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 R&D Newsletter 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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: www.northyorksresearch.nhs.uk/sops.html

SOP Reference:	Pharm/S70
Version Number:	3.0
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Implementation date of current version:	2nd March 2015

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	Date:	4th February 2015

This SOP will normally be reviewed every 2 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

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 (Practice Guidance on Pharmacy Services to Clinical Trials, Royal Pharmaceutical Society of Great Britain (RPSGB), June 2005).

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 levels of IMP is carried out to ensure that there are always sufficient supplies for dispensing to trial patients in accordance with the mandated procedures for patient treatment contained within each study protocol. Inability to provide IMP as per the protocol is considered a protocol deviation and must be avoided to ensure that the research undertaken by the Sponsor can be considered safe, effective and compliant with Good Clinical Practice (GCP). Managing the stock levels of IMPs is therefore an important part of the role of Pharmacy in clinical research as described above.

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.

This SOP describes the activities relating to the monitoring and ordering of all types of IMP however, Pharm/S43 describes the procedures for procurement of IMP from a third party manufacturer and the particular requirements of this process in more detail.

In addition to this SOP, further information regarding the management of IMP at Investigator sites can be found in section 6 of the Good Clinical Practice guide (the grey guide).

2 Who Should Use This SOP

This SOP should be used by all members of the clinical trials team within Pharmacy at York and Scarborough Hospital, which form part of York Teaching Hospital NHS Foundation Trust.

The primary responsibility for activities within this SOP lies with the Senior Assistant Technical Officer for clinical trials. In their absence it will be performed by another member of the clinical trials team within Pharmacy.

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
- Topping up clinical trials stock levels on the Pharmacy stock control system (JAC) using the 'top up procedure'

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. More detail of what this SOP will contain can be found in Pharm/S76 – Storage and dispensing of Investigational Medicinal Products outside of Pharmacy.

4 Procedure(s)

The following procedures should be followed.

4.1 Routines for monitoring stock levels of IMP

Stock levels of all IMPs should be monitored on a monthly basis. This is to ensure there are always sufficient supplies of all IMPs required for each trial. When the trial involves normal hospital stock, the monitoring of supplies will be performed more frequently (e.g. once weekly) to ensure that adequate stock is available for dispensing.

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 trials that are 'double blind' in design, 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). In this instance the supplies are classed as **Sponsor provided IMP** and the Pharmacy clinical trials team do not accept responsibility for ordering the IMP.

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.
6. Record the expiry date and quantity of any stock due to expire within 3 to 6 months.
7. Record the current stock level of each drug. Compare this to the trial master accountability log. Any discrepancies against the stock level recorded on the accountability log for the trial should be reported to the Clinical Trials Manager/Pharmacist for investigation.
8. Use the patient information within the trial file plus study design to predict the stock requirements for the following 3 months.
9. Record these findings on the form.
10. Calculate the amount of IMP to be ordered and record 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

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 (See Pharm/S50 for more details).
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 in the relevant box of the ‘Clinical Trials Monthly Stock Check Form’ to confirm the stock requirements have been ordered. Also, indicate in the ‘ordered from’ column on the form, the Institution from which the IMP has been ordered e.g. the name of the Trial Sponsor or Manufacturer.
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 a clinical trial, York or Scarborough hospital may maintain a clinical trials stock level on the JAC system for this purpose. The process of maintaining this would then involve 'topping up' the levels of stock to a pre-determined level each week. This top up procedure is described below. This should be performed at least once a week.

- Obtain clinical trials top up file.
- Check the physical stock against the level required on the top up sheet.
- Complete the weekly top up sheet with quantity required to order. If no stock is required tick against the item checked.
- Follow the procedure for a manual requisition from Pharmacy stores as described below:

    1. Log onto JAC computer system.
    2. Select 'ordering and invoicing'.
    3. Select RNEW.
    4. Select 'Clinical Trials' from the drop down menu for destination location.
    5. Select 'create released requisition'.
    6. A small box will appear stating source location select 'Pharmacy main' from the drop down menu.
    7. From the completed table *'weekly top up sheet'* order the items required from pharmacy stores.
    8. Enter the drug name required then click 'search'.
    9. Select the correct drug, strength, form and pack size from the list available.
    10. In 'requisition quantity' enter the amount required in whole packs then select 'requisition'.
    11. A small box will appear stating item added to released requisition.
    12. To add more items repeat steps 8-12.
    13. When all items are added click 'close'.
    14. This has generated a requisition which has been given a number.
    15. From the ordering and invoicing menu select 'RTAKE'.
    16. Select destination as **clinical trials** then select the correct requisition number and click 'OK'.
    17. Another screen will appear displaying the order and a tab labelled 'take stock' click on this tab.
    18. A box will appear stating requisition processed click 'OK' then close.
    19. At the bottom of this screen is a tab called 'picking list', click on this.
    20. Return to the ordering and invoicing screen when all items have been picked in stores and have been checked off and signed as correct.
    21. Select 'RPUT' for this requisition.

22. Select **clinical trials** as destination location.
23. Double click on the requisition number.
24. A box will appear stating requisition processed.
25. Click on ‘OK’.
26. Then close.

All delivery notes must be filed in the pocket provided in the top up file.

Please note: as described in Section 4.1, and depending on the individual trial arrangements, it is acceptable for a site to not maintain a clinical trial stock level on JAC, as long as the site is confident that supply of normal hospital stock to a clinical trial would not be compromised by this arrangement. In these circumstances, the availability of stock would be maintained through normal hospital Pharmacy standard operating procedures, and if required, stock would be requisitioned for use from an available location via JAC.

5 Related SOPs and Documents

Practice Guidance for Pharmacy Service to Clinical Trials, Royal Pharmaceutical Society of Great Britain.

Pharm/S76	Storage and dispensing of Investigational Medicinal Products outside of Pharmacy.
Pharm/T25	Pharmacy Trial Instructions
Pharm/S50	Preparation, Review and Approval of Pharmacy Study Specific Trial Instructions
Pharm/S43	How to procure an Investigational Medicinal Product
Pharm/S61	Maintenance of the trials status inventory dispensary list
Pharm/F63	Clinical trials monthly stock check form

Good Clinical Practice Guide, MHRA, 2012.