STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_019

SOP Title: Accuracy checking of clinical trial medication

Role	Name	Signature	Date
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SOP Review Date	**June 2020**		

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	27-May-2016	Initial Version	09-Feb-2016
2	1-June-2018	Reviewed to ensure content still current. Removed references to doctors final checking	05-Apr-2018

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1. PURPOSE AND CONTEXT

1.1. To describe the procedures for performing accuracy checking of dispensed clinical trial medication and drug accountability records

1.2. Covers the process of accuracy checking dispensed clinical trial medication and checking records of drug accountability

2. DEFINITIONS

IxRS – Integrated phone and web drug management system.

3. PROCEDURE and RESPONSIBILITIES

3.1 Accuracy checking of dispensed clinical trial medication

3.1.1 Locate the relevant pharmacy site file and refer to the trial specific pharmacy instructions. These list the specific issues that require particular attention during accuracy checking

3.1.2 Perform a cross check against a unique trial identifier (e.g. trial name, R&D number, EudraCT number) to ensure that the trial specific pharmacy instructions selected are correct for the prescription.

3.1.3 The original prescription is needed before any medication can be released from pharmacy. Ensure that the identity of the prescriber has been checked against the trial delegation log prior to dispensing.

3.1.4 Follow the procedures as described in the trial specific pharmacy instructions. Check the prescription against each item and each label (both sponsor and locally generated labels as appropriate). In general, these check include, as appropriate:

- Confirm the correct clinical trial medication has been selected, including, as applicable:
  - Medication details (e.g. name, strength, form)
  - Unique trial identifier (e.g. EudracT number, protocol number)
  - Unique pack number (e.g. Kit ID, pack ID, bottle no.) against those listed on the prescription or IxRS confirmation fax/email.
- Confirm the correct quantity has been dispensed.
- Confirm that the expiry date of the dispensed clinical trial medication is valid for the treatment duration.

- Confirm any required fields have been completed on the sponsor label, including, as applicable:
  - Name of investigator
  - Participant trial number / randomisation number
  - Visit number
  - Directions of use
- Confirm any locally generated labels are correct, including, as applicable:
  - Medication details (e.g. name, strength, form)
  - Participant initials/name
  - Directions of use
- Ensure any locally generated dispensing labels do not obscure the sponsor label.
- For multi-language booklet label, ensure the English page is flagged opened.
- Any additional points as specified in the trial specific pharmacy instructions.

3.1.5 Where errors are identified, liaise with the relevant staff to rectify the error.

3.1.6 Perform quality check of end product. If the product is defective, e.g. particles in infusion bags, broken tablets, precipitation in oral suspension, contact the clinical trial pharmacy team immediately, and:

- Place the defective product into quarantine
- Contact the research team and/or participant to explain the situation
- Contact the sponsor and proceed as instructed

3.1.7 Once satisfied, sign and date prescription **in BLACK ink** as a record of accuracy checking.

3.2 Checking drug accountability records

3.2.1 Confirm that the necessary drug accountability records are completed fully **in BLACK ink** and accurately, and records to check may include:

- Participant details
- Batch number
- Expiry date
- Unique pack number (e.g. Kit ID, pack ID, bottle no.)
- Quantity dispensed
- Tear-off labels
- Any additional points as specified in the trial specific pharmacy instructions

3.2.2 Where errors are identified, liaise with the relevant staff to rectify the error.

3.2.3 Once satisfied, sign and date accountability records as a record **in BLACK ink** of accuracy checking.

3.2.4 File the accountability records in the relevant section of the pharmacy site file.

3.2.5 Return the pharmacy site file to the appropriate location.

3.3 Packaging

3.3.1 Pack the dispensed clinical trial medication in accordance to the trial specific pharmacy instructions.

3.3.2 If required, mark the bag with the correct participant details.

3.3.3 Locate and store clinical trial medication in the storage area as required for the product, ensuring the area has been approved as a suitable storage area for clinical trial medication, or hand out the drug to the patient / study nurse with appropriate counselling or return to ward/department or research nurse as appropriate to the specific study.

	Responsibility	Undertaken by	Activity
1	Chief pharmacist	Clinical trials pharmacist	Ensure procedures are in place.
2	Clinical trials pharmacist	Pharmacist and Site team	Accuracy checking may be undertaken by pharmacists, pharmacy technicians or nurses only, as per the delegation log.
3			

4. SUPPORTING MATERIAL and ATTACHMENTS

- Pharmacy Signature and training Log (Form 01)
- CP/R&D_007 SOP : Dispensing of clinical trial medication

5. TRAINING

The specific Clinical Trials Details for each individual trial must have been read. These include the following information:

- Study Summary
- Contact details for research staff for that study.
- Code Break instructions and location.
- Storage conditions of the drugs.
- Dispensing instructions
- How to complete the drug accountability forms (will be included in dispensing instructions)
- Directions for additional labelling
- Returns instructions
- Complete pharmacy signature and training log

6. REFERENCES