INVESTIGATIONAL MEDICINAL PRODUCT MANAGEMENT AT CLINICAL TRIAL COMPLETION

1 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the procedures for managing investigational medicinal product (IMP) at the end of clinical trials.

This SOP ensures compliance with ICH Guideline for Good Clinical Practice (ICH GCP) and national and international laws and regulations, specified in the SOP legislation and guidelines.

2 SCOPE

This SOP is valid for all clinical drug trials sponsored by hospitals that have implemented the NorCRIN SOPs.

3 RESPONSIBILITIES

The sponsor has overall responsibility for ensuring that this SOP is followed.

The sponsor's responsibilities shall be described in the quality system of the sponsor institution. Tasks are delegated according to SOP Roles and Responsibilities in clinical trials implemented in the institution.

The sponsor may transfer any or all of the sponsor's trial-related duties and functions to a third party vendor such as a Contract Research Organisation (CRO), but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The sponsor should ensure oversight of any trial-related duties and functions carried out on its behalf. Transfer of duties shall be specified in a written agreement.

The coordinating investigator has the responsibility for managing IMP at the end of a trial and filing documentation in the trial master file (TMF) according to the requirements of this SOP.

The principal investigator at each site is responsible for managing IMP at the end of a trial at his/her site and filing investigational medicinal product documentation in the investigator site file (ISF).

4 PROCEDURES

4.1 Final Disposal of IMP

As a general rule, all IMPs which were delivered from the centre should be returned to the centre, whether it is unused IMPs or empty packaging.

Returned IMPs will be counted and documented and compliance will be calculated, unless agreed otherwise.

IMP accounting records should be verified to confirm completeness and accuracy. Any discrepancies should be explained and documented.

Destruction of IMPs must be done according to established pharmacy or hospital/institution procedures and as agreed with the project leader.

For unauthorised IMPs and unauthorised auxiliary medicinal products a total reconciliation should be performed, see IMP reconciliation and destruction should be documented, see IMP Destruction.

5 DOCUMENTATION

All required IMP documentation and accounting records produced during the trial must be complete and filed in ISF and the sponsor's TMF at the end of the trial. See SOP Study Files

The required authorisation documents for organisations which have manufactured IMPs should be filed in the sponsor's TMF.

Agreements which apply to IMPs must be filed in the sponsor's TMF.

See Checklist Completion of Clinical Trial - Sponsor and Checklist Completion of Clinical Trial – Centre for a detailed overview.

6 NON-COMPLIANCE MANAGEMENT

Non-compliance should be handled according to the procedures for handling non-compliance of the individual institution. Protocol deviations should be reported according to the study protocol or the Protocol Deviation Handling plan.

7 REFERENCES

7.1 External references

- ICH Guideline for Good Clinical Practice (GCP) E6 (R2) particularly Chapter 5
- REGULATION (EU) No 536/2014 of The European Parliament and of the Council on clinical trials on medicinal products for human use, chapter IX

7.2 Internal references

- SOP Medicinal Product Management at Trial Start
- SOP Investigational Medicinal Product management during Trial
- SOP Study Files
- SOP Protocol Deviation Handling

- Checklist Completion of Clinical Trial - Sponsor
- Checklist Completion of Clinical Trial – Centre
- IMP Destruction
- IMP Reconciliation

8 ATTACHMENTS

9 DEFINITIONS

SOP Definitions.

Abbreviation	Term
CRO	Contract Research Organisation
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
IMP	Investigational Medicinal Product
ISF	Investigator Site File
SOP	Standard Operating Procedure
TMF	Trial Master File

10 CHANGES SINCE LAST VERSION

CT SOP version no 1.0

Main changes from LM SOP 4.02: Adapted to the clinical trial regulation.