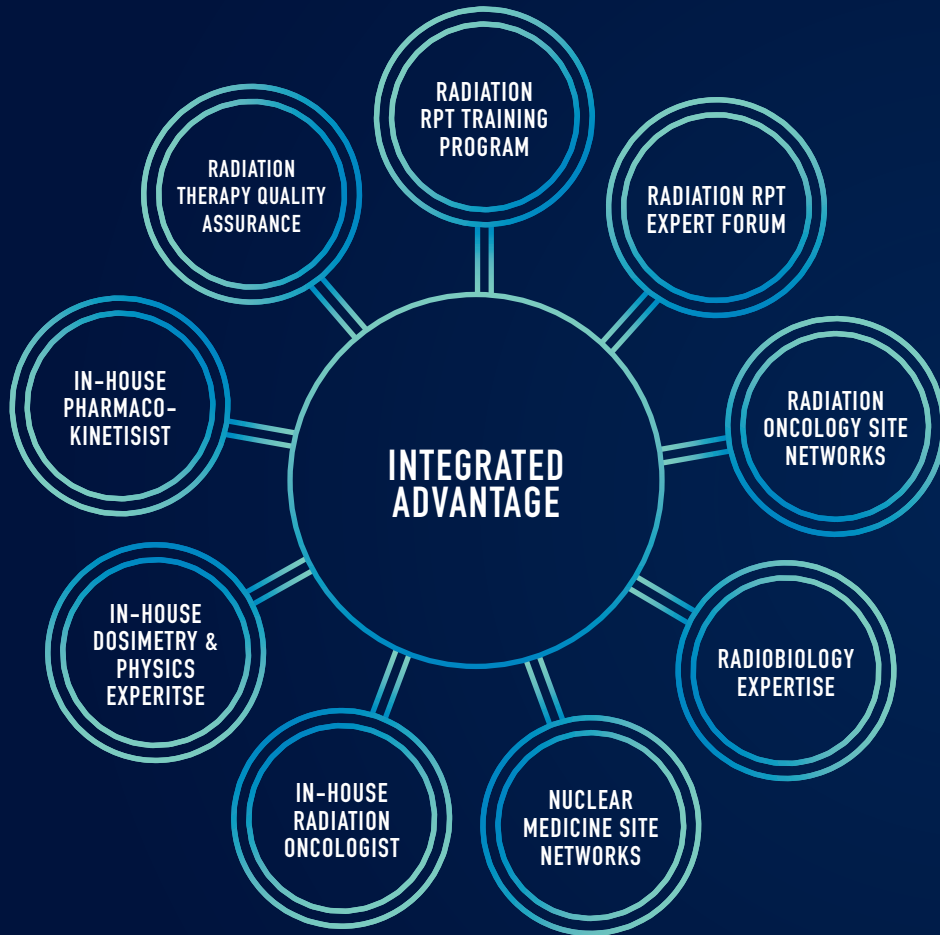


RADIOPHARMACEUTICALS

A COMPETITIVE EDGE FOR TARGETED RADIATION TRIALS



RADIATION ONCOLOGY TRIALS

- In house expertise in Radiation Oncology, Radiopharmaceuticals and Theragnostics
- Expertise in beta-emitter and alpha emitter radiopharmaceutical (RPT) oncology trials
- Expertise in Imaging based dosimetry calculations
- Biological sample based dosimetry calculation and estimation
- Data collection/ management of radioactive samples and gamma counts
- PK calculations from radioactive samples' gamma counts
- Scanner calibration for dosimetry (PET and SPECT)
- Dose calibrator qualification and calibration
- Gamma counter calibration

DIFFERENTIATORS & BENEFITS

- Full time, in-house ABR certified Radiation Oncologist and Radiologists with expertise in RPT trials
- Long-standing and ongoing relationships with US, EU, and global oncology radiation, oncology sites equipped for RPT trials
- Integrated Core Imaging Lab comprised of dosimetrists and physicists
- In-depth understanding of dosimetry techniques and requirements
- Nuclear Medicine Imaging Technologists; expertise in data acquisition protocols, scanner calibration and dosimetry
- Global and US-based radiation/ radiopharmaceutical expert forums
- Cohesive radiation study team with experience in specific requirements for regulatory strategy, site start-up, and monitoring of complex radiopharmaceutical oncology studies
- Ability to gain edge in a constantly changing competitive landscape

RADIOPHARMACEUTICALS

A COMPETITIVE EDGE FOR TARGETED RADIATION TRIALS

DOSIMETRY

- Image based dosimetry
- Blood/urine/plasma based dosimetry
- Protocol advice
- MIRD-S value (OLINDA)
- Voxel-based method
- Hybrid method (planar and SPECT)
- Expertise in alpha, beta, gamma and positron emitters
- Source organ, target organ and tumor
- Activity, TAC, TIAC, absorbed doses
- WB effective absorbed doses
- Absorbed dose estimation of a therapeutic candidate from it's diagnostic surrogate
- Estimation of the dose to be injected at next cycle
- Customizable data deliverables

PHARMACOKINETICS

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

SCANNER CALIBRATION

- Scanner calibration done during site qualification
- Use of the mock shipment (if any) for efficient start-up
- Use of phantom scan to calculate calibration factor and to verify SUV accuracy
- Calibration/qualification certificates

NUCLEAR MEDICINE INSTRUMENT CALIBRATION

- Gamma/well counter and dose calibrators, calibration verification during site qualification and then on an ongoing basis
- Dose calibrator cross calibration during scanner calibration
- Gamma/well counter calibration during site qualification