

Closing Remarks

Akira Soma J3C Chair Master Principal Solution Consultant Oracle Health Sciences Global Business Unit

CDISC Status in Japan

- Became mandatory since April 2020. > Daily life with CDISC
- With Standards Unlock the power of the data
- P21 validation error free = high quality data?
- Think Globally, Act Locally
- End-to-End Data management with CDISC
 - Clinical electronic Structured Harmonized Protocol (CeSHarP) ICH M11
 - Clinical Trial Data Sharing / Publication
 - Metadata management/MDR







Thank you

J3C team CDISC team

J3C team member 2021 ~ 2022 One for all, All for One





Thank you

Speakers

Highlights

With Standards – Unlock the power of the data

- DDF: Digital Data Flow
- DRAGON project (Al)
- No Standard No automation
- TMF Reference Model
- FHIR (transfer) to CDISC (repository)
- CORE & COSA
- RWE/RWD
- Individual patient data sharing & the Privacy
 - No absolute date for Data sharing

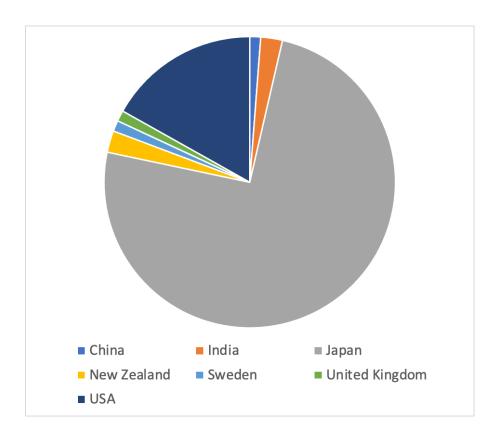




Thank you

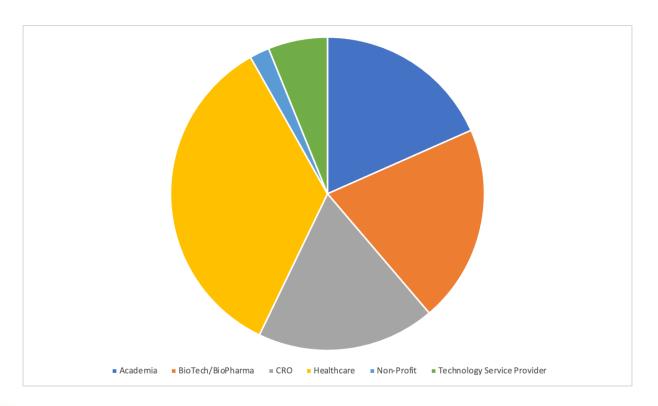
Attendees

Attendance by Industry

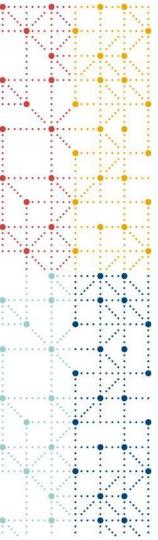




Attendance by Industry







Contents Access

Contents Access

- Europe Interchange recordings will be shared with Japan Interchange attendees after you complete the feedback survey.
- Japan Interchange recording will be post to the platform within a few hours
 of the end of each session, after a short processing period. Those will be
 available in the platform for at least 6 months. Those will be posted onto the
 CDISC website where anyone who is logged in as a CDISC members
 should be able to view them.





2023 Japan Interchange Tentative Venue: Tokyo Tentative Date: <u>July</u> 10th – 11th 2023



STAY TUNED FOR MORE UPDATES!

Thank You!

