

Regulatory Science Research in PMDA

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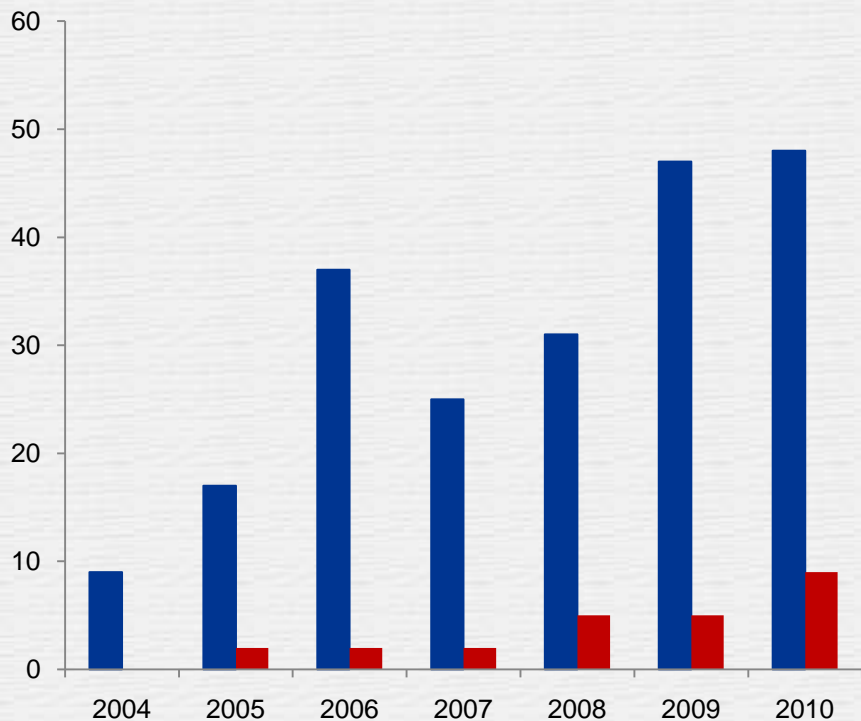
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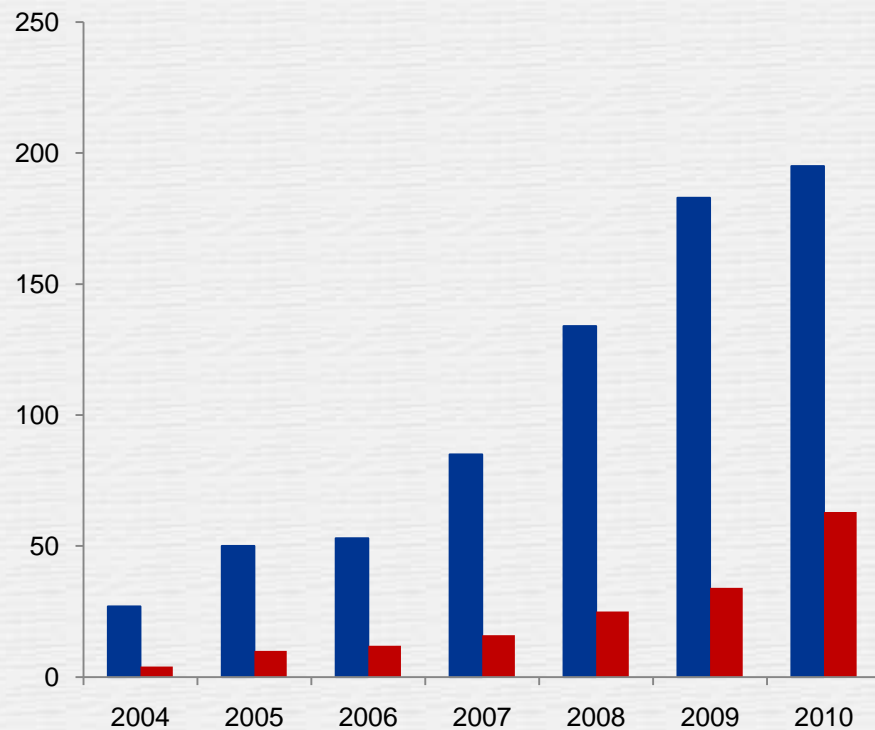
www.diahome.org

Publication/Presentation from PMDA

Articles



Presentation



■ Total ■ English



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Recent Examples of the Published Articles

Adaptive clinical trials for new drug applications in Japan	Eur Neuropsychopharmacol. 21: 175-179, 2011.
PMDA's Challenge to Accelerate Clinical Development and Review of New Drugs in Japan.	Clin Pharmacol Ther. 88(4): 454-457, 2010.
Discussion of "Adaptive and Model-Based Dose-Ranging Trials: Quantitative Evaluation and Recommendations"	Statistics in Biopharmaceutical Research. 2(4): 462-465, 2010.
Participation of elderly patients in registration trials for oncology drug applications in Japan.	Ann Oncol. 21: 2112-2118, 2010.
Practical issues and lessons learned from multi-regional clinical trials via case examples: a Japanese perspective.	Pharm Stat. 9: 190-200, 2010.
Drug interaction studies on new drug applications: current situations and regulatory views in Japan	Drug Metab Pharmacokinet. 25(1):3-15, 2010.
Effective Global Drug Development Strategy for Obtaining Regulatory Approval in Japan in the Context of Ethnicity-Related Drug Response Factors	Clin Pharmacol Ther. 87: 362-366, 2010.



Regulatory Science (RS) Research Division

- Established in October 2010
 - To promote the public health
 - Strengthen in-house research activities
 - Research Operation/Coordination
 - Disseminate knowledge/information
 - Exclusive Intra-site, Periodical e-mail

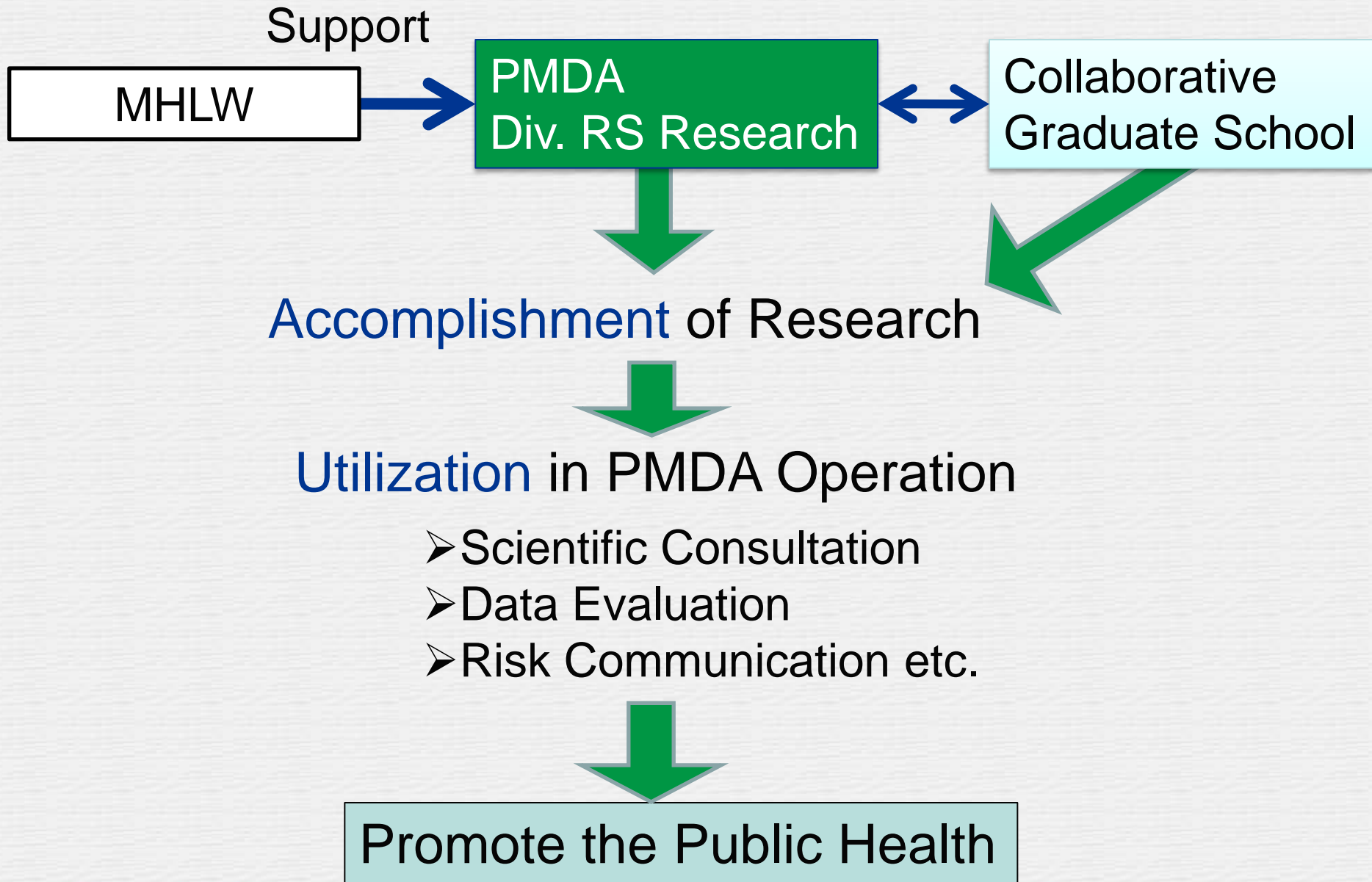


RS Research in PMDA

- Drug /Device Development/Review
- Safety Measurement
- Adverse Event Relief

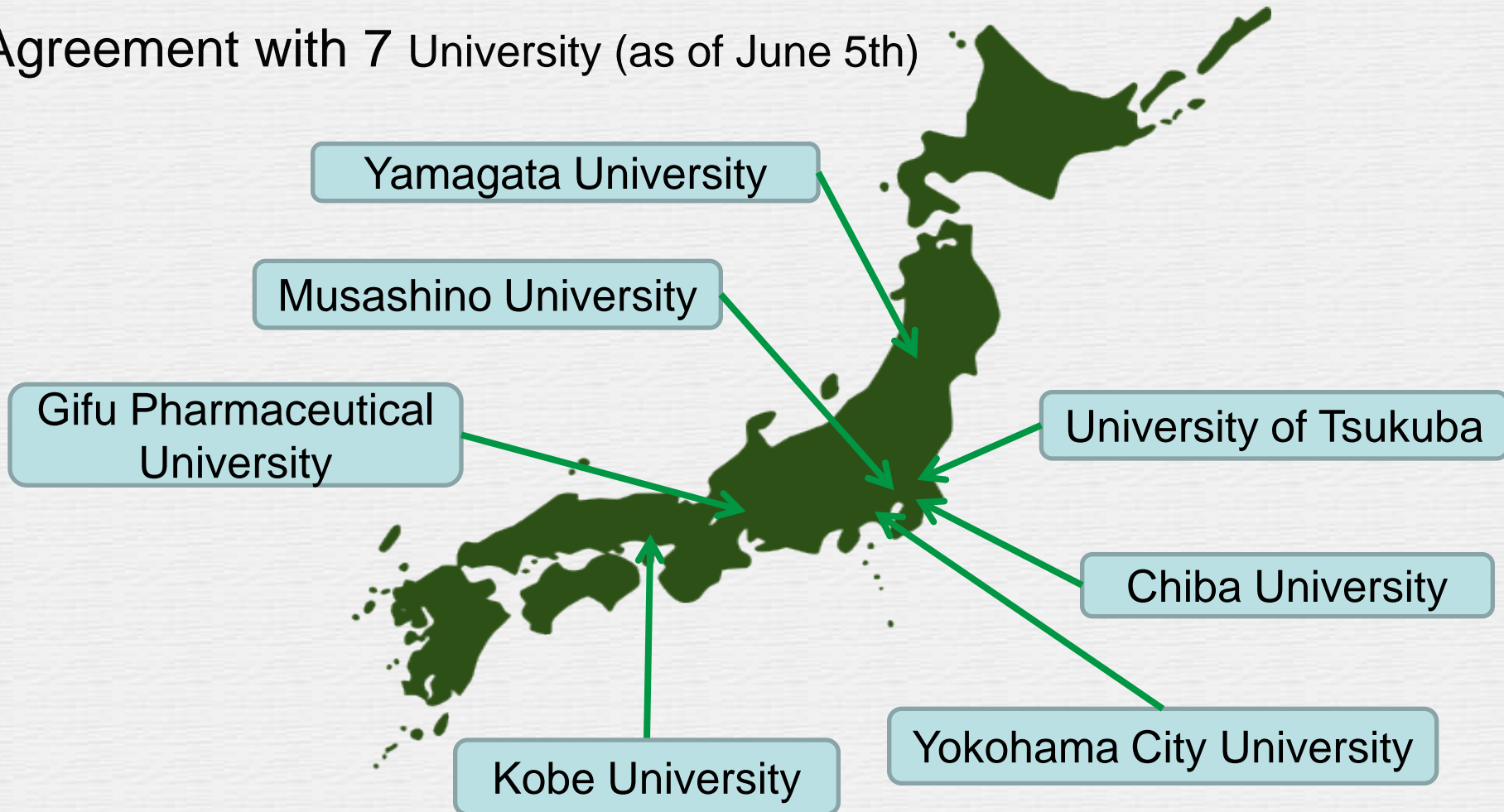
Improve Quality of PMDA's Operations
with More Transparent and Objective Decision
based on Clear Evidences





Collaborative Graduate studies Program

Agreement with 7 University (as of June 5th)



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