

## **1.0** **SDTM VALIDATION CRITERIA**

***[Instructional, to be removed:]***

***When the FDA processes study data received in the Study Data Tabulation Model (SDTM), format validation criteria is applied. The sponsor should be aware of errors that may be generated during the load of the data and specify any issues that the FDA may encounter.***

***The sponsor can search the FDA website for information on the SDTM validation specifications and include a list of errors that are present. If the sponsor has a pre-formatted error listing it can be inserted directly into the Reviewer's Guide. The following is intended as a guide and identifies the minimum content to be represented for FDA reviewers ]***

Table 1. Sample Error Explanations

<i>Domain</i>	<i>Error Message</i>	<i>Explanation</i>
EX	<b>High Severity:</b> This subject is not found in the EX domain.	Subjects assigned to an ARMCD but who are missing exposure data did not take study medication.
VS, LB, EG, DA	No Baseline result	<b>Not an error:</b> The subjects without Baseline result flags are Screen Failures.
LB	Missing units on value	<b>Not an error:</b> Qualitative tests in LB have no standardized numeric results or units.
CM	Start date expected when end date provided	<b>Not an error:</b> Start date is unknown.

## **2.0** **NOTES FOR THE TABULATION DATASETS**

[Instructional, to be removed:

*Any domain specific information that may be helpful to the reviewer can be described within this section.]*

### **2.1** **DEMOGRAPHICS (DM)**

Two subjects in the Demographics (DM) domain were randomized but did not receive study drug. These subjects were assigned a treatment arm, but do not have any records in the Exposure (EX) domain. This will cause a HIGH severity error. A list of the subjects and treatment arms are in Table 3–1.

**Table 3–1. Subjects Randomized and Did Not Receive Drug**

<i>Subject</i>	<i>Treatment Arm</i>
STUDY01-10001	XXXCD
STUDY01-10010	YYYCD

## **3.0** **ERRATA (OPTIONAL)**

[Instructional, to be removed:

*If there are known errata in the data the sponsor may choose to address the data within the Reviewer's Guide.]*

## **4.0** **ADOBE ACROBAT 7.0 (OPTIONAL)**

### **4.1** **ADOBE 7 BLANKCRF.PDF**

There is a known problem with Adobe 7 using a hyperlink in an HTML page to link to a specific named destination or page in a PDF, in this case an XML file rendered in a web browser. In the submission example the links within the define.xml are defined to point to a specific page, through a name destination link, within the blankcrf.pdf. If you are using other than Adobe 7 the links should work perfectly. However, if you are using Adobe 7 the link will always point to the first page within the blankcrf.pdf.

## Reviewers' Guide

A link to a description and possible solutions for the problem:

<http://www.adobe.com/cfusion/knowledgebase/index.cfm?id=326332>