Case Study

Customized Scale Development

November 22, 2017

Area of concern

Pediatric Psychotic Disorder

Location

International, 8 Countries located in North America, Latin America and Europe

Size

120 Sites, 480 Raters

Services Provided

We provided comprehensive training and quality control services, as well as one-on-one training in interview technique, providing all key training and materials **in the rater's language.**

Challenge

Regulatory authority requested additional measures of adverse events; no measures were available

During the course of regulatory submission, an international regulatory agency requested that the protocol include a measure of a specific subset of possible adverse events. Since we were engaged on the project, the Sponsor asked our Research and Training Development team for scale recommendations. Some well-validated scales that could be appropriate were suggested, but rejected by regulators as not being sufficiently specific.

Solution

Customized Scale Development

In this case, we created an introductory program for the subset of raters with less experience, adding it to the existing program of initial and ongoing training. This allowed the sites to participate in the trial. A specified trainer and project manager from us were assigned to the program with instructions to assist the less experienced raters and monitor their progress often. Each site completed the introductory training and was able to join the trial and receive standardized rater training with their trial peers at an Investigators' Meeting.

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Result

The less experienced raters surpassed many of the more trial-experienced raters in measures of performance during the certification process

Data collected during training and subsequent certification exercises proved that inter-rater reliability of the raters from less experienced sites was equivalent to and at times exceeded the levels documented at more experienced sites. The Sponsor in this study was able to obtain access to a drug-naïve population in a more naturalistic setting, which was crucial to conducting a study of effectiveness, in addition to the efficacy component that a more experienced site could deliver.