



Expectation for RAPID project

Sara Takahashi
Reviewer
Office of Medical Devices III
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Disclosure Statement of Financial Interest

I, (Sara Takahashi) DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Current situation of Peripheral Artery Disease in Japan

- Number of patients with peripheral vascular disease is increasing along with aging population, dialysis and DM.
 - Evaluation of endovascular device for PAD is difficult (especially about Critical Limb Ischemia) because there are many confounding factors about clinical outcome and standard treatment has not been established.
-
- Prognosis of CLI is very poor and few medical devices are useful for CLI.
 - Further development of medical devices for CLI is urgent.



Global development is expected to be one of the solution.

PMDA perspective to RAPID project

Globally harmonized core data set enables registry data;

- To be utilized for development or improvement of medical devices
- To be one of the reliable references in the review of medical devices

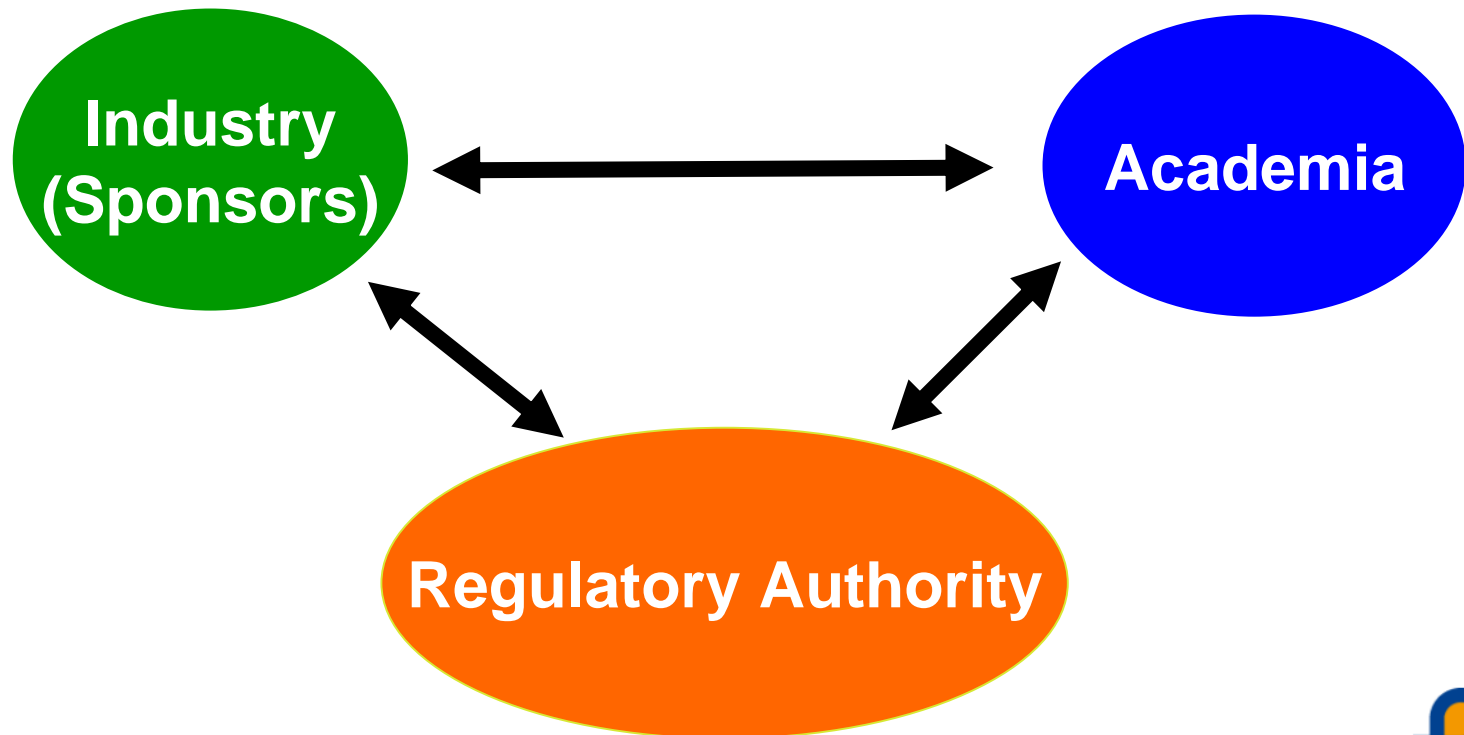


PMDA definitely agrees with the attempt of RAPID to standardize the core data elements necessary to evaluate devices across different registries.

Upcoming challenges

- Consolidation of data infrastructure
- Cooperation with Japanese academia and industry

Japanese academia is interested in using registry data for the development of medical devices.



Upcoming challenges

- PMDA have collaborated with FDA, academia and industries through Harmonization By Doing (HBD) activity.
- Such new technologies will not remain in one country, but will be distributed globally, sooner or later.
- Through HBD activity, PMDA believe global collaboration have enormous significance in promotion of development of innovative medical devices.

- We would definitely like to continue discussions with RAPID members.
- We will have further discussions among stakeholders in Japan and share the ideas with you.

We are looking forward to future progress!

A close-up photograph of pink cherry blossoms in full bloom, with some buds still visible. The background is a soft-focus outdoor setting with a body of water and a building.

**PMDA/MHLW always support global
developments of Medical Devices!**