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12 November 2019

Deputy Director General Zhou
Center for Drug Evaluation
National Medical Products Administration

Re: eCTD中临床试验数据库及相关资料. 的申报要求

Dear Mr. Zhou:

On behalf of CDISC and the global community of clinical data standards, it is my privilege to provide strong and complete support for the recently released electronic common technical document (eCTD) for submission of data sets to the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA). We perceive this recent technical guidance as strengthening the relationship between NMPA and CDISC while supporting continued positive development of the Chinese pharmaceutical industry.

CDISC standards are the global standard for clinical research. The data standards are utilized in China, the European Union, USA, Japan, India, and elsewhere to support rapid and accurate review of data sets by regulatory bodies charged with ensuring public health through the approval of pharmaceuticals suitable for human use. Use of the CDISC standards help medical and statistical reviewers understand the efficacy and safety claims of sponsors, and consistent use of CDISC standards supports a well-run, predicable, and efficient global clinical trial framework. CDISC standards are developed in a global, consensus-based system that relies on industry, regulators, and scientists working together for the common good of humanity.

The details of the eCTD document are well aligned with how CDISC standards are utilized globally. We commend the CDE and all involved in developing this technical document. We note two items where a change in this or a future version of the eCTD would support harmonious clinical trial data standards around the globe.

First, the document sets a split size of 4 GB for data sets. This is not fully aligned with global use of the CDISC standards where 5GB is the common upper limit. CDISC respectfully suggests 5GB limit.

Second, the document indicates the data description file is generally XML (including the corresponding XSL file) or PDF format. CDISC respectfully suggests referring only to the CDISC define.xml file (https://www.cdisc.org/standards/data-exchange/define-xml). This is a common standard used by other regulatory agencies in current submissions. In addition, this file can be automatically validated by a number of open source tools.

CDISC standards are supported by a robust and talented volunteer community. Members of the Chinese CDISC Coordinating Council (C3C) have been working since 2012 to support the successful implementation of CDISC standards in China. For the last three years, C3C volunteers have successfully planned an international CDISC standards conference in Beijing. I have been privileged to attend each year where I have seen the growing community of CDISC-users in China and across Asia. This global community, the C3C, and the CDISC Executive Team which I am privileged to lead are all united in supporting the forward-looking direction of NMPA in regards to global data standards.

If I can ever be of any service, do not hesitate to contact me at dbobbitt@cdisc.org.

Thank you for your time and attention.

Sincerely,

David R. Bobbitt, MSc, MBA
President and CEO