

## J3C: PLEASE FIND SESSION SCRIPT HERE.

### 10 - 11 June Japan Interchange

Day	Session	Presentation Time	**TIMING CHECKPOINTS**	Presentation Title	Presenter Name	Reg. Type	Presentation in Sharepoint	Presenter Email	Presenter Mobile #	Presenter Organization
10 June	1 9:00 - 10:40  <b>Session Chair:</b> Akira Soma <a href="mailto:akira.soma@oracle.com">akira.soma@oracle.com</a>  +81 8081955162	Pre-Conference	8:00 Begin Webinar in Practice Mode (Bernard)  8:59 Countdown to pushing Broadcast button - Show Session 1 slide (Bernard)	During Practice Mode:  1. Double check interpretation 2. sure "Allow Panelist Start Video" is checked 3. From the "Chat" window, make sure "Allow attendees to chat with: NO ONE" is checked 4. Remind about staying muted unless speaking 5. Remind about not using chat 6. Double check all speakers' microphones and screen share						
		9:00 - 9:20	9:00 Message Akira Soma to START (Andrea)  9:18 2-minute end warning (Andrea)	Welcome Address & State of the CDISC Union	Dave Evans	CDISC Staff	Yes	<a href="mailto:devans@cdisc.org">devans@cdisc.org</a>	+1-484-881-2411	CDISC
		9:20 - 10:00	9:15 5-min start warning (Andrea)  9:55 5-min end warning (Andrea)	Keynote Presentation	Dr. Norio Ohmagari	Speaker Invited	Yes	<a href="mailto:nomagari@hosp.ncgm.go.jp">nomagari@hosp.ncgm.go.jp</a>	+81-80-5113-9407	Lead, COVID-19 registration program, National Center for Global Health and Medicine
		10:00 - 10:40	9:55 5-min start warning (Andrea)  10:35 5-min end warning (Andrea)  10:40 Play rolling slides (Bernard)  ~10:50 Show Session 2 slide (Bernard)	State of CDISC Standards	Bess LeRoy	CDISC Staff	Yes	<a href="mailto:bleroy@cdisc.org">bleroy@cdisc.org</a>	+1-520-237-8689	CDISC
2	11:10 - 12:40  <b>Session Chair:</b> Dr. Takuhiro Yamaguchi <a href="mailto:yamaguchi@med.tohoku.ac.jp">yamaguchi@med.tohoku.ac.jp</a>  +81 (0)90 8941 6354	11:10 - 11:40	<b>PRE-RECORDED PRESENTATION</b>  11:05 5-min start warning to Dr. Yamaguchi (Andrea)  11:35 5-min end warning to Dr. Yamaguchi (Andrea)	CDISC 360 Update (Pre-Recorded)	Peter Van Reusel	CDISC Staff	No	<a href="mailto:pvanreusel@cdisc.org">pvanreusel@cdisc.org</a>	+32 476 545 917	CDISC
		11:40 - 12:10	11:35 5-min start warning (Andrea)  12:05 5-min end warning (Andrea)	CDISC Library Update	Anthony Chow	CDISC Staff	Yes	<a href="mailto:achow@cdisc.org">achow@cdisc.org</a>	+1-267-978-7709	CDISC
		12:10 - 12:40	12:05 5-min start warning (Andrea)  12:35 5-min end warning (Andrea)  12:40 Play rolling slides (Bernard)	CRF Library	Alana St. Clair	CDISC Staff	Yes	<a href="mailto:astclair@cdisc.org">astclair@cdisc.org</a>	+1 512 773 5907	CDISC
3	13:40 - 15:50  <b>Session Chair:</b> Dr. Hideto Yokoi <a href="mailto:yokoi@med.kagawa-u.ac.jp">yokoi@med.kagawa-u.ac.jp</a>	13:40 - 14:20	13:35 5-min start warning (Andrea)  14:15 5-min end warning (Andrea)	PMDA Update	Dr. Yuki Ando Dr. Daisuke Iwata	Speaker Invited Speaker Invited	Yes	<a href="mailto:ando-yuki@pmda.go.jp">ando-yuki@pmda.go.jp</a>  <a href="mailto:iwata-daisuke@pmda.go.jp">iwata-daisuke@pmda.go.jp</a>	Yuki: +81-90-8104-7303	PMDA
		14:20 - 14:50	14:15 5-min start warning (Andrea)  14:45 5-min end warning (Andrea)	Enhancement of the Role of Clinical Programming in the age of CDISC	Yasutaka Moriguchi and Natsumi Kawase	Platinum Member Speaker	Yes	<a href="mailto:yasutaka.2.moriguchi@gsk.com">yasutaka.2.moriguchi@gsk.com</a>  <a href="mailto:natsumi.2.kawase@gsk.com">natsumi.2.kawase@gsk.com</a>	Yasutaka: +81-80-5447-1749 Natsumi: +81 90-9549-9605	GlaxoSmithKline K.K.
		14:50 - 15:20	14:45 5-min start warning (Andrea)  15:15 5-min end warning (Andrea)	Simplifying the Integration Riddle	Arvind Sri Krishna Mani	Speaker	Yes	<a href="mailto:arvind.m@ziford.com">arvind.m@ziford.com</a>	+91 98945 46153 (India - Mobile)	Zifo RnD Solutions
		15:20 - 15:50	15:15 5-min start warning (Andrea)  15:45 5-min end warning (Andrea)  15:50 Play rolling slides (Bernard)	Submitting Data with Japanese Characters to PMDA: The UTF-8 and Other Encodings Discussion	Dr. Jozef Aerts	Speaker	Yes	<a href="mailto:Jozef.Aerts@XML4Pharma.com">Jozef.Aerts@XML4Pharma.com</a>	+43-6818-1512436	XML4Pharma
4	16:20 - 17:30  <b>Session Chair:</b> Dr. Yuki Ando <a href="mailto:ando-yuki@pmda.go.jp">ando-yuki@pmda.go.jp</a>	16:20 - 16:50	16:15 5-min start warning (Andrea)  16:45 5-min end warning (Andrea)	The Age Old Problem: A Discussion of Age Derivation and Imputation Techniques	Will Greenway and Joel Clarke	Speaker Gold Member	Yes	<a href="mailto:will.greenway@quanticate.com">will.greenway@quanticate.com</a>  <a href="mailto:joel.clarke@quanticate.com">joel.clarke@quanticate.com</a>	Will: <b>+447578143263</b> Joel: <b>+447536115511</b>	Quanticate International, LTD
		16:50 - 17:30	16:45 5-min start warning (Andrea)  17:25 5-min end warning (Andrea)	EMA Presentation	Frank Pétavy	Speaker Invited	Yes	<a href="mailto:Frank.Petavy@ema.europa.eu">Frank.Petavy@ema.europa.eu</a>	+31628561224	

		17:30	17:30 End of Day 1 Wrap-Up Play rolling slides (Bernard)	End of Day 1 Wrap-Up	Akira Soma						
<b>11 June</b>	5 9:00 - 10:30  <b>Session Chair:</b> Dr. Toshiki Saito toshiki.saito@nnh.go.jp  +81-90-3045-7898	Pre-Conference	8:00 Begin Webinar in Practice Mode (Bernard)  8:59 Countdown to pushing Broadcast button + show Session 5 Slide (Bernard)	During Practice Mode:  1. Double check interpretation 2. sure "Allow Panelist Start Video" is checked 3. From the "Chat" window, make sure "Allow attendees to chat with: NO ONE" is checked 4. Remind about staying muted unless speaking 5. Remind about not using chat 6. Double check all speakers' microphones and screen share							
		9:00 - 9:30	9:00 Message Saito-sensei to START (Andrea)  Saito-sensei welcomes back everyone to Day 2 of the conference. Introduces Helena.  9:25 5-minute end warning (Andrea)	Policy Frameworks for Submitting Study Data to FDA	Helena Sviglin	Speaker I invited	No	<a href="mailto:Helena.Sviglin@fda.hhs.gov">Helena.Sviglin@fda.hhs.gov</a>	+1-205-910-4522	FDA-CDER	
		9:30 - 10:00	9:25 5-min start warning (Andrea)  9:55 5-min end warning (Andrea)	CDER's experience with ADaM traceability assessment and common data quality issues	Jesse Anderson	Speaker I invited	Yes	<a href="mailto:Jesse.Anderson@fda.hhs.gov">Jesse.Anderson@fda.hhs.gov</a>	+1-202-365-9157	FDA-CDER	
		10:00 - 10:30	9:55 5-min start warning to Saito-sensei (Andrea)  10:25 5-min end warning to Saito-sensei (Andrea)  10:30 Play rolling slides (Bernard)	Q&A Session			N/A				
6 11:00 - 12:30  <b>Session Chair:</b> Dr. Hideto Yokoi yokoi@med.kagawa-u.ac.jp	11:00 - 11:30	10:55 5-min start warning (Andrea)  11:25 5-min end warning (Andrea)	Utilizing CDISC SEND Data to Generate Historical Control Incidence from a Large Database of Toxicology Studies	William Houser	Speaker	Yes	<a href="mailto:william.houser@bms.com">william.houser@bms.com</a>	+1 812 550-2162	Bristol Myers Squibb /BioCelerate		
	11:30 - 12:00	11:25 5-min start warning (Andrea)  11:55 5-min end warning (Andrea)	Create the Define.XML v2.1 with Python	Hengwei Liu	Speaker	Yes	<a href="mailto:hengwei_liu@yahoo.com">hengwei_liu@yahoo.com</a>	1-732-668-4584	Daiichi Sankyo, Inc.		
	12:00 - 12:30	11:55 5-min start warning (Andrea)  12:25 5-min end warning (Andrea)  12:30 Play rolling slides (Bernard)	NMPA Submissions	Yiyuan Ma	Speaker	Yes	<a href="mailto:Yiyuan.Ma@sanofi.com">Yiyuan.Ma@sanofi.com</a>	wechat number is mayiyuan5007x	Sanofi		
7 13:30 - 15:00  <b>Session Chair:</b> Hideaki Kosaka hideaki.kosaka.z9@croit.com	13:30 - 14:00	12:25 5-min start warning (Andrea)  13:55 5-min end warning (Andrea)	Use Cases Report on Integrated Analysis and Legacy Data Conversion	Miu Susuki	Speaker	Yes	<a href="mailto:miu.susuki@ppd.com">miu.susuki@ppd.com</a>	+8190-1599-1994	JCROA		
	14:00 - 14:30	13:55 5-min start warning (Andrea)  14:25 5-min end warning (Andrea)	Global Reg Submission Challenges in submitting CDISC datasets to multiple regulatory agencies – toward a new stage of standards –	Hiroshi Haneji	Speaker	Yes	<a href="mailto:Hiroshi.Haneji@sanofi.com">Hiroshi.Haneji@sanofi.com</a>	+81-80-9549-4572	JPMA CDISC Taskforce Representative		
	14:30 - 15:00	14:25 5-min start warning (Andrea)  14:55 5-min end warning (Andrea)  15:00 Play rolling slides (Bernard)	Gap Analysis of CDISC Standards Implementation in Academia and CDISC-Annotated CRF Repository in Japan (AMED project)	Dr. Toshiki I. Saito	J3C	Yes	<a href="mailto:toshiki.saito@nnh.go.jp">toshiki.saito@nnh.go.jp</a>	+81-90-3045-7898	NHO Nagoya Medical Center		
8 15:30 - 17:00  <b>Session Chair:</b> Hidemi Hasegawa hide.mi.hasegawa@bcehringer-ingelheim.com	15:30 - 16:00	15:25 5-min start warning (Andrea)  15:55 5-min end warning (Andrea)	CDISC Presentation	John Owen	CDISC Staff	Yes	<a href="mailto:jowen@cdisc.org">jowen@cdisc.org</a>	+44 7956 929 228	CDISC		
	16:00 - 16:45	15:55 5-min start warning to Peter (Andrea)  16:40 5-min end warning to Peter and John O. (Andrea)	CDISC Q&A	Peter Van Reusel	CDISC Staff	No - Andrea to create	<a href="mailto:pvanreusel@cdisc.org">pvanreusel@cdisc.org</a>	+32 476 545 917	CDISC		
	16:45 - 16:50	16:40 5-min start warning (Andrea)	Final Remarks from the CDISC Board	Dr. Hiroshi Masumoto	CDISC Board		<a href="mailto:masumoto.hiroshi.e7@daiichisanryo.co.jp">masumoto.hiroshi.e7@daiichisanryo.co.jp</a>	+81 80490018 45	Daiichi Sankyo, CDISC Board Member		
	16:50 - 17:00	16:45 5-min start warning (Andrea)	Closing Remarks	Akira Soma	J3C	No	<a href="mailto:akira.soma@oracle.com">akira.soma@oracle.com</a>	+81 8081955162	Oracle, J3C Chair		