PhaseWell RESEARCH

CASE STUDY / CNS

#1 enrolling site worldwide in a *psychedelic* TRD trial.

A PhaseWell Research site randomized 23 patients, about one in seven across 45 sites in four countries, and kept 96% of them through study completion, on one of psychiatry's most operationally demanding protocols.

ENROLLMENT

1 in 7

Of all randomized patients worldwide (23 of 156), from one of 45 sites

96%

Retention: 22 of 23 randomized patients completed

EFFICIENCY & QUALITY

38%

Screen-fail rate (14 of 37), vs. 71% study-wide

24–48 hr

eCRF turnaround, with minimal deviations

THE CHALLENGE

A first-of-its-kind therapy, a hard-to-reach population, and no margin for error.

An emerging biotech needed sites that could find, qualify and retain patients who had already failed multiple therapies, on a complex, multi-vendor protocol.

High prescreen failure rates

Narrow eligibility, including at least two failed antidepressant treatments, meant most interested patients would not qualify.

Complex multi-vendor coordination

Across raters, eCOA and central labs.

Controlled-substance requirements

The site handled all of its own DEA approvals, and each dosing day meant 1.5 hours of pre-dose work and 8 hours of post-dose monitoring with a therapist, monitor, coordinator, PI or Sub-I, and lab tech.

STUDY SNAPSHOT

SPONSOR	INDICATION	PHASE	SITE
Emerging psychedelic biotech	Treatment-resistant depression	Phase II · 45 sites in 4 countries	Bio Behavioral Health, A PhaseWell Company

WHAT DROVE SUCCESS

A recruitment engine, a disciplined prescreen, and data the sponsor could trust.

Many channels, not one

A targeted digital recruitment partnership reached patients actively searching for trials online, and the site's prescreening turned those leads into most of its randomized patients.

A prescreen that protected the sponsor's budget

An optimized prescreening pipeline filtered out ineligible patients before costly screening visits, so 23 of 37 screened patients went on to randomize.

Rater rigor from day one

Experienced, credentialed raters delivered consistent scoring, critical in a TRD trial where efficacy rests on rater-administered endpoints.

Clean, fast data

Real-time data capture, 24–48-hour eCRF turnaround and rapid query resolution, backed by deviation control and routine internal audits.

Retention by design

Flexible scheduling and end-to-end logistics coordination kept 22 of 23 randomized patients engaged through study completion.

THE OUTCOME

What it meant for the sponsor.

> *Bio Behavioral Health has been an exceptional partner — the highest-enrolling site, exceeding targets with excellent data quality, minimal deviations, and strong retention despite a complex protocol.*

STUDY SPONSOR

One site, one in seven patients worldwide

As the #1 of 45 sites, the site randomized 23 of the study's 156 patients, with a 96% retention rate and a 38% screen-fail rate.

Fewer wasted screening visits

Against a 71% screen-fail rate study-wide, the site kept the sponsor's screening spend on patients who could qualify.

Planning your next CNS study?

Let's talk about what our sites can do for your trial.

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