



Expertise to Advance Complex Neuroscience Clinical Trials

Highlights in the past 5 years:

130+ NEUROSCIENCE
CLINICAL TRIALS

30+ INDICATIONS

2,200+ SITES

27,000+ 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 130 trials in multiple neurology, 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 relationships with 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 the lives of patients and caregivers. We offer flexibility to address your specific needs with full scope clinical development programs, standalone services or rescue studies.

Neurology:

- Alzheimer's Disease
- Parkinson's Disease
- Multiple Sclerosis

- Non-AD Dementias
- Minimal Cognitive Impairment (MCI)
- Frontotemporal Dementia
- Louis Body Dementia
- Vascular Dementia
- Huntington's Disease
- Movement Disorders
- Regenerative Medicine within Neurology Indications including Diabetic Neuropathy, Stroke, Diabetic Foot Ulcer, Neuro-Regeneration after Spinal Cord Injury (SCI), Traumatic Brain Injury (TBI), ALS, and others
- Stroke, Post-Stroke recovery and rehabilitation
- Epilepsy (Pediatric/Adults/Geriatric)
- Myelin Disorders (Pediatric/Adults) including Neuromyelitis Optica (NMO)
- Traumatic Brain Injury (TBI) and mild TBI (Concussion)
- Amyotrophic Lateral Sclerosis (ALS; Lou Gehrig's Disease)
- Progressive Multifocal Leukoencephalopathy (PML)
- Spasticity due to other conditions and botulinum toxins
- Restless Leg Syndrome (RLS)

Pain:

- Migraine
- Pain linked to Cancer
- Post Operative
- Chronic Pain control including Peripheral Neuropathies
- Diabetic Polyneuropathy
- Radiculopathies
- Chemotherapy-induced Neuropathy
- Migraine and Migraine Prophylaxis
- Fibromyalgia
- Acute Pain
- AIDS Neuropathy
- Rheumatoid Arthritis (RA)
- Osteoarthritis (OA)
- Dental Pain

Psychiatry:

- Addiction
- Major Depressive Disorder and other Depressive Disorders
- Schizophrenia and Schizoaffective Disorders
- Bipolar Disorders and Bipolar Spectrum (Pediatric/Adults)
- Attention-Deficit Hyperactivity Disorder (ADHD)
- Anxiety Disorders
- Generalized Anxiety Disorder (GAD)
- Post-traumatic Stress Disorder (PTSD)
- Social Anxiety Disorder (SAD)
- Smoking Cessation and Addiction Medicine
- Primary Insomnia (Pediatric/Adults)
- Sleep Maintenance Insomnia

Case Study: Synteract Exceeds Expectations in Migraine Clinical Trials

A pharmaceutical company headquartered in North America was focused on developing novel pain management solutions. Synteract partnered with it for the development of its first compound, and has since been named its primary provider of CRO services, working on over 10 studies with two different compounds in multiple pain indications. Synteract partnered with the customer 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 the customer 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 the customer continued their partnership with the development of the customer's second drug candidate.

About Synteract

Synteract is an innovative, full-service CRO supporting biopharma companies across all phases of drug development to help bring new medicines to market. Synteract has conducted 4,000 studies on six continents and in more than 60 countries, working with more than 26,000 investigative sites and 750,000 patients. It has contributed to more than 240 product approvals. Synteract offers a notable depth of expertise in oncology, general medicine, dermatology, and neuroscience indications, as well as rare and orphan, pediatric, and immunotherapy studies.

For more information on how we can support your clinical trial, please visit www.synteract.com/Therapeutic-Expertise/Neuroscience or ContactUs@synteract.com.

Synteract.com

BRINGING CLINICAL TRIALS TO LIFE™