Clinical Trial Phases

Newly developed treatments go through clinical trials under the supervision of physicians and other research professionals. Each phase is different depending on who can participate, how long the trial takes and what type of information the researchers are trying to understand.

PHASE I
- About 20 to 100 healthy participants
- Investigates how the body processes a treatment and side effects at different dosage levels
- Lasts for several months
- About 70% of drugs pass this phase and go onto Phase II

PHASE II
- Hundreds of patient participants
- Investigates how safe and effective a new treatment is compared to a currently approved treatment
- Lasts for several months to two years
- About 33% of drugs pass this phase and go onto Phase III

PHASE III
- 300 to 3,000 patient participants
- Investigates how safe and effective a new treatment is compared to a currently approved treatment and long-term benefits and possible side effects
- Lasts for 1 to 4 years
- About 25% to 30% of drugs pass this phase and request FDA approval

PHASE IV
There are also Phase IV studies (often called Post Marketing Surveillance Trials) after a drug or treatment has been approved and is on the market. These are different from other clinical trial phases because they are observational – they compare the treatment with others on the market and monitor long-term effectiveness and safety. Phase IV studies often involve several thousand patient participants.