Japan Regulatory Update

Toshiyoshi Tominaga, Ph.D.

Associate Executive Director (for International Programs)

Pharmaceuticals and Medical Devices Agency

Pharmaceuticals and Medical Devices Agency

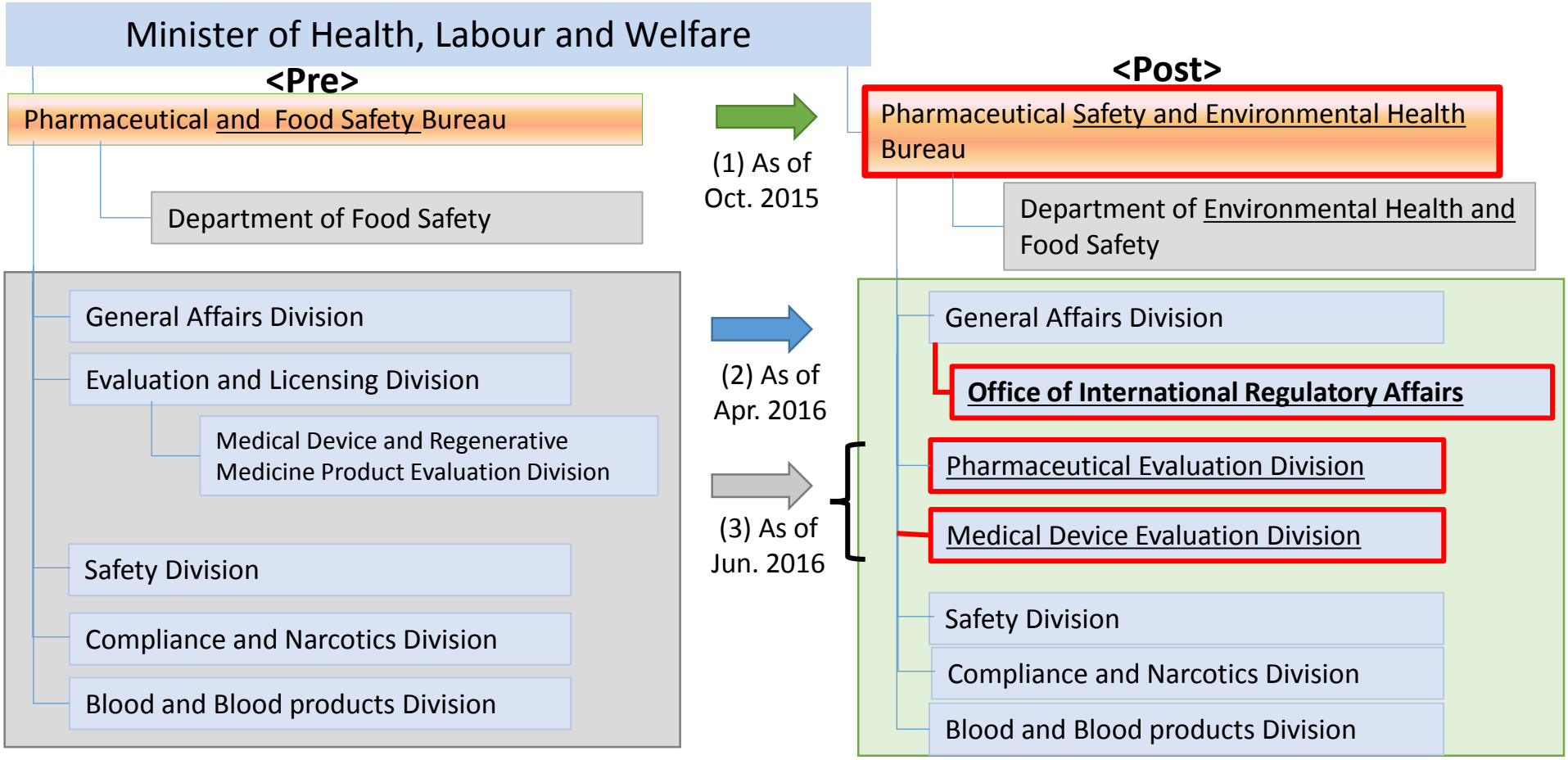
Today's Agenda

1. Organizational Updates
   - MHLW : International Office, Medical Devices Evaluation Division
   - PMDA : Asia Training Center, Hokuriku Branch

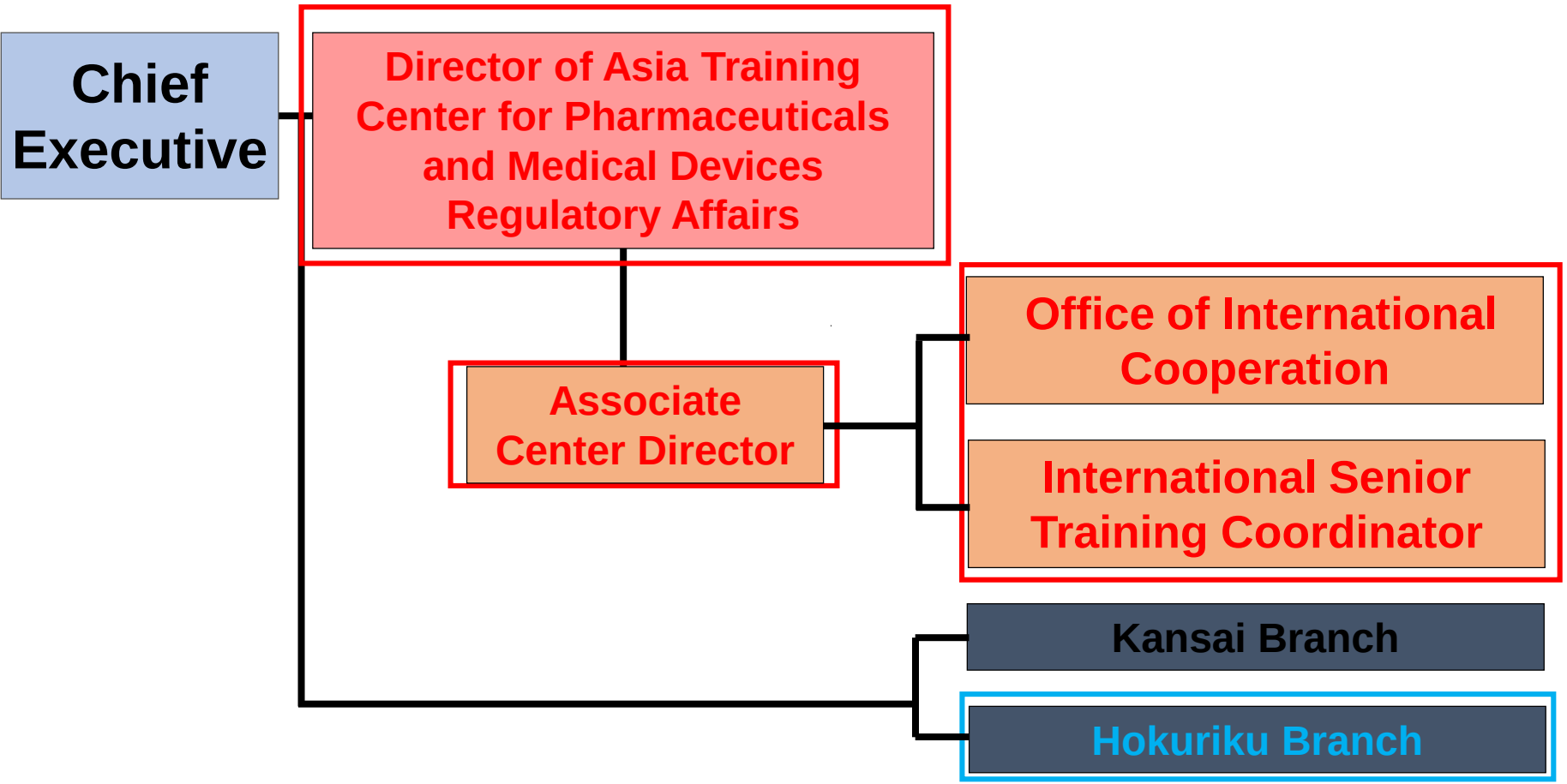
2. Update of Products Review
   - Approval time for New drugs
   - Sakigake designation Update
   - Utilization of electronic data

3. Update of Safety Measures
   - MID-NET project

Reform of Pharmaceutical Safety Bureau in MHLW



PMDA Organizational Update



As of April 1, 2016

As of June 21, 2016

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)
-established on April 1, 2016 -

ATC's Activities in FY2016 (April 2016 – March 2017)

- PMDA-ATC Pharmaceutical Review Seminar (July 25-29, PMDA)
- PMDA-ATC Pharmaceutical Review Seminar (Sept.26-29, Bangkok, Thailand)
- PMDA-ATC Medical Devices Seminar (Nov. 7-11, PMDA)
- PMDA-ATC GMP Inspections Seminar (Dec. 5-9, Toyama, Japan)
- APEC-LSIF-RHSC CoE Pilot Workshop
  - ➢ Good Registration Management (Nov. 15-17, Chinese Taipei)
  - ➢ MRCT/GCP inspection (January 23-26, 2017, PMDA)
  - ➢ Pharmacovigilance (February 6-9, 2017, PMDA)
    - ✓ **Registration on-going! Visit our website**
- Ad-hoc trainings conducted per request from regulatory authorities

Regulatory Harmonization Steering Committee

APEC Life Sciences Innovation Forum

2016 APEC

Good Registration Management (GRM)

Regulatory Science Center of Excellence Pilot Workshop

Save the Date 2016.11.15-11.17

Taipei / Chang Yung-Fa Foundation

Program Overview

A 3-day program focusing on Good Review Practices (GRevPs), Good Submission Practices (GSubPs), and GRM with lectures, group discussions and applied case studies.
The program includes Common Sessions, Reviewer-Specific Sessions, and Applicant-Specific Sessions.

Target Audience

1) Regulatory professionals from regulatory authority or industry,
2) with at least three years of hands-on experience in the management of regulatory reviews or regulatory submissions,
3) who are interested in understanding guidelines such as GRevPs or GSubPs,
4) who are actively involved in training of regulatory staff within their organizations

Registration

- Available from 14 September to 14 October via e-mail ONLY. No registration fee required
- Pre-registration is required by submitting application form with information on hands-on experiences in the management of regulatory review or submission. Please contact rapstaiwn@tcfst.org.tw for the form.
- Limited seats are available (approx. 50 in total; 25-30 each for Reviewer-and Applicant-Specific Sessions)
- Priority will be given to the nominated representatives of APEC member economies

Travel & Accommodation

Funding for travel eligible economies may be available.

Contact information

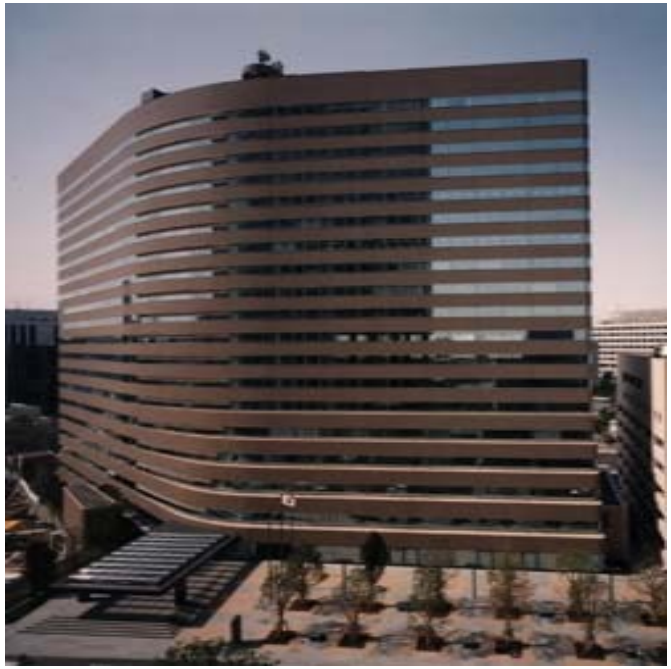
Dr. Yu-Hua Huang Email: yhhuang@tcfst.org.tw
RAPS Taiwan Chapter Email: rapstaiwan@tcfst.org.tw

APAC Asia Pacific Conference of Pharmaceutical Associations · Pmda · FDA · AHC APEC Harmonization Center · RAPS

Pharmaceuticals and Medical Devices Agency

Kansai Branch

Launched on
Oct. 1, 2013



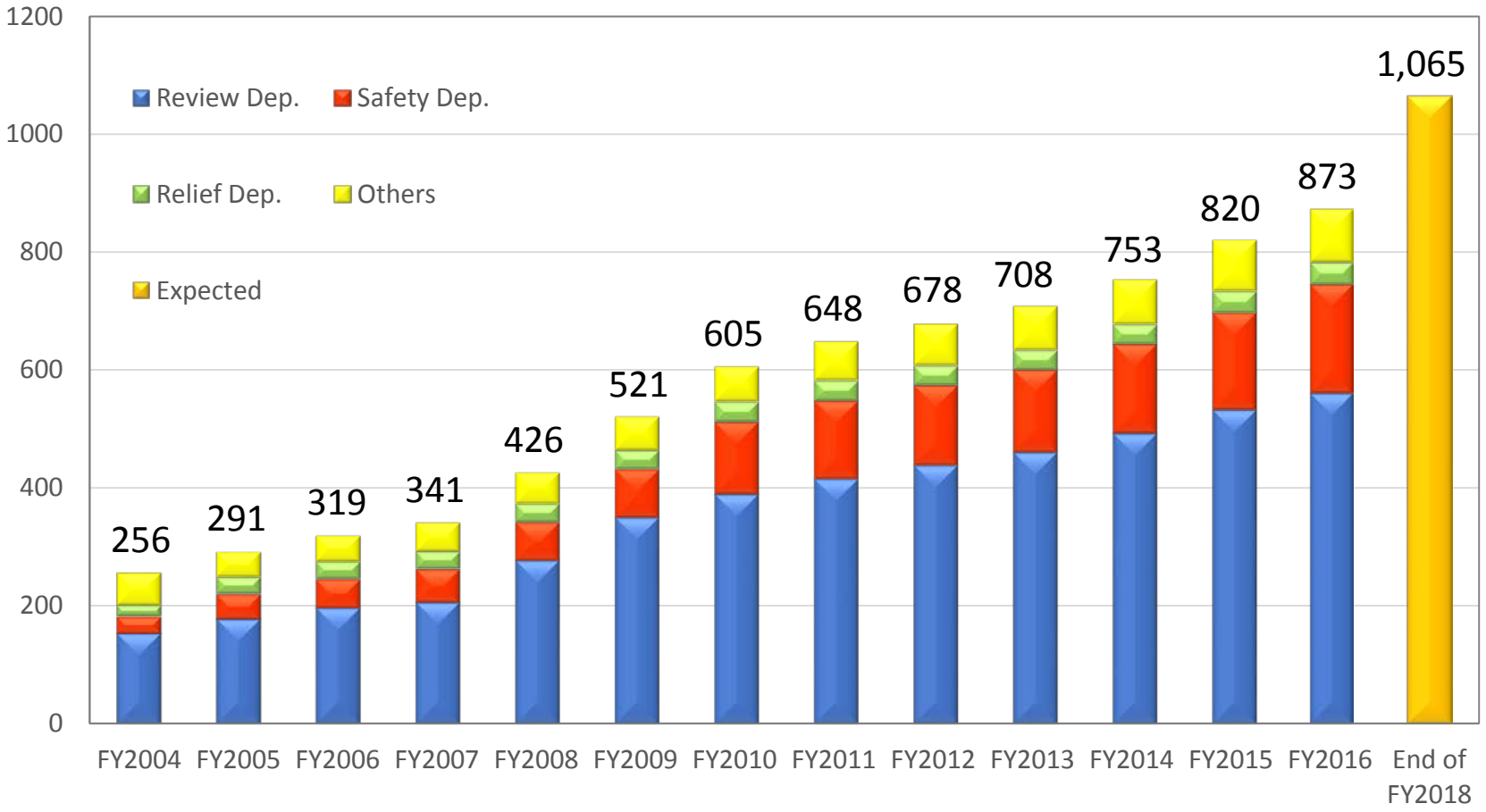
Headquarter

Established
in 2004

Hokuriku Branch

Launched on
June 9, 2016

Transition of number of staffs at PMDA



（FY2004 – 2016 : Number as of 1st April）

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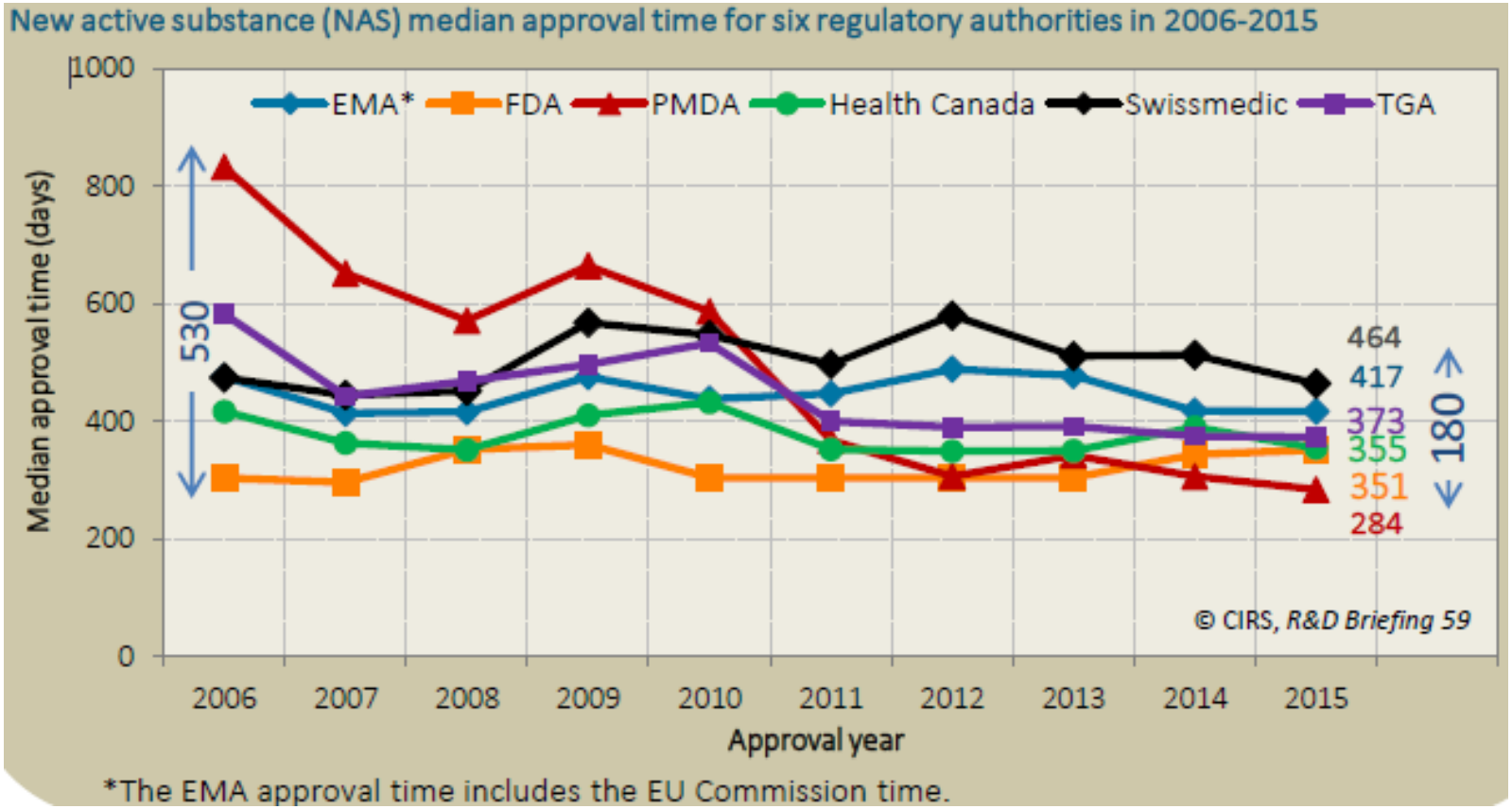
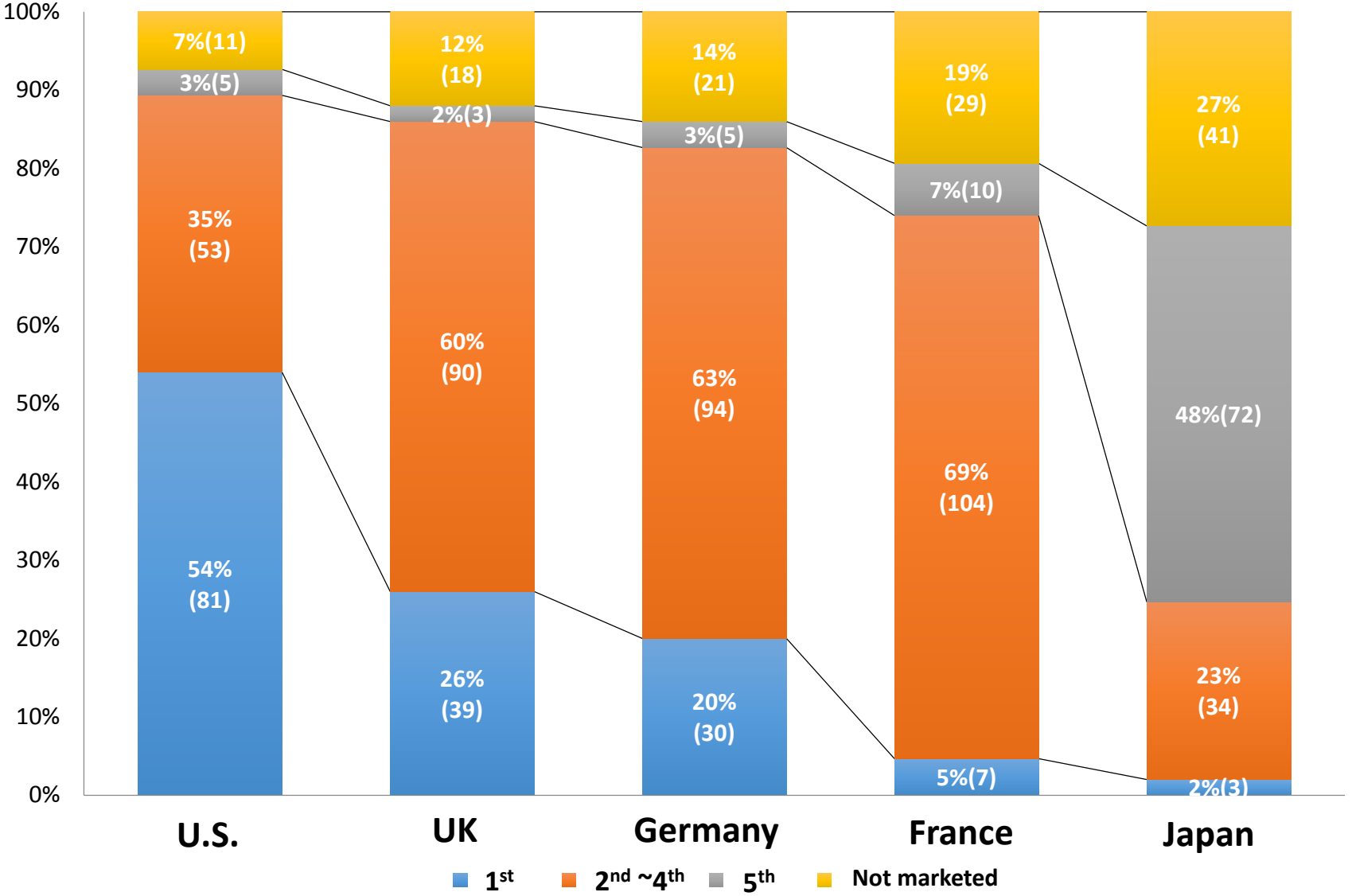
PMDA maintains fastest approval time for New Active Substances



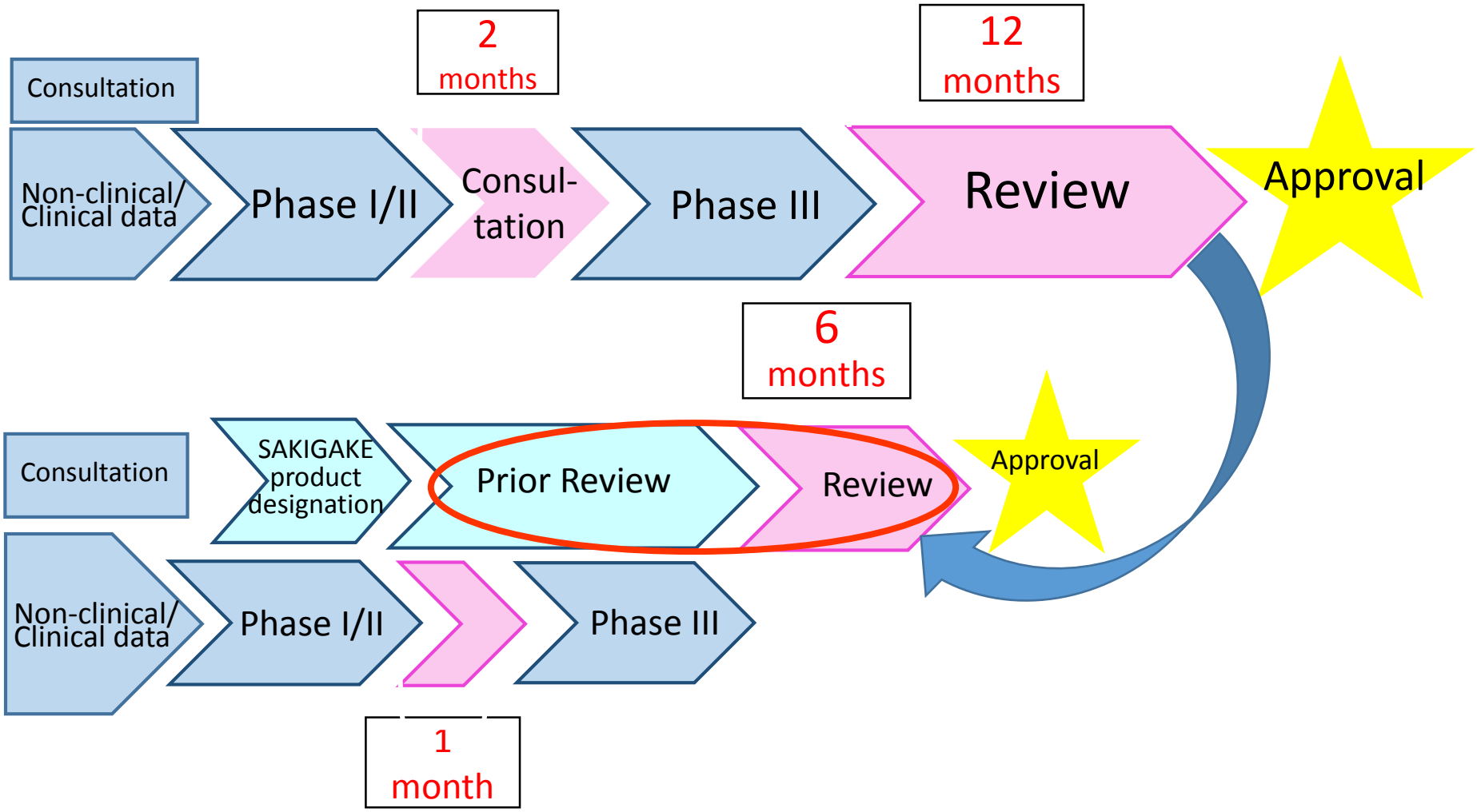
Captured from
http://www.cirsci.org/wp-content/uploads/2016/05/CIRS_RD_-Briefing_59_23052016.pdf

In which country are new drugs marketed first in the world?



Source: ⓒ2015 IMS Health. World Review, Life Cycle, created by Pharmaprojects, Office of Pharmaceutical Industry Research（no reprint or copy）
Note: Surveyed in February 2015

Prioritized Consultation and Rolling Review under SAKIGAKE



SAKIGAKE Designated Products

(Drugs, as of Oct. 2015)

Name of drug	Proposed indication	Name of applicant
Sirolimus (NPC-12G)	Angiofibroma associated with tuberous sclerosis	Nobelpharma Co., Ltd.
NS-065/NCNP-01	Duchenne muscular dystrophy (DMD)	Nippon Shinyaku Co., Ltd
S-033188	Influenza A or B virus infection	Shionogi & Co., Ltd.
BCX7353	Management of angioedema attacks in patients with hereditary angioedema (HAE)	Integrated Development Associates Co., Ltd.
ASP2215	First-relapsed or treatment-resistant FLT3 mutation-positive acute myeloid leukaemia	Astellas Pharma Inc.
Pembrolizumab (genetical recombination)	Unresectable, advanced and recurrent gastric cancer	MSD K.K.

Name in Red: Products that had undergone R&D Strategy Consultation before Sakigake-Designation

SAKIGAKE Designated Products

(Medical Devices and Regenerative Medical Products, as of Feb. 2016)

Name of medical products	Proposed indication	Name of applicant
Titanium Bridge (Hinge-type plate with titanium)	Adduction-type spasmodic dysphonia	Nobelpharma Co., Ltd.
Bioresorbable adhesion barrier (THN-01: Trehalose solution)	Postoperative adhesion prevention	Otsuka Pharmaceutical Factory, Inc.
STR01 (Autologous bone marrow-derived mesenchymal stem cell)	Nerve syndrome and dysfunction caused by spinal cord injury	NIPRO Medical Co., Ltd.
G47Δ (Growth-controlled oncolytic herpes simplex virus type 1)	Malignant glioma	Daiichi Sankyo Co., Ltd. The University of Tokyo, Institute of Medical Sciences
Autologous cardiac progenitor/stem cells	Pediatric congenital heart disease (single ventricle physiology)	Japan Regenerative Medicine Co., Ltd.

Name in Red: Products that had undergone R&D Strategy Consultation before Sakigake-Designation

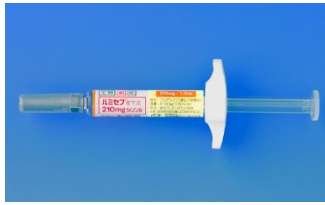
Newly approved products

New Chemical Entities

- LUMICEF® (Brodalumab) Subcutaneous Injection 210 mg, Kyowa Hakko Kirin, (Approved in July 4, 2016)

  Approved for the treatment of psoriasis vulgaris, psoriatic arthritis, pustular psoriasis, and psoriatic erythroderma.

  The first approval of the product worldwide.



New Medical Devices

- HAL For Medical Use (Lower Limb Type), CYBERDYNE Inc. (Approved in November 25, 2015)

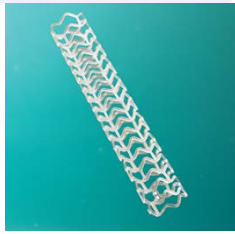
  Improve walking function in patients with impaired ambulation

  The first approval of the product worldwide.

- Absorb GT1, Abbott Vascular (Approved in November 7, 2016)

  Bioresorbable Vascular Scaffold.

  Treatment of patients with symptomatic ischemic heart disease due to *de novo* coronary artery lesions



Next-Generation Review/Consultation

NDA Submission

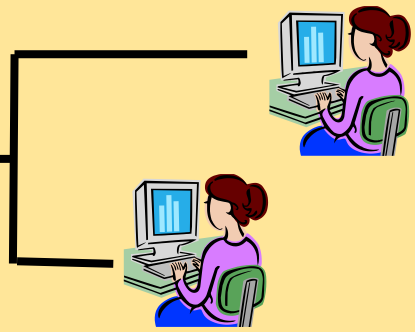
Database in Server

- Clinical data & pre-clinical data submitted electronically

Approval Review

Utilization of Data

- Reviewers access to Individual clinical data, etc.
- Analysis within PMDA



Utilization of Data

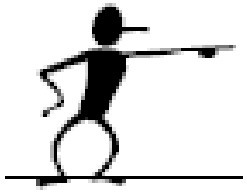
Unified Info. from Cross-Products Analysis

- Utilization for Review and Consultation
- Utilization of Model and Simulation, etc.
- Guidelines

Improved Review, Consultation, GIs for effective drug development

Scientific discussion/decision
Based on internal analysis

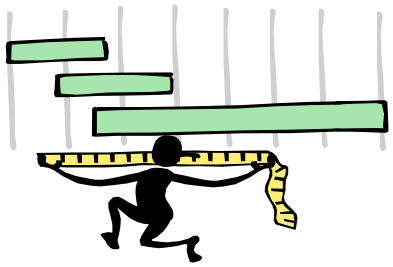
Plan and Current Position



We are here

FY2016

Set up e-data management and utilization scheme

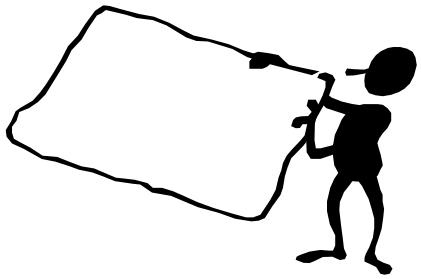


FY2018

Standardization of utilization of e-data in product review

FY2019 - 2021

Start full-fledged cross-product analysis



FY2022 - 2023

Publication of guidelines to contribution to drug development

First-class review authority

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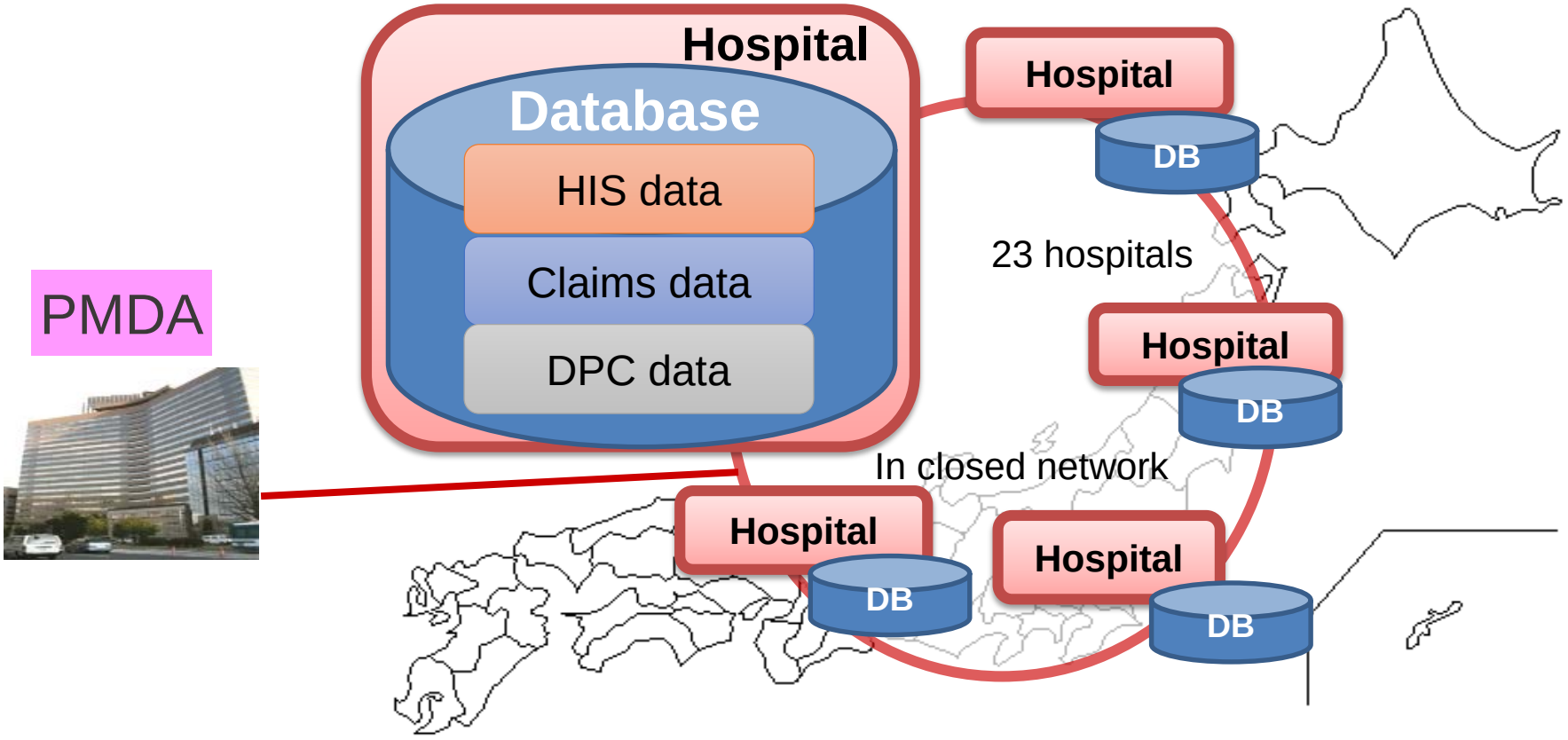
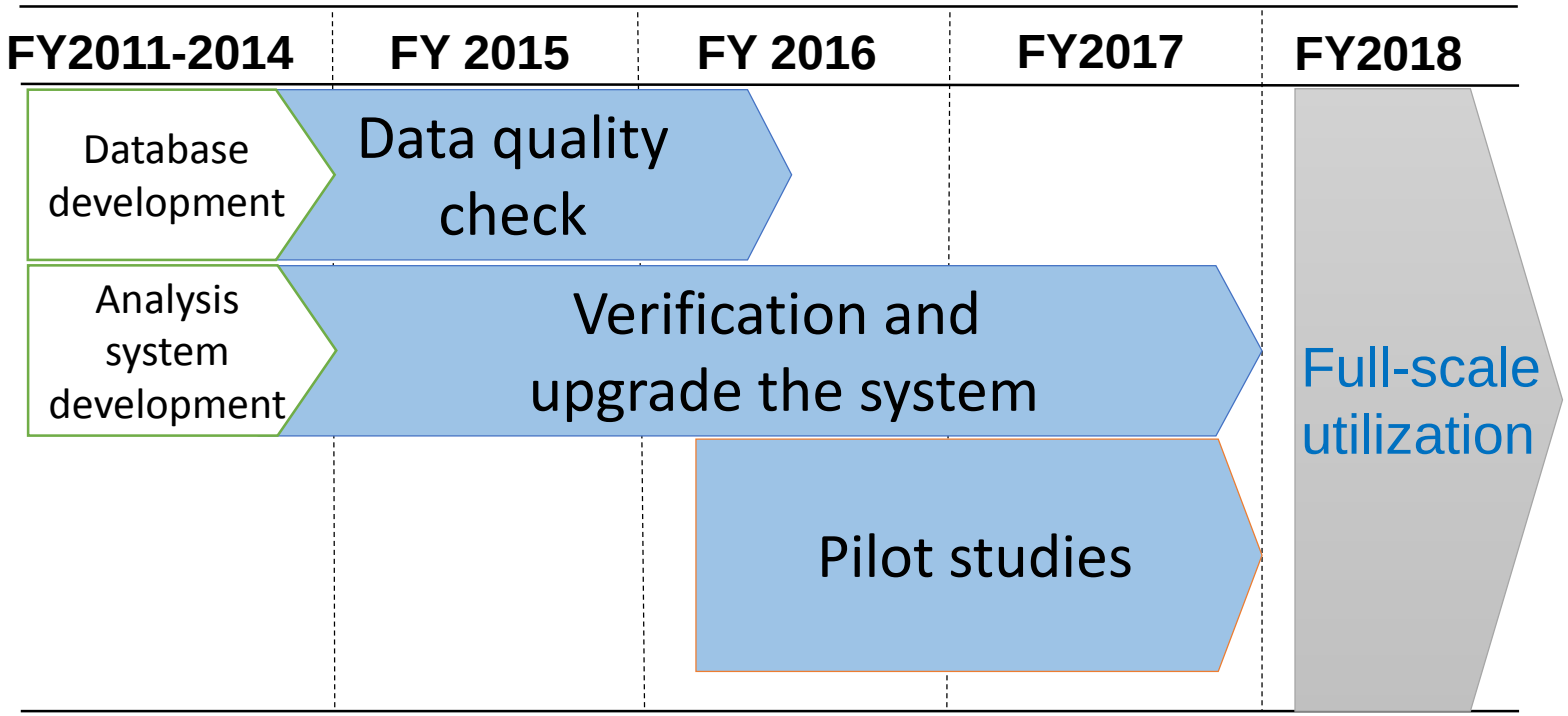
MID-NET Project

Electronic medical record database in Japan for a real-time assessment of drug safety aiming to store up to 3 million patients' data by 2018



Plan and Current Position



Thank you!

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Pharmaceuticals and Medical Devices Agency