Sections Directed by President

Strategic Planning Bureau

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Introduction

The Strategic Planning Bureau started as a think tank under the supervision of the president of the National Cancer Center in July, 2012. The mission assigned to the Strategic Planning Bureau has been to organize tasks involving not only our center, but also cancer control throughout Japan, and to construct policies for advising industry, government, and academia from the National Cancer Center.

The staff of the Strategic Planning Bureau consists primarily of young members who serve as chief physicians, deputy directors of research groups, or administrators responsible for front-line medical care or research. Therefore we are able to provide system which makes use of the problems which confront staff to make policies.

Multidisciplinary Research (MDR) Support Office: MDRSO

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Introduction

The Multidisciplinary Research Support Office (MDRSO) was set up on August 12, 2010, under the direct control of the Chief Director of the National Cancer Center to promote clinical research, public health research, and basic research and to help the NCC departments work closely together. To be specific, the MDRSO works on the Biobank, develops the infrastructure for research and conducts the audit for clinical studies and investigator initiated trials. The MDRSO also provides information that may be helpful to conduct research projects.

Routine activities

1. Biobank related office work

1) Preparation for Biobank organization

The MDRSO is involved with setting up a "National Cancer Center Biobank Coordination Committee" that constantly oversees the correct and consistent working of the National Cancer Center Biobank. After its establishment on January 13, 2011, the MDRSO works as this Committee's secretariat. The MDRSO reviewed the current system of research partnership requests, then coordinated and distributed the results throughout the NCC in the shift to a new system.

2) Research Concierge Desk

The MDRSO is in charge of asking hospital patients for their cooperation in research projects after giving them an adequate explanation. The MDRSO hired new two "Research Concierges" and trained them to be able to handle the explanation to patients. Seven thousand and nine new patients were approached this year, from whom 6,264 agreed to participate, giving a consent rate of 89.4%. Also the Concierges support new patients with processes such as explaining common preliminary diagnosis cards and infection tests. The MDRSO supported 7,841 new patients from January 4 through December 28.

3) National Cancer Center Biobank Coordination Committee Secretariat

The MDRSO works not only as a secretariat of the Committee, but also a supporter of working groups in many fields. The MDRSO organized 10 Coordination Committees in total and 9 WGs during the year. The MDRSO held one briefing session for newcomers to the Tsukiji campus on April17, and 154 staff members participated in the session.

Pertinent regulations for the NCC Biobank were updated 3 times for appropriately managing the NCC Biobank and the use of samples by researchers.

The MDRSO has released the Biobank website to the NCC staff on September 13, 2012. This website aims to enhance information about the NCC Biobank allowing sharing among all staff members.

Twenty six visitors from 5 agencies came to see the National Cancer Center Biobank.

2. Research infrastructure building and offering functions

1) Clinical research education

1)-1 Planning and coordinating for research ethics seminars

The MDRSO organized research ethics seminars three times for the NCC staff in cooperation with the Cancer Control Programs Administration Division. The total number of participants was 606 (Table 1).

Table 1. Research ethics seminars

Date	Mar 15, 2012	Apr 16, 2012	Oct 10, 2012
Programs & Speakers	Research Ethics and Human Research Protection by Dr. Akihiro Sato Application procedure for a new protocol by IRB Office	Lecture on the ethical guidelines for clinical Research by Dr. Akihiro Sato Research Ethics and Human Research Protection By Dr. Masashi Ando Application procedure for a new protocol by IRB Office	Research Ethics and Human Research Protection By Dr. Tsutomu Yonemori Application procedure for a new protocol by IRB Office
No. of Participants	104	376	126

1)-2 Management of the completion history of seminars by researchers

The MDRSO manages researchers' attendance history at research ethics seminars in a unified manner. The MDRSO also corresponds to helps researchers to give information about attendance history at research ethics seminars for 62 times.

1)-3 Creation of clinical research teaching materials

The MDRSO revised teaching materials on "Guidance on the Method of Clinical Trial Registration" and "How to write an informed consent form" then uploaded these to the NCC's internal server where researchers can easily access them.

2) Construction of quality control of, and the quality assurance system for clinical studies and invetigator initiated trials

2)-1 Arrangement of the acceptance procedure of the audit and monitoring from the outside

The MDRSO established Standard Operation Procedures (SOPs) on accepting audits and monitoring of clinical studies on March 7.

2)-2 Construction of the audit system for clinical studies and investigator initiated trials

The MDRSO is in charge of auditing investigator initiated trials conducted in accordance with GCP and clinical studies based on the ethical guidelines. SOPs for these audits were established on October 1. Four auditors have been appointed by the Head of NCC as of October 1.

3) Inquiry about clinical research for patients

The MDRSO started a system where receptionists primarily respond to inquiries, complaints and so on from patients regarding clinical studies and related matters.

The MDRSO has now started to serve as the first contact for patients who have complaints, questions and inquires about clinical studies. Two patients placed quieries by telephone, which were successfully answered by the MDRSO.

4) Planning for and coordinating of research conferences

To encourage joint research inside the NCC, the MDRSO planned and carried out 7 research conferences jointly with the Office for Strategic Initiatives (OSI), at which 19 researchers made presentations and led discussions. The speakers and the number of participants at each conference were as follows (Table 2).

5) Alliance / partnership activity support

The MDRSO held a meeting to support cooperative activities between the NCC researchers and companies that match alliance contracts, aiming for early development tests. (No. of participants: 35 on Dec 4)

Table 2. Research conferences

Date	Presenter	No. of Participant
Jan 16, 2012	Tetsuo Akimoto/Takahiro Ochiya	253
Feb 15, 2012	Tomotaka Sobue/Kenji Tamura	181
Jun 18, 2012	Yasuhide Yamada/ Toshikazu Ushijima/Toshihiko Doi	275
Jul 10, 2012	Takashi Kohno/Koichi Goto	276
Sep 11, 2012	Atsushi Ohtsu/Akihiro Sato /Noboru Yamamoto/Teruhiko Yoshida	247
Oct 9, 2012	Kazuaki Shimada /Shinichi Yachida/Daisuke Kubotae	205
Nov 13, 2012	Ryuzo Ueda / Yuji Heike/Tetsuya Nakatsura	255

Multi-institutional Clinical Trial Support Center

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Introduction

The Multi-institutional Clinical Trial Support Center is a sector reporting directly to the Chief Director 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 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 3,000 physicians from 190 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 kind of peer-review based committee activities.

Routine activities

At the end of 2012, the Center had supported 34 open trials, 22 trials on follow-up, 16 trials in preparation, and the yearly patient accrual was 2,985, which increased by 9% compared to 2011. As for safety management, 54 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 48 protocol amendments/revisions. The Audit Committee made site visits for 34 sites in 10 hospitals, and a total of 106 cases were audited. A central pathology review is on-going in 5 trials (2 on lymphomas, 1 on osteosarcomas, 1 on gastric 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 25 trials among 34 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 timing analysis of local Institutional Review Board approval, a timing analysis of publication after the final analysis report, the exploration of factors associated with serious adverse events, an association analysis between timeliness of case report form submission and protocol deviation, a validity analysis of clinical tumor response and pathological tumor response by chemotherapy, and a validity analysis of surrogate time-to-event endpoints.

List of papers published in 2012
Journal

1. Nakamura K, Shibata T, Takashima A, Yamamoto S, Fukuda H. Evaluation of three definitions of progression-free survival in preoperative cancer therapy (JCOG0801-A). Jpn J Clin Oncol, 42:896-902, 2012

2. Ando N, Kato H, Igaki H, Shinoda M, Ozawa S, Shimizu H, Nakamura T, Yabusaki H, Aoyama N, Kurita A, Ikeda K, Kanda T, Tsujinaka T, Nakamura K, Fukuda H. A randomized trial comparing postoperative adjuvant chemotherapy with cisplatin and 5-fluorouracil versus preoperative chemotherapy for localized advanced squamous cell carcinoma of the thoracic esophagus (JCOG9907). Ann Surg Oncol, 19:68-74, 2012

3. Niho S, Ohe Y, Ishikura S, Atagi S, Yokoyama A, Ichinose Y, Okamoto H, Takeda K, Shibata T, Tamura T, Saijo N, Fukuoka M. Induction chemotherapy followed by gefitinib and concurrent thoracic radiotherapy for unresectable locally advanced adenocarcinoma of the lung: a multicenter feasibility study (JCOG 0402). Ann Oncol, 23:2253-2258, 2012

4. Katayama H, Ito S, Sano T, Takahari D, Mizusawa J, Boku N, Tsuburaya A, Terashima M, Sasako M. A Phase II study of systemic chemotherapy with docetaxel, cisplatin, and S-1 (DCS) followed by surgery in gastric cancer patients with extensive lymph node metastasis: Japan Clinical Oncology Group study JCOG1002. Jpn J Clin Oncol, 42:556-559, 2012

5. Rossi A, Di Maio M, Chiodini P, Rudd RM, Okamoto H, Skarlos DV, Fruh M, Qian W, Tamura T, Samantas E, Shibata T, Perrone F, Gallo C, Gridelli C, Martelli O, Lee S-M. Carboplatin- or cisplatin-based chemotherapy in first-line treatment of small-cell lung cancer: the COCIS meta-analysis of individual patient data. J Clin Oncol, 30:1692-1698, 2012

6. Azuma T, Tobinai K, Takeyama K, Shibata T, Hidaka M, Kurosawa M, Kasai M, Chou T, Fukushima N, Mukai K, Tsukasaki K, Shimoyama M. Phase II study of intensive post-remission chemotherapy and stem cell transplantation for adult acute lymphoblastic leukemia and lymphoblastic lymphoma: Japan Clinical Oncology Group Study, JCOG9402. Jpn J Clin Oncol, 42:394-404, 2012

7. Matsumoto K, Katsumata N, Saito I, Shibata T, Konishi I, Fukuda H, Kamura T. Phase II study of oral etoposide and intravenous irinotecan for patients with platinum-resistant and taxane-pretreated ovarian cancer: Japan Clinical Oncology Group Study 0503. Jpn J Clin Oncol, 42:222-225, 2012

8. Kitagawa Y, Ando N, Nakamura K, Shibata T, Fukuda H. The role of adjuvant chemotherapy for localized squamous cell esophageal cancer: current Japanese standard and the unending role of the drawing board. Ann Surg Oncol, 19:1425-1427, 2012

9. Kagami Y, Itoh K, Tobinai K, Fukuda H, Mukai K, Chou T, Mikuni C, Kinoshita T, Fukushima N, Kiyama Y, Suzuki T, Sasaki T, Watanabe Y, Tsukasaki K, Hotta T, Shimoyama M, Ogura M. Phase II study of cyclophosphamide, doxorubicin, vincristine, prednisolone (CHOP) therapy for newly diagnosed patients with low- and low-intermediate risk, aggressive non-Hodgkin's lymphoma: final results of the Japan Clinical Oncology Group Study, JCOG9508. Int J Hematol, 96:74-83, 2012

10. Kunieda F, Kitamura H, Niwakawa M, Kuroiwa K, Shinohara N, Tobisu K, Nakamura K, Shibata T, Tsuzuki T, Tsukamoto T, Kakehi Y. Watchful waiting versus intravesical BCG therapy for high-grade pT1 bladder cancer with pT0 histology after second transurethral resection: Japan Clinical Oncology Group Study JCOG1019. Jpn J Clin Oncol, 42:1094-1098, 2012

11. Shien T, Nakamura K, Shibata T, Kinoshita T, Aogi K, Fujisawa T, Masuda N, Inoue K, Fukuda H, Iwata H. A randomized controlled trial comparing primary tumour resection plus systemic therapy with systemic therapy alone in metastatic breast cancer (PRIM-BC): Japan Clinical Oncology Group Study JCOG1017. Jpn J Clin Oncol, 42:970-973, 2012

12. Atagi S, Kawahara M, Yokoyama A, Okamoto H, Yamamoto N, Ohe Y, Sawa T, Ishikura S, Shibata T, Fukuda H, Saijo N, Tamura T. Thoracic radiotherapy with or without daily low-dose carboplatin in elderly patients with non-small-cell lung cancer: a randomised, controlled, phase 3 trial by the Japan Clinical Oncology Group (JCOG0301). Lancet Oncol, 13:671-678, 2012

International Contribution

Education and international contribution are one of the National Cancer Center's missions. From its very foundation, the NCC has widely accommodated international visiting fellows, mainly as clinical visiting fellows. Although most of them are not allowed to perform clinical work due to the law in Japan, the NCC attracts many visiting fellows.

The NCC has also been a longtime host institution for a group of doctors supported by the Japan International Cooperation Agency (JICA), the biggest Japanese organization supporting developing countries. In the year 2012, too, eight JICA doctors came and underwent training at the six divisions.

About half of the visiting fellows come to the Endoscopy and learn Endoscopic Submucosal Dissection and Chromo-Endoscopic Diagnosis, in which the NCC Endoscopy team takes the lead world-wide, whereas the majority of the rest join surgical departments and learn NCC's unique techniques. Radiation and Pathology are popular, too.

The duration is agreed upon by host divisions and fellows and is from 4 days, the minimal fellowship dates, to up to about one year. The NCC takes many short-term (1- 3 days) visitors, as well.

Most fellows come to the Tsukiji campus but the number of visiting fellows is on the rise at the Kashiwa campus, too.

The fellows are not limited to clinical fields. There are some research fellows, too. They come and join researchers working on studies at our Research Institute departments.

Following their warm welcome from the host divisions and the support they receive from fellowship administrators, overseas fellows complete their fellowship with high satisfaction. Some fellows come back to the NCC for further fellowship. As the NCC staff's international work continues, more and more fellows may continue to visit.

Annual JICA training "Latest Cancer Diagnosis and Treatment" 2012
Dates: October 22 to November 22, 2012
Number of fellows: 8
Countries: Armenia, Costa Rica, Macedonia, Nigeria, Serbia, Sri Lanka and Uruguay
Fellowship divisions:
Gynecology, Colorectal Surgery, Endoscopy, Radiology Oncology, Musculoskeletal Oncology, Thoracic Oncology

Table 1. Clinical and research visiting fellows by country

Citizenship	Number of fellows
Armenia	1
Benin	3
Bhutan	1
Brazil	6
China	25
Costa Rica	2
El Salvador	1
Germany	1
India	1
Indonesia	2
Iran	1
Iraq	1
Italy	2
Korea	6
Macedonia	1
Malaysia	1
Malta	1
Nigeria	1
Oman	1
Peru	2
Philippines	1
Russia	4
Serbia	1
Singapore	1
Spain	2
Sri Lanka	1
Taiwan	21
Thailand	4
Turkey	1
United Kingdom	5
United States	1
Uruguay	1
Total	103

January - December, 2012
Both campuses of Tsukiji and Kashiwa
short-term visitors are not included.