Advanced Safety Reporting in Global Clinical Trials 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 modern drug development landscape is defined by Globalization, Digitalization, and rigorous Regulatory Scrutiny. As clinical trials become increasingly complex incorporating Decentralized Clinical Trials (DCTs) and novel therapies like Gene and Cell Therapies the core discipline of safety reporting must evolve. Traditional pharmacovigilance (PV) processes are no longer sufficient to manage the massive volumes of heterogeneous data generated globally. Advanced Safety Reporting in Global Clinical Trials Training Course is specifically engineered to bridge the gap between foundational PV knowledge and the strategic, data-driven expertise required to operate in this dynamic environment. We focus on mastering the intricacies of global expedited reporting, advanced signal detection using machine learning, and ensuring perpetual audit-readiness across all major jurisdictions, including the latest ICH E6(R3) and EU Clinical Trial Regulation (CTR) mandates.

This essential training will empower professionals to move beyond mere compliance to become strategic safety leaders. You'll gain mastery over the Advanced Quality Management Systems (QMS), lead benefit-risk assessments, and drive proactive pharmacovigilance programs. The curriculum places a strong emphasis on practical, real-world application, covering topics from MedDRA coding expertise and ICSR quality to the development of sophisticated Risk Management Plans (RMPs) in a global context. By focusing on data integrity, AI-powered automation, and strategic regulatory responses, this course ensures participants are equipped to protect patient safety while accelerating product lifecycle management in an era of unprecedented clinical innovation.

Programme Curriculum

Advanced Safety Reporting in Global Clinical Trials Training Course

Introduction

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Course Objectives

Upon completion of this course, participants will be able to:

1. Master the latest ICH E2B(R3) and EU Clinical Trial Regulation (CTR) requirements for expedited global safety reporting.
2. Design and implement Advanced Pharmacovigilance Quality Management Systems (QMS) to ensure perpetual audit-readiness.
3. Execute complex benefit-risk assessments and update Reference Safety Information (RSI) based on emerging safety data.
4. Develop and maintain robust Development Safety Update Reports (DSURs) and Periodic Benefit-Risk Evaluation Reports (PBRERs).
5. Apply Medical Dictionary for Regulatory Activities coding expertise to ensure high-quality Individual Case Safety Reports (ICSRs).
6. Formulate effective Signal Detection Plans using data mining algorithms and advanced statistical tools.
7. Manage Safety Data Reconciliation between Clinical (CTMS) and Safety (Argus/Veeva) databases in Decentralized Clinical Trials (DCTs).
8. Interpret and address global regulatory variations, specifically between FDA IND Safety Reporting and EudraVigilance submissions.
9. Integrate Artificial Intelligence (AI) and smart automation tools to enhance case processing and PV data quality.
10. Lead cross-functional teams in the development and execution of tailored Risk Management Plans (RMPs) and Risk Evaluation and Mitigation Strategies (REMS).
11. Prepare for and successfully navigate rigorous GVP Inspections and regulatory authority audits

12. Oversee specialized safety reporting for Advanced Therapy Medicinal Products (ATMPs), including Gene and Cell Therapies.
13. Conduct root-cause analysis for safety report discrepancies and implement effective Corrective and Preventive Actions (CAPAs).

Target Audience

1. Senior Drug Safety/Pharmacovigilance Associates and Specialists
2. Pharmacovigilance Managers and Team Leaders
3. Clinical Research Associates (CRAs) and Clinical Data Managers
4. Regulatory Affairs Professionals (focused on Safety)
5. Quality Assurance (QA) Auditors and GVP Inspectors
6. Safety Database System Owners and Administrators
7. Physicians and Scientists in Drug Safety/Medical Review
8. Project Managers overseeing Global Clinical Trials

Course Modules

Module 1: The Global Regulatory Landscape & Advanced Compliance

- ICH E6(R3) and the principles of Quality by Design (QbD) in PV.
- Deep dive into the EU Clinical Trial Regulation (CTR) and the Clinical Trials Information System (CTIS).
- Mastering the distinction between IND Safety Reports (FDA) and SUSARs
- Establishing a Global Safety Reporting Network (GSRN) and managing international Safety Data Exchange Agreements (SDEAs).
- Case Study: Analyzing a regulatory authority's warning letter due to non-compliance with global reporting timelines.

Module 2: Mastery of Individual Case Safety Reports (ICSRs)

- Advanced techniques for Causality Assessment and determining Expectedness in complex cases.
- Applying the latest ICH E2B(R3) data standards for electronic submission via EudraVigilance and FDA Adverse Event Reporting System.
- Expert-level training on MedDRA Coding for challenging medical events and Drug Coding consistency.
- Developing High-Quality Safety Narratives for unexpected and rare adverse events.
- Case Study: Drafting a complete, E2B(R3) compliant ICSR for a drug interaction leading to a fatal outcome in a DCT.

Module 3: Pharmacovigilance Quality Management Systems (QMS)

- Designing an Advanced QMS framework for global PV operations, including defining Quality Tolerance Limits (QTLs).
- Developing and maintaining robust Standard Operating Procedures (SOPs) for continuous audit-readiness.
- Implementing a systematic approach to Corrective and Preventive Actions following safety process deviations.
- Utilizing Key Performance Indicators and Quality Metrics to monitor PV system health.
- Case Study: Root-cause analysis and CAPA implementation plan following a critical internal audit finding on missing follow-up information.

Module 4: Advanced Signal Detection and Management

- Principles of Proactive and Reactive Signal Detection and the use of Disproportionality Analysis.
- Utilizing Data Mining Algorithms and statistical methods for analyzing high-volume safety database data.
- The Signal Management Lifecycle from detection and validation to assessment and regulatory action.
- Interpreting signals from Real-World Evidence (RWE) and other non-traditional data sources
- Case Study: Evaluating a new safety signal detected via an automated statistical tool and creating a subsequent action plan.

Module 5: Aggregate Safety Reporting Expertise (DSUR/PBRER)

- Structuring and authoring the Development Safety Update Report (DSUR) as per ICH E2F guidelines.
- Content and submission requirements for the Periodic Benefit-Risk Evaluation Report and its role in product lifecycle.
- Techniques for Data Aggregation and presentation of cumulative safety data to regulatory bodies.
- Establishing the criteria for a formal Cumulative Benefit-Risk Assessment within periodic reports.
- Case Study: Drafting the most challenging sections of a DSUR for a complex trial, focusing on the interval summary and overall safety analysis.

Module 6: Risk Management Plans (RMPs) and Risk Minimization

- Core components and regulatory expectations for the Risk Management Plan in EU and other regions.
- Developing Risk Evaluation and Mitigation Strategies for the US market
- Designing and evaluating the effectiveness of Routine and Additional Risk Minimization Measures
- Conducting Effectiveness Studies of RMMs and updating the RMP throughout the product lifecycle.
- Case Study: Creating a mock RMP for a novel therapy, including the design of a mandatory patient registry

Module 7: Safety Data Management and Database Systems

- Implementing Safety Data Reconciliation processes between the Clinical Data Management System (CDMS) and the PV Safety Database.
- Data Migration and System Validation requirements for PV database upgrades and transfers.
- Ensuring Data Integrity and security within global safety systems.
- Leveraging safety databases for Automated Workflow and compliance tracking.
- Case Study: Resolving complex data discrepancies identified during the interim safety data review for an ongoing Phase 3 trial.

Module 8: Pharmacovigilance in Decentralized Clinical Trials (DCTs)

- Safety reporting challenges and solutions for adverse events collected via digital health technologies
- Regulatory expectations for patient-reported safety information and its inclusion in the ICSR process.
- Developing Safety Management Plans (SMPs) tailored for hybrid and fully decentralized trial designs.
- Ensuring subject safety and data privacy compliance in a multi-jurisdictional DCT setting.
- Case Study: Creating a safety event workflow diagram for an international DCT using telemedicine visits and remote monitoring.

Module 9: Audits and Regulatory Inspections Management

- Preparing the entire organization and documentation for a **GVP Inspection** or an **FDA BIMO Audit**.
- Managing the inspection process: from the opening meeting to the daily logistics and answering inspector queries.
- Developing effective and timely responses to **Regulatory Findings**

- The role of the **Qualified Person for Pharmacovigilance (QPPV)** and their strategic responsibilities.
- Case Study: Role-playing a mock GVP inspector interview, focusing on a critical process area

Module 10: Special Populations and Unique Safety Scenarios

- Safety reporting requirements for Pediatric and Geriatric studies and their unique safety reporting challenges.
- Handling adverse events in trials involving Pregnant Women and the management of exposure registries.
- Safety considerations and reporting for Medical Devices and Combination Products
- Safety monitoring and reporting for biosimilars and generics.
- Case Study: Analyzing a safety event in an elderly population, requiring age-related causality assessment and potential protocol amendment.

Module 11: Advanced Therapy Medicinal Products (ATMPs) Safety

- Unique safety reporting criteria and endpoints for Gene and Cell Therapies and Tissue-Engineered Products.
- Long-term safety follow-up and the regulatory requirements for post-authorization safety studies.
- The role of vector shedding and insertional oncogenesis in safety surveillance.
- Managing the safety of Oncology (IO) and Vaccine Pharmacovigilance
- Case Study: Developing a long-term safety monitoring strategy for a new CAR-T cell therapy product.

Module 12: AI and Automation in Pharmacovigilance

- The application of Machine Learning (ML) for automated case processing and expedited report generation.
- Using Natural Language Processing (NLP) for efficient extraction of safety data from unstructured sources
- Evaluating and implementing Smart Automation tools for quality checks and reconciliation.
- Addressing data privacy and cybersecurity concerns related to the use of AI in PV systems.
- Case Study: Assessing a mock AI system's output on causality assessment and determining when a human review is mandatory.

Module 13: Clinical-PV Interface and Unblinding Procedures

- Strategic alignment of the Clinical Operations and Pharmacovigilance functions for seamless safety management.
- Establishing clear and compliant procedures for Unblinding in emergency situations
- Developing a robust Safety Management Plan (SMP) and charter for cross-functional safety governance.
- Managing and communicating Urgent Safety Measures (USMs) and trial modifications across global sites.
- Case Study: Simulating an emergency unblinding event and tracking the subsequent expedited reporting and regulatory communication.

Module 14: Safety Review Meetings and Data Monitoring Committees (DMC)

- Best practices for organizing and presenting data at Internal Safety Review Team meetings.
- The role, responsibilities, and communication with the Data Monitoring Committee
- Preparing and interpreting Line Listings, Tabulations, and Signal Detection Reports for review.
- Formalizing the process for recommending protocol amendments based on emerging safety trends.

- Case Study: Preparing a full safety review package for an upcoming DMC meeting, including an evaluation of aggregated unblinded data.

Module 15: Strategic PV Leadership and Crisis Management

- Developing a Pharmacovigilance Crisis Communication Plan for unexpected high-profile safety events.
- Effective Proactive Risk Communication strategies to regulatory bodies, investigators, and the public.
- Ethical and legal considerations in global patient safety and data sharing.
- Forecasting Future Trends in PV, including Digital Therapeutics and regulatory harmonization
- Case Study: Simulation of a high-profile product safety crisis with an organized response and regulatory communication strategy.

Training Methodology

This course utilizes an experiential and blended learning methodology to maximize skill transfer and practical application:

- Interactive Workshops.
- Case-Based Learning.
- Simulation Exercises.
- Expert-Led Lectures.
- Technology Demonstrations.

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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