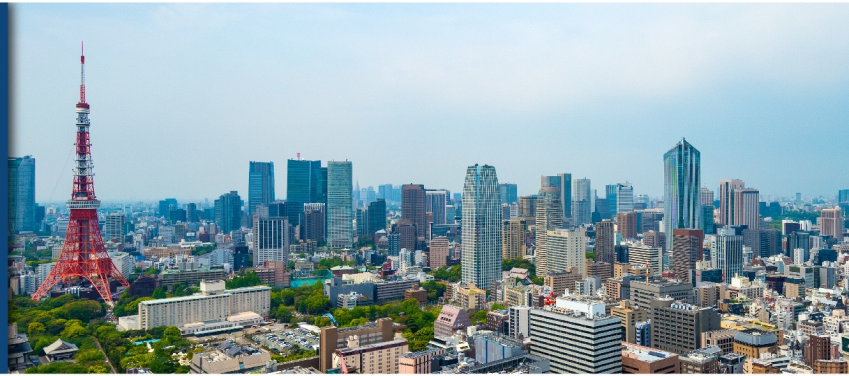
cdisc

2023 JAPAN INTERCHANGE

TOKYO | 10-11 JULY



Closing panel

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

Panelist

- Mr. Peter Van Reusel, CDISC: Chief Standards Officer
- Ms. Rhonda Facile, CDISC: Vice President, Partnerships and Development
- Dr. Sam Hume, CDISC: Vice President, Data Science
- Dr. Wenjun Bao, JMP Clinical: CDISC Board of director
- Dr. Yuki Ando, PMDA
- Mr. Akira Soma, Japan Oracle, J3C chair, (Facilitator)

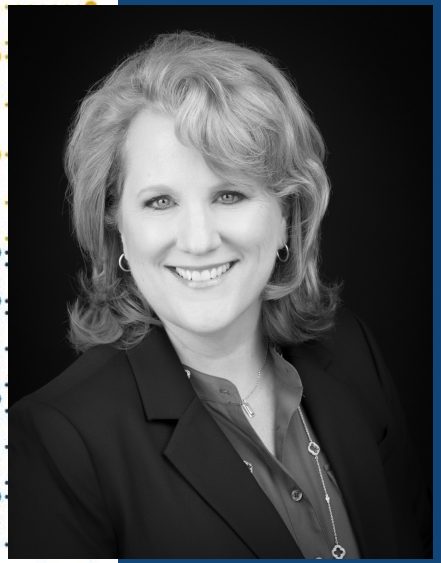
Meet the Speaker

Peter Van Reusel

Title: Chief Standards Officer
Organization: CDISC

Peter Van Reusel provides executive leadership to the development and implementation of clinical standards in line with CDISC's strategy and operational plans, working closely with the President and CEO, as well as CDISC staff and stakeholders. He has over 20 years' experience in senior roles in pharma and at CROs, providing standards expertise and carrying out other standards work in various organizational settings. A long-time, CDISC-authorized instructor, Peter has helped significantly in developing CDISC training courses.

He previously served as CDISC's European Liaison, shepherding relationships with key European regulatory, academic, and biopharma stakeholders. Peter is also an active PHUSE collaborator.



Meet the Speaker

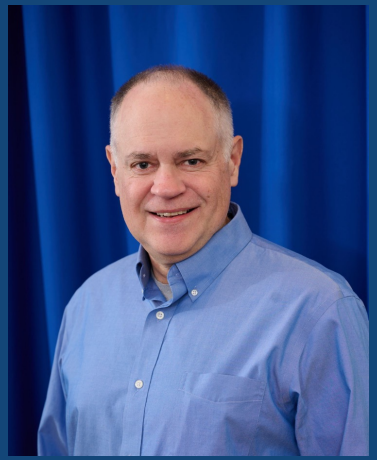
Rhonda Facile, MS

Title: VP, Partnerships and Development

Organization: CDISC

Rhonda Facile is Vice President, Partnerships and Development at CDISC where she oversees business development and new project development. She brings together, key and diverse stakeholder communities to establish effective collaboration structures to ensure project success. At CDISC Rhonda has led numerous standards development projects and initiatives including CDASH, therapeutic area guides and more recently CDISC RWD Connect. Prior to joining CDISC, Rhonda worked in clinical operations and regulatory affairs in Pharmaceutical, Biotechnology, and Contract Research Organizations in the US and Europe.

Meet the Speaker



Sam Hume

Title: VP, Data Science

Organization: CDISC

Sam Hume leads the CDISC Data Science team, which collaborates with CDISC staff and stakeholders to develop tools and standards that support clinical and translational data science. Sam directs delivery of the CDISC Library metadata repository that houses all CDISC standards, co-leads the CDISC Data Exchange Standards team, co-leads CORE, and leads the technical CDISC RWD efforts. He has 25 years' experience in clinical research informatics and has held a number of senior technology positions in the biopharmaceutical industry. He holds a doctorate in information systems.

Meet the Speaker

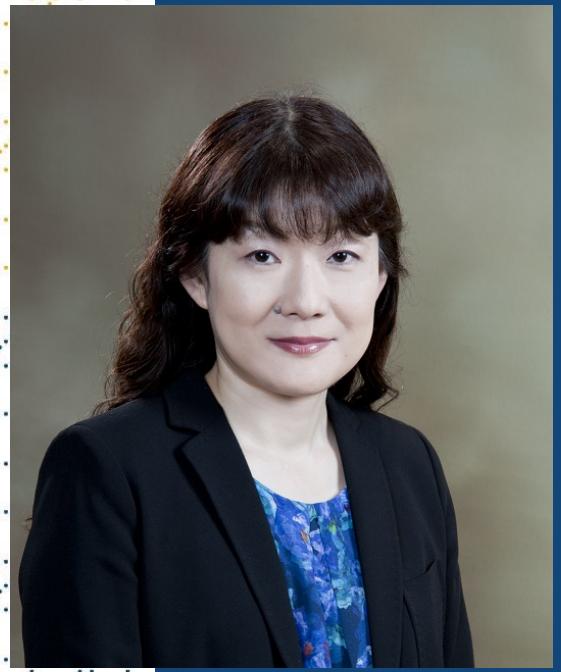
Name: Wenjun Bao

Title: Chief Scientist and Director of Advanced Analytics R&D

Organization: JMP Statistical Discovery, a subsidiary of SAS

Dr. Bao obtained her PhD from Oregon Health & Science University in Portland, OR. She was an IRTA Fellow at the National Institutes of Health (NIH), a professor at Duke University, and a scientist at the US Environmental Protection Agency before joining JMP. She has extensive experience in the clinical, bioinformatics, biochemistry, molecular biology fields. She continues to publish in the peer-reviewed journals.

Dr. Bao serves as a board of director for CDISC and an adjunct professor of Fudan University. She is also a NC Precision Health Collaborative Steering Committee member, a leadership role for the Massive Analysis and Quality Control (MAQC) Society. She has been a research grant review committee member for NIH since 2005 and research advisor for scientists at numerous universities and government agencies around the world.



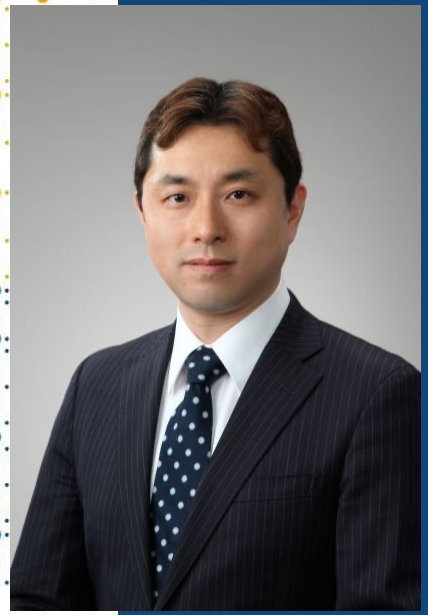
Meet the Speaker

Yuki Ando, PhD

Title: Principal Senior Scientist for Biostatistics

Organization: Pharmaceuticals and Medical Devices Agency

Dr. Yuki Ando is a Principal Senior Scientist for Biostatistics of the Pharmaceuticals and Medical Devices Agency (PMDA), Japan. She has over 20 years‘ experience as Biostatistics Reviewer, and currently she is responsible for the biostatistics review and consultation in the new drug and device review offices in the PMDA. Additionally, she works for Office of Regulatory Science Coordination (formerly Office of Advanced Evaluation with Electronic Data), the office which is responsible for accepting patient level electronic study data that are submitted with new drug applications. She is a member of Real World Data (RWD) Working Group and Global Clinical Study Working Group that are projects across multi-offices in the PMDA.



Meet the Speaker

Akira Soma

Title: Solution Director

Organization: Japan Oracle

Akira Soma is a Solution Director at Oracle Health Sciences Global Business Unit with over 8 years' experience in both clinical development and pharmacovigilance. He has over 15 years of experience working in the pharmaceutical industry both in Japan and the United States primarily focused on clinical data management and IT. He has been an authorized instructors for SDTM Theory and Application for several years and has been chair of J3C since 2021.

Topics: Standards

- What are your thoughts on the latest developments in CDISC standards?
- CDISC標準の最新の進展についてどのように思いますか？

Topics: Standards

- What are the latest trends in data standardization and how might they impact CDISC and clinical development?
- データ標準化の最新トレンドは何ですか？それらはCDISC、臨床開発にどのような影響を及ぼしますか？

Topics: Vision

- What actions are planed for eTMF?
- eTMFについてどんなactionを想定していますか？

Topics: Globalization

- Can you talk about the challenges of international adoption and dissemination of CDISC standards?
- これまでのCDISC標準の国際的な適用や普及についての挑戦や課題について話していただけますか？

Topics: Vision

- How do you think the rise of big data and AI/ML will influence the development and application of CDISC standards?
- ビッグデータやAI/MLの増加がCDISC標準の開発や適用にどのような影響を及ぼすと考えますか？

Topics: Vision

- What is your vision for the future of CDISC standards?
- CDISC標準の未来についてのビジョンを聞かせてもらえますか？

Topics: Pharma company & CROs

- CDISC has already been mandatory in Japan. What do you think what is next action item with CDISC would be for pharmaceutical companies especially Small and Mid size companies?
- CDISCは日本ではすでに義務化されました。製薬会社やCRO（特に中規模）にとってCDISCを使用した次のアクションは、どのようなものになると思いますか?

Topics: Academic research

- What are the main benefits of implementing CDISC standards especially for Academic Research Organizations (AROs)?
- AROsにとってCDISC標準を実施することで得られる主な利点は何ですか？

Topics: Academic research

- What are the main challenges and solutions when implementing CDISC standards especially for Academic Research Organizations (AROs)?
- AROsにとってCDISC標準を導入する際の主な課題とその解決策は何ですか？

Topics: Academic research

- What are your thoughts on CDISC promotion activities in Academia in Japan?
- 日本でのAcademiaにおけるCDISCの普及についてどう考えていますか？

Topics: Healthcare

- How do you view the interplay/interoperability between healthcare data and CDISC standards? How should I understand the relationship between HL7 and CDISC?
- 医療データとCDISC標準との相互作用・相互運用性についてどう思いますか？HL7とCDISCの関係についてどう捉えたらいいのでしょうか？

Thank You!