

Progress report 2015

## Department of Clinical Trial Data Management

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### Outline of Department

The Department of Clinical Trial Data Management was established in 2007 and carries out educational and research activities on Clinical Data Management (CDM) in collaboration with The Department of Biostatistics and The Clinical Research Support Center in University of Tokyo.

As compared to the situation of CDM in the United States and Europe, technical aspects (data collection, entry, check...) have been mainly focused in Japan. However, the essence of CDM which is to ensure quality of clinical data to appropriate level for fair and scientific evaluation, has not been recognized in many educational activities. CDM should be defined as a technical system to conduct clinical trials scientifically, ethically and efficiently and to draw correct conclusion and also as an academic discipline with theory and practice that applies statistics, quality control and clinical knowledge. It can optimize the whole clinical trial process, keep the level of data quality and cost appropriately.

One of our missions is to promote research on CDM aimed at improving the quality of clinical trials. Another important mission is to provide educations to clinical data

managers under the new educational system which can look around all the clinical trial process to adapt rapid change of medical environment and recent improvement of e-clinical trials.

### Educational activities

1. Clinical Research Methodology Seminar 2015. Linking EDC and other systems: Real word practice and challenges. November 13<sup>th</sup> 2015. The University of Tokyo Hospital. Tokyo, Japan

2. Division of Biostatistics, Tohoku University Graduate School of Medicine - Department of Clinical Trial Data Management, Graduate School of Medicine, The University of Tokyo Joint seminar on Data Management. February 5 2016. A2 Healthcare Corporation, Tokyo, Japan

### Research activities

1. Medical research consultation

We conducted medical research and biostatistical consultation to medical researchers and hospital staffs. Number of consultation requests in 2015 were below:

Table1. Number of consultation request in 2015.

	New item	Continued item
Biostatistical consultation	9	5
Medical research consultation	0	2

## 2. Data management and Statistical analysis support

We are supporting various clinical studies which are conducted in the University of Tokyo Hospital. For example our department supports “A clinical study of an oncolytic herpes simplex type 1 (HSV-1) G47delta for patients with castration resistant prostate cancer” which are conducted at Translational Research Center (TRAC) and Department of Urology in the University of Tokyo Hospital respectively. Moreover, we also have collaborative works with other universities and medical institutions for several clinical research. Finally, as the collaborative department of the Clinical Research Support Center (CresCent), we also involved in their projects as biostatisticians and clinical data managers.

## 3. SCDM Academia Task Force

As a member of Society for Clinical Data Management Academia Task Force, we are involved in a project which is fostering global network on academia data managers.

## Research Achievements

### Publication (English only)

1. Kinoshita H, Maeda I, Morita T, Miyashita M, Yamagishi A, Shirahige Y, Takebayashi T, Yamaguchi T, Igarashi A, Eguchi K. Place of death and the differences in patient quality of death and dying and caregiver burden. *Journal of Clinical Oncology* 2015; 33(4): 357-63.
2. Shiraya T, Kato S, Araki F, Yamaguchi T, Kaiya T. Comparison of burn sizes resulting from photocoagulation using a transpupillary laser and an endolaser. *Acta Ophthalmologica* 2015 Jan 7. doi:10.1111/aos.12656. [Epub ahead of print] No abstract available. PMID:25565294
3. Miyano K, Minami K, Yokoyama T, Ohbuchi K, Yamaguchi T, Murakami S, Shiraishi S, Yamamoto M, Matoba M, Uezono Y. Tramadol and its metabolite m1 selectively suppress transient receptor potential ankyrin 1 activity, but not transient receptor potential vanilloid 1 activity. *Anesthesia & Analgesia* 2015; 120(4): 790-8.
4. Kunimatsu-Sanuki S, Iwase A, Araie M, Aoki Y, Hara T, Nakazawa T, Yamaguchi T, Ono H, Sanuki T, Itoh M. An assessment of driving fitness in patients with visual impairment to understand the elevated risk of motor vehicle accidents. *BMJ Open* 2015; 5(2): e006379.

5. Aoki A, Tan X, Yamagishi R, Shinkai S, Obata R, Miyaji T, Yamaguchi T, Numaga J, Ito H, Yanagi Y. Risk Factors for Age-Related Macular Degeneration in an Elderly Japanese Population: The Hatoyama Study. *Investigative Ophthalmology & Visual Science* 2015; 56(4): 2580-5. PMID: 26105516
6. Kizawa Y, Morita T, Miyashita M, Shinjo T, Yamagishi A, Suzuki S, Kinoshita H, Shirahige Y, Yamaguchi T, Eguchi K. Improvements in Physicians' Knowledge, Difficulties, and Self-Reported Practice After a Regional Palliative Care Program. *Journal of Pain and Symptom Management* 2015; 50(2): 232-40.
7. Omodaka K, Takada N, Yamaguchi T, Takahashi H, Araie M, Nakazawa T. Characteristic correlations of the structure-function relationship in different glaucomatous disc types. *Japanese Journal of Ophthalmology* 2015; 59(4): 223-9.
8. Iwase S, Kawaguchi T, Yotsumoto D, Doi T, Miyara K, Odagiri H, Kitamura K, Ariyoshi K, Miyaji T, Ishiki H, Inoue K, Tsutsumi C, Sagara Y, Yamaguchi T. Efficacy and safety of an amino acid jelly containing coenzyme Q10 and L-carnitine in controlling fatigue in breast cancer patients receiving chemotherapy: a multi-institutional, randomized, exploratory trial (JORTC-CAM01). *Support Care in Cancer* 2015 Jun 24. [Epub ahead of print]
9. Takenaka K, Nishida T, Asano-Mori Y, Oshima K, Ohashi K, Mori T, Kanamori H, Miyamura K, Kato C, Kobayashi N, Uchida N, Nakamae H, Ichinohe T, Morishima Y, Suzuki R, Yamaguchi T, Fukuda T. Cytomegalovirus reactivation after allogeneic hematopoietic stem cell transplantation is associated with a reduced risk of relapse in patients with acute myeloid leukemia who survived to day 100 after transplantation: the Japan Society for Hematopoietic Cell Transplantation Transplantation-related Complication Working Group. *Biology of Blood and Marrow Transplantation* 2015 Jul 23. pii:S1083-8791(15)00496-6. doi: 10.1016/j.bbmt.2015.07.019. [Epub ahead of print] PMID: 26211985
10. Iwase S, Kawaguchi T, Tokoro A, Yamada K, Kanai Y, Matsuda Y, Kashiwaya Y, Okuma K, Inada S, Ariyoshi K, Miyaji T, Azuma K, Ishiki H, Unezaki S, Yamaguchi T. Assessment of Cancer-Related Fatigue, Pain, and Quality of Life in Cancer Patients at Palliative Care Team Referral: A Multicenter Observational Study (JORTC PAL-09). *PLoS One* 2015; 10(8): e0134022.
11. Kawaguchi T, Sekine Y, Azuma K, Yamaguchi T, Soeda H, Takeuchi H, Amano K, Fukutake K, Akashi T, Unezaki S. Quantitative assessment of the effect of pharmacist counseling

on decisional conflict - Analysis in the patients infected with human immunodeficiency virus -.Japanese Journal of Pharmaceutical Health Care and Sciences 2015; 39(12).

12. Miyaji T, Nagasawa M, Yamaguchi T, Tsutani K. Tackling the Pharmaceutical Frontier: Regulation of cannabinoid-based medicines in postwar Japan. Cannabis and Cannabinoid Research. January 2016, 1(1): 31-37.
13. Yamamoto D, Iwase S, Tsubota Y, Ariyoshi K, Kawaguchi T, Miyaji T, Sueoka N, Yamamoto C, Teramoto S, Odagiri H, Kitamura K, Nagumo Y, Yamaguchi T. Randomized study of orally administered fluorinated pyrimidines (capecitabine versus S-1) in women with metastatic or recurrent breast cancer: Japan Breast Cancer Research Network 05 Trial. Cancer Chemother Pharmacol. 2015 Jun;75(6):1183-9.
14. Ariyoshi K, Miyaji T, Maeda I, Iwase S, Yamaguchi T. Development of a Research Network and an Infrastructure for the Nationwide Registry Study in Palliative Care in Japan. Pharmacoepidemiol Drug Saf, 2015 Sep; 24(s1):455
15. Iwase S, Kawaguchi T, Miyaji T, Ishiki H, Ariyoshi K, Yamaguchi T. Assessment of Cancer-Related Fatigue, Pain, and Quality of Life in Cancer Patients after Palliative Care Team Referral: A Multicenter

Observational Study (JORTC PAL-09). J Clin Oncol 2015;33 (suppl; abstr e20550).

#### International Conference Presentation

1. Ariyoshi K, Miyaji T, Maeda I, Iwase S, Yamaguchi T. Development of a Research Network and an Infrastructure for the Nationwide Registry Study in Palliative Care in Japan. Poster presented at: 31st International Conference on Pharmacoepidemiology & Therapeutic Risk Management; 2015 Aug 22-26; Boston, MA, USA.