Medidata Global Library Optimization Service

Maximize the Value of Standards

It is commonly recognized in our industry that standards are key to unlocking study build efficiencies. However, without having a robust process in place to define how standards are created, used and maintained, realizing efficiencies is difficult. The Medidata Global Library Optimization Service helps you define your process and overcome difficult challenges—particularly when working with one or more vendors—to maximize the value of your clinical research.

Drive Efficiency in Study Start-up by Reducing Duration and Resource Levels

The Medidata Global Library Optimization Service reduces the amount of effort needed to execute key processes during the study start-up process. Time spent on building study components such as electronic case report forms (eCRFs) or system integrations is streamlined by creating an effective and reusable process.

Streamline the study build process

In order to drive efficiency in the study build process, new objects should not be created for one-time use, but should be designed to be applicable to many future studies. Achieving this requires discipline by all parties involved. As a foundational element of the service, Medidata delivers a well-documented best-practice process for study object reuse, with all roles and responsibilities clearly defined.

Improve clinical and enterprise system integration

Clients are increasingly opting to link the Medidata Clinical Cloud® with other internal or cloud-based clinical and enterprise 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.

The process for configuring these integrations must be considered in a good study start-up process and must also be standardized to further enhance the value of the standards process. Medidata's Global Library Optimization Service team ensures that your process includes integration configuration optimization and also minimizes the amount of re-work when linking these systems.

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.

Optimize study start-up

Reviewing and testing study configurations is a time-consuming activity that requires input from key sponsor stakeholders. Alleviating this burden is immensely valuable but also arguably the greatest challenge in a developing a good standards process. Our Global Library Optimization Service ensures that there is a reliable process in place that gives key decision makers the confidence to "step back" and allow study builders to proceed without input.

Drive Study Quality Through Standardization and Reuse

By designing a study build process that enforces standardization, Medidata's Global Library Optimization Service ensures that high-quality study components are created and then reused. Building objects that meet sponsor standards and best practices leads to fewer defects in study deployment. Reuse of these standard objects ensures consistently high-quality studies.

Reduce study amendments

It is well understood that study amendments significantly increase study deployment costs. They are a burden to resources and create risk by introducing change to an ongoing study.

The standardization process implemented as part of the Medidata Global Library Optimization service significantly reduces study amendments caused by study build quality issues, misunderstandings in eCRF requirements and study additions due to missed timelines during initial study build.

By using proven study components, study teams confidently deploy studies knowing that their requirements will be met.

Decrease data entry errors

As sites become accustomed to a standard style of user experience in an EDC system, data entry errors are reduced.

Numerous aspects of study user experience can be standardized, for example the layout of a study's visit structure, or the way query text is written. In today's technical world, there are countless examples of users becoming comfortable with a certain system and not wanting to change—from sticking with a certain brand of smartphone to learning and staying with a certain brand of operating system on their home computer. People respond to consistency, and having a process in place that enforces standards ensures that consistent study builds will lead to higher-quality data entry.

Ensure standards compliance

Making sure all relevant staff and stakeholders are compliant with the new process requires training and support during study rollout. Medidata's Global Library Optimization Service not only creates a tailored process, but also develops a customized enablement approach to ensure success.

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.

Maximize Value of Process Improvements by Harmonizing Internal and External Team Activities

We recognize that vendors have processes that are optimized for their organizations, and our remit is to ensure that those processes continue with minimal disruption. Medidata's Global Library Optimization Service ensures that all parties involved in the study build process—both internal and external—work in the same manner in the key standard areas. This gives sponsors the ability to make changes and improvements in those key areas knowing that all vendors will benefit.

Enable continuous improvement

Any good process must be continuously updated and improved to adapt to changing conditions and incorporate lessons learned. When vendors are working separately or following separate practices, it is impossible to consistently apply improvements. That's why it is imperative that study build processes are harmonized in key areas. For example, if we want to invest time in updating a standards review process, we do not want to make multiple versions of that improvement to allow for multiple processes. We want to make one update and know that it will function for all vendors. This is the level of control that an optimized process can provide.

Optimize review and approval process

One of the main deliverables of Medidata's Global Library Optimization Service is a standards approval process that is inclusive of all relevant functional areas. We recognize that high-quality standard eCRF objects do much more than just improve eCRF build. They also optimize the build and deployment of a multitude of supporting objects and processes, such as custom reports, SDTM data extracts, integrations and monitoring processes. We strive to build a standards process that is inclusive of these different functional areas to ensure that they have a similar level of input and control in the direction of company standards.

Define operational business process

Medidata's Global Library Optimization Service doesn't stop at defining content. Transferring final approved content to a sponsor's governing documentation, such as SOPs, work instructions or working practice documents ensures that all relevant parties change behavior and adopt the newly developed process.

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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