MAY 6-7, 2024 • THE BETHESDAN HOTEL • BETHESDA, MD

Dose Optimization in Radiopharmaceutical Therapy Development Workshop

SNMMI

Day 1 – May 6, 2024

Time	Topics	Moderators/Speakers
8:00-8:10 am	**Welcome, Goals, and Opening Remarks**	SNMMI
	SESSION 1: SETTING THE STAGE	
8:10-8:20 am	**Development of Cancer Therapies and Tolerance of Toxicities**	Oliver Sartor, MD (Mayo Clinic)
8:20-8:30 am	**Realizing the Full Potential of RPTs**	Mike Morris, MD (MSKCC)
8:30-8:40 am	**Industry Perspective: Challenges in Dose Optimization and Overview of Workshop**	Amanda Walker, MD (AdvanCell)
8:40-8:50 am	**FDA Perspective: Regulatory Challenges in RPT Development**	Sundeep Agrawal, MD (FDA-CDER)
8:50-9:00 am	**Patient Perspective**	
9:00-9:30 am	**Discussion**	**Panelists:** Oliver Sartor, MD; Mike Morris, MD; Amanda Walker, MD; Sundeep Agrawal, MD
9:30-9:45 am	**BREAK**	
	SESSION 2: PRINCIPLES OF RADIOPHARMACEUTICAL DOSING AND DOSIMETRY	
9:45-10:00 am	**Comparison of EBRT and RPT (Biology and Dosimetry)**	Stephen Graves, PhD, DABR (University of Iowa)
10:00-10:15 am	**Bio-Effect Modeling for RPT – Can We Reliably Calculate Biologically Effective Dose for RPTs?**	Rob Hobbs, PhD (Johns Hopkins University)
10:15-10:30 am	**Current Uncertainties in Absorbed Dose Calculations in Nuclear Medicine Dosimetry**	John Sunderland, PhD (University of Iowa)
10:30-10:45 am	**Tumor Dosimetry for Predictive Efficacy**	Amir Iravani, MD (University of Washington)
10:45-11:15 am	**FDA Perspective: Regulatory Considerations of Radiation Dosimetry for RPT Development**	Donika Plyku, PhD (FDA- DIRM) Cynthia Goodman Mumma, MS, MSE (Eng), DABR (FDA-CDRH)
11:15 am-12:15 pm	**Discussion**	**Co-Moderators:** Anthony Fotenos, MD (FDA-CDRH) Amir Iravani, MD **Panelists:** Donika Plyku, PhD, Cynthia Goodman Mumma, MS, MSE (Eng), DABR; Stephen Graves, PhD, DABR; Rob Hobbs, PhD
12:15-1:00 pm	**LUNCH**	
	SESSION 3: CONSIDERATIONS FOR DOSE OPTIMIZATION OF RADIOPHARMACEUTICALS: FOCUS ON RENAL TOXICITY	
1:00-1:20 pm	**Renal Toxicity: RPTs, Emami, and Quantec**	Ana Kiess, MD, PhD (Johns Hopkins University)
1:20-1:35 pm	**Challenges and Approaches to Accounting for Prior Radiation**	Zach Morris, MD, PhD (University of Wisconsin)
1:35-1:50 pm	**Lutetium RPTs: Long-term Dose Effect Relationships**	Yuni Dewaraja, PhD (University of Michigan)
1:50-2:05 pm	**Early Biomarkers of Kidney Injury**	Diana Zepeda-Orozco, MD (Nationwide Children's Hospital, Ohio)
2:05-2:20 pm	**FDA Perspective: Key Regulatory Considerations for Dose Optimization of Radiopharmaceuticals**	Will Maguire, MD, PhD (FDA-CDER)
2:20-3:15 pm	**Discussion: Focusing on Key Toxicity Endpoints and Trial Design**	**Co-Moderators:** Will Maguire, MD, PhD (Clinical DO1) Daniel Pryma, MD (UPenn) **Panelists:** Diana Bradford, MD (Clinical DO2); Sriram Subramaniam, PhD (Clinical pharmacology); Calvin Han, MD (DIRM)
3:15-3:30 pm	**BREAK**	

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	SESSION 4: ALPHA-EMITTING THERAPIES	
3:30-3:50 pm	**Dosimetry for Alpha Emitters: Challenges and Solutions**	George Sgouros, PhD (Johns Hopkins University)
3:50-4:05 pm	**Approaches to Re-define Organ Absorbed Dose Thresholds for Alpha Emitters in RPT**	Jacob Hesterman, PhD (Ratio Therapeutics)
4:05-5:00 pm	**Panel Discussion**	**Moderator:** Jacek Capala, PhD (NCI) **Panelists:** Donika Plyku, PhD; William Maguire, MD, PhD, Christy John, PhD, Haleh Saber, PhD (FDA-CDER); George Sgouros, PhD; Ethan Balkin, PhD (DOE)
5:00-5:10 pm	**Wrap up and Plan for Day 2**	

Day 2 – May 7, 2024

8:00-8:05 am	**Goals for Day 2**	John Sunderland, PhD (University of Iowa)
8:05-9:05 am	**Mock Trial Design Discussion** (one alpha/one beta) • Trial 1- Academic • Trial 2- Industry	Tom Hope, MD (UCSF) Dushen Chetty, PhD (Novartis)
9:05-9:55 am	**Dosimetry and Quantitative Imaging in RPT Development Recap:** • 10-minute Summary from Day 1 • Areas of divergent opinions • Action plan to address • Specific science or data needed	**Discussion Leader:** Stephen Graves, PhD (University of Iowa)
9:55-10:05 am	**BREAK**	
10:05-10:55 am	**Dose Optimization Strategies in RPT Development Recap:** • 10-minute Summary from Day 1 • Areas of divergent opinions • Action plan to address • Specific science or data needed	**Discussion Leader:** Daniel Pryma, MD (University of Pennsylvania)
10:55-11:45 am	**Alpha-Emitting Therapies Recap:** • 10-minute Summary from Day 1 • Areas of divergent opinions • Action plan to address • Specific science or data needed	**Discussion Leader:** Peter Scott, PhD (University of Michigan)
11:45 am-12:00 pm	**Adjourn**	