
Crown Bioscience Joins C-Path's New Approach Methodologies Developer Coalition

Global contract research organization specializing in translational oncology brings its preclinical model and biomarker capabilities to the coalition's work advancing the adoption and qualification of new approach methodologies.

TUCSON, Ariz., July 16, 2026 — Critical Path Institute's® (C-Path) New Approach Methodologies Developer Coalition (NAMs-DC) today announced the addition of Crown Bioscience as its ninth member, bringing expertise in patient-derived models and biomarker analysis to the coalition's efforts to advance the adoption, validation, and qualification of new approach methodologies (NAMs) for drug discovery and development. Crown Bioscience joins existing members CN Bio, 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. Many pharmaceutical companies have adopted these tools for drug discovery, but their applications in the regulatory space have lagged and remain unstandardized. Applying NAMs 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 robust qualification framework that supports broader adoption.

Crown Bioscience contributes capabilities across patient-derived xenograft (PDX) models, tumor organoids, ex vivo patient tissue platforms, and biomarker analysis. The company maintains a large commercially available collection of preclinical oncology models and integrates bioinformatics and biomarker services to support translational research from discovery through clinical stages. These capabilities expand the range of human-relevant model systems represented within the coalition and support its goal of aligning developers and end users around qualification pathways that regulators can trust.

“At C-Path, we believe the fastest path to better treatments runs through collaboration among developers building these technologies, end-user companies and the regulators who evaluate them,” said NAMs-DC Executive Director Nicholas King, M.S. “Crown Bioscience has spent years building patient-derived models and biomarker capabilities. Bringing that into the coalition gives developers and regulators a clearer path to implementing these tools for use.”

“We are proud to join C-Path's NAMs Developer Coalition and contribute our expertise in patient-derived models, ex vivo platforms, and biomarker analysis to this precompetitive effort,” said Crown Bioscience Vice President, Research and Innovation, Ludovic Bourré, Ph.D. “Advancing the validation and regulatory qualification of new approach methodologies requires the developer community to work in concert with regulators, and we are committed to that shared goal.”

The coalition's mission is to facilitate the innovative use of NAM tools and close the gap in regulatory adoption. 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.

As the coalition grows, C-Path's NAMs-DC will continue convening developers and regulators to establish standards that support confident adoption and implementation of new approach methodologies across the drug development pipeline.

Organizations interested in learning more about the NAMs-DC can contact C-Path Scientific Director Graham Marsh (gmarsh@c-path.org) or Project Manager Samantha Wilkins (swilkins@c-path.org) and visit c-path.org.

About Critical Path Institute

Critical Path Institute® (C-Path) is an independent, nonprofit organization 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 in Tucson, Arizona; C-Path's Europe subsidiary is headquartered in Amsterdam, Netherlands. For more information, visit c-path.org.

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About Crown Bioscience

Crown Bioscience, a JSR Life Sciences company, is a global contract research organization (CRO) dedicated to accelerating drug discovery and development in oncology and immuno-oncology. We partner with biotech and pharmaceutical companies to provide innovative, tailored solutions spanning preclinical research, translational platforms, and clinical trial support. With the world's largest commercially available patient-derived xenograft (PDX) collection and approximately 1,000 tumor organoid models powered by Hubrecht Organoid Technology, we offer unparalleled insights across 35 cancer indications. Our expertise spans *in vivo*, *in vitro*, *ex vivo*, and *in silico* methods, complemented by advanced laboratory services that span the entire drug development continuum.

Additionally, our extensive biobank of liquid and human biospecimens, complete with clinical histories, enhances oncology research capabilities. Operating from 11 state-of-the-art facilities across the US, Europe, and APAC, our laboratories meet the highest industry standards, including accreditation by the College of American Pathologists (CAP) and the International Organization for Standardization (ISO). To learn more, visit www.crownbio.com.

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