CASE STUDY

Patient-centric ePRO strengthens retention and compliance in a Phase III bladder cancer trial

"Low accrual" of participants is cited as the most common reason that urologic cancer clinical trials are terminated, according to a recently published research article.[1] Learn how Fortrea addressed this challenge, employed digital health technologies and maintained high retention and compliance rates to gather meaningful data for a sponsor.

Understanding the inherent challenges in bladder cancer trials

The targeted patient group in this study's protocol was highly impacted by their condition and experienced significant health challenges associated with bladder cancer. Knowing that these factors contributed to a low expected participation rate in the study, Fortrea needed to work with hundreds of sites across 30 countries and enroll 830 patients.

Each enrolled patient in this study was especially valuable, stressing the importance of:

- Maintaining follow-up to support key analyses, such as the risk to overall survival
- Reducing patient fatigue in the study
- Encouraging study compliance

KEY HIGHLIGHTS

Reducing patient fatigue—and collecting critical data—through ePRO

In this Phase III study, Fortrea's thoughtful use of digital health technology:

- Reduced patient fatigue by avoiding overly complicated questionnaires
- Collected complete responses with patient-centric technology
- Delivered near real-time compliance data and enabled rapid follow-up with sites and patients
- Achieved 80% patient retention and 84% questionnaire compliance

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Taking an active role in promoting recruitment and retention

To mitigate recruitment and retention challenges, Fortrea implemented a multi-faceted approach. This involved:

- **Designing digital health technology:** A Fortrea design and delivery expert was engaged early in the process to create a global electronic patient-report outcome (ePRO) design that minimized patient fatigue while still collecting valuable data
- **Training sites:** Fortrea took an active role in training sites on the study's needs and tips for improving patient engagement
- **Educating patients:** Patients were given materials about the importance of the study and their role in participating
- **Deploying electronic questionnaires:** Patients received electronic Quality of Life (QoL) questionnaires and automated reminders to help promote compliance
- **Monitoring patient compliance:** With electronic questionnaires, sites could run near real-time compliance checks to improve data quality, and the clinical study team could work with sites on course correction, as needed

Reviewing the results and lessons learned

By promptly engaging a Fortrea delivery expert and leveraging their experience, the team set the study up for success with thoughtful questionnaire design and timely delivery. Proactive planning was also critical to support the necessary ePRO documentation, given that the country selection process spanned 30 countries.

As a result of Fortrea's efforts to emphasize retention and compliance in this difficult-to-reach cohort, they have achieved an 80% patient retention rate and 84% questionnaire compliance over the last three years. Fortrea will continue its efforts to keep patients engaged and help the sponsor gain valuable data that may ultimately make a difference for people living with bladder cancer.

Learn how Fortrea supports patients and sites through high-touch, high-tech solutions.
Explore our Digital Health Solutions.

Reference

1. Alhajahjeh A, Hmeidan M, Elatrsh M, et al. Understanding the Termination of Urologic Cancer Clinical Trials: Insights and Challenges. *JCO Glob Oncol.* 2024 Jan;10:e2300349

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