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

Virtual Training Program
March 13 - 15, 2024

Wednesday, March 13, 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***
Geetika Srivastava, MD, MSPH
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***

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 – 4:00 PM **Regulatory Actions and Outcomes for NDAs and BLAs** ***4***

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

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

Thursday, March 14, 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 **Gene and Cell Therapy Introduction** ***5***
Pashna N. Munshi, MD
Associate Professor
University of Pennsylvania

Planned Topics
- Overview of Gene Therapy
- Gene Editing: Clinical Uses
- Approved CAR-T cell therapies

11:15 – 11:30 AM ***Stretch Break***

11:30 AM – 12:30 PM **Drug Development in Gynecologic Malignancies** ***6***
Gwynn Ison, MD
Office of Oncologic Diseases
Center for Drug Evaluation & Research
U.S. Food and Drug Administration

Planned Topics
- Ovarian, cervical, and endometrial cancers

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

Breast Cancer Clinical Update ***8***

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

3:45 – 4:00 PM

End of Day Two

Friday, March 15, 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 **Colorectal Cancer Clinical Update** ***9***
Benjamin A. Weinberg, MD
Associate Professor of Medicine, Division of Hematology and Oncology
Gastrointestinal Medical Oncologist, Lombardi Comprehensive Cancer Center Georgetown University Medical Center

Planned Topics
- Review IDEA data of 3 vs. 6 months of adjuvant chemotherapy
- Review current NCCN guidelines for metastatic disease
- Updates on BRAF-targeted therapy

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 – 1:45 PM ***Lunch Break***

1:45 – 2:45 PM **Nonclinical Development of Oncologic Agents** ***11***
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

2:45 – 3:00 PM ***Afternoon Break***

3:00 – 4:00 PM **Pediatric Regulations and FDA Initiatives Supporting Development for Pediatrics** ***12***

Kristin Wessel, 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

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