



**Cancer: Pathophysiology, Current Therapies,
Clinical Trials and Drug Development**
Virtual Training Program
March 22 – 24, 2023

Wednesday, March 22, 2023 – 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**

Shruti Gandhi, MD, PhD
Medical Officer, Division of Oncology III
Office of Oncologic Diseases
Center for Drug Evaluation & Research
U.S. Food and Drug Administration

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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**

Ankit Shah, Senior Clinical Pharmacologist
Division of Cancer Pharmacology I
Office of Clinical Pharmacology
U.S. Food and Drug Administration

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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 22, 2023 (continued)

All Times Listed EDT

**Session
No.
3**

1:30 PM – 2:30 PM

Design and Analysis of Oncology Studies

Malini Iyengar, PhD

Head of Clinical Pharmacology, Respiratory and Oncology Statistics
TEVA Pharmaceuticals

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

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3:45 – 4:00 PM

End of Day One

Thursday, March 23, 2023 – Program Day 2

All Times Listed EDT

**Session
No.**

10:00 – 10:15 AM	<p><u>Day Two Overview, Welcome</u> Jo Ann Zoul, Course Manager The Pharmaceutical Education and Research Institute, Inc.</p>	
10:15 – 11:15 AM	<p><u>Gene and Cell Therapy Introduction</u> Pashna N. Munshi, MD Associate Clinical Director Stem Cell Transplant and Cellular Immunotherapy Program MedStar Georgetown University Hospital</p> <p><i>Planned Topics</i></p> <ul style="list-style-type: none"> • Overview of Gene Therapy • Gene Editing: Clinical Uses • Approved CAR-T cell therapies 	5
11:15 – 11:30 AM	<p><i>Stretch Break</i></p>	
11:30 AM – 12:30 PM	<p><u>Drug Development in Gynecologic Malignancies</u> Asma Dilawari, MD Office of Oncologic Diseases Center for Drug Evaluation & Research U.S. Food and Drug Administration</p> <p><i>Planned Topics</i></p> <ul style="list-style-type: none"> • Ovarian, cervical, and endometrial cancers 	6
12:30 – 1:30 PM	<p><i>Lunch Break</i></p>	
1:30 – 2:30 PM	<p><u>Prostate Cancer Clinical Update</u> Marijo Bilusic, MD, PhD Medical Oncology/GU Site Disease Group Lead Sylvester Comprehensive Cancer Center/University of Miami Health System</p> <p><i>Planned Topics</i></p> <ul style="list-style-type: none"> • Current treatment landscape for metastatic prostate cancer • Immunotherapy for prostate cancer • Novel treatment options 	7
2:30 – 2:45 PM	<p><i>Afternoon Break</i></p>	

Thursday, March 23, 2023 (continued)

All Times Listed EDT

**Session
No.**

2:45 – 3:45 PM

Breast Cancer Clinical Update

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

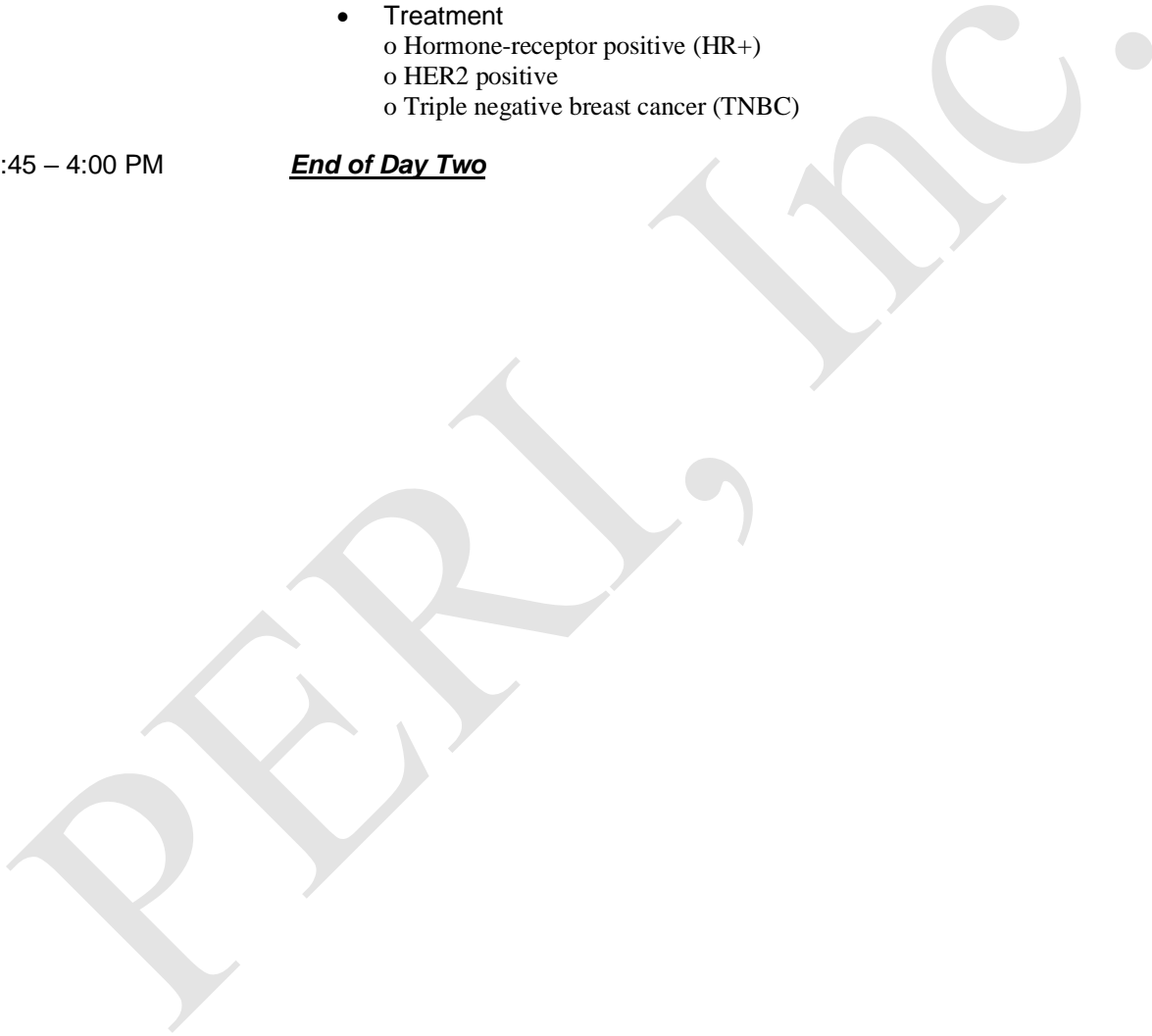
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Planned Topics

- Background
- Diagnosis & Staging
- Treatment
 - o Hormone-receptor positive (HR+)
 - o HER2 positive
 - o Triple negative breast cancer (TNBC)

3:45 – 4:00 PM

End of Day Two



Friday, March 24, 2023 – 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>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 	9
11:15 – 11:30 AM	<i>Morning Break</i>	
11:30 AM - 12:30 PM	<u>Pediatric Regulations and FDA Initiatives Supporting Development for Pediatrics</u> Kristin Wessel, 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 	10
12:30 – 1:30 PM	<i>Lunch Break</i>	
1:30 – 2:45 PM	<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 VI Interactions • Complete Response, Approval, Appeals • PMR/PMC, REMS 	11

Friday, March 24, 2023 (continued)

All Times Listed EDT

**Session
No.**

2:45 – 3:00 PM

Afternoon Break

3:00 – 4:00 PM

Pancreatic Cancer: Clinical Update

Benjamin A. Weinberg, MD

Associate Professor of Medicine, Division of Hematology and Oncology

Gastrointestinal Medical Oncologist, Lombardi Comprehensive Cancer

Center Georgetown University Medical Center

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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

4:00 PM

End of Course