THE DRUG DEVELOPMENT PROCESS

DRUG DISCOVERY

Researchers find compounds that **may treat a certain disease or condition**.

10,000's of Potential Drugs

PRE-CLINICAL DEVELOPMENT

Animal and lab studies are conducted to **test for toxicity and effectiveness** in treating a certain disease or condition.

Researchers apply to conduct **human studies** and **obtain FDA approval**. This is called an Investigational New Drug (IND) Application. The FDA then works with researchers on clinical trial design throughout the clinical trial phases.

250 Potential Drugs

CLINICAL TRIALS

PHASE 0: Tests a very small amount of a drug in healthy individuals to assess safety.

PHASE 1: Tests a drug in small numbers of healthy individuals for safety.

PHASE 2: Tests a drug in a small number of participants with a certain disease or condition for effectiveness and continued safety.

PHASE 3: Tests the effectiveness and continued safety of the drug in a much larger number of people with a certain disease or condition.

5 Potential Drugs

Researchers submit a New Drug Application (NDA) to the FDA for approval.

FDA REVIEW

The FDA makes its decision based on the safety and efficacy data from ALL the animal and human studies that were conducted and reviews the drug labels and the manufacturing facilities where the drug will be made.

FDA APPROVAL

1 APPROVED DRUG

POST-MARKETING

PHASE 4: After a drug has been approved and is being used in the real world, phase 4 studies monitor for any additional side effects and continued safety and effectiveness.