

## **The Clinical Trials Process**

The clinical trials process takes a drug or therapy from the concept or research stage to the pharmacy or into standard treatment. The exact process of a trial depends on the type of trial being conducted or the type of therapy or aspect of care under evaluation. Types of clinical trials include treatment trials, prevention trials, diagnostic trials, screening trials, and quality-of-life trials. There are, however, certain standard steps that a patient enrolling in any trial can expect:

1. **Eligibility.** Trials are designed with inclusion and exclusion criteria (such as age and type of cancer) for prospective participants. Patients are selected according to these criteria through a screening process.
2. **Information.** In this stage eligible patients are given a detailed explanation of the entire trial process, including the course of the study, potential benefits, special instructions, and expected results and risks (this stage is called informed consent).
3. **Consent.** If the patient and his or her health care provider are sure that the patient understands the details of the trial and wants to participate, he or she must sign a consent form.
4. **Instructions.** Detailed, written instructions are provided about the schedule and, for drug trials, the doses to be given.
5. **Monitoring.** As the trial progresses, patient health is carefully monitored. This can include exams, tests, and scans.
6. **Follow-up.** After the course of treatment is finished (active treatment phase), some trials include extensive follow-up. where patients are monitored for long-term outcomes.