Pfizer Expands Clinical Trial Data Access Policy And Launches Data Access Portal

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Pfizer Inc. (NYSE: PFE) today announced an update of its clinical trial data access policy that will simplify and broaden access to information gathered in Pfizer-sponsored clinical trials. The updated policy builds upon and expands the company's established methods of clinical trial information sharing, including Pfizer's long track record of submitting for publication results from all interventional clinical trials in patients and its pioneering efforts to provide clinical trial results and data to study participants.

Pfizer's updated policy meets or exceeds the "Principles for Responsible Data Sharing" issued by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) in July 2013.

Key elements of Pfizer's expanded policy, effective January 1, 2014, are:

· Pfizer's INSPIIRE public web portal for investigator-initiated research (iirsubmission.pfizer.com) will offer qualified researchers a standard form and process for requesting access to anonymized patient-level data from Pfizer-sponsored trials of approved (or discontinued) products/indications posted on clinicaltrials.gov that have been complete for 24 months.

· An external Independent Review Panel will consider all requests denied or only partially approved by Pfizer and make a final decision.

· Pfizer will publish, on Pfizer.com, synopses of clinical study reports (CSRs) filed with regulatory agencies for approved products for which basic results are posted in the clinicaltrials.gov registry (dating back to September 2007). These CSR synopses will include summary results for all primary and secondary endpoints; any data that could be used to identify individual patients will be removed.

· Pfizer will produce and distribute lay-language summaries of clinical trial results to trial participants who wish to receive them, starting with trials that begin enrolling in 2014, in countries where regulations permit.

· Pfizer is piloting the use of "Blue Button™" technology (launched by the U.S. Departments of Veterans Affairs and Health and Human Services) to enable Pfizer trial participants to download their own electronic clinical data collected in the trial.

Pfizer's expanded clinical data access policy also reinforces the company's current practice of submitting for publication manuscripts for all interventional clinical trials in patients, regardless of outcomes, within 18 months of study completion, and the company's commitment to register and post summary results for interventional human clinical trials to clinicaltrials.gov in the United States and to registries outside the United States as required.

"Increasing use of new analytical tools and processes to better understand patient outcomes suggests that broadening access to information from clinical trials, including patient-level data, when done responsibly, may benefit medical research and public health," said Freda Lewis-Hall, M.D., Pfizer's executive vice president and chief medical officer. "Pfizer's expanded policy is part of a larger and evolving effort by those who create and use clinical data to arrive at a transparent, harmonized process to expand

access in ways that protect patient privacy, respect the regulatory process and maintain incentives to conduct new research."

Pfizer has put in place a number of safeguards designed to protect patient privacy and commercially confidential information, and will ask those requesting patient-level data to sign a data-sharing agreement. All research proposals will be assessed to ensure there is scientific rationale for the research, a well-documented and rigorous statistical analysis plan, and a commitment to publish any resulting findings. Any proposals not fully approved by Pfizer will go to an Independent Review Panel for review and final decision.

The full version of Pfizer's expanded policy, the clinical data request form, the searchable CSR database, the Independent Review Panel membership roster and charter, and more information, including Frequently Asked Questions, are available at http://www.pfizer.com/TrialDataandResults.

Providing Trial Data and Information to Participants

Pfizer is the first company to have provided summaries of trial results directly back to participants in a lay language format. In 2009, Pfizer partnered with the Center for Information & Study on Clinical Research Participation (CISCRP) on a patient lay summary pilot project. Pfizer is working now with CISCRP to begin offering such summaries to trial participants, starting with studies that begin in 2014. In addition to study results, Pfizer has announced the launch of the Pfizer Blue Button™ Project, enabling patients the ability to access their own electronic clinical data.

"Access to clinical data empowers today's patients with information and resources to better manage their health and wellness," said Craig Lipset, head of Clinical Innovation for Pfizer Worldwide Research and Development. "As Pfizer generates clinical data during studies to develop new medicines, we look forward to exploring new ways to make this data meaningful and actionable for our trial participants and their healthcare providers."

Pfizer’s site for clinical trial participants is http://www.pfizerlink.com (registration required and access is limited to alumni of Pfizer-sponsored clinical trials).

About Pfizer:

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com.

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