York Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S52

Expiry Date Monitoring (Clinical Trials)

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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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	6th August 2009	
2.0	1st January 2010	Pharmacy SOP put into revised template. Cross referenced forms and SOPs updated
3.0	28th October 2013	Change of SOP Controller. Removal of references to the North and East Yorkshire Alliance. Inclusion of Scarborough as a site using this SOP. Removal of form F38 and F39 from use. Simplification of expiry date check process in line with Monthly stock check procedures detailed in Pharm/S70. Addition of information about additional expiry date checks performed in Section 4.3.
4.0	19th January 2016	Change of references to labelling SOP (Pharm/S45 to Pharm/S105) and removal of references to Pharm/T25. Other minor changes in the process.

Contents

1 Introduction, Background and Purpose

It is important to ensure that out of date Investigational Medicinal Products (IMP) are not dispensed to trial participants. This procedure describes the process of monitoring expiry dates for IMP and normal hospital stock (ring fenced for use within clinical trials) stored in the Pharmacy Departments at York and Scarborough hospitals, which form part of York Teaching Hospital NHS Foundation Trust.

Any IMP that is stored outside Pharmacy for use in a clinical trial will also require its' expiry date to be checked on a regular basis. The procedures for doing this are not described here but should be detailed in a study specific SOP produced for each trial (where IMP is stored outside Pharmacy) to cover the arrangements and responsibilities for managing the IMP in these circumstances. This SOP should be written in line with procedures described in Pharm/S76 – Storage and dispensing of Investigational Medicinal Products outside of Pharmacy and Pharm/S47 – Storage of Clinical Trials Supplies.

2 Who Should Use This SOP

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

3 When this SOP Should be Used

This SOP applies to checking expiry dates of IMP, clinical trial supplies and normal hospital stock (ring fenced for use within clinical trials).

This SOP includes expiry date monitoring of supplies managed using Interactive Voice/Web Response Systems (IVRS/IWRS), although in these circumstances, the expiry date checks conducted by Pharmacy should act as a second check over and above those in place through these systems to monitor product expiry dates.

4 Procedure(s)

4.1 Procedure for checking expiry dates of IMP

All locations (e.g. fridges, freezers and room temperature) where clinical trial materials/IMPs are stored will be checked every month.

This expiry date check forms part of the monthly stock monitoring process that is described in the SOP Stock Management of IMP in Pharmacy (Pharm/S70).

During this procedure, a member of the Pharmacy clinical trials team is required to check the expiry date of all Sponsor provided IMP or IMP ordered from a third party supplier, and record the expiry date (and quantities) found in the relevant column of the Clinical Trials Monthly Stock Check Form (Pharm/F63).

Because Clinical Trials stock is usually dispensed in courses, ranging from 1-6 months for example, it is imperative that the stock held will have sufficient expiry to cover the whole course to be dispensed.

For each product held as stock the trials instructions and/or the prescription will give an indication of the amount of product to be dispensed at each visit. From this the “minimum shelf life” (i.e. the minimum expiry of any product that can be given in that dispensing episode) can be calculated. This should be considered when performing the expiry date checks.

Once the process of checking expiry dates has been conducted, the procedures in section 4.1.1 and 4.1.2 should be followed. Once completed, Pharm/F63 should be reviewed by the Clinical Trials Manager (or designated individual), signed and dated and then filed in the ‘expiry date checking file’ in the clinical trials dispensary.

4.1.1 Product with an expiry date of less than the minimum shelf life

1. Remove the product from the storage location to reduce the risk that this product will get dispensed.

2. Place this product in the quarantine location relevant to its storage conditions. i.e. If a refrigerated product, store in the quarantine area of the clinical trials fridge. If a room temperature product, store in the quarantine area of the clinical trials dispensary. Complete quarantine documentation (refer to Pharm/S59 – Quarantine of IMP).

3. Contact the Clinical Research Associate (CRA) or Sponsor Representative e.g. Trial Manager to make them aware of the expiry date of the product and request confirmation of the action to be taken for this product.

4. Await response from the CRA / Sponsor representative.

5. Following confirmation of action required from the CRA / Sponsor representative, arrange for return or destruction of the stock in line with the arrangements for that trial detailed in the protocol or Pharmacy file. If the Sponsor indicates that the products expiry date is to be extended, refer to study specific instructions from the Sponsor (if provided) and the Pharmacy SOP relating to expiry date extension of IMP.

6. Complete quarantine documentation (Refer to Pharm/S59) as appropriate.

7. Complete drug accountability records to document return or destruction of the product appropriately. Refer to Pharm/S55 for details of returning IMP to a sponsor and Pharm/S57 for information on destruction of Investigational Medicinal Product.

8. File all correspondence and relevant documentation in the Pharmacy file for that study.

9. Check the remaining physical stock level of IMP to ensure that sufficient is available for future patient visits. If not, order more stock in line with Pharm/S70 – Stock Management of IMP in Pharmacy.

4.1.2 Product that is approaching it's minimum shelf life

1. Highlight the expiry date of this stock on the clinical trial monthly stock check form (Pharm/F63).

2. Complete a 'caution notice' sign with the expiry date of the product. These are stored in the 'expiry date checking file' in the clinical trials dispensary.

3. Place this sign at the front of the expiring stock in it's storage location (note: several notices may be in use for differing expiry dates). Ensure stock is rotated so the shortest dated stock is at the front.

4. Pass the Clinical Trials Monthly Stock Check Form to the Clinical Trials Manager (or designated individual) to review and sign.

5. Order more stock if required in line with Pharm/S70 – Stock Management of IMP in Pharmacy.

File completed forms (Pharm/F63) within the 'expiry date checking file' in the clinical trials dispensary.

4.2 Procedure relating to normal hospital stock (ring fenced for use in trials)

This stock is replenished regularly by a member of the Pharmacy clinical trials team (e.g. Senior Pharmacy Assistant). The expiry dates of these products must be checked as part of this 'top-up' process at a frequency equivalent to once a month. Follow the process below;

1. As part of the top-up process, write the expiry dates on the top up list.

2. Highlight those due to expire within 12 weeks.

3. Bring to the attention of the Clinical Trials Manager or Senior Pharmacy Technician. They will decide whether more stock should be ordered, and also, whether this stock can be exchanged for stock with a longer expiry date through liaison with dispensary/stores staff.

4. If stock cannot be exchanged, re-order if necessary through procedures described in Pharm/S70 – Stock Management of IMP in Pharmacy.

5. Place a 'caution notice' with the stock to alert clinical trials staff of the impending expiry date. These are stored in the 'expiry date checking file' in the clinical trials dispensary.

6. Once stock has expired, or exceeded it's minimum shelf life, remove stock from location, book out to the relevant consultant, and dispose of in line with the hospital Pharmacy SOP – SOPQA7 Disposal of Pharmaceutical waste (on q-pulse).

4.3 Additional expiry date checks conducted by Pharmacy

To ensure an effective quality system, the IMP expiry date is checked at three additional stages during the trial;

1. Upon receipt at site.
2. During the dispensing process.
3. Prior to final release to the patient by a Pharmacist.

The Pharmacy Trial Instructions contain specific instructions of how to complete these additional checks for each trial.

5 Related SOPs and Documents

Pharm/S70	Stock Management of IMP in Pharmacy
Pharm/F63	Clinical Trials Monthly Stock Check Form
Pharm/S59	Quarantine of IMP
Pharm/F42	Quarantine Notice
Pharm/F43	Quarantine Log
Pharm/S47	Storage of Clinical Trial Supplies
Pharm/S55	Returning Clinical Trial Material and Investigational Medicinal Product from Pharmacy Stores to the trial Sponsor
Pharm/S57	Destruction of Investigational Medicinal Product
Pharm/S76	Storage and dispensing of Investigational Medicinal Products outside of Pharmacy
SOPQA7	Disposal of Pharmaceutical Waste
Pharm/S105	Production and Control of Clinical Trials Labels