Regulatory Science
in Pharmaceutical Regulatory Affairs

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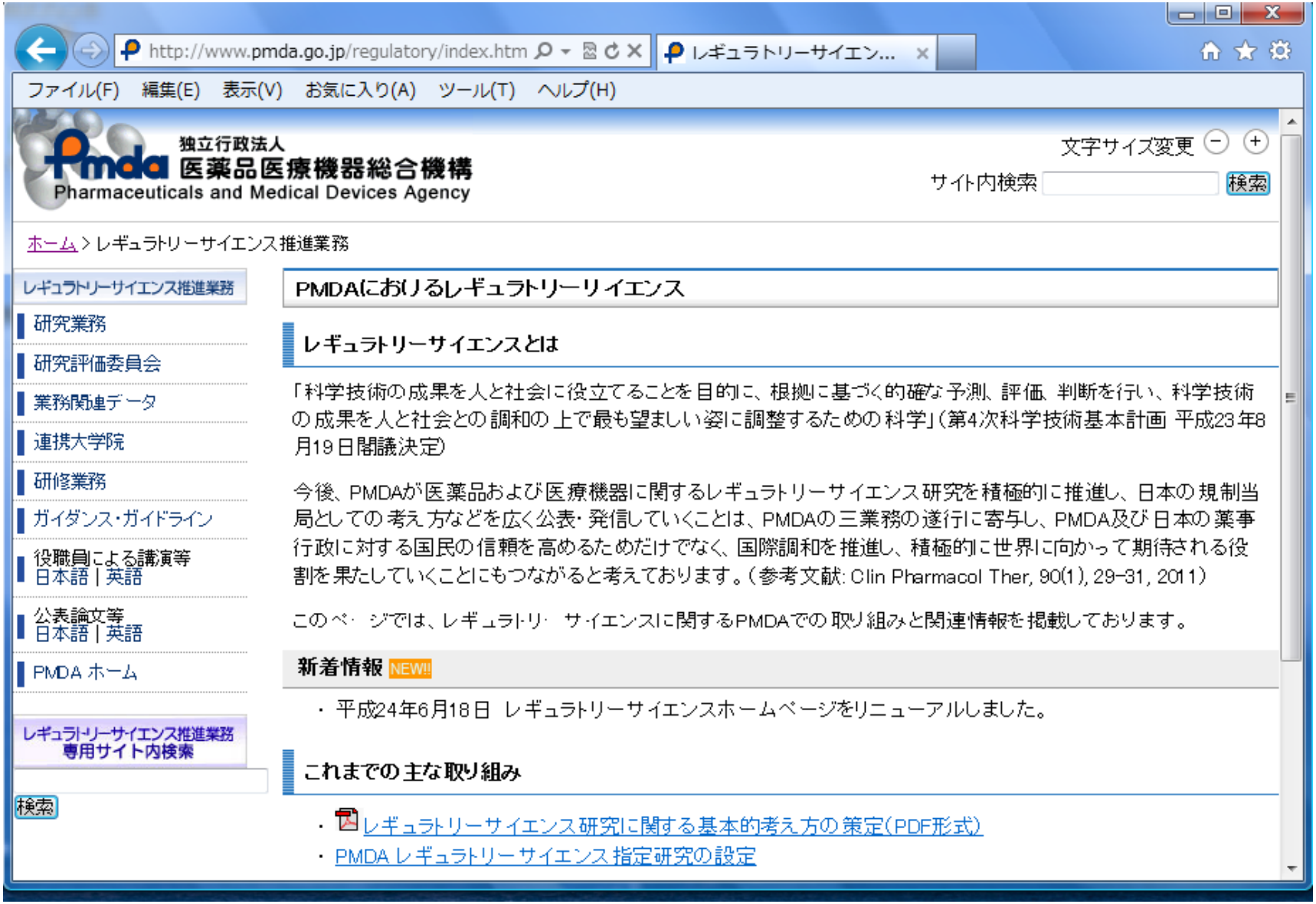
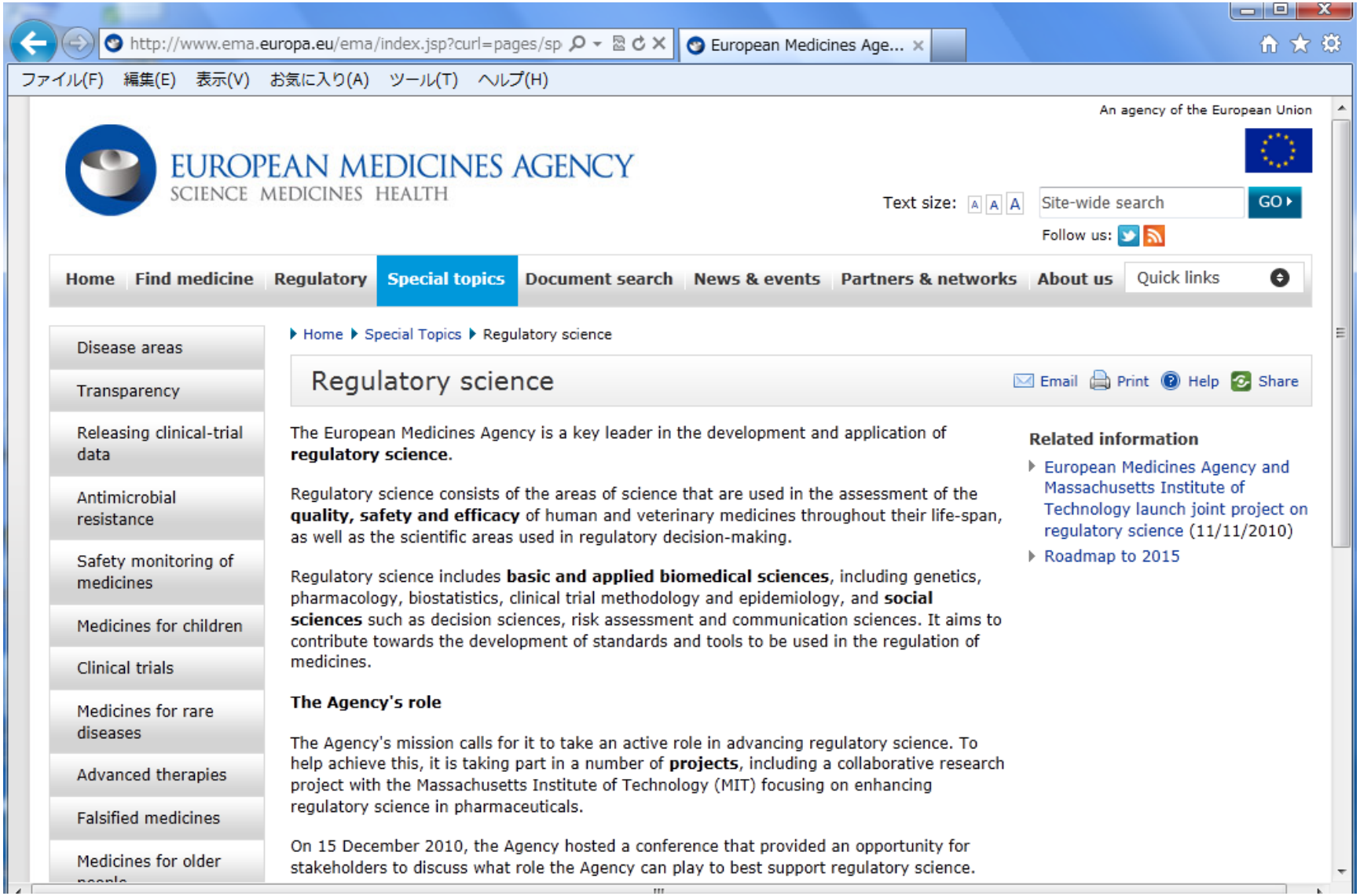
Regulatory science, which began in Japan

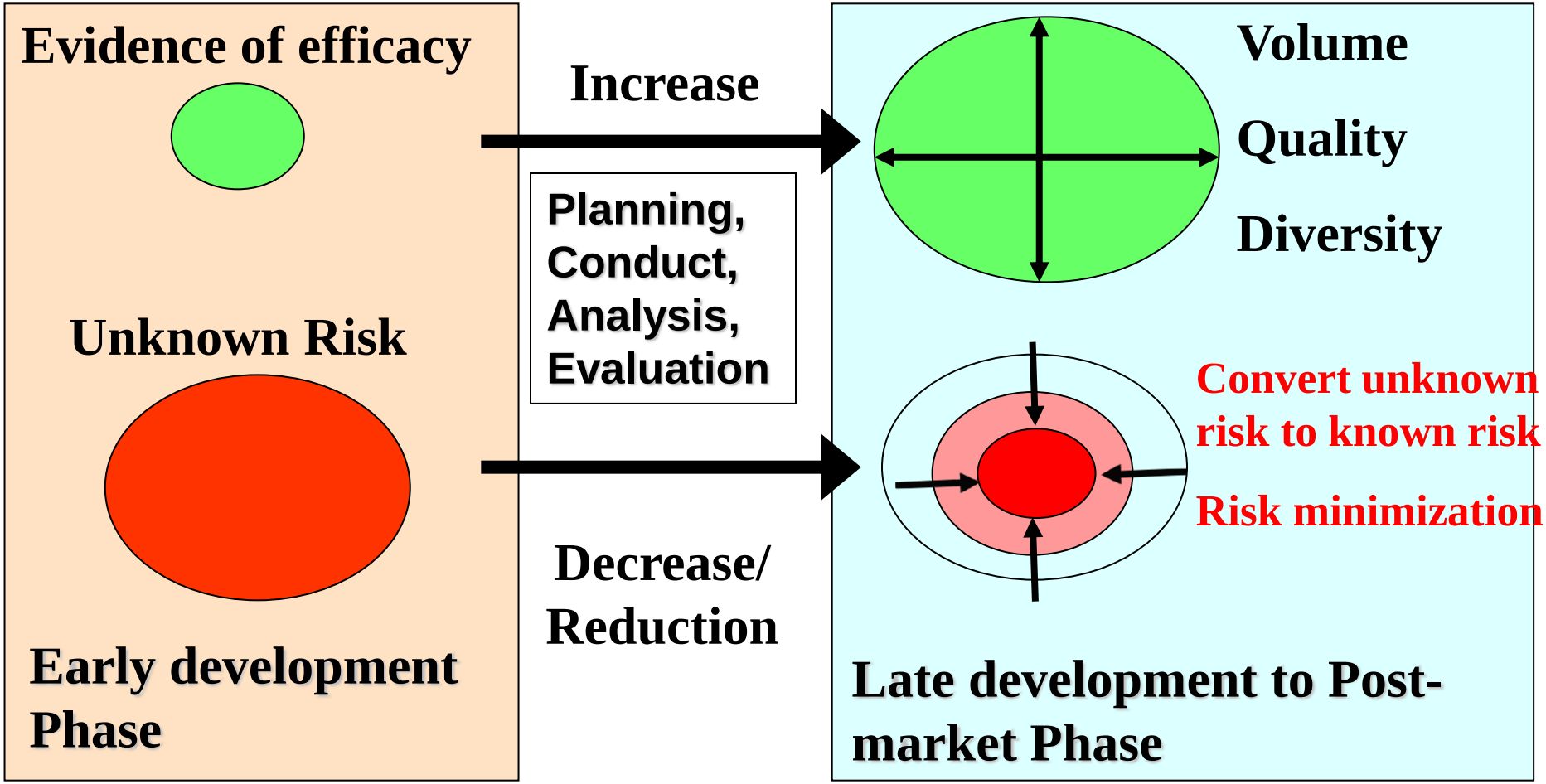


Global boom today! (EMA's site)

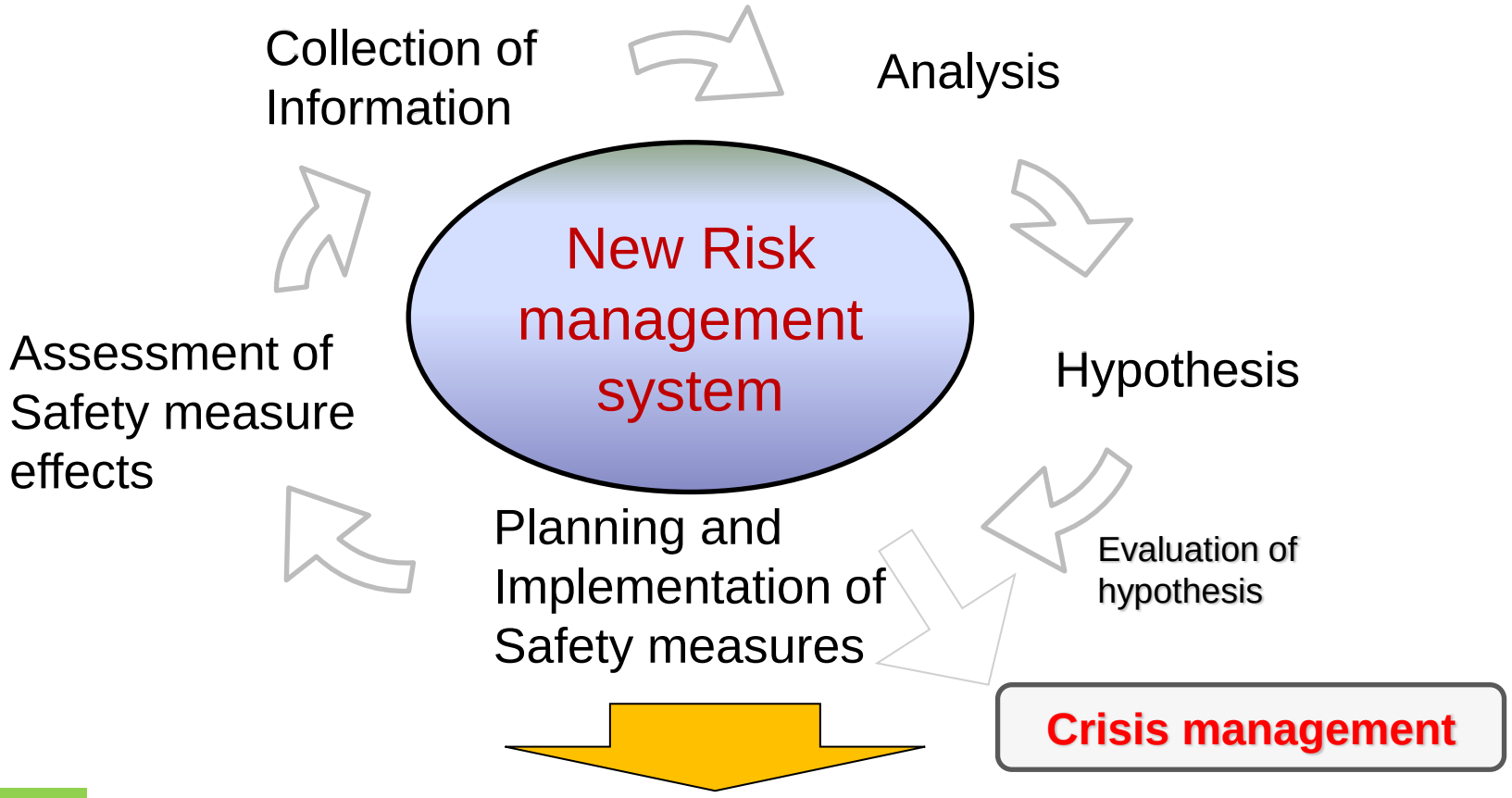


Global boom today! (FDA's site)

Continuous Improvement of B/R valance 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.

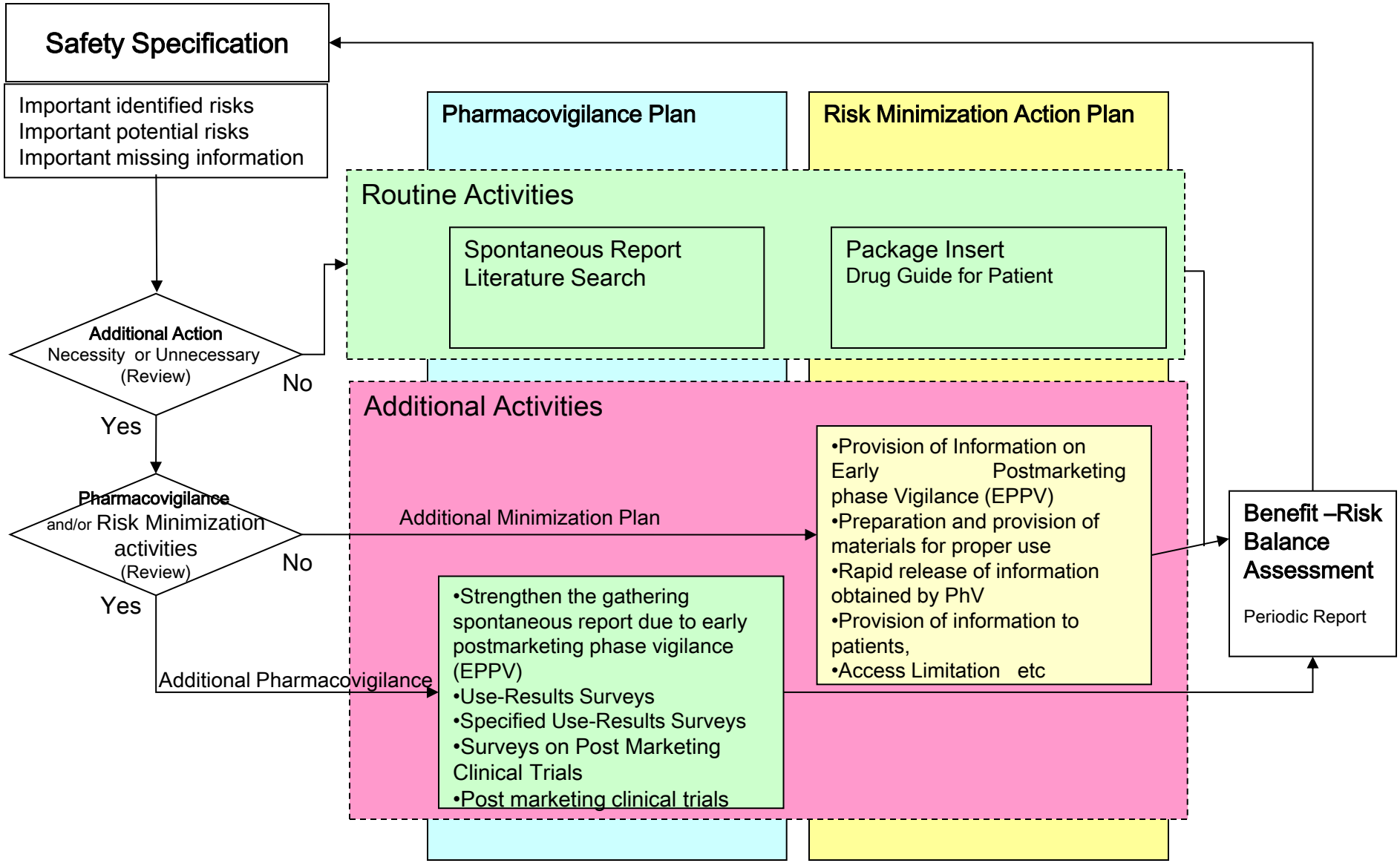
Risk Management Plan Guidance

- Risk Management Plan (RMP) Guidance was finalized on April 11, 2012

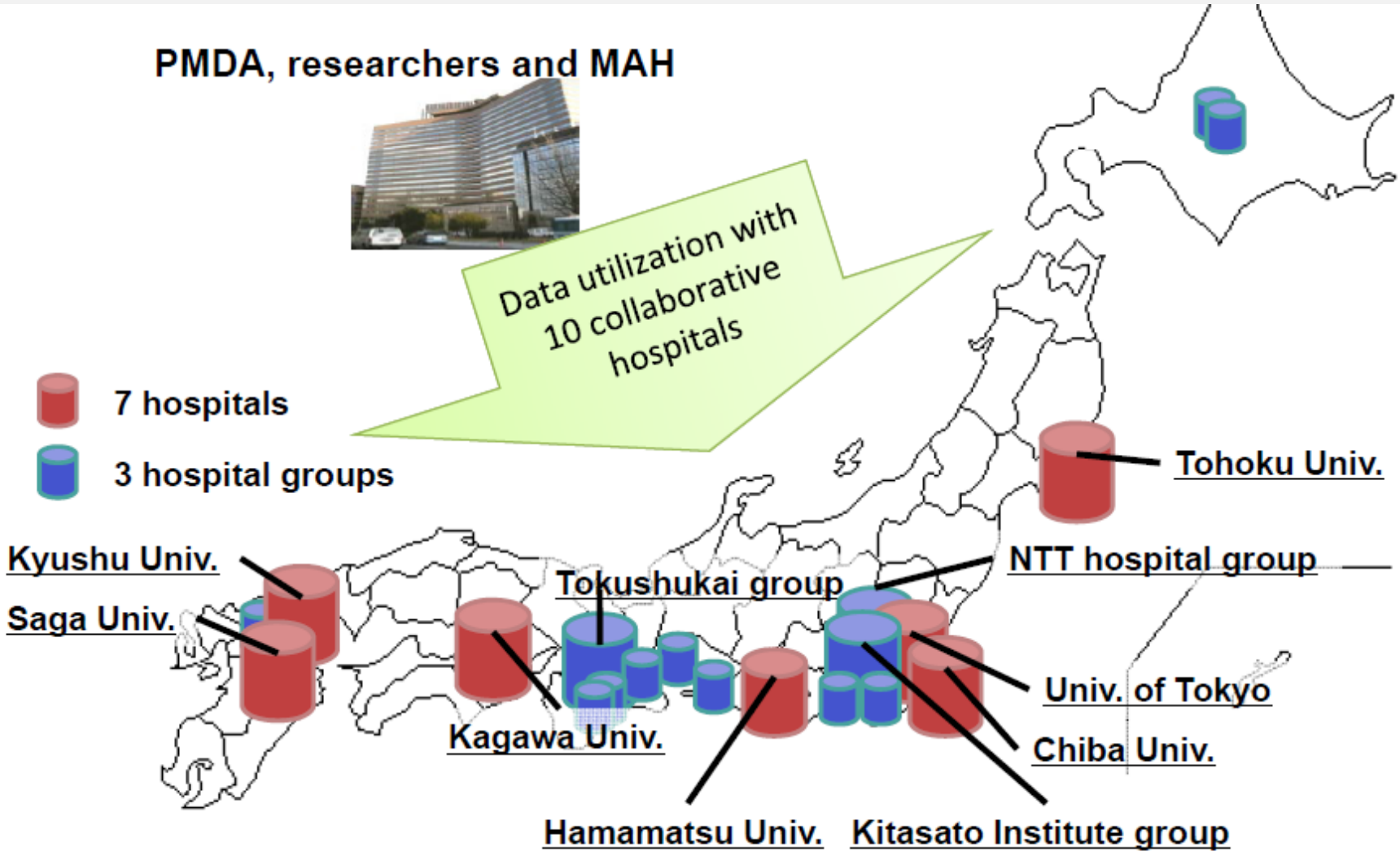
- This guidance is intended to propose a standard concept for “Pharmacovigilance Plan” and “Risk Minimization Plan”
By MAH (marketing authorization holder)

- 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 to10 millions patients data)



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

Key word : “Regulatory Science” & “Management”

All the players in good harmony

Thank you for your attention