## Section 3 Promotion of Life Innovation

Life Science is the field of science that elucidates the complicate and elaborate mechanisms of life phenomena of all living creatures, and its achievements will lead to great advances in medicine and solutions of food and environmental issues, eventually contributing to improved nation's life and developed national economy.

To promote life science, four key issues (1)-(4) have been set out in the fourth-term basic plan as below, and MEXT and the agencies concerned are addressing them.

### 1 Policies for Achieving Key Issues

(1) Development of innovative disease preventive methods

1) Realization of next-generation medicine

MEXT is promoting "the Tohoku Medical Mega-Bank Project" by focusing on the coastal areas affected by the GEJE. The project, which intends to promote long-term epidemiological research (genomic cohorts) including genomic information, is being implemented for the regional medical information sharing, in parallel with the construction of infrastructures under the support of MIC and MHLW. This project intends to restore the medical systems in the affected regions and to realize the next generation medicine, such as tailor-made medication. To do this, MEXT is addressing "the order-made medicine realization program" (the second term). By utilizing the world's largest-scale Biobank that controls patients' blood samples and clinical information, MEXT is promoting the program to identify genes of diseases which may greatly affect nation's health, and to clarify the relationship between adverse drug effects and genetic information. RIKEN is also promoting the research to find out the causes of diseases in conjunction with this project.

2) Efforts to clarifying environmental risks to children

Recently, the possibility of increased environmental risks to children is pointed out.

In FY 2010, MOE started the large-scaled long-term cohort research, "Japan Environment and Children's Study (JECS)," by targeting 100,000 pairs of parents-children in order to clarify the influence of environmental chemical agents on children's health (Figure 2-2-7). Under this research that started at the end of January 2011 and will last for three years, participants (pregnant women) are recruited and their biological samples, such as blood, umbilical blood, breast milk, etc., are taken and the follow-up study will be conducted using questionnaires until the children reach 13 years old.

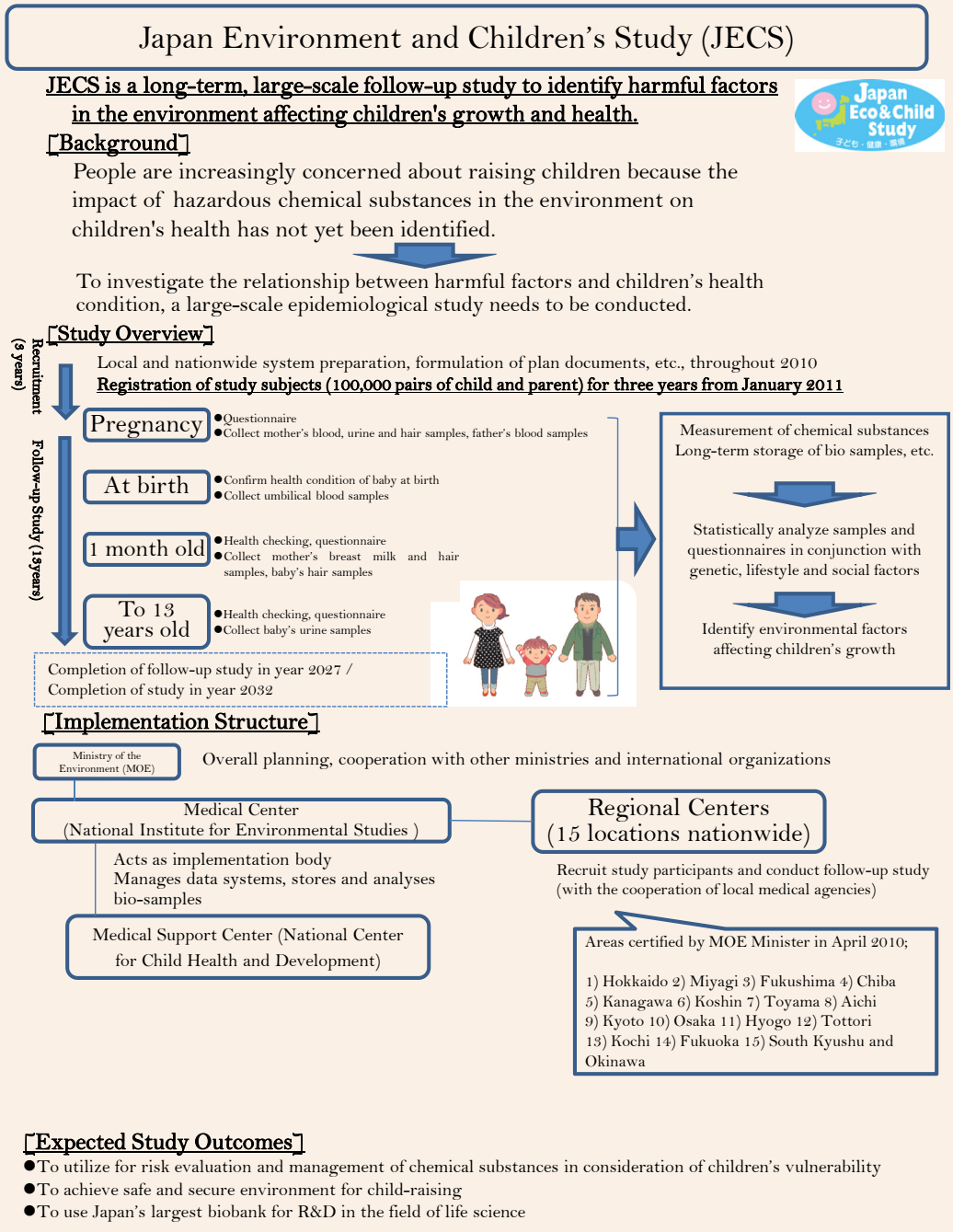
Under JECS, the National Institute for Environmental Studies (a core center) is analyzing the data and specimens to summarize the results of the research, and the National Center for Child Health and Development (a medical support center) is providing medical supports. Meanwhile, unit centers, publicly recruited and designated universities from 15 districts across the country, are recruiting participants and conducting the follow-up studies of coming babies.

In addition, by taking into consideration the prevailing health concern about radiation in the wake of the accident at TEPCO Fukushima Daiichi Nuclear Power Station, MOE decided that JECS should include the estimated figures of exposure dose into the environmental factors and conduct the analysis of

health conditions, in order to assess whether the radiation exposure could influence on health. Since October 2012, JECS has been expanded from 14 municipalities including Fukushima City to all areas of Fukushima Prefecture.

Based on the knowledge obtained by this research and through the improved management of risky chemical substances, MOE intends to realize children's' health and safety and secure child-raising environment. MOE expects that the bank of 100,000 pairs of biological samples and data will contribute to maintaining Japan's international competitiveness in the field of basic research as a shared infrastructure of medical- and health-related studies.

Figure 2-2-7/ JECS on Children's Health and Environment




Source: Created by MOE

3) Efforts to Overcome Emerging and Reemerging Infectious Diseases

Recently the world has been paying attention to emerging infectious diseases that have newly been discovered, and reemerging infectious diseases that appear to have been completely controlled but are devastating again. These diseases need to be investigated furthermore regarding pathogens, infectious routes, infectability, and underlying mechanisms.

MEXT is working on the program, "Japan Initiative for Global Research Network on Infectious Disease" by

using 13 research bases in eight countries in Asia and Africa; promoting R&D to take measures against these diseases; helping accumulate knowledge; and nurturing human resources.

MHLW is working on the development of proper diagnostic techniques, treatment strategies and preventive methods that lead to facilitating necessary administrative responses. In particular, concerning preventive inoculations that are important means against infectious diseases, MHLW is doing research for the evaluation of medical safety and economic efficiency, helping the vaccination administration. In the field of novel influenza, MHLW is also making research into cell culture-based vaccines and intranasal vaccines, so that more effective and simpler vaccines can quickly be provided for people against the occurrence of novel pandemic influenza.

4) Psychological and Neurological Disorders

The research of brain science is the research field that is expected to contribute to the improved quality of social life and medicine as well as the creation of new technology and new industries.

Because it is crucial to promote the research of brain science strategically and to return the results of research to society, MEXT compiled the first report on the "Basic Concept and Promotion Measures for Brain Science Development from a Long-Term Viewpoint" for the June-2009 Council for Science and Technology. Based on the report, MEXT is implementing the "Strategic Research Program for Brain Scientists" toward the social contribution through brain science; exploring biological indicators (social brain markers) concerning humans' social behaviors, i.e., the study about the relationship of genetic factors with environmental stress; studying the mechanism of occurrence of psychological and neurological disorders; and aiming at helping early diagnosis, treatment and prevention of these disorders.

In RIKEN and JST, the research for brain science is also being promoted regarding molecular structures, nerve cells, neural networks and so on, under the Strategic Basic Research Program.

(2) Development of Novel and Early Diagnostic Technology

(Study of molecular imaging and promotion of image diagnostic technology)

To protect nation's health, it is important to develop diagnostic methods to detect disorders early. Therefore, the government is promoting the development of highly accurate, early diagnostic technology.

MEXT is implementing the "Japan Advanced Molecular Imaging Program Strategy (J-AMP)," the molecular imaging technology in which in vivo molecular behaviors of living creatures can be visualized alive. Aiming at early application of this technology, MEXT has constructed the research system consisting of the Center for Drug Development Molecular Imaging & the Center for PTET[1] Diagnosis; universities; and hospitals, promoting joint R&D toward the demonstration of this technology.

To detect disorders early, MHLW is addressing the development of molecular imaging technology and image diagnostic equipment that utilize nanotechnology, etc.; promoting the toxicity assessment of candidate compounds for drugs in the pre-development stage; and searching for proteins useful for the effectiveness assessment. In particular, MHLW is promoting R&D focused on the commercialization of the innovative image diagnostic technology that uses novel and cancer-specific biologic indicator, by targeting the type of cancers that are otherwise difficult to treat.

METI is implementing "Comprehensive R&D of an Early Stage Diagnosis Method and Instruments to Treat Cancer" to develop an image diagnostic system, which enables to detect cancer in the extremely early

stage and to understand the characteristic of cancer correctly.

In addition, to diagnose Alzheimer disease and develop drugs for its basic remedy, METI has addressed the establishment of technology that can evaluate correctly and objectively the progress of mild cognitive impairment toward Alzheimer disease.

(3) Realization of Safe and Effective Therapies

1) Promotion of scientific research of cell generation, differentiation and regeneration

Research of cell generation, differentiation and regeneration is the study that is aimed at the clarification of the mechanism, in which one cell differentiates into various tissues and organs to form and maintain the body. This constitutes the basics of regenerative medicine. The field of regenerative medicine has rapidly advanced recently, gaining attention in the world; Professor Yamanaka at Kyoto University received a Nobel Prize in Physiology & Medicine in December 2012 for discovering iPS cells. Aiming at the early realization of regenerative medicine and drug development using stem cells including iPS cells, the agencies concerned are promoting research in cooperation with each other.

Based on the "Revised Comprehensive Strategy for Accelerating the iPS Cells Research" (decision by the minister of MEXT in January 2009), MEXT is improving the center where the research of stem cells, such as iPS cells, can be conducted comprehensively under the "Project for Realization of Regenerative medicine" (the second term)". In addition, MEXT is promoting studies to apply the basic research to the clinical application to achieve the goal that was set under the "Road Map on iPS Cell Research (the February-2013 CST's Subdivision on R&D Planning and Evaluation, the Life Science Committee, and the stem cell, reproduction and medicine strategy taskforce)." Besides, MEXT is conducting basic research under the JST Strategic Basic Research Programs supported by Japan Science and Technology Agency, and also, similar research is being conducted in RIKEN. Furthermore, the agencies concerned are working as a whole to improve the research systems and secure necessary research funds to maintain and manage intellectual properties. In collaboration with MHLW, they are promoting the research for diseases and drug development using patient-derived iPS cells for the "Incurable diseases using disease-specific induced Pluripotent Stem cells research" that was newly started in FY 2012.

MHLW aims to establish the base of technology for safe and effective regenerative medicine that uses human cells, such as iPS cells, in order to promote the research of tumorigenic, rejection, etc., which are the challenge of early clinical application of regenerative medicine. To accelerate the process of drug development, MHLW is also promoting the research to make human iPS cells differentiate and induce into target human cells, and the basic technology that will serve for the search and selection of candidate compounds for drugs in the pre-development stage.

METI is implementing the "Research and Development of Next-generation Regenerative Technology" to develop regenerative devices that stimulate regeneration of self-tissues within the body, and conducting the research to establish the evaluation technology for the safety and effectiveness of regenerative tissues. In addition, METI is promoting R&D for the safety of drugs that use iPS cells in order to make the process of drug development more effective, and also, from FY 2011, promoting the development of basic technology for the stable mass-production of high-quality stem cells that will be needed for the realization of regenerative medicine that uses stem cells, such as iPS cells.

2) Promotion of Innovative Cancer Research

In Japan, one in two people has a possibility to have cancer and one of three dies from this disease (360,000 persons/year as of 2011), which remains a serious problem for nation's life and health. Therefore, the government has promoted the development of the novel methods of prevention, diagnosis, and treatment of cancer, based on the "Third term Comprehensive 10-Year Strategy for Cancer Control" (decision of the Minister of Education, Culture, Sports, Science and Technology and the Minister of Health, Labour and Welfare on July 25, 2003), "Cancer-fighting Basic Act" (Act No.98 of 2006), and the "Basic Plan to Promote Cancer Control Programs" (Cabinet decision on June 15, 2007).

Since Japan will see the final year of the "Third term Comprehensive 10-Year Strategy for Cancer Control" in 2013, the government is planning to overview the current status of domestic and foreign research of cancer and to formulate new comprehensive cancer research strategies during FY 2013 which show the future direction and the specific items, so that the agencies concerned can promote strategic research as a whole.

MEXT is implementing the "Project for Development of Innovative Research on Cancer Therapeutics (P-DIRECT)" in cooperation with MHLW and METI; selecting carefully the results of the innovative basic research toward the establishment of next-generation medicine; and promoting the development of compounds useful for diagnosis, drug trials, etc. Also, MEXT is promoting the research based on personal genetic information toward the tailored-medicine for cancer by means of drug therapy.

MHLW is continuing the past strategic cancer research, and promoting the development of innovative therapies that can restrict and eradicate cancer stem cells, mainly by targeting refractory cancers. Because the cancer vaccine therapy is rapidly advancing as the fourth therapy following the operation, radiation therapy and chemotherapy, MHLW is promoting high-quality non-clinical trials and international-level of doctor-centered clinical trials for drug development mainly for refractory and/or orphan cancer, by taking advantage of Japan's rich performance of studies. These include cancer vaccine therapy, molecular target drugs (such as antibody drugs), nucleic acid medicine, and cancer peptide vaccine. MHLW is also promoting research for palliative care for cancer patients and their family, such as the methods for effective caner pain evaluation, advanced information communication, and palliative care quality assessment, in order to improve physical pain, cancer-specific pain, depression and anxiety, psychological and mental pain, and social distress including work and money problems.

METI is implementing the "Comprehensive R&D of an Early Stage Diagnosis Method and Instruments to Treat Cancer," and developing an image diagnostic system that enables cancer to be detected in the extremely early stage and that the characteristic of cancer can be understood correctly.

3) Analysis of Protein Structure and Function

MEXT is implementing the "Drug Development and Life Science Research Support Infrastructure Project" by utilizing the technology bases for protein structure and function analysis, which were improved through the protein 3000 project and the target protein research program; supporting the research for their commercialization including drug development; and promoting their upgrade.

RIKEN is also utilizing the protein production technology, structure and function analysis technology, and computational science, in order to upgrade the protein structure prediction.

To accelerate drug development using genetic information, METI is implementing R&D toward the

basic technology: such as the technology to make drug development effective by using and simulating the structural information of membrane proteins that play an important role in vivo; and the technology to analyze the acquired genomic modification accurately.

4) Promotion of Genomic Science Research

Based on the completed and accurate human genome decoding and the subsequent genome function analysis, MEXT is implementing the "Research Program of Innovative Cell Biology by Innovative Technology (Cell Innovation)" from FY 2009 to decode the complex system of life by targeting cancer cells, by utilizing the innovative analyzing technology such as the next-generation sequencer.

5) Promotion of R&D for Radiation Therapy Equipment

The National Institute of Radiological Sciences is promoting the research of heavy-ion cancer therapy that is expected as a breakthrough therapy for refractory cancer, and making efforts to propagate it home and abroad. Based on the R&D performed by the National Institute of Radiological Sciences, Gunma University has installed a small type of heavy-ion cancer therapy facility to provide patients with medical treatment.

6) Promotion of Dynamic Biological Systems Science

Biological systems are comprised of multiple factors intertwined spatiotemporally. Understanding these systems and controlling "Dynamic Biological Systems Science" are expected to contribute greatly to innovative technologies, including regenerative medicine and pathological prediction.

MEXT launched the Dynamic Biological Systems Science Promotion Project for drug development and others in accordance with the 2011 report about "How to Promote the Dynamic Biological Systems Science" (The Working Group of CST's Subdivision on R&D Planning and Evaluation, and the Life Science Committee, on July 19, 2011), and started improving the center toward the development of research of the relevant field. RIKEN and Osaka University are proactively implementing the state-of-the-art technology of measuring, calculating, and modeling the life phenomena to reconstruct cell functions. They are also implementing further research aimed at the creation of basic technology under the JST Strategic Basic Research Programs.

7) Other Efforts for Safe and Effective Treatment

RIKEN is implementing basic research for allergy and immunology diseases. RIKEN and Sagamihara National Hospital have executed the collaborative research agreement to promote basic and clinical combined research efficiently.

To realize safer treatment for patients, MHLW is promoting the development of test drugs for appropriate selection for patients who require drug administration, and the development of non-invasive/minimal invasive medical equipment that uses nanotechnology.

(4) Improvement of QOL in Elderly, Disabled, and Patients

(Promotion of medical and welfare technology development)

In Japan, an aging society with a declining birthrate is rapidly progressing unlike any other country in

the world. The government is pressed to respond to this serious problem and improve nation's QOL and welfare.

To make use for clinical applications and life support, MIC, MEXT and MHLW aim to develop a Brain Machine Interface (BMI) that can decode the information inside the brain in the non-invasive/minimal invasive way, and that can treat, recover and interpolate the physical functions.

MIC is implementing R&D for the network robot technology serving for healthcare and support, which can achieve sophisticated behaviors through information collection and circumstantial analysis.

To support disabled people's independence and participation into society, MHLW has been implementing the "Project for Development and Promotion of Equipment to Support Independence of Persons with Disabilities" since FY 2010 to develop convenient support apparatuses that can be used easily by disabled people by reflecting their needs.

METI is promoting the project to provide support for private business operators who are engaged in R&D for welfare apparatuses. METI established the "Focused area of robot technology used for care" on November 12, 2012, and organized the "Robot care apparatus development partnership" in cooperation with MHLW to intensively support the development and commercialization of robot care apparatuses.

METI is also working on the data collection, analysis, and global standardization of safety verification methods that are essential for robots that directly operate in contact with people for life support.

## 2 System Reform toward Life Innovation Promotion

To promote life innovation, it is necessary to lay out policies for critical medical issues, and to improve the systems that link the results of research with prompt commercialization of medical drugs and equipment. MEXT and the agencies concerned are developing support bases for R&D for medical drugs and equipment, and preparing biological resources and database that become bases of life science. It is also critical to address proper animal testing, bioethical issues, and safety in life science.

(Improvement of systems for medical R&D promotion toward commercialization)

To promote medical innovation addressed by the agencies concerned as a whole, the Medical Innovation Council decided the "Five-Year Medical Innovation Strategy" on June 6, 2012, and its content was included in the "Japan Revitalization Strategy" that was decided in the Cabinet on July 31, 2012.

(Promotion of drug development and medical technology support bases)

To improve the drug development and medical technology support bases that link the excellent results of basic research with commercialization of innovative drugs, MEXT is developing the technological bases (such as the world's highest level of the Radiation Facility and Compound Library Facility, and the protein production and bioinformatics technologies); upgrading them; and promoting the "Platform for Drug Discovery, Informatics, and Structural Life Science," so that they are shared among industries and universities.

(Improvement of systems for conducting bridge linking research and clinical studies/trials)

MEXT has been promoting since FY 2007 the "Coordination, Support and Training Program for Transitional Research" in cooperation with MHLW and METI to improve the support bases for the

bridge linking research toward commercialization, by targeting universities that have the prospective achievements of basic research. In addition, MEXT started the "Bridge Linking Research Acceleration Network Program" in FY 2012 to enrich the support bases and to make them networked, by aiming at acceleration and enhancement of the seed nurturing abilities and making the bases perpetual.

To produce Japan's innovative medical drugs and equipment, MHLW is promoting the "Project of Early Exploratory Clinical Trial Bases for Specific Research Areas" by targeting hospitals and national centers that provide patients with advanced and specialized medical care. Thus, MHLW is improving the trial bases where clinical trials can be conducted for new drugs and equipment used for the first time for humans, ahead of any other countries. In addition, MHLW is promoting the "Clinical Research Core Hospital Development Project" from FY 2012 to improve the bases where international level of clinical research and doctor-centered clinical trials can be conducted. MHLW is also promoting the "Japan-Centered Global Clinical Research System Development Project" to conduct international joint research, in which planning and adjustment of participating medical institutions can be made consistently. Besides, MHLW is developing and supporting doctor-centered trials from FY 2011 in Iwate, Miyagi, and Fukushima prefectures to create innovative medical equipment by using the strength of Tohoku regions, and eventually to invite industries, create jobs and restore Tohoku regions' local economy.

The Pharmaceuticals and Medical Devices Agency (PMDA) started "the pharmaceutical affairs consultation on R&D strategy" in July 2011 to commercialize academia ventures' excellent seeds.

To promote the development of medical equipment, METI is implementing the "Program to formulate guidelines designed to promote development and commercialization of medical equipment" in cooperation with MHLW, in which the evaluation items on the technological and biological stability of medical equipment are clarified for future prospective commercialization.

(Improvement of biological resources)

Biological resources are essential to pave the way for new research areas. They are required to be developed, collected, stored and provided from the national viewpoint.

Under the "National BioResource Project," MEXT is improving the systems so that biological resources including animals and plants that may become the base of life science and strategically important for the country can be collected, stored and provided in a systematic manner. METI is actively implementing the development of biological genetic resources in Asia, by executing the bilateral agreement with each of Asian countries under the Convention on Biological Diversity (CBD), and by forming the multilateral collaboration system (Asia Consortium) to conserve and sustainably use microbial resources.

(Promotion of integrated life science data base)

Recently, DNA sequencing data, protein conformational data, and genetic expression data have been produced on a massive scale because of advanced life science studies. To use such database effectively, it is important to improve the integrated database of biological information and to promote bioinformatics that relates to life science and IT (information technology).

In May 2009, the integrated DB taskforce meeting set up in the "Council for Science and Technology Policy (CSTP) Life Science PT" prepared and published the report about a concept of the data center; so

that necessary functions can constantly be provided for users seeking information; the databases can be used for new information input, and maintained and managed; the useful data/database collected and prepared by the agencies concerned in the individual projects can be effectively promoted; and their scattering can be prevented. Based on the report, MEXT has integrated the "Integrated Database Project" and the "Bioinformatics Research and Development (BIRD)," established the "Bioscience Database Center (NBDC)" in FY 2011; started the "Life Science Database Integrated Project," and is promoting R&D necessary for the integration of life science databases that were made by various research institutes. In addition, MEXT, MHLW, MAFF, and METI have established the joint portal site[1] to display both the database integration policies and the achievements in life science being addressed by the four ministries, while the steering committee is operating the site by discussing the security and the operation guidelines.

The ministries decided every October 5th would be "Integration Day," and held symposiums to discuss database integration-related issues.

(Issues on System Improvement in Life Science Research)

1) Efforts for proper implementation of animal trials

The "Act on Welfare and Management of Animals" was amended in June 2005 by the legislation introduced by Diet members, and the concepts of 3R (Replacement, Reduction, and Refinement) in animal trials have been stipulated.

The act has been separated between laboratory animals and animal trials: the criteria of laboratory animals would be decided by the Environment Minister, and the "Standards Relating to the Care and Management of Laboratory Animals and Relief of Pain (Care and Management Standards)" were publicly notified on April 28, 2006.

MEXT, MHLW, and MAFF have established the unified basic guidelines for the jurisdictional institutions, enforcing proper animal trials under the guidelines.

2) Approach for bioethical issues

Today's rapidly advancing life science is beneficial for people, but includes ethical questions of threatening human dignity and rights, for which the agencies concerned have taken necessary regulations.

The research of human embryonic stem cells has a potential of great contribution to the development of medicine and biology, but involves bioethical issues because they are taken from human embryos. The agencies concerned have taken proper measures for the research of derivation, distribution, and utilization of human ES cells, based on the "Guidelines on the Derivation and Distribution of Human Embryonic Stem Cells" (MEXT public notice No. 86 of 2010) and "Guidelines on the Utilization of Human Embryonic Stem Cells" (MEXT public notice No. 87 of 2010). They have also taken proper measures for the research of utilizing human cloning, based on the "Act on Regulation of Human Cloning Techniques" (Public notice No. 146 of 2000).

In light of recent trend in human genome/gene research and advances of analytic techniques, MEXT, MHLW and METI reviewed the "Ethical Guidelines for Human Genome/Gene Analysis Research," and

1 http://integbio.jp/ja/

completely revised the guidelines in February 2013. Concerning epidemiological research, MEXT and MHLW are jointly reviewing the "Ethical Guidelines for Epidemiological Research."

3) Efforts to secure safety in life science

Recombinant DNA technology can bring a new combination of genes that do not exist in nature, and has been broadly applied to the basic biological research, drug manufacturing, and improvement of agricultural products. To prevent the influence on biodiversity, necessary restrictions have been made against the use of living modified organisms, based on the "Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Act No. 97 of 2003)."

Concerning the clinical research for gene therapies, appropriate efforts have been promoted based on the "Guidelines for Gene Therapy Clinical Research (MEXT/MHLW public notice No. 2 of 2004)."

Table 2-2-8/ Major Policies for Promotion of life Innovation (FY 2012)

| Ministry or Agency | Implementing Agency | Project/Program |
|---|---|---|
| Ministry of Internal Affairs and Communications (MIC) | MIC | Novel and Innovative R&D Making Use of Brain Structure |
| | National Institute of Information and Communications Technology (NICT) | Research and Development of Universal Communication Basic Technology |
| | | Research and Development of Future Information and Communication Basic Technology |
| Ministry of Education, Culture, Sports, Science and Technology (MEXT) | MEXT | Japan Initiative for Global Research Network on Infectious Diseases |
| | | Japan Advanced Molecular Imaging Program Strategic (J-AMP) |
| | | Project on the Implementation of Personalized Medicine |
| | | Project for Development of Innovative Research on Cancer Therapeutics (P-DIRECT) |
| | | Life Science Research Support Basic Project (Including Drug Development) |
| | | Accelerated Bridging Research Network Program |
| | | Project for Realization of Regenerative Medicine |
| | | Strategic Research Program for Brain Science |
| | | Research Program of Innovative Cell Biology by Innovative Technology (Cell Innovation) |
| | | Tohoku Medical Megabank Project |
| | | National BioResource Project |
| | National Institute of Radiological Sciences | Research in Heavy-ion Cancer Therapy |
| | | Disease Diagnosis Research with Molecular Imaging Technology |
| | | Research on Radiation Safety |
| | | Research on Radiation Emergency Medicine |
| | | Research on Radiation Emergency Assessment |
| | | Basic Technology Development in Radiation Science Field |
| | Institute of Physical and Chemical Research (RIKEN) | Comprehensive Research Project on Brain Science |
| | | Plant Science Research Project (RIKEN Plant) |
| | | Immunity and Allergy Science Integrated Research project |
| | | Genomic Medicine Research Project (RIMEN Genome) |
| | | Generative and Regenerative Science Integrated Research Project |
| | | Molecular Imaging Research Project |
| | | Bio-Resources Project (RIKEN Bio-Resources) |
| | | Life Science Research Centers (RIKEN Life Science Platform) |
| | | Life System Research Project |
| | Japan Science and Technology Agency (JST) | Life Sciences Database Integrated Project |
| | | JST Strategic Basic Research Programs (Yamanaka iPS Cells Special Project, CREST "Creation of Basic Technology to Understand and Control Dynamic Biological Systems", and Sakigake (PRESTO) "Clarification and Control of Dynamic Homeostasis and Modification Mechanism of Body", etc.) |

| | | |
|---|---|---|
| Ministry of Health, Labour and Welfare (MHLW) | MHLW | Innovative Drug, Medical Equipment, Regenerative Medical Product Commercialization Promotion Project |
| | | Commercialization Study Project for Intractable Diseases and Cancer (Cancer-Related Study Field) |
| | | Research Project on Emerging and Re-emerging Infectious Diseases, including Pandemic Influenza |
| | | Children's Specific Chronic Disease Treatment Research Expenses |
| | | Grants-in-Aid for Radiation Effects Research Foundation |
| | | Health and Labour Sciences Research Grants |
| | | Specific Disease Treatment Research Grants |
| | | Entrustment Expense Fees for Toxic Gas Disability Person Investigation |
| | | Clinical Research Core Hospital Improvement Project |
| | | Project of Early Exploratory Clinical Trial Bases for Specific Research Areas |
| | | Japan-Centered Global Clinical Research System Improvement Project |
| | National Institute of Infectious Diseases (NIID) | Expenses for Manufacturing and Testing of Serum and Others |
| | National Institute of Health and Nutrition | Health Food Safety Information Network Project |
| | | Research of Efficiency Evaluation and Health Effects of Health Food Components |
| | | Research of Exercise & Diet Combined Effects for lifestyle Disease Prevention |
| Ministry of Agriculture, Forestry and Fisheries (MAFF) | National Agriculture and Food Research Organization (NARO) | Research Project on Development Agricultural Products and Foods with Health-promoting benefits |
| Ministry of Economy, Trade and industry (METI) | METI | Program to Formulate Guidelines Designed to Promote Development and Commercialization of Medical Equipment |
| | | Problem-Solving Medical Equipment Development Project |
| | National Institute of Advanced Industrial Science and Technology (AIST) | Healthcare Support Technologies using Cell-Manipulation and Biomaterial Technologies |
| | | Technologies to Characterize and Analyze the Functions of Biomolecules |
| | | Drug Discovery Support Technologies and Diagnostic Techniques through the Amalgamation of Information Processing and Bioanalysis |
| | | Advanced Measurement Technologies of Human Functions and Behaviors |
| | | Assessment Technique of Health Condition based on Biomedical Information |
| | | Development of Technologies to Restore Health and Achieve healthy Life |
| | | Development of National Measurement Standards to Support Life Innovation |

| | | |
|---|---|---|
| | | Establishment of Safety of Personal Care Robots |
| | | Development of Highly Efficient and Functional Systems Through the Use of IT |
| | New Energy and Industrial Technology Development Organization (NEDO) | Project for Ultralow Power Devices to Realize Low Carbon (Generating) Society |
| | | Comprehensive R&D of an Early Stage Diagnosis Method and Instruments to Treat Cancer |
| | | Research and Development of Next-generation Regenerative Technology |
| | | Life Support Robot Commercialization Project |
| | | Fundamental Technology Development for Promoting the Industrial Application of Stem Cells |
| | | Fundamental Technology Development for Promoting the Industrialization of Stem Cells |
| | | Fundamental Technology Development for Drug Discovery Using Epigenetic Genome Modification Mechanisms |
| Ministry of the Environment (MOE) | MOE, National Institute for Environmental Studies (NIES) | Japan Environment and Children's Study (JECS) |

## Section 4 System Reform toward Promotion of Science and Technology Innovation

### 1 System Reform toward Promotion of Science and Technology Innovation

(1) Establishment of "Science, technology and innovation (STI) Strategy Councils (tentative name)"

"The Council for Science and Technology Policy (CSTP)" has established the "Science, technology and innovation (STI) Strategy Councils" under the expert panel on STI policy promotion.

The STI Strategy Councils have been established as a forum where industry-wide key persons and related-persons can cooperate with each other to address nation's critical issues and innovations, because individual results from R&D in each field had not been linked to the solution of social issues by the time of the third-term basic plan. In the STI Strategy Councils, people concerned are discussing drafted action plans and necessary system reforms (regulations, system reforms, deployment acceleration, etc.) to unify strategic plans from R&D to system reforms.

In March 2012, the STI Strategy Councils established three bodies, i.e., "Recovery and reconstruction Strategic Council," "Green Innovation Strategy Council," and "Life Innovation Strategic Council" that deal with three major issues, respectively, as those mentioned in "Chapter 2, Basic Plan," and formed the action plans in July 2012, and coordinated the system reforms to promote innovations in each field in December 2012.

(2) Improvement of "Knowledge" Network of Business-Academia-Government Collaboration

Innovation can serve for Japan's economic growth. To link the excellent results of research from universities and public institutions with innovation, it is necessary to improve the "knowledge" network of business-academia-government collaboration. The following section describes the status of their

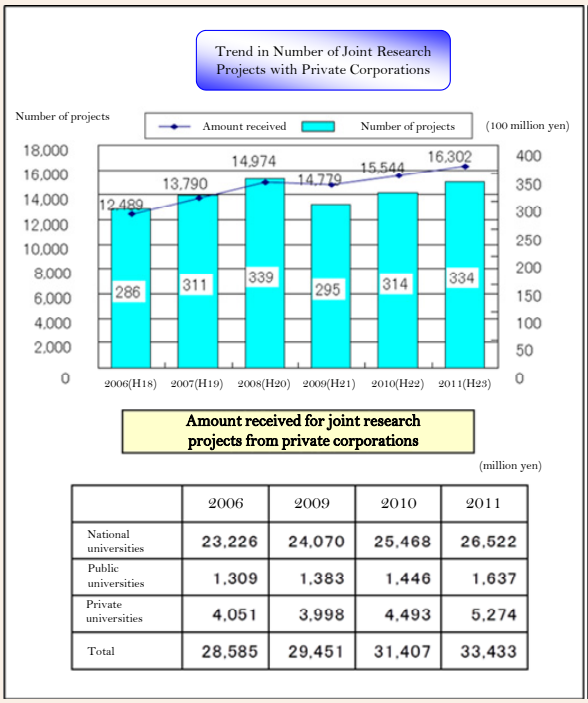
cooperative activities, and the government's efforts to improve such cooperation.

1) Current status of cooperative industrial-academic activities home and abroad

(i) Status of business-academia-government collaboration in universities

Since the corporatization of national universities in April 2004, cooperative business-academia-government activities have been achieved steadily, especially in universities. In FY 2011, "the number of the collaborative research activities" between universities and private corporations was 16,302 (increased by 4.9% compared with the previous year) and "the amount received for joint research from private corporations" was about 3.34 billion yen (increased by 6.5% compared with the previous year). When compared with FY 2006, "the number of the cooperative research activities" increased about 1.3 times, and "the number of the patent licensing" increased to 5,645, up about 2.3 times that of FY 2006 (Figure 2-2-9).

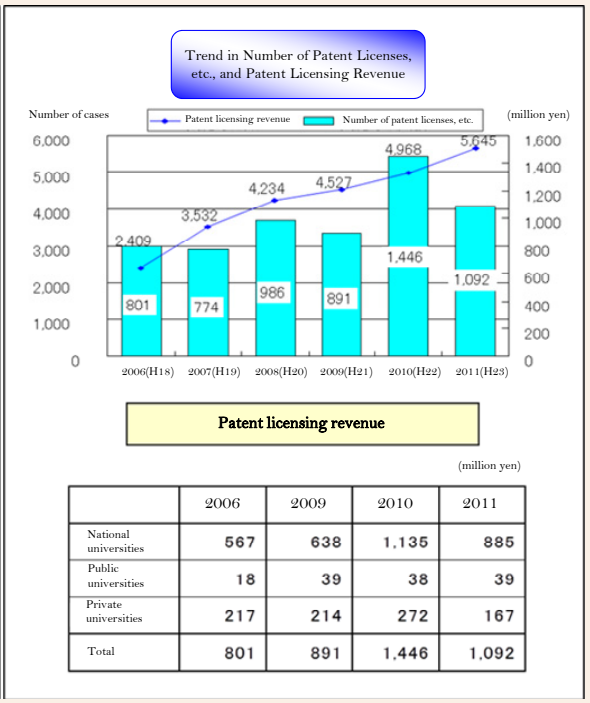
Figure 2-2-9/ Transition in Achievement of Cooperative Research in Universities




**Amount received for joint research projects from private corporations**

(million yen)

| | 2006 | 2009 | 2010 | 2011 |
|---|---|---|---|---|
| National universities | 23,226 | 24,070 | 25,468 | 26,522 |
| Public universities | 1,309 | 1,383 | 1,446 | 1,637 |
| Private universities | 4,051 | 3,998 | 4,493 | 5,274 |
| Total | 28,585 | 29,451 | 31,407 | 33,433 |




**Patent licensing revenue**

(million yen)

| | 2006 | 2009 | 2010 | 2011 |
|---|---|---|---|---|
| National universities | 567 | 638 | 1,135 | 885 |
| Public universities | 18 | 39 | 38 | 39 |
| Private universities | 217 | 214 | 272 | 167 |
| Total | 801 | 891 | 1,446 | 1,092 |

Note 1. Subject: National, public and private universities
2. The term "Universities" indicates junior colleges, technical colleges and inter-university research institutes.
3. The number of patent licenses, etc. denotes the number of patents which have been licensed or transferred (patent at the stage of "to be received" included).
4. Total" amount and "total of intermediate total of national, public and private universities" amount may not match because any amount less than a million yen is rounded off.

Source: Implementation Status of Industry-Academia-Government Collaborations at Universities (2011)," MEXT (as of October 26, 2012)

(ii) Activities of Technology Licensing Organization (TLO)

TLO is an organization that provides an enterprise with the license of a patent obtained from research by a university, and that receives a licensing fee from the enterprise in consideration of the license, then

returns the fee to the university or researcher (inventor) as research funds.

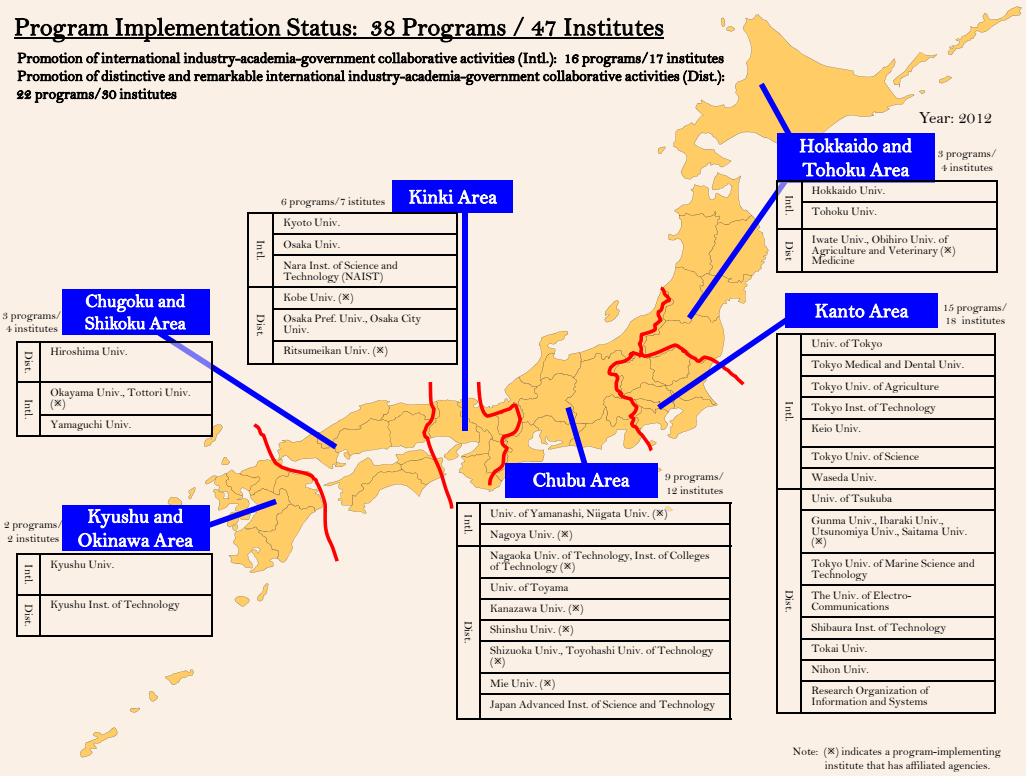
As of March 1, 2013, 39 TLOs have been approved by MEXT and METI under the "Act on the Promotion of Technology Transfer from Universities to Private Business Operators" (Act No.52 of 1998). In FY 2011, the number of patent licenses reached 3,123.

2) Effort for expanding business-academia-government collaboration

(i) Development of business-academia-government collaboration system in universities

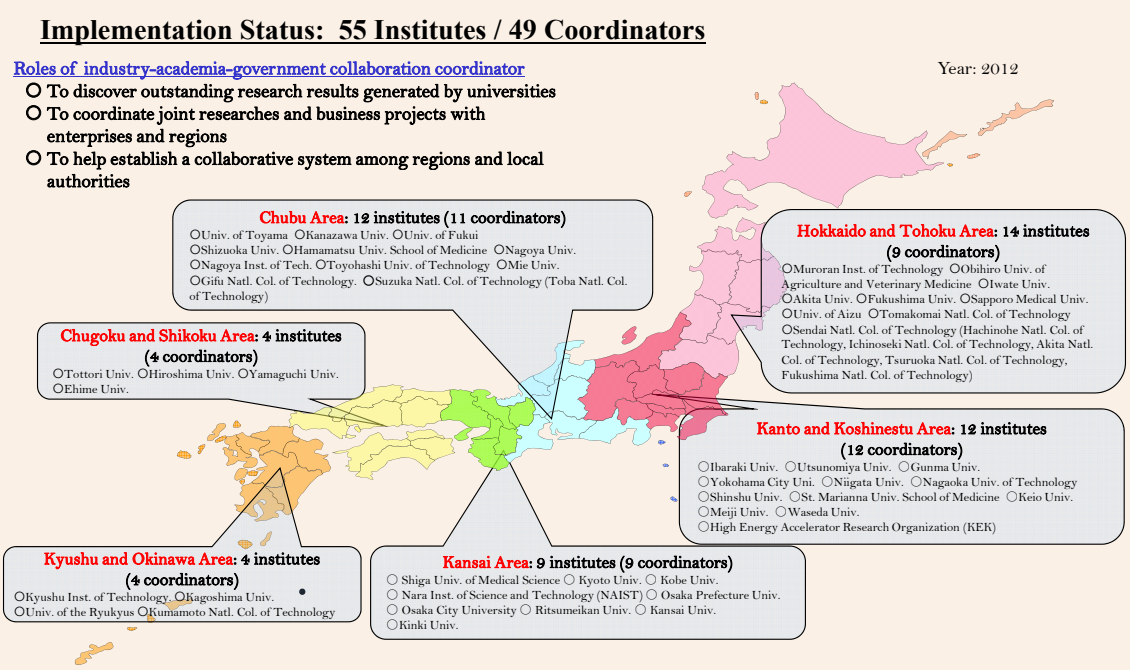
To effectively link the results of universities' research with society, MEXT has supported the international business-academia-government and inter-university collaborations, and arranged coordinators to enhance the uniqueness of activities and to improve the environment for collaboration under "The Program for Promoting Self-Sustaining Management of Industry-Academia-Government Collaboration in Universities" (Figures 2-2-10 & 2-2-11).

Figure 2-2-10/ List of Universities Supported by "The Program for Promoting Self-Sustaining Management of Industry-Academia-Government Collaboration in Universities [Function Enhancement Support Type" (FY 2012)




Source: Created by MEXT

Figure 2-2-11/ List of Universities Supported by "The Program for Promoting Self-Sustaining Management of Industry-Academia-Government Collaboration in Universities [Coordinator Support Type" (FY 2012)




Source: Created by MEXT

Each university has unified the Industry-Academia-Government Collaboration Division and the Intellectual Property Management Division to develop the university-wide cross-cutting system with its vice president centered and to make the basic rules for intellectual property policies, and thus formulated and revitalized the basic system and industry-academia-government collaboration activities (Table 2-2-12).

Table 2-2-12/ Status of Improvement in IP Management and Utilization System (university's IP management center) (FY 2012)

| | Already developed (institution) | Scheduled to be developed (institutions) | Not scheduled to be developed (institution) | Number of universities responded (institution) |
|---|---|---|---|---|
| Total | 244 (230) | 161 (154) | 535 (495) | 940 (879) |
| National universities | 77 ( 75) | 4 ( 4) | 10 ( 12) | 91 ( 91) |
| Private universities | 133 (123) | 139 (132) | 480 (435) | 752 (690) |
| Public universities | 34 ( 32) | 18 ( 18) | 45 ( 48) | 97 ( 98) |

Source: Created by MEXT

The Japan Patent Office has sent "university network IP advisors" (experts of university's intellectual property management) to wide-area networks configured by multiple universities, through the National Center for Industrial Property Information and Training (INPIT), in order to construct university's IP management systems and to enhance the IP management function toward the development of industry-academia-government collaboration.

MIC is promoting cooperative industry-academia-government R&Ds and demonstration tests using the New Generation Network Testbed (JGN-X) that has been constructed and managed by the National Institute of Information and Communications Technology (NICT) (Refer to Part 2, Chapter 3, Section 1, 2 (2)).

Through "The Regional Support Coalition of Industry-Academia Collaborative Activities," MAFF has allocated coordinators (experts of the agriculture, forestry and fisheries and food industries) across the country to collect research seeds and to support research plan making.

(ii) Enhancement of R&D through industry-academia-government collaboration

To return the universities' innovative technology to society and link it to innovation, the Japan Science and Technology Agency has publicly launched on the "Industry-Academia Cooperative Commercialization Development Project" as a near-to-mid-term commercialization efforts by using the FY 2012 supplementary budget, so that it can support corporations which intend to carry out the development of projects using universities' technology.

In addition, the Agency is promoting three programs: "The Adaptable Seamless Technology Transfer Program through Target-driven R&D (A-STEP)," which seamlessly supports from the discovery of prospective seeds in universities and public research institutes to the commercialization; "The Strategic Promotion of Innovative R&D (S-Innovation)," which supports R&D carried out under the theme based on excellent results and expected to become a new industry creation base; and "The Collaborative Research Based on Industrial Demand," which supports universities' basic research that could resolve technical challenges faced by industries.

METI provides support for the approved TLOs so that they can launch technology transfer projects, strengthen collaboration and unification among organizations, and commercialize and industrialize universities' research results.

3) Promotion of constructing industry-academia-government network

To promote the construction of industry-academia-government networks, it is essential to raise shared awareness between industries and academia. The country is gathering people of private corporations and universities throughout the country and promoting matching among them by opening lectures and seminars in a form of forums. On the other hand, to share information, universities disclose their achievements by means of workshops, publication of periodic journals including annual reports, presentation of research papers in various meetings and on academic journals, or patent disclosures. The major efforts by the country are as follows:

(The 2012 Industry-academia-government collaboration promotion meeting [September 27 and 28, 2012])

"The 2012 Industry-academia-government collaboration promotion meeting" was held under the

sponsorship of the Cabinet Office, eight agencies, two institutions, and 10 independent administrative institutions. In the meeting, 14 outstanding achievements that contributed greatly to the industry-academia-government collaboration were awarded (Table 2-2-13).

Table 2-2-13/ Award Winners Contributed to Industry-Academia-Government Collaboration

| Award | Project | Winner's Name and Affiliations | |
|---|---|---|---|
| Prime Minister's Prize | Implantable auxiliary artificial heart, Development of "EVAHEART" | Shunichi Yamazaki<br>Kenji Yamazaki | President, Sun Medical Co., Ltd.<br>Chairperson, Ph.D. in Medicine, Cardiovascular Surgery, Tokyo women's Medical University Hospital |
| Minister' Award, Ministry of State for Science and Technology Policy | Development of Nano-precision machining method and aspherical glass lens high-precision method | Tsunemoto Kuriyagawa<br>Junichi Iisaka<br>Yutaka Hayashi | Professor, Department of Engineering Research, Tohoku University Graduate School<br>Technical Advisor, Department of New Project Development Sendai Office, Nikon Co. Ltd.<br>Head of Department of Machining System Research R&D Center, Jtekt Corporation |
| Minister's Award, Ministry of Internal Affairs and Communications (MIC) | Research promotion and demonstration of ultra reality communication technology | Hiroshi Harashima | Honorary Professor, The University of Tokyo<br>Special Invitation Professor, Ritsumeikan University |
| Minister's Award, Ministry of Education, Culture, Sports, Science and Technology (MEXT) | Development of electronic compass and motion sensor using magnetic impedance (MI sensor) | Kaneo Mouri<br>Yoshinobu Honkura | Honorary Professor, Nagoya University<br>Managing Director, Aichi Steel Corporation |
| | Development of "Monoclonal antibody rapid manufacturing technology" (ADLib® system) | Masaaki Fujiwara<br>Satoshi Ohta | President, CHIOME Bioscience Inc.<br>Outside Director and Professor, Graduate School of Arts and Sciences, and Environmental Science, The University of Tokyo |
| Minister's Award, Ministry of Health, Labour and Welfare (MHLW) | Commercialization of "Hepatocyte differentiated and induced from Human iPS Cells" | Kenji Kawabata<br>Hiroyuki Mizuguchi<br>CHikafumi Yokoyama | Project Leader of Stem Cell Control Project, National Institute of Biomedical Innovation<br>Professor of Molecular Biology field, Osaka University Graduate School of Medical Research<br>President, Reprocell Inc. |
| Minister's Award, Ministry of Agriculture, Forestry and Fisheries (MAFF) | Development of "easy preprocessing BSE test kit" | Takashi Yokoyama<br>Yuko Ushiki<br>Takuji Yamamoto | Senior Researcher (Project Leader), Prion Disease Research Center, National Institute of Animal Health National Agriculture and Food Research Organization<br>Section Chief, Nippi Research Institute of Biomatrix<br>Assistant Section Chief, Nippi Research Institute of Biomatrix |

| | | | |
|---|---|---|---|
| Minister's Award, Ministry of Economy, Trade and Industry (METI) | Development of "Nanoe" produced with nanoparticle technology | Kikuo Okuyama<br>Toshiyuki Yamauchi<br>Hiroshi Suda | Professor, Faculty of Engineering Hiroshima University Graduate School<br>Counselor, Material and Technology Research Center, Technology Headquarters, Panasonic Corporation, Appliance Corporation<br>Chief Engineer, Home Appliance Development Center, Technology Headquarters, Panasonic Corporation, Appliance Corporation |
| | Development of "swirling jet type ozone waste treatment system that reduces sludge to one-tenth" | Manabu Iguchi<br>Moriyoshi Shitara | Honorary Professor, Hokkaido University<br>President, HUENS CO., Ltd. |
| Minister's Award, Ministry of Land, Infrastructure, Transport and Tourism (MLIT) | Development of unprecedented shield tunneling method (shield machine can depart from/arrive at ground surface) | Kazuo Nishimura<br>Mitsutaka Sugimoto<br>Masayoshi Izawa | Professor, Urban Environment Science Research Department, Tokyo Metropolitan University<br>Professor, Engineering Department, Nagaoka University of Technology<br>Section Chief of Tokyo Headquarters, Obayashi Corporation |
| | Development and commercialization of VOC (volatile organic compounds) and paint that reduce resistance of ship's hull | TOA-Chugoku Paints Co., Ltd<br>Hitachi Chemical Co., Ltd.<br>National Maritime Research Institute<br>Ship's Bottom Anti-fouling Low VOC Paints Development and Commercialization Team | |
| Minister's Award, Ministry of the Environment (MOE) | Development of optimal control technology of low carbon type office facilities using integrated intelligent lighting and radiation panel air conditioner systems | Kenji Hosokane<br>Takaharu Kawase<br>Mitsunori Miki | City Planning Project Manager, Mitsubishi Estate Co., Ltd.<br>Professor, Chiba University Graduate School of Engineering<br>Professor, Doshisha University Graduate School of Engineering |
| Chairman's Award, Japan Economic Federation | Development of "1700℃-level gas turbine cooling technology" | Eisaku Ito<br>Keizo Tsukagoshi<br>Kenichiro Takeishi | Assistant Manager of Gas Turbine Engineering Division and Chief of Technology Management Department, Mitsubishi Heavy Industries Ltd.<br>Chief Engineer and Executive Advisory Engineer of Motor Business Headquarters, Mitsubishi Heavy Industries Ltd.<br>Professor, Osaka University Graduate School of Engineering |
| President's Award, Science Council of Japan (SCJ) | Development of "Disturbance observer applied technology" | Kohei Ohnishi<br>Tojiro Aoyama<br>Yasuhiro Kakinuma | Professor, Department of Science and Engineering, Keio University<br>Professor, Department of Science and Engineering, Keio University<br>Assistant Professor, Department of Science and Engineering, Keio University |

(Innovation Japan [September 27 & 28, 2012])

To actively return the advanced achievements in universities and public institutions to society[1], MEXT and METI held the "Innovation Japan 2012," Japan's largest scale matching forum, by gathering

1 This event has been held simultaneously with the industry-academia-government collaboration promotion meeting since 2011.

people in universities, public research institutions, and private corporations, in cooperation with the Japan Science and Technology Agency and the New Energy and Industrial Technology Development Organization (NEDO).

(Agribusiness Creation Fair [November 14–16, 2012])

In cooperation with each ministry and institution, MAFF holds "Agribusiness Creation Fair" every year to exhibit technology seeds from private corporations, universities, public experimental research institutions, and independent administrative institutions, all of which are engaged in research in the field of the agriculture, forestry and fisheries and food industries, so that they can collaborate with institutions which are in need of technology. In FY 2012, the exhibition was held next to the exhibition hall of private corporations that are promoting industrial use of their new technology. In the fair, nationwide 189 institutions exhibited their seeds and about 33,000 people participated. The coordinators, who were allocated in the hall to mediate between industries and universities, promoted the matching between the participants and the visitors by giving the guided tour in the hall. Local agribusiness creation fairs were also held in three places in the country, strengthening the industry-academia-government collaboration network in local regions.

(3) Construction of "Forums" for Industry-Academia-Government Collaboration

To promote scientific and technological innovation effectively and promptly, it is required to construct "forums" where industry-academia-government can cooperate with each other.

1) Formation of Open Innovation Complexes

(i) Improvement of industry-academia joint R&D facilities

To support the improvement of industry-academia joint R&D facilities including a vision of local vitalization (a part of it is being improved), METI is carrying out the "Technology Bridge Development Program" (joint R&D facilities) by earmarking the FY 2010 first supplementary budget, so that both the universities addressing advanced R&D for commercialization and the private corporations aiming at the realization of such universities' technology can construct a joint research system and can work on the activities ranging from research and application to product testing.

(ii) Enhancement of Functions in Tsukuba Science City and Kansai Science City

"The National Spatial Strategy (National Plan)" (Cabinet decision of July 4, 2009) has stated as follows: "Universities and national and research and development institutions, including those in Tsukuba Science City and Kansai Science City, are important intellectual/human resources and they are to be utilized to contribute to our nation's development". Based on this statement, Tsukuba Science City and Kansai Science City are working on the following activities.

The Fourth-term basic plan has also stated, "International R&D complexes including Tsukuba Science City and Kansai Science City have been improved, but their already accumulated complexes are to be further enhanced functionally."

a) Tsukuba Science City

Tsukuba Science City was constructed by intending to become a high-level public research and education institution as a whole and to relieve the excess concentration of Tokyo. It has more than 300 research institutes, including 32 national experimental research and education institutes, and has been promoting a lot of governmental plans, such as research exchange and improvement of functions for international research exchange.

Because the City is accumulated with advanced nanotechnology research facilities and human resources, its four bodies, i.e., Tsukuba University, National Institute for Materials Science (NIMS), National Institute of Advanced Industrial Science and Technology (AIST), and Japan Business Federation (hereinafter referred to as "4 core institutes"), have formed a core under the support of MEXT and METI, and launched in June 2009 "Tsukuba Innovation Arena" (TIA), the base of industry-academia-government collaboration cluster aimed at becoming a world nanotechnology research base. In addition, the City has improved the research base and expanded the ways of technology use toward the start of new projects by taking advantage of the core research infrastructure; as such, it became the full-fledged research base. When the City had a questionnaire by targeting related-corporations to seek opinions about the TIA management system and facilities, there were some suggestions about TIA's centralized offering system and for effective promotion. In response to these suggestions, "The TIA Executive Council" consisting of the 4 core institutes decided in March 2012 to start one-stop service for the use of shared facilities in each institute, and launched a public information campaign through "TIA open symposiums" in July 2012. In April 2012, the High Energy Accelerator Research Organization (KEK) that possesses Photon Factory newly participated in TIA, leading to the enhancement of TIA research base.

To nurture the global and next-generation nanotechnology human resources who will create Japan's new industries in the future, TIA will establish a power-electronics course and a Nano-green course from FY 2013 in the "TIA graduate school," in addition to the Nano-electronics course, which is gaining attention from the industries.

In parallel with these activities, as an R&D base opened to the industry, academia and government, TIA is expanding collaboration networks with private corporations and universities, and promoting the industrialization of nanotechnology and the development of human resources, by supplying sample materials obtained by projects to user corporations and letting them feedback for the evaluation.

The National Institute of Advanced Industrial Science and Technology (AIST) is comprehensively working on industry-academia-government collaboration under the "Research and Innovation Promotion Headquarters" that were set up in FY 2010 to enhance open innovation hub functions; e.g., capturing various technological needs from the industries and society; exploring technological seeds; and promoting R&D projects. Specifically, AIST helped TIA to become an open innovation hub; participated in 20 technology research associations to create joint innovation forums; and carried out 21 large-scaled external funding projects. In addition, AIST held the "AIST Open Lab" to send the results of its research to business managers, researchers, engineers, universities and public research institutions.

b) Kansai Science City

The Kansai Science City is promoting the construction of towns that will play a role of the base for

developing world's culture, science and research, and nation's economy. As of the end of 2012, it has at least 110 facilities rolling out various research activities.

2) Construction of "Industry-academia collaboration platform" where industry and universities interact through conversations

The Japan Science and Technology Agency constructed the "Industry-academia collaboration platform" to promote conversations between industries and universities, and is implementing "Collaborative Research Based on Industrial Demand" so that universities can be engaged in basic research of technical issues faced by industries to speed up the solution of such issues.

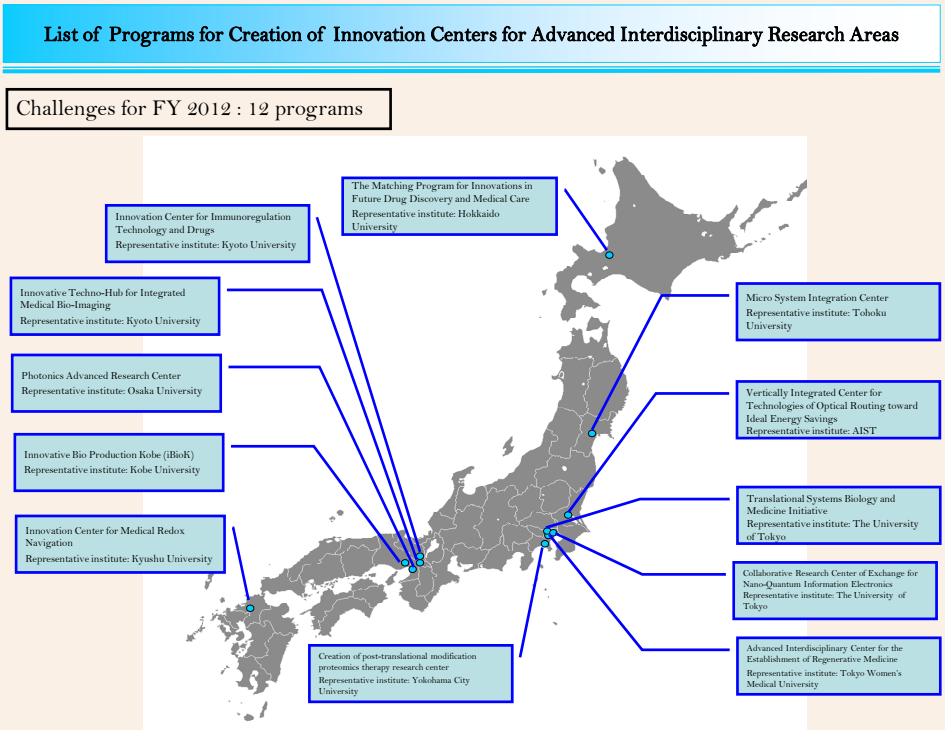
In addition, the Agency has taken up the issues faced by the industries in Tohoku region to promote the creation of research performance toward the recovery of the affected regions, in collaboration with the industry organizations (Tohoku Economic Federation, and others) and municipalities.

MAFF arranges the coordinators who promote industry-university collaboration, and hosts local matching forums to support the diffusion of local R&D and technology, so that people involved in the process from R&D to its diffusion and industrialization can address collaboratively toward the same goal.

3) Creation of Innovation Centers for Advanced Interdisciplinary Research Areas

MEXT is promoting the "Creation of Innovation Centers for Advanced Interdisciplinary Research Areas" to support institutions that form the base of R&D from the basic stage to the future commercialization under the industry-university collaboration for advanced interdisciplinary research areas, which are considered important for innovation creation; currently 12 projects are supported (Figure 2-2-14).

Figure 2-2-14/ List of Projects Being Implemented under the Creation of Innovation Centers for Advanced Interdisciplinary Research Areas




Source: Created by MEXT

4) Improvement of international science innovation bases using local resources under industry-university collaboration

To survive the global competition, Japan has to create drastic and continuous innovations and vitalize economy. By earmarking the FY 2012 supplementary budget, MEXT is working on the "International Science Innovation Base Improvement Project" to improve the "international science innovation bases" ("platforms"), where R&D for innovative projects is performed by industry-academy-government collaboration under the interdisciplinary fusion system to create new industries and new jobs under the same roof by using local resources flexibly; currently 15 bases have been supported.

## 2 Construction of New System for Science and Technology Innovation

(1) Environmental Improvement to Support Industrialization

To create new industries and jobs and vitalize economy, it is essential to activate start-up businesses by using the results of advanced scientific technology.

Approximately 2,000 University ventures have been created by the end of 2008 across the country by the industry-academia-university efforts. However, the number decreased to 69 companies in 2011 compared with 252/year, a peak in 2004 and 2005. Therefore, MEXT has been promoting the environmental improvement for start-ups by supporting seamlessly from the initial stage of R&D to industrialization.

1) Support for "university-launched venture companies"

MEXT has implemented "the project to create new industry from universities (START)" since FY 2012; by utilizing persons knowledgeable about industrialization of venture capitals; integrating R&D support with business nurturing from the pre-industrialization stage by combining government funds and industrialization knowhow; developing the business strategy and IP initiative for technological seeds that seek high-potential but high-risk world markets; and constructing a Japanese style innovation model as a sustainable system.

2) Support for R&D type ventures

RIKEN has established a preferential treatment system for patent licensing to promote the quick diffusion and industrialization of achievements. Venture capitals have to start by mainly using RIKEN's research results and to be certified by RIKEN as useful for diffusion.

The National Agriculture and Food Research Organization (NARO) has set the venture fostering framework under the "Basic Research Promotion Program for Creation of Innovation" to support the R&D by venture capitals that will play an important role in creating of new businesses and new industries.

In addition, under the "Program for promotion of private-sector commercialization research," NARO has been utilizing various resources ubiquitous in the rural areas, and taking into consideration of market needs and costs, to promote the R&D of private corporations that is in the commercializing stage, toward the sextiary industrialization in the rural areas.

3) Support by Small Business Innovation Research System (SBIR system)

A small business innovation research system (SBIR system) is the system, under which the agencies concerned constantly and jointly support R&D and industrialization in small and medium enterprises that use new technology. To assist R&D for new technology that might produce new businesses of small and medium enterprises, the subsidies and entrustment expense fees have been granted, while several support measures, including the cut-down of patent fees and low-interest loans by Japan Finance Corporation, have been taken for industrialization. In FY 2012, seven ministries (MIC, MEXT, MHLW, MAFF, METI, MLIT, and MOE) designated 119 special subsidies in all, and earmarked about 4.53 billion yen as expenditures for small and medium enterprises.

(2) Regulations and Systems to Accelerate Innovations

R&D activities are sources for creation of new "knowledge" and creation of new industries and new markets through innovations, thereby strengthening Japan's sustainable development and global competitiveness. Although regulations and systems have been established inherently for promoting safe and smooth R&D, they might hamper innovations because of excessive strictness. The government has been promoting comprehensive special zone systems, such as preferential measures in regulations, and support measures in taxation and finance, which will be expected to accelerate innovations.

(Efforts for comprehensive special zone systems)

The government has carried out the first to third designation of the comprehensive special zones, and decided seven areas as "international strategic zones" intended to form industrial and functional clusters that will become the engine of nation's economic growth, and 37 areas as "local vitalization comprehensive zones" intended to strengthen local power through local vitalization with maximum use of local resources.

Of the areas that were decided as the international strategic zones, "Tsukuba," which has many advanced research centers and Japan's largest international R&D base, had some problems: e.g. their results of research are not linked directly to new business and new industry, and the number of cases is few that are addressed in cooperation among multiple institutes with the same goal of the creation of new business and industry. To solve these issues and to promote life innovation and green innovation, "Tsukuba" is going to utilize the relaxation of regulations, such as the Act of Normalization of Grants provided by "the comprehensive special zone system," further shared use of its world's advanced research facilities, and more extensive inter-organizational personnel exchange beyond industry-academia-government collaboration.

(3) Construction of Local Area Innovation System

To promote efforts to solve various issues at a local level and to vitalize local areas with science and technology power, it is important to utilize the merits, diversity, uniqueness and originality that each area possesses. The agencies concerned have constructed mechanisms to jointly support local efforts so that each area can utilize its merits and characteristics for scientific and technological activities. These efforts intend to make local areas powerful through local scientific and technological innovations, and to recover from the Great East Japan Earthquake, which will eventually lead to Japan's upgrade and diversification

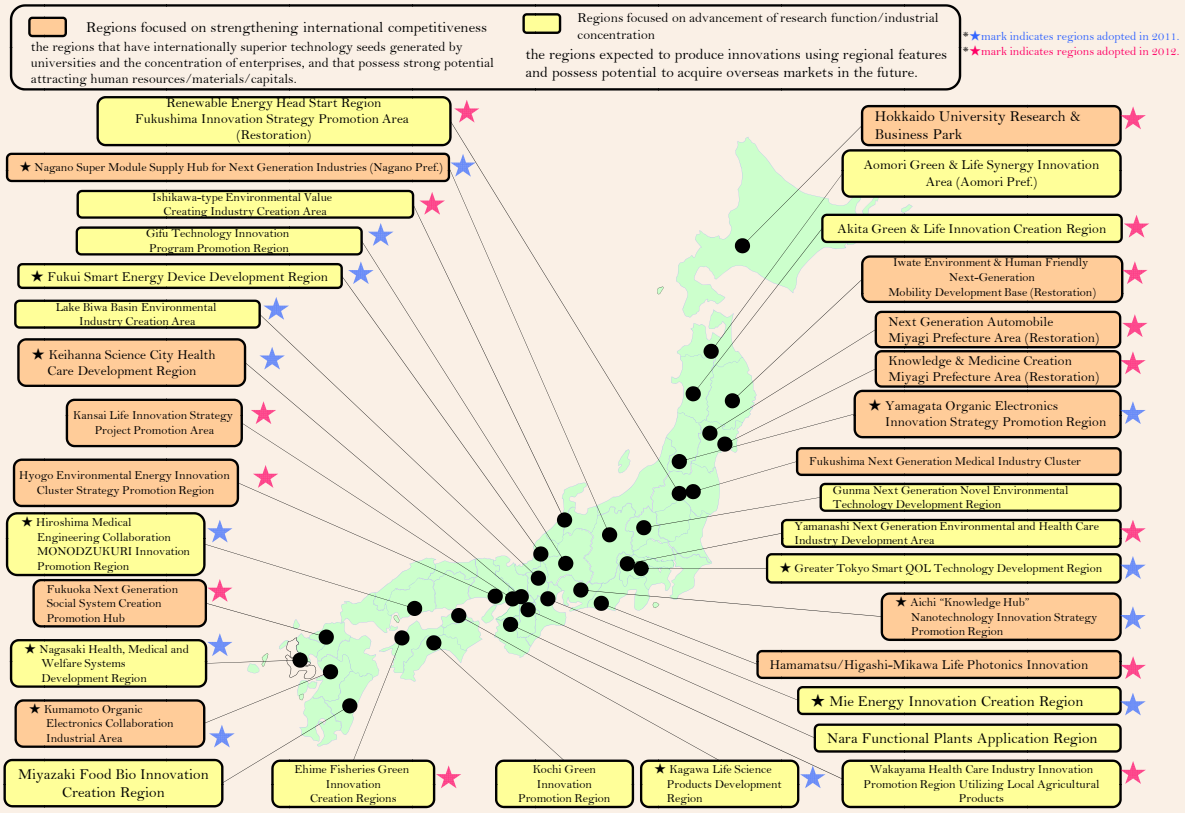
in science and technology and to strengthen industries' competitiveness.

In FY 2011, toward local area innovation, MEXT, METI and MAFF selected regions having proactive and excellent concepts laid out by local governments, universities' research institutes, industry and financial institutions, as "Regional Innovation Strategy Promoting Regions," and constructed support systems to assist their continuous process from the research stage to the industrialization by mobilizing all the policies of the agencies concerned. In addition, in FY 2012, these three ministries newly decided to support independent and excellent concepts conceived by the industry-academia-government in the affected regions that aim at local area innovation by utilizing local areas' merits and properties. This is called "Great East Japan Earthquake Recovery Support Type" and supported by four ministries; the Reconstruction agency, MEXT, METI and MAFF. In FY 2012 following FY 2011, these three ministries selected five areas as "Regions Focused on International Competitiveness": two of them, which were designated as "Regions Focused on International Competitiveness", have strong potential to attract manpower, goods and money from abroad because of the technology seeds of internationally superior universities and the cluster of industries; three of them, which were designated as "Regions Focused on Advancement of Research Function/Industrial Concentration," have potential to capture overseas markets in the future and are expected to do innovations utilizing the area's property. Now, when totaled, such 11 "Regions Focused on International Competitiveness" and 18 "Regions Focused on Advancement of Research Function/Industrial Concentration" come to 29 areas. Concerning the "Great East Japan Earthquake Recovery Support Type," the four ministries selected four areas as the Regional Innovation Strategy Promoting Regions: three are "Regions Focused on International Competitiveness" and one is "Region Focused on Advancement of Research Function/Industrial Concentration."

1) The Ministry of Education, Culture, Sports, Science and Technology (MEXT)

Out of the "Regional Innovation Strategy Promoting Regions," MEXT has been supporting 27 areas which can be expected to contribute greatly to the Science, Technology and Innovation Strategy in local areas in terms of the development of intellectual property and human resources. Concerning the "Great East Japan Earthquake Recovery Support Type," MEXT has been supporting the efforts intended to construct mechanisms for sustainable and developmental innovations (Figure 2-2-15).

Figure 2-2-15/ Regions whose Innovation Promotion Strategies have been supported: List of regions selected in FY 2012

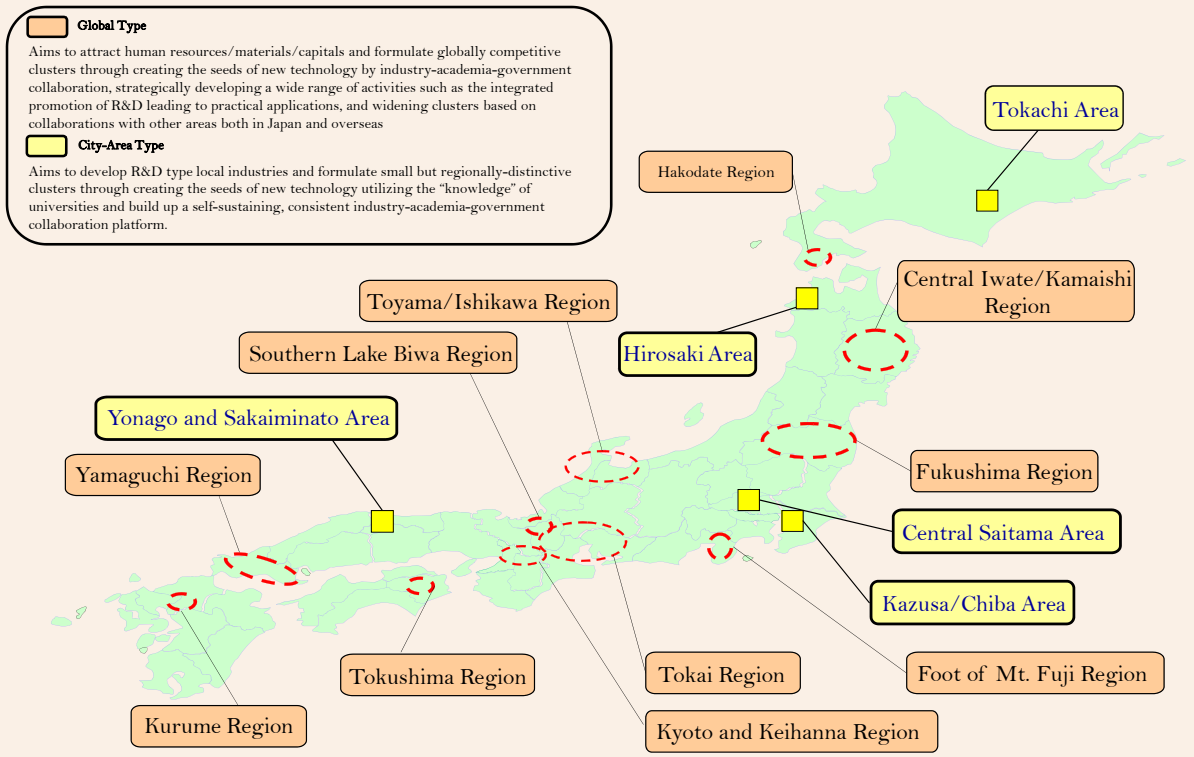



Source: Created by MEXT

Under the "the Regional Innovation Strategy Support Program", MEXT supported 16 regions across the country which have been making efforts through the Knowledge Cluster Initiative[1], so that they can continue to develop the past results to construct regions' sustainable cluster (Figure 2-2-16).

1 MEXT's "Knowledge Cluster Initiative" is a project aiming to stimulate the local economy with the formulation of "Knowledge Clusters" under the local initiative. A knowledge cluster is a technology innovation system that consists of the core public research institutes such as universities with own R&D themes and potential, along with various parties including enterprises within and outside the region under the local initiative. This project has started in FY 2002.

Figure 2-2-16/ Regional Innovation Strategy Support Program (regions where the program is ongoing)




Source: Created by MEXT

In addition, MEXT is implementing the Strategic Funds for the Promotion of Science and Technology, "The Center Creation of Regional Revitalization Human Resources Development," in which regional universities are supported to form the bases for producing excellent human resources contributing to the region, by utilizing their uniqueness and characteristics and in cooperation with the local government and private business operators. As of FY 2012, MEXT is promoting this approach in 53 bases that serve for local vitalization using science technology.

To support local areas' innovations, the Japan Science and Technology Agency is implementing R&D ranged from the discovery of seeds to the industrialization seamlessly, using sophisticated assistance by science and technology coordinators under the "Adaptable Seamless Technology Transfer Program through Target-driven R&D (A-STEP)."

In addition, toward economic recovery in the affected regions, the Agency is addressing some approaches in cooperation with the Tohoku Economic Federation and the local authorities: e.g., fostering technology seeds of universities across the country; transfer of technology seeds to the affected regions' industries; support of the affected regions' industry-academia-government cooperative research by experts; and practical application of universities' innovative technology seeds to the affected regions' industries.

2) Ministry of Internal Affairs and Communications (MIC)

For "the promotion of local industries through ICT (Information and Communications Technology)

R&D" under the "Strategic Information and Communications Research and Development Promotion Program," MIC is promoting the industry-university joint research of IT that would contribute to the creation of new local industries and the promotion and vitalization of local industries and local society.

3) Ministry of Agriculture, Forestry and Fisheries (MAFF)

Under "The Practical Technology Development Program for Promotion of New Agricultural, Forestry and Fishery Policies," MAFF has set the research types that could lead to the local vitalization using free ideas and the solution of issues faced by manufacturers, to promote cooperative industry-academia-university R&D led by the prefectural experimental research institutions and the local universities; especially it is supporting the research of the local innovation strategies. In addition, MAFF has allocated industry-academia-university collaborative coordinators nationwide who are experts of agriculture, forestry and fisheries and food industries, in order to promote the R&D in the local industries through the support for preparation of research planning.

4) Ministry of Economy, Trade and Industry (METI)

METI has supported joint research organizations' demonstrative studies that have optimally combined resources from industry-academia-universities including small and medium enterprises, in order to vitalize the creation of new businesses and industries that utilize local resources and technologies.

In addition, to accelerate the innovation and industry clustering of the strong research field in Tohoku regions' universities and manufacturers, METI has been supporting industry-academia-government collaborative R&D and the industrialization through "Establishing New Industry-Academic-Government Collaborative Framework in the Tohoku Area."

The eight local bases of the National Research Institute of Advanced Industrial Science and Technology (AIST) have been designated either as research bases, where the world highest level researches are led in response to the regional peculiarity or needs, or as collaborative bases, where AIST bridges its own technologies to local industries. This designation makes AIST play a role of open innovation hub and tackle vitalization of local industries through technological support for, joint research with or accepting human resources from SMEs, local universities and organizations.

(4) Promotion of Intellectual Property Strategy and International Standardization Strategy

The world has entered the boderless age, with information, money, goods, technology, and people freely moving transnationally, and the "global network era" has emerged to link the world seamlessly through the high-speed Internet. Today, global enterprises have been competing fiercely using any and all intellectual properties.

To respond to the changing times and to strengthen global competitiveness, the Intellectual Property Strategy Headquarters have laid out the Intellectual Property Strategic Program 2012, promoting the "Competitive Strategy for IP Innovation" under the "IP Management" by utilizing every IP tool, including patents, designs, and international standards.

With this strategy, the Intellectual Property Strategy Headquarters are coordinating patent systems toward the global age of IP systems, promoting international standardization in the important fields, supporting small and medium venture enterprises to strengthen their global competitiveness, and

nurturing human resources who can play an active part in the international stage by strategically utilizing IP and international standards.

1) Efforts for policy making and implementation toward international standardization strategy

Based on the IP Promotion Plan, METI is working on international standardization through the innovation and dissemination of R&D achievements to strengthen competitiveness: in FY 2012 it participated in the standardization meetings of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), where it offered a suggestion that Japan's excellent technology should become international standards. In the "Project to Promote Strategic International Standardization", METI has carried out intensively and continuously the additional research and verification tests, mainly of excellent products and technologies that have been developed in Japan, such as those of smart-grid-related technology in the environmental energy field. In addition, METI is implementing collaborative R&D mainly in the field of nanotechnology, energy environment, bios, etc. toward international standardization, jointly with the world's top research institutions, such as the National Institute of Advanced Industrial Science and Technology (AIST), and the National Institute of Standards and Technology (NIST) under the U.S. Department of Commerce.

At home, METI is steadily promoting basic standardizations, such as JIS, for a safe and secure social environment that is beneficial for everyone, including the elderly and disabled.

To foster human resources involved in standardization, METI dispatches lecturers to the standardization courses in universities and the international standardization training seminars in enterprises. Also, it provides international standardization manpower training to nurture those who would proactively work in the ISOs and actively promote international standardization in Japan. To enhance incentives and nurture human resources, the Engineering Standardization Awards have been provided for those who promoted international and engineering standardization activities.

MIC is promoting standardization of smart-grids, digital signages[1], and next-generation browsers in the International Telecommunication Union (ITU) and forums.

Because water supply has been included in one of the specific strategic fields for international standardization, MLIT and MHLW are promoting its strategic international standardization under the IP promotion plan, so that Japanese corporations launching the business of water supply and sewerage systems in the global market can achieve high-competitiveness. Currently, these two ministries have actively participated in the Project Committee on Wastewater Reuse for Irrigation (ISO/PC253), and the Asset Management Area (ISO/TC224 WG6 & ISO/PC251) and the Crisis Management Area (ISO/T224 WG7) to lay out the policies for ISO International Standards. Also they are reviewing the ISO standards for wastewater reuse in Japanese cities.

2) Review of IP Systems and Improvement of IP Activity-Related Systems

In response to changes in the world innovation environment, the relevant authorities are promoting the following approaches to develop and implement international standardization strategies, review IP systems, and improve IP activity-related systems.

1 Digital signage is a system that transmits information using electric displays in the locations such as outdoors, store front, public space and transportation facilities

(The Japan Patent Office)

a) Promotion of global IP initiative

In the midst of growing economic globalization and opened innovation, the Japan Patent Office is promoting the Global IP Initiative (laid out by the Japan Patent Office in July 2011) to improve global IP infrastructures one by one, so that Japanese companies can do business smoothly in the world. Currently, the Japan Patent Office is implementing the "patent prosecution highway (PPH)" along with 25 countries (as of March 2013) to realize the initiative, so that patent applicants, whose patent is first determined to be patentable, can apply for early examination in the other countries. In addition, the Japan Patent Office is promoting environmental improvement, including the use of machine-aided translation to examine patent documents, especially, increased Chinese and Korean ones.

b) Acceleration of examination system

In response to needs from patent applicants for patent right acquisition timing, the Japan Patent Office is implementing the accelerated examination system under certain conditions, and additionally from August 2011, implementing the "Accelerated Examination and Accelerated Appeal Examination to Support Recovery from Earthquake Disasters" to examine earlier the patent applications from people and business facilities affected by the GEJE to allow them to utilize intellectual properties for restoration.

c) Information service concerning licensable patents and research tools

For the smooth use of IPs, the Japan Patent Office provides information of licensable patents and research tools in the form of database through the National Center for Industrial Property Information and Training (INPIT).

d) Implementation and publication of trend survey in technology

To utilize patent information for R&D strategies, it is necessary to link IP information with R&D strategies in the stage of policy making process. Therefore, the Japan Patent Office has comprehensively analyzed technology trends by analyzing "patent application trends" in light of "R&D trends" and "market trends" and published the results.

e) Development and securing of human resources

To diffuse knowledge about IP, the Japan Patent Office is supporting high-schools and technical colleges that provide practical IP education, through the National Center for Industrial Property Information and Training (INPIT).

(ii) Japan Science and Technology Agency

The Japan Science and Technology Agency is making efforts ranging from the discovery of excellent research achievement, support for patent acquisition, to industrialization. Specifically, the Agency is supporting the utilization of intellectual properties comprehensively through the "Promotion of the Use of Intellectual Property": including, support for the strategic acquisition of foreign patents by universities by using their research results, with clustering of patents also being intended; supply of research and test

expenses to researchers who want to intensify patents or to acquire additional data for commercialization; offer of universities' patent information free of charge through the Internet (J-STORE); and providing research environments (Science and Technology Commons) where universities' patents are released open so as not to restrict other ongoing research.