Medidata Study Implementation Service

Fast, Flexible, Optimally Designed Trials

With Medidata Study Implementation Service, Medidata builds fast, flexible and optimally designed trials on behalf of sponsors and their CRO partners. Medidata has unmatched expertise and experience that ensures that your study will be built using best practices, accelerating your clinical trial while ensuring high quality.

Your business operates multiple clinical and enterprise systems that you may need to integrate with your clinical trial solutions. Medidata offers technical services that ensure that you can easily leverage all of your existing systems through integration at the application, analytic or data level.

Medidata Study Implementation Service is available for pharmaceutical, biotech and medical device manufacturers across all therapeutic areas and every trial phase, and can be applied both to new and currently ongoing studies.

Accelerate Your Study While Ensuring Quality

The Medidata Study Implementation Service team helps clients deliver fast, flexible and optimally designed clinical trials. Our robust, life sciences-specific implementation methodology has evolved through the successful planning, managing and implementation of thousands of trials over many years, guided by industry experience and best practices. Our implementation services team takes a consultative approach that involves the client in key decisions throughout the engagement process, and our collaborative project managing ensures that the project moves forward smoothly with clear communications, expectations and timelines.

Save time with a proven, evolving and innovative methodology

Medidata has developed a unique implementation methodology that allows for rapid configuration of the Medidata platform. The methodology guides the client through engagement by clearly defining expectations and touch points between team members. By leveraging Rapid Study Builder—a cloud-based tool used for collecting, recording and approving user requirements—appropriate team members can engage in efficient communication and perform real-time configuration updates.

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.

Ensure quality study design, ease of use and productivity with a best practice consultative approach

Medidata Implementation teams have implemented thousands of studies and are experts at taking clinical requirements and turning them into successful solutions. Our team partners with each client to understand the workflow and process for capturing information in order to create the best design and user experience possible, as well as recommend the most effective solution for their operational needs. This consultative approach is applied to such application areas as forms, edit checks, randomization design, patient-reported outcome screens and trip reports.

Reduce risk through collaborative project management

The Medidata project manager works closely with the sponsor and other parties to guide the project forward, manage key handoffs and communicate next steps and expectations. This collaborative approach is supported by project management technologies such as Smartsheet, a web-based application shared between team members that provides the project schedule—including activities, due dates, key milestones and responsibilities—meeting minutes and key contact information. SmartSheet sends an email alert to team members each morning when any changes have been made to the project.

Leverage Your Existing Infrastructure with Technical Services

Medidata's technical services ensure that our implemented solutions fit seamlessly with the sponsor's current clinical and enterprise systems. Our technical experts are able to configure information exchange with your existing systems at the application, analytics and data levels.

Data imports and exports

Medidata solutions offer a variety of import and export services, both in the form of built-in application features (e.g., in our clinical trial management system and protocol design tool) and standards-based web services (e.g., in our electronic data capture system, Medidata Rave®). It is also possible to import and export comma-separated value (CSV) and extended markup language (XML) data files. Additionally, data can be exported as a SAS dataset for SAS-specific or SDTM applications.

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.

Reporting

Medidata delivers custom reports using the built-in reporting capabilities available across the Medidata Clinical Cloud™. Additionally, we can create custom reports for listings, analytics, dashboards or predictive analytics in the reporting tool of the client's choice using Amazon cloud technologies.

Application integration

Using standard tools delivered as part of the Medidata Clinical Cloud, we can connect our solutions with the sponsor's or CRO's internal or cloud-based systems. These may include clinical and R&D related systems such as adverse event, regulatory, and preclinical systems or enterprise systems such as program planning, accounts payable or HR.

Ensure Your Business Needs Are Met

Medidata Study Implementation Service fits the specific needs of any clinical trial sponsor, including pharmaceutical, biotech and medical device manufacturers, across any study phase and therapeutic area. Medidata has extensive experience in Phase-I to late-phase trials and rescue studies, working with a single sponsor or across multiple entities such as sponsors, CROs and technology partners.

Focused offering around Phase-I and late-phase clinical trials

Medidata recognizes that clinical trials vary greatly in scale, complexity and duration depending on the phase and therapeutic area. That's why we provide specific offerings to meet the unique challenges around Phase-I and late-phase trials.

Medidata's Phase-I standards factor in the lower number of subjects and shorter study durations generally associated with early-stage trials, significantly reducing the cost of configuration and accelerating study timelines.

We also have extensive experience configuring late-phase and registry studies. Our team is able to guide customers in optimal trial configuration, accounting for a large number of subjects, long timeframes and observational as well as investigational studies.

Proven methodology to accommodate rescue studies, joint investigations and CDASH standards

Clients may opt to move an ongoing study from an existing commercial or custom-built application to Rave. This transition may be motivated by problems with an existing vendor or solution, a decision to discontinue custom development or a desire to standardize on Rave.

We have successfully transferred studies to the Medidata platform with an efficient and timely methodology—one that takes database characteristics into account. Medidata also has experience in study URL migration for when two or more sponsors engaged in a joint clinical trial decide to end their partnership.

Medidata has developed CDASH compliant forms that are available for use by our clients. These forms can be used as a starting point for your study design to ensure outputs are CDASH compliant.

Medidata Study Implementation Service—available for sponsors and CROs of any size

Medidata works with a wide range of company and study team sizes. Whether a single data manager, clinical team members with CRO support, CROs who elect to have Medidata build their studies or sponsors with significant infrastructure in place but use Medidata services to deliver a specific study—Medidata is adaptable and easy to work with across diverse implementation scenarios.

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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