Pfizer Conducts First “Virtual” Clinical Trial Allowing Patients to Participate Regardless Of Geography

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Pilot Study Will Compare Results to Previous Trial Data to Assess Validity of New Approach

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(BUSINESS WIRE)--Pfizer Inc. announced today that it is conducting the first-ever randomized clinical trial under an investigational new drug (IND) application that manages study participation entirely using electronic tools and allows patients to participate in the clinical trial regardless of their proximity to clinical sites. The pilot project, initiated following review from the U.S. Food and Drug Administration (FDA), uses mobile phone and web-based technology to collect necessary data for the trial without clinic visits.

The Research on Electronic Monitoring of OAB Treatment Experience – REMOTE – is a U.S.-based Participatory Patient-Centered (PPC) clinical trial designed to assess the safety and efficacy of Detrol LA (tolterodine tartrate), a treatment for overactive bladder (OAB). Pfizer and its research partners hope to determine whether the results of the pilot REMOTE “virtual trial” can replicate the results of a previously completed Phase IV Detrol LA trial, and in this way begin to validate virtual, patient-centered approaches to clinical research.

“With the REMOTE virtual trial pilot, for the first time we can make it possible for patients to participate in clinical trials without having to visit physical sites,” said Pfizer Executive Vice President and Chief Medical Officer Freda Lewis-Hall, M.D., who announced the new trial today during remarks at the National Library of Medicine (NLM) Clinical Trials Conference in Bethesda, MD. “Studies like REMOTE could make biomedical science much more accessible to people who have long been excluded from or under-represented in clinical trials. Putting research within reach of more diverse populations has the potential to advance medical progress and lead to better outcomes for more patients.”

The REMOTE trial is the first-ever randomized “virtual” clinical trial under an IND application to secure patient consent online using video/multimedia and online testing. Study investigators will ship all blinded study medication to patients at home rather than dispensing it at a clinic visit. Researchers will manage study conduct remotely, and share clinical trial data and results with patients, enabling them to add them to their own personal health records.

Investigators in the REMOTE trial plan to enroll about 600 patients from about 10 states across the United States. Enrolled patients will participate in the study screening process through the Internet, actively manage their own trial activity and report results directly to a trial investigator who keeps close oversight of patient eligibility and safety. As a result, researchers expect to save time and obtain better quality, more reliable data through increased patient compliance, lower withdrawal rates and real-time data collection.

“This approach, if proven successful, holds considerable promise in speeding up clinical trials while improving their quality,” said Briggs W. Morrison, M.D., Pfizer’s senior vice president of Worldwide Medical Excellence. “This program and similar programs that may follow could lead to an entirely new way for patients to participate in trials and contribute to biomedical research.”

The REMOTE clinical trial pilot is consistent with the mission of the FDA’s Clinical Trials Transformation Initiative (CTTI) to improve the quality and efficiency of clinical trials. Pfizer has been an active participant in multiple CTTI projects.

“Modernization of clinical trials is a key initiative of FDA. We commend Pfizer’s progress on the REMOTE pilot and encourage all manufacturers considering other novel ideas in advancing clinical trials to have prospective discussions with the Agency regarding trial design and oversight," said Janet Woodcock, M.D., director, Center for Drug Evaluation and Research at FDA. For more information about CTTI, visit www.trialstransformation.org.

“This virtual method enables scientists to conduct trials more efficiently. Additionally, as more people participate in trials conveniently from home, the results of trials may apply to a broader patient population,” said Dr. Steven Cummings, M.D., Emeritus Professor of Medicine at the University of California San Francisco.

Pfizer has reviewed the study approach with the FDA and two institutional review boards have approved the study. Physicians will carefully monitor patient data and patient safety throughout the trial. Patients will be able to interact with study physicians remotely 24 hours a day.

Patients interested in participating can visit the trial site at http://oab.mytrus.com/home or learn more at this YouTube link: http://www.youtube.com/watch?v=0fEx5V45zp4

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This release contains forward-looking information about the pilot REMOTE trial and potential virtual approaches to clinical research, including their potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development and the other risks and uncertainties set forth in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and in its reports on Form 10-Q and Form 8-K.

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