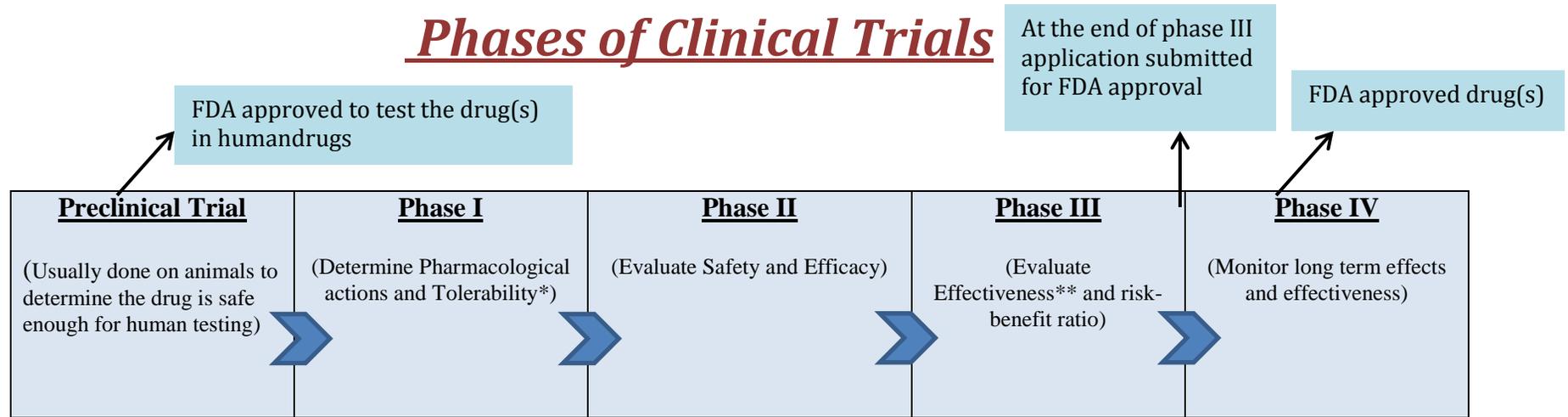


Phases of Clinical Trials



<u>Duration</u>	3-6 years since the drug discovery	Months	Months-Years	Years	Ongoing following FDA approval
<u>Sample size</u>	Not specific	Small	Large	Larger	Impacting larger beyond
<u>Population</u>	In vitro and In vivo animals	Healthy population / may be with targeted disease e.g. cancer, T.B. etc.	Population with target disease	Diverse population with target disease	Diverse population with target disease & new age groups, gender
<u>Types of studies</u>	Not specific	Unblinded & Uncontrolled	May be Placebo (inactive substance) & Active, Controlled	Randomized & controlled	Expanded safety comparison
<u>Factors to be identified</u>	Mechanism of action, Efficacy (ability of drug to act against pathogen/disease), Safety (concerns the medical risk to the patient)	Pharmacodynamics (side effect / desire effect, mechanism of action of drug) Pharmacokinetics (absorption, distribution, metabolism & elimination of drug), Tolerated dose	Drug-Drug & Drug-Disease interaction, Efficacy at various doses, Patient safety	Dosage intervals, Risk-benefit information, Efficacy and safety for subgroups	Epidemiological data, Efficacy and safety within large diverse populations, Pharmacoeconomics (comparison of value of one pharmaceutical drug or drug therapy to another)

*Tolerability: Represents the degree to which overt adverse effects can be tolerated by the patient.

**Effectiveness: The extent to which a drug achieves its intended effects.

References:

1. <http://www.nlm.nih.gov/services/ctphases.html>
2. <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm>
3. http://www.innovation.org/drug_discovery/objects/pdf/RD_Brochure.pdf