ASPIS

Open Symposium 2-3 July 2026 Maastricht The Netherlands

# EU-funded NAM research: future perspectives

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# EU-funded NAM research 2007-2025



## ☑ AI-based screening of CORDIS

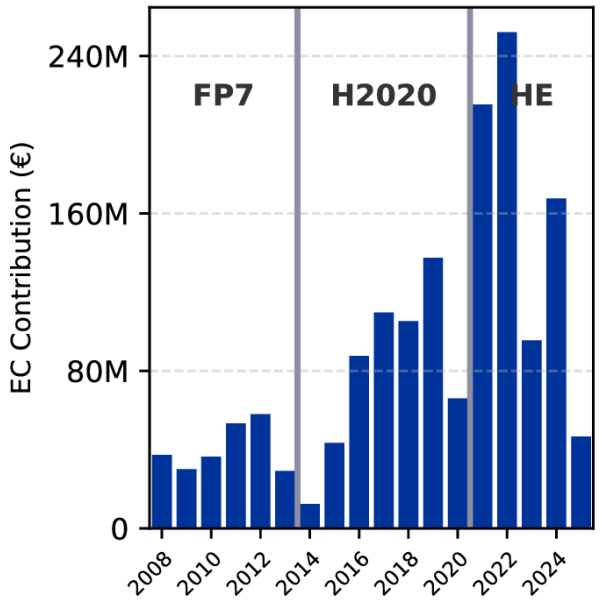
- Seventh Framework Programme (2007-2013)
- Horizon 2020 (2014-2020)
- Horizon Europe (2021-2027)

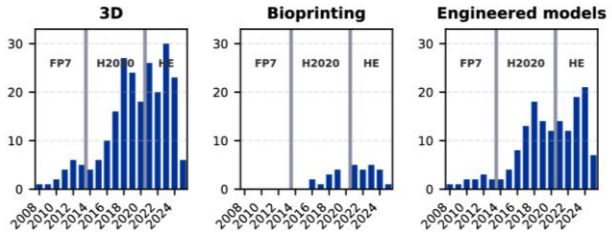
## ☑ Increased NAM funding

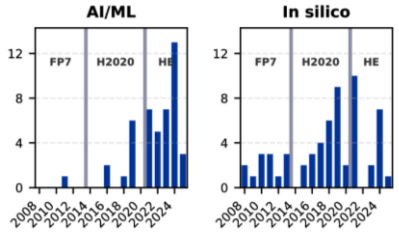
- 539 NAM / 3Rs projects with €1.5 billion funding
- 40% toxicology projects with 50% of all funding

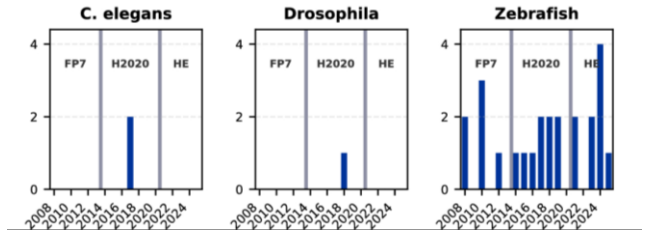
## ☑ Increased use of NAMs

- Advanced *in vitro* systems
- *In silico* modelling and AI
- Alternative species




Matyjasiak *et al.* (2026) *Arch. Toxicol.* 100: 2855-2867.

# NAM flagship projects / clusters



SEURAT-1

EUTOXRISK

ASPIS

**€50 million** | **€30 million** | **€60 million**

**2011-2016** → **2016-2021** → **2021-2026**

**70 partners** | **40 partners** | **70 partners**

ScreenTox

HeMiBio

COACH

DETECTIVE

ToxBank

COSMOS

NOTOX

iNTOX

PRECISION TOX

RISK HUNT3R

# Recent NAM calls



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## Integrating New Approach Methodologies (NAMs) to advance biomedical research and regulatory testing

HORIZON-HLTH-2026-01-TOOL-03

Topic **Call for proposal**

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### General information

**Programme**
Horizon Europe (HORIZON)

**Call**
Cluster 1 - Health (Single stage - 2026) (HORIZON-HLTH-2026-01)

**Type of action**
HORIZON-RIA HORIZON Research and Innovation Actions

**Type of MGA**
HORIZON Lump Sum Grant [HORIZON-AG-LS]

Closed

**Deadline model**
single-stage

**Opening date**
10 February 2026

**Deadline date**
16 April 2026 17:00:00 Brussels time

# Recent NAM calls



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## Support to European Research Area (ERA) action on accelerating New Approach Methodologies (NAMs) to advance biomedical research and testing of medicinal products and medical devices

HORIZON-HLTH-2026-01-TOOL-06

Topic **Call for proposal**

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**General information**

**Programme**
Horizon Europe (HORIZON)

**Call**
Cluster 1 - Health (Single stage - 2026) (HORIZON-HLTH-2026-01)

| Type of action | Type of MGA | |
|---|---|---|
| HORIZON-CSA HORIZON Coordination and Support Actions | HORIZON Lump Sum Grant [HORIZON-AG-LS] | Closed |

| Deadline model | Opening date | Deadline date |
|---|---|---|
| single-stage | 10 February 2026 | 16 April 2026 17:00:00 Brussels time |

# Recent NAM calls



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## Translating Disruptive New Approach Methodologies (NAMs) into Practice

HORIZON-EIC-2026-AIC-02

Topic **Call for proposal**

### Internal navigation

- General information
- Topic description
- Topic updates
- Conditions and documents
- Budget overview
- Start submission

### General information

**Programme**
Horizon Europe (HORIZON)

**Call**
EIC Advanced Innovation Challenge (HORIZON-EIC-2026-AIC)

| | | |
|---|---|---|
| **Type of action**<br>HORIZON-EIC HORIZON EIC Grants | **Type of MGA**<br>HORIZON Lump Sum Grant [HORIZON-AG-LS] | Closed |
| **Deadline model**<br>single-stage | **Opening date**<br>03 December 2025 | **Deadline date**<br>26 February 2026 17:00:00 Brussels time |

# Relevance of NAMs for EU policies



## ☑ Roadmap towards phasing out animal testing for chemical safety assessments

- Roadmap announced on 23 July 2023 (released on 1 June 2026): Communication from the Commission on the European Citizens' Initiative "Save cruelty-free cosmetics: commit to a Europe without animal testing'"

- Goal: guide plan for accelerating the path towards replacing, reducing and refining animal testing for the safety assessments of chemicals

- Strategy: focus on human health, environmental safety and change management

- Position of NAMs:
  - Core to the transition strategy
  - Central in the working groups
  - Gradual integration in legislative frameworks

*"The roadmap places NAMs at the heart of its strategy to phase out animal testing. The roadmap is being designed around accelerating NAM development, validation, uptake and regulatory acceptance across chemical safety assessment legislation, making NAMs the primary tools for achieving an animal-free regulatory system in the long term."*

# Relevance of NAMs for EU policies



## ☑ Strategy for European Life Sciences

- Launched on 2 July 2025: Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: choose Europe for life sciences: a strategy to position the EU as the world's most attractive place for life sciences by 2030

- Goal: position Europe as the world's most attractive place for life sciences by 2030

- Strategy: optimise the research and innovation ecosystem to promote global competitiveness, ensure rapid market access for life science innovations, boost trust, uptake and use of these innovations

- Position of NAMs:
  - Centrally positioned
  - Aligned with EU research and innovation policy
  - Supported by EU funding
  - Integrated in regulatory agencies
  - Part of sustainability strategy
  - Catalyst for innovation and competitiveness

*"NAMs can complement or replace certain animal studies, speeding up the development of safe and effective medicines and improving safety assessments of chemicals and other products. By adopting and investing in these new tools, industry can innovate faster, reduce costs and make research and development more sustainable."*

# Relevance of NAMs for EU policies



## ☑ Biotech Act

- Proposal published on 16 December 2025: Regulation of the European Parliament and of the Council on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938

- Goal: ensure that biotech innovation, investment and production remain in Europe, rather than European discoveries being commercialised abroad

- Strategy: strengthen Europe's competitiveness in (health) biotechnology by accelerating clinical trials, simplifying regulatory frameworks, simulation of alternative approaches through regulatory sandboxes, improving access to funding and boosting EU-based biomanufacturing

- Position of NAMs:
  - Explicitly mentioned
  - For all phases of biotech life cycle
  - Part of innovation strategy
  - Link to strategy project support
  - Subject of regulatory sandboxes

*"NAMs applied in biological research, early discovery, preclinical development, and the regulatory and quality testing of medicinal products and medical technologies, have the potential to generate scientific and technological data that are comparable to, or in some cases more informative and generated more rapidly than, those obtained through current standard methods. The resulting advantage will contribute to strengthen the innovation ecosystem and enhanced European competitiveness in biotechnology."*

# Relevance of NAMs for EU policies



- ☑ **EU Start-up and Scale-up Strategy**
- ☑ **One Substance One Assessment**
- ☑ **Assessment Framework for Safe and Sustainable by Design**
- ☑ **European Health Data Space Regulation**
- ☑ **European Strategy for Artificial Intelligence in Science**

# Relevance of NAMs for US policies



## ☑ FDA roadmap to reducing animal testing in preclinical safety studies

- Published on 10 April 2025: plan to significantly scale back animal testing in drug development, starting with monoclonal antibodies and progressively incorporating advanced, human-relevant approaches to replace animal studies
- Foundation: FDA Modernization Act 2.0 (2022; authorized the use of NAMs for investigational new drug applications)
- Operationalization: FDA Modernization Act 3.0 (2025; regulatory uptake of NAMs for investigational new drug applications)

## ☑ NIH prioritisation of human-based research technologies

- Announced on 29 April 2025: reduce and replace animal testing by using *in vitro* system (organoids/chips), computational systems/AI and real-world (human) data
- Operationalization: establishment of the Office of Research Innovation, Validation, and Application (ORIVA) to develop, validate, and scale the use of NAMs across NIH's biomedical research portfolio and serve as a hub for interagency coordination and regulatory translation for public health protection