

Accelerating NAMs for Regulatory Readiness through the FNIH Validation and Qualification Network (VQN) of Public Private Partnerships

Agenda

1 | Design Phase - FNIH and Public-Private Partnership Model

2 | Workstreams - Building a Sustainable Infrastructure

3 | Pilot Projects

4 | Implementation Phase - The Future of the VQN

1 | Design Phase

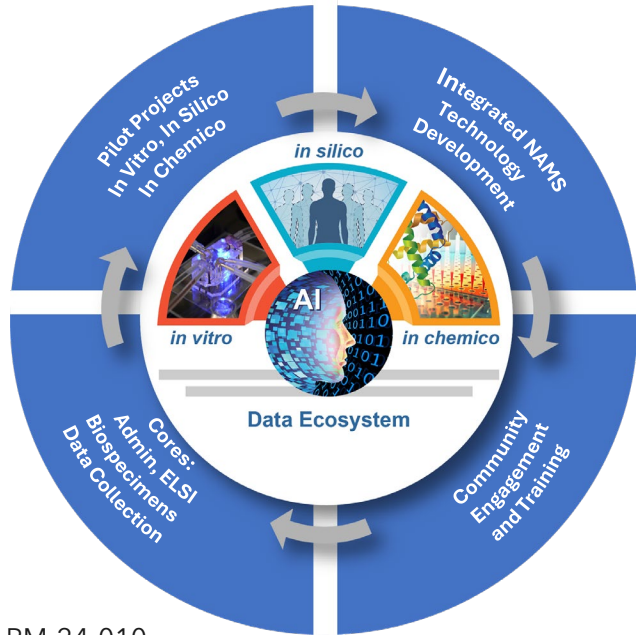
Complement-Animal Research in Experimentation (Complement-ARIE)

NCATS, NIEHS, NIAAA, NIAID, NIAMS,
NCI, NICHD, NIDCD, NIDCR, NEI, NHLBI,
NIA, NINDS, NIBIB, NIMH, NIDA, NCCIH,
NIDDK, NLM, ODSS, ORIP, ORWH, OSP



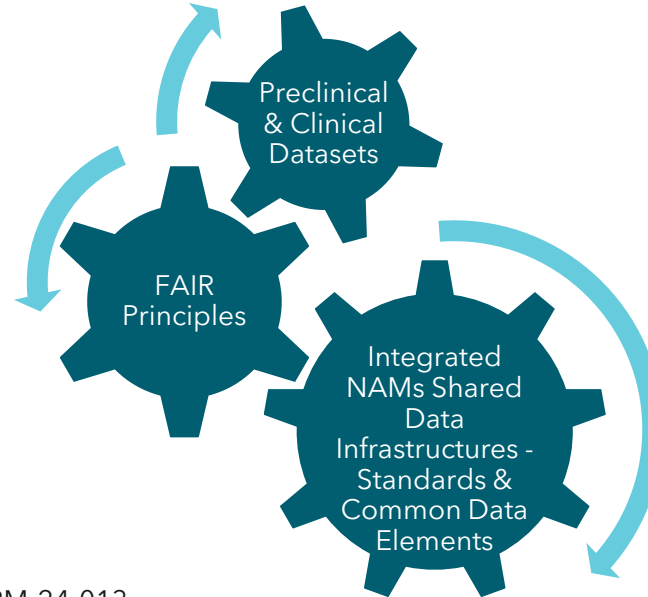
Summary: Complement-ARIE Consortium

NAMs Tech Dev Centers



RFA-RM-24-010

NAMs Data Hub and Coordinating Center



RFA-RM-24-013

Validation and Qualification Network Foundation of NIH



- Regulatory Partners
 - Industry Partners
- ICCVAM/Other Agencies
- International Partners
 - Non-Profits
 - Other end users



Building Bridges to Breakthroughs

- The Foundation for the National Institutes of Health (FNIH) is a non-profit organization chartered by the U.S. Congress and launched in 1996 to support the mission of NIH.
- Science has the power to cure, but no single organization can do it alone.
- We connect world-leading NIH researchers with the ingenuity and expertise of public and private sector leaders to accelerate medical breakthroughs.

Partnering with world-class organizations to tackle the most pressing health challenges

Long-standing relationships with renowned public and private sector institutions

NIH & OTHER GOVERNMENT AGENCIES



We support the mission of the nation's premier biomedical research agency, driving discoveries that improve health and save peoples' lives

LIFE SCIENCES COMPANIES & ACADEMIA



We collaborate with leading R&D organizations to advance research that will lead to new therapies, diagnostics, and potential cures

FOUNDATIONS & PATIENT ORGANIZATIONS



We work with foundations and patient organizations to address urgent issues in global health and accelerate biomedical innovation across a range of diseases

The Validation & Qualification Network

- The VQN is a public-private partnership managed by the FNIH in collaboration with NIH.
- Our goal is to accelerate the deployment and regulatory acceptance of NAMs by ensuring they are robust, reliable, and reproducible. We will demonstrate biological relevance of NAMs to ensure each NAM is “fit for purpose.”

Get involved by joining:

- The Steering Committee
- A cross-cutting workstream
- A project design team



Why the Design Phase for the VQN?

- Diverse Steering Committee (SC) drives decision making, including which projects are developed within the VQN
 - **20 public sector partner organizations**
 - **44 private sector partner organizations**
- Request for Information called for NAM project proposals that were reviewed, scored, and voted on by the SC
 - SC members provide direct input to develop projects that will benefit the scientific community
 - Project funding combines private fundraising with cost sharing from the NIH to support significantly expanded efforts for validation and/or qualification studies
- Pre-competitive space enables collaboration between stakeholders using different technologies to advance the same context of use

List of Currently Participating Organizations

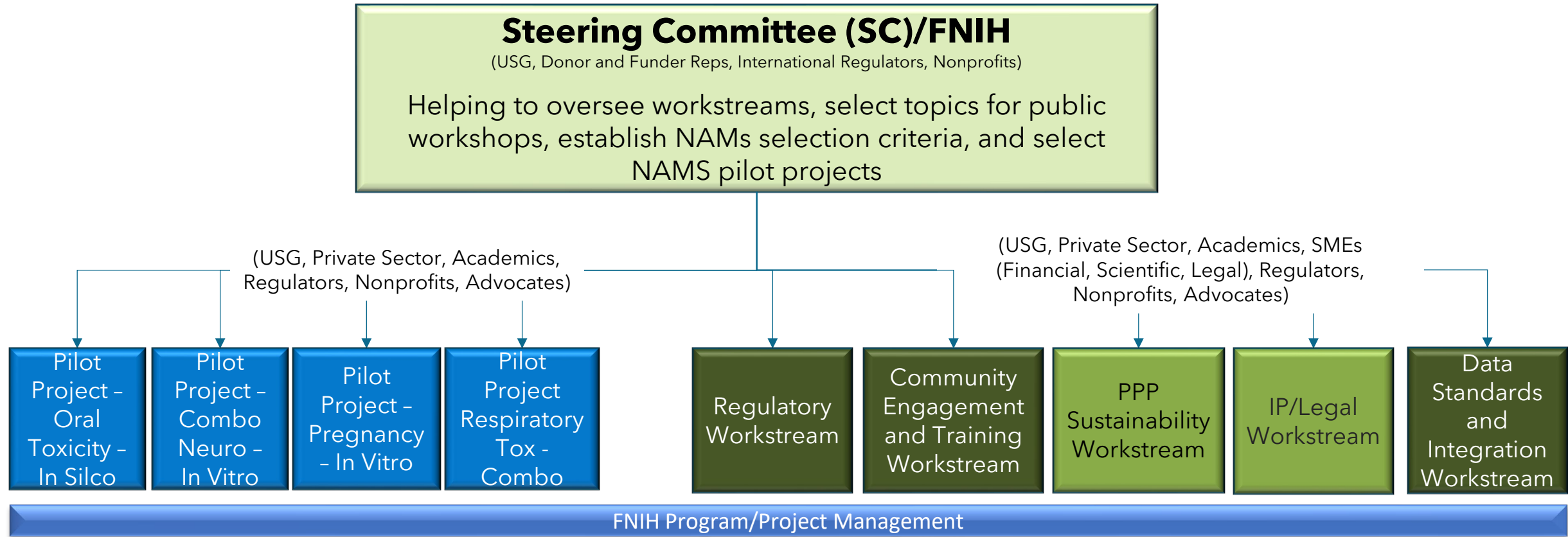
Public-Sector Partners

- Advanced Research Project Agency-Health
- Biomedical Advanced Research and Development Authority
- Biotechnology Industry Research Assistance Council (BIRAC) (India)
- Consumer Product Safety Commission
- Department of Defense Congressionally Directed Medical Research Program
- Defense Threat Reduction Agency
- Environmental Protection Agency
- European Commission (Europe)
- Food and Drug Administration
- India Council of Medical Research (India)
- Interagency Coordinating Committee on the Validation of Alternative Methods
- National Aeronautics and Space Administration
- National Centre for the Replacement, Refinement, and Reduction of Animals in Research (Europe)
- National Institutes of Health
- National Institute of Health Sciences (Japan)
- National Institute of Standards and Technology
- National Science Foundation
- Pharmaceuticals and Medical Devices Agency (Japan)
- US Department of Agriculture
- Veterans Administration

Private-Sector Partners (Industry and Nonprofit)

- Alternatives Research and Development Foundation
- American Chemistry Council
- Americans for Medical Progress
- American Type Culture Collection
- Ananda Devices Inc.
- Animal Welfare Institute
- AstraZeneca
- Asymmetrex
- BioIVT
- Charles River Laboratories
- CN Bio
- Critical Path Institute
- Draper
- Eyescreen, Inc.
- GlaxoSmithKline
- Health and Environmental Sciences Institute
- Hesperos
- Humane World for Animals
- Humane World for Animals International
- Humble Alliance L3C
- IBM
- Institute for In Vitro Sciences
- International Foundation for Ethical Research
- International Collaboration on Cosmetics Safety
- International Society for Stem Cell Research
- The Jackson Laboratory
- JRF Global
- Labcorp
- Mattek
- Mimetas
- Nomic
- Novo Nordisk
- Physicians Committee for Responsible Medicine
- Precision Quantomics
- Radahaim
- Sanofi
- Spanios
- SRI International
- The 3Rs Collaborative
- Toxys
- UCB
- Unilever
- Vivodyne
- The WellBio

NAMs VQN Design Phase Governance



Design of Pilot Implementation Projects

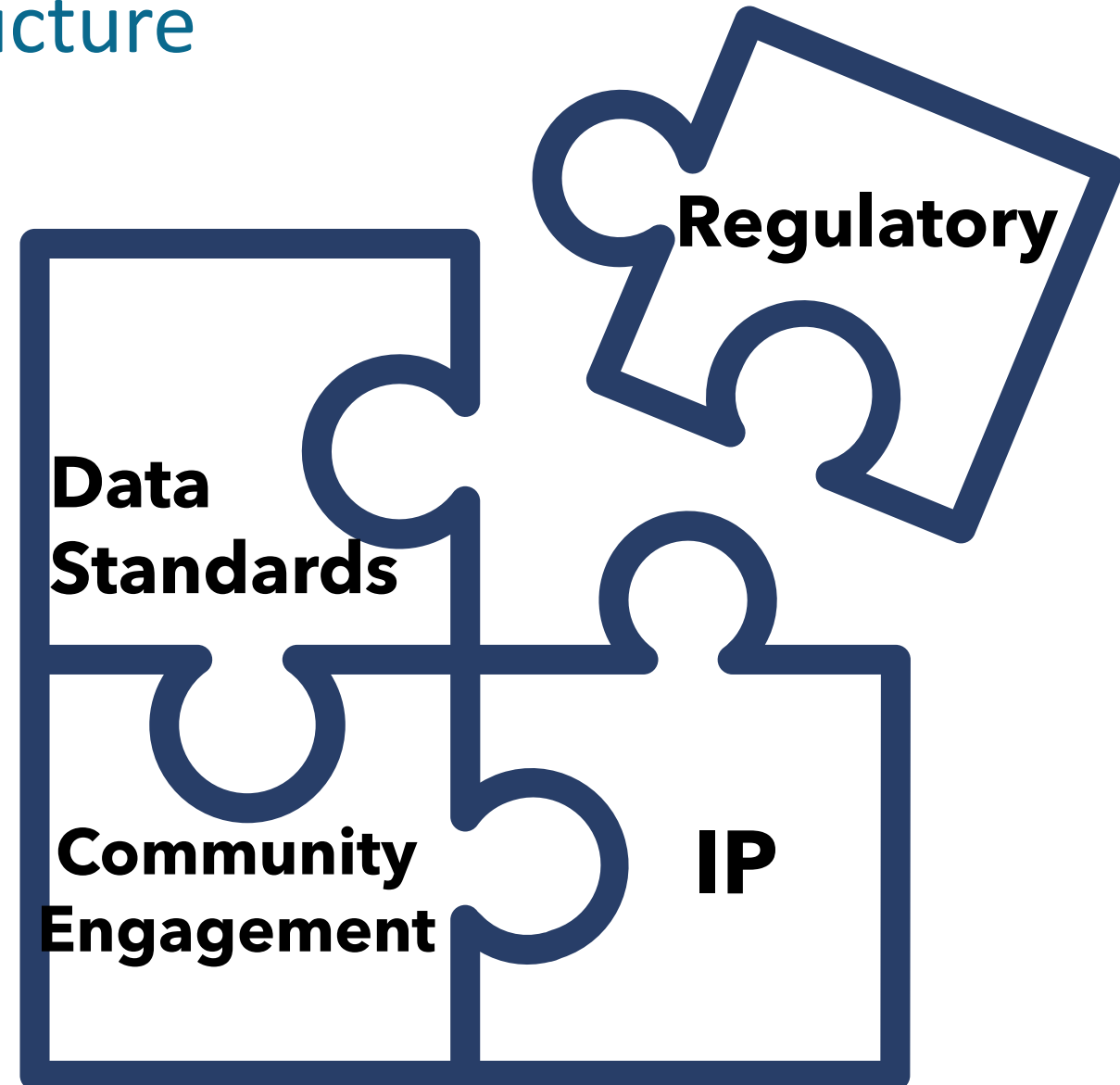
Design of Elements Critical to the Overarching VQN PPP

2 | Workstreams

Building a Sustainable Infrastructure

Workstreams support the development of translational, pre-competitive projects

Together, these workstreams function as **enabling infrastructure for the NAMs VQN**: they do not replace scientific innovation, but they ensure that innovation can move efficiently from project concept to broadly usable, regulator-relevant tools that serve the entire NAMs community.



3 | Pilot Projects

Pilot Projects: RFI Submission Overview

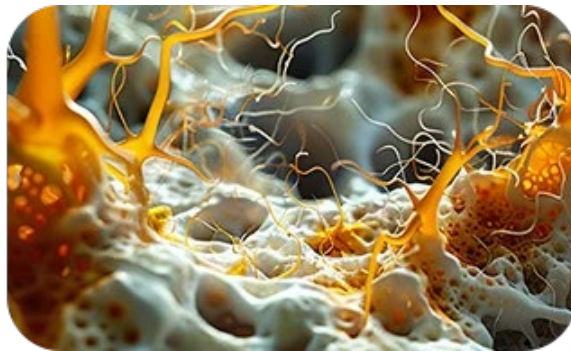
- Pilot Project ideas were selected via a Request for Information (RFI) launched in summer 2025
 - Across two submission rounds, the **NAMs VQN RFI received ~140 proposals**
 - **4 selected from round 1, round 2 selections currently being finalized**
- Submissions covered a wide range of organ systems/disease areas, as well as organ/disease agnostic tools
 - **Organ Systems:** Cardiology, Developmental/Reproductive, Hepatology, Inflammation/Immunity, Neurology, Ocular, Oncology, Respiratory, Skin/Dermal, etc.
 - **Cross-Cutting Areas:** Chemical Structure Evaluation, Drug Development, Drug Safety, NAM Development Tools, etc.

Initial Concepts Selected for Pilot Project Development



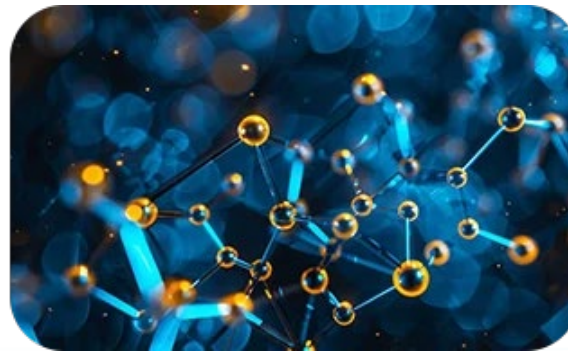
Preterm Birth Risk

Combinatorial NAM that evaluates pregnancy-related exposures linking signals to stratify preterm birth risk and inform therapeutic decisions



Developmental Neurotoxicity

Microphysiological system (MPS) that captures six key neurodevelopmental processes when exposed to potentially harmful substances



Acute Oral Toxicity

Computational NAM for predicting acute oral toxicity while identifying potential modes of action for small organic chemical exposures



Inhalation Toxicity

MPS that can evaluate the safety of inhaled substances while mimicking the structure and behavior of the lungs

Learn more at
[FNih.org/NAMs](https://fnih.org/NAMs)



Help us shape these into pre-competitive projects. We need input from industry partners, end users, subject matter experts, and complementary methods developers.

Future Concepts for Project Development



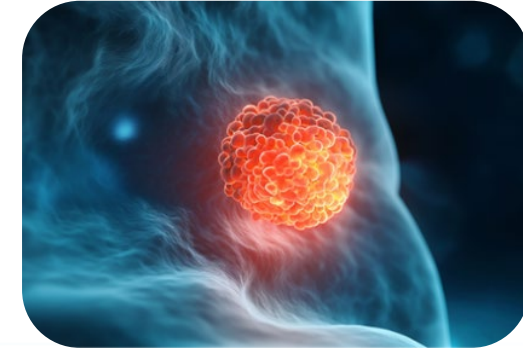
Developmental Toxicity

Lab-based model that uses human stem cells to determine if compounds cause birth defects to support safer drug development



Cardiac Safety

Human stem cell-based platform that combines advanced imaging with AI to assess whether drug candidates can harm cardiac tissue



Cancer Therapies

Advanced human tumor platform that combines engineered tissue models with AI to recreate how cancer interacts with the immune system

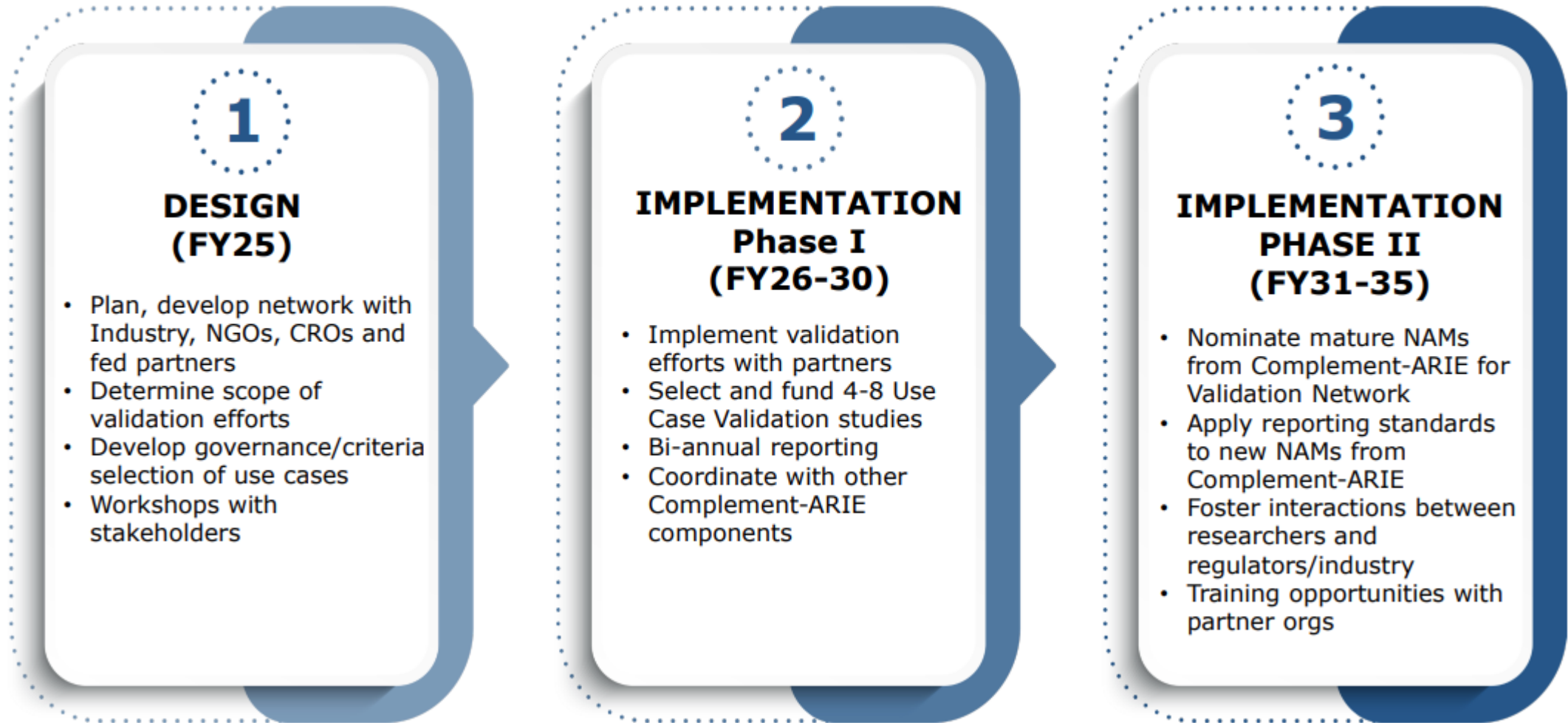
Learn more at
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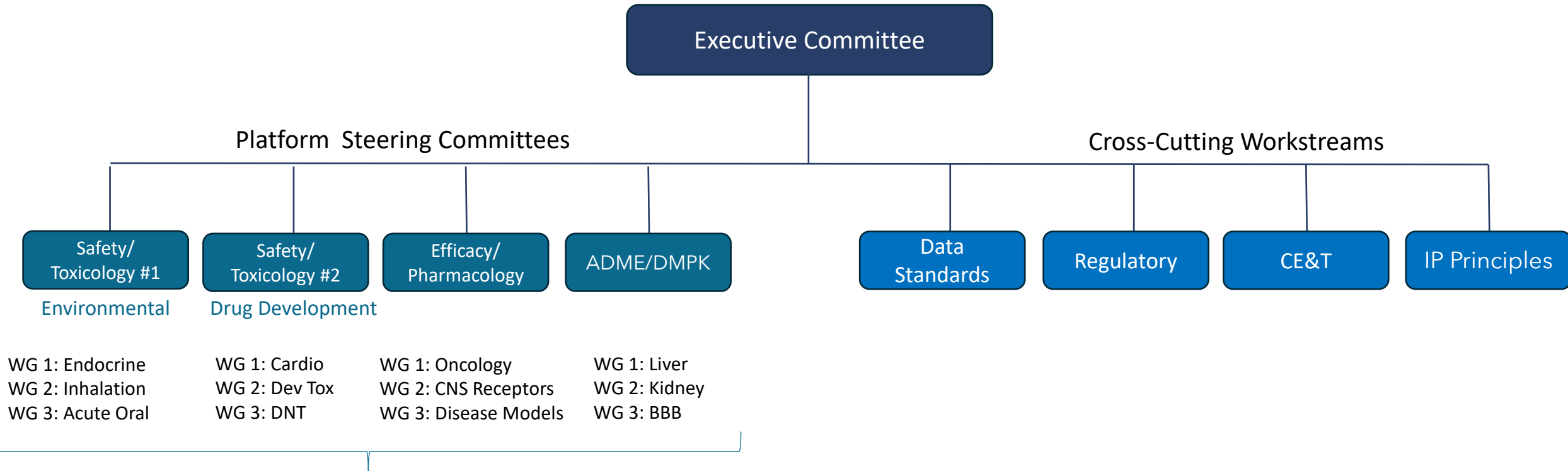
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4 | Implementation Phase

Original VQN Timeline



Proposed Governance Architecture



Working Groups (Proposed): Form around organ systems/disease areas/topics of greatest need to generate PDTs and PETs; exact selections will be made by SC, and will reflect the highest priority selections of that SC

Ultimate VQN Goals/Vision

- **Accelerate deployment and regulatory implementation of NAMs** by preparing them to enter existing agency-specific validation and qualification pipelines more efficiently, reducing barriers to implementation
- **Establish shared validation and qualification frameworks** by working pre-competitively with regulators, industry, and the research community to define fit-for-purpose evidence expectations, contexts of use, and performance criteria
- **Develop standardized reporting and common data elements** for preclinical, clinical, and safety performance to ensure NAMs generate interoperable, reproducible, and regulator-usable data
- **Support generation of high-quality data packages** aligned with existing regulatory validation and qualification frameworks, enabling smoother review and broader acceptance across agencies and authorities
- **Operate in the pre-competitive space as a neutral convener**, building consensus, sharing costs with NIH, and coordinating multi-sector stakeholders to advance NAMs that broadly benefit the scientific, regulatory, and industrial communities



Thank you!

To learn more, please contact:

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To learn more about the VQN, visit: <https://fnih.org/our-programs/validation-qualification-network-design-phase>