



Our position on Responsible Care and Use of Animals



What is the issue?

To get ahead of disease we must continue to discover and develop new vaccines and medicines - all of which must be studied and tested to ensure that they work and are safe for patients.

Technological advances such as computer modelling, isolated cells, tissues, and complex *in vitro* models means that much of our research can be done using non-animal methods. However, at this moment in time these methods do not always provide the exact insight our scientists need to determine how a potential vaccine or medicine affects disease mechanisms or biological systems.

Studies in animals are therefore still needed. Humans are biologically similar to other mammals, with most of the same organs performing similar functions and controlled by comparable mechanisms, such as the circulatory, nervous and immune system. Research in animals is needed to provide data expected by regulatory authorities around the world to support whether a medicine or vaccine is safe and effective.

We recognise animal use is a sensitive subject that presents concern and ethical dilemmas. This paper sets out our view on current and future approaches to animal use and our commitments and responsibilities to ensuring high standards of care, welfare and treatment for animals involved in research and development (R&D) and Quality Control.

What is GSK's view?

- GSK would like to see the health benefits of R&D achieved and applied to humans without the need for animals. However, the journey towards this goal must always be driven by scientific evidence. Many factors must be considered, including different approaches and limitations across different therapy areas, indications, and drug modalities; further development, characterisation, validation, and refinement of new technologies; and how regulatory frameworks can facilitate use of alternative methods of research.
- GSK is committed to the replacement, reduction, and refinement of animal studies (3Rs). We work to develop and validate experimental methods that can provide alternatives to the use of animals. Wherever possible, we use these alternatives.
- For now, animal studies remain a small but vital part of our work. Currently, they are the only method that can show the effects of a potential new treatment or intervention in a complex living organism. Safety studies are required by regulatory authorities before approval of a compound in clinical trials or licensing of a new medicine for use in humans. Currently, not all safety considerations can be adequately answered in alternative models for several reasons which include the prolonged study time, the complexity and interdependence of the body systems involved, metabolic considerations of the materials being tested, and other logistical challenges that are not adequately assessed by non-animal methods.
- GSK is fully committed to high standards of humane care and treatment for animals. Our internal company-wide policy defines expected practices for the care, welfare, and treatment of animals, irrespective of whether our studies are conducted in GSK facilities or by partner institutions.

Our commitments and responsibilities

Reviews

The need for animals to be used in a study is carefully considered and determined after a scientific and ethical review, and/or by regulatory requirements that also include an ethical review. Reviews are carried out by experienced GSK scientists such as veterinarians, biologists, statistical experts and representatives of the public.



The 3Rs

We apply the 3Rs of 'replace', 'reduce', and 'refine' each time we consider the need for animal testing. Through discussion, ethical debate and independent scientific review, GSK seeks to replace animal studies wherever possible. For example, we are expanding the use of CIVMs (Complex In Vitro Models), which include "organ on a chip" and microphysiological systems, as an alternative to using animals. We also aim to reduce the animal numbers required per study and refine the study paradigm to reduce pain and distress animals experience during our studies. We work closely with regulatory authorities to eliminate or reduce the need for animals in batch and stability testing.

Alternatives

GSK is actively engaged in efforts to develop and validate experimental methods that can provide alternatives to the use of animals in research and quality control. Human-derived models are used extensively to address questions on the effectiveness and the safety of potential new medicines and vaccines. Such approaches are valuable in early work on new drug targets, evaluating how potential medicines work and in predicting toxicity.

GSK recognises that continued development and investment is required to advance animal alternatives and is actively involved in Public Private Partnerships and Trade Associations to develop and progress advanced human-based methods.

Standards

GSK commits to high standards of humane care, welfare, and treatment for all animals in our laboratories. Veterinarians are employed to ensure robust veterinary care programmes exist at all research sites, and all staff carrying out procedures and caring for animals undertake specific training. Every site, independent of ownership by GSK or country location, must meet our principles on the care, welfare, and treatment of animals.

Staff

Every GSK staff member working with animals is specially trained to understand the behaviour and needs of specific animals and the science of the study. Every facility has veterinarians designated and trained in laboratory animal medicine.

Animals

Our work in the discovery, development, and testing of new treatments (including vaccines), is mostly done in rodents (mice, rats, and guinea pigs). Some rodents are genetically altered to be more closely aligned with human diseases. This work is only carried out once the required ethical and scientific reviews have been completed. Other animals that GSK uses include dogs, rabbits, pigs, poultry, fish and Non-Human Primates (NHPs).

All our animals are bred specifically for laboratory use. Animals are sourced from providers approved by welfare regulatory bodies/agencies and/or accreditation bodies such as [AAALAC International](#).

We pledge to never use great apes.

Genetically altered animals (GAA)

GAA animals (rats or mice) are only used when scientifically validated. As with all animals we have, the care, welfare and treatment of GAA animals is provided by trained staff, including veterinarians.



Non-Human Primates

We still need to use Non-Human Primates (NHPs), but this research is kept to an absolute minimum, and are only used when scientifically necessary, for example a new medicine may be based on a target produced only in primates, including humans, and studies would not be viable in other species.

We have species-specific practices and housing environments in place designed to allow for normal behaviours, such as climbing and swinging. In addition, staff are specifically trained in NHP behaviour and the provision of species-specific housing, acclimation and care.

Cloning

We pledge never to clone animals. For more information see our policy on cloning, available on [gsk.com](https://www.gsk.com).