

Scaling the Science: The Maturation of NAMs and the Demand for Validated Scaling

The commercial and regulatory reality of New Approach Methodologies (NAMs) materialized rapidly this conference season. Across the exhibition floors of the Microphysiological Systems (MPS) World Summit, the Biotechnology Innovation Organization (BIO), the European Organ-on-Chip Society (EUROoCS), and the European Society of Toxicology In Vitro (ESTIV), a decisive shift was evident to developers, sponsors, and researchers in attendance. The sector has accelerated into a highly practical phase of industry implementation, driven by urgent business needs and a demand for validated scaling.

For Kim Ward Barowicz of Critical Path Institute (C-Path), the primary takeaway from BIO was how rapidly NAMs evolved from cool science into an urgent commercial reality. Sponsors now see a definitive business case for these tools, and developers are delivering usable technology at a remarkable pace. This rapid commercialization puts C-Path's NAMs Developer Coalition in a highly advantageous position, as the organization serves as the central hub connecting proactive pharmaceutical sponsors with developers who possess commercially ready technology.



This maturation is highly visible in the shifting demographics of conference attendees. Nick Geisse of Curi Bio recalled that earlier iterations of the MPS World Summit felt heavily academic. For startup companies investing thousands of dollars to exhibit, the priority has always been about connecting with actual customers. That coordinated push to involve the industry more has yielded tangible results. Industry participation at the MPS World Summit has expanded significantly in recent years, bringing together pharmaceutical representatives, technology developers, new startups, and the next generation of researchers. Government and regulatory interest continues to grow as well, with agencies such as the National Institutes of Health (NIH) participating and ongoing engagement from the U.S. Food and Drug Administration (FDA).

As pharmaceutical companies evaluate how to incorporate NAMs into existing development pipelines, implementation strategies remain varied. Some organizations are actively integrating these technologies into discovery and development workflows, while others are exploring adoption through smaller pilot projects. Across the ecosystem, there is growing recognition that shared standards and collaborative validation efforts will be essential to building confidence and accelerating broader implementation. The NAMs Developer Coalition exists to bridge these gaps and build this confidence towards adopting the technology across the board.

The global marketplace is also putting pressure on domestic adoption. Yuan Tian of VivoSphere highlighted a significant presence of Asian companies at BIO, noting that some arrived equipped with extensive, book-

length portfolios of commercial case studies ready for immediate review. That level of international commercial readiness suggests global players are actively looking to enter the U.S. market, prompting domestic developers to seriously consider the global competitive landscape.

The financial stakes for early-stage developers are equally high. Jenna DiRito of Revalia noted intense interest at BIO from early biotechs who require NAMs technology to validate their own systems. Investors are increasingly demanding robust, human-centric NAMs validation before releasing subsequent tranches of funding for newer technologies, creating a clear mandate for reliable platforms. Conversations are increasingly centered on how established platforms can enable and validate emerging biotech innovations.

To meet these commercial and investment demands, the underlying science is scaling up. Armelle Pindon of the Myhre Syndrome Foundation highlighted a vital scientific progression at the MPS World Summit. Researchers are actively moving beyond healthy cell applications and introducing complex disease models into the MPS environment. The surrounding dialogue has also matured to match, focusing heavily on standardization, validation, and scaling up models for broader use.

Those themes continued across the academic conferences, where the emphasis shifted toward building the scientific and regulatory foundation needed for widespread implementation. At ESTIV, presentations highlighted collaborative efforts linking Adverse Outcome Pathways with omics technologies and in silico models, while consortium results demonstrated the growing maturity of these integrated approaches. At EUROoCS, regulatory agencies including the European Medicines Agency and the Joint Research Centre led discussions on establishing clear contexts of use for organ-on-chip technologies. Together, these meetings underscored a shared focus on developing standardized validation frameworks that will enable regulators and industry to evaluate NAMs with greater confidence.

Despite rapid commercialization, a bridge still needs to be built between the broader industry and academia. Emily Richardson of CN Bio noted that many academic researchers continue to rely heavily on self-built models for their research. Demonstrating the tangible value versus the financial cost of commercial platforms remains a highly critical next step for developers looking to properly support researchers and academic institutions.

The mandate for the NAMs Developer Coalition emerging from this conference season is clear with commercial demand, investor expectations, scientific innovation, and regulatory engagement becoming increasingly aligned around a common goal: transforming promising technologies into validated, scalable tools that can be confidently adopted across the drug development pipeline.