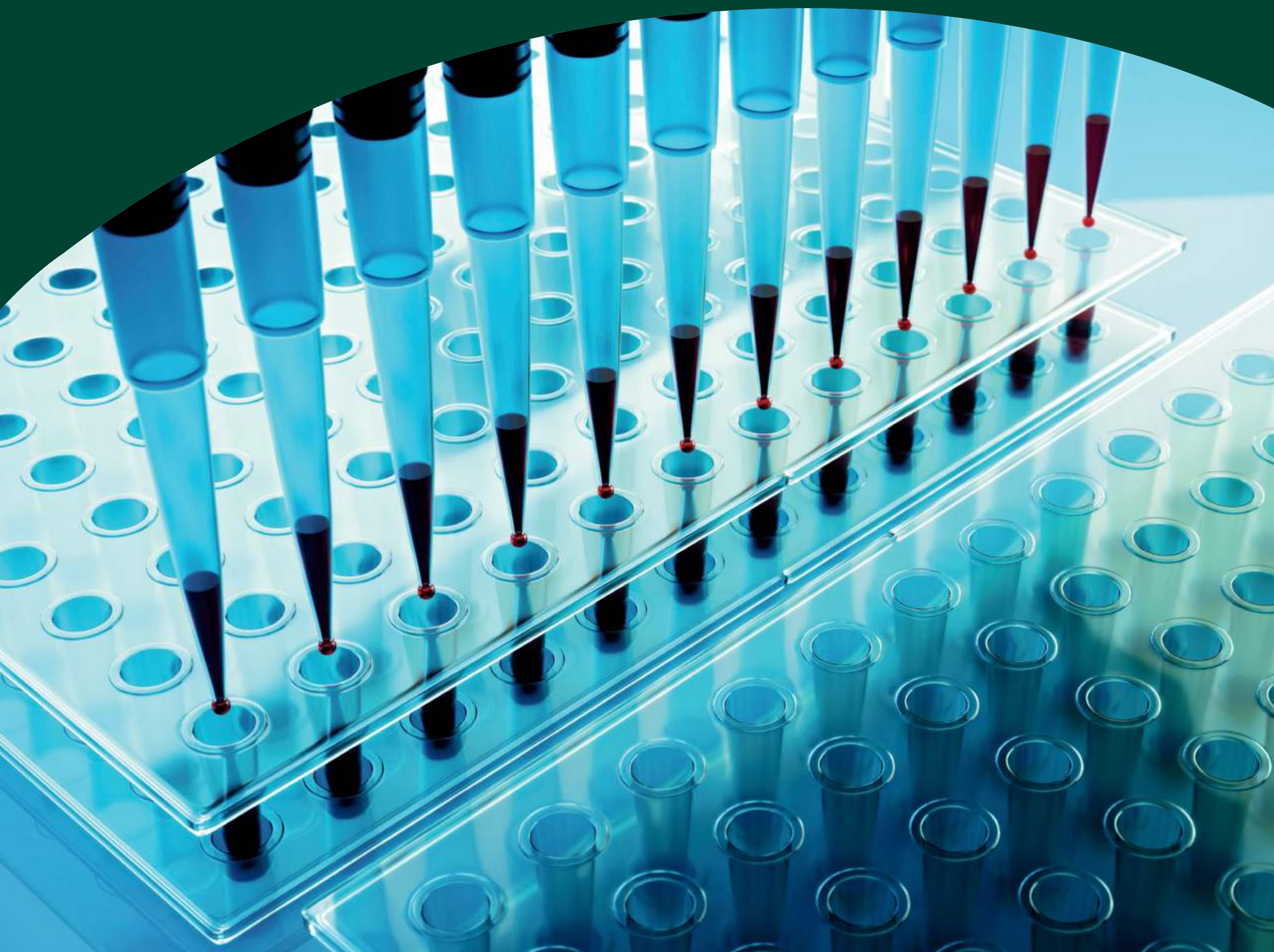
BIOMED21 COLLABORATION

Policy Paper

A Moonshot for NAMs

Leveraging non-animal methods to position Europe as global leader in health research



Who we are

The Biomedical Research for the 21st Century (BioMed21) Collaboration is an international group of scientists, policy specialists, and communication experts promoting human-relevant research to tackle urgent health challenges, improve patient outcomes, advance science, and reduce reliance on animals.

Organizations supporting this initiative:

A Moonshot for NAMs

Leveraging non-animal methods to position Europe as global leader in health research

NAMs in the Strategy for European Life Science

A Missed Opportunity?

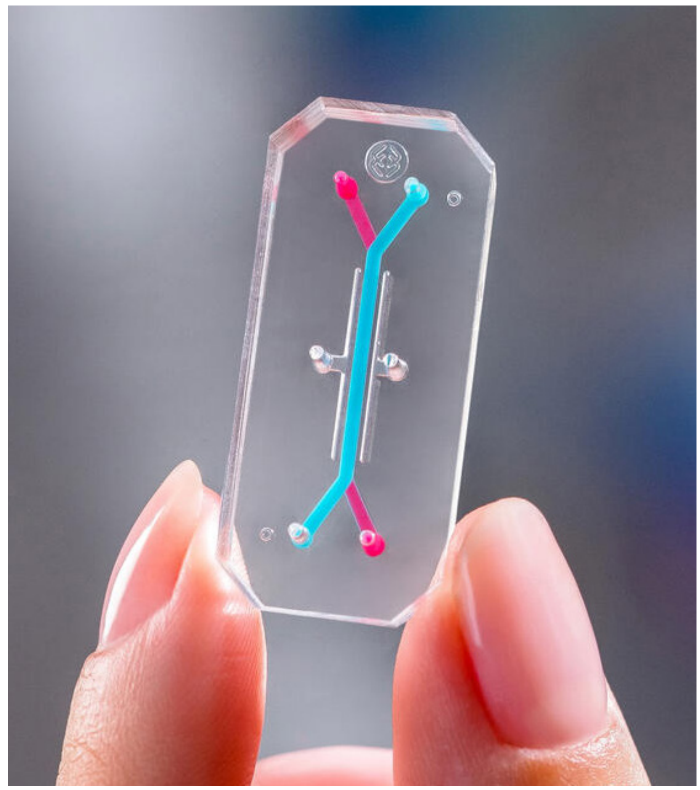


PHOTO CREDIT: EMULATE, INC

In July 2025, the European Commission unveiled “Choose Europe for life sciences”, a strategy with the ambitious goal to “position the EU as the world’s most attractive place for life sciences by 2030”[1]. Backed by 10 billion € annually from EU funding programmes (Horizon Europe, EU4Health, Digital Europe, LIFE, Innovation Fund, Erasmus+), the strategy highlights health as one of the sectors where Europe’s excellence must be maintained due to its benefits to society, namely “accelerating medical innovations to preventing and treating disease”.

As the Commission rightly points out in its strategy, the EU is suffering from “an alarming failure to translate innovation into products or services”. This problem is particularly acute in the context of biomedical research, an area where only a very small proportion of laboratory discoveries lead to actual advances for patients. This has been referred to as the “valley of death” in drug discovery, with an estimate of 95% of promising drugs failing at clinical stage[2]. Beyond the rising financial expense per successful drug, the “valley of death” entails substantial socio-economic and societal costs, including the loss of innovation potential due to the collapse of small enterprises unable to translate their discoveries, reduced research productivity and career dissatisfaction among scientists, as well as the erosion of public trust as patients and families face repeated therapeutic disappointments.

Despite the growing body of evidence indicating the limited ability of animal models to accurately predict human biological responses, animal models continue to dominate research. This translational research gap is also compounded by systemic factors, including poor reproducibility, publication bias, disease heterogeneity, and limitations in the design and implementation of clinical trials.

Non-animal methods, also referred to as new approach methodologies (NAMs), can be a critical enabler of a broader shift toward more predictive, reproducible, and human-relevant science. Several countries have launched major programmes to develop emerging NAMs based on microphysiological systems (MPS) (e.g., organs-on-chips and organoid models), advanced computing (*in silico* and AI) technologies, and other approaches. By making use of human cells, tissues and large datasets, these cutting-edge methods are already advancing research in cancer, Alzheimer’s disease, chemical risk assessment, and pharmaceutical safety testing. Already, a human liver-on-chip has proven to be more accurate than animal models in predicting drug-induced liver injury, and its broad adoption could generate

1 https://research-and-innovation.ec.europa.eu/document/download/411698e8-6062-41af-96e5-af54474d70f5_en

2 https://www.frontiersin.org/journals/drug-discovery/articles/10.3389/fddsv.2024.1355044/full

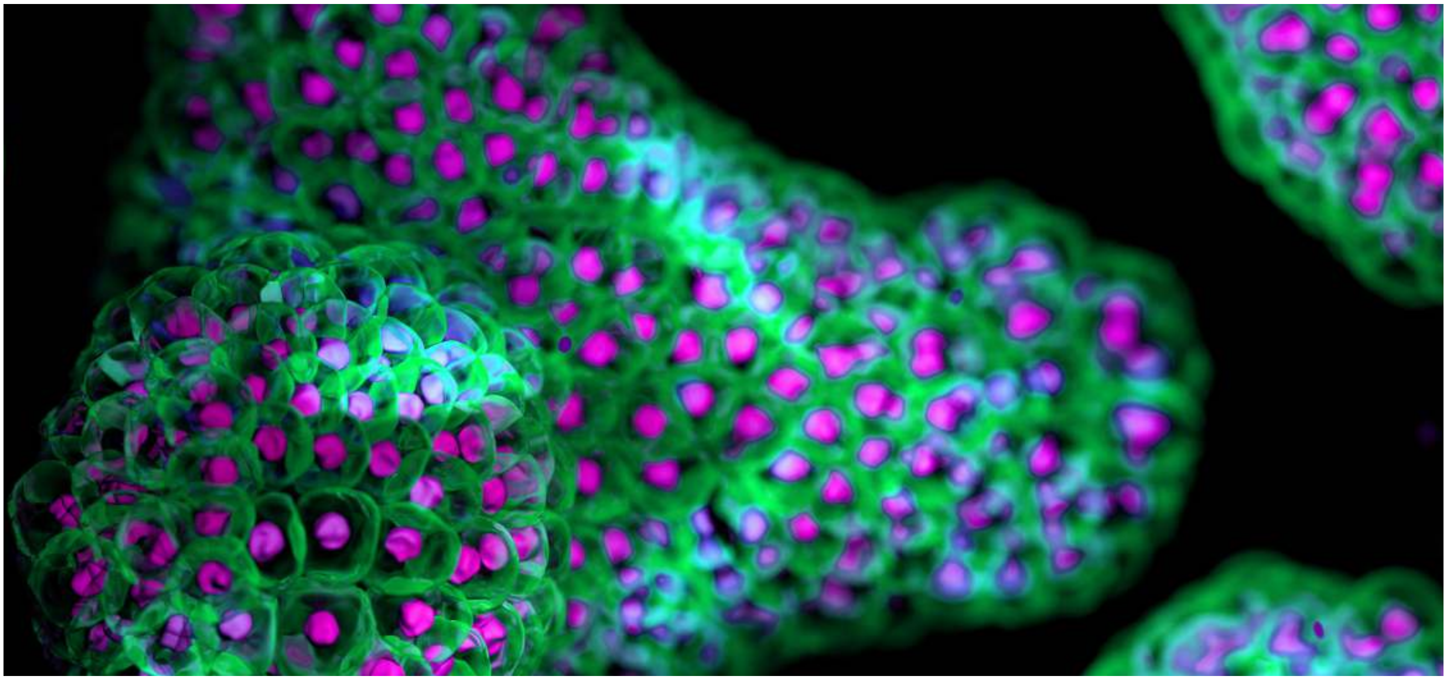


PHOTO CREDIT: THOM LEACH / SCIENCE PHOTO LIBRARY/GETTY IMAGES

as much as 3 billion € annually for the drug development industry due to increased R&D productivity[1]. The broad implementation of human-relevant methods with enhanced predictive capabilities can ultimately lead to better health outcomes for patients affected by these diseases. The US was the first country to recognise the strategic value of NAMs for patients and industry, and to heavily invest in them. In 2024, the National Institutes of Health (NIH) unveiled a 10-year comprehensive strategy to promote NAMs entitled Complement-ARIE[2], supported by a $400 million budget. The Utrecht Ombion Centre for Animal-Free Biomedical Translation, inaugurated in mid-2025 and backed by a 245 million € budget (125 million € from the Dutch Government's growth fund and the remainder from 60+ partners), remains the only initiative of a comparable scale in Europe[3]. Very recently, the UK has launched its £75 million strategy to support the development, validation and uptake of alternative methods[4].

Despite NAMs being mentioned in the recent Strategy for European Life Sciences, their strategic role and societal impact could have been further emphasised, including bolder investment plans. This could be the perfect opportunity for a stronger European position on these technologies, which would be well in line with the historical leadership of the EU in validating alternative methods to animal testing, setting ethical standards for animal use in science[5], and phasing out the use of animals in safety testing, first for cosmetics, then, in the future, for all chemicals[6].

While the Commission recognises that "innovative experimental methods that do not involve live animals can accelerate innovation, reduce costs, and increase efficiency in industrial R&I", its plan to allocate 50 million € through the Horizon Europe work programme 2026-2027 falls short of the current US or Dutch initiatives. It is also a very small proportion of the annual 10 billion € budget that the Commission is planning to spend to support its strategy during that period, suggesting that NAMs' strategic importance has not yet been fully acknowledged.

There is still time to correct this. While the Strategy for European Life Sciences covers the 2025-2030 period, it remains silent about financial commitments beyond 2027, which is the end of the current Horizon Europe programme. Beyond that, the Horizon Europe 2028-2034 takes over, with a budget that would double that of its predecessor, and plans for visionary "moonshot" projects[7]. Bolstering funding for NAMs is an opportunity that cannot be missed.

1 https://www.nature.com/articles/s43856-022-00209-1

2 https://commonfund.nih.gov/complementarie

3 https://site.ombion-cpbt.nl/

4 https://assets.publishing.service.gov.uk/media/690e073c896fad804b050fa6/replacing_animals_in_science_strategy-web-version.pdf

5 In particular with the adoption of Directive 2010/63/EU on the protection of animals used for scientific purposes.

6 https://single-market-economy.ec.europa.eu/sectors/chemicals/reach/roadmap-towards-phasing-out-animal-testing_en

7 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52025PC0543&qid=1753802854776

Crafting a European Moonshot Strategy for NAMs

The BioMed21 Collaboration approach

The explanatory memorandum of the draft regulation establishing Horizon Europe for the 2028-2034 period outlines plans for moonshot projects, defining them as “projects with a strong scientific component, boosting EU-wide value creation and strategic autonomy” and organised around a “coherent sequence between research and innovation, demonstration, development and deployment, focusing efforts and funding, from the EU and national, public and private sector”. The memorandum provides an indicative list of possible moonshot projects and although transitioning biomedical research to NAMs is not one of them, the Commission proposes “investing in innovative therapies for human regeneration for healthier lives and a stronger economy” and “address diseases that have currently no cure”, as well as “developing and applying the world’s next generation AI”. Such projects can only be a success if the EU also invests substantially in human-centred NAMs.

Indeed, NAMs are not only about improving the efficiency of biomedical research when researching new chemical drug molecules; they also hold significant promise for advancing both basic and applied research, by elucidating disease mechanisms—particularly those underlying chronic conditions that reduce health-related quality of life and productivity—and by enabling the development of preventive and therapeutic pharmacological and non-pharmacological interventions, ultimately delivering tangible benefits to patients. In addition, NAMs can open new avenues of progress that are inaccessible through traditional models. For instance, these technologies can be leveraged to explore human genetic diversity and susceptibility, enabling gene therapy, precision medicine approaches and better serving populations typically not well represented in clinical trials, such as women, minority groups or rare disease patient populations. Advanced therapies, such as gene therapies, immunotherapies, stem-cell therapies or tissue engineered products are so human- and patient-specific that only NAMs can play a major role in supporting the translation of innovation in these fields[1].

The Horizon 2028-2034 moonshot projects represent a great opportunity to increase funding for NAMs as part of the Strategy for European Life Sciences and craft a programme matching the US competition. The European Research Area (ERA) action on accelerating NAMs to advance biomedical research and testing of medicinal products and medical devices, recently voted as part of the ERA Policy

Box 1

Public health challenges and unmet medical needs for prioritisation in research-policy agenda

A survey consultation coordinated by the BioMed21 Collaboration identified key public health challenges that should be prioritised in the EU research and policy agenda. These include:

- Mental health disorders
- Metabolic syndrome
- Cancer
- Antimicrobial resistance
- The impact of environmental pollution on disease risk
- Cardiovascular diseases

Among the unmet medical needs, the five most selected were:

- Early detection and diagnosis
- Primary prevention
- Better understanding the impact of environmental factors in the onset of diseases
- Personalised medicine approaches
- Better access to care and therapies

Prioritisation efforts should focus on areas where innovation can have the greatest impact, ensuring that research and funding align with pressing societal and patient needs.

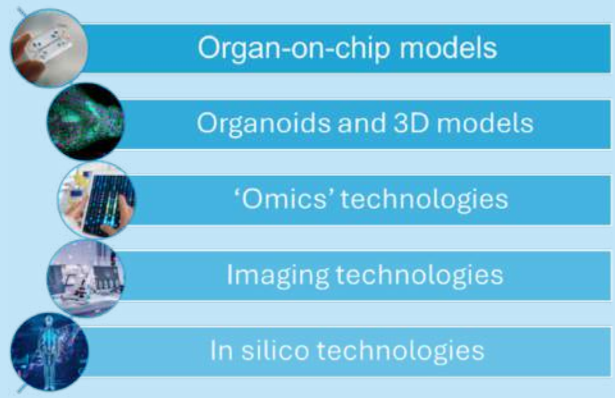
1 https://pubs.rsc.org/en/content/articlelanding/2024/lc/d3lc00876b

Agenda 2025-2027[1], could provide a springboard to that effect. Its four working groups on infrastructure, NAM development, education, and awareness are due to deliver their proposals for concrete plans and actions by 2028[2]. The Commission's intention to elevate the ERA as a pillar of Horizon 2028-2034 and better coordinate Member State science funding and objectives raises hopes that the proposals produced by the ERA action on NAMs will translate into substantial funding to implement them.

As a contribution to this important dialogue, the Biomedical Research for the 21st Century (BioMed21) Collaboration has convened strategic science discussions as to how an ambitious European NAMs programme could take shape. When envisioning such initiatives, effective cross-sector dialogue among interest-holders is key to align goals, harmonise strategies, cross-fertilise ideas, and propose evidence-driven policies that deliver tangible benefits for public health and society.

Figure 1

NAMs based on organ-on-chip, organoids and 3D models, 'omics', advanced imaging, and computational (*in silico*) technologies, are already available and can be used in basic and applied research and drug development.



In this spirit, on 18 November 2024, a BioMed21 science policy workshop was convened to identify priority areas requiring multidisciplinary interventions for improving the impact of biomedical research on human health[3]. The challenges and proposals presented herein stem directly from these discussions.

The scientific challenge

Overcoming the limitations of traditional research models to respond to unmet medical needs

Despite significant advances in biomedical research, many common diseases, such as cardiovascular, oncological, metabolic, neurodegenerative diseases, and mental health disorders, continue to pose a major challenge to public health. Recent data shows that, in Europe, diseases such as cardiovascular conditions and cancer are collectively responsible for about 54% of deaths[4]. Between 2011 and 2021, the global probability of prematurely dying from a non-communicable disease has improved by only 1.5%[5], falling significantly short of the 25% reduction target set by the UN Political Declaration on Non-Communicable Disease[6].

In addition, there is the emergence of new infectious diseases[7] and the increasingly critical threat of antimicrobial resistance (AMR), with bout 39 million people expecting to die from drug-resistant pathogens alone in the next 25 years[8,9].

As a contribution to the reflections on these challenges, the BioMed21 Collaboration has conducted a consultation via the EUSurvey platform, which was disseminated throughout the organisations and individuals participating in our workshops (**Box 1**).

The heavy reliance on traditional models, such as animal models and oversimplistic experimental systems that are not representative of human biology and physiology, has been identified as a major barrier to tackling these challenges due to their limited translatability to

1 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CONSIL%3AST_8469_2025_INIT
2 https://data.consilium.europa.eu/doc/document/ST-8469-2025-INIT/EN/pdf
3 https://www.sciencedirect.com/science/article/pii/S3050620425000181
4 https://ec.europa.eu/eurostat/web/products-eurostat-news/w/ddn-20240325-2
5 https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(24)02845-9/fulltext
6 https://www.who.int/teams/ncds/surveillance/monitoring-capacity/gmf
7 https://hsph.harvard.edu/news/next-pandemic-not-if-but-when/
8 https://asm.org/articles/2024/october/antimicrobial-resistance-pandemic-breaking-silence
9 https://www.nature.com/articles/s41467-024-50457-z

human clinical contexts[1]. This is reflected, for example, in the high failure rates in the development of drugs for diseases such as cancer and Alzheimer's disease[2], with success rates often below 10 percent[3].

In recent years, the landscape of biomedical research methods has been undergoing a profound transformation, with the emergence of human-centred models and approaches. Advanced tools such as organoids, MPS, *in silico* technologies, digital twin, and other NAMs offer more human-relevant methods than traditional approaches (**Figure 1** and **Box 2**). However, considerable efforts are still needed to refine and widely disseminate these methods within a research community that has relied on and heavily invested in animal models for more than a century.

The term "moonshot project" is usually employed to describe visionary, ambitious projects requiring groundbreaking innovations and massive investments to be completed, but resulting in huge rewards, in reference to the NASA moon missions of the 1960s. Some of the moonshot projects proposed by the Commission in the explanatory memorandum of the draft Horizon Europe 2028-2034 regulation include building the Future Circular Collider or achieving commercial nuclear fusion.

Achieving a high degree of translational relevance in biomedical research models would represent a worthy and ambitious moonshot project; highly challenging, yet immensely rewarding for countries that pursue it. NAMs contribute to the generation of human-relevant data and samples, which are critical for understanding human-specific diseases and developing human-relevant treatments and preventive strategies.

The societal benefits would be incalculable, spanning from improved patient outcomes and quality of life to strengthened public health services through reduced spending for chronic diseases, greener and more sustainable biomedical research by reducing reliance on animal experimentation, and significant societal and economic gains through more effective innovation. Such progress would also foster global leadership in science and technology, setting new standards for how research translates into real-world impact. This would clearly require a broad funding plan.

1 https://www.frontiersin.org/journals/drug-discovery/articles/10.3389/fddsv.2024.1355044/full

2 https://pmc.ncbi.nlm.nih.gov/articles/PMC9198803/

3 https://pmc.ncbi.nlm.nih.gov/articles/PMC9293739/

Funding NAMs from early-stage research to market adoption

Crafting a comprehensive strategy for Horizon Europe 2028-2034

Based on insights gathered from various interest-holders during the workshop and consultation activities, the BioMed21 Collaboration advocates for Horizon 2028-2034 to strengthen support for human-relevant and interdisciplinary research. This is essential for tackling major public health challenges, enhancing human safety and disease prevention, while also supporting the One Health approach, which promotes the interconnected protection of all ecosystems (human, environmental and animal health) – by e.g. reducing unnecessary animal use, better environmental sustainability and improved public health outcomes.

In the context of a broad moonshot project that should cover “a coherent sequence between research and […] deployment”, programmes and calls for proposals should encompass the full spectrum of technology readiness levels (TRLs) (**Box 3**). This includes early-stage research to develop innovative human-centred technologies, typically supported at the academic level and by contract research organisations (CROs); as well as medium and high TRL activities aimed at fostering qualification, integrated implementation, building users' trust, and promoting regulatory acceptance and market adoption. In this framework, NAMs are not merely tools applied during early discovery, but technologies that evolve through their own readiness levels toward regulatory acceptance and implementation. Increased funding for NAMs should therefore target not only early research and development phases (TRL 1–4), but also their validation[1],

Box 2

The NAMs toolbox

Organ-on-chip (OoC) systems are suitable for modeling human physiology, disease mechanisms, and drug responses in a more predictive and human-relevant manner than traditional in vitro or animal models. OoCs are microfluidic systems containing small culture chambers and microchannels, in which key structural and functional aspects of human organs and diseases are emulated, making them valuable for studying drug toxicity, efficacy, and metabolism, as well as for personalised medicine applications.

Organoids and 3D models are suitable for studying human development, disease mechanisms, and drug responses in a more physiologically relevant environment than traditional 2D cell cultures. Derived from stem cells or patient-specific cells, organoids can mimic the architecture and function of specific human tissues, making them valuable for precision medicine, drug screening, and toxicology studies.

'Omics technologies, including genomics, transcriptomics, proteomics, and metabolomics, are suitable for comprehensive, high-throughput analysis of biological systems at the molecular level. They enable the identification of disease biomarkers, mechanisms of drug action, and patient-specific responses, making them essential for precision medicine, drug discovery, and toxicology studies.

Imaging technologies like magnetic resonance imaging (MRI), positron emission tomography (PET), computed tomography (CT), and high-content microscopy are suitable for non-invasive, high-resolution visualisation of biological structures, cellular processes, and disease progression in real time. They are essential in biomedical research, drug development, and clinical diagnostics, enabling applications such as live-cell imaging and tissue characterisation.

***In silico* technologies**, mechanistic models including AI used for knowledge acquisition are suitable for accelerating biomedical research, drug discovery, and precision medicine by simulating biological processes and predicting outcomes with high accuracy. AI-driven models can analyse vast datasets, identify patterns, and optimise drug candidates, while digital twins—virtual representations of organs, patients, or populations—enable personalised treatment simulations and risk assessments. Beyond traditional *in silico* approaches, regulatory-grade digital twins—virtual representations of human systems validated through real-world and experimental data—enable predictive trials for safety, efficacy, and dose optimisation. These models form the backbone of the emerging Virtual Physiological Human (VPH) ecosystem and are essential to ensuring translational continuity between NAMs and clinical deployment.

1 For instance, the call ValNAM aims for validation of new approach methods in a regulatory context https://www.valnam.eu/

Box 3

TRLs for human-centred NAMs in the drug development pipeline

Technology Readiness Levels (TRLs) provide a structured framework to assess the maturity of a technology, from early concept to regulatory and market acceptance. For NAMs, TRLs help describe both their own developmental trajectory and their integration into the drug development value chain. Below, TRLs are grouped into three main stages: Research (TRL 1–3), Development (TRL 4–6), and Deployment (TRL 7–9).

Research — TRL 1–3: Concept, Prototype Research, and Early Feasibility

TRL 1 – Basic principles observed: Conceptualisation of novel NAMs grounded in human biology, including identification of key cell types, signalling pathways, endpoints, or computational architectures.

TRL 2 – Technology formulation: Initial R&D stages aimed at demonstrating technical feasibility and refining core components.

TRL 3 – Technology optimisation: Demonstration of functionality and within-laboratory reproducibility using relevant biological or computational benchmarks.

Development — TRL 4–6: Validation, Context-of-Use Definition, and Preclinical Integration

TRL 4 – Laboratory validation: Refinement and testing of NAMs under controlled conditions, comparison with reference data, and demonstration of robustness, scalability, and inter-lab reproducibility.

TRL 5 – Pre-regulatory qualification: Testing NAMs in defined contexts of use (e.g., safety, efficacy) with initial alignment to regulatory standards (e.g., OECD, EMA guidance).

TRL 6 – Preclinical integration: Application of qualified NAMs within industrial preclinical pipelines for candidate screening, hazard and risk assessment, or mechanistic studies.

Deployment — TRL 7–9: Regulatory Integration, Acceptance, and Broad Market Use

TRL 7 – Use in regulatory decision-making: Implementation of NAMs in regulatory submissions, supported by case studies or cross-sector qualification efforts (e.g., EMA frameworks).

TRL 8 – Full regulatory qualification and adoption: Official recognition of NAMs for specific regulatory purposes (e.g., EMA qualification procedures).

TRL 9 – Broad implementation and market readiness: Routine use of NAMs across sectors for preclinical testing and decision-making, supported by harmonised standards, guidance documents, training, and infrastructure.

qualification, and integration into decision-making and broad market use (TRL 5–9), ensuring they can effectively replace or supersede traditional animal-based approaches across the entire drug development pipeline.

In addition, to bridge the “valley of death” in translational research, it is essential to allocate sufficient funding for follow-up studies after proof-of-concept, and to foster cross-sector partnerships between academia and industry.

The scale of funding also matters. Considering the amounts already committed in the US (more than 400 million $), as well as the fact that Horizon 2028-2034 will nearly double the budget of its predecessor, from 95 billion € to 175 billion €, a one billion € Moonshot NAMs programme, aligned with the proposals emerging from the four working groups of the ERA Action on NAMs (validation, infrastructure, education, and awareness) would be proportionate, given the societal benefits at stake. Such a programme could establish governance structures, validation standards, and key performance indicators, addressing the large-scale implementation and regulatory uptake of validated NAMs, the creation of a coordinated European NAMs Integration Hub, development of education and capacity-building programmes, broad public engagement, and impact assessment. Such an approach would align with Horizon Europe’s results-oriented framework and ensure an efficient, accountable, and ambitious use of resources.

Understanding the NAMs’ value chain is critical to assess their current applicability, identify existing gaps, and prioritise funding strategies. In the context of drug development, human-centred NAMs are already used on a small scale at different levels of the value chain, from basic and applied research to druggable target identification, preclinical and clinical testing, regulatory approval, manufacturing, scale-up, up to post-marketing surveillance, spanning the full TRL spectrum.

Notably, artificial intelligence (AI) technologies, such as large language models, hold great potential to advance research and innovation, yet their reliability and impact critically depend on access to high-quality, harmonised, and robust data. Digital twin and *in silico* trial technologies provide the computational counterpart of physical NAMs across TRLs 4–8. By integrating organ-on-chip and omics data into mechanistic simulation frameworks, they enable virtual preclinical and clinical trials capable of estimating efficacy, variability, and long-term safety *in silico* before human exposure. Their regulatory maturation, guided by frameworks such as the EMA Qualification Advice[1] represents a crucial step to bridge human-relevant models and real-world clinical validation.

It should be considered that while some NAMs—such as 'omics' technologies applied across the drug development pipeline, advanced imaging tools used at the clinical level, and digital twin or *in silico* trial technologies—have already reached higher technology readiness levels (TRLs > 4), others, including microphysiological systems and various computational approaches, remain at the research or early development stage (**Figure 2**). The Moonshot for NAMs initiative aims to accelerate their technological maturity, deployment, and acceptance by fostering standardisation, reproducibility, scalability, and validation.

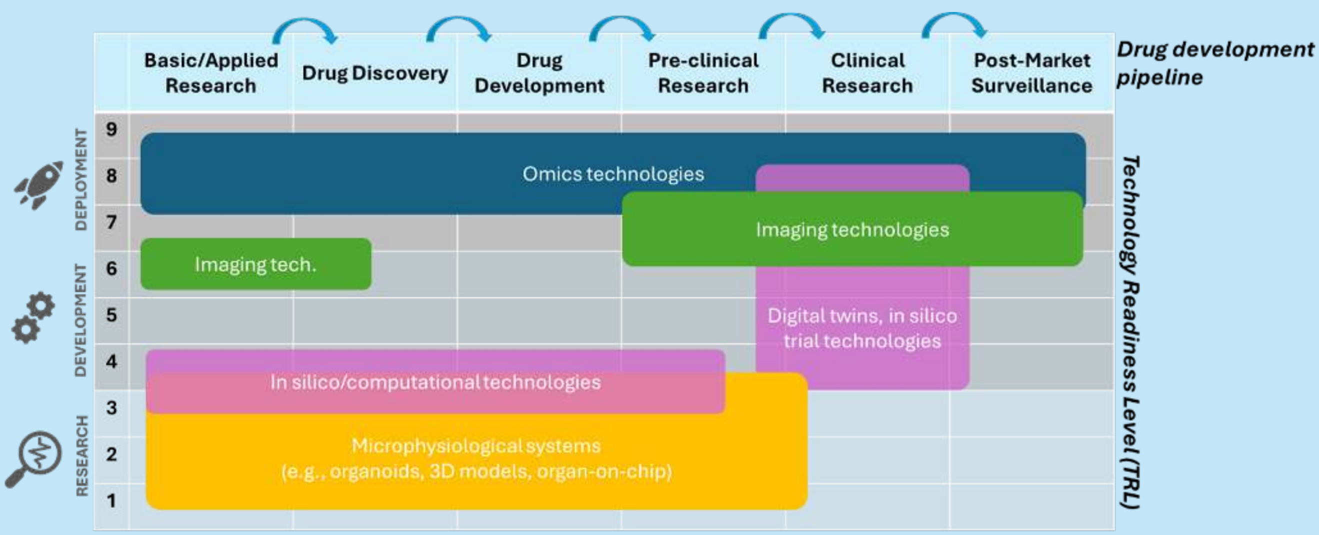
Better leveraging human-centered NAMs throughout the drug development pipeline can significantly reduce R&D costs by improving predictivity, minimising late-stage failures, and shortening development timelines. This strategic shift would not only enhance the efficiency and sustainability of pharmaceutical innovation but also generate substantial cost savings for healthcare systems through more effective and safer therapies.

Multidisciplinary strategies are needed to overcome challenges in NAM adoption. These include enhanced collaboration and dialogue among key interest-holders, including funding institutions, model developers and end-users, as well as educators, scientific journals, clinicians, risk assessors, regulators and the pharmaceutical industry. These efforts must be driven by real-world patient and societal needs, ensuring that innovative methodologies translate into tangible benefits for public health and medical progress. Well-funded transformative policies are needed to support science-driven, human-relevant research, including the role of education and training as well as social sciences and humanities (SSH).

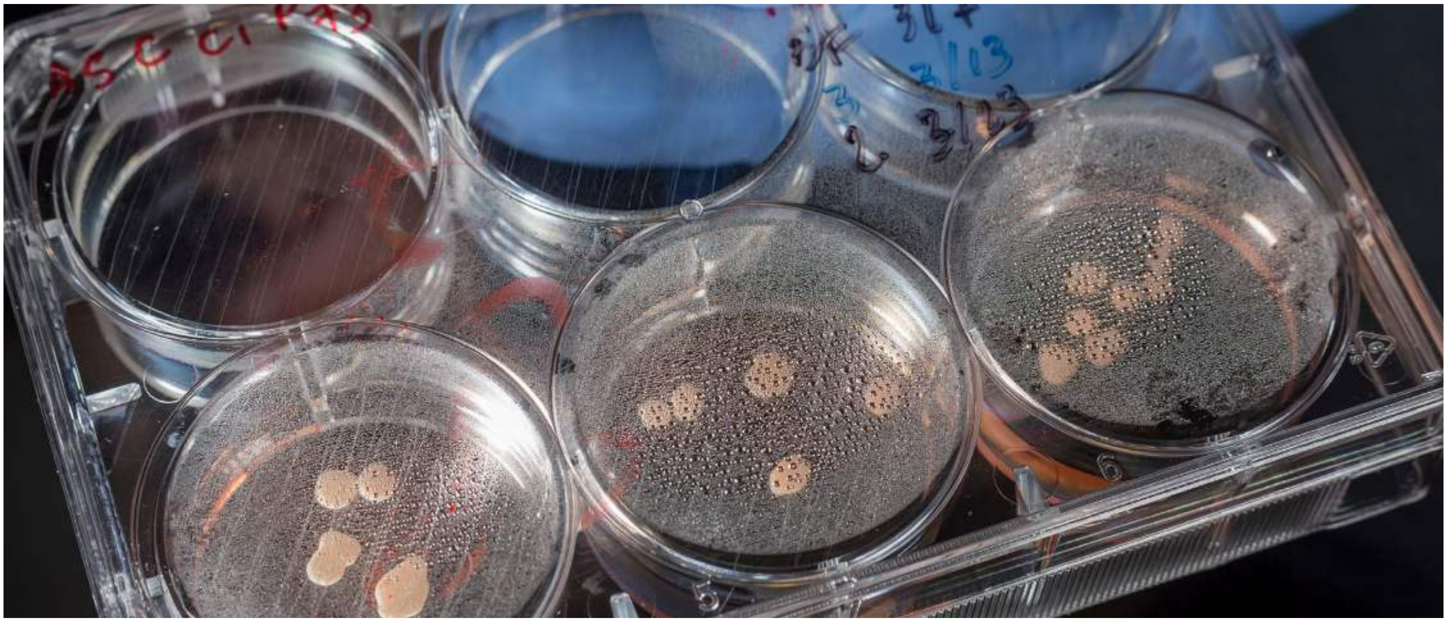
Building on the momentum of the recent ERA Action supporting NAMs, as outlined in the ERA Policy Agenda 2025–2027, there is a compelling case for establishing a dedicated NAM moonshot programme. Such an initiative could act as a strategic driver to accelerate innovation, enhance the human relevance and translatability of biomedical research, enabling the generation of and access to human-relevant high-quality data. Beyond advancing drug discovery and disease understanding, the same human-centric approaches can

Figure 2

NAMs used in drug development, their TRLs and gaps in maturity



1 https://www.ema.europa.eu/en/qualification-novel-methodologies-medicine-development



transform safety assessment of chemicals, aligning with the EU's One Health and Zero Pollution[1] ambitions.

In the field of regulatory toxicology, the NAM Moonshot programme could be implemented in support of the Three-Basket conceptual framework[2], proposed to the European Commission in the context of the EU Roadmap towards phasing-out animal testing[3]. This systematic sorting will enable Europe to implement evidence-based prioritisation, guiding targeted policy measures, regulatory dialogues, and investment decisions. The NAM Moonshot programme would ensure that the EU Roadmap is equipped with the necessary resources, according to scientific and regulatory readiness levels. Basket 1 can drive immediate engagement with authorities, physicians, and NGOs to accelerate regulatory and societal acceptance of existing NAMs. Basket 2 can channel public and private investments toward the development and qualification of emerging methods. Meanwhile, Basket 3 can highlight areas where exploratory research remains essential, maintaining transparency about current limitations while encouraging continuous hypothesis generation.

A dedicated Regulatory Science Workstream within the NAM Moonshot could drive these efforts under the EMA, EFSA, and OECD to define context-of-use-based validation of NAMs. This would ensure that, for instance, *in silico* and digital-twin evidence meets regulatory-grade standards for safety and efficacy assessment, accelerating acceptance of virtual trials in decision-making. In addition, 'dynamic reference'[4] by allowing legislation to evolve in step with scientific progress, could be a powerful enabler for the rapid uptake of NAMs.

The NAM moonshot programme would serve as an enabling and incentivising structure — stimulating collaboration among NAM developers and end-users, including academic researchers, educators, industry, CROs, SMEs, and regulators. It could also facilitate the strategic alignment and integration both of existing EU funding instruments, from the Horizon Europe 2028-2034 and the EU Competitiveness Fund[5], and European Research Infrastructure Consortia (ERICs) operating in this domain such as BBMRI-ERIC[6], EATRIS[7], ECRIN[8], and EuroBioimaging[9], to create synergies and amplify the return on investment in human-relevant, next-generation research technologies.

Europe's key challenge is not only limited funding but the fragmentation of NAM-related efforts. Existing initiatives often operate in isolation, possibly leading to duplication, limited knowledge exchange, and reduced collective impact. A coordinated framework, such as a European NAMs Integration Hub, could enhance alignment, foster synergy, and accelerate the uptake of human-relevant approaches across sectors.

1 https://environment.ec.europa.eu/strategy/zero-pollution-action-plan_en

2 https://www.efpia.eu/media/meef32ki/efpia-recommendations-on-phasing-out-animal-testing-for-chemical-safety-assessments.pdf

3 https://single-market-economy.ec.europa.eu/sectors/chemicals/reach/roadmap-towards-phasing-out-animal-testing_en

4 In some regulatory systems when scientific guidelines are updated, the law automatically adapts as well, and this is referred to as 'dynamic reference'

5 The EU Competitiveness Fund is a new strategic funding instrument proposed for the 2028-2034 Multiannual Financial Framework (MFF) to boost Europe's innovation, industrial resilience, and technological leadership. See more here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52025PC0555&qid=1753802586340

6 https://www.bbmri-eric.eu/

7 https://eatris.eu/

8 https://ecrin.org/

9 https://www.eurobioimaging.eu/

Four strategic areas of action

For the Horizon 2028-2034 programme, the following four key areas of action should be considered to support innovative human-centred research and increase impact and translatability of funded research outputs:

1. Funding and policy

Establish a dedicated €1 billion human-centred NAMs moonshot programme under the Horizon Europe 2028-2034 and the European Competitiveness Fund. This programme should coordinate and align existing funding instruments to support NAM developers and users across academia, industry, SMEs, and regulatory sectors. It should support all TRLs, from NAM research and development to market adoption, through long-term funding, ensuring sustainability. The proposed allocation, aligned with the four working groups of the ERA Action on NAMs, should ensure a balanced approach that addresses both scientific and systemic barriers. Prioritising validation will strengthen confidence, regulatory readiness and acceptance (via EMA/FDA alignment, OECD test guidelines); investing in infrastructure will enable scalability and technological maturity; while education and awareness will build the skilled workforce and societal support needed to sustain long-term adoption. This coordinated investment should include and prioritise One Health research and unmet medical needs in work programmes and calls for proposals. It should provide resources to the future EU Roadmap towards phasing-out animal testing grounded in the Three-Basket conceptual framework. Ultimately, the NAMs Moonshot programme could catalyse innovation, foster competitiveness, and advance the EU's leadership in next-generation life science research.

2. Education and training

Embed NAMs and human-centred experimental design into educational curricula, considering inter- and transdisciplinary learning, cooperation with social sciences, and including use and integration of complex in vitro models, *in silico* tools, and AI, to equip future researchers with essential knowledge and skills. Training programmes should include data stewardship, mechanistic modeling, AI integration, and regulatory aspects of *in silico* evidence, creating a new generation of hybrid scientists fluent in both biological experimentation and computational model qualification. Moreover, training should focus on the industrialisation phases that should be considered also at very low TRL in research labs.

3. Repositories and a coordinated European NAMs Integration Hub

Promote open-access research repositories driven by AI technologies and foster inter- and trans-disciplinary collaboration and workforce, and incentivise the formation of a coordinated European NAMs Integration Hub, which could enhance alignment, foster synergy, and accelerate the uptake of human-relevant approaches across academia, industry, regulators and international partners. This will help avoid fragmentation and new silos being built, enabling full knowledge sharing. Such a Hub should enhance research excellence, accelerate access to human-centred innovations and support small-medium size collaborative consortia spanning fundamental research (lower TRLs) to market application (higher TRLs).

4. Social science and societal engagement

Leverage Social Sciences and Humanities (SSH) in funded biomedical research, to ensure fair partnerships with patient groups, regulators and other interest-holder groups. This will help align research with real-world needs, clarify the intended end-product and feasibility of the approach, and ultimately facilitate the uptake and acceptance of NAMs[1] along the TRL scale and at a societal, industry and regulatory level.

1 See, for instance, https://www.nwo.nl/en/researchprogrammes/dutch-research-agenda-nwa/thematic-programming/animal-free-assessment-models-acceptance-and-implementation

Our mission

The Biomedical Research for the 21st Century (BioMed21) Collaboration—comprised of an international team of scientists, policy specialists, and communications experts—works in partnership with academic institutions, governments, charities, agencies, and the corporate sector to advance and promote human-centric nonanimal science research.

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