

CURRICULUM VITAE

Shigeyuki MATSUI, Ph.D.

Professor, Department of Biostatistics,
Nagoya University Graduate School of Medicine
65 Tsurumai-cho, Chuo-ku, Nagoya, Japan
Tel/Fax: +81-52-744-2487/2489
E-mail: smatsui(at)med.nagoya-u.ac.jp

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

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)

Annals of Oncology Review Board (2015-present)

Japanese Journal of Biometrics, Editor-in-chief (2009-2016)

Japanese Journal of Statistics and Data Science, Coordinating Editor (2018-2019)

The Biometric Society of Japan, Director (2007-2018), President (2019-2020)

Books:

1. Matsui S, Buyse M, Simon R (Editors). Design and Analysis of Clinical Trials for Predictive Medicine. CRC Press, 2015.
2. Matsui S, Crowley J (Editors). Frontiers of Biostatistical Methods and Applications in Clinical Oncology, Springer, 2017.
3. Hirakawa A, Sato H, Daimon T, Matsui S. Modern Dose-Finding Designs for Cancer Phase I Trials: Drug Combination and Molecularly Targeted Agents. Springer, 2018
4. Emura T, Chen YH, Matsui S, Rondeau V. Survival Analysis with Correlated Endpoints: Joint Frailty-Copula Models, Springer, 2019.
5. Daimon T, Hirakawa A, Matsui S. Dose-Finding Designs for Early-Phase Cancer Clinical Trials: A Brief Guidebook to Theory and Practice, Springer, 2019.

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. (2014). Design of phase III clinical trials with predictive biomarkers for personalized medicine. In Developments in Statistical Evaluation of Clinical Trials (eds K. van Montfort, J. Oud, W. Ghidney), Springer.

5. Hirakawa A, Matsui S. (2014). Dose-finding for two-agent combination phase I trials. In *Developments in Statistical Evaluation of Clinical Trials* (eds K. van Montfort, J. Oud, W. Ghiddey), Springer.
6. Simon R, Matsui S., Buyse M. (2015). Clinical trials for predictive medicine: new paradigms and challenges. In *Design and Analysis of Clinical Trials for Predictive Medicine*. (eds. S. Matsui, M. Buyse, R. Simon), CRC Press.
7. Daimon T, Hirakawa A, Matsui S. (2015). Phase I dose-finding designs and their applicability to targeted therapies. In *Design and Analysis of Clinical Trials for Predictive Medicine*. (eds. S. Matsui, M. Buyse, R. Simon), CRC Press.
8. Matsui S., Choai Y, Nonaka T. (2015). Phase III all-comers clinical trials with a predictive biomarker. In *Design and Analysis of Clinical Trials for Predictive Medicine*. (eds. S. Matsui, M. Buyse, R. Simon), CRC Press.
9. Matsui S. (2015). Statistical issues in clinical development and validation of genomic signatures. In *Design and Analysis of Clinical Trials for Predictive Medicine*. (eds. S. Matsui, M. Buyse, R. Simon), CRC Press.
10. Noma H, Matsui S. (2015). Univariate analysis for gene screening: beyond the multiple testing. In *Design and Analysis of Clinical Trials for Predictive Medicine*. (eds. S. Matsui, M. Buyse, R. Simon), CRC Press.
11. Matsui S. (2015). Development and validation of continuous genomic signatures in randomized clinical trials. In *Design and Analysis of Clinical Trials for Predictive Medicine*. (eds. S. Matsui, M. Buyse, R. Simon), CRC Press.
12. Matsui S. (2017). Phase III clinical trial designs incorporating predictive biomarkers: an overview. In *Frontiers of Biostatistical Methods and Applications in Clinical Oncology*. (eds. S. Matsui, J. Crowley), Springer.
13. Matsui S., Igeta M, Toyoizumi K. (2019). Biomarker-based phase II and III clinical trials in oncology. In *Textbook of Clinical Trials in Oncology*. (eds. S. Halabi and S. Michiels), CRC Press.

Research Papers

Methodologies in Biostatistics:

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.
23. Hirakawa A, Hamada C, Matsui S. (2013). A dose-finding approach based on shrunken predictive probability for combinations of two agents in phase I trials. *Statistics in Medicine*, 32, 4515-4525.
24. Matsui S, Choai Y, Nonaka T. (2014). Comparison of statistical analysis plans in randomize-all phase III trials with a predictive biomarker. *Clinical Cancer Research* 20, 2820-2830.
25. Hirakawa A, Matsui S. (2014). Response to Letter to the Editor by Drs Wages et al. *Statistics in Medicine*, 33, 12.
26. Hirakawa A, Wages NA, Sato H, Matsui S. (2015). A comparative study of adaptive dose-finding designs for phase I oncology trials of combination therapies. *Statistics in Medicine* 34, 3194-3213.
27. Hirakawa A, Matsui S. (2015). Operating characteristics of restrictions on skipping dose level for adaptive dose-finding method in two-agent phase I trials. *Japanese Journal of Biometrics*, 36, 1-12.
28. Choai Y, Matsui S. (2015). Estimation of treatment effects in all-comers randomized clinical trials with a predictive marker. *Biometrics* 71, 25-32.
29. Noma H, Tanaka S, Matsui S, Cipriani A, Furukawa TA. (2017). Quantifying indirect evidence in network meta-analysis. *Statistics in Medicine* 36, 917-927.
30. Sugasawa S, Noma H, Otani T, Nishino J, Matsui S. (2017). An efficient and flexible test for rare variant effects. *European Journal of Human Genetics* 25, 752-757.
31. Toyozumi K, Matsui S. (2017). Correcting estimation bias in randomized clinical trials with a test of treatment-by-biomarker interaction. *Statistics in Biopharmaceutical Research* 9, 172-179.
32. Matsui S, Crowley J. (2018). Biomarker-stratified phase III clinical trials: enhancement with a subgroup-focused sequential design. *Clinical Cancer Research* 24, 994-1001.
33. Matsui S, Noma H, Qu P, Yoshio Sakai, Matsui K, Heuck C, Crowley J. (2018). Multi-subgroup gene screening using semi-parametric hierarchical mixture models and the optimal discovery procedure: application to a randomized clinical trial in multiple myeloma. *Biometrics* 74, 313-320.
34. Emura T, Nakatochi M, Matsui S, Michimae H, Rondeau V. (2018). Personalized dynamic prediction of death according to tumour progression and high-dimensional genetic factors: Meta-analysis with a joint model. *Statistical Methods in Medical Research* 27, 2842-2858.
35. Otani T, Noma H, Nishino J, Matsui S. (2018). Re-assessment of multiple testing strategies for more efficient genome-wide association studies. *European Journal of Human Genetics* 26, 1038-

1048.

36. Shimamura F, Hamada C, Matsui S, Hirakawa A. (2018). Two-stage approach based on zone and dose findings for two-agent combination phase I/II trials. *Journal of Biopharmaceutical Statistics* 8:1-13.
37. Igeta M, Takahashi K, Matsui S. (2018). Power and sample size calculation incorporating misspecifications of the variance function in comparative clinical trials with over-dispersed count data. *Biometrics* 74, 1459-1467.
38. Nishino J, Ochi H, Kochi Y, Tsunoda T, Matsui S. (2018). Sample size for successful genome-wide association study of major depressive disorder. *Frontiers in Genetics* 9: 227.
39. Nishino J, Kochi Y, Shigemizu D, Kato M, Ikari K, Ochi H, Noma H, Matsui K, Morizono T, Boroevich K, Tsunoda T, Matsui S. (2018). Empirical Bayes estimation of semi-parametric hierarchical mixture models for unbiased characterization of polygenic disease architectures. *Frontiers in Genetics* 9: 115.
40. Otani T, Noma H, Sugasawa S, Kuchiba A, Goto A, Yamaji T, Kochi Y, Iwasaki M, Matsui S, Tsunoda T. (2019). Exploring predictive biomarkers from clinical genome-wide association studies via multidimensional hierarchical mixture models. *European Journal of Human Genetics* 27, 140-149.
41. Emura T, Matsui S, Chen HY. (2019). compound.Cox: univariate feature selection and compound covariate for predicting survival. *Computer Methods and Programs in Biomedicine* 168, 21-37.
42. Nonaka T, Igeta M, Matsui S. (2019). Statistical testing strategies for assessing treatment efficacy and marker accuracy in phase III trials. *Pharmaceutical Statistics* 18, 459-475.
43. Kawabata T, Emoto R, Nishino J, Takahashi K, Matsui S. (2019). Two-stage analysis for selecting fixed numbers of features in omics association studies. *Statistics in Medicine* 20; 38, 2956-2971.

Practice of Biostatistics:

44. 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.
45. 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.
46. Sakai R, Matsui S, Fukushima M, Yasuda H, Miyauchi H, Miyachi Y. (2005). Prognostic factor analysis for plaque psoriasis. *Dermatology*, 211, 103-106.
47. 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.
48. 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.
 49. 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.
 50. 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.
 51. 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.
 52. 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.
 53. 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.
 54. 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.
 55. 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.
 56. 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.
 57. 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.
 58. 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.
59. 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.
 60. 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.
 61. 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.
 62. 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.
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 64. Kokubo T, Matsui S, Ishiguro M. (2013). Meta-analysis of oro-cecal transit time in fasting subjects. *Pharmaceutical Research*, 30, 402-411.
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 67. Nakashima T, Sato H, Gyo K, Hato N, Yoshida T, Shimono M, Teranishi M, Sone M, Fukunaga Y, Kobashi G, Takahashi K, Matsui S, Ogawa K. (2014). Idiopathic sudden sensorineural hearing loss in Japan. *Acta Oto-Laryngologica*, 134, 1158-1163.

68. Nakamura T, Matsumoto T, Sugimoto T, Hosoi T, Miki T, Gorai I, Yoshikawa H, Tanaka Y, Tanaka S, Sone T, Nakano T, Ito M, Matsui S, Yoneda T, Takami H, Watanabe K, Osakabe T, Shiraki M, Fukunaga M. (2014). Fracture risk reduction with denosumab in Japanese postmenopausal women and men with osteoporosis: denosumab fracture intervention randomized placebo controlled trial (DIRECT). *J Clin Endocrinol Metab.*, 99, 2599-2607.
69. Yanagida K, Iwase T, Yamamoto K, Ra E, Kaneko H, Murotani K, Matsui S, Terasaki H. (2015). Sex-related differences in ocular blood flow of healthy subjects using laser speckle flowgraphy. *Invest Ophthalmol Vis Sci.* 56, 4880-4890.
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76. Nishikimi M, Matsuda N, Matsui K, Takahashi K, Ejima T, Liu K, Ogura T, Higashi M, Umino H, Makishi G, Numaguchi A, Matsushima S, Tokuyama H, Nakamura M, Matsui S. (2016). CAST: a new score for early prediction of neurological outcomes after cardiac arrest before therapeutic hypothermia with high accuracy. *Intensive Care Med.* 42, 2106-2107.
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- Humphrey Field Analyzer 10-2 in patients with Retinitis Pigmentosa. *Scientific Reports* 7, 16383.
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- of hypoxic encephalopathy on early CT images in patients with post-cardiac arrest syndrome. *Resuscitation* 128, 11-15.
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