FACT SHEET

WOMEN'S HEALTH

YOUR CROFOR

SCOPE

SCOPE International is an international contract research organization (CRO) with a proven track record in successfully delivering phase I through phase IV studies in all major indications, including pediatric trials, orphan drugs, biologics and medical devices, non-interventional studies (NIS) and post authorization studies. Using our close connections with leading investigators and key opinion leaders, we believe in providing the highest quality solutions worldwide.

49

Women´s Health Studies

1,412

Sites

26,000

Subjects

For the last 20 years, SCOPE has been at the forefront of delivering trials in **Women's Health**, focusing on the many unmet medical needs while working to improve existing drug and device therapy in both reproductive health, age related conditions and other indications.

SCOPE has the distinct ability to consistently provide this expertise to deliver the recruitment and treatment goals for your **Women's Health clinical trials** on time and in budget. In business since 2000, we have conducted more than **260 studies** with **over 70,000 subjects worldwide**. We have **14 offices** in **different countries across Europe** and **Ukraine** operating with **250 permanent employees** covering more than 30 countries and all major markets.

SCOPE has vast experience in conducting phase III Women's Health trials, ranging from protocol design, feasibility and site selection to full development programs depending on our client's specific needs. In recent years, we have conducted **more than 49 studies in Women's Health** indications involving more than **26,000 subjects in Europe and the USA**. We cover a broad range of indications within gynecology as well as indications that mainly affect women.

Whether it's a clinical developmental trial (phase I-III), post-authorization (phase IV), rescue, adaptive design study or even a complex device or diagnostic combination design, we have the expertise, know-how and resources to guide you through all development phases while meeting your objectives in a timely and cost-efficient manner.

STUDY DESIGN AND MANAGEMENT

By utilizing more than two decades of industry experience, coupled with the professional experience of our staff, SCOPE provides a well-established approach for successful Women's Health trials.

HERE'S WHAT SETS US APART:

- **Highly experienced project team**
- **Specific clinical Women's Health study expertise gathered during more than 20 years of experience**
- **Strong global network of investigators in Women´s Health**
- **Expertise in implementing advanced technology solutions improving study outcomes**
- **Anticipating and contingency planning to avoid pitfalls which only experience can predict**

ACCURATE AND APPROPRIATE FEASIBILITY

Recruitment is pivotal in achieving the desired outcome of the study. The SCOPE team is highly experienced in developing therapeutically appropriate and insightful feasibility questionnaires and extrapolating this to our enrollment plans. Our teams recognize that the delivery of feminine healthcare has considerable variability in settings across countries and local cultures, requiring sensitivity and local knowledge. SCOPE therefore conducts a feasibility survey to confirm projected recruitment rates and utilizes feedback from local Principal Investigators (PI) as part of our standard proposal process.

SITE TRAINING AND QUALIFICATION

SCOPE project teams are experts in the design and delivery of site training to ensure protocol-consistent enrollment and efficacy assessments, using electronic data capture systems (EDC, eCOA e. g. ePRO) and innovative study tools including our own project management tool.

ART, e. g. IVF, ICSI

Contraception

Endometriosis

Fibromyalgia Syndrome (FMS)

Obstetrics

Oncology

Pain Management

PCOS

Polymyalgia Rheumatica

Postmenopausal Complaints

Preterm Labor

Rheumatoid Arthritis

Vaginitis

Vulvar and Vaginal Atrophy

Vulvovaginal Candidiasis

EXPERIENCE IN WOMEN´S HEALTH

STRATEGIC
DEVELOPMENT

MEDICAL
WRITING

BIOSTATISTICS AND
SAS® PROGRAMMING

QUALITY
MANAGEMENT

CLINICAL
OPERATIONS

CLINICAL DATA
MANAGEMENT

SAFETY
MANAGEMENT

REGULATORY
AFFAIRS

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