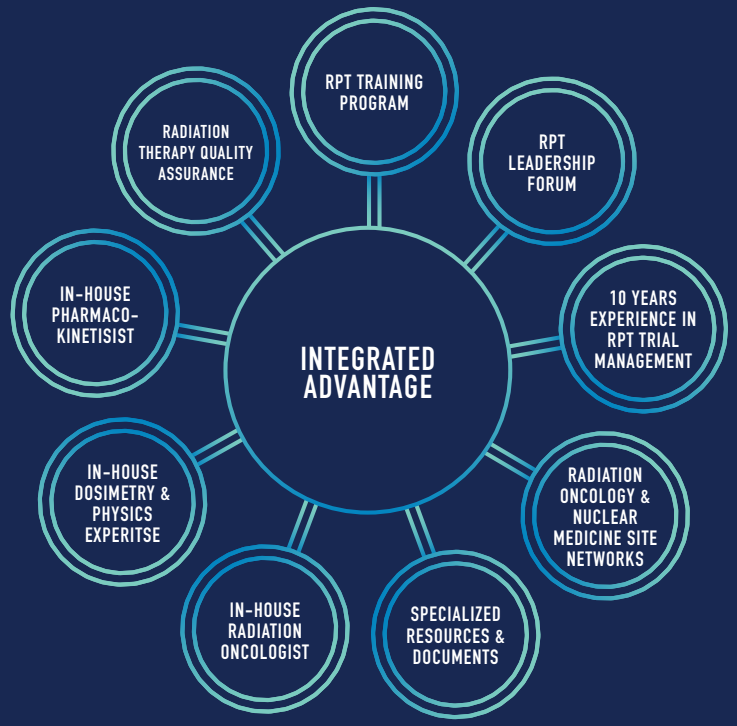
RADIOPHARMACEUTICALS

A COMPETITIVE EDGE FOR TARGETED RADIATION TRIALS



10 YEARS RADIOPHARMACEUTICAL EXPERTISE

- Beta-emitter and alpha emitter radiopharmaceutical (RPT) trials
- Diagnostic, therapeutic and theragnostic studies
- Global reach: North America, South America, Europe and Asia Pacific
- Studies involving central and local manufacturing processes
- Oncology and non-malignant indications
- Radiation device studies

DIFFERENTIATORS & BENEFITS

- Industry Leading radiopharmaceutical study teams with experience in specific requirements for regulatory strategy, site start-up, and monitoring of complex radiopharmaceutical studies
- Full time, in-house ABR certified Radiation Oncologist and Radiologists with expertise in RPT trials
- Biometrics teams with experience in collection, cleaning and analysis of specialized RPT data and support of safety committees and DSMBs
- Dynamic teams and flat management structure able to quickly react and overcome study challenges
- Long-standing relationships with US, European, and global sites equipped for RPT trials
- Comprehensive internal training program for Radiopharmaceuticals ensures all team members are knowledgeable of both clinical and non-clinical considerations
- Established study tools and templates specifically for RPT trials guarantees the quality of study-specific processes and documents
- Radiopharmaceutical Leadership Forum ensures each Clinical Trial Manager is aware of the most current RPT intelligence within Medpace and industry-wide
- Safety surveillance teams experienced in RPT trials provide complete oversight of safety profile including radiation-specific adverse events
- Fully integrated Core Imaging Lab:
  - Nuclear Medicine Imaging Technologists: expertise in data acquisition protocols and scanner calibration for quantification
  - Dosimetry specialists and physicists: in-depth understanding of dosimetry techniques and requirements
- Constant improvement and innovation in this field: Ability to gain edge in a constantly changing competitive landscape

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RADIOPHARMACEUTICALS

A Competitive Edge For Targeted Radiation Trials

STUDY MANAGEMENT

- Highly experienced Operations teams located throughout US, Europe and Asia Pacific
- Local regulatory teams knowledgeable on country-specific processes and requirements
- Regulatory Technical Advisor specializing in RPT document requirements
- CRAs experienced in monitoring RPT trials
- Advanced Clinical Practitioners with on-the-ground experience running RPT studies at sites
- Set-up and management of Safety Committees and DSMBs
- Support site qualifications and calibrations (including PET and SPECT, dose calibrator, gamma counter)
- Specifically designed eCRF templates for radiopharmaceutical IP
- Safety surveillance including radiation-specific toxicities
- Integrated Clinical Packaging & Supplies department capable of advising on and managing IP and NIMP distribution
- Dedicated Logistics department support ordering supplies for RPT studies and establishing relationships with specialist suppliers
- Medpace Reference Laboratory: Data collection and management of radioactive samples
- Regulatory Affairs provides nonclinical program guidance and supports regulatory strategy development

MAKING THE COMPLEX SEAMLESS®

DOSIMETRY

- Expertise in alpha, beta, gamma and positron emitters
- Protocol review
- Image-based and blood-based dosimetry
  - Organ and lesion dosimetry
  - Model-based dosimetry methods using OLINDA/EXM v2.0
  - Dosimetry methods using PET/CT; SPECT/CT; Hybrid (planar imaging and SPECT/CT)
- Customizable data deliverables
  - Activity, Fractions of Administered Activity (FAA)
  - Time Activity Curves, Time-Integrated Activity Coefficients (TIAC)
  - Absorbed Doses (Gy), Absorbed Dose Coefficients (mGy/MBq)
  - Whole-body effective doses (Sv) for diagnostic radiotracers
  - Projected absorbed doses for a therapeutic candidate from absorbed doses with a diagnostic surrogate
  - Estimation at first cycle of cumulative activity not to exceed dose limits to organs at risk

PHARMACOKINETICS

- Training of sites and central data collection
- On-site measurements of count rates in urine, blood and/or plasma
- Conversion of count rates into activity concentrations
- Creation of ADaM datasets
- Non-compartmental analysis (NCA) in Phoenix WinNonlin
- Common PK parameters include Cmax, Tmax, AUC, Vd, CL, and t1/2 for blood/plasma and fraction excreted for urine

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