



Roche Clinical Trials Policy in Low and Middle Income Developing Countries

The purpose of this document is to state Roche's clinical trials policy in low and middle income developing countries¹.

This policy applies to all Roche pharmaceutical products used in clinical trials in low and middle income developing countries and is ancillary to the Roche Global Position on Clinical Research.

1. Policy

There are certain circumstances when, for the well-being of patients participating in a trial, continued access to the Roche investigational medicinal product is necessary. Examples are serious, life-threatening or disabling diseases such as HIV/AIDS, cancer, or lupus, when no alternative treatment is commercially available. In these situations, following termination of the Roche Sponsored Clinical Trial, an adequate supply of treatment will be assured for all the Roche Sponsored Clinical Trial participants until the Roche investigational medicinal product becomes available commercially in their country, provided participants continue to receive medical benefit from that medication and the benefit-risk ratio for the product continues to support such use.

Provisions for post trial care should be secured before the trial commences and be clearly specified in the patient informed consent forms. Determinants of treatment failure should also be agreed in writing in advance.

Before commencing a Roche Sponsored Clinical Trial in a low or middle income developing country, Roche will ensure that a description of post trial drug supply is written and incorporated into the protocol and patient informed consent forms. The preferred route is a written agreement obtained by the national health system assuring continuous medication and eligibility of all patients within national treatment systems, post completion of the Roche Sponsored Clinical Trial.

Where the results from a Roche Sponsored Clinical Trial in a low and middle income 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 low and middle income country in which the trial was conducted.

Where there are no plans to apply for marketing authorization of a particular medicinal product in a low or middle income country, Roche will not conduct clinical trials with that particular medicinal product in the concerned low or middle income country.

2. Support for third party sponsored clinical trials in low and middle income countries

Roche will only consider donating medicines or providing support to third party sponsored clinical trials in low and middle income countries where:

- The standard of care is according to accepted standards of therapy for the treatment of the disease as defined in WHO treatment guidelines for resource limited settings or international treatment guidelines.
- The ethical standards are demonstrably equivalent to those of a high income country. This is evident via additional Ethics Committee / Institutional Review Board (IRB) approval from a high income country.

Preference is given to studies incorporating centres in high income countries as well as low or middle income countries.

This policy was up-dated November 2008

¹ World Bank Definitions of Low and Middle Income Countries: <http://data.worldbank.org/country>