

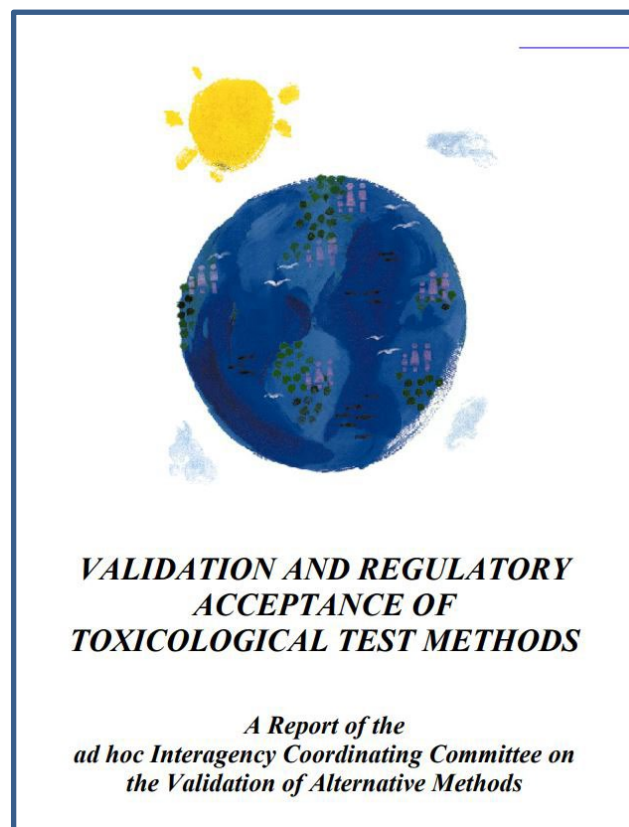


ICCVAM: Validation Workgroup

Updating the ICCVAM Report

ICCVAM Sponsor Agencies:
CPSC, FDA/CFSAN

Participating Agencies:
EPA/OPP, EPA/ORD,
ATSDR, VA ORD, DOD,
NIST, OSHA, NIEHS, NIH,
FDA/CDER,/CTP,/OCS,/CDRH



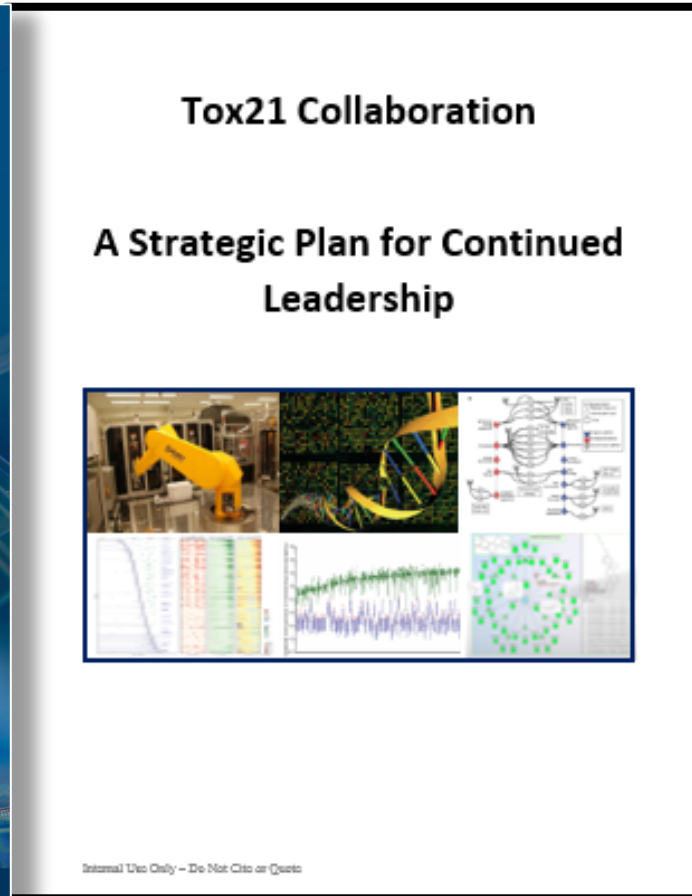
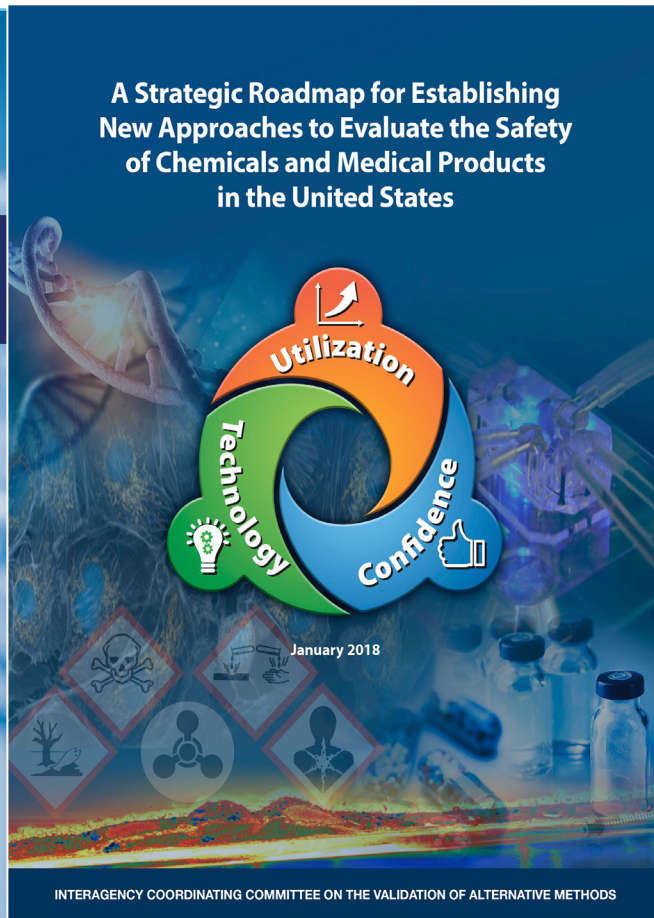
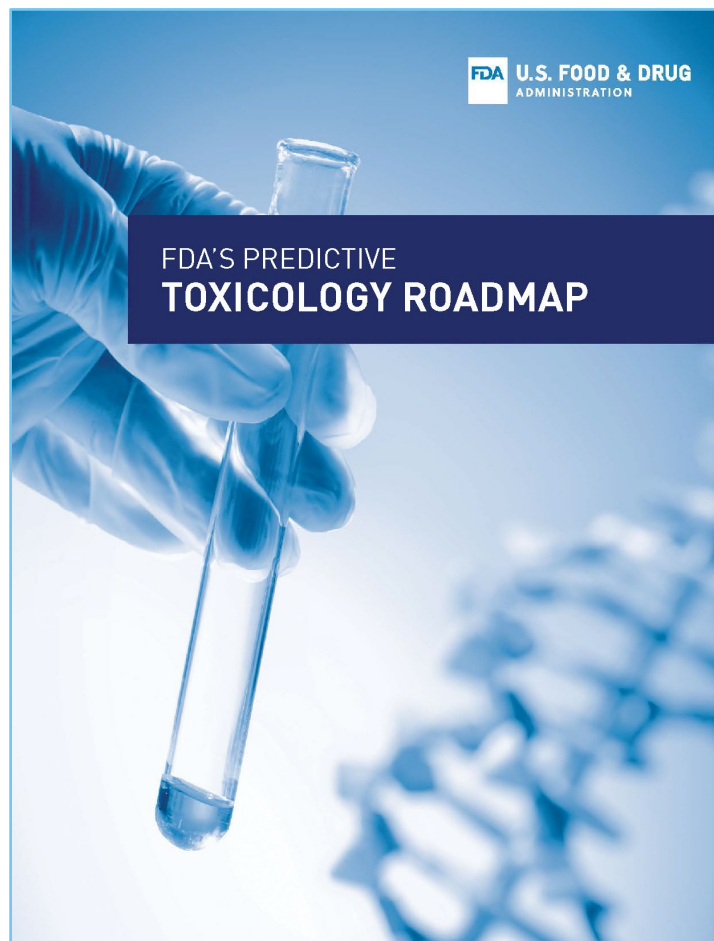
NIH PUBLICATION NO: 97-3981

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U.S. Public Health Service
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March 1997

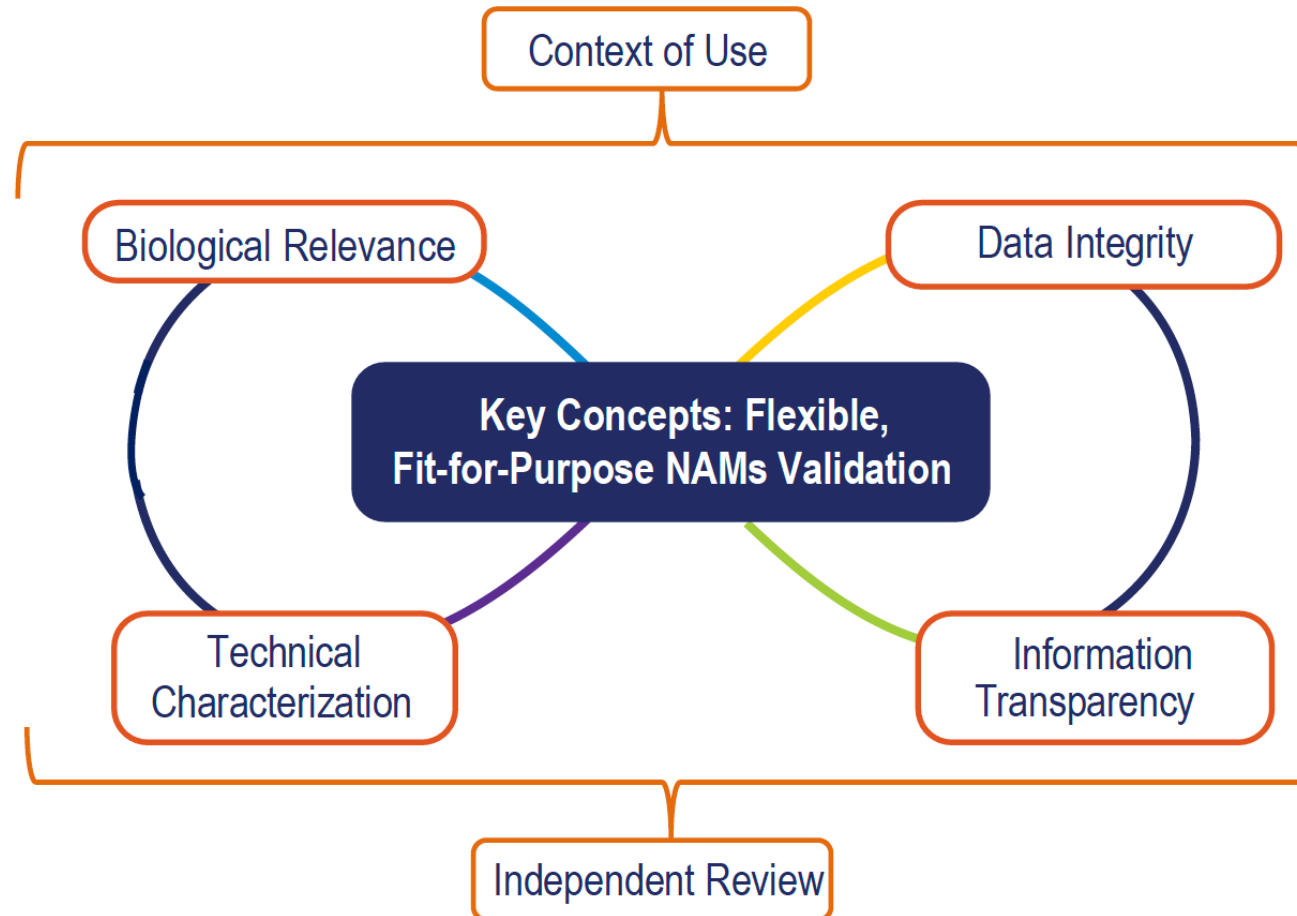
Roadmaps all emphasize the 3 C's- Collaboration, Communication, and Commitment



Why a New Guidance?

- Underlying principles from OECD 34 remain the same in this new Guidance.
- Introduce the “context of use” terminology
- New guidance will emphasize that validation process should be flexible and adaptable.
- Emphasize the need for communication because regulatory needs may vary across the federal agencies

Guiding Principles





Start with a Regulatory Question- Context of use

- What question needs to be answered and for what purpose?
- How much “validation/qualification” is needed for a particular assay will depend on the particular context of use.



- Helps define acceptable applicability domain and limitations
- Context could be expanded over time
- Choice of Reference Standards Related to Context of Use

Topics Covered in this Guidance

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

- Clearly delineate testing requirements and context of use
- Promote the use of new approaches for establishing confidence
- Utilize public workshops and/or public-private partnerships to promote cross-sector communication and cooperation

Topics Covered in the New Guidance

- Relevance of New Approach Methods
 - Biological Relevance
 - Biological Plausibility
 - Mechanistic Relevance
- Importance of Quality Reference Data
- Role of Legacy Animal Data

Topics Covered in New Guidance

- Examination of best practices for quality and quality systems development
- Assessment of key sources of variability in the NAM
- Discussion of “Good or Better Standard” for qualification/validation.
- Incorporation of selected data quality tools such as:
 - Building a statistical model
 - Setting specifications

Topics Covered in the New Guidance

- How new principles of validation can fit into a globally harmonized approach to allow for continued mutual acceptance of data
- Reference to existing and well-vetted documents (e.g., GIVIMP, OECD GD34, GD69 on QSAR Validation, FDA Guidance for Industry, etc.)

Role of ICCVAM

- Assure an independent validation process
- Advise federal agencies on validation strategies
- Facilitate cross-agency collaborations through work group/conferences
- Encourage global communication/harmonization on validation criteria through conferences, seminars and meetings



Next Steps Prior to Finalization

- Format and organization of the document still under consideration.
- Input from the ICCVAM Federal Agencies still being incorporated through the VWG
- Draft document will be sent to ICCVAM agencies for review and sign off.
- Stakeholders will have opportunity to comment on the document.