Interagency Coordinating Committee on the Validation of Alternative Methods

A Strategic Roadmap for the Implementation of New Approaches to Safety Evaluation

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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

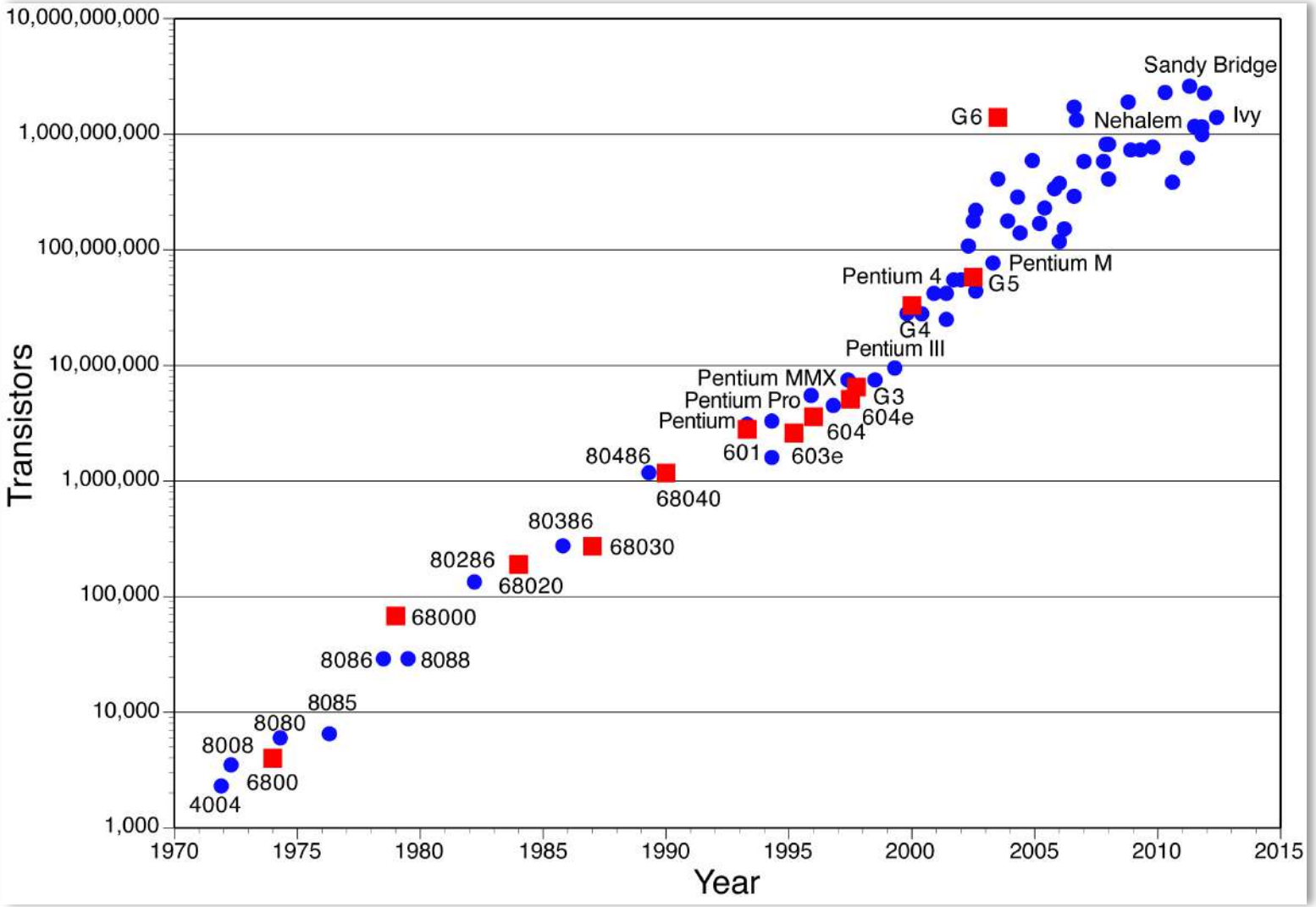
In Francis Collins' recent testimony to the congressional subcommittee with NIH budget oversight responsibility, he offered that :

"Animal safety testing for environmental chemicals and drugs will largely be replaced by tissue chips and iPS cells in 10 years."

"…..giving results that are more accurate, at lower cost and higher throughput."

http://www.appropriations.senate.gov/hearings/hearing-on-fy2017-national-institutes-of-health-budget-request

Moore's Law



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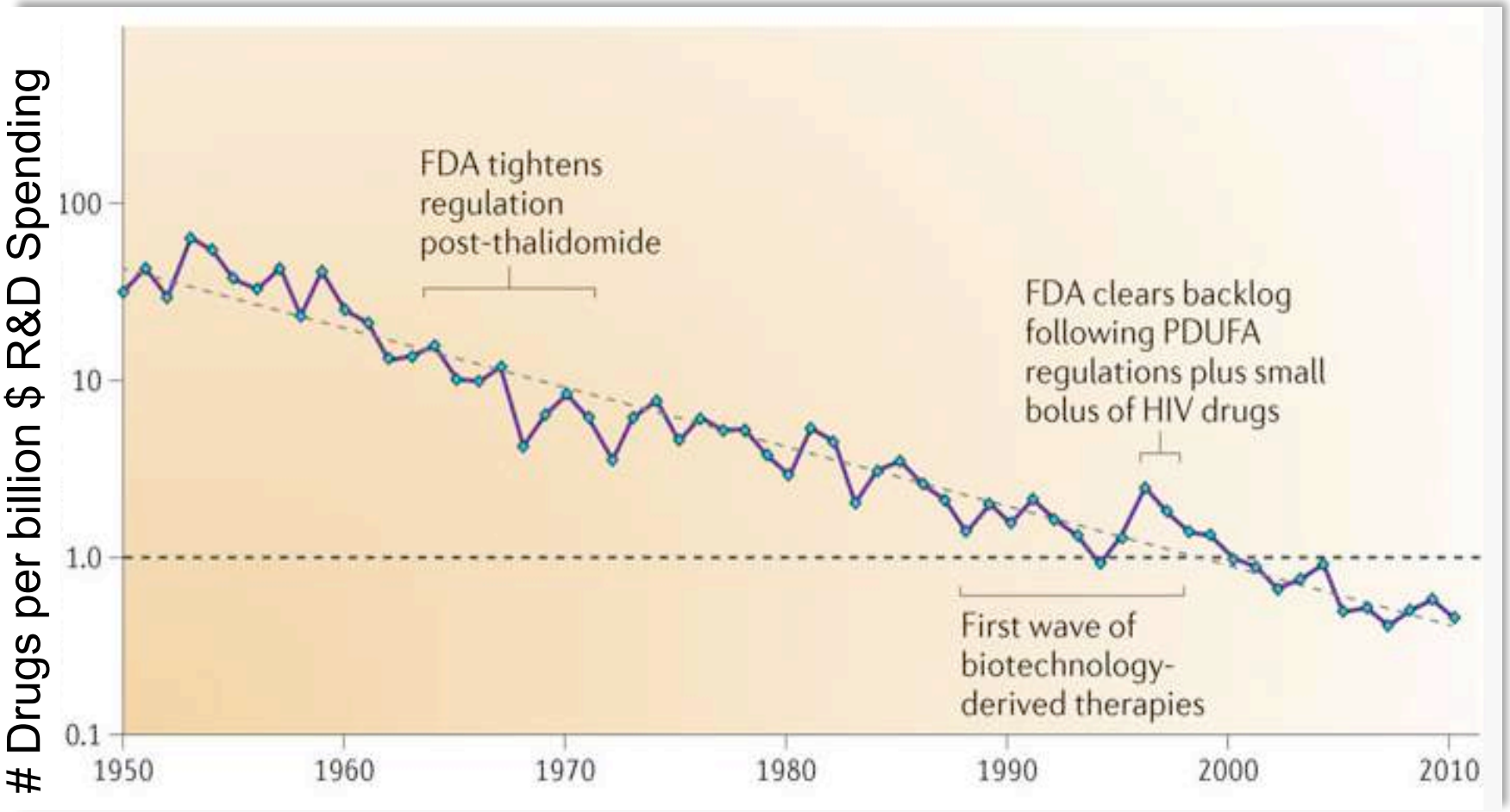
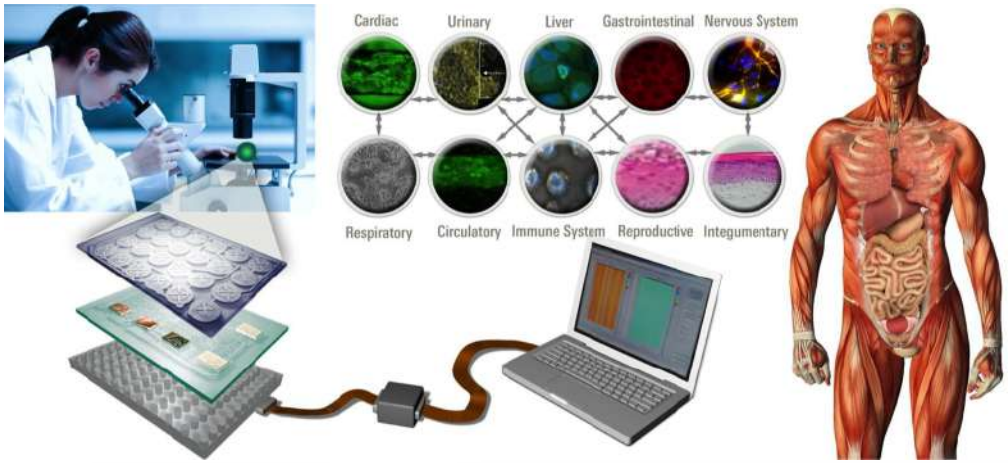
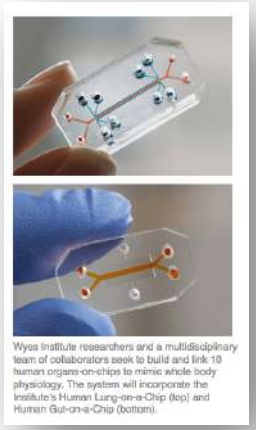
Eroom's Law



Diagnosing the decline in pharmaceutical R&D efficiency
Jack W. Scannell, Alex Blanckley, Helen Boldon & Brian Warrington
Nature Reviews Drug Discovery 11, 191-200 (March 2012)

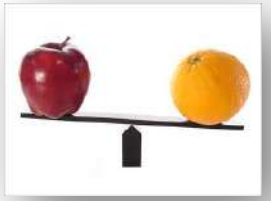
It is difficult for evolving institutional practices to keep pace with revolutionary advances in science and technology




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).

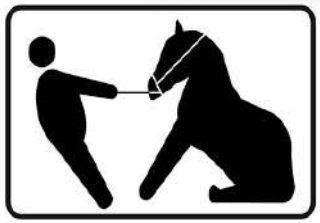
Barrangou & Doudna, Nat. Biotech 933–941 (2016)

- Animal Data as the Reference for Validation



- Insufficient Human Data

- Institutional Resistance



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

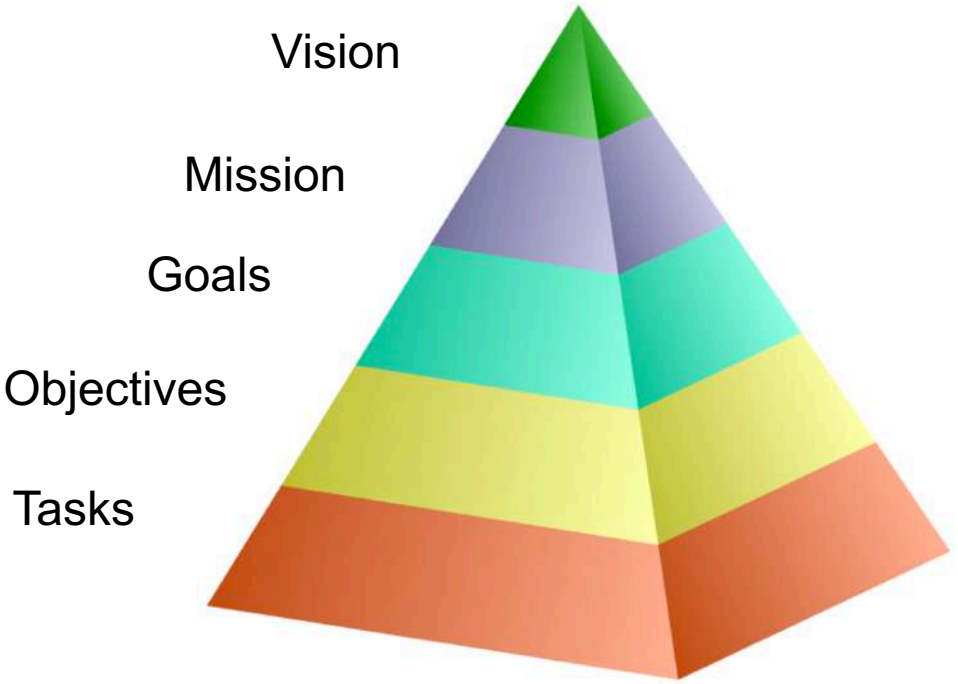
We Need a National Metro Map

- 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

Feb 2017

2-day face-to-face Interagency meeting to start process of establishing mission / vision / goals / objectives

85 participants from 16 Agencies / Professional Facilitation



VISION:

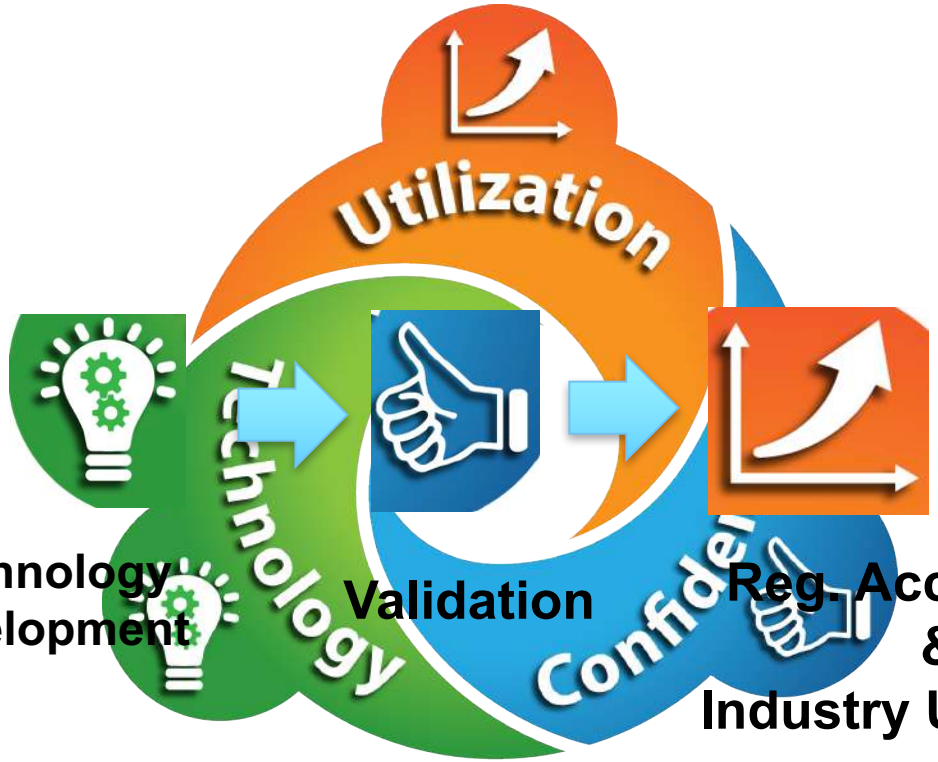
To facilitate the development and use of new approaches for evaluating the safety of chemicals and medical products in the United States that will increase confidence in alternative methods and improve their relevance to human health, while maintaining a commitment to replace, reduce, and refine animal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

- **Help end-users (agencies and industry) guide the development of new tools to support regulatory and research needs**
- **Foster the use of timely, flexible and robust practices to establish confidence in new methods, and**
- **Encourage the adoption and use of new approaches by Federal agencies and regulated industries.**

Start Here!



Technology Development

Validation

Reg. Acceptance & Industry Utilization

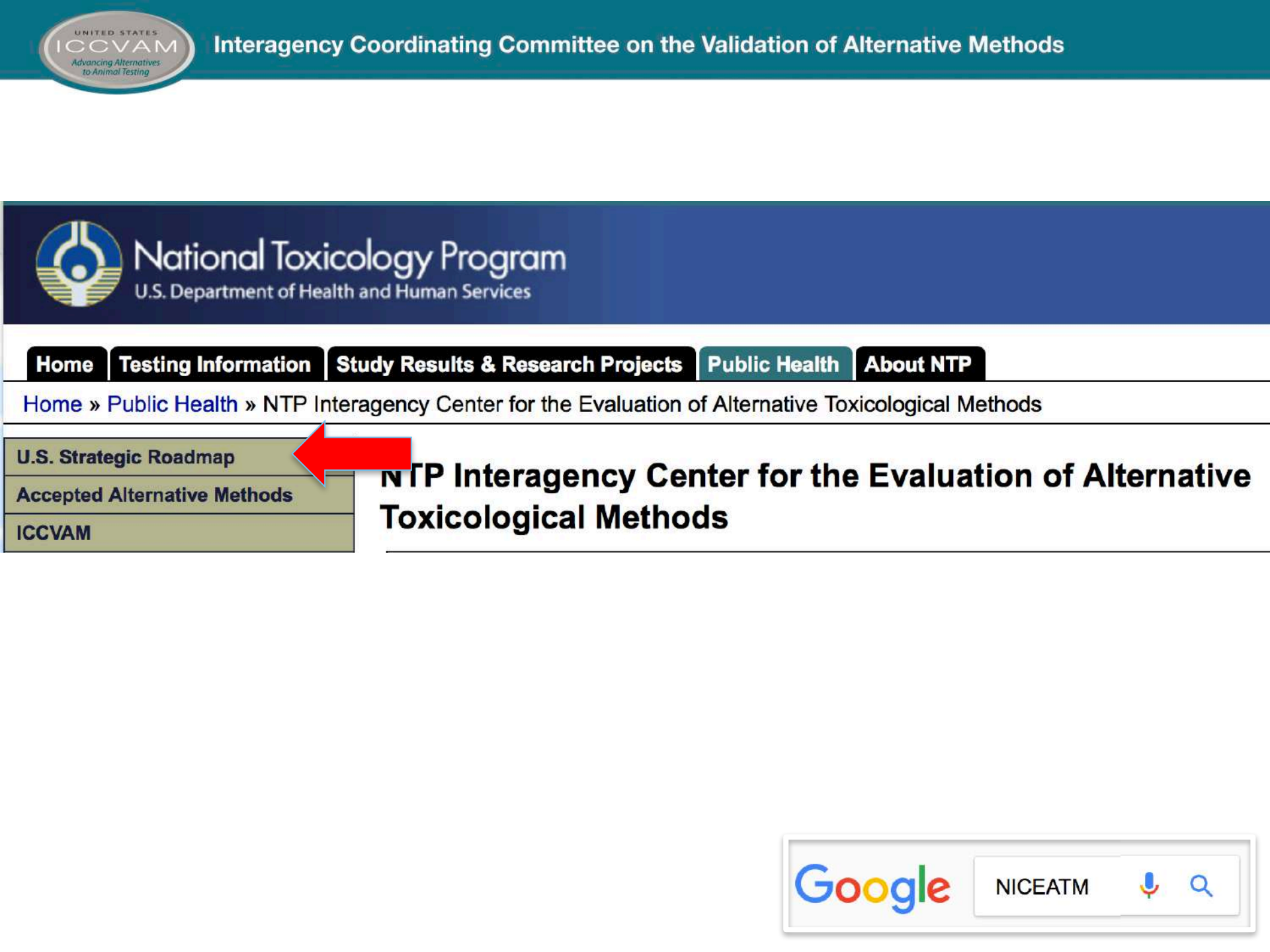
Selected OBJECTIVES:

- Promote communication and data sharing across product-sectors and help unify efforts to develop alternative methods
- Identify and promote resources that can foster the development and utilization of new or enhanced approaches
- Explore new approaches for establishing the scientific validity of new test methods and approaches and publish best practices for their development and evaluation
- Establish appropriate metrics for prioritizing activities, monitoring progress, and measuring success

18-19 Sep
SACATM
NIH, Bethesda

Dec
Publish Final

14 Aug
Publish Draft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Advancing Alternatives to Animal Testing
Interagency Coordinating Committee on the Validation of Alternative Methods
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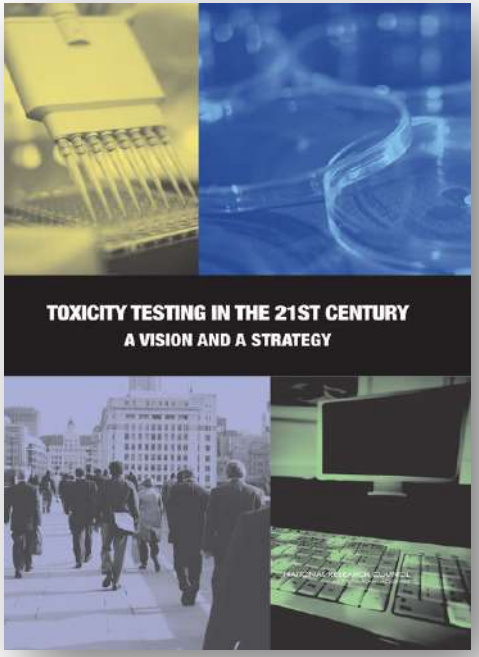
Thank you!

Answers?

FAQ

- How is this different?



2007

2016

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
- Public-private partnerships to focus on key areas
  - Read Across
  - In Vitro to In Vivo Extrapolation (IVIVE)
  - Developmental and Reproductive Toxicology (DART)

Variability in animal studies
Harmonized Acceptance criteria

How do we measure success
How to integrate disciplines without alienating them?
Work in non-regulated space will likely be the first success

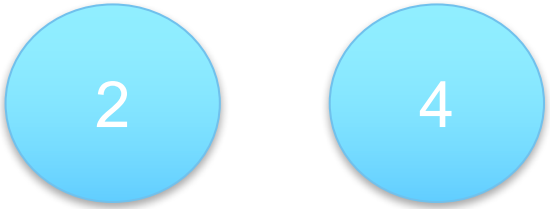
Method Development

Validation

Compare to existing method

Regulatory Acceptance

Industry Adoption



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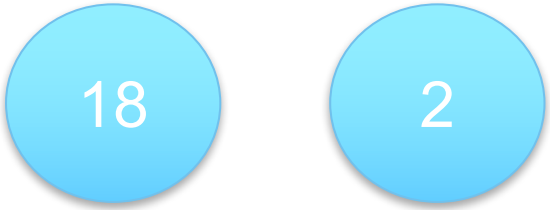

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