ALTASCIENCES
CLINICAL SERVICES

# PSYCHEDELIC
## CLINICAL RESEARCH AND TRIALS

With specialized experts on site, dedicated facilities, and the ability to manage programs seamlessly from preclinical through clinical development, we offer a truly end-to-end solution for psychedelic research. **As North America's first early-phase CRO to provide comprehensive psychedelic research capabilities**, we have pioneered the unique methodological and clinical adaptations required for early-phase studies in this emerging field.

Our turnkey approach delivers high-quality, regulatory-ready data under one trusted partner. From protocol design and project management to bioanalytical support, regulatory guidance, and report writing, we provide seamless expertise across the development pathway. Having successfully completed IND-enabling preclinical programs and a wide range of clinical trials, including first-in-human and specialized Thorough QT (TQT) studies, we bring proven expertise and dedicated focus to the complexities of psychedelic research.

## WHY CHOOSE ALTASCIENCES FOR YOUR PSYCHEDELIC CLINICAL RESEARCH?

- A comprehensive turnkey solution that includes protocol design, project and site management, bioanalytical support, data management, biostatistics, regulatory support, and report writing.
- Completed preclinical IND-enabling programs for multiple molecules, with successful filings and program advancement.
- Delivered a range of preclinical and clinical programs, both completed and ongoing/planned.
- Conducted clinical first-in-human (FIH) to clinical pharmacology trials in healthy participants, including a successful Thorough QT (TQT) study with a psychedelic drug—demonstrating our expertise and careful attention to set and setting.

Completed **DOZENS OF STUDIES** involving psychedelic and dissociative compounds in healthy volunteers

**3** clinical pharmacology units

**12** on-site driving simulators for cognitive testing

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# PSYCHEDELIC CLINICAL TRIAL EXPERTISE YOU CAN TRUST

## Customized Solutions Specific to Psychedelic Studies

- Integrated preclinical to clinical POC, including manufacturing and bioanalysis, with Schedule I licenses for psychedelics and hallucinogens
- Dedicated psychedelic trial units and flexible set/setting spaces
- Secure, locked facilities and compounding pharmacies
- Specialized procedures, including CSF sampling, imaging, EEGs, and ECGs

## Study Start-Up and Recruitment

- Schedule I licenses, support for all DEA arrangements, and the expertise to get drug product on-site in time for study start
- Database of 400,000+ healthy volunteers with targeted screening for psychedelic readiness
- Best-in-class timelines for FIH, TQT, FE, RelBA, and DDI enrollment while supporting specialized operational needs
- Trusted site network for trials requiring patients
- Safe, adaptable environments designed for retention and compliance

## Highly Experienced Staff and Facilitators

Our highly experienced team combines scientific expertise with clinical insight to deliver excellence in psychedelic research. Qualified facilitators, skilled in diverse study methodologies, bring hands-on experience to every trial. An on-staff licensed psychiatrist leads as Principal Investigator, supported by clinical neuropsychologist-driven training for pharmacodynamic assessments. With regulatory and scientific specialists ensuring compliance and robust study design, and a strong foundation in CNS and neurology from psychiatrists and neuroscientists, we offer unmatched expertise to advance the future of psychedelic medicine.

**Proactive monitoring of abuse/dependence-related adverse events is a regulatory requirement for drug submissions in the U.S. and Canada.**

## Safety and Study Integrity

- Monitoring oversight by fully accredited facilitators
- Well-developed procedures for participant safety, including Safety and Security Officers
- Adverse event monitoring to deliver all required regulatory data and ensure participant safety
- Mitigation strategies to address functional unblinding
- Protocol design and reviews by experienced psychedelic trial experts
- Deep understanding of evolving regulatory requirements, including 8-Factor Analyses and Human Abuse Potential (HAP) studies

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