

Because of the complexity of early development clinical trials for central nervous system (CNS) drugs, in-depth clinical expertise is crucial to the success of your programs. Incorporating cognitive and subjective drug measures can provide critical pharmacology, safety, and proof-of-concept early in clinical development, helping to strategically characterize a drug product. Evaluating cognition and implementation of models requires expert staff, consistency, precision, and a customized environment to ensure the integrity and reproducibility of data collection.

Altasciences is a leader in early phase clinical CNS trials. With decades of experience in conducting complex studies across various therapeutic indications within CNS, our team of Principal Investigators, neuropsychologists, clinicians, nurses, neuroscientists, and clinical pharmacologists has an extensive understanding of psychiatric and neurologic disorders. This expertise translates into a smooth process and clinical results you can rely on.

Study Types and CNS-Related Procedures

- First-in-human (FIH) with strategic cognitive testing
- Imbedded or standalone proof of concept (PoC)
- Human abuse potential (HAP)
- Driving simulation
- Pain models
- Psychedelic drug evaluation
- Respiratory research, capnography
- Sleep efficiency evaluation with polysomnography
- Pupillometry
 - Cerebrospinal fluid (CSF) collection
 - EEG with ERP
 - Electronic visual analog score (VAS)/ questionnaires
 - CO2 challenge for anxiety

Special Population and Patient Access

Altasciences' extensive databases of over 400,000 study participants include a diverse population of healthy normal volunteers and special populations often recruited for CNS trials, including recreational drug users, elderly participants, and smokers.

Our access to patient populations enables us to recruit small cohorts for early phase studies, including patients diagnosed with:

- ADHD
- Epilepsy
- Migraine
- Pain
- Neuropathies
- Restless leg syndrome
- Age-related cognition issues
- Sleep disorders
- Anxiety and panic disorders
- Major depressive disorder
- Fibromyalgia
- Premenstrual dysphoric disorder
- Binge eating disorder
- Osteoarthritis
- Substance use disorders

Patients with other CNS disorders can be identified upon request.

Cognitive Testing

Our expert neuroscientists rely on their increased understanding of medication-induced neurocognitive effects to recommend targeted cognitive markers. This enables go/no-go decisions during early clinical drug development. Strategically selected cognitive testing provides meaningful information about the safety profile and/or risks of impairment, and may even serve to waive additional studies (e.g., abuse potential, driving simulation). We partner with Cambridge Cognition, a leading neuroscience technology company, to digitally administer non-invasive test batteries of brain function.

Cognitive Domains

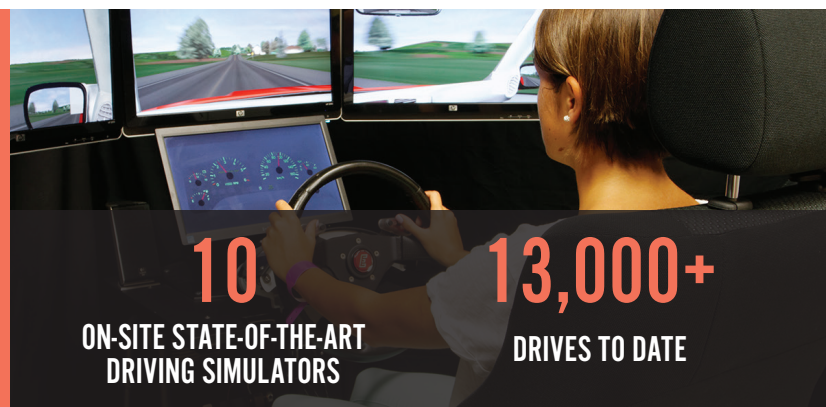
- Complex attention
- Learning and memory
- Language
- Executive function
- Social cognition
- Perceptual-motor function

Examples of Cognitive Assessments

- Choice reaction time
- Divided attention
- Digit vigilance
- Digit symbol substitution
- Spatial working memory
- Sternberg short-term memory
- Hopkins verbal memory
- Naming tests
- Paired associates learning
- Go/no-go tasks
- Questionnaires
- VAS
- Rating scales
- Balance platform
- Finger tapping
- Simple reaction time

Driving Simulation

Together with Cognitive Research Corporation (CRC), we provide state-of-the-art driving simulator study solutions with healthy and patient populations. In less time, for lower costs, and with no risk of property damage or injuries, the driving simulator provides accurate performance data comparable in sensitivity to over-the-road-testing. The CRC driving simulator has proven sensitivity to the effects of drowsiness, age, trauma, neurologic disease, CNS depressant, and stimulant drugs.



Customized Facilities

Our clinical units are designed to accommodate controlled cognitive testing environments. Our units are adapted to control for light, temperature, noise, and other stimuli to minimize distraction and collect valid, reliable, reproducible test results. Our clinic staff carefully monitor subjects throughout testing sessions to provide safety oversight and ensure consistent completion of testing.

Comprehensive Training

Successful conduct of cognitive tests requires training of both staff and subjects. Our team of experts design comprehensive standard operating procedures and training manuals adapted to meet the specific requirements of each study. Both staff and subjects are rigorously trained on study-specific procedures for CNS drug testing. Training and practice sessions are incorporated into each study to confirm that subjects fully understand, and are able to adequately complete, all the testing requirements tasks as instructed. Some procedures may require that subjects achieve a specific response on tasks to qualify for study entry. Our team of experts will ensure that the best practices are implemented in your study design.

Regulatory Complexities

We are experienced in adaptive trial designs and have vast experience working with central institutional review

boards (IRBs). Our internal protocol review ensures the protocol is IRB-submission ready, minimizes the risk of amendments, and shortens study start-up time.

Specialized Secure Pharmacy

Altasciences' robust pharmacy capabilities and vast experience include extemporaneous and intravenous preparation (including biologics). Our pharmacists have extensive experience in preparing and dosing studies via oral, sublingual, intranasal, and parenteral routes. Our secured pharmacy is licensed for the storage of scheduled controlled substances and is protected by electronic key fob access, video monitoring, and facial recognition technology.

Dedicated Research Physicians

Our Principal Investigators have diverse medical backgrounds including psychiatry, anesthesiology, and pain management. They are involved in all aspects of clinical trials, ensuring that proper medical and technical procedures are completed to the highest degree of quality.

Partnerships

For your CNS testing, Altasciences partners with:

- Cognitive Research Organization
- Cambridge Cognition