

Overview of Clinical Trials

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Clinical Research: Regulatory Considerations

History of clinical research
Laws, regulations, and guidance documents

Ethics and Regulations concerning Ethical considerations

History leading to ethical considerations

Organizations performing oversight of clinical studies

Regulations on ethical requirements

Informed Consent

Steps in the Clinical Trial Process

Clinical SOPs
Protocol Development
Investigator and Site Selection (intro)
Finalizing protocol and Case Report Forms
Developing Consent form and Obtaining IRB Approval
Setting up Database and Resolving Queries
Monitoring and Auditing

Investigator and Site Selection

Qualifications of a Clinical Investigator

Site Visit: facilities, personnel,
equipment, patient population

Regulations and Required Documents

Essential Documents

Pre-study
During the study
After the study
Miscellaneous

Study Initiation

Preparation for first enrolled subject

Initiation Visit

Follow-up after initiation visit

Monitoring visits

Early visits: Pre-study and initiation
Routing monitoring visits
Close-out visits
“For cause” visits
Monitoring “tools”

Database Management and Biostatistical Analysis and Evaluation

Setting up Database
Issuing/resolving queries
Closing database
Biostatistical Analysis
Evaluation of Data
Create final Statistical report

Adverse Experience Reporting

Definitions of AE
Determination if event is an AE
AE Reporting
AE Follow-up
Use of Data Safety Monitoring Boards (DSMBs)

Study Close-Out

Study-Close-Out Visit
Investigator Records
Investigator Reports

Records and Reports

Sponsor Study Records
(Documentation System)
SOP for Doc. System
Sponsor Reports
Investigator Reports
Adverse Event Reports

Quality Assurance Clinical Audits

Clinical SOPs

Audits and/or Inspections at Inv. Site

Audits and/or inspections at Company Facility

In-House Personnel and/or 3rd Party Contract Audits

FDA Bioresearch Monitoring Inspections

Premarket Submissions

Clinical Research Department
Support for Submissions

Postmarketing Clinical Research: regulations and guidance documents

Post-marketing study commitments as
a condition of approval

Post-marketing studies for marketing or
publication purposes