



Unit 2: Appendix D: Clinical Trials Information Chart

Trial Phase	Human/Animal	# of subjects	Rationale	Purpose
Preclinical	<i>In vitro</i> <i>In vivo</i> - Animal		Wide range of doses Efficacy Toxicity What does it do	Whether or not to continue development in humans
Phase I	Humans	20-80	Safety Dosage range Side effects	Finding appropriate dose HEALTHY volunteers Side effects – is it safe
Phase II	Humans	100-300	How well does it work Dosage Efficacy/toxicity	Patient with disease Dose response curve
Phase III	Humans	1000-3000	How effective vs. best treatment Is it better than what we already use	Document on large sample size Submit to FDA If any adverse effects – immediate recall
Phase IV	Humans	3000+	After market Safety surveillance Tech support	Applying drug to new market Apply to another disease Drug interactions Detect rare or long term adverse effects