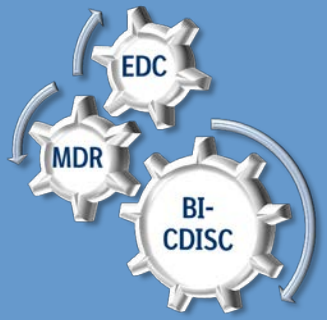
CDISC GS User Group Meeting
05 September 2017

# PMDA Update

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# Update on Guidance Documents

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- Data Standards Catalog (2017-03-03)
- Study Data Validation Rules (2015-11-18)
- FAQs on Electronic Study Data Submission (Excerpt)

FAQs last updated Feb 2017

**PMDA Data Standards Catalog (2017-03-03) - Terminology Standards**

| Terminology Standard | Version(s) | Date Support Begins (YYYY-MM-DD) | Date Support Ends (YYYY-MM-DD) | Notes |
|---|---|---|---|---|
| CDISC Controlled Terminology | Between 2009-02-17 (inclusive) and 2011-06-10 (exclusive) | 2016-10-01 | 2017-06-30 | When using the version indicated in "Version(s)" column, consult PMDA at the consultation on data format of the submission of electronic study data. |

# 2017 Japan Interchange
# PMDA Update and Best Practice in Regulatory Submission

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- Refer also to **2017 Japan Interchange** presentations at CDISC



## Session 3: PMDA Update

Current Status of Electronic Data Submission in PMDA
Dr. Yuki Ando, PMDA

Experiences Receiving and Using Electronic Data in PMDA
Chikako Ishige, PMDA

Implementation of Therapeutic Area Standards in Japan
Hiroshi Sakaguchi, PMDA

## Session 6: Best Practice in Regulatory Submissions

Experiences in Electronic Study Data Submission
Takuma Oda, Janssen Pharmaceuticals

Experience and Challenges in Simultaneous Electronic Data Submission to PMDA and FDA
Mayumi Kominami, Novartis

Lessons Learned from e-Data Submission
Hiroshi Haneji, Sanofi

# Some Findings and Recommendations

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- Applicants are strongly recommended to request the consultation for e-data submission, and we would like to have fruitful discussion in the meetings.

- Frequently raised issues: explanation of sponsors‘ validation results and reasons of “Error”

- Other issues:
  - Product dependent issues such as use of SUPPQUAL, custom domains, and traceability
  - Information to be included in the Trial Design Model
  - Issues related to WHO DDs coding
  - SI units
  - How to submit study data for multiple time points
  - Use of particular variables such as USUBJID, RACE
  - Submission format for clinical pharmacology data

# Recent Experience on a Data Submission to PMDA

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- Submission preparation required multiple eCTD Consultation Meetings
- Validator findings requested for review prior to data submission
- Reviewed by PMDA upfront for feasibility
- Feedback and resolution loop on remaining issues