Updates from our User Group and Colleagues in Japan

A recent CDISC Japan User Group (CJUG) meeting was held on Wednesday, 10 July 2013 from 15:30 to 17:30 at CAC EXICARE Corporation in Tokyo. The CJUG SDTM team discussed various topics including the development of their guidelines and terms based on the CDISC User Networks Operational Procedure (COP-11) (http://www.cdisc.org/stuff/contentmgr/files/0/4c011269a1cb48cb0e8ea2c3e172694/misc/cdisc_cop_011_user_networksfinal3.pdf). The team also discussed the GJUG Activity presentation that will be offered during the DIA Annual on 8 November 2013 in Tokyo. The team went through the details of another CJUG Activity presentation scheduled for the 33rd Joint Conference on Medical Information on 21-23 November 2013 in Kobe. And finally, the team members concluded the meeting by emphasizing their joint effort with the Japanese CDISC Coordinating Committee (J3C).

The CJUG SDTM team attended an online meeting with the CDISC New Jersey User Group on 17 June 2013 with the following team members in attendance: Mr. Mitubishi SOMA of Tanabe Pharma Development America, Inc. who partaked in the event in New Jersey; Mr. SHIMIZU of AC Medical INC. who joined online from Japan and Mr. MORIGUCHI of Santen Pharmaceutical Co. Ltd.

The CJUG SDTM team has been recently very active. Mr. MORIGUCHI of Santen Pharmaceutical Co. Ltd., who is also the leader of the CJUG SDTM LISaS sub-team, presented feedback and updates on the Study Data Reviewer’s Guide (SDRG) core team to the PhUSE corporation. In addition, the CDISC SDTM sub-team “Five-Wheeler” led by Mr. SHIMIZU of AC Medical Inc., provided feedback on the CDISC SDTM survey that was recently conducted from 4 to 9 June 2013 in Japan. Moreover, Four visitors from Japan, three CJUG members and another staff member visited the CDISC booth at the DIA Annual in June 2013 in Boston, MA, where they met with Dr. Rebecca Kush, President and CEO of CDISC, and discussed the latest updates from the team.

Recently, another CJUG SDTM Team meeting was held on Friday 12 July from 13:00 to 17:00 at the EPS Corporation in Japan where 47 members attended this conference. During this meeting, four new members have joined CJUG: Mr. Takaharu OSANA of Intellim Corporation, Ms. Yuki ANDO and Mr. Eisuke HIDA of the Pharmaceuticals and Medical Device Agency (PMDA), and Mr. yu TAKATSUTO of SRD Co., Ltd. Four sessions were scheduled during this meeting starting with the following topics during session one: a. SDTM data implementation updates, b. EDC Builder, c. Protocol, d. Study Data Reviewer’s Guide (this group will meet again in August), e. Trial Conduct. During the second session, Mr. SHIMIZU of AC Medical Inc. presented about the CDISC New Jersey User Group that he attended in June. Ms. HASHIO of Glaxo SmithKline K.K. presented on the SDTM-IG 3.1.4 and Therapeutic Area standards during the third session. And finally, the conference was concluded with the fourth session where Mr. HOMMA of the Ministry of Health, Labor and Welfare (MHLW), Office of Clinical Trial Promotion Research and Development Division Health Policy Bureau, who presented on the "Clinical Research and Clinical Trial Activation Five-Year Plan 2012 and Promotion IT Systems".

A CDISC seminar was held on Wednesday 17 July from 9:00 to 15:30 at SAS Institute Ltd., in Tokyo. The meeting commenced with a CDISC Overview session presented by professor Takahiro KIUCHI of the University of Tokyo, UMIN Center from 9:00 to 10:30. The day continued with updates on the CDISC SDTM, ODM and ADaM standards, presented by Mr. Yoshiteru CHIBA of the University of Tokyo.

Other Updates from our colleagues in Japan:

The UMIN Center published a Japanese version of the "UMIN INDICE Lower level data communication protocol for CDISC ODM" document. Please see the following link (http://www.umin.ac.jp/cdisc/dl/api_ver27/INDICE_CDISC_API Ver27.pdf) for details. This document is intended for system development, illustrating how Clinical Study Data from HIS/EHR or EDC is being sent electronically to direct UMIN INDICE.
UMIN, a member of the CDISC CSTAR, was established in 1989 for service to academia and hospital. Internet Data and Information Center for Medical Research (INDICE) system - an EDC researcher led - has registered over 2,430,000 (2.4 million) data, in addition to 194 studies in May 2013. UMIN INDICE has implemented ODM input function, and has published this document in Japanese while planning to publish the English version soon.

Upcoming CJUG meetings:

The next CJUG SDTM team meeting will be held on Friday, 9 August 2013 at Asahi Kasei Pharma Corporation. The meeting is scheduled from 13:00 to 17:00 where three sessions will be offered. The first session will start with a discussion on the SDTM implementation latest updates, the second session will follow with a presentation on the SDRG Trial Feedback, by Mr. MORIGUCHI of Santen Pharmaceutical Co. (a LISaS sub-team member). And the day will end with a presentation on "Spotfire" by TIBCO Software. Additionally, CJUG team members will be presenting during the DIA Japan conference scheduled on 8 November 2013. An overview on CDISC SDTM will be presented by MR. Taku SHIMIZU, and another overview on CDISC ADaM will be provided by Ms. Yumiko ASAMI.

The Japanese CDISC Coordinating Committee is working on scheduling a CDISC Japan Interchange during the first week of December 2013. Information will be posted very soon on our website, stay tuned.