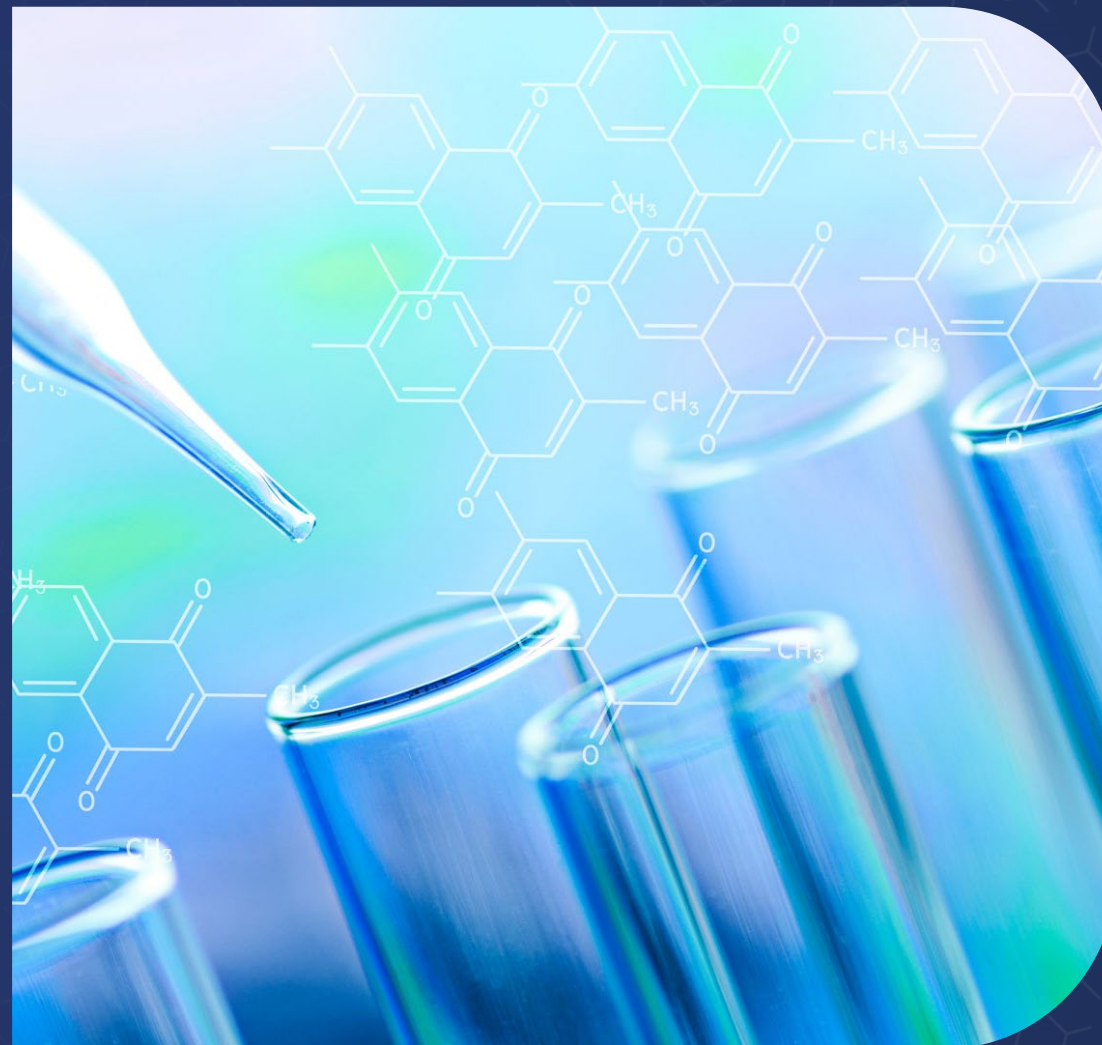




May 20-21, 2024

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Scientific Confidence Frameworks

- ACC applauds ICCVAM's adoption of a scientific confidence framework (SCF) to operationalize 'fit-for-purpose' "validation" amongst federal agencies.
- This should accelerate the adoption and evolution of New Approach Methods (NAMs).
- It is important to note that the regulatory science community will need training and encouragement to embrace SCFs:
 - Our community is conditioned to expect lists;
 - Lists may one day be "out" as SCFs are phased "in".

AI in Tox & Chemical Safety Evaluation

- The ‘end of the tox as we know it’ (Kleinstreuer &, Hartung 2024):
 - Already happening.
- Convergence of tox and AI:
 - Lesson from Toxicology in the 21st Century: it takes the whole regulatory scientific community.
- We ask ICCVAM to identify opportunities for meaningful engagement for all stakeholders in this transition.

ACC Funds NAMs Research

Long-Range Research Initiative (LRI)

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Mission

LRI's mission is to catalyze innovations in chemical safety science.

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The Long-Range Research Initiative (LRI) of the American Chemistry Council (ACC) promotes innovations in chemical safety assessment. It invests in science essential for understanding the impact of chemicals on human health and the environment.

With a focus on biologically-relevant exposures, LRI adopts an integrated approach to exposure and hazard characterization to promote a shift in focus away from development of safety assessments based solely on hazard or exposure data.

Through integration and translation of its research outcomes, LRI transforms this information into knowledge that can inform decisions and policies about the safety of chemicals relevant to current environmental and public health challenges.

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<https://www.americanchemistry.com/chemistry-in-america/research/long-range-research-initiative-lri>

Some Examples of Current ACC LRI NAMs Research

Improve Chemical Safety Testing Technologies: Design Fit-for-Purpose Assays and Advance Data Interpretation

Project Title: [Omics for Assessing Signatures for Integrated Safety \(OASIS\)](#)
[Consortium](#)

Consortium Manager: Chrissy Crute, Ph.D.

Research Institution: Health and Environmental Sciences Institute (HESI)

Project Title: [Exploring Tissue Chips for Toxicity Testing: Testing Consortium at Texas A&M University \(TEX-VAL\)](#)

Principal Investigators: Ivan Rusyn, Ph.D.,; Courtney Sakolish, Ph.D.,; Clifford Stephan Ph.D.

Research Institution: Texas A&M University

Project Title: [Development of a Fit-For-Purpose In Vitro Model of Lung Toxicity](#)

Principal Investigator: Les Recio, Ph.D.

Research Institution: ScitoVation

Project Title: [Application of Toxicogenomics in Next-Generation Risk Assessment](#)

Principal Investigator: Rasim Barutcu, Ph.D.

Research Institution: ScitoVation

VOI for NAMs Regulatory Use

- **Value of Information (VOI) analysis should be considered as an additional consideration in the evaluation of utility of adopting NAMs for regulatory use:**
 - 2023: EPA published a VOI analysis in 2023 for 5-day ETAP vs traditional human health risk assessment (THHA);
 - 2024: We publish VOI analysis for TTC, ETAP, and THHA (Simon et al.);
 - VOI can be used to inform tiered testing frameworks (e.g. TTC then ETAP then longer-duration *in vivo*)