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. MENEFEE, 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

Join the conversation with #OCETobaccoUse
<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Moderator/Presenter</th>
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<tbody>
<tr>
<td>10:05</td>
<td>The impact of smoking on lung cancer treatment</td>
<td>Roy S. Herbst, MD, PhD, Yale Cancer Center</td>
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<td>10:25</td>
<td>Implementing assessment of tobacco use in cooperative group cancer trials</td>
<td>Elyse Park, PhD, Massachusetts General Hospital</td>
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<td>10:45</td>
<td>Oncology drug development: Industry perspective</td>
<td>Cathy Pietanza, MD, Merck</td>
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<td>11:05</td>
<td>PANEL DISCUSSION and AUDIENCE Q&amp;A</td>
<td>Session II speakers and the following additional panelist: Naomi Horiba, MD, U.S. Food and Drug Administration</td>
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<td>11:35</td>
<td>LUNCH BREAK (ON YOUR OWN)</td>
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<td>12:45</td>
<td>Community-based cessation services: What services exist and how do smokers access them?</td>
<td>Linda Bailey, JD, MHS, North American Quitline Consortium</td>
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<td>1:00</td>
<td>Integration of tobacco cessation in a surgery oncology program</td>
<td>Matthew Steliga, MD, Winthrop P. Rockefeller Cancer Institute</td>
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<td>1:15</td>
<td>Smoking cessation and harm reduction in context of oncology clinical care: clinical guidelines</td>
<td>Laura Bierut, MD, Washington University School of Medicine</td>
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<td>1:30</td>
<td>PANEL DISCUSSION and AUDIENCE Q&amp;A</td>
<td>Session III speakers and the following additional panelists: Adnan Jaigirdar, MD, U.S. Food and Drug Administration, James Pantelas, Patient Advocate</td>
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<td>2:00</td>
<td>Tobacco cessation in oncology patients: challenges and strategies</td>
<td>Brenna VanFrank, MD, MSPH, Centers for Disease Control and Prevention</td>
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<td>2:15</td>
<td>Tobacco cessation at cancer centers: lessons learned</td>
<td>Glen D. Morgan, PhD, National Cancer Institute</td>
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<td>2:30</td>
<td>Financial considerations for smoking and cancer treatment</td>
<td>Graham Warren, MD, PhD, Medical University of South Carolina</td>
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<td>2:40</td>
<td>Financial toxicity in cancer treatment in America</td>
<td>Fumiko Chino, MD, Memorial Sloan Kettering Cancer Center</td>
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<td>2:50</td>
<td>PANEL DISCUSSION and AUDIENCE Q&amp;A</td>
<td>Session IV speakers and the following additional panelist: Sundeep Agrawal, MD, U.S. Food and Drug Administration</td>
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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