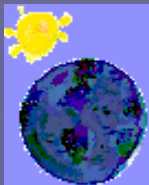


ICCVAM Strategic Plan: Mission, Vision, and Strategic Priorities

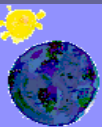
Report to the Scientific Advisory Committee on Alternative
Toxicological Methods (SACATM)
March 10-11, 2004

Leonard M. Schechtman, Ph.D., FDA/NCTR, ICCVAM Chair
Marilyn L. Wind, Ph.D., CPSC, ICCVAM Vice Chair



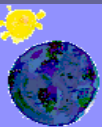
ICCVAM Strategic Planning Meeting Participants

- Cecilia Aguila, FDA
- Brad Blackard, NICEATM/ILS
- Rajendra Chhabra, NIEHS
- William Cibulas, ATSDR
- Tim Fallon, Facilitator,
TSI Consulting Partners
- Suzanne Fitzpatrick, FDA
- Karen Hamernik, EPA
- David Hattan, FDA
- Jerry Heindel, NIEHS
- Vera Hudson, NLM
- Steve Hwang, DOT
- Abby Jacobs, FDA
- Devaraya Jagannath, FDA
- Jodie Kulpa-Eddy, USDA
- Debbie McCarley, NIEHS
- Richard McFarland, FDA
- Suzanne McMaster, EPA
- Joe Merenda, EPA
- Alan Poland, NCI
- Barnett Rattner, DOI
- Amy Rispin, EPA
- Harry Salem, DOD
- Len Schechtman, FDA
- Doug Sharpnack, NIOSH
- Maggie Snyder, NIH
- Marvin Stodolsky, DOE
- Bill Stokes, NIEHS
- Marjorie Strobel, NCI
- Melvin Stratmeyer, FDA
- Ray Tice, NICEATM/ILS
- Marilyn Wind, CPSC



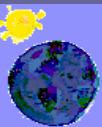
ICCVAM Strategic Planning Meeting

- Venue: National Institutes of Health, January 7-8, 2004
- Contributors: 30 energetic, indefatigable participants, exceptionally facilitated by Tim Fallon, TSI Consulting Partners, Inc., Kalamazoo, MI
- Breakout Groups were formed to assess the current ICCVAM situation/endeavors and future prospects, and report in plenary sessions where issues were further deliberated/discussed
- Issues examined
 - Strengths of ICCVAM
 - ICCVAM challenges/areas for improvement
 - Critical organizational issues ICCVAM will face over the next 3 years
- From those discussions and mindful of the mandates of the ICCVAM Authorization Act
 - An **ICCVAM Mission** was developed
 - An **ICCVAM Vision** was drafted
 - These were discussed, debated, revised repeatedly, and fashioned into **ICCVAM Mission and Vision Statements** unanimously accepted by all ICCVAM agency participants



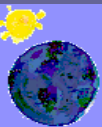
Key Strengths of ICCVAM [1]

- ICCVAM Authorization Act provides a strong foundation and clear mission
- ICCVAM's track record
- Expert review of test methods
- Fundamentally good science and public health policy
- ICCVAM's role as a central resource for validation-related activities
- Tasks and direction well-defined
- Established processes and standard operating procedures
- Interagency participation from diverse members
 - Multiple agencies
 - Broad expertise
 - Varied experience
- Representatives are interested, enthusiastic, committed



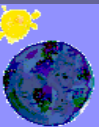
Key Strengths of ICCVAM [2]

- Good working atmosphere
 - Strong communication
 - Voluntary participation
 - Representatives are interactive and cooperative
 - A "level playing field" where everyone has opportunity to interact
- Strong leadership
- NICEATM's role as a supporting organization
 - Committed staff
 - Efficiency
 - Good organization and continuity
- Public perception of ICCVAM
- Interaction with animal advocacy groups
- Excellent international ties, especially with ECVAM



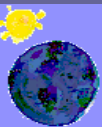
Key Challenges ICCVAM Faces [1]

- ICCVAM needs to be even more proactive in:
 - Stimulating the development of new test methods
 - Developing criteria for prioritizing which methods to review
- ICCVAM needs to continue to work to achieve the right balance between:
 - Reduction and refinement of animal tests as well as replacement
 - Human health and environmental issues
- Functioning effectively with very limited resources
 - ICCVAM has limited dedicated resources to carry out its mandate
 - Budget
 - Staff
 - Labs
 - The time constraints of ICCVAM representatives (who have to meet both their agency and ICCVAM responsibilities)
 - Effectiveness of ICCVAM and its working groups is dependent on largely volunteer participation



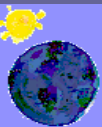
Key Challenges ICCVAM Faces [2]

- Continuing to optimizing ICCVAM's internal processes in order to:
 - Empower working groups
 - Coordinate the efforts of working groups
 - Decrease project completion timelines
- Maintaining ICCVAM continuity and effectiveness as turnover occurs among agency representatives
- Continuing to communicate effectively with its stakeholders in order to:
 - Achieve appropriate visibility in the scientific community
 - Inform the public and ensure that its process is transparent
 - Build credibility with animal advocacy groups
 - Strengthen appreciation and support of ICCVAM's contribution
- Continuing to align the diverse interests of multiple stakeholders in order to:
 - Ensure that upper management and agency leadership understand the strengths and limitations of animal testing
 - Build the commitment from upper management for the importance of its work and the need for adequate resources to carry it out



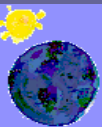
Key Challenges ICCVAM Faces [3]

- Clarifying the relationship between ICCVAM, SACATM, and NICEATM/NTP
- Working effectively with agencies that participate in ICCVAM to:
 - Increase understanding of and support for ICCVAM's mission
 - Strengthen awareness of the payoff of working with ICCVAM
 - Coordinate effective use of the expertise of these agencies
 - Increase agency commitment to implementation of new test methods
 - Manage the differences in approaches and priorities among agencies that participate in ICCVAM
- Building more effective industry cooperation with and support for ICCVAM to:
 - Ensure ICCVAM is well known to industry
 - Secure appropriate access to industry data
 - Build financial support from industry



Key Challenges ICCVAM Faces [4]

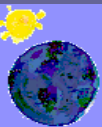
- Dealing effectively with international influences on animal use
 - Animal rights
 - How ECVAM contributes to the regulatory process
- Strengthening international relations/partnerships with Europe and the Pacific Rim, including:
 - Managing differences in strategic plans/laws with European countries
 - Developing effective strategies for working in a more direct and formal way with OECD to:
 - Harmonize test guideline issues
 - Encourage the use of ICCVAM-validated protocols
 - Secure the inclusion of ICCVAM-recommended performance standards in OECD guidelines
 - Encourage the use of appropriate scientific/peer review



ICCVAM Mission

Approved by Strategic Planning Meeting Participants
Adopted by ICCVAM 11 February 2004

ICCVAM's mission is 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.



ICCVAM Vision

Approved by Strategic Planning Meeting Participants
Adopted by ICCVAM 11 February 2004

ICCVAM will—

1. Be recognized as a leading authority on test method development and validation both within the federal government and internationally

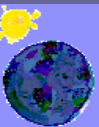
ICCVAM Vision

Approved by Strategic Planning Meeting Participants
Adopted by ICCVAM 11 February 2004

ICCVAM will—

2. Play a leading role in:

- Promoting high quality science as the basis of national and international regulatory policy
- Setting & harmonizing international standards for scientific validation of test methods
- Promoting & facilitating development of priority alternative test methods
- Identifying key alternative test methods & strategies & facilitating their validation & acceptance
- Fostering humane & ethical approaches to testing that replace, reduce, & refine the use of animals
- Promoting awareness & adoption of scientifically validated test methods by regulatory agencies both nationally & internationally

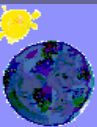


ICCVAM Vision

Approved by Strategic Planning Meeting Participants
Adopted by ICCVAM 11 February 2004

ICCVAM will—

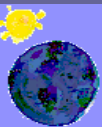
3. Develop the internal & collaborative capacity to:
 - Ensure the scientific quality & integrity of its work
 - Implement reliable processes & operating procedures that are credible, effective, & efficient
 - Build national & international partnerships with governmental & non-governmental groups, including academia, industry, advocacy groups, & other key stakeholders
 - Secure the necessary human & financial resources to effectively carry out its mission



ICCVAM's Strategic Map

■ Strategic Map

- a tool for defining/describing an organization, its *raison d'être*, and its guiding principles
- is based upon:
 - the organization's current state-of-affairs
 - its strengths
 - areas warranting improvement
 - a plan/roadmap to achieve its aims
- Product: a graphic depiction of the organization's profile, i.e.,
 - its starting point
 - its goals and priorities
 - the direction it needs to take to achieve its purpose and attain its goals
 - the unifying outcomes that help establish/define its responsibilities and its sphere of influence

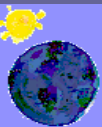


ICCVAM's Strategic Map

- Components of the ICCVAM Strategic Map
 - ICCVAM's Central Challenge
 - Defines the primary factor that will influence ICCVAM's strategic direction for the foreseeable (near-term) future
 - ICCVAM's Strategic Priorities
 - Outlines the principal elements that underpin ICCVAM's Central Challenge
 - ICCVAM's Strategic Objectives
 - Supporting objectives that further define ICCVAM's Strategic Priorities
- *Living Document—*
 - approved by Strategic Planning Meeting participants, 8 January 2004
 - adopted by ICCVAM 11 February 2004 as part of its Mission—Vision—Strategic Priorities
 - to be revisited periodically for self-evaluation and revision as necessary

Creation of ICCVAM's Strategic Map

- Process involved:
 - breakout group brain-storming
 - in-depth plenary discussions
 - composing, editing, refining, and finalizing the map's components
- Result:
 - identification of the **Central Challenge** ICCVAM faces over the next 3 years
 - establishment of **Strategic Priorities** that would facilitate ICCVAM fulfilling that Central Challenge
- The Central Challenge and Strategic Priorities formed the basis of ICCVAM's Strategic Map
- Developed ICCVAM's **Strategic Map** for 2004-2006
 - i.e. a roadmap for ICCVAM to follow for the next 3 years
- A **Rationale** for each Strategic Priority was created
- **Supporting Objectives** for each Strategic Priority were identified that detail the specifics (i.e. *building blocks*) that comprise each Strategic Priority
- **Accountabilities** for implementation were detailed



ICCVAM Strategic Map*

for the Next 3 Years: 2004-2006

Strengthen ICCVAM's Impact
Nationally and Internationally

Set Priorities for
Evaluating Test
Methods and
Carry Out
Reviews

Facilitate
Collaborative
Scientific
Validation
Internationally

Stimulate Development
of Priority
Test Methods
and Strategies

Foster
Appropriate Use
of Validated
Test Methods

Strengthen
ICCVAM
Capability
and Sustainability

Strengthen Interaction with Stakeholders

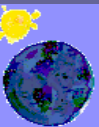
*Central Challenge: oval

Strategic Priorities: boxes

ICCVAM's Central Challenge

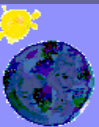
- Central Challenge ICCVAM faces over the next 3 years:

To strengthen ICCVAM's impact nationally and internationally



ICCVAM Strategic Priorities

- Set priorities for evaluating test methods and carry out reviews
- Facilitate collaborative scientific validation internationally
- Stimulate development of priority test methods and strategies
- Foster appropriate use of validated test methods
- Strengthen ICCVAM capability and sustainability
- Strengthen interaction with stakeholders



ICCVAM Strategic Map: 2004-2006

**Strengthen ICCVAM's Impact
Nationally and Internationally**

**Set Priorities for
Evaluating Test
Methods and
Carry Out
Reviews**

Implement
Priority Setting
Process

Periodically
Evaluate Stakeholder
Priorities

Develop
Review Documents
and Performance
Standards

Conduct
Appropriate
Review Activity

Develop and
Forward
Recommendations
to Federal Agencies

**Facilitate
Collaborative
Scientific
Validation
Internationally**

Foster Network
of International
Collaborators

Build Consensus
On Validation and
Collaboration
Processes

Develop ICCVAM
Infrastructure to
Promote and Track
Collaborative Efforts

**Stimulate Development
of Priority
Test Methods
and Strategies**

Establish ICCVAM
Priorities for Test
Method Development

Conduct Technical
Meetings on
State of the Science
in Priority Areas

Formulate Research
Recommendations
and Stimulate
Research

Evaluate
Research
Progress and Results
In Prioritized Areas

Facilitate Nomination
of Promising Test
Methods for Validation
Studies

**Foster
Appropriate Use
Of Validated
Test Methods**

Promote
Awareness of
Validated Methods

Provide Education
On Utility,
Advantages,
and Disadvantages

Support Implementation
of New Methods
Using Workshops & Training

**Strengthen
ICCVAM
Capability
and Sustainability**

Document
Organizational
Procedures and
Partnerships

Publish Accomplishments
and Explore Other
Outreach Opportunities

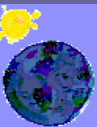
Attract/Obtain
Dedicated
Funding

Develop and Implement
ICCVAM Representative
Succession Plan

Explore Possibility
of Expanding
Resources and
Capabilities

Seek Ex-Officio
Status with OECD and
Other International
Organizations

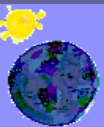
Strengthen Interaction with Stakeholders



Strategic Priority 1:

Set priorities for evaluating test methods and carry out reviews

- Rationale:
 - ICCVAM's ability to fulfill its legislative mandate requires that it function with both effectiveness and efficiency
 - Specific objectives are set to ensure ICCVAM's effectiveness, including —
 - implementation of the priority setting process that has already been developed
 - periodic evaluation of the priorities of its stakeholders
 - Other supporting objectives are intended to ensure that ICCVAM continues to carry out quality reviews while improving timeliness and efficiency
- Accountability:
 - ICCVAM
 - NICEATM



ICCVAM Strategic Map: 2004-2006

Strengthen ICCVAM's Impact Nationally and Internationally

Set Priorities for Evaluating Test Methods and Carry Out Reviews

Implement Priority-Setting Process

Periodically Evaluate Stakeholder Priorities

Develop Review Documents and Performance Standards

Conduct Appropriate Review Activity

Develop and Forward Recommendations to Federal Agencies

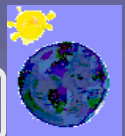
Key

Central Challenge: oval

Strategic Priority: green box

Strategic Objectives: white boxes

Strengthen Interaction with Stakeholders



Strategic Priority 2: *Facilitate collaborative scientific validation internationally*

■ Rationale:

- ICCVAM's effectiveness in validating alternative test methods that replace, reduce and refine the use of animals in testing requires it to engage in a wide range of international collaborations
- These collaborations provide the basis for ICCVAM to ensure sound science serves as the foundation for —
 - validating alternative methods
 - promoting broad use of validated alternative methods
 - encouraging the harmonization of scientific approaches to validation and review

■ Accountability:

- ICCVAM
- NICEATM

ICCVAM Strategic Map: 2004-2006

Strengthen ICCVAM's Impact Nationally and Internationally

Facilitate Collaborative
Scientific Validation
Internationally

Foster Network of
International Collaborators

Build Consensus on
Validation and Collaboration
Processes

Develop ICCVAM Infrastructure
to Promote and Track
Collaborative Efforts

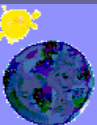
Key

Central Challenge: oval

Strategic Priority: green box

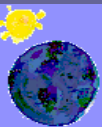
Strategic Objectives: white boxes

Strengthen Interaction with Stakeholders



Strategic Priority 3: *Stimulate development of priority test methods and strategies*

- Rationale:
 - Test methods must be developed and validated in order for them to be evaluated by ICCVAM
 - Key objectives are outlined that ICCVAM needs to carry out in order to stimulate the development of test methods and testing strategies by others
 - Actions are identified that ICCVAM will take to establish priorities for —
 - test method development
 - stimulating method development in prioritized areas
 - facilitating the nomination of promising test methods
- Accountability:
 - ICCVAM
 - NICEATM



ICCVAM Strategic Map: 2004-2006

Strengthen ICCVAM's Impact Nationally and Internationally

Stimulate Development of
Priority Test Methods
and Strategies

Establish ICCVAM Priorities
for Test Method Development

Conduct Technical Meetings on
State of the Science in Priority Areas

Formulate Research Recommendations
and Stimulate Research

Evaluate Research Progress
and Results in Prioritized Areas

Facilitate Nomination of Promising
Test Methods for Validation Studies

Key

Central

Challenge: oval

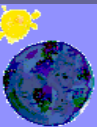
Strategic

Priority: green box

Strategic

Objectives: white boxes

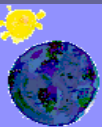
Strengthen Interaction with Stakeholders



Strategic Priority 4:

Foster appropriate use of validated test methods

- Rationale:
 - Achieving ICCVAM's goal of replacing, reducing, and refining the use of animals in testing requires that validated test methods realize widespread appropriate use
 - This strategic priority and its supporting objectives outline key actions that ICCVAM will take to —
 - promote the awareness of those validated methods
 - educate key stakeholders on their appropriate use
 - provide support for their effective implementation
- Accountability:
 - ICCVAM
 - NICEATM



ICCVAM Strategic Map: 2004-2006

Strengthen ICCVAM's Impact Nationally and Internationally

Foster Appropriate Use
of Validated Test Methods

Promote Awareness of
Validated Methods

Provide Education
on Utility, Advantages,
and Disadvantages

Support Implementation of
New Methods Using
Workshops and Training

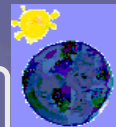
Strengthen Interaction with Stakeholders

Key

Central Challenge: oval

Strategic Priority: green box

Strategic Objectives: white boxes



Strategic Priority 5: *Strengthen ICCVAM capability and sustainability*

■ Rationale:

- ICCVAM's ability to carry out its legislative mandate requires both strong core capability and sustainable resource support
- ICCVAM's success in implementing this **Strategic Plan** is dependent on the human and financial resources available to support the plan
- As a result, this priority and its supporting objectives set forth efforts to —
 - obtain dedicated funding
 - explore the possibility of expanding resources and capabilities
 - ensure the effective succession of ICCVAM agency representatives
 - continue ongoing efforts to ensure that ICCVAM develops effective organizational processes and operating procedures

■ Accountability:

- ICCVAM
- NICEATM

ICCVAM Strategic Map: 2004-2006

Strengthen ICCVAM's Impact Nationally and Internationally

Strengthen ICCVAM Capability and Sustainability

Document Organizational
Procedures and Partnerships

Publish Accomplishments and
Explore Other Outreach Opportunities

Attract / Obtain
Dedicated Funding

Develop and Implement ICCVAM
Representative Succession Plan

Explore Possibility of Expanding
Resources and Capabilities

Seek Ex-Officio Status with OECD
and Other International Organizations

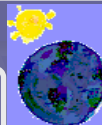
Key

Central Challenge: oval

Strategic Priority: green box

Strategic Objectives: white boxes

Strengthen Interaction with Stakeholders



(Cross-Cutting) Strategic Priority 6: *Strengthen interaction with ICCVAM stakeholders*

■ Rationale:

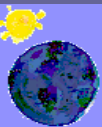
- Effective interaction with stakeholders is an essential component of implementing each ICCVAM strategic priority
- Strengthening interaction with stakeholders will help ICCVAM —
 - improve its effectiveness and efficiency in setting priorities for evaluating test methods and carrying out reviews
 - develop international collaborations that promote sound science in validating alternative methods and encourage broad use of validated alternative methods
 - stimulate others to develop test methods and strategies in prioritized areas
 - promote the awareness of validated methods among key stakeholders and provide implementation support for their appropriate use
 - build strong base capability and secure sustainable resource support

■ Accountability:

- ICCVAM
- NICEATM

Next Steps

- ICCVAM Mission and Vision statements adopted by ICCVAM 11 Feb 2004
- Draft Strategic Map adopted by ICCVAM 11 Feb 2004
- ICCVAM will have distributed the Mission—Vision—Strategic Priorities to SACATM in advance of the March 10-11, 2004 meeting
- The SACATM will have the opportunity to discuss the ICCVAM Strategic Plan, i.e., Mission—Vision—Strategic Priorities, including the Strategic Map
- ICCVAM will establish member Working Groups to begin the process of developing strategies for the Implementation of the Strategic Plan



Next Steps

- During the April 27/28, 2004 ICCVAM meeting:
 - comments from SACATM and the public will be reviewed & discussed
 - the final ICCVAM Strategic Map will be adopted
 - the draft Implementation Plan will be discussed and revised as needed
- At the fall 2004 SACATM meeting, ICCVAM will:
 - present its final Strategic Map
 - update SACATM on results achieved to date
 - highlight key aspects of Implementation Plan for the next 12 months

