Perspectives on electronic non-clinical data Submission in Japan

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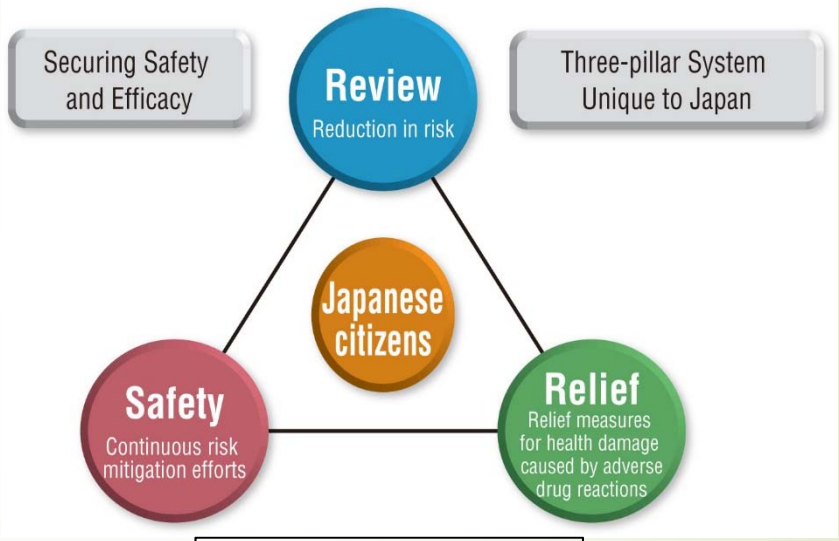
Disclaimer

The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the PMDA.

About PMDA

PMDA (Pharmaceuticals and Medical Devices Agency) is Japanese regulatory agency, working together with Ministry of Health, Labour and Welfare.



Safety Triangle

<Established>
April 1, 2004

<Legal classification>
Incorporated administrative agency with non-civil service status

Health and Medical Care Strategy

(Agreement of Chief Cabinet Secretary, Minister of Health, Labour and Welfare and other concerned Ministers; June 14, 2013)

Three Basic Principles

- Achievement of a healthy, long-lived society
- Contribution to economic growth
- Global contribution

Specific strategy

Enhancing the PMDA

- Enhancement of the Pharmaceutical Affairs Consultation on R&D Strategy
- Organizing and enhancing the consultation service in close coordination with the Drug Discovery Support Network
- **PMDA-initiated promotion of research and analysis based on clinical study data**
- Increase of the quantity and quality of the large-scale medical information database for early achievement of the 10-million data set
- Identification of an appropriate financial base for the PMDA's tasks and necessary measures
  * Including more proactive proposals than those made for the Japan Reconstruction Strategy and matters not discussed therein.

Back Ground

-Implementation of Electronic Data Submission in Japan-

2013.Jun

- Healthcare and Medical Care Strategy (Agreement of Chief Cabinet Secretary, Minister of Health, Labour and Welfare and other concerned Ministers)

2013.Sept

- Establishment of “Task Force for advanced Review and consultation with electronic data”
- 1st Pilot Project for advanced review

2014.Apr

- The Task Force was reorganized as “Advanced Review with Electronic Data Promotion Group”

2014.Jun

- Issuance of “Basic Principles on Electronic Submission of Study Data for New Drug Applications”

2015.Apr-May

- Issuance of “Notification on Practical Operations of Electronic Study Data Submission” , “Technical Conformance Guide” and “Notification on the consultation for the clinical e-data submission”

Advanced workflow of Review/consultation

Analysis by PMDA

Giving additional scientific value to submitted data

Cooperation with Academia

Regulatory Science

Practical use of Innovative Medical Products

More rational & effective evaluation process for regulatory decision

NDA etc.

e-Submission of study data

Data Accumulation

Database

Sophisticated review

- Each reviewer utilizes innovative assessment techniques

Cross-Products Analysis

- Advanced evaluation methods
- Active utilization of Modeling & Simulation
  - Disease model
  - Objective B/R assessment
  - Identifying AE-related factors etc.

Sophisticated Consultation

- More evidence-based consultation

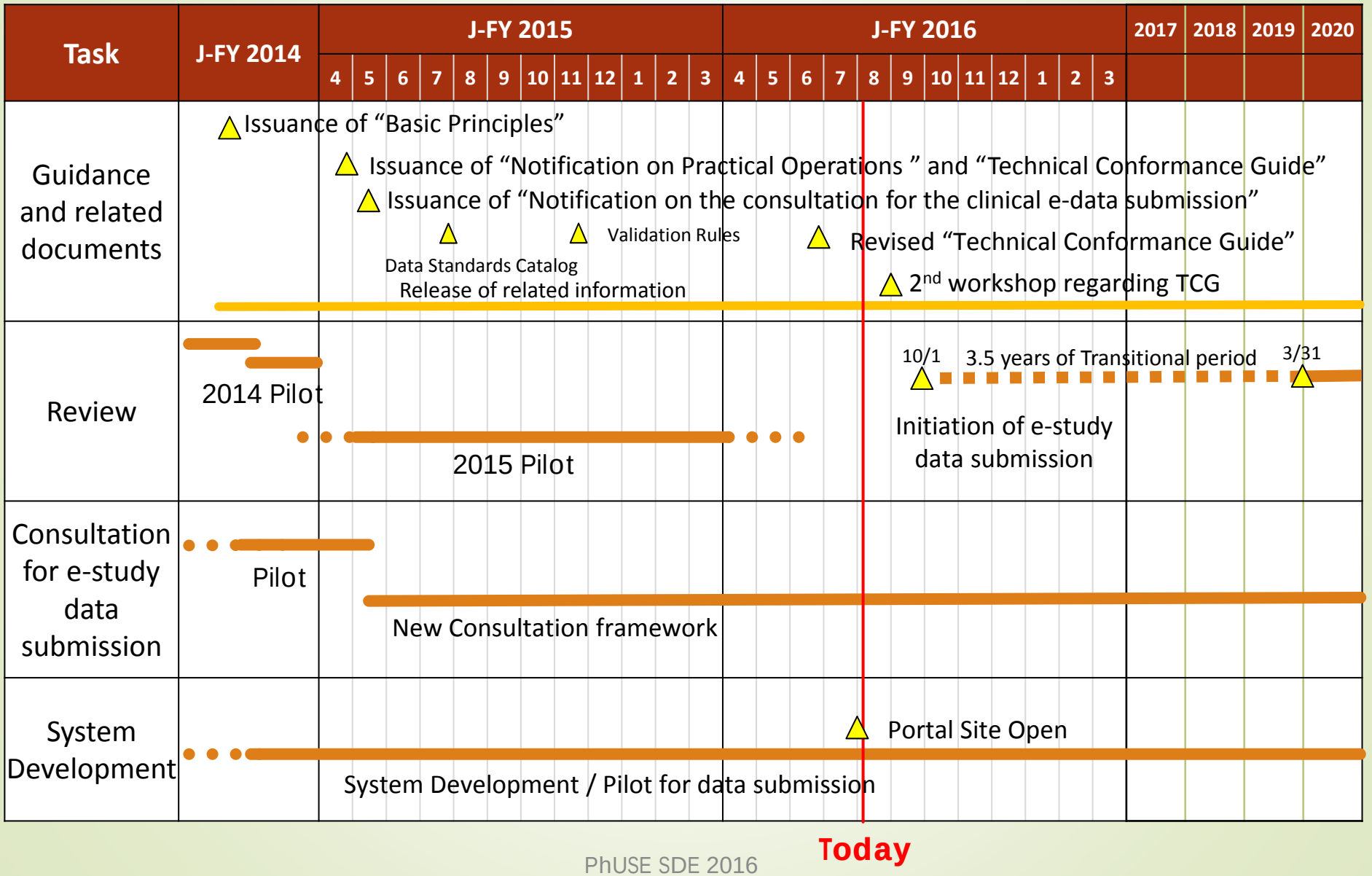
More effective and high quality Review

- More predictable efficacy/safety after approval
- Reduction of applicant's work load
- More scientific regulatory decision

More efficient and Successful Development

- Epoch-making proposal leading the world
- Proactive publication of guideline

Timeline for implementation of electronic data submission



Medium- and long-term Prospect

Tentative assumption and expectation

Start e-study data submission for NDA* from Oct 1st, 2016

*NDA=New Drug Application

- e-study data can be received and managed appropriately
- e-study data can be utilized in the review
- Industries' workload is reduced gradually while keeping the same review period

Present

J-FY2016

Setup e-data management and utilization

- More predictable efficacy/safety
- Consideration of expanding the scope of e-data utilization to toxicological study and post-approval clinical study

J-FY2018

Ordinary utilization of e-data in the product review

Promotion of paperless operation

Transitional period are taken until March 31st, 2020

- Preparations of guidelines and related documents
- Earnest on cross-product analysis and development of disease models

J-FY2019 - 2021

Starting earnest cross-product analysis

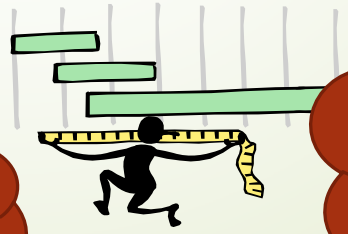
- Establishment of disease models
- Publication of disease-specific guidelines

J-FY2022 -

Publication of guidelines to contribute to drug development

First-class review authority

e.g. guidelines and disease models based on data on Asian population



Status of standardized e-data submission in each Regulatory Authority

RA	Clinical data	Nonclinical data
PMDA	Going to be required on data of NDAs from 1st of Oct 2016 with 3.5 years of transitional period.	Under consideration
FDA	Going to be required on study data started after Dec 17th 2016. ※Required for INDs,NDAs and all	Going to be required on study data started after Dec 17th 2016. ※Required for INDs,NDAs and all
EMA	Not required	Not required

SEND in the “Basic Principles”

- 2. 2)
  - … Please note that utilization of electronic data for studies other than clinical studies (e.g. nonclinical studies) and for clinical studies conducted after approval are also concurrently being discussed, and that study types subject for submission of electronic data may possibly be modified in the future.
- Q&A No.4 “…What specifically may be the expected modifications?”
  - Regarding data of those other than clinical studies, nonclinical study data of toxicity studies based on SEND (The Standard for Exchange of Nonclinical Data), which is one of the CDISC standards, are currently being considered for a future requirement of electronic submission.

“Implementation of SEND in Japan is necessary”
Is it true?

Basic Benefits of Utilization of Standardized Electronic Data

- More efficient and simple data-sharing
- Promoting standardization and unification of terminology
- Visualization and analysis of data by browsing software
- Possibility of data-mining

Expected Benefits by Submitted Electronic Clinical Data

Points of Consideration for better utilization of SEND data-sets

- Timing of SEND data-sets submission
- Scope of the SEND data-sets required
- Actual plan for utilizing accumulated SEND data-sets

Points of Consideration for better utilization of SEND data-sets

➢ Timing of SEND data-sets submission

＜Preferable Status＞

- Accumulation of nonclinical data in developing phase is preferable for more effective safety prediction.

By using consultation framework , it’s might be possible to accumulate nonclinical data in developing phase.

Points of Consideration for better utilization of SEND data-set

- Scope of the SEND data-sets required
- Actual plan of utilizing accumulated SEND data-sets

We need more discussion to clarify actual purpose or plan of utilizing SEND data-sets.
PhUSE is expected to be good platform for discussion about policy of utilizing SEND data-sets.

References

- Basic Principles on Electronic Submission of Study Data for New Drug Applications
  - Japanese: http://www.pmda.go.jp/files/000159962.pdf
  - English: http://www.pmda.go.jp/files/000160019.pdf
- Notification on Practical Operations of Electronic Study Data Submissions
  - Japanese: http://www.pmda.go.jp/files/000204726.pdf
  - English: https://www.pmda.go.jp/files/000206451.pdf