In the United States, it takes an average of 12 years for an experimental drug to travel from the laboratory to your medicine cabinet. That is, if it makes it.

Only 5 in 5,000 drugs that enter preclinical testing progress to human testing. One of these 5 drugs that are tested in people is approved. The chance for a new drug to actually make it to market is thus only 1 in 5,000. Not very good odds.

The process of drug approval is controlled in most countries by a governmental regulatory agency. In the U.S., the Food and Drug Administration (FDA) governs this process. The FDA requires the following sequence of events before approving a drug.

- **Preclinical Testing**: A pharmaceutical company conducts certain studies before the future drug is ever given to a human being. Laboratory and animal studies must be done to demonstrate the biological activity of the drug against the targeted disease. The drug must also be evaluated for safety. These tests take on the average 3 1/2 years.

- **Investigational New Drug Application (IND)**: The pharmaceutical company files an IND with the FDA to begin testing the drug in people. The IND becomes effective if the FDA does not disapprove it within 30 days. The IND must include the following information: the results of previous experiments; how, where and by whom the new studies will be conducted; the chemical structure of the compound; how it is thought to work in the body; any toxic effects found in the animal studies; and how the compound is manufactured. The IND must also be reviewed and approved by the Institutional Review Board where the studies will be conducted.

- **Phase I Clinical Trials**: Phase I studies are usually the first tests of a drug under development in healthy volunteers. These studies involve about 20 to 80 volunteers. The tests determine a drug's safety profile, including the safe dosage range, plus how the drug is absorbed, distributed, metabolized and excreted, and the duration of its action. Phase I trials take on the average 1 year.

- **Phase II Clinical Trials**: These are slightly larger studies that are done in patients with the disease for which the drug is intended. This phase is usually designed to identify what are the minimum and maximum dosages. The trials generally involve 100 to 300 volunteer patients and are controlled in design. They are done to assess the drug's effectiveness. Phase II typically takes about 2 years.

- **Phase III Clinical Trials**: These are the definitive, large randomized trials that are submitted to the FDA in order to obtain approval of a drug. This phase examines the effectiveness as well as the safety (adverse events) of the new drug. Phase III trials usually involve 1,000 to 3,000 patients in clinics and hospitals. Patients are usually asked a list of possible side effects, often derived from what was observed in phase II studies. Patients are also free to report any other side effects that occur while they are on the new drug or the placebo (the "sugar pill" that is given to a percentage of patients in a trial study). Phase III takes on the average 3 years.

- **New Drug Application (NDA):** Following the Phase III Clinical Trials, the drug manufacturer analyzes all the data from the studies and files an NDA with the FDA (provided the data appear to demonstrate the safety and effectiveness of the drug). The NDA contains all of the data gathered to date about the drug. (An NDA typically consists of at least 100,000 pages.) The average NDA review time for new drugs approved in 1992 was close to 30 months (2 1/2 years).

- **Phase IV Studies**: Phase IV is any organized collection of data from patients who are taking a drug that has already received approval from the FDA. In Phase IV studies, patients may check boxes on a list (as in phase III studies) or they may just report other symptoms. Phase IV studies are commonly called "post-marketing studies."

Although there are other routes that can expedite the process (referred to as fast-tracking), this is the usual journey for a drug from invention to market in the U.S.

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