Presentation Abstracts and Background Materials

SCIENTIFIC ADVISORY COMMITTEE ON ALTERNATIVE TOXICOLOGICAL METHODS

Session II: Data Standards, Validation, and Qualification
Thursday, September 11, 2025

Validation and Qualification Network (VQN) Public-Private Partnerships for Adoption and Implementation of New Approach Methodologies (NAMs)

Presenter: Dr. Margaret Ochocinska, National Institutes of Health (NIH)

The Complement Animal Research In Experimentation (Complement-ARIE) program is focused on the development and validation of novel combinatorial 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 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-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

- Sunderic, Kristifor, et al. "Complement-ARIE: Catalyzing the Development and Adoption of New Approach Methodologies." NAM Journal (2025): 100026. https://doi.org/10.1016/j.namjnl.2025.100026.

International Harmonization of Test Method Validation – the Role of Readiness Criteria to Amplify Success

Presenter: Dr. Alison Harrill, U.S. Environmental Protection Agency (EPA)

The development of NAMs has accelerated over the last decades from simple in vitro assays to more complex cell models, computational models, and integration of multiple assays into coordinated testing strategies and defined approaches. Consequently, there is a need to modernize the guidance on how to validate these new or updated test methods and approaches for use in regulatory applications. This talk will give an update on the ongoing international effort to revise the Organisation for Economic Co-operation and Development (OECD) Guidance Document 34 on how to validate a new method for inclusion in the formal test guidelines program. The talk will focus on criteria for assessing a method's state of readiness to enter and progress through cost- and time-intensive transferability studies that are foundational to building confidence in a method's capabilities and reproducible results. Because the bar is very high for test method validation, qualification, and finally acceptance by regulatory agencies, defined readiness criteria are key to selecting methods for validation and for assessing validation program progress. Moreover, standardization and harmonization efforts for reporting templates related to readiness criteria will be discussed, with linkages to the NIH Complement-ARIE program's VQN highlighted.

Background

- OECD Guidance Document 34: Validation and International Acceptance of New or Updated Internationally Acceptable Test Methods for Hazard Assessment.

ICCVAM Common Data Elements (CDE) Workgroup

Presenter: Dr. Geetha Senthil, National Center for Advancing Translational Sciences (NCATS)

Common data elements (CDEs) are standardized, precisely defined terms and formats that are used to collect and share data across studies. Consistency, interoperability, and integrative analysis of data are all critical for comparing the performance and applicability of NAMs.

ICCVAM's CDE Workgroup (CDE-WG) was established in 2025 and will guide the identification and development of structured data elements for NAMs evaluation and regulatory adoption. This includes identifying CDEs across NAM categories, cataloging those used by ICCVAM agencies and international organizations, resolving conflicting terms, identifying gaps where new CDEs are needed, and proposing standardized terminology and data structures for consistency and interoperability.

These efforts will support the NIH-led Complement-ARIE program to develop and implement NAMs that better reflect human biology, aiming to complement or replace animal models in research. This program supports technology development, validation, and data infrastructure through NAM Development Centers, a Resource Coordinating Center, and a VQN to facilitate regulatory acceptance. ICCVAM agencies play a key role in ensuring NAM validation meets regulatory standards, with standardized CDEs essential for consistency and comparability across NAM data in research and regulatory use.

Background

- https://commonfund.nih.gov/sites/default/files/Complement-ARIE-Landscape-Analysis-29-Feb-2024-508.pdf
- https://commonfund.nih.gov/complementarie/vqn
- https://commonfund.nih.gov/complementarie/strategicplanning