

Medidata Risk-Based Monitoring Service

Enhanced Adoption of Risk-Based Monitoring

Despite the ever-increasing volume of information on risk-based monitoring (RBM), today's available guidance is often not detailed enough for life sciences organizations to successfully design and implement a holistic RBM strategy.

That's why Medidata's Strategic Consulting Service is dedicated to providing robust and ongoing support to our business partners as they transform their internal operations to implement an RBM program. By collaborating with over 400 biopharmaceutical companies and accumulating one of the largest data troves in the industry, we've developed unmatched expertise and experience in clinical trials. As such, Medidata is well positioned to act as a trusted advisor to organizations as they transition to an RBM methodology—helping them to reduce trial costs and increase site quality.

Medidata Strategic Consulting Services offers a turn-key solution that can establish or enhance our client's RBM strategy through risk management planning, reduced source document verification (SDV) strategies, centralized risk detection, targeted monitoring and compliance tracking.

Review Existing Monitoring Program to Identify Strategies and Objectives

In order to prepare for the RBM strategy workshops, our consultants review existing operational processes and interview key stakeholders in order to have a complete understanding of the client's current monitoring strategy. If an RBM strategy has already been conceptualized or put into practice, Medidata will review this "as-is" scenario against best practices observed across all of our customers. Our goal is to enhance any existing strategy and build upon the existing foundation.

Organizational preparedness through stakeholder communication and identification of objectives

With any large transformational initiative, it is imperative to prepare your organization for the changes to come. Providing clear, ongoing communications to your internal organization and preferred partners will effectively facilitate the RBM adoption process. Our consulting team has experience with establishing communication plans and internal governance models that actively prepare organizations for transformation.

Medidata Professional Services

Medidata professional services offer unmatched expertise in clinical trials and broad expertise across study phases and therapeutic areas. Whether you are a leading multinational sponsor, an innovative medical device start-up or a CRO, Medidata professional services has the skills and experience to meet your needs.

Medidata Study Implementation Service delivers fast, flexible, optimally designed trials. Our proven methodology and consultative approach will save you time and money.

Medidata Sponsor Enablement Service lets you continuously realize the full value of your Medidata solution. Training and mentoring enable you to take full ownership of your clinical trial systems and process.

Medidata CRO Support Service extends the full expertise of Medidata professional services to our CRO partners.

Medidata Strategic Consulting Services offer expertise in outsourcing governance, protocol design review, trial design and randomization, risk-based monitoring strategies and more.

As-is analysis of existing documentation and key stakeholder interviews

In order to customize our solution for each customer, Medidata strategic consultants will perform a current state analysis of important areas and documents (including SOPs, templates, work instructions, job descriptions and KRI reports) in order to fully understand each client's corporate goals and objectives. This as-is analysis will provide the opportunity to identify potential procedural gaps based on a comparison of existing industry best practices.

Performance benchmarking using data analytics to identify opportunity gaps in key business metrics

Part of the current state analysis is evaluating key performance metrics from the Medidata Insights™ database to determine how each customer measures up against industry medians. By performing this benchmarking, the customer will be able to quantify the potential opportunity to improve both cost and quality value drivers through their RBM program. This process will also serve as the baseline measurement for the improvements implemented through our Strategic Consulting Services.

Establish RBM Blueprint Through Structured Workshops and Best Practices

In order to build and deploy a fully operational RBM strategy, each client needs to design how the organization will execute on this transformational model. The initial step is to create a blue print that provides the necessary specification to build the strategy based on an existing structure or from scratch. Our Strategic Consulting Services will create draft blue prints that are reviewed during the workshops and will revise these drafts based on customer feedback.

Develop optimized RBM blueprint based on industry best practices and initial discovery

Following the current state discovery phase, the Medidata Strategic Consulting team will customize existing Medidata RBM collateral in order to adapt the content to each customer's organization and business objectives. This customized collateral will enable our team to facilitate a kick-off RBM strategy workshop with cross-functional attendees to create a blue print that defines all of the components and timelines necessary to launch an enhanced RBM strategy

Conduct workshop series to present initial blueprint, collect additional client feedback and enhance blueprint

Key stakeholder feedback will be solicited during the RBM workshops to refine the customized collateral and ensure organizational support for the optimized blue print. The final blue print will include an organizational design, process maps, roles and responsibilities, and operational templates and tools. Additionally, the blue print will define all of the necessary materials that need to be developed and delivered as part of the rollout of the solution.

Strategic Consulting Services

By powering a significant portion of the world's clinical trials, Medidata has developed unique expertise in R&D change management and business process optimization. Available strategic services include:

Risk-based monitoring

Reduce trial costs and increase site quality by developing a strategic monitoring program based on effective risk assessment and categorization.

Facilitated study design and review

With optimal protocol and study design you can streamline and enhance trial processes and decrease your overall study cost and complexity.

Outsourcing and CRO governance

Reduce costs and risk through optimal outsourcing governance, CRO selection and data-driven management processes.

Supply chain optimization

Reduce costs and create a demand-driven supply chain. Apply best practices in packaging design, supply distribution strategy, external network integration and randomization design.

Business transformation

Drive best practices and optimal study design through business transformation, change management and analytics and benchmarking.

Define success criteria and business objectives to measure value achievement

Part of the strategy workshops will be to establish success criterion that align with the customer's corporate business objectives. Key performance indicators will be defined and measured over time to ensure value attainment. These KPIs will then be included in a value-based dashboard reviewed during future steering committee meetings.

Accelerate Organizational Adoption of RBM Strategy

Once a blue print has been established, the work effort increases dramatically as companies start to build their RBM solution. Many companies have spent over one year implementing their RBM solution based on the level of change required to roll-out and scale a global solution. The Medidata Strategic Consulting team is capable of expediting this adoption process by using our expertise to guide customers through this process, allowing their internal teams to stay focused on executing their existing clinical trials.

Implement RBM blueprint through project roadmap

As with any project, having a very detailed project plan is essential to drive the organization through the necessary steps to deploy the final solution. Medidata will build a project roadmap that includes a recommended project charter, detailed timelines and project assumptions, resourcing requirements and critical path decision points. Our clients can execute the RBM roadmap themselves, or our consulting team can be engaged to establish a project management office to lead the implementation of the roadmap.

Roll out new processes and mobilize organization

During roadmap implementation, there will be defined steps that continue to prepare the organization in a stepwise approach. Company-wide updates will keep the organization informed of progress and when they can anticipate getting involved. Team members closely involved in the implementation will be briefed as needed and put through a rigorous, detailed training plan.

Continuously measure value attainment through ongoing governance model

A cross-functional Medidata team will periodically meet with customers to assess the ongoing value attainment of their RBM program based on the initial objectives. Whenever actual measurements vary from projections, our consultants will support additional analyses to identify the root cause. Based on this analysis, recommended corrective actions will be presented and reviewed during the steering committee.

About Medidata

Medidata Solutions is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud® brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

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Medidata Support for Success

The Medidata professional services team is ready to help your life science organization realize the full potential of the Medidata Clinical Cloud®. We offer industry-leading expertise in clinical trial processes and technology, and broad knowledge and skills across study phases and therapeutic areas. To get started, contact your Medidata account manager or services project manager, or email us at

MedidataConsulting@mdsol.com.

Medidata Clinical Cloud®

Cloud-based clinical research solutions | Innovative technology | Data-driven analytics
Reduced costs | Improved time to market | Faster decisions | Minimized risk