Drug Development

Drug development begins after researchers discover, identify, or create agents that show promising effects against a disease or disorder. These agents must pass through many stages of development and exploration and meet strict regulatory requirements before they can be tested on humans.

A major part of drug development requires that developers conduct clinical trials or studies. After testing in laboratories and/or on animals, a drug must be carefully tested in humans. Researchers use clinical trials with human subjects to test the effects of a drug with the goal of determining effectiveness, side effects, toxicity, and interactions. During the study or trial, the effect of the active drug is compared with a **placebo.** A placebo is an inactive (inert) substance that is sometimes given to participants in clinical trials to compare the response the patient has with an inert substance with the response they have to an active substance. The study drug may also be compared with a drug already on the market. For example, ibuprofen was possibly compared with other, well-known pain relievers such as aspirin or acetaminophen (Tylenol).

Study participants are randomly assigned to one of at least two groups (Fig. 4-1). One group is the placebo or **control group;** the other group receives the active study drug or drugs. Because the participants do not know whether they are receiving the active or inactive drug, they are prevented from invalidating the study by reporting effects they were not truly experiencing. Similarly, if the clinician conducting the study knew which patients were taking the active drug, the scientist could change the results, consciously or subconsciously. Therefore, to be sure the results of the drug trials are uncompromised, most studies are **double-blind,** meaning that neither the participants nor the clinicians know

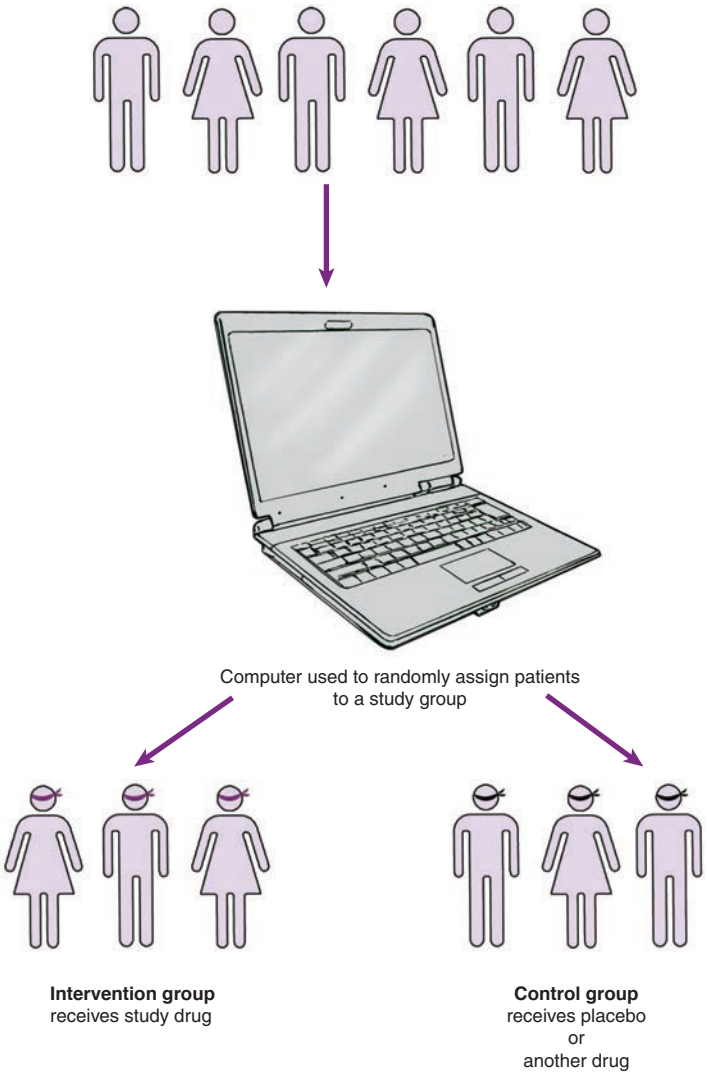

FIGURE 4-1: Double-blind clinical trial. In a randomized, double-blind clinical trial, neither patients nor clinicians know who is receiving the drug or placebo.