



# Advancing Psychedelic Therapies:

## Comprehensive Data and Regulatory Support

Expert Guidance Across the Full Development Lifecycle

[mms Holdings.com](https://mms Holdings.com)

# End-to-End Data and Regulatory Support for Psychedelics Development

The life science industry's renewed interest in psychedelic therapies is driven by emerging evidence of their potential to address challenging mental health conditions like post-traumatic stress disorder (PTSD), depression, and substance use disorders. As regulatory pathways evolve and public perception shifts, development efforts are intensifying across a range of product types including MDMA, ketamine, and psilocybin-based treatments.

## Why Psychedelic Development Needs the Right Specialist Guidance

This resurgence of R&D activity presents both significant opportunities and complex challenges. Sponsors must navigate unique considerations in trial design, safety monitoring, and regulatory engagement—areas where specialist expertise is essential. MMS offers unmatched experience across the full psychedelics landscape, helping clients overcome development hurdles and regulatory complexity. From early strategy and KerusCloud®-enabled trial design to NDA support and REMS planning, we provide end-to-end guidance grounded in a track record of delivery.

## Therapeutic and Compound Breadth

MMS has the largest experience base of any provider in data and regulatory support for psychedelic development, with expertise spanning key compound classes including MDMA, ketamine, and psilocybin.

Experience includes work across a range of therapeutic targets, including PTSD, substance use disorder, and depression.



## End-to-End Development Expertise

MMS offers comprehensive, end-to-end support from regulatory strategy and study design optimization using KerusCloud®, through end-to-end biometrics services execution, safety and medical writing, to NDA coordination, REMS design, and implementation.

We have significant experience in authoring and leading NDA applications for psychedelics, including active participation in formal FDA meetings and Advisory Committee (AdCom) proceedings.

# Strategic and Academic Collaboration

We work closely with academic key opinion leaders, the Veterans Affairs (VA) system, the Department of Defense (DoD), and other public-sector stakeholders.

Team members are recognized industry thought leaders, shaping psychedelic development standards through conference presentations, guidance documents, and publications.

Our strong relationships and endorsements from consortia, clinicians, sponsors, and investor groups position us as trusted partners across the psychedelic treatment landscape.

MMS has supported applications reviewed by the Psychopharmacologic Drugs Advisory Committee and offers deep insight into the FDA's 2023 guidance on psychedelic drug development, with a clear understanding of how to operationalize regulatory expectations.

## Proactive Management of Complexity and Data Risk

**Our team brings detailed, hands-on knowledge of the risks, challenges, and success factors unique to psychedelic development, including:**

- Deep understanding of endpoint types specific to psychedelic trials—such as guided psychedelic therapy—and the associated failure modes and data quality risks in highly subjective, non-standardized outcomes.
- Familiarity with complex patient dynamics, including high rates of concurrent substance misuse and associated behavioral and compliance challenges.
- Data oversight and design optimization technology (DataCise®, KerusCloud®) tailored to risk mitigation in psychedelic drug development and regulatory review.



## The Value We Bring



### #1 in Psychedelic Regulatory Support

Most extensive experience supporting key compound classes including MDMA, ketamine, and psilocybin development across data and regulatory submissions.



### Agency-Facing Track Record

Experience with Advisory Committee preparation, FDA meetings, and applications reviewed by the Psychopharmacologic Drugs Advisory Committee.



### Strategic Influence

Active contributors to guidance, publications, and key industry consortia.



### Oversight and Risk Mitigation

DataCise® and KerusCloud® enable real-time oversight and mitigate development risk.

## A Specialist Partner for the Complexity Ahead

As trial complexity and data volume continue to grow, MMS is committed to staying ahead. We're investing in people, process, and technology to help sponsors navigate both today's challenges and tomorrow's innovations.

Scan the QR code to learn more about our clinical development and regulatory solutions.



### Award Finalist: Fierce CRO Awards



Excellence in Client Service and Partnership 2025 Award

MMS Holdings (MMS) is an award-winning, data-focused clinical research organization (CRO) that supports the pharmaceutical and biotech industries with a proven, scientific approach to complex trial data and regulatory submission challenges. Strong industry experience, an 19-year track record, AI technology-enabled services, and a data-driven approach to drug development make MMS a valuable CRO partner. With a global footprint across four continents, MMS maintains an industry-leading customer satisfaction rating.

[mmsholdings.com](https://mmsholdings.com)

