# The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Common Data Elements (CDE) Workgroup

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September 11, 2025

National Institutes of Health
*Turning Discovery Into Health*

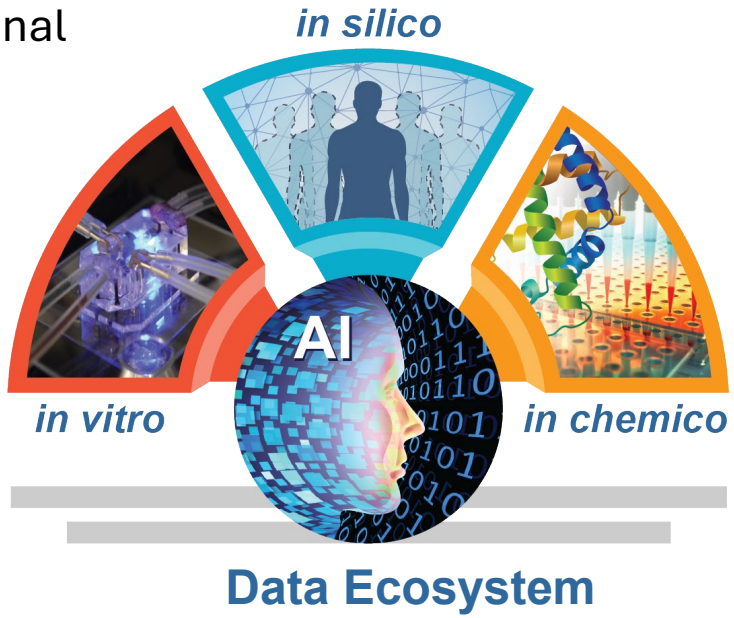
National Center for Advancing Translational Sciences

# Background

**New Approach Methodologies (NAMs)** are approaches that better reflect human biology are designed to complement, or in some cases replace, traditional animal models

**NIH** multi-agency Common Fund Initiative- **Complement Animal Research In Experimentation (Complement-ARIE)** to develop, standardize, validate, and implement NAMs for biomedical research and regulatory applications.

- Technology Development Centers
- NDHCC – Data coordination (NDHC)
- Validation Qualification Network (VQN)




**Data Standards for NAMs is critical for validation and qualification.**

The Interagency Coordinating Committee on the Validation of Alternative Methods - **ICCVAM agencies are key stakeholders in Complement-ARIE** – particularly in ensuring that validation and qualification activities meet agency-specific regulatory standards.

# ICCVAM Common Data Elements Workgroup (CDE-WG)

**ICCVAM CDE Workgroup (CDE-WG)** established in June 2025 to guide the development of structured data elements to support NAM evaluation, validation, and regulatory adoption across Complement-ARIE activities

**Common Data Elements (CDEs) -** standardized terminologies and formats - **are essential** to promoting consistency, comparability, and interoperability of NAM data across studies for research and regulatory purposes

**Charge 1**: Identify existing CDEs by agency and NAM modality

**Charge 2**: Identify CDEs used by key international organizations

**Charge 3**: Charge 3: Identify conflicting terms

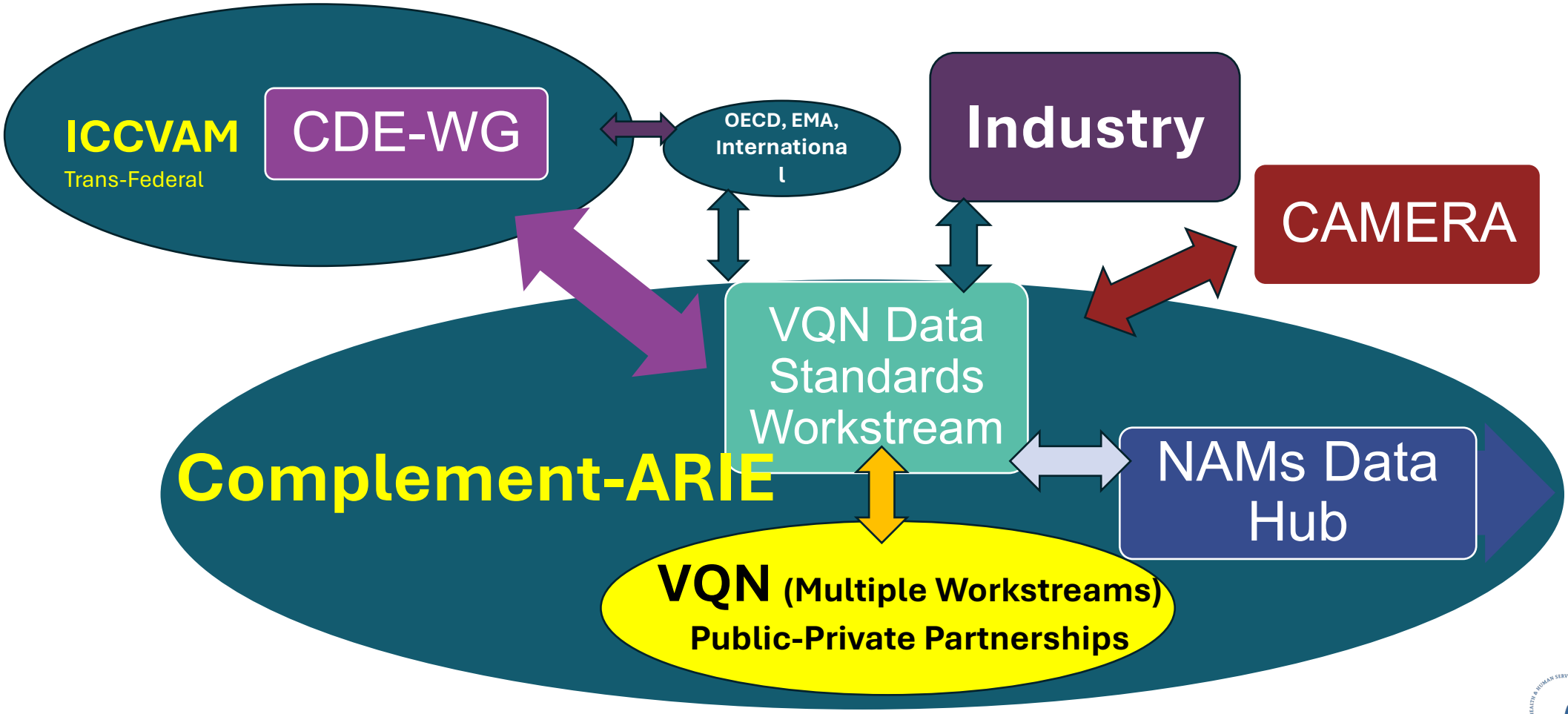
**Charge 4:** Identify gaps where CDEs are needed

**Charge 5**: Propose harmonized nomenclature for new CDEs

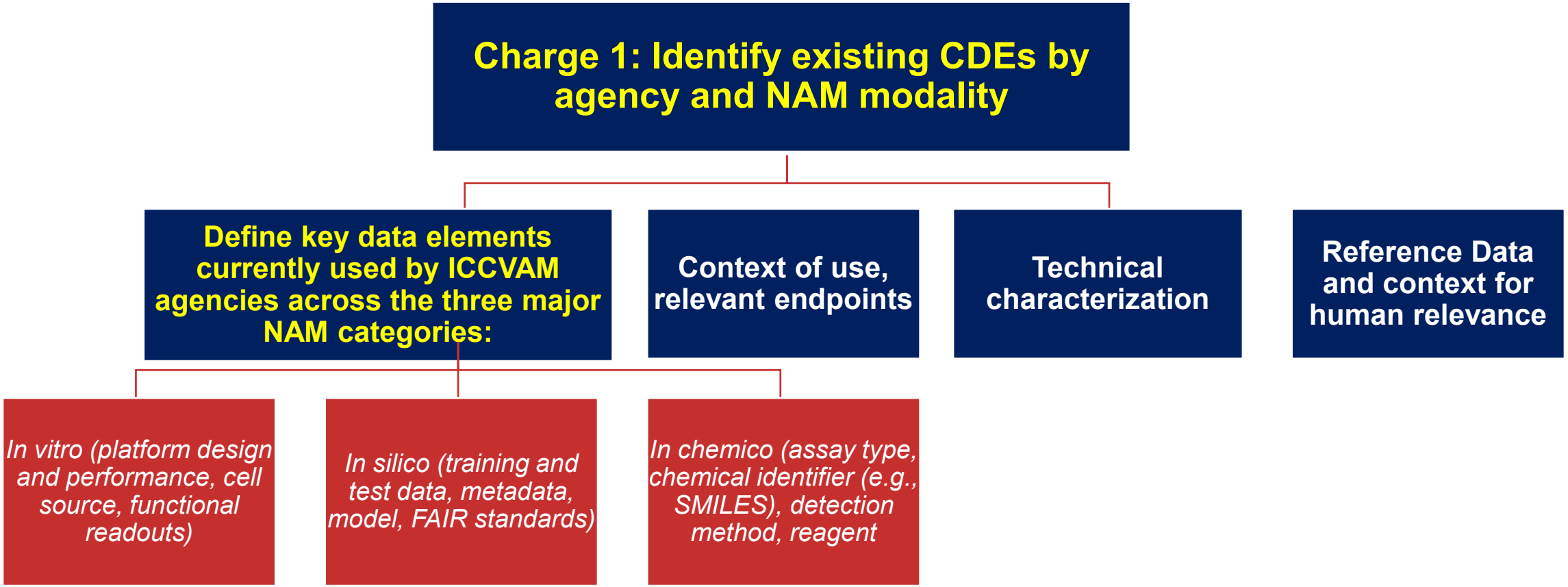
| AGENCY | NAME |
|---|---|
| CPSC | John Gordon |
| DOD | Chris Earnheart |
| DOD | Brad Norwood |
| FDA/CFSAN | **Suzanne Fitzpatrick** |
| NIEHS | **Warren Casey** |
| NIEHS | Helena Hogberg |
| NIST | John Elliott |
| NIST | Elija Petersen |
| NIH | Geetha Senthil |
| NLM | Robin Taylor |
| NLM | Yanli Wang |

# ICCVAM CDE-WG Coordination

Working in parallel ICCAVAM CDE-WG and NDHCC the VQN Data Standard WG will assess existing CDEs for areas of alignment or duplication and critical gaps, ensure consistency and alignment with existing standards.



# ICCVAM CDE-WG Charge



# ICCVAM CDE-WG Charge

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**Charge 2: Identify CDEs used by key international organizations**

- Catalog existing CDEs used by relevant international organizations (e.g., OECD, ICH) and regulatory bodies (e.g., EFSA, ECHA, EMA), noting differences by NAM modality where applicable.

3

**Charge 3: Identify conflicting terms**

- Identify CDEs that use different names to refer to the same component.

4

**Charge 4: Identify gaps where CDEs are needed**

- Determine where CDEs do not currently exist but would provide value in supporting standardization, reproducibility, or regulatory utility.

5

**Charge 5: Propose harmonized nomenclature for new CDEs**

- Develop proposed terminology and data structures for new CDEs to ensure consistency across Complement-ARIE and ICCVAM agency-specific guidance and regulatory documents.

# THANK YOU

## Warren Casey, Suzanne Fitzpatrick & ICVVAM CDE WG members

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| CPSC | John Gordon |
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# NAMs VQN Steering Committee: Data Standards Workstream

This workstream will focus on the following activities in collaboration with the ICCVAM CDEWG who will take the lead in coordinating with NDHCC and NIH leadership input the following:

- Identify existing CDEs by NAM modality.
- Identify conflicting CDEs
- Identify gaps where CDEs are needed
- All proposed CDEs must undergo field usability testing in at least one live pilot project or relevant use-case simulation (whether inside the VQN or with another project), with feedback loops established between pilot project teams and the Data Standards Workstream. Usability metrics will include:
- Propose harmonized nomenclature for new CDEs by produce comprehensive documentation including data dictionaries, templates and guidance materials.
- In conjunction with the NDHCC, CAMERA, and ICCVAM CDEWG, develop proposed terminology and data structures for new CDEs to ensure consistency across ICCVAM CDEWG and Complement-ARIE specific guidance and regulatory documents and traceability to existing FDA/OECD-aligned standards, minimize duplicative fields, and maintain forward compatibility with future OECD Harmonized Templates.