While most people will never have to decide whether to participate in a clinical drug trial, this decision can be commonplace for individuals diagnosed with a disease. How their participation comes about can vary. Either a physician, researcher or drug company asks them to participate, or individuals themselves seek out trials in an effort to find answers to their treatment.

Participation in clinical drug trials can offer benefits to all parties involved: individuals seeking treatment, drug companies striving to develop the most effective diagnoses and medicines, and researchers looking to test the effectiveness and dosages of medicines by themselves or in combination for certain populations. And while apparently healthy individuals may not often participate in drug trials, they can play an important role in them — specifically in the disease diagnosis process — which can be especially important for those with autoimmune and primary immune diseases, many of whom search for answers to their medical problems for years before being diagnosed.

**What Is a Clinical Drug Trial?**

Thousands of clinical drug trials are conducted every year across the U.S. and abroad. The purpose of clinical trials is to study drug reactions in people to answer specific health questions. The different types of clinical trials include prevention options; new treatments or new ways to use existing treatments; new screening and diagnostic techniques; and options for improving the quality of life for people who have serious medical conditions. Typically, trials compare a new product or therapy to another to see if it works as well or better to treat or prevent a disease or condition.

Because clinical trials are sponsored by various entities, such as physicians or other healthcare providers, pharmaceutical companies and federal agencies, participation details, such as location, frequency, duration, demographics, etc., will vary. It is up to the sponsoring organization to determine where participants will need to go and how often, but in most cases, participants receive treatments at universities, medical centers, clinics, doctors’ offices, hospitals and federally and industry-funded research sites.

All clinical trials are regulated according to strict guidelines set by the U.S. Food and Drug Administration (FDA). The FDA has established five phases of clinical trials, with Phase 0 being the newest designation. Phase 0 is designed to determine if a drug behaves in humans the same way it did in preclinical testing, and it typically involves a small number of subjects. Phase I, the first major testing stage, monitors a small group of subjects in in-patient clinics to determine a drug’s toxicity, side effects, interaction with the body and proper dosage levels. Phase II commences after a drug’s safety is established, and further studies the drug’s effectiveness, but on a larger
group of people. Phase III trials, considered the last step on a drug's way from the lab to the pharmacy, test large groups of subjects to compare the drug against the current standard (existing) treatment for a particular condition. Phase IV trials take place after the drug has been approved and released, and are used to further understand the drug, such as how it interacts with other medications and what its long-term effects may be.

What Are the Possible Risks and Benefits to Patients?

FDA guidelines for clinical drug trials are intended to protect patients from unreasonable risks. Prior to participation, researchers must provide study subjects with complete and accurate information about what to expect during the trial, after which an "informed consent" document must be signed by participants. All participants are free to leave a trial at any time. This is not to say, however, that clinical trials are not without risks. The most common risks include unexpected and serious side effects, an additional commitment burden on the participant, and even the possibility that the treatment will be ineffective. Oftentimes, the benefits outweigh the risks. Participating in clinical drug trials allows eligible participants to get actively involved in their healthcare, and offers many other advantages. In some instances, trials enable participants to receive medicines free of charge. In most trials of immune globulin products, patients receive free medication for the duration of the study, which typically lasts between 12 and 18 months. In addition, they are provided access to expert medical care for their condition. In some trials, participants are compensated for either their time and/or their expenses. Of course, the greatest benefit of all is treatment that works. In this instance, it's important that individuals understand that not only are they personally benefiting from participation, but they are helping future patients by contributing to medical research.

How Do Patients Locate the Right Trial?

While greater awareness has been raised concerning clinical drug trials, companies and researchers are finding that getting people to participate in these trials is becoming more challenging than ever before. This is mainly due to an increasing number of clinical trials, requiring more patients. To compete, researchers have resorted to nontraditional tactics, such as newspaper and radio advertising, email postings and even Internet-based social networks that attract people who share a particular disease.

Patients seeking out a clinical trial pertaining to their disease can look to a few sources. The most complete listing of clinical trials can be found at clinical-trials.gov, an interactive online database managed by the National Library of Medicine for locating federally and privately supported clinical trials for a wide range of diseases and conditions. As of this writing, there were 111 posted clinical trials for intravenous immune globulin (IVIG) and five posted trials for subcutaneous immune globulin (SCIG). The site is updated regularly and offers information on each trial's purpose, who is eligible to participate, locations and phone numbers to call for additional information.

Patients should also consider consulting with their physicians to see if they can recommend a clinical trial. And, they can also visit their local medical facilities, which will oftentimes list drug trials being conducted by specialty physicians.

Physician Support

With the growing number of clinical drug trials being conducted in the world today, patients have more options than ever to play a role in their healthcare treatment. The key is to carefully evaluate whether a trial may be beneficial for them, and remember that it is a trial, not a guarantee, that their participation will provide the answers that will help them, as well as others.

References

