Translational/Clinical Research in Japan

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Today’s Talk

- Characteristics of Translational/Clinical Research

- Situation in Japan

- For the Promotion of Translational/Clinical Research
  - Activities of CSTP (The Council for Science and Technology Policy) and CPHR (The Council for the Promotion of Health Research)
  - Activities of Kitasato University
  - Introduction of the Research on Japanese Sentinel Network (by Mr. Murakami)
Several Stages of Clinical Research

- To clarify the disease mechanism and to develop basic theories based on patient/disease research
  【Patient-oriented Research, Disease-oriented Research】

- To convert the basic theories to diagnostic/treatment techniques
  【Translational Research】

- To evaluate the efficacy and safety of the treatment

- To raise a new challenge
  【Clinical Research/Studies】(narrowly-defined)
Clinical Research for the Development of New Therapies

Development of New Therapies = Goal of Life Science Research
Return the Fruits to Society

Non-clinical Research → Patient-oriented/Disease-oriented Research → Clinical Studies → Epidemiological Research

Clinical Research for the Development of New Therapies

(Document by Cabinet Office with some alterations)
Shares of Countries for Research Articles

**Basic-Science Articles**

- US: 66.4%
- Canada: 4.8%
- France: 3.1%
- Germany: 4.8%
- Netherlands: 1.1%
- Switzerland: 1.9%
- Australia: 0.9%
- Others: 7.4%

**Clinical Articles**

- US: 53.7%
- UK: 18.3%
- Others: 18.4%
- Japan: 0.6%
- Germany: 0.9%
- Australia: 1.1%
- Italy: 1.2%
- France: 1.4%
- Netherlands: 1.6%
- Canada: 2.8%

Research Productivity for Global and First-in-class NCEs

EXHIBIT 3
Proportional Ratio Of Global And First-In-Class New Chemical Entities (NCEs) To Research And Development Industry Funding In The United States, Europe, And Japan, In Two Time Periods (1982–1992 And 1993–2003)

Proportional ratio

1.5

1.2

0.9

0.6

0.3

0.0

Global, 1982–1992

Global, 1993–2003

First in class, 1982–1992

First in class, 1993–2003

SOURCE: Author’s analysis based on data in Exhibits 1 and 2.
NOTES: 1.00 equals innovation proportionate to investment, as shown in Exhibit 2. Percent change in productivity from first to second time period: Global, U.S. –26%; Europe, 30%; Japan, zero. First in class, U.S. –25%; Europe, 36%; Japan, –40%.

(Health Affairs 2009;w969)
Environment for Science & Technology
– Change in the Number of Researchers in each Country

(White Paper by MEXT. 2009)
Japan’s Tipping Point

With changing demographics, a tight economy and increasing competition, Japan could slide from the top ranks of research nations. Drastic action in needed.

(Nature 2009;460:151)
The Council for Science & Technology Policy (CSTP)

- The Control Tower for the Promotion of Science & Technology Policy in Japan
  - One of the four Councils for important policies of Cabinet Office
  - Chaired by the Prime Minister, composed of related Ministers and Experts

- Task
  - Planning and coordination of general and fundamental policy for science & technology
  - Allocation of resources (national budget and personnel) for science & technology
  - Evaluation of important R&D projects
Activities of CSTP

■ The 3rd Basic Plan for Science and Technology, the Sectoral Promotion Strategy (Mar 2006)
  ● Selected “Clinical/Translational Research” as one of the strategic and priority areas
  ● Pointed out the importance of the following four measures for the promotion of clinical research
    – Improvement and buildup of the support system for clinical research
    – Fostering of researchers and other workers relevant to clinical research
    – Improvement of the environment for clinical research and new drug review
    – Active participation by the public

■ Reform for the Promotion of Science & Technology and Return their Fruits to Society (Dec 2006)
  ● Made specific recommendations for the improvement of the clinical research system
Activities of CPHR
(The Council for the Promotion of Health Research)

- The Control Tower for the Promotion of Health Research
  (Clinical/Translational Research) in Japan
  - Composed of Ministers (Cabinet Office, MEXT, MHLW and METI) and an Expert

- Task
  - Formulate a comprehensive strategy for Health Research
  - Formulate an overall budget policy for Health Research
For the Promotion of Clinical Research in Japan

- Establishment and Strengthening of “Center of Excellence”
- Development and Ensuring of Human Resources

- Formation of Open and Globalized Research System
  - Collaboration of industry and academia
  - Collaboration among industries
  - Collaboration in Asian countries
Percentage of Companies that Conduct R&D Activities in Collaboration with External Institutions

- Universities (Domestic): 88.3%
- Public Institutions (Domestic): 63.9%
- Companies (Domestic): 73.4%
- Universities (Foreign): 22.0%
- Public Institutions (Foreign): 13.3%
- Companies (Foreign): 35.5%

(MEXT. 2007)
Activities of Kitasato University

- Selected as a “Center Institution” for clinical trials
- Established KCRC (Kitasato Clinical Research Center)

### Activities in Shirokane-area

**Education**
- Graduate school for students working in the area of clinical research & development

**Research**
- New drug R&D strategy
- Post-market pharmacovigilance
- Education program on clinical data management

**Support for Investigator-initiated Research**
- Randomization, data management, …
Open and Globalized Research System

- Clever Distinction between Open and Closed System is needed
  - Based on the stage of the development
  - Based on the characteristics of the research (closeness to the commercial activity, …)

- Synergistic Effect is expected through:
  - selection/concentration of research programs
  - risk hedging
Clinical Research in Various Stages

- Basic Research
- Non-clinical Research
- Translational Research
- Clinical Studies for NDA
  - Exploratory
  - Confirmatory
- Epidemiological Research

Launch
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Thank you for your kind attention.