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Education: Bachelor of Engineering, Dept. of Transportation Engineering, Tokyo Univ. of Sci.,
1991

Master of Engineering, Dept. of Civil Engineering, Tokyo Univ. of Sci., 1993

Degree: Doctor of Engineering, Tokyo Univ. of Sci., 1999, Title of the Thesis: Design and
analysis of randomized clinical trials with recurrent events.

Employment: 1993.4-1995.3, Biostatistician, Rhone-Poulenc Rorer, Inc.

1998.4-2001.3, Research Associate, Department of Health Sciences, Oita University
of Nursing and Health Sciences

2001.4-2002.4, Assistant Professor, Department of Health Sciences, Oita University
of Nursing and Health Sciences

2002.5-2008.6, Associate Professor, Department of Pharmacoepidemiology, Kyoto
University School of Public Health

2008.7-2009.9, Associate Professor, Department of Data Science, The Institute of
Statistical Mathematics

2009.10-2013.3, Professor, Department of Data Science, The Institute of Statistical
Mathematics

2013.4-present, Professor, Department of Biostatistics, Nagoya University Graduate
School of Medicine

Research Themes: Design and analysis of clinical studies, Analysis of genomic data

Papers:

Research on biostatistical methodologies:

1. Matsui S, Ohashi Y. (1999). Analysis of recurrent events: Application to a clinical trial of colony stimulating factor with the endpoint of febrile neutropenia. *Statistics in Medicine*, 18, 2409-2420.

2. Matsui S, Miyagishi H. (1999). Design of clinical trials for recurrent events with periodic monitoring. *Statistics in Medicine*, 18, 3005-3020.
3. Matsui S. (2004). Analysis of times to repeated events in two-arm randomized trials with noncompliance and early withdrawal. *Biometrics*, 60, 965-976.
4. Matsui S. (2005). Sample size calculations for comparative clinical trials with over-dispersed Poisson process data. *Statistics in Medicine*, 24, 1339-1356.
5. Matsui S. (2005). Stratified analysis in randomized trials with noncompliance. *Biometrics*, 61, 816-823.
6. Matsui S. (2006). Reducing false positive findings in statistical analysis of pharmacogenomic biomarker studies using high-throughput technologies. *Current Drug Safety*, 1, 135-141.
7. Matsui S. (2006). Predicting survival outcomes using subsets of significant genes in prognostic marker studies with microarrays. *BMC Bioinformatics*, 7, 156.
8. Matsui S, Ito M, Nishiyama H, Uno H, Kotani H, Watanabe J, Guilford P, Reeve A, Fukushima M, Ogawa O. (2007). Genomic characterization of multiple clinical phenotypes of cancer using multivariate linear regression models. *Bioinformatics*, 23, 732-738.
9. Matsui S, Zeng S, Yamanaka T, Shaughnessy J. (2008). Sample size calculations based on ranking and selection in microarray experiments. *Biometrics*, 64, 217-226.
10. Matsui S, Yamanaka T, Barlogie B, Shaughnessy J, Crowley J. (2008). Clustering of significant genes in prognostic studies with microarrays: application to a clinical study for multiple myeloma. *Statistics in Medicine*, 27, 1106-1120.
11. Matsui S, Oura T. (2009). Sample sizes for a robust ranking and selection of genes in microarray experiments. *Statistics in Medicine*, 28, 2801-2816.
12. Oura T, Matsui S, Kawakami K. (2009). Sample size calculations for controlling the distribution of false discovery proportion in microarray experiments. *Biostatistics*, 10, 694-705.
13. Noma H, Matsui S, Omori T, Sato T. (2010). Bayesian ranking and selection methods using hierarchical mixture models in microarray studies. *Biostatistics*, 11, 281-289.
14. Noma H, Matsui S. (2010). Optimality of gene ranking based on univariate P-values for detecting differentially expressed genes. *Japanese Journal of Biometrics*, 31, 13-21.
15. Matsui S, Noma H. (2011). Estimation and selection in high-dimensional genomic studies for developing molecular diagnostics. *Biostatistics*, 12, 223-233.
16. Matsui S, Noma H. (2011). Estimating effect sizes of differentially expressed genes for power and sample size assessments in microarray experiments. *Biometrics*, 67, 1225-1235.
17. Noma H, Matsui S. (2012). The optimal discovery procedure in multiple significance testing: an empirical Bayes approach. *Statistics in Medicine*, 31, 165-176.
18. Matsui S, Simon R, Qu P, Shaughnessy J, Barlogie B, Crowley J. (2012). Developing and validating continuous genomic signatures in randomized clinical trials for predictive medicine.

Clinical Cancer Research, 18, 6065-6073.

19. Noma H, Matsui S. (2013). Empirical Bayes ranking and selection methods via semiparametric hierarchical mixture models in microarray studies. *Statistics in Medicine*, 32, 1904-1916.
20. Mori K, Oura T, Noma H, Matsui S. (2013). Cancer outlier analysis based on mixture modeling of gene expression data. *Computational and Mathematical Methods in Medicine*, Article ID: 693901.
21. Noma H, Matsui S. (2013). An empirical Bayes optimal discovery procedure based on semiparametric hierarchical mixture models. *Computational and Mathematical Methods in Medicine*, Article ID: 568480.
22. Matsui S. (2013). Genomic biomarkers for personalized medicine: development and validation in clinical studies. *Computational and Mathematical Methods in Medicine*, Article ID: 865980.

Practice of biostatistics:

23. Shinohara M, Toyokuni S, Morimoto T, Matsui S, Honjo T, Shinohara T. (2003). Functional assessment of self-renewal activity of male germline stem cells following cytotoxic damage and serial transplantation. *Biology of Reproduction*, 68, 1801-1807.
24. Matsui S, Sadaike T, Hamada C, Fukushima M. (2005). Creutzfeldt-Jakob disease and cadaveric dura mater grafts in Japan: an updated analysis of incubation time. *Neuroepidemiology*, 24, 22-25.
25. Sakai R, Matsui S, Fukushima M, Yasuda H, Miyauchi H, Miyachi Y. (2005). Prognostic factor analysis for plaque psoriasis. *Dermatology*, 211, 103-106.
26. Watanabe D, Suzuma K, Matsui S, Kurimoto M, Kiryu J, Kita M, Suzuma I, Ohashi H, Ojima T, Murakami T, Kobayashi T, Masuda S, Nagao M, Yoshimura N, Takagi H. (2005). Erythropoietin as a retinal angiogenic factor in proliferative diabetic retinopathy. *New England Journal of Medicine*, 353, 782-792.
27. Manzoni P, Maestri A, Gomirato G, Takagi H, Watanabe D, Matsui S. (2005). Erythropoietin as a retinal angiogenic factor. *New England Journal of Medicine*, 353, 2190-2191; author reply 2190-2191.
28. Nishimura T, Tada H, Nakagawa M, Teramukai S, Matsui S, Fukushima M. (2006). Lessons from gefitinib-induced interstitial lung disease in Japan and proposal for the prevention of serious drug-induced suffering: Problems in approval, pharmacovigilance, and regulatory decision-making procedures. *Pharmacy Practice*, 4, 168-178.
29. Ito M, Nishiyama H, Kawanishi H, Matsui S, Guilford P, Reeve A, Ogawa O. (2007). P21-activated kinase 1: a new molecular marker for intravesical recurrence after transurethral resection of bladder cancer. *Journal of Urology*, 178, 1073-1079.
30. Tada H, Matsui S, Kawahara M, Hosoe S, Hamada C, Fukushima M. (2008). Efficacy, toxicity

and cost analysis for non-platinum triplet (gemcitabine and vinorelbine followed by docetaxel) vs. platinum-based chemotherapy in IIIB/IV non-small cell lung cancer: Single institution experience. *European Journal of Cancer Care*, 17, 120-126.

31. Tsubouchi M, Morishita R, Tabata Y, Matsui S, Kawakami K. (2008). Critical issues for effective collaboration between academia and industry in the field of regenerative medicine in Japan. *Regenerative Medicine*, 3, 497-504.
32. Tsubouchi M, Matsui S, Banno Y, Kurokawa K, Kawakami K. (2008). Overview of the clinical application of regenerative medicine products in Japan. *Health Policy*, 88, 62-72.
33. Yamashita S, Hbujo H, Arai H, Harada-Shiba M, Matsui S, Fukushima M, Saito Y, Kita T, Matsuzawa Y. (2008). Long-term probucol treatment prevents secondary cardiovascular events: a cohort study of patients with heterozygous familial hypercholesterolemia in Japan. *Journal of Atherosclerosis Thrombosis*, 15, 292-303.
34. Yamaguchi K, Mandai M, Oura T, Matsumura N, Hamanishi J, Baba T, Matsui S, Murphy SK, Konishi I. (2010). Identification of an ovarian clear cell carcinoma gene signature that reflects inherent disease biology and the carcinogenic processes. *Oncogene*, 29, 1741-1752.
35. Yoshimura K, Kamoto T, Ogawa O, Matsui S, Tsuchiya N, Tada H, Murata K, Yoshimura K, Habuchi T, Fukushima M. (2010). Medical mushrooms used for biochemical failure after radical treatment for prostate cancer: An open-label study. *International Journal of Urology*, 17, 548-554.
36. Matsumura N, Mandai M, Okamoto T, Yamaguchi K, Yamamura S, Oura T, Baba T, Hamanishi J, Kang HS, Matsui S, Mori S, Murphy SK, Konishi I. (2010). Sorafenib efficacy in ovarian clear cell carcinoma revealed by transcriptome profiling. *Cancer Science*, 101, 2658-2663.
37. Sugano K, Matsumoto Y, Itabashi T, Abe S, Sakaki N, Ashida K, Mizokami Y, Chiba T, Matsui S, Kanto T, Shimada K, Uchiyama S, Uemura N, Hiramatsu N. for the Lansoprazole Ulcer Prevention Study Group (Low-Dose Aspirin Therapy). (2011). Lansoprazole for secondary prevention of gastric or duodenal ulcers associated with long-term low-dose aspirin therapy: Results of a prospective, multicenter, double-blind, randomized, double-dummy, active-control trial. *Journal of Gastroenterology*, 46, 724-735.
38. Shoji S, Suzuki M, Tomono Y, Bockbrader HN, Matsui S. (2011). Population pharmacokinetics of pregabalin in healthy subjects and patients with postherpetic neuralgia or diabetic peripheral neuropathy. *British Journal of Clinical Pharmacology*, 72, 63-76.
39. Sugano K, Kontani T, Katsuo S, Takei Y, Sakaki N, Ashida K, Mizokami Y, Asaka M, Matsui S, Kanto T, Soen S, Takeuchi T, Hiraishi H, Hiramatsu N. (2012). Lansoprazole for secondary prevention of gastric or duodenal ulcers associated with long-term non-steroidal anti-inflammatory drug (NSAID) therapy: Results of a prospective, multicenter, double-blind, randomized, double-dummy, active-controlled trial. *Journal of Gastroenterology*, 47, 540-552.

40. Negoro H, Kanematsu A, Doi M, Suadicani SO, Matsuo M, Imamura M, Okinami T, Nishikawa N, Oura T, Matsui S, Seo K, Tainaka M, Urabe S, Kiyokage E, Todo T, Okamura H, Tabata Y, Ogawa O. (2012). Involvement of urinary bladder Connexin43 and the circadian clock in coordination of diurnal micturition rhythm. *Nature Communications*, 3: 809.
41. Ishiguro M, Mochizuki H, Tomita N, Shimada Y, Takahashi K, Kotake K, Watanabe M, Kanemitsu Y, Ueno H, Ishikawa T, Uetake H, Matsui S, Teramukai S, Sugihara K. (2012). Study protocol of the SACURA trial: a randomized phase III trial of efficacy and safety of UFT as adjuvant chemotherapy for stage II colon cancer. *BMC Cancer*, 12:281.
42. Sakaki N, Ashida K, Mizokami Y, Asaka M, Matsui S, Kanto T, Hiraishi H, Hiramatsu N, Sugano K. (2012). Endoscopic evaluation of non-steroidal anti-inflammatory drug (NSAID)-induced gastric and duodenal ulcers during prophylaxis with lansoprazole. *Journal of Gastroenterology and Hepatology Research*, 1, 260-265.
43. Kokubo T, Matsui S, Ishiguro M. (2013). Meta-analysis of oro-cecal transit time in fasting subjects. *Pharmaceutical Research*, 30, 402-411.
44. Atagi S, Katakami N, Yoshioka H, Fukuoka M, Kudoh S, Ogiwara A, Imai M, Ueda M, Matsui S. (2013). Nested case control study of proteomic biomarkers for interstitial lung disease in Japanese patients with non-small-cell lung cancer treated with erlotinib: a multicenter phase 4 study (JO21661). *Clinical Lung Cancer*, 14, 407-417.
45. Tsuchiya N, Matsui S, Narita S, Kamba T, Mitsuzuka K, Hatakeyama S, Horikawa Y, Inoue T, Saito S, Ohyama C, Arai Y, Ogawa O, Habuchi T. (2013). Distinct cancer-specific survival in metastatic prostate cancer patients classified by a panel of single nucleotide polymorphisms of cancer-associated genes. *Genes & Cancer* (In press).

Books/Book chapters:

1. Matsui S. (2006). Statistical applications using DNA microarrays for cancer diagnosis and prognosis, *Handbook of Statistics in Clinical Oncology*, 2nd edn. (eds J.J. Crowley and D.P. Ankerst), CRC Press, Boca Raton.
2. Matsui S, Noma H. (2012). Analysis of DNA microarrays, *Handbook of Statistics in Clinical Oncology*, 3rd edn. (eds JJ. Crowley and A Hoering), CRC Press, Boca Raton.
3. Noma H, Matsui S. (2012). Bayesian Ranking and Selection Methods in Microarray Studies, *Statistical Diagnostics for Cancer*. (eds M. Dehmer and F. Emmert-Streib), Wiley.
4. Matsui S, Nonaka T, Choai Y. (2013). Design of phase III clinical trials with predictive biomarkers for personalized medicine. *Developments in Statistical Evaluation of Clinical Trials*, Springer. (In press)
5. Hirakawa A, Matsui S. (2013). Dose-finding for two-agent combination phase I trials. *Developments in Statistical Evaluation of Clinical Trials*, Springer. (In press)

6. Matsui S, Buyse M, Simon R. Design and Analysis of Clinical Trials for Predictive Medicine. CRC Press (To Appear in 2014)

Membership of Academic Societies:

International Biometric Society, American Statistical Association, Japan Statistical Society, The Biometric Society of Japan, Japanese Society of Applied Statistics, Japanese Society of Public Health

Professional Services:

Visiting Researcher, Translational Research Informatics Center, Foundation for Biomedical Research and Innovation (2002-present)

The International Biometric Society, Representative Council Member (2011-2014), Nominating Committee (2013-2014)

Current Drug Safety Editorial Board (2005-present)

Japanese Journal of Clinical Oncology Review Board (2005-present)

The Biometric Society of Japan, Director (2007-2014)

Japanese Journal of Biometrics, Editor-in-chief (2009-2014)