



CASE STUDY: 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

Limited Drug Supply

SOLUTION

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

Subject Retention to Meet PK Sample Size Required for Analysis

SOLUTION

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 and outcome

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.

