CRITICAL PATH INSTITUTE

Critical Path Institute Launches New Approach Methodologies Developer Coalition to Advance Human-Relevant Tools for Drug Development

Global coalition unites NAMs developers to accelerate validation, qualification, and regulatory adoption of human-relevant methodologies, reducing reliance on animal models and improving the efficiency of drug development.

TUCSON, Ariz., and **AMSTERDAM**, May 19, 2026 — Critical Path Institute® (C-Path) today announced the launch of the New Approach Methodologies Developer Coalition (NAMs-DC), a precompetitive, public-private initiative bringing together companies that develop new approach methodologies (NAMs) to accelerate their adoption, validation, and qualification as tools for drug discovery and development. The coalition formally launches ahead of the MPS World Summit, which convenes the global microphysiological systems community the week of May 25, 2026.

Bringing new drugs to market is a costly and time-intensive process, and many promising therapies fail in clinical trials because of safety or efficacy issues that do not surface in animal studies. New approach methodologies, including complex in vitro models (CIVMs), microphysiological systems, organ chips and computational approaches, can generate human-relevant safety and efficacy information by replicating organ-level physiology with cell-cell interactions, three-dimensional architecture, fluid flow and shear, and computational modeling. Pharmaceutical companies have integrated NAMs into development workflows for years, and momentum is building across the regulatory landscape; both the FDA and EMA have made formal commitments to advance NAMs as a priority in modern drug development. Translating that momentum into consistent qualification standards across contexts of use remains the critical next step.

NAMs-DC is designed to close that gap and to help deliver on those regulatory commitments. The coalition unites in vitro model developers in a precompetitive setting, advances a robust qualification framework specifically for CIVMs, engages pharmaceutical and biotechnology end users, and serves as a unified voice for the developer community in conversations with global regulators. Through the coalition led by C-Path, a framework for qualifying tools will be developed, allowing end users to evaluate specific contexts of use, removing one of the central bottlenecks to broader regulatory adoption. Leveraging this neutral platform to foster innovative partnerships offers a streamlined and flexible approach to maximize impact in advancing regulatory science and therapeutic innovation.

“The launch of NAMs-DC marks a turning point for the integration of human-relevant science into regulatory drug development,” said Klaus Romero, M.D., M.S., FCP, chief executive officer of C-Path. “For decades, the field has needed a neutral convener to translate the promise of new approach methodologies into validated, qualified tools that regulators and developers can rely on with confidence. Through this coalition, C-Path is bringing together the developers advancing this science with the sponsors, regulators, and those with lived experience who will benefit from it. This is precisely the kind of precompetitive, multi-stakeholder collaboration that C-Path was built to lead, and it positions the NAMs community to move from individual technical breakthroughs to a coordinated path toward regulatory readiness.”

By aligning developers around shared qualification standards, the coalition reduces duplicative validation efforts and helps regulators evaluate methodologies with greater consistency. A standardized framework

gives end users a clearer path for selecting tools fit for specific contexts of use, whether assessing hepatotoxicity, modeling cardiac function, evaluating drug transport across biological barriers, or studying disease-specific tissue responses. The framework also strengthens the dialogue between technology developers and regulatory agencies on the evidence required to support qualification decisions.

“NAMs developers have built remarkable technologies, and the path from a promising platform to a regulatory-ready tool has often been fragmented, with each developer navigating qualification on their own,” said Graham Marsh, Ph.D., scientific director at C-Path and program lead for NAMs-DC. “The coalition gives this community a structured way to share learnings, align on qualification approaches, and engage regulators with a coordinated voice. Our goal is to advance a transparent, science-based qualification framework that gives developers a clear path forward and gives regulators the confidence to integrate these tools into their decision-making for drug discovery and development.”

NAMs-DC founding members represent a cross-sector group of organizations advancing human-relevant drug development through experimental, computational, and patient-centered approaches. Current founding members include CN Bio, Curi Bio, Emulate, InSphero, Modelus, Revalia Bio, VivoSphere, and the Myhre Syndrome Foundation. Additional members are expected to join as the coalition continues to expand.

The launch comes ahead of the MPS World Summit the week of May 25, where C-Path will engage the broader microphysiological systems community on the goals of NAMs-DC and the pathways for participation. Founding members are coming together now. To learn more or inquire about membership, visit c-path.org/nams-dc or contact scientific director Graham Marsh (gmarsh@c-path.org) or project manager Samantha Wilkins (swilkins@c-path.org).

About Critical Path Institute
Critical Path Institute ® (C-Path) is an independent, nonprofit established in 2005 as a public-private partnership in response to the FDA’s Critical Path Initiative. C-Path’s mission is to lead collaborations that advance better treatments for people worldwide. Globally recognized as a pioneer in accelerating drug development, C-Path has established numerous international consortia, programs and initiatives that currently include more than 1,600 scientists and representatives from government and regulatory agencies, academia, patient organizations, disease foundations and pharmaceutical and biotech companies. With dedicated team members located throughout the world, C-Path’s global headquarters is located in Tucson, Arizona and C-Path’s Europe subsidiary is headquartered in Amsterdam, Netherlands. For more information, visit c-path.org
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Media Contacts:

Roxan Triolo Olivas
C-Path
520.954.1634
rolivas@c-path.org

Kissy Black
C-Path
615.310.1894
kblack@c-path.org