“Investigative Commission for the Mid-Term Review of the New 5 Yearly Clinical Trial Activation Plan” Report

January 19, 2010

Investigation Regarding the Mid-Term Review of the "New 5 Yearly Clinical Trial Activation Plan"

The Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labour and Welfare established a "New 5 Yearly Clinical Trial Activation Plan" ("5 Yearly Plan") in March 2007 with the objective of evaluating the accomplishments of the "3 Yearly National Clinical Trial Activation Plan" ("3 Yearly Plan") that had been implemented since April 2003, setting new challenges and further developing the implementation system.

In addition to infrastructure development for the clinical trial implementation system that was undertaken in the 3 Yearly Plan, the necessity of responding to issues relating to the reinforcement of the implementation systems for the entirety of clinical research leading to the infrastructure development was pointed out for the establishment of the 5 Yearly Plan, and thus the "Expected Image of Clinical Trials and Studies from the Implementation of the 5-Yearly Plan" was indicated and priorities for its accomplishment (action plan) was established in the 5 Yearly Plan.

As the 5 Yearly Plan stipulates that it is "appropriate to take measures that reflect the situation in Japan by evaluating the progress made in the mid-term year and conducting necessary reviews based upon this evaluation, etc.," an "Investigative Commission for the Mid-Term Review of the New 5 Yearly Clinical Trial Activation Plan" was established and reviews were conducted as follows:

2009	June 30	1st meeting of the Investigative Commission
	July 30	2nd meeting of the Investigative Commission
	August 27	1st meeting of the working groups
	September 15	2nd meeting of the working groups
	October 3	3rd meeting of the Investigative Commission
	October 15	4th meeting of the Investigative Commission
	October 28	5th meeting of the Investigative Commission
	December 1	6th meeting of the Investigative Commission
	December 15	7th meeting of the Investigative Commission
2010	January 19	8th meeting of the Investigative Commission

In the mid-term review, the items that were being worked upon up to now for the infrastructure development of clinical trials and studies centered on core hospitals and central medical institutions, etc., were evaluated in view of the changes in the clinical

trial/study environment, such as the rapid increase in the number of multinational clinical trials after the establishment of the 5 Yearly Plan, and the following items were set as the points for consideration:

- ○ Evaluate the infrastructure development conditions of core hospitals and central medical institutions, etc., and indicate the functions required of core hospitals and central medical institutions, etc., in a clearer manner.
- ○ Visualize the image (ultimate goal) of clinical trials and studies that is expected to be achieved through the implementation of the 5 Yearly Plan, such as those below:
  - · The cost, speed, and quality of clinical trials and studies have been improved to the level of foreign countries, such as the United States.
  - · The number of multinational clinical trials that have been implemented has increased to the level of neighboring Asian countries or above.
- ○ Establish a new action plan and consider the need to change the existing action plan in order to achieve the visualized ultimate goal.
- ○ Other items required for consideration of the abovementioned content.

Etc.

Based on the results of the past reviews, the necessity and direction of clinical trial/study activation, the progress made in the first half of the 5 Yearly Plan and the efforts to be made in the second half of the plan were assembled and shall be reported as follows.

1. Necessity and direction of clinical trial/study activation

In terms of the necessity and direction of clinical trial/study activation, it was affirmed that there be a common awareness regarding the content below, and that quick infrastructure development for clinical trials and studies that are required for the timely and seamless creation of innovative pharmaceuticals and medical devices by Japan in particular be reinforced.

- ○ The ultimate goal that should be achieved from the activation of clinical trials and studies is the realization of a system in which the latest high-quality medical treatment in the world can be provided to patients in Japan.
- ○ At the same time, it should be reaffirmed that autonomous development of pharmaceuticals and medical devices will lead to the establishment of constant safety in Japan. In addition, it should also be reaffirmed that the establishment and reinforcement of a domestic implementation system for clinical research that include clinical trials for pharmaceuticals and medical devices, as set as the goal of the 5

Yearly Plan, are essential for the creation of Japanese innovation, which will be the foundation of international competitiveness of the relevant Japanese industries, as well as for the transmission of the obtained evidence to the world.

- The abovementioned items were also included as one of the goals in the "5-Year Strategy for the Creation of Innovative Pharmaceuticals and Medical Devices" (April 2007 Cabinet Office, Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labour and Welfare, and the Ministry of Economy, Trade and Industry) so that Japan, which has few natural resources, use its superior research and development abilities to participate in the global development and provision system of innovative pharmaceuticals and medical devices as well as expand the share of innovative pharmaceuticals and medical devices developed in Japan in the global market, thereby allowing the pharmaceutical and medical device industry to drive Japan's growth. Measures for the development of the clinical trial and clinical research environment required to realize this goal were set forth, and this 5-Year Plan plays an important part of these measures.
- Strategic efforts to create innovative medical technologies are already being taken in the United States and Europe, and infrastructure development to enable clinical research to be conducted quickly and safely at an earlier stage in the development process is underway. National efforts are also being taken in neighboring Asian countries. Implementation systems for clinical trials in the later stages of development have nearly been established, and furthermore, efforts are being made to develop implementation systems for clinical research at an early stage in the development process, as in the United States and Europe. There are thus increasing concerns that Japan must further accelerate and reinforce its efforts in order to survive the fierce global competition.
- Until now, the emphasis on efforts in Japan tended to be placed on developing the implementation system for clinical trials in the later stages of development. However, in order to create innovative pharmaceuticals and medical devices, it is necessary to place more importance on conducting clinical trials at early stages in development and clinical research such as POC (Proof of Concept) tests, etc., in the future, to strongly recognize that reliable development of a system to accelerate the implementation of such trials and studies in Japan is a pressing issue, to develop new seeds in Japan in a smooth, quick, and efficient manner, and to take measures as quickly as possible so that these innovations can be accessed by eagerly awaiting patients. In addition, clinical trials in the later stages of development, clinical trials and studies aiming to expand indications, and clinical research leading to the

creation of evidence are also important for medical development, and it is also necessary to further develop systems to promote such clinical trials and studies.

2. Progress made towards achieving priorities (action plan)

Discussions were held regarding the evaluation of progress made thus far regarding priorities and efforts that need to be further reinforced in the future.

In particular, as the streamlining of clinical trials, etc., require detailed reviews, a "Working Group Regarding the Streamlining of Clinical Trials, etc." was established, and reviews centered on the three main items of cost, speed, and quality were conducted. Although steady overall improvements were seen due to efforts made by the relevant parties thus far, it was shown that there are issues that still need to be resolved in order for Japan to receive a certain level of recognition in terms of an environment to implement clinical trials from a global perspective, and uniform evaluation indicators need to be established for these items, etc. (refer to Attachment 2 "Working Group Investigation Results Regarding the Streamlining of Clinical Trials").

The specific content of discussions of the Investigative Commission based on the reports of the "Working Group Regarding the Streamlining of Clinical Trials, etc." is shown in "Attachment 1 Progress Made in the "New 5-Year Clinical Trial Activation Plan," etc."

Items that were listed as issues to further accelerate and reinforce efforts in the future are shown below:

○ Increasing the number of case series

There are concerns that costs may be affected due to barriers in the streamlining of clinical trials from the fact that the number of case series of the medical institutions is not necessarily high, and the difficulty in grasping the number of patients suffering from the target disorder who are candidates for trials in the medical institutions. It is necessary to make efforts to increase the number of case series in a more proactive manner, such as keeping track of the number of disorder cases and increases in the number of cases at each hospital and securing the number of cases in collaboration with multiple institutions, in addition to making this information visible externally to trial subject candidates and sponsors, etc.

○ Streamlining of clinical trials and studies

With regards to clinical trials, prompt and reliable efforts are required to maintain and reinforce the international competitiveness of Japan as a place to implement clinical trials by clarifying the minimum necessary procedures that are in line with the Good Clinical Practice for pharmaceuticals and for medical devices

(GCP) and organizing items that are not necessarily required.

In addition, it is necessary to conduct reviews regarding the specific modality of the dissemination of joint review boards, etc.* and effective utilization methods, etc.

*Includes review boards that can conduct reviews based on requests from the heads of other clinical trial medical institutions and clinical research institutions, and joint review boards that have been established jointly by the heads of multiple clinical trial medical institutions and clinical research institutions.

○ Development of researchers

In order to develop researchers that lead clinical trials and clinical research that enable the creation of innovative pharmaceuticals and medical devices and the establishment of evidence for standard treatment, etc., education regarding research ethics of trial subject protection, etc. and clinical research methodology, etc. is important. Since physicians in particular are required to aim towards advances in health care through clinical trials and studies, it is important that they constantly obtain the knowledge required for research through pre-graduate, post-graduate, and lifelong education.

○ Securement of personnel required for the implementation of clinical trials and studies

The need for clinical research coordinators (CRC), biostatisticians, data managers, and personnel knowledgeable in medical and pharmaceutical affairs has been increasing, as shown in the 5-Year Plan, in view of the rapid globalization of clinical trials in recent years and the expansion of support for clinical research, etc. From the standpoint of developing such personnel as well as securing talented personnel and placing them in appropriate positions, a system enabling the stable hiring of such personnel in medical institutions needs to be developed. In this respect, a more adequate calculation method for clinical trial costs for required work and effective utilization of public research funds need to be considered.

In order to promote clinical research that can withstand scientific evaluation in particular, the involvement of biostatisticians are important from the research planning stages, and a further increase in personnel is desired, but the reality is that the absolute number is low. It is hoped that industry-academia personnel exchanges are promoted along with the expansion in venues for personnel development, such as graduate education.

○ Disclosure of clinical trial and study information

It is necessary to strengthen education in order to gain the further understanding

and cooperation of citizens with regards to the significance, necessity, and mechanisms, etc., of clinical trials and clinical research.

At the same time, a search system that enables a cross-sectional search of clinical trials and clinical research being implemented in Japan was constructed, but it needs to be improved so that it can be more easily understood and used by citizens in order for this system to be used more widely and lead to information provision and education of citizens involved in clinical trials and clinical research.

In addition, considerations regarding the methods of communicating and disclosing clinical trials/research results are also desired.

○ Optimization of the cost, speed, and quality of clinical trials

It can be said that costs are decreasing, but in general, costs are still higher than the United States and Europe, and active efforts are required by both medical institutions and clinical trial sponsors to cut costs.

For medical institutions, considerations of payment methods based on performance, adequate calculation methods for necessary work, and the securement of transparency are required, and for clinical sponsors, considerations for the optimization of costs needed for the streamlining of relevant work such as monitoring are required.

In terms of speed, in general, Japan is comparable to the United States and Europe at the present time. There are no major issues in terms of “quality” from the standpoint of compliance to the clinical trial protocol; however, it is necessary for all parties involved in clinical trials to continue making constant and appropriate efforts while continuing to pay attention to the situation in foreign countries and taking note of excessive response.

3. Future efforts

All relevant parties should reaffirm that the activation of clinical trials and clinical research by means of the 5-Year Plan is aimed at creating innovative pharmaceuticals and medical devices in Japan and transmitting evidence of the latest and high-quality medical treatment to the world, and should work on steadily resolving the issues that remain among the priorities required of each person.

As part of these efforts, the “functions required of core hospitals and central medical institutions” were clarified based on discussions held by the investigative commission, and issues for which proactive response by the core hospitals and central medical institutions are requested and system development milestones were indicated (refer to Attachment 3 “Functions Required of Core Hospitals and Central Medical

Institutions").

In order to develop and reinforce a firm and internationally competitive infrastructure required for the implementation of clinical trials and clinical studies that lead to the creation of innovative pharmaceuticals and medical devices in Japan, it is necessary to steadily advance infrastructure development indicated in the "Functions Required of Core Hospitals and Central Medical Institutions" in core hospitals and central medical institutions, and this should be used as reference to improve the clinical trial and clinical research environment throughout Japan in other medical institutions as well. It is also hoped that the government will consider the modality of adequate quality control of clinical trial data together with relevant parties, etc. Also, in order for highly ethical, scientific, and socially valuable clinical research to be conducted, active efforts by all relevant parties involved in clinical research, in addition to the researchers, is required, such as the appropriate creation and review of the research plan, reliable implementation according to the plan, and management of data quality. In addition, further developments to promote clinical research are desired, such as reducing systemic obstacles in order to conduct clinical research at an early stage in the development process or to adequately implement clinical research that reveals new applications for existing pharmaceuticals, etc.

Furthermore, in order to create innovative pharmaceuticals and medical devices and establish evidence for standard treatment, etc., utilizing the system developed through efforts in the 5-Year Plan, it is necessary to secure an environment in which researchers involved in such research can concentrate on their research and to educate future researchers with the know-how to implement high-quality clinical trials and clinical research through experience.

The 5-Year Plan requires an implementation system in which the medical institutions and clinical research institutions implementing the clinical trials and clinical research as well as pharmaceutical companies, medical device companies, and government officials do their part and collaborate systematically. Pharmaceutical companies and medical device companies, etc., should also continue to actively contribute to the implementation of priorities (action plan), and in order to realize this system, investigative commissions, etc., should be established as needed, so that their efforts lead to prompt and reliable results.

Members of the Investigative Commission for the Mid-Term Review of the New 5-Year Clinical Trial Activation Plan

Shigetetsu Arai	Chairperson of the GCP Committee, The Japan Federation of Medical Devices Associations
Yoshihiro Arakawa	Vice Director, Clinical Research Support Center, The University of Tokyo Hospital
Tatsuhiko Ichiki	Executive Director, Japan CRO Association
Suminobu Ito	National Hospital Organization Director Department of Clinical Research, Clinical Research Center National Hospital Organization Headquarters
Yukiko Enomoto	Director, Nihon University Itabashi Hospital Clinical Trial Department
Naoko Kakee	Chief, Division of Health Policy and Bioethics, Department of Health Policy, National Research Institute for Child Health and Development
Hideo Kusuoka	Director General, National Hospital Organization Osaka National Hospital
Fumiaki Kobayashi	Director, Clinical Research Division, Japan Medical Association Center for Clinical Trials
Takuya Sakuhiro	Chairperson, Drug Evaluation Committee, Japan Pharmaceutical Manufacturers Association
Toshihiko Satoh	Professor, Kitasato Clinical Research Center
Yuji Sato	Director and Professor, Keio Center for Clinical Research
Shinro Tashiro	Vice-Chairman, Japan Association of Site Management Organizations
Yoshiko Tsujimoto	Chairman, Consumer Organization for Medicine & Law
Seiichiro Yamamoto	Section head, Statistics and Epidemiology section, Cancer Information Services and Surveillance Division, Center for Cancer Control and Information Services, National Cancer Center
Haruko Yamamoto	General Manager, Department of Clinical Research and Development, National Cerebral and Cardiovascular Center
Hiroshi Watanabe	Professor, Department of Clinical Pharmacology and Therapeutics, Hamamatsu University School of Medicine

(○: Chairman Japanese syllabary order; honorifics omitted)

Members of the Working Group Regarding the Streamlining of Clinical Trials, etc.

Hiroyuki Aono	European Federation of Pharmaceutical Industries and Associations
Yukiko Enomoto	Nihon University Itabashi Hospital
Toshiyuki Okada	Japan Pharmaceutical Manufacturers Association
Yoshihiko Ono	Pharmaceutical Research and Manufacturers of America
Koichi Kawano	European Federation of Pharmaceutical Industries and Associations
Takeshi Kuriyama	National Center for Child Health and Development
Ryuun Shoji	Pharmaceutical Research and Manufacturers of America
Chieko Suzuki	Seirei Hamamatsu General Hospital
Norio Tamura	Japan Medical Association Center for Clinical Trials
Tadayoshi Nakashima	Japan Pharmaceutical Manufacturers Association
Takeshi Fukui	R&D Head Club
Tatsuya Fukushima	R&D Head Club
Minako Yamagishi	National Center of Neurology and Psychiatry

(Japanese syllabary order; honorifics omitted)

List of Attachments

1. Progress Made in the “New 5-Year Clinical Trial Activation Plan, etc.
2. Working Group Investigation Results Regarding the Streamlining of Clinical Trials
3. Functions Required of Core Hospitals and Central Medical Institutions

Attachment 1

Progress Made in the "New 5-Year Clinical Trial Activation Plan, etc.

The progress made, etc., with regard to the priorities (action plan) from April 2007 to the end of September 2009 were assembled.

(1) System development of Core clinical research centers and Major clinical trial institutions

Body of plan	Progress, etc.	Review results, etc.
Government efforts		
Started in FY2007		
○ Establish a system of about 48 Core clinical research centers and Major clinical trial institutions that play a central role in clinical trials, etc., and implement clinical trials and clinical studies in a prompt and effective manner and reinforce the functions of the staff development network. These medical institutions provide functions such as common IRB, etc., and accept the medical care of trial subjects that have suffered from a serious adverse effect at collaborating medical institutions, etc.	[FY2007] · For the Ministry of Health, Labour, and Welfare, 10 core clinical research centers and 30 Major clinical trial institutions were selected, and for the Ministry of Education, Culture, Sports, Science, and Technology, 7 research support bases were selected by the Coordination, Support and Training Program for Translational Research (1 was added in FY2008). [FY2007 onwards] -The various institutions cooperated with one another to establish a council (council of Core clinical research centers/ Major clinical trial institutions, etc.) that aims to establish a system	· The efforts of the action plan of this plan have been advanced by Core clinical research centers and Major clinical trial institutions, etc., and some results have been seen in terms of the prompt and efficient implementation of clinical trails, such as improvements in the speed of clinical trial procedures. · Meanwhile, in terms of network function, although there have been many results in terms of staff development efforts, there have not been many efforts that contribute to prompt and efficient implementation. · In order to achieve prompt and efficient implementation, "increasing the number of

	that can promptly and efficiently implement clinical trials and clinical research based on the "New 5-Year Clinical Trial Activation Plan" (March 30, 2007 Ministry of Education, Culture, Sports, Science, and Technology and the Ministry of Health, Labour, and Welfare), and information is being shared. [FY2007 onwards] Based on the results of the clinical trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc. (As of April 2009) · 26 networks were established for identical disorders and regions in which Core clinical research centers and Major clinical trial institutions play a central role for activities such as the commissioning of clinical trials, implementation of clinical research, and training, etc. 13 networks have the common IRB function.	case series" is the most important issue in addition to the collectivity of networks. · Proactive efforts in the following areas are required by individual institutions such as Core clinical research centers and Major clinical trials institutions, etc.: - Information disclosure (promoting the disclosure of medical care records of medical institutions, number of trial subject candidates, past performance, scope of services, facility maintenance conditions, etc.) - Highly accurate response in terms of the number of trial subjects on which the individual clinical trials can be implemented - Streamlining through the consolidation and lumping of the clinical trial review committee functions - Progress management (guidance with respect to contract execution), etc. · With regards to the modality of the shared IRB, etc., its role and functions, etc., need to

	The results of the clinical trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc., will be analyzed separately and are due to be publicized.	be organized in the future. · With regards to the "network" function, discussions need to be continued regarding what the sponsor requires of the network and what the network requires of the sponsor, etc.
○ The medical institutions and universities, etc, selected as core hospitals/central medical institutions/translational research bases as part of the program of the Ministry of Education, Culture, Sports, Science, and Technology and the Ministry of Health, Labour, and Welfare, shall form a shared network, and the medical institutions shall cooperate with one another to create a system that makes adjustments so that clinical translational research and clinical trial/clinical study plans are implemented.	[FY2007 onwards] Based on the results of the clinical trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc. (As of April 2009) · 12 institutions are collaborating in terms of joint research that includes clinical trials · Currently under consideration in the other six institutions The results of the clinical trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc, will be analyzed separately and are due to be	

	publicized. [FY2007 onwards] · Information regarding the activities conducted by the various institutions is shared at the council of Core clinical research centers/Major clinical trial institutions, etc.	
Items other than government efforts		
<Japan Medical Association Center for Clinical Trials> ○ Promotes collaboration between the large-scale clinical trial network and Core clinical research centers/Major clinical trial institutions, and supports training, etc	<Japan Medical Association Center for Clinical Trials> [FY2007 onwards] · Number of clinical trials introduced through the large-scale clinical trial network: 47 · Holding workshops, etc. Clinical trial promotion regional liaison meeting (3 times per year): 6 times Luncheon seminars at academic conferences: 4 times Meeting regarding the promotion of global clinical trials: 3 times Clinical trial network forums (once per year): 2 times Meeting regarding the implementation	· A system that responds to people's intention to participate in clinical trials through the large-scale clinical trial network and surveys of the specific number of candidates has already been established. If further system expansion and development is necessary in the future, reviews will be conducted.

	of clinical research: Once	
<Core clinical research centers/Major clinical trial institutions> ○ Staff members to support clinical trials and clinical studies (CRC with experience such as qualifications, full-time CRC, biostatisticians, data managers, office workers, etc.) will be secured systematically.	<Core clinical research centers/Major clinical trial institutions> [FY2007 onwards] The results of the clinical trial/clinical research infrastructure development status investigation of the council of clinical trial core hospitals/central medical institutions, etc., will be analyzed separately and are due to be publicized.	· About 30% of the CRC in core hospitals and central medical institutions, etc., are employed part-time, and the development of a system to develop and stably employ CRC is desired. · The involvement of biostatisticians is important from the research planning stages for the promotion of clinical research, and further personnel increases are desired. · For CRC, the appellation of “clinical research coordinator” was indicated to enable them to play an active role in the field of clinical research, and relevant parties should cooperate so that CRC can live up to their name and reliably execute work both in clinical research and clinical trials. · In order to utilize data managers, it is necessary to further clarify the content of their work and increase the number of data managers. · There is a low absolute number of

		biostatisticians, etc., in Japan, and the development of biostatisticians as well as the promotion of industry-academia personnel exchanges is desired. · At various institutions, the required number of various personnel should be distributed based on the analysis of the current status of personnel distribution.

(2) Development and securement of personnel implementing clinical trials and clinical research

Body of plan	Progress, etc	Review results, etc
Government efforts		
Started in FY2007		
○ Implement advanced training for experienced CRC and new training for data managers and committee members such as IRB, in an exemplary manner.	[FY2007 onwards] · New training for senior CRC (held in three locations in FY2007 and 2 locations in FY2008 onwards), local data managers (once a year), and committee members such as IRB (once a year) was started (document scheduled to be attached). · Number of eligible trainees and total number of trainees Senior CRC: 203 people Local data managers: 211 people Clinical trial and clinical research ethical review committee members: 180 people	· The development of a system to develop personnel and to stably employ them in medical institutions, from the perspective of securing talented personnel, is desired. · In terms of the securement of personnel, it is necessary to consider the appropriate distribution of personnel such as CRC based on an analysis of the clinical trial/clinical research implementation status in the various institutions, in light of an increase in the amount of work and an expansion in support for clinical research, etc., associated with an increase in global clinical trials. · The training for local data managers is more a training for clinical trials, but the development of personnel that can
○ Encourage training programs for physicians, committee members such as IRB, and office workers in Core clinical research centers/Major	[FY2007 onwards] Based on the results of the clinical trial/clinical research infrastructure development status investigation of the	

clinical trial institutions.	council of Core clinical research centers/Major clinical trial institutions, etc. (FY2008 status) · Training record Average times held: 9 times/institution (Maximum number of times: 41 times/institution) The results of the clinical trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc, will be analyzed separately and are due to be publicized.	handle the local data management for general research is also required in order to enhance the quality of clinical research. · In order to develop researchers, education regarding research ethics such as trial subject protection and clinical research methodology, etc., is important. Since physicians in particular are required to aim towards advances in medicine through clinical trials and studies, it is important that they constantly obtain the knowledge required for research through pre-graduate, post-graduate, and lifelong education.
○ Encourage Core clinical research centers, Major clinical trial institutions, and relevant organizations to cooperate in order to improve the evaluation (hospital treatment, dissertation evaluation by academic societies, acquisition of	[FY2007 onwards] · Core clinical research centers and Major clinical trial institutions are encouraged to conduct reviews regarding the modality of incentives in the various institutions Based on the results of the clinical	· When evaluating research organizations, efforts to create evaluation indicators have been made in some areas, but it is preferred that these indicators be expanded to other organizations and include the evaluation of researchers.

academic degrees) of the clinical performance of physicians, etc.	trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc. (FY2006~FY2008 status) · Examples of efforts to increase incentives for physicians Performance evaluation Devise ways of distributing research funds and devise ways to use research funds Review the division of work and secure time to concentrate on clinical trials, etc. Official commendations, etc. The results of the clinical trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc, will be analyzed separately and are due to be publicized.	
○ In order to popularize clinical trials and clinical research, shift the ratio of	[FY2007 onwards] · Transition in the ratio of research	· The ratio of Health and Labor Sciences Research Grants for clinical

Health and Labor Sciences Research Grants, etc., from basic research to clinical trials and clinical research. In particular, when adopting clinical research with an appropriate plan and established morality that is internationally recognized, the researchers' clinical trial/clinical research achievements should be added to the evaluation indicators and considerations should be made to secure research funding.	funds of the Research and Development Division provided to basic research and clinical research (document scheduled to be attached) · Compliance to guidelines regarding the various research, etc., is a requirement for receiving the Health and Labor Sciences Research Grant	research is increasing. · Considerations for a framework of research funds that is more compatible with the reality of clinical research, where it takes a long time to achieve results, is desired. - Planning preparation: 1 year - Implementation of research: 3 years - Analysis of results: 1 year, etc.
○ Consider the involvement of biostatisticians in research planning when adopting clinical research that will be conducted using public research funds.	[FY2007 onwards] · For the adoption of Health, Labor and Sciences Research, reviews are implemented based on a plan that describes whether or not an epidemiologist/biostatistician is involved.	· The involvement of biostatisticians are important from the research planning stages for the promotion of clinical research, and further personnel increases and the development of a system to stably employ biostatisticians in clinical research institutions are desired. · There is a low absolute number of biostatisticians, etc., in Japan, and the development of biostatisticians

		through the expansion of educational institutions such as graduate schools and interaction between clinical research institutions and universities (lectures, practical training, etc.), etc., is desired. In addition to the development of biostatisticians, the promotion of industry-academia personnel exchanges for the utilization of the limited biostatisticians is desired.
○ Encourage appropriate in-hospital distribution of clinical trial funded research funds in Core clinical research centers/Major clinical trial institutions.	[FY2007 onwards] The results of the clinical trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc., will be analyzed separately and are due to be publicized.	· In order to secure the required personnel, more appropriate calculation methods for clinical trial costs with respect to work and uses of public research funds should be considered.
Implement by FY2011		
○ Unify the training content among the training organizations, and aim to develop 3000 new CRC.	[FY2007 onwards] · Training record at the Japanese Society of Hospital Pharmacists; Japanese Nursing Association;	· In the training for the CRC development stages, it is desired that the content include knowledge regarding medical devices in addition

	Japanese Association of Medical Technologists; Ministry of Education, Culture, Sports, Science, and Technology; Pharmaceuticals and Medical Devices Agency (Ministry of Health, Labour, and Welfare) FY2007 470 people FY2008 452 people FY2009 333 people (As of the end of September 2009; not yet implemented by the Japanese Association of Medical Technologists)	to knowledge regarding pharmaceuticals.
○ Of the Core clinical research centers and Major clinical trial institutions, in medical institutions lacking CRC, aim to place at least 0.5 CRC per one principal investigator or so that each CRC is in charge of planning around 7 to 8 clinical trials per year, in order to secure the quality of clinical trials and clinical research.	[FY2007 onwards] The results of the clinical trial/clinical research infrastructure development status investigation of the council of clinical trial core hospitals/central medical institutions, etc, will be analyzed separately and are due to be publicized.	· Due to the increase in global clinical trials and expansion in support for clinical research, etc., the workload of CRC is increasing, and the majority of institutions has not achieved the target of having each CRC be in charge of planning around 7 to 8 clinical trials per year. · Meanwhile, in some institutions, the number of clinical trials planned by

		each CRC per year greatly exceeds 7 to 8. · The placement of the necessary number of CRC based on an analysis of the current conditions of each institution is required.
○ Aim to place at least one biostatistician per medical institution in the Core clinical research centers and at least one data manager per Major clinical trial institution in the Core clinical research centers and Major clinical trial institutions.	[FY2007 onwards] The results of the clinical trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc, will be analyzed separately and are due to be publicized.	· In order to utilize data managers, it is necessary to further clarify the content of their work and increase the number of data managers.
○ Aim for 30% or above of CRC of the various core hospitals and central medical institutions to acquire the qualifications of the relevant academic societies.	[FY2007 onwards] The results of the clinical trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc, will be analyzed separately and are due to be publicized.	· Approximately 30% of CRC employed in Core clinical research centers/Major clinical trial institutions have qualifications of academic societies, etc.
○ Secure and expand opportunities for education relating to clinical trials and	[FY2007] · The model core curriculum of “basic	· It is extremely important to educate future physicians while they are in

clinical research in the training process of physicians, etc.	qualities required of physicians" and "Medical evaluation/validation and scientific research" was revised, based on the final report of the investigative study collaborator's meeting regarding the improvement and enhancement of medical education.	medical school that they are expected to aim for advances in medicine through clinical trials and clinical research. · Emphasis should be placed on training physicians and researchers with the ability to lead clinical trials and clinical research as research representatives.
○ Enhance training content relating to clinical trials/research, biostatistics, and research ethics in the training process for all specialties in health care that may be involved in clinical trials/research in the future, such as pharmacists, nurses, and clinical technicians, and enhance understanding regarding clinical trials and clinical research by including such questions in the test criteria for national exams.	[FY2008] · In the "Primary report of the investigative commission regarding the modality of pharmaceutical personnel training" (March 23, 2009), in graduate schools based on departments with six-year curriculums, conducting education research with an emphasis on training pharmacists, etc., with excellent research abilities was set as one of the main objectives. · Basic knowledge regarding the protection of human rights, such as the	· Items regarding clinical research and clinical trials, etc., are set in the test criteria in the national exam for medical practitioners, and questions regarding these topics already appear on exams, but it is preferred that the number of questions on these topics are increased.

	right to self-determination and informed consent, etc., is included in the test criteria for the national exam for health nurses, maternity nurses, and clinical nurses, and education on this topic is provided in the various training institutions.	
○ Review the detailed regulations for handling Health and Labor Sciences Research Grants so that the use of research funds is compatible with the actual status of clinical research.	[FY2008 onwards] · From FY2008 onwards, detailed regulations regarding wages in the Health and Labor Sciences Research Grants were revised, so that wages could be supplied to people involved in clinical research (part-time employee benefits, travel allowance, accommodation allowance, dependant allowance, local allowance, and insurance).	· It is necessary to further disseminate regulations, etc., regarding the handling of public research funds. · In particular, in-depth notice regarding regulations that have been changed from the previous fiscal year is desired, such as making the changes clearer.
Items other than government efforts		
<Core clinical research centers and Major clinical trial institutions> ○ Allow physicians, etc., implementing clinical trials and clinical research to	<Core clinical research centers and Major clinical trial institutions> [FY2007 onwards] Based on the results of the clinical	

secure research time and research funds.	trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc. (FY2006-2008 status) · Examples of efforts to increase incentives for physicians Performance evaluation Devise ways of distributing research funds and devise ways to use research funds Review the division of work and secure time to concentrate on clinical trials, etc. Official commendations, etc. The results of the clinical trial/clinical research infrastructure development status investigation of the council of clinical trial core hospitals/central medical institutions, etc, will be analyzed separately and are due to be publicized.	
<Core clinical research centers and Major clinical trial institutions> ○ Take into account the clinical trial/clinical research accomplishments of physicians, etc., in employee evaluations, etc.		
<Core clinical research centers and Major clinical trial institutions, etc.> ○ Consider a mechanism that takes into account the accomplishments of clinical trials and clinical research in the acquisition of academic degrees, in cooperation with educational institutions.		
<Academic societies, etc>	<Academic societies, etc>	

○ Advance efforts to evaluate accomplishments of physicians with regards to clinical research, with the cooperation of academic societies.	Efforts such as establishing the training of researchers and physicians' clinical research achievements as a specialist certification renewal requirement are being taken in multiple academic societies.	
<Core clinical research centers and Major clinical trial institutions> ○ Ensure a constant number of CRC to be employed full-time, and make improvements in terms of career paths.	<Core clinical research centers and Major clinical trial institutions> [FY2007 onwards] The results of the clinical trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc., will be analyzed separately and are due to be publicized.	· According to the results of the clinical trial/clinical research infrastructure development status investigation of Core clinical research centers/Major clinical trial institutions, etc., the reality is that about 30% of CRC are employed part-time. · The development of a system to train and stably employ CRC in the various medical institutions is desired.
<Ministry of Health, Labour, and Welfare/Pharmaceutical companies/Medical device companies, etc.> ○ Change the name of CRC from "clinical trial coordinators" to "clinical research coordinators."	<Ministry of Health, Labour, and Welfare/Pharmaceutical companies/Medical device companies, etc.> [FY2007 onwards] · This was clearly specified in the "New 5-Year Clinical Trial Activation Plan." · The "9th Meeting Regarding CRC and	· The participation of CRC in clinical research is increasing in the core hospitals and central medical institutions, etc. In order to implement high-quality clinical research, the further participation of support personnel such as CRC is desired.

	Clinical Trials in Yokohama" with the theme of "the future of clinical research coordinators" was held (September 12 & 13, 2009), and discussions were held regarding the expansion of CRC activities to the field of clinical research as well.	
<Ministry of Health, Labour, and Welfare/Pharmaceutical companies/Medical device companies, etc> ○ Develop an environment in which the work experience of physicians, etc., who conducted reviews in regulatory agencies and pharmaceutical development, etc., in the industrial world is recognized, and smooth personnel exchange is conducted.	<Ministry of Health, Labour, and Welfare/Pharmaceutical companies/Medical device companies, etc> [FY2007 onwards] The results of the clinical trial/clinical research infrastructure development status investigation of the council of clinical trial core hospitals/central medical institutions, etc, will be analyzed separately and are due to be publicized.	
<Ministry of Health, Labour, and Welfare/Pharmaceutical companies/Medical device companies, etc.> ○ Industry, government, and academia		Already described

should collaborate and encourage the exchange and cooperation of biostatisticians.		
	<Japan Medical Association Center for Clinical Trials> [FY2007] · E-Learning training, “e Training Center for Clinical Trials,” was started. · Number of users: 6000; number of questions: 1250 (as of the end of September 2009) <Other> [FY2007] · Health and Labor Sciences Research Grant Clinical Research Infrastructure Development Promotion Research Project (training-type) · A clinical research training program using the Internet for all people involved in clinical research (researchers, clinical research coordinators (CRC), Ethics Review	

	Committee (IRB) members, IRB secretariat staff members, etc.) was developed and “ICR web Introduction to Clinical Research” was started. · Number of users 4869; Number of people issued an introductory class certificate: 1718 (As of the end of September 2009)	

(3) Increasing public awareness and encouraging participation in clinical trials and clinical research

Body of plan	Progress, etc	Review results, etc
Government efforts		
Started in FY2007		
○ Provide a clinical research registration database portal site.	[FY2007] · The National Institute of Public Health built a portal site enabling cross-sectional searches of registration information at three places in Japan (National University Hospital Council of Japan UMIN Clinical Trials Registry, Japan Pharmaceutical Information Center Japic CTI, and Japan Medical Association Clinical Trials Registry) · Started operation in October 2007 [FY2008] · The three abovementioned clinical research registration institutions were named the Japan Primary Registries Network (JPRN), and this was certified by the World Health Organization (WHO) as a clinical	· It was confirmed that a search system that enables cross-sectional searches of domestic clinical trial/clinical research was established. · As the portal itself is hard to find, it is hoped that measures will be taken to encourage wider use. · Further improvements are desired from the standpoint of disseminating clinical research to the general public in the future.

	trial/clinical research registration institution (WHO Primary Registry) designated by WHO.	
○ Encourage medical institutions and pharmaceutical companies, etc., to continue treatment after the clinical trial if treatment was effective for trial subjects and follow up on the approval information of the test drug, etc.	[FY2007 onwards] Based on the results of the clinical trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc. · Medical institutions conduct efforts such as providing the results of the clinical trial to trial subjects who desired this information during the clinical trial.	· More actively anticipate the provision of the results of the clinical trial to trial subjects desiring this information after completion of the clinical trial/clinical research.
○ Review the modality of reducing costs borne by trial subjects.	Not yet started.	· In the future, it is necessary to review overall reduction of costs borne by trial subjects when investigating the actual conditions of clinical trial sponsors and clinical trial medical institutions.
○ Encourage Core clinical research centers and Major clinical trials institutions to disclose information	[FY2008] · Ministerial Ordinance on Good Clinical Practice for Drugs (1997	· The active disclosure of information regarding the distribution of disorders and number of patients in the medical

regarding the implementation system and performance of clinical trials and clinical research at the facility and IRB meetings, etc.	MHW Ordinance No. 28; partially revised in February 2008; enforced in April 2009) · In order to create an environment in which information regarding the clinical trial review board can be easily acquired by people involved in clinical trials and be widely disseminated to the public, the Pharmaceuticals and Medical Devices Agency began registering the name of the clinical trial review board, the name of the establishing person, the address and website address, and began disclosing information registered from the website. (Registration of information regarding the clinical trial review board (Notification No. 1001013 of the Pharmaceutical and Food Safety Bureau dated October 1, 2008)) · Ministerial Ordinance on Good Clinical Practice for Medical Devices	institutions, etc., should be encouraged primarily from the standpoint of clinical performance as information required by patients in their selection of a medical institution, and is thought to contribute to the efficient selection of institutions that implement clinical trials. · The disclosure of information regarding clinical trials and clinical research is desired in order to promote patient education and voluntary participation in clinical trials, as well as from the standpoint of streamlining the selection of institutions that implement clinical trials. · By recognizing medical institutions that conduct over a certain number of clinical trials and clinical research using a treatment remuneration mechanism, etc., such as the existing clinical training hospital in-patient treatment remuneration, the reputation

	(2005 MHLW Ordinance No. 36; partially revised in March 2009; enforced in April 2010) · Ethical Guidelines Regarding Clinical Research (2008 Notification No. 415 of the Ministry of Health, Labour and Welfare; revised in July 2008; enforced in April 2009)	of the medical institutions will improve, and it is expected that this will lead to the promotion of public awareness and participation in clinical trials and clinical research.
○ Encourage a “patient consultation service function” to promote communication between patients and healthcare professionals to be established in Core clinical research centers and Major clinical trial institutions.	[FY2007 onwards] Based on the results of the clinical trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc. · In all the Core clinical research centers and Major clinical trial institutions, information is provided by means of information desks where people affiliated with the medical institution can respond to general inquiries regarding clinical trials.	· By clarifying the roles of CRCs, increasing their work independence, and having them fulfill their roles of easing patient anxiety and mistrust, it is hoped that they will contribute to creating an environment in which people can participate in clinical trials and clinical research at ease.

Items other than government efforts		
<Core clinical research centers and Major clinical trial institutions> ○ Provide an environment that enables patients to participate easily by using patient referral systems and patient databases, etc.	<Core clinical research centers and Major clinical trial institutions> [FY2007] The results (as of April 2009) of the clinical trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc., will be analyzed separately and are due to be publicized.	· A system in which the implementation conditions, etc., of clinical trials in the various networks and medical institutions are disclosed and can be browsed from one location is required.
<Core clinical research centers, Major clinical trial institutions, pharmaceutical companies, medical device companies> ○ The medical institutions and companies should develop an information provision system so that patients can access information regarding the results of the clinical trial and clinical research and check whether the said clinical trial drug (medical devices) have been launched on the market, etc, after participating	<Core clinical research centers and Major clinical trial institutions> [FY2007 onwards] The results (as of April 2009) of the clinical trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc, will be analyzed separately and are due to be publicized. <Pharmaceutical companies> · Revision of the "Clinical trial register	· Transmitting clinical research results in an accurate and effective manner through the efforts of each facility and by using mass media, etc., is thought to be effective for raising awareness regarding clinical research, but there is concern that the inundation of information may cause confusion. · In addition to considering the method of publicizing clinical trial/clinical research results, at the same time, it is also necessary to consider providing

in clinical trials/clinical research.	and common guidelines regarding the disclosure of clinical trial information using a database" by IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) (scheduled for November 2009) <Medical device companies> · New medical devices that have received pharmaceutical approval are publicized under "review reports" on the Pharmaceuticals and Medical Devices Agency website, along with clinical trial results.	support to help the public understand the publicized information. · A system that enables the clinical research results to be seen is required.
<Pharmaceutical companies, medical device companies, Japan Medical Association Center for Clinical Trials, etc.> ○ Actively provide information regarding clinical trials and clinical research and implement campaigns to improve the image of clinical trials.	<Japan Pharmaceutical Manufacturers Association> [FY2007] · Clinical trial educational campaign Good Communication 2007 "Team Clinical Trial" [FY2008] · Clinical trial educational campaign Good Communication 2009	· According to the report of the "Qualitative study regarding the public awareness of clinical research" (FY2007 Health and Labor Sciences Research Grant Special Research Chief Researcher: Hideo Kusuoka): - Many citizens have heard of the terms clinical trial and clinical research, but do not fully

	"Everyone has a role in making medicine" [FY2009] · Good communication 2009 under the theme, value of new drugs "1/20000 The development of new drugs is an opportunity to achieve big dreams" (scheduled) <Japan Medical Association Center for Clinical Trials> [FY2007 onwards] · Holding and helping out with clinical trial education campaigns · Clinical trial education events for the general public "Clinical trial fiesta" held one time · Creation of a clinical trial education cell phone site for the general public	understand what they mean, - Among the people that understand the terms, there is a good balance of positive and negative views, with no bias towards one or the other, - There has been a tendency for people that initially had a negative impression of clinical trials and clinical research to gradually form a positive impression after hearing details regarding the subject, and it is hoped that with further education and increased understanding in the future, more people will participate in clinical trials and clinical research · It is impossible for all citizens to always be well-informed about clinical trials, and it is therefore important to repeatedly conduct educational activities. · Public awareness efforts are being

		conducted by various medical institutions, pharmaceutical companies, and the Japan Medical Association Center for Clinical Trials, etc., but it is presumed that collaborative efforts may produce more effective results.
<Pharmaceutical companies, medical device companies, Japan Medical Association Center for Clinical Trials, etc.> ○ Create teaching materials to provide knowledge regarding pharmaceutics and medical devices at schools.	<Japan Pharmaceutical Manufacturers Association> · Publish "Pharmaceutical information for elementary and middle school students" on the Internet. [FY2009] · A TV program "Ishinyakushin Yume no Medi-Shinden" that explains the development process and mechanisms of new drugs, interaction with patients and the clinical setting, drug discovery, clinical trials, and drug growth., etc, is scheduled to be aired for six months starting in October 2009. <Japan Medical Association Center for	· A clinical trial educational manga has been created and is being distributed to medical institutions, etc., but methods for the manga to be used as teaching material at elementary and middle schools will be considered in the future.

	Clinical Trials> [FY2008] · A clinical trial educational manga “Do you know what clinical trials are?” was made (20,000 issues)	

(4) Effective implementation of clinical trials and reduction of corporate sponsorship

Body of plan	Progress, etc	Review results, etc
Government efforts		
Started in FY2007		
○ Encourage the creation of a model check sheet by relevant medical institutions and organizations and pharmaceutical organizations that shows the model form for documents to be used for the clinical trial, model calculation of research costs, and the appropriate division of roles between companies and medical institutions.	[FY2007] - “Uniform Forms Regarding Clinical Trial Applications, etc.” (Notification No. 1221002 of the Research and Development Division, Health Policy Bureau, Ministry of Health, Labour and Welfare dated December 21, 2007,; 19 Higher Medical Education No. 17 notification of the Medical Education Division, Higher Education Bureau, Ministry of Education, Culture, Sports, Science and Technology dated January 16,	· Clinical trial procedures were streamlined through the creation of uniform forms and promotion of their introduction. · With regards to clinical trial speeds, the overall level of Japan is comparable to the United States and Europe. · Making excessive demands regarding speed (in particular, to the start of clinical trials) risks exhausting the responding side, and may also lead to

	2008) was released. [As of April 2009] Based on the results of the clinical trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc. (As of April 2009) · Already introduced among Core clinical research centers/Major clinical trial institutions, etc. except for two institutions · Introduced at all medical institutions as of September 2009. <Japan Pharmaceutical Manufacturers Association> [FY2007] · "Effective Division of Clinical Trial Work – Suggestions from the Clinical Trial Sponsor –" (May 2007 Japan Pharmaceutical Manufacturers Association Drug Evaluation Committee Clinical Evaluation Panel)	an increase in costs. · In addition, asking for sufficient IRB discussions, etc., to be shortened as well risks reducing the quality of the reviews. · It is therefore necessary to indicate numerical goals to be achieved at each stage unless there are exceptional circumstances, taking into account the allotted time of both the medical institutions and the clinical trial sponsors. · At the same time, clarification of the basic minimum procedures, etc., regarding clinical trial procedures that are to be implemented according to the requirements of the GCP ordinance should also be considered. · It is also necessary to consider reducing the time relating to facility selection before clinical trial application to various medical institutions from the standpoint of

	was put together. [FY2008 onwards] · "Considerations Regarding the Streamlining of the Clinical Trial Process" (April 2009 Japan Pharmaceutical Manufacturers Association Drug Evaluation Committee Clinical Evaluation Panel) was put together.	comparison to other countries in global clinical trials.
○ Encourage the centralization of contact point regarding contract for clinical trial in medical institutions.	[As of April 2009] The results of the clinical trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc, will be analyzed separately and are due to be publicized.	
Implement by FY2011		
○ Use common clinical trial-related forms at Core clinical research centers and Major clinical trial institutions, and aim for the clarification of work by using the model check sheet.	[As of April 2009] Based on the results of the clinical trial/clinical research infrastructure development status investigation of the council of Core clinical research centers/Major clinical trial institutions, etc.	Same as the previous item

	(as of April 2009) · Already introduced among the Core clinical research centers/Major clinical trials institutions, etc. except for two institutions · Introduced at all medical institutions as of September 2009. · Model check sheet not yet started.	
○ Aim to standardize relevant systems to facilitate the electronic collection and accumulation of clinical trial information at Core clinical research centers and Major clinical trial institutions.	[FY2008] · A clinical trial information computerization review team was established under the Working Group for the Streamlining of Clinical Trials, etc. · The review results were put together in the "Report on the computerization of clinical trial information" and recommendations were made to medical institutions, clinical trial sponsors, regulatory authorities, and vendors from a short-term standpoint.	· It is necessary to continue efforts towards the realization of the recommendations touched upon in the "Report on the computerization of clinical trial information" from a short-term standpoint.
○ Aim for improvements to contracts to be made in medical institutions, such	[FY2008] · Of the clinical trials completed in	· It can be said that clinical trial-related costs are decreasing, but overall costs

as fee-for-service systems and refunds for unfinished contract cases, etc.	2008, 20% of institutions have not yet received refunds for prepayments. (Based on the review results of the Working Group for the Streamlining of Clinical Trials, etc)	are still high compared to the United States and Europe, and it is necessary to make active efforts to reduce costs not only for the portion paid to medical institutions, but also other portions, such as the monitoring costs of clinical trial sponsors, etc. · Clinical trial sponsors need to consider ways of streamlining monitoring and trial planning. · There have been cases in which the medical institutions implementing the clinical trials still have not been reimbursed for pre-paid costs, even if the contract case number was not reached. This is not appropriate in terms of conventional wisdom, and prompt and reliable response is required. · The expense point calculation table, which is currently being widely used for the calculation of clinical trial costs to be paid to medical institutions,

		has the advantage of reducing the burden of cost calculation. However, it is also thought to have some disadvantages that make it inappropriate for the current situation, such as the fact that no considerations are given for long-term trials and the fact that the implementation difficulties are not easily reflected. Therefore, it is necessary to consider more flexible methods rather than relying solely on the point table so that clinical trial costs are more adequately paid with respect to the required work. · A certain level of transparency should be secured in terms of the content of the paid expenses. · It is also necessary to consider working on enhancing the incentives of those involved in the development and implementation of clinical trial/clinical research systems by further clarifying the distribution of

		costs including overhead costs of clinical trial income and public research funds within the medical institutions.
Items other than government efforts		
<Ministry of Health, Labour, and Welfare; pharmaceutical companies; medical device companies, etc.> ○ Continue to review whether it is possible to streamline areas of clinical trial work in which the quality is too high.	[FY2008] ○ A Working Group for the Streamlining of Clinical Trials, etc., was established. ○ The infiltration conditions and usage issues of the uniform form regarding clinical trial applications, etc., were reviewed. ○ An "Investigative report regarding the operating conditions of the uniform form and uniform form entry support system" was put together.	· With regards to "quality" from the standpoint of clinical trial implementation, there are no significant issues in the quality of Japan's clinical trials in terms of the indicator of clinical trial implementation plan compliance, and it is sufficient to maintain the current level. · It is important to maintain a certain quality level, but it is necessary for relevant parties to keep in mind not to go overboard in terms of quality.

(5) Other issues

Body of plan	Progress, etc	Review results, etc
Government efforts		
Started in FY2007		

○ Review GCP ordinances based on contrasts between ICH-GCP, and facilitate clinical trials.	[FY2008] · Ministerial Ordinance on Good Clinical Practice for Drugs (1997 MHW Ordinance No. 28; partially revised in February 2008; enforced in April 2009) · Ministerial Ordinance on Good Clinical Practice for Medical Devices (2005 MHLW Ordinance No. 36; partially revised in March 2009; enforced in April 2010)	· It is desirable to reduce systemic impediments for the adequate implementation of clinical research in the early developmental stages and clinical research to reveal new uses for existing pharmaceutics, etc., and to make further improvements for strong promotion of such clinical research.
○ Compatibility with the "Ethical Guidelines Regarding Clinical Research" is kept in mind when public research funds are granted, and in the future, a system will be established in which the compatibility is investigated and supervised in the implementation stages.	[FY2008] · Ethical Guidelines Regarding Clinical Research (Notification No. 415 of the Ministry of Health, Labour, and Welfare for FY2008; revised July 2008; enforced April 2009)	
○ Continue reviews regarding the clinical trial system of medical devices.	[FY2007 onwards] · HBD (Harmonization By Doing), organized jointly by the government, academia, and private sectors of Japan	· It is hoped that various issues in terms of operating clinical trials that are unique to the clinical trials of medical devices will be revealed, and further

	and the United States from 2003 with the aim of achieving harmonization through practice with regards to medical device regulations in the United States and Japan, is also being continued in FY2007 onwards and repeated reviews are being conducted.	improvements will be made, such as the consideration of response measures, etc. · In addition, further improvements to promote clinical research, such as the reduction of systemic impediments for the adequate implementation of clinical research, is desired.
Implement by FY2008		
○ Investigate the actual operating conditions and issues of the "Ethical Guidelines Regarding Clinical Research" and conduct reviews based on this.	[FY2008] · Ethical Guidelines Regarding Clinical Research (Notification No. 415 of the Ministry of Health, Labour, and Welfare for FY2008; revised July 2008; enforced April 2009) · Revision of Ethical Guidelines Regarding Clinical Research Q&A (Notification No. 0612001 of the Health Policy Research dated June 12, 2009)	

Attachment 2

Investigative Commission for the Mid-Term Review of
the "New 5-Year Clinical Trial Activation Plan"
Working Group for the Streamlining of Clinical Trials, etc.
Review Results

1. General

- Steady improvements were seen overall thanks to the efforts of relevant parties. However, several issues still need to be resolved in order for Japan to gain a certain level of recognition as an environment in which to conduct clinical trials from a global standpoint.
- Certain evaluation indices need to be established for items that should be improved (cost, speed, quality).

2. Cost

- It can be said that costs are decreasing, but overall costs are still high compared to the United States and Europe, and it is necessary to make active efforts to reduce costs not only for the portion paid to medical institutions, but also other portions, such as the monitoring costs of clinical trial sponsors, etc. There have been cases in which the medical institutions implementing the clinical trials still have not been reimbursed for pre-paid costs, even if the contract case number was not reached. This is not appropriate in terms of conventional wisdom, and prompt and reliable response is required.
- The expense point calculation table, which is currently being widely used for the calculation of clinical trial costs to be paid to medical institutions, has the advantage of reducing the burden of cost calculation. However, it is also thought to have some disadvantages that make it inappropriate for the current situation, such as the fact that no considerations are given for long-term trials and the fact that the implementation difficulties are not easily reflected. Therefore, it is necessary to review the calculation method, etc., so that clinical trial costs are more adequately paid with respect to the required work. In addition, a certain level of transparency should be secured in terms of the content of the paid expenses.
- With regards to the impact caused by the fact that the case series number is not necessarily high, although the impact on overall clinical trials in terms of speed has been limited due to the efforts of both the medical institutions and the clinical trial sponsors, it is necessary to continue efforts to increase the number of case series in

the future.

3. Speed

- Overall, Japan's level is comparable to the United States and Europe.
- Making excessive demands regarding speed (in particular, to the start of clinical trials) risks exhausting the responding side, and may also lead to an increase in costs. It is therefore necessary to indicate numerical goals to be achieved at each stage unless there are exceptional circumstances, taking into account the allotted time of both the medical institutions and the clinical trial sponsors.

4. Quality

- The working group discussed "quality" from the standpoint of clinical trial implementation, but no significant issues were seen in the quality of Japan's clinical trials in terms of the indicator of clinical trial implementation plan compliance, and it is sufficient to maintain the current level in terms of "quality."
- It is important to maintain a certain quality level, but it is necessary for relevant parties to keep in mind not to go overboard in terms of quality.

End

Investigative Commission for the Mid-Term Review of
the "New 5-Year Clinical Trial Activation Plan"
Working Group for the Streamlining of Clinical Trials, etc.
Content of Documents for Review

Cost

- Document 1: Percentage of medical institution costs and CRA costs, etc., in clinical trial costs
- Document 2: Productivity of Clinical Research Associates
- Document 3: Clinical trial cost payment method (by medical institution management organization)

Speed

- Document 4: Speed of clinical trials (by medical institution management organization)
- Document 5: International comparison of clinical trial speed (from IRB approval to First Patient In) (Pharmaceutical company A)
- Document 6: International comparison of case registration speed for the same protocol (Pharmaceutical company B)
- Document 7: International comparison of case registration speed for the same protocol (Pharmaceutical company C)

Quality

- Document 8: International comparison of implementation/data quality for the same protocol
- Document 9: Transition of indicated matters in the GCP audit

Document 1

Percentage of medical institution costs and CRA costs, etc, in clinical trial costs

- Number of clinical trials, etc:
  12 clinical trials (Trials for which the data was locked in FY2008. 11 companies which belong to Clinical Evaluation Panel, Drug Evaluation Committee, Japan Pharmaceutical Manufacturers Association)

- Development phase:
  Phase II, Phase III

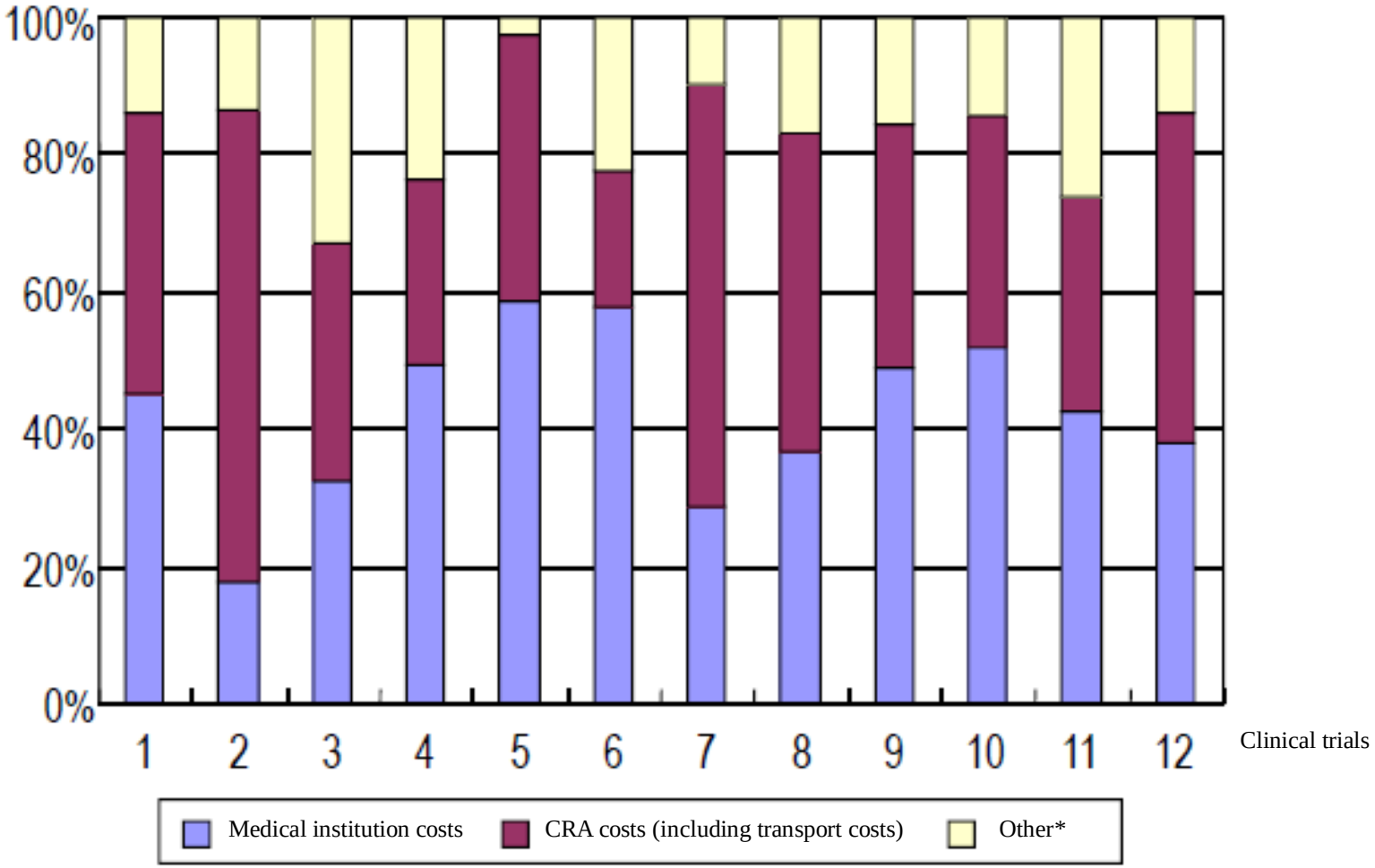
- Field of disorder:
  Endocrine and metabolic disorders (3); Cardiovascular disorders (2); Infectious disease (1); Psychoneurotic disorders (1); Gastrointestinal disorders (1); Other (4)

- Scale of clinical trial:
  12 to 339 cases / 5 to 67 facilities

- Clinical trial period (trial application to database lock):
  8 to 34 months

Document 1

Percentage of medical institution costs and CRA costs, etc., in clinical trial costs



* Direct costs relating to the clinical trial (specified medical care coverage, meeting costs, clinical examination commission expenses, data management commission expenses, registration center commission expenses, allocation costs)

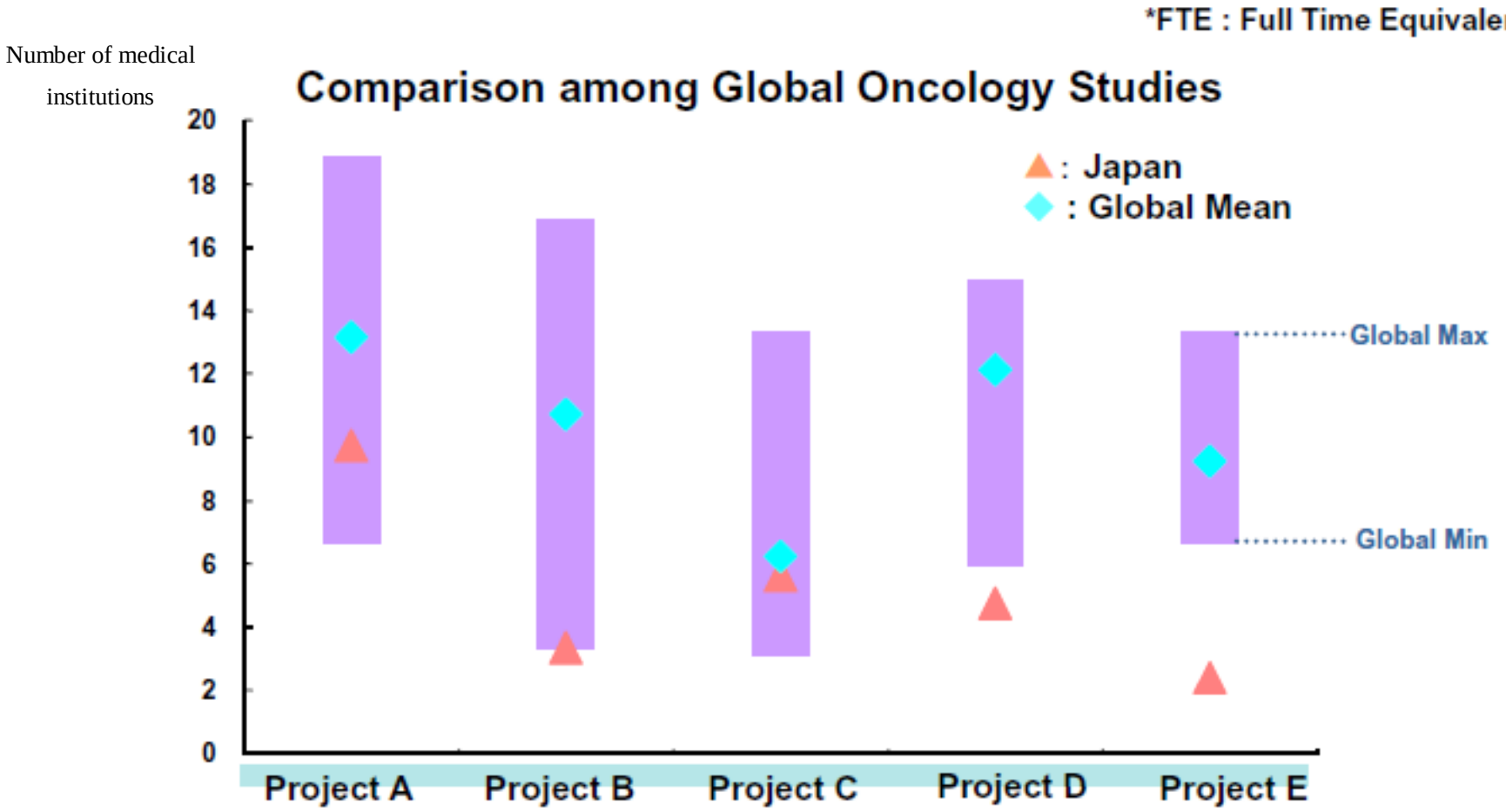
Researched by the Clinical Evaluation Panel, Drug Evaluation Committee, Japan Pharmaceutical Manufacturers Association

Document 2

Productivity of Clinical Research

(Number of medical institutions/clinical research associates*)

*FTE : Full Time Equivalent

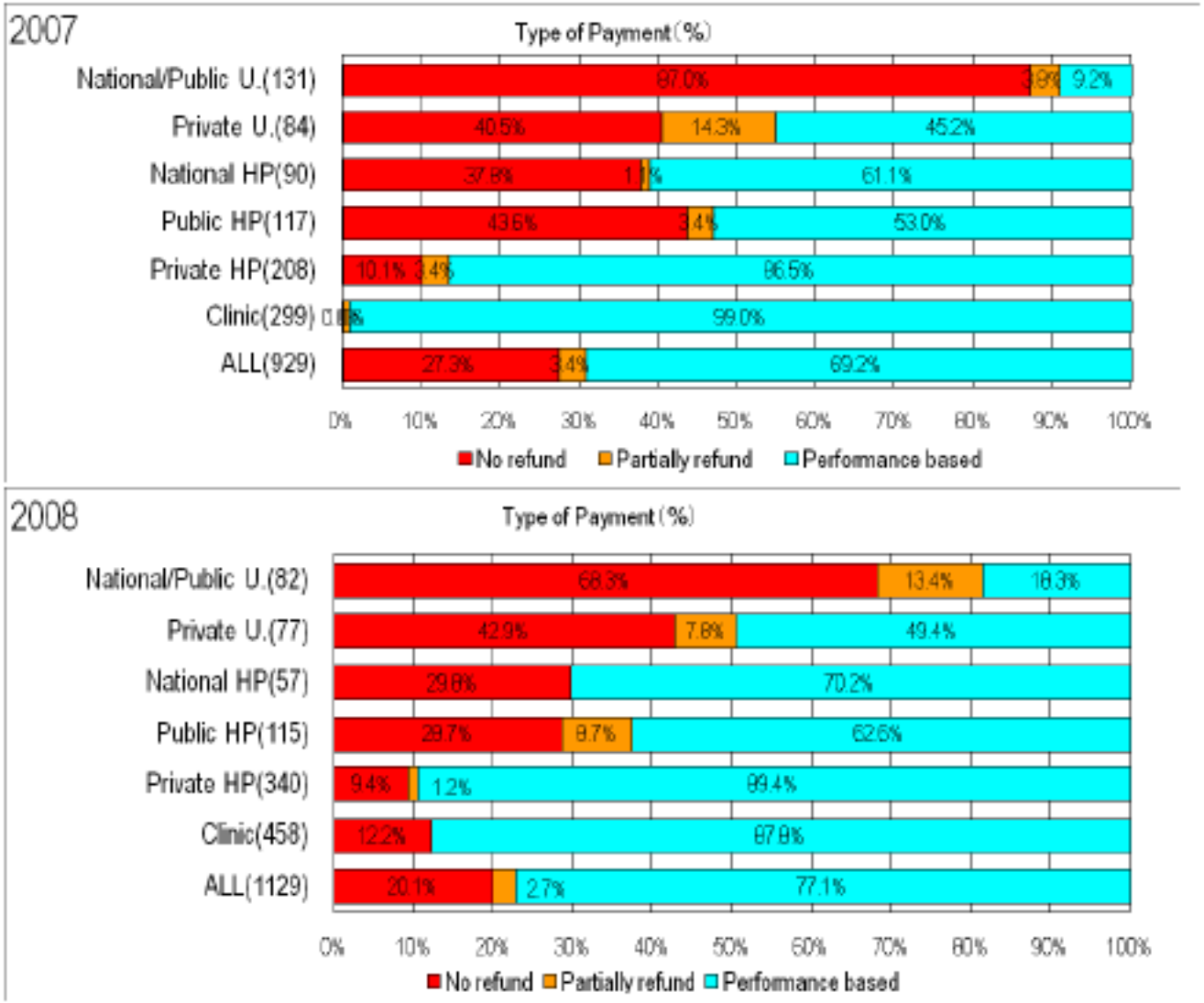


Pfizer Japan Internal Data

Cited from the DIA 45th Annual Meeting presentation material

Document 3

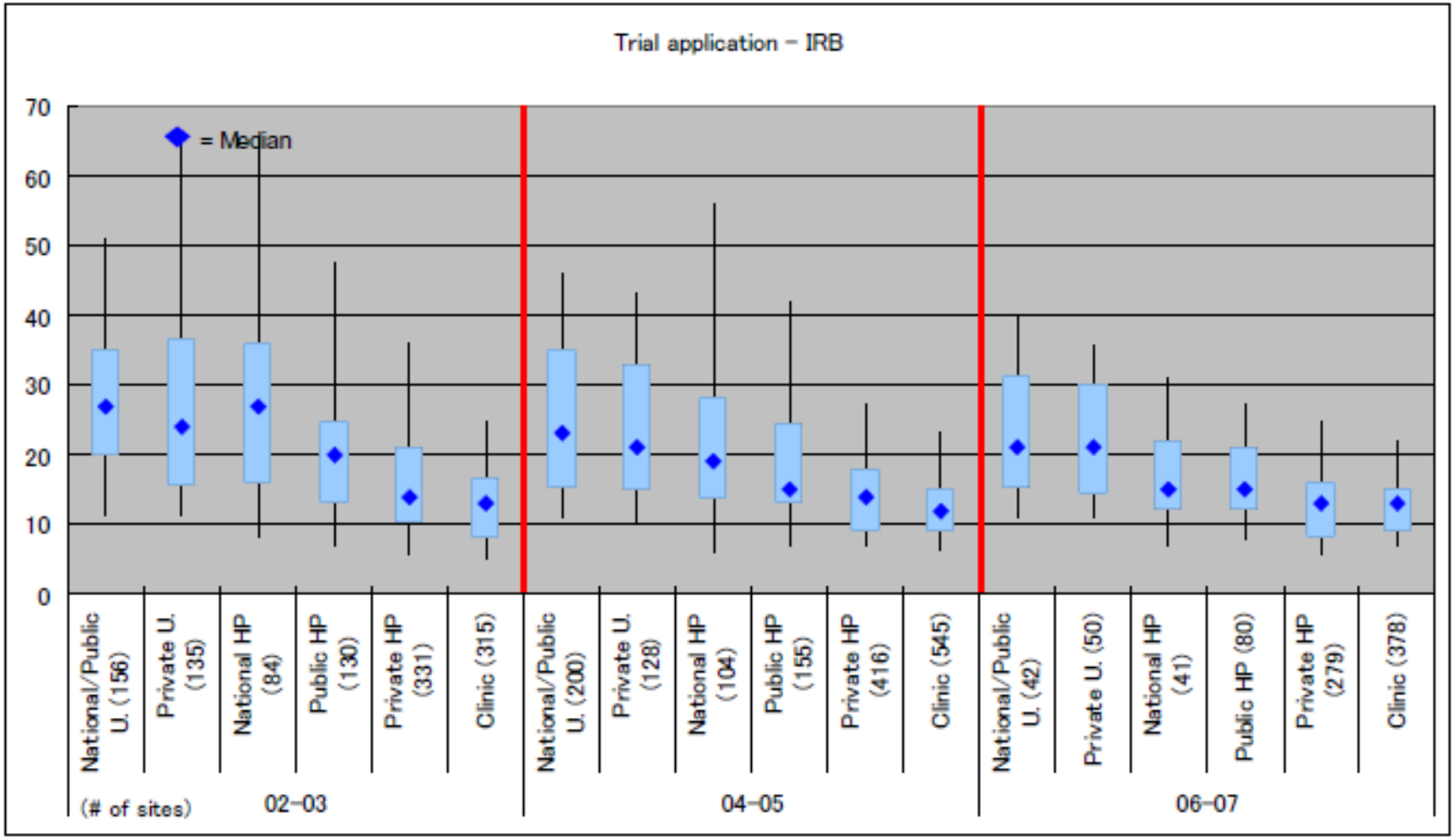
Clinical trial cost payment method
(by medical institution management organization)



Document 4

Speed of clinical trials (by medical institution management organization)

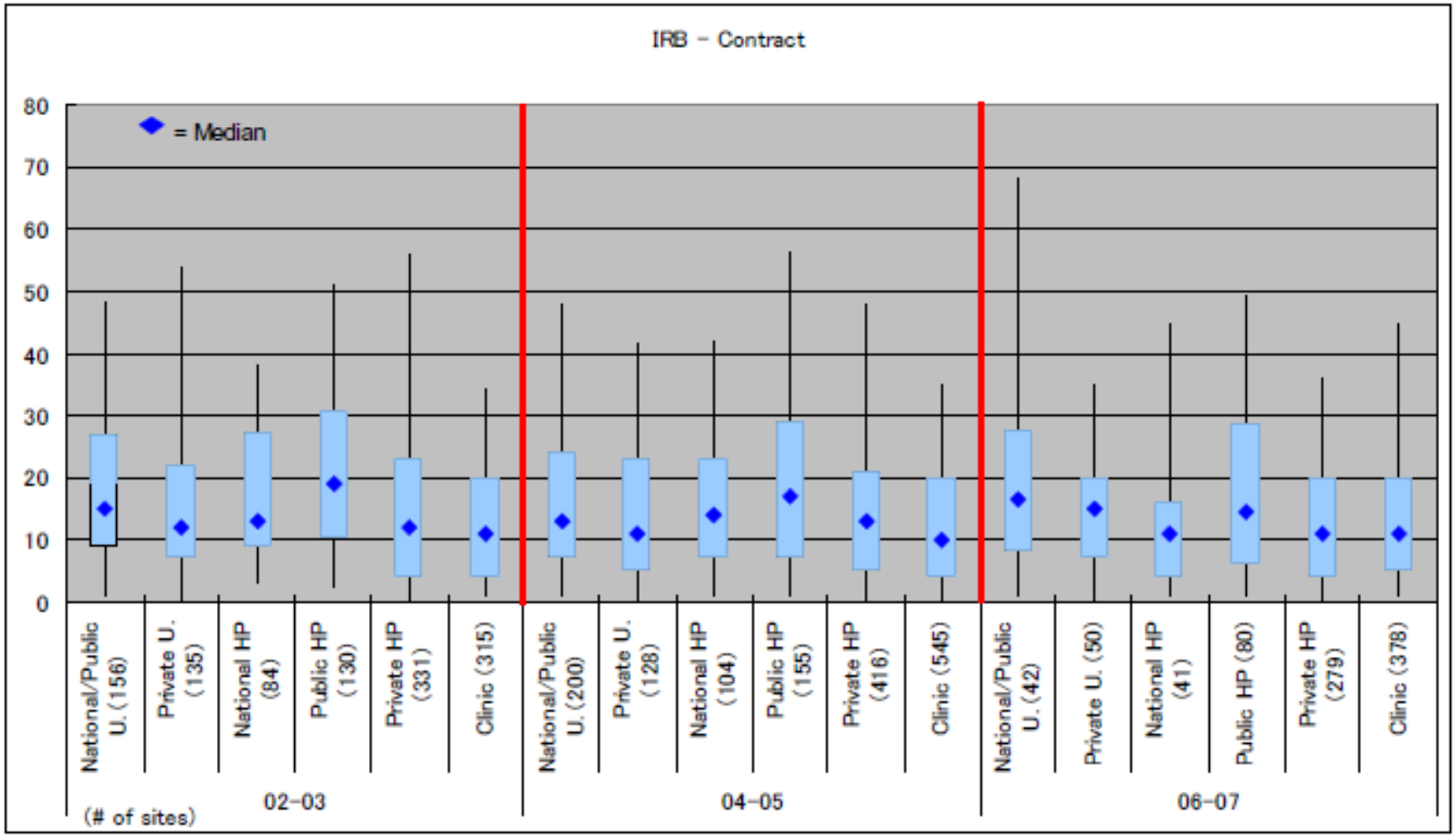
(From trial application to IRB)



Document 4

Speed of clinical trials (by medical institution management organization)

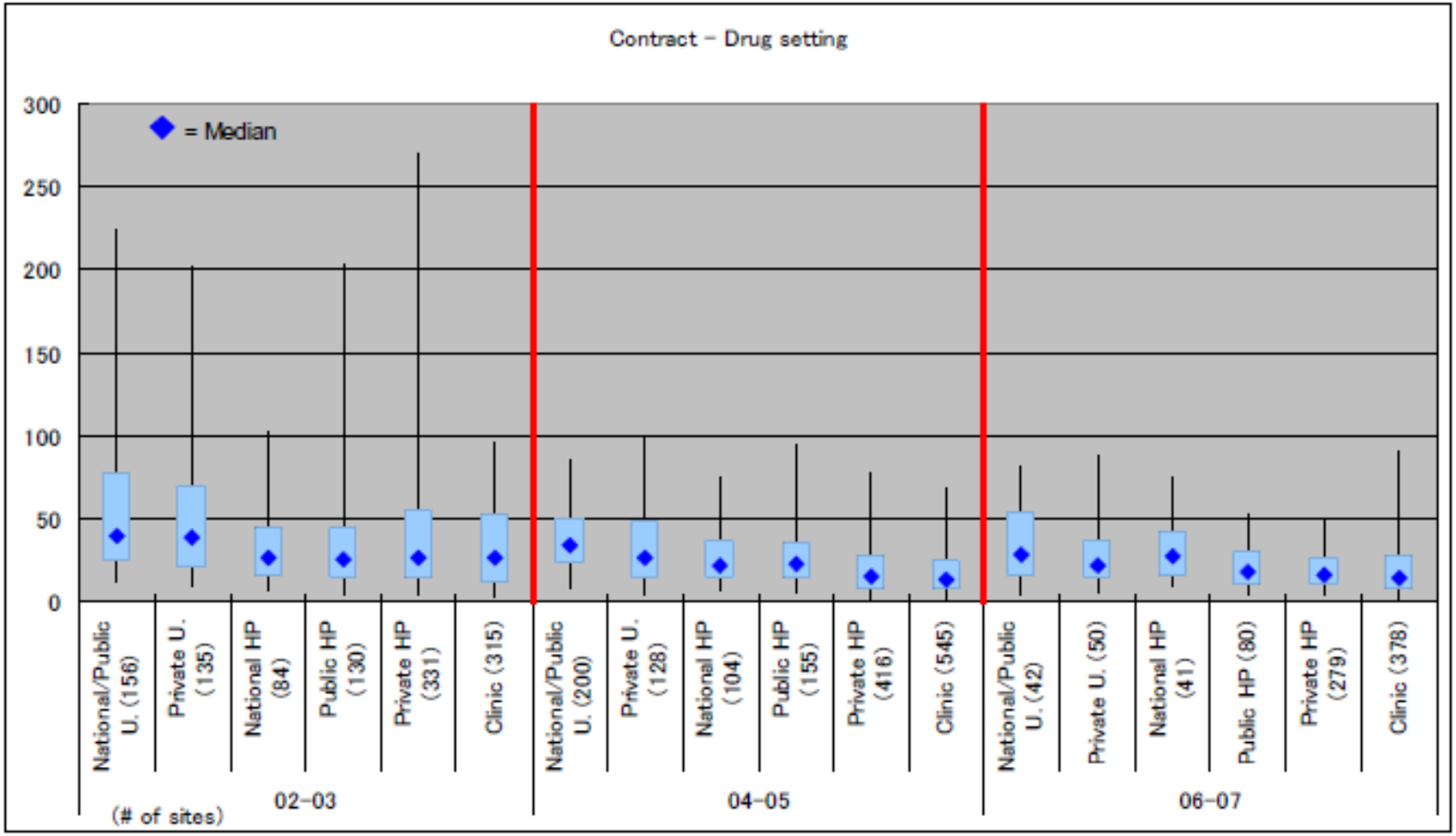
(From IRB to contract)



Document 4

Speed of clinical trials (by medical institution management organization)

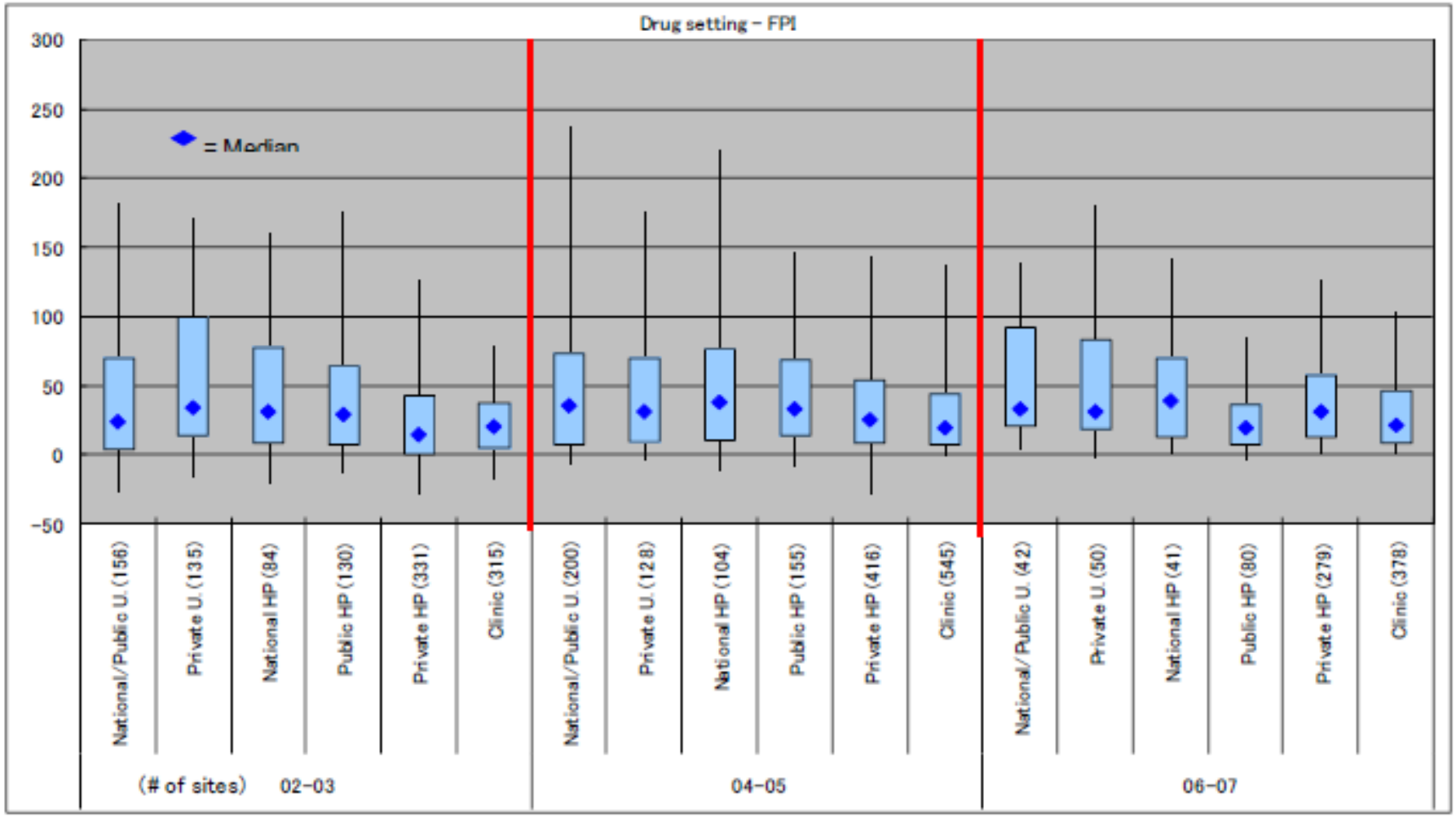
(From contract to drug setting)



Document 4

Speed of clinical trials (by medical institution management organization)

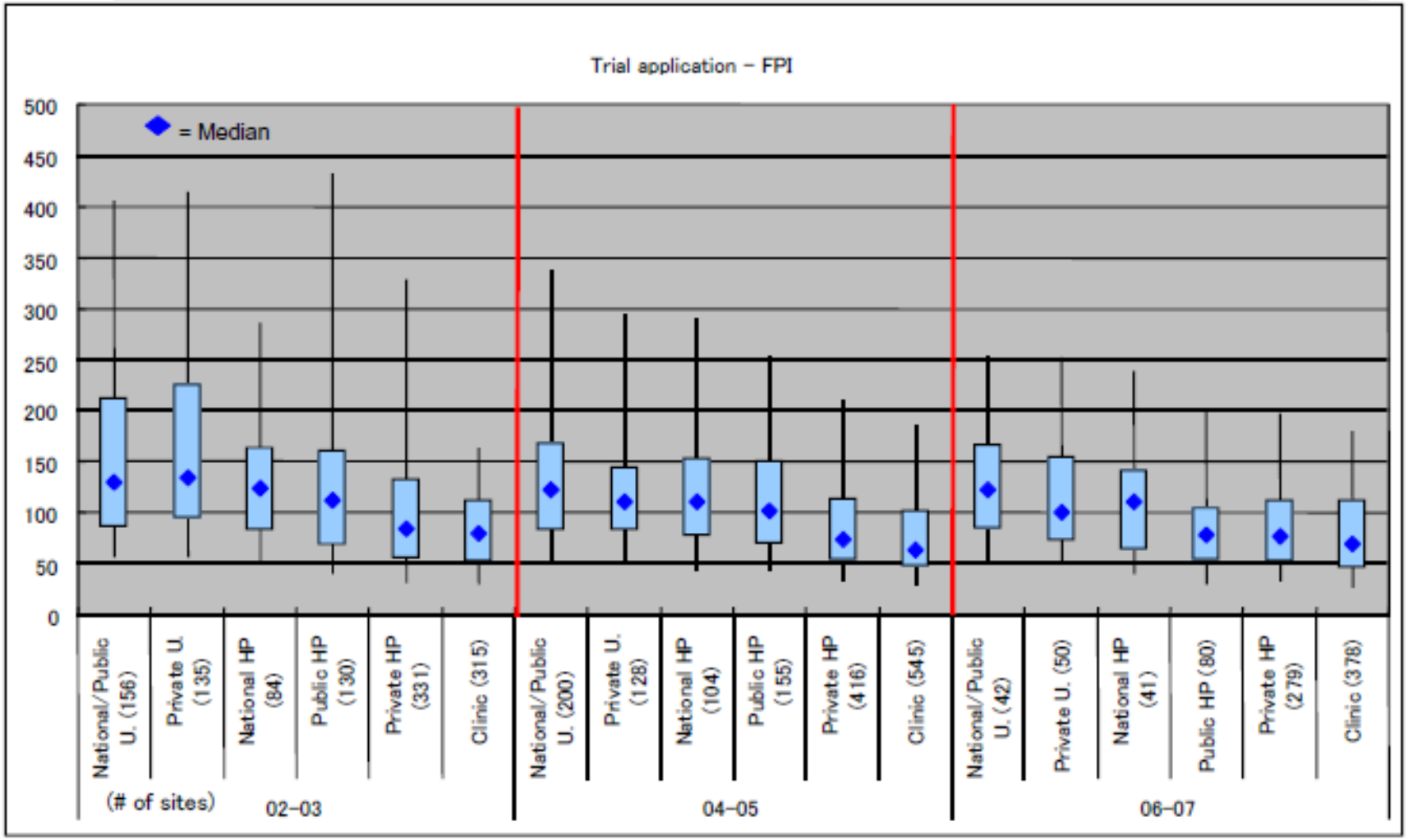
(From drug setting to First Patient In)



Document 4

Speed of clinical trials (by medical institution management organization)

(From trial application to First Patient In)



Document 5

International comparison of clinical trial speed
(from IRB approval to First Patient In) (Pharmaceutical company A)

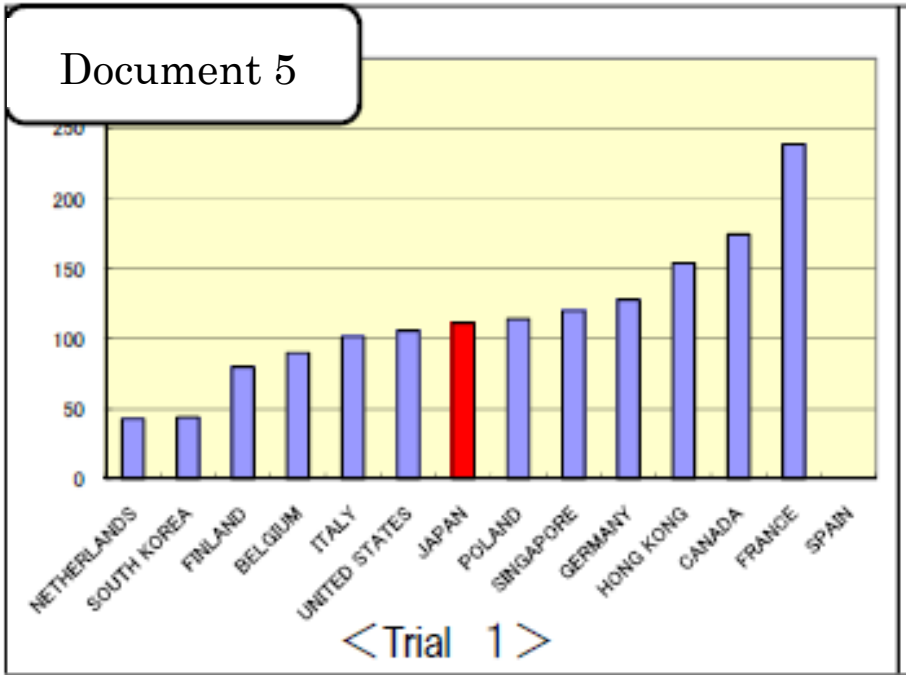
○ **Target clinical trial background, etc.**

Trial	Phase	Field of disorder	Number of countries	Number of facilities	Time when last case was registered
Trial 1	Phase II	Cancer	14	53	2009/12 (scheduled)
Trial 2	Phase III	Cancer	24	118	2010/05 (scheduled)
Trial 3	Phase III	Cancer	10	25	2010/11 (scheduled)
Trial 4	Phase III	Cardiovascular	48	452	2010/03 (scheduled)
Trial 5	Phase III	Cardiovascular	10	14	2010/07 (scheduled)
Trial 6	Phase III	Cardiovascular	15	27	2010/07 (scheduled)
Trial 7	Phase III	Contrast agent	7	51	2009/04
Trial 8	Phase III	Ophthalmology	26	186	2009/09

○ **Points to note when viewing the graphs (on the following pages)**

- The vertical axis represents the day (median value) and the horizontal axis represents the countries
- For countries not shown on the graph, data was not yet ready at the time of compilation.

Document 5



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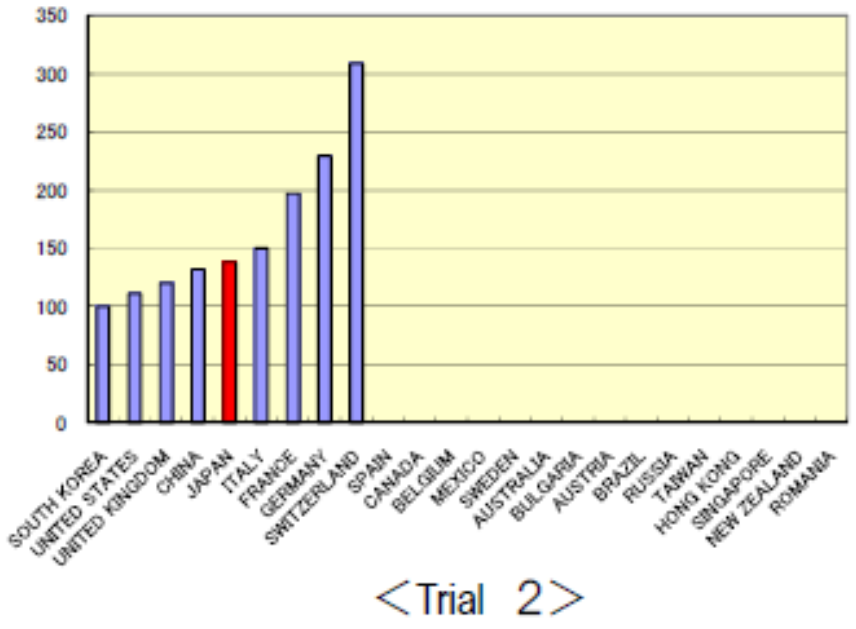

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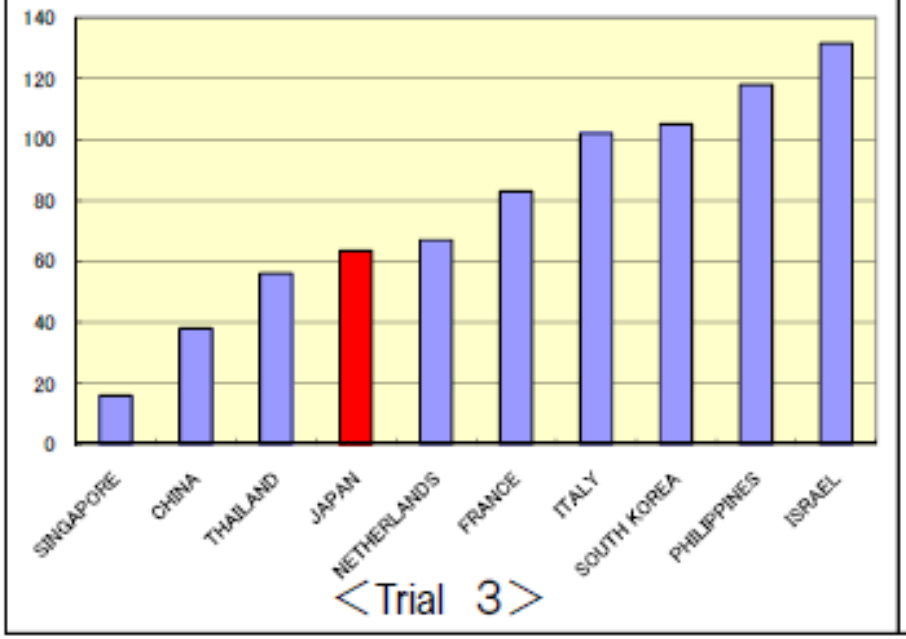

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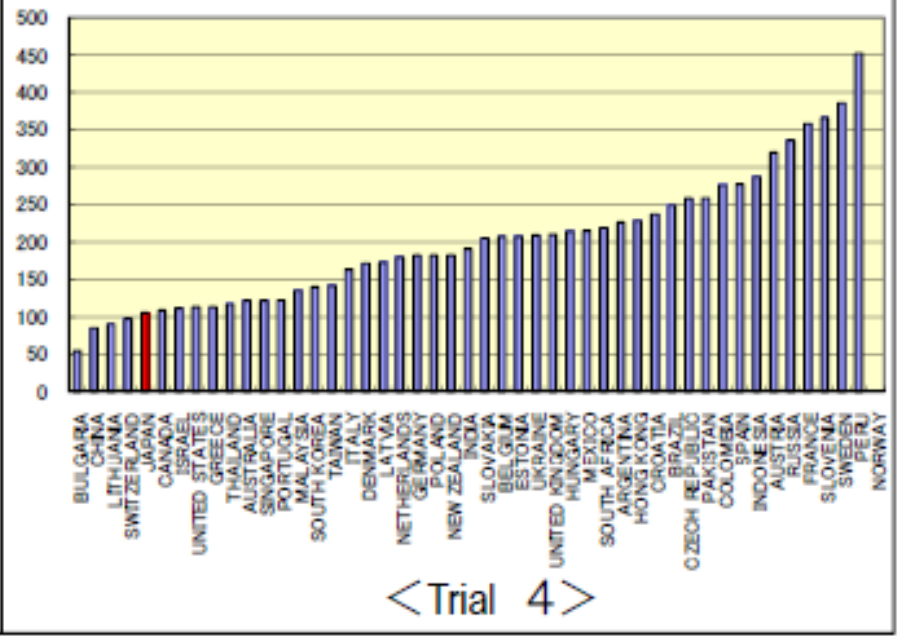

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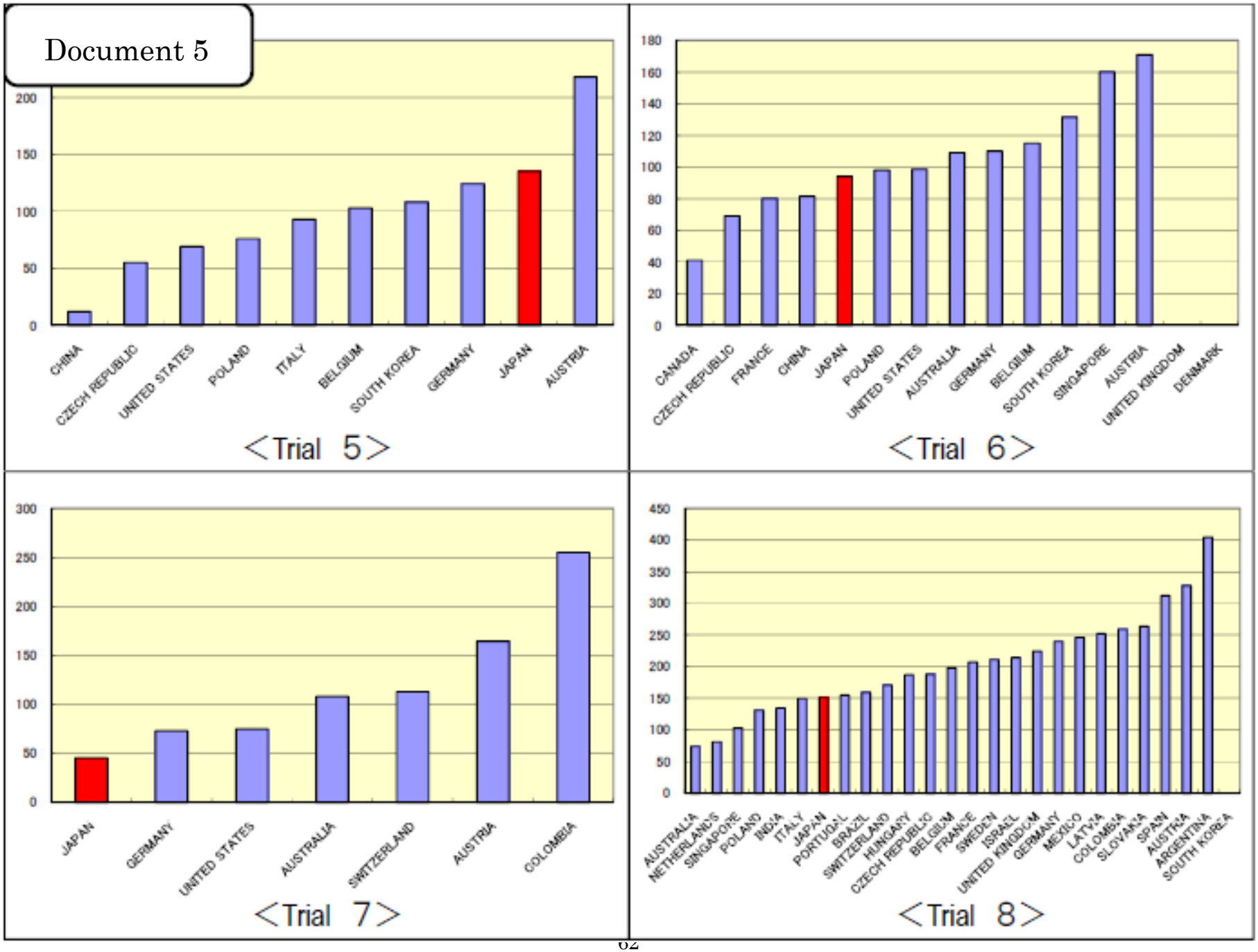
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PORTUGAL
BRAZIL
SWITZERLAND
HUNGARY
CZECH REPUBLIC
BELGIUM
FRANCE
SWEDEN
ISRAEL
UNITED KINGDOM
GERMANY
MEXICO
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SLOVAKIA
SPAIN
AUSTRIA
ARGENTINA
SOUTH KOREA
<Trial 8>

Document 6

International comparison of case registration speed for the same protocol
(Pharmaceutical company B)

		Registration start date		Registration end date	Number of days taken	Number of cases	Number of institutions
Oncology 1	Japan	January 31, 2006	~	May 21, 2007	475 days	13 cases	3 institutions
	Global	January 31, 2006	~	May 21, 2005	475 days	78 cases	19 institutions
Oncology 2	Japan	February 6, 2009	~	August 6, 2009	181 days	30 cases	6 institutions
	Global	April 23, 2008	~	September 9, 2009	504 days	158 cases	57 institutions
Oncology 3	Japan	November 26, 2007	~	December 26, 2008	396 days	70 cases	13 institutions
	Global	November 29, 2006	~	April 8, 2009	861 days	482 cases	147 institutions
Oncology 4	Japan	January 23, 2008	~	October 10, 2008	261 days	114 cases	10 institutions
	Global	July 10, 2007	~	October 10, 2008	458 days	622 cases	170 institutions
Oncology 5	Japan	January 22, 2009	~	July 31, 2009	190 days	11 cases	3 institutions
	Global	March 14, 2008	~	August 3, 2009	507 days	171 cases	48 institutions

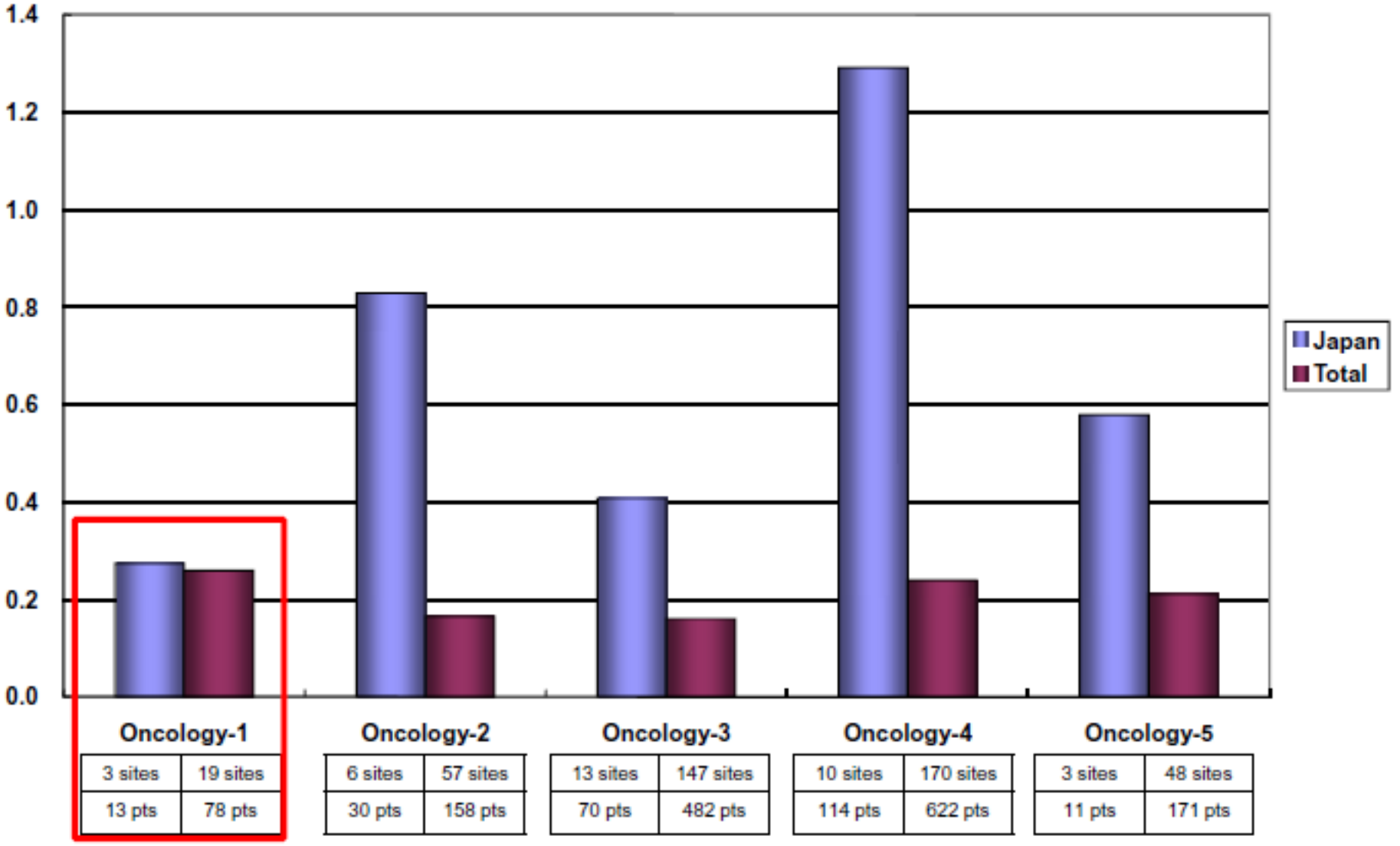
Points to note:

The registration start date to registration end date for “global” is the number for the entire protocol, and does not represent the mean value for the data of the various countries. For instance, if the United States registers the first case and Japan registers the last case, the day from the first case registration of the United States to the last case registration of Japan is the “number of days taken.”

Document 6

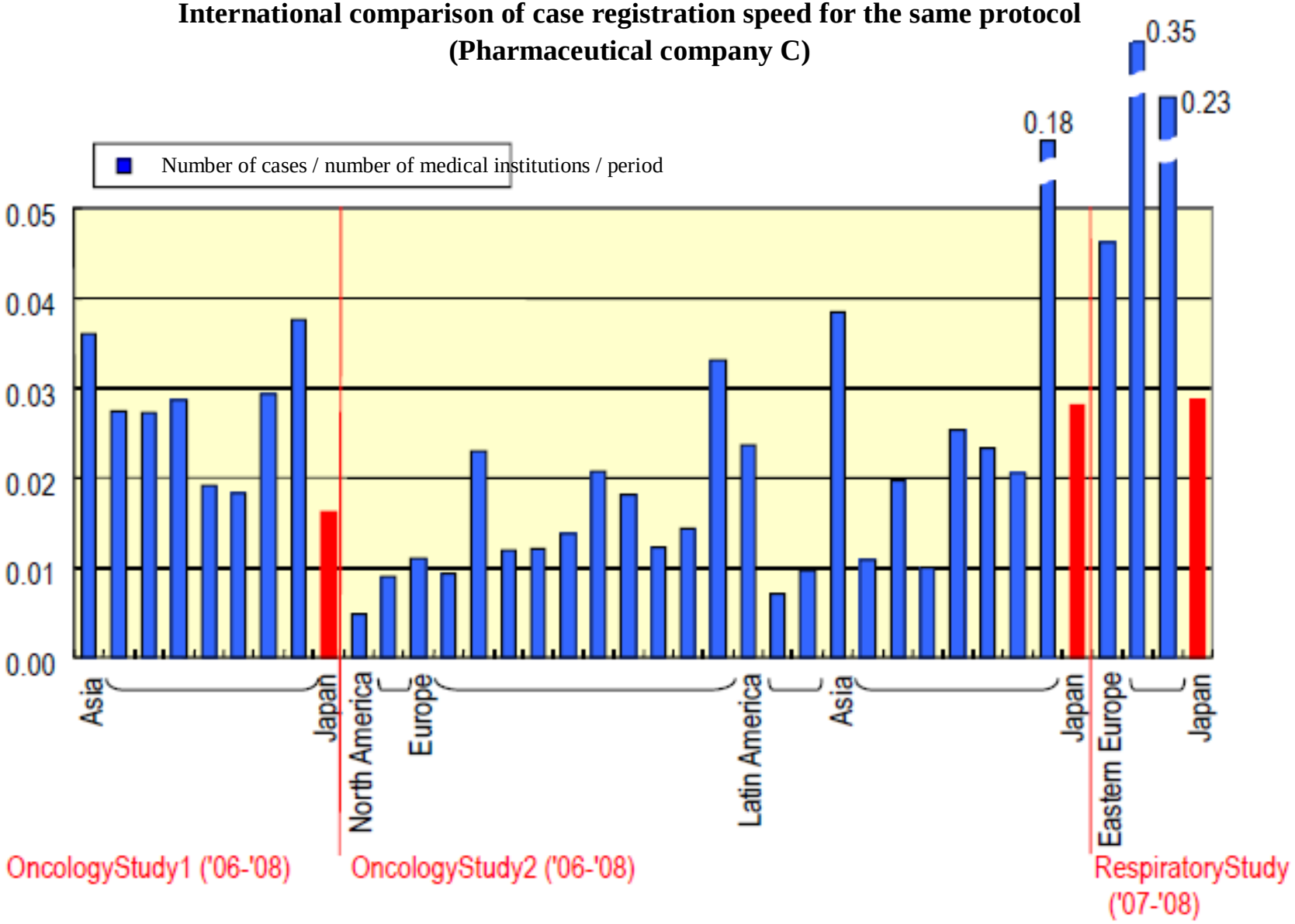
International comparison of case registration speed for the same protocol

Vertical axis: Number of cases / Number of medical institutions / Number of months



Document 7

International comparison of case registration speed for the same protocol (Pharmaceutical company C)



Document 8

International comparison of implementation/data quality for the same protocol

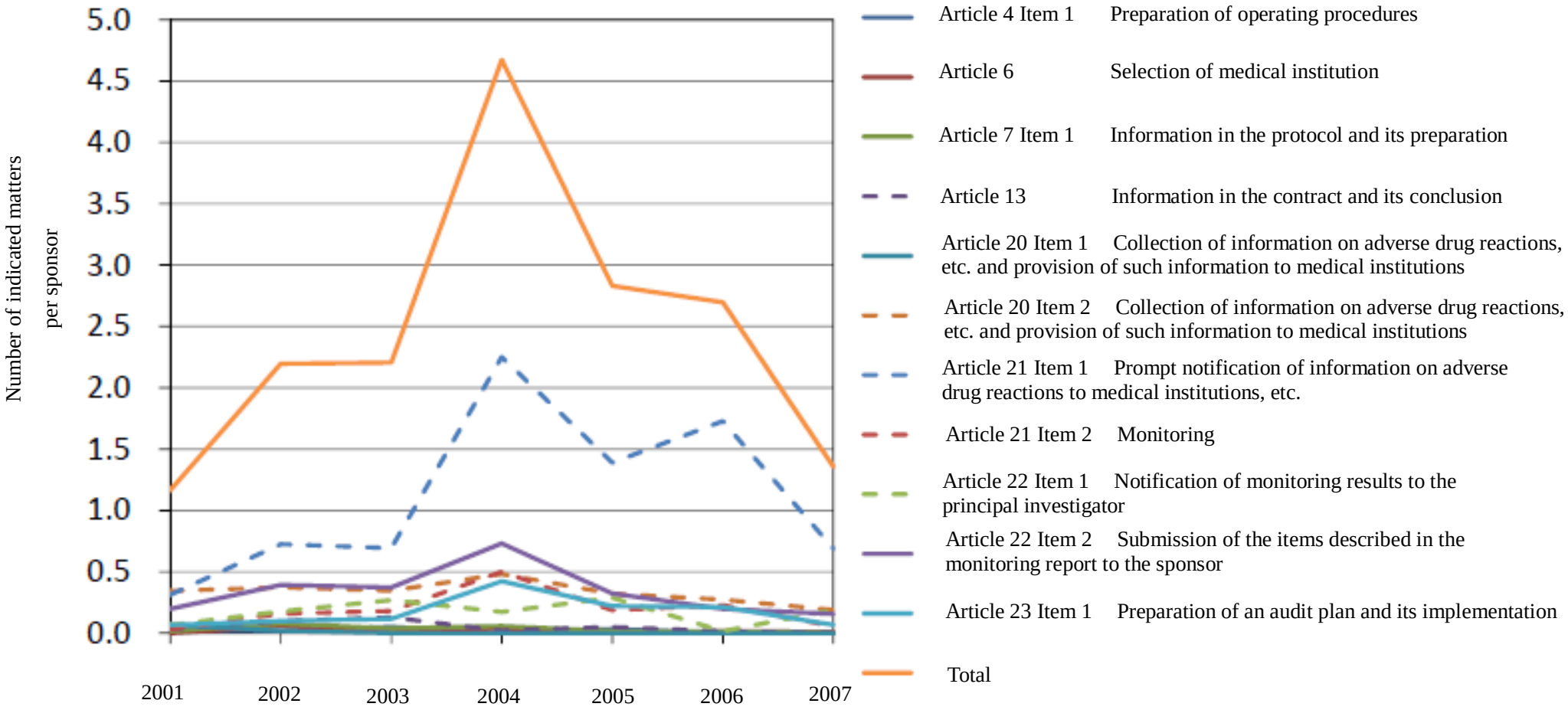
	US	EU	Japan
Number of medical institutions	100	150	45
Number of registered patients	1000 patients/30 months	700 patients/25 months	50 patients/15 months
Registration efficiency (number of registrations/month/medical institution)	0.33	0.19	0.07
Percentage dropped at screening (%)	50	30	15
Cases of deviation due to errors in the dosing procedure by the medical institution	400	200	0
Severity of central screening	+	++	+++
Protocol deviation	+++	++	+
Data ambiguity	+++	++	+

Cited from the slide of Professor Yuji Sato, Center for Clinical Research, Keio University

Document 9

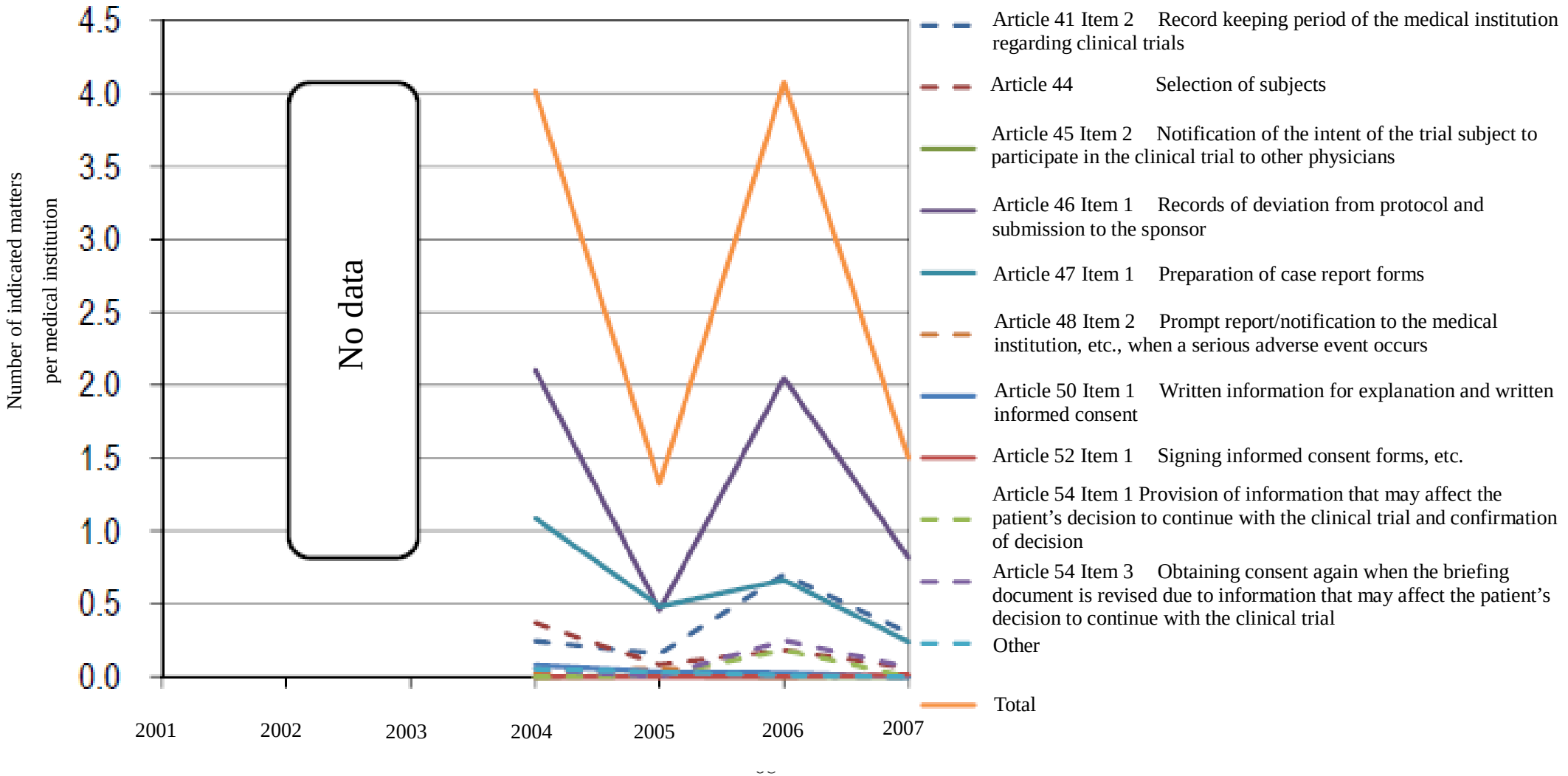
Transition of indicated matters in the GCP audit

(Domestic testing of new pharmaceuticals: clinical trial sponsors)



Document 9

Transition of indicated matters in the GCP audit
(Domestic testing of new pharmaceuticals: medical institutions)



Attachment 3

Functions Required of Core Clinical Research Centers and Major Clinical Trial Institutions

The functions required of Core clinical research centers and Major clinical trial institutions are shown on Page 9 Table 1 (Core clinical research centers) and Page 11 Table 2 (Major clinical trial institutions) of the New 5-Year Clinical Trial Activation Plan, and efforts are currently being undertaken at the various institutions.

More active improvements are required for the following items based on the discussions of the investigative commission up to now.

○: Previous efforts that should be further reinforced
△: Items to which functions should be added
●: New items

<Personnel>
● Stably employ personnel required for implementing clinical trials and clinical research in the medical institutions.
● Allocate personnel to support clinical research.

<Functions>
△ Have a function provision system for the joint review panel, etc., and improve efficiency through the use of this system. *
● Actively undertake clinical research and investigator-initiated clinical trials that lead to the development of innovative pharmaceuticals and medical devices.
*Improve efficiency by consolidating reviews to determine the suitability of conducting clinical trials, etc., including review panels that can conduct reviews based on requests from the chiefs of other medical institutions implementing clinical trials and clinical research institutions, and joint review panels that are jointly established by the chiefs of clinical research institutions.

<Patient management>
● Use the briefing document, etc, to inform clinical trial subjects who participated in clinical trials and clinical research that they may receive the results of the clinical trial/clinical research if they desire this information.

<Administration/IRB, etc.>
△ Establish a department specializing in secretariat work regarding clinical research.
△ Actively update and publicize information for patients and clinical trial applicants regarding the clinical trial implementation system of the hospital, documents required for contract procedures, clinical trial/clinical research performance, and disorder area/number of patients by disorder (excluding personal information, and information that infringes upon the confidentiality agreement, such as corporate secrets, etc.).
● Clarify the scope of service in the medical institution from the standpoint of adequately dividing roles between the clinical trial applicant and medical institution, and release this information to the clinical trial applicant.
△ Establish a so-called joint review panel, etc., that can also be used by core hospitals, central medical institutions, and relevant medical institutions.
△ Review the content of the clinical trial implementation plan and establish a mechanism that enables a prompt and highly accurate response regarding operability (number of possible cases, etc.).

● In addition to undertaking specific efforts to increase the number of contract clinical trials and individual clinical trial contract cases, ensure that the overall implementation rate of clinical trials implemented at each medical institution is 80% or above unless there were exceptional circumstances [*1].
● When research costs are paid by the clinical trial applicant to the clinical trial medical institution, make sure that the method taken is based on performance. In addition, ensure transparency so that payment is appropriate for the work conducted when calculating research costs.
● Streamline the process from clinical trial application to case registration, and ensure that measures are taken to achieve the following required time targets unless there are exceptional circumstances.

	Actual value at each institution [*2]	Minimum time based on the SOP* of each institution (Allotted time for each medical institution)[*1]
Application ~ IRB	Within 40 days	15 to 20 days
IRB approval ~ Contract	Within 20 days	Within 10 days
Drug delivery ~ FPI**	Within 80 days	Within 7 days
Application ~ FPI	Within 160 days	

*SOP: Standard Operating Procedure
**FPI: First Patient In; the day of the first case registration at each institution

Rationale for values

*1 FY2007 2nd Council of Clinical Trial Core Hospitals and Central Medical Institutions, etc.
Document 2 Targets that should be achieved by FY2008
*2 Period for administrative procedures (Application ~ Contract)
- Number of days assuming that the allotted time for the clinical applicant is the same amount of time as the minimum time based on the SOP of each institution.

Other than the above
- 75th quartile of the graph in Document 4 "Speed of Clinical Trials" in Document 1 "Review Results of the Working Group Regarding the Streamlining of Clinical Tests, etc." of the 3rd Investigative Commission for the Mid-Term Review of the New 5-Year Clinical Trial Activation Plan.
  The numerical values used were those of national and public university hospitals, private university hospitals, and national hospitals (including national centers), which account for the majority of the core hospitals and central medical institutions.

System Development Milestones for Core Clinical Research Centers

	Systems/infrastructure requiring development
Within FY2009	<Personnel> ○ CRC that support clinical research as well as clinical trials and CRC that have acquired experience and take on an educational role, etc., are employed. <Functions> ○ There are secretariat functions such as the planning, management, and coordination of investigator-initiated clinical trials. ○ Clinical trials and clinical research are planned and implemented in cooperation with central medical institutions, etc., using the clinical trial/clinical research implementation support system. ○ Highly convenient and effective training programs and various specialized training courses that busy medical service personnel can easily take are created and offered for the staff of core hospitals and collaborating central medical institutions (expected to be actively used together with the existing e-learning system and training programs, etc.). <Patient management> ○ There is a "patient consultation service function" that facilitates communication between patients and healthcare professionals and provides information regarding clinical trials and clinical research. ○ There is a function to accept the medical care of trial subjects that have suffered from a serious adverse effect at collaborating medical institutions, etc. ○ A briefing document, etc., is used to inform clinical trial subjects that participated in clinical trials and clinical research that they may receive the results of the clinical trial/clinical research if they desire this information. <Administration and IRB, etc.> ○ There is a specialized department, and consultation services have been centralized and clinical trial-related forms have been standardized as set forth in "4. (2) Issues for the further reinforcement and streamlining of consultation services regarding clinical trial contracts of medical institutions." ○ Training of IRB committee members, etc., is conducted on a periodic basis (about once per year) in order to enhance the quality and transparency of IRB reviews, etc., and the establishment of IRB, etc., and the review board committee/outline of proceedings are actively and promptly publicized (excluding personal information and information that infringes upon the confidentiality agreement, such as corporate secrets, etc.). ○ The clinical trial implementation system of the hospital, documents required for contract procedures, clinical trial/clinical research performance, and disorder area/number of patients by disorder (excluding personal information, and information that infringes upon the confidentiality agreement, such as corporate secrets, etc.) are actively updated and publicized for patients and clinical trial applicants. ○ From the standpoint of adequately dividing roles between the clinical trial applicant and medical institution, the scope of service in the medical institution has been clarified and this information is released to the clinical trial applicant. ○ EDC and English case reports can be accommodated. ○ In addition to implementing specific measures to increase the number of contract clinical trials and the number of individual clinical trial contract cases, the implementation rate at the time of completion is 80% or above, unless exceptional circumstances occur. ○ The process from clinical trial application to case registration has been streamlined, and measures are taken to achieve the required time targets, unless exceptional circumstances occur.

By FY2010	<Personnel> ○ Physicians, etc., that implement the clinical trials and clinical research receive the treatment set forth in (2)③ "Motivating physicians, etc., to conduct clinical trials and clinical research, and ensuring implementation" in "2. Developing and hiring personnel that implement clinical trials/clinical research" ○ CRC that plan and implement clinical research, biostatisticians, and data managers, etc., have been assigned. <Functions> ○ There is a specialized department that handles secretariat work regarding clinical research. ○ The hospital actively participates in clinical research and investigator-initiated clinical trials that lead to the development of innovative pharmaceuticals and medical devices. ○ It is possible to receive consults from central medical institutions. Information regarding clinical trials and clinical research can be transmitted. <Patient management> Maintenance and improvement of developed systems and infrastructure <Administration and IRB, etc.> ○ The content of the clinical trial implementation plan is reviewed and a mechanism that enables a prompt and highly accurate response regarding operability (number of possible cases, etc.) has been established. ○ When research costs are paid by the clinical trial applicant to the clinical trial medical institution, the payment method is based on performance. In addition, transparency is ensured so that payment is appropriate for the work conducted when calculating research costs.
By FY2011	<Personnel> ○ Intensive training regarding clinical trials and clinical research is conducted, and physicians, etc., that have received this training are assigned on a priority basis. ○ Personnel that are required in order to adequately implement the clinical trials and clinical research are stably employed within the medical institutions. <Functions> ○ There is a provision system of functions such as a so-called joint review panel, and efficiency is improved through its use. <Patient management> ○ An environment that enables people that want to participate in clinical trials and clinical research to easily do so has been developed by using patient referral systems and clinical trial subject databases, etc. <Administration and IRB, etc.> ○ There are administrative functions such as IRB in order to promptly and smoothly conduct clinical trials requested by corporations from commissioning to clinical trial implementation, in cooperation with central medical institutions, etc. ○ There is a data management function that is used. (It is not necessarily required for each core hospital to have a data center.) ○ A so-called joint review panel, etc., has been established that can also be used by core hospitals, central medical institutions and relevant medical institutions in order to implement clinical trials and clinical research reviews in an adequate and efficient manner.

System Development Milestones for Major Clinical Trial Institutions

	Systems/infrastructure requiring development
Within FY2009	<Personnel> ○ Permanent or full-time CRC have been assigned. <Functions> ○ A shared program to educate and train staff members in collaborating medical institutions has been adopted and is implemented among central medical institutions and regions. ○ The core hospital/central medical institution network is used to resolve clinical trial and clinical research issues and exchange information on a regular basis. <Patient management> ○ There is a "patient consultation service function" that facilitates communication between patients and healthcare professionals and provides information regarding clinical trials and clinical research. ○ There is a function to accept the medical care of trial subjects that have suffered from a serious adverse effect at collaborating medical institutions, etc. ○ A briefing document, etc., is used to inform clinical trial subjects that participated in clinical trials and clinical research that they may receive the results of the clinical trial/clinical research if they desire this information. <Administration and IRB, etc.> ○ There is a specialized department, and consultation services have been centralized and clinical trial-related forms have been standardized as set forth in "4. (2) Issues for the further reinforcement and streamlining of consultation services regarding clinical trial contracts of medical institutions." ○ Training of IRB committee members, etc., is conducted on a periodic basis (about once per year) in order to enhance the quality and transparency of IRB reviews, etc., and the establishment of IRB, etc., and the review board committee/outline of proceedings are actively and promptly publicized (excluding personal information and information that infringes upon the confidentiality agreement, such as corporate secrets, etc.). ○ The clinical trial implementation system of the hospital, documents required for contract procedures, clinical trial/clinical research performance, and disorder area/number of patients by disorder (excluding personal information, and information that infringes upon the confidentiality agreement, such as corporate secrets, etc.) are actively updated and publicized for patients and clinical trial applicants. ○ From the standpoint of adequately dividing roles between the clinical trial applicant and medical institution, the scope of service in the medical institution has been clarified and this information can be released. ○ EDC and English case reports can be accommodated. ○ In addition to implementing specific measures to increase the number of contract clinical trials and the number of individual clinical trial contract cases, the implementation rate at the time of completion is 80% or above, unless exceptional circumstances occur. ○ The process from clinical trial application to case registration has been streamlined, and measures are taken to achieve the required time targets, unless exceptional circumstances occur.

By FY2010	<Personnel> ○ Physicians, etc., that implement the clinical trials and clinical research receive the treatment set forth in (2)③ "Motivating physicians, etc., to conduct clinical trials and clinical research, and ensuring implementation" in "2. Developing and hiring personnel that implement clinical trials/clinical research" ○ CRC and data managers, etc., that support clinical research have been assigned. <Functions> ○ There is a specialized department that handles secretariat work regarding clinical research. ○ The institution actively participates in clinical research and investigator-initiated clinical trials that lead to the development of innovative pharmaceuticals and medical devices. <Patient management> Maintenance and improvement of developed systems and infrastructure <Administration and IRB, etc.> ○ The content of the clinical trial implementation plan is reviewed and a mechanism that enables a prompt and highly accurate response regarding operability (number of possible cases, etc.) has been established. ○ When research costs are paid by the clinical trial applicant to the clinical trial medical institution, the payment method is based on performance.
By FY2011	<Personnel> ○ Intensive training regarding clinical trials and clinical research is conducted, and physicians, etc., that have received this training are assigned on a priority basis. ○ Personnel that are required in order to adequately implement the clinical trials and clinical research are stably employed within the medical institutions. <Functions> ○ Joint clinical trials and joint clinical research with core hospitals/other central medical institutions can be implemented. ○ There is a provision system of functions such as a so-called joint review panel, and efficiency is improved through its use. <Patient management> ○ An environment that enables people that want to participate in clinical trials and clinical research to easily do so has been developed by using patient referral systems and clinical trial subject databases, etc., centered on the inter-central medical institution network. <Administration and IRB, etc.> ○ There are administrative functions such as IRB in order to promptly and smoothly conduct clinical trials requested by corporations from commissioning to clinical trial implementation, in cooperation with central medical institutions, etc. ○ A so-called joint review panel, etc., has been established that can also be used by central medical institutions and relevant medical institutions in order to implement clinical trials and clinical research reviews in an adequate and efficient manner.