

# Case Study

## In-study Quality Control

November 22, 2017

### Area of concern

Sleep Disorder

### Location

United States

### Size

60 Sites, 150 Raters

### Services Provided

We provided comprehensive training and quality control services on key efficacy measures and the appropriate way to collect Patient Reported Outcomes (PRO) data. Extensive interview training was conducted and raters were provided with interview guides and other resources for use in-study.

### Challenge

#### Overrepresentation from Rapidly Enrolling Sites

The study had a handful of sites that were enrolling rapidly. The study Sponsor was concerned that data from these sites would be overrepresented in the study. If the data were unreliable and invalid, then it would likely skew the findings and lead to a failed trial.

### Solution

#### On-Site Training

We carefully reviewed training data collected from the raters at these sites and crafted targeted additional training objectives. We sent our trainers to each of the sites to monitor clinical interviews, ensure that the study measures were used properly, and conduct additional training on interview techniques.

### Result

#### Data quality was maintained and the study produced a reliable outcome

Providing the site staff with additional review and support fortified the quality of the data being collected and ensured that patients at high-volume sites were assessed appropriately. The program for this intervention was created in the course of the study, upon Sponsor request, and was deployed within 2 weeks. Most importantly, it did not affect the overall timelines of the study or the pace of enrollment at those sites.

