

MEDIDATA TRIAL DESIGN

Accelerate Approval of Novel Therapies

Make critical, data-driven decisions throughout the product development lifecycle and increase your probability of success

OVERVIEW

The state of clinical development is constantly evolving, and while new therapies are bringing promise, what remains are increasingly complex diseases that require increasingly complex solutions.

You are under pressure to develop therapies, obtain approval by regulators, and deliver hope to patients, while simultaneously overcoming the obstacles commonly encountered along the path from discovery to approval.

Consider this: the average therapy costs \$1B to \$2B to develop, while only 12% of medications ever gain regulatory approval and launch into the marketplace. That means every clinical trial-related decision you make is critical. And the more information you have to inform your decisions the better. Development teams must often rely on publications and regulatory filings when making million-dollar decisions. Having patient-level data from recent trials provides beneficial insights into increasingly specific populations. You need to move fast and save money while designing safe, effective treatments.

ADDRESSING INDUSTRY CHALLENGES

Medidata Trial Design allows you to access unparalleled cross-industry, curated, historical clinical trial data from 30,000 trials across more than 9 million patients, combined with advanced analytics and deep industry and regulatory expertise to help your clinical development teams use both novel and proven approaches.

Evaluate therapeutic efficacy

Accelerate patient recruitment and enrollment with a better understanding of unmet medical need within your specific sub-populations and determine those most likely to respond to your new therapy.

Design safer trials

Leverage historical data and benchmark against commonly collected trial data to predict which patients will most likely experience adverse events and use those insights to proactively intervene—mitigating risk, resulting in safer trials, and avoiding trial failure.

Prevent trial failure

Evaluate possible protocol designs and model trial scenarios to create the most optimal protocol—predicting and overcoming obstacles before they can lead to patient attrition and trial failures, and proactively avoiding untoward outcomes.

ACCELERATING CLINICAL DEVELOPMENT

Trial Design Solutions from Medidata brings together the power of historical trial data, complete with the endpoints and covariates as they were captured within their original trials.

This unique and powerful dataset equips your team to bridge evidence gaps with cross-trial data—to gain powerful insights, make evidence-based decisions, and increase the probability of technical and regulatory success.



TAKE ADVANTAGE OF HISTORICAL CROSS-INDUSTRY DATA

Medidata has curated the world's largest database of CAR-T patients across 30,000 trials across more than 9 million patients of approved and investigational products.

SUMMARY OF MEDIDATA TRIAL DESIGN BENEFITS

- Providing powerful insights to better predict therapeutic efficacy
- Informing evidence-based decisions, leading to safer trial design
- Increasing the probability of success, minimizing the risk of trial failures



EXAMPLES OF TRIAL DESIGN SOLUTIONS

Predicting patient drop-out

For a pivotal Phase III study, historical clinical trial data was leveraged to predict which patients were at highest risk of dropping out. This data was used to inform recruitment and proactively develop risk mitigation strategies, resulting in fewer trial delays.

Designing adaptive trials and treatment regimens

In indications where it's difficult to develop pragmatic clinical trials, Medidata can determine clinical margins and sample sizes to inform your dosing strategy and help you design pre-conditioning+Jac regimens to help mitigate or manage adverse events (AEs).

Demonstrating unmet medical need under current standard of care (SOC)

In a competitive CAR-T development landscape, Medidata was able to help a global biopharma to include additional patient subgroups with high unmet medical need, identified by consistently poor outcomes under the existing standard of care, in DLBCL. This provided a competitive advantage in recruitment and resulted in more favorable trial outcomes for this previously hard to treat population.

Expanding disease understanding

A mid-sized biotech in KRAS development was able to leverage past trial data to demonstrate correlations between certain biomarkers and specific endpoints, validate disease progression models, and understand the relationships between comorbidities. This evidence was used to support regulatory and market access conversations.

Refining inclusion/exclusion criteria

Trial Design worked with a US biotech to identify and avoid an "impossible to recruit" patient subgroup by comparing patient outcomes from historical randomized controlled clinical trials (RCTs) and real-world data.

Predicting efficacy and safety outcomes

A top-10 global biopharma partnered with Medidata to use benchmarks from past clinical trials to identify patients that were likely to experience high-grade CRS under their CAR-T treatment protocol. This enabled them to develop risk mitigation strategies and avoid trial stoppage or failure.

THE MEDIDATA AI ADVANTAGE

From planning to launch, we are your collaborative partner—pushing innovation through unparalleled technology, expertise, advanced analytics, and predictive modeling. Medidata AI is dedicated to ensuring that new possibilities are always on the horizon for you, the patients we ultimately serve, and life sciences as a whole.

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