CRITICAL PATH INSTITUTE

Advancing Drug Development. Improving Lives. Together.

NAMs-DC: NEW APPROACH METHODOLOGIES DEVELOPER COALITION

Scope

Organizations that are building or deploying NAMs for drug discovery and development, as well as those that stand to benefit from the adoption of NAMs. Focus on leveraging their expertise to increase the broader adoption of NAMs in the pharmaceutical industry.

What Are the Goals of the Coalition?

Collectively engage and facilitate precompetitive collaboration to facilitate broader adoption of NAMs and deliver significant value to developers through:

- **Unified engagement** and advocacy for implementation in drug discovery
- **Regulatory Engagement:** Work with global health authorities to define evidentiary considerations for the validation and regulatory review and potential endorsement of NAMs as Drug Development Tools.
- **Industry Engagement:** Act as trusted partners to identify issues and develop solutions through proactively engaging pharmaceutical and biotechnology companies.
- **Qualification Advancement:** Advance a robust NAMs qualification framework to facilitate their adoption by end users and regulators.

Why We Need the Coalition

With the creation of the NAMs-DC, C-Path aims to expedite the development and application of new technologies for regulatory science. There are myriad reasons for adopting NAMs for drug discovery and development, including reducing the use of animal models in assessing drug efficacy and safety and providing more human-relevant data pre-clinically. Applying these tools for regulatory science requires significant effort to validate the models for specific regulatory-grade Contexts of Use (COUs). While many pharmaceutical companies have adopted them as tools for drug discovery, their applications in the regulatory space have lagged and are not standardized.

The NAMs-DC is advancing the innovative use of NAMs and helping bridge the gap to regulatory adoption. This will significantly improve the drug development process, eliminate inefficiencies, and reduce delays caused by redundant efforts. An effort led by the NAMs-DC to validate and scale NAMs would increase confidence in alternative methods. This would enable end users to identify and evaluate tools for specific COUs and unmet needs, streamlining the selection and assessment of NAMs and addressing a key bottleneck to their broader adoption.

Together, by supporting regulators and the developer community of member companies, the NAMs-DC is positioned to drive adoption by facilitating discussions and aligning end-users with developers.

Consortium Members

Curi Bio
CN Bio
Crown Bioscience
Emulate
Modelus
Myhre Syndrome Foundation
Revalia Bio
VivoSphere

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c-path.org/fda-acknowledgement

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