Global Data Standards Become a Hot Topic in China

By Linda Wang (C3C)

With the globalization of clinical research and drug development in China, the standardization of data in clinical research becomes a hot topic. In May, there were three meetings/events held in China, where the data standards of clinical research were intensively discussed. At all these events, members from the C3C (CDISC China Coordinating Committee) were in attendance and gave great presentations on CDISC and C3C activities in China.

- The Center for Drug Evaluation (CDE), China FDA, organized a 2-day public workshop on drug regulatory evaluation 9-10 May in Beijing, attended by nearly 500 attendees from the pharmaceutical industry, clinical research sites and academia. On the second day, topics ranging from safety evaluations, issues in labeling, data management, data standards and clinical trial registration were covered. Dr. Zibao Zhang (PPD and Chair of the C3C), was invited to present on data standards in clinical trials. Dr. Zhang spoke briefly on why the industry needs data standards and what CDISC standards are. He also gave a brief overview on CDASH before speaking on the two important submission data standards - SDTM and ADaM. Finally Dr. Zhang shared some updates on CDISC activities in China - translation project (C-STAR) and C3C plans for 2013 and beyond. This topic was very well received and was followed by many questions during the panel discussions. Dr. Qin Huang, Deputy Director of Biostatistics Office, in turn, shared some information on the China data standards plan during the panel discussions, with more updates to come in the next few months. The data standards initiative from CDE, China FDA created great interest at the workshop. However, more details are needed for the industry to be prepared. C3C is committed to supporting this initiative for both the China FDA CDE and the industry.

- The 5th DIA China Annual Meeting on the theme of “Patient Safety – A Sustained Focus from Scientific Ideas to Innovative Medicines” was held in Beijing 12-15 May. The meeting was co-sponsored by the China Center for Pharmaceutical International Exchange (CCPIE) of the China Food and Drug Administration (CFDA). A session on the topic “Data Standards in Real World Clinical Research” was co-chaired by Dr. Zibao Zhang and Yazhong Deng (Covance), with focus on the added value of data standardization and implementation approaches globally. Some companies also shared their successful experience in addressing the key challenges of integrating standards into
clinical trials. Besides Dr. Zhang, several other C3C members were also active participants at this meeting - Victor Wu (Covance and also C3C Vice-Chair) gave a presentation on “Case Studies with CDISC Standards: from CDASH to SDTM and AdaM”; Linda Wang (Novartis and C3C member) provided an update on the status of CDISC standards implementation in China. Intensive discussions followed after the presentations and the question of opportunities and challenges of adoption of CDISC standards in China became a hot topic.

- Pharmaceutical Users Software Exchange (PhUSE) held the first China event in Shanghai on Friday, 24 May. This was a one-day event on the theme of "Global Data Standards in Clinical Research and Development" attended by about 50 professionals from the pharmaceutical industry. The purpose of this event was to share experiences on how global data standards are applied and helping shape clinical research and development, now and in the future. The experts shared their experiences in data standards implementation and provided a CDISC standards introduction at the event. Simon Wang (Roche and C3C ex-Chair) gave an introduction of what the C3C is, while John Wang (J&J) shared topics on “The Challenges and Strategies for Legacy Data Conversion to SDTM and ADaM” and “Creating Define.xml using SAS CST”.

It was indeed a busy month for the C3C in China and definitely helped promote CDISC and the activities of the C3C.