

The main responsibilities of the FDA include:

- Ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices
- Ensuring safety of the nation's food supply, cosmetics, and products that emit radiation
- Regulating manufacturing, marketing and distribution of tobacco products to reduce tobacco use, especially by minors
- Providing accurate, science-based health information to the public
- Advancing public health by speeding innovations in medical products
- For official website of FDA, click here : <https://www.fda.gov>

Application and Approval Pathways:

The **IND** and **NDA** application and approval pathways offered by FDA in the US are as follows:

- Investigational New Drug (IND): Through an Investigational New Drug (IND) application, Sponsors seek US FDA authorization to begin testing new drugs or biologics in humans
- New Drug Application (NDA): To market a new drug, the sponsor submits an NDA, including safety, effectiveness, manufacturing, and labeling data for review
- The FDA application process for IND and NDA is conducted primarily through electronic submissions via the FDA's Electronic Submissions Gateway using the eCTD (electronic Common Technical Document) format. The FDA requires that regulatory communications, application forms and supporting documentation be submitted in English
- Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials. During this time, FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk
- The FDA's standard review time for New Drug Applications (NDAs) is generally 10 months from the date of submission acceptance. In case of a Priority

Review, the FDA aims to complete its review within 6 months instead of the standard 10 months

- To make promising treatments for serious diseases available faster especially when they are the first of their kind or better than existing options, the FDA uses four key pathways:
1. **Priority Review:** Priority Review means the FDA aims to decide on a drug application within 6 months
 2. **Breakthrough Therapy:** A process that speeds up drug development and review for treatments that may work significantly better than current options
 3. **Accelerated Approval:** These rules let drugs for serious conditions with unmet needs get approved based on substitute measures that are expected to predict real clinical benefits
 4. **Fast Track:** Fast Track is a process that helps speed up the development and review of drugs for serious conditions that lack effective treatments

Inspection:

The FDA regulates all clinical trials through its BIMO program to ensure safety, ethics, data accuracy and dependability BIMO is The FDA's Bioresearch Monitoring (BIMO) program. It conducts inspections of clinical trials to:

- Protect the rights and safety of participants
- Ensure trials follow ethical and legal standards
- Confirm the data submitted to the FDA is trustworthy

Who gets inspected? – Clinical investigators, sponsors, contract research organizations (CROs), Institutional Review Boards (IRBs) and others involved in research

What do they check? Compliance with Good Clinical Practice (GCP), proper documentation, protocol adherence, and data integrity

For more information on FDA's Bioresearch Monitoring Program click here:

Bioresearch Monitoring Program Information | FDA

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/processes-and-practices-applicablebioresearch-monitoring-inspections>