CRC COGNITIVE RESEARCH CORPORATION

Case Study: IND to FDA Approval

Supporting a New Standard of Care for Acute Agitation in Schizophrenia and Bipolar Disorders

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 disorders.

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

- 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.

Looking for a Better CRO Experience?

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