Medidata Rave Design Optimizer

Data-driven, lean, objective study design

Rave Design Optimizer 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

Rave Design Optimizer capabilities are leveraged to:

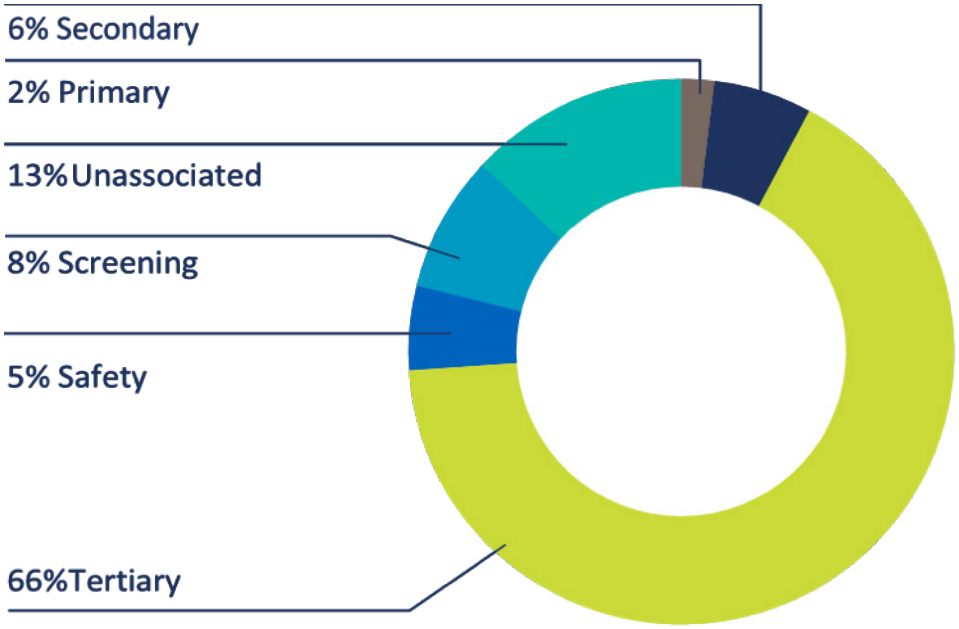
- ***Optimize* study design and procedure selection.** Our benchmarks compare your study's design to other studies of a similar phase/indication to help guide design decisions; additionally, they inform if procedures are commonly or less commonly used in your indication, eliminating "nice to have" procedures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

Study Design for Optimal Execution



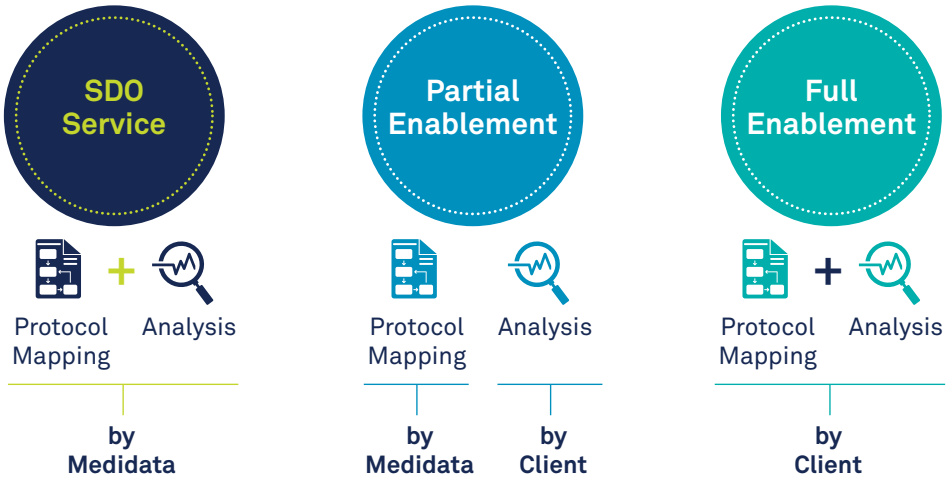
Line of Sight

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.

The Platform of Choice for Clinical Research

The Medidata Rave Clinical Cloud is the cutting-edge platform that transforms the clinical trial experience for patients, sponsors, CROs, and research sites. Designed with a unified data platform, the Rave Clinical Cloud creates a single source of truth for all study-related data. Simply put, enter data once and let the platform master and populate it throughout the end-to-end suite of Rave applications. Optimize operational execution, decrease the data entry and maintenance burden, and reduce the number of clinical systems across your study teams. Throw away your list of passwords, you are now on a truly unified platform.

Rave Design Optimizer Engagement Options



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

- **Design Optimizer 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 Optimizer 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 leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers.

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