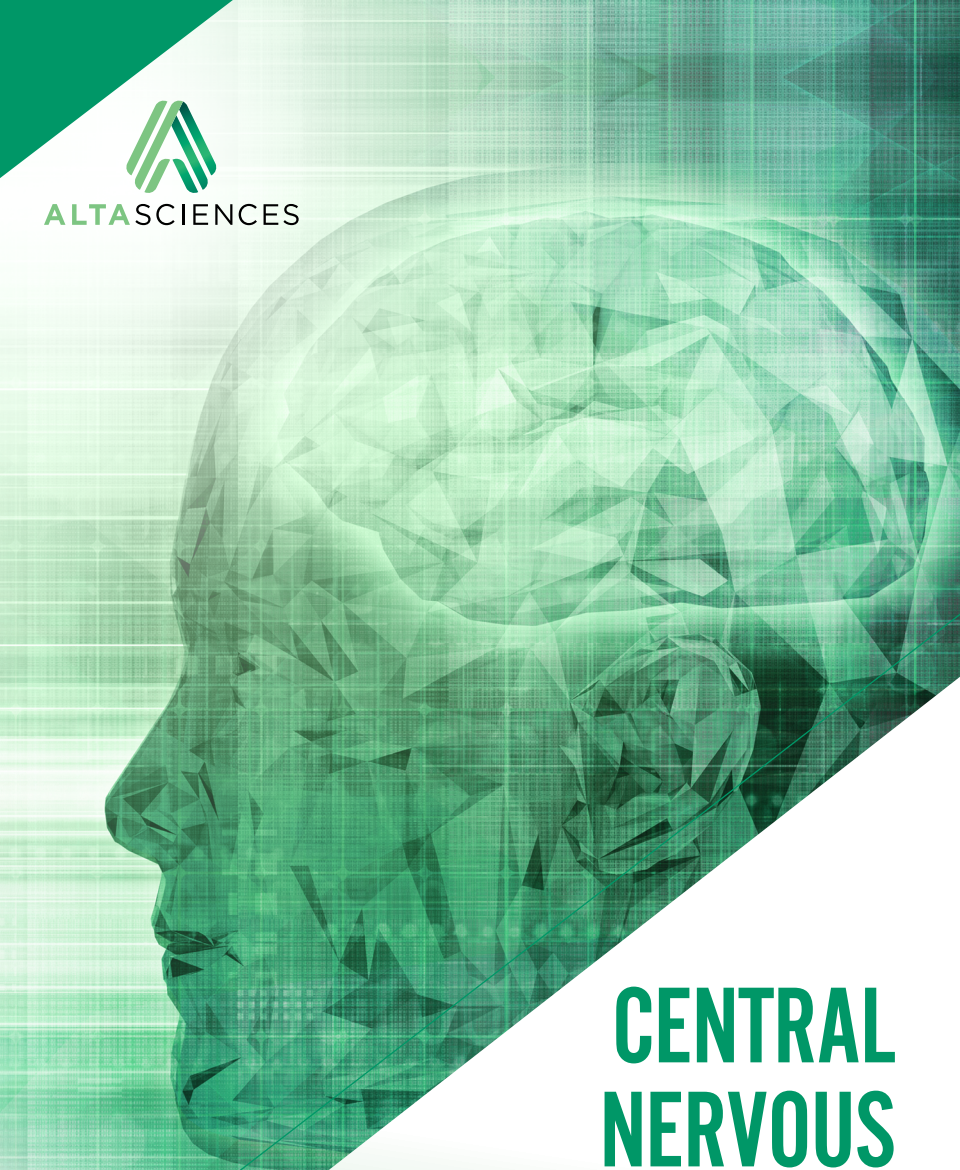
ALTASCIENCES

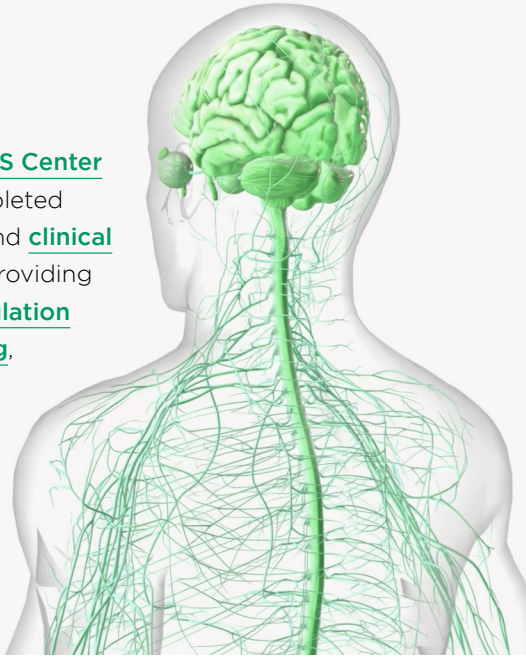


CENTRAL NERVOUS SYSTEM (CNS)

DRUG DEVELOPMENT, SIMPLIFIED

Your Partner From Discovery to Commercialization

Recognized globally as a **CNS Center of Excellence**, we have completed more than 200 **preclinical** and **clinical** CNS studies, in addition to providing **bioanalytical support**, **formulation development**, **manufacturing**, and **analytical services**.



End-to-End CNS Drug Development Services That Deliver

With **over 30 years of experience** in drug development and manufacturing, we can help move your small and large molecules through early development seamlessly and efficiently, from discovery to commercialization. Our integrated approach streamlines your path to market, enabling rapid, informed decisions at every step. With our model, you can safely **reduce your development timelines by up to 40%**.

Our Solutions, at a Glance

- Formulation and Manufacturing
- Preclinical Safety Testing
- Clinical Research
- Bioanalysis
- CRO Services

Formulation Development and Manufacturing Services

Our cGMP, FDA-registered facility is DEA-licensed for Schedule I-V drugs with specialized manufacturing suites for **potent compounds** and controlled substances. We are also equipped with R&D and formulation laboratories for all required analytical testing, including **method development** and validation, **ICH stability testing**, and **drug product release testing**.

We offer advanced techniques like **nanomilling** to resolve solubility and bioavailability issues common with CNS compounds, and produce **tablets**, **sterilized injectables**, **liquid**- and **powder-filled** capsules, and most other dosage forms.

Our manufacturing expertise includes:

- Drug product characterization
- Seamless transition from prototype formulation to clinical proof-of-concept
- Micro and nanoparticulate formulations
- Method development for low-concentration formulations
- Scale-up and process optimization of low-concentration formulations of potent and controlled substances
- Clinical supply manufacturing for Phases I to IV
- Finished dosage form manufacturing and packaging
- Commercial batch manufacturing

View a **CASE STUDY** *on scaling up the manufacturing of a sponsor's nanosuspension drug product.*

CASE STUDY

Nonclinical Safety Testing of Your CNS Compounds

We have decades of expertise in nonclinical research for CNS indications, and provide comprehensive *in vivo* GLP and non-GLP studies across multiple species, to thoroughly assess the safety profile of your CNS drug compounds. Our services include **IND/CTA-enabling and NDA/BLA-enabling studies**, and bioanalytical services for both small and large molecules, designed to identify potential neurotoxic effects, seizure risks, and impacts on cognitive and motor functions. Our integrated approach combines behavioral analysis, neurochemical profiling, electrophysiology, and imaging to deliver comprehensive data that meets global regulatory requirements.

Our three preclinical research facilities include a dedicated site with expertise in non-GLP exploratory CNS research in nonhuman primates, focused on cell and gene therapies and oligonucleotides, among others. We also have vast experience with cognitive measures, functional observational batteries, EEG-implanted telemetry equipment, MRI scanning, and other imaging modalities.

Comprehensive Testing

Our full range of CNS nonclinical research covers:

- Exploratory primate surgical models
- Exploratory primate CNS research
- **Lead optimization**
- **Preclinical pharmacology**
- **Pivotal toxicology**
- **Pharmacokinetics/pharmacodynamics**
- **Dose range finding/maximum tolerated dose**
- **Safety pharmacology**

Integrated Approach

Our preclinical and clinical teams work together to ensure a rapid and smooth transition from safety testing to first-in-human trials, providing briefing documents and support for all types of global regulatory meetings along the way.

View a **CASE STUDY** *on gene therapy and stem cell transplantation via MRI-guided intraparenchymal delivery into brain regions.*

CASE STUDY

Maximizing Early-Phase Clinical Trials of CNS-Active Drugs

We offer a comprehensive suite of **clinical services** to support the development of CNS drugs, combining therapeutic expertise with specialized assessments to ensure high-quality data and efficient trial conduct.

Our capabilities include protocol design, patient recruitment, biomarker development, and a full range of CNS-specific evaluations, such as specialized imaging, EEG, CSF collection, cognitive testing, neuropsychiatric evaluations, pain models, dependence evaluations, abuse potential studies, and safety monitoring. We are especially recognized for our expertise in assessing the cognitive effects of centrally acting drugs, including regulatory-required **driving simulation studies**.

With access to our three North American clinical pharmacology sites, specialized investigator networks, and proven expertise in indications like neurodegenerative diseases, psychiatric disorders, and pain management, our tailored solutions help swiftly bring your CNS therapies to market with confidence.

Our clinical team has completed CNS/neurological studies in:

- **First-in-human**
- **Proof-of-concept**
- **Human abuse potential** (over 50 studies)
- Psychedelics
- Physical dependency
- Factor 8 Analysis
- **Driving simulation**
- Cognition
- Pain
- **Cannabis products** (over 40 studies)

Our clinical pharmacology units are purpose-built to support complex pharmacodynamic assessments and comprehensive safety monitoring, with the necessary DEA/narcotics licensing in place. Our state-of-the-art pharmacies feature advanced security systems and multilayered controlled access, operated by experienced pharmacists skilled in the preparation of CNS, substance abuse, and human abuse potential (HAP) study drugs for oral, sublingual, intranasal, and parenteral administration.

Our **adaptive clinical pharmacology units** are specially configured to support trials involving diverse patient populations and controlled substances, including psychedelics, cannabinoids, and opioids. In addition, they feature a dedicated **driving simulation** unit, where we have conducted over 13,000 simulated drives to date—providing valuable data on the cognitive and psychomotor effects of CNS-active compounds.

500+	12	400K+
BEDS	DRIVING SIMULATORS	PARTICIPANTS IN OUR DATABASE

We maintain a robust participant database that includes healthy normal volunteers for **first-in-human trials**, as well as patients and special populations to support your **clinical proof-of-concept studies**. In addition to the study types mentioned above, we have extensive experience in insomnia, Parkinson's disease, Alzheimer's disease, ADHD, depression, social anxiety, and other therapeutic areas.

View a **CASE STUDY** *where we demonstrated, through driving simulation studies, that there was no impairment to driving the morning after nighttime dosing of a CNS-active drug.*

CASE STUDY

Bioanalytical Expertise for CNS Drug Development

Our **bioanalytical** scientists work seamlessly with our preclinical, clinical, and CRO services teams to ensure the accurate collection, dissection, and handling of your CNS samples.

With over 300 dedicated scientists supporting both small and large molecules, we perform comprehensive bioanalysis for drug quantitation, systemic exposure assessment, biomarkers, and immunogenicity testing.

Our state-of-the-art instrumentation and **assay platforms** (LC-MS/MS, LBA, or hybrid LBA/LC-MS/MS) achieve the ultra-low sensitivity necessary for plasma or serum TK/PK samples in CNS drug development. We are an industry-recognized leader in small molecule bioanalysis using mass spectrometry, and have proven scientific expertise in the development and validation of bioanalytical assays supporting CNS indications. For clinical trials, we specialize in cerebrospinal fluid (CSF) drug sampling.

Discover our **validated list of bioanalytical assays**, including those for CSF.

CRO Services

As part of our full-service offering, we provide comprehensive **CRO services**, including **regulatory and scientific guidance**, protocol development, project management, clinical monitoring, medical writing, biostatistics, data management, **CDISC**, and **SEND**.

Our regulatory team is integrated with our preclinical, clinical, bioanalytical, and manufacturing teams, for a holistic oversight of your program. This ensures all data is collected and analyzed efficiently—streamlining the transfer of information and giving you access to real-time data.

Be it an IND submission in the U.S. or a CTA in Canada or Europe, our integrated solutions model provides comprehensive regulatory support at every drug development stage—from early product development to commercialization.

Our robust understanding of the CNS safety protocols in the ICH S7A regulatory guideline also ensures that your program rapidly advances to clinical trials.

Our comprehensive services include:

- Drug development and regulatory guidance
- Gap analyses
- Chemistry, manufacturing, and control (CMC) support
- Target product profile and clinical development plans
- Investigator's Brochure (IB) preparation
- Pre-IND and/or Pre-CTA meeting support
- Submission assembly and maintenance
- IND and CTA post-approval maintenance

Whether you need end-to-end support or help with a single element, we offer you complete flexibility.

From Bench to Bedside—Simplified by One Integrated Partner

When you partner with us from the very beginning of your drug development program, you benefit from streamlined data sharing and a fully aligned team for rapid, informed decisions at every step. **Our integrated approach can reduce your development timelines by up to 40%**, accelerating your path to market.

Speak with one of experts today to discover how we can help move your CNS compound through the early phases of drug development seamlessly and efficiently.

CONTACT US

RELATED RESOURCES

Scientific Journals (eBooks):

- CNS, Psychedelics, and Other Schedule I Drugs
- Navigating the Complexities of CNS-Active Drugs
- CNS Drug Development—Integrated Solutions Lessen Complexity
- Studying the Effects of Drugs on Driving
- Assessing Human Abuse Potential to Limit the Misuse of Prescription Drugs

Webinars:

- Inside the Pharmacokinetic Toolbox
- The Importance of Cognitive and Pharmacodynamic Testing During First-in-Human Trials
- The Unique Attributes of Psychedelic Drug Development

Webpage:

- Altasciences' End-to-End CNS Drug Development Services

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