Demystifying Clinical Trials: How Do They Work?

"Declare the past, diagnose the present, foretell the future."

— Hippocrates

Hippocrates could almost be describing how a clinical trial is set up: clinical trial teams, which include doctors, nurses, social workers, and other health care professionals, check your health at the beginning of the trial, give you instructions, keep a careful eye on you during the trial, and follow up with you after the trial.

Whether or not you are eligible to be in a clinical trial depends on criteria decided in advance and based on age, gender, the type and stage of disease, previous medical history, and other medical conditions. Some research studies want people with the illness to be studied, but other times they need healthy patients. The eligibility criteria helps keep participants safe as well as enabling researchers to answer the study questions efficiently.

To eliminate skewed results, clinical trials use several different testing methods:

- Prospective Trials—You are one of a group of specific people followed over time.
- Randomized Trials—Patients are grouped by chance into an experimental treatment group and a control group. The control group receives either the non-experimental, traditional treatment or a placebo—an inactive substance. Control group results are compared with the treatment group results.
- Cross-over Trials—You receive both the treatment and the placebo at various times.
- Double-blinded Trials—Neither you nor the researcher knows if you are receiving the treatment or the placebo.

In some clinical trials, called *open label studies*, both you and the researcher know that you're receiving treatment and not a placebo.

Every clinical trial in the United States must be approved and monitored by an Institutional Review Board (IRB), an independent committee of physicians, statisticians, community advocates, and others. The IRB's job is to be sure that all clinical trials within a given medical institution are ethical and that the rights of the participants in those trials are protected.

Some clinical trials involve more tests and medical appointments than you would normally have for your illness. Clinical trials are best when you are in touch with the research team frequently and strictly follow the trial guidelines.