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REPORT

Accreditation

Pfizer First Pharma Company to Receive Accreditation for Study Subject Protections

Pfizer Inc. said April 1 it received accreditation for its programs designed to protect people who agree to participate in early-stage clinical drug trials, becoming the first pharmaceutical company to earn such approval of its human subject protection program.

The Association for the Accreditation of Human Research Protection Programs Inc. (AAHRPP) also announced the granting of full accreditation status to Pfizer's three clinical research units (CRUs) in New Haven, Conn.; Belgium; and Singapore. The drug company explained that the CRUs are where Pfizer conducts most of its phase I clinical research, or early-stage testing of products in healthy populations.

AAHRPP has accredited nearly 175 organizations, but most of them have been universities, research institutions, Department of Veterans Affairs medical centers, and institutional or independent review boards.

To earn full accreditation status, AAHRPP and Pfizer engaged in a 15-month process that included auditing Pfizer's three CRUs. The drug company had to demonstrate it met requirements under the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), as well as research regulations in the United States, European Union, and Singapore, the announcement said.

''Pfizer is committed to upholding the highest ethical standards in all of our clinical research activities,'' Martin Mackay, president of Pfizer Global Research & Development, said in the announcement. ''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.''

In addition to earning accreditation for its CRUs, AAHRPP said Pfizer will use only central institutional review boards (IRBs) accredited by AAHRPP to approve its U.S. multi-site clinical trials. Justin McCarthy, chief counsel for Pfizer Global Research and Development, said Pfizer also will encourage its study teams to use research sites accredited by AAHRPP, and ''will continue to support the adoption of the AAHRPP standards internationally.''

Universal Accreditation Urged. Felix Khin-Maung-Gyi, chief executive officer of Chesapeake Research Review, an AAHRPP-accredited independent IRB based in Maryland, said in the Pfizer announcement that he hoped all others in the research enterprise, including fellow independent IRBs, sponsors, research institutions and sites, and clinical research organizations, will follow Pfizer's lead. Gyi is a former member of the Health and Human Services Secretary's Advisory Committee on Human Research Protections.

''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,'' he said in statement.

Marjorie A. Speers, AAHRPP president and chief executive officer, said in a statement that Pfizer's commitment to accreditation will expand the number of study participants covered by AAHRPP standards.

''And that's important, because setting uniform, high standards across the research enterprise—in industry, government, and non-profit sectors—will improve protections for research participants in the U.S. and internationally,'' Speers said.

Pfizer's chief counsel said at an AAHRPP conference in February that the drug company's decision to seek accreditation voluntarily stemmed from what he said was an erosion of public trust in clinical research (8 MRLR 172, 3/4/09). Pfizer, which AAHRPP described as ''the world's largest research-based pharmaceutical company,'' currently is involved in litigation on allegations of misrepresentations about a clinical study of the

arthritis drug Celebrex (8 MRLR 115, 2/18/09), along with a lawsuit in Nigeria over allegations of harming children involved in a clinical study for the antibiotic Trovan (*see related item in the this section*).

Rachel Harrigan, Pfizer's senior vice president of development operations, said safety and scientific excellence are the constant themes of the drug company's work.

''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,'' she said in the April 1 announcement.

Additional Organizations Accredited. In addition to Pfizer, AAHRPP announced the accreditation of another 15 organizations, bringing the total to 175 organizations representing more than 830 entities.

Receiving full accreditation were 13 organizations:

- Binghamton University, State University of New York;
- Birmingham Veterans Affairs Medical Center, Birmingham, Ala.;
- Duke Medicine, Durham, N.C.;
- James H. Quillen VA Medical Center, Mountain Home, Tenn.;
- Lehigh Valley Health Network, Allentown, Pa.;
- Rhode Island Hospital, Hasbro Children's Hospital, The Miriam Hospital, Emma Pendleton Bradley Hospital, and Newport Hospital—part of Lifespan, Providence, R.I.;
- Minneapolis Veterans Affairs Medical Center, Minneapolis;
- Nemours, Jacksonville, Fla.;
- RCRC Independent Review Board, LLC, Austin, Texas;
- San Francisco Veterans Affairs Medical Center;
- St. Cloud Veterans Affairs Medical Center, St. Cloud, Minn.;
- University of California, Riverside; and
- Utah State University, Logan, Utah.

Two organizations received qualifying accreditation: the Kansas City VA Medical Center in Kansas City, Mo., and the White River Junction VA Medical Center in White River Junction, Vt.

More information on AAHRPP accreditation is available at http://www.aahrpp.org.

More information on clinical trials sponsored by Pfizer is available at http://www.pfizer.com/research/clinical_trials/clinical_trials.jsp.

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