October 31, 2012

Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Road
Beltsville, MD 20705-1266

Re: CDISC Pilot Project, Updated SDTM/ADaM Sample Submission, Sample Number 900172

Dear Sir/Madam:

This letter serves as an introduction to the update of the original CDISC SDTM/ADaM Pilot Project. Reference is made to the original Pilot Project submission (Sample Number 900170, submitted July, 2006) and the first final submission (Sample Number 900171, submitted February 13, 2007). The objective of the CDISC SDTM/ADaM Pilot Project was to test the concept that data submitted to the FDA using CDISC standards will meet the needs and the expectations of the FDA reviewers, including assessing the data structure/architecture, resources and interoperability needed to transform data from legacy data sets into the SDTM and ADaM formats.

Since the original Pilot Project submission, many standards have changed and new standards have been created. As a result, CDISC's ADaM team initiated an update to the original submission as a benefit to the community of users and implementers of CDISC clinical data. Table 1 below summarizes the standards used in the original final submission, including implementation guide (IG) versions, and the standards used in this updated one.

Table 1: Standards Used in the Original and Current Pilot Project Submissions

Standard	Original Submission (from February, 2007)	Current Submission (from October, 2012)
SDTM data	Model Version 1.1 IG Version 3.1.1	Model Version 1.3 (draft) IG Version 3.1.3
ADaM data	Model Version 2.0 (IG N/A)	Model Version 2.1 IG Version 1.0 Final ADAE and ADTTE appendices
SDTM CRT-DDS (i.e. SDTM define.xml)	CRT-DDS Version 1.0, ODM draft version 1.3.1, (Metadata Submission Guidelines [MSG] N/A)	CRT-DDS Version 1.0.0, ODM Version 1.2.1, MSG Final Version 1.0
ADaM CRT-DDS (i.e. ADaM define.xml)	CRT-DDS Version 1.0, ODM draft version 1.3.1, (Metadata Submission Guidelines [MSG] N/A)	CRT-DDS Version 1.0.0, ODM Version 1.2.1, Based on a currently unreleased draft set of ADaM MSG

Other documents considered when updating this submission include the FDA Study Data Specification (Version 1.6), CDER Common Data Issues document (Version 1.1), and the eStudy Data Draft Guidance.   To the best extent possible, advice provided in these documents was adhered to.

Like the original submission, this update includes one abbreviated study report, Study CDISCPILOT01, which documents the analysis results of the legacy data. The folder structures in Module 1 and for the study report in Module 5 have remained unchanged and continue to follow the CTD standard. The folder structures for the datasets in Module 5 have changed, however, to match the specifications of the SDTM MSG Version 1.0. As this submission was intended only to be used for the purposes of a mock review, additional submission components beyond those provided for Study CDISCPILOT01 are not provided.

In the original pilot submission a reviewer's guide was appended to the cover letter. The original intent for this updated submission was to replace that submission-wide reviewer's guide with data guides specific to each set of data—the SDTM tabulation data and the ADaM analysis data. However, there is currently collaborative work underway between FDA and industry representatives to develop an industry standard for the format and content of data guides and reviewer guides. As a result, for this submission, it was decided to not create an SDTM data guide that might ultimately conflict with the efforts of that group.

Most publicly available resources of example reviewer guides and data guides are focused on SDTM data. Therefore, in this updated submission, a data guide for the ADaM data is provided. This guide resides in the same directory as the ADaM data sets. It should be noted that this is an example only for this Pilot Project update and it should not be interpreted as an "industry standard." Although this ADaM data guide may be used as a starting point for the development of an industry standard, there is no guarantee that the final draft standard will bear any resemblance to the version herein.

On behalf of the SDS and ADaM teams, the Pilot Project Update team hopes that you find these new implementations of SDTM and ADaM data and metadata standards to be helpful resources when developing your own CDISC data implementation project.

Kind regards,

The ADaM Pilot Project Update team