



Neuroscience.

Through the concentration of resources and dedication of staff focused on neuroscience research, Premier Research provides the therapeutic expertise and depth of experience that only a therapeutically focused CRO can offer.

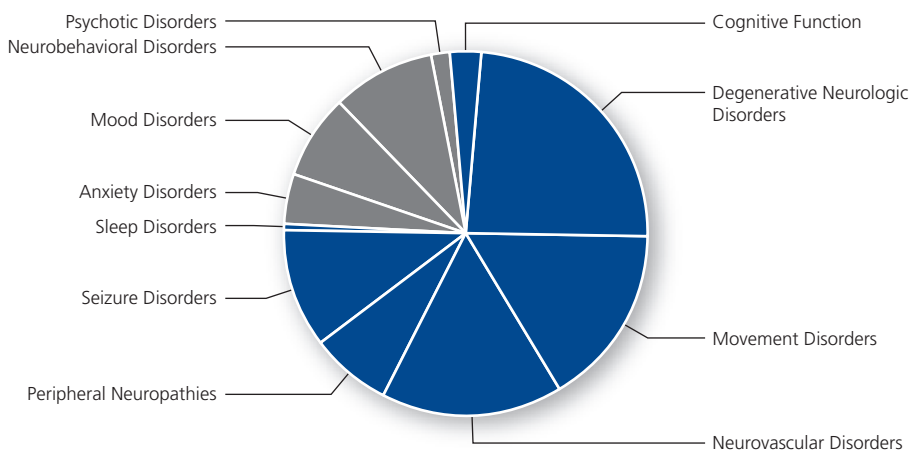
Proven Experience

- More than 80 clinical trials and 15 consulting projects in neurology indications and 25 clinical trials and 5 consulting projects in psychiatry indications in the past five years
- More than 27,000 patients treated with neurological and psychiatric disorders in the past five years
- Dedicated specialty research clinics equipped with quiet psychometry suites
- Global team with local knowledge and expertise allows us to recruit neuroscience trials
- Experience with all major CNS disorders

Expertise: The People

- More than 66% of project managers/directors and CRAs experienced in neuroscience clinical research
- Thought leader level medical and scientific expertise in neuroscience drug development
- Board certified neurologist focused on the complexities of neuroscience research
- In-house regulatory consultants provide guidance on development and regulatory strategy

Experience Within the Past 5 Years



■ Neurological Disorders ■ Psychiatric Disorders

Case Study: Managing an Alzheimer's Disease Study with Complex Assessments

Premier Research managed a double-blind, randomized study to evaluate the effects of the investigational product versus an active comparator on sleep, attention, and gastrointestinal tolerance in patients with mild to moderate Alzheimer's disease for a global pharmaceutical company.

This study included multiple complex assessments including CT/MRI scan, Actigraphy, Sleep Logs, Pittsburgh Sleep Quality Index, Choice Reaction Time/ Simple Reaction Time, Verbal Series Attention Tests, Stroop Test, and genetic analysis in addition to other efficacy measures.

Premier Research implemented steps to ensure the standardization of the multiple outcome assessments through the recruitment of experienced sites, initial study-specific training, ongoing rater training, and documentation of site staff qualifications.

Premier Research

North America: 215.282.5500
 Europe: +44 (0) 118 936 4000
info@premier-research.com

www.premier-research.com

Visit our website for our global locations.

Neuroscience.

Neuroscience is one of the key therapeutic areas with continuing medical need and one with many compounds in the research pipeline. Premier Research's expertise is therefore focused on bringing these compounds through the clinical development process as quickly and efficiently as possible, while maximizing the value of the data and information produced.

Evolving Neuroscience Research

Premier Research recognizes that the field of neuroscience is rapidly changing with innovative neuro-imaging techniques and breakthroughs in molecular biology that are ultimately expected to benefit both patients and their families but present substantial clinical and operational challenges for drug development programs in the neurosciences. Complex issues such as drug target validation and drug delivery to the central nervous system with novel delivery systems can complicate early clinical trials and must be critically evaluated to insure optimization of clinical trial design.

We realize that the success of clinical trials in neuroscience is dependent on a seamless interaction between sponsor, CRO, and investigational sites. Such studies require a thorough understanding of study design and methodology, knowledge of the use and limitations of biologic surrogate endpoints, understanding of the complexity of patient assessment tools, as well as awareness of investigator and patient needs.

Successful execution of a well-designed study also requires an experienced team. Our neuroscience experts draw upon years of experience managing clinical trials and relationships with networks of investigators with proven track records for subject recruitment and quality data. Our experts select the investigators and study site that are best-suited to meet the goals of each study and the objectives of the sponsor. Our teams are committed to efficient, effective study execution and meticulous monitoring.

Rating Scales in Neuroscience Research

Despite the evolution of novel neuro-imaging and use of biologic surrogate endpoints in clinical trials in diseases of the CNS, the use of investigator and patient rating scales still remain the most commonly employed efficacy measures in these trials. The challenge presented by these scales must be understood including differences in reporting outcomes with multiple observers, the need for standardization in a global research environment, and sensitivity to cultural differences that may affect outcomes. Practical considerations such as appropriate rater training are key to the success of the trial and must be clearly defined.

Premier Research has years of clinical trial expertise utilizing a range of clinical assessment tools or scales performed by the patient, caregiver, and clinical personnel including but not limited to:

- Assessment of Disability Scales or Health Status Scales
- Disease Specific Quality of Life Questionnaires
- Clinical Global Impression Scales
- Global Assessment of Functioning (GAF) Scales
- Side Effect Scales
- Scales Assessing Personality Dimensions
- Schedules for Clinical Assessment in Neuropsychiatry (SCAN)

The IVRS/IWRS technology used by Premier Research helps to address the challenges presented by rating scales for subjects in clinical trials. The technology allows subjects to enter their self assessments in a user friendly manner by simple phone script entry or web-based entry.

Case Study: Thorough Training and Experienced Team

Following the successful completion of two pediatric Phase 3 trials in children with ADHD studies that included an Analog Classroom setting, a global biopharmaceutical company contracted with Premier Research to conduct a third ADHD trial utilizing the Analog Classroom setting within the adult population for a Workplace Environment Study.

The high quality data that resulted from this trial was a direct result of Premier Research's emphasis on thorough understanding of outcome measurement tools combined with a hands-on experienced clinical study team. The team confirmed there was qualified site staff with significant documented experience prior to being approved to conduct the study assessments and provided thorough site training. They also ensured that the appropriate CRA resources were available to support the large volume of source documents and CRF data needing to be reviewed following classroom visits.

The continuity and longevity of the clinical team and the operational efficiencies established prior to study start led to its overall success. As a result of our proven clinical track record, Premier Research was awarded two additional Phase 3 trials in an adolescent population as well as an additional post-marketing trial in an adult population, resulting in six contracted studies within a 20-month time period.



Premier Research

North America: 215.282.5500
Europe: +44 (0) 1344 752375
info@premier-research.com

www.premier-research.com

Visit our website for our global locations.