

PHASES of a CLINICAL TRIAL



Preclinical LABORATORY STUDIES

Duration: Several years

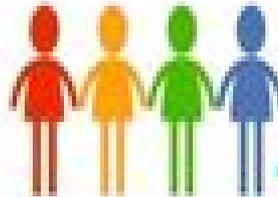
- ✓ Provide information on dosing and toxicity levels



Phase 1 SAFETY

Duration: Several months

- ✓ Evaluate safety
- ✓ Gather information about how a drug interacts with the human body



Phase 2 SAFETY AND DOSING

Duration: Several months

- ✓ Further evaluate safety
- ✓ Monitor side effects
- ✓ Check which dose works best
- ✓ Check effectiveness



Phase 3 SAFETY AND EFFICACY

Duration: Several years

- ✓ Confirm effectiveness
- ✓ Monitor safety



Phase 4 POST MARKETING SAFETY AND EFFICACY

- ✓ Gather information on the drug's effect in various populations and any side effects associated with long-term use

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Clinical Trials

Steven Piantadosi, Curtis L. Meinert



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