



# Central Nervous System



Early development clinical trials for CNS drugs are complex and can require in-depth clinical expertise. When conducting CNS trials, it is critical that contract research organizations implement thorough processes in areas such as volunteer eligibility and operational conduct. To meet these demands CNS study teams should possess both therapeutic and technical expertise.

**Altasciences Clinical Research** is a leader in the field of early phase clinical conduct for CNS trials. Our Principal Investigators, Clinicians, Technical Staff, Nurses, and Management Team have an extensive understanding of psychiatric and neurologic disorders stemming from our fifteen-year history of conducting complex studies in various therapeutic indications within CNS.

## Regulatory Complexities

We are experienced in adaptive trial designs often associated with CNS therapies and our vast experience in working with a central IRB means we understand their requirements for study document approval. Our internal protocol review ensures the protocol is IRB submission ready, minimizes the risk of amendments and shortens study start-up time.

## Specialized Pharmacy

Our 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. Additionally, our pharmacy is secured with electronic key fob access, video monitoring and facial recognition security.

## Distinctive Recruitment Strategies

The ability to recruit the right patient population is especially important in studies involving CNS acting drugs due to their target therapies. Our in-house recruitment team with eight full-time recruiters is essential to the effective and efficient recruitment strategies that Vince & Associates employs in order to reliably meet our Sponsors' targeted milestones.

## Dedicated Research Physicians

Our Principal Investigators are intricately involved in all aspects of clinical trials, ensuring that proper medical and technical procedures are completed to the highest degree of quality. Significant physician involvement is a key element when successfully executing CNS trials due to the adverse event profile and safety concerns with this drug class.



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# Altasciences' CNS Experience

Over the past twenty-five years Altasciences has been involved in clinical trials in the following special populations:

- Human Abuse Liability
- Substance Abuse/Dependence
  - Methadone/Buprenorphine
  - Hydromorphone Challenge
  - Opioid Dependence
  - Cocaine
  - Alcohol
- Cognitive Testing
- Epilepsy
- Generalized Anxiety Disorder
- CO2 Challenge
- Smoking Cessation
- Panic Disorder
- Depression
  - Pediatric
  - Adult
  - Elderly
  - Treatment Resistant
- Sleep
  - Insomnia
  - Transient Insomnia
  - Insomnia with Pain
  - Insomnia with RA
  - Dim Light
  - ADHD with Insomnia
  - Sleep Apnea
  - Shift Work Sleep Disorder
  - Delayed Sleep Phase Syndrome
- Pain
  - Migraine
  - Migrainous Disorder
  - Fibromyalgia
  - Osteoarthritis
  - Acute
  - Sports Injury
  - Chronic Low Back Pain
- ADHD
  - Adult
  - Pediatric
  - Adult Workplace Environment (AWE)
  - Analog Classroom

Others upon request



## Cognitive Testing

We have partnered with Cognitive Research Corporation (CRC) to provide sponsors with a state-of-the-art driving simulator study solution to test the impairing effects of a wide variety of drugs on driving abilities in both normal and patient populations. The simulator provides accurate driving performance data comparable in sensitivity to over-the-road-testing, but in less time, for less cost, and with no risk of property damage or injuries. The CRC driving simulator has proven sensitivity to the effects of age, trauma, neurologic disease, drowsiness, CNS depressants and CNS stimulants.

We are proud to have partnered with CRC in establishing the lack of driving impairment following nighttime dosing of flibanserin in premenopausal women. The study, sponsored by Sprout Pharmaceuticals, was described as "reassuring" by the FDA.

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