

# Sections Directed by President

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## OFFICE OF POLICY, STRATEGIC PLANNING BUREAU

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Yasuhiro Fujiwara, Yasuhiro Fujii, Chikara Tsukamoto, Teruhiko Yoshida, Toshikazu Ushijima, Tatsuhiro Shibata, Takashi Kono, Kenkichi Masutomi, Hisao Asamura, Minoru Esaki, Akira Kawai, Hidehito Horinouchi, Kenji Tamura, Miyuki Sone, Ken Ohashi, Ken Shimizu, Fumiko Mori, Yoshinori Makino, Nobuko Ushirozawa, Atsushi Ohtsu, Toshihiko Doi, Tetsuo Akimoto, Takayuki Yoshino, Akimasa Ito, Atsushi Ochiai, Takeharu Yamanaka, Katsuya Tsuchihara, Miho Kurahara, Yasuhiko Ichida, Fumihiko Wakao, Takahiro Higashi, Tatsuhiro Shibata, Hiroshi Kajino, Yasuhiro Kuroda, Yasunori Kikuchi, Kota Tagawa, Shoko Koike, Kiyotaka Watanabe, Miyako Horikoshi, Chie Shirai, Tomoe Yoneyama, Yuki Hatano, Seiichi Yamamoto, Sakiko Suzuki, Maria Imada

The underlining delineates members of the Office of Policy.

### Introduction

The Strategic Planning Bureau of the National Cancer Center (NCC) was established as a think tank to serve the President of the NCC. The Bureau works on: 1) Identifying the tasks faced by the NCC and the nation-wide challenges associated with controlling cancer in Japan; 2) Disseminating their findings to the Japanese industry, academia, and government; 3) Providing data that contribute to the nation's policy planning; and 4) Proposing policy, in cooperation with the Division of Health Services Research at the Center for Cancer Control and Information Services and the Department of Public Health Policy at the Research Center for Cancer Prevention and Screening.

In 2013, the Bureau completed three major tasks. First, we prepared a proposal to be submitted to the Panel of Experts on the Future of Cancer Research, which was chaired by our President. Second, we discussed the future directions of the NCC and compiled these into a report. Third, we established and documented an opinion on the role that the National Center should play among the Centers for Creating Innovative Medical Technologies, to be submitted to the Special Advisor Meeting on the Health and Medical Strategy for which our President serves as a special advisor.

### The future direction of cancer research

In the Panel of Experts on the Future of Cancer Research, which was chaired by the President, Dr. Hotta, and held from April 15 to August 9, 2013, we reported the results of our evaluation and analysis of the whole Research Program at the 3rd-term Comprehensive Strategy for Cancer Control. This was conducted under the 3rd-term Comprehensive 10-year Strategy for Cancer Control, at about the 8.5 year mark. An interim report, the "Future Direction of Cancer Research", was awarded the Health and Labour Sciences Research Grant and

was conducted as a designated program in the 3rd-term Comprehensive Strategy for Cancer Control. The Principal Investigator on the interim report was Tomomitsu Hotta. We also contributed to preparing a report issued by a panel of experts on the future of cancer research: "The Future Direction of Cancer Research—Radical Cures, Prevention, and Coexistence—Cancer Research Working in Partnership with Society" (August 2013, the Panel of Experts on the Future of Cancer Research) <http://www.mhlw.go.jp/stf/shingi/0000014994.html>.

### The future direction of the NCC

Since the end of 2012, the NCC has been discussing the future mission and role of our Center with respect to cancer control in Japan, considering the government's policy on cancer control as a whole, in order to make policy proposals to the President.

We have held 24 meetings of core members to discuss the NCC's current state and challenges, as well as future directions and required countermeasures for each issue. Also, we held five symposiums asking for honest opinions from outside experts on how NCC could improve.

Based on the above, we compiled a "Report on the Future Direction of the NCC" (Strategic Planning Bureau, October 25, 2013) and submitted it to the President.

Although we think that the role of the NCC may vary over time, considering the development of cancer control measures and scientific technologies in the world, we hope that the report will contribute to the President's current decisions on the NCC's direction. For some issues, we have only proposed alternative countermeasures.

We also feel that it is important that we continue to work as patient advocates, and that we advance this mission by having opportunities to regularly meet with and solicit feedback from patients and citizens receiving NCC's services.

<Archive of the Core Member Meeting of Strategic Planning Bureau (review meeting)>

1st	October 22, 2012 (Mon)
2nd	November 26, 2012 (Mon)
3rd	December 12, 2012 (Wed)
4th	January 11, 2013 (Wed)
5th	January 31, 2013 (Thu)
6th	February 25, 2013 (Mon)
7th	March 11, 2013 (Mon)
8th	April 1, 2013 (Tue)
9th	April 8, 2013 (Tue)
10th	April 22, 2013 (Mon)
11th	May 13, 2013 (Mon)
12nd	May 27, 2013 (Mon)
13th	June 10, 2013 (Mon)
14th	June 26, 2013 (Wed)
15th	July 9, 2013 (Tue)
16th	July 22, 2013 (Mon)
17th	August 5, 2013 (Mon)
18th	August 19, 2013 (Mon)
19th	August 26, 2013 (Mon)
20th	September 2, 2013 (Mon)
21th	September 12, 2013 (Thu)
22nd	September 17, 2013 (Tue)
23th	September 19, 2013 (Thu)
24th	October 1, 2013 (Tue)

< Archive of the Symposium “How should NCC be performing in the future?” >

- The 2nd symposium

April 15, 2013 (Mon)

Theme: The role of NCC in medical treatment and cultivating human resources

Symposiasts (honorific titles omitted):

Manabu Muto (Professor of the Department of Therapeutic Oncology, Kyoto University Graduate School of Medicine)

Kagami Yoshikazu (Professor of the Department of Radiology, School of Medicine, Showa University)

Hideo Kunito (Director of the Department of Respiratory Medicine of Mitsui Memorial Hospital)

Takeshi Sano (Director of the Department of Gastroenterological Surgery, the Cancer Institute Hospital of JFCR)

- The 3rd symposium

June 24, 2013 (Mon)

Theme: What can we expect from the NCC research projects?

Symposiasts (honorific titles omitted):

Kohei Miyazono (Dean and Professor, Graduate School of Medicine, The University of Tokyo)

Hiroyuki Mano (Professor, the Department of Cellular Signaling, Graduate School of Medicine, the University of Tokyo)

Keitaro Matsuo (Director of the Division of Epidemiology and Prevention, Aichi Cancer Center Research Institute)

Tomotaka Sobue (Professor of the Division of Environmental Medicine and Population Sciences, Department of Social and Environmental Medicine, Graduate School of Medicine, Osaka University)

- The 4th symposium

July 26, 2013 (Fri) Theme: The role to be played by and expectations for the NCC internationally

Symposiasts:

Dr. Jin Soo Lee (President of the National Cancer Center, Korea)

Dr. Ann Chao (Cancer research program director, Beijing Office of the National Cancer Institute, United States)

Dr. Patrick Johnston (Dean of the Medical School, Queen's University Belfast, United Kingdom)

Dr. Bruce A. Chabner (Clinical Research Director, Cancer Center of Massachusetts General Hospital, United States)

- The 5th symposium

September 24, 2013 (Tue)

Theme: Expectations for Nursing in the NCC

Symposiasts (honorific titles omitted):

Kazue Aoki (Vice President, Shizuoka Cancer Center)

Masako Akiyama (Director of Hakuju-ji Home Visit Nursing Station)

Noriko Morishita (Director of the National Hospital Organization Osaka Medical Center Clinical Research Center)

Hiroko Komatsu (Professor, Faculty of Nursing and Medical Care)

### **Preparation of the opinion to be submitted to the Special Advisor Meeting on Health and Medical Strategy**

We prepared an opinion on the significance of the NCC as a part of the Center for Creating Innovative Medical Technologies to be submitted by President Hotta, a member of the Special Advisor Meeting, to the Special Advisor Meeting on Health and Medical Strategy (<http://www.kantei.go.jp/jp/singi/kenkouiryou/sanyokaigou/kaisai.html>), which studies and discusses the growth strategy for the health and medical sectors and important issues associated with medical research.

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## OFFICE OF PUBLIC RELATIONS, STRATEGIC PLANNING BUREAU

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Kiyotaka Watanabe, Shinichiro Takahashi, Rika Kojima, Miyako Horikoshi, Chie Shirai, Kajitsu Ogawa, Yuki Hatano

### 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. Our task is management of the NCC homepage (<http://www.ncc.go.jp/>), publication of reports, coverage and delivery of press conferences and preparing press releases. By sharing the mission and vision between staff 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 Strategic Planning Bureau, we performed prompt decision making regarding the public relations policy; organized a PR committee and received information on the publicity work from each department; and drafted out the publication plan. Also, through distribution of intramural information for staff members, we shared vital messages via e-mail and/or bulletin boards to facilitate communication between the staff and the executive. We distributed information promptly by publishing and sharing press releases, press conference and seminars about novel treatment, research activities and notable accomplishments within NCC and elsewhere.

- Renewal of homepage (September): PR activities, event information, booklet, etc.
- Public information magazine "hibiho" (November): for patients in NCC Hospital and NCC Hospital East
- Revision of NCC pamphlet (June)
- Crisis control PR seminar for executive and staff (December)
- Support of events, seminars and distribution of public information (idea exhibition for daily life 2013, Black-Jack seminar 2013, the seventh NCC Hospital East campus day, etc.)
- Media support at press conferences, press releases and media coverage

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## OFFICE OF INTERNATIONAL AFFAIRS, STRATEGIC PLANNING BUREAU

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Seiichiro Yamamoto, Sakiko Suzuki, Maria Imada

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.

### Human resource development

The Office is preparing several MOUs (Memorandum Of Understanding) with cancer centers world-wide and will sign them next year. Along with the MOUs, we are planning to exchange staff and conduct collaborative research projects. This plan aims to develop human resources not only for medical doctors and researchers but also for staff in every department. As the first step, the office supported the dispatch of a medical oncologist to the US National Cancer Institute and is in preparation to send nurses to Massachusetts General Hospital next year.

### 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.

### Medical contributions

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 2013, the NCC has had 95 visiting fellows, 146 a-couple-of-days observers at both the Tsukiji (Tokyo) and Kashiwa (Pref. of Chiba) campuses. They came mostly from Asian countries. The Office has begun an alumni organization of fellows this year to allow us all to keep in contact.

As an another important topic, NCC supports several activities planned and conducted by the Japanese government such as the Ministry of Health, Labour, and Welfare and the Ministry of Economy, Trade and Industry for inbound and outbound expansion of Japanese medicine and cutting-edge medical technology.

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# MULTI-INSTITUTIONAL CLINICAL TRIAL SUPPORT CENTER

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**Haruhiko Fukuda, Taro Shibata, Kenichi Nakamura, Harumi Kaba, Hiroshi Katayama, Noriko Yamashita, Shogo Nomura, Atsuo Takashima**

## **Introduction**

The Multi-institutional Clinical Trial Support Center is a direct sector reporting directly to the President of the National Cancer Center. The Center supports multi-institutional clinical trials conducted by the Japan Clinical Oncology Group (JCOG) aiming to improve the standard treatment for cancer patients. The JCOG is a nationwide, multi-institutional, multi-disease, multi-modality cooperative study group supported by the National Cancer Center Research and Development Fund and the Health Sciences Research Grants from the Ministry of Health, Labour and Welfare. The JCOG has 16 disease-oriented or modality-oriented subgroups covering most cancer types except leukemia and pediatric cancer, and approximately 4,000 physicians from 200 hospitals participate in the JCOG.

The Clinical Investigations Section, Biostatistics and Epidemiology Section, Regulatory Science Section, Data Management Section, and Project Management Section of the Center are jointly managing the JCOG headquarters, the JCOG Data Center and the JCOG Operations Office, in collaboration with a non-profit organization named the Clinical Oncology Research and Education (CORE). The Center and the CORE support all JCOG trials for study design, protocol development, patient registration and randomization, data management, interim central monitoring, statistical analysis, adverse event reporting, quality assurance site visit audits, quality control of radiotherapy, central review of imaging and pathology, publication, and various kinds of peer-review based committee activities.

## **Routine activities**

At the end of 2013, the Center had supported 36 open trials, 30 trials on follow-up, 14 trials in preparation, and the yearly patient accrual was 2,827. As for safety management, 70 adverse event reports for serious and/or unexpected adverse events were submitted to and reviewed by the Data and Safety Monitoring Committee (DSMC). The DSMC also reviewed 3 interim analysis reports, and 68 protocol amendments/revisions. The Audit Committee made site visits for 56 sites in 18 hospitals, and a total of 166 cases were audited. A central pathology review is on-going in 5 trials (2 on lymphomas, 1 on osteosarcomas, 1 on lung cancer, and 1 on pancreatic cancer). The quality control program for radiotherapy continued in 13 trials. A web-based 24-hour online patient registration system is available in 31 trials among 36 open trials.

As for activities other than support of the JCOG, the Center also acts as the secretariat of the Clinical Trial Working Group (CTWG) under the Liaison Council of Prefectural Designated Cancer Care Hospitals. The CTWG aims to enhance the resources for investigator-initiated cancer clinical trials in the Designated Cancer Care Hospitals and to promote the efficiency of investigator-initiated cancer therapeutic development nationwide.

## **Research activities**

The Center is conducting intramural studies related to clinical trial methodology including statistical methods and data management, such as a timing analysis for streamlining clinical trial protocol development, a validity analysis of clinical tumor response and pathological tumor response by chemotherapy, an outcome analysis of institutional difference, a propensity score analysis comparing stereotactic body radiotherapy and lobectomy for operable clinical stage IA lung cancer, and a validity analysis of surrogate time-to-event endpoints.

## List of papers published in 2013 Journal

1. Kurokawa Y, Shibata T, Ando N, Seki S, Mukaida H, Fukuda H. Which is the optimal response criteria for evaluating preoperative treatment in esophageal cancer: RECIST or histology? *Ann Surg Oncol*, 20:3009-3014, 2013
2. Shirao K, Boku N, Yamada Y, Yamaguchi K, Doi T, Goto M, Nasu J, Denda T, Hamamoto Y, Takashima A, Fukuda H, Ohtsu A. Randomized Phase III study of 5-fluorouracil continuous infusion vs. sequential methotrexate and 5-fluorouracil therapy in far advanced gastric cancer with peritoneal metastasis (JCOG0106). *Jpn J Clin Oncol*, 43:972-980, 2013
3. Iwasaki Y, Sasako M, Yamamoto S, Nakamura K, Sano T, Katai H, Tsujinaka T, Nashimoto A, Fukushima N, Tsuburaya A. Phase II study of preoperative chemotherapy with S-1 and cisplatin followed by gastrectomy for clinically resectable type 4 and large type 3 gastric cancers (JCOG0210). *J Surg Oncol*, 107:741-745, 2013
4. Nakamura K, Katai H, Mizusawa J, Yoshikawa T, Ando M, Terashima M, Ito S, Takagi M, Takagane A, Ninomiya M, Fukushima N, Sasako M. A phase III study of laparoscopy-assisted versus open distal gastrectomy with nodal dissection for clinical stage IA/IB gastric Cancer (JCOG0912). *Jpn J Clin Oncol*, 43:324-327, 2013
5. Takizawa K, Takashima A, Kimura A, Mizusawa J, Hasuike N, Ono H, Terashima M, Muto M, Boku N, Sasako M, Fukuda H. A phase II clinical trial of endoscopic submucosal dissection for early gastric cancer of undifferentiated type: Japan Clinical Oncology Group study JCOG1009/1010. *Jpn J Clin Oncol*, 43:87-91, 2013
6. Mukai H, Watanabe T, Mitsumori M, Tsuda H, Nakamura S, Masuda N, Yamamoto N, Shibata T, Sato A, Iwata H, Aogi K. Final results of a safety and efficacy trial of preoperative sequential chemoradiation therapy for the nonsurgical treatment of early breast cancer: Japan Clinical Oncology Group Study JCOG0306. *Oncology*, 85:336-341, 2013
7. Ogura M, Itoh K, Ishizawa K, Kobayashi Y, Tobinai K, Kinoshita T, Hirano M, Ueda R, Shibata T, Nakamura S, Tsukasaki K, Hotta T, Shimoyama M, Morishima Y. Phase II study of ABV (doxorubicin with increased dose, bleomycin and vinblastine) therapy in newly diagnosed advanced-stage Hodgkin lymphoma: Japan Clinical Oncology Group study (JCOG9705). *Leuk Lymphoma*, 54:46-52, 2013
8. Shibui S, Narita Y, Mizusawa J, Beppu T, Ogasawara K, Sawamura Y, Kobayashi H, Nishikawa R, Mishima K, Muragaki Y, Maruyama T, Kuratsu J, Nakamura H, Kochi M, Minamida Y, Yamaki T, Kumabe T, Tominaga T, Kayama T, Sakurada K, Nagane M, Kobayashi K, Nakamura H, Ito T, Yazaki T, Sasaki H, Tanaka K, Takahashi H, Asai A, Todo T, Wakabayashi T, Takahashi J, Takano S, Fujimaki T, Sumi M, Miyakita Y, Nakazato Y, Sato A, Fukuda H, Nomura K. Randomized trial of chemoradiotherapy and adjuvant chemotherapy with nimustine (ACNU) versus nimustine plus procarbazine for newly diagnosed anaplastic astrocytoma and glioblastoma (JCOG0305). *Cancer Chemother Pharmacol*, 71:511-521, 2013
9. Morizane C, Okusaka T, Mizusawa J, Takashima A, Ueno M, Ikeda M, Hamamoto Y, Ishii H, Boku N, Furuse J. Randomized phase II study of gemcitabine plus S-1 versus S-1 in advanced biliary tract cancer: a Japan Clinical Oncology Group trial (JCOG 0805). *Cancer Sci*, 104:1211-1216, 2013
10. Yamada Y, Boku N, Nishina T, Yamaguchi K, Denda T, Tsuji A, Hamamoto Y, Konishi K, Tsuji Y, Amagai K, Ohkawa S, Fujita Y, Nishisaki H, Kawai H, Takashima A, Mizusawa J, Nakamura K, Ohtsu A. Impact of excision repair cross-complementing gene 1 (ERCC1) on the outcomes of patients with advanced gastric cancer: correlative study in Japan Clinical Oncology Group Trial JCOG9912. *Ann Oncol*, 24:2560-2565, 2013

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## DEPARTMENT OF BIOSTATISTICS

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Takeharu Yamanaka, Aya Kuchiba, Shogo Nomura, Seiichiro Yamamoto, Taro Shibata

### Introduction

The Department of Biostatistics was newly launched in July 2013. One of our major activities is to provide essential collaboration with medical researchers, from devising efficiently-designed research projects, driving studies, drawing up analytical plans, and implementing statistical analyses, to publishing the results. We target all types of medical research carried out in the National Cancer Center (NCC). As an interdisciplinary department shared by the entire NCC that covers both the Tsukiji and Kashiwa Campuses, our Department aims at providing cross-sectional and essential contributions.

### Routine activities

Biostatistics is a major field of statistics that focuses on medical and public hygiene research tasks, and studies how to collect data (design) and how best to draw information from the data (analysis). At the Department of Biostatistics, staff members take part in actual medical research projects, and provide the standard or the latest statistical methodologies, and, at the same time, use such experiences to identify on-site problems and develop new statistical methods using mathematical techniques. These two-way activities may be likened to the wheels of a car; indeed, our mission is to contribute to enhancing the quality and quantity of research carried out at the NCC through the two activities. As of December 31, 2013, the Department of Biostatistics is an organization comprising five expert biostatisticians, an impressive lineup that makes the Center one of the top research institutions in Japan and thus enables us to continue releasing high-quality research results.

### Research activities

Through joint research, we work to identify statistical problems that arise from various fields of application, and develop new research frameworks and mathematical models to solve those problems. After next year, we plan to successively publish our research results for statistical methodology. Our researchers tackle a broad range of themes, from clinical study methodologies to genomic analyses, and molecular epidemiology research, to name just a few. Besides, with the goal of training outstanding personnel who contribute to promoting clinical research and activating the center's clinical studies, we carry out diverse lectures and seminars on the methodology and practice of biostatistics and clinical research. Part of the content is already being distributed nationwide via the web (<http://www.icrweb.jp/>).



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## OFFICE FOR ADVANCED MEDICAL CARE EVALUATION

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**Yasuhiro Fujiwara, Kan Yonemori, Natsuko Okita, Takeharu Yamanaka, Seiichiro Yamamoto, Tatsuhiro Shibata, Aya Kuchiba, Shogo Nomura, Nobuko Ushirozawa**

### **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. Specifically, we assist

the said 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, Doxil (multiple myeloma) and <sup>131</sup>I-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.

# INTELLECTUAL PROPERTY AND RESEARCH ALLIANCE DIVISION

Shizuo Ao, Genta Ohno, Yuji Shinoda, Yasuo Murata, Reiko Takizaki, Shizuka Makino, Aki Okano, Hiroshi Sato

The National Cancer Center (NCC) promotes the development of cancer diagnosis and treatment, and the improvement of quality of life of cancer patients through its research results which are then made available to society. The Intellectual Property and Research Alliance (IPRA) promotes the practical use of diagnostic agents, therapeutic agents, and medical devices through translation of research results jointly with private companies and academia partners under collaborative research agreements with them.

## Activities

IPRA mainly performs activities such as acting as the administrative office for both the NCC Collaborative Research Review Committee and for the NCC Invention Review Committee. This includes the following:

1. Agreement administration including collaborative agreements, licensing agreements, material transfer agreements and confidential disclosure agreements, and so on.
2. Research results administration including inventions such as patent applications and their maintenance associated with acquisition of intellectual property rights and licensing.
3. Coordinating industry-academia partnerships.

The number of NCC's collaborative research

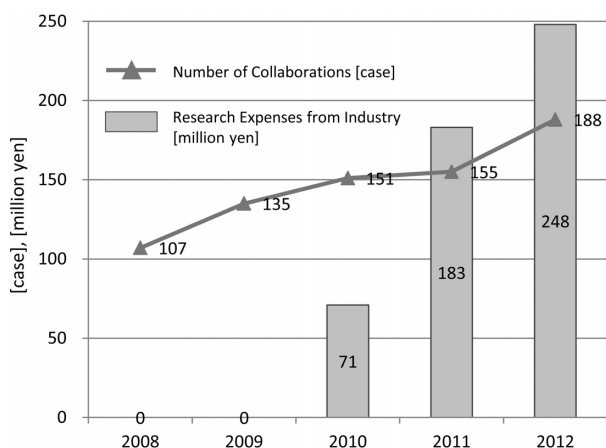


Figure 1. Collaborative Research with Industry

agreements and related research fees have been increasing significantly in recent years as shown in Figure 1: (1) The number of agreements Year 2011 (155), Year 2012 (188), (2) The total research fees Year 2011 (¥183 M), Year 2012 (¥248 M).

NCC has a number of patent applications with companies and academia research institutes. In order to focus on promising patents, NCC cuts its cost for the maintenance of patents or/patent applications from a practical perspective. As shown in Figure 2, The number of patent applications in 2012 was 36, the number of abandoned patent applications was 53 and the number of maintained patents and/or patent applications was 218. Compared to 2011 (235) the number of maintained patents and/or patent applications in Year 2012 dropped by 17.

## Patent applications

NCC's research results are globally significant and fulfill novel and inventive steps required for patentability.

Recent years have seen a large drop in the worth of patents concerning potential drug targets and screening methods which are not directly linked to the commercialization of products. NCC needs to promote translational research and to make a joint effort with pharmaceutical companies or academic research organizations to achieve commercially available products. Considering the

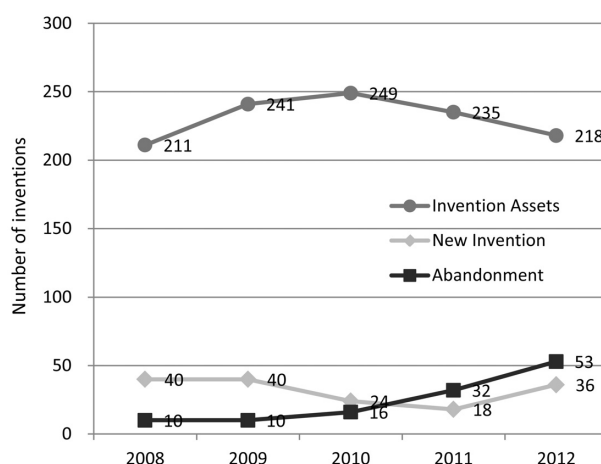


Figure 2. Invention Management

obstacle mentioned above, capability of assessment from the viewpoint of marketability is required in the implementation of a patent application. IPRA performs its duties at a high level, with four staff members having experience in research development, licensing and patents with pharmaceutical companies or medical device companies, and 3 staff members educated to doctoral level in related fields.

### Open innovation

In recent years independent companies have found it difficult to develop the technology related to diagnostic drugs and drug discovery on their own. Many companies used to have research and development strategies to complete research and development independently using their own internal resources. Companies now tend towards collaboration with external organizations such as NCC as a research partner.

The cases mentioned below are examples of the tendency of pharmaceutical companies toward collaboration with academia research institutes such as NCC as a research partner.

Daiichi Sankyo has started to fund to universities and academia research institutes to enter into drug discovery collaborative research (TaNeDS) with researchers at universities and academia research institutes in Japan. Astellas has A-cube, and Shionogi runs FINDS to provide grants to academia

institutes to enter into collaboration research.

After NCC's transformation into an independent administrative institution, it is important that NCC acquires external funds from industry besides its subsidized operating expenses and other competitive funds.

### Organizational academia-industry collaboration

IPRA is developing a system of organizational collaborative research with a partner company or academic institute to promote collaboration under its trend of openness on innovation.

IPRA supports more organizational and more effective collaborative research performance tailored to NCC's research capability and to partner company's or academic institutes' needs.

IPRA foresees the possibility of developing comprehensive collaborative research, and to further the research being performed by both industry researchers and NCC researchers. IPRA performs its activities with the aim of fulfilling such comprehensive research activities so that IPRA promotes collaboration with companies and academia research institutes such as Daiichi Sankyo, RIKEN for drug discovery research, Sysmex for diagnostic products development, Shimadzu for medical devices and AstraZeneca, Merck Serono for clinical trials and translational research.

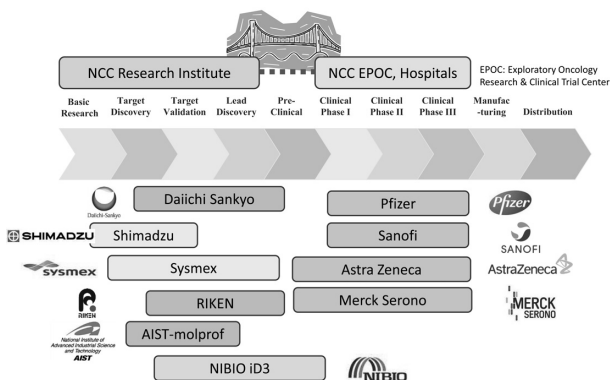


Figure 3. Strategic Alliance with industry

### Commercialized products by our research

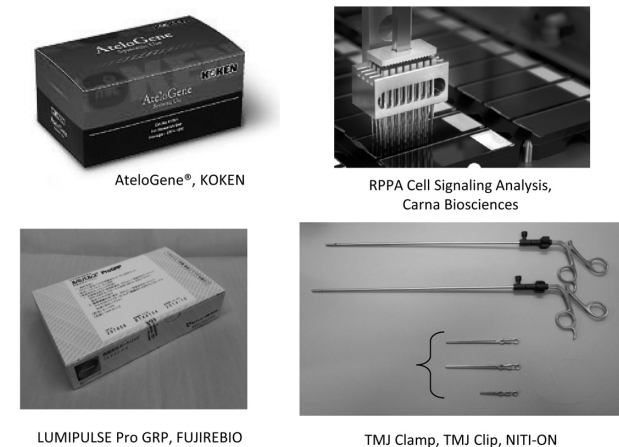


Figure 4. Commercialized products

**Press release in relation to academia-industry collaboration**

2013/11/07 Sanofi and NCC signed a partnership agreement for clinical trials.

2013/10/28 Sysmex and NCC signed a partnership agreement for the diagnostic drug development of cancer.

2013/09/24 Merck Serono and NCC signed a partnership agreement for clinical trials and translational research.

2013/07/04 Molecular Profiling Research Center for Drug Discovery of Advanced Industrial Science and Technology (AIST) and NCC signed a drug discovery research collaboration agreement.

2012/05/22 Daiichi Sankyo and NCC signed a comprehensive research alliance agreement in drug discovery.

2011/07/19 AstraZeneca and NCC signed a master clinical study agreement.

2011/06/05 Shimadzu and NCC signed a comprehensive collaborative research agreement.

2011/05/25 Pfizer Japan and NCC signed a partnership agreement for clinical trials.