Sections Directed by President

Office of Public Relations, Strategic Planning Bureau

Hiroshi Nokihara, Miyako Horikoshi, Mari Hatakeyama, Toru Kishida, Hironobu Ohmatsu, Rika Kojima, Kajitsu Ogawa, Rey Yoshida

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 to the Office of Public Relations 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 Relations, we performed prompt decision making regarding the public relations policy and shared information about our tasks by using a 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, a bulletin board and/or an 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 treatments, research activities and notable accomplishments within the NCC and elsewhere.

- Homepage improvement and updates
- 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 families in the NCC Hospitals
- Support of the event, seminar and public information
- Media support at press conferences, press releases and media coverage

We held six press conferences (projected cancer statistics in 2015, development of a novel nucleic acid drug discovered by the NCC, genetic testing lab established within the NCC Hospital, etc.) and published 38 press releases.

The future direction

We need to renew the NCC homepage into a more attractive, informative, and accessible page for users to be informed about NCC's activities in cancer care, research, screening, prevention, and policy making. We also feel it is important to move forward public relations activities towards expansion to overseas media via our homepage and press releases. We hope that all staff members in the NCC share their information and thoughts and will move 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 the NCC's activities with these goals as its aim, and supports other international activities and those related with foreign countries and people.

As for 1. above, the NCC has dispatched a nurse to Massachusetts General Hospital, a prestigious hospital in the USA. The nurse stayed four weeks and exchanged information about cancer nursing, nursing education, cancer survivorship, support for clinical trials, etc.

In May, the embassies of the USA, the UK, France and Korea and the NCC co-organized an international symposium on cancer clinical trials, where attendees shared updated information about development of precision medicine and established platform for future collaboration.

The NCC has a lot of collaborative work projects that have been 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 just after its establishment. In 2015, the NCC had 159 visiting fellows (at both campuses of Tsukiji and Kashiwa). The number of visitors keeps rising. As for the few-day visitors, the NCC had 121. (See the table below for details.) Including the few-hour visitors, the NCC has had over 400 in total. The majority of visitors come from Asian countries, followed by European countries. As a recent trend, visitors from the Middle East are also on the rise. In order for continuous support, an international party was held to interact with employees from foreign countries, international temporary visitors, and Japanese staff. In addition, the Office continues to support former fellows through the alumni organization to keep in touch with them.

As another important topic, the NCC has made donations for earthquake victims in Nepal through the Embassy of Nepal. The donation was collected from employees and totaled one million yen.

The NCC works closely with the ministries of Japan. In 2015, the NCC was involved in a project supported by the Ministry of Economy, Trade and Industry. This project was led by FUJIFILM Corporation, aiming to establish a cancer screening center in Brazil. The NCC's endoscopists fully cooperated.

Fellowship (with and without fees)…4 days or more
Short-term visit…Within 3 days

Table 1. Visiting fellows (with and without fees) of the hospital

Visitors by region		Country of home organization	Hospital																				
			Head & Neck Surg.	Plastic & Reconstructive Surg.	Breast and Medical Oncology	Thoracic Oncology	Esophageal Surg.	Gastric Surg.	Colorectal Surg.	Gastrointestinal Medical Oncology	Gastrointestinal Endoscopy	Respiratory Endoscopy	HPB Surg.	Urology	Hematology	Diagnostic Radiology	Radiation Oncology	Pathology	Thoracic Surg.	Nursing	Total # by division*	Total (Actual #)
Asia		India														2					2	2
		Singapore							1				1								2	1
		Thailand									2			1							3	5
		Korea						2	3		3	1	1							2	12	10
		China				1	3		1		12	1	2					1	3		24	19
		Taiwan			1				2	1	14	13			1	9				3	44	40
		Hong Kong							2		3										5	3
		Philippines	1				1	1	2			1	2								8	5
		Vietnam									3					1**					4	4
		Malaysia														2					2	2
	92	Myanmar															1				1	1
Oceania	1	Australia						1													1	1
N America	6	USA									5							1			6	6
L America		Colombia						1													1	1
		Brazil											1								1	1
		Peru		1																	1	1
	8	Mexico	1								3		1						1		6	5
M East		UAE									3										3	3
		Iran									1										1	1
		Saudi Arabia									1										1	1
	7	Turkey									2										2	2
Europe		Italy									3										3	3
		UK						1			2										3	3
		Austria									1										1	1
		Netherlands									1										1	1
		Georgia						1	1		1		1								4	1
		Spain					1	4			8					1					14	13
		Germany						1													1	1
		Poland									1										1	1
		Portugal									1										1	1
		Romania						1													1	1
	27	Russia									1										1	1
		Total	2	1	1	1	5	13	12	1	71	16	9	1	1	14	1	2	4	5	161	141

* Total number by division (Some visitors rotate between multiple divisions)
** A Vietnamese citizen, enrolled in a university in Japan, is counted as Vietnam because they may return to their home country one day.

Fellowship (with and without fees)…4 days or more
Short-term visit…Within 3 days

Table 2. Visiting fellows (with and without fees) of all centers except the 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
			Head & Neck Surg.	Plastic & Reconstructive Surg.	Esophageal Surg.	Gastric Surg.	HPB Surg.	Radiation Oncology	Total # by division*	Total (Actual #)	Molecular and Cellular Medicine	Rare Cancer Research	Genome Biology	Cancer Genomics	Total # by division*	Total (Actual #)	Total (Actual #)	Total (Actual #)	Developmental Therapeutics	Total # by division*	Total (Actual #)	Total (Actual #)
Asia		Indonesia																	1	1	1	
		China				6	2		8	8												
		Taiwan						1	1	1												
		Hong Kong	1						1	1												
	12	Philippines			1	1			2	1												
N America	1	USA												1	1	1						
L America	1	Peru		1					1	1												
Europe		Switzerland									1				1	1						
		Sweden									1				1	1						
		Spain			1	1		1	3	2												
		Germany										1	1		2	2						
	7	Portugal							1	1												
Other**	1	Japan									1				1	1						
		Total	1	1	3	8	2	2	17	15	3	1	1	1	6	6	0	0	1	1	1	0

* Total number by division (Some visitors rotate between multiple divisions)
** A Malaysian citizen, enrolled in a university in Japan, is counted as Japan

Fellowship (with and without fees)…4 days or more
Short-term visit…Within 3 days

Table 3. Short-term (within three days) visitors of the hospital

Visitors by region	Country of home organization	Hospital																	
		Head & Neck Surg.	Gastrointestinal Endoscopy	Respiratory Endoscopy	Gastric Surg.	Colorectal Surg.	HPB Surg.	Esophageal Surg.	Thoracic Surg.	Hematopoietic Stem Cell Transplantation	Dermatologic Oncology	Anesthesia and Intensive Care	Diagnostic Radiology	Radiation Oncology	Pathology	Nursing	Pharmacy	Clinical Trial Coordination (& Support) Office	Total
Asia	Indonesia		1																1
	Singapore												1						1
	Thailand		1					1							4				6
	China		11			1				5		6		6					29
	Taiwan	4						3	7							3			17
	Korea		1																1
	Philippines			1															1
	Vietnam																3		3
62	Malaysia												3						3
Oceania	New Zealand		1																1
1																			
N America	USA		1								2		15				2		20
21	Canada							1											1
S America	Brazil		3					1											4
4																			
Europe	Sweden		3																3
8	Russia		3			2													5
M East	Israel		1																1
3	Kuwait				1		1												2
Unknown*	Unknown							1		1					1			2**	5
5																			
	Total	4	26	1	1	3	1	7	7	6	2	6	19	6	5	3	5	2	104

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

** Same visitors as the visitors at the Research Coordination of Control for Research Administration & Support

Fellowship (with and without fees)…4 days or more
Short-term visit…Within 3 days

Table 4. Short-term (within three days) visitors of all centers except the 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	
		Radiation Oncology	Total	Total	Health Services Research	Total	Screening Practice	Floor for Screening	Total	Cancer Immunotherapy	Total	Research Coordination	Total
Asia	China	2	2				10	2	12				
2	Korea				5	5							
N America	USA									1	1		
1													
Europe	Russia	1	1										
1													
Unknown*	Unknown											2**	2
2													
	Total	3	3	0	5	5	10	2	12	1	1	2	2

* Because an application form for a short-term visit does not require the country of the home organization of applicants, it is unknown, unless otherwise declared by the applicant

** Same visitors as the visitors at Clinical Trial Coordination (& Support) Office of Hospital

Center for Research Administration and Support (CRAS)

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

Introduction

The Center for Research Administration and Support (CRAS) was established on July 16, 2014. At that time, CRAS started with approximately 160 staff members, who together offer diverse functions and specialties, ranging from research fund administration, alliances with the private sector, intellectual properties, clinical research coordinators and data managers, monitoring and audit, biostatistics support, offices for research ethics (IRB) and COI committees.

Dr. Hotta, President of the National Cancer Center (NCC), explained the reason and the purpose of the creation of CRAS in NCC News 2014 Vol. 5/ No. 3 (in Japanese). 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 infrastructure, support activities in NCC had become fragmented and scattered with the possibility of gaps and redundancies. Dr. Hotta approached the Strategic Planning Bureau and put together the "NCC New Vision" in 2014, in which he proposed integration and communication of various research support functions in NCC.

The NCC Hospital and Hospital East have been certified as the Core Clinical Research Hospital based on the Medical Care Acts of August and September 2015, respectively. It is then required that the support functions for clinical research, especially those concerning clinical trials, need to be operated under the responsibility of a hospital director. As a result, the governance of the Research Coordination Division, Research Promotion Division and Regulatory Science Section of CRAS have now been moved to the Clinical Research Support Office, which belong to the common departments of each hospital. The annual report of the activities of the three divisions and the section will be found in the respective hospital sections.

(Future Prospects)

The mission of CRAS is to enhance the research support and administration capabilities of NCC based on the "NCC New Vision". It entails well-functioning integration and interaction of both campuses, Tsukiji and Kashiwa, as a solid and efficient NCC system. However, the integration should not necessarily mean homogenization but should respect differences in roles and various characteristics of each NCC campus to make the most of their strong points. Similar to last year, CRAS will keep evolving through a further trial-and-error process to find the best-fit system, with bridging both campuses being its fundamental spirit and agenda.

Activities and Future Prospects of each Division/Section

1. Research Administration Division

1) Research Administration Section

The Research Administration Section is a central office in charge of various administrative work related to research funding including application and reporting. The major external funding sources of NCC are competitive grants from the government and government-supported agencies, such as the Ministry of Health, Labour and Welfare (MHLW), Japan Science and Technology Agency (JST) and Japan Agency for Medical Research and Development (AMED). The Section also serves as an administrative office for the NCC Research and Development Fund, which is provided directly from the government to NCC for fulfillment of its mission as the national core institute of cancer control. The Section organized seminars regarding research funding and its rules to prevent financial misconduct.

(Future Prospects)

The Guidelines for Managing and Auditing Public Research Funds at Research Institutes was updated by the Ministry of Education, Culture, Sports, Science and Technology (MEXT) in February 2014 and adopted by MHLW in March 2014. The Section serves as a compliance promotion office of the Guidelines and has established a new system for research fund administration, which is fully compatible with the new Guidelines.

2) Research Administrators

Research administrators (RA) helped the Director of the Research Institute to review the research achievements in 2015 and to develop research plans in 2016. RA also offered to undertake administrative office work for the NCC Seeds Selection Committee, which was established in 2015 to identify promising research and development seeds of cancer diagnostics and therapeutics in NCC; in 2015, 11 seeds were selected to be funded for 1 year by the NCC in-house grant.

RA has supported the promotion of the commercial viability of research outcomes based upon three main pillars: a comprehensive alliance with companies, academic drug discovery research supported by the Drug Discovery Support Network, and establishment of NCC-launched venture companies. Candidate compounds for clinical development have been provided by collaboration with business enterprises, and four themes are in progress as a Drug Discovery Support Network. In 2015, one venture company was established as an NCC-spin off.

(Future Prospects)

RA promotes translation of innovative research in NCC to clinical diagnostic and therapeutic development and to patient care through four major mechanisms: the NCC Seeds Selection Committee, comprehensive alliances with leading companies, participation in the academic Drug Discovery Network, and establishment of NCC spin-off venture companies.

3) Research Auditor

For clinical studies led by the National Cancer Center's (NCC's) investigator, thirteen audits were conducted on GCP trials, and internal audits were conducted on departments in the NCC conducting clinical research. Other activities included GCP-related training and consultation as well as support of regulatory inspection management.

(Future Prospects)

Audit and its related activities will be continued to boost the quality of NCC's clinical research. In addition, as clinical interventional studies with invasive procedures will come into audit targets along with the implementation of "Ethical Guidelines for Medical and Health Research Involving Human Subjects", preparation of processes and techniques will be critical for the new type of audit. Moreover, building a risk-based audit plan will be effective for improvement of our research process.

4) Research Alliance Section and Intellectual Property Section

To make the NCC research outcomes clinically useful products available to cancer patients, the Research Alliance Section promotes collaborative research arrangements with the private sector. The number of collaborative research projects and their funds has been increasing each year (Figure. 1). As of December 31, 2015, the number of collaborations was 199, and their research funds amount to approximately 1.0 billion yen, which exceeded those of 2014. NCC has developed a comprehensive collaboration research system with companies and academic institutions. With the addition of a new collaborative framework this year, NCC has eight comprehensive collaborative alliances (Figure. 2). The section supported a nationwide genomic screening project with the participation of major pharmaceutical companies and institutions across Japan (SCRUM-Japan "Cancer Genome Screening Project for Individualized Medicine in Japan"), which was launched in March 2015. Currently, 14 pharmaceutical companies have registered (Figure. 3). The section has also assisted regional alliances with medium-sized medical device companies.

The Intellectual Property (IP) Section constantly reviews IPs and declines those that cannot find a business sponsor within a certain period; the limited budget can then be focused

on IPs that are commercially viable. The number of patent licensing agreements in recent years is shown in Figure. 4.

Staff members actively participate in seminars with regard to IP laws and regulations to update their knowledge and elevate their skills to promote academic-industrial alliances. Their competency in problem solving gained through OJT and effective consultation with experts will enable them to face new challenges in innovative fields.

(Future Prospects)

In the trend of Open Innovation, the Section will keep supporting the creation of systemic and effective collaborative research frameworks. It also foresees the possibility of a new laboratory setup where research is being performed by researchers from both industry and NCC, and should lead to more functional collaboration.

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

2. Biostatistics Division

The Biostatistics Division has a responsible role in study design, analysis, interpretation and publication, especially in the Japan Clinical Oncology Group (JCOG) and the Exploratory Oncology Research & Clinical Trial Center (EPOC) clinical trials. We have also committed to support the investigator-initiated clinical trials led by investigators in the NCC Hospitals.

We provided introductory biostatistics lectures (10-part series) for investigators in NCC to learn and review the elementary aspects of biostatistics. We had a cumulative total of 447 participants. In addition, we newly launched advanced biostatistics lectures to cover the important biostatistical side of various application fields. We hosted 7 lectures and a cumulative total of 418 investigators participated.

Furthermore, we have provided biostatistical consultation and expertise, which supports NCC investigators working on basic, translational, clinical and epidemiological research. We offered advice regarding 117 problems (74 in the Tsukiji campus and 43 in the Kashiwa campus) for which biostatistical consultation was requested.

(Future Prospects)

NCC has a critical role for providing clinical service, education, conducting research and making policy recommendations/proposals, which all need decisions on the basis of solid and scientific evidence from reliable data and information. The mission of the Biostatistics Division is to contribute to providing the best evidence and the improvement of clinical practices and public health through the development and application of statistical methods. The Biostatistics Division is expanding its independent and collaborative research within a range of areas, including prevention and policy recommendations/proposals, as well as treatment development. We are also opening up a new methodological research area in which a mathematical approach will serve as a solid basis.

3. Human Research Protection Section

The major role of the Human Research Protection Section has been its function as a secretariat for various research ethics committees (IRBs) in NCC for human subject research. In 2015, the Section led efforts involving various sections in NCC to overhaul the NCC codes, rules and Standard Operating Procedures to adapt the newly enforced Ethical Guidelines for Medical and Health Research Involving Human Subjects in April 2015. Moreover, the Section has revised and developed the system to accept the ethics review requests from other institutions including those protocols that do not include NCC researchers; this will be an important step forwards to the future evolution to the Central IRB.

On the other hand, however, one major issue in the Section has been the long review waiting list fueled partly by the review complexities introduced by the new Ethics Guidelines and by an increase in the ethics review requests from other institutions. However, the more fundamental problem is the

paucity of human resources in the field of the research ethics review.

(Future Prospects)

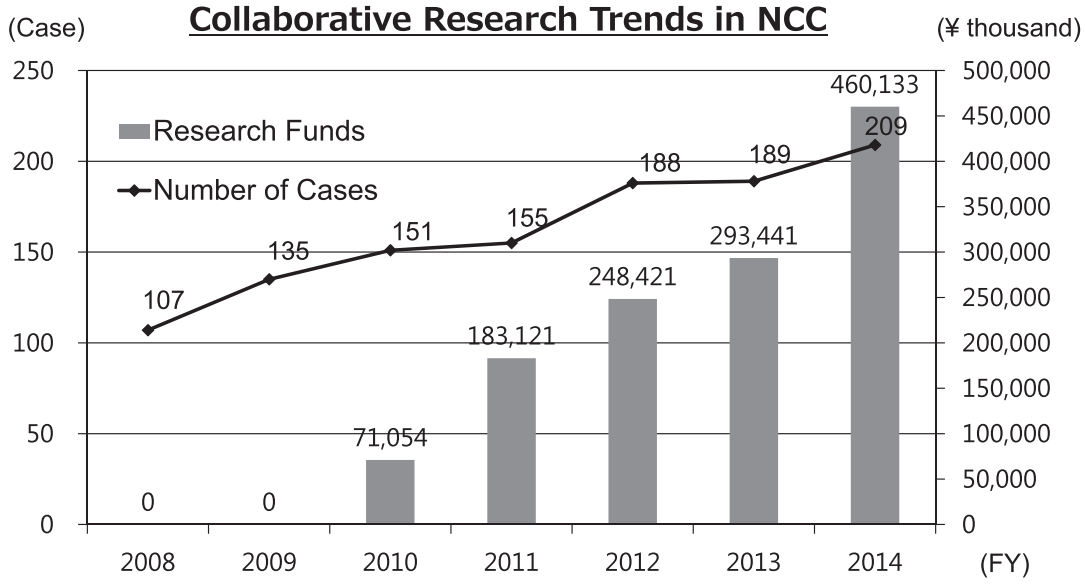
The CRAS and Clinical Research Support Offices in both hospitals keep working to further update the research support system in NCC, which will enable the IRB to concentrate more on its core responsibility of ethics reviews. Sometime in 2016, the Human Research Protection Section is planning to call regular IRB meetings twice a month and in both campuses alternatively, to respond to the increasing demands for ethics reviews and to enhance the equal participation and communication of both campuses in the process.

4. Bioethics Section

The Bioethics Section provides research ethics consultation service to researchers/research support staff, IRB members/staff, and other stakeholders in research enterprises throughout the lifecycle of a study. The research ethics consultation service plays a strictly advisory role and is independent from IRB decisions. The Bioethics Section started providing an ethics consultation service from 2015 and received about 100 calls a year. Also, this Section provides ethics education to researchers and IRB members/staff.

(Future Prospects)

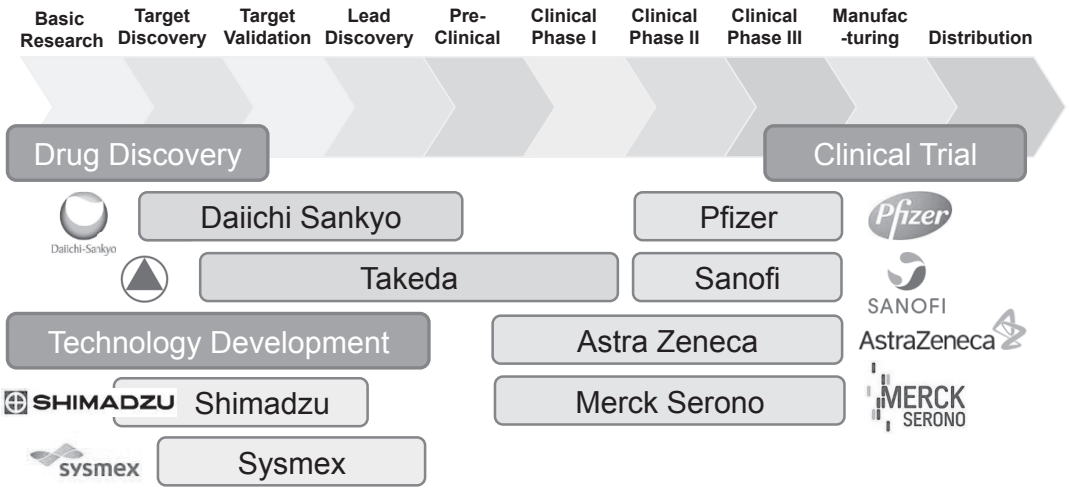
The Bioethics Section will produce a standard format for requesting a consultation service and improve quality of the consultation service. Also, the Section will provide advanced education on research ethics as well as basic education.



Collaborative Research Funds from industry have increased each year since the IP and Research Alliance Division was set up in 2010.

Figure 1. Collaborative Research (FY 2008-2014)

Major Industry Partners of NCC



NCC has concluded a number of partnership agreements with Pharma-, Diagnostic- and Med-Device Industries at various R&D stages.

Figure 2. NCC-Industry Partnership

The Screening Project for Precision Medicine as Academic-Industrial Collaboration

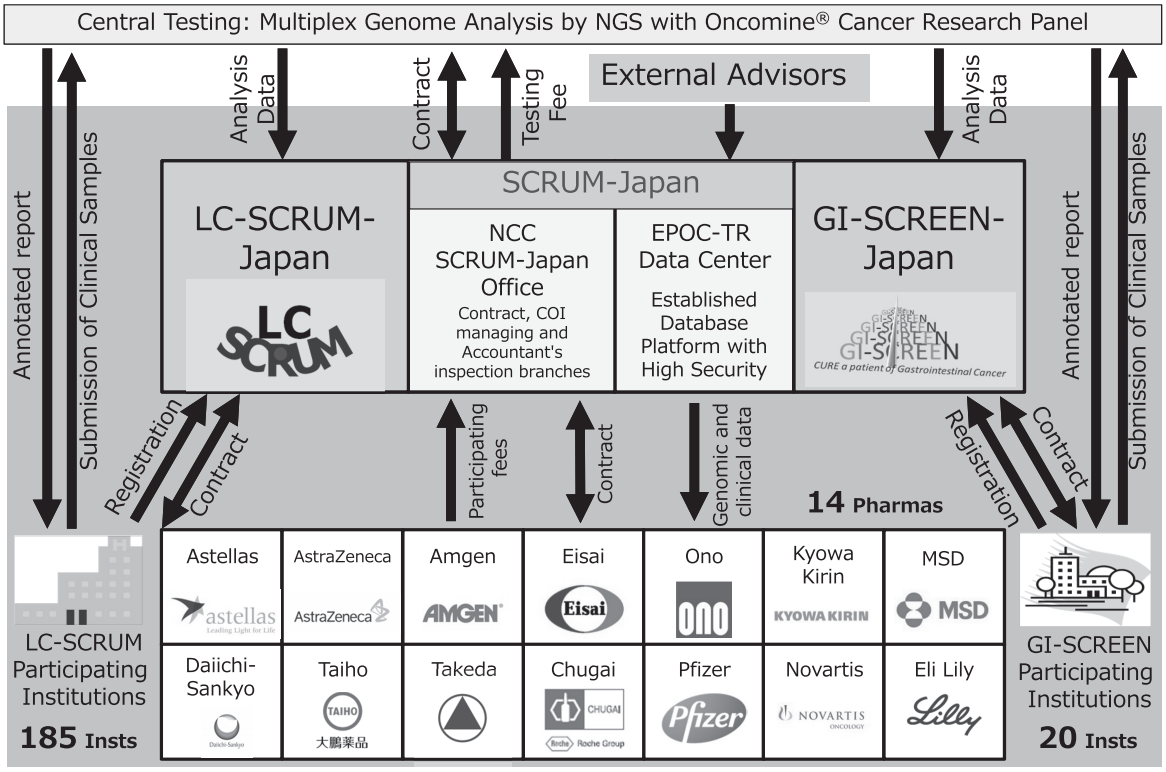
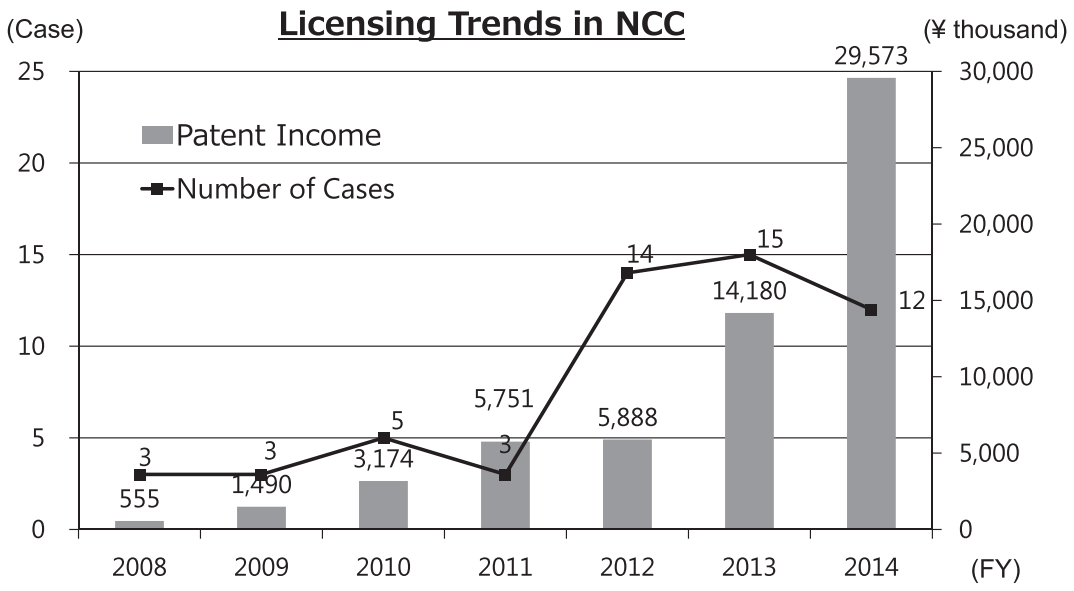


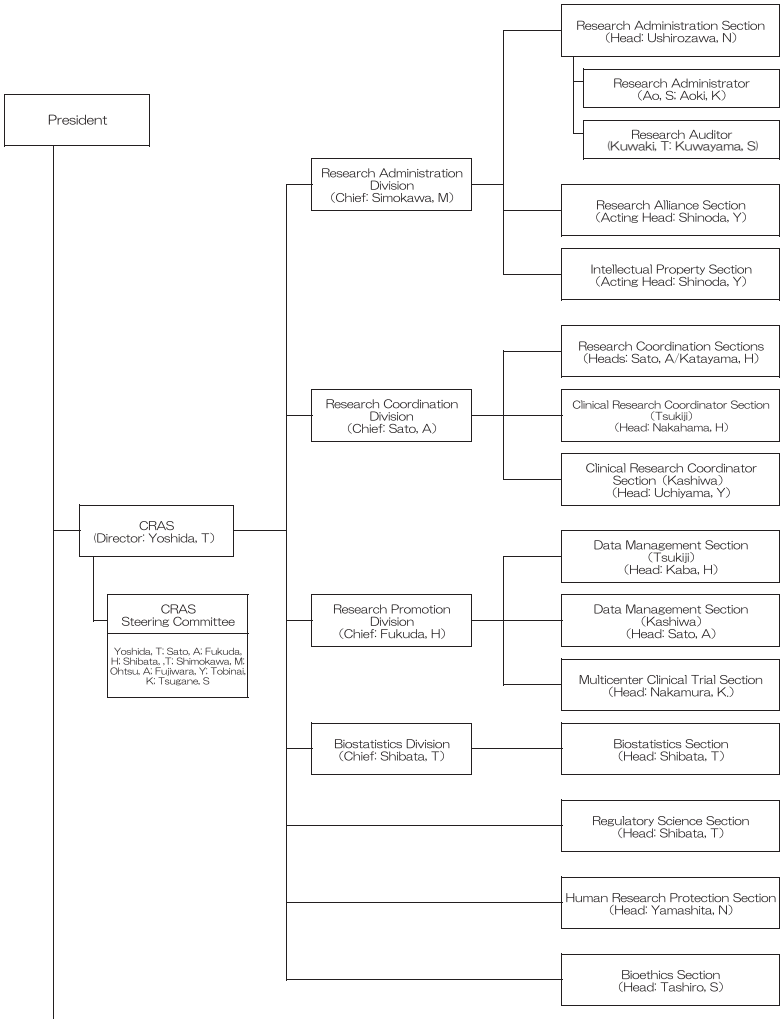
Figure 3. SCRUM-Japan (established in February 2015)



Patent income has increased each year, especially in later years.

Figure 4. Licensing Deals (FY2008-2014)

Organization of Center for Research Administration and Support (CRAS) (as of June 20, 2015)



List of papers published in 2015

Journal

1. Kataoka K, Aoyama I, Mizusawa J, Eba J, Minashi K, Yano T, Tanaka M, Hanaoka N, Katayama H, Takizawa K, Fukuda H, Muto M, Gastrointestinal Endoscopy Study Group (GIESG) of the Japan Clinical Oncology Group. A randomized controlled Phase II/III study comparing endoscopic balloon dilation combined with steroid injection versus radial incision and cutting combined with steroid injection for refractory anastomotic stricture after esophagectomy: Japan Clinical Oncology Group Study JCOG1207. Jpn J Clin Oncol, 45:385-389, 2015

2. Tsukada H, Yokoyama A, Goto K, Shinkai T, Harada M, Ando M, Shibata T, Ohe Y, Tamura T, Saijo N, Lung Cancer Study Group of the Japan Clinical Oncology Group (JCOG). Randomized controlled trial comparing docetaxel-cisplatin combination with weekly docetaxel alone in elderly patients with advanced non-small-cell lung cancer: Japan Clinical Oncology Group (JCOG) 0207†. Jpn J Clin Oncol, 45:88-95, 2015

3. Kurokawa Y, Sasako M, Sano T, Yoshikawa T, Iwasaki Y, Nashimoto A, Ito S, Kurita A, Mizusawa J, Nakamura K, Japan Clinical Oncology Group (JCOG9502). Ten-year follow-up results of a randomized clinical trial comparing left thoracoabdominal and abdominal transhiatal approaches to total gastrectomy for adenocarcinoma of the oesophagogastric junction or gastric cardia. Br J Surg, 102:341-348, 2015

4. Tahara M, Kiyota N, Mizusawa J, Nakamura K, Hayashi R, Akimoto T, Hasegawa Y, Iwae S, Monden N, Matsuura K, Fujii H, Onozawa Y, Homma A, Kubota A, Fukuda H, Fujii M. Phase II trial of chemoradiotherapy with S-1 plus cisplatin for unresectable locally advanced head and neck cancer (JCOG0706). Cancer Sci, 106:726-733, 2015

5. Kato T, Takashima A, Kasamatsu T, Nakamura K, Mizusawa J, Nakanishi T, Takeshima N, Kamiura S, Onda T, Sumi T, Takano M, Nakai H, Saito T, Fujiwara K, Yokoyama M, Itamochi H, Takehara K, Yokota H, Mizunoe T, Takeda S, Sonoda K, Shiozawa T, Kawabata T, Honma S, Fukuda H, Yaegashi N, Yoshikawa H, Konishi I, Kamura T, Gynecologic Oncology Study Group of the Japan Clinical Oncology Group. Clinical tumor diameter and prognosis of patients with FIGO stage IB1 cervical cancer (JCOG0806-A). Gynecol Oncol, 137:34-39, 2015

6. Satoh T, Tsuda H, Kanato K, Nakamura K, Shibata T, Takano M, Baba T, Ishikawa M, Ushijima K, Yaegashi N, Yoshikawa H, Gynecologic Cancer Study Group of the Japan Clinical Oncology Group. A non-randomized confirmatory study regarding selection of fertility-sparing surgery for patients with epithelial ovarian cancer: Japan Clinical Oncology Group Study (JCOG1203). Jpn J Clin Oncol, 45:595-599, 2015

7. Tanaka K, Mizusawa J, Fukuda H, Araki N, Chuman H, Takahashi M, Ozaki T, Hiruma T, Tsuchiya H, Morioka H, Hatano H, Iwamoto Y. Perioperative chemotherapy with ifosfamide and doxorubicin for high-grade soft tissue sarcomas in the extremities (JCOG0304). Jpn J Clin Oncol, 45:555-561, 2015

8. Suzuki K, Watanabe S, Mizusawa J, Moriya Y, Yoshino I, Tsuboi M, Mizutani T, Nakamura K, Tada H, Asamura H, Japan Lung Cancer Surgical Study Group (JCOG LCSSG). Predictors of non-neoplastic lesions in lung tumours showing ground-glass opacity on thin-section computed tomography based on a multi-institutional prospective study†. Interact Cardiovasc Thorac Surg, 21:218-223, 2015

9. Etoh T, Inomata M, Watanabe M, Konishi F, Kawamura Y, Ueda Y, Toujigamori M, Shiroshita H, Katayama H, Kitano S. Success rate of informed consent acquisition and factors influencing participation in a multicenter randomized controlled trial of laparoscopic versus open surgery for stage II/III colon cancer in Japan (JCOG0404). Asian J Endosc Surg, 8:419-423, 2015

10. Onimaru R, Shirato H, Shibata T, Hiraoka M, Ishikura S, Karasawa K, Matsuo Y, Kokubo M, Shioyama Y, Matsushita H, Ito Y, Onishi H. Phase I study of stereotactic body radiation therapy for peripheral T2N0M0 non-small cell lung cancer with PTV<100 cc using a continual reassessment method (JCOG0702). Radiother Oncol, 116:276-280, 2015

11. Nagata Y, Hiraoka M, Shibata T, Onishi H, Kokubo M, Karasawa K, Shioyama Y, Onimaru R, Kozuka T, Kunieda E, Saito T, Nakagawa K, Hareyama M, Takai Y, Hayakawa K, Mitsuhashi N, Ishikura S. Prospective Trial of Stereotactic Body Radiation Therapy for Both Operable and Inoperable T1N0M0 Non-Small Cell Lung Cancer: Japan Clinical Oncology Group Study JCOG0403. Int J Radiat Oncol Biol Phys, 93:989-996, 2015

12. Foster NR, Renfro LA, Schild SE, Redman MW, Wang XF, Dahlberg SE, Ding K, Bradbury PA, Ramalingam SS, Gandara DR, Shibata T, Saijo N, Vokes EE, Adjei AA, Mandrekar SJ. Multitrial Evaluation of Progression-Free Survival as a Surrogate End Point for Overall Survival in First-Line Extensive-Stage Small-Cell Lung Cancer. J Thorac Oncol, 10:1099-1106, 2015

13. Wang M, Kuchiba A, Ogino S. A Meta-Regression Method for Studying Etiological Heterogeneity Across Disease Subtypes Classified by Multiple Biomarkers. Am J Epidemiol, 182:263-270, 2015

14. Kojima M, Puppa G, Kirsch R, Basturk O, Frankel WL, Vieth M, Lugli A, Sheahan K, Yeh M, Lauwers GY, Risio M, Shimazaki H, Iwaya K, Kage M, Akiba J, Ohkura Y, Horiguchi S, Shomori K, Kushima R, Nomura S, Ajioka Y, Adsay V, Ochiai A. Blood and lymphatic vessel invasion in pT1 colorectal cancer: an international concordance study. J Clin Pathol, 68:628-632, 2015

15. Yamada M, Sakamoto T, Otake Y, Nakajima T, Kuchiba A, Taniguchi H, Sekine S, Kushima R, Ramberan H, Parra-Blanco A, Fujii T, Matsuda T, Saito Y. Investigating endoscopic features of sessile serrated adenomas/polyps by using narrow-band imaging with optical magnification. Gastrointest Endosc, 82:108-117, 2015

16. Sugiyama E, Umemura S, Nomura S, Kirita K, Matsumoto S, Yoh K, Niho S, Ohmatsu H, Tsuboi M, Ohe Y, Goto K. Impact of single nucleotide polymorphisms on severe hepatotoxicity induced by EGFR tyrosine kinase inhibitors in patients with non-small cell lung cancer harboring EGFR mutations. Lung Cancer, 90:307-313, 2015

17. Guidance Development Review Committee, Working Group for Clinical Studies of Cancer Immunotherapy, Working Group for Effector Cell Therapy, Working Group for CMC/Non-clinical Studies, Working Group for Cancer Vaccines and Adjuvants, Working Group for Anti-immune Checkpoint Therapy and Comprehensive Cancer Immunotherapy, Biostatistics Subcommittee. 2015 Guidance on cancer immunotherapy development in early-phase clinical studies. Cancer Sci, 106:1761-1771, 2015

18. Hojo T, Masuda N, Mizutani T, Shibata T, Kinoshita T, Tamura K, Hara F, Fujisawa T, Inoue K, Saji S, Nakamura K, Fukuda H, Iwata H. Intensive vs. Standard Post-Operative Surveillance in High-Risk Breast Cancer Patients (INSPIRE): Japan Clinical Oncology Group Study JCOG1204. Jpn J Clin Oncol, 45:983-986, 2015

19. Homma A, Nakamura K, Matsuura K, Mizusawa J, Onimaru R, Fukuda H, Fujii M. Dose-finding and efficacy confirmation trial of superselective intra-arterial infusion of cisplatin and concomitant radiotherapy for patients with locally advanced maxillary sinus cancer (JCOG1212, RADPLAT-MSC). Jpn J Clin Oncol, 45:119-122, 2015

20. Tsukada H, Yokoyama A, Goto K, Shinkai T, Harada M, Ando M, Shibata T, Ohe Y, Tamura T, Saijo N. Randomized controlled trial comparing docetaxel-cisplatin combination with weekly docetaxel alone in elderly patients with advanced non-small-cell lung cancer: Japan Clinical Oncology Group (JCOG) 0207. Jpn J Clin Oncol, 45:88-95, 2015

21. Abe T, Takeda K, Ohe Y, Kudoh S, Ichinose Y, Okamoto H, Yamamoto N, Yoshioka H, Minato K, Sawa T, Iwamoto Y, Saka H, Mizusawa J, Shibata T, Nakamura S, Ando M, Yokoyama A, Nakagawa K, Saijo N, Tamura T. Randomized Phase III Trial Comparing Weekly Docetaxel Plus Cisplatin Versus Docetaxel Monotherapy Every 3 Weeks in Elderly Patients With Advanced Non-Small-Cell Lung Cancer: The Intergroup Trial JCOG0803/WJOG4307L. J Clin Oncol, 33:575-581, 2015

22. Eba J, Shimokawa T, Nakamura K, Shibata T, Misumi Y, Okamoto H, Yamamoto N, Ohe Y, Lung Cancer Study Group of the Japan Clinical Oncology Group. A Phase II/III study comparing carboplatin and irinotecan with carboplatin and etoposide for the treatment of elderly patients with extensive-disease small-cell lung cancer (JCOG1201). Jpn J Clin Oncol, 45:115-118, 2015

23. Kitagawa R, Katsumata N, Shibata T, Kamura T, Kasamatsu T, Nakanishi T, Nishimura S, Ushijima K, Takano M, Satoh T, Yoshikawa H. Paclitaxel plus carboplatin versus paclitaxel plus cisplatin in metastatic or recurrent cervical cancer: the open-label randomized phase III trial JCOG0505. J Clin Oncol, 33:2129-2135, 2015

24. Kunieda F, Kasamatsu T, Arimoto T, Onda T, Toita T, Shibata T, Fukuda H, Kamura T, Gynecologic Cancer Study Group of the Japan Clinical Oncology Group. Non-randomized confirmatory trial of modified radical hysterectomy for patients with tumor diameter 2 cm or less FIGO Stage IB1 uterine cervical cancer: Japan Clinical Oncology Group Study (JCOG1101). Jpn J Clin Oncol, 45:123-126, 2015

25. Matsumoto K, Katsumata N, Shibata T, Satoh T, Saitou M, Yunokawa M, Takano T, Nakamura K, Kamura T, Konishi I. Phase II trial of oral etoposide plus intravenous irinotecan in patients with platinum-resistant and taxane-pretreated ovarian cancer (JCOG0503). Gynecol Oncol, 136:218-223, 2015

26. Yokota M, Kobayashi A, Nomura S, Nishizawa Y, Ito M, Nagai K, Saito N. Patterns and treatment of recurrence following pulmonary resection for colorectal metastases. World J Surg, 39:1758-1766, 2015

27. Nozaki I, Kato K, Igaki H, Ito Y, Daiko H, Yano M, Udagawa H, Mizusawa J, Katayama H, Nakamura K, Kitagawa Y. Evaluation of safety profile of thoracoscopic esophagectomy for T1bN0M0 cancer using data from JCOG0502: a prospective multicenter study. Surg Endosc, 29:3519-3526, 2015

28. Sasaki T, Fuse N, Kuwata T, Nomura S, Kaneko K, Doi T, Yoshino T, Asano H, Ochiai A, Komatsu Y, Sakamoto N, Ohtsu A. Serum HER2 levels and HER2 status in tumor cells in advanced gastric cancer patients. Jpn J Clin Oncol, 45:43-48, 2015

29. Fujiwara Y, Yonemori K, Shibata T, Okita N, Ushirozawa N. Japanese universal health care faces a crisis in cancer treatment. Lancet Oncol, 16:251-252, 2015

30. Yokota T, Ando N, Igaki H, Shinoda M, Kato K, Mizusawa J, Katayama H, Nakamura K, Fukuda H, Kitagawa Y. Prognostic Factors in Patients Receiving Neoadjuvant 5-Fluorouracil plus Cisplatin for Advanced Esophageal Cancer (JCOG9907). Oncology, 89:143-151, 2015

31. Shinoda M, Ando N, Kato K, Ishikura S, Kato H, Tsubosa Y, Minashi K, Okabe H, Kimura Y, Kawano T, Kosugi S, Toh Y, Nakamura K, Fukuda H, Japan Clinical Oncology Group. Randomized study of low-dose versus standard-dose chemoradiotherapy for unresectable esophageal squamous cell carcinoma (JCOG0303). Cancer Sci, 106:407-412, 2015

32. Kataoka K, Nakamura K, Mizusawa J, Fukuda H, Igaki H, Ozawa S, Hayashi K, Kato K, Kitagawa Y, Ando N. Variations in survival and perioperative complications between hospitals based on data from two phase III clinical trials for oesophageal cancer. Br J Surg, 102:1088-1096, 2015

33. Kataoka K, Tsushima T, Mizusawa J, Hironaka S, Tsubosa Y, Kii T, Shibuya Y, Chin K, Katayama H, Kato K, Fukuda H, Kitagawa Y, Japan Esophageal Oncology Group/Japan Clinical Oncology Group. A randomized controlled Phase III trial comparing 2-weekly docetaxel combined with cisplatin plus fluorouracil (2-weekly DCF) with cisplatin plus fluorouracil (CF) in patients with metastatic or recurrent esophageal cancer: rationale, design and methods of Japan Clinical Oncology Group study JCOG1314 (MIRACLE study). Jpn J Clin Oncol, 45:494-498, 2015

34. Tahara M, Fuse N, Mizusawa J, Sato A, Nihei K, Kanato K, Kato K, Yamazaki K, Muro K, Takaishi H, Boku N, Ohtsu A. Phase I/II trial of chemoradiotherapy with concurrent S-1 and cisplatin for clinical stage II/III esophageal carcinoma (JCOG 0604). Cancer Sci, 106:1414-1420, 2015

35. Kataoka K, Tokunaga M, Mizusawa J, Machida N, Katayama H, Shitara K, Tomita T, Nakamura K, Boku N, Sano T, Terashima M, Sasako M, Stomach Cancer Study Group/Japan Clinical Oncology Group. A randomized Phase II trial of systemic chemotherapy with and without trastuzumab followed by surgery in HER2-positive advanced gastric or esophagogastric junction adenocarcinoma with extensive lymph node metastasis: Japan Clinical Oncology Group study JCOG1301 (Trigger Study). Jpn J Clin Oncol, 45:1082-1086, 2015

36. Nakamura K, Kuwata T, Shimoda T, Mizusawa J, Katayama H, Kushima R, Taniguchi H, Sano T, Sasako M, Fukuda H. Determination of the optimal cutoff percentage of residual tumors to define the pathological response rate for gastric cancer treated with preoperative therapy (JCOG1004-A). Gastric Cancer, 18:597-604, 2015

37. Mizutani T, Tanaka M, Eba J, Mizusawa J, Fukuda H, Hanaoka N, Takeuchi M, Aoyama I, Kojima T, Takizawa K, Ono H, Muto M, Gastrointestinal Endoscopy Study Group of the Japan Clinical Oncology Group (JCOG). A Phase III study of oral steroid administration versus local steroid injection therapy for the prevention of esophageal stricture after endoscopic submucosal dissection (JCOG1217, Steroid EESD P3). Jpn J Clin Oncol, 45:1087-1090, 2015

Center for Education and Professional Career Development

Yuichiro Ohe, Hidehito Horinouchi, Tomonori Yano, Ayako Mori, Mayumi Tsukagoshi, Naoko Nishikimi, Hironobu Hashimoto, Tomohiko Aso, Yuzuru Kouno, Yoshihisa Abe, Satoshi Nakajima, Mayumi Miyauchi, Noriko Kobayashi, Miki Ito, Miho Kurihara, Kazue Hayasaka, Yasuhiko Ichida, Tetsuo Akimoto, Yoshihisa Muramatsu, Mitsuhiro Yoshida, Eichi Yoshikawa, Haruka Chitose, Miki Fukutani, Tosikazu Usijima, Gen Fujii, Takahiro Ochiya, Akihiro Sato, Noriko Yamashita, Taro Shibata, Hatoe Sakamoto, Kayoko Miyata, Kazuyuki Fukuda, Hiroji Yamakabe, Masaru Furuichi, Hideyuki Yoshizumi, Shinichi Kouno, Rie Nakashima, Namiko Aoshima, Miyoko Tanaka, Mika Asari, Yukiyo Fujita

Introduction

The Center for Education and Professional Career Development was established in July 2014. The purposes of the Center are nurturing and securing of able human resources, clarification of career paths in each type of job, and improvement of systematic educational programs. Under the director of the 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 conducts career path development of each professional, strategic securing of able professionals, and management of the information about alumnus. The Office for Graduate Medical Education conducts the promotion of the cooperative post-graduate school and management of the education program for residents. The Office for Professional Education Management conducts the planning of education programs for all the center staff, the planning and implementation of common training programs at the time of adoption, the planning and implementation of the individual education program for each professional field, and the management of attendance on various lectures.

The resident educational program of the National Cancer Center has a history of nearly 50 years, and has started the re-examination of the resident educational program to effectively produce more able cancer specialists. We carry out discussions to build a new resident educational program that can cope with the change of a new board certification system that will start in 2017.

Education

The cooperative post-graduate school program with Keio University and Juntendo University were started in 2012. In 2015, 16 and 55 post-graduate students, 71 in total, were registered at the cooperative post-graduate school program with Keio University and Juntendo University, respectively. Among them, 23 post-graduate students received a PhD.

Future prospects

The National Cancer Center has to nurture experts in a variety of job types to engage in medical treatment and cancer research, support cancer patients and provide such experts throughout Japan. It is also expected that we nurture able professionals who should be leaders in their field in the near future. We want to aim at the construction of a system performing personnel training by all types of jobs about medical treatment and cancer research, and support of cancer patients including office workers as well as doctors.

Innovation Center for Supportive, Palliative and Psychosocial Care

Yosuke Uchitomi, Yutaka Matsuoka, Takuhiro Yamaguchi, Kyoko Akutsu

Introduction

The scientific background about supportive, palliative and psychosocial care to reduce both physical and mental distress caused by cancer treatment and/or cancer itself is insufficient. In particular, the development of new medical interventions regarding symptom control in the progressive period and the end-of-life period are insufficient worldwide. We have many experience-based guidelines for pain, vomiting, fatigue, numbness, dysgeusia, insomnia, depression, anxiety and delirium, but said guidelines are not well supported by evidence. Developing a standard treatment based on scientific evidence for supportive, palliative and psychosocial care is our responsibility as a developed country. However, there isn't a secure base for conducting clinical research and developing a support organization in Japan. First, we made preparations to establish the Innovation Center for supportive, palliative and psychosocial care at the National Cancer Center Hospital Japan in 2015. Second, we are building J-SUPPORT [Japan Supportive, Palliative and Psychosocial Oncology Group] as an open hub for multi-institute collaborative clinical research for supportive, palliative and psychosocial care.

Routine activities

We cooperate in providing consultation services and expert advice on clinical research design and statistics to investigators as they launch new research projects in the field of supportive, palliative and psychosocial care. This service includes face-to-face clinical design and biostatistics consultation. In addition, we adjust collaborative studies with other study groups or institutions.

Research activities

We have made preparations to start J-SUPPORT. In particular, we organize operating structures, basic constitutions, and procedures to review study protocol. We classified a study implementing group into five regions: 1) medicine and device development, 2a) supportive care, 2b) palliative care, 3) psychosocial and behavioral care, 4) research methodology, 5) needs survey and implementation. First, we launched a protocol review committee, which was held in August and October 2015.

Future prospects

We plan to hold the protocol review committee regularly and are going to launch the J-SUPPORT website in spring 2016. According to a roadmap (Figure 1), we plan to expand J-SUPPORT as an open hub to contribute to the development of supportive, palliative and psychosocial care for cancer patients.

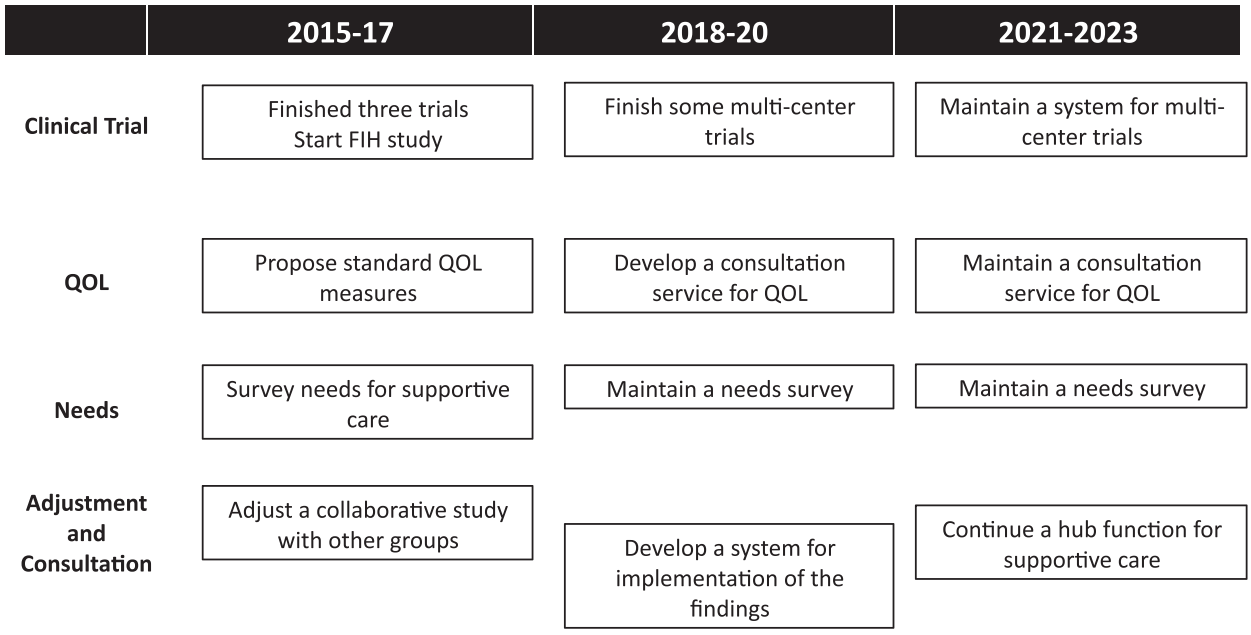


Figure 1. Roadmap of J-SUPPORT

List of papers published in 2015

Journal

1. Wada S, Shimizu K, Inoguchi H, Shimoda H, Yoshiuchi K, Akechi T, Uchida M, Ogawa A, Fujisawa D, Inoue S, Uchitomi Y, Matsushima E. The Association Between Depressive Symptoms and Age in Cancer Patients: A Multicenter Cross-Sectional Study. J Pain Symptom Manage, 50:768-777, 2015

2. Higuchi Y, Uchitomi Y, Fujimori M, Koyama T, Kataoka H, Kitamura Y, Sendo T, Inagaki M. Exploring autistic-like traits relating to empathic attitude and psychological distress in hospital pharmacists. Int J Clin Pharm, 37:1258-1266, 2015

3. Ishida M, Onishi H, Toyama H, Tsutsumi C, Endo C, Tanahashi I, Takahashi T, Uchitomi Y. Missing memories of death: Dissociative amnesia in the bereaved the day after a cancer death. Palliat Support Care, 13:1787-1790, 2015

4. Umezawa S, Fujimori M, Matsushima E, Kinoshita H, Uchitomi Y. Preferences of advanced cancer patients for communication on anticancer treatment cessation and the transition to palliative care. Cancer, 121:4240-4249, 2015

Office for Advanced Medical Care Evaluation

Yasuhiro Fujiwara, Kan Yonemori, Nobuko Ushirozawa, Seiichiro Yamamoto, Taro Shibata, Aya Kuchiba, Shogo Nomura, Natsuko Okita

Introduction

In November 2013, our Office was established by the NCC 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 for 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 the European Union, but not in Japan) for the understanding of drugs as a target of this system.