SCOPE

FACT SHEET

YOUR CRO OF CHOICE FOR

NEUROLOGY

SCOPE International is an international full-service contract research organization (CRO) with a proven track record in managing all major indications in clinical phases I – IV, including paediatric trials, orphan drugs and medical devices, non-interventional studies (NIS) and post-authorization studies. With our close relationships with leading investigators and key opinion leaders worldwide, we can deliver the highest quality solutions in time and budget.

Despite the enormous steps that have been taken in the understanding of central nervous system (CNS) diseases, healthcare systems worldwide face an unprecedented challenge in dealing with the unmet need associated with neurological disorders. CNS diseases, and in particular, mental health disorders, are, in the light of an aging population, one of the major health challenges of the 21st century (Race et al., 2013).

SCOPE International's CNS / neurology team is here to help your clinical development program flourish, with innovative recruitment strategies, strong site networks and local standard of care knowledge across an array of neurological disorder conditions. Our dedicated CNS project managers combine best practice and up-to-date knowledge of the relevant rating instruments in neurologic and psychiatric study development which is underpinned by our strong local and global regulatory insight.

SCOPE International's team has conducted a variety of CNS studies across the major aetiologies. With a full range of services and profound experience, we can define a strong development plan for your drug, device, or combination product and oversee the study from concept to delivery of the final report. We have successfully conducted more than 26 studies in neurology involving more than 1,000 clinical sites and 6,500 patients in both adult and paediatric indications. SCOPE International has established networks of investigators across different CNS indications; by maintaining close relationships with neurologists, psychiatrists, pain / palliative specialists and key opinion leaders.

We are able to provide rapid and accurate feasibility estimates at outset. We build upon our long-term relations with experienced, qualified and motivated sites to deliver your trial. From identifying the best sites, recruiting the right patients, to assuring assessments are properly completed by trained personnel, SCOPE has always met the challenges and targets across a wide range of study designs and hard to recruit indications in CNS. Your program will be monitored by experienced clinical research associates, project managers, medical monitors and scientists who are familiar with the specific nuances, pitfalls and opportunities in these type of studies.

26

NEUROLOGICAL STUDIES

1,000

SITES

6,500

SUBJECTS

EXPERIENCE IN **NEUROLOGICAL INDICATIONS**

- **Epilepsy (including paediatrics)**
- **Parkinson's Disease**
- **Bipolar Disorder**
- **Mania**
- **Depression**
- **Alzheimer´s**
- **Sensorineural Disorders**
- **Multiple Sclerosis**
- **Narcolepsy**

PRIMARY ENDPOINTS AND **PATIENT CENTRICITY**

As CNS trials are highly reliant upon subjective endpoints, the choice of suitable psychometric instruments is essential to demonstrate efficacy. Our staff can advise in selecting appropriate, well-defined and guideline-conforming tools appropriate for the use in clinical trials. These measures and their changes over time are coupled with support in standardisation and rater-trainings to ensure consistency and evaluable data.

Most trial patients find it cumbersome to record health-related information using paper diaries, especially when the instruments require observer information. Therefore, technology driven data collection models for patient data collection, including handheld devices such as tablets, smartphone apps downloaded on patients' phones, and electronic Patient Reported Outcome (e-PRO) instruments are a major consideration for a successful study set-up and reduce the burden for the patients.

SCOPE works with selected providers for electronic Clinical Outcome Assessments (eCOA), our monitors assist study coordinators in training patients to complete self-rated scales, ensuring timely capture and review of responses captured through patient diary data. Our site communications continually focus upon training, assessment, and feedback to ensure quality and consistency across all participating centers. At the outset our trained project managers identify and mitigate study risks.

POWER TO **YOUR PROJECT**

- Strategic Development
- Clinical Operations
- Medical Writing
- Clinical Data Management
- Biostatistics and SAS® Programming
- Safety Management
- Quality Management
- Regulatory Affairs

SCOPE INTERNATIONAL AG

Konrad-Zuse-Ring 18
68163 Mannheim, Germany
Phone +49 621 42939 0

FOR FURTHER INFORMATION

Please contact SCOPE's Business Development Team at
contact@scope-international.com

www.scope-international.com