York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S103

Creating, reviewing and approving clinical trial accountability logs

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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Author:	Rachel Spooner
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Approved by:	Name/Position:	Poppy Cottrell-Howe, Pharmacy Clinical Trials Manager
	Date:	17th January 2024
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	17th January 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	29th May 2015		
2.0	10th July 2017		Two year review. Minor changes
3.0	11th August 2020		Change of link to R&D website. Change of author. Change of who can approve updated section about superseding old versions. Remove reference to Scarborough site.
4.0	14th February 2024	Rachel Spooner	Change of author. Minor clarifications to wording.

Contents

1 Introduction, Background and Purpose

Accurate accountability is essential for clinical trials to enable a full audit trail to be created to document the receipt, dispensing, and return/destruction of Investigational Medicinal Products (IMPs). Recording details such as the batch number and expiry date of the products issued to participants is essential for ensuring IMP recall procedures can be followed.

Master accountability logs enable an accurate inventory of IMPs at site to be recorded; whilst participant specific accountability logs capture the details of all dispensing episodes and accountability activities relating to a specific participant. Accountability logs will be closely examined during monitoring, auditing and inspection visits.

This SOP describes the procedures to be followed when creating, reviewing and approving drug accountability logs for use in a clinical trial. The design of an accountability log and its subsequent completion should allow data to be recorded in a precise, clear and unambiguous way thus ensuring standardisation and consistency.

2 Who Should Use This SOP

This procedure 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 when creating, amending, reviewing and approving accountability logs to be used for a clinical trial.

4 Procedure(s)

4.1 Creating a master or participant specific drug accountability log

If a Sponsor has not provided a master or participant specific drug accountability log (and one is required), then create an accountability log using the relevant template. The following templates are available;

- Pharm/T36 (Template master accountability log (double blind trial))
- Pharm/T37 (Template master accountability log (open label trial))
- Pharm/T38 (Template participant specific accountability log)

Amend the templates accordingly to ensure they enable all information required to be captured for the specific trial. Follow section 4.3 for guidance on reviewing, approving and managing the documents.

4.2 Amending an accountability log provided by a Sponsor

If a Sponsor has provided an accountability log, this may be used if it captures all of the information required to ensure full accountability is recorded. The following templates can be referred to for comparison;

- Pharm/T36 (Template master accountability log (double blind trial))
- Pharm/T37 (Template master accountability log (open label trial))
- Pharm/T38 (Template participant specific accountability log)

If the log needs to be amended to ensure all the necessary details are captured, then the CRA/Sponsor representative can be contacted to request that the accountability log be amended. Alternatively, create an accountability log using the above-mentioned templates.

4.3 Accountability log review, approval and management

Accountability logs produced or amended by the pharmacy clinical trials team should be reviewed and authorised prior to implementation.

A draft version of the accountability log should be created and given a version number (e.g. version 1.0). This should be sent to the deputy chief pharmacist overseeing Pharmacy clinical trials, or pharmacy clinical trials manager for review. Any comments received should be incorporated if applicable.

The final version of the accountability log should be version controlled (see example below);

Version Number:	Supercedes Number:	Written by:
Date active:	Checked and authorised by:	

Once authorised, the accountability log should be scanned and saved electronically on the X drive, ensuring old versions are superseded. If required, send a copy of the authorised accountability log to the CRA/Sponsor representative for approval, and print their approval email and file with the accountability log in the Pharmacy site file in the relevant section. Ensure the relevant members of staff have signed the master copy of the accountability log; laminate the master copy and place in the relevant section in the PSF ensuring old versions are superseded.

When processing an amendment that requires a change to the accountability log, amend the previous version using track-changes - do not replace or save over the previous version, but save it as a new document. Ensure it is checked and authorised as explained above. All previous versions of the log must be superseded both electronically and in the Pharmacy site file.

5 Related SOPs and Documents

Pharm/T36 Template master accountability log (double blind trial)

Pharm/T37 Template master accountability log (open label trial)

Pharm/T38 Template participant specific accountability log

Pharm/S79 Receipt and review of amendments in Pharmacy