FDA Takes Steps to Enhance Clinical Trial Transparency

Agency is exploring new ways to share information about product approvals.

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FDA Statement

FDA Commissioner Scott Gottlieb, M.D., on new steps FDA is taking to enhance transparency of clinical trial information to support innovation and scientific inquiry related to new drugs

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Scientific progress and new drug innovation don't take place in a vacuum. The exchange of information that informs decisions to undertake research, invest in new scientific endeavors, and prescribe and use certain treatments effectively are a critical part of enabling the development and dissemination of new medical technology. Transparency related to this information can play a critical role in maximizing the public health value of the resulting innovations.

As part of our efforts to enhance transparency around our drug approval decisions, we're exploring new ways the U.S. Food and Drug Administration can continue to build on its obligation to share information about product approvals. We're especially focused on information that can improve patient care and better inform providers about the products they prescribe. One place where we are evaluating how we can release information that may better inform scientists, providers, and patients is clinical study reports (CSRs).

Right now, when a drug is approved, the FDA releases certain information that the agency used when reviewing the new drug application (NDA). This includes summaries written by our medical reviewers that capture their assessment of the data, the proposed labeling or other requirements, and other important, relevant data supporting safe and effective use. This information is included in our drug approvals database, Drugs@FDA.

These summaries provide important context on the basis for our approval decisions. But they are packaged in a format that can sometimes make it difficult for external audiences to extract all of the detailed clinical evidence that supported the FDA's approval decisions.

Today we're launching a new pilot program to evaluate whether disclosing certain information

included within CSRs following approval of a NDA improves public access to drug approval information. In this pilot, we will select up to nine recently-approved NDA whose sponsors volunteer to participate and post portions of clinical trial-related summaries from the pivotal trials that were submitted to the FDA by the drug's sponsor on Drugs@FDA.

These company-generated summaries are called "clinical study reports" (CSRs). A CSR is a portion of the drug file, related to a clinical trial, that contains detailed summaries of the bottom line information on the methods and results of a clinical trial. A CSR is a scientific document addressing efficacy and safety. A detailed summary of the information contained in the CSR can be found on the website of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. We expect that making a CSR publicly available after a drug's approval will provide stakeholders with more information on the clinical evidence supporting a drug application and more transparency into the FDA's decision-making process.

As part of this effort, we intend to post the parts of the CSRs that were most important to the FDA's assessment of the safety and efficacy of the drug. Specifically, we'll include the study report body, the protocol and amendments, and the statistical analysis plan for each of the participating product's pivotal studies. The CSRs will be posted on a new web page on the FDA's website that describes the pilot program, in addition to appearing on Drugs@FDA along with the drug's approval information, soon after a drug is approved.

The pilot will begin this month. It will ultimately include up to nine new drug applications across a range of disease areas. We intend for initial participation in the pilot to reflect products that are novel (including drugs that are new molecular entities, or NMEs) and of scientific interest (e.g., certain NDA efficacy supplements). Soon we'll begin contacting sponsors to see if they are interested in participating in the pilot. We will provide participating sponsors with additional information to ensure their understanding of the process. We will also continue to protect patient privacy, trade secret, and confidential commercial information in the CSRs we release as part of the pilot.

Once the clinical trial transparency pilot program is complete, we'll seek public feedback through a Federal Register notice and docket for public comments, and we look forward to learning more about the benefits of expanding this effort, and how to support our stakeholders' needs.

To augment our CSR pilot, we're also announcing an additional, new effort to increase transparency and access to information about the trials associated with particular products.

A significant number of publicly and privately supported clinical trials register on the National Institutes of Health's database, ClinicalTrials.gov, which provides easy access to information on studies in a wide range of diseases and conditions. Many of the global trials listed on ClinicalTrials.gov relate to research involving new drugs, and may eventually form the basis of an application seeking FDA approval. Yet right now, tracking a specific clinical trial listed on ClinicalTrials.gov and correlating that trial to its relevance in informing FDA related activities – from advisory committee meetings to FDA approval decisions and to the inclusion of the results of

a clinical trial into a drug product's label – can be challenging.

So, another way we plan to help foster greater transparency around clinical research is adding to FDA materials for future FDA drug approvals the ClinicalTrials.gov identifier number (called the NCT #). This number will make it easier to associate the clinical trial listings on ClinicalTrials.gov to FDA communications about specific drugs, including product labeling and even our advisory committee meeting materials. Members of the patient, academic and scientific communities can easily use this number to identify and track clinical research from a drug's development throughout the regulatory process. Including this number on FDA materials could greatly benefit all those interested in following the progress of specific clinical research.

We're committed to enhancing transparency about the work we do at the FDA, especially when it has the potential to foster further research and discovery across the scientific community, and better inform patients and providers. We'll continue to seek new ways to enable greater access to key scientific information that can advance scientific inquiry and improve public health.

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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