

Roche Position on Clinical Research¹

Background

As a research-focused global healthcare company, Roche aims to contribute to the quality of human life by providing pharmaceutical and diagnostics products and services for the prevention, screening, diagnosis, classification, prognosis, prediction, treatment and monitoring of diseases. Roche is committed to producing safe and effective medicines and diagnostics products and solutions that benefit patients and physicians by addressing unmet medical needs. To do this, the company makes use of the most recent advances in science and technology to understand the molecular basis of diseases and to identify and test novel medicines and diagnostics products and solutions.

Clinical studies are an integral part of the process for developing new medicines. Before a new medicine can be made available, evidence of its safety and effectiveness must be shown in well-designed, well-controlled, and carefully monitored clinical studies in healthy volunteers and/or patients who consent to participate. The same rules apply for the development of certain type of diagnostics products and solutions, where studies are not only conducted to demonstrate proof of technical performance and accuracy, but also their clinical evidence and value.

Patients may choose to participate in clinical studies, hoping that their contributions will help in the development of new therapies for the condition affecting them. However, taking part in a clinical study raises questions for study participants and family members or caregivers. For example, patients want to know what risks a study entails, how the study will be conducted, and how their personal information will be safeguarded.

Roche is committed to the ethical conduct of clinical trials and to providing information on the safety and effectiveness of its medicines and diagnostics products to patients, physicians, researchers, and health authorities in order to protect patient safety, inform medical decisions, and facilitate further research. Roche is committed to sharing information while protecting patients' personal data.

Ethical Conduct of Clinical Trials

The clinical studies that Roche sponsors are conducted according to international standards of Good Clinical Practice (GCP), Good Pharmacovigilance Practice (GVP), and the Declaration

¹ Pertains to SDGs 3 and 16



of Helsinki, as well as according to local laws and regulations. Whenever Roche conducts new studies in the field of transplantation, Roche adheres to the Declaration of Istanbul on Organ Trafficking and Transplant Tourism and the WHO guiding Principles on Human Cell, Tissue and Organ Transplantation.

All patients considering participation in a clinical trial are provided information on the risks and potential benefits of participation, as well as treatment options, as part of the informed consent process. Roche makes every effort to protect patients from emotional or physical harm from having participated in a Roche clinical study. All Roche employees as well as external contractors working with Roche, are required to adhere strictly to local and international laws and regulations, to conduct clinical research with integrity, and to apply the highest standards of medical care and respect for patients at all times.

Ethics and integrity are central to the way in which Roche employees work. The company has a system in place for reviewing ethical issues that may arise during the conduct of clinical research, as there are times when employees can face gray areas. The process Roche has put in place allows ethical issues to be raised early. It also provides a support mechanism for Roche employees so they know that they need not face difficult issues alone, and can get independent advice from the [Scientific Ethics Advisory Group \(SEAG\)](#).

Clinical Studies in Low and Middle Income Developing Countries

Where Roche undertakes such studies, the same international regulations and high standards of ethical conduct and scientific integrity will be adhered to, with the ultimate goal of delivering robust and credible results at the conclusion of the clinical research. Roche intends to seek marketing authorization in all countries where we conduct clinical studies for a particular medicine or diagnostics product.

Continued Access to Investigational Medicines

Roche offers patients who participate in Roche sponsored clinical studies continued access to the investigational medicinal product that they received after study completion when

- The patient has a life threatening or severe medical condition, and his/her wellbeing requires continued administration of the investigational medicinal product.
- There are no appropriate alternative treatments available to the patient and the medication is not reasonably accessible to the patient via their local healthcare system.

Learn more about Roche's approach to continued access by reading the company's [Global Policy on Continued Access to Investigational Medicinal Product](#).

Sharing of Clinical Study Information and Protection of Personal Data

Roche shares clinical data because we understand it helps physicians, patients and healthcare providers to make informed treatment decisions. Data Sharing can also enable researchers to more easily build on our research and the research of others, in the hope of advancing scientific progress.

Roche commits to protect the privacy of all individuals participating in clinical trials and clinical trial data is shared in a manner that safeguards personal information.

We seek to share our data in four important ways:

- We publish information from our protocols and clinical study results on clinical trial registries
- We disclose clinical study documentation
- We publish in peer-reviewed journals and share data in scientific meetings
- We provide qualified researchers access to individual patient data

Learn more about Roche's approach to data sharing by reading the company's [Global Policy on Sharing of Clinical Study Information](#).

Additional Information for Patients Considering Participation in a Clinical Trial

To address patients' questions and concerns, Roche has, together with the European Genetic Alliances Network, EGAN, prepared a booklet with some of the questions that are frequently asked by those thinking about joining a clinical study (<http://www.biomedinvo4all.com/en/publications/faq-on-clinical-trials-various-languages/>). The content is a common effort by experts from the patient community as well as by Roche experts responsible for carrying out clinical studies.

For further reading, please see FAQ on [Clinical Research](#).

This updated position paper was proposed by the Corporate Sustainability Committee and adopted by the Corporate Executive Committee on February 20, 2017 and entered into force the same day.

It was reviewed in March 2019.