

Medidata Study Design Optimization Service™

Medidata is driving game-changing innovation in the evolution of study design by leveraging a best-practice approach to study review, organizational roles and processes and a metrics-driven realization of value. Medidata’s Study Design Optimization Service optimizes your study design for dramatically improved operational execution, maximizes adoption of better study design methodologies and supports the realization of reduced patient burden.

The service consists of: Medidata’s entry of a sponsor’s protocol design into the design optimization application, documented opportunities and recommendations based on industry benchmarks of the sponsor’s protocol design and access to the design optimization application. Medidata manages the entire study design process with input from the sponsor until the structured design is considered complete—all in preparation for the final draft protocol. Sponsors are granted full, web-based access to their studies, hosted in the Medidata Clinical Cloud®, which they can visit at any point throughout the life of their contract.

Scope of Service

Design Optimizer™ Deployment

- Deployment of client division with read-only user access
- Access to iMedidata eLearnings training

Protocol Coding

- PICAS® activity selection and structured time and events entry
- Objectives, endpoints and activity purpose linking

Protocol Analysis

- Two iterative protocol analyses
- Line-of-sight alignment of objectives, endpoints and activities
- Cost and complexity benchmarks
- Activity frequency and usage benchmarks
- Cost distribution per objective

Summary Report, Executive Summary and Findings

- Presentation of study reports to sponsor
- Explanation of study metrics and identification of opportunities
- Recommendation of activity frequency/usage
- Assessment of value realized for the total engagement

The Medidata Services team works hand in hand with your organization to ensure the success of your studies.



Resources and Planned Activities for Success

Medidata resources

- Coder
- Project manager
- SDO Lead (Professional Services Principal, and/or Senior Consultant)
- Account manager

Sponsor resources

- Project Sponsor
 - Project owner responsible for project financials and contract
 - Point of contact for Medidata Sales and Professional Services leadership
 - Individual responsible for identifying protocols for analysis and managing sponsor study team interactions with Medidata
- Study team –typically comprised of clinical development or clinical operations personnel such as:
 - Clinician
 - Medical writer
 - Biostatistician
 - Study manager
 - Data manager
 - Budgeting/finance representative
- Sponsor deliverables
 - Protocol outline, synopsis and/or draft
 - Final protocol

SDO Engagement Activities

Activity	Sponsor Resource	Medidata Resource
Kick-off Meeting <ul style="list-style-type: none"> • Service objectives & expectations • Communication plan • Process implications 	Project Sponsors	SDO Lead
Provide Initial Version of Protocol	Project Sponsor, Study Team	N/A
SDO Analysis [2 weeks]	N/A	SDO Lead, Coder, Implementation Consultant
Review of SDO Analysis	Project Sponsor, Study Team	SDO Lead
Provide Iterative Version of Protocol	Project Sponsor, Study Team	N/A
SDO Analysis [2 weeks]	N/A	SDO Lead, Coder, Implementation Consultant
Review of SDO Analysis	Project Sponsor, Study Team	SDO Lead

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

Medidata Clinical Cloud®

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