

STATE OF THE SCIENCE ON DEVELOPMENT AND USE OF NAMS FOR CHEMICAL SAFETY TESTING

Location: U.S. Environmental Protection Agency
William Jefferson Clinton East Building
William D. Ruckelshaus Conference Center



Date: October 12-13, 2022

Agenda

12:30 pm – 1:00 pm Registration/Check-In

Day 1 Welcome and Opening

1:00 pm – 1:10 pm Welcome Christopher Frey (EPA)

1:10 pm – 1:25 pm Current Status and Key Goals for the Meeting Rusty Thomas (EPA)

Variability and Relevance of Traditional Toxicity Tests

1:25 pm – 1:40 pm Variability in Chronic Rodent Bioassays Christoph Helma (In Silico Toxicology GmbH)

1:40 pm – 2:00 pm Using Big Data to Evaluate the Concordance of Toxicity of Pharmaceuticals in Animals and Humans Thomas Steger-Hartmann (Bayer)

2:00 pm – 2:20 pm Conservation of Pharmacodynamic and Pharmacokinetic Modes-of-Action in Rodents and Humans Alan Boobis (Imperial College)

2:20 pm – 2:40 pm Break

Variability and Relevance of Current Animal Tests and Expectations for NAMS

2:40 pm – 3:00 pm Variability and Relevance of Animal Studies for Acute Toxicity, Skin Sensitization, and Mechanistic Responses Nicole Kleinstreuer (NICEATM)

3:00 pm – 3:20 pm Qualitative and Quantitative Variability of Repeat Dose Animal Toxicity Studies Katie Paul-Friedman (EPA)

3:20 pm – 3:40 pm Inter-Species Concordance of Toxicological Endpoints Chad Blystone (NIEHS)

3:40 pm – 4:00 pm	Concordance of the Toxicity of Pharmaceuticals in Animals and Humans: Lessons from the DruSafe Consortium	Tom Monticello (Amgen)
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Concurrent Breakout Group Discussions

4:00 pm – 5:20 pm	Multiple Groups with Discussion Leads	EPA Staff
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Closing

5:20 pm – 5:30 pm	Closing	Michal Freedhoff (EPA)
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12:30 pm – 1:00 pm	Registration/Check-In	
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Day 2 Welcome and Opening

1:00 pm – 1:10 pm	Welcome	Rick Keigwin (EPA)
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1:10 pm – 1:40 pm	Report Out from Discussion Groups	Tala Henry (EPA)
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Evolution of Validation and Scientific Confidence Frameworks to Incorporate 21st Century Science

1:40 pm – 2:00 pm	ICCVAM Strategic Roadmap for Validating New Methods	Warren Casey (NIEHS)
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2:00 pm – 2:20 pm	CPSC NAM Guidance	John Gordon (CPSC)
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2:20 pm – 2:40 pm	Predictive Toxicology Roadmap at FDA	Suzanne Fitzpatrick (FDA)
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2:40 pm – 3:00 pm	Evolution of Validation and Scientific Confidence in Europe	Maurice Whelan (JRC)
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3:00 pm – 3:20 pm	OECD Perspectives on the Future of NAMs, Mutual Acceptance of Data, and Test Guidelines	Patience Browne (OECD)
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3:20 pm – 3:50 pm	Break	
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3:50 pm – 4:10 pm	Draft Outline for the EPA Scientific Confidence Framework	Alison Harrill (EPA)
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4:10 pm – 5:10 pm	Panel Discussion on Validation and Scientific Confidence Frameworks	Doug Wolf (Syngenta) Sue Marty (Dow Chemical) Kristie Sullivan (PCRM) Rashmi Joglekar (Earth Justice)
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Closing

5:10 pm – 5:30 pm	Closing	Maureen Gwinn (EPA)
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