

Statement on the Declaration of Helsinki and the Ethical Conduct of Clinical Studies

May 2008

Pfizer supports the work of the World Medical Association (WMA) and both governmental and non-governmental organizations, to establish strong ethical standards for clinical studies. We conduct our studies in compliance with recognized international standards, including the International Conference on Harmonization (ICH), the Council for International Organizations of Medical Sciences (CIOMS) and the principles of the Declaration of Helsinki. Pfizer provided the WMA with comments on its proposed revisions to the Declaration.

All Pfizer-sponsored clinical studies, in every country, follow accepted ethical, scientific and medical standards that protect the rights of participants. These include policies on informed consent, independent review, post-study care, and the use of placebos. Collectively, these policies are intended to ensure the same standards are applied to all our studies, wherever they are conducted.

Before any study can start, Pfizer requires informed consent from all study participants, and the review and approval of study protocols, including patient information forms, by independent ethics committees. As part of the consent process, clinical study participants are informed about the risks and benefits of participating in a study and whether and how long they will continue receiving therapy after the study is completed.

Where there is no serious risk to the participants, and subject to approval of a qualified ethics committee and government regulators, we use placebo controls in some studies in the U.S., in Europe, and in other countries. Such controls are appropriate where there is no established effective treatment, and where adequate results cannot be obtained by comparing the experimental medicine against an existing therapy.

We never withhold life-saving therapy from patients in a clinical study, nor deny effective treatments, where doing so would pose a significant risk to the health or well-being of the study participants.

Before starting any study – anywhere in the world – we train the participating clinical investigators and site medical staff on the protocol, ethical standards and good clinical practice obligations. We also conduct pre-study assessments of the clinical research facilities to determine their ability to conduct the studies to international standards and in accordance with Company procedures.

All our studies in patients are registered at www.clinicaltrials.gov, which lists the locations of study sites. The great majority are conducted in North America, Western Europe, and Japan. Elsewhere, we are doing more studies in those countries that have established the necessary scientific and medical infrastructure for clinical research. In some cases, our studies are in specific regions where the target diseases are more common, or untreated. For example, we are conducting studies for malaria in Africa and Latin America, but not in the U.S., Western Europe nor Japan, where the disease is rare. For those trials, we work with local authorities and physicians to ensure the necessary support and ethical oversight of those studies. We only run studies in countries where we plan to commercialize the investigational drug, if and after it is shown to be safe and effective.

We regularly audit the conduct of studies and all are overseen by qualified clinical research monitors, who assess whether investigators are following the protocol for the study, international good clinical practice requirements, local regulatory requirements, and Pfizer policies and procedures.

For more information about Pfizer clinical studies, please visit:

www.pfizer.com/research/clinical_trials/clinical_trials.jsp

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