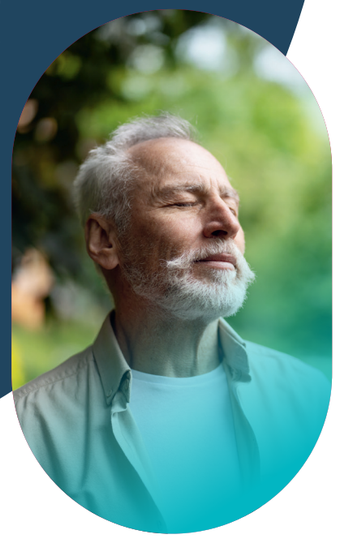
SCOPE

Case Study

Respiratory

For this non-interventional post-authorization study on a respiratory drug, what initially seemed like a smooth trial turned out to be more complex. Conducted across **11 EU countries**, the study required a **tailor-made site strategy** and **customized tracking tools**. Despite unforeseen setbacks, SCOPE successfully delivered **results within timelines** and **under budget**.



10/d / **Recruitment Rate**

250 / **Qualified Sites**

2,500 / **Subjects**

Customized Solutions

SCOPE tackled these challenges with a highly cost-efficient and adaptive approach, combining on-site and remote monitoring. Processes were tailored to each site, leveraging the EDC system to generate actionable data. Reporting tools provided real-time oversight and ensured focus on the most critical issues.

Highlights of SCOPE's approach:

- Adaptive monitoring: on-site + remote
- Bespoke EDC data evaluation for actionable insights
- Custom reporting tools for reliable decision-making
- Optimized CRA travel routes – ~50% travel cost reduction
- Structured communication & intensive training for site staff
- Risk mitigation plan: back-up countries on standby
- Navigated regulatory changes due to PRAC migration

Your CRO of Choice for _____ Respiratory

Study Overview

The study was planned across **continental Europe**. As often is the case with non-interventional studies, the sponsor **independently selected almost all sites**. This introduced several unknowns: site experience and recruitment potential were untested, staff often lacked clinical research experience, and investigator fees were low. In addition, regulatory delays in three countries increased pressure on recruitment targets.

Key Challenges

- **Most sites without prior clinical study experience**
- **Tight budget with low investigator fees**
- **Recruitment target: 10 subjects/day**
- **Regulatory delays in three countries**

Outcomes & Benefits

Thanks to this structured and flexible approach, the recruitment process was finalized ahead of timeline. Sites were motivated and engaged, while cost savings were realized through optimized monitoring and travel planning. Ultimately, the study delivered highest-quality data, within both timelines and budget.

Key Results:

- Recruitment target achieved before timeline
- Efficient time management
- Motivated site teams despite low fees
- Significant cost savings
- Highest-quality data delivered

SCOPE's Solutions

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

PROVEN RESULTS IN RESPIRATORY

★★★★★

"Reliable delivery in complex respiratory trials"

SCOPE combined strong respiratory expertise with pragmatic study management. Recruitment targets were met despite complex protocols and demanding timelines.

Clinical Development Lead, 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

Follow us on