

# Clinical Research

## The Gateway to Safe and Effective Medicines

### **What is a clinical study?**

Clinical studies are carefully designed experiments that test the effects of a medicine (or medical device) on a group of volunteers. Clinical studies measure the medicine's ability to treat a medical condition and how safe it is to use. Many clinical studies test medicines that have not been approved by the U.S. Food and Drug Administration (FDA) for safety and effectiveness. These potential medicines are therefore not available to the general public.

### **Why are clinical studies conducted?**

Every year, drug companies and research centers develop new medicines to save, extend and improve the quality of many lives. But before these new medicines can become available to patients, they must first be tested in clinical studies that follow strict FDA rules. The FDA looks at the results of these clinical studies to decide whether to approve new medicines for the general public. Without these clinical studies, you would not know which medicines are safe and effective.

### **Who conducts clinical studies?**

Drug companies select a limited number of qualified physicians to conduct clinical studies. These physicians have expertise in the medical condition being studied and training in the FDA regulations for conducting clinical studies. A team of study coordinators, nurses, pharmacists and other healthcare professionals assist them in the studies.

### **Who can be in a clinical study?**

People with the condition being studied can participate in clinical studies. Each study has specific requirements for volunteers, such as age, sex and medical condition. The study physician reviews each volunteer's medical history to determine who can participate.

### **Why do people volunteer for clinical studies?**

Every year, millions of people volunteer to participate in clinical studies. They participate for reasons such as:

- They have a medical condition that is not adequately treated by available medicines.
- They want the additional medical care – physical exams, diagnostic tests, lab tests and physician advice – that is often provided to participants at no cost.
- They may learn more about their medical condition.
- They may discover undiagnosed health problems.
- They may help in discovering new medicines for themselves, family members, and their community.

### **How do I obtain the information I need to make a decision?**

Before participating in any clinical study, you must give your "informed consent." In other words, you must be informed and then you must give your consent. The FDA requires that potential volunteers for a study receive comprehensive information about the study. This information includes explanations of the study procedures, the potential risks and benefits, and other aspects of the study. You can ask as many questions as you like, and receive answers. You may talk to your friends, relatives and doctor before making a decision.

### **Who looks out for my interests?**

In addition to the physician, the drug company, and the FDA, U.S. law requires that an ethics committee (called an Institutional Review Board (IRB)) look out for your interests. The IRB consists of a group of independent healthcare professionals and community members chartered to protect the safety and rights of study volunteers. IRBs must approve clinical studies before they begin. They also monitor studies as they proceed, and can halt any study if, in their judgment, that study does not protect the safety and rights of participants.