Essential Clinical Trials Documents

Essential Clinical Trial Documents

- Documents that individually and collectively evaluate the conduct of a trial and preserve the integrity of the data.
- Demonstrate the compliance of the investigator and sponsor with the standards of GCP and all applicable regulatory requirements

Essential Clinical Trial Documents

1. Protocol
2. Informed Consent Document (ICD)
3. Investigator's Brochure (IB)
4. Case Record Form / Clinical Report Form(CRF)
5. Source Data/Document (SD)
6. Regulatory Approval
7. ERB/IRB/IEC/EC Approval
8. Advertisement
9. Financial Agreement

Essential Clinical Trial Documents

10. Insurance Statement
11. Curriculum Vitae (CV)
12. Laboratory Reference Range
13. Monitoring Report
14. Investigational Product Accountability
15. Certificate(s) of Analysis (COA)
16. SAE Reporting
17. Correspondence
18. Queries
19. Clinical Study Report (CSR) *etc.*

Protocol

- Document that states the background, objectives, rationale, design, methodology, (including the methods for dealing with AEs, withdrawals etc.) and statistical considerations of the study.
- Unless otherwise specified, always relates to the latest amended version.

General Tips on Protocol

- A version date and a version number should identify the approved protocol.
- Regulatory and ERB approval must be obtained for each clinical trial protocol.
- Version control should be maintained for all subsequent amendments.
- A tracking log should be maintained to record version(s) control.

Informed Consent Document (ICD)

- Document for voluntary written consent of a subject's willingness to participate in a particular study.
- Contain information about the trial including an explanation of its status as research, its objectives, potential benefits, risks and inconveniences, alternative treatment that may be available and of the subject's rights and responsibilities.
- A version date and a version number should identify each ICD and its all subsequent amendments.

Informed Consent Document (ICD)

- Translation of ICD in vernacular languages must be approved by ERB.
- Only the ERB approved version of ICD should be administered to the patients.
- A tracking log should be maintained to record version(s) control.

General Tips on ICD

- ICD should be obtained before non-routine screening procedures are performed and/or before any change in the subject's current medical therapy is made for the purpose of the clinical trial.
- Investigator or designee should personally obtain the ICD from the subject.
- Subject should receive a copy of the signed ICD.

Investigational Brochure (IB)

- Document containing data (including justification for the proposed study) for the Investigator consisting of all the clinical as well as non-clinical information available on the Investigational Product (s) known prior to the onset of the trial.
- Relevant data is generated during the trial, the information in the Investigator's Brochure must be updated.

General Tips on IB

- A version date and a version number should identify each IB.
- ERB must review each version of IB.
- IB should be updated on a regular interval to include all new data on the Investigational product.
- Previous version of IB should be destroyed once the updated version is available.

Case Report Form (CRF)

- Document designed in consonance with the protocol, to record data and other information on each trial subject.
- The CRF should be in such a form and format that allows accurate input, presentation, verification, audit and inspection of the recorded data.
- CRF may be in printed or electronic format.

General Tips on CRF

- CRF should be designed to include all the required data.
- CRF should preferably be made of NCR (no carbon required) paper.

Source Data/Document (SD)

- Source data/document refers to the original documents (or their verified and certified copies) necessary for evaluation of the Clinical Trial.
- Source document include Study Subject's files, recordings from automated instruments, tracings, X-Ray and other films, laboratory notes, photographic negatives, magnetic media, hospital records, clinical and office charts, Subject's diaries, evaluation checklists, and pharmacy dispensing records.

General Tips on Source Document

- All entries in worksheets or patient files should have the date and initials of person making the entry.
- All the records of a patient should be filed in one file or together. If the patient is referred to another department/hospital, all the relevant records should be included in the source document.
- Start and stop date for all adverse event(s) and corrective medication(s) should be clearly stated in the patient's source document.
- Environmental control (protection from fire, flood, termite *etc*.) must be maintained throughout the duration of archival

Regulatory Approval

Document to grant permission for the conduct of a trial at respective investigator site(s) in a country.

General Tips on Regulatory Approval

- Regulatory approval must be obtained prior to initiating any clinical trial in India.
- Regulatory approval must contain the duration of approval

ERB/IRB/IEC/EC Approval

Document to grant permission for the conduct of a trial at individual investigator site

General Tips on ERB/IRB/IEC/EC Approval

- ERB approval should include the name and version(s) of the documents reviewed for granting approval.
- ERB approval must contain signature, date and seal of chairperson; list of voting members; and list of members who were absent.
- ERB approval must contain the duration of approval.
- ERB approval must be obtained prior to initiating a clinical trial at any site.

Advertisement

- Document for subject recruitment (if used) that provides brief study outline.
- It is important to ensure that recruitment measures are appropriate and not coercive.

General Tips on Advertisement

- All trial related advertisement must be approved by ERB/IRB/IEC.
- Wordings of advertisement should be such that it does not coerce the patient(s) to participate in a clinical trial.

Financial Agreements

Document to disclose the financial aspect of the trial between the investigator/ institution and the sponsor.

General Tips on Financial Agreements

- All trial related financial agreement should be in compliance with the individual institution and the local laws.
- The hospital administration and the ERB/IRB/IEC should be made aware of the financial aspect of the trial.
- All trial related grants/payments should be made in accordance with the financial agreement.

Insurance Statement

Document to indemnify that the compensation to subject(s) for trial-related injury will be available.

General Tips on Insurance Statement

- Sponsor should provide the insurance statement prior to initiating the trial at a particular site.
- Insurance statement should include the compensation clause for all trial related injuries.

Curriculum Vitae (CV)

Document to provide qualifications and eligibility of investigator(s), sub-investigator(s), co-investigator(s), coordinator(s), nurse/pharmacist, sponsor designee(s) and other relevant study personnel.

General Tips on Curriculum Vitae (CV)

- CV must be obtained from all the concerned personnel prior to initiating a clinical trial.
- CV should be personally sign and dated by the concerned personnel

Laboratory Reference Range

Document containing normal values and/or ranges of the laboratory test at the individual trial site/laboratory

General Tips on Laboratory Reference Range

- Laboratory reference range must be obtained prior to initiating the clinical trial at a particular site.
- It should be personally sign and dated by the concerned personnel.

Monitoring Report

Document prepared by the sponsor’s designee on the trial progress at individual trial site(s) after the monitoring/inspection visit

General Tips on Monitoring Report

- Monitoring report should include all finding and issues with actionable and timelines.
- Monitoring report should document all violations and protocol non-compliance.

Investigational Product Accountability

Document to provide complete accountability of investigational product including receipt, dispensing, returned, destruction etc. at all levels (sponsor, investigator and patient level).

General Tips on Investigational Product Accountability

- Investigation product(s) should be stored at required temperature/ humidity conditions.
- Temperature/humidity logs should be maintained on a daily basis.
- Investigational product should be kept under proper access control.
- Any deviation in storage condition should be reported appropriately and the material should be inspected for potency (if required)
- Reconciliation of all used/unused Investigational Product(s) should be available at the site(s) level.
- Reconciliation of all used/unused Investigational Product(s) should be available at the sponsor level.
- Any loss/damage/breakage *etc*. should be properly documented.
- Destruction certificate of Investigational Product(s) should be available at all levels

Certificate (s) of Analysis (COA)

Document to provide identity, purity and strength of investigational product (s) used in a trial.

General Tips on Certificate (s) of Analysis (COA)

- COA should be present for each batch and class of investigational product(s).
- COA should be available prior to initiating the clinical trial.

SAE Reporting

Document or template to report Serious Adverse Event(s) of a trial to the sponsor and the ERB/IRB/IEC

General Tips on SAE Reporting

- An SAE should be reported only if it meets the requirements of a valid case (*i.e.* an identifiable patient; an identifiable reporter; a suspect drug or biological product; and an adverse event or fatal outcome).
- All SAEs must meet the reporting timelines as specified by the sponsor.
- All the SAEs and follow-up reports at a particular site should be reported to respective ERB/IRB/EC.
- All the valid SAE cases should be reported to applicable regulatory authority(ies) within the stipulated timeframe

Correspondence

Documentation of trial specific communication between various involved parties (sponsor, investigator, ERB, regulatory agency etc.)

General Tips on Correspondence

- All correspondence should contain a date and an identifiable reporter.
- All correspondence should be filed to provide an audit trail.

Queries

Documentation of CRF corrections including all changes/ additions or corrections made to CRF after initial data is reviewed and collected

General Tips on Queries

- The designated personnel should sign all queries.
- Individual query should be filed with the respective CRF page for which the query is generated

Clinical Study Reports (CSR)

A report prepared at the end of a trial including results and interpretation

General Tips on Clinical Study Reports (CSR)

- A CSR should be prepared irrespective of the trial outcome (positive or negative).
- CSR should be submitted to applicable regulatory bodies.

THANK YOU


SPECT
Society for
the Promotion
of Ethical
Clinical Trials