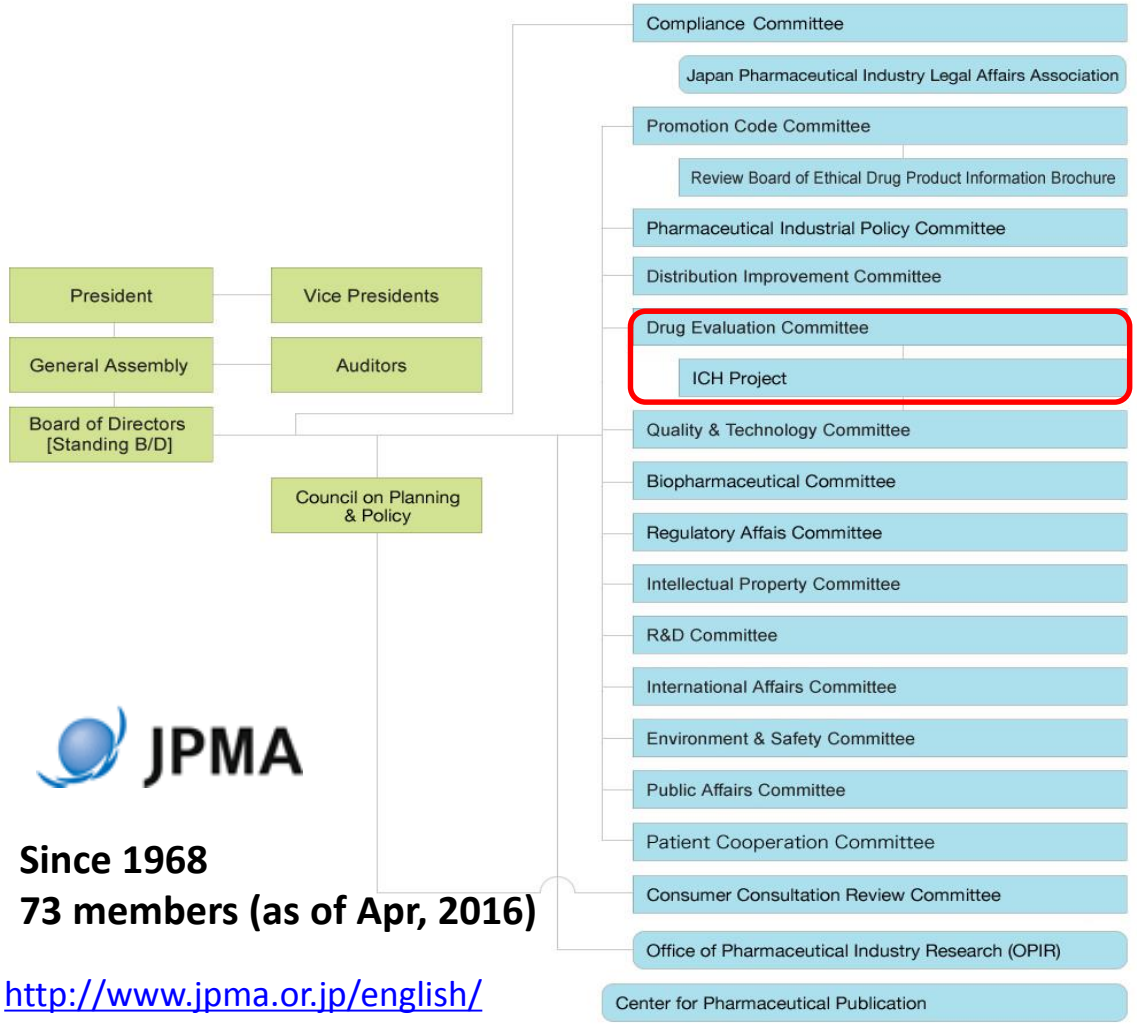
SEND Implementation in Japanese Pharmaceutical Companies and the JPMA's Involvement

August 4, 2016

Non-clinical Evaluation Expert Committee
Drug Evaluation Committee
Japan Pharmaceutical Manufacturers Association

Kiyoshi Ohtaki , Team leader

Japan Pharmaceutical Manufacturers Association (JPMA)



Drug Evaluation Committee promotes appropriate measures for research and development of new drugs, post-marketing safety measures, and appropriate use of drugs. It proposes policies and strategies based on research results on technology, regulatory science and regulation.

JPMA

Since 1968
73 members (as of Apr, 2016)

http://www.jpma.or.jp/english/

PhRMA
Pharmaceutical Research and Manufacturers of America

efpia
European Federation of Pharmaceutical Industries and Associations

Past Action (1)

November 2013

Joint seminar by JPMA and JACL*

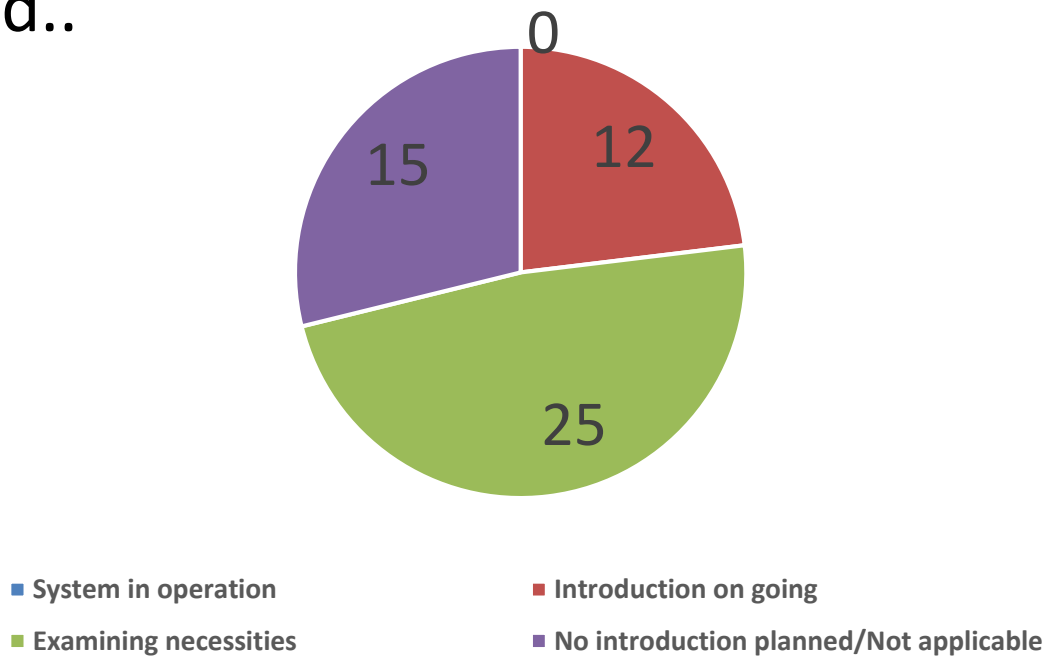
* Japan Association of Contract Laboratories for Safety Evaluation

- JPMA recommended early actions
- JACL suggested that a cooperative system between a pharmaceutical company and a CRO is necessary

Past Action (2)

- September 2015

  We did a questionnaire about SEND-adaptive situations: Out of 61 companies, 52 companies answered. However, the situation in detail could hardly be grasped..



Past Action (3)

November 2015

Joint seminar by JPMA and JACL (continued)

The following items were reported.

- The results of questionnaire about SEND
  - Questionnaire by JPMA
  - Questionnaire by JACL
- SEND-adaptive situations of 3 CROs
- Promotion and prospects of the electronic application in Japan by PMDA
- How to advance SEND by CJUG SEND Team

Current Structure (1)

- April 2016
  - We launched a SEND Sub-team within Non-clinical Evaluation Expert Committee of JPMA Drug Evaluation Committee
  - The number of member companies were 11.

Current Structure (2)

- July 2016
  - In a SEND Sub-team meeting, information was exchanged among PhUSE, CJUG and JSQA
  - As for the future, they will be mutually working together

Current Action Policy

- The following documents will be prepared based on the situations where nonclinical studies are being conducted
  - Guidance for preparing each domain
  - Guidance for establishing SDRG, etc.

- Contribution will be made to corporate members and affiliates when they establish SEND

Example (1)

- Preparation of terminologies which are not found in the controlled terminologies
  - Example: In the Trial Design Model Datasets of SENDIG*, “SCREEN” is described as an example of EPOCH and ELEMENT, though “SCREEN” is a terminology not familiar to nonclinical researchers
  - Recommendation should be made from more familiar terminologies such as “PRETREATMENT” or “acclimation”

* SENDIG: Standard for Exchange of Nonclinical Data Implementation Guide

Example (2)

- Domains
  - In collaboration with CJUG, necessities of items in each domain, which have been recommended by JPMA, will be proposed
  - Example: COMMENTS domain should not be usually prepared.

Example (3)

■Japanese guidance for preparing SDRG

Nonclinical SDRG, which are open to the public via the website of PhUSE, will be translated into Japanese and explained.

http://www.phusewiki.org/wiki/index.php?title=Nonclinical_SDRG_Template_and_Guide

Thank you for your attention.