Risk Management for Clinical Research

Ensure you meet the latest regulatory requirements – also relevant for pharmacovigilance and regulatory affairs

23 September 2019 • 23 March 2020 London

Book before 9 August 2019 and SAVE £100/€140

Benefits of attending:

- Understand risk management tools and when and how the tools are used in clinical research projects
- Learn how to plan risk-based approaches, how to document and where to focus to meet regulatory requirements and expectations
- Develop and apply risk management principles and tools to your clinical trials, including risk-based monitoring
- Identify and share best practices for implementing risk-based tools and principles

Expert trainer:

Dr Laura Brown
Independent Pharmaceutical Training Consultant and Course Director of the MSc in Clinical Research, School of Pharmacy, University of Cardiff

‘A fabulous overview of risk management throughout the industry. Laura’s energy, knowledge and enthusiasm were excellent.’

Christine Henderson, ADAMAS

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FEE: The fee includes all meals and refreshments for the duration of the course and a complete set of course materials. If you have any particular requirements, please advise customer services when booking.

PLEASE NOTE: Management Forum Ltd reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, Management Forum will refund the registration fee and disclaim any further liability.

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Risk management is becoming increasingly important to running clinical trials and ensuring compliance with regulatory expectations. There are now numerous pharmaceutical guidelines covering risk management including ICH Q9 and the revised ICH GCP R2 guideline.

This essential one-day course will explain the importance of using risk management techniques in clinical research to comply with the latest focus on inspection in this area. It will show you how risk management can improve the quality of your clinical trials and demonstrate the importance of using risk analysis and risk management techniques in clinical trials and risk-based monitoring. You will learn how to identify, evaluate and implement specific risk-based techniques for risk management used in clinical trials.

This course will enable you to develop quality risk management principles applicable to clinical research, as well as to identify and share best practices for implementing risk management tools and approaches.

Who should attend?
Anyone working on clinical trials including CRAs, monitors, clinical managers, project managers, lead clinical research associates, data managers, statisticians, study managers and those in QA/audit/QC and document management. It will also be relevant to those who work alongside the study team, such as regulatory affairs and pharmacovigilance.

Introduction and objectives
- Why risk management is important
- Definitions of key risk management terminology
- Brief overview of regulations and guidelines which cover risk management applied to clinical study-level risk management

Risk-based quality management system (QMS) – what does this really mean? How does it look?
- What are the elements of a QMS which include risk?
- What a regulatory inspector would expect to be in place for clinical trials
- Group discussion on using a clinical QMS, including risk

Risk-based processes/tools and techniques
- Examples of risk management processes
- Risk-based tools including:
  - Root cause analysis
  - Risk breakdown structure
  - Risk log
  - Failure modes and effects analysis (FMEA)
  - Risk matrix
  - Examples of pharmaceutical risk tools for clinical trials including RACT (Risk Assessment Categorization Tool)

Risk-based approach to the protocol
- Quality by design (QbD) applied to the protocol
- How this is being applied to the design of protocols

Risk-based approach to monitoring
- Different approaches to risk-based monitoring and examples of how this is carried out
- Discussion of what approaches and documents are used
- Case study example

Brief review of risk-based approaches to QC/QA (auditing)
- Example of best practice guide – RQA (Research Quality Association)

Final discussion session

Summary and close

Previous attendees have said:
‘Very interesting training, excellent for a clear and well-structured introduction to risk management in clinical research.’
Myriam Mouhib, JT International