York Foundation Trust R&D Unit
SOP
Pharm/S105

Production & Control of Clinical Trials Labels

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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.northyorksresearch.nhs.uk/sops.html and/or Q-Pulse

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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	Details of significant changes
1.0	27th July 2015	
2.0	31st July 2017	Two year review

Contents

1 Introduction, Background and Purpose

The labelling requirements of Investigational Medicinal Products used in clinical trials are governed by the Medicines for Human Use (Clinical Trials) Regulations 2004. Depending on the nature of the Investigational Medicinal Product in use in the trial, the requirements of the Medicines for Human Use (Marketing Authorisations) Regulations 1994 and the requirements of Annex 13 of Good Manufacturing Practice will also apply.

This SOP describes:-

- The procedure for producing a dispensing label for an Investigational Medicinal Product (IMP) or Non-Investigational Medicinal Product (NIMP).
- The procedure for recording the creation of a master dispensing label or amendment of a master dispensing label.
- The procedure for authorisation of the final label and to ensure that the master label meets the requirements of Annex 13 of Good Manufacturing Practice (GMP).
- The procedure for printing batches of authorised labels and accountability of the printed labels.

2 Who Should Use This SOP

This procedure should be followed by all members of the Clinical Trials Team within the Pharmacy Departments at York Teaching Hospital NHS Foundation Trust and Pharmacists involved in the clinical or accuracy checking of a clinical trial prescription and authorisation of the Master Labels.

3 When this SOP Should be Used

This SOP should be used when creating and approving a master label, printing and approval of label batches and during the dispensing and accuracy checking of a clinical trial prescription.

4 Procedure(s)

All labels created by the Pharmacy Clinical Trials Team for labelling an IMP/ NIMP for use within a clinical trial should comply with the regulations as detailed in the introduction section of this SOP. Although the regulations refer to the use of the IMP and its Marketing Authorisation, the Trust will use a label template which covers all of the requirements of the regulations.

4.1 Labelling requirements for an IMP (regardless of Marketing Authorisation)

IMPs should be labelled according to the requirements for a dispensed medicine (Medicines for Human Use Regulations 1994) and Annex 13 of Good Manufacturing Practice.

All IMPs (where permissible) will be labelled with additional approved labels containing the above information. Care should be taken to ensure that when these labels are placed on original container/packaging the original label is still visible and not obscured (this can be done by flagging the labels with clear flags).

4.2 Creating Labels

Create labels using the Authorised Clinical Trial Label Templates (Pharm/F40) as follows:

1. To create labels for use in a clinical trial, open the Label Template which can be found on the X drive.

2. Use the 'save as' option to save each label template in the relevant trial folder (in the labels folder) and rename it with the study title, drug name/ dose level and version number (version 1.0 for a newly created label).

3. Amend the label template to relate to the relevant IMP, study and protocol.

4. Save these changes.

5. Repeat the above process to create further labels if necessary.

4.3 How to check and authorise a new label

All labels produced by Pharmacy for use in a clinical trial should be checked and authorised by a Pharmacist before use, as follows:-

1. Print the completed label.

2. Obtain a blank Master Label Form (Pharm/F33) from the Approved Label File in the Clinical Trials Office/Dispensary.

3. Apply the label to the allotted space on the form.

4. Complete the top part of the form with the relevant information.

5. Complete the prepared by section of the form.

6. The label should be approved by a Clinical Trials Pharmacist and checked against the Approved Master Label Template (located in the Approved Master Label File).

7. Once the label has been approved the person who approved the label must complete the checked and authorised section of the form and sign over one

corner of the label on to the form (care should be taken as not to sign over any printed information).

8. This form is then filed as the Master copy in the Approved Label file (the approved/superceded label forms are then transferred to the study pharmacy file as part of the close down process).

4.4 How to print authorised labels ready for use

1. Labels will normally be printed in batches. The quantity printed will depend on anticipated usage.

2. Select the appropriate label from the study file on the X drive.

3. Check the label against the current approved master label (located in the Approved Label Folder).

4. Print the required number of labels.

5. Complete the label preparation part of form Pharm/F104 (Label Accountability Form) and record the label identification numbers on the form and on the back of the label (this is the R&D reference and then sequential numbers, where there may be multiple labels for a study use an identification letter after the R&D reference e.g. SNE2422a001 & SNE2422b001).

6. Affix the first label from the batch to the form in the designated area and complete the accountability record for this label.

4.5 Approval of a batch of labels

To ensure that the current version of label has been used and that the label is fit for use, a Quality Control check must be completed before any labels from a printed batch can be used.

1. A Senior Pharmacy Technician or a Clinical Trials Pharmacist/Manager should complete the Quality Control check on the Label Accountability Form (Pharm/F104) for each label and then approve the labels for use, by checking each label against the approved master label. The label identification numbers will also need to be checked before approval.

2. For each batch of labels printed a record is kept of all labels printed and their identification numbers, this form (Pharm/F105) is located on the reverse side of the approved master label wallet and should be completed at the time of printing and checking.

3. Once the batch of labels has been checked the checker should then sign the label checked by box on each label approved.

4. The checked labels and the corresponding accountability paperwork should then be filed in the relevant study pharmacy file (in the label section).

5. If any of the labels are incorrect or not fit for purpose, the quantity will need to be recorded in the 'number of labels rejected' section and the labels are then destroyed. The person destroying the labels will need to sign the 'rejected labels destroyed by' section.

4.6 Label reconciliation

After each batch of labels have been used the reconciliation of the labels must be recorded on the bottom section of the Label Accountability Form (Pharm/F104).
This form can then be filed in the superseded section of the pharmacy site file.

4.7 Label amendments

If at any time during the study the label needs to be amended complete the process as follows:-

1. Amend the word label and save as the next version number.

2. Complete the form Pharm/F34 (Master Label Amendment Form), ensuring that the new version number is documented.

3. The Clinical Trials Pharmacist will need to approved the new version and sign the Master Label Amendment Form (Pharm/F34) and sign across both new label and form.

4. Once the label is approved, reconcile and remove any remaining labels of the old version that were in use. Supersede the old Master Label. This can then be filed in the superseded section of the Trial Pharmacy File.

5. Complete the label reconciliation part of the Label Accountability Form (Pharm/F104) to reflect this and destroy the labels.

6. The new authorised label is then stored in the Approved Master Label File.

5 Related SOPs and Documents

Pharm/F33	Master Label Form
Pharm/F34	Master Label Amendment Form
Pharm/F40	Clinical Trial Label Templates
Pharm/F104	Label Accountability Form
Pharm/F105	Record of Labels Printed

Annex 13, Good Manufacturing Practice