Understanding Clinical Research

Prepared by

SIKHS IN CLINICAL RESEARCH

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Clinical Research

Over 3 million individuals participate in clinical research across the globe every year!

What Is Clinical Research? Clinical research, also referred to as clinical trials or clinical studies, tests new treatments, drugs, or medical devices to evaluate their safety and effectiveness. These studies help doctors and scientists develop better ways to prevent, diagnose, and treat diseases.

In today's clinical trials, participants' health and safety are the most important things.

Without clinical research, we wouldn't have the medicines and treatments we use today.

Phases of Clinical Research

Before a treatment reaches human clinical trials, scientists spend years conducting preclinical research, including laboratory experiments and animal testing, to assess its safety and potential effectiveness.

For a new drug to be approved and made available to the public, it must go through a highly regulated, multi-phase process designed to ensure its safety, effectiveness, and overall impact on public health. This process is rigorous and can take several years, with each phase carefully evaluating the drug's effects.

Here's a breakdown of the key phases involved:

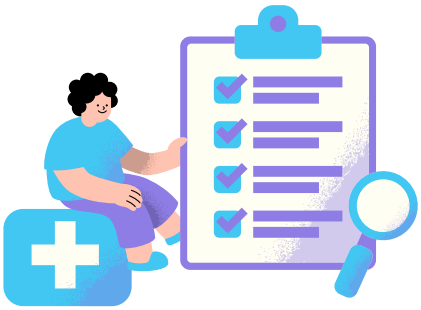
Phase - 1	Phase - 2	Phase - 3	Phase - 4
			
Purpose: Determine the right and safe dose of the study drug. The highest dose that can be given to treat the disease safely.	**Purpose:** Evaluate safety and effectiveness in larger number of people.	**Purpose:** Compare the study drug to existing treatments. Evaluate Safety and effectiveness over a long period of time in large groups of people.	**Purpose:** Monitor long-term safety and effects in the real world after approval.

Sometimes people have heard misconceptions or incorrect information about clinical research. Being open and honest with your concerns and asking questions can help make sure you have accurate and up-to-date information.

How Participants are Protected in Clinical Research

- **Ethical Review:** An Institutional Review Board (IRB), an expert panel approves the research study to ensure patient safety and rights.
- **Informed Consent:** Participants are fully informed about the study before they agree to join voluntarily.
- **Trained Professionals:** Qualified doctors and researchers ensure safety and follow strict guidelines.
- **Monitoring:** Participants' health is closely monitored throughout the study.
- **FDA Oversight:** Federal regulations are in place to ensure participant safety and compliance adhering to ethical guidelines and laws.
- **Data Protection:** Personal and medical information is kept secure and confidential.

Participation is optional, and you can withdraw from the study at any time for any reason, with the help of the research staff to do so safely.



The Informed Consent Process

If you choose to participate in a clinical research study, you are:

- Provided with detailed information about the trial, including treatment and procedures involved.
- Informed about all potential risks, benefits, side effects, or discomforts.
- Informed about the trial's purpose and expected duration.
- Given information on available alternative treatments and how they compare to the study medication.
- Encouraged to ask questions about the trial at any time before or during your participation.
- Made aware of any compensation associated with the trial.
- Given the opportunity to discuss with family members or friends before deciding to participate.
- Given as much time as you need to make an informed decision about participating.
- Provided with materials in your preferred language and given access to an interpreter if needed.
- Given a signed and dated copy of the informed consent form.

Remember, joining a clinical research study or clinical trial is entirely your choice. You can withdraw participation or choose to leave at any time. Signing the consent form acknowledges your understanding of the study but does not commit you legally, or affect your rights.

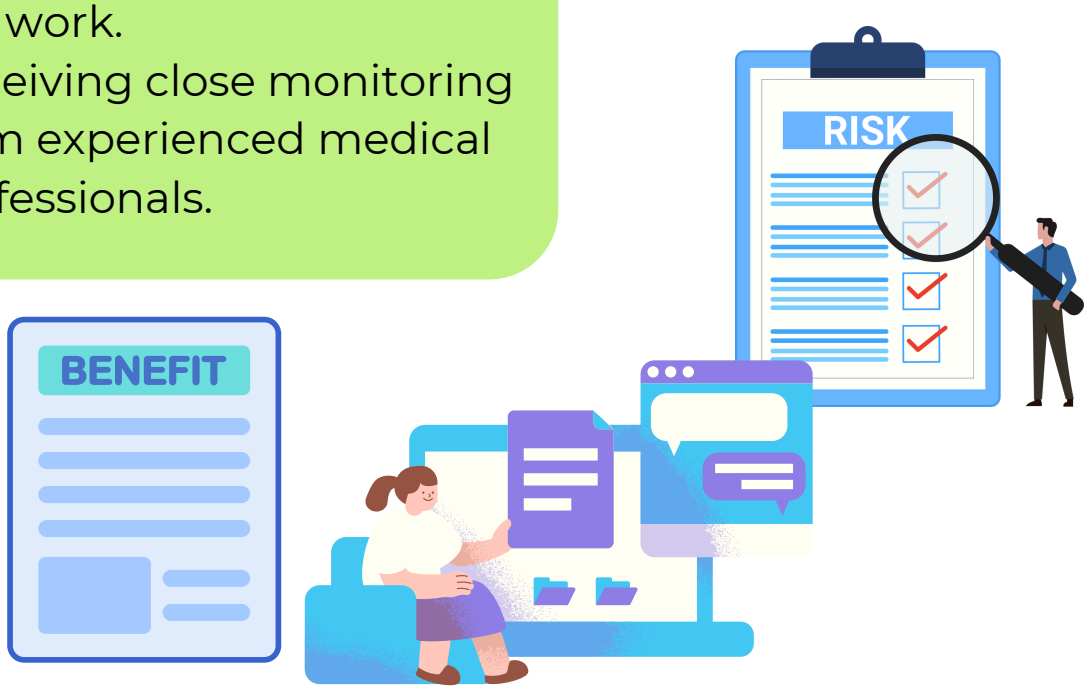
Benefits & Challenges of Clinical Trials

Potential Benefits

- Early access to innovative treatment options.
- Study treatment at no cost.
- Health insurance may not be required.
- There may be compensation for time and travel.
- Opportunity to explore new options when there is no other treatment available or the existing treatments do not work.
- Receiving close monitoring from experienced medical professionals.

Possible Challenges

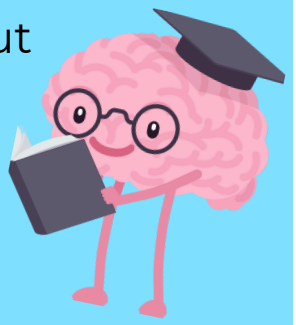
- The trial treatment may not benefit you.
- Side effects could occur from the treatment.
- Frequent tests or blood draws may be required.
- Participation may require time commitment.



How can I Participate?

1. **Ask Your Doctor:** Request trial referrals.
2. **Verify Eligibility:** The research team checks your medical history.
3. **Get Informed:** Understand the trial details.
4. **Provide Consent:** Sign the consent form if you agree.
5. **Stay Involved:** Attend study visits and follow instructions.

MYTH: If there's a clinical trial that could benefit me, my doctor will inform me about it.



FACT: Doctors may not be aware of all the clinical research studies.

You can visit clinicaltrials.gov to find a clinical trial in your area or reach out to 'Sikhs in Clinical Research' for assistance.

What to Expect During a Clinical Trial?

1. Initial Screening
The study team will assess your eligibility by asking about your health, medications, and conducting physical exams and tests.

2. Treatment Phase
You will be randomly assigned to receive the investigational drug or a placebo. Regular health check-ups, including exams and tests, will help monitor your progress.

3. Post-Treatment Follow-up
After completing the treatment, you may have additional visits to track your health and identify any long-term effects.

A placebo looks like a trial treatment but doesn't contain active ingredients. Placebos give researchers something to compare with the study medication to better understand its effects. Placebos are rarely used in cancer trials.

Why is My Participation Important?

Improved Access to Treatments

For some people, participating in a clinical trial can provide access to new treatment options for their condition. For example, cancer is a serious disease, and clinical trials can offer new possibilities for treatment.

Historically, many clinical trials lacked participation from different backgrounds due to:

- *Limited access to information.*
- *Language and cultural barriers.*
- *Mistrust in the medical system.*

One Size Doesn't Fit All

A person's response to a disease or medicine depends on many factors, including age, sex/gender, race/ethnicity, lifestyle (how a person lives), and environment (where a person lives), among others. People from different backgrounds can respond differently to medical treatments due to genetic, environmental, and lifestyle factors. Including diverse communities in clinical research ensures that:

- *Side effects and risks are accurately understood.*
- *Treatments are effective for everyone.*
- *Health disparities are addressed.*

For example, if trials only include certain groups, like one ethnicity or age group, the treatment might not work the same for others and could even cause side effects. Representation in trials is important to make treatments safer and effective for all.

Example

- Black Americans and Indigenous Peoples have the highest asthma rates compared to other races and ethnicities.
- Asian Americans have historically been found to have high rates of liver cancer in the U.S.

By ensuring clinical trials represent people with different backgrounds, researchers may discover valuable information that helps assess how the investigational study drug works for different groups. This knowledge is key in promoting fairer healthcare and ensuring that people from underserved groups receive proper care.

Ref. 1. American Lung Association. Current asthma demographics. Accessed August 19, 2024.
2. UCLA Health. Liver disease in Asians. Accessed August 19, 2024.

Oncology

Cancer and Clinical Trials

Receiving a cancer diagnosis can be overwhelming for individuals and their families. According to the American Cancer Society, nearly 2 million people are diagnosed with cancer every year. While treatments such as surgery, chemotherapy, and radiation can be effective for many types of cancer, they do not work for everyone and can lead to unwanted side effects like fatigue, nausea, and weight loss. In some instances, these treatments may not work at all, highlighting the need for continuous research into new therapies.

What to Expect in an Oncology Clinical Trial

Oncology clinical trials follow a set of procedures that participants can expect. Before joining the trial, participants typically undergo a screening process to ensure they are the right fit for the trial. Doctors may perform tests, such as blood and urine samples, vital sign monitoring, and imaging scans, to assess the participant's health.

During the trial, participants may receive trial treatment, standard cancer treatment, or a combination of both. Comparing these options allows researchers to evaluate how well the new treatment works. In some cases, if the trial treatment proves effective, doctors may recommend continuing with the trial treatment for as long as it benefits the participant. Health monitoring continues throughout the trial.

Once the trial concludes, participants may be asked to participate in follow-up assessments, which can include phone calls or visits for further testing.

Questions Researchers Seek to Answer

Researchers use clinical trials to answer critical questions regarding the effectiveness and safety of cancer treatments. Some of the key questions include:

- Does the treatment increase the survival rate of participants?
- Does the treatment help participants live longer without their cancer progressing?
- Does the treatment cause a significant reduction or disappearance of the cancer?
- Does the treatment improve the participants' quality of life compared to standard treatments?

Pediatric Clinical Trials: What You Need to Know

Pediatric clinical trials are research studies to learn if medicines, treatments, or therapies are safe and work well for children.

Since children's bodies process medications differently than adults. These trials help determine the safest and most effective treatments and dosages specifically for children.

Questions to Discuss with Doctor

When thinking about a clinical trial for your child, here are some helpful questions to ask:

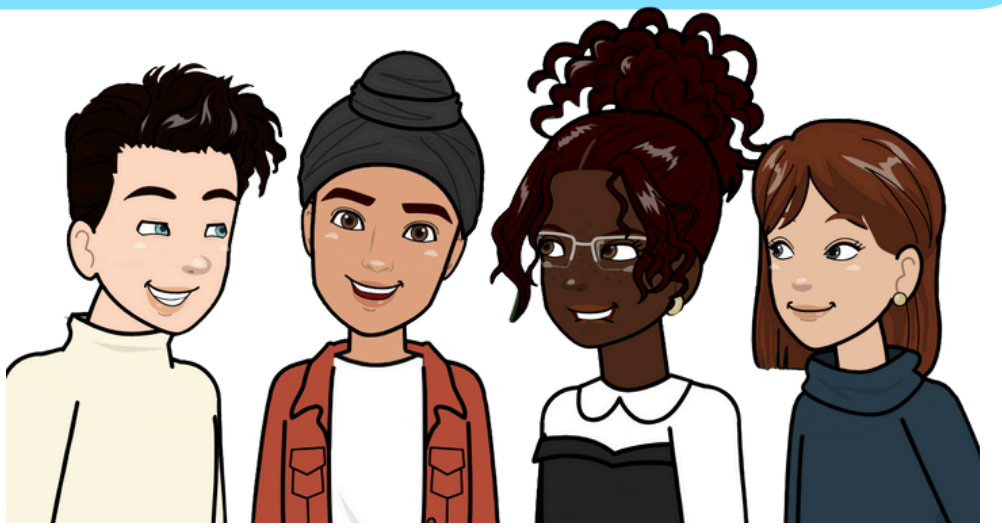
- What is the purpose of this trial?
- How will my child's safety be monitored during the trial?
- What makes researchers think this treatment could work?
- Are there any risks or benefits, and how do they compare to current treatments?
- Do the potential benefits outweigh the risks?
- What tests or procedures will my child need to go through?
- Are there any costs, and will insurance cover them?
- How will my child's personal health information remain private?

Deciding if a Clinical Trial is Right for Your Child

Take time to learn and decide what's best for your child.

You'll receive an Informed Consent Form outlining the risks, benefits, treatments, and schedule. Your child will receive an assent form explaining the study in a way easy to understand.

Talk to the trial team, other healthcare providers, or families with experience in trials to get different perspectives and make an informed decision.



Payments & Reimbursement

Cost Overview:
Most clinical trial procedure costs, including the cost of the study treatment, are covered by the trial sponsor. The Informed Consent Form will detail what is covered and what is not.

Insurance:
You may not need health insurance to join a clinical trial.

Reimbursement:
You may get compensation for your time and travel for study visits. Reimbursement for travel and expenses may require receipts.

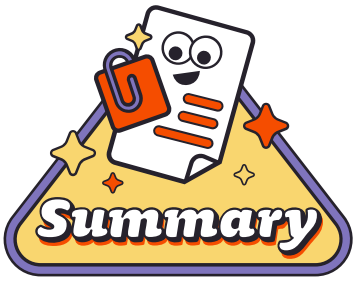
Fair Compensation:
All payments are approved by an IRB to ensure fairness. Compensation may come as cash, check, or a prepaid card.

Tax Information:
If you receive compensation, it may be taxable. Please consult a tax accountant.

Questions to Ask:
Before joining, ask the trial staff about costs and reimbursements.
Key questions include:

- What costs am I responsible for?
- Will my insurance be required?
- Will I be reimbursed for travel?

Summary of Key Points



- Clinical research or clinical trials are conducted to test new treatments, drugs, or medical devices to evaluate their safety and effectiveness.
- Before a new treatment reaches humans in clinical trials, scientists spend years conducting preclinical research, including laboratory experiments and animal testing, to assess its safety and potential effectiveness.
- Clinical research allows you to explore new treatment options when existing treatments do not work.
- Participation in a clinical trial is voluntary, with your safety and privacy always protected.
- Your health is closely monitored by trained and qualified staff through regular check-ups during your participation.
- It is important for clinical trials to represent people from all backgrounds to make sure that the new treatments are safe and effective for everyone.
- For those diagnosed with cancer, oncology clinical trials can be explored for new treatment options that may help.
- Pediatric clinical trials are conducted to learn if new treatments are safe and work well for children.
- Most of the costs related to the trial are covered by sponsors, and you might even receive compensation for your participation.

Other Ways to Contribute to Clinical Research

Participating in a clinical trial is just one way to make a difference. If participating in a clinical trial isn't suitable for you, there are other ways to contribute to research:

- **Help raise awareness about clinical research:** Spreading the word about the importance of clinical research and its potential to change lives can inspire people to explore new options and make informed decisions about their health and well-being. By sharing information, attending awareness events, or engaging with your community, you can help increase understanding and encourage participation.

- **Consider a career in clinical research:** Whether as a researcher, coordinator, doctor, or in other related roles, joining the clinical research workforce impacts the development of new treatments and therapies. The field offers diverse career opportunities that contribute to scientific advancement and improve patient care.

By getting involved, you help advance science, improve healthcare for future generations, and support equitable access to effective treatments.

Notes

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