

Recording and monitoring of dispensing errors in 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/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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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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	Date:	19 th 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	20 th August 2015		
2.0	21 st December 2017		Change of author and minor word changing to accommodate for altered corresponding log
3.0	5 th January 2021		Change of author, KPI data collection for errors
4.0	8 th October 2024	Rachel Spooner	Change of author – review of CT related errors to improve procedures.

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1 Introduction, Background and Purpose

It is essential that the Pharmacy clinical trials service has a process for recording dispensing errors to ensure lessons are learnt from mistakes. Therefore the purpose of this SOP is to ensure all dispensing errors are recorded and monitored so corrective action can be taken. Errors are also reported on a monthly basis in the KPI data.

2 Who Should Use This SOP

This procedure applies to all staff working within 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 if staff have made a dispensing error and followed by Pharmacists and ACTs who are performing checks on clinical trials prescriptions.

4 Procedure(s)

If a dispensing error is detected the person who detects the error must:

1. Obtain the Dispensing Error Reporting Log kept in the clinical trials room/dispensary.
2. On the next free line of the Dispensing Error Reporting Log complete the following sections as appropriate:
 - Time
 - Prescription Type
 - Error Code
 - Escaped (Yes/No)
 - Name of trial
 - Details of error
 - Dispenser's full name
 - Checker's full name
3. Identify the member of staff who has made the error and provide them with appropriate feedback - acknowledge whether or not this has been completed by stating 'Yes' or 'No' in the appropriate column. Where possible feedback should always be given immediately after an error has been detected. If you are unable to give feedback this must be documented.
4. If feedback has been given, obtain the signature from the member of staff making the error as evidence that they have received the feedback. They should sign in the 'Feedback Received' column.
5. The pharmacy clinical trials manager or delegate will take any logs with errors documented on them to the training team. Trials specific errors e.g. incomplete accountability logs etc will be reviewed by a senior member of the pharmacy clinical trials team. As the trials specific instructions or sponsor provided information may need updating or improving to reduce further errors from occurring.

Related SOPs and Documents

Pharm/F29 – Dispensing Error Reporting Log and codes

UNCONTROLLED DOCUMENT WHEN PRINTED