FACT SHEET

YOUR CRO FOR PAIN

SCOPE

At SCOPE International our pain management study teams have conducted a wide variety of clinical studies for mild to severe, acute, chronic and breakthrough pain indications. With a full range of services and profound experience, we can define a strong development plan for your drug, device, or combination product and manage the study from concept to delivery.

54

Pain Studies

1,600

Sites

12,000

Subjects

SCOPE International has successfully conducted **more than 54 pain studies** involving more than **1,600 clinical sites** and **12,000 subjects** in both **adult and pediatric pain indications**. We have established networks of investigators across a variety of pain indications; by maintaining close relationships with neurologists, pain clinics, palliative specialists, surgeons, anesthesiologists, general practitioners, and key opinion leaders (KOL), we are able to provide rapid and accurate feasibility estimates at outset. We build upon our **well-established relationships with experienced, qualified and motivated sites** to ensure the success of your trial.

Your program will be monitored by **experienced clinical research associates**, **project managers**, and **medical monitors** who are familiar with the specific nuances of these types of studies. Moreover, because pain is a subjective experience, the choice of an adequate instrument to measure the primary endpoint is essential to demonstrating the efficacy of an analgesic. Our staff can advise on selection of appropriate, well-defined and guideline-conforming tools including those suitable for use in the setting of a clinical trial to measure changes over time. These include all the commonly utilized tools such as:

- **Brief Pain Inventory**
- **MPI, Mood and Symptom Questionnaire**
- **West Haven Yale Multidimensional Pain Inventory**
- **Neurological Impairment Set**
- **Numeric Rating Scales**
- **Visual Analog Scales**
- **Brief Pain Inventory**
- **Likert Scales**

PRIMARY PAIN ENDPOINTS & PATIENT CENTRICITY

Most trial patients find it cumbersome to record data in paper diaries provided to them to capture patient outcome, especially when they are in pain. However, according to the FDA Guidance, efficacy endpoints in an analgesic trial should reflect a direct rating of pain intensity by the subject for all settings in which subjects can communicate in a reliable manner. Reducing the burden for patients in clinical trials is imperative for achieving good compliance, which is also the basis for high quality data. At SCOPE we use electronic clinical outcome assessments (eCOA) to facilitate data capture by patients (e. g. ePRO, eDiary) and site personnel by collecting the data through an app or web-based on provisioned or personal devices such as tablets, smartphones, or PCs.

CLINICAL ENDPOINTS IN PAIN STUDIES

SCOPE works with selected providers for electronic Clinical Outcome Assessments (eCOA). Our monitors also assist study coordinators in training patients to complete self-rated pain scales, ensuring timely capture and review of responses captured through patient diary data. Our site communications continually emphasize training, assessment, and feedback with sites to provide quality and consistency across all study sites. Our trained project managers identify and mitigate study risks at the outset. In case of participation of young children or subjects who cannot provide self report, observers (e. g., parents, caregivers) can report on observable indicators of disease or health condition through measurement of an observer-reported outcome (ObsRO). ObsRO concepts include only those events, behaviors, or signs that can be detected by an observer's senses (i. e., wincing, crying, or squirming). Similarly, a clinician reported outcome instrument to be completed by the study investigator should be limited to those concepts that are observable.

- **Pain intensity**
- **Function**
- **Health related quality of life**
- **Rescue medication**
- **Global single item assessment**
- **Opioid sparing**
- **Sleep**

CONTROLLED DRUG MANAGEMENT

SCOPE has extensive experience in the requirements for handling of controlled drugs / narcotics with a network of local offices able to ensure compliance with local regulation and avoid issues with handling.

Acute Postoperative / Procedural pain

Arthritis related pain

Bladder Pain Syndrome

Cancer pain

Chronic pain

Headache / Migraine

Lower back pain

Neuropathic pain

Post-surgery pain management

EXPERIENCE IN PAIN STUDIES

STRATEGIC
DEVELOPMENT

MEDICAL
WRITING

BIOSTATISTICS AND
SAS® PROGRAMMING

QUALITY
MANAGEMENT

CLINICAL
OPERATIONS

CLINICAL DATA
MANAGEMENT

SAFETY
MANAGEMENT

REGULATORY
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