

Clinical Trial Protocol Format

Title Page

Includes the protocol title, product name, IND number (if applicable), author/sponsor/monitor names, investigator name/site, IRB name/address, protocol date; may also include signatures of investigator/sponsor representative.

Table of Contents

Introduction

Includes a detailed description of previous pre-clinical and/or clinical studies involving the compound or device to be studied.

Objective

A concise statement of the goal(s) of the current study.

Experimental Design

A synopsis of the operational aspects of the study, including type of study, number of patients/subjects, control compound(s), duration of treatment, laboratory studies, etc.

Patient Selection

A comprehensive list of inclusion and exclusion criteria, screening procedures etc.

Study Design

A detailed description of all procedures to be performed on the study patient and the schedule for each.

Statistical Analysis

A statement of the types of data to be analyzed and, to the extent possible, the statistical methods to be employed.

Adverse Events

A description of the procedures for receiving, evaluating and managing reports of adverse events of any type and degree of severity.

Subject Withdrawal

A description of conditions under which patients may withdraw from and/or be withdrawn from the study and procedures for their replacement (if applicable).

Drug Accountability

A detailed description of the manner in which clinical supplies will be packaged, including randomization schemes, label contents, coding, etc.

Case Report Forms

Description of and instructions for completion and review of Case Report Forms.

Informed Consent

Instructions for obtaining legally valid written informed consent from each prospective study patient/subject.

Institutional Review Board

Information concerning the requirement for prior approval of the protocol and the Informed Consent form as well as continuing contact between investigator and the IRB.

Discontinuation of Study

A statement that the Company may discontinue study at any time and a description of any actions that may follow such discontinuation of clinical approach, numbers of subjects/patients, time frames, previous study data, etc.

Data Disclosure/Publication

A statement of Company policy regarding publication or other disclosure of the data collected during the study.

Documentation

A list of documents and data required to be provided to the sponsor before, during and after the study (optional).

Project Timetable/Flowchart

A graphic or tabular depiction of the procedures and chronology of the study.

References

(optional).

Appendices

Tables, figures, descriptions of special procedures, etc. (optional).