

## Roche Clinical Trials Policy in Low and Middle Income Developing Countries

Effective April 2005

This policy applies to all Roche pharmaceutical products except HIV/AIDS in Low and Middle Income Countries and is ancillary to the Roche Global Position on Human Subject Research. Please note the separate HIV/AIDS Clinical Trials Policy in Low and Middle Income Developing Countries.

### 1. Roche Sponsored Clinical Trials

#### **Standard of care**

In Low and Middle Income Countries, Roche complies with its global standard Roche Clinical Trials policy, the global standard Roche SOP for clinical trials, applicable local regulatory requirements and the content of the WHO Good Clinical Practice guidelines whichever afford better protection to patients.

All Clinical trials using Roche pharmaceutical products, where Roche is the Trial Sponsor (“Roche Sponsored Clinical Trial”), will be conducted according to standards of international Good Clinical Practice as laid down in the ICH GCP Guideline E6. Roche will ensure that Good Clinical Practice (GCP) training is provided to those involved in conduct of the study.

In April 2005 Roche defined its Clinical Trials Policy in Low and Middle Income Developing Countries:

Roche commits to register sponsored clinical trial protocols at or prior to inception, and to publish the results of sponsored Phase II – IV Clinical Trials conducted in any country, including but not limited to, low and middle income countries, as classified by the World Bank as per the Roche Publication Policy announced on January 21, 2005.

Roche will make every effort to support the local healthcare infrastructure where appropriate. However as a research based pharmaceutical company it is not in a position to provide such infrastructure where none exists.

Roche commits to provide the investigational product, as required by GCP and in accordance with the regulatory requirements of the country. Roche commits to provide the investigational medicinal product free for the duration of the study.

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 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.

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

Roche commits, to the best of its ability, to protect the ethical rights and privacy of patients participating in Roche Sponsored Clinical Trials and to avoid violations of personal data protection rights and stigma against patients associated with any disease Roche is intending to treat through such Clinical Trials.

Where the results from a Roche Sponsored Clinical Trial in a low or middle income country are used for the purposes of registering the Roche medicinal product in another country, Roche commits to apply for marketing authorisation of the medicinal product in the low or middle income country in which the trial was conducted.

Roche commits that in conducting Roche Sponsored Clinical Trials in low and middle income countries it will work with local investigators and will respect local laws and customs, provided such laws and customs do not compromise patients safety, human rights and dignity, ethical principles, or Good Clinical Practice.

## **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 or international treatment guidelines.
- The ethical standards are demonstrably equivalent to those of a high income country. This is evident via 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.
- There is commitment to publish information about the trial on a public Clinical Trials Registry and finally the results and outcomes of that trial on a public repository.