

OVERALL SURVIVAL IN ONCOLOGY CLINICAL TRIALS

July 18, 2023 | 8 a.m.-5 p.m. | Bethesda, Maryland



Welcome

Richard Pazdur, MD, *FDA*

INTRO:

Nicole Gormley, MD, *FDA*

WORKSHOP OVERVIEW:

Ken Anderson, MD, FAACR
Dana-Farber Cancer Institute

Ruixiao Lu, PhD
Alumis Inc./ASA

Session 1: Trial Design Considerations for Optimal Assessment of Overall Survival

MODERATOR:

Ken Anderson, MD, FAACR
Dana-Farber Cancer Institute

OVERVIEW OF RECOMMENDATIONS SESSION CHAIR:

Mikkael Sekeres, MD
*Sylvester Comprehensive Cancer Center
University of Miami*

ADDITIONAL PANELISTS:

- 'Lola Fashoyin-Aje, MD, MPH, *FDA*
- Alexei Ionan, PhD, *FDA*
- Margret Merino, MD, *FDA*
- Tatiana Prowell, MD, *FDA*
- Roy S. Herbst, MD, PhD, *Yale Cancer Center*
- Pabak Mukhopadhyay, PhD, *AstraZeneca*
- Anas Younes, MD, *AstraZeneca*
- Godwin Yung, PhD, *Genentech/Roche*

Session 2: Overall Survival as a Pre-specified Endpoint

MODERATOR:

Lisa Rodriguez, PhD, *FDA*

INTRO:

Michael Shan, PhD, *Bayer*

OVERVIEW OF RECOMMENDATIONS SESSION CHAIR:

Ruben Mesa, MD, *Atrium Health*

ADDITIONAL PANELISTS:

- R. Angelo de Claro, MD, *FDA*
- Xin Gao, PhD, *FDA*
- Jaleh Fallah, MD, *FDA*
- Jian Zhao, PhD, *FDA*
- Boris Freidlin, PhD, *NCI*
- George Demetri, MD, FAACR, *Dana-Farber Cancer Institute*
- Laura J. Esserman, MD, MBA, FAACR, *UCSF*
- Qi Xia, PhD, *AbbVie*

Session 3: Post-hoc Analyses of Overall Survival Endpoints

MODERATOR:

Jonathon Vallejo, PhD, *FDA*

INTRO:

Qing Xu, PhD, *FDA*

OVERVIEW OF RECOMMENDATIONS SESSION CHAIR:

Steven Snapinn, PhD, FASA
Seattle-Quilcene Biostatistics LLC

ADDITIONAL PANELISTS:

- Wenjuan Gu, PhD, *FDA*
- Bindu Kanapuru, MD, *FDA*
- Paz Vellanki, MD, PhD, *FDA*
- Grzegorz Nowakowski, MD, *Mayo Clinic*
- Qian Shi, PhD, *Mayo Clinic*
- Emmanuel Zuber, PhD, *Novartis Pharma AG*

Session 4: Subgroup Considerations

MODERATOR:

Ruixiao Lu, PhD
Alumis Inc./ASA

INTRO:

Anup Amatya, PhD, *FDA*

OVERVIEW OF RECOMMENDATIONS SESSION CHAIR:

Keith Flaherty, MD, FAACR
MGH Cancer Center

ADDITIONAL PANELISTS:

- Harpreet Singh, MD, *FDA*
- Jianjin Xu, PhD, *FDA*
- Elizabeth Garrett-Mayer, PhD, *ASCO*
- Marjorie C. Green, MD, *Merck*
- Mary Redman, PhD, *Fred Hutchinson Cancer Center*

Session 5: Incorporation of Overall Survival into the Benefit-Risk Assessment

MODERATOR:

Nicole Gormley, MD, *FDA*

OVERVIEW OF RECOMMENDATIONS SESSION CHAIR:

George Demetri, MD, FAACR
Dana-Farber Cancer Institute

ADDITIONAL PANELISTS:

- Pallavi Mishra-Kalyani, PhD, *FDA*
- Nicholas Richardson, DO, MPH, *FDA*
- Cong Chen, PhD, FASA, *Merck*
- David Mitchell, *Patient Advocate*
- Grzegorz Nowakowski, MD, *Mayo Clinic*
- Craig Tendler, MD, *Janssen of Johnson & Johnson*

Summary and Closing Remarks

Ken Anderson, MD, FAACR
Dana-Farber Cancer Institute

Lisa Rodriguez, PhD, *FDA*