Clinical Trials 101
Learn about clinical trials, how they work, things to consider before participating in a trial, and more.

What is a clinical trial?
Clinical trials are studies where scientists (often called researchers) recruit volunteers (also known as research participants) to test new treatments or medicines to make sure they are safe and effective.¹

What are the phases of a clinical trial?
Clinical trials occur in multiple phases, each phase helping researchers answer different questions. Each phase includes more volunteers than the last, starting with as few as 10 and ending with tens of thousands of research participants.²

“Pre-clinical” studies
Clinical trials start with “pre-clinical” studies where new potential treatments or medicines are tested in test tubes, lab dishes, and sometimes in animals. This helps researchers determine if and how a new treatment, medicine, or medical intervention may work.

Assess for safety & effectiveness
In the next phases, researchers assess the new treatment for its safety and effectiveness. Once these phases are complete, researchers make sure the new treatment is better than any existing treatments for the same illness.

Monitor in large populations over time
Finally, clinical trials enter a phase where treatments and medicines are monitored in large populations over long periods of time.²
How will I be protected during a clinical trial?

In the past, clinical trials and western researchers have violated the rights of Native research participants and violated the trust of our communities. Now, as the result of our advocacy, we've secured the right to participate in clinical trials without our privacy and rights being violated.5

Many different safety monitoring boards ensure participants are never exposed to unnecessary risk or potential harm during trials. Additionally, these safety boards ensure that your personal health information is collected in a way that satisfies very strict privacy and safety standards.

Most importantly, clinical trials use informed consent to ensure participants understand all necessary information about the clinical trial. When a participant signs an informed consent form, they are confirming that they are aware of and understand any potential benefits or risks of the study.

Signing an informed consent form or providing consent is not a contract and does not mean you cannot leave the study. You can always withdraw and leave a study at any time, even if the study is not over.1

Remember: Research is ALWAYS voluntary!5

Native Contributions to Health

Native people have greatly contributed to the health of our own communities and beyond by participating in clinical trials. Scan the QR codes to the right with your smartphone camera to learn more about how Native communities have contributed to local and global health.
Thinking about volunteering for a clinical trial? The following sections include questions that can be asked directly to your doctor or the research staff working on the clinical trial.

Preparing to discuss clinical trials with a researcher or doctor:

- Plan some questions to ask in advance, but do not hesitate to ask any new questions you think of.
- Consider taking a family member or friend along to appointments for support. They can help you ask important questions, record answers, or help ensure any access needs are met.
  - If you are not able to bring anyone but still need translation help, ask if translation services are provided.
- Think about writing or recording all the answers to your questions so that you can review them later.
  - If you’d prefer, ask if you can audio record your visit so you can recall the information later.

Important Clinical Trial Questions to Ask

1. What is being studied? Why do researchers think it might work?
2. What will I have to do?
3. Has this treatment or intervention been tested before?
4. Could I experience side effects from the experimental drug, treatment, or intervention?
5. Do I get anything or benefit from being in this trial?
6. Will I know which intervention I receive? Does this trial use placebos?
7. Who is the principal investigator (PI) of this clinical trial?
8. Will the results of the study be shared with me?
9. What type of long-term follow-up care is part of this trial?
10. Who can answer my questions throughout the clinical trial? How can I contact them?
11. Who will oversee my medical care during the trial?
12. Will the results of the study be shared with me?
13. Do you provide traditional, religious, or spiritual resources before, during, or after the clinical trial?
14. How often will I have to visit the hospital or clinic site?

Financial Questions

15. Will this cost me money? Do I have to pay anything to take part?
16. Who will pay for my participation?
17. Will health expenses be covered? Who do I speak with to receive these services?
18. Will costs, such as travel to the trial or childcare while I am away, be compensated or reimbursed?
19. Will I be reimbursed for other expenses?
20. If I get paid for participating in a clinical trial, is that money taxable? If so, how do I report this on my taxes?

Safety Questions

21. If I no longer want to participate in the clinical trial, can I leave at any time?
  - Remember: The answer to this question is always yes. Signing an informed consent or providing consent is not a contract. Participation in a clinical trial is completely voluntary. You may withdraw and leave a clinical trial at any time, even if the clinical trial is not over.
22. How is my identity protected during the trial?
23. If I get sick or injured during the clinical trial, what are my options?
24. How will my health information be kept private throughout the clinical trial and afterward?
25. Will samples be taken from my body (ex. blood sample, urine, or saliva)? Will I get those samples back or will they be destroyed?
26. Will my samples be used in other research outside of this study?
27. Could my family or community be put at risk by my participation?
28. Which Institutional Review Board (IRB) approved this clinical trial? How can I contact them if I have questions?
29. If the treatment or intervention works, will I get to keep using it after the trial?
30. If the experimental drug, treatment, or intervention does not work, what happens next?
31. How will the results be used after the clinical trial is over? Will I be told when it is being used?
Vaccines & Treatment Dictionary

These are terms you can find in this booklet and others that you may hear or read during a clinical trial.

Anaphylaxis
A severe allergic reaction that often makes it hard to breathe. This requires immediate medical attention and treatment with medicine.

Antibodies
Small germ fighters (proteins) are produced by our immune system to recognize invaders like viruses, bacteria, and other things that our body perceives as a threat to prevent them from infecting/harming us. Every antibody is specific to the part of the virus/bacteria that is responsible for the infection.

Biospecimen
Bio refers to life and specimen refers to sample. Biospecimens are samples or pieces of life from an individual. These are used for various types of testing. Common biospecimens are nasal swabs and urine, blood, and tissue samples.

Clinical Trial
A specific type of medical research with humans that involves assigning study participants to one or more interventions to observe and understand the impacts of those interventions. Interventions can be vaccines, drugs, behavioral changes, medical or therapeutic devices, and much more.

Double-Blind Study
In this type of study, neither the participants nor the researcher knows which treatment people are receiving. This approach is taken so that there is no bias in the study results.

Emergency Use Authorization (EUA)
Emergency Use Authorization is approved for use under limited specific conditions granted by the FDA after a thorough review of safety and efficacy information. This is not full approval for use.

Effectiveness
How well a treatment or intervention works in natural conditions once it is being used outside of the study in the real world.

Efficacy
How well a treatment or intervention works in ideal and controlled study conditions.

Food and Drug Administration (FDA)
United States Food and Drug Administration is the federal regulatory organization responsible for ensuring public health and safety by approving and monitoring medications, medical devices, treatments, food, vaccines, cosmetics, etc.

Immune Response
Our first line of defense for our body is our immune system. When it detects something in our body that shouldn’t be there; the immune response is when our antibodies seek out viruses or bacteria and then destroy or try to destroy them.

Informed Consent
Informed consent is key to ensuring that research participants are safe. Its purpose is to ensure that all study participants understand the study purpose, activities, risks, and benefits before agreeing to volunteer for a study. No matter what you sign or agree to, at any time during the research process you can choose to stop, and all study activities for you should stop.

International Review Board (IRB)
The Institutional Review Board (IRB) is an administrative organization that protects the rights and well-being of research participants recruited to participate in research activities.

Placebo
In a clinical trial, the intervention or treatment needs to be tested against something that mimics or mirrors the intervention/treatment but is not an actual treatment or intervention. This is called a placebo control and is used to measure the psychological effect of treatment versus the physical effect of the treatment. The placebo is usually a sugar pill or a saltwater solution.

Pre-Clinical Trial
Before treatments or interventions enter human clinical trials, they must be tested on animals beforehand to ensure they are safe.

Principal Investigator (PI)
A Principal Investigator (PI) is the person responsible for the preparation, conduct, and administration of a clinical trial or research study.

Randomized Study
Participants are divided randomly into separate groups that compare different treatments or interventions. Using randomization to divide people means that each group will be similar and the effects of the treatments/interventions they receive can be compared more fairly.

Treatment
The treatment is also known as the ‘intervention’ in the study. The intervention or treatment can be vaccines, medications, devices, mental health therapy, medical or surgical practices, and much more.

Vaccine
A safe mixture of organic materials that the body can process without illness, while keeping the added genetic instructions to protect itself.

Vaccine Platforms: Adenovirus Vector
An adenovirus vector is a type of virus that has been changed to safely teach our bodies the information in vaccines to protect ourselves.

Vaccine Platforms: mRNA
mRNA is a type of messenger protein that delivers instructions to our cells. These instructions teach our bodies to protect themselves.

Variable
A variable in research refers to something that researchers are trying to measure in some way. Variables have a cause-and-effect relationship with what is being studied.

References

3. FDA: Office of the Commissioner. Clinical Trial Diversity. FDA. Published online June 14, 2021.