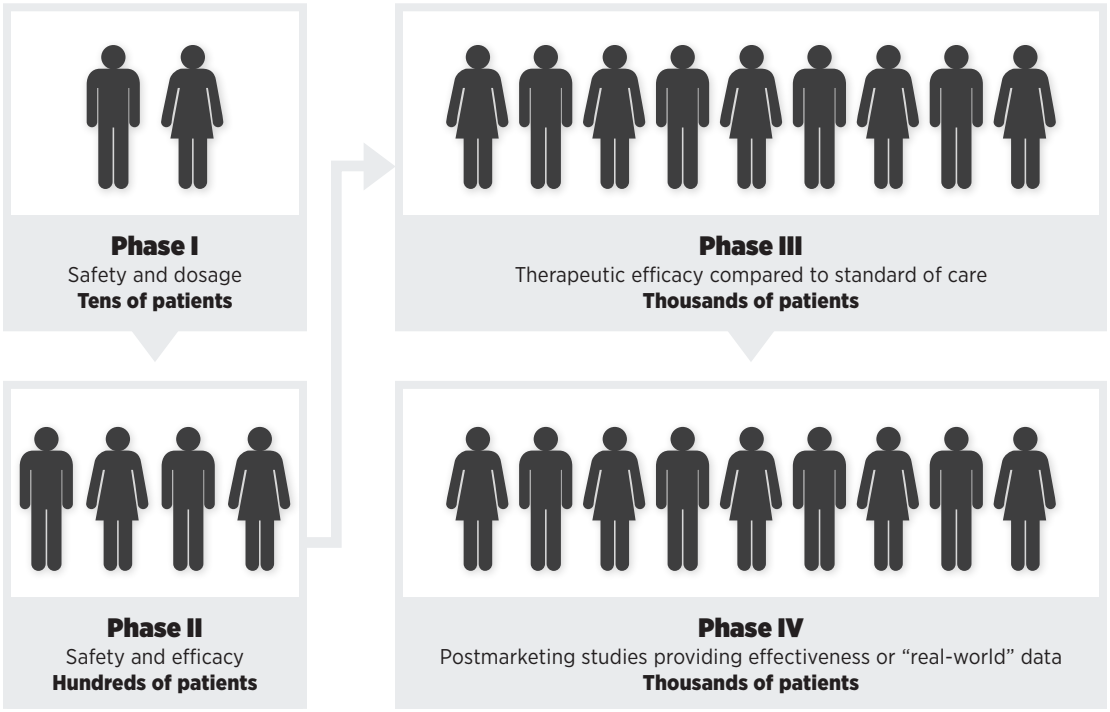
FIGURE 12 PHASES OF CLINICAL TRAILS



Clinical trials evaluating potential new therapeutics for treating patients with cancer have traditionally been done in three successive phases, each with an increasing number of patients. Phase I studies are designed to determine the optimal dose of an investigational anticancer therapeutic, how humans metabolize it, and the potential toxicities. Phase II studies are designed to determine the initial efficacy of an investigational therapy, in addition to continually monitoring for potential toxicities.

Phase III studies are large trials designed to determine therapeutic efficacy as compared with standard of care (placebos are rarely used in cancer clinical trials). When successful, the results of these trials can be used by the U.S. Food and Drug Administration (FDA) to approve new therapeutics or new indications for existing therapeutics. Phase IV studies are conducted after a therapy is provisionally approved by the FDA and provide additional effectiveness or "real-world" data on the therapy.

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