

Biographical Sketch for the nomination of ISoP Board Member  
Yusuke Tanigawara, Ph.D.  
Professor of Clinical Pharmacokinetics and Pharmacodynamics,  
Keio University School of Medicine, Tokyo, Japan.

I am pleased to submit an application document for the nomination of ISoP Board Member. I am ready to serve as an ISoP Board Member for the following reasons:



- 1) I am an active ISoP member.
- 2) I am an experienced expert in PK/PD modeling & simulations since I have been studying this field for more than 30 years and I am still active. My first publication in 1981 reported a pharmacokinetic analysis program for microcomputer which was cited more than 2600 times.
- 3) I am a Japanese leader in the field of pharmacometrics because I have been serving as the President of the population approach group in Japan (PAGJA) since 2006, as an Executive Board member of WCoP, as the General Secretary of the International Association of Therapeutic Drug Monitoring and Clinical Toxicology (IATDMCT), and as the Chair of the 15th IATDMCT Congress in Kyoto in 2017.
- 4) I have close network within pharmacometricians in Asia. Pharmacometricians of Japan, China and Korea hold a regular meeting once a year for scientific exchange and networking. I serve as a board member to organize the Asian joint meeting and will host the Asian Pharmacometric Conference this October in Japan.
- 5) I organized the “ISoP-JSCPT Joint Symposium on Pharmacometrics” during JSCPT annual conference in December 2015, where we invited Donald Mager, Stephan Schmidt, Vikram Sinha and Sander Vinks. The symposium was very successful and contributed to high reputation of ISoP in Japanese community.
- 6) I am also eager to educate pharmacometric science to young generation. I currently run pharmacometrics training courses to foster pharmacometric experts which is supported by Japanese Governmental funding (Japan Science and Technology Agency).
- 7) I also experienced a number of governmental appointments. Through these occasions, I always enlightened the importance of pharmacometrics to the regulatory people in MHLW and PMDA. Currently, I am a member of working group drafting a population pharmacokinetic/pharmacodynamic guideline which will be issued by the Japanese Government.

I stand on a central leadership position in pharmacometrics in Japan and in Asian region. I have long and enough experiences and wide networks both in national and international communities. Thus, I am ready and happy to contribute to the ISoP for its global expansion, particularly as “liaison person” to Asia, together with the progress of pharmacometric science and application.

## Curriculum Vitae

### Education:

- |      |  |
|------|--|
| 1978 | BSc, Faculty of Pharmaceutical Sciences, Kyoto University, Japan           |
| 1983 | Ph.D., Graduate School of Pharmaceutical Sciences, Kyoto University, Japan |

### Professional Experiences:

- |              |   |
|--------------|---|
| 1985-1990    | Instructor, Department of Pharmacy, Kyoto University Hospital, Japan  |
| 1990-1993    | Lecturer, Department of Pharmacy, Kyoto University Hospital, Japan  |
| 1991-1992    | Research fellow of Prof. Malcolm Rowland, School of Pharmacy, University of Manchester, U.K.                        |
| 1993-1998    | Associate Professor and Vice Director, Department of Pharmacy, Kobe University Hospital, Japan                      |
| 1998-2007    | Director of Hospital Pharmacy, Keio University Hospital, Japan  |
| 1998-present | Professor, Department of Clinical Pharmacokinetics and Pharmacodynamics, School of Medicine, Keio University, Japan |

### Major Activities in Academic Organizations:

1. President of PAGJA (Population Approach Group in Japan), 2006 – present.
2. Executive Board member of WCOP (World Conference of Pharmacometrics), 2013 – present.
3. General Secretary and Executive Board member of IATDMCT (International Association of Therapeutic Drug Monitoring and Clinical Toxicology), 2013 –present.
4. Executive Board member of JSTD (Japanese Society of Therapeutic Drug Monitoring) 2002 – present. President of JSTD, 2005 – 2011.
5. Executive Board member of JSCPT (Japanese Society of Clinical Pharmacology and Therapeutics), 2005 – 2008 and 2010 – 2014.
6. Others: 20 past experiences of Council or Executive Committee member and Conference

Chair of medical and pharmaceutical organizations.

Major Regulatory Activities:

1. ICH Rapporteur (The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use), 2002 –2005.
2. Advisory Board member of the governmental committee for approval of new drugs (Ministry of Health, Labour and Welfare of Japan), 1996 –2007.
3. Working Group member to develop a PMDA guideline “Guideline on Population Pharmacokinetic and Pharmacodynamic Analysis” (Pharmaceuticals and Medical Devices Agency of Japan), 2014 –present.
4. Others: More than 25 past experiences of Governmental commitments.

Contact address:

Department of Clinical Pharmacokinetics and Pharmacodynamics,  
Room 2N9,

Keio University School of Medicine,  
Tokyo 160-8582, Japan.

E-mail: [tanigawara@a7.keio.jp](mailto:tanigawara@a7.keio.jp)

Tel. +81-(0)3-5363-3847 direct

Fax. +81-(0)3-5269-4576

## List of Publications and Invited Lectures for Prof. Yusuke Tanigawara

### Peer-reviewed original articles

1. K. Yamaoka, Y. Tanigawara, T. Nakagawa, T. Uno, A pharmacokinetic analysis program (MULTI) for microcomputer, *J. Pharm. Dyn.*, 4(11), 879-885 (1981).
2. K. Yamaoka, Y. Tanigawara, T. Nakagawa, T. Uno, Capacity-limited elimination of cefmetazole in rat, *Int. J. Pharm.*, 10(4), 291-300 (1982).
3. Y. Tanigawara, K. Yamaoka, T. Nakagawa, T. Uno, Moment analysis for the separation of mean *in vivo* disintegration, dissolution, absorption and disposition time of ampicillin products, *J. Pharm. Sci.*, 71(10), 1129-1133 (1982).
4. Y. Tanigawara, K. Yamaoka, T. Nakagawa, T. Uno, New method for the evaluation of *in vitro* dissolution time and disintegration time, *Chem. Pharm. Bull.*, 30(3), 1088-1090 (1982).
5. Y. Tanigawara, K. Yamaoka, T. Nakagawa, M. Nakagawa, T. Uno, Correlation between *in vivo* mean dissolution time and *in vitro* mean dissolution time of ampicillin products, *J. Pharm. Dyn.*, 5(5), 370-372 (1982).
6. Y. Tanigawara, K. Yamaoka, T. Nakagawa, T. Uno, Absorption kinetics of carbenicillin phenyl sodium and carbenicillin indanyl sodium in man, *Chem. Pharm. Bull.*, 30(6), 2174-2180 (1982).
7. M. Yamada, Y. Uda, Y. Tanigawara, Mechanism of enhancement of percutaneous absorption of molsidomine by oleic acid, *Chem. Pharm. Bull.*, 35(8), 3399-3406 (1987).
8. M. Yamada, Y. Tanigawara, The design of membrane-controlled transdermal therapeutic systems containing molsidomine, *Chem. Pharm. Bull.*, 35(8), 3407-3412 (1987).
9. R. Hori, Y. Tanigawara, Y. Saito, Y. Hayashi, T. Aiba, K. Okumura, K. Kamiya, Moment analysis of drug disposition in kidney: Transcellular transport kinetics of p-aminohippurate in the isolated perfused rat kidney, *J. Pharm. Sci.*, 77(6), 471-476 (1988).
10. I. Kishimoto, Y. Tanigawara, K. Okumura, R. Hori, Blood oxygen tension-related change of theophylline clearance in experimental hypoxemia, *J. Pharmacol. Exp. Ther.*, 248(3), 1237-1242 (1989).
11. Y. Tanigawara, R. Hori, K. Okumura, J. Tsuji, N. Shimizu, S. Noma, J. Suzuki, D. J. Livingston, S. M. Richards, L. D. Keyes, R. C. Couch, M. K. Erickson, Pharmacokinetics in chimpanzees of recombinant human tissue-type plasminogen activator produced in mouse C127 and Chinese hamster ovary cells, *Chem. Pharm. Bull.*, 38(2), 517-522 (1990).
12. A. Kamiya, Y. Tanigawara, Y. Saito, Y. Hayashi, T. Aiba, K. Inui, R. Hori, Moment Analysis of Drug Disposition in Kidney. II: Urine pH dependent tubular secretion of tetraethylammonium in the isolated perfused rat kidney, *J. Pharm. Sci.*, 79(8), 692-697 (1990).

13. Y. Tanigawara, Y. Saito, T. Aiba, K. Ohoka, A. Kamiya, R. Hori, Moment analysis of drug disposition in kidney. III: Transport of p-aminohippurate and tetraethylammonium in the perfused kidney isolated from uranyl nitrate-induced acute renal failure rats, *J. Pharm. Sci.*, 79(3), 249-256 (1990).
14. Y. Saito, Y. Tanigawara, N. Okamura, H. Shimizu, A. Kamiya, R. Hori, Moment analysis of drug disposition in rat kidney: Role of basolateral membrane transport in renal transepithelial transport of p-aminohippurate, *J. Pharm. Pharmacol.*, 43(5), 311-316 (1991).
15. R. Hori, Y.-L. He, Y. Saito, A. Kamiya, Y. Tanigawara, Moment analysis of drug disposition in kidney. V: *In vivo* transepithelial transport of p-aminohippurate in rat kidney, *J. Pharmacokin. Biopharm.*, 19(1): 51-70 (1991).
16. Y. Tanigawara, Y.-L. He, K. Okumura, R. Hori, Pulmonary and hepatic disposition of hippuryl-L-histidyl-L-leucine, *Chem. Pharm. Bull.*, 39(3): 761-764 (1991).
17. T. Heya, H. Okada, Y. Tanigawara, Y. Ogawa, H. Toguchi, Effects of counter anion of TRH and loading amount on control of TRH-release from copoly (d,l-lactic/glycolic acid) microspheres prepared by an in-water drying method, *Int. J. Pharm.*, 69(1), 69-75 (1991).
18. Y.-L. He, Y. Tanigawara, M. Yasuhara, R. Hori, Effect of folinic acid on tissue residence and excretion of methotrexate in rats, *Drug Metab. Dispo.*, 19(4): 729-734 (1991).
19. Y.-L. He, Y. Tanigawara, A. Kamiya, R. Hori, Moment analysis of drug disposition in kidney. VI: Assessment of *in vivo* transmembrane transport of p-aminohippurate in tubular epithelium, *J. Pharmacokin. Biopharm.*, 19(6), 667-690 (1991).
20. Y. Tanigawara, I. Yano, M. Yasuhara, R. Hori, Effect of leukotriene C<sub>4</sub> on theophylline disposition in guinea pigs, *Am. Rev. Respir. Dis.*, 146, 616-620 (1992).
21. R. Hori, Y.-L. He, T. Shima, K. Inui, S. Aoki, K. Okumura, Y. Tanigawara, Total body and hepatic clearance in rats of recombinant tissue-type plasminogen activator expressed in mouse C127 and Chinese hamster ovary cells, *Drug Metab. Dispo.*, 20(4), 541-546 (1992).
22. Y. Tanigawara, N. Okamura, M. Hirai, M. Yasuhara, K. Ueda, N. Kioka, T. Komano, R. Hori, Transport of digoxin by human P-glycoprotein expressed in a porcine kidney epithelial cell line (LLC-PK<sub>1</sub>), *J. Pharmacol. Exp. Ther.*, 263(2), 840-845 (1992).
23. K. Ueda, N. Okamura, M. Hirai, Y. Tanigawara, T. Saeki, N. Kioka, T. Komano, R. Hori, Human P-glycoprotein transports cortisol, aldosterone, and dexamethasone but not progesterone, *J. Biol. Chem.*, 267(34), 24248-24252 (1992).
24. I. Yano, Y. Tanigawara, M. Yasuhara, H. Mikawa, R. Hori, Population pharmacokinetics of theophylline I: Intravenous infusion to children in the acute episode of asthma, *Biol. Pharm. Bull.*, 16(1), 59-62 (1993).

25. I. Yano, Y. Tanigawara, M. Yasuhara, K. Okumura, K. Kawakatsu, K. Nishimura, R. Hori, Population pharmacokinetics of theophylline II: Intravenous infusion to patients with stable chronic airway obstruction, *Biol. Pharm. Bull.*, 16(5), 501-505 (1993).
26. T. Saeki, K. Ueda, Y. Tanigawara, R. Hori, T. Komano, Human P-glycoprotein transports cyclosporin A and FK506, *J. Biol. Chem.*, 268(9), 6077-6080 (1993).
27. R. Hori, N. Okamura, T. Aiba, Y. Tanigawara, Role of P-glycoprotein in renal tubular secretion of digoxin in the isolated perfused rat kidney, *J. Pharmacol. Exp. Ther.*, 266(3), 1620-1625 (1993).
28. N. Okamura, M. Hirai, Y. Tanigawara, K. Tanaka, M. Yasuhara, K. Ueda, T. Komano, R. Hori, Digoxin-cyclosporin A interaction: Modulation of the multidrug transporter P-glycoprotein in the kidney, *J. Pharmacol. Exp. Ther.*, 266(3), 1614-1619 (1993).
29. T. Saeki, K. Ueda, Y. Tanigawara, R. Hori, T. Komano, P-glycoprotein-mediated transcellular transport of MDR-reversing agents, *FEBS Lett.*, 324(1), 99-102 (1993).
30. Y. Tanigawara, I. Yano, K. Kawakatsu, K. Nishimura, M. Yasuhara, R. Hori, Predictive performance of the Bayesian analysis: Effects of blood sampling time, population parameters and pharmacostatistical model, *J. Pharmacokin. Biopharm.*, 22(1), 59-71 (1994).
31. Y. Hashimoto, A. Odani, Y. Tanigawara, M. Yasuhara, T. Okuno, R. Hori, Population analysis of the dose-dependent pharmacokinetics of zonisamide in epileptic patients, *Biol. Pharm. Bull.*, 17(2), 323-326 (1994).
32. T. Aiba, Y. Itoga, H. Shimizu, Y. Tanigawara, R. Hori, Renal handling of tobramycin in the isolated perfused rat kidney, *J. Pharm. Sci.*, 83(5), 723-726 (1994).
33. Y. Tanigawara, H. Nomura, N. Kagimoto, K. Okumura, R. Hori, Premarketing population pharmacokinetic study of levofloxacin in normal subjects and patients with infectious diseases, *Biol. Pharm. Bull.*, 18(2) 315-320 (1995).
34. M. Hirai, K. Tanaka, T. Shimizu, Y. Tanigawara, M. Yasuhara, R. Hori, Y. Kakehi, O. Yoshida, K. Ueda, T. Komano, K. Inui, Cepharanthin, a multidrug resistant modifier, is a substrate for P-glycoprotein, *J. Pharmacol. Exp. Ther.*, 275(1), 73-78 (1995).
35. Y. Tanigawara, F. Komada, T. Shimizu, S. Iwakawa, T. Iwai, H. Maekawa, R. Hori, K. Okumura, Population pharmacokinetics of theophylline. III: Premarketing study for a once-daily administered preparation, *Biol. Pharm. Bull.*, 18(11), 1590-1598 (1995).
36. K. Nishiguchi, K. Ishida, M. Nakajima, T. Maeda, F. Komada, S. Iwakawa, Y. Tanigawara, K. Okumura, Effects of transfection with Cu, Zn-superoxide dismutase gene on xanthine/xanthine oxidase-induced cytotoxicity in fibroblasts from rat skin, *Pharm. Res.*, 13(4), 575-580 (1996).
37. F. Komada, K. Nishiguchi, Y. Tanigawara, T. Akamatsu, X.-Y. Wu, S. Iwakawa, K. Okumura, Effect of transfection with a superoxide dismutase expression plasmid on superoxide anion induced cytotoxicity in cultured rat lung cells, *Biol. Pharm. Bull.*, 19(2), 274-279 (1996).

38. K. Tanaka, M. Hirai, Y. Tanigawara, M. Yasuhara, R. Hori, K. Ueda, K. Inui, Effect of cyclosporin analogues and FK506 on transcellular transport of daunorubicin and vinblastine via P-glycoprotein, *Pharm. Res.*, 13(7), 1073-1077 (1996).
39. K. Nishiguchi, K. Ishida, M. Nakajima, T. Maeda, F. Komada, S. Iwakawa, Y. Tanigawara, K. Okumura, Pharmaceutical studies for gene therapy: Expression of human Cu, Zn-superoxide dismutase gene transfected by lipofection in rat skin fibroblasts, *Biol. Pharm. Bull.*, 19(8), 1073-1077 (1996).
40. F. Komada, K. Nishiguchi, Y. Tanigawara, T. Akamatsu, X.-Y. Wu, S. Iwakawa, K. Okumura, Effect of transfection with superoxide dismutase expression plasmid on xanthine/xanthine oxidase-induced cytotoxicity in rat lung cultured cells, *Biol. Pharm. Bull.*, 19(8), 1100-1102 (1996).
41. K. Tanaka, M. Hirai, Y. Tanigawara, K. Ueda, M. Takano, R. Hori, K. Inui, Relationship between expression level of P-glycoprotein and daunorubicin transport in LLC-PK<sub>1</sub> cells transfected with human *MDR1* gene, *Biochem. Pharmacol.*, 53(5), 741-746 (1997).
42. K. Okumura, T. Kita, S. Chikazawa, F. Komada, S. Iwakawa, Y. Tanigawara, Genotyping of N-acetylation polymorphism and correlation with procainamide metabolism, *Clin. Pharmacol. Ther.*, 61(5), 509-517 (1997).
43. F. Komada, K. Nishiguchi, Y. Tanigawara, M. Ishida, X.-Y. Wu, S. Iwakawa, R. Sasada, K. Okumura, Protective effect of transfection with secretable superoxide dismutase (SOD) (a signal sequence-SOD fusion protein coding cDNA) expression vector on superoxide anion-induced cytotoxicity *in vitro*, *Biol. Pharm. Bull.*, 20(5), 530-536 (1997).
44. M. Okazaki, Y. Tanigawara, T. Kita, F. Komada, K. Okumura, Cross-reactivity of TDX and OPUS immunoassay systems for serum digoxin determination, *Therapeutic Drug Monitoring*, 19, 657-662 (1997).
45. Y. Ku, N. Kusunoki, T. Kitagawa, I. Maeda, T. Fukumoto, T. Iwasaki, M. Tominaga, Y. Suzuki, Y. Kuroda, Y. Tanigawara, Y. Saitoh, Pharmacokinetics of adriamycin and cisplatin for anhepatic chemotherapy during liver transplantation, *Cancer Chemother. Pharmacol.*, 40, 457-462 (1997).
46. K. Okumura, K. Nishiguchi, Y. Tanigawara, S. Mori, S. Iwakawa, F. Komada, Enhanced Anti-Inflammatory Effects of Cu, Zn-superoxide dismutase delivered by genetically modified skin fibroblasts *in vitro* and *in vivo*, *Pharm. Res.*, 14(9), 1223-1227 (1997).
47. E. Fuse, H. Tanii, N. Kurata, H. Kobayashi, T. Shimada, T. Tamura, Y. Sasaki, Y. Tanigawara, R. D. Lush, D. Headlee, W. D. Figg, S. G. Arbuck, A. M. Senderowicz, E. A. Sausville, S. Akinaga, T. Kuwabara, S. Kobayashi. Unpredicted clinical pharmacology of UCN-01 caused by specific binding to human  $\alpha$ 1-acid glycoprotein, *Cancer Research*, 58(15): 3248-3253 (1998).

48. N. Kusunoki, K. Takara, Y. Tanigawara, A. Yamauchi, K. Ueda, F. Komada, Y. Ku, Y. Kuroda, Y. Saitoh, K. Okumura, Inhibitory effects of a cyclosporin derivative, SDZ PSC 833, on transport of doxorubicin and vinblastine via human P-glycoprotein, *Jpn. J. Cancer Res.*, 89(11): 1220-1228 (1998).
49. K. Nishiguchi, F. Komada, Y. Tanigawara, Y. Sakai, S. Iwakawa, K. Okumura. Effects of Cu, Zn-superoxide dismutase delivered by genetically modified skin fibroblasts on cold-induced skin edema in rats, *Biol. Pharm. Bull.*, 21(12): 1379-1381 (1998).
50. Y. Tagawa, K. Miwa, K. Yamashita, R. Tsukuda, Y. Yoshimura, S. Tanayama, Y. Tanigawara. Possible factor for nonlinear pharmacokinetics of TAK-603, a new antirheumatic agent, in rats, *Biopharm. Drug Disposition*, 20(1): 11-18 (1999).
51. Y. Tagawa, K. Miwa, R. Tsukuda, Y. Yoshimura, S. Tanayama, Y. Tanigawara, Effect of Its demethylated metabolite on the pharmacokinetics of unchanged TAK-603, a new antirheumatic agent, in rats, *Drug Metabolism Disposition*, 27(4): 495-501 (1999).
52. F. Komada, K. Nishiguchi, Y. Tanigawara, S. Iwakawa, K. Okumura. Effects of secretable SOD delivered by genetically modified cells on xanthine/xanthine oxidase and paraquat-induced cytotoxicity *in vitro*, *Biol. Pharm. Bull.*, 22(8): 846-853 (1999).
53. K. Takara, Y. Tanigawara, F. Komada, K. Nishiguchi, T. Sakaeda, K. Okumura, Cellular pharmacokinetic aspects of reversal effect of itraconazole on P-glycoprotein-mediated resistance of anticancer drugs, *Biol. Pharm. Bull.*, 22(12): 1355-1359 (1999).
54. Y. Tanigawara, N. Aoyama, T. Kita, K. Shirakawa, F. Komada, M. Kasuga, K. Okumura, *CYP2C19* genotype-related efficacy of omeprazole for the treatment of infection caused by *Helicobacter pylori*, *Clin. Pharmacol. Ther.*, 66(5): 528-534 (1999).
55. K. Shirakawa, K. Takara, Y. Tanigawara, N. Aoyama, M. Kasuga, F. Komada, T. Sakaeda, K. Okumura, Interaction of docetaxel ("Taxotere") with human P-glycoprotein, *Jpn. J. Cancer Res.*, 90(12): 1380-1386 (1999).
56. N. Aoyama, Y. Tanigawara, T. Kita, T. Sakai, K. Shirakawa, D. Shirasaka, F. Komada, K. Okumura, and M. Kasuga, Sufficient effect of 1-week omeprazole and amoxicillin dual treatment for *Helicobacter pylori* eradication in cytochrome P450 2C19 poor metabolizers, *J. Gastroenterol.*, 34 (11): 80-83(1999).
57. K. Takara, Y. Tanigawara, F. Komada, K. Nishiguchi, T. Sakaeda, K. Okumura, The novel Anticancer drug KRN5500 interacts with, but is hardly transported by human P-glycoprotein, *Jpn. J. Cancer Res.*, 91: 248-254(2000).
58. K. Takara, Y. Tanigawara, F. Komada, K. Nishiguchi, T. Sakaeda, K. Okumura, Nifedipine and itraconazole inhibited transcellular transport of digoxin, *Pharm. Pharmacol. Commun.*, 6: 167-171 (2000).



59. S. Aoki, N. Shimizu, J. Koyama, Y. Kato, M. Kitagawa, K. Okumura, Y. Tanigawara, Influence of N-terminal peptide and oligosaccharide on the clearance of t-PA, *Biol. Pharm. Bull.*, 23(4): 477-481 (2000).
60. H. Minami, T. Ohtsu, H. Fujii, T. Igarashi, K. Itoh, N. Uchiyama-Kokubu, T. Aizawa, T. Watanabe, Y. Uda, Y. Tanigawara, Y. Sasaki, Phase I study of intravenous PSC-833 and doxorubicin: Reversal of multidrug resistance, *Jpn. J. Cancer Res.*, 92: 220-230(2001).
61. S. Aoki, N. Shimizu, M. Shimonishi, M. Kitagawa, K. Okumura, Y. Tanigawara, Influence of sugar chain on fibrin affinity of recombinant t-PA, *Biol. Pharm. Bull.*, 24(3): 295-298(2001).
62. T. Nakamura, M. Kakumoto, K. Yamashita, K. Takara, Y. Tanigawara, T. Sakaeda, K. Okumura, Factors influencing the prediction of steady state concentrations of digoxin, *Biol. Pharm. Bull.*, 24(4): 403-408(2001).
63. T. Kita, Y. Tanigawara, N. Aoyama, T. Hohda, Y. Saijoh, F. Komada, T. Sakaeda, K. Okumura, T. Sakai, M. Kasuga, CYP2C19 genotype related effect of omeprazole on intragastric pH and antimicrobial stability, *Pharm. Res.*, 18(5): 615-621(2001).
64. T. Sakai, N. Aoyama, T. Kita, T. Sakaeda, K. Nishiguchi, Y. Nishitora, T. Hohda, D. Shirasaka, T. Tamura, Y. Tanigawara, M. Kasuga, K. Okumura, CYP2C19 genotype and pharmacokinetics of three proton pump inhibitors in healthy subjects, *Pharm. Res.*, 18(6): 721-727(2001).
65. T. Kita, Y. Tanigawara, S. Chikazawa, H. Hatanaka, T. Sakaeda, F. Komada, S. Iwakawa, K. Okumura, N-acetyltransferase 2 genotype correlated with isoniazid acetylation in Japanese tuberculous patients, *Biol. Pharm. Bull.*, 24(5): 544-549(2001).
66. H. Takama, H. Tanaka, T. Sudo, T. Tamura, Y. Tanigawara, Population pharmacokinetic modeling and model validation of a spicamycin derivative, KRN5500, in phase I study, *Cancer Chemother. Pharmacol* , 47(5): 404-410(2001).
67. Y. Tanigawara, T. Kita, M. Hirono, T. Sakaeda, F. Komada, K. Okumura, Identification of N-acetyltransferase 2 and CYP2C19 genotypes for hair, buccal cell swabs, or fingernails compared with blood, *Ther Drug Monit.*, 23(4):341-346(2001).
68. Y. Ito, K. Aiba, N. Horikoshi, T. Saotome, T. Irie, K. Sugiyama, M. Nakane, D. Hashimoto, N. Yoshida, N. Mizunuma, S. Takahashi, Y. Tanigawara, Dose-finding phase I study of simultaneous weekly infusion with doxorubicin and docetaxel in patients with advanced breast cancer, *Int. J. Clin. Oncol.*, 6(5):242-247(2001).
69. T. Sakaeda, K. Takara, M. Kakumoto, N. Ohmoto, T. Nakamura, K. Iwaki, Y. Tanigawara, K. Okumura, Simvastatin and lovastatin, but not pravastatin, interact with MDR1, *J. Pharm. Pharmacol.*, 54: 419-423 (2002).
70. K. Takara, M. Kakumoto, Y. Tanigawara, J. Funakoshi, T. Sakaeda, K. Okumura, Interaction of digoxin with antihypertensive drugs via MDR1, *Life Sciences*, 70: 1491-1500 (2002).

71. Y. Tanigawara, T. Kita, N. Aoyama, M. Gobara, F. Komada, T. Sakai, M. Kasuga, H. Hatanaka, T. Sakaeda, K. Okumura, N-acetyltransferase 2 genotype-related sulfapyridine acetylation and its adverse events, *Biol. Pharm. Bull.*, 25(8): 1058-1062 (2002).
72. K. Takara, T. Sakaeda, Y. Tanigawara, K. Nishiguchi, N. Ohmoto, M. Horinouchi, F. Komada, N. Ohnishi, T. Yokoyama, K. Okumura, Effects of 12 Ca<sup>2+</sup> antagonists on multidrug resistance, *MDRI*-mediated transport and *MDRI* mRNA expression, *Eur. J. Pharm. Sci.*, 16: 159-165 (2002).
73. T. Kakimoto, Y. Hattori, S. Okamoto, N. Sato, T. Kamata, M. Yamaguchi, K. Morita, T. Yamada, N. Takayama, H. Uchida, N. Shimada, Y. Tanigawara, Y. Ikeda, Thalidomide for the treatment of refractory multiple myeloma: Association of plasma concentrations of thalidomide and angiogenic growth factors with clinical outcome, *Jpn. J. Cancer Res.*, 93(9): 1029-1036 (2002).
74. M. Kakimoto, K. Takara, T. Sakaeda, Y. Tanigawara, T. Kita, K. Okumura, *MDRI*-mediated interaction of digoxin with antiarrhythmic or antianginal drugs, *Biol. Pharm. Bull.*, 25(12): 1604-1607 (2002).
75. S. Tatami, A. Sarashina, N. Yamamura, T. Igarashi, Y. Tanigawara, Population pharmacokinetics of an angiotensin II receptor antagonist, telmisartan, in healthy volunteers and hypertensive patients, *Drug Metabol. Pharmacokin.*, 18(3): 203-211 (2003).
76. N. Yamamoto, T. Tamura, Y. Kamiya, H. Ono, H. Kondoh, K. Shirao, Y. Matsumura, Y. Tanigawara, Y. Shimada, Phase I and pharmacokinetic study of KRN5500, a spicamycin derivative, for patients with advanced solid tumor, *Jpn. J. Clin. Oncol.*, 33(6): 302-308 (2003).
77. E. Comets, K. Ikeda, P. Hoff, P. Fumoleau, J. Wanders, Y. Tanigawara, Comparison of the pharmacokinetics of S-1, an oral anticancer agent, in western and Japanese patients, *J. Pharmacokin. Pharmacodyn.*, 30(4): 257-283 (2003).
78. T. Tsutsumi, A. Tokumura, M. Yamaguchi, S. Kitazawa, Y. Tanigawara, Phorbol myristate acetate stimulates degradation of a structural analogue of platelet-activating factor to a neutral lipid in human leukemic K562 Cells: Relevance to the release of lipids, *Biol. Pharm. Bull.*, 27(1): 24-28 (2004).
79. K. Kosaki, K. Tamura, R. Sato, H. Samejima, Y. Tanigawara, T. Takahashi, A major influence of CYP2C19 genotype on the steady-state concentration of N-desmethyleclobazam, *Brain and Development*, 26(8):530-534 (2004).
80. Y. Takahashi, J. Sakamoto, T. Takeuchi, M. Mai, T. Kubota, M. Kitajima, Y. Tanigawara, Y. Komatsu, T. Toge, S. Saji, A randomized phase II clinical trial of tailored CPT-11+S-1 vs S-1 in patients with advanced or recurrent gastric carcinoma as the first line chemotherapy, *Jpn. J. Clin. Oncol.*, 34(6): 342-345 (2004).

81. M. Inoue, K. Takeda, K. Morita, M. Yamada, Y. Tanigawara, Y. Oguchi, Vitreous concentrations of triamcinolone acetonide in human eyes after intravitreal or subtenon injection, *Am. J. Ophthalmol.*, 138: 1046-1048 (2004).
82. S. Tatami, A. Sarashina, N. Yamamura, T. Igarashi, Y. Tanigawara, Relationship between pharmacokinetic parameters and occurrence of adverse events in clinical trials performed in Europe and United States for an angiotensin II receptor antagonist, telmisartan, *Drug Metab. Pharmacokinet.*, 19(1): 24-32 (2004).
83. S. Tatami, N. Yamamura, A. Sarashina, CL Yong, T. Igarashi, Y. Tanigawara, Pharmacokinetic comparison of an angiotensin II receptor antagonist, telmisartan, in Japanese and western hypertensive patients using population pharmacokinetic method, *Drug Metab. Pharmacokinet.*, 19(1): 15-23 (2004).
84. T. Matsumoto, T. Miki, H. Hagino, T. Sugimoto, S. Okamoto, T. Hirota, Y. Tanigawara, Y. Hayashi, M. Fukunaga, M. Shiraki, T. Nakamura, A new active vitamin D, ED-71, increases bone mass in osteoporotic patients under vitamin D supplementation: a randomized, double-blind, placebo-controlled clinical trial, *J. Clin. Endocrinol. Metab.*, 90 (9): 5031-5036 (2005).
85. T. Udaka, C. Torii, D. Takahashi, T. Mori, M. Aramaki, R. Kosaki, Y. Tanigawara, T. Takahashi, K. Kosaki, Comprehensive screening of the thiopurine methyltransferase polymorphisms by denaturing high-performance liquid chromatography, *Genet. Test.*, 9 (2): 85-92 (2005).
86. Y. Hattori, M. Yabe, S. Okamoto, K. Morita, Y. Tanigawara, Y. Ikeda, Thalidomide for the treatment of leptonigeal multiple myeloma, *Eur. J. Haematol.*, 76: 358-359 (2006).
87. N. Shimasaki, T. Mori, H. Samejima, R. Sato, H. Shimada, N. Yahagi, C. Torii, H. Yoshihara, Y. Tanigawara, T. Takahashi, K. Kosaki, Effects of methylenetetrahydrofolate reductase and reduced folate carrier 1 polymorphisms on high-dose methotrexate-induced toxicities in children with acute lymphoblastic leukemia or lymphoma, *J. Pediatric Hematol. Oncol.*, 28(2) :64-68(2006).
88. Y. Yamayoshi, T. Watanabe, M. Tanabe, K. Hoshino, K. Matsumoto, Y. Morikawa, M. Shimadzu, M. Kitajima, Y. Tanigawara, Novel application of protein chip technology exploring acute rejection markers of rat small bowel transplantation, *Transplantation*, 82(3):320-326(2006).
89. Y. Tanigawara, R. Sato, K. Morita, M. Kaku, N. Aikawa, K. Shimizu, Population pharmacokinetics of arbekacin in patients infected with methicillin-resistant *staphylococcus aureus*, *Antimicrobial Agents Chemother.*, 50(11):3754-3762(2006).
90. R. Sato, Y. Tanigawara, M. Kaku, N. Aikawa, K. Shimizu, Pharmacokinetic-pharmacodynamic relationship of arbekacin for treatment of patients infected with methicillin-resistant *staphylococcus aureus*, *Antimicrobial Agents Chemother.*, 50(11):3763-3769(2006).

91. Y. Yamada, A. Ohtsu, N. Boku, Y. Miyata, Y. Shimada, T. Doi, K. Muro, M. Muto, T. Hamaguchi, K. Mera, T. Yano, Y. Tanigawara, K. Shirao, Phase I/II study of oxaliplatin with weekly bolus fluorouracil and high-dose leucovorin (ROX) as first-line therapy for patients with colorectal cancer, *Jpn. J. Clin. Oncol.*, 36(4): 218-223 (2006).
92. Y. Yamada, T. Tamura, N. Yamamoto, T. Shimoyama, Y. Ueda, H. Murakami, H. Kusaba, Y. Kamiya, H. Saka, Y. Tanigawara, J. P. McGovren, Y. Natsumeda, Phase I and pharmacokinetic study of edotecarin, a novel topoisomerase I inhibitor, administered once every 3 weeks in patients with solid tumors, *Cancer Chemother. Pharmacol.*, 58: 173-182 (2006).
93. K. Tabata, M. Kawashima, A. Kawamura, A. Kaibara, Y. Tanigawara, Population pharmacokinetic analysis of micafungin in Japanese patients with fungal infections, *Drug Metab. Pharmacokinet.*, 21(4) 324-331(2006).
94. K. Tabata, M. Kawashima, A. Kawamura, A. Kaibara, Y. Tanigawara, K. Sunagawa, Linear pharmacokinetics of micafungin and its active metabolites in Japanese pediatric patients with fungal infections, *Biol. Pharm. Bull.*, 29(8) 1706-1711(2006).
95. K. Shirao, Y. Matsumura, Y. Yamada, K. Muro, M. Gotoh, N. Boku, A. Ohtsu, F. Nagashima, Y. Sano, M. Mutoh, Y. Tanigawara, Phase I study of single-dose oxaliplatin in Japanese patients with malignant tumors, *Jpn. J. Clin. Oncol.*, 36(5): 295-300 (2006).
96. K. Kosaki, C. Yamagishi, R. Sato, H. Semejima, H. Fujita, K. Tamura, K. Maeyama, H. Yamagishi, A. Sugaya, H. Dodo, Y. Tanigawara, T. Takahashi, 1173C>T polymorphism in VKORC1 modulates the required warfarin dose, *Pediatr. Cardiol.*, 27(6): 685-688 (2006).
97. N. Boku, A. Ohtsu, I. Hyodo, K. Shirao, Y. Miyata, K. Nakagawa, T. Tamura, K. Hatake, Y. Tanigawara, Phase II study of oxaliplatin in Japanese patients with metastatic colorectal cancer refractory to fluoropyrimidines, *Jpn. J. Clin. Oncol.*, 37(6): 440-445 (2007).
98. N. Shimasaki, T. Mori, C. Torii, R. Sato, H. Shimada, Y. Tanigawara, K. Kosaki, T. Takahashi, Influence of MTHFR and RFC1 polymorphisms on toxicities during maintenance chemotherapy for childhood acute lymphoblastic leukemia of lymphoma, *J. Pediatr. Hematol. Oncol.*, 30(5): 347-352 (2008).
99. N. Honda, S. Nakade, H. Kasai, Y. Hashimoto, T. Ohno, J. Kitagawa, A. Yamaguchi, C. Hasegawa, S. Kikawa, T. Kunisawa, Y. Tanigawara, Y. Miyata. Population pharmacokinetics of landiolol hydrochloride in healthy subjects, *Drug Metab. Pharmacokinet.*, 23(6):447-455(2008).
100. K. Shirao, T. Yoshino, N. Boku, K. Kato, T. Hamaguchi, H. Yasui, N. Yamamoto, Y. Tanigawara, A. Nolting, S. Yoshino, A phase I escalating single-dose and weekly fixed-dose study of cetuximab pharmacokinetics in Japanese patients with solid tumors, *Cancer Chemotherap. Pharmacol.*, 64(3): 557-564 (2009).

101. K. Asano, S. Nakade, T. Shiomi, T. Nakajima, Y. Suzuki, K. Fukunaga, T. Oguma, K. Sayama, H. Fujita, Y. Tanigawara, A. Ishizaka, Impact of pharmacokinetics and pharmacodynamics on the efficacy of pranlukast in Japanese asthmatics, *Respirology*, 14: 822-827 (2009).
102. Y. Tanigawara, K. Yoshihara, K. Kuramoto, K. Arakawa, Comparative pharmacodynamics of olmesartan and azelnidipine in patients with hypertension: a population pharmacokinetic/pharmacodynamic analysis, *Drug Metab. Pharmacokinet.*, 24(4): 376-388 (2009).
103. K. Takara, T. Sakaeda, M. Kakumoto, Y. Tanigawara, H. Kobayashi, K. Okumura, N. Ohnishi, T. Yokoyama, Effects of  $\alpha$ -adrenoceptor antagonist doxazosin on *MDR1*-mediated multidrug resistance and transcellular transport, *Oncology Research*, 17: 527-533 (2009).
104. T. Hirose, K. Fujita, K. Nishimura, H. Ishida, K. Yamashita, Y. Sunakawa, K. Mizuno, K. Miwa, F. Nagashima, Y. Tanigawara, M. Adachi, Y. Sasaki, Pharmacokinetics of S-1 and *CYP2A6* genotype in Japanese patients with advanced cancer, *Oncology Report*, 24: 529-536 (2010).
105. K. Kiyotani, T. Mushiroda, C. K. Imamura, N. Hosono, T. Tsunoda, M. Kudo, Y. Tanigawara, D.A. Flockhart, Z. Desta, T.C. Skaar, F. Aki, K. Hirata, T. Takatsuka, M. Okazaki, S. Ohsumi, T. Yamakawa, M. Sasa, Y. Nakamura, H. Zembutsu, Significant effect of polymorphisms in *CYP2D6* and *ABCC2* on clinical outcomes of adjuvant tamoxifen therapy for breast cancer patients, *J. Clin. Oncol.*, 28: 1287-1293 (2010).
106. M. Abe, N. Tsuji, F. Takahashi, Y. Tanigawara, Overview of the Clinical Pharmacokinetics of Eldecalcitol, a New Active Vitamin D<sub>3</sub> Derivative, *Jpn. Pharmacol. Ther.*, 39: 261-274 (2011).
107. K. Miyata, M. Abe, K. Terao, T. Kawanishi, N. Tsuji, M. Shiraki, T. Nakamura, T. Matsumoto, Y. Tanigawara, Pharmacokinetics of eldecalcitol in primary osteoporosis patients – Randomized, double-blind, multicentre, long-term phase III clinical study -, *Jpn. Pharmacol. Ther.*, 39: 299-307 (2011).
108. Y. Ohata, Y. Tomita, M. Nakayama, K. Tamura, Y. Tanigawara, Optimal treatment schedule of meropenem for adult patients with febrile neutropenia based on pharmacokinetic-pharmacodynamic analysis, *J. Infect. Chemother.*, DOI 10.1007/s10156-011-0271-9 (2011).
109. Y. Ohata, Y. Tomita, M. Nakayama, T. Kozuki, K. Sunakawa, Y. Tanigawara, Optimal dosage regimen of meropenem for pediatric patients based on pharmacokinetic/ Pharmacodynamic considerations, *Drug Metab. Pharmacokinet.*, 26(5): 523-531 (2011).
110. Y. Tanigawara, K. Nozawa, H. Tsuda, Optimal dose finding of garenoxacin based on population pharmacokinetics/pharmacodynamics and Monte Carlo simulation, *Eur. J. Clin. Pharmacol.*, DOI 10.1007/s00228-011-1095-3 (2011).

111. K. Tsuruta, Y. Yamada, M. Serada, Y. Tanigawara, Model-based analysis of covariate effects on population pharmacokinetics of thrombomodulin alfa in patients with disseminated intravascular coagulation and normal subjects, *J. Clin. Pharmacol.* 51:1276-1285 (2011).
112. M. Watanabe, Y. Horai, SM Houten, K. Morimoto, T. Sugizaki, E. Arita, C. Matak, H. Sato, Y. Tanigawara, K. Schoonjans, H. Itoh, J. Auwerx, Lowering bile acid pool size with a synthetic farnesoid X receptor (FXR) agonist induces obesity and diabetes through reduced energy expenditure, *J. Biol. Chem.* 286(30):26913-20 (2011).
113. T. Matsumoto, M. Ito, Y. Hayashi, T. Hirota, Y. Tanigawara, T. Sone, M. Fukunaga, M. Shiraki, T. Nakamura, A new active vitamin D3 analog, eldecalcitol, prevents the risk of osteoporotic fractures--a randomized, active comparator, double-blind study, *Bone.* 49(4): 605-612 (2011).
114. Kiyotani K, Mushiroda T, Tsunoda T, Morizono T, Hosono N, Kubo M, Tanigawara Y, Imamura CK, Flockhart DA, Aki F, Hirata K, Takatsuka Y, Okazaki M, Ohsumi S, Yamakawa T, Sasa M, Nakamura Y, Zembutsu H. A genome-wide association study identifies locus at 10q22 associated with clinical outcomes of adjuvant tamoxifen therapy for breast cancer patients in Japanese, *Hum Mol Genet.* 2011 Dec 16. [Epub ahead of print]
115. S. Suzuki, Y. Yamayoshi, A. Nishimuta, Y. Tanigawara, S100A10 protein expression is associated with oxaliplatin sensitivity in human colorectal cancer cells, *Proteome Science* 2011, 9:76, DOI:10.1186/1477-5956-9-76.
116. H. Matsuoka, T. Arao, C. Makimura, M. Takeda, H. Kiyota, J. Tsurutani, Y. Fujita, K. Matsumoto, H. Kimura, M. Otsuka, A. Koyama, CK. Imamura, Y. Tanigawara, T. Yamanaka, K. Tanaka, K. Nishio, K. Nakagawa, Expression changes in arrestin  $\alpha 1$  and genetic variation in catechol-O-methyltransferase are biomarkers for the response to morphine treatment in cancer patients, *Oncology Reports*, DOI: 10.3892/or.2012.1660 (2011)
117. K. Kiyotani, T. Mushiroda, T. Tsunoda, T. Morizono, N. Hosono, M. Kubo, Y. Tanigawara, C. Imamura, D. Flockhart, F. Aki, K. Hirata, Y. Takatsuka, M. Okazaki, S. Ohsumi, T. Yamakawa M. Sasa, Y. Nakamura, H. Zembutsu, A genome-wide Association study identifies locus at 10q22 associated with clinical outcomes of adjuvant tamoxifen therapy for breast cancer patients in Japanese, *Human Molecular Genetics*, (2012)
118. K. Kiyotani, T. Mushiroda, C. K. Imamura, Y. Tanigawara, N. Hosono, M. Kubo, M. Sasa, Y. Nakamura, H. Zembutsu, Dose-adjustment study of tamoxifen based on *CYP2D6* genotypes in Japanese breast cancer patients, *Breast Cancer Res. Treat.*, DOI 10.1007/s10549-011-1777-7., 131: 137-145 (2012).
119. A. Hirasawa, T. Akahane, Y. Tanigawara, D. Aoki, Blood-direct InvaderPlus® as a new method for genetic testing, *Personalized Medicine*, 9(6): 657–663 (2012)

120. A. Hirasawa, T. Zama, T. Akahane, H. Nomura, F. Kataoka, K. Saito, K. Okubo, E. Tominaga, K. Makita, N. Susumu, K. Kosaki, Y. Tanigawara, D. Aoki, Polymorphisms of UGT1A1 gene predict adverse effects of irinotecan treatment for gynecologic cancer in Japanese. *J Hum Genet* 2013;58(12):794-98(2013)
121. J. Fujita, Y. Niki, J. Kadota, K. Yanagihara, M. Kaku, A. Watanabe, N. Aoki, S. Hori, Y. Tanigawara, H. L. Cash, S. Kohno, Clinical and bacteriological efficacies of sitafloxacin against community-acquired pneumonia caused by Streptococcus pneumoniae: nested cohort within a multicenter clinical trial, *J Infect Chemother*, 19:472-479(2013)
122. S. Kohno, Y. Niki, J. Kadota, K. Yanagihara, M. Kaku, A. Watanabe, N. Aoki, S. Hori, J. Fujita, Y. Tanigawara, Clinical dose findings of sitafloxacin treatment: pharmacokinetic-pharmacodynamic analysis of two clinical trial results for community-acquired respiratory tract infections, *J Infect Chemother*, 19:486-494(2013)
123. Y. Tanigawara, M. Kaku, K. Totsuka, H. Tsuge, A. Saito, Population Pharmacokinetics and pharmacodynamics of sitafloxacin in patients with community-acquired respiratory tract infections, *J Infect Chemother*, 19:858-866(2013)
124. H. R. Kim, H. S. Park, W. S. Kwon, J. H. Lee, Y. Tanigawara, S. M. Lim, H. S. Kim, S. J. Shin, J. B. Ahn, S. Y. Rha, Pharmacogenetic determinants associated with sunitinib-induced toxicity and ethnic difference in Korean metastatic renal cell carcinoma patients, *Cancer Chemother Pharmacol*, 72:825-835(2013)
125. R. Tanoshima, F. G. Bournissen, Y. Tanigawara, J. H. Kristensen, A. Taddio, K. F. Ilett, E. J. Begg, I. Wallach, S. Ito, Population PK modeling and simulation based on fluoxetine and norfluoxetine concentrations in milk: a milk concentration-based prediction model, *British J Clin Pharmacol*, 78:4, 918-928 (2014)
126. S. Suzuki, Y. Tanigawara, Forced expression of S100A10 reduces sensitivity to oxaliplatin in colorectal cancer cells, *Proteome Science*, 12:26(2014)
127. Y. Miura, C.K. Imamura, K. Fukunaga, Y. Katsuyama, K. Suyama, T. Okaneya, T. Mushiroda, Y. Ando, T. Takano, Y. Tanigawara, Sunitinib-induced severe toxicities in a Japanese patient with the ABCG2 421 AA genotype, *BMC Cancer*, 14:964(2014)
128. E. Booka, C.K. Imamura, H. Takeuchi, Y. Hamamoto, D. Gomi, T. Mizukami, T. Ichiyama, K. Tateishi, T. Takahashi, H. Kawakubo, K. Soejima, N. Boku, Y. Tanigawara, Y. Kitagawa, Development of an S-1 dosage formula based on renal function by a prospective pharmacokinetic study, *Gastric Cancer*, 19:3, 876-886(2016)
129. C.K. Imamura, K. Furihata, S. Okamoto, Y. Tanigawara, Impact of Cytochrome P450 2C19 Polymorphisms on the Pharmacokinetics of Tacrolimus When Coadministered With Voriconazole, *The Journal of Clinical Pharmacology*, 56:4, 408-413(2016)
130. K. Yoshida, C.K. Imamura, K. Hara, M. Mochizuki, Y. Tanigawara, Effect of everolimus on the

- glucose metabolic pathway in mouse skeletal muscle cells (C2C12), *Metabolomics*, 13:98, (2017)
131. A. Ose, M. Serada, K. Yamashita, K. Tsurui, Y. Tanigawara, Population Pharmacokinetic and Exposure–Response Analysis of Weekly Teriparatide in Osteoporosis Patients, *The Journal of Clinical Pharmacology*, 2017, in press.
  132. R. Kizu, K. Nishimura, R. Sato, K. Kosaki, T. Tanaka, Y. Tanigawara, T. Hasegawa, Population Pharmacokinetics of Diazoxide in Children with Hyperinsulinemic Hypoglycemia, *Hormone Research in Pediatrics*, 2017, in press.
  133. H. Kenmotsu, CK. Imamura, A. Ono, S. Omori, K. Nakashima, K. Wakuda, T. Taira, T. Naito, H. Murakami, T. Takahashi, Y. Tanigawara, The Effects of Advanced Age and Serum  $\alpha$ 1-Acid Glycoprotein on Docetaxel Unbound Exposure and Dose-limiting Toxicity in Cancer Patients, *British Journal of Clinical Pharmacology*, 2017, in press.

*Additional 47 peer-reviewed articles in Japanese.*

**Book chapters and Review articles (selected for English publications only)**

1. R. Hori, A. Kamiya, Y. Saito, Y. Tanigawara, Kidney perfusion systems in drug disposition studies, in "Topics in Pharmaceutical Sciences 1987," D. D. Breimer & P. Speiser, editors, Elsevier, Amsterdam, pp. 211-219, 1987.
2. R. Hori, A. Kamiya, M. Yasuhara, Y. Tanigawara, K. Inui, Drug disposition in renal disease, in "Xenobiotic Metabolism and Disposition," R. Kato, R. W. Estabrook and M. N. Cayen, editors, Taylor & Francis, London, pp. 411-418, 1989.
3. R. Hori, K. Okumura, M. Yasuhara, Y. Tanigawara, Population pharmacokinetics and the Bayesian method for individualization of drug dosage regimens, in "Advances in Therapeutic Drug Monitoring," K. Tanaka, C. E. Pippenger, T. Mimaki, P. D. Walson, S. Ohgitani, editors, Enterprise, Tokyo, pp. 109-113, 1990.
4. M. Yasuhara, Y. Tanigawara, R. Hori, Estimation of population pharmacokinetic parameters in Japanese patients, in "Topics in Pharmaceutical Sciences 1991," D. J. A. Crommelin and K. K. Midha, Editors, Medpharm Scientific Publishers, Stuttgart, pp. 461-469, 1992.
5. Y. Tanigawara, R. Hori, Population approach in post-marketing dose adjustment, in "New Strategies in Drug Development and Clinical Evaluation: The Population Approach," M. Rowland and L. Aarons, Editors, Commission of the European Communities, Brussels, pp. 223-232, 1992.
6. R. Hori, Y. Tanigawara, M. Hirai, M. Yasuhara, K. Ueda, T. Komano, Substrates for P-glycoprotein in kidney, in "Transport in the Liver," D. Keppler and K. Jungermann, Editors, Kluwer Academic Publishers, Dordrecht, pp. 223-232, 1994.



7. K. Ueda, T. Saeki, M. Hirai, Y. Tanigawara, K. Tanaka, N. Okamura, M. Yasuhara, R. Hori, K. Inui, T. Komano, Human P-glycoprotein as a multi-drug transporter analyzed by using transepithelial transport system, *Jap. J. Physiol.*: 44, Suppl. 2, S67-S71 (1994).
8. K. Ueda, K. Kino, Y. Taguchi, K. Yamada, T. Saeki, Y. Tanigawara, T. Komano, Role of P-glycoprotein in the transport of hormones and peptides, in "Multidrug Resistance in Cancer Cells," S. Gupta and T. Tsuruo, Editors, John Wiley & Sons Ltd., Sussex, England, pp. 303-319, 1996.
9. Y. Tanigawara, Recent applications of the population pharmacokinetic approach: pre-marketing and post-marketing, in "The Population Approach: Measuring and Managing Variability in Response, Concentration and Dose," L. Aarons, L. P. Balant, *et al.* (editors), European Commission, Directorate-General, Science, Research and Development, Brussels, pp. 25-37, 1997.
10. Y. Tanigawara, Role of P-Glycoprotein in drug disposition, *Therapeutic Drug Monitoring*, 22(1): 137-140 (2000).
11. Y. Yamayoshi, E. Iida, Y. Tanigawara, Cancer pharmacogenomics: international trends, *Int. J. Clin. Oncol.*, 10(1): 5-13 (2005).
12. S. Nakade, J. Kitagawa, R. Higashi, C. Hasegawa, S. Kikawa, H. Nakane, C. Amano, Y. Tanigawara, S. Higuchi, M. Ogawa, A survey of population pharmacokinetic study on new drug applications in Japan, *Japanese Journal of TDM*, 26(1):21-17(2009).
13. Y. Hamada, I. Tokimatsu, H. Mikamo, M. Kimura, M. Seki, S. Takakura, N. Ohmagari, Y. Takahashi, K. Kasahara, K. Matsumoto, K. Okada, M. Igarashi, M. Kobayashi, T. Mochizuki, Y. Nishi, Y. Tanigawara, T. Kimura, Y. Takesue, Practice guidelines for therapeutic drug monitoring of voriconazole: a consensus review of the Japanese Society of Chemotherapy and the Japanese Society of Therapeutic Drug Monitoring, *J Infect Chemother* 19:381-392 (2013).
14. K. Matsumoto, Y. Takesue, N. Ohmagari, T. Mochizuki, H. Mikamo, M. Seki, S. Takakura, I. Tokimatsu, Y. Takahashi, K. Kasahara, K. Okada, M. Igarashi, M. Kobayashi, Y. Hamada, M. Kimura, Y. Nishi, Y. Tanigawara, T. Kimura, Practice guidelines for therapeutic drug monitoring of vancomycin: a consensus review of the Japanese Society of Chemotherapy and the Japanese Society of Therapeutic Drug Monitoring, *J Infect Chemother* 19:365-380(2013).
15. K. Okada, T. Kimura, H. Mikamo, K. Kasahara, M. Seki, S. Takakura, I. Tokimatsu, N. Ohmagari, Y. Takahashi, K. Matsumoto, M. Igarashi, M. Kobayashi, Y. Hamada, T. Mochizuki, M. Kimura, Y. Nishi, Y. Tanigawara, Y. Takesue, Clinical practice guidelines for therapeutic drug monitoring of arbecacine: A consensus review of the Japanese Society of Chemotherapy and the Japanese Society of Therapeutic Drug Monitoring, *J Infect Chemother* 20:1-5(2014).
16. H. Kenmotsu, Y. Tanigawara, Pharmacokinetics, dynamics and toxicity of docetaxel : Why the Japanese dose differs from the Western dose, *Cancer Science*, 106(5): 497-504 (2015).

*Additional 266 book chapters and review articles in Japanese.*

**Invited lectures at international meetings**

1. Y. Tanigawara and R. Hori, "Noncompartmental Analysis of Drug Disposition in the Kidney," *Fourth Japanese-American Conference on Pharmacokinetics and Biopharmaceutics*, San Francisco, August 1988.
2. Y. Tanigawara, "Population Approach in Post-Marketing Dose Adjustment," *New Strategies in Drug Development and Clinical Evaluation: The Population Approach*, Manchester, September 1991.
3. Y. Tanigawara, "Premarketing and Postmarketing Population Pharmacokinetic Studies," Population Pharmacokinetics Workshop, *Fourth International Congress of Therapeutic Drug Monitoring and Clinical Toxicology*, Vienna, September 1995.
4. Y. Tanigawara, "Recent Applications of the Population Pharmacokinetic Approach: Pre-marketing and Post-marketing," *Conference on the Population Approach: Measuring and Managing Variability In Response, Concentration and Dose*, Geneva, February 1997.
5. Y. Tanigawara, "Overcoming Racial Differences: Pharmacokinetic & Pharmacodynamic Bridging Studies," *4th Annual Biostatistics Meeting of Drug Information Association*, Tokyo, August 1997.
6. Y. Tanigawara, "Population Pharmacokinetic/Pharmacodynamic Approach for the Development of Anticancer Agents," *13th Nagoya International Cancer Treatment Symposia*, Nagoya, October 1997.
7. Y. Tanigawara, "Recent Applications of the Population Pharmacokinetic and pharmacodynamic approach: Candesartan and Docetaxel", *9th Japanese-American Conference on Pharmacokinetics and Biopharmaceutics*, Nagoya, July 1998.
8. Y. Tanigawara, "Population PK/PD and Formulation Design," *Strategies for Optimizing Oral Drug Delivery: Scientific to Regulatory Approaches*, Kobe, April 1999.
9. Y. Tanigawara, "Population PK/PD Approaches for Global Drug Development," *Formulation Optimization and Clinical Pharmacology*, Tokyo, April 1999.
10. Y. Tanigawara, "The Role of P-glycoprotein in Drug Disposition," *International Congress of Therapeutic Drug Monitoring and Clinical Toxicology*, Cairns, September 1999.
11. Y. Tanigawara, "Population PK/PD Modeling in Bridging Studies" *Millennial World Congress of Pharmaceutical Sciences*, San Francisco, April 2000.

12. Y. Tanigawara, "Population Pharmacokinetic and Pharmacodynamic Approach for Global Drug Development", *Pharmacy and Pharmaceutical World Congress 2001*, Singapore, September 2001.
13. Y. Tanigawara, "New Trends in Clinical Pharmacokinetics", *14th International Symposium on Microsomes and Drug Oxidations*, Sapporo, July 2002.
14. Y. Tanigawara, "Role of Pharmacokinetics and Pharmacodynamics in Drug Development", *APEC Tokyo Meeting*, September 2002.
15. Y. Tanigawara, "Pharmacovigilance Planning (E2E)," *6th International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)*, Osaka, November 2003.
16. Y. Tanigawara, "Nobel PK/PD Approaches to Predict Dose-Response Relationships", *2nd Pharmaceutical Sciences World Congress 2004*, Kyoto, March 2004.
17. Y. Tanigawara, "Importance of Population PK/PD Approach for Bridging Strategy in Global Drug Development," *7th Annual Meeting of Population Approach Group in Australia and New Zealand (PAGANZ)*, Brisbane, February 2005.
18. Y. Tanigawara, "Importance of Clinical PK/PD and Population PK in Global Drug Development Including Bridging Strategy," *International Society for Study of Xenobiotics*, Hawaii, October 2005.
19. Y. Tanigawara, "Recent Results and Hopes in Pharmacogenomics - Personalized Medicine," *European Biotech Crossroads*, Lille, November 2005.
20. Y. Tanigawara, "The Concept of ICH E2E Guideline," *Drug Information Association (DIA) 2nd Multitrack Workshop*, Tokyo, April 2006.
21. Y. Tanigawara, "Japanese View on the Role of PK/PD in Drug Approval – Discussion on the Basis of Examples," *5th International Symposium on Measurement and Kinetics of In Vivo Drug Effects*, Noordwijkerhout, The Netherlands, April 2006.
22. Y. Tanigawara, "Importance of PK/PD in Internationally Harmonized Drug Development", *International Symposium on Modeling & Simulation in Drug Development and Clinical Applications*, Seoul, November 2006.
23. Y. Tanigawara, "Population Pharmacokinetics and PK/PD Analysis of Antimicrobial Agents", *10th Western Pacific Congress on Chemotherapy and Infectious Diseases*, Fukuoka, December 2006.
24. Y. Tanigawara, "The Usefulness of Early Post-Marketing Pharmacovigilance," *3rd Pharmaceutical Sciences World Congress*, Amsterdam, April 2007.

25. Y. Tanigawara, “The Creation, Use and the Impact of ICH E2E Guideline in Japan,” *International Society for Pharmacoepidemiology (ISPE) 2nd Asian Meeting*, Tokyo, October 2007.
26. Y. Tanigawara, “Ethnic Difference in Drug Response and its Implications in Regional Drug Use”, *DUPHAT2009-Dubai International Pharmaceuticals and Technologies Conference*, Dubai, March 2009.
27. Y. Tanigawara, “Pharmacogenomics and Personalized Medicine,” *DUPHAT2009-Dubai International Pharmaceuticals and Technologies Conference*, Dubai, March 2009.
28. Y. Tanigawara, “Pharmaco-proteomics and Metabolomics for Personalized Medicine, Approach of Individualized Medicine in Near-Future”, *FIP and JSPHCS International Conference on Individualized Medicine: Bridging between Scientific and Clinical Studies*, Nagasaki, October 2009.
29. Y. Tanigawara, “Cancer Pharmacogenomics in Asia: Post-genome Proteomic and Metabolic Analysis for Pharmacological Responses to Anticancer Agents”, *9th International Conference of the Asian Clinical Oncology Society*, Gifu, August 2010.
30. Y. Tanigawara, “Metabolomic and Proteomic Analyses for Pharmacotherapy,” *Annual Congress of International Pharmaceutical Federation (FIP 2010)*, Lisbon, September 2010.
31. Y. Tanigawara, “PK/PD and Therapeutic Drug Monitoring for Antibacterial Agents,” *International Association of Therapeutic Drug Monitoring and Clinical Toxicology (IATDMCT) Regional Meeting*, Beijing, September 2010.
32. Y. Tanigawara, “Summary of the Work and Outcome of the ICH E2E Working Group and the Impact on Pharmacovigilance Activities,” *FIP Pharmaceutical Sciences World Congress 2010 in association with the AAPS Annual Meeting and Exposition*, New Orleans, November 2010.
33. Y. Tanigawara, “Cancer metabolomics by MS technology,” *12<sup>th</sup> Congress of IATDMCT*, Stuttgart, October 2011.
34. Y. Tanigawara, “Pharmaco-metabolomics of anticancer drugs,” *10th International Conference of the Asian Clinical Oncology Society*, Seoul, June 2012.
35. Y. Tanigawara, “Cancer biomarkers in diagnostics and pharmacotherapy,” *FIP and PSI*, Dublin, September 2013.
36. Y. Tanigawara, “Biomarkers: Integrating genomics, proteomics and metabolomics for pathway analysis in oncology,” *Systems Pharmacology in Drug Discovery & Development*, The Netherlands, April 2014.
37. Y. Tanigawara, “Personalised Pharmacotherapy for Cancer,” *IATDMCT Regional Meeting*, Sibiu, Romania, June 2014.
38. Y. Tanigawara, “PK/PD and TDM of Antibacterial Agents,” *IATDMCT Regional Meeting*, Sibiu, Romania, June 2014.
39. Y. Tanigawara, “Optimized Pharmacotherapy based on Therapeutic Drug Monitoring,”

Asia-Pacific Regional Conference for Academic Exchange of Therapeutic Drug Monitoring, Beijing, November 2014.

40. Y. Tanigawara, “Pharmaco-Metabolomics of Oncology Drugs,” 10th Global Gator Symposium New Developments in Clinical Pharmacy and Clinical Pharmacology, Utrecht, June 2015.
41. Y. Tanigawara, “Science and Practice of TDM: Recent progress and future perspective of personalized medicine”, First Asia-Pacific Symposium on Therapeutic Drug Monitoring (APSTDM), Beijing, September 2015.
42. Y. Tanigawara, “TDM for oncology: a new scientific committee”, 14th International Congress of Therapeutic Drug Monitoring & Clinical Toxicology, Rotterdam, October 2015.
43. Y. Tanigawara, “Population PK/PD and TDM for personalized cancer care”, IATDMCT Asia & Pacific Regional Meeting, 2016, China, August 2016.
44. Y. Tanigawara, “Individualized Pharmacotherapy based on Therapeutic Drug Monitoring”, The China-Japan Friendship Hospital’s First International Forum on Individualized Pharmacotherapy, China, September 2016.
45. Y. Tanigawara, “Implementation of pharmacogenomics-informed personalized dosing”, The 6th National Annual Conference on Therapeutic Drug Monitoring, China, September 2016.

*Additional 119 invited lectures at Japanese national meetings.*