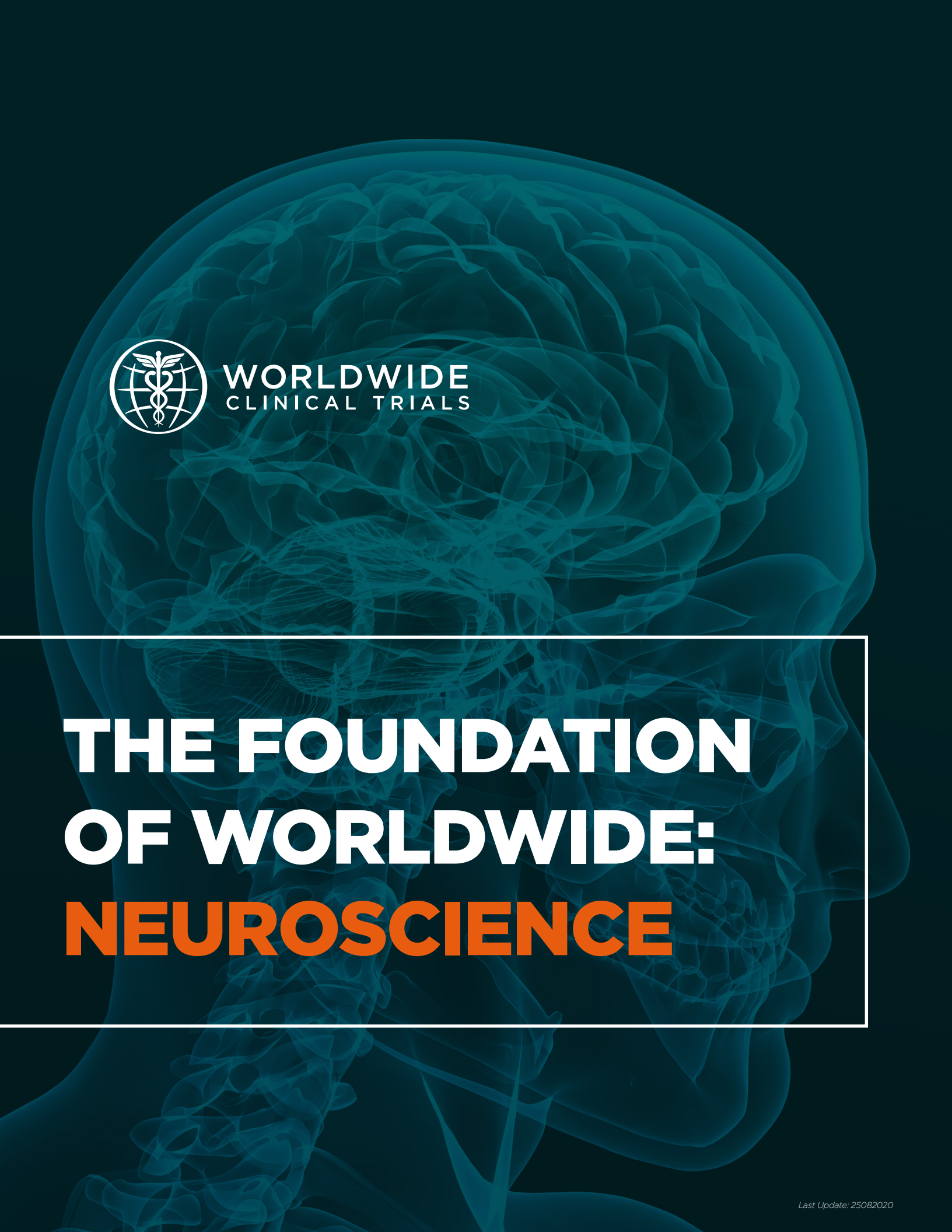

WORLDWIDE
CLINICAL TRIALS

THE FOUNDATION OF WORLDWIDE: NEUROSCIENCE

Last Update: 25082020

THE CNS CHALLENGE: BALANCING RISK WITH REWARD

NEUROSCIENCE PORTFOLIO

Neuroscience at Worldwide is organized into the following sub-therapeutic areas, with leading indications including:

NEUROLOGY

- Multiple Sclerosis
- Parkinson's Disease
- Other Movement Disorders
- Epilepsy and Seizure Disorders
- Traumatic Brain Injury
- Restless Leg Syndrome

ALZHEIMER'S DISEASE & COGNITION

- Mild to Moderate Alzheimer's Disease
- Moderate to Severe Alzheimer's Disease
- Frontotemporal Dementia
- Lewy Body Dementia
- Mild Cognitive Impairment

PSYCHIATRY & CNS RARE DISEASES

- Attention Deficit Hyperactivity Disorder (pediatric and adult)
- Bipolar Disorder
- Schizophrenia (acute, chronic, negative symptoms, cognition)
- Generalized Anxiety Disorder
- Major Depressive Disorder
- Addiction/Drug Dependencies
- Smoking Cessation
- CNS Rare/Orphan Diseases

ACUTE & CHRONIC PAIN

- Diabetic Neuropathic Pain
- Post-Herpetic Neuralgia
- Osteoarthritic Pain
- Migraine
- Post-Operative Pain
- Neuropathic Pain
- Lower Back Pain
- Breakthrough Cancer Pain

FOUNDED ON NEUROSCIENCE

Medicine and Science in Collaboration

Neuroscience is in the DNA of Worldwide Clinical Trials. Founded by a team of neuroscientists, Worldwide has worked in CNS since the late 1970s when the first cholinesterase inhibitors emerged as a cognitive therapeutic. Our breadth and depth of experience continues more than 40 years later, as we continue to innovate and adapt in our commitment to advancing research.

This desire is powered by the rigor of research experts who know what it takes to translate a lifesaving therapeutic solution into a compelling data set demonstrating efficacy and value. Because we understand that, in CNS indications, the success or failure of a compound rides on the quality of the end points, we are one of the only midsize CROs that has an in-house rater training team. Today, our Clinical Analytics, Training, and Surveillance group is fully integrated with the study team and systems in your clinical trial. We know patient needs, we know how to keep them safe, we know how to identify the appropriate end points, and we know how to manage the data to demonstrate your treatment's effectiveness. We hold patient dignity and data integrity in balance.

Dedicated Neuroscience Business Unit

While other CROs may use resources from any and all disciplines, Worldwide's Neuroscience Business Unit is made up of dedicated clinical research professionals, individuals uniquely committed to work in this specific therapeutic area. These individuals have chosen neurological, psychiatric, and pain indications as their area of commitment and focus. Each of our senior team members brings at least 20 years of experience working with CROs and sponsors. Our project managers bring greater than 10 years of experience, while CRAs and LCRAs average about 8 years. We work hard to nurture strong relationships with our investigator sites, an investment that has paid off in a low turnover rate. This cohesiveness in Worldwide's CNS organization translates into increased efficiency and streamlined processes for our sponsor partners.

Investigator and Site Relationships

Your trial is only as strong as the investigators who interact with the patients and report the assessments. At Worldwide Clinical Trials, not only do we have an extensive global network of investigators but also work to nurture these relationships. Because we have such strong engagement with our participating investigators and clinicians, we can identify where training or additional support may be needed at the outset, and we can intervene as needed during the course of the study.

Because we've invested so much in our investigator relationships, we have a strong sense of their sites. When we embark on a clinical trial, we can identify those investigative sites with capacity to fit your study's recruitment and protocol requirements. We will ensure that staff understand the end points and are equipped and trained to safeguard data integrity, while engaging effectively with patients to reduce turnover and support retention.

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WORLDWIDE CLINICAL TRIALS

INTEGRATED TECHNOLOGY

- Clinical Trial Management System (CTMS)
- Electronic Data Capture
- Interactive Voice Response System (IVRS)
- Interactive Web Response
- System (IWRS) IxRS Technology

Worldwide is a leader in developing bespoke IxRS solutions for sponsors. With the capability to integrate complex IxRS needs into sponsor data systems, we can reduce costs while enhancing both quality and efficiency.

CRO LEADERSHIP AWARDS 2020

Capabilities, Compatibility, Expertise, Quality, and Reliability

Undertaking a clinical trial in any CNS indication is not for the faint of heart. The sheer amount that remains unknown about the human brain makes it an elusive therapeutic target. The blood-brain barrier poses an added level of complexity with respect to drug effectiveness. CNS therapies tend to have longer development timelines and higher failure rates compared to treatments for other indications. With respect to clinical trial design, these challenges add to the complexities around identifying effective outcome measures and ensuring patient safety.

Team of Thought Leaders

Worldwide Clinical Trials was founded on neuroscience. Our current team comprises neuropsychologists and neuroimaging experts who have contributed to the development of every drug class applicable to Alzheimer's disease in the last 30 years. Contributing experience and expertise from pharmaceutical companies, research organizations, regulatory agencies, and academia, our team members combine education in pharmacy, medicinal biochemistry, clinical neurology, biology, and pharmacology. Their combined portfolio includes both development and application of novel methodology for interventional research, using small molecules and biologics. Coming from a variety of geographic and cultural backgrounds, our team members have both innate empathy for cultural diversity and a deep understanding of regional variations in patient care. Collectively, our senior scientific team has authored four books and more than 100 articles focusing specifically on Alzheimer's disease and related dementias.

Complete Study Transparency

At Worldwide Clinical Trials, we don't care for bells and whistles, but we do know which technology solutions will best serve your study's needs. For your CNS study, we can identify appropriate solutions for eConsent and observational data reporting, as well as a range of clinical, project management, and data handling solutions. With our many strong vendor relationships, we can secure solutions for your trial to optimize patient engagement, data quality, and workflow efficiencies at minimal cost.

End Points and Data

CNS drug development calls for a high level of collaboration between the medical and scientific disciplines. A successful CNS clinical trial requires a sophisticated understanding of appropriate biomarkers and their validation for the indication under study. When dealing with CNS indications, studies must effectively translate subjective measures into scientifically and medically sound data that demonstrates conclusive positive results.

Worldwide Clinical Trials is one of the few CROs that can offer an in-house training team. Our Global Clinical Assessments team brings an added layer of quality assurance. Our monitors are fully connected and trained to spot any signs of error or inconsistency in your data reporting. That means you are assured of quick intervention and, where needed, course correction. Our global assessments team is what makes the difference between inconsistent reporting and a robust and reliable data set.

WORLDWIDE
CLINICAL TRIALS

ISR reports

RATED OVERALL TOP PERFORMER FOR:

- Budget Factors
- Delivery Factors
- Staff Characteristics
- Accessibility
- Services
- Customer Loyalty

Global Footprint, Agile Operations

Today, Worldwide has clinical operational capabilities in over 60 countries. We are small enough to take on your early phase trial with keen attention to any pain points. We also have the organizational heft to carry your compound through commercialization and beyond to real-world evidence studies. More than 50% of Worldwide's work is in Phase III registrational trials.

Worldwide has recruited 40,635 patients across indications. We understand not only how to recruit but also how to retain, assist, and work with investigators and supportive caregivers to make it easy to participate in clinical trial research.

Patient Safety Is Our Priority

When you need to establish safety and efficacy for your novel therapy, Worldwide has on-site facilities with capacity to manage your early phase work. Our state-of-the-art clinical pharmacology unit (CPU) in San Antonio, Texas, is equipped with a cGMP Phase I pharmacy, a full-service clinical laboratory, and a fully equipped sample processing laboratory. Our top-ranking bioanalytical laboratory in Austin, Texas, is easily accessible from our CPU, enabling quick transfer of samples and facilitating quick decision-making.

DON'T JUST TAKE OUR WORD FOR IT

We believe, better than anything we could say about ourselves, the appreciation of our customers says it best. In the 2020 CRO Quality Benchmarking Reports, based on a survey of sponsors conducted by ISR, Worldwide Clinical Trials emerged as a Top Performer — across all phases — in the categories of Budget, Delivery, and Staff. Consistently, we rank among the best CROs in responsiveness, study design, therapeutic expertise, timely communication, and project manager quality. Over and over again, we live up to the trust our customers invest in us.

Whatever your company size, wherever you are on your clinical trial journey, we'll meet you there to provide anything from consultancy to full-service support. We are the Cure for the Common CRO.

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MEET YOUR PARTNERS

Many large CROs offer “off-the-shelf” advice and solutions to their customers. Worldwide delivers tailored and pragmatic advice, regardless of the size or complexity of the project. Our collaborative, customized project teams with phase- and indication-specific expertise develop successful strategies for even the most novel therapies.

Neal R. Cutler, M.D.

Chief Executive Officer

Dr. Cutler has served in leadership positions in the pharmaceutical industry, both for-profit and non-profit organizations. He is a board-certified psychiatrist and board-qualified in both neurology and clinical pharmacology. He has been active at the National Institutes of Health, the National Institute on Aging, and the American Foundation for Clinical Pharmacology.

Dr. Cutler has been instrumental in the design and clinical development of nearly 200 compounds in numerous therapeutic areas, with particular expertise in central nervous system disorders. He developed the revolutionary “dynabridge” and “bridging” study methodologies, which made feasible the study of the dynamic activity of a compound in the brain and facilitated the rapid and effective development of a number of subsequent compounds.

Dr. Cutler has given several hundred international and national presentations in the fields of aging, clinical pharmacology, and drug development. He has authored over 278 publications, including nine books on the topics of clinical pharmacology, aging, Alzheimer’s disease, schizophrenia, anxiety disorders, and diabetes.

Michael Murphy, M.D., Ph.D.

Chief Medical and Scientific Officer

Dr. Murphy’s professional career has spanned 30 years, and his positions within the pharmaceutical industry emphasize the integration of medical and scientific acumen with operational excellence. He is board-certified in psychiatry and has a doctorate in pharmacology, with training at Tulane University, Stanford University, and Mt. Sinai School of Medicine.

Dr. Murphy worked with Dr. Cutler to articulate Worldwide’s vision when the company was established as a global CRO in 1995 and was responsible for consulting services for protocol and program design and executive oversight for the execution, analysis, and interpretation of clinical trials across multiple therapeutic areas.

His supervisory responsibilities as Chief Medical & Scientific Officer at Worldwide are international in scope and include the design and implementation of protocol feasibility assessments, protocol development for phases I-IV including non-interventional research, the provision of medical monitoring and drug safety services, medical writing, and coordination of rater certification and surveillance activities for clinical trial assessments.

Angelico Carta, M.D.

President

Dr. Carta has more than 20 years’ experience in the international pharmaceutical industry and CRO management. He is a board-certified neurologist and holds an M.D. from the University of Rome School of Medicine, with training in neurology from King’s College Hospital in London. Dr. Carta’s vision combined with that of Dr. Neal Cutler, Dr. Neil Kurtz, and Dr. Michael Murphy led to the founding of Worldwide Clinical Trials in the mid 1990s.

Dr. Carta is the first co-author of over 30 papers on clinical neuropsychopharmacology published in internationally renowned journals. Additionally, he has co-authored six reference texts on clinical development of Alzheimer’s disease, antipsychotic drugs, and CNS drug development. Dr. Carta continues to present and review clinical data at numerous clinical neurology and neuropsychiatry meetings internationally.

Henry J. Riordan, Ph.D.

Chief Development Officer

Dr. Riordan has been involved in the assessment, treatment, and investigation of various CNS disorders in both industry and academia for more than 20 years; he was one of the original Worldwide members beginning in 1998 and a cofounder of the current Worldwide.

Dr. Riordan has been the primary author of numerous protocols in neurologic, psychiatric, and analgesic indications across all phases of development. He has been involved in several clinical development programs and has participated in numerous advisory boards and regulatory interactions. He has advanced training in quantitative methods, biostatistics, experimental design, neurophysiology, neuroimaging, and clinical neuropsychology and has published 120 peer-reviewed abstracts, articles, book chapters, and books.