

# Increasing engagement and collaborative practices in two Phase III oncology trials



## A KEY QUESTION



How can a CRO address challenges in highly complex oncology studies and apply best practices to meet critical milestones?

## KEYWORDS

Oncology Clinical Trial, Lung Cancer, Skin Cancer, Immune Checkpoint Therapy, Patient Recruitment

Fortrea was selected by a large biopharmaceutical company to run two Phase III trials of an immunotherapy targeting both lung and skin cancers.

This case study highlights the challenges Fortrea faced and the solutions the team implemented to increase collaboration across sites and vendors, boost recruitment and meet database lock (DBL) milestones.

Study challenge	Fortrea solution
<p><b>Inconsistent targeting of study participants:</b> After patients underwent surgery, they were approached by the oncologist and investigators for study inclusion, but Fortrea recognized that this approach varied between institutions.</p>	<p><b>Incorporating surgical and medical oncology input:</b> Fortrea developed patient mapping and site recruitment plans for each site prior to the site initiation visit (SIV) and recommended an assessment of a percentage of patients who are seen at a site for surgery only to create a more consistent process.</p>
<p><b>A restrictive protocol impacting enrollment:</b> Restrictive clinical trial eligibility criteria limited the number of patients who could enroll in the lung cancer study.</p>	<p><b>Supporting a protocol amendment:</b> With a change in surgical criteria, more patients were potentially eligible to enroll.</p>

Study challenge	Fortrea solution
<p><b>Limited study awareness:</b> Both the skin cancer and lung cancer trials involved complex surgeries; therefore, potential participants may not learn about the option to join a clinical trial as a treatment option.</p>	<p><b>Increasing education and study engagement:</b> Targeting high volume surgical centers, Fortrea enlisted local medical doctors to write to referring medical oncologists and educate them about treatment options at main institutions. Sites also included surgeons to become sub-investigators, which boosted study engagement.</p>
<p><b>Managing data complexities:</b> While Fortrea led medical monitoring and biostats, a well-established cooperative group led data management in its electronic data capture (EDC) platform.</p>	<p><b>Developing a close collaboration:</b> In both studies, Fortrea established a close collaboration with the cooperative group and jointly reviewed bi-yearly data cuts to support safety monitoring and provide consistent, high-quality data for regulatory submissions.</p>

## Recognizing the results and making a difference for patients

Working closely with sites, surgical specialists, medical oncologists and the cooperative group, Fortrea met critical database lock (DBL) milestones for the sponsor. The skin cancer study reached the primary and secondary endpoints, while the lung cancer treatment was ultimately granted U.S. FDA approval.

Learn how Fortrea navigates the complexity of oncology trials to accelerate development and help deliver innovative treatments to patients.

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