Medidata Study Design Optimization Service

Game-changing innovation in study design

Medidata's Study Design Optimization is a data-driven solution that streamlines your study design, reducing inefficiencies and site/patient burden. Our unique benchmark data and analytics ensure a lean and objective study that meets your clinical and statistical outcomes while minimizing cost, complexity and the site/patient burden.

In the 2-stage, iterative model of our Study Design Optimization Service, Medidata provides structured data entry of the protocol into Design Optimizer® and full optimization analytics. The documented findings and recommendations are presented and discussed during interactive review sessions with relevant stakeholders on the study team such as Clinical Scientists and Clinical Operations personnel. 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.

Medidata's Study Design Optimization capabilities are leveraged to:

- *Optimize* **study design and procedure selection.** Our benchmarks compare your study's design to other studies of a similar phase/indication to help guide design decisions; additionally, they inform if procedures are commonly or less commonly used in your indication, eliminating "nice to have" procedures or reinforcing must-have procedures for novel study designs.

- *Reduce* **protocol complexity and site/patient burden**. The collective use of Medidata's industry benchmark data relative to protocol usage, number of visits, subject participation duration and activity quantity provides study teams with advanced design insight that can lead to protocol adjustments which reduces site impact and downstream burden on the patient.

- *Improve* **line of sight**. Clear line of sight and visibility on how all data collected will be used in support of the core objectives of the study; e.g., primary, secondary and safety endpoints. Eliminate or reduce instances of data collection that do not support core objectives of the study, or increase costs and complexity.

In the 2-stage, iterative model of our Study Design Optimization Service, Medidata provides structured data entry of the protocol into Design Optimizer and full optimization analytics.

Scope of Service

Design Optimizer®™ Deployment
- Deployment of client division with read-only user access
- Access to iMedidata eLearnings training

Protocol Mapping
- 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
- Activity frequency and usage benchmarks
- Cost and complexity benchmarks by procedure
- Cost and complexity distribution by objective
- Cost and complexity by visit

Summary Report, Benchmark Summary and Findings
- Presentation of study reports to sponsor
- Explanation of study metrics and identification of opportunities
- Recommendation of activity frequency/usage
- Implications of study design on site/patient burden
- Assessment of value realized for the total engagement

Resources and Planned Activities for Success

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:
  - Clinical Physician/Clinical Scientist
  - Global Study Manager
  - Feasibility Specialist
  - Contracts & Grants Lead

Sponsor deliverables
- Protocol concept or synopsis and draft protocol
- Final approved protocol

Medidata resources
- Protocol Mapping Specialist
- Project Manager
- SDO Lead (Principal, and/or Senior Consultant)
- Value Realization Lead
- Account Manager

About Medidata

Medidata is reinventing global drug and medical device development by creating the industry's leading cloudbased solutions for clinical research. Through our advanced applications and intelligent data analytics, Medidata helps advance the scientific goals of life sciences customers worldwide, including nearly 850 global pharmaceutical companies, biotech, diagnostic and device firms, leading academic medical centers, and contract research organizations.

The Medidata Clinical Cloud® brings a new level of quality and efficiency to clinical trials that empower our customers to make more informed decisions earlier and faster. Our unparalleled clinical trial data assets provide deep insights that pave the way for future growth. The Medidata Clinical Cloud is the primary technology solution powering clinical trials for 17 of the world's top 25 global pharmaceutical companies and is used by 16 of the top 20 medical device developers—from study design and planning through execution, management and reporting.

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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