Session	Questions
Session 1	
Welcome Address & State of the CDISC Union Dave Evans, CDISC President and CEO	N/A
COVID-19 Registry JapanCOVIREGI-JP Dr. Norio Ohmagari, Director, Disease Control and Prevention Center, National Center for Global Health and Medicine, Japan	1. What was the biggest obstacle in building the registry? 2. How do you think the registry should be used in the future? 3. What do you think should be the future use of registries, and if you were to create one, what would you keep in mind?
State of CDISC Standards Bess LeRoy, CDISC Head of Standards Development	1. Is there a mechanism to request new topics for the Knowledge Base, or to pitch an article etc? 2. 3.
Session 2	
CDISC 360 Update Peter Van Reusel, CDISC Chief Standards Officer	1. 2. 3.
CDISC Library Update Anthony Chow, CDISC Director of Data Science	1.You mentioned executable conformance rules as a part of the CORE initiative. What do you mean by that? 2. Can you describe the general process for signing up a CDISC Library account? 3. How many more releases do you plan to do this year?
The CDASH eCRF Portal Alana St. Clair, CDISC Project Manager	1. What is the difference between the eCRF Portal and the Examples Collection? 2. Can I provide feedback on the case report forms? 3. Can I request a particular CRF be added?
Session 3	
PMDA Update Dr. Yuki Ando and Daisuke Iwata, PMDA	1. Will PMDA request correction when terminology is consistent within a study but different across multiple studies within a single submission? 2. Is there a timeline for when the PMDA will accept submissions according to SDTM IG 3.3? 3. As of 01-Apr-2020 submissions to the PDMA require submissions in the CDISC Standards. What did PDMA experience after one year of submissions in the CDISC Standards, like efficiency gains etc. What can PMDA recommend to other authorities? 4. Does PMDA still require standard units in SI units (and only SI units)? 5. How does currently authorities/regulators work on cross collaborations/discussions among themselves? Do we see in future such forum where data standards differences will be discussed and resolved to make such vision/dream reality? 6. From when (approx time) ADaM v1.1 data package is recommended to get submitted?
Enhancement of the Role of Clinical Programming in the Age of CDISC Yasutaka Moriguchi and Natsumi Kawase, GlaxoSmithKline K.K.	1. Does presenter have any ideas what type of ability, actions and/or opportunities are needed to work as a professional of clinical programming? 2. Presenters explained 7 discussion points in the presentation. Which one does presenter find particularly difficult? 3. In Page 18, presenter explained 6 examples of CDISC data flows. Does presenter still have an experience of such a variety of data flows?
Simplifying the Integration Riddle Arvind Sri Krishna Mani, Zifo RnD Solutions	1. These are legacy studies and quite old. Do you still see the same or similar issues with recent studies as well? 2. Why not just create the analysis datasets directly from source data? Why update the SDTM and then the ADaM? 3. What can be done to avoid these problems you describe in the presentation?

Submitting Data with Japanese Characters to PMDA: The UTF-8 and Other Encodings Discussion Dr. Jozef Aerts, XML4Pharma	1. Wouldn't it be a good idea to use SHIFT-JIS encoding instead of UTF-8? 2. You mentioned APIs and RESTful web services. How would these be useful to regulatory authorities such as PMDA? 3. Could we also use simple UTF-8 encoded CVS instead of SAS Transport?
Session 4	
The Age Old Problem: A Discussion of Age Derivation and Imputation Techniques Will Greenway and Joel Clarke, Quanticate International Ltd.	1. Age is often used for more than one purpose, for example initially for enrolment criteria, and then later on for summarising by age groups. How do you normally see this handled? 2. On the month and day imputation, you showed data for 3 countries: USA, UK and Japan, did you analyse other countries and did you spot any differences? 3. Would your recommendation of SAS function change for paediatric studies?
EMA Presentation Dr. Frank Pétavy, Head of Methodology, European Medicines Agency	1. How does currently authorities/regulators work on cross collaborations/discussions among themselves? Do we see in future such forum where data standards differences will be discussed and resolved to make such vision /dream reality? 2. How can people participate in the Data Strategy Workshop? 3. Recently, we heard the announcement that EMA's new Clinical Trials Information System passed the audit and will be launched in January next year. Will some of the Data Standards you were mentioning earlier, be already implemented to the CTIS at the moment of launch? 4. If data standards are to be implemented to EMA's CTIS, will there be a transition period for this implementation? In what degree the changes might affect the submissions as they are done today?
Session 5	
Study Data Standards and COVID-19 Helena Sviglin, FDA CDER	1. What is the difference between a FDA developed Technical Specification and a CDISC developed TAUG? 2. The recent proposed changes to SV in response to FDA's business needs around regulatory review are probably changes that should have taken place much sooner, how can we facilitate more dialogue like that? 3. How does standards development balance the needs of regulatory review against the costs of change? 4. When the Technical Conformance Guide makes a recommendation/request that is inconsistent with the current standards (e.g. the requested changes to SV), can we assume that the agency preference is for submission packages to follow the TCG and that related validation issues will not be a problem?
CDER's Experience with ADaM Traceability Assessment and Common Data Quality Issues Jesse Anderson, FDA CDER	1. So far in your experience with data packages that CDER has received, how often do basic things like keeping the sequence variable for SDTM and ADaM, is this done regularly? 2. Are full details of the comparison rules you have described available publicly? 3. Does the CDER use any open-source software to do these reconciliations?
Q&A Session	N/A
Session 6	
Utilizing CDISC SEND Data to Generate Historical Control Incidence from a Large Database of Toxicology Studies William Houser, Bristol Myers Squibb / BioCelerate	1. Is sendigR only useful for historical control analysis or is it useful for other cross study analyses? 2. Can the R Shiny application be used to view proprietary datasets or connect to a proprietary database within my organization? 3. Where can I get more information about the Common Protocol Template and the Common Report Template?
Create the Define.XML v2.1 with Python Hengwei Liu, Daiichi Sankyo, Inc.	1.Compared with other programming language, what advantage does Python have in creating the define.xml? 2. This presentation discussed the creation of define.xml for ADaM. Can the same approach be used to create the define.xml for SDTM? 3. If a programming team wants to use the approach in this presentation to create the define.xml, how to design the data specifications for the ADaM datasets?
NMPA Submissions Yiyuan Ma, Sanofi	1. Will CDISC standards be mandatory in future NMPA submission? 2. Do we have electronic submission in China? 3. Do we have to follow the same folders structure when we are putting all the submission materials together?
Session 7	

Use Cases Report on Integrated Analysis and Legacy Data Conversion Miu Susuki, JCROA	1.For which group and when were these cases collected? 2. Are there any other cases of clinical pharmacology? 3. Were there any cases related to the version upgrade of Pinnacle21 Community?
Challenges in Submitting CDISC Datasets to Multiple Regulatory Agencies: Toward a New Stage of Standards Hiroshi Haneji, Sanofi, JPMA	1. Which language is generally entered in the CRF in Japan? 2. Do you know a database that supports multiple languages? 3. What are your future challenges regarding the translation process?
Gap Analysis of CDISC Standards Implementation in Academia and CDISC-Annotated CRF Repository in Japan (AMED project) Dr. Toshiki I. Saito, NHO Nagoya Medical Center	1. -What will be the key to help academia in Japan to actually use CDISC standards by themselves? / CDISC 2. Is academia only user for the aCRF.jp 3. Can pharmaceutical company or CRO can ask to upload their annotated CRF?
Session 8	
CDISC Presentation John Owen	1. Have any of the academic TAUG team members tried to implement the CDISC standards? 2. How would you suggest that someone unfamiliar with CDISC standards start to learn about CDISC standards? 3. Was there a big difference in the way that industry TAUG team members and Academic TAUG team members collected data?
CDISC Q&A Peter Van Reusal	Questions in PowerPoint