The comments in this presentation are those of the Validation Workgroup. They have not been reviewed or approved by, and may not necessarily reflect the views of any federal agency.

Validation Workgroup

SACATM

September 29, 2021

Agency for Toxic Substances and Disease Registry • Consumer Product Safety Commission • Department of Agriculture • Department of Defense
Department of Energy • Department of the Interior • Department of Transportation • Department of Veterans Affairs Office of Research and Development
Environmental Protection Agency • Food and Drug Administration • National Cancer Institute • National Institute for Occupational Safety and Health
National Institute of Environmental Health Sciences • National Institute of Standards and Technology • National Institutes of Health
National Library of Medicine • Occupational Safety and Health Administration

Validation Workgroup Roster

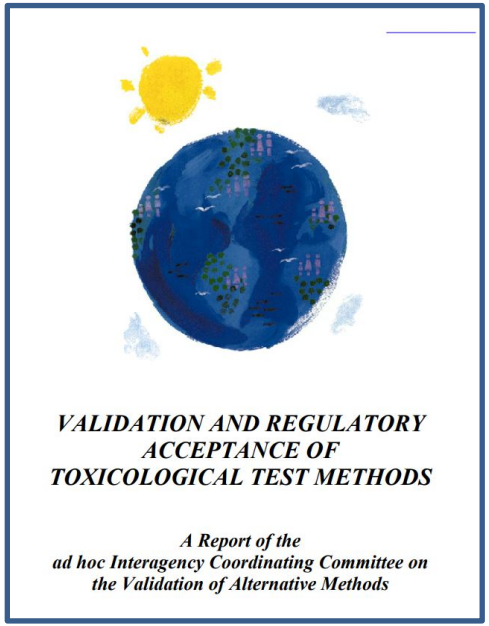
ATSDR	Moiz Mumtaz, PhD
CPSC	John Gordon, PhD (Co-chair)
DOD	Donald Cronce, PhD
DOD	Natalia Garcia-Reyero Vinas, PhD
DOD	Matthew Johnson, DVM, DACLAM
DOD	Emily N. Reinke, PhD, DABT
VA ORD	George Lathrop, Jr., DVM, MS, DACLAM
EPA/OPP	Anna Lowit, PhD
EPA/OPP	Scott Lynn, PhD
EPA/OPP	Monique Perron, PhD
EPA/ORD	Stephanie Padilla, PhD
EPA/ORD	Nisha Sipes, PhD
FDA/CDER	Paul C. Brown, PhD
FDA/CDRH	Jennifer Goode, BS
FDA/CFSAN	Suzanne Fitzpatrick, PhD, DABT (Co-chair)
FDA/CFSAN	Anneliese Striz, PhD
FDA/CTP	Jueichuan (Connie) Kang, PhD
FDA/OCS	Tracy Chen, PhD, DABT
NIEHS	Warren Casey, PhD, DABT
NIEHS	Nicole Kleinstreuer, PhD
NIST	Elijah Petersen, PhD (Co-chair)
OSHA	Janet Carter, MS, MPH

NICEATM Support Staff:

ILS	David Allen, PhD
ILS	Amber Daniel, MTox
ILS	Agnes Karmaus, PhD

ICCVAM: Validation Workgroup

Updating the ICCVAM Report



NIH PUBLICATION NO: 97-3981

National Institute of Environmental Health Sciences
Research Triangle Park, North Carolina 27709

National Institutes of Health
U.S. Public Health Service
Department of Health and Human Services

March 1997

Topics of Consideration

1. Foster the use of efficient, flexible, and robust practices to establish confidence in new methods
   - Clearly delineate testing requirements and context of use
   - Promote the use of new approaches for establishing confidence
   - Utilize public-private partnerships to promote cross-sector communication and cooperation

Topics of Consideration

2. Developing and evaluating flexible practices that consider context of use to build confidence in new methods
   - Biological and mechanistic relevance to human or appropriate taxa
     - Components of NAMs and how they map to taxa appropriate mechanistic information (e.g., using AOP frameworks)
     - Integrating multiple NAMs together into IATAs and DAs that provide sufficient biological coverage to predict endpoints in humans or other species of interest
   - Characterization of the animal reference data and their relevance to humans or other relevant taxa
   - Case studies/examples

Topics of Consideration

3. Recommendations to facilitate regulatory acceptance
   - Regulatory considerations
     - Understanding regulatory needs and decision contexts
   - Understanding how NAMs fit into regulatory requirements/decision contexts
     - Application within context of use/fit for purpose
     - Regulatory decision frameworks (e.g., classification and labeling, risk assessment)
   - Intra- and interagency coordination and harmonization
   - Communication and training to encourage use of NAMs

Topics of Consideration

4. Determine how new principles of validation can fit into a globally harmonized approach to allow for continued mutual acceptance of data

5. Reference existing and well-vetted documents (e.g., GIVIMP, OECD GD34, GD69 on QSAR Validation, FDA Guidance for Industry, etc.)

6. Outlining best practices
   - Sensitivity, reproducibility, robustness, etc.

Topics of Consideration

7. Examining best practices for quality and quality systems development
   - Incorporation of selected quality tools
     - Control charting
     - In-process control measurements
     - Flowcharts
     - Check sheets
   - Building a statistical model
   - Setting specifications

Next Steps

- Moving forward:
  - Format and organization of the document still under consideration.
  - VWG members and NICEATM staff will contribute to the drafting and editing.
  - ICCVAM at large will review and provide comment.
  - We encourage stakeholders to comment on the document.