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

Virtual Training Program
March 12 – 14, 2025

Wednesday, March 12, 2025 – Program Day 1 ***Session No.***

All Times Listed ET

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***
Justin S. Collazo, Pharm.D., M.S.
Clinical Pharmacology Reviewer
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, March 12, 2025 (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***

Melanie T. Hartsough, PhD
Independent Consultant

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

Thursday, March 13, 2025 – 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 **Topic to be Announced** ***6***

12:30 – 1:30 PM ***Lunch Break***

1:30 – 2:30 PM **Breast Cancer Clinical Update** ***7***
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

2:30 – 2:45 PM ***Afternoon Break***

2:45 – 3:45 PM

Prostate Cancer Clinical Update ***8***

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

3:45 – 4:00 PM

End of Day Two

Friday, March 14, 2025 – 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 **Pancreatic 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 current standards-of-care for adjuvant therapy and data on neoadjuvant therapy
- Review standards for advanced disease
- Discuss novel therapeutic options and ongoing clinical trials for patients with advanced disease

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 – 2:45 PM **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, March 15, 2025 (continued)
All Times Listed EDT

2:45 – 3:00 PM ***Afternoon Break***

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

Caitlin Tydings, MD
Division of Oncology 3
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
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4:00 PM ***End of Course***