

Roche Position on Clinical Research

Background

Clinical trials are an integral part of the new drug or diagnostics discovery and development process. Before a new medicine or diagnostic assay can be made available, evidence of its safety and effectiveness must be provided by well-designed, well-controlled, and carefully monitored clinical studies in healthy volunteers and/or patients consenting to participate. Beyond conducting high-quality trials, Roche is committed to providing healthcare stakeholders with full transparency on risks associated with its clinical trials and ensuring the protection of patient safety as well as patients' personal data.

Patients Expect Disclosure on Risk Associated with Studies

Patients with chronic or life-threatening diseases are often eager to participate in clinical trials, hoping that their contributions will help in the development of new therapies for the condition affecting them. However, taking part in a clinical trial raises questions either for those in the trial itself or for the family members or care givers. In particular, patients want to know what risks a study entails for participants, or how their personal information will be safe-guarded.

Roche Committed to open Dialog with All Stakeholders

We are committed to open dialog with all stakeholders and to providing full transparency on our policies and procedures.

OBJECTIVES. As a research-focused global healthcare company, Roche aims to contribute to the quality of human life by providing pharmaceutical and diagnostic products and services for prevention, diagnosis and treatment of diseases. Roche is committed to producing safe and effective medicines and diagnostics that benefit patients and physicians by addressing unmet medical needs and as a result have a lasting positive impact on Public Health. To do this, the company makes use of the most recent advances in life-sciences and technology to understand the molecular basis of diseases in order to identify and test novel medicines and diagnostics. Clinical trials are an integral part of this process.

RESPONSIBILITY AND STANDARDS. All clinical studies where Roche is the trial sponsor or where Roche is providing substantial support are conducted according to international standards of Good Clinical Practice (GCP) as well as according to local regulations. Roche respects human rights and believes that one of its most important aspects is the freedom to choose. Roche is



focused on protecting human dignity, patient safety, and ethical principles in the conduct of clinical trials. Roche is committed to act ethically and to provide the highest standards of care to individuals participating in Roche sponsored or supported clinical trials. Whenever Roche conducts new trials in the field of transplantation, Roche adheres to the Declaration of Istanbul on Organ Trafficking and Transplant Tourism (first published on July 5, 2008) and the WHO guiding Principles on Human Cell, Tissue and Organ Transplantation. Roche will not support any activity (e.g. clinical trials and conferences) that violate these Principles.

Roche Strives to Protect Safety of Clinical Trial Participants and Personal Data

CONTROL OF STANDARDS. Roche has developed internal standards and systems to ensure that we comply with the most stringent guidelines, regulations, and legal requirements in place. Roche commits to protect the privacy of all individuals participating in Roche trials. This commitment aims at safeguarding all personal data. Moreover, we will make every effort to ensure that no patients suffer any emotional or physical harm because of having participated in a Roche clinical trial. All Roche employees who work on clinical trials for Roche products, as well as external contractors working with Roche, are required to adhere strictly to local laws and international guidelines, to conduct their research with integrity, and to apply the highest standards of medical care and respect for patients at all times. Internal mechanisms allow employees to report any suspicions of abuse without fear of repercussions.

ETHICS. Roche's goal is to ensure high ethical standards in clinical research. Therefore the company has a system in place for reviewing ethical issues that may arise during the conduct of clinical research. Ethics and integrity are central to the way in which Roche employees work, however there are times when employees can face gray areas, where the "right" decision is not always clear cut. The process Roche has put in place allows ethical issues to be raised early and resolved as quickly and efficiently as possible. 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 Science and Ethics Advisory Group (SEAG).

TRANSPARENCY. Roche is committed to registering its studies on a publicly available website to help patients, their caregivers and physicians find clinical trials that may be appropriate for them. Roche has always been dedicated to transparency in clinical trials and we are committed to publishing both positive and negative results in a publicly available site to ensure health care providers, patients and their caregivers have ready access to study results.

Roche policy requires that all company sole sponsored interventional and observational study protocols are posted on ClinicalTrials.gov. In addition, Roche Diagnostics interventional study protocols involving advanced diagnostic products are also posted. Once a trial is registered it will

never be removed. Any trial registered will have a corresponding entry in a publicly available results database, regardless of the outcome of that trial. Summaries of the results of all studies are posted on roche-trials.com in the E3 format. If the study is covered by the FDAAA law in the US, then results are also posted on ClinicalTrials.gov. - the registry managed by the National Institutes of Health in the US. Protocols may also be registered in other registries if required by local regulations.

Clinical Trials in Developing Countries

IDENTICAL STANDARDS. Conduct of clinical trials in developing countries presents a unique set of ethical demands. 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 credible results at the conclusion of the clinical research. Where the results from a Roche sponsored clinical trial in a developing country are used for the purposes of registering the Roche medicinal product in another country, Roche commits to apply for marketing authorization of the medicinal product in the developing country where the trial was conducted. In the case where there are no plans to apply for marketing authorization, Roche will not conduct clinical trials with that particular medicinal product in the developing country.

Roche engagement with advocacy groups

COMMUNICATION AND DIALOGUE. In order to address questions and concerns of patients, 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 trial (<http://www.biomedinvo4all.com/en/publications/faq-on-clinical-trials-various-languages/>). The questions were brought in from the patient side, and the content is a common effort by experts from the patient community as well as by Roche experts responsible for carrying out clinical trials.

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

This position paper was updated and approved by the Corporate Sustainability Committee on July 1, 2011. It was reviewed in April 2012.