
GATC Health Joins C-Path's New Approach Methodologies Developer Coalition

Tech-bio company brings AI-driven in silico modeling and multiomic data analysis to the coalition's work advancing the validation, qualification, and adoption of new approach methodologies.

TUCSON, Ariz., October 1, 2026 — Critical Path Institute's® (C-Path) New Approach Methodologies Developer Coalition (NAMs-DC) today announced that GATC Health has joined as a contributing member, bringing computational modeling and multiomic data analysis to the coalition's efforts to advance the adoption, validation, and qualification of new



GATC Health

approach methodologies (NAMs) for drug discovery and development. GATC Health joins existing members CN Bio, Crown Bioscience, Curi Bio, Emulate, InSphero, Modelus, Myhre Syndrome Foundation, Revalia Bio, and VivoSphere, alongside a growing community of developers, end users, and regulatory colleagues working to close the gap between NAM development and regulatory acceptance.

New approach methodologies include a broad range of methods such as complex in vitro and in silico models that can provide drug efficacy and safety data while reducing reliance on animal testing. Applying them for regulatory science requires significant effort to validate and qualify the models for specific contexts of use. NAMs-DC was launched in the spring of 2026 to convene developers, engage regulators, and advance a qualification framework supporting broader adoption.

GATC Health's proprietary Operon® is an AI-powered discovery engine that integrates multiomic data to simulate human biology and predict a drug candidate's efficacy and safety ahead of clinical testing. GATC Health extends the coalition's work into computational approaches, widening the range of human-relevant methods for which NAMs-DC is working to define qualification pathways.

"Expanding the range of methodologies represented within NAMs-DC is essential to building qualification approaches that can keep pace with innovation in drug development," said Graham Marsh, Ph.D., Scientific Director at Critical Path Institute and program lead for NAMs-DC. "GATC brings a distinct computational and in silico perspective to the coalition, and we look forward to its contributions as we work across the developer community, industry, and regulators to advance human-relevant tools that will positively impact drug development."

"Today, AI models are already playing a role in determining which drug candidates advance through development, yet there is still no broadly accepted framework for evaluating the quality, reliability, and performance of those models," said Jayson Uffens, Chief Technology Officer and Chairman of GATC Health. "No single company can establish that standard independently. Internal performance metrics are important, but they do not, on their own, create a common benchmark for the field. We joined NAMs-DC to bring the in silico capabilities behind Operon into direct dialogue with technology developers, biopharmaceutical companies and regulators, and to help advance a shared understanding of what meaningful qualification should look like."

On April 10, 2025, FDA announced a plan to phase out animal testing requirements for monoclonal antibodies and other drugs. FDA's *Roadmap to Reducing Animal Testing in Preclinical Safety Studies*, published the same day, identifies AI-based computational models of toxicity as one alternative to those requirements.

By acting as trusted partners to pharmaceutical and biotechnology companies, engaging global health authorities, and advancing a qualification framework for complex in vitro models, NAMs-DC works to make NAM selection and evaluation more efficient for end users and regulators. C-Path's New Approach Methodologies team focuses on the scalability, translation, validation, and qualification of NAMs so that valid technologies are positioned to realize their potential.

Organizations interested in learning more about NAMs-DC can contact C-Path Scientific Director Graham Marsh (gmarsh@c-path.org) or Project Manager Samantha Wilkins (swilkins@c-path.org), or visit <https://c-path.org/program/new-approach-methodologies-developer-coalition-nams-dc/>.

About Critical Path Institute

Founded 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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