What Can PMDA do in early development stage of Medical Devices?

Atsushi TAMURA, PhD
International Coordination officer for Medical Devices,
Pharmaceuticals and Medical Devices Agency

Agenda

- PMDA Update
- PMDA's consultation
- Current Status of Pharmaceutical Affairs Consultation on R&D Strategy

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)

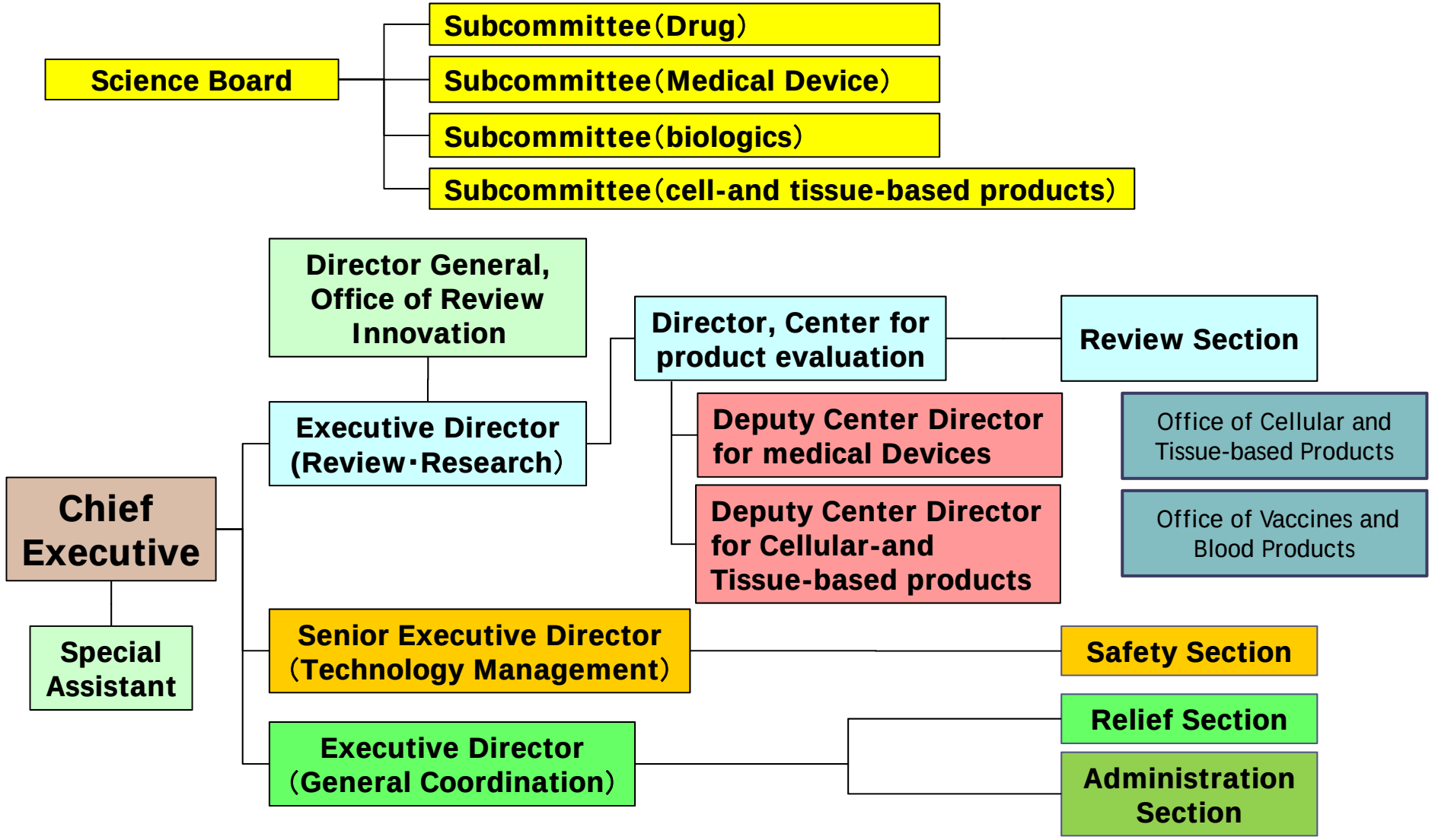
Organizational Changes(Oct. 2012)

- Office of Cellular and Tissue-based Products (cellular and tissue-based products, CMC of gene therapy products, CMC/quality of biologics, biosimilars, Cartagena Act relatedwork)
- Office of Vaccines and Blood Products (vaccines, blood products, antitoxins)

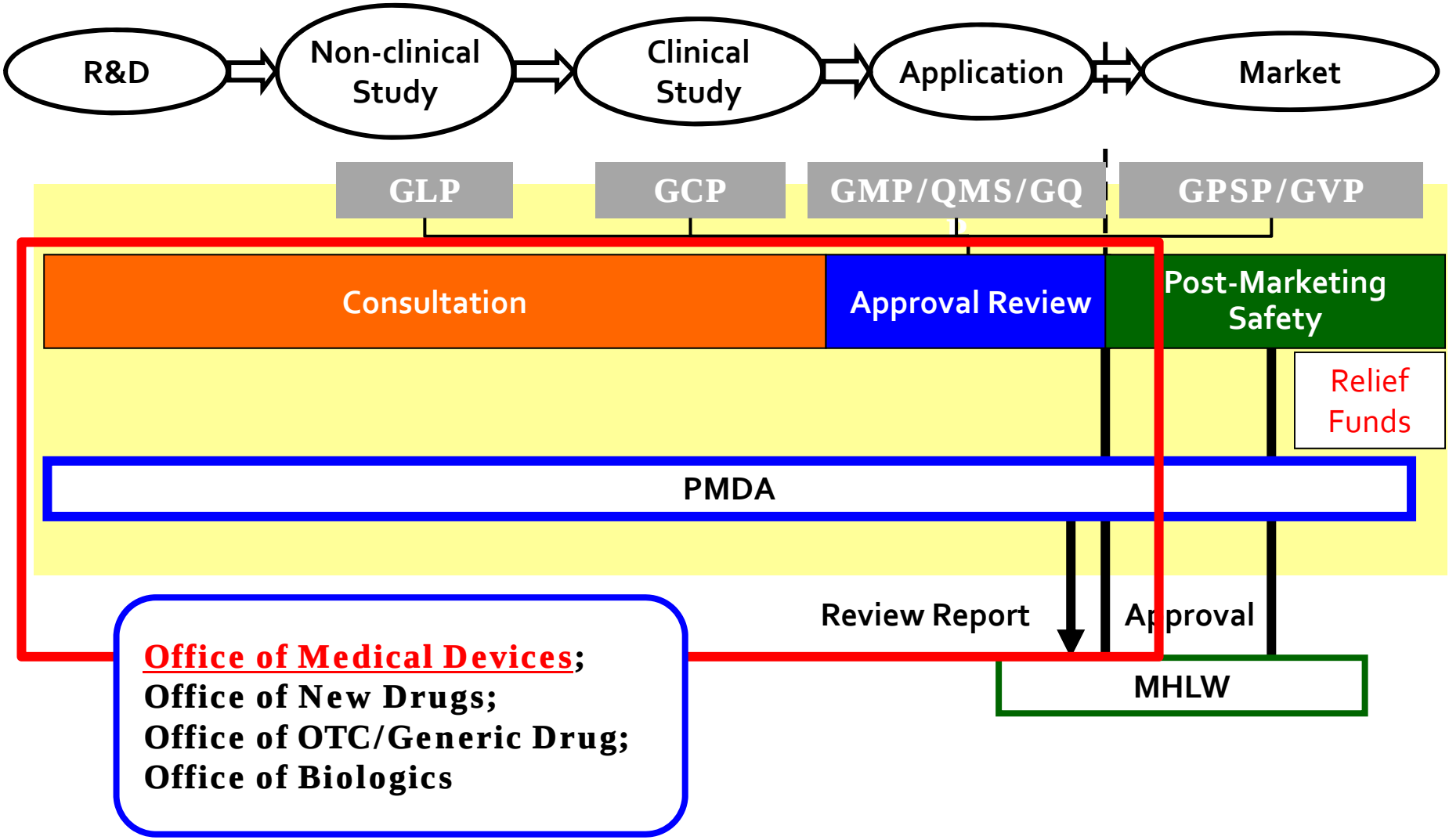
Strengthen Review System in PMDA

- Enhance partnership with academia -

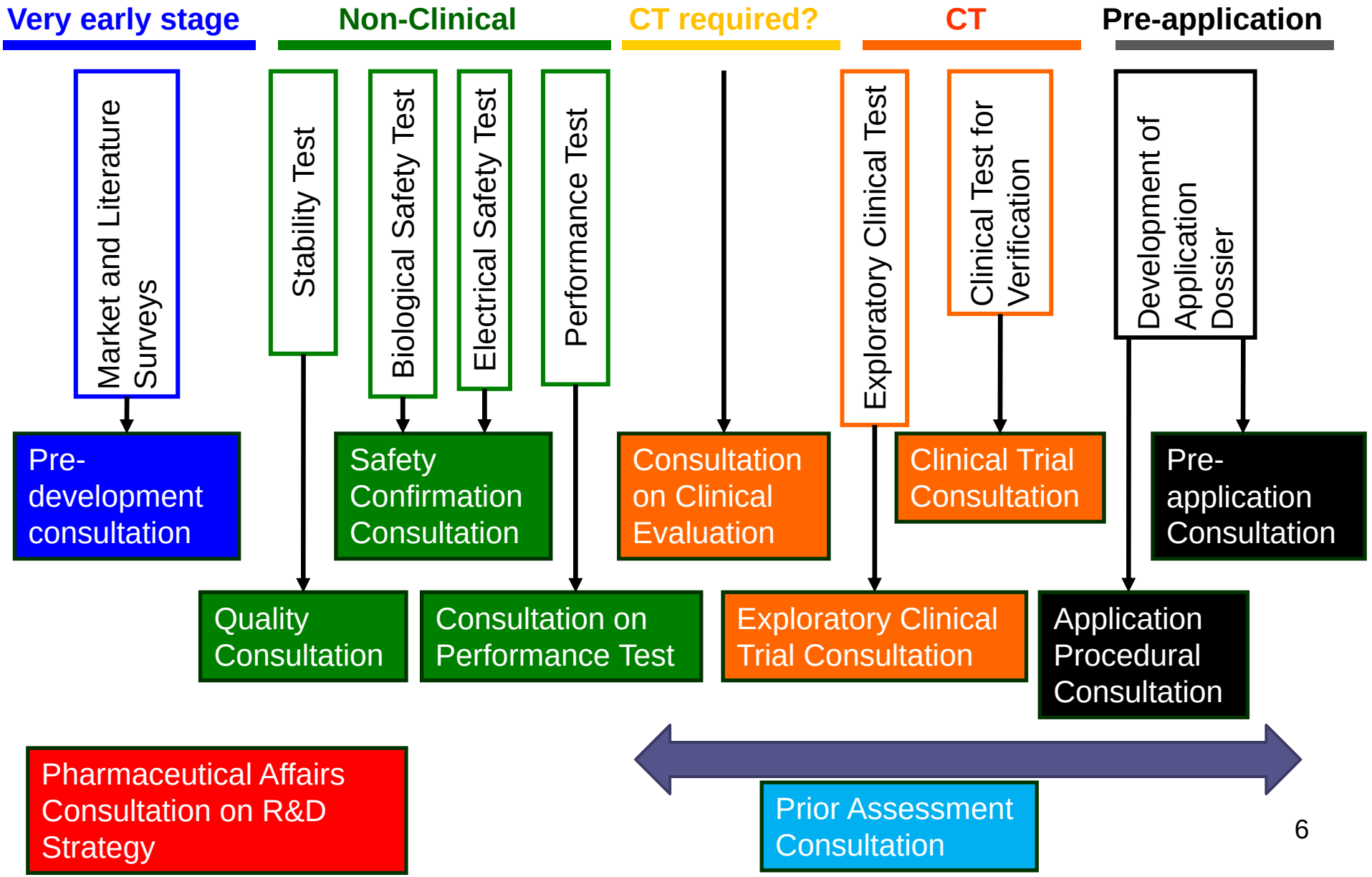
Set up Office of Review Innovation (April 2012) and the Science Board (May 2012)



Roles of PMDA



PMDA's Consultation Menu



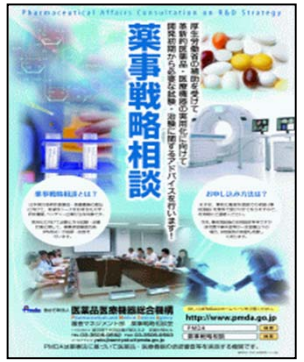
Pharmaceutical Affairs Consultation on R&D Strategy

- Background:
  - Universities, Research institutes and venture companies are unfamiliar with the development strategy on the Pharmaceutical Affairs Law
- Purpose:
  - Early approval of innovative drugs and medical devices made in Japan
  - Elimination of drug lag and device lag

Pharmaceutical Affairs Consultation on R&D Strategy

- Major target :
  - Universities, Research institutes and venture companies which have valuable technology and desire medical application
- Summary:
  - Since very early stage, PMDA advises the R&D strategy regarding non-clinical/clinical studies necessary for approval
- *Please contact us!!*

Pharmaceutical Affairs Consultation on R&D Strategy



Pmda

Strategic Consultation

Basic Research

Pharmaceutical and Medical Devices candidates originating from Japan

Quality Study

Non-Clinical Study

Clinical Trial

Up to the level of POC studies

Practical Use

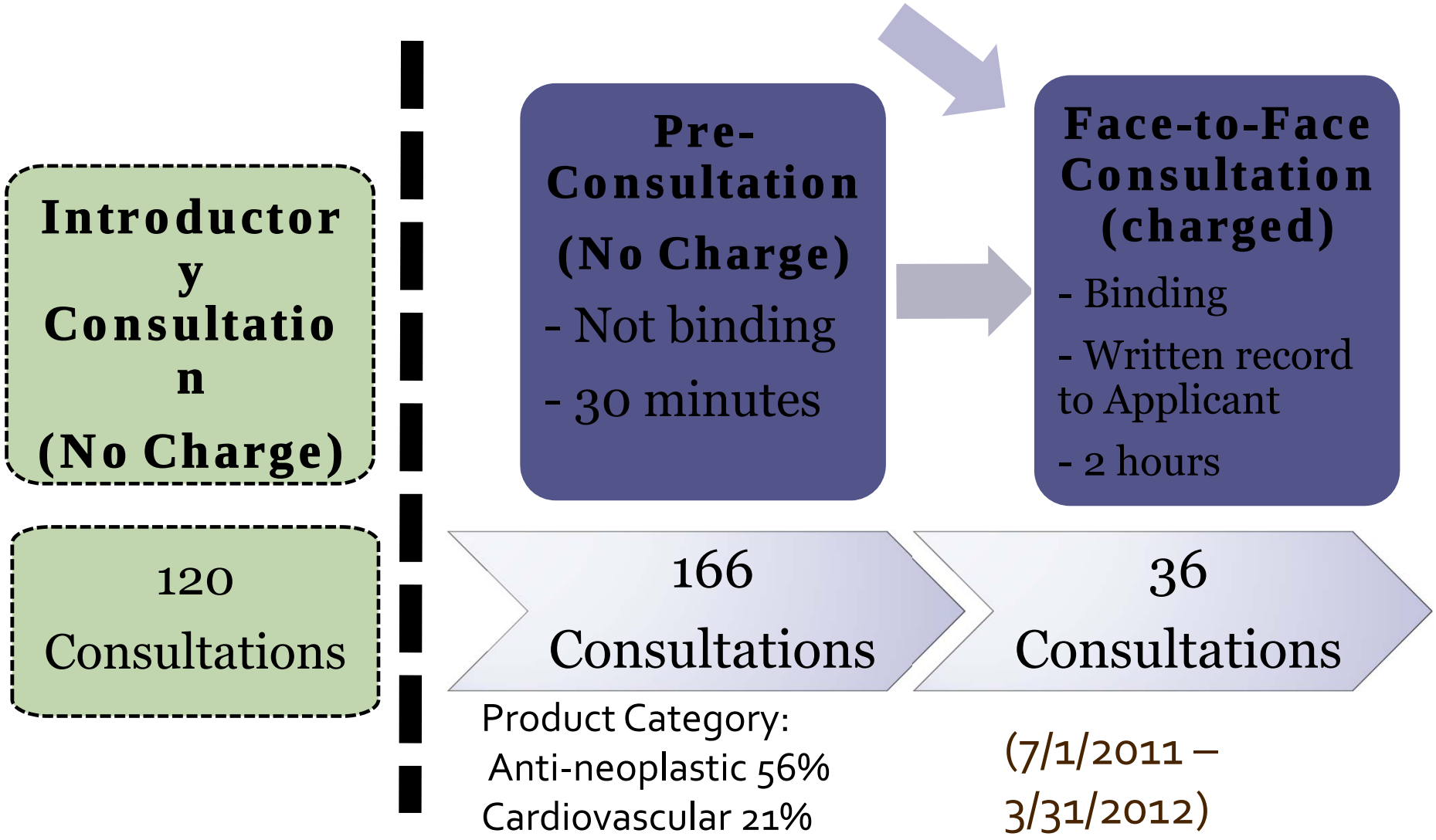
Innovative Products originated from Japan

* Further studies are handled by the Regular Consultation

Consultation on quality or toxicity study of biologics, cell-and tissue-based products

Consultation on endpoints or sample size of early clinical trial

Flow of R&D Strategy Consultation



Thank you!!

http://www.pmda.go.jp/english/

Pharmaceuticals and Medical Devices Agency