(CRFs). Thus, the CRO statisticians will provide additional statistical tables, analysis listings, and graphs. This additional work increases the cost of the study due to the additional statistical and medical writing man-hours needed. Although these data may be required for an NDA BA study, they are not required for a generic BE study.

Many CROs have developed their own "standardized" format for BE studies, which, although quite abbreviated, is adequate for submission to the FDA Office of Generic Drugs (OGD). These reports include a relatively short summary of the clinical and analytical conduct and the pharmacokinetic and statistical results. The clinical report, analytical report, CRFs, and statistical output are merely attached to the report as supportive documentation. This report format requires fewer man-hours and is substantially less expensive that its ICH counterpart. However, the FDA is recommending that even these BE summary reports be prepared in common technical document (CTD) format. It is recommended that sponsors proactively discuss report format requirements with CROs.

If the client requires a report that may also be submitted (at a later date) to the European authorities, then they may expect a CTD (or eCTD) formatted report. However, if the CRO assumes a report formatted for OGD (i.e., not CTD formatted), then the client will not be satisfied with the final product (i.e., report). On the other hand, if the CRO assumes that an ICH format and content are necessary, but the client requires only the more abbreviated OGD report, then the price of the study will be much higher than needed. The CRO will appear to be noncompetitive with other CROs that assumed an OGD format.

Submission of Data and Reports to the FDA

The FDA OGD currently requires ANDA applicants to submit information from all BE studies conducted on the same formulation of the drug product contained in an ANDA [3]. In addition, they recommend that BE summary reports be submitted in CTD format; OGD expects BE data to be submitted using data summary tables consistent with CTD-formatted applications; sample tables are available for download [4].

The following tables are required for a BE review:

- Submission summary (or, alternatively, provide an electronic copy of Form 356H)
- Summary of BA studies, which provides study reference numbers, objectives, designs, treatments, and subjects as well as summary statistics for pharmacokinetic parameters
- Statistical summary of comparative BA data (AUC_{0-t}, $AUC_{0-\infty}$, and C_{max}), which provides least squares geometric means, ratio of means, and 90% confidence intervals
- Summary of bioanalytical method validation data
- Summary of in vitro dissolution studies
- Summary of formulation data (qualitative and quantitative composition)
- Demographic profile of subjects for each BE study
- Summary of adverse events for each study
- Bioanalytical reanalysis of study samples
- Study information for each study
- Product information with batch numbers and size, potency, and content uniformity