

# Alternative Methods in Pharmaceutical Development (AMPD) Workshop

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     | Session Title                                                                       | Presenter                                                                                                                                |
|----------|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| 9:30 AM  | Registration/Networking                                                             |                                                                                                                                          |
| 10:00 AM | Welcome and Opening Remarks                                                         | Brian Cholewa, NCI                                                                                                                       |
|          | Session I: Current State of NAMs in Drug Development                                | Chairs: Warren Casey (NIH ORIVA), Piotr Grodzinski (NIH/NCI)                                                                             |
| 10:10 AM | The NIH View on NAMs in Biomedical Research and Drug Development                    | Margaret Ochocinska, NIH Office of the Director                                                                                          |
| 10:30 AM | 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) |
| 10:50 AM | Human-Relevant Models for Drug Development: Turning NAMs into Decision-Making Tools | Randy Daughters, Emulate, Inc.                                                                                                           |
| 11:10 AM | Opportunities for Human-Based NAMs in Drug Development                              | Thomas Hartung, Johns Hopkins University                                                                                                 |
| 11:30 AM | Panel Discussion and Q&A                                                            |                                                                                                                                          |
| 12:00 PM | ORIVA Effort to Identify Early Pre-Clinical Pharma Needs for NAMs                   | Amber Daniel, General Dynamics Information Technology, contractor supporting NIH ORIVA                                                   |
| 12:05 PM | Lunch                                                                               |                                                                                                                                          |
|          | Session II: Regulatory and Scientific Barriers to NAM Adoption                      | Chairs: Jue Chen (NIH/NHLBI), Brian Cholewa (NIH/NCI)                                                                                    |
| 1:25 PM  | Challenges in IND-Enabling Development Using NAMs                                   | Chris Sheth, Aclairo                                                                                                                     |

*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           | Session Title                                                                                                                                                                             | Presenter                                                                                                     |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|
| 1:45 PM        | Advancing Oncology Development Through Nonclinical Efficiency: Current Approaches and the Path Forward                                                                                    | Haleh Saber, Division of Hematology Oncology Toxicology (DHOT), FDA                                           |
| 2:05 PM        | Industry Implementation Challenges                                                                                                                                                        | Imein Bousnina, Genentech                                                                                     |
| 2:25 PM        | Panel Discussion and Q&A                                                                                                                                                                  |                                                                                                               |
| 2:55 PM        | Break<br><i>Visit the interactive demonstration featuring phantoms from the <a href="#">National Medical Phantom Library (NMPL)</a> during any of the breaks or before/after sessions</i> |                                                                                                               |
| <b>3:10 PM</b> | <b>Special Remarks</b>                                                                                                                                                                    | <b>Anthony Letai, NCI, Director</b>                                                                           |
|                | Session III: Regulatory and Government Initiatives and Future Directions                                                                                                                  | Chairs: Margaret Ochocinska (NIH/OD), David White (NIH/NIDA)                                                  |
| 3:20 PM        | FDA Initiatives Supporting NAM Adoption                                                                                                                                                   | Jeffrey Siegel, FDA Center for Drug Evaluation and Research (CDER), Office of Drug Evaluation Sciences (ODES) |
| 3:40 PM        | International Regulatory Perspectives                                                                                                                                                     | Sonja Beken, Belgian Federal Agency for Medicines and Health Products (FAMHP)                                 |
| 4:00 PM        | NIH and Federal Programs Supporting NAM Development                                                                                                                                       | Warren Casey, NIH ORIVA                                                                                       |
| 4:20 PM        | How the Catalyze Program is Supporting NAMs                                                                                                                                               | Rahul Thakar, NIH/NHLBI                                                                                       |
| 4:40 PM        | Panel Discussion and Q&A                                                                                                                                                                  |                                                                                                               |
| 5:10 PM        | Day 1 Wrap-Up                                                                                                                                                                             |                                                                                                               |

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## Day 2: Wednesday, October 21, 2026

| Time     | Session Title                                                                                                                                 | Presenter                                                 |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
|          | Session IV: NAMs in Disease Biology and Biomedical Research                                                                                   | Chairs: Ronald Johnson (NIH/NCI), Rajeev Agarwal (NIH/OD) |
| 10:00 AM | NAMs in Biomedical Research and Disease Modeling                                                                                              | Joseph Wu, Stanford University School of Medicine         |
| 10:20 AM | Organoids and Tissue Microenvironment Models                                                                                                  | Michael Shen, Columbia University                         |
| 10:40 AM | Organ-on-Chip and Microphysiological Systems in Practice                                                                                      | Jason Meyer, Indiana University School of Medicine        |
| 11:00 AM | Human-Based Technologies Using AI and Computational Applications                                                                              | Rong Xu, Case Western Reserve University                  |
| 11:20 AM | 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 | Panel Discussion and Q&A                                                                                                                      |                                                           |
| 12:10 PM | Day 2 Wrap-Up                                                                                                                                 |                                                           |

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