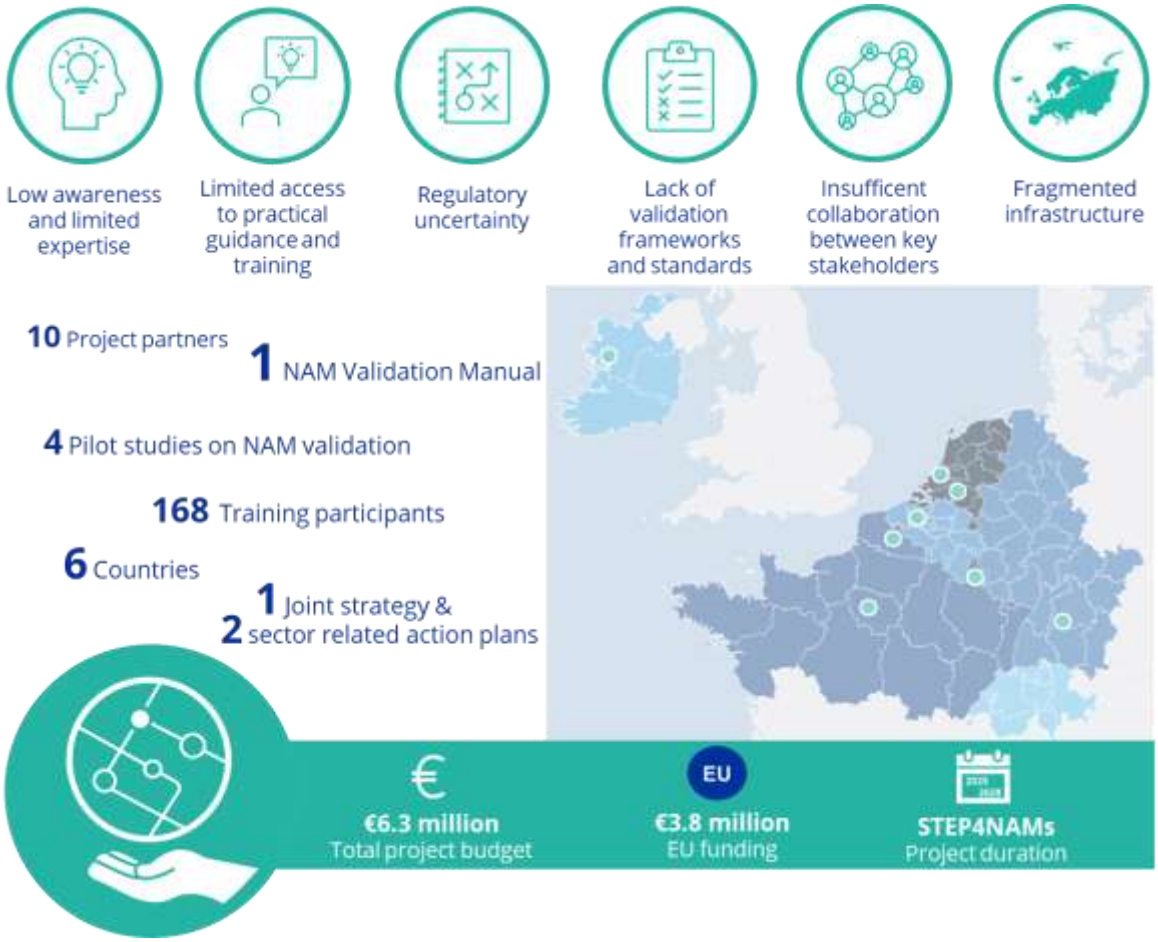
Interreg Co-funded by the European Union
North-West Europe
STEP4NAMs

STEP4NAMs Pilot Catalogue

Content

About STEP4NAMs

STEP4NAMs (2025–2028) is an European project driving the adoption of New Approach Methodologies (NAMs) to replace animal testing in the (Bio)Pharma and MedTech sectors. It tackles key barriers, technical and infrastructural, by validating cutting-edge technologies such as Organ-on-Chip, Organoids, Digital Twins and Bio-printed physiological models and promoting their implementation.



The project develops a NAM Validation Manual, conducts four pilot studies on NAM validation and provides a targeted training programme to build capacity across the NAM value chain. Backed by €3.8 million in ERDF funding from the Interreg NWE Programme, the consortium includes 10 partners from six countries, coordinated by BioRegio STERN Management GmbH (Germany).

For more information:

🌐 step4nams.nweurope.eu

🔗 LinkedIn – STEP4NAMs

STEP4NAMs Partners

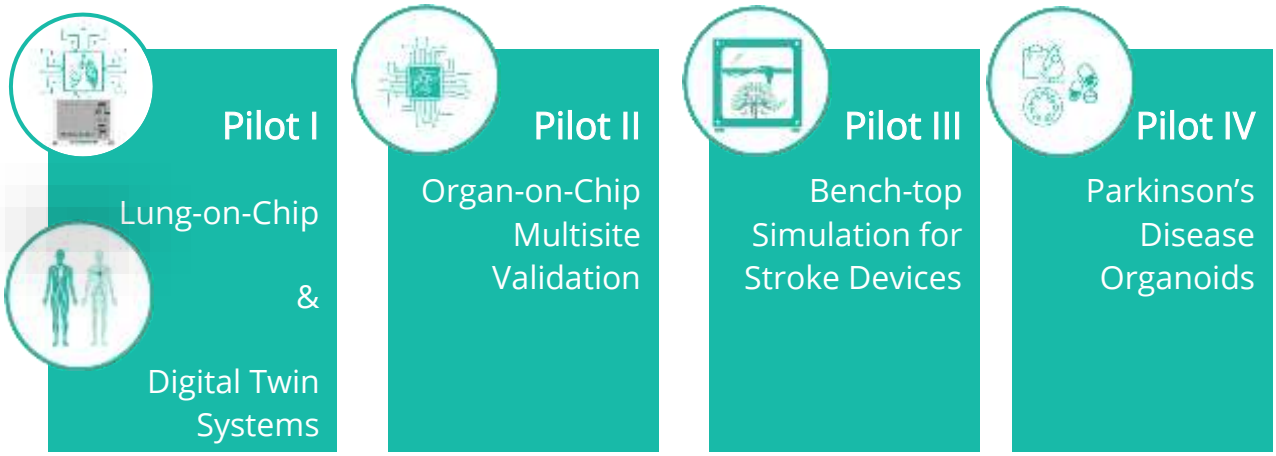
	BioRegio STERN Management GmbH	Germany
	3R-Center for In vitro Models and Alternatives to Animal Testing	Germany
	Atlantic Technological University	Ireland
	Brabant Development Agency	Netherland
	Eurasante	France
	Biovia	Belgium
	Innovation Quarter	Netherland
	Medicen Paris Region	France
	University of Galway	Ireland
	University of Luxembourg	Luxembourg

About the pilots

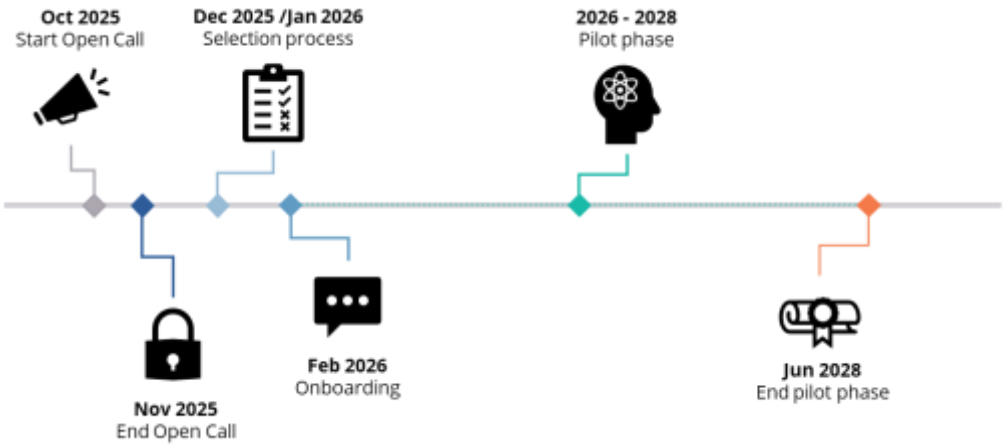
Robust evidence on the effectiveness, relevance and usability of selected NAM technologies will be generated through the pilot projects, forming the foundation of the NAM Validation Manual and supporting the further refinement of the training programme.

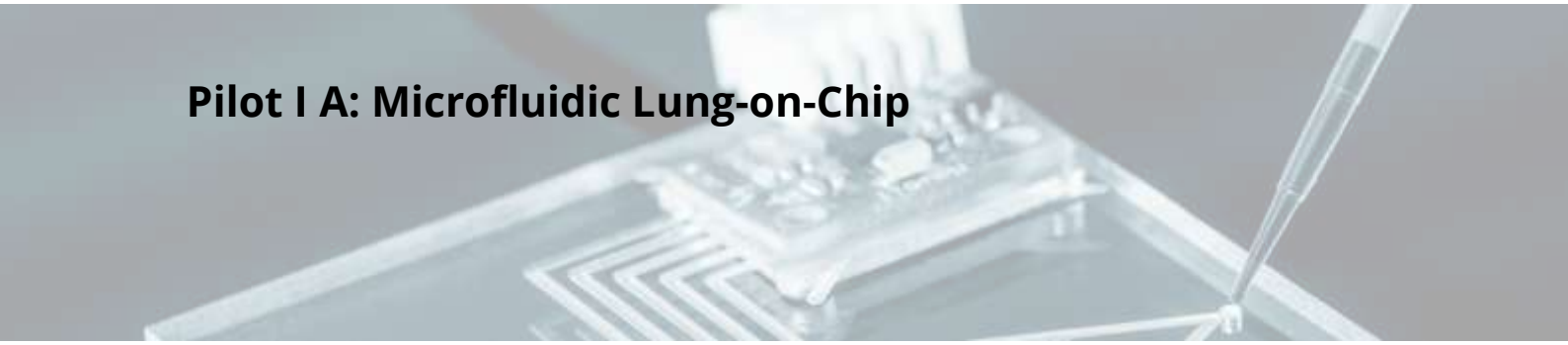
Participation in the pilots is open to SMEs, research institutions and CROs. Interested stakeholders are encouraged to apply: check out the pilots described in the catalogue, verify your eligibility, complete the application form and submit your request.

*Click on an icon to access detailed information on each pilot, including **objectives**, **participation requirements** and **application guidelines**.*



The pilots will be carried out over a period of approximately two and a half years, starting in early 2026 and continuing until mid-2028. Involvement in the pilots will offer visibility and the opportunity to contribute directly to the broader acceptance and implementation of NAMs.





Pilot I A: Microfluidic Lung-on-Chip

"We are developing a Lung-on-Chip model that replicates human lung physiology using patient-derived samples offering a scientifically robust NAM to assess drug responses more accurately than animal models."

- Replicates Acute Lung Injury (ALI) using intensive care unit (ICU)-derived serum
- Integrates perfusion, shear stress and barrier integrity measurements
- Simulates physiological blood flow and ALI progression
- Uses historical ICU data and Digital Twin for validation and personalization
- Validates Parkinson's disease drug candidates from midbrain organoids

Eligible applicants: Companies or SMEs developing adaptable microfluidic chips or perfusion systems seeking pre-market testing and validation.

What you can do

Validate your technology
Test your microfluidic or perfusion systems in a cutting-edge LoC model using real patient data

Speed up market entry
Gain regulatory-relevant validation data to support faster commercialisation

Connect & co-develop
Collaborate with leading experts across the STEP4NAMs innovation network

Application process

Who should apply	Enterprises/ SMEs developing microfluidic chips or perfusion systems.
Number of selected participants	2
Participation requirements	Active engagement Onsite participation if required by the pilot design
Lead Organisation &Location	University of Galway, Dep. Anaesthesia and Intensive Care, Mathematics, Computer Science Adress University Road H91 TK33 Galway Ireland
Open call start	27th of October 2025
Open call closed	16th of November 2025
Eligibility criteria	Applicants from Interreg NWE region are prioritised (particularly partner regions) EU wide applications are welcome
Selection process	*December 2025 Assessment* *December 2025/ January 2026 Interviews* *January 2026 Candidate selection* *February 2026 Announcement of selected participants* *February 2026 Onboarding*
Terms of reference	[Link to terms of reference]
Application Form	[Application Form]
Contact (Questions & Application)	step4nams@bioregio-stern.de

About the pilot lead

University of Galway

Ranked 289th in the 2024 QS World University Rankings, the University of Galway combines research excellence with expertise in medical device innovation, acute respiratory distress syndrome and near-patient testing. The CerebroMachines Lab, led by Dr. Mihai Lomora, develops microfluidics and organ-on-chip platforms for drug testing, forming the basis of the Lung-on-Chip pilot.

For more information, click here University of Galway

Pilot I B: Digital Twin System

"This pilot brings together validated respiratory and renal models of acute lung injury into a digital twin that simulates patient-specific responses which is leading the way for in-silico NAMs in drug and device development."

- Integrates in-silico respiratory mechanics, gas exchange and renal hemodynamics in one framework
- Personalizes simulations with patient-specific ICU data
- Enables virtual testing of ventilator settings, fluid management and novel therapeutics
- Uses machine learning to match patient trajectories for key clinical parameters
- Supports regulatory-grade virtual trials to speed pre-clinical testing and reduce animal use

Eligible applicants: Pharma or BioTech enterprises/ SMEs developing drug candidates or medical devices with expertise in real-time simulation, pharmacokinetic/pharmacodynamic (PK/ PD) profiling or clinical data integration.

What you can do

Test virtually before trials
Assess drug candidates and devices in a lung–kidney Digital Twin ICU simulation.

Optimise treatment strategies
Evaluate ventilator, fluid, and drug effects before in vivo or clinical trials

Co-develop high-impact tools
Partner with experts to build regulatory-grade virtual trial platforms for critical care.

Application process

Who should apply	Enterprises/ SMEs with drug candidates or medical devices for pre-clinical testing with expertise in real-time simulation, PK/PD profiling or clinical data integration for their product
Number of participants	2
Participation requirements	Active engagement Onsite participation if required by the pilot design
Lead Organisation &Location	University of Galway, Dep. Anaesthesia and Intensive Care, Mathematics, Computer Science Adress University Road N/A H91 TK33 Galway Ireland
Open call start	27th of October
Open call closed	16th of November
Eligibility criteria	Applicants from Interreg NWE region are prioritised (particularly partner regions) EU wide applications are welcome
Selection process	*December 2025 Assessment* *December 2025/ January 2026 Interviews* *January 2026 Candidate selection* *February 2026 Announcement of selected participants* *February 2026 Onboarding*
Terms of reference	[Link to terms of reference]
Application Form	[Application Form]
Contact (Questions & Application)	step4nams@bioregio-stern.de

About the pilot lead

University of Galway

Ranked 289th in the 2024 QS World University Rankings, the University of Galway combines research excellence with expertise in medical device innovation, acute respiratory distress syndrome and near-patient testing. The CerebroMachines Lab, led by Dr. Mihai Lomora, develops microfluidics and organ-on-chip platforms for drug testing, forming the basis of the Lung-on-Chip pilot.

For more information, click here. University of Galway

Pilot II: Multi-Site Functional Validation of Organ-on-Chip Models

"By validating Organ-on-Chip systems across multiple sites and compounds, we are building the reproducibility data needed to qualify these technologies as NAMs for industrial use."

- Standardises protocols to minimise inter-site variability
- Assesses basic functionality and long-term stability of OoC models in three key phases across a minimum of three sites
- Evaluates dose–response using six well-characterized compounds
- Validates predictive accuracy with six blinded compounds

Eligible applicants: Pharmaceutical and biotechnology companies / SMEs with prior OoC experience, either as end users conducting in-house testing or as technology providers submitting NAMs and participating to standardized testing.

What you can do

Benchmark your technology
Have your OoC systems independently tested for stability, reproducibility, and predictive power

Demonstrate technology readiness
Generate robust, multi-site data to support regulatory acceptance and customer confidence

Boost your market position
Use independent validation results as a strong selling point in marketing and investor communications

Application process

Who should apply	Pharmaceutical and biotechnology companies / SMEs with OoC experience as end users conducting in-house testing or as technology providers
Number of participants	2 – 5
Participation requirements	Active engagement Onsite participation if required by the pilot design
Lead Organisation &Location	3R-Center for in vitro models and animal testing alternatives Adress Waldhörnlestraße 22 72072 Tuebingen Germany
Open call start	27th of October
Open call closed	16th of November
Eligibility criteria	Applicants from Interreg NWE region are prioritised (particularly partner regions) EU wide applications are welcome
Selection process	*December 2025 Assessment* *December 2025 Interviews* *January 2026 Candidate selection* *February 2026 Announcement of selected participants* *February 2026 Onboarding*
Terms of reference	[Link to terms of reference]
Application Form	[Application Form]
Contact (Questions & Application)	3rcenter@uni-tuebingen.de step4nams@bioregio-stern.de

About the pilot lead

3R-Center Tübingen

The 3R-Center Tübingen connects research, policy, education and public outreach to advance human-relevant in vitro models and reduce animal testing. Working closely with regulators, decision-makers and end users of NAMs, the center develops and qualifies Organ-on-Chip systems in collaboration with the µOrganoLab for applications in basic research, pharma, personalized medicine and toxicology. It also provides tailored training to support adoption and knowledge exchange.

For more information, click here. 3R Center Tübingen

Pilot III: Bench-top Simulation for Stroke Devices

"We are designing standardized bench-top models that mimic neurovascular conditions using utilising a range of fabrication techniques including 3D-bioprinting. This gives opportunities for the implementation of a clinically relevant NAM to support thrombectomy device development."

- Validates mechanical neuro-thrombectomy technologies using standardized bench-top simulations
- Replicates clot–vessel wall adhesions with 3D-bioprinted materials
- Ensures geometrical and mechanical compliance of simulation models
- Establishes guidelines for clot analogue fabrication and characterization
- Simulates physiological flow, pressure and temperature in AIS scenarios

Eligible applicants: Medtech enterprises/SMEs and research organisations including universities and institutes developing vascular or thrombectomy technologies, willing to participate in design input, validation protocol review and device performance testing.

What you can do

Validate in realistic stroke models
Test your thrombectomy devices in standardized, clinically relevant bench-top systems.

Accelerate product development
Use reproducible simulation results to refine designs faster and cut R&D timelines.

Strengthen your market pitch
Showcase independent validation as proof of performance for customers and investors.

Application process

Who should apply	MedTech enterprises / SMEs or research organisations developing vascular or thrombectomy technologies seeking validation of devices
Number of selected participants	2 – 5
Participation requirements	Active engagement Onsite participation if required by the pilot design
Lead Organisation &Location	Atlantic Technological University, Medical & Engineering Technologies Centre Adress Dublin RD N/A H91 T8NW Galway Ireland
Open call start	27th of October
Open call closed	16th of November
Eligibility criteria	Applicants from Interreg NWE region are prioritised (particularly partner regions) EU wide applications are welcome
Selection process	*December 2025 Assessment* *January 2026 Interviews* *January 2026 Candidate selection* *February 2026 Announcement of selected participants* *February 2026 Onboarding*
Terms of reference	[Link to terms of reference]
Application Form	[Application Form]
Contact (Questions & Application)	step4nams@bioregio-stern.de

About the pilot lead

Atlantic Technological University (ATU)

ATU hosts the ISO 9001-accredited Medical and Engineering Technologies (MET) Gateway, supporting R&D in MedTech, Life Sciences, Engineering, Food, Beverage and Sports. Internationally recognised, MET works with clinical and industrial partners in medical imaging, anatomical modelling, physiological replication, design optimisation, tissue engineering, biofabrication and innovations in nutrition and sports technologies.
For more information, click here. Atlantic Technological University

Pilot IV: Parkinson's Disease Organoids for Predicting Drug Efficacy

"Using midbrain organoids generated from patients with Parkinson's Disease, we are examining drug responses in a model that closely mirrors human pathology. This showcases how organoids can serve as predictive NAM for clinical drug trials in neurodegenerative research."

- Uses organoids from familial (GBA mutated) PD patients and matched control cell lines which recapitulate key PD hallmarks, including dopaminergic neuron loss
- Assesses drug effects via high-content imaging and PD cellular phenotype analysis
- Compares predictive value against pre-clinical animal model outcomes
- Offers a cost-effective, patient-specific animal-free testing platform for neurodegenerative drug R&D

Eligible applicants: Enterprises and SMEs with drug compounds for neurodegenerative diseases (mainly PD), tested in pre-clinical and clinical settings or untested compounds in early clinical development.

What you can do

Put your compounds to the test
Evaluate PD drug candidates in patient-derived organoid models.

De-risk clinical pipelines
Identify failures earlier and save time, cost, and resources before late-stage trials.

Gain independent proof points
Use validation data to strengthen stakeholder confidence

Application process

Who should apply	Enterprises/ SMEs with PD or other neurodegenerative drug candidates. Compounds tested in pre-clinical and/or clinical settings, including untested or ongoing candidates.
Number of selected participants	4
Participation requirements	Active engagement Onsite participation if required by the pilot design
Lead Organisation &Location	University of Luxembourg, Research group Developmental & Cellular Biology Adress Biotech II 6, avenue du Swing L-4367 BELVAUX Luxembourg
Open call start	27th of October
Open call closed	16th of November
Eligibility criteria	Applicants from Interreg NWE region are prioritised (particularly partner regions) EU wide applications are welcome
Selection process	*December 2025 Assessment* *January 2026 Interviews* *January 2026 Candidate selection* *February 2026 Announcement of selected participants* *Late February 2026 Onboarding*
Terms of reference	[Link to terms of reference]
Application Form	[Application Form]
Contact (Questions & Application)	step4nams@bioregio-stern.de

About the pilot lead

University of Luxembourg

Based at the University of Luxembourg, the Developmental & Cellular Biology group develops advanced human brain models to study both healthy and disease states in the context of neurodegenerative diseases. Using brain organoid and assembloid technologies, the group models physiological and pathological processes, with a strong focus on PD as a growing societal challenge.

For more information, click here Developmental & Cellular Biology | University of Luxembourg

Rules of procedure and data protection regulation

By applying to participate in a STEP4NAMs pilot study, applicants agree to the following:

Confidentiality:

Depending on the pilot, STEP4NAMs partners may request the signing a Non-Disclosure Agreement to protect any confidential information shared during the application, evaluation and implementation process.

Use of data:

Data provided in the application will only be used for the purposes of evaluation, project implementation and aggregated reporting within the STEP4NAMs consortium. No confidential data will be shared publicly without prior written consent.

Communication & dissemination:

By applying, applicants consent to the use of non-confidential information (e.g. company name, project participation, general project description) in STEP4NAMs communication and dissemination activities, such as project websites, newsletters, events and reports.

Expected commitment:

Selected participants are expected to actively engage in the pilot activities, provide necessary technical input and feedback and participate in agreed evaluation, validation and communication measures throughout the project duration.

Data protection

All personal and company-related data will be processed in compliance with EU Regulation 2016/679 (General Data Protection Regulation – GDPR).

Abbreviations

Table 1 Abbreviations.

Abbreviation	Description
ALI	Acute Lung Injury
ICU	Intensive Care Units
LoC	Lung-on-Chip
NAM	New Approach Methodology
NWE	North-West-Europe
OoC	Organ on Chip
PD	Parkinson's Disease
PD	Pharmacodynamic
PK	Pharmacokinetic
SME	Small- and mid-sized enterprise