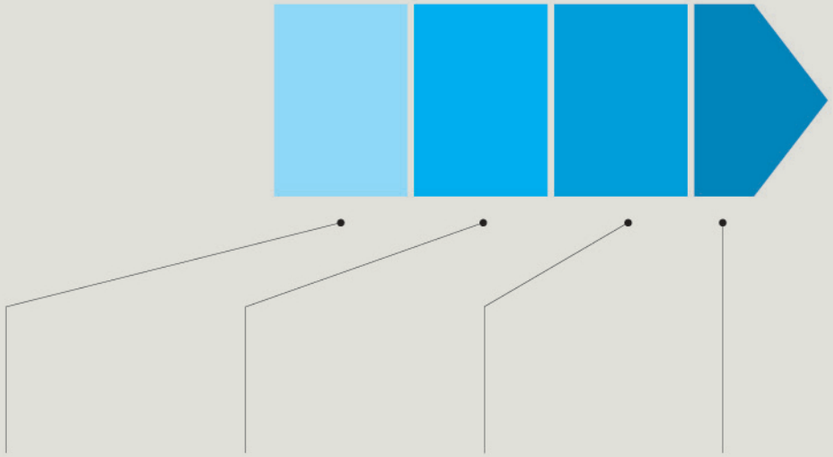
Traditional Clinical Trials versus Basket Trials

The standard approach for developing many cancer treatments has been built upon a series of clinical trials to establish the effectiveness of drugs in specific cancers — for example, in breast or colon cancer. (See the infographic below.) A novel approach to clinical trial design called a "basket" trial starts with one trial, the basket, and one or more "targets" and allows patients with different diseases to enroll in a group or cohort. (See the infographic on the opposite page.) This allows for exploration of a treatment's effectiveness across many diseases early, quickly, and in one trial. The goals of such trials are to accelerate the translation of scientific discoveries into new therapies and to increase the number of patients who can benefit from innovative mechanistic approaches with molecularly targeted therapies.

Traditional Clinical Trial Design



Phase I

A treatment is tested to establish a dose (often the maximum tolerated dose) and to establish safety and learn about side effects. Traditional phase I trials are generally small.

Phase II

A treatment is evaluated typically in about 35 patients with the same type of cancer and with the dose established in the phase I study. The goal is to observe tumor shrinkage over a period of time.

Phase III

The same treatment is tested in a randomized trial with a large number of patients organized into groups to assess the effectiveness of the new agent often compared to a standard of care treatment.

Phase IV

If the new drug is approved by the FDA, phase IV trials may be continued to learn more about how best to use it, as well as its long-term benefits and side effects.

Basket Clinical Trial Design