



Interagency Coordinating Committee on the Validation of Alternative Methods

Report on ICCVAM and NICEATM Activities

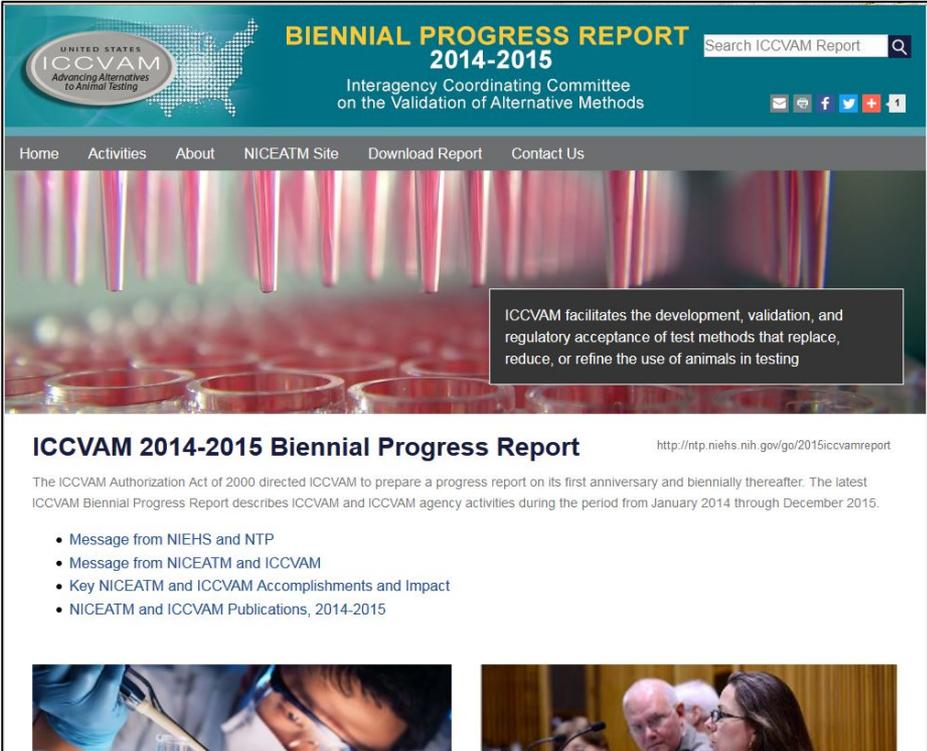
Nicole Kleinstreuer, Ph.D.
Deputy Director, NICEATM

National Institute of Environmental Health Sciences
SACATM Meeting, September 27, 2016
Research Triangle Park, NC

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
Environmental Protection Agency • Food and Drug Administration • National Institute for Occupational Safety and Health
National Institutes of Health • National Cancer Institute • National Institute of Environmental Health Sciences
National Library of Medicine • Occupational Safety and Health Administration

ICCVAM Biennial Progress Report

- Congressionally mandated
- Comprehensive summary of member agency activities (2014-2015) relevant to the ICCVAM mission
- This and future editions will be published as searchable websites; downloadable PDF available
- Published August 2016



UNITED STATES
ICCVAM
Advancing Alternatives
to Animal Testing

BIENNIAL PROGRESS REPORT
2014-2015

Search ICCVAM Report

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on the Validation of Alternative Methods

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ICCVAM facilitates the development, validation, and regulatory acceptance of test methods that replace, reduce, or refine the use of animals in testing

ICCVAM 2014-2015 Biennial Progress Report <http://ntp.niehs.nih.gov/go/2015iccvamreport>

The ICCVAM Authorization Act of 2000 directed ICCVAM to prepare a progress report on its first anniversary and biennially thereafter. The latest ICCVAM Biennial Progress Report describes ICCVAM and ICCVAM agency activities during the period from January 2014 through December 2015.

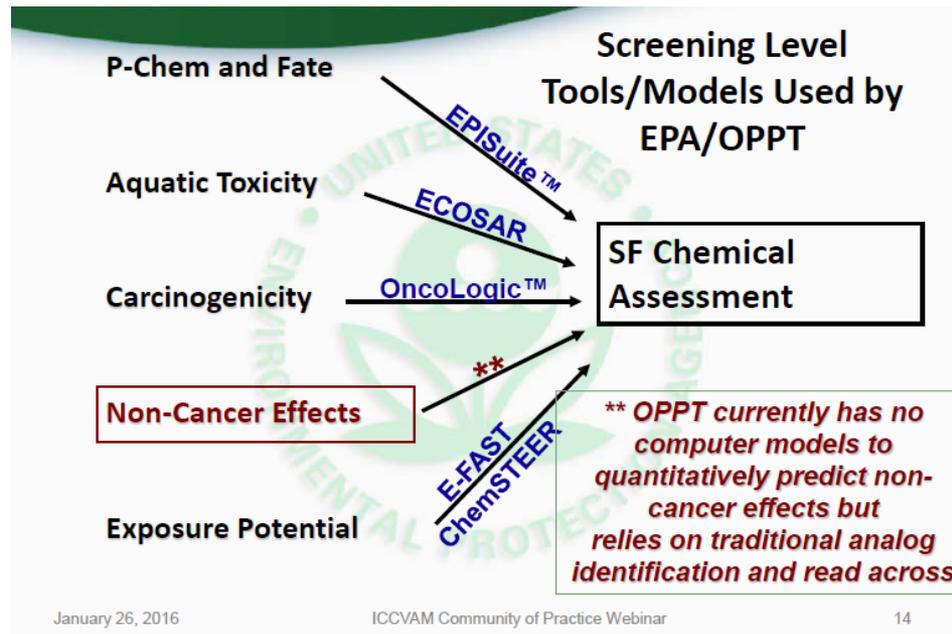
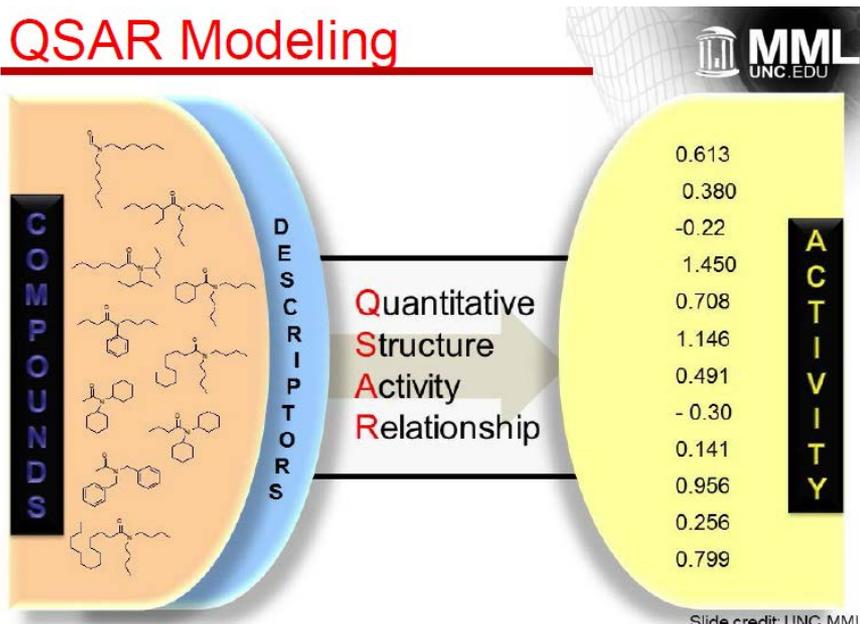
- Message from NIEHS and NTP
- Message from NICEATM and ICCVAM
- Key NICEATM and ICCVAM Accomplishments and Impact
- NICEATM and ICCVAM Publications, 2014-2015



Communities of Practice Webinar

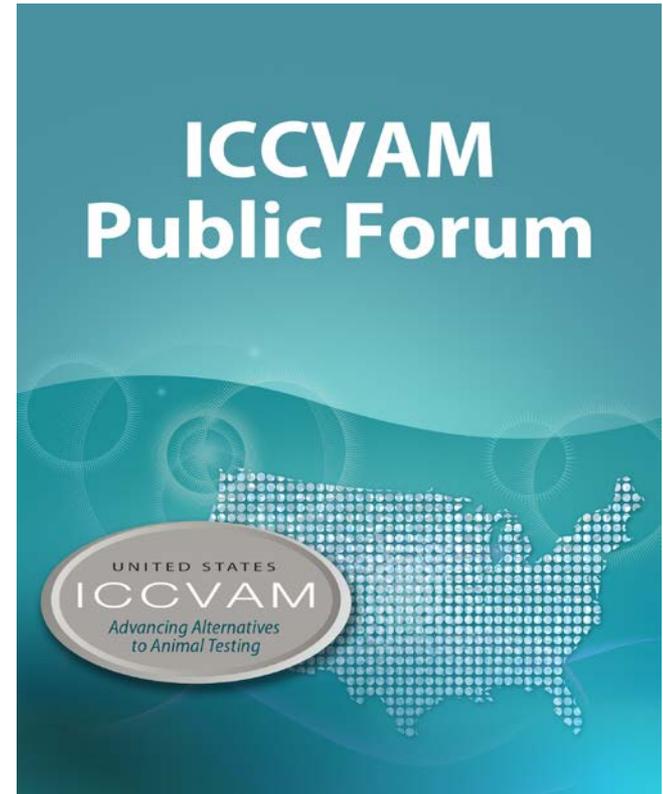
- Fundamentals of Using Quantitative Structure-Activity Relationship Models and Read-across Techniques in Predictive Toxicology, Jan 2016
 - Alex Tropsha, Ph.D., University of North Carolina at Chapel Hill
 - Louis Scarano, Ph.D., Office of Pollution Prevention and Toxics, EPA

QSAR Modeling



ICCVAM Public Forum

- May 25, 2016
Natcher Conference Center
NIH, Bethesda, MD
- Updates by NICEATM and ICCVAM agencies
on current activities
- 33 in-person (from 12 ICCVAM agencies)
and 160 webcast views
- Opportunities for public comments and
questions
- Roadmap concept for replacing animal use
for the “6-pack”
- Implementation Plan
- Next ICCVAM Public Forum: May 23, 2017



Alternatives for Acute Toxicity Workshop

- Over 60 participants from industry, academia, NGOs, and regulatory agencies
- Breakout groups charged with identifying key aspects to address in order to replace the in vivo acute systemic toxicity test methods within 3 years
- Recommendations included:
 - Publish a white paper on the regulatory landscape
 - Organize expert groups that will focus on specific tasks (resulted in the Sep 2016 inhalation tox workshop)
 - Work towards global harmonization of testing requirements
 - Provide training and promotion of alternative approaches
 - Collect and collate available data in centralized repositories
- Workshop report submitted (Tox In Vitro)
- See also <http://ntp.niehs.nih.gov/go/atwksp-2015>

 National Toxicology Program
 U.S. Department of Health and Human Services

Alternative Approaches for Identifying Acute Systemic Toxicity: Moving From Research to Regulatory Testing

September 24 – 25, 2015
9:00 a.m. – 5:00 p.m.

Porter Neuroscience Research Center
 National Institutes of Health
 Bethesda, Maryland

For agenda and registration information, visit
<http://ntp.niehs.nih.gov/go/atwksp-2015>




Individuals with disabilities who need accommodation to participate in this event should contact Elizabeth Maull at 919-316-4668 or maull@niehs.nih.gov. TTY users should contact the Federal TTY Relay Service at 800-877-8339. Requests should be made at least 5 business days in advance of the event.

 **PCRM** Physicians Committee for Responsible Medicine
 **PETA INTERNATIONAL** SCIENCE CONSORTIUM LTD. 

Workshops in 2016: A New Model

- Designed to encourage consistent engagement and maximize productive participation
- Topics driven by ICCVAM agency needs
- Organizing committees with broad stakeholder representation
- Education via pre-workshop webinar series
- Increased emphasis on breakout groups

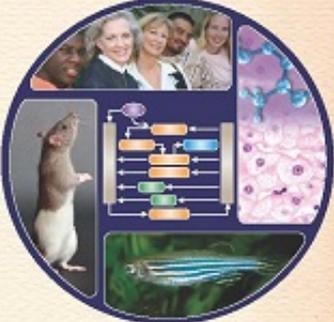
IVIVE Workshop

- Workshop goals
 - Review state of the science
 - Identify data gaps
 - Describe practices and case study examples
- ~100 attendees from industry, academia, NGOs, and government
- 3 workshop themes
 - Toxicokinetic (TK) model considerations
 - In silico and non-animal methods for obtaining TK parameters
 - Application to prioritization/screening/risk assessment



National Toxicology Program
 U.S. Department of Health and Human Services

In Vitro to In Vivo Extrapolation for High Throughput Prioritization and Decision Making



WORKSHOP

Wednesday, February 17, 2016 • 8:00 a.m. – 6:00 p.m.
 Thursday, February 18, 2016 • 8:30 a.m. – 3:00 p.m.

U.S. Environmental Protection Agency
 Research Triangle Park, North Carolina

For agenda and registration information,
 visit <http://ntp.niehs.nih.gov/go/ivive-wksp-2016>

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Any individual seeking access to the EPA campus will need to be prepared to show a photo ID (e.g., driver's license, or a company, government, or university ID) and provide either a copy of this flyer or pertinent information about the seminar (e.g., name of the speaker, host, or title of the seminar).




Pre-Workshop IVIVE Webinar Series

- Average attendance ~130 participants, ~400 registered
- Provided background in preparation for the in person workshop

October 7: Setting the Stage: Purpose, Definitions, Scope, and Assumptions
Barbara Wetmore, Ph.D., ScitoVation

November 4: Building Fit-for-purpose Pharmacokinetic Models
John Wambaugh, Ph.D., U.S. Environmental Protection Agency

December 3: The Role of Pharmacokinetic Model Evaluation
Lisa Sweeney, Ph.D., Naval Medical Research Unit Dayton

January 6: Framework for Establishing an Internal Threshold of Toxicological Concern
Corie Ellison, Ph.D., The Procter & Gamble Company

IVIVE Workshop Action Items

- Quantitative high throughput TK (HTTK) model review article
- Database for in vitro and in vivo PK/TK data and models
- Best practices for use of IVIVE in a prioritization and risk decision making setting
- Workshop report in prep
 - Case studies highlighting where IVIVE can currently be used
 - Challenges that new data or different models may address

Alternative Approaches for Acute Inhalation Toxicity Testing to Address Global Regulatory and Non-regulatory Data Requirements

**September 22-23, 2016
Bethesda, MD**

September 22: Bldg. 35 Porter Neuroscience Center, NIH campus
September 23: Hilton Garden Inn Washington DC/Bethesda



- Co-organized with PETA International Science Consortium
- Experts from industry, government, academia, and NGOs
- Compiled an inventory of information on validation status of alternatives
- Identified data gaps
- Outlined a strategy for implementation; action items/responsible parties

Pre-Workshop Inhalation Tox Webinar Series

- Average attendance ~100 participants, >500 registered
- Detailed the state-of-the-science in preparation for the in person workshop

March 29: Current Testing Practices: Regulatory Requirements and Non-regulatory Testing
Jon Hotchkiss, Dow Chemical Co.
Ian Indans, UK Chemicals Regulation Directorate

June 28: GHS Additivity Approach to Classify Mixtures Based on Ingredient Toxicity
Marco Corvaro, Dow AgroSciences

April 26: State-of-the-science, Practical Application, and Dosimetry Considerations for In Vitro and Ex Vivo Methods
Annie Jarabek, Ph.D., EPA
Marianna Gaca, British American Tobacco

July 12: Adverse Outcome Pathways
Mathieu Vinken, Free University of Brussels
Barbara Buckley, EPA

May 26: State-of-the-science and Practical Application of In Silico Methods
Grace Patlewicz, EPA
Dan Wilson, Dow Chemical Co.

September 8: 21st Testing Approaches
Kelly BéruBé, Cardiff University
Dan Huh, University of Pennsylvania

SACATM Liaisons

- **Lauren Black:** ICCVAM Communities of Practice Webinar 2016 - Fundamentals of Using QSAR Models and Read-across Techniques in Predictive Toxicology
- **Pam Spencer:** ICCVAM 2016 Public Forum
- **Kate Willett:** Workshop on Alternative Approaches for Identifying Acute Systemic Toxicity: Moving from Research to Regulatory Testing and Alternative Approaches for Acute Inhalation Toxicity to Address Global Regulatory and Non-regulatory Data Requirements
- **Brian Berridge:** Workshop on In Vitro to In Vivo Extrapolation for High Throughput Prioritization and Decision Making