

Introduction and Overview

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2019 PhUSE CSS



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Topics

2019 PhUSE CSS Food and Drug Administration

Mission

IND
Application

New Drug
Application
(NDA)

Phases of
Clinical
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The
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Q&A

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Mission

The mission of the FDA's Center for Drug Evaluation and Research (CDER) is to ensure that drugs marketed in this country are safe and effective



CDER is the largest of the FDA's six centers. It has responsibility for both prescription and non-prescription or over-the-counter (OTC) drugs.

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IND Application



Sponsors-companies, research institutions, and other organizations take responsibility for developing a drug. They must show the FDA results of preclinical testing in laboratory animals and what they propose to do for human testing.



FDA decides whether it is reasonably safe for the company to move forward with testing the drug in humans.



Clinical Trials - Drug studies in humans can begin only after an IND is reviewed by the FDA.

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Phases of Clinical Testing



Phase 1 studies determine what the drug's most frequent side effects are and, often, how the drug is metabolized and excreted. Emphasis is on safety.

Phase 2 studies aim to obtain preliminary data on whether the drug works in people who have a certain disease or condition. The emphasis is on effectiveness.



Phase 3 studies begin if evidence of effectiveness is shown in Phase 2. These studies gather more information about safety and effectiveness, studying different populations and different dosages and using the drug in combination with other drugs.

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New Drug Application

What is an NDA?



The formal step a drug sponsor takes to ask that the FDA consider approving a new drug for marketing in the United States

What does an NDA include?



- All animal and human data
- Analyses of the data
- Information about how the drug behaves in the body
- How the drug is manufactured

The FDA can refuse to file an application that is incomplete



60
Days

For the FDA to decide whether to file, so the NDA can be reviewed

CDER expects to review and act on at least 90% of NDAs for standard drugs no later than 10 months after they are received.
priority drugs the review goal is six months.



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The Review Process



The official review time is the length of time it takes to review a new drug application and issue an action letter, an official statement informing a drug sponsor of the agency's decision.



Once a new drug application is filed, an FDA review team evaluates whether the studies the sponsor submitted show that drug is safe and effective for its preferred use.



The review team analyzes study results and looks for possible issues with the application. Reviewers determine whether they agree with the sponsor's results and conclusions, or whether they need any additional information to make a decision.



Each reviewer prepares a written evaluation containing conclusions and recommendations about the application. These evaluations are then considered by team leaders, division directors, and office directors, depending on the type of application.



Sometimes the FDA calls on advisory committees, who provide FDA with independent opinions and recommendations.

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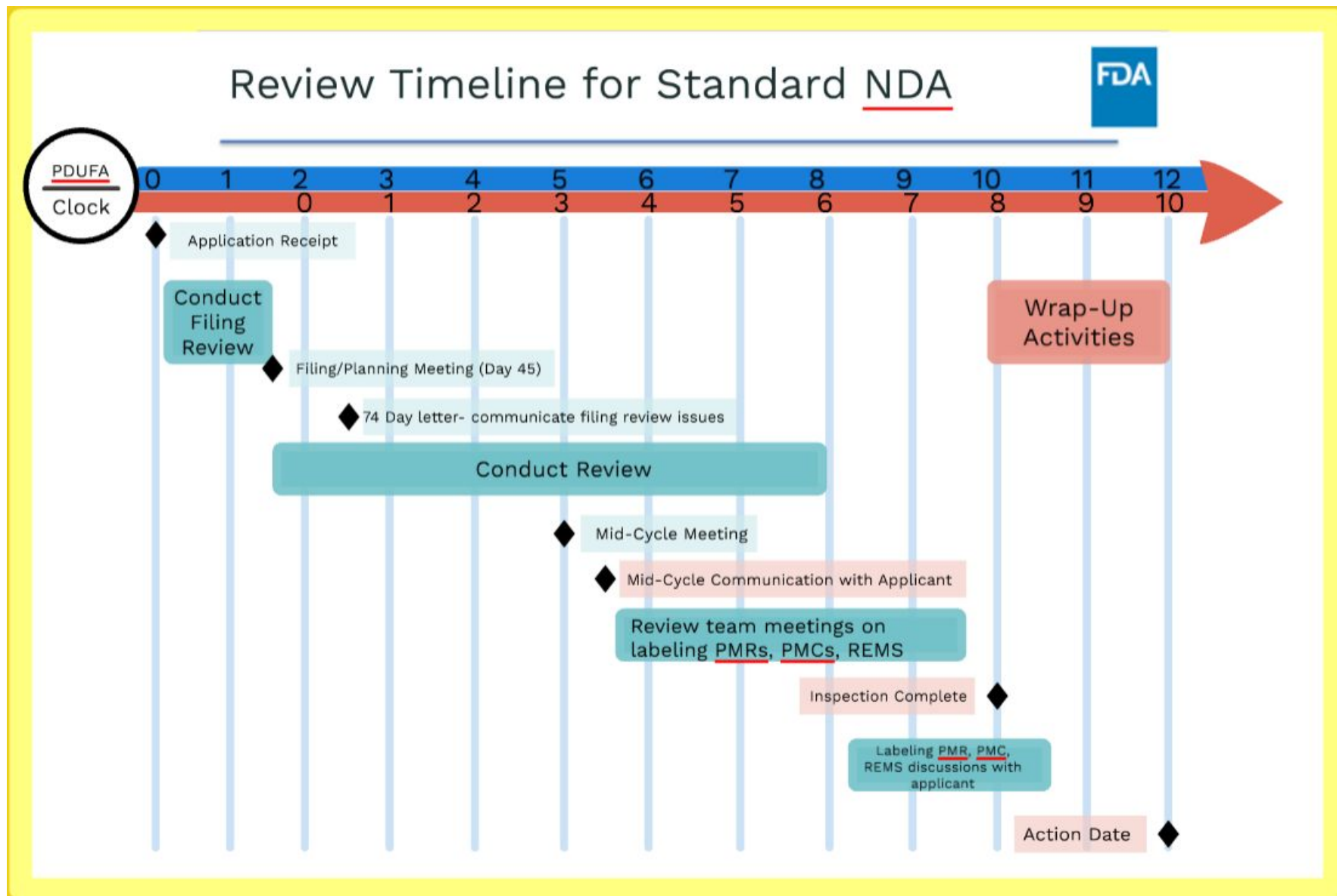
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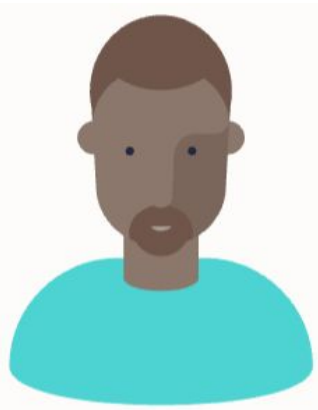
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Nonclinical
Reviewer



Clinical
Reviewer



Statistician



Clinical
Pharmacologist



Chemist

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