

Regulatory Science in Pharmaceutical Regulatory Affairs

Kazuhiko Mori

Chief Safety Officer

Pharmaceuticals and Medical Devices Agency



The screenshot shows the PMDA website's Regulatory Science page. The browser address bar displays the URL: <http://www.pmda.go.jp/regulatory/index.htm>. The page header includes the PMDA logo and the text "独立行政法人 医薬品医療機器総合機構" (Pharmaceuticals and Medical Devices Agency). A search bar is located in the top right corner.

The main content area is titled "PMDAにおけるレギュラトリーサイエンス" (Regulatory Science at PMDA). Below the title, there is a section "レギュラトリーサイエンスとは" (What is Regulatory Science?).

The text in this section reads: 「科学技術の成果を人と社会に役立てることを目的に、根拠に基づいた確かな予測、評価、判断を行い、科学技術の成果を人と社会との調和の上で最も望ましい姿に調整するための科学」(第4次科学技術基本計画 平成23年8月19日閣議決定)

It continues: 今後、PMDAが医薬品および医療機器に関するレギュラトリーサイエンス研究を積極的に推進し、日本の規制当局としての考え方などを広く公表・発信していくことは、PMDAの三業務の遂行に寄与し、PMDA及び日本の薬事行政に対する国民の信頼を高めるためだけでなく、国際調和を推進し、積極的に世界に向かって期待される役割を果たしていくことにもつながると考えております。(参考文献: Clin Pharmacol Ther, 90(1), 29-31, 2011)

At the bottom of this section, it states: このページでは、レギュラトリーサイエンスに関するPMDAでの取り組みと関連情報を掲載しております。

Below this is a "New Information" section (新着情報) with a "NEW!!" tag, containing the update: ・平成24年6月18日 レギュラトリーサイエンスホームページをリニューアルしました。

The next section is "これまでの主な取り組み" (Main activities to date), which includes:

- レギュラトリーサイエンス研究に関する基本的考え方の策定(PDF形式)
- PMDA レギュラトリーサイエンス指定研究の設定

Global boom today! (EMA's site)



The screenshot shows the EMA website interface. At the top, there is a navigation bar with the following items: Home, Find medicine, Regulatory, **Special topics**, Document search, News & events, Partners & networks, About us, and Quick links. The 'Special topics' menu is expanded, showing a list of categories: Disease areas, Transparency, Releasing clinical-trial data, Antimicrobial resistance, Safety monitoring of medicines, Medicines for children, Clinical trials, Medicines for rare diseases, Advanced therapies, Falsified medicines, and Medicines for older people.

The main content area is titled 'Regulatory science' and includes a breadcrumb trail: Home > Special Topics > Regulatory science. Below the title, there are icons for Email, Print, Help, and Share. The text describes the EMA's role in regulatory science, mentioning its focus on quality, safety, and efficacy, and its involvement in projects with MIT.

Regulatory science

The European Medicines Agency is a key leader in the development and application of **regulatory science**.

Regulatory science consists of the areas of science that are used in the assessment of the **quality, safety and efficacy** of human and veterinary medicines throughout their life-span, as well as the scientific areas used in regulatory decision-making.

Regulatory science includes **basic and applied biomedical sciences**, including genetics, pharmacology, biostatistics, clinical trial methodology and epidemiology, and **social sciences** such as decision sciences, risk assessment and communication sciences. It aims to contribute towards the development of standards and tools to be used in the regulation of medicines.

The Agency's role

The Agency's mission calls for it to take an active role in advancing regulatory science. To help achieve this, it is taking part in a number of **projects**, including a collaborative research project with the Massachusetts Institute of Technology (MIT) focusing on enhancing regulatory science in pharmaceuticals.

On 15 December 2010, the Agency hosted a conference that provided an opportunity for stakeholders to discuss what role the Agency can play to best support regulatory science.

Related information

- ▶ [European Medicines Agency and Massachusetts Institute of Technology launch joint project on regulatory science \(11/11/2010\)](#)
- ▶ [Roadmap to 2015](#)

Global boom today! (FDA's site)



U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

Protecting and Promoting *Your* Health

A to Z Index | Follow FDA | FDA Voice Blog

SEARCH

Most Popular Searches

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

Science & Research

Home Science & Research Science and Research Special Topics Advancing Regulatory Science

Science and Research Special Topics

- Advancing Regulatory Science
- Strategic Plan for Regulatory Science
- ARS Collaborations
- ARS News and Upcoming Events
- ARS Past News and Events
- Centers of Excellence in Regulatory Science and Innovation (CERSI)

Resources for You

Advancing Regulatory Science

Moving Regulatory Science into the 21st Century



Regulatory Science is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products.

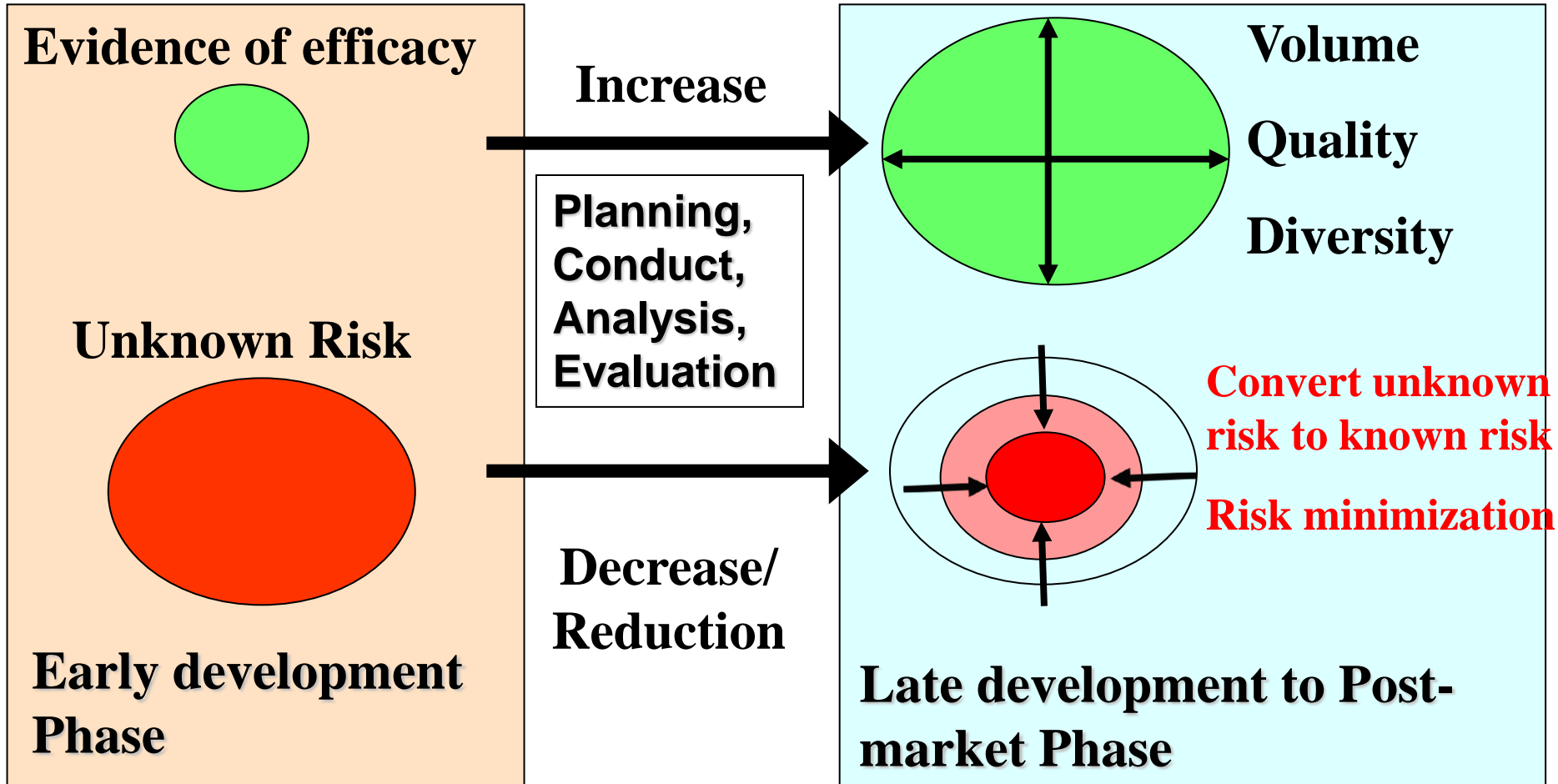
On February 24, 2010, FDA launched its Advancing Regulatory Science Initiative (ARS), building on the achievements of existing Agency programs, like the Critical Path Initiative's groundbreaking efforts to transform the way medical products are developed, evaluated, and manufactured.

Recognizing the success of the Critical Path model, ARS is expanding its scope to encompass every dimension of regulatory science. The goals of the Advancing Regulatory Science Initiative, highlighted below, span the breadth of FDA's regulatory activities.

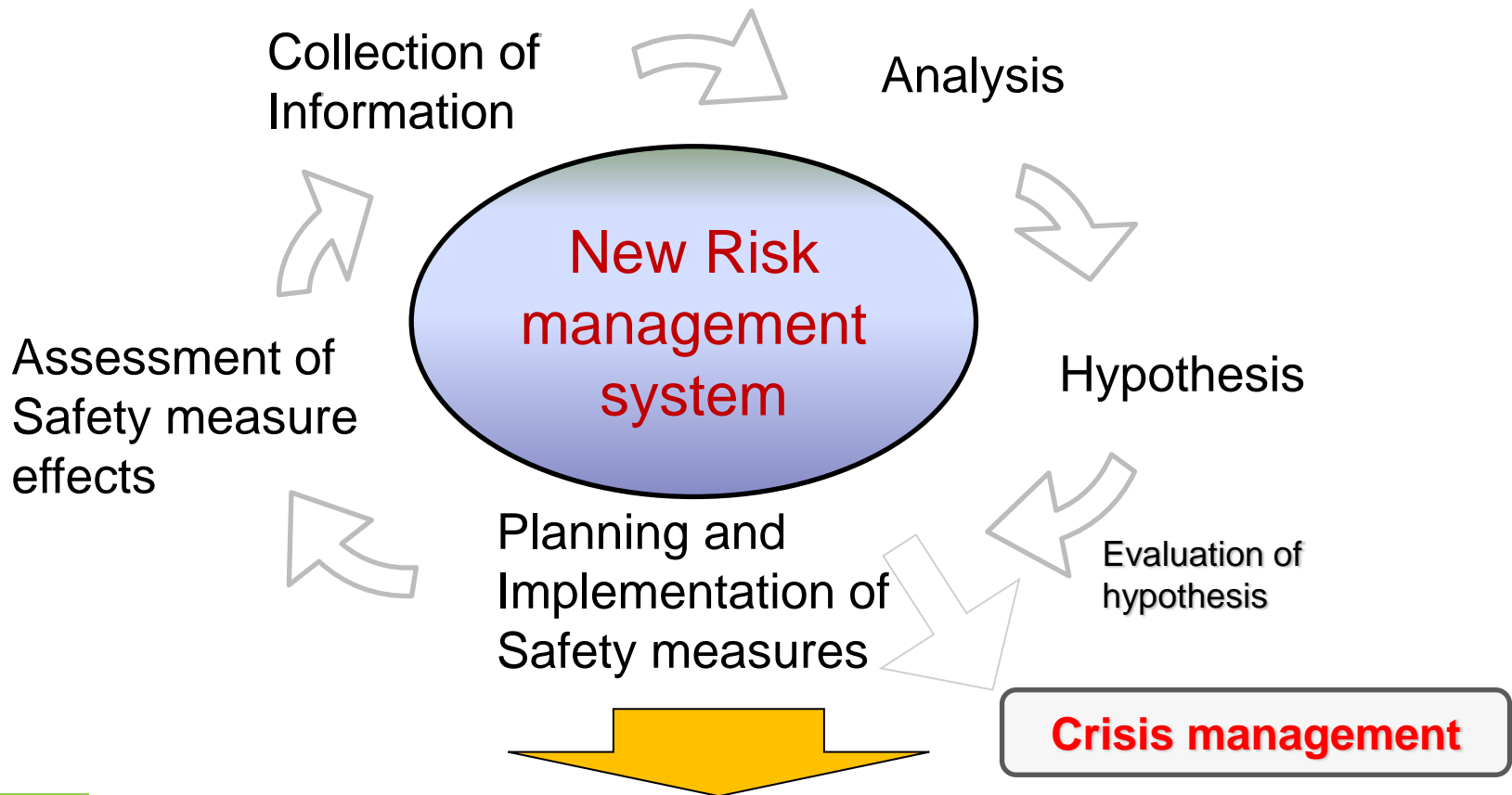
Spotlight

- Watch the complete webinar of FDA's Nov. 13-15, 2012 Clinical Investigator Training Course!!!
- Broad Agency Announcement: FDA Solicits for Research and Development to Support Regulatory Science and Innovation
- Watch the full Webcast of the April 16 Reproductive and Developmental Toxicology Workshop: From In Vivo to In Vitro!
- Centers of Excellence in Regulatory Science and Innovation (CERSI)

Through Life-Cycle of Product



Improving Safety Measures (Continuous risk management)



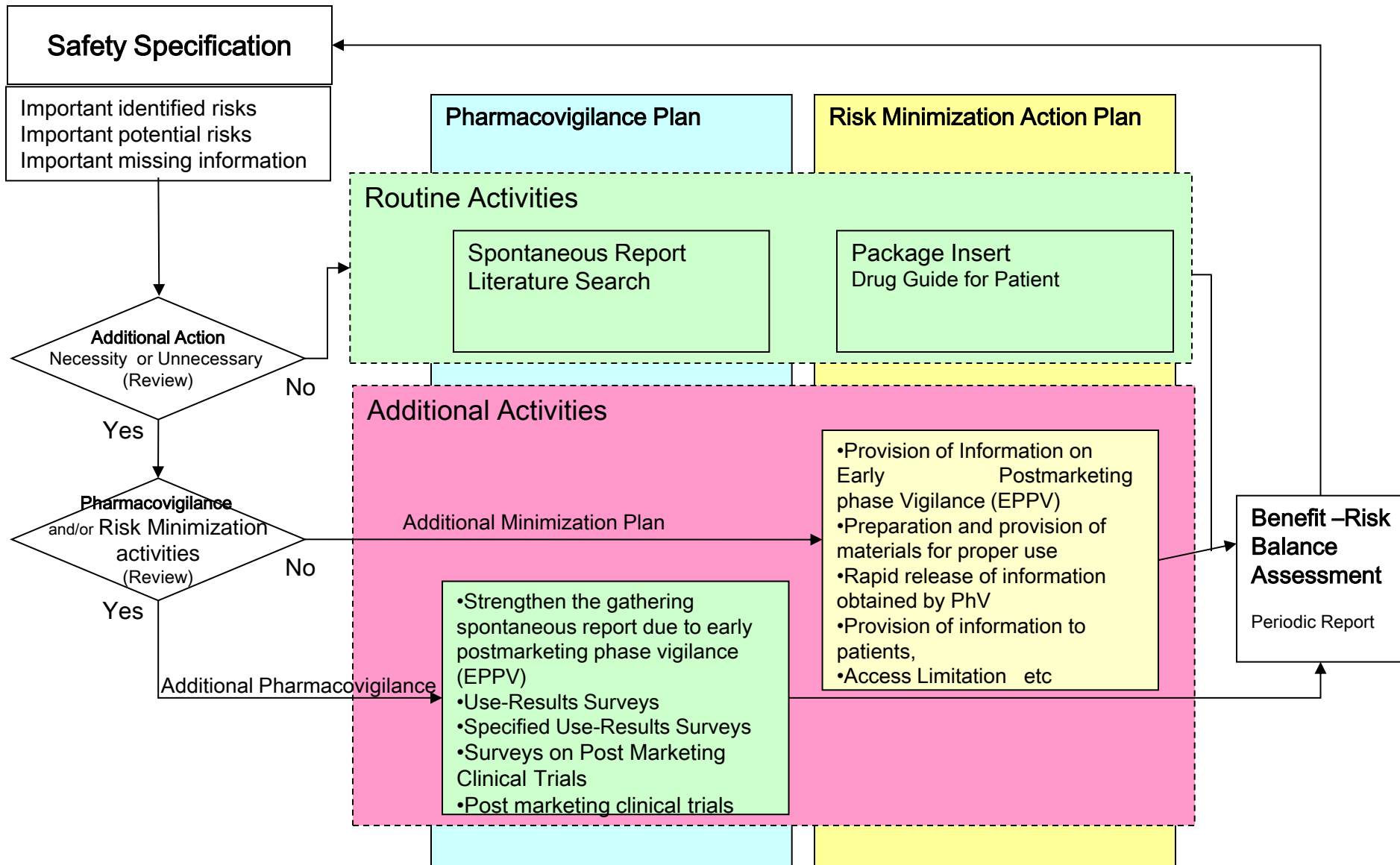
Goal

- Prevention of serious drug safety-related crisis from Japan
- Effective encouragement of proper drug use.
- Ensuring credibility to post-market safety management system.

Risk Management Plan Guidance

- Risk Management Plan (RMP) Guidance was finalized on April 11, 2012
- This guidance is intended to propose a standard concept for “Pharmacovigilance Plan” and “Risk Minimization Plan”
By MAH (marketing authorization holder)
- Complete implementation after 1-year transition period on New drug application (later implementation on generic drugs)

J-RMP Conceptual Diagram



Development of EMR Network in Japan (Up to 10 millions patients data)

PMDA, researchers and MAH



Data utilization with
10 collaborative
hospitals

7 hospitals

3 hospital groups

Kyushu Univ.

Saga Univ.

Kagawa Univ.

Tokushukai group

Hamamatsu Univ.

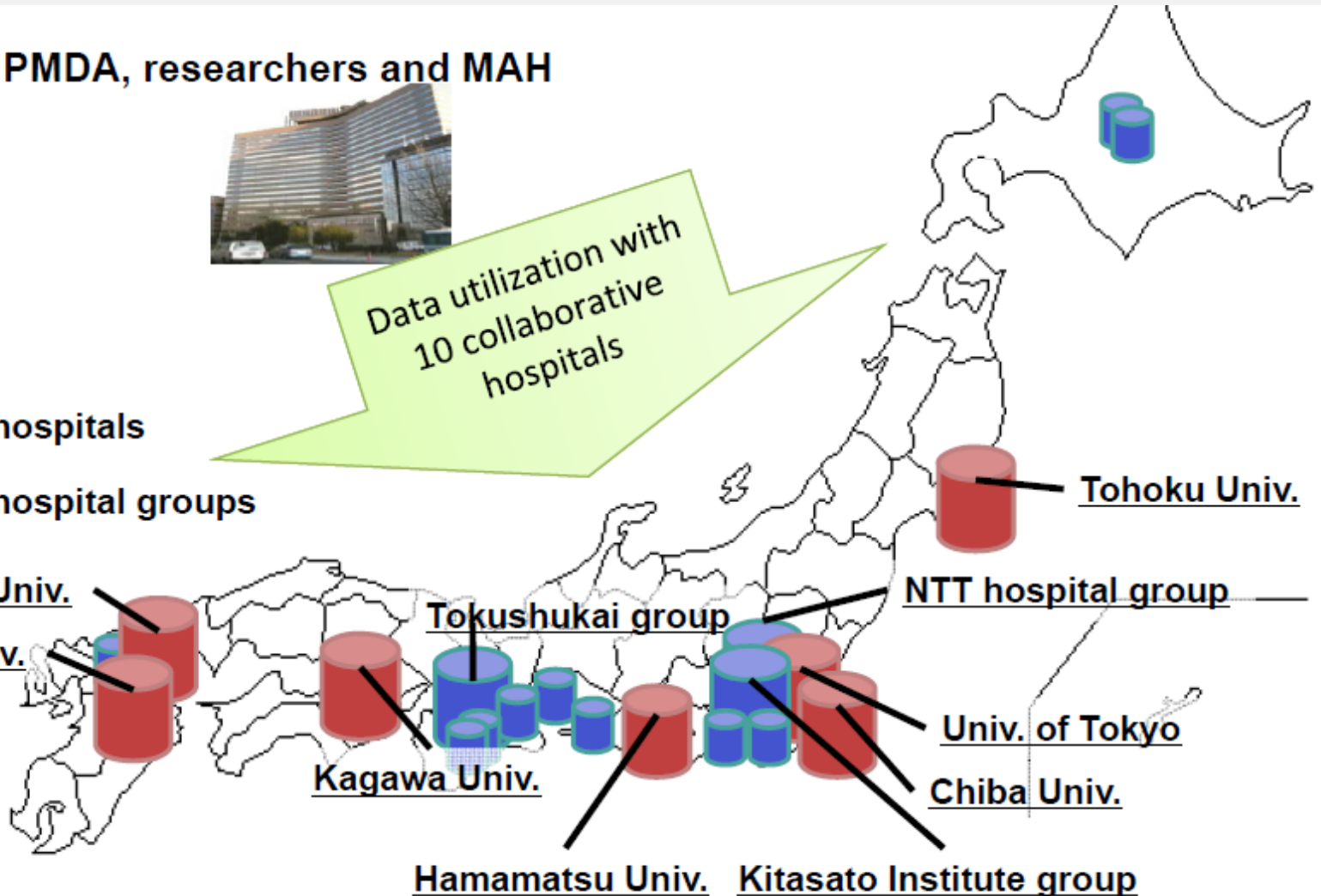
Kitasato Institute group

NTT hospital group

Univ. of Tokyo

Chiba Univ.

Tohoku Univ.



But it might fight with giant !?

A major milestone towards a nationwide electronic medical product safety system
FDA's "Mini-Sentinel" safety pilot program is up and running, demonstrating rapid analysis of medical product safety questions

FDA's "Mini-Sentinel" pilot program, the Agency's first step towards building a nationwide rapid-response electronic safety surveillance system for drugs and other medical products (which will be called the Sentinel System), is now up and running, enabling scientists to evaluate safety questions far more rapidly than using traditional channels.

In actuality, the Mini-Sentinel database is not so "mini"; the pilot project, which took two years to develop, includes 17 data partners across the U.S., and encompasses the data of nearly *100 million patients*. Mini-Sentinel evaluations will help scientists better understand potential safety issues associated with FDA-approved medical products. Importantly, scientists can get responses to their questions in a matter of weeks, as compared to months, or even longer using traditional surveillance methods.

Mini-Sentinel at-a-glance

- 99 million individuals
- 2.9 billion prescription drug dispensings
- 2.4 billion unique medical encounters, including 38 million acute inpatient hospital stays

All the players in good harmony



Thank you for your attention