

CASE STUDY

Designing patient-centric ePROs to reduce patient burden and promote study compliance in a multinational Phase III oncology trial



Fortrea was selected to run a multinational Phase III study and needed to recruit patients living with metastatic or locally advanced non-small cell lung cancer (NSCLC). Understanding that the NSCLC patient journey and standard of care can be complex, this case study shares how Fortrea evaluated and designed a patient-centric approach to meet the needs of patients in the study and generate high-quality qualitative data for the sponsor.

Recognizing the challenges

Addressing the patient burden of multiple assessments

The sponsor's study required multiple patient-reported outcomes (PROs) to fully document patients' symptoms and quality of life. These lengthy and often detailed assessments contribute to patient burden in a clinical trial—and can lead to poor compliance, threatening data quality.

Supporting a large geographical breadth of patients and numerous sites

With the task of recruiting 225 patients from 220 sites across 27 countries, Fortrea recognized the need for an efficient method to collect and collate data, which could help reduce time-consuming processes and alleviate site burden.

Designing and deploying a patient-centric ePRO strategy

To deliver multiple questionnaires that patients would tolerate, Fortrea proposed using electronic assessments as part of a digital health strategy. These ePROs/eDiaries offered numerous benefits across the trial for:

- **Patients**, who could complete the questionnaire at their own pace, access training for eDiary entries and receive timely reminders
- **Study staff**, who could review centralized, collated data, provide near real-time compliance checks and support patient compliance as needed
- **Sites**, that can easily monitor questionnaire data between in-clinic visits

Working with the sponsor, Fortrea first discussed specific language choices for the assessments to match patients' expectations and promote ease of data collection. These discussions were initiated early in the planning phase to minimize the potential for downstream changes and delays.

Fortrea also assigned a dedicated Digital Health Delivery project manager, who led the eCOA/eDiary setup to deliver an on-time deployment.

Driving results with digital health innovation

With careful planning and a patient-focused approach, Fortrea:

- **Enabled early recruitment:** Study recruitment was completed ahead of schedule
- **Achieved high retention rates:** Patient retention in the study reached ~86%, exceeding the original estimate by 5%
- **Promoted high eCOA compliance rates:** ~87% of patients completed their electronic symptom diaries, benefiting from rapid patient support during the study
- **Minimized eCOA-related protocol deviations:** Less than 3% of protocol deviations were related to eCOA
- **Delivered high-quality data:** The use of ePRO reduced patient fatigue and generated high-quality qualitative data to support the trial

Learn how Fortrea can minimize the impact on patients' lives and improve data quality with thoughtful [digital health innovations](#).

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