STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_017

SOP Title: Trial Close-out

Role	Name	Signature	Date
SOP Author	Alex Weston- Principal Pharmacist R&D		02-Mar-2018
SOP Reviewer	Victoria Croome- Clinical Trials Technician		07-Mar-2018
SOP Authoriser	Raj Parekh- Chief Pharmacist		05-APR-2018
SOP Review Date	**June 2020**	Effective date stamp	

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	27-May-2016	Initial Version	12-Jan-2015
2	1-June-2018	Reviewed to ensure content still current	05-Apr-2018

STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_017

SOP Title: Trial Close-out

1. PURPOSE AND CONTEXT

1.1 To describe the trial close-out procedures

1.2 Covers the procedures to follow at the conclusion of a trial, including:

- Arranging close-out visit
- On-site close-out visit
- Remote close-out visit

2. DEFINITIONS

3. PROCEDURE and RESPONSIBILITIES

3.1 Arranging close-out visit

3.1.1 Obtain written confirmation of trial closure from the sponsor. (Note: pharmacy close-out visit may be conducted prior to the actual trial closure, in particular for clinical trials with long participants follow up).

3.1.2 Liaise with the local research team and contact the sponsor (directly or via the local research team) to arrange a date for the close-out visit.

3.1.3 Establish with the sponsor the time required to conduct the close-out visit and allocate the time accordingly.

3.1.4 Before the close-out visit, a member of the clinical trials team should review carry out the following activities:

- Prepare all clinical trial medication supplies for reconciliation in readiness for the close-out visit, unless this has already been completed at previous monitoring visits or the sponsor has agreed to do so at the close-out visit.
- Check whether all pharmacy payments have been processed and follow up on any outstanding payments.

3.2 On-site close-out visit

3.2.1 Allow the sponsor's representative to review the pharmacy site file and reconcile any remaining clinical trial medication.

3.2.2 The following activities should be carried out by the sponsor's representative with the support of a member of the pharmacy clinical trial team:

- Check to ensure that expected documentations are in the pharmacy site file - the contents of the file should be checked against the required contents as defined by the sponsor.
- Check to ensure all documentation is completed accurately and in full. Any discrepancies in documentation and drug accountability must be addressed. If applicable, create and file signed and dated file note to describe the discrepancy and explain what has been done to try to resolve the issue.
- File copies of the temperature logs/reports covering the time period the clinical trial medication has been stored on site, or create and file a signed and dated file note stating that the temperature logs/reports have been reviewed and detailing where these logs/reports can be found if they are needed.
- File any temperature excursion reports.
- File code-break envelopes or equivalent (if applicable).
- Print and file copies of all relevant correspondence.

3.2.3 Once reconciliation of clinical trial medication has been completed, proceed with disposal/destruction of clinical trial medication in line with the trial specific pharmacy instruction and the standard operating procedure on *Disposal/destruction of clinical trial medication SOP* (CP/R&D_009).

3.2.4 Confirm with the sponsor's representative what remaining actions are required by pharmacy.

3.2.5 Confirm with the sponsor's representative that a final trial close-out report confirming all activities required have been completed will be sent.

3.2.6 Following the close-out visit, action any remaining items as required.

3.2.7 Print and file copies of all relevant correspondence following the close-out visit if necessary.

3.2.8 Once received, file the final trial close-out report in the relevant section of the pharmacy site file.

3.2.9 Proceed with archiving in line with the standard operating procedure on *Archiving of pharmacy clinical trials documentation SOP* (CP/R&D_011).

3.3 Remote close-out visit

3.3.1 Confirm that the sponsor has provided written confirmation for a remote close out visit.

3.3.2 Request from the sponsor a list of activities (e.g. a closedown checklist) which pharmacy is required to action.

3.3.3 Action the closedown activities as requested.

3.3.4 In line with the sponsor's instructions, complete and return the closedown checklist to the sponsor.

3.3.5 File a copy of the completed closedown checklist in the pharmacy site file.

3.3.6 Follow steps 3.2.4 to 3.2.9.

	Responsibility	Undertaken by	Activity
1	Chief Pharmacist	Clinical Trials Pharmacist	To ensure that close-outs of clinical trials are completed correctly
2			
3			

4. SUPPORTING MATERIAL and ATTACHMENTS

- CP/R&D_009: Disposal/destruction of clinical trial medication
- CP/R&D_011: Archiving of pharmacy clinical trials documentation

5. TRAINING

6. REFERENCES

Notes to consider:
Close-out visits are conducted by sponsor to ensure that the investigator site file including the pharmacy site file is completed and that all necessary documentation has been filed. For pharmacy, the focus is on ensuring there is an accurate record providing an audit trail of clinical trial medication receipt to their removal from site or destruction. For more detailed guidance, refer to section 10.7.4 of the MHRA Good Clinical Practice Guide.