Developing a Strategic Roadmap To Establish New Approaches for Evaluating the Safety of Chemicals and Medical Products in the United States

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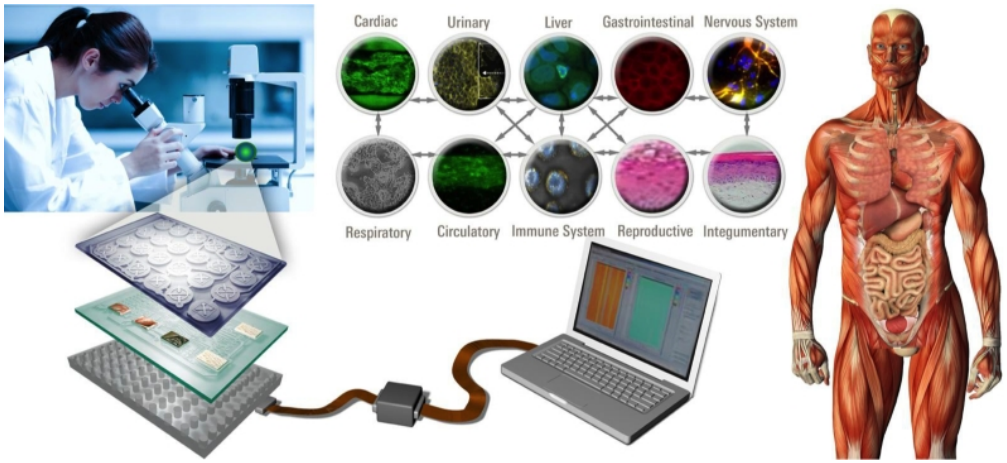
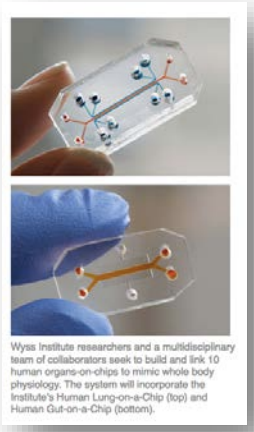
NTP Interagency Center for the Evaluation of Alternative Toxicological Methods

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

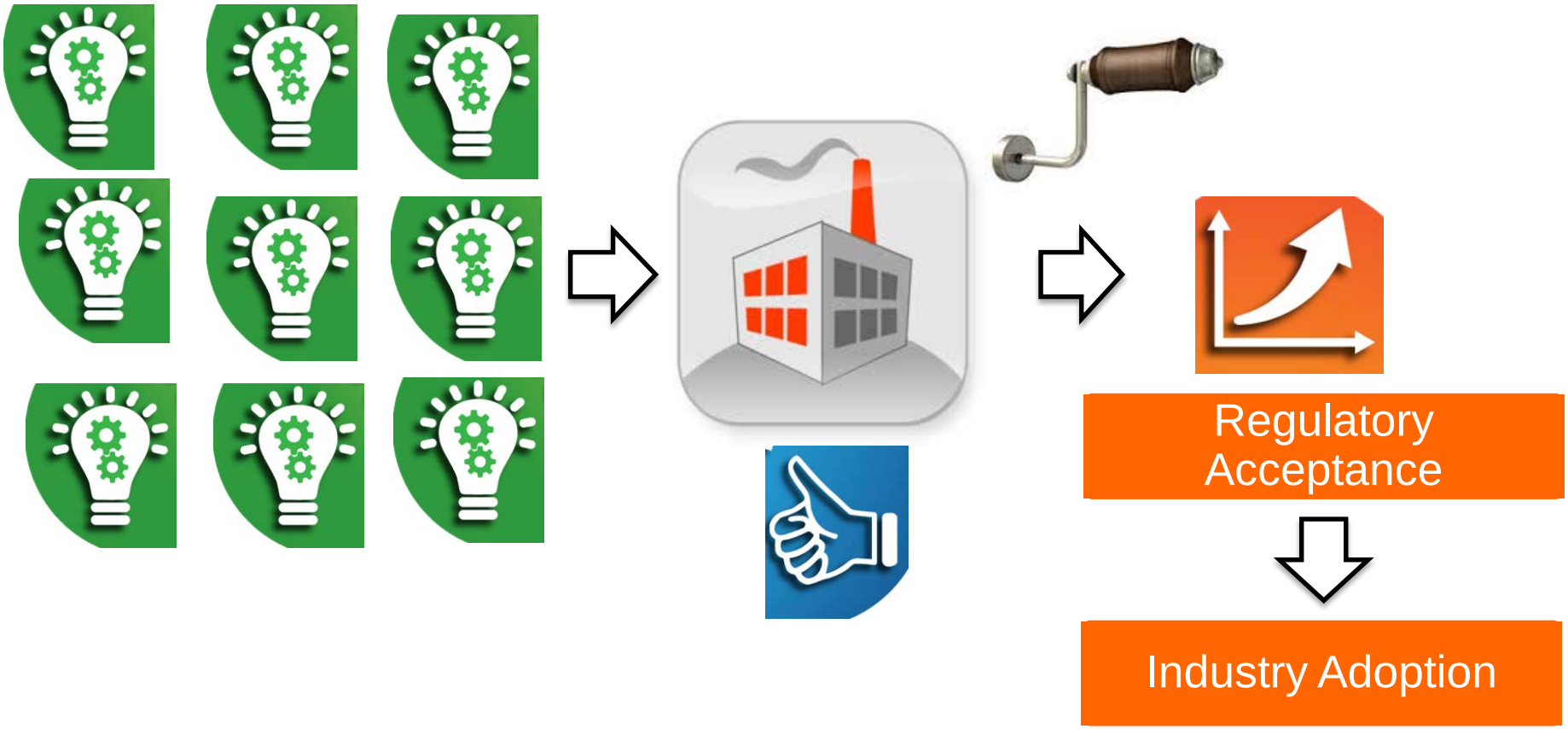
It is difficult for evolving *institutional practices* to keep pace with revolutionary advances in science and technology

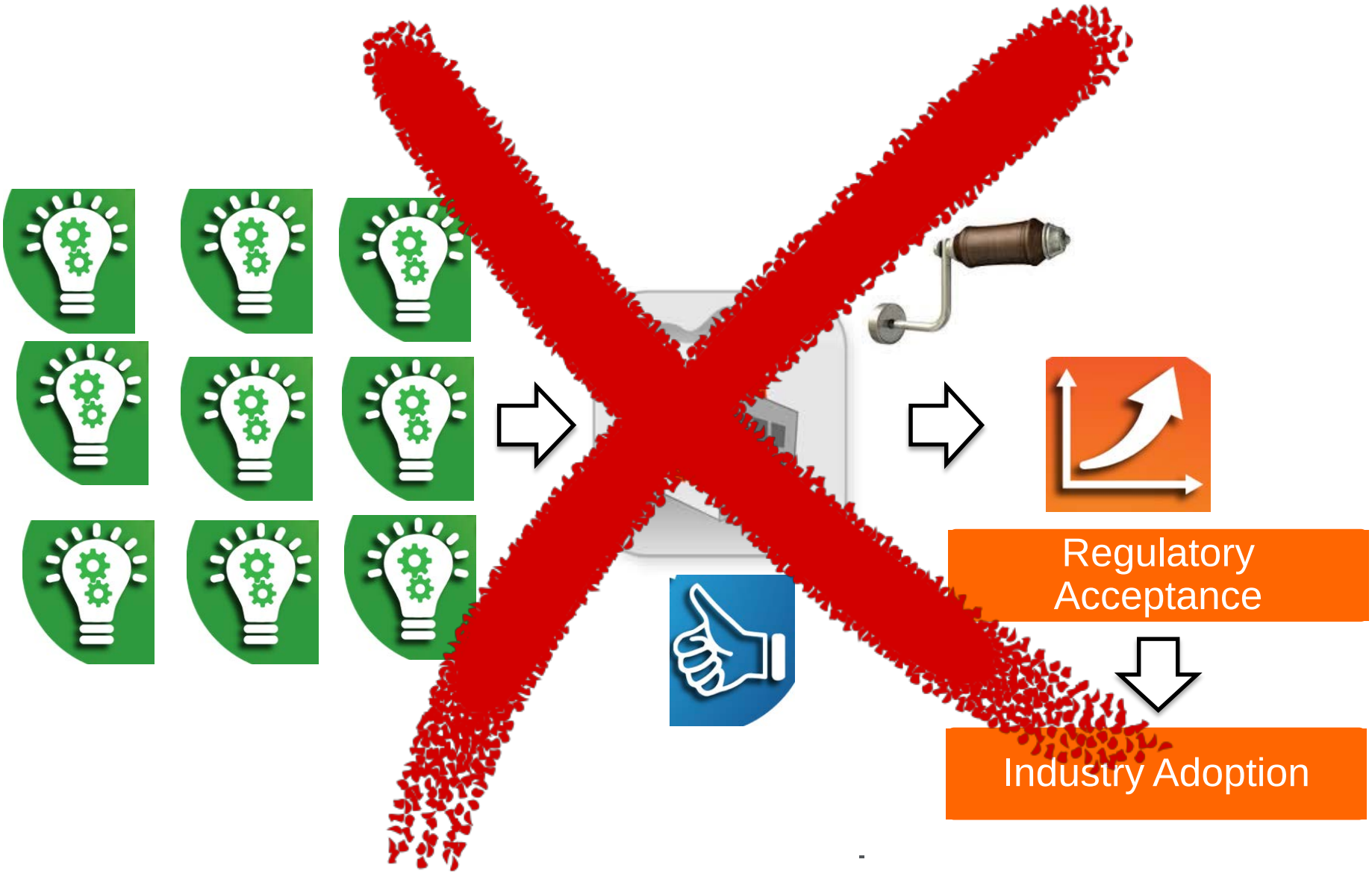



Wyss Institute researchers and a multidisciplinary team of collaborators seek to build and link 10 human organs-on-chips to mimic whole body physiology. The system will incorporate the Institute's Human Lung-on-a-Chip (top) and Human Gut-on-a-Chip (bottom).

Barrangou & Doudna, Nat. Biotech 933–941 (2016)

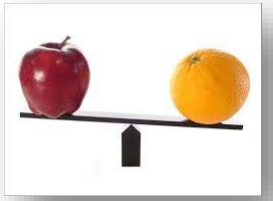
Method Development → Validation → Regulatory Acceptance


Regulatory Acceptance
Industry Adoption


Regulatory Acceptance
Industry Adoption

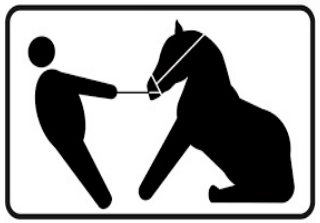

WELL, THERE'S YOUR PROBLEM

- **Animal Data as the Reference for Validation**



- **Insufficient Human Data**

- **Institutional Resistance**



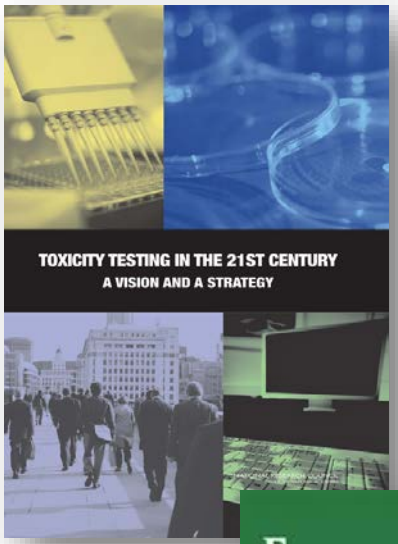
- **Harmonization**

We Need a National Roadmap

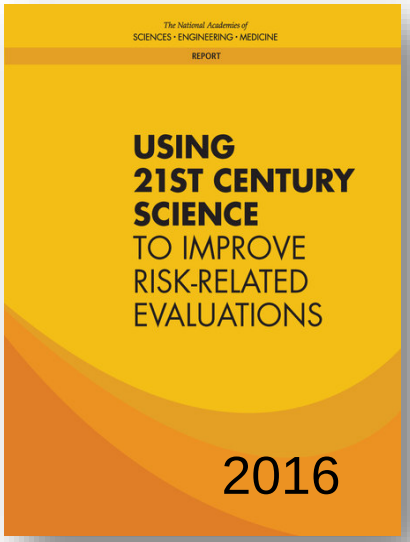
- Helps federal agencies identify consensus goals and coordinate key activities required to achieve them
- Provides a framework to support the planning and coordination of technology development
- Facilitates communication and collaboration within and between government agencies, stakeholders, and international partners

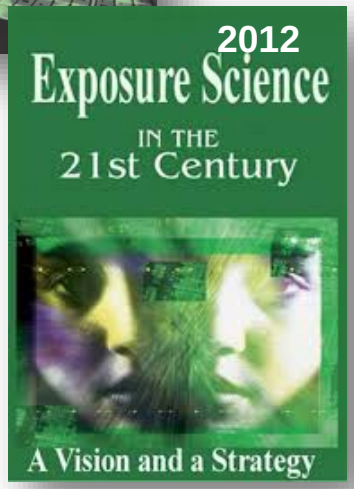
How is this different?

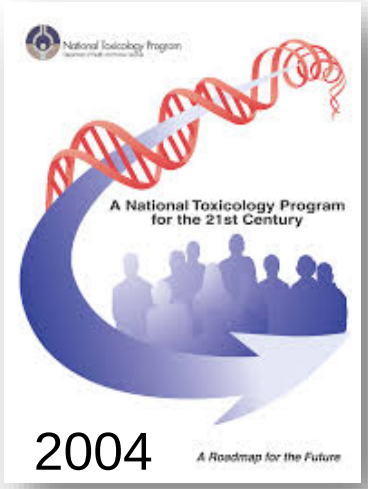
2007



2014







How is this different?

- Driven by Federal agencies (”top down” vs “bottom up”)
- Includes both chemicals and medical products
- Paired with implementation plans that will be tracked and publically reported

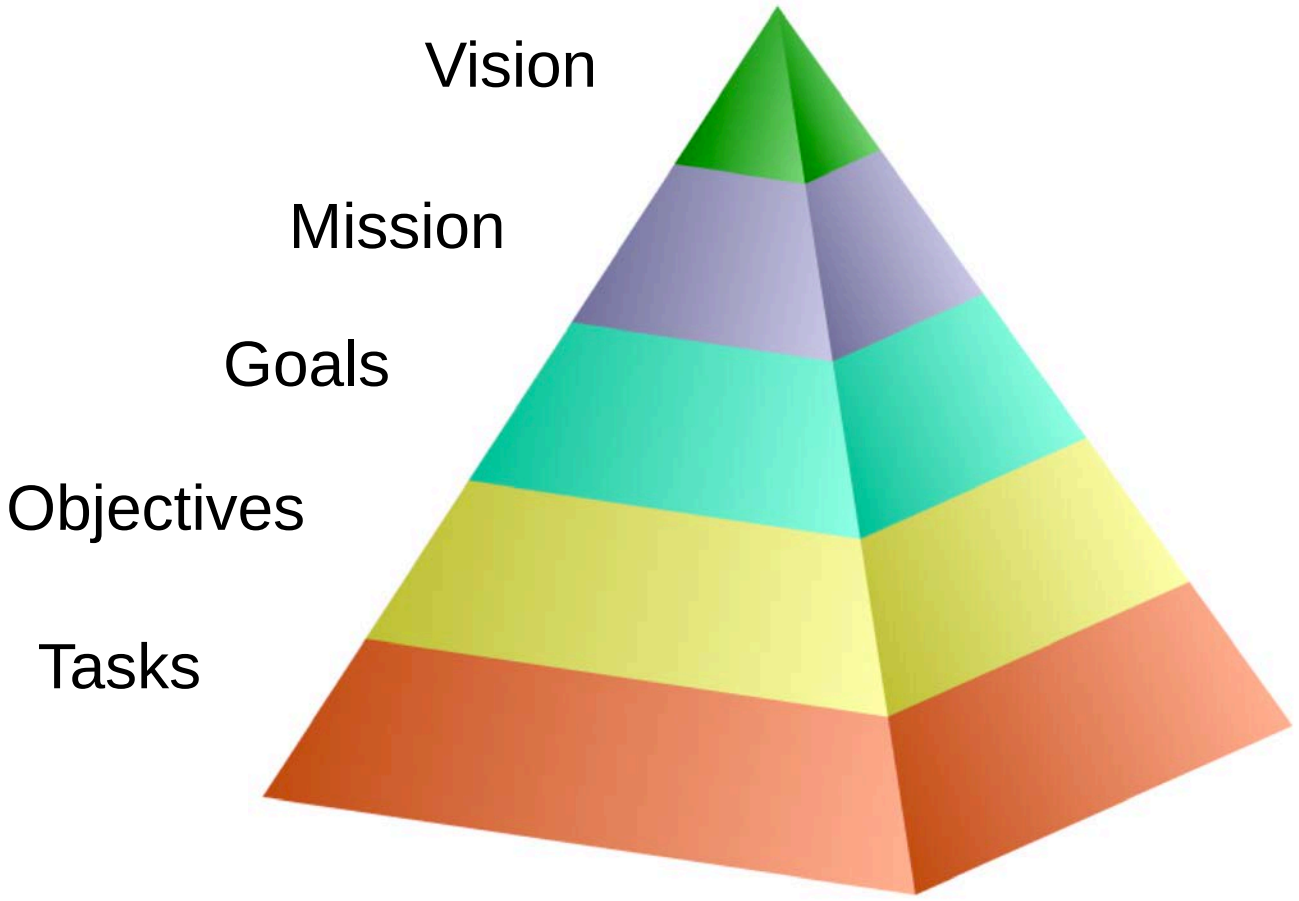
Agencies Strategic Plans are aligned…

Feb 2017

2-day face-to-face Interagency (not just ICCVAM) meeting to start process of establishing mission / vision / goals / objectives

85 participants / Professional Facilitation

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

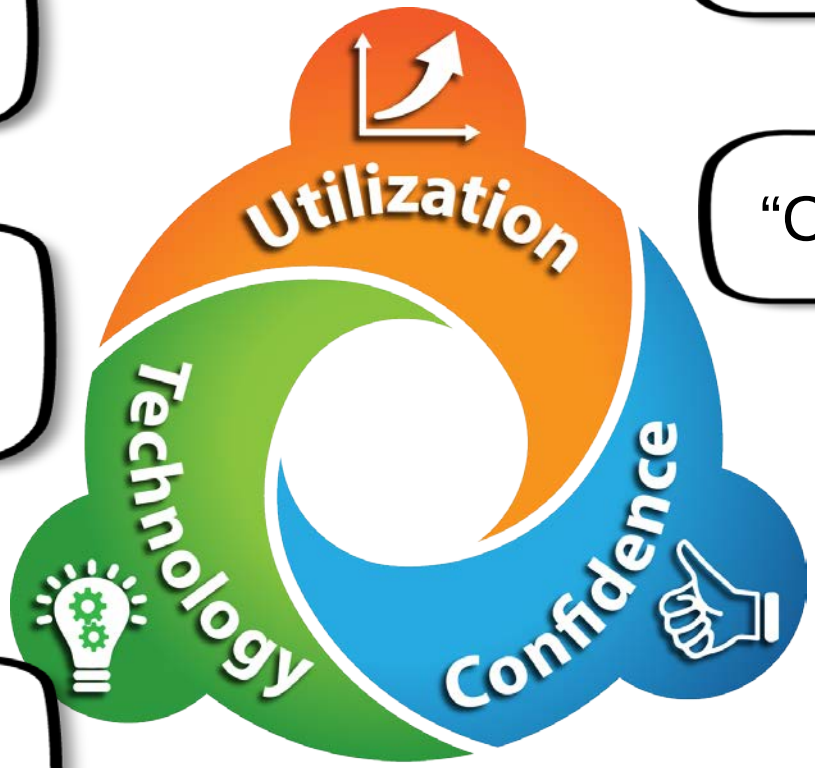

Vision
Mission
Goals
Objectives
Tasks

Start Here!

"Communication"

"Commitment"

"Collaboration"



"Fit for Purpose"

"Context of use"

Disclaimer: *"The draft outline was developed by representatives from ICCVAM agencies along with other Federal partners and interagency workgroups. The text represents a generalized perspective that does not reflect opinions or policy of any specific agency and may not be applicable to all Federal agencies.“*

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.

GOALS:

(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

(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**

2. **Streamline processes for regulatory acceptance of new methods**

3. **Collaborate with international partners to facilitate global harmonization and regulatory acceptance of new methods and approaches**

4. **Promote communication and data sharing across product-sectors and help unify efforts to develop alternative methods**

5. **Identify and promote resources that can foster the development and utilization of new or enhanced approaches**

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**

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.

23 May
Public Forum
NIH, Bethesda

18-19 Sep
SACATM
NIH, Bethesda

Dec
Publish Final

14 Aug
Publish Draft

COORDINATED by ICCVAM

Interagency Coordinating Committee on the Validation of Alternative Methods

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

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- U.S. Strategic Roadmap
- Accepted Alternative Methods
- ICCVAM

NTP Interagency Center for the Evaluation of Alternative Toxicological Methods

Strategic Roadmap: New Approaches to Evaluate the Safety of Chemicals and Medical Products

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. Scientific and technological advances in toxicology can significantly improve and protect public health. However, a national strategy is required to ensure the safe, effective, and timely implementation of human-based, predictive approaches in toxicity testing.

Provide input on the Strategic Roadmap

Vision

To establish 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 outcomes while maximizing efficiency and maintaining a commitment to replace, reduce, and refine animal use.

Mission

Federal agencies, the regulated community, non-governmental organizations, and other technical experts will work together to explore new approaches for evaluating the safety of chemicals and medical products that will:

- Help guide the development of new tools to support regulatory and research needs
- Use knowledge of human and animal biology as appropriate to help establish confidence in new approaches
- Facilitate and encourage the implementation and use of these new approaches by federal agencies and regulated industries

U.S. Strategic Roadmap
Background and More Information
Provide Input
Stay Informed & Contact Us

Strategic Roadmap: Provide Input

Interested persons are invited to provide input relevant to this effort. To submit comments, use the online form or email ICCVAMquestions@niehs.nih.gov by **August 31.** Emailed comments should include:

- Commenter's name and affiliation (if applicable)
- Mailing address
- Telephone
- Email
- Sponsoring organization (if any)

Comments submitted will be posted on this page; therefore, no proprietary, classified, confidential, or sensitive information should be included in the comments. *View NTP guidelines for public comments.*

Opportunities for Public Comments

Three public meetings in 2017 will provide opportunities for 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

Details on these meetings will be posted on the linked pages when they are available.

Comments Received

- Physicians Committee for Responsible Medicine (May 12; included in comments for 2017 ICCVAM Public Forum)
- People for the Ethical Treatment of Animals (May 12)
- Christine Rowen (May 11)
- Geoff Daly (May 9)
- Jan Elbert (May 9)
- Calvin Willhite (March 31)

Thank you!

Questions?