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CASE STUDY

Critical Database Lock Milestone Achieved Through Rapid FSP Support for BioXcel Therapeutics, Inc.

Introduction

BioXcel Therapeutics, Inc. is developing innovative treatments to address agitation associated with bipolar disorders and schizophrenia. A key part of their pivotal clinical program was the SERENITY At-Home Phase 3 trial, designed to support a planned supplemental New Drug Application (sNDA) for IGALMI® (BXCL501). Keeping this trial on schedule was essential to maintain alignment with regulatory timelines and their goal of expanding treatment access to patients outside of medically supervised settings.

Challenge

BioXcel's study was at 63% enrollment when their primary CRO could no longer provide the additional monitoring support required to meet growing study demands.

With timelines tightening and site needs increasing, BioXcel needed a rapid, reliable solution to keep the trial on track and ensure data integrity.

Solution

ProPharma deployed an FSP solution to provide immediate operational support.

- **Rapid Deployment:** Within three weeks, ProPharma deployed two experienced CRAs and a Clinical Trial Manager to provide operational coverage.
- **Adaptive Oversight:** CRA site assignments shifted frequently based on evolving study timelines and site-specific needs. The team adapted quickly and maintained proactive, responsive oversight during the 12-week, double-blind, placebo-controlled trial.
- **Collaborative Approach:** The CRAs worked closely with both the sponsor and the incumbent CRO, ensuring seamless coordination and site support.

Results

Through strong collaboration and proactive site management, ProPharma supported BioXcel in achieving a key milestone within aggressive study timelines.

- When the database lock was moved up by one month, CRAs increased on-site presence and achieved 100% SDV.
- The study reached database lock on the accelerated timeline, safeguarding both quality and delivery expectations.
- This milestone supported BioXcel's ability to stay on track for their planned Q1 2026 sNDA submission for IGALMI® (BXCL501) for at-home use, moving one step closer to expanding treatment options for patients living with bipolar disorder or schizophrenia.