



**Cancer: Pathophysiology, Current Therapies,
Clinical Trials and Drug Development**
Virtual Training Program
October 23 - 25, 2024

Wednesday, October 23, 2024 – Program Day 1

All Times Listed EDT

**Session
No.**

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**

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**

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

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Wednesday, October 23, 2024 (continued)

All Times Listed EDT

**Session
No.
3**

1:30 PM – 2:30 PM

Design and Analysis of Oncology Studies

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

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

All Times Listed EDT

**Session
No.**

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

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

12:30 – 1:30 PM

Lunch Break

1:30 – 2:30 PM

Prostate Cancer Clinical Update

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

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Thursday, October 24, 2024 (continued)

All Times Listed EDT

**Session
No.**

2:45 – 3:45 PM

Malignant Melanoma

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

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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

PERI, Inc.

Friday, October 25, 2024 – Program Day 3

All Times Listed EDT

**Session
No.**

10:00 – 10:15 AM	<u>Day Three Overview, Welcome</u> Jo Ann Zoul, Course Manager The Pharmaceutical Education and Research Institute, Inc.	
10:15 AM – 11:15 PM	<u>Pediatric Regulations and FDA Initiatives Supporting Development for Pediatrics</u> Michael Barbato, MD Division of Oncology 2 Office of Oncologic Diseases Center for Drug Evaluation & Research U.S. Food and Drug Administration <i>Planned Topics</i> <ul style="list-style-type: none">• Challenges and Opportunities in Pediatric Oncology Trials• Legislation Impacting Drug Development in Pediatric Oncology Pediatric Oncology at FDA	9
11:15 – 11:30 AM	<i>Morning Break</i>	
11:30 AM - 12:30 PM	<u>Lung Cancer Clinical Update</u> Chul Kim, MD, MPH Assistant Professor, Thoracic Oncology MedStar Georgetown University Hospital <i>Planned Topics</i> <ul style="list-style-type: none">• Overview of molecular pathogenesis of lung cancer• Staging and treatment of lung cancer	10
12:30 – 1:30 PM	<i>Lunch Break</i>	
1:30 – 2:45PM	<u>Regulatory Actions and Outcomes for NDAs and BLAs</u> Florence Houn, MD, MPH, FACP Consultant, Drug Development & Regulatory Capacity Building <i>Planned Topics</i> <ul style="list-style-type: none">• Refuse to file, filing over protest, withdrawal• PDUFA VII Interactions• Complete Response, Approval, Appeals• PMR/PMC, REMS	11

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

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

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Planned Topics

- Background
- Diagnosis & Staging
- Treatment

4:00 PM

End of Course