CLINICAL TRIALS AND MARKET RESEARCH

AAKP's role in Clinical Trials and Market Research

AAKP supports innovation in the kidney space. We are actively involved in market research - to share the patient voice and experience with renal companies and clinical trials - to create more and better treatment options for kidney patients, so they can achieve their aspirations.

You may have heard the term "clinical trials" but wonder what that means. Is a clinical trial something you can participate in? What do you need to do to get started? We have pulled together some information that you might find helpful as you decide whether you would like to participate in a clinical trial.

What is a clinical trial?

A clinical trial is a type of research study that looks at new ways to prevent, detect, or treat disease. A clinical trial is the last phase of research, and looks at the safety and effectiveness of a medicine, medical device, or treatment option. The drug or device needs approval from the Food & Drug Administration (FDA) before being made available to the public.

Most clinical trials in the U.S. are approved and monitored by an Institutional Review Board (IRB), an independent committee (meaning the individuals are not directly associated with the trial). The IRB works to ensure clinical trials are ethical and that participants' rights and safety are protected.

Groundbreaking advancements in medicine are possible with the participation of volunteers in clinical research.

How can I get involved? What are the current opportunities to participate in clinical trials?

- Visit https://aakp.org/clinical-trials/

What are some possible risks of participating in a clinical trial?

- You may have more health visits than you normally would with your regular doctor
- The study or medicine may not make you feel better
- Unpleasant, serious, or life-threatening side effects
- You may have to spend more money than usual for traveling to visits, the medications, and testing, that is not covered by insurance
- Improve the way doctors, nurses and other health professionals are trained
- Influence health laws and funding for health services

What are some potential benefits of participating in a clinical trial?

- Help others who have your disease by contributing to medical research
- Help doctors and researchers learn more about your disease
- Learn more about your disease or medical condition
- Gain access to new research treatments before they are widely available
- Receive regular and careful medical attention from a research team that includes doctors and other health professionals
- In some cases, you may be paid for your participation.

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What are the different Phases of Clinical Trials?

The Food and Drug Administration (FDA) describes five phases of a clinical trial, each having a different purpose and helping to answers different questions.

Phase I:	Researchers test a drug or treatment in a small group of people for the first time. The purpose is to study the drug or treatment to learn about safety and identify side effects.
Phase II:	A new drug or treatment is given to a larger group of people to determine its effectiveness and to further study its safety. Studies that gather preliminary data on effectiveness (whether the drug works in people who have a certain disease or condition). For example, participants receiving the drug may be compared to similar participants receiving a different treatment, usually an inactive substance, called a placebo, or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.
Phase III:	A new drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it with standard or similar treatments, and collect information that will allow the new drug or treatment to be used safely. Studies that gather more information about safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs.
Phase IV:	Studies occurring after a drug is approved by the FDA and made available to the public (available on the market). Researchers track its safety in the general population, seeking more information about a drug or treatment's benefits, and optimal use.

Remember, choosing to participate in a clinical trial is YOUR DECISION. You should never feel pressured to participate, and if you are uncomfortable continuing, you can stop at any time.

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What questions should I ask if I am thinking about participating in a clinical trial?

- What is the purpose of the study?
- Why do researchers think this will be effective?
- What are possible short-term and long-term benefits?
- What are possible short-term and long-term risks and side effects?
- How are the study results and safety of the participants monitored?
- How long will the study last?
- What will my responsibilities be if I participate?
- Will I have to pay for any part of the trial such as tests, the study drug?
- What is my health insurance likely to cover?
- Is transportation, or financial assistance with transportation, for appointments provided?
- What kinds of therapies, procedures, tests, etc. will I have during the trial?
- Will I be able to take my regular medications while taking part in the clinical trial?
- Who will be in charge of my care, and where will I go?
- How would participating in this study affect my daily life?
- Can I talk to other people in the study?
- How is my safety protected?

Can I speak to someone who has participated in a clinical trial?

Clinical trial participants typically can't share specific information about the trial they are involved in, but they can share about the process, how they decided it was a good fit for them, etc.

What happens after a clinical trial is completed?

After a clinical trial is completed, the researchers examine the information collected during the study. They will make decisions about the meaning of the study results and determine whether further testing is needed. Results are often published in peer-reviewed scientific journals, where experts review the report before it is published.

Where can I go for additional information?

- NIH Clinical Trials and You web site: https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics
- ClinicalTrials.gov glossary of common terms: https://www.clinicaltrials.gov/ct2/about-studies/glossary