PMDA's Activities for Regulatory Utilization of Real World Data

- Introduction of New Consulting Category -

Office of Standards and Compliance for Medical Devices,
Pharmaceutical and Medical Devices Agency (PMDA)

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Disclaimer

The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to PMDA .

Introduction

Pharmaceuticals and **M**edical **D**evices **A**gency

●Established in April 2004

● Number of permanent staff
256 (Apr. 2004)
→ 936 (Apr. 2019)

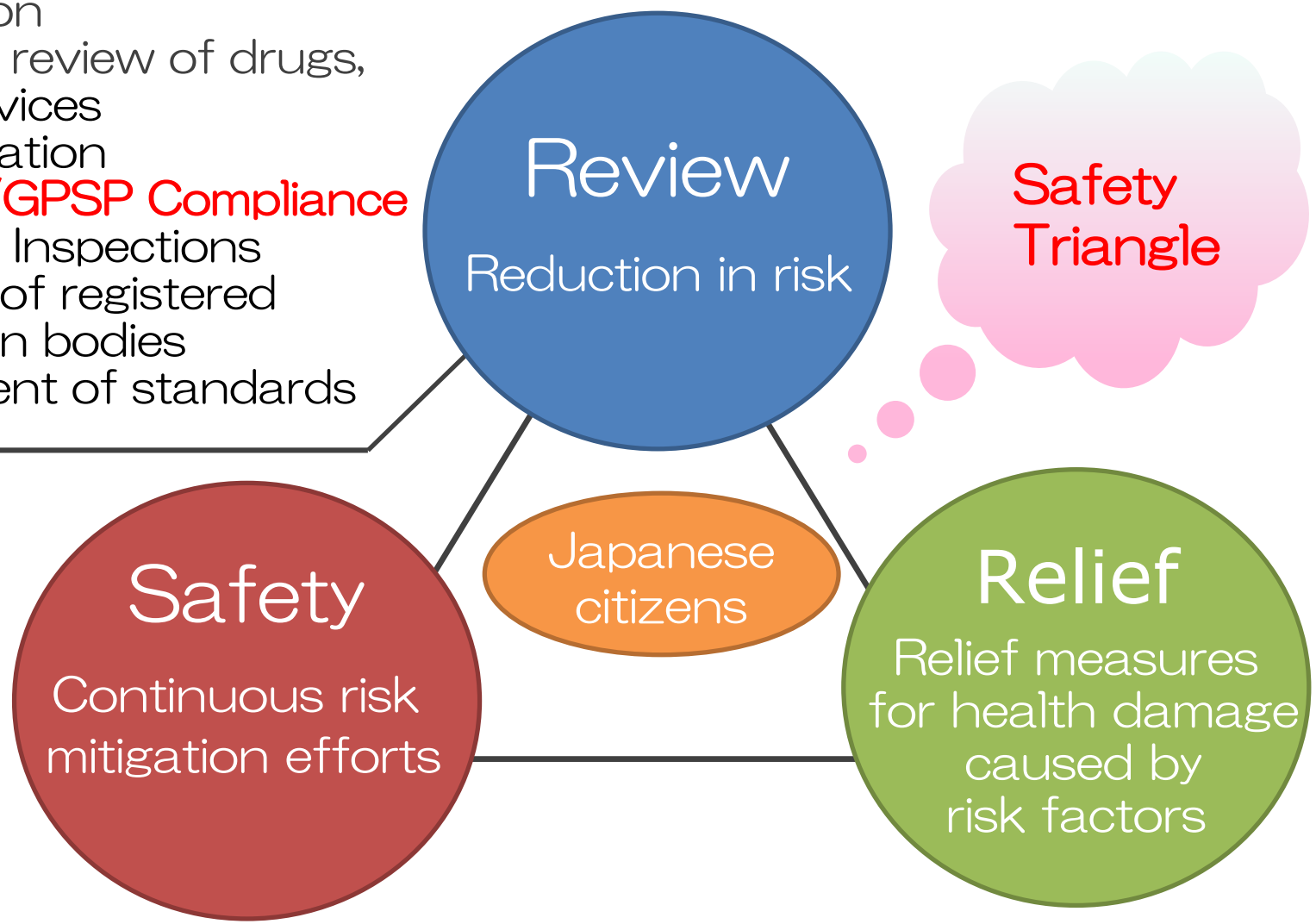
● Services of PMDA

- Review
- Post-marketing Safety Measures
- Relief Services for Adverse Health Effects

Three-Pillar System Unique to Japan

Comprehensive Risk Management **through the Three Functions**

- Consultation
- Regulatory review of drugs, medical devices
- Re-examination
- GLP/GCP/GPSP Compliance
- GMP/QMS Inspections
- Inspection of registered certification bodies
- Development of standards



Agenda

1. The trend of Real World Data（RWD）application
2. The application of the patient registry data
3. The system of consultation
   about quality/compliance of registry data

International Trend of RWD Application

International Trend

～Action to New Drug/Medical Devices Application～

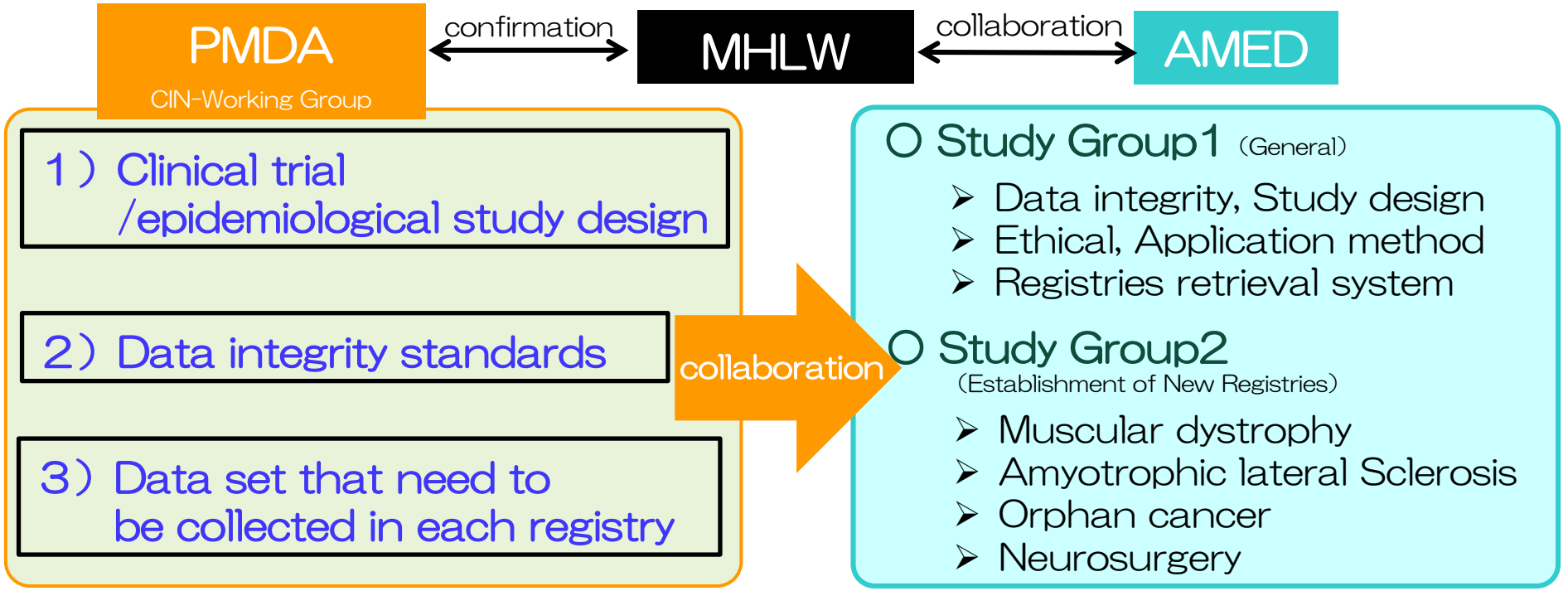
- FDA : Publish the guidance
  (Use of Real-World Evidence to support regulatory decision-making for Medical devices)
- EMA : Publish the discussion paper
  (Patient Registry Initiative-Strategy and Mandate of the Cross-Committee Task Force)
- ICH GCP Renovation : Modernization of E8/ Renovation of E6
- IMDRF : Publish the guidance
  (Principles of International System of Registries linked to other data sources and tools)

Utilizing Patient Registry Data （In the Future）

- New Drugs/Medical Devices Development
- Post-Marketing Surveillance (PMS)

Japan’s Attempt of RWD Application

Clinical Innovation Network（CIN）Project



MHLW

Ministry of health, labor, and wealfare

AMED

The Japan Agency for Medical Research and Development (AMED) is an independent administrative institution of the Japanese Government, which engages in research and development in the field of medicine, establishing and maintaining an environment for this R&D, and providing funding.

Data Integrity About Utilizing the RWD

Use of Electronic health record data in Post-Marketing Surveillance (PMS)

<Industries-PMDA collaboration>

PMS

- **Revision of GPSP※ Ordinance:**
  → Publication : Oct 2017,
  → Enforcement : April 2018
- **Notification :**
  Points of attention about "Drug" Post-Marketing Surveillance using Big data
  → Publication : Feb 2018

※GPSP : Good Post-marketing Study Practice

Integration

Use of Registry data in New Drugs/Medical Devices Application

<AMED ⟷ PMDA/MHLW>

Study Group1

PMS

New Drug/Medical Devices Application

AMED Report

Study Group1

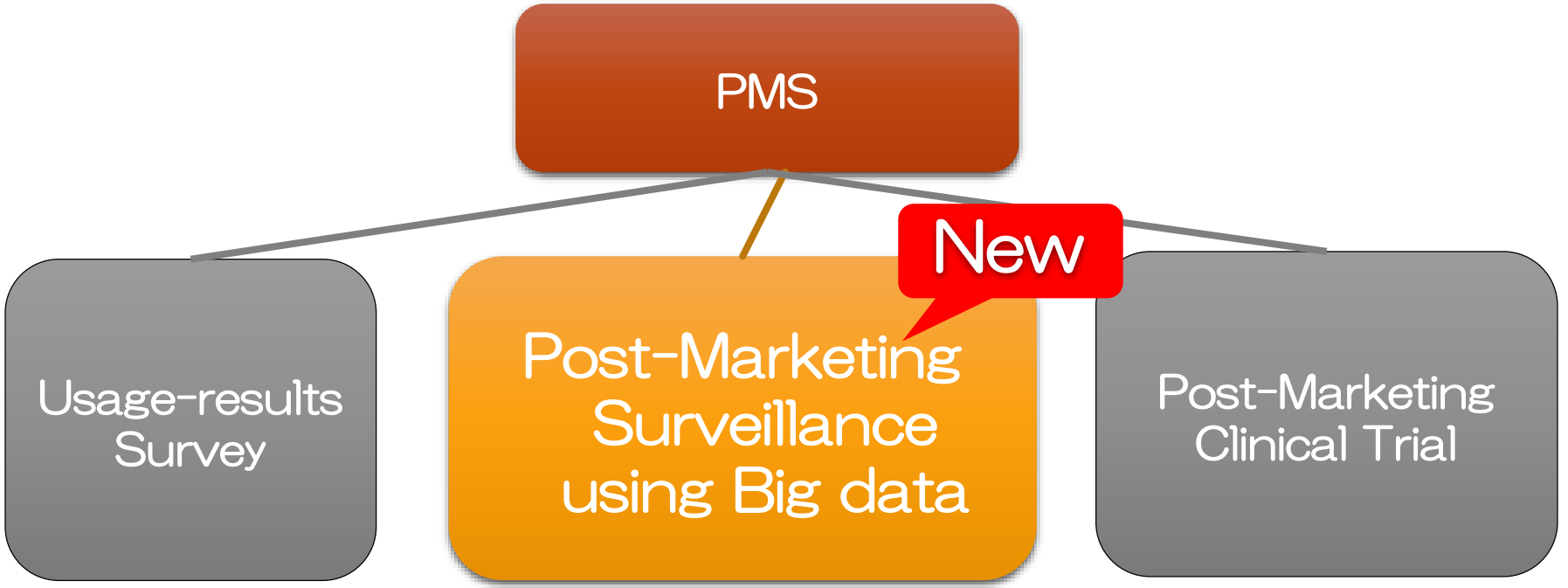
→ Preliminary Draft

Renovation of ICH E8/E6

Finalize /Publication

Utilization of Post-Marketing Surveillance

○ The GPSP ordinance was revised
to use the Big data complying the data integrity in PMS



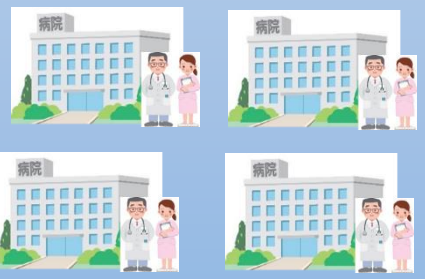
Publication : Oct 2017
Enforcement : April 2018

Notification : Points of attention about "Medical Device" Post-Marketing Surveillance using Big data (Publication Dec 2018)

The Concern About Data Integrity in the Registry Data

Database(DB)

Institution/Hospital



SCOPE

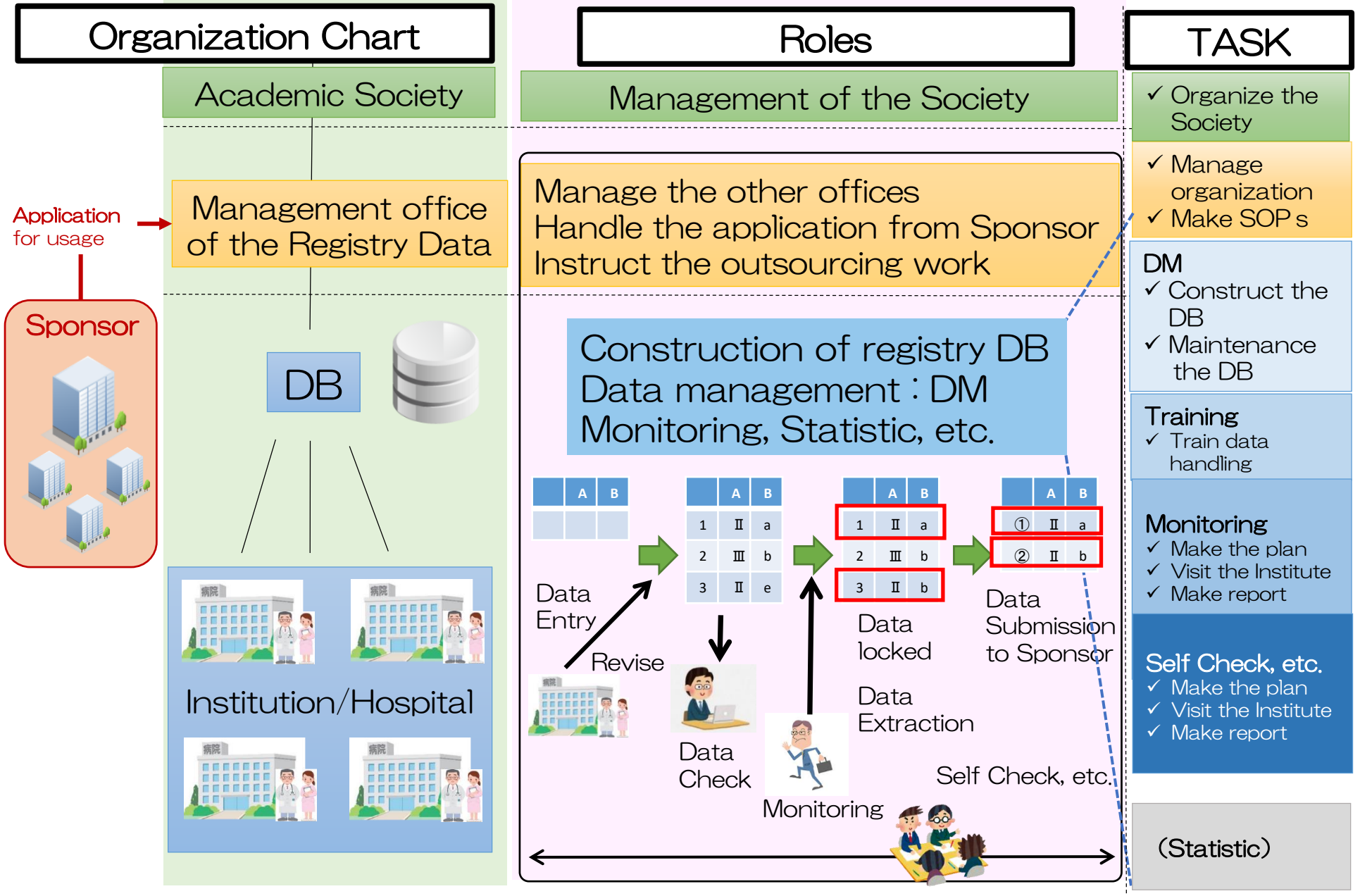
✓Using as control group of clinical trial (New Drugs/Medical Devices Development)

✓Using as PMS

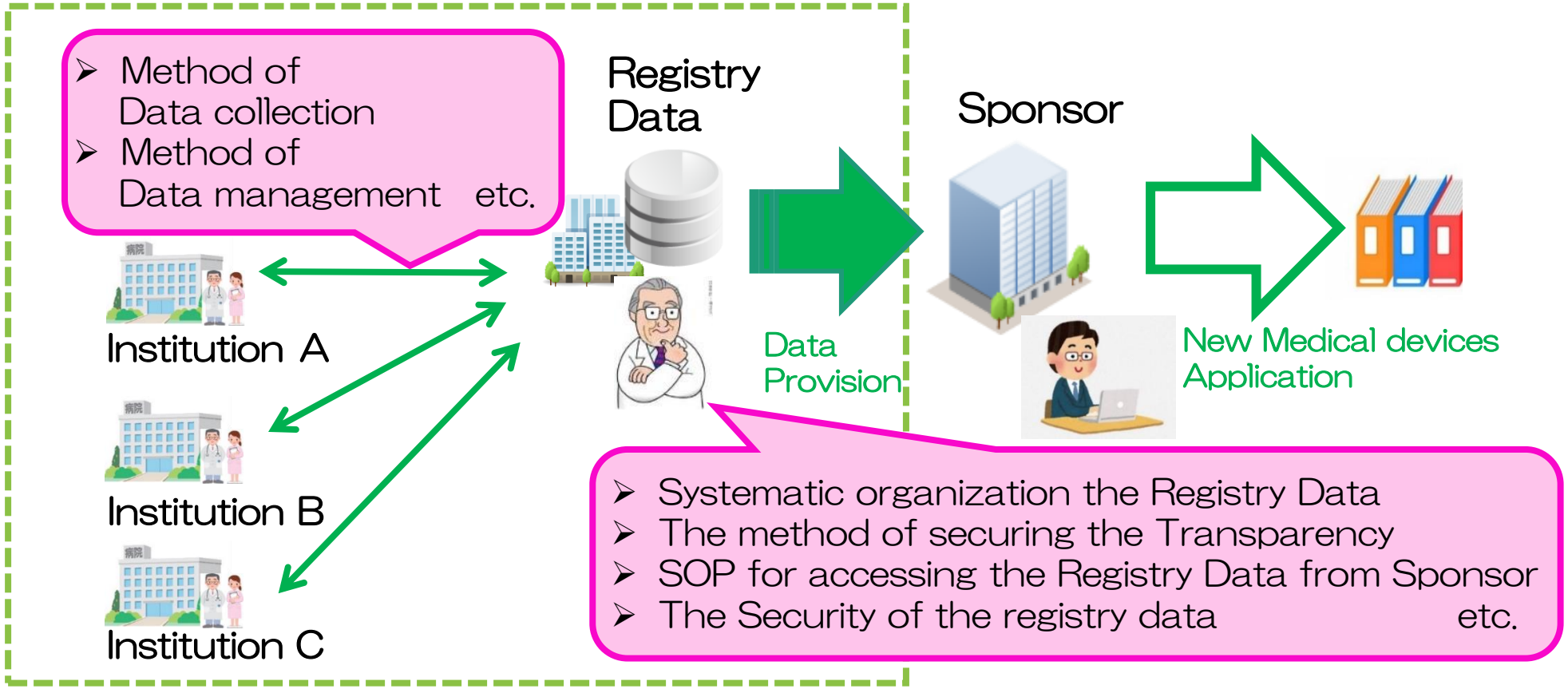
Is our DB complying good manner and data integrity？

How we improve the quality of DB?

Map of the Registry Data of Academic Society



The Concern About Quality/Compliance of the Registry Data



Launch the new consultation system about Quality/Compliance of the Registry Data Apr 2019

Consultation System for the Development of the Registry Data

- Member : Registry organization(mainly Academia Society), Sponsor (attendable)
- Content : Advise appropriateness of development plan utilizing registry data
  Advise method of ensuring the data integrity of registry data for approval/reexamination applications
- Exempt : In case of application to the individual new Drug/Medical Device

Office of Standards and Compliance for Medical Device
Office of Non-clinical and Clinical Compliance

Pre Meeting

- Confirm Meeting material
  - Contents
  - Consult Schedule
- Announce the method to make consult documents
- Others

Consultation (～1 hour)

- PLACE :
  at PMDA(basically)
- Contents:
  - Advice for the application plan using the Registry data
  - Advice for the content of the Protocols/SOPs from the perspective of ethics, data utilization, data entry, validation, etc.

Follow up

- Send consultation record
- Advice the improvable points for SOPs

Consultation System for the Quality/Compliance of the Registry Data

- Member : Sponsor , Registry organization (attendable)
- Content : Check and advice the data integrity of registry data for approval/reexamination applications corresponding to the individual new Drug/Medical Device

Office of Medical Devices
Office of New Drug

Office of Standards and Compliance for Medical Devices
Office of Non-clinical and Clinical Compliance

Application for New Drugs/ Medical Devices

Get the agreement about the application plan

- Fulfillment of Evaluation
- Propriety of Plan

Usage for PMS

Confirm about the plan

- Fulfillment of Evaluation
- Propriety of Plan

Pre Meeting

- Confirm Meeting material
  - Contents
  - Consult Schedule
- Announce the method To make consult documents
- Others

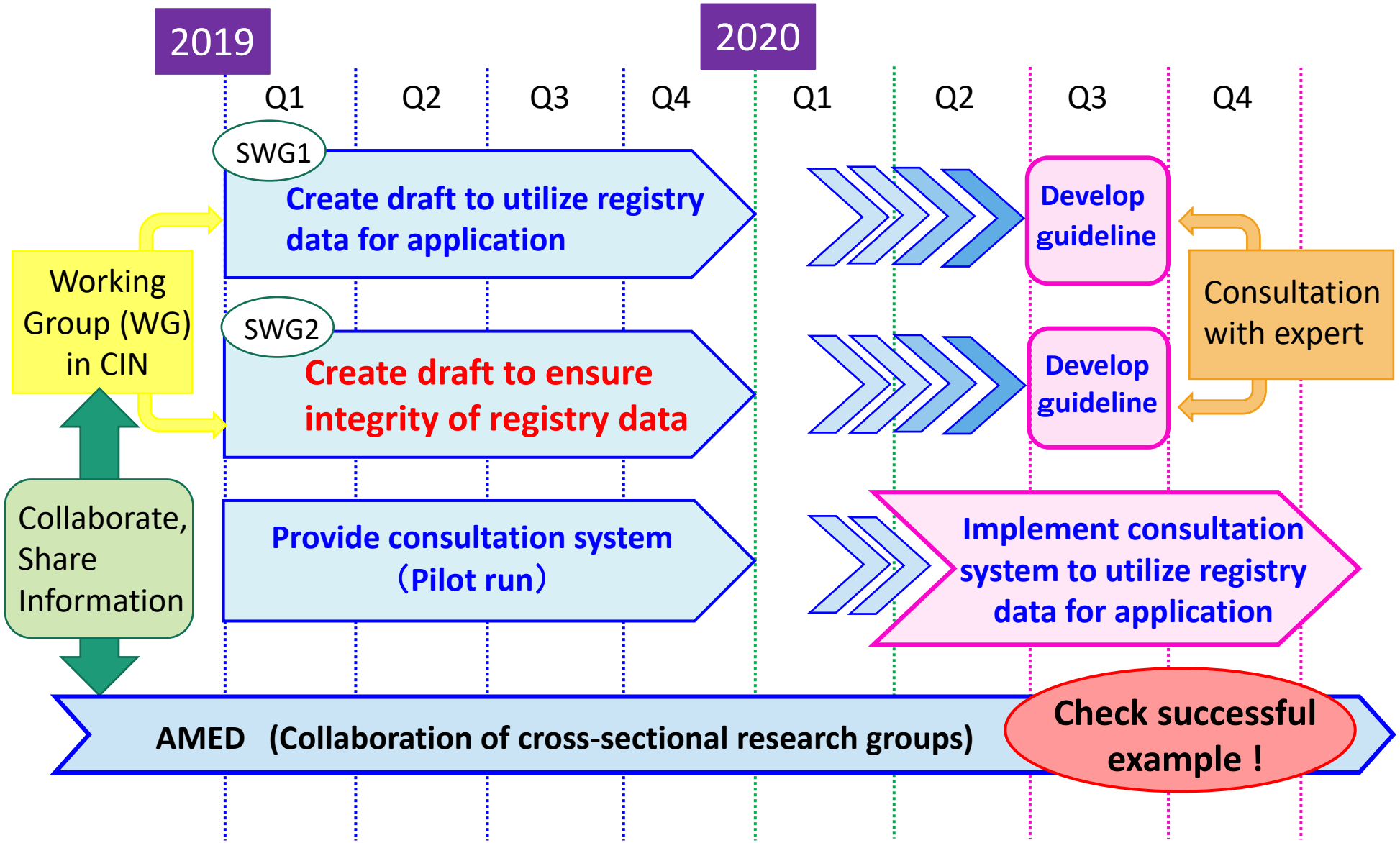
Consultation - (1 Day)

- PLACE : at PMDA(basically)
- Contents:
  - Check and advice the Quality/Compliance of the Registry Data according to the protocols/SOPs based on source documents
  - In case of newly constructing the Registry Data, check and advice for the content of the Protocols/SOPs

Follow up

- Send consultation record
- If necessary, follow up consultation(free)
- If the critical issue about compliance and any changes is required, the additional consultation is needed (charged)

Roadmap of Guideline Development to Ensure Registry Data Integrity for Approval/Reexamination Applications



Thank You for Kind Attention

PMDA HP (English)

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