



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 **customised tracking tools**. Despite unforeseen setbacks, SCOPE successfully delivered **results within timelines** and **under budget**.



10/d / Recruitment Rate

250 / Qualified Sites

2,500 / Subjects

Case Study



Customised 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
- Optimised CRA travel routes – approx. 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 finalised ahead of timeline. Sites were motivated and engaged, while cost savings were realised through optimised 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

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