Non-animal approaches in biomedical research and testing of pharmaceuticals

European Commission

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ERA Objectives

Non-animal approaches in biomedical research and testing of pharmaceuticals

Focus: Promote development, validation and use of **n**on-animal New Approach Methodologies (NAMs) in biomedical research and testing of pharmaceuticals

Aim: Coordinate and streamline Member States' actions on NAMs

- Identify opportunities & priorities for development & validation
- Share good practices & drive synergy
- Leverage expertise, infrastructure in EU

All actors involved: European Commission, relevant ministries, regulatory agencies, EMA, research funders, academia, research institutes & infrastructures, pharma and MedTech industry, CROs, journal editors, citizens & patients

WG1: Development of NAMs and common EU infrastructures

WG2: Validation, acceptance and implementation of NAMs

WG3: Education and training

WG4: Openness & awareness

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3 years: Q3 2025-Q3 2028

WG1: Development of NAMs and common EU infrastructures

- Actions

Identification of opportunities for the development and implementation of NAMS

→ To potentially replace animals effectively
- Certain disease areas, biological processes
- Safety, quality and efficacy assessment endpoints for pharmaceuticals

Identification of opportunities for key EU infrastructures needed for NAMs

→ Development, sustainability and accessibility
- Biobanks, super computers, lab facilities for multi-organ cultures or synthetic antibodies, etc.

- Outcomes

NAM EU development and infrastructure agenda

→ Identifying areas where NAMs are most needed and expected to have the highest impact Q4 2027

→ MS + stakeholders jointly develop new NAMs and related infrastructures Q1 2028

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WG2: Validation, acceptance and implementation of NAMs

- Actions

Identification of criteria NAMs need to meet to

→ Be implemented in basic and applied biomedical research

→ Enable their acceptance for the regulatory assessment of pharmaceuticals

Proposal of priorities for the validation and qualification of NAMs in regulatory testing of pharmaceuticals

- Outcomes

EU NAM validation, acceptance and implementation strategy

→ Identifying criteria for the use of NAMs — Q3 2027

→ MS + stakeholders jointly support validation of few NAMs intended for acceptance in regulatory testing of pharmaceuticals — Q4 2027 - Q3 2028

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WG3: Education and training

- Actions

  Mapping and quality/outreach assessment of worldwide education and training programmes

  → NAMs and 3Rs (Replacement, Reduction, Refinement)
    - Students, researchers, technicians, regulators

- Outcomes

  EU NAM education and training plan

  → Identification of opportunities to better inform researchers and regulators on NAMs and the 3Rs principles — Q1 2027

  → MS + stakeholders develop common education and training programmes based on best practices — Q2 2027- Q2 2028

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WG4: Openness & awareness

- Actions

Develop common policies to improve openness of research

→ Publishing available NAM protocols

→ Publishing negative/neutral results from NAMs and animal experiments

Share best practices to

→ Ensure similar level of awareness for ethical and funding committees, reviewers, regulators

→ Improve confidence of regulators in NAMs

Raise awareness in civil society and patients

- Outcomes

EU NAM openness and awareness programme Q2 2028

Conference for raising awareness of the civil society and patients Q3 2028

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Panelists

1. Dr **Sonja Beken**
   - ✓ Belgian Federal Agency for Medicines and Health Products, Unit of non-clinical assessors.
   - ✓ Master in Biological Sciences and Applied Toxicology and a PhD in Pharmaceutical Sciences.
   - ✓ Chair of the 3Rs Working Party and Member of the Non-Clinical Working Party at EMA.

2. **Philippe Hubert**
   - ✓ CEO of the French public/private platform for the validation of methods for the characterization of endocrine disruptors (PEPPER).
   - ✓ Engineer from Ecole Polytechnique, and statistician.
   - ✓ CEO of the French platform FRANCOPA on development of alternatives to animal testing.

3. Prof. Dipl.-Ing. Dr **Winfried Neuhaus**
   - ✓ Austrian Institute of Technology, Unit Molecular Diagnostics.
   - ✓ PhD in Pharmacy.
   - ✓ Development/Validation of *in vitro* models of biological barriers, especially blood-brain barrier and diseases of the central nervous system.

Panelists

4. Dr **Marta Agostinho**
   - ✓ Executive Director of EU-LIFE - alliance of independent research institutes in the life sciences across EU.
   - ✓ PhD in Cell Biology and post-graduation in Science Communication.
   - ✓ Co-designs and oversees the implementation of EU-LIFE's overall strategy, including leading the science policy area, representing EU-LIFE externally and supervising the EU-LIFE office.

5. **Bas de Waard**
   - ✓ Policy officer of the Transition Programme towards Animal-free Innovation at the Dutch Ministry of Agriculture, Fisheries, Food Security and Nature.
   - ✓ Background in neuroscience.
   - ✓ Experience in science policy and funding (animal-free and 3Rs methodologies).

6. Dr **Orla Moriarty**
   - ✓ Scientific Officer in Translational Sciences, European Medicines Agency (EMA), and Seconded National Expert from the Irish Health Products Regulatory Authority (HPRA).
   - ✓ PhD in translational neuroscience.
   - ✓ Experience in academic research and non-clinical assessor. Scientific support to the 3Rs working party.

Panelists

7. Prof **Maurice Whelan**
   - ✓ Head of the Systems Toxicology Unit and the EU Reference Laboratory for alternatives to animal testing (EURL ECVAM) of the European Commission's Joint Research Centre (JRC).
   - ✓ Mechanical engineer biomechanic and PhD in biomechanic and orthopedic implants.
   - ✓ Co-chair of the OECD Advisory Group on Molecular Screening and Toxicogenomics that is responsible for the OECD programme on Adverse Outcome Pathways.

8. Dr **Nicolas Dudoignon**
   - ✓ Chief Veterinary Officer at Sanofi.
   - ✓ Veterinary medical degree and PhD in toxicology.
   - ✓ Experience in ethics committees and leading global animal welfare compliance programs.
   - ✓ Represents EFPIA (European Federation of Pharmaceutical Industries and Associations), where he is involved with the Research and Animal Welfare group, fostering an open dialogue on the use of animals for scientific purposes and the phasing-in of NAMs in biomedical research and testing.

Thank you!

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