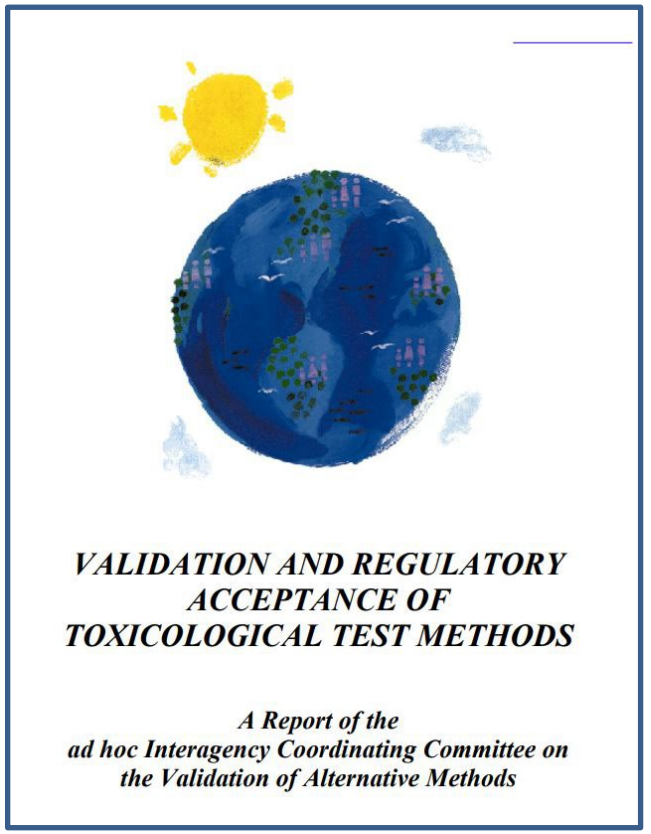
ICCVAM: Validation Workgroup

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



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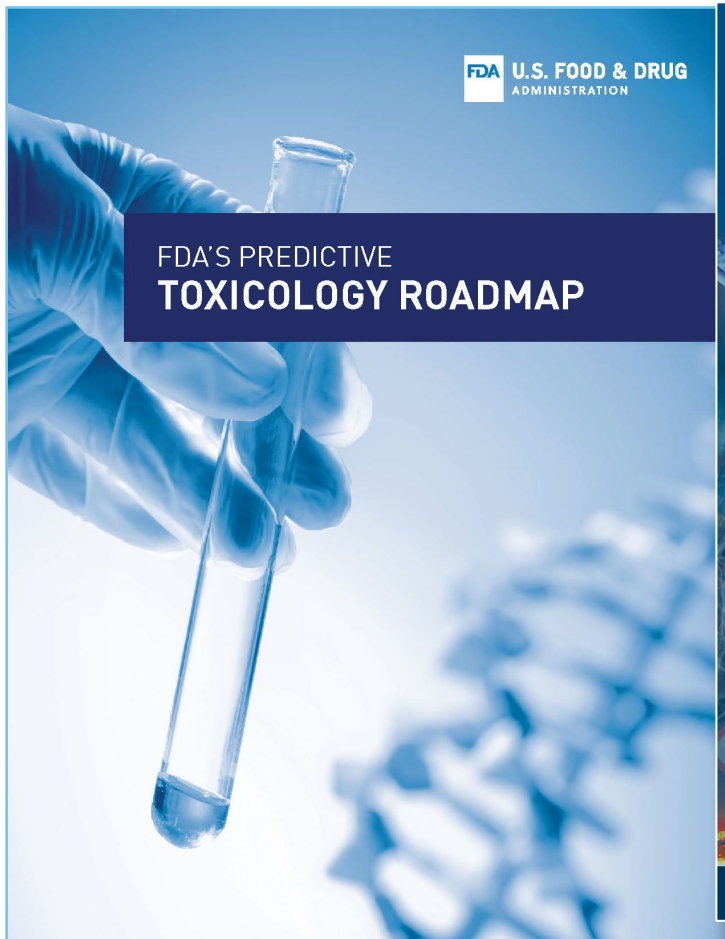
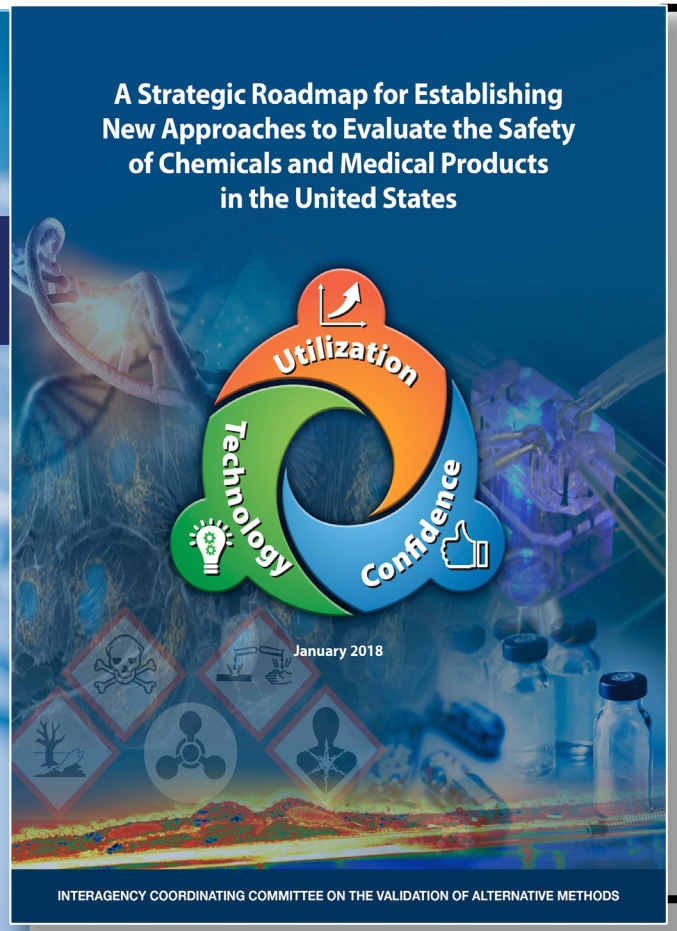
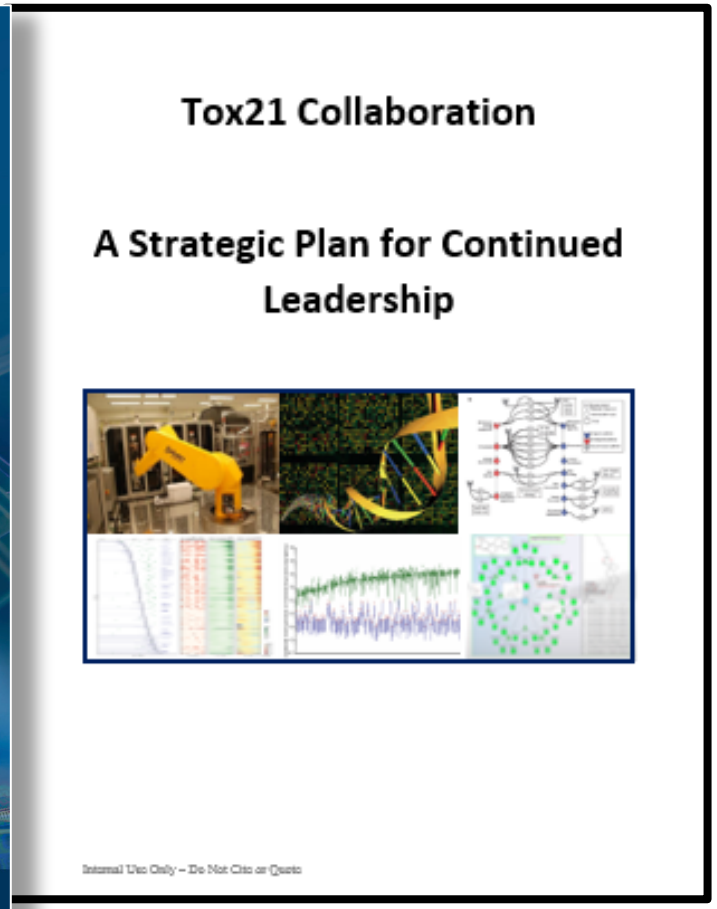
Roadmaps all emphasize the 3 C's- Collaboration, Communication, and Commitment



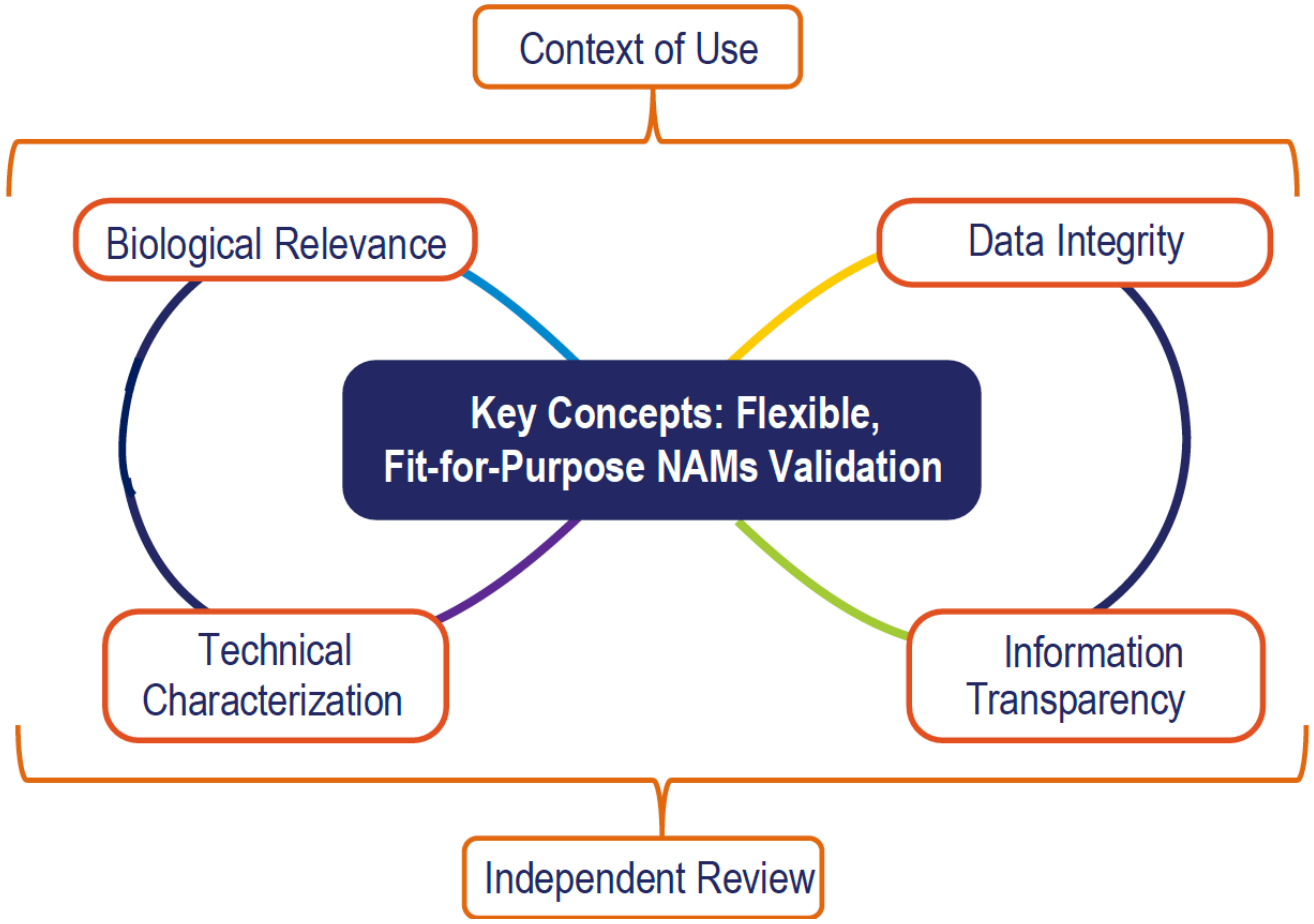




Why a New Guidance?

- 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.