THE KIDNEY CITIZEN

DPC EDUCATION CENTER

Clinical Research 101: Participating in a Trial

Written by **Kurt Mussina**, MBA, Frenova Renal Research

What Is Clinical Research?

Long before a medicine is approved by the U.S. Food and Drug Administration and put on the market, it undergoes rigorous testing to ensure it is safe and effective — a process that can take many years. Testing new and/or already approved medicines in people is what we call clinical research. Although there are many different types of clinical trials, I am focusing here on the clinical development and approval process for drugs and devices, in particular.

Clinical research is vital to finding ways to improve quality of life and to finding cures for diseases. It gives researchers all kinds of information they need to make good decisions. For example, it tells the researcher if the medicine works well in pill form or if it possibly works better as an injection. It helps the researchers determine the size of the dose and how much should be given at a time and how often. It tells the researchers how effective the medicine is. And much more. Without clinical research, there simply would be no new medicines. Without clinical research, we can forget about finding better treatments for kidney disease. That is the simple truth.

What Does Clinical Research Have to Do With You?

Join us for an education webinar on December **7** at **2pm** ET **entitled Clinical Research 101: Participating in a Trial** visit www.dpcedcenter.org for more information

Unfortunately, most people don't know much about clinical research or about studies that are available. That makes clinical research difficult, because we need many people willing to step up and participate in clinical research — all kinds of people.

Sometimes medicines are tested in healthy volunteers. For example, a cold medicine may be tested in people who are generally healthy. But often, patients with a particular disease or condition are required. After all, it's hard to test a new medicine for a particular cancer unless you can test it on people who have that cancer.

Similarly, if researchers want to test how well a treatment for kidney disease works, then they are going to need to test it in people with kidney disease. Sometimes, too, volunteers

with kidney disease may be needed even if the treatment isn't specifically targeted to kidney disease. For example, researchers may want to learn how well a medicine for heart disease works for people who have kidney disease.

This is where you come in.

What Are Clinical Trials?

When researchers are ready to test a medicine in people, they organize a clinical trial. There are more than 254,000 of these clinical trials for all types of diseases underway now around the world, and more than 44,000 of these studies are actively looking for people to participate in them. (This is information from ClinicalTrials.gov, a federal website that tracks all the trials.)

It's not just medicines that need to be tested. Medical devices — such as the stents surgeons place in heart patients or the monitors that diabetes patients use to test their blood — need to be tested in clinical trials, too. Some trials even study surgical procedures to help doctors determine what procedure will help their patients the most.

Perhaps you heard the word "phase" used in connection with clinical trials. There are four different phases of clinical trials. You might want to think of them as elimination rounds. If the medicine or medical device fails in any phase, then the trial ends right there. Here's generally how it works:

Phase I — The medicine is typically tested on 15 to 30 healthy volunteers just to make sure that it is safe and doesn't cause any bad side effects.

Phase II — The medicine is tested in a larger group of people, maybe 100 to 200. In this phase, researchers are trying to determine how effective the medicine is. Does it actually help treat the condition, and does it help treat the condition better than other medicines that are already available?

Phase III — Researchers test the medicine on many more people, perhaps 1,000 or more. They are looking to make sure that there aren't any major side effects in some people. They are also hoping to confirm what they found out in Phase II about how well the medicine worked.

If the first three phases — or elimination rounds — go well, then the company developing the medicine or medical device can ask the U.S. Food and Drug Administration (FDA) for approval to start selling it. If the FDA approves, then it goes on the market. That takes us to the final phase.

Phase IV — After the medicine is already on the market, and presumably being used by people around the country, some drug companies may still have an obligation to make sure its medicine is safe. So, the company will conduct tests in an even larger group of people to make sure the medicine is safe and not causing any additional side effects.

Why Participate? What Do You Get Out of It?

Many of us have heard of someone who is really sick and is participating in a clinical trial. Maybe this person hasn't been helped by any of the medicines available today and hopes to get help from a new medicine not yet on the market. Certainly, this is an excellent reason to participate in a trial.

But researchers need more than these people. There simply aren't enough people willing to volunteer. They need healthy people to volunteer for trials, and they need patients with specific health conditions to participate.

You may decide you want to participate to learn more about kidney disease and its treatments. Or, you may want to participate to see if the medicine can improve your day-to-day life. Or, you may just want to have a role in helping others who are living with kidney disease or people who will get kidney disease in the future. Whatever your reason, we hope that you will consider joining a clinical trial.

How Can You Get Involved?

If you think you might be interested in clinical research or you just want to know more, your first step is to talk to your doctor. Let him or her know of your interest. You can also explore the many online resources available that provide additional information about clinical trials, such as the Center for Information & Study on Clinical Research Participation, or ClinicalTrials.gov, where you can search for all kinds of available trials.

Once you decide on a potential study, you can contact the study team, who will lead you through the process. Keep in mind that you are in no way committed to a clinical trial yet. This is just your chance to find out more.

You will meet with a nurse or doctor on the team who will probably ask for some information about your medical history. This information helps the study team determine if you meet the requirements for study participation and if you can safely join the research study.

The nurse or doctor then will meet with you to tell you all the details about the study and what will be required of you. If you want to bring a family member or a friend with you, that is perfectly fine. You will learn what drug company is behind the study and what the medicine is supposed to do. You will learn what the medicine's potential benefits and risks are, and you will learn what will be required of you. Most importantly, you will have an opportunity to ask all your questions. In fact, the study team is required by law to make sure that all your questions are answered, so don't be afraid to ask any question! Here's a partial list of questions you should ask. Again, be sure to add questions of your own:

- What is the main purpose of the study?
- Does the study involve a placebo or a treatment that is already on the market?
- How long will the trial last?
- What am I required to do?
- Will I need to travel to a clinic? Where? How often? Will I be required to stay overnight?
- Will I need to have my blood drawn? How often? When?
- What are the potential benefits of the study drug?
- What are the potential risks and side effects?
- Will I be reimbursed for travel and other expenses?
- Do I need health insurance to participate in the trial?
- When and how will the results of the clinical trial be provided to me?

Once you feel you have all the information you need, then you can decide if you want to participate. If you want to talk it over more with your family first, then you can do that. If you decide you want to participate, then you will be asked to sign an informed consent form, which basically acknowledges that you have been given all the information you want and that you willingly agree to participate.

Here's something very important for you to know: By law, you can quit the study at any time — and you don't even have to give a reason. Your decision to participate is your choice and remains your choice at all times.

At some point, you likely will be asked to undergo some initial procedures, such as getting your height, weight, temperature and blood pressure measured or perhaps giving a blood or urine sample. There might be a physical exam. This is because the doctor in charge of the clinical trial needs to know about your health and medical history to ensure the study is safe for you. The doctor's most important job by law is to make sure all volunteers in the study remain safe.

So, some people — because of their medical history or the medications they are taking or for some other reason — will not be allowed to participate in the study. The clinical trial's doctor will let you know whether or not you are accepted. If you are accepted, then you'll be given instructions, such as a time when you need to report to the clinic.

Should You Be Concerned About Your Safety?

Absolutely. But you also should know that there are many others looking out for your safety, too. As mentioned earlier, the most important job of the doctor in charge of the clinical trial is to keep you safe. If you experience an unexpected side effect, that doctor will make sure you are taken care of. So, be sure to always let the study team know how you are feeling and always ask any questions you have.

Secondly, long before you or any of the other study volunteers can get involved in a study, a group of independent doctors and researchers — people who have absolutely no connection with the study at all — is required by law to take an in-depth look at all the plans for the study. They also look at all the research that has already occurred. Not until they say everything looks okay, can the study begin. Plus, they also keep tabs on the study as it goes along.

And, never forget, if you ever want to drop out of the study, you are allowed to do so.

What if Clinical Trials Aren't for You?

Volunteering for a clinical trial is always your choice. If you decide to volunteer for a trial, you should take pride in knowing that you are helping to find better treatments to help people lead healthier lives. But, if you choose not to volunteer, that is fine too. Maybe this isn't a convenient time for you. Or, maybe you feel this just doesn't feel right to you. That's okay. We understand. We hope that you will spread the word and teach others about the importance of clinical research. Perhaps by telling others, you will find that some of your family members or friends will want to volunteer for other studies.

When we go to the pharmacy to pick up a prescription or when we have to go for a treatment in a clinic or a hospital, we seldom think about how that medicine came to be. We never think about the thousands of people who volunteered to take that medicine as an experiment before it was ever approved. Thanks to the volunteers who participate in clinical research, we are being helped every day and we have hope that doctors can find better treatments, better medicine, to improve our lives in the future.