Medidata Study Design Optimization

Data-drive, lean, objective 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.

A sound study design will impact all downstream areas of study conduct. It benefits sponsors to create a lean study design up front for efficient study conduct

Medidata's Study Design Optimization capabilities are leveraged to:

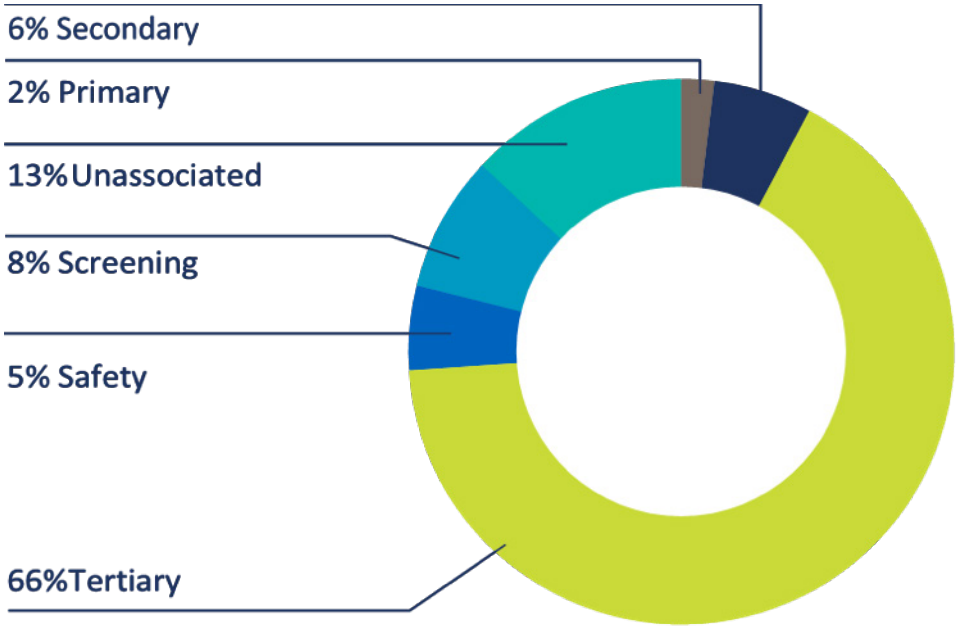
- ***Optimize* study design and procedure selection.** Our benchmarks compare your study's design to other studies of a similar phase/indication to help guide design decisions; additionally, they inform if procedures are commonly or less commonly used in your indication, eliminating "nice to have" procedures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

Available as a Medidata managed service or self-service by an enabled sponsor/CRO, Study Design Optimization is a data-driven solution to streamline your study design: Optimize, Reduce, Improve.

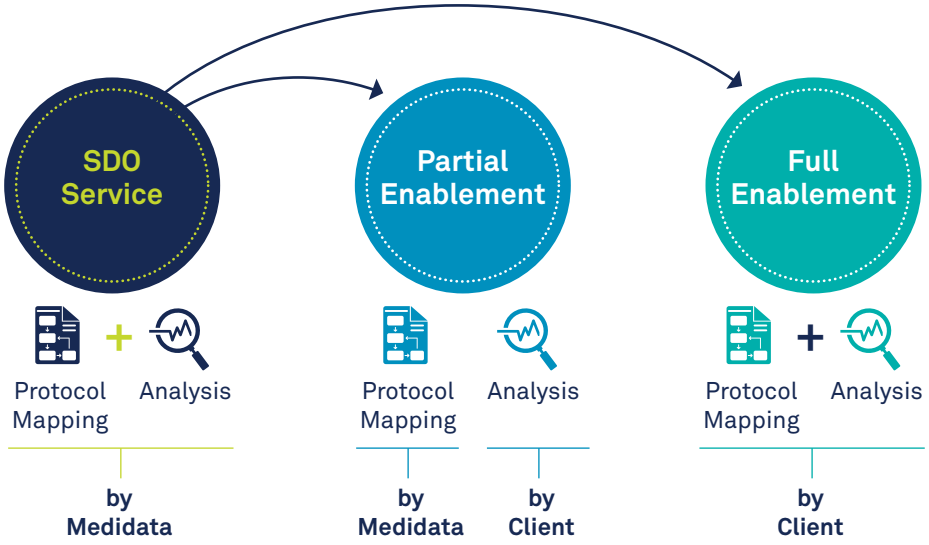
Study Design for Optimal Execution



Line of Sight

Currently sponsors tend to collect far more data than is needed to support primary and secondary objectives. Line of Sight resolves this issue by reviewing the association between procedures-endpoints-objectives. Users can easily identify procedures that are “unassociated” (not tied back to an objective), as well as lay out clearly which activities are being performed in support of which objectives. Cost by Objective and Complexity by Objective helps users understand what activities are being performed in support of each objective type in a given study and how they impact cost and complexity.

Designer Optimizer Engagement Options



Medidata Design Optimizer® can be adopted in three ways within an organization:

- **Study Design Optimization as a Service** (Medidata Protocol Mapping Services + Medidata Analysis): In this 2-stage, iterative model, Medidata performs structured data entry (Protocol Mapping Services) of the protocol into Design Optimizer and full optimization analytics. Once in the system, advanced analytics are run on your study design and it is measured against industry benchmarks from PICAS. 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.

- **Partial Enablement** (Medidata Protocol Mapping Services + Self-Service Analysis): In this model, Medidata performs the protocol mapping; the Design Optimization tool runs the analytics. Your study team is granted web-based access to the study in Design Optimizer, where you can review the results and formulate your own optimization strategies based on the findings.

- **Full Enablement** (Self-Service Protocol Mapping + Self-Service Analysis): In this model, you perform both the protocol mapping of the protocol into Design Optimizer, as well as the analysis based on the benchmark findings and analytics outputs from Design Optimizer.

About Medidata

Medidata is reinventing global drug and medical device development by creating the industry's leading cloud-based solutions for clinical research. Through our advanced applications and intelligent data analytics, Medidata helps advance the scientific goals of life sciences customers worldwide, including more than 850 global pharmaceutical companies, innovative 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 18 of the world's top 25 global pharmaceutical companies and is used by 18 of the top 25 medical device developers—from study design and planning through execution, management and reporting.

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