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| **Investigational Medicinal Product Management Plan for**  **<< Insert Short Title>>**  **EDGE :<< Insert>>** | | | | | |
| **Version Number:** | |  | |  | |
| **Implementation Date :** | | **<< date>>** | | **Review Date: << date>>** | |
|  | | **Superseded version:**  **(if applicable)** | |  | |
| **Role** | **Print Name** | | **Signature** | | **Date** |
| **Author** |  | |  | |  |
| **Reviewer 1** |  | |  | |  |
| **Chief Investigator** |  | |  | |  |
| **Pharmacy representative** |  | |  | |  |
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# **Abbreviations << please update as applicable>>**

|  |  |
| --- | --- |
| CECM | Centre for Experimental Cancer Medicine |
| CI | Chief Investigator |
| CTC | Clinical Trials Coordinator |
| IMP | Investigational Medicinal Product |
| IVRS | Interactive Voice Response System |
| IWRS | Interactive Web Randomisation System |
| NHS | National Health Service |
| QP | Qualified Person |
| TMF | Trial Master File |

# **Background**

This procedure is for the <<INSERT short title>> study << Insert full title>>.

In this study, patients are randomised to XXXXXX or XXX, in 1:1 ratio. Both XXX and XXx are Investigational Medicinal Product (IMPs) for this study.

Patients will be randomised using<<Insert>> .

The following parties are involved in IMP management:

* Sponsor and XXXXXX Coordinating team (Oversight of IMP, ordering of initial site supplies and accountability)
* Insert IMP Manufacture
* Insert labelling and distribution
* Insert any other involved party eg Interactive Voice Response System (IVRS/ Interactive Web Randomisation System (IVWS) or randomisation

Roles and responsibilities pertinent to this guidance document are listed above. However, further information regarding roles and responsibilities between these parties are documented in the contracts and agreements, and the Pharmacy Manual for sites. These can all be found in the << Insert Short title>>Trial Master File (TMF)

<<IMP>> is sourced by sites from commercial National Health Service (NHS) supplies, and subsequently <<reimbursed by the sponsor>> <<covered by NHS commissioning>>

# **Purpose**

This guidance document describes the procedure for IMP management, including site set-up procedures, drug ordering and subsequent IMP management for the << Insert Short title>>study.

# **Scope**

This guidance document only applies to the << Insert Short title>>study.

# **Policy**

Only <<Insert Coordinating centre or team>> individuals delegated by the Chief Investigator (CI) and that have received trial specific training can undertake IMP activities included in this guidance document.

# **Procedure**

## Delegating staff to perform IMP management activities

* + 1. The coordinating team delegation log is used to document who is able to perform IMP management (including IMP ordering) activities.
    2. In order to perform IMP-related tasks, a member of the coordinating team or site study team must have undergone training by the << Insert Short title>>clinical trial coordinator.
    3. Insert details of anything else needed – eg IVRS/IWRS accounts

## Addition of sites:

### In order for IMP to be ordered, sites need to << insert detail- IVRS/IWRS access/ inform Manufacture etc>>

### Before the site initiation visit, <<Insert detail>>

### << Insert Short title>> trial coordinator will update the user spreadsheet with names and contact details of new users before a site is activated (spreadsheet can be found in the << Insert >> electronic folder), highlight any changes made to the spreadsheet Please also add any generic email addresses to the user information spreadsheet requested by the site. Site staff to notify the Clinical Trials Coordinator (CTC) if there are any changes in site staff involved in the study. Addition or removal of any site staff will be updated on the user spread sheet by the CTC.

* Sites will only be activated after the site initiation visit and once all documents are in place and issued permission to recruitment from the trial management team. IMP will not be shipped to sites prior to permission to recruitment being given by the trial management team.
* Once a site has been activated, trial coordinator will << Insert How IMP will get to site>>

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| --- | --- | --- |
| **Table 1: Initial supply of XXXXXXXXX** | | |
| Enrolment Level | Initial Quantity -25 mg | Initial Quantity – 10 mg |
| Low | 10 | 4 |
| Medium | 15 | 6 |
| High | 25 | 10 |

## 6.3 IMP Management:

### 6.3.1 Ordering IMP1:

<<Insert detailed Step by step process of how to order IMP>>

### 6.3.2 Ordering IMP 2:

<<Insert detailed Step by step process of how to order IMP>>

### 6.3.3 IMP receipt by sites

* Pharmacy will receive xxxxxxx as detailed in the pharmacy manual. Once a shipment of xxxxxxx is received, pharmacy staff will confirm shipment via <<Insert>> . ‘Shipment confirmation’ form (Appendix X)., should be completed and returned.
* Insert details
  + 1. Overall IMP accountability Please insert detail in to this section – the below is an example.
* Trial management team will have an oversight of the overall IMP accountability.
* When routine monitoring visits are performed, the trial coordinator will also review IVRS/IWRS specific documents- e.g. verification of randomisation, verification of completed manual re-order forms etc.
* Trial coordinator will also reconcile accountability with any invoice sent from the site, during monitoring visits. Trial coordinator will update xxxxxxx reimbursement spreadsheet to confirm reconciliation is correct or any other comments.
* Trial coordinator to print ‘Unblinded Site Inventory Summary Report’ for each site which has been activated on a quarterly basis and file in the TMF. This report details the amount of medication left at site as well as if any bottles have been damaged in transit etc.
* XXXXXX will be contracted to transport IMP to sites.
* IMP temperature will be monitored while in storage and during transit and must remain within XXXX-XXXX temperature range.
* Trial management team will receive email confirmation of all shipments received at site once this has been confirmed by site staff. These email confirmations should be printed and filed in the site section of the TMF.
* Trial management team will work along side XXXXXX Insert distributer project manager to work out if more IMP needs to be ordered for the study. The CTC along with the lead research pharmacist will make a decision if the balance stock is adequate for the number of sites open to recruitment and current number of patients recruited onto the study..
* If more XXXXXX is needed, XXXXX will order the amount needed from XXXXX and label the drug for clinical trial use along with Qualified Person (QP) release certificates before being distributed to sites.

## Order placed in error for Insert IMP

Insert detail proceudre

## Removal of sites

* Should a site close the <<insert Site>> study prior to completion of the study, they will need to be deactivated.

## 6.6 Site Monitoring

* Site monitoring will be in line with the study monitoring Plan (insert version and date).
* During the pharmacy monitoring visit, confirmation emails should be reconciled with trial activity. All the emails should be filed in the pharmacy file and should be available for review during monitoring visits.
* The amount of IMP dispensed at site for this study should be reviewed for invoicing purposes.
* An assessment of IMP quantity at site for this study should also be made during monitoring visits.

# **REFERENCES**

Medicines and Healthcare products Regulatory Agency. (2012). *Good Clinical Practice Guide*. Fourth Impression London: The Stationary Office

World Medical Association (2018). *WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*. [online] Available from: <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects> [ Accessed 29.01.2020]

# **APPENDICES**

## Appendix A: Detailed Revision History (if necessary)

## 8.1 Appendix A: Detailed Revision History (if necessary)

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| Name | Change | Reason | New Version Number |
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