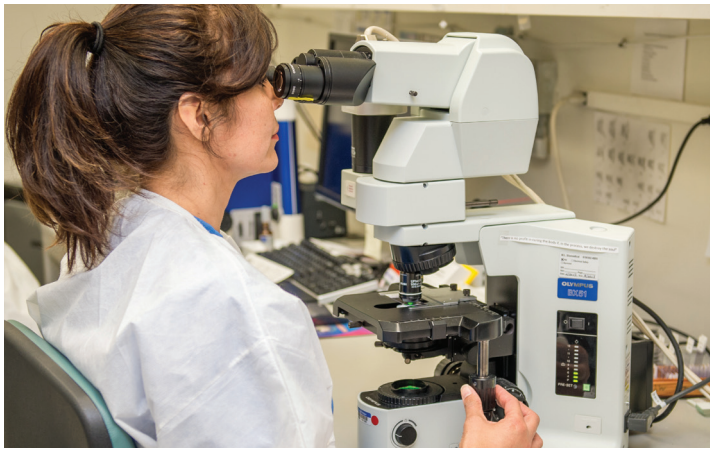
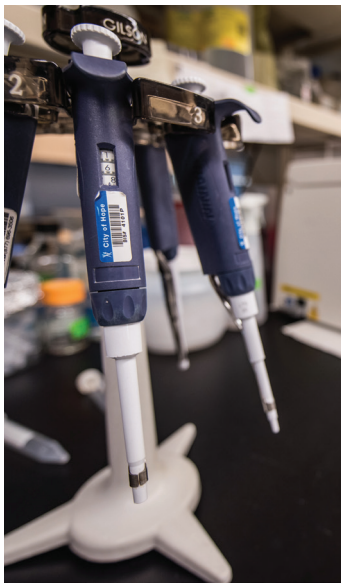
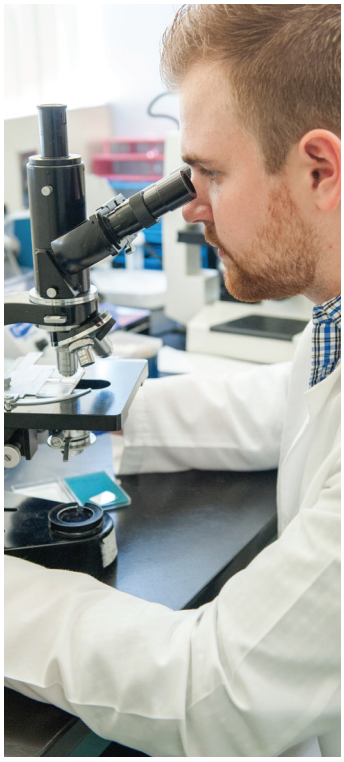




LIFE CYCLE OF A CLINICAL TRIAL

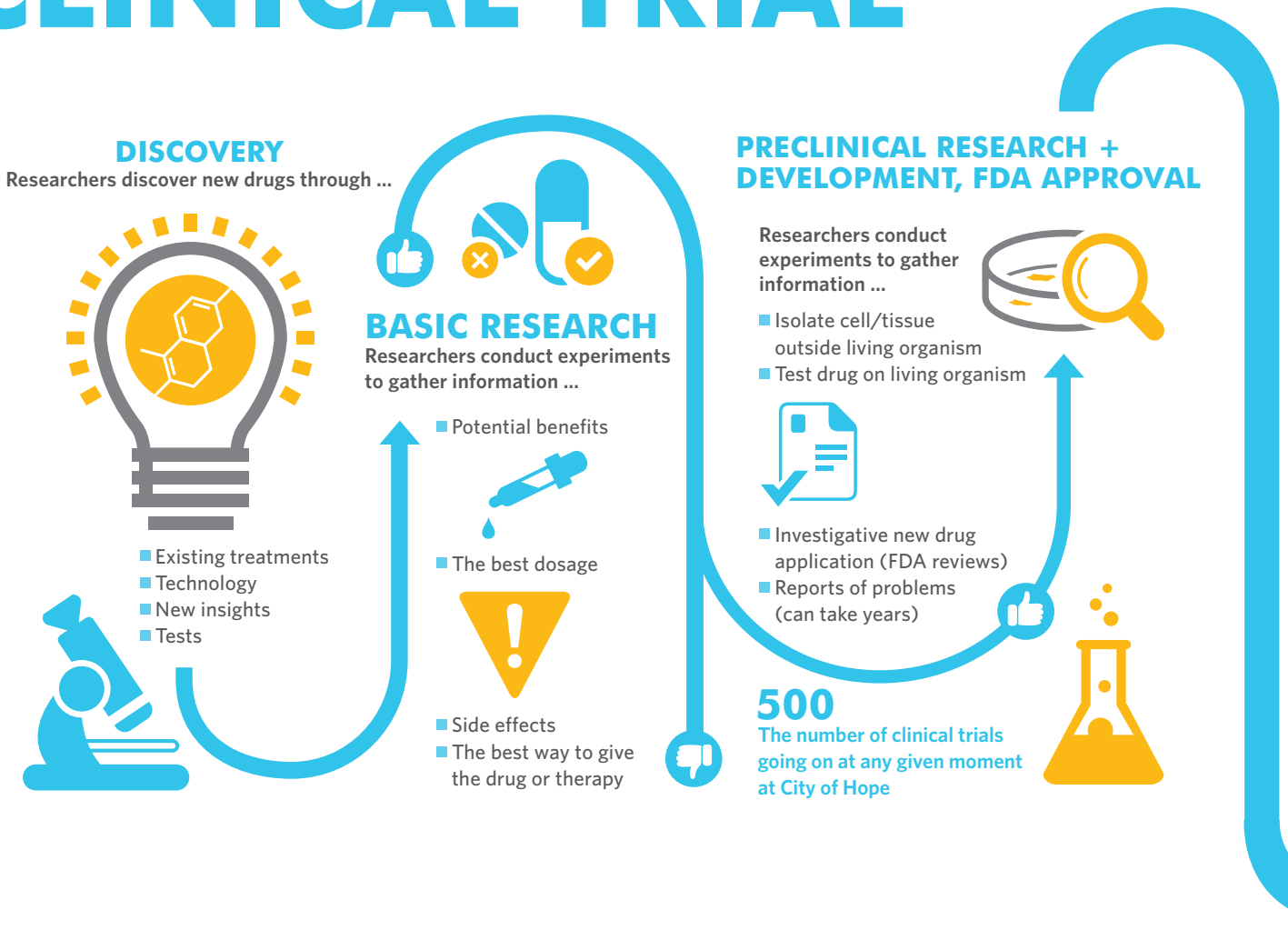
at City of Hope



the MIRACLE of SCIENCE with SOUL

City of Hope®

BEHIND THE SCENES OF A CLINICAL TRIAL



Most people know that the U.S. Food and Drug Administration (FDA) must approve a drug before it reaches the market or a hospital room. But few people outside of the medical field know what happens before the drug gets to the FDA.

Clinical trials are medical studies that focus on establishing the safety and effectiveness of new, potentially beneficial drugs by testing them on increasingly large groups of human subjects. These trials can involve new medications, treatments, devices and even immunotherapy. It's a years-long process that involves constant study and research before the new drug is ever presented to the FDA.

City of Hope is currently conducting 500 clinical trials, enrolling more than 6,200 patients are going on at any given time. To help illuminate the process, here are five facts you should know about clinical trials.

1. Clinical trials require approval before commencing.

Clinical trials are only approved once an institutional review board, or independent ethics committee, has weighed the potential benefits against the possible risks and determined the testing worthy. The institutional review board or independent ethics committee pores over all materials related to the study before and during the trials.

Often years of preclinical work has gone into researching and experimenting on isolated living cells, while zeroing in on potential benefits, appropriate dosage ranges, problems and side effects, and the most effective ways of applying the drug, before human subjects can become involved.

2. There are different types of trial subjects.

Often, existing patients with a specific condition or particular set of characteristics, such as age, gender or stage of disease, will volunteer to participate in a clinical trial. In other instances, trials will make use of volunteers who are otherwise healthy, depending on the type of drug or device being tested.

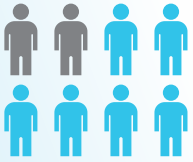
Patients already under medical care may choose to participate because the trial gives them access to new treatments not available to others. Many volunteers sign on because they want to help advance science and medicine toward new cures. All participants must go through a process of informed consent with the trial's principal investigators before it starts.

CLINICAL TRIALS

Clinical trials are conducted in four different phases with each phase serving a specific purpose to researchers.

PHASE 1

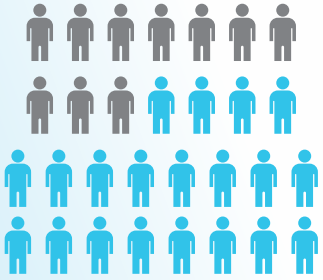
Assess the safety of a new drug.



- Test drug on small group of people (20 to 80).
- Evaluate how the body handles the drug.

- Safe dosage ranges
- Record side effects.

PHASE 2



- The drug or treatment is given to a larger group (100 to 300).

- Determine effectiveness.
- Continue to evaluate safety.

PHASE 3

This phase helps confirm the effectiveness of the drug, gauge side effects and gather information so the drug or treatment can be used safely.

- Hundreds or even thousands (300–3,000) of people may receive a new drug or treatment and be followed for several years.

PHASE 4

Researchers gather additional safety information on an even larger group of people.

- Gather data on long-term effectiveness and affect on quality of life.
- Evaluated for cost and against other similar drugs.
- Receives FDA approval and is widely marketed.

3. Clinical trials are run by special investigators.

Medical professionals who are trained in the "Good Clinical Practice" guidelines designed to safeguard subjects and assure proper collection of data can become investigators on clinical trials. By participating, investigators can position themselves to discover new developments and stay on the front edge of emerging medical discoveries, especially in their fields of expertise.

They can have an impact on advancements while authoring papers and articles that push their field forward. Investigators are often paid for their work, unlike the subjects of clinical trials.

4. There are four distinct phases of a clinical trial.

Phase 1 focuses on safety by keeping the sample group small, from 20 to 80 people. It's an initial evaluation of how the human body handles a new drug, while investigators take note of safe dosage ranges and any side effects.

In phase 2, the experiment group grows to 100-300 subjects, with more of a focus on effectiveness, though safety is always being evaluated.

During phase 3, investigators increase the sample size to 300-3,000 subjects and lengthen the amount of time the drug is taken, while the same safety and efficacy parameters are studied.

Phase 4 requires an even larger sampling group, with a focus on long-term effectiveness and safety, as well as how the new drug compares with other similar drugs and their costs, before approval is sought from the FDA.

5. Only a small percentage of new drugs ever hit the market.

The review process takes anywhere from six to 12 months, depending on whether the new drug is only a minor improvement on an existing therapy, a major advancement or a completely new treatment. Right now, the National Institutes of Health service ClinicalTrials.gov lists more than 215,000 clinical studies currently in progress around the world.

HOW DO I FIND OUT MORE ABOUT CLINICAL TRIALS AT CITY OF HOPE?

You may search through our active clinical trials online. To speak with one of our care professionals about treatment at City of Hope, contact our New Patient Services online or call us at 626-218-1133.

Cityofhope.org

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