

## DESIGN OPTIMIZER

# DATA-DRIVEN STRATEGY FOR OPTIMIZED STUDY DESIGN

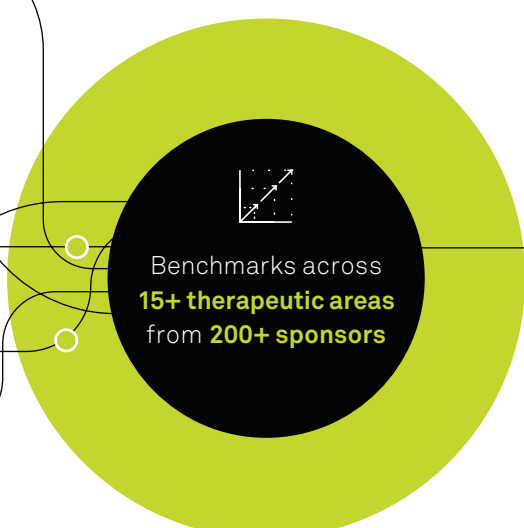
Understanding the impact of each data point collected during a study enables the successful design of a lean yet thorough protocol and drives downstream benefits of study conduct.

To enhance these data points, Medidata Design Optimizer provides site and patient **burden benchmark data** and **analytics** to streamline your design while meeting your clinical and statistical outcomes.



## BENCHMARK TO MINIMIZE COST, PATIENT AND SITE BURDEN

Identify common or uncommon procedures from other studies of similar phase and indication. Guide your design decisions by **benchmarking your protocol** in terms of effort required from sites and patients, while gaining greater **visibility into procedural costs**.



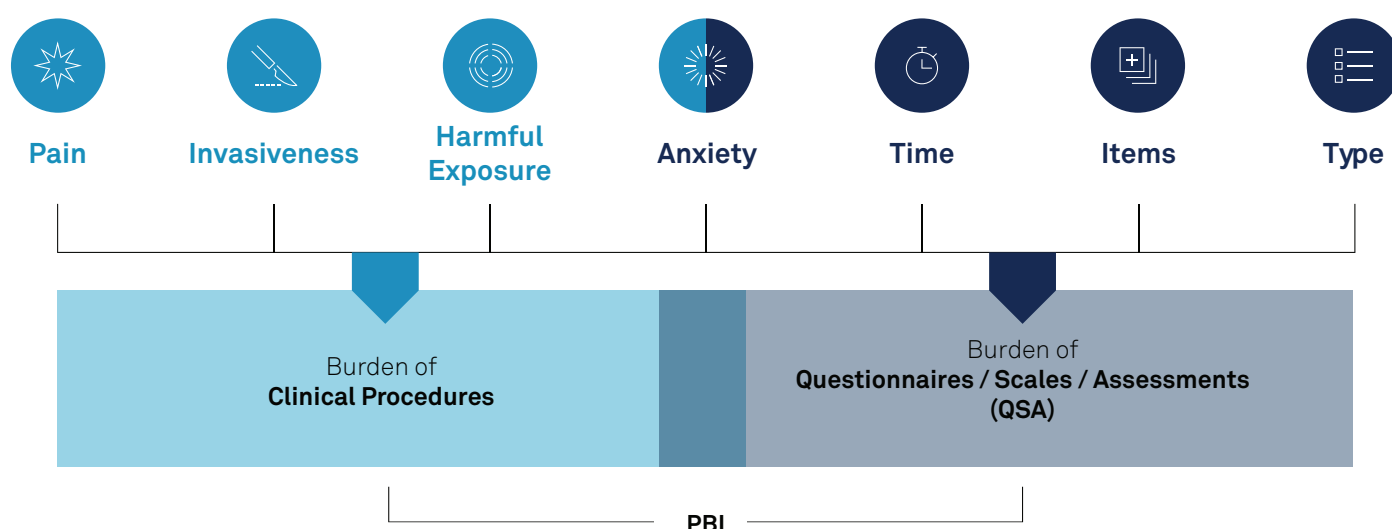
## INTEGRATING A PATIENT-CENTRIC APPROACH WITH PBI

Design Optimizer utilizes Medidata's proprietary Patient Burden Index (PBI), a **quantitative** measure of the patient burden that considers **objective** and **subjective** factors associated with standardized study activities.



# PATIENT BURDEN INDEX

CLINICAL ACTIVITY COMPONENTS



PBI provides study teams with advanced study design insight that can lead to protocol adjustments to support:

Patient and site-centric protocol design

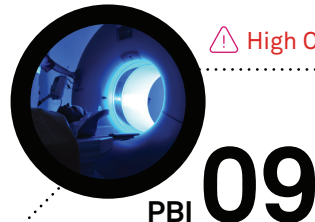
Procedures that minimize patient burden

Reduced risk of poor subject recruitment and potential dropout

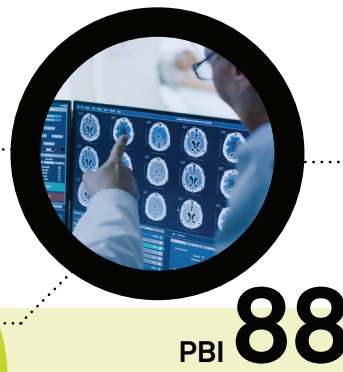


## IMPROVE YOUR LINE OF SIGHT

Quantifying the cost and effort of collecting all data against your study's objectives **improves your line of sight** for early insight and faster decision-making. It also enables you to reduce allocation of resources against **non-core activities** and exposes procedures for which no objective or endpoint has been defined.



Increased Complexity High Patient Drop Out



Medidata Design Optimizer is the industry's most powerful study design and PBI tool. Assess the impact of design decisions early and drive significant improvements throughout your study's life cycle.

### DESIGN WITH

- Patient centric protocol design
- Line of sight
- Early insights
- Visibility into procedural costs

### ACCOUNT FOR

- Site and patient burden
- Risk of poor subject retention
- Potential patient dropout
- Complexity and cost