

Agenda

September 29, 2018

SESSION I: Introduction

8:00 am – 9:00 am

Social Foyer

Registration / Continental Breakfast

9:00 am – 9:15 am

Hunsaker Ballroom

Overview of Course

*H. Kim Lyerly, MD
Duke University*

9:15 am – 9:45 am

Hunsaker Ballroom

The Importance of the Patient Advocate in Anticancer Drug Development

*Carol Matyka, MA
CARE Advocates Network*

9:45 am – 10:30 am

Hunsaker Ballroom

Determining Value of New Cancer Therapies

*Leeza Osipenko, PhD
National Institute for Health and Care Excellence (NICE)*

10:30 am – 10:45 am

Social Foyer

Break

SESSION II: Early Anticancer Drug Development

Moderator: Bruce Chabner, MD, Harvard Medical School/Dana Farber Cancer Institute

10:45 am – 11:30 am

Hunsaker Ballroom

Questions and Designs for Early Drug Development

*Steven Piantadosi, PhD
Harvard Medical School/Brigham and Women's Hospital*

11:30 am – 12:15 pm

Hunsaker Ballroom

Clinical Pharmacology and Dose Optimization

- **Dose-response, exposure-response principles in dose selection**
- **Translational PK/PD for dose/ schedule selection**
- **Pharmacodynamics in early drug development**
- **Population PK and Exposure-Response Analyses**
- **Scenarios of altered exposure: DDI's, organ impairment, food effect, ethnicity**

*Karthik Venkatakrishnan, PhD, FCP
Takeda Oncology*

12:15 pm – 1:15 pm

Luscomb Ballroom

Lunch

DUKE AND THE HARVARD-MIT CENTER FOR REGULATORY SCIENCE
Anticancer Drug Development Workshop
for Investigators & Patient Advocates

SESSION III: Bringing a Drug to Market:
Expedited Programs and the Drug Approval Process

Moderator: Brian Alexander, MD, Harvard Medical School/Dana Farber Cancer Institute

1:15 pm – 2:00 pm

Hunsaker Ballroom

Expedited Programs and Approval Pathways

Jennifer Gao, MD

U.S. Food and Drug Administration

2:00 pm – 2:30 pm

Hunsaker Ballroom

Early Efficacy Trials, Selected Endpoints, and PROs

Lola Fashoyin-Aje, MD, MPH

U.S. Food and Drug Administration

SESSION IV: Companion Diagnostics, and Positioning
in the Treatment Armamentarium

Moderator: Brian Alexander, MD, Harvard Medical School/Dana Farber Cancer Institute

2:30 pm – 3:15 pm

Hunsaker Ballroom

Design and Analysis Considerations in Late Stage Trials

Meredith Regan, ScD

Harvard Medical School/Dana Farber Cancer Institute

3:15 pm – 3:30 pm

Social Foyer

Break

3:30 pm – 4:15 pm

Hunsaker Ballroom

**Biomarkers, Diagnostic Development, and the
Post-marketing Setting**

Lola Fashoyin-Aje, MD, MPH

U.S. Food and Drug Administration

4:15 pm – 4:30 pm

Hunsaker Ballroom

Wrap-Up

H. Kim Lyerly, MD

Duke University

4:30 pm

Adjourn