eclipse clinical technology

RIGHT SOLUTIONS. RIGHT NOW.

Risk Based Monitoring (RBM)

Drug costs are soaring. The pharmaceutical, biotech and CRO industries are more competitive than ever before. Companies like yours are looking for ways to reduce expenses and increase efficiency. Eclipse offers RBM services that help customers better allocate resources while maintaining quality data and ensuring patient safety. Our innovative technology solutions coupled with the knowledge of our expert team make our RBM program one of the most effective in the industry.

What is Risk Based Monitoring?

Clinical on-site monitoring is one of the most costly factors of a clinical trial. RBM is an alternative monitoring strategy that uses reduced source data verification (SDV). It is a strategic approach intended to streamline efforts by enabling companies to allocate resources based on identified risks related to patient safety and data integrity.

Traditionally, clinical trial teams have had to allocate equal resources to all trial sites, regardless of need. But recently, U.S. and E.U regulatory agencies have expressed support for a risk based model which allows teams to allocate resources based on risk and needs.

An effective RBM strategy allows you to optimally use your time by focusing on the most important data and trial factors. You'll also mitigate risk by proactively identifying potential problems before they arise.

Eclipse's approach to RBM

Eclipse has decades of experience partnering with leading and emerging pharmaceutical, biotechnology and CRO companies. We also benefit from close working relationships with the FDA and extensive regulatory experience. We rely on innovative technology and the brightest minds in the business to manage every step of your clinical trial monitoring. Our approach is always forward thinking so that we can proactively identify and address potential data and protocol issues that may cause

Eclipse Risk Based Monitoring Benefits & Capabilities

- **Allocate resources more efficiently, ultimately saving time and money**
- **Reduce site monitoring costs**
- **Improve data quality by freeing up time for site monitors and investigators**
- **Identify and eliminate redundancies**
- **Foster collaboration between sites and site managers**
- **Prioritize data and study factors more effectively**
- **Proactive approach helps you identify problems before they occur**
- **Work with eclipse's team of seasoned experts to better analyze and understand data and make informed decisions more quickly**
- **RBM approach is optimized by using eclipse's cutting-edge technology solutions to further increase efficiency and save time and money**

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problems further into a study. This ensures strategic allocation of time and resources, on-time and on-budget database lock and data that is clean, regulation-compliant and analysis-ready.

As part of the RBM process, we identify key factors such as protocol, data integrity and patient safety and monitor them throughout the length of the study. We'll help you identify and eliminate redundancies and foster collaboration between sites and site managers. With our help, you'll better analyze and understand data and make quicker, more informed decisions.

The role of technology

RBM is most effective when used in tandem with innovative technology solutions. Eclipse's remote data capture (RDC) and clinical trial management systems (CTMS) support a Risk Based Monitoring approach. Our suite of technology solutions allow for easier and more accurate real-time data collection, standardization,aggregation, analysis, reporting and risk and operations management, maximizing the performance and cost effectiveness of your clinical trials. In short, they help you make the RIGHT decision every step of the way.

Our secret? Our people.

With university origins and continuing academic ties, our biostatisticians ensure they're abreast of cutting-edge methodologies. They also continually participate in rigorous training sessions to reinforce fundamental practices. To guarantee the integrity and accuracy of study data, our data management team strictly adheres to established and proven internal quality processes.

Eclipse's senior scientists enjoy close working relationships and frequent dialogues with the FDA, possess extensive regulatory experience and have held governance roles within the Drug Information Association (DIA), American Statistical Association (ASA) and Society for Clinical Trials (SCT).

Our entire team is passionate about customer service. We will work with you every step of the way, ensuring you understand the ins and outs of RBM, and reap as many benefits as possible from the increasingly popular strategy.

Why Eclipse

Eclipse is a clinical technology company that collaborates with you to deliver the RIGHT technology solutions and data management services to ensure your clinical trial is a success. We're ISO9001:2008 registered, a testament to our commitment to providing products and services that meet customer and legal requirements. Through our partnership with Oracle and with our own proprietary products, we help companies leverage best-in-class technology solutions, but it's our unwavering commitment to client satisfaction that separates us from the competition. We are not satisfied until you achieve your goals - a trait our customers affectionately refer to as a genuine obsession with client service.

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