York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S56

Trial Closedown 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/and/or Q-Pulse

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	Date:	19th September 2024
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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	1st February 2011		
2.0	22nd July 2013		Removal of references to the North and East Yorkshire R&D Alliance. Change of SOP Controller.
3.0	20th August 2015		Minor amendments
4.0	8th March 2019		Change of author and changes to reflect new Pharmacy Trial Closedown Form. Change of link to R&D website
5.0	28th October 2020		Change of author. Addition of new, more detailed archiving instructions.
6.0	11th January 2021		Change of author. Minor amendments.
7.0	9th October 2024	Rachel Spooner	Change of author. Removal of details regarding final invoicing and included reference to Pharm/S42. Updated email addresses.

Contents

1 Introduction, Background and Purpose

During the closedown of a trial, it is an important requirement to ensure that all the documents that provide an audit trail are present in the Pharmacy site file. The Pharmacy site file and documents contained within are required to complete the trial master site file and therefore at all times should contain the essential documents relating to the clinical trial.

This SOP describes a procedure for preparing a pharmacy related study for archiving or closing down.

This SOP should be used in conjunction with the relevant R&D Trial Close out SOP's.

A trial site can be considered closed when all study related activities at a particular site are reconciled and/or completed.

The exact date of closure of a clinical trial will be defined by the Sponsor, and the Pharmacy department will be notified by the Sponsor in advance of the closure of the trial in writing. However, a sponsor or research team may ask for a study to be prepared for archiving prior to the close out date being arranged. For commercial trials, this communication may come from the Clinical Research Associate, or for non-commercial trials, the Trial Manager of the relevant study. For trials Sponsored by York and Scarborough Teaching Hospitals NHS Foundation Trust, this notification will come from the R&D Unit.

The closure of a clinical trial within Pharmacy will usually take the form of a trial close-out visit conducted by the trial Sponsor. However, in some circumstances, the trial Sponsor will request confirmation from Pharmacy that all relevant close-out activities have been completed by the Pharmacy department at the trial site.

The purpose of this SOP is to ensure that the Pharmacy file is ready for archiving/closure, including final trial payments. This SOP also describes what actions should be taken during the process of study closure or close-out visit conducted by the trial Sponsor.

2 Who Should Use This SOP

This applies to all members of the pharmacy clinical trials from York and Scarborough Teaching Hospitals NHS Foundation Trust.

3 When this SOP Should be Used

The procedure should be used;

- When requested to close down a trial by the trial Sponsor.
- During the trial close-out visit by the trial Sponsor.
- When preparing the Pharmacy file for archiving.

4 Procedure(s)

Trial close-out will usually take the form of a close-out visit and the relevant member of the Pharmacy clinical trials team should follow the procedure outlined below.

In some circumstances, Pharmacy staff may be asked by the trial Sponsor to close down the study in the absence of a Trial Monitor or Clinical Research Associate. This may include completion of a closedown checklist (provided by the trial Sponsor via post or email) which you are required to action, complete and return. In these circumstances you should comply with the request from the trial Sponsor and follow the actions specified below, which would normally occur during the trial closedown visit. In this case, Pharmacy would assume the responsibility of performing these tasks. A copy of any completed closedown documentation should be filed with the Pharmacy trial file, and the original documents should be filed in the 'Closed studies – gone to archive' file in the Pharmacy clinical trials office.

Obtain and complete the process on Pharm/F87 - Pharmacy Trial Closedown Form. Prior to completing the Pharmacy Trial Closedown form (Pharm/F87), a Pharmacy Clinical Trial Maintenance Form (Pharm/F82) must be completed. A copy of this form should then be filed with Pharm/F87 and any other close down checklists in the front of the Pharmacy file and as well as the originals being filed in the 'Closed studies' folder in the Pharmacy Clinical Trials office.

4.1 Final Pharmacy payments

If applicable, prior to the trial close-out visit, a member of the Pharmacy clinical trials team must ensure that all final pharmacy invoices have been raised for the study, following Pharm/S42 (Pharmacy Financial Agreements and Invoicing).

If required by the sponsor, supply a copy of the financial agreement and any other relevant financial documents at the study close-out visit. Any financial documents filed in the Pharmacy site file must not contain any confidential information. All financial correspondence/invoices must be kept in the studies electronic folder on the X:Drive and a file note should be placed in the pharmacy site file detailing this.

4.2 The trial close-out visit and archiving

The trial close-out visit will be conducted by the Sponsor in the presence of a member of the Pharmacy clinical trials team at York and Scarborough Teaching Hospitals NHS Foundation Trust. At the close-out visit the following activities should be carried out by the Sponsor representative with the support of a member of the Pharmacy clinical trials team:

- Reconciliation of the trial medication supplies or Investigational Medicinal Product. This should include a check that all IMP has been returned by patients. All IMP accountability logs must be checked for accuracy and any discrepancies accounted for.

- Check all the essential documents are in the Pharmacy file

In preparation for this a member of the Pharmacy clinical trials team is responsible for ensuring that:

- Copies of all storage temperature graphs covering the period the IMP has been stored on site are reviewed and archived centrally. A signed and dated file note should be placed in the Pharmacy trial file documenting that the temperature graphs have been reviewed and describing where these can be obtained if required. Temperature graphs should be stored in York and Scarborough Teaching Hospitals NHS Foundation Trust and archived by the Trust periodically. It is also acceptable for the temperature graphs to be stored in the Pharmacy file itself if requested by the sponsor.

- All randomisation code break envelopes (if applicable) are present in the Pharmacy file.

- Copies all essential correspondence are printed and filed in the relevant sections of the Pharmacy file.

- All documentation is completed accurately and in full (any discrepancies in documentation and drug accountability must be accounted for and file notes written, as applicable, to describe these).

- All payments to Pharmacy have been made (see procedure details in Pharm/S42).

After the close-out visit, the Sponsor will write to Pharmacy to confirm that all activities required for trial close-out have been completed, or describe what actions are required by Pharmacy (i.e. if IMP discrepancies were noted during the Trial close-out visit then these will need to be satisfactorily explained). This will take the form of a final trial close-out monitoring report (usually a letter via post or email). Once confirmation of the trial close-out visit has been received from the Sponsor and all actions contained within have been completed as applicable, the report should be filed within the Pharmacy file and the following activities can take place;

- Removal or on-site destruction of trial medication supplies or Investigational Medicinal Product (if applicable) and documentation of this activity.

If no IMP discrepancies are noted during the trial close-out visit, the Sponsor representative may return IMP to the Sponsor during this visit. If IMP discrepancies are present, then these must be satisfactorily explained and accepted by the Sponsor prior to return of the IMP. Returns to the Sponsor should be documented within the Pharmacy file (usually by obtaining a copy of the completed Sponsor provided returns documentation). Where IMP is to be destroyed on-site, destruction should only be conducted following written authorisation from the Sponsor. A certificate of destruction should be completed and filed within the Pharmacy trial file.

Archiving

Ensure the closeout documentation provided by the sponsor is completed as well as working through Pharm/F87 Pharmacy Trial Closedown Form. Once a study has

been prepared for archive, add the comment “prepared for archive” to the relevant study on the ‘Clinical Trials List’ spreadsheet on the clinical trials X:Drive.

Liaise with CTA support at yhs-tr.CTAsupport@nhs.net regarding the closure of the PSF and inform CTAs when files are ready for collection, so that the PSF can be archived alongside the ISF by R&D. Store form Pharm/F87 in the front of the study’s pharmacy site file and retain in the ‘prepared and ready for archive’ bay of the clinical trials dispensary until the file is ready to be collected/dropped off (See 4.3 for next steps).

ISFs must **not** be sent for archiving by R&D until both the PSF and LSF (as applicable) are prepared for archiving and are placed with the ISF.

However, on the rare occasion that the ISF has already been archived or is otherwise located, liaise with CTA support to establish the whereabouts of the folders and when it was archived. If the ISF has already been archived it will be necessary for pharmacy clinical trials staff to complete the archiving process for the PSF. When preparing PSFs for archive clinical trials staff should contact Labs staff to establish the presence/location of the corresponding LSF so that archiving can take place simultaneously. To complete the archiving process within Pharmacy clinical trials, Form Pharm/F87 must be used in conjunction with **R&D/F56** and **R&D/S11.**

Make two copies of **R&D/F56** and complete the labels for the folders being archived. The ‘Sponsor’ and ‘Short project title & R&D Study Reference No.’ can be found on the trial folders, and the brief description should detail the PSFs and/or LSFs in the box and their quantity. To complete the ‘R&D Box Reference Number’ contact the named archivist in R&D using first yhs-tr.Research,Governance@nhs.net or yhs-tr.CTAsupport@nhs.net as a secondary point of contact. The ‘Date box is collected’ and ‘Destruction date’ are to be left blank as these are to be completed by the named archivist.

Place one copy of the label inside the archiving box and affix the other to the top of the box inside a plastic sleeve to protect from damage/fading. Once the box is ready for collection notify the named archivist or CTA support to establish if the box can be collected and stored within R&D. If this occurs see section 4.3 for documents to be retained upon handover.

In the event that completed boxes cannot be stored in R&D, they must be stored as efficiently as possible within the clinical trials dispensary until such a time as they are able to be collected for archive.

4.3 Documents to be kept by Pharmacy

Prior to sending the Pharmacy file for archiving as described above, including finalising any outstanding the financial payments, retain and complete the following:

1. Complete Pharm/F82 Pharmacy Clinical Trials Maintenance form and retain a copy in the front of the Pharmacy site file, and the original in the ‘Closed studies – gone to archive’ file in the Pharmacy clinical trials office.
2. Complete Pharm/F87 Pharmacy Trial Closedown Form and keep in the ‘Closed Studies – gone to archive’ folder. Ensure the member of staff collecting the pharmacy site file completes their section of the form. A copy of Pharm/F87 must be stored in the front of the

pharmacy site file. Pharmacy clinical trials should also retain copies of any other sponsor closedown checklists and a printout of the permission given by the sponsor to archive.

3. Update the Clinical Trials List spreadsheet to reflect the change in status of this study once archived.

5 Related SOPs and Documents

Pharm/F87	Pharmacy Trial Closedown Form
Pharm/F82	Pharmacy Clinical Trials Maintenance Form.
R&D/F56	Archive Box Label
R&D/S11	Archiving of Research Study Documents
Pharm/S42	Pharmacy Financial Agreements and Invoicing