Radiopharmaceutical Therapy

Complete Radiopharmaceutical Therapy & Theranostics Services

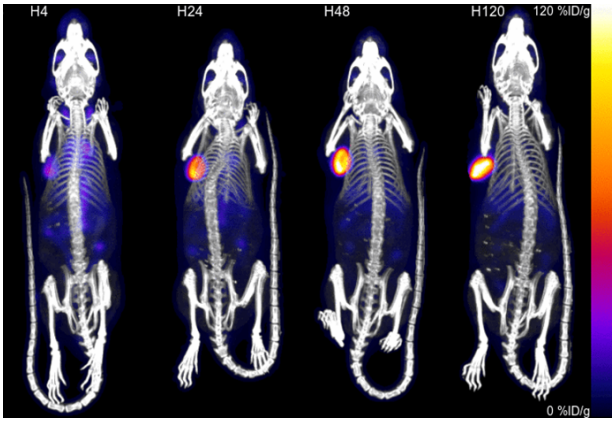
Radiochemistry | Preclinical | Clinical | Image Analytics

Radiopharmaceutical therapies represent an effective way to treat solid cancers by using tumor targeting small molecules, peptides or biologics to deliver a cytotoxic payload that induces DNA damage in tumor cells, while limiting damage to normal and healthy tissue.

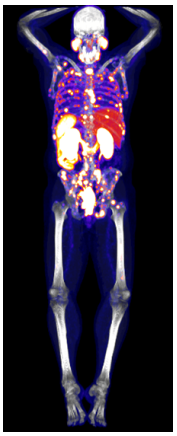
Streamlined development, evaluation and clinical translation of radiopharmaceuticals requires a partner that has extensive scientific, regulatory and operational expertise. Working with a CRO that provides a complete solution ensures data is delivered in a timely manner to make a go/no-go decision on your imaging or therapeutic candidates.

Services include:

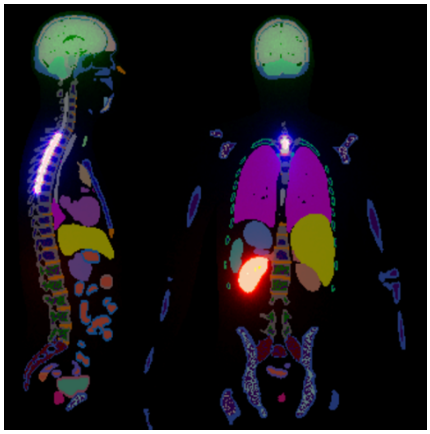
- Radiochemistry development - conjugation, radiolabeling, stability and immunoreactivity
- Preclinical proof-of-concept studies - biodistribution, efficacy, toxicology
- Investigational New Drug (IND)/Clinical Trial Application (CTA) submission support with clinical protocol development
- Single-site, first-in-human through multi-site, late phase clinical study support
- GMP radiochemistry development and production support for imaging agents
- Preclinical and clinical dosimetry and advanced quantitative analysis



Antibody imaging and radionuclide therapy - Imaging radiotherapy distribution in tumor postive mice

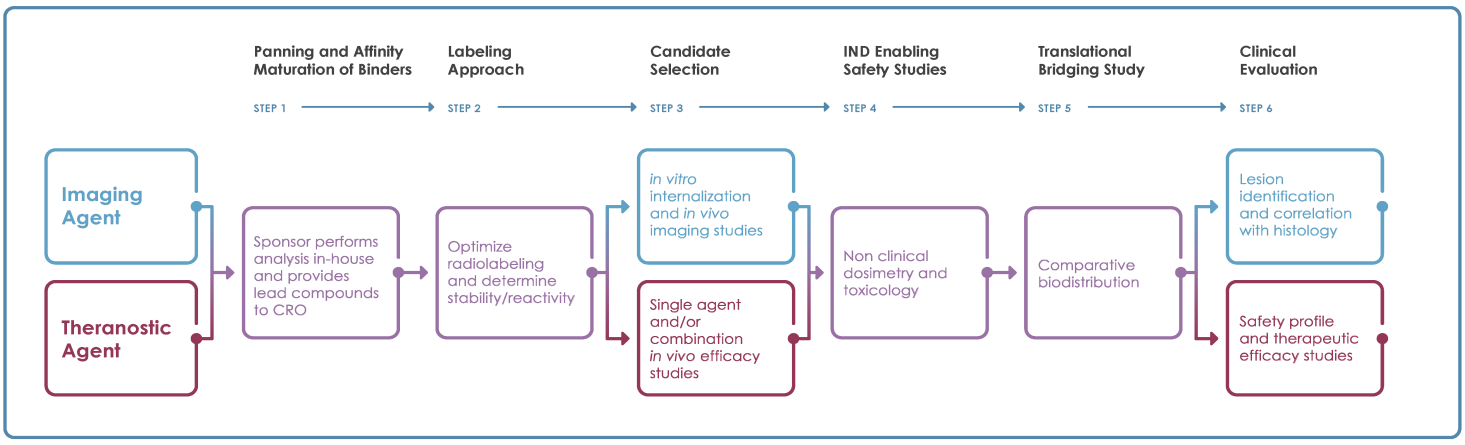


68Ga-PSMA-11 PET/CT



Three-Dimensional Dosimetry for Radiation Safety Estimates from Intrathecal Administration
(Hesterman et al, JNM 2017)

Development Process



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CAPABILITIES

Radiochemistry

Our team has experience with novel and commercially available radioisotopes used for targeted radiotherapy. Our capabilities for novel radiotracers span preclinical to first-in-human clinical studies and GMP production in conjunction with CMO partners. Invicro has experience working with the following isotopes:

- 225Ac
- 131I
- 68Ga/177Lu
- 203Pb/212Pb
- 177Lu
- 111In
- 111In/225Ac
- 67Cu/64Cu

Preclinical

Bringing new therapeutic radiopharmaceuticals to the market is a complex and challenging process. When filing an IND or CTA prior to the initiation of human trials, it is crucial to have strong non-clinical data to support a new candidate. Invicro provides complete preclinical support of your project, including:

- Primary Pharmacology
- Safety Pharmacology/Toxicology/Efficacy
- Radiochemistry and Immunoreactivity
- Animal Biodistribution and Dosimetry

Early/Late Phase Clinical

Seamless transition of your radiopharmaceutical into the clinic requires an imaging partner with experience supporting first-in-human through late phase studies. Invicro has the unique blend of scientific expertise and operational experience to deliver on studies from Phase 0-IV. Clinical radiopharmaceutcal therapeutic development services include:

- First-in-human, single-site clinical trial support
- Study design and consultation
- Criteria-based, centralized independent reviews and internal analysis
- Late phase, multi-center global trial support
- Advanced image analytics including dosimetry
- Safety profile and therapeutic efficacy studies

Dosimetry and Advanced Analytics

Our in-house image analytics team has experience supporting preclinical and clinical radiopharmaceutical therapy studies, ranging from customized and automated image processing techniques using deep learning to dosimetry analysis for safety profile analysis. Some advanced image analytic techniques include:

- Algorithms for automated and semi-automated lesion identification
- Image quality control and co-registration
- Preclinical dosimetry safety studies and validated clinical workflows
- Extrapolating dosimetry of therapeutics from imaging agents
- Expertise across various species, radionuclides and novel administration routes