# Use of animals in pharmaceutical research

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# Why are animals used in pharmaceutical research?

- The use of animals in medical and pharmaceutical research is essential to the understanding of disease and the safe development of medicines.
- Testing the safety of a medicine in animals, prior to testing in humans, significantly reduces the risk of serious adverse reactions occurring in humans during clinical trials.
- Pharmaceutical companies must strictly adhere to rigorous international and UK regulatory requirements for the development of a new medicine.
- Medicines regulators globally, including the UK's medicines regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), require animal testing to provide essential safety data about a potential new medicine before it is used in any human clinical trials.
- Animal models are also used in medical research to understand the biological causes of a disease. Once the biological mechanism of a disease is understood, it is possible to develop a medicine to specifically target that disease pathway.

# What are new approach methodologies (NAMs)?

- The pharmaceutical industry is committed to the principles of reduction, replacement, and refinement (3Rs) of animal testing.
- Increasingly, animals are only used in pharmaceutical research where there is no available alternative, or their use is required to satisfy essential regulatory and safety requirements.
- New approach methodologies (NAMs) are non-animal based approaches that can provide information to further understand the safety of a medicine and how the medicine may potentially react in a living organism. NAMs include technologies and methods such as computational modelling and laboratory (in vitro) tests.

# Why isn't full replacement of animals possible right now?

- NAMs have the potential to significantly reduce the use of animals in pharmaceutical research. However, more research is needed to develop and validate these models across a range of diseases, different body tissues and organs before they are acceptable as valid and safe alternatives to animal models by medicines regulators.
- Due to the complexity and uncertainty involved, even when a NAM exists, global regulators including the UK's MHRA, may still require accompanying animal safety testing to be carried out, if there are any potential risks to human health in subsequent clinical trials.
- Because validated NAMs must encapsulate all conditions and replicate all types of body tissues, there are many circumstances where currently no alternative non-animal models exist.
- For these reasons, animal models remain the only currently viable means of assessing the safety of a potential new medicine before it can be tested in a human.

# What are the unintended consequences of banning the use of animals in pharmaceutical research?

- **Delays in UK patients accessing new medicines.** If animal testing were banned in the UK in the absence of an approved and validated NAM alternative, it would not be possible to get the clinical safety data needed for UK clinical trials in humans, and the development of promising medicines would be stalled. This might also delay, or in some cases, even prevent UK patients from accessing innovative medicines that would be available to patients in other countries.
- **Lack of alignment with domestic and international R&D regulatory requirements.** Banning animal testing in the UK would be out of alignment with internationally accepted regulatory requirements for medicines development. It would also be at odds with the UK government's commitment to improving the environment for the delivery of commercial clinical trials.
- **Deter inward industry R&D investment in the UK.** A total UK ban on animal testing would mean industry could not perform essential animal safety studies in the UK that are required by medicines regulators globally. This would deter commercial R&D investment in the UK and undermine the government's desire for the UK to be a global life science superpower.
- **Reputational risk.** There are international examples where other countries have publicly committed to banning the use of animals in research, only to have to publicly reverse this decision. For example, in 2024, the US regulatory agency, The Environmental Protection Agency (EPA) backtracked on their public commitment to completely phase out animal testing by 2035 after this was successfully challenged by sector experts and public health officials as unworkable.

### Use of dogs in research

Dogs have special protection under UK law where they cannot be used if another animal species could be used instead. Dogs are only used in 0.2% of animal research in the UK.

### Use of small mammals in research

The most commonly used species is mice, accounting for 72% of all animal research in the UK.

# Latest UK government commitments

The ABPI has welcomed commitments made by the UK Government in February 2024 to:

- Double investment to speed up the research and development of NAMs over the next year. The investment will reach £20m across the system in 2024/25.
- Publish a cross-government plan by the summer to accelerate the development, validation, and uptake of technologies and methods to reduce reliance on the use of animals in science.
- Reinstate the Ipsos-Mori, 'Public attitudes to animal research,' survey, with results due to published in the autumn of 2024.


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