



INTERNATIONAL
ASSOCIATION
FOR THE STUDY
OF LUNG CANCER
Conquering Thoracic Cancers Worldwide

FDA-AACR-IASLC Workshop to Address the Criticality of Tobacco Use Assessment in Oncology Therapeutic Trials

February 28, 2020

U.S. Food and Drug Administration Great Room | Silver Spring, MD

Workshop Cochairs:

U.S. Food and Drug Administration:

Michael E. Menefee, MD, Medical Oncologist, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

American Association for Cancer Research:

Roy S. Herbst, MD, PhD, Ensign Professor of Medicine, Associate Director for Translational Research, Yale Cancer Center

International Association for the Study of Lung Cancer:

Matthew Steliga, MD, Division Chief, Thoracic Surgery, Medical Director-Smoking Cessation, Rockefeller Cancer Institute, University of Arkansas

AGENDA

INTRODUCTION

8:00 AM Introduction and welcome
Roy S. Herbst, MD, PhD, Yale Cancer Center

8:05 AM Opening remarks
Paul G. Kluetz, MD, U.S. Food and Drug Administration

SESSION I: ASSESSMENT OF TOBACCO IN ONCOLOGIC THERAPEUTIC TRIALS: INTRODUCTION AND RATIONALE SESSION MODERATORS: CAROLYN M. DRESLER, MD, MPA, & MICHAEL E. MENELEE, MD

8:10 AM Overview
Carolyn M. Dresler, MD, MPA

8:20 AM Tobacco/nicotene biology and lung cancer
Paul A. Bunn, Jr., MD, FASCO, University of Colorado, Denver

8:40 AM Addressing tobacco use by cancer patients: clinical and biologic considerations
Graham Warren, MD, PhD, Medical University of South Carolina

9:00 AM Assessment of tobacco use in cancer clinical trials
Stephanie Land, PhD, National Cancer Institute

9:15 AM PANEL DISCUSSION and AUDIENCE Q&A

Panelists: Session I speakers and the following additional panelists:
Priscilla Callahan-Lyon, MD, U.S. Food and Drug Administration
Nichelle Stigger, Patient Advocate

9:45 AM BREAK

@FDAOncology

@IASLC

@AACR



Join the conversation with #OCTobaccoUse

SESSION II: ASSESSMENT OF TOBACCO IN ONCOLOGY THERAPEUTIC TRIALS: IMPLEMENTATION
SESSION MODERATORS: ROY S. HERBST, MD, PHD, & STEPHANIE LAND, PHD

- 10:05 AM** **The impact of smoking on lung cancer treatment**
Roy S. Herbst, MD, PhD, Yale Cancer Center
- 10:25 AM** **Implementing assessment of tobacco use in cooperative group cancer trials**
Elyse Park, PhD, Massachusetts General Hospital
- 10:45 AM** **Oncology drug development: Industry perspective**
Cathy Pietanza, MD, Merck

11:05 AM **PANEL DISCUSSION and AUDIENCE Q&A**

- Panelists:** **Session II speakers and the following additional panelist:**
Naomi Horiba, MD, U.S. Food and Drug Administration

11:35 AM **LUNCH BREAK (ON YOUR OWN)**

SESSION III: PROVIDING TOBACCO CESSATION ASSISTANCE TO CANCER PATIENTS
SESSION MODERATORS: LINDA BAILEY, JD, MHS, & MATTHEW STELIGA, MD

- 12:45 PM** **Community-based cessation services: What services exist and how do smokers access them?**
Linda Bailey, JD, MHS, North American Quitline Consortium
- 1:00 PM** **Integration of tobacco cessation in a surgery oncology program**
Matthew Steliga, MD, Winthrop P. Rockefeller Cancer Institute
- 1:15 PM** **Smoking cessation and harm reduction in context of oncology clinical care: clinical guidelines**
Laura Bierut, MD, Washington University School of Medicine

1:30 PM **PANEL DISCUSSION and AUDIENCE Q&A**

- Panelists:** **Session III speakers and the following additional panelists:**
Adnan Jaigirdar, MD, U.S. Food and Drug Administration
James Pantelas, Patient Advocate

SESSION IV: TOBACCO CESSATION IN ONCOLOGY PATIENTS: CHALLENGES AND LESSONS LEARNED
SESSION MODERATOR: BRENNA VAN FRANK, MD, MSPH

- 2:00 PM** **Tobacco cessation in oncology patients: challenges and strategies**
Brenna VanFrank, MD, MSPH, Centers for Disease Control and Prevention
- 2:15 PM** **Tobacco cessation at cancer centers: lessons learned**
Glen D. Morgan, PhD, National Cancer Institute
- 2:30 PM** **Financial considerations for smoking and cancer treatment**
Graham Warren, MD, PhD, Medical University of South Carolina
- 2:40 PM** **Financial toxicity in cancer treatment in America**
Fumiko Chino, MD, Memorial Sloan Kettering Cancer Center

2:50 PM **PANEL DISCUSSION and AUDIENCE Q&A**

- Panelists:** **Session IV speakers**
Sundeep Agrawal, MD, U.S. Food and Drug Administration



3:20 PM BREAK

**SESSION V: FUTURE DIRECTIONS & NEXT STEPS
SESSION MODERATOR: STEPHANIE LAND, PHD**

**3:30 PM Nicotine, smoking and response to therapy: future directions
Srikumar Chellappan, PhD, Moffitt Cancer Center**

**3:45 PM Future directions in tobacco use assessment in oncology therapeutic trials
Paul A. Bunn, Jr., MD, FASCO, University of Colorado, Denver**

**4:00 PM Future directions & next steps: perspective from NCI's cancer therapy evaluation program
Shakun Malik, MD, National Cancer Institute**

4:15 PM PANEL DISCUSSION ON NEXT STEPS and AUDIENCE Q&A

**Panelists: Session V speakers and the following additional panelist:
Harpreet Singh, MD, U.S. Food and Drug Administration
James Pantelas, Patient Advocate**

**4:50 PM Oncology Center of Excellence perspective
Harpreet Singh, MD, U.S. Food and Drug Administration**

**4:55 PM Wrap up: summary
Matthew Steliga, MD, Rockefeller Cancer Institute**

5:00 PM ADJOURN

