CRC COGNITIVE RESEARCH CORPORATION

Case Study: Supporting the FDA Approval of a Novel Formulation for the Treatment of Schizophrenia

BACKGROUND

A clinical-stage biopharmaceutical company engaged Cognitive Research Corporation to help design, implement, and conduct two pivotal studies to evaluate a novel formulation of a marketed compound for the treatment of schizophrenia.

CRC SOLUTIONS

CRC conducted two pivotal trials involving an innovative formulation of a marketed compound in patients with schizophrenia:

PIVOTAL TRIAL A

Conducted a trial involving the novel formulation across **9 sites**, **randomizing 281 subjects in 10 months**.

CHALLENGE	SOLUTION
Limited Drug Supply	Worked closely with client to ensure optimal timing and delivery to the investigative sites.
Managing Site Procurement of the Reference Drug Supply	Proactively worked with sites to coordinate procurement of the reference drug supply to meet FPI milestone.

PIVOTAL TRIAL B

Conducted a trial examining differing routes of administration of the novel formulation across **9 sites**, **randomizing 89 subjects in 5 months**.

CHALLENGE	SOLUTION
Subject Retention to Meet PK Sample Size Required for Analysis	Collaborated with PIs and site staff to emphasize the importance of retaining enrolled subjects, encouraging proactive engagement and timely escalation to CRC for any subjects at high risk of dropout.

KEYS TO SUCCESS

- Effective Management of Pharmacokinetic Sampling & Processing
- Commitment to Timeline Adherence to Meet NDA Submission Goal

OUTCOME

Two pivotal studies were completed on time and at budget, leading to a successful NDA application and FDA approval.

Looking for a Better CRO Experience?

info@cogres.com
(727) 897-9000
WWW.COGRES.COM