All Monitoring IS RISK BASED

Contributed By:

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Drug developers must introduce innovation across the entire life cycle of product development to more effectively bring new therapies to markets. The innovations will be recognized by the use of smarter and faster methods for discovery of new drug entities and companion diagnostics, use of flexible trial designs, implementation of an end-to-end clinical trial platform, and the successful leverage of business intelligence tools. In particular, clinical trial monitoring will benefit through the design of higher quality protocols and processes, and more effective management of risks to patients, trial endpoints, data integrity, and commercial objectives. Often, risk-based monitoring is recognized as a potential point of innovation within overall trial monitoring.

Evaluation of Risk

Risk-based monitoring is a popular buzz term in our industry, however, all monitoring has been, and will continue to be, fundamentally risk based in nature, regardless of the type of strategy or percentage of source documentation review required. Ultimately, all aspects of clinical trial monitoring begin with the end in mind — protecting patients; delivering high-quality, reliable data; overall compliance with good clinical practice and regulations; and maximizing the value of the drug development investment. Therefore, an adaptive approach to all aspects of the clinical trial process — starting with early protocol development through the entire life of the product development — is the most effective foundation for a risk-based monitoring and trial management strategy.

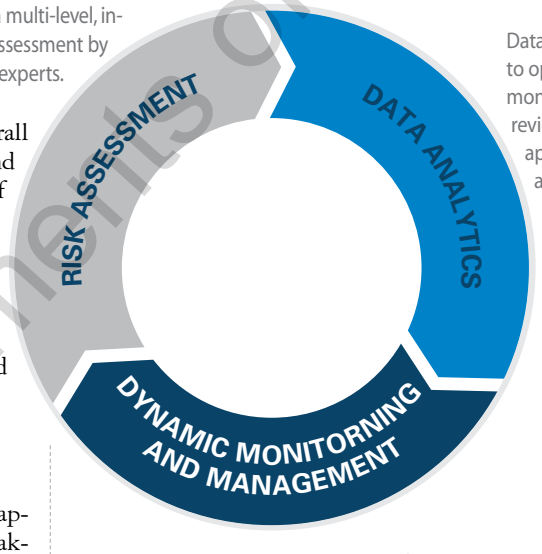
Beginning with the End in Mind

We believe a data-driven, adaptive approach to risk management and decision making should be applied to all trials, regardless of the source document percentage, monitoring frequency, or use of centralized resources. It is critical to develop the adaptive monitoring approach with the end in mind and then develop a comprehensive risk assessment and data-driven strategy for delivery of the program or trial. Each clinical trial should be evaluated and optimized by adaptive monitoring techniques during, or even before, completion of the final protocol. A variety of factors can influence the overall approach, including:

- Study phase and design
- Primary and secondary study objectives
- Safety profile of product/device
- Treatment paradigm and standard of care
- Complexity of study-specific requirements
- Number of subjects as well as statistical methodologies to reduce sample size
- Patient-centric approach for determining country and site placement
- Site profile (ie, research naïve, patient care pathways)
- Study duration
- Geographic regions
- Availability of real-time data from the patient or site
- Number of vendors contributing data

Considering the possible combinations of complex factors, it is obvious that risk-based monitoring is not a one-size-fits-all strategy. Therefore, an effective risk-based strategy would encompass a near constant cycle of risk assessment, real-time analytics to detect signals of risk and determine root cause, and adaptive decision making and strategy.

Adaptative monitoring trial execution starts with a multi-level, in-depth risk assessment by study team experts.



Data analytics allow us to optimize and adapt monitoring and data review procedures and apply the right actions at the right time.

Dynamic monitoring and management (on-site, centralized) driven by analytics.

Taking an Adaptive Approach

Through the integration of systems, data, processes, and clinical trial expertise, a clinical trial platform is able to manage the significant volume of trial data and protocol complexity required for effective decision making and timely risk mitigation, yet still provides each client the flexibility to configure the clinical monitoring strategy according to the risk profile of their asset, protocol, or individual company requirements. Specifically, the concept of adaptive monitoring would apply to all services, not just site monitoring — the site monitoring plan would be derived based on quality requirements and statistical methodologies, rather than random sampling or estimated percentages of source document verification; the use of centralized (remote) monitoring for risk/issue detection and resolution would be considered based on a careful assessment of value and the alignment with investigator relations; risks and issues for all sites and services would be managed within global work flows to ensure timely, complete resolution and regulatory documentation.

With an end-in-mind approach to quality, a clinical trial platform should ensure that all clinical trials benefit from use of a wide range of data sources for trial optimization, powerful analytics, and agile decision making, while maintaining flexibility for the overall monitoring frequency, source document verification percentage, or to accommodate a customer's comfort with less traditional monitoring methodologies. PV

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COMPREHENSIVE PHASE I-IV BIOPHARMACEUTICAL DRUG DEVELOPMENT

PRA Health Sciences is working to provide our clients with a number of advanced monitoring options that empower them to choose what study data to verify. These customized alternative-monitoring strategies result in a positive impact across all clinical development studies, from data integrity and study efficiency, to on-site visit frequency.

By providing innovative solutions for our clients we move drug discovery forward and develop life-saving and life-improving drugs. We help change people's lives for the better every day. It's who we are. Innovating to help people is at the heart of our process, but it's even more than that. It's also our privilege.

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