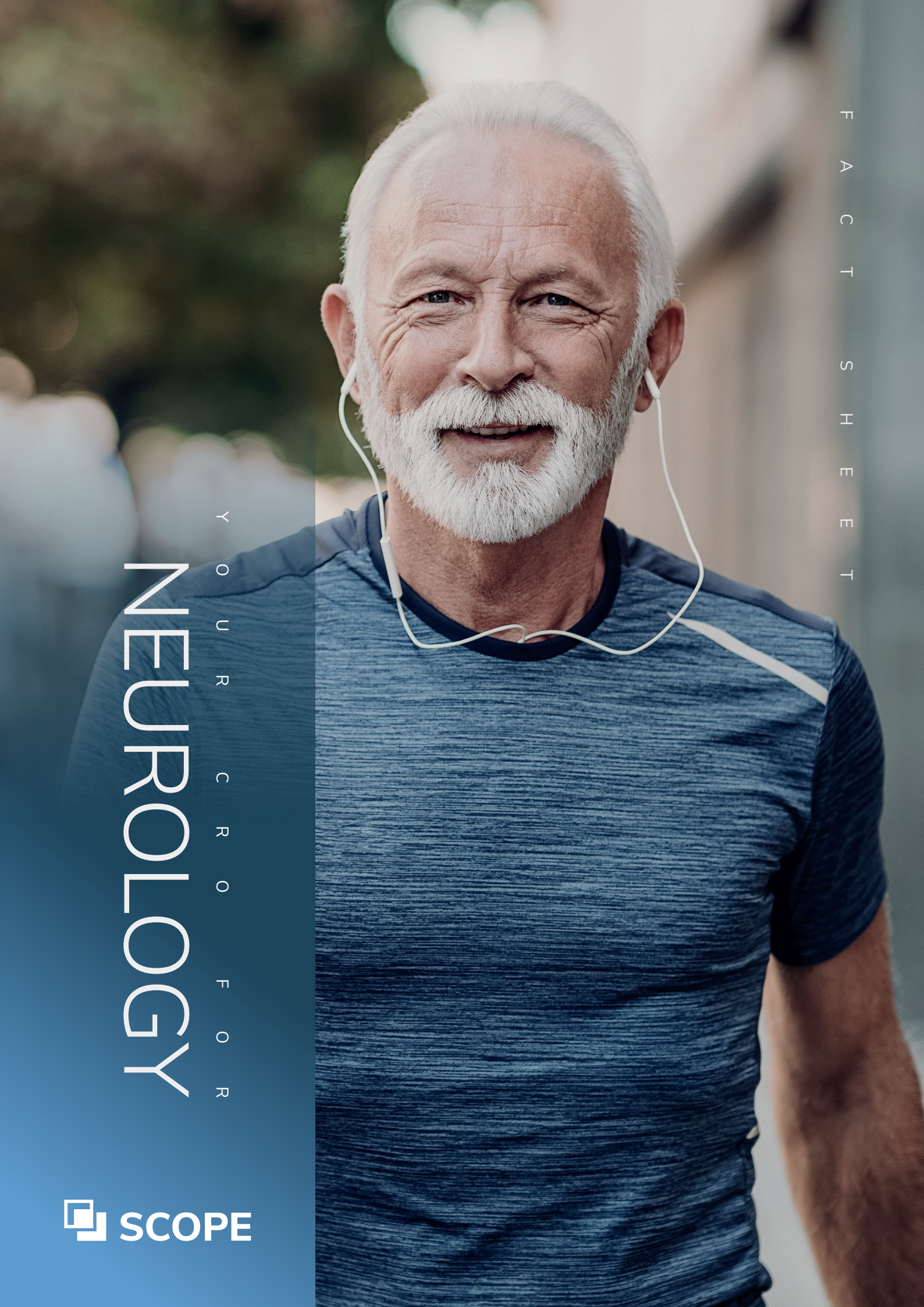

FACT SHEET

NEUROLOGY

YOUR CROFOR

SCOPE

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 pediatric 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.

31

Neurological Studies

1,100

Sites

6,500

Subjects

Despite the enormous steps that have been taken in the understanding of the central nervous system (CNS) diseases, **healthcare systems worldwide face an unprecedented challenge** in dealing with the unmet needs 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 **neurological 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 etiologies. 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 31 studies in neurology** involving **more than 1,100 clinical sites** and **6,500 subjects in both adult and pediatric 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.

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 standardization 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.

EXPERIENCE IN NEUROLOGICAL INDICATIONS

Epilepsy (including pediatrics)

Parkinson's Disease

Bipolar Disorder

Mania

Depression

Alzheimer´s Disease

Sensorineural Disorders

Multiple Sclerosis

Narcolepsy

STRATEGIC
DEVELOPMENT

MEDICAL
WRITING

BIOSTATISTICS AND
SAS® PROGRAMMING

QUALITY
MANAGEMENT

CLINICAL
OPERATIONS

CLINICAL DATA
MANAGEMENT

SAFETY
MANAGEMENT

REGULATORY
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