synteract®

Expertise to Advance Complex Neuro Degenerative Clinical Trials

In the past 5 years, Synteract has conducted:

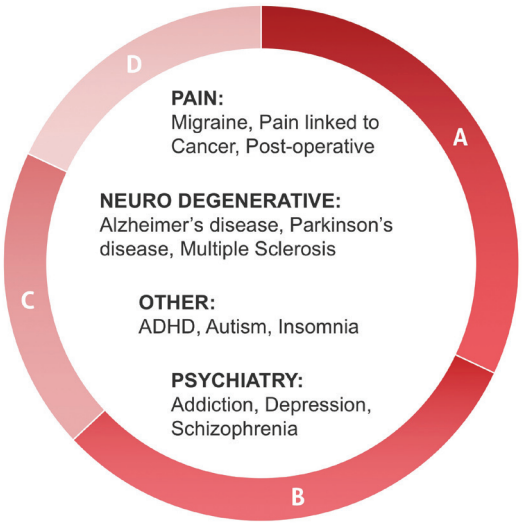
140+	30+	2,500	30,000
NEURO DEGENERATIVE CLINICAL TRIALS	INDICATIONS	SITES	PATIENTS

Anticipating the Challenges Ahead

While diseases of the central nervous system can impact patients of all ages, they are set to rise as elderly populations double between 2011 and 2050. Developing drugs across the spectrum of these complex disorders requires specialized understanding and experience. In just the last 5 years, we have managed more than 140 trials in multiple cognitive, pain, and psychiatric indications. You can rely on our experience to guide your trials through this diverse landscape.

Drawing on the Knowledge You Need

We understand these challenges, from drug compliance and accountability to patient consent and retention. At Synteract, our knowledgeable project teams, therapeutic experts, and access to top investigative sites can help you develop the best strategies to conduct your clinical studies and focus on what matters most: developing treatments to improve functioning and help the lives of patients and caregivers. We offer flexibility to address your specific needs with full scope clinical development programs, a la carte services or rescue studies.



A - Pain: 32%
B - Neuro Degenerative disease: 31%
C - Other: 19%
D - Psychiatry: 18%

Contact us to leverage our three decades of Neuro Degenerative experience to advance your clinical trial.

Linda Rawlings, MSc, FIBMS, Vice President, Neuro Degenerative Development

- 27 years in the CRO, pharmaceutical and medical device sectors
- Master of Science degree in Chemical Analysis
- More than a decade in operational and commercial roles, with a keen focus on developing and implementing strategies designed to deliver excellence at the local, international, and global level

CASE STUDY

Synteract Exceeds NeurAxon Expectations in Migraine Clinical Trials

NeurAxon is a pharmaceutical company headquartered in North America, focused on developing novel pain management solutions. Synteract partnered with it for the development of its first compound in 2007, and has since been named its primary provider of CRO services, working on over 10 studies with two different compounds in multiple pain indications. In 2009, Synteract partnered with NeurAxon to execute two Phase II studies to evaluate safety and efficacy of its lead compound in migraines with and without aura. Trials were conducted in the U.S. and Canada.

Challenges

- Enrollment timelines were critical to the company and investors.
- Synteract was handling two similar studies for NeurAxon simultaneously. Patient enrollment occurred quickly so resources needed to be carefully managed to maintain study progress and ensure data collected was of the highest quality.
- The study drug itself was being provided to the subjects to self-administer at home. Sites needed to oversee compliance.

Our Solutions

- To capture efficiencies across the similarly designed studies, a comparable project team structure was adopted to share best practices yet function independently.
- To manage monitoring at the pace needed to achieve study objectives, regional monitoring teams were arranged to reduce travel and allow for flexible visits. "Floating" monitors could also supplement efforts at sites with heavy workloads or competing demands.
- With enrollment timing the most critical factor impacting success, Synteract identified primary site lists with a 30% overage to proactively replace underperforming sites as needed while maintaining study momentum.
- To manage patients administering medications from home, Synteract deployed an IVRS solution that tracked randomization and dosing of subjects. The system alerted sites after a patient had dosed and needed follow-up.

Program Success

- Both Phase II migraine studies completed enrollment earlier than scheduled.
- The IVRS solution allowed Synteract to carefully track the exact number of doses in real time and manage the expected workload at sites.
- With the Phase II studies completed, Synteract and NeurAxon continued their partnership with the development of NeurAxon's second drug candidate.

Tom Lategan, NeurAxon's Vice President of Regulatory Affairs, says, *"As a small company, we have relied heavily on Synteract's experience and infrastructure to give us the reach to conduct multicenter, multi-country studies. Synteract has worked well with our other vendors and consultants, and has been a pleasure to work with."*