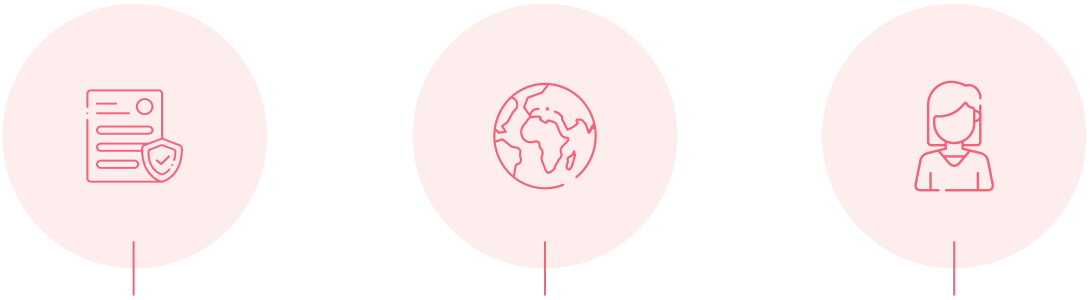
CASE STUDY

YOUR CRO FOR

WOMEN'S HEALTH

SCOPE

While contraception trials in adolescents are principally more complex than in older populations, the recent phase III safety trial of an oral contraceptive proved particularly challenging: unexpected legal hurdles caused delays and required an adaptation of trial design. By implementing a structured, flexible and supportive approach, aided by custom-made, user-friendly documentation tools, SCOPE International successfully conquered all difficulties and delivered high-quality data within a tight timeframe.



MASTERING THE UNEXPECTED

Despite recent declines, the rates of unintended pregnancies among adolescents remain high in many countries. Supplying adolescents with effective means of contraception adapted to their specific needs remains an important pillar of family planning worldwide. Due to particular legal requirements that vary nationally, running studies on contraceptives in this age group is a demanding task. In addition to this precondition, SCOPE International faced a number of individual **challenges** in its **phase III** safety trial of an **oral contraceptive**. To achieve the study goals, SCOPE International's dedicated Women's Health team developed a range of **tailor-made solutions**.

The trial was to be carried out with **100 female adolescents** aged **twelve to seventeen years**, depending on local regulations, in three European countries. The study sites in Ukraine, Finland and Germany included state and academic hospital clinics as well as private practices. The study stipulated an overall treatment duration of six cycles in the core phase plus seven further cycles in the extension phase to achieve a twelve-month treatment for completion of 13 cycles. Despite the **special study population** and the **long treatment**, the **dropout rate was a low 5 percent**.

SCOPE International's approach to site selection was perfectly suited to meet the study's budget constraints: Rather than purely financial criteria, it was based primarily on a site's proposed contribution to recruitment and its commitment and past performance in similar studies. With the exception of one site, SCOPE International selected all sites based upon **extensive experience in clinical conduct** so that

recruitment potential, performance and motivation of sites were predictable. By providing easy-to-use documentation, support where needed and a rapid follow-up of issues, the SCOPE team helped to reduce the workload of investigators, influenced the study budget positively and built **excellent monitoring** relationships that proved critical during the study.

FLEXIBILITY IS KEY

Despite the short contractual period of only **three months between the study award and the initial submission** to the Ethics Committees and Competent Authorities (EC / CA), the SCOPE International team provided the sponsor with a well-constructed and detailed proposal that would have allowed work to commence immediately. However, the start of recruitment was delayed for several months by rejection of the study in one country in the core phase of the trial. By applying a **risk mitigation strategy** with an **outstanding performance**, SCOPE International provided a replacement country and caught up on time delays.

An additional challenge was an **unforeseen global amendment** to the study protocol requested by one EC stipulating an **altered trial design**, which was implemented during the initial submission and approval phases of the rescue country. By designing a new version of the case report form and managing re-consent of all subjects enrolled until then, SCOPE International's team was able to **make up lost time** and achieved an efficient and smooth transition to the new trial design in the respective countries.

SCOPE International mastered the **challenge of limited supply** of the investigational medicinal product at the start of the project with carefully monitored site performance to avoid wastage. The team developed a validated, controlled and intricate re-allocation process from sites with low enrollment rates to those with many subjects to secure supply as required.

HIGH-QUALITY RESULTS

Despite time delays and although not all countries started in parallel, the study was still **finalized within timelines** and without any impact on the budget. By using an experienced and flexible team with a profound knowledge of local specifics and the legal situation in the individual countries where the study was performed, SCOPE International was able to deliver the trial with **high-quality results** and **compensate for much of the time lost** due to regulatory specifications in the core phase. As activity on the study continued during the extension and reporting phase, SCOPE International maintained its **high level of careful oversight**, thus making the study a success for the client.

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