CONFERENCE SCHEDULE

12 June 2024 — DAY 1

Wednesday 12 June

08:00 – 17:10	**Registration**
08:00– 17:10	**Exhibition Open**
09:00 – 10:00	**Session 1: Opening Plenary & Keynote Presentation** Chair: Akira Soma, J3C Chair, Oracle
09:00 – 09:15	**CDISC Strategy: Rebuilding our Foundation and Transforming the Standards Paradigm** Chris Decker, CDISC President and CEO
09:15 – 10:00	**Opening Keynote Presentation** Dr. Shusaku Tsumoto, Professor of Medical Informatics, Shimane University; President, Japanese Society of Artificial Intelligence (JSAI)
10:00 – 10:30	**Morning Break**
10:30 – 12:00	**Session 2: Second Plenary - Updates from CDISC** Chair: Hidemi Hasegawa, Boehringer Ingelheim
10:30 – 11:00	**CDISC Roadmap: Focus on the First Steps to Realize the Long-Term Vision** Chris Decker, CDISC President and CEO
11:00 – 11:30	**Digital Health Technologies (DHTs): A Path to Data Standardization** Christine Connolly, CDISC
11:30 – 12:00	**CDISC Technical Landscape** Anthony Chow, CDISC
12:00 – 13:30	**Lunch Break**
13:30 – 15:10	**Session 3: CDISC Implementation and Use Cases** Chair: Akari Kamitani, Shionogi & Co., Ltd.
13:30 – 13:55	**Examination of 42 Cases of Blunders in CDISC/SDTM in Physician-led/Industry-led Clinical Trials: Insights from the Field** Shizuko Takahara, University of Fukui Hospital
13:55 – 14:20	**Challenge in utilizing CDISC standards for integrating individual participants' data from cohort studies in Japan: the EPOCH-JAPAN Study** Dr. Anna Tsutsui and Dr. Yoshitaka Murakami, Toho University
14:20 – 14:45	**Unveiling Efficiency: Automated SAS Macros for aCRF Annotation and Bookmarking** Sarani Selvakumar, Zifo RnD Solutions
14:45 – 15:10	**Streamlining e-Data Submission Process with Evolving PMDA Regulations** Koichi Yamaguchi, Eli Lilly
15:10 – 15:40	**Afternoon Break**
15:40 – 17:10	**Session 4: Regulatory & Healthcare Interoperability** Chair: Dr. Yuki Ando, PMDA
15:40 – 16:10	**Overview of HL7 FHIR Accelerator Vulcan, for Bringing Interoperability to Clinical Research** Mika Ogasawara, Pfizer
16:10 – 16:40	**PMDA Presentation** Dr. Yoshinori Ochiai, PMDA
16:40 – 17:10	**Supporting Submission and Standardisation of Data, An EMA Update** Eftychia-Eirini Psarelli, EMA
17:20 – 18:30	**Evening Networking Event** (You must have selected Evening Networking Event during registration to attend.)

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2024 JAPAN INTERCHANGE

CONFERENCE SCHEDULE

13 June 2024 — DAY 2

Thursday 13 June

08:00 – 17:30	**Registration & Exhibition Open**
09:00 – 10:00	**Session 5: Regulatory Updates, Part II** Chair: Yoshiko Kitagawa, ONO Pharmaceutical Co.
09:00 – 09:30	**US FDA's Study Data Policy Framework and Recent Activities** Helena Sviglin, FDA-CDER
09:30 – 10:00	**Dataset-JSON Pilot Report and Next Steps** Jesse Anderson, FDA-CDER; Dr. Sam Hume, CDISC
10:00 – 10:30	**Morning Break**
10:30 – 11:50	**Session 6: Data Science** Chair: Yoshiteru Chiba, UMIN Center
10:30 – 10:55	**Feedback from Dataset-JSON Submission Pilot Workshop and Prospects of Adoption in Japan** Yuichi Nakajima, Novartis Pharma K.K.
10:55 – 11:20	**Creating Dataset-JSON Using proc JSON and Extended Attribute in SAS** Yutaka Morioka and Yuki Nakagawa, EPS Corporation
11:20 – 11:50	**Data Standards Governance, Challenges and MDR** Miho Hashio, GSK
11:50 – 13:20	**Lunch Break**
13:20 – 14:35	**Session 7: TMF Topics** Chair: Dr. Toshiki Saito, NHO Headquarters & Nagoya Medical Center
13:20 – 13:45	**How We are Navigating Global TMF Regulations and Inspections: A Real Example on How a Japanese Sponsor Address Diverse Regulatory TMF Requirements and Overcome Disparities** Yuto Kanda, Chugai
13:45 – 14:10	**Unleashing your eTMF with advanced TMF metrics and KPIs Framework** Franciska Darmer, Independent
14:10 – 14:35	**People in TMF Management** Miyuki Taguchi, InSeption Group
14:35 – 15:05	**Afternoon Break**
15:05 – 16:45	**Session 8: Novelty in Clinical Trials and CDISC Standards** Chair: Hidetoshi Misawa, Pfizer
15:05 – 15:30	**Making the Electronic Protocol a Reality: The TransCelerate/CDISC Digital Data Flow Project, ICH M11 Protocol, and How They Work Together** Chris Decker, CDISC President and CEO
15:30 – 15:55	**DDF: The Art of the Possible Becomes Reality** Barrie Nelson and Frederik Malfait, Nurocor
15:55 – 16:20	**Integrating Digital Data Flow with Generative AI for Enhanced Clinical Trial Automation** Kunihito Ebi and Daisuke Seyama, Fujitsu Limited
16:20 – 16:45	**Delivering a Data-Driven Clinical Protocol - ICH M11** Dr. Ron Fitzmartin, FDA
16:45 – 17:25	**Session 9: Closing Plenary** Chair: Dr. Hideto Yokoi, Kagawa University Hospital
16:45 – 17:15	**ICH M11 Guideline: A Breakthrough for Future Clinical Trials in the Data Society** Satoru Tsuchiya, Sumitomo Pharma
17:15 – 17:25	**Closing Remarks** Akira Soma, J3C Chair

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