BUILDING EUROPE'S CAPACITY FOR NEW APPROACH METHODOLOGIES

The STEP4NAMs project aims to overcome barriers to the adoption of New Approach Methodologies (NAMs) in Europe's biomedical research, translating evidence into practical support. Dr Margot Jehle from BioRegio STERN Management GmbH explains

Across Europe, New Approach Methodologies (NAMs) are increasingly recognised as tools for more human-relevant, predictive and ethically responsible biomedical research. They include organ-on-chip systems, organoids, computational models, digital twins and advanced simulations. Yet uptake in (Bio)Pharma and MedTech development remains slower than scientific progress would suggest. This is not simply a technology problem.

Within STEP4NAMs, partners from six North-West European countries examined the conditions shaping NAM adoption. The analysis drew on publicly available information. It was complemented by 45 stakeholder interviews with NAM developers, users and organisations working with animal models. Feedback from the project's Strategic Advisory Board, which brings together experts from across the NAM ecosystem, added another perspective. Together, these sources helped clarify why promising methods still struggle to move from research into wider use.

What prevents wider adoption?

The findings point to four closely connected barriers. First, validation remains demanding. Developers must demonstrate reliability, reproducibility and relevance within a clearly defined context of use. Advanced systems may require standardised protocols, robust reference data and evidence from several laboratories. This takes resources that many developers, particularly SMEs, cannot easily mobilise. Animal data also remain the main benchmark, even where the model itself has limitations.

Second, education and practical skills are fragmented. Strong centres of expertise exist, but access is uneven and NAM-related content is not consistently embedded in curricula or professional training. Hands-on opportunities are scarce because specialised equipment and experienced trainers are concentrated in relatively few locations. Regulators, senior scientists and industry decision-makers also need confidence in interpreting NAM-generated evidence.

Third, funding often supports invention more readily than implementation. Grants may help create a model, but fewer resources are available for inter-laboratory studies, regulatory engagement, standardisation and long-term validation. Public funding is often project-based, typically spanning two to three years, while NAM validation and regulatory acceptance can take eight to ten years or longer.

Fourth, regulatory uncertainty affects industrial decisions. Existing frameworks can allow NAM use in defined contexts, but acceptance remains cautious and case-specific. Companies may therefore use NAM data as supplementary evidence while retaining conventional studies to reduce regulatory risk. The interviews also reveal a gap between organisational ambition and implementation. Among the interviewed (Bio)Pharma NAM users, 80% reported having a strategy to prioritise methods that reduce or eliminate animal use. Yet, only 44% felt that NAM-based research methods were sufficiently considered in decision-making.

Taken together, these findings make one point particularly clear: scientific excellence alone is not enough. Successful NAM implementation also requires coordinated capacity building across the wider innovation ecosystem.

WHY THE STEP4NAMS CONSORTIUM MATTERS

STEP4NAMs brings together two capabilities that are often separated: access to companies and scientific expertise in New Approach Methodologies.

From evidence to practical support

STEP4NAMs created a three-pillar Training and Support Programme that helps stakeholders move from awareness towards application. Rather than treating training as a standalone activity, the programme links knowledge directly with implementation.

EDUCATE provides the entry point. The self-paced online offer is open to SMEs, researchers, industry professionals, regulators and public authorities. It introduces NAM fundamentals, applications, regulatory aspects and implementation potential. A core module provides a common foundation, while specialised modules explore organ-on-chip systems, organoids, digital twins and bench-top simulations. Organisations often hesitate because they are unsure whether a NAM is relevant to their technology, product or development question. Accessible training can reduce that uncertainty before significant resources are committed. It also helps technical experts, business teams and regulatory professionals develop a shared language.

ENABLE moves closer to practical application. Selected SMEs receive tailored support through mentoring, technical guidance, regulatory input, hands-on training and one-to-one advice. The programme includes on-site training at Atlantic Technological University in Ireland and at the 3R-Center Tübingen in Germany. Individual consulting supports status analysis, model selection and implementation planning. There is no single route to NAM adoption. A medical device company faces different questions from a biotech SME evaluating a therapeutic candidate. Both may need expert input, but not the same input.

APPLY is the most implementation-oriented pillar. It connects SMEs and start-ups with concrete challenges defined by industrial challenge providers. In 2026, these include Sanofi and Ipsen. Selected companies work on real BioPharma use cases through structured mentoring and training, exploring how their solutions can respond to specific industrial needs. A second round will follow in 2027, with plans to broaden the scope to include MedTech challenges alongside BioPharma.

Together, the three pillars form a progression. EDUCATE builds understanding. ENABLE supports informed technical and regulatory choices. APPLY creates a setting in which knowledge can be tested through direct collaboration with industry.

Why capacity building is innovation infrastructure

Europe already invests substantially in NAM research. But scientific progress alone will not drive adoption. Researchers need to generate robust evidence, SMEs need access to expertise and infrastructure, and regulators need the confidence to assess emerging methods consistently. Capacity building is therefore not an add-on to innovation, but part of the infrastructure needed to implement it.

Training cannot remove every regulatory or financial barrier. It can, however, help developers define a clear context of use, engage earlier with regulators and build stronger evidence packages. This is particularly important in a fragmented European landscape, where access to expertise, infrastructure and implementation support remains uneven.

Wider adoption will ultimately depend on collaboration between developers, industry, regulators, public authorities and research organisations. STEP4NAMs contributes to this by connecting knowledge with practical support and opportunities to apply NAMs in real development settings.

Business support and ecosystem access: BioRegio STERN Management GmbH, Brabant Development Agency, InnovationQuarter, Biovia, Eurasanté and Medicen Paris Region connect the project with SMEs, larger companies and regional Life Sciences and MedTech ecosystems.

Scientific, technical and training expertise: The University of Tübingen and its 3R-Center, Atlantic Technological University, the University of Galway and the University of Luxembourg contribute expertise in areas including organ-on-chip systems, organoids, digital twins and advanced simulation models.

This combination allows STEP4NAMs to identify practical industry needs, connect companies with relevant experts and infrastructure and translate scientific knowledge into training, pilot activities and implementation support.

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BioRegio STERN

Dr Margot Jehle
Head of European Affairs
BioRegio STERN Management GmbH
Tel: +49 173 180 8924
WEBSITE BioRegio STERN
EMAIL Dr Jehle
Dr Margot Jehle
WEBSITE STEP4NAMs
EMAIL STEP4NAMs
STEP4NAMs