SCOPE

Case Study

Women's Health

While contraception trials in adolescents are generally more complex than those in adults, the recent Phase III safety trial of an oral contraceptive presented additional challenges. Unexpected legal hurdles caused delays and required adaptations to the trial design. By implementing a structured, flexible, and supportive approach – supported by custom-made, user-friendly documentation tools—SCOPE International successfully overcame these challenges and delivered high-quality data within a tight timeframe.

III / Phase

3 / Coutries

100 / Female Adolescents

High-Quality Results

- Despite delays and staggered country starts, the study was completed **within timelines and budget**
- Experienced and flexible teams, combined with deep **knowledge of local regulations**, ensured high-quality trial delivery
- Continued oversight during the extension and reporting phases maintained study integrity and success

Your CRO of Choice for Women's Health

Mastering the Unexpected

Rates of unintended pregnancies among adolescents remain high in many countries, making effective contraception trials essential. Conducting such trials in this age group is demanding due to **country-specific legal requirements** and the particular needs of the population.

For this study, SCOPE's Women's Health team developed **tailor-made solutions** to address:

- Recruitment and retention of 100 female adolescents aged 12–17 years in three European countries (Ukraine, Finland, Germany)
- Integration of multiple study site types, including state and academic hospital clinics and private practices
- An overall treatment duration of 13 cycles (six core + seven extension) with a low dropout rate of 5%

Site selection strategy was based not only on budget considerations but also on:

- Predicted recruitment contribution
- Site commitment and previous performance in similar studies
- Extensive experience in clinical conduct, ensuring predictable recruitment potential, performance, and motivation

SCOPE provided **easy-to-use documentation**, **timely support**, and **rapid issue follow-up**, which:

- Reduced the workload for investigators
- Positively influenced the study budget
- Built strong monitoring relationships critical to study success

Flexibility is Key

Despite a short contractual period of only three months between award and initial submission to Ethics Committees and Competent Authorities, SCOPE delivered a detailed, ready-to-implement proposal. However, recruitment was delayed due to:

- Rejection of the study in one core-phase country
- Unforeseen global amendments to the study protocol by an EC

SCOPE addressed these challenges by:

- Implementing a **risk mitigation strategy**, introducing a replacement country
- Designing a new **case report form** and managing re-consent of already enrolled subjects
- Ensuring an **efficient transition** to the new trial design across affected countries

The team also managed **limited investigational product supply** by:

- Monitoring site performance to prevent wastage
- Developing a controlled **re-allocation process** from low-enrollment sites to high-enrollment sites

SCOPE's Solutions

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

PROVEN RESULTS IN WOMEN'S HEALTH

★ ★ ★ ★ ★

"A partner who understands Women's Health"

SCOPE demonstrated a deep understanding of Women's Health indications, patient pathways, and site dynamics, resulting in smooth execution and reliable outcomes.

Medical Director, Pharmaceutical Company

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:
contact@scope-international.com

www.scope-international.com

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