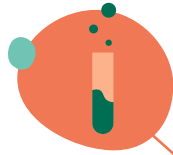


# Process of Clinical Trials

Clinical trials ensure treatments are safe and effective. Each phase helps answer a different question about the treatment. The phases can be combined or referred to as early, late, and/or pivotal stages of development.



**Application Period**  
Researcher submits an Investigational New Drug (IND) application to the FDA for a proposed clinical trial.



## Preclinical Study

Learning how a treatment works in test tubes and animals to determine potential safety and effectiveness.

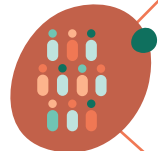
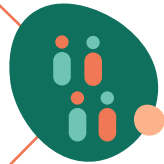


## Phase 1

Involves the fewest participants, making sure the therapy is safe and finding the right dosage.

## Phase 2

More participants and researchers look for favorable or useful effects while monitoring safety.



## Phase 3

The longest phase with the most participants, proves the therapy has the desired result while being safe.

## FDA Final Approval

Biologics License Application (BLA) is submitted to the FDA and is thoroughly reviewed to determine approval. The whole process, from preclinical to approval takes many years, but the FDA has various ways to accelerate the process for some therapies.



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