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# Kanagawa Medical Device Regulatory Science Center

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# Background

YNU and Kanagawa prefecture concluded a research contract in April 2014. Then, YNU established “Kanagawa Medical Device Regulatory Science Center” in July and organized “Medical Device Regulatory Science Consortium ” consisting of academia, industry and local government in August 2014

# What is the Regulatory Science?

- The Regulatory Science is to regulate a certain thing based on the scientific analysis and evaluation, harmonizing the risks and merits.
- This basic approach should be applied to approval of the medical devices, too.

# Outline of the center

- Place: Yokohama, Japan
- Consortium members: 40 organizations consisting of academia, industry, local government authority
- Purposes:
  - 1) To support primarily companies to obtain the MD approval by the authority and also support their research & development.
  - 2) To support their marketing, including world wide business matching
  - 3) To develop human resources specialized in medical device regulatory science.
- Objective device: We mainly focus on the medical devices combined together with sensor components and body area network.

## Japanese law and issues

- Revision:  
A revised law for the Pharmaceuticals and Medical Devices was enforced in last November in Japan. Under the law, the medical device is defined and a simple substance program is included in the MDs.
- Interesting Issues :
  - 1) To make guidelines for the evaluation of efficacy and safety for newly created advance MDs
  - 2) How to draw a line between MDs and non MDs
  - 3) Who take the responsibility of making a wrong diagnosis?

# Current situation

- It is required that evaluation methods to verify the efficacy and safety of the medical device are created by the party itself who wants to get an MD approval from the authorities.
- Academia has a chance to make an important role for the creation of evaluation methods.
- We would like to hold this workshop in the next ISMICT2017.