Neurology

Experience in Neurology Clinical Trials

Worldwide Clinical Trials takes pride in bringing a depth of knowledge to your study based on experience in trials across a range of neurologic disorders.

Our clinical experience enables us to work with you at any stage of drug development from Phase I through Phase IV for traditional, as well as, highly innovative clinical targets.

Worldwide has participated in the design, execution, or analysis of 105 trials, over 550 sites and 2840 patients since 2008. Of the 105 total trials, 55 studies have included at least clinical monitoring or project management. A majority of these studies have been conducted globally including unique capabilities in Russia, Ukraine and Eastern Europe.

Representative capabilities for neurological disorders include the following:

- Scale selection appropriate to culture and language including the credentialing of investigative site staff, and methods of surveillance following study initiation.
- Specialized patient-based assessments for various neurologic disorders, particularly in proof of concept trials.
- Utilization of novel pain questionnaires unique to medical device applications in breakthrough episodic pain and postoperative neuropathic pain.
- In-house analytical and pharmacokinetic capabilities including novel assay development, and the transfer and validation for established analytes in various matrices.

NEUROLOGY PORTFOLIO

- Neurodegenerative Disorders (Alzheimer's Disease, Frontotemporal Dementia, Mild Cognitive Impairment and Parkinson's Disease)
- Autoimmune Neurological Disorders (Multiple Sclerosis)
- Movement Disorders
- Neuromuscular Disorders (Disease of Peripheral Nerve, Neuromuscular Junction and Muscle)
- Epilepsy and Seizure Disorders
- Sleep Disorders
- Pain Syndromes (Postoperative Neuropathic Pain, Postherapetic Neuralgia, Breakthrough Episodic Pain, Low Back Pain, Diabetic Neuropathy, Nerve Trauma and Migraines)

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Problem Solving for Uninterrupted Trial Progress – Case Study

Challenge	• Worldwide Clinical Trials was retained to intervene in a Phase IIb, multinational, randomized, double-blind, placebo-controlled study, in subjects with progressive cognitive decline compatible with the diagnosis of prodromal AD. For this highly complex study, the original CRO had failed to meet enrollment expectations due to inadequate vetting of site capabilities for this unique diagnostic category which required the use of multiple, sophisticated screening assessments which served as a "gatekeeper" for patient eligibility. The study had been launched in over 30 centers by the sponsor with virtually no patient enrollment prior to Worldwide Clinical Trials' engagement.
Action	• Dedicated a Worldwide neuropsychologist to oversee clinical monitoring, site selection and enrollment. • Structured the sequence of test applications for compatibility with protocol design and standard of care. • Reevaluated site attributes and rater qualifications for administration of battery of neuropsychological tests; many of which required specialized training in a highly codified sequence.
Outcomes	• Worldwide Clinical Trials' conceptual, operational and assessment services oversaw the study's extension into neighboring countries. • Supervision and training by the Worldwide therapeutic specialist on measures that affected patient eligibility, accelerated patient randomization and the study completed one week prior to the original target date.

Leading with Innovation

Worldwide Clinical Trials is recognized as the leader in CNS clinical research. This translates into innovative solutions applied to your study, exemplified by our execution of a Phase Ia study evaluating the pharmacokinetic and pharmacodynamic properties of a small molecule in patients with amnestic mild cognitive impairment (aMCI). Our medical and scientific team evaluated relevant hypotheses, and proposed a novel study design based on the most relevant biomarkers for aMCI in CSF and plasma. As a result of our efforts, we received the following comments from the President and CEO of this company:

> " This is a challenging project, many Clinical Research Organizations (CRO) were contacted regarding this study, but none of the contacted CRO competitive companies provided this type of knowledge and understanding in this area. We are very impressed with your team's approach to problem solving and vigilance".
>
> President & CEO

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KEY SUPPORTING SERVICES

- Site and Protocol Feasibility Assessment
- Protocol Design
- Site Identification
- Global Project Management
- Regional Monitoring
- IVRS/IWRS for Supply Management and Randomization
- Rater Training Services and Supporting Technology
- Clinical Trial Management System
- Endpoint Adjudication Process
- DSMB Charters and Management
- Clinical Assessment Technologies
- Biostatistical Services
- Medical Writing
- Data Management

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