

OVERVIEW

Over the last 20 years, Worldwide Clinical Trials has become the standard among CROs for our expertise in global central nervous system (CNS) trials. Our knowledgeable scientific, medical and operational staff conducts clinical trials for CNS disorders across all phases (Phase I-IV) in studies with remarkably diverse hypotheses and designs.

- *Intense therapeutic focus drives our ability to link experimental design with operational execution.*

RESEARCH AND TECHNOLOGY SOLUTIONS

Worldwide Clinical Trials' clinicians, scientists, management team and staff have remarkable intellect and experience in the area of CNS disorders. The leadership team has published more than 400 articles in peer-reviewed journals and authored more than nine textbooks in the field of CNS pharmaceutical research. Our Clinical Assessment team has developed proprietary technologies and worked with several vendors who offer unique and complementary systems. This use of technology enables the assessment and gathering of data on cognition, psychiatric ratings and rater training/tracking.

Our Clinical Assessment technology offerings include, but are not limited to:

- Cognitive and psychiatric assessments
- Electronic Data Capture (EDC) and Interactive Voice Response (IVR) technology for assessment and compliance
- Web portals for rater training and tracking purposes

Our expert staff have shaped novel and composite pain scales that are used in registration trials today.

CASE STUDIES

Psychiatry

A representative clinical study in psychotic disorders is a Phase II, randomized, double-blind, double-dummy, placebo-controlled, adaptive and dose-range design study to evaluate the safety and efficacy of the study drug administered to acutely exacerbated schizophrenic inpatients. This adaptive trial design was awarded to Worldwide Clinical Trials based upon a protocol-specific feasibility assessment at each center where the protocol was to be implemented, deliberately highlighting design issues that potentially could affect patient accrual, retention or other qualitative aspects of the trial. Practical site and country-specific suggestions on diagnostic, outcome and operational measures prior to the initiation of the trial were highlighted in a process of preemptive trial management. During an eight-month enrollment period, over 100 patients were successfully enrolled in the study. Comprehensive clinical trial services

INDICATIONS

Psychiatry

- *Schizophrenia*
- *Major Depressive Disorder*
- *Bipolar Disorder*
- *Smoking Cessation*
- *ADHD*
- *Psychosis in VCSF*

Neurology

- *Alzheimer's Disease*
- *Mild Cognitive Impairment*
- *Multiple Sclerosis*
- *Parkinson's Disease*
- *Epilepsy*
- *Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)*

Analgesia

- *Chronic Pain*
- *Low Back Pain*
- *Neuropathic Pain*
- *Post-Operative Pain*

Continued on Back >



Continued >

were provided, including clinical monitoring, project management, investigator’s meetings, translation, regulatory services, drug supply, logistic support and quality assurance.

Neurology

One clinical study representative of our capabilities in neurology was recently conducted in subjects with multiple sclerosis. This multicenter, randomized, double-blind study assessed the effects of “add-on” medication in relapsing-remitting multiple sclerosis (RR-MS) subjects and was able to achieve an extraordinarily high enrollment rate of 4.92 patients/site/month during a 2-month enrollment period. Primary outcomes included not only the typical clinical endpoints but also changes in magnetic resonance imaging (MRI), demonstrating our capability to conduct sophisticated MS studies in the Russia and Eastern European Countries (EEC). For this study, Worldwide Clinical Trials provided project management, safety monitoring, clinical monitoring, regulatory service, and drug depot and logistics.

Analgesia

Worldwide Clinical Trials’ clinical research experience in analgesia is showcased by a Phase II, randomized, double-blind, placebo- and active-controlled, parallel group evaluating analgesic efficacy of the study drug in subjects undergoing third molar extraction. The primary endpoint was total pain relief (TOTPAR) through six hours following the first dose of study medication. Worldwide Clinical Trials managed clinical monitoring of the study at two sites in the United States. In a four-month enrollment period, over 250 patients were screened as planned, and 250 patients were enrolled (enrollment rate was 31.5 patients/site/month).

KEY SERVICES

Worldwide Clinical Trials routinely utilizes both Electronic Data Capture (EDC) and Interactive Voice Response (IVR) technologies to aid scale administration, scoring, rater training/tracking and even outpatient compliance with completing scales in a timely manner.

Our proprietary NODES®-EDC system is not only unique in its ability to capture CRF data, but also serves as an in-study monitoring tool, enabling WCT to evaluate rater drift across the length of the study on a real-time basis

As part of our unique set of services, WCT also provides in-house analytical and pharmacokinetic capability adaptable to a wide range of therapeutic indications, including:

- Development and Analyses (Biomarkers)
- Dose Selection
- Patient Segmentation
- Regimen Selection
- Proof-of-Mechanism

