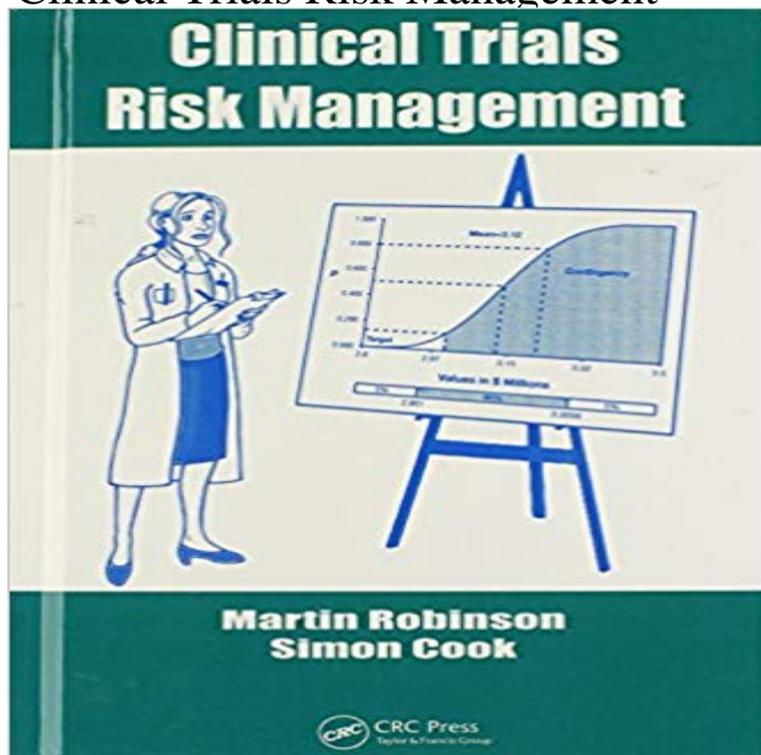


# Clinical Trials Risk Management



Drug development is risky business. It is against the backdrop of huge financial, scientific, technical and medical risks that a clinical trials manager is expected to function, effectively identifying and managing all project risks, to deliver a successful outcome. Focusing on the day-to-day needs of a clinical trials manager, *Clinical Trials Risk Management* explains the key concepts and principles of risk management, as well as showing how best to apply them directly to real life clinical trial situations. After building a foundation of basic principles, the authors lead you through specific methods for handling the risks characteristically encountered in clinical trials. Their combined years of experience in pharmaceutical research and development shine through the narrative, making the prose both lively and informative. They discuss concepts using worked examples and include a summary of the main points at the end of each chapter. In addition to diagrams and Risk and Precision Tree charts, the text is sprinkled with humorous line drawings that reinforce the concepts. After reading this book, you will know how to: Prepare a Risk Assessment Design an Impact-Probability Matrix Compile a Risk Register Run a Monte Carlo Simulation Set up a Project Decision Tree Plan preventative and contingency actions The stand-alone chapters provide easy access to topics, while anecdotal and visual examples make them easy to remember. Martin Robinson and Simon Cook deliver a clear interpretation of complex information, thus saving you the time it would take to wade through a lengthier text, adopting a straightforward approach to examining clinical trials from a risk managers perspective. A practical, readable guide, the book is filled with information that can be put to immediate use to improve current or planned clinical trials.

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**has been rather under-used in drug - PPD** Defining the risks of the IMP using a simple IMP risk categorisation (Type A,B and C) The Risk-adapted Approaches to the Management of Clinical Trials of Jul 2, 2014 By Jane Tucker. Independent Risk Management Consultant and Trainer. ICH Q9 is the ICH guideline on Quality Risk Management, and relates **Clinical Research Risk Management Risk Management and** Apr 1, 2012 Risk Assessment and Mitigation. A quantitative approach to enhancing risk assessment and mitigation in drug development. Regulatory authorities routinely conduct inspections to ensure compliance with good clinical practice (GCP) in the conduct of clinical trials sponsored by pharmaceutical companies.