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# Pfizer Becomes The First Pharmaceutical Company To Be Accredited For Protection Of Human Rights In Clinical Research

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Accreditation places Pfizer at Forefront of Highest Ethical and Safety Standards in Clinical Research

(BUSINESS WIRE)--Pfizer Inc announced today that it has become the first pharmaceutical company to be accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) for ensuring the protection of human subjects taking part in early-stage clinical trials.

The AAHRPP accreditation was awarded to Pfizer's clinical research units (CRUs) in New Haven, CT, Brussels, Belgium and Singapore, where the company conducts most of its Phase I clinical research. To earn the accreditation, Pfizer participated in a rigorous, 15-month examination of the clinical research practices at these units.

AAHRPP is an independent, non-profit accrediting body that promotes ethically sound research of the highest quality. Organizations seeking accreditation must provide tangible evidence — through policies, procedures, and practices — of their commitment to ensure human rights protection in clinical research.

"Pfizer is committed to upholding the highest ethical standards in all of our clinical research activities," said Martin Mackay, PhD, president of Pfizer Global Research & Development. "AAHRPP accreditation is tangible evidence of our continuing commitment to maintain the highest global standards for research by protecting the human rights of the individuals who take part in our early-stage clinical trials."

**CRUs and Phase I Research**

Pfizer allowed AAHRPP to audit its three CRUs and demonstrated that these facilities met the high quality and ethical standards set by AAHRPP including requirements for research set by the International Conference on Harmonization (ICH), as well as research regulations in the United States, European Union and Singapore. The process included site visits, interviews and an application for accreditation that exceeded 1,000 pages.

Pfizer's CRUs are staffed by doctors and other health professionals who maintain close ties with nearby hospitals to advance scientific knowledge and share best practices.

Phase I trials are the first studies of an investigational drug in humans. In these trials, small doses of an investigational medicine are administered under close medical supervision to healthy volunteer subjects. This allows researchers to measure responses to the investigational medicine, determine how it is absorbed by the body and how long it remains in the bloodstream, and assess the safety and tolerability of different doses.

“Safety and scientific excellence are the constant themes of our work,” said Rachel Harrigan, MD, Pfizer’s senior vice president of Development Operations**.** “This accreditation acknowledges the commitment of Pfizer’s physicians and other staff to the well-being of our volunteers and to our efforts to conduct the highest quality clinical trials at all stages.”

Pfizer voluntarily sought accreditation to demonstrate its commitment to integrity in research and because it wanted to be among more than 150 of the world’s best universities, hospitals, institutional review boards (IRBs) contract research organizations (CROs), and other organizations that are AAHRPP-accredited.

Pfizer worked closely with IRBs and ethics committees in New Haven, Brussels and Singapore, all of which invested considerable effort to evolve their standard procedures and methods of review for Pfizer studies in order to meet AAHRP standards.

“We are very pleased that Pfizer took a leadership position by demonstrating its commitment to human research protections by seeking and successfully achieving AAHRPP Accreditation,” said Felix Khin-Maung-Gyi, PharmD, chief executive officer of Chesapeake Research Review, an AAHRPP-accredited independent IRB based in Maryland. “I hope all others in the research enterprise, including fellow independent IRBs, sponsors, research institutions and sites, and CROs will follow Pfizer’s lead.

“While many companies strive for excellence in this area, there is no substitute for AAHRPP accreditation to cement the American public’s trust in our partnership for conducting clinical trials,” Dr. Khin-Maung-Gyi added. “It is our shared responsibility to those who both participate in and rely upon results from these trials to devote the necessary and appropriate resources for high quality, ethical research.”

**Integrity in Research**

The AAHRPP accreditation is another step in Pfizer’s ongoing efforts to earn public trust for integrity in research. Others include:

- Requiring that all Pfizer sponsored trials – regardless of where they are conducted -- are carried out under the same international standards, including the International Conference on Harmonization (ICH) 1996 Guidelines for Good Clinical Practice and the global principles set forth in the Declaration of Helsinki.
- Beginning in November 2008, requiring that all Pfizer U.S. multi-center clinical trials are reviewed only by central IRBs that are AAHRPP-accredited.
- Registering clinical trials on the public database www.clinicaltrials.gov. As of 2008, the company registers all clinical trials conducted on a Pfizer product (Phase I and beyond), as well as non-interventional studies with prospective data collection. To date, the company has registered more than 1,000 trials.
- Posting the results of its clinical trials at www.clinicalstudyresults.org. As of 2005, summary results of all patient studies conducted on a Pfizer product (Phase I and beyond) are posted, and starting in 2008, the results of all clinical studies, whether in patients or normal volunteers, are posted, as well as the results of prospective observational studies.
- Providing a regularly updated public website, describing compounds in its drug development pipeline and detailing their progress
- Building infrastructure of the developing world countries, where an increasing number of clinical trials are taking place. This work is conducted in partnership with local authorities and research institutions.
- Conducting training programs in good clinical practice (GCP) standards around the world in countries such as India, a top location for clinical research.

Pfizer is committed to conducting clinical trials globally according to the highest ethical and scientific standards.

Drug development is a worldwide effort and clinical trials are conducted in many countries, providing experience with different patient populations and reflecting the prevalence and incidence of the diseases for which Pfizer is developing medicines. Pfizer posts key company policies related to human subject protection at http://pfizer.com/sciencepolicy.

**About AAHRPP**

AAHRPP accredits high-quality human research protection programs in order to promote excellent, ethically sound research. Through partnerships with research organizations, researchers, sponsors, and the public, AAHRPP encourages effective, efficient, and innovative systems of protection for human research participants. AAHRPP, through accredited research programs worldwide, will ensure that all human research participants are respected and are protected from unnecessary harm.

**Pfizer Inc: Working together for a healthier world™**

Founded in 1849, Pfizer is the world's largest research-based pharmaceutical company taking new approaches to better health. We discover, develop, manufacture and deliver quality, safe and effective prescription medicines to treat and help prevent disease for both people and animals. We also partner with healthcare providers, governments and local communities around the world to expand access to our medicines and to provide better quality health care and health system support. At Pfizer, more than 80,000 colleagues in more than 90 countries work every day to help people stay happier and healthier longer and to reduce the human and economic burden of disease worldwide.

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