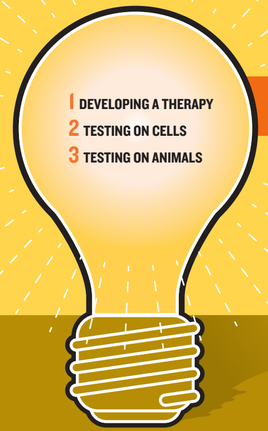
Clinical Trials & Tribulations

To become approved treatments, experimental therapies must first complete the journey through the clinical trial process. This involves considerable hurdles: Clinical trials take an average of eight years to complete; cost thousands of dollars for each participant; and struggle to recruit enough candidates. The majority will not reach the ultimate destination. But those that do represent true advances in medicine.

Pre-trial

While clinical trials follow a long path, they are preceded by a lengthy and involved process. It begins with an idea that is translated into some sort of therapy and tested on the cellular level. It may then be tested on animals. If the therapy appears safe and effective, it will be tested on humans in a clinical trial.

Timeline: 4½ years



All individuals who enroll in a clinical trial must learn about the purpose, procedures, risks and benefits of the trial before agreeing to take part. This is called informed consent

Key: Positive outcome — Trial can end here

The Protocol

The principal investigator is the researcher leading a clinical trial. He or she must create a detailed plan — the protocol — spelling out the study procedures and the potential risks and benefits to participants.

Timeline: ½ year

Clinical Trial: Phase I

Phase I looks for the safest and most effective dose level for the new therapy or technique and how best to administer it. Researchers want to see how the body reacts to the treatment, and whether it causes any side effects. FDA approval is required.

Timeline: ½ year

Clinical Trial: Phase II

Phase II trials generally involve about 100 people, and can last from several months to several years. They determine whether the new treatment has an effect on a particular kind of cancer. Approximately one third of all Phase II trials will pass this hurdle.

Timeline: 3 years

Clinical Trial: Phase III

Phase III trials enroll hundreds or thousands of people to compare the new treatment with the current therapy for that type of cancer. These trials are conducted in locations around the country or throughout the world.

Timeline: 2–4 years

After the Phase III Trial

Researchers analyze the data to see whether the results are statistically significant and have medical importance.

Timeline: ½ year

FDA Approval

If the new therapy has been shown to work better than the existing one, it is submitted to the FDA for approval.

Timeline: 1½ years

Timeline total: 14½ yrs.

Who Between five and 30 people participate in this first stage. Each study's protocol has guidelines for who can or cannot participate in the study.

Where Clinical trials are conducted simultaneously at multiple institutions. This gives investigators increases the size and diversity of the group of people, being studied insuring the results can be repeated.

How Randomly assigned participants receive the regular therapy or the new treatment. Participants don't know which treatment they're receiving. In a double blind study, the researchers also don't know which treatment each patient is receiving until the end.

REVIEW BY INDEPENDENT PANEL OF EXPERTS

NATIONAL OR GLOBAL TESTING

Results may be published in scientific or medical journals. Journal articles allow physicians around the world to learn about the latest research developments. More than 300 papers by Cedars-Sinai researchers appear in peer-reviewed medical journals each year.

FDA APPROVED

FDA

Is it safe and effective?

Does it have appropriate labeling, quality control?

Requests for more information or studies

* Cedars-Sinai's Internal Review Board operates under a Federal-Wide Assurance approved by the Department of Health and Human Services which requires the hospital to conduct human-subjects research in accordance with the Belmont principles of respect for persons, beneficence, and justice.