



CASE STUDY: IND TO FDA APPROVAL

— background

A clinical-stage biopharmaceutical company engaged Cognitive Research Corporation to help design, implement, and conduct a series of studies to investigate a novel therapy for the acute treatment of agitation associated with schizophrenia and bipolar disorder.

— CRC solutions

FULL TRIAL SUPPORT

Conducted a two-stage, adaptive Phase 1b trial across 15 sites, randomizing 127 subjects in less than 2 months.

Ran two Phase 3 trials during the COVID pandemic, randomizing 380 subjects with schizophrenia and 378 subjects with bipolar disorder across 15 sites in 3.5 months.

FULL BIOMETRICS SUPPORT & REGULATORY EXPERTISE

Delivered all analysis deliverables for critical path studies.

Authored Integrated Summary Analysis addressing complex issues.

Navigated regulatory filing requirements with the FDA.

Provided strategic input and representation in key regulatory meetings.

— keys to success and outcome

KEYS TO SUCCESS

Expertise in Recruiting & Retaining Challenging Patient Populations

Strong Relationships with Study Sites for Efficient Enrollment

Rigorous Rater Training for High Data Quality

OUTCOME

The collaboration between CRC and the sponsor from Phase I to III resulted in a successful NDA application with exceptional speed and FDA approval.

[LEARN MORE](#)

FACING TIGHT CLINICAL TIMELINES?
CONTACT US AT +1(727) 897-9000.