「2018 CDISC Japan Interchange」
プログラム

2018 年7 月10 日（火）9:00～20:00　2018 年7 月11 日（水）9:15～17:00
伊藤謝恩ホール（東京大学本郷キャンパス内/〒113-0033 東京都文京区本郷7-3-1）
https://www.u-tokyo.ac.jp/ext01/iirc/access.html

【7/10午前】 9:00～12:10

Opening Remarks	Stephen Pyke David R. Bobbitt	GSK, CDISC Board Chair CDISC President and CEO
Quality Management Systems and CDISC Standards in Clinical Research in Japan	Dr. Takuhiro Yamaguchi	Professor and Director, Division of Biostatistics, Tohoku University Graduate School of Medicine and Clinical Research Data Center, Tohoku University Hospital J3C member
What's New and What's Next & TA Standards Update	Rhonda Facile	CDISC
Coffee Break	–	–
CDISC Myths & Misconceptions: Creating Clarity	Dr. Diane Wold and Kit Howard	CDISC
SHARE 2.0 Update	Dr. Sam Hume	CDISC
CNIO Mapping for Non-Interventional Research: Principles	Jon Neville	CDISC

【7/10午後】 13:40～17:40

Electronic Data Submission in Japan - Current Status and future	Dr. Yuki Ando	Senior Scientist for Biostatistics, PMDA
Experiences of Receiving and Using Electronic Data - Updates and some points to be considered	Takami Suwa	Office of Advanced Review with Electronic Data, PMDA
Points to consider for e-data submission : perspectives from Clinical Pharmacology	Takahiko Tanigawa	Head of Clinical Sciences Japan, Bayer Yakuhin, Ltd.,JPMA
TBD	Toshihiko Watanabe	JCROA
Coffee Break	–	–
Investigating mapping procedure of standardized clinical information, from the Standardized Structured Medical record Information eXchange(SS-MIX) to Clinical Data Interchange Standards Consortium (CDISC)	Dr. Takahiro Kiuchi	Professor, University Hospital Medical Information Network Center
Supporting system for EDC entry based on Japanese standard storage system	Dr. Hideto Yokoi	Professor of Department of Medical Informatics, Director of Clinical Research Support Center, Kagawa University Hospital J3C member
Generating eCRF in ODM by direct data capture from electronic medical record	Dr. Yasushi Matsumura	Professor, Osaka University Graduate School of Medicine, Department of Medical Informatics
AMED's contribution to penetration of CDISC in academia	Dr.Sae Ochi	Agency for Medical Research and Development (AMED)Department of Clinical Research and Trials
Increase Quality and Reduce SDTM Development Time with Test Study Data Simulator	Bhaskar Subramanian	Chiltern (Covance)
Building SHARE-like private tool	Hajime Shimizu	Takeda PRA

NETWORKING RECEPTION　18:00～20:00

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【7/11午前】 9:15～12:25

FDA-CDER Presentation	Representative Invited	FDA-CDER
Coffee Break	–	–
Challenges of CDISC implementation and submission to both of PMDA and FDA	Janet Reich[*1], Yumiko Asami[*2], Yutaka Noguchi[*2], Yasuyuki Okuda[*2]	[*1]: Amgen Inc., [*2]:Daiichi Sankyo Co., Ltd.
Challenges for Simultaneous eData Submission to PMDA and FDA	Sho Hibino	Chugai
Legacy data to CDISC standards – It's not as hard as it seems.	Arvind Sri Krishna Mani	Zifo RnD Solutions

【7/11午後】 13:55～17:00

CJUG update	Yoshiteru Chiba	CJUG J3C Vice-Chair
JPMA Results Summary	Keiichi Koizumi	JPMA
eData Submission from Japan CRO's Perspective	Yuya Ikeda	JCROA stat/dm member J3C member
Coffee Break	–	
Data Mapping using Machine Learning	Ben Bocchicchio	SAS Institute
SDTM Automation Using Computer-Readable SDTM Specs	Kunihito Ebi	Fujitsu Limited
Special Q&A with PMDA and CDISC		Panel Discussion
Closing Remark	Hidetoshi Misawa	J3C Chair