SOP Number: CP R&D_015

SOP Title: Relabelling of Investigational Medicinal Product

	NAME	TITLE	SIGNATURE	DATE
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Review History

Effective Date	Review Undertaken/Significant Changes	Date Approved
	Initial Version	

STANDARD OPERATING PROCEDURE (SOP)

CP R&D_015 Relabelling of Investigational Medicinal Product

VERSION CONTROL

Version No	Valid From	Valid To	Approved By	Date Approved
1.0			David Jones Chief Pharmacist	

1. PURPOSE AND CONTEXT

Provide guidance on the actions to be taken to relabel investigational medicinal product (IMP) in the event of there being an extension to the expiry date of the IMP currently held at site.

2. DEFINITIONS

QP – Qualified Person responsible for certifying the quality of the batch of IMP prior to release for use in a clinical trial

3. PROCEDURE

	Responsibility	Undertaken by	Activity
1	Chief Pharmacist	Clinical Trials Pharmacist	Oversee relabelling process
2	Clinical Trials Pharmacist	Research and pharmacy staff	Relabelling

3.1 General Information

- Documentation must be available to confirm that the expiry date can be extended. This will usually be in the form of a certificate signed by the Qualified Person (QP) confirming that they have reviewed all paperwork and are satisfied with the new expiry date.
- Two people should be involved in the relabelling process to provide a check that the work has been carried out correctly.
- The sponsor may provide labels showing the batch number and new expiry date, documents to be completed and a standard operating procedure for the relabelling process. Where this is provided it should be followed.
- Where the sponsor does not provide an SOP then the trust SOP should be followed.

- If not provided by the sponsor the clinical trials pharmacist will provide a document on which to record the relabelling process. This document will include:
    - Name of the trial
    - Protocol number
    - Number and type of containers being relabelled or where the treatment kits have individual numbers then these will be recorded
    - Where a container eg bottle or blister pack is packed inside another container this will be recorded
    - Batch number and old expiry date
    - New expiry date
    - The name and signature of the persons carrying out the relabelling process
    - The date the process was carried out

3.2 Relabelling Procedure

- Clear a working area.
- Gather together the documentation confirming that the relabelling may take place, the paperwork for recording the process and the IMP to be relabelled.
- Deal with one kit/container at a time.
- Check that the IMP is included in the batch to be relabelled.
- Add the label provided if supplied by the sponsor.
- If labels are not provided draw a line through the old expiry date write the new one on the label and initial and date the change being careful not to obliterate any other information.
- Complete the relabelling document.
- A second person should then check the relabelling and sign and date the relabelling document if appropriate.
- Complete the process for each container before proceeding to the next one.
- Once the process has been completed for all the IMP to be relabelled follow the instructions from the sponsor. This may be that a copy of all the paperwork is faxed or posted to the sponsor.
- File a copy of the paperwork in the clinical trial pharmacy file.

4. SUPPORTING MATERIAL

CP 41 Medicines Control, Administration and Prescribing Policy