

Central Nervous System (CNS)

Preview

INC Research's global full-service capabilities

- Full service clinical development programs from IND submissions to Phase I-IV clinical study execution
- Phase I studies in healthy volunteers and the patient population
- Proof-of-Concept studies
- Pivotal Phase III studies
- Phase IV post-marketing studies
- Clinical trials in orphan indications

At INC Research, we appreciate the complexities of the nervous system and the widely varying disciplines that explore CNS function, dysfunction and drug research. Working with CNS specialists and drawing upon an extensive network of academic and private practice physician investigators, we have directed clinical trials for more than 20 years in psychiatry, neurology and pain (including indications such as sleep, movement disorders and schizophrenia), earning worldwide recognition as leaders in CNS drug and product development.

Comprehensive CNS expertise

We've earned a reputation as CNS experts by staying true to and growing our therapeutic focus. The strength of our team's in-depth knowledge of psychiatry, neurology and pain is brought directly to bear on our customers' critical CNS drug development programs. INC Research's CNS Practice offers a flexible array of services fully customized to the specific requirements of the individual trial and the unique needs of each valued customer. With a wealth of experience in both adult and pediatric research, we design and implement full research programs, deliver discrete services for any part of a single trial, and even rescue failing trials.

Global reach, individualized solutions

INC Research's CNS team has an extensive database and well-nurtured relationships with key investigators specializing in CNS drug development in both private practice and academic settings across the globe. Our long-standing relationships with experienced investigators provide access to a vast population of treatment-naïve, compliant and highly motivated patients. Well connected and supported by the most advanced technology, our international project teams are dedicated to meeting and often exceeding each customer's unique research, development and regulatory needs. We focus our energies, expertise and resources where and when you need them to meet your individual CNS drug development goals.

Specialty population recruitment

Our team has a full-time recruitment department with database access to specialty populations, including drug use disorders and dementia. We also can customize campaigns to draw on our local network of referring physicians. We have a referral arrangement in place with the University of Toronto and have access to a robust network of methadone clinics in Ontario, allowing us to maintain a high enrollment success rate for such studies.

Analgesia case study

In a study for patients with chronic, non-malignant pain, INC Research's CNS Practice was tasked with enrolling 100 patients at 25 sites in 12 weeks. The customer had not anticipated IRB issues concerning the use of Schedule 2 narcotics and there was a significant start-up delay, reducing the actual enrollment time to less than 6 weeks. Because of INC Research's previous experience with the clinical centers, only five pre-study site visits were required for 25 sites, and 17 initiation site visits were conducted in just 9 days. INC Research exceeded the required enrollment by 23 percent in one-half of the allotted time.

Neurology case study

In a recent North American stroke trial, INC Research's CNS Practice was hired to rescue a failing study. After giving management of the study to INC Research, the project manager, having had extensive stroke trial experience, enacted a strategic addition of 50 percent more sites immediately. Several of the added sites were under key thought leaders in stroke – investigators with whom INC Research had developed longstanding relationships. On the advice of INC Research, the customer adopted recommended protocol changes. Previous enrollment had stalled at a total 20 patients at 30 sites during a 12-month period. However, with the addition of key sites and the protocol changes recommended by INC Research, the rate of enrollment increased significantly, from 0.06 patients/site/month to 0.54 patients/site/month, and 147 patients were enrolled in the following 6 months.

Psychiatry case study

In a recent North American trial of insomnia associated with generalized anxiety disorder (GAD), the INC Research CNS Practice was hired to manage all aspects of the study. Immediately after study award, our CNS project manager along with the core team, implemented study planning and execution strategies utilizing the INC Research Trusted Process® and leveraging years of experience in this area. Several of the sites were under key thought leaders in psychiatry, including investigators with whom INC Research had developed long-standing relationships. The study had very aggressive timelines for enrollment completion and database lock. Despite the need to screen 60 percent more patients and enroll 20 percent more patients than originally planned, the CNS team was able to complete enrollment by the initially-projected target date and lock the database ahead of schedule.

For more information

about INC Research's capabilities in CNS, please contact us at info@incresearch.com or at one of the telephone numbers below:

North America

Raleigh, NC, United States. Tel: +1 919 876 9300

Europe/Middle East/Africa

Winnersh, United Kingdom. Tel: +44 118 933 5300

Asia/Pacific

Port Adelaide, Australia. Tel: +61 8 8447 3500

Beijing, China. Tel: +86 10 5809 2300

Gurgaon, India. Tel: +91 124 464 2400

Latin America

Mexico City, Mexico. Tel: +52 55 2169 0300

Corporate Headquarters

3201 Beechleaf Court, Suite 600, Raleigh, NC 27604-1547 Tel: +1 919 876 9300
Email: info@incresearch.com www.incresearch.com



Therapeutic Foresight.
Trusted Results™