

## Animal Research

Animal research is key to many of the great medical advances of today, including cancer treatments; medicines to treat neurological diseases such as multiple sclerosis, medicines for diseases that have high morbidity and mortality rates around the world like high blood pressure, diabetes, malaria and much more.



In addition, animal research is important for the development of new treatments such as radioligand, and cell and gene therapies.

Novartis fully supports the replacement of animals with non-animal alternatives wherever feasible, while meeting our obligations to patients and the expectations of regulatory agencies. More information about the Novartis position on animal research is provided in our position statement:

[Novartis position on animal research \(173 KB\)](#)



and applicability of scientific studies. Good animal welfare is a prerequisite for good science.



We have a Global [Animal Welfare Policy](#) and a set of Animal Welfare Standards that define key principles, responsibilities and explicit requirements governing animal research. All Novartis sponsored studies, whether conducted internally or externally, must adhere to this policy and set of standards.



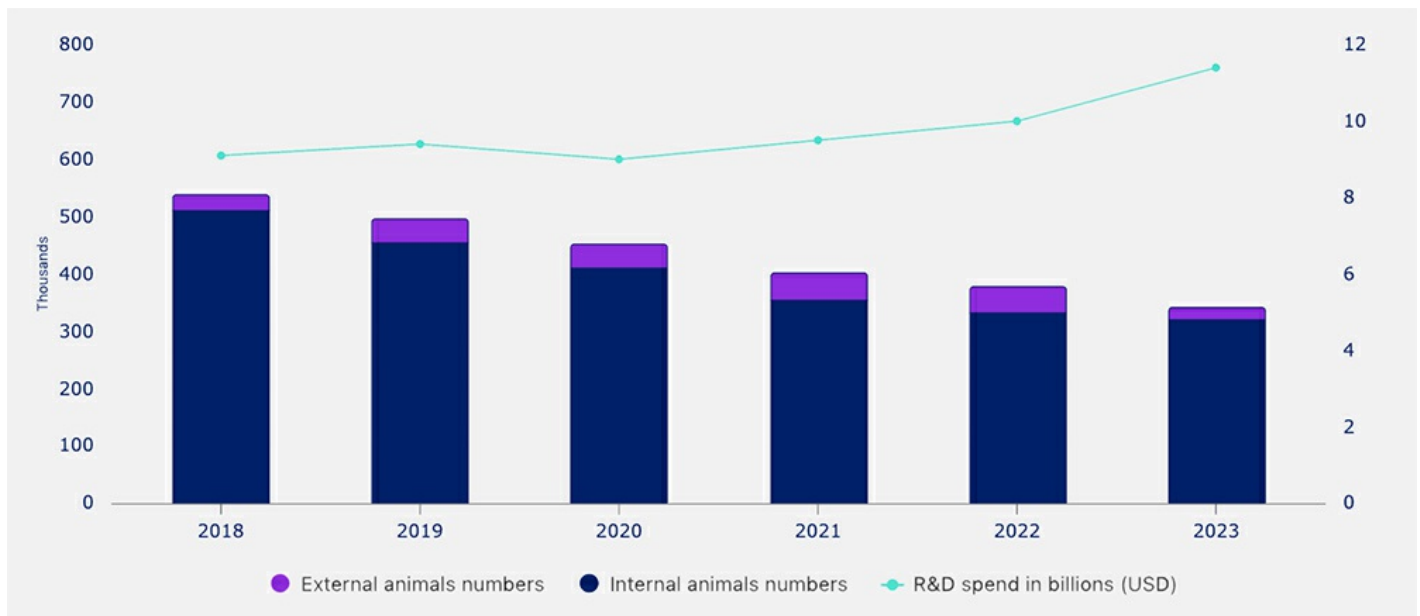
We transparently report the numbers of animals needed for research and development at Novartis each year. Data on the internal animal numbers is reported in our [Novartis in Society Integrated Report](#).

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## Our Commitments to Animal Welfare

- Promote high standards of animal welfare.
  - All individuals working with animals are trained to ensure proper care and handling.
  - Actively advance the 3Rs Principles (Reduce, Refine, Replace).
  - Ensure animals needed for research are treated and cared for respectfully.
  - Special attention is given to species-specific needs.
  - Any discomfort, distress, or pain is minimized in accordance with current veterinary practices.
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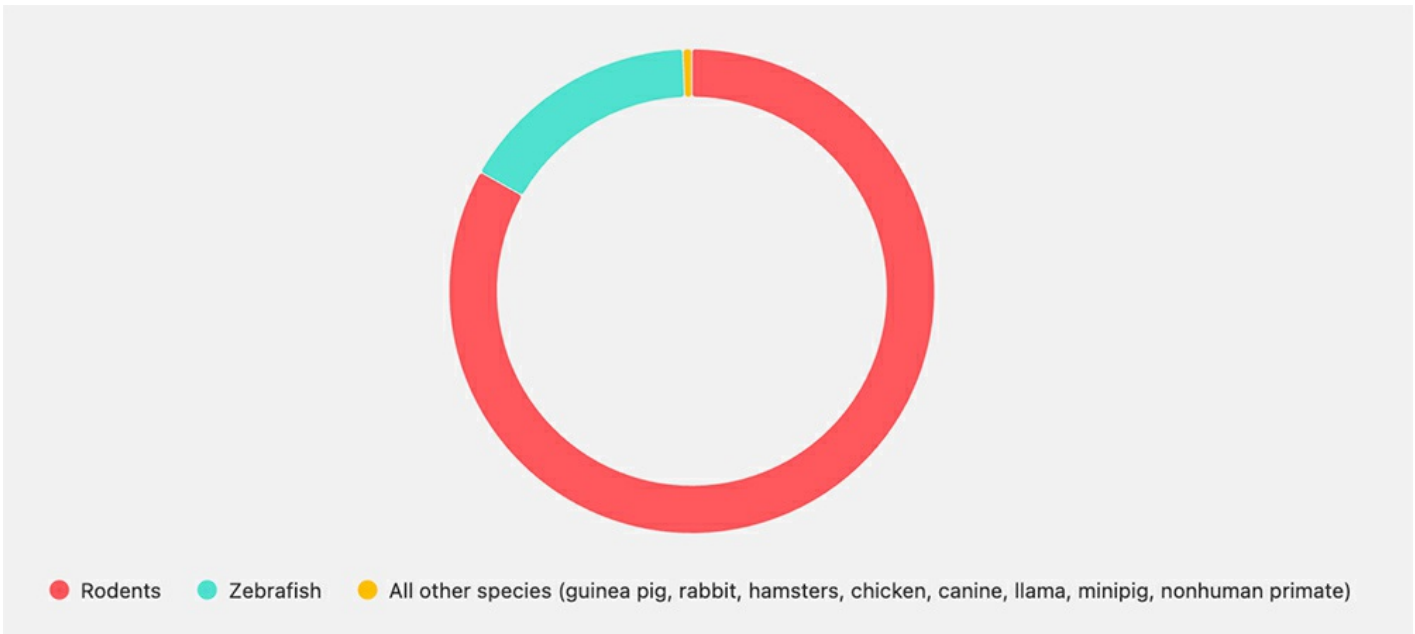
## Number of animals needed vs Research and Development spend



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## Animals needed by species in 2023

(Proportion of total animals needed by species)



## Did you know?

Animal research is still necessary to discover and develop innovative, safe and life-saving medicines for patients.

### Discovery and development

Because of animal studies, organ transplantation, antibiotics, artificial heart valves, and now personalized medicine have all been made possible. Once prevalent diseases, like polio and small pox are now rare or eradicated through the development of effective vaccines using animal research.

[Learn more here](#)

Until recently, patients suffering from some acute lymphoblastic leukemias had very few effective treatment options. But through study of mice with humanized immune systems, a revolutionary new type of therapy, CAR-T, is now available and is saving lives.

### Regulatory Requirements



The health and welfare of our patients is the top priority for Novartis and regulatory authorities around the world. In most cases animal studies are required to prove that our medicines are safe and effective for patients.

## AAALAC International Accreditation

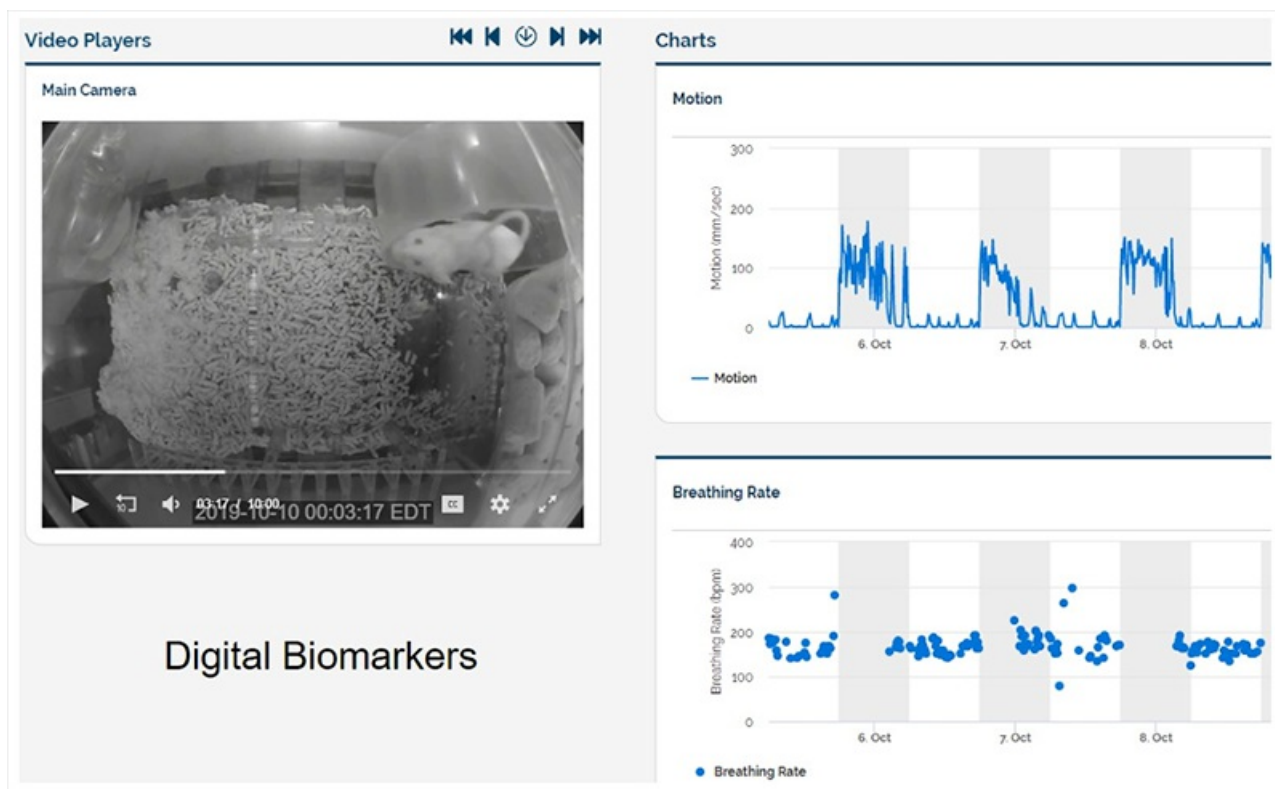
All Novartis Institutes for BioMedical Research in-vivo research sites earned independent, voluntary, international gold-standard accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC international), underscoring our commitment to achieving the highest standards in responsible research with animals. AAALAC international is an independent, non-profit organization that promotes the humane treatment of animals in science with the aid of voluntary evaluation and accreditation programs.

## Unique Animal Welfare Role

We have a specialty-trained veterinarian to liaise between internal scientists and those conducting sponsored animal studies at external partner sites. This role facilitates greater implementation of the 3R principles, and enhances the level of ethical oversight before, during and after animal studies conducted by third parties. Further, our team of animal welfare experts prospectively and continually audit third parties.

## Emerging technologies

New emerging technologies, such as specialized digital rodent housing, allows our scientists to study mice in their home environments. This reduces stress on the animals from handling and eliminates the need to disturb them while they are resting. These technologies are leading the way for the discovery of better and more targeted medicines.



Digital housing allows mice to engage in normal behaviors such as nest building and wheel running, undisturbed, and in their natural circadian rhythm, while simultaneously measuring important clinical metrics such as motion and respiratory rate.

## Our commitment to the 3Rs

Novartis is committed to the 3Rs principles (Reduction, Refinement, Replacement) and is driving innovation and efforts to advance the 3Rs both internally and in collaboration with external organizations.

- Reduction - Improve existing methods so fewer animals are required.
- Refinement - Refine studies so animals experience as little stress and as much comfort as possible.
- Replacement - Develop & implement alternatives to replace animals in research wherever possible.

### **Further “R” awards:**

- Responsibility – the award for our 4<sup>th</sup> R was launched in 2022 to acknowledge colleagues that work outside of the in-vivo community and have gone above and beyond to support animal welfare.
- The Novartis Exemplary Award was launched in 2018 to recognize employees who have contributed outstanding and continuous efforts to implement the 3Rs.

We have an animal welfare Ph.D.-trained 3R Scientist role to further strengthen our culture of ethical science at Novartis and to help advance the reduction, replacement and refinement of animal studies.

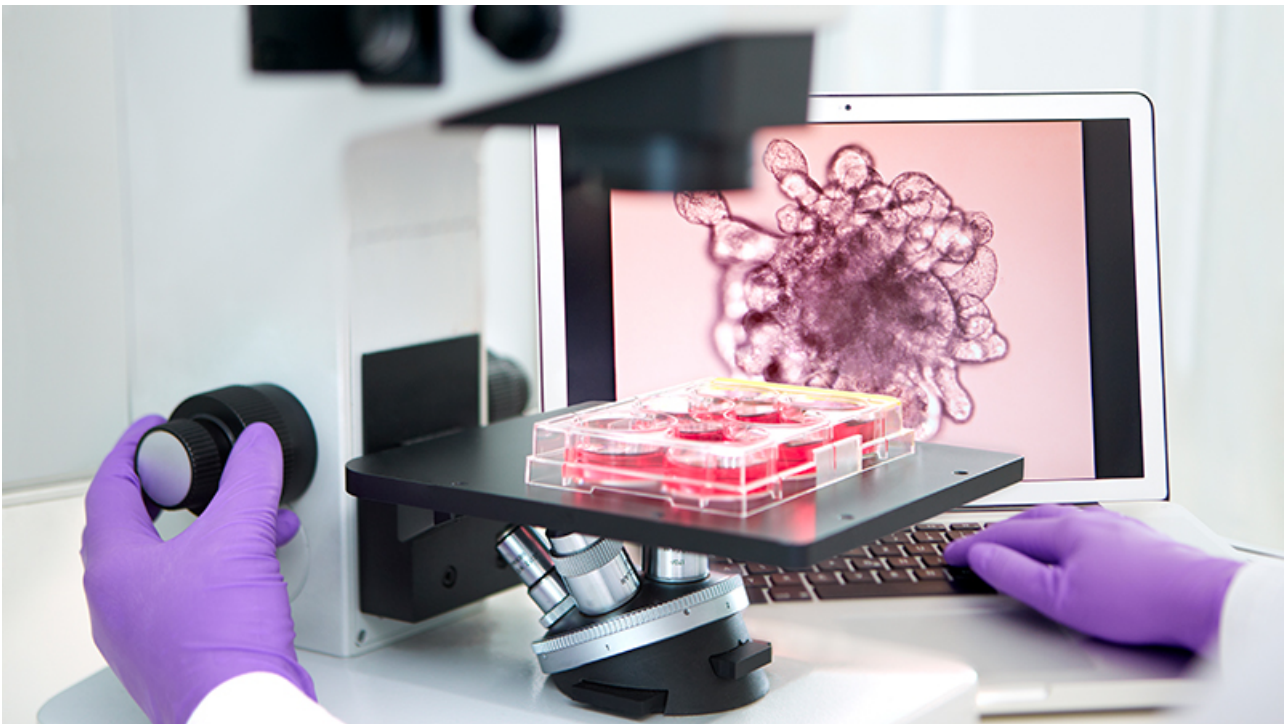
### **Innovation in 3Rs**

In 2022 we launched our Innovation in 3Rs granting program. The purpose of this program is to inspire and support Novartis scientists to reimagine how they conduct their research by granting the resources they need to innovate and validate new ways to Replace, Reduce, and Refine animal studies. This program complements the 3Rs Awards, which retrospectively recognizes and celebrates recently achieved 3Rs advancements. The Innovation in the 3Rs grant program selects and prospectively supports novel research projects in order to further strengthen the implementation of the 3Rs.

Newly funded 3Rs Innovation research projects in 2024 are exploring the impact of positive reinforcement training on rat welfare, characterizing pharmacokinetic properties of human intestinal organoids for future intestine-on-a-chip model development, testing the efficacy of new analgesics, evaluating a new methodology for producing genetically engineered mouse models to reduce animal numbers, and validating an in-vivo test used to identify “masked” pyrogenicity with an in-vitro monocyte activation test.

### **Replacement of animals with non-animal alternatives**

Novartis fully supports the replacement of animals with non-animal alternatives wherever feasible, while meeting our obligations to patients and the expectations of regulatory agencies. In fact, Novartis has made great strides in adopting and even creating advancements in non-animal methods for drug discovery and development from computer and cell-based culture to organ-on-a-chip technology. For example, our scientific team developed a new method of using brain cells cultured in the lab to replace animals when screening new therapeutic compounds for potential negative neurological side effects.



Tissue cell culture is one of many non-animal alternatives utilized at Novartis.

Despite these advancements, there are still many areas where better understanding of disease mechanisms cannot be achieved without animals. The knowledge acquired through such studies is essential for the development of innovative treatments for unmet medical needs.

## Reduction and Refinement



In addition to Novartis requirements to replace animals with non-animal alternatives whenever possible, our scientists and animal care experts lead efforts in developing new and innovative ways to leverage data, statistics, and study design to significantly reduce the number of animals needed for study and improve the animals' experience on study.

## Examples of 3Rs advancements at Novartis

Since 2007, Novartis has recognized significant advancements in the 3Rs through annual local and global 3Rs Awards which are evaluated for:

- their impact on numbers of animals required for study
- optimizing the animals state of being
- replacement by a less sentient species
- replacement of procedures involving animals entirely

## Reduction

- The implementation of longitudinal Computerized Tomography (CT) monitoring enabled an 88% reduction in the number of animals otherwise needed and improved the accuracy in a tumor study.
- The reduction of the number of animals needed for studying tumor metastasis through use of luciferase labelled cancer cells.
- The 10-fold reduction in the number of animals needed for an ophthalmology study via adoption of a novel study design.

## Refinement

- The use of machine deep learning (DL) approaches for magnetic resonance image (MRI) analysis resulted in significantly reduced imaging times and thereby significantly shortened the length of anesthesia required.
- The adoption of a non-invasive alternative technique for genotyping transgenic fish.
- Use of a new artificial intelligence approach for automated image analysis strengthened reproducibility and eliminated the need for repeat experiments.

## Replacement

- A new in-vitro system using white blood cells from human whole blood replaced the need for a mouse model of gout.
- The replacement of mice in a rheumatoid arthritis study through use of a novel human cell-based in-vitro tests.
- The replacement of animals needed to train scientific associates on key principles of surgery through the creation of a novel digital surgical training platform that allows the trainee to receive initial and refresher training on demand.

## Training and outreach

Training is provided to all associates responsible for internally and externally conducted animal research in order to ensure consistent high standards of animal welfare. In addition, special educational events and advanced training are offered throughout the year to help associates stay current with best practices.

Novartis celebrated our fifth annual Biomedical Research Awareness Day (BRAD) in 2023. BRAD was launched in 2016 by Americans for Medical Progress (AMP) in the US and is now celebrated globally. On this day we raise awareness about the continued need for and critical contributions of animals to the development of new medications and therapies for patients. Novartis celebrated BRAD globally with numerous presentations highlighting our efforts to improve human – animal interactions, both for human therapy, and improving the experience of animals' on study, as well as recognizing 3Rs advancements achieved by our annual Local and Global 3Rs Award Winners and new 3Rs Innovation Grant Award winners.

Novartis is a signatory of the Swiss Transparency Agreement on Animal Research (STAAR): [Swiss Transparency Agreement on Animal Research \(STAAR\)](#). This agreement aspires to improve communication and transparency regarding the continued value and need for animals in research.

Novartis is also a signatory of the [Marseille Declaration \(PDF 0.8 MB\)](#), the first joint pharmaceutical industry declaration of support for high standards of animal welfare.



## Human-Animal Interactions Art Challenge



For our 2023 BRAD focus on human-animal interactions, we invited Novartis associates to express their creative self by proposing an artistic interpretation of what human-animal interactions means to them with the artistic medium of their choice.

This is the winner of our 2023 Art Challenge.

Annual art challenge submissions have ranged from poetry, charcoal drawings, and graphic illustrations to needle point embroidery and wood cutting.

The artist titled this work "Trust - Human animal bond can't be made without mutual trust."

## External resources

Together, with external organizations, such as the Swiss 3R Competence Center, we are working to evolve the field to find alternatives to animal research, reduce the number of animals needed for research, and improve animal welfare. We also partner with organizations that help share the impact of these advancements.



[Swiss 3R Competence Center](#)  
[Institution Officials Consortium](#)  
[International Consortium for Innovation and Quality](#)  
[European Animal Research Association](#)  
[Americans for Medical Progress](#)  
[AnimalResearch.info](#)  
[Foundation for Biomedical Research](#)  
[Understanding Animal Research](#)  
[Come See Our World](#)  
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