RISK BASED MONITORING

SUCCESSFUL ADOPTION OF A RISK BASED APPROACH TO CLINICAL MONITORING.

HighPoint FOR LIFE SCIENCES

WHAT IS RISK BASED MONITORING (RBM)?

Clinical Monitoring is the practice of assuring that human research subjects' rights and well-being are protected, research data is accurate and properly recorded, and research protocol is properly understood and complied with. Traditional clinical monitoring accomplishes this with frequent clinical site inspections by qualified site monitors.

RBM is the practice of assessing specific and systematic risks, investigating and mitigating them in a focused and targeted manner. RBM may result in fewer site visits over the life of a clinical trial, and more site visits and investigative focus in areas and sites that need it most.

WHY ADOPT RBM?

Several factors compel and enable sponsors to adopt a risk-based approach to clinical monitoring. The first is regulatory. With ICH E6(R2), there is incontrovertible support and encouragement for risk-based monitoring. Sponsors realize that this regulatory push is a quality by design measure that not only promotes higher data quality, but also makes the most efficient use of their research resources.

Emerging and established technologies are converging to allow remote, central and sophisticated tracking of trial progress and identification of problematic data and performance. These technologies assist site monitors in navigating increasingly complex trial protocols. These converging influences (regulatory, a drive for quality, the need for increased efficiency, enabling technology, and more complex clinical trials) are driving the adoption of risk-based clinical monitoring.

KEY DRIVERS FOR RBM:

Enabling Regulatory Shift	Enabling New Technology	Increased Protocol Complexity	Increased Trial Cost	Desire for Improved Trial Execution	Desire for Smarter Resource Allocation
• ICH E6 (R2) • FDA & EMA Guidelines	• EDC • eCOA/ePRO/eDiary • BYOD, Mobile apps • eConsent, RBM • Tighter integrations	• Challenging Indications • Immunotherapy, Genetics • Adaptive Trial Designs	• Competition for sites and patients • More data required	• Identify GCP and data issues earlier while intervention is still possible	• Focus limited resources based on risk

CHALLENGES YOU'LL FACE

Adopting RBM can be challenging. Some organizations are reluctant to fully adopt the approach for these three reasons:

01

Fear that the Risk Based Approach will fail to identify a risk.

Though ample research and case studies of successful implementations clearly show that RBM is more effective than traditional monitoring, stakeholders in some organizations may be concerned about being held accountable for undetected problems.

02

Service providers have few incentives to change their monitoring approach.

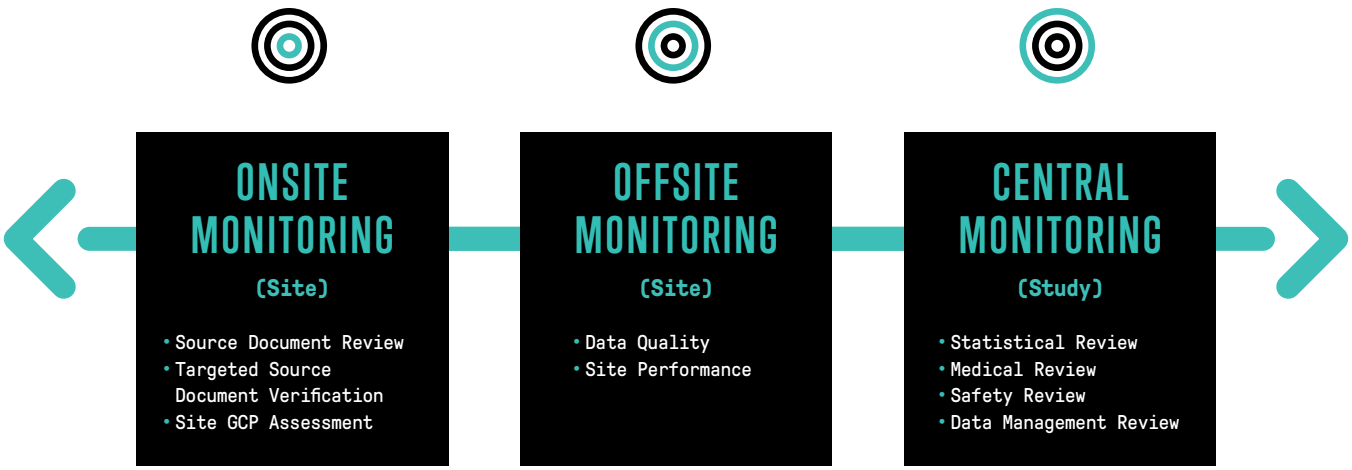
The reality is that most Contract Research Organizations (CROs) are optimized to deliver traditional Clinical Monitoring, and many of their customers are not demanding a Risk-Based approach. Some CROs are partially adopting RBM, some have a skilled RBM team, and there remain many teams with inadequate experience in the area.

03

Skilled staff to conduct Central Monitoring are in short supply.

Central Monitoring - the remote assessment of trial risks requires an understanding of clinical trial operations, clinical data and advanced analytical tools and techniques. Individuals with these skills are almost always engaged in traditional clinical research activities: statistical analysis, data management, project management and traditional clinical monitoring. Only forward-thinking sponsors and CROs will redeploy these talents in new areas.

THE TIERS OF MONITORING



HOW CAN HIGHPOINT HELP?

HighPoint Solutions is uniquely positioned to provide both consulting and functional service provider (FSP) services for Risk-Based Monitoring. We embrace RBM as an opportunity to transform the way we conduct clinical trials and take pride in providing factual, evidence-based advice and solutions as an objective third party with no financial interest in the clinical trial execution.

CONSULTING

For companies wanting to establish or mature their in-house RBM capabilities, our team brings experience and qualifications to help you throughout the project lifecycle:

ASSESSMENT AND ROADMAP

Whether your organization is new to RBM or already has some experience, we can help you define a robust RBM framework, assess your current situation and maturity, identify areas for improvement, define your desired future state and develop a realistic roadmap to get there, taking relevant constraints into consideration.

VENDOR SELECTION

Based on our proven approach to vendor selection, our experience and in-depth knowledge of the technologies available on the market, we can help you select the right RBM solution.

IMPLEMENTATION

Establishing an operational RBM capability takes more than technology, and we can help you get there. We can:

01: manage the project and the organizational change;

02: provide experienced experts to work with your team to define or re-design business processes and develop a robust, industry-compliant solution design;

03: manage the validation of the solution;

04: develop and/or update Standard Operating Procedures and working instructions;

05: develop and execute training of your teams

FUNCTIONAL SERVICE PROVIDER (FSP)

For sponsors that wish to adopt an FSP approach to RBM, our experienced and skilled team provides Centralized Monitoring as a Service working with you and your partners. We guide stakeholders through the risk assessment process, complying with the Risk Assessment Categorization Tool, or other Risk Assessment tools. We write the RBM elements of the Monitoring and Data Management plans. We configure the analytics reports and risk workflows, and provide the central monitoring service; a regular, in-depth review and interpretation of the analytics and aggregate data. We then document each review, and act upon emergent risks.

Centralized Monitoring as a Service is provided on an interim basis, allowing your organization to establish an operational RBM capability, or for the entire life of the clinical trial.

WHY HIGHPOINT

At HighPoint, our consultants bring an average of 13 years of personal industry experience to each and every engagement. We support life sciences companies at every project phase to deliver business value and competitive advantage to clients worldwide.

For more information, please contact our experts in Europe or the United States. We can discuss the state of risk-based monitoring for your ongoing and upcoming trials, and are excited to help.

FREDERICO BRAGA
Senior Director
Life Sciences Europe
+41 79 555 58 65
Frederico.Braga@
highpointsolutions.com

JENS-OLAF VANGGAARD
Director
R&D Practice, Europe
+41 76 587 3907
Jensolaf.Vanggaard@
highpointsolutions.com

LEE WALKE
Director
R&D Practice, U.S.
+1 859.446.6842
Lee.Walke@
highpointsolutions.com