Presentation Abstracts and Background Materials

SCIENTIFIC ADVISORY COMMITTEE ON ALTERNATIVE TOXICOLOGICAL METHODS

Session II: Federal Efforts Addressing Method Development Challenges
Wednesday, November 4, 2026

Optimizing the Method Development Pipeline to Accelerate End User Adoption

Presenter: Ms. Amber Daniel, General Dynamics Information Technology (GDIT)

As outlined in ICCVAM's "A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the Unted States" and further expanded upon in the 2024 report on "Validation, Qualification, and Regulatory Acceptance of New Approach Methodologies," cross-sector collaboration and efficient communication is critical to building confidence in new methodologies and advancing their implementation. When regulatory and industry end users clearly articulate their needs and information requirements early in the development process, developers are better positioned to design methods that are suitable for a specific context of use. Furthermore, because contexts of use and domains of applicability may evolve as data are generated, collaboration and communication should remain iterative throughout the development process.

ICCVAM and D-NICEATM aim to facilitate this type of communication by organizing workshops, webinars, and other scientific forums that bring together method developers and end users. The 2024 Method Developers Forum (MDF) highlighted ten approaches to carcinogenicity testing and provided an opportunity for scientific discussion among relevant stakeholders. However, efforts to organize similar forums addressing additional endpoints have slowed. This talk will review the challenges encountered while organizing the MDF, such as scheduling conflicts and difficulties in identifying and engaging end users to communicate their needs and information requirements. This talk will also discuss additional strategies currently being explored to foster collaboration and communication among method developers and stakeholders. Namely, D-NICEATM will lead an effort to publish a white paper describing pharmaceutical industry requirements for the adoption of methods for early-stage drug discovery and preclinical development.

Background

- ICCVAM. 2018. A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States. https://ntp.niehs.nih.gov/go/iccvam-rdmp. https://dx.doi.org/10.22427/NTP-ICCVAM-ROADMAP2018.
- ICCVAM. 2024. Validation, Qualification, and Regulatory Acceptance of New Approach Methodologies. https://doi.org/10.22427/NICEATM-2.
- Webpage: Method Developers Forum 2024: New Approach Methodologies for Carcinogenicity Testing. https://ntp.niehs.nih.gov/go/developers-forum-2024

Lessons Learned from the Complement-ARIE Program – Federal Perspective

Presenter: Dr. Margaret Ochocinska, on Detail to the National Institutes of Health (NIH) Office of Research Innovation, Validation, and Application

The Complement-ARIE Program is focused on the development and validation of novel combinatorial new approach methodologies (NAMs) and will build upon existing U.S. and international efforts to ultimately provide more cost-effective,

rapid, human-relevant NAMs for drug discovery, chemical safety testing, and wider biomedical research approaches to bring NAMs products to market. NIH in collaboration with the Foundation for the NIH (FNIH) is developing a Validation and Qualification Network (VQN) Public-Private Partnership (PPP) involving scientists at multiple levels of government (including funding agencies and regulators), industry, nongovernmental organizations, and academic institutions to catalyze the development, standardization, validation and use of human-based NAMs. The VQN is one of three components of the NIH Complement Animal Research In Experimentation (Complement-ARIE) Program that will accelerate validation and/or regulatory approval and deployment of NAMs for biomedical research. The goal of the VQN is to establish and apply validation or qualification frameworks by working with regulatory and other federal agencies, industry partners, non-profits, and other collaborators. The VQN aims to establish a process for evaluating NAMs and channeling use cases through the frameworks in a pre-competitive environment, paving the way for broader adoption and application by industry and biomedical researchers globally.

Background

- Webpage: Complement Animal Research In Experimentation (Complement-ARIE) Program. https://commonfund.nih.gov/complementarie
- Sunderic K, Wright AM, Kleinstreuer N, Ledbetter V, Milora KA, Happel C, Shaughnessy D, Johnstone CP, Casco DA, Macioce N, Marzec J, Kano K, Ochocinska MJ, Tagle DA. 2025. Complement-ARIE: Catalyzing the development and adoption of new approach methodologies. NAM J 1:100026. https://doi.org/10.1016/j.namjnl.2025.100026.

Challenges Encountered by the VQN Around Validation – FNIH Perspective

Presenter: Mr. Nicholas King, Foundation for the National Institutes of Health

This session will provide an update on the FNIH NAMs Validation and Qualification Network (VQN), as the effort moves from design phase to implementation. The previous presentation to SACATM described the FNIH public-private partnership (PPP) model and the stakeholders engaged in designing the VQN, this update will describe the governance and operating structure that will carry the network forward and how learnings in the design phase impacted the implementation phase. Briefly, an executive committee will lead the strategy, supported by four application-area steering committees: environmental safety and toxicology, therapeutic development safety and toxicology, therapeutic efficacy and pharmacology, and DMPK/ADME. Three cross-cutting workstreams will support all application areas by addressing data standards, health authority regulatory applications and considerations, and community engagement and training. The session will also report on pilot projects currently in development, which are drafting advanced validation project plans for acute oral toxicity, pregnancy models, drug-induced inhalation toxicity, and developmental neurotoxicity. Future projects will be identified and developed through the platform-specific steering committees. Progress on the implementation timeline will be shared, along with opportunities for SACATM members and the broader community to provide input and engage with the network.

Background

- Baker TK, Van Vleet TR, Mahalingaiah PK, Grandhi TSP, Evers R, Ekert J, et al. 2024. The Current Status and Use of Microphysiological Systems by the Pharmaceutical Industry: The International Consortium for Innovation and Quality Microphysiological Systems Affiliate Survey and Commentary. Drug Metab Dispos 52(3):198–209. https://doi.org/10.1124/dmd.123.001510
- Baran SW, Brown PC, Baudy AR, Fitzpatrick SC, Frantz C, Fullerton A, et al. 2022. Perspectives on the evaluation and adoption of complex in vitro models in drug development: Workshop with the FDA and the pharmaceutical industry (IQ MPS Affiliate). ALTEX. 39(2):297–314. https://doi.org/10.14573/altex.2112203

SACATM Discussion

Lead Discussants: Dr. Gina Hilton, PETA Science Consortium International e.V.; Dr. Kambez Benam, University of Pittsburgh

Discussion Questions

- What collaboration outreach efforts could we focus on to increase the effectiveness of the method development programs presented?
- How can we educate researchers in the regulatory context for using methods and how these contexts differ from their use in research?
- Discuss specific ways we can further promote information sharing between method developers, end users, and regulators.