

Alternative Methodologies in Pharmaceutical Development (AMPD) Workshop

Please note that this draft is subject to change. Last updated October 2.

Sponsored by the NIH National Cancer Institute (NCI) and NIH Office of Research Innovation, Validation, and Application (ORIVA)

October 20-21, 2026

NIH Facility, 6001 Executive Blvd., Rockville, MD, 20852

Day 1: Tuesday, October 20, 2026

Time	Min.	Session Title (tentative)	Presenter
9:30 AM	30	Registration/Networking	
10:00 AM	15	Welcome and Opening Remarks	Anthony Letai, NCI, Director
		Session I: Current State of NAMs in Drug Development	
10:15 AM	20	The NIH View on NAMs in Biomedical Research and Drug Development	Margaret Ochocinska, NIH Office of the Director
10:35 AM	20	Overview of NAMs and Emerging Technologies	Helena Hogberg-Durdock, NIH ORIVA Division of the National Interagency Center for the Evaluation of Alternative Test Methods (D-NICEATM)
10:55 AM	5	ORIVA Effort to Identify Early Pre-Clinical Pharma Needs for NAMs	Amber Daniel, General Dynamics Information Technology, contractor supporting NIH ORIVA
11:00 AM	10	Break <i>Visit the interactive demonstration featuring phantoms from the National Medical Phantom Library (NMPL)</i>	

Attendees will be responsible for meals and/or light refreshments on their own, at their own cost. The Government and/or Government contractors are not involved in facilitating the provision of food and/or light refreshments.

Time	Min.	Session Title (tentative)	Presenter
		<i>during any of the breaks or before/after sessions</i>	
11:10 AM	20	Human-Relevant Models for Drug Development: Turning NAMs into Decision-Making Tools	Randy Daughters, Emulate, Inc.
11:30 AM	20	Opportunities for Human-Based NAMs in Drug Development	Thomas Hartung, Johns Hopkins University
11:50 AM	30	Panel Discussion and Q&A	
12:20 PM	80	Lunch	
		Session II: Regulatory and Scientific Barriers to NAM Adoption	
1:40 PM	20	Challenges in IND-Enabling Development Using NAMs	Chris Sheth, Aclairo
2:00 PM	20	Advancing Oncology Development Through Nonclinical Efficiency: Current Approaches and the Path Forward	Haleh Saber, Division of Hematology Oncology Toxicology (DHOT), FDA
2:20 PM	20	Industry Implementation Challenges	Imein Bousnina, Genentech
2:40 PM	30	Panel Discussion and Q&A	
3:10 PM	15	Break	
		Session III: Regulatory and Government Initiatives and Future Directions	
3:25 PM	20	FDA Initiatives Supporting NAM Adoption	Jeffrey Siegel, FDA Center for Drug Evaluation and Research (CDER), Office of Drug Evaluation Sciences (ODES)
3:45 PM	20	International Regulatory Perspectives	Sonja Beken, Belgian Federal Agency for Medicines and Health Products (FAMHP)
4:05 PM	20	NIH and Federal Programs Supporting NAM Development	Warren Casey, NIH ORIVA
4:25 PM	20	How the Catalyze Program is Supporting NAMs	Rahul Thakar, NIH/NHLBI
4:45 PM	30	Panel Discussion and Q&A	
5:15 PM	5	Day 1 Wrap-Up	

Attendees will be responsible for meals and/or light refreshments on their own, at their own cost. The Government and/or Government contractors are not involved in facilitating the provision of food and/or light refreshments.

Day 2: Wednesday, October 21, 2026

Time	Min.	Session Title	Presenter
		Session IV: NAMs in Disease Biology and Biomedical Research	
10:00 AM	20	NAMs in Biomedical Research and Disease Modeling	Joseph Wu, Stanford University School of Medicine
10:20 AM	20	Organoids and Tissue Microenvironment Models	Michael Shen, Columbia University
10:40 AM	20	Organ-on-Chip and Microphysiological Systems in Practice	Jason Meyer, Indiana University School of Medicine
11:00 AM	20	Human-Based Technologies Using AI and Computational Applications	Rong Xu, Case Western Reserve University
11:20 AM	20	Development of Human Microphysiological Systems for Modeling Disease Complexity and Testing Interventional Strategies for Alzheimer's Disease	Anna Curle, Mass General Brigham & Harvard Medical School
11:40 AM	30	Panel Discussion and Q&A	
12:10 PM	10	Day 2 Wrap-Up	

Attendees will be responsible for meals and/or light refreshments on their own, at their own cost. The Government and/or Government contractors are not involved in facilitating the provision of food and/or light refreshments.