

eCOA ASTHMA CASE STUDY

Deploying eCOA to improve patient retention and compliance in a Phase III asthma study



People living with asthma can use pharmacological treatments to help control their symptoms, prevent exacerbations and increase their quality of life.¹ However, patient adherence to asthma medications is routinely suboptimal, with reported non-adherence ranging from 22–78%.²

Fortrea needed to overcome this inherent issue when recruiting and enrolling asthma patients in a Phase III study spanning Europe, Latin America and North America. This case study outlines how Fortrea managed a complex protocol in a low-compliant population and incorporated digital solutions to promote retention and compliance.

Managing the needs of patients and sites

A myriad of factors, such as patient knowledge/education, inhaler device convenience and satisfaction, can contribute to asthma patient non-adherence.² Understanding these challenges, Fortrea wanted to ensure that study participants would observe the study's medication regimen and follow the protocol's requirements to ensure quality data.

Patient burden at the site level was also examined as travel to the site could fatigue patients and lead to non-compliance or dropouts. However, on-site study visits helped sites maintain adequate oversight, stressing the need to find an optimal balance between patients' expectations and sites' needs.

KEY TAKEAWAYS

Addressed inherent patient compliance challenges:

Fortrea examined how to best support patients who have a poor history of observing asthma medication regimens.

Enabled sites: Fortrea ensured sites had adequate patient oversight by balancing on-site visits with eCOA for remote compliance monitoring.

Incorporated patient-centric solutions: An eDiary, home-based device and patient application supported retention and protocol compliance, reducing the patient burden associated with frequent site visits.

Demonstrated the value of eCOA: A thoughtful digital strategy resulted in on-target recruitment, excellent protocol compliance and high patient retention.



Implementing digital solutions

To strengthen patient- and site-centricity in the trial and reduce patient travel, Fortrea employed several digital solutions to supplement monthly on-site study visits. For patients, these solutions included:

- **An eDiary** that collected patient-reported outcomes (PROs) to assess symptoms, function and quality of life
- **A patient application** that provided educational materials, reminders of medication compliance and important dosing information, such as the acceptable dosing ranges
- **A home-based device** for patients to measure peak expiratory flow (PEF), an indication of lung function based on airflow³

At the site level, Fortrea implemented:

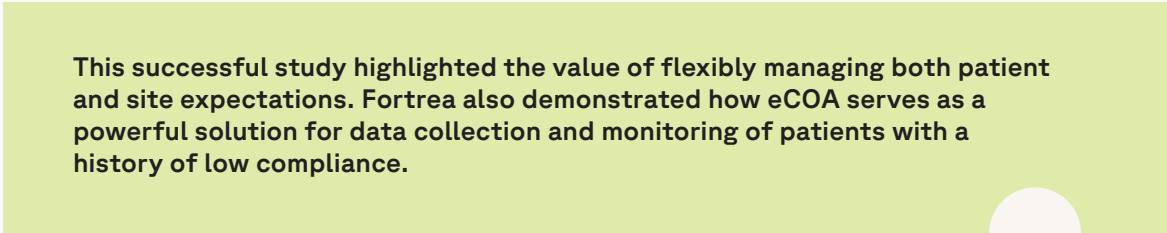
- **eCOA** (electronic clinical outcome assessments) to help the sites track remote compliance through eDiaries
- **Continuous education and training** of site staff to reinforce the study purpose, support retention practices and provide reminders on how to communicate with patients through the deployed tools

Reflecting on the results and lessons learned

Within 12 months, Fortrea met the target recruitment by enrolling 310 patients in the study. Using the eCOA solution, sites could track patients in their care, enabling proactive intervention and rapid follow-up when concerns were identified.

Patients were also supported with the patient-facing application, which helped reinforce protocol compliance and dosing requirements. Data collection through the eDiary reduced the need for more frequent study visits at the site.

By applying their deep experience in developing, deploying and integrating effective eCOA elements, Fortrea achieved 93% compliance with the questionnaire and medication diary and a patient retention rate of 91.3%.



This successful study highlighted the value of flexibly managing both patient and site expectations. Fortrea also demonstrated how eCOA serves as a powerful solution for data collection and monitoring of patients with a history of low compliance.



Learn more about how Fortrea can address your digital health innovation needs.

References

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2. Mäkelä MJ, Backer V, Hedegaard M, Larsson K. Adherence to inhaled therapies, health outcomes and costs in patients with asthma and COPD. *Respir Med.* 2013 Oct;107(10):1481-90.
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