CLINICAL EXCELLENCE CONSULTING

Regulatory Documents for Clinical Trials

Regulatory Compliance • Site Requirements • Safety Reporting • Ongoing Oversight • Audit Readiness

Ethical Compliance

Ensures trials meet ethical standards and protect participant rights throughout.

Data Integrity

Maintains accuracy and reliability of all study data throughout the trial.

Risk Management

Identifies and mitigates potential risks throughout the clinical trial lifecycle.

Audit Readiness

Prepares sites for audits by maintaining organized and complete documentation.

Regulatory Authority Approvals

IND	Investigational New Drug application required for US studies.
CTA	Clinical Trial Application required in many international countries.
IRB APPROVAL	Institutional Review Board approval required before trial initiation.
ETHICS	Ethics Committee approval is critical for trial conduct and compliance.
DOCUMENTATION	Ensure all regulatory submissions are documented, tracked, and filed.

Investigator & Study Site Requirements

PI CV	Identify audit objectives and define the scope and criteria clearly.
SUB-IS CVs	Collect necessary documents and data for a comprehensive audit review.
LICENSES	Analyze findings against predefined standards and applicable regulations.
FDA FORM 1572	Document audit results and suggest corrective actions with clear timelines.
DELEGATION LOG	Analyze findings against predefined standards and applicable regulations.

Understanding Essential Documents

COMPLIANCE	Ensure clinical trials meet regulatory and ethical standards throughout their lifecycle.
DOCUMENTATION	Maintain thorough records of approvals, protocols, and informed consent forms at all stages.
MONITORING	Facilitate ongoing oversight to safeguard participant safety and data integrity during trials.

Safety Reporting Requirements

SUSARs	Report all Serious Unexpected Adverse Reactions promptly to regulatory authorities.
SAFETY REPORTS	Compile and submit regular safety reports per regulatory guidelines.
IRB UPDATES	Notify IRBs of any SAEs; update protocols based on emerging safety findings.

Final Compliance Review

- Ensure all documents are signed, dated, and correctly versioned for filing.
- Confirm documents are filed correctly in both TMF and ISF at all times.
- Maintain continuous inspection readiness using compliance checklists.

Ongoing Oversight & Trial Operations

- Ensure ongoing IRB/IEC approvals; submit safety reports and implement amendments.
- Maintain logs, ICFs, and training records; keep documentation inspection-ready.