

Standard Operating Procedure

Clinical Study Report

Identification No.: CLI08

Version: 2

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1. ABBREVIATIONS

ASST-PG23: Azienda Socio Sanitaria Territoriale-Papa Giovanni XXIII

CSR:	Clinical Study Report
DM:	Data Manager
FROM:	Fondazione per la Ricerca Ospedale Di Bergamo
GCP:	Good Clinical Practice
ICH:	International Conference of Harmonization
ISF:	Investigator Site File
PI:	Principal Investigator
PM:	Project Manager
SOP:	Standard Operating Procedure
TMF:	Trial Master File

2. SCOPE

The aim of this Standard Operating Procedure (SOP) is to describe responsibilities and procedures to produce an integrated (clinical and statistical) report.

3. FIELD OF APPLICATION

This SOP applies to clinical trials sponsored or supported by FROM or sponsored by ASST-PG23.

4. RESPONSIBILITIES

Principal Investigator (PI)

- Drafts the Clinical Study Report (CSR).
- Signs the CSR.

Statistician

- Drafts the Statistical sections of the CSR.

Reviewer

- Reviews the CSR sections of competence and provides inputs and comments to the PI.

Project Manager (PM)

- Support the PI in drafting the CSR.
- Collects inputs from the reviewers and implement them in the CSR (if needed).
- Ensures that the document is reviewed and approved by all concerned parties.
- Collects and assembles all relevant appendices.
- Ensures the final approval of the CSR.
- Files the CSR in the Trial Master File.
- Distributes the CSR.

5. PROCEDURE

The CSR is an integrated report of an individual trial conducted in human subjects, in which the clinical and statistical description, presentations and analyses are integrated into a single report.

Whether a trial is completed or prematurely terminated, and whether the results are positive or negative, the CSR should be prepared and provided to the concerned Ethics Committees and national Competent Authority according to the applicable regulations and should represent the main source of information for any public disclosure of trial results.

5.1 Clinical Study Report drafting, development and approval

It is the responsibility of the PI to ensure that a CSR is prepared for each trial enrolling subjects and to decide whether it should be a full or abbreviated report.

The report is written according to the **Clinical Study Report Template (T.CLI08.01)**

which includes all applicable contents described in the ICH guideline E3- Structure and content of clinical study reports.

The CSR should provide a clear explanation on how the trial was carried out. It should describe the trial results in detail incorporating tables and figures.

The structure presented in the abovementioned template is applicable to most kinds of trials, but it can be adapted and some topics omitted or added as appropriate.

Abbreviated reports presenting summarized data or with some sections deleted, may be acceptable in particular for:

- uncontrolled trial,
- trial not designed to establish efficacy,
- aborted trial.

However, a full description of safety aspects should nevertheless be included in these cases.

It is also important to identify ways in which the trial was conducted differently from the protocol.

The PI responsible for CSR drafting collects in advance all relevant information and final documentation (e.g. trial protocol and amendments, statistical analysis, data management documentation, administrative information, list of significant protocol deviations).

The support of the Statistician for drafting the relevant statistical sections and for the interpretation of trial results is crucial.

The draft CSR should be reviewed by the main concerned parties (e.g. Pharmacovigilance) as appropriate to ensure that the document accurately reflects the methods applied, the trials conduct, the results and their interpretation.

The final CSR is signed by the Principal Investigator promoting the trial. According to the “EMA Note for guidance on coordinating Investigator signature of clinical study reports” if a Clinical Trial Coordinator is appointed for a multicenter trial, he/she can sign the CSR and no signatures from other participating investigators have to be collected.

5.2 Amended Trial Report

Changes in the content of a signed CSR affecting the conclusions of the trial or any significant new information (e.g. new data) must be documented as an amendment to the CSR.

The amendment must be reviewed according to the concerned competences and approved by the PI or by Clinical Trial Coordinator (i.e. for multicenter trial).

5.3 Submission to Ethics Committee(s), Regulatory Authority and Investigator's

Copy of the synopsis or the main body of the CSR is uploaded and distributed to the Italian Ethics Committee(s) and Competent Authority. A copy of the synopsis/main body of the CSR is also distributed to the Principal Investigators participating in the trial. Appendices of the CSR are provided only upon request.

The submissions should occur within one year from the end of trials completion. A scientific publication does not replace the CSR, then it should not be submitted in place of a CSR.

5.4 Clinical Study Report archiving

The complete CSR including all appendices is to be filed in the Trial Master File.

The the synopsis/main body of the CSR is distributed to participating investigators for filing in Investigator Site File along with the relevant correspondence.

CSR amendments/addenda, if any, are archived in the TMF next to the original document as well as in the Investigator Site File (ISF) along with the relevant correspondence.

6. REFERENCES

- Guideline for good clinical practice E6(R2) (CPMP/ICH/135/95).
- International Conference of Harmonization - Structure and Content of Clinical Trial Reports (E3) (EMA Note for guidance on coordinating Investigator signature of clinical study reports(CPMP/ICH/137/95).
- Decree 21st December 2007 - Directions for submitting the request for authorization of a clinical trial on a medicinal product for human use to the Competent Authority, for communicating substantial amendments, for declaring the end of the trial and for the request of an opinion to the Ethics Committee.
- Determinazione 20 marzo 2008 – Linee guida per la classificazione e conduzione degli studi osservazionali sui farmaci.
- Ministerial Degree dated November 15th, 2011 – Definition of the minimum requirements which a CRO shall satisfy in order to work within clinical trials on medicinal products.
- Determina n.809/2015 dated June 19th, 2015 inerente i requisiti necessari per le strutture sanitarie che eseguono sperimentazioni di fase I di cui all'art.1 del decreto del Presidente della Repubblica 21 settembre 2001, n.439 e di cui all'art.31, comma 3 del decreto legislativo 6 novembre 2007, n.200.

7. TEMPLATE

T.CLI08.01/2: Clinical Study Report Template.

8. VERSION HISTORY

Version	Date	Reason for revision
1	30 Sept 2016	Starting document.
2	15 Jan 2020	General review of the document.