Monday, June 22, 2020 – Program Day 1

10:00 – 10:15 AM  PERI Welcome and Course Overview
Lauren Kirk, Education Director
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
May Tun Saung, MD
Physician, 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 – 11:25 AM  Morning Break

11:25 AM – 12:30 PM  Improved Strategies for Selecting Recommended Phase 2 Dosing: Moving Beyond Maximum Tolerated Dose  2
Lanre Okusanya, PharmD, MS
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 – 1:15 PM  Lunch Break
**Monday, June 22, 2020 (continued)**

1:15 PM – 2:30 PM  **Design and Analysis of Oncology Studies**  
Malini Iyengar, PhD  
Head of Clinical Pharmacology  
TEVA Pharmaceuticals  

*Planned Topics*  
- Study Design  
- Trials with Objective Response Rates  
- Trials with PFS, OS

2:30– 2:40 PM  **Afternoon Break**

2:40 – 3:55 PM  **Breast Cancer Clinical Update**  
Melanie Royce, MD, PhD  
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

3:55 – 4:00 PM  **End of Day One**

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**Tuesday, June 23, 2020 – Program Day 2**

10:00 – 10:15 AM  **Day Two Overview, Welcome**  
Lauren Kirk, Education Director  
The Pharmaceutical Education and Research Institute, Inc.

10:15 – 11:15 AM  **Gene and Cell Therapy Introduction**  
Pashna N. Munshi, MD  
Associate Clinical Director  
Stem Cell Transplant and Cellular Immunotherapy Program  
MedStar Georgetown University Hospital
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| 11:25 AM – 12:30 PM | 6          | **Gynecologic Malignancies: Project Orbis Case Study**  
Shaily Arora, PharmD  
Associate Director for Safety (Acting)  
Office of Oncologic Diseases  
Center for Drug Evaluation & Research  
U.S. Food and Drug Administration  
Planned Topics  
- Genesis of Project Orbis  
- Collaborative Review Process  
- Regulatory Insights |
| 12:30 – 1:15 PM |             | **Lunch Break**   |
| 1:15 – 2:30 PM | 7           | **Lung Cancer Clinical Update**  
Chul Kim, MD, MPH  
Associate Professor, Thoracic Oncology  
MedStar Georgetown University Hospital  
Planned Topics  
- Overview of molecular pathogenesis of lung cancer  
- Staging and treatment of lung cancer |
| 2:30 – 2:40 PM |             | **Afternoon Break** |
| 2:40 – 3:55 PM | 8           | **Nonclinical Development of Oncologic Agents**  
Simon Williams  
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 |
| 3:55 – 4:00 PM |             | **End of Day Two** |
Wednesday, June 24, 2020 – Program Day 3

10:00 – 10:15 AM  **Day Two Overview, Welcome**
Lauren Kirk, Education Director
The Pharmaceutical Education and Research Institute, Inc.

10:15 – 11:15 AM  **Pediatric Regulations and FDA Initiatives Supporting Development for Pediatrics**
Sonia Singh, MD
Pediatric Oncologist, Division of Oncology II
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 – 11:25 AM  **Morning Break**

11:25 AM – 1:00 PM  **Regulatory Actions and Outcomes for NDAs and BLAs**
Florence Houn, MD, MPH, FACP
VP, Global Regulatory Science
Bristol Myers Squibb

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

1:00 – 1:45 PM  **Lunch Break**

1:45 – 2:45 PM  **Emerging Concepts in Cancer Immunotherapy**
Julius Strauss, MD
Assistant Research Physician, Laboratory of Tumor Immunology and Biology
Co-Director, Clinical Trials Group
Center for Cancer Research
National Cancer Institute

*Planned Topics*
- Immune Checkpoint Inhibition
- Update on therapeutic cancer vaccines
- Biomarker development
- Developing immune combinations and the next generation of immunotherapy
Wednesday, June 24, 2020 (continued)

2:45 – 2:55 PM

Afternoon Break

2:55 – 3:55 PM

Prostate Cancer Clinical Update
Marijo Bilusic, MD, PhD
Associate Research Physician, Genitourinary Malignancies Branch
Program Director, NIH Hematology Oncology Fellowship
National Cancer Institute

Planned Topics
- Current treatment landscape for metastatic prostate cancer
- Immunotherapy for prostate cancer
- Novel treatment options

3:55 – 4:00 PM

End of Course