MEDPACE

NEURODEGENERATIVE DISEASES CLINICAL DEVELOPMENT

Neurodegenerative Diseases span a wide range of illnesses including Alzheimer's disease, Parkinson's disease, and Huntington's disease. Addressing the increased complexity of neurodegenerative disease drug development can be challenging in an ever-evolving field.

These diseases affect many individuals causing nerve cells in the brain or peripheral nervous system to lose function over time and ultimately die. The risk of developing a neurodegenerative disease increases substantially with age and there is currently no cure or way to slow disease progression. Recently, trials have begun to focus on small genetically defined populations within the larger patient population.

Medpace has extensive experience and expertise in the design and completion of advanced therapy complex studies involving patients with unique conditions.

INDICATION EXPERIENCE

- Symptomatic and Disease Modification Studies
  - Multiple Sclerosis
  - Alzheimer's Disease
  - Huntington's Disease
  - Parkinson's Disease
- Complex Studies
  - Advanced Therapy Medicinal Products (ATMPs)
  - Rare disease indications with similar neurologic elements

MAKING THE COMPLEX

SEAMLESS™

EXPERTS

- Accomplished, in-house neurology physicians experienced in clinical drug development for symptomatic and disease modification studies in psychiatry, and neurodegenerative diseases including Alzheimer's, Huntington's, Parkinson's
- Seasoned medical, regulatory and clinical project teams with extensive experience designing and conducting neurodegenerative diseases trials
- Other key expertise includes pain, stroke, neuromuscular, seizure disorders, neuroimaging, depression, and addiction

EXPERIENCE

- Accomplished in complex studies with Advanced Therapy Medicinal Products (ATMPs)
- Experienced in rare disease indications relevant to neurologic indications with similar neurological elements
- Accomplished in conducting studies with hard to find patients with complex conditions
- Experienced in conducting large and complex global studies involving multi-country regulations and requirements

EXECUTION

- Full-service integrated model to deliver efficient and streamlined execution
- Relationships with Rater Scale companies
- Flexible ePRO system for Patient Reported Outcomes that is customizable to fit any study needs
- Fully-integrated laboratory services including global central laboratories, bioanalytical laboratory, biorepository services, ECG core lab, and imaging core labs, as well as a clinical pharmacology unit

INTEGRATED SERVICES

Medpace has many services in our full-service model. Integrating core clinical trial services delivers efficient and streamlined execution and higher quality results.

ePRO CAPABILITIES

Patient reported outcomes are important in neurodegenerative studies. Patients, family or caregivers can measure symptoms and progress electronically in real time, yielding more accurate data. The Medpace ePRO system is flexible and customizable to fit any study needs. This system combats compliance issues with automated reminders and alerts for patients – experiencing over 95% compliance on some studies. Medpace also has experience with passive monitors installed in patients' homes.

Medpace is experienced with using our ePRO system, utilizing it in 50% of our studies. The ePRO system is seamlessly integrated into our CTMS, ClinTrak® EDC. This integration allows for a clean flow of data from the ePRO directly to EDC. Sites can access the data if necessary, reducing issues in data variability.

IMAGING EXPERTISE

Imaging is a critical tool in evaluating the underlying biology of degenerative diseases. Consistency is necessary in imaging of neurodegenerative disease over the course of months and years. Our dedicated team of experts ensures that each read is of consistent high quality. The integrated Core Labs allow seamless communication and ease of data transfer.

CENTRAL LAB CAPABILITIES

Medpace Central Laboratories has deep experience with biomarkers. These include amyloid, tau, and a variety of inflammatory markers. The Medpace central laboratory biomarker team is led by PhD level scientists who oversee the robust pipeline of new biomarker validations. The central lab validates all assays based on guidelines from the Clinical and Laboratory Standards Institute (CLSI) and in accordance with CAP and CLIA regulations. Medpace also has established micro particle brain assays. Medpace's logistics senior management has years of experience in the central laboratory industry, providing the study team unparalleled support, including knowledge of global import/export regulations. Medpace manages logistics in the central lab for esoteric samples and can redistribute to other locations. Biorepository services allow preservation and long-term storage of samples if required. Medpace experts receive superior training for complicated, complex studies. Our central lab team has the ability to do: the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.

- Cerebral Spinal Fluid (CSF) sampling
- Brain sampling
- Lumbar puncture
- Kinetics and distributions of the drug
- Imaging, brain chemistry and volume of the brain
- Genotyping by qPCR, Sanger Sequencing and Next Generation sequencing

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a global full-service clinical research organization providing Phase I-IV core development services for drug, biologic, and device programs. With medical and regulatory expertise in multiple therapeutic specialties. Medpace has assembled therapeutically focused teams to execute at every level of the company's operations, providing complete and seamless drug and device development services.

WE CAN'T SIMPLIFY CLINICAL DEVELOPMENT – BUT WE CAN EXECUTE IT SEAMLESSLY.