

## **Animal Research " >**

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

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While the end of medical research involving animals might be a future possibility, it is not possible today. Often, animal studies are required by regulatory agencies around the world to better understand complex disease mechanisms and to prove that medicines are safe and effective.

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The welfare of animals in Novartis studies is a primary concern to us for reasons of ethics, accuracy, reliability and applicability of scientific studies. Good animal welfare is a prerequisite for good science.

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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.

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

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## **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**

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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.

## **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.

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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.

## **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.

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[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](#)  
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## **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.

## **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.

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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**

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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

Sharing the successful implementation of these 3Rs strategies inspires Novartis associates to be curious and think of new, innovative, and impactful ways to advance the 3Rs. Examples of recent advancements in the 3R areas are highlighted below.

### **Reduction**

- Use of a 3D tissue culture organoid to replicate key features of liver regeneration, significantly reduced the number of rodents needed for study.
- Adoption of a minimally invasive technique, allowing monitoring of animals over time, significantly reduced the number of dogs needed for study and eliminated inter-animal variability, thus improving the quality of the data.
- Development of a new benchtop screening method significantly reduced the number of nonhuman primates needed for large molecule studies.

### **Refinement**

- Use of digital technologies for the observation and study of mice in their home environments, without disturbing their natural cycles of rest, while also improving the scientific quality of the data.
- Minimally invasive telemetry to measure heart rate without handling, therefore reducing animal stress and substantially increasing the quality and amount of data collected.
- A novel approach to studying tissues rather than live animals to screen for potential negative side effects

on kidneys when assessing the safety of new medicines.

## Replacement

- Use of human derived cell cultures instead of animal derived cell cultures to screen for potential seizure side effects when assessing the safety of new medicines.
- Use of liver cells as a non-animal alternative for screening of drugs against liver stage Malaria parasites, replacing the need for this kind of study in nonhuman primates.
- Successfully achieving regulatory approval of a non-animal alternative in lieu of previously required animal data.

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