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

Virtual Training Program
October 12 - 14, 2022

Wednesday, October 12, 2022 – 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***
Shruti Gandhy, MD, PhD
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***

Wednesday, October 12, 2022 (continued) — ***Session No.***

All Times Listed EST

1:30 PM – 2:30 PM — **Design and Analysis of Oncology Studies** — ***3***

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 — **Breast Cancer Clinical Update** — ***4***

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

Planned Topics

- Background
- Diagnosis & Staging
- Treatment
  - Neo/Adjuvant
  - Advanced/Metastatic

3:45 – 4:00 PM — ***End of Day One***

Thursday, October 13, 2022 – Program Day 2 — ***Session No.***

All Times Listed EST

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 — **Lung Cancer Clinical Update** — ***5***

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

Thursday, October 13, 2022 (continued) ***Session No.***
All Times Listed EDT

11:15 – 11:30 AM ***Stretch Break***

11:30 AM – 12:30 PM **Gene and Cell Therapy Introduction** ***6***
Pashna N. Munshi, MD
Associate Clinical Director
Stem Cell Transplant and Cellular Immunotherapy Program
MedStar Georgetown University Hospital

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

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 **Nonclinical Development of Oncologic Agents** ***8***
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

3:45 – 4:00 PM ***End of Day Two***

Friday, October 14, 2022 – Program Day 3 ***Session No.***
All Times Listed EST

10:00 – 10:15 AM **Day Three Overview, Welcome**
Jo Ann Zoul, Course Manager
The Pharmaceutical Education and Research Institute, Inc.

10:15 – 11:15 AM **Pediatric Regulations and FDA Initiatives Supporting Development for Pediatrics** ***9***
Marjilla Seddiq, 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

11:15 – 11:30 AM ***Morning Break***

11:30 AM – 12:45 PM **Regulatory Actions and Outcomes for NDAs and BLAs** ***10***
Florence Houn, MD, MPH, FACP
Consultant, Drug Development & Regulatory Capacity Building

Planned Topics
- Refuse to file, filing over protest, withdrawal
- PDUFA VI Interactions
- Complete Response, Approval, Appeals
- PMR/PMC, REMS

12:45 – 1:45 PM ***Lunch Break***

1:45 – 2:45 PM **Pancreatic Cancer: Clinical Update** ***11***
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

Friday, October 14, 2022 (continued) All Times Listed EDT		***Session No.***
2:45 – 3:00 PM	***Afternoon Break***	
3:00 – 4:00 PM	**Drug Development in Gynecologic Malignancies** Asma Dilawari Office of Oncologic Diseases Center for Drug Evaluation & Research U.S. Food and Drug Administration *Planned Topics* • Ovarian, cervical, and endometrial cancers	***12***
4:00 PM	***End of Course***	

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