FDA’s Project Facilitate Will Help Providers Access Experimental Cancer Therapies for Patients

New initiative will help health care providers navigate the process of submitting expanded access requests.

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FDA announces Project Facilitate to assist physicians seeking access to unapproved therapies for patients with cancer

Today, the U.S. Food and Drug Administration Oncology Center of Excellence announced a new pilot program to assist oncology health care professionals in requesting access to unapproved therapies for patients with cancer. A new call center called Project Facilitate will be a single point of contact where FDA oncology staff will help physicians treating patients with cancer through the process to submit an Expanded Access request for an individual patient, including follow-up of patient outcomes.

“For decades, the FDA has been deeply committed to helping facilitate access to investigational medical products for patients with serious or immediately life-threatening diseases, while also protecting patients and helping them to be able to make informed decisions with their physicians. The first option for patients who have exhausted available treatments is to enroll in a clinical trial, but when that is not an option, we support Expanded Access and are exploring ways to make it easier for patients, their families and health care professionals to understand the process and how to access investigational therapies,” said Acting FDA Commissioner Ned Sharpless, M.D. “The FDA has been working diligently to improve the Expanded Access framework, including development of an updated and more streamlined application form, but despite recent improvements, we understand that for many patients or health care professionals, especially those not familiar with the Expanded Access program, the process may appear confusing or burdensome. Today’s launch of Project Facilitate is part of our continued commitment to Expanded Access and we hope that this pilot program will simplify the process for oncologists, and ultimately benefit patients.”

The FDA recently issued guidances encouraging companies to broaden their eligibility criteria to allow more patients with cancer to participate in clinical trials. But in those cases where patients do not fit the trial requirements or live too far from a trial site, health care professionals can

request permission from the FDA to treat a patient with an investigational medical product through Expanded Access.

Expanded Access is a pathway for a patient with an immediately life-threatening or serious disease or condition to gain access to an investigational medical product (drug, biologic or medical device) for treatment outside of clinical trials when there are no comparable or satisfactory alternative therapy options available.

Because investigational medical products have not yet been approved or cleared by the FDA and have therefore not been found safe and effective for their specific use, part of the FDA's role in granting Expanded Access requests is helping weigh whether the potential benefit of the investigational treatment justifies the potential risks. To make a request, the patient's physician will contact the pharmaceutical company to ask for its agreement that it will provide the medical product. The company has the right to approve or disapprove the physician's request. The FDA authorizes the vast majority of these requests. This process can be perceived as complex to navigate, particularly for oncologists who don't have experience working with clinical trials or these types of requests.

"Ultimately, a patient cannot submit an application for an investigational medical product; only a qualified physician is able to officially make the request. The new Project Facilitate call center aims to help in making these requests as streamlined and efficient as possible for physicians who would like to request access to investigational therapies for their patients with cancer," said Richard Pazdur, M.D., director of the FDA's Oncology Center of Excellence and acting director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "Through this pilot program, experienced FDA oncology staff will be available to support physicians and other healthcare professionals with their questions, assist in filling out the appropriate paperwork and acting as a facilitator for the process."

The new pilot call center will enhance the FDA's efforts to gather data on the Expanded Access program to help improve the process for physicians and patients. Prior to the pilot program launch, Expanded Access requests for patients with cancer arrived at multiple places within the FDA and were forwarded separately to FDA oncology or hematology divisions. The pilot program includes a central office for oncology requests so that the FDA can follow up on individual requests and gather data, such as how many patients received the investigational medical products and if not, why the requests were denied. The FDA can use this data to determine how the process is benefiting patients and health care professionals. In addition, the data could assist in encouraging sponsors to open clinical trials to study drugs for additional indications.

The FDA's Oncology Center of Excellence, in conjunction with the Reagan-Udall Foundation for the FDA, held a public workshop on May 16, 2019, to obtain input regarding gaps in patient and health care professionals' knowledge of the current system for Expanded Access requests and to gain feedback on the Project Facilitate pilot program. The Reagan-Udall Foundation for the FDA, an independent 501(c)(3) not-for-profit organization created by Congress for the purpose of advancing regulatory science to support the FDA's mission, recently updated its Expanded Access

Navigator web resource designed to educate patients and health care professionals about the FDA Expanded Access process. The Navigator offers information provided by companies about their Expanded Access policies and now includes Expanded Access programs listed in ClinicalTrials.gov.

The Project Facilitate phone number is 240-402-0004 and the email address is OncProjectFacilitate@fda.hhs.gov. Health care professionals may call during regular business hours, 9 a.m. to 5 p.m., Eastern Daylight Time, Monday through Friday. Patients and families with questions can call 301-796-3400 or email druginfo@fda.hhs.gov.

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http://beta.docker.tusaludmag.com/article/fdas-project-facilitate-will-help-providers-access-experimental-cancer-therapies-patients