WHO Seeks to Standardize Clinical Trial Registries

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The World Health Organization has launched a major initiative to standardize the way information on clinical trials is made available to the public.

In an attempt to address growing public concerns about the transparency of medical research involving human participants, the World Health Organization is recommending 20 key details that all clinical trial registries should include.

"Registration of all clinical trials and full disclosure of key information at the time of registration are fundamental to ensuring transparency in medical research and fulfilling ethical responsibilities to patients and study participants," Dr. Timothy Evans, assistant director-general of the World Health Organization, said in a statement.

WHO's International Clinical Trials Registry Platform is not itself a registry, but instead provides standards for all clinical trial registries. These standards require inclusion of information about the following: sources of monetary or material support, primary and secondary sponsors, contacts for public and scientific queries, countries of recruitment, health conditions or problems studied, interventions, key inclusion and exclusion criteria, study design, date of first enrollment, target sample size, recruitment status, and primary and secondary outcomes.

The voluntary initiative is part of a growing movement toward greater accessibility to clinical trial information, prompted in part by high-profile cases involving the suppression of data by pharmaceutical companies.

In the European Union, all clinical trials conducted in member states are required to be registered in the EudraCT database, supervised by the European Medicines Agency. In the United States, www.ClinicalTrials.gov (developed and run by the National Institutes of Health) enrolls publicly and privately funded clinical trials worldwide.

However, there are several hundred other national and private clinical trial registries located around the world. The Registry Platform seeks to bring participating registries together in a global network to provide a single point of access to the information stored in them, according to a World Health Organization statement.

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The World Health Organization has acknowledged the need to balance increased transparency with the protection of competitive advantage, and it appears that this issue may come down to a question of the timing of disclosure.

In comments submitted to a World Health Organization formal consultation on disclosure timing policy in April, the Pharmaceutical Research and Manufacturers of America noted "there may be infrequent instances where companies may regard certain data elements as sensitive for competitive reasons and wish to delay public disclosure."

In particular, the organization said that companies may wish to delay the disclosure of the official scientific title of the study, specific mechanism or molecular identifiers of the intervention, target sample size, primary outcome, and key secondary outcomes.

The WHO Registry Platform is expected to launch a Web-based search portal later this year. This search portal would allow interested individuals to search among participating registries for clinical trials taking place or completed throughout the world. ■

For more information on the WHO Registry Platform, visit www.who.int/ictrp/en.

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