



# European Research Area action

*“Towards medical sciences and regulatory testing without the use of animals”*

**August 2023**

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## Towards medical sciences and regulatory testing without the use of animals

In its response<sup>1</sup> to the European Citizens' Initiative 'Save cruelty-free cosmetics – Commit to a Europe without animal testing', the Commission proposed a European Research Area (ERA) policy action to reduce animal use in research and regulatory testing. This action aims to mobilise Member States to streamline their national and regional policies to reduce the use of animals in research and testing, while accelerating the development, validation and uptake of non-animal methods. This objective is in line with the goal of the European Union to fully replace the use of animals in science<sup>2</sup>, and the continued calls from citizens from all EU Member States<sup>3</sup> to accelerate the transition to non-animal science. Moving towards non-animal science has become a priority of the European Commission, not only for ethical reasons, but also to better protect human health and the environment. That transition will occur through more robust and harmonised regulatory decision-making, and the use of biologically relevant non-animal methods that are more sustainable as well as more accurate and effective in understanding, preventing and treating human diseases.

Achieving the goal to phase-out the use of animals in science requires the active involvement of a substantial number of stakeholders operating at Member State level. These actors include national/regional regulatory agencies, ministries, industry, other funding bodies, academia and ethics committees. This working document provides examples of actions that can be taken jointly by Member States to accelerate the transition towards medical science and regulatory testing without the use of animals.

### 1. Establish clear milestones

Setting clear milestones helps to focus minds, and to motivate and drive activities towards the desired goal. Working within the 2024-2027 timeframe proposed by the Commission, objectives could be set to facilitate meaningful progress toward ending the harmful use of animals in education and training; ensuring that replacement to animal use is included in the next Horizon Europe strategic planning for 2025-2027; developing a roadmap to end the use of animals in regulatory testing; and harmonising education and training in non-animal new approach methodologies (NAMs) in life sciences.

<sup>1</sup> [https://single-market-economy.ec.europa.eu/system/files/2023-07/C\\_2023\\_5041\\_1\\_EN\\_ACT\\_part1\\_v6.pdf](https://single-market-economy.ec.europa.eu/system/files/2023-07/C_2023_5041_1_EN_ACT_part1_v6.pdf)

<sup>2</sup> <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:en:PDF#::~:~:;text=This%20Directive%20establishes%20measures%20for%20scientific%20or%20educational%20purposes>

<sup>3</sup> [https://europa.eu/citizens-initiative/initiatives/details/2021/000006\\_en](https://europa.eu/citizens-initiative/initiatives/details/2021/000006_en)

## 2. Identify key research areas

The path and speed at which the EU can transition to entirely non-animal science may vary from one scientific area to another. Identifying key areas of research, regulatory testing or education where there are strong incentives to replace animal use can provide valuable insights, allowing us to focus and prioritise resources and efforts effectively. For example, the [EURL ECVAM reviews of advanced non-animal models](#)<sup>4</sup> in seven disease areas and their [Recommendation on Non-Animal-Derived Antibodies](#)<sup>5</sup>, the [target images](#)<sup>6</sup> on animal-free research by the Netherlands National Committee for the protection of animals used for scientific purposes (NCad), and EU-level priorities such as Horizon Europe's [Mission on Cancer](#)<sup>7</sup> and the recently launched [Communication on Mental](#)<sup>8</sup> Health all serve to assist Member States in identifying key areas for the development of concrete plans to replace tests on animals with innovative non-animal approaches.

## 3. Direct an appropriate level of funding towards non-animal technologies

The balance between funding of animal-based and non-animal research is an important consideration. National and regional resources can be mobilised to significantly increase support for the development, implementation and use of non-animal technologies, and public funding of animal research should be subject to increased scrutiny. Potential actions could include increased support for innovative start-ups addressing human health and environmental related issues via biologically relevant non-animal approaches; incentives to encourage scientists to use non-animal methods (for example, by creating a fund to acquire or establish non-animal models and technologies in research infrastructures); and replacement of the use of animal-derived materials in research and routine production.

## 4. Direct large-scale support for building key infrastructure

Strategic funding for the establishment of skills labs, core facilities, or 'hubs' to support researchers with hands-on training, ready-to-use models, equipment hire, knowledge sharing or scientific advice would significantly increase access, uptake and broader use of existing and new non-animal technologies. In the same vein, Member States could facilitate access and functional sharing of equipment or non-animal derived materials across universities and other research institutions within their own nations and in neighbouring countries.

<sup>4</sup>[https://joint-research-centre.ec.europa.eu/eu-reference-laboratory-alternatives-animal-testing-eurl-ecvam/biomedical-research\\_en](https://joint-research-centre.ec.europa.eu/eu-reference-laboratory-alternatives-animal-testing-eurl-ecvam/biomedical-research_en)

<sup>5</sup><https://publications.jrc.ec.europa.eu/repository/handle/JRC120199>

<sup>6</sup><https://english.ncadierproevenbeleid.nl/advice/target-images-on-animal-free-research>;

[https://www.nfu.nl/sites/default/files/2022-10/Streefbeeld\\_proefdiervrije\\_innovatie\\_in\\_het\\_postacademisch\\_onderwijs\\_0.pdf](https://www.nfu.nl/sites/default/files/2022-10/Streefbeeld_proefdiervrije_innovatie_in_het_postacademisch_onderwijs_0.pdf)

<sup>7</sup>[https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/eu-mission-cancer\\_en](https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/eu-mission-cancer_en)

<sup>8</sup>[https://health.ec.europa.eu/system/files/2023-06/com\\_2023\\_298\\_1\\_act\\_en.pdf](https://health.ec.europa.eu/system/files/2023-06/com_2023_298_1_act_en.pdf)

## 5. Promote clinical research, epidemiology and other human-based approaches

Our rapidly increasing understanding of human biology is unlocking opportunities to improve health and prevent disease. Tools such as large-scale biomedical databases are already contributing to the advancement of modern medicine and treatment, including through the early detection of disease. Likewise, clinical research, combined with new technologies allowing rapid assimilation, sharing and analysis of results, now provides unprecedented opportunities to transform our understanding of human disease and to [increase translational impact of research](#)<sup>9</sup>. These tools, along with increased use of [cell](#)<sup>10</sup> and [tissue banks](#)<sup>11</sup>, patient information and epidemiological data are in line with the EU objective of [developing sustainable approaches to delivering person-centred therapies](#)<sup>12</sup>. They should also be recognised as core activities associated with the replacement of animal based research.

## 6. Harmonise education and training in non-animal technologies

Education and training activities serve as effective means to support, encourage and inspire scientists, educators, students and regulators in the use of non-animal approaches. Resources can be mobilised to ensure that students are well-educated in non-animal science and to enable young graduates to bring state-of-the-art knowledge to their workplaces, as recently [promoted by the European Commission](#)<sup>13</sup>.

## 7. Promote better data sharing within the scientific community

Researchers, regulators, project evaluators and animal welfare bodies often lack knowledge of available non-animal technologies. Open science principles are in line with the [objectives of Horizon Europe](#)<sup>14</sup>, promoting the exchange of best practices, data and tools through collaborative efforts with regulatory agencies, academia, industry, and research institutes. The facilitation of such principles within Member State policy actions will help to increase transparency, prevent duplication of research, and to identify innovative biologically-relevant approaches that can enable significant advances in science. This can be achieved, for example, through the creation and maintenance of a knowledge infrastructure where available information on non-animal methods is easily accessible and can be shared. Enhancing [open data sharing policy](#)<sup>15</sup> with a special focus on health data, are of particular importance.

<sup>9</sup><https://pubmed.ncbi.nlm.nih.gov/37386455/>

<sup>10</sup><https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6603147/>

<sup>11</sup><https://www.vitaltissue.nl/>

<sup>12</sup>[https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2023-2024/wp-4-health\\_horizon-2023-2024\\_en.pdf](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2023-2024/wp-4-health_horizon-2023-2024_en.pdf)

<sup>13</sup><https://publications.jrc.ec.europa.eu/repository/handle/JRC123343>

<sup>14</sup><https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/9570017e-cd82-11eb-ac72-01aa75ed71a1>

<sup>15</sup>e.g., The European Open Science Cloud (EOSC) <https://eosc-portal.eu/>

## 8. Implement more robust and harmonised project evaluation and authorisation processes

To achieve harmonised project evaluations both within and across Member States, several actions can be undertaken. For instance, by training project evaluators on the basis of common learning objectives, by establishing a common framework for understanding and implementing [ethics and the 3Rs](#)<sup>16</sup> with a priority focus on replacement, and by making project evaluation and authorisation processes public to increase transparency. [Systematic reviews](#)<sup>17</sup> can play a particularly important role in taking decisive and immediate action to halt projects that are poorly designed, lack meaningful value toward advancing the transition away from animal experimentation, raise significant ethical concerns, or employ animal-based methods known to be of limited utility. Addressing these issues is particularly crucial because, despite these concerns, animal projects (depending on location) often have a relatively low or 'zero' rejection rate. Policy actions taken under this remit should facilitate the shared understanding among all Member States competent authorities that no approvals for animal use are to be granted when viable non-animal replacement methods are available.

**A radical change in mindset and practice is needed to accelerate the transition to non-animal science. This starts with the European Commission and EU Member States committing to move towards non-animal science, and prioritising this transition in all research, innovation and education initiatives.**

<sup>16</sup><https://pubmed.ncbi.nlm.nih.gov/31329258/>

<sup>17</sup><https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6941037/>

A large, semi-transparent orange silhouette of a mouse is positioned in the background, facing right. The background is a solid orange color with a subtle grid pattern.

**Cruelty Free Europe**  
[crueltyfreeeurope.org](http://crueltyfreeeurope.org)

**Eurogroup for Animals**  
[eurogroupforanimals.org](http://eurogroupforanimals.org)

**European Coalition to End Animal Experiments (ECEAE)**  
[eceae.org](http://eceae.org)

**Humane Society International / Europe**  
[hsi-europe.org](http://hsi-europe.org)

**PETA Foundation UK**  
[peta.org.uk](http://peta.org.uk)