



The Food and Drug Administration's Accelerated Approval Process for New Pharmaceuticals

A Virtual Workshop

January 30-31, 2023

AGENDA

January 30, 2023

12:00 pm *	Welcome
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Harold Varmus (Meyer Cancer Center, Weill Cornell Medicine), Co-chair, Committee on Science, Technology, and Law of the National Academies of Sciences, Engineering, and Medicine

Workshop Planning Committee Co-chairs:

Barbara E. Bierer, Harvard University and Brigham and Women's Hospital
William B. Schultz, Zuckerman Spaeder LLC

12:20 pm	The U.S. Food and Drug Administration's Accelerated Approval Program: An Overview
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Moderator: **William K. Hubbard,**** Independent Consultant

Speakers:

Jacqueline Corrigan-Curay, Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration
Joshua Sharfstein, Johns Hopkins Bloomberg School of Public Health

1:00 pm	Discussion with Committee
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1:30 pm	Q&A with Audience
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1:40 pm	Break
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1:55 pm	Surrogate Markers and Endpoints
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Moderator: **Frank W. Rockhold,**** Duke University Medical Center

Speakers:

David L. DeMets, University of Wisconsin, Madison

Peter Stein, Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration

Scott S. Emerson, University of Washington

Steve Pearson, Institute for Clinical and Economic Review (ICER)

2:40 pm	Discussion with Committee
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3:10 pm	Q&A with Audience
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3:20 pm	Break
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3:35 pm	Confirmatory Trials
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Moderator: **Barbara E. Bierer,**** Harvard University and Brigham and Women's Hospital

Speakers:

Joseph S. Ross, Yale University School of Medicine

Ginny Beakes-Read, Amgen

Marc Buyse, International Drug Development Institute

4:15 pm	Discussion with Committee
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4:45 pm	Q&A with Audience
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4:55 pm	Adjourn
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12:00 pm	Welcome
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12:05 pm	The Accelerated Approval Process: Potential Benefits and Adverse Consequences
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Moderator: **Halima Amjad**, ** Johns Hopkins University School of Medicine

Speakers:

John K. Jenkins, Greenleaf Health
Lee A. Fleisher, Center for Clinical Standards and Quality, Centers for Medicare and Medicaid Services
Donna Cryer, Global Liver Institute
Gideon Blumenthal, Merck
Aaron S. Kesselheim, Harvard Medical School

12:55 pm	Discussion with Committee
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1:25 pm	Q&A with Audience
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1:40 pm	Break
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1:55 pm	Other Nations' Approaches to Accelerated/Conditional Drug Approval
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Moderator: **Rogério Gaspar,**** World Health Organization

Speakers:

Yasuhiro Fujiwara, Pharmaceuticals and Medical Devices Agency (Japan)
Daniel O'Connor, Medicines and Healthcare products Regulatory Agency (UK)
Anabela Marçal, European Medicines Agency

2:35 pm	Discussion with Committee
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3:05 pm	Q&A with Audience
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3:15 pm	Accelerated Approval: New Directions
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Moderator: **William B. Schultz,**** Zuckerman Spaeder LLC

Speakers:

Pilar N. Ossorio, University of Wisconsin, Madison School of Law
Rachel Sherman, Rachel Sherman Partners LLC
Bert Leufkens, Utrecht University
Holly Fernandez Lynch, University of Pennsylvania

4:05 pm	Discussion with Committee
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4:35 pm	Q&A with Audience
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4:45 pm	Concluding Thoughts from Workshop Planning Committee
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Speakers:

Barbara E. Bierer, Harvard University and Brigham and Women's Hospital

William B. Schultz, Zuckerman Spaeder LLC

Halima Amjad, Johns Hopkins University School of Medicine

Rogério Gaspar, World Health Organization

William K. Hubbard, Independent Consultant

Frank W. Rockhold, Duke University Medical Center

5:15 pm	Adjourn
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***All times U.S. Eastern**

****Member of the workshop planning committee**