



FDA–NIH Workshop: Reducing Animal Testing July 7, 2025 Agenda

EST Time	Presentation/Presenter
10:00 am	<p><u>FDA Introductions: Opening and Welcome Remarks (60 min)</u></p> <p>Marty Makary, M.D., M.P.H. FDA Commissioner</p> <p>Tracy Beth Høeg, M.D., Ph.D. Senior Advisor for Clinical Sciences, Office of the Commissioner & Center for Biologics Evaluation and Research</p> <p>Jacqueline Corrigan-Curay, J.D, M.D. Acting Director, Center for Drug Evaluation and Research</p> <p>Haleh Saber, Ph.D. Division Director of Hematology, Oncology and Toxicology, Center for Drug Evaluation and Research</p> <p>Steven Musser, Ph.D. Associate Commissioner for Human Foods Research</p> <p>Q&A (10 min)</p>
11:00 am	Break (10 min)
11:10 am	<p><u>FDA Presentations: AI, Toxicology, Implementation (40 min)</u></p> <p>Jeremy Walsh Chief Artificial Intelligence Officer</p> <p>Tucker Patterson, Ph.D. Director, National Center for Toxicological Research</p> <p>Steve Kozlowski, M.D. Acting Chief Scientist</p> <p>Tracy Chen, Ph.D., D.A.B.T. Senior Advisor, Regulatory Science Collaborative Community, Office of the Chief Scientist</p>



11:50 am	Lunch/In-Person Q&A (25 min)
12:15 pm	<u>NIH and ARPA-H Presentations (40 min)</u> Nicole Kleinstreuer, Ph.D. Acting NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives, National Institutes of Health Warren Casey, Ph.D., DABT Director of Strategic Partnerships in the Office of Portfolio Strategy and Research Management, Division of Translational Toxicology, National Institute of Environmental Health Sciences, National Institutes of Health Brian Cholewa, Ph.D. Senior Toxicologist/Program Director, Chemopreventive Agent Development Research Group, National Cancer Institute, National Institutes of Health Andrew Kilianski, Ph.D. Acting Deputy Director, Health Science Futures, Advanced Research Projects Agency for Health (ARPA-H)
12:55 pm	Break/In-Person Q&A (10 min)
1:05 pm	<u>International Regulator Presentations (40 min)</u> Sonja Beken, Ph.D. MSc Chair 3 Rs Working Party (3RsWP), European Medicines Agency (EMA) (Belgium) Philip Marx-Stoelting, Ph.D. Scientific Director, Testing and Assessment Strategies, Pesticides Safety Department, German Federal Institute for Risk Assessment (BfR or Bundesinstitut für Risikobewertung) (Germany) Mineo Matsumoto, Ph.D. Associate Senior Scientist for Toxicology, Office of New Drug V, Pharmaceuticals and Medical Devices Agency (PMDA) with Jihei Nishimura, Ph.D. Associate Senior Scientist for Toxicology, Office of New Drug IV, Pharmaceuticals and Medical Devices Agency (PMDA) (Japan) Colin Clyne, Ph.D., B.Sc. Senior Toxicologist, Therapeutic Goods Administration (Australia)



1:45 pm	<u>Questions and Closing Remarks (15 min)</u> Marty Makary, M.D., M.P.H. FDA Commissioner Tracy Beth Høeg, M.D., Ph.D. Senior Advisor for Clinical Sciences, Office of the Commissioner & Center for Biologics Evaluation and Research
NLT 2:00 pm	Adjourn