A Strategic Roadmap to Establish New Approaches for Toxicity Testing in the United States

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It is difficult for evolving institutional practices to keep pace with revolutionary advances in science and technology.
Method Development ➔ Validation ➔ Regulatory Acceptance ➔ Industry Adoption
One size fits all: OECD GD 34
International Cooperation on Alternative Test Methods (ICATM)

Validation of Alternative Methods: The “VAMs”

ICCVAM EURL-ECVAM KoCVAM CCVAM
BraCVAM JaCVAM ChiCVAM
AGENCIES ARE ALIGNED

NEW APPROACHES

collaboration

relevance

increase capacity

overcome bottlenecks

risk management
decision-making

scientific tools
cost effective
best science solutions
“3Cs”

COMMUNICATION

COLLABORATION

COMMITMENT
“FIT FOR PURPOSE”

“CONTEXT OF USE”
WORDS MATTER
“To expedite the use of 21st Century science to protect public health and the environment, Federal agencies and stakeholders must work together to establish new approaches for the development, evaluation, and utilization of toxicological tests that are more human-relevant and that reduce or eliminate the need for testing in animals.”
MUST START HERE!!
Strategic Goals

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

Help end-users guide the development of the new tools needed to support their needs.

Foster the use of efficient, flexible, and robust practices to establish confidence in new methods.
HOW IS THIS DIFFERENT?

• Driven by Federal agencies ("Top down" vs "Bottom up")

• Includes both chemicals and medical products

• Protecting public health and improving human relevance are key drivers

• Paired with implementation plans will be tracked and publically reported
The U.S. strategic roadmap is intended as a resource to help guide the efforts of federal agencies and stakeholders seeking to adopt new approaches for use in safety and risk assessment.

The document was developed by representatives from 16 federal agencies and multiple interagency workgroups. As such, it represents a consensus perspective, does not necessarily reflect opinions or policy of any specific agency or workgroup, and should not be taken as a commitment by any federal agency.
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THANK YOU!