FDA Program Will Communicate Patient Reported Outcomes from Cancer Clinical Trials

Project Patient Voice is going to provide patient-reported symptoms from cancer trials for marketed treatments.

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FDA Announces First of Its Kind Pilot Program to Communicate Patient Reported Outcomes from Cancer Clinical Trials

The U.S. Food and Drug Administration today launched Project Patient Voice, an initiative of the FDA's Oncology Center of Excellence (OCE). Through a new website, Project Patient Voice creates a consistent source of publicly available information describing patient-reported symptoms from cancer trials for marketed treatments. While this patient-reported data has historically been analyzed by the FDA during the drug approval process, it is rarely included in product labeling and, therefore, is largely inaccessible to the public.

"Project Patient Voice has been initiated by the Oncology Center of Excellence to give patients and health care professionals unique information on symptomatic side effects to better inform their treatment choices," said FDA Principal Deputy Commissioner Amy Abernethy, MD, PhD. "The Project Patient Voice pilot is a significant step in advancing a patient-centered approach to oncology drug development. Where patient-reported symptom information is collected rigorously, this information should be readily available to patients."

Patient-reported outcome (PRO) data is collected using questionnaires that patients complete during clinical trials. These questionnaires are designed to capture important information about disease- or treatment-related symptoms. This includes how severe or how often a symptom or side effect occurs.

Patient-reported data can provide additional, complementary information for health care professionals to discuss with patients, specifically when discussing the potential side effects of a particular cancer treatment. In contrast to the clinician-reported safety data in product labeling, the data in Project Patient Voice is obtained directly from patients and can show symptoms before treatment starts and at multiple time points while receiving cancer treatment.

The Project Patient Voice website will include a list of cancer clinical trials that have available

patient-reported symptom data. Each trial will include a table of the patient-reported symptoms collected. Each patient-reported symptom can be selected to display a series of bar and pie charts describing the patient-reported symptom at baseline (before treatment starts) and over the first 6 months of treatment. This information provides insights into side effects not currently available in standard FDA safety tables, including existing symptoms before the start of treatment, symptoms over time, and the subset of patients who did not have a particular symptom prior to starting treatment.

In the first phase of this pilot website, only one trial will be included while the FDA seeks public feedback on how the information is presented. The FDA will use this feedback to consider improvements to the website in order to make the information as user-friendly as possible.

The visualizations and data included on the website are voluntarily provided by the drug companies that conducted the clinical trials. AstraZeneca is the first company to provide patient-reported outcome data for one of their FDA-approved drugs and has collaborated with the FDA to identify methods to display the information in a way that is informative to health care professionals and patients.

“There have long been calls to provide information to patients about how they may feel and function when receiving a cancer treatment. By initiating Project Patient Voice, we are moving towards standardized methods to display these outcomes, starting with patient-reported symptomatic adverse events,” said Paul Kluetz, MD, deputy director of the FDA’s OCE. “We encourage sponsors to collect this data systematically and look forward to welcoming additional sponsor collaboration as we work to help further serve the patient community.”

Project Patient Voice is not meant to replace the clinician-reported safety information that is available as part of a drug’s labeling. Data from Project Patient Voice should not substitute for advice from a health care professional. Rather, Project Patient Voice serves as a complement to FDA patient labeling and patient information, not a sole source of information on which to make decisions about medical care.

The FDA will seek public feedback regarding the Project Patient Voice pilot effort at a virtual public workshop co-sponsored with the American Society of Clinical Oncology on July 17. The “Clinical Outcome Assessments in Cancer Clinical Trials” workshop will include health care providers, patients, health outcomes researchers, industry, advocacy groups and other stakeholders interested in rigorous measurement of symptom and functional outcomes. In addition to discussing trial design considerations to obtain patient-reported symptomatic side effects, the FDA will obtain feedback on the presentation of PRO symptomatic side effect data on the Project Patient Voice website to further ensure that the information is clear and meaningful to health care professionals and patients.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible

for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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