York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
SOP
R&D/S69

Delivery Team Requirements in the Event of an Investigational Medicinal Product Recall

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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 July 2022
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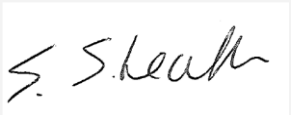
	Signature:	
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This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

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	Details of significant changes
1.0	16th August 2022	

Contents

1 Introduction, Background and Purpose

This SOP describes the actions to be taken by Delivery Teams (Nurses, Doctors and Research Practitioners) in the event of an instruction to recall a product used within a clinical trial. This SOP works alongside SOP Pharm/S58 (Actioning a Clinical Trial Investigational Medicinal Product Recall

2 Who Should Use This SOP

Principle Investigators, other members of the medical team, Nurses and Research Practitioners involved in the delivery of Clinical Trials of Investigational Medicinal Products.

3 When this SOP Should be Used

This SOP should be referred to when any member of the team is notified of a recall of a licensed medicines used in clinical trials and Investigational Medicinal Products supplied by pharmaceutical companies and/or trial sponsors

4 Procedure(s)

4.1 Drug Alerts from the MHRA

Drug Alerts from the MHRA will relate to medicines with a UK Marketing Authorisation.

4.1.1 Notification

A member of the Pharmacy team will notify the clinical trials team of the receipt of a national drug alert notification. They will provide a copy of the MHRA alert and product details, and will state the urgency of the alert and the necessary action to be taken (including recall of the affected batches).

4.1.2 Inform PI

- A member of the clinical trials team will inform the Principal Investigator (PI) for each trial affected by the drug alert and forward a photocopy of the Trial Drug Recall Summary Sheet (Pharm/F41) to the PI and Research Nurse they designate responsibility to. It is the responsibility of the Principal Investigator to contact the clinical trial patients affected by the recall as appropriate. Under normal circumstances this responsibility will be delegated to the Research Nurse.

4.1.3 Contact affected participants

- The PI should assess whether the patient needs to be reviewed for safety assessment and whether they need to be seen urgently to replace their medication with unaffected stock.

- The Research Nurse will contact patients who have been supplied with IMP from the affected batch and take action as assessed by the PI .The team should ensure that all contact details for patients on CTIMPS are stored in both paper and electronic format to ensure contact could be made in the event of and IT Failure.

- The Research Nurse will request that the patient returns their trial medication to Pharmacy as soon as possible for checking and replacement with alternative stock if available. They will arrange for new prescriptions to be completed if required. They will return their copy of the Trial Drug Recall Summary Sheet (Pharm/F41) to Pharmacy after completing section E. A photocopy of the Trial Drug Recall Summary Sheet should be filed in the Trial Master file to show evidence of the patients being contacted.

- Patients may have concerns around the safety of continuing in the trial and they should be given the opportunity to discuss their continued involvement or withdrawal with the PI. All Actions and contacts with patients should be documented in the patients notes (either on CPD or I paper notes). A copy of the Trial Drug Recall Summary Sheet should be filed in the site file.

- In the event that a patient is uncontactable this should be recorded in the notes and repeat attempts made until successful contact is made.

4.2 Out of Hours

If the on call pharmacist receives an MHRA Drug alert, they will follow pharmacy procedures for responding to a MHRA drug alert. Pharm/S58 - Actioning a Clinical Trial IMP Recall Version 5.0 Page 6 of 7 In the case of the drug being an Investigational Medicinal Product, this alert should be given to a member of the clinical trials team to action as soon as possible the next working day as no IMP will be dispensed from Pharmacy out of hours. The clinical trials team will then follow the 'during normal working hours' process as described in section 4.1 above. The same process applies to receipt of an IMP recall initiated by the sponsor of a clinical trial out of hours. The only exception to the above would be a drug alert or recall for studies where IMP's are stored outside the Pharmacy. The details of these can be found in each trial pharmacy site file. In these cases, the Principal Investigator of the study should be contacted immediately by the on call Pharmacist and the process for 'during normal working hours' followed as detailed above, as the IMP is at risk of being dispensed.

4.3 Testing the IMP Recall process

- This should be conducted by a member of the Pharmacy clinical trials team and a Research Nurse/Principal Investigator from the relevant speciality.

- Testing of this process should be conducted on a yearly basis.

- The process should be tested on two trials (one trial from the York site and one from the Scarborough site).

- The trials tested should be selected from a different speciality each year and this should be documented on the IMP Recall Test Form – Pharm/F49. Of the two trials selected for testing, one should be commercially sponsored and one non-commercially sponsored where possible.

- If an actual MHRA drug alert or IMP recall is actioned during the year, the requirement for testing will be reduced accordingly.

- Follow the procedure detailed below and record actions on the IMP Recall Test Form (Pharm/F49):

1. Pharmacy to select a trial that is open to recruitment.

2. Locate the accountability log and select a batch number of the medication listed (which has been dispensed).

3. Using the batch number and medication selected, identify the patients that have received this batch.

4. Pharmacy to complete the Trial Drug Recall Summary Sheet (Pharm/F41) as required. Write 'TEST' in the recall details section of the form in capital letters. Attach this form to the IMP Recall Test Form (Pharm/F49) after the process has been completed.

5. Pharmacy to contact the Research Nurse to inform them that you are performing a IMP recall test and ask them to confirm that they would be able to contact all patients who have received the IMP. IT IS NOT NECESSARY TO CONTACT THE ACTUAL PATIENTS. Confirm if they would be able to get replacement prescriptions so the patient can receive new medication

6. If applicable contact the sponsor to confirm with them that if necessary they could get medication to us within a short space of time.

7. The Research Nurse should complete section E once all the patient contact numbers have been obtained/verified as present.

8. The process should be reviewed by the Pharmacy clinical trials team and the Research Nurse/Principal Investigator after the test.

9. The outcome of the test and any further actions should be agreed and documented on the IMP Recall Test Form (Pharm/F49).

10. The IMP Recall Test Form (Pharm/F49) should be filed in the relevant trial pharmacy site file provide evidence of compliance with this SOP.

5 Related SOPs and Documents

Pharm/F41 Trial Drug Recall Summary Sheet
Pharm/S59 Quarantine of IMP
Pharm/S58 Actioning a Clinical Trial Investigational Medicinal Product Recall
Pharm/F49 IMP Recall Test Form