

EU initiatives on NAMs

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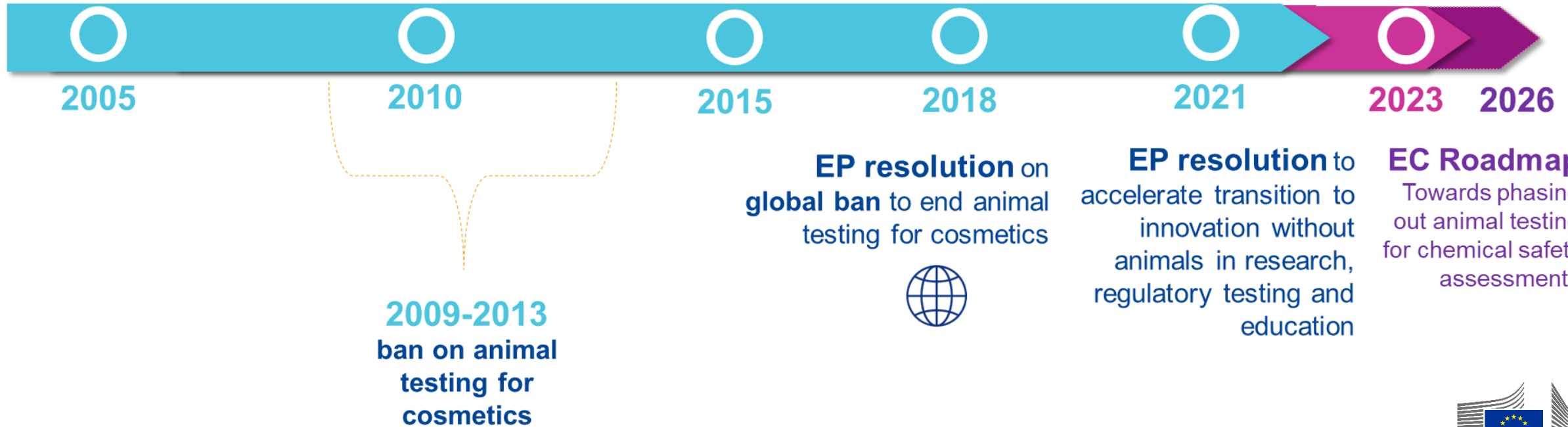
Increasing political and societal pressure in the EU to phase out animal testing



Directive 2010/63
protection of animals for
scientific purposes

**European Citizen
Initiative (ECI)**
 STOP VIVISECTION

**European Citizen
Initiative (ECI)**



Recent actions by the European Commission to catalyse the use of NAMs: **legislative**

- **New Pharmaceutical Legislation:**
 - Regulation Art. 6(5) and Directive Art.6(7) prioritise NAMs: “Marketing authorization applicant shall not carry out animal tests in case *scientifically satisfactory non-animal testing methods are available*”
- **Medical Device Regulation (MDR) & In-Vitro Diagnostics Regulation (IVDR):**
 - Proposal (COM(2025)1023): “As the safety and performance of many devices other than high-risk devices can be sufficiently demonstrated using non-clinical data, *including NAMs*, the possibility to use non-clinical data [...] in the conformity assessment should therefore be *made more prominent* in Regulation (EU) 2017/745”
- **European Biotech Act I:**
 - Proposal (COM(2025)1022): “*promoting and integrating the use of NAMs* in areas such as biological research, discovery and preclinical development, regulatory and quality testing and production of medicinal products and medical technologies”



Recent actions by the European Commission to catalyse the use of NAMs: **non-legislative**

- **2025** **European Research Area Action on NAMs** for biomedical research and regulatory testing of medicinal products and medical devices
<https://european-research-area.ec.europa.eu/era-actions-2025-2027>
- **2025-2026** **Call for proposals** for the use of NAMs in biomedical research and testing (~80 million under Horizon Europe Cluster 1, EIC and the Innovative Health Initiative)
- **06.2026** **Roadmap** towards phasing out animal testing for chemical safety assessments
https://single-market-economy.ec.europa.eu/sectors/chemicals/reach/roadmap-towards-phasing-out-animal-testing_en



Major initiatives to phase out animal testing outside of EU

- **Bans on animal testing for cosmetics** in several countries: UK, India, New Zealand, Brazil, Canada
- **Other roadmaps** to phase out or reduce animal testing:
 - **2022** US FDA Modernization Act 2.0 allows NAMs instead of animals in regulatory submissions for evaluating new drugs
 - **2023** Korean MFDS revised the "Regulation on Pharmaceuticals Approval, Notification and Review" to include NAMs
 - **2025** US FDA Modernization Act 3.0 further emphasises the use of NAMs
 - **2025** FDA Roadmap to Reducing Animal Testing in Preclinical Safety Studies
 - **2025** UK government "Replacing animals in science: A strategy to support the development, validation and uptake of alternative methods"



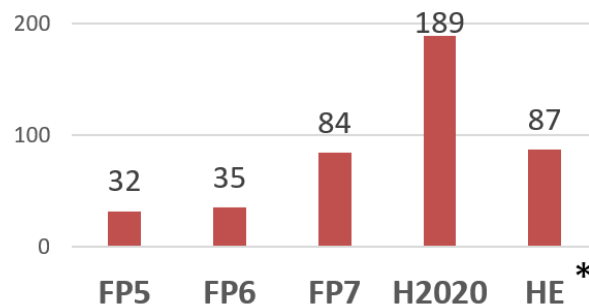
EU funding of NAM-related R&I

Since 1998 (FP5):

> 430 projects

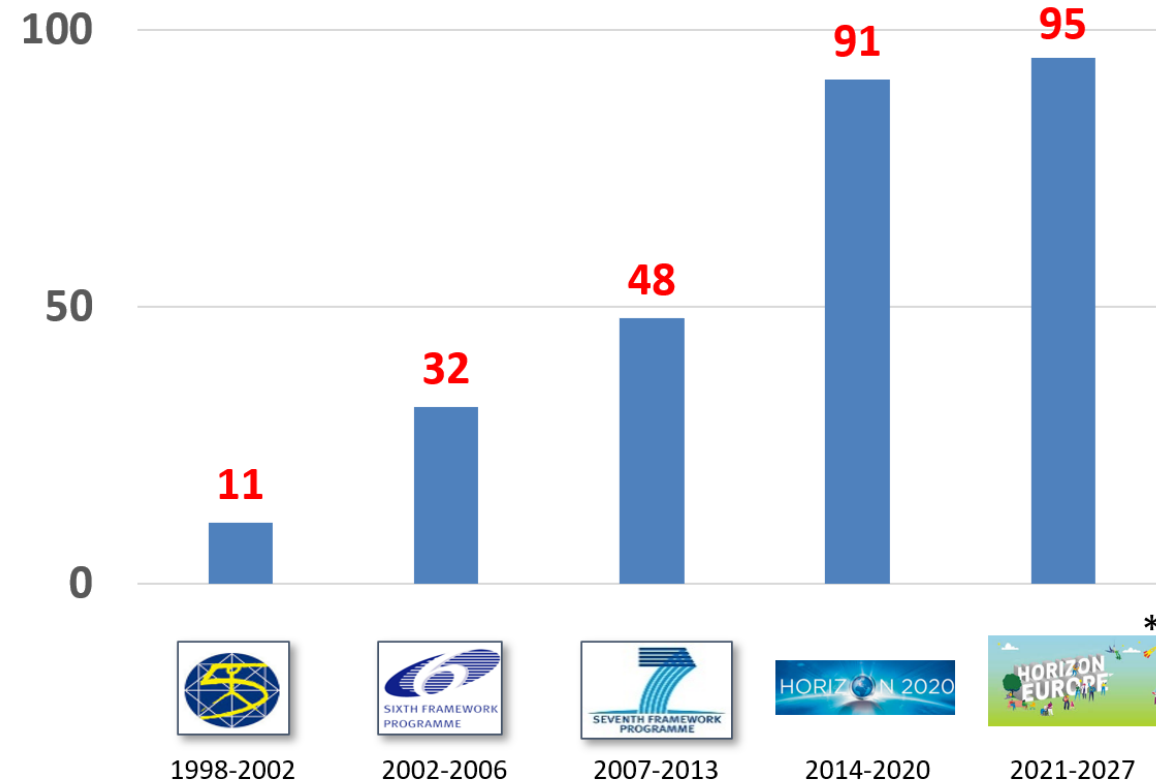
1.5 billion €

Number of projects



* Up to May 2026

Average annual budget (million €)



Source: Christian Desaintes



Successful project: SENS-IT-IV

Developed the GARDskin (Genomic Allergen Rapid Detection) test

NAM designed to **replace animal testing for assessing skin sensitisation**

(i) exposes human dendritic-like cells to test substance, (ii) extracts RNA, and (iii) uses machine learning to analyse gene expression (200 genes) to classify whether a substance is a "sensitiser" or "non-sensitiser"

Outperforms traditional animal methods like LLNA

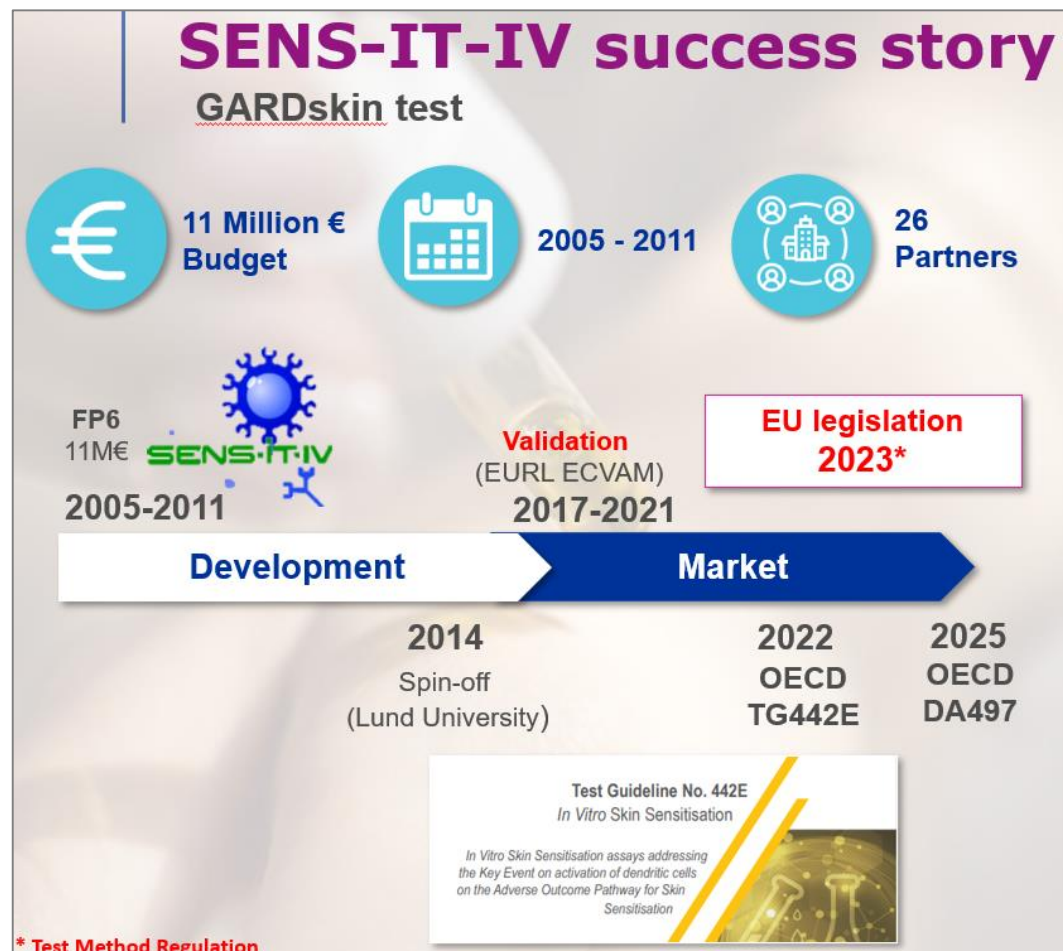
Required many years despite targeting a well understood toxicological endpoint

IMPACT

- 2022: incl. under OECD Test Guideline TG442E for assessment of skin sensitisation
- 2023: integrated in EU law

Applications:

chemicals, cosmetics, medicinal products & medical devices



Source: Christian Desaintes



Long-term EU commitment to funding research on animal-free chemical safety assessment

Major EU-funded projects include:

- **SEURAT-1** cluster (2011-2016, FP7): Safety Evaluation Ultimately Replacing Animal Testing
- **EU-ToxRisk** (2016-2018, H2020): An Integrated European 'Flagship' Program Driving Mechanism-based Toxicity Testing and Risk Assessment for the 21st Century
- **ASPIS** cluster (2012-2026, H2020): Animal-free Safety assessment of chemicals: Project cluster for Implementation of novel Strategies
- **EURION** cluster: (2019-2024; H2020): European Cluster to Improve Identification of Endocrine Disruptors
- **ENKORE** cluster (2024-2028, Horizon Europe): Endocrine disrupting chemicals and Knowledge On health-Related Effects
- **PARC** (2022-2029, Horizon Europe): European partnership for the Assessment of Risks from Chemicals
-



NAM-related call topics in 2026

Health Cluster, EIC, IHI

- Integrating NAMs to advance biomedical research and regulatory testing (budget EUR 49 million) **204 proposals received**
- Support to ERA action on accelerating NAMs to advance biomedical research and testing of medicinal products and medical devices (budget EUR 3 million)
- EIC Advanced Innovation Challenges: translating disruptive NAMs into practice (budget EUR 3 million) **284 proposals received**

RIA

CSA

**under
evaluation**

- EIC Pathfinder Challenges: NAMs to enable the future development of interventions for healthy ageing (budget EUR 6-8 million): **deadline 28 October 2026**
- IHI JU: An AI foundation toxicology model and framework to support waiving a second species in drug safety studies (budget EUR 9 million EU + 7 million industry): **deadline Q3-Q4 2026 (tbc)**

**Huge interest for NAMs
in the scientific community**



The challenge with NAMs in Europe is...

Despite

- Significant public investment in research & innovation on NAMs
- Large public interest and political pressure

There has been a **slow uptake of NAMs** in routine R&I and **regulatory testing**

Why is this?

- **Little incentive for industry** to engage in validation/qualification of NAMs
 - Why take a risk with a yet unproven model?
 - Why invest in a method that may become a “public good”?
- **Shared competence/authority** across the EMA, ECHA and EFSA
- **Varying interpretations** across national agencies cause inconsistent adoption and difficult for industry to apply a unified approach on NAMs



Responding to the challenge: European Research Area (ERA) action on NAMs



Aim: Coordinate and streamline EU, MS and other stakeholders' actions on NAMs

Focus: Medicinal products **AND** medical devices

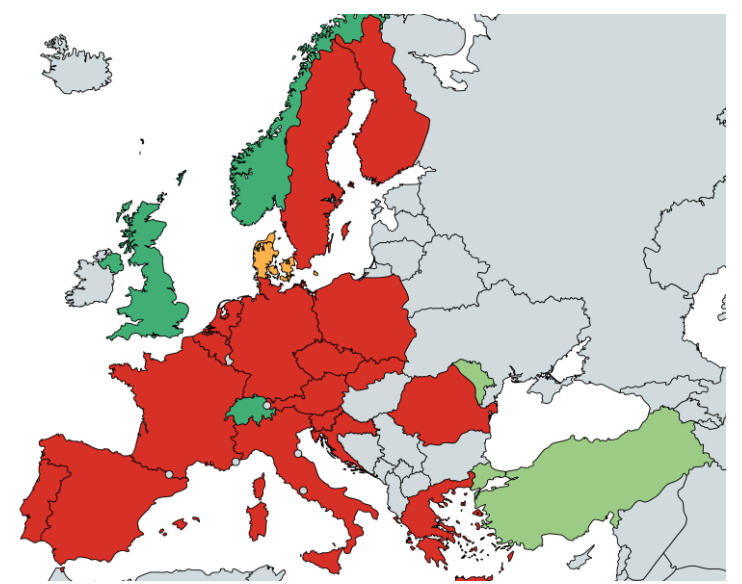
Scope: All stages of biomedical research, from discovery to regulatory testing, training and implementation

JOINT initiative between EU, MS and Stakeholders: Commission, relevant ministries, EMA, national regulatory agencies, academia, industry, civil society...

Currently: Involvement of representatives from 5 national regulatory agencies (BE, IT, NL, PT, UK) and 3 members of EMA's 3Rs Working Party

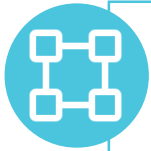


ERA Action supported by 4 Working Groups



WG1: Development of NAMs and common EU infrastructures

**WG1:
75 Experts**



WG2: Validation, acceptance and implementation of NAMs

**WG2:
75 Experts**



WG3: Education and training

**WG3:
50 Experts**

**WG4:
46 Experts**



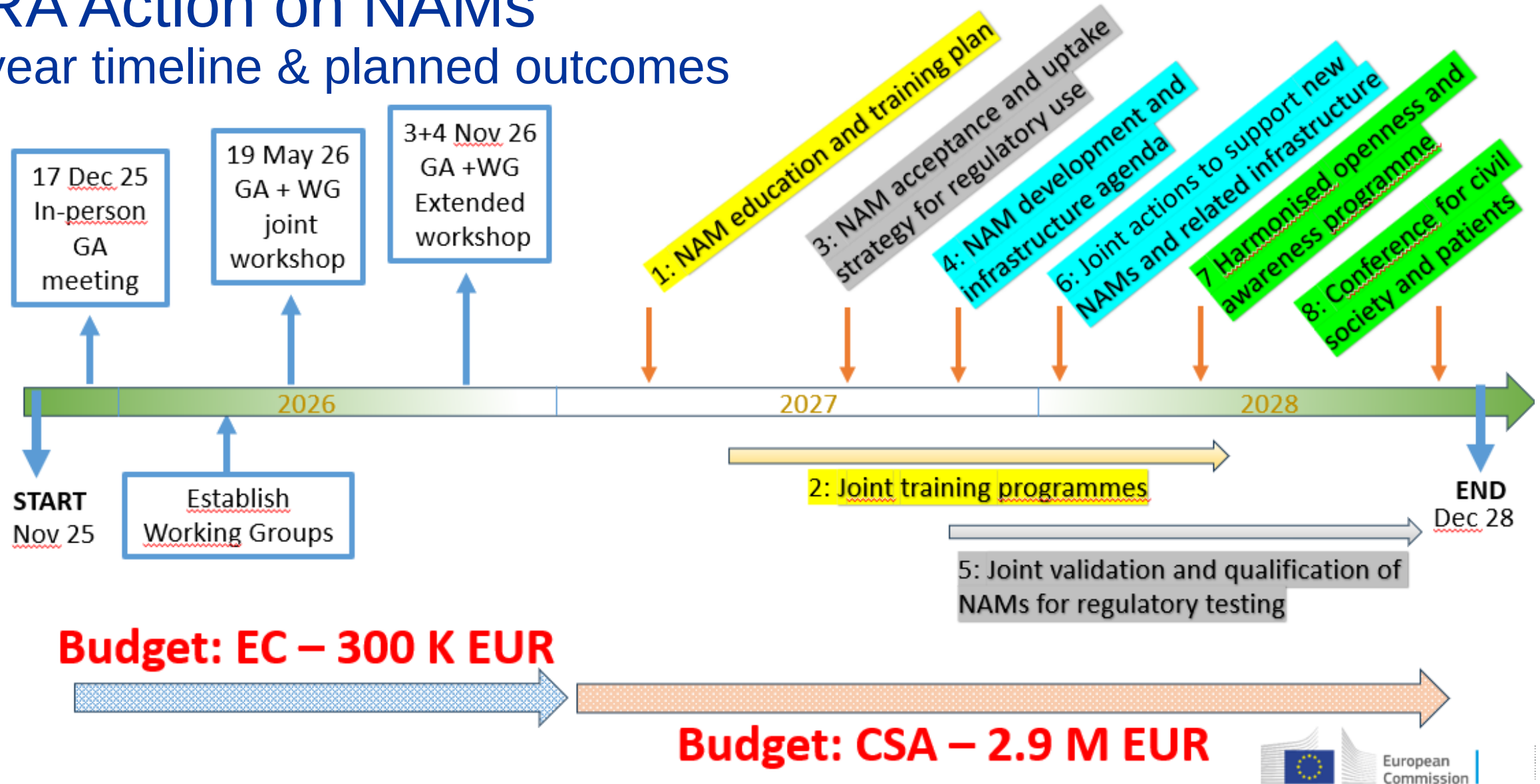
WG4: Openness & awareness

- Steering Team (EC, EU-LIFE, NL)
- General Assembly (incl. 18 MS, 5 AC, 6 stakeholders)



ERA Action on NAMs

3-year timeline & planned outcomes





Thank you for your attention!

