

FAQs on Animal Research and Testing

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Animal Research: Reasons & Rules

1. What is the industry's position on animal research from an ethical perspective?

Whether or not it is ethical to use animals in pharmaceutical research is a complex issue with no easy answers.

It is a fact that animal research saves (human and animal) lives. While most of us are committed to avoiding unnecessary suffering of all living beings, research shows that for a large majority of people, human health and well-being come first. In consequence, we have to accept that it is impossible to create new or more effective medicines without using animals, at least for the foreseeable future. For ethical reasons, it is essential that we use as few animals as possible and avoid all unnecessary distress.

2. Is animal research really necessary?

Many serious diseases (such as, Alzheimer's disease, Parkinson's disease, hepatitis, cancer, cardiovascular diseases, and diabetes) are not entirely understood, with treatments being far from ideal. Therefore, new and more effective therapies and diagnostic tools are needed to improve the quality of patients' lives.

Before human clinical trials for new medications can be conducted, regulatory bodies worldwide require efficacy and safety data based on animal experimentation. This safety testing in a living organism prior to approval for use with human beings helps to minimize the risks for patients in clinical trials and beyond. Pre-clinical testing is aimed at closely

mimicking the functioning of a human body in a whole organism, so that clinical trials may be conducted with maximum safety and efficacy.

The rationale for the use of animals as a surrogate model for humans is based on years of basic scientific research that has identified (sometimes even near identical) genetic, cellular, and physiological similarities in drug targets and physiological responses to medicines between animals and humans. Approximately 70% of severe adverse effects that would occur in humans are identified during the animal testing stage. The results of animal research enable researchers to determine which experimental compounds in advanced development are unsuitable for use in humans (~30-40%) – either because the risk of potential toxicity is too great, or because they don't show the desired pharmacokinetic profile, thus likely rendering them ineffective.

Therefore, animal testing is extremely beneficial in minimizing the risks to humans in clinical trials. Alternatives are used whenever possible.

3. How can results from animals be applied to humans?

Humans are biologically very similar to other mammals. All mammals, including humans, have many of the same organs (such as the heart, lungs, kidneys, and liver), and these same organs perform the same functions and are controlled by the same mechanisms, e.g., the blood stream and nervous system. However, there are also some differences which, from a scientific perspective, can be actually helpful sometimes. For instance, the revelation of why certain animals do not suffer from a human disease could lead to a new idea for a treatment.

4. What is the contribution of animal research to advances in medical science?

Animal research has played a vital role in virtually every major medical advance of the last century for human and animal health. Be it antibiotics or blood transfusions, dialysis or organ-transplantation, vaccinations or chemotherapy, bypass surgery or joint replacement – practically every present-day procedure for the prevention, treatment, cure and control of disease, pain and suffering is based on knowledge obtained through research with animals.

Ample proof of the success of animal research can be found in the range of Nobel-Prize winners in physiology and medicine. Seven of the last ten awarded discoveries in medicine relied at least in part on animal research. The use of animals was crucial in many discoveries made in drug development and biomedical research: monoclonal antibodies, antibiotics, anaesthesia, vaccines, and tissue culture.

5. Are there concrete examples of Roche pharmaceuticals where very important results were based on animal research?

Animal research has enabled Roche to discover and develop new anticancer medications (Mabthera and Herceptin, for example) which are both far more effective as well as better tolerated than conventional chemotherapy therapies.

Animal research also showed that Accutane/Roaccutan, a medicine used to treat disfiguring skin diseases, is highly likely to cause birth defects. As a result, doctors are aware of the dangers in prescribing the drug to a pregnant woman.

Without animal research, Roche could not have developed modern, highly effective AIDS medications with an acceptable safety profile (such as Invirase, Fortovase, Viracept and Fuzeon) that enhance the quality of life of many AIDS patients. The same applies to CellCept, the leading medication for preventing rejection reactions in patients who received organ transplants.

6. Which requirements & standards does Roche fulfil in animal testing?

Roche is committed to act ethically and to apply high standards of care and use related to animals.

Our company complies with international rules, such as the ones developed by:

- the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Guidelines)
- the Organization for Economic Co-operation and Development (OECD)
- the Council of Europe (European Convention for the protection of vertebrate animals used for experimental and other scientific purposes, ETS 123)

Moreover, there is a number of regional (e.g., the EU Directive on animal welfare, 86/609; Public Health Service Guide for the Care and Use of Laboratory Animals, and the Animal Welfare Regulations of the US Department of Agriculture), national, as well as local laws and regulations. They are applied in the various countries where Roche operates.

7. Does Roche also apply other standards?

Industry standards also govern the use of animals in laboratory research and testing. For example, the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) accredits research animal care and use programs.

Within Roche, all Pharma research sites have received accreditation from AAALAC, International, and the goal is to have them maintain accreditation in the future. AAALAC enhances life sciences by promoting the responsible treatment of animals used in research, teaching and testing through voluntary accreditation and assessment programs.

Finally, Roche has developed [Principles of Care and Use](#) in order to ensure that every Roche employee working with animals acts ethically and with respect for the animals in their care. These standards require compliance with the existing laws, regulations, and guidelines, going the extra step to achieve excellence in animal care and use, as well as the implementation of alternative methods to animal research (the so-called 3Rs, see questions 23 et. seq.). These standards apply to the use of animals during experimentation, to their housing and care, to the training and education of the personnel involved in their care and use, and to the conduct of the investigative staff.

8. How is the correct application of laws and standards controlled?

In order to ensure that animal tests conducted by Roche and its contractors comply with laws and standards, Roche has internal control processes, conducted either by an internal committee (institutional animal care and use committees, which include one to two external community members not affiliated with Roche) or by an animal welfare officer (Switzerland, Germany). In the US, the institutional animal care and use committee's responsibilities include maintaining compliance with the Animal Welfare Act, regulations, and standards, in addition to internal and other established animal care guidelines. In Europe, the animal welfare officers cooperate closely with approval authorities and/or external ethics committees. In several countries (e.g. Switzerland, Germany), animal welfare organizations are represented on the external ethics committees.

Moreover, the company's behavior is controlled regularly by external bodies. In order to maintain the accreditation of the AAALAC, Roche has to deliver annual reports. In addition, evaluation teams of the AAALAC visit the research sites every three years and review their procedures, including animal care and use policies and responsibilities, the environment and enrichment the animals receive, housing and management, as well as veterinary medical care.

Roche also fully supports and complies with unannounced inspections of their facilities by regulatory agencies (e.g., the USDA), which issue sanctions whenever rules are breached. Additionally, there are internal regulatory compliance procedures that require staff members to report concerns about animal welfare or mistreatment of animals, protecting them from reprisal.

9. What is Roche's relationship with contractors and how do you know that the animal testing conducted at the contract laboratories you use is being conducted humanely and in compliance with the law?

Roche works with various external contractors in the field of animal testing. In the interest of a fair and competitive business environment, Roche does not disclose the names of those vendors

Since the proper care and use of laboratory animals is of fundamental importance for Roche, contract laboratories are pre-qualified prior to starting a collaboration. For example, in the United States, one of several requirements is that the contract laboratory have an attending veterinarian, as well as their own animal care and use committee that reviews all research proposals in compliance with all applicable laws and regulations. For non-clinical safety studies, Roche has internal teams with the specific obligation to monitor contract laboratories during the conduction of animal studies. These teams include trained personnel from the non-clinical safety department and the research quality assurance group. In addition, members of the laboratory animal resources department inspect the animal facilities of contract laboratories. Recently, Roche has developed a global audit checklist that the Roche laboratory animal personnel uses for evaluating the contractors and animal vendors. This checklist allows us to standardize assessment criteria and quickly determine if they are in compliance with the relevant animal welfare regulations.

Animals Use & Care

10. What types of medicinal research use animals?

- **Basic research** helps advance our scientific knowledge about how animals and humans behave, develop and function biologically. Basic research tends to be publicly funded with some private funding from industry and medical research charities. In the EU, for instance, basic research accounts for approximately [35%](#)¹ of all animals used for research purposes.
- **Translational research** furthers our scientific understanding of diseases and facilitates the transition of research findings from “bench to bedside.”. This type of research is both publicly and privately funded and translates, or puts into use, the discoveries obtained from basic research. Translational research is the second largest area where animals are used. In the EU this accounts for approximately [28%](#)² of animals used for research purposes.
- **Quality and safety research** (e.g., toxicological studies) tests pharmaceutical compounds and medical devices for adverse reactions in animals, prior to testing in humans. This research is required by North American and European legislation and international guidelines. In the EU, [16%](#)³ of all animals used are for safety and quality testing of human and veterinary vaccines.
- A further 10% of animals are used in **toxicological or other product safety evaluations**. Of these 10%, more than half of the animals are used for medicinal testing, with the remainder used to obtain quality and safety data from household and industrial chemicals, herbicides, fertilizers, and food additives. Quality and safety tests are usually funded by private organizations.

11. What kinds of animals does Roche use?

We use primarily mice and rats. These species comprise more than 95% of all laboratory animals used by Roche globally. The remaining 5% include dogs, rabbits, guinea pigs, and non-human primates (marmoset, squirrel monkey, and cynomolgus).

12. Does Roche use pound or shelter animals?

No, Roche does not use pound or shelter animals. Roche purchases all animals from selected vendors who breed them specifically for research purposes.

13. Does Roche breed animals for research?

¹ http://ec.europa.eu/environment/chemicals/lab_animals/pdf/com_2005_7_en.pdf

² Loc. cit. fn.2

³ Loc. cit. fn.2

Roche purchases all animals from professional breeders, the only exception being specific rodent strains that aren't commercially available (e.g. transgenic mouse strains).

14. Why must non-human primates be used in biomedical research?

As independent reviews confirm, there is a moral and scientific case for the carefully justified use of non-human primates in research.⁴

The areas of biomedical research where usage of primates cannot be completely replaced include several vital research programs on infectious diseases (such as HIV, Malaria, TB, Hepatitis, SARS, Influenza), neuro-degenerative disorders (Parkinson, Alzheimer, etc), mental disorders (schizophrenia, depression, etc.), immune based diseases (diabetes, multiple sclerosis, immunotoxicity, allergy) and on oncology (monoclonal antibodies), which is of particular importance for Roche.

The main use of non-human primates, accounting for over 90% of the total use, is to evaluate the efficacy and safety of certain drugs and vaccines, prior to the testing in humans. These studies meet the needs of regulatory authorities worldwide (for example the European Medicines Evaluation Agency and the U.S. Food and Drug Administration). The Roche Group has been developing treatments specifically designed to mark particular molecules in the human body and thus block their disease-causing effects for years. Such therapies are called monoclonal antibodies (MABs). As those MABs are very species-specific, negative and / or positive effects must be shown by testing the substances in organisms which are as close as possible to the human body, i.e. in non-human primates.

The remaining 10% of the non-human primates used involve basic research to advance human knowledge, such as the study of the nervous system, including the brain, and infectious and brain disease studies.

15. What would happen if non-human primate use was banned in parts of the world?

Banning the use of non-human primates (in Europe, for example) will not stop this type of research. It simply means that the research will be conducted outside of Europe. While global companies can influence the standards of their research sites in those countries, they can't necessarily influence the regulations themselves.

If (non-human) primate research was banned globally, there would be areas of greater medical need that could not be met. The reputational, regulatory, logistic, and cost barriers to using non-human primates in research are high; nevertheless, regulatory requirements and overwhelming scientific need mean that their use remains essential. Therefore, until alternatives to using non-human primates are found, they will remain a vital part of the discovery and development of new medicines.

⁴ E.g. the 2007 Weatherall Report

16. How do you know that animals are not experiencing pain and distress?

Most research involves only slight or momentary pain such as taking blood samples, giving a single injection, or having a change of diet.

However, just as humans might experience pain and distress caused by a disease, a research animal serving as a model for a disease might experience the same. If more invasive procedures are necessary, anesthetics and/or pain relieving drug are given in nearly all cases – unless their application would endanger the scientific validity of the experiment.

Animal welfare is a of vital importance, with trained animal technicians looking after the animals under the supervision of veterinarians. All research, pain minimizing measures included, is closely scrutinized before approval is given, and monitored afterwards by animal care and use committees and/or animal welfare officers. Each project submitted for approval includes a detailed explanation of the animal research purpose, the likely effects on the animals, and why the research cannot be done using other methods. It is in the researchers' own interest to ensure that pain and distress is minimized - not only because it's ethically the right thing to do, but also because unnecessary pain and distress would compromise the reliability and reproducibility of the research results. The prevention of undue suffering is the main task for animal welfare officers as well as animal care and use committees.

17. What does Roche do to reduce the pain and distress of animals?

This issue is addressed in every animal research proposal before the research is approved either by the Roche Institutional Animal Care and Use Committee (IACUC) or the approving state authority (Switzerland, Germany). Any animal research proposal that may potentially cause pain or distress in animals must be scientifically justified, including an assurance that alternatives to this painful proposal are not available. This assurance includes a review of the literature to determine that there is no other alternative to the use of animals. Similarly, every animal research proposal must have an assurance that the proposal does not unnecessarily duplicate other animal research.

18. Does Roche administer anesthesia to animals?

Anesthesia, analgesia and/or tranquilization are utilized whenever possible, except in specific circumstances when this would interfere with research results. For surgical procedures, anesthesia is always administered.

19. Why might a few procedures be carried out without anesthetics, or analgesics?

Most procedures cause no pain (or only slight and momentary one), meaning that they wouldn't require the administration of a general anesthetic or analgesic. For example, an

injection, the oral administration of a medicine or the taking of blood would not warrant the use of anesthetics or analgesics in animals any more than it would in people.

The regulations require that any pain or distress have to be prevented or reduced to the minimum amount possible given the nature of the research. This is realized, for instance, by using analgesics (i.e., pain killers), as well as by ensuring that those doing the research have all the necessary skills to perform procedures in a way that causes as little distress as possible and, in the case of surgery, results in a favourable outcome.

20. What happens to an animal at the end of an experiment?

At the end of a study, most animals are euthanized. This allows for a full examination of their tissues, which is necessary to see details of the effect of the compound being tested. Many of the non-rodent species that are used for drug metabolism or behavioral studies are re-used following a “washout period”, once the compound they received has been fully metabolized and excreted. These types of studies involve the administration of compounds at dosages that are unlikely to cause adverse effects while still providing useful information regarding pharmacokinetic and/or behavioral effects, with all procedures that are performed (i.e., injections, blood collection, etc.) judged as non-painful.

21. If scientists behave within strict guidelines, why do animal rights groups have pictures and videos of alleged misconduct and animal suffering?

A lot of the pictures displayed by animal rights groups aren't examples of current practices; instead, they represent examples of outdated methods that are no longer considered acceptable by the scientific community. Furthermore, many are taken out of context, and are edited to illicit a negative public response about animal research. Such practices are unacceptable and undermine any trust between researchers and animal rights groups because they obstruct the pursuit of an open and factual discussion about animal research.

Researchers are concerned about the welfare of all animals they use, and their concern is both humane and scientific. They have no excuse to mistreat research animals, and many reasons for treating them well because the use of unhealthy, stressed or frightened animals reduces the reliability of experimental results. The veterinary staff is responsible for ensuring that research animals are well fed, free of infections and other illnesses and kept in an appropriate environment .

22. Is Roche willing to have a dialogue with animal welfare organizations?

Of course. Roche considers constructive dialogue to be a crucial point in this complex issue and has regular contacts with animal welfare organizations. We take public concerns about using animals in scientific procedures very seriously.

Alternative Testing: Research & Application

23. What are the alternatives to using animals?

Alternative methods refer to three categories which are known as the **3Rs**:

- Replacement
- Reduction
- Refinement

Replacement is how most people interpret the term "alternatives to animal testing": research animals are replaced by using either methods that don't involve animals at all (absolute replacement) or by methods that use only the cells or tissues of animals (relative replacement). Many replacement alternatives involve these in vitro ("in a test tube or artificial environment") techniques, where studies are done with cells or tissues in culture.

Other replacement alternatives include cell and bacterial cultures, computer simulations, mathematical modeling and the use of isolated animal organs. These methods are very useful for studies on particular types of tissue and help to considerably limit the number of animals used in experiments. However, irrespective of their level of sophistication, these methods are not able to simulate the complexity and level of coordination and integration of an entire organism with all its cells, tissues and systems working together.

Unfortunately, replacement alternatives are not always an option. For the foreseeable future, any research that has reached a certain stage will require studies of the whole living organism in order to acquire as much information as possible about a potential new medicine before taking it into human clinical trials.

In these cases, researchers still can work to reduce the number of animals used in a given study. With careful experimental design and sophisticated statistical techniques, it is often possible to significantly reduce the number of animals needed for a study while still getting valid results (reduction). If reduction is not possible, there is still the option to refine existing testing procedures by decreasing any potential for suffering and continuously looking for advancements in husbandry and animal care practices (refinement).

24. Did alternative methods lead to a significant change in the number of animals used for research?

Yes. As the following examples show, the number of experimental animals required for research has already been significantly reduced:

- In the EU, the number of animals needed for research declined from 11,646,130 in 1996 to 10,731,020 in 2002, which marks a decrease of roughly 8% in six years.⁵
- The statistical data in Switzerland (industry and academia) show that the number of research animals has been reduced by over 70% since 1980.⁶ This includes figures from Roche where we can see a similar evolution.

⁵ http://ec.europa.eu/environment/chemicals/lab_animals/pdf/com_2005_7_en.pdf

- In the US, for species covered by the Animal Welfare Act, the total number of animals used by research in FY (Fiscal Year) 1973, versus research animals used in FY 2006, has decreased by 33%.⁷

25. Which alternative methods are implemented at Roche?

Roche is dedicated to implementing the 3Rs (i.e., reduction, refinement, and replacement). Where regulations allow, and where it is scientifically possible and ethical, Roche employs medical testing procedures that do not require animals.

Alternative techniques are incorporated wherever possible, and we continue working on projects designed to identify compounds with specific therapeutic action. We also discontinued the screening of large numbers of compounds on various species of animals, a technique that was much more prevalent in the past. Roche continues to improve upon and uses automated *in vitro* screening methods to identify promising compounds before they are ever tested in animals. These screening methods help us ensure that the compounds that end up being tested in animals are much more likely of being made into useful new pharmaceutical products. *In vitro* screening as well as other alternative methods prevent a lot of animals from being used to test compounds in the early phases of development.

In addition, all Roche research sites implemented a computer program that predicts the absorption of active substances in humans without animal tests. The program utilises data on solubility and cell permeability.

Determining whether a drug is safe without the aid of animal tests is a major scientific challenge due to the complexity of the processes involved. Roche is a worldwide promoter of computerised techniques for determining pharmacokinetics and tolerability using data from cell tests and clinical studies in humans.

26. Does Roche actively support the development of new alternative methods?

Yes. Around the world, Roche is supporting the development of experimental models that will help replace animal tests both during and after the initial screening phase. One of the objectives of Roche's global Multidimensional Medicines Optimisation programme is to develop new cell-based tests producing results that can be reliably applied to humans.

Roche is also at the forefront of research in toxicogenomics, a technology that will enable us to use information on genetic predispositions to determine drug tolerability – with the promise of reducing the need for some animal toxicology testing in the future.

⁶ <http://www.bvet.admin.ch/tv-statistik/Jasta-05/D/31/Grafik.html>

⁷ <http://www.aphis.usda.gov/>

Roche's latest effort to advance alternative methods is the internal global "3Rs-Award," launched in March 2008, which includes a financial award for the applicants. The aim is to increase awareness among Roche employees and scientists about the 3Rs, to encourage the discovery of alternative methods, and to make Roche a more innovative and productive company. 24 applications were made from all Roche Pharma research sites, Basel, Nutley, Penzberg and Palo Alto. This high global participation demonstrates Roche's steadfast commitment to work on the 3Rs. The first place in the Laboratory Animal Care category was given to a team working on a project that minimizes stress and helps assess behavioral problems in nonhuman primates. First place in the Scientific category went to a team that developed new in vitro screening methods for projects with bone marrow toxicity concerns.

We are also working with external organizations to introduce techniques that will further reduce the number of animal experiments. For example, Roche was a founding member of the Swiss 3R Foundation, which we continue to support. The goal of the foundation is to reduce animal testing by funding research projects for new methods in line with the 3R principles of reduction, refinement and replacement. Moreover, Roche participates at the European partnership for Alternative Approaches to Animal Testing (EPAA), aimed at promoting the development of new 3R-based methodologies and modern alternative approaches to safety testing in Europe.

27. How long will it take to develop and validate alternatives?

Nowadays, researchers are continuously striving to improve the alternative techniques and processes in use. The overwhelming majority of R&D expenditure by the pharmaceutical industry goes towards non-animal methods. Many alternative methods employed in non-regulatory areas are used in the R&D process as soon as they are developed.

Different criteria apply to the field of regulatory testing. Here, testing methods are used for getting the market authorization of a product. In order to be accepted by regulators, the development of an assay has to be followed by a scientific validation process. Altogether, a process like this can take more than 10 years.

28. Should there be more data sharing to minimize duplication of animal experiments?

The pharmaceutical industry is involved in applied research (toxicology and safety evaluations, research & development, production and control of human and veterinary drugs and vaccines), usually performed on novel patented compounds. Therefore, the likelihood of duplicated experiments is fairly small.

Consequently, full open disclosure prior to publication won't have much of an effect on the number of research animals, yet it would endanger the competitive base of companies and academia. This being said, the industry supports pre-competitive data sharing. It has been realized for large projects such as the Innovative Medicines Initiative, and it is also implemented in cases such as the sharing of information on non-active substances.

There are also other mechanisms established to avoid the duplication of animal tests, such as the publication of peer-reviewed research in scientific journals and presentations at conferences.

2. Useful Links

Ethicalposition:

<http://www.nuffieldbioethics.org/fileLibrary/pdf/NuffShortReport.pdf>

http://www.nuffieldbioethics.org/go/browseablepublications/ethicsofresearchanimals/report_304.html

<http://www.aaalac.org/>

Standards of Care and Use:

http://www.roche.com/ar_principles.pdf

Results from Animals applied to humans:

<http://www.medicalprogress.org/uploads/docs/UHanimalsFINALsmall.pdf>

Medical Research through Animal Research:

http://www.rdsblog.info/index.php/weblog/bmj_vote_for_top_medical_milestones/

<http://www.pro-forschung.de/impressum/impressum.php>

Types of Research:

http://ec.europa.eu/environment/chemicals/lab_animals/pdf/com_2005_7_en.pdf

Animals used:

www.efpia.eu

<http://www.bvet.admin.ch/themen/tierschutz/00777/index.html?lang=de>

<http://www.bvet.admin.ch/tv-statistik/Jasta-05/D/31/Grafik.html>

http://ec.europa.eu/environment/chemicals/lab_animals/pdf/com_2005_7_en.pdf

http://ec.europa.eu/environment/chemicals/lab_animals/pdf/sec_2005_0045_1.pdf

Non-Human Primates:

http://www.nhpstudy.com/NHP_Study-Final_report.pdf

<http://www.nhpstudy.com>

http://ec.europa.eu/environment/chemicals/lab_animals/pdf/sec_2005_0045_1.pdf

http://ec.europa.eu/food/fs/sc/ssc/out253_en.pdf

Risks through stopping Animal Testing:

http://ec.europa.eu/health/ph_risk/committees/sct/documents/out217_en.pdf

Alternative methods:

<http://altweb.jhsph.edu/>

http://ec.europa.eu/enterprise/epaa/index_en.htm

www.efpia.eu

<http://ecvam.jrc.it/index.htm>

<http://www.forschung3r.ch/en/information/index.html>

Data sharing:

http://www.nuffieldbioethics.org/go/browseablepublications/ethicsofresearchanimals/report_432.html