 

**<< SHORT TITLE>>**

**<< Full Title>>**

**Pharmacy Manual**

|  |  |
| --- | --- |
| Chief Investigator: | <<INSERT>> |
| Sponsor: | <<INSERT>> |
| Sponsor Reference: | <<INSERT Reda number >> |
| EudraCT Number: | <<INSERT>> |

*Property of Queen Mary University of London/Barts Health NHS Trust
 May not be used, divulged, published or otherwise disclosed
without the consent of the Chief investigator*

|  |  |  |
| --- | --- | --- |
| Prepared by:(Print & sign) |  (Clinical Trial Coordinator) | Date: |
| Approved by:(Print & sign) |  (Senior Research Pharmacist) | Date: |

**Contents**

[Abbreviations 3](#_Toc333501450)

[Contacts 3](#_Toc333501451)

[1. Scope of Pharmacy Manual 4](#_Toc333501452)

[2. Trial Investigational Medicinal Products (IMP’s) 4](#_Toc333501453)

[3. Ordering and Supply 4](#_Toc333501454)

[4. Receipt of IMP’s 4](#_Toc333501457)

[5. Storage of IMP’s 5](#_Toc333501460)

[6. Randomisation Procedures 5](#_Toc333501463)

[7. Prescribing IMPs 5](#_Toc333501464)

[8. Dispensing IMP’s 6](#_Toc333501465)

[9. Administration of IMP’s 8](#_Toc333501468)

[10. Unblinding Procedures 8](#_Toc333501471)

[11. Returns and Reconciliation 8](#_Toc333501472)

[12. IMP Destruction 9](#_Toc333501475)

[13. Protocol Amendments 9](#_Toc333501478)

[14. Monitoring 9](#_Toc333501478)

[15. Archiving 9](#_Toc333501478)

# Abbreviations

|  |  |
| --- | --- |
| BD | Bis in Die *(Twice daily)* |
| OD | Omni Dei *(Once a day)* |
| CRF | Case Report Forms |
| IMP | Investigational Medicinal Product |
| XXX | IMP (also referred to as XXXXXXl) |
| IM | Intramuscular |
| QP | Qualified Person |
| SC | Subcutaneous  |
| MHRA | Medicines and Healthcare Products Regulatory Agency |
|  |  |
|  | Check and insert as applicable |
|  |  |
|  |  |
|  |  |

#

# Contacts

|  |  |
| --- | --- |
| **XXXXXXX Trial Coordinator:**Inserts name & addressTel: Fax:Email:  | **XXXXXXXXX Trial Pharmacist:**Inserts name & addressTel: Fax:Email:  |
| **IMP Supplier:**Inserts name & addressTel: Fax:Email:  | **IMP IMPORTER /Distributor/QP release:**Inserts name & addressTel: Fax:Email:  |

# Scope of Pharmacy Manual

This Pharmacy Manual is applicable to the Principal Investigator, Lead Pharmacist and any other member of staff having responsibilities within the <<INSERT SHORT NAME>>trial for ordering, receipt, storage, handling, dispensing and / or destruction of any of the investigational medicinal products (IMP’s) used within the trial. Only subjects enrolled in the study may receive IMP, in accordance with all applicable regulatory requirements. Only authorized site staff may supply or administer investigational product.

# Trial IMP

Within the <<INSERT SHORT NAME>>trial the following are classed as IMP:

* <<Insert IMP name>>– XX mg tablets
* <<Insert IMP name>>– XX mg injection

# Ordering and Supply

## **3.1 <<INSERT IMP NAME>>**

<<INSERT IMP NAME>> will be provided free of charge to hospital sites for use in patients being treated within this trial.

<<INSERT IMP NAME>> will be supplied from <<Insert Manufacturer name>>, via <<Insert distributer name>> Clinical Services.

An initial supply of <<INSERT IMP NAME>> will be shipped to sites following confirmation of all necessary regulatory approvals. The initial supply will consist of **xx bottles** with xx tablets per bottle.

Subsequent supplies need to be requested by emailing or faxing the <<INSERT DISTRIBUTER NAME>> shipping request form (found in the pharmacy site file) to the <<INSERT SHORT NAME>>clinical trial team.

Email:

Fax:

**5 working days** should be allowed for delivery of <<INSERT IMP NAME>>.

<<INSERT IMP NAME>> will be shipped and stored at ambient temperature at less than **XX °C**.

## **3.2 <<Insert IMP name>>**

Generic hospital supplies are allowed to be used for <<Insert IMP 3 name>>. Specific brands need not be used. Each hospital site is responsible for the ordering and ensuring sufficient supplies of this IMP. If supply problems are encountered with any of the IMPs, sites should inform the <<INSERT SHORT NAME>>Trial Coordinator at the earliest opportunity.

# Receipt of IMP’s

## **4.1 <<INSERT IMP NAME>>**

Once an order has been received, please complete section 2 of the drug order form to confirm supplies have been received and are in acceptable condition. Please fax this completed drug order form to the <<INSERT SHORT NAME>> clinical trial team (fax number:).

Ordering and delivery records for <<INSERT IMP NAME>> must be retained in the Pharmacy Site File.

Drug accountability will be recorded on the study-specific IMP accountability log. Shipments of IMP received at the pharmacy will be logged onto the accountability log. The accountability log will be kept in the study-specific Pharmacy File.

Use of the sites own accountability logs are permitted as long as all relevant information is recorded. Sites will be requested to provide a template of their accountability logs to the <<INSERT SHORT NAME>>Trial Coordinator for approval prior to use.

Qualified Person release certificates will be supplied with each delivery of <<INSERT IMP NAME>> shipped to site. These must be stored in the pharmacy file.

## **4.2 <<Insert IMP name>>**

No specific trial records are required to be kept for the receipt of <<Insert IMP 2 name>>used within this trial. If the decision is made at a specific hospital site to order IMP supplies for specific use within the trial that are to be ‘ring-fenced’, please ensure that full details of the procedure for ordering, accountability, receipt and storage are noted in the Pharmacy File.

# Storage of IMP’s

Pharmacists should ensure that the location of temperature logs for the area(s) where the IMP’s are stored is referenced in the Pharmacy Site File. Any deviations in temperature must be communicated immediately to the Coordinating Centre. A daily minimum and maximum temperature must be recorded. These logs must be available for review during monitoring visits. If a temperature excursion occurs, please quarantine stock until advised by Clinical Trial Coordinator if the stock is suitable to use.

## **5.1 <<INSERT IMP NAME>>**

<<INSERT IMP NAME>> should be stored at less than XX °C.

## **5.2 <<Insert IMP name>>**

<<Insert IMP 2 name>> should be stored under appropriate conditions as specified by the manufacturer’s storage instructions.

# Randomisation Procedures

The research team will use the ranomisation form to randomise patients. On receipt of the randomisation form, the co-ordinating centre will assign the patient treatment (Arm A: treatment with <<INSERT IMP NAME>> and <<Insert IMP 2 name>> followed by surgery or Arm B alone) and issue a unique trial identifier number (eg. XXXX); this should be used to identify the patient on all subsequent correspondence.

The co-ordinating site will provide Pharmacy with the patient randomisation details.

# Prescribing IMPs

The <<INSERT SHORT NAME>> Trial Prescription template is provided in the Pharmacy File; however site specific prescriptions are permitted to be used in this trial after approval from the senior research pharmacist. If using a site specific prescription, these must contain the following trial specific information and must be signed by a member of the trial team who is authorised to prescribe trial medication:

* Trial Name: <<INSERT SHORT NAME>>
* ‘For Clinical Trial Use’
* Trial Number for the patient
* Specific details of the trial medication required according to the protocol.

# Dispensing IMP’s

## **8.1 <<INSERT IMP NAME>>**

1. All dispensing episodes for <<INSERT IMP NAME>> must be recorded on the study-specific accountability logs found in the Pharmacy File. Use of sites own accountability logs are permitted as long as all relevant information is recorded. Sites will be requested to email their accountability logs to us for approval prior to use.
2. <<INSERT IMP NAME>> will be dispensed on day 1 of each 28 day cycle for six months. Patients must be counselled to return their medication at each visit.
3. Quantities of <<INSERT IMP NAME>> must be dispensed in accordance with the table below:

|  |  |  |  |
| --- | --- | --- | --- |
| **Dose level** | **Dose** | **No. of bottles (XxXXXmg tablets) for one cycle** | **Anticipated number of tablets to be returned** |
| Starting Dose(XXmg BD) | xxmg AMxxmg PM | x | x |
| 1st Dose Reduction | xxmg AMxmg PM | x | x |
| 2nd Dose Reduction | xxmg AMxmg PM | x | x |

1. Only whole bottles of each <<INSERT IMP NAME>> should be dispensed, do not open the bottle to add or remove tablets.
2. Dispensing records and clinical trial prescriptions for the <<INSERT SHORT NAME>> trial must be filed in the pharmacy file. They should be easily accessible in the event of regulatory inspection or product recall.
3. In line with sites local policy, additional labels are permitted. All IMP’s provided will be labeled in line with Annex 13.

<<INSERT IMP NAME>> **labelled in accordance with Annex. 13**

**NOTE: The below is an example annex 13 compliant label. If using this template, please ensure that it is submitted to the MHRA as part of the regulatory application for the trial. If an alternative template has been submitted to the MHRA, please insert it into this document and remove the below.**

## ***<<INSERT SHORT NAME>> (EudraCT NoXXX)***

XX x <<INSERT IMP NAME>> Tablets XXmg

Take ...... tablets in the morning and ...... tablets in the evening, as directed

FOR ORAL USE

Expiry date dd/mm/yyyy Batch Number XXXXXX

Patient Initials ……………... Patient Study Number…………..

Date of Dispensing............................ Visit...................................

Investigators Name………….. Site.....................

Store in original package, do not store above XXXoC, do not freeze.

FOR CLINICAL TRIAL USE ONLY

KEEP OUT OF THE REACH OF CHILDREN

Queen Mary University of London /Barts Health NHS Trust

Joint Research Management Office

QM Innovation Building, 5 Walden Street, London, E1 2EF

 Tel: 020 7882 7351

## **8.2 <<Insert IMP name>>**

1. All dispensing episodes for <<Insert IMP name>> must be recorded on the study-specific accountability logs found in the Pharmacy File. Use of sites own accountability logs are permitted as long as all relevant information is recorded. Sites will be requested to fax their accountability logs to us for approval.
2. Please ensure that dispensing records and clinical trial prescriptions for the <<INSERT SHORT NAME>>trial are filed in the pharmacy file. They should be easily accessible in case of regulatory inspection or product recall.
3. Reconstitution - <<Insert IMP name>> should be reconstituted in accordance to the current SMPC or IB.
4. <<Insert IMP name>> will be labelled by the trial pharmacist at site at the point of dispensing. All IMP’s must be labelled in accordance with Annex. 13. Dispensing labels can be provided to site upon request

**<<Insert IMP name>> labelled in accordance with Annex. 13**

**NOTE: The below is an example annex 13 compliant label. If using this template, please ensure that it is submitted to the MHRA as part of the regulatory application for the trial. If an alternative template has been submitted to the MHRA, please insert it into this document and remove the below.**

## ***<<INSERT SHORT NAME>> (EudraCT NoXXX)***

XX x <<INSERT IMP NAME>> Tablets XXmg

Take ...... tablets in the morning and ...... tablets in the evening, as directed

FOR ORAL USE

Expiry date dd/mm/yyyy Batch Number XXXXXX

Patient Initials ……………... Patient Study Number…………..

Date of Dispensing............................ Visit...................................

Investigators Name………….. Site.....................

Store in original package, do not store above XXXoC, do not freeze.

FOR CLINICAL TRIAL USE ONLY

KEEP OUT OF THE REACH OF CHILDREN

Queen Mary University of London /Barts Health NHS Trust

Joint Research Management Office

QM Innovation Building, 5 Walden Street, London, E1 2EF

 Tel: 020 7882 7351

Commercial supplies of <<Insert IMP 2 name>>will be used in this study. The batch number, storage conditions and expiry date will be present on the original manufacturers packaging and are therefore not included above.

# Administration of IMP’s

## **9.1 <<INSERT IMP NAME>>**

At every clinic visit, patients should be counselled as to how to take <<INSERT IMP NAME>> and will be provided with the <<INSERT SHORT NAME>>patient diary by the research nurse to document their administration.

## **9.2 <<Insert IMP name>>**

<<Insert IMP name>> can be administered subcutaneously or by intramuscular injection, as per site’s local procedures.

The administration of <<Insert IMP name>>should be documented in the Case Report File (CRF).

# Unblinding Procedures

Not applicable for this study as there are no blinded IMP’s.

OR: Details of the unblinding procedure are described in the <<study title>>

# Returns and Reconciliation

## **11.1 <<INSERT IMP NAME>>**

All patients will be instructed to return all <<INSERT IMP NAME>> bottles (both empty and partially used). The number of tablets dispensed and returned is to be documented on the accountability log, and reconciled by site personnel. Unused <<INSERT IMP NAME>> can be stored up to XX°C until inventoried by the <<INSERT SHORT NAME>> Trial Coordinator.

All bottles of returned <<INSERT IMP NAME>> (including empty bottles) will be retained by the site personnel until the study monitor has verified the tablet count.

## **<<Insert IMP name>>**

<<Insert IMP name>> is administered by Intramuscular (IM) or Subcutaneous (SC) injection in clinic. In case of any unused vials, these will be returned to pharmacy and logged.

# 12. IMP Destruction

## **12.1 <<INSERT IMP NAME>>**

In accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004 , IMPs must be destroyed as hazardous waste. Records of the destruction of any returned IMPs must be kept and filed in the Pharmacy Site File, and / or written confirmation provided to the Sponsor at the end of the trial to confirm destruction of surplus IMP, in accordance with local policies and procedures.

Records of the destruction of any unused IMPs must be confirmed by the Sponsor and be kept and filed in the Pharmacy Site File, and / or written confirmation provided to the Sponsor at the end of the trial to confirm destruction of surplus <<Insert IMP 2 name>> in accordance with local policies and procedures.

IMP may not be destroyed until written confirmation has been received from the clinical trial coordinator/sponsor.

## **12.2 <<Insert IMP name>>**

Used vials may be destroyed on-site according to local procedures.

# 13. Protocol Amendments

The sponsor will inform sites of any amendments made to the protocol. The pharmacy sites will be provided with new versions of the protocol, and the associated approval documentation (i.e. MHRA, Ethics approval letters). These must be filed in the Pharmacy Site File.

# 14. Monitoring

# Monitoring visits will  take place in accordance with the <<study title>> monitoring plan.

# 15. Archiving

At the end of the trial the pharmacy file will be archived with the Investigator Site File, in line with site specific local procedures.