



Interagency Coordinating Committee on the Validation of Alternative Methods

Strategic Roadmap

Warren Casey, PhD, DABT
Director, NICEATM

SACATM Meeting
September 5, 2018

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 Institute of Standards and Technology • National Library of Medicine • Occupational Safety and Health Administration



PUBLIC LAW 106–545 : ICCVAM Authorization Act of 2000

- Review and evaluate new or revised or alternative test methods.
- Coordinate interagency and international 3R activities
- Facilitate and provide guidance on the development of validation criteria and processes for alternative test methods.



Anna Lowit
EPA OPP



Emily Reinke
Dept. of Defense

- Consumer Product Safety Commission
- Department of Agriculture
- 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



- Agency for Toxic Substances and Disease Registry
- National Cancer Institute
- National Inst of Env. Health Sciences
- National Library of Medicine
- National Institutes of Health
- Department of Defense
- Department of Energy
- National Institute of Standards and Technology

- Other participants: NCATS , Tox21



ICCVAM Workgroups

- Acute lethality (LD50 / IC50)
- Skin Sensitization
- Ocular / Dermal Irritation and Corrosion
- Developmental Tox
- Eco Tox
- Nano Tox
- Read Across
- IVIVE

NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)



U.S. Strategic Roadmap

Introduction

Implementation

Acute Systemic Toxicity

Skin and Eye Irritation

Skin Sensitization

Development

Contributors

References

Strategic Roadmap: Implementation

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<https://ntp.niehs.nih.gov/go/838279>

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 (the European Union Reference Laboratory for Alternatives to Animal Testing, the Japanese Center for the Evaluation of Alternative Methods, the Korean Center for the Evaluation of Alternative Methods, and Health Canada) are then invited to participate in the workgroup.





ICCVAM Public Forum

ICCVAM Public Forum: May 2018

May 24, 2018

William H. Natcher Conference Center

National Institutes of Health

Bethesda, Maryland, USA

SHARE THIS:

<https://ntp.niehs.nih.gov/go/iccvamforum-2018>



[Read a summary of the Public Forum in the July 2018 NIEHS Environmental Factor newsletter](#)

[Final agenda](#)

[Videocast recording](#) on NIH VideoCasting and Podcasting website

Approximately 4 hrs 30 min – requires Adobe Flash installed and Java Script enabled

[Presentations](#) ▾

[Public Comments](#) ▾



**UNITED STATES
ICCVAM
Advancing Alternatives
to Animal Testing**

BIENNIAL PROGRESS REPORT 2016-2017

Interagency Coordinating Committee
on the Validation of Alternative Methods

[Home](#) [Activities](#) [Outreach](#) [About](#) [NICEATM Site](#) [Download Report](#) [Contact Us](#)

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

ICCVAM 2016-2017 Biennial Progress Report

<https://ntp.niehs.nih.gov/go/2017iccvamreport>

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 2016 through December 2017.

The International Cooperation on Alternative Test Methods (ICATM)



- Promote international cooperation in the areas of:
 - validation studies,
 - independent peer review, and
 - development of harmonized test methods and recommendations.



Organisation for Economic Co-operation and Development



Quick facts

History: established in 1961

Headquarters: Paris, France

Membership: 36 countries

Budget: EUR 374 million

OECD Secretary-General: Angel Gurría

Secretariat staff: 2 500

Publications: 250 new titles/year

[Annual report](#)

[OECD Observer](#)

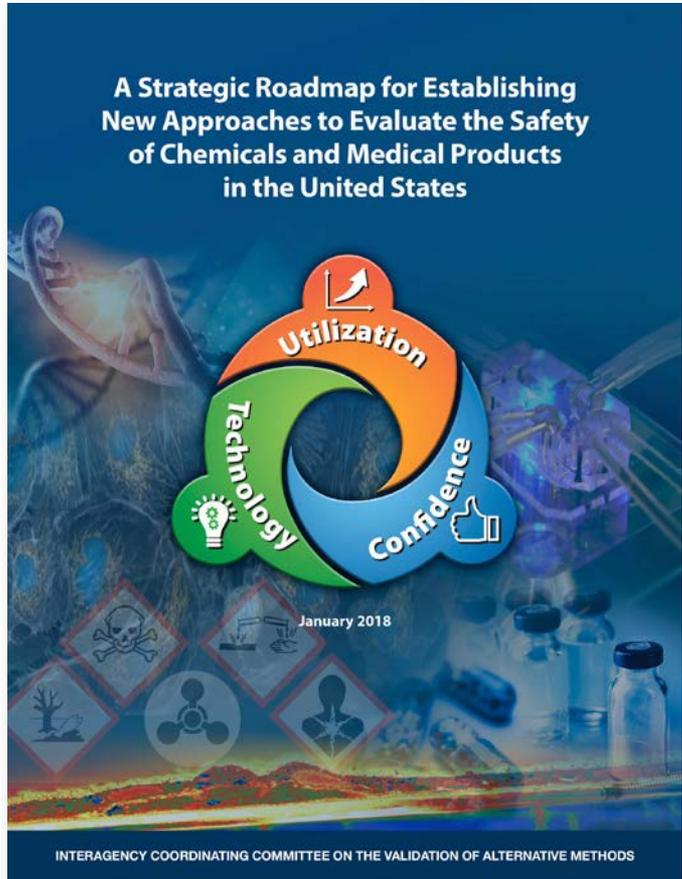
[OECD Yearbook](#)

The Organisation for Economic Co-operation and Development (OECD)



NAM

New Alternative Methodologies



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>

A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States

January 2018

INTERAGENCY COORDINATING COMMITTEE ON THE VALIDATION OF ALTERNATIVE METHODS

Um roteiro estratégico para o estabelecimento
 de novas abordagens de avaliação da
 segurança de produtos químicos e de produtos
 hospitalares nos Estados Unidos

Janeiro de 2018

COMITÉ DE COORDENACIÓN INTERINSTITUCIONAL PARA LA VALIDACIÓN DE MÉTODOS ALTERNATIVOS
 INTERAGENCY COORDINATING COMMITTEE ON THE VALIDATION OF ALTERNATIVE METHODS

为评估美国化学品及医疗产品
 安全性建立新方案的战
 略发展蓝图

2018年1月

替代方法验证委员会

Una guía estratégica para establecer
 nuevos enfoques para evaluar la seguridad
 de productos químicos y médicos
 en los Estados Unidos

Enero de 2018

COMITÉ DE COORDENACIÓN INTERINSTITUCIONAL PARA LA VALIDACIÓN DE MÉTODOS ALTERNATIVOS

미국 내 화학 제품 및 의약품 안전
 평가를 위한 새로운 접근법 확립을
 위한 전략적 로드맵

2018년 1월

대체시험법 확립을 위한 국제간 조정위원회

米国の化学薬品と医薬品の
 安全性評価に対する新
 しいアプローチを確立する
 ための戦略的ロードマップ

2018年1月

代替法の検証に関する国際調整委員会



**Develop
Technology**

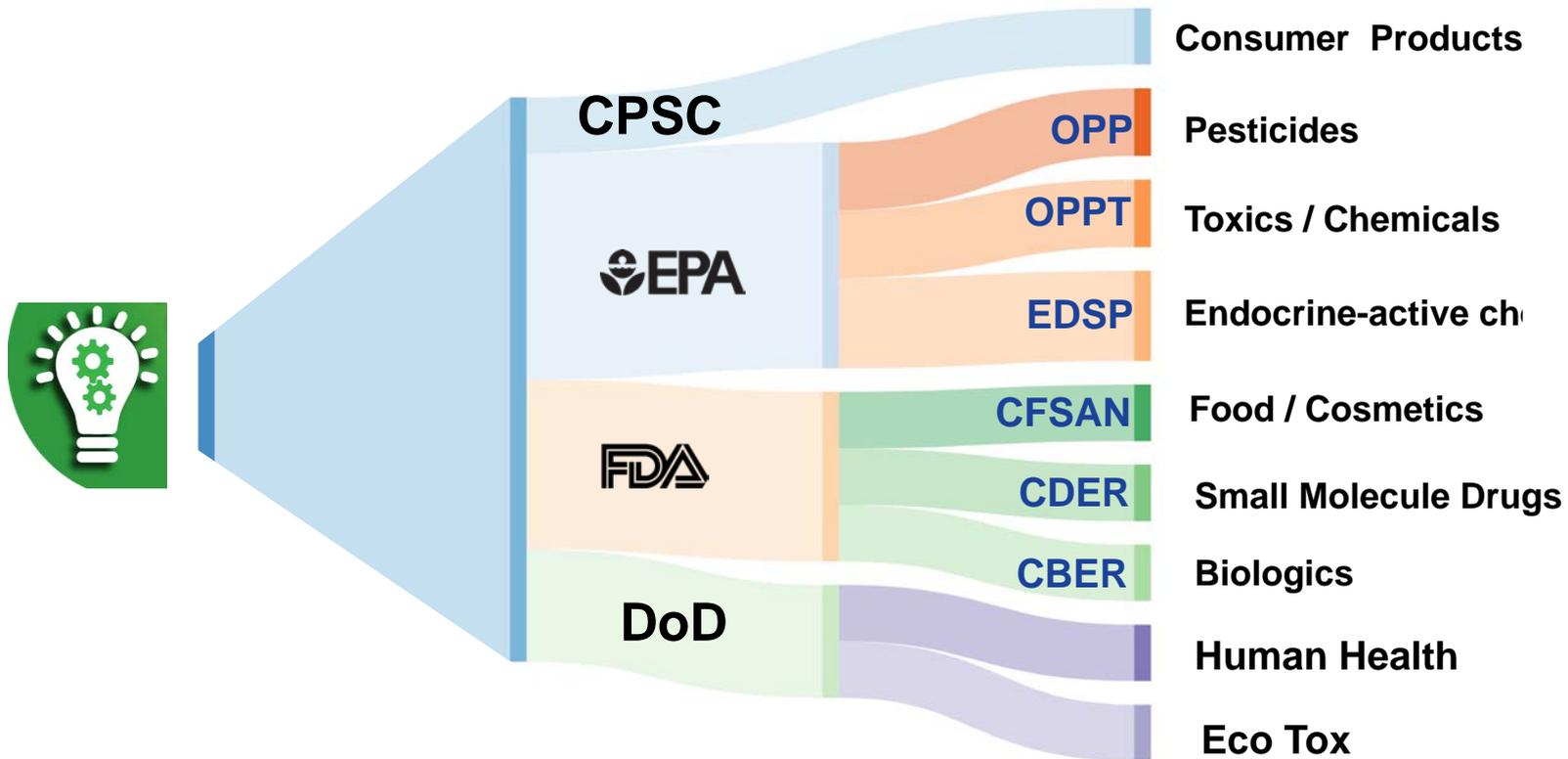


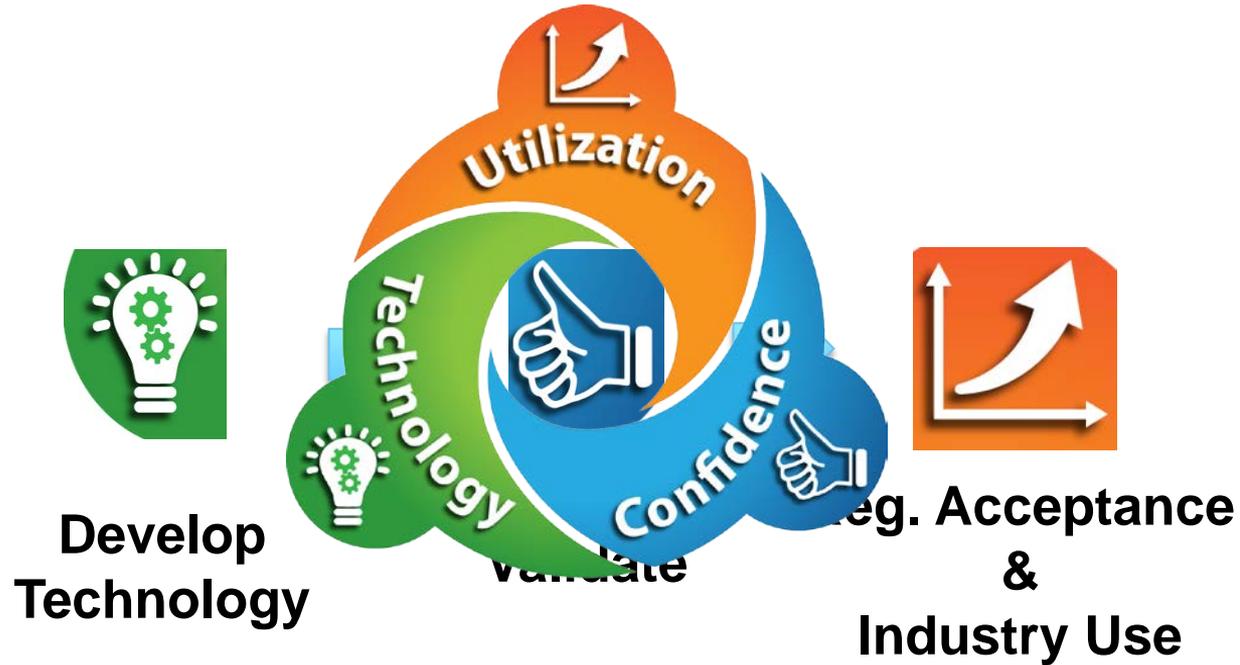
Validate

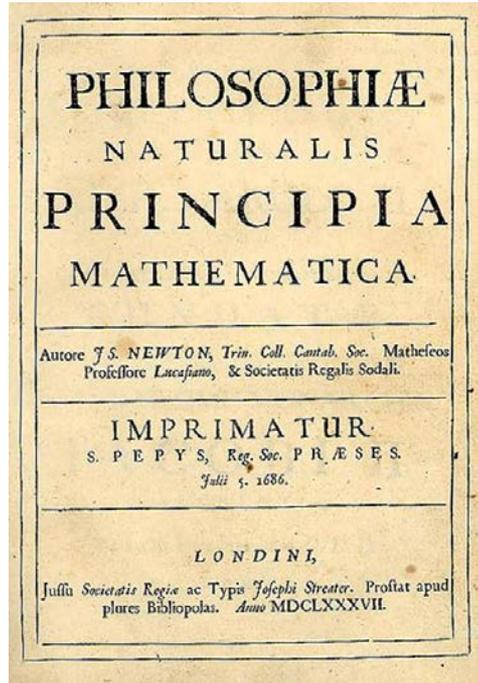


**Reg. Acceptance
&
Industry Use**

Each “toxicity test” has MANY potential purposes







1687

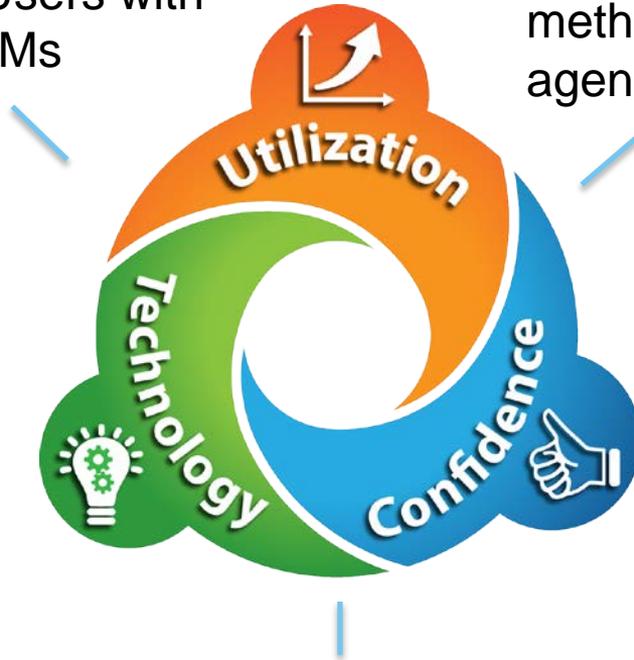


Every body perseveres in its state
of being at rest or of moving
uniformly straight forward,
except insofar as it is
compelled to change its
state by forces impressed.

Isaac Newton

Connecting End-Users with
Developers of NAMs

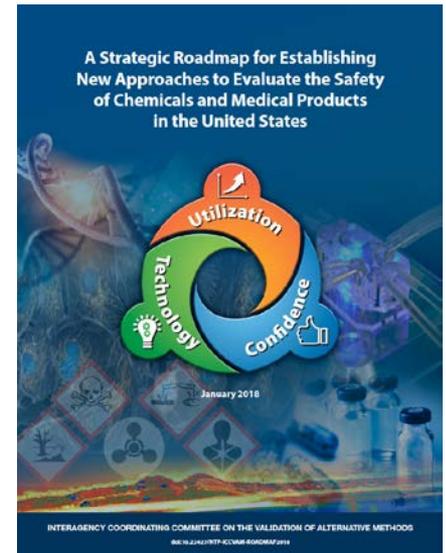
Encourage the adoption and use of new
methods and approaches by federal
agencies and regulated industries



Foster the use of efficient, flexible, and robust
practices to establish confidence in new methods.

Connecting End-Users with Developers of NAMs

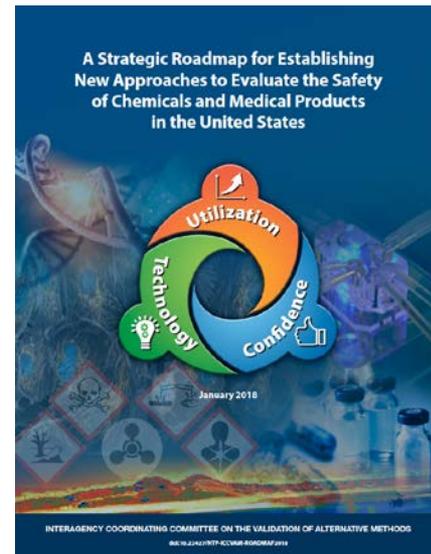
- Identify anticipated testing requirements
- Encourage the establishment of grant review criteria tailored to the development of NAMs
- Develop mechanisms to improve communication between end users and researchers



Connecting End-Users with Developers of NAMs

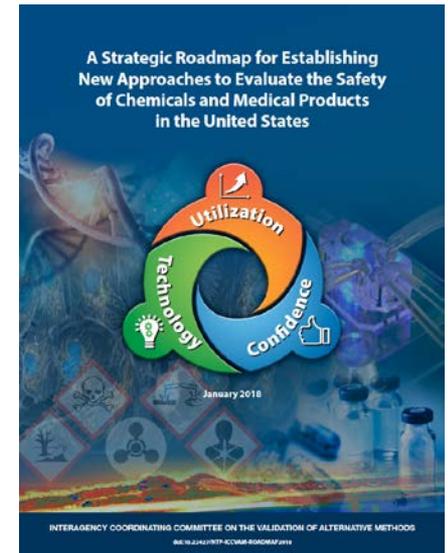
- **Identify anticipated testing requirements**

Agencies and industry stakeholders need to work together to identify and communicate their anticipated science and technology needs for safe product development and registration.



Connecting End-Users with Developers of NAMs

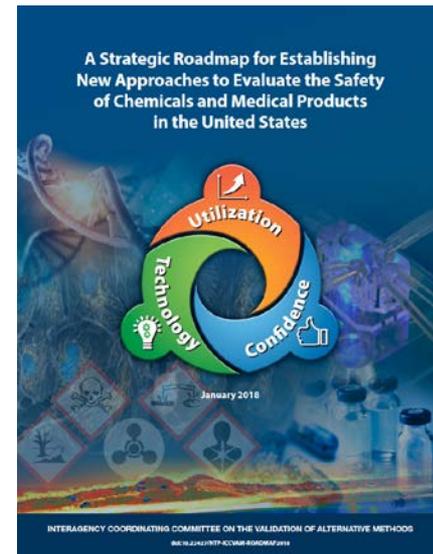
- **Identify anticipated testing requirements**
 - Technology: Microphysiological Systems
 - Approaches: Read Across
 - Endpoints: Cancer



Connecting End-Users with Developers of NAMs

- **Identify anticipated testing requirements**

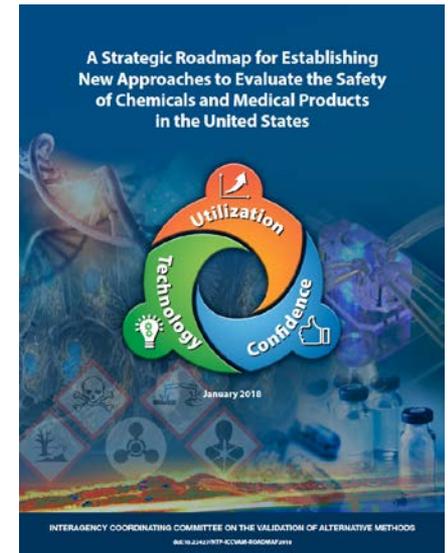
Agencies and industry stakeholders need to work together to identify and communicate their anticipated science and technology needs for safe product development and registration.



Connecting End-Users with Developers of NAMs

- **Encourage the establishment of grant review criteria tailored to the development of NAMs**
 - NIH Notice Number: NOT-TR-18-027

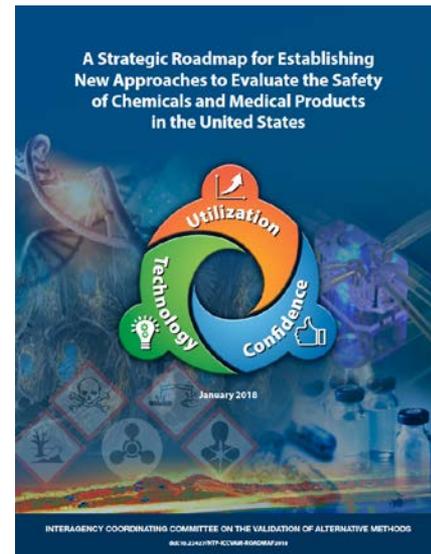
Notice of Availability of Administrative Supplements for Tissue Chip Consortium Awardees: Development of Tissue Chips to Model Nociception, Opioid Addiction and Overdose



Connecting End-Users with Developers of NAMs

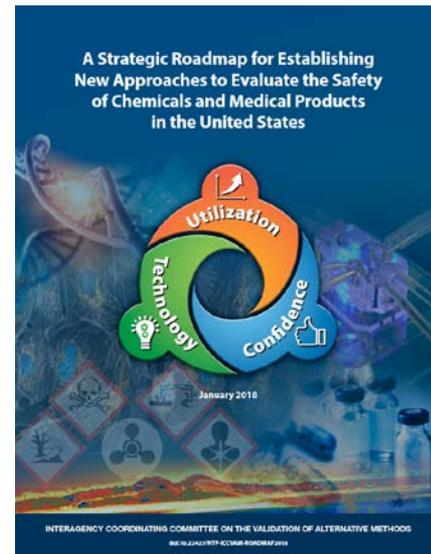
- **Develop mechanisms to improve communication between end users and researchers**

One of the most cost-effective and impactful actions that can be taken immediately is to foster efforts that improve the dialog between end users and test-method developers. Federal agencies and industry stakeholders should collaborate to develop programs and processes that encourage an open dialog between test-method developers and end users.



Connecting End-Users with Developers of NAMs

- **Develop mechanisms to improve communication between end users and researchers**
 - [Communities of Practice Webinar](#): January, 2019
 - [Exhibitor Hosted Session](#), SOT: March 2019
 - [Public Forum](#): May, 2019





Clarifying Questions?