York Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S70

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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SOP Reference:	Pharm/S70
Version Number:	5.0
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Implementation date of current version:	19th December 2017

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	Date:	21st November 2017

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	Details of significant changes
1.0	27th February 2012	
2.0	22nd 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	2nd March 2015	Removal of Trial status inventory “How to obtain “ IMP
4.0	18th October 2017	
5.0	19th December 2017	Merged procedure for both York and Scarborough sites for the maintenance of stock levels on the pharmacy stock control system (JAC)

Contents

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 Teaching Hospital 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 who the supplier is. 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 Teaching Hospital 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 Teaching Hospital 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
- Ordering IMP from a trial Sponsor
- Performing expiry date checks on IMP and clinical trials stock
- Topping up clinical trials stock levels on the Pharmacy stock control system (JAC) using the ‘top up procedure’ or ‘K-TRANS procedure depending on site.

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 of the clinical trials, the levels of IMP relating to the relevant treatment arms of the trial are usually 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. Locate the Pharmacy trial file for each trial classed as 'Sponsor provided' or 'third party' (files may be stored with the IMP or, in the case of fridge supplies, on the designated shelf in the dispensary or clinical trials office).
3. Record the name of the member of staff carrying out the monthly stock check and the date the monthly stock check is being carried out at the top of the form. Add your signature.
4. Record the trial name.
5. 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 in the clinical trials diary to highlight to all staff members when this needs removing from the shelf.

   Any stock that is found that has expired will need to be placed into quarantine, and dealt with as study specific instructions state.
6. Record the current physical stock level of each drug
7. Record the current stock level on master accountability log (if applicable)
8. Record the current stock level on JAC or IWRS etc.
9. Complete the method of ordering e.g. manual, automatic on the form
10. Order the appropriate amount of IMP to be and record your actions on the form.
11. Once completed for all relevant trials, proceed to follow the procedures for ordering each IMP detailed within the trial instructions for that trial and described in section 4.2. These procedures are contained within the Pharmacy file for the study.

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 either emailed or faxed to the Sponsor, who will initiate a shipment of relevant drugs to the Pharmacy at York or Scarborough Hospital.
4. File the individual trial order paperwork as indicated in the trial instructions.
5. Sign name in the relevant box of the 'Clinical Trials Monthly Stock Check Form' to confirm the stock requirements have been ordered, where from and 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 monitoring file located in a designated area.

4.3 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 computer system using individual log in details

2) Select programme ' Stock management'

3) Select K-TRANS

4) Type in drug name

5) Select correct drug and strength from the list given

6) Select the relevant source location

7) Select the relevant destination location

8) Select pack size

9) Select printer from the list for K-TRANS report to be printed

10) Select amount you need (number of containers or dose units)

11) Click on ‘OK’ ,collect stock and print off

12) Move stock to clinical trials dispensary and file K-TRANS report in designated file in clinical trials dispensary.

5 Related SOPs and Documents

Pharm/F63	Clinical trials monthly stock check form