From preclinical to approval: How clinical trials bring new treatments to market.

Potential new drugs can be found almost anywhere – after all, aspirin was originally derived from the bark of willow trees – but before it can be safely taken by people, all drugs go through a rigorous testing process. Here's a break-down of what's involved in the drug development process, from preclinical through to commercialization and post-approval monitoring.

How do I get involved?

Check out the PatientsLikeMe Clinical Trial Finder – it's where you can search for clinical trials based on what would be a good fit for you.

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Preclinical

Before testing a drug in people, researchers need to find out whether the drug has any potential side effects or could cause serious harm (toxicity). Preclinical studies tend to be quite small, but their purpose is to provide detailed information on toxicity levels and to determine a safe dose for the first in-human tests in phase I.

Phase I

Phase I trials usually last for a few months and generally involve 20 to 100 volunteers who are healthy or are living with the condition the drug is intended for. These trials test whether the new treatment is safe and well tolerated in patients and investigates how it interacts with the human body - researchers look at things like side effects, dosing levels and how best to administer the drug.

Phase II

These trials can last from months to a couple of years and generally involve up to several hundred participants living with the condition the drug is designed to treat. Here researchers test the treatment's efficacy – is it doing what it is supposed to be doing? These trials also continue to evaluate the drug's safety and tolerability profile in more patients by measuring side effects.

Phase III

Phase III involves around 300 to 3000 participants who are living with the condition that the drug is intended to treat. These trials typically last from 1-4 years and help researchers understand whether the study drug works to prevent or treat the condition it's designed for. If the treatment shows sufficient evidence of positive benefit for patients, it's now able to be approved by a regulatory agency.

Phase IV

The full effects of a drug may not be completely known, even after testing on thousands of people, which is why many approved drugs are watched over a long period of time in phase IV studies. This phase also evaluates the treatment's effectiveness in the real world and the safety of the treatment over time. They can also look at things like cost effectiveness and quality of life. In most cases, it takes a drug candidate more than 10 years to move from Phase I testing to real-world use.

Member Gail shares her clinical trial experience…

Member Gail (@GailL0319) who is living with multiple myeloma and participated in a clinical trial, opens up about her experience.

"I learned about the clinical trial through my doctor at Swedish Cancer Institute in Seattle. My doctor said he thought I was a good candidate and began the process of making sure I qualified while I read over in detail the consent form and the details of the trial."

Gail was only the third patient in the hospital for the trial and explained that the trial staff and nurses watched over her very carefully during her initial infusions – asking her questions and taking vitals every thirty minutes.

What advice would she give to others? "If it seems to work for you, I would say go for it. You're looking for the best outcome for yourself and at the same time helping others in the future with the disease. You can always leave a trial if you decide to," she said. "In my case, I have obtained very positive results, I had minimal side effects and I feel very positive about the experience."