

# **Emerging Opportunities to Streamline Cancer Drug Development**

December 9, 2016 | Arlington, VA
The Ritz-Carlton Pentagon City | The Diplomat Room



@PresCancerPanel | #CancerRxValue

## **Agenda**

8:00	Registration
8:30	Welcome and Introductions
9:10	Session 1, Part 1: Bringing Drugs that Add Value to Market Faster
	<ul> <li>Presentation: Richard Pazdur, MD, Acting Director, Oncology Center of Excellence, U.S. Food and Drug Administration (15 min)</li> </ul>
	- Moderated Discussion (40 min)
10:10	Break
10:25	Session 1, Part 2: Bringing Drugs that Add Value to Market Faster
11:25	Session 2, Part 1: Accelerating Throughput and Learning from Clinical Trials
	<ul> <li>Presentation: Lisa LaVange, PhD, Director, Office of Biostatistics, Center for Drug Evaluation and Research, U.S. Food and Drug Administration (10 min)</li> </ul>
11:40	Public Comment
11:45	Lunch
12:45	Session 2, Part 2: Accelerating Throughput and Learning from Clinical Trials
	<ul> <li>Presentation: James Zwiebel, MD, Chief, Investigational Drug Branch,</li> <li>Cancer Therapy Evaluation Program, National Cancer Institute (10 min)</li> <li>Moderated Discussion (60 min)</li> </ul>
1:55	Break
2:10	Session 3: Evaluating and Approving Combination Therapies
	<ul> <li>Presentation: Gary Gilliland, MD, PhD, President and Director, Fred Hutchinson Cancer Research Center (10 min)</li> </ul>
	<ul> <li>Presentation: Roy Baynes, MD, PhD, Senior Vice President and Head, Global Clinical Development, and Chief Medical Officer, Merck Research Laboratories (10 min)</li> </ul>
	- Moderated Discussion (60 min)
3:30	Conclusions and Cross-Cutting Recommendations
3:45	Public Comment
3:50	Wrap-up and Next Steps
4:00	Adiourn



## **Emerging Opportunities to Streamline Cancer Drug Development**

## **Participant List**

#### Margaret Anderson, MSc

Executive Director
FasterCures
@MargaretAinDC

## Roy Baynes, MD, PhD

Senior Vice President and Head Global Clinical Development Chief Medical Officer Merck Research Laboratories Merck & Co., Inc.

## Donald A. Berry, PhD

Professor
Department of Biostatistics
The University of Texas
M. D. Anderson Cancer Center

## **Danielle Carnival, PhD**

Chief of Staff and Senior Policy Director White House Cancer Moonshot Task Force Office of the Vice President

#### Jason V. Cristofaro, JD, PhD

Intellectual Property Program Manager Division of Cancer Treatment and Diagnosis National Cancer Institute

## Kathleen A. Denis, PhD

Associate Vice President The Rockefeller University

## Ann M. Geiger, PhD, MPH

Chief
Healthcare Assessment
Research Branch
Healthcare Delivery Research
Program
Division of Cancer Control and
Population Sciences
National Cancer Institute
@NCI\_AMGeiger

## Gary Gilliland, MD, PhD

President and Director
Fred Hutchinson Cancer Research Center

## Hill Harper, JD

Member President's Cancer Panel Author, Actor, and Philanthropist @hillharper

## Clifford A. Hudis, MD, FACP

Chief Executive Officer American Society of Clinical Oncology @CliffordHudis

#### Suleika Jaouad

New York Times Columnist Young Adult Cancer Advocate @SuleikaJaouad

## Aaron Kesselheim, MD, JD

Associate Professor of Medicine
Harvard Medical School
Director
Program on Regulation, Therapeutics, and Law
Division of Pharmacoepidemiology and
Pharmacoeconomics
Brigham and Women's Hospital
@akesselheim



## **Emerging Opportunities to Streamline Cancer Drug Development**

## **Participant List**

## Lisa LaVange, PhD

Director
Office of Biostatistics
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

#### Lori M. Minasian. MD

Deputy Director
Division of Cancer Prevention
National Cancer Institute

## Shelley Fuld Nasso, MPP

Chief Executive Officer
National Coalition for Cancer Survivorship
@sfuldnasso

### Richard Pazdur, MD

Acting Director
Oncology Center of Excellence
U.S. Food and Drug Administration

## Vinay K. Prasad, MD, MPH

Assistant Professor Oncology Oregon Health & Science University @vinayprasad82

## Barbara K. Rimer, DrPH

Chair
President's Cancer Panel
Dean and Alumni Distinguished
Professor
UNC Gillings School of Global Public
Health

## Mace Rothenberg, MD

Chief Development Officer Oncology Pfizer Global Product Development Pfizer, Inc.

## Abby B. Sandler, PhD

Executive Secretary
President's Cancer Panel
Special Assistant to the Director
Rare Tumors Initiative
Center for Cancer Research
National Cancer Institute

## George A. Scangos, PhD

Chief Executive Officer Biogen

## Greg Simon, JD

Executive Director
White House Cancer Moonshot Task Force
Office of the Vice President

## Philip J. Stella, MD

Medical Director
Oncology Program
St. Joseph Mercy Hospital—Ann Arbor

## Owen Witte, MD

Member
President's Cancer Panel
University Professor
Director
Eli and Edythe Broad Center of Regenerative
Medicine and Stem Cell Research
University of California, Los Angeles

## James Zwiebel, MD

Chief Investigational Drug Branch Cancer Therapy Evaluation Program National Cancer Institute