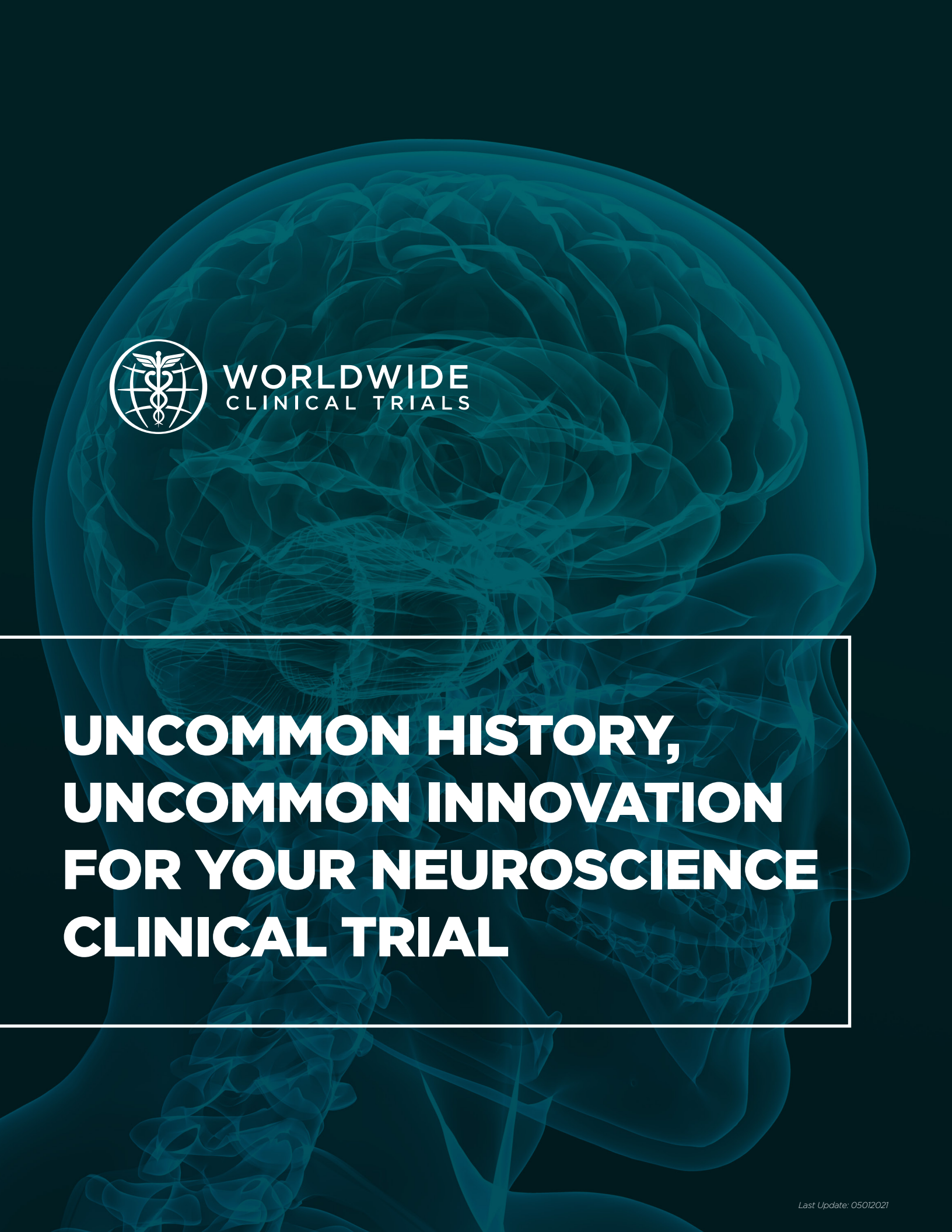

WORLDWIDE
CLINICAL TRIALS

UNCOMMON HISTORY, UNCOMMON INNOVATION FOR YOUR NEUROSCIENCE CLINICAL TRIAL

Last Update: 05012021

THE NEUROSCIENCE 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 & NEUROSCIENCE 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
- Neuroscience Rare/Orphan Diseases

PAIN

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

Undertaking a clinical trial in any neuroscience 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. Neuroscience 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.

End Points and Data

Our team of experts have undisputed experience in translating basic research into clinical development in a variety of therapeutic areas, including central and peripheral nervous system disorders. We know the regulatory requirements you're up against. We know the language and culture of leading and emerging countries around the world. We have over 20 years of deep therapeutic expertise to provide you with recommendations that we are confident about – and we can show you proof of our success! This, coupled with a true commitment to the success of each and every clinical trial, means Worldwide is ideally placed to be your neuroscience study partner.

Technology

Your neuroscience study demands technological support from a variety of vendors, whether for accurate recording and management of observational data, for home-based diagnostic solutions, or for the most advanced imaging procedures. All stakeholders must have the willingness and the capacity to work with tech solutions and to adapt to innovations as needed. Beyond that willingness, your success will depend on strong relationships with the appropriate vendors so that you have the correct solutions, supplied at the right time, and for the right price.

Recruitment

While neuroscience conditions affect such a high percentage of the world's population, our current knowledge indicates an increasing granularity in differentiators within common conditions. With so much diversity, recruitment for neuroscience clinical trials must be executed with the kind of innovation and broad reach typically applied in orphan disease trials. Your inclusion/exclusion criteria must be established strategically, and you'll need to cast a wide net to find the appropriate study participants.

Site Partnerships

Keen discernment must be applied to selection of clinical site partners. Clinicians will need training, not only in the necessary protocols but also in the technological aspects of data reporting and management. Sites should have logistical capacity to carry out the required procedures within the agreed-upon budget and timeline parameters. Above all, neuroscience studies demand a level of trust in the selected clinical sites, based on an established history of reliability.

Regulatory Relationships

Many drug developers view regulatory agencies as hurdles in their novel therapy's path to marketing success. However, bear in mind that a strong relationship with regulatory can be your most valuable resource as you seek to navigate the approval process. You share the goal of helping patients with regulatory agencies, and a proactive relationship with your regulatory counterparts will be crucial to your ultimate success. This may call for an effective liaison who can bridge the gap between your goals and regulatory conditions.

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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

ISR reports

RATED OVERALL TOP PERFORMER FOR:

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

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WORLDWIDE CLINICAL TRIALS: STRIKING THE UNCOMMON BALANCE

With so much at stake for your neuroscience clinical trial, you want to leverage your investment to mitigate risk and optimize your chance of success. When you enter into a CRO partnership with Worldwide Clinical Trials, you know from the start that you are getting the full force of our medical and scientific expertise, achieved through decades of groundbreaking neuroscience research.

Medicine and Science in Collaboration

Worldwide Clinical Trials was founded by physicians motivated by the humane desire to help patients and their families. 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 that can demonstrate its efficacy and its value to the patient. 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.

Local Knowledge on a Global Scale

When your study calls for a broad geographic reach, you need Worldwide's global footprint on your side. Employing more than 1,900 professionals, we have talent and infrastructure in more than 60 countries. For your neuroscience study, that means you already have access to hard-to-find patient populations and strong site relationships without doing any of the preliminary legwork. And because we've had feet on the ground for many years, we understand the variations in regional standards of care and can avoid potential cultural or geographic pitfalls. We've already established our regulatory partnerships; we can anticipate any local regulatory concerns.

Technology Done Right

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 neuroscience 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.

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.

Uncommon History, Uncommon Innovation

Worldwide Clinical Trials has been working in neuroscience research since the advent of cholinesterase inhibitors as a cognitive therapeutic in the late 1970s. Today, we continue that 40-year tradition of clinical trial excellence, combining our long and deep experience with our persistent desire to advance research and innovation. But, when we talk about innovation, we're not just looking at the long arc of history. We are determined to stay agile in every moment, so that when the unexpected arises in your neuroscience clinical trial, we are ready to pivot and keep your study moving forward.

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.

Tamara Ast, Ph.D.

Senior Vice President, Project Delivery Services, Neuroscience

Dr. Tamara Ast has 20 years of industry experience across a variety of neuroscience indications. She has held leadership roles for Project Management and Operations delivery at Worldwide Clinical Trials for the past five years, and now oversees the Neuroscience therapeutic area. This business unit includes Worldwide’s most experienced neuroscience clinical research professionals to ensure that the Worldwide team provides sponsors with the best possible regulatory and scientific, medical and operational strategy and clinical trial execution.

Dr. Ast’s primary therapeutic and operational expertise has had a specific emphasis on neurological conditions, such as Alzheimer’s disease, Parkinson’s disease, multiple sclerosis, pain, and psychiatric indications such as schizophrenia, mood disorders, and substance use disorders. Dr. Ast obtained her Ph.D. in medicinal biochemistry from The School of Pharmacy, University of London, United Kingdom.

Tom Babic, M.D., Ph.D

Vice President, Neuroscience Franchise

Dr. Babic is a board-certified neurologist and Affiliate Professor of Clinical Neurology. At Worldwide Clinical Trials, he is responsible for the scientific and medical leadership of global neurology clinical research initiatives. This includes aspects of hypothesis generation and testing, protocol/strategic program design and development, as well as assistance in the analysis and clinical interpretation or results for all phases of clinical drug development.

Dr. Babic, a therapeutic leader in neurology medical and scientific affairs, has designed protocols and programs for randomized controlled clinical trials in populations with early and advanced Parkinson’s disease, Alzheimer’s disease, multiple sclerosis, epilepsy, stroke, migraine, and neurodegenerative disorders, implementing the up-to-date evidence-based science in clinical drug research and development.

Stephen Coates

Executive Director, Franchise Leader, Alzheimer's Disease & Dementias

Stephen leads the Alzheimer’s Disease and Dementias franchise, within the Neuroscience group at Worldwide. He began his journey in the industry in 1998. Following a BSc (Hons) in pharmacology and MSc in clinical pharmacology, Stephen progressed through the ranks from Clinical Research Associate up through study/project management, building a strong portfolio of therapeutic experience before focusing on Alzheimer’s disease and dementia.

Having worked in the pharmaceutical industry for Roche, GSK, Pfizer, and Takeda, in addition to time at Kendle and Covance in the CRO sector, Stephen joined Worldwide in the summer of 2015. Stephen’s position as Executive Director, Project Management, within the Neuroscience group allows him to share his operational expertise across dementia programs and offers full support to the internal project team and Worldwide’s clients.

MEET YOUR PARTNERS (CONTINUED)

Natalia Drosopoulou

Executive Director of Global Project Management, Neuroscience

Natalia is an Executive Director of Global Project Management and a Franchise Area Lead in Neuroscience at Worldwide Clinical Trials.

As a Franchise Area Lead, Natalia provides operational oversight to projects within Neuroscience and works with the team to provide strategy and risk mitigation as well as operational expertise. With over 19 years in the clinical research industry, Natalia's experience spans from small intricate Phase I studies to large global Phase III programs primarily within neurology, psychiatry, pain and pediatrics. Natalia attained her Ph.D. in biochemistry, specializing in developmental neurobiology from the University of London, followed by a position of a Postdoctoral Fellow at the National Hellenic Research Foundation, Athens, Greece.

Lisa Gamez

Associate Director, Project Management, Neuroscience

Ms. Gamez is an Associate Director of Project Management, has been in the clinical research arena for 21+ years, and specializes in growth of Worldwide Clinical Trials' Pain Franchise. She has coordinated, monitored and managed complex, global, multi-service, Phase I-IV clinical trials. Her therapeutic expertise lies within neuroscience with indications in Alzheimer's, Parkinson's disease, sleep disorders, multiple indications in pain, schizophrenia and migraine headaches, in addition to other areas including endocrinology, respiratory, cardiovascular and oncology trials. Ms. Gamez has proven her ability to lead her cross-functional teams to exceed operational excellence. Ms. Gamez has a bachelor's degree in biology from the University of Texas El Paso and holds ACRP Certification in Clinical Research.

AnneClaude Muratet

Executive Director, Global Project Management, Neuroscience, Neurology Franchise Lead

Anne-Claude Muratet has more than 20 years of clinical research experience at both CRO and pharmaceutical companies. In the past 15 years, her focus was centered around oversight strategy and management of global programs, line management, and business development activities.

Ms. Muratet's experience includes a variety of indications in psychiatry and neurology (multiple sclerosis, acute ischemic stroke, agitation in Alzheimer's disease patients, epilepsy, schizophrenia, major depressive disorder, generalised anxiety disorder, sleep, and neuropathic pain) as well as several other indications in rare diseases, spanning the full spectrum of activities and services in Phase I to Phase IV studies and programs.

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

Chief Medical and Scientific Officer

Dr. Murphy's professional career has spanned 25 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 the 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.