ICCVAM Update on Implementing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States

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 Institute of Standards and Technology • National Institutes of Health • National Cancer Institute • National Library of Medicine
National Institute of Environmental Health Sciences • Occupational Safety and Health Administration
Speakers

- Warren Casey, NICEATM
- Brian Berridge, NTP
- Suzy Fitzpatrick, FDA CFSAN
- Anna Lowit, EPA OPP
- Gino Scarano, EPA OPPT
- Emily Reinke, DoD
U.S. agencies and stakeholders will work together to build a new framework to develop, establish confidence in, and encourage use of new approaches to toxicity testing that improve human health relevance and reduce or eliminate testing in animals.

- Published Jan 30, 2018
- https://ntp.niehs.nih.gov/go/natl-strategy
Help end-users guide the development of the new methods

Encourage the adoption of new methods

Use efficient and flexible approaches to establish confidence in new methods
Acute 6-Pack Studies

- Acute oral
- Acute dermal
- Acute inhalation
- Eye irritation
- Skin irritation
- Skin sensitization
Strategic Roadmap: Implementation

View details of ongoing and planned activities for implementation of the Strategic Roadmap in the following areas:

- **Acute Systemic Toxicity**
- **Eye and Skin Irritation**
- **Skin Sensitization**

ICCVAM establishes temporary ad hoc workgroups to perform specific tasks identified by the committee as being important for the development or validation of new approach methodologies, and it is envisioned that ICCVAM workgroups will play a key role in implementing the goals of the strategic roadmap. The workgroups are chaired by representatives from agencies that use or require data from the topic of interest. The chairs are responsible for developing the group's scope and charge, which is then reviewed and approved by ICCVAM. ICCVAM member agencies and partners in the International Cooperation on Alternative Test Methods (EURL ECVAM, JaCVAM, KoCVAM, and Health Canada) are then invited to participate in the workgroup.
United States regulatory requirements for skin and eye irritation testing.

Choksi NV\textsuperscript{1}, Truax J\textsuperscript{1}, Layton A\textsuperscript{2}, Matheson J\textsuperscript{3}, Mattie D\textsuperscript{4}, Varney T\textsuperscript{5}, Tao J\textsuperscript{6}, Yozzo K\textsuperscript{6}, McDougal AJ\textsuperscript{7}, Merrill J\textsuperscript{8}, Lowther D\textsuperscript{9}, Barroso i\textsuperscript{10}, Linkes B\textsuperscript{11}, Casey W\textsuperscript{12}, Allen D\textsuperscript{1}


Skin sensitization testing needs and data uses by US regulatory and research agencies.

Strickland J\textsuperscript{1}, Daniel AB\textsuperscript{2}, Allen D\textsuperscript{2}, Lehmann DM\textsuperscript{10}, Matheson J\textsuperscript{11}, Reir


Alternative approaches for acute inhalation toxicity testing to address global regulatory and non-regulatory data requirements: An international workshop report.


International regulatory requirements for skin sensitization testing.

Daniel AB\textsuperscript{1}, Strickland, Park HK\textsuperscript{11}, Lee JK\textsuperscript{12}, K


Status of acute systemic toxicity testing requirements and data uses by U.S. regulatory agencies.

Strickland J\textsuperscript{1}, Clippinger AU\textsuperscript{2}, Brown J\textsuperscript{3}, Allen D\textsuperscript{4}, Jacobs A\textsuperscript{5}, Matheson J\textsuperscript{6}, Lowit A\textsuperscript{7}, Reinke EN\textsuperscript{8}, Johnson MS\textsuperscript{9}, Quinn MJ Jr\textsuperscript{10}, Mattie D\textsuperscript{11}, Fitzpatrick SC\textsuperscript{12}, Ahir S\textsuperscript{13}, Kleinstreuer N\textsuperscript{14}, Casey W\textsuperscript{15}. 
New Approaches for Establishing Confidence
From

- Centralized ("VAMs")
- Discrete (Validated / Not)
- Stand Alone (1:1)
- Generic Applicability: regulatory context and chemical space (one size fits all)

Towards

- Decentralized (End Users)
- Evolving Confidence
- Integrative (Many:1, Many:?)
- Customer-Focused (Fit for Specific Purpose)
The objective of the CIPA initiative is to facilitate the adoption of a new paradigm for assessment of cardiotoxicity. The new CIPA paradigm will be driven by a suite of mechanistically based in vitro assays coupled to in silico reconstructions of cellular cardiac electrophysiologic activity.
Future Directions
Web Tool Demos

Visit the NTP booth at ToxExpo (#3428) for an overview and hands-on tutorial on the Open Structure-Activity/Property Relationship App (OPERA) and the Integrated Chemical Environment (ICE).

- **Monday, March 11** – 2:30-4:00 p.m.
- **Tuesday, March 12** – 2:00-4:00 p.m.
- **Wednesday, March 13** – 10:00 a.m.-noon
Collaboration between academic and private-sector partners to create a comprehensive, relational, N-dimensional “data translator” that integrates multiple types of existing data sources.
We are building a research program of 1,000,000+ people

The mission of the All of Us Research Program is to accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us.

The future of health begins with you.

The All of Us Research Program has a simple mission. We want to speed up health research breakthroughs. To do this, we’re asking one million people to share health information. In the future, researchers can use this to conduct thousands of health studies.
Interagency Coordinating Committee on the Validation of Alternative Methods

NICEATM / ILS Support Staff

RTP, NC

National Institute of Environmental Health Sciences
Your Environment. Your Health.
Questions?