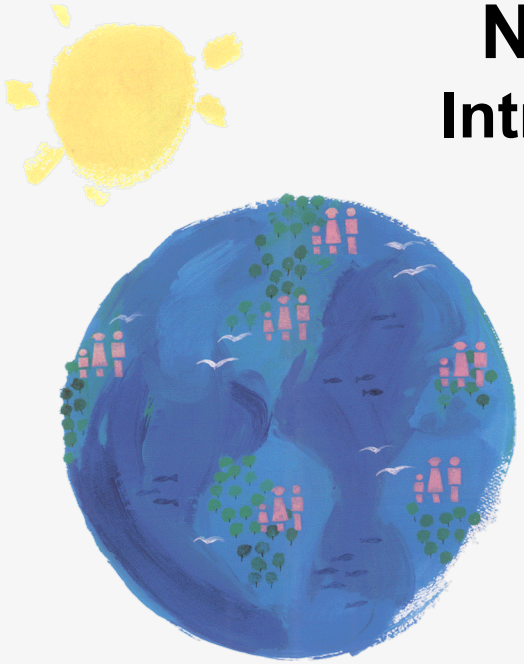
NICEATM

National Toxicology Program
Interagency Center for the Evaluation of Alternative Toxicological Methods

ICCVAM

Interagency Coordinating Committee on the Validation of Alternative Methods



NICEATM-ICCVAM 5-Year Plan:
Introduction and Development Process

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ICCVAM-NICEATM 5-Year Plan Town Meeting

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National Institutes of Health
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National Toxicology Program

NIEHS

NATIONAL INSTITUTES OF HEALTH

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA

Outline

- Overview of NICEATM and ICCVAM
- Congressional Mandate
- Development Process

What is ICCVAM ?

Interagency Coordinating Committee on the Validation of Alternative Methods

It is a permanent interagency committee composed of members designated by the heads of 15 federal agencies.

ICCVAM Member Agencies

Regulatory Agencies

- 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

Research Agencies

- Agency for Toxic Substances and Disease Registry
- Department of Defense
- Department of Energy
- National Cancer Institute
- National Institute of Environmental Health Sciences
- National Institute for Occupational Safety and Health
- National Library of Medicine
- National Institutes of Health

What is NICEATM?

National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods

- A component of the NIEHS, NIH, DHHS
  - Research Triangle Park, North Carolina
- Functions:
  - Administer ICCVAM
  - Provide scientific and operational support for ICCVAM
  - Convene test method peer reviews, expert panel meetings, and workshops
  - Communicate and partner with stakeholders
  - Conduct independent validation studies
- http://iccvam.niehs.nih.gov

History of ICCVAM

1994: *ad hoc* ICCVAM established in response to NIEHS directives in the NIH Reauthorization Act (P.L. 103-43) to:

- *Develop criteria for validation and regulatory acceptance of test methods*
- *Develop a process to achieve regulatory acceptance of scientifically validated methods*

1997: Final report of the *ad hoc* ICCVAM

1997: ICCVAM established

- Replaced *ad hoc* ICCVAM
- Implemented NIEHS directives: P.L. 103-43

1998: NICEATM established

2000: ICCVAM Authorization Act of 2000: P.L. 106-545

- Established “permanent” ICCVAM

ICCVAM's Mission Statement[1]

- To *facilitate* development, validation and regulatory acceptance of new and revised regulatory test methods that
  - reduce, refine, and replace the use of animals in testing
  - while maintaining and promoting scientific quality and the protection of human health, animal health, and the environment

[1]Adopted by ICCVAM February 2004

All of ICCVAM's activities are grounded in the U.S. Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training

http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples

What are the Purposes of ICCVAM?[1]

- To increase the efficiency and effectiveness of U.S. Federal agencies' test method review
- To eliminate unnecessary duplicative efforts and share experiences between U.S. Federal regulatory agencies
- To optimize the utilization of scientific expertise outside the U.S. Federal government
- To ensure that new and revised test methods are [adequately] validated to meet the needs of U.S. Federal agencies
- To reduce, refine, or replace the use of animals in testing, where feasible

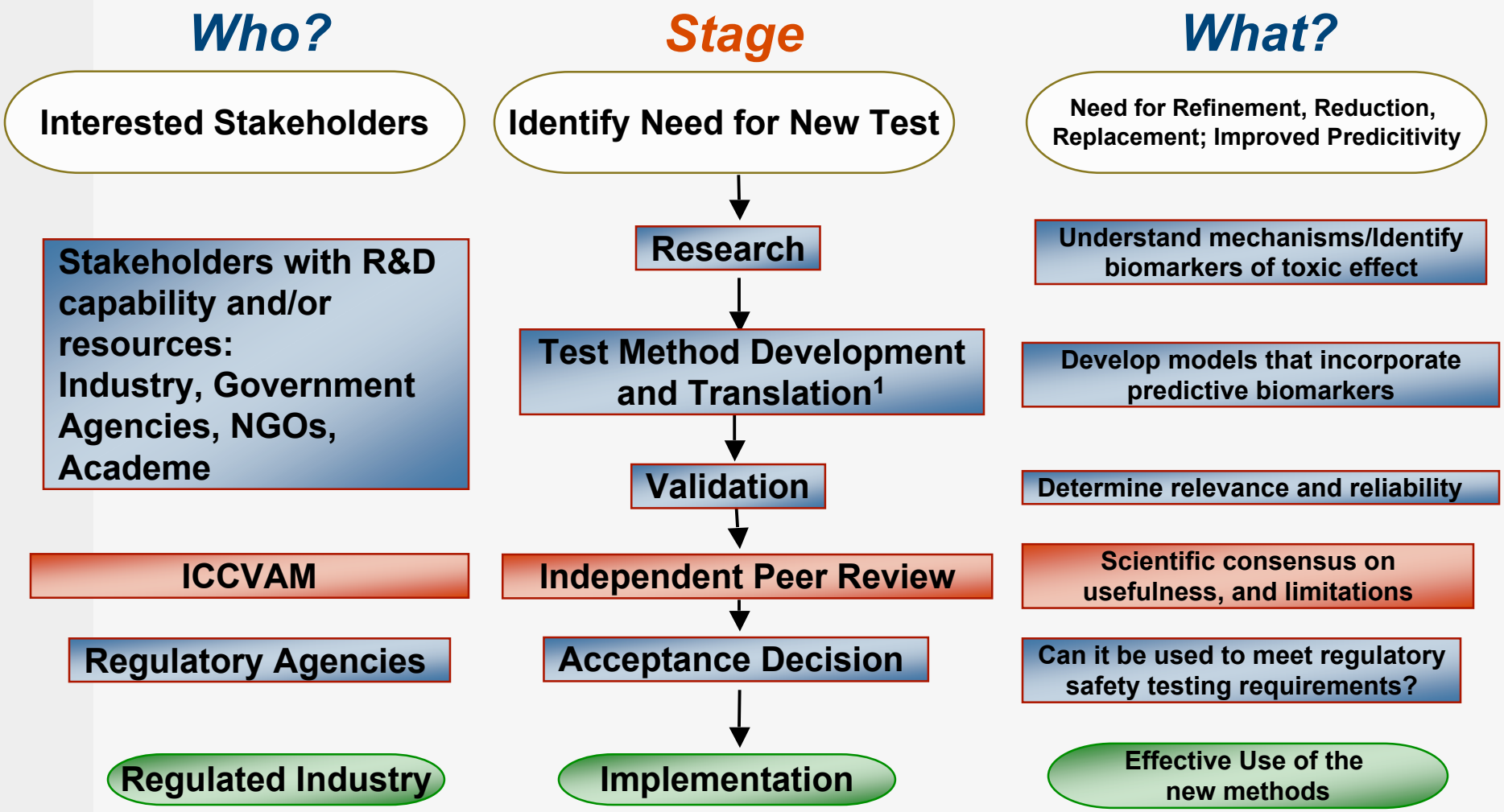
[1]ICCVAM Authorization Act of 2000, 42 U.S.C. 285l–3

What are ICCVAM's Duties?[1]

- To consider petitions from the public for review and evaluation of validated test methods
- To review and evaluate new, revised, and alternative test methods
- To submit test method recommendations to U.S. Federal agencies and make agency responses (due within 180 days) available to the public
- To facilitate and provide guidance on:
  - test method development
  - validation criteria and processes
- To facilitate:
  - acceptance of scientifically valid test methods
  - interagency and international harmonization

[1]ICCVAM Authorization Act of 2000, 42 U.S.C. 285l–3

How do New Test Methods Evolve?



[1]Initial determination of relevance or applicability of method (A proof of principal)

NICEATM-ICCVAM Contributions

- Over 150 test methods evaluated since 1997
- Impact
  - Alternative methods recommended and/or adopted internationally for four of the 6 most common product safety tests
  - Recommendations provided for R&D, translation,and validation activities to advance alternative methods
- Performance standards to expedite validation studies and regulatory acceptance
- Criteria and guidance for validation and regulatory acceptance of new, revised, and alternative methods

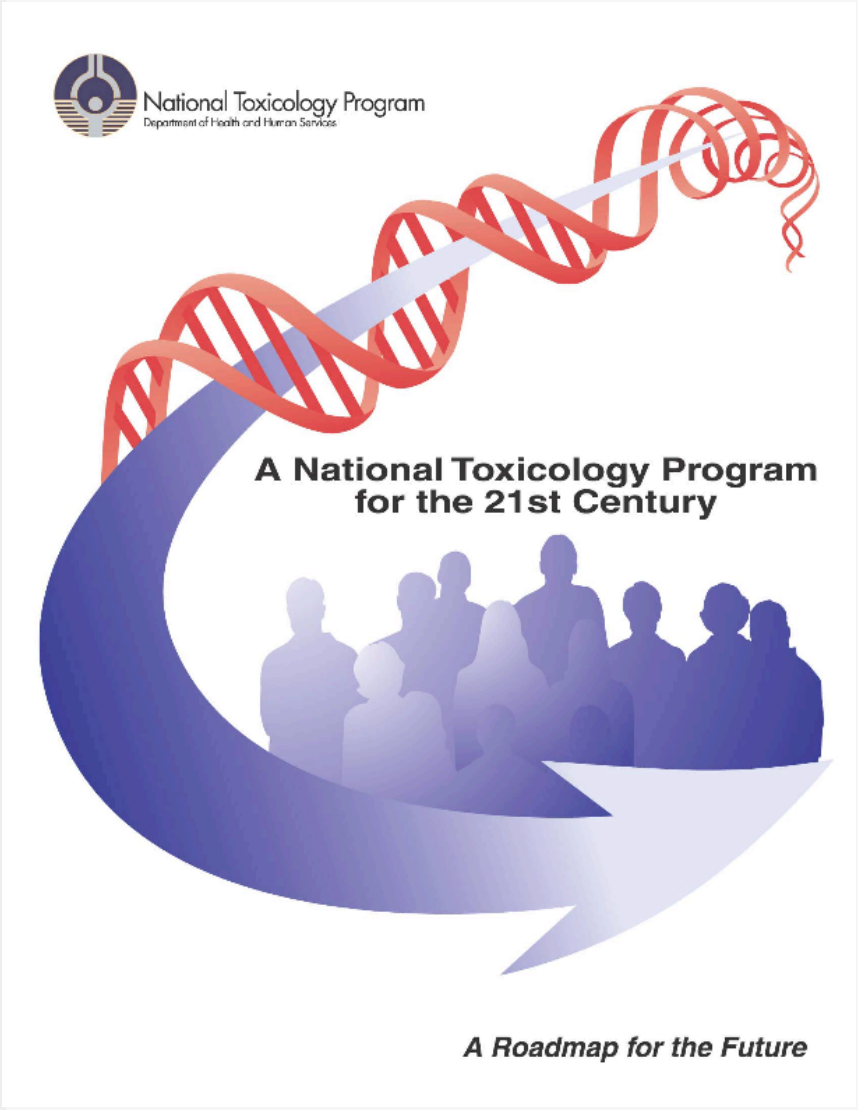
NICEATM-ICCVAM 5-Year Plan

Background

U.S. House and Senate Appropriations Committees: Fiscal Year 2007 Requests

- **Requests NICEATM/ICCVAM, in partnership with relevant federal agency program offices, to build on the NTP Roadmap to create five-year plan to:**
  - **Research,Develop,Translate, and Validate** new and revised non-animal and other alternative assays for integration of relevant and reliable methods into the Federal agency testing programs.
  - Identify areas of high priority for new and revised non-animal and alternative assays or batteries of those assays to create a path forward for the 3Rs, when this is scientifically valid and appropriate.
- **Plan Requested by:**
  - **Senate: Status, Spring 2007**
  - **House: November 15, 2007**

Building on NTP Roadmap



- Goal 2 of the Roadmap:
  - "*Develop and validate improved testing methods and, where feasible, ensure that they reduce, refine, or replace the use of animals.*"
- From page 7:
  - *"Activities and assays developed under the NTP Roadmap will be done in cooperation and consultation with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) to maximize their value to regulatory agencies."*

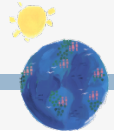
NIEHS Guidance to NICEATM and ICCVAM

- for development of Congressional Appropriations Committee Report (5-Year Plan)

- Report should be aimed at an audience of policymakers (Congress Members and staff)
- Body of report should be limited to no more than 20 pages
- Report must be submitted to NIEHS Budget Office by September 15, 2007 in order to complete clearance by congressional deadline of November 15, 2007

NICEATM-ICCVAM 5-Year Plan Process

(See Appendix C of Draft Plan)



NICEATM-ICCVAM 5-Year Plan Process

Phase I - Gather Information

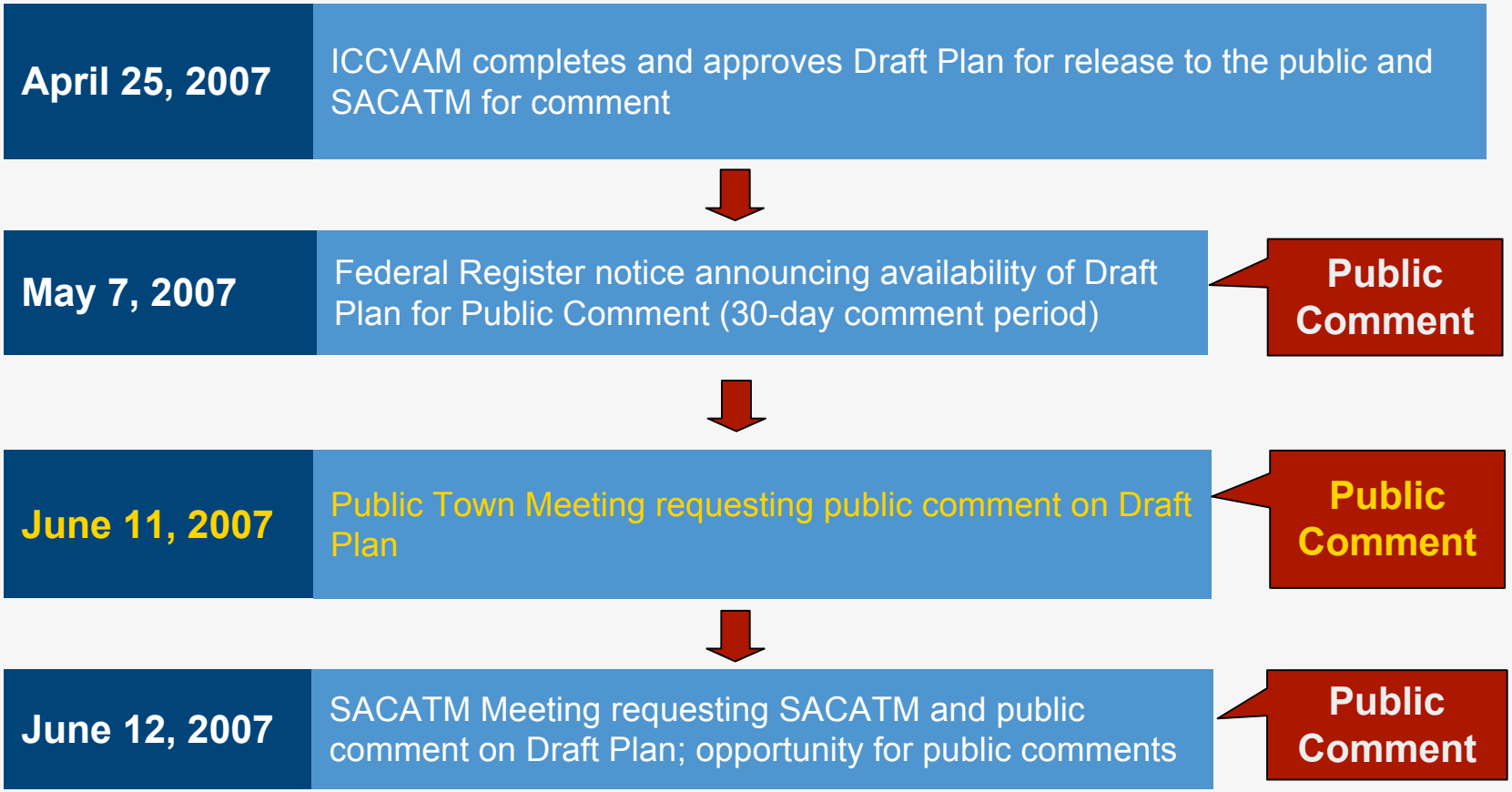
August 23, 2006	ICCVAM considers congressional mandate; establishes Five-Year Plan Subcommittee to develop recommendations on process and timeline for compliance
October 30, 2006	Request to ICCVAM Agencies to provide relevant information to consider as the Plan is developed; Public comments provided to agencies: Jan 07
November 9, 2006	Federal Register notice requesting public comments by December 31 for ICCVAM to consider in preparing the Plan
November 30, 2006	SACATM meeting requesting SACATM and public comments relevant to development of the Plan

Public Comment

Public Comment

NICEATM-ICCVAM 5-Year Plan Process

Phase II - Develop Initial Draft and obtain comments



NICEATM-ICCVAM 5-Year Plan Process

Phase III - Prepare and Submit Final Plan

June13,2007 - August 8, 2007	ICCVAM considers public and SACATM comments, revises draft ICCVAM discusses and approves Final Plan
September 15, 2007	Concurrence and clearance approval from ICCVAM agencies on the Final NICEATM-ICCVAM Five-Year Plan due
Sep. 24, 2007- Nov 15, 2007	NIEHS forwards to plan to NIH; NIH/HHS forwards Final NICEATM-ICCVAM Plan to House and Senate Appropriations
December 2007	Public Release of final Five-Year Plan

Summary

- **NICEATM and ICCVAM, in partnership with relevant federal agency program offices, are preparing a congressionally-mandated five-year plan to:**
  1. **Research, Develop, Translate, and Validate** new and revised non-animal and other alternative assays for integration of relevant and reliable methods into the Federal agency testing programs
  2. **Identify areas of high priority for new and revised non-animal and alternative assays** or batteries of those assays to create a path forward for the 3Rs, when this is scientifically valid and appropriate
- **Today we are presenting a draft of this plan for your comment.**
- **Current and previous public comments will be considered in finalizing the Plan, and prioritizing future ICCVAM activities.**
- **The final NICEATM-ICCVAM plan will be submitted for agency/HHS clearance in August in order to reach congressional budget committees by November 15, 2007.**
  - **It will be made available to the public after submission to Congress**

Acknowledgements: ICCVAM Agency Representatives

Agency for Toxic Substances and Disease Registry
• Moiz Mumtaz, Ph.D.

Consumer Product Safety Commission
• Marilyn L. Wind, Ph.D. (Chair)
* Patricia Bittner, M.S.
* Kristina Hatlelid, Ph.D.

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◊ Elizabeth Goldentyer, D.V.M.

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◊ Patty Decot
* Harry Salem, Ph.D.

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◊ Marvin Stodolsky, Ph.D.

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◊ Steve Hwang, Ph.D.

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* Deborah McCall

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Center for Devices and Radiological Health
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Center for Biologics Evaluation and Research
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Center for Food Safety and Nutrition
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• Principal Agency Representative
◊ Alternate Principal Agency Representative
* Other Designated Agency Representatives

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  - Dr. Amy Rispin
  - Dr. Margaret Snyder
  - Dr. William Stokes
  - Dr. Marilyn Wind, ICCVAM Chair
  - Dr. Sheila Newton, NIEHS Liaison, Planning Office
- **Agency Program Offices and ad hoc Working Groups**
- **Stakeholders**