

Radiopharmaceutical Development at Worldwide Clinical Trials

Worldwide is thrilled to be working with sponsors advancing novel oncology treatments like radiopharmaceutical therapy (RPT). As these more effective and targeted therapies advance into clinical trials, sponsors need to partner with a CRO capable of matching their innovation with personalized solutions that address the complexities and unique demands of working with radiopharmaceuticals.

Worldwide offers specialized services tailored to the fast-paced and complex landscape of radiopharmaceutical development and focuses on building a partnership that drives program success in the following modalities:

- » Radionuclide therapy, including peptide receptor radionuclide therapy (PRRT)
- » Theranostic pairs
- » Radiosensitizers
- » Nanomedicine

Worldwide's Experience

We leverage our expertise to deliver a solution unique to your needs – not a one-size-fits-all approach. Radiopharma studies require experienced strategic and operational leaders who are well-versed in the latest therapeutic developments and committed to advancing these novel therapeutics. Combining their personal passion with Worldwide's flexible approach, you can expect our committed study team to deliver with excellence.

worldwide.com

Therapeutic Areas of Expertise



Rare Disease



Oncology



Hematology



Neurology



Metabolic



Cardiovascular

Our strategic and project leaders have:

- ✓ Experienced in delivering Phase I-III radiopharma studies using several isotopes, including ^{177}Lu , ^{64}Cu , and ^{227}Th
- ✓ Radiotherapeutic/diagnostic experience in studies, including rare disease and gene therapies
- ✓ Pediatric radiopharma experience
- ✓ Nanomedicine experience
- ✓ Vendor relationships specific to radiopharma studies, including dosimetry, central and specialist laboratory vendors
- ✓ Site relationships in the US, EU, and APAC, specific to successfully delivering radiopharma studies, including central and locally labeled IMP
- ✓ Logistics coordinator role established to ensure streamlined management of IMP, samples, and patient visit forecasting

Worldwide's Key Focus Areas in Radiopharmaceuticals

01

Site Selection

Here are some essential factors to consider when selecting sites:

Regulatory Compliance

Sites must have experience and capability in adhering to local and international regulations.

Radiopharmacy Facilities

Availability of a licensed radiopharmacy or nuclear pharmacy to prepare and dispense radiopharmaceuticals.

Robust infrastructure for handling, storage, and disposal of radioactive materials.

Radiation Safety

Sites must have radiation safety protocols in place and personnel trained in radiation safety to protect patients and staff.

Adequate equipment, such as dose calibrators, shielding, and monitoring devices, should be available.

02

03

Patient Recruitment Considerations

At Worldwide, we understand that patient recruitment is challenging, as only a small group of patients typically qualify for radiopharmaceutical trials due to their specificity. To ensure your trial enrolls the adequate number of needed participants, we offer:

- » **Patient Education:**
We provide proper educational materials at our sites.
- » **Advocacy Collaboration:**
We partner with patient advocacy organizations to help raise awareness of trials.
- » **Use of Real-World Data:**
We utilize electronic health records and disease registries to help identify suitable participants.
- » **Targeted Outreach:**
Using our relationships with KOLs, we offer a referral pipeline for potential candidates.
- » **Open Communication:**
We inform patients of the risks and benefits of participation, while addressing possible concerns with an emphasis on transparency and patient autonomy.

Meet Your Team



Sue Batchelor

Executive Director, Project Management, Oncology and Rare Disease



Lucie Matthews

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Missy Green

Associate Director, Project Management, Oncology and Rare Disease



Worldwide is a leading full-service global CRO that offers innovative end-to-end customized solutions in partnership with biotechnology and pharmaceutical companies advancing radiopharmaceuticals. Founded on an unwavering commitment to therapeutic excellence and personalized attention, we bring scientific expertise, a specialized and flexible oncology team, and a shared passion for advancing new medicines from discovery to reality.

Learn more about our experience in radiopharmaceuticals and how we can assist your program [→](#)