

# AstraZeneca Bioethics

**Bioethics is a central component of AstraZeneca's commitment to Sustainability in bringing innovative medicines to patients. This infographic details the way we manage the ethics of biological and medical research in seven areas vital to advancing science and developing new treatments, as well as the care AstraZeneca takes to act ethically and in full compliance.**

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Navigate between pages by clicking the tabs along the top of each page or by returning to home using the back button and clicking one of the options below. Each page has an introduction to the topic with further areas to explore by hovering your mouse over the tabs under the introduction, or clicking on the icons on the right hand side of the page. Each tab delves deeper into key issues while the icons further explore areas of importance.



## Animals in Research

Rapid advances in technology in recent years have led to the increasing availability and use of alternatives to animal use in research. However, these alternatives cannot yet provide all the essential information needed about how a potential new medicine works on disease and the living body, and what the possible side effects might be. Animal studies continue to play a small but vital role in the search for new and improved medicines. Practically all medicines we have available today have involved some animal research, and animal studies are required by regulators before they approve a new medicine to be tested in humans during clinical trials. Pre-clinical animal studies ensure safety for clinical trials with patients and provide scientific benefit for future discoveries.

### Links for Further Reading





## **Human Biological Samples**

**The use of human biological samples, such as solid tissue, biofluids and their derivatives and genomic information (e.g. from DNA, and/or RNA within human tissues and preclinical models), plays a vital role in developing a deeper understanding of human diseases and their underlying mechanisms, thereby helping to develop effective, new and personalised medicines. Human biological samples are key to all aspects of the development of new treatments, from early research through to being used as potential therapeutics, for example, they can be used to identify new biomarkers, to predict the likely effectiveness of a potential new medicine and to identify some of the possible unwanted effects.**



## Precise Genome Editing

**Precise Genome Editing (PGE) is a technique whereby DNA can be inserted, replaced, removed or corrected at specifically chosen locations within the genome. It is a rapidly developing field with the potential to provide important treatments for patients with diseases of unmet need. Within AstraZeneca we apply Precise Genome Editing using CRISPR/Cas9 to create cellular and animal models of disease to identify new drug targets and to understand the mechanism of action of our medicines.**

### Links for Further Reading





## Nagoya Protocol

**The Nagoya Protocol (see links box) is an international agreement to ensure fair reward is given to the country of origin that supplies non-human genetic resources used in R&D. It regulates access to biological materials and ensures that communities that live where the resources are sourced receive their fair share of benefits. AstraZeneca supports the principles of the Nagoya Protocol to protect and value biodiversity.**

**AstraZeneca has created three main resources to facilitate implementing the principles at our company:**

### Links for Further Reading





# Clinical Trials and Patient Safety

## Clinical Trial Transparency

- We are fully committed to global clinical trial transparency and believe there are important public health benefits associated with making clinical study information available to healthcare professionals and the public in a timely, accurate, meaningful and objective way.

## Patient Safety

- We are committed to detecting any adverse reactions to our investigational products and approved medicines as early as possible and to providing updated information to investigators, prescribers, consumers and research subjects as appropriate.
- All reports of adverse events must be scrutinised by medically qualified individuals. Individual cases judged to be potential safety signals will trigger further analyses of existing data and possible subsequent actions.
- Safety data from development projects and marketed products must be regularly analysed to ensure adverse reactions and possible safety signals are identified from both clinical and non-clinical sources.
- Research subject risk management plans must be prepared for all products in clinical development. These documents will evolve as safety data become available, so that we can minimise risk and optimise benefits.
- AstraZeneca follows a defined process aimed at ensuring all relevant patient safety information is incorporated in product labelling and Investigator's Brochures.
- All employees are required to report any adverse events they become aware of involving any AstraZeneca investigational product or approved medicine.

## Conduct of Clinical studies

- We conduct all clinical studies in accordance with the International Conference of Harmonization Good Clinical Practices (ICH-GCP) and the Declaration of Helsinki as well as all local regulatory and ethical requirements.

## Links for Further Reading





## Working with Genetically Modified Organisms

**AstraZeneca believes that the use of Genetically Modified Organisms (GMOs) is an essential activity in the discovery and development of new and improved medicines. GMOs enable us to produce materials that are vital for our research in drug discovery and development. They allow us to better understand the role that specific genes and associated individual proteins play in human disease and the potential for therapeutic intervention. In fact, some of our medicines are classified as GMOs, such as vaccines for influenza or types of oncolytic viruses. Medicines such as these are always manufactured, tested and used in compliance with national regulations.**

**GMOs may be:**

- **Laboratory animals, micro-organisms (viruses, bacteria, fungi, yeast) and genetically modified animal and human cells. In some cases, the genetically modified human cells may be derived from human embryonic stem cells.**



## Data & AI

**Data & AI is core to support AstraZeneca's strategic priorities predicted to transform how our business is run. Analysis of Data is already the lifeblood of AstraZeneca as a science-led, pure-play pharmaceutical company and elevated to critical for the delivery of the AstraZeneca corporate strategy – in which Data, AI and Digital is a foundational value driver for Innovative Science, and a potential corporate differentiator.**