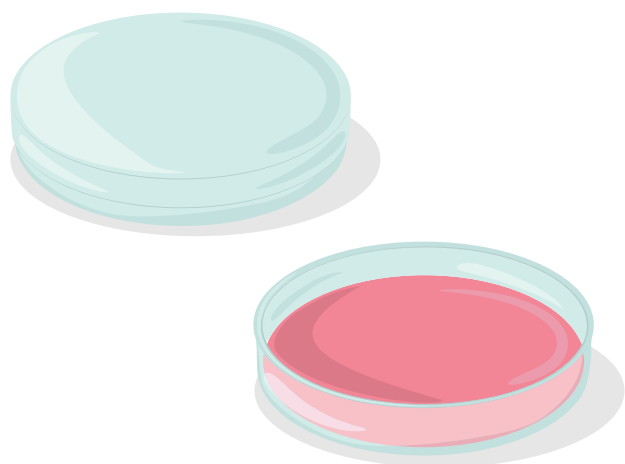




UNDERSTANDING THE PHASES OF CLINICAL TRIALS



All prescription drugs that are approved for use in the US must be thoroughly studied to prove they are **safe and effective for treating IBD**. The entire process can take up to 13 years before a new drug is approved for doctors to prescribe.



After a drug is extensively researched in the lab to show that it has potential to treat IBD, the **Food and Drug Administration** (FDA) gives researchers the approval to study it in people.

There are **4 phases** of clinical trials that build on each other and are each designed to answer a different question about the experimental drug.



PHASE 1:

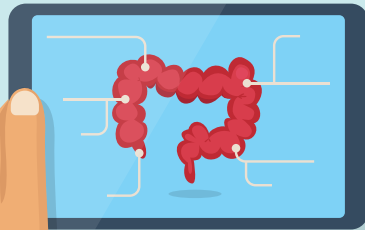
Is the drug safe to use?



This phase is usually done in about 20 healthy people who don't have IBD, but occasionally phase 1 studies will include people with IBD. Researchers are looking to see **how the body reacts to the drug**, if the drug is safe, and what dose of the drug is likely to work best.

PHASE 2:

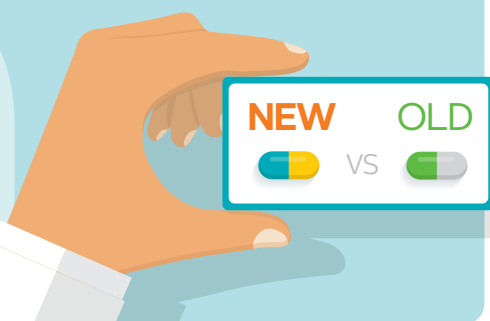
Is the drug effective?



If the drug is safe in healthy people, then it is given to 25 to 100 people with IBD to see if it is effective for treating IBD and whether it causes any short term side effects. **Participants are randomly assigned to different treatment groups to determine efficacy.**

PHASE 3:

Does the drug work better than already available drugs for IBD?



If positive results are seen in phase 2, then the drug is studied in several hundred people with IBD to see how well the drug works compared to the standard treatment drug. These trials usually **pick people at random** to receive either the new drug, standard drug, or a placebo. **Phase 3** trials usually last longer than the first two phases.

Submission to the FDA for Approval

If **positive results** are seen in all three clinical trial phases, then the drug company submits an application to the FDA. The FDA reviews all of the results from the trials and decides if the drug will be approved.



PHASE 4:

How does the drug work in “real life”?



After the drug is approved by the FDA, drug companies may continue to monitor the drug to see how well it works in “real life.” This phase usually follows thousands of patients who are using the new drug for several years to evaluate for **long-term side effects** and any potential new uses for the drug.

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