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BASIC SCIENCE RESEARCH




In this phase, researchers test the drug/therapy in the laboratory or in animals before it can be tested in humans.

IND




Results from laboratory and animal research become the basis for an investigational new drug (IND) application to the Food and Drug Administration (FDA). An IND application seeks permission to use the drug/therapy in a Phase I trial.

PHASE I




The drug/therapy is tested in a small group (20 to 100) of healthy volunteers who are not at risk for disease. Phase I trials focus primarily on drug/therapy safety.

PHASE II




In addition to assessing the drug/therapy safety in a larger pool (20 to 300) patients with the disease the drug/therapy is designed to treat, Phase II also focuses on drug/therapy efficacy (how well the drug/therapy works compared to a placebo).

PHASE III



This is the final phase of drug/therapy testing prior to seeking marketing approval. Phase III trials involve many patients in a number of treatment centers.


NDA



The researcher files a new drug application (NDA) based on the result of the clinical trial. To receive approval, the drug/therapy must:

- be safe;
- be effective;
- have benefits that outweigh the risks;
- have accurate labeling;
- and be producible in a consistent quality and purity.

PHASE IV



This is a post-marketing phase, where the FDA may require the researcher to continue research to better understand a drug's/therapy's performance and other possible uses.

