Cancer: Pathophysiology, Current Therapies, Clinical Trials and Drug Development

Virtual Training Program
October 23 - 25, 2024

Wednesday, October 23, 2024 – Program Day 1 ***Session No.***

All Times Listed EDT

10:00 – 10:15 AM **PERI Welcome and Course Overview**
Jo Ann Zoul, Course Manager
The Pharmaceutical Education and Research Institute, Inc.

10:15 AM – 11:15 AM **Considerations for Clinical Trial Design and Endpoints Toward U.S. Drug Approval** ***1***
Steven Clark Cunningham, MD, MLA, FACS
Medical Officer, Division of Oncology III
Office of Oncologic Diseases
Center for Drug Evaluation & Research
U.S. Food and Drug Administration

Planned Topics
- Safety and Efficacy requirements for approval
- Clinical Trial Endpoints, trial designs, types of approval
- Expedited Review Procedures

11:15 – 11:30 AM ***Morning Break***

11:30 AM – 12:30 PM **Improved Strategies for Selecting Recommended Phase 2 Dosing: Moving Beyond Maximum Tolerated Dose** ***2***
Miao Zhao, Senior Clinical Pharmacologist
Division of Cancer Pharmacology I
Office of Clinical Pharmacology
U.S. Food and Drug Administration

Planned Topics
- Learnings from “toxic” examples
- Clinical Pharmacology driven decision making
  - Dose-response and exposure-response
- Non-oncology learnings
- Dose Selection
  - Importance and process
  - Alternatives to toxicity driving RP2D
  - Pharmacodynamic endpoints in early drug development

12:30 – 1:30 PM ***Lunch Break***

Wednesday, October 23, 2024 (continued) ***Session No.***

All Times Listed EDT

1:30 PM – 2:30 PM **Design and Analysis of Oncology Studies** ***3***

Malini Iyengar, PhD
Biometrics Team Leader, Hematology-Oncology Statistics
AstraZeneca

Planned Topics

- Study Design
- Trials with Objective Response Rates
- Trials with PFS, OS

2:30– 2:45 PM ***Afternoon Break***

2:45 – 3:45 PM **Nonclinical Development of Oncologic Agents** ***4***

Simon Williams, PhD
Pharmacologist, Division of Hematology Oncology Toxicology
Office of Oncologic Diseases
Center for Drug Evaluation & Research
U.S. Food and Drug Administration

Planned Topics

- Defining Targets
- Safety & Toxicology

4:00 PM ***End of Day One***

Thursday, October 24, 2024 – Program Day 2 ***Session No.***

All Times Listed EDT

10:00 – 10:15 AM **Day Two Overview, Welcome**
Jo Ann Zoul, Course Manager
The Pharmaceutical Education and Research Institute, Inc.

10:15 – 11:15 AM **Drug Development in Gynecologic Malignancies** ***5***
Gwynn Ison, MD
Medical Officer
Division of Oncology 1
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Planned Topics
- Ovarian, cervical, and endometrial cancers

11:15 – 11:30 AM ***Stretch Break***

11:30 AM – 12:30 PM **FDA Review of RWE in Breast Cancer Therapy** ***6***
Catherine Lerro, PhD, MPH
Senior Pharmacoepidemiologist
Oncology Center of Excellence
U.S. Food and Drug Administration

12:30 – 1:30 PM ***Lunch Break***

1:30 – 2:30 PM **Prostate Cancer Clinical Update** ***7***
Marijo Bilusic, MD, PhD
Medical Oncology/GU Site Disease Group Lead
Sylvester Comprehensive Cancer Center/University of Miami Health System

Planned Topics
- Current treatment landscape for metastatic prostate cancer
- Immunotherapy for prostate cancer
- Novel treatment options

2:30 – 2:45 PM ***Afternoon Break***

2:45 – 3:45 PM **Malignant Melanoma** ***8***

Sekwon Jang, MD
Hematology Oncology, Inova Medical Group
Director, Melanoma and Cutaneous Oncology Therapeutics and Research
Inova Melanoma and Skin Cancer Center, Inova Schar Cancer Institute
Associate Professor of Medicine, Virginia Commonwealth University

Planned Topics

- Background & Staging of disease
- Risk factors and screening
- Overview of Current treatment standard of care – pros/cons
- Recent approvals
- Overview of future treatment horizons

3:45 – 4:00 PM ***End of Day Two***

Friday, October 25, 2024 – Program Day 3 ***Session No.***
All Times Listed EDT

10:00 – 10:15 AM **Day Three Overview, Welcome**
Jo Ann Zoul, Course Manager
The Pharmaceutical Education and Research Institute, Inc.

10:15 AM – 11:15 PM **Pediatric Regulations and FDA Initiatives Supporting Development for Pediatrics** ***9***
Michael Barbato, MD
Division of Oncology 2
Office of Oncologic Diseases
Center for Drug Evaluation & Research
U.S. Food and Drug Administration

Planned Topics
- Challenges and Opportunities in Pediatric Oncology Trials
- Legislation Impacting Drug Development in Pediatric Oncology
  Pediatric Oncology at FDA

11:15 – 11:30 AM ***Morning Break***

11:30 AM - 12:30 PM **Lung Cancer Clinical Update** ***10***
Chul Kim, MD, MPH
Assistant Professor, Thoracic Oncology
MedStar Georgetown University Hospital

Planned Topics
- Overview of molecular pathogenesis of lung cancer
- Staging and treatment of lung cancer

12:30 – 1:30 PM ***Lunch Break***

1:30 – 2:45PM **Regulatory Actions and Outcomes for NDAs and BLAs** **11**
Florence Houn, MD, MPH, FACP
Consultant, Drug Development & Regulatory Capacity Building

Planned Topics
- Refuse to file, filing over protest, withdrawal
- PDUFA VII Interactions
- Complete Response, Approval, Appeals
- PMR/PMC, REMS

Session No.

Friday, October 25, 2024 (continued)

All Times Listed EDT

2:45 – 3:00 PM ***Afternoon Break***

3:00 – 4:00 PM **Breast Cancer Clinical Update** ***12***

Melanie Royce, MD, PhD
Senior Physician / Clinical Reviewer, Division of Oncology I
Office of Oncologic Diseases
Center for Drug Evaluation & Research
U.S. Food and Drug Administration

Planned Topics

- Background
- Diagnosis & Staging
- Treatment

4:00 PM ***End of Course***