

between different CROs, it is best to evaluate any additional assumptions that the CRO made with regard to these criteria.

Laboratory Chemistries/Special Tests/Physicals

The number of laboratory chemistries, physical examinations (by a physician), and special tests (such as electrocardiograms [ECGs], x-rays, blood glucose monitoring, and special biomarkers) will have a significant effect on the cost of the study. Although the protocol may be very specific regarding the timing and numbers of tests, this information must be present in the RFP to provide an accurate proposal.

Dose and Safety Considerations

For most drug products, the reference listed drug (RLD) and strength(s) to be used in the BE study are provided in the FDA “Orange Book” [7]. Generally, the dose of the RLD is safe to administer to healthy volunteers. However, for some drug products, that dose may cause adverse events and the clinical trial will require additional safety considerations. For example, prazosin has a significant first dose effect that is exhibited by marked postural hypotension; prazosin studies usually require that volunteers stay in a reclined position for several hours after dosing and that blood pressure be routinely monitored. Diltiazem and other calcium channel blockers can cause significant AV block; studies with this type of drug should include serial lead II ECGs to monitor for cardiac adverse events.

Because it is in the best interest (and required by the institutional review board [IRB]) for both the CRO and the pharmaceutical company to ensure subject safety, any known adverse events should be communicated early in the RFP process so that safety procedures can be included in the study budget. If this information is left out of the RFP, then competitive bids may or may not include safety considerations (depending on each CRO’s experience with the drug) that could result in two proposals with very different prices.

Clinical Conduct

Clinical bids are based on the version of the study outline or protocol submitted with the RFP. A number of factors affect the price of clinical studies. Some of these are shown as follows:

- Population (volunteers vs. patients, males vs. males and females, postmenopausal females)
- Number of volunteers or patients
- Inclusion/exclusion criteria
- Volunteer stipend
- Number of laboratory chemistries and special tests (ECGs, blood glucose monitoring, etc.)
- Dose (with regard to safety and adverse events)
- Washout period
- Number of blood draws and urine collections and times of sampling

Protocol revisions or amendments that change or add services, including but not limited to laboratories, samples, procedures, personnel or clinical summary report writing, will usually require a revised or amended cost quotation.