

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

# Dose Optimization in Radiopharmaceutical Therapy Development Workshop



Day 1 – May 6, 2024

Time	Topics	Moderators/Speakers
8:00-8:10 am	<b>Welcome, Goals, and Opening Remarks</b>	FDA and SNMMI
8:10-8:25 am	<b>Development of Cancer Therapies and Tolerance of Toxicities</b>	Oliver Sartor, MD (Mayo Clinic)
8:25-8:40 am	<b>Realizing the Curative Power of RPTs</b>	Mike Morris, MD (MSKCC)
8:40-9:00 am	<b>Industry Perspective: Challenges in Dose Optimization and Overview of Workshop</b>	Amanda Walker, MD
9:00-9:15 am	<b>FDA Perspective: Regulatory Challenges in RPT Development</b>	Sundeep Agrawal, MD (FDA-CDER)
9:15-9:30 am	<b>Patient Perspective</b>	
9:30-9:45 am	<b>BREAK</b>	
<b>SESSION 1: PRINCIPLES OF RADIOPHARMACEUTICAL DOSING AND DOSIMETRY</b>		
9:45-10:00 am	<b>Comparison of EBRT and RPT (Biology and Dosimetry)</b>	Stephen Graves, PhD, DABR (University of Iowa)
10:00-10:15 am	<b>Bio-Effect Modeling for RPT – Can We Reliably Calculate Biologically Effective Dose for RPTs?</b>	Rob Hobbs, PhD (Johns Hopkins University)
10:15-10:30 am	<b>Current Uncertainties in Absorbed Dose Calculations in Nuclear Medicine Dosimetry</b>	John Sunderland, PhD (University of Iowa)
10:30-10:45 am	<b>Tumor Dosimetry for Predictive Efficacy</b>	<i>Amir Iravani, MD (University of Washington)</i>
10:45-11:15 am	<b>FDA Perspective: Regulatory Considerations of Radiation Dosimetry for RPT Development</b>	Donika Plyku, PhD (FDA- DIRM) Cynthia Goodman Mumma, MS, MSE (Eng), DABR (FDA-CDRH)
11:15 am-12:15 pm	<b>Discussion</b>	<b>Co-Moderators:</b> Anthony Fotenos, MD (FDA-CDRH) Amir Iravani, MD <b>Panelists:</b> Donika Plyku, PhD, Cynthia Goodman Mumma, MS, MSE (Eng), DABR; Stephen Graves, PhD, DABR; Rob Hobbs, PhD
12:15-1:00 pm	<b>LUNCH</b>	
<b>SESSION 2: CONSIDERATIONS FOR DOSE OPTIMIZATION OF RADIOPHARMACEUTICALS: FOCUS ON RENAL TOXICITY</b>		
1:00-1:20 pm	<b>Renal Toxicity: RPTs, Emami, and Quantec</b>	<i>Ana Kiess, MD, PhD (Johns Hopkins University)</i>
1:20-1:35 pm	<b>Challenges and Approaches to Accounting for Prior Radiation</b>	Zach Morris, MD, PhD (University of Wisconsin)
1:35-1:50 pm	<b>Lutetium RPTs: Long-term Dose Effect Relationships</b>	Yuni Dewaraja, PhD (University of Michigan)
1:50-2:05 pm	<b>Early Biomarkers of Kidney Injury</b>	Diana Zepeda-Orozco, MD (Nationwide Children's Hospital, Ohio)
2:05-2:20 pm	<b>FDA Perspective: Key Regulatory Considerations for Dose Optimization of Radiopharmaceuticals</b>	Will Maguire, MD, PhD (FDA-CDER)
2:20-3:15 pm	<b>Discussion: Focusing on Key Toxicity Endpoints and Trial Design</b>	<b>Co-Moderators:</b> Jessica Jensen (POINT) Will Maguire, MD, PhD (Clinical DO1) <b>Panelists:</b> Diana Bradford, MD (Clinical DO2), Sriram Subramaniam, PhD (Clinical pharmacology), Calvin Han, MD (DIRM)
3:15-3:30 pm	<b>BREAK</b>	

*Names in italics are invited*

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

# Dose Optimization in Radiopharmaceutical Therapy Development Workshop



## Day 1 – May 6, 2024

Time	Topics	Moderators/Speakers
<b>SESSION 3: ALPHA-EMITTING THERAPIES</b>		
3:30-3:50 pm	<b>Dosimetry for Alpha Emitters: Challenges and Solutions</b>	George Sgouros, PhD (Johns Hopkins University)
3:50-4:05 pm	<b>Approaches to Re-define Organ Absorbed Dose Thresholds for Alpha Emitters in RPT</b>	Jacob Hesterman, PhD (Ratio Therapeutics)
4:05-5:00 pm	<b>Panel Discussion</b>	<b>Moderator:</b> Jacob Hesterman, PhD <b>Panelists:</b> Donika Plyku, PhD; Cynthia Goodman Mumma, MS, MSE (Eng), DABR; George Sgouros, PhD
5:00-5:10 pm	<b>Wrap up and Plan for Day 2</b>	

## Day 2 – May 7, 2024

8:00-8:05 am	<b>Goals for Day 2</b>	John Sunderland, PhD (University of Iowa)
8:05-9:05 am	<b>Mock Trial Design Discussion</b> (one alpha/one beta) <ul style="list-style-type: none"> <li>• Trial 1- Academic</li> <li>• Trial 2- Industry</li> </ul>	Tom Hope, MD (UCSF)
9:05-9:55 am	<b>Dosimetry and Quantitative Imaging in RPT Development Recap Discussion Leader:</b> <ul style="list-style-type: none"> <li>• 10-minute Summary from Day 1</li> <li>• Areas of divergent opinions</li> <li>• Action plan to address</li> <li>• Specific science or data needed</li> </ul>	
9:55-10:05 am	<b>BREAK</b>	
10:05-10:55 am	<b>Dose Optimization Strategies in RPT Development Recap Discussion Leader:</b> <ul style="list-style-type: none"> <li>• 10-minute Summary from Day 1</li> <li>• Areas of divergent opinions</li> <li>• Action plan to address</li> <li>• Specific science or data needed</li> </ul>	
10:55-11:45 am	<b>Alpha-Emitting Therapies Recap Discussion Leader:</b> <ul style="list-style-type: none"> <li>• 10-minute Summary from Day 1</li> <li>• Areas of divergent opinions</li> <li>• Action plan to address</li> <li>• Specific science or data needed</li> </ul>	
11:45 am-12:00 pm	<b>Adjourn</b>	