

Elements of a Clinical Research Protocol

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General Information

1. Protocol title, version # and date.
2. Name, address and telephone contact of principal investigator.
3. Name, title, address of location(s) where study will be performed.
4. Name and address of the sponsor and monitor (if other than sponsor).
5. Name, title, address and telephone number of the sponsor's medical expert for the trial.
6. Name and address of clinical laboratory and other medical and/or technical departments and/or institutions involved in the trial.

If applicable, the following information should also be included:

7. Name and title of the person(s) authorized to sign the protocol and the protocol amendment(s) for the sponsor.
8. Name, title, address and telephone number(s) of the qualified physician (or dentist, if applicable) who is responsible for all site related medical (or dental) decisions applicable to the trial (if other than the investigator).

Background Information

1. Review of the condition or disease under study, including epidemiology, etiology and clinical presentation as well as currently available treatment(s).
2. Name and description of investigational product.
3. Summary of findings from non-clinical studies that potentially have clinical significance, and from clinical trials that are relevant to the trial.
4. Summary of the known and potential risks and benefits, if any, to human subjects.
5. References to literature and data that are relevant to the trial and that provide background for the trial.
6. Description of and justification for the dose, route of administration, dosage regimen and treatment period(s).

Trial Objectives and Purpose

Detailed description of the objectives and purpose of the trial, including:

1. Rationale for the conduct of the trial.
2. Hypothesis being evaluated, key questions that are being addressed in the trial.

Trial Design

The trial design has a significant impact on the scientific integrity and credibility of the data derived from the conduct of the trial. The following are components to be included in the description of the trial design:

1. Identification of the primary endpoints and the secondary endpoints.

Trial Design (continued)

2. Description of the type/design of the study (double-blind, placebo-controlled, parallel design, etc.). Include a schematic diagram of the trial design, procedures and study phases.
3. Description of the trial treatments or interventions, including description of the dosage, dosage form and dosage regimen, product packaging and labeling, and treatment period(s).
4. Description of the population to be studied, number of subjects to be enrolled
5. Description of subject identification, recruitment and informed consent process.
6. Measures being taken to minimize/avoid bias (randomization, blinding).
7. Expected duration of subject participation and description of the sequence and duration of all trial periods, including follow-up, if any.
8. Description of the stopping rules or discontinuation criteria for individuals subjects, study phases, entire trial.
9. Description of accountability procedures for the investigational product(s), including placebo or comparator product(s) if applicable.
10. Maintenance of trial treatment randomization codes and procedures for breaking codes.
11. Identification of data that will be directly entered on the case report forms (CRFs) (i.e., no previous written or electronic record of the data) and that information which is to be considered as source data.

Selection and Withdrawal of Subjects

1. Subject criteria: Include age range, gender, disease, and stage of treatment. Justify excluding subjects based on race or gender (including child-bearing potential for women) or age (children).
2. Subject inclusion criteria.
3. Subject exclusion criteria.
4. Subject withdrawal criteria and procedures, specifying:
 - a. When and how subjects to withdraw subjects from the trial/investigational product treatment.
 - b. Type and timing of data to be collected in subjects withdrawn from the trial.
 - c. Whether and how withdrawn subjects are to be replaced.
 - d. Follow-up to be conducted for subjects withdrawn from trial treatment.

Subject Exposure to Investigational Product

1. Treatment(s) to be administered, including the name of the product, dose, dosing schedule, route of administration, treatment period, follow-up period for subjects should be specified for each investigational product treatment/trial treatment group/arm of the trial.
2. Identification of medications/treatments permitted, including rescue medications, as well as those not permitted before and/or during the trial.
3. Specific procedures to be utilized to monitor subject compliance.

Efficacy Assessment

1. Specification of efficacy parameters.
2. Identification of methods, timing, for assessing, recording and analyzing specified parameters.

Safety Assessment

1. Specification of safety parameters.
2. Identification of methods, timing for assessing, recording and analyzing specified parameters.
3. Definition of adverse event, serious adverse event.
4. Procedures for eliciting reports of, and for recording, adverse events, intercurrent illnesses, concomitant medication/treatment use.
5. Procedure for reporting adverse events, serious adverse events and unanticipated problems involving subjects or others (UPIRSOs) per protocol, regulations, and institutional requirements.
6. Identification of the type and duration of follow-up of subjects after adverse events.
7. Procedure for recording and reporting any deviation from the approved plan.
8. Description of data and safety monitoring plan, including assessment and reporting to IRB, FDA, etc. Identify if the plan will involve an independent medical monitor, data monitoring committee, and/or data and safety monitoring committee.

Statistical Analysis

1. Description of statistical methods to be utilized, including timing of interim analysis if appropriate.
2. Number of subjects to be enrolled.
3. Rationale for choice of sample size (power calculation and clinical justification).
4. Level of significance to be used.
5. Criteria for trial termination.
6. Procedure for accounting for missing, unused or data which cannot be authenticated.
7. Selection of subjects to be included in the analysis (e.g., all subjects enrolled, all subjects dosed, all evaluable subjects).

Direct Access to Source Data/Documents

The protocol should specify that the investigator/investigator's institution will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspection by providing direct access to source data/documents.

Data Management and Recordkeeping

The protocol should include a description of privacy and confidentiality safeguards (i.e., how records and individually identifiable health information will be protected - coding), as well as management and storage of the study records and specimens. If a multi-site protocol, an overall study management plan should be provided.

Quality Control and Quality Assurance - monitoring of the conduct of the research for compliance with GCPs.

Ethics and Legal Aspects

A statement that the study will be conducted in compliance with the protocol, GCP, informed consent of subjects and the applicable regulatory requirement(s) or codes of conduct (i.e, Declaration of Helsinki).

Supplements/Attachments/Appendixes - Instruments/Questionnaires/Subject Diaries

Publication Policy (if not addressed in a separate agreement).

Financing and Insurance (if not addressed in a separate agreement) - including costs covered by research and anticipated costs to the subject, if any.

(optional) Use of Study Findings - Next steps and future studies based upon anticipated results.