Advanced Data Science for Clinical Research 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

Advanced Data Science for Clinical Research Training Course outlines the paramount need for Advanced Data Science skills in the rapidly evolving domain of Clinical Research and Drug Development. The convergence of Big Data from Decentralized Trials, Real-World Evidence, and Genomic sequencing has fundamentally transformed the biopharma landscape. Traditional statistical methods alone are no longer sufficient to navigate the complexity and volume of this modern data ecosystem. This course provides participants with mastery over cutting-edge Machine Learning, Deep Learning, and Generative AI techniques, specifically tailored for application in clinical trials, Precision Medicine, and Pharmacovigilance. Our focus is on transitioning theoretical knowledge into practical, regulatory-compliant solutions, enabling professionals to drive innovation from Phase I studies to post-market surveillance.

This program moves beyond foundational analytics to address the most critical challenges in the industry: Clinical Trial Optimization, identifying hidden Biomarkers, ensuring Data Integrity, and accelerating the path to market for novel therapeutics. Participants will gain proficiency in leading-edge tools like Python/R for Biostatistics, Cloud-Native Analytics on platforms like AWS/Azure, and ethical handling of sensitive data under HIPAA and GDPR. By emphasizing hands-on application through Case Studies in areas like Patient Recruitment Prediction and Adverse Event Detection, this training ensures that graduates are prepared to become Data Science Leaders who can leverage AI/ML to reduce trial costs, enhance patient safety, and fundamentally reshape the future of evidence-based healthcare.

Programme Curriculum

Advanced Data Science for Clinical Research Training Course

Introduction

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Course Duration

10 days

Course Objectives

Upon completion, participants will be able to:

1. Design and implement Adaptive Clinical Trial strategies using Reinforcement Learning models.
2. Master Predictive Analytics for Patient Recruitment and retention optimization in Decentralized Trials
3. Apply Natural Language Processing to extract structured Real-World Evidence from Electronic Health Records
4. Develop Deep Learning models for analysis of medical images and Time Series Data from Wearable Devices.
5. Perform advanced Genomic Data Analysis and integrate multi-omics data for Biomarker Discovery in Precision Medicine.
6. Utilize Causal Inference methods to strengthen RWE study designs.
7. Implement Fairness and Explainability (XAI) techniques to ensure ethical, regulatory-compliant, and transparent AI/ML models in clinical decision-making.
8. Architect Cloud-Native Data Pipelines using technologies like Spark and Kubernetes for scalable Clinical Data Management.
9. Apply Unsupervised Learning to identify novel patient subgroups and refine inclusion/exclusion criteria.
10. Automate Pharmacovigilance and Adverse Event (AE) Detection using Text Mining and anomaly detection algorithms.
11. Ensure Data Security and Privacy in clinical data processing through advanced anonymization and Blockchain concepts.
12. Conduct advanced Statistical Modeling in a reproducible manner using Python and R.
13. Lead the development of a Digital Twin concept to simulate control arms and optimize trial power.

Target Audience

1. Clinical Data Scientists and Analysts
2. Biostatisticians and Statistical Programmers (SAS/R/Python)
3. Clinical Trial Managers and Clinical Operations Specialists
4. RWE and Pharmacoepidemiology Professionals
5. Bioinformaticians and Computational Biologists
6. Medical Informaticians and Health Data Engineers
7. Regulatory Affairs and Data Governance Specialists
8. R&D and Clinical Development Team Leaders

Course Modules

Module 1: Foundational Clinical Data Ecosystem

- Data Standards in Clinical Research.
- Advanced SQL and distributed data processing for massive clinical datasets.
- Data Quality Assurance (DQA) and automated outlier/inconsistency detection.
- Introduction to the Clinical Data Lake and Cloud-Native analytics infrastructure.
- Case Study: Developing a scalable ETL pipeline for merging Phase II data from EDC, Labs, and Wearables.

Module 2: Advanced Biostatistics & Reproducibility

- Bayesian Statistics and its application in small population and rare disease trials.
- Advanced Survival Analysis
- Propensity Score Matching (PSM) and other techniques for mitigating confounding in RWE studies.
- Reproducible Research via RStudio/Jupyter Notebooks and version control.
- Case Study: Using Bayesian methods to re-analyze a Phase III trial's primary endpoint, comparing results to frequentist analysis.

Module 3: Machine Learning for Clinical Trial Optimization

- Supervised learning for Predictive Modeling
- Feature engineering tailored for clinical endpoints.
- Model selection, cross-validation, and performance metrics relevant to clinical data
- Techniques for handling Imbalanced Data in rare event prediction.
- Case Study: Building a classification model to predict patient non-compliance or dropout risk early in a Phase III study.

Module 4: Deep Learning for Biomedical Data

- Introduction to Neural Networks
- Applying CNNs for analysis of medical images in diagnosis/prognosis.
- Utilizing LSTMs for Time Series Forecasting and pattern recognition in patient monitoring data.
- Transfer learning and pre-trained models in healthcare
- Case Study: Developing a CNN to automatically classify tumor presence in pathology images, benchmarking against human expert performance.

Module 5: Natural Language Processing (NLP) for Real-World Data

- Fundamentals of Text Mining and tokenization of unstructured clinical text.
- Using NLP for feature extraction from Electronic Health Records, physician notes, and patient narratives.
- Entity recognition and linking using advanced models.

- Automated Adverse Event and Drug Safety signal detection from public literature and internal reports.
- Case Study: Designing an NLP pipeline to identify and standardize adverse drug reactions from a set of free-text post-marketing safety reports.

Module 6: Real-World Evidence (RWE) and Causal Inference

- Sources and quality assessment of RWE
- Advanced Causal Inference methods: Instrumental Variables and Difference-in-Differences.
- Target Trial Emulation and addressing biases.
- Data linkage strategies and privacy-preserving record linkage.
- Case Study: Utilizing claims data and PSM to estimate the real-world effectiveness of a newly launched drug, controlling for unobserved confounding.

Module 7: Genomics and Multi-Omics Data Integration

- Handling high-dimensional Genomic Data.
- Statistical and ML methods for Biomarker Discovery and validation
- Integrating multi-omics data for a holistic view of disease and drug response.
- Machine learning for Personalized Dosing and treatment selection.
- Case Study: Applying a federated ML approach to integrate genomic and clinical trial data across multiple research sites to identify responders to a targeted therapy.

Module 8: Adaptive Trial Design and Simulation

- Statistical principles and operational aspects of Adaptive Trials
- Utilizing Simulation and Monte Carlo methods to evaluate adaptive design operating characteristics.
- Implementation of response-adaptive randomization and group sequential methods.
- Regulatory considerations and reporting for adaptive designs
- Case Study: Simulating a Phase II/III seamless design trial where the Phase III sample size is adapted based on interim Phase II efficacy data.

Module 9: Data Security, Privacy, and Ethics (HIPAA, GDPR)

- Clinical Data Governance and regulatory mandates
- Advanced anonymization and de-identification techniques
- Introduction to Federated Learning for cross-institutional data analysis without data sharing.
- Ethical considerations for AI bias and model transparency in clinical decision support.
- Case Study: Designing a system architecture that employs differential privacy to share aggregate clinical trial results publicly while minimizing patient re-identification risk.

Module 10: Model Explainability and Trust (XAI)

- The critical need for Explainable AI (XAI) in regulatory submissions
- Local and Global explainability methods
- Interpreting complex models for clinical relevance and feature attribution.
- Debugging and mitigating Model Bias and drift over time in a clinical setting.
- Case Study: Applying SHAP values to an ML model that predicts a patient?ÇÖs response to immunotherapy to identify which clinical features drove the prediction for a specific patient.

Module 11: Digital Twin and Synthetic Control Arms

- Concept of Digital Twins in clinical research.

- Methodologies for creating Synthetic Control Arms from historical trial data or RWE.
- Statistical methods for integrating SCA data with concurrent treatment arm data.
- Regulatory acceptance and validation standards for SCAs in drug approvals.
- Case Study: Developing an SCA using pooled historical data to reduce the required patient enrollment for the control arm of an Orphan Drug trial.

Module 12: Data Visualization and Communication

- Designing interactive, actionable dashboards for clinical operational and safety data
- Principles of effective data storytelling for non-technical stakeholders
- Automating reporting of statistical analysis results and generating audit trails.
- Visualizing complex AI/ML outputs
- Case Study: Creating a real-time dashboard to monitor site-specific recruitment rates, data query volumes, and predicted trial timeline variance.

Module 13: Decentralized Trials (DCT) and Mobile Health (mHealth)

- Data acquisition and integration challenges from Wearable Devices and mHealth apps.
- Validation and calibration of digital endpoints and continuous data streams.
- Analysis of High-Frequency Time Series Data from physiological sensors.
- Regulatory and operational considerations for remote data capture in DCTs.
- Case Study: Analyzing high-frequency accelerometer data from a DCT to quantify patient mobility and activity as a secondary efficacy endpoint.

Module 14: Advanced Pharmacovigilance and Risk Management

- Proactive Safety Signal Detection using advanced statistical process control and control charting.
- Applying NLP and deep learning for automated triage of safety case narratives.
- Predictive modeling of drug-drug interactions and patient susceptibility to Adverse Events
- Integration of genetic factors into Pharmacovigilance risk models.
- Case Study: Developing an anomaly detection model using patient lab results and clinical text to detect potential emerging safety signals in a post-market surveillance study.

Module 15: The Future: Generative AI in Clinical R&D

- Introduction to Generative AI models and their potential in clinical research.
- Using LLMs for automated protocol design, CRF generation, and informed consent drafting.
- Synthetic data generation for model training and privacy-preserving data sharing.
- Ethical and regulatory roadmap for deploying Generative AI in regulated environments.
- Case Study: Using a Generative Adversarial Network to create a synthetic dataset of pediatric patient records for training a diagnostic model, preserving the original data's statistical properties.

Training Methodology

The training employs a **Project-Based, Hands-On Learning** methodology, focusing on immediate, practical application of skills.

1. Expert-Led Lectures.
2. Live-Coding Workshops.
3. Real-World Case Studies.
4. Capstone Project.
5. Regulatory 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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