

Have you ever wondered how new medications become available? How do we know that drugs are safe? What are the benefits of being a research participant? These are all important questions and should be asked before you become a research participant.

### What you should know

The development of new drugs is usually a multi-year process. Before a new drug can be available at your pharmacy, it must go through a series of clinical trials or investigative studies and be approved as safe for use in humans by the Food and Drug Administration (FDA).

- First, scientists test drugs in the lab on individual cells held in “dishes.” If a drug seems promising, it is then tested in animals. If the drug continues to look promising, it is tested in humans. When a new drug is tested in humans, it is called a clinical trial. Clinical trials have four “phases.”
  - A Phase I trial is when testing in humans, usually healthy volunteers, begins. The main purpose of this phase is to observe side effects, judge the safety of the drug in humans, and determine safe dose ranges. Scientists also look at how the body metabolizes the drug and whether the drug damages any organs. If the risks do not outweigh the potential benefits of the drug, testing may move on to Phase II.
  - Phase II trials involve more people and include people who have the symptoms or illness that the drug is designed to treat. Scientists continue to monitor the safety of the drug, and they also collect information on the effectiveness of the drug. Is the drug accomplishing what it is meant to accomplish without causing more harm? If a Phase II trial is successful, the trial may move on to Phase III.
  - Phase III trials include testing the drug in a much larger number of individuals with the disease. In addition to testing the effectiveness of the drug and recording possible adverse effects, scientists compare the drug to similar approved drugs or to a placebo (dummy pill). During this phase, scientists use randomization (Study participants are assigned to a treatment group using a chance method.) and double-blind method (neither patient nor investigator knows which drug a patient is taking) to prevent bias.
    - When the Phase III trials are complete and if they are successful, the drug company can send their research to the FDA and apply for drug

approval. Once approval is granted, the drug becomes available in the pharmacy.

- At this point, some drugs will be studied further in Phase IV trials to see if there are additional benefits. Also, scientists evaluate the possible long term effects of taking the drug.

### **Additional information about clinical trials:**

- Each trial or study has very specific “criteria” to determine who is eligible to participate in the study.
- An Institutional Review Board (IRB) approves and monitors every clinical trial conducted in the United States. An IRB is a committee of doctors and community members who protect the rights of study participants and who ensure that the trial is conducted ethically. Participants can leave a trial at any time.
- Drug trials are not the only type of clinical trials. Some examples of research studies not involving medications include:
  - Dance Video Game Training and Falling in Parkinson’s disease
  - Study of How Speech Disorders Associated with PD Affect Communication in Day to Day Activity
  - Barriers in Healthcare Utilization in Parkinson’s Disease (PD): A Brief Survey for People with PD.
- Clinical trials as well as other types of research are conducted on the motor aspects of PD (including levodopa, dopamine agonist therapy, and deep-brain stimulation surgery); non-motor aspects (including speech, memory, and mood); and complications of therapy (including wearing-off and dyskinesias).

### **Involving Your Team:**

If you are considering taking part in a clinical trial, consult your doctor. Trial enrollment usually involves a doctor to doctor referral.

You can also ask your doctor if there are any current research studies that you might be eligible for.

If a friend or family member tells you about a new treatment for PD or when new drugs become available, ask your doctor about the clinical results that support the use of this treatment. Be active in promoting research!