Japan Update

- New measures to improve access to innovative MDs/IVDs -

September, 2015
Topics

1. New international regulatory harmonization strategies by MHLW and PMDA

2. Official participation in MDSAP Pilot

3. Implementation of Strategy of Sakigake

4. Clinical Innovation Network
1. Establishment of new international regulatory harmonization strategies by MHLW and PMDA

*International Regulatory Harmonization Strategy by MHLW* and *PMDA International Strategic Plan 2015 by PMDA* have been published on 26 June 2015. Based on the *mutually complementary* strategies, the following measures will be taken:

A) Promotion of Regulatory Science
   Guidelines related to medical device regulations in Japan will be prepared and internationally announced.

B) Establishment of Training Center for regulatory matters
   PMDA will provide regulators outside Japan with training for capacity building.

C) Active commitment to IMDRF as well as advancement of bilateral collaboration
   *IMDRF has been reaffirmed as one of the most important activities.*
Japan made an announcement on the **official participation in MDSAP Pilot** on 23 June 2015. Further information will be provided in a timely manner.

Shown at right is the press release on the official participation in MDSAP Pilot in Japan (written in Japanese).

You can find the announcement in English here; [http://www.fda.gov/MedicalDevice\s/InternationalPrograms/MDSAPPilot/ucm452243.htm](http://www.fda.gov/MedicalDevice\s/InternationalPrograms/MDSAPPilot/ucm452243.htm)
An innovative MD/IVD for patients in urgent need of innovative therapy may be designated as a Sakigake Product if:
1) its premarket application will be filed in Japan firstly or simultaneously in some countries including Japan, AND
2) prominent effectiveness can be expected.

Once an MD/IVD is designated, its developer can enjoy such benefits as:

A) Prioritized Consultation by PMDA
B) Pre-application substantive review
C) Prioritized Review (12 months → 6 months [MD])
D) Review Concierge assigned by PMDA
4. Clinical Innovation Network (CIN)

The **clinical study infrastructure** in Japan will be improved under the CIN project so that cost effective clinical studies can be performed **with disease registries**, based on Regulatory Science. The improvement will accelerate clinical studies in Japan by enterprises around the world, which would result in the contribution to extended healthy life expectancy for people.
Thank you