

Our Alzheimer's Expertise

Our tradition of excellence is centered on Alzheimer's Disease, with our unparalleled experience in this indication (including related dementias) allowing us not only to understand the complexities associated with evaluating patients with various phenotypes, but also to implement specific design features through the use of strategies to mitigate the risks and challenges in the Alzheimer's field.

Worldwide has executed 14 Alzheimer's trials, delivering clinical monitoring, project management, or full clinical research services for all of them.

The majority of these studies have been conducted globally, and include full service capabilities in Latin America, Asia Pacific, Russia, and Eastern Europe.

Unrivalled Team

Worldwide delivers this expertise through our team of scientific, medical, operational, and regulatory staff, who all contribute unique skills to help our partners meet the special demands of Alzheimer's disease clinical research. Our established relationships with key investigators, regulatory bodies, and academic research organizations in the Alzheimer's field ensure delivery of high quality and clinically relevant data.

Our expert team includes neuropsychologists and neuroimaging experts who have contributed to the development of every drug class applicable to Alzheimer's disease in the past 30 years, and have undisputed

experience in this field in both the development and application of novel methodology for interventional research using small molecules, as well as biologics. This, coupled with a true commitment to the success of each and every clinical trial, means Worldwide is ideally positioned to be your Alzheimer's study partner.

Worldwide's senior scientific team has authored three books and more than 100 articles with a specific focus in Alzheimer's, and is currently working on a new book that will explore the design and conduct of trials in Alzheimer's disease from transitional research initiatives through studies mandated for successful commercialization.

Unique and Diverse Offering

Worldwide's unique and diverse services include complete program development in Alzheimer's, from the use of IND enabling data to inform first-in-human studies through observational research initiatives to enhance commercialization. Our expertise in supporting sponsors with the preclinical to clinical transition is an important differentiator.

We provide innovation in experimental design, including first-in-human trials using a variety of standard and novel designs. We

can also develop adaptive designs and embedded functional and quantitative neuroimaging studies across all phases of development. Program design and operational capabilities are complemented by in-house analytical and pharmacokinetic services, including novel assay development, analyses for Alzheimer's biomarkers and unique clinical procedures that are particularly useful in proof-of-concept or registration trials.

ALZHEIMER'S DISEASE AND COGNITION

Mild to Moderate Alzheimer's Disease

Moderate to Severe Alzheimer's Disease

Frontotemporal Dementia

Mild Cognitive Impairment

Traumatic Brain Injury

Cognitive Deficits in other Neurodegenerative Conditions

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Recruitment and Retention

Recruitment will be critical for the success of any Alzheimer's program, given the competitive landscape, restrictive eligibility criteria tailored to a specific subset of these patients, and the historically high screen failure and dropout rates in these type of clinical trials. Studies within the MCI to Mild classification of Alzheimer's disease, as an example, require a very specific recruitment strategy as well as retention plan, and we at Worldwide are armed with the knowledge and ability to do this.

Worldwide implements innovative strategies to find the right patients and reduce screen failure rates, and to enhance patient retention. Our feasibility team will identify

the ideal sites while our clinical operations team will use its expertise to foster and maintain good site relationships with the aim to overcome competitive hurdles.

We understand that many challenges will develop over the course of a clinical trial; sites will conduct other trials, change staff, adapt new standards of care, and change as a dynamic organization. The key to successfully working with sites throughout the duration of a project is to understand these potentialities; work with the sites to adapt strategies and working practices to these changes; and remain vigilant in both communication and oversight of their performance.

Strong Site Relationships

We recognize the critical importance of very strong site relationships that transcend individual studies, and understand that selecting and identifying the right sites and patients is essential to ensuring subject safety, maximizing enrollment rates, reducing the screen failure rate, and increasing retention rates.

Worldwide has established a culture that emphasizes developing and maintaining these relationships and fostering a good working partnership with them, and as

such, is currently working with many of the leading Alzheimer's investigators around the world. We believe that our commitment to these relationships ensures that our studies are given priority for the sites we work with and ultimately, helps us to design and execute better trials. To this end, Worldwide has created a group whose focus will be upon ensuring these site relationships are maintained, to ensure delivery continues at the high-level Worldwide and its sponsors expect.

KEY SUPPORTING SERVICES

Site and Protocol
Feasibility Assessment

Protocol Design

Program 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

About Worldwide Clinical Trials

A full-service CRO, Worldwide Clinical Trials (Worldwide) delivers fully integrated clinical development and bioanalytical services for studies small to large, multi-site clinical trial programs, and first-in-human through phase IV clinical research programs, for customers of all sizes. Worldwide helps sponsors move from medical discovery into clinical development and commercialization, helping to bring innovative solutions to market that deliver enhanced value and improve patient lives.

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