Medidata CRO Support Service

Enabling CROs to deliver fast, high-quality studies

Medidata CRO Support Service is dedicated to helping contract research organizations (CROs) get the most out of the Medidata Clinical Cloud®, reducing study costs, accelerating timelines and lowering risk. With unmatched expertise in clinical trials and broad knowledge across study phases and therapeutic areas, our deep and unique understanding of the latest technology, R&D practices and business processes enables us to support our CRO partners so that they can deliver fast, high-quality studies to their sponsors.

The Medidata services team is dedicated to providing support throughout the entire clinical trial lifecycle. At study start-up, we help CROs quickly and efficiently get their trial up and running, making sure the right technology is available and fit for purpose. Throughout study execution, we engage in regular meetings, consultations and monitoring to ensure the study stays on track. And when study close approaches, we work closely with each CRO to create a project completion plan—providing documentation as needed, generating end-of-study media and conducting an end-of-study review to capture study learnings and apply them to future trials.

Study Start-up

Confirm study scope, roles and responsibilities

Engagement starts with a cross-organizational Project Kickoff meeting—also known as a Project Initiation Meeting (PIM)—to clarify the scope of work, deliverables, key dates, and roles and responsibilities of both the Medidata and CRO team. We then integrate timelines with the CRO's study plan, labor and capital resource planning and allocation, and project quality management plan to ensure alignment throughout all study processes.

Secure availability of environment and applications

Medidata delivers an accessible URL for hosting the trial—defining which applications and modules are activated—ensuring scripts, reports or other components and add-ons are loaded and tested.

The project manager then coordinates installation of e-learning and dictionary coding, and activates and tests additional products and utilities including a translation workbench, script utility and subject loader.

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.

Our team holds subsequent regular program management meetings with the CRO to advise on new study design, reusability, and the application of sponsor standards and libraries. For studies delivered on the sponsor's URL, we review the standard operating procedures and integration considerations with the CRO.

Clarify communication and escalation plans

Medidata clarifies and confirms the communication and escalation plans, and then identifies roles and responsibilities—such as project manager, IT and helpdesk members—as well as clarifies methods of communication. The helpdesk is made aware of the study team structure in order to expedite support.

Create and deliver study documentation

In order to facilitate regulatory compliance, Medidata creates and delivers study documentation required by CRO and/or Medidata standard operating procedures. The documentation is delivered and maintained in a study binder that contains documents such as: contracts, change documentation, the study plan, study requirements specification, support documents, signed work requests for any system activities, study close requirements, status reports, configuration specifications for any services rendered and production go-live forms.

Study Conduct

Regular cross-organizational team meetings

During the study, the Medidata team meets regularly with the CRO to monitor progress and provide advice around technology and best practices, including leveraging standards, global library, and reporting and technical integrations. We can also provide advice on study design or augment the CRO team where needed. We have the expertise to provide advice and support across all of the Medidata solutions used within the study.

Proactive consultative support

Medidata assists with problem resolution for study implementation issues that have unintended consequences or impact on the clinical trial (i.e., in areas like data and safety monitoring board (DSMB) monitoring, data management or the review of lab data). We also support the CRO in planning software upgrades, migrations or patching if needed and proactively monitor system performance and address any issues that arise.

Study scope monitoring and review

The Medidata team liaises with the CRO partner on any required or potential study scope changes, such as study extensions or additional formal deliverables, and prepares the necessary rationale, cost/benefits and plans for the associated services.

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.

Study Close

Plan for study close

Our team works closely with the CRO to create a project closure plan that aligns with sponsor expectations well in advance of the close date. When the time comes to close the study, Medidata initiates a meeting and completes the study close requirements document.

Peak load readiness

During the final phase of a study, higher demands will be placed on the Medidata Clinical Cloud due to increased activity and the number of users. Medidata professional services ensure that our customer care, product support and operations teams are prepared for the peak study load and are ready to address any issues that arise.

End-of-study media

Medidata then proceeds to create the end-of-study media and database archive. This includes generating and gaining approval for documents specified in the study design, coordinating and managing the delivery of media, notifying the client of progress in end-of-study study media generation and coordinating shipment. Additionally, our team organizes the archival of the database and if applicable, coordinates decommissioning of the URL.

End-of-study review meeting

Once the study is completed, Medidata professional services facilitate an end-of-study meeting to review each team's performance in helping to achieve the study requirements. Any lessons learned are reviewed so that improvements can be made to working practices, leading to continuous improvement in study speed and quality.

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.

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