



case study:

i3 CNS EXCEEDS GOALS DESPITE TOUGH POPULATION, DESIGN

Challenge: Unique population, study design.

A sponsor was faced with a particularly tough project: a Phase III study of treatment-resistant depression — a patient population normally excluded from standard efficacy trials of antidepressants. The study design itself was also unique: an open-label prospective period to confirm treatment resistance, followed by an open-label augmentation phase in previous non-responders, and a double-blind, placebo-controlled relapse prevention period — all to demonstrate maintenance of remission and long-term benefit in treatment-resistant patients. The international trial included sites in the US, UK, France, and Canada.

Solution: Category expertise, global reach, close integration. i3 CNS's deep therapeutic expertise helped meet the challenges of the unique population and design. From directors to field monitors, i3 was able to assemble a team with experience running complex psychiatric or depression trials.

i3's global capabilities were critical to the success of the study. With project teams in Europe and the US and one global director overseeing the entire project, i3 was able to maintain consistency across all sites and teams and manage the complexities of the different arms of the study.

i3's integrated services enabled different functional teams to work closely together; data management, biostatistics, and the clinical group interfaced seamlessly with each other and the sponsor. i3 also had to work closely with other vendors throughout the project, maintaining direct contact with central labs, interactive voice response systems to maintain balanced randomization and manage drug inventory and resupply, rater training services, and other vendors.

Results: Beat the timeline, exceed enrollment numbers. i3 completed enrollment ahead of schedule, despite the fact that the sponsor required an additional 100 patients above the original target of 400 — a particular feat given the challenging nature of the patient population. To date, i3 has successfully performed two interim database locks, with a third interim analysis currently under way.