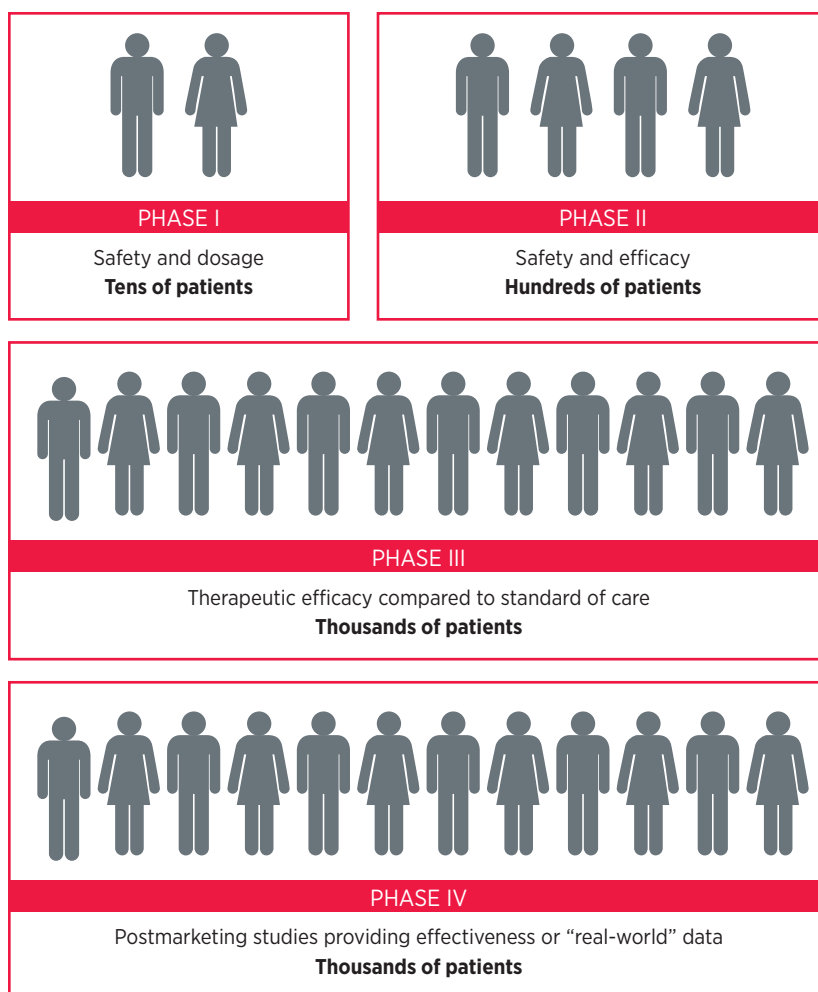


FIGURE 8

PHASES OF CLINICAL TRIALS



monitoring for potential toxicities. Phase III studies are large trials designed to determine therapeutic efficacy as compared to 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. Recent studies found that it takes about 13 years to complete phases I-III of clinical testing and regulatory assessment (161)(162). These studies also showed that the rate of success is low, with fewer than 10 percent of anticancer therapeutics that enter clinical trials ultimately obtaining FDA approval for use in cancer care.

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 process it, and potential toxicities. Phase II studies are designed to determine the initial efficacy of an investigational therapy, in addition to continually

Adapted from (36)