

Animal Welfare Report 2022

Association of research-based
pharmaceutical companies

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Foreword



Dr. René P. Buholzer
CEO Interpharma

“Control rather than ban” is one of the tried-and-tested principles of Swiss research policy. On 13 February 2022, 79 percent of voters demonstrated their support for this principle by resoundingly rejecting the popular initiative to ban animal and human testing in a referendum. Swiss voters have recognised the importance of animal research in developing new medicines and vaccines. By doing so, they have clearly signalled their support for Switzerland as a competitive research hub.

Despite this commitment to medical research, it is still important to keep improving animal welfare. Our members are constantly working to develop new research methods, to minimise the number of animal experiments they conduct and to constantly improve the methods they use so that animals are exposed to as little stress as possible. The 3Rs principles of replace, reduce and refine are the undisputed basis for animal experiments in Switzerland today.

Responsible approach to animal use

Despite this, the fact remains that animal experiments are still essential for researching ubiquitous diseases such as various forms of cancer, multiple sclerosis and Alzheimer's disease, and in developing new treatments. A large number of patients rely on effective treatments to crucially improve their quality of life. It is therefore important that pharmaceutical companies give top priority to responsible animal use and actively implement the 10-point Animal Welfare Charter adopted by member companies of Interpharma in 2010.

One of our core topics for this year – “Animals travelling from breeding facility to laboratory” – addresses a good example of this. The article on the subject highlights vividly what research-based pharmaceutical companies are doing at a practical level to take account of animal welfare, including in their dealings with breeders and transport companies.

We hope you will find our Animal Welfare Report 2022 interesting reading.

Essential animal experiments and transferability of the results to humans

Breakthrough innovative medicines and treatments are partly the result of animal experiments. Given the biological similarities between humans and animals, it is possible to transfer the results of experiments.

In pharmaceutical research, animal experiments take place in the preclinical phase of the long path that leads to a market-ready medicine. It usually takes many years to reach this stage. Researchers generally test hundreds of thousands of substances before they find one with the potential to inhibit or positively influence the course of a particular disease.

At first, the experiments in this journey of discovering new active pharmaceutical ingredients (APIs) involve solutions and cell cultures. Animal experiments only take place once certain conditions have been fulfilled. They are used to determine how the drug candidate is metabolised by the organism and if it produces detrimental effects.

Only when a substance has successfully completed all the prescribed preclinical trials – in other words, once it has been shown to be safe and effective in cell cultures and animal experiments – can it be tested in clinical trials in humans. Why only then?

Ethics and safety

The international community has committed to ethical and legal principles for human research by adopting various reports and declarations. For example, the World Medical Association's Declaration of Helsinki of 1964 states that the testing of new treatments must protect the health and interests of the people taking part in research. The Declaration of Helsinki became and remains the basis of many countries' legislation on biomedical research. Accordingly, clinical trials involving a small number of healthy volunteers and subsequent trials in patients are only permissible today if the associated risks have been minimised or can be excluded.

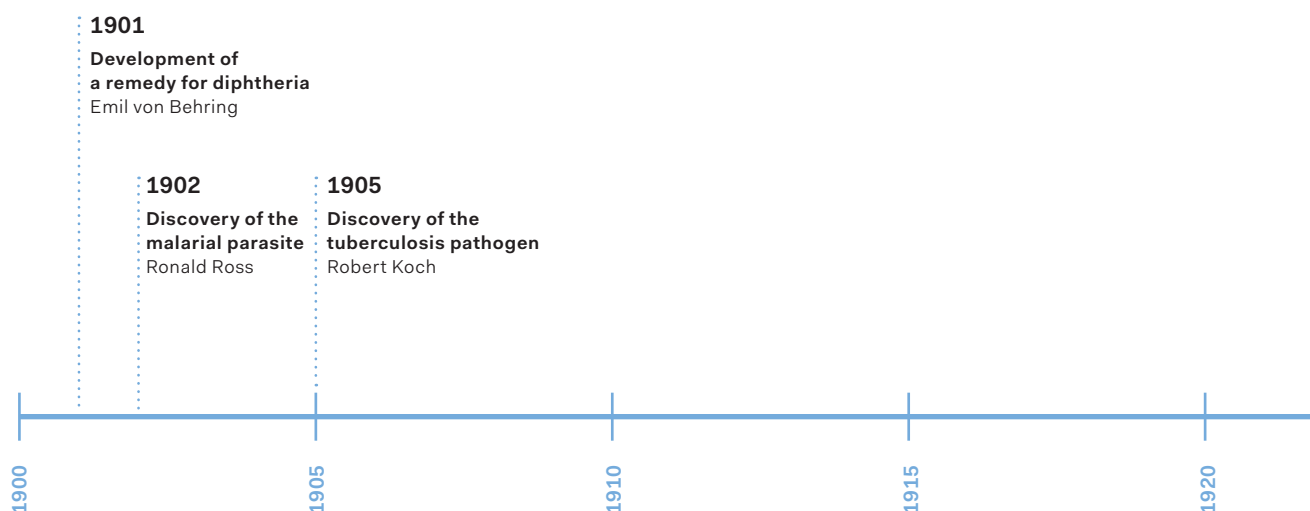
Ethical principles applicable for human research

1. The Declaration of Helsinki (1964) describes the balance that has to be struck between the need to obtain reliable medical knowledge and the need to protect the health and interests of the people taking part in research.
2. The Belmont Report (1978) sets out moral principles, such as respecting human dignity.

This means that as much as possible has to be known about the safety and efficacy of a new API before it enters clinical trials in humans. To ensure this is the case, animal experiments are still prescribed in addition to methods that do not involve animals, such as cell and tissue cultures, computer simulations or what is known as organ-on-a-chip, which reduce or partially replace animal experiments. One of the aims of animal experiments is often to identify the harmful effects of a new API at an early stage. Ensuring the animals' well-being to the maximum extent possible is a priority in such cases.

Alternative methods that do not involve animals, such as those mentioned above, are now commonplace in biomedical research. They are frequently used for biological systems that have already been extensively researched.

A list of Nobel Prize winners shows the importance of animal experiments in research.



Same structures and physiological processes

The process of programmed cell death plays an important role in the development of various diseases, including cancer. In 2002, the process was even found to exist in nematodes, tiny organisms just a few millimetres in length.

When there aren't enough volunteers

In addition to basic ethical considerations, one of the reasons researchers use animals for experiments is because humans are not always ideal subjects for investigating biomedical issues. Organisms that reproduce quickly, such as zebrafish or mice, are more suitable, particularly for researching hereditary diseases.

There are often insufficient human volunteers for scientists to be able to research the genetic, physiological or anatomical causes of many rare diseases. This means that animal experiments are needed to gain an understanding of the disease or to develop APIs to treat it. But why are experiments involving animals even suitable in the first place?

Evolutionary kinship

Every medicine, every treatment and almost all medical devices that are used worldwide to alleviate disease or help

patients recuperate were developed with the aid of animal experiments. There are various reasons why animal experiments are necessary to research diseases and develop new medicines and innovative treatments. One key reason is that such research is by its very nature biology-driven.

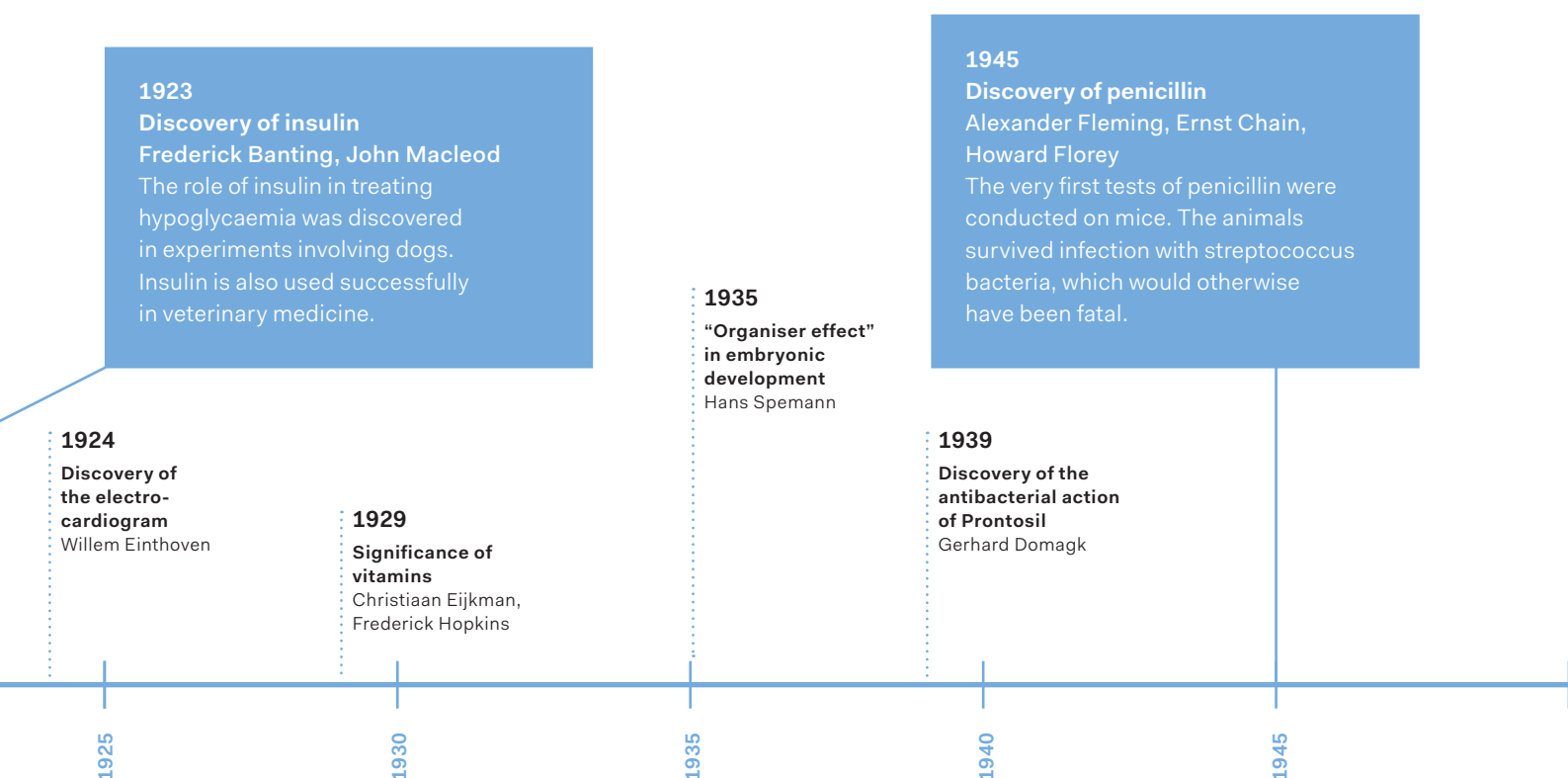
Basic biological research is impossible to conduct without living organisms. Without biological research involving living organisms, we would not now know how animals survive in their environment, for example, and what they need to do so. This knowledge also benefits medicine and pharmaceuticals because things that make animals ill are frequently also harmful to humans.

Valuable pointers on the cause of disease

In evolutionary terms, animals and humans are related. They share common ancestors and thus also biological similarities, even if these are not always equally pronounced. As evolution has progressed, nature has retained a large number of processes. Hence research with animals can deliver valuable pointers on the cause of diseases and the effect of medicines. It provides information on desirable effects and brings around 70 percent of undesirable effects to light.

Results are transferable

Choosing a suitable animal model is key to ensuring that the results of animal experiments can be transferred to humans.



That means that the animal must be as similar as possible to humans both genetically and in terms of the biological functions to be investigated. This is the case with zebrafish, fruit flies and rodents, particularly mice.

Mice and humans share a very similar development, physiology and genome. The genetic and physiological match between the two species is around 95 percent. This is why mice are the species most commonly used in preclinical research involving animals. Mouse models provide information about human health and disease.

A large number of mouse models are now in use in research in Europe and around the world. In addition, disease models have been developed, phenotyped and archived for research. In the disease model, a disease is artificially induced in the test animal. The researchers make sure that the disease process in the mouse is generally the same as if the disease had broken out by itself. As a result it is possible to make inferences about the situation in humans. Differences obviously remain, however. This is why any medicine, new therapy or new treatment method has to be tested on at least two species of animal – rodent and non-rodent – before it can enter the clinical phase and trials in healthy human volunteers.

Animal experiments benefit veterinary medicine too

Dogs, cats and rodents are no strangers to cataracts, all species of animal can develop cancer in various organs, and ep-

ilepsy is found in dogs, cats and rabbits. These are just a few of the diseases that people share with animals. Virtually every human disease exists in the same or a similar form in animals and is treated in essentially the same way. There are several areas of common ground between human and veterinary medicine. Many veterinary medicines contain the same API as their human counterpart. Thus, animal experiments also benefit other animals.

Animal experiments and COVID-19 vaccines

Animal experiments played a key role in enabling researchers to understand SARS-CoV-2 itself, the mechanisms by which it is transmitted and the safety and efficiency of the vaccines that have been produced to date, thus bringing us one step closer to the end of the COVID-19 pandemic.

Major progress thanks to animal experiments

Animal experiments are only permitted if they are essential for elucidating as yet unresolved questions. They are part of basic research and prescribed by law for the development of new medicines and treatments (preclinical research). The

1953

Elucidation of the citric acid cycle

Hans Krebs,
Fritz Lipmann

1956

Discovery of cardiac catheterisation

André Cournand,
Werner Forsmann,
Dickinson Richards

1966

Discoveries connected with the cause and the treatment of cancer

Peyton Rous,
Charles Huggins

1955

1960

1965

1970

1975

intention of animal experiments is not only to create specific applications, but also to generate knowledge that can be used to develop innovative medicines and therapies. Or in other words, studies and experiments involving animals increase our knowledge of the natural world. They help us gain a better understanding of diseases. Findings from animal experiments can be transferred to humans with sufficient certainty to be able to deduce principles of action and harmful effects. There can be no question that animal experiments make a major contribution to the development of new methods of medical treatment. For example, it is now possible to cure childhood leukaemia in 80 percent of cases thanks to animal experiments. The most recent example is the rapid and successful development of various COVID-19 vaccines.

Animal experiments reduce animal experiments

Research has not yet progressed to a point where it can dispense with animal experiments. Although it is possible to go a long way using computer models and cell cultures, while technologies such as organ-on-a-chip can be used to replicate simple processes, the complex processes that take place within an organism cannot (yet) be reproduced with the methods currently available. This is because even the processes that take place within a single cell are too complicated for a computer. Animal experiments are therefore still needed for the time being – partly to continuously improve them and to replace them at ever smaller intervals.

1979

Development of computer-assisted tomography

Godfrey Hounsfield,
Allan Cormack

1982

Discovery of prostaglandins

Bengt Samuelsson, John Vane,
Sune Bergstrom

1985

Description of cholesterol metabolism regulation

Michael Brown,
Joseph Goldstein

1990

Organ transplantation techniques in humans

Joseph Murray,
Donnall Thomas

1995

Research into the genetic control of early embryonic development

Edward Lewis,
Christiane Nüsslein-Volhard,
Eric Wieschhaus

1980

1985

1990

1995

2000

Well-being comes first for animals travelling from breeding facility to laboratory

Animals that are used for experiments in Switzerland are generally bred specifically for this purpose. How the animals are bred, kept, transported and received at the destination laboratory is strictly regulated. Animal well-being comes first at all times.

The research-based pharmaceutical companies obtain the vast majority of the animals they need for experiments from certified breeding facilities in the international marketplace, primarily Europe. The animals used in an experiment must possess specific features to suit the purpose of the research. To reduce the variance in the results, and thus also the number of animals, experiments are standardised. Standardisation comprises a combination of the conditions in which the animals are kept (exogenous factors) and properties of the animals themselves (endogenous factors such as age, sex, genotype, physical condition and physiology). A decision is also taken on whether a particular genetic mutation is required. Working with preferred partners ensures that animals of a certain quality are available and that there is compliance with specifics. Standardisation of animal health status is also key, since animals bred for experiments have to be free of germs and pathogens that could make other animals ill or impact the results of the experiment. All this requires breeding facilities and research-based pharmaceutical companies with experience and expertise.

Strict requirements for companies and breeders

Research institutions and companies in Switzerland and throughout Europe may only order, keep or breed animals for research if they comply with specific conditions. Holding a permit to keep the animals is essential. Breeding facilities count as animal keeping facilities and must therefore fulfil

similar conditions to research-based pharmaceutical companies or other research institutions. These include strict legal requirements governing infrastructure and technical installations such as ventilation, temperature, drinking water supply, bedding, feed and hygiene, but also cage size, material and resilience, and staff training. A large number of pharmaceutical companies also require breeders to comply with additional requirements beyond those prescribed by law. These include, for example, environmental enrichment – providing toys, things to climb on, raised platforms or other things that are beneficial to the animals' well-being.

Regular inspections and audits

The authorities in European countries conduct inspections in accordance with the applicable European and national legislation governing animal keeping and breeding facilities. In addition, many pharmaceutical and biotechnology companies, universities, hospitals and other research institutes around the world have been accredited by the Association for the Assessment and Accreditation of Laboratory Animals Care and Use (AAALAC), a private international non-profit organisation that offers voluntary assessment and accreditation programmes that promote the humane treatment of animals. This means that they have been certified and are regularly audited by AAALAC. AAALAC accreditation guarantees an international standard on which research-based companies can rely. Furthermore, the research-based pharmaceutical com-



“We need trained experts, clear responsibilities and effective cooperation throughout the entire process, from specifying the animals we require, through ordering them from the breeding facility, transporting and receiving them, and settling them in at their destination.”

Dr. Tobias Schnitzer

Chapter Lead In Vivo Sciences, Roche

panies that are members of Interpharma regularly conduct their own audits of the breeders they work with using comprehensive checklists (shared audits; see Animal Welfare Charter p. 20 and Audit process p. 33).

Transport as short and stress-free as possible

In view of the strict requirements that apply throughout Europe, there is an ongoing process of consolidation under which breeding facilities are becoming bigger. Since there are no longer any such facilities in Switzerland, the animals used in the country come primarily from France, Germany, Denmark and, to a lesser extent, Italy. More rarely, laboratory animals are imported from the USA and Asia. However, the shorter distances the animals have to travel and the associated smaller risk of delays and other incidents make Europe preferable. To avoid the animals becoming stressed and exhausted, it is important to ensure that they are exposed to as little stress and have to travel as short a distance as possible. In most cases, the animals are therefore transported by road in climate-controlled vehicles. This is more tolerable for the animals than flying. When animals do have to travel between continents (from overseas), they always do so by air, by direct flight with no stopovers wherever possible.

Meticulous planning with experienced partners

From settling the animals in their carriers through to arrival at their destination, sender and recipient have to plan everything in detail and work together very closely. All the paperwork that will be required has to be determined and completed well in advance (export and import licence, official health certificate valid from the breeding facility and declarations on the animals' carriers). The companies that transport the animals must be specialised in handling experimental animals. They

must have appropriate vehicles and standardised carriers. It is important for the animals to have enough food and water, including reserves in case they are delayed en route. Carriers must never be opened while the animals are in transit to prevent additional microorganisms that could detrimentally affect the research from getting in.

Strict rules and emergency plans

Switzerland's Animal Welfare Ordinance lays down strict criteria for transporting animals. It specifies the responsibilities of the sender, transport company and recipient. The people who transport the animals must be proficient and trained in the conditions associated with transporting experimental animals. Customs brokers who work hand-in-hand with the transport companies are used to ensure there are no hold-ups at customs. In complex cases, border veterinary inspectors may be notified in advance so they can be involved. Transport companies must have a disaster plan for incidents such as road congestion, accidents, extreme weather, fire or earthquake and situations associated with pandemics. This plan must describe the actions to be taken in each scenario.

Animals are settled in at their destination

The rules for the animals when they arrive at their destination vary depending on species, origin and hygiene standard. Each animal is examined to assess its health status. In certain cases – depending on species, hygiene status, health status and company requirements – animals may have to be quarantined; otherwise they are taken straight to the housing facility. If there are any anomalies or concerns, the animals are examined for infectious pathogens. All animals have a mandatory one-week acclimatisation period.

Legal framework

- Laws such as the overarching EU Directive 2010/63 of the European Parliament and of the Council on the protection of animals used for scientific purposes sets minimum standards for the whole of the EU and EEA. Individual countries have used this Directive as the basis for their own national legislation, which may include further-reaching requirements than the Directive.
- In Switzerland, the Animal Welfare Act and the Animal Welfare Ordinance provide the legal basis for research involving animals. Swiss legislation is among the strictest in the world and promotes ethically responsible research.
- The Animal Welfare Ordinance also governs the transport of laboratory animals. In addition, the International Air Transport Association (IATA) issues annually updated regulations for animal transport. These include clear specifications on how individual species have to be prepared for carriage (carrier size, etc.).

A complex process demands exact planning

The process of specifying the laboratory animals needed for a particular research goal, ordering the animals from the breeding facility, transporting them to their destination and settling them in there is demanding. It requires experts, clear responsibilities and effective collaboration between the point of contact at the pharmaceutical company, the researchers and the breeders. Thanks to foresighted and exact planning of the cohorts that will be needed for a particular experiment and the timeframes in which they will be required, the quality of biomedical research involving animals can be constantly improved and the number of animals required can be reduced. This is an active contribution to the 3Rs: refinement in terms of the species that are needed and when, and reduction in terms of optimising breeding schedules.

All member companies of Interpharma are working on alternatives to animal experiments. For the time being, however, in vivo research is still needed to develop new treatments for severe diseases. It is therefore important to ensure that this research remains possible, subject to strict conditions, in Switzerland and throughout Europe.



“Mice share around 95 percent of their genes with us and many of their reactions to new substances are the same or similar. This is why mice are the species most frequently used in preclinical research.”

Dr. Birgit Ledermann

Novartis 3Rs Leader,
Novartis Institutes for BioMedical Research

“Mendel’s laws of inheritance cannot be overridden”

Research institutions keep more animals than they use in experiments. Daniel Breustedt, Team Leader in the Scientific Operations/Comparative Medicine department at Novartis’ NIBR, explains why this cannot be completely avoided and what options are available for reducing animal use.

Part of the process of developing new and innovative treatments involves testing the APIs in animals. This is to test their efficacy and tolerability in preclinical research. But more animals are bred than are actually needed. Why?

There are various reasons. The most important is ensuring the scientific reliability of the research involving animals. Very often, particular research issues require animals with particular genetic features. As part of the process of breeding animals with these specific features, other animals are inevitably born.

You talk about genetic features. What role do the laws of inheritance play in the fact that more animals are born than are actually used in the experiment?

Breeding genetically modified lines – and that's what I'm talking about here – is subject to the laws of biology. Gregor Mendel used peas to find out how inheritance works as long ago as the second half of the 19th century. And Mendel's laws apply to humans, mice and essentially all living things. They cannot be overridden. That's why animals that do not have the genetic features needed for a particular experiment are inevitably also born.

Can you give an example to illustrate that?

Even if we're breeding a mouse line with only one genetic modification, for example, we get animals that don't have the feature we want as well as ones that do. That's pretty much prescribed by Mendel's laws (see also illustration on p. 17). However, the biological processes we're investigating are becoming more complex and that means the animal and mouse models we use are becoming more complex too. Today around 50 percent of our animals have one genetic modification, around 30 percent have two and about 20 percent have three or more.

Let me give you an example to explain. Let's assume that we have to combine three genetic features – A, B and C – in one mouse line for an experiment. Feature A is a genetic on/off switch and is found in mouse line A. Feature B, in mouse line B, is a target gene that can be disabled and is associated with a disease, for example. Feature C in mouse line C is a fluorescent dye that can be activated. Breeding the ABC mouse line needed for the experiment is a complex task because it is impossible to combine all three features in one breeding step. We can only ever pair a male mouse with feature A with a female mouse with feature B. Their offspring will then have features A and B. The next step is then to pair an

AB mouse with a mouse with feature C. This multiple-stage breeding process means that more animals are born than are used in the experiment.

What happens to the animals that are not used in an experiment?

Surplus animals from complex breeding processes are used as sentinels, for example. That means they are used to monitor the health of research colonies. Sentinels live in their own cages and have regular contact with other animals' bedding and/or used cage components. That means that pathogens may potentially be present.

A vet examines the sentinels regularly, which gives us a way of periodically checking the colony's hygiene status. Apart from that, we also offer the animals that have not acquired the genetic modification required for the experiment to our researchers for other research or training purposes – say if a new surgical method such as inserting a microchip needs to be learnt.

Are there ways of minimising the number of animals you breed and is that something you're working towards?

That's our ambition. Careful planning and smart breeding strategies can decrease the number of animals both



“Our ambition is to minimise the number of animals we breed that do not have the genetic features required for the experiment.”

Dr. Daniel Breustedt

Team Leader in the Scientific Operations/
Comparative Medicine department at Novartis' NIBR

in simple cases with just one genetic modification and in more complex cases too. We've centralised animal breeding for that purpose. Today, experienced breeding and genetics specialists are the link between researchers and animal carers. Their task is to plan, review and implement complicated breeding strategies. Implement means having the necessary number of animals of the appropriate age and with the correct genotype – the specific genetic features, in other words – available for a specific experiment at a specific point in time. Using smart breeding schemes, we can reduce the number of animals that are bred quite substantially. However, it is still important to understand that we can never completely avoid surplus animals because of the biological laws at play.

The right number of appropriate animals. That sounds immensely challenging. What's the reason for this level of precision?

It's connected to the statistical robustness of the experiment. Quite simply, biological processes produce variety even in animals that are genetically identical. That means that two identical

animals do not have to behave exactly the same in an experiment. To obtain robust and meaningful results, there is therefore a statistically necessary number of animals, which is accurately determined by a biostatistician.

Why is the animals' age so important?

Their age range is relevant because the effect that we want to measure – what we call the phenotype – develops and expresses itself over time. That's why it's important to have a comparable age group. If an eight-week-old animal behaves differently from a twelve-week-old one, the comparability of the data is limited and the robustness and reliability of the experiment is not guaranteed. I would like to use two examples to illustrate a second factor connected with the animals' age. Alzheimer's is a disease that tends to manifest at an advanced age. Accordingly, transgenic mouse models use older mice in this case. By contrast, immunological research uses younger animals because their immune systems work and respond better than those of older animals.

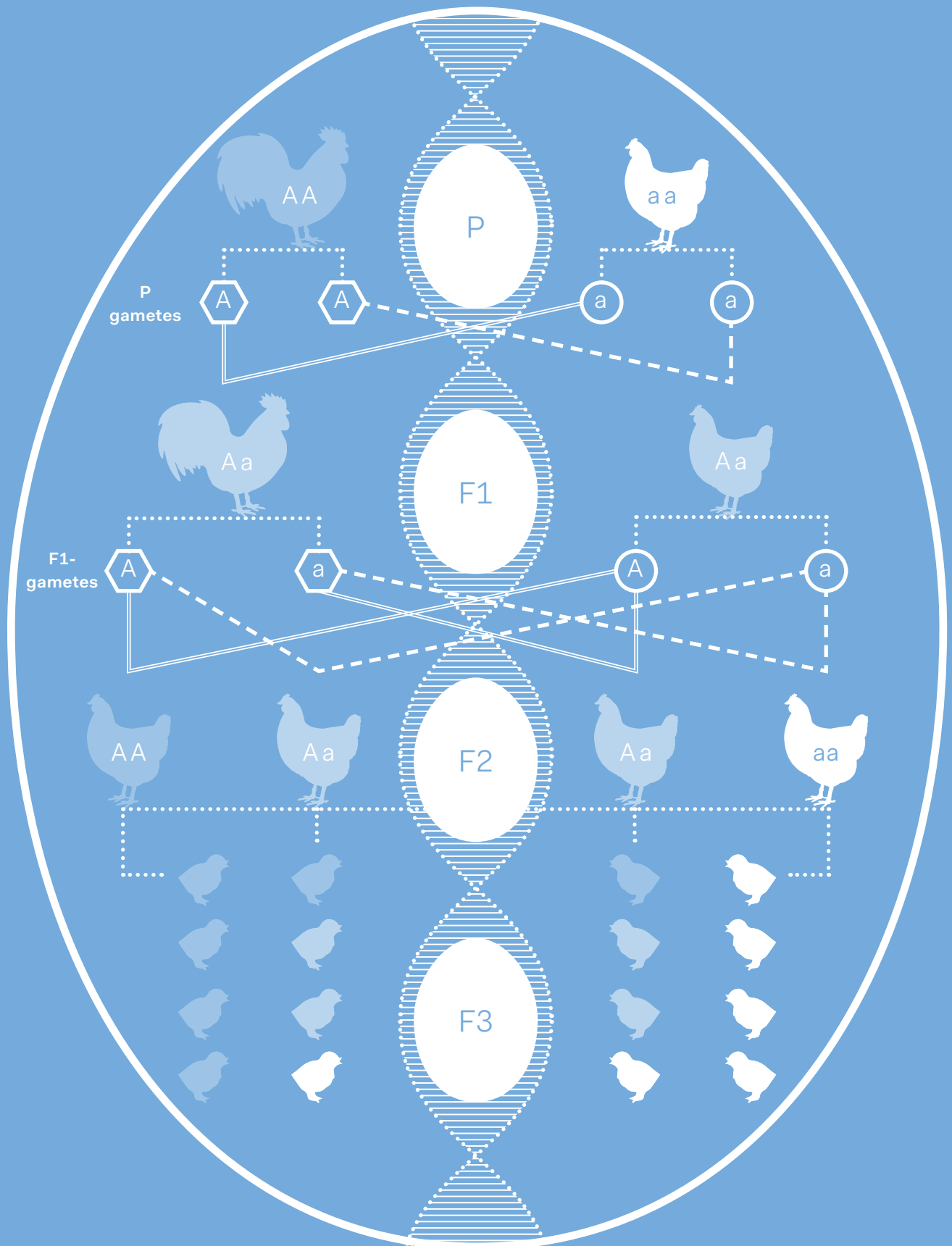
How relevant is the animals' homogeneity to the quality and robustness of the experiments?

We generally aim for the greatest possible group homogeneity. In biological and medical research in particular, some of the changes we have to observe and measure in the processes we investigate are tiny. To be able to do that, we have to reduce the amount of "background noise". That means making sure that both the intrinsic factors – in other words homogeneity – and extrinsic factors are constant. The extrinsic factors include, for example, the way the animals are handled by their carers, the temperature in the animal facility, ambient noise and vibrations, the cycle of lightness and darkness and the smell. The intrinsic factors, by which I mean what we call homogeneity within the animals, depend on factors such as the animals' age.

Furthermore, there are some experiments where we have to look closely at the animals' family tree because the animals used in the experiment and the animals used as controls have to be siblings from the same litter. The animals' intestinal flora can also be a factor. For example, two identical animals or two animals from an identical line but from

Mendel's laws

Mendel's laws of inheritance – the law of dominance and uniformity, the law of segregation of genes and the law of independent assortment – are a fact of nature. They describe the rules followed by genes when they are transmitted to the next generation.



Source: Kompaktlexikon der Biologie, Scheme for a monohybrid, intermediate inheritance using the example of plumage colouration in chickens.

two different institutions normally have slightly different intestinal flora and this can be detected in some experiments.

What technologies can you employ to reduce the number of animals used in research?

We have animals in conservation breeding that are used to continue a particular strain because researchers do not want to lose animals with genetic modifications or other features.

One reduction option here is cryo-conservation. This involves freezing embryos in liquid nitrogen at a temperature below minus 195 degrees Celsius. If the strain has to be started afresh at some point, the embryos can be inserted into a surrogate mother. There is also the relatively new technology of CRISP/Cas9. This enables us to edit genes so that we can give animals new genetic modifications faster and more accurately. Doing so skips a few breeding steps or enables us to insert several desired properties into the genome of the original animals in a mouse line at once.

Like any new technology CRISP/Cas9 also presents new challenges, and we must keep a close eye on these

“Key to reducing animal experiments are smart breeding schemes and regular dialogue on the subject with all stakeholders.”

if we intend to take an open approach to this new technology. The key thing for me is reducing the number of animal experiments by adopting smart breeding schemes and holding regular dialogue on the subject with all stakeholders, including other institutes, so that we can keep research animal breeding as efficient as possible.

Novartis and other companies regularly present internal 3Rs awards at national and international level. Daniel Breustedt and his team received a 3Rs award in 2019 for their work on process optimisations intended to reduce the number of animal experiments.

Animals for research

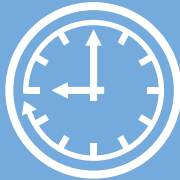
Why there are animals that are not used in experiments and how the number of research animals can be continuously reduced.

Experiment quality criteria influence the number of animals needed.



Genetic properties

Certain research projects require specific animals that possess several genetic features. These animals have to be bred. The laws of biology mean that animals that do not have all the features needed for the experiment are also born.



Age homogeneity

Researchers often have narrow time windows in which to conduct their experiments. To enable them to compare data sets from different experimental groups, the animals need to be approximately the same age when the experiment is conducted. Breeding must take account of the animals' ageing process.



Backcrossing

Combining genetic changes from different backgrounds creates cross-breeds. Backcrossing the genetic change in animals with a definite, clearly defined background is important for ensuring the comparability of experiments.



Sentinels

Sentinels are the "health monitors" of animal facilities. They live in their own environment, where they are brought into contact with litter from other animals and are regularly examined by a vet. They therefore provide information on the health status of the entire colony by proxy.

What helps reduce the number of animals needed for experiments?



Dialogue

Pharmaceutical companies and other research institutes are stepping up cooperation and extensively sharing experience on harmonising strategies.



Cryoconservation

A method of not losing animals with genetic modifications that avoids the need to breed continuously to maintain the strain. It involves freezing embryos and reinserting them in a surrogate mother when they are needed.



In vitro fertilisation

Fusing egg and sperm cells in a Petri dish. This is done using sperm or egg cells suitable for the animals to be obtained and specifically reduces the need for complex backcrossing and thus the number of animals.



Gene editing

CRISPR/Cas9 technology, a new molecular biology-based method for precisely cutting and modifying DNA, has made it possible to give animals genetic modifications faster and with greater accuracy.

In the 10-point Animal Welfare Charter, Interpharma member companies undertake to:

1

apply and actively promote the 3Rs (reduction, refinement and replacement of animal studies), especially with regard to the research, development and implementation of methods and techniques which allow further replacement of animal studies, a reduction in the number of animals used or alleviation of the pain and stress suffered by laboratory animals before, during and after the experiment.

2

ensure high-quality and state-of-the-art housing and care conditions for our laboratory animals and strive to continuously improve these conditions.

3

develop, foster and support education and training for all our employees and associates who work with animals.

4

contractually oblige external partners to comply with our high standards of animal welfare when they conduct animal studies for us or supply us with animals.

5

apply rigorous internal auditing systems to ensure compliance with the animal welfare standards agreed upon.

6

commit to joint efforts to audit our external partners on animal welfare standards and compliance at a global level.

7

promote, in addition to regular official inspections, the development of external, independent assessment programmes for our animal welfare standards and facilities worldwide.

8

promote the validation and regulatory acceptance of methods suitable for replacing, reducing or refining animal studies.

The 10-point Animal Welfare Charter was initiated in 2010 by Interpharma member companies. Its aim is to continually improve the protection and well-being of laboratory animals during breeding, in the housing facility and during necessary animal experiments.

9

contribute to a continuous, open and constructive dialogue on animal research and welfare with the public at large as well as with authorities, policymakers and other interested stakeholders.

10

report annually on the progress made with regard to this charter.

Promotion of the 3Rs

The aim of the 3Rs principles is to Replace as many animal experiments as possible, to Reduce the number of laboratory animals used and to keep stress to a minimum (Refine).

Animal Welfare Strategy

Animal experiments for medical purposes are prescribed by law on both ethical and scientific grounds to ensure patient safety. It goes without saying that in this regard, our members always act in compliance with all applicable laws and regulations. To make sure compliance with the highest ethical standards is improved even further, an Interpharma member has developed a new animal welfare strategy, the aim of which is to define binding company-wide rules for the use of laboratory animals. This includes the implementation of efficient organisational structures and the definition of specific key performance indicators (KPIs).

To reinforce this animal welfare approach, a newly developed governance structure has been introduced and a new organisation established. The aim of these efforts is to achieve the overarching goal of replacing animal experiments with alternative methods, reducing their number and improving them. The member company concerned appoints animal welfare officers and laboratory animal experts with local responsibility at all its sites around the world where animals are kept. These report directly to the company's governance unit – regardless of the business. They act as advocates for the animals, and their mission is to ensure ongoing improvement in this field. A Global Animal Welfare Committee, which is chaired by the company's CEO and on which representatives of all business units have a seat, serves as a communication and implementation body.

What the animal welfare approach means:

- The member company attaches great importance to the ethical principles of the 3Rs – Replace, Reduce and Refine – in the context of laboratory animal use.
- Moreover, the company has introduced a fourth R: Responsibility. Everyone in the company, as individuals or as members of a team, is called on to take responsibility for the animals or products of animal origin used, to show maximum respect for the animals and the colleagues who work with animals, and to play an active role in the development of alternative methods to the use of animals. In this context, a company-wide 4Rs programme has been developed, which brings together expertise from all areas of the organisation in a collaborative effort to replace, reduce and refine the use of animals through innovative approaches and live up to our responsibility for all the animals that are used on the company's behalf.
- Governance of animal welfare and laboratory animal science as well as compliance specific to the research area in question are organised on the basis of four key themes: Animal Welfare, Animal-Using Vendor Management (governance of providers that use animals), Vivarium Oversight (governance of the company's in-house animal facilities) and the 4Rs principles.
- Providers that use or keep animals on behalf of the company must be regularly qualified and audited.

- Independent, multidisciplinary and verified company committees (Animal Usage Review Boards) will approve all work that involves the use of animals in-house and on behalf of the company.
- A new centralised IT tool is being implemented to facilitate and improve processes across all functions, to create transparency with respect to work with animals and to allow knowledge to be shared.
- A comprehensive, company-wide set of regulations is currently being drawn up for Animal Science & Welfare and organisational changes and processes are being implemented in support of businesses.

Project name:	Animal Welfare Strategy
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Charter articles:	1, 2
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Institute for Translational Bioengineering

The Institute for Translational Bioengineering (ITB) was founded in Basel for the purpose of using and promoting new human model technologies in drug discovery and the early phases of development. Current animal models cannot reliably predict what will happen in patients. Recent breakthroughs in the use of human cell culture technologies have shown that they can predict clinical safety, efficacy and pharmacokinetics with greater accuracy. The data from these new tissue and disease models will supplement the in silico algorithms used for modelling and simulation. Work in this emerging field focuses on organoids – tiny, self-assembled three-dimensional tissue constructs derived from stem cells – and organ-on-a-chip technology. Such next-generation cultures can be designed to replicate the structural and functional complexity of a human organ or express certain aspects of it, for example only to produce certain tissue types. Organ-on-a-chip technology enables researchers to cultivate human cells representing organs under physiological conditions such as mechanical stimulation.

Project name:	Institute for Translational Bioengineering ITB
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Charter article:	1
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47,000

people were employed in Switzerland's
pharma industry in 2021.

Cross-department efforts to profile neuroinflammatory pathways in a model of ALS reduces number of animals needed for experiments

Amyotrophic lateral sclerosis (ALS) is a neurodegenerative disease that causes progressive loss of motor neurones that control voluntary muscles. Various disease areas are working on several projects that could provide neuroinflammatory modulators for ALS. The team initiated a partnership between several disease areas to reduce the number of animals required for experiments and to maximise understanding by shared use of tissue and comparative analysis of the data from all programmes as part of a joint study. As a result of these efforts, 86 percent fewer animals were needed.

Project name: Amyotrophic lateral sclerosis ALS

Charter articles: 1, 2

Animal welfare

has long ceased to be a sideshow –
it is now established in the corporate
decisions of our members.

Replacing animals by creating a digital surgical training platform

In the past, scientists needed training animals to learn the in vivo surgical techniques they required for their research. The training team created a digital surgical training platform to eliminate the need to use research animals to demonstrate the key surgical principles. The platform provides a new, advanced digital media interface that enables trainees to obtain the necessary initial and refresher training on demand.

Project name: Digital surgical training platform

Charter articles: 1, 2

Biomedical Research Awareness Day (BRAD)

One Interpharma member company will be holding its fourth annual Biomedical Research Awareness Day (BRAD) in 2022. BRAD was launched in the USA in 2016 by Americans for Medical Progress (AMP). The day is an opportunity to inform the company's employees about the necessity of and framework conditions for animal research in the development of new medicines and therapies and to raise employee awareness of them. The Interpharma member company celebrates BRAD globally in October with an extensive programme of presentations highlighting the company's transparent approach to animal research, acknowledging advances achieved in the global 3Rs (Reduce, Refine, Replace) awards and recognising the company's efforts to ensure veterinary and ethical oversight of all projects involving animals that have been outsourced to third-party locations. The Swiss site kicks off the event with presentations on the various phases of drug development.

Project name: BRAD

Charter articles: 1, 3, 9

Using iRFP-labelled CAR T cells to reduce research animal numbers

As part of a revolutionary new cancer treatment, T cells (a type of immune cell) are harvested from patients with leukaemia, then genetically modified to express a synthetic chimeric antigen receptor (CAR). This transforms the cells into CAR T cells, which are then reinserted in the patient. The CAR T cells then identify specific proteins or antigens on the surface of the cancer cells and kill them. Additional studies involving rodents were required to better understand and improve this novel therapeutic effect. To be able to see how the CAR T cells infiltrated and spread in tumours in mice in real time, the research team developed a CAR T cell that was labelled with infrared fluorescent protein (iRFP). By labelling the cells, the scientists were able to compare the anti-tumour activity mediated by CAR T cell proliferation to that mediated by CAR T effector function without having to euthanise the mice. As a result, they were able to observe the same animals for a longer period, which improved data quality and reduced the number of animals needed for the study.

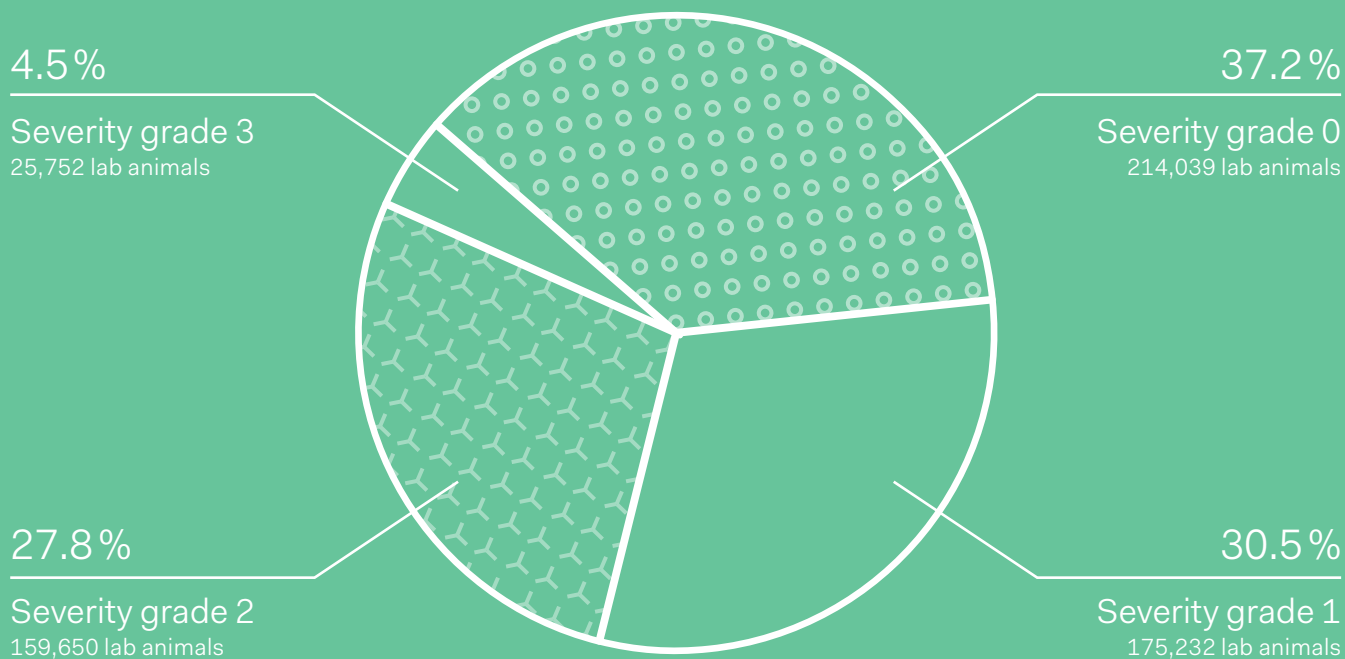
Project name: iRFP-labelled CAR T cells

Charter articles: 1, 2

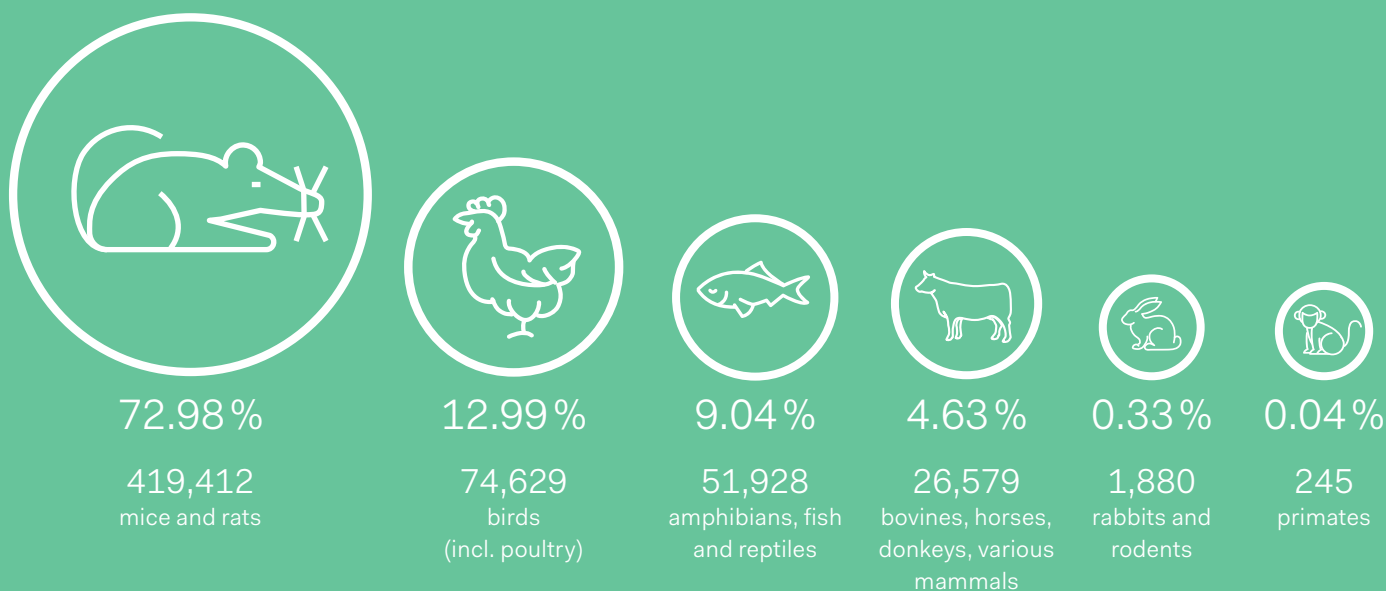
Animal experiments in Switzerland in 2021

All animal experiments requiring approval that were conducted by hospitals, universities, ETH, industry, the federal government, cantons and other parties.

Severity



Animal species



8.9 billion

Interpharma members invested CHF 8.9 billion in research and development in 2021.

Internal awards as a means of promoting the 3Rs

Some member companies of Interpharma regularly present internal 3Rs awards nationally and internationally. Researchers from different departments have the opportunity to submit their work and developments as a way of motivating them to further advance the 3Rs. The member companies are agreed that animal welfare is a global issue and that everyone has a responsibility for it. The aim is to open hearts and minds in support of the 3Rs. That this is succeeding is apparent from the annual increases in the number and quality of submissions for the awards. These serve to reward efforts to reduce, refine and replace animal experiments and promote engagement with the issue of laboratory animal welfare.

Project name:	Awards
Charter article:	3

Animal Research Tomorrow

The goal of Animal Research Tomorrow (formerly the Basel Declaration Society) is to reinforce public trust in animal-based biomedical research and to foster open and transparent communication between researchers and the general public. It seeks to help ensure that ethical principles such as the 3Rs are applied in animal research worldwide. At present, more than 4,500 researchers around the world have signed the declaration. The activities of Animal Research Tomorrow include participation in meetings and events concerning animal experiments, regular publication of the magazine "Mice Times" and also the hosting of an international congress every two years. In addition, the organisation awards an annual prize for the harmonisation of quality standards in the use and treatment of laboratory animals. Interpharma and its member companies have provided financial support for the Animal Research Tomorrow project for many years.

Project name:	Animal Research Tomorrow
Charter articles:	1, 9
Link:	www.animalresearchtomorrow.org

National promotion of the 3Rs by the 3RCC

The 3RCC was founded in 2018 with the aim of further promoting the implementation of the 3Rs principles in science. The partners in the 3RCC include 11 Swiss universities (represented by swissuniversities), the association of Switzerland's research-based pharmaceutical companies (Interpharma), the Federal Food Safety and Veterinary Office (FSVO) and Swiss Animal Protection (SAP). The 3RCC is financed by the Swiss government and Interpharma and receives benefits in kind from member companies that must be equal to the value of the resources provided by the government.

The 3Rs Research Foundation, the predecessor to the 3RCC, provided funding of around CHF 20 million to research projects between 1987 and 2018. In 2021, the Swiss government launched National Research Programme "Advancing 3Rs – Animals, Research and Society" (NRP 79), providing funds of CHF 20 million in the period up to 2028 for the purpose of further accelerating the development of 3Rs applications.

The first targeted call was published in 2021 and aims to fund a single research project. While the 3Rs principles should be applied to all research work involving animals, we often think of the experiments that cause animals the greatest stress when we consider the question of priorities. For this reason, the targeted call published in 2021 aims to provide an alternative, integrated 3Rs approach for specific high-risk animal models. In contrast to the previous open call, this targeted call is looking to provide total funding of CHF 920,000 for a single project. 32 project outlines were submitted, eight of which have been invited by the Scientific Advisory Boards to present a full proposal.

Project name:	3RCC
Charter article:	2

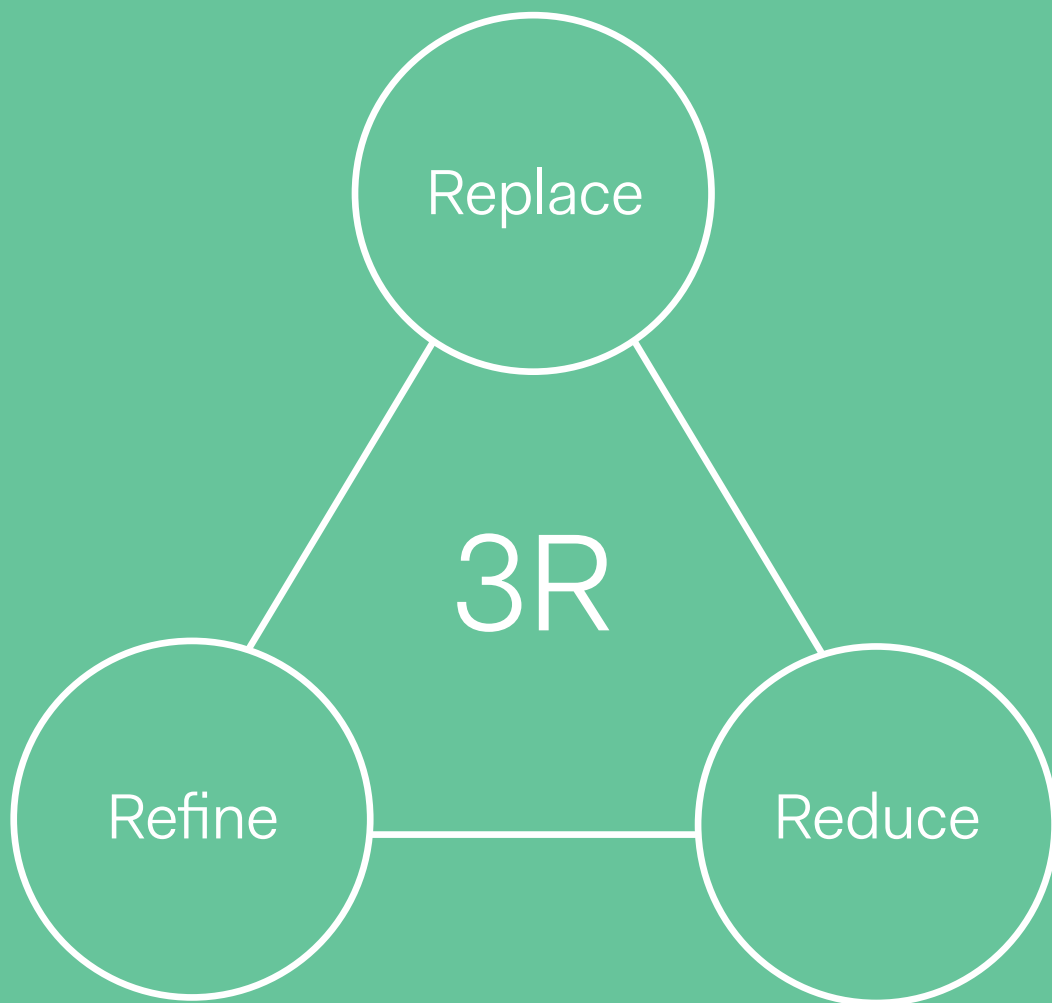
Innovation in the 3Rs programme

One member company has set up an "Innovation in the 3Rs" programme. The aim of this programme is to inspire and support the member company's scientists in rethinking the way they conduct their research by providing them with the resources they need to develop and validate new ways of replacing, reducing and refining animal experiments. The "Innovation in the 3Rs" programme selects and supports novel research projects that would otherwise be unlikely to come to fruition.

Project name:	Innovation in the 3Rs
Charter articles:	1, 2, 3

First published in 1959, the 3Rs principles are now an established part of national and international animal welfare legislation.

They aim to replace live and sentient laboratory animals with non-sentient material such as cell models wherever possible.



The laboratory animals used must be treated as humanely as possible at all stages of their lives, including breeding, transport, housing, experimental use and, where applicable, euthanasia.

Experiments should achieve their goals with as few animals as possible.

Working groups and projects

A large number of projects and working groups have already been in existence for many years, promoting national and international cooperation in the field of the 3Rs and benefiting the well-being of laboratory animals.

AAALAC International (Association for Assessment and Accreditation of Laboratory Animal Care)

AAALAC is an independent, non-profit organisation that promotes the humane treatment of animals in science with the aid of voluntary evaluation and accreditation programmes. More than a thousand institutions, including pharmaceutical companies, universities and biotech firms in 50 countries, have been accredited by AAALAC. Several sites belonging to Interpharma member companies are also AAALAC-certified. Interpharma has had a seat in the delegation of member organisations since 2013 and a seat on the Board of Directors since 2020. It is thus able to directly influence the promotion of independent animal welfare certification programmes. To ensure that research with animals and animal care are monitored and conducted in accordance with tried and tested procedures, AAALAC has more than 360 ad hoc consultants who accompany committee members during on-site visits and make recommendations. These consultants – some of whom work for Interpharma member companies – can offer expertise that extends beyond conventional laboratory animal species and can in some cases provide additional expertise in fields such as applied neuroscience, behavioural science, toxicology, pharmacology or physiology.

Project name:	AAALAC International
Charter articles:	2, 7
Link:	www.aaalac.org

IQ Consortium (International Consortium for Innovation and Quality)

Member companies of Interpharma work in the IQ Consortium and participate in its 3Rs Leadership Group. The group was established to promote the sharing and adoption of high-quality scientific practices and thus to advance the 3Rs principles in animal research conducted as part of the discovery and development of new medicines, vaccines, medical devices and health products for use in humans and animals. The European Liaison Working Group, a subgroup with which Interpharma maintains official contact, promotes the sharing of 3Rs expertise and their mutual interest in similar objectives being pursued both in the USA and in Europe. In addition to a global 3Rs award programme, the group also offers 3Rs training and continuing education courses.

Projektname:	IQ Consortium
Charter articles:	1, 3, 9
Link:	www.iqconsortium.org

Interpharma Animal Welfare Working Group

The Animal Welfare Working Group is one of Interpharma's seven permanent working groups. Various company representatives plus a representative of the University of Zurich meet regularly to address the ongoing improvement of animal welfare and the promotion of the 3Rs. In accordance with the 10-point charter launched in 2010, this group undertakes to produce an annual report on its activities and advances in the area of the 3Rs and animal welfare.

Project name:	Interpharma Animal Welfare Working Group
Charter article:	1

EPAA (European Partnership for Alternative Approaches to Animal Testing)

Interpharma members actively support the EPAA, a voluntary partnership between the European Commission and various industrial sectors that uses knowledge and resource sharing to improve the development, validation and acceptance of animal-free methods of research. In the past two decades, the EPAA has organised around 50 workshops and issued numerous publications. The EU Commission and 38 companies from seven industrial sectors (chemicals, pharmaceuticals, cosmetics, perfume, soap, detergent and animal health) have agreed a new collaboration to run until 2025. The new Action Programme 2021-2025 focuses on facilitating regulatory acceptance. The EPAA intends to keep vigorously driving forward the international harmonisation of regulatory safety requirements, whenever appropriate and possible.

Project name:	EPAA
Charter articles:	1, 2, 8
Link:	ec.europa.eu/growth/sectors/chemicals/epaa

-60%

In 2021, 60 percent fewer animals were used for research in Switzerland than in 2006.

EFPIA network for animal welfare

Member companies of Interpharma contribute ideas for high animal welfare standards at a pan-European level in the EFPIA Research and Animal Welfare (RAW) Group. One of the primary functions of this group is to collaborate actively in efforts to implement EU Animal Welfare Directive 2010/63 in EU Member States. Implementation of this directive was reviewed by the European Commission in 2017 and found to provide a solid regulatory foundation for the welfare of animals used for scientific purposes. The group also advocates the open exchange of ideas and effective collaboration with other organisations that support research in the area of the 3Rs. The group is made up of experts in toxicology, pharmacology, ethics, law, public affairs and animal welfare, as well as observers from academic and regulatory institutions. In addition, EFPIA publishes an annual 3Rs report online.

Project name:	EFPIA network for animal welfare
Charter articles:	1, 2, 8, 9

3Rs Competence Centre (3RCC)

The national 3Rs Competence Centre (3RCC) was founded on 27 March 2018 to promote the 3Rs principles in Switzerland. In addition to 11 universities, participants in the 3RCC include Interpharma, Swiss Animal Protection and the Federal Food Safety and Veterinary Office (FSVO). The Centre's objectives are to fund high-quality 3Rs research projects, to develop a strategy for 3Rs-based training and continuing education, and to establish a professional communications strategy. The 3RCC gives all participants access to the latest information on the 3Rs and alternatives to animal experiments. The centre offers its services to authorities, teaching and educational institutions and other interested groups. It also monitors the progress achieved in these areas in Switzerland. Before the national centre was established, 3Rs research projects were supported and funded by the 3Rs Research Foundation Switzerland for over 30 years. From the outset, the Foundation was financed equally by the federal government and Interpharma. In 2021, the Swiss government launched National Research Programme "Advancing 3Rs – Animals, Research and Society" (NRP 79), providing funds of CHF 20 million in the period up to 2028 for the purpose of accelerating the development of 3Rs applications.

Project name:	3RCC
Charter articles:	1, 3, 9
Link:	www.swiss3rcc.org



“Studies and experiments with animals help to increase our knowledge about nature. They help us to better understand the origin of diseases.”

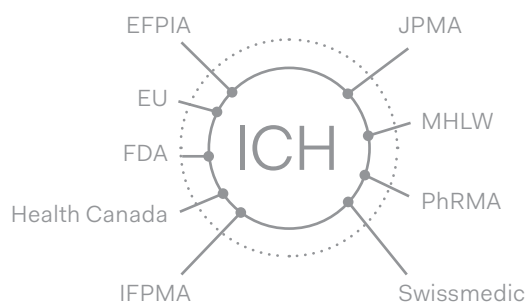
Nathalie Stieger
Head of Group Government Affairs, Roche

89%

According to the gfs.berne Health Monitor 2022
89 percent of the Swiss electorate are convinced,
that pharmaceutical research remains necessary, as
long as there are still diseases that cannot be cured.

ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use)

The ICH brings the pharmaceutical industry together with regulatory authorities from Europe, Japan and the USA to discuss scientific and technical aspects of pharmaceutical product registration. The purpose of the ICH is to harmonise the tests used during the research and development of new medicines and the technical standards and requirements for product registration. The aim of standardisation is to ensure that resources are deployed more cost-effectively and to eliminate unnecessary delays in the global development and availability of new medicines. The harmonisation process is complex and can take several years. It covers quality, safety (the category covering animal experiments), efficacy and multidisciplinary fields.



Project name:	ICH
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Charter articles:	1, 8
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Link:	www.ich.org
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TEDD (Tissue Engineering – Drug Development)

Organ-like human tissue and cell models are a major tool in drug development and API assessment. TEDD is a national centre of excellence that pools and transfers knowledge and technology with the aim of driving forward the further development and application of in vitro cell and tissue cultures. New technologies that offer a physiologically more relevant representation of the function and structure of healthy and diseased tissues and organs are gaining ground. However, they are still in an early phase of development and are of only limited suitability for routine use. To exploit their full potential, new methods of analysis will have to be developed, while controlled and standardised tissue production, preservation, automation, routine application and quality control will have to be refined. Concrete research projects in a network of partners from various stakeholders – including several member companies of Interpharma – have resulted in a platform that is actively helping to shape the development and application of alternative test methods for routine use in industry.

Project name:	TEDD
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Charter article:	1
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Verein Forschung für Leben

The independent Forschung für Leben (Research for Life) association was founded with the aim of informing the Swiss population about the importance of and latest results from biomedical research. The idea is to foster dialogue between scientists and the lay public and to explain in clear and straightforward language not only the benefits but also the hazards of research. In addition to regularly publishing the “BioFokus” brochure and granting awards to high school students for baccalaureate projects, the association can also provide a “gene laboratory” to any schools that are interested. Interpharma works together with the association on animal experiments and welfare in particular.

Project name:	Verein Forschung für Leben
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Charter articles:	1, 3, 9
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Link:	www.research-life.ch
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The Animal Welfare Charter of the pharmaceutical industry established milestones that academic researchers recognised as groundbreaking.

Internal training

Each year, a member company in Switzerland offers a range of federally approved training courses and one special day of continuing education, enabling employees who work with animals in the research environment to fulfil their statutory training obligation.

The topics covered by the continuing education day include:

- Updating the company's "Innovation in the 3Rs" programme
- The science behind and impact of award-winning 3R projects
- Efforts to ensure veterinary and ethical supervision of all animal projects subcontracted to third parties
- The contribution of animals and alternatives to the development of COVID-19 vaccines
- The use of micropipette-managed medicine delivery procedures in mice
- Update on the statutory initiatives in Switzerland that impact animal research

The training day also provides information on any changes, including amendments to legislation and directives. This ensures that the employees are informed about the current legislative status and about the concerns of the Animal Experimentation Commission.

Furthermore, this member company provides practical training via its Training Services group. All new employees working in animal research receive training as a way of guaranteeing uniform standards. Additionally, special events and advanced training are also available to experienced employees. These courses officially count as part of the mandatory training obligation.

Project name:	Interne Weiterbildungen
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Charter articles:	1, 3, 9
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Joint audits of Interpharma member companies

Research institutions that conduct animal experiments on behalf of Interpharma members – including their partner companies and subsidiaries – undertake to comply with technical and ethical standards of care and housing for laboratory animals. Some Interpharma member companies conduct regular, pre-announced, joint audits of external research partners and breeders all over the world. These audits not only serve to ensure harmonised standards and safeguard animal welfare, they also help develop expertise. The dialogue that takes place facilitates optimal implementation of the legal requirements and simplifies further-reaching efforts to apply the 3Rs. The audit results are jointly discussed within the member companies under conditions of confidentiality. The decision on whether to enter into a business relationship with the audited organisation rests with the individual company. In addition to conducting joint audits, member companies verify compliance with defined quality standards within individual procedures at their own research institutions around the world. All the criteria verified are documented in writing and apply worldwide.

Project name:	Interpharma audits
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Charter articles:	4–6
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Dialogue with Swiss Animal Protection

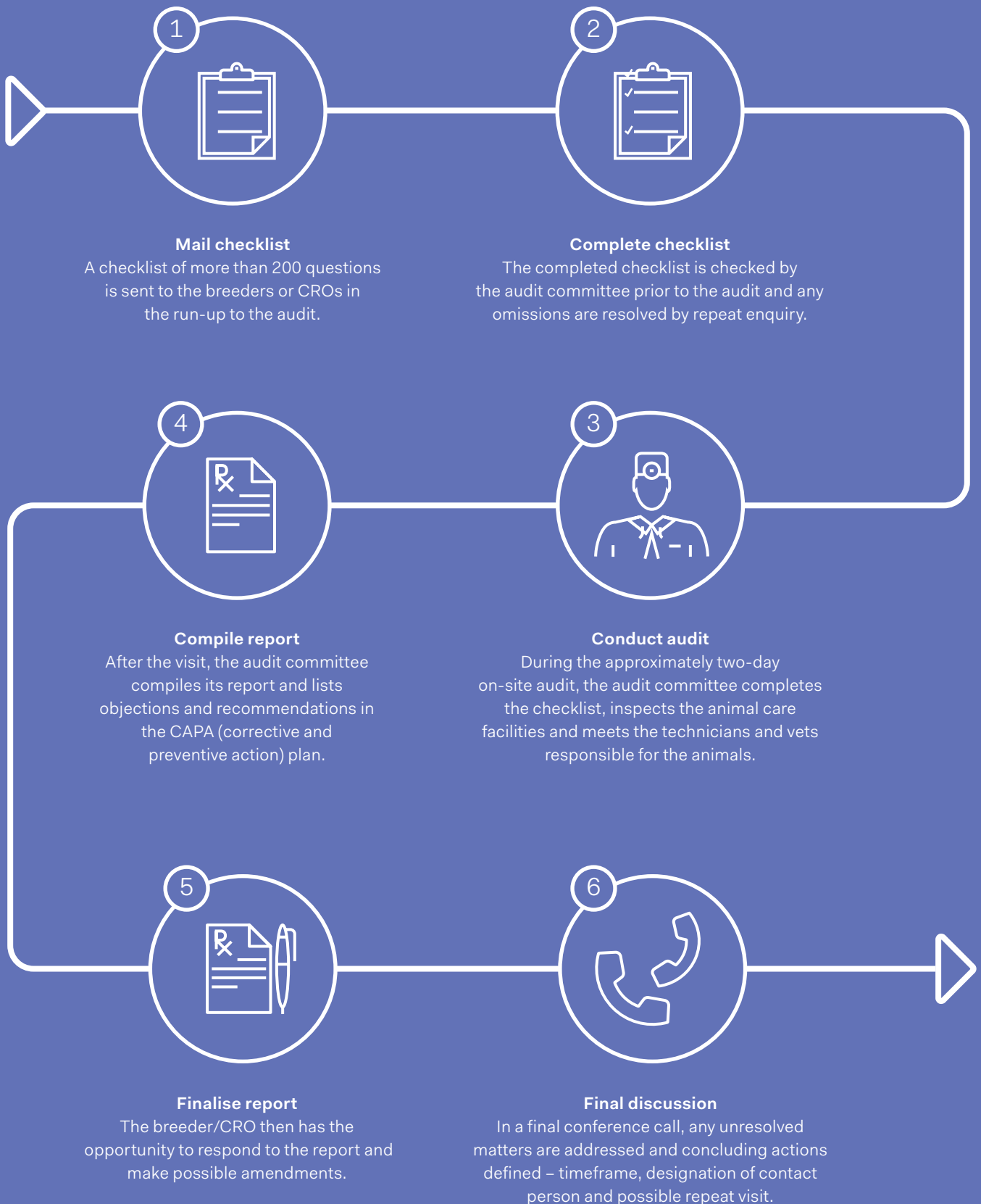
Interpharma has held dialogue meetings with Swiss Animal Protection (SAP) for more than eight years. viva3R and the Zurich animal protection group Zürcher Tierschutz also started attending meetings some years ago. The twice-yearly meetings serve to encourage reciprocal understanding, explore animal welfare issues and address technical issues associated with animal experiments and laboratory animal welfare.

Project name:	Dialogue with SAP
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Charter article:	9
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The audit process

Some member companies of Interpharma have been conducting regular joint audits of breeders and contract research organisations (CROs) around the world since 2014.



Recommended websites

Alternatives to Animal Experimentation – ALTEX

www.altex.ch

American Association for Laboratory Animal Science – AALAS

www.aalas.org

Animal experimentation explained

naturalsciences.ch/animal-experimentation-explained

Animalfree Research

www.animalfree-research.org

Animal Research Tomorrow

www.animalresearchtomorrow.org

Association for Assessment and Accreditation of Laboratory Animal Care International – AAALAC

www.aaalac.org

Competence Centre TEDD

www.zhaw.ch/de/lisfm/forschung/chemie-und-biotechnologie/competence-centre-tedd

European Federation of Pharmaceutical Industries and Associations – EFPIA

www.efpia.eu

European Partnership for Alternative Approaches to Animal Testing – EPAA

www.ec.europa.eu/growth/sectors/chemicals/epaa

Federation of European Laboratory Animal Science Associations

www.felasa.eu

Institute for Laboratory Animal Research

www.dels.nas.edu/ilar

International Consortium for Innovation and Quality – IQ

www.iqconsortium.org

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use – ICH

www.ich.org

International Council for Laboratory Animal Science

www.iclas.org

Johns Hopkins University Center for Alternatives to Animal Testing – CAAT

caat.jhsph.edu

LAS Interactive

www.las-interactive.de

National Centre for the Replacement, Refinement and Reduction of Animals in Research

www.nc3rs.org.uk

New Jersey Association for Biomedical Research

www.njabr.com

Swiss Animal Protection (SAP)

www.animal-protection.net/

Swiss Laboratory Animal Science Association (SGV)

sgv.org/en

The Swiss 3R Competence Centre (3RCC)

www.swiss3rcc.org

Tierversuche verstehen (understanding animal experiments) – an information initiative by scientists

www.tierversuche-verstehen.de

Understanding Animal Research

www.understandinganimalresearch.org.uk

Zürcher Tierschutz (Zurich Animal Protection)

www.zuerchertierschutz.ch/en/

About Interpharma

Interpharma, the association of Switzerland's research-based pharmaceutical industry, was founded in 1933. Its 23 member companies together account for more than 90 percent of market share in patented medicines in Switzerland and invest CHF 8.9 billion annually in research and development in the country. Interpharma is a driving force of an efficient, high-quality healthcare system that gives patients rapid access to innovative treatments and the best possible care. Both in Switzerland and abroad we are committed to ensuring that patients receive first-class healthcare, that innovations are rewarded and that our industry is able to make a key contribution to Switzerland's prosperity, growth and competitiveness.

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