The following table shows a representative time schedule detailing the several integrated steps that must transpire after 1 to 5 years of basic research from the time of selection of the potential clinical candidate to the institution of the broadscale clinical trials.

The same procedures and time schedule are involved in the case of a combination product containing a new drug substance. The sponsor, in the majority of instances a pharmaceutical manufacturer, having already filed FDA Form 1571, is now required to obtain FDA Form 1572 from each investigator. The investigator in singing confirms his understanding of the nature of the drug product he will study; guarantees supervision of every aspect of the study by himself or one or more named associates who are directly responsible to him; describes the facilities available to him; and confirms his understanding that the product will be administered only to volunteers or patients to whom he has made a full disclosure of its actions, the purpose of administering it, and the benefits to be derived from the study, and from whom an informed consent has been obtained for the administration of the drug product.

The investigator, in signing FDA Form 1572, accepts all of the limitations on the investigational use of the experimental drug product as set forth in the sponsor's brochure. He further agrees to report promptly any event of clinical importance which may be observed in the subjects included in the study whether or not, in his judgment, the event is related to the product's administration. It is the responsibility of the sponsor to report these events to the FDA with an evaluation of the observation.

Phase I is a carefully restricted trial of the drug product in normal man, a relatively few volunteers who agree to take the drug product hopefully to confirm the information already established in a variety of animal species. Those qualified to investigate a drug product in this area of development must necessarily be carefully selected and knowledgeable in regard to drug action as it may affect all body systems and functions. This phase may involve no more than two investigators and perhaps 10 to 20 persons.

Phase II studies are warranted when the probably working-dose range has been ascertained and the human tolerance to the product has been established. At this phase of the investigation, a few selected patients suffering from the illness for which the product may be indicated are given the drug.

It is the customary practice in the industry that a single physician employee be assigned to monitor the investigations. He is responsible for the supplies of the investigational drug product, the filing of an FDA Form 1572 for each investigator, along with a protocol detailing the purpose of the particular study, its duration, and the numbers of patients expected to participate. Should an investigator, at any time or for any reason, elect to deviate from the protocol, the change must be reported to the FDA.

Studies during this period are most critical. The drug product must