



### R&D in Developing Countries

#### Tackling a unique set of ethical challenges

Conducting clinical trials in developing countries presents a unique set of ethical issues. For example, there may not be adequate clinical resources available to carry out a study to the same standards applied in developed countries. Also, legislation for assuring ethical practices is often less stringent than in developed countries.

We apply our global position statement on clinical research, the ICH & WHO Good Clinical Practice guidelines, and any applicable local regulations – whichever is most stringent – when conducting clinical trials in low- and middle-income countries. Because of the additional ethical issues present, we also have two ancillary policies specific to low- and middle-income countries: one for clinical trials in general, and one specific to trials of HIV/AIDS treatments. These describe the specific measures Roche takes to ensure that high ethical standards are applied when conducting trials in the developing world, such as:

- Applying for marketing approval in developing countries where the clinical trials for a product are performed, as well as in other countries where the results are used to obtain marketing approval
- Working with local authorities and respecting local customs when conducting clinical trials, provided they do not compromise patient safety, human rights, or personal dignity (as defined by the WHO)
- Working with local healthcare providers when carrying out clinical trials in developing countries, without overstressing their resources.

Read the policies in full:

- Roche [clinical trials policy in low- and middle-income countries](#)
- Roche [HIV/AIDS clinical trials policy in low- and middle-income countries](#).

#### Research into neglected diseases

Roche acknowledges that comparatively low resources are invested in R&D for many of the infectious diseases common in less-developed countries. Many factors contribute to this, such as the intrinsic difficulty of finding safe and effective therapies for many of the diseases caused by parasites, viruses and other pathogens, and the associated challenges of creating a commercially-viable product that will indeed be available to patients.

Roche focuses its R&D efforts on five disease areas. When we discover new therapies within those areas that may meet the needs of patients in developing countries, we are committed to addressing the specific needs of those countries. Examples include developing a formulation of our HIV treatment saquinavir for children, as the vast majority of children infected HIV live in the developing world, and new treatments for hepatitis B and C, which are endemic in the developing world.

Our efforts to increase access to healthcare in the developing world focus on improving the resources available within those regions. Find out more in [Access to healthcare](#).

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