WORLDWIDE
CLINICAL TRIALS

MOVING MULTIPLE SCLEROSIS TRIALS FORWARD, FASTER

Last Update: 07012021

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MOVING MULTIPLE SCLEROSIS TRIALS FORWARD, FASTER

The development of new medicines targeting multiple sclerosis (MS) can take 10 to 15 years from testing in a laboratory to becoming commercially available. For every 10,000 compounds tested, fewer than one or two become licensed treatments. Many are rejected on the grounds of their safety, quality, and efficacy.[1]

YOUR CRO PARTNER CAN HAVE A SIGNIFICANT IMPACT ON THE SUCCESS OR FAILURE OF YOUR CLINICAL STUDY AND PROGRAM.

As a full-service CRO, Worldwide Clinical Trials has an outstanding track record in starting up and executing MS studies, including beta-interferons, glatiramer acetate monoclonal antibodies, and oral preparations for disease-modifying approaches.

SPECIALIZATION IN MS PROGRAMS FOR ACCELERATED TRIALS

When timing is critical and everyday delays can cost millions, Worldwide's simple, thorough, streamlined operations are critical to your neurology development program.

Whether your study is a small, focused single-region trial or a study that requires global reach, we designed our specialty MS team – neurologists; experienced clinical monitors and project managers; and regulatory, data management, statistical, scientific, and medical experts – to work collaboratively with you to help you overcome the high-risk, high-cost, time-intensive challenges of MS drug development.

- Flexibility to manage study size, trial speed, and patient access.
- Automated technologies and systems to eliminate traditional bottlenecks in the flow of clinical data – expediting your trial while keeping costs down.
- Dedicated feasibility and clinical science start-up team that uses predictive analytics to speed recruitment and drive enrollment.
- Strategic alliances with the world's largest network of accredited panels, experienced board members, and thousands of investigators and institutions – enabling us to assemble knowledgeable resources quickly for a smoother, faster, less expensive path for your trial.
- Timely, accurate, and transparent communications by our operational teams with the support of eClinical tools (e.g., EDC, CTMS, eTMF, Safety) for performance and risk management.

AWARD-WINNING CRO

Our award-winning, specialized Central Nervous System teams deliver uncommon value, helping emerging and established biopharma, biotech, and pharmaceutical companies test, validate, and de-risk the process of developing better treatments for all forms of MS.

CRO LEADERSHIP AWARDS2019

Capabilities, Compatibility, Expertise, Quality, and Reliability

UNCOMMON GLOBAL SITE AND INVESTIGATOR NETWORKS FOR FASTER PATIENT RECRUITMENT

With Worldwide, you get the best of both worlds: A specialized, MS-focused CRO with global coverage. What does this mean for you? Access to sites, investigators, and patients across the globe, without the hefty price tag and cookie-cutter approach you get from large, consolidating CROs.

[1] https://www.medicalnewstoday.com/articles/319061.php

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"Worldwide recently identified a risk that would have affected the continuation of our project, developed a mitigation strategy, and worked closely across functions and with sponsor stakeholders to develop a solution. Not only was the plan well executed by the team, but it also worked!"

- Worldwide Customer, Global Project Management

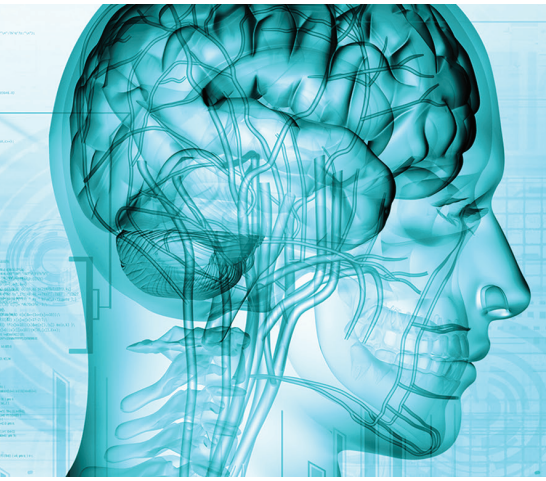
DEEP EXPERIENCE WITH THE SPECIALIZED PROCEDURES USED TO DIAGNOSE AND ASSESS MS

Worldwide has earned its reputation for delivering critical analysis and quality data. Whether you're assessing clinical outcomes, using MRI to view MS-related changes and detect myelin lesions, or studying cerebrospinal fluid (CSF) biomarkers (such as neurofilament measures), we can help. Through our integrated Clinical Assessment Technologies (CAT) group, our network of experts, and our preferred vendors, we support validated clinical assessments, including scale acquisition and rater training and surveillance, such as:

- Expanded Disability Status Scale (EDSS)
- Functional Independence Measure
- Modified Fatigue Impact Scale
- MS Functional Composite
- MS Impairment Scale
- Paper-based and Computerized Cognitive Assessments
- Patient-reported Outcome Instruments (MSQOL, FAMS, MSIS-29)
- Scripps Neurological Rating Scale
- Relapse Assessment Measures (e.g., annualized relapse rate, proportion of subjects who remain qualified relapse-free)

We also work with our preferred vendors to support you with these services:

- Imaging: Conventional and Advanced MRI
- Central Laboratory
- Specialty Laboratory
- PK Analyses
- ePROs



"In implementing the international, Ph2b GNC-003 (CHANGE-MS) study, GeNeuro, along with our co-development partner, Servier, chose Worldwide Clinical Trials as our CRO partner for several reasons, not the least of which was their global reach. Working as partners, we exceeded expectations in the time needed to fully recruit the patient cohort for the study, with Last Patient First Visit achieved a full 5 months ahead of planned. Once both Week 24 and Week 48 Database Locks were complete, we collaborated with Worldwide on a strategy for managing multiple outcome measures and complex comparative data analyses. Overall, the collaboration helped to enable us to discover a potential novel treatment for patients with MS."

- GeNeuro

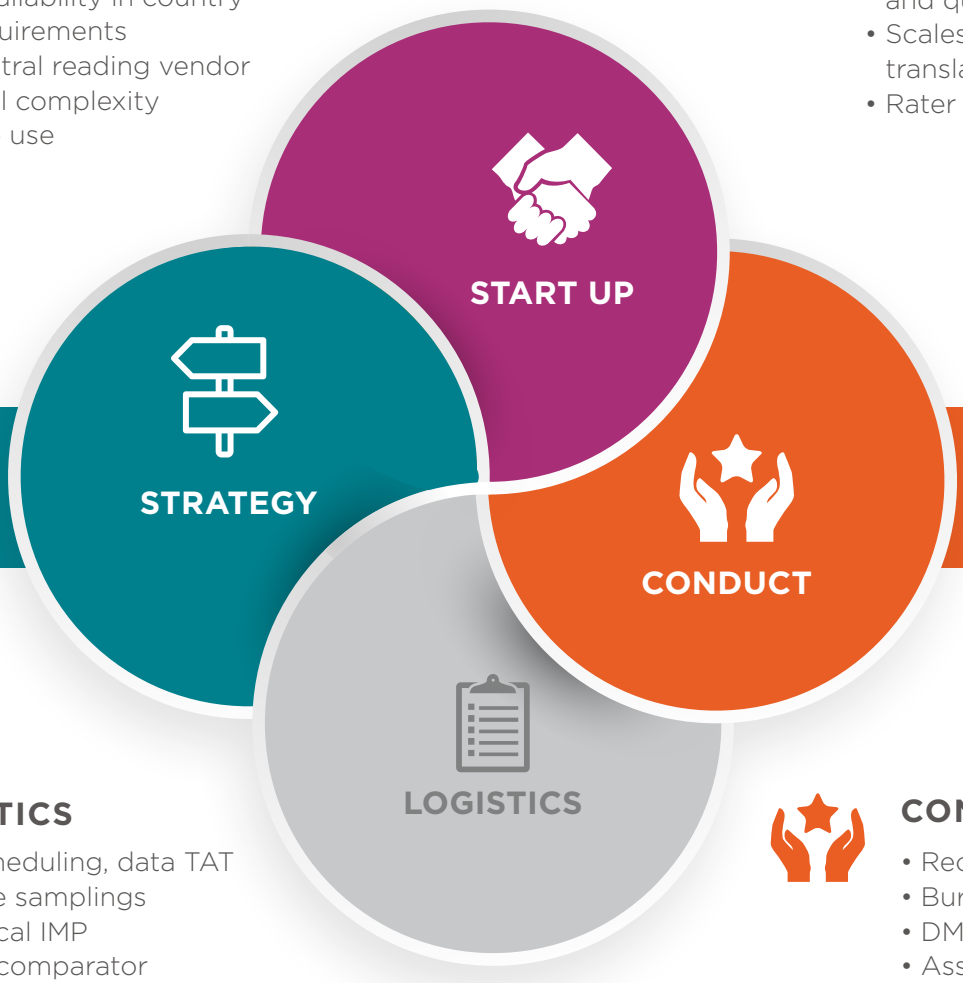
CRITICAL OPERATIONAL ISSUES TO CONSIDER FOR MS TRIALS

STRATEGY

- Congested landscape
- DMT availability in country
- MRI requirements
- MRI central reading vendor
- Protocol complexity
- Placebo use

START UP

- MRI contracts and qualification
- Scales licenses/ translations/material
- Rater qualification



LOGISTICS

- MRI scheduling, data TAT
- Multiple samplings
- Biological IMP
- Active comparator
- Hospitalizations
- IMP and material import

CONDUCT

- Recruitment and retention
- Burden on patients
- DMT wash-out
- Assessment consistency
- MRI scans
- Blinding

THERE'S NO SUBSTITUTE FOR UNCOMMON EXPERTISE. MEET YOUR PARTNERS.

Worldwide is committed to delivering uncommon value. In fact, we go above and beyond to deliver solutions and services that exceed your expectations. 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.

Tomislav 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 of 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.

AnneClaude Muratet, Pharm.D.

Executive Director, Global Project Management, Neuroscience

Dr. Muratet has over 20 years of clinical research experience at both CRO and pharmaceutical companies.

During the past 15 years, her focus has centered around oversight strategy and management of global programs, line management, and business development activities.

Dr. Muratet's experience includes a variety of indications in psychiatry, neurology, and rare diseases, spanning the full spectrum of activities and services in Phase I to Phase IV programs. Dr. Muratet's current responsibilities include the overall management of Worldwide's global project management team in neurology indications to ensure excellence in the delivery and quality of programs. This involves line management of project management staff, project oversight, and liaising with customers. Dr. Muratet holds a Pharm.D. from the University of Lille, France.