2026 AAADV FOUNDATION WORKSHOP

FINAL CONFERENCE AGENDA

THURSDAY · NOVEMBER 5

NORTH BETHESDA, MARYLAND

8:30 AM

Registration & Breakfast

9:30 AM

Welcome, Introductions & Sponsor Acknowledgements

Richard L. Schilsky, MD, FACP, FSCT, FASCO
Professor Emeritus, University of Chicago; Chair, AAADV Workshop Foundation; Program Committee Member, AAADV Workshop
Opening Remarks on Behalf of the AAADV Workshop Foundation

Renzo Canetta, MD
Board member, AAADV Foundation; Chair, Program Committee, AAADV Workshop
Workshop Overview & Program Committee Acknowledgements

H. Kim Lyerly, MD
Executive Director, AAADV Workshop Foundation
Sponsor Acknowledgements

10:00 AM / KEYNOTE I

The Right Patient, on the Right Trial, at the Right Time

Monica Bertagnolli, MD (Virtual)
President, National Academy of Medicine

10:30 AM / KEYNOTE II

Globalization of Cancer Drug Development: A Fireside Chat

Richard L. Schilsky, MD, FACP, FSCT, FASCO
Professor Emeritus, University of Chicago; Chair, AAADV Workshop Foundation; Program Committee Member, AAADV Workshop

Richard Pazdur, MD
Founding Director (former), FDA Oncology Center of Excellence

11:00 AM / SESSION 1

Balancing Benefit and Risk in Regulatory Decision-Making

MODERATOR

Thomas R. Fleming, PhD (Virtual)
Professor of Biostatistics, University of Washington; Board member, AAADV Workshop Foundation; Program Committee Member, AAADV Workshop

Robert M. Califf, MD, MACC
Former Commissioner, U.S. FDA; Donald F. Fortin Distinguished Professor of Cardiology, Duke University School of Medicine
Managing/Addressing Uncertainty in Drug Development: Balancing Pre- and Post-Approval Evidence Generation

Harald Enzmann, MD, PhD
Head, European and International Affairs, BfArM; former Chair, EMA CHMP
Overview of Regulatory Benefit-Risk Assessment Frameworks

Scott Evans, PhD, MS
Professor and Founding Chair, Biostatistics and Bioinformatics, George Washington University; Board Member, AAADV Workshop Foundation; Program Committee Member, AAADV Workshop
Considerations for Designing and Analyzing Oncology MRCTs

12:30 PM

Lunch Break — Day 1

1:00 PM / SESSION 2

Multi-Regional Clinical Trials (MRCTs)

MODERATOR

Jaap Verweij, MD, PhD
Professor Emeritus, Erasmus University Medical Center; Board Member, Cancer Drug Development Forum; Program Committee Member, AAADV Workshop

Eva Skovlund, MSc Pharm, PhD
Professor of Medical Statistics, Norwegian University of Science and Technology (NTNU), Trondheim; Special adviser Norwegian Medical Products Agency. Member, EMA-CHMP
Considerations for Evidence Generation in Multiregional Clinical Trials: A European Regulatory Perspective

Susan Galbraith, MBBChir, PhD (Virtual)
Executive Vice President, Oncology Hematology R&D, AstraZeneca; Board Member, AAADV Workshop Foundation
Multiregional Oncology Development Programs for Global Regulatory Decision-Making: An Industry Perspective

Scott Evans, PhD, MS
Professor and Founding Chair, Biostatistics and Bioinformatics, George Washington University; Board Member, AAADV Workshop Foundation; Program Committee Member, AAADV Workshop
Key Considerations for Designing and Analyzing Oncology MRCTs

3:30 PM / SESSION 3

Dose Optimization for Novel Therapeutics

MODERATOR

Vivek Subbiah, MD
Associate Director for Drug Development & Precision Oncology, Stanford Cancer Institute; Professor of Medicine, Stanford University; Program Committee Member, AAADV Workshop

Tim Yap, MD (Virtual)
MD Anderson Cancer Center
Project Optimus: Implications for Early Oncology Trials

Patricia LoRusso, DO
Yale University
Dose Optimization in Novel Modalities: ADCs, Bispecifics, and Beyond

Murad Melhem, MD
GlaxoSmithKline (GSK)
The Industry Perspective: Implementing Optimized Dose-Finding Strategies

5:30–7:00 PM / SESSION X

Cancer Drug Development in China

MODERATOR

Ke Liu, MD, PhD
Chief Development Officer, Marengo Therapeutics, Inc.
Welcome & framing remarks

CO-MODERATOR

Jun Ren, MD, PhD (Virtual)
Ruijin Hospital, Shanghai Jiao Tong University

PANELISTS

Xiaoyuan Chen, PhD
Professor, Tsinghua University; former NMPA reviewer
Evolution in Regulatory System and Clinical Trial Regulation in China

Dan Zhang, MD
Co-Founder and Co-Chairman, Jiangsu Hengrui Biopharma
Why Speed Matters: China's Clinical and Manufacturing Advantage

Jian Wang, PhD
Head, Global Regulatory Affairs, Hengrui USA / Jiangsu Hengrui Pharmaceutical
Oncology Drug Development in China — A Chinese Pharma Perspective

Hui Zhou, PhD (Virtual)
Innovent Bio

MODERATED DISCUSSION

Ke Liu, MD, PhD
Marengo Therapeutics, Inc.

Jun Ren, MD, PhD (Virtual)
Ruijin Hospital, Shanghai Jiao Tong University

In person: Xiaoyuan Chen, Jian Wang, Dan Zhang and Ke Liu. All other Session X speakers are virtual.

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9:00 AM

Breakfast

9:45 AM

Introductory Remarks

H. Kim Lyerly, MD
Executive Director, AAADV Workshop Foundation

10:00 AM / KEYNOTE III

Expediting the Expedited: Advancing the Pace of Medical Product Development

Peter Marks, MD, PhD
Former Director, FDA Center for Biologics Evaluation and Research; Board Member, AAADV Workshop Foundation; Program Committee Member, AAADV Workshop

10:30 AM / SESSION 4

Mitigating I(o) Toxicity

MODERATORS

Elad Sharon, MD, MPH
Dana-Farber Cancer Institute and Harvard Medical School; Program Committee Member, AAADV Workshop

Brandy Heckman-Stoddard, PhD, MPH
National Cancer Institute, National Institutes of Health

SPEAKERS

Kevin N. Heller, MD
Venture Partner, Oncology, Harbour BioMed

Historical Perspective on Infliximab Labeling for Immune-Related Adverse Events: On-Label for Ipilimumab, Off-Label for Infliximab

Tomas G. Neilan, MD, MPH, MRCPI
Director, Cardio-Oncology Program, Massachusetts General Hospital; Professor of Medicine, Harvard Medical School

The Largest Myocarditis Trial in the Field: Lessons from an IND-Exempt 183-Patient Study

Professor Dr. Robert Zeiser, MD (Virtual)
Department of Hematology and Oncology, University of Freiburg, Germany

Novel therapies for acute GVHD and immune mediated side effects after ICI

12:00 PM

Lunch Break — Day 2

1:00 PM / KEYNOTE IV

Price Is What You Pay, Value Is What You Get

Thomas G. Roberts, MD
Farallon Capital Management

1:30 PM / SESSION 5

Me Too or Not Me Too

MODERATOR

Eric Rubin, MD
Former Senior Vice President, Clinical Oncology, Merck; Board Member, AAADV Workshop Foundation; Program Committee Member, AAADV Workshop

SPEAKERS

Ronald Alan Peck, MD
Veritas Oncology, LLC

Beyond "Me Too": Potential Evolution of PD-(L)1 Therapy

Edith Perez, MD
Cornerstone Network; Professor Emeritus, Mayo Clinic

ERBB-Targeted Therapies: Increased Understanding of the Initial Target and Its Expansion; Patient Selection, Comparator Choice, and Non-Inferiority vs. Superiority Considerations

Samer Al Hadidi, MD, MS (CRDSA), FACP
Harold C. Simmons Comprehensive Cancer Center

BCMA Saturation: Redundancy or Real Choice?

Invited Discussant: Christine Hodgdon
Guiding Researchers & Advocates to Scientific Partnerships – GRASP

3:30 PM / SESSION 6

Failure to Launch

MODERATOR

H. Kim Lyerly, MD
Executive Director, AAADV Workshop Foundation

SPEAKERS

Meera Mohan, MD, MS, FACP
Associate Professor of Medicine, Lymphoma/Myeloma, UT MD Anderson Cancer Center

Belantamab Mafodotin in Combination with Pomalidomide and Dexamethasone

Renzo Canetta, MD
Board member, AAADV Foundation; Chair, Program Committee, AAADV Workshop

Camrelizumab (PD-1) and Rivoceranib (VEGFr) for HCC: Combination of Two Non-Approved Components

Lynn M. Schuchter, MD
Milday and Leonard Abramson Professor of Clinical Oncology; Director, Tara Miller Melanoma Center

Vusolimogene Oderparepvec and Nivolumab

Invited Discussant: Kristin McJunkins
Advocate; Yale College

5:00 PM

Adjourn / Closing Remarks

H. Kim Lyerly, MD
Executive Director, AAADV Workshop Foundation

Wrap-up and acknowledgements