Clinical trial phases

Clinical trials of medicines typically proceed through 'phases' of development whereas clinical trials of devices typically proceed through 'stages' of development. In the early phases or stages of development the new treatment is tested in a small number of participants to assess safety and effectiveness. If the treatment is promising, it may move to later phases/stages of testing where the number of participants is increased to collect more information on effectiveness and possible side effects.

The tables below provide a summary and comparison of the phases and stages of clinical trials involving the use of investigational products.

Summary of clinical trial phases for medicines:

Phase	Indicative number of participants	Objectives
Phase 0:	10–15 Testing includes a limited number of people with a limited range of doses, for a limited period of time	**Assess pharmacokinetics** New treatments are tested to gather data on how drugs move around the body and are eliminated from the body.
Phase I:	10–100 This phase may involve the first administration to people, usually small numbers of healthy volunteers or patients	**Safety and tolerance** Tests identify a safe dose and how best to administer it, and they uncover any side effects for new treatments, by gathering data on how drugs move around and are eliminated from the body.
Phase II:	100–300 Tests include a larger group of patients (up to several hundred)	**Efficacy and safety** New treatments are tested to demonstrate their effectiveness, optimal dose and safety.
Phase III:	300–3000 Testing usually involves a large group of patients (from several hundred to several thousand)	**Safety, efficacy or effectiveness** New treatments are tested to demonstrate their effectiveness and safety in the patient group the treatment is intended to benefit.
Phase IV:	1000s Testing involves thousands of people	**Post-marketing surveillance or resolution of treatment uncertainties** Approved treatments are tested after they've been marketed. These studies are designed to monitor the effectiveness of a treatment in the general population, and to collect information about any side effects associated with widespread use over longer periods of time. They may also be used to investigate the potential use of the treatment in a different condition or in combination with other treatments.

Summary of clinical trial stages for medical devices:

Stage	Indicative number of participants	Objectives
Pre-market pilot	10–30 Testing usually involves a small group of patients	**Exploratory** New devices are tested to gather data on safety and performance, and to see if modifications to the design are necessary.
Pre-market pivotal	100s Testing involves hundreds of people	**Confirmatory** New devices are tested to determine their safety and performance for their intended use.
Post-market	1000s Testing involves thousands of people	**Confirmatory or Observational** New devices are tested to determine safety and performance in broader populations. OR New devices are tested to better understand safety, long-term outcomes and health economics.