AI and Automation in Clinical Trial Design Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

The field of drug development is experiencing a paradigm shift driven by the integration of Artificial Intelligence (AI) and Hyper-Automation. Traditional clinical trial design plagued by high failure rates, immense costs, and prolonged timelines is no longer sustainable in a world demanding Precision Medicine and accelerated regulatory pathways. AI and Automation in Clinical Trial Design Training Course provides an essential, practical framework for clinical researchers and industry professionals to transition from conventional methods to data-driven, AI-optimized clinical trial design. We focus on leveraging technologies like Machine Learning (ML), Natural Language Processing (NLP), and Predictive Analytics to revolutionize core processes such as protocol development, Intelligent Patient Recruitment, and risk-based monitoring. Mastering these tools is crucial for enhancing trial efficiency, ensuring Data Quality at scale, and achieving faster, more successful regulatory submissions, positioning your organization at the forefront of Pharmaceutical Innovation.

The future of pharmaceutical R&D hinges on the ability to deploy Intelligent Automation effectively across the entire clinical development lifecycle. This course is engineered to deliver hands-on expertise in the practical application of AI/ML for tasks from Biomarker Discovery and Digital Twin Simulation to automated Adverse Event (AE) Reporting and site selection optimization. Participants will learn how to design Adaptive Trials with AI-driven models, mitigating operational risks and unlocking significant cost and time savings. By integrating AI-powered insights, professionals can construct patient-centric, scientifically robust, and regulatory-compliant trials, ultimately accelerating the delivery of life-saving therapies to market. This skillset represents the critical convergence of Clinical Research, Data Science, and Regulatory Strategy, making it a key competitive differentiator in the Biopharma sector.

Programme Curriculum

AI and Automation in Clinical Trial Design Training Course

Introduction

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Course Duration

10 day

Course Objectives

Upon completion, participants will be able to:

1. Strategize AI-Optimized Trial Protocols to maximize statistical power and minimize amendments.
2. Apply Machine Learning models for Intelligent Patient Recruitment and enrollment forecasting.
3. Implement Natural Language Processing (NLP) to extract Real-World Evidence (RWE) from unstructured data sources
4. Design and execute Adaptive Clinical Trials using AI-driven simulation and dynamic decision-making tools.
5. Establish effective Risk-Based Monitoring (RBM) frameworks powered by Predictive Analytics.
6. Evaluate and select optimal trial sites and investigators using AI-Enabled Site Selection algorithms.
7. Integrate Digital Biomarkers and Remote Patient Monitoring (RPM) data for continuous, secure data capture.
8. Utilize Generative AI tools for rapid drafting of regulatory documents and protocol summaries.
9. Mitigate bias and ensure Ethical AI and Data Governance compliance in trial operations.
10. Forecast Trial Failure and dropout rates using advanced Time-to-Event Modeling techniques.
11. Streamline Pharmacovigilance and Adverse Event Detection through automated processing.
12. Develop a comprehensive Data Strategy for a Decentralized Clinical Trial (DCT) ecosystem.
13. Quantify the ROI of automation in clinical development for Cost-Efficiency and Time-to-Market acceleration.

Target Audience

1. Clinical Operations Managers / Directors.
2. Clinical Data Scientists / Biostatisticians.
3. Clinical Research Associates (CRAs) / Trial Monitors.
4. R&D Strategy and Innovation Leads.
5. Regulatory Affairs Professionals.
6. Biopharma/MedTech IT and Digital Transformation Teams.
7. Protocol Writers and Trial Design Experts.
8. Pharmacovigilance and Drug Safety Specialists.

Course Modules

Module 1: AI/ML Fundamentals for Clinical Research

- Introduction to Artificial Intelligence, Machine Learning, and Deep Learning concepts.
- Understanding the data lifecycle in clinical trials as AI feedstock.
- Differentiating between automation and intelligent automation.
- Classification, Regression, and Predictive Modeling
- Translating clinical questions into AI-solvable problems.
- Case Study: Analyzing the Pfizer-BioNTech COVID-19 Trial's use of real-time data analytics for fast decision-making.

Module 2: AI-Driven Protocol Optimization

- Using ML to analyze historical trials for Protocol Complexity and feasibility scoring.
- Automating the drafting of protocol sections using Natural Language Generation
- Simulating trial outcomes before patient enrollment begins.
- Identifying and optimizing primary/secondary endpoints based on predictive models.
- Applying Genetic Algorithms for optimal study design parameters
- Case Study: Application of Genetic Algorithms by Takeda/other firms to reduce blood sampling points in PK/PD studies without compromising data quality.

Module 3: Intelligent Patient Recruitment and Site Selection

- Leveraging NLP to parse Electronic Health Records and unstructured physician notes for eligibility.
- Predictive modeling for accurate patient enrollment forecasting and outreach strategies.
- AI-Enabled Site Selection based on historical performance, patient demographics, and site capacity.
- Mitigating recruitment bias and improving diversity using AI-driven demographic analysis.
- Integration of public data into the recruitment pipeline.
- Case Study: IQVIA's use of AI modeling to predict top-enrolling sites and accelerate recruitment by 10-15% across therapeutic areas.

Module 4: Decentralized Clinical Trials (DCTs) and Digital Tools

- Core components of a DCT
- Data ingestion and harmonization from Wearable Devices, Sensors, and Digital Biomarkers.
- Designing protocols compatible with a hybrid or fully decentralized model.
- Ensuring data security and patient privacy in a distributed data ecosystem
- Automated data query generation and resolution in EDC systems.

- Case Study: Novartis or Pfizer?ÇÖs implementation of DCT models using RPM for capturing continuous, real-time activity and physiological data.

Module 5: Risk-Based Monitoring (RBM) and Predictive Safety

- Developing a central monitoring plan using Predictive Risk Indicators.
- AI algorithms to flag sites with elevated risk for non-compliance, fraud, or poor performance.
- Automating source data verification using algorithms and machine vision.
- Real-Time Anomaly Detection in clinical data for early warning of safety issues.
- Optimizing site visit schedules based on AI-calculated risk scores.
- Case Study: Bayer's centralized ML-driven engine for streamlining the identification and reporting of Adverse Events (AEs), reducing manual workload.

Module 6: Natural Language Processing (NLP) in Clinical Data

- Fundamentals of NLP.
- Applying NLP to extract structured data from physician notes, lab reports, and imaging descriptions.
- Using NLP for automated review of regulatory documents and literature for safety signals.
- Developing and training custom clinical ontologies and dictionaries.
- Compliance and ethical considerations when using NLP on patient data.
- Case Study: Utilization of NLP by a CRO to mine unstructured RWE data for inclusion/exclusion criteria refinement.

Module 7: AI in Pharmacovigilance and Drug Safety

- Automating the end-to-end processing of Adverse Event reports and case narratives.
- ML for signal detection in large safety databases
- Using Optical Character Recognition and NLP for auto-ingestion of safety data from faxes/PDFs.
- Predictive toxicology and forecasting potential safety concerns early in the trial design.
- Enhanced coding descriptions and MedDRA term automation.
- Case Study: Implementation of an AI system to auto-ingest and triage safety cases from various media, significantly improving processing speed and auditability.

Module 8: Biostatistics and Adaptive Trial Design

- Statistical foundations of Adaptive Designs
- Implementing Bayesian statistics and simulations for dynamic dose-finding and sample size adjustments.
- AI for Trial Simulation and modeling complex interactions between endpoints and patient subgroups.
- Ethical and regulatory requirements for deploying an adaptive design
- Automating interim analysis and statistical reporting.
- Case Study: Successful Phase I/II oncology trials that used adaptive randomization and dose escalation driven by real-time ML-guided interim data.

Module 9: Machine Learning for Biomarker and Endpoint Selection

- ML algorithms for identifying novel Prognostic and Predictive Biomarkers from omics data.
- Using clustering and classification models to define patient subgroups and inform precision medicine trials.
- Optimizing the choice of surrogate endpoints using predictive correlation models.
- Integrating imaging data with computer vision and Deep Learning models
- Translating a biomarker hypothesis into an AI-driven trial design

- Case Study: Deep Learning model achieving high sensitivity/specificity in identifying infectious diseases from medical images, guiding subject selection in infectious disease trials.

Module 10: Regulatory and Ethical AI in Clinical Trials

- Navigating FDA and EMA guidance on AI/ML in drug development
- Principles of Good Machine Learning Practice and algorithm validation.
- Addressing bias, fairness, and transparency in AI models.
- Data governance, audit trails, and GxP compliance for automated workflows.
- Ethical Review Board (IRB) considerations for AI-driven patient interactions and adaptive protocols.
- Case Study: Analyzing the regulatory approval pathway for a novel AI-driven diagnostic tool used for patient enrichment in a clinical study.

Module 11: Building the AI-Ready Clinical Data Infrastructure

- Designing a unified Clinical Data Repository to feed AI models
- Cloud-native platforms for scalable AI computation.
- Data harmonization, standardization, and ETL/ELT processes for automation.
- Implementing Federated Learning to train models across multiple data siloes while preserving privacy.
- Selecting and evaluating commercial AI platforms/vendors
- Case Study: A biopharma company's migration to a cloud-based data lake architecture to enable real-time analytics and ML modeling across its R&D portfolio.

Module 12: Financial Modeling and ROI of Automation

- Quantifying the financial impact of trial delays, failure, and protocol amendments.
- Developing a Return on Investment case for AI/Automation projects in clinical operations.
- Cost-benefit analysis of intelligent patient recruitment versus traditional methods.
- Modeling the value of Accelerated Time-to-Market and patent life extension.
- Budgeting for AI software, data acquisition, and specialized data science talent.
- Case Study: Analysis of a large pharma company?ÇÖs reported cost savings from implementing AI-driven risk-based monitoring across their global trial portfolio.

Module 13: AI for Trial Manager Copilots and Operations

- Utilizing Generative AI to summarize large trial documents, meeting minutes, and regulatory updates.
- Creating an AI Copilot for clinical trial managers to prioritize urgent site issues and alerts.
- Automating the creation of personalized communication and queries to sites/investigators.
- Machine learning for forecasting drug supply logistics and inventory optimization.
- Developing custom dashboards for real-time, integrated operational insights.
- Case Study: Implementation of an AI-driven "Clinical Control Tower" dashboard that provides predictive insights and prioritizes action items for trial managers.

Module 14: Future Trends: Synthetic Data and Digital Twins

- Introduction to Synthetic Data Generation for model training and privacy-preserving analysis.
- Concept of Digital Twins virtual patient models for simulating treatment responses and refining protocols.
- The role of Quantum Computing in future drug discovery and trial design optimization.
- Integrating Augmented Reality (AR)/Virtual Reality (VR) for site training and remote monitoring.
- Exploring the regulatory acceptance and current limitations of synthetic control arms.

- Case Study: A research consortium utilizing digital twins to simulate different therapeutic regimens for a complex disease, reducing the need for extensive human trials.

Module 15: Implementation and Organizational Change

- Assessing organizational readiness for AI Adoption and data infrastructure maturity.
- Strategies for upskilling and training the clinical workforce
- Developing a pilot testing and scaling-up strategy for new AI tools.
- Building effective cross-functional teams
- Best practices for vendor selection, partnership, and data security agreements.
- Case Study: A successful roadmap for phased AI integration, detailing how a CRO moved from pilot projects to full-scale enterprise adoption.

Training Methodology

The course employs a blended learning approach focused on practical application:

- Interactive Lectures.
- Software Demonstrations.
- Hands-on Workshops
- Case Study Analysis.
- Group Project/Simulation.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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