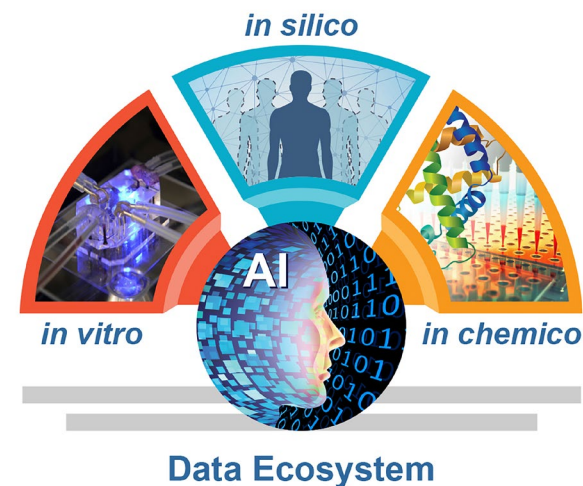# New interactive database of validated/qualified NAMs

- Proposed by ICCVAM agency partners to facilitate access to validated NAMs

- NIEHS funding initial beta version development

- DTT supporting contractor as senior project manager

- NICEATM to sustain outyear maintenance via support contract

- Need for interoperability with ICE, Complement-ARIE Data Hub, CEBS, (others?)

Integrated Chemical Environment

in silico

AI

in vitro

in chemico

Data Ecosystem

- **What should be included in the Database?**

  – Types of NAMs (stage of validation)?

  – Validation study data?

  – Acceptance/guidance? Use case examples

  – Protocols (or links out)? Date/version control of protocols and/or approvals

  – Applicability domain

  – Context of use (protocol variations)

- **How to avoid redundancy and provide added value to EURL-ECVAM Tracking System for Alternative methods toward Regulatory acceptance (TSAR)?**

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European Commission

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TSAR - Tracking System for Alternative methods towards Regulatory acceptance

TRACKING SYSTEM FOR ALTERNATIVE METHODS TOWARDS REGULATORY ACCEPTANCE

TSAR tracks the progress of alternative, non-animal methods, for testing chemicals or biological agents such as vaccines towards acceptance as a recognised test method for use in various sectors

TSAR

TSAR indicates the stages methods have reached in terms of acceptance as a recognised test method for use in various sectors together with a summary description. Where available, TSAR also includes relevant records and documents associated with a method linked to the different steps of the entire process: submission, validation, peer-review, recommendations and regulatory acceptance including international standards represented in the tracking system.

Show Filters ⌄

Results 1 - 5 of 141   Download (Excel compatible) 🔲 All methods

Epidermal Sensitization Assay

TM Status:	🔓 **Open**	**Topic(s):** Skin sensitisation
Test Method Number:	TM2018-01 (JAP)	
Short Name of TM:	EpiSensA	
Responsible Organisation:	JaCVAM - Japan	

✓ SUBMISSION	✓ VALIDATION	✓ PEER-REVIEW	n/a RECOMMENDATION	⧗ REGULATORY ACCEPTANCE/STANDARDS
Finalised	Finalised	Finalised	Not applicable	Ongoing

https://tsar.jrc.ec.europa.eu/

- **How should users be able to interact with CAMERA?**

  – Ability to search by endpoint, by agency, by availability, by "R", …?

  – Leverage NICEATM cheminformatics toolbox to provide similarity metrics/applicability domain estimates

- **What should the interface provide?**

  – Intuitive, user-friendly experience

  – Data presentation vs. graphics

  – Report that can be downloaded?

- **How are NAMs considered/added?**

  - **Criteria?**

    - Technically characterized

    - Independent review

    - Not necessarily fully validated?

    - Aligned with concepts in new ICCVAM guidance on Validation, Qualification and Regulatory Acceptance of NAMs.

  - **Where to start?**

    - ~130 methods already listed on NICEATM <u>website</u>

      - Majority are OECD test guidelines

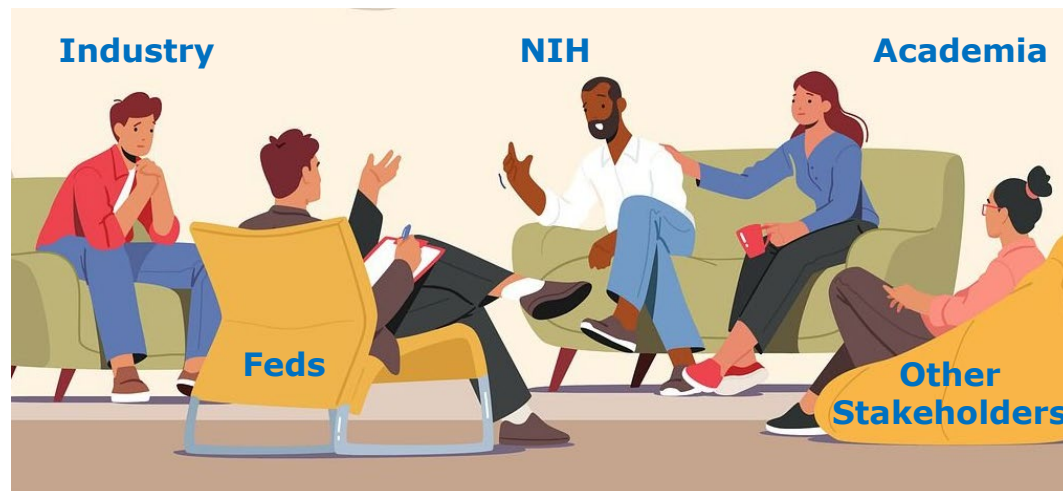   - Many are refinement/reduction approaches – prioritize non-animal NAMs?

National Institute of
Environmental Health Sciences
Division of Translational Toxicology

– **Method sources?**

  • ASTM, ISO, TSAR (ECVAM), USP

  • Poll agency partners/other stakeholders for prioritized endpoints.

– **User-based submission?**

  • ICATM partners

  • Mutually accepted validation?

  • How to review user-based submissions?

  • Agency submission of NAMs being considered/used/submitted.

- **New or existing ICCVAM WG?**

  – Steering committee (standing) vs. workgroup (temporary)

- **Workshop to solicit input from stakeholders?**

- **Link to process – how often to consider scope/inclusion of new NAMs?**

QUESTIONS?