Curriculum Vitae

Yazen M Alnouti
Department of Pharmaceutical Sciences
College of Pharmacy
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Education

Ph.D. **2004**
Bioanalytical Chemistry & Pharmacokinetics
College of Pharmacy, University of Georgia

B.Pharm. **2000**
Pharmacy
College of Pharmacy, Jordan University of Science and Technology

Highlights of Research Experience

High-Throughput Bioanalytical Chemistry

Qualitative and quantitative analysis of biologically active compounds in complex biological matrices using LC-MS/MS, Capillary Electrophoresis, HPLC, and robotic on-line sample preparation systems in support of high-throughput DMPK (drug metabolism and pharmacokinetics) and ADMET (absorption, distribution, metabolism, excretion, and toxicity) studies.

Drug Metabolism and Disposition

Study the expressional regulation and the kinetics of transporters, enzymes (phase I and II), and transcription factors involved in drug metabolism and disposition. Characterize the metabolic stability, metabolite identification, inhibition/induction and drug-drug interaction (DDI) kinetics, enzyme mapping/phenotyping, formation of reactive metabolites, and kinetics of reversible and irreversible protein binding of small molecules in *in vitro* cell lines, hepatocytes, hepatic microsomes, S9, and cytosolic fractions, and in *in vivo* knock-out animal models using LC-QTRAP-MS/MS analysis. Characterize the kinetics of drug transport and permeability across biological barriers using *in vitro* systems including Caco2 and lymphatic endothelial cells (LECs). Development of novel preclinical in vitro and in vivo system to characterize and predict PK and ADMET profiles of small molecules. Extrapolation of DMPK profiles between animal species and from *in vitro* to *in vivo* systems (IVIVE).

Pharmacokinetics

Study the influence of combinational therapy on the maternal/ fetal pharmacokinetics and placental transport of antiviral drugs in pregnant rats using compartmental and non-compartmental pharmacokinetic analysis using WinNonlin. Preclinical pharmacokinetic studies (toxicokinetics, bioavailability, dose proportionality, quantitative tissue distribution, and allometric scaling) in mouse, rat, and monkey animal models.

Bile Acids Metabolism

Discovery and validation of biomarkers for hepato-biliary diseases, drug-induced liver injury (DILI), and metabolic syndrome (type-2 diabetes mellitus and obesity) based on bile acid metabolism by sulfation and other metabolic pathways. Study the role of bile acids in the development, prognosis, and outcomes of pharmacological treatment, and surgical intervention including bariatric surgery.

Experience

Associate Professor with Tenure **03/2014-Present**

Department of Pharmaceutical Sciences, University of Nebraska Medical Center (UNMC)

- Develop *in vitro* assays to characterize the mechanisms regulating the distribution of small molecules into the lymphatic system using bidirectional permeability and transport studies across lymphatic endothelial cells (LECs).
- Discovery and validation of diagnostic and prognostic biomarkers of hepatobiliary diseases based on the metabolic profiles of bile acids using receiver operating characteristic (ROC), logistic regression, ANOVA, and survival analyses.
- Determine the role of bile acids in the metabolic syndrome and in diabetes remission in morbidly obese patients undergoing bariatric surgery
- Study species-differences of the metabolism of bile acids.
- Characterize the species differences and role of bile acid metabolism in idiosyncratic drug-induced hepatotoxicity/liver injury (DILI) using novel preclinical *in vivo* and *in vitro* systems.
- Discovery and validation of clinical biomarkers of DILI based on subjects' capabilities to metabolize bile acids for the early detection of DILI in Phase-I clinical trials.

Fulbright Research/Teaching Scholar **09/2017-04/2018**

Department of Pharmacology-College of Medicine, United Arab Emirates University (UAEU)

Started a clinical trial in collaboration with the UAEU and Tawam's hospital to investigate the role of bile acids in diabetes remission after bariatric surgery.

Chair of the UNMC AAPS Chapter **07/2010-06/2016**

The AAPS (American Association of Pharmaceutical Scientists)-UNMC College of Pharmacy student chapter has in average 40-50 graduate (Ph.D. and M.S.) students.

Chair of PSGP **07/2011-06/2014**

The Pharmaceutical Sciences Graduate Program (PSGP) in the UNMC College of Pharmacy has in average 40-50 graduate (Ph.D. and M.S.) students.

Assistant Professor **03/2008-03/2014**

Department of Pharmaceutical Sciences, University of Nebraska Medical Center (UNMC)

- Provide bioanalytical and pharmacokinetics support to the preclinical-development of novel nano-delivery systems of antiviral drugs (toxicokinetics, bioavailability, dose proportionality, quantitative tissue distribution, andallometric scaling) in mouse, rat, and monkey animal models.
- Drug metabolism studies including metabolic stability, metabolite identification, inhibition/induction kinetics, and enzyme mapping/phenotyping in *in vitro* systems (hepatocytes, hepatic microsomes, S9, cytosolic fractions, and stably-transfected cell lines) using LC-QTRAP-MS/MS analysis.
- Drug absorption, permeability, and carrier-mediated transport studies using transcellular assays in Caco2, other endothelial, and transporter-transfected cell lines.
- Extrapolation of DMPK profiles between animal species and from *in vitro* to *in vivo* systems (IVIVE).
- Characterize the formation of reactive metabolites and the resulting adducts formation and irreversible/covalent protein binding *in vivo* and *in vitro* using trapping agents.
- Characterize the kinetics of plasma and blood protein binding using blood-plasma partitioning, ultrafiltration, charcoal-binding, dialysis, and ultracentrifugation methods.
- Characterize the kinetics of sulfation of bile acid substrates by sulfotransferases (SULT2A1) stably expressed in cells (HEK293).

Research Assistant Professor **08/2005-02/2008**

Department of Pharmacology, Toxicology, and Therapeutics, University of Kansas Medical Center (KUMC)

- Build, maintain, and direct the bioanalytical/ DMPK laboratory in the University of Kansas Medical Center.
- Characterize the contribution of transporters and metabolic enzymes (phase I and II) to the pharmacokinetic, pharmacodynamic, and toxicological behavior of xenobiotics. These studies were performed in *in vitro* cell lines (HEK293) and in *in vivo* knock-out animal models (Wistar Kyoto rats, PXR-, CAR-, AHR-, and Nrf2-null mice).
- Build a stably transfected cell line to characterize the metabolic stability, metabolic profile, and enzyme kinetics

of phase II metabolic enzymes (SULT2A1)

Postdoctoral Fellow **09/2004-08/2005**
Department of Pharmacology, Toxicology, and Therapeutics, University of Kansas Medical Center (KUMC)
- Study the expressional regulation of transporters (OCTs), phase I (ALDHs), and phase II enzymes (SULTs, UGTs) involved in drug metabolism and disposition. The studies aimed to characterize tissue distribution, ontogeny, expressional regulation by prototypical microsomal inducers, and the mechanisms underlying gender-specific expression.

Co-op Fellow **02/2004-08/2004**
Global Research and Development, Pharmacokinetics-Dynamics, and Drug Metabolism, Pfizer Inc
- Develop a novel test to evaluate the performance of HPLC and MS systems. A database was created that automatically displays and interprets data obtained from the test. The test was designed to evaluate multiple criteria that help diagnose and troubleshoot common problems encountered in LC-MS/MS instrumentation.

Summer Intern **06/2003-10/2003**
Global Research and Development, Pharmacokinetics-Dynamics, and Drug Metabolism, Pfizer Inc
- Develop a set of generic, automated, and high-throughput LC-MS methods for the quantification of a wide spectrum of pharmaceutical compounds in biological fluids and tissues.
- Set up a fully automated On-line solid phase extraction/ LC-MS system. The system was able to perform automatic method development, sample extraction, addition of internal standards, and sample analysis. This robotic system was applied in hands-free and high-throughput analysis of model pharmaceuticals in plasma.

Teaching & Research Assistant **01/2001-08/2004**
College of Pharmacy, University of Georgia (UGA)
- Develop analytical assays to quantify antiviral nucleoside analogues (NRTIs) in complex biological matrices. Various LC-MS/MS, HPLC-UV, and CE methods were developed and validated according to FDA guidelines to quantify antiviral drugs in rat plasma, amniotic fluid, placental, and fetal tissues.
- Study the pharmacokinetic interactions between combination regimens of antiviral drugs in the pregnant rat model. These studies aimed to characterize the maternal/fetal pharmacokinetics and placental transport profiles of antiviral cocktail regimens. Results were analyzed using compartmental and non-compartmental pharmacokinetic analysis with WinNonlin software. A five-compartment model was created to describe the rate of placental and fetal transfer of model compounds (3TC and AZT). Changes in the rate of transfer constants and the relative exposure indices of the fetal compartments were used to characterize the pharmacokinetic interaction.

Medical Representative **06/2000-01/2001**
Department of Scientific Marketing, Arab Pharmaceuticals Inc

Raw Material Analyst **02/2000-06/2000**
Department of Quality Control, Alhayat Pharmaceuticals Inc

Analytical Techniques

Tandem Mass Spectrometry
Sciex API 6500, 6000, 5500, 5000, 4000, 4000 Q-Trap, 3000, 2000, 2000 Q-Trap, 365, and Waters Xevo TQ-XS, Ultima Premier ESI, APPI, and APCI quadrupole/ion trap mass spectrometers

HPLC and UPLC
Agilent HP 1090, 1100, Beckman, CTC-PAL, Shimadzu, and Waters ACQUITY LC systems

Capillary Electrophoresis
Beckman P/ACE 5000 CE system

Robotic On-line Sample Preparation
Symbiosis (Prospeket) on-line SPE and Cohesive turbo-flow sample preparation systems

Radio-Chemical analysis
Beckman LS 6500 Liquid Scintillation and on-line radio-chemical systems

RNA Analysis
Branched DNA Amplification (bDNA), polymerase chain reaction (PCR), and real-time PCR

Cell Culture

Gel electrophoresis, stable and unstable cell transfection, western blotting, BCA assays, immunoflourecense microscopy, transwell permeability assays, transepithelial electrical resistance (TEER), confocal microscopy, and flow cytometry

Pharmacokinetics, Enzyme Kinetics, Drug Metabolism, and Statistics Software

- WinNonlin
- SigmaPlot
- SPSS (Statistical Product and Service Solutions)
- Lightsight

Honors & Awards

2018 Consultant-Genentech, USA
2017 Fulbright Research/Teaching core scholarship, Fulbright-UAEU
2016 Fulbright Research/Teaching core scholarship, Fulbright-Kuwait University
2015 Distinguished Scientist Award, UNMC
2014 Consultant-Phoenix Bio Co, Japan
2013 Academic advisor for the Industrial Consortium on safety evaluations
2013 Outstanding Research and Creative Activity Award, UNMC
2013 Outstanding Faculty Advisor, American Association of Pharmaceutical Scientists
2012 Wallace Coulter Foundation Early Career Award
2012 Vice Chair AAPS PPDM (pharmacokinetics, pharmacodynamics, and drug metabolism) Focus Group
2011 Vilcek Prize for Creative Promise in Biomedical Science
2011 Outstanding Faculty Advisor, American Association of Pharmaceutical Scientists
2009 Publication in Toxicology selected as "Exceptional" by "Faculty of 1000 Biology: the expert guide to the most important advances in biology"
2009 Selected by "Who's Who in America" as a scientist with outstanding achievements
2007 Outstanding Teacher of the year, Department of Pharmacology, Toxicology, and Therapeutics-KUMC
2004 Outstanding Student Research Award, Pfizer Inc
2003 Student Travel Award, American Association of Pharmaceutical Scientists
2002 Teaching Assistant of the year, University of Georgia

Teaching Experience

Professional Level (M.D, Pharm.D)

- Drug absorption, distribution, metabolism, and excretion (ADME) (PHSC-670: Pharmaceutical Sciences II): Course Coordinator (2008-present)
- Pharmacokinetics (PHSC-672: Pharmaceutical Sciences III): Course Coordinator (2008-present)
- Pharmacokinetic-Based Drug Interactions (PHSC-693: Mechanisms of Drug Interactions): Course Coordinator (2010-present)
- Role of Transporters in Pharmacokinetics (PHSC-514: Applied Biochemistry) (2008-present)

Graduate Level (Ph.D.)

- Mass Spectrometry and Chromatography (PHSC-845: Quantitative Pharmaceutical Sciences) (2008-present)
- Pharmacokinetics and Drug Metabolism (PHSC-910: Pharmacokinetics and Biopharmaceutics): Course Coordinator (2017-present)
- Toxicokinetics (ENV 888/CPH 597: Principles of Toxicology) (2009-present)

Faculty/Students/Fellows/ Scientist Mentoring

Research Assistant Professor

Nagsen Gautam, Ph.D.	07/2018-present

Visiting Scientists

Marwan Draid, Ph.D. (Fulbright Scholar)	01/2014-07/2014
Yanhui Gao, Ph.D. (China Scholarship Council (CSC) Scholar)	07/2015-07/2016
Laith Numan, M.D. (Jordan University of Science and Technology)	08/2015-02/2016
Audai Maayah, M.D. (Jordan University of Science and Technology)	08/2016-08/2017

Mohammad Abu Arja, M.D. (University of Jordan)	12/2016-08/2017

Instructors

Nagsen gautam, Ph.D.	06/2015-06/2018

Postdoctoral Fellows

Jiangeng Huang, Ph.D.	09/2008-08/2010
Nagsen gautam, Ph.D.	09/2010-06/2015
Yashpal S Chhonker, Ph.D.	10/2014-06/2016
Sushil Kumar, Ph.D.	07/2017-present

Ph.D. Students

Sai praneeth R Bathena	08/2008-08/2013
Rajesh Wakaskar	08/2008-12/2014
Adrian A Epstein	08/2009-08/2014
Pavan Puligujja	08/2010-03/2015
Wen Shi	08/2011-08/2015
Rhishikesh Thakare	08/2012-01/2018
Shrey S Kanvinde	08/2013-08/2018
Jawaher Alamoudi	05/2015-present
Yosif H Almoshari	08/2016-present
Ibrahim Ibrahim	04/2018-present
Gang Zhao	08/2017-present

Master Students

Marwa A Mohammad	08/2018-present

Interns/Fellows

Qing Cao, Pharm.D. student	08/2018-present
Anna Vu, undergraduate student	08/2018-present

Scientific Media Coverage

- NIDA (National Institute of Drug Abuse) Notes, Oct 8 **2014**, New Approach Uses Immune Cells To Deliver Anti-HIV Medications (http://www.drugabuse.gov/news-events/nida-notes/2014/10/new-approach-uses-immune-cells-to-deliver-anti-hiv-medications)
- UNMC News Room, Jan 20 **2015**, Meet Distinguished Scientist Yazen Alnouti, Ph.D. (http://www.unmc.edu/news.cfm?match=16340)

Consulting positions

- Panelist, NCI Technical Evaluation Panel on "Preclinical Pharmacokinetic and Pharmacological Studies of Anticancer Agents" to evaluate proposals responding to "RFP N01-CM-07014-39" on June **2010**.

- Reviewer for Institutional Development Grants (IDG) submitted to the "Kentucky Science and Engineering Foundation R&D Excellence Grants" on March **2011**.

- Panelist, A panel formed by the government of Singapore that regularly review research proposals submitted to the "Singapore Science and Engineering Research Council (SERC) AGENCY FOR SCIENCE" on July **2011**.

- Reviewer for Institutional Development Grants (IDG) submitted to the "Science and Technology Development Program-North Carolina Biotechnology Center" on August **2011**.

- Panelist, A panel formed by the government of Singapore that regularly review research proposals submitted to the "Singapore Science and Engineering Research Council (SERC) AGENCY FOR SCIENCE" on Jan **2012**.

- Academic Editor for the British Journal of Pharmaceutical Research on December **2012**.

- Reviewer for The Scientific Peer Advisory and Review Services division of the American Institute of Biological Sciences (AIBS) to review proposal submitted to the US Army Medical Research and Materiel Command's (USAMRMC's) solicitations on April **2013**.

- Academic advisor for an Industrial Consortium to study the utilization of Chimeric Mouse models for preclinical drug metabolism, pharmacokinetics (DMPK), and safety evaluations on September **2013**.

- Editorial Board: Pharmaceutical Sciences and Biomedical Analysis Journal, Data Set Papers in Pharmacology, Journal of Molecular Pharmaceutics & Organic Process Research, JSM Clinical Pharmaceutics **2013-2016**.

- Reviewer for the following journals: European J Pharmaceutical Research, Journal of Pharmacy and Pharmacology; Molecular Pharmaceutics, Molecular Pharmacology, Pharmaceutical Research, Journal of Chromatography A, Journal of Chromatography B, Biomedical Chromatography, basic and clinical pharmacology and toxicology, toxicological sciences, BBA-Molecular cell research, Xenobiotica, and Current Drug Metabolism, Analytica Chimica Acta, Drug Metabolism and Pharmacokinetics, "Food", International Journal of Molecular Sciences, Journal of Medicinal Chemistry, The Journal of Pediatrics, Journal of Clinical PsychoPharmacology, and "Bioanalysis".

- Academic advisor for the Industrial Consortium on safety evaluations **2013**.

- Consultant-Phoenix Bio Co, Japan **2014**.

- Consultant for Critical Path Institute-Predictive Safety Testing Consortium (*PSTC)* **2016**.

- Consultant-Genentech, USA, **2018**.

Professional Memberships

- International Congress of International Liver Transplantation Society (ILTS)
- Data Set Papers in Pharmacology: Editorial Board
- Journal of Molecular Pharmaceutics & Organic Process Research: Editorial Board
- British Journal of Pharmaceutical Research: Academic Editor
- American Association of Colleges of Pharmacy (AACP)
- American Society for Mass Spectrometry (ASMS)
- American Association of Pharmaceutical Scientists (AAPS)
- Society of Toxicology (SOT)
- International Society for the Study of Xenobiotics (ISSX)
- Nebraska Student AAPS Chapter (Mentor)

Committee Assignments

- Center for Drug Delivery and Nanomedicine (CDDN)
- Mass Spectrometry and Proteomics Core Facility
- Center for Neurodegenerative Disorders
- Pharmaceutical Sciences Graduate Program (PSGP) (Chair)
- AAPS University of Nebraska Medical Center (UNMC) College of Pharmacy student chapter (Advisor)
- Grade Appeals Committee
- Student Discipline Committee
- Curriculum Committee
- UNMC Graduate Council
- University Fellowship Review Panel-Genetics (Chair)
- Pharmacy Education Engagement Committee (Member)
- Academic Performance (Member)
- Educational Technology

Publications (*h* index: 25)

1. **Al-nouti Y**, Bartlett MG. Comparison of local anesthetic-cyclodextrin non-covalent complexes using capillary electrophoresis and electrospray ionization mass spectrometry. *J Am Soc Mass Spectrom*. **2002** Aug; 13(8):

928-35. PMID: 12216733.

2. **Alnouti Y**, White CA, Bartlett MG. Determination of lamivudine in plasma, amniotic fluid, and rat tissues by liquid chromatography. *J Chromatogr B AnalytTechnol Biomed Life Sci*. **2004** Apr 25; 803(2): 279-84. PMID: 15063336.

3. **Alnouti Y**, White CA, Bartlett MG. Simultaneous determination of zidovudine and lamivudine from rat plasma, amniotic fluid and tissues by HPLC. *Biomed Chromatogr*. **2004** Nov;18 (9): 641-7. PMID: 15386504.

4. **Alnouti Y**, White CA, Bartlett MG. Simultaneous quantitation of zidovudine and zidovudine monophosphate from plasma, amniotic fluid and tissues by micellar capillary electrophoresis. *Biomed Chromatogr*. **2004** Oct; 18(8): 523-31. PMID: 15386521.

5. **Alnouti Y**, Lewis SR, White CA, Bartlett MG. Simultaneous determination of zidovudine and lamivudine from rat tissues by liquid chromatography/tandem mass spectrometry. *Rapid Commun Mass Spectrom*. **2005**; 19(4): 503-8. PMID: 15678520.

6. Li M, **Alnouti Y**, Leverence R, Bi H, Gusev AI. .Increase of the LC-MS/MS sensitivity and detection limits using on-line sample preparation with large volume plasma injection. *J Chromatogr B AnalytTechnol Biomed Life Sci*. **2005** Oct 25; 825(2): 152-60. PMID: 15936252.

7. **Alnouti Y**, Srinivasan K, Waddell D, Bi H, Kavetskaia O, Gusev AI. Development and application of a new on-line SPE system combined with LC-MS/MS detection for high throughput direct analysis of pharmaceutical compounds in plasma. *J Chromatogr A*. **2005** Jul 8; 1080(2): 99-106. PMID: 16008047.

8. **Alnouti Y**, Petrick JS, Klaassen CD. Tissue distribution and ontogeny of organic cation transporters in mice. *Drug Metab Dispos*. **2006** Mar; 34(3): 477-82. PMID: 16381671.

9. **Alnouti Y**, Li M, Kavetskaia O, Bi H, Hop CE, Gusev AI. Method for internal standard introduction for quantitative analysis using on-line solid-phase extraction LC-MS/MS. *Anal Chem*. **2006** Feb 15; 78(4): 1331-6. PMID: 16478130.

10. **Alnouti Y**, Klaassen CD. Tissue distribution and ontogeny of sulfotransferase enzymes in mice. *Toxicol Sci*. **2006** Oct; 93(2): 242-55. PMID: 16807285.

11. **Alnouti YM**, Shelby MK, Chen C, Klaassen CD. Influence of phenobarbital on morphine metabolism and disposition: LC-MS/MS determination of morphine (M) and morphine-3-glucuronide (M3G) in Wistar-Kyoto rat serum, bile, and urine. *Curr Drug Metab*. **2007** Jan; 8(1): 79-89. PMID: 17266525.

12. **Alnouti Y**, Klaassen CD. Regulation of sulfotransferase enzymes by prototypical microsomal enzyme inducers in mice. *J Pharmacol Exp Ther*. **2008** Feb; 324(2): 612-21. PMID: 17993606.

13. **Alnouti Y**, Klaassen CD. Tissue distribution, ontogeny, and regulation of aldehyde dehydrogenase (Aldh) enzymes mRNA by prototypical microsomal enzyme inducers in mice. *Toxicol Sci*. **2008** Jan; 101(1): 51-64. PMID: 17998271.

14. Liu XM, Quan LD, Tian J, **Alnouti Y**, Fu K, Thiele GM, Wang D. Synthesis and evaluation of a well-defined HPMA copolymer-dexamethasone conjugate for effective treatment of rheumatoid arthritis. *Pharm Res*. **2008** Dec; 25(12): 2910-9. PMCID: PMC2593120.

15. **Alnouti Y**, Csanaky IL, Klaassen CD. Quantitative-profiling of bile acids and their conjugates in mouse liver, bile, plasma, and urine using LC-MS/MS. *J Chromatogr B AnalytTechnol Biomed Life Sci*. **2008** Oct 1; 873(2): 209-17. PMCID: PMC2582521.

16. **Alnouti Y**. Bile Acid sulfation: a pathway of bile acid elimination and detoxification. *Toxicol Sci*. **2009** Apr; 108(2): 225-46. PMID: 19131563. Not directly supported by NIH. Selected as "**Exceptional**" by "Faculty of 1000 Biology: the expert guide to the most important advances in biology"

17. Huang J, Bathena SP, Tong J, Roth M, Hagenbuch B, **Alnouti Y**. Kinetic analysis of bile acid sulfation by stably expressed human sulfotransferase 2A1 (SULT2A1). *Xenobiotica*. **2010** Mar; 40(3):184-94. PMID: 20102295. Not directly supported by NIH.

18. Dong Y, Chollet J, Vargas M, Mansour NR, Bickle Q, **Alnouti Y**, Huang J, Keiser J, Vennerstrom JL. Praziquantel analogs with activity against juvenile Schistosomamansoni. *Bioorg Med ChemLett*. **2010** Apr 15; 20(8): 2481-4. PMID: 20303754.

19. Quan LD, Yuan F, Liu XM, Huang JG,Wang D, **Alnouti Y**. Pharmacokinetic and biodistribution studies of N-(2-hydroxypropyl) methacrylamide copolymer-dexamethasone conjugates in adjuvant-induced arthritis rat model. *Mol Pharm*. **2010** Aug 2; 7(4): 1041-9. PMCID: PMC2914173.

20. Huang J, Bathena SP, **Alnouti Y**. Metabolite profiling of praziquantel and its analogs during the analysis of in vitro metabolic stability using information-dependent acquisition on a hybrid triple quadrupole linear ion trap mass spectrometer. *Drug MetabPharmacokinet*. **2010**; 25(5): 487-99. PMID: 20877135. Not directly supported by NIH.

21. **Alnouti Y**, Klaassen CD. Mechanisms of gender-specific regulation of mouse sulfotransferases (Sults). *Xenobiotica*. **2011** Mar; 41(3):187-97. PMID: 21091322.

22. Huang J, Bathena SP, Csanaky IL, **Alnouti Y**. Simultaneous characterization of bile acids and their sulfate metabolites in mouse liver, plasma, bile, and urine using LC-MS/MS. *J Pharm Biomed Anal*. **2011** Jul 15; 55(5): 1111-9. PMID: 21530128. Not directly supported by NIH.

23. Gor P, **Alnouti Y**, Reed GA. Buspirone, fexofenadine, and omeprazole: quantification of probe drugs and their metabolites in human plasma. *J Pharm Biomed Anal*. **2011** Jul 15; 55(5): 1127-35. PMCID: PMC3100389.

24. Bathena SP, Huang J, Nunn ME, Miyamoto T, Parrish LC, Lang MS, McVaney TP, Toews ML, Cerutis DR, **Alnouti Y**. Quantitative determination of lysophosphatidic acids (LPAs) in human saliva and gingival crevicular fluid (GCF) by LC-MS/MS. *J Pharm Biomed Anal*. **2011** Sep 10; 56(2): 402-7. PMCID: PMC3134166.

25. Huang J, Gautam N, Bathena SP, Roy U, McMillan J, Gendelman HE, **Alnouti Y**. UPLC-MS/MS quantification of nanoformulated ritonavir, indinavir, atazanavir, and efavirenz in mouse serum and tissues. *J Chromatogr B AnalytTechnol Biomed Life Sci*. **2011** Aug 1; 879(23): 2332-8. PMCID: PMC3144699.

26. Flynn CA, **Alnouti Y**, Reed GA. Quantification of the transporter substrate fexofenadine in cell lysates by liquid chromatography/tandem mass spectrometry. *Rapid Commun Mass Spectrom*. **2011** Aug 30; 25(16): 2361-6. PMCID: PMC4076838.

27. Bathena SP, Huang J, Epstein AA, Gendelman HE, Boska MD, **Alnouti Y**. Rapid and reliable quantitation of amino acids and myo-inositol in mouse brain by high performance liquid chromatography and tandem mass spectrometry. *J Chromatogr B AnalytTechnol Biomed Life Sci*. **2012** Apr 15; 893-894: 15-20. PMCID: PMC3322302.

28. Kanmogne GD, Singh S, Roy U, Liu X, McMillan J, Gorantla S, Balkundi S, Smith N, **Alnouti Y**, Gautam N, Zhou Y, Poluektova L, Kabanov A, Bronich T, Gendelman HE. Mononuclear phagocyte intercellular crosstalk facilitates transmission of cell-targeted nanoformulated antiretroviral drugs to human brain endothelial cells. *IntJ Nanomedicine*. **2012**; 7:2373-88. PMCID: PMC3357981.

29. Oberoi HS, Nukolova NV, Laquer FC, Poluektova LY, Huang J, Yokohira M, Arnold LL, Kabanov AV, Cohen SM, Bronich TK, **Alnouti Y**. Cisplatin-loaded core cross-linked micelles: comparative pharmacokinetics, antitumor activity, and toxicity in mice. *Int J Nanomedicine*. **2012**; 7:2557-71. PMCID: PMC3383348.

30. Roy U, McMillan J, **Alnouti Y**, Gautum N, Smith N, Balkundi S, Dash P, Gorantla S, Martinez-Skinner A, Meza J, Kanmogne G, Swindells S, Cohen SM, Mosley RL, Poluektova L, Gendelman HE. Pharmacodynamic and antiretroviral activities of combination nanoformulatedantiretrovirals in HIV-1-infected human peripheral blood lymphocyte-reconstituted mice. *J Infect Dis*. **2012** Nov 15; 206 (10): 1577-88. PMCID: PMC3570176.

31. Dash PK, Gendelman HE, Roy U, Balkundi S, **Alnouti Y**, Mosley RL, Gelbard HA, McMillan J, Gorantla S, Poluektova LY. Long-acting nanoformulated antiretroviral therapy elicits potent antiretroviral and neuroprotective responses in HIV-1-infected humanized mice. *AIDS*. **2012** Nov 13; 26(17): 2135-44. PMCID: PMC4024396.

32. Radhakrishnan P, Bryant VC, Blowers EC, Rajule RN, Gautam N, Anwar MM, Mohr AM, Grandgenett PM, Bunt SK, Arnst JL, Lele SM, **Alnouti Y**, Hollingsworth MA, Natarajan A. Targeting the NF-κB and mTOR Pathways with a Quinoxaline Urea Analog That Inhibits IKKβ for Pancreas Cancer Therapy. *Clin Cancer Res*. **2013** Apr 15; 19(8): 2025-35. PMCID: PMC3630250.

33. Gautam N, Bathena SP, Chen Q, Natarajan A, **Alnouti Y**. Pharmacokinetics, protein binding and metabolism of a quinoxaline urea analog as an NF-κB inhibitor in mice and rats by LC-MS/MS. *Biomed Chromatogr*. **2013** Jul; 27(7): 900-9. PMCID: PMC3760428.

34. Gautam N, Roy U, Balkundi S, Puligujja P, Guo D, Smith N, Liu XM, Lamberty B, Morsey B, Fox HS, McMillan J, Gendelman HE, **Alnouti Y**. Preclinical Pharmacokinetics and Tissue Distribution of Long-Acting Nanoformulated Antiretroviral Therapy. *Antimicrob Agents Chemother*. **2013** Jul; 57(7): 3110-20. PMID: 23612193. PMCID: PMC3697338. **Featured** by MDlinx in the area of Infectious Diseases on Dec 2013.

35. Epstein AA, Narayanasamy P, Dash PK, High R, Bathena SP, Gorantla S, Poluektova LY, **Alnouti Y**, Gendelman HE, Boska MD. Combinatorial assessments of brain tissue metabolomics and histopathology in rodent models of human immunodeficiency virus infection. *J NeuroimmunePharmacol*. **2013** Dec; 8(5): 1224-38. PMCID: PMC3889226.

36. Bathena SP, Mukherjee S, Olivera M, **Alnouti Y**. The profile of bile acids and their sulfate metabolites in human urine and serum. *J Chromatogr B Analyt Technol Biomed Life Sci*. **2013** Dec; 942-943:53-62. PMID: 24212143. Not directly supported by NIH.

37. Wang L, Hartmann P, Haimerl M, Bathena SP, Sjöwall C, Almer S, **Alnouti** Y, Hofmann AF, Schnabl B. Nod2 deficiency protects mice from cholestatic liver disease by increasing renal excretion of bile acids. *J Hepatol*. **2014** Jun; 60(6): 1259-67. PMID: 24560660. PMCID: PMC4028388.

38. Gautam N, Puligujja P, Balkundi S, Thakare R, Liu XM, Fox HS, McMillan J, Gendelman HE, **Alnouti Y**. Pharmacokinetics, Biodistribution, and Toxicity of Folic Acid-Coated Antiretroviral Nanoformulations. *Antimicrob Agents Chemother*. **2014** Oct 6. pii: AAC.04108-14. PMID: 25288084. PMCID: PMC4249580. **Featured** by MDlinx in the area of Infectious Diseases on Dec 2014. **Featured** by World Biomedical Frontiers in the area of Infection and Immunity on Sep 2015 (http://biomedfrontiers.org/inf-2015-9-8/).

39. Bathena SP, Thakare R, Gautam N, Mukherjee S, Olivera M, Meza J, **Alnouti Y**. Urinary Bile Acids as Biomarkers for Liver Diseases I. Stability of the baseline profile in healthy subjects. *Toxicol Sci*. **2015** Feb, 143 (2): 296-307. PMID: 25344562.

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Book Chapters and Review Articles

1. **Alnouti Y**. Bile Acid sulfation: a pathway of bile acid elimination and detoxification. *Toxicological Sciences*. Apr **2009**, 108 (2): 225-246.PMID: 19131563. Selected as "Exceptional" by "Faculty of 1000 Biology: the expert guide to the most important advances in biology"

2. Huangui Xiong and Howard E. Gendelman (**2013**). Current Laboratory Methods in Neuroscience Research. New York, NY, Springer, (ISBN-13: 978-1461487937). Chapter 52: Metabolomics, **Y Alnouti**: 425-451.

3. Thakare R, Chhonker YS, Gautam N, Alamoudi JA, **Alnouti Y**. Quantitative analysis of endogenous compounds. *J Pharm Biomed Anal*. **2016** Sep. 128:426-37. PMID: 27456759.

Invited Presentations

- LC-MS/MS Analysis of Individual Bile Acids and their Metabolites in Mouse Tissues and Fluids. *The Department of Internal Medicine-College of Medicine-University of Kansas Medical Center*, Kansas City-Kansas, February **2008**.
- The Bile Acid Profile: A Novel Biomarker of hepatocyte function. *XenoTech, LLC*, Lenexa-Kansas, March **2008**.
- Bile Acid Sulfation as a Biomarker for the Severity and Prognosis of Hepatobiliary Diseases. *The Department of Internal Medicine-College of Medicine-University of Nebraska Medical Center*, Omaha-Nebraska, October **2008**.
- Sulfation is the Primary Detoxification Pathway of Bile Acids in Humans. *Division of Hepatology-The veterinary Affairs Health System*, Omaha-Nebraska, April **2010**.
- The Kinetics of Bile Acid Sulfation by the Human Sulfotransferase (SULT2A1). *International Society for the Study of Xenobiotics annual meeting (ISSX).* Istanbul-Turkey, September **2010**.
- A novel biomarker of hepatobiliary diseases. *College of Pharmacy-University of Georgia*, Athens-Georgia, April **2011**.
- Profiling of bile acids and their sulfate metabolites in human urine. *Globalization of Pharmaceutics Education Network (GPEN)*. Melbourne-Australia, Dec **2012**.
- The formation of reactive metabolites and irreversible protein binding of quinoxaline urea analog. *International Society of Xenobiotics (ISSX)*. Torontao-Canada, Sep **2013**.
- The role of bile acids in metabolic disorders. *Division of Endocrinology- College of Medicine-University of Nebraska Medical Center,*Omaha-Nebraska, April **2013**.
- Sulfation of Bile Acids (BAs) and the Diagnosis and Prognosis of Hepatobiliary Diseases. *The Department of Surgery- College of Medicine-UNMC*, Omaha-Nebraska, July **2013**.
- The formation of reactive metabolites and irreversible protein binding of quinoxaline urea analog. *The department of Chemistry-University of Nebraska Omaha*, Omaha-Nebraska, October **2013**.
- Bile acids role in diabetes. *Department of Family Medicine- College of Medicine-University of Nebraska Medical Center*, Omaha-Nebraska, November **2013**.
- Species Differences in Bile acid metabolism and preclinical evaluation of DILI. *Discovery Toxicology -Amgen Inc*, Thousand Oaks-California, January **2014**.

- Novel Biomarkers for Hepatobiliary Diseases. *Joint International Congress of International Liver Transplantation Society (ILTS), European Liver and Intestine Transplant Association (ELITA) & Liver Intensive Care Group of Europe (LICAGE)*. London-UK, Jun **2014**.
- Species Differences in bile acid metabolism. *Critical Path Institute-Predictive Safety Testing Consortium (PSTC)-BSEP Webinar Series* - Current trends in BSEP inhibition and perturbation to bile acid homeostasis as mechanisms of drug-induced liver injury. May-July **2016**.
- The role of bile acids in DILI and liver diseases. Drug-Induced Liver Injury (DILI): Risk Assessment of Drug Candidates and Metabolites in Drug Discovery and Clinical Development Symposium by *Pharmaceutical & Bioscience Society - San Francisco Bay (PBSS)*. San Francisco-California. June **2017**.
- The controversial roles of bile acids in health and disease. *College of Medicine & Health Sciences-United Arab Emirates University (UAEU)*. Al Ain-UAE. Jan **2018**.

Presentations and Posters

- Non-Covalent Complexes in the Gas Phase. *University of Georgia.* Athens-Georgia, January **2002**.
- Comparison of Cyclodextrin Non-Covalent Complexes Using Capillary Electrophoresis and Electrospray Ionization Mass Spectrometry. *American Society of Mass Spectrometry annual meeting (ASMS).* Orlando-Florida, June **2002**.
- Evaluation of On-line and Off-line SPE for Rapid Method Development and High Throughput Analysis of Biological Sample. *Pfizer Inc*, Groton-Connecticut, August **2003**.
- Determination of Lamivudine in Rat Tissue by HPLC-UV. *American Association of Pharmaceutical Scientists annual meeting (AAPS).* Salt Lake City-Utah, October **2003**.
- Simultaneous Determination of AZT and 3TC in Pregnant Rat Tissues Using LC-MS. *American Society of Mass Spectrometry annual meeting (ASMS).* Nashville-Tennessee, May **2004**.
- Development of Combined on-line SPE and Monolithic Column LC-MS Methods for Bioanalytical Support. *American Society of Mass Spectrometryannual meeting (ASMS).* Nashville-Tennessee, May **2004**.
- The Role of Organic Cation Transporters (Octs) in Drug Metabolism and Disposition.*University of Kansas Medical Center.* Kansas City-Kansas, December **2004**.
- Tissue Distribution and Ontogeny of Organic Cation Transporters (Octs) in Mice.*Society of Toxicology annual meeting (SOT).* New Orleans-Louisiana, March **2005**.
- Expressional Regulation of Sulfotransferase Enzymes (Sults) by Microsomal Enzyme Inducers (MEIs) in Mice. *Society of Toxicology annual meeting (SOT).* San Diago-California, March **2006**.
- **Yazen Alnouti** and Curtis D. Klaassen. The Influence of Phenobarbital on Morphine Metabolism and Diposition. *International Society for the Study of Xenobioticsannual meeting (ISSX).* Rio Grande-Puerto Rico, October **2006**.
- The Exponential Power of LC-MS in Biomedical and Pharmaceutical Research. *University of Kansas Medical Center.* Kansas City-Kansas, May **2007**.
- The Mechanism of the Gender Differences of Morphine Pharmacokinatics and Pharmacodynamics in Rats. *American Association of Pharmaceutical Scientists annual meeting (AAPS).* San Diego-California, November **2007**.
- LC-MS in Drug Discovery and Development. *University of Nebraska Medical Cente.* Omaha-Nebraska, October **2008**.
- **Yazen Alnouti** and Curtis D. Klaassen. Quantitative Profiling of Individual Bile Acids and their Metabolites in Mouse Tissues and Fluids. *American Association of Pharmaceutical Scientists annual meeting (AAPS).* Atlanta-Georgia, November **2008**.
- Megan Roth, **Yazen Alnouti**, and Bruno Hagenbuch. Characterization of a stable cell line expressing human

Na+/taurocholatecotransporting polypeptide for high throughput screening. *The American Society for Pharmacology and Experimental Therapeutics meeting.* New Orleans-Louisiana, April **2009**.

- Zhonghua Sheng, **Yazen Alnouti**, and Bruno Hagenbuch. Substrate specificity of rat Na^+/taurocholatecotransporting polypeptide. *The American Society for Pharmacology and Experimental Therapeutics meeting*. New Orleans-Louisiana, April **2009**.
- Hardeep S. Oberoi, Fredric C. Laquer, Nataliya V. Nukolova, Jiangeng Huang, **Yazen Alnouti** and Tatiana K. BronichBiodistribution and comparative pharmacokinetics of cisplatin loaded core cross-linked micelles in mice. *International Nanonmedicine and Drug Delivery Symposium*. Indianapolis-Indiana, October **2009**.
- **Yazen Alnouti** and Curtis D. Klaassen. The Hormonal Regulation of the Gender-Specific Expression of Sulfotransferases (Sults). *American Association of Pharmaceutical Scientists annual meeting (AAPS).* Los Angeles-California, November **2009**.
- Ari Nowacek, Z Ma, J McMillan, J Huang, S P Bathena, C Fletcher, A Anderson, **Y Alnouti**, H Dou, and H Gendelman. Laboratory Macrophage Screening Assays Predict Pharmacokinetics of Controlled Release Nanoformulated Antiretroviral Drugs. *17th Conference on Retroviruses and Opportunistic infections*, San Francisco-California, February **2010**.
- DR Cerutis, **Y Alnouti**, M Weston, SPR Bathena, TP McVaney, AOgunleye, and KV Headen.LPA regulates the inflammatory and healing responses of oral fibroblasts. *International Association of Dental Research Meeting.* Barcelona-Spain, July **2010**.
- Keith Olsen and **Yazen Alnouti**. Comparison of Telavancin, Ceftriaxone and Vancomycin Efficacy in a Rat Model of Pneumococcal Pneumonia. *Interscience Conference on Antimicrobial Agents and Chemotherapy*. Boston-Massachusetts, September **2010**.
- Upal Roy, Prasanta Dash, Shantanu Balkundi,Jiangeng Huang, Ari Nowacek, Andrea Martinez-Skinner, Adrian Epstein, Jaclyn Knibbe, Santhi Gorantla, Larisa Poluektova, JoEllyn McMillan, Howard E. Gendelman, **Yazen Alnouti**. Pharmacokinetics and Therapeutic Activities of Nanoformulated Antiretroviral Drugs. *International Nanonmedicine and Drug Delivery Symposium*. Omaha-Nebraska, October **2010**.
- Sai P.R. Bathena, Jiangeng Huang, **Yazen Alnouti**. Salivary LPAs in patients with periodontal diseases. *Globalization of Pharmaceutics Education Network Annual Meeting (GPEN)*. Chapel Hill-North Carolina, October **2010**.
- Sai Praneeth R Bathena, Jiangeng Huang, Myron Toews, Delie Roselyn Cerutis, **Yazen Alnouti**. Quantification of LPAs in human saliva by liquid chromatography tandem mass spectrometry. *American Association of Pharmaceutical Scientists (AAPS)* Annual meeting. New Orleans- Louisiana, November **2010**.
- Jiangeng Huang, Sai P.R. Bathena, **Yazen Alnouti**. Kinetics of human sulfotransferase enzymes. *American Association of Pharmaceutical Scientists annual meeting (AAPS)*. New Orleans-Louisiana, November **2010**.
- A Nowacek, I Kadiu, S Balkundi, U Roy, G Kanmogne, L Poluektova, P Dash, **Y Alnouti**, J McMillan, and H E Gendelman. NanoART for Improved Antiretroviral Drug Delivery. *18th Conference on Retroviruses and Opportunistic Infections.* Boston-Massachusetts, February **2011**.
- Upal Roy, Prasanta Dash, Shantanu Balkundi, Sai P.R. Bathena, Ari Nowacek, Larisa Poluektova, JoEllyn McMillan, Courtney Fletcher, **Yazen Alnouti** and Howard E. Gendelman. Biodistribution and Efficacy of Nanoformulated Antiretroviral Drugs. *Conference of Society on NeuroImmune Pharmacology*. Clearwater Beach-Florida, Apr **2011**.
- Nagsen Gautam, Jiangeng Huang, Sai Praneeth R Bathena, Upal Roy, Nathan A Smith, JoEllyn McMillan, Howard E. Gendelman, **Yazen Alnouti**. Pharmacokinetics and UPLC-MS/MS Quantification of Nanoformulated Ritonavir, Indinavir, Atazanavir, and Efavirenz in Mous. *American Association of Pharmaceutical Scientists annual meeting(AAPS)*. Washington-DC, Oct **2011**.
- Sai Praneeth R Bathena, Jiangeng Huang, Adrian A. Epstein, Howard E. Gendelman, Michael D. Boska, **Yazen Alnouti**.Rapid and Reliable Quantification of Amino Acids and Myo-inositol in Mouse Brain by High Performance Liquid Chromatography and Tandem Mass Spectrometry. *American Association of Pharmaceutical Scientists annual meeting (AAPS)*. Washington-DC, Oct **2011**.
- Howard Gendelman, **Yazen Alnouti**, Prasanta Dash, Upal Roy, Susan Swindells, Santhi Gorantla, Shantanu Balkundi, Georgette Kanmogne, JoEllyn McMillan and Larisa Poluektova. Pre-clinical development of sustained

release combination nanoformulated ART. *19th Conference on Retroviruses and Opportunistic Infections.* Seattle-Washington, March **2012**.

- Nagsen Gautam,QianyiChen, Amarnath Natarjan, **Yazen Alnouti**. Preclinical Pharmacokinetics, Protein Binding, and Metabolism of a Novel NF-κB Inhibitor. *International Society of Xenobiotics (ISSX)*. Amsterdam-Netherlands, Jun **2012**.
- Nagsen Gautam, Sai Praneeth R Bathena, Qianyi Chen, Amarnath Natarajan, **Yazen Alnouti**. Pharmacokinetics of a Novel NF-κB inhibitor for the Treatment of Pancreatic Cancer in Mice and Rats. *American Association of Pharmaceutical Scientists annual meeting (AAPS).*Chicago-IL, Oct **2012**.
- Nagsen Gautam, Upal Roy, Shantanu Balkundi, JoEllyn McMillan, Howard Fox, Howard Gendelman, **Yazen Alnouti**. Pharmacokinetics and Disposition of NanoformulatedAtazanavir and Ritonavir: Long Acting Combination Antiretroviral Therapy in Mice and Monkeys. *American Association of Pharmaceutical Scientists annual meeting (AAPS)*. San Antonio-Texas, Nov **2013**.
- Lirui Wang, Phillipp Hartmann, Michael Haimerl, Sai P. Bathena, **Yazen Alnouti**, Alan F. Hofmann, and Bernd Schnabl. Nod2 deficiency protects mice from cholestatic liver disease by increasing renal excretion of bile acids. *The American Association for the Study of Liver Diseases Annual Meeting (*AASLD Liver Meeting*)*. Washington-DC, Nov **2013**.
- Nagsen Gautam, Pavan Puligujja, Shantanu Balkundi, Rhishikesh Thakare, JoEllyn McMillan, Xin-Ming Liu, Howard S. Fox, Howard E. Gendelman, **Yazen Alnouti**. Pharmacokinetics, Biodistribution, and Toxicity of Folic Acid-Coated Nanoformulated Antiret. *American Association of Pharmaceutical Scientists annual meeting (AAPS)*. San Diego-California, Nov **2014**.
- Rhishikesh Thakare, **Yazen Alnouti**. Species Differences in Chemical-Induced Hepatotoxicity due to Bile Acid Metabolism. *Chemical and Biological Defense Science and Technology Conference (CBD S&T)*. St. Louis-Missouri, May **2015**.
- Nagsen Gautam, Rhishikesh Thakare, Sandeep Rana, Amarnath Natarajan, **Yazen Alnouti**. Mechanisms of in vivo instability of an Anticancer Compound (BI-94). *American Association of Pharmaceutical Scientists annual meeting (AAPS)*. Orlando-Florida, Oct **2015**.
- Phillipp Hartmann, Angela Horvath, Peng Chen, Caroline T. Seebauer, Cristina Llorente, Lirui Wang, **Yazen Alnouti**, Alan Hofmann, Derrick Fouts, Lei Ling, Stephen J. Rossi, Alex M. DePaoli, Ruth T. Yu, Michael Downes, Ronald M. Evans, David A. Brenner, Bernd Schnabl. Restoration of bile acid homeostasis improves alcoholic liver disease in mice. *The American Association for the Study of Liver Diseases Annual Meeting (AASLD Liver Meeting)*. Boston-MA, Nov **2016**.
- Nagsen Gautam, Rhishikesh Thakare, Sandeep Rana, Amarnath Natarajan, **Yazen Alnouti**. Preclinical Pharmacokinetics of a Novel anticancer agent (628A1) for the Treatment of Pancreatic Cancer. *American Association of Pharmaceutical Scientists annual meeting (AAPS)*. Denver-Colorado, Nov **2016**.
- Krause C, Helm M, Oleynikov D, Kothari V, Kohli, R Thakare R, Alamoudi J, Kindel T, **Alnouti Y**. Early weight loss after sleeve gastrectomy is significantly correlated to increased hyocholic acid. *Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Annual meeting*. Houston-Texas, March **2017**.
- Nagsen Gautam and **Yazen Alnouti**. Simultaneous Quantification of Intracellular Triphosphate Metabolites of Lamivudine and Abacavir in in-vitro and in-vivo Samples. *American Association of Pharmaceutical Scientists annual meeting (AAPS)*. San Diego-California, Nov **2017**.
- Soliman GA, Shukla SK, Etekpo A, Gunda V, Steenson S, Gautam N, **Alnouti Y**, Singh PK. The Impact of mTOR Nutrient-Sensing Metabolic Pathway and AMPK Activator Metformin on the Growth of Pancreatic Cancer Cells Lines in C57/BL6 Mice. American Society for Nutrition, June **2018**, Boston, USA.
- Gautam N, Ibrahim IM, McMillan J, Gendelman HE, and **Alnouti Y**. Quantification of Intracellular Triphosphate Metabolites of Emtricitabine by LC-MS/MS. American Association of Pharmaceutical Scientists annual meeting (AAPS), November **2018**, Washington DC, USA.

Ongoing Research Support

Funding agency: Genentech Inc.
Title: Quantifying species differences in bile acid metabolism for prediction of DILI
Duration: 10/2017 – 10/2020
Direct Cost: $180,000
Funding Type: Contract with Pharmaceutical Industry
PI: Yazen Alnouti
Role: PI
Description: The goal of this contract is to quantify species differences in bile acid metabolism to facilitate the development of in vitro and in vivo models for the prediction of drug-induced liver injury (DILI).

Funding Agency: The Center for Clinical and Translational Research and Great Plains Health Research Consortium Translational Research
Grant Title: Bile Acid Sulfation as a Biomarker for Hepatobiliary Diseases
Funding Type: Pilot Grant
Duration: 10/2010 – 10/2020
Direct Cost: $180,948
PI: Yazen Alnouti
Role: PI
Description: The goal of this proposal is to determine the detailed urinary bile acid profile in healthy controls and patients with various hepatobiliary diseases. The central hypothesis is that the capability of patients to sulfate bile acids is correlated with the severity and prognosis of the diseases.

Funding Agency: DHHS/NIH/NIDA (PO1DA028555-06A1)
Grant Title: NanoART Manufacture, Delivery, and Pharmacokinetics for Optimizing Drug Adherence
Funding Type: PO1
Duration: 07/2015-06/2020
Direct Cost: $9,312,151
Program Director (PD): Gendelman, Howard E
Role: PI of Core C (Pharmacokinetics and Drug-Drug Interactions) (2.4 calendar months)
Description: The goal of this program project is to develop antiretroviral nanoparticles (nanoART) that are carried within circulating immunocytes and delivered to virus-target tissues. NanoART can be taken up within minutes by circulating monocytes and released in tissues over a period of two weeks. The objective of Core C is to guide and scale the preclinical pharmacokinetic study in control and infected mice in rodents and rhesus macaques.

Funding agency: DHHS/NIH/NIA (1RO1AI124965)
Title: The Lymphoid Tissue Pharmacology of Antiretroviral Drugs
Duration: 04/07/2016 – 03/31/2021
Direct Cost: $2,600,000
Funding Type: RO1
PI: Fletcher, CV
Role: Co-Investigator (1.2 calendar months)
Description: The goal of this project is to develop new anti-HIV regimens with enhanced penetration to the lymphatic system to achieve a long-term remission and thereby avert the consequences of persistent virus production. Our role in this project is to elucidate the mechanisms underlying the penetration of anti-HIV drugs into the lymphatic system via novel *in vitro* and *in vivo* approaches.

Funding agency: DHHS/NIH/NIAID (1RO1AI119090)
Title: Nanomedicine development for systemic lupus erythematosus
Duration: 05/26/2016 – 04/30/2021
Direct Cost: $1,250,000
Funding Type: RO1
PI: Wang, Dong
Role: Co-Investigator (0.6 calendar months)
Description: The goal of this project is to develop novel nanomedicine approaches to enhance efficacy and reduce toxicity of pharmacotherapy of systemic lupus erythematosus. Our role in this project is to guide and scale the preclinical pharmacokinetic study in rodent models.

Funding Agency: Gilead Pharmaceuticals
Grant Title: Mechanism of Bosentan Hepatotoxicity in Rats
Funding Type: Industry Fund/Contract
Duration: 01/2008-Present
Direct Cost: $134,000
PI: Alnouti, Yazen &Jaeschke, Hartmut
Role: Co-PI
Description: This is a contract by Gilead Pharmaceuticals to understand role of bile acids in the hepatotoxicity of Bosentan.

Funding Agency: University of Nebraska Medical Center (UNMC)
Grant Title: UNMC Start-up Grant
Funding Type: Start-up Grant
Duration: 03/2008-Present
Direct Cost: $760,000
PI: Alnouti, Yazen
Role: PI
Description: This is a start-up funding provided by the University of Nebraska Medical Center to new tenure-track faculty to establish their research program and aid in obtaining extramural funding for their research

Completed Research Support

Funding Agency: DHHS/NIH/NCI (R01 CA143460-01)
Grant Title: NOC in processed meat as a likely cause of colon cancer
Funding Type: R01
Duration: 12/009-12/2013
Direct Cost: $779,625
PI: MIRVISH, SIDNEY S
Role: Co-Investigator (0.6 calendar months)
Description: The goal of this study is to determine the role of non-volatile apparent (ANC) N-nitroso compounds (NOC) in colon cancer etiology and to learn how to reduce exposure to ANC.

Funding Agency: DHHS/NIH/NIDA (PO1 DA028555-01)
Grant Title: NanoART Manufacture, Delivery, and Pharmacokinetics for Optimizing Drug Adherence
Funding Type: PO1
Duration: 07/2010-07/2015
Direct Cost: $9,312,151
Program Director (PD): Gendelman, Howard E
Role: PI of Core C (Pharmacokinetics and Drug-Drug Interactions) (2.4 calendar months)
Description: The goal of this program project is to develop antiretroviral nanoparticles (nanoART) that are carried within circulating immunocytes and delivered to virus-target tissues. NanoART can be taken up within minutes by circulating monocytes and released in tissues over a period of two weeks. The objective of Core C is to guide and scale the preclinical pharmacokinetic study in control and infected mice in rodents and rhesus macaques.

Funding agency: GlaxosmithKline (GSK) ViiV Health Care
Grant Title: Targeted nano formulations for ART
Funding Type: Industry Fund/Contract
Duration: 09/2013 – 08/2014
Total Amount: $225,000
PI: Howard E Gendelman
Role: Co-Investigator (0.24 calendar months)

Funding Agency: Nebraska Research Initiative (NRI)
Grant Title: NRI POC AWARD FY 16-17 " Novel Pyrrolomycins as Anti-anthrax and Anti-MRSA Agents"
Duration: 02/01/2016-01/31/2017
Total Amount: $225,000

NRI POC AWARD FY 16-17, Nebraska Research Initiative (NRI)
PI: Li, Rongshi
Role: Co-I (0.6 calendar months)
Description: The goal of this project is to develop analogs of anti-anthrax and anti-MRSA Agents, with enhanced oral bioavailability and pharmacokinetic profiles. The role of my laboratory is to characterize the metabolism and pharmacokinetics of the developed analogs in in vitro and in vivo animal models.

Funding Agency: Nebraska Research Initiative (NRI)
Grant Title: NRI POC AWARD FY 14-15 "Improve Potency & Oral Bioavailability of Lead Compound 13-197"
Duration: 04/2015-04/2017
Total Amount: $225,000
CO-PI: Amarnath Natarajan & Yazen Alnouti
Role: Co-PI
Description: The goal of this project is to develop analogs of 13-197, a small molecule with anti- pancreatic tumor activity, with enhanced oral bioavailability and pharmacokinetic profiles. The role of my laboratory is to characterize the metabolism and pharmacokinetics of the developed analogs in in vitro and in vivo animal models.

Funding Agency: USAMRIID
Grant Title: Screening for BoNT/A inhibitors using the BoTest® A/E BoNT Detection Assay (TO-0014)
Duration: 06/2014 – 11/2016
Direct cost: $1,920,000 (subproject $422,772)
Program Director (PD): Kenneth W Bayles
Role: Project Leader (2.4 calendar months)
Description: The goal of this project is to develop and optimize lead compounds against Botulinum Toxin Serotype A (BONT/A). The role of my laboratory is to characterize the chemical and metabolic stability of compounds as primary criteria for lead optimization.

Funding agency: Society of American Gastrointestinal and Endoscopic Surgeons (SAGE)(36-5360-2186-001)
Title: The effect of sleeve gastrectomy on post-prandial serum bile acids
Duration: 03/2015 – 03/2018
Direct Cost: $30,000
Funding Type: Society, External, Individual Investigator Research Award, Direct Costs Only
PI: Kindel, Tammy L
Role: Co-Investigator
Description: The goal of this clinical study is to understand the mechanisms of weight loss and the role of bile acids homeostasis after bariatric surgeries, such as sleeve gastrectomy (SG).

Funding agency: DHHS/NIH/NHLBI
Grant Title: Prostaglandin Inhibition for Emphysema (1UM1HL112958-01A1)
Funding Type: UM1
Duration: 09/2013 – 09/2017
Direct cost:$4,407,519
PI: Rennard, Stephen I
Role: Co-Investigator (0.36 (year 1) and 1.8 calendar months years 2 and 3)
Description: The goal of this clinical study is to evaluate the role of PGE in COPD. The project hypothesizes that repair processes are diminished in COPD patients, at least in part, due to increased levels of PGE. The objective of the project is to investigate the role of PGE as a biomarker for COPD by correlating the local levels of PGE and other prostanoids in the lungs with several COPD biochemical and clinical outcomes. In addition, the effect of PGE inhibition using NSAIDs on COPD will be evaluated. The role of my laboratory in this project is to provide the bioanalytical support required to identify and validate novel biomarkers for COPD.

Funding Agency: NIH
Grant Title: Development of Chol-DsiRNA Polyplexes to Improve the Treatment of Breast Cancer (1R41TR001902-01A1)
Funding Type: Actorius Pharmaceuticals, LLC
Duration: 09/15/2016-08/31/2017

Total Amount: $129,558
PI: Joseph Vetro
Role: Co-I (0.6 calendar months)
Description: The overall objective is to demonstrate that EP67-based targeted vaccines are likely to improve the treatment of breast cancer. Our role in this project is to guide and scale the preclinical pharmacokinetic study in rodent models.