

CURRICULUM VITAE

Name: Raymond Miller
Effective Date: March, 2016
Present Position: Executive Director, Modeling and Simulation
Daiichi Sankyo Pharma Development
Edison, New Jersey

Education:

Institution	Major	Degree	Year
University of California, SF	Clinical pharmacology	Diploma	1979
Potchefstroom University	Pharmacology	D.Sc.	1974
Potchefstroom University	Pharmacology	M.Sc.	1971
Potchefstroom University	Pharmacology	B.Sc. Honours	1969
Potchefstroom University	Pharmacy/Chemistry	B.Sc. Pharmacy	1968

Experience:

Employer	Title	Date
Daiichi Sankyo, Inc Edison, New Jersey	Executive Director Modeling and Simulation	03/10-present
Pfizer Global Research and Development Ann Arbor, Michigan	Senior Director, Pharmacometrics	07/04-02/10
Pfizer Global Research and Development Ann Arbor, Michigan	Director, Pharmacometrics	07/99- 07/04
Food and Drug Administration United States of America	Acting Director, Pharmacometrics	02/94-06/99
Department of Pharmacology University of Durban-Westville, Durban, South Africa	Professor and Chairman	01/84-01/94
Medical Research Council Research Unit for the Design of Catecholaminergic Drugs.	Senior Chief Research Officer and Associate Professor	01/82-12/83

Medical Research Council
Research Unit for the Design of
Catecholaminergic Drugs
Potchefstroom University, South Africa

Senior Research Officer 01/69-12/81
leading to Chief Research
Officer

Recent Career Accomplishments

- Developed the Pharmacometrics group at Parke Davis/Pfizer Ann Arbor from its inception.
- Initiated the Pharmacometrics Community of Practice within Pfizer globally to foster cross site interaction.
- Championed the implementation of model-based meta-analysis to enhance decision making in drug development
- Enlisted and mentored four post-doctoral candidates who have all subsequently been hired by Pfizer as colleagues.
- Enlisted Prof Yoon Kim from Dankook University, Korea as visiting scientist for a one year sabbatical during 2008-2009.
- Collaborating with Uppsala University on the analysis of count data using novel modeling approaches.
- Currently serve as Pharmacometrics point of contact for the Primary Care Business Unit in New London.
- Pharmacometrics point of contact for the Alzheimer's Disease Program
- Pharmacometrics point of contact for Lyrica (pregabalin) programs.
- Serve on the faculty of the NIH department of Clinical Pharmacology
- Served on the organizing committee for the American Conference on Pharmacometrics for the inaugural 2008 meeting and 2009.
- Served on the organizing committee for the 2009 DIA/FDA/PhRMA conference on modeling and simulation.
- Serve on the Editorial Advisory Board of the Journal of Pharmacokinetics and Pharmacodynamics.
- 2008 AAPS Outstanding Manuscript in Modeling and Simulation winner for the publication "Ito K, Hutmacher MM, Liu J, Qiu R, Frame B, Miller R. Exposure-response Analysis for Spontaneously Reported Dizziness in Pregabalin-treated Patient With Generalized Anxiety Disorder. Clin Pharmacol Ther 2008; 84: 127-135. "
- Elected a Fellow of the American Association of Pharmaceutical Scientists at the 2010 FIP PSWC/AAPS Annual Meeting & Exposition in New Orleans, Louisiana.
- Elected a Fellow of the International Society of Pharmacometrics at the 2014 Annual Conference on Pharmacometrics in Las Vegas, Nevada.

Professional Affiliations and Honors:

Award by the Academy of Pharmaceutical Sciences

1994

for the best publication in 1993 in the category pharmacology,
"Moosa RS, McFadyen ML, Miller R, Rubin J. Carbamazepine
and metabolites in neuralgias: concentration-effect relationship.
Eur J Clin Pharmacol 1993; 45:297-301."

Award by the Academy of Pharmaceutical Sciences 1993
for the best publication in 1992 in the category pharmacology,
"Botha JH, Tyrannes I, Miller R, Wesley AG. Pharmacokinetic
consultation program in a pediatric asthma clinic. Am J Hosp
Pharm 1992; 49: 1936-40."

Medical Research Council Sabbatical Grant, 1993
Study project in the United States - R10000.00

University of Durban Westville Research Grant, 1986
R300 000,00 to establish the Drug Studies Unit.

Council for Scientific & Industrial Research Fellowship 1985
Three month subsistence for foreign scientist to participate
in research project. Prof P Veng Pedersen, University of Iowa, U.S.A.

Award for the best scientific oral presentation at the 1984
5th Annual Congress, Academy of Pharmaceutical Sciences,
"The influence of reabsorption on bioavailability:
Ranitidine."

Pharmaceutical Manufacturers Foundation Travel grant, 1982
Research project, University of Glasgow, Scotland.

Boehringer Bursary, 1982
South African Pharmacological Society,
Research project, University of Glasgow, Scotland.

Scholarship for postdoctoral study overseas, 1977
South African Medical Research Council.

Boehringer Bursary, 1974
South African Pharmacological Society,
Research project in the Netherlands.

Memberships:

Pharmacist:- SA Pharmacy Council 1968

Specialist in Clinical Pharmacokinetics:- 1992
SA Pharmacy Council.

American Society for Clinical Pharmacology and Therapeutics 2001

American Association of Pharmaceutical Scientists 2001

Special Courses

Institution	Course Description	Date
University of Michigan Business School	Leadership Training 5 day course	22/09/03
University of Michigan Business School	Decision Analysis	8/20/01
Insightful Corporation	Statistical Modeling in S-Plus	4/17-4/19
A short course in Population Pharmacokinetic Analysis using the NONMEM system.	In introduction to nonlinear mixed effect modeling using the NONMEM software.	4/20-22/98
Intermediate workshop in Population Pharmacokinetic Data analysis using the NONMEM system.	Advanced methods in modeling and simulation using the NONMEM software.	4/23-24/98
Workshop on Advanced Methods in Pharmacokinetics and Pharmacodynamics	Application of PK/PD in the medical sciences with emphasis on relating pharmacokinetics to underlying physiological processes and pharmacodynamics.	4/6-11/97

Publications:

Nyberg J, Karlsson K, Jönsson S, Yin QP, **Miller R**, Karlsson MO, Simonsson USH. Edoxaban exposure-response analysis and clinical utility index assessment in patients with symptomatic deep-vein thrombosis or pulmonary embolism. *Pharmacometrics & Systems Pharmacology*, March 21, 2016 [Paper #PSP-2016-0009DR]

Krekels EHJ, Niebecker R, Karlsson MO, **Miller R**, Shimizu T, Karlsson KE, Ruff CT, Simonsson USH, Jönsson S. Population Pharmacokinetics of Edoxaban in patients with Non-Valvular Atrial Fibrillation in the ENGAGE AF-TIMI 48 Study, a Phase III Clinical Trial. *Clin Pharmacokinet*, 2016. [Epub ahead of print]

Niebecker R, Jönsson S, Karlsson MO, **Miller R**, Nyberg J, Krekels EHJ, Simonsson USH. Population pharmacokinetics of edoxaban in patients with symptomatic deep-vein thrombosis and/or pulmonary embolism – the Hokusai-VTE phase 3 study. *Br J Clin Pharmacol*, 2015 Dec;80(6):1374-87.

Yin, QP; Merante D; Truitt K; **Miller R**. Population Pharmacokinetic Modeling and Simulation for Assessing Renal Impairment Effect on the Pharmacokinetics of Mirogabalin. *J Clin Pharmacol*. 2016 Feb;56(2):203-12.

Hutmacher MM, Frame B, **Miller R**, Truitt K, Merante D. Exposure-response modeling of average daily pain score, and dizziness and somnolence, for mirogabalin (DS-5565) in patients with diabetic peripheral neuropathic pain. *J Clin Pharmacol*. 2016 Jan;56(1):67-77.

Jönsson S, Simonsson US, **Miller R**, Karlsson MO. Population pharmacokinetics of edoxaban and its main metabolite in a dedicated renal impairment study. *J Clin Pharmacol*. 2015, Nov;55(11):1268-79.

Yin OQ, **Miller R**. Population pharmacokinetics and dose-exposure proportionality of edoxaban in healthy volunteers. *Clin Drug Investig*. 2014 Oct;34(10):743-52.

Yin, OQ, Tetsuya, K, and **Miller, R**. Edoxaban population pharmacokinetics and exposure-response analysis in patients with non-valvular atrial fibrillation. *Eur J Clin Pharmacol*. 2014; **70**: 1339–1351

Song S, Kang D, A, Halim A-B, **Miller R**. Population Pharmacokinetic-Pharmacodynamic Modeling Analysis of Intrinsic FXa and Bleeding From Edoxaban Treatment. *Journal of Clinical Pharmacology*. *J Clin Pharmacol*. 2014 Aug;54(8):910-6.

Song S, Carrothers TJ, Moore H, Green M, **Miller R**, Rohatagi S, Lee J, Wang A, Melino M, Patel M, Heyrman R, Salazar DE. Model-Supported Development of CS-8635: A Fixed-Dose Combination of Olmesartan, Amlodipine, and Hydrochlorothiazide. *Clinical Pharmacology in Drug Development* 2013;2:103-112.

Delattre M, Savic RM, **Miller R**, Karlsson MO, Lavielle M. J Pharmacokinet Pharmacodyn (2012) 39:263–271.

Ahn JE, Plan EL, Karlsson MO, and **Miller R**. Modeling Longitudinal Daily Seizure Frequency Data from Pregabalin Add-On Treatment. J Clin Pharmacol., 2012;52:880-892.

Lalovic B, Hutmacher MM, Frame B, and **Miller R**. Modeling Dropout From Adverse Event Data: Impact of Dosing Regimens Across Pregabalin Trials in the Treatment of Generalized Anxiety Disorder. J. Clin. Pharmacol., 2011;51:706-718.

Ito K, Corrigan B, Zhao Q, French J, **Miller R**, Soares H, Katz E, Nicholas T, Billing B, Anziano R, Fullerton T, Alzheimer's Disease Neuroimaging Initiative. Disease progression model for cognitive deterioration from Alzheimer's Disease Neuroimaging Initiative database. Alzheimer's & Dementia 2011; 7: 151-160.

Miller R, Ito K, Lalovic B. Models for event-driven data: Longitudinal daily adverse event and dropout. J Clin Pharmacol 2010; 50 (1): 58S-62S.

Bockbrader HN, Wesche D, **Miller R**, Chapel S, Janiczek N, Burger P. A Comparison of the Pharmacokinetics and Pharmacodynamics of Pregabalin and Gabapentin. Clin Pharmacokinet 2010; 49(10): 661-669.

Frame B, **Miller R**, Hutmacher MM. Joint Modeling of dizziness, drowsiness, and dropout associated with pregabalin and placebo treatment of generalized anxiety disorder. J Pharmacokinet Pharmacodyn 2009; 36: 565-584.

Trocóniz IF, Plan EL, **Miller R**, Karlsson MO. Modeling overdispersion and Markovian features in count data. J Pharmacokinet Pharmacodyn 2009; 36: 461-477.

Ito K, Hutmacher MM, Liu J, Qiu R, Frame B, **Miller R**. Exposure-response Analysis for Spontaneously Reported Dizziness in Pregabalin-treated Patient With Generalized Anxiety Disorder. Clin Pharmacol Ther 2008; 84: 127-135.

Gupta P, Hutmacher MM, Frame B, **Miller R**. An alternative method for population pharmacokinetic data analysis under noncompliance. J Pharmacokinet Pharmacodyn 2008; 35: 219-233.

Frame B, Beal SL, **Miller R**, Barrett J, Burger P. Mixed effects modeling of weight change associated with placebo and pregabalin administration. J Pharmacokinet Pharmacodyn 2007; 34(6): 753-770.

Lalonde RL, Kowalski KG, Hutmacher MM, Ewy W, Nichols DJ, Milligan PA, Corrigan BW, Lockwood PA, Marshall SA, Benincosa LJ, Tensfeldt TG, Parivar

K, Amantea M, Glue P, Koide H and **Miller R**. Model-based drug development. *Clin Pharmacol Ther* 2007; 82: 21-32.

Kowalski KG, Ewy W, Hutmacher MM, **Miller R**, Krishnaswami S. Model-Based Drug Development - A New Paradigm for Efficient Drug Development. *Biopharmaceutical Report* 2007; 15: 2-22.

Hermann D, **Miller R**, Hutmacher M, Ewy W, Kowalski KG. Design and Analysis of Clinical Exposure: Response Trials. In: Ette EI, Williams PJ, editors. *Pharmacometrics: The Science of Quantitative Medicine*. John Wiley and Sons, Inc., Hoboken, NJ. 2007, pp 803-826.

Miller R, Ewy W, Corrigan B, Ouellet D, Hermann D, Kowalski G, Lockwood P, Koup J, Donevan S, El-Kattan A, Li C, Werth J, Feltner D, Lalonde L. How modeling and simulation have enhanced decision making in new drug development. *Journal of Pharmacokinetics and Pharmacodynamics* 2005;32(2):185-197.

Miller R, Hermann DJ, Ewy W, Kowalski KG. The Strategic Role and Application of Pharmacokinetic/Pharmacodynamic Modeling in Drug Development. In: Bonate P, Howard D, editors. *Pharmacokinetics in Drug Development: Regulatory and Development Paradigms (Volume 2)*. AAPS Press, Arlington VA. 2004, pp 317-347.

Miller R, Frame B, Corrigan B, Burger P, Bockbrader H, Garofalo Elizabeth, Lalonde R. Exposure-response analysis of pregabalin add-on treatment of patients with refractory partial seizures. *Clin Pharmacol Ther* 2003;73:491-505.

Kowalski KG, McFadyen L, Hutmacher MM, Frame B, **Miller R**. A two-part mixture model for longitudinal adverse event data. *J Pharmacokinetic Pharmacodyn* 2003;30(5):315-336.

Frame B, **Miller R**, Lalonde R. Evaluation of Mixture Modeling with Count Data using NONMEM. *J Pharmacokinetic Pharmacodyn* 2003;30(3):167-183.

Chetty M, **Miller R**. Oral contraceptives increase the plasma concentrations of chlorpromazine. *Ther Drug Monit* 2001; 23(5): 556-558.

Ette EI, Lockwood P, **Miller R**, Mandema J. Analysis of Analgesic Trials. In: Millard SP, Krause A, editors. *Applied Statistics in the Pharmaceutical Industry*. New York: Springer-Verlag; 2001. p. 237-266.

Miller R. Population Pharmacokinetics. In: Atkinson AJ, Daniels CE, Dedrick RL, Grudzinskas CV, Markey SP, editors. *Principles of Clinical Pharmacology*. San Diego: Academic Press; 2001. p. 113-119.

Frame B, Koup J, **Miller R**, Lalonde R. Population Pharmacokinetics of Clinafloxacin in Healthy Volunteers and Patients with Infections. *Clin*

Pharmacokinet 2001; 40(4): 307-315.

Derendorf H, Lesko LJ, Chaikin P, Colburn WA, Lee P, **Miller R**, Powell R, Rhodes G, Stanski D, Venitz J. Pharmacokinetic/pharmacodynamic modeling in drug research and development. *J Clin Pharmacol* 2000; 40(12 Pt 2): 1399-418.

Jackson AJ, Conner DP, **Miller R**. First measured plasma concentration value as C-max; impact on the C-max confidence interval in bioequivalence studies. *Biopharm Drug Disp* 2000; 21(4): 139-146.

Wang D, **Miller R**, Zheng J, Hu C. Comparative Population Pharmacokinetic/Pharmacodynamic Analysis for Piroxicam- β -Cyclodextrin and Piroxicam. *J Clin Pharmacol* 2000;40:1257-1266.

Valodia PN, Seymour MA, McFadyen ML, **Miller R**, Folb PI. Validation of population pharmacokinetic parameters of phenytoin using the parallel Michaelis-Menten and first-order elimination model. *Ther Drug Monit* 2000;22(3):313-9.

Machado SG, **Miller R**, Hu C. A regulatory perspective on pharmacokinetic/pharmacodynamic modelling. *Statistical Methods in Medical Research* 1999; 8: 217-245.

Valodia P, Seymour MA, **Miller R**, McFadyen ML, Folb PI. Factors influencing the population pharmacokinetic parameters of phenytoin in adult epileptic patients in South Africa. *Ther Drug Monit* 1999;21(1):57-62.

Chetty M, Gouws E, **Miller R**, Moodley SV. The use of a side effect as a qualitative indicator of plasma chlorpromazine levels. *Eur Neuropsychopharmacol* 1999;9(1-2):77-82.

Gray AL, Botha JH, **Miller R**. A model for determination of carbamazepine clearance in children on mono- and polytherapy. *Eur J Clin Pharmacol* 1998; 54(4):359-62.

Chetty M, **Miller R**, Seymour MA. Phenytoin auto-induction. *Ther Drug* 1998;20(1):60-2.

Botha JH, du Preez MJ, **Miller R**, Adhikari M. Determination of population pharmacokinetic parameters for amikacin using mixed effect models. *Eur J Clin Pharmacol* 1998;53(5):337-41.

Ette EI, **Miller R**, Gillespie WR, Huang SM, Lesko L, Williams R. The population approach: FDA experience. Proceedings of conference on the population approach: measuring and managing variability in response, concentration and dose. European Cooperation in the Field of Scientific and Technical Research (Project COST B1, round III), 1997; pp 271 - 275.

Combrink M, McFadyen L, **Miller R**. A comparison of the standard approach and the NONMEM approach in the estimation of bioavailability in man. *J Pharm Pharmacol* 1997;49(7):731-3.

McFadyen ML, **Miller R**, Ludden TM. Ketotifen pharmacokinetics in children with atopic perennial asthma. *Eur J Clin Pharmacol* 1997;52(5):383-6.

Hosseini M, Wright E, Baweja R, Ludden T, **Miller R**. Nonlinear Mixed Effect Modeling of single dose and multiple dose data for an immediate release (IR) and a controlled release (CR) dosage form of alprazolam. *Pharm Res* 1997; 14: 309-315.

Chetty M, Pillay VL, Moodley SV, **Miller R**. Response in chronic schizophrenia correlated with chlorpromazine, 7-OH-chlorpromazine and chlorpromazine sulfoxide levels. *Eur Neuropsychopharmacol* 1996; 6(2): 85-91.

Botha JH, Gray AL, **Miller R**. Determination of phenobarbitone population clearance values for South African children. *Eur J Clin Pharmacol* 1995; 48: 381-383.

Allbrecht CF, Kruger PB, Smit BJ, Freestone M, Gouws L, **Miller R**, van Jaarsveld PP. The pharmacokinetic behaviour of hypoxoside taken orally by patients with lung cancer in a phase I trial. *S Afr Med J* 1995; 85: 861-865.

Botha JH, Gray AL, **Miller R**. A model for estimating individualized valproate clearance values in children. *J Clin Pharmacol* 1995; 35: 1020-1024.

Miller R. Contribution of biopharmaceutics and pharmacokinetics to improve drug therapy (Abstract 3.17.1). *Brazilian Journal of Toxicology* 1995; 8: 119.

Chetty M, **Miller R**, Moodley SV. Smoking and body weight influence the clearance of chlorpromazine. *Eur J Clin Pharmacol* 1994; 46: 523-526.

Chetty M, Moodley SV, **Miller R**. Important metabolites to measure in pharmacodynamic studies of chlorpromazine. *Ther Drug Monit* 1994; 16(1): 30-6.

Moosa RS, McFadyen ML, **Miller R**, Rubin J. Carbamazepine and its metabolites in neuralgias: concentration effect relations. *Eur J Clin Pharmacol* 1993; 45(4): 297-301.

Botha J, Tyrannes I, **Miller R**, Wesley AG. Determination of theophylline clearance in South African children. *Eur J Clin Pharmacol* 1993; 44: 369-375.

Miller R, Ludden TM. Bioavailability of controlled release carbamazepine estimated by mixed effect modelling. *Eur J Clin Pharmacol* 1993; 44: 225-229.

Botha JH, Tyrannes I, **Miller R**, Wesley AG. Pharmacokinetic consultation program in a pediatric asthma clinic. *Am J Hosp Pharm* 1992; 49: 1936-40.

Dilraj A, Botha JH, Rambiritch V, **Miller R**, van Dellen JR. Plasma and cerebrospinal fluid catecholamine levels in aneurysmal subarachnoid hemorrhage. *Neurosurgery* 1992; 31: 42-51.

Miller R, McFadyen ML. The use of pharmacokinetics to optimise anti-epileptic therapy. *Continuing Medical Education* 1991; 9: 1535-1543.

Botha J, **Miller R**, Moodley M. Estimating phenytoin dosages in black African and Indian children. *Clin Pharm* 1991; 10:928-31.

Chetty M, **Miller R**. The influence of storage on chlorpromazine and metabolites. *Ther Drug Monit* 1991; 13: 350-355.

Pillai G, **Miller R**, Rambiritch V. The theophylline content of bronchodilator preparations on the South African market. *S Afr Med J* 1991; 80: 240-243.

Pillai G, **Miller R**, Rambiritch V. Evaluation of a new dry-phase, strip immunoassay technique for analysis of serum theophylline concentrations. *S Afr Med J* 1991; 79: 682.

Wiseman IC, **Miller R**. A pharmacokinetic approach to assist in quantifying noncompliance in patients receiving digoxin. *S Afr Med J* 1991; 79: 155-157.

Majosi B, Botha J, McFadyen L, **Miller R**. The effect of Carbenoxolone on Rat Uterine contractility. *S Afr J Sci* 1990; 86: 270-271.

McFadyen ML, **Miller R**, Juta M, Hodgson V. The relevance of a First World therapeutic drug monitoring service to the treatment of epilepsy in Third-World conditions. *S Afr Med J* 1990; 78: 587-590.

Thurman GD, McFadyen ML, **Miller R**. The pharmacokinetics of phenobarbitone in fasting and non-fasting dogs. *J S Afr vet Assoc* 1990; 61: 86-89.

Botha JH, Bobat R, Moosa A, **Miller R**. Therapeutic drug monitoring in a paediatric epilepsy clinic. *S Afr Med J* 1990; 77: 511-514.

Wallis J, **Miller R**, McFadyen ML, Carlile J. A comparative study of standard and slow-release oral lithium carbonate products. *S Afr Med J* 1989;76:618-620.

Miller R, Rheeders M. Effect of source of population data on phenytoin dosage predictions in black patients. *Clin Pharm* 1989;8:56-59.

Miller R, Bill PLA, Du Toit J. Phenytoin auto-induction? *S Afr Med J* 1989;75:332-333.

Miller R. Antiepileptic drug therapy in paediatric patients. *Pedmed* 1988;2:19-24.

Pillai G, **Miller R**, Clinical experience with theophylline, a case for monitoring serum concentrations. *S Afr Med J* 1988;73:640-642.

Veng Pedersen P, **Miller R**. Deconvolution at steady-state: determination of gastrointestinal bioavailability of sustained release theophylline. *Int J Clin Pharmacol Therap Toxicol* 1987;25(5):233-237.

Miller R, Rheeders M, Klein C, Suchet I. Population pharmacokinetics of phenytoin in South African Black patients. *S Afr Med J* 1987;72:188-190.

Klein C, Suchet I, Scher LG, Rheeders M, **Miller R**. Therapeutic Drug Level Monitoring in the Management of Epilepsy. *S Afr Med J* 1987;71:83-85.

Veng Pedersen P, **Miller R**. Relative Deconvolution. An explicit method for bioavailability comparison not requiring intravenous administration. *Int J Clin Pharmacol Therap Toxicol* 1987;25(1):10-14.

Miller R, Oliver I. The influence of oxygen tension on theophylline clearance in the isolated perfused rat liver. *J Pharm Pharmacol* 1986;38:236-238.

Oliver IF, **Miller R**. Teofillienopruiming in die geisorleerde geperfuseerde rotlewer. *S A Pharm J* 1984;51:545-547.

Miller R. Pharmacokinetics and bioavailability of ranitidine in humans. *J Pharm Sci* 1984;73:1376-1378.

Miller R, Rheeders M. Bioavailability of two theophylline sustained-release products in smokers. *S Afr Med J* 1984;65:1045-1048.

McFadyen ML, Folb PI, **Miller R**, Keeton GR, Marks IM. Pharmacokinetics of ranitidine in patients with chronic renal failure. *Eur J Clin Pharmacol* 1983;25:347-351.

McFadyen ML, Folb PI, **Miller R**, Marks IN, Moshal MG. The pharmacokinetics of ranitidine in patients with chronic duodenal ulceration: A comparison of responders and non-responders. *Eur J Clin Pharmacol* 1983;24:441-447.

Miller R, Nowosiad D, Warnes DM. The role of the pharmacist in an outpatient epilepsy clinic. *S A Pharm J* 1982;49(9):439-441.

Miller R, Nowosiad D, Warnes DM, De Wet JM. The role of therapeutic drug monitoring in the care of epileptic patients. *S Afr Med J* 1982;62:512-515.

Veng Pedersen P, **Miller R**. Pharmacokinetics and Bioavailability of Cimetidine in Humans. *J Pharm Sci* 1980;69(4):394-398.

Veng Pedersen P, **Miller R**, Pharmacokinetics of Doxycycline Reabsorption. *J Pharm Sci* 1980;69(2):204-207.

Miller R. Clinical Pharmacology of Theophylline (Letter). S Afr Med J 1980;57:389.

Miller R. Clinical Pharmacy in South Africa - fantasy or reality? S A Pharm J 1979; special edition: 20-21.

Venter JL, **Miller R**, Offermeier J. Aspekte van die farmakokinetika van verskeie B-Adrenergiese Geneesmiddels. S Afr Med J 1977;52:411.

Miller R. Guide to Drug Interactions, 1973. Published by A.P.S. Journal (Pty) Ltd.

Miller R. Mechanisms of Drug Interactions. Interactions which Affect Drug Excretion. S A Pharm J 1973;41(6):234-236.

Miller R. Mechanisms of Drug Interactions. Interactions due to Changes in Drug Metabolism. S A Pharm J 1973;41(5):165-167.

Miller R. Mechanisms of Drug Interactions. Interactions at Drug Receptor site, II. S A Pharm J 1973; 41(4):121-124.

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Miller R. Mechanisms of Drug Interactions. Interactions which affect Drug Absorption. S A Pharm J 1973;41(1):5-8.

Offermeier J, **Miller R**, Brandt H D. The effect of Bromhexine on the Concentration of Oxytetracycline in Nasal Mucus. S Afr Med J 1972;46:1509-1511.

Abstracts/Posters/Presentations:

Yin OQ, Merante D, Truitt K, Miller R. Longitudinal exposure-response relationship for mirogabalin in patients with diabetic peripheral neuropathic pain. *Journal of Pharmacokinetics and pharmacodynamics* 2015; 42:S19 [Abstract M-20]. Presented at 2015 Annual meeting of American Conference on Pharmacometrics, October 2015, USA.

Hutmacher MM, Frame B, Miller R, Truitt K, Merante D. Exposure-Response Modeling of Average Daily Pain Score, and Dizziness and Somnolence, for Mirogabalin (DS-5565) in Patients With Diabetic Peripheral Neuropathic Pain. Presented at the 5th International Congress on Neuropathic Pain (NEUPSIG); May 14-17, 2015; Nice, France.

Yin OQ, Merante D, Miller R. Population pharmacokinetic modeling for assessing renal impairment effect on the pharmacokinetics of mirogabalin. Presented at 2014 Annual Meeting of American College of Clinical Pharmacology, September 2014, USA.

Yin OQ, Song S, Truitt K, Miller R. Population pharmacokinetic modeling for mirogabalin in healthy subjects and patients with diabetic peripheral neuropathic pain. *Journal of Pharmacokinetics and pharmacodynamics* 2015; 41:S19 [Abstract M-20]. Presented at 2014 Annual meeting of American Conference on Pharmacometrics, October 2014, USA

Kang D, Miller R. Diabetes Toolkit: A Multi-Function Clinical Trial Simulation Program. American Conference on Pharmacometrics: Harbor Beach Fort Lauderdale Marriott Resort & Spa, May 12-15, 2013.

Song S, Kang D, Mendell, J, Halim AB, Miller R. Modeling the Intrinsic Factor Xa From Edoxaban Treatment. American Conference on Pharmacometrics: Harbor Beach Fort Lauderdale Marriott Resort & Spa, May 12-15, 2013.

Yin OPQ, Miller R. Population Pharmacokinetic Modeling for Edoxaban in Healthy Subjects and Patients with Non-valvular Atrial Fibrillation (NVAF). American Conference on Pharmacometrics: Harbor Beach Fort Lauderdale Marriott Resort & Spa, May 12-15, 2013.

Lim LA, Miller R, Park K. Dose-Response-Dropout analysis for somnolence in pregabalin treated patients with Generalized Anxiety Disorder. 19th Annual Population Approach Group Meeting: Berlin, Germany, 8-11 June, 2010.

Delattre M, Savic R, Miller R, Karlsson MO, Lavielle M. Estimation of mixed hidden Markov models with SAEM. Application to daily seizure data. 19th Annual Population Approach Group Meeting: Berlin, Germany, 8-11 June, 2010.

Miller R. Influencing the design of dose titration schemes to minimize AE's and

subsequent dropout. Predictive Modeling in Drug Development Satellite Meeting. St. Petersburg, Russia, 23 June, 2009.

Goel V, Hanson TE, Corrigan B, Miller R, Brundage RC. A Bayesian multivariate model for repeated measures of correlated data. 18th Annual Population Approach Group Meeting: St. Petersburg, Russia, 23-26 June, 2009.

Lalovic B, Hutmacher MM, Frame B, Miller R. Impact of dosing regimens on dropout across pregabalin trials in the treatment of generalized anxiety disorder: Model refinements and external validation. 18th Annual Population Approach Group Meeting: St. Petersburg, Russia, 23-26 June, 2009.

Goel V, Miller R, Ito K, Zhao Q, Corrigan BW. A Population PD0200390 Exposure-Response Model for Number of Awakenings (NAASO-2) in Patients with Primary Insomnia. Clin Pharmacol Ther 2009; 85(1) : S62.

Goel V, Miller R, Ito K, French J, Zhao Q, Corrigan BW. Development of a Stochastic Multi-Attribute Decision Based Clinical Utility for Phase III Dose Selection. Clin Pharmacol Ther 2009; 85(1) : S65.

Miller R. Short course "Pharmacodynamic Modeling of Non-standard Endpoints": Modeling Count Data. 2008 AAPS Annual Meeting and Exposition, 15-19 November, 2008.

Miller R. Population Pharmacokinetics. National Institute of Health lecture series in Clinical Pharmacology. Bethesda, USA, 12 November, 2008.

Miller R. Evolution of the Exposure Response Guidance: Regulatory and Industry Perspective. 1st American Conference on Pharmacometrics: Tucson, AZ, USA , 9-12 March, 2008.

Ito K, Hutmacher M, Liu J, Qiu R, Frame B, Miller R. Exposure-Response Analysis for Spontaneously Reported Dizziness in Pregabalin Treated Patients with Generalized Anxiety Disorder. 1st American Conference on Pharmacometrics: Tucson, AZ, USA , 9-12 March, 2008.

Gupta P, Hutmacher MM, Frame B, Miller R. Evaluation of an alternative approach for multiple-dose population pharmacokinetic data analysis in the presence of noncompliance. 1st American Conference on Pharmacometrics: Tucson, AZ, USA , 9-12 March, 2008.

Kjellsson MC, Ouellet D, Miller R, Karlsson MO. Modeling Sleep Using Markov Mixed Effects Models. 16th Annual Population Approach Group Meeting: Copenhagen, Denmark, 13-15 June, 2007.

Lalovic B, Hutmacher MM, Frame B, Ito K, Miller R. Modeling the Dropout from Longitudinal Adverse Event Data: Selecting Optimal Titration Regimens. 16th Annual Population Approach Group Meeting: Copenhagen, Denmark, 13-15

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