Advanced Data Science in Pharmacovigilance 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 landscape of drug safety is undergoing a digital transformation, moving from reactive case processing to proactive, intelligent safety surveillance. The exponential growth of Big Data from Electronic Health Records and social media to traditional regulatory reports has created an urgent demand for professionals who can leverage Artificial Intelligence and advanced analytics to detect, assess, and manage drug safety signals with unprecedented speed and accuracy. Traditional pharmacovigilance methods can no longer keep pace with the volume and complexity of Real-World Evidence. This course is designed to close that critical skill gap.

Advance Data Science in Pharmacovigilance Training Coursed empowers PV experts and data scientists to master the convergence of these two critical disciplines. You will gain proficiency in cutting-edge techniques like Natural Language Processing for unstructured data extraction, predictive modeling for risk forecasting, and developing AI-powered signal detection systems. By mastering machine learning application in regulatory compliance and benefit-risk assessment, participants will transform into Intelligent Pharmacovigilance leaders, ready to drive innovation, ensure patient safety, and uphold global regulatory compliance in the era of Human Data Science.

Programme Curriculum

Advanced Data Science in Pharmacovigilance Training Course

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Course Objectives

1. Master the application of Artificial Intelligence (AI) and Machine Learning (ML) for Proactive Signal Detection in large-scale PV datasets.
2. Develop high-fidelity Predictive Safety Models to forecast emerging drug risks and optimize Risk Management Plans (RMPs).
3. Implement Natural Language Processing (NLP) techniques to automate the extraction and analysis of Unstructured Safety Data from EHRs and social media.
4. Design and manage Big Data Architectures and Real-World Evidence (RWE) pipelines for comprehensive drug safety surveillance.
5. Apply Advanced Statistical Methods for Quantitative Signal Validation and causality assessment.
6. Ensure Global Regulatory Compliance by automating aggregate report generation and adhering to GVP guidelines with data-driven methods.
7. Construct dynamic Interactive Data Visualization dashboards for effective communication of Safety Insights to stakeholders.
8. Evaluate and integrate data from Digital Health sources and Wearable Devices into the core PV workflow.
9. Develop a strategic framework for Automated Case Processing and Narrative Generation using intelligent automation and Robotic Process Automation (RPA).
10. Analyze Benefit-Risk profiles throughout the product lifecycle using advanced, data-driven methodologies and Multi-Criteria Decision Analysis (MCDA).
11. Perform robust Data Governance and Quality Control (QC) checks on integrated, multi-source PV data, including MedDRA and WHODD standardization.
12. Explore the ethical and privacy considerations of using patient-level AI in PV
13. Leverage specialized PV systems for advanced analytics and workflow optimization.

Target Audience

1. Pharmacovigilance Scientists/Managers.
2. Data Scientists & Data Analysts.
3. Drug Safety Physicians
4. Regulatory Affairs Specialists
5. Biostatisticians.

6. IT/Informatics Professionals
7. Safety Outsourcing Professionals
8. Public Health & Epidemiology Researchers.

Course Modules

Module 1: Data Science Foundation for Intelligent PV

- Evolution of Pharmacovigilance
- Big Data Sources.
- The PV Data Pipeline
- Data Governance, Quality, and Privacy Compliance in a Big Data environment.
- Case Study: Designing a unified data model integrating clinical trial data and post-marketing RWE for a new biologic.

Module 2: Advanced Statistical Signal Detection

- Traditional Quantitative Methods.
- Advanced Bayesian Methods and Hierarchical Models for signal refinement and prioritization.
- Longitudinal Data Analysis.
- Statistical principles of Disproportionality Analysis across diverse safety databases.
- Case Study: Applying a Bayesian approach to analyze a low-frequency, high-severity ADR signal across multiple global datasets.

Module 3: Natural Language Processing (NLP) for Unstructured Data

- Fundamentals of NLP.
- Automated extraction of key safety entities from free-text narratives.
- Sentiment Analysis and Social Media Listening for early Adverse Event (AE) detection.
- Handling ambiguity, abbreviations, and misspellings in unstructured patient reports.
- Case Study: Using transformer models for automated extraction of causality and seriousness criteria from physician notes in EHRs.

Module 4: Machine Learning for Adverse Event Triage and Automation

- Classification models for automated case triage and seriousness prediction.
- Clustering for identifying novel patient subgroups at risk.
- ML-driven Narrative Generation from structured AE data.
- Implementing Robotic Process Automation for repetitive case processing and data entry.
- Case Study: Developing and validating a Random Forest model to automate the classification of incoming reports into expedited vs. non-expedited categories.

Module 5: Predictive Analytics and Risk Forecasting

- Time-Series Analysis.
- Survival Analysis and Hazard Ratios for long-term safety outcome prediction.
- Causal Inference in Observational Data.
- Building a Predictive Risk Score model to prioritize drugs for targeted surveillance.
- Case Study: Applying PSM to RWE to compare the incidence of a specific side effect between two competing drugs while controlling for baseline patient factors.

Module 15: The Future of PV: AI, Blockchain, and Next-Gen Strategies

- Advanced Deep Learning applications in sequential safety data.
- Integrating Blockchain technology for secure, transparent drug safety data exchange.
- Developing a "Human-in-the-Loop" AI strategy for optimal system performance and expert oversight.
- Regulatory Perspective on AI/ML.
- Case Study: Proposing an organizational roadmap for transitioning to an end-to-end Intelligent PV Platform utilizing AI and cloud infrastructure.

Training Methodology

The course utilizes a blended, hands-on, and highly practical methodology:

- Interactive Lectures.
- Hands-on Labs
- Real-World Case Studies.
- Capstone Project.
- Expert Sessions.

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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