

Sections Directed by President

OFFICE OF POLICY, STRATEGIC PLANNING BUREAU

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The Strategic Planning Bureau was founded as a think tank for the chairman of the board of directors. The Bureau cooperates with both the Center for Cancer Control and Information Services of the Division of Health Services Research and the Center for Cancer Prevention and Screening Research of the Division of Health Policy Research. This cooperative organizes issues related to cancer management in all of Japan, not just limited in those issues within the National Cancer Research Center, and handles strategic and policy planning for data and policy proposals made for industry, government, and academia.

In 2014, we (1) took on secretarial duties for “Research on reporting and evaluating the third comprehensive anti-cancer strategy” from the Scientific Research Grant Group of the Ministry of Health, Labour and Welfare (MHLW); summarized self-inspection reports from researchers who received grants as part of the third strategy for cancer control, in preparation for an evaluation conducted by the Council for Science, Technology and Innovation in the Cabinet Office of the Government of Japan; and implemented an external committee’s evaluations; and (2) reviewed and developed submission documents regarding the role of the National Center in innovative medical treatments and technologies for the Health and Medical Treatment Strategies Council Meeting.

1) Evaluation of the third anti-cancer comprehensive strategy

President Hotta was the research representative from January to March 2014. In April 2014, Strategic Planning Director Fujiwara became the new research representative. As part of the third 10-year anti-

cancer comprehensive strategy from 2004 to 2013, we summarized and reported the analysis of the third anti-cancer comprehensive research project. At the same time, we evaluated the third anti-cancer comprehensive research grants supported by scientific research grants from the MHLW (hereinafter, the “third anti-cancer”), based on the aforementioned report and follow-up research data.

First Evaluation Committee

May 25, 2014 (Sunday) 10:30–13:30

Second Evaluation Committee

September 21, 2014 (Sunday) 10:30–14:00

In future, the evaluation report of the third anti-cancer comprehensive strategy and research projects summarized by the said committee will be used to evaluate the general direction of research development in Japan. The evaluation will be conducted by the MHLW, which advanced the 10-year comprehensive strategy, as well as the Council for Science, Technology and Innovation.

2) Review of submissions for the Health and Medical Treatment Strategies Council Meeting

The Health and Medical Treatment Strategies Council Meeting investigates important matters related to policies for research development in the field of medicine, as well as growth strategies for health and medical therapy.

Reviews and draft articles regarding proposals for future policies were produced with participation of President Horita. They can be found at:
<http://www.kantei.go.jp/jp/singi/kenkouiryou/sanyokaigou/kaisai.html>.

OFFICE OF PUBLIC RELATIONS, STRATEGIC PLANNING BUREAU

Hiroshi Nokihara, Kiyotaka Watanabe, Miyako Horikoshi, Chie Shirai, Yuki Hatano, Hironobu Ohmatsu, Shinichiro Takahashi, Rika Kojima, Kajitsu Ogawa

Introduction

The Office of Public Relations has been organized as one branch of the Strategic Planning Bureau which was assigned as a public section under the supervision of the president of the National Cancer Center (NCC) in April, 2013. A full-time staff member was newly assigned at the Office of Public Relation in April, 2014. Our task is management of the NCC homepage (<http://www.ncc.go.jp/>), publication of reports, coverage and delivery of press conferences and press releases. By sharing the mission and vision between staff members throughout the NCC, we provide information about NCC's most outstanding activities in cancer care, research, screening, prevention, and policy making.

Activities

During the weekly meetings of the Office of Public Relation, we performed the prompt decision making regarding of the public relations policy and shared information about our task by using TV conference system between Tsukiji and Kashiwa campuses. We received information on the publicity work from each department, and drafted the publication plan. Also, by distribution of the intramural information for staff members in the NCC, we shared vital messages via e-mail, bulletin board and/or information magazine to facilitate communication between the staff and the executive. We distributed information promptly by publishing and sharing press releases, press conferences and seminars about novel treatment, research activity and notable accomplishments within the NCC and elsewhere.

- Homepage renewal: NCC top page, site of Hospital and Hospital East, site of Rear Cancer Center etc.
- Public information magazine "The National Cancer Center News": for external hospitals, academia, research institutions, administrative agencies
- Public information magazine "hibiho": for patients in center Hospital and east Hospital
- Intramural information brochure "challenge": for staff members and their family in NCC Hospitals
- Support of the event, seminar and public information (idea exhibition for daily life 2014, Black-Jack seminar 2014, the eighth east hospital campus day, etc.)
- Media support at press conference, press release and media coverage

We held nine cases of press conference (new establishment of Rear Cancer Center, industry-academia-government cooperation project of developing novel next-generation system for cancer diagnosis, projected cancer incidence and deaths in 2014, etc.) and published 32 cases of press releases.

The future direction

We need to renew the NCC homepage into more attractive, informative, and accessible page for users to inform NCC's activities in cancer care, research, screening, prevention, and policy making. We also feel it is important to progress public relations activities towards expansion to overseas media via our homepage and press releases. We hope that all staff members in the NCC share information and thoughts and walk in the same direction to execute NCC's mission.

OFFICE OF INTERNATIONAL AFFAIRS, STRATEGIC PLANNING BUREAU

Seiichiro Yamamoto, Sakiko Suzuki, Mitsuko Otani

The main strategy of the international activities of the National Cancer Center (NCC) is as follows:

1. Develop human resources to work in the fields of oncology practice and research, and build networks through exchanges of personnel with world-leading oncology centers.
2. Contribute scientifically through international collaborative studies, and enhance our international presence,
3. Contribute medically to Asian countries as a responsibility for leadership.

The Office of International Affairs supports NCC's activities with these goals as its aim, and supports other international activities and those related with foreign countries and people.

Focusing on the number 1 above, we have proudly signed the Memorandum of Understanding with 3 institutions; US National Cancer Institute (NCI), Massachusetts General Hospital, and French National Cancer Institute (Originally, Institut National Du Cancer, abbreviated as INCa), which the Office worked on since the year before. The MoU with NCI was brought up as a topic during the talk between Prime Minister of Japan and President of United States in April when the President visited Japan in April.

To the NCI, one Medical oncologist was dispatched since last March, as a part of personnel exchanges. Currently the Office is preparing for other personnel exchanges of a nurse and a pathologist for the next year.

In August, the NCC invited the INCa President to Japan and exchanged ideas on situations in Japan and France. We had a mutual understanding that INCa and the NCC will work closely together.

Collaborative studies

The NCC has many collaborative works that have completed or are currently on-going and some of them have achieved major accomplishments. See the details in the reported activities of each department.

Visiting fellowship (mainly observership)

One of the NCC's longstanding medical contributions is to accommodate medical professionals around the globe as visiting fellows. The NCC began this fellowship as far back as almost the NCC's establishment. In the year 2014, the NCC has had 138 visiting fellows (at both campuses of Tsukiji and Kashiwa). This is about 1.5 times more than last year's. As for the few-day visitors, the NCC had 146 visitors. (See the table below for details.) Including a few hour visitors, the NCC has had nearly 400 visitors in total last year. Visitors are mainly come from Asian countries, but there also are visitors from institutions that are renowned world widely. The Office continues to support former fellows through the alumni organization of fellows which the Office started last year.

As an another important topic, the NCC works closely with the Japanese government such as the Ministry of Health, Labour, and Welfare, the Ministry of Economy, Trade and Industry, the Ministry of Internal Affairs and Communications, and Medical Excellence JAPAN, a company aiming to expand Japanese medicine globally. As experts, the NCC gives advises to those ministries and support their projects.

Table 1. January - December, 2014 Visiting fellowship (with and without fee) - Hospital

Visitors by region	Country of home organization	Hospital																Total # by division*	Total (Actual #)					
		Head & Neck Surg.	Plastic & Reconstructive Surg.	Breast Surg.	Esophageal Surg.	Gastric Surg.	Colorectal Surg.	Gastrointestinal Endoscopy	Respiratory Endoscopy	Urology	HPB Surg.	Gynecology	Diagnostic Radiology	Pathology	Gastrointestinal Medical Oncology	HPB Oncology	Musculoskeletal Oncology & Rehabilitation			Thoracic Surg.	Breast & Medical Oncology			
	India							2													4	4		
	Singapore								1													2	2	
	Sri Lanka						1															1	1	
Asia	Thailand			1	3	1	8	1		1	4			1								20	16	
	China			1		4		9	1	1				1	1	1	1					20	16	
	Taiwan							12	2	1												22	21	
	Hong Kong									1													1	1
	Philippines		1	1		1	1	1			3			1	1				1				12	7
	70 Viet Nam									1											1		2	2
Oceania	Australia						1	1						1								3	3	
3																								
North America	USA								3													3	3	
3																								
Latin America	Chile								1													1	1	
	Honduras													1								1	1	
3	Mexico						1		1													2	1	
Middle East	Turkey				1																	1	1	
2	Egypt							1		1												2	1	
Europe	Italy								3													3	3	
	UK				3	2		9					1									15	12	
	The Netherlands			1																		1	1	
	Kazakhstan			1**																		0	1	
	Spain			1	2	3		5														11	9	
	Germany												1									1	1	
	Poland					1																1	1	
	France								1						1	1						3	2	
35	Russia								4					1								5	5	
	Total	1	1	4	8	17	3	60	11	2	4	4	9	7	2	1	1	1	1	1	137	116		

* Total number by division (Some visitors rotate multiple divisions)

** Currently enrolled in a graduate school in Japan, but count as Kazakhstan because the one is going back to its home country Kazakhstan soon.

Total # by facility/# of visitors		Hospital	Hospital East	Research Institute	Cntr. for Cancer control and Info. Services	Research Cntr. for Prevention & Screening	EPOC ***	Cntr. for Research Administration & Support	# of visitors
		Visiting fellowship (with and without fee)	116	21	4	0	0	0	0
Short term Visit (within 3 days)	141	11	4	4	0	3	1	155**	

* 3 visitors had fellowship both hospoitals in Tokyo and Chiba

** Some visitors visited divisions beyond

*** Exploratory Oncology Research & Clinical Trial Center

Table 2. January - December, 2014 Visiting fellowship (with and without fee) - All centers except Hospital

Visitors by region	Country of home organization	Hospital East										Research Institute				Total	Total	Total	Total										
		Plastic & Reconstructive Surg.*	Gastric Surg.	Gastrointestinal Endoscopy	Pathology	Colorectal Surg.	Head & Neck Surg.	Palliative Medicine	Nursing	Total # by division*	Total # of visitors	Virology	Molecular & Cellular medicine	Metastasis & Invasion Signaling	Total # by division*					Total # of visitors									
Asia	Sri Lanka							1									1	1											
	China		2	3	1	1		1	1	9	8																		
	Taiwan								10	10	10																		
	Philippines	1								1	1																		
21	Malaysia											1					1	1											
North America	USA														1	1	1												
1																													
Europe	Spain			1													1	1											
Other**	Japan									1	1						1	1											
1																													
	Total	1	2	4	1	1	1	1	11	22	21	1	2	1	4	4	0	0	0	0	0	0	0	0	0	0	0	0	0

* Total number by division (Some visitors rotate multiple divisions)

** An American citizen, enrolled in a university in Japan

Table 3. January - December, 2014 Short term (within 3 days) Visit - Hospital

Visitors by region	Country of home organization	Hospital													Total # of visitors	
		Gastrointestinal Endoscopy	"Hematopoietic Stem Cell Transplantation"	Diagnostic Radiology	Radiation Oncology	Dermatologic Oncology	Ophthalmic Oncology	Pathology	Colorectal Surg.	Appearance Support Cntr.	Office for Advanced Medical Care Evaluation	Critical Trial Support Office	Pharmacy	Patient relations		
	South Korea		1	2						4	3					10
	India				1											1
Asia	Indonesia	2														2
	Thailand	1		2				4								7
	China	12														12
	Taiwan			2										9		11
	Philippines	2														2
	46 Malaysia	1														1
Oceania	Australia		1	2												3
	3															
North America	USA	1		2												3
	3															
South America	Argentina	1														1
	2 Chile	1														1
	UK								1							1
	Italy			1												1
Europe	Austria			20	40											60
	Hungary	1														1
	Belgie									1						1
	France						1									1
Mid. East	UAE	1														1
	1															
Unknown*	Unknown	19										1	1			21
	21															
	Total	42	2	31	41	1	1	4	2	4	3	1	1	9		141

* Because application for short term visit does not require a country of home organization of applicant, it is unknown otherwise declared by applicant

Table 4. January - December, 2014 Visiting fellowship (with and without fee) - All centers except Hospital

Visitors by region	Country of home organization	Hospital East					Research Institute		Cntr. for Cancer Control & Info. Services		Research Cntr. for Cancer Prevention & Screening		Exploratory Oncology Research & Clinical Trial Cntr.			Cntr. for Research Administration & Support	
		Gastrointestinal Endoscopy	Radiation Oncology	Diagnostic Radiology	HPB Oncology	Total	Cancer Genomics	Total	Cancer Survivorship Research	Total	Total	Experimental Therapeutics	Immunotherapy	Total	Research Promotion Division / JCOG Operations Office	Total	
	China		1	1		2											
Asia	Thailand						4*	4									
	India		1			1											
	Viet Nam				2	2											
	Taiwan											1	1				
Oceania	5 South Korea							4**	4								
	New Zealand	2				2											
	2																
Europe	UK			3		3											
	Russia					0											
	Belgie																
	3 Germany										1		1		1***	1	
Unknown****	Unknown											1	1				
	Total	2	2	4	2	10	0	4	4	4	0	1	2	3	0	1	

* Same visitor as the visitor at Pathology division of Hospital

** Same visitor as the visitor at Appearance Support Center of Hospital

*** Same visitor as the visitor at Colorectal Surgery of Hospital

**** Because application for short term visit does not require a country of home organization of applicant, it is unknown otherwise declared by applicant

CENTER FOR RESEARCH ADMINISTRATION AND SUPPORT

See the CRAS Organization Chart for Division Chiefs and Section Heads.

Introduction

The Center for Research Administration and Support (CRAS) was established in July 16, 2014 by approximately 160 staffs. The CRAS comprises diverse functions and specialties, ranging from research fund administrations, alliance with private sectors, intellectual properties, Clinical Research Coordinators (CRC) and Data Managers (DM), monitoring and audit, biostatistics support, offices for research ethics (IRB) and COI committees. Dr. Hotta, President of NCC, explained the reason and the purpose of the CRAS creation in the NCC News 2014 Vol.5/No.3 (in Japanese). National Cancer Center (NCC) was founded in 1962, and since then, it has added several new segments and organizations to evolve as a comprehensive cancer center. Because each segment needed its own research infrastructures, support activities in NCC have become fragmented and scattered with possible gaps and redundancies. Meanwhile, Dr. Hotta assembled the "NCC New Vision" in 2014, in which he proposed integration and communications of various research support functions in NCC.

(Future Prospects)

The mission of CRAS is to enhance research support and administration capabilities of NCC based on the "NCC New Vision." Although the integration and communications are primary agenda of CRAS, it is also crucial to make the most of the existing, well-functioning subsystems. The CRAS will evolve through some further trials and errors to find the best-fit system, but NCC has placed an important step forward to the Challenge and Change.

Activities and Future Prospects of each Division/Section

1. Research Administration Division

1.1 Research Administration Section

The Research Administration Section has been a central office in charge of various administrative works related to research funding including application and reporting. The major external funding sources are competitive grants from the government, such as the MHLW, MEXT and METI, and from government-supported agencies, such as the JST, NiBio and NEDO. The Section also serves as an administrative office for the National Cancer Center Research and Development Fund, which is provided directly from the government to NCC for fulfillment of its mission as the national core institute of the cancer control. The Section organized seminars regarding research funding and its rules to prevent financial misconducts.

(Future Prospects)

The Guidelines for Managing and Auditing Public Research Funds at Research Institutes has been updated by the MEXT in February 2014 and adopted by the MHLW in March 2014. In 2015, the Section will lead NCC to establish a new system for research fund administration, which is fully compatible with the new Guidelines.

1.2 Research Administrator

Research administrators (RA) functioned as a secretariat of study group "Enforcement and Assessment of Research and Development Management concerning Practical Research for Innovative Cancer Control (representative: Tomomitsu Hotta)" to monitor the 165 awarded grants of a research program "Practical Research for Innovative Cancer Control" granted by the Ministry of Health, Labour and Welfare in Japan.

RA has also supported the promotion of the commercial viability of research outcomes based

upon 3 main pillars: comprehensive alliance with the companies, academic drug discovery research with Drug Discovery Support Network, and supporting NCC-launched venture companies. A development candidate compound is provided by the cooperation with the business enterprise, and 4 themes are in progress as a Drug Discovery Support Network, and 1 venture company is established.

(Future Prospects)

RA collect information and make cross-sectorial coordination among researchers to obtain large-scale research funds and promote the commercial viability of research outcomes based upon three main pillars.

1.3 Research Auditor

For clinical studies led by NCC's investigator, 6 audits were conducted on GCP trials, and 3 on B type advanced medical service trials. Also 14 internal audits were conducted on departments in NCC conducting clinical research, as part of self-inspection required in the ethics guideline. Other activities included GCP-related training and consultation as well as support of regulatory inspection management.

(Future Prospects)

Audit and its related activity will be continued to boost quality of NCC's clinical research. In addition, as clinical studies with invasion and intervention will come into audit targets from October 2015 along with the implementation of "Ethics Guideline Regarding Medical Research on Human", preparation of process and technique will be critical for the new type of audit.

1.4. Research Alliance Section and 1.5. Intellectual Property Section

The Research Alliance Section promotes collaborative research arrangements with private sectors in order for NCC's research outcomes to bring into useful products available to cancer patients. As of December 31, 2014, No. of collaboration is 181, the research fees from private sectors amount to ca. 260 million yen (Fig. 1). Both figures would exceed by the end of the fiscal year on

a year-to-year comparison. NCC has been formed comprehensive collaboration research system with a partner company or academic institution (Fig. 3). The Section supported a nationwide genomic screening project with the participation of over 10 pharmaceutical companies and institutions across Japan (SCRUM-Japan "Cancer Genome Screening Project for Individualized Medicine in Japan"), that is about to launch soon. The Section has also assisted collaboration with medium-sized medical device companies in regions.

The Intellectual Property (IP) Section constantly reviews IPs and abandons ones that has not received business inquiry for a certain period (Fig. 2). Then limited budget should be focused on IP which is commercially viable.

As a part of contributions in education, staff members actively participate in seminars with regard to the IP laws and regulations to update their knowledge and elevate their skills to promote academic-industrial alliance. Their competency in problem solution gained through OJT and effective consultation with experts will enable them to new challenge to innovative affairs.

(Future Prospects)

In a trend of openness on innovation, the Sections support creation of systemic and effective collaborative research framework. It also foresees the possibility of new laboratory setup where research is being performed by researchers from both industry and NCC, and lead to more functional collaboration.

As to the IP management, NCC employs patent strategies to protect the potential value of the invention to industry, through which the translation of academic science and technology is made available to the patient bedside. The IP Section plays an important role in assisting NCC's comprehensive decision making, taking aspects such as incubation of innovative technology, cost and effect balance, and risk management into consideration.

2. Research Coordination Division

The Research Coordination Division has a role of clinical study management and coordination. This Division consists of the Research Management Section and Clinical Research Coordinator Section.

The Research Management Section supports planning and management through protocol development, essential document management, project management, and source document verification. The Clinical Research Coordinator Section support facilitates and coordinates the daily clinical trial activities and plays a critical role in the conduct of the study.

(Future Prospects)

Add the staff to deal with increasing study number and promote rationalization and efficiency in routine practice. Promote education about Good Clinical Practice to all concerned in clinical trials.

3. Research Promotion Division

The Research Promotion Division is responsible for data management and study monitoring in the investigator-initiated clinical trials for cancer therapeutic development. The Division consists of Data Management Section in each campus, Tsukiji and Kashiwa, for data management and central monitoring, and the Multicenter Clinical Trial Section for coordinating multi-institutional clinical trials. In 2014, the Data Management Sections worked on data management and monitoring for JCOG trials, EPOC trials and in-house clinical trials, and made effort to develop electric data capturing (EDC) system. The Multicenter Clinical Trial Section organized the Japanese Cancer Trial Network (JCTN), which is a voluntary consortium consisting of 6 major cancer cooperative groups in Japan (JALSG, JCOG, J-CRSU, JGOG, JPLSG, and WJOG) and issued 3 common guidelines: (i) central monitoring, (ii) site visit audit and (iii) adverse events reporting.

(Future Prospects)

In 2015, the Division emphasizes the translocation of JCOG Biobank into BioBank Japan and conducting related translational researches, facilitates clinical trials with off-label drug use under the Advanced Medical Care B system, and explores the online report and review system for adverse events.

4. Biostatistics Division

The Biostatistics Division has a role of responsibility in study design, analysis, interpretation and statistical aspect of publications, especially in JCOG and EPOC clinical trials. We are also providing introductory Biostatistics lecture series to investigators in NCC as basic training in quantitative research methods. A cumulative total of more than 950 investigators participated in the 9 lectures provided in 2014. Furthermore, we are providing biostatistical consultation and expertise, which supports NCC investigators working on basic, translational, clinical and epidemiological researches. We offered advice to about 80 problems for which biostatistical consultation was requested in 2014.

(Future Prospects)

The NCC has a critical role for providing clinical service, education, conducting researches and making policy recommendation/proposal, which are all required to make a decision on the basis of solid and scientific evidence from reliable data and information. The mission of the Biostatistics Division is to contribute to the providing best evidence and the improvement of clinical practice and public health through the development and application of quantitative methods. The Biostatistics Division is expanding on its independent and collaborative research with a range of areas including observational and interventional researches for prevention and policy recommendation/proposal, as well as clinical trials. We are also opening up a new methodological research area in which mathematical approach will serve as a solid basis.

5. Regulatory Science Section

Achievements in clinical trials and clinical researches include 2 important aspects: the academic accomplishments and the providing solutions based on the scientific evidence to clinical practice. With the object of the latter, clinical trials and clinical researches for development of new drugs and medical devices are conducted complying and/or conforming to the regulations and rules under the Pharmaceuticals, Medical Devices and Other Therapeutic Products Act,

formerly known as the Pharmaceutical Affairs Law. All the current members of the Regulatory Science Section have experience in working at the PMDA. Our division provided a support to develop study strategies in conducting investigator initiated clinical trials and to formulate road map for marketing approval/reimbursement under the National Health Insurance.

(Future Prospects)

The Regulatory Science Section is considering the new framework and concrete shape of our activities including consultation and supporting system.

6. Human Research Protection Section

The major role of the Human Research Protection Section has been its function as a secretariat for review board committees in NCC for human subject research. In 2014, the Section was involved in the establishment of the Special Certified Committee for Regenerative Medicine. The current challenge for the Section is the waiting list of the review. It is partly due to the increased demand both in the quality and quantity of the ethical and COI reviews following several widely publicized misconducts in clinical research and by the coming enforcement of the new Ethical Guidelines for Medical and Health Research Involving Human Subjects in April 2015. However, the more fundamental problem is the paucity of the human resource in the field of the research ethics review. The major reason for the resignation is the high level of knowledge and understanding required for the job and the often stressful dialogue

with the researchers during the review process. On the other hand, a significant progress in 2014 was that the long-awaited web review system was launched, which is expected to be a powerful tool to cope with the increasing number of the protocols submitted to the committee.

(Future Prospects)

The Section should seek further understanding and cooperation from the researchers for the effective and sustainable review process. By the April 2015, when the Ethical Guidelines for Medical and Health Research Involving Human Subjects will come into effect, the Section will extensively review and revise the NCC rules and procedure manuals. In a more mid to longer term perspective, demand for the ethics review seems to be proliferating and spreading to the realm of the clinical practice, such as the reviews for the regenerative medicine, patient request medical treatment and Japanese version of the compassionate use of the investigational drugs. NCC may need to start discussing the scope and positioning of the Human Research Protection Section within the NCC organization.

For clinical studies led by NCC's investigator, 6 audits were conducted on GCP trials, and 3 on B type advanced medical service trials. Also 14 internal audits were conducted on departments in NCC conducting clinical research, as part of self-inspection required in the ethics guideline. Other activities included GCP-related training and consultation as well as support of regulatory inspection management.

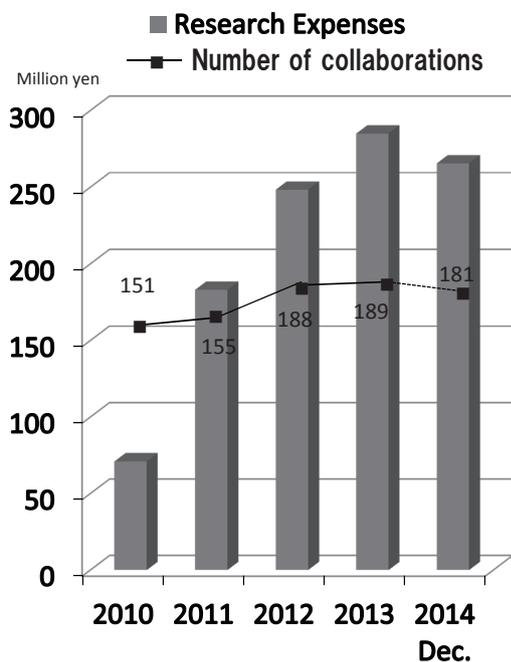


Figure 1. Collaborative Research with Industry

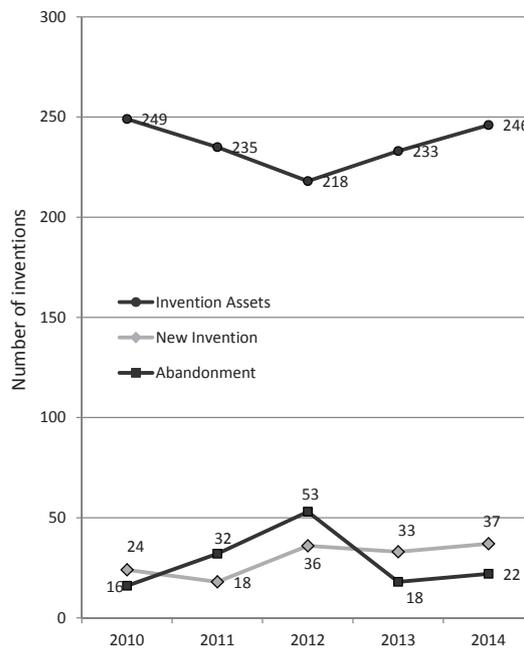


Figure 2. Invention Management

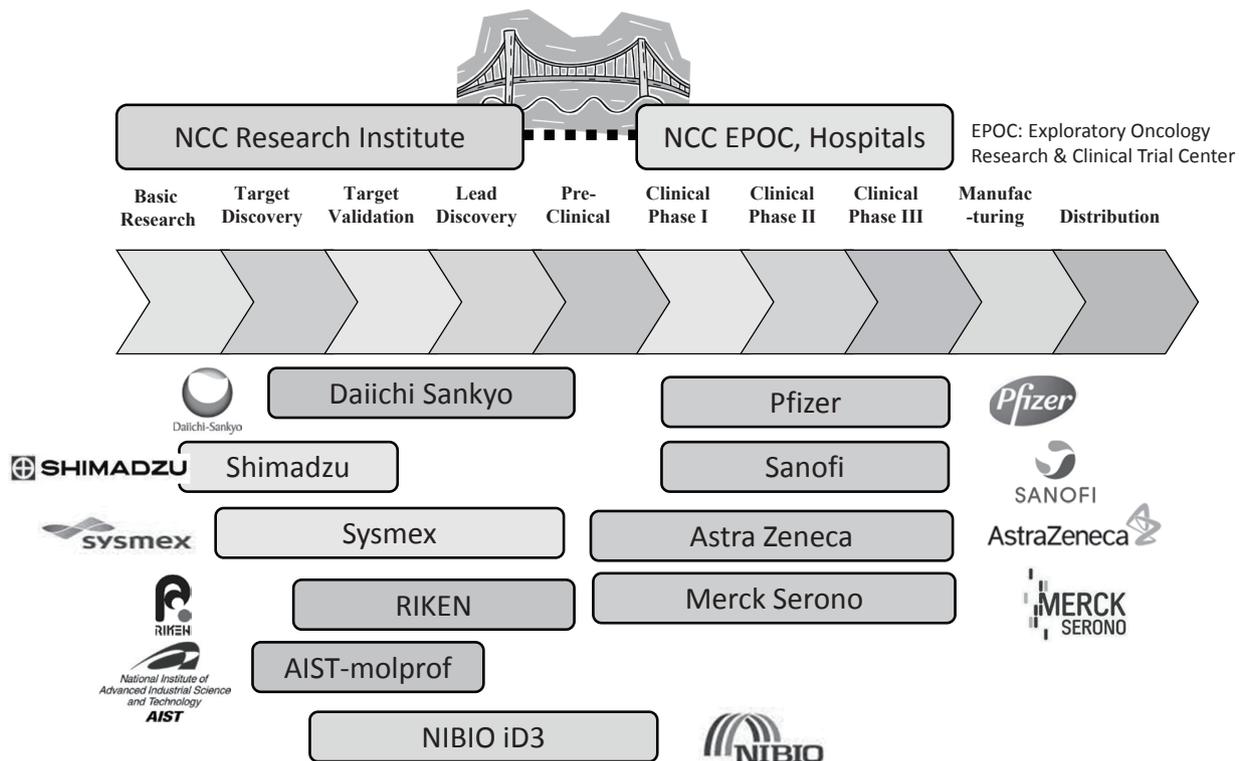
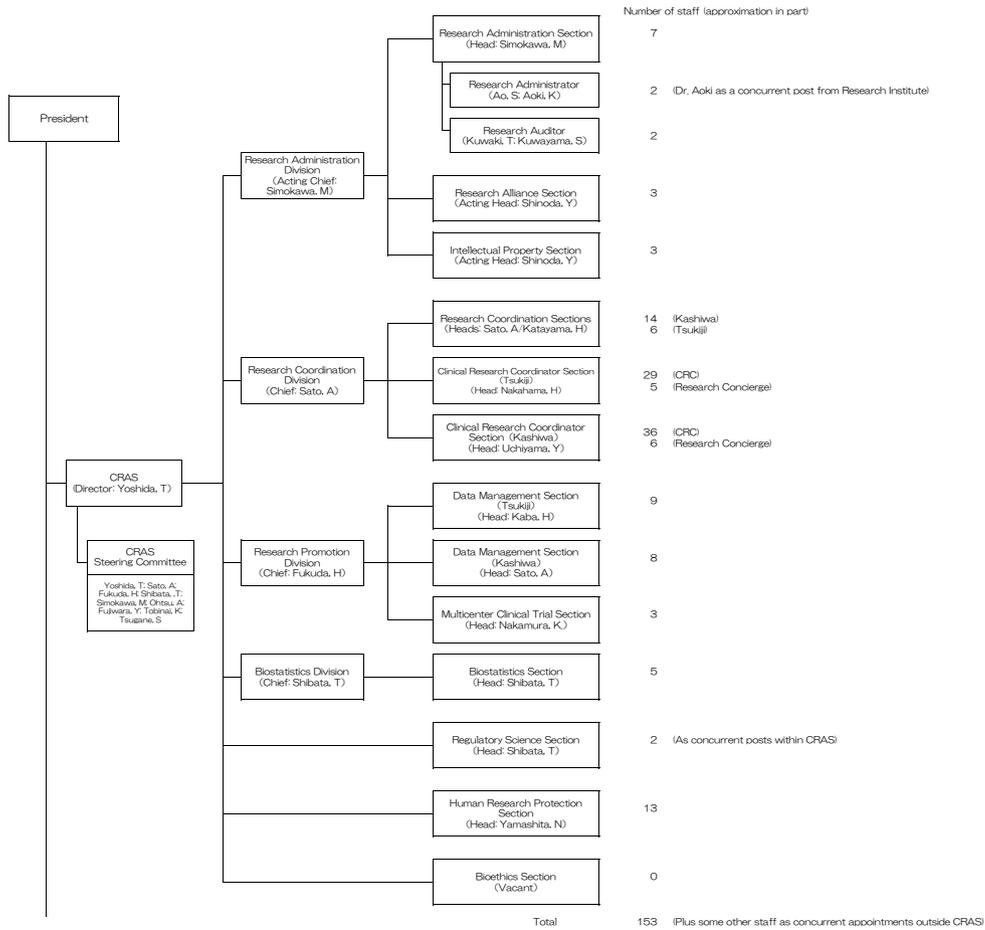


Figure 3. Strategic Alliance with industry

Organization of Center for Research Administration and Support (CRAS) (as of November 1, 2014)



List of papers published in 2014

Journal

- Shien T, Iwata H, Fukutomi T, Inoue K, Aogi K, Kinoshita T, Ando J, Takashima S, Nakamura K, Shibata T, Fukuda H. Tamoxifen plus tegafur-uracil (TUFT) versus tamoxifen plus Adriamycin (doxorubicin) and cyclophosphamide (ACT) as adjuvant therapy to treat node-positive premenopausal breast cancer (PreMBC): results of Japan Clinical Oncology Group Study 9404. *Cancer Chemother Pharmacol*, 74:603-609, 2014
- Shien T, Iwata H, Aogi K, Fukutomi T, Inoue K, Kinoshita T, Takahashi M, Matsui A, Shibata T, Fukuda H. Tamoxifen versus tamoxifen plus doxorubicin and cyclophosphamide as adjuvant therapy for node-positive postmenopausal breast cancer: results of a Japan Clinical Oncology Group Study (JCOG9401). *Int J Clin Oncol*, 19:982-988, 2014
- Eba J, Kenmotsu H, Tsuboi M, Niho S, Katayama H, Shibata T, Watanabe S, Yamamoto N, Tamura T, Asamura H. A Phase III trial comparing irinotecan and cisplatin with etoposide and cisplatin in adjuvant chemotherapy for completely resected pulmonary high-grade neuroendocrine carcinoma (JCOG1205/1206). *Jpn J Clin Oncol*, 44:379-382, 2014
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CENTER FOR EDUCATION AND PROFESSIONAL CAREER DEVELOPMENT

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Introduction

The Center for Education and Professional Career Development has been established on July, 2014. The purposes are upbringing and securing of able human resource, clarification of the career path in each type of job, improvement of systematic educational program. Under the director of center and two vice-directors, the Office for Career Management, the Office for Graduate Medical Education, and the Office for Professional Education Management are placed.

Routine activities

The Office for Career Management is conducting the career path development of each professional, the strategic securing of able professionals, and management of the information about alumnus. The Office for Graduate Medical Education is conducting the promotion of the cooperative post-graduate school and management of the education program for residents. The Office for Professional Education Management is conducting the planning of education programs for the whole center stuffs, the planning and enforcement of common training program at the time of the adoption, the planning and enforcement of the individual education program for each professional field, and the management of attendance on various lectures.

In 2014, hearings were carried out in each section to clarify what kind of personnel training, education was carried out in each section and what kind of career path was built. The systematic personnel training, education was carried out in

medical doctors, nurses and pharmacists section which relatively had a lot of staff but enforcement of the systematic personnel training, education was difficult in the small sections. Moreover the career path was not clear in small sections. Because it was a facility specialized in cancer, an opinion that it was difficult to perform the education and training for the benign disorder enough was sent from plural sections, and it was thought that an opportunity of the training in other facilities was necessary.

A resident educational program of the National Cancer Center (NCC) has the history for nearly 50 years, but it started the re-examination of the resident educational program to produce more able cancer specialists effectively. We carry out a discussion in the working group, the hearing from chief doctor of each department, the questionnaire to persons who completed resident and senior resident educational program to build a new resident educational program that can cope with change of a new board certification system which will start in 2017, the medical and social situation and the request from the young doctors.

Education

The cooperative post-graduate school program with Keio University and Juntendo University were started in 2012. As of in 2014, 14 and 44 post-graduate students, 58 in total were registered at the cooperative post-graduate school program with Keio University and Juntendo University, respectively. 4 post-graduate students of them received a Ph.D. degree.

Future prospects

The NCC has to bring up the experts of variety types of job to engage in medical treatment and research for cancer, support of cancer patients and provide them in the whole of Japan. It is also expected that we bring up the able professionals

who should be leaders in their field in near future. We want to aim at the construction of the system performing the personnel training by all types of job about medical treatment and research for cancer, support of cancer patients including office workers as well as doctors.

OFFICE FOR ADVANCED MEDICAL CARE EVALUATION

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Introduction

In November 2013, our Office was established by the National Cancer Center as a secretariat to “evaluate advanced medical treatments involving anti-cancer drugs due to high unmet medical needs,” a project commissioned by the Health Policy Bureau of the Ministry of Health, Labour and Welfare (MHLW).

Our Office’s mission is to provide support to institutions, including the “core clinical research hospitals,” that are going to conduct clinical studies of anti-cancer drugs identified as potential treatments for diseases with high unmet medical needs by the Evaluation Committee on Unapproved or Off-label Drugs with High Medical Needs, within the framework of the Advanced Medical Care B program of the MHLW.

Routine activities

We assist institutions by 1) preparing their study plans, 2) supporting their application procedures, e.g., facilitating discussions with regulatory authorities, and 3) reviewing the technical adequacy of the applications and the content of the study implementation plans by establishing and operating the Assessment Committee on Advanced Medical Care. We also report the assessment results to the Advanced Medical Care meeting.

As of now, the anti-cancer drugs expected to be covered by this system include 131I-MIBG (pheochromocytomas, neuroblastoma, medullary thyroid cancer, etc.). We are currently discussing their development strategy in coordination with clinical experts, the pharmaceutical industry, and regulatory authorities.

We also make a list of unapproved anticancer drugs (i.e., those approved in the United States and/or European Union, but not in Japan) for the understanding of drugs as a target of this system.