R&D Challenges at MEXT in Developing Innovative Medicines and Pharmaceuticals

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Science & Technology Policies for Life Sciences

- The Third Science and Technology Basic Plan (FY 2006-2010) (approved by the Cabinet, March 2006)
  - “Promotion strategies of the four scientific fields with primary priority”:
    - Life sciences, Information and Communication, Environment, and Nanotechnology and Materials

- The Basic Plan specifies several areas below as “Strategic Prioritized S&T” in life sciences field
  - Creation of human in silico
  - Clinical research and translational research
  - Innovative cancer treatment technologies including targeted therapeutics
  - Science and technology to overcome emerging and reemerging infectious diseases
  - Upgrading research infrastructures - beyond “world’s best standards”

- Long-term Strategic Guidelines “Innovation 25” (approved by the Cabinet, June 2007) also shows the importance of innovation exemplified above in the field of drug discovery
### Outline of 5-Year Strategies for Creation of Innovative Drugs and Medical Devices

#### [1] Intensive investment of research funds
- Emphasize and expand budgets related to drugs/medical devices
- Establish coordinating organizations in areas such as emphasized developments with industry-government-academia cooperation
- Improve and strengthen tax credit for R&D
- Special zone for state-of-the-art healthcare development
  -> Emphasize and intensively allocate research funds
  -> Measures for comprehensive and efficient management of research funds

#### [2] Nurturing of venture companies
- Improve and expand research funds
- Commoditize facilities and instruments, etc.
- Re-organize the corporatization support system, utilize retired human resources, enhance consultation services, etc.
- Expand supportive measures related to utilization of the Angel taxation system, etc.
- Provide supports for bio-venture’s international expansion
- Promote corporatization/development of new technologies that are important for the national economy
- Discuss supports for review fees
- Discuss measures for activation of providing of medical device’s components

#### [3] Improvement of Environments of Clinical Research/Clinical Trials
- Promote global joint clinical trials
- Enhance “Healthcare Clusters” that promotes clinical research with close industry-government-academia collaboration, centering around the national highly-specialized medical centers.
- Create bases for translational research, regenerative medicine, and clinical research systems
- Make bases/networks and introduce IT for clinical trials, centering around the Healthcare Cluster
- Nurture and secure human resources that support doctors and clinical studies
- Make efforts to improve the evaluation of clinical achievements of doctors, etc.
- Promote adjustment of regulations for research study
- Create global bases for clinical research that have central IRB function, etc, and can conduct advanced global joint research
- Establish opportunities to conduct parallel discussions from development stages between researchers/developers and regulatory officers in the special zone for state-of-the-art healthcare development

#### [4] Collaborations with Asian Nations
- Promote joint research on important diseases
- Joint research on methods of utilizing data collected in East Asian Nations

#### [5] Speed-up and Improvement of Quality of Reviews
- Shorten the period to the launch of new drugs by 2.5 years (resolve drug lags)
- Double and improve the quality of review staffs (increase by 236 members in 3 years)
- Make clear the ways and criteria for approval review; improve management of GCP
- Create a system to deal with all clinical trial consultations in a timely manner
- Deliberate the introduction of joint clinical trial consultations among Japanese, U.S., and European reviewing authorities
- Secure the safety of medical devices, and simultaneously promote the rationalization/simplification of clinical trial/approval reviews
- Discuss the enrichment and reinforcement of review/consultation systems for medical devices
- Improve the management of medical device GCP

#### [6] Proper Evaluation of Innovations
- Make more proper evaluations of innovative products under the drug price system, etc.

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**Measures aimed at most advanced R&D in Japan and worldwide R&D challenges which Japan plays important roles**

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**Providing world’s best drugs and medical devices to the public**

**The drug/medical devices industries as the driving force for the growth of Japanese economy**

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**Outline of 5-Year Strategies for Creation of Innovative Drugs and Medical Devices**

April 2007
May 2008 (revised)
February 2009 (revised)
CAO, MEXT,
◎MHLW, METI

**[7] Public-Private Conversations**

Reinforcement of Collaborations among Related Ministries, Research Institutions, and Industries

Implementation of Periodical Public-Private Conversations
Council for Science and Technology Policy (June 19, 2008)

“A whole picture of the budget for S&T in FY2009 and Policy of resources distribution”:
In the “Health research area”, as the first example, we start to deal with setting up of strategic plans and budget compilation at the integration of related offices and administrations.

Establishment of “Council for the Promotion of Health Research”

- Functional role as a “control tower” in promoting translational and clinical researches
- Consists of four related Ministers and leading scientists/experts
- Established at the Cabinet Office
- Utilization of systems of “Super Special Consortia for supporting the development of cutting-edge medical care”

Special subcommittee on Basic matters, Council for Science and Technology Policy

The 1st report: Consideration aiming at promoting comprehensively clinical researches
Establishment of “Council for the Promotion of Health Research”

Council for the Promotion of Health Research

(Cabinet Office)

- Minister of Science & Technology Policy
- Minister of Education, Culture, Sports, Science & Technology
- Minister of Health, Labor & Welfare
- Minister of Economy, Trade & Industry
- Leading Scientists and Experts

- To frame comprehensive strategy
- To formulate a guideline of budget proposal
- To integrate application and reviewing processes, and management system of research grants

Prioritized allocation of research grants

Integrated management of research grants
Implementation and securement of Special Consortia’s budget

Implemented in FY2009

Reflection of opinion from private sector

Public-Private Dialog for Innovative Drugs

Public-Private Dialog for BT Strategic Promotion

Comprehensive promotion of bio-technology

Council for Science and Technology Policy

- Budget for Innovative technology
- Strategy for promotion of Life science
Coordination, Support and Training Program for Translational Research (starting from FY 2007)

【Background and Necessity】
The results of basic research in life sciences in Japan has been published as articles in major scientific magazines such as Nature and Science, and is highly regarded in the world. (For example: The ratio of papers written by Japanese researchers in Science increased from 1% in 1983 to 5% in 2002.) However, due to lack of infrastructure and support, translation of basic research into clinical research and clinical practices has not been upgraded sufficiently in Japan. This has led to the results of basic research not being sufficiently translated into clinical practice (such as medicine and drug manufacturing), and consequently the public has not benefited enough from the research. Therefore, through collaboration with related ministries and other organizations, measures to translate results of basic research into clinical trials and clinical practices are required.

【Outline and Purpose】
The purpose of this project is to increase the application of basic research to patient care, through promoting organizations, within universities to become centers of translational research. Such centers would not only increase the interaction between basic and clinical scientists, but also accelerate translational development of new drugs, and treatment strategies from the laboratory bench into clinical testing.

1. Upgrading and expanding organizations that support translational research
   Upgrading of functions is necessary to provide support for seed development not only for the support organizations but also for the other institutions including formulation of development strategies.

2. To train and hire qualified personnel
   For successful implementation of a permanent translational research program, a system that can train qualified personnel including biological statisticians is essential.

3. Securing funds for translational research
   In order to maintain the safety of patients and to obtain final results, research funds allocation for test sample preparation based on the GMP (Good manufacturing practice) is required.
Managing systems
Program Director, Program Officer

Review system
Translational research support promotion program Evaluation Committee

Support Center
Translational Research Informatics Center
Foundation for Biomedical Research and Innovation (FBRI)

Supporting Organizations for Translational Research
Sapporo Medical University (Hokkaido University, Asahikawa Medical College)
Tohoku University
The University of Tokyo
Kyoto University
Osaka University
Institute of Biomedical Research and Innovation laboratory, FBRI
Kyushu University

Collaboration among Ministries through “Council of core clinical trial hospitals and key medical institutions”
Creation of innovative medicines and medical devices and equipments
The technology of molecular imaging makes possible the in vivo visualization, in living organisms, of the behavior of various molecules such as genes and proteins, the early diagnosis of a variety of diseases, and visual identification of efficacy of new candidate substrates.

This program get two research centers ready and perform personnel training and, in collaborating with the universities research institutesorganizations such as a university and the private enterprise, perform a collaboration.

(1) Research Center for exploring New Drugs (RIKEN)
- Development of high-speed 11C-methylation reaction
- Development of 68Ga-labeled peptide, protein, and nucleic acid probes
- Construction of simultaneous imaging system of multiple molecules

(2) Research Center for PET Diagnosis (National Institute of Radiological Sciences)
- Construction of molecular probe library
- Success in super-high-ratio radio-activation with the highest level in the world
- Development of automatic synthesizing equipment for medium half-life nuclei

Universities

Research Institutes

Human resources development

collaboration
University Hospital-Collaborative Program for Promotion of Cultivation of Advanced Medical Professionals

Background/Purpose

- Absence of excellent specialists and clinical researchers due to deterioration of educational/research functions of university hospitals
- Concern about cultivation of future doctors have become actualized due to deterioration of functions/shortage of doctors at university hospitals

→ It is necessary to reinforce educational research/supply functions at university hospitals with collaboration/cooperation among university hospitals, in order to improve the quality of specialists and clinical researchers and to produce attractive university hospitals

Main proposals, etc.: “Basic policies for economic and financial reforms 2008” (cabinet decision, June 2008), “Five reassurance plans” (July 2008), “Urgent measures to secure doctors” (government party, May, 2007), etc.

Program Outline

Construct a circulating-type doctor’s carrier forming system conducted by multiple university hospitals closely collaborating/cooperating with each other → Further expand bases (30 projects nationwide)

- Cultivate high-quality specialists and clinical researchers with academic mind, by drawing up and implementing an university hospital-collaborative cultivation program
- Realize acquisition of wide-ranging knowledge/techniques by mutually complementing areas of specialty between inner-city university hospitals and local university hospitals
- Support for obtaining of specialist licenses by enriching educational training systems and securing a necessary number of cases (rear-area supporting hospitals)
- Also contribute to solution of shortage of doctors in local areas by activating the circulation of specialized medical interns

National/Public/Private University Hospitals

Reinforce functions as career-forming supporting centers
- Assignment of full-time coordinators
- Develop and evaluate human resources development programs
- Create networks/databases
- Support for life-long educations, FD implementation, etc.

Reinforce educational research instruction systems at university hospitals
- Assignment of instructors/instruction-supporters
- Arrange simulators/skill labs

Circulation of specialized medical interns

Specialists cultivation system by the university hospital-collaborative cultivation program

Board-based collaboration/cooperation beyond prefectural regions

Activate the circulation of specialized medical interns

- Allowances for burdens for trips/stays of specialized medical interns and circulating supervisory doctors

Specialized training at university hospitals
- Enhance and enrich environments
  - Allowances for collaborative supervisors
  - Enhance environments of conference/practical training

Allowances for collaborative supervisors
- Enhancements for collaborative supervisors
- Enhance environments of conference/practical training
**Future Initiatives**

- **Translational research and Clinical research**
  - Strong promotion of translational research in order to return fruits of basic research to society as innovative medical treatment
  - Enhancement of the supporting system of clinical research
  - Ensuring human resources such as clinical researchers and their supporters
  - Environmental improvement for approval process

- **Alliance of Medicine, Engineering and Science**
  - Collaboration of applied science and pure science
  - Construction of new field as a fusion of life science and other fields

- **Intellectual property**
  - Strategic acquisition and use of intellectual property as resources for industrial competitiveness

- **Fostering and promotion of Bio-venture companies**
  - Securing reliability and homogeneity through measuring technology, realization of international standards for enforcing international competitive power of bio-venture companies, etc.

- **Promoting cooperation among government, industry and academia**
  - Cooperation with applied science and pure science, creation of new trans-disciplinary fields of life science and other fields, etc.