1

New Japanese Graduate School Programs for Human Resources Development in Clinical Research

YUKO ITO
Life Science Research Unit

1 Introduction

Clinical research*1 has been defined as "medical research for the purposes of improving preventive methods, diagnostic methods, and therapeutic methods for disease in medical treatment, understanding the causes and pathology of diseases, and improving the quality of life of patients, with human beings as its object (including research on materials and data of human origin which can designate individuals)."[1]

In short, however, clinical research is "research on human beings." As such, it includes the "clinical tests"*2 used to investigate the safety and efficacy of candidate substances and practices in the development of new drugs and therapeutic methods. In this, clinical tests which are carried out in order to obtain approval for the manufacture and sale of pharmaceuticals, etc. from the Ministry of Health, Labour and Welfare are called "clinical trials."*3

The creation of numerous new drugs and therapeutic methods through progress in clinical research has large direct benefits in maintaining and improving the health of Japanese citizens. In the coming years, Japanese elderly ratio (percentage of population 65 years of age or older to the total population) will increase, and will eventually exceed the level defining a "ultra-aged" or "elderly-dominated" society (terms vary; but refer to an elderly ratio of 21% or higher). This means that activation of clinical research, including clinical trials and clinical tests, is an extremely important challenge for Japan.

At present, Japan is one of the small number of nations in the world with the capability to develop new drugs by own country. In 2004, pharmaceutical products developed in Japan accounted for 13 of the world's top 100 pharmaceuticals in terms of sales value, ranking 3rd behind the United States, which ranked 1st with 39 products, and the 2nd-ranking United Kingdom, with 14.[2] On the other hand, the percentage of Japanese papers published in leading journals on clinical research was lower than the percentage carried in journals such as "Nature" and "Science," which publish high quality papers on basic research in the life sciences.[3] These conditions can be considered to reflect the basic difficulty of clinical research in Japan, which can be attributed to the inadequate clinical research system in this country, and to the lack of a "translational system" for translating high quality basic research in the life sciences into clinical research. As another problem, it has also been pointed out that the system for reviews and clinical trials of pharmaceuticals is inadequate in comparison with those in the United States and Europe.

The common, fundamental issue for solving these various problems and activating clinical research in Japan is considered to be the training of clinical researchers. The main organizations engaged in clinical research are university graduate schools, and the persons principally involved are physicians. Therefore, this paper will examine several interesting new training programs for human resources in the field of clinical research currently in progress in graduate school medical research departments, which have been developed for graduates from medical schools. In particular, the distinctive features of these programs are identified, the content of the

programs is discussed, and future policies for training clinical researchers are discussed.

2 Distinctive features of clinical research

Because its object of clinical research is human beings and materials of human origin, clinical research must consider safety and bioethics. In carrying out such research, it is necessary to follow various guidelines, as shown in Table 1.

Furthermore, the single term "clinical research" encompasses research for a variety of different purposes, including "clinical trials" for approval of pharmaceuticals and the like, "clinical tests" other than clinical trials, which are conducted, for example, to improve standard treatment methods, and "translational research (TR),"*4 which is a type of research bridging basic research and clinical research with the aim of developing new medical technologies efficiently.[4] (See Table 2.) For this reason, the necessary guidelines will differ, depending on the type of clinical research. Concretely, detailed standards for clinical trials are spelled out in Japan's Pharmaceutical Affairs Law and the Ordinance on Good Clinical Practice (GCP; ordinance concerning standards for implementation of clinical trial of pharmaceuticals).

In addition, when considering human resources for activation of clinical research, appropriate human resource, development policies will differ depending on the type of clinical research. For example, the training policies for clinical research oriented "basic research" such as TR, are different from those for research which must be carried out in accordance with a process prescribed by a system, as in as clinical trials.

Table 1 : Representative laws, guidelines, etc. for clinical research

Law, guideline, etc.	Date of adoption or enforcement	Body responsible for adoption, enforcement, etc.
Declaration of Helsinki (Ethical principles for medical research involving human experimentation)	June 1964	World Medical Association (WMA)
Ethical Guidelines for Clinical Research	July 2003	Ministry of Health, Labour and Welfare (MHLW)
Guidelines for Clinical Research on Gene Therapy	March 2002	Ministry of Education, Culture, Sports, Science and Technology (MEXT), MHLW
Ethical Guidelines for Research on Human Genome/Gene Analysis	March 2001	MEXT, MHLW, Ministry of Economy, Trade and Industry (METI)
Ethical Guidelines for Epidemiological Research	June 2002	MEXT, MHLW
Ideal Form of Research and Development using Human Tissue Obtained in Medical Operations, Etc.	December 1998	Health Sciences Council (Report)
Guidelines for Establishment and Use of Human Embryonic Stem (ES) Cells	2001	MEXT (Notification)
Act concerning Protection of Personal Information	May 2003	
Common Ethical Review Guidelines for Translational Research	January 2004	The University of Tokyo, Institute of Medical Science, Research Hospital, Advanced Clinical Research Institute; Nagoya University Hospital, Center for Regenerative Medicine; Kyoto University Hospital, Translational Research Center; Osaka University Hospital, Medical Center for Translational Research; Kyushu University Hospital, Department of Advanced Medical Engineering Therapeutics/Clinical Research Center; Foundation for Biomedical Research and Innovation, Institute of Biomedical Research and Innovation (IBMR)/Translational Research Informatics Center (TRI)
Guideline for Good Clinical Practice (Ministerial Ordinance; GCP Ordinance)	March 1997	MHLW *Related law: Pharmaceutical Affairs Law

Prepared by the STFC

Table 2 : Comparison of translational research (TR), Physician-led clinical tests, and clinical trials

	TR	Physician-led clinical test	Clinical trial
Purpose	Efficient development of new medical technology	Innovation or improvement of standard therapeutic method	Application/approval of new medical technology
No. of subjects	Small	Small to Large	Small to Large
Leader	Researcher or Physician	Physician	Private company or Physician
Source of research funds	National government, private company, venture capital, researcher	Private company, national government, researcher	Private company
Supplier of reagents/test product	Researcher, private company, national government	Private company	Private company

From Reference [4]

3 Types of clinical researchers required in the future

Various recommendations and policies for science and technology policy related to the promotion of clinical research were announced from 2006 to 2007. Here, four representative sets of recommendations will be discussed. (See section 3-1, (a) to (d).) These four sets of recommendations are divided into "Recommendations mainly concerning clinical research" and "Recommendations mainly concerning clinical trials." Types of the clinical researchers who will be required in the future of Japan will become apparent from the outline of these respective items and description of human resources for clinical research.

3-1 Recent recommendations and policies

(1) Recommendations mainly concerning promotion of clinical research

(a) In the field of Life Sciences in Promotional Strategies by Field (Cabinet Resolution of March 28, 2006)[5] in the Third Science and Technology Basic Plan laid out by the Japanese Cabinet's Council for Science and Technology Policy (CSTP), "Translational research to clinical research and clinical trials" was selected as a Strategically prioritized S&T for investment on a priority basis during the period of the 3rd Plan (FY2006-FY2010).

The content of this research and development is shown below.

- Translational research, clinical research, and clinical trials contributing to the use of research results and innovative diagnostic and therapeutic methods aiming at early practical application, and to the use of pharmaceuticals and others which are generally used in other foreign countries but have not been approved in Japan.
- Improvement of the support system for clinical research and translational research.
- Training and securing human resources contributing to promotion of clinical research (including human resources with expertise in epidemiology and biostatistics).
- Research and development promoting practical application of results, such as higher efficiency in the drug discovery process.

As a policy for the Life Sciences field, the plan advocates "creation of a system for promoting clinical research," and mentions that, "in order to return the results of research to the Japanese people in the form of new pharmaceutical products, medical equipment, etc., it is important to promote four efforts, namely, creating and strengthening the support system, securing and training clinical researchers and clinical research support personnel, creation of an environment for promoting research and examination and approval, and participation of the Japanese people."

(b) In December 2006, the Center for Research and Development Strategy (CRDS) of the Japan Science and Technology Agency (JST) published "Strategy Recommendations for Clinical Research —Aiming at Fundamental Reform of the Clinical Research System in Japan."[6] This was followed by "Promotion of Integrative Celerity Research (ICR)—

Innovation in Health and Medical Care" in March 2007.[7]

It is assumed that "a wealth of knowledge on the life sciences is being accumulated as a result of substantial investment in basic research in the life sciences, but because the system for implementing clinical research is weak, and there are also problems in the organizations responsible for review and approval (of pharmaceuticals), it is difficult to translate the results of basic research into practical applications quickly." Therefore, fundamental reform of the clinical research system and the review and approval system is recommended.

Concrete recommendations include "Establishment of Clinical Research Basic Law," which positions clinical research as one of the most critical items for national policy, "Creation of centers for clinical research, establishment of composite clinical research bodies, and formation of a network" to enable researchers in different fields to routinely create cooperative systems by placing the functions of basic research, clinical research, and advanced medical research and development in one location, and "Measures for promoting Integrative Celerity Research (ICR): Securing funds, systemic reform, and training of human resources."

(2) Recommendations mainly concerning activation of clinical trials

(c) In the area of clinical research in Japan, including clinical trials, the Expert Panel on Basic Policy in the Cabinet's above-mentioned Council for Science and Technology Policy positioned "elimination of systemic and administrative obstacles to smooth science and technology activities and return of results" as one necessary issue. A review was begun in June 2006, and an interim report was issued on July 26, 2006.[8]

In the report, the following are mentioned as directions in reforms for system improvement.

- Creation and strengthening of support systems, etc.
- Securing and training clinical researchers and clinical research support personnel.
- Improvement of the environment for promoting research and review/approval (improvement of the framework for promoting clinical research, improving speed and efficiency in reviews and approvals of pharmaceutical products, etc., and joint international clinical trials).
- Participation of the Japanese people (deregulation of information distribution activity on clinical trials, incentives for subjects in clinical research).

(d) On March 30, 2007, MEXT and the Ministry of Health, Labour and Welfare announced a "New 5-Year Clinical Trial Activation Plan."[9] This corresponds to the following plans in the "National 3-Year Clinical Trial Activation Plan" adopted in April 2003.

In the New 5-Year Clinical Trial Activation Plan, the following items are mentioned as issues for achieving a higher level of activity in clinical trials and clinical research.

- Creation of a system of core hospitals and base medical institutions.
- Training and securing human resources to implement clinical trials and clinical research.
- Popularization to and enlightenment of the Japanese people, and promotion of participation in clinical trials and clinical research.
- Efficient implementation of clinical trials and alleviation of the burden on private business.
- Other issues (elimination of obstacles to joint international clinical tests/clinical research, study of a system for reporting the start of clinical research, review of "Ethical Guidelines for Clinical Research," and other matters related to review of "Ordinance on Good Clinical Practice (GCP)," etc.).

3-2 Content of recommendations on training of human resources for clinical research

All of the recommendations discussed in the previous section 3-1 mentioned items related to the training of human resources for clinical research. These will be discussed in detail in the following.

The above-mentioned item (a) recommended securing and training human resources to support clinical research (clinical trial coordinators, biostatisticians, clinical epidemiologists, pharmacists, data managers, etc.). A huge number of data are generated in clinical research. In order to interpret these data and determine the subsequent direction of research, clinical research support personnel who manage and perform statistical analyses of these data are necessary and indispensable. The recommendations for securing (and hiring) this number of clinical researchers and clinical research support personnel include improvement of education for this purpose and providing career paths and economic incentives for researchers.

Although (a) did not present concrete policy recommendations on the training of clinical research personnel for the physicians, who are the main persons carrying out clinical research, the following may be mentioned as concrete efforts related to the item "Creation of a support system for clinical research/translational research."

- Efforts not only to develop "seeds" from basic research to clinical development, but also to tie "seeds" from the clinical viewpoint to basic research.
- Collection of information on world trends, such as new technique and research efforts in clinical research, and so on, and study of the application of those techniques/research.
- Expansion and strengthening of joint systems between physicians and researchers in basic medical science and other fields (in particular, engineering-related and pharmacology-related fields).
- Creation of facilities, institutes, and networks for search-type development of candidate substances for pharmaceutical products and implementation of the search for such substances, and improvement of the research infrastructure, including cell/tissue banks, specialized non-clinical test facilities, etc.

Although these are mentioned in connection with the research support system, if "research infrastructure" in the final item is changed to "training of clinical researchers," virtually the same language describes a human resources training policy, as follows:

- Training of clinical researchers who implement research which not only develops the "seeds" from basic research to clinical research, but also tie "seeds" from the clinical viewpoint to basic research.
- Training of clinical researchers who grapple actively with new techniques and research in clinical research.
- Training of clinical researchers who can actively implement joint research with physicians and researchers in basic medical science and researchers in other fields.

As human resources which are indispensable for promoting clinical research, item (b) mentioned physicians who carry out clinical research, biostatisticians, human resources with a knowledge of regulatory science, data managers, clinical trial coordinators, human resources working in genomics and other technologies, human resources working in informatics, human resources promoting medical-engineering collaboration (information science, nanobiology, engineering), and human resources in the areas of intellectual property and legal affairs. In addition, it is also necessary to improve and expand graduate schools of public health for comprehensive education of these human resources.

Next, assuming that it is necessary to train the physicians who carry out clinical research in medical schools and graduate schools, the followings are mentioned as concrete measures.

- Improvement of the clinical research curriculum in medical school education.
- Education in clinical research and implementation of research in graduate schools.
- Establishment of post-doctoral fellowships for physicians involved in clinical research.
- Education in summer schools and the like in clinical research centers as on-the-job training (OJT).
- Establishment of an evaluation system which provides incentives to physicians participating in clinical research.

As in item (a), (c) also refers to training/securing clinical research support personnel. However, in addition to this, it also mentions the followings as problems related to the training of the physicians responsible for clinical research.

- Inadequacy of human resources for clinical research: As the causes of this, because universities tend to prioritize basic experimental medical science, clinical trials and clinical research tend to be a less important priority. Moreover, because the latter types of work require time, they do not lead to promotions, and as a result, university researchers tend to avoid these fields.
- The weakness of universities, hospitals, research institutes, and others that educate/train human resources for clinical research is also a problem.

Where training of clinical researchers is concerned, the followings were recommended in (c):

- Universities should shift education and research to fields closer to clinical research.
- It is necessary to create an environment in which clinical researchers are fairly evaluated as specialists, and to establish a career path which reflects their actual performance in clinical research.

Item (d) recommends concrete measures in connection with incentives for physicians engaged in clinical trials and clinical research:

- Urge cooperation in core hospitals, base medical institutions, and related bodies in order to improve the evaluation of the clinical performance of physicians and others (including their treatment in hospitals, evaluation of academic society papers, acquisition of degrees).
- Shift the share of Health and Labour Sciences Research Grants and other grants from basic research to clinical trials and clinical research in order to popularize clinical trials/clinical research.
- Secure and increase opportunities for education related to clinical trials and clinical research in the curriculum for physicians and related professions.
- Make it possible for physicians and others involved in clinical trials and clinical research to secure time and financial resources for research.

3-3 Types of clinical researchers required in the future

Summarizing the foregoing discussion, it is thought that the following four types of clinical researchers will be required in the future:

(A) Researchers who have strong ability in both basic research and clinical research.
(B) Researchers who are oriented toward collaborative/interdisciplinary work with other fields.
(C) Specialists in clinical research as such.
(D) Researchers who play a leadership role in implementing clinical trials.

4 Graduate school programs for training human resources for clinical research

First, the current problems in training human resources for clinical research in Japanese graduate schools will be discussed in section 4-1. Next, section 4-2 describes human resources development programs in graduate schools supported by the national government. Section 4-3 presents an outline of the human resources development programs in graduate school medical science departments selected under the national programs in 4-2, focusing on those which appear to be capable of training the "clinical researchers required in the future."

4-1 Current problems in postgraduate training of human resources for clinical research

Because clinical research centers on research through medical treatment, clinical researchers should desirably be persons who possess the fundamental knowledge and skills required in physicians and who have also received training as researchers. It is also necessary to train a large number of clinical researchers of this type. However, a substantially long period of time is required for a physician to become a clinical

researcher.

After completing 6 years of medical education (medical school) in order to acquire the basic knowledge, skills, etc. necessary in physicians, physicians are legally required to receive 2 years of clinical training under the New Postgraduate Medical Training System, which was established in April 2004, so as to master a wide range of basic medical capabilities. Then, in order to acquire qualification as a specialist (physician who has received education and training satisfying specified standards in a designated clinical field or disease and passed a test in this specialization), some physicians receive specialized medical training for 3-5 years following New Postgraduate Medical Training.

If a physician wishes to go on to graduate school with the aim of becoming a researcher, he or she must first complete New Postgraduate Medical Training. This means that medical researchers begin their careers considerably later than researchers in other fields. Moreover, it has been reported that persons 30-34 years of age are the largest age group currently entering graduate schools[10], suggesting that many physicians actually complete specialized medical training before going on to graduate school.

The Final Report of the "Cooperating Members Committee on Studying Improvement of Medical Education (MEXT)[10] offered the following recommendations for improving graduate school education based on these point as above.

- Clarification of the purpose of graduate school (training of researchers and training of Physicians), and positioning of medical occupations for research purposes in the university hospital in the graduate school curriculum.
- Implementation of autumn admissions in order to allow physicians adequate time to prepare to enter graduate school after completing New Postgraduate Medical Training.
- Establishment of a graduate school course allowing early advance to graduate school without receiving New Postgraduate Medical Training.
  (As examples of early advancement to graduate school, 17 universities are attempting to establish MD/Ph.D. courses in which persons who have completed the credits required by the university with outstanding records are allowed to enter graduate school medical research departments after completing their fourth year of medical school, and then, upon completing their Ph.D., are readmitted to the 5th year of medical school, and go on graduate.)
- Incorporation of training intended to develop a "researcher's mentality" for personal career path to become educators or researchers in the future in the training period other than the basic training courses of the New Postgraduate Medical Training and required courses.
- Improvement of graduate school efforts to train medical specialists by cooperation between graduate schools and university hospitals.
- Efforts to give a real feeling that receiving the Ph.D. degree is the "starting line" for educators and researchers.
- Clarification of the respective career paths for physicians, clinical researchers, and basic medical researchers, and support for career formation.

If the merits and incentives for physicians going on to graduate school are not clear, there is concern that the number of persons going on to postgraduate education will decline in the future.

4-2 Clinical researcher training programs in nationally-supported graduate schools

As "Support for University Education Reform throughout National, Public, and Private Universities," MEXT provides support for selected programs with distinctive features at universities and graduate schools. The budget for these activities was ¥60.2 billion in FY2007, up from ¥56.2 billion in FY2006.[11]

This includes "Creation of the World's Highest Level Education and Research Centers with International Competitiveness (Global COE, 21st Century COE Program)," "Promotion of Training of Persons in Specialized Occupations Responding to Social Needs (Program for

Promotion of Education in Specialized Graduate Schools, Etc., Program for Promotion of Training of High Quality Medical Personnel Responding to Regional Medicine and other Social Needs, Cancer Professional Training Program)," "Training of Human Resources Capable of Responding to Contemporary Issues and Development of Diverse Functions of Universities (Contemporary Educational Needs Support Program, University Education Internationalization Promotion Program, Program for Promotion of Education Responding to Adult Reeducation Needs, Student Support Program Responding to New Social Needs)," "Advancement/Enrichment of Educational Content/Methods, Etc. Corresponding to Courses (Distinctive University Education Support Program, Graduate School Educational Reform Support Program, Initiatives for Attractive Education in Graduate Schools: Table 3)."

The following will discuss the programs, among those mentioned above, which also function as training programs for human resources in the field of clinical research.

(1) "Initiatives for Attractive Education in Graduate Schools"[12]

The "Initiatives for Attractive Education in Graduate Schools" program (MEXT, Higher Education. Bureau, University Promotion Division, and Japan Society for the Promotion of Science) is a support program which gives priority to active and original graduate school educational programs aimed chiefly at training of young researchers responding to social needs.

In this program, among the medical topics selected in 2005 (19 items) and 2006 (11 items), themes of educational programs related to clinical research were selected, as shown Table 4. Examples of these will be discussed in the following section 4-3.

Table 3 : Outline of the "Initiatives for Attractive Education in Graduate Schools" program

"Initiatives for Attractive Education in Graduate Schools"

(Outline)

- **Provides prioritized support for educational programs to enable young researchers to acquire, in an organized and systematic manner, the attributes newly required in young researchers and the capability to carry our research activities independently, and promotes strengthening of researcher training functions.**
- **Promotes strengthening of organizational development of educational issues and pioneering of new research guidance methods from the viewpoint of advancing graduate school education responding to the needs of the times.**

(Applicable objects)

In principle, applied to the course having a doctoral program.

(Scale of project)

- **The amount of grants provided by the national government has an upper limit of \50 million/year for each item within the scope of the program scale, considering its content, etc., and in principle is provided continuously for 2 years.**

(Budget)

Budget for fiscal year 2006: \4.2 billion (for FY2005: \3.0 billion).

(Record of awards)

- **FY2006: 268 applications were received from 129 universities; of these, 46 items from 35 universities were selected to receive grants. This included 11 items in medical fields.**
- **universities were selected, including 19 items in medical fields.**

Prepared by the STFC, referring to references[11 and12]

(2) "Program for Promotion of Training of High Quality Medical Personnel Responding to Regional Medicine and other Social Needs"[13]

The objectives of the "Program for Promotion of Training of High Quality Medical Personnel Responding to Regional Medicine and other Social Needs" (MEXT, Higher Education, Bureau, Medical Education Division) are to encourage a higher level of activity in university education and promote the training of the high quality medical personnel required by society. This promotion program provides financial support for distinctive outstanding programs for training high quality medical personnel from among programs in applications submitted by national, public, and private universities which have set themes responding to regional medicine and other social needs.[13]

Under this program, the announced themes for applications differ each year. The themes for FY2006 were "Training of physicians responding to unbalanced distribution by field" and "Training of pharmacists for improvement of clinical capabilities," while those for FY2007 were "Training of human resources for clinical research/research support" and "Encouraging female physicians/nurses to enter/remain in clinical work and support for return to work."

The budget for the two themes in FY2007 is ¥1.31 billion. Continuing financial support

Table 4 : Examples of programs selected under the "Initiatives for Attractive Education in Graduate Schools" program (items related to clinical research)

Year selected	University	Specialization	Educational program	Object of program
2005	Gunma University	Graduate School of Medicine, Medical Science Course	Bilateral Evolution and Practice in Education in the Graduate School of Medicine	Fusion of basic medicine and clinical medicine
2005	Kyoto University	Graduate School of Medicine	Horizontal Systematic Medical Research Career Path Formation	Interdisciplinary/integrated medical research
2005	Yamaguchi University	Graduate School of Medicine, Applied Medical Engineering Science Course	Education Program on Applied Medical Engineering Science (AMES)	Fusion of medicine and engineering
2005	Nagasaki University	Graduate School of Biomedical Sciences, Infection Research Course (Note: Emerging infectious disease pathology and control science)	International Infectious Disease Researcher/Medical Specialist Training Program	Training of infectious disease researchers and medical specialists
2006	Mie University	Graduate School of Medicine, Life and Medical Science Course	Training of Researchers in Medical Science/Therapeutics Responding to Region and Times	Fusion of basic and clinical research
2006	Kyushu University	Department of Integrative Biomedical Sciences, Graduate School of Medical Sciences	Reform of Graduate School Education for Activation of Clinical Research	Specialized educational system for clinical research
2006	Kumamoto University	Graduate School of Medical Science, Pathological Informatics Course	AIDS Researcher Training Program	Translational research related to AIDS
2006	Miyazaki University	Faculty of Medicine, Bioregulation Course	Educational Center Integrating Clinical Research and Translational Medicine	Translational medicine from discovery of seeds to clinical application
2006	Yokohama City University	Graduate School of Medicine, Biomolecular and Informatics Medical Science Course	Program for Training Clinical Trial Leaders	Clinical trials and clinical tests
2006	Keio University	Graduate School of Medicine, Medical Science Course	Initiative for Integrated Master/Doctor Education for Encouragement of Cancer Research	Integrated basic and clinical research on cancer

Prepared by the STFC

Table 5 : Universities and programs selected for FY2007 Theme, "Training of Human Resources for Clinical Research/Research Support"

University	Program
Gunma University	Training of Human Resources for Clinical Testing by Postgraduate Integrated OJT
Kobe University	Reform of Clinical Research Education by Advanced CRESP — Development of Clinical Research Expert Specialization Program (CRESP) in the Kobe Local Medical Cluster —
Yamaguchi University	Training of Human Resources for Support of Clinical Research by Graduate School Course — Centering on the "Clinical Test Support Center" —
Kyushu University	Training of Human Resources for Support of High Quality Doctor-Led Clinical Tests — Creation of Infrastructure for Construction of Evidence for the Japanese People —
Ryukyus University	Clinical Research Specialist Doctor and Top Class CRC Training Program
Jikei University	Training of Primary Care Site Clinical Researchers
Kitasato University Keio University Juntendo University	Clinical Research Human Resource Training and Education Consortium — Construction and Implementation of Education System through Domestic and International Collaboration —

Source: http://www.mext.go.jp/b_menu/houdou/19/07/07072516.htm

(approximately 3 years) is given to selected programs.

The object of the theme for 2007, "Training of human resources for clinical research/research support," is for programs in connection with the training of high quality clinical researchers and research support personnel (clinical test coordinators, biostatisticians, clinical epidemiologist, data managers, etc.) with the aim of further promoting clinical research contributing to drug discovery/development new therapeutic technologies and translational research to clinical research.

The universities selected under the themes for FY2007 were announced on July 25, 2007. In the area of "Training of human resources for clinical research/research support," 7 programs were selected from among 30 applications. It appears that programs which are expected to have practical and concrete effects were chosen. Table 5 shows the programs selected.

4-3 Introduction of programs selected under "Initiatives for Attractive Education in Graduate Schools"

From Table 4, educational programs related to the following types of human resources for clinical research required in the future were selected: (A) Researchers who have strong ability in both basic research and clinical research, (B) Researchers oriented toward collaborative/interdisciplinary research with other fields, (C) Specialists in clinical research, and (D) Researchers with a leadership role in clinical trials. The features of the selected programs are outlined below.

(A) Training of researchers who have strong ability in both basic research and clinical research

◦ Interdisciplinary Systematic Medical Education Career Path Formation (Kyoto University)

[Background]

Considering the current rapid progress and international competition in medical research, strong social demand for return of research results to society, and similar factors, acquisition of more comprehensive, total medical knowledge and technology, acquisition of opinions and ethics that include cooperation with society, independence and originality that contribute to the development of new areas, and diverse international communications skills have become essential conditions.

[Objective]

The objective of this program is to construct a comprehensive and holistic graduate school education system including all persons, which rationally introduces a wide perspective in

education in line with the new environment of the times, while continuing to provide the intensive individual education given in traditional postgraduate education in medical fields in the past.

[Content of program]

- Six existing fields of specialization (physiology, pathology, internal medicine, surgery, molecular biology, and neuroscience) are unified in one integrated major course.
- In the integrated major course, in addition to the conventional field of specialization, 12 graduate level courses cutting across basic, clinical, and social medicine are newly established as a systematic educational curriculum unit. (These courses are Cell Biology/Cell Physiology, Development and Morphogenesis, Immunology, Allergy, and Infectious Diseases, Oncology, Genetic/Genomic Medicine, Neuroscience, Lifestyle-related Disease, Aging, and Metabolic Medicine, Regenerative Medicine/Organ Reconstruction Medicine, Pathophysiology, Clinical Research (Clinical Epidemiology/Clinical Innovation), Health and Social Medicine, and Medical-Engineering Collaboration).
- Students take at least one graduate school course while simultaneously belonging to their existing field of specialization, and carry out degree-related research while receiving education/research guidance from both systems until receiving their degree.

(Features and future expectations)

The program is expected to train researchers who have strong ability in both basic research and clinical research by providing an educational program that combines a horizontal element of specialized knowledge in a wide range of medical fields and a vertical element of deep expertise.

(B) Training of researchers oriented toward collaborative/interdisciplinary research with other fields

◦ Medical-Engineering Integrated Practical Education Program (Yamaguchi University)

[Background]

The Yamaguchi University, Graduate School of Medicine, Applied Medical Engineering Sciences (AMES) Course is an independent specialized graduate school which was established by merging the Medical School and Engineering Faculty in April 2001, and is the first school of its type in Japan. Its objective is to train human resources with the wide, creative vision necessary in developmental research on advanced medical devices and materials and theory, responding to new trends in medicine and welfare, based on digitization of biological information. It is the only graduate school in Japan which awards a medical engineering degree (Ph.D.).

[Objective]

The objective of AMES is to train researchers with rich humanity, who are creative, possess a wide vision, and can work actively internationally in the field of medical engineering.

[Content of program]

- As required courses in the basic curriculum in medical engineering, classes in the basic medical curriculum are given for non-medical students (basic anatomy and physiology, basic biochemistry, basic pathology, medical statistics, basic internal medicine, basic surgery, etc.), and classes in the basic engineering curriculum are given for non-engineering students (fundamentals of biomechanics, biosensing, biotargeting, biomaterials, biomimetics, biosystems, etc.).
- The second half of the Ph.D. course comprises a specialized medical engineering course and a developmental research course. Training in experimental and analytical techniques is given to enable students to develop integrated medical-engineering research.
- As motivation for medical engineering, persons from medical backgrounds learn the principles of advanced medical/analytical devices and gain engineering experience through practice in methods of use, while persons from engineering learn medical needs through clinical experience, for example, by seeing actual medical operations, etc.

- The program trains "physicians who have knowledge of engineering" and "engineering researchers who are familiar with the field of medicine."

(Features and expectations)

Linkage of medicine and engineering is no longer a new experiment. However, this type of program, which substantially integrates medical and engineering education and research with its focus narrowed to advanced medical equipment and materials is extremely novel and is expected to have an important effect.

(C) Training of specialists in clinical research

◦ Reform of Graduate School Education for Activation of Clinical Research (Kyushu University)

[Background]

Due to the rapid increase in the content of medical school education, introduction of the new system of clinical training after medical school graduation, etc., students and physician trainees no longer have the luxury of considering graduate school education. Under these conditions, graduate schools cannot fulfill their purpose of training human resources, creating obstacles to research.

[Objective]

Kyushu University will begin educational reform of its medical graduate school program with the creation of a specialized educational system for clinical research as the core element. Prior to respective technical field education, basic education covering the entire area of clinical research is first essential. Although it is necessary to train a large number of physicians for clinical research, young physicians must also acquire qualifications as specialists. For this reason, the creation of a system which allows physicians to attend graduate school as adult students is needed.

[Content of program]

- The creation of a specialized educational system for clinical research in the Ph.D. course and systematic course education will enable students to acquire the capability to perform proper clinical research.
- In order to provide opportunities for physicians to study in the graduate school as adult students, classes will be scheduled on evening or holidays.
- The specialized educational system for clinical research in the Ph.D. course and a basic researcher training system will be established, with free access to both systems.

(Features and expectations)

This program for training specialists in clinical research, which considers the personal career path as a physician, is expected to become a model program for encouraging physicians to go on to postgraduate education in the future.

(D) Training of researchers with a leadership role in clinical trials

◦ Program for Training Clinical Trial Leaders (Yokohama City University)

[Background]

To overcome the weakness of poor international competitiveness in clinical research in Japan, improvement of the system for clinical tests and new drug development/evaluation under physicians' leadership is urgently needed in Japan.

[Objective]

The objective of this program is to train graduate students in graduate school Ph.D. courses as leaders who can widely develop clinical research and clinical tests in order to improve the clinical test system in Japan, raise the level of clinical therapeutics, and improve the system for safe and secure medical treatment.

[Content of program]

- Establishment of a systematic, individual guidance system, including basic knowledge, education, and cultivation of perspectives, spanning multiple fields of medical treatment and research.
- Establishment of an advanced medical

research course and a clinical test expert course.
- The clinical test expert course will take the form of practice in performing clinical tests, and will make it possible to master the processes necessary to implement clinical tests and clinical trials.
- An agreement on cooperation in the training of human resources through development and implementation of an advanced joint scientific training program has been concluded with the Food and Drug Administration (FDA) in the United States, which is responsible for approving drugs in that country, and training at the FDA will be possible in the future.
- An international research education system is being introduced, for example, through a cooperation agreement with the University of Iowa in the US, which allows physicians licensed in Japan to practice medicine.

(Features and expectations)

This program is a graduate school specializing in the training of researchers (physicians) who will serve as leaders in clinical trials and clinical tests. Although this is the only graduate school in Japan with an actual course focusing on the training of clinical trial physicians, the number of graduate schools with this type of program is expected to increase in the future.

5 Conclusion

In spite of the continuing development of science and technology, as in the past, the number of issues facing medicine shows no signs of decreasing. Moreover, the structure of diseases is expected to become more complex in the future due to aging, changes in lifestyle and habits, and globalization. New challenges will include an increase in diseases that had been comparatively rare in the past, the appearance of new medical conditions and infectious diseases, and increased prevalence of compound diseases. Given these conditions, the needs and expectations for medical treatment will continue to increase.

The broad goals for medicine are to ensure that the Japanese people will receive better and more effective medical treatment than in the past in Japan, and at the same time, to enable progress in clinical research in this country. For this, it will be necessary to introduce new systems suited to the times in place of the conventional practices in actual medical treatment, in medical schools and other forms of education, and in research.

It takes more than 10 years after graduation from medical school for a physician to become fully qualified and experienced. Likewise, it also requires about 10 years to become a fully-qualified basic researcher. In either case, whether for a physician or basic researcher, human resources development requires a lengthy period.

To confront today's complex medical problems, human resources with wide clinical knowledge as physicians, a high level of specialization in medical treatment, advanced knowledge of research, and excellent research skills are necessary. Ideally, each individual should possess all of these qualifications, but in actuality, this may not be possible. It is nevertheless important to attempt to train diverse human resources with a breadth of expertise and high level of knowledge in universities. As discussed in this paper, various universities in Japan are beginning to implement distinctive training programs for human resources in the field of clinical research. As these have only begun, the results will not be apparent until some time in the future. However, the development of human resources who are both physicians and basic researchers is a challenge with which Japan must grapple from a long-term perspective.

Promotion of these types of human resources development programs in graduate schools at the national level will be extremely important for Japan in securing human resources with the high level of expertise necessary in the coming years. This is true of all fields, and not simply clinical research. In the future, it will be necessary to expand programs that support young researchers, including research funding and financial assistance for everyday needs, for individuals participating in these human resources development programs, in coordination with those programs.

Glossary

*1 Clinical research: Medical research implemented for the purpose of improving preventive methods, diagnostic methods, and therapeutic methods for diseases in medicine, understanding the pathogenesis and pathology of diseases, and improving the quality of life of patients (in addition to direct medical research, also includes research in connection with dental science, pharmacology, nursing science, rehabilitation science, preventive medicine, and health science) on human subjects (including research on materials and data of human origin which can designate an individual human).
Source: Ethical Guidelines for Clinical Research (established July 30, 2004 by the Ministry of Health, Labour and Welfare).

*2 Clinical test: Research conducted in accordance with an implementation plan specified in advance by performing interventionary acts such as use of drugs, surgical operations, etc. on human subjects.

*3 Clinical trial : Clinical test performed for the purpose of obtaining the data necessary for application to the Ministry of Health, Labour and Welfare for approval of the manufacture, import, or sale of medical and pharmaceutical products, etc.

*4 Translational research :Clinical research on human subjects using small molecular compounds, polymer compounds, genes, cells, tissues, etc. when the appropriateness of human use has been confirmed publicly from both the ethical and scientific viewpoints.

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Yuko ITO, PhD
Head, Life Science Research Unit, Science and Technology Foresight Center

Ph.D. in Pharmaceutical sciences. Formerly engaged in experimental research on structural/functional analysis of human chromosomes. Currently specializing in science and technology policy. Dr. Ito's interests include trends in advanced life sciences, competitive funding for young researchers, and processes leading to the utilization of scientific knowledge in society in the life science field, focusing on S&T policy outcomes.

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