CBER Computer Assisted License Application (CALA) Questionnaire

Date:
Subject: Anticipated **BLA/CALA** submission to CBER

QUESTION	RESPONSE
1. What is the planned target date for the submission of your BLA/CALA?	BLA: CALA:
2. Will the submission conform to CBER's current guidances?	
3. What information will be provided electronically? On paper? a) **Complete** BLA text? b) Clinical datasets & codes (SAS)? c) Case Report Forms (CRFs)? d) Case Report Tabulations (CRTs)? e) Other? (i.e., images,)	a) b) c) d) e)
4. Total number (ballpark estimate) of patients in study? Anticipated number of patients for which you will submit CRF's as an e-doc.	
5. What is the total size, in gigabytes, of the electronic submission?	
6. Will electronic tables of contents be provided (main TOC and item TOCs)?	
7. When will a CDrom containing a demo of your CALA be provided (at least 4 months prior to the submission date)?	
8. Will the applicant provide reviewer training in the use of the CALA, no more than 2 to 3 weeks after the submission of the BLA/CALA? Will the applicant provide a quick reference manual to aid the review team in the use of the electronic submission?	

QUESTION	RESPONSE
9. When will a copy of your annotated CRF's be submitted to the IND for review?	
10. When will a description of the datasets, intended to support your application, be submitted to the IND?	
11. When will listings of all statistical/clinical variables planned for the submission be submitted to the IND? Please present this universal list of variables in alphabetical order. For each variable, three items should be reflected in column format: variable name, file name and description.	
12. When will copies of your Proc Contents', for each dataset, be made available for review? Please present the following four items for each variable in column format: variable number, variable name, format and label.	
13. Will all variables presented as part of datasets have labels, up to 40 characters, associated with them?	
14. How will your statistical/clinical data be presented? Will it be presented as a SAS transport file (XPORT not CPORT)? Data files should not be zipped, nor should there be multiple data files in one SAS transport file.	
15. Will scientific and technical support be provided once the review has started, if the reviewer has questions or problems with the CALA?	

Outstanding Sponsor Issues/Questions: