# CNS
## Clinical Trial Solutions in Europe

## Pharmnet expertise

Pharmnet Group has significant expertise in the field of neurology and psychiatry with more than 100 projects completed over the past 30 years. The experience is within I-IV phase clinical trials and telemedicine projects and includes medical writing. We have extensive experience with the following indications:


Other: Restless leg syndrome, Bipolar affective disorder, Muscular dystrophy (pediatric population), Borderline personality disorder

We can offer our experience and access to patients with neurologic or psychiatric disorders at more than 300 sites in the central European region and even more centers around all Europe in cooperation with our long-term partners. This includes specialized sites with a focus on certain central nervous system (CNS) pathologies with highly targeted patient populations from common pathologies such as Multiple Sclerosis (MS) centers or Stroke emergent units to sites dedicated to rare diseases such as pediatric Duchenne Muscular Dystrophy care centers. Our presence at these highly specialized European sites is essential for successful recruitment in rare disease projects as well as more common pathologies. Moreover, with Pharmnet´s Medical Director still active as a part-time psychiatrist, we have excellent access to the community through on-going relationships with Key Opinion Leaders throughout the central European region (mainly, but not limited to, the Czech Republic, Slovakia and Hungary).

## Why conduct a clinical trial with us?

We have access to the key sites in Europe that will command the greatest concentration of patients. Most have comparable treatment strategies. Our access to these sites and patients, along with detailed knowledge of patient management standards, allows us to propose the most efficient allocation of clinical sites across countries for given protocol design. This ensures fast execution of patient recruitment.

We maintain a diagnosis-oriented approach in doing top-line feasibility for selected countries. We present an executive summary of results for a specific pathology/protocol and propose scenarios to help our clients choose an optimal study solution in terms of study realization speed and cost.

## Key figures in neurology and psychiatry in Europe

The number of patients in neurology and in psychiatry is increasing in the EU with the aging population being a key factor.

Specialized procedures are performed centrally at specialized clinics with a high concentration of patients. These clinics have easy access to subjects for clinical trials. The following examples in common pathologies like MS, stroke and dementia, with patients distributed across the whole population, show how centralized health care allows the industry to benefit from an increasing number of patients.

**Cerebrospinal Multiple Sclerosis,** as an autoimmune chronic inflammatory demyelinating disease of the central nervous system, affects young people from age 20 years and older. Europe has more than 741 million inhabitants and nearly 1 million have MS.

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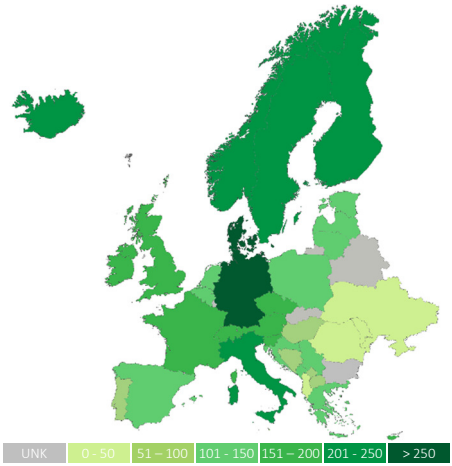
***Number of people with MS. Prevalence per 100,000 people:***




Patients with MS symptoms are referred to specialized sites at many EU countries for diagnosis confirmation and further treatment, e.g., in one country where we can conduct an MS trial, only 15 MS centers follow more than 20,000 patients providing access to more than 1,000 at one site. As MS remains an incurable disease, there is still high motivation among such sites to take part in MS clinical trial programs.

It is estimated that over one million people in Europe have a **stroke**, and 460,000 die as a result of stroke, every year. Almost 10 million people are living with the impact of stroke. In the next generation, it is estimated that the number of people living with a stroke will rise by 26%. Patient concentration can be illustrated with an example of a country of ten million people where the majority of stroke patients are managed within the dedicated network of 30 specialized Stroke centers providing complex care.

**Dementia** is an overall term that covers a range of conditions, with the most prevalent type being **Alzheimer's disease**. In 2019, the incidence of Alzheimer's disease and other dementias in Europe was approximately 188 per 100,000. The overall number of people living with dementia in EU countries is expected to rise by about 60% over the next two decades to reach 14.3 million in 2040. Treatment for these types of dementia can only temporarily improve symptoms, there is no cure for these diseases creating the high unmet medical need of the treatment. In the majority of European countries, specialized societies take care of patients. In this way, Alzheimer's patients for example, are easily identifiable for clinical trials.

## Case Study

Our strategic approach to clinical development is exemplified by a recent collaboration with a biotech company seeking to advance their development program in neurological disorder tardive dyskinesia (TD). The company faced recruitment challenges in their Phase I trial conducted by another CRO. Pharmnet's innovative solution involved parallel preparation of Phase II and Phase IIb/III documentation, securing approvals across four EU countries. To address the immediate need for patient data, we implemented a strategic protocol amendment incorporating an open-label cohort of 12 subjects. Through our extensive site network, we achieved complete recruitment of the open-label cohort within two months, delivering preliminary safety and efficacy insights within seven days of the last patient visit.

Due to the favorable risk-benefit profile, we successfully obtained approval for an extension study, ensuring a smooth, uninterrupted treatment transition for all patients from the core study. A notable achievement is that every participant completed the entire 58-week study as planned, with zero SAEs reported. This is a particularly exceptional outcome for a study population with TD. The long-term use data gathered through this study further reinforced the safety profile of the compound.

Our flexible and proactive approach successfully balanced the client's need for operational adaptability with the security required for confident program execution.

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Version: Oct-25