

Guohua An, MD, PhD

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EMPLOYMENT

- Oct 2014 – Present Assistant Professor
Department of Pharmaceutical Sciences and Experimental Therapy
College of Pharmacy
University of Iowa
Iowa City, Iowa
- Dec 2012 – Sep 2014 Assistant Professor
Department of Pharmaceutics (Orlando Campus)
College of Pharmacy
University of Florida
Orlando, Florida
- Aug 2010 – Nov 2012 Senior Clinical Pharmacokineticist
Department of Clinical Pharmacology and Pharmacometrics
Global Pharmaceutical R&D
Abbott Laboratories
Abbott Park, Illinois
- 2003 – 2005 Clinical Pharmacist and Research Scientist
Clinical Pharmacology Lab
Department of Pharmacy
Ruijin Hospital
Shanghai, China

EDUCATION

2005~2010 Ph.D. in Pharmaceutical Sciences, SUNY at Buffalo, Buffalo, NY, USA

2000~2003 M.S. in Clinical Pharmacology, Fudan University, Shanghai, China

1995~2000 M.D. Taishan Medical College, Shandong, China

GRADUATE RESEARCH EXPERIENCE

Ph.D. Project: The effects of flavonoids on the BCRP-mediated pharmacokinetics and pharmacodynamics of Mitoxantrone

- **Effects of single flavonoid and multiple flavonoid combinations on the accumulation and cytotoxicity of mitoxantrone in BCRP-overexpressing breast cancer cells.** Mitoxantrone accumulation study was conducted and samples were analyzed using flow cytometry. Mitoxantrone cytotoxicity study was also carried out to confirm the inhibitory effect of flavonoids on BCRP-mediated mitoxantrone resistance.
- **Effects of flavonoids on the bi-directional transport of mitoxantrone in BCRP-transfected MDCK cells.** Mitoxantrone bi-directional transport study was carried out and samples were analyzed by HPLC.
- **Effect of 5,7-dimethoxyflavone and multiple flavonoid combinations on the ABCG2-mediated PK and tissue distribution of mitoxantrone in mice.** Mitoxantrone PK and tissue distribution study was carried out in mice and samples were analyzed by HPLC. The PK parameters of mitoxantrone were characterized using WinNonlin.
- **The effect of 5,7-dimethoxyflavone and multiple flavonoid combinations on the PD of mitoxantrone in murine xenograft breast tumor model.** A xenograft breast tumor model was constructed. Tumor growth, histology results and survival rates among different treatment groups were compared. Cell proliferation in tumors was determined using immunohistochemical analysis.
- **Physiologically based pharmacokinetic modeling of mitoxantrone in mice.** A mechanistic PBPK model of mitoxantrone incorporating DNA and protein binding was constructed and successfully scaled up to humans. (software used: WinNonlin and ADAPT5)
- **Mechanism study: to investigate the role of BCRP in the transport of flavonoids biochanin A and kaempferol.** Flavonoids bi-directional transport study was carried out and the concentrations of biochanin A and kaempferol were determined by LC/MS/MS.

PROFESSIONAL EXPERIENCE

2010 Aug ~ 2012 Nov

Senior Research Pharmacokineticist

Department of Clinical Pharmacology and Pharmacometrics

Global Pharmaceutical R&D

Abbott Laboratories

Clinical Study Support

- Provided modeling & simulation support for dose selection and clinical trial design for Phase 1, Proof of Concept and Phase 2b studies
- Developed various mechanistic modeling (e.g. PK/PD modeling on uric acid, exposure-response model on pain intensity, exposure-heart rate model, exposure-adverse event model, exposure-adverse event-dropout model, target-mediated drug disposition model and drug-drug interaction model)
- Predicted PK behavior of two ABT compounds in humans and recommended the first-in-human dose based on in vitro-in vivo correlation and allometric scaling analysis

- Predicted drug-drug interaction in humans based on the preclinical data for one ABT compound (software: SimCYP).
- Provided scientific and technical input to clinical protocols, clinical development plans, investigator's brochure and clinical pharmacology section of regulatory filing documents
- Wrote a white paper on the pharmacokinetic interaction between valproic acid (Depakote) and ritonavir (Norvir) to support the labeling update of Depakote
- Author and reviewer of 14 Phase I clinical study reports, 4 Phase 2 clinical study reports

Research Projects

- **Exposure-response Modeling for Pharmacokinetics, Efficacy, Safety and Dropout of ABT-652 in Subjects with Osteoarthritic Pain.** *(finished; equal contributor with Dr. Wei Liu, manuscript under preparation)*
A phase 2a proof of concept study was conducted for ABT-652 and the results demonstrated that ABT-652 has significant improvement in efficacy, dose-dependent increase in heart rate, higher incidence of adverse event (AE) and higher dropout rate over placebo. Model-based population PK analysis and exposure-response analysis was conducted to characterize observed data. All the models were constructed using NonMEM. The results of this project played key role in ABT-652 dose selection for further Phase 2b/3 studies.
- **CYP3A-mediated interaction model between ABT-384 and Ketoconazole in Humans.** *(finished; leading scientist of this project)*
ABT-384 exposure was found to be increased 19-fold for AUC and 3.5-fold for Cmax after ketoconazole co-administration. In order to characterize the observed drug-drug interaction (DDI) data and improve the accuracy of predicted interaction magnitude for future DDI studies, I developed a semi-PBPK model for CYP3A-mediated inhibition of ABT-384 clearance by ketoconazole. This semi-PBPK model can be utilized in other CYP3A-based DDI and has the capability of being more informative for drug interaction assessments.
- **Population pharmacokinetics and pharmacodynamic modeling of ABT-639 after single and multiple dose administration in healthy volunteers** *(finished, leading scientist of this project)*
All the models were constructed using NonMEM. ABT-639 PK was well characterized by a two compartment model with dose-dependent bioavailability and different absorption rate between morning dose and evening dose. An indirect response PD model was used to capture the dose-dependent decrease of uric acid concentrations.
- **Model-based Meta-analysis on the Pain Related Endpoints in OA Pain Clinical Trials.** *(finished, leading scientist,)* The data were obtained from published literature, FDA, EMEA websites and results posted on clinicaltrials.gov. The results of this project are expected to establish relative potency ratios and therapeutic indices for evaluated compounds. Through leveraging exist information, the model-based meta-analysis will increase precision in decision making for compounds that are under development for pain indications.

2003 ~2005 Clinical Pharmacist and Research Scientist

Clinical Pharmacology Lab, Department of Pharmacy, Ruijin Hospital, Shanghai, China

Projects participated:

- Bioequivalence of ibuprofen orally disintegrating tablets in healthy volunteers, (Mar 2004 ~ July 2004)
- Investigation on the population pharmacokinetics of mycophenolate mofetil in kidney transplantant recipients (2004~2005, Collaborated with Prof. Francoise Bressolle, Department of Pharmacy, University Montpellier I, France)

2001~ 2002 Research Assistant, School of Pharmacy, Fudan University.

1999 ~ 2000 Medical Intern, rotations in the First Affiliated Hospital Taishan Medical College.

PUBLICATIONS

Book Chapter

- **An G** and Morris ME, Enzyme- and Transporter-Based Drug-Drug Interactions- Progress and Future Challenge, book edited by Pang KS, Rodrigues AD and Peter RM. Springer **2010**, pp.555-584.

Peer-Reviewed Articles

1. **An G***. Small Molecule Compounds Exhibiting Target Mediated Drug Disposition (TMDD) – a Mini-review. (**To be submitted** to *Journal of Clinical Pharmacology*)* **Corresponding author**
2. Ziegler D, Duan R, **An G**, Thomas JW, and Nothaft W. A Randomized Double-blind, Placebo- and Active-Controlled Study of T-Type Calcium Channel Blocker ABT-639 in Patients with Diabetic Peripheral Neuropathic Pain (**To be submitted** to *Pain*)
3. Alsultan A, **An G**, and Peloquin CA. Limited Sampling Strategy and Target Attainment Analysis for Leveofloxacin in Patients with Tuberculosis. *Antimicrobial Agents & Chemotherapy* (**submitted**)
4. **An G***, Liu W, and Dutta S. Small Molecule Compounds Exhibiting Target Mediated Drug Disposition (TMDD) – a Case Example of ABT-384. *Journal of Clinical Pharmacology* (**submitted**) * **Corresponding author**
5. Cope J, Bushwitz J, **An G**, Antigua A, Patel A, and Zumberg M. Reply: Clinical experience with fondaparinux in critically ill patients with moderate to severe renal impairment and renal failure requiring renal replacement therapy. *Annals of Pharmacotherapy* **2015** (**In press**)
6. **An G***, Mukker JK, Derendorf H, and Frye RF. Enzyme- and Transporter-Mediated Beverage-Drug Interactions: an Update on Fruit Juices and Green Tea. *Journal of Clinical Pharmacology* (**under revision**) * **Corresponding author**
7. **An G***, Liu W, Duan R, Nothaft W, Awni W, and Dutta S. Population Pharmacokinetics and Exposure-Uric Acid Analyses after Single and Multiple Doses of ABT-639, a Calcium Channel Blocker, in Healthy Volunteers. *The AAPS Journal* **2015**, Jan 8 [Epub ahead of print] * **Corresponding author**

8. Fleisher B, Uum J, Shao J, and **An G***. Ingredients in Fruit Juice Interact with Dasatinib through Inhibition of BCRP: A New Mechanism of Beverage-Drug Interaction. *Journal of Pharmaceutical Sciences* **2015** Jan;104(1):266-75. *Corresponding author. PMID: 25418056
9. Bei D and **An G***. Quantification of 5,7-Dimethoxyflavone in Mouse Plasma using Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) and its Application to a Pharmacokinetic Study. *Journal of Chromatography B* **2015** Jan; 978-979:11-7 * Corresponding author PMID: 25531865
10. Cope J, Bushwitz J, **An G**, Antigua A, Patel A, and Zumberg M. Clinical experience with fondaparinux in critically ill patients with moderate to severe renal impairment and renal failure requiring renal replacement therapy. *Annals of Pharmacotherapy* **2014** Dec 16 [Epub ahead of print]
11. Shao J, Markowitz JS, Bei D, and **An G***. Enzyme- and Transporter-Mediated Drug Interactions with Small Molecule Tyrosine Kinase Inhibitors. *Journal of Pharmaceutical Sciences* **2014** Dec;103(12):3810-33. * Corresponding author. PMID: 25308414
12. Egelund EF, Isaza R, Brock AP, Alsultan A, **An G**, and Peloquin CA. Population Pharmacokinetics of Rifampin in the Treatment of Mycobacterium Tuberculosis in Elephants. *Journal of Veterinary Pharmacology and Therapeutics* **2014** Sep 18 [Epub ahead of print]
13. **An G***, Liu W, Katz D, Marek G, Awni W, and Dutta S. Population Pharmacokinetics of the 11 β -Hydroxysteroid Dehydrogenase Type 1 Inhibitor ABT-384 in Healthy Volunteers following Single and Multiple Dose Regimens. *Biopharmaceutics & Drug Disposition* **2014**;35(7):417-429 * Corresponding author
14. **An G**, Wang X, and Morris ME. Dietary Flavonoids are Inhibitors of Human Organic Anion Transporter 1 (OAT1). *Drug Metabolism and Disposition* **2014**;42(9):1357-66.
15. Deng J, Shao J, Markowitz JS, and **An G***. ABC Transporters in the Multi-drug Resistance and ADME-Tox of Small Molecule Tyrosine Kinase Inhibitors. *Pharmaceutical Research* **2014**; 31(9):2237-55 * Corresponding author.
16. Katz DA, Liu W, Locke C, Jacobson P, Barnes DM, Basu R, **An G**, Rieser MJ, Daszkowski D, Groves F, Heneghan G, Shah A, Gevorkyan H, Jhee SS, Ereshefsky L, Marek GJ. Peripheral and central nervous system inhibition of 11 β -hydroxysteroid dehydrogenase type 1 in man by the novel inhibitor ABT-384. *Translational Psychiatry* **2013**; 3:e295, 1-7.
17. **An G***, Liu W, Katz D, Marek G, Awni W, and Dutta S. Effect of Ketoconazole on the Pharmacokinetics of ABT-384 and Its Two Active Metabolites in Healthy Volunteers: Population Analysis of Data from a Drug-Drug Interaction Study. *Drug Metabolism and Disposition* **2013**; 41(5): 1035-45. * Corresponding author
18. **An G** and Morris ME. A physiologically based pharmacokinetic model of mitoxantrone in mice and scale-up to humans: a semi-mechanistic model incorporating DNA and protein binding. *The AAPS Journal* **2012**; 14(2):352-64.
19. Tsiklauri L, **An G**, Alaniya M, Kemertelidze E, Morris ME. Optimal Parameters of HPLC for Simultaneous Determination Robinin and Kaempferol. *Pharmaceutical Chemistry Journal* **2012**,46(1):49-52.

20. **An G** and Morris ME. The sulfated conjugate of biochanin A is a substrate of breast cancer resistant protein (ABCG2). *Biopharmaceutics & Drug Disposition* **2011**; 32(8):446-457.
21. **An G**, Wu F, and Morris ME. 5,7-Dimethoxyflavone and multiple flavonoids in combination alter the ABCG2-mediated tissue distribution of mitoxantrone in mice. *Pharmaceutical Research* **2011**;28(5):1090-9.
22. **An G**, Gallegos J, and Morris ME. The bioflavonoid kaempferol is an Abcg2 substrate and inhibits Abcg2-mediated quercetin efflux. *Drug Metabolism & Disposition* **2011**;39(3):426-32.
23. Tsiklauri L, **An G**, Ruszaj DM, Alaniya M, Kemertelidze E, Morris ME. Simultaneous determination of the flavonoids robinin and kaempferol in human breast cancer cells by liquid chromatography-tandem mass spectrometry. *J Pharm Biomed Anal* **2011**,55(1):109-13.
24. **An G** and Morris ME. Effects of single and multiple flavonoids on BCRP-mediated accumulation, cytotoxicity and transport of mitoxantrone in vitro. *Pharmaceutical Research* **2010**;27(7): 1296-308.
25. **An G**, Ruszaj DM, and Morris ME. Interference of a sulfate conjugate in quantitative liquid chromatography/tandem mass spectrometry through in-source dissociation. *Rapid Communications in Mass Spectrometry* **2010**; 24:1817-1819.
26. **An G** and Morris ME. The effect of isoflavonoid biochanin A on the transport of mitoxantrone in vitro and in vivo. *Biopharmaceutics & Drug Disposition* **2010**; 31:340-350.
27. **An G** and Morris ME. HPLC analysis of mitoxantrone in mouse plasma and tissues: Application in a pharmacokinetic study. *J Pharm Biomed Anal* **2010**; 51(3): 750-3.
28. Moon YJ, Shin BS, **An G** and Morris ME. Biochanin A inhibits breast cancer tumor growth in a murine xenograft model. *Pharmaceutical Research* **2008**; 25(9): 2158-63.
29. Yu Z, Chen B, Zhang W, Fang J, **An G** and Cai WM. Relative bioavailability and bioequivalence of ibuprofen orally disintegrating tablets in healthy volunteers. *Chinese Journal of Clinical Pharmacy* **2006**;15(5): 280-283.
30. Yu Z, Zhou P, Wang X, Xu D, Chen B, Zhang W, **An G** and Fang J. Limited sampling strategy for the estimation of mycophenolic acid area under the plasma concentration-time curve in adult Chinese renal recipients. *Chinese Journal of Clinical Pharmacology* **2006**;22(6): 243-247.
31. Yu Z, Chen B, Zhang W, **An G**, Fang J, and Cai WM. Pharmacokinetics of Pazufloxacin Mesilate in Chinese Healthy Volunteers. *Chinese Pharmaceutical Journal* **2006**; 41(15): 1168-1171.
32. Di Q, Zhu B, **An G**, and Cai WM. The application status and future trend of parenteral nutrition preparation. *China Pharmacy* **2005**; 16(11): 862-863
33. **An G**, Ji MC, Geng XF, and Cheng NN. The cost-effective analysis of different antihyperglycemic therapies in patients with type 2 diabetes mellitus. *Chinese Journal of Hospital Pharmacy J* **2004**; 24(7):423-424.
34. **An G**, Geng XF, and Ji MC. Interactions of antihyperglycemic agents and drugs, *Chinese Journal of Clinical Pharmacology* **2003**; 19(1): 67-70.

35. **An G**, Geng XF, and Ji MC. Prescribing patterns and therapeutic implications in a cohort of 200 outpatients with type 2 diabetes and hypertension. *Chinese Journal of Pharmacoepidemiology* **2003**; 12(2): 80-82.
36. Ji MC, Geng XF, and **An G**. The rational drug use analysis in insomniac patients in comprehensive hospital. *Chinese Academic Medical Magazine of Organisms* **2002**; 3:38-41.
37. **An G**, Geng XF, and Ji MC. The application of evidence-based medicine in the drug therapy of type 2 Diabetes Mellitus. *Chinese Academic Medical Magazine of Organisms* **2002**; 3: 57-59.

Poster Abstracts

1. Fleisher B, Uum J, Shao J, and **An G**. Grapefruit Juice Ingredients Interact with Dasatinib through Inhibition of Breast Cancer Resistance Protein (BCRP): A New Type of Beverage-Drug Interaction. **ASCPT, 2015** (*Abstract accepted*)
2. Uum J, Fleisher B, Shao J, and **An G**. Orange Juice and Apple Juice Ingredients Inhibit Dasatinib Efflux via P-Glycoprotein and Breast Cancer Resistance Protein: A New Type of Beverage-Drug Interaction. **ASCPT, 2015** (*Abstract accepted*)
3. Bei D and **An G**. Quantification of 5,7-Dimethoxyflavone in Mouse Plasma using Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) and its Application to a Pharmacokinetic Study. **AAPS, San Diego, Nov 1-5, 2014**
4. Alsultan A, Derby R, **An G**, and Peloquin C. Bayesian Estimation of Levofloxacin Pharmacokinetics in Patients with Tuberculosis. **ICAAC, 2014**.
5. Tsiklauri L.K., **An G**, Tsagareishvili G.V., Alaniya M, Kemertelidze E, Morris M.E. Investigation of Functional Role of Membrane Transporters in Oral Bioavailability of Robinin. **III International Scientific and Practical Conference “Topical issues in medicine”, West Kazakhstan Marat Ospanov State Medical University. Aktobe, Kazakhstan, April 17-18, 2014**
6. Gottipati G, Lin C, Venitz J, Lesko L, and **An G**. Model-based Meta-analysis (MBMA) of Adverse Events (AE) and Dropouts (DO) for Drugs Evaluated for the Treatment of Fibromyalgia pain (FMP), **ASCPT, Atlanta, Mar 18-21, 2014**.
7. Gottipati G, Trame, MN, Lin C, Venitz J, Lesko L, and **An G**. Model-based Meta-analysis (MBMA) of Efficacy at End-of-Trial and Efficacy-Time Course for Drugs Evaluated for the Treatment of Fibromyalgia pain (FMP). **ASCPT, Atlanta, Mar 18-21, 2014**. [**Gottipati received Presidential Trainee Award for this poster**].
8. Deng J, Lesko L, and **An G**. A Physiologically Based Pharmacokinetic Model of Gefitinib Disposition: from Rat to Man. **ASCPT, Atlanta, Mar 18-21, 2014**.

9. Deng J, Lesko L, and **An G**. Prediction of Gefitinib Human Pharmacokinetics From Animal Data - Comparative Assessment of Different Allometric Scaling Approaches. **ASCPT**, Atlanta, Mar 18-21, **2014**.
10. Shao J*, Deng J*, Bei D, and **An G**. Nilotinib is a dual P-gp and BCRP inhibitor and inhibits P-gp-mediated dasatinib efflux and BCRP-mediated gefitinib efflux. (*contributed equally) **UF Health Cancer Center Research Poster Day**. Gainesville, Mar 11, **2014**
11. Shao J, Deng J, Bei D, and **An G**. Exploring the Synergy of TKIs Combination Therapy – A Pilot Study of P-gp-mediated Interaction between Dasatinib and Imatinib in LLC PK1 Cells. **UF COP Research Showcase**. Gainesville, Feb 20, **2014**.
12. Cope J, Antigua A, Bushwitz J, **An G**, Patel A, and Zumberg M. Fondaparinux Use in Severe Renal Impairment and Renal Failure Requiring Renal Replacement Therapy. **Society of Critical Care Medicine Annual Congress**. San Francisco, January 9-13, **2014**.
13. Deng J, Lesko L, and **An G**. A Physiologically Based Pharmacokinetic Model of Gefitinib Disposition: from Rat to Man. **Graduate Research Day**, Gainesville, Oct 31st, **2013**.
14. Deng J, Jiang XL, Schmidt S, Lesko L, and **An G**. Physiologically-Based Pharmacokinetic Model for the CYP3A-mediated Inhibition of Midazolam Inhibition by Itraconazole. **9th Retrometabolism Based Drug Design and Targeting Conference**, Orlando, May 12-15, **2013**.
15. **An G***, Wang X*, and Morris ME. Dietary Flavonoid Fisetin is a Substrate and Inhibitor of Human Organic Anion Transporter 1 (OAT1). (* contributed equally) **AAPS**, Chicago, Oct 14-18, **2012**.
16. **An G**, Liu W, Awni W, and Dutta S. Model-Based Meta-Analyses of Efficacy and Safety of COX-2 Inhibitors in Patients with Osteoarthritis Pain. **AAPS**, Chicago, Oct 14-18, **2012**.
17. Liu W, **An G**, Dutta S, Nothaft W, Duan R, Jain R, Awni W. ABT-652 Phase 2b Dose Selection Based on Exposure-Response Analyses of Efficacy, Safety (Heart Rate, Adverse Effects) and Dropout from Proof of Concept Study in Subjects with Osteoarthritic Pain. **Abbott Day of Science and Technology**, Chicago, Nov 14-15, **2011**.
18. **An G** and Morris ME. A physiologically based pharmacokinetic model of mitoxantrone in mice: a mechanism-based model incorporating DNA and protein binding. **ACoP**, San Diego, April 3-6, **2011**
19. **An G** and Morris ME. The bioflavonoid kaempferol is an Abcg2 substrate and inhibits Abcg2-mediated quercetin efflux. **AAPS**, New Orleans, Nov 14-18, **2010**
20. **An G** and Morris ME. The sulfated conjugate of biochanin A is a substrate of breast cancer resistant protein (ABCG2). **AAPS**, New Orleans, Nov 14-18, **2010**

21. **An G** and Morris ME. A PBPK model of mitoxantrone in mice: a mechanism-based model incorporating macromolecule binding. **Pharmacology Day**, University at Buffalo, July 27, **2010**
22. **An G** and Morris ME. Determination of mitoxantrone in mouse plasma and tissues by an improved HPLC method and its application in a pharmacokinetic study. **AAPS**, Los Angeles, Nov 7-11, **2009**
23. **An G** and Morris ME. Transport and efflux of quercetin and biochanin A in MDCK cell monolayers- role of efflux transporters. **AAPS**, Los Angeles, Nov 7-11, **2009**
24. Liu JH, **An G** and Morris ME. The effect of flavonoids on transport of mitoxantrone in ABCG2 transfected MDCK cells. **Sigma Xi**, University at Buffalo, April, **2009**
25. **An G** and Morris ME. Inhibition of the BCRP-mediated transport of mitoxantrone by the flavonoids Biochanin A and Kaempferide. **AAPS**, Atlanta, Nov7-11, **2008**.
26. **An G** and Morris ME. Effect of multiple flavonoid combinations on Breast Cancer Resistance Protein (ABCG2) mediated transport. **AAPS**, Atlanta, Nov 7-11, **2008**

TEACHING EXPERIENCE

Course Co-Coordinator

-**PHA5128 Dose Optimization II** Spring 2013, Spring 2014 University of Florida
(Taught following 7 lectures)

Lecture 1. Bioavailability and Bioequivalence

Lecture 2. Pharmacokinetics and Dosage Adjustment in Renal Disease

Lecture 3. Body-Size Measures for Dose Normalization

Lecture 4. Pharmacokinetics and Dosage Adjustment in the Elderly

Lecture 5. Pharmacokinetics and Dosage Adjustment in the Children

Lecture 6. Drug and Drug Interactions

Lecture 7. Food and Drug Interactions

Lecturer

-PHM527 *Drug interactions with herbal supplements* March, 2009 SUNY at Buffalo

-*Rational drug use* Spring 2004, Spring 2005, Ruijin Hospital, China

Teaching Assistant

-MT501 *Methods of analysis* Fall Semester 2006, SUNY at Buffalo

-PHC421 *Pharmaceutical principals* Spring Semester 2008, SUNY at Buffalo

-*Rational use of Antibiotics* Spring 2002, Spring 2003, Fudan University, China

SERVICES TO SCHOLARLY AND PROFESSIONAL JOURNALS

Editorial Board Member:

- *Drugs in R&D*
- *Journal of Clinical Pharmacology*

Journal reviewer

- **Scientific Advisor to the Editors** of *Journal of Pharmaceutical Sciences*
- the *AAPS Journal*
- the *Journal of Pharmacology and Experimental Therapeutics*
- *Drug Metabolism and Disposition*
- *Clinical Therapeutics*
- *Asian Biomedicine*
- the *Journal of Clinical Pharmacology*
- *Clinical Pharmacokinetics*
- *Drugs in R&D*
- *TALANTA*
- *British Journal of Clinical Pharmacology*
- *Pharmaceutical Research*
- *Biopharmaceutics & Drug Disposition*

PROFESSIONAL AFFILIATIONS

American Association of Pharmaceutical Sciences (AAPS), since 2006

American Society for Clinical Pharmacology and Therapeutics (ASCPT), since 2010

American Society of Pharmacometrics (ASOP), 2012

International Society for the Study of Xenobiotics (ISSX), since 2013

American College of Clinical Pharmacology (ACCP), 2014

EXPERTISE

➤ Pharmacokinetics/ Pharmacodynamics / Pharmacometrics

- *Pharmacokinetic analysis and modeling*: extensive hands-on experience with *NonMEM7*, *WinNonlin* and *ADAPT5*; proficient in *Pheonix*, *Simcyp*, *R*, and *Trial Simulator*; familiar with *Fortran*, *GastroPlus*
- *Statistical analysis*: SAS and SPSS
- *Analytical techniques*: Expert in HPLC and LC/MS/MS
- *Xenograft tumor model construction*: Pellet implantation; Cancer cell inoculation to nude mice
- *Laboratory animal handling and surgery*: jugular vein cannulation; I.P, I.M, and I.V administration; penile vein injection; blood sampling from the retro-orbital plexus, the heart or the abdomen vein; mice tissue collection

- Extensive working knowledge and experience in preclinical and clinical drug-drug interaction study design and a variety of in vitro drug transport studies and in vivo animal studies
- Extensive hands-on experiences in population-based PK/PD analysis and model-based meta-analysis.
- Rich hands-on experience in clinical trial study design and clinical study support at various phases

➤ **Cell culture, Molecular biology and other skills**

Rich hands-on experience in a wide variety of lab techniques and bio-analytical assays such as:

- Cell line cell culture
- Western Blot
- Immunohistochemistry
- Bi-directional transport study
- Flow cytometry
- PCR
- Scintillation counting
- In vitro metabolism and metabolites analysis

WORKSHOPS and SYMPOSIUMS ATTENDED

- **Grant Writing Workshop**. December, **2013**. Gainesville, University of Florida
- ISSX Short course on “**Metabolomic Profiling as a Tool for Identifying Novel Drug-Target Interactions**”. September **2013**. Toronto, Ontario, Canada.
- **1st Annual Workshop on Metabolomics “From Design to Decision”**. July 22-25, **2013**. The University of Alabama at Birmingham (I was financially sponsored by the Center of Acute Kidney Injury at University of Alabama at Birmingham)
- **PKPD modeling of continuous and categorical data in NonMEM7** (taught by Dr. Mats Karlsson and Dr. Andrew Hooker from Uppsala University). Dec **2011**, Abbott Laboratories, IL
- **R Workshop** (taught by Richard Pugh from Mango Solutions), Sep **2011**, Abbott Laboratories, IL [*Topic: Introduction to R*]
- **SAS workshop** (taught by Dr. Balakrishna Hosmane from Northern Illinois University), April **2011**, Abbott Laboratories, IL [*Topic: Basic SAS for Regression Analysis*]
- **AAPS Transporter Workshop**, April **2011**, Bethesda, Maryland [*topic: Drug Transporters in ADME: From the Bench to the Bedside*]
- **SimCYP Workshop** (taught by Dr. Amin Rostami-Hodjegan from University of Manchester), April **2010**, University at Buffalo
- **S-Adapt workshop, 2010**, University at Buffalo
- Center for Protein Therapeutics/ 2nd Annual Symposium (Buffalo, New York), July **2010**, University at Buffalo
- **Software Short Course on Modeling and Data Analysis in PK/PD using ADAPT5**. April **2010**, Buffalo, NY
- **Introduction to NONMEM® workshop, 2007**, University at Buffalo

RESEARCH PROPOSALS AWARDED

- 1) PhRMA Foundation (research starter grant; \$100,000 for 2-year period)

Proposal title: Mechanistic Physiologically-Based Pharmacokinetic Model of Anthracyclines and Taxanes from Mice to Humans: Application in Safety Assessment and Anticancer Therapy Optimization

My role: PI

Status: Awarded (funding period is 01/01/2014 to 12/31/2015)

2) Agency: Gate's foundation (**3-year project; \$342,000**)

Proposal title: Pharmacokinetics and pharmacodynamics of tuberculosis drugs in patients with active disease

My role: Co-investigator

PI: Dr. Charles Peloquin

Status: Awarded (20% of my salary is covered every year for three years; funding period is 3/1/2014 to 3/1/2017)

3) Agency: Agilent Technologies (**1-year project; \$120,000**)

Proposal title: Identification of Biomarkers for Early Detection of Drug-Induced Nephrotoxicity using Metabolomics Approaches

My role: Co-PI

PI: Dr. Larry Lesko

Status: Awarded (Sep 2014 to Sep 2015; Proposal wrote by An; lost this grant due to job change)

4) Agency: UF Clinical and Translational Science Institute (**1-year project; \$43,800**)

Proposal title: Explore the synergy of combination TKI therapy – a pilot study to evaluate the effect of imatinib on dasatinib pharmacokinetics in healthy volunteers

My role: PI

Status: Awarded (Funding period 3/27/2014 to 3/26/2015, Funding returned to UF due to job change)

MY RESEARCH GROUP:

Present members:

Qiang Fu -Postdoc Fellow Nov 2014 ~ present

Sumeet Singla, PhD student, rotation from Jan 2015 ~ present

Past members:

Jie (Joy) Shao (PhD Student, August 2013 ~ September 2014)

Jiexin (Jason) Deng (PhD Student, June 2013 ~ June 2014)

Di Bei (PhD student, Jan 2014 ~ September 2014)

Brett Fleisher (PharmD student, Summer Intern, May 15th ~ July 30th, 2014)

Jesse Unum (PharmD student, Summer Intern, May 27th ~ July 27th, 2014)

Gopichand Gottipati (Summer Intern, July 1st ~ September 30th, 2013)