Revealing Opportunities Through Insightful Informatics: Cardiovascular Outcomes Case Study

A global pharmaceutical company engaged Covance to conduct a large Phase III cardiovascular outcomes study.

Understanding the Challenge

- Modeling predictive trajectory curves for event incidence
- Monitoring the event rate and comparing actual event trajectories to those predicted to ensure study timelines are met and statistical power achieved
- Developing a "rapid activation" backup plan to mitigate potential problems with event incidence that could lead to study delays

Dynamic Modeling Transforms Results

In preparation for this event-driven mega-trial, our team of informatics experts drew upon their past experience and insight to determine the rate at which a recurrence of events would occur. First, the team implemented a sophisticated set of algorithms that had been modified and validated by more than a decade of clinical trial experience to help develop study timelines. Trajectories with 95% confidence intervals were created based on historical country and site startup times, past recruitment and literature-based, disease-specific event rates. Next, leveraging our extensive database of country, site and investigator-specific metrics, the team devised a backup plan consisting of sites that could be rapidly initiated.

Once the trial began, we followed event-driven outcomes as adjudicated by a third-party academic research organization. We also used our own projection software to dynamically model the outcomes event timeline and, as a result, we detected a divergence between predicted and actual event rates. Driven to deliver solutions – and proactively looking to reduce risk – our clinical operations team recommended initiating rapid startup sites based on input from client affiliates and our own extensive central laboratory database. This led to 31 new sites, five of which were in a new country, and almost 2,000 additional randomized patients. The team then used best-in-class procedures and an efficient system to facilitate endpoint workflow, setting our client up for success as the new patients led to increased events. In the end, our client was able to achieve the outcome rate sooner than if the issue had not been recognized and sites had not been added.

Sophisticated informatics and study performance monitoring are keys to ensuring your outcomes trial meets your anticipated timelines. Partner with a team that is relentless in implementing critical study adjustments before it is too late.

Learn more about our drug development solutions at www.covance.com

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