International Regulatory Harmonization Strategy
（Regulatory Science Initiative : RSI）

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International Regulatory Harmonization Strategy

– Regulatory Science Initiative (RSI) – (June 2015)

I. Objective

Proactively contribute to the international regulatory harmonization and cooperation by disseminating Japan's knowledge on regulations (regulatory science) to the world.

⇒ **Aim to resolve the global drug/device lag and contribute to global health**

⇒ **Revitalize the pharmaceutical and medical device industries**

International Regulatory Harmonization Strategy setting out the mid–long term vision and **priority of its measures**

II. Reflecting on Japan's current status

Competitive edge

- **National health insurance system**
  - ➡ Prompt **insurance reimbursement** and **clinical data gathering**
- **PMDA structural reinforcement**
  - ➡ Greater **predictability and speed** of product approvals
- World's highest level of **medical technology and science**
  - ➡ Technological basis for first-in-the-world development

Issues

- **Low incentives of investment in development** due to the **market size** and **costs of clinical trials**
- **Low capacity of information dissemination** on Japanese regulations and **weak international system** of MHLW and PMDA

III. Actions required (1)
– for Japan to become a "world reference country" –

1. Establishment of the basis for approving innovative products
– To promote Japan's reliability and attractiveness –

(1) Promote 'the SAKIGAKE Review and Designation System'

(2) Establish an infrastructure for clinical development: 'Clinical Innovation Network'

(3) Promote regulatory science to the global level: 'Regulatory Science Center'

Each measure detailed in the following slides→

(1)-1 SAKIGAKE Designation System

– To put innovative products into practice in Japan first in the world –

Designation Criteria

- Medical products for diseases in dire need of innovative therapy
- Applied for approval firstly or simultaneously in Japan
- Prominent effectiveness can be expected based on non-clinical study and early phase of clinical trials

Designation Advantage

1. Prioritized Consultation [Waiting time: 2 months→1 month]

2. Substantialized Pre-application Consultation [de facto review before application]

3. Prioritized Review [12 months → 6 months]

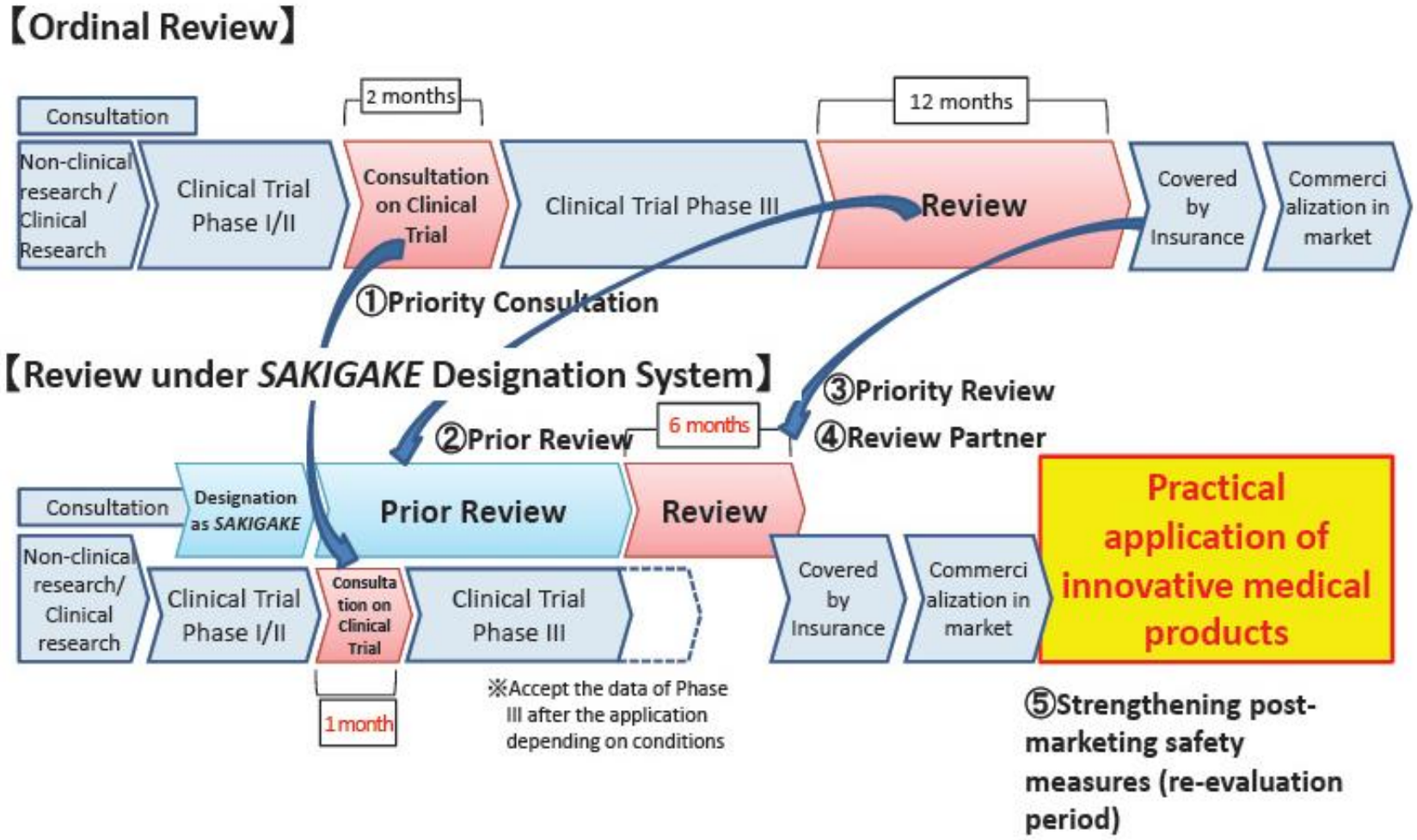
4. Review Partner [PMDA manager as a concierge]

5. Substantial Post-Marketing Safety Measures[Extension of re-examination period]

Designation Procedure

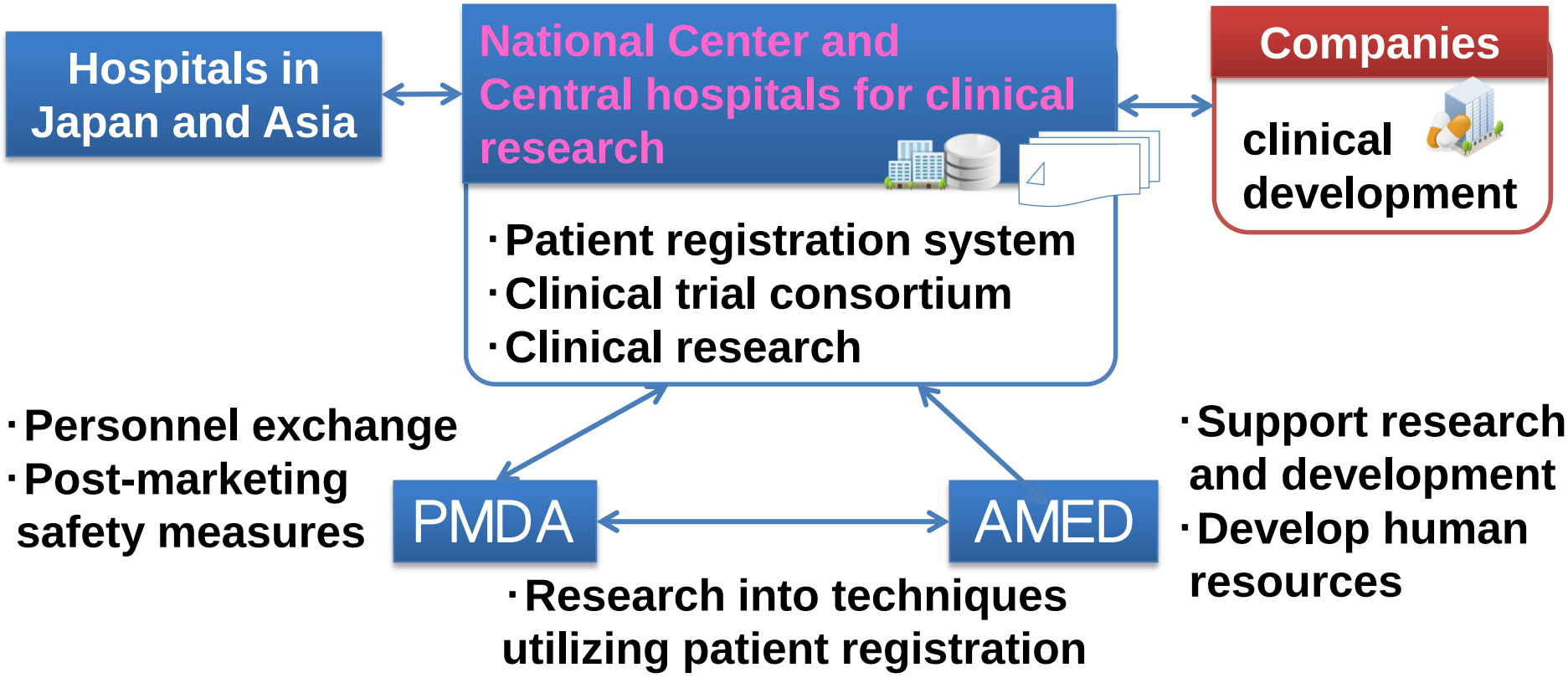
1. Initiation by applicant 2. Initiation by the MHLW

(1)-2 SAKIGAKE General Timeframe



(2) Clinical Innovation Network

・Create an infrastructure that allows efficient clinical trials to be implemented using patient's registered information
・Speed up clinical development in Japan
・Support expanding the market for products to the Asian region



(3) Regulatory Science Center

- **PMDA will set up Regulatory Science Center in 2018**
- **Analyze big data** (data submitted for approval and diagnostic data databases such as **MID-NET**)
- Develop new efficacy evaluation indices and techniques to evaluate safety and efficacy

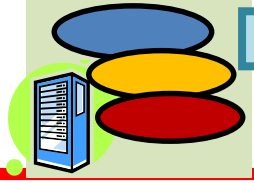
➡ Draw up **guidelines** and **disseminate to the world**

Electronic data of approval application

Regulatory Science Center

Database

MID-NET



Investigate advanced analysis techniques

Analyze common information on products

Drug epidemiology survey based on diagnostic data

Enhance **review / consultation** procedure

Guidelines

Enhanced **safety measures**

III Actions required
– for Japan to become a "world reference country " – (2)

2. Proactive information dissemination to international society
– Distribute Japanese know-how worldwide –

- **Establish "Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs"** within PMDA (→Next slide)
- Establish **a local collaborative system** by dispatching liaisons of PMDA
- Promptly **provide information** and **respond to inquiries on safety measures**
- **Disseminate information** in English **on Japan's regulations**

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs

- Plan, design and coordinate training for Asian regulatory authority staff
- Provide **training opportunities** including **on-site training**

➡ Help raise the level of regulations in Asia as a whole.

III Actions required – for Japan to become a "world reference country" – (3)

3. Priorities in each product area

Pharmaceuticals

- Contribute to the regulatory systems in **Asia** as a constituent of **ICH**
  - ➢ Short term: Aim to **achieve an equivalent position to US and EU** in the abbreviated review system of key ASEAN countries
  - ➢ Mid-long term: **Promote the global clinical trial and the cooperation in review process**

Medical devices

- Promote **bi-lateral cooperation in clinical trial consultation and product review** by utilizing discussions in **IMDRF**

Regenerative medicine products

- **Promote making achievements** and share the knowledge
- **Establish the framework for international dialogue**

III Actions required
– for Japan to become a "world reference country " – (4)

4. Promotion of the initiatives in a continuous manner

- **Establish a global unit in MHLW and PMDA** and introduce **a managerial system per country and region**

- The global unit in MHLW undertakes **a control tower function**
  - ➢ **Periodical progress control** of strategy
  - ➢ **Revision of strategy** considering industry-ideas and up-to-date international situation

➡ **Take a leadership in the international society**

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Ministry of Health, Labour and Welfare

Thank you for your attention !

RSI in English:

http://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/150827-01.html