

Roche Global Policy on Continued Access to Investigational Medicinal Product

Executive Summary

Roche is committed to a high standard of quality and ethical conduct in all aspects of conducting clinical trials. As part of this commitment and in accordance with the Declaration of Helsinki, Roche offers patients who participate in Roche-sponsored clinical trials continued access to the Roche investigational medicinal product that they received during the clinical trial, when appropriate, as described below. The intent is to bridge the gap for patients, ensuring treatment is not interrupted between completion of the clinical trial and commercial availability of the drug. Therefore, this policy does not apply to study participants randomized to the control/standard of care or placebo arm of the trial and have never received the investigational medicinal product, unless other provisions were made in the study protocol.

Global Policy

The purpose of this Global Policy is to describe the principles that govern when a patient who participates in a Roche-sponsored clinical trial of an investigational medicinal product shall have continued access to that product after completion of the clinical trial, free of charge, while under the care of a personal physician. All of the following criteria must be met:

1. The patient has a life threatening or severe medical condition and his/her well-being requires continued administration of the investigational medicinal product; and
2. There are no appropriate alternative treatments available to the patient; and
3. The patient and his/her doctor comply with and satisfy any legal or regulatory requirements applicable to them.

Upon receipt of a continuing access request from a qualified physician, Roche will employ prompt and fair decision-making and ensure a consistent global approach in compliance with applicable local laws and regulations.

During the provision of continued access to the investigational medicinal product, the patient should be evaluated for continued benefit and risks by their physician and adverse events reported.

Exceptions

Roche will not provide continued access to investigational medicinal product as described above if any of the following criteria are met:

1. The investigational medicinal product is commercially available in the patient's country and is reasonably accessible to the patient (e.g., is covered by the patient's insurance or wouldn't otherwise create a financial hardship for the patient); or
2. Roche has discontinued development of the investigational medicinal product or data suggest that the investigational medicinal product is not effective for the relevant indication; or
3. Roche has safety concerns regarding the investigational medicinal product and/or the benefit risk ratio for the concerned indication is deemed negative; or
4. Provision of investigational medicinal product would not be permitted under the laws and regulations of the patient's country.

In these situations, as well as when the investigational drug has ceased to be manufactured or the time-period for provision of continued access to the investigational drug according to the protocol and informed consent form has been met, the investigator and local health care system should transition the research participant to an appropriate therapy.

Entry into Force

This policy was reviewed by Pharma Development Medical Affairs and adopted by the Pharma Development Leadership on 28 July 2023 and entered into force the same day.