STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_004

SOP Title: Receipt of clinical trial medication

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Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	01-Nov-2012	Initial Version	01-Nov-2012
2	27-May-2016	Template updated to include additional sections and further guidance in preparation of SOPs	
3	1-June-2018	Reviewed to ensure content is still relevant	05-Apr-2018

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1. PURPOSE AND CONTEXT

1.1 To describe the procedures for handling the receipt of clinical trial medication.

2.1 Covers the procedures to follow upon receipt of clinical trial medication shipments, including

- Accepting clinical trial medication shipments
- Processing clinical trial medication shipments
- Management of shipments received in poor conditions or incorrect shipments
- Release of clinical trial medication shipments

3.1 The process for quarantining received clinical trial medication is covered in the procedure for Quarantine of clinical trial medication

2. DEFINITIONS

QP – Qualified person responsible for certifying the quality of the batch of IMP prior to release for the use in clinical trials.

QP Certificate - Document signed by the QP certifying that the batch of IMP complies with the principles and requirements of Good Manufacturing Practice and the product specifications, and can be released for use in clinical trials.

CE – The CE marking is the manufacturer's declaration the product meets the requirements of the applicable EC directives.

IxRS – Integrated phone and web drug management system.

3. PROCEDURE and RESPONSIBILITIES

3.1 Procedure

3.1.1 As part of the trial review and set up process, ascertain the specific instructions for the receipt of clinical trial medication, and document the process in the trial specific pharmacy instructions.

3.1.2 As part of the trial review and set up process, provide the sponsor with the pharmacy delivery address including the name of the recipient which should either be name of individual(s) responsible for the processing of clinical trial medication shipment or a general reference to the clinical trials team.

3.1.3 Use the 'Receipt of clinical trial medication form' as a tool to help receipt in the stock. (Form 02)

3.2 Accepting clinical trial medication shipments

3.2.1 Immediately report all clinical trials medication shipments to a member of the site team who is responsible for the processing of clinical trial medication shipments. In the event that these staff are not contactable, the person accepting the shipment should either refer to trained individuals or proceed with steps 3.2.2 to 3.2.11.

3.2.2 Check that the address on the package(s) is correct i.e. the shipment is for the site and the number of packages/boxes delivered matches the quantity noted on the delivery documents. Highlight any issues to the delivery personnel.

3.2.3 Check the outer packaging and note any defects or tampering of security seal. Highlight any defects to the delivery personnel and make a note of the defects on the delivery documents as appropriate. Good conditions mean:

- Closure tape is intact
- Outer packaging is visibly intact

3.2.4 If any items or paperwork are missing or damaged then inform the sender and trial monitor and follow their instructions.

3.2.5 Sign the delivery documents and return to the delivery personnel.

3.2.6 In the event that staff referred to in point 3.2.1 remain uncontactable, send an email to all those concerned alerting them of the shipment

3.2.7 Assess whether the shipment needs to be unpacked immediately by referring to the instructions on the outer packaging; check the storage conditions of the shipment i.e. room temperature, refrigerated, or freezer. If in doubt, seek advice from a senior member of the site team.

3.2.8 Unpack the shipment as follows:

- Room temperature storage: unpack the shipment and store the contents in appropriate condition under quarantine.
- Refrigerated storage: unpack the shipment and store in appropriate condition under quarantine. (Note: placing the delivery including all the outer packaging in refrigerated conditions may lead to a temperature deviation).

3.2.9 For shipments with a temperature monitoring device, follow any instructions provided with the delivery. This usually involves stopping the temperature monitoring device and recording the transit temperature. If in doubt always leave the temperature monitoring device with the product at the appropriate storage temperature.

3.2.10 Print your name, date and time of receipt on the delivery document provided. If there is no specified place, simply write in a space on the document and fill out the 'Receipt of clinical trial medication form'. (Form 02)

3.2.11 By reference to the instructions on the delivery document, either discard or retain the outer packaging.

3.2.12 Pass on all delivery documents, the temperature monitoring device, and outer packaging as appropriate to individual(s) responsible for the processing of clinical trial medication shipments.

3.3 Processing clinical trial medication shipments

Individual(s) responsible for the processing of clinical trial medication shipments:

3.3.1 Locate relevant pharmacy site file and follow the trial specific pharmacy instructions on processing of clinical trial medication shipments.

3.3.2 Check the contents of the shipment against the delivery documents. The following details should be checked:

- Trial name/ details
- Site name/number (if appropriate)
- Drug/ product name, strength and form (i.e. tablets, oral solution)
- Bottle/ medication/ pack number (if appropriate)
- Batch number/Lot number
- Expiry date
- Total quantity

3.3.3 Check for any evidence of damage or tampering, "Good condition" means:

- The clinical trial medication container is undamaged
- The clinical trial medication container is unopened and any tamper seal is intact.

3.3.4 If any items or paperwork are missing or damaged then inform the sender and trial monitor and follow their instructions

3.3.5 Follow the instructions on delivery documents to record/download data from the temperature monitoring device where applicable. Assess whether the transit temperature was in range.

3.3.6 For all consumables or devices, check that they are CE marked.

3.3.7 Check all relevant quality documents have been received e.g. certificate of analysis, QP certification, in line with the trial specific pharmacy instructions. Depending on the sponsor and distributor, quality documents may be provided with each shipment or at the set-up phase. If the latter, ensure that documentation covers the batch numbers received in the shipment. If any of the documentation expected are not included, or the information on the document(s) does not match the contents of the shipment, quarantine the clinical trial medication and contact the trial sponsor. Note, this is not required for licensed products.

3.3.8 For blinded studies utilising code-break envelopes, check that code-break envelopes have been received and match the clinical trial medication received. Store code-break envelopes in the appropriate designated area. If the expected blinding information is not included in the shipment, quarantine the clinical trial medication and contact the sponsor. Document any discrepancy, damage, temperature excursion, or absent documentation on the delivery documents, and notify the sponsor immediately. Follow the sponsor's procedure for reporting where applicable.

3.4 Release of clinical trial medication shipments

3.4.1 Follow the delivery document instructions to notify the sponsor of the receipt of clinical trial medication shipment, e.g. fax, email, via interactive response systems (IxRS – web or voice),

3.4.2 For clinical trial medication shipment that is correct, not damaged, transit temperature in range, and not requiring confirmation of usability from the sponsor, proceed to step 3.4.4

3.4.3 For clinical trial medication shipments requiring confirmation of usability from the sponsor, place shipment in the appropriate quarantine storage area and wait until sponsor confirmation as fit for use before proceeding to step 3.4.4.

3.4.4 Confirm receipt of clinical trial shipment via interactive response systems (IxRS – web or voice), where applicable. (Note: steps 3.4.1 and 3.4.4 may be combined for some trials)

3.4.5 Update accountability logs as per trial specific pharmacy instructions.

3.4.6 File relevant paperwork (e.g. delivery notes/packing slips/shipment records, QP certificates, Certificates of Analysis, Clinical Trial Delivery Product Inspection Form, inventory logs, IxRS confirmation reports, fax acknowledgments) in the appropriate sections of the pharmacy file.

3.4.7 Once all the above steps have been completed, store clinical trial medication in the designated area (ensuring the shortest dated stock is placed at the front, where applicable).

	Responsibility	Undertaken by	Activity
1	Chief Pharmacist	Clinical Trials Pharmacist	Confirming that a QP certificate of release has been supplied by the sponsor for all the batches of IMP received or obtaining a statement from the sponsor confirming that they have the QP certificates.
2	Clinical Trials Pharmacist	Pharmacy and site staff who have undergone training.	Receive deliveries and complete paperwork.
3			

4. SUPPORTING MATERIAL and ATTACHMENTS

- Receipt of clinical trial medication form (Form 02)

5. TRAINING

The Clinical Trials details that are specific to each individual trial must have been read.

6. REFERENCES

For more detailed guidance/reference, refer to:

- MHRA Good Clinical Practice Guide, 2012