



Clinical Research: What you should know



Clinical research starts with an idea in the laboratory at various research institutions or universities.



After few years of research, pre-clinical testing or animal studies are performed to answer basic questions about a drug's safety.

4 PHASES OF CLINICAL TRIAL

Phase 1 Trials - safety and dosage

- Several months
- 20-100 research healthy volunteers or with disease
- According to FDA, 70% of drugs move to the next phase.

1

Phase 2 Trials - efficacy & side effects

- Several months- 2 years
- Several hundreds of research volunteers with disease or condition.
- According to FDA, 33% of drugs move to the next phase.

2

Regulatory Approval

**FDA approves drug as safe and effective. Drug can go into market.



4

3

Phase 4 Trials - long term safety & efficacy

- Occurs after FDA approves treatment for marketing.
- Can last for years

Phase 3 Trials - efficacy and monitoring adverse events

- 1- 4 years
- 300-3,000 volunteers with disease or condition
- According to FDA, 25-30% of drugs move to the next phase.