CASE STUDY

Psychedelic Science Meets Precision Strategy: Bracken's Role in a Novel Neuropsychiatric Program

THE SCENARIO

A biopharmaceutical company exploring novel therapies for neuropsychiatric disorders initially engaged Bracken's consultants to assist with an oncology acid drug development program for soft tissue sarcoma. During this engagement, the company invited Bracken to evaluate its emerging Psychedelics for Neuropsychiatric Disorders (PFN) program. At the time, psychedelic drug development was in its early stages as a therapeutic approach, particularly for central nervous system (CNS) disorders. Given the complexities of CNS research—compounded by historical failures in Alzheimer's and other neurodegenerative conditions—Bracken's team was tasked with assessing the scientific, regulatory, and clinical feasibility of psychedelics as a treatment modality.

THE CHALLENGE

Bracken's team faced several key challenges in advancing the company's PFN program:

Scientific Uncertainty:

Psychedelics operate through neuroplasticity rather than a strict mechanism of action, requiring a novel approach to evaluating efficacy.

Regulatory Complexity:

With psychedelics being classified as controlled substances, regulatory agencies had not yet developed clear frameworks for approval.

Clinical Trial Design:

Traditional placebo-controlled, double-blind trials presented ethical and practical challenges, as the psychedelic experience itself is difficult to mask.

Broad Applicability

Psychedelics showed potential across multiple conditions, including depression, binge eating disorder, fibromyalgia, and irritable bowel syndrome (IBS), necessitating a tailored strategy for each indication.

THE DELIVERABLES

Clinical Trial Design & Patient Experience:

Bracken evaluated emerging "set and setting" protocols—where patients undergo preparatory therapy sessions before psychedelic administration and integration therapy afterward—to determine how best to structure trials for measurable outcomes.

Regulatory Consultation:

The team examined the challenges of placebo-controlled trials given the obvious psychoactive effects of the drug. Bracken explored alternative trial designs, including dose-dependent response models and comparator studies with existing medications.

Defining Success Metrics:

For indications like binge eating disorder, Bracken developed a daily diary system for participants to track eating behaviors, mood, and compliance before, during, and after treatment. This approach allowed for clear baseline measurements and quantifiable therapeutic impact.

THE RESULTS

Bracken's expertise helped shape a rigorous, scalable approach to psychedelic drug development, yielding several key outcomes:

Demonstrated Therapeutic Efficacy:

In a binge eating disorder trial, patients showed an 80% decrease in binge eating episodes and an 85% reduction in loss-of-control eating behaviors following psychedelic-assisted therapy, with sustained effects lasting 30 to 90 days.

Regulatory & Clinical Strategy Development:

Our experts provided strategic insights into clinical trial design, including dose-response methodologies and comparator studies (e.g., benchmarking against existing treatments like Lyrica for fibromyalgia).

Expanded Scientific Understanding:

The engagement reinforced the idea that psychedelic therapy is not solely drug-dependent but a combined treatment paradigm requiring both pharmacological and psychological components.

Future Regulatory Considerations:

Bracken's insights contributed to broader industry discussions on how regulatory bodies might evaluate psychedelic therapies, similar to past shifts seen in immuno-oncology.

BY THE NUMBERS

80%↓	85%↓	90+ →
DECREASE IN BINGE EATING EPISODES	REDUCTION IN LOSS-OF-CONTROL EATING BEHAVIORS	# OF DAYS WHERE SUSTAINED EFFECTS LASTED

CONCLUSION

Through our collaborative and integrated approach, Bracken's team helped position the PFN program for long-term success, transforming psychedelic-assisted therapy from a novel concept into a clinically viable treatment strategy across multiple neuropsychiatric indications.

BRACKEN
TheBrackenGroup.com
215.648.1208
12 Penns Trail
Newtown, PA 18940