SOP 003_03

Title	Study Analysis and Reporting
SOP Code	SOP 003_03
Effective Date	30-June-2023

Site Approval/Authorization to Adopt

Name and Title of Local Personnel (Type or print)	**Signature**	**Date dd/Mon/yyyy**
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1.0 PURPOSE

This Standard Operating Procedure describes the analysis and reporting of results from a clinical study.

2.0 SCOPE

This SOP is applicable to investigator-initiated human participant research whereby study analysis and reporting is the responsibility of the sponsor-Investigator.

3.0 RESPONSIBILITIES

The Sponsor-Investigator or Principal Investigator (PI)/Qualified Investigator (QI) is responsible for ensuring that the study analysis and reporting processes meet all of the applicable regulatory, International Conference on Harmonisation (ICH) Good Clinical Practice (GCP), sponsor, and local requirements.

Any or all parts of this procedure may be delegated to appropriately trained study team members, but remain the ultimate responsibility of the Sponsor-Investigator or Principal Investigator (PI)/Qualified Investigator (QI).

4.0 PROCEDURE

4.1 Study Analysis and Reporting Activities

4.1.1 Study analysis and reporting includes all activities, from the last participant visit, to the finalization of the study report, including, but not limited to the following:

- database cleaning
- serious adverse event (SAE) reconciliation
- database freeze
- finalization of study narratives
- finalization and sign off of the statistical analysis plan prior to database lock
- database quality control (QC) and database lock
- implementation of the statistical analysis plan
- review of the results
- clinical report writing
- reporting study outcome and results to regulators, and Research Ethics Board (REB)/Independent Ethics Committee (IEC)
- archiving of the trial master file (TMF).

4.2 Study Analysis and Report Format

4.2.1 Determine the appropriate format of the Study Analysis and Report,

1. defined as part of the study publication policy in the protocol and/or contract, where applicable; or
2. decided by the study team, based on the type of study, any funder obligations and intended recipients of the report; or
3. for some smaller studies: study report published in a peer-reviewed journal may be sufficient; etc.

4.3 Preparation and Review of Analysis Output

4.3.1 Prepare/present study data as tables, figures, listings, and statistical output, as outlined in the statistical analysis plan for the study.

4.3.2 Sponsor-Investigator or PI/QI and study team members: Review the analysis output. Incorporate changes, as necessary.

4.4 Study Analysis and Report Content

4.4.1 Prepare sections of the Study Analysis and Report using the following inputs, where appropriate:

- Proposal for funding
- Protocol and protocol amendments
- Statistical analysis plan
- Case Report Form
- Investigator brochure or equivalent document with product information
- References (including, but not limited to those cited in the protocol)
- Statistical methods used to design and analyze the study.
- Tables, figures, listings, and analysis output
- Appendix materials
- Safety database
- Interim analysis (if applicable)

4.4.2 Optional: Prepare shell report, before the final data analysis is completed. Sections of the shell report usually include:

- Title
- Synopsis
- Table of contents
- Abbreviations
- Ethics
- Study structure
- Introduction

- Objectives
- Investigational plan

4.5 Study Analysis and Report Approval/Sign-off

4.5.1 Distribute the draft analysis and report for review. Reviewers may include (but not be limited to), the following study team members: PI/QI, trial manager, statistician, and other reviewers, e.g., study funders, data monitoring and REB/IEC members. Refer to the publication policy, as defined in the protocol.

4.5.2 Apply version control to draft documents, if desired for tracking purposes.

4.5.3 Resolve or incorporate comments, and finalize report.

4.5.4 Obtain final approval/sign-off, as required

4.6 Regulatory and REB/IEC Reporting

4.6.1 Provide a summary of the study analysis and report to the appropriate regulator(s), and REB/IEC, meeting all of the applicable regulatory, ICH, and Sponsor requirements.

5.0 REFERENCES

Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), June 20, 2001.

Health Canada, Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997.

Health Canada, Guideline for Industry, Structure and Content of Clinical Study Reports, ICH Topic E3, 1996.

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2014.

Department of Justice (Canada), Personal Information Protection and Electronic Documents Act (PIPEDA), updated 2006.

Health Canada, Guidance for Industry, Clinical Safety Data Management Definitions and Standards for Expedited Reporting, ICH Topic E2A, 1995.

Pharmaceutical Inspection Convention, Pharmaceutical Inspection Co-operation Scheme, Annexe 11, Computerised Systems.

US Food and Drug Administration, Code of Federal Regulations, Title 21, Volume 1:

- Part 11, Electronic Records; Electronic Signatures, (21CFR11).
- Part 50, Protection of Human Subjects, (21CFR50).
- Part 54, Financial Disclosure by Clinical Investigators, (21CFR54).
- Part 56, Institutional Review Boards, (21CFR56).
- Part 312, Investigational New Drug Application (21CFR312).
- Part 314, Applications for FDA Approval to Market a New Drug (21CFR314).

US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46).