

Maintaining Pharmacy Clinical Trial Files

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

SOP Reference:	Pharm/S39
Version Number:	5.0
Author:	Dominic Burns
Implementation date of current version:	15 th October 2024

Approved by:	Name/Position:	Poppy Cottrell-Howe, Pharmacy Clinical Trials Manager
	Date:	15 th October 2024
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	17 th September 2024

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	18 th July 2016		New SOP
2.0	6 th March 2019		Change of link to R&D website. Change of author and reviewed to accommodate updated form
3.0	30 th December 2019		Updated to include documents which may need to be requested/retrieved from sites other than York. Included information that all PSFs will be kept on the York site. Change of author.
4.0	11 th January 2021		Change of author. Addition of link to Pharmacy Closedown
5.0	15 th October 2024	Rachel Spooner	Change of author. Addition of matching X:\ & physical folders.

Contents

	<u>Page No</u>
Version	2
1 Introduction, Background and Purpose	1
2 Who Should Use This SOP	1
3 When this SOP Should be Used	1
4 Procedure(s)	1
5 Related SOPs and Documents	2

1 Introduction, Background and Purpose

It is important to ensure that all Pharmacy Clinical Trial Files are kept up to date and complete.

This SOP describes the process of maintaining Pharmacy Clinical Trial Files.

2 Who Should Use This SOP

This SOP should be followed by all members of the Pharmacy Clinical Trials team at York and Scarborough Teaching Hospitals NHS Foundation Trust.

3 When this SOP Should be Used

This SOP should be used on a regular basis when maintaining Pharmacy Clinical Trials Files.

4 Procedure(s)

During this procedure, a member of the Pharmacy Clinical Trials Team is required to carry out a Pharmacy Clinical Trials file maintenance check following the Pharmacy Clinical Trials File Maintenance form (Pharm/F82)

All Pharmacy Clinical Trials Files will need to be maintained on a regular basis. The frequency at which file checks are carried out will be determined by the number of patients recruited to individual trials or following requests from the sponsor, following a large amendment and other contributing factors.

Maintenance of the Pharmacy Clinical Trial file must also be carried out prior to a Pharmacy Clinical Trial file being closed down and prepared for archiving. Once completed, the relevant section of the Pharmacy Closedown form (Pharm/F87) should be signed and dated to confirm that the file has been checked and maintained.

Individual trial monitors should be contacted in order to obtain a list of current working documents so that we can ensure that we are working to the correct versions of all documents.

Pharmacy site files are kept in the pharmacy clinical trials dispensary on the York Hospital site. The dispensary is a secure storage location and the room is locked when not in use.

Pharmacy sites files for other sites such as Scarborough and Bridlington will also be kept within the dispensary on the York site. This is so the documentation/paperwork related to the IMP are kept together. All pharmacy site files will be maintained from the York site, unless the sponsor is performing a monitoring visit and requests that a member of pharmacy bring the pharmacy site file to the monitoring visit in Scarborough. If this is the case, ensure the files are packaged securely and transported between sites with Trust approved secure transport.

Procedure for maintaining Pharmacy Clinical Trials Files:

1. Obtain a blank copy of the Pharmacy Clinical Trials File Maintenance form (Pharm/F82)
2. Locate the Pharmacy Clinical Trial File for the individual trial which you are wishing to carry out the check.
3. Contact the trial monitor in order to obtain a list of current working documents for the trial.
4. Ensure that the physical folder and X:\ folder layout match (sections 1-23 on both)
5. Work through the Pharmacy Clinical Trials File Maintenance form going through the pharmacy file section by section. Tick the sections on the form once they have been reviewed or actions completed. Provide comments about any issues that need following up.
6. If any of the documents currently in use in the file are not the most current version then they must be replaced with the most up to date version, the old version superseded and placed in the superseded section of the Pharmacy Clinical Trial File.
7. If any of the documents in the Pharmacy Clinical Trial File have been produced by the trust, ensure that these are in date and the current approved version is in use. If any of these documents require replacing put the new version into the relevant section of the file and supersede the old version of the document by marking with the word superseded and the date before placing it in the superseded section of the Pharmacy Clinical Trial File.
8. All original prescriptions must be kept in the pharmacy sites file unless otherwise agreed with the sponsor. If any patient prescriptions or accountability information is missing and cannot be located, write a file note for each of these instances and record these on the file note log.
If the study is carried out at a different site to York (e.g. Scarborough) the research team may have copies of the original prescriptions in the research office. These should be requested/retrieved as part of the file maintenance process. You will also need to request/retrieve any completed Pharm/F84 - Transporting IMP between York and Scarborough Sites Forms which must be kept with the patient's prescriptions in the pharmacy site file.
9. Ensure all essential correspondence is printed and included in the relevant section of the Pharmacy Clinical Trial file with the relevant documentation.
10. On completing the Pharmacy Clinical Trial File maintenance check, file the Pharmacy Clinical Trials File Maintenance form (Pharm/F82) in the Pharmacy Clinical Trials Maintenance Form folder in the clinical trials dispensary.

5 Related SOPs and Documents

Pharm/F82 Pharmacy Clinical Trials Maintenance Form

Pharm/F87 Pharmacy Closedown Form

Pharm/F84 Transporting IMP between York and Scarborough Sites Form