IDENTIFICATION OF APPROPRIATE CROs

It is important that your CRO has validated corporate procedures for all segments of clinical study conduct. These procedures are used to ensure that all aspects of a study, including but not limited to clinical conduct, laboratory analysis, data management, biostatistics, pharmacokinetics, and medical writing, are performed in compliance with Good Clinical Practices (GCP), Good Laboratory Practices (GLP), and other applicable regulatory practices and guidelines. These procedures, in short, guarantee the credibility of the data and protect the rights and integrity of the study subjects.

Assessment of Capabilities and Experience

Before "shopping" for a CRO or vendor, a company needs to first identify specific services to be outsourced. If the pharmaceutical company has project management resources available, then it may be able to work with multiple vendors to complete a single study. For example, the company could separately contract with a clinical facility (a university clinic, a commercial standalone clinic, or a CRO with clinical capabilities), an analytical unit, and a pharmacokineticist to write the report. Note that the company could also contract the project management duties to one of these three vendors. Alternatively, the company could contract with a CRO that provides clinical, bioanalytical, pharmacokinetic, statistical and report writing services. This "one-stop shopping" generally facilitates the conduct of these studies, assuming that the CRO can provide the experience and meet the company's timeline and pricing expectations.

To identify the CRO that will conduct a potential study, it is necessary to first develop a list of potential CROs. The list will be made up of those CROs that provide all services and those that provide clinic-only or analytical-only services. The list is often composed of those CROs with which the company (or individuals) has worked with in the past. Although there are many CROs that advertise in the trade publications, most of these will not have the necessary BA/BE expertise or capabilities that are required for the study. Thus, the company will need to evaluate all CROs and will need to make the initial "cut." Evaluating the experience and capabilities of the CRO and their ability to meet the company's timeline are the first two screening criteria. For the purpose of this discussion, it is assumed that the pharmaceutical firm will use a single CRO for all services. For those companies who prefer to subcontract the clinical, bioanalytical, and pharmacokinetic resources, the mechanism to identify the most appropriate vendor is the same but must be repeated for each vendor.

Clinical Capabilities

The first step to CRO qualification is the assessment of their capabilities and experience. The ability of a CRO to recruit a particular patient or volunteer population is a primary requirement. The CRO should be able to recruit the entire study population at a single center, preferably as a single group. Healthy volunteer populations are the easiest to recruit; however, some studies may require large numbers of subjects or