

■ PARTNERS



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■ THE PROJECT

STEP4NAMs is a European initiative promoting New Approach Methodologies (NAMs) to replace animal testing in (Bio)Pharma and MedTech. It tackles regulatory, technical, and infrastructural barriers, fostering NAMs adoption through validation guidance, strategic frameworks, and collaboration while supporting NAM stakeholders with training & support programmes and a NAM Validation Manual.

Total project budget
€6,3 million

EU funding
€3,8 million

Timeline
2025 - 2028

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Interreg
North-West Europe



Co-funded by
the European Union

STEP4NAMs



**Innovation
and resilience**



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**Boosting the use of New
Approach Methodologies to
replace Animal Testing**

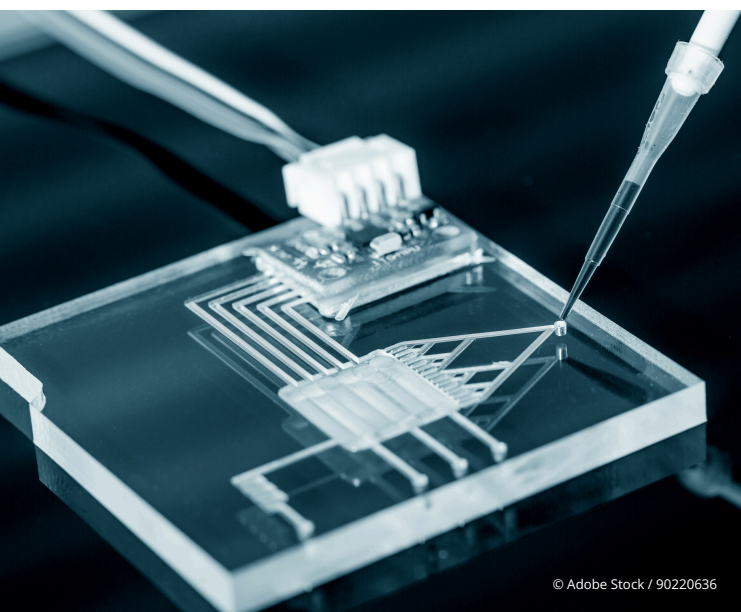
■ CHALLENGE

NAMs, including digital and biotech models, provide reliable data, reduce animal testing and enhance clinical trials. However, they remain underutilized in biomedical research, with many still in early development for regulatory approval.

Key challenges include:

- Limited awareness & expertise – many researchers and companies lack knowledge and technical skills to implement NAMs effectively.
- Regulatory uncertainty – existing approval processes are still largely based on traditional methods, slowing NAM acceptance.
- Financial & infrastructure barriers – funding gaps and fragmented research ecosystems hinder NAM development and implementation.

STEP4NAMs addresses these barriers by validating NAM technologies within 4 pilot studies, fostering regulatory acceptance, and supporting their integration into (Bio)Pharma and MedTech.



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■ OBJECTIVES

STEP4NAMs aims to create conditions for a widespread adoption of NAMs in the (Bio)Pharma and MedTech sector by:

- Developing a joint strategy & two sector related action plans
- Validating and demonstrating NAM applications within four key areas: Organ-on-Chip, Organoids, Digital Twins, Bioprinting
- Developing a NAM Validation Manual to guide researchers, industry, and regulators
- Providing a NAM stakeholder training & support programme to enhance expertise and accelerate adoption
- Strengthening transnational collaboration across the NWE region to promote NAMs adoption



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■ EXPECTED RESULTS

STEP4NAMs will drive the adoption of New Approach Methodologies (NAMs) by establishing a clear strategy, validating effective methods and providing practical guidance for researchers and stakeholders.

- Validated NAM technologies – practical demonstration of four key NAM applications.
- Regulatory & industry guidance – a comprehensive NAM Validation Manual to facilitate implementation.
- Skilled workforce – 186 trained professionals equipped to apply NAMs in their fields.
- Stronger collaboration – a transnational network of researchers, industry, and regulators promoting NAM innovation.

By the end of the project, a significant step will have been taken towards integrating NAMs into the BioPharma and MedTech sectors, enhancing efficiency, reliability and fostering innovation across Europe.