A Roadmap for the Implementation of New Approaches for Safety Testing

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Background Materials

https://ntp.niehs.nih.gov/pubhealth/evalatm/natl-strategy/index.html

Overview

In 2007 the National Research Council published the seminal report "Toxicity Testing in the 21st Century: A Vision and a Strategy" (https://www.nap.edu/catalog/11970/toxicity-testing-in-the-21st-century-a-vision-and-a)that envisioned using human-based assays and model information to provide a more efficient, predictive, and economic system for assessing the effects of chemicals on human health. Over the ensuing decade, significant investments in technology development and biomedical research have resulted in many scientific advances necessary for implementing the vision outlined in the 2007 report. However, these advances have not yet resulted in a concomitant increase in our ability to more accurately predict potential adverse human health effects caused by exposure to chemicals.

Achieving the full potential to improve and protect human health offered by these advances in science and technology necessitates a national strategy for the safe, effective, and timely implementation of human-based, predictive approaches for toxicity testing. To initiate this process, ICCVAM is coordinating the development of a strategic roadmap for incorporating new approaches into safety testing of chemicals and medical products in the United States. The vision and mission for this effort are as follows:

VISION: To facilitate the development and use of new approaches for evaluating the safety of chemicals and medical products in the United States that will increase confidence in alternative methods and improve their relevance to human health, while maintaining a commitment to replace, reduce, and refine animal use.

MISSION: Federal agencies, the regulated community, and interested stakeholders will work together to explore new approaches for evaluating the safety of chemicals and medical products in the United States while collaborating with international partners to facilitate global harmonization of new testing approaches. The successful development and implementation of new approaches will require integrated efforts that (1) help end-users (agencies and industry) guide the development of new tools to support regulatory and research needs (2) foster the use of timely, flexible and robust practices to establish confidence in new methods, and (3) encourage the adoption and use of new approaches by Federal agencies and regulated industries.

OBJECTIVES:

1. **Communicate the decision contexts and needs of Federal agencies**
   - **a.** Clearly delineate the toxicological testing requirements and/or context of use by ICCVAM agencies
   - **b.** Develop and communicate cross-agency and individual agency priorities
   - **c.** Explore new approaches to validation and publish best practices for the development and evaluation of new methods and approaches
   - **d.** Adopt clear language on the acceptance of, and preference for, new methods and approaches, when applicable

2. **Streamline processes for regulatory acceptance of new methods**
   - **a.** Actively solicit the submission of parallel data from animal studies and alternative methods
   - **b.** Establish forums to discuss best approaches for expedite regulatory acceptance of methods already in use for in-house screening by industry
   - **c.** Host regular interagency discussions to share ways in which successful programs at one agency can be applied at another
   - **d.** Explore processes to incentivize the use of new methods.

3. **Collaborate with international partners to facilitate global harmonization and regulatory acceptance of new methods and approaches**
   - **a.** Identify and prioritize key areas where efforts can increase international harmonization

4. **Promote communication and data sharing across product-sectors and help unify efforts to develop alternative methods**
   - **a.** Utilize public-private partnerships to facilitate the development, evaluation, and utilization of new test methods and approaches
   - **b.** Identify and make public case studies from ICCVAM agencies, the regulated community, and other stakeholders where alternative approaches have been evaluated or implemented

5. **Identify and promote resources that can foster the development and utilization of new or enhanced approaches**
   - **a.** Establish and promote training programs for personnel who conduct, recommend, or review toxicology studies, to include: hands-on training on *in vitro* or *in silico* methods, workshops and webinars, factsheets, tutorials, and videos
   - **b.** Identify funding sources for applied research that supports agency needs
   - **c.** Encourage the development of grant review processes specifically for alternative methods

d. Identify and collate sources of high quality human toxicological data relevant to assessment of new alternative methods

e. Create a centralized access point of high-quality data that is publicly available and easily accessible

6. Establish appropriate metrics for prioritizing activities, monitoring progress, and measuring success

7. Develop a communication plan for transmitting and receiving information related to the Strategic Roadmap

a. Ensure broad distribution of information related to the acceptance of new methods, data sharing opportunities, and other efforts.

This effort will continue throughout 2017, and updates and additional information will be posted on this webpage. Announcements of relevant activities will be sent via the NICEATM News email list: subscribe to NICEATM News.

Request for Public Input

Interested persons are invited to provide input relevant to this effort. Submit comments by email to ICCVAMquestions@niehs.nih.gov by **August 31.** Comments should include the commenter's name, affiliation (if applicable), mailing address, telephone, email, and sponsoring organization (if any). Comments submitted will be posted on this page, therefore no proprietary, classified, confidential, or sensitive information should be included in comments. *View NTP guidelines for public comments.*

Opportunities for Public Comments

Three public meetings in 2017 will provide opportunities to comment on topics relevant to this effort.

- ICCVAM Public Forum: May 23, National Institutes of Health, Bethesda, MD
- NTP Board of Scientific Counselors meeting: June 29, NIEHS, Research Triangle Park, NC
- Scientific Advisory Committee on Alternative Toxicological Methods meeting: September 18-19, National Institutes of Health, Bethesda, MD