



**Cancer: Pathophysiology, Current Therapies,  
Clinical Trials and Drug Development**  
Virtual Training Program  
October 22 - 24, 2025

**Wednesday, October 22, 2025 – Program Day 1**

All Times Listed ET

**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**

Francis Green, 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***

**1**

**2**

**Wednesday, October 22, 2025 (continued)**

**All Times Listed ET**

**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**

Melanie T. Hartsough, PhD

Independent Consultant

**4**

4:00 PM

**End of Day One**

**Thursday, October 23, 2025 – Program Day 2**

All Times Listed ET

**Session  
No.**

10:00 – 10:15 AM	<b><u>Day Two Overview, Welcome</u></b> Jo Ann Zoul, Course Manager The Pharmaceutical Education and Research Institute, Inc.	
10:15 – 11:15 AM	<b><u>Colorectal Cancer Clinical Update</u></b> Benjamin A. Weinberg, MD Associate Professor of Medicine, Division of Hematology and Oncology Gastrointestinal Medical Oncologist, Lombardi Comprehensive Cancer Center MedStar Georgetown University Hospital  <i>Planned Topics</i> <ul style="list-style-type: none"><li>• Review IDEA data of 3 vs. 6 months of adjuvant chemotherapy</li><li>• Review current NCCN guidelines for metastatic disease</li><li>• Updates on BRAF-targeted therapy</li></ul>	<b>5</b>
11:15 – 11:30 AM	<b><u>Stretch Break</u></b>	
11:30 AM – 12:30 PM	<b><u>Upper Gastrointestinal Malignancies: An Overview of Therapy</u></b> Benjamin A. Weinberg, MD  <i>Planned Topics</i> <ul style="list-style-type: none"><li>• Pancreatic cancer</li><li>• Stomach cancer</li><li>• Hepatocellular carcinoma</li></ul>	<b>6</b>
12:30 – 1:30 PM	<b><u>Lunch Break</u></b>	
1:30 – 2:30 PM	<b><u>Breast Cancer Clinical Update</u></b> <i>Speaker Invited</i>	<b>7</b>
2:30 – 2:45 PM	<b><u>Afternoon Break</u></b>	
2:45 – 3:45 PM	<b><u>Prostate Cancer Clinical Update</u></b> Marijo Bilusic, MD, PhD Medical Oncology/GU Site Disease Group Lead Sylvester Comprehensive Cancer Center/Uni. of Miami Health System  <i>Planned Topics</i> <ul style="list-style-type: none"><li>• Current treatment landscape for metastatic prostate cancer</li><li>• Immunotherapy for prostate cancer</li><li>• Novel treatment options</li></ul>	<b>8</b>
3:45 – 4:00 PM	<b><u>End of Day Two</u></b>	

**Friday, October 24, 2025 – Program Day 3**

All Times Listed ET

**Session  
No.**

10:00 – 10:15 AM	<b><u>Day Three Overview, Welcome</u></b> Jo Ann Zoul, Course Manager The Pharmaceutical Education and Research Institute, Inc.	
10:15 AM – 11:15 PM	<b><u>Drug Development in Gynecologic Malignancies</u></b> <i>Speaker Invited</i>	<b>9</b>
11:30 AM - 12:30 PM	<b><u>Lung Cancer Clinical Update</u></b> Chul Kim, MD, MPH Assistant Professor, Thoracic Oncology MedStar Georgetown University Hospital  <i>Planned Topics</i> <ul style="list-style-type: none"><li>• Overview of molecular pathogenesis of lung cancer</li><li>• Staging and treatment of lung cancer</li></ul>	<b>10</b>
12:30 – 1:30 PM	<b><u>Lunch Break</u></b>	
1:30 – 2:45 PM	<b><u>Regulatory Actions and Outcomes for NDAs and BLAs</u></b> <i>Speaker Invited</i>	<b>11</b>
2:45 – 3:00 PM	<b><u>Afternoon Break</u></b>	
3:00 – 4:00 PM	<b><u>Pediatric Regulations and FDA Initiatives Supporting Development for Pediatrics</u></b> Caitlin Tydings, MD Division of Oncology 3 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"><li>• Challenges and Opportunities in Pediatric Oncology Trials</li><li>• Legislation Impacting Drug Development in Pediatric Oncology Pediatric Oncology at FDA</li></ul>	<b>12</b>
4:00 PM	<b><u>End of Course</u></b>	