China SFDA organized a workshop on clinical data management, data standards, and statistical analysis in Tianjin, a harbor city near Beijing, on 28-29 June 2012. This workshop was envisioned to promote data quality through clinical data management best practices and data standards. The recently published China SFDA clinical data management technical guideline was also reviewed and discussed. Approximately 500 clinical researchers from the regulatory agency, industry, clinical research sites and academia across China attended this workshop.

Dr. Zibao Zhang, an associate director from PPD and a member of C3C (China CDISC Coordinating Committee), was invited to present on CDISC standards. In his presentation that lasted for one and a half hour, Dr. Zhang opened his talk by highlighting the key messages from the Clinical Data Management and Data Standards Expert Workshop that occurred in January 2012. He emphasized that the Center for Drug Evaluation (CDE), SFDA planned to establish a data standard working group, and will require the applicants to submit SDTM-formatted data gradually. Dr. Zhang introduced the CDISC organization and provided an overview on the current set of developed CDISC data standards from clinical protocol to data submission through data collection and analysis/reporting, including PRM, CDASH, LAB, SDTM, ADaM, Glossary, Controlled Terminology, BRIDG model and ODM/Define.XML. The three CDISC strategic goals were also briefed during his talk: Therapeutic Area standards, SHARE project and Healthcare Link Initiative.

Finally, Dr. Zhang presented the CDISC groups to the audience (C3C, CCAC-China Expert Group and CDISC User Groups in China) and closed his session by announcing the CDISC activities in China including the translation project C-STAR (CDISC Standards Translation And Review).

This talk was welcomed and appreciated by the workshop attendees who came from various regions of China to attend this event. For more information about this workshop and recently published technical guidelines on clinical trial data management, please visit SFDA CDE website at www.cde.org.cn.