Why we support research involving animals

We support research using animals where alternative methods are not available, where the potential benefits to health are compelling, and where acceptable ethical and welfare standards can be met.

We support European Directive 2010/63/EU ('the Directive') on the protection of animals used for scientific purposes and do not support the European Citizens' Initiative (ECI) Stop Vivisection which calls for the abrogation of the Directive and a ban on research involving animals.

Major breakthroughs in human and veterinary medicine have been facilitated by the use of animals at some stage in the research, development or testing of new therapies. Breakthroughs have been made across the scientific spectrum, from advances in surgical techniques to diagnostics and therapies in cancer and neurodegenerative disorders.

Animals have been, or are being, used in medical research with a number of aims, including:

- Basic biomedical research to increase the understanding of the cause and development of diseases, with the aim of being able to identify targets for new therapies and early interventions.
- To identify new therapies directly, for example where animal physiology differs to that of human.
- To test the safety of therapeutic interventions. This includes vaccines which prevent between 2 and 3 million deaths every year worldwide

Animals are a valuable model for biomedical research because humans are biologically very similar to other mammals. All mammals, including humans, have most of the same organs such as the heart, lungs, kidneys and liver that perform the same functions and are controlled by the same mechanisms e.g. the blood stream and nervous system. Mice share over 90% of their genes with humans. There are differences, but from a scientific perspective these differences are far outweighed by the remarkable similarities. Nearly 90% of the veterinary medicines that are used to treat animals are the same as, or very similar to, those developed to treat humans.

There are however limits to the usefulness of animals and sometimes animal research has not been able to offer as much information to aid medical research as hoped. Sometimes this is because the model is poor; the disease might not develop in the same way in animals, or the model for inducing the disease or injury is too dissimilar to the human condition. Sometimes animal models are limited because the physiological differences between humans and animals are too great. Research animals are also a more similar to each other than humans are; research animals are affected only by the disease being investigated, whereas a typical group of patients is more diverse, both in terms of the severity of their disease and other illnesses that may affect treatments.

Basic biomedical research involving animals: Gene therapy for muscular dystrophy

Muscular dystrophies (MD) are a group of diseases that cause progressive muscle weakness and premature death and affect approximately 20-25 people per 100,000. Certain species of mice and dogs are also affected by MD, studies of these animals have improved understanding of the condition, its causes and how it develops. Specifically the mdx mouse strain is naturally occurring and exhibits a form of MD similar to Duchenne MD (DMD), the most severe form of MD. These mice are being used to develop gene therapies to slow or reverse progression in DMD; although at a very early stage some of these therapies are now undergoing clinical testing in patients.

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What would happen if the Directive was repealed and research involving animals was banned across Europe?

Undermine progress in improving human and animal health. Around half the diseases in the world still have no treatment. Vital medical and veterinary research, from understanding the complex processes of the brain to unraveling the genetics of cancer, would stall if responsible use of animals in research was banned across Europe. No new medicines, treatments and vaccines could be brought to market without changes to safety testing legislation and alternative means of testing safety.

Compromise animal welfare. Many welfare provisions brought in by the Directive, including increased protection for primates[1], a ban on the use of Great Apes[2] and stray and feral animals[3] would be lost if the legislation was repealed. As would the newly introduced ethical review, benefit-harm evaluation, a detailed severity scale to assess the impact of procedures on animals and defined euthanasia methods, training and competence requirements for staff working with animals and enhanced housing conditions, all of which have had a positive impact on the welfare of animals used in research.

Damage Europe's leading role in biomedical research and create disparity. Confusion and uncertainty regarding the regulatory framework for undertaking research using animals in Europe would seriously undermine Europe's attractiveness as a location for scientific research. As such this research may be moved overseas where animal welfare standards and protection for research animals is lower. Not only would this undermine Europe's role in biomedical research, it would be bad for animal welfare.

Safe medical products

Currently toxicology safety assessments can only be performed on whole animals. This is because therapeutics can interact in many places throughout the whole body, and effects upon one process can cause unexpected consequences in others. Currently, this complexity cannot be mimicked by non-animal methods on individual parts of the body. Toxicology testing is not only scientifically essential; it is also a legal requirement to ensure the safety of medicinal products used by patients .

[1] Article Articles 4 and 13 are specifically included with the aim of encouraging the use of other procedures where possible. As explained in the accompanying Q&A, "wherever possible" is in relation to the scientific satisfaction of the method.
[2] Article 38.1.b and Recital 39: Research involving non-human primates requires rigorous evaluation, which is open to challenge, and explicit justification as to why other species cannot be used.
[3] Article 55.2: Other than for preservation of the species or an unexpected outbreak of a life-threating disease in humans

> **The Directive provides one of the most progressive and stringent frameworks worldwide for the protection of animals used in scientific research.**

Why do we support the Directive?

The Directive provides one of the most progressive and stringent frameworks worldwide for the protection of animals used in scientific research. It has reduced disparity across the EU by raising the minimum standard as well as introducing the concepts of refinement, replacement and reduction, for the benefit of animal welfare and biomedical research.

Extensive and rigorous discussion took place between a wide range of stakeholders, including animal welfare groups, before adoption of the Directive in 2010. The new directive updated and strengthened the predecessor directive on animals in research (86/609/EEC). It will be reviewed in 2017 as part of the EU's normal legislative review process.

The Directive places an explicit obligation on licensed researchers to adopt the '3Rs':

Reduction - using fewer animals to achieve the same scientific goals. The Directive contains measures to ensure the principle of reduction is upheld, including re-use of animals where appropriate and considerations of animals welfare have been taken into account, including consideration of cumulative effects.

Refinement - optimising the welfare of animals. Specific provision for animal housing and handling is made. Appropriate anesthetics and analgesics must be used for all procedures, including those which use neuromuscular blocking agents.

Replacement - using non animal alternatives where available. The Directive specifically mandates the use of alternatives to live animals where they are available and scientifically suitable[4], and places no limitations on what alternative methods can be used, allowing novel alternatives to animal testing to be adopted as soon as they are deemed appropriate for use. Replacement also extends to using animals of lower sentience, for example rodents and fish rather than non-human primates and dogs.

Replacing animals to study solid cancers in children

Treatment of these deadly cancers in children remains extremely difficult, they spread and are often resistant to conventional therapies. There is a major clinical need to develop new drugs for these and other types of cancer. Preclinical testing of potential therapies is usually done in 2D cell cultures before animal models. However 2D models of solid tumours are limited in this use as they do not fully reflect in-body conditions, such as the difficulty of getting drugs into the centre of these cancers. Researchers have developed 3D models of cancer cells, which closely mimic the in-body conditions of these cancers. These 'micro-cancers' can now be used as a more comprehensive screening tool to aid the development of new drugs, reducing the number of potential therapies being tested in animal models.

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