Clarivate™

Case Study | Clarivate Consulting Services

Informing clinical trial design with longitudinal biomarker modeling

A top 10 global pharmaceutical company wished to accelerate their proof-of-concept decision making for immunological therapies.

To achieve this, the company aimed to apply statistical modeling and simulation to longitudinal biomarkers (for example, Crohn's disease and lupus activity indices) to quantify the relationship between measurement frequency, study size and statistical power in immunological clinical trials.

Developing actionable insights about trial design.

Because the Clarivate™ Discovery and Translational Services consulting team has access to comprehensive data sources and industry leading analytics, they're able to translate complex datasets into actionable Insights about trial design and statistical analysis plans. Using historical datasets for similar studies as the input, the team performed model fitting using mixed-effects models and calculated power estimation versus sample size. Then, models were simulated to test the "missingness" effect, because missing data are common in studies for these diseases, and sampling frequency.

Based on the output, the company benefitted from the following:

- an understanding of the conditions that would improve the statistical power to differentiate the active arm from the placebo arm,
- differentiation of treatment groups earlier in the clinical trial timeline,
- predictive capabilities for power estimation between the treatment arms at the final time point and
- the ability to use the same methodology for any measure / indication with historical data.

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For more information on how the Discovery and Translational Sciences consulting team can help accelerate your research with advanced analytics and actionable insights, visit our website at:

clarivate.com/products/clarivate-consulting-services/