At the end of phase III **Phases of Clinical Trials** application submitted for FDA approval FDA approved drug(s) FDA approved to test the drug(s) in humandrugs **Preclinical Trial** Phase I **Phase II Phase III Phase IV** (Determine Pharmacological (Evaluate Safety and Efficacy) (Monitor long term effects (Evaluate (Usually done on animals to actions and Tolerability*) Effectiveness** and riskand effectiveness) determine the drug is safe benefit ratio) enough for human testing)

<u>Duration</u>	3-6 years since the drug discovery	Months	Months-Years	Years	Ongoing following FDA approval
Sample size	Not specific	Small	Large	Larger	Impacting larger beyond
Population	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
Types of studies	Not specific	Unblinded & Uncontrolled	May be Placebo (inactive substance) & Active, Controlled	Randomized & controlled	Expended safety comparison
Factors to be identified	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.

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

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