STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_007

SOP Title: Dispensing of clinical trial medication

Role	Name	Signature	Date
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SOP Review Date	**June 2020**		Effective date stamp

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	01-Nov-2012	Initial Version	01-Nov-2012
2	27-May-2016	Template updated to include additional sections and further guidance in preparation of SOPs	12-Jan-16
3	1-June-2018	Reviewed to ensure content still current. Removed reference to doctor dispensing	05-Apr-2018

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1 PURPOSE AND CONTEXT

1.1 To describe the procedures for dispensing clinical trial medication and completing drug accountability records.
1.2 Covers the process of dispensing clinical trial medication and completing records of drug accountability

2 DEFINITIONS

IxRS – Integrated phone and web drug management system

3 PROCEDURE and RESPONSIBILITES.

3.1 Locating the correct trial specific pharmacy instructions

3.1.1 Clinical Trial Prescriptions will be received by the staff in the pharmacy room and will contain the trial name or number to identify the trial. The original prescription is needed before any medication can be released from pharmacy.
3.1.2 Identify the correct trial from this. Locate the study pharmacy file and trial medication in the pharmacy room.
3.1.3 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 the correct procedures against which to dispense the prescription.
3.1.4 Follow the specific dispensing instructions located in the appropriate section of the study working documents file and as detailed below.

3.2 Dispensary based clinical trial medication

3.2.1 Ensure that the identity of the prescriber has been checked against the trial delegation log prior to dispensing.
3.2.2 If necessary, calculate the required quantity for each requested clinical trial medication.
3.2.3 Collect the required quantity of each clinical trial medication. Check the following (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, vial no.) against those listed on the prescription and/or IxRS confirmation fax/email.

3.2.4 Confirm that the expiry date of the clinical trial medication is valid for the treatment duration.

3.2.5 Apply local dispensing labels as applicable ensuring the content of the label is correct, including:

- Medication details (e.g. name, strength, form)
- Participant initials/name
- Directions of use

3.2.6 Attach any locally generated dispensing labels to each pack of clinical trial medication, ensuring these labels do not obscure the sponsor label.

3.2.7 Complete any required fields on the sponsor label, including, as applicable:

- Name of investigator
- Participant trial number / randomisation number
- Visit number
- Directions of use

3.2.8 For multi-language booklet label, ensure the English page is flagged opened.

3.2.9 Carry out any additional points as specified in the trial specific pharmacy instructions.

3.2.10 Sign and date prescription as a record of dispensing

3.3 Trials requiring pharmacy to access treatment allocation on IxRS

3.3.1 For confirmation of clinical trial medication unique pack numbers where pharmacy is blinded (e.g. Kit ID, pack ID, bottle no, vial no):

- Prior to dispensing, those authorised to access IxRS must generate and print off treatment allocation confirmations.

3.3.2 For clinical trial medication treatment allocation where pharmacy is unblinded (knowledge of active vs. placebo), and other research staff are blinded:

- Those authorised to access IxRS must follow the trial specific pharmacy instructions to generate and print off treatment allocation confirmation.

3.4 Completing drug accountability records

3.4.1 Locate the correct accountability log(s) from the pharmacy site file. This may include participant specific accountability log and/or product specific cumulative accountability log.

3.4.2 Complete the accountability log(s) **in BLACK ink**, including, as applicable:

- Participant details
- Investigator details
- Medication details
- Batch number
- Expiry date
- Unique pack number (e.g. Kit ID, pack ID, bottle no.)
- Quantity dispensed
- Affix tear-off labels

- Any additional points as specified in the trial specific pharmacy instructions

3.4.3 Perform a two way stock level check (actual vs. log). If incorrect, refer to the clinical trial pharmacist/technician.

3.4.4 Sign and date accountability records as a record of dispensing.

3.4.5 After dispensing and completing all drug accountability documents the prescription must be signed and endorsed by the dispenser – **in BLACK ink**

3.4.6 Once the above steps have been completed, follow the trial specific pharmacy procedures for Accuracy checking of clinical trial medication SOP. (CP/R&D_019)

3.4.7 Once the accuracy check is complete file the prescription, plus any photocopies/faxes/scans of prescription in the correct section of the specific working documents file.

	Responsibility	Undertaken by	Activity
1	Chief Pharmacist	Clinical Trials Pharmacist	Ensure procedures are in place
2	Prescribers	Prescribers	Completing and signing prescriptions
3	Clinical trials pharmacist	Pharmacists, and authorised members of the site team.	Dispensing may be undertaken by pharmacists or other members of the site team authorised to do so. **Note that doctors are not permitted to dispense in line with wider Trust policy.**

4 SUPPORTING MATERIAL and ATTACHMENTS

- Pharmacy Signature and Training log (Form 01)
- CP/R&D_019 : Accuracy checking of clinical trial prescriptions SOP

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

6 REFERENCES