
FDA 101: A Road Map to Getting Started

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FDA Mission

- Promote public health
 - Review clinical research and take action with regard to marketing of regulated products in a timely manner
 - Foods are safe, & properly labeled
 - Human and veterinary drugs are safe and effective
 - Medical devices are safe and effective
 - Cosmetics are safe & properly labeled
- Participate in regulatory harmonization with other countries
- When appropriate, FDA can achieve its mission through consultation with experts and through cooperation with consumers, users, manufacturers of regulated products

FDA Overview

- Created by the Food, Drug, and Cosmetic Act of 1938
- Part of the Executive Branch of US government
- Within the Department of Health and Human Services
 - Commissioner of FDA is appointed by the president, but must be confirmed by the Senate (term of 5 years)
- Comprised of six Centers
 - CDER, CBER, CDRH, CFSAN, CVM, CTP
 - Each regulate a specific class of “articles” and has some unique policies and procedures
 - Each Center further broken down into Divisions and Offices

FDA Centers

- Center for Drug Evaluation & Research (CDER)
- Center for Biologics Evaluation & Research (CBER)
- Center for Devices and Radiological Health (CDRH)
- Center for Food Safety & Applied Nutrition (CFSAN)
- Center for Tobacco Products (CTP)
- Center for Veterinary Medicine (CVM)

Life Cycle Regulatory Process

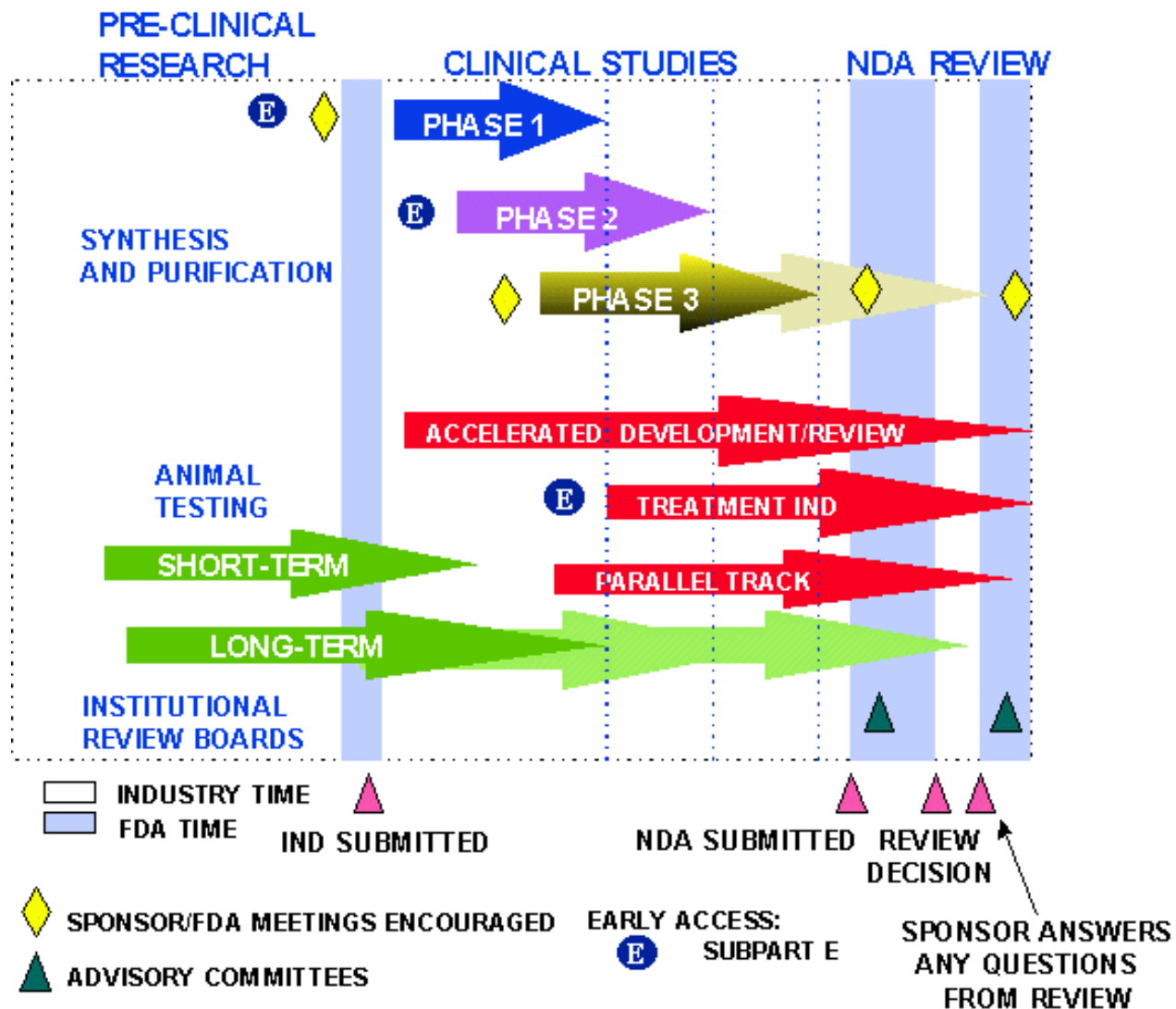
Sponsor Action

- ❑ Discovery Research
- ❑ Pre-Clinical
- ❑ Clinical
 - IND
- ❑ Regulatory Submission
 - NDA/BLA/ANDA
 - Questions
 - Appeal (formal and informal)
- ❑ Post Approval
 - Reports (Annual, Adverse Event)
 - Compliance Inspections
 - Post Approval Studies and Supplements
 - Promotional material submission
 - Compliance and enforcement actions
 - Phase IV Studies
 - REMS

FDA Action

- ❑ Minimal Involvement
- ❑ Good Laboratory Practices
- ❑ Review/Approval/Hold of
 - IND
- ❑ Review: Approval/Rejection
 - NDA/BLA, ANDA
 - Audit of clinical data and pre approval inspection(s)
- ❑ Post Approval
 - Review of Reports
 - Inspections
 - Enforcement

New Drug Development Process



Starting the IND Process

- Consult FDA Guidance documents
 - <http://www.fda.gov/regulatoryinformation/guidances/default.htm>
- Request a pre-IND meeting with the appropriate division of FDA
- Prepare specific questions for FDA to address
- Submit briefing document that contains adequate information for FDA to respond to your questions
- Prepare IND incorporating advice and recommendations received from FDA at the pre-IND consultation

IND Content & Format

■ Regulations

- ❑ 21 CFR 312.21: Phases of an Investigation
- ❑ 21 CFR 312.23 (a)(7)(iv): CMC Information Content

■ Guidance Documents

- ❑ Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products
- ❑ INDs for Phase 2 and Phase 3 Studies Chemistry, Manufacturing, and Controls Information
- ❑ Others as specific to your product

IND Review Criteria

- Safety of the use of the investigational drug for the proposed studies
 - Benefits exceed risk for the intended investigational use and population
- Adequate observations and controls are included in the clinical study design
- An IND goes into effect 30 days after the FDA receives the IND, unless the FDA notifies the sponsor of a clinical hold
- Regulations emphasize the graded nature of CMC information needed as drug development progresses under an IND

Keys to a Successful Relationship with FDA

- Remember that the FDA's mission is to protect the public health
- Know the legal requirements
- Use technical and regulatory experts
- Understand the Agency's policies and historical positions
- Know the scientific and factual issues
- It is OK to respectfully disagree when data and facts support your position
- Present truthful and accurate positions supported by facts
- Remember the FDA motto, "in data we trust"