NIH and FDA Launch New Human Gene Transfer Research Data System

GeMCRIS will facilitate faster reporting of adverse events in human gene transfer trials

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) announced today that they have launched a new Genetic Modification Clinical Research Information System (GeMCRIS) — a Web-accessible database on human gene transfer. GeMCRIS, developed collaboratively by the two agencies, is a unique public information resource as well as an important new electronic tool to facilitate the reporting and analysis of adverse events on these trials. The new system will provide information to the public directly and will improve the government's ability to monitor adverse events in gene transfer research, also known as gene therapy.

NIH Director Elias A. Zerhouni, M.D., said, "GeMCRIS is an important achievement and a unique resource for scientists, patients, and the public. GeMCRIS will help advance gene therapy, while allowing NIH, FDA, and the research community to maintain appropriate oversight."

Acting FDA Commissioner Lester M. Crawford, D.V.M, Ph.D., emphasized that "the development of GeMCRIS illustrates the government's commitment to addressing public and patient concerns about safety while advancing gene therapy. Providing accurate and complete information about ongoing gene therapy studies is the best way to achieve this goal."

GeMCRIS will enable patients, research participants, scientists, sponsors, and the public at large to become better informed about human gene transfer research. Through drop-down menus and preformatted reports, individuals can easily navigate the GeMCRIS site to view information on particular characteristics of clinical gene transfer trials. For example, GeMCRIS users can learn where trials are taking place, which diseases or health conditions are being studied, and what investigational approaches are being taken. While offering a rich array of information of value to many types of users, GeMCRIS also includes special security features to protect patient privacy and confidential commercial information.

Investigators and sponsors conducting human gene transfer trials will now be able to report...
adverse events using a secure electronic interface on the GeMCRIS system. With this tool, reports can be submitted instantaneously to the NIH. Investigators and sponsors can save their NIH submission on their own computer and send a copy to the FDA in accordance with 21 CFR 312.32 together with a FDA Form 1571. This can be done either by mailing or faxing a signed hard copy or by making an electronic submission in accordance with 21 CFR 11. FDA Form 1571 can be found at http://forms.psc.gov/forms/FDA/fda.html. Those submitting electronic documents should also refer to the Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format-General Consideration at http://www.fda.gov/cber/gdlns/elecgenrev1.htm and related guidance at http://www.fda.gov/cber/esub/esubguid.htm. Additional copies can be routed to Institutional Review Boards, Institutional Biosafety Committees, Data Safety and Monitoring Boards, and other local officials and review bodies as appropriate. The electronic reporting tool is key to efforts by both agencies to improve safety oversight and reporting in human gene transfer trials through the harmonization of NIH and FDA reporting requirements.

The public GeMCRIS site is available at: http://www.gemcris.od.nih.gov. Investigators and sponsors who wish to use the system to report adverse events occurring on human gene transfer trials should send a written request on institutional letterhead by U.S. mail or fax to: GeMCRIS Systems Administrator, NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892; Fax: 301-496-9839.

*The National Institutes of Health — the Federal government's focal point for medical research in the United States — is part of the U.S. Department of Health and Human Services.*