Oncology and hematology

Advancing radiopharmaceuticals

Radiopharmaceutical theranostics are revolutionizing new approaches to cancer treatment. This field is emerging as an essential pillar in oncology and is considered a personalized method in treating cancer, using both diagnosis and therapy tools as part of the treatment plan to improve patient care and outcomes. It may be a particularly suitable therapy for some patients who have not responded to other therapies or who have complex metastases, including metastatic prostate cancer and neuroendocrine tumors.

Though promising, radiopharmaceutical trials can be complicated. Some common challenges include:

- Availability of the required radioisotope
- Experience using highly-regulated radioactive substances
- A lack of skilled professionals to run centers involving radiotheranostics

Advancing product development in this area requires specialized expertise and the ability to develop well-designed prospective trials based on established pre-clinical and clinical oncological principles.

The PPD™ clinical research business of Thermo Fisher Scientific has the necessary expertise to manage the unique complexities of developing a radiopharmaceutical product from the concept stage through to trial execution and approval. Our expertise spans across Phases I-III and a broad range of disease areas.

In the past five years, we supported 22 global radiopharmaceutical studies, which include seven healthy volunteer studies.

Oncology: 6 trials

Neurology: 5 trials

Cardiovascular: 2 trials

Psychiatry: 1 trial

Respiratory: 1 trial

Phase	Number of studies
Phase I	7
Phase II	3
Phase III	5
Other	7

Radiopharmaceutical operational logistics

Executing radiopharmaceutical trials requires the support of a comprehensive team of scientific, clinical operations, and clinical supply logistics personnel that use their expertise to effectively manage the complexity of these trials.

Comprehensive experience in radiopharmaceuticals

22 studies using radioligand/radiolabelled drug or radiotracer-accompanied imaging

in **14 countries**

at **160 sites**

Enrolling **1,550 patients studies**

The experts at the PPD clinical research business offer the knowledge needed to deliver successful outcomes at every stage of radiopharmaceutical trials. Paired with our global infrastructure — which provides comprehensive management and oversight of radiopharmaceutical products from manufacturing to the patient — we have the knowledge and operations drug developers need to succeed.

Clinical logistics monitor

Our clinical logistics monitor provides a wide range of support and serve as a single point of contact for all site communications, including trackability and traceability. This critical role oversees site allocation and infusion timelines with the radiolabeling manufacturer and site coordinator. In addition to closely liaising with the sponsor and clinical teams, the clinical logistics monitor is highly trained to coordinate scheduling and storage while maintaining a chain of custody for radio therapies.

Total transportation management

Our Total Transportation Management service provides complete oversight of the supply chain process from shipment preparation to final delivery.

We use data to choose the best courier for your needs, mitigating risk across the supply chain. Our traceability and trackability efforts offer peace of mind, providing product chain of custody, certificate of release, shipment order number, shipment records, and confirmation of condition and radioactivity. Logistics services comply with international regulations by using Type A packaging and follow guidelines on current good radio pharmacy practice for the small-scale preparation of radiopharmaceuticals, as well as DOT and 49 CFR requirements.

Total global relationships and resources

Facilitate strategic site identification, start up and recruitment efforts for your radiopharmaceuticals trial by leveraging our strong relationships with key opinion leaders, investigators, clinical sites, and specialized vendors. These relationships, combined with a robust feasibility strategy, translate into expedited site selection and patient recruitment to support your development objectives.

Move your radiopharmaceutical clinical development program forward

Learn more at **ppd.com/therapeutic-expertise/oncology-and-hematology-cro/**