SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

Case Study Signant SmartSignals Rater Training & Blinded Data Analytics

SIGNANT STEPS IN TO HELP SPONSOR'S RARE PEDIATRIC DISEASE TRIAL

Signant was brought in to help with a rare disease pediatric trial of an investigational drug by leveraging our rater training and blinded data analytics services to ensure high-quality clinical data.

OVERVIEW:

When a Sponsor's rare pediatric disease trial required a complex assessment tool to be completed by academic key opinion leader experts, Signant stepped in. The sponsor was concerned that the previous rater training vendor was insufficiently experienced in training, retraining, and interacting with sites that had a high level of disease expertise. Having worked with Signant in the past and knowing our scientific leadership team's level of indication-specific knowledge and experience, the sponsor contacted us to assist with enhanced training, refreshers, and data quality monitoring and remediation.

CHALLENGES:

01 In order to take on the study, Signant had to ensure a smooth transition from the previous vendor so that the trial could be completed and submitted for regulatory approval on time.

02 Signant needed to seamlessly and expertly refine the training and remediation program to help re-engage investigators as well as ensure data integrity.

03 In addition to providing enhanced training and refreshers, Signant needed to track anomalous data patterns and provide targeted remediation discussions with investigators throughout the trial to assure clinical precision.

SOLUTIONS:

01 Signant retained productive working relations with the previous vendor to facilitate a seamless transition.

02 Signant coordinated effective, collegial training and remediations that were led by experts.

03 We provided Blinded Data Analytics services to proactively monitor trial data for changes in consistency and accuracy, as well as recommend preventative or corrective actions to help optimize endpoint reliability.

RESULTS:

The sponsor's trial was completed in time and data were submitted to regulatory agencies, which ultimately led to the first drug approval for this pediatric rare disease.