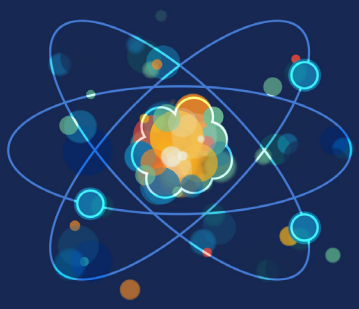
Case Study:

OPERATIONALIZING EARLY-PHASE RADIOPHARMACEUTICAL TRIALS: NAVIGATING DOSIMETRY, IMAGING, AND PATIENT SELECTION IN COMPLEX GLOBAL ONCOLOGY STUDY



PROGRAM DESCRIPTION

A First-In-Human (FIH), Phase I, multi-center clinical trial evaluating a novel theranostic approach using an imaging and radiotherapeutic isotope pair in patients with advanced solid tumors. This trial required integration of nuclear medicine, dosimetry, and oncology practices across global sites.

OPERATIONAL AND SCIENTIFIC STRATEGIES FOR RADIOPHARMACEUTICALS

Medpace Approach to Streamlining Imaging Site Qualification and Technical Validation:

- Implemented a real-time, weekly imaging readiness review cadence.
- Coordinated Sponsor-supported phantom distribution to accelerate site qualification.
- Provided hands-on technical support and cross-functional engagement to reduce start-up variability.

Medpace Approach to Managing Stringent Eligibility Criteria and a Fragile Patient Population:

- Proactively educated sites on ideal patient profiles.
- Enabled flexible screening windows aligned with IP availability and regulatory constraints.
- Maintained high-touch communications to support patient identification and minimize screen burden.

Medpace Approach to Mitigating Investigational Product (IP) Supply Delays and Protecting Enrollment Timelines:

- Integrated clinical and supply teams to align screening timelines with IP readiness.
- Introduced an enhanced slot allocation process to transparently coordinate product availability with patient scheduling.
- Helped sites adapt workflows to ensure patients remained eligible while minimizing protocol deviations.

Medpace Approach to Supporting Cohort Management During Prolonged Dose-Limiting Toxicity (DLT) Windows:

- Facilitated ongoing Sponsor-site communication to manage expectations and retain patient commitment.
- Implemented contingency planning for cohort replacement and adaptive recruitment pacing to keep timelines on track.

RESULTS

- **Accelerated Imaging Qualification:** Reduced start-up variability through weekly readiness reviews and targeted technical support.
- **Operational Continuity Maintained:** Despite supply limitations, proactive site coordination preserved patient access and retention.
- **FIH Execution Delivered in Complex Setting:** Achieved initial cohort enrollment within a challenging regulatory and logistical landscape,
- **Insights Gained for Future Trials:** Lessons learned on UP coordination, fragile patient population support, and adaptive cohort strategies continue to inform ongoing study success.

WHY BIOPHARMA CHOOSES MEDPACE

Redefining Excellence in Radiation Oncology Clinical Trials

At Medpace, we don't simply manage radiation oncology trials—we set the threshold and define how these important studies should be conducted.

As the only full-service CRO with in-house expertise in , medical physics, and radiopharmaceuticals, Medpace offers a uniquely integrated approach to radiation therapy and oncology research. Our global infrastructure, coupled with deep therapeutic focus, empowers us to seamlessly navigate the complexities of imaging, investigational product logistics, and evolving regulatory demands.

In an environment where patient vulnerability and operational precision converge, Medpace delivers unmatched consistency, quality, and foresight—setting the standard for clinical trial excellence in radiation oncology.

MAKING THE COMPLEX SEAMLESS®