

Regulatory use of innovative tools in drug development

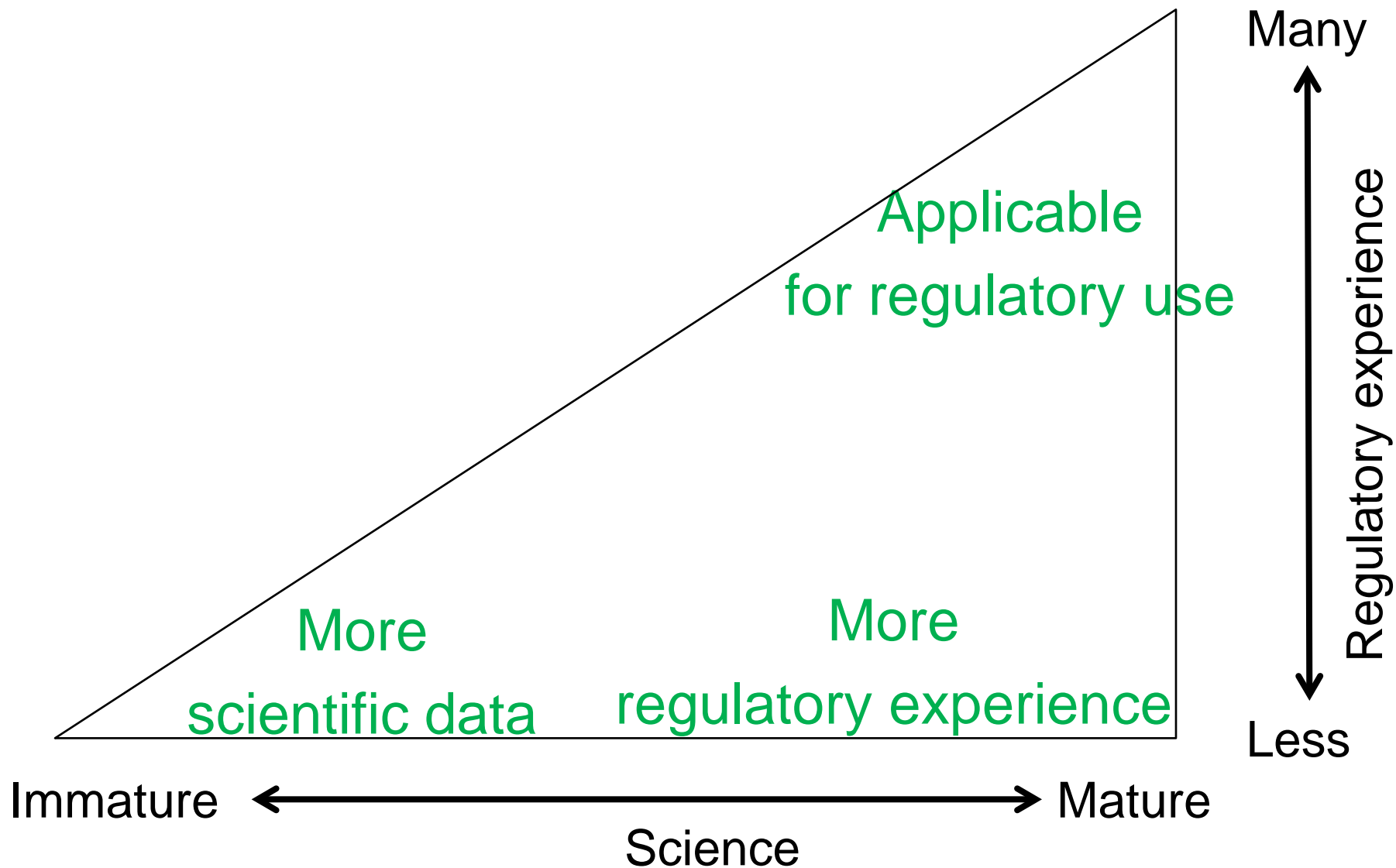
Yoshiaki Uyama, Ph.D.

Pharmaceuticals & Medical Devices Agency (PMDA)

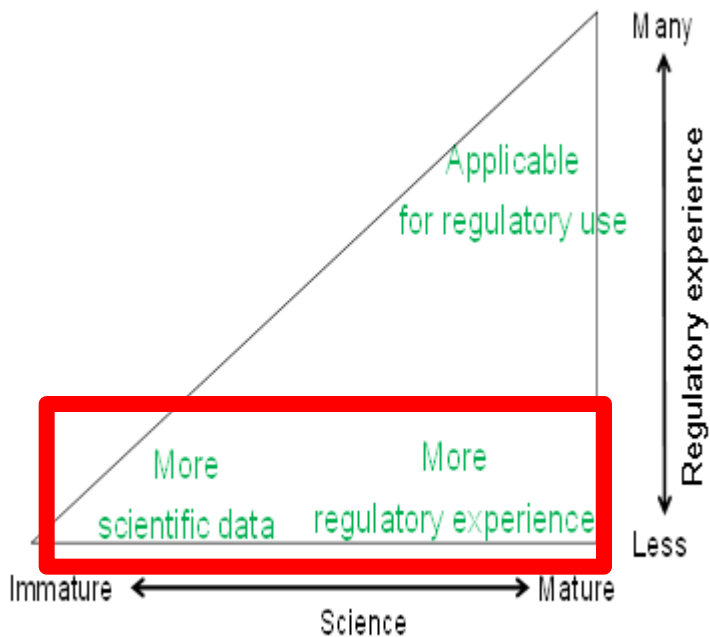
Visiting Professor, Graduate School of Advanced Clinical Science, Chiba University

Visiting Professor, Graduate School of Medicine, Nagoya University

Innovation & Regulatory Experiences



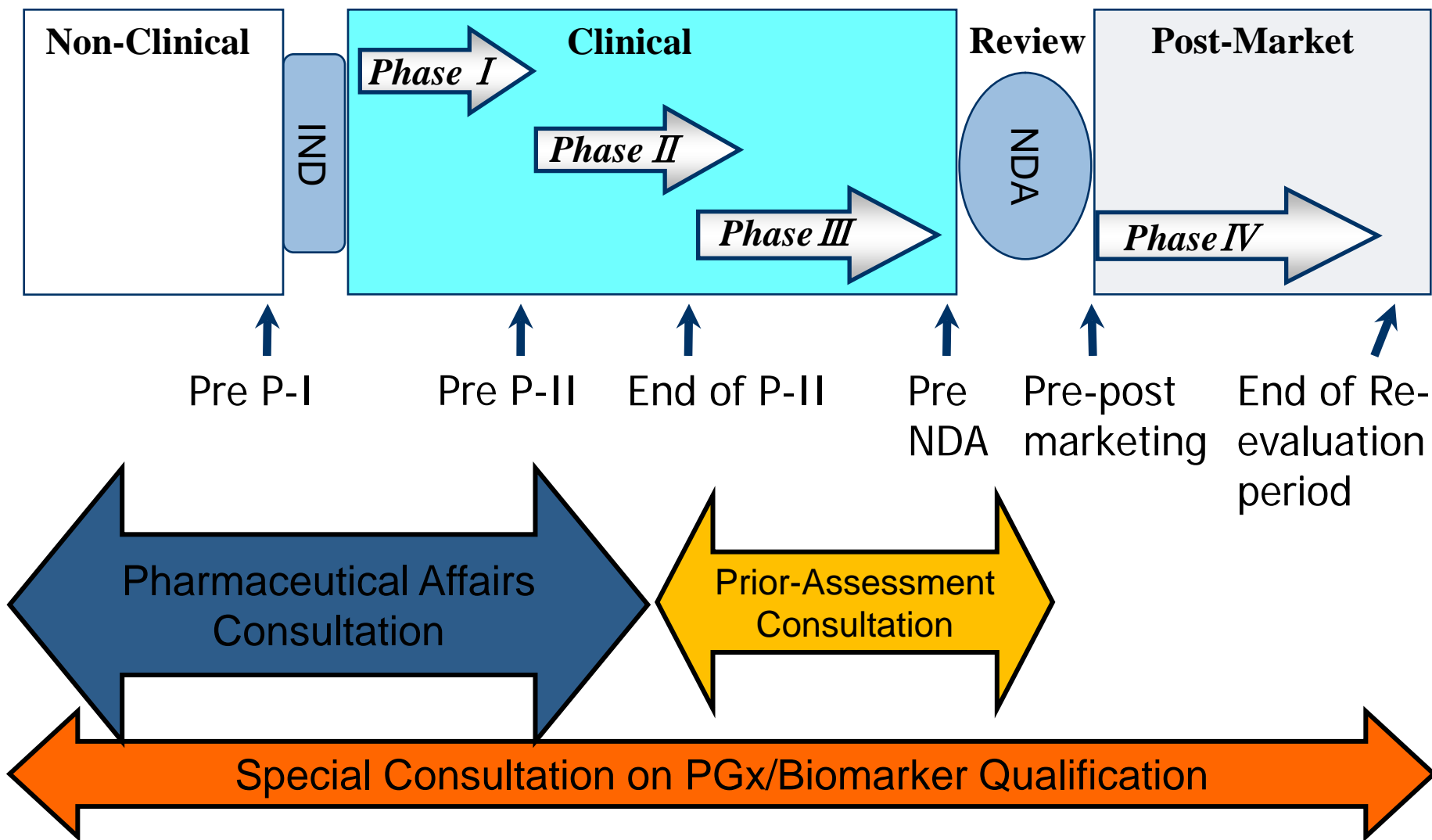
PMDA's approaches to promote scientific innovation in drug development



- Encouraging an exploratory use in drug development
 - Formal/informal scientific discussion
 - ◆ Scientific consultation
 - ◆ Scientific conference/workshop
- More cooperation with academia
 - Science Board
 - Human resource exchange program
 - Collaborative graduate school program

Recent PMDA's initiatives to advance “Regulatory Science”

Scientific Consultations & Drug Development Stage



Modified from Figure by Ichimaru K et al, *Clin Pharmacol Therapeut*, 88: 454-457, 2010

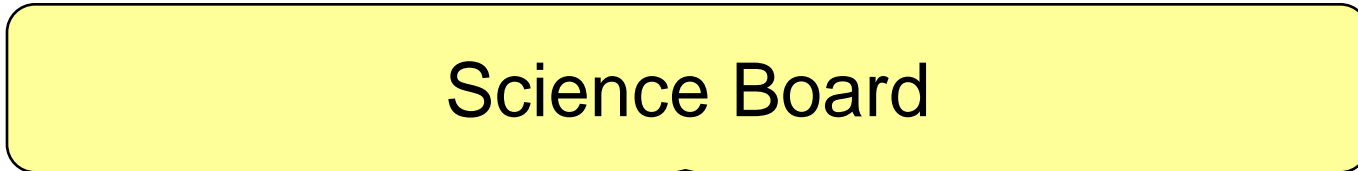
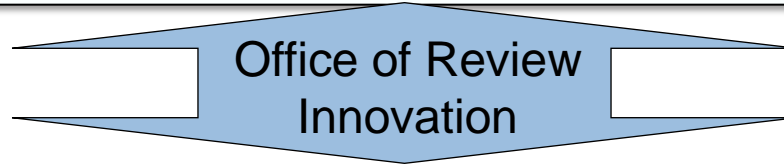
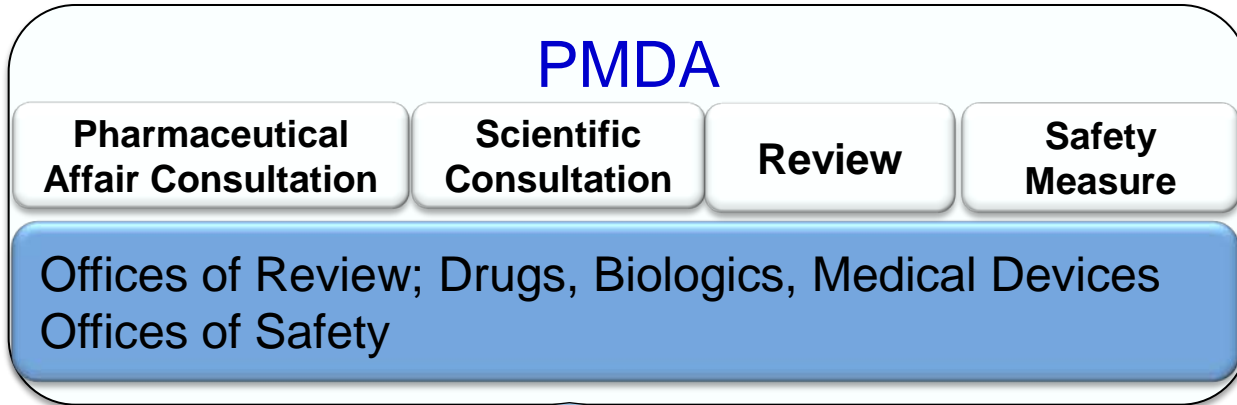
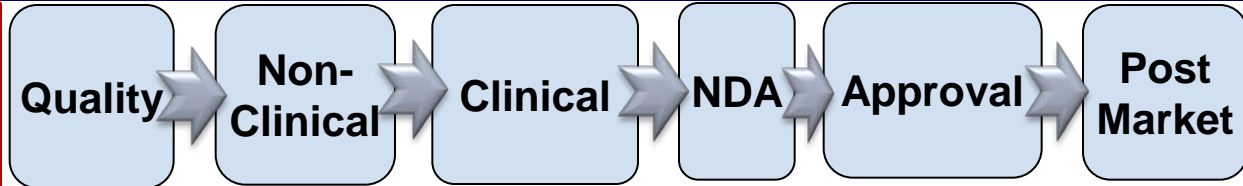
PMDA Science Board

Basic Research

Seeds of medical products discovered in Japan

Discovery in Basic research
e.g;

iPS 



Practical Use

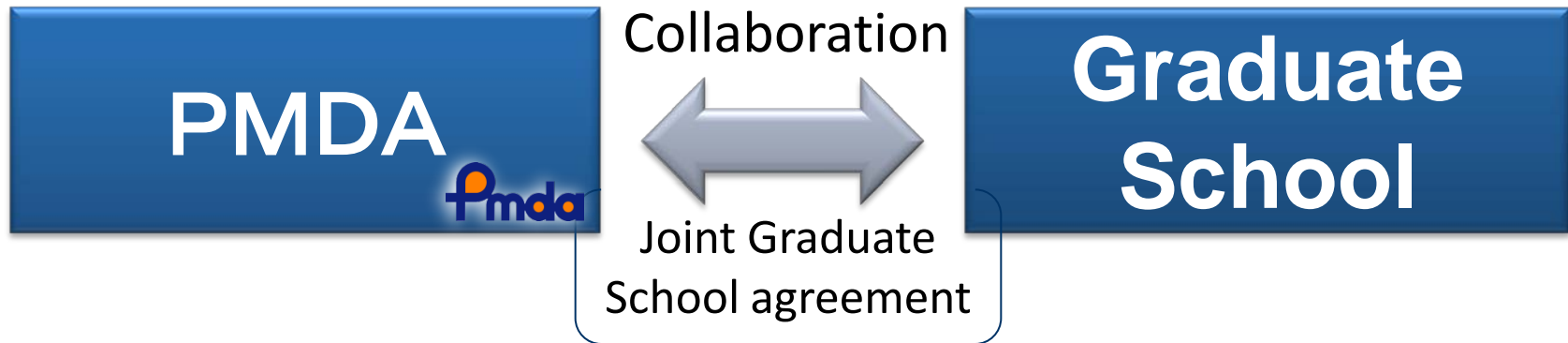
Innovative Medical Products



e.g.;

HAL

iPS-derived products 

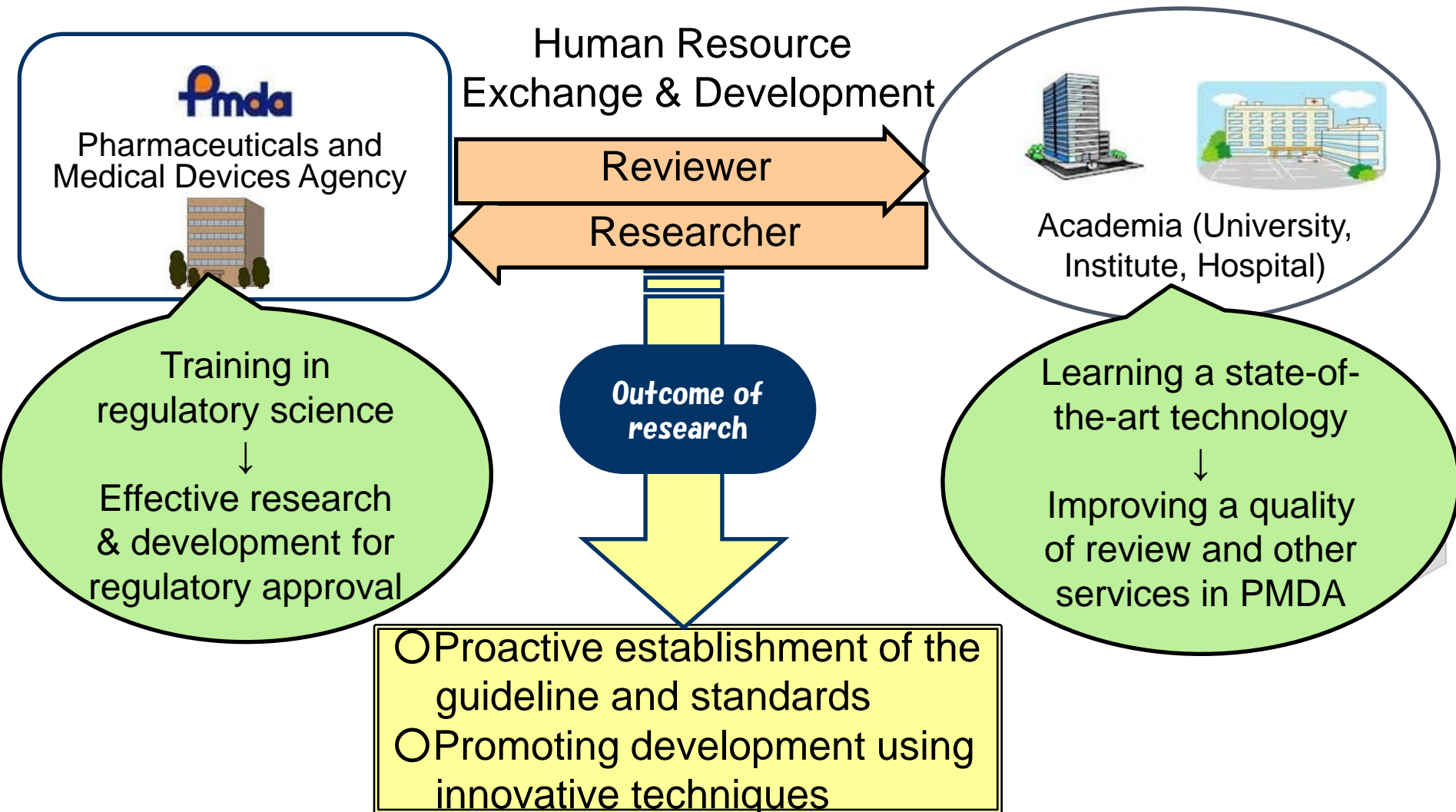


- PMDA Staff The agreement with 17 Universities (as of March 2013)
 - Visiting Professor (Lecture in regulatory science)
 - Graduate student (Ph.D. program); Research in University

- University student
 - Graduate student (Ph.D. program); Research in PMDA

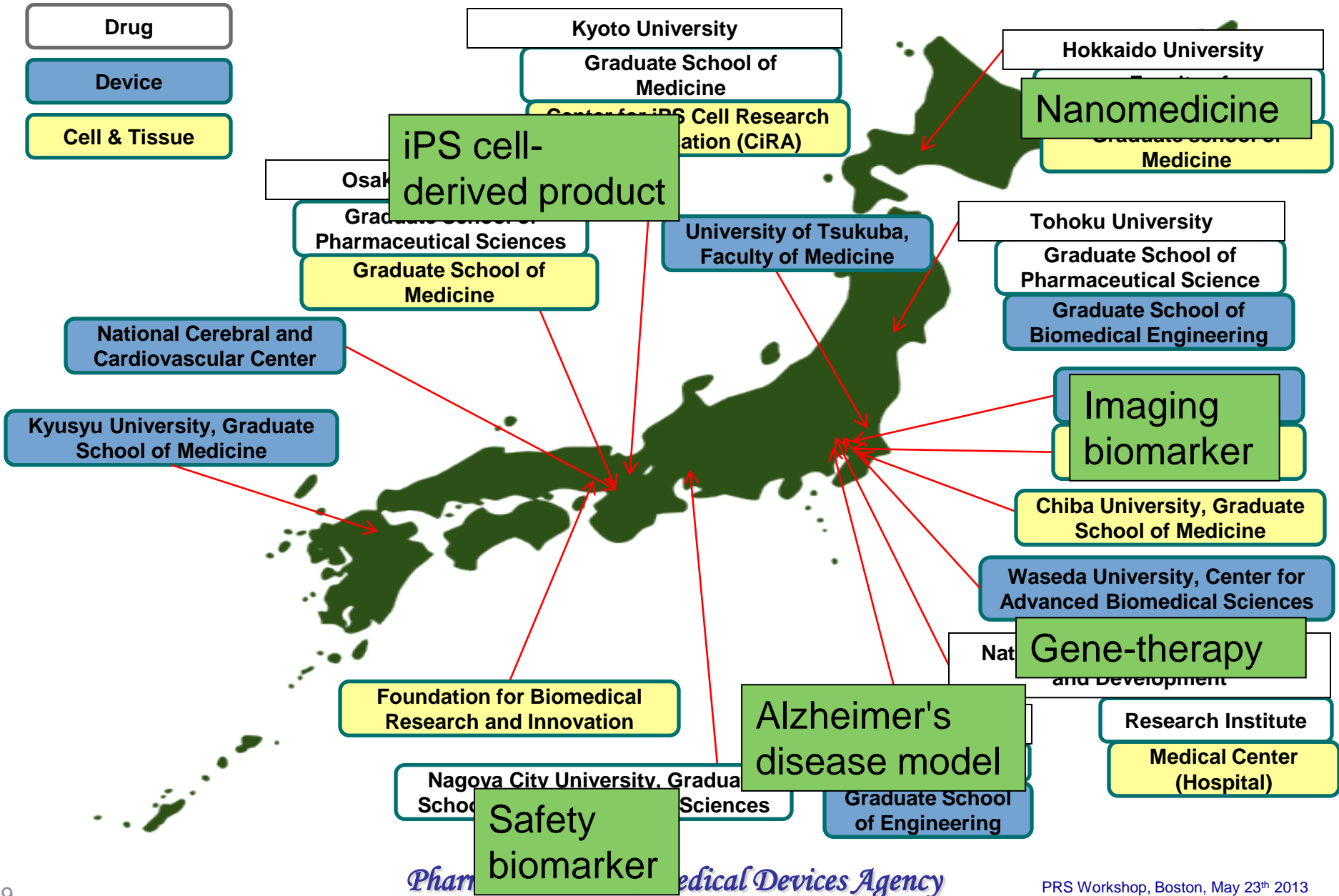
Regulatory Science Research & Human Resource Exchange Program

(for developing innovative drug, device, cell & tissue products for practical use)

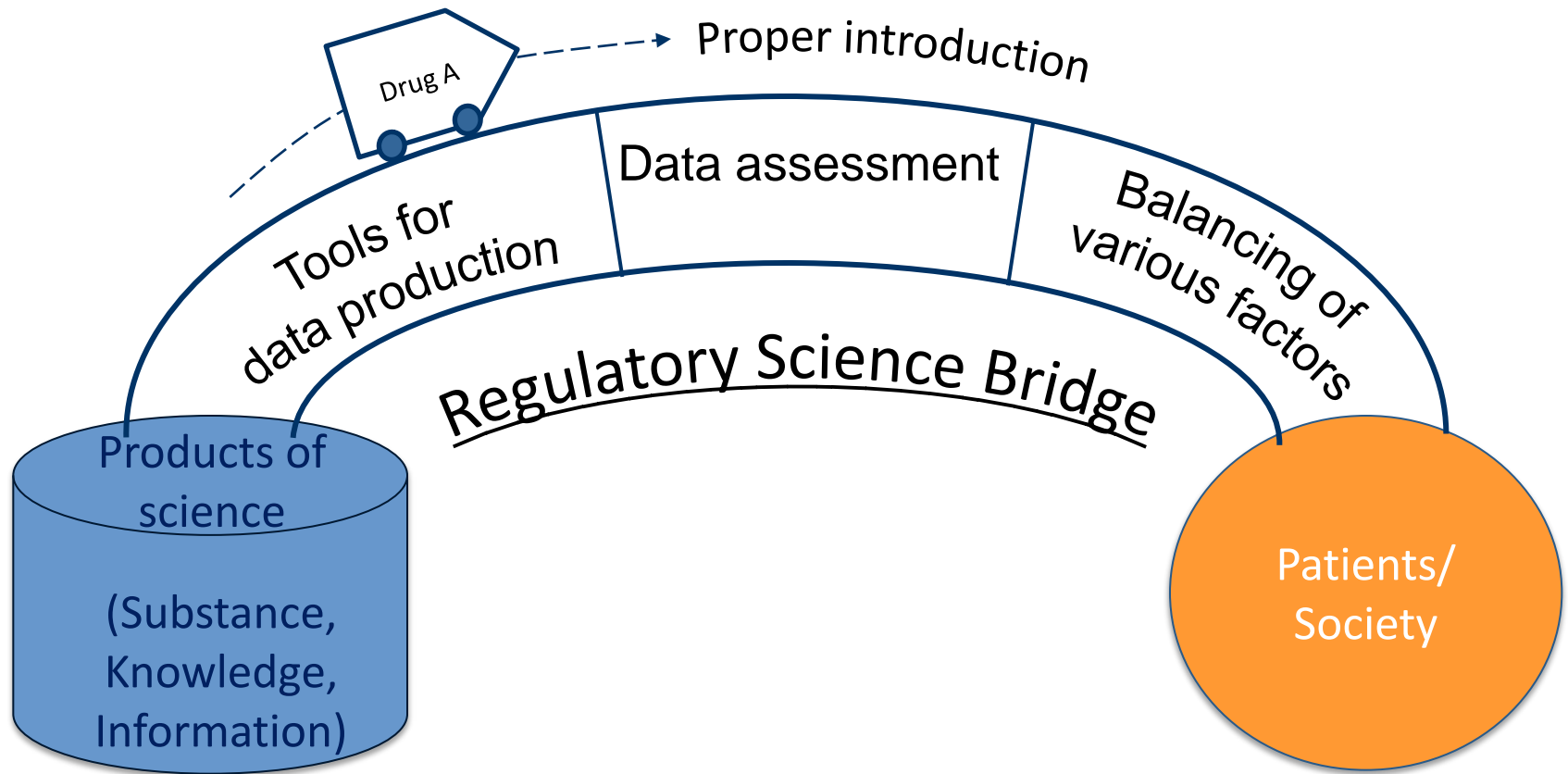


Research funds for developing innovative drug, device, cell & tissue products for practical use

- Drug
- Device
- Cell & Tissue

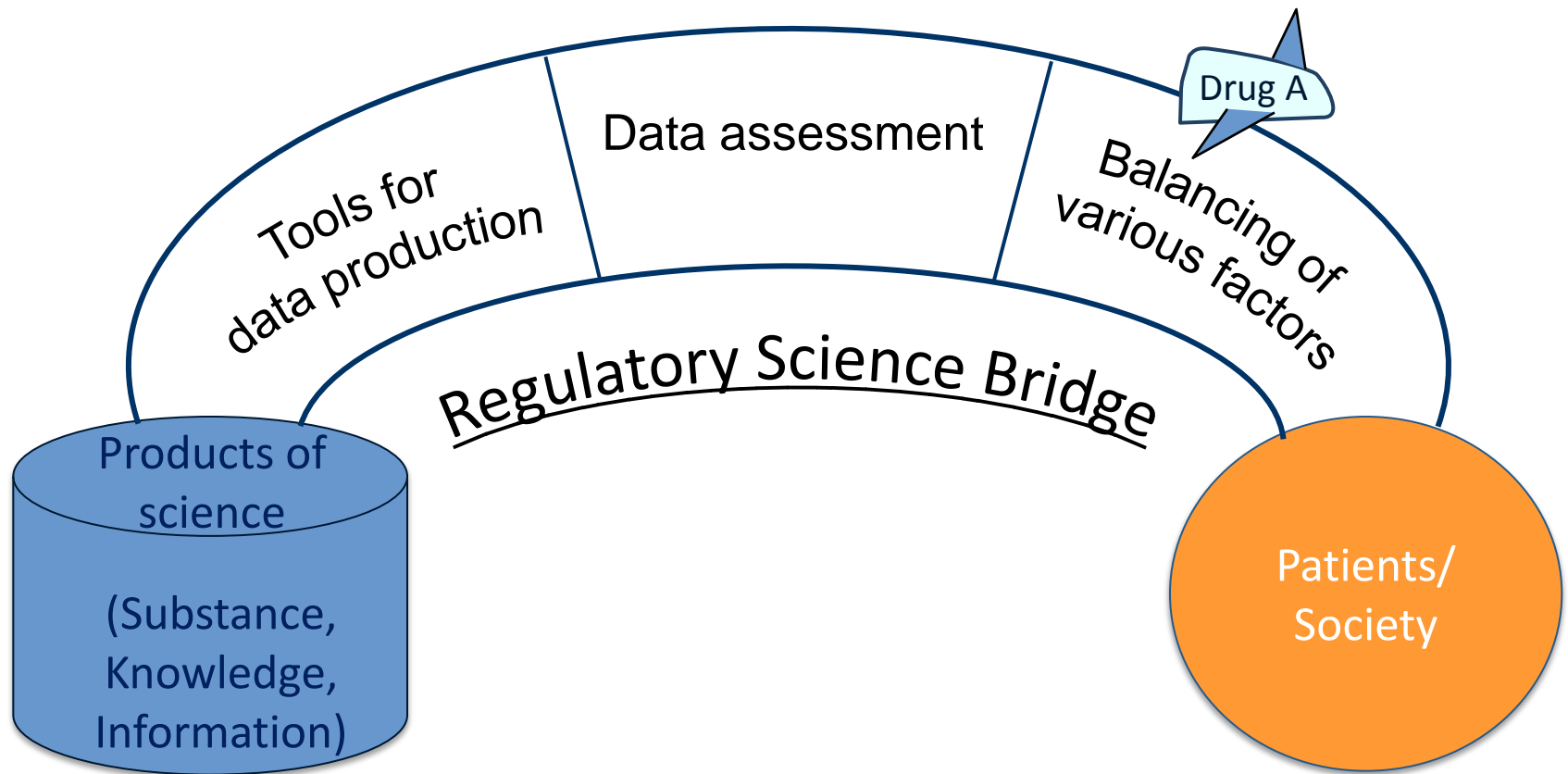


Regulatory Science Bridge



Tominaga T et al, *Clin Pharmacol Ther*, 90: 29-31, 2011

Regulatory Science Bridge



**Stronger & More Complete Regulatory Science Bridge
will help us in the future drug developments**

Tominaga T et al, *Clin Pharmacol Ther*, 90: 29-31, 2011

- HOMEPAGE (English)
<http://www.pmda.go.jp/english/index.html>
- Regulatory Science Page
<http://www.pmda.go.jp/regulatory/index.html>
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Thank you for your attention