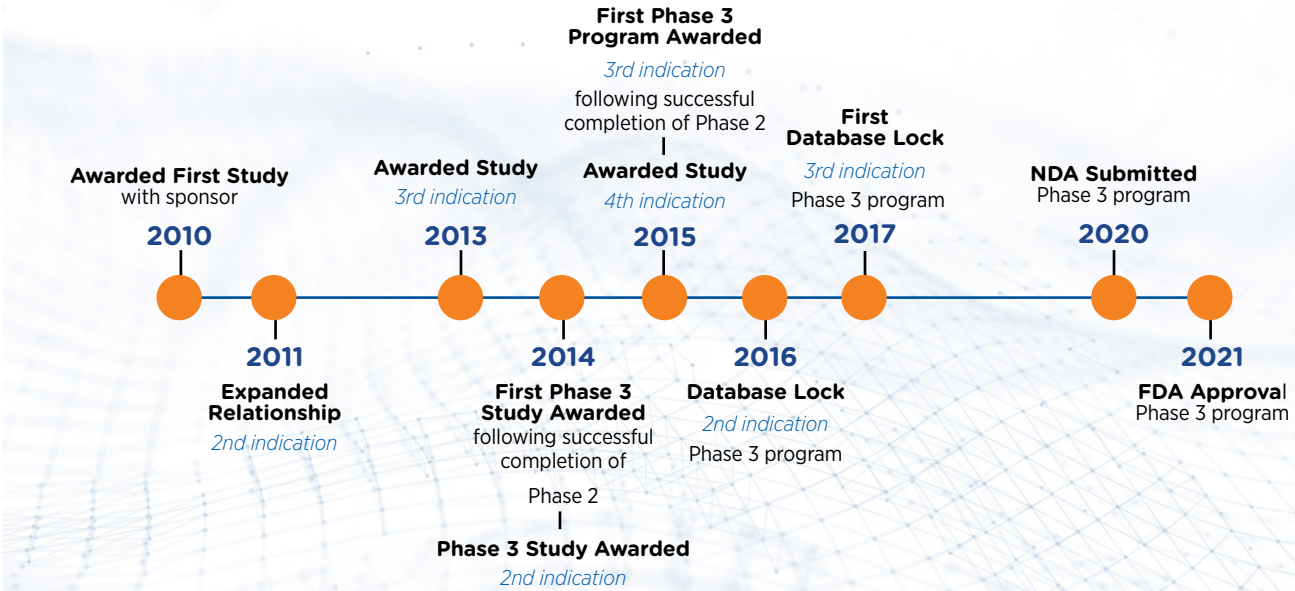
Premier Insight 278

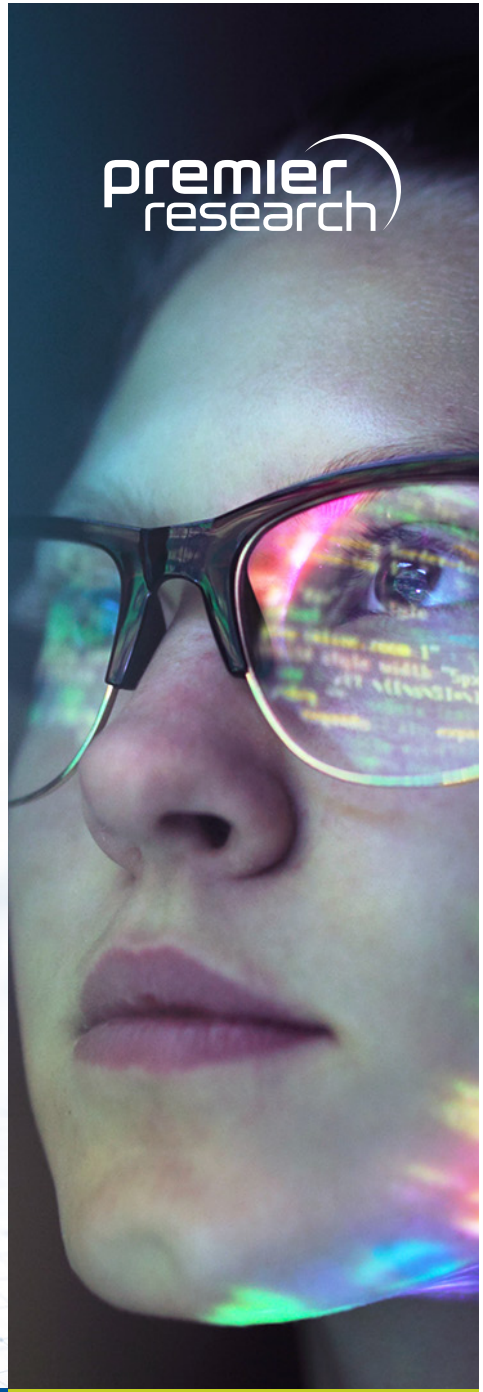
A Decade-Long Partnership Culminates in FDA Approval

Background

Psychiatric conditions are complex, chronic, often debilitating diseases, and there remains a persistent need for novel medications with proven efficacy and safety. Many of the established antipsychotic agents are highly effective but are associated with significant side effects that may negatively impact adherence and patients' experiences with treatment. Thus, recent research has focused on developing new antipsychotics, including those that address the need for efficacy without compromising psychiatric or physical well-being.

Conducting clinical trials of psychiatric diseases and mental illness can be challenging due to the interplay of genetic, biological, social, and environmental factors that give rise to these conditions. As a result, sponsors of psychiatric clinical trials may face obstacles in collecting the quality data necessary for supporting regulatory approvals. Close collaboration between the sponsor and contract research organization (CRO) is critical to maximizing data quality and study success.





NEUROSCIENCE / PSYCHIATRY

Summary of sponsor-CRO relationship

A biopharmaceutical company sought to develop a novel combination antipsychotic for a psychiatric disorder that is one of the top 15 leading causes of disability worldwide. In 2013, based on the strength of prior work with this sponsor, Premier Research was engaged to plan and execute a Phase 2 study for this drug, marking the first time Premier had conducted a trial in this indication. Prior to this study's End-of-Phase 2 (EOP2) meeting, the sponsor engaged Premier as its sole CRO to manage all proof-of-concept studies spanning from Phase 2 to approval.

Serving as a true partner in all aspects of development

The sponsor held a high level of trust and confidence in Premier Research's work – as evidenced by the timing of the award for the Phase 3 studies of this drug to Premier prior to the EOP2 meeting when the sponsor had not yet defined the Phase 3 program. Leveraging our deep understanding of both the compound and the sponsor's business objectives, we participated actively in Phase 3 strategy development and focused on going the extra mile. With our flexible and nimble Built for Biotech℠ mindset, we co-presented data with the sponsor at key conferences and performed certain sponsor visits in their stead. Our subject matter expert also sat on their advisory board and supported data analysis on the sponsor's behalf.

To help ensure goals, alignment, and seamless execution across all six Phase 3 studies, we developed and convened a first-of-its-kind joint operations committee to facilitate proactive planning and risk mitigation. In addition, we held monthly management-level calls with sites for feedback and brainstorming.

To live up to our commitment to data quality, we invested significant attention and time in developing processes, procedures, and training to support the accuracy and completeness of data collection. Premier also developed a pre-enrollment data review process and an electronic database that the sponsor continues to use today.

Takeaway

Clinical trials of psychiatric and neurological indications present unique challenges and may require innovative processes for ensuring optimal study execution and data quality. By going above and beyond the typical CRO relationship, Premier earned a partnership built on trust and helped the sponsor achieve a milestone business objective.

Premier Research has performed more than 300 neuroscience trials in the past five years, with 100 in psychiatric disorders. We have a history of breakthrough work, including the first post-traumatic stress disorder study in military veterans, and our neuroscience studies have involved more than 50,000 patients.

Contact us to schedule a consultation with our neuroscience experts.

Study Description

Six Phase 3 studies of a once-daily, novel combination antipsychotic

Therapeutic Area

Neuroscience / Psychiatry

Geographic Scope

Global

Number of Patients Enrolled

1,655

Outcome

FDA approval for two psychiatric indications

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