EU initiatives on NAMs

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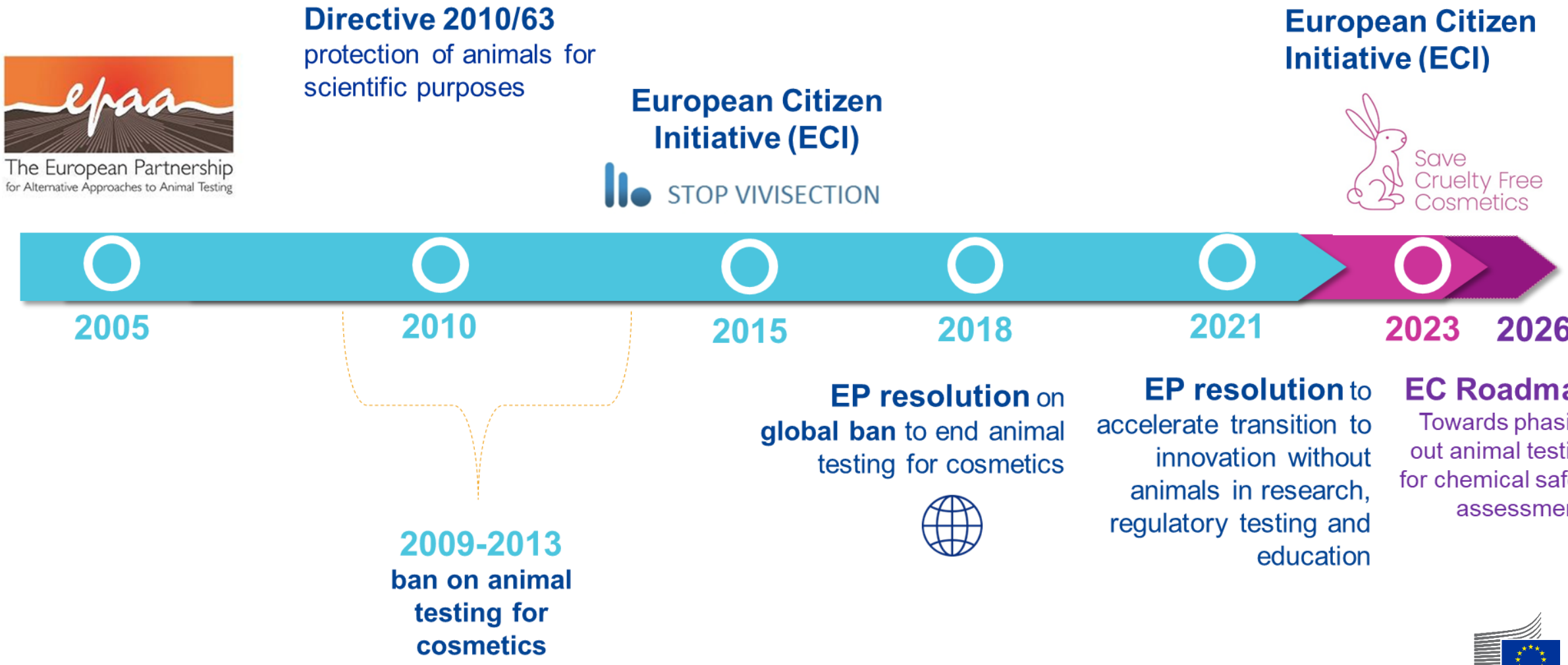
Increasing political and societal pressure in the EU to phase out animal testing



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

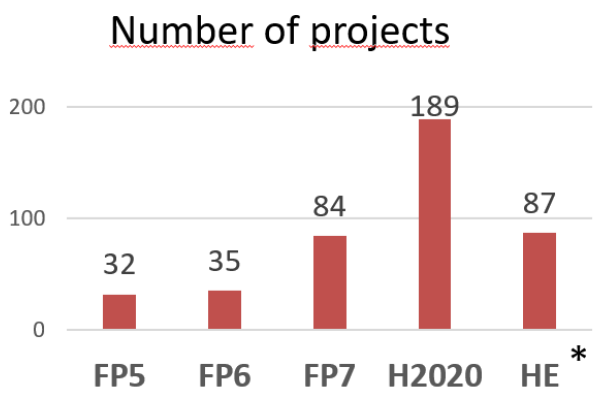
- **Bans on animal testing for cosmetics** in several countries: UK, India, New Zealand, Brazil, Canada
- **Other roadmaps** to phase out or reduce animal testing:
  - 2022 US FDA Modernization Act 2.0 allows NAMs instead of animals in regulatory submissions for evaluating new drugs
  - 2023 Korean MFDS 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”

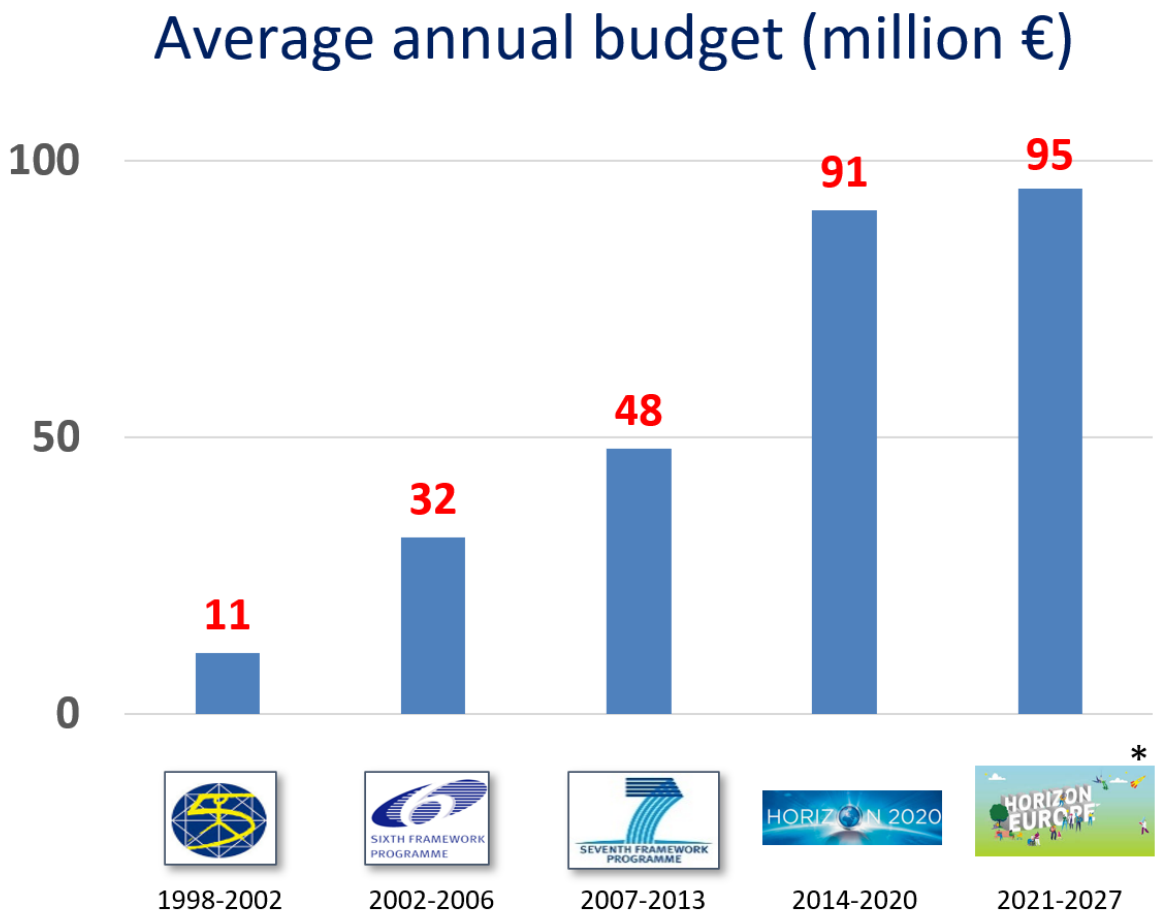
EU funding of NAM-related R&I

Since 1998 (FP5):

> 430 projects

1.5 billion €





* Up to May 2026

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"

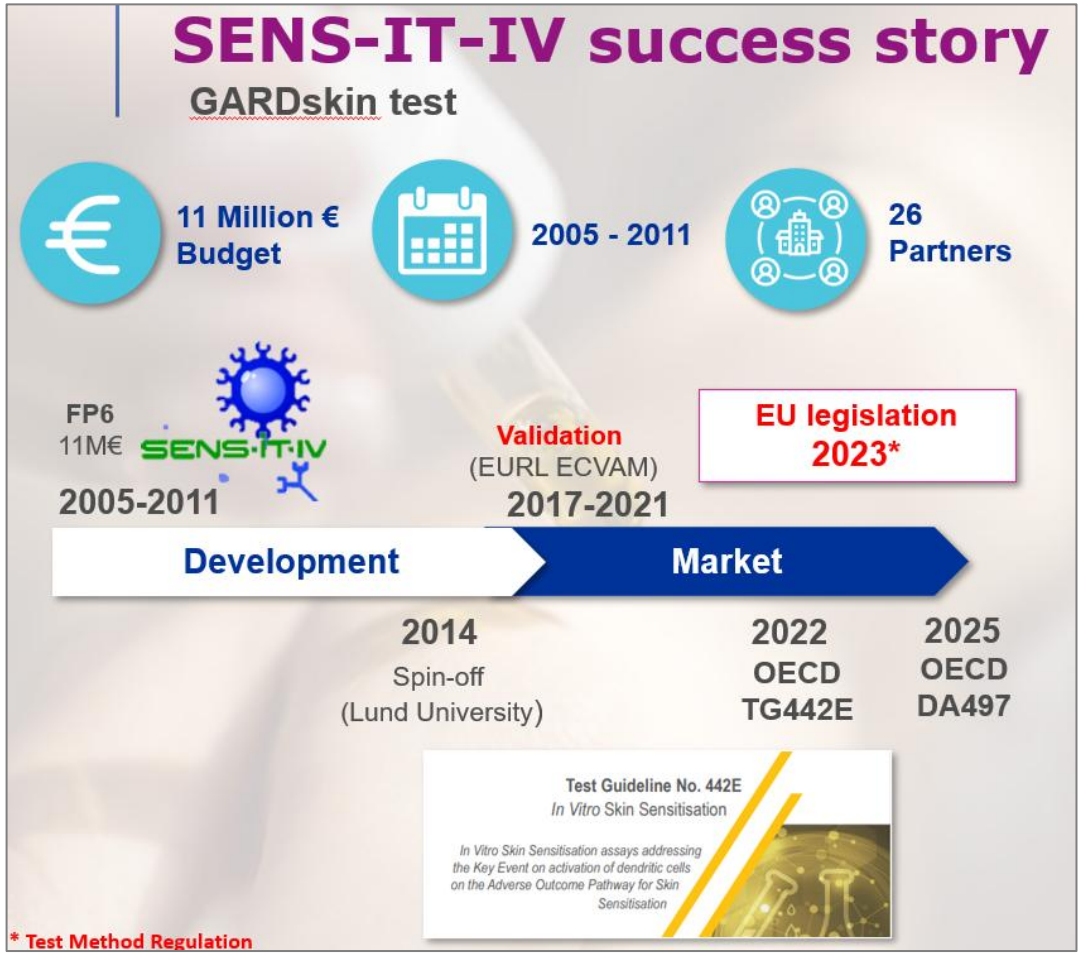
Outperforms traditional animal methods like LLNA

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

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

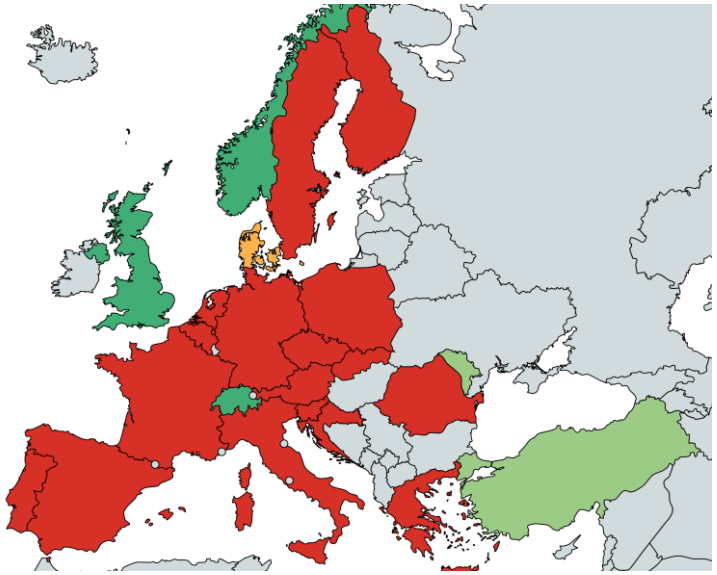
Focus: Medicinal products **AND** medical devices

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

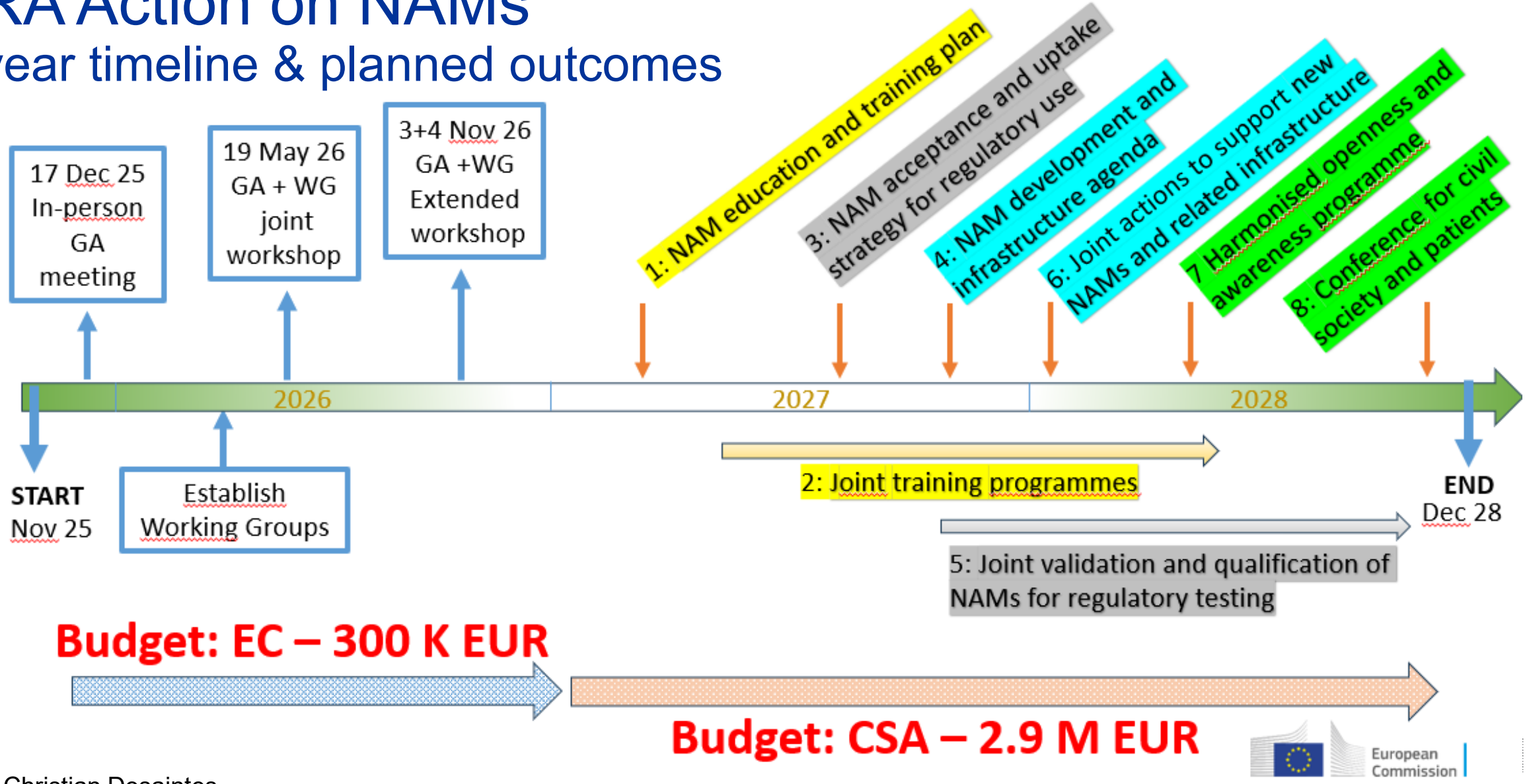
WG4:
46 Experts

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



European Commission

Source: Christian Desaintes

Thank you for your attention!