



case study:

i3 CNS TACKLES CHALLENGING SCHIZOPHRENIA STUDY

Challenge: A global schizophrenia study with a difficult endpoint. Pursuing a label change for its product, the sponsor proposed a study designed to demonstrate a decreased risk for suicide among schizophrenic and schizoaffective subjects. The Phase IV, open-label, randomized trial of the sponsor's product and another marketed product had several challenges — most importantly, the primary endpoints for the study were completed suicide, suicide attempt or hospitalization to prevent suicide, all serious adverse events. The unique endpoint, combined with the fact that the Phase IV study would be conducted in multiple countries and languages around the world, made it a project many CROs might have walked away from. Not i3 Research.

Solution: Expertise, responsiveness, global capabilities. From the start, i3 CNS was involved with protocol development, lending scientific expertise on how to handle a difficult endpoint and a unique patient population. i3's medical monitoring team played a pivotal role in the success of the study, from providing support at meetings to responding to randomization requests around the clock. In fact, the medical monitoring team responded to randomization requests within 30 minutes or less, processing more than 900 patients and 1200 SAEs throughout the study.

i3's global reach and integrated services made it possible to handle the large scope of the project: the study spanned 11 countries and eight languages around the world, including 31 sites in the US. i3 provided project management, site identification and management, regulatory, medical monitoring, data management, biostatistics, quality assurance, investigator meetings, and rater training services over the 3+ years of the project.

Result: Single pivotal study resulted in label change. With i3's help, the sponsor received the label change based on the single trial, gaining access to an important market segment and providing therapy for a tough-to-treat patient group.