

Case Study

Accelerating Psychiatry Development: From One Study to Full CNS Portfolio Through Flexibility & Speed

A small biotech sponsor approached Worldwide Clinical Trials to support a Phase II study evaluating an antipsychotic therapy in patients with acute schizophrenia. Given their limited internal clinical operations experience and the complexities of the inpatient study design, the sponsor needed a CRO partner that could provide not only strong execution, but also strategic guidance, operational flexibility, and the ability to scale quickly.

By operating as a true extension of the sponsor team, Worldwide helped transform what began as a single Phase II study into a broader neuroscience development partnership supporting multiple indications and long-term portfolio growth. Through a combination of agile execution, senior leadership engagement, and strategic consultancy, Worldwide supported both the successful delivery of the initial study and the sponsor's broader value creation objectives as the asset advanced through development.

This case study highlights the performance of the first study in the development sequence and the collaborative partnership approach that laid the foundation for continued program expansion.

Study Challenges



Translating Scientific Innovation into Clinical Execution

As a newly formed biotech, the sponsor had minimal experience in clinical trial operations. They required hands-on guidance across protocol development, site strategy, and execution.



Complex Inpatient Study Design

Acute schizophrenia studies require inpatient confinement, creating high operational complexity, significant cost burden (e.g., bed rates, site fees), and increased reliance on specialized site networks.



Aggressive Enrollment Expectations

Based on industry benchmarks and comparable studies, enrollment was projected to take ~18 months, creating pressure to meet long timelines while managing costs.

Study Portfolio Overview

- **Sponsor**
Small biotech start-up
- **Indications**
Acute schizophrenia (initial study) expanded into bipolar disorder and major depressive disorder (MDD)
- **Study Type**
Phase II, randomized, double-blind, placebo-controlled, multicenter
- **Study Design**
Inpatient acute schizophrenia study evaluating efficacy and safety
- **Sites**
25 active sites (29 vetted)
- **Country**
United States (Phase II); expansion to global (MDD program)
- **Primary Objective**
Change from baseline in PANSS total score
- **Secondary Objectives**
Clinical improvement measures (CGI-S and PANSS subscales), safety, tolerability, and pharmacokinetics



Unexpected Rapid Enrollment

Enrollment significantly exceeded expectations, completing in 6 months. While advantageous, this created downstream challenges, including compressed monitoring timelines, accelerated data cleaning and database lock requirements, and budget strain due to condensed resource utilization and specialized site networks..



Scaling Operational Resources

The rapid pace required immediate scaling across clinical monitoring, data management, and biostatistics, all without compromising quality or timelines.

Worldwide's Solutions



Strategic Study Design & Partnership

Worldwide partnered closely with the sponsor from the outset, acting as an extension of their team. We provided guidance on protocol development and feasibility, while supporting decision-making with real-time data and industry benchmarks. Importantly, we established a transparent, collaborative working model, and this early partnership laid the foundation for long-term success.



Cost-Conscious Operational Strategy

Given the high cost of inpatient trials, Worldwide worked closely with the sponsor to optimize financial efficiency by negotiating inpatient bed rates and investigator grants, while balancing cost constraints with enrollment and quality goals. Worldwide also provided transparency into budget forecasting and adjustments.



End-to-End Operational Flexibility

Worldwide's integrated, full-service model enabled seamless coordination across site management, clinical monitoring, data management, and biostatistics.

By aligning all functions, the team was able to:

- Maintain data quality
- Accelerate timelines
- Preserve the sponsor's time advantage



Targeted Site Selection & Engagement

Success in inpatient psychiatry trials depends heavily on site quality and engagement. Worldwide worked with the sponsor to:

- Vet 29 and activate 25 high-performing sites
- Leverage strong relationships with experienced inpatient psychiatry centers
- Ensure sites were equipped to manage complex inpatient protocols

This approach enabled rapid activation and prioritization of the study across sites.



Agile Resourcing & Rapid Scaling

To address accelerated enrollment, Worldwide implemented a flexible resourcing model that rapidly deployed CRAs, co-monitors, and data teams. We also reallocated resources across the study lifecycle, and accelerated downstream activities (e.g., monitoring data cleaning, and DBL readiness). These measures ensured that the study could maintain momentum without delays.

Study Outcomes

Worldwide's comprehensive approach enabled both speed and quality, delivering measurable success, as highlighted below.

- * Accelerated Enrollment**
 - Enrollment completed 3x faster than expected, in 6 months vs. 18-month projection
 - 359 patients randomized (target ~350)
 - ~2.0 patients/site/month enrollment rate
- * High-Quality Data Delivery**
 - Successful monitoring and data cleaning despite compressed timelines
 - Database lock achieved without delays
 - Maintained full data integrity
- * Program Expansion & Long-Term Impact**

The success of this Phase II study directly led to:

 - 4 additional studies awarded
 - Expansion into Phase III schizophrenia trials
 - Expansion into bipolar disorder treatment
 - Creating a global MDD program

Key Successes

- 3x faster enrollment than planned
- Seamless scaling of operational resources
- Strong sponsor partnership and trust
- Conversion from single study to a multi-study portfolio
- Continued CRO selection without rebidding

Strength of Partnership & Support for Growth

As the sponsor rapidly evolved from a small startup into a growing biopharma organization, Worldwide served as a consistent strategic and operational partner throughout that growth. Built on transparency, trust, and close collaboration across both study teams and executive leadership, the partnership enabled scalable support aligned to the sponsor's expanding pipeline and long-term development strategy.

Conclusion

Fast enrollment alone doesn't guarantee success.

Worldwide ensured that speed translated into a sustained clinical and strategic advantage, helping this sponsor transform one successful study into a growing CNS development program.

Why Worldwide Clinical Trials

Worldwide's ability to combine therapeutic expertise, operational flexibility, and true partnership enabled this sponsor to move faster and stay ahead.

For complex CNS trials, regardless of sponsor team size, Worldwide delivers:

- Deep CNS experience across all major therapeutic areas (psychiatry, neurology, pain, rare CNS, and dementias)
- Agile, scalable resourcing
- End-to-end execution excellent, and continuous financial transparency