information may additionally be collected, for example data on pharmacokinetics, correlations between a drug's efficacy and the subject's genetic makeup, and correlations between the drug's adverse effects and the subject's genetic makeup.

The instructions for conducting a clinical trial are contained in a document called a Clinical Study Protocol. The Clinical Study Protocol may include a flow chart (or drawing or table) called a schema. The schema is the best way to communicate the structure and timeline of any clinical trial. Shown below are various hypothetical study schema, followed by a collection of representative schema from actual clinical trials.

III. THE STUDY SCHEMA

The treatment schedule or timeline used in clinical trials is represented by a diagram called a schema. The schema can take the form of a flow chart, histogram, or table. When included in a Clinical Study Protocol, or in a research publication, the schema aids in understanding the dosing schedule. Moreover, when designing a clinical trial, the principal investigator may draw several versions of the schema, before arriving at the final version to be used in the study.

Where only writing is used to describe the study design, and where the study design includes multiple branching points (or multiple segments), and where the entire study is described in a single lengthy sentence, the narrative risks ambiguity.

Additionally, where only writing is used to describe study design, and where the sentences include multiple phrases, and where the exact meaning depends on the placement of each comma, ambiguity is the predictable result. Moreover, the term "biweekly," which is often used to describe trial design, is distinguished in that it has two different meanings. "Biweekly" means twice per week. "Biweekly" also means once every two weeks. For the above reasons, a schema should be considered for even the simplest trial designs.

At its simplest, the study schema might take the form shown in Fig. 2.1. This particular study schema can be used for clinical trials in oncology, infectious diseases, immune disorders, metabolic diseases, and so on. The schema shown in the figure has two arms, where one arm receives the study drug and the other arm receives a placebo, six boxes and four arrows.

The study design may also be one that contains only one arm, that is, a single arm study, as shown in the schema in Fig. 2.2. The schema contains four blocks and two arrows. In a single arm study, the patient may serve as his own control. In this situation, the patient's health immediately prior to enrolling in the study (baseline) is used for comparison purposes. In another type of single arm study, the outcome for each patient may be compared to the outcome of a historical control. The historical control group can be from the same institution or same investigators as in the present single arm study, or it can be from a totally unrelated group of investigators.