

Case Study

Suicidality Assessment in China

November 22, 2017

Area of concern

Schizophrenia

Location

China

Size

20 Sites, 90 Rater

Services Provided

All training materials and consultation were provided in Mandarin. A custom patient-simulation video was created with a Mandarin-speaking clinician interviewing a Mandarin-speaking patient. Additionally, all communication from our study management team was likewise directed through our US-based Mandarin-speaking project management team.

Challenge

A suicidal event was recorded during a trial, requiring additional focused training in suicidality assessment in the study population

Training on outcomes measuring suicidality was conducted at the start of the trial, and there was no indication that the suicide was related to problems with how suicidality was assessed and tracked in the trial. However, it was determined by the Sponsor that all sites would benefit from additional training that focused on this aspect of assessment. The response had to be comprehensive and deployed quickly.

Solution

Focused, specialized training

With **2-week lead time**, our scientific team conducted a review of the training on suicidality assessments provided for this trial and created a self-paced, interactive training module for this topic, including simulation components that were deployed to all study sites. We created a post-test component that allowed our team to track compliance with the new training requirement, as well as measure and report on investigator performance.

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Result

Improvement in validity and reliability of suicidality assessments performed in the trial

All sites received the additional enriched training on assessing suicidality in their population; opportunity was provided for ongoing in-study consultation with our experts. Our statisticians were able to include measures of inter-rater reliability for suicidality assessment in our overall data analysis and thus provide the Sponsor with evidence that investigators in this study were adequately trained to perform this assessment in a valid and reliable manner.

