

Leveraging digital health capabilities to retain patients in a perceived “low benefit” Phase IV study

A KEY QUESTION



How can digital health innovation help attract and retain patients in a clinical trial perceived as offering low personal benefit?

KEYWORDS

Digital Health Technology, Patient Recruitment, Patient Retention, Phase IV Study, Heart Failure, eConsent, eCOA/ePRO, Remote Monitoring, Protocol Compliance, Patient-Centric Strategy, Data Quality



Many factors influence a patient's participation in a clinical trial, but “personal benefit” is often cited as one of the main reasons.¹ If a trial has few perceived benefits for potential study participants, creative solutions are required to highlight the value of the study, address concerns and promote enrollment.

This case study shares how Fortrea used digital health technology as part of a multi-faceted strategy to attract and retain patients in a multinational, placebo-controlled Phase IV study for recalcitrant heart failure.

Key highlights

A patient-centric, digital health strategy targets hard-to-reach and hard-to-keep participants.

Fortrea delivered a successful Phase IV study by:

- Developing a range of accessible educational materials to highlight participation benefits
- Designing digital health innovations to integrate with patients' lives
- Monitoring compliance and protecting study endpoints
- Reaching recruitment and retention goals and promoting data quality

Creatively responding to challenges

To recruit more than 300 patients living with symptomatic heart failure, Fortrea first worked to understand the unique needs of the targeted population. They recognized that the population often had variable adherence to the standard of care medications and participants may be unmotivated to join a clinical trial.

With this knowledge, Fortrea developed a strategy that included:

- **Creating accessible educational materials:**
As part of the eConsent package, Fortrea developed a range of accessible educational materials highlighting the benefits of joining the Phase IV study. Special attention was placed on creating multiple formats of materials, such as eLearning and videos, to adapt to patients' attitudes and suit individual learning styles
- **Promoting study compliance through eCOA:**
To record outcomes, Fortrea employed several electronic clinical outcomes assessment (eCOA) and patient-reported outcomes (ePRO) techniques focused on at-home completion of eQuestionnaires through mobile devices, which included built-in reminders to promote compliance
- **Remote monitoring to prompt intervention:**
When needed, study teams could quickly recognize and correct non-compliance as they remotely monitored participation levels, keeping patients, and the trial, on track

Delivering value to the sponsor

With the team's combined efforts across three continents, Fortrea recruited 360 patients and met all Last Patient In (LPI) targets. Fortrea also demonstrated how conveniently integrating the study into participants' lives helped promote enrollment and retention, resulting in a 95% patient retention rate.

The use of digital trial solutions through eCOA/ePRO promoted adherence and high compliance, with only ~2% of protocol deviations attributed to missed ePRO/eDiary completion. This patient-centric technology also helped Fortrea protect the study endpoints as they delivered an on-time study with quality data to advance the sponsor's goals.

Learn more about how Fortrea's [digital health solutions](#) enhance patient reach and improve participation in clinical trials.

LEARN MORE at fortrea.com

Reference

1. Sheridan, R., Martin-Kerry, J., Hudson, J. et al. Why do patients take part in research? An overview of systematic reviews of psychosocial barriers and facilitators. *Trials* 21, 259 (2020).