U.S. FOOD & DRUG ADMINISTRATION

Facts About FDA and Cancer Products

Patients are at the center of what the U.S. Food and Drug Administration does and are vital to our work protecting the public health. One of the FDA's top public health priorities is regulating medical products, including cancer treatments, to make sure they are safe and effective.

The FDA Oncology Center of Excellence (OCE) serves as the FDA's hub for the clinical review of oncology products, bringing together experts from across the FDA to conduct expedited review of drugs, biological products, and, in consultation with the FDA product centers, certain devices intended to diagnose or treat patients with cancer. OCE also has many projects (available at www.fda.gov/oceprojects) to advance innovation in cancer product development, support research, and engage with patients and advocacy groups, researchers, health professionals and international regulatory agencies to create an efficient regulatory process.

Here are the facts on the FDA and how cancer treatments are regulated.

Patient Engagement

FDA incorporates patient input during the oncology drug and device development and review process.

The FDA regularly engages with patients and caregivers about FDA-regulated products. To inform our priorities and decisions, we gather information about the patient experience through many different patient engagement programs.

Go to www.fda.gov/patients and www.fda.gov/about-fda/oncology-center-excellence/project-community to learn more about patient engagement at the FDA.

Diversity, Equity, and Inclusion

FDA works to make cancer clinical trials more diverse and representative of the populations who experience cancer.

The FDA has oncology-specific projects and programs to:

- Encourage efforts to enroll clinical trial participants who more closely reflect the demographic representation of patients with cancer for whom the products are intended.
- Conduct outreach to people living in underserved communities who are at greater cancer risk.
- Bring focus and awareness to underrepresented populations like Asian American, Native Hawaiian, and other Pacific Islander patients with cancer.
- Increase representation of adults who are 65 years and older in cancer clinical trials.

Faster Review

FDA prioritizes approving safe and effective cancer treatments as soon as possible.

The FDA developed five approaches to help make new treatments available as quickly as possible. An application may be designated with any combination of these five approaches:

- Fast Track
- Priority Review
- Accelerated Approval
- Breakthrough Therapy
- Regenerative Medicine Advanced Therapy

Developed in 1992 in response to the HIV/AIDS crisis, the accelerated approval approach has been used extensively for oncology and hematology indications, allowing access to life-saving treatments a median of about 3 years earlier.

The FDA also has oncology-specific projects and programs to:

- Accelerate the development of breakthrough therapy-designated drugs and biological products.
- Begin evaluating applications earlier by encouraging researchers to submit topline efficacy and safety results before they submit a complete application.
- Allow concurrent submission and review of oncology products among international partners.
- Enable certain patients to receive an investigational medical product outside of clinical trials when there are no comparable or satisfactory treatments available.

Rigorous and Independent Review

FDA independently and carefully examines the safety and efficacy of all FDA-regulated products.

Prior to approval, each drug and biologic marketed in the U.S. must go through a rigorous, multi-step FDA review process. When an application receives one or more of the approaches used to accelerate availability of new treatments, it does not change the scientific and medical standards for approval. The FDA conducts a thorough and efficient review to assure the evidence necessary for FDA approval is of satisfactory quality. We make independent and unbiased regulatory decisions based on scientific data and evidence.

In certain cases, we get outside perspective from the Oncology Drug Advisory Committee on challenging applications. Our advisory committee meetings are public, and we present the rationale behind our scientific decision-making publicly. We also don't stop evaluating a medical product upon FDA approval. We may request post-marketing trials and we continuously monitor post-market safety to assure newly approved treatments continue to be safe and work as intended.

Modernizing Evidence Generation

FDA works to modernize and accelerate cancer clinical trials.

The FDA has oncology-specific projects and programs to:

- Open and complete clinical trials more quickly, using more pragmatic trial designs answering clinical questions important to patients and their doctors.
- Explore more efficient cancer drug development defined by molecular alterations, rather than by organ or cancer site.
- Advance the current standards in oncology drug development to better assess patient safety and tolerability during the dose selection and testing phase.

The FDA prioritizes reviewing applications for new cancer treatments as soon as possible. Assuring the safety and efficacy of all oncology products is our top priority. Our regulatory process is comprehensive, independent from bias and influence, and relies solely on scientific data and evidence. And today the FDA works to modernize and accelerate cancer clinical trials to include diverse and representative populations while incorporating patient input.