SCOPE

FACT SHEET

YOUR CRO OF CHOICE FOR

WOMEN´S HEALTH

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 paediatric 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.

For the last 20 years, SCOPE has been at the forefront of delivering trials in Women's Health, focusing upon the many unmet medical needs and 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 on budget. In business since 2000, we have conducted more than 250 studies with over 65,000 patients worldwide. We have offices in 17 countries across Europe, Russia, Ukraine and the USA operating with 250 permanent employees covering more than 30 countries and all major markets.

SCOPE has wide 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 39 studies in Women's Health indications involving more than 20,000 patients in Europe and the USA. We cover a broad range of indications within gynaecology 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.

39

WOMEN´S HEALTH STUDIES

1,000

SITES

20,000

SUBJECTS

EXPERIENCE IN **WOMEN'S HEALTH**

- **ART, e. g. IVF, ICSI**
- **Endometriosis**
- **Contraception**
- **Postmenopausal Complaints**
- **Vulvar and Vaginal Atrophy**
- **Vaginitis**
- **Rheumatoid Arthritis**
- **Fibromyalgia Syndrome (FMS)**
- **Polymyalgia Rheumatica**
- **Oncology**
- **Pain Management**
- **Obstetrics**

STUDY DESIGN AND MANAGEMENT

By utilising 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 enrolment plans. Our teams recognise 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 enrolment and efficacy assessments, using electronic data capture systems (EDC, eCOA e. g. ePRO) and innovative study tools including our own project management tool.

POWER TO **YOUR PROJECT**

Strategic Development

Clinical Operations

Medical Writing

Clinical Data Management

Biostatistics and SAS® Programming

Safety Management

Quality Management

Regulatory Affairs

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FOR FURTHER INFORMATION

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