

# Driving a faster respiratory clinical trial for a biotech

## A KEY QUESTION



How did Fortrea and the biotech company achieve global enrollment and deliver ahead of target time through their close collaboration?

## KEYWORDS

COPD, Respiratory Clinical Trials, Global Enrollment, Recruitment, Site Engagement



Since 2011, Fortrea and a European sponsor have collaborated closely to advance the clinical development of respiratory drugs through a supportive governance structure and tailored solutions that mitigated risks and enhanced study efficiency. This allowed Fortrea to achieve recruitment goals ahead of target and in one study, the outcome was a recruitment rate increase of over 80% in the U.S.

## Collaboration background

In parallel, Fortrea leveraged advanced technology platforms and real-time data analytics to strengthen operational oversight and accelerate decision-making. Centralized data monitoring, automated quality checks and predictive enrollment insights enabled the teams to identify risks earlier, optimize site performance and maintain high data integrity across global regions, time data analysis to strengthen operational oversight and accelerate decision-making.

## The challenge

Chronic Obstructive Pulmonary Disease (COPD) is the fourth leading cause of death worldwide, causing 3.5 million deaths in 2021, approximately 5% of all global deaths.<sup>1</sup> Recruiting patients for large-scale clinical trials in this area requires balancing global enrollment targets, regulatory complexities and the need for rapid, data-driven decision making. Additional challenges include:

- Understanding variations in standard of care treatments across different countries
- Ensuring treatment and protocol compliance in a highly competitive clinical trial landscape

## Specific initiatives at Fortrea

- **Site budgets:** Ensured the budgets were competitive and reflective of the work required, including enhanced pre-screening, database reviews and referral discussions
- **SEM visits:** Assigned site engagement managers to each site to specifically support recruitment challenges through on-site or virtual motivational/support meetings
- **Continuous data cleaning:** Implemented a batch-cleaning approach to reduce backlog and enable ongoing data trending and assessment
- **New sites:** Activated additional clinical sites to expand access to potential patients and extend geographic reach supporting faster enrollment
- **Vendor management:** Leveraged strategic partnership relationships with external vendors specializing in recruitment and site support. Each vendor contributed different capabilities such as direct-to-patient outreach, medical record retrieval or support for site activation in new regions

- **Accountability:** Assumed clear ownership of delivery from day one, acting as an extension of the sponsor team with oversight and ownership that drives outcomes
- **Transparency:** Provided visibility at every step through consistent, clear communication and timely reporting, building confidence in timelines, decisions and results

## Outcomes

- Significant cycle time reductions, specifically in achieving last patient last visit earlier than planned, with a subsequent reduction in budget
- Strong site relationships and site engagement for current and future studies
- Technology and data-driven approaches unlocked additional efficiencies and supported proactive risk mitigation
- High data quality was achieved resulting in data base locks ahead of target

## Conclusion

The teams' strengthened site performance and data integrity through targeted recruitment and operational initiatives. This contributed to cycle-time reductions, strong site relationships and high data quality that helped to achieve global enrollment and delivered ahead of target time.

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### Reference

1. Chronic obstructive pulmonary disease (COPD), *WHO*, November 2024, [https://www.who.int/news-room/fact-sheets/detail/chronic-obstructive-pulmonary-disease-\(copd\)](https://www.who.int/news-room/fact-sheets/detail/chronic-obstructive-pulmonary-disease-(copd))