What are the Phases of Clinical Trials?	Definition
Phase I Trials	In **Phase I** trials, researchers test an experimental drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
Phase II Trials	In **Phase II trials**, the experimental study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.
Phase III Trials	In **Phase III trials**, the experimental study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.
Phase IV Trials	In **Phase IV trials**, post marketing studies delineate additional information including the drug's risks, benefits, and optimal use.

Device Classes	General Definition	Examples
Class I: General Controls	Class I devices are subject to the least regulatory control. They present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices. Class I devices are subject to "General Controls" as are Class II and Class III devices.	Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments.
Class II: Special Controls	Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness, and existing methods are available to provide such assurances. In addition to complying with general controls, Class II devices are also subject to special controls.	Examples of Class II devices include powered wheelchairs, infusion pumps, and surgical drapes.
Class III: Premarket Approval	Class III is the most stringent regulatory category for devices. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls. Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.	Examples of Class III devices which currently require a premarket notification include implantable pacemaker pulse generators and endosseous implants

Medical Devices	Definition
Category A	Experimental - Innovative devices believed to be in class III for which absolute risk of the device type has not been established (i.e., initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type is safe and effective).
Category B	Nonexperimental and/or investigational devices believed to be in classes I or II or devices believed to be in Class III where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.