ESSENTIAL DOCUMENTS

Understanding the essential document aspect of clinical trials.

KEY LEARNINGS

Essential Documents are those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements.

- Requirements of essential documents
- Importance of essential documents
- Documents requirements for DAIDs
- Knowledge of DAIDs SOPs
- Identify essential documents
- Rationale behind collection of every essential document
- Filing requirements
- Knowledge GCP guidelines for essential documents

EXAMPLES OF ESSENTIAL DOCUMENTS

BEFORE THE TRIAL

Investigator Brochure
Signed Protocol
Informed consent form
Financial Aspects
Insurance statement
Signed Agreement
IRB/IEC approval

Regulatory Approval
Curriculum Vitae
Normal Lab ranges
Lab Accreditation
Label samples
IP related documentations
Pre-trial and initiation visit report

DURING THE TRIAL

Investigator Brochure
Signed Protocol
Signed Informed consent form
Source documents
Completed CRFs
Subject screening log
Subject enrollment log

IP Accountability at site
Annual reports
Safety reports
Relevant communications
Documentation of CRF corrections
Monitoring visit reports

AFTER THE TRIAL

Documentation of IP destruction
Subject identification code list
Treatment allocation
Clinical study reports
IP accountability at site
Subject enrollment log