient supplies of all IMPs required for each trial and that IMP is fit for use.

The procedures for monitoring (and ordering) of **normal hospital stock** for use in a trial are contained within section 4.3. It should be noted that this process may also be used for ordering NIMPs (non-Investigational Medicinal Products) and other medicines that may be required as supportive medication in a trial e.g. anti-emetics.

In some clinical trials, the levels of IMP relating to the relevant treatment arms of the trial are monitored and replenished automatically by the Sponsor or through an IVRS (Interactive Voice Recognition System) or IWRS (Interactive Web based Recognition System).

The procedures for monitoring **Sponsor provided IMP** or **IMP ordered from a third-party supplier** are described below;

1. Obtain a blank copy of the 'Clinical Trials Monthly Stock Check Form' (Pharm/F63).
2. Record the name of the member of staff carrying out the monthly stock check, the date the monthly stock check is being carried out, and the location of the IMP being checked at the top of the form. Add your signature. A new sheet should be completed for each location of IMP storage, for example different fridges or storage areas.
3. Record the trial name.
4. List the name of the drug(s) involved in the trial.

Record the expiry date of the physical stock, and if less than 6 months, record on the clinical trials shared Outlook calendar so that all staff members are aware when this needs to be removed from the shelf.

Any stock that is found that has expired will need to be placed into quarantine and dealt with by following the trial specific SOP which details how to quarantine/ destroy different IMP.

5. Record the current physical stock level of each drug.
Once you have checked of the IMP on the shelves, check the current stock level on the Master Accountability logs kept in the trial file.
6. Complete the method of ordering e.g. manual or automatic, on the form
7. See if any of the IMP with manual ordering is running low and if it is, follow the process detailed in section 4.2.

Note: The form should be annotated accordingly if any part of the above procedure is not carried out with the reason for the deviation.

In some circumstances, where the site is confident that there will be adequate stock available for a particular trial, it may be appropriate for the site to use normal hospital stock that is kept at site for use for any hospital patient (i.e. non trial patients) in the main Pharmacy dispensary. This stock would not be routinely monitored by the Clinical Trials Team.

4.2 Ordering IMP from a Trial Sponsor/Third party supplier (where applicable)

The procedure detailed below should be followed;

1. Use the completed 'Clinical Trials Monthly Stock Check Form' to identify the IMP to be ordered.
2. Refer to each specific trial file and locate the relevant procedure for ordering of trial supplies (every trial has a specific procedure to follow for this). The procedure is contained within the Trial instructions that are written by the Pharmacy clinical trials team for each trial.
3. Place the order by following the trial procedure. In most cases, an order form is emailed to the Sponsor, who will initiate a shipment of relevant drugs to the Pharmacy at York Hospital.
4. File the individual trial order paperwork as indicated in the trial instructions.
5. Sign in the relevant box of the 'Clinical Trials Monthly Stock Check Form' to confirm the stock requirements have been ordered, including what date it was ordered.
6. Once completed for all trials that require IMP, file the completed 'Clinical Trials Monthly Stock Check Form' in the clinical trials stock checks file located in a designated area.

4.3 Checks and Maintenance of storage locations within Pharmacy clinical trials where IMP/NIMP is stored:

To ensure the safe storage of Clinical Trial medication and that IMP/NIMP is fit for use, all medication storage locations within Pharmacy clinical trials must be cleaned on a regular basis using the processes documented in Pharm/S96 (Cleaning of clinical trials IMP storage locations).

Each month, upon completing the monthly stock check, select two storage locations documented on Pharm/F40 (Clinical Trials IMP storage location cleaning schedule), and record these on the designated section of Pharm/F63 (monthly stock check form).

Follow the processes documented in Pharm/S96 to complete the cleaning of these areas, ensuring that any specific temperature requirements for the IMP stored in the areas chosen are maintained and monitored throughout.

The locations of cleaning should be chosen as per the schedule on Pharm/F40, taking into consideration any upcoming prescriptions, monitoring visits, and the amount of stock stored in the chosen location at the time.

Once cleaning has been completed for the month, tick to confirm that the chosen locations have been cleaned in the designated section on the monthly stock check form (Pharm/F63) and document the cleaning on the cleaning schedule

(Pharm/F40). Cleaning schedules can be found in the 'Temperature Monitoring File' in the clinical trials office.

4.4 Procedures for maintaining clinical trials stock levels on the Pharmacy stock control system (JAC)

To ensure the availability of normal hospital stock for use in clinical trials is available and fit for use, monthly checks should be performed using the 'Clinical Trials Monthly Stock Check Form' (Pharm/F63).

- 1) Log onto JAC/CMM computer system using individual log in details
- 2) Select programme 'Stock management'
- 3) Select 'KANAL'
- 4) Type in drug name
- 5) Select correct drug and strength from the list given
- 6) Select 'Clinical Trials' as the source location
- 7) Check that the figures on JAC match what is currently in Clinical Trials Pharmacy.

5 Related SOPs and Documents

Pharm/S96	Cleaning of Clinical Trials storage locations
Pharm/F63	Clinical trials monthly stock check form
Pharm/F40	Clinical Trials storage locations cleaning schedule