

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	Welcome, Goals, and Opening Remarks	Helen Nadel, MD and John Sunderland, PhD
<b>SESSION 1: SETTING THE STAGE</b>		
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	Carl Pritchard
9:00-9:30 am	Discussion	<b>Panelists:</b> Oliver Sartor, MD; Mike Morris, MD; Amanda Walker, MD; Sundeep Agrawal, MD; Carl Pritchard
9:30-9:45 am	<b>BREAK</b>	
<b>SESSION 2: PRINCIPLES OF RADIOPHARMACEUTICAL DOSING AND DOSIMETRY</b>		
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 for RPT Dosimetry Investigation	Donika Plyku, PhD (FDA- DIRM) Cynthia Goodman Mumma, MS, MSE (Eng), DABR (FDA-CDRH)
11:15 am-12:15 pm	Discussion	<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; Ana Kiess, MD, PhD, Zach Morris, MD, PhD, Yuni Dewaraja, PhD; Diane Zepeda-Orozco, MD
12:15-1:00 pm	<b>LUNCH: FIALOVA RESTAURANT</b>	
<b>SESSION 3: CONSIDERATIONS FOR DOSE OPTIMIZATION OF RADIOPHARMACEUTICALS: FOCUS ON RENAL TOXICITY</b>		
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 Dosage Optimization of Radiopharmaceuticals	Will Maguire, MD, PhD (FDA-CDER)
2:20-3:15 pm	Discussion: Focusing on Key Toxicity Endpoints and Trial Design	<b>Co-Moderators:</b> Will Maguire, MD, PhD (Clinical DO1) Daniel Pryma, MD (UPenn) <b>Panelists:</b> Ana Kiess, MD, PhD; Zach Morris, MD, PhD; Yuni Dewaraja, PhD; Diana Zepeda-Orozco, MD; Diana Bradford, MD (Clinical DO2); Sriram Subramaniam, PhD (Clinical pharmacology); Calvin Han, MD (DIRM)
3:15-3:30 pm	<b>BREAK</b>	

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## Day 1 – May 6, 2024

Time	Topics	Moderators/Speakers
<b>SESSION 4: 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> Jacek Capala, PhD (NCI) <b>Panelists:</b> Donika Plyku, PhD; William Maguire, MD, PhD, Christy John, PhD, Haleh Saber, PhD (FDA-CDER); George Sgouros, PhD; Ethan Balkin, PhD (DOE); Jacob Hesterman
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) Dushen Chetty, PhD (Novartis)
9:05-9:55 am	<b>Dosimetry and Quantitative Imaging in RPT Development Recap:</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>	<b>Discussion Leader:</b> Stephen Graves, PhD (University of Iowa)
9:55-10:05 am	<b>BREAK</b>	
10:05-10:55 am	<b>Dose Optimization Strategies in RPT Development Recap:</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>	<b>Discussion Leader:</b> Daniel Pryma, MD (University of Pennsylvania)
10:55-11:45 am	<b>Alpha-Emitting Therapies Recap:</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>	<b>Discussion Leader:</b> Peter Scott, PhD (University of Michigan)
11:45 am-12:00 pm	<b>Adjourn</b>	