December 4, 2014

Clinical Data Interchange Standards Consortium
401 West 15th Street
Suite 975
Austin, TX 78701

Re: CDISC Standard for Exchange of Nonclinical Data Implementation Guide Version 3.1

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Clinical Data Interchange Standards Consortium (CDSIC) for the opportunity to submit comments on its Standard for Exchange of Nonclinical Data Implementation Guide (SENDIG) Version 3.1.

BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

BIO appreciates the opportunity to review and comment on this version of the SENDIG. BIO's member companies are committed to transitioning to an all-electronic FDA review environment and supports submitting all Investigational New Drug (IND) applications, New Drug Applications (NDAs), and Biologics License Applications (BLAs), in electronic format as phased-in under PDUFA V.[i,ii,iii,iv] The continuing implementation of the SEND standard will play an important role in that process over the coming years.

There are a number of areas where BIO requests additional clarification of how the SEND standard will be implemented. For example, it is unclear whether studies that are conducted under non-good laboratory practice (non-GLP) conditions are required to be in SEND format upon finalization of guidances by regulatory bodies, including the Food and Drug Administration.

BIO believes that the SEND requirements should only apply to GLP studies that support INDs, NDAs, and BLAs, or the equivalent in other jurisdictions, and *not* to early non-GLP studies such as dose-range finding studies (DRF studies).

Requiring the data from non-GLP studies to be SEND compliant should be based on the utility of the data in human risk assessment. In order to maintain flexibility in experimental approaches to understanding, for example, mechanism of action or toxicology, not all nonclinical studies will be designed to be SEND compliant. For example, DRF studies are often non-GLP, but are conducted to inform both feasibility of

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achieving a therapeutic window and the study design of subsequent safety studies. Additionally, these requirements would be onerous to many, particularly small, companies, as they often do these non-GLP studies in-house and do not have the infrastructure or personnel needed to be SEND compliant.

BIO agrees that GLP studies such as pivotal repeat dose studies and carcinogenicity studies should be submitted in SEND format as part of the IND, while safety pharmacology and reproductive toxicity studies should be considered next for SEND implementation.

We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/s/

Andrew J. Emmett
Managing Director, Science and Regulatory Affairs
Biotechnology Industry Organization (BIO)

References:

[i] PDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2013 THROUGH 2017, http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf

"Requirements for electronic submission shall be phased in according to the following schedule:

1. *Twenty-four (24) months after publication of the final guidance: All new original NDA and BLA submissions, all new NDA and BLA efficacy supplements and amendments, all new NDA and BLA labeling supplements and amendments, all new manufacturing supplements and amendments, and all other new NDA submissions.*

2. *Thirty-six (36) months after publication of the final guidance: All original commercial INDs and amendments, except for submissions described in section 561 of the Federal Food, Drug, and Cosmetic Act. "*

[ii] FDA, "*Guidance for Industry Providing Regulatory Submissions in Electronic Format - Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act*" ("final guidance:), expected to be finalized no later than May 2015 (no later than 1 year after release of a new draft guidance, issued 2014-02-05, and its 90-day public review, ended 2014-05-06).
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM384686.pdf

[iii] FDA "*Guidance for Industry - Providing Regulatory Submissions in Electronic Format - Standardized Study Data*" ("eStudy Data guidance"), expected to be finalized no later than May 2015 (no later than 1 year after release of a new draft guidance, issued 2014-02-05, and its 90-day public review, ended 2014-05-06).
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM292334

[iii] BIO, PhRMA comments on *Revised Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format – Standardized Study Data*, May 7, 2014, https://www.bio.org/sites/default/files/PhRMA-BIO%20Comments%20FDA-2012-D-0097%20Final.pdf