SOPs in Clinical Studies

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Definition

As per the ICH guidelines, Standard Operating Procedure (SOP) is defined as "**Detailed, written instructions to achieve uniformity of the performance of a specific function**"

Source: ICH E6 GCP guidance for industry

List of Contents

- List of SOPs applicable before clinical phase of study
- List of SOPs applicable during clinical phase of study
- List of SOPs applicable after clinical phase of study
- List of SOPs applicable for data management in clinical study
- List of SOPs applicable for study site in clinical study
- List of SOPs applicable for regulatory communication in clinical study
- Contents of SOP

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List of SOPs Applicable Before Clinical Phase of Study

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SOPs before clinical phase

- Clinical study protocol and its amendments
- Case Report Form (including designing of electronic Case Report Form)
- Consent Documents (ICD, Assent form, AV consent form)
- Investigator's Brochure
- Translation of essential clinical study documents (ICD, Assent form, diary cards, dosing instructions etc.)
- Execution of clinical study agreements/contracts
- Blinding & unblinding procedures
- Protocol training of sponsor’s staff and delegation of duties / responsibilities
- Site feasibility and selection
- Registration of clinical study with clinical trial registry
- Ethics Committee submission and communication (through investigator)
- Laboratory equipment, supplies, and tests

List of SOPs Applicable During Clinical Phase of Study

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SOPs during clinical phase

- Investigators' meeting
- Site initiation visit
- Protocol training of site staff
- GCP training of site staff
- Site monitoring visit (including remote monitoring)
- Clinical study forms and logs
- Preparation and management of study files (Trial Master File & Site Master File)
- Investigational product storage, accountability & management
- Shipment of Investigational product and handling of loss or damage during shipment
- Adverse event reporting and monitoring
- Data Safety Monitoring Board / Data Monitoring Committee
- Management of misconduct/fraud in clinical study
- Premature termination or suspension of a clinical study

List of SOPs Applicable After Clinical Phase of Study

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SOPs after clinical phase

- Clinical study report
- Site close-out visit
- Archival of essential documents

List of SOPs Applicable for Data Management in Clinical Study

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SOPs related to data management

- Sample size determination
- Randomization plan
- Data management plan
- Data management activities
- Statistical analysis plan
- Statistical analysis and report

List of SOPs Applicable for Study Site in Clinical Study

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SOPs related to study site (1/2)

- Ethics Committee submission & communication
- Subject screening & recruitment
- Informed consent process and documentation
- Eligibility confirmation
- Source documentation
- Biological sample processing, storage & shipment
- Dispensing of investigational products
- Handling and reporting of adverse events and serious adverse events
- Handling of acute clinical emergency
- Handling of subject withdrawal or dropout during the study
- Handling and reporting of protocol deviations

SOPs related to study site (2/2)

- Remuneration of clinical study participants
- Maintenance of Site Master File
- Maintenance of confidentiality of information
- Audit of clinical study (sponsor, EC or regulatory agency)
- Archival of essential documents

List of SOPs Applicable for Regulatory Communication in Clinical Study

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SOPs related to regulatory communication

- Regulatory submission and communication

Contents of SOP

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Contents of SOP

- Title & signature page
- Purpose
- Scope
- Responsibility
- Accountability
- Definitions
- Procedures
- Abbreviations
- References
- Annexures
- Document History

Thank you

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