A Top 10 Pharma Company Doubles High-Performing Site Count in a Priority Indication with Medidata AI Intelligent Trials

Key Takeaways

- A top 10 biopharmaceutical company wanted to expand their site list in a priority indication and gain a deeper understanding of how existing sites in their database performed.
- Medidata AI integrated cross-industry clinical trial data with the sponsor's data to create a more robust view of site performance.
- Originally,the sponsor had only 99 sites categorized as high performing, or Tier 1. By incorporating Medidata AI data, the team identified 31 Tier 1 sites the sponsor did not have experience with, and reclassified 104 sites previously thought to be low performing. Ultimately, Medidata AI more than doubled the amount of Tier 1 sites to select from.

Challenge

A top 10 biopharmaceutical company was looking to gain agility and confidence in their trial planning, site selection, and enrollment decisions in a priority indication. Typically, the sponsor used a proprietary methodology based on internal data as well as a prominent data-sharing initiative to categorize and prioritize Tier 1 sites for site selection. As they embarked on upcoming clinical trials, the sponsor wanted to expand their site list and gain a deeper understanding of how existing sites in their database performed.

As the clinical trial landscape grows more complex, running successful clinical trials becomes more and more difficult. Currently, 80% of trials do not enroll within target enrollment timeframes and 55% of terminated trials cite low patient accrual as the main reason.1, 2 These enrollment issues are impacted by many factors, including site selection, industry competition, increasingly targeted patient populations for precision medicine treatments, and changing trial conditions. In such a cut-throat environment, it was critical for this top sponsor to choose high-performing sites based on reliable data to set their trials up for success.

Solution

The biopharmaceutical company partnered with Medidata AI to identify and rank high-performing sites for their upcoming trials. Intelligent Trials is the only clinical trial analytics solution that brings together cross-industry performance metrics from 1,800+ customers and 27,000+ trials with granularity at the country and site level, real-time insights into the current competitive landscape, and predictive modeling capabilities to give sponsors a competitive edge.

Study Feasibility, a module of Intelligent Trials, is a self-service tool that gives sponsors access to country, study, and site level metrics. Metrics from the Study Feasibility module are derived from actual real-time data captured in Rave EDC, including active studies and closed studies. Some of these metrics include site enrollment percentile rank, enrollment rank variability, relative trial congestion, and enrollment competition per site relative to patient population. The Study Feasibility module also provides data quality metrics in the form of data entry lag and data correction rates. Further, the Study Feasibility module accounts for complexity by using relative ranking of site performance within a study, regardless of complexity. And, with the multivariate ranking functionality, users can select which metrics are more important to them in ranking sites.

1 Clinical trial delays: America's patient recruitment dilemma. Clinical Trials Arena. Available from: https://www.clinicaltrialsarena.com/marketdata/featureclinical-trial-patient-recruitment/

2 Desai M. Recruitment and retention of participants in clinical studies: Critical issues and challenges. Perspect Clin Res [serial online] 2020;11:51-3. Available from: https://www.picronline.org/text.asp?2020/11/2/51/283844

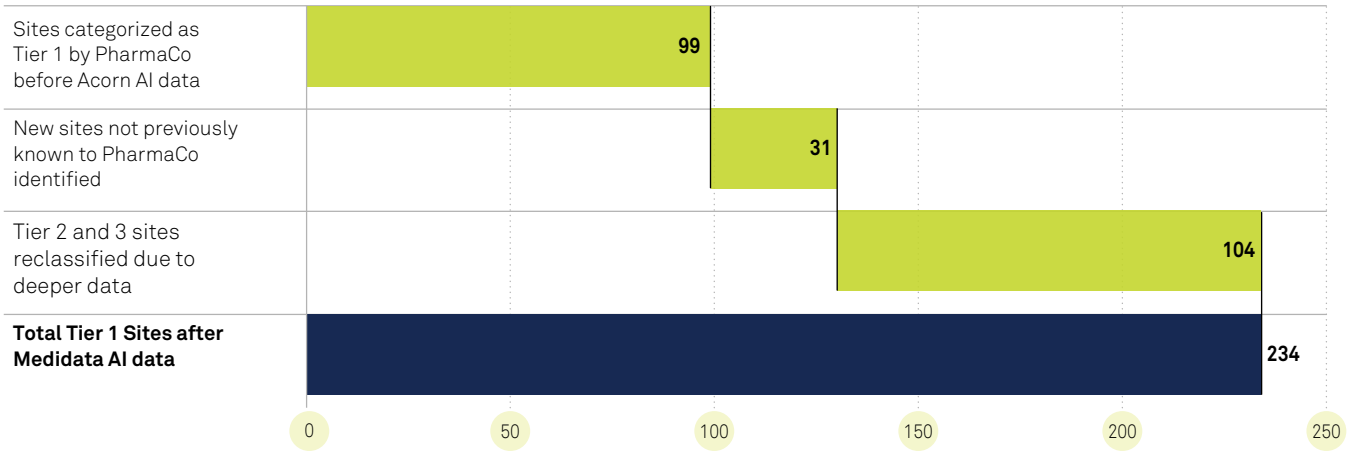
The Benefits of Medidata AI Data vs. Publicly Available Data

	Publicly Available Data	Medidata Acorn AI Study Feasibility Data
Use Cases	• Broad perspective based on unmasked studies and sponsor details • Allows for direct competitive study analysis • Does not support in-depth performance metrics	• Broad industry perspective based on 27,000+ studies run on the Medidata platform • True performance metrics at the country, study and site level based on patient-level data captured in Rave EDC • Enables predictive modeling based site segmentation and study forecasting
Information Availability	• Relies on sponsor self-reporting accuracy, completeness, and timeliness	• Based on time-stamped events and milestones in Rave EDC • Near real-time information availability
Performance Metrics	• Rough study-level site enrollment can be estimated, but assumes all sites are enrolling at the same time • Sites can be tiered based on sponsor and CRO experience but without information on actual enrollment, screen failures, quality, data lag, etc.	• Actual performance metrics available down to the site level to classify high and low enrolling sites • Data enables predictive model-driven ranking and enrollment forecasts

Results

Medidata AI integrated cross-industry clinical trial data with the sponsor's data to create a more robust view of site performance. Originally,the sponsor had only 99 sites categorized as Tier 1. After incorporating Medidata AI data, the team identified 31 new Tier 1 sites the sponsor did not have experience with and reclassified 104 sites previously thought to be lower performing. Ultimately, Medidata AI more than doubled the amount of Tier 1 sites to select from.

Medidata AI Data more than Doubled the Number of Tier 1 Sites Identified in a Priority Indication



Armed with new sites and increased confidence in sites with little data from other sources, this top sponsor is positioned to enroll faster, respond quicker, and compete better in future clinical trials.