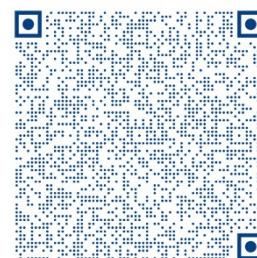# Addressing Resistance in the Development of Cancer Immune Modulator Therapeutics

A Collaborative Workshop Convened by the
National Cancer Policy Forum
Forum on Drug Discovery, Development, and Translation

2101 Constitution Ave., NW
Lecture Room
Washington, DC 20418

AGENDA

November 14, 2022 - Eastern Time Zone	
8:00 am	**BREAKFAST AND REGISTRATION**
8:30 am	**WELCOME FROM THE NATIONAL CANCER POLICY FORUM** *Planning Committee Co-Chairs:* Samir N. Khleif, Georgetown University Medical Center George J. Weiner, Holden Comprehensive Cancer Center
8:40 am	**KEYNOTE: IMPLICATIONS OF SCIENTIFIC INNOVATIONS ON HIGH-QUALITY CANCER CARE AND PATIENT OUTCOMES** • Elizabeth M. Jaffee, President's Cancer Panel; Johns Hopkins University (Virtual)
9:00 am	**SESSION 1: CRITERIA TO MOVE SINGLE AGENTS INTO CLINICAL TRIALS** *Co-Moderators:* Samir N. Khleif, Georgetown University Medical Center Tom Curran, Children's Mercy Research Institute; Kansas City University **Single Agent Activity Anti-PD1** • Suzanne L. Topalian, Johns Hopkins University **Single Agent Activity Anti-Lymphocyte Activation Gene-3 Antibody** • Hussein Tawbi, MD Anderson Cancer Center **Challenges in the Development of Agonist T Cell Antibody Therapy** • John Janik, CullinanOncology **Perspective on Resistance to CAR-T: Lessons from Blood Cancer** • Stephan A. Grupp, Children's Hospital of Philadelphia (Virtual) **FDA Regulatory Perspective: What has Changed and What is Missing?** • Peter F. Bross, Center for Biological Evaluation and Research, Food and Drug Administration **Panel Discussion**
10:30 am	**BREAK**

WORKSHOP WEBSITE AND BRIEFING MATERIALS
https://www.nationalacademies.org/event/11-14-2022/addressing-resistance-in-the-development-of-cancer-immune-modulator-therapeutics-a-workshop

10:40 am	**SESSION 2: CURRENT CHALLENGES AND OPPORTUNITIES: SELECTION OF EXPERIMENTAL AGENTS IN COMBINATIONS** *Co-Moderators:* Gideon Blumenthal, Merck Marc Theoret, Oncology Center of Excellence, Food and Drug Administration **Understanding Immune Therapy Efficacy, Preclinical Models, and Combination Resistance** • Samir N. Khleif, Georgetown University Medical Center **Clinical Trials in PD-1/L1 Refractory Cancers** • Jane A. Healy, Merck Research Labs **Anti-PD1 and Epacadostat vs. IDO Inhibition: Lessons Learned** • Jason J. Luke, University of Pittsburgh Medical Center **Intra-Lesional Approaches: Regulatory Issues** • George J. Weiner, Holden Comprehensive Cancer Center **Panel Discussion**
12:00 pm	**LUNCH BREAK**
1:00 pm	**SESSION 3: CURRENT CHALLENGES AND OPPORTUNITIES: BIOMARKERS AND SURROGATE ENDPOINTS** *Co-Moderators:* Kimryn Rathmell, Vanderbilt University Medical Center Chris Boshoff, Pfizer Inc (Virtual) **Genetic Biomarkers: 9p21 Loss Drives Immune-Cold, Checkpoint-Inhibitor Resistance in HPV⁻ Head and Neck Squamous Cancer** • Teresa Davoli, NYU Langone Health (Virtual) **Diagnostic Imaging** • Marius Mayerhoefer, Memorial Sloan Kettering Cancer Center **Immune Metabolism** • Hildegund C.J. Ertl, The Wistar Institute **Novel Surrogate Biomarkers for Immune Therapy Response and Resistance** • Kimryn Rathmell, Vanderbilt University Medical Center **Biomarkers and Imaging: Current Regulatory Landscape** • Reena Philip, Oncology Center of Excellence, Food and Drug Administration **Surrogate Endpoint Development** • Nicole Gormley, Center for Drug Evaluation and Research, Food and Drug Administration **Panel Discussion**
2:40 pm	**BREAK**

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2:50 pm	**SESSION 4: CURRENT CHALLENGES AND OPPORTUNITIES: THE ROLE OF DATA AND COMPUTATIONAL TOOLS** *Co-Moderators:* Nancy E. Davidson, Fred Hutchinson Cancer Center Julie R. Gralow, American Society of Clinical Oncology **Regulatory and Access Considerations in Mining Big Data** • Ahmad A. Tarhini, H. Lee Moffitt Cancer Center and Research Institute **Advanced Computing Tools** • Jack D. Hidary, SandboxAQ (Virtual) **Data Driven Approaches for Modeling Response and Resistance** • Dana Pe'er, Memorial Sloan Kettering Cancer Center **Leveraging Real World Data to Characterize Immune Related Adverse Events** • Prakirthi Yerram, Flatiron Health **AI, Data Science, and BigData Approaches to Accelerate and Expand Research and Evaluation** • Usama Fayyad, Institute for Experiential Artificial Intelligence. Northeastern University **Panel Discussion**
4:20 pm	**Closing Remarks** *Planning Committee Co-Chairs:* Samir N. Khleif, Georgetown University Medical Center George J. Weiner, Holden Comprehensive Cancer Center
4:30 pm	**ADJOURN TO RECEPTION – NAS GREAT HALL**

November 15, 2022 - Eastern Time Zone

8:00 am	**BREAKFAST AND REGISTRATION**
8:30 am	**WELCOME AND OVERVIEW OF DAY 2** *Planning Committee Co-Chairs:* Samir N. Khleif, Georgetown University Medical Center George J. Weiner, Holden Comprehensive Cancer Center
8:40 am	**SESSION 5: CRITERIA TO ASSESS CANCER IMMUNOTHERAPY COMBINATIONS IN EARLY-PHASE CLINICAL TRIALS: TYPES OF CLINICAL TRIAL DESIGNS NEEDED FOR REGULATORY APPROVAL** *Co-Moderators:* Roy S. Herbst, Yale Comprehensive Cancer Center (Virtual) Hedvig Hricak, Memorial Sloan Kettering Cancer Center **Novel Immunotherapy Clinical Trial Design**

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	• Keith T. Flaherty, Massachusetts General Hospital; Harvard Medical School
	Public Private Partnership Perspective • Roy Herbst, Yale Comprehensive Cancer Center (Virtual) **Selected Regulatory Considerations for Cancer Immunotherapeutic Combinations: Contribution of Individual Components to Effect of Combination** • Marc Theoret, Oncology Center of Excellence, Food and Drug Administration **National Cancer Institute Perspective on Novel Trial Designs for Immunotherapy Resistance** • Elad Sharon, NCI Cancer Therapy Evaluation Program **An Industry Perspective** • Alexandra Snyder, Generate Biomedicines **Challenges of Trial Design: Incorporating Pharmacodynamics** • Jedd Wolchok, Weill Cornell Medicine (Virtual) **Panel Discussion**
10:10 am	**BREAK**

10:20 am	**SESSION 6: PANEL DISCUSSION**
	REFLECTIONS ON THE WORKSHOP AND NEXT STEPS TO OVERCOME RESISTANCE TO IMMUNE MODULATOR THERAPIES FOR CANCER TREATMENT
	Co-Moderators:
	George J. Weiner, Holden Comprehensive Cancer Center
	Scott M. Lippman, University of California, San Diego
	
	Panelists:
	    Session 1: Samir N. Khleif and Tom Curran
	    Session 2: Gideon Blumenthal and Marc Theoret
	    Session 3: Kimryn Rathmell and Chris Boshoff (Virtual)
	    Session 4: Nancy E. Davidson and Julie R. Gralow
	    Session 5: Roy S. Herbst (Virtual) and Hedvig Hricak
	
	Open Discussion

11:50 am	**CLOSING REMARKS** *Planning Committee Co-chairs:* Samir N. Khleif, Georgetown University Medical Center George J. Weiner, Holden Comprehensive Cancer Center
12:00 pm	**ADJOURN**

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