PMDA's effort to accelerate medical devices development

-Introduction of PMDA's development support systems

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Today's Topics

- Introduction
- What is "Device Lag"?
- Acceleration of Medical Devices development
- Overview of PMDA's development support systems

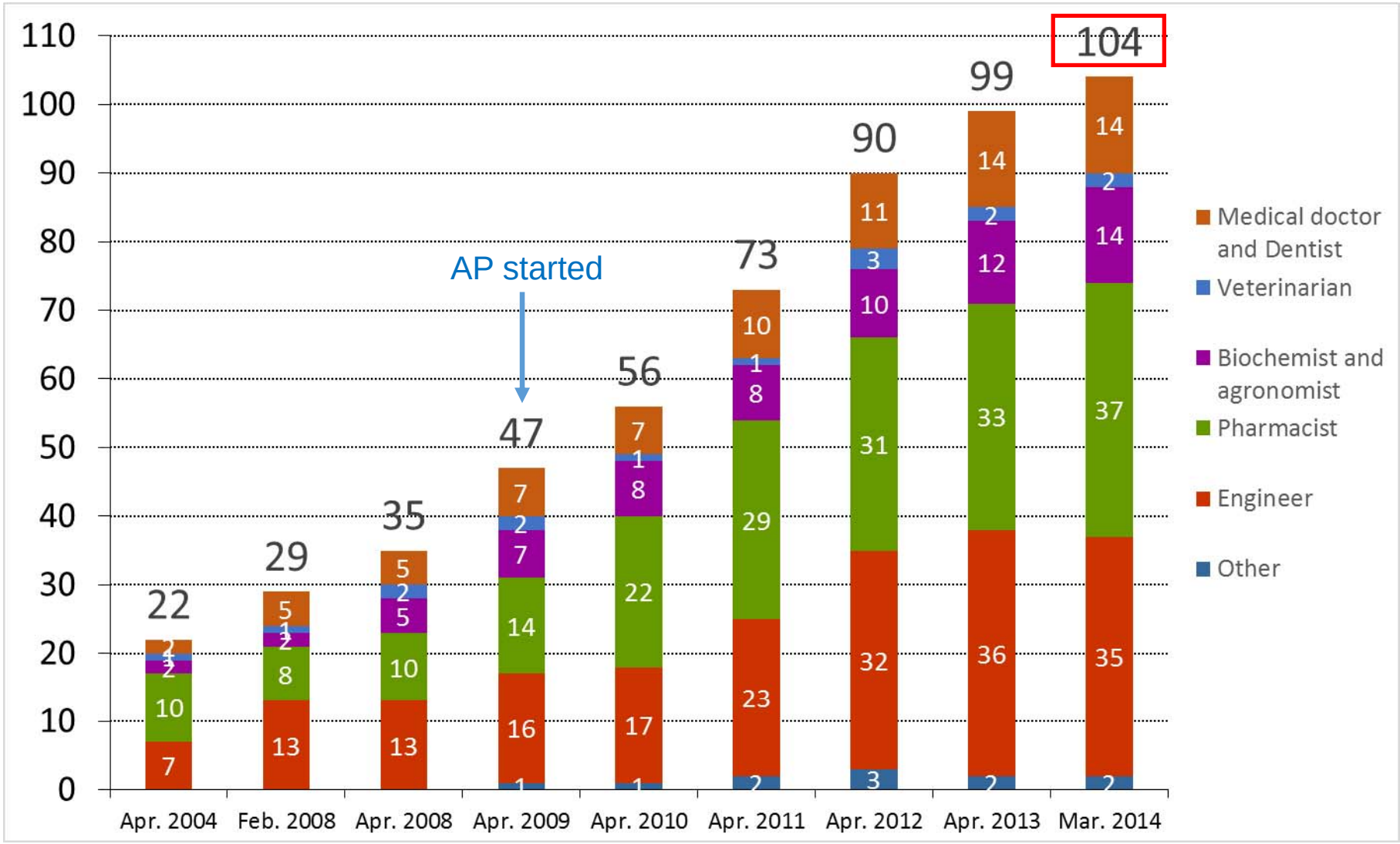
Review Teams for MDs/IVDs

OMD I & II: New/Improved Device Teams 1-8

OMD III: Me-too Device Teams 1-8

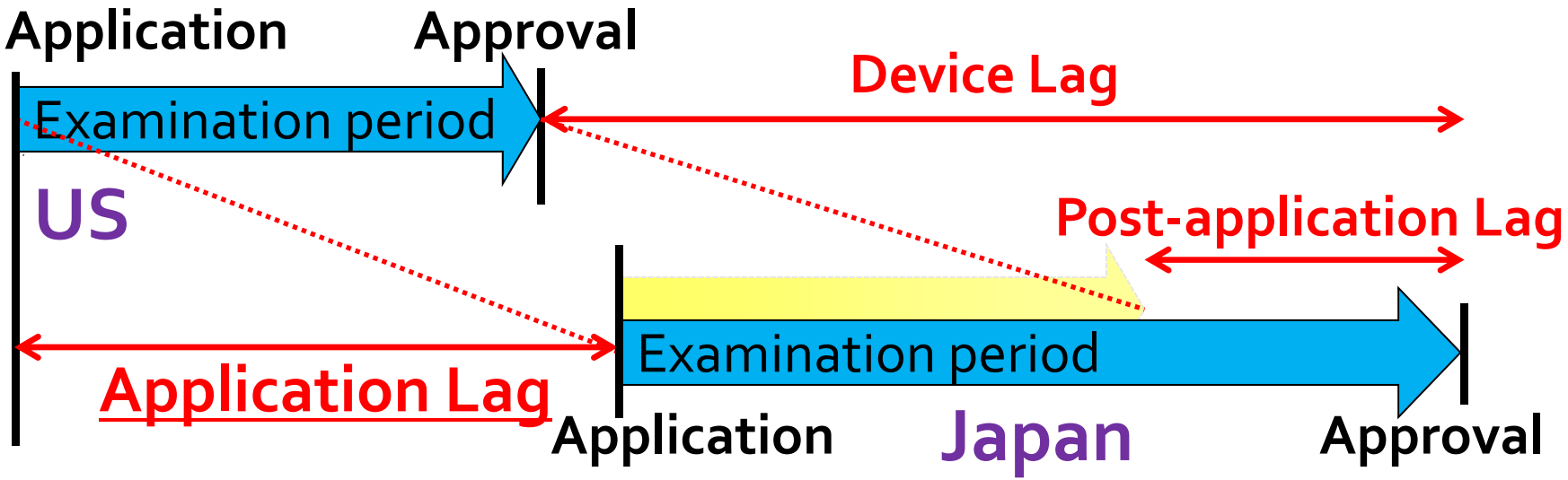
Team 1	Field of ophthalmology, otorhinolaryngology
Team 2	Field of dentistry
Team 3	Field of neurosurgery, cardiology, vascular surgery, respiratory
Team 4	Field of neurosurgery, cardiology, vascular surgery, respiratory (electronic devices)
Team 5	Field of gastroenterology, urology, gynecology
Team 6	Field of orthopedics, plastic surgery, dermatology
Team 7	In vitro diagnostic medical devices
Team 8	Others

Quantitative Increase and Background of Medical Device Reviewers

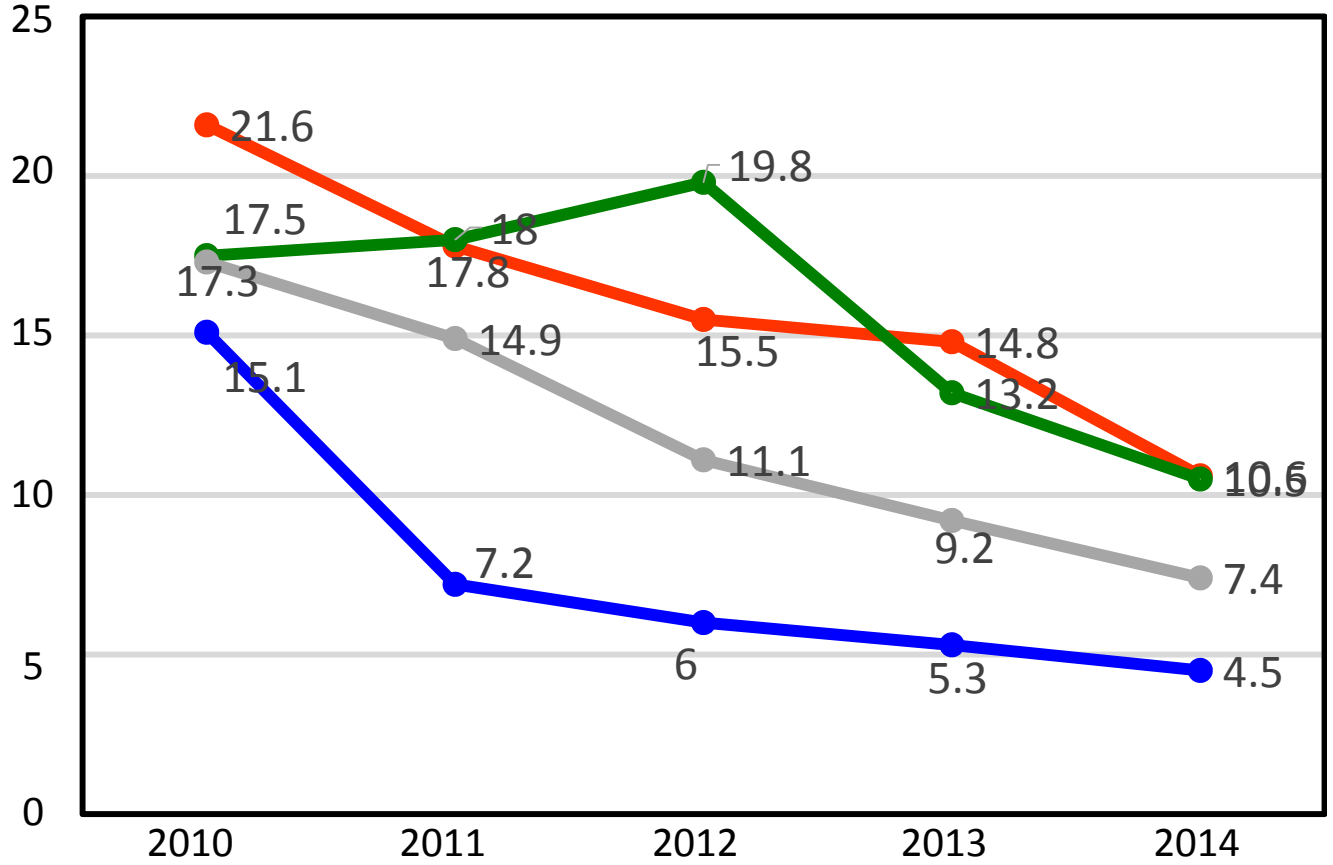


What is “Device Lag”

- “Device Lag” means the period of lag between US Approval of medical devices and Japan Approval



Review Times for Medical Devices



Completion rate

Category	FY	2010	2011	2012	2013	2014
New（80% tile)		92.9%	100%	98.4%	90.2%	31.3%
Improved (w clinical data, 60%tile)		100%	100%	97.6%	82.6%	17.0%
Improved (w/o clinical data, 60% tile)		99.4%	98.8%	99.0%	94.2%	38.3%
Generic　(60% tile)		98.9%	98.8%	98.2%	93.8%	63.9%

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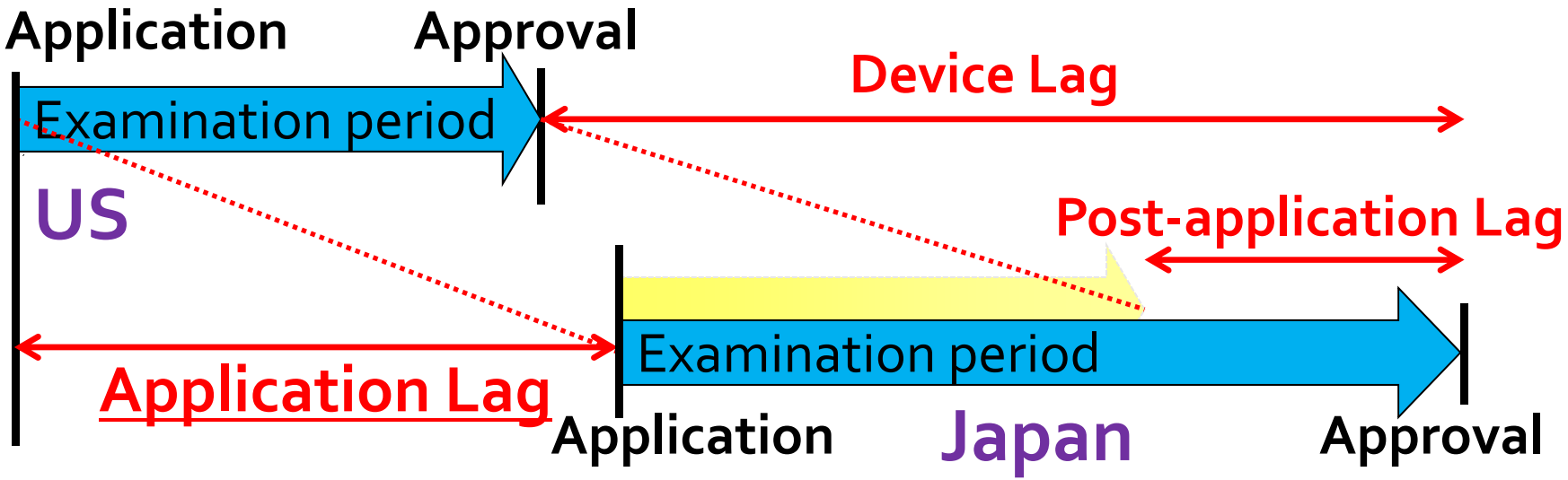
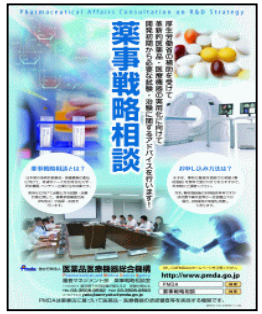


Pharmaceutical Affairs Consultation on R&D Strategy

Valley of Death

-Shortage of funds, Knowledge on Regulation and developmental strategy



Strategic Consultation

Basic Research	Quality Study	Non-Clinical Study	Clinical Trial (Up to POC studies)	Practical Use
Pharmaceuticals and Medical Devices candidates				Innovative Products

* Further studies are handled by the Regular Consultation

Consultation on quality and battery of pre-clinical, including examining tumorigenicity, biological ingredient safety

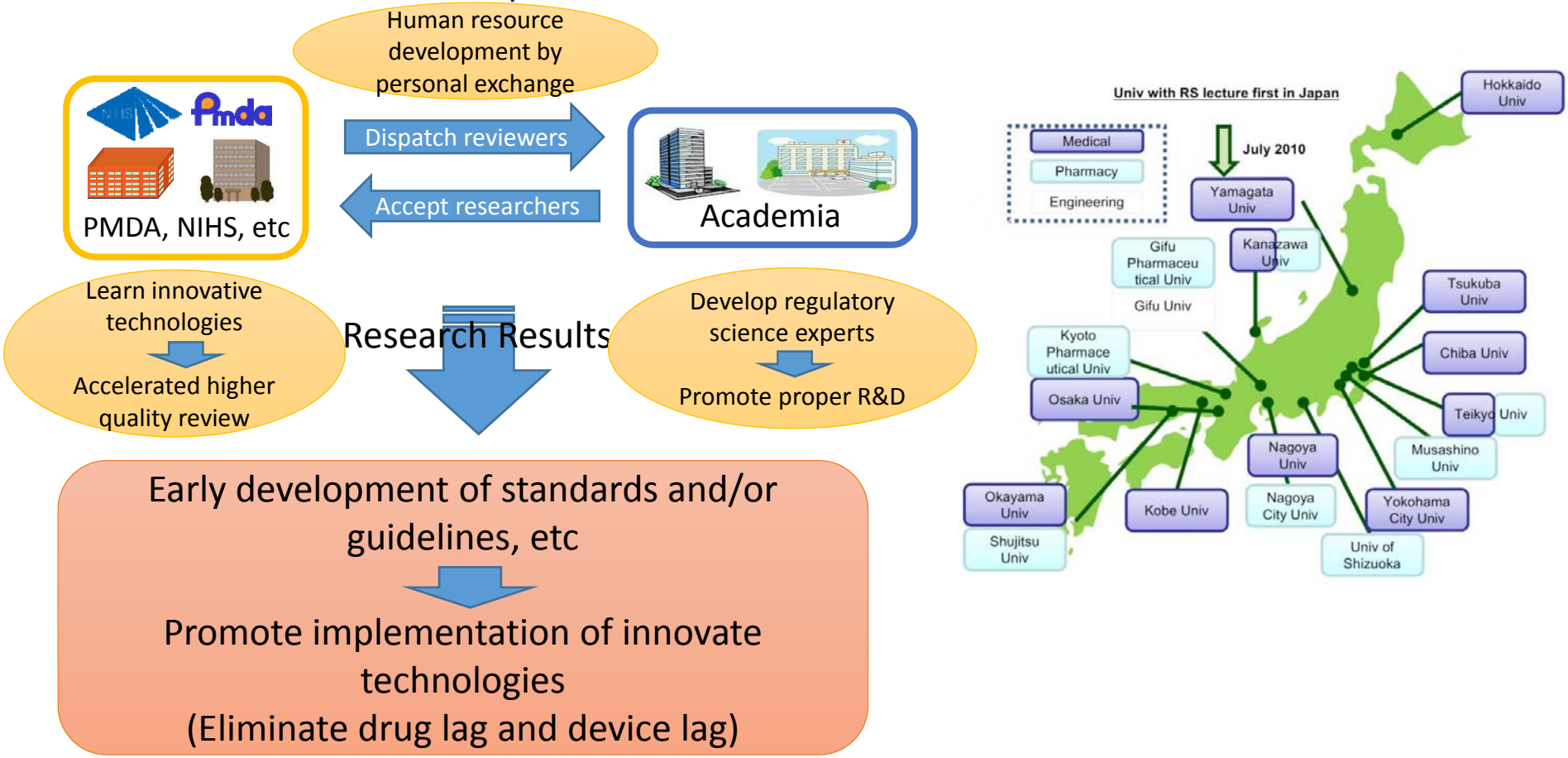
Consultation on endpoints or sample size of early clinical trial

Flow of Strategy Consultation	Introductory Consultation (684)	Pre-Consultation (813)	Face-to-Face Consultation (209)

(7/1/2011 – 6/30/2014)

Initiative to facilitate development of innovative drugs, medical devices and cellular and tissue-based products

- Support establishment of evaluation system for safety and efficacy with R&D as the basis at research facilities researching technology
- Enhance human resources between universities, NIHS, PMDA, and train resources adept in RS



Establishment of Science Board

Basic Research

Seeds of new drug / medical devices

Quality Tests → Non-clinical tests → Clinical Trial → Review → Approve → Post Marketing

Pharmaceutical consultation on R&D Strategy | Clinical Trial Consultation | Review | Post Marketing Safety Measure

Offices of Review (Drugs & Medical Devices), Office of Safety

Office of Review Innovation

Practical use

Innovative medical products

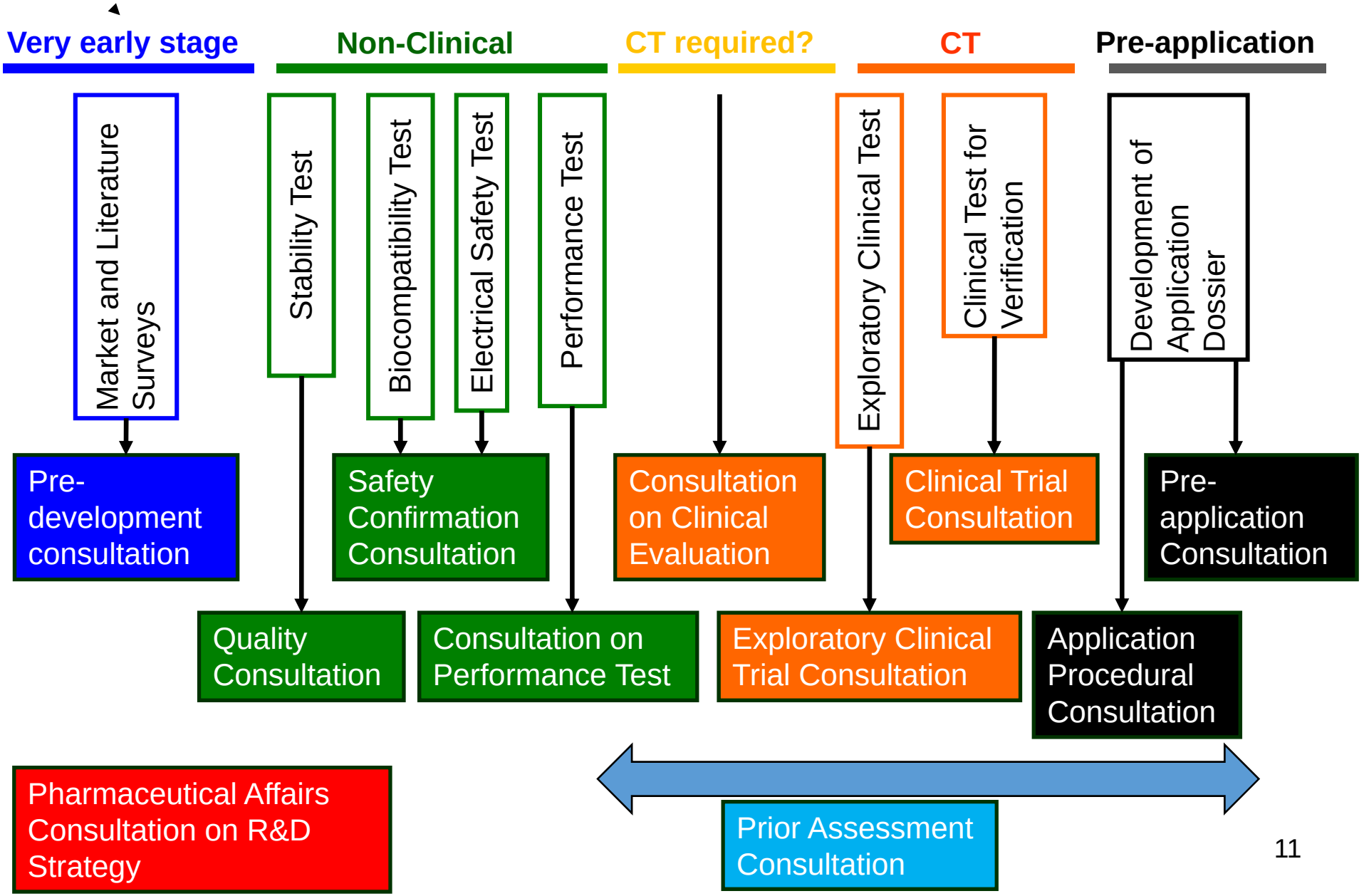
Establishment of the Science Board

The Science Board was established in May 2012 to discuss how PMDA can better cope with products with advanced science & technology, in each developmental stage such as basic research, development support, product review, and post market safety measures.

Board members

Academia (Knowledge of the Latest Innovative Technologies)

PMDA's Consultation Menu



PMDA's Consultation

Number of consultation for medical devices

FY2010	FY2011	FY2012	FY2013	FY2014
106	140	168	173	207

Number of pharmaceutical affairs consultation on R&D Strategy for medical devices

FY2010	FY2011	FY2012	FY2013	FY2014
-	6	5	38	16

Further Collaboration with Industry

To further shorten the development period, we need ・・

・Applicant's cooperation
- appropriate evaluation of the devices
- suitably-preparation of application documents

・Oversea manufacturer's cooperation
- giving accurate information to Japanese distributors
- quick response to inquiry from Japan

・Joining the meeting with PMDA in early stage

Thank you!!

Pharmaceuticals and Medical Devices Agency

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