Case Study

Engaging Research-naive Sites

November 22, 2017

Area of concern

Mood Disorder

Location

International, 15 Countries located in North America, Asia and Europe

Size

200 Sites, 600 Raters

Services Provided

We provided comprehensive training and quality control services including all key training and materials **in the rater's language.**

Challenge

Sites had limited experience with study measures and clinical trial conduct

There were some sites in this study where no raters met the qualification criteria for participation. The available raters were experienced with the study population but were unfamiliar with the metrics used in the study and had never participated in a clinical trial. The projected patient population for the sites was study-naïve and therefore ideal for this trial. The study Sponsor and CRO wanted to find a solution which would allow these sites to participate in the trial.

Solution

Stratification of Training

In addition to the existing program of initial and ongoing training, our research staff designed an introductory training program for the subset of less experienced raters in order for the sites to be allowed to participate in the trial. Our trainer and project manager were assigned to the program to assist targeted raters and to monitor their progress closely. All sites completed the introductory training, joined the trial, and received the standardized rater training with their trial peers at an Investigators' Meeting.

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Result

The raters from the sites in question outperformed many of the more trial-experienced raters from other sites and countries during certification exercises

Data collected during training and subsequent certification and recertification exercises showed that the inter-rater reliability of the raters at less experienced sites matched and at times exceeded the levels recorded at the more experienced sites. The Sponsor was also able to gain access to a drug-naïve population in a more naturalistic setting. This was critical in conducting a study of effectiveness in addition to the efficacy component that more experienced sites deliver.