



## case study:

### i3 CNS BEATS THE TIMELINE, USES FEWER RESOURCES

**Challenge: Complex study design, low investigator grant.** As part of a commitment to the FDA to study the efficacy of their schizophrenia drug in doses lower than those previously proven to be effective, the sponsor needed to conduct a Phase IV randomized study of three fixed dosages compared to placebo in the treatment of acute schizophrenia in adults over a period of six weeks. Not only were the dosages expected to be non-efficacious, but the patients had to remain in the hospital for the entire treatment period, making the study a challenge for sites. The burden on the sites was made even greater by an initially low investigator grant and slow reimbursement process for hospital day costs.

**Solution: Find the right sites, get creative.** i3's therapeutic experience enabled them to select sites known for experience and excellence in schizophrenia. i3 successfully negotiated a larger investigator grant with the sponsor which helped recruit and retain these good sites. Because the slow reimbursement process for hospital day sites caused many sites to have to wait months for reimbursement, i3 worked with the sponsor to establish a pool of money which i3 could use to pay investigators as the pass-through receipts were approved. This creative solution greatly improved relations with the investigators.

**Result: Finish ahead of schedule, using fewer resources.** A total of 36 sites in the U.S. enrolled patients with a target of 370 patients randomized. The projected enrollment period was 13 months; i3 completed enrollment in only 8 1/2 months. In addition, the study was completed using 14 fewer sites than initially proposed, resulting in considerable cost savings to the sponsor. The final deliverable was 3 1/2 months early, with the entire study — from project award to final deliverable — being completed in approximately 20 months.