Drug Approval Pathways

Standard Approval

1. Drug/medication is developed.
2. Drug goes through a clinical trial.
3. The clinical trial shows the drug has clinical benefits.
4. The clinical trial shows that the benefits of the drug outweigh the risks.
5. FDA grants standard approval and the drug is made available for public use.

Accelerated Approval

1. Drug/medication is developed.
2. Drug goes through a clinical trial.
3. Surrogate endpoints suggest it may be effective.
4. FDA grants accelerated approval and the drug is made available for public use.
5. Confirmatory study is required to show that there are clinical benefits, and that the benefits

Standard Approval

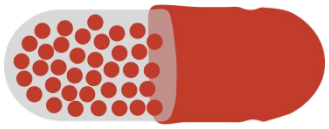
Up to 7 years

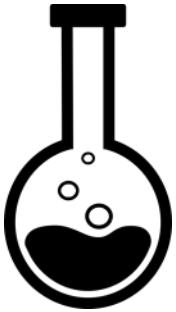
New drug is developed

Clinical trial

Clinical benefit

FDA Standard Approval





Accelerated Approval

New drug is developed

Clinical trial

Sign of possible clinical benefit

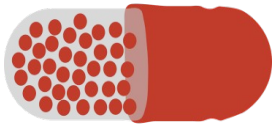
FDA Accelerated Approval

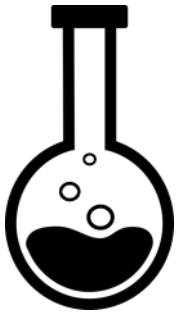
Confirmatory study required

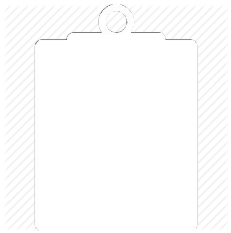
FDA Standard Approval

OR

Approval withdrawn







Definitions

- Clinical trial: A scientific way to measure the benefits and risks of a new drug.
- Surrogate endpoint: A measure of a drug's effect that may or may not be associated with clinical benefit (e.g., a tumor gets smaller or blood tests get better).
- Clinical benefit: A drug is shown to help people live longer and/or to improve their symptoms.

Label Term Definitions

- Response rate: The proportion of people for whom the tumor shrinks.
- Duration of response: How long the benefit of the drug lasts over time (e.g., how long the drug is able to shrink or stop the tumor from growing).