FDA-AACR Workshop on
How Much is Enough? Trial Designs for Treatment Regimens with Multiple Phases

Bethesda Marriott Pooks Hill

May 9 | 9:00 AM – 4:00 PM

Workshop Co-chairs:

Harpreet Singh, MD, Director, Division of Oncology 2, U.S. Food and Drug Administration

Elizabeth Jaffee, MD, FAACR, FCP, Deputy Director, Sidney Kimmel Comprehensive Cancer Center

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AGENDA

9:00 AM	**INTRODUCTION**
9:00 AM	**Welcome & Introduction**: **Elizabeth Jaffee, MD,** Sidney Kimmel Comprehensive Cancer Center
9:05 AM	**Overview of Workshop:** **Harpreet Singh, MD,** U.S. Food and Drug Administration
9:15 AM	**SESSION 1: CURRENT LANDSCAPE FOR PERIOPERATIVE TRIAL DESIGNS**
9:15 AM	**Moderator Introduction:** **Erin Larkins, MD**, U.S. Food and Drug Administration
9:20 AM	**Current Therapeutic Landscape for Early-Stage Solid Tumors:** **Oladimeji Akinboro, MD,** U.S. Food and Drug Administration
9:30 AM	**Biomarker-Guided Perioperative Clinical Trials:** **Valsamo Anagnostou, MD, PhD,** Sidney Kimmel Comprehensive Cancer Center
9:40 AM	**Implementing Sequential, Multiple, Randomized (SMART) Trial Designs:** **Kelley Kidwell, PhD,** University of Michigan School of Public Health
9:50 AM	**PANEL DISCUSSION**
	• **Anup Amatya, PhD**, U.S. Food and Drug Administration • **Paz Vellanki, MD,** U.S. Food and Drug Administration • **Thelma Brown,** Translational Breast Cancer Research Consortium • **Roy Herbst, MD, PhD**, Yale University • **Mark Kris, MD,** Memorial Sloan Kettering Cancer Center • **Aarón Sosa Mejia, MD,** European Medicines Agency • **Craig Tendler, MD,** Johnson & Johnson Innovative Medicine
10:45 AM	**BREAK**

10:55 AM	**SESSION 2A: OPTIMIZING PERIOPERATIVE TREATMENT REGIMENS**
10:55 AM	**Moderator Introduction:** **Elizabeth Jaffee, MD**, Sidney Kimmel Comprehensive Cancer Center
11:00 AM	**Optimizing the Regimen: Cooperative Group Perspective:** **Jhanelle Gray, MD,** Moffitt Cancer Center
11:10 AM	**Cumulative and Long-Term Toxicity with Immunotherapy:** **Mark Yarchoan, MD,** Sidney Kimmel Comprehensive Cancer Center
11:20 AM	**PANEL DISCUSSION**

- **Vishal Bhatnagar, MD,** U.S. Food and Drug Administration
- **Tatiana Prowell, MD,** U.S. Food and Drug Administration
- **Michael Axelson, MD,** Loxo@Lilly
- **Fred Hirsch, MD, PhD,** The Tisch Cancer Institute at Mount Sinai
- **Jane Perlmutter, PhD, MBA,** Gemini Group
- **Sara Tolaney, MD, MPH,** Dana-Farber Cancer Institute

12:20 PM	**LUNCH BREAK**
12:50 PM	**FIRESIDE CHAT WITH FDA DIVISION DIRECTORS**

- **Angelo de Claro, MD,** Hematologic Malignancies I
- **Nicole Gormley, MD,** Hematologic Malignancies II
- **Laleh Amiri-Kordestani, MD,** Oncology I
- **Steven Lemery, MD,** Oncology III
- **Harpreet Singh, MD,** Oncology II

1:20 PM	**SESSION 2B: THE FUTURE OF REGISTRATIONAL TRIALS WITH MULTIPLE ARMS**
1:20 PM	**Moderator Introduction:** **Bernardo Haddock Lobo Goulart, MD,** U.S. Food and Drug Administration
1:25 PM	**Statistical Considerations for Future Perioperative Trials:** **Chi Song, PhD,** U.S. Food and Drug Administration
1:35 PM	**Industry Perspective on Future Perioperative Trials:** **Minghua Shan, PhD,** Bayer Pharmaceuticals
1:45 PM	**PANEL DISCUSSION**
	• **Nicole Gormley, MD,** U.S. Food and Drug Administration • **Pallavi Mishra-Kalyani, PhD,** U.S. Food and Drug Administration • **Patrick Forde, MD,** Johns Hopkins Medicine • **Giuseppe Giaccone, MD, PhD,** Weill Cornell Medical College • **Joshua Reuss, MD,** MedStar Georgetown • **Kathleen Winson, MS,** Genentech, Inc.
2:45 PM	**BREAK**
2:55 PM	**Session 3: Considerations in Other Therapeutic Areas**
2:55 PM	**Moderator Introduction:** **Mirat Shah, MD,** U.S. Food and Drug Administration
3:00 PM	**Where Do We Go from Here? Considerations for NSCLC & Other Therapeutic Areas:** **Harpreet Singh, MD,** U.S. Food and Drug Administration
3:10 PM	**PANEL DISCUSSION**
	• **Stephanie Wethington, MD,** U.S. Food and Drug Administration • **Naomi Horiba, MD, MPH,** U.S. Food and Drug Administration • **Christine Gause, PhD,** Merck • **Manju George, PhD, MVSc,** Colontown • **Cristina Migali, MD, PhD,** European Medicines Agency • **Thomas Powles, MD,** Barts-Cancer Institute, London
3:55PM	**Concluding Remarks** **Harpreet Singh, MD,** U.S. Food and Drug Administration
4:00 PM	**ADJOURN**