AAADV
Accelerating Anticancer Agent Development and Validation

2026 Workshop

CONFERENCE PROGRAM / FINAL AGENDA

THURSDAY

NOVEMBER 5, 2026

Virtual speakers indicated in rust

9:00 AM

Registration & Breakfast

9:30 AM

Welcome, Introductions, and Sponsor Acknowledgements

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

Renzo Canetta, MD
Chair, AAADV Workshop Foundation
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; 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; Member, AAADV Workshop Foundation Program Committee; Program Committee Member, AAADV Workshop

SPEAKERS

Robert M. Califf, MD, MACC
Former Commissioner, U.S. Food and Drug Administration; Donald F. Fortin, M.D. 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, Section European and International Affairs, German Federal Institute for Drugs and Medical Devices (BfArM); Former Chair, EMA Committee for Medicinal Products for Human Use (CHMP)
Overview of Regulatory Benefit-Risk Assessment Frameworks: Evidentiary Standards for Approval of Oncology Medicines

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

12:30 PM | LUNCH BREAK

Lunch: Day 1

1:30 PM | SESSION 2

Multi-Regional Clinical Trials (MRCTs)

MODERATOR

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

SPEAKERS

Eva Skovlund, MSc Pharm, PhD
Professor of Medical Statistics, Norwegian University of Science and Technology (NTNU); Senior Researcher, Norwegian Institute of Public Health; Member, EMA-CHMP; Board Member, Cancer Drug Development Forum (CDDF)
Considerations for Evidence Generation in Multiregional Clinical Trials: A European Regulatory Perspective

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

Scott Evans, PhD, MS
Professor and Founding Chair, Department of Biostatistics and Bioinformatics, George Washington University Milken Institute School of Public Health; Member, AAADV Workshop Foundation Program Committee; Board Member, AAADV Foundation
Key Considerations for Designing and Analyzing Oncology MRCTs to Support Robust Evidence Generation

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 (Oncology), Stanford University School of Medicine; Program Committee Member, AAADV Workshop

SPEAKERS

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

Patricia LoRusso, MD
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)
Professor at Ruijin Hospital, Shanghai Jiao Tong University

PANELISTS

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

Hui Zhou, PhD (Virtual)
Innovent Bio

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

Jian Wang, PhD
Head, Global Regulatory Affairs, Hengrui USA, Jiangsu Hengrui Pharmaceutical Co., Ltd.
Oncology Drug Development in China – A Chinese Pharma Perspective

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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FRIDAY

NOVEMBER 6, 2026

Virtual speakers indicated in rust

9:00 AM

Breakfast

9:45 AM

Introductory Remarks

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

Sponsor Acknowledgements

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 Foundation

10:30 AM | SESSION 4

Mitigating IO 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, OncologyHarbour 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; co-Director, Cardiovascular Imaging Research Center (CIRC)/Cardiology Division, Massachusetts General Hospital; Michel and Kathryn Park Endowed Chair of Cardiology; Professor of Medicine, Harvard Medical School

The Largest Myocarditis Trial in the Field: Lessons from an IND-Exempt 183-Patient Study and Implications for Regulatory Pathways

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

Pending talk title

12:00 PM | LUNCH BREAK

Lunch: 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 Foundation

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 Hogdon
Guiding Researchers & Advocates to Scientific Partnership – GRASP

3:30 PM | SESSION 6

Failure to Launch

MODERATOR

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

SPEAKERS

Renzo Canetta, MD
Chair, AAADV Workshop Foundation

Camrelizumab (PD-1) and Rivoceranib (VEGF) for HCC: Combination of two non-approved components

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

Belantamab mafodotin in combination with pomalidomide and dexamethasone

Lynn M. Schuchter, MD
Madlyn 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