

Coordinating complexity: Delivering global diagnostic imaging studies across modalities and patient populations

A KEY QUESTION



How can sponsors navigate the complexities of global diagnostic imaging studies without compromising timelines or quality?

KEYWORDS

Diagnostic Imaging, Patient Pathway Coordination, Radiotracer Manufacture, Radiotracer Validation, Theranostics, Multidisciplinary Teams, Imaging Protocol Complexity, Resource Constraints, International Study Delivery



Introduction

Diagnostic imaging studies are a highly specialized area of clinical development requiring tightly coordinated, multidisciplinary delivery within strict procedural timelines. Radiotracer-based research depends on coordination between radiology, pharmacy/radiopharmacy, medical physics, surgery and laboratory functions across imaging visits, investigational medicinal product (IMP) manufacture and administration. These operational demands are often compounded by the need to recruit and retain patients who may already be managing significant disease burden and complex treatment schedules.

Fortrea has delivered diagnostic imaging studies across adult and pediatric populations in the United States and Europe for oncology, neurology and cardiovascular programs. This experience includes running multi-modal imaging studies across diverse therapeutic areas and countries, including:

- Positron emission tomography (PET)
- PET/computed tomography (CT)
- Single-photon emission computed tomography (SPECT)

- Magnetic resonance imaging (MRI)
- Theranostic imaging approaches
- Case agent studies with ultrasound and electrocardiogram (ECG)-based imaging

This breadth of activity is underpinned by early radiotracer development and validation, supporting reliable imaging data within complex clinical study designs.

Challenges

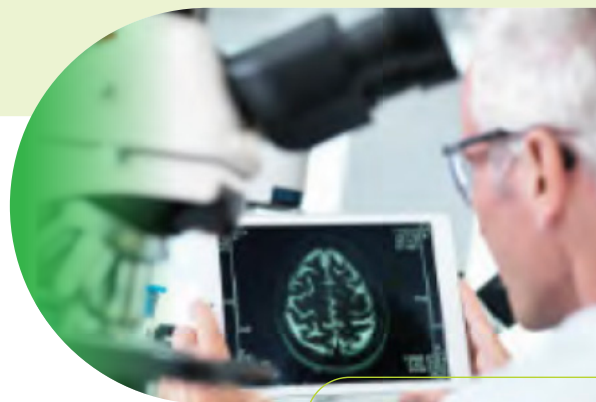
- Diagnostic imaging studies are inherently complex and typically do not provide direct clinical benefits compared with standard of care, requiring careful patient and site engagement throughout study delivery
 - The patient pathway spans multiple clinical departments, with imaging specialists frequently not acting as principal investigators and not always experienced in managing large, multidisciplinary study teams
 - Radiotracer manufacture and validation are technically demanding processes that require early coordination to support alignment with study timelines and regulatory requirements
 - Imaging protocols introduce additional operational complexity and can place significant strain on site capacity, particularly where scanner and scheduling availability are limited
- To optimize complex imaging study delivery, early collaboration with hospitals was used to refine imaging procedures and protocol design, reducing site burden and confirming protocol feasibility before site activation. Site qualification measures, including phantom scans where appropriate, supported imaging compliance and the generation of evaluable images, helping to avoid downstream delays
 - To support imaging readiness at site level, test image qualification was completed early during the setup phase

Actions and solutions

- To support patient engagement in studies offering no direct clinical benefit versus standard of care, patient recruitment and engagement strategies were prioritized from study outset, helping to achieve early alignment with participating sites and referral pathways
- To manage the multidisciplinary patient pathway, close collaboration was facilitated across radiology, pharmacy, surgery and laboratory teams, enabling smoother workflows and clearer alignment across the study
- To reduce risk in radiotracer manufacture and validation, early validation work was started before finalizing the main study agreement, helping to achieve readiness and alignment with study timelines from the outset

Outcomes

Successful delivery across studies was supported by Fortrea's study teams with hands-on experience in managing complex, site-specific imaging workflows, enabling proactive risk mitigation and consistent oversight throughout the study. Fortrea's structured patient pathway mapping approach was also applied to support cross-department alignment at site level, supporting protocol adherence and improving early study readiness.



Key learnings

Several key learnings emerged from delivering national and international diagnostic imaging studies across multiple clinical teams and workflows.

- Early planning and cross-functional engagement are critical to successful study delivery, particularly where multiple departments must align to protocol requirements
- Patient recruitment and retention should be considered alongside operational planning, particularly where study participation adds complexity for patients already managing significant disease and treatment burden
- Assessing site capacity and imaging readiness early, and clearly defining imaging requirements, can help mitigate delays and support consistent study delivery across sites

Experience across diverse site environments has reinforced Fortrea's ability to anticipate, mitigate and manage risks before they impact study timelines, quality or patient experience. In addition, Fortrea's structured patient pathway mapping supports early cross-department alignment, helping establish clear understanding of protocol requirements from the start of the study.

Conclusion

Delivering diagnostic imaging studies across multiple diverse populations, countries and modalities highlights the importance of early planning and cross-functional coordination. Fortrea's depth of experience demonstrates the value of skilled study teams and a structured approach to study setup and delivery.

This integrated model supports the reliable delivery of high-quality imaging data across complex, national and international clinical programs, helping studies run efficiently across diverse sites and patient populations.

Collaborate with Fortrea to support your delivery of complex diagnostic imaging studies across global clinical programs.

LEARN MORE at fortrea.com