

# A HUMANE DEAL: TRANSITIONING TO A NEW ERA OF SCIENCE, TOGETHER

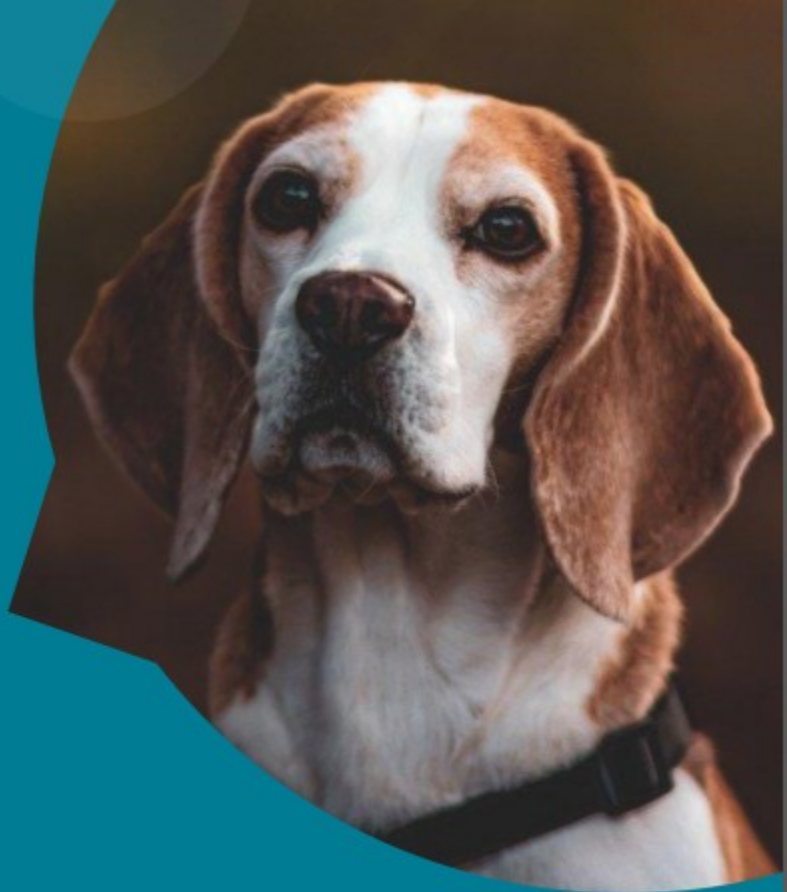
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Laurence Walder

[l.walder@eurogroupforanimals.org](mailto:l.walder@eurogroupforanimals.org)

Luísa Bastos

[l.bastos@eurogroupforanimals.org](mailto:l.bastos@eurogroupforanimals.org)



# CURRENT STATE OF PLAY IN THE EU

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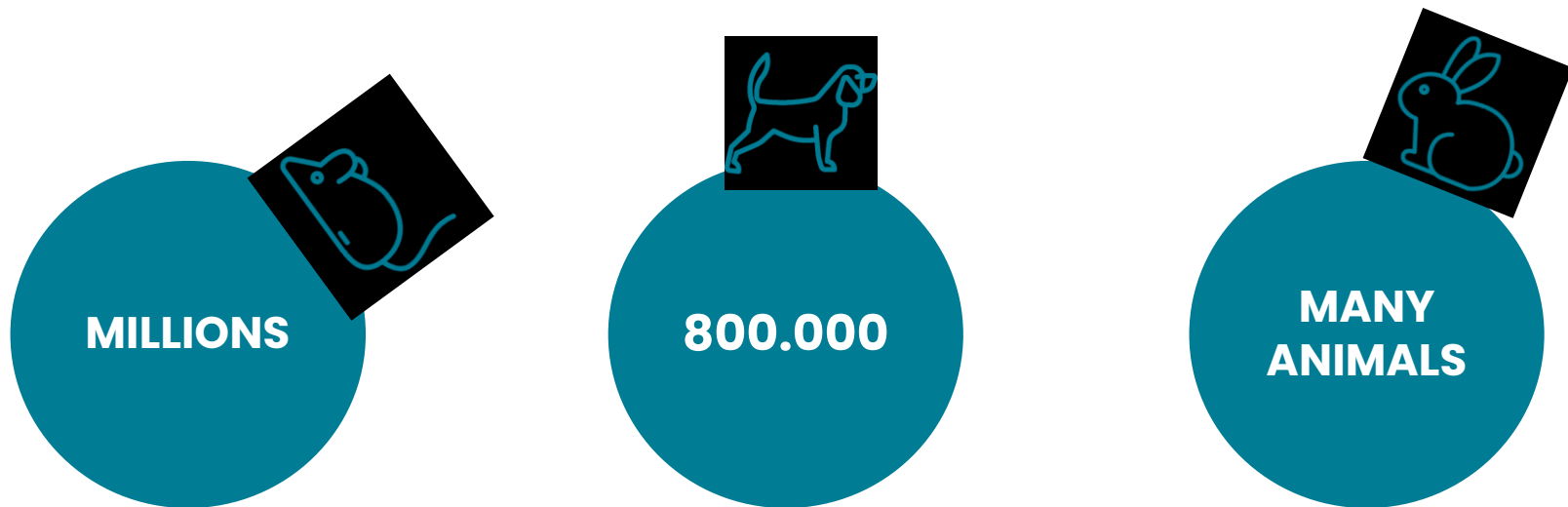
Laurence Walder

DANISH 3Rs SYMPOSIUM | 7 November 2023



**EUROGROUP  
FOR  
ANIMALS**

“The EU is committed to **animal welfare**, to improving public health and protecting the environment”



of animals are still **used every year**  
**in the EU** in experiments

animals experienced a **‘severe’**  
**level of pain, suffering or distress**

are still being used in areas where  
**other, non-animal methods are**  
**available**

Source: Summary Report on the statistics on the use of animals for scientific purposes in the Member States of the European Union and Norway in 2020

## Joint Research Centre's studies to review available and emerging non-animal models for research in seven disease areas



Respiratory tract diseases



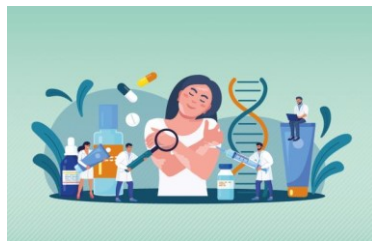
Breast cancer



Neurodegenerative disorders



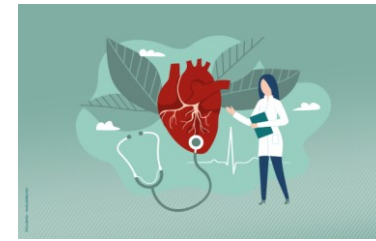
Immuno-oncology



Autoimmune diseases



Immunogenicity testing for  
advanced medicinal therapy  
products



Cardiovascular diseases

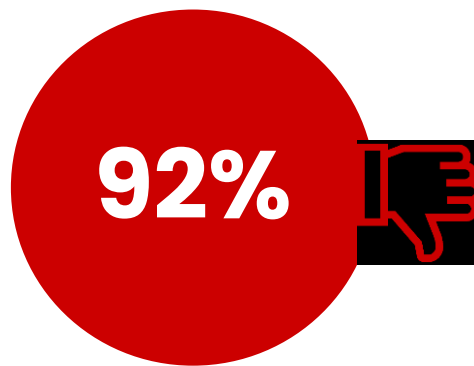
“The EU is committed to animal welfare, to **improving public health** and protecting the environment”

Around 10 000 diseases affect humans,  
but only about



have **treatments available**

The average **failure rate of drug development**  
remains above



Limited translation of  
research results from  
animal-based studies to  
the human situation

**Sources:**

- National Center for Advancing Translational Sciences. 2023. Speeding More Treatments for All Fact Sheet.
- Thomas et al. 2021. Clinical development success rates and contributing factors 2011-2020.
- Pistollato et al. *Animals*. 2020.10:1194.
- Pound & Ritskes-Hoitinga. *J Transl Med*. 2018.16:304.
- Marshall et al. *Alternatives to Laboratory Animals*. 2023. 51(2):102-135.

“The EU is committed to animal welfare, to **improving public health** and **protecting the environment**”

European Environment Agency



0.5%

of the chemicals available on the market **have been fully assessed** in terms of hazards and exposure risks

10%

have **fairly well** been assessed

20%

have only been **poorly** assessed

Source: EEA, 2020, The European Environment - State and outlook report.

“The EU is committed to animal welfare, to **improving public health** and **protecting the environment**”

Respiratory diseases

Cardiovascular diseases

Allergies

Cancer

**AROUND 70% OF THE CHEMICALS ON THE EUROPEAN MARKET HAVE NOT BEEN ASSESSED FOR SAFE USE!**

Impact on wildlife

Impact on ecosystems

## Why aren't we better protected from chemicals?



**Animal tests are  
time-consuming**



**Translation of  
animal-based  
studies to the  
human situation  
not always clear**



**Animal tests are  
costly**

### Sources:

Swaters et al. *Alternatives to Laboratory Animals*. 2022;50(5):322-329.  
Schmeisser et al. *Environment International*, 2023. 178:108082,  
Berggren. *Regul Toxicol Pharmacol.* 2023. 142:105431.



## Professionals working with animals in laboratories may be at high risk of compassion fatigue

*“combination of physical, emotional and psychological exhaustion associated with working with and caring for animals used in research”*



- **Cause:** care provided for research animals that may ultimately become sick or be euthanized for research studies
- **Symptoms:** depression, anxiety, cynicism and chronic physical ailments to isolation, absenteeism, hopelessness, denial, nightmares, substance abuse, and even suicid

Source: Van Hooser et al. Front. Vet. Sci. 2021. 8:731003.



# URGENT NEED FOR CHANGE

Replacing existing practices with innovative solutions to address the current health and environmental issues.

- Development & acceptance of scientifically sound **non-animal approaches based on human biology**
- In many areas, non-animal methods based on human biology have been shown to **better represent the human situation** than animal models

**Sources:**

Ewart et al.. Commun Med. 2022. 2:154.

Passini et al.. Front Physiol.. 2017.12:8:668.

[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)

## A transition to human-based, non-animal science could:

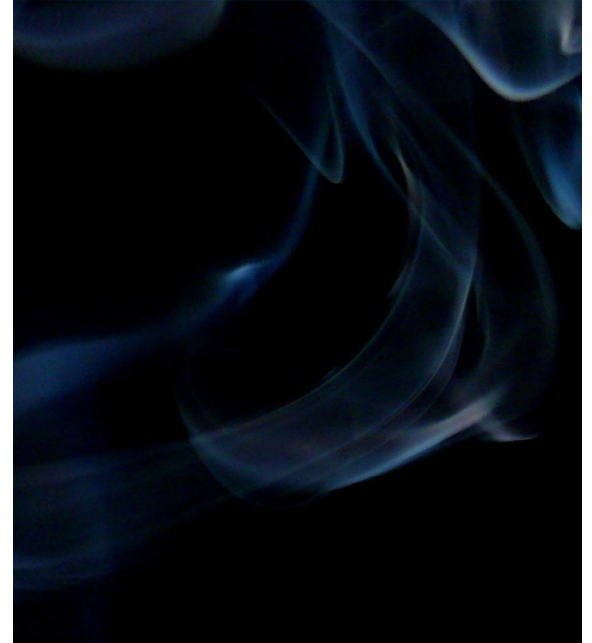
IMPROVE OUR UNDERSTANDING OF  
HUMAN DISEASE



ACCELERATE THE DISCOVERY OF  
EFFECTIVE THERAPIES



PROVIDE BETTER SAFETY  
INFORMATION



## The transition to non-animal science is supported by a large number of different actors and stakeholders



#Act4LabAnimals

2021

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Home > News > A win for animals! The European Parliament votes in favour of a comprehensive plan to phase-out experiments on animals

### A win for animals! The European Parliament votes in favour of a comprehensive plan to phase-out experiments on animals

95% of MEPS voted in favour of a resolution on plans and actions to accelerate a transition to non-animal science

DANISH 3Rs SYMPOSIUM | 7 November 2023



#Act4LabAnimals

2023

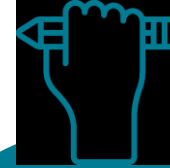
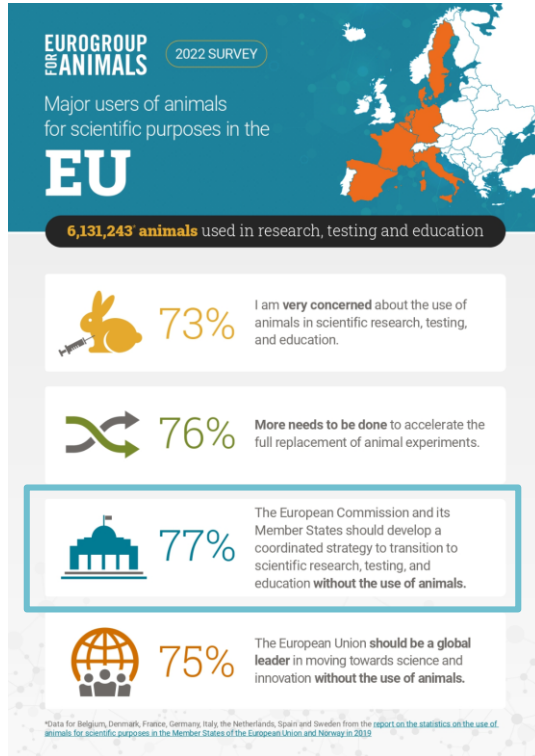
Home > News > European scientists continue to support an EU roadmap to accelerate the transition to non-animal science

### European scientists continue to support an EU roadmap to accelerate the transition to non-animal science

Hundreds of EU scientists signed an open letter to call on the EC and Member States to accelerate the transition to non-animal science.

**EUROGROUP**  
**FOR**  
**ANIMALS**

# The call for a shift towards more fit for purpose, human-relevant science has also repeatedly been expressed by EU citizens



1.2 MILLION SIGNATURES

for the ECI Save Cruelty Free Cosmetics - Commit to a Europe Without Animal Testing (2022)

## Research practices are evolving in the pharmaceutical and chemical industry, and the consumer goods sector



“Our long-term aspiration is to be a **pioneer in phasing out animal use**”



“GSK would like to see the health benefits of research achieved and applied to humans **without the need for animals**”



“We are committed to making **animal testing obsolete**”



“Cefic members fully support the development and use of **fit-for-purpose alternative testing methods**”



“Since the 1980s, our scientists have been developing and using **alternatives to animal tests**”.



“EFPIA members are committed to the **science-based phase-in of methods to replace the use of animals** for scientific purposes and the **deletion of animal tests** which are obsolete or redundant”



Institute of  
Human Biology

“**Organoids** have the exciting potential **to more closely mirror the biology of human health and disease** than has been possible in animal models”

The phasing out of animal testing is also becoming an important issue in a certain number of EU institutions



Strategy + roadmap to actively **reduce and replace animal tests**



2025 Regulatory Science Strategy includes recommendations to **use non-animal methods** + **reduce and replace animals** in medicines testing



“The European Partnership for Alternative Approaches to Animal Testing works to **replace the use of animals in testing**”

## European Commission itself has stated that:

### “Animal testing should be phased out in Europe”

Virginijus Sinkevičius, Commissioner for Environment, Oceans and Fisheries - 25/07/2023



“EU legislation is unique as it sets a **final goal of full replacement of all animals** used for scientific and educational purposes and is taking **concrete action towards that goal**”

“The Commission will immediately launch the work to develop a roadmap [...] that would be prerequisites for a **transition towards an animal-free regulatory system**”

“The Commission is exploring the possibility of **developing a European Research Area (ERA) policy action** to reduce animal uses” in biomedical research and education

#### Sources:

European Commission’s reply to the ECI ‘Save Cruelty Free Cosmetics - Commit to a Europe without Animal Testing’

[https://environment.ec.europa.eu/topics/chemicals/animals-science\\_en](https://environment.ec.europa.eu/topics/chemicals/animals-science_en)



## Several EU Member States have also declared their intention to reduce and replace the use of animals in research, testing, and education



### THE NETHERLANDS | Transition Programme for Innovation without the use of animals (TPI)

Source: <https://www.animalfreeinnovationtpi.nl/>



### GERMANY | Strategy to reduce animal experiments and support animal-free research

Source: Koalitionsvertrag. 2021. Mehr fortschritt wagen bündnis für freiheit, gerechtigkeit und nachhaltigkeit koalitionsvertrag 2021-2025.



### SWEDEN | Preliminary strategy to limit the use of animals in research, testing and education

Source: Sveriges 3R-center (2021) Återrapportering av ytterligare åtgärder för att begränsa användningen av försöksdjur.



### BELGIUM (Flanders) | Action plan to reduce the use of animals for scientific purposes in Flanders

Source: Technopolis. Actieplan gericht op het verminderen van het aantal dierproeven in Vlaanderen. 2023.



WHAT DO WE NEED TO SUCCESSFULLY ACHIEVE THE GOAL OF  
**TRANSITIONING TO NON-ANIMAL SCIENCE** AND DELIVERING A  
HUMANE DEAL FOR SCIENCE?



# HOW TO ACHIEVE THIS HUMANE DEAL?

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Luísa Bastos



A humane deal for science leaves no one behind.



HOW CAN WE DELIVER  
THIS **HUMANE DEAL?**



Berthold Gunster



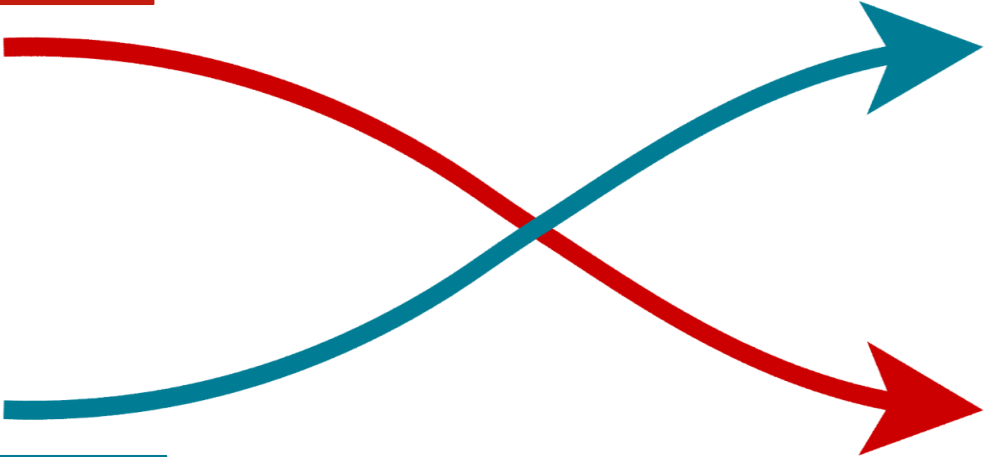
# FLIP THINKING

The Life-Changing Art  
of Turning **Problems**  
into **Opportunities**



Transition from current practices that we want to end or limit to very low levels towards new practices that are not the norm today

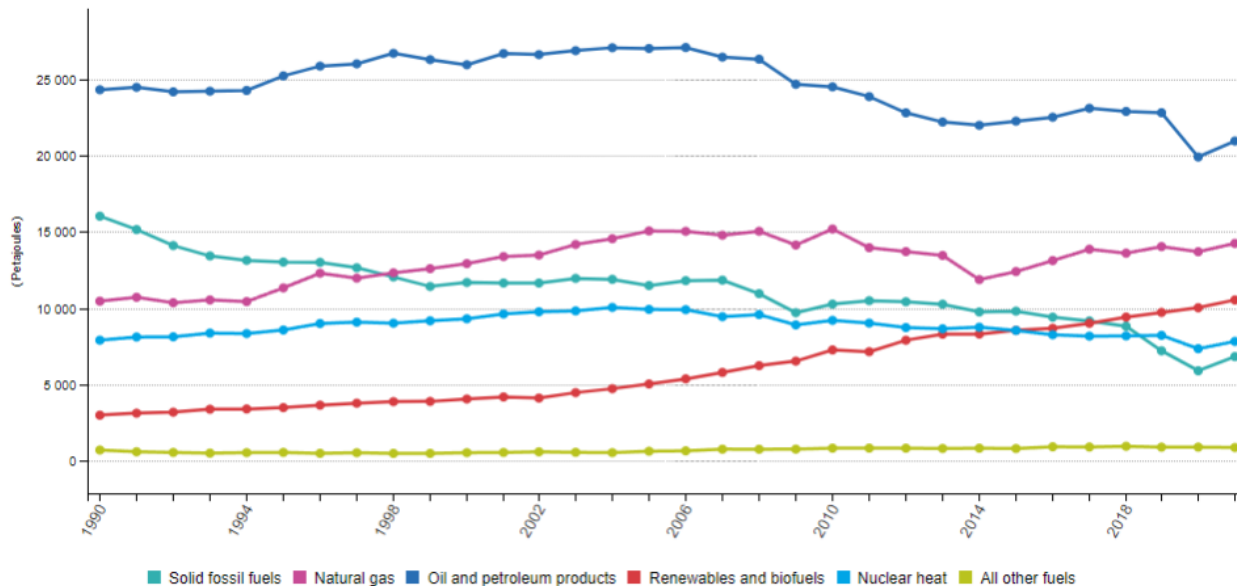
Phasing out of current practices



Phasing in of new innovative practices

## The energy transition as an example of a unsuccessful phase-in phase-out strategy


Gross available energy, EU, 1990-2021



Source: Eurostat (online data code: nrg\_bal\_s)

eurostat

## Conflicting actions:

 **Funding & tender opportunities**  
Single Electronic Data Interchange Area (SEDIA)

[HOME](#) [SEARCH FUNDING & TENDERS](#) [HOW TO PARTICIPATE](#) [PROJECTS & RESULTS](#)



### Accelerating the implementation of New Approach Methodologies and other innovative non-animal approaches for the developme...

HORIZON-JU-IHI-2023-05-01 **Call for proposal**  
Horizon Europe (HORIZON)

### Expanding translational knowledge in minipigs: a path to reduce and replace non-human primates in non-clinical safety assessment

HORIZON-JU-IHI-2023-04-01-two-stage **Call for proposal**  
Horizon Europe (HORIZON)





# KEY ELEMENTS TO FLIP-THINK THE TRANSITION TO NON-ANIMAL SCIENCE



1

## EU-WIDE COLLABORATION AND COORDINATION

Commission's directorates-general, agencies and governments' ministries responsible for aspects of research, regulatory testing, education, and funding. **An overarching coordination is needed to bring all of them together.**

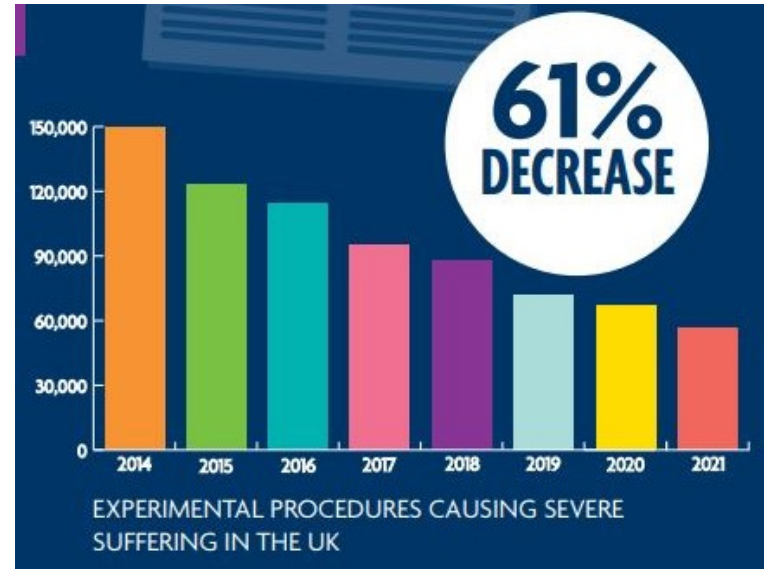


## 2

### CLEAR MILESTONES

#### Examples:

- transform 50% of the EU animal research infrastructure into **non-animal methods labs by 2040**
- review the Curricula in life sciences to achieve a **harm-free educational system by 2035**
- **end severe suffering by 2030.**



Source: RSPCA. Focus Severe Suffering infographic. 2022.  
<https://focusonseveresuffering.co.uk/>

3

# IDENTIFICATION OF KEY RESEARCH AREAS

Where do we start?



## Joint Research Centre's studies to review available and emerging non-animal models for research in seven disease areas



Respiratory tract diseases



Breast cancer



Neurodegenerative disorders



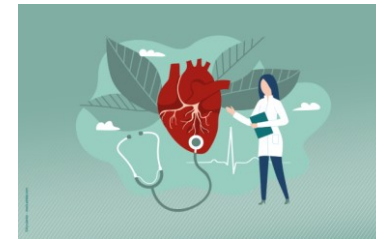
Immuno-oncology



Autoimmune diseases



Immunogenicity testing for  
advanced medicinal therapy  
products



Cardiovascular diseases

4

# INFRASTRUCTURE

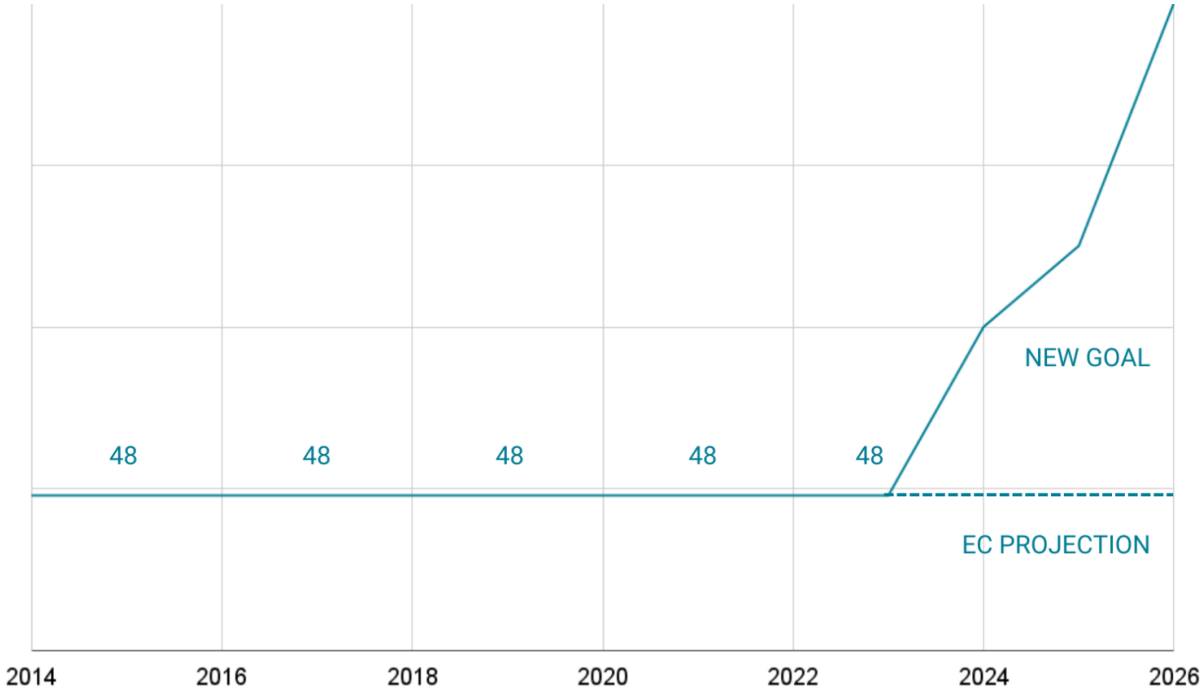
Assess, expand and transform key infrastructure that can allow for **fuller exploitation of non-animal methods.**



5

# FUNDING

Funds committed to research projects on the development of non-animal alternative methods (in million euros)



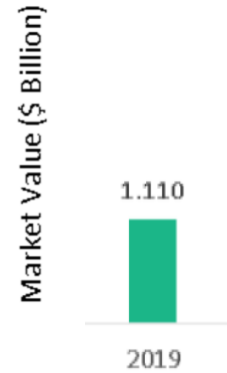
5

# FUNDING

Global animal testing market size 2019



Global non-animal testing market size 2019



Source: The Business Research Company. Animal Testing And Non-Animal Alternative Testing Global Market Opportunities And Strategies To 2035. 2023.





### Directive 2010-63-EU | Article 23 - Competence of personnel

1. Member States shall ensure that each breeder, supplier and user has **sufficient staff on site**.
1. The staff shall be adequately educated and trained before they perform any of the following functions:
  - a. carrying out **procedures on animals**;
  - b. designing procedures and projects;
  - c. **taking care of animals**; or
  - d. **killing animals**.

### Directive 2010-63-EU | Article 24 - Specific requirements for personnels

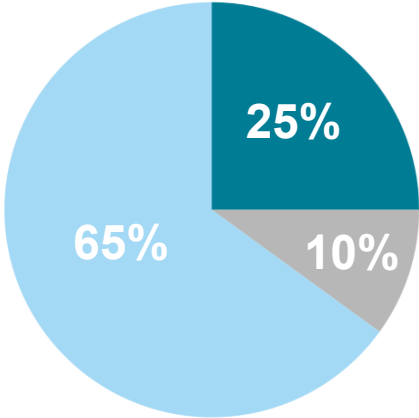
1. Member States shall ensure that each breeder, supplier and user has one or several persons on site who shall:
  - a. be responsible for overseeing the **welfare and care of the animals** in the establishment;
  - b. ensure that the staff dealing with animals have access to **information specific to the species housed** in the establishment;
  - c. be responsible for ensuring that the staff are **adequately educated, competent and continuously trained** [...]

# 6

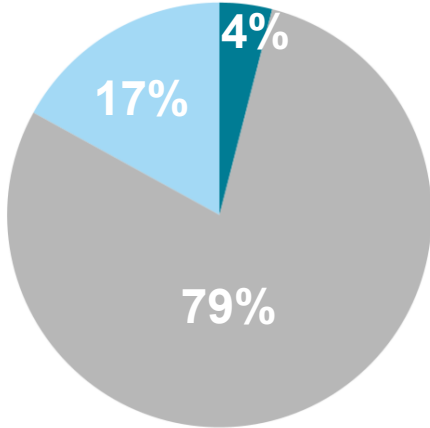
## EDUCATION AND TRAINING

“In your teaching activity, are you mostly presenting human or animal experimental works ?”

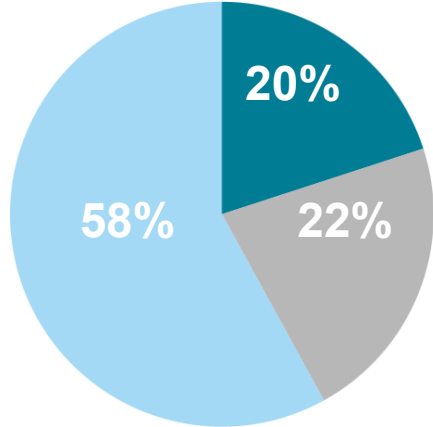
Animal-based model users



Human-based model users



Both users



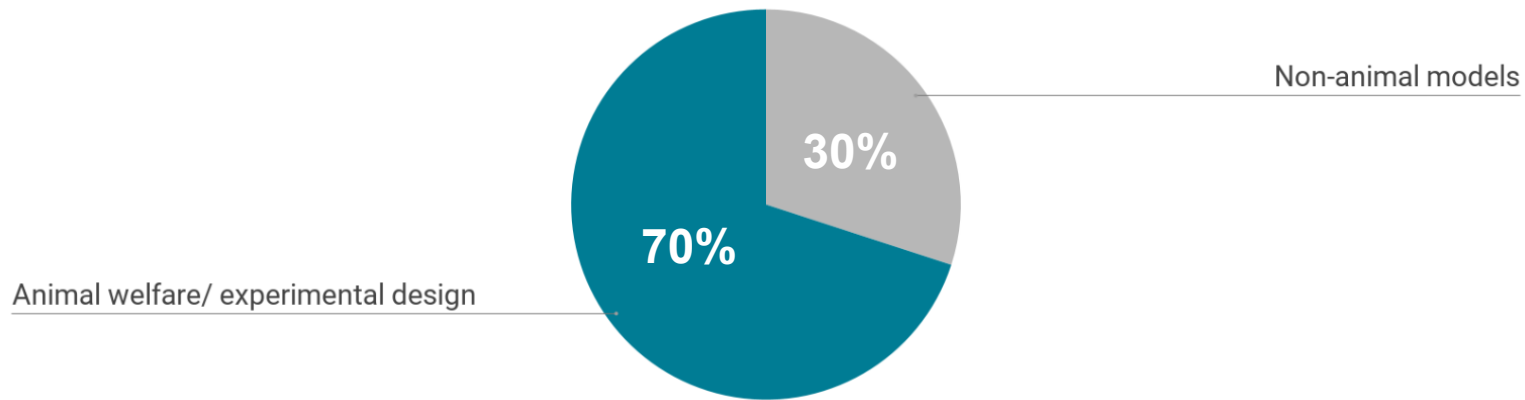
● Animal-based teaching ● Human-based teaching ● Both

Source: Del Pace et al. Animals. 2022. 14;12(20):2778.

# 6

## EDUCATION AND TRAINING

“Have you ever attended any **workshop/ course on... ?**”



Source: Del Pace, L.; Viviani, L.; Straccia, M. Researchers and Their Experimental Models: A Pilot Survey in the Context of the European Union Health and Life Science Research. *Animals* 2022,12,2778. [https:// doi.org/10.3390/ani12202778](https://doi.org/10.3390/ani12202778)

# THE 3M



**MILESTONES**

**Coordinated transition  
strategy**

**MONEY**

**Appropriate level of  
funds**

**MINDSET**

**Education and  
continuous training**





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OUR WORK



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THANK  
YOU