Curriculum Vitae

Fatemeh Akhlaghi, Pharm.D., Ph.D.

Summary: I am a clinical pharmacologist with proven leadership, management and management skills. I have achieved expertise in clinical pharmacology, pharmacokinetics, translational sciences, drug metabolism, pharmacogenomics, diagnostics as well as pharmacokinetic/pharmacodynamic (PK/PD) modeling and simulation through over 25 years of clinical research in academia. I have superb oral and written communication skills as well as management and organizational abilities as evidenced by my ability to establish and maintain a fully functional mass spec. based clinical pharmacokinetics laboratory for over 18 years. I have experience with several therapeutic areas including immunology/inflammation, endocrinology, hematology, hepatology, nephrology and psychiatry. Moreover, in collaboration with NIAAA/NIH, my laboratory has been developing a novel ghrelin receptor inverse agonist (PF-5190457) to treat patients with alcohol use disorder.

I am proficient in the design and implementation of clinical PK/PD studies, quantification of drug concentration and metabolites using LC-MS/MS and modeling of PK/PD data using standard or population pharmacokinetics methods. Furthermore, I have experience in pre-clinical DMPK and transporter studies as well as in genomic or proteomic-based biomarker discovery. To date, I have received substantial extramural funding from National Institutes of Health, Pfizer, Novartis, Takeda, Roche, the American Heart Association, CVS, etc. which has enabled me to train over 30 clinical pharmacologists or DMPK scientist for their masters or Ph.D. degrees or post-doctoral fellowship. Besides, I have been the clinical pharmacology expert witness for numerous patent litigation cases between generic and brand name pharmaceutical companies.

At this stage of career, I seek new challenges and would like to experience an intense drug development environment and to work with a multidisciplinary team of talented scientists toward the development of new pharmacological agents.

Work Address

Department of Biomedical and Pharmaceutical Sciences
495A Avedisian Hall, College of Pharmacy, 7 Greenhouse Road
University of Rhode Island
Kingston, RI 02881
Phone: (401) 874 9205 / Fax: (401) 874 5787
Email: fakhlaghiPhD@gmail.com or fakhlaghi@uri.edu
Departmental Website URI: http://web.uri.edu/pharmacy/research/akhlaghi/
Laboratory Website URI: http://akhlaghilab.com/
Website Brown University: https://vivo.brown.edu/display/fakhlagh
Google Scholar: https://scholar.google.com/citations?user=wdnBYOAAAAAJ&hl=en
Linkedin site: http://www.linkedin.com/in/akhlaghi
ORCID ID: orcid.org 0000-0002-3946-7615

EMPLOYMENT HISTORY

Jul 2014-present	University of Rhode Island	Ernest Mario Distinguished Chair in Pharmaceutics
Jul 2014-present	Brown University Medical School	Adjunct Professor of Medicine
Jul 2011-present	University of Rhode Island	Full Professor
Jul 2010-2014	Brown University Medical School	Adjunct Associate Professor
Jan-Jul 2008	Millennium Pharmaceuticals Inc, Cambridge, MA	Sabbatical fellow

Advisor: Dr. Li Yu while working on PK/PD *modeling of Bortezomib*

Jul 2006-2010	University of Rhode Island	Associate Professor with Tenure
Jan 2001-2006	University of Rhode Island	Assistant Professor (Tenure Tack)
Mar 1998-2001	University of Cambridge, U.K.	Senior Clinical Scientist

Advisor: Andrew K. Trull Ph.D.; Funded by Novartis, Roche Laboratories and Papworth Hospital NHS Research Trust)

Aug 1996-1998	University of Sydney, Australia	Post-Doctoral Research Associate

Advisors: Kenneth F. Brown Ph.D. and Andrew J McLachlan Ph.D.; Funded by Novartis and Janssen Cilag Australia

Jun 1992-1996	University of Sydney, Australia	Teaching assistant for various laboratories and courses in the School of Pharmacy

EDUCATION

1984-1990 **University of Mashhad, Iran** **Doctor of Pharmacy**
Project title: Use of CD4 to CD8 ratio as a marker for kidney transplant rejection
Major Professor: Behrouz Nikbin M.D.

1992-1997 **University of Sydney, Australia** **Ph.D. in Pharmaceutical Sciences**
Project title: Cyclosporine distribution in cardiopulmonary transplant recipients
Major Professors: Kenneth F. Brown Ph.D. and Anne M. Keogh M.D.

FURTHER TRAINING

Dec 7-22, 1998
"A course in Pharmacokinetic and Pharmacodynamic with Clinical Applications"; four credit points; Department of Clinical Pharmacology, Karoliniska Institute, Stockholm, Sweden; Instructors: Drs. Gunnar Alvan, Ole Borga, Lars Gustafsson, Johan Gabrielsson and many scientists from AstraZeneca.

Jan 9-15, 1999
"A course in Pharmacokinetic and Pharmacodynamic Modeling using WinNonlin" one credit point; Department of Clinical Pharmacology, Karoliniska Institute, Stockholm, Sweden; Instructor: Dr. Ole Borga.

Sept 27-29, 1999
Beginning level short course on "Population Pharmacokinetics using NONMEM Computer Program"
Instructors: Drs. Lewis Sheiner and Stuart Beal; Uppsala Sweden.

Jun 2002
A three full days hands-on course "Operator's Training on Sciex API2000 Liquid Chromatography Mass Spectrometer" University of Rhode Island, also organized the course.
Instructor: Dr. Bill Sawyers, Applied Biosystems.

Jul 26-30, 2004
A weeklong hands-on course entitled "Molecular Genetic Methodologies for Pharmaceutical Scientists"; Department of Pharmaceutical Sciences, University of Buffalo;
Instructor: Dr. Dan Brazeau.

Sept 12-14, 2005
A three-day hands-on course on "Wings for NONMEM Population Pharmacokinetics Modeling"; Instructors: Drs. Nick Holford and Dianne Mould
Also organized the course with Dr. Sara Rosenbaum.

Sept 16, 2006
Course in Pharmacokinetic/Pharmacodynamic Modeling
Instructors: Drs. William J. Jusko and Jogarao Gobburu.

Oct 4, 2009
Phoenix NLME - A Next Generation Tool for Population PK/PD Analysis
Instructor: Dr. Dan Weiner, Pharsight Corporation.

Mar 29-31, 2011
Triple Quadrupole System Training using Analyst® Software for Quantitation
AB Sciex, Framingham, MA.

Mar 19-21, 2012
The Introductory GastroPlus™ Simulation and Modeling Workshop
Cambridge, MA.

May 1-5, 2012
Fisher / Shafer NONMEM Course
An Intermediate to Advanced NONMEM course with PLT tools
Bethesda, MD

Jan-Mar, 2013
Hands on data manipulation using R
Instructor: Dr. Kaori Ito, Pfizer Groton

Jul 6-10, 2015
Model-Based Drug Development: Incorporating Population Variability into Mechanistic Prediction of PK and Modelling PK-PD
A course on Simcyp, Certara Corporation

Mar 13, 2016
Design and Analysis of Quantitative Proteomic Experiments: Introduction to Statistical Methods and Practical Examples using Skyline, one-day workshop part of Human Proteomics Organization meeting in Boston, MA

Jun 25-29, 2018
Simcyp full workshop
Hands-on Experience with Model-informed Drug Development: Incorporating Population Variability into Mechanistic Prediction of PK and Modeling PK/PD
Cambridge, MA

Oct 19-20, 2018
Mentor Training for Biomedical Researchers
Brown University, Providence, RI

Aug 5-6, 2019
Transporters in Drug Discovery and Development; Driving Knowledge from Laboratory to Label
University of Rhode Island, Kingston, RI

Aug 12, 2019

FDA Workshop
Precision Dosing: defining the need and approach to deliver individualized drug dosing in the real-world setting, Silver Spring, Maryland

Oct 3, 2019
MonolixSuite, Workshop; Lixoft, Cambridge, Massachusetts

Dec 9, 2019
FDA Workshop
Leveraging Clinical Pharmacology to Optimize Drug Development for Nonalcoholic Steatohepatitis (NASH) and Cholestatic Liver Diseases, Silver Spring, Maryland

Feb 3-7, 2020
Tufts CSDD's 47th Annual Postgraduate Course in Clinical Pharmacology, Drug Development and Regulation; Boston, Massachusetts

PK/PD DATA ANALYSIS

- IVIVC analysis by Phoenix toolkit for prediction of plasma conc from dissolution data.
- MonolixSuite and related packages, Lixoft
- Nonlinear regression: Sigma plot and Graphpad prism
- NONMEM: experience with standard and complex PK/PD evaluations including multiple analytes, drug + metabolites, enterohepatic recycling, and multiple peak absorption models (e.g. transit type models and sequential absorption models). Pharmacodynamic evaluations including direct, indirect, transit models, and effect compartment modeling as well as sequential and concurrent PK/PD modeling. Have used PLT tools and xpose.
- Phoenix WinNonlin for non-compartmental (NCA) of PK or PD data as well as non-linear modeling of individual PK or PD data; can also perform full NCA analysis with Excel or a scientific calculator.
- Physiologically based pharmacokinetics modeling: Gastroplus, ADMET predictor PKPlus™ (simulation plus), Simcyp
- Proficient in dose adjustment based on renal or hepatic function, therapeutic monitoring calculations for immunosuppressive agents, phenytoin, digoxin, lithium, methotrexate, aminoglycosides and vancomycin (by calculation or Antibiotic Kinetics)
- Proficient in linear, non-linear and various statistical analyses using IBM SPSS
- Proteomic softwares: Analyst (AB Sciex), Skyline, Maxquant, Protein pilot
- Pumas Enterprise Solutions, a Julia-based comprehensive platform for pharmaceutical modeling and simulation.
- Simulation: Microsoft Excel, Stella and Berkeley Madonna for nonstochastic simulation work, NONMEM for stochastic simulation.

HONORS AND AWARDS

1992	Levy Maill Pattinson Award, Faculty of Pharmacy, Uni. of Sydney
1993-96	Faculty of Pharmacy Postgraduate Scholarship, Uni. of Sydney
2002	University of Rhode Island New Faculty Development Award
2006	Outstanding Intellectual Property Award, University of Rhode Island
2008	Paul-Ehrlich Magic Bullet-Award 2008, Nurnberg Germany
2010	Outstanding Intellectual Property Award, University of Rhode Island
2018	*Drug Metabolism and Review* Best Paper Award 2017 for manuscript: Cobbina E, **Akhlaghi F**. Non-alcoholic fatty liver disease (NAFLD) - pathogenesis, classification, and effect on drug metabolizing enzymes and transporters. *Drug Metab Rev.* 2017;49(2):197-211; Award received in the North American ISSX meeting, Jul 2018, Montreal, Canada
2018	Outstanding Poster in the Applied Pharmaceutical Analysis 2018 conference Barlock BJ, Jamwal R, **Akhlaghi F**. Presence of drug metabolizing enzyme inducer artifacts in commercially available human liver samples increases protein levels of clinically relevant enzymes; poster presentation in Applied Pharmaceutical Analysis Conference, Oct 1-3, Boston, MA (selected as Outstanding Poster in the APA 2018 conference)

PROFESSIONAL SOCIETY MEMBERSHIP

1990-present	The Medical Council of Iran (Registered Pharmacist)
1993-1998	Australasian Society for Clinical and Experimental Pharmacology and Toxicology (ASCEPT)
1993-1998	Australasian Pharmaceutical Science Association (APSA)
1997-2001	International Society of Heart and Lung transplantation (ISHLT)
1998-2001	Transplantation Society
1996-present	International Association of Therapeutic Drug Monitoring and Clinical Toxicology (IATDM&CT)
1997-present	American Association of Pharmaceutical Scientists (AAPS)
2001-present	American Association of Colleges of Pharmacies (AACP)
2008-present	American Society for Clinical Pharmacology and Therapeutics (ASCPT)
2017-Present	International Society of Study of Xenobiotics (ISSX)

CONSULTING ACTIVITIES

1996	Physicochemical characteristics of ingredients of an antacid suspension, consultant for Park Davis Pharmaceuticals in collaboration with Dr. Elizabeth Gipps, University of Sydney
1997-1998	Droplet size determination of nebulized solutions of Salbutamol and Ipratropium Bromide using Marple - Miller cascade impactor, in collaborating with Dr. Kim Chan, University of Sydney
2000	Attended Novartis summit meeting in Basle Switzerland representing the clinical pharmacology section of Cambridge UK, organ transplantation programs
2001-2003	Pharmacokinetics of intravenous immunoglobulin (IVIG), I have analyzed the pharmacokinetic data from several phase III studies conducted by Bio Products Limited, UK
2003	Member of Mycophenolic Acid TDM Advisory Board (Opticept clinical trial, an 800 patient trial conducted by Roche Laboratories to evaluate the need for mycophenolic acid therapeutic drug monitoring)
2005	Consulting on a case study conducted at the Department of Emergency Medicine, RI hospital on the elimination of carboxy hemoglobin
2005-2007	Expert witness in a personal injury case involving cyclosporine generic substitution and risk of organ rejection
2007	Expert witness in a patent dispute case between two major pharmaceutical companies
2008-2009	PK/PD modeling of bortezomib in cynomongolus monkeys, Millennium Pharmaceuticals
2007-2010	Clinical pharmacology consultant for a clinical trial on the intra-nasal use of ketamine in children with laceration, Department of Emergency Medicine, Hasbro Children Hospital, Providence, RI.
2011	Consultant on concentration–projection of a modified release tablet by two different manufacturers.
2014	Expert witness for a non-infringement trial for two Canadian companies
2014	Consultant on bioequivalence studies on a generic versus a brand name drug
2016-2017	Consultant on a patent dispute case involving a combination anti-hyperglycemic agent
2017-	Consultant on a patent dispute case involving bioequivalence of controlled release formulations
2017-	Expert witness on a patent dispute involving patent “obviousness”
2017-2018	Consultant clinical pharmacology expert witness for a patent infringement case involving ANDA
2017-2018	Expert witness for an Inter Partes review involving patent invalidity
2018-2019	Expert witness in a case involving obviousness of the patent for an anti-obesity drug
2019-	Expert witness for a clinical pharmacology related case for the Department of Justice (DOJ)

FAMILIARITY WITH REGULATORY GUIDELINES

In my capacity as a researcher, teaching clinical pharmacology and consultant for patent litigation cases, I have thoroughly reviewed the following FDA Guidance for Industry documents:

- Alcoholism: Developing Drugs for Treatment
- Bioanalytical Method Validation
- Bioavailability Studies Submitted in NDAs or INDs – General Considerations
- Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application
- Clinical Drug Interaction Studies — Study Design, Data Analysis, and Clinical Implications
- Developing Drugs for Treatment, Safety Testing of Drug Metabolites (MIST)
- Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations
- Food-Effect Bioavailability and Fed Bioequivalence Studies
- In Vitro Metabolism- and Transporter- Mediated Drug-Drug Interaction Studies
- Investigational New Drug Applications (INDs)-Determining Whether Human Research Studies Can Be Conducted Without an IND
- Noncirrhotic Nonalcoholic Steatohepatitis with Liver Fibrosis: Developing Drugs for Treatment
- Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling
- Pharmacokinetics in Patients with Impaired Renal Function — Study Design, Data Analysis, and Impact on Dosing and Labeling
- Physiologically Based Pharmacokinetic Analyses — Format and Content
- Statistical Approaches to Establishing Bioequivalence

INVITED PRESENTATIONS

DATE	PRESENTATION TITLE/LOCATION
Nov 1999	"Pharmacokinetics of cyclosporine in patients receiving metabolic inhibitors" Invited speaker at PKUK99 meeting, Oxford, UK.
Aug 16 2001	"Clinical pharmacology of immunosuppressive agents" Lecture to the Nephrology Residents, Department of Nephrology, Brown University Medical School, Providence, RI.
Oct 1 2001	"Novel strategies for monitoring immunosuppressive agents" invited speaker at the Department of Pediatrics Nephrology and Transplantation, the Boston's Children Hospital, University of Harvard Medical School, Boston, MA.
Oct 23 2001	"Monitoring cardiothoracic transplant recipients" Seminar to the Heart Transplant Group, the Brigham and Woman's Hospital, University of Harvard Medical School, Boston, MA.
Jan 25 2002	"Novel strategies for monitoring immunosuppressive agents" Seminar to Kidney Transplantation Services, Rhode Island Hospital, Providence, RI.
Jul 11 2003	"Pharmacokinetics and pharmacodynamics of immunosuppressive agents" oral presentation at RI-BRIN annual retreat, Alton Jones Campus, RI.
May 20 2004	Speaker at the workshop "Hot and alternative research funding" Title: How to Get Funding from the Industry, University of Rhode Island, Kingston, RI.
Apr 7 2005	"Pharmacokinetics of immunosuppressive agents in diabetic patients" Presentation to the Transplant Services, RI Hospital, Providence, RI.
Jan 25 2006	"Pharmacokinetics and –dynamics of immunosuppressive agents" Center for the New Stem Cell Biology Visiting Professors Seminar Series, COBRE program, Roger Williams Hospital, Providence, RI.
May 24 2006	Poster Judge at the Joint RI-COBRE symposiums, Providence, RI.
May 31 2007	"Review of transplant pharmacology" invited speaker at "Transplant Pharmacology: Keys to Medication Management in Organ Transplant Recipients"; Pharmacist CE program, Providence, RI.
Sept 11 2007	Research presentation "pharmacokinetic of immunosuppressive agents in diabetic patients" Millennium Pharmaceuticals, Boston, MA.
Oct 2 2007	"Novel monitoring methods for immunosuppressive agents PK/PD" Research presentation at College of Pharmacy, University of Kentucky, Lexington, KY.

Oct 24 2007 "Immunosuppressive agents PK/PD and diabetes mellitus" Visiting professor program, Department of Pharmacology and Experimental Therapeutics, Tufts University School of Medicine, Boston, MA.

Jan 2 2008 "Effect of diabetes mellitus on drug metabolism and transporter" Hallett Center for Diabetes and Endocrinology Disorders, Brown University, Providence, RI.

Jul 25 2008 "Pharmacokinetics and –dynamic modeling of bortezomib in cynomonglous monkeys" Department of Clinical Pharmacology, Millennium Pharmaceuticals, Cambridge, MA.

Sept 3 2008 "Introduction to pharmacokinetic/pharmacogenomics modeling and application: a Velcade® case study" R&D presentation, Millennium Pharmaceuticals, Cambridge, MA.

Oct 5 2008 "Effect of diabetes mellitus on pharmacokinetics and pharmacodynamics of immunosuppressive agents: ciclosporin, tacrolimus and mycophenolic acid" Invited speaker at EHRLICH II, 2nd World Conference on Magic Bullets, Nurnberg, Germany.

May 20 2009 "Application of clinical pharmacology to improve the quality of use of medicines in diabetes and transplantation" invited speaker at Division of Clinical Pharmacology, Johns Hopkins University, Baltimore, MD.

May 2 2010 "Drug monitoring in distinct patient populations; pharmacokinetic differences between transplant recipients of different ethnicities", invited speaker at Sunrise symposium, the American Transplant Congress, May 2010, San Diego, CA.

Sept 7 2010 "Diabetes, reduced CYP3A4 activity and the possible role of statin lactone in statin induced myopathy"; presentation at the department of cardiology, Hartford Hospital, Hartford, CT.

Sept 28 2010 Invited participant in an FDA workshop on "Pharmacodynamic and Pharmacogenomics biomarkers in solid organ transplantation", Food and Drug Administration, White Oak Campus, MD.

Dec 14 2010 "Diabetes altering biotransformation and pharmacodynamics of immunosuppressive agents"; Invited speaker at the Department of Pharmaceutical Sciences, University of Colorado Health Science Center, Anschutz Medical Campus Aurora, CO.

Mar 23 2011 Diabetes and side effects of statins, American Heart Association Friends of Heart Luncheon, Center for Biotechnology and Life Sciences (CBLS) building, University of Rhode Island

Oct 8 2011	Influence of diabetes mellitus on the disposition of immunosuppressive agents and statins, PDM department, Pfizer Center Research, Groton, CT.
Aug 28, 2012	Impact of protein binding on drug disposition and action, College of Pharmacy, University of Technology, Sydney, Australia via Video conferencing.
Oct 22, 2012	Altered disposition of xenobiotics by diabetes mellitus, Division of Clinical Pharmacology, Johns Hopkins Medical Institute, Baltimore, MD.
Aug 8, 2013	Altered disposition of xenobiotics by diabetes mellitus and fatty liver, College of Pharmacy, University of Houston, Tx.
Nov 18, 2013	Effect of diabetes on pharmacokinetics and pharmacodynamics of immunosuppressive agents, Division of Transplantation, Methodist Hospital, Houston, Tx.
Mar 13, 2014	AACP Academic Research Fellows Program; Model of Team Science IV: Collaboration between academia, government, industry supported by NCATS; Rockville, MD.
Aug 7, 2014	Invited Speaker at "Pharmacogenomic Interplay in Biotransformation and Pharmacokinetics"; Pharmacokinetic consequences of metabolic syndrome; University of Rhode Island
Mar 12, 2015	Invited Speaker at the 30th Annual Seminar by the Sea; Northeast Regional Continuing Education Conference for Pharmacists "Statin Interactions: Food, Supplements and Other Drugs"
Jul 13, 2015	AACP Academic Research Fellows Program; Model of Team Science IV: Collaboration between academia, government, industry supported by NCATS; Potomac, MD.
Oct 20, 2015	Presentation of the result of phase 1b of PF-05190457 study in subjects with alcohol use disorders; NIH Clinical Center, Bethesda, MD.
Nov 5, 2015	Workshop leader on Mechanisms of Drug-Drug Interactions; International Congress of Quality, Safety and Rationale Use of Drugs, University of Mashhad, Mashhad, Iran
Nov 6, 2015	"Clinical Pharmacology and Therapeutic Monitoring of Immunosuppressive Agents" International Congress of Quality, Safety and Rationale Use of Drugs, University of Mashhad, Mashhad, Iran
Feb 2, 2016	Invited speaker in Connecticut Mass Spec Discussion group

Title: Pharmacokinetic Consequences of Metabolic Syndrome: Challenges and Opportunities for Proteomic Mass Spectrometry

Dec 6, 2016 Invited speaker, Pfizer Cambridge

Pharmacokinetics Consequences of Type 2 Diabetes (T2DM) and Non Alcoholic Fatty Liver Disease (NAFLD)

Feb 8, 2017 Invited speaker, department of gastroenterology, Beth Israel Deaconess Medical Center

May 7, 2017 Invited speaker, Diabetes Research Unit, Hamad Hospital Medical Center, Doha, Qatar

May 10, 2017 Invited speaker, College of Pharmacy, Qatar University, Doha, Qatar

Sept 26, 2018 Invited speaker, ISSX Proteomics Workshop, Sept 26-27, 2018; Cambridge, MA

Dec 12, 2018 Invited speaker; School of Pharmacy, University of Sydney, Australia

A Non-targeted Proteomic Approach to Characterize the Effect of Diabetes and Non-Alcoholic Fatty Liver Disease (NAFLD) on Drug Disposition

Mar 2019 Invited to give a lecture in the Spring meeting of the New England Drug Metabolism Discussion Group (NEDMDG), March 27th, Waltham, MA.

Apr 2019 Invited speaker at QSP Summit, Cambridge, MA

Title: Quantitative Analysis of Human Hepatic Drug Metabolizing Enzymes in NAFLD and its Application in PBPK Modeling

Jun 2019 Invited lecture at the Department of Pharmacy, the University of Oslo, Norway.

Title: Variability in the Expression and Activity of Cytochrome P450 and Transporters in Diabetes and Non-Alcoholic Fatty Liver Disease (NAFLD) Alters Immunosuppressants Concentration and Effect.

Nov, 2019 Invited speaker at the Hepatocyte Expert Program (HEP), Cambridge, MA

Title: Pharmacokinetics Challenges Associated with Drug Development in NAFLD/NASH

Feb 13, 2020 Invited speaker at NIH Intramural, Clinical Center (Building 10), Bethesda, MD

Title: Pharmacokinetics Challenges Associated with Drug Development in Diabetes and Non-Alcoholic Fatty Liver Disease

AD HOC REVIEWER FOR SCIENTIFIC JOURNALS

2001-present	British Journal of Clinical Pharmacology
2003-present	Clinical Pharmacokinetics
2003-present	Journal of Chromatography B
2002	Pharmacoeconomics
2004	Transplantation
2006-present	Journal of Pharmacology and Experimental Therapeutics (JPET)
2006-present	Clinica Chemica Acta
2007-present	Clinical Pharmacology and Therapeutics
2009	European Journal of Clinical Pharmacology
2009	Liver Transplantation
2010-present	British Journal of Pharmacology
2010-	Journal of Pharmaceutical and Biomedical Analysis
2011-	European Journal of Medicinal Chemistry
2013-	Lancet
2016-	New England Journal of Medicine
2016-	Current Drug Metabolism
2016-	Pharmacotherapy
2016-	Alcohol and Alcoholism
2016	Medical Science Monitor

JOURNAL EDITORIAL BOARD

2013-present	Clinical Pharmacokinetics
2015-present	Journal of Pharmaceutics and Drug Research

GRANT REVIEWS

2007	Department of Defense, Chemical and Biological Defense Research Program
2009	The Czech Science Foundation, Czech Republic (GACR)
2013	National Science Center, Poland
2013-present	Qatar National Research Foundation (QNRF)
2014 Apr	NIAID special emphasis panel; ZAI1 PA-I M1, ad hoc reviewer
2014 Jun	XNDA study section, ad hoc reviewer
2014 Aug	ZTR1 CI-6 (01) review of NCATS X02 grants
2015 Mar	ZTR1 CI-6 (02); Study section for review of NCATS UH2/UH3 grants
2015 Oct	CIDO Study section, ad hoc reviewer, Chicago, Illinois
2016 May	ZAI1-BDP-I-M4 study section, mail in reviewer
2016 Jun	BCHI study section, mail in reviewer
2017 Jan	ZAI1 PA-I (M2) 1 NIAID R34 review study section
2017 Nov	ZAI1 GEB-I (J1) NIAID R34 and U01 review study section
2018 Apr	Qatar National Research Foundation (QNRF) 11th cycle grant reviewer
2018 May	ZAI1 TC-I (S1) NIAID R34 review study section
2018 Nov	ZRG1 EMNR-C (02) study section
2019 Jan	Kuwait University grant program

2018 Feb reviewer	Qatar National Research Foundation (QNRF) 12th cycle Undergraduate grant
2019 Mar	Reviewer for RI CTR Mentored Research Awards
2019 Jun	Qatar National Research Foundation (QNRF) 12th cycle research grant reviewer
2020 Feb	Grant reviewer for study section ZDE1 YM (16) NIDCR
2020 April	Grant reviewer for U54 study section ZAT1 AJT (15) Center of Excellence for Natural Product Drug Interaction Research,
2020 April	Grant reviewer for R21 applications submitted to study section ZAT1 AJT (16)

TEACHING RESPONSIBILITIES

BPS403	Pharmacokinetics I (Basic Pharmacokinetics)	2002-2004, Team-taught (50%)
PHC427	4th year Interactive Learning	2002, Sole instructor
BPS 446	Biotechnology, Biologics and Biosimilars	2015-present, team taught
BMS540	Drug metabolism (experimental)	2003, Team taught
BPS502	Drug development *Pharmacokinetics in various phases of drug development*	2005- present, Team taught
BPS504	Pharmacokinetics II (Clinical Pharmacokinetics and Therapeutic Drug Monitoring)	2001- present, every Fall Semester Sole instructor
BPS525	Experimental techniques in biomedical sciences *Use of mass spectrometry in quantitative analysis*	2004-2012, Team taught
PHP516	Pharmacy practice laboratory II	2002-2011, Team taught
BPS530	Topics in drug metabolism *Pharmacokinetics and drug-drug interaction studies*	2005, 2007, 2011, 2013, 2015, 2017, 2019, Team taught
PHC597	5th year Interactive Learning (1 section)	2003- 2007, 2015, Sole Instructor
BPS693/ 694	Graduate seminar	2002-2004, 2015-present
APS670	Advanced pharmacokinetics	2001, 2003, 2009, 2014, 2016 Sole instructor

Average student evaluation of teaching score: 4.5 out of 5 in didactic courses

DESCRIPTION OF MAJOR DIDACTIC TEACHING

BPS 504 Pharmacokinetics II (3 credits, sole instructor) Applied pharmacokinetics, principles of clinical pharmacology, therapeutic drug monitoring and dose individualization, sources of variability on pharmacokinetics. (Lec. 3) Pre: Basic Pharmacokinetics, fifth-year Doctor of Pharmacy students, class size ~130 students, taught every fall semester.

BPS 526 Foundations of Human Disease VI: Hematology-Oncology (2 credits, team taught) The etiology, pathogenesis, symptomatology, and diagnosis of hematology and oncology diseases in people. Introduction to pharmacogenomics, gene-drug interactions, and genetic therapy in human disease; Pre: fifth-year Doctor of Pharmacy students, class size ~130 students

BPS 530 Drug Metabolism (3 credits, team taught), Mechanisms of Phase 1 (oxidation, reduction, hydrolysis) and Phase 2 (conjugations and synthesis) of drug metabolism, fundamental clinical pharmacology and drug-drug interaction studies; offered every spring in alternate years,

BPS 670 Advanced Pharmacokinetics (3 credits, sole instructor) Application of classical compartmental and noncompartmental analyses to pharmacokinetics and pharmacodynamics emphasizing the use of PK/PD analysis employed in the pharmaceutical industry and well as PBPK analysis. Pre: BPS 403 or permission of instructor; class size ~ 10 graduate students.

SERVICE ACTIVITIES IN THE UNIVERSITY OF RHODE ISLAND

2005	Member of URI Sabbatical Review Committee
2008-2011	URI president appointee at the "Intellectual Property Committee (IPC)"
2009-2017	Member of "URI Institutional Review Board (IRB)"
2007-2008	Member of search committee for "Assistant Vice President for Research, Intellectual Property Management and Commercialization"
2009	Member of search committee for "Technology Transfer Specialist"
2010	Member of search committee for biostatistics faculty in the department of Computer Science and Statistics
2014	Member of search committee for biostatistics faculty in the department of Computer Science and Statistics
2015-2017	Member of Faculty Senate, URI
2018	Member of URI Sabbatical Review Committee

Service Activities in College of Pharmacy (COP) or the Department of Biomedical and Pharmaceutical Sciences (BPS)

2006-current	Member of research and graduate studies committee, COP
2010-2013	Program assessment committee, vice chair, COP
2007-08	Member of ad-hoc promotion and tenure standards committee, BPS
2003, 05, 07	Member of various faculty search committees, BPS
2010	Member of search committee for two pharmaceutics positions, BPS
2011	Member of search committee for Pharmacogenomics faculty, BPS
2010-2011	Coordinator of INBRE seminar series, college of pharmacy

2012	Member of search committee for BPS departmental chair
2012-	Coordinator of College of Pharmacy College Wide Seminar series
2013-	Chair of liver and metabolic disorders working group, COP
2013-current	Chair of faculty development committee, BPS
2013	Chair of promotion and tenure committee, COP
2013	Chair of the Full Professors committee, COP
2013	Member of medicinal chemistry search committee, BPS
2014	Chair of Pharmaceutics faculty search committee, BPS
2015	Member of Pharmacogenomic faculty search committee, BPS
2016	Chair of Search Committee; Assistant Professor of Pharmaceutics, BPS
2016	Chair of Search Committee; Associate Professor of Pharmaceutics, BPS
2017	Chair of search committee for Assistant/Associate Professor of Pharmaceutics, BPS
2018-2019	Chair of search committee for Assistant Professor in Precision Medicine, BPS

ORGANIZATION OF SCIENTIFIC CONFERENCES

2012	Co-chair of 1st International Conference on Frontiers in Pharmaceutical Sciences: Global Perspectives; Sept 28-30, 2012
2014	Member of organizing committee for Pharmacogenomic Interplay in Biotransformation and Pharmacokinetics, Aug 7th & 8th, 2014
2016	Member of organizational committee for Boston Society 2016 Applied Pharmaceutical Analysis conference
Sept 14, 2016	Session chair, Non-P450 Metabolism / Electron Pushing / Unusual Metabolism in 2016 Applied Pharmaceutical Analysis conference

STATEMENT OF RESEARCH

My research program is aimed at improving the quality of use of medications by means of identifying sources of variability in dose-concentration and concentration-effect relationships. Identification of new or improved biomarkers for drug effect is also another aim of this research. This type of research is usually identified as a branch of "Clinical/translational Pharmaceutical Sciences" within pharmacy schools but also is known as "Clinical Pharmacology" in the medical schools. During the drug development process (Phase I-III), Food and Drug Administration of United States (FDA) and other regulatory agencies avidly scrutinize a new agent for its safety and effectiveness; however many aspects of a new drug including side effects or drug-drug interactions are only discovered after the new drug is prescribed to a large number of patients. My research effort is focused on the evaluation of safety and effectiveness of post-marketed drugs (Phase IV) with an emphasis on the immunomodulators. The three main objectives of my research program include:

Several projects are currently underway aiming to:

I. Development of A Novel Compound for Alcoholism Treatment: a Translational Strategy
II. Clinical pharmacology of various medications used in the treatment of Alcohol Use Disorder

III. To characterize the effect of diabetic mellitus and Non-Alcoholic Fatty Liver Disease (NAFLD) on the expression and activity of various CYP and non-CYP drug metabolizing enzymes
IV. Proteomic analysis of NAFLD in search of a novel biomarker
V. The use of oral fluids as a non-invasive specimen for therapeutic drug monitoring of immunosuppressive agents.

Maintaining a Clinical Pharmacokinetics Laboratory

The basic requirement for a research laboratory in clinical pharmacology and DMPK is the availability of sensitive, specific and reproducible analytical methods for drug concentration measurement. Currently, such assays require the use of a very expensive and difficult to maintain liquid chromatography mass spectrometry system (LC-MS/MS). The operation of these instruments requires specialized personnel and highly controlled environment (i.e. restricted user access). In addition, every assay either chromatography or immunoassay based, must be validated according to the guidelines set forth by the FDA and preferably published in a peer reviewed journal. The requirement is so fundamental that a clinical study performed using non-validated assays is usually not publishable in a reputable journal. Because of this requirement, much of our effort is devoted to the development and validation of analytical methods using HPLC and LC-MS/MS.

The following assays are now available in my laboratory all of that have been validated according to the FDA "Guidance for Industry: Bioanalytical Method Validation" and were published as manuscript or conference abstract.

- Acetaminophen concentration for determination of gastric emptying time (HPLC-UV)
- Acetaminophen glucuronide and sulfate concentrations (LC-MS/MS)
- Atorvastatin and metabolites [atorvastatin (ATV) lactone, o-hydroxy ATV, o-hydroxy ATV lactone, p-pydroxy ATV, p-hydroxy ATV lactone (LC-MS/MS)
- AZT (3'-azido-3'-deoxythymidine) glucuronidation as a probe for UGT2B7 activity (LC-MS/MS)
- Baclofen concentration in plasma by LC-MS/MS
- Chlorzoxazone hydroxylation as a probe for P450 2E1 activity (LC-MS/MS)
- Cortisol metabolite (6 β hydroxy cortisol) and free cortisol concentration in urine (HPLC-UV)
- Cyclosporine; total concentration (LC-MS/MS)
- Estradiol-glucuronidation as a probe for UGT1A1 activity (HPLC-UV)
- Iodixanol concentration for determination of GFR (HPLC-UV)
- Iohexol concentration for determination of Glomerular Filtration Rate (GFR) (HPLC-UV)
- Ketoconazole concentration in human plasma (LC-MS/MS)
- Midazolam, 1'-OH and 4-OH midazolam (LC-MS/MS)
- Mifepristone concentration in rabbit plasma
- Mycophenolic acid (MPA) metabolites; concentration of MPAG and Acyl MPAG (HPLC-UV)
- Mycophenolic acid (MPA), total concentration (HPLC-UV)
- Oseltimivir and carboxylate (LC-MS/MS)
- PF-05190457 concentration in human and rat plasma and rat brain
- Pioglitazone and keto pioglitazone metabolite in human plasma (LC-MS/MS)
- Prednisolone, prednisone, cortisol and cortisone concentrations (LC-MS/MS)
- Propofol glucuronidation as a probe for UGT1A9 activity (HPLC-UV)

- Rosuvastatin acid, n-desmethayl rosuvastatin and rosuvastain lactone in plasma (LC-MS/MS)
- Sirolimus; total concentration (LC-MS/MS)
- Tacrolimus; total concentration (LC-MS/MS)
- Testosterone and 6-beta-testostrone (HPLC)
- Thyroid hormones, T3 and T4 (LC-MS/MS and ICP-mass spec.)

Unbound (free) concentration of drugs

- Cyclosporine; unbound concentration (equilibrium dialysis using [^{3}H] cyclosporine as tracer)
- Mycophenolic acid, unbound concentration (ultrafiltration followed by LC-MS/MS)
- Tacrolimus; unbound concentration (equilibrium dialysis using [^{3}H]tacrolimus as tracer)
- Prednisone, prednisolone and cortisol concentrations (ultrafiltration followed by LC-MS/MS)

Concentration of drugs in saliva

- Cyclosporine, saliva concentration (LC-MS/MS)
- Mycophenolic acid, saliva concentration (LC-MS/MS)
- Tacrolimus, saliva concentration (LC-MS/MS)
- Sirolimus, saliva concentration (LC-MS/MS) (under development)

Pharmacodynamic assays for immunosuppressive agents

- Measurement of inosine 5'-monophosphate dehydrogenase type–II (IMPDH-II) activity in peripheral blood mononuclear cells; this method is a pharmacodynamics marker for mycophenolic acid (enzymatic reaction followed by LC-MS/MS)
- mRNA expression using Taqman and SYBR green methods (rtPCR).
- Measurement of intracellular cytokine (IL-2, TNF-α, IFN-gamma) production in mitogen stimulated peripheral blood T-lymphocytes (intracellular immunostaining followed by flow cytometer; this method is one of the Pharmacodynamics assays to access the immunosuppressive activity of calcineurin inhibitors at T-cell level).
- Measurement of phenotypic markers (CD86, CD54 and CD95) expression in mitogen stimulated peripheral blood B-lymphocytes ($CD19^+$ cells); immunostaining followed by flow cytometer.
- ImmuKnow™ test (Cylex Inc): this test detects cell-mediated immunity by measuring the concentration of ATP from CD4+ cells following stimulation. The assay is the only FDA-cleared assay that directly assesses the cell-mediated immune response.

Preclinical studies

To explain many observations originated from clinical PK/PD studies, one has to utilize various techniques commonly used in the basic biomedical science or the preclinical stages of drug development. Among these techniques employed in my laboratory are the followings:

- Characterization of metabolic capacity of human liver microsomes in metabolizing CYP or UGT substrates.
- Western blot and rtPCR.
- Pharmacokinetics and drug-drug interaction studies in Sprague Dawley rat.
- Isolation and fractionation of lipoproteins from plasma to access plasma distribution of drugs among lipoprotein fractions.
- Plasma protein studies of new drugs and binding of drugs to different blood cells (i.e. red blood cells and lymphocytes).

- Transwell assay using MDCK cell lines transfected with human MDR1 (*ABCB1*) or MRP2 (*ABCC2*) genes. This assay is employed to characterize the drug-drug interaction at transporter level.
- Caco-2 transwell assay
- Development of a lipid loaded HepaRG cell line as an invitro model of hepatic steatosis
- SWATH-MS proteomics for characterization of drug metabolizing enzymes and xenobiotic transporters

CURRENT AND PAST COLLABORATORS

Amir Houshang Mohammadpour, Mashhad University of Medical Sciences, Mashhad, Iran
Anders Åsberg Ph.D.; College of Pharmacy, University of Oslo, Norway
Andrew Bostom M.D.; Brown University Medical School, Providence, RI
Andrew McLachlan, University of Sydney, Australia
Angela Slitt, BPS department, URI
Anne Keogh MBBS; St. Vincent's Hospital, Sydney, NSW, Australia
Ayman El-Kattan, Ph.D., IFM Therapeutics
Bingfang Yan Ph.D.; University of Cincinnati Ohio
Deyu Lee, BPS department, URI
Jack Wands, M.D., Dept. of Gastroenterology, Brown University
Li Yu Ph.D.; Roche Pharmaceuticals
Lorenzo Leggio M.D., Ph.D.; NIAAA, NIH
M. Liliana Gonzalez Ph.D.; Department of Computer Science and Statistics, URI
Mary Lee, NIAAA, NIH
Michael Court D.V.M Ph.D.; Washington State University, WA
Navindra Seeram, BPS department, URI
Nisanne Ghonem, BPS department, URI
R. Scott Obach, Ph.D., Pfizer Groton Central Research, CT
Reginald Gohh M.D.; Brown University Medical School, Providence, RI
Ruitang Deng, Ph.D.; BPS department, URI
Sara Rosenbaum Ph.D.; BPS department, URI
Susie Hu M.D.; Brown University Medical School, Providence, RI
Suzanne DeLaMonte M.D., MPH, Liver Research Unit, Brown University
Tim Flanigan, M.D., Brown University, Providence, RI
Uwe Christians M.D.; Ph.D.; Uni. of Colorado, Denver, CO

RESEARCH STUDENTS

Current graduate students

Name	Degree candidate	Title of project
Kyle Wald, B.Sc.	Ph.D.	Metabolomic studies of fatty liver disease in collaboration with Pfizer biomarker group

Former graduate students/post docs

Graduate Name	Degree and year	Present employment
Anitha Sravankumar, M.Sc.	Ph.D., Dec 2019	Takeda, MA
Benjamin Barlock, B.Sc.	Ph.D., Dec 2019	Merck, MA
Armin Sadighi	Ph.D., Dec 2018	Pharmacyclics, CA
Ghadah Alghaith, Pharm.D.	M.Sc. Dec 2018	University of Manchester, UK
Enoch Cobbina	Ph.D., May 2018	CSL Behring, PA
Sravani Adusumali,	Ph.D., Dec 2017	Cypotex, MA
Abdullah AlJutayli	M.Sc., Aug 2016	King Saud University, SA
Dr. Mohammad Al Zaabi, MD, Ph.D.	Sabbatical fellow (2015-2016)	Professor, Sultan Qaboos University, Oman
Mwlod Ghareeb	PhD Dec 2015	University of Cincinnati, Ohio
Dr. Arial Topletz	Post-doctoral fellow supported by grant # 5T32DA013911; PI Flannigan	Seattle Genetics
Dr. Amir Hooshang Mohammad Pour	Sabbatical fellow (2012-2013)	Professor, University of Mashhad, Iran
Dr. Ken Ogasawara	Postdoctoral research associate (2011-2013)	Celgene, NJ
Ileana Ionita	Ph.D. graduate (2013)	Pfizer Pharmaceuticals, CT
Joyce Macwan	Ph.D. graduate (2013)	Simulation Plus Inc., CA
Shripad Chitnis	Ph.D. graduate (2012)	Novartis Pharmaceuticals, MA
Dr. Miroslav Dostalek	Postdoctoral research associate (2009-2011)	Novartis Pharmaceuticals, Basle
Karen Thudium	MSc graduate (2010)	Novartis Pharmaceuticals, NJ

Dimple Pabla*	Ph.D. graduate (2009)	Novel Laboratories, Inc., NJ
Rajesh Narwal*	Ph.D. graduate (2008)	AstraZeneca, MD
Shripad Chitnis	MSc graduate (2008)	Novartis Pharmaceuticals, MA
Komal Paryani	MSc graduate (2008)	CVS Pharmacy, Tx
Anisha Mendonza	Ph.D. graduate (2007)	Novartis Pharmaceuticals, MA
Chirag Patel	Ph.D. graduate (2006)	Bayer Pharmaceuticals, MA
Dr. Wei-Johhn Sam*	Postdoctoral research associate (2005-2007)	National Institutes of Health
Dr. Hamim Zahir	Postdoctoral research associate (2003-2004)	Daiichi-Sankoyo, NJ
Rohit Soman	MSc graduate (2005)	Hospital Pharmacist
Jenana Maker (Halilovic)	Pharm. D. (2005)	Associate Professor, Uni. of the Pacific
Anisha Mendonza	MSc graduate (2004)	Novartis Pharmaceuticals, MA
Chirag Patel	MSc graduate (2004)	Takeda/Millennium MA
Julie Jones*	Ph.D. graduate (2003)	Jjo, Inc
Ghatem Baheti*	MSc graduate (2003)	CSL Behring, PA

* Co-advisor with other pharmaceutics faculty

Undergraduate/Pharm.D. Research Students

Ido Preis, BA	Medical student, Brown Uni, 2004
Matthew Harmon	Biology student, Brown Uni, 2005
Karen Thudium	Pharm.D. student, URI, 2006-
James Rebbello	Pharm.D. student, URI, summer 2008
Shayan Gates	BSc student, URI, summer 2009
Elyse Kim	PharmD student, 2012
Alyssa Dantonio	BSPS student 2013
El-Araby, Nermeen	Pharm.D. student, 2013-2014
Meghan Kelly	Pharm.D. Student, Summer 2014
Benjamin Barlock	BSPS student, Summer 2014
Julia Suits	INBRE summer student 2015
Anthony Giuliani	PharmD student, Summer 2015
Julia Scott	BSPS student, Fall 2015
Xin Bush	BSPS student, 2016-2018
Rachel Ryu	PharmD student, 2016-2017
Noah Steinberg	BSPS student, 2018-
Hassan Bhahati	Chem Eng student, 2018-

Thesis committee advising/membership in the University of Rhode Island

Anasuya Ghosh; MSc student (BMS)
Major Professor: Roberta King; Defense chair, Graduated Fall 2002.

Vishwasenani Balasubramanyam; MSc Student (BMS)
Major Professor: Nasser Zawia; Defense chair, Graduated Spring 2002.

Gutam Jha; MSc Student (BMS)
Major Professor: Roberta King; Defense chair, Graduated Fall 2002.

Julie Jones; PhD student (APS)
Major Professor: Sara Rosenbaum; Graduated Spring of 2003.

Ghatem Baheti; MSc Student (APS),
Major Professor: Dr. Sara Rosenbaum, Graduated Summer of 2003.

Chandra Vemavarapu; PhD student (APS),
Major Professor: Dr. Tom Needham, Graduated Spring 2003

Yuxin Li; PhD student (BMS),
Major Professor: Dr. Bingfang Yan, Graduated Fall 2003

Rina Chokshi; PhD student (APS)
Major Professor: Dr. Hussain Zia, Graduated Spring 2004.

Karuna Sachdeva; PhD Student (BMS),
Major Professor: Dr. Clinton Chichester, Graduated Fall 2004.

Rajesh Narwal; PhD Student (BPS)
Major Professor: Dr. Sara Rosenbaum; graduated Jul 2008

Sandy Weiner; PhD Student (BPS), Major Professor: Dr. Bingfang Yan.
Member of graduate committee, PhD Comprehensive exam, May 7th, 2004.

Dimple Pabla; Ph.D. student (BPS),
Major Professor: Dr. Hussain Zia; graduated Dec 2009.

Guofeng Ye; Ph.D. student (BPS), Major Professor: Dr. Keykavous Parang
Member of graduate committee.

Carolyn Higgins; MSc candidate,
Department of Chemistry, Major Professor Dr. Jimmie Oxley, graduated Apr 2008.

Jason Simione; MSc candidate,
Department of Pharmacy Practice, Major Professor Dr. Brian Quillam, graduated Apr 2008.

Vijay More; MSc candidate, Department of Biomedical and Pharmaceutical Sciences, Major Professor, Dr. Angela Slitt, Defense Date Nov 2009.

Brian Corbett; Ph.D. candidate, Department of Chemistry
Major Professor: Jacoda Major, Defense date Jan 2010.

Jae Joon Song; MSc candidate, Department of Computer Science and Statistics, Major professor: Dr. Gonzalez, Jul 2010.

Aderemi Dosunmu; Ph.D. student (BPS), Major Professor: Dr. Nasser Zawia.
Member of graduate committee; defended Ph.D. in Aug 2010.

John Yanusas; Ph.D. student (BPS), Major Professor: Dr. Thomas Needham
Member of graduate committee; PhD defense, May 2012

Dale Steele MD; MSc student in biostatistics
Member of graduate committee; MSc defense, Dec 2011

Ruohan Wang; MSc student in biostatistics
Member of graduate committee; MSc defense, Dec 2011

Hong Lu; PhD student in Pharmaceutical Sciences
Member of graduate committee; PhD defense, Jul 2013

Yu Seon Jung; MSc student in Pharmacy Practice
Member of graduate committee; MSc defense, Jul 2014

Prateek Kakar; PhD student in Biomedical and Pharmaceutical Sciences
Member of graduate committee

External examiner of Ph.D. thesis:

Aug 2004: external examiner for Ph.D. thesis by Hamim Zahir, University of Sydney, Australia; Major professor: Andrew J. McLachlan

Nov 2008: external examiner for Ph.D. thesis by Hongmei Xu, University of Sydney Australia; Major professor: Andrew J. McLachlan

Oct 2009: external examiner for Ph.D. thesis by Lily Zhang, University of Sydney Australia; Major professor: Andrew J. McLachlan

Feb 2012: external examiner for Ph.D. thesis by Lisa Longato, Brown University; Providence, RI, Major professor: Suzanne de la Monte

Aug 2012: external examiner for Ph.D. thesis by Michael Hanley, Pharm.D., Tufts University; Boston, MA; Major professor: David Greenblatt

Jun 2019: external examiner (opponent) for a PhD thesis of Erlend Johannessen Egeland in the University of Oslo, Norway, major professor: Anders Asberg

GRANTS AND FUNDING

Ongoing Research Support

National Institutes of Health, NCATS **2013-2019**
Novel Strategies for Treating Alcoholism: A Translational Approach $1,665,126
1UH2TR000963 Akhlaghi
[TR12-004] - limited competition for NIH-industry pilot program: discovering new therapeutic uses for existing molecules (UH2/UH3) portion
A collaborative project between NIH, Pfizer and URI to develop a Pfizer asset PF-5190457 as a novel therapeutic agent for alcoholism.
PI: Akhlaghi, Fatemeh (Contact); Leggio, Lorenzo (NIAAA, NIH)

CVS grant **2018-2019**
Personalized Warfarin Dosing in Patients with Diabetes and Fatty Liver Disease $100,000
Akhlaghi (PI) and Wen.

United Therapeutics **2019-2022**
A Phase I/II Study Evaluating the Preliminary Safety and Efficacy of Treprostinil (Remodulin®) In Reducing Ischemia-Reperfusion Injury During De Novo Adult Kidney Transplantation $400,000
Ghonem, Gohh (RIH), Akhlaghi

Completed Research Support

Baystate Medical Center **2016-2018**
Subcontract on 3R01 DA038082-02S1 $58,130
Implementation to motivate physician response to opioid dependence in HIV settings (supplement)
PI: Friedmann, Peter D., MD, PI of the Subcontract: Akhlaghi, Fatemeh

National Institutes of Health, R15 GM101599 **2013-2017**
Altered Hepatic Disposition of Statins by Diabetes mellitus $323,000
Role: PI

National Institutes of Health, SBIR proposal to NIMH **2013-2015**
NMDA receptor NR2D subtype-selective allosteric modulator for the treatment $ 76,792
of impulsivity disorders (1R43MH098467-0) Akhlaghi
Collaboration with Chinglu Pharmaceutical Research LLC portion

Pfizer Pharmaceuticals Inc. (0468X1-4536) **2009-2013**
Investigator initiated grant program $190,170
Pharmacokinetics and -dynamics of sirolimus in diabetic kidney transplant recipients
Role: PI

Novartis Pharmaceuticals, IIRP-1027 **2010-2013**

SmartPill technology for exact evaluation of gastrointestinal residence time in diabetic kidney transplants after conversion to EC-MPS — $232,042
Role: PI

Rhode Island Science and Technology Council (RI-STAC) — **2010-2012**
Novel oral fluid based methods for non-invasive determination of total exposure to active immunosuppressive agents — $111,878
Role: PI

Novartis Pharmaceuticals (CERL080-US68) — **2008- 2012**
Investigator initiated grant program — $198,458
Effect of diabetes mellitus on pharmacodynamics of immunosuppressive agents and characterization of UGT activity in diabetic liver and kidney
Role: PI

American Heart Association (0855761D) — **2008-2011**
Grant-in-aid, Founders Affiliate, $60,000/year direct cost for three years — $198,000
Individualized statin therapy in type 2 diabetics
Role: PI

Millennium Pharmaceuticals — **2008-2009**
Pharmacokinetics and pharmacodynamics modeling of bortezomib — $40,000
Role: PI

Investigator initiated grant, Novartis Pharmaceuticals — **2005-2008**
Pharmacokinetics and –dynamics of mycophenolate sodium in diabetes — $160,500
Role: PI

Investigator initiated grant, Roche Pharmaceuticals — **2004-2007**
Monitoring mycophenolic acid in saliva — $107,500
Role: PI

Proposal development grant, Uni. of Rhode Island Council for Research — **2006**
Biomarkers of immunosuppression in diabetic kidney transplant recipients — $10,000
Role: PI

Investigator initiated grant, Roche Laboratories — **2003-2005**
Pharmacokinetics of mycophenolic acid in diabetes — $139,700
Role: PI

Investigator initiated grant, Novartis Pharmaceuticals NJ — **2003-2004**
Clinical evaluation of cyclosporine C-2 in lung transplant recipients — $35,313
Role: PI

Rhode Island Foundation Medical Research Grant — **2003-2004**
Monitoring of cyclosporine in saliva — $10,000

Role: PI

National Center for Research Resources (NIH) **2002-2004**
New Investigator's support as part of the RI-BRIN program $100,671
PI: Zahir Shaikh, 3P20RR016457-02S1
Pharmacokinetics and pharmacodynamics of immunosuppressive agents
Role: Junior Investigator

National Center for Research Resources (NIH) **2002**
Pilot/feasibility study grant to RI-BRIN program $19,982
Distribution and metabolism of immunosuppressive agents

Bio Products Limited, UK **2002**
Pharmacokinetics of intravenous immunoglubulins $20,000

University of Rhode Island **2002**
Proposal development fund $9,958

Novartis Pharmaceuticals, U.K. **2000**
Unbound concentration of prednisolone and heart allograft rejection £9,723

Roche Educational Grant **2000-2001**
Pharmacokinetics of Cellcept in heart or lung transplant recipients £25,000

Transplant Charitable Fund, Papworth Hospital **1998-2000**
PK/PD of corticosteroids after heart and lung transplantation £96, 253
Evaluating various risk factors for organ rejection following heart transplantation

Janssen-Cilag Pty. Ltd, Australia **1997-1999**
Distribution of tacrolimus in heart transplant recipients: A$151,788
A determinant of immunosuppressant efficacy
Role: postdoctoral research associate

PENDING GRANT APPLICATIONS

National Institutes of Health, NIDDK
Role of MRP2 Polymorphism in Tacrolimus Disposition and Adverse Effects; 1 R21 DK095208-01A1
Scored 30 but not funded, to be submitted as an R01
PI: Akhlaghi, Fatemeh

National Institutes of Health
Clopidogrel resistance in diabetes and NASH
To be submitted as R01
PI: Akhlaghi, Fatemeh

National Institutes of Health, NCCAM

Natural Product Drug Interaction Research and Education Center (NP-DIREC); 1 U54 AT008910
Application for center for excellence in natural products drug interaction
Amount requested: $10.7 Million
Scored, not funded

PATENTS

1. European Union Patent 1996067; **Akhlaghi F** and Mendonza AE; Monitoring Cyclosporine in Saliva; patent granted in 2013
2. United States Patent Application 20080255765; **Akhlaghi F** and Mendonza AE; Monitoring Cyclosporine in Saliva - 10-16-2008
3. United States Patent Application 20080318322; **Akhlaghi F** and Mendonza AE; Analysis of mycophenolic acid in saliva using liquid chromatography tandem mass spectrometry - 12-25-2008
4. United States Patent Application US 10,126,316 B2**; F Akhlaghi,** M Ghareeb; Systems and Methods for the Measurement of Tacrolimus in Oral Fluids by Liquid Chromatography Tandem Mass Spectrometry**.** *A United States patent was granted and all 20 claims were allowed https://patents.google.com/patent/US10126316B2/en*

PEER-REVIEWED PUBLICATIONS

Link to Pubmed

https://www.ncbi.nlm.nih.gov/pubmed/?term=(Akhlaghi+F)+AND+(rhode+OR+sydney+OR+cambridge+OR+transplant)

Link to Google Scholar
https://scholar.google.com/citations?user=wdnBYOAAAAAJ&hl=en

SUBMITTED OR IN REVISION

1. Cobbina E, Lee MR, Leggio L, **Akhlaghi F**; A population pharmacokinetic analysis of PF-5190457, a novel ghrelin receptor inverse agonist, in healthy volunteers and in heavy alcohol drinkers; To be submitted to *Clinical Pharmacokinetics*
2. Saravanakumar A, Tierney CA, He W, Bush X, Johnson JG, Rodrigues D, **Akhlaghi F**. Transcriptomic analysis of a lipid-loaded HepaRG model for steatosis reveals altered regulation of drug metabolizing enzymes and transporters; Submitted to *Mol Pharmaceutics.*
3. Sadighi A, Leggio L, **Akhlaghi F**; Development of a physiologically based pharmacokinetic model for prediction of ethanol concentration-time profile in different organs; Submitted to *Alcohol and Alcoholism*
4. Jamwal R, Barlock BJ, Adusumalli S, **Akhlaghi F**. SWATH-MS based method for relative quantification of human hepatic drug transporters and its application to study gender differences. Under revision *Journal of Proteomics*

5. Barlock BJ, Jamwal R, Mahta A, **Akhlaghi F**. Presence of drug metabolizing enzyme inducers in commercially available human liver samples increases protein levels of clinically relevant enzymes; to be submitted to *Drug Metabolism and Disposition*

6. Marques E, Pfohl M, Auclair A, Jamwal R, Barlock BJ, Sammoura FM, Goedken M, **Akhlaghi F**, Slitt A; Proteomics reveals PFOS-induced alteration of lipid utilization and xenobiotic metabolism in a model of PFOS-augmented diet-induced fatty liver; submitted to *Toxicological Sciences*

PUBLISHED OR ACCEPTED FOR PUBLICATION

7. Lee MR, Farokhnia M, Cobbina E, Saravanakumar A, Li X, Battista JT, Farinelli LA, **Akhlaghi F**, Leggio L. Endocrine effects of the novel ghrelin receptor inverse agonist PF-5190457: results from a placebo-controlled human laboratory alcohol co-administration study in heavy drinkers; *Neuropharmacology.* 2019 Sep 23:107788. doi: 10.1016/j.neuropharm.2019.107788. [Epub ahead of print]

8. Rose KN, Barlock BJ, DaSilva NA, Johnson SS, Liu C, Ma H, Nelson R, **Akhlaghi F**, Seeram NP. Anti-neuroinflammatory effects of a food-grade phenolic-enriched maple syrup extract in a mouse model of Alzheimer's disease; *Nutr Neurosci.* 2019 Oct 4:1-10. doi: 10.1080/1028415X.2019.1672009. [Epub ahead of print]

9. Adusumalli S, Jamwal R, Leggio L, Akhlaghi F. Analysis and validation of an assay for a novel ghrelin receptor inverse agonist PF-5190457 and its major hydroxy metabolite (PF-6870961) by LC-MS/MS in human plasma; *J Chromatogr B Analyt Technol Biomed Life Sci.* 2019 Nov 1;1130-1131:121820. doi: 10.1016/j.jchromb.2019.121820. Epub 2019 Oct 8.

10. Adusumalli S, Jamwal R, Obach RS, Ryder TF, Leggio L, **Akhlaghi F**. Role of molybdenum-containing enzymes in the biotransformation of the novel ghrelin receptor inverse agonist PF-5190457: a reverse translational bed-to-bench approach. Drug Metab Dispos. 2019 Jun 10. pii: dmd.119.087015. doi: 10.1124/dmd.119.087015. [Epub ahead of print] PubMed PMID: 31182423.

11. Saravanakumar A, Sadighi A, Ryu R, **Akhlaghi F**. Physicochemical properties, biotransformation, and transport pathways of established and newly approved medications: a systematic review of the top 200 most prescribed drugs vs. the FDA-approved drugs between 2005 and 2016. Clin Pharmacokinet. 2019 Apr 10. doi: 10.1007/s40262-019-00750-8. [Epub ahead of print] Review. PubMed PMID: 30972694.

12. Farokhnia M, Deschaine SL, Sadighi A, Farinelli LA, Lee MR, **Akhlaghi F**, Leggio L. A deeper insight into how GABA-B receptor agonism via baclofen may affect alcohol seeking and consumption: lessons learned from a human laboratory investigation. *Mol Psychiatry.* 2018 Oct 31. doi: 10.1038/s41380-018-0287-y. [Epub ahead of print] PubMed PMID: 30382188.

13. Farokhnia M, Lee MR, Farinelli LA, Ramchandani VA, **Akhlaghi F**, Leggio L. Pharmacological manipulation of the ghrelin system and alcohol hangover symptoms in heavy drinking individuals: Is there a link? Pharmacol Biochem Behav. 2018 Sept;172:39-49. doi: 10.1016/j.pbb.2018.07.004. Epub 2018 Jul 17. PubMed PMID: 30030128.

14. Bouhlal S, Farokhnia M, Lee MR, **Akhlaghi F**, Leggio L. Identifying and Characterizing Subpopulations of Heavy Alcohol Drinkers Via a Sucrose Preference Test: A Sweet Road to a Better Phenotypic Characterization? *Alcohol Alcohol.* 2018 Jul 17. doi: 10.1093/alcalc/agy048. [Epub ahead of print] PubMed PMID: 30016385.

15. Jamwal R, de la Monte SM, Ogasawara K, Adusumalli S, Barlock BB, **Akhlaghi F**. Nonalcoholic fatty liver disease and diabetes is associated with decreased CYP3A4 protein expression and activity in human liver. *Mol Pharm*. 2018 Jul 2;15(7):2621-2632. doi: 10.1021/acs.molpharmaceut.8b00159. Epub 2018 Jun 11.

16. Lee MR, Tapocik JD, Ghareeb M, Schwandt ML, Dias AA, Le AN, Cobbina E, Farinelli LA, Bouhlal S, Farokhnia M, Heilig M, **Akhlaghi F**, Leggio L. The novel ghrelin receptor inverse agonist PF-5190457 administered with alcohol: preclinical safety experiments and a phase 1b human laboratory study. *Mol Psychiatry*. 2018 May 4. doi: 10.1038/s41380-018-0064-y. [Epub ahead of print]; PubMed PMID: 29728704.

17. Lee MR, Scheidweiler KB, Diao XX, **Akhlaghi F**, Cummins A, Huestis MA, Leggio L, Averbeck BB. Oxytocin by intranasal and intravenous routes reaches the cerebrospinal fluid in rhesus macaques: determination using a novel oxytocin assay. *Mol Psychiatry*. 2018;23(1):115-22. doi: 10.1038/mp.2017.27. PubMed PMID: 28289281.

18. Ghareeb M, Gohh RY, **Akhlaghi F**. Tacrolimus concentration in saliva of kidney transplant recipients: factors influencing the relationship with whole blood concentrations. *Clin Pharmacokinet*. 2018. doi: 10.1007/s40262-017-0626-1. PubMed PMID: 29330784.

19. Valanejad L, Ghareeb M, Shiffka S, Nadolny C, Chen Y, Guo L, Verma R, You S, **Akhlaghi F**, Deng R. Dysregulation of Delta(4)-3-oxosteroid 5beta-reductase in diabetic patients: Implications and mechanisms. *Mol Cell Endocrinol*. 2017. doi: 10.1016/j.mce.2017.10.005. PubMed PMID: 29024782.

20. Tang Q, Cai A, Bian K, Chen F, Delaney JC, Adusumalli S, Bach AC, 2nd, **Akhlaghi F**, Cho BP, Li D. Characterization of Byproducts from Chemical Syntheses of Oligonucleotides Containing 1-Methyladenine and 3-Methylcytosine. *ACS Omega*. 2017;2(11):8205-12. doi: 10.1021/acsomega.7b01482. PubMed PMID: 29214236; PMCID: PMC5709782.

21. Jamwal R, Topletz AR, Ramratnam B, **Akhlaghi F**. Ultra-high performance liquid chromatography tandem mass-spectrometry for simple and simultaneous quantification of cannabinoids. *J Chromatogr B Analyt Technol Biomed Life Sci.* 2017;1048:10-8. doi: 10.1016/j.jchromb.2017.02.007. PubMed PMID: 28192758; PMCID: PMC5697720.

22. Jamwal R, Barlock BJ, Adusumalli S, Ogasawara K, Simons BL, **Akhlaghi F**. Multiplex and Label-Free Relative Quantification Approach for Studying Protein Abundance of Drug Metabolizing Enzymes in Human Liver Microsomes Using SWATH-MS. *J Proteome Res.* 2017;16(11):4134-43. doi: 10.1021/acs.jproteome.7b00505. PubMed PMID: 28944677.

23. Haass-Koffler CL, **Akhlaghi F**, Swift RM, Leggio L. Altering ethanol pharmacokinetics to treat alcohol use disorder: Can you teach an old dog new tricks? *J Psychopharmacol.* 2017;31(7):812-8. doi: 10.1177/0269881116684338. PubMed PMID: 28093021; PMCID: PMC5768306.

24. Cobbina E, **Akhlaghi F**. Non-alcoholic fatty liver disease (NAFLD) - pathogenesis, classification, and effect on drug metabolizing enzymes and transporters. *Drug Metab Rev.* 2017;49(2):197-211. doi: 10.1080/03602532.2017.1293683. PubMed PMID: 28303724; PMCID: PMC5576152 (recognized as the best paper published in 2017 in Drug Metabolism Review)

25. **Akhlaghi F**, Matson KL, Mohammadpour AH, Kelly M, Karimani A. Clinical pharmacokinetics and pharmacodynamics of antihyperglycemic medications in children and adolescents with type 2 diabetes mellitus. *Clin Pharmacokinet.* 2017;56(6):561-71. doi: 10.1007/s40262-016-0472-6. PubMed PMID: 27832452; PMCID: PMC5425330.

26. Ghareeb M, **Akhlaghi F**. Development and validation of a sensitive and selective LC-MS/MS method for determination of tacrolimus in oral fluids. *J Chromatogr B Analyt Technol Biomed Life Sci.* 2016;1038:136-41. doi: 10.1016/j.jchromb.2016.10.008. PubMed PMID: 27771258.

27. Lin S, Henning AK, **Akhlaghi F**, Reisfield R, Vergara-Silva A, First MR. Interleukin-2 receptor antagonist therapy leads to increased tacrolimus levels after kidney transplantation. *Ther Drug Monit*. 2015 Apr;37(2):206-13. PubMed PMID: 25162212.

28. Ghareeb M, Leggio L, El-Kattan A, **Akhlaghi F**. Development and validation of an UPLC-MS/MS assay for quantitative analysis of the ghrelin receptor inverse agonist PF-5190457 in human or rat plasma and rat brain. *Anal Bioanal Chem*. 2015 Jul;407(19):5603-13. PubMed PMID: 25943263. PMCID: 4499019.

29. Ghareeb M, **Akhlaghi F**. Alternative matrices for therapeutic drug monitoring of immunosuppressive agents using LC-MS/MS. Bioanalysis. 2015;7(8):1037-58. PubMed PMID: 25966013. PMCID: 4480919.

30. Robertsen I, Asberg A, Granseth T, Vethe NT, **Akhlaghi F**, Ghareeb M, et al. More potent lipid-lowering effect by rosuvastatin compared with fluvastatin in everolimus-treated renal transplant recipients. Transplantation. 2014 Jun 27;97(12):1266-71. PubMed PMID: 24521776. PMCID: 4127422.

31. Ionita IA, Ogasawara K, Gohh RY, **Akhlaghi F**. Pharmacokinetics of total and unbound prednisone and prednisolone in stable kidney transplant recipients with diabetes mellitus. Ther Drug Monit. 2014 Aug;36(4):448-55. PubMed PMID: 24452065. PMCID: 4109138.

32. Patel CG, Ogasawara K, **Akhlaghi F**. Mycophenolic acid glucuronide is transported by multidrug resistance-associated protein 2 and this transport is not inhibited by cyclosporine, tacrolimus or sirolimus. Xenobiotica. 2013 Mar;43(3):229-35. PubMed PMID: 22934787. PMCID: 4116557.

33. Ogasawara K, Chitnis SD, Gohh RY, Christians U, **Akhlaghi F**. Multidrug resistance-associated protein 2 (MRP2/ABCC2) haplotypes significantly affect the pharmacokinetics of tacrolimus in kidney transplant recipients. Clin Pharmacokinet. 2013 Sept; 52(9):751-62. PubMed PMID: 23633119. PMCID: 3755037.

34. Mohammadpour AH, **Akhlaghi F**. Future of cholesteryl ester transfer protein (CETP) inhibitors: a pharmacological perspective. Clin Pharmacokinet. 2013 Aug; 52(8):615-26. PubMed PMID: 23658137. PMCID: 3720705.

35. Dostalek M, Gohh RY, **Akhlaghi F**. Inosine monophosphate dehydrogenase expression and activity are significantly lower in kidney transplant recipients with diabetes mellitus. Ther Drug Monit. 2013 Jun;35(3):374-83. PubMed PMID: 23666569. PMCID: 4109137.

36. Chitnis SD, Ogasawara K, Schniedewind B, Gohh RY, Christians U, **Akhlaghi F**. Concentration of tacrolimus and major metabolites in kidney transplant recipients as a function of diabetes mellitus and cytochrome P450 3A gene polymorphism. Xenobiotica. 2013 Jul;43(7):641-9. PubMed PMID: 23278282. PMCID: 4116556.

37. Tsze DS, Steele DW, Machan JT, **Akhlaghi F**, Linakis JG. Intranasal ketamine for procedural sedation in pediatric laceration repair: a preliminary report. Pediatr Emerg Care. 2012 Aug;28(8):767-70. PubMed PMID: 22858745.

38. Macwan JS, Ionita IA, **Akhlaghi F**. A simple assay for the simultaneous determination of rosuvastatin acid, rosuvastatin-5S-lactone, and N-desmethyl rosuvastatin in human plasma using liquid chromatography-tandem mass spectrometry (LC-MS/MS). Anal Bioanal Chem. 2012 Jan;402(3):1217-27. PubMed PMID: 22108655.

39. Longato L, Ripp K, Setshedi M, Dostalek M, **Akhlaghi F**, Branda M, et al. Insulin resistance, ceramide accumulation, and endoplasmic reticulum stress in human chronic alcohol-related liver disease. Oxid Med Cell Longev. 2012;2012: 479348. PubMed PMID: 22577490. PMCID: 3347750.

40. Dostalek M, Sam WJ, Paryani KR, Macwan JS, Gohh RY, **Akhlaghi F**. Diabetes mellitus reduces the clearance of atorvastatin lactone: results of a population pharmacokinetic analysis in renal transplant recipients and in vitro studies using human liver microsomes. Clin Pharmacokinet. 2012 Sept 1;51(9):591-606. PubMed PMID: 22775412.

41. Dostalek M, **Akhlaghi F**, Puzanovova M. Effect of diabetes mellitus on pharmacokinetic and pharmacodynamic properties of drugs. Clin Pharmacokinet. 2012 Aug 1;51(8):481-99. PubMed PMID: 22668340.

42. **Akhlaghi F**, Dostalek M, Falck P, Mendonza AE, Amundsen R, Gohh RY, et al. The concentration of cyclosporine metabolites is significantly lower in kidney transplant recipients with diabetes mellitus. Ther Drug Monit. 2012 Feb;34(1):38-45. PubMed PMID: 22210099.

43. Macwan JS, Ionita IA, Dostalek M, **Akhlaghi F**. Development and validation of a sensitive, simple, and rapid method for simultaneous quantitation of atorvastatin and its acid and lactone metabolites by liquid chromatography-tandem mass spectrometry (LC-MS/MS). Anal Bioanal Chem. 2011 Apr;400(2):423-33. PubMed PMID: 21359569.

44. Dostalek M, Court MH, Yan B, **Akhlaghi F**. Significantly reduced cytochrome P450 3A4 expression and activity in liver from humans with diabetes mellitus. Br J Pharmacol. 2011 Jul;163(5):937-47. PubMed PMID: 21323901. PMCID: 3130941.

45. Dostalek M, Court MH, Hazarika S, **Akhlaghi F**. Diabetes mellitus reduces activity of human UDP-glucuronosyltransferase 2B7 in liver and kidney leading to decreased formation of mycophenolic acid acyl-glucuronide metabolite. Drug Metab Dispos. 2011 Mar;39(3):448-55. PubMed PMID: 21123165. PMCID: 3061563.

46. Bolin P, Jr., Gohh R, Kandaswamy R, Shihab FS, Wiland A, **Akhlaghi F**, et al. Mycophenolic acid in kidney transplant patients with diabetes mellitus: does the formulation matter? Transplant Rev (Orlando). 2011 Jul;25(3):117-23. PubMed PMID: 21530217.

47. Pabla D, **Akhlaghi F**, Zia H. Intestinal permeability enhancement of levothyroxine sodium by straight chain fatty acids studied in MDCK epithelial cell line. Eur J Pharm Sci. 2010 Aug 11;40(5):466-72. PubMed PMID: 20580671.

48. Narwal R, **Akhlaghi F**, Asberg A, Hermann M, Rosenbaum SE. Development of a population pharmacokinetic model for atorvastatin acid and its lactone metabolite. Clin Pharmacokinet. 2010 Oct;49(10):693-702. PubMed PMID: 20818835.

49. Ionita IA, **Akhlaghi F**. Quantification of unbound prednisolone, prednisone, cortisol and cortisone in human plasma by ultrafiltration and direct injection into liquid chromatrography tandem mass spectrometry. Ann Clin Biochem. 2010 Jul;47(Pt 4):350-7. PubMed PMID: 20592334.

50. Hu S, **Akhlaghi F**, Chitnis S, Chiu R, Go S, Rout P, et al. Comparison of plasma clearance of iodixanol during versus after angiography. Am J Kidney Dis. 2010 Dec;56(6):1219-20. PubMed PMID: 21094917.

51. Dostalek M, Macwan JS, Chitnis SD, Ionita IA, **Akhlaghi F**. Development and validation of a rapid and sensitive assay for simultaneous quantification of midazolam, 1'-hydroxymidazolam, and 4-hydroxymidazolam by liquid chromatography coupled to tandem mass-spectrometry. J Chromatogr B Analyt Technol Biomed Life Sci. 2010 Jun 1;878(19):1629-33. PubMed PMID: 20434409.

52. **Akhlaghi F**, Gohh RY. The level of ATP production in mitogen-stimulated CD4+ lymphocytes is independent of the time of ingestion of immunosuppressive agents. Ther Drug Monit. 2010 Feb;32(1):116-7. PubMed PMID: 20104140.

53. Teasdale ME, Liu J, Wallace J, **Akhlaghi F**, Rowley DC. Secondary metabolites produced by the marine bacterium Halobacillus salinus that inhibit quorum sensing-controlled phenotypes in gram-negative bacteria. Appl Environ Microbiol. 2009 Feb;75(3):567-72. PubMed PMID: 19060172. PMCID: 2632121.

54. Sam WJ, **Akhlaghi F**, Rosenbaum SE. Population pharmacokinetics of mycophenolic acid and its 2 glucuronidated metabolites in kidney transplant recipients. J Clin Pharmacol. 2009 Feb;49(2):185-95. PubMed PMID: 19179297.

55. Pabla D, **Akhlaghi F**, Zia H. A comparative pH-dissolution profile study of selected commercial levothyroxine products using inductively coupled plasma mass spectrometry. Eur J Pharm Biopharm. 2009 May;72(1):105-10. PubMed PMID: 18996189.

56. Ionita IA, Fast DM, **Akhlaghi F**. Development of a sensitive and selective method for the quantitative analysis of cortisol, cortisone, prednisolone and prednisone in human plasma. J Chromatogr B Analyt Technol Biomed Life Sci. 2009 Mar 15;877(8-9):765-72. PubMed PMID: 19237320.

57. Pabla D, **Akhlaghi F**, Ahmed A, Zia H. Development and validation of an inductively coupled plasma mass spectrometry method for quantification of levothyroxine in dissolution studies. Rapid Commun Mass Spectrom. 2008 Apr;22(7):993-6. PubMed PMID: 18320549.

58. Mendonza AE, Gohh RY, **Akhlaghi F**. Blood and plasma pharmacokinetics of ciclosporin in diabetic kidney transplant recipients. Clin Pharmacokinet. 2008;47(11):733-42. PubMed PMID: 18840028.

59. Falck P, Asberg A, Guldseth H, Bremer S, **Akhlaghi F**, Reubsaet JL, et al. Declining intracellular T-lymphocyte concentration of cyclosporine a precedes acute rejection in kidney transplant recipients. Transplantation. 2008 Jan 27;85(2):179-84. PubMed PMID: 18212621.

60. Chitnis SD, **Akhlaghi F**. Development and validation of an HPLC-UV method for iodixanol quantification in human plasma. J Chromatogr B Analyt Technol Biomed Life Sci. 2008 Jun 15;869(1-2):133-7. PubMed PMID: 18502708.

61. Plante T, Harris D, Savitt J, **Akhlaghi F**, Monti J, Jay GD. Carboxyhemoglobin monitored by bedside continuous CO-oximetry. J Trauma. 2007 Nov;63(5):1187-90. PubMed PMID: 17993970.

62. Patel CG, Richman K, Yang D, Yan B, Gohh RY, **Akhlaghi F**. Effect of diabetes mellitus on mycophenolate sodium pharmacokinetics and inosine monophosphate dehydrogenase activity in stable kidney transplant recipients. Ther Drug Monit. 2007 Dec;29(6):735-42. PubMed PMID: 18043470. PMCID: 4082794.

63. Patel CG, Harmon M, Gohh RY, **Akhlaghi F**. Concentrations of mycophenolic acid and glucuronide metabolites under concomitant therapy with cyclosporine or tacrolimus. Ther Drug Monit. 2007 Feb;29(1):87-95. PubMed PMID: 17304155.

64. Mendonza AE, Zahir H, Gohh RY, **Akhlaghi F**. Tacrolimus in diabetic kidney transplant recipients: pharmacokinetics and application of a limited sampling strategy. Ther Drug Monit. 2007 Aug;29(4):391-8. PubMed PMID: 17667791.

65. Zahir H, Keogh AM, **Akhlaghi F**. Apparent clearance of sirolimus in heart transplant recipients: impact of primary diagnosis and serum lipids. Ther Drug Monit. 2006 Oct;28(5):614-22. PubMed PMID: 17038875.

66. Zahir H, Keogh A, **Akhlaghi F**. Apparent clearance of sirolimus in heart transplant recipients: impact of primary diagnosis and serum lipids. Ther Drug Monit. 2006 Dec;28(6):818-26. PubMed PMID: 17203553.

67. Shi D, Yang J, Yang D, LeCluyse EL, Black C, You L, et al. Anti-influenza prodrug oseltamivir is activated by carboxylesterase human carboxylesterase 1, and the activation is inhibited by antiplatelet agent clopidogrel. J Pharmacol Exp Ther. 2006 Dec;319(3):1477-84. PubMed PMID: 16966469.

68. Patel CG, **Akhlaghi F**. High-performance liquid chromatography method for the determination of mycophenolic acid and its acyl and phenol glucuronide metabolites in human plasma. Ther Drug Monit. 2006 Feb;28(1):116-22. PubMed PMID: 16418705.

69. Mendonza AE, Gohh RY, **Akhlaghi F**. Analysis of mycophenolic acid in saliva using liquid chromatography tandem mass spectrometry. Ther Drug Monit. 2006 Jun;28(3):402-6. PubMed PMID: 16778726.

70. **Akhlaghi F**, Patel CG, Zuniga XP, Halilovic J, Preis IS, Gohh RY. Pharmacokinetics of mycophenolic acid and metabolites in diabetic kidney transplant recipients. Ther Drug Monit. 2006 Feb;28(1):95-101. PubMed PMID: 16418701.

71. Zahir H, McLachlan AJ, Nelson A, McCaughan G, Gleeson M, **Akhlaghi F**. Population pharmacokinetic estimation of tacrolimus apparent clearance in adult liver transplant recipients. Ther Drug Monit. 2005 Aug;27(4):422-30. PubMed PMID: 16044097.

72. Soman RS, Zahir H, **Akhlaghi F**. Development and validation of an HPLC-UV method for determination of iohexol in human plasma. J Chromatogr B Analyt Technol Biomed Life Sci. 2005 Feb 25;816(1-2):339-43. PubMed PMID: 15664368.

73. Rosenbaum SE, Baheti G, Trull AK, **Akhlaghi F**. Population pharmacokinetics of cyclosporine in cardiopulmonary transplant recipients. Ther Drug Monit. 2005 Apr;27(2):116-22. PubMed PMID: 15795639.

74. **Akhlaghi F**, Gonzalez L, Trull AK. Association between cyclosporine concentrations at 2 hours post-dose and clinical outcomes in de novo lung transplant recipients. J Heart Lung Transplant. 2005 Dec;24(12):2120-8. PubMed PMID: 16364860.

75. Trull AK, **Akhlaghi F**, Charman SC, Endenberg S, Majid O, Cornelissen J, et al. Immunosuppression, eotaxin and the diagnostic changes in eosinophils that precede early acute heart allograft rejection. Transpl Immunol. 2004 Jan;12(2):159-66. PubMed PMID: 14967314.

76. Patel CG, Mendonza AE, **Akhlaghi F**, Majid O, Trull AK, Lee T, et al. Determination of total mycophenolic acid and its glucuronide metabolite using liquid chromatography with ultraviolet

detection and unbound mycophenolic acid using tandem mass spectrometry. J Chromatogr B Analyt Technol Biomed Life Sci. 2004 Dec 25;813(1-2):287-94. PubMed PMID: 15556544.

77. Mendonza A, Gohh R, **Akhlaghi F**. Determination of cyclosporine in saliva using liquid chromatography-tandem mass spectrometry. Ther Drug Monit. 2004 Oct;26(5):569-75. PubMed PMID: 15385841.
78. Ray JE, Keogh AM, McLachlan AJ, **Akhlaghi F**. Cyclosporin C(2) and C(0) concentration monitoring in stable, long-term heart transplant recipients receiving metabolic inhibitors. J Heart Lung Transplant. 2003 Jul;22(7):715-22. PubMed PMID: 12873538.
79. **Akhlaghi F**, Trull AK. Distribution of cyclosporin in organ transplant recipients. Clin Pharmacokinet. 2002;41(9):615-37. PubMed PMID: 12126456.
80. **Akhlaghi F**, Jackson CH, Parameshwar J, Sharples LD, Trull AK. Risk factors for the development and progression of dyslipidemia after heart transplantation. Transplantation. 2002 Apr 27;73(8):1258-64. PubMed PMID: 11981418.
81. Trull AK, Charman SC, Endenburg S, **Akhlaghi F**, Majid O, Cornelissen J, et al. Eotaxin and prednisolone concentrations regulate the mobilisation of peripheral blood eosinophils preceding heart allograft rejection. J Heart Lung Transplant. 2001 Feb;20(2):161. PubMed PMID: 11250241.
82. Majid O, **Akhlaghi F**, Lee T, Holt DW, Trull A. Simultaneous determination of plasma prednisolone, prednisone, and cortisol levels by high-performance liquid chromatography. Ther Drug Monit. 2001 Apr;23(2):163-8. PubMed PMID: 11294518.
83. **Akhlaghi F**, Keogh AM, McLachlan AJ, Kaan A. Pharmacokinetics of cyclosporine in heart transplant recipients receiving metabolic inhibitors. J Heart Lung Transplant. 2001 Apr;20(4):431-8. PubMed PMID: 11295581.
84. Trull AK, Steel LA, Sharples LD, **Akhlaghi F**, Parameshwar J, Cary N, et al. Randomized trial of blood eosinophil count monitoring as a guide to corticosteroid dosage adjustment after heart transplantation. Transplantation. 2000 Sept 15;70(5):802-9. PubMed PMID: 11003362.
85. **Akhlaghi F**, Keogh AM, Brown KF. Unbound cyclosporine and allograft rejection after heart transplantation. Transplantation. 1999 Jan 15; 67(1):54-9. PubMed PMID: 9921795.
86. **Akhlaghi F**, Ashley J, Keogh A, Brown K. Cyclosporine plasma unbound fraction in heart and lung transplantation recipients. Ther Drug Monit. 1999 Feb; 21(1):8-16. PubMed PMID: 10051049.
87. **Akhlaghi F**, Ashley JJ, Keogh AM, Brown KF. Indirect estimation of the unbound fraction of cyclosporine in plasma. Ther Drug Monit. 1998 Jun; 20(3):301-8. PubMed PMID: 9631927.
88. **Akhlaghi F**, McLachlan AJ, Keogh AM, Brown KF. Effect of simvastatin on cyclosporine unbound fraction and apparent blood clearance in heart transplant recipients. Br J Clin Pharmacol. 1997 Dec;44(6):537-42. PubMed PMID: 9431828. PMCID: 2042891.

PUBLICATION IN PREPARATION

The following manuscripts are currently in preparation (undergoing revision) for submission to scientific journals; most of the work is already completed and/or presented at scientific meetings:

1. Enoch Cobbina, Anitha Sravankumar, **Fatemeh Akhlaghi.** Impact of Non-Alcoholic Fatty Liver Disease (NAFLD) on Human Hepatic CYP2B6 Enzyme: A Crucial Consideration for CYP2B6 Substrates in Precision Medicine. To be submitted to *Clinical Pharmacology and Therapeutics*
2. Shripad D. Chitnis, Miroslav Dostalek, **Fatemeh Akhlaghi**. Influence of Diabetes Mellitus on the Pharmacokinetics and Pharmacodynamics of the Immunosuppressive Agents used in Organ Transplantation. To be submitted to *Clinical Pharmacokinetics.*
3. Kim JH, Maker J, El-Araby N, **Akhlaghi F**. Pharmacokinetic drug interactions with mTOR inhibitors: sirolimus, everolimus and temsirolimus (invited review article) to be submitted to *Clinical Pharmacokinetics.*
4. **Akhlaghi F**, Chitnis SD, Mendonza AE, Ionita IA, Gohh RY. Reduced level of biomarkers of immunosuppressive activity in diabetic kidney transplant recipients is related to diabetes type and glucose control; to be submitted to *Transplantation.*
5. **Akhlaghi F**, Monbaliu J, Kadambi V, Yu L. Blood and plasma pharmacokinetics of bortezomib in relation to blood 20s proteasome activity after single and multiple dosing in cynomongolus monkeys; to be submitted to *Journal of Pharmacology and Experimental Therapeutics.*
6. **Akhlaghi F**, Monbaliu J, Kadambi V, Prakash S, Lee F, Yu L. Development of an integrated pharmacokinetic and pharmacodynamic model for bortezomib to allow predication of 20s proteasome activity from plasma concentrations; to be submitted to *Cancer Chemother Pharmacol.*
7. Chitnis SD, Gohh RY, **Akhlaghi F**. Diabetic renal transplant recipients maintained on sirolimus therapy exhibit lower expression of CD95 pharmacodynamic marker with minimal effect on sirolimus pharmacokinetics; to be submitted to *Transplantation.*

CONFERENCE ABSTRACTS
(IN REVERSE CHRONOLOGICAL ORDER)

1. Kyle Wald, Anitha Sravankumar, **Fatemeh Akhlaghi**, Matthew Blatnik. Fructose Fluxomics of Fatty Acid Treated HepRG Cells to predict flux in NASH patients via LC-HRMS, Poster presentation at ASMS Conference on Mass Spectrometry and Allied Topics, May 31 - June 4, 2020, Houston, Texax
2. Rohitash Jamwal, Benjamin Barlock, **Fatemeh Akhlaghi**. Quantitative analysis of human hepatic drug metabolizing enzyme alterations in non - alcoholic fatty liver disease and its application in physiologically based pharmacokinetic (PBPK) modeling; Poster and podium presentation as lightening talk at Applied Biomath QSP Summit meeting, Apr 25-26, 2019, Cambridge, MA.
3. **Fatemeh Akhlaghi**, Rohitash Jamwal, Benjamin Barlock, Anitha Sravankumar. Use of a SWATH-MS Proteomic Approach Towards Improving Drug Development and Biomarker Discovery for Non-Alcoholic Fatty Liver Disease (NAFLD); Poster Presentation at 3rd Annual NASH summit, Apr 22-25, 2019; Boston, MA
4. Meiwen Ding, Evelyn Tolbert, Mark Birkenbach, Chun-Shiang Chung, Reginald Gohh, **Fatemeh Akhlaghi**, and Nisanne S. Ghonem. Treprostinil Attenuates Renal Ischemia-Reperfusion Injury in Rat; Poster presentation in the American Transplant Congress 2019 meeting
5. * Benjamin J. Barlock, Rohitash Jamwal, **Fatemeh Akhlaghi**. Presence of drug metabolizing enzyme inducer artifacts in commercially available human liver samples increases protein levels of clinically

relevant enzymes; poster presentation in Applied Pharmaceutical Analysis Conference, Oct 1-3, Boston, MA (selected as Outstanding Poster in the APA 2018 conference).

6. Rohitash Jamwal, Benjamin J Barlock, **Fatemeh Akhlaghi**. Comparison of data dependent and data independent acquisition based proteomic approaches for quantification of hepatic human cytochrome P450 enzymes. poster presentation in Applied Pharmaceutical Analysis Conference, Oct 1-3, Boston, MA.
7. Anitha Saravanakumar, Benjamin J Barlock, Rohitash Jamwal, Scott Heyward, **Fatemeh Akhlaghi**. Comparative proteomic analysis of cryopreserved hepatocytes and hepatic cell lines using SWATH-MS reveal significant variations in drug metabolizing enzymes. Poster presentation in ISSX Workshop on LC-MS Proteomics, Sept 27 & 28, 2018; Cambridge, MA
8. Benjamin J. Barlock, Rohitash Jamwal, **Fatemeh Akhlaghi**. Presence of drug metabolizing enzyme inducer artifacts in commercially available human liver samples increases protein levels of clinically relevant enzymes. Poster presentation in ISSX Workshop on LC-MS Proteomics, Sept 27 & 28, 2018; Cambridge, MA.
9. Rohitash Jamwal*, Benjamin J Barlock, **Fatemeh Akhlaghi**. Comparison of data dependent and data independent acquisition based proteomic approaches for quantification of hepatic human cytochrome P450 enzymes. Poster presentation in ISSX Workshop on LC-MS Proteomics, Sept 27 & 28, 2018; Cambridge, MA
10. Farokhnia M, Deschaine S, Sadighi A, **Akhlaghi F**, Leggio L. A deeper insight into how baclofen may affect alcohol consummatory behavior: Biobehavioral results from a human laboratory investigation. Research Society on Alcoholism (RSA) 41st annual meeting, San Diego, CA; Jun 2018. Abstract in Alcohol Clin Exp Res. 2018 Jun;42(S1):235A
11. Farokhnia M, Deschaine S, Sadighi A, **Akhlaghi F**, Leggio L. A deeper insight into how GABA-B receptor agonism via baclofen may affect alcohol seeking and consummatory behaviors: Lessons learned from a human laboratory investigation. Society for Neuroscience (SfN) annual meeting, San Diego, CA; Nov 2018 (Links: https://www.abstractsonline.com/pp8/#!/4649/presentation/32779)
12. Farokhnia M, Deschaine S, Sadighi A, Farinelli LA, Lee MR, **Akhlaghi F**, Leggio L. A deeper insight into how GABA-B receptor agonism via baclofen may affect alcohol seeking and consumption: Lessons learned from a human laboratory investigation. American College of Neuropsychopharmacology (ACNP) 57th annual meeting, Hollywood, FL; Dec 2018 (Please note: A. I have not received formal acceptance for this abstract yet, but it will most likely be accepted; B. This abstract will be published in Neuropsychopharmacology)
13. Saravanakumar A*, Sadighi A*, Ryu R, **Akhlaghi F** (*equal contribution). Contribution of Cytochrome P450 and Other Enzymes to the Metabolism of FDA Approved Drugs Between 2005-2016; Abstract accepted for Poster presentation at the International Society for the Study of Xenobiotics (ISSX) 21st North American ISSX Meeting; Sept 24-28, 2017; Providence, RI.
14. Cobbina E, Saravanakumar A, **Akhlaghi F**. Alteration in the intrinsic clearance of CYP2B6 by NAFLD: evidence of the involvement of the metabolic syndrome in variable drug response; Abstract accepted for Poster presentation at the International Society for the Study of Xenobiotics (ISSX) 21st North American ISSX Meeting; Sept 24-28, 2017; Providence, RI.
15. Sadighi A, Leggio L, **Akhlaghi F**. Physiologically Based Pharmacokinetic Modeling of Ethanol Concentration in Different Organs after Ingestion of Three Common Alcoholic Beverages; Abstract

accepted for Poster presentation at the International Society for the Study of Xenobiotics (ISSX) 21st North American ISSX Meeting; Sept 24-28, 2017; Providence, RI.

16. Jamwal R, Barlock BJ, Adusumalli S, Ogasawara K, Simons BL, **Akhlaghi F**. Use of SWATH-MS to relatively quantify the expression of hepatic drug metabolizing enzymes in human liver microsomes using a label-free approach; Abstract accepted for Poster presentation at the International Society for the Study of Xenobiotics (ISSX) 21st North American ISSX Meeting; Sept 24-28, 2017; Providence, RI.
17. Saravanakumar A, Cobbina E, Bush X, **Akhlaghi F**. Hepatic Lipid Accumulation in Experimental HepaRG Model for Steatosis Influences Bupropion Biotransformation; Gordon Research Conference in Drug Metabolism, Jul 9-14, 2017; Holderness School, Holderness, NH.
18. Jamwal R, Barlock BJ, Adusumalli S, Ogasawara K, Simons BL, **Akhlaghi F**; A Label-Free Relative Quantification Approach to Study Protein Expression of Phase I and Phase II Drug Metabolizing Enzymes in Human Liver Microsomes by SWATH-MS; Gordon Research Conference in Drug Metabolism, Jul 9-14, 2017; Holderness School, Holderness, NH.
19. **Akhlaghi F**, Ogasawara K, Cobbina E, Sravankumar A, Barlock B, Puggioni G, DeLaMonte S. Creation of a Repository of Human Liver to Study the Effect of Diabetes and Non Alcoholic Fatty Liver Disease (NAFLD) on Drug Disposition. Poster presentation at Gordon Research Conference: Drug Metabolism, Jul 10-15, 2016, Holderness School, NH.
20. Cobbina E, **Akhlaghi F**; Activity of Cytochrome P450 2B6 in Liver from Subjects with Diabetes and Non-Alcoholic Fatty Liver Disease (NAFLD). Poster presentation at Gordon Research Conference: Drug Metabolism, Jul 10-15, 2016, Holderness School, NH.
21. Jamwal R, **Akhlaghi F**; Impact of Diabetes and Non Alcoholic Fatty Liver Disease (NAFLD) on CYP3A Activity and Clint and Preliminary PBPK Modeling. Poster presentation at Gordon Research Conference: Drug Metabolism, Jul 10-15, 2016, Holderness School, NH.
22. Sadighi A, Leggio L, **Akhlaghi F**. Effect of Ethanol on the Expression of Gastrointestinal Tight Junction Protein ZO-1 and P-glycoprotein in Caco-2 Cell Monolayer; Gordon Research Conference in Alcohol-Induced End Organ Diseases, Metabolic Reprogramming and Molecular Mechanisms of Tissue Injury by Alcohol; Mar 26-31, 2017, Ventura, CA.
23. Macwan JS, Lukacova V, Fraczkiewicz G, Bolger MB, **Akhlaghi F**, Woltosz WS. Physiologically Based Pharmacokinetic Modeling of Rosuvastatin and Prediction of Transporter-Mediated Drug-Drug Interactions Involving Gemfibrozil; Journal of Pharmacokinetics and Pharmacodynamics 2015, Volume 42 Pages S39-S39.
24. Tapocik JD, Pilling A, Pincus A, Frable C, **Akhlaghi F**, Heilig M, Leggio L. A Novel Ghrelin Receptor Antagonist May Serve as a Therapeutic Target for Alcoholism. Poster presentation in American College of Neuropsychopharmacology, Dec 7-11, 2014, Phoenix, Arizona; published in Neuropsychopharmacology (2014) 39, S597.
25. Ogasawara K, Chitnis SD, Gohh RY, Christians U, and **Akhlaghi F**. Haplotypes of Multidrug Resistance-Associated Protein 2 (MRP2) affect the pharmacokinetics of tacrolimus in kidney transplant recipients; Oral presentation at Up Close and Personalized (UPCP 2013), Jul 2013, Paris, France.

26. Macwan JS, Bolger MB, **Akhlaghi F.** Physiologically-based pharmacokinetic modeling of atorvastatin acid and major metabolites in stable kidney transplant recipients with diabetes mellitus. Poster Presentation at the American College of Pharmacometrics, May 2013, Orlando, FL.

27. Macwan JS, Sam WJ, Gohh RY, **Akhlaghi F.** Development of a complex combined parent-metabolite population pharmacokinetic model for atorvastatin acid and its lactone metabolite: implication of renal transplantation. Poster Presentation at the American College of Pharmacometrics, May 2013, Orlando, FL.

28. Dostalek M, Gohh RY, **Akhlaghi F.** Inosine monophosphate dehydrogenase (IMPDH) gene and protein expression and activity is markedly lower in kidney transplant recipients with diabetes mellitus. Poster presentation at the American Society for Clinical Pharmacology and Therapeutics, 113th Annual Meeting, Abstract Published in Clinical Pharmacology and Therapeutics, Vol 91, Suppl. 1, S87, Mar 2012.

29. Dostalek M, Sam W-J, **Akhlaghi F.** Diabetes mellitus reduces the clearance of atorvastatin lactone: the results of a population pharmacokinetic analysis and *ex vivo* studies using livers from diabetic donors. Poster presentation at the American Society for Clinical Pharmacology and Therapeutics, 113th Annual Meeting, Abstract Published in Clinical Pharmacology and Therapeutics, Vol 91, Suppl. 1, S88, Mar 2012.

30. **Akhlaghi F**, Chitnis SD, Ionita I, Christians U, Asberg A. Impact of diabetes mellitus on metabolism of immunosuppressive agents: cyclosporin, tacrolimus and prednisone. Poster Presentation at the International Association of Therapeutic Drug Monitoring and Clinical Toxicology (IATDM&CT), Oct 2011, Stuttgart, Germany. Abstract was published in Ther Drug Monit: 2011; 33 (4).

31. **Akhlaghi F**, Dostalek M, Mendonza AE, Chitnis SD, Gohh RY. Reduced levels of biomarkers of immunosuppressive activity in diabetic kidney transplant recipients. Poster/Podium Presentation at the International Association of Therapeutic Drug Monitoring and Clinical Toxicology (IATDM&CT), Oct 2011, Stuttgart, Germany. Abstract was published in Ther Drug Monit: 2011; 33 (4).

32. **Akhlaghi F**, Mendonza AE. Non-invasive monitoring of mycophenolic acid in saliva: factors influencing the correlation between saliva and unbound plasma concentration. Poster Presentation at the International Association of Therapeutic Drug Monitoring and Clinical Toxicology (IATDM&CT), Oct 2011, Stuttgart, Germany. Abstract was published in Ther Drug Monit: 2011; 33 (4).

33. Norris DC, Gohh RY, **Akhlaghi F**, Morrissey PE. Kalman Filtering for tacrolimus dose titration in the early hospital course after kidney transplant, poster presentation in the American Transplant Congress, May 1-4, 2011, Philadelphia, PA.

34. Macwan JS, **Akhlaghi F**. Development of a simple method for analysis of atorvastatin (ATV) and metabolites in acid and lactone forms by liquid chromatography-tandem mass spectrometry (LC-MS/MS); Poster presentation at the FIP Pharmaceutical Sciences 2010 World Congress/AAPS Annual Meeting and Exposition, Nov 14 - 18, 2010, New Orleans, LA.

35. Chitnis SD, **Akhlaghi F**. Development and validation of a simple method for quantitative estimation of sirolimus in human whole blood using liquid chromatography-tandem mass spectrometry (LC-MS/MS); Poster presentation at the FIP Pharmaceutical Sciences 2010 World Congress/AAPS Annual Meeting and Exposition, Nov 14 - 18, 2010, New Orleans, LA.

36. Chitnis SD, Moll V, Schniedewind B, Christians U, **Akhlaghi F**. Diabetic kidney transplant recipients exhibit elevated levels of tacrolimus metabolites; Poster presentation at the FIP Pharmaceutical Sciences 2010 World Congress/AAPS Annual Meeting and Exposition, Nov 14 - 18, 2010, New Orleans, LA.

37. Thudium KE, **Akhlaghi F**. Development and validation of an assay for determination of urinary 6 beta hydroxycortisol to cortisol ratio, a noninvasive marker for CYP3A activity; Poster presentation at the FIP Pharmaceutical Sciences 2010 World Congress/AAPS Annual Meeting and Exposition, Nov 14 - 18, 2010, New Orleans, LA.

38. Ionita IA, Gohh RY, **Akhlaghi F**. Pharmacokinetics of prednisolone and cortisol suppression in diabetic and nondiabetic stable kidney transplant recipients; Poster presentation at the FIP Pharmaceutical Sciences 2010 World Congress/AAPS Annual Meeting and Exposition, Nov 14 - 18, 2010, New Orleans, LA.

39. **Akhlaghi F**, Gohh RY, Mendonza AE, Flack P, Åsberg A. Reduced cyclosporine Metabolism in Diabetic Stable Kidney Transplant Recipients; Poster presentation at the FIP Pharmaceutical Sciences 2010 World Congress/AAPS Annual Meeting and Exposition, Nov 14 - 18, 2010, New Orleans, LA.

40. Dostalek M, Yan B, **Akhlaghi F**. Significantly reduced cytochrome P450 3A4 expression and activity in liver from human with diabetes mellitus; Poster presentation at the FIP Pharmaceutical Sciences 2010 World Congress/AAPS Annual Meeting and Exposition, Nov14 - 18, 2010, New Orleans, LA.

41. Hu S, **Akhlaghi F**, Chitnis SD, Chiu R, Go S, Rout R, Steffes M, Abbott JD, Dworkin L, Bostom A. Accurate prediction of true glomerular filtration rate (GFR) by both immediate post−angiography iodixanol clearance, and pre−angiography estimated GFR. Poster presentation at the American Society of Nephrology (ASN), 43rd Annual Meeting and Scientific Exposition, Nov 18−21, 2010, Denver, CO.

42. **Akhlaghi F**, Chitnis SD, Mendonza AE, Ionita IA, Gohh RY. Utilization of B- and T-cell activity markers to evaluate the degree of immunosuppression in diabetic kidney transplant recipients. Invited poster presentation at "Pharmacodynamic and Pharmacogenomic Biomarkers in Solid Organ Transplantation", Sept 28, 2010; Food and Drug Administration, White Oak Campus.

43. Lin S, Henning AK, **Akhlaghi F**, Reisfield R, Vergara-Silva A, First MR. Interleukin-2 receptor antagonist induction therapy leads to increased tacrolimus levels after kidney transplantation. Presented as Mini Oral Presentation at the XXIII International Congress of The Transplantation Society (TTS 2010) Aug 15 – 19, 2010, Vancouver, BC, Canada.

44. **Akhlaghi F**, Chitnis SD, Mendonza AE, Ionita IA, Gohh RY. Reduced level of biomarkers of immunosuppressive activity in diabetic kidney transplant recipients is related to diabetes type and glucose control, Poster presentation at American Transplant Congress May 1-5, 2010, San Diego, CA.

45. Pabla D, **Akhlaghi F**, Zia H. Intestinal permeability enhancement of levothyroxine sodium by medium chain fatty acids studied in MDCK epithelial cell line. Poster presentation at the AAPS Annual meeting and exposition, Nov 2009, Los Angles; also abstract published at AAPS Journal (2009).

46. **Akhlaghi F**, Monbaliu J, Kadambi V, Yu L. Blood and plasma pharmacokinetics of bortezomib in relation to blood 20s proteasome activity after single and multiple dosing in cynomongolus monkeys. Poster presentation at the American Conference on Pharmacometrics, Oct 4-7, 2009, The Grand Pequot at Foxwoods Resort, Mashantucket, CT.

47. **Akhlaghi F**, Monbaliu J, Kadambi V, Prakash S, Lee F, Yu L. Development of an integrated pharmacokinetic and pharmacodynamic model for bortezomib to allow predication of 20s proteasome activity from plasma concentrations. Poster presentation at the American Conference on Pharmacometrics, Oct 4-7, 2009, The Grand Pequot at Foxwoods Resort, Mashantucket, CT.

48. Paryani K, Gohh R, **Akhlaghi F**. Elevated atorvastatin lactone concentration in patients with diabetes mellitus; Poster presentation at the American Society for Clinical Pharmacology and Therapeutics (ASCPT) 110th Annual Meeting, Washington, DC, Mar 18-21, 2009; Abstract published at Clinical Pharmacology and Therapeutics, volume 85 supplement 1, page S36 (2009).

49. Narwal R, **Akhlaghi F**, Asberg A, Hermann M, Rosenbaum SE. Development of a population pharmacokinetic model for atorvastatin acid and its lactone metabolite; Poster presentation at the American Society for Clinical Pharmacology and Therapeutics (ASCPT) 110th Annual Meeting, Washington, DC, Mar 18-21, 2009; Abstract published at Clinical Pharmacology and Therapeutics, volume 85 supplement 1, page S32-S33 (2009).

50. **Akhlaghi F**, Chitnis SD, Mendonza AE, Patel CG, Gohh RY. Effect of diabetes mellitus on pharmacokinetics and pharmacodynamics of immunosuppressive agents: ciclosporin, tacrolimus and mycophenolic acid; Invited speaker at EHRLICH II, 2nd World Conference on Magic Bullets, Oct 3-5, 2008, in Nürnberg, Germany.

51. Pabla D, **Akhlaghi F**, Zia H. A comparative pH-dissolution profile study of selected commercial levothyroxine products using inductively coupled plasma mass spectrometry (ICP-MS) assay, Poster presentation at the AAPS Annual meeting and exposition, Nov 2008, Atlanta also abstract published at AAPS Journal, 10(S2), Abstract No. T2063 (2008).

52. Patel CG, **Akhlaghi F**. Evaluation of transporter mediated drug interactions for mycophenolic acid and metabolites using MDCK-II/MRP-2 cells. Poster presentation at the AAPS Annual meeting and exposition, Nov 2007, San Diego.

53. Chitnis SD, **Akhlaghi F**. Development and validation of an HPLC-UV method for quantitative estimation of iodixanol in human plasma. Poster presentation at the AAPS Annual meeting and exposition, Nov 2007, San Diego.

54. Pabla D, Zia H, **Akhlaghi F**. Development and validation of an ICP-MS method for quantification of levothyroxine in dissolution studies. Poster presentation at the AAPS Annual meeting and exposition, Nov 2007, San Diego.

55. **Akhlaghi F**, Sam WJ, Rosenbaum SE, A population pharmacokinetic model for mycophenolic acid and metabolites in kidney transplant recipients; Poster presentation in American Transplant Congress, May 5-9 2007, San Francisco.

56. **Akhlaghi F**, Mendonza AE, Caldarusa M, Gohh RY, Diabetic kidney transplant recipients exhibit reduced biomarkers of T- and B-cell activity; Poster presentation in American Transplant Congress, May 5-9 2007, San Francisco.

57. Jones J, Narwal R, **Akhlaghi F**, Rosenbaum S. Population pharmacokinetics of prednisolone in heart and lung transplant patients. Poster presentation at 2006 AAPS Annual Meeting and Exposition, Oct 28-Nov 2, 2006, San Antonio, Texas.

58. Paryani K, **Akhlaghi F**. Development of an LC-MS/MS method for determination of atorvastatin and its acid and lactone metabolites in human plasma, Poster presentation at 2006 AAPS Annual Meeting and Exposition, Oct 28-Nov 2, 2006, San Antonio, Texas.

59. Patel C, Richman K, Gohh R, **Akhlaghi F**. Pharmacokinetics and pharmacodynamics of mycophenolic acid (MPA) in diabetic kidney transplant recipients. Poster presentation at 2006 AAPS Annual Meeting and Exposition, Oct 28-Nov 2, 2006, San Antonio, Texas.

60. Mendonza AE, Richman K, Gohh R, **Akhlaghi F**. Effect of diabetes mellitus on pharmacokinetics and pharmacodynamics of calcineurin inhibitors cyclosporine and tacrolimus. Poster presentation at 2006 AAPS Annual Meeting and Exposition, Oct 28-Nov 2, 2006, San Antonio, Tx.

61. Mendonza AE, Gohh R, **Akhlaghi F**. Influence of diabetes mellitus on the pharmacokinetics of cyclosporine. Poster presentation at 2006 AAPS Annual Meeting and Exposition, Oct 28-Nov 2, 2006, San Antonio, TX.

62. **Akhlaghi F**, Patel CG, Richman K, Gohh RY. Pharmacodynamics (PD) but not the pharmacokinetics (PK) of mycophenolic acid is altered by diabetes. Poster presentation at the World Transplant Congress, Jul 2006, Boston.

63. **Akhlaghi F**, Mendonza AE, Richman K, Zuniga P, Gohh RY. Diabetes mellitus affect pharmacokinetics of cyclosporine but not tacrolimus. Poster presentation at the World Transplant Congress, Jul 2006, Boston, MA.

64. Sam W, **Akhlaghi F**, Rosenbaum S. Population pharmacokinetics of mycophenolic acid and its metabolites in renal transplant patients. Poster presentation at the 2006 American Society for Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting, Mar 2006, Baltimore, MD; Abstract published at Clinical Pharmacology & Therapeutics 2006;79(2), P47.

65. **Akhlaghi F**, Patel CG, Zuniga XP, Gohh RY. Absorption, distribution and metabolism of mycophenolate mofetil (MMF) in diabetic kidney transplant recipients. Poster presentation in "the American Society of Nephrology (ASN) 38th Annual Renal Week Meeting" Philadelphia, Nov (2005) and abstract published at Journal of American Society of Nephrology 2005; 16:234A.

66. Patel CG, **Akhlaghi F**. Pharmacodynamic (PD) monitoring of mycophenolic acid (MPA): an evaluation of inosine 5'- monophosphate dehydrogenase type–II (IMPDH-II) activity in peripheral blood mononuclear cells. Poster presentation at "the American Association of Pharmaceutical Scientists (AAPS) Annual Meeting and Exposition" Nashville, Nov (2005) and abstract published at The AAPS Journal, Vol. 7, No. S2, Abstract T2292 (2005).

67. **Akhlaghi F**, Patel CG, Zuniga P, Gohh R. Pharmacokinetics of mycophenolic acid in diabetic kidney transplant patients. Poster presentation at "the American Association of Pharmaceutical Scientists (AAPS) Annual Meeting and Exposition" Nashville, Nov (2005) and abstract published at The AAPS Journal, Vol. 7, No. S2, Abstract M1278 (2005).

68. Patel CG, Gohh R, **Akhlaghi F**. The effect of cyclosporine versus tacrolimus on the pharmacokinetics of mycophenolic acid and its metabolites: the possible influence of ketoconazole co-administration. Poster presentation at "the American Association of Pharmaceutical Scientists (AAPS) Annual Meeting and Exposition" Nashville, Nov (2005) and abstract published at The AAPS Journal, Vol. 7, No. S2, Abstract M1297 (2005).

69. Mendonza AE, **Akhlaghi F**, Gohh R. Determination of mycophenolic acid (MPA) in saliva using liquid chromatography tandem mass spectrometry (LC-MS/MS). Poster presentation at "the American Association of Pharmaceutical Scientists (AAPS) Annual Meeting and Exposition" Nashville, Nov (2005) and abstract published at The AAPS Journal, Vol. 7, No. S2, Abstract M1042 (2005).

70. **Akhlaghi F**, Mendonza AE, Halilovic D, Zuniga P, Gohh RY. Pharmacokinetics of cyclosporine in diabetic kidney transplant recipients and its correlation with acetaminophen absorption. Poster presentation at "the American Transplant Congress" Seattle, May 2005 and abstract published in the American Journal of Transplantation, Supplement 11, vol 5, page 224 (2005).
71. **Akhlaghi F**, Patel CG, Zuniga P, Gohh RY. The effect of calcineurin inhibitors cyclosporine and tacrolimus on the pharmacokinetics of mycophenolic acid and its acyl and phenol glucuronide metabolites. Poster presentation at "the American Transplant Congress" Seattle, May 2005 and abstract published in the American Journal of Transplantation, Supplement 11, Vol 5, page 484 (2005).
72. **Akhlaghi F**, Zahir H, Keogh AM. Factors influencing dosing and concentrations of sirolimus in de novo heart transplant recipients, Poster presentation at "the American Transplant Congress" Seattle, May 2005 and abstract published in the American Journal of Transplantation, Supplement 11, Vol 5, page 169 (2005).
73. Halilovic D, Zuniga XP, Gohh RY, and **Akhlaghi F**. Use of acetaminophen (APAP) absorption method in characterizing delayed gastric emptying time in diabetic kidney transplant recipients, Poster presentation at "the 3rd International Congress on Immunosuppression" San Diego, Dec (2004).
74. Zahir H, Mendonza AE, Zuniga XP, Gohh RY, **Akhlaghi F**. Comparative pharmacokinetics of cyclosporine and tacrolimus in diabetic and nondiabetic kidney transplant recipients, Poster presentation at "the 3rd International Congress on Immunosuppression" San Diego, Dec (2004).
75. Zahir H, **Akhlaghi F**. Development and validation of a rapid LC-MS/MS technique for simultaneous determination of cyclosporine and tacrolimus in human blood. Poster presentation at "the American Association of Pharmaceutical Scientists (AAPS) Annual Meeting & Exposition" Baltimore, Nov (2004).
76. Patel CG, **Akhlaghi F**. A method for determination of total mycophenolic acid (MPA) and mycophenolic acid glucuronide (MPAG) by HPLC-UV. Poster presentation at "the American Association of Pharmaceutical Scientists (AAPS) Annual Meeting & Exposition" Baltimore, Nov (2004).
77. Patel CG, **Akhlaghi F**. Development and validation of a LC-MS/MS method for determination of unbound mycophenolic acid (MPA) in human plasma. Poster presentation at "the American Association of Pharmaceutical Scientists (AAPS), Annual Meeting & Exposition" Baltimore, Nov (2004).
78. **Akhlaghi F**, Patel CG, Zuniga P, Lin S, Yango A, Gohh R. Unbound but not total concentration of mycophenolic acid (MPA) is higher in diabetic kidney transplant recipients. Poster presentation at "the American Association of Pharmaceutical Scientists (AAPS), Annual Meeting & Exposition" Baltimore, Nov (2004).
79. Halilovic D, Zuniga P, Gohh R, **Akhlaghi F**. Use of an acetaminophen absorption method for characterizing delayed gastric emptying time in diabetic kidney transplant recipients. Poster presentation at "the American Association of Pharmaceutical Scientists (AAPS), Annual Meeting & Exposition" Baltimore, Nov (2004).
80. Mendonza AE, **Akhlaghi F**. Development and validation of a novel method for determination of cyclosporine (CsA) in saliva using liquid chromatography-tandem mass spectrometry. Poster presentation at "the American Association of Pharmaceutical Scientists (AAPS), Annual Meeting & Exposition" Baltimore, Nov (2004).

81. Soman R, Zahir H, Zuniga P, Gohh R, **Akhlaghi F**. Development and validation of a simple HPLC-UV method for estimation of iohexol concentration in plasma. Poster presentation at "the American Association of Pharmaceutical Scientists (AAPS), Annual Meeting & Exposition" Baltimore, Nov (2004).

82. Zahir H, Keogh AM, **Akhlaghi F**. Population pharmacokinetics of sirolimus in heart transplant recipients. Poster presentation at "the American Association of Pharmaceutical Scientists (AAPS), Annual Meeting & Exposition" Baltimore, Nov (2004).

83. **Akhlaghi F**, Patel CG, Zuniga P, Lin S, Yango A, Gohh R. Concentration of total mycophenolic acid (MPA), mycophenolic Acid glucuronide (MPAG) and unbound MPA in diabetic kidney transplant recipients. Poster presentation at "the American Transplant Congress" Boston, May (2004) and abstract published at American Journal of Transplantation supplement 8 vol 4, page 232 (2004).

84. Zahir H, Nelson A, Gleeson M, McCaughan G, McLachlan AJ, **Akhlaghi F**. Population pharmacokinetic study of tacrolimus (FK506) in adult liver transplant recipients. Poster presentation at "the American Transplant Congress" Boston, May (2004) and abstract published at American Journal of Transplantation supplement 8 vol 4 , page 365 (2004).

85. Mendonza AE, **Akhlaghi F**. An analytical method for measuring cyclosporine A (CsA) in saliva using liquid chromatography tandem mass spectrometry (LC-MS/MS). Poster presentation at "the AAPS Workshop on Exposure Response to Immunomodulators" Washington, DC, Sept (2003).

86. Patel CG, Holt DW, Trull AK, **Akhlaghi F**. A method for determination of total mycophenolic acid (MPA) and mycophenolic acid glucuronide (MPAG) by HPLC-UV. Poster presentation at "the AAPS Workshop on Exposure Response to Immunomodulators" Washington, DC, Sept (2003).

87. **Akhlaghi F** and Trull AK. Association between cyclosporine blood concentrations at time two (C-2) and clinical outcomes in lung transplant recipients. Oral presentation at "the American Transplant Congress" Washington DC, Jun (2003) and abstract published at American Journal of Transplantation, Supplement 5, vol 3, 157 (2003).

88. **Akhlaghi F**. A Capillary electrophoresis method for quantification of cyclosporine. Poster presentation at "the American Association of Pharmaceutical Scientists (AAPS), Annual Meeting & Exposition" Toronto, Canada, Nov (2002).

89. Baheti G, Rosenbaum SE, **Akhlaghi F**, Trull AK. Population pharmacokinetics of cyclosporine in lung transplant recipients. Poster presentation at "the American Association of Pharmaceutical Scientists (AAPS), Annual Meeting & Exposition" Toronto, Canada, Nov (2002).

90. Gohh R, Fischer S, Morrissey P, Gautam A, Monaco A, Yango A, **Akhlaghi F**. The pharmacologic interaction between anti-retroviral agents and tacrolimus. Abdominal Organ Transplantation from Living Donors: State of the Art. Gubbio, Italy Jun (2002)

91. **Akhlaghi F**, Steel L, Price C, Wallwork J, Trull A. Cyclosporine (CYA) concentration at time 2 hours post dose correlates with rejection and renal function after lung transplantation, Poster presentation at "the 7th International Congress of Therapeutic Drug Monitoring and Clinical Toxicology" Washington DC, Sept (2001) and abstract published in Ther Drug Monit, vol 23: 462 (2001).

92. Trull AK, Charman SC, Endenburg S, **Akhlaghi F**, Majid O, Cornelissen J, Sharples LD, Steel LD, Parameshwar J, Wallwork J. Eotaxin and prednisolone concentrations regulate the mobilisation of peripheral blood eosinophils preceding heart allograft rejection. Presented at "21st Annual Meeting

and Scientific Sessions of the International Society of Heart and Lung Transplantation" Vancouver, Canada, Apr (2001) and abstract published at J Heart Lung Transplant, vol 20: 161 (2001).

93. **Akhlaghi F**, Jackson C, Sharples LD, Parameshwar J, Trull AK. Hypercholesterolaemia after heart transplantation: an evaluation of the risk factors. Poster presentation at "the XVIII International Congress of the Transplantation Society" Rome, Italy, Aug (2000).
94. **Akhlaghi F**, Jackson C, Sharples LD, Parameshwar J, Trull AK. Unbound cyclosporine fraction: is it an important predictor of heart allograft rejection? Oral presentation at "the XVIII International Congress of the Transplantation Society" Rome, Italy, Aug (2000).
95. Majid O, **Akhlaghi F**, Trull AK. Pharmacokinetics (PK) and pharmacodynamics (PD) of prednisolone (PRL) in lung transplant recipients. Poster presentation at "the XVIII International Congress of the Transplantation Society" Rome, Italy, Aug (2000).
96. **Akhlaghi F**, Jackson C, Sharples L, Parameshwar J, Trull AK. Risk factors for the development of hypercholesterolaemia after heart transplantation. Oral presentation at "the European Meeting of Organ Damage and Dysfunction (EMBODY), Cambridge, UK, Apr (2000).
97. **Akhlaghi F**, Majid O, Trull A. The pharmacokinetics (PK) and pharmacodynamics (PD) of prednisolone (PRL) in lung transplant recipients. Oral presentation at "the European Meeting of Organ Damage and Dysfunction (EMBODY), Cambridge, UK, Apr (2000).
98. **Akhlaghi F**, Sharples L, Jackson C, Trull A. Plasma lipids, the unbound fraction of cyclosporin and the risk of heart allograft rejection. Poster presentation at "the 9th congress of the European Society for Organ Transplantation (ESOT)" Oslo, Norway, Jun (1999).
99. Keogh A, **Akhlaghi F**, Aboyoun C, Spratt P. Pharmacokinetics of Neoral® in transplant recipients receiving metabolic inhibitors. Presented at "the International Society for Heart and Lung Transplantation (ISHLT) 18th Annual Meeting and Scientific Sessions" Chicago Apr (1998) and abstract published at The Journal of Heart and Lung Transplantation, vol 17, pages 108-109 (1998).
100. **Akhlaghi F**, Keogh AM, Ashley JJ, Brown KF. Cyclosporin fraction unbound, lipoproteins and clinical outcomes after transplant. Presented orally at "the 5th International Congress of Therapeutic Drug Monitoring and Clinical Toxicology" Vancouver, Canada, Nov (1997) and abstract published at Ther Drug Monit vol 19, No 5, page 553 (1997).
101. **Akhlaghi F**, Keogh A, Ashley JJ, Brown KF. Plasma free fraction of cyclosporin in heart and lung transplant recipients, Presented at "the International Society for Heart and Lung Transplantation (ISHLT) 17th Annual Meeting and Scientific Sessions" London, England Apr (1997) and abstract published at the Journal of Heart and Lung Transplantation, vol 16, page 77 (1997).