

## 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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.research.yorkhospitals.nhs.uk/sops-and-guidance-/](http://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/) 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.

<b>Version</b>	<b>Date Implemented</b>	<b>Details of significant changes</b>
1.0	27 <sup>th</sup> July 2015	
2.0	31 <sup>st</sup> July 2017	Two year review
3.0	29 <sup>th</sup> November 2019	Change of author. Change of link to R&D website. Changes to creating labels, authorising new labels, approval of batches and label amendments to reflect current procedure. Removal of reference to Pharm/F40

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## **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

## **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 as follows:

1. To create labels for use in a clinical trial, open the Clinical Trials Label Template which can be found within the Admin Labels file on the X:Drive.
2. Use the 'save as' option to save the label template in the relevant trial folder (in the labels folder- draft labels should be saved in a sub folder named drafts). The template should be renamed with the Label ID (This is the R&D reference followed by an identification letter e.g. A) and the version number (version 1.0 for newly created labels). The drug name/dose level can also be added to the file name for ease.
3. Amend the label template to relate to the relevant IMP, study and protocol. The information you require on the label will depend on the individual study, hence the template can be added to or altered as required.
4. Save these changes.
5. Repeat the above process to create further labels if necessary. The identification letter should be changed alphabetically for each new label created (e.g. A for the first label created, B for the second label created and so on).

#### **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. Print a blank Master Label Form (Pharm/F33) from the R&D website
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.

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 section 3 of the relevant study's Pharmacy Site File.
9. The approved labels electronic file can be moved out of drafts and into the current labels folder in the relevant trial folder on the X:Drive.

#### **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 label section of the relevant study's pharmacy site file).
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.
7. Complete a new line on Pharm/F105 (Record of labels printed) which is kept with the Master Label to reflect the new batch of labels created. If this is the first batch of labels or the form is full then a new form can be printed from the R&D website and the top section filled in with the study and label details.
8. The batch is now ready for a quality control check and approval.

#### **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 different member of the Pharmacy Clinical Trials Team to who printed the batch of labels should complete the Quality Control check on the Label Accountability Form (Pharm/F104) and then approve the labels for use, by checking each label against the approved master label and ensuring the labels are readable. 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 pharmacy site 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 has 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. The labels backing and any reconciled 'wasted' labels can be put into confidential waste.

#### **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 label word document 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 approve the new version and sign the Master Label Amendment Form (Pharm/F34), also signing 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. Complete the label reconciliation part of the Label Accountability Form (Pharm/F104) to reflect this and destroy the labels.
5. Supersede the old Master Label, filing the document in the superseded section of the Pharmacy Site File.

6. The new authorised Master Label is then stored in study's label section of the Pharmacy Site File.
7. Electronically the newest authorised label can be moved into the current labels and old versions moved into superseded within the relevant study's folder on the X:Drive.

## 5 Related SOPs and Documents

Pharm/F33	Master Label Form
Pharm/F34	Master Label Amendment Form
Pharm/F104	Label Accountability Form
Pharm/F105	Record of Labels Printed
Annex 13, Good Manufacturing Practice	