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
Richard Pazdur, 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 biology
Paul Bunn, Jr., MD, FASCO, University of Colorado, Denver

8:40 AM  Addressing tobacco use by cancer patients
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

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Join the conversation with #OCETobaccoUse
SESSION II: ASSESSMENT OF TOBACCO IN ONCOLOGY THERAPEUTIC TRIALS: IMPLEMENTATION
SESSION MODERATORS: ROY S. HERBST, MD, PHD, & STEPHANIE LAND, PHD

10:05 AM 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: Background, initiatives and strategies
Linda Bailey, JD, MHS, North American Quitline Consortium

1:00 PM Smoking cessation resources within and outside of cancer care
Matthew Steliga, MD, Winthrop P. Rockefeller Cancer Institute

1:15 PM Smoking cessation in context of oncology clinical care: Clinical guidelines
Laura Bierut, MD, Washington University School of Medicine in St. Louis

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 Challenges/strategies
Brenna VanFrank, MD, MSPH, Centers for Disease Control and Prevention

2:15 PM Lessons learned from NCI’s Cancer Centers Cessation Initiative
Glen D. Morgan, PhD, National Cancer Institute

2:30 PM Financial considerations around smoking and cancer treatment
Graham Warren, MD, PhD, Medical University of South Carolina

2:40 PM Financial considerations
Fumiko Chino, MD, Memorial Sloan Kettering Cancer Center

2:50 PM PANEL DISCUSSION and AUDIENCE Q&A
Panelists: Session IV speakers

3:20 PM BREAK

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| 3:30 PM | Future directions and research needs  
          Srikumar Chellappan, PhD, Moffitt Cancer Center                   |
| 3:45 PM | Future directions  
          Paul Bunn, Jr., MD, FASCO, University of Colorado, Denver        |
| 4:00 PM | Perspective from NCI 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:  
          James Pantelas, Patient Advocate                                 |
| 4:50 PM | Oncology Center of Excellence perspective  
          Harpreet Singh, MD, U.S. Food and Drug Administration, Oncology Center of Excellence (OCE) |
| 4:55 PM | Wrap up: Summary  
          Matthew Steliga, MD, Rockefeller Cancer Institute                |
| 5:00 PM | ADJOURN                                                              |