



Clinical Trial Operations and GCP Training: Site Management, Monitoring and TMF



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Introduction:

Clinical trial operations and GCP training on site management, monitoring and TMF is a 5-day course for study site, monitoring and clinical operations teams at research hospitals, research organisations and sponsors, ending with a Site Monitoring and TMF Readiness Plan for a case trial. Trials lose time and data credibility when sites open unprepared, consent records are incomplete, monitoring misses source discrepancies and the trial master file lags behind conduct. Nominees already coordinate, investigate or monitor studies and work through case studies on site files, monitoring reports and TMF extracts. CoreConcept Training Center delivers this clinical trial operations course.

Course Objectives:

- Apply ICH E6R3 Good Clinical Practice principles to the division of duties between sponsor, investigator, monitor and study site staff
- Prepare a study site for activation through feasibility, qualification, contracting, ethics and authority submissions and a site initiation visit
- Run the informed consent process, participant enrolment, investigational product accountability and adverse event recording at site to protocol
- Conduct risk-based monitoring with source data verification and review, and turn findings into follow-up letters and corrective actions
- Maintain a trial master file or eTMF structured on the TMF Reference Model so that it is current, complete and ready for inspection
- Prepare a Site Monitoring and TMF Readiness Plan covering start-up, monitoring intensity, close-out and inspection preparation for a case trial

Target Audience:

- Study site staff who coordinate visits, consent participants and keep source records and site files
 - Investigator teams accountable for protocol conduct, delegation of duties and participant safety at their site
 - Monitoring staff who qualify, initiate, visit and close research sites on behalf of a sponsor or contract research organisation
 - Clinical operations staff who plan site start-up, track enrolment and oversee vendors across studies
 - Clinical quality staff who review trial records, manage deviations and prepare sites and sponsors for inspection
 - Trial documentation staff who file, index and reconcile essential records in paper or electronic master files
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Course Outline:

Day 1: Clinical Trial Lifecycle, GCP Principles and Site Readiness Baseline

- Clinical Trial Phases and the Site-Level Operational Lifecycle
- ICH E6R3 Principles for Participant Protection and Reliable Results
- Sponsor, Investigator and Monitor Responsibility Split Under GCP
- Quality by Design Applied to Critical-to-Quality Trial Factors
- Site Readiness Self-Assessment Against a GCP Operations Checklist

Day 2: Site Feasibility, Start-Up Submissions and Site Initiation

- Site Feasibility Questionnaire and Patient Recruitment Capacity Estimate
- Clinical Trial Agreement and Site Budget Negotiation Points
- Ethics Committee and Authority Submission Package Assembly Steps
- Delegation of Duties Log and Investigator Site Staff Training Records
- Site Initiation Visit Agenda and Activation Green-Light Checklist

Day 3: Participant Consent, Site Conduct and Source Documentation

- Informed Consent Process Walkthrough From Discussion to Signed Form
- Screening and Enrolment Logs With Eligibility Verification Records
- Investigational Product Receipt, Storage and Accountability Logs
- Adverse Event and Serious Adverse Event Site Recording Timelines
- Source Document Agreement and Case Report Form Completion Rules

Day 4: Risk-Based Monitoring, Deviations and Trial Master File Quality

- Risk Assessment and Categorisation Tool for Monitoring Plan Intensity
- Source Data Verification Versus Source Data Review Sampling Choices
- Centralised Monitoring Key Risk Indicators and Site Signal Escalation
- Protocol Deviation Classification and CAPA Follow-Up at Sites
- TMF Reference Model Zones and eTMF Completeness Quality Checks

Day 5: Case Study on a Site Monitoring and TMF Readiness Plan

- Case Trial Site Risk Profile and Monitoring Visit Frequency
 - Case Monitoring Visit Report and Follow-Up Letter Drafting
 - Case eTMF Gap Review Against Expected Essential Records List
 - Site Close-Out Visit and Archiving Arrangements for the Case Trial
 - Site Monitoring and TMF Readiness Plan Completion and Peer Defence
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Skills You Will Gain:

- GCP Responsibility Mapping
- Site Feasibility Assessment
- Consent Process Oversight
- Investigational Product Accountability
- Source Data Verification
- Risk-Based Monitoring Planning
- Essential Records Filing
- Inspection Readiness Preparation

Why Attend This Course:

- Deliver a Site Monitoring and TMF Readiness Plan for a case trial to the head of clinical operations and the principal investigator
- Decide how intensively each site should be monitored and which records need full source data verification rather than review
- Avoid delayed site activation, unreported safety events and critical inspection findings caused by incomplete consent records and lagging master files
- Share consent checklists, monitoring report templates and eTMF quality checks with site coordinators and monitoring colleagues

Conclusion:

Back at work, the participant gives the head of clinical operations and the principal investigator a Site Monitoring and TMF Readiness Plan that sets site activation steps, monitoring intensity by risk, close-out tasks and inspection preparation. The study team uses it to agree monitoring visit frequency, assign filing duties and schedule TMF quality checks before the next trial opens. After the first monitoring cycle under the plan, the team should review open action items, deviation rates, query ageing and TMF completeness and adjust the plan.

Frequently Asked Questions FAQ:

What should participants know before clinical trial operations and GCP training?

Participants should already work on a study site, in monitoring or in clinical operations and know basic trial terminology. Bringing an anonymised delegation log, monitoring report or site file index helps them apply the checklists and templates to their own studies.

How does clinical trial operations and GCP training differ from a medical writing or ethics committee course?

It covers running a trial at site: start-up, consent, conduct, monitoring, master files and close-out. Medical writing courses cover authoring protocols and study reports, and ethics committee courses cover how committees review and approve research, which this course touches only at site level.

Why does risk-based monitoring matter in clinical trial operations and GCP?

Risk-based monitoring directs visits, source data verification and central review to the data and processes most critical to participant safety and result reliability, as the ICH GCP guideline expects, instead of checking every data point at every site equally.

What do participants take back from clinical trial operations and GCP training on site management, monitoring and TMF?

Participants take back a Site Monitoring and TMF Readiness Plan for a case trial, with a site initiation checklist, a consent process checklist, a monitoring visit report template and an eTMF quality check list they can adapt.