TABLE 12.2
List of Those Areas to Be Included in the Clinical Site Assessment

	Check (✓) When Complete
Clinical Site Evaluation	
Assess the volunteer (or patient) population pool	
Evaluate CRO procedures for adverse effects investigation	
Assess training records for the clinical team	
Evaluate CRO's ability to coordinate plasma/urine shipments to different bioanalytical facilities	
Assess ability to coordinate functional handoffs (e.g., timely delivery of protocol to clinic, samples to laboratory, and bioanalytical data to the pharmacokineticist)	
Assess clinical project management capabilities	
Clinical Data Management	
Assess the validation of the data collection system	
Evaluate query generation, SOPs, CRF, and database correction, change control	
Evaluation of Clinical Deliverables	
CRFs (CRO or sponsor format)	
Database (when applicable)	
Blood/plasma/urine collection procedures/SOPs and transport procedures to bioanalytical unit	
Content of the written clinical report (i.e., CRO clinical report to be incorporated into the final study report)	

Bioanalytical Site Qualification

Candidate CROs for bioanalytical laboratory work (for drug, metabolite, and/or biomarker assays) should also be assessed. The personnel and their qualifications and analytical method and validation should be assessed before awarding the study. The company audit should also include cGLP compliance and an assessment of the laboratory's inspection history. Copies of the inspection history with all FDA 483's and Establishment Inspection Reports should be reviewed. Laboratory project management should be assessed for their ability to coordinate all processes with the client, clinic, and pharmacokineticist.

Finally, the CRO should provide written documentation as to the content of the final analytical report that should contain additional project specific validation data (e.g., frozen matrix stability determined for the length of sample storage; i.e., from time of first clinical sample collection to the time that the last sample is analyzed) to support the BA/BE study. The FDA requires that full validation be performed to support BA and BE studies in NDAs and ANDAs [1,2].

Pharmacokinetic Site Qualification

The pharmaceutical firm should also qualify the CRO site (or department) that is responsible for pharmacokinetic and statistical analyses and completion of the final