PMDA Current Situation and Aim for the Future

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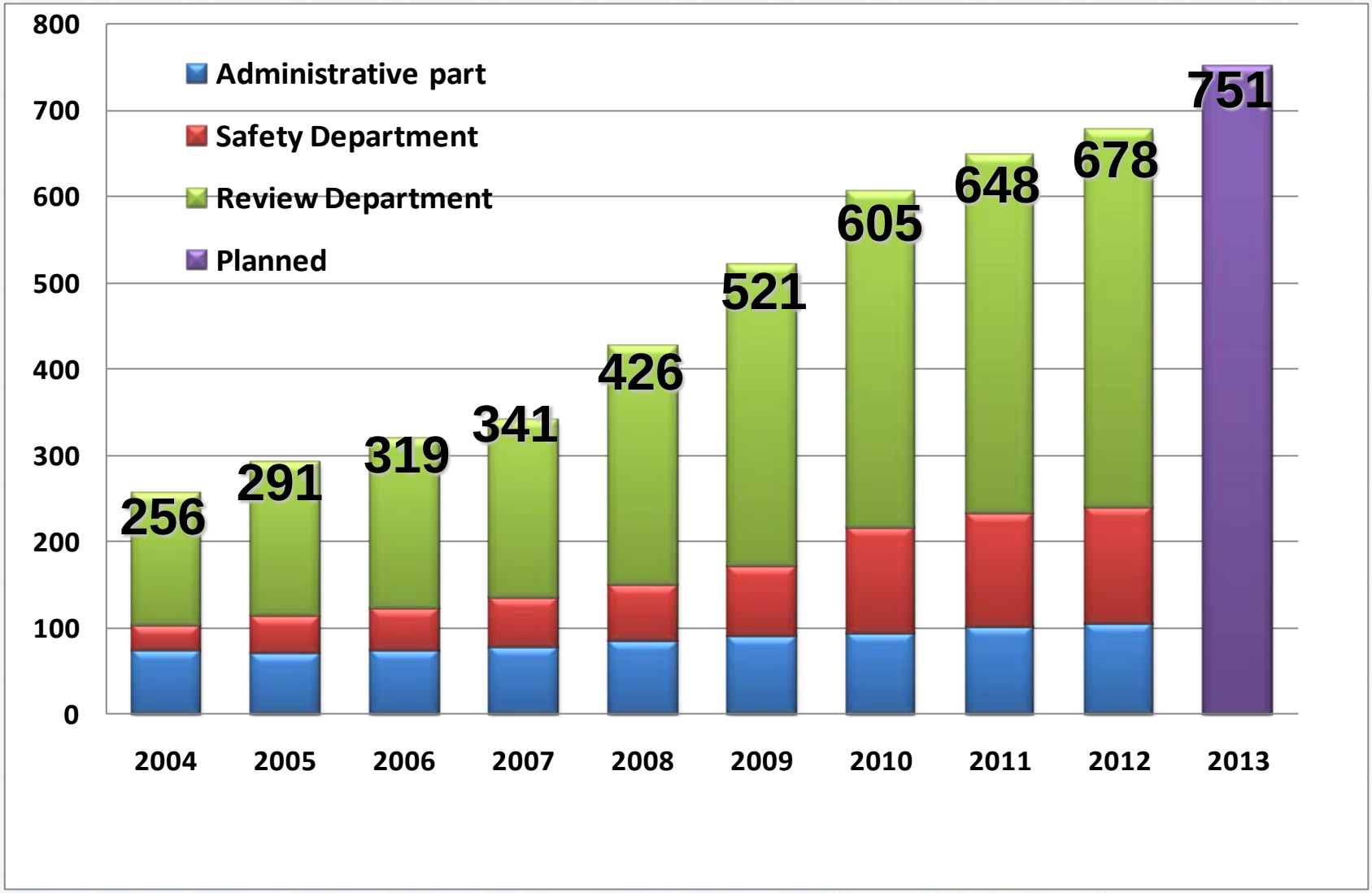
1. Organizational Updates

- Staff Size
- Strengthen Review System

PMDA Staff Size



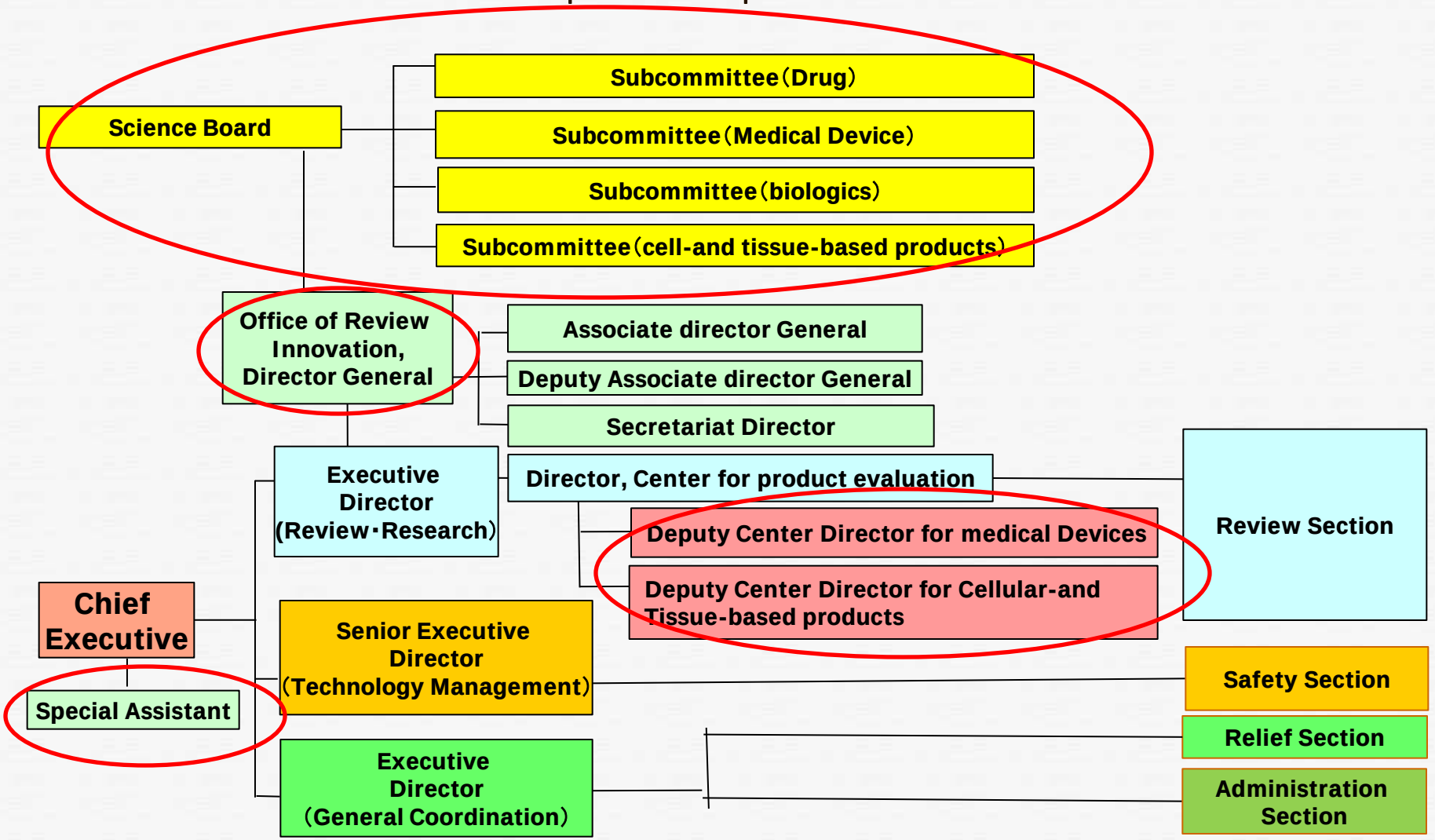
Strengthen Review System in PMDA-

- Special Assistant for Chief Executive (Feb. 2012)
- Office of Review Innovation (Apr. 2012)
- Science Board (May 2012)
- 2 Deputy Directors for Center for Product Evaluation (June 2012)

New Organization

- Enhance partnership with academia -

（as of June 2012）



2. Approval Review

- Review Time
- Drug Lag

Review Time for New Drugs

Priority Review Products

	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY2011 Target
Total Review Time (Month)	12.3	15.4	11.9	9.2	6.5	9
Regulatory Review Time	4.9	7.3	3.6	4.9	4.2	6
Applicant's time	6.5	6.8	6.4	3.4	2.0	3

Standard Review Products

Total Review Time (Month)	20.7	22.0	19.2	14.7	11.5	12
Regulatory Review Time	12.9	11.3	10.5	7.6	6.3	9
Applicant's time	7.9	7.4	6.7	6.4	5.1	3

Drug Lag against USA

(provisional calculations) (Years)

	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Pre-Application Lag	1.2	2.4	1.5	1.5	1.0
Post-App. (in Review) Lag	1.2	1.0	0.7	0.5	0.1
Drug Lag (Sum)	2.4	3.4	2.2	2.0	1.1

- Pre-Application Lag: Median years of difference between USA/Japan application for each product
- IN-Review Lag: Median years of difference between Review time (USA/Japan) for each product approved in Japan

To reduce Submission Lag

1. Promoting Global Clinical Trial

- Developing Guidelines
- Holding MRCT Workshop

2. Consultation

- Pharmaceutical Affairs Consultation on R&D Strategy
- Prior Assessment Consultation on Drugs

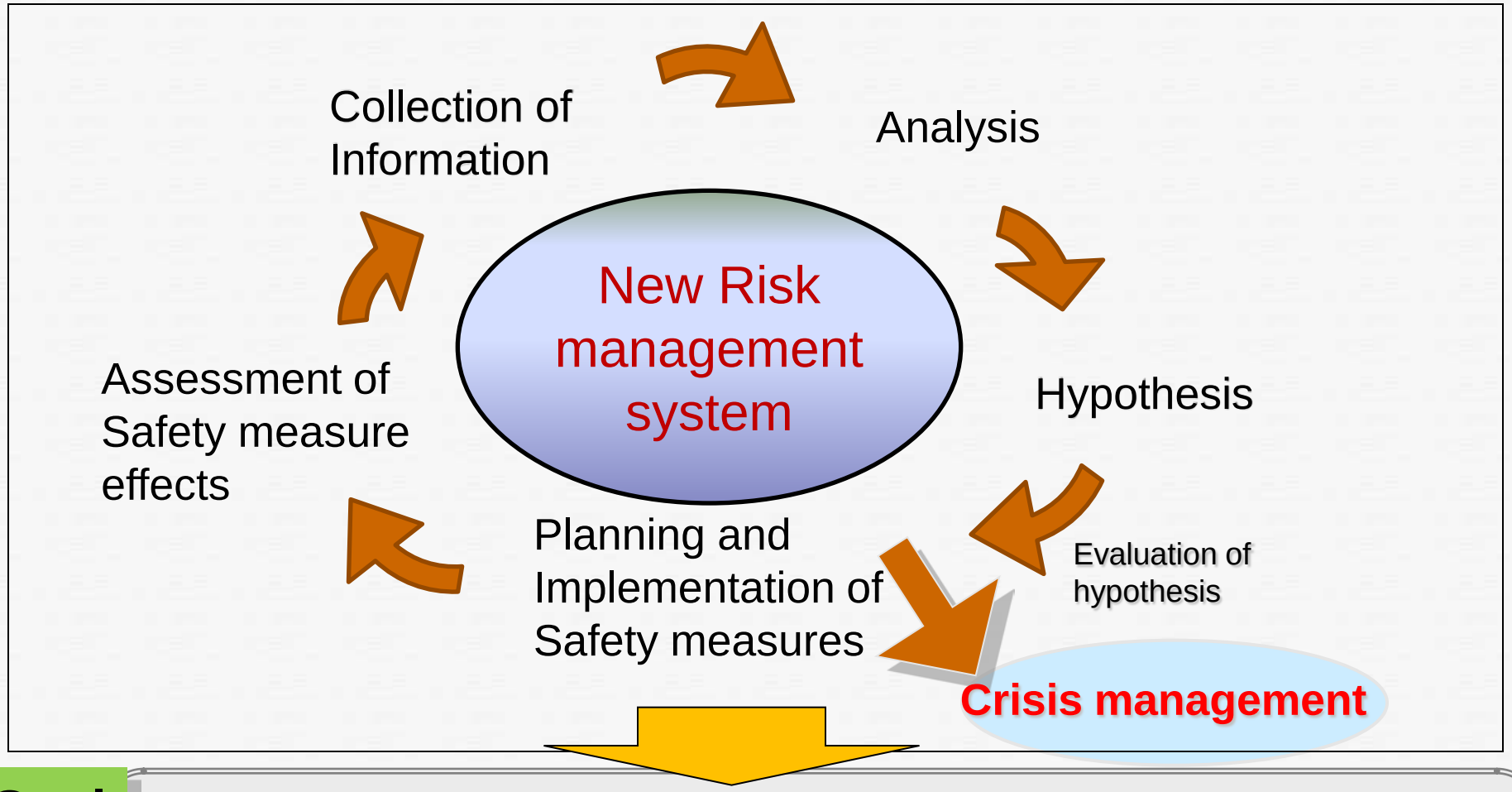
3. Efforts in Regulatory Science

- Collaboration with Academia
- Establishment of the Science Board
- MHLW/PMDA/Academia Collaborative Study

3. Safety Measures

- New Risk Management System
- Electronic Medical Record Network Project for Drug Safety

Improving Safety Measures

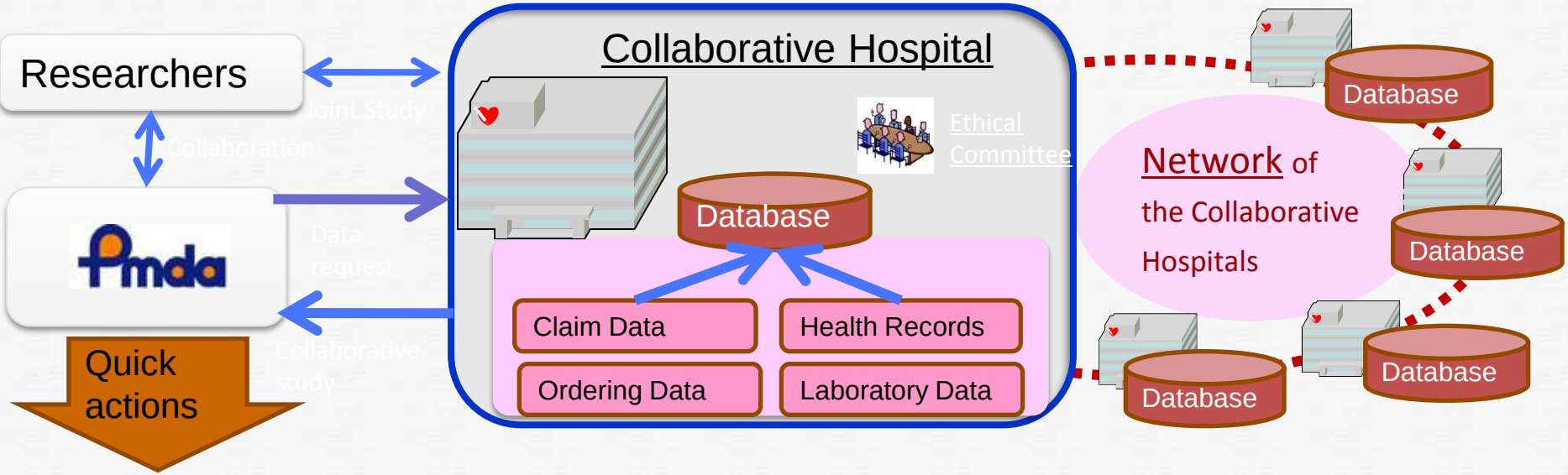


Goal

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

Electronic Medical Record Network Project for Drug Safety

- Budget approved FY2011 Governmental to initiate “Safety 10Mil. Data project”
- The network construction will be completed by FY2013.



Desired Outcomes:

- Risk & benefit review of medical technologies to provide safer healthcare.
- Quick and appropriate measures to ensure drug safety.

4. PMDA International Vision

PMDA International vision

PMDA EPOCH TOWARD 2020

Concrete goals for PMDA to attain by 2020 as one of world's premier medical products regulatory agencies

(Published in November 2011)

- PMDA *EPOCH* toward 2020 -

1. ***E***xcellence in ***P***erformance

2. ***P***artnership with the ***O***rient

3. ***C***ontribution to ***H***armonization

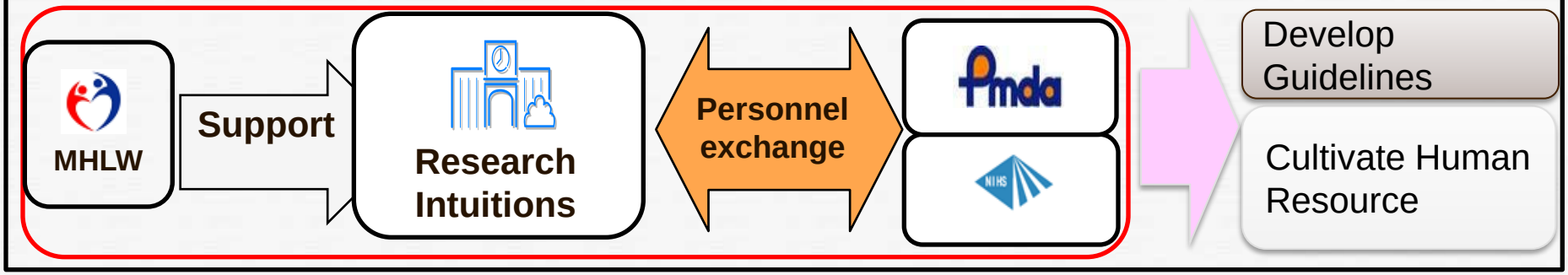
5. Regulatory Science

- MHLW/PMDA/Academia Collaborative Study
- Regulatory Science Cycle

MHLW /PMDA /Academia Collaborative Study (MHLW FY 2012 Budget)

1.2B yen (about $15M US)

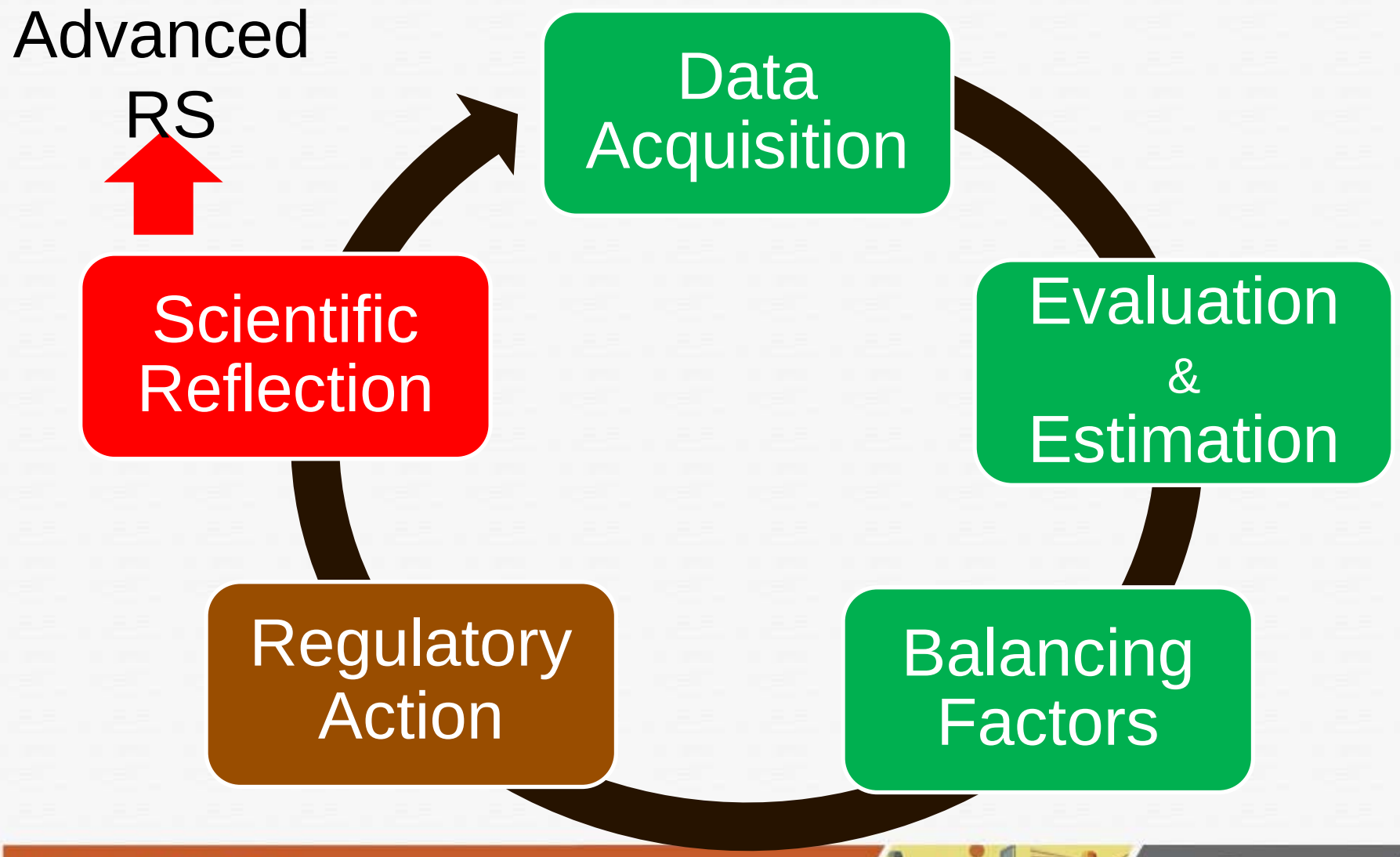
- Establishment of evaluation methods for safety and efficacy based on Regulatory Science
- Enhancement of personnel exchange among PMDA, Research Institutes, NIHS



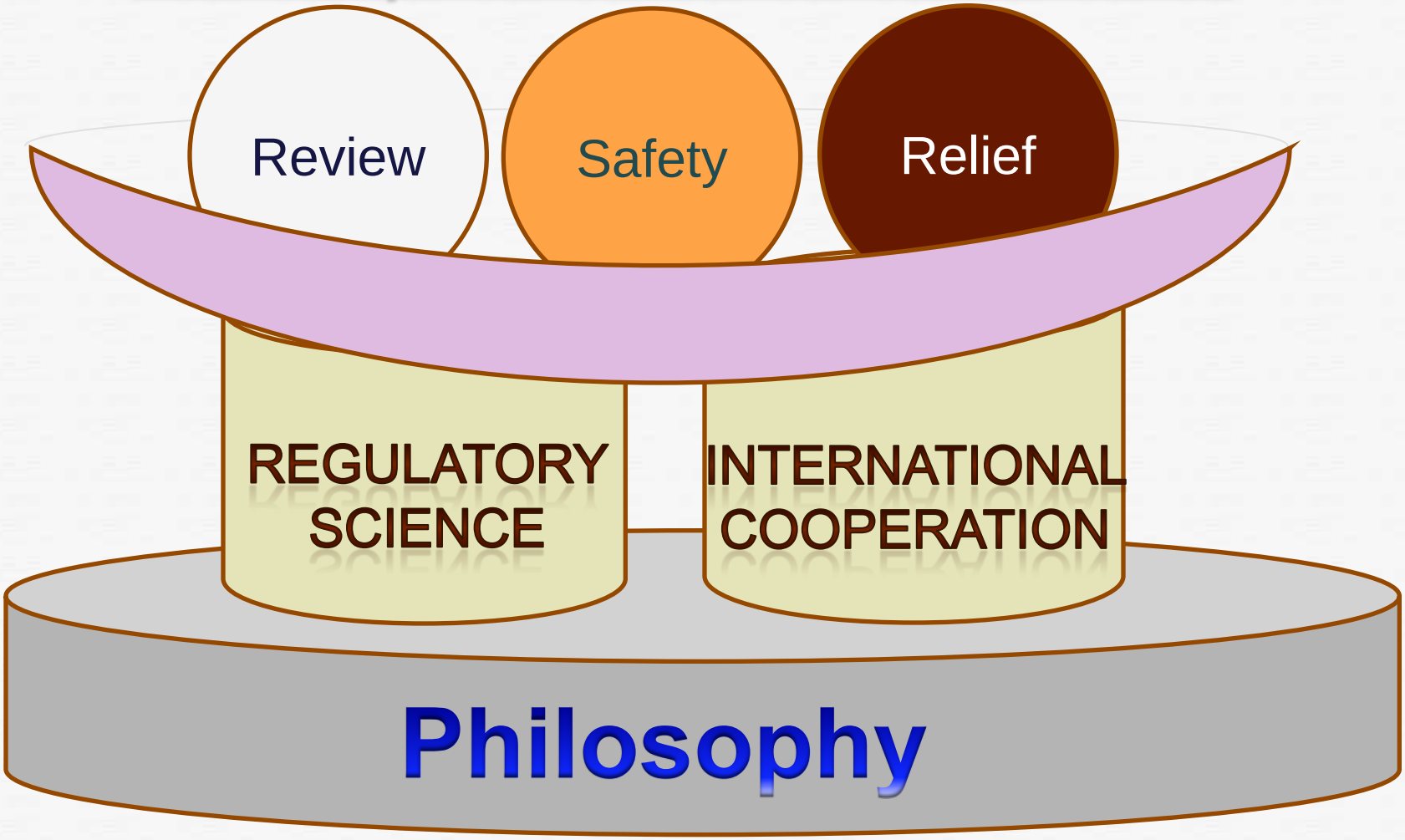
366M yen (about $4.6M US) for;

- **Developing guidance for innovative drug/medical device/biologics to streamline review process**

Regulatory Science Cycle



To Improve Public Health



Thank you
for
your attention!