**Background**

Pharmaceuticals and Medical Devices Agency (PMDA) started receiving CDISC electronic clinical study data (e-data) through PMDA’s gateway system for NDA in Japan since Oct 2016. Since Feb 2016, PMDA has been receiving CDISC electronic clinical study data (e-data) through PMDA’s gateway system for NDA in Japan since Oct 2016.

- Standardized electronic submission is voluntary until March 2020, it will be mandatory from April 2020.
- PMDA published notifications, technical conformance guide, validation rules, and data standard catalog.
- PMDA provides consultation services for applicants regarding e-data preparation.

**Summary**

- PMDA pilot project
  - Data Store and Management & Feasibility of Analyses incl. PPK/PD
  - Characteristics of PMDA’s requirements & recommendations
  - CDISC Standards, Validation Rules, ARM, and Programs
  - Difference between FDA and PMDA
  - SEND requirement, Regulatory clock (Deadlines), and SI unit

Efficient utilization of e-data will benefit the public through the enhancement of drug development and predictability of safety and efficacy of the drug.

**Accumulation and Utilization of Data**

- **Integration of Accumulated Data**
  - Use of electronic data
  - Accessible, visualized electronic data for each reviewer
  - Easy to identify individual clinical case data, drilling down of data
  - Operation of various analyses - simple, subgroup analysis for the present
  - Use of electronic data in the dedicated server and registration in the database

**Timeline for Implementation of e-data Submission**

- **PMDA Pilot Project (2013-2015)**
  - Submitted data store and management with in-house system
  - Analysis of the stored data by reviewer with introduced software
  - Skilled reviewers were able to conduct

- **Analysis to obtain the necessary for the review using submitted data**
  - Utilization of submitted data for PPK/PD analyses
  - Skilled reviewers were able to conduct

**PMDA’s Characteristics & Difference between FDA and PMDA**

**General**

- CDISC Standards
- Data Standards Catalog
- New Drugs (Incl. Biologics)

**Validation Rules**

- CDISC validation of e-data for acceptance
- PMDA will perform validation using Pinnacle 21 Enterprise

**ARM**

- Define.xml for ADaM datasets preferably includes: Analysis results metadata (ARM)

**Programs**

- Programs used to create the ADaM datasets and analysis programs (if difficult, specifications showing the analysis algorithm) must be submitted

**Comparison on some differences between U.S.FDA and PMDA**

<table>
<thead>
<tr>
<th>Item</th>
<th>U.S.FDA</th>
<th>PMDA</th>
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</thead>
<tbody>
<tr>
<td>Electronic data to be submitted</td>
<td>Electronic data standards are listed in the Data Standards Catalog (SEND, SDTM, ADaM, etc.)</td>
<td>All phases of clinical studies</td>
</tr>
<tr>
<td>Regulatory clock for standardized submission</td>
<td>Required for studies start after Dec. 17, 2016 in NDAs, BLAs, ANDAs</td>
<td>For Com. IND, the requirement starts after Dec. 17, 2017</td>
</tr>
<tr>
<td>Sl unit</td>
<td>The use of SI unit is recommended</td>
<td>Store both the original data and the converted data in SI units</td>
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**Disclaimer**

The contents of this poster represent the view of the presenters only, and do not represent the views and/or policies of PMDA and FDA.

**Acknowledgement**

We thank Mina Mohlen and Stephen Wilson for their support and encouragement in organizing this poster. We also thank all of the members of Advanced Review with Electronic Data Promotion Group, PMDA.