

AI Governance for Clinical Trials and Research Training Course

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Overview

AI Governance for Clinical Trials and Research Training Course is a one-week advanced course for clinical research managers, trial operations leaders, governance personnel, coordinators, data teams, assurance specialists, and sponsors, who leave with a Clinical Research AI Control Framework. Participants connect responsible AI in clinical research, clinical trial AI governance, protocol feasibility support, participant recruitment controls, and AI-assisted trial monitoring to data quality, human oversight, traceability, equity, and accountable decisions. Agile Leaders Training Center provides training in AI governance for clinical trials.

Who Should Attend

- Clinical research leadership personnel responsible for study portfolios, operating models, and research outcomes
- Trial operations personnel responsible for feasibility, sites, recruitment, monitoring, and delivery controls
- Research governance personnel responsible for ethics, accountability, participant protection, and oversight
- Clinical data personnel responsible for data quality, lineage, representativeness, and controlled analysis
- Quality assurance personnel responsible for evidence, deviations, vendors, audits, and corrective actions
- Research sponsorship personnel responsible for decisions, resources, risk acceptance, and external providers

The course assumes participants can manage clinical research processes and risk decisions, and it leaves out model coding, statistical programming, healthcare diagnosis, and medical device engineering.

Departments and Industries

The course supports clinical research governance across pharmaceutical development, biotechnology, contract research, academic research, healthcare institutions, and digital-health services.

- Clinical development and trial operations
- Research governance and ethics support
- Clinical data management and biostatistics oversight
- Quality assurance and risk management
- Safety, medical monitoring, and participant protection
- Research technology and vendor management

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Learning Objectives

By the end of this course, participants will be able to:

- Analyze clinical-research use cases and define accountable AI boundaries
- Evaluate data fitness, representativeness, bias, and traceability
- Apply controls to feasibility, recruitment, monitoring, and safety support
- Build human-review, vendor, change, and incident governance
- Prioritize performance, equity, quality, and participant-protection evidence
- Build a clinical research AI control framework

Course Agenda

Day 1: Research Context and Accountability

- Clinical Research AI Use-Case Inventory
- Context-of-Use and Decision-Impact Canvas
- ICH E6R3 Quality and Accountability Mapping
- Participant Rights and Human-Oversight Matrix
- AI Governance Roles and Escalation Charter

Day 2: Data, Bias, and Trial Design Support

- Protocol Feasibility Evidence Map
- Site and Population Representativeness Review
- Clinical Data Fitness and Lineage Checklist
- Bias, Equity, and Subgroup Impact Assessment
- AI-Assisted Trial Design Decision Record

Day 3: Recruitment, Monitoring, and Safety

- Participant Identification and Recruitment Control Grid
- Consent, Privacy, and Data-Minimization Review
- Risk-Based Monitoring Prioritization Method
- Safety Signal Triage and Human Review Route
- Clinical Operations Exception and Override Log

Day 4: Assurance, Vendors, and Lifecycle Control

- AI Vendor Due-Diligence Questionnaire
- Performance, Drift, and Representativeness Dashboard
- Model and Workflow Change-Control Register
- Documentation Traceability and Audit-Evidence File
- AI Incident Review and Corrective-Action Protocol

Day 5: Clinical Research Governance Practice

- Suggested Exercise: Screen a Clinical Research AI Use Case
- Suggested Exercise: Evaluate Data and Population Fitness
- Suggested Exercise: Govern Recruitment and Monitoring Support
- Suggested Exercise: Review Vendor, Change, and Incident Evidence
- Capstone Exercise: Clinical Research AI Control Framework

Practical Exercises

The course uses suggested activities that turn clinical-research AI decisions into traceable governance artifacts.

- Suggested activity: define context of use, decision impact, accountable roles, participant safeguards, and escalation points
- Suggested activity: evaluate feasibility evidence, data lineage, population representation, subgroup effects, and design assumptions
- Suggested activity: control recruitment, consent, monitoring priorities, safety-signal review, exceptions, and human overrides
- Suggested activity: assemble vendor evidence, performance measures, change records, incident actions, and audit traceability

FAQs

Who suits AI governance for clinical trials, and what does the course assume?

AI governance for clinical trials suits research managers, trial operations leaders, governance personnel, coordinators, data teams, assurance specialists, and sponsors. The course assumes experience managing clinical research processes and risk decisions.

How does clinical trial AI governance differ from healthcare AI model validation?

Clinical trial AI governance controls research uses, participant impacts, trial workflows, vendors, human decisions, changes, incidents, and evidence, while healthcare AI model validation concentrates on evaluating a model's technical and clinical performance.

How should AI support participant recruitment in clinical trials?

AI recruitment support should use defined eligibility logic, fit-for-purpose data, fairness checks, privacy controls, documented exclusions, human confirmation, participant-sensitive communication, and monitoring for unequal access or burden.

What evidence supports AI-assisted trial monitoring?

AI-assisted trial monitoring requires traceable data, documented risk indicators, explainable priorities, reviewable alerts, human decisions, override records, performance checks, and evidence that monitoring remains proportionate to participant and data risks.

How should clinical research teams govern AI vendors and changes?

Clinical research teams should define responsibilities, assess vendor controls and data handling, establish performance and change thresholds, review updates before use, preserve version and decision records, monitor incidents, and maintain exit and continuity plans.

Conclusion

Participants take back a Clinical Research AI Control Framework linking use cases, data, participant safeguards, trial operations, vendors, human review, changes, incidents, evidence, and accountability. It changes how research teams move from isolated AI pilots to controlled lifecycle decisions. The framework supports traceability, proportionate oversight, equitable research practice, and auditable management action.

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