Readiness Assessments for Sponsors

Your first step: Understand your organizational readiness to push your business forward

Life Science organizations are facing unprecedented transformation. New regulatory requirements, acceleration of M&A activities, and advances in technologies drive fierce competition and declining margins. Required to proactively optimize their approach to clinical trial management, Sponsors have to adopt new risk-based monitoring (RBM) practices, while maintaining the highest standards in technology and transparency.

While navigating the increasing complexities to conduct and accelerate accurate, timely, and cost-efficient studies, Sponsors are positioned to transform at a faster pace, improving performance and safeguarding profitability.

Through its portfolio of Readiness Assessments (RAs), the Medidata Strategic Consulting Services experts partner with you to identify gaps, assess existing tools and resources, understand best practices, and move towards streamlined and understand decision-making.

Determine your Clinical Trial readiness

Identify gaps and opportunities to optimize your clinical trials. Map out your systematic, prioritized, risk-based approach to monitoring. Deploy technology, such as electronic capture, storage, and integration of study data and documentation, to proof your trials. Optimize payment management to reduce losses and deliver transparency.

Highlight value added activity

Uncover practices and tools drive a value added approach. Eliminate wasteful or redundant effort in your trial execution. Reduce R&D spend through sub-optimal practices. Transform to a cost-efficient model.

Lead with competitive advantage

Understand how to advance your team's ability to be a leading-edge operator. Set specific workstream charters that allow teams to evolve from existing baseline process to a new innovative way of working.

WHY MEDIDATA'S STRATEGIC CONSULTING SERVICES

RANKED #1

As part of the industry's #1 Professional Services[1], we support you with:

- Over 10+ years of experience in areas of focus
- Agnostic analysis of people, process, and system paradigms
- Proven success in aligning strategic vision to strategic initiatives

"We have a very good understand of our entire program beginning with Phase I all the way through to Phase III, and know ahead of time that we plan to start as a single site in Phase I, and rapidly expand as a global program."

John Lee
Chief Medical Officer
PHASE Bio

45%

of life science CIOs ranked Enterprise Content Management as a top priority based on company spending plans in 2016-2017[2]

We work with you to identify and overcome sub-optimal practices by delivering assessments across multiple areas of focus:

Data Management Optimization

Your RA will map out strategies to manage data deluge, drive efficiency and quality in data management practice

- Analyze current data collection methods and strategy
- Review use of third-party data and data workflows
- Analyze data governance and standards compliance
- Analyze data cleaning/data quality practices to ensure streamlined DBL procedures

Rave Risk Based Monitoring (RBM)

Your RA will outline how to implement consolidated, cross-functional data quality and risk management capabilities

- Assess current RBM process and tool use
- Examine quality and agility of business processes
- Translate risk assessments into actionable data and on-site monitoring processes
- Understand how to program effective KPIs and metrics to oversee data quality and compliance
- Analyze how to create a closed-loop process

Rave Site Payments

Your RA will identify ineffi ciencies around payment quality and frequency to support site satisfaction

- Analyze cost accrual to last-mile disbursement process
- Review payment frequency and impact on site satisfaction
- Assess financial reporting and process impacts

Rave eTMF

Your RA will recommend improvements to document processing and audit readiness

- Evaluate content creation and collection business processes
- Examine workflows and approval process
- Assess audit readiness capabilities and associated activities
- Analyze impact of eTMF visibility, collaboration, and compliance

1. Survey of Life Science end-users and decision makers in July 2017. N=120. Survey conducted by Life Science Strategy Group in partnership with Medidata Market/Competitive Intelligence. Score against Oracle, Parexel, Bioclinica, Veeva, IQvia and Covance.

2. 2017 CIO Agenda: A Life Science Perspective, Feb 2017, Stephan Davies, Michael Shanler

About Medidata Solutions

Medidata is reinventing global drug and medical device development by creating the industry's leading cloud-based solutions for clinical research. Through our advanced applications and intelligent data analytics, Medidata helps advance the scientific goals of life sciences customers worldwide, including nearly 850 global pharmaceutical companies, biotech, diagnostic, and device firms, leading academic medical centers, and contract research organizations.

The Medidata Clinical Cloud® brings a new level of quality and efficiency to clinical trials that empower our customers to make more informed decisions earlier and faster. Our unparalleled clinical trial data assets provide deep insights that pave the way for future growth. The Medidata Clinical Cloud is the primary technology solution powering clinical trials for 18 of the world's top 25 global pharmaceutical companies and is used by 18 of the top 20 medical device developers—from study design and planning, through execution, management, and reporting.

info@mdsol.com | mdsol.com
+1 866 515 6044