

Speaker	Session Chair	Script
First Block		
Bernard Klinke	Hidetoshi Misawa	Welcome to the Virtual 2020 CDISC Japan Interchange. I am Hidetoshi Misawa, CDISC J3C Chair. As we get started today, I am going to ask that Bernard Klinke, CDISC Education and Events Coordinator, provide some important housekeeping information for Zoom Webinar and Slack. Bernard, please go ahead and begin.
David R. Bobbitt		Thank you, Bernard. Our first speaker will be David R. Bobbitt, CDISC President and CEO, who will be presenting the Welcome Address & State of the CDISC Union. David, please begin when you are ready.
Dr. Yasuhiro Fujiwara	David R. Bobbitt	David will introduce Dr. Fujiwara
Bess LeRoy	Hidetoshi Misawa	Thank you, Dr. Fujiwara, for that excellent Keynote presentation. Our next speaker will be Bess LeRoy, CDISC Head of Standards Development, who will present the State of CDISC Standards & COVID-19 Interim User Guide. Bess, please begin your presentation when you are ready.
After Bess		Thank you, Bess, for your presentation. Everyone, we will now take a 30-minute break. During this time, we encourage you to visit our sponsors and exhibitors, and participate in the Virtual Scavenger Hunt! Please also leave your questions for our speakers in their topic channels.
Second Block		
Dr. Yuki Ando	Kaoru Matsumi	Welcome back after the break. I am Kaoru Matsumi, J3C member. I would like to introduce our next speaker, Dr. Yuki Ando, Senior Scientist for Biostatistics at the PMDA, who will be providing an update from the PMDA. Dr. Ando, please begin when you are ready.
Dr. Wenjun Bao		Thank you, Dr. Ando, for that excellent update from the PMDA. Our next speaker will be Dr. Wenjun Bao, Chief Scientist, JMP Life Sciences, SAS Institute, and CDISC Board Member. She will be presenting Machine Learning for Understanding CDISC/FDA Documents and Clinical Trial Data. Dr. Bao, please begin when you are ready.
After Dr. Bao		Thank you Dr. Bao, for your informative presentation. Everyone, we will now break for 30 minutes for lunch. During this time, we encourage you to visit our sponsors and exhibitors, and participate in the Virtual Scavenger Hunt! Please also leave your questions for our speakers in their topic channels.
Third Block		
Mai Ishikawa	Akira Soma	Welcome back after lunch, everyone. I am Akira Soma, J3C member. Our next speaker will be Mai Ishikawa of Zifo RnD Solutions, who will present Simplifying the Integration Riddle. Mai, please begin when you are ready.
Stanley Wei		Thank you, Mai, for your presentation. Our next speaker is Stanley Wei of Novartis. Stanley will be presenting Introduction of a New Concept: Analysis Results Data Model (ARDM). Stanley, please begin when you are ready.
Jung Hyun Lee		Thank you, Stanley, for your presentation. The next speaker today will be Jung Hyun Lee of Clinical Trial Center at Asan Medical Center. She will be presenting Implementing Study Data Tabulation Model(SDTM) in RECIST/iRECIST Data of Multinational Clinical Trial: Central Imaging Core Lab. Jung Hyun, please begin when you are ready.
Naoto Awaji		Thank you, Jung Hyun, for your presentation. Our next presenter will be Naoto Awaji of Chugai Pharmaceuticals and the JPMA. He will be presenting CDISC Implementation in JPMA Companies: Behind the Scenes. Naoto, please begin when you are ready.
Denislav Ganchev		Thank you, Naoto, for your presentation. Our next presenter will be Denislav Ganchev of Biodome Clinical Ltd. He will be presenting CDISC Standards with Python and Data Pipelines. Denislav, please begin when you are ready.
After Denislav		Thank you, Denislav. Everyone, we will now take a 30 minute break. During this time, we encourage you to visit our sponsors and exhibitors, and participate in the Virtual Scavenger Hunt! Please also leave your questions for our speakers in their topic channels.
Fourth Block		
Gitte Frausing	Dr. Yuki Ando	Welcome back from the break, everyone, I am Dr. Yuki Ando, Senior Scientist at the PMDA. I would like to introduce our next speaker, Gitte Frausing, of Data Standards Decisions Aps. Gitte will be presenting Development of a SEND Data Model and Accompanying QC checks. Gitte, please begin when you are ready.
Sofia Zastavnik		Thank you, Gitte, for your presentation. Our final speaker today will be Sofia Zastavnik, data analyst at the European Medicines Agency. Sofia will be presenting HMA - EMA Joint Big Data Taskforce: Evolving Data Driven Regulation. Sofia, please begin when you are ready.

After Sofia	Hidetoshi Misawa	Thank you, Sofia, for your excellent presentation. This concludes the presentations for the first day of the Virtual Japan Interchange. As a reminder, our Slack Networking Space remains available throughout the conference for you to continue networking with your colleagues and peers, and to ask questions about the presentations in our topic channels. We will begin our second day of the conference promptly at 9:00 AM Japan Time. Thank you, everyone.
Fifth Block		
Dr. Matilde Kam	Satoru Tsuchiya	Welcome back everyone, to Day 2 of the Virtual CDISC Japan Interchange. I am Satoru Tsuchiya, J3C Member. We will begin today with presentations from participants from the FDA. Our first speaker is Dr. Matilde Kam, Associate Director of Analytics and Informatics at FDA-CDER. Dr. Kam will be presenting Helpful Tips for Review-Ready NDA/BLA Submissions to FDA CDER. Dr. Kam, please begin when you are ready.
Helena Sviglin		Thank you, Dr. Kam, for your informative presentation. Our next presenter is Helena Sviglin, Regulatory Information Specialist at FDA CDER, who will be presenting Collaboration and A Public Health Crisis. Helena, please begin when you are ready.
Dr. Alan Shapiro		Thank you, Helena, for your presentation. Our next presenter is Dr. Alan Shapiro, Pediatrician Infectious Diseases Specialist, FDA CDER. Dr. Shapiro will be presenting Assessing Liver Toxicity: Approach & Tools. Dr. Shapiro, please begin when you are ready.
William Houser		Thank you, Dr. Shapiro, for your presentation. Our next presenter will be William Houser, Principal Scientist at Bristol Myers Squibb and BioCelerate Team Member. William will be presenting Using SEND Data Sets to Enable Large-Scale Data Analytic Approaches for Preclinical Toxicology Data . William, please begin when you are ready.
After William		Thank you, William for your presentation. Everyone, we will now take a 30-minute break. During this time, we encourage you to visit our sponsors and exhibitors, and participate in the Virtual Scavenger Hunt! As a reminder, you must submit your responses to the Scavenger Hunt survey no later than the end of lunch for your chance to be entered into our prize drawing! Please also leave your questions for our speakers in their topic channels. The CDISC Q&A will be held at the end of the day today, so make sure to add your question to our CDISC Q&A channel in Slack to participate!
Sixth Block		
Nao Makino	Hideto Yokoi	Welcome back from the break, everyone, from the break. I am Dr. Hideto Yokoi, J3C Member. Our next presenter will be Nao Makino of EPS Corporation and JCROA, who will present Standardization and Continuous Improvement of eData Submission Process . Nao, please begin when you are ready.
Minoru Mizutome		Thank you, Nao, for your presentation. Our next presenter will be Minoru Mizutome of UCB Japan. Minoru will be presenting SDTM Review, Practice and Challenge . Minoru, please begin when you are ready.
After Minoru		Thank you, Minoru, for your presentation. Everyone, we will now break for 30 minutes for lunch. During this time, we encourage you to visit our sponsors and exhibitors, and participate in the Virtual Scavenger Hunt! As a reminder, responses to the Scavenger Hunt Survey are due by the end of lunch to be considered for our prize drawing! Please also leave your questions for our speakers in their topic channels. The CDISC Q&A will be held at the end of the day today, so make sure to add your question to our CDISC Q&A channel in Slack to participate! We will only accept questions for the CDISC Q&A through the end of lunch.
Seventh Block		
Keiichiro Sakuraba	Shiro Hinotsu	Welcome back from lunch, everyone. I am Dr. Shiro Hinotsu, J3C Member. Our next presenter will be Keiichiro Sakuraba of the CDISC Japan User Group SDTM Team. He will be presenting SDTM Datasets Made from Ongoing Study Data for J-NDA . Keiichiro, please begin when you are ready.
Arvind Sri Krishna Mani		Thank you, Keiichiro, for your presentation. Our next presenter will be Arvind Sri Krishna Mani of Zifo RnD Solutions. Arvind will be presenting Handling Re-Screening Subjects in SDTM Data . Arvind, please begin when you are ready.
Yugo Miki		Thank you, Arvind, for your presentation. Our next presenter will be Yugo Miki of FMD K&L Japan. Yugo will be presenting Articulating ADaM Design Decisions: How to Communicate Your Analysis Dataset Design . Yugo, please begin when you are ready.
Yumiko Asami		Thank you, Yugo, for your presentation. Our next presenter will be Yumiko Asami of CSL Behring. Yumiko will be presenting Standardization of Statistical Documents Aiming for Automation of ADaM Specification Creation . Yumiko, please begin when you are ready.
Trevor Mankus		Thank you, Yumiko, for your presentation. Our next presentation will be from Trevor Mankus of Pinnacle 21. He will be presenting Looking Back: A Decade of ADaM Standards . Trevor, please begin when you are ready.
After Trevor		Thank you, Trevor, for your presentation. Everyone, we will now take a 30-minute break. Please remember to visit our sponsors and exhibitors, and network with your colleagues and peers!
Eighth Block		

Peter Van Reusel	Hidetoshi Misawa	Welcome back from the break, everyone. We will now begin our final presentation of the day, CDISC Q&A. Peter Van Reusel, CDISC Chief Standards Officer, has joined us today to answer questions on behalf of CDISC. Thank you to everyone that provided questions in the CDISC Q&A channel for this part of the conference. Please understand that due to time limitations, we will likely not get to everyone's question, but the Slack Networking Space will be available for two weeks following the conference, so I am sure that we will get to most questions. Peter, are you ready to begin?
Hidetoshi Misawa		Thank you, Peter, for providing such thoughtful answers to these questions. Everyone, any additional questions will be addressed through the Slack Networking Space. This now concludes the second day of the Virtual CDISC Japan Interchange. We would like to thank first and foremost all of our J3C members for their tireless efforts in making this first Virtual Japan Interchange a success. Additionally, we would like to thank all of the speakers who so graciously pivoted to making this event virtual, changing their schedules, learning how to use Zoom and Slack, and more. Also, we would like to thank our Global Diamond Sponsor, Pinnacle 21 and our exhibitors for their continued dedication to this conference - thank you so much.