

Medidata Sponsor Enablement Service

Medidata Professional Services

Continuously Realize the Full Value of Your Medidata Solution

The Medidata Sponsor Enablement Service is dedicated to helping clients get the most out of the Medidata Clinical Cloud™, reducing study costs, accelerating timelines and lowering risk.

The first phase of engagement is to help clients simplify, standardize and optimize their clinical trial processes, based on industry best practices. Medidata consultants work closely with client teams, providing training and mentoring on Medidata solutions so that the client develops the capability to autonomously create efficient, best-practice studies, without being dependent on contract research organizations (CROs) or Medidata. Simplification, standardization and self-sufficiency drive significant cost savings.

The emphasis of the enablement service then transitions to continuous process improvement, achieved both through progressive adoption of the Medidata Clinical Cloud and ongoing process refinement. As a result, clients experience a continuous acceleration of their studies.

Throughout the engagement, Medidata provides comprehensive program management, including project management, performance management and client advocacy, greatly reducing risks typically associated with systems and process enhancements.

Reduce Study Cost through Simplification and Standardization

Configuration and build enablement

Our configuration and build enablement service is customized to the unique needs and business strategy of each client. By sharing our broad and deep expertise, we empower our clients' study teams to become proficient in creating efficient, best-practice studies using our solutions.

We provide training, mentoring and support on specific application areas that may include study design, form design with edit checks and custom functions, randomization, supply management, coding, safety reconciliation, patient reported data, site contracting and site payment.

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.

Business process optimization

Medidata professional services works closely with the client to evolve and optimize their clinical trial business processes. By implementing innovative applications and sharing industry best practices (acquired from more than 8000 studies gathered from over 400 sponsor organizations), clients will enjoy the cost savings inherent in running the fastest and best-quality studies possible.

Installation (URL) management

The Medidata Clinical Cloud is designed to support and maximize reusability and open standards, resulting in greater study quality and efficiency (e.g., the reuse of a standard set of forms and functions). Medidata also offers reusable standards-based tools that enable you to import and export data and integrate the Medidata platform with third-party systems. Medidata uses open standards including CDISC, ODM and Web Services. Our professional services team works with clients to install and manage the tools to maximize reuse as well as leverage data flows between systems and processes.

Speed Time to Market through Continuous Process Improvement

Operational consulting and advisory services

During the initial phase of our Enablement program, clients often opt to focus on a specific business area and set of Medidata technology (like electronic data capture with Medidata Rave®). Since Medidata's extensive SaaS-based product line is always evolving—with new products like Medidata Patient Cloud™ for patient data capture being delivered over time—operational consulting and advisory services enables clients to efficiently adopt new product capabilities and explore and implement additional products at their own pace.

Continuous process improvement

Continuous process improvement enables clients to progressively refine and improve their clinical development approach. Every client is different, and each will move forward at a distinct pace with specific business objectives. Medidata supports each client's evolution as a partner with a shared goal of optimizing and accelerating clinical studies.

Clients may decide to adopt risk-based monitoring, optimize supply management or randomization, reconcile safety data or optimize study design approaches.

Ongoing training and support

Medidata provides training and support to accompany new capabilities within the Medidata Clinical Cloud, new product adoption and new members of the client teams.

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.

Lower Risk with Comprehensive Program Management

Program and project management

Medidata Sponsor Enablement Service is a repeatable service that is governed by an industry-specific, proven and evolving methodology that includes underlying templates and documentation, training and workshops around business process and optimization.

Medidata minimizes risk through comprehensive program management, tailored to the specific needs of a client and based on real-world experience and industry insights. Our team takes approaches that have been proven to be successful and avoid potential pitfalls.

Operational performance management

To ensure business goals are met, a custom set of key performance indicators (KPIs) that reflect their strategic objectives are established for each client.

Examples include monitoring cost reduction, reducing time to study go-live, decreasing protocol amendments, faster data analysis or accelerating study completion time.

By explicitly defining success and measuring attainment throughout the program, Medidata ensures that the unique needs of each client are met. We refer to this approach as “operational performance management.”

Client advocate

The core Medidata team assigned to the client will include project management resources, such as project managers or directors and implementation consultants, augmented by subject matter experts on various aspects of functionality to support workshops or training.

Throughout the program, Medidata professional services develops a deep knowledge of the client, their business strategy, and processes and application of Medidata solutions, and is therefore able to serve as a client advocate. Our team identifies a single point of contact at Medidata and within the client in order to bring continuity and the ability to optimize activities towards the client’s desired outcome.

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**.

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 Clinical Cloud™

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