Risk-Based Monitoring (RBM) in 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 Risk-Based Monitoring (RBM) approach is revolutionizing the landscape of clinical trials by focusing on identifying and mitigating potential risks throughout the study lifecycle. Risk-Based Monitoring (RBM) in Clinical Trials Training Course is designed to equip clinical research professionals with the essential knowledge and skills required to implement RBM strategies effectively. Participants will gain a deep understanding of how to monitor clinical trials using a risk-based methodology, ensuring higher efficiency, reduced costs, and improved patient safety. With an increasing demand for data-driven decision-making and cost optimization in clinical research, RBM has emerged as the gold standard in clinical trial monitoring, significantly reducing the burden on site management and improving the quality of trial outcomes.

The course will delve into key RBM concepts such as centralized monitoring, risk identification, and data integrity. Practical applications and real-world case studies will be used to demonstrate the effectiveness of risk-based monitoring techniques. Participants will also explore advanced methods in clinical data analysis, audit trails, and risk assessment matrices. As clinical trials continue to grow in complexity, adopting RBM strategies is becoming more critical for organizations seeking to meet regulatory compliance and optimize trial resources. By the end of this training, participants will be prepared to apply RBM principles to real-world clinical trials, optimizing trial management, improving data quality, and ensuring successful study outcomes.

Programme Curriculum

Risk-Based Monitoring (RBM) in Clinical Trials Training Course

Introduction

In today's complex and highly regulated clinical trial landscape, traditional monitoring methods are no longer sufficient. The advent of **Risk-Based Monitoring (RBM)** has revolutionized the industry, offering a more efficient and effective approach to ensuring **patient safety** and **data quality**. This paradigm shift, endorsed by major regulatory bodies like the FDA and EMA, moves away from the resource-intensive, 100% source document verification (SDV) model to a proactive, risk-centric methodology. By identifying and mitigating critical risks early in the study lifecycle, RBM allows for a dynamic and targeted allocation of resources, ultimately leading to improved trial oversight, enhanced data integrity, and significant cost and time savings.

Risk-Based Monitoring (RBM) in Clinical Trials Training Course is designed to equip clinical research professionals with the essential knowledge and practical skills required to successfully implement and manage an RBM framework. We will delve into the core principles of **quality management**, **centralized monitoring**, and **adaptive site monitoring**. Through a blend of theoretical understanding and hands-on application, participants will learn how to conduct robust **risk assessments**, define **Key Risk Indicators (KRIs)**, and develop a comprehensive **monitoring plan**. Our focus is on practical, real-world application, ensuring that you can translate theoretical knowledge into tangible process improvements within your organization, driving greater efficiency and compliance.

Course Duration

10 days

Course Objectives

1. Master the principles of **Good Clinical Practice (GCP)** within an RBM context.
2. Conduct comprehensive **protocol risk assessments** to identify critical data and processes.
3. Design and implement a robust **risk management plan**.
4. Define and utilize **Key Risk Indicators (KRIs)** and **Quality Tolerance Limits (QTLs)**.
5. Perform effective **centralized monitoring** and data surveillance.
6. Strategize and execute **targeted on-site and remote monitoring**.
7. Develop an RBM-centric **monitoring plan**.
8. Understand and leverage **predictive analytics** for proactive issue detection.
9. Navigate and ensure compliance with **ICH E6(R2)** and other regulatory guidelines.
10. Implement effective **change management** strategies for RBM adoption.
11. Optimize site performance and enhance **investigator satisfaction** through RBM.
12. Reduce clinical trial costs and timelines without compromising **data quality**.
13. Foster **cross-functional collaboration** between clinical operations, data management, and biostatistics.

Target Audience

- Clinical Research Associates (CRAs)
- Clinical Project Managers
- Clinical Operations Managers
- Data Managers
- Clinical Quality Assurance Professionals
- Study Coordinators
- Investigators and Site Staff
- Regulatory Affairs Professionals

Course Modules

Module 1: RBM Foundational Concepts

- Introduction to RBM and its regulatory context.
- The shift from traditional to risk-based monitoring.
- Core principles of quality management and quality-by-design (QbD).
- Understanding the RBM lifecycle.
- **Case Study:** Analyzing a mock clinical trial protocol to identify inherent risks.

Module 2: Risk Assessment & Management

- Techniques for conducting a comprehensive risk assessment.
- Developing a risk management plan and risk mitigation strategies.
- Categorizing risks based on probability and impact.
- Using a risk assessment and categorization tool (RACT).
- **Case Study:** Creating a risk matrix and mitigation plan for a specific study.

Module 3: Defining and Using Key Risk Indicators (KRIs)

- Defining and selecting appropriate KRIs.
- Establishing Quality Tolerance Limits (QTLs).
- Data sources for KRI tracking and analysis.
- Setting up alerts and triggers for risk signals.
- **Case Study:** Defining and tracking KRIs for a study with a high-risk population.

Module 4: Centralized Monitoring Techniques

- Principles and components of centralized monitoring.
- Statistical analysis and data review for trend detection.
- Identifying and investigating data anomalies and outliers.
- Using centralized monitoring for oversight of site performance.
- **Case Study:** Using provided data sets to identify a poorly performing site and a potential data fraud scenario.

Module 5: Developing the RBM Monitoring Plan

- Creating a comprehensive RBM-specific monitoring plan.
- Integrating centralized and on-site monitoring activities.
- Defining roles and responsibilities in the RBM model.
- Documenting the monitoring plan and its amendments.
- **Case Study:** Drafting a full RBM monitoring plan for a Phase III oncology trial.

Module 6: Targeted On-Site Monitoring

- Strategies for planning and conducting targeted on-site visits.
- Focusing on critical data points and processes.
- Techniques for efficient source data verification (SDV) and source data review (SDR).
- Addressing protocol deviations and non-compliance at the site level.
- **Case Study:** Role-playing a targeted on-site visit to a site with a high number of patient safety-related KRIs.

Module 7: Leveraging Technology for RBM

- Overview of eClinical technologies for RBM.
- Utilizing dashboards and data visualization for real-time insights.

- The role of AI and machine learning in predictive analytics.
- Challenges and best practices for system integration.
- **Case Study:** Interpreting a KRI dashboard to make real-time decisions on monitoring frequency.

Module 8: RBM Implementation and Change Management

- Strategies for implementing RBM within an organization.
- Overcoming resistance from clinical staff and sites.
- Effective communication and training plans for RBM adoption.
- Measuring the success and ROI of an RBM program.
- **Case Study:** Developing a change management strategy for a CRO transitioning to an RBM model.

Module 9: Patient Safety and Data Integrity in RBM

- How RBM enhances patient protection.
- Monitoring for safety signals and adverse events.
- Ensuring the integrity and reliability of clinical trial data.
- The role of medical monitors in a risk-based approach.
- **Case Study:** Responding to a serious adverse event (SAE) signal identified through centralized monitoring.

Module 10: RBM for Different Trial Phases and Designs

- Adapting RBM for different phases (I, II, III, IV).
- Applying RBM in specific therapeutic areas.
- Considerations for decentralized and hybrid trials.
- Addressing unique risks in rare disease and complex trials.
- **Case Study:** Modifying an RBM plan to suit a decentralized trial model.

Module 11: Audits and Inspections in an RBM World

- Preparing for regulatory inspections and sponsor audits.
- Documentation requirements for an RBM approach.
- Common findings and how to address them.
- Demonstrating the effectiveness of your RBM strategy.
- **Case Study:** Preparing a mock audit response to a regulatory finding on RBM documentation.

Module 12: Advanced RBM Concepts

- Exploring advanced statistical methods for risk detection.
- The future of RBM: from reactive to proactive and predictive.
- Using AI to automate risk identification.
- Integration with other quality management systems.
- **Case Study:** Presenting a vision for a fully predictive RBM model using emerging technologies.

Module 13: RBM in a Global Context

- Addressing regional and country-specific regulatory requirements.
- Navigating cultural differences in RBM adoption.
- Establishing a global RBM framework.
- Ensuring consistency across international sites.

- **Case Study:** Analyzing a global trial scenario with varying regulatory requirements and adapting the RBM strategy.

Module 14: Measuring RBM Performance and ROI

- Defining metrics for measuring the success of RBM.
- Calculating cost savings and efficiency gains.
- Demonstrating improved data quality and patient safety.
- Reporting RBM performance to leadership and stakeholders.
- **Case Study:** Developing a presentation for a senior leadership team on the ROI of implementing RBM.

Module 15: Capstone RBM Simulation

- A full-scale, hands-on simulation of an RBM-driven clinical trial.
- Participants work in teams to apply all learned concepts.
- Activities include risk assessment, KRI monitoring, centralized data review, and site management.
- Teams must make strategic decisions and respond to real-time events.
- **Case Study:** A comprehensive, multi-phase simulation where teams must manage a full clinical trial from start to finish using RBM.

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

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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